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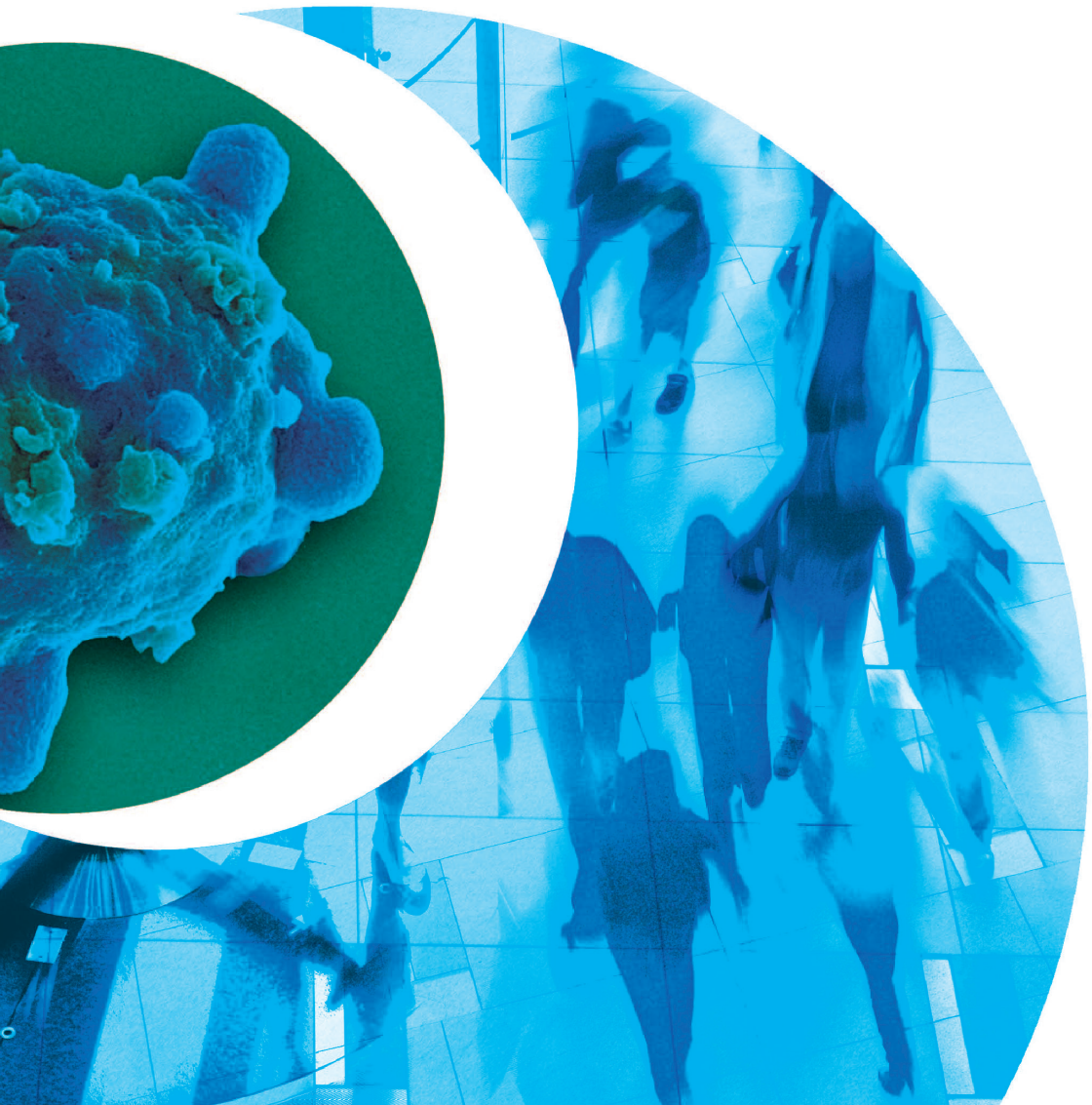
14th European Breast Cancer Conference (EBCC-14)

20–22 March 2024
Milan, Italy

ABSTRACT BOOK



THE OFFICIAL JOURNAL OF

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The future of cancer therapy

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European Journal of Cancer

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Abstract Book

14th European Breast Cancer Conference (EBCC-14)

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AWARD AND ORAL ABSTRACT SESSION 20 March 2024 11.00–12.55

YOUNG INVESTIGATOR INNOVATION AWARD AND ORAL ABSTRACTS

1LBA LBA Oral

Adjuvant chemotherapy with or without atezolizumab for stage II and III triple-negative breast cancer: final analysis of the ALEXANDRA/IMpassion030 phase 3 trial

H. McArthur[1], A. Bailey[2], S. Saji[3], S. El-Abed[4], G. Nader Marta[5], O. Metzger[6], A. Seiller[7], Y. Shparyk[8], H.J. Kim[9], N. Bonichon Lamichhane[10], J.L. Alonso[11], A. Ellingson[12], A. Zimina[13], T. Yamashita[14], S. Mohan[15], Z. Shao[16], G. Viale[17], M. Piccart[18], M. Ignatiadis[5], R. Gelber[19]. *[1]UTSW, Internal Medicine, Dallas, USA; [2]Frontier Science, Frontier Science, Inverness-Shire, United Kingdom; [3]Fukushima Medical University, School of Medicine, Fukushima, Japan; [4]Breast International Group, Breast International Group, Brussels, Belgium; [5]Institut Jules Bordet, Institut Jules Bordet, Brussels, Belgium; [6]Dana-Farber Cancer Institute, Dana-Farber Cancer Institute, Boston, USA; [7]Roche, Roche, Basel, Switzerland; [8]Lviv State Oncology Regional Treatment and Diagnostic Center, Department of Chemotherapy, Lviv, Ukraine; [9]Soonchunhyang University, Department of Oncology, Dongnam, South Korea; [10]Clinique Tivoli Ducos, Medical Oncology, Bordeaux, France; [11]Hospital Clinico Universitario Virgen de la Arrixaca, Hospital Clinico Universitario Virgen de la Arrixaca, El Palmar, Spain; [12]Frontier Science, Frontier Science, Kingussie, United Kingdom; [13]Omsk Clinical Oncology Dispensary, Department of Oncology, Omsk, Russia; [14]Kanagawa Cancer Center, Department of Breast Surgery, Nakao, Japan; [15]Genentech, Genentech, San Francisco, USA; [16]Fudan University Shanghai Cancer Center, Department of Breast Surgery, Shanghai, China; [17]University of Milan, European Institute of Oncology, Milan, Italy; [18]Institut Jules Bordet, Boston, USA; [19]Dana-Farber Cancer Institute, Cancer Institute, Boston, USA*

Background: Early-stage triple negative breast cancer (TNBC) is associated with a high risk of distant relapse. ALEXANDRA/IMpassion030 is a global, prospective, randomized, open-label, phase 3 trial that investigated the efficacy and safety of adjuvant atezolizumab (atezo) plus standard anthracycline/taxane chemo (atezo+chemo) versus standard anthracycline/taxane chemo (chemo alone) in early-stage TNBC.

Material and Methods: In ALEXANDRA/IMpassion030 (NCT03498716) patients with resected stage II-III TNBC, confirmed by central pathology review, were randomized 1:1 to receive adjuvant chemo with or without atezo. Patients were stratified by type of surgery (breast conserving vs mastectomy), axillary nodal status (0 vs 1-3 vs ≥4 nodes), and centrally assessed PD-L1 status (IC0 vs IC1/2/3). Adjuvant chemo consisted of weekly paclitaxel 80 mg/m^2 for 12 weeks followed by dose-dense anthracycline (epirubicin 90 mg/m^2 or doxorubicin 60 mg/m^2) and cyclophosphamide 600 mg/m^2 for 4 doses every 2 weeks given concomitantly with atezo 840 mg every 2 weeks followed by maintenance atezo 1200 mg every 3 weeks until completion of 1 year of atezo or the same chemo regimen alone. The primary endpoint was invasive disease-free survival (iDFS) in the intention-to-treat population (ITT). Recruitment stopped after 2199 of the planned 2300 patients were enrolled (1101 atezo+chemo and 1098 chemo alone) on the recommendation of the independent data monitoring committee (IDMC). At the Interim Analysis (IA) with ~25 months median follow-up and 239 iDFS events the hazard ratio (HR) for iDFS (primary endpoint) crossed the pre-specified futility boundary. The final analysis with ~32 months median follow-up and 266 iDFS events is reported here.

Results: At the final analysis, the HRs remained stable compared to the IA for iDFS at 1.11 (0.87, 1.42) and for secondary endpoints: iDFS in the PDL1+ subset 1.00 (0.73, 1.35), iDFS in the node-positive subset 1.32 (0.97, 1.8), and overall survival 1.23 (0.87, 1.73) for the 2199 patients in the ITT population. At the final analysis, 2177 (99%) were safety-evaluable, 1567 (71.3%) had PD-L1 positive disease and 1067 (48.5%) had node-positive disease. The incidence of grade≥3 treatment related adverse events remained stable with 54.3% in the atezo+chemo arm vs 44.1% in the chemo alone arm.

Conclusions: At the final analysis, the addition of atezo to adjuvant anthracycline- and taxane-based chemo did not improve iDFS in the ITT population of stage II-III TNBC or in any of the subgroups interrogated. Safety data remain consistent with the known profile of atezo in early TNBC.

Conflict of interest: Advisory Board: Dr. McArthur has consulted for Amgen, Bristol-Myers Squibb, Celgene, Eli Lilly, Genentech/Roche, Immunomedics, Merck, OBI Pharma, Pfizer, Puma, Spectrum Pharmaceuticals, Syndax Pharmaceuticals, Peregrine, Calithera, Daiichi-Sankyo, Seattle Genetics, AstraZeneca, Gilead, Crown Bioscience, and TapImmune.

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2LBA LBA Oral

Immune subtyping in the Response Predictive Subtypes (RPS) identifies a subset of triple negative (TN) early-stage breast cancer patients with a very low likelihood of response to neoadjuvant immunotherapy (IO): results from 5 IO arms of the I-SPY2 TRIAL

D.M. Wolf[1], C. Yau[2], J. Haan[3], D. Wehkamp[3], A. Witteveen[3], A. Glas[3], M. Campbell[2], R. Nanda[4], J. Chien[5], R. Shatsky[6], C. Isaacs[7], A. Barcura[3], L. Mittempergher[3], M. Kuilman[3], D. Yee[8], A. DeMichele[9], J. Perlmutter[10], L. Pusztai[11], L. Esserman[2], L.J. van 't Veer[12]. *[1]University California San Francisco, Laboratory Medicine, San Francisco, USA; [2]University California San Francisco, Surgery, San Francisco, USA; [3]Agendia, Research and Development, Amsterdam, The Netherlands; [4]University Chicago, Medicine, Chicago, USA; [5]University California San Francisco, Medicine, San Francisco, USA; [6]University California San Diego, Medicine, San Diego, USA; [7]Georgetown University, Medicine, Washington DC, USA; [8]University Minnesota, Masonic Cancer Center, Minneapolis, USA; [9]University Pennsylvania, Medicine, Philadelphia, USA; [10]Gemini Group, Advocacy, Ann Arbor, USA; [11]Yale University, Medicine, New Haven, USA; [12]University California San Francisco, Helen Diller Family Comprehensive Cancer Center, San Francisco, USA*

Background: Neoadjuvant immunotherapy (IO) has become standard of care for early stage TN breast cancer. However, not all patients respond and IO poses significant risk of permanent, life altering immune related adverse events (iRAEs) including adrenal insufficiency and thyroid dysfunction. Previously we showed immune gene expression signatures dominated by STAT1/chemokine/cytokine/dendritic markers associate with pathologic complete response (pCR) in TN treated with IO and developed a clinically applicable Immune classifier (ImPrint) predicting response to IO for both TN and HR+ that is now being used in I-SPY2.2 as part of the Response Predictive Subtypes. This initial ImPrint classifier performed with high accuracy for TN and HR+ patients combined, though we noticed that this classifier could be further improved by reducing the false-negative rate for TN (ie high negative predictive value). Here we report the performance of a refined version of ImPrint for TN patients (ImPrintTN) from 5 IO arms of the I-SPY2 trial.

Methods: 150 TN patients from 5 pooled IO arms (anti-PD1, anti-PDL1/PARPi, anti-PD1/TLR9 dual-IO, and anti-PD1 +/- LAG3 dual-IO, all plus taxane/anthracycline) and 128 patients from the taxane/anthracycline concurrent control arm were included in this analysis. Patients in IO arms with FFPE pre-treatment biopsies were divided into treatment- and response-balanced training and test sets; and an IO-response classifier was developed including additional immune signaling and checkpoint markers using pre-treatment mRNA from the training set (n=55). Patient biopsies were classified ImPrintTN+ (likely sensitive) vs. ImPrintTN- (likely resistant), by Agendia Inc using pre-treatment expression data. Performance of ImPrintTN for predicting pCR to IO in the test set, and overall was characterized using standard methods.

Results: Overall, the pCR rate for TN over the 5 pooled IO arms was 54%. 66% of TN patients were ImPrintTN+. pCR rates with IO in the independent test set were 71% in ImPrintTN+ vs. 22% in ImPrintTN- (delta-pCR rate 49%; sensitivity = 87%; negative predictive value (NPV) = 78%). Similar results were observed in all 5IO arms taken together (test plus training), where pCR rates with IO were 74% in ImPrintTN+ vs. 16% in ImPrintTN- (delta-pCR rate 58%; sensitivity = 90%; NPV = 84%). In the control arm, pCR rates were 30% in ImPrint+ and 15% in ImPrint-, delta-pCR 15%).

Conclusions: The ImPrintTN single-sample classifier for TN predicts response and non-response to a variety of IO regimens tested in I-SPY2. Within the ImPrintTN- subset, pCR rates to IO regimens are very low, and similar to that of non-IO containing regimens. Prospective validation is ongoing in I-SPY2.2. Our current data suggest that ImPrintTN may help

inform prioritization of IO vs other treatments for TN patients to best balance likely benefit vs risk of serious irAEs.

Conflict of interest Ownership: Stocks Agendia.

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3LBA LBA Mini Oral

Real-world data on the safety and efficacy of trastuzumab deruxtecan and sacituzumab govitecan in patients with advanced breast cancer: the experience of the Hellenic Cooperative Oncology Group

E. Fountzilas[1], T. Lalla[1], G. Karakatsoulis[1], K. Papazisis[1], K. Exarchos[1], A. Koumarianou[1], A. Nikolaidi[1], I. Binas[1], D. Mauri[1], S. Karageorgopoulou[1], E. Razis[1], A. Christopoulou[1], A. Boutis[1], G. Douganiotis[1], F. Zagouri[1], S. Stamatopoulou[1], N. Spathas[1], D. Tryfonopoulos[1], A. Psyrri[1], A. Koutras[1]. [1]*Hellenic Cooperative Oncology Group HeCOG, Data Office, Athens, Greece*

Background: Antibody-drug conjugates (ADCs) have significantly changed the therapeutic landscape of advanced breast cancer. Trastuzumab deruxtecan (T-DXd), a HER2-targeting ADC and sacituzumab govitecan (SG), a TROP-2-targeting ADC, recently demonstrated superior efficacy over standard of care treatments depending on breast cancer subtype. Our aim was to evaluate real-world efficacy and toxicity data of treatment with T-DXd and SG in patients with advanced breast cancer (aBC).

Methods: We performed a retrospective multicenter review of medical records of patients with aBC who received treatment with T-DXd and SG at Departments of Oncology, affiliated with Hellenic Cooperative Oncology Group (HeCOG). Eligible patients with triple-negative (TNBC), HER2-positive and/or hormone receptor positive aBC who received at least one cycle of T-DXd and/or SG at any of line of treatment were included. Pathology data were recorded in detail from the most recent histology report. The primary endpoint was toxicity rate of each drug. Secondary endpoints included progression-free survival (PFS), overall survival (OS) and PFS in patients with central nervous system metastases.

Results: Overall, data from 200 patients were included in the analysis; 158 patients (79%) received T-DXd and 51 (25.5 %) SG, while 11 (5.5 %) patients had received both agents in 19 major HeCOG-affiliated cancer centers. T-DXd was administered as first, second, or subsequent line of treatment in 6 (3%), 38 (19%) and 103 (51.5%) patients, respectively, while SC in 1 (2%), 9 (17,6%) and 41 (80.4%) patients, respectively. Adverse events (AEs) were reported in 71 (49.3%) patients with T-DXd and 23 (46.9%) with SG; most common AEs were nausea (24.7%), fatigue (18.4%) and vomiting (12.7%) with TDXd, and fatigue (23.1%) and anemia, diarrhea, nausea, neutropenia and thrombocytopenia (all 9.6%) with SG. Interstitial lung disease (ILD) was observed in 8 (5.6%) patients with TDXd and 0 (0%) with SG. Treatment related AEs leading to dose reduction occurred in 18 (9%) patients. Specifically, 17 (12.7%) patients demonstrated primary resistance to T-DXd and 10 (24.4%) to SG. Median follow-up after ADC treatment was 23.2 months. Outcome data are shown in Table (NR: Not Reached, NE: Non-estimable).

Conclusions: Real-world data on the use of two novel agents, T-DXd and SG, in patients with aBC provides significant toxicity and efficacy clinical insight. Further research on the optimal use and sequence of each therapeutic agent is warranted.

	AEs	PFS	OS
T-DXd	All grades: 71 (49.3%) Grade 3/4: 6 (4.2%)	NR (NE, NE)	NR (NE, NE)
HER2 positive		16.98 (15.37, NE)	NR (16.99, NE)
HER2-low		15.27 (10.05, NE)	NR (NE, NE)
Brain metastasis			
SG	All grades: 23 (46.9%) Grade 3/4: 6 (12.2%)		
TNBC		5.68 (3.61, NE)	NR (5.68, NE)
HR+/HER2-		7.85 (3.84, NE)	9.63 (6.47, NE)
Brain metastasis		5.68 (1.57, NE)	NR (3.84, NE)

No conflict of interest.

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AWARD AND ORAL ABSTRACT SESSION 21 March 2024 9:30–10:55

Young Investigator Innovation Award and Oral Abstracts

4LBA LBA Mini Oral

Young boost randomized phase III trial of high vs low boost radiation in young breast cancer patients: 10-year results

S. Bosma[1], E. van Werkhoven[2], H. Bartelink[3], A. Fourquet[4], C. Hurkmans[5], J. Maduro[6], E. Rutgers[7], L. Scheijmans[8], D. Schinagl[9], M. Stam[10], M.J. van de Vijver[11], H. Westenberg[10], A. Scholten[3], P. Poortmans[12], L. Boersma[13]. [1]*The Netherlands Cancer Institute, Radiation oncology, Amsterdam - HollandPTC- Delft, The Netherlands;* [2]*Erasmus MC Cancer Institute, Statistics, Rotterdam, The Netherlands;* [3]*The Netherlands Cancer Institute, Radiation oncology, Amsterdam, The Netherlands;* [4]*Institute Curie, Radiation oncology, Paris, France;* [5]*Catharina Hospital, Radiation oncology, Eindhoven, The Netherlands;* [6]*University Medical Center Groningen, Radiation oncology, Groningen, The Netherlands;* [7]*The Netherlands Cancer Institute, Surgical Oncology, Amsterdam, The Netherlands;* [8]*Institute Verbeeten, Radiation oncology, Tilburg, The Netherlands;* [9]*Radboud University Medical Center, Radiation Oncology, Nijmegen, The Netherlands;* [10]*Radiotherapiegroep, Radiation oncology, Arnhem, The Netherlands;* [11]*Amsterdam UMC, Pathology, Amsterdam, The Netherlands;* [12]*Iridium Netwerk, Antwerp, Belgium, University of Antwerp, Faculty of Medicine and Health Sciences, Radiation oncology, Antwerp, Belgium;* [13]*MAASTRO-GROW School for Oncology and Developmental Biology- Maastricht University Medical Centre, Radiation oncology, Maastricht, The Netherlands*

Background: An extra radiation boost dose to the primary tumour bed in addition to whole-breast irradiation (WBI) reduces local recurrence (LR) risk after lumpectomy. As young age is a risk factor for LR, the young boost trial (NCT00212121) investigated whether an increased boost dose could improve local control in young patients. Here, we present the results of the 10-year primary analysis.

Material and Methods: Between 2004 and 2011, patients≤50 yrs with pT1-2,pN0-2a invasive breast cancer after a microscopically complete excision (focally involved margins were allowed) were randomly assigned to receive a boost of 26 Gy (high) or 16 Gy (low) to the tumour bed. Patients were stratified by age, tumour size, lymph node involvement, interstitial/external boost, and institution. Primary endpoint was local control at 10 years. The revised design (2008) assumed a 3.5% difference in local control at 10 years (from 92 to 95%; power 90%; two-sided significance level α of 5%). All new tumours in the ipsilateral breast were counted as LR. We used competing risk analysis with death as competing risk.

Results: In total, 2421 patients were randomized in 32 centres in the Netherlands, France, and Germany. 1211 patients were assigned to a high and 1210 patients to a low boost. Median follow-up was 11.7 years. Baseline characteristics were well-balanced between both two arms. Median age at diagnosis was 45 years (IQR 41-48), the median pathological diameter was 15 mm (IQR 1-80), and 70% was pN0. Tumours were grade 2 or 3 in.82 % and subtype was 67% ER+HER2-, 20% TNBC, and 13% HER2pos. 65% was treated with a sequential boost; 35% with a simultaneously integrated boost. Boost techniques consisted of X-ray beams in 75%, electrons in 20%, 1% interstitial boost and 4% others. Systemic treatment was given to 82% of patients. In total, 109 local recurrences have occurred (61 low boost, 48 high boost). LR was the first event for 42 patients in the low boost and 23 patients in the high boost arm. The 10-year LR-rate for patients treated with a low boost was 4,4% (95% CI 3,4-5,8) versus 2,8% (95% CI 1,9-3,9) in patients treated with a high boost, HR 0.61 (95% 0.39-0.96), p 0.032. Factors significantly associated with LR in multivariable analysis were boost dose, final margin status, subtype, and the use of chemotherapy. The cumulative incidence of marked or moderate fibrosis in the boost area was 27% patients treated with a low boost vs 48% patients treated with a high boost.

Conclusions: Local control in young breast cancer patients was excellent. The primary endpoint that a high radiation boost after whole-breast irradiation

improves local control by at least 3.5% was not met. The small statistically significant benefit does not justify the increased impact on cosmetic outcomes.

No conflict of interest.

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ORAL ABSTRACT SESSION **22 March 2024 9:30–11:15**

Oral abstract session

5LBA LBA Mini Oral

Significant higher satisfaction with breast and psychosocial well-being and low complication rate – First report of the 24 months follow-up results from the prospective international mesh-supported pre-pectoral breast reconstruction trial (PRO-Pocket-Trial clinicaltrials.gov: NCT03868514)

S. Paepke[1], E. Klein[1], A. Andrulat[2], C. Ankel[3], L. Bauer[4], A. Faridi[5], V. Fink[6], C. Gerber-Schäfer[7], D. Gschwantler-Kaulich[8], J. Heil[9], S. Kümmel[10], R. Ohlinger[11], M. Thill[12]. *[1]Klinikum rechts der Isar, Department of Gynecology and Obstetrics, Technical university of Munich, Munich, Germany; [2]Rotkreuzklinikum, Interdisciplinary Breast Center, Munich, Germany; [3]DRK-Kliniken, Breast Center, Berlin, Germany; [4]GRN Klinik Weinheim, Certified Breast Center, Weinheim, Germany; [5]Universitätsklinikum Bonn, Department of senology with certified breast center, Bonn, Germany; [6]Universitätsklinikum Ulm, Breast center, Ulm, Germany; [7]Vivantes Klinikum am Urban, Breast Center, Berlin, Germany; [8]Ordinationszentrum PK Döbling, Breast center, Vienna, Germany; [9]Klinik St. Elisabeth, Breast Center, Heidelberg, Germany; [10]Kliniken Essen Mitte, Breast Center, Essen, Germany; [11]Universitätsmedizin Greifswald, Interdisciplinary breast center, Greifswald, Germany; [12]Agaplesion Markus Krankenhaus, Breast Center, Frankfurt, Germany*

Background: Safety and breast aesthetics of direct-to-implant techniques are well recognized. Pre-pectoral techniques add a new dimension supported by the next generation of titanized mesh-pockets but have to be proofed in prospective analyses.

Material and Method: A prospective international, multicentre trial was performed in 12 breast centres in Germany and Austria. Patient reported outcome after mesh-supported (titanized mesh TiLOOP®Bra-Pocket) pre-pectoral breast reconstruction is assessed via Patient-Reported-Outcome (Breast-Q questionnaire). Furthermore, complications are documented. The results of the 24 months follow-up (FU) are presented.

Results: From 06/2019 until 03/2021, 311 patients with TiLOOP®Bra-Pocket supported breast reconstructions were included. The last patient visit was in June 2023 (follow up 2-4 years). Patients' age was between 23 and 80, mean BMI was 24.6±4.5 kg/m^2. The most frequent indication for surgery was invasive cancer followed by high breast cancer risk. Breast-Q data are available for 222 patients. The mean score of the scales "satisfaction with breasts" and "psychosocial well-being" increased by 8.3±20 and 5.2±20.3 points, respectively, from prior surgery to 24 months FU. The mean score for "sexual well-being" increased by 5.3±22.7 points. Currently, 7.3% seroma, 8.8% capsular fibrosis, 3.8% wound healing disorders, 3.8% infections, 2.3% necroses, and 2.5% revision needing bleedings are documented.

Conclusion: Use of titanized breast meshes enables the only prospective validated standard of pre-pectoral breast reconstruction preserving the natural anatomy, thereby avoiding adverse effects associated with sub-muscular reconstruction and minimizing postoperative pain. Patient-reported outcome showed postoperative increased satisfaction with breast and psychosocial well-being.

Conflict of interest: Advisory Board: Marc Thill: Agendia, Amgen, AstraZeneca, Aurikamed, Becton/Dickinson, Biom'Up, ClearCut, Clovis, Daiichi Sankyo, Eisai, Exact Sciences, Gilead Science, Grünenthal, GSK, Lilly, MSD, Neodynamics, Novartis, Onkowissen, Organon, Pfizer, pfm Medical, Pierre-Fabre, Roche, RTI Surgical, Seagen, Sirius Medical, Sysmex. Other Substantive Relationships: Anne Andrulat: Kongressteilnahme und Referententätigkeit: AstraZeneca, Exact Sciences, Gilead, Lily, Novartis, Roche.

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6LBA LBA Mini Oral

Minimal vs. maximal invasive axillary management after neoadjuvant systemic therapy in node positive breast cancer: 5-year follow-up results of the Dutch MINIMAX registry study

S. de Wild[1,2], L. Koppert[3], M.J. Vrancken Peeters[4,5], M. Smidt[1,2], J. Simons[2,6,7]. *[1]Maastricht University Medical Center+, Surgery, Maastricht, The Netherlands; [2]Maastricht University Medical Center+, GROW School for Oncology and Reproduction, Maastricht, The Netherlands; [3]Erasmus Medical Center, Surgery, Rotterdam, The Netherlands; [4]Netherlands Cancer Institute, Surgery, Amsterdam, The Netherlands; [5]Amsterdam University Medical Center, Surgery, Amsterdam, The Netherlands; [6]Erasmus Medical Center Rotterdam, Radiotherapy, Rotterdam, The Netherlands; [7]MINIMAX, Study Group, Maastricht, The Netherlands*

Background: A large variety of staging and treatment strategies is used in daily practice for clinically node positive (cN+) breast cancer treated with neoadjuvant systemic therapy (NST). A nationwide retrospective registry study was conducted to assess the long-term oncologic safety of these strategies.

Material and Methods: All patients diagnosed with pathologically proven cN1-3 breast cancer in 2014-2017 were included if treated with NST followed by surgery of the breast and axilla. Groups were made based on extent of axillary surgery and axillary radiotherapy (ART). Five-year disease free and overall survival (DFS, OS) were assessed with Kaplan Meier functions for the whole cohort, and each group, and separately for patients with ypN0 or ypN+ disease, and separately for patients with cN3 disease.

Table 1:

	Whole cohort N = 3550 (%)	No ALND, no ART N = 325 (9.2)	ART, no ALND N = 1160 (32.6)	ALND, no ART N = 597 (16.8)	ALND with ART N = 1468 (41.4%)	*p*-value
Age (years), median [IQR]	50 [44-59]	49 [43-58]	50 [44-59]	50 [45-59]	51 [45-60]	0.006
Molecular subtype						
HR+HER2-	1914 (54.3)	109 (33.6)	646 (55.9)	297 (49.9)	862 (59.4)	<0.0001
HR+HER2+	532 (15.1)	83 (25.6)	184 (15.9)	88 (14.8)	177 (12.2)	
HR-HER2+	448 (12.7)	71 (21.9)	136 (11.8)	79 (13.3)	162 (11.2)	
Triple Negative	632 (17.9)	61 (18.8)	189 (16.4)	131 (22.0)	251 (17.3)	
cT-status						
cT1	539 (15.2)	77 (23.7)	219 (18.9)	81 (13.6)	162 (11.0)	<0.0001
cT2	1877 (52.9)	199 (61.2)	649 (56.0)	380 (63.7)	649 (44.2)	
cT3	803 (22.6)	45 (13.9)	242 (20.9)	103 (17.3)	413 (28.1)	
cT4	331 (9.3)	4 (1.2)	50 (4.3)	33 (5.5)	244 (16.6)	
cN-status						
cN1	2871 (80.9)	302 (92.9)	974 (84.0)	548 (91.8)	1047 (71.3)	<0.0001
cN2	137 (3.4)	5 (1.5)	35 (3.0)	10 (1.7)	87 (5.9)	
cN3	542 (15.3)	18 (5.5)	151 (13.0)	39 (6.5)	334 (22.8)	
Primary tumor response						
ypT0/is	1112 (31.3)	186 (57.2)	379 (32.7)	190 (31.8)	357 (24.3)	<0.0001
ypT+	2438 (68.7)	139 (42.8)	781 (67.3)	407 (68.2)	1111 (75.7)	
Nodal response						
ypN0	1306 (36.8)	264 (81.2)	427 (36.8)	263 (44.1)	352 (24.0)	<0.0001
ypN+	2244 (63.2)	61 (18.8)	733 (63.2)	334 (56.0)	1116 (76.0)	
Outcomes						
Regional recurrence	224 (6.3)	21 (6.5)	47 (4.1)	39 (6.5)	117 (8.0)	
5-year DFS %	77.7	86.9	82.3	80.0	71.1	
in ypN0	*84.7*	***89.6***	*81.7*	*87.1*	*83.1*	
in ypN+	*73.6*	*74.6*	*82.7*	*74.4*	*67.4*	
5-year OS %	85.0	92.6	89.6	84.9	79.8	
in ypN0	*90.1*	***95.0***	*89.0*	*89.3*	*88.4*	
in ypN+	*82.1*	*81.9*	*90.0*	*81.4*	*77.1*	

Kruskal-Wallis test was used to compare the groups with regard to age. Other variables were compared with the Pearson's Chi^2-test.

Results: 3550 patients were included (median follow-up 6 years). Table 1 depicts patient, tumor and treatment characteristics with regional recurrence,

DFS and OS outcomes for the whole group and each treatment group. DFS and OS outcomes are also given separately for ypN0 or ypN+ disease. In cN3 patients (N = 542), irrespective of ypN-status, 5-year DFS was 72.2% for no ALND or ART, 75.7% for ART without ALND, 53.7% for ALND without ART and 61.6% for ALND and ART.

Conclusions: Omitting ALND and ART in cN1 patients with axillary pCR resulted in excellent 5-year DFS and OS.

No conflict of interest.

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Poster abstract session

29LBA (PB-010) LBA Poster

A randomized, double-blind, phase III study in India to evaluate efficacy, safety, pharmacokinetics (PK), and immunogenicity of ZRC-3277 (pertuzumab biosimilar) in comparison with Perjeta® (pertuzumab) in patients with HER2-positive metastatic breast cancer

R. Kothari[1], M. Doshi[2], P.K. Chaithanya[3], S.C. Thungappa[4], A. Kumar[5], K. M. Mallavarapu[6], R. Nagarkar[7], V. Mahobia[8], N. Bhatt[9], K.L. Priyadarshini[10], A. Gogia[11], T. Maksud[12], S. Prasad[13], V. Kandappan[14], R.L. Krishnappa[15], P. Shanthemarahalli Shivanna[16], V. Talreja[17], R. Shrivastava[18], D. Parmar[19], S.I.G. Study Investigator Group[20]. *[1]Narayana Multispeciality Hospital, Medical Oncology, Ahmedabad, India; [2]Zydus Research Center, Clinical R and D, Ahmedabad, India; [3]MNJ Institute of Oncology & Regional Cancer Centre, Medical Oncology, Hyderabad, India; [4]HealthCare Global Enterprises Ltd, Medical Oncology, Bengaluru, India; [5]Oncoville Cancer Hospital & Research Centre, Medical Oncology, Bengaluru, India; [6]Basavatarakam Indo American Cancer Hospital & Research Institute, Medical Oncology, Hyderabad, India; [7]HCG Manavata Cancer Centre, Surgical Oncology, Nashik, India; [8]Government Medical College & Hospital, Radiation Oncology, Nagpur, India; [9]Kailash Cancer Hospital & Research Center, Medical Oncology, Vadodara, India; [10]HCG city cancer centre, Medical Oncology, Vijayawada, India; [11]All India Institute of Medical Sciences, Medical Oncology, New Delhi, India; [12]Unique Hospital-Multispeciality & Research Institute, Medical Oncology, Surat, India; [13]Kingsway Hospitals, Medical Oncology, Nashik, India; [14]Erode cancer centre, Medical Oncology, Erode, India; [15]The Bengaluru Hospital, Medical Oncology, Bengaluru, India; [16]K.R. Hospital, Clinical Research Medical Oncology, Mysore, India; [17]Regency Hospital Ltd, Medical Oncology, Kanpur, India; [18]Zydus Research Center, Clinical R&D, Ahmedabad, India; [19]Zydus Therapeutics Inc., Clinical R&D, Pennington, USA; [20]Study Investigator Group, Study Investigator Group, Study Investigator Group, India*

Background: Pertuzumab in combination with trastuzumab and docetaxel is a standard-of-care treatment for HER2-positive metastatic breast cancer (MBC). Pertuzumab biosimilar will increase accessibility and provide cost-effective treatment options for HER2 positive MBC patients. We report first-ever result of a pertuzumab biosimilar study. This phase 3 study evaluated the efficacy, safety, pharmacokinetics (PK), and immunogenicity of ZRC-3277 in comparison with Perjeta® in previously untreated patients with HER2-positive MBC.

Materials and Methods: This phase III, multicenter, double-blind study was conducted at 38 sites across India. A total of 268 patients were enrolled (1:1) in the study. For PK assessment, first 53 patients from both the groups were included. Patients of both groups also received trastuzumab and docetaxel as per standard practice. A total of six cycles were given. Efficacy was compared via the objective response rate (ORR), which was determined by a centrally blinded radiologist as per Response Evaluation Criteria in Solid Tumor (RECIST 1.1). The secondary outcomes included the comparison of PK, immunogenicity, and safety between the two groups.

Results: At the end of six cycles, the ORR was 87.39 and 91.94 in the ZRC-3277 and Perjeta® groups, respectively, in the mITT population (N = 243) (Table 1). For predefined -15% non-inferiority margin, obtained two-sided 95% CIs (-12.19%, 3.11%) for the difference in ORR (-4.55%) between the two groups demonstrated the non-inferiority of ZRC-3277 to Perjeta®. PK, immunogenicity, and safety were similar between the two study groups. The incidence of treatment-emergent adverse events (TEAE) was comparable between treatment groups. The most frequently reported TEAEs were diarrhoea, vomiting, pyrexia, alopecia, and rash. Majority of adverse events were mild or moderate in severity between treatment groups.

Table 1. Tumor response.

Response Criteria	Biosimilar (n = 119) n (%)	Reference (n = 124) n (%)	Total (n = 243) n (%)
Complete response	3 (2.52)	2 (1.61)	5 (2.06)
Partial response	101 (84.87)	112 (90.32)	213 (87.65)
Progressive disease	5 (4.20)	2 (1.61)	7 (2.88)
Stable disease	10 (8.40)	8 (6.45)	18 (7.41)
Overall response rate	104 (87.39)	114 (91.94)	218 (89.71)
Risk difference	–4.54%		
95% CI	(–12.19%, 3.11%)		
p-value	0.2442		

N = number of patients in each treatment group; Objective response rate = complete response + partial response; Values are represented as number, n (%).

Conclusions: Biosimilarity was observed between ZRC-3277 and the Perjeta® in terms of efficacy. No significant difference was observed in PK, immunogenicity, and safety. Hence ZRC-3277 will be a useful cost-effective alternative for treating HER2-positive MBC in India.

No conflict of interest.

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30LBA (PB-011) LBA Poster

A single centre prospective audit of surgical site infections following breast surgery

M. Corden[1], Y. Akmal[1], C. Roshanlall[1]. *[1]East Cheshire NHS Trust, Breast Surgery, Macclesfield, United Kingdom*

Background: Surgical site infections (SSIs) represent a major cause of post-operative morbidity in breast surgery patients, despite being a largely clean and elective specialty. The present audit aimed to determine the SSI rate at a single centre in Northwest England, and identify risk factors associated with SSIs.

Material and Methods: A prospective audit of 92 female patients at East Cheshire NHS Trust (ECNT) was performed between 1st April 2023 and 30th June 2023. Patients were recruited upon initial presentation to the breast clinic and followed for the duration of their care. Demographic and procedure-related data were collected for all patients. SSI was diagnosed according to 2013 Surgical Site Infection Surveillance Service definitions. Risk factors were identified through comparison of demographic data between those that developed SSI and those that did not.

Results: From 1st April 2023 till 30th June 2023, 92 patients had 98 breast operations. 9/98 (9.18%) operations led to SSI; all except one SSI was identified by active surveillance via the breast clinic. Risk factors associated with SSI included: age (median 68 versus 63 years), presence of cardiovascular disease (44.4% versus 27.4%) and undergoing more than one operation (33.3% versus 16.4%). Smokers and diabetics did not develop SSI and only one patient with respiratory comorbidity developed SSI. In patients with SSI, postoperative drain insertion was less common than those that did not develop SSI (11.1% versus 38.2%). Provision of perioperative antibiotics fully adhered to Association of Breast Surgeons (ABS) guidance, but was similar for patients with and without SSI (33.7% versus 33.3%).

Conclusions: The present audit identified an SSI rate of 9.18% following breast surgery at ECNT, which is in line with previously published national data. Observed risk factors for SSI included age, cardiovascular comorbidity and undergoing multiple operations. Provision of intraoperative antibiotics was in accordance with ABS guidance, but did not impact upon SSI rates.

No conflict of interest.

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31LBA (PB-012) LBA Poster

Pre-operative single-fraction stereotactic radiosurgery for early-stage breast cancer: pathological results

C. Reverberi[1], A. Prisco[1], G. Facondo[1], E. Moretti[2], L. Seriau[3], S. Bertozzi[3], E. Pegolo[4], M. Orsaria[4], C. DiLoreto[4], P. Scalchi[2], C. Zuiani[5], C. Cedolini[3], M. Trovò[1]. *[1]ASUFC, Radiotherapy, Udine, Italy; [2]ASUFC, Medical Physics, Udine, Italy; [3]ASUFC, Breast Unit, Udine, Italy; [4]ASUFC, Pathology, Udine, Italy; [5]ASUFC, Radiology and imaging, Udine, Italy*

Background: We present pathological findings of our Phase II clinical trial investigating the role of pre-operative stereotactic radiosurgery (SRS) in early-stage breast cancer.

Materials and Methods: We run a phase II clinical trial enrolling women older than 50, with proven breast invasive non special type carcinoma, hormonal receptors positive/HER2 negative, any grade, tumor size <3cm, unifocal, with no nodal involvement, candidates to conservative surgery. The Gross Tumor Volume (GTV) comprises the tumor. The Clinical Target Volume (CTV) is equal to GTV. The Planning Target Volume (PTV) is created by adding a 3mm margin to CTV. The total dose is 30-36 Gy prescribed to the 95% of the PTV. Breast conservative surgery was performed 8 to 28 weeks after SRS. The pathological response was defined as complete response (pCR) if no residual tumor cells were found, partial response (pPR), or stable disease (SD). The pPR group was subdivided into 3 categories based on the rate of residual disease: <10% (near-pCR), 10-50%, and >50%. We defined "Major Response" the sum of pCR and near-pCR. The post-operative Ki67 was evaluated in patients with residual disease and compared to pre-operative Ki67 value found at the diagnostic biopsy.

Results: From January 2022 to November 2023, we treated 49 patients with a single-fraction SRS upfront lumpectomy. According to the study protocol, for the first 16 patients, the total dose prescribed was 30 Gy and surgery was performed at 9 weeks (range 8-18). We prescribed 33 Gy to the next 16 patients and delayed their surgery to 15 weeks (range 14-21). We treated the last 17 patients with 36 Gy and performed surgery at 20 weeks (range 19-28). Nine patients (18%) achieved pCR, and 18 patients (37%) obtained a Major Response. Thirty-seven patients (76%) had pPR, of which 9 had residual disease <10% (near-pCR), 12 patients between 10-50%, and 16 over 50%. Patients treated with 36 Gy achieved a statistical significant higher Major Response rate compared to the 30-33 Gy group: 59% vs. 25%, respectively ($p = 0.03$). The median Ki67 difference between pre- and post-radiotherapy was 4.5 (IQR 0-13.6) ($p<0.01$, 95%CI 5.05-11.3).

Conclusions: Pre-operative single-fraction SRS leads to high rate of major response. The higher dose correlates with pathological response. We found a significant reduction in Ki-67 value pre- and post-treatment, suggesting its role as potential prognostic factor.

No conflict of interest.

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32LBA (PB-013) LBA Poster

The impact of adjuvant radiotherapy on immediate prepectoral implant-based breast reconstruction

E. Ostapenko[1]. *[1]National Cancer Institute, Breast Surgery and Oncology Department, Vilnius, Lithuania*

Background: Immediate prepectoral implant-based breast reconstruction (IBBR) rates have increased in recent years owing to improved cosmetic, and psychological benefits. However, there is a lack of studies regarding complications rates following adjuvant radiotherapy (RT) among patients undergoing immediate prepectoral IBBR.

Methods: We conducted a retrospective monocentric analysis of a cohort of consecutively treated patients who underwent NSM following immediate prepectoral IBBR at our institution between March 2017 and November 2021. Patient demographics, quality of life, complication rates, and oncological safety were evaluated in the RT and non-RT groups. Data analysis was performed using IBM SPSS Version 24 (IMB Corp., Armonk, NY, USA).

Results: A total of 98 patients were examined: 70 were assigned to have prepectoral IBBR without RT and 28 to the group who had prepectoral IBBR with RT. There was a statistically significant difference in overall capsular contracture rate between the RT and non-RT group (18% vs. 4.3%, $p = 0.04$). The total implant loss in the cohort was 4% (10.7% vs. 1.4%, $p = 0.05$). We obtained a high percentages of all BREAST-Q categories in both groups; however, satisfaction with the breast and sexual well-being was higher in the non-RT group. The three-year overall survivals was 97.4% in the RT group and 98.5% in the non-RT group.

Conclusion: Our findings showed that patients in the RT group had a higher rate of capsular contracture, and implant loss than those in the non-RT group. However, complication rates were within acceptable range and with accurate preoperative information patients have more benefits from immediate reconstruction showing excellent overall quality of life irrespectively of radiation.

No conflict of interest.

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33LBA (PB-014) LBA Poster

Integration of simulated triple assessment clinics into undergraduate medical education to improve preparedness for clinical practice

A. Samanta[1], R. Murphy-Lonergan[2]. *[1]Imperial College London, Faculty of Medicine, London, United Kingdom; [2]Chelsea and Westminster Hospital, Undergraduate Department, London, United Kingdom*

Introduction: New graduates nationally report poor preparedness for clinical practice, which can be addressed through simulation. Simulation is used frequently in medicine but is less well explored in surgery. We explore the use of simulated triple assessment clinics to improve undergraduate confidence and competence with diagnosis, investigation and management of breast pathology and aid preparedness for practice.

Methods: Third year students (n = 20) took part in a 4-station simulated triple assessment clinic, practicing history taking, breast examination, interpretation of imaging and discussion of ongoing management. Participants' confidence and preferential learning environments were assessed pre- and post-session using anonymous questionnaires, utilising Likert scales and free text questions. Qualitative analysis was undertaken to extract common themes and statistical analysis was performed using a Wilcoxon signed-rank test to determine significance.

Results: Global confidence increased significantly post-session ($W = 1292.5$, p-value <2.2e-16). Most marked improvements were seen in the identification of risk factors, interpretation of examination findings and ordering appropriate investigations. Students rated simulated clinical environments for learning highly due to its usefulness, relevance to future practice, active learning process, and increased understanding and confidence when on clinical placement.

Conclusions: Integrating simulated breast clinics into the undergraduate curriculum aids development of clinical skills through active learning and confidence in applying clinical knowledge in breast surgery, which students value highly. Student are enthused to participate when the relevance to future practice is clear.

No conflict of interest.

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34LBA (PB-015) LBA Poster

Risk of atrial Fibrillation in breast cancer patients treated with radiotherapy

C. Georgiou[1], C. Cloconi[1], A. Christodoulou[2], D. Sokratous[2], K. Ferentrinos[2]. *[1]German Oncology Center, Research, Limassol, Cyprus; [2]German Oncology Center, Radiation Oncology, Limassol, Cyprus*

Background: Cardiovascular complications are the most common non-malignant cause of death among cancer survivors treated with radiotherapy (RT) (Ellahham et al., 2022). Post-operative adjuvant RT is commonly used to treat localized breast cancer (BC) and generally results in significant improvements in tumor control and a reduced risk of cancer-related deaths after treatment. However, BC survivors can develop a variety of cardiotoxic complications related to cardiac radiation exposure that occur months to years after RT (Soumarova et al., 2020), (Valiyaveettil et al, 2023), such as cardiovascular disease (CVD), with atrial fibrillation (AF) often reported among them (Mauro et al., 2022). The aim of the study is to investigate the potential risk of AF in BC patients treated with RT.

Methodology: A comprehensive search of PubMed, Cochrane Library and Google Scholar electronic databases was performed to find articles between 2017-2023 according to framework suggested by Arksey and O'Malley, towards a methodological framework to examine the articles based

on the research questions by two reviewers (Arksey & O'Malley, 2005). This review was limited to individuals >18 years old, with BC treated by RT (with/without systematic therapy) and diagnosed with AF. and limited to the Greek and English language.

Results: A total of 6 studies are included in this scoping review. According to Mauro et al, 2017, 2.7% of the participants developed AF. D'Souza et al., 2018, presented a relationship between the age and the risk of AF showing that (>60y) patients were in a higher risk to diagnosed with AF (p =0001). In the study of Grewal et al., 2022, a history of RT was found to be associated with an increase in all-cause in-hospital mortality among admissions with BC and AF (7.09% vs 3.94%, p = 0.01). The likelihood of AF was noted to be higher in those who received beam radiation as the first treatment of choice vs. no radiation therapy (p <0.05), (p < 0.011) (Guha et al., 2023), (Jacobs et al., 2023), (Mery et al., 2020). Although according to Apte et al., 2021, radiation therapy for cancer is an independent risk factor for AF. The known association between cancer and AF may be mediated, at least in part, by the effects of radiation therapy among patients with a history of cancer, with only 2.9% having a concomitant diagnosis of AF (p = 0.001) (Apte et al., 2021). No correlation among the studies was found between left and right BC patients.

Conclusions: BC patients had an increased long-term incidence of AF. The risk of developing AF was almost doubled in patients older than 60 years of compared with the background population. Radiation therapy in cancer patients might partially influence the link between cancer and AF.

No conflict of interest.

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35LBA (PB-016) LBA Poster

Post-Mastectomy reconstruction practices and outcomes for older women in a UK Tertiary Care Centre

J.Z. Hashmi[1], F. Naz[2], S. Mandal[2], H. Khalil[2], A. Kayani[2]. *[1]University Hospitals Birmingham, Breast surgery, Birmingham, United Kingdom; [2]University Hospitals Birmingham NHS Foundation Trust, Breast Surgery, Birmingham, United Kingdom*

Background: Older women represent an under-studied subset of patients in breast cancer. In this audit, we review the indications and kind of reconstruction in this cohort within our institution.

Methods: A retrospective analysis of women above 70 years at University Hospitals Birmingham (UHBT) between 2015-23 for post-mastectomy reconstruction surgery. At baseline, we collected information regarding demographics, oncological features, we then identified the type of breast reconstructive surgery performed.

Results: Our cohort consisted of 25 patients (age Range: 70-84, mean 71.5). Invasive ductal carcinoma accounted for majority of tumours (n = 8), followed by radiation-associated angiosarcomas (n = 6), invasive lobular carcinoma (n = 4), and ductal carcinoma in-situ (n = 4), Malignant phyllodes n = 1, Squamous cell n = 1, metaplastic carcinoma n = 1. Eight patients were classified as T1 (tumour size <20mm), eleven as T2 (20-50mm), and 7 as T3 (>50mm). Majority (n = 24) had no nodal involvement.

While eleven patients received no adjuvant treatment, two had Neo-adjuvant and all others any combination of the three.

Forty-eight percent received resurfacing soft tissue coverage(n = 12), Latissimus Dorsi flap(n = 10), was commonly used procedure (TRAM for 2), followed by 2-stage expander/implant-based immediate delayed reconstruction (n = 10), immediate breast reconstruction performed in three (DIEP, LD and implant -one each).

Thirty-two per cent experienced short-term complications (n = 8), 4 returned to theatre (16%). Eight patients experienced long-term complications, 6(24%) requiring revisional surgery.

Conclusion: Our cohort consisted of large number of locally advanced cancers requiring soft tissue coverage with autologous flaps technique used in most women. A cautious approach of tissue expansion utilised as immediate delayed two stage reconstruction. Our findings, however, are limited by its small sample size and highly selected cohort of patients.

No conflict of interest.

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36LBA (PB-017) LBA Poster

Multimodal Predictive Modelling for Axillary Nodal Involvement: Integrating Pathology and Clinicopathological EUSOMA Data

S. Steyaert[1], B. Bussels[2], F. Dedeurwaerdere[3], L. Berteloot[1], I. Kindts[4], A. Roelstraete[5], P. Poortmans[6], P. Vermeulen[6], C. de Beukelaar[7], K. Van VarenBergh[8], P. De Jaeger[1]. *[1]AZ Delta, RADar Learning & Innovation Centre, Rumbeke, Belgium; [2]AZ Delta, Department of Radiation Oncology, Rumbeke, Belgium; [3]AZ Delta, Department of Pathology, Rumbeke, Belgium; [4]AZ Groeninge, Department of Radiation Oncology, Kortrijk, Belgium; [5]OLVZ Aalst, Department of Radiation Oncology, Aalst, Belgium; [6]GZA, Department of Oncological Research, Antwerpen, Belgium; [7]AZ Groeninge, Clinical Trial Center, Kortrijk, Belgium; [8]OLVZ Aalst, Clinical Trial Center, Aalst, Belgium*

Background: Accurate prediction of axillary nodal involvement is crucial for guiding treatment decisions in breast cancer patients. Here, we present a multimodal approach integrating pathology data from primary tumour biopsies with pre-operative clinicopathological features in clinically node-negative patients to develop predictive models for axillary lymph node (ALN) metastasis.

Material and Methods: Pathology data from 309 patients, comprising 831 whole-slide images (WSIs) from a single institution, were processed and analysed. After pre-processing and quality control, a unimodal model was constructed. Additionally, a multimodal model was developed, integrating pathology data with pre-operative clinicopathological features from the European Society of Breast Cancer Specialists (EUSOMA) database. The dataset was split into training and test sets (80-20 stratified split on patient level), and models were evaluated based on their performance metrics including area under the receiver operating characteristic curve (AUC), sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and F1 score.

Results: The unimodal model based on pathology data achieved an AUC of 0.88 on the training set and 0.69 on the test set. When using only clinicopathological data, the unimodal model scored an AUC of 0.70 on both the training and test sets. The multimodal model, incorporating both pathology and clinicopathological data, demonstrated improved predictive performance with an AUC of 0.95 on the training set and 0.83 on the test set. Sensitivity, specificity, PPV, NPV, and F1 score also showed favourable results for the multimodal model compared to the unimodal approaches for the risk prediction of ALN involvement in early breast cancer.

Conclusions: This proof-of-concept study highlights the effectiveness of a multimodal data fusion approach for predicting ALN metastasis risk in breast cancer patients. Integrating pathology data with clinicopathological features enhances the predictive accuracy of the model, underscoring the potential of such approaches for personalised treatment decision-making. Future work will focus on expanding the dataset to include pathology data from additional institutions, thereby further enhancing the robustness and generalisability of the predictive model.

No conflict of interest.

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37LBA (PB-018) LBA Poster

Prognostic significance of complete cell cycle arrest in patients with HR+HER2- breast cancer receiving neoadjuvant chemotherapy

S. Moon[1], K. Yoonwon[1], B. SeungHo[1], L. SeungEun[1], K. Junghyun[1], K. MinJi[1], B. SoongJune[1], J. Joon[1], L. SaeByul[2], A. SungGwe[1]. *[1]Gangnam Severance Hospital, Surgery, Seoul, South Korea; [2]Asan Medical Center, Surgery, Seoul, South Korea*

Background: Complete cell cycle arrest (CCCA) has been regarded as a biomarker associated with endocrine responsiveness and recurrence-free survival in HR+HER2- breast cancer. We evaluated a prognostic influence

CCCA in patients with HR+HER2- breast cancer who had residual tumors after neoadjuvant chemotherapy (NAC).

Methods: Between 2007 January and 2021 June, we retrospectively identified 1,178 patients with ER+HER2- breast cancer who underwent NAC in two academic institutes. Among these, 918 who had Ki67 index in surgical specimen with residual invasive cancer were included. CCCA was defined as Ki67 less than or equal to 2.7%. We investigated the recurrence-free survival (RFS).

Results: In 918 patients, the CCCA rate was 60.1% (552/918). The rate was 63.7% in grade 1/2, whereas it was 37.0% in grade 3. At a median follow-up of 57.8 months, the RFS differed significantly according to the CCCA ($p < 0.001$); The 7-year RFS of the CCCA group was 75.8% (95% CI, 71.3-80.6%), whereas that of the non-CCCA group was 63.9% (95% CI, 58.0-70.4%). CCCA was associated with superior RFS in both grade 3 and clinical stage 3 groups. In multivariable analyses, achieving CCCA was demonstrated as a prognostic factor for RFS (hazard ratio 0.50, 95% CI, 0.37-0.67) independent of stage, age, and grade.

Conclusions: Among the patients with HR+HER2- breast cancer who do not attain pathologic complete response after NAC, achieving CCCA is associated with a favorable prognosis.

No conflict of interest.

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38LBA (PB-019) LBA Poster

BTUH breast implant outcomes

D. Fraser[1]. [1]*NHS, Basildon hospital, Essex, United Kingdom*

Background: Breast reconstruction surgery for cancer can be a debilitating and life changing experience for patients, with complex affects on physical and mental health throughout the rehabilitation journey. We conduct a study on a cohort of patients undergoing this procedure, with focus on Patient reported outcome measures.

Materials and Methods: We reviewed all patients who underwent breast reconstruction surgery from 2017 to 2023. Data on demographic, diagnosis, pre- and post-operative adjuvant treatment, and implant characteristics were collected. Outcome measures were the patient reported outcome measures of Breast-Q psychosocial well being, physical wellbeing, satisfaction with breasts. Independent t-test was conducted to find differences between PROMs for each group, and linear regression of age and implant size on each score.

Results: A total of 69 patients were included in the study, with 39 patients having PROMS collected. The mean age of patients at operation was 57.6 years old. 40% of patients had smoked before, and 40.8% had BMI>30. For indication of surgery, 25 patients were for multifocal, 7 were for intra-lobar, 21 were for intraductal, and 15 were for ductal carcinoma in situ. Pre-surgery, 16 patients received chemotherapy, 13 received hormonal therapy, 5 received radiotherapy and 3 triple therapy. 29 patients had pre pectoral placement and 40 had subpectoral placement. 17 patients had smooth implants and 52 had textured. The average size of implant was 330mm. Having a single stage immediate implant reconstruction was associated with a lower psychosocial score (66.0 vs 86.9, $p = 0.24$) compared to double stage implant reconstruction. Sub pectoral placement was associated with a higher (75.7 vs 61.9 $p = 0.046$) psychosocial score than pre pectoral placement. Textured surface was associated with lower physical score than smooth surface (34.7 VS 50.2 $P = 0.046$). On linear regression, age was positively associated ($p = 0.007$) with psychosocial score

Conclusion: The study reveals significant factors affecting breast reconstruction surgery outcomes. Single stage (immediate) implants were linked to lower psychosocial scores compared to Double stage, while subpectoral placement correlated with higher psychosocial scores than prepectoral placement. Textured surface implants were associated with lower physical scores than smooth ones. Additionally, age showed a positive association with psychosocial scores. These findings underscore the importance of personalized approaches in surgery, considering implant type, placement technique, and patient age. Surgeons should prioritize patient preferences and needs to optimize post-surgical satisfaction and well-being, acknowledging the impact of implant characteristics on psychosocial and physical outcomes.

No conflict of interest.

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39LBA (PB-020) LBA Poster

COVID-19 and the impact of the social determinants of health on health-related outcomes in women with breast cancer: a prospective cohort study

C. Myers[1]. [1]*Royal College of Surgeons in Ireland, School of Population Health, Dublin, Ireland*

Background: The aim of this research is to evaluate the impact of COVID-19 on health and health care of women with breast cancer (BC) and in relation to the social determinants of health (SDH). The research examines social inequalities in an Irish context, while addressing the efficacy of health care systems to manage and adapt to changing environments.

Material and Methods: The overall research study is structured as a prospective cohort study, using an explanatory sequential design. Study one includes surveys distributed to women with BC during the pandemic to examine the impact of COVID-19 on health care services and quality of life (QoL). Study two includes a qualitative interviews with women, recruited through the baseline survey, and explores experiences with accessing health care and well-being during the COVID-19 pandemic. Study three follows up with the same women to explore their perspectives for improving BC health care post-pandemic. Finally, study four involves a cross-country analysis, comparing the impact of COVID-19 on QoL post-pandemic in Ireland and Canada.

Results: From study one, high COVID-19 impact was associated with greater disruption to BC services and lower QoL. Health insurance status was found to moderate the effect of COVID-19 on disruption of BC services and QoL. Themes from study two included: BC services (screening, active treatment, and routine care); BC support and communication (continuity of care, role of liaison, and support services); and QoL (emotional, social well-being, and functional well-being). Themes varied by socio-economic status (SES) and region of residence (urban versus rural). Study three identified unmet needs and patient-priorities, including improving the transition from active to post-treatment, enhancing support resources, and implementing telemedicine appropriately. Women from low-SES background experienced more severe unmet needs. The cross-country comparison (study four) found that in both countries, QoL improved from pandemic to post-pandemic, however it remained sub-optimal to pre-pandemic comparisons. High COVID-19 impact was associated with lower QoL in both countries, therefore COVID-19 stressors may have an on-going detrimental impact.

Conclusion: Women with BC in Ireland were impacted greatly regarding their health and well-being, however the impact was not the same for all women. Low-SES and health insurance status were associated with worse health outcomes. However, the impact of COVID-19 modifies this relationship. COVID-19 stressors are on-going psychosocial determinants for QoL, and this is comparable across countries. Moving forward post-pandemic, it is important to understand the unmet needs, especially crises-related stressors, from varying backgrounds to improve health care policies and to eliminate health inequalities.

No conflict of interest.

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40LBA (PB-021) LBA Poster

Setting up breast services Improvements and Learning bridges in Kyrgyzstan: the SILK project

M. Somaini[1], B. Shaimbetov[2], O. Pagani[3], A. Richetti[3], F. Peccatori[4], M. DelGrande[5], G. Pruneri[6], L. Lippolis[7], S. Morell[8], T. Sabyrbekova[9], N. Bakirova[9], F. Cavalli[10]. [1]*Ospedale Maggiore di Milano or Ca' Granda Ospedale Maggiore Policlinico, University of Milan - Hypertension Center, Milan, Italy;* [2]*National Center of Oncology and Haematology, Bishkek-Kyrgyz Republic, Kyrgyzstan;* [3]*European School of Oncology, Milan, Italy;* [4]*European Institute of Oncology, Milan, Italy;* [5]*IOSI Oncology Institute of Southern Switzerland, Bellinzona, Switzerland;* [6]*National Cancer Institute, Milan, Italy;* [7]*Foundation IRCCS Ca' Granda Ospedale Maggiore Policlinico,*

Milan, Italy; [8]Zhibek Association, Ticino, Switzerland; [9]Public Fund Egene, Bishkek, Kyrgyzstan; [10]European School of Oncology ESO, Milan, Italy

Background: Breast cancer (BC) incidence is increasing in low-middle-income countries (LMICs), where mortality rates are high due to unavailability of early detection and affordable treatments. Kyrgyzstan has 5,6 million inhabitants (last 2012 estimate). The World Bank classifies Kyrgyzstan as a LMIC.

Material and Methods: In 2011, the Swiss Development Cooperation in Central Asia audited for a BC project in Kyrgyzstan. The audit found a dramatic situation in imaging, histologic diagnosis, and treatment (local and systemic). A multi-step program was funded, supported by the European School of Oncology (ESO), the Swiss Cancer League and the Swiss Association against Cancer in close collaboration with the local ONG Ergene (Europa Donna member), the Swiss Embassy and the Kyrgyz Ministry of Health. The first priorities were mammographic and histologic diagnosis. From 2017, Swiss and Italian breast specialists periodically visited Kyrgyzstan to supply materials, teach health professionals and trace progress and problems; Kyrgyz doctors were trained in Switzerland and Italy, patients were provided educational support and devices (prostheses, wigs).

Results - next steps: Improvements were significant. The mammography quality is now acceptable, pathologists routinely assess hormonal receptors, HER-2 and Ki-67. Diagnostic/therapeutic guidelines have been implemented with local physicians. Thanks to a Canadian donation, modern radiotherapy technologies have replaced old, unsafe equipment. Next steps involve training of the radiation oncology team and surgeons in adequate BC loco-regional approaches and availability of drugs of the WHO list of essential medicines, as well as tele pathology and mobile mammography.

Following the holistic vision of the project, attention is also focusing on nutritional and rehabilitation aspects. Next steps involve improvement of the hospital menu and quality of meals, spread of the nutritional WCRF/AIRC BC guidelines and active information and support to patients to promote nutritional awareness and address treatment side effects.

The rehabilitation aspect includes active on-site and self-done massages in the context of Eutonia, a rehabilitation technique helping patients recovering after locoregional treatments. During the pandemic a subtitled video was developed and biweekly online sessions with patients were organized, still ongoing, thanks to Zhibek Association. Next steps include promotion and wider availability of services by personnel and patients' training.

Conclusions: The SILK project shows effective BC cooperative programs in LMICs are feasible. Strict and continuous collaboration with local governments, patient's organizations and health professionals is vital to ensure their success. SILK is a model adaptable and exportable to other critical situations across the world.

No conflict of interest.

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41LBA (PB-022) LBA Poster

Drain-less surgery – is this the way forward?

S. Bezzaa[1], R. Law[1], S. Horn[1], L. Noor[1], W. AlSarakbi[1], K. Breen[1], G. Yankson[1], R. Tagoe[1], S. Madigan[1], C. Norman[1]. *[1]Croydon University Hospital, Breast Surgery, London, United Kingdom*

Background: Post-operative drain use in Breast surgery is controversial. Many surgeons leave drains to reduce seroma formation as this can lead to patient distress, multiple attendances and interventions. Drain practice varies between centres. There is a sparsity of national guidelines and evidence in the literature. We aimed to review use of post-operative drains and seroma formation in a single District General Hospital to inform the literature.

Material and Methods: All cases undergoing drain insertion over a 3-month period from May-August 2023 were reviewed. Equivalent cases without drains were also reviewed. Data was collected from electronic medical records retrospectively.

Results: 15 patients underwent drain insertion during the 3-month period. 18 patients did not have drains for equivalent procedures during this time.

The mean age was 54.6 years in the drain group and 59.6 years in the no-drain group. Six (40.0%) of patients had seromas in the drain group and eight (44.4%) patients in the no-drain group. One patient required drain insertion after return to theatre secondary to haematoma after wide local excision.

Operation N (%)	No Drain Seroma	Drain Aspiration	N (%) Seroma	Aspiration	
Implant exchange	3 (17)		2 (13)	1 (7)	
Implant removal	2 (11)	2 (11)	2 (13)		1 (7)
Axillary Node Clearance	7 (39)	2 (11)	3 (17) 4 (27)	3 (20)	1 (7)
Mastectomy	6 (33)	4 (22)	4 (27)	2 (13)	
Implant based reconstruction			2 (13)		
Median mastectomy weight (IQR)	404g (307.5g–535g)	NA	587g (493g–1312g)		

Conclusions: The results indicate that there is little difference in seroma outcomes in the drain vs. no drain populations. A randomised control trial would provide definitive evidence and may indicate whether drain usage impacts cosmetic results. Novel haemostatic agents applied directly to the surgical cavity may offer an alternative to reducing post-operative seroma formation.

No conflict of interest.

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42LBA (PB-023) LBA Poster

Incidence and survival of male Breast Cancer in Goias: A 10-year analysis (2010–2020)

R. Dutra[1], P. Loyola[1], L. Soares[1]. *[1]Federal University of Goias - UFG, Department of Mastology, Goiania, Brazil*

Background: Male breast cancer is a rare pathology in the population, representing approximately 0.2% of all cancers and only 1% of the incidence of breast cancer. The fact of low incidence makes patients neglect the possibility, which makes diagnosis and treatment of this type of disease difficult, which represents 0.1% of cancer deaths in men. For the year 2021, the National Cancer Institute (INCA) estimated 66,280 new cases of breast cancer and a number of deaths of 18,295, of which 18,068 were women and 227 men. The objective is to describe the epidemiological characteristics of breast cancer in the male population in Goiás and analyze survival from 2010 to 2020. Estimate survival depending on age group, tumor morphology, tumor grade, tumor phenotype and extent of the disease.

Material and Methods: This is an ecological global survival study carried out between 2010 and 2020. The data were collected from the Goiânia Population-Based Cancer Registry database in the state of Goiás, Brazil. Men with breast cancer residing in Goiás, diagnosed annually between 2010 and 2020, were included in the study. Survival curves were carried out applying the Log Rank and Tarone-Ware tests and the method used in logistic regression was that of Backward.

Results: In the 10-year period analyzed, 138 male breast cancers were diagnosed in patients living in Goiás, Brazil. The most prevalent clinical profile were lesions located in the left breast (57.2%) and of localized extension (50.0%). Survival depending on age group presented a median of 123.50 months in patients aged less than 50 years, 126 months in patients aged between 50-69 years and 141.50 months in patients aged 70 years and over; depending on tumor morphology, it presented a median of 141 months in invasive ductal tumors and 121 months in other tumor types; depending on the tumor grade, it presented a median of 141.50 months in grade I tumors, 139 months in grade II tumors and 138 months in grade III tumors; depending on the tumor phenotype, it presented a median of 114 months in luminal HER tumors, 149 months in luminal tumors and 123 months in triple-negative tumors; depending on the extent of the disease, it was 133.50 months in localized disease, 141 months in regional disease and 115 months in metastatic disease.

Conclusions: In the period from 2010 to 2020, 138 male patients were diagnosed with breast cancer in the state of Goiás. The prevalent age group was between 50-69 years old, corresponding to 59.6%. Patients under the age of 50 and over or equal to 70 years together represented 40.4% of cases. Regarding ethnicity, the vast majority of patients did not have their race informed (51.4%), followed by self-declared white patients (26.9%). As of

December 31, 2020, 75 patients (52.7%) were alive and 46 patients (34.5%) died.

No conflict of interest.

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AWARD AND ORAL ABSTRACT SESSION 20 March 2024 11.00–12.55

Young Investigator Innovation Award and Oral abstracts

1 Oral

Effects of exercise on fatigue and health-related quality of life (HRQoL) in patients with metastatic breast cancer (mBC) – do the positive effects apply to all? The multinational randomized controlled PREFERABLE-EFFECT study

A. Hiensch[1], J. Depenbusch[2], M. Schmidt[3], D. Clauss[4], N. Ancizar Lizarraga[5], M. Trevaskis[6], H. Rundqvist[7], J. Wiskemann[8], J. Mueller[8], N. Gunasekara[4], M. Lachowicz[9], E. van der Wall[10], N. Aaronson[11], E. Senkus[9], A. Urruticoechea[12], E. Zopf[13], M. Stuiver[14], Y. Wengstrom[15], K. Steindorf[3], A. May[1], on behalf of the PREFERABLE Consortium.
[1]University Medical Center Utrecht, Julius Center for Health Sciences and Primary Care, Utrecht, Netherlands; [2]German Cancer Research Center DKFZ and National Center for Tumor Diseases NCT, Division of Physical acitvity, Prevention and Cancer, Heidelberg, Germany; [3]German Cancer Research Center DKFZ and National Center for Tumor Diseases NCT, Division of Physical Activity, Prevention and Cancer, Heidelberg, Germany; [4]German Sport University Cologne, Molecular and Cellular Sports Medicine, Cologne, Germany; [5]Donostialdea IHO, Oncology, San Sebastian, Spain; [6]Australian Catholic University, Mary MacKillop Institute for Health Research, Melbourne, Australia; [7]Karolinska Institutet, Laboratory Medicine, Stockholm, Sweden; [8]National Center for Tumor Diseases NCT, Medical Oncology, Heidelberg, Germany; [9]Medical University of Gdańsk, Oncology and Radiotherapy, Gdańsk, Poland; [10]University Medical Center Utrecht, Medical Oncology, Utrecht, Netherlands; [11]Netherlands Cancer Institute/ Antoni van Leeuwenhoek Hospital, Psychosocial Research and Epidemiology, Amsterdam, Netherlands; [12]Fundación Onkologikoa, R&D department, San Sebastian, Spain; [13]Cabrini Cancer Institute, The Szalmuk Family Department of Medical Oncology, Melbourne, Australia; [14]Netherlands Cancer Institute/ Antoni van Leeuwenhoek Hospital, Center for Quality of Life/Psychosocial Research and Epidemiology, Amsterdam, Netherlands; [15]Karolinska Institute, Nursing, Department of Neurobiology, Care Sciences, and Society, Stockholm, Sweden

Background: The PREFERABLE-EFFECT study (NCT04120298) was designed to assess effects of a 9-month supervised exercise program in patients with mBC on fatigue, HRQoL and cancer- and treatment-related side effects. Here we investigate whether exercise effects are consistent across subgroups of patients.

Materials and Methods: PREFERABLE-EFFECT is a multinational RCT including patients with mBC from five European countries (DE, PL, ES, SE, NL) and Australia. Participants were randomly assigned to usual care (UC) or a 9-month supervised, combined aerobic and resistance exercise program (EX). All participants received general exercise advice (physical activity ≥30 min/day) and an activity tracker. Our primary outcomes physical fatigue (EORTC QLQ-FA12 subscale) and HRQoL (EORTC QLQ-C30 summary score), were assessed at baseline, 3, 6, and 9 months. Intervention effects (intention-to-treat) were determined by comparing the change from baseline to 3, 6 (i.e., primary endpoint) and 9 months between groups using mixed effects models for repeated measures, adjusted for baseline values of the outcome variable and stratification factors (line of treatment and study center). A significant improvement of either or both primary outcomes was considered as successful. Subgroup effects were investigated by adding interaction terms to the model for age, tumor receptor status, disease-free interval and one relevant EORTC QLQ-C30 symptom scale 'pain'.

Results: Between 2019–2022, we included 357 patients with mBC: 178 randomized to EX and 179 to UC. Patients were, on average, 55.4 years of age (SD = 11.1), most patients received 1st/2nd line of treatment at study enrollment (74.8%) and had bone metastases (73.9%). At 6 months, participation in the exercise program resulted in statistically significant positive effects on both primary outcomes, compared to UC: physical fatigue was lower (mean difference: −5.3, 95% CI −10.0; −0.6, effect size (ES) = 0.22) and HRQoL was better (+4.8, 2.2;7.4, ES = 0.33). We also found positive effects on numerous QLQ-C30 scales, including pain (−7.1, −12.1; −1.9, ES = 0.28). These positive effects did not differ significantly as a function of tumor receptor status or disease-free interval. Larger effects on HRQoL were found for patients who were younger (<50 years (31%); +8.4, 3.2;13.6 vs ≥50 years; +3.3, 0.2;6.5) or reported pain above the clinically important threshold at baseline (58%) compared to patients without pain (+6.0, 2.0;10.0 vs +2.5, −0.8;5.7).

Conclusion: Supervised exercise during palliative treatment led to beneficial effects on mBC patients' fatigue and HRQoL. The effects were more pronounced in younger patients and patients who reported pain. Based on these findings, we recommend supervised exercise for all patients, and in particular those who report pain, as part of supportive care regimens during palliative treatment of mBC.

No conflict of interest.

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2 Mini Oral

The effect of pain neuroscience education and behavioural graded activity in breast cancer survivors: a randomised controlled multi-center trial

A. Lahousse[1], J. Nijs[1], D. Beckwée[1], E. Roose[1], C. Fernández-de-las-Peñas[2], C. Fontaine[3], M. Vanhoeij[4], E. Huysmans[1], K. Mostaqim[1], I. Reynebeau[1], A. Malfliet[1], L. Leysen[1]. *[1]Vrije Universiteit Brussel, Department of Physiotherapy, Human Physiology and Anatomy, Faculty of Physical Education and Physiotherapy, Brussels, Belgium; [2]Universidad Rey Juan Carlos, Department of Physical Therapy, Occupational Therapy, Physical Medicine and Rehabilitation, Madrid, Spain; [3]University Hospital Brussels, Medical Oncology Department, Brussels, Belgium; [4]University Hospital Brussels, Breast clinic, Brussels, Belgium*

Background: Chronic pain in breast cancer survivors (BCS) remains undertreated and a challenge for healthcare providers. After cancer, pharmacological approaches are generally less recommended due to potential associated side effects. Therefore, there is a need to investigate non-pharmacological treatments that can effectively address the complex nature of chronic pain in BCS and ultimately improve their health-related quality of life (HRQoL).

The objective of this study is to compare the effectiveness of pain neuroscience education (PNE) combined with behavioural graded activity (BGA) to usual care in reducing pain, improving HRQoL, and enhancing endogenous pain modulation among BCS with chronic pain.

Methods: In this double-blinded clinical trial (September 2020–December 2022, Belgium), 122 women with a breast cancer history were enrolled. Randomly assigned to either the intervention or control group, the intervention group received one PNE session with five BGA sessions. The controls received a leaflet written by 'Kom op tegen Kanker'. Outcomes were measured at baseline, post-intervention, 3 and 12 months post-intervention. The Primary outcomes were pain severity/interference (Brief Pain Inventory (BPI)). Secondary outcomes were HRQoL (EORTC-QLQ-C30), and endogenous pain modulation (thresholds, conditioned modulation, temporal summation). The explanatory outcomes were patient characteristics, pain measures, activity, sleep, mood, and pain cognition. For the analyses, linear mixed models for repeated measures were performed.

Results: Of the 122 participants, 62 were assigned to the experimental group (mean ± SD age, 54.98 ± 9.64 years) and 60 to the control group (53.90 ± 8.63 years). Significant TimexTreatment interaction effects were found for pain severity and interference (BPI), central sensitization index (CSI), pain catastrophizing scale (PCS) and pain vigilance and awareness questionnaire (PVAQ).

Posthoc analyses showed significant improvements for pain severity *(Cohen's d [CI 95%], −0.41*[−0.77; −0.05])*, interference *(−0.47*[−0.83; −0.12])*, PCS *(−0.47*[−0.83; −0.11)* and PVAQ *(−0.47*[−0.83; −0.11])*, as well as a reduction in CSI with a change from baseline to post-intervention of −14.62% *($I_{T1\text{-}T2}$: p_{time} < 0.001)*, and the control group of −3.35% *($C_{T1\text{-}T2}$: p_{time} = 0.12)* after intervention in favour of PNE with BGA.

At 3-month follow-up, the improvements in pain interference *(−0.39* [−0.75; −0.03])*, PCS *(−0.40*[−0.76; −0.04])*, and PVAQ *(−0.40* [−0.76; −0.04])* remained significant.

Conclusions: PNE with BGA did result in a significant short-term reduction in pain severity and interference compared to usual care in BCS with chronic pain. Additionally, large improvements in maladaptive cognitions were observed. However, observed changes in pain did not significantly improve patients' HRQoL and endogenous pain modulation.

No conflict of interest.

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3 Young Investigator Awardee

Intermediate clinical endpoints in early-stage breast cancer: an analysis of individual patient data from the Gruppo Italiano Mammella (GIM) and Mammella Intergruppo trials (MIG)

E. Blondeaux[1], W. Xie[2], L. Carmisciano[3], S. Mura[4], V. Sanna[4], M. De Laurentiis[5], R. Caputo[5], A. Turletti[6], A. Durando[7], C. De Angelis[8], G. Bisagni[9], E. Gasparini[9], A. Rimanti[10], F. Puglisi[11], E. Landucci[12], A. Fabi[13], L. Boni[1], M. Lambertini[14], L. Del Mastro[14], M.M. Regan[2]. *[1]IRCCS Ospedale Policlinico San Martino, U.O. Epidemiology Unit, Genoa, Italy; [2]Dana-Farber Cancer Institute, Division of Biostatistics, Boston, USA; [3]Università di Pisa, Dipartimento di Medicina Clinica e Sperimentale, Pisa, Italy; [4]University Hospital of Sassari, Department of Medical Oncology- UOC Oncologia Medica, Sassari, Italy; [5]Fondazione Pascale IRCCS, Istituto Nazionale per lo Studio e la Cura dei Tumouri, Naples, Italy; [6]Ospedale Martini ASL Città di Torino, Medical Oncology, Turin, Italy; [7]Ospedale S. Anna, Breast Unit, Città della Salute e della Scienza, Turin, Italy; [8]Department of Clinical Medicine and Surgery, University of Naples Federico II, Naples, Italy; [9]Azienda USL-IRCCS di Reggio Emilia, Department of Oncology and Advanced Technology, Oncology Unit, Reggio Emilia, Italy; [10]ASST Mantova, Azienda Ospedaliera Carlo Poma, Mantova, Italy; [11]Department of Medical Oncology- Unit of Medical Oncology and Cancer Prevention, Centro di Riferimento Oncologico di Aviano CRO IRCCS, Aviano, Italy; [12]S. Chiara Hospital, Medical Oncology, Pisa, Italy; [13]Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Precision Medicine Breast Unit, Scientific Directorate, Department of Women, Children and Public Health Sciences, Rome, Italy; [14]IRCCS Ospedale Policlinico San Martino, Department of Medical Oncology, U.O. Clinica di Oncologia Medica, Genoa, Italy*

Background: In the adjuvant breast cancer setting, intermediate clinical endpoints (ICEs), such as disease-free survival (DFS), are frequently used as primary endpoint in randomized trials (RCTs). We aim to assess whether changes in ICEs can predict changes in overall survival (OS) in adjuvant breast cancer trials.

Material and Methods: Individual patient level data from adjuvant phase III RCTs conducted by the GIM and MIG study groups were used. ICEs were computed according to STEEP criteria v2.0 definitions. Using a two-stage meta-analytic model, we assessed the surrogacy of each ICE at both the outcome (i.e., OS and ICE are correlated irrespective of treatment) and trial (i.e., treatment effects on ICE and treatment effect on OS are correlated) levels. The estimates of the degree of correlation were obtained by copula models and weighted linear regression. Kendall's τ and $R^2 \geq 0.70$ were considered as indicators of a clinically relevant surrogacy. Subgroup analyses including only patients with hormone receptor-positive/HER2-negative disease were performed.

Results: A total of 12,397 patients were enrolled in the 6 RCTs between November 1992 and July 2012. Median age at enrolment was 57 years. After a median follow-up of 10.3 years, 2,131 (17.2%) OS events were observed, with 1,390 (65.2%) attributed to breast cancer. At the outcome-level, Kendall's τ correlation coefficients ranged from 0.69 for breast cancer-free interval (BCFI) to 0.84 for distant relapse-free survival (DRFS) (Table). For all ICEs, over 95% of the 8-year OS variability was attributable to the variation of the 5-year ICE. At the trial-level, treatment effects for the different ICEs and OS were strongly correlated, with the highest correlation for recurrence-free survival (RFS) and DRFS and the lowest for BCFI (Table).

	Outcome-level surrogacy		Trial-level surrogacy
ICE	Correlation at the Patient Level (Kendall's τ)	Regression of 8-Year OS Rate v 5-Year ICE Rate (R^2)	Regression of Log(HR)-OS v Log (HR)-ICE (R^2)
DFS	0.75	0.95	0.82
DDFS	0.82	0.95	0.86
RFS	0.80	0.96	0.88
DRFS	0.84	0.96	0.88
IBCFS	0.77	0.97	0.84
RFI	0.73	0.96	0.76
DRFI	0.77	0.95	0.77
BCFI	0.69	0.96	0.70

Abbreviations: DDFS, distant-DFS; RFI, recurrence-free interval; DRFI, distant relapse-free interval; IBCFS, invasive breast cancer-free survival.

Results for patients with hormone receptor-positive/HER2-negative disease (n = 7718) provided similar results at the outcome-level surrogacy while no correlation was found at the trial-level ($R^2 < 0.7$ for all ICEs).

Conclusions: Our results provide evidence supporting the use of all ICEs, except for BCFI, proposed by STEEP v2.0 as primary endpoint in breast cancer adjuvant trials. RFS and DRFS presented the strongest correlation with OS. For patients with hormone receptor-positive/HER2-negative, none of the ICEs met the criteria to be considered a surrogate endpoint of OS.

No conflict of interest.

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4 Oral

Neoadjuvant pembrolizumab or placebo + chemotherapy, followed by adjuvant pembrolizumab or placebo plus endocrine therapy for early-stage high-risk ER+/HER2– breast cancer: Results from the phase 3 KEYNOTE-756 study

F. Cardoso[1], J. O'Shaughnessy[2], H. McArthur[3], P. Schmid[4], J. Cortes[5], N. Harbeck[6], M.L. Telli[7], D.W. Cescon[8], P. Fasching[9], Z. Shao[10], D. Loirat[11], Y.H. Park[12], M. Gonzalez Fernandez[13], G. Rubovszky[14], S.A. Im[15], R. Hui[16], T. Takano[17], F. André[18], H. Yasojima[19], Z. Liu[20], Y. Ding[21], L. Jia[21], V. Karantza[21], K. Tryfonidis[21], A. Bardia[22]. *[1]Champalimaud Clinical Centre, Breast Unit, Lisbon, Portugal; [2]Baylor University Medical Center- Texas Oncology, US Oncology Network, Oncology Department, Dallas, TX, USA; [3]University of Texas Southwestern Medical Center, Department of Medicine, Dallas, TX, USA; [4]Barts Cancer Institute, Queen Mary University London, Centre for Experimental Cancer Medicine, London, United Kingdom; [5]International Breast Cancer Center, Quironsalud Group, Barcelona, Spain and Universidad Europea de Madrid, Faculty of Biomedical and Health Sciences, Department of Medicine, Madrid, Spain; [6]Dept. OB&GYN, LMU University Hospital, Breast Center, Munich, Germany; [7]Stanford University School of Medicine, Department of Medicine, Stanford, CA, USA; [8]Princess Margaret Cancer Centre, Department of Medical Oncology, Toronto, Ontario, Canada; [9]University Hospital Erlangen, Comprehensive Cancer Center Erlangen-EMN, Bavarian Cancer Research Center BZKF, Department of Gynecology and Obstetrics, Erlangen, Germany; [10]Fudan University Shanghai Cancer Center, Shanghai Medical College, Fudan University, Department of Breast Surgery FUSCC, Department of Oncology SMCFU, Shanghai, China; [11]Institut Curie, Medical Oncology Department, Paris, France; [12]Samsung Medical Center, Sungkyunkwan University School of Medicine, Division of Hematology-Oncology, Department of Medicine, Seoul, South Korea; [13]IMAT-Oncomedica, Hemato Oncólogo, Montería, Colombia; [14]National Institute of Oncology, Department of Clinical Pharmacology, Budapest, Hungary; [15]Seoul National University Hospital, Cancer Research Institute, Seoul National University College of Medicine, Department of Internal Medicine, Seoul, South Korea; [16]Westmead Breast Cancer Institute, Westmead Hospital and the University of Sydney, Sydney, NSW, Australia, and Centre of Cancer Medicine, the University of Hong Kong, Hong Kong, Department of Medical Oncology; [17]The Cancer Institute Hospital of JFCR, Breast Medical Oncology Department, Tokyo, Japan;*

[18]Paris-Sud XI, Gustave Roussy, Faculté de Medicine, Villejuif, France; [19]NHO Osaka National Hospital, Department of Surgery Breast Oncology, Osaka, Japan; [20]Henan Breast Cancer Center, Affiliated Cancer Hospital of Zhengzhou University & Henan Cancer Hospital, Department of Breast Disease, Zhengzhou, Henan, China; [21]Oncology, Merck & Co., Inc., Rahway, NJ, USA; [22]Breast Cancer Treatment Program, Massachusetts General Hospital, Harvard Medical School, Boston, MA, USA

Background: KEYNOTE-756 (NCT03725059) is a global phase 3 study of neoadjuvant pembrolizumab (pembro) or placebo (pbo) + chemotherapy (chemo) followed by adjuvant pembro or pbo + endocrine therapy (ET) in patients (pts) with early-stage high-risk $ER^+/HER2^-$ breast cancer. We report primary pCR results and residual cancer burden (RCB) outcomes.

Materials and Methods: Pts with T1c-2 (≥2 cm) cN1-2 or T3-4 cN0-2, centrally confirmed, grade 3, invasive ductal $ER^+/HER2^-$ breast cancer were randomized 1:1 to receive neoadjuvant pembro 200 mg Q3W or pbo, both given with paclitaxel QW for 12 wk, then 4 cycles of doxorubicin or epirubicin + cyclophosphamide (neoadjuvant treatment). After definitive surgery (± radiation therapy), pts received pembro or pbo for 9 cycles + standard ET. Stratification factors include region, tumor PD-L1 status, nodal involvement, ER positivity, and anthracycline schedule. Dual primary endpoints are pCR (ypT0/Tis ypN0) and EFS. Secondary endpoints include OS, pCR defined as ypT0 ypN0 and ypT0/Tis, and safety. RCB was an exploratory endpoint and was assessed by a local pathologist at the time of surgery. RCB-0, −1, −2, and −3 denote increasingly larger residual disease. An institutional review board at each site approved the protocol. Patients provided written informed consent.

Results: 1278 pts were randomized to pembro + chemo (n = 635) or pbo + chemo (n = 643). At the final pCR analysis (May 25, 2023, first interim analysis data cutoff), median follow-up was 33.2 mo (range, 9.7–51.8). In the ITT population, pembro + chemo showed a statistically significant improvement in pCR (ypT0/Tis ypN0) vs pbo + chemo: 24.3% (95% CI, 21.0–27.8) vs 15.6% (95% CI, 12.8–18.6); estimated difference, 8.5 percentage points (95% CI, 4.2–12.8); $P = 0.00005$; results were consistent for the secondary pCR definitions, ypT0 ypN0 (21.3% vs 12.8%) and ypT0/Tis (29.4% vs 18.2%). The benefit of pembro + chemo on pCR was generally consistent in the prespecified subgroups. There were more pts with RCB-0 (24.7% vs. 15.6%) and RCB-1 (10.2% vs 8.1%) and fewer pts in the RCB-2 (40.8% vs. 45.3%) and RCB-3 categories (20.5% vs. 28.9%) in the pembro group versus the pbo group. In the neoadjuvant phase, grade ≥3 treatment-related AE rates were 52.5% with pembro + chemo and 46.4% with pbo + chemo, with 1 death in the pembro arm due to acute myocardial infarction. EFS results are immature and continue to be evaluated.

Conclusion: Addition of pembro to chemo significantly increased the pCR rate and shifted RCB to lower residual disease categories in pts with early-stage high-risk $ER^+/HER2^-$ breast cancer. Safety was consistent with the known profiles of each regimen.

Conflict of interest:

Other Substantive Relationships:

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AWARD AND ORAL ABSTRACT SESSION 21 March 2024 09.30–10.55

YOUNG INVESTIGATOR INNOVATION AWARD AND ORAL ABSTRACTS

5 Young Investigator Awardee

Predictors of long-term adverse quality of life following breast cancer treatment – Insights from the REQUITE cohort study

H. Jandu[1], C. Veal[1], P. Seibold[2], D. Azria[3], J. Chang-Claude[2], A. Choudhury[4], A.M. Dunning[5], D. De Ruysscher[6], S. Gutierrez-Enriquez[7], T. Rancati[8], B.S. Rosenstein[9], E. Sperk[10], H. Stobart[11], R.P. Symonds[1], C. J. Talbot[1], R. Valdagni[12], A. Vega[13], L. Veldeman[14], A.J. Webb[1], C. West[15], T. Rattay[1]. *[1]University of Leicester, Department of Genetics and Genome Biology, Leicester, United Kingdom; [2]German Cancer Research Center, Division of Cancer Epidemiology, Heidelberg, Germany; [3]University Federation of Radiation Oncology of Mediterranean Occitanie, Université de Montpellier, Institut de Recherche en Cancérologie de Montpellier, Montpellier, France; [4]University of Manchester, Manchester Academic Health Science Centre, Christie Hospital, Translational Radiobiology Group-Division of Cancer Sciences, Manchester, United Kingdom; [5]University of Cambridge, Centre for Cancer Genetic Epidemiology, Strangeways Research Laboratory, Cambridge, United Kingdom; [6]Maastricht University Medical Center, MAASTRO Clinic, GROW School for Oncology and Developmental Biology, Maastricht, Netherlands; [7]Vall d'Hebron Barcelona Hospital Campus, Hereditary Cancer Genetics Group, Vall d'Hebron Institute of Oncology VHIO, Barcelona, Spain; [8]Fondazione IRCCS Istituto Nazionale dei Tumori, Unit of Data Science, Milan, Italy; [9]Icahn School of Medicine at Mount Sinai, Department of Radiation Oncology, New York, USA; [10]University of Heidelberg, Medical Faculty Mannheim, Mannheim, Germany; [11]Patient Advocate, Independent Cancer Patients' Voice, Cambridge, United Kingdom; [12]Fondazione IRCCS Istituto Nazionale dei Tumori, Unit of Radiation Oncology, Milan, Italy; [13]Fundacion Publica Galega Medicina Xenomica, Xenómica, Santiago de Compostela, Spain; [14]Ghent University Hospital, Department of Radiation Oncology, Ghent, Belgium; [15]University of Manchester, Institute of Cancer Sciences, Manchester, United Kingdom*

Background: Previous research indicated discrepancies between health professionals and patients in their assessments of side-effects (toxicity) from cancer treatment. However, the relationship between toxicity and health-related quality of life (QoL) remains unclear and has not been explored very well in clinical trials of breast cancer radiotherapy. The aim of this study was to assess the association between clinician-recorded toxicity and patient-reported outcomes (PROs) up to two years following treatment in the multi-centre REQUITE breast cancer cohort (www.requite.eu).

Methods: Breast cancer patients (n = 2,057) were recruited prospectively following breast-conserving surgery (with or without chemotherapy) and prior to radiotherapy across 18 centres in Europe and the US between 2014 and 2016. Toxicity was recorded by the treating physician using CTCAE v4. PROs were assessed using EORTC-QLQ-C30 and -BR23, at baseline, end of radiotherapy, and annual follow-up. Multivariable linear mixed-effects models were fitted to identify patient, tumour and treatment variables associated with adverse QoL. The additional impact of adverse toxicity on QoL was also tested in multivariable models.

Results: Clinician-reported toxicity was poorly correlated with PROs across all timepoints. Patient age and alcohol use were associated with increasing fatigue ($p = 0.024$ and $p = 0.04$) and a reduction in global health status ($p = 0.02$). Post-operative complications (haematoseroma or infection) negatively affected body image ($p = 0.02$) and arm symptoms ($p = 0.008$), whereas baseline use of analgesia was associated with fewer arm symptoms ($p = 0.02$). Hypo-fractionated radiotherapy was associated with improved global health status ($p = 0.04$), whereas radiotherapy boost was associated with worse global health ($p < 0.001$) and increased fatigue ($p = 0.007$). There was no association of QoL with chemotherapy or endocrine treatment. Breast atrophy (shrinkage) ≥grade (G) 1 at 2 years was associated with worse global health status ($p = 0.02$), worse breast ($p = 0.002$) and arm symptoms ($p = 0.02$) in multivariable models. Telangiectasia ≥G1 was associated with worse global health status ($p = 0.02$) and arm symptoms ($p = 0.01$).

Conclusion: Surgical complications and radiotherapy boost were associated with adverse overall QoL, body image and fatigue, while hypo-fractionation appeared to be protective in terms of overall health status. Radiotherapy-related toxicities, notably, breast atrophy, induration and telangiectasia independently affected multiple QoL domains. These findings emphasize the importance of comprehensive treatment toxicity assessments that integrate both patient and clinician perspectives, and confirm that reducing treatment complications and toxicity will lead to improved health-related QoL in long-term breast cancer survivors.

No conflict of interest.

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6 Mini Oral

Adjuvant Hypofractionated Whole Breast Irradiation (WBI) Versus Accelerated Partial Breast Irradiation (APBI) in Postmenopausal Women with Early Stage Breast Cancer: 5-Years Update of the HYPAB Trial

D. Franceschini[1], L. Lo Faro[1], A. Fogliata[1], R. Spoto[1], L. Dominici[1], A. Bertolini[1], C. Franzese[1], M. Scorsetti[1]. *[1]IRCCS-Humanitas Research Hospital, Radiotherapy And Radiosurgery, Rozzano-Milan, Italy*

Background: Therapeutical strategies in breast cancer are continuously updating. Recent researches assessed the possibility of irradiating only the surgical bed in selected patients (Partial Breast Irradiation, PBI). In 2014 we designed a study to evaluate toxicity and cosmesis of APBI using Volumetric Modulated Arc Therapy-Rapid Arc compared with hypofractionated whole breast irradiation (WBI). These are the updated data after 5 years of follow-up.

Material and Methods: HYPAB (NCT02375048) was a single-institution randomized trial that recruited 172 patients from 2015 to 2018. Patients with Luminal A or B early stage breast cancer underwent conserving surgery and were randomized to either adjuvant WBI or APBI, delivered with VMAT-RA technique. Clinical evaluation was performed during the first visit, at the simulation CT, once a week during radiotherapy and during follow up. Cosmesis was assessed using the Harvard Scale for Breast Cosmesis.

Primary endpoints of the analysis were toxicity and cosmesis. Secondary endpoints included Local Control, Disease free survival (DFS) and Overall survival (OS).

Results: At the time of the analysis 161 patients were eligible, 86 in the WBI and 75 in the APBI group. Median follow-up was 67 months.

The most common late skin toxicity was oedema, reported as G1 in 45 patients (28%), and G2 in 5 patients (3%), with no G3 side effects. The only variable correlated with increased late toxicity was the different fractionation, in terms of HypoWB or APBI irradiation ($p = 0.001$). The incidences of other late effects were: fibrosis as G1 in 51 patients (32%), G2 in 3 patients (2%); hyperpigmentation in 7 patients (4%); telangiectasia in 4 patients (3%); liponecrosis in 28 patients (17%); mastodynia in 20 patients (12%). Fibrosis and liponecrosis tended to correlate with fractionation, in favour of APBI ($p = 0.09$). No cardiac or pulmonary toxicity events were recorded. Cosmesis was rated excellent at last follow-up in 21 cases (11 APBI, 10 HWBI), good in 134 patients (64 APBI, 70 HWBI) and poor in the remnant 6 cases. No difference was detected according to treatment arm.

Of the 161 analysed patients, 6 (3.7%) presented only local failure, 1 isolated axillary relapse (0.6%), 3 (1.8%) developed distant metastases, and one (0.6%) had both local and axillary progression. The loco-regional progression significantly correlated only with fractionation ($p = 0.037$), being the HWBI more favourable.

DFS at 5 and 7 years were 95.6 ± 1.6. The estimated mean OS was 90.6 ± 0.4%.

Conclusion: Mature results confirm the safety and efficacy of APBI in selected early stage breast cancer patients. Late toxicity is improved in the APBI arm at the cost of a slight increase in local relapse. Further studies are ongoing to better elucidate the use of APBI as a de-escalation approach.

No conflict of interest.

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7 Mini Oral

Pre-operative magnetic resonance guided single dose partial breast irradiation: five-year results of the ABLATIVE trial

Y. Civil[1], J. Vasmel[2], R. Charaghvandi[3], A. Houweling[2], C. Vreuls[4], P. van Diest[4], A. Witkamp[5], A. Doeksen[6], T. van Dalen[7], J. Felderhof[2],

I. van Dam[2], H. Verkooijen[8], S. van der Velde[9], F. van der Leij[2], D. van den Bongard[1]. [1]*Amsterdam UMC- location VUmc, Radiation Oncology, Amsterdam, Netherlands;* [2]*UMC Utrecht, Radiation Oncology, Utrecht, Netherlands;* [3]*Radboud University Medical Center, Radiation Oncology, Nijmegen, Netherlands;* [4]*UMC Utrecht, Pathology, Utrecht, Netherlands;* [5]*UMC Utrecht, Surgery, Utrecht, Netherlands;* [6]*St. Antonius Hospital, Surgery, Utrecht, Netherlands;* [7]*Erasmus MC Cancer Institute, Surgery, Rotterdam, Netherlands;* [8]*UMC Utrecht, Imaging Division, Utrecht, Netherlands;* [9]*Amsterdam UMC- location VUmc, Surgery, Amsterdam, Netherlands*

Background: Preoperative partial breast irradiation (PBI) can result in decreased irradiated volumes compared with postoperative PBI and may therefore lead to less toxicity and improved cosmetic outcome. In the multicenter ABLATIVE trial (NCT02316561), 15/36 patients achieved pathologic complete response 6–8 months after preoperative single-dose PBI. We now present long-term outcomes of preoperative single-dose PBI and breast conserving surgery (BCS) including late toxicity, tumor recurrence, survival, cosmetic outcome and quality of life in low-risk breast cancer patients.

Methods: Between 2015 and 2018, 36 patients were treated with preoperative single-dose PBI (20 Gy) followed by BCS after 6 (n = 15) or 8 (n = 21) months. Toxicity was scored at baseline and yearly visits until 5 years after PBI according to the Common Terminology Criteria for Adverse Events, and cosmetic outcome was assessed by patient and physician. Quality of life was evaluated yearly until 4 years after PBI using the EORTC-QLQ-C30 and -BR23 questionnaires, and the Hospital Anxiety and Depression Scale. Changes in cosmetic outcome and quality of life scores from baseline over time were analyzed using linear mixed models.

Results: All women were aged ≥50 years and had invasive, unifocal, non-lobular breast cancer, ER-positive, HER2-negative, and a tumor negative sentinel node. After a median follow-up of 5.5 years (IQR, 5.1–6.0 years), grade 1 breast fibrosis and breast discomfort/pain were present in 83% and 35% of the patients, respectively. One patient had grade 2 fibrosis at 5 years. Two (6%) patients developed ipsilateral breast events (DCIS (n = 1) and invasive lobular carcinoma (n = 1)) and two (6%) distant metastases. Five-year disease-free and overall survival rates were 91% and 94%, respectively. Shortly after BCS at 12 months, the proportion of patients (very) satisfied with the cosmetic results decreased from 89% (baseline) to 63%, before improving to 78% at 5 years ($p = 0.7$). Physicians rated the cosmetic result as excellent/good in 75% of the patients at 5 years versus 100% at baseline ($p < 0.01$). The 4-year median global quality of life score was 83 (IQR 67–92), and similar to baseline (83 (IQR 75–83), $p = 0.42$). Median anxiety scores remained constant over 4 years ($p = 0.6$). The median depression score showed a significant increase at 4 years ($p < 0.01$).

Conclusion: Preoperative single-dose PBI followed by BCS may be an oncological ysafe treatment with mild late toxicity, and no decline in cosmetic results and quality of life during 5 years of follow-up. This means that preoperative instead of standard postoperative irradiation has the potential to challenge the current clinical practice of breast-conserving therapy.

No conflict of interest.

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8 Mini Oral

Quality assurance of radiation therapy among patients in the BOOG 2013-08 trial

V. Wintraecken[1,2], L. Boersma[3,4], L. van Roozendaal[5], J. de Vries[6,7], S. van Kuijk[8], M. Vane[2,4], T. van Dalen[9,10], J. van der Hage[11], L. Strobbe[12], S. Linn[13], M. Lobbes[4,14,15], P. Poortmans[16,17], V. Tjan-Heijnen[4,18], K. van der Vijver[19,20,21], H. Westenberg[22], H. de Wilt[23], M. Smidt[2,4], J. Simons[4,24], On behalf of the BOOG 2013-08 group. [1]*Maastricht University, GROW - School for Oncology and Developmental Biology, Maastricht, Netherlands;* [2]*Maastricht University Medical Centre+, Department of Surgery, Maastricht, Netherlands;* [3]*Maastricht University Medical Centre+, Department of Radiation Oncology Maastro, Maastricht, Netherlands;* [4]*Maastricht University, GROW - School for Oncology and Reproduction, Maastricht, Netherlands;* [5]*Zuyderland Medical Center, Department of Surgical Oncology, Sittard-Geleen, Netherlands;* [6]*Tilburg University, Department of Medical and Clinical Psychology, Tilburg, Netherlands;* [7]*Admiraal de Ruijter ziekenhuis, Board member, Goes, Netherlands;* [8]*Maastricht University Medical Centre+, Department of Clinical Epidemiology and Medical Technology Assessment, Maastricht, Netherlands;* [9]*Diakonessenhuis Hospital, Division of Surgical Oncology, Utrecht, Netherlands;* [10]*Erasmus Medical Centre, Department of Surgery, Rotterdam, Netherlands;* [11]*Leids University Medical Center, Division of Surgical Oncology, Leiden, Netherlands;* [12]*Canisius-Wilhelmina Hospital, Division of Surgical Oncology, Nijmegen, Netherlands;* [13]*Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital, Division of Medical Oncology, Amsterdam, Netherlands;* [14]*Maastricht University Medical Centre+, Department of Radiology and Nuclear Medicine, Maastricht, Netherlands;* [15]*Zuyderland Medical Center, Department of Medical Imaging, Sittard-Geleen, Netherlands;* [16]*Iridium Network, Department of Radiation Oncology, Antwerp, Belgium;* [17]*University of Antwerp, Faculty of Medicine and Health Sciences, Antwerp, Belgium;* [18]*Maastricht University Medical Centre+, Division of Medical Oncology, Maastricht, Netherlands;* [19]*Ghent University Hospital, Department of Pathology, Ghent, Belgium;* [20]*Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital, Center for Gynecological Oncology Amsterdam CGOA, Department of Gynecology, Amsterdam, Netherlands;* [21]*Ghent University, Department of Diagnostic Sciences- Cancer Research Institute Ghent CRIG, Ghent, Belgium;* [22]*Radiotherapiegroep location Arnhem, Radiation Oncology, Arnhem, Netherlands;* [23]*Radboud University Medical Centre, Division of Surgical Oncology, Nijmegen, Netherlands;* [24]*Erasmus Medical Centre, Department of Radiotherapy, Rotterdam, Netherlands*

Background and purpose: In the BOOG 2013-08 trial (NCT02271828), cT1-2N0 breast cancer patients were randomized between breast conserving surgery with or without sentinel lymph node biopsy (SLNB) followed by whole breast radiotherapy. While awaiting primary endpoint results, this study aims to perform a quality assurance analysis on protocol adherence and incidental axillary radiation therapy (RT) dose.

Materials and Methods: Data on prescribed RT and (in 25% of included patients) PTV parameters were recorded for axillary levels I–IV and compared between treatment-arms.

Results: 1,439/1,461 included patients (98.5%) were treated according to protocol and 5.9% patients received regional RT (SLNB 10.9%, no-SLNB 1.5%). In 326 patients included in the subgroup analysis, the mean incidental PTV dose at axilla level I was 59.5% of the prescribed breast RT dose (table 1). In 5 patients (1.5%) the mean PTV dose at level I was ≥95% of the prescribed breast dose. No statistically differences regarding incidental axillary RT dose were found between the treatment-arms.

Conclusion: RT-protocol adherence was high and incidental axillary RT dose was low in the BOOG 2013-08 trial. Potential differences between treatment-arms regarding the primary endpoint can not be attributed to different axillary radiation doses.

No conflict of interest.

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9 Mini Oral

Impact of PET/MRI on early breast cancer management: Results from a prospective trial

R. Di Micco[1], S. Riccardi[1], N. Rotmensz[1], V. Zuber[1], S. Baleri[1], G. Cisternino[1], M. Rampa[1], S. Corona[1], F. Calabretto[1], L. Pitoni[1], C. Canevari[2], F. Gallivanone[3], P. Scifo[2], I. Neri[2], E. Venturini[4], G. Bianchini[5], I. Sassi[6], P. Panizza[4], A. Chiti[2], O.D. Gentilini[1]. [1]*IRCCS San Raffaele University and Research Hospital, Breast Surgery Unit, Milan, Italy;* [2]*IRCCS San Raffaele University and Research Hospital, Department of Nuclear Medicine, Milan, Italy;* [3]*CNR- Consiglio Nazionale per la Ricerca, Biomedical Imaging, Milan, Italy;* [4]*IRCCS San Raffaele University and Research Hospital, Breast Radiology Unit, Milan, Italy;* [5]*IRCCS San Raffaele University and Research Hospital, Breast Oncology Unit, Milan, Italy;* [6]*IRCCS San Raffaele University and Research Hospital, Breast Pathology Department, Milan, Italy*

Background: Accurate staging is crucial in breast cancer (BC) management and could potentially improve prognosis. Recent studies reported that PET/MRI is a novel hybrid imaging tool which provides a simultaneous assessment of locoregional extent and metastatic spread. This study evaluated the impact on BC management of FDG PET/MRI at diagnosis in patients who were candidates for primary surgery.

Material and Methods: We carried out an unplanned preliminary analysis within the prospective interventional study SNB vs PET/MRI 2 (ClinicalTrials.Gov NCT04829643) that is aimed at assessing the capability of PET/MRI to detect macrometastatic axillary lymph nodes. We analyzed 205 BC patients

Table 1: (abstract: 8): Dose volume parameters of planning target volumes in a subselection of BOOG 2013-08 participants

Parameter	Overall N = 326	SLNB arm (pN- and pN+) N = 148	No-SLNB arm N = 178	P
Breast				
Mean dose in Gy, mean; SD(range)	44.1; 3.7(28.5–56.5)	44.4; 3.4(39.3–56.5)	43.8; 4.0(28.5–55.8)	0.195
• % of prescribed breast dose, mean; SD(range)	102.5; 4.1(96.9–125.5)	102.7; 4.2(98.1–124.1)	102.3; 3.9(96.9–125.5)	0.189
V95%, mean (%); SD (range)	98.1; 1.7(89–100)	98.4; 1.3(91–100)	97.8; 1.9(89–100)	**0.002**
Axillary level I				
Mean dose in Gy, mean; SD(range)	25.6; 8.8(2.5–46.1)	26.3; 8.8(5.1–46.1)	25.0; 8.9(2.5–45.6)	0.294
• % of prescribed dose, mean; SD(range)	59.5; 19.9(5.9–101.2)	60.8; 19.6(12.0–101.2)	58.4; 20.1(5.9–100.1)	0.449
V95%, mean (%); SD (range)	31.1; 18.1(0–87)	33.4; 19.1(0–84)	29.3; 17.1(0–87)	0.198
Axillary level II				
Mean dose in Gy, mean; SD(range)	14.8; 8.2(1.3–51.0)	15.9; 8.1(1.3–51.0)	13.9; 8.2(1.4–36.0)	0.075
• % of prescribed dose, mean; SD(range)	34.4; 19.1(3–119.7)	36.8; 18.6(3.1–119.7)	32.5; 19.3(3.0–83.4)	0.091
V95%, mean (%); SD (range)	7.6; 10.0(0–69)	8.9; 10.2(0–46)	6.6; 9.7(0–69)	**0.034**
Axillary level III				
Mean dose in Gy, mean; SD(range)	3.5; 4.4(0.1–45.9)	3.5; 3.7(0.4–21.2)	3.5; 5.0(0.1–45.9)	0.330
• % of prescribed dose, mean; SD(range)	8.2; 10.0(0.2–98.3)	8.1; 8.4(0.9–49.9)	8.2; 11.2(0.2–98.3)	0.367
V95%, mean (%); SD (range)	0.3; 1.4(0–14)	0.2; 1.4(0–14)	0.4; 1.5(0–12)	0.184
Axillary level IV				
Mean dose in Gy, mean; SD(range)	1.0; 0.5(0.1–3.3)	1.0; 0.5(0.3–3.3)	1.0; 0.5(0.1–2.9)	0.959
• % of prescribed dose, mean; SD(range)	2.3; 1.1(0.2–7.8)	2.3; 1.0(0.7–7.8)	2.3; 1.2(0.2–6.5)	0.851
V95%, mean (%); SD (range)	0	0	0	1.000

enrolled at San Raffaele Hospital from July 2020 to October 2023. Each patient underwent FDG PET/MRI at diagnosis. For this preliminary analysis, unplanned study endpoints included: changes in the treatment pathway following the exam, positive predictive value (PPV) of new breast lesions visible only on PET/MRI and new findings in other sites.

Results: PET/MRI substantially influenced treatment strategies in 27.8% (57/205) of patients, leading to modification in clinical recommendation. Eighteen patients underwent primary systemic therapy or systemic therapy for metastatic or other diseases; 9 patients underwent mastectomy instead of previously planned breast conserving surgery (BCS), 12 patients underwent axillary dissection or node sampling instead of sentinel node biopsy, 12 patients underwent bilateral surgery and 6 oncoplastic remodeling instead of standard BCS. In 12 of these patients (21%), pathology showed that additional lesions seen on PET/MRI were not malignant.

Analyzing 210 index breasts (including 5 bilateral cases), PET/MRI had a PPV of 58.3% for detecting new foci of disease in the same breast and 45.5% in the contralateral breast. Its sensitivity for visualizing multifocal BC was 68.4% and specificity 88.9%. Of the 55 newly detected lesions at different sites, 37 warranted further tests like CT scans, X-rays, ultrasounds, or biopsy. This led to the diagnosis of 3 metastatic disease, 1 lung cancer, 11 benign tumors, and 10 benign conditions.

Conclusions: Our preliminary results showed that FDG PET/MRI has potential utility in the management of early BC patients, influencing treatment decisions in almost 30% of women who were candidates to surgery as primary treatment. Furthermore, it provides a good diagnostic performance in detecting multifocal and bilateral tumors. However, false positive result may lead to overtreatment so any new finding should be confirmed by further biopsy.

No conflict of interest.

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10 Mini Oral

Proportion of suboptimal baseline 18F-FDG PET/CT exams in oestrogen positive breast cancer patients according to 18F-FDG uptake in primary tumour – a single center retrospective analysis

M. Lenaerts[1], L. van der Voort[2], M. Smidt[1], T. van de Weijer[3], A. Voogd[4], V. Tjan-Heijnen[5], F. Gallagher[6], L. Aloj[6], T. van Nijnatten[3]. *[1]Maastricht University Medical Center+, Department of Surgery, Maastricht, Netherlands; [2]Maastricht University, Faculty of Health- Medicine and Life Sciences, Maastricht, Netherlands; [3]Maastricht University Medical Center+, Department of Radiology and Nuclear Medicine, Maastricht, Netherlands; [4]Maastricht University, Department of Epidemiology, Maastricht, Netherlands; [5]Maastricht University Medical Center+, Department of Medical Oncology, Maastricht, Netherlands; [6]Addenbrooke`s Hospital, Department of Radiology, Cambridge, United Kingdom*

Background: The extent of breast cancer is an important prognostic factor in locally advanced breast cancer (LABC). Therefore, adequate staging at diagnosis using 18F-FDG PET/CT is recommended for optimal treatment. However, previous studies have confirmed a significantly lower degree of 18F-FDG uptake in primary breast tumours of the oestrogen receptor (ER)-positive subtype compared to other subtypes. Consequently, suboptimal 18F-FDG uptake in ER+ LABC might lead to suboptimal staging. This study aims to assess the proportion of ER-positive tumours with suboptimal 18F-FDG uptake.

Methods: Baseline 18F-FDG PET/CT scans of female patients diagnosed with ER+ LABC in the Maastricht University Medical Centre between 2011–2022 were retrospectively collected. The maximum standardized uptake value (SUVmax) of the primary tumour was measured. Different SUVmax cut-off values were applied to determine the proportion of suboptimal 18F-FDG PET/CT exams. Multivariable logistic regression was performed to determine the possible correlation between clinicopathological predictors and the SUVmax of the primary tumour.

Results: A total of 74 patients were included in the present study. SUVmax cut-off values of 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, and 5.0 correspond with a proportion of women with a SUVmax of the primary tumour below the cut-off value of 6.8%, 16.2%, 24.3%, 31.1%, 39.2%, 40.5%, 45.9%, respectively. When considering 3.0 as an arbitrary cut-off value for SUVmax of the primary tumour, multivariable logistic regression of both ER-percentage (10–100%) and tumour grade (1–2 vs. 3) showed a lower tumour grade to be significantly correlated with a lower SUVmax (0.07 [0.008–0.562]; p = 0.013).

Conclusion: A considerable proportion of ER+ LABC patients have a relatively low SUVmax value of the primary tumour, indicating a potential suboptimal staging on the baseline 18F-FDG PET/CT exam. When considering SUVmax 3.0 as an arbitrary cut-off value of the primary tumour, 24.3% of the patients might have a suboptimal baseline 18F-FDG PET/CT exam. Further research is needed to determine the most appropriate SUVmax cut-off point and to evaluate the necessity of using a more suitable PET tracer for these patients.

No conflict of interest.

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11 Mini Oral

[18F]FDG whole-body PET-MR including an integrated breast MR protocol for locoregional and distant staging in breast cancer patients – a feasibility study

T. van Nijnatten[1], C. de Mooij[1], C. Mitea[1], J. Houwers[1], M. de Boer[2], M. Smidt[3], F. Mottaghy[1], J. Wildberger[1]. [1]*Maastricht University Medical Center +, Radiology and Nuclear Medicine, Maastricht, Netherlands;* [2]*Maastricht University Medical Center +, Division of Internal Medicine-Department of Medical Oncology, Maastricht, Netherlands;* [3]*Maastricht University Medical Center +, Surgery, Maastricht, Netherlands*

Background: Since the introduction of [^{18}F]FDG PET-MR as opposed to [^{18}F]FDG PET/CT, a combination of locoregional staging with breast MR and distant staging with whole-body (WB) [^{18}F]FDG PET-MR within a single protocol has not been investigated yet. Therefore, the aim of our study was to investigate in a feasibility study the combination of [^{18}F]FDG WB PET-MR including an integrated breast MR within a single protocol for locoregional and distant staging in breast cancer patients.

Material and Methods: Consecutive patients with a breast cancer diagnosis according to conventional imaging modalities (full-field digital mammography (FFDM) and ultrasound (US)) were prospectively included. All patients underwent [^{18}F]FDG WB PET-MR including an integrated breast MR protocol. The protocol consisted of dedicated breast MR (prone position) and WB PET-MR (supine position). Results of [^{18}F]FDG WB PET-MR, including integrated breast MR, versus conventional imaging modalities were compared in terms of clinical tumour (cT), nodal (cN) and distant (cM) status.

Results: From April 2021-April 2022, 28 patients were included. On conventional imaging, cT1-2 breast cancer was present in 22 (FFDM) and 23 (US) out of 28 patients. With regard to clinical nodal status, eight patients were considered cN0, eighteen cN1 (1–3 suspicious lymph nodes) and two patients cN2 (four suspicious axillary lymph nodes/internal mammary lymph node metastasis). [^{18}F]FDG WB PET-MR, including an integrated breast MR protocol, upstaged clinical tumour status in two patients and clinical nodal status in nine patients according to both [^{18}F]FDG WB PET-MR and breast MR findings. In addition, distant metastases were detected in three patients (liver/bone) and another patient was diagnosed with a synchronous primary tumour (lung cancer).

Conclusions: [^{18}F]FDG WB PET-MR, including an integrated breast MR within a single protocol, in breast cancer patients is feasible and provides a promising new approach in breast cancer patients with regard to locoregional and distant staging.

Conflict of interest: Other Substantive Relationships: T.v.N.: funding by speakers bureau by Bayer and GE Healthcare, outside of the submitted work. J.W.: institutional grants Bard, Bayer, Boston, Brainlab, GE, Philips, Siemens, all outside of the submitted work.

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ORAL ABSTRACT SESSION **22 March 2024** **09.30–11.15**

Oral Abstract Session

12 Oral

Drivers of choice and outcomes of breast-conserving surgery versus mastectomy in breast cancer patients with complete response following neoadjuvant therapy: a retrospective analysis from the EUSOMA database

F. Martorana[1], G. Catanuto[2], D. Gentile[3], M. Tomatis[4], A. Ponti[4], L. Marotti[4], C. Aristei[5], M.J. Cardoso[6], K.L. Cheung[7], G. Curigliano[8], J. de Vries[9], D. Santini[10], F. Sardanelli[11], V.D. Peter[12], I.T. Rubio[13], EUSOMA Working Group. [1]*University of Catania, Department of Clinical and Experimental Medicine, Catania, Italy;* [2]*Humanitas - Istituto Clinico Catanese, Chirurgia Senologica, Misterbianco CT, Italy;* [3]*IRCCS Humanitas Research Hospital, Breast Unit, Rozzano MI, Italy;* [4]*European Society of Breast Cancer Specialists, Eusoma, Florence, Italy;* [5]*University of Perugia, Radiation Oncology Section- Department of Medicine and Surgery, Perugia, Italy;* [6]*Champalimaud Clinical Center/Champalimaud Foundation, Breast Unit, Lisbon, Portugal;* [7]*University of Nottingham, United Kingdom, Nottingham Breast Cancer Research Centre, United Kingdom;* [8]*European Institute of Oncology- IRCCS, Division of New Drugs and Early Drug Development for Innovative Therapies, Milan, Italy;* [9]*University Medical Center, University Medical Center, Groningen, Netherlands;* [10]*IRCCS Azienda Ospedaliero-Universitaria di Bologna, Pathology Unit, Bologna, Italy;* [11]*IRCCS Policlinico San Donato, Unit of Radiology, San Donato Milanese MI, Italy;* [12]*Antwerp University Hospital, Multidisciplinary Oncologic Center, Edegem, Belgium;* [13]*Cancer Center Universidad de Navarra, Breast Surgical Oncology, Clinica Universidad de Navarra, Madrid, Spain*

Introduction: Neoadjuvant therapy (NAT) may favor breast-conserving surgery (BCS) in non-metastatic breast cancer patients (NMBC), especially in those achieving tumor shrinkage. Deciding between BCS and mastectomy is not always straightforward in this population. We conducted a retrospective study to investigate drivers of surgical decision in NMBC patients with ypT0 after NAT. Additionally, we analyzed survival outcomes in ypT0 ypN0 (pCR) population.

Materials and Methods: This retrospective analysis was conducted on anonymous data uploaded in the EUSOMA data warehouse by fifty-five EUSOMA certified centers between 2017 and 2022. We included NMBC patients with ypT0 after NAT, excluding those with known deleterious germline mutations conferring an increased breast cancer risk. Drivers of surgical decisions (BCS versus mastectomy) were evaluated using uni- and multivariate analysis in patients with ypT0, regardless of pathological nodal status. For homogeneity, survival outcomes were analyzed only in the pCR population, using log-rank test.

Results: 2193 patients with ypT0 NMBC were included, 1440 of which held the necessary information for performing the multivariate analysis. Pre-operative features significantly associated with mastectomy both at uni- and multi-variate analysis included younger age (OR 0.96, $p < 0.001$), multi-focality (OR 2.16, $p < 0.001$) or multicentricity (OR 12.02, $p < 0.001$), tumor dimension (OR for cT3 3.21, p 0.001; OR for cT4 16.9, $p < 0.001$) and positive nodal status (OR 1.57, p 0.008). The probability of undergoing a mastectomy was significantly higher in 2021 (p 0.011) and 2022 ($p < 0.001$). In the pCR population (n = 1416, 956 BCS and 460 mastectomy), local recurrence free survival, regional recurrence free survival, breast cancer specific survival and overall survival did not significantly differ between patients treated with BCS or mastectomy.

Conclusion: Baseline tumor extension, including tumor size and nodal involvement, was the main predictor of mastectomy in patients with ypT0 after NAT. However, BCS did not negatively affect survival outcomes in patients with pCR, either in terms of local and distant recurrence. An effort should be made to avoid potentially unnecessary mastectomy in this population, aiming at minimizing surgery-associated toxicities and improving patients' quality of life.

No conflict of interest.

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13 Mini Oral

Invasive recurrence after breast conserving treatment of ductal carcinoma in situ of the breast in the Netherlands between 1989 and 2021: Time trends and the association with tumour grade

R. O'Leary[1], L. Duijm[2], L. Boersma[3], M. van der Sangen[4], L. de Munck[5], J. Wesseling[6], R.J. Schipper[7], A. Voogd[1]. [1]*Maastricht University, Department of Epidemiology, Maastricht, Netherlands;* [2]*Canisius Wilhelmina Hospital, Department of Radiology, Nijmegen, Netherlands;* [3]*Maastricht University Medical Centre, Department of Radiation Oncology MAASTRO, Maastricht, Netherlands;* [4]*Catharina Hospital, Department of Radiation Oncology, Eindhoven, Netherlands;* [5]*Netherlands Comprehensive Cancer Organization, Department of Research and Development, Utrecht, Netherlands;* [6]*The Netherlands Cancer Institute, Department of Pathology, Amsterdam, Netherlands;* [7]*Catharina Hospital, Department of Surgery, Eindhoven, Netherlands*

Background: The aim of this study was to provide insight in trends and up-to-date figures of the risk of invasive ipsilateral breast cancer (iIBC) after breast conserving surgery (BCS) of ductal carcinoma in situ (DCIS) with or without adjuvant radiotherapy (RT) and to compare these figures with the risk to develop an invasive breast cancer in the contralateral breast (iCBC). A second aim was to analyze the association between DCIS grade and the risk of iIBC and to compare DCIS grade with the histological grade of the subsequent iIBC.

Patients and Methods: In this population-based, retrospective cohort study, the Netherlands Cancer Registry collected information on 25,719 women with DCIS diagnosed in the period 1989–2021 who underwent BCS. Of these 19,034 (74%) received adjuvant radiotherapy. Kaplan-Meier and Cox multivariable regression analyses were performed.

Results: 1,135 patients experienced an iIBC. The 10-year cumulative iIBC incidence rates for patients diagnosed in the periods 1989–1998, 1999–2008 and 2009–2021 and undergoing BCS only were 12.6%, 9.0% and 5.0% (P < 0.001), respectively. For those undergoing BCS with RT these figures were 5.7%, 3.7%% and 2.2%, respectively (P < 0.001). The 10-year iCBC rates remained stable: 4.4%, 5.5% and 4.5%, respectively, for the periods 1989–1998, 1999–2008 and 2009–2021 (P = 0.24).

In the multivariable analysis, no statistically significant association was found between the grade of DCIS and the risk of iIBC, neither for the patients undergoing BCS only, nor for those undergoing BCS with RT; the hazard ratio's for iIBC for DCIS grade 3 versus DCIS grade 1 were 1.11 (95% CI 0.84–1.48, P = 0.47) and 1.04 (95% CI 0.80–1.37, P = 0.75) for the patients who underwent BCS and those undergoing BCS with RT, respectively.

Information on grade of DCIS and grade of the subsequent iIBC was available for 721 patients (63.5%). Of the 189 patients with DCIS grade 1, 23 (12%) developed grade 3 iIBC, compared to 62 (24%) of the 256 patients with DCIS grade 2 and 123 (45%) of the 275 patients with DCIS grade 3 (P < 0.001)

Conclusions: Since 1989 the risk of iIBC has decreased substantially in patients with DCIS undergoing BCS. Patients currently treated with BCS without RT have a risk of iIBC that is similar to the risk of developing iCBC and patients with adjuvant RT have a risk of iIBC which is 50 percent lower than the risk of iCBC. These low risks of iIBC might have implications for the clinical follow-up of patients with DCIS, such as the frequency of control visits and mammography. Our findings that DCIS grade is not significantly associated with the risk of iIBC stresses the need to intensify research on the tumour biology of DCIS. First, to identify those lesions that have a high risk to become invasive and recur as poorly differentiated invasive breast cancer and second, to identify the ones that are most sensitive to RT.

No conflict of interest.

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14 Oral

Omission of axillary lymph node dissection in cN2-3 breast cancer patients with an excellent response on primary systemic treatment is safe: 4-year oncologic outcome of the MARI protocol

A. van Hemert[1], A.A. van Loevezijn[1], M.S.P.D. Baas[1], M.P.M. Stokkel[2], E. Groen[3], C. Loo[4], V. van der Noort[5], G.S. Sonke[6], N.S. Russell[7], F.H. van Duijnhoven[1], M.J.T.F.D. Vrancken Peeters[1]. *[1]Antoni van Leeuwenhoek/Netherlands Cancer Institute, Surgical Oncology, Amsterdam, Netherlands; [2]Antoni van Leeuwenhoek/Netherlands Cancer Institute, Nuclear Medicine, Amsterdam, Netherlands; [3]Antoni van Leeuwenhoek/Netherlands Cancer Institute, Pathology, Amsterdam, Netherlands; [4]Antoni van Leeuwenhoek/Netherlands Cancer Institute, Radiology, Amsterdam, Netherlands; [5]Antoni van Leeuwenhoek/Netherlands Cancer Institute, Biometrics, Amsterdam, Netherlands; [6]Antoni van Leeuwenhoek/Netherlands Cancer Institute, Medical Oncology, Amsterdam, Netherlands; [7]Antoni van Leeuwenhoek/Netherlands Cancer Institute, Radiotherapy, Amsterdam, Netherlands*

Background: Axillary lymph node staging techniques (e.g., sentinel lymph node biopsy, MARI = Marking Axillary lymph nodes with Radioactive Iodine seeds, and TAD = targeted axillary dissection) after primary systemic therapy (PST) are associated with low false negative rates. This observation has stimulated the use of tailored axillary treatment, including the omission of axillary lymph node dissection (ALND). However, robust data on the oncologic outcomes following tailored axillary treatment after PST are lacking, especially in patients with extensive nodal disease. In this study, we present the axillary recurrence rate, disease free survival and overall survival of node positive breast cancer patients with >3 suspicious axillary lymph nodes treated according to the MARI-protocol.

Methods: This prospective registry study was conducted between 2014 and 2021. We enrolled patients with pathologically proven node positive breast cancer and >3 suspicious axillary lymph nodes who were treated according to the MARI protocol. Clinical nodal stage pre-PST was assessed by FDG-PET/CT. After PST, the MARI node was excised. Patients with a pathologic complete response (pCR) of the MARI node received radiation treatment. Patients with residual disease of the MARI node received ALND plus radiotherapy (RT). Primary endpoint was axillary recurrence rate (aRR). Secondary endpoints were invasive disease-free survival (DFS) and overall survival (OS). Survival estimates were calculated using the Kaplan-Meier method.

Results: Of 218 patients included, 86 (39%) patients had hormone receptor positive (HR+)/ human epidermal growth factor 2 negative (HER2-) breast cancer; 41 (19%) HR+/HER2+; 36 (17%) HR-/HER2+ and 55 (25%) had triple negative (TN) breast cancer. Median (IQR) age was 50 (42–57) years. FDG-PET/CT identified extra-axillary lymph nodes (periclavicular/parasternal) in 39% (*n* = 85) of the patients. 47% of patients (103 of 218) had a pCR of the MARI node and were treated with RT alone, whereas 53% of patients (115 of 218) had residual disease of the MARI node and underwent ALND plus RT. Median (IQR) follow up was 44 (26–62) months. As shown in table 1, aRR was 2.9% (*n* = 3) in the MARI-pCR group treated with RT alone and 3.5% (*n* = 4) in MARI-non pCR group treated with ALND and RT. Invasive DFS and OS was worst in MARI-non pCR patients who underwent ALND plus RT.

Table 1: Oncologic outcome by response and treatment group

	Total N = 218	MARI-pCR/RT N = 103	MARI-non pCR/ ALND + RT N = 115
aRR (n)	3.2% (7)	2.9% (3)	3.5% (4)
iDFS (95% CI)	85% (0.80–0.90)	89% (0.83–0.96)	82% (0.74–0.90)
OS (95% CI)	93% (0.89–0.96)	95% (0.91–0.99)	90% (0.85–0.96)

Conclusion: Omission of axillary lymph node dissection after PST in selected node positive breast cancer patients with >3 suspicious lymph nodes using the MARI protocol is associated with an excellent oncologic outcome.

No conflict of interest.

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16 Oral

Heterogeneity of ER, PgR, HER2 and Ki67 in multifocal/multicentric breast cancer with a single histotype and same grade: implications for pathologists and oncologists from a large multi-institutional series

C. Scatena[1], E. Lemmi[2], A. Cremonini[3], A. Bello[1], L. Alessandrini[4], E. Orvieto[4], E. Sajjadi[5], B. Cerbelli[6], V. Mancini[7], C. Rossi[8], M. Pedriali[9], P. Querzoli[9], A. Ravarino[10], A.G. Giannone[11], G. Tuccari[12], A. Rizzo[13], V. Vezzosi[2], M.P. Foschini[3], B. Bendinelli[14], A.G. Naccarato[1]. *[1]University of Pisa, Department of Translational Research and New Technologies in Medicine and Surgery, Pisa, Italy; [2]University of Florence, Department of Health Sciences, Florence, Italy; [3]University of Bologna, Department of Biomedical and Neuromotor Sciences, Bologna, Italy; [4]University of Padua, Department of Medicine DIMED, Padua, Italy; [5]European Institute of Oncology, Department of Oncology and Hemato-Oncology- University of Milan, Milan, Italy; [6]Sapienza University, Department of Radiological-Oncological- and Anatomo-Pathological Science, Rome, Italy; [7]University of Siena, Department of Medical Biotechnology, Siena, Italy; [8]Azienda Unità Sanitaria Locale ASL5 La Spezia, Dipartimento Oncologico, La Spezia, Italy; [9]University of Ferrara, Department of Morphology- Surgery and Experimental Medicine, Ferrara, Italy; [10]University of Cagliari, Department of Medical Sciences and Public Health, Cagliari, Italy; [11]University of Palermo, Department of Scienze per la Promozione della Salute e Materno Infantile, Palermo, Italy; [12]University of Messina, Department of Human Pathology of the Adulthood and Developing Age "Gaetano Barresi", Messina, Italy; [13]Humanitas Cancer Center, Division of Pathology, Catania, Italy; [14]Istituto per lo studio- la prevenzione e la rete oncologica ISPRO, S.C. Epidemiologia Clinica e di Supporto al Governo Clinico, Florence, Italy*

Background: The incidence of multifocal/multicentric breast cancer (MBC) has a wide variation, between 6.1% and 77%, mostly due to the lack of a standardized definition. Compared to unifocal tumors, MBC are associated to a higher incidence of lymph node metastasis, lower survival rates and a higher risk of local recurrence. For MBC with a single histotype and same grade the current guidelines from the College of American Pathologists (CAP) recommend testing hormonal receptors and HER2 only in the largest focus. Our study aims to assess heterogeneity in the expression of ER, PgR, proliferative activity/Ki-67, and HER2 among different foci in a large case

series of MBC with a single histotype and same grade. The identification of significant differences could potentially have a considerable clinical impact, particularly in terms of benefit from adjuvant therapies.

Materials and Methods: A total of 485 consecutive cases were retrospectively retrieved from 13 Italian Breast Units. Cases were exclusively selected if they exhibited multiple tumors with the same histotype and histological grade in all foci. Male patients, those under 18 years of age, and patients undergoing neoadjuvant therapy were excluded. The study was approved by the local Ethical Committee. Written consent was obtained from each participant. A total of 1186 foci were tested for ER, PgR, Ki-67, and HER2 by immunohistochemistry (and ISH if necessary). The frequencies and percentages of cases with at least one discordant smaller focus for ER and PgR (positive/negative, cut-off: 1%, sec. ASCO/CAP 2020), HER2 (positive/negative, sec. ASCO/CAP 2018), and Ki-67 (low/high, cut-off: 25%) were evaluated. Analyses were conducted using the statistical software STATA 14.1 (StataCorp LP, College Station, Texas, USA).

Results: 65,4% (317/485) of cases were NST, 26,2% (127/485) lobular and 8,5% (41/485) mixed NST and lobular or rare special types (sec. WHO 2019). 53,6% (260/485) of cases were Nottingham grade 2, 36.1% (175/485) grade 3 and 10,3% (50/485) grade 1.

Interestingly, 14% (4/29) of ER negative cases in the largest focus showed ER positivity in at least one smaller focus. Moreover, 5% (16/327) of low proliferative cases in the largest focus exhibited high Ki67 in smaller foci. Finally, 2% (9/434) of HER2-negative cases in the largest focus had HER2-positive smaller foci, mostly in grade 3 tumors (8/9).

Conclusions: These results confirm that MBC with a single histotype and same grade exhibit non-negligible discrepancies in the expression of ER, PgR, Ki-67 and HER2, important to clinical decision-making.

No conflict of interest.

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17 Oral

Integrating spatial and single cell transcriptomics to identify and characterize biologically driven subgroups in invasive lobular carcinoma

M. Serra[1], A. Papagiannis[1], M. Rediti[1], F. Lifrange[2], N. Occelli[1], L. Collet[1], D. Vincent[1], G. Rouas[1], D. Fimereli[1], L. Craciun[3], D. Larsimont[3], D. Venet[1], F. Duhoux[4], M. Vikkula[5], F. Rothé[1], C. Sotiriou[1]. *[1]Institut Jules Bordet, Breast Cancer Translational Research Laboratory J-C Heuson, Brussels, Belgium; [2]University Hospital Center of Liege, Department of Pathology, Liege, Belgium; [3]Institut Jules Bordet, Laboratoire d'Anatomie Pathologique, Brussels, Belgium; [4]Institut Roi Albert II- Cliniques universitaires Saint-Luc and Institut de Recherche Expérimentale et Clinique pôle MIRO, Department of Medical Oncology, Brussels, Belgium; [5]de Duve Institute- Université Catholique de Louvain, Human Molecular Genetics, Brussels, Belgium*

Background: Invasive lobular carcinoma (ILC) is the second most common histological breast cancer subtype; however, little is known about its tumor microenvironment (TME). Here, we aimed to identify and to characterise ILC subgroups based on TME heterogeneity by combining spatial transcriptomics (ST) and single cell RNA-sequencing (scRNA-seq).

Methods: We performed ST (Visium 10x Genomics) on frozen tumor samples from 41 primary hormone receptor positive (HR+), HER2-negative (HER2-) ILCs. Information coming from the morphological annotation of ST slides and the gene expression-based clustering of ST spots was integrated and used as input for a patient level classification (using intNMF algorithm). Subgroups of patients were annotated using morphology, gene set enrichment analysis and ST deconvolution based on scRNA-seq data (CARD software). SCAN-B bulk RNA-seq dataset was used as validation set (HR+, HER2- ILC samples, n = 853).

Results: Four subgroups of patients were identified: proliferative (P, n = 12, enriched in tumor cells and proliferation-related pathways), normal-stroma enriched (NSE, n = 10, enriched in fibroblasts, stroma-related pathways and showing an higher level of colocalization between invasive and in situ carcinoma), metabolic (M, n = 9, enriched in metabolic related-pathways) and metabolic-immune enriched (MIE, n = 10, enriched in adipocytes, metabolic and immune-related pathways). Deconvolution of ST spots with single cell data revealed matching results with morphology (in terms of cell types). We observed an enrichment of myofibroblasts in NSE, an enrichment of cancer epithelial in P and, interestingly, an enrichment of endothelial cells in M subgroup (fdr < 0.25). MIE was characterised by perivascular like-endothelial cells and myeloid cells (monocytes and macrophages, fdr < 0.25). Of note, at the level of the ST slide, myeloid cells in MIE subgroup were more present in the adipose tissue compartment (fdr < 0.25) compared to the rest of the slide. NSE subgroup showed a trend for association with better prognosis. Gene signature-based assignment identified the same four subgroups in SCAN-B: GSEA analysis and comparisons among the four subgroups showed matching results between our dataset and SCAN-B. Of note, in SCAN-B, we observed differences in prognosis among the subgroups, with NSE showing better, M and MIE intermediate and P worse prognosis for overall survival and relapse free interval ($p < 0.01$).

Conclusions: Four subgroups of ILC based on TME heterogeneity and showing differences in prognosis were identified and validated in external cohort. Of note, two of these groups were related to metabolism, highlighting the value of such process in ILC biology. Importantly, myeloid cells were the predominant immune cell types in ILC, and they showed a specific compartmentalisation inside the TME. Further validation is needed.

Conflict of interest:

Other Substantive Relationships:

Pr. Christos Sotiriou: ASTELLAS, CEPHEID, VERTEX, SEATTLE GENETICS, PUMA, AMGEN, Merck & Co.Inc. [Grants or contracts from any entity], EISAI, PRIME ONCOLOGY, TEVA, EXACT SCIENCES [Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events], ROCHE, GENENTECH, PFIZER [Support for attending meetings and/or travel].

Pr. Francois Duhoux: ROCHE, PFIZER, ASTRAZENECA, LILLY, NOVARTIS, AMGEN, DAIICHI SANKYO, PIERRE FABRE, GILEAD SCIENCES, SEAGEN, MSD [Consulting fees], AMGEN, ROCHE, TEVA, PFIZER, DAIICHI SANKYO, ASTRAZENECA, GILEAD SCIENCES [Support for attending meetings and/or travel].

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POSTER IN THE SPOTLIGHT **20 March 2024** **10.30–11.00**

Poster in the Spotlight

20 (PB-1) Poster Spotlight

Real-world clinical outcomes in patients with HER2+ metastatic breast cancer receiving tucatinib therapy after 2 or more prior HER2-directed therapies

C. Anders[1], E. Neuberger[2], K. Bartley[2], B. Pittner[2], A. Sow[3], S. Wang[4], P. Kaufman[5]. *[1]Duke Cancer Institute, Duke Cancer Center Breast Clinic, Durham NC, USA; [2]Seagen Inc., Seagen Inc., Bothell WA, USA; [3]Seagen, Seagen International Gmbh, Zug, Switzerland; [4]Genesis Research, Genesis Research, Hoboken, NJ, USA; [5]University of Vermont Medical Center, Division of Hematology and Oncology, Burlington VT, USA*

Background: Tucatinib (TUC) is an oral, highly selective HER2-targeted therapy approved by the European Medicines Agency (EMA) in Feb 2021 for use in combination with trastuzumab and capecitabine (TRA+CAP) for patients with HER2+ locally advanced or metastatic breast cancer (MBC) previously treated with ≥2 prior HER2-directed regimens. In the randomized HER2CLIMB (H2C) trial, median (95% CI) overall survival (mOS) and progression-free survival for patients receiving TUC+TRA+CAP were 21.9 (18.3–31.0) and 7.8 (7.5–9.6) months, respectively. Median duration of therapy was 7.3 months. Patients in the TUC-arm of H2C had a median of 3 prior metastatic lines; 48% had brain metastases (BM), including stable and active central nervous system disease. This study evaluated patients receiving TUC in line with the EMA label, and also the subgroup receiving TUC following fam-trastuzumab deruxtucan (T-DXd).

Methods: This retrospective study included US patients in the Flatiron Health nationwide, de-identified electronic health record–derived MBC database diagnosed with MBC between Jan 2017 and Dec 2022 who began TUC+TRA+CAP in line with the EMA label after US (FDA) approval in Apr 2020. Patient characteristics were assessed during the baseline period (≤6 months prior to TUC initiation). Key outcomes, assessed from the TUC initiation date using the Kaplan-Meier method, were OS, time to next treatment (TTNT), and time to discontinuation (TTD) in TUC-treated patients who previously received ≥2 HER2-directed therapies.

Results: Of 16,733 patients diagnosed with MBC during the study period, 3449 had evidence of HER2+ disease, of which 216 received TUC and met all inclusion criteria. Of these, 89 received TUC+TRA+CAP after ≥2 prior

HER2-directed regimens in the metastatic setting. In total, 28 patients received TUC in the third line setting (3L) and 61 in fourth line or later; median line of metastatic therapy (LOT) for TUC was 4. There were 30 patients who received TUC immediately post-T-DXd (TUC median LOT, 4). Median follow-up from TUC initiation was 11 months. Overall, 51 patients (57%) had BM prior to initiating TUC, 6 (20%) in the post-T-DXd subgroup. In the overall group, median (95% CI) TTD, TTNT, and OS were 5.9 (5.0–9.4), 8.4 (6.2–11.8), and 24.9 (15.6–not reached [NR]) months, respectively. In the post-T-DXd subgroup (n = 30), these results were 6.4 (3.6–11.6), 6.4 (4.5–11.9), and 12.6 (11.9–NR), respectively. Median TTD for prior T-DXd therapy was 5.9 months. Prior to TUC therapy, 89 (100%) patients previously received trastuzumab, 79 (89%) pertuzumab, 78 (88%) trastuzumab emtansine, 25 (28%) lapatinib/neratinib, and 34 (38%) T-DXd.

Conclusion: The real-world outcomes observed with TUC-based treatment after ≥2 prior HER2-directed metastatic lines underscore the efficacy observed in H2C and indicate durable response to TUC in the post-T-DXd setting.

Conflict of interest:

Ownership: Edward Neuberger, Karen Bartley, Brian T. Pittner, and Amadou Sow are employees of, and own stock in, Seagen Inc.

Corporate-sponsored Research: This study was sponsored by Seagen Inc., Bothell, WA, USA, in collaboration with Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

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Other Substantive Relationships: Peter Kaufman reports financial relationships with Amgen, Astra Zeneca, Eisai, H3 BioMedicine, Lilly, Macrogenics, Pfizer, Polyphor, Roche/Genentech, and Sanofi. Carey Anders declares compensated consultant role for Genentech (1/2019-), Eisai (1/2019-), IPSEN (2/2019-), Seagen Inc. (11/15/2019–11/15/2020) Astra Zeneca (3/2020 -), Novartis (5/2020–5/2022), Immunomedics (10/1/2020–9/22/2021), Elucida (9/2020), Athenex (2/2021–2/2023). Honoraria: Genentech, Eisai, IPSEN, Seattle Genetics, Astra Zeneca, Novartis, Immunomedics, Elucida, Athenex. No dates. Royalties: UpToDate, Jones and Bartlet.

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21 (PB-2) Poster Spotlight

Effects of a physical exercise program on quality of life, physical fitness and circulating biomarkers of breast cancer survivors – the MAMA_MOVE Gaia After Treatment trial

A. Joaquim[1,2,3], A. Amarelo[1,3], P. Antunes[1,4], C. Garcia[1,5], I. Leão[1,3], E. Vilela[6], B. Duarte[1], M. Vieira[1,7], V. Afreixo[8], A. Góis[9], A. Soares[9], H. Ferreira[10], I. Guerra[10], A. Afonso[11], V. Geraldes[11], A. Capela[1,3], S. Viamonte[1,12], R. Domingues[10], L. Helguero[13], A. Alves[1,5], ONCOMOVE.
[1]Associação de Investigação de Cuidados de Suporte em Oncologia AICSO, OncoMove, Vila Nova de Gaia, Portugal; [2]EORTC, Medical, Brussels, Belgium; [3]Centro Hospitalar Vila Nova de Gaia/Espinho, Medical Oncology, Vila Nova de Gaia, Portugal; [4]Beira Interior University, Research Center in Sport Sciences, Health, and Human Development CIDESD, Covilhã, Portugal; [5]University of Maia, Research Center in Sport Sciences, Health, and Human Development CIDESD, Maia, Portugal; [6]Centro Hospitalar Vila Nova de Gaia/Espinho, Cardiology, Vila Nova de Gaia, Portugal; [7]SC Fitness SA, Solinca Classic SA, Lisbon, Portugal; [8]University of Aveiro, Mathematics, Aveiro, Portugal; [9]University of Aveiro, Medical Sciences, Aveiro, Portugal; [10]University of Aveiro, Chemistry, Aveiro, Portugal; [11]University of Lisbon, Faculty of Medicine, Lisbon, Portugal; [12]Centro Hospitalar Vila Nova de Gaia/Espinho, Centro de Reabilitação Do Norte, Vila Nova de Gaia, Portugal; [13]University of Aveiro, Department of Medical Sciences, Aveiro, Portugal

Background: Health-related quality of life (HRQOL) and physical fitness in early breast cancer survivors are compromised after treatment, being associated with increased risk of chronic inflammation status, cardiovascular and metabolic comorbidities. Physical exercise (PE) has emerged as a supportive care; however, the improvements on quality of life and physical fitness show low to moderate magnitude and high heterogeneity, which, combined with organizational barriers, makes its implementation challenging. Furthermore, the impact of PE on inflammatory and metabolic circulating biomarkers of breast cancer survivors is not well defined.

Methods: MAMA_MOVE Gaia After Treatment (NCT04024280) was a 16-week control phase (CP) followed by a 16-week intervention phase (IP) trial, conducted in early breast cancer survivors to evaluate the impact of a supervised group-class PE program with limited equipment, on: 1) global health status (primary endpoint) and other domains of HRQOL (EORTC QLQ C30 and BR23); 2) physical fitness [upper limb strength, lower limb functionality, body mass index (BMI) and waist circumference], and 3) safety. Outcomes were evaluated at baseline, 8 and 16 weeks (CP), and 24 and 32 weeks (IP). Additionally, an exploratory analysis of immunological, inflammatory, cardiometabolic, and fatty acid biomarkers was performed in a subgroup of patients who accepted to collect blood at 16 (CP) and 24 weeks (IP).

Results: Of the 82 participants included, only 37 completed IP, mainly due to COVID-19 pandemic constraints. Global health status decreased during CP (−10,1; 95% CI −19.8 to −0.4; p = 0.040) and stabilized during IP. Physical and sexual functioning increased during the IP (p = 0.008; p = 0.017), upper limb strength and lower limb functionality increased during both phases [CP: p < 0.0001, p = 0.001 (surgical and nonsurgical arm), p = 0.028; IP: p < 0.0001, p = 0.002, p = 0.009], BMI decreased during IP (p = 0.026) and waist circumference increased in the CP (p = 0.001) and decreased in the IP (p = 0.010). No serious adverse events related to exercise were reported. A tendency to decrease the saturated fatty acid C20:0 [−0.08; D Cohen effect size (ES) = −0.53], neutrophils (−240; ES = −0.72), myeloperoxidase (−48449, ES = −0.43) and IFNγ (−146.6, ES = −0.06) was observed in the 15 patients included in the exploratory analysis.

Conclusions: The PE program was able to mitigate the decline of HRQOL and improve the physical and sexual functioning and body composition. Moreover, it showed possible positive effects on immune cells, inflammatory cytokine, and plasma fatty acids. Our work suggests that the implementation of group class-based programs with limited equipment may be a viable option for promoting improvements in quality of life and overall health in breast cancer survivors. Larger studies may elucidate the implications of PE on metabolism.

No conflict of interest.

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22 (PB-3) Poster Spotlight

National breast cancer surgery snapshot study: breast cancer surgery after neoadjuvant systemic therapy in primary breast cancer (MANS study)

G. Kramer[1], J. Volders[2], M.J. Vrancken Peeters[1],
Surgical Breast Cancer Research Group the Netherlands. *[1]Antoni van Leeuwenhoek- cancer institute, Surgical Oncology, Amsterdam, Netherlands; [2]Diakonessenhuis, Surgical Oncology, Utrecht, Netherlands*

Introduction: Neoadjuvant systemic treatment (NST) has led to an increase in breast conserving treatment (BCT) worldwide. This study creates an overview of the different reasons for applying NST in the Netherlands and how often NST results in conversion to BCT or axillary down staging where axillary lymph node dissection (ALND) is omitted.

Methods: This National Breast Cancer Surgery Snapshot is a multicenter prospective cross-sectional study in 70 breast cancer care providing hospitals in the Netherlands. For a period of two months the reason of NST in newly diagnosed breast cancer patients were registered together with patient- and tumor characteristics. Furthermore, the expectation of BCT and axillary conserving treatment before and after NST was noted. The main outcome is to create a national overview of variation in different reasons to apply NST in the Netherlands. This study will provide insight in how often NST, in different breast cancer tumor types, results in conversion from mastectomy to BCT as well as how often NST results in axillary down staging by which ALND is omitted.

Results: 462 patients were registered eligible for NST between March and May 2022 by 70 hospitals in the Netherlands. The main reasons for NST were in 119 (25%) Her2 positivity, 120 (25%) a triple negative tumor and in 122 (25%) axillary down-staging. In 98 patients (48%) NST converted a mastectomy to BCT, whereof 38 patients (40%) had a pathological complete response (pCR). In case of uncertainty before NST, 24 out of 37 patients (65%) finally resulted in BCT, where 6 (25%) had a pCR. Breast cancer patients with HER2 positivity resulted in conversion to BCT in 69% of hormone positive tumors and 46% of hormone negative tumors. Considering axillary lymph node metastases, axillary downstaging was achieved by NST in 85% of the patients, omitting ALND in 169 out of 198 patients, whereof 67 patients with eventually ypN0 (40%).

Conclusion: In the Netherlands NST is successfully applicated to converse mastectomy to BCT and is even more successful in axillary downstaging omitting ALND in 85% of the patients. This confirms that the national set goal of downstaging in breast cancer patients is accomplished by NST, with a strong prognostic value of response and great impact in patient related outcomes.

No conflict of interest.

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POSTER IN THE SPOTLIGHT **21 March 2024** **11.00–11.30**

Poster in the Spotlight

23 (PB-4) Poster Spotlight

Development of an explainable AI prediction model for arm lymphoedema following breast cancer surgery and radiotherapy

T. Rattay[1], G. Bologna[2], A. Bombezin-Domino[3], G. Cortellessa[4], A. Dekker[5], F. Fracasso[4], M. Joore[6], A. Pannison[7], A. Perotti[7], B.L.T. Ramaekers[6], S. Rivera[8,9], A. Romita[10], C. Roumen[11], J. van Soest[5,10,12], A. Traverso[5,13], F. Tohidinezhad[14], K. Verhoeven[5], A.J. Webb[15], I. Koutsopoulos[16], C.J. Talbot[15], PRE-ACT Study Consortium. *[1]University of Leicester, Leicester Cancer Research Centre, Leicester, United Kingdom; [2]University of Applied Sciences and Arts of Western Switzerland, School of Engineering, Architecture and Landscape HEPIA- HES-SO, Geneva, Switzerland; [3]Therapanacea, Therapanacea, Paris, France; [4]Consiglio Nazionale delle Ricerche CNR, ISTC Roma, Rome, Italy; [5]Maastricht University Medical Center+, Department of Radiation Oncology MAASTRO, Maastricht, Netherlands; [6]Maastricht University Medical Center+, Department of Clinical Epidemiology and Medical Technology Assessment, Maastricht, Netherlands; [7]Centro di Ricerca dell'AI CENTAI, Centro di Ricerca dell'AI CENTAI, Turin, Italy; [8]Institut Gustave Roussy, Department of Radiotherapy, Paris, France; [9]Fédération des Centres de Lutte Contre le Cancer UNICANCER, Fédération des Centres de Lutte Contre le Cancer UNICANCER, Paris, France; [10]Medical Data Works B.V., Medical Data Works B.V., Maastricht, Netherlands; [11]Maastricht University, Department of Health Services Research- Care and Public Health Research Institute CAPHRI, Maastricht, Netherlands; [12]Maastricht University, Brightlands Institute for Smart Society BISS, Maastricht, Netherlands; [13]Università Vita-Salute San Raffaele, School of Medicine, Milan, Italy; [14]Maastricht University Medical Cente+, Department of Radiation Oncology MAASTRO, Maastricht, Netherlands; [15]University of Leicester, Department of Genetics and Genome Biology, Leicester, United Kingdom; [16]Athens University of Economics and Business, Department of Informatics, Athens, Greece*

Background: PRE-ACT (Prediction of Radiotherapy side Effects using explainable AI for patient Communication and Treatment modification) is an ongoing multi-disciplinary European collaborative study with the goal of using Artificial Intelligence (AI) to predict long-term side effects (toxicity) from radiotherapy in breast cancer patients. Some of the factors that increase the risk for clinically significant toxicity are already known, but current approaches to risk prediction mainly use low-dimensional statistical approaches and do not use complex genomics and imaging data. AI and machine learning are already used in some aspects of radiotherapy delivery. The aim of PRE-ACT is to leverage its huge potential towards accurate toxicity prediction, and at the same time provide an easily understood explanation to support shared treatment decision-making between patient and physician.

Methods: We developed discretized interpretable multi-layer perceptron (DIMLP) neural network, random forest and gradient boosted tree models for arm lymphoedema following surgery and radiotherapy +/- chemotherapy in three breast cancer patient datasets from European and French multi-centre breast cancer cohorts (REQUITE, Hypo-G, CANTO, total n = 6,361). Using patient demographic and treatment-related features (m = 32), we trained the models with 10-fold cross-validation in a 90:10 random-split data set to predict arm lymphoedema (defined as ≥10% increase in arm circumference 15 cm proximal and/or 10 cm distal to the ipsilateral olecranon relative to baseline) up to three years from the start of radiotherapy.

Results: The incidence of arm lymphoedema was 6% across the three datasets. Our best-performing model was based on gradient-boosted decision trees retaining all 32 patient- and treatment-related features with an average AUC of 0.84 (±0.003). Average sensitivity and specificity were 81.6% and 72.9%, respectively. We extracted propositional rules from gradient-boosted decision trees to explain the output, for example:

- If cN STAGE is 0, HER2 STATUS is Unknown, and SENTINEL NODE BIOPSY is True, then NO arm lymphoedema;
- If no INTENSITY-MODULATED RADIOTHERAPY and no ADJUVANT_CHEMOTHERAPY and type of surgery is LUMPECTOMY and PR_STATUS is POSITIVE and no DIABETIES, then NO arm lymphoedema.

Conclusion: We generated explainable predictions for arm lymphoedema by applying DIMLP algorithms to patient demographic and treatment features. Further inclusion of genomic and radiomic markers are likely to improve accuracy. These AI models will be incorporated into a web interface for providing the explanations to physicians and patients, to identify patients who may benefit from supportive intervention or even a change in treatment plan. As part of the PRE-ACT study, the interface which will be tested in a clinical trial and evaluated in a health economic analysis.

No conflict of interest.

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24 (PB-5) Poster Spotlight

An international consensus for the diagnosis of breast lesions: defining the best technique for each case

W. Sanderink[1], J. Camps-Herrero[2], A. Athanasiou[3], H.L. Couto[4], K. Mehta[5], P.B. Popat[6], P. Jagmohan[7], S.E. Vázquez-Manjarrez[8], S. Nakamura[9], R.M. Mann[1]. *[1]Radboud University Medical Center, Department of Medical Imaging, Nijmegen, Netherlands; [2]Ribera Salud Hospitals, Department of Radiology, Valencia, Spain; [3]Mitera Hospital, Breast Imaging Department, Athens, Greece; [4]Radimama-Redimasto, Breast Unit, Belo Horizonte, Brazil; [5]Imaging Associates/Eastern Health, Department of Radiology, Melbourne, Australia; [6]Tata Memorial Hospital and Homi Bhabha National Institute, Department of Radiology, Mumbai, India; [7]National University Hospital, Department of Diagnostic Imaging, Singapore, Singapore; [8]National institute of Health Sciences and Nutrition Salvador Zubiran, Imagen Mamaria, Mexico City, Mexico; [9]Showa University School of Medicine, Department of Surgery, Tokyo, Japan*

Background: In this abstract we present the developed consensus recommendations regarding the appropriate choice of different biopsy techniques for diagnosis and re-biopsy of breast lesions.

Material and Methods: Following an adapted version of the RAND-UCLA Appropriateness Method, a consensus was sought based on the existing literature and experience of eight breast imaging experts from around the world. Two independent (non-voting) Chairs facilitated the meeting. Biopsy techniques discussed included fine needle aspiration (FNA), core needle biopsy (CNB) and vacuum assisted biopsy (VAB). Guiding techniques included ultrasound (US), mammography or tomosynthesis (MG) and MRI.

Results: In lesions only visible on MG or MRI VAB was always considered the first choice. For lesions visible under US, CNB is regarded the first choice. FNA was never considered first choice for solid lesions. Other biopsy techniques for US guided biopsy may be considered depending on lesion type, lesion size and indication of tissue sampling. In small masses (<5 mm), complex cyst with small solid parts, small intraductal masses, architectural distortions and calcifications visible on US, diagnosis with VAB was considered preferable over CNB.

In the setting of re-biopsy for inconclusive findings or high-risk lesions the panel recognized two extensions to VAB. An extended vacuum assisted biopsy (EVAB) is considered as a preferable technique over excisional biopsy and aims to obtain sufficient tissue to classify lesions unambiguously. The term vacuum assisted excision (VAE) was reserved for situations where the actual aim is to remove a lesion completely. Following the diagnosis of lobular neoplasia, flat epithelial atypia or ADH as an incidental finding on

CNB, a re-biopsy with VAB or EVAB is recommended. For incidental findings of lobular neoplasia and flat epithelial atypia on VAB a follow-up was regarded sufficient. For phyllodes tumors, benign or borderline, found with initial CNB or VAB, a surgical excision is recommended. Only for small (<2 cm) benign phyllodes tumors a VAE can be considered. For scar lesions and papillary lesions with or without atypia, a re-biopsy with EVAB was recommended.

Conclusion: This expert consensus recommendation provides a clinical guideline for the choice of biopsy technique depending on guiding method, lesion type, lesion size and indication for tissue sampling.

No conflict of interest.

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25 (PB-6) Poster Spotlight

An early cost-effectiveness analysis of active surveillance for low-risk ductal carcinoma in situ

D. Byng[1], M. Schaapveld[1], E. Lips[2], F. van Duijnhoven[3], J. Wesseling[2], W. van Harten[1], V. Retel[4], Grand Challenge PRECISION Consortium. *[1]NKI-AVL, Psychosocial Research and Epidemiology, Amsterdam, Netherlands; [2]NKI-AVL, Molecular Pathology, Amsterdam, Netherlands; [3]NKI-AVL, Surgical Oncology, Amsterdam, Netherlands; [4]The Netherlands Cancer Institute, Psychosocial Research and Epidemiology, Amsterdam, Netherlands*

Background: An active surveillance (AS) strategy is currently being evaluated as an alternative to surgical resection in ongoing clinical trials for women diagnosed with low-risk primary ductal carcinoma in situ (DCIS). In early development, the degree of evidence and underlying data on new technologies (e.g. biomarkers), organizational approaches, or treatment procedures is limited. This results in levels of uncertainty in which policy advice may be most wanted. To identify, measure, value, and compare the economic impact and consequences of the AS strategy for DCIS, an early cost-effectiveness analysis has been performed.

Materials and Methods: A cost-effectiveness analysis was conducted using a semi-Markov modeling approach. We simulated a cohort of women undergoing immediate breast conserving surgery ± radiotherapy to treat their DCIS, and a cohort containing a low-risk subgroup identified by means of a biomarker who could undergo an AS strategy, based on the SEER database and biomarker research from the PRECISION consortium. Standard pathological information on DCIS grade (low-to-intermediate) and estrogen-receptor-positive status was used to identify the low-risk subgroup, similar to the eligibility criteria of ongoing prospective trials for AS. 10-year incremental costs (€) and quality-adjusted life years (QALYs) were estimated from a Dutch healthcare perspective. Scenario and headroom analyses were performed to evaluate a hypothetical better-performing biomarker using information on COX-2 protein expression and breast adipocyte size to select the low-risk subgroup.

Results: Introducing an AS strategy resulted in life years lost (−0.06, 95% confidence interval (CI) −0.26 to 0.16). The application of utilities positively shifted the health effects towards an average QALY gain of 0.4, with an accompanying average per patient cost saving of €6,353 over the time horizon. Scenario analyses maintained survival outcomes and maximized QALYs.

Conclusions: Introducing an AS option to selected DCIS patients with low-risk features can be a cost-effective alternative to immediate surgery and adjuvant radiotherapy. Cost-effectiveness analysis demonstrated substantial cost-savings, gain in quality of life, despite an expected elevated rate of subsequent ipsilateral invasive breast cancer. A better-performing biomarker to select low-risk women can maximize quality-adjusted outcomes.

No conflict of interest.

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POSTER IN THE SPOTLIGHT **22 March 2024** **11.00–11.30**

Poster in the Spotlight

26 (PB-7) Poster Spotlight

Core Needle Biopsy outperforms Fine-Needle Aspiration Cytology in diagnosing axillary lymph node metastasis in breast cancer patients

L. Kooreman[1], S. Dieleman[2], T. Nijnatten[3], A. Koemans[4], F. Harmsen van der Vliet[4], S. de Wit[4], A. zur Hausen[1], M. Smidt[5], H. Grabsch[6]. *[1]Maastricht University Medical Center- GROW School for Oncology and Reproduction, Pathology, Maastricht, Netherlands; [2]Maastricht University Medical Center- GROW School for Oncology and Reproduction, Pathology and surgery, Maastricht, Netherlands; [3]Maastricht University Medical Center- GROW School for Oncology and Reproduction, Radiology and Nuclear Medicine, Maastricht, Netherlands; [4]Maastricht University Medical Center, Pathology, Maastricht, Netherlands; [5]Maastricht University Medical Center- GROW School for Oncology and Reproduction, Surgery, Maastricht, Netherlands; [6]Maastricht University Medical Center- GROW School for Oncology and Reproduction and Leeds Institute of Medical Research at St. James's, University of Leeds, Leeds, UK; Pathology and Data Analytics, Maastricht, Netherlands and Leeds, UK*

Background: The regional lymph node (LN) status is important for predicting prognosis and informs treatment decisions. In newly diagnosed breast cancer with clinically suspicious LN findings, either fine-needle aspiration cytology (FNAC) or core needle biopsy (CNB) is used for histopathological confirmation. The methods differ regarding sensitivity, costs and patient impact. Inconclusive results and the need for repeat testing impact on the time to diagnosis and the costs. In this study, we explored the use of FNAC and CNB to diagnose suspicious axillary LNs in the Netherlands. The FNAC or CNB based diagnosis is compared to the diagnosis based on the LN resection.

Material and Methods: Data from patients with pathological analysis of the breast and LN in 2019 was retrospectively retrieved from the Dutch Pathology Registry. Patients with pathological analysis of the breast and LN were evaluated. The method and diagnoses on FNAC and CNB were collected. Costs were calculated using the average of a publicly available pricelist for these procedures from 16 different Dutch hospitals. The sensitivity of FNAC/CNB was based on the diagnosis after LN resection without neoadjuvant therapy.

Results: 36750 pathology reports from 7169 patients were retrieved and 1571 cases were selected for initial analyses. 975 (62%) patients had invasive breast cancer. FNAC was used in 717 (74%) patients compared to CNB in 247 (25%) patients or simultaneous use of both techniques in 11 (1%) patients. There was insufficient diagnostic material or inconclusive results in 17% when using FNAC vs 3% when using CNB. 44% of FNAC were malignant vs 65% of CNB. 140 repeated sampling of LN was necessary after FNAC (18%) vs 15 after CNB (4%). Average costs of diagnosis per patient was €535.41 in the primary FNAC group and €648.49 in the primary CNB group. This cost difference is largely due to increased pathology costs for CNB. In patients without neoadjuvant treatment, 23% of benign FNAC cases and 13% of benign CNB were false negative based on finding macrometastasis (≥N1a) in the LN resection specimen, see table. Sensitivity of FNAC is 59%, whereas sensitivity of CNB is 82%. pT2 patients with benign FNAC had significantly more often a macrometastasis in the LN.

	Diagnosis	LN resection	≤N1mi	≥N1
FNAC n = 717 (74%)	Benign n = 283 (39%)	n = 168	129 (77%)	39 (23%)
	Insufficient n = 118 (17%)	n = 49	37 (76%)	12 (24%)
	Malignant n = 316 (44%)	n = 55	-	55 (100%)
CNB n = 247 (25%)	Benign n = 78 (32%)	n = 47	41 (87%)	6 (13%)
	Insufficient n = 8 (3%)	n = 3	2 (68%)	1 (33%)
	Malignant n = 161 (65%)	n = 28	-	28 (100%)

Conclusion: Despite higher costs, CNB is recommended as a first-choice screening method for establishing the LN status in breast cancer patients due to better sensitivity and shorter time to diagnosis because of less repeats.

No conflict of interest.

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27 (PB-8) Poster Spotlight

Role of contrast enhanced spectral mammography (CESM) in the evaluation of breast lesions

R. Chen[1], B.K. Chong[2], N. Chotai[3], E.Y. Tan[1,4,5]. *[1]Tan Tock Seng Hospital, General Surgery, Singapore, Singapore; [2]Tan Tock Seng Hospital, Diagnostic Radiology, Singapore, Singapore; [3]Radlink Diagnostics, Diagnostic Radiology, Singapore, Singapore; [4]Institute of Molecular and Cell Biology, Agency for Science, Technology and Research ASTAR, Singapore, Singapore; [5]Nanyang Technological University, Lee Kong Chian School of Medicine, Singapore, Singapore*

Background: Contrast enhanced spectral mammography (CESM) is emerging as a modality particularly useful in women with dense breasts, in whom complementary ultrasound is often done. Our hypothesis is that CESM reduces the false negative rate of mammography and the false positive rate of ultrasound.

Materials and Methods: We prospectively evaluated 91 patients between 21 August 2016 to 18 October 2023 who had CESM done in addition to conventional mammography and breast ultrasound. CESM was done as either as part of work-up for suspected breast cancer, as cancer surveillance or as a second-line evaluation of indeterminate lesions.

Results: A total of 463 lesions in 91 patients detected on CESM, mammography and/or ultrasound were evaluated. Cancer was confirmed on biopsy in 74 lesions. All breast lesions except one (38-year-old with a 27mm palpable hypoechoic mass confirmed as ductal carcinoma in situ (DCIS)) were detected on CESM. One case of an invasive lobular carcinoma presented as an enhancing mass on CESM but was not seen on either mammography or ultrasound; another patient with DCIS had non-mass enhancement on CESM seen as microcalcifications on mammogram, without any corresponding sonographic lesion. 20 cancers (27%) were seen on CESM and ultrasound but not on mammography, and 51 cancers (69%) were seen on CESM, mammography and ultrasound.

There were 152 enhancing masses detected on CESM. Biopsy was done in 101 of these masses and 58 breast cancers were confirmed. There were 29 patients with non-mass enhancement (NME) and 19 patients had biopsies, of which 15 were confirmed as cancers. CESM detected cancers with a sensitivity of 98.6% and specificity of 73.5%. Positive predictive value was 60.8%, negative predictive value was 98.7%. Fibroadenoma was the most common benign lesion (16 biopsies), followed by papilloma (9 biopsies). For enhancing masses, 13 cancers were not seen on mammography and for NME, 8 cancers were not seen on mammography.

Conclusion: CESM was 98.7% sensitive in detecting cancers. Cancer was confirmed on biopsy in 60.8% of lesions deemed significant on CESM, and negative predictive value was 98.7%.

No conflict of interest.

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28 (PB-9) Poster Spotlight

Resolution impact on breast cancer diagnosis: individual micro-CT microcalcifications in focus

R. Brahimetaj[1], J. Cornelis[1], C. Van Ongeval[2], J. De Mey[3], B. Jansen[1]. *[1]Vrije Universiteit Brussel VUB, Department of Electronics and Informatics ETRO, Brussels, Belgium; [2]Universitair Ziekenhuis Leuven, Department of Radiology, Leuven, Belgium; [3]Universitair Ziekenhuis Brussel, Department of Radiology, Brussels, Belgium*

Background: Breast microcalcifications (MCs) are the main manifestation and/or robust marker of an early non-palpable breast cancer. However, they are not always restricted to malignancies as they are also present in common benign lesions. Traditionally, breast MCs are only analysed in clusters because regular in vivo mammography has limited resolution for conducting individual MC analysis. With our study [1], we markedly deviate from conventional methods/studies by: (a) focusing on *individual breast MCs* instead of clusters; (b) investigating the influence of image resolution on breast cancer diagnosis using radiomics features extracted from high-resolution 3D micro-CT individual MC images.

Material and Methods: We analysed 707 MCs (extracted from 86 female patients) at four distinct spatial resolutions: 8 µm (original resolution) and simulated image resolutions of 16 µm, 32 µm, and 64 µm. Radiomic features were extracted at each resolution to identify a concise feature signature capable of distinguishing benign/malignant MCs. The benign/malignant MC labels were assigned based on the pathological diagnosis of the sample they originated from. Machine learning algorithms were employed to classify individual MCs and samples (i.e., patients). For sample diagnosis, a custom-based thresholding approach was used to combine individual MC results into sample results. Classification performance was measured in terms of accuracy, sensitivity, specificity, AUC, and F1 score.

Results: Our results demonstrate that at an 8 µm resolution (the highest evaluated), the individual MC classification achieved an accuracy of 77.27%, an AUC of 83.83%, an F1 score of 77.25%, sensitivity of 80.86%, and specificity of 72.2%. Notably, the F1 score showed a 2.29% decrease when using 16 µm, a 4.01% decrease when using 32 µm, and a 10.69% decrease when using 64 µm resolution instead of 8 µm. Sample-level results at 8 µm resolution exhibited an accuracy and F1 score of 81.4%, sensitivity of 80.43%, and specificity of 82.5%. Comparatively, using 16 µm, 32 µm, and 64 µm resolutions resulted in F1 score reductions of 6.3%, 4.91%, and 6.3%, respectively.

Conclusions: We demonstrated a *strong association between individual breast MCs and malignancies*. *The highest classification performance was achieved at the highest resolution (8 µm)*. Our findings suggests that if breast MC characteristics can be visualised and captured in 3D at resolutions higher than those currently employed in digital mammograms, breast cancer diagnosis could be significantly enhanced.

No conflict of interest.

Reference

[1] Brahimetaj R., Cornelis J., Van Ongeval C., De Mey J., and Jansen B., "The impact of (simulated) resolution on breast cancer diagnosis based on high-resolution 3D micro-CT microcalcification images" Medical Physics, 2023.

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POSTER SESSION 20 March 2024 9.00–18.30

Advocacy

50 (PB-050) Poster

Ensuring inclusivity of patient participation in clinical trials

A. Sinha[1,2], L. Barwell[3], H. Jeffery[1,2], Z. Peterson[1,2], B. Shifa[1,2], M. Attia[2], K. Badawy[3], A. Purushotham[1,2]. [1]*King's College London, School of Cancer and Pharmaceutical Sciences, London, United Kingdom;* [2]*Guy's and St Thomas' NHS Foundation Trust, Breast Surgery, London, United Kingdom;* [3]*King's College London, Medical School, London, United Kingdom*

Background: Several studies have shown that certain groups of patients are underrepresented in clinical trials including non-Caucasian ethnicity, neurodivergence, advanced age, non-English speaking, large Body Mass Index (BMI) and low socioeconomic status. There is a need to ensure adequate representation of these groups to ensure the results of any clinical trial accurately reflect the underlying population base.

Our breast surgery clinical trials unit based at Guy's Hospital in London which has a diverse multi-ethnic population, aims to be wholly inclusive in clinical trial recruitment.

The aim of this study was to review the pathway to recruitment and patients recruited into two clinical trials including the aforementioned sub-groups.

Methods: The Breast Cancer Research Database at Guy's Hospital was reviewed, and the English Indices of Deprivation was used to populate the Index of Multiple Deprivation (IMD) for each patient using their postcode. A bespoke questionnaire was undertaken in interview form to assess patients' satisfaction with the pathway for recruitment.

Results: In total, 648 patients were eligible to participate, between September 2020 to May 2023. Of these, 131 (20.2%) were recruited to these two trials. In all, 100% of patients eligible for these trials were approached and screened for participation. Eligible patients had a mean age of 55.1 years. Recruited patients were younger on average than those not recruited (49.1 years vs 56.6 years, $p < 0.0001$). Many older patients although initially classified as eligible, had changes in their management plan due to their WHO performance status and other co-morbidities, and were generally more reluctant to participate for various reasons. No patients requiring interpreters participated in the clinical trials.

There was no difference in the deprivation index ($p = 0.69$), BMI ($p = 0.75$) and neurodiversity ($p = 0.22$) between patients recruited into clinical trials and those who were not. Patient feedback showed 95.5% overall satisfaction with the pathway of recruitment.

Conclusion: Using a pathway such as the one used by the Breast Research team at Guy's allows inclusivity of all minority groups in recruitment. The recruitment process was well received by patients, although extra steps may also be taken to reduce language barriers, such as information sheets and videos in the patient's native language where possible.

No conflict of interest.

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51 (PB-051) Poster

Basic household activities has huge role of reduce the occurrence of lymphedema in post MRM cases

A. Manna[1]. [1]*MAS Clinic &- Hospital, Oncology, Purba Medinipur, India*

Introduction and aim: This is a condition, where swelling in an arm found, and caused by lymphatic system blockage in post MRM cases. It is mainly found in breast cancer patients due to the removal or damage of lymph node. But, the cases are lessen particularly rural Indian population particular these study group. During studies we found that, rural women are less likely get affected with lymphedema. So, the focus of the study is to find out the reason behind this and to improve the quality care to reduce the occurrence of lymphedema.

Method: This study was conducted for a period of 4 years in MAS Clinic and Hospital. This was a qualitative exploratory study design via randomized way of selected post MRM patients. Data were collected through focus group discussion and data were analyzed by content analysis.

Results: The study shows that only 2% of rural women are affected with lymphedema. Daily household activities, agricultural activities, animal husbandry etc helps to reduce the chances of occurrence of lymphedema among rural women.

Conclusion: This research helps to find us that a basic household activities has huge role of reduce the occurrence of lymphedema rather than doing any kind of exercise with instruments. A rural women who is doing her daily household activities (like: collecting water, washing clothes, mopping house, etc.), agricultural activities, animal husbandry etc, are less likely get affected with lymphedema. They didn't maintain exercises and also they didn't have to give a special time for their health purposes.

No conflict of interest.

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52 (PB-052) Poster

The role of volunteers in quality palliative care

A. Manna[1]. [1]*MAS Clinic &- Hospital, Oncology, Purba Medinipur, India*

Introduction: Here in India almost 75% of cancer patient die a sad death of neglect due to lack of awareness about palliative care and low economic level. Surveys in India show that two third of cancer patient do not get proper care during the terminal phase of their life. Palliative care through volunteers can make a significant difference in this respect.

Objective: To identify and try to solve, to the extent possible, the main difficulties in giving palliative care to the terminal cancer patients of the area. And evaluate the impact of volunteer's direct care of palliative patients and their families.

Methods: Feedback from patients and their relatives regarding the palliative care they receive from nursing home and from volunteers and compare the two. Also feedback from volunteers regarding their positive and negative experience while delivering palliative care service. Then evaluate the data to compare and improve the quality of service.

Results: We carried out two studies. One study was undertaken in nursing home palliative care and another was in home setting by volunteers. Both studies were in adult palliative care services. Since January 2023, 416 cases were studied to enquire about their experience in both home based care and nursing home care. Both the studies fulfilled our quality appraisal criteria. One found that those families and patients who received home visits from volunteers were significantly more satisfied. The study highlighted the value of the role of volunteers in better satisfaction of patients and their families.

Conclusions: Further research is needed to evaluate the role of volunteers in palliative care and how it can be delivered appropriately and effectively. We also wish to compare our findings with similar studies elsewhere.

No conflict of interest.

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53 (PB-053) Poster

Pilot between peer support and hospital

S. Grosfeld[1], S. Kroon[2], S. Boogerd[3], M. Ernst[3]. [1]*Alexander Monro Hospital, Utrecht, Horssen, Netherlands;* [2]*Cancer Connert, Noord-Holland, Amsterdam, Netherlands;* [3]*Alexander Monro Ziekenhuis, Utrecht, Bilthoven, Netherlands*

Background: Patients who are diagnosed with cancer often do not know what to expect, both practically as emotionally. They need a listening ear, practical tips from experiential knowledge (e.g. hairpiece or coldcap, reconstruction or not), information (right apps, communication, podcasts) and experiences of (ex) patients. This helps them to maintain control and make the right choices.

The Alexander Monro Hospital is a breast cancer hospital with national coverage. Cancer Connect is a national network of experts by experience. They use their knowledge and experience to provide support to fellow sufferers.

Cancer Connect and the Alexander Monro Hospital have conducted a joint pilot to arrive at a well-developed plan for peer support.

Material/Methods: Experts from Cancer Connect were present in the hospital twice a week to inform patients and staff. The patient registered via the Cancer Connect website. A match was made between the patient and a peer supporter using a special app through a secure registration form. The peer supporter was able to consult the network. The pilot was evaluated and

monitored monthly by sending evaluation forms to the patient and peer supporter.

Results: In the six-month pilot, 105 peer supporters and 58 patients joined the program. 100% of patients rated the conversation as useful with a score between 7 and 10. 91.6% of patients would recommend contact with a peer supporter. 87.5% are considering becoming a peer supporter themselves in the future. 87.5% of peer supporters felt sufficiently supported by the organization in their role as peer supporter. More than 50% of patients and peer supporters found it important to communicate in an app environment where personal information is not visible. Soon, a major health insurer will collaborate, making the program free for patients and hospitals.

Conclusions: Peer support is an important addition to the medical and care offered in hospitals and should therefore be offered to patients as standard.

No conflict of interest.

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55 (PB-055) Poster

Mobile technology have expanded the scope in palliative care for better management of terminal cancer patients in rural India – an NGO based approach

S.K. Mondal[1]. [1]*MAS Rural Initiative, Oncology, Tamluk, India*

Aim: Due to financial incapability and absence of manpower poor families often fail to carry their advanced cancer patients to the nodal centres. This pilot study will explore whether communication by mobile phone can lessen this burden.

Method: Initially a plan was generated regarding management of an advanced cancer patient in a nodal centre at District Head Quarter. Subsequently every two week a trained social worker attached to nodal centre will follow up and give necessary advice and emotional support to the patients and their families through their registered mobile phone number. Patient's family were also encouraged to communicate with the team by phone in case of fresh complain and urgency in between.

Results: Since last one year, 193 cancer patients were contacted by mobile phone every two weeks to enquire about their difficulties. In 76% of the situation trained social workers could give necessary advice by phone regarding management of their physical symptoms. Moreover patient's family were really overwhelmed by the emotional support offered by the team over phone. Only 24% of cancer patients has to attend the nodal centre for expert advice from Palliative Care specialists.

Conclusion: This novel approach helped * In providing regular physical and emotional support to the patients and their families.

* In significantly reducing the financial and manpower problems of carrying patients to the nodal units. * In improve the quality of life of patients by continuous guidance.

More and more team members can take help of this new strategy for better communication and uninterrupted care.

No conflict of interest.

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56 (PB-056) Poster

Palliative counselling at home, is effective than hospice care for Advanced breast cancer patients

S. Rithara[1], G.G. Kimani[2]. [1]*Ongata Ngong Palliative Care Community, Nursing, Nairobi, Kenya;* [2]*Ongata Ngong Palliative Care Community, counselling, Nairobi, Kenya*

Background: Home palliative care service is becoming the choice of many patients with palliative needs in Kenya especially in rural areas where hospices/hospitals are far away.

The care under the relative is more preferred by patients but lack professional palliative care to manage distressing symptoms and pain.

Aim: To assess the benefit of palliative care service at home. The survey was done in Kajiado-West.

Method: 20 community health volunteers and 24 patients with palliative needs were invited to participate, the survey purpose was explained to the patients and CHVs.

Result: 100% patients and 80% CHVs accepted to be interviewed, 75% patients preferred home care with specialised palliative care 25% in-patient hospice. 60% referred for Hospice pain management but declined due to long distance, 25% purchased pain killer locally, 50% received palliative care at the Hospice, 25% traditional medicine, 80% had several symptoms requiring a specialist. 90% preferred the care with a specialist palliative care. 10% preferred a health worker from different area. 40% CHVs referred home care as burden to family while 60% fulfilling. 85% CHVs required palliative care training.

Conclusion: there is need for training and incorporating community health volunteers in palliative care services at home for better symptom approach. Involving private health institutions and the community at large, hence ensuring all who need the service receives with less strain.

No conflict of interest.

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57 (PB-057) Poster

What is role of community health volunteers in palliative care services at home for patients with palliative care needs?

S. Rithara[1], G.G. Kimani[2]. [1]*Ongata Ngong Palliative Care Community, Nursing, Nairobi, Kenya;* [2]*Ongata Ngong Palliative Care Community, counselling, Nairobi, Kenya*

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No conflict of interest.

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58 (PB-058) Poster

Is breast organ specific practice the way forward? Surgeons' perspective

A. Choudhury[1], N. Ahirwar[2], R. Bezbaruah[3]. [1]*Dr B. Borooah Cancer Institute, Surgical Oncology, Guwahati, India;* [2]*Zydus Hospital, Surgical Oncology, Ahmedabad, India;* [3]*Dr B. Borooah Cancer Institute, Oncopathology, Guwahati, India*

Background: There is a constant debate regarding organ specific practice or generalized practice in our country. Gradually the world is moving towards sub specialization but we are yet to know the attitude of Indian surgeons on this topic. This discussion becomes all the more important in breast cancer which is the most common cancer in India. This study was conducted with the aim to evaluate surgeons' perspective towards breast organ specific practice.

Materials and Methods: Cross sectional study conducted in July 2022 in 100 surgeons of India using a self-administered google form questionnaire. Responses were evaluated and assessed.

Results: Out of 100 responses, 45% were from private/corporate setting, 39% from government institutes. 30.6% were from west,27.6% from east,22.4% from south zone. 55% were from surgical oncology, 36.4% were from general surgery. As per the study, Breast (31%) and Gastro-surgery (29%) were the subspeciality of choice. 47.5% agreed that they would be interested in breast specific surgery practice if proper training was available. 30.9% considered this to be less stressful with fewer complications. Majority (48%) thought that lack of patient awareness about breast cancer specific surgeon was the biggest disadvantage of organ specific practice. 22% considered it to be technically undemanding. 51% and 27.1% suggested that a dedicated and recognized training is required and organ specific practices are required at hospitals/institutions respectively.

Conclusion: Breast organ specific oncosurgery practice is still uncommon in India. More dedicated training programs are required along with adequate employment opportunities to fill the lacunae in promoting the same.

No conflict of interest.

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59 (PB-059) Poster

"Una volta per tutte" (once and for all) – Europa Donna Italia makes breast cancer patients' voice heard nationwide

R. D'Antona[1], L. Pau[1]. [1]*Europa Donna Italia, Milan, Italy*

Europa Donna Italia, an independent non-profit organization, aims to raise awareness of breast cancer and, through a network of 185 volunteer associations spread nationwide, calls for improved breast cancer education, appropriate screening, and optimal treatment.

Our priorities are primary and secondary prevention – drawing attention to their importance and securing equal access to diagnosis&screening – and the adherence of the Italian Breast Units to the national and European guidelines.

To spread our message, however, we need to cooperate with patients, doctors, and Institutions. Therefore in 2023, in the wake of Italian Metastatic Breast Cancer Awareness Day, we launched the "Una volta per tutte" (Once and for all) campaign, in the hope that MBC patients' voice may finally be heard. Five requests: easy access to diagnostic tests, a constantly updated database listing all the clinical trials conducted in Italy, the implementation of new drugs as soon as approved by the Italian Medicines Agency, the availability of psycho-oncologists in every Breast Unit and a quicker procedure to obtain a declaration of legal disability.

A short video stars 4 patients demanding their needs to be taken care of. Some frames have been turned into billboards and hung around Milan and other main Italian cities. Its media coverage has been relevant, being on our national TV and radio and widely discussed in the press. The video has also been also posted on our Facebook, Instagram, LinkedIn, and X pages and overall registered more than 10.000 interactions.

The campaign includes an advocacy tool for our decision makers, a 3-minute-long video message, in which doctors of multi-disciplinary teams working at the BUs, patients, institution representatives, celebrities address needs and clear requests to address optimal MBC treatment. It has therefore been mailed to the Government, MPs, and institutions relevant to the Italian National Health Service. We also discussed it with Europa Donna Parlamento, a parliamentary alliance established in 2021 and currently made of 27 members. We stressed the importance of granting equal access to screening tests nationwide and remembered how having a psycho-oncologist available in every BU is fundamental, as declared also by our National Cancer Plan. The video message has widely appeared in the press and registered over a million interactions on our social media channels and will keep being our main MBC advocacy asset for the near and mid-future.

No conflict of interest.

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POSTER SESSION **20 March 2024** **9.00–18.30**

Lifestyle, Prevention Including Secondary Prevention

60 (PB-060) Poster

The global, regional, and national disease burden of breast cancer attributable to tobacco from 1990 to 2019: a global burden of disease study

T. Lan[1], Q. Guo[2], Y. Lu[3]. [1]*Hangzhou TCM Hospital Affiliated to Zhejiang Chinese Medical University- Hangzhou Hospital of Traditional Chinese Medicine, Department of Breast Surgery, Hangzhou, China;* [2]*Affiliated Jinhua Hospital- Zhejiang University School of Medicine, Department of Medical Oncology, Jinhua, China;* [3]*The First People's Hospital of Xiaoshan District- Xiaoshan Affiliated Hospital of Wenzhou Medical University, Department of Cardiology, Hangzhou, China*

Background: Tobacco has been identified as a significant contributory element to the development of breast cancer. Our objective was to evaluate the spatiotemporal trends of tobacco-related breast cancer at the global, regional, and national scales during 1990–2019.

Material and Methods: We extracted data on mortality, disability adjusted of life years (DALYs), age-standardized mortality rate (ASMR), and age-standardized DALYs rate (ASDR) from the Global Burden of Disease (GBD) study 2019. Estimated annual percentage change (EAPC) was computed to assess the temporal change in ASDR and ASMR.

Results: In 2019, the deaths and DALYs attributed to tobacco-related breast cancer were estimated to be 35,439 (95% UI: 22,179–48,119) and 1,060,590 (95% UI: 622,550–1,462,580), respectively. These figures accounted for 5.1% and 5.2% of the total burden of breast cancer. ASMR and ASDR increased in low SDI regions, remained stable in low-middle and middle SDI regions and declined in high and high-middle SDI regions. The burden of breast cancer attributable to tobacco varied notably among regions and nations. Oceania, Southern Latin America, and Central Europe were the GBD regions with the highest number of ASMR and DALYs. There was a positive relationship between age-standardized rate and SDI value in 2019 across 204 nations or territories. A negative association was observed between the EAPC in ASMR or ASDR and the human development index (HDI) in 2019 ($R = -0.55$, $p < 0.01$ for ASMR; $R = -0.56$, $p < 0.01$ for ASDR).

Conclusions: Tobacco is one important and modifiable risk factor for breast cancer. The heterogeneity in both the spatial and temporal distribution can be attributed to factors such as aging, population growth, and SDI. These findings substantiate the necessity of expediting the enforcement of tobacco-free legislation in order to safeguard populations from the detrimental effects of tobacco.

No conflict of interest.

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61 (PB-061) Poster

Effects of exercise and education programs on cancer-related fatigue after initial treatment for breast cancer: Secondary endpoint from a randomized controlled trial in the Setouchi Breast Project-10

Y. Zhu[1,2], T. Iwamoto[3], K. Kawada[2], M. Uno[2], Y. Suzuki[2], K. Shinichiro[4], D. Takabatake[5], Y. Miyoshi[5], M. Yamamoto[4], Y. Ogasawara[6], M. Hatono[2], S. Yoshitomi[7], K. Hara[7], S. Ohsumi[8], M. Ikeda[4], H. Doihara[9], Y. Mizota[10], S. Yamamoto[10], N. Taira[3]. [1]*Cancer Hospital of Dalian University of Technology, Department of Breast Surgery, Shenyang, China;* [2]*Okayama University, Department of General Thoracic Surgery and Breast and Endocrinological Surgery, Graduate School of Medicine Dentistry and Pharmaceutical Sciences, Okayama, Japan;* [3]*Kawasaki Medical School Hospital, Breast and Thyroid Surgery, Kurashiki, Japan;* [4]*Fukuyama Citizens Hospital, Department of Breast and Thyroid Surgery, Fukuyama, Japan;* [5]*NHO Shikoku Cancer Center, Breast Oncology, Matsuyama, Japan;* [6]*Kagawa Prefectural Center Hospital, Department of Breast Endocrine Surgery, Takamastu, Japan;* [7]*Red Cross Okayama Hospital, Department of Breast and Endocrine Surgery, Okayama, Japan;* [8]*NHO Shikoku Cancer Center, Breast Oncology, Mastuyama, Japan;* [9]*Kawasaki Medical School*

General Medical Center, Department of Breast Surgery, Okayama, Japan; [10]Shizuoka Graduate University of Public Health, Shizuoka Graduate University of Public Health, Shizuoka, Japan

Background: Evidence indicated that maintaining higher physical activity after diagnosis for breast cancer patients reduced the risk of all-cause mortality and cancer-specific mortality. Physical activity interventions are considered to be effective as a treatment for cancer-related fatigue (CRF) and improve the quality of life for cancer survivors. Thus, this study aimed to evaluate the effects of exercise and education programs on CRF after initial breast cancer treatment.

Material and Methods: This study was a secondary endpoint analysis of a prospective randomized controlled trial for patients with stage 0 to III breast cancer after initial treatment with surgery or adjuvant chemotherapy. Patients were randomized to an exercise group, EX (specified exercise program 3 times a week for 4 months), an education group, ED (face-to-face lectures and exercise guidance by medical professionals), and a control group, C (performed their regular physical activity level). The primary endpoint was the amount of physical activity one year after registration, and the secondary endpoint was CRF, investigating the Cancer Fatigue Scale (CFS) at baseline, 2 months, 4 months, 6 months, and 1 year after enrollment. We applied mixed-effects models for repeated measures (MMRM), the change from the baseline at 2, 4, 6, and 12 months for each group, and the difference between groups was modeled for CFS. The CFS dimensions include cognitive fatigue, psychological fatigue, physical fatigue, and total fatigue.

Results: From March 16, 2016, to March 15, 2020, 356 breast cancer patients were enrolled in this trial, of which 342 (C, 114; ED, 120; EX, 108) were assessed, excluding those who withdrew, relocated, or experienced an early recurrence. The average age was 55 years old, and the proportions of Stage 0, I, II, and III cases were 11%, 46%, 32%, and 11%. MMRM analysis showed that there were significant differences over time in ED for Physical Fatigue (difference in mean of change over time: −0.33, 95% CI: −0.60, −0.07, $P = 0.01$) and Total Fatigue (difference in mean of change over time: −0.48, 95% CI: −0.92, −0.03, $P = 0.04$) in relative to C. Additionally, there were significant differences over time in EX for Cognitive Fatigue (difference in mean of change over time: −0.33, 95% CI: −0.51, −0.15, $P < 0.01$) and Total Fatigue (difference in mean of change over time: −0.60, 95% CI: −1.10, −0.10, $P = 0.02$) in relative to C.

Conclusions: In both ED and EX, the CFS of total fatigue was significantly lower than in C. As a result, exercise intervention and education instructions played a favorable role in alleviating CRF in breast cancer.

No conflict of interest.

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62 (PB-062) Poster

Survival after risk-reducing salpingo-oophorectomy for BRCA1/2 germline pathogenic variant carriers with a history of breast cancer: introducing an alternative approach for confounding adjustment in observational studies

A. Heemskerk-Gerritsen[1], L. Terra[2], M. Beekman[2], A. Maas[3], F. van Leeuwen[2], M. Hooning[1]. *Hereditary Breast and Ovarian Cancer Research Group, Netherlands; [1]Erasmus MC Cancer Institute, Medical Oncology, Rotterdam, Netherlands; [2]Netherlands Cancer Institute-Antoni van Leeuwenhoek Hospital, Division of Psychosocial Research and Epidemiology, Amsterdam, Netherlands; [3]Radboud University Medical Center, Department of Cardiology, Nijmegen, Netherlands*

Background: Previous studies showed reduced mortality after risk-reducing salpingo-oophorectomy (RRSO) in *BRCA1/2* germline pathogenic variant (gPV) carriers with breast cancer (BC). Performing RRSO shortly after BC diagnosis – even at very young age – was suggested. However, commonly used survival analysis methods may be subject to inadequate adjustment for confounding. This study aims to introduce an alternative analysis method for confounding adjustment and herewith potentially revise previous results.

Study population and methods: We selected *BRCA1/2* gPV carriers with invasive BC from the Hereditary Breast and Ovarian Cancer Netherlands study. We investigated the association between RRSO and mortality using a multivariable Cox model. Alternatively, to adjust for imbalanced groups, we used the Inverse Probability of Treatment Weighting (IPTW) method to obtain the average treatment effect of RRSO after BC on survival. We included – among others – time between BC and disease recurrence in the IPTW model.

Results: Among *BRCA1* gPV carriers, the median follow-up was 9.3 years for 610 patients with RRSO, and 3.8 years for 157 patients without RRSO. The adjusted hazard ratio was 0.51 (95%CI 0.33–0.8) for all-cause mortality, and 0.82 (95%CI 0.48–1.38) for BC-specific mortality. Among *BRCA2* gPV carriers, the median follow-up was 8.6 years for 350 patients with RRSO, and 4.3 years for 81 patients without RRSO. The adjusted hazard ratio was 0.55 (95%CI 0.33–0.91) for all-cause mortality, and 0.6 (95%CI 0.32–1.1) for BC-specific mortality. However, patients in the non-RRSO groups more often had BC at very young age, and showed recurrent disease more often and sooner after BC, suggesting worse prognosis and introducing confounding by contra-indication. Using the IPTW method, we estimated that if all *BRCA1* gPV carriers in this population would undergo RRSO, the average time to death would be 0.68 years longer (non-significantly; 95%CI −2.69–4.06) than if no *BRCA1* gPV carriers would undergo RRSO. In case all *BRCA2* gPV carriers would undergo RRSO, the average time to death would be 3.66 years longer (significantly; 95%CI 1.72–5.59) compared to if no *BRCA2* gPV carriers underwent RRSO.

Conclusions: Using the standard Cox analyses, we found comparable risk-reducing effects of RRSO on mortality as previously described. When using the IPTW method, which allows for more thorough adjustment for confounding, there appears to be a protective effect for *BRCA2* gPV carriers but not for *BRCA1* gPV carriers.

No conflict of interest.

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63 (PB-063) Poster

A prospective randomized controlled study of a mobile messaging system versus breast nurse contact to improve adherence to adjuvant therapy and follow-up visits, as well as quality of life among women with breast cancer

E. Angelidou[1]. *[1]Euromedica General Clinic Dodecanese, Breast Unit-Gynecological Department, Rhodes, Greece*

Background: Adjuvant endocrine therapy (ET) in women with hormone receptor positive breast cancer reduces the risk of cancer recurrence, but adverse symptoms often contribute to lower adherence. Moreover, a lot of patients, especially the older ones, frequently forget their follow-up visits, which could lead to late diagnosis of local relapse or metastasis and worse overall survival. We evaluated the effectiveness of a mobile messaging system (MMS) that reminds to the patients their follow up visits by our breast unit doctors, the adherence to their ET and gives information about how to manage the side effects of the therapy. This MMS was evaluated versus the effectiveness of the personal telephone communication with a breast nurse (BN) for the follow up visits and the ET of breast cancer patients. The quality of life of these patients was also evaluated.

Material and Methods: From January 2018 to January 2022 450 women with hormone positive breast cancer initiating ET where blindly randomized into 3 arms: (1) A MMS group that received instructions for managing side effects and reminding to continue therapy in weekly basis, as well as reminding of the follow-up visits at the doctors of the breast unit. (2) A group that received BN personal telephonic contact to encourage the continuation of the ET giving instructions for coping with the side effects weekly and organizing the appointments of the follow-up visits of the patients. (3) A group of patients with no intervention at all. The intervention lasted at least 12 months and participants completed surveys at their enrollment, at 6 and 12 months after. Severe side effects from the ET, missed doses of the ET and missed follow-up visits were prospectively reported as well as mental, physical, and sexual quality of life (QL) of the patients. All statistical analyses were conducted using SPSS Statistics, version 25.0 (IMB Corp. Armonk, NY USA). P values <0,05 were considered statistically significant.

Results: Overall, 450 women were blindly randomized: 150 at the (1) MMS 150 at the (2) BN group and 150 at the (3) no intervention group. The 3 groups were well matched concerning age, financial situation, and degree of education. There was statistically significant better adherence to ET, better adherence to follow-up visits, better management of side effects and better QL in the (2) BN group compared to the other groups, whereas the group (3) presented the worst results.

Conclusions: The intervention with MMS and BN did improve the adherence to ET and follow up visits, the management of the side effects of

ET and the QL of the patients. Both the interventions could increase the favorable outcome for patients with breast cancer, but the best results were achieved through the personal human conduct with the BN.

No conflict of interest.

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64 (PB-064) Poster

Mode of Recurrence/ Metastasis Detection in Breast cancer survivors

A. Munir[1], A. Huws[1], S. Khan[1], Y. Sharaiha[1], S. Khawaja[1]. [1]*Prince Philip Hospital, Breast Surgery, Llanelli, United Kingdom*

Background: Follow-up of patients after primary treatment of breast cancer is aimed to detect recurrences at an early/ asymptomatic stage. Cochrane review of the randomized control trials suggests that follow-up programs based on regular physical examination and yearly mammogram alone are as effective as more intense approaches based on regular performance of laboratory tests and imaging in detecting recurrence, overall survival, and quality of life. This study's objective was to assess the pattern of detection of Metastasis/local/regional recurrence in Breast cancer survivors treated in a single center in Southwest Wales.

Material and Methods: This was a retrospective review of patients diagnosed between 2016 and 2017. Their initial presentation clinical parameters and stage of diagnosis, and the treatment received was documented. The patients were followed up for 5 years and any event (defined as local recurrence, regional recurrence, metastasis, or death) was recorded. Patient's records were also reviewed to identify the cause of death. At the time of the event, the mode of presentation/detection was also recorded.

Results: A total of 494 patients were diagnosed with breast cancer who had therapeutic surgery (breast conserving surgery or mastectomy) between 2016 and 2017. Patients were routinely followed up, annually, in the clinic from 2017 to 2023. Of the 494 patients, 33 patients (6%) were diagnosed with a recurrent/ metastatic event. Breast cancer local recurrence rate was 1.4% (6 patients) Regional axillary recurrence rate was 1% (4 patients) and distant metastasis rate was 4.4% (20 patients). 79.5% (26/34) of the patients were symptomatic at the time of diagnosis of recurrence/ metastasis. 20.5% (7/34) of the patients were asymptomatic. GP referral was the main route of recurrence/metastasis detection at 50%, followed by on-demand follow-up examination (breast team) at 26.9%. Among other routes, 18.2% cases were investigated by other specialties. Routine annual follow-ups in breast clinic only identified 6 patients (all with loco-regional recurrent disease, with one patient also having synchronous distant metastasis. The three cases of local recurrence would have been detected on surveillance mammograms – clinical exam did not add to the early detection. Three cases of regional recurrence were detected on clinical/ US exam and would have been missed on surveillance mammograms – All three cases had high risk biology and did not receive chemotherapy.

Conclusions: High self-referral rate shows that the open access clinic has enabled the patients to seek medical attention immediately when a concern arise. Routine follow-up performed well in detecting local and regional recurrence, but detection of distant metastasis remains a challenge. Metastasis detection heavily relies on referral from GP, other specialties and self-referral.

No conflict of interest.

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65 (PB-065) Poster

Are we breast aware yet?

A. Choudhury[1], R. Bezbaruah[2], N. Ahirwar[3]. [1]*Dr B. Borooah Cancer Institute, Surgical Oncology, Guwahati, India;* [2]*Dr B. Borooah Cancer Institute, Oncopathology, Guwahati, India;* [3]*Zydus Hospital, Surgical Oncology, Ahmedabad, India*

Background: Breast cancer is the most common cancer worldwide. Educating women about the risk factors of breast cancer is the first step towards early detection. Nurses are in a strong position to impart health education so it is essential to invest in their education regarding risk factors and screening methods. This study was performed with the aim to assess the level of breast cancer awareness among nurses working in our hospital.

Materials and Methods: A cross−sectional survey was conducted using a self-administered Google form questionnaire. It had three parts – personal data; knowledge regarding breast cancer risk factors; and awareness of screening methods. Participation was voluntary and no incentive was proposed.

Results: Of 200 respondents, 65% were female and 35% were male. 73.5% were in the age group of 21 to 30 years. The risk associated with early menarche, late menopause, nulliparity, family history, hormone replacement therapy, alcohol and obesity was correctly identified by 39.5%, 47%, 48.5%, 73%, 77.5%, 76.5% and 77.5% nurses respectively. 69% knew that lump is the most common symptom. Only 47.5% knew that breast self-examination (BSE) was to be done monthly and 63.5% knew that it should be started from 20 years. 68.5% knew that clinical breast examination (CBE) is to be performed by doctors but only 35% were aware of the correct frequency. Only 52.5% were aware that screening mammography should be started from 40–45 years and only 48.5% knew that it has to be done yearly.

Conclusion: Nursing staff is the backbone of healthcare. The nursing curriculum can be modified to lay more stress on preventive aspects of diseases. Also, hospitals can conduct training modules to improve their cancer awareness. More studies in this direction can help better understand the level of knowledge amongst nurses.

No conflict of interest.

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66 (PB-066) Poster

Utilisation of palliative care service in Pakistani patients with metastatic breast cancer. Exploring the impact of social determinants of health

A. Fatima[1]. [1]*Shaukat Khanum Cancer Hospital, Surgical Oncology, Lahore, Pakistan*

Background: Guideline recommends integrating palliative care (PC) with standard oncologic care for patients with metastatic cancer. Despite this, there is limited evidence on Palliative Care utilization in breast cancer patients, particularly concerning area-level social determinants of health (SDoH) factors.

Aims: Our study aimed to explore the relationships between county-level factors and Palliative care utilization in individuals with metastatic breast cancer.

Methods: Patient-level data from 21,062 cases diagnosed between 2018 and 2023 were included. Palliative care utilization since cancer diagnosis was identified using specific diagnostic codes. We investigated differences in Palliative care utilization in relation to county-level SDoH factors, such as poverty rate, transportation resources, provider supply, and racial segregation, through bivariate analysis. Multivariable Poisson regression, incorporating significant factors identified in bivariate analysis, was employed to compare PC utilization across these SDoH factors.

Results: The overall prevalence of Palliative care utilization in our study population was 11.6%. Palliative care utilization was more common among metastatic breast cancer patients in counties with higher poverty rates and an increased supply of advanced practice providers, general surgeons, and nursing homes. Conversely, lower PC utilization was observed in counties with higher proportions of residents identifying as immigrants, limited language proficiency, lacking personal transportation, and experiencing higher racial segregation. Adjusted analysis revealed that a greater supply of Advance practice providers (coefficient: 0.12) and nursing homes (coefficient: 0.09) correlated with increased PC utilization. Conversely, racial segregation was associated with decreased PC utilization (coefficient: −0.07).

Conclusion: Palliative care utilization among metastatic breast cancer patients was linked to various county-level SDoH factors. Notably, lower Palliative care utilization was associated with racial residential segregation and fewer advance practice providers and nursing homes. Further research is warranted to identify mediators in these relationships, aiming to enhance the effectiveness of Palliative care for individuals with metastatic breast cancer.

No conflict of interest.

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67 (PB-067) Poster

The cross-sectional study about life style behaviors in healthy Women with Familial History of Breast Cancer: A Multicenter Study in South Korea

J.S. Lee[1], A. Jeongshin[2], L. Hyunjoo[3]. [1]*Inje University Haeundae Paik Hospital, Surgery, Busan, South Korea;* [2]*Ewha Womans Univeristy Mokdong Hospital, Department of Surgery, Seoul, South Korea;* [3]*Gangnam Severance Hospital, Yonsei University College of Medicine, Department of Pediatrics, Seoul, South Korea*

Background: We investigated the lifestyle of healthy women who participated in voluntary genetic screening tests. Among the effects on the participation for genetic screening tests, the prognosis of patients treated for breast or ovarian cancer is likely to be correlated with genetic test, cancer screening, and other healthier life modification.

Methods: This study investigated BRCA 1/2 gene abnormalities in healthy women aged over 25 who had a family history of breast cancer in their second-degree relatives. This multicenter study involved three hospitals. Each hospital had 200, 200, and 177 patients, respectively, totaling 577 participants. Their family histories were verified through a diagnosis of breast or ovarian cancer within a second-degree relative. Additionally, surveys were conducted regarding family cancer history, medical history, eating habits, and lifestyles. Blood samples were collected from these volunteers, and the BRCA 1/2 genetic test was conducted using next-generation sequencing.

Results: Among 577 participants, mean age is 37.6 (±9.7) years and mean menarche is 11.3 (±2.4) years. 304 (52.7%) women was married, and 222 (38.5%) women had lactation for baby. We found that women with both negative BRCA-1 and 2 was 95.2%, positive BRCA-1 women is 17 (2.9%), positive BRCA-2 is 11 (1.9%), women with Variant with unsignificant is 169 (29.2%). Death with breast or ovarian cancer was reported in 98 women (16.9%), neither breast nor ovarian cancer death was in 148 women (25.6%). Table 1 was shown the correlation between life style of participants and the prognosis of patients treated for cancer.

Table 1: The correlation between lifestyle of participants and the prognosis of patients treated for cancer

	Cancer related deaths(–)	Breast/Ovarian Cancer related deaths(+)	Other cancer related death(+)	p-value
Mean age (years)	37.1 (9.5)	40.3 (11.0)	36.9 (8.9)	0.01
Mean menarche (years)	10.9 (2.4)	10.4 (2.3)	10.37 (2.3)	0.001
Duration of lactation (months)	11.9	11.3	11.28 (9.0)	0.91
Screening(–)	79 (27.9%)	11 (12.1%)	46 (34.6%)	0.005
Screening(+)	202 (71.4%)	79 (86.8%)	85 (63.9%)	
HRT(–)	300 (90.1%)	90 (92.8%)	133 (91.1%)	0.61
HRT(+)	18 (5.4%)	6 (6.2%)	8 (5.5%)	
OC(–)	310 (93.1%)	92 (94.8%)	144 (98.6%)	0.014
OC(+)	23 (6.9%)	5 (5.2%)	2 (1.4%)	
Alcohol(–)	85 (59.4%)	18 (60.0%)	66 (52.0%)	0.05
Alcohol(+)	51 (35.7%)	11 (36.7%)	61 (48.0%)	
Supplement(–)	101 (30.4%)	21 (21.6%)	80 (54.8%)	<0.001
Supplement(+)	110 (33.1%)	30 (30.9%)	63 (43.2%)	
Supplement(++)	121 (36.4%)	46 (47.4%)	3 (2.1%)	

Conclusion: Relatively young women with family history have very concerned the genetic condition for their health in Korea. Familial history of breast or ovary cancer, especially with worse clinical outcome, may influence the life style modification: less user of oral contraceptive, attention to cancer screening, but did not decrease their alcohol consumption.

No conflict of interest.

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68 (PB-068) Poster

Availability and appropriateness of exercise services for people with breast cancer in regional Western Australia

C. Andrew[1], A. Dennett[2], A. De Leo[1], C. McIntyre[3], Y. Zissiadis[4], J. Lewis[1], M. Kennedy[1]. [1]*Edith Cowan University, Nutrition and Health Innovation Research Institute, Joondalup, Australia;* [2]*Eastern Health, Allied Health, Box Hill, Australia;* [3]*Edith Cowan University, Exercise Medicine Research Institute, Joondalup, Australia;* [4]*GenesisCare, Oncology, Perth, Australia*

Background: National guidance directs all health care professionals in oncology to refer patients to exercise as part of standard care. However, these referrals happen rarely in practice leading to a critical research-to-practice gap. One major barrier preventing exercise oncology referrals is a lack of appropriate exercise programming. This lack of programming is more prevalent in rural and regional areas as compared to metropolitan areas for several reasons, including poor availability of trained exercise professionals, long distances to appropriate facilities, and low socio-economic status of the population. The aims of this study are to 1) determine the availability of exercise oncology programs in a regional area of Western Australia; and 2) explore the appropriateness of these resources to meet the needs of the cancer population in the region. This work will inform the development of a strategy to ensure all patients receive a referral to exercise as part of routine oncology care.

Methods: A comprehensive search was completed online to identify all exercise services available in the South West region of Western Australia for people with cancer. Services were then categorised using the Cancer Rehabilitation to Recreation (CaReR) Framework, which was developed to identify appropriateness of exercise programs and services for people with cancer based on their needs related to symptom burden, functional status, and self-efficacy. Finally, the geographical make-up and demographics of the cancer population in the South West was matched to the services provided to identify gaps.

Results: The South West region of Western Australia covers over 23,000 square kilometres comprising 12 local government areas (LGAs). Approximately 3,700 people were diagnosed with breast cancer in the region. Sixty-six exercise oncology services were identified as appropriate for serving this population with 62% of all programs located in the two largest LGAs in the region. Sixty percent of services were categorised as CaReR Phase 1, providing targeted, supervised care for high needs patients with a primary focus of improved function; 79 percent as Phase 2, providing targeted, supervised care for medium needs patients with a primary focus on improved physical fitness; and 28 percent as Phase 3, independent, community-based care for low needs patients with a primary focus of improved overall health.

Conclusion: The South West region is significantly under resourced to meet the national directive to embed exercise referrals into care for all people with cancer. Issues of accessibility and workforce development underpin this inability to provide best practice care. Implementation focused research is required to close this critical research-to-practice gap.

No conflict of interest.

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69 (PB-069) Poster

Prehabilitation and rehabilitation in breast cancer surgery patients – a pilot study

S. Wooldrik[1]. [1]*Franciscus Gasthuis & Vlietland, Surgery, Rotterdam, Netherlands*

Introduction: Breast cancer is the most common malignancy in women. The diagnosis and treatment of breast cancer, of which surgery is the cornerstone, have a severe impact on both physical and mental well-being. Most patients experience a variety of complaints, such as fatigue, pain, weight gain or loss, anxiety and/or depressive symptoms, which have a major impact on HRQOL. These problems may last for months to years and result in complex and heterogeneous rehabilitation needs. Therefore, an individualized approach is required. In accordance with the increasing survivorship, a focus on quality of life is warranted. Furthermore, the outcomes of implementation interventions earlier in the process (prehabilitation) in cancer surgery to improve functional capacity and perioperative outcome measures are promising. However, this has not yet been investigated in patients with breast cancer.

Objective: To explore the feasibility of prehabilitation and rehabilitation through an individualised lifestyle coaching programme on HRQOL.

The primary aim of the study is to investigate whether health-related quality of life (HRQOL) in women diagnosed with breast cancer can be improved through an individualised prehabilitation and rehabilitation programme.

Study design: A 2-arm randomised pilot study.

Feasibility parameters: Feasibilty of the study is based on inclusion rate, willingness to be randomised, attendance, adherence, achievement of primary and secondary endpoints and withdrawals. Overall satisfaction with the programme will be evaluated.

Main study parameters/endpoints:

- The primary outcome is HRQOL
- Secondary endpoints are BMI, functional capacity, postoperative functional recovery, postoperative complications, smoking status, patient reported breast cancer specific HRQOL and satisfaction and cost-effectiveness.

No conflict of interest.

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POSTER SESSION **20 March 2024** **9.00–18.30**

Neoadjuvant Treatments

70 (PB-070) Poster

Exploring the predictive and prognostic significance of HER2 in HER2-negative early breast cancer

M. Corianò[1,2], N.M.L. Battisti[3], H. Aziz[4], N. Joharatnam Hogan[4], F. Turkes[3], N. Cunningham[3], J. Needham[4], M. Sun[5], J. Waterhouse[3], C. Tommasi[1,2], A. Musolino[1,2], A. Ring[3]. *[1]Azienda Ospedaliero-Universitaria di Parma, Medicine and Surgery - Breast Unit, Parma, Italy; [2]Gruppo Oncologico Italiano di Ricerca Clinica, Medicine, Parma, Italy; [3]The Royal Marsden NHS Foundation Trust, Breast Unit - Department of Medicine, London, United Kingdom; [4]The Royal Marsden NHS Foundation Trust, Department of Medicine, London, United Kingdom; [5]University College London, Medicine, London, United Kingdom*

Background: Breast cancer (BC) is a global health concern with significant outcome variation across different subtypes and populations. Pathological complete response (pCR) after neoadjuvant chemotherapy (NACT) for early BC (eBC) is a prognostic factor for relapse-free survival (RFS) and overall survival (OS). Despite recent therapeutic developments for eBC, a significant proportion of patients still does not achieve pCR, and the emergence of "HER2-low" BC as a new disease subtype may provide additional opportunities to improve treatment outcomes. In this study we evaluated the correlation of HER2-low status with pathological complete response (pCR) and prognosis.

Material and Methods: We retrospectively evaluated 754 patients with stage I-III HER2-negative BC, treated at The Royal Marsden NHS Foundation Trust, London, between 2013 and 2023. Patients were classified based on estrogen receptor (ER) status and further stratified into HER2-low and HER2-zero subgroups. HER2-low status was defined as HER2 1+ on immunohistochemistry (IHC) or 2+ on IHC without in situ hybridization gene amplification. We analyzed pCR rates, relapse-free survival (RFS), and overall survival (OS) to investigate the implications of HER2 status in these distinct subgroups.

Results: Median follow-up time was 45.6 (interquartile range 13.7–70.4) months. The mean age of the overall population was 49.4 ± 11.0 years. pCR rate was 8.9% in the ER-positive/HER2-low, 16.5% in the ER-positive/HER2-zero, 38.9% in the ER-negative/HER2-low and 35.9% in the ER-negative/HER2-zero eBC ($p < 0.001$).

Multivariable Cox-regression model showed a significantly lower pCR rate in HER2-low compared to HER2-zero BC in the ER-positive subgroup (OR 0.49 [95% CI, 0.24–0.95], $p = 0.038$). Furthermore, our results emphasize the potential prognostic role of HER2-low status, with longer OS observed in HER2-low compared to HER2-zero patients in the overall (HR 0.64 [0.44–0.93], $p = 0.018$) and in the ER-positive population (HR 0.56, [95% CI, 0.33–0.93] $p = 0.022$). We did not find any impact of HER2-low status on pCR, RFS or on OS in the ER-negative population.

Conclusions: The dynamic nature of HER2 expression, coupled with ongoing debates about the predictive and prognostic significance of HER2-low, underscore the complex biology of HER2-negative BC. This study highlights the need for further exploration to clarify the role of HER2-low status and its implications on treatment strategies, ultimately aiming to improve the outcomes of patients with HER2-negative eBC.

Conflict of interest:

Advisory Board: N. Battisti: Pfizer, Abbott, Sanofi, Astellas.

Other Substantive Relationships: A. Ring: Honoraria for consultancy and talks: Novartis, AstraZeneca, Roche, Pfizer, Lilly, Gilead, Daiichi-Sankyo, Seagen, Stemline, MSD and Zuellig-Pharma.

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71 (PB-071) Poster

Zoledronic acid in combination with standard neoadjuvant anthracycline and taxane-based chemotherapy regimen in patients with early and locally advanced triple-negative breast cancer – A single-arm open-label phase II study (ZACT)

B. Dubashi[1], D. Bala[2], A. Hegde[2], Y. Nisha[2], S. Dahagama[2], N. Krishnamoorthi[2], T. Nakka[2], P. Ganesan[2], S. Kayal[2], P. Ch Toi[3], K. Dharanipragada[4]. *[1]Professor, Department of Medical Oncology, Puducherry, India; [2]Jawaharlal Institute of Postgraduate Medical Education & Research, Department of Medical Oncology, Puducherry, India; [3]Jawaharlal Institute of Postgraduate Medical Education & Research, Department of Pathology, Puducherry, India; [4]Jawaharlal Institute of Postgraduate Medical Education & Research, Department of General Surgery, Puducherry, India*

Background: There is large preclinical evidence suggesting that bisphosphonates promote apoptosis, inhibit cell adhesion and prevent metastasis. The therapeutic impact of bisphosphonates on tumor growth remains a topic of ongoing discussion and debate. The objective of this study was to see the efficacy of zoledronic acid in combination with neoadjuvant chemotherapy in women with early and locally advanced triple negative breast cancer.

Methods: This was an open label phase II study of Zoledronic acid 4 mg administered on day 2 of each cycle of neoadjuvant chemotherapy with FEC 100 × 3 cycles followed by Docetaxel 75 × 4 cycles once every week in triple-negative breast cancer patients. The study was conducted from 21st August 2019 to 30th July 2022 at a tertiary cancer center in India. The primary endpoint was pathological complete response (pCR), while Disease-free survival (DFS) and Overall survival (OS) were secondary endpoints. The sample size was calculated by Flemming's two-stage design assuming a difference in pCR rate to be 12%, an increase from 30% to 42% at 80% power and alpha error of 0.05, one-sided significance, the total number of patients to be recruited n = 117, with n1 = 52 (for stage 1 analysis). If the response was less than 16 (a1) or 23 (b1) then the study would be discontinued for futility or have proven efficacy respectively.

Results: A total of 95 patients were screened of which fifty- two were enrolled in the study with median age of 50 (44–55) years. Early and locally advanced breast cancer was seen in 3 (5.7%) and 49 (94%) respectively. The primary endpoint pCR (ypT0) was seen in 11 (21%) patients. 90% of the patients completed seven doses of ZA. Patients tolerated ZA with chemotherapy reasonably well with minimal toxicity.

Characteristics	N = 52
Menopausal status: Pre Post	16 (30.8) 36 (69.2)
Grade: 1 2 3	4 (7.6) 18 (34.61) 30 (57)
Stage: Pretreatment cT(tumor) T1-2 T3 T4 T4b	9 (17.30) 26 (50) 4 (7.6) 13 (25)
cN(nodal status) N0 N1 N2 N3	5 (9.6) 29 (55.8) 14 (26.9) 4 (7.6)
Time to surgery: (median in weeks)	6.1(4.0–8.0)
Type of surgery: MRM BCS	44 (84.61) 8(15.38)
Zolendronic acid related Adverse effects (Any grade) Infusion reaction Watery eyes Jaw necrosis	1 1 1

Conclusion: The addition of Zoledronic acid (ZA) to neoadjuvant chemotherapy failed to show an improvement in pathological complete response in a well-selected triple negative breast cancer population.

No conflict of interest.

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72 (PB-072) Poster

Exploring locoregional outcome reporting in neoadjuvant systemic anticancer therapy breast cancer studies: A systematic review

M. Jiang[1], S. McIntosh[2], S. Potter[1]. *PRECEDENT Steering Group,* *[1]University of Bristol, Bristol Population Health Science Institute, Bristol, United Kingdom; [2]Queen's University Belfast, Patrick G Johnston Centre for Cancer Research, Belfast, United Kingdom*

Background: Neoadjuvant systemic anticancer therapy (neoSACT) has several advantages for patients with breast cancer, including the ability to tailor adjuvant therapies based on treatment response and to offer response adjusted surgery, improving outcomes and reducing morbidity.

Accurate information about locoregional treatments after neoSACT, however, is vital to support surgical decision-making and allow meaningful interpretation of long-term oncological outcomes such as locoregional recurrence. Issues related to the quality of locoregional treatment reporting in neoSACT studies have recently been highlighted. The aim of this systematic review was to explore the current quality of outcome reporting so that it can be improved.

Methods: A systematic search of PubMed identified primary research studies published in English between 01/01/2018 and 08/09/2023 reporting outcomes in patients receiving neoSACT of any modality for breast cancer with curative intent followed by locoregional treatment. Included were randomised controlled trials (RCTs) and non-randomised studies (NRS) with >250 participants reporting at least one outcome related to the locoregional treatment received. Outcomes were extracted verbatim and categorised using content analysis. Descriptive statistics were used to summarise results.

Results: Of the 3,111 abstracts screened, 138 studies (22 RCTs and 116 NRS) reporting at least one locoregional outcome in 575,639 patients who had received neoSACT were included.

A total of 516 surgical outcomes were extracted. The median number of surgical outcomes per study was 3 (range 1–12). No single outcome was reported in all 138 studies. Type of breast (n = 130, 94.2%) and axillary (n = 87, 63.0%) surgery were reported most frequently. Only 34% (n = 47) reported how response was assessed following treatment, with fewer studies reporting how this informed surgical decision-making. Information regarding surgical downstaging such as the number of patients downstaged from mastectomy to breast conserving surgery following neoSACT was only reported in 28 (20.3%) studies. Downstaging was inconsistently described with 59 different outcomes identified.

Only half of studies (n = 70, 50.7%) reported any radiotherapy-related outcome. Target volume (n = 47, 67.1%) and indication (n = 34, 48.6%) were the most commonly reported with fewer studies reporting dose/fractionation (n = 26, 37.1%) or technique (n = 10, 14.3%).

Conclusions: Current reporting of locoregional treatment outcomes in neoSACT studies is poor, inconsistent and urgently needs to be improved. The BIG-NCTN PRECEDENT project aims to develop a core outcome set and reporting guidelines that will standardise outcome reporting and improve the quality and value of future research.

Conflict of interest:

Advisory Board: Professor Stuart McIntosh reports advisory boards for MSD, Lilly, and Novartis.

Corporate-sponsored Research: Professor Stuart McIntosh reports institutional research funding from Novartis.

Other Substantive Relationships: Professor Stuart McIntosh reports speaker honoraria from MSD, Roche, BD, Lilly, Novartis and Astra Zeneca, and conference travel and support from Roche, Lilly and MSD.

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73 (PB-073) Poster

Integrative predictive machine-learning based modelling for pathological complete response to neoadjuvant chemotherapy in breast cancer: A comprehensive analysis of breast microbiota, imaging, and clinical features

R. De Sanctis[1], C. Pozzi[2], L. Antunovic[3], C. Miggiano[1], P. Tiberio[4], R. Sarti[1], D. Braga[2], M. Lizier[2], F. Jacobs[1], M. Gaudio[1], R. Torrisi[4], A. Zambelli[1], A. Santoro[1], M. Rescigno[1]. *[1]Humanitas University, Department of Biomedical Sciences, Pieve Emanuele Milan, Italy; [2]IRCCS Humanitas Research Hospital, Laboratory of Mucosal immunology and Microbiota, Rozzano Milan, Italy; [3]IRCCS San Raffaele Scientific Institute, Nuclear Medicine Department, Milan, Italy; [4]IRCCS Humanitas Research Hospital, Medical Oncology and Hematology Unit, Rozzano Milan, Italy*

Background: Response to neoadjuvant chemotherapy (NAC) in breast cancer (BC) involves a complex tumor-host interaction. As a relevant part of the tumor microenvironment, we focused on breast microbiota and on quantification of disease heterogeneity through advanced imaging features extracted from staging [18]F-FDG PET/CT scan. This prospective observational study aims to develop a translational predictive model for pathological complete response (pCR).

Materials and Methods: BC patients eligible for NAC were enrolled between August 2019 and September 2022. All patients received anthracycline-based (doxorubicin and cyclophosphamide) followed by taxane-based NAC (weekly carboplatin plus paclitaxel in triple-negative, docetaxel plus trastuzumab in HER2+, and docetaxel alone in luminal-like BC). The study was approved by the IRCCS Humanitas Research Hospital Ethics Committee (ONC/OSS-02/2019). Before starting NAC, a staging [18]F-FDG PET/CT scan was performed, and fresh BC tissue was collected for microbiota analysis. Patients underwent genetic counselling according to international guideline criteria. We analysed the association of pCR with clinical-pathological characteristics, tissue microbiota, genetic information, and imaging features from [18]F-FDG PET/CT scan. Features were selected using least absolute shrinkage selection operator (LASSO) regression, then a logistic regression machine learning (ML) model was employed. Model performance was evaluated using the receiver operating characteristic (ROC) and calculating the area under curve (AUC).

Results: Among 105 BC patients (52.4% HER2+, 38.1% triple-negative, and 9.5% luminal-like), 46.7% achieved pCR. Of all patients, 14.3% had germline pathogenic variants (GPVs) predisposing for BC; of these, 73% had pCR ($p = 0.05$). *Corynebacterium* was significantly present in the baseline breast biopsy of patients not achieving pCR (62.5% with residual disease vs. 36.7% with pCR; $p = 0.01$). Three radiomic features extracted from staging [18]F-FDG PET/CT were associated with response to NAC: Intensity Histogram Variance SUV (Standardized Uptake Value), GLCM (Gray Level Co-occurrence Matrix) Cluster Shade, and NGTDM (Neighborhood Gray-Tone Difference Matrix) Busyness. The integrated ML model combining pre-treatment microbiota characterization and [18]F-FDG PET/CT radiomic features of the breast lesion, and GPVs presented an AUC of 0.79 ± 0.09 in predicting pCR.

Conclusion: This study introduces a novel and comprehensive model for predicting pCR to NAC. By integrating breast microbiota, [18]F-FDG PET/CT radiomic characteristics, and GPVs, the model offers valuable insights into tumor-host interactions. Ongoing recruitment for external validation of this model holds the potential to significantly enhance pre-treatment patient stratification, offering personalized (de)escalation strategies to improve patient outcome.

Conflict of interest:

Advisory Board:

Armando Santoro: Bristol-Myers Squibb (BMS), Servier, Gilead, Pfizer, Eisai, Bayer, Merck Sharp & Dohme (MSD).

Rita De Sanctis: Novartis, Istituto Clinico Gentili, Amgen, EISAI, Lilly and Gilead.

Other Substantive Relationships:

Armando Santoro: consultancy for Arqule, Sanofi, Incyte. Speaker's Bureau: Takeda, BMS, Roche, Abb-Vie, Amgen, Celgene, Servier, Gilead, Astrazeneca, Pfizer, Arqule, Lilly, Sandoz, Eisai, Novartis, Bayer, MSD.

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Maria Rescigno is founder and chief scientific officer of Postbiotica S.r.l.

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74 (PB-074) Poster

Surgical treatment outcomes and prognosis in HER2+ invasive breast cancer patients with a DCIS component treated with neoadjuvant systemic therapy

R. Ploumen[1,2], E.L. Claassens[1], L.F.S. Kooreman[2,3], K.B.M.I. Keymeulen[1], M.A.C.E. van Kats[4], S.M.J. van Kuijk[5], S. Siesling[6,7], T.J.A. van Nijnatten[2,8], M.L. Smidt[1,2]. *[1]Maastricht University Medical Centre+, Department of Surgery, Maastricht, Netherlands; [2]GROW, School for Oncology and Reproduction, Maastricht, Netherlands; [3]Maastricht University Medical Centre+, Department of Pathology, Maastricht, Netherlands; [4]Maastricht University Medical Centre+, Department of Medical Oncology, Maastricht, Netherlands; [5]Maastricht University Medical Centre+, Department of Clinical Epidemiology and Medical Technology Assessment, Maastricht, Netherlands; [6]University of Twente, Department of Health Technology and Services Research, Technical Medical Centre, Enschede, Netherlands; [7]Netherlands Comprehensive Cancer Organisation, Department of Research and Development, Utrecht, Netherlands; [8]Maastricht University Medical Centre+, Department of Radiology and Nuclear Medicine, Maastricht, Netherlands*

Background: In up to 72% of HER2+ invasive breast cancer (IBC), a ductal carcinoma in situ (DCIS) component is present. The presence of DCIS is associated with increased positive surgical margins in both primary surgery and after neoadjuvant systemic therapy (NST). Therefore, patients with a DCIS component are more often treated with mastectomy. Recent studies show a complete response of DCIS to NST in 50% of HER2+ IBC patients. The aim of this study was to assess surgical treatment in a nationwide cohort of HER2+ IBC patients with versus without a DCIS component treated with NST. Subsequently, in patients treated with breast-conserving surgery (BCS), the rate of positive surgical margins, locoregional recurrence free survival (LRFS) and overall survival (OS) were compared between IBC +DCIS and IBC only.

Materials and Methods: Women diagnosed with HER2+ IBC treated with NST, between 2010–2020, were selected from the Netherlands Cancer Registry and linked to the Dutch Nationwide Pathology Databank for reassessment of pathology reports. Multivariable logistic regression analysis was used to assess for characteristics associated with mastectomy. In patients treated with BCS, surgical margins were assessed based on "no ink on tumor" for both invasive and in situ disease. Locoregional recurrence was defined as a recurrence (in situ/invasive) in the ipsilateral breast and/or regional lymph nodes after primary treatment. Kaplan-Meier and Cox regression analyses were performed to determine LRFS and OS and associated clinicopathological variables. Surgical margins and prognosis were compared between IBC+DCIS and IBC only.

Results: A total of 5307 HER2+ IBC patients were included: 3056 (57.6%) primarily treated with BCS and 2251 (42.4%) with mastectomy. The presence of DCIS was independently associated with a higher rate of mastectomy (OR 1.589, $p < 0.001$). In 3056 patients treated with BCS, 1832 (59.9%) had IBC only and 1224 (40.1%) IBC+DCIS. Patients with IBC+DCIS had significantly more often positive surgical margins compared to IBC (12.8% vs. 4.9%, $p < 0.001$). Five-year LRFS was significantly lower in IBC+DCIS compared to IBC (89.0% vs. 92.8%, $p < 0.001$) in Kaplan-Meier analysis. In multivariable Cox regression analyses, cT3-4, cN+, ypT+ and ypN+ were independently associated with worse 5-year LRFS, but not the presence of DCIS. Five-year OS did not differ between IBC and IBC+DCIS (95.7% vs. 94.9%, $p = 0.293$).

Conclusion: In this nationwide cohort of HER2+ IBC patients treated with NST, patients with IBC+DCIS were significantly more often treated with mastectomy. When treated with BCS, a significantly higher rate of positive surgical margins was found compared to patients with IBC only. The presence of DCIS was not associated with lower LRFS and OS when adjusted for confounders. Further research is necessary to adequately select IBC+DCIS patients for BCS after NST.

No conflict of interest.

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75 (PB-075) Poster

Prediction of response to neoadjuvant chemotherapy in HER2 positive breast cancer by MammaTyper®

C. Scatena[1], E. Belcastro[1], R. Scarpitta[1], A.G. Naccarato[1]. *[1]University of Pisa, Department of Translational Research and New Technologies in Medicine and Surgery, Pisa, Italy*

Background: Neoadjuvant therapy has become the standard of care for HER2-positive breast cancer (BC). However, only half of the patients achieve a pathological complete response (pCR). Our study aims to test the CE/IVD MammaTyper® kit (Cerca Biotech) as a predictor of response to neoadjuvant chemotherapy (NACT).

Materials and Methods: Fifty-three HER2-positive/3+ IHC-score invasive BC patients undergoing NACT were enrolled. The study was approved by the local Ethical Committee and written consent was obtained from each participant. Four patients were excluded due to insufficient amount of RNA required for analysis, therefore a total of 49 FFPE preoperatory biopsies samples were selected and tested. Of these, 25 were hormone-positive (HR+) and 24 hormone-negative (HR-), 33 obtained a pCR and 16 a pathological partial response (pPR). MammaTyper®, a molecular *in vitro* diagnostic RT-qPCR test, was used to assess the relative mRNA expression levels of ERBB2 (HER2), ESR1 (ER), PGR (PgR) and MKI67 (Ki67) genes. A machine-learning, Python-based Decision Tree Algorithm was used to predict pCR from the $\Delta\Delta$Cq values of ERBB2, ESR1, PGR, and MKI67. Samples were divided based on hormone receptors (ER and/or PgR) status from MammaTyper®. Focusing on a balance of interpretability and generalizability, we tuned key hyperparameters and used GridSearchCV with 5-fold cross-validation. Analytical accuracy was analyzed in terms of sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV).

Results: Of the Decision Trees generated, two were selected showing high specificity and sensitivity, and plausible biomarkers hierarchy. In detail, the selected tree for HR+ tumors had a sensitivity of 94%, a specificity of 83%, a PPV of 94% and a NPV of 83%; instead, that for HR- tumors had a sensitivity of 94%, a specificity of 86%, a PPV of 94% and a NPV of 86%.

Conclusions: MammaTyper® could discriminate patients with HER2-positive BC who will achieve pCR from those who will not, representing a powerful decision tool in terms of escalation/de-escalation treatment approaches. However, these promising and preliminary data need to be confirmed on a larger cohort of patients.

Funding: Research Project "Tuscany Health Ecosystem" Ecosistema dell'innovazione sulle scienze e le tecnologie della vita in Toscana (THE) - Spoke 6: Precision Medicine & Personalized Healthcare - Advanced biomarkers for patient stratification. CUP I53C22000780001.

No conflict of interest.

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77 (PB-077) Poster

Significance of Ki-67 level after neoadjuvant systemic therapy in HR-positive, HER2-positive breast cancer

S.J. Bae[1], S. Moon[2], Y. Kook[2], S.H. Baek[2], M.J. Lee[2], J.H. Kim[3], S.G. Ahn[2], J. Jeong[2]. *[1]Gangnam Severance Hospital, Yonsei University College of Medicine, Surgery, Seoul, South Korea; [2]Gangnam Severance Hospital, Surgery, Seoul, South Korea; [3]Gangnam Severance Hospital, Internal Medicine, Seoul, South Korea*

Background: Recent studies have highlighted the prognostic significance of changes in Ki-67 during the neoadjuvant systemic therapy (NAST) for hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer. While pathologic complete response (pCR) also serves as a valuable prognostic marker for HR+HER2+ breast cancer, its relevance is comparatively lower than in HR-HER2+ breast cancer. This study aimed to explore the potential of post-NAST Ki-67 level, in addition to pCR, in predicting survival outcomes for HR+HER2+ breast cancer.

Methods: We identified 187 patients with HR+HER2+ breast cancer who underwent NAST followed by curative surgery between January 2007 and December 2022. We defined a pCR as no evidence of invasive cancer residue in the breast and all axillary lymph nodes (ypT0/is, ypN0). Post-NAST Ki-67 level was assessed in the residual invasive tumor after NAST. Patients achieving either pCR or a post-NAST Ki-67 level below 2.7% were categorized into the excellent pathologic response group.

Results: Of 187 patients, 84 (50.9%) achieved a pCR, and 39 (14.9%) had a post-NAST Ki-67 level below 2.7%. Consequently, 123 (65.8%) patients comprised the excellent response group. During the median follow-up of 47 months (range 5–191 months), the pCR group exhibited a trend toward better recurrence-free survival (RFS) than the non-pCR group, though not statistically significant. Meanwhile, the excellent pathologic response group had a significantly favorable RFS compared to the non-excellent pathologic response group (4-year RFS; 97.9% vs. 91.2%; log-rank $P = 0.016$). Multivariable analysis revealed a significant association between the excellent pathologic response group and adverse RFS (adjusted HR 0.18; 95% CI, 0.04–0.87; $P = 0.033$). Notably, among the patients with residual

invasive disease, those achieving a Ki-67 level below 2.7% experienced no recurrence.

Conclusions: In patients with HR+HER2+ breast cancer, approximately 65% demonstrated an excellent pathologic response to NAST, and this specific subgroup exhibited a favorable prognosis. Our findings suggest that incorporating post-NAST Ki-67 level to pCR enhances the predictive value for clinical outcomes in HR+HER2+ breast cancer.

No conflict of interest.

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78 (PB-078) Poster

Prognostic factors for cancer-specific survival in pCR patients with triple-negative breast cancer after neoadjuvant therapy: a SEER-based retrospective study

W. Lv[1], P. Wu[1]. *[1]Xinhua Hospital Affiliated to Shanghai Jiao Tong University School of Medicine, Department of Breast Surgery, Shanghai, China*

Background: Current guidelines recommend no further adjuvant therapy for triple-negative breast cancer (TNBC) patients who achieve pathological complete remission (pCR) after neoadjuvant therapy, as they have a favorable prognosis. However, some pCR patients still experience poor cancer-specific survival, indicating the need to identify prognostic factors.

Material and Methods: We selected TNBC patients with pCR after neoadjuvant therapy from the SEER database (2010–2015) and examined the association of clinicopathological features with cancer-specific survival. We aimed to identify prognostic factors for poor outcomes in this subgroup of TNBC patients.

Results: Of 1237 TNBC patients without distant metastases who achieved pCR after neoadjuvant therapy, the 5-year cancer-specific survival rate was 91.7%. We used age (≥40 or <40 years), TNM stage (AJCC 7th edition), and lymph node metastasis as covariates in a multivariate COX proportional hazards model. The results showed no significant difference in survival between stage II and stage I patients (HR = 0.920, 95%CI 0.433–1.952, P = 0.828), but a significant difference between stage III and stage I patients (HR = 2.512, 95%CI 1.090–5.790, P = 0.031). Lymph node metastasis was also a significant predictor of survival (HR = 1.881, 95%CI 1.150–3.077, P = 0.012), while age was not (HR = 1.056, 95%CI 0.643–1.733, P = 0.829).

Conclusions: Age is not a prognostic factor for TNBC patients with pCR. Stage III or lymph node metastasis patients may require further adjuvant therapy after pCR to improve their outcomes. The optimal type of adjuvant therapy needs to be verified by future prospective clinical trials.

No conflict of interest.

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79 (PB-079) Poster

Effect of oral Vitamin D supplementation on response to neoadjuvant chemotherapy in patients with locally advanced breast cancer

S. Gupta[1], S. Singh[2], A. Ghosh[3], S.K. Singh[4]. *[1]Institute of Medical Sciences- BHU, General Surgery, Varanasi, India; [2]Institute of Medical Sciences- BHU, Surgery, Varanasi, India; [3]Institute of Medical Sciences- BHU, Pathology, Varanasi, India; [4]Institute of Medical Sciences- BHU, Endocrinology, Varanasi, India*

Introduction: Vitamin D is believed to play an anti-proliferative and pro-apoptotic role by increasing chemotherapy induced cell death in breast cancer cell lines and animal models. The aim of this study was to evaluate whether vitamin D levels correlate with response to NACT in patients with locally advanced breast cancer (LABC).

Materials and Methods: Thirty patients with newly diagnosed locally advanced breast cancer (LABC) were included in the study. Patients were allocated into Group I who did not receive oral Vitamin D supplementation and Group II who received oral Vitamin D 600000 IU /weekly and 500 mg daily oral calcium for 5 weeks. All patients received 3 cycles of neoadjuvant chemotherapy (NACT) followed by modified radical mastectomy (MRM). Serum Vitamin D levels were measured before 1st cycle and before and after 3rd cycle of NACT. Tumour response was assessed two weeks after third cycle.

Results: Baseline vitamin D levels were low in all patients (Group I- 28.34 ng/ml, Group II - 24.38 ng/ml). Amongst the 15 patients in Group I, 12 patients had partial response while 3 patients had stable disease. In Group II, all 15 patients showed partial response. The mean serum Vitamin D levels were higher before the 3rd cycle of chemotherapy as compared to the pre-treatment levels in patients who showed partial response (30.58 ng/ml vs 26.13 ng/ml) (p = 0.017). However in patients who did not respond to chemotherapy (those with stable disease), the Vitamin D levels before the 3rd cycle of chemotherapy were lower than the pre-treatment levels (24.00 ng/ml vs 28.40 ng/ml) (p = 0.072).

Conclusions: There is poor response to neoadjuvant chemotherapy in locally advanced breast cancer patients who have low vitamin D levels initially. Oral Vitamin D supplementation appears to improve the response to neoadjuvant chemotherapy.

No conflict of interest.

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80 (PB-080) Poster

The impact of the gut microbiota on neoadjuvant chemotherapy for breast cancer: the Setouchi Breast Project-14

Y. Kajiwara[1], S. Nakamoto[2], A. Hida[3], K. Taniguchi[4], Y. Miyoshi[5], T. Kin[1], M. Yamamoto[6], D. Takabatake[7], S. Kubo[6], T. Shien[2], H. Hikino[8], Y. Ogasawara[9], C. Kuwahara[6], T. Yamashita[6], M. Kochi[5], M. Ikeda[6], H. Doihara[10], N. Taira[11], T. Iwamoto[11]. *Setouchi Breast Project Comprehensive Support Organization, [1]Hiroshima City Hiroshima Citizens Hospital, Breast Surgery, Hiroshima, Japan; [2]Okayama University Hospital, Breast and Endocrine Surgery, Okayama, Japan; [3]Matsuyama Shimin Hospital, Diagnostic Pathology, Matsuyama, Japan; [4]Hiroshima City Hiroshima Citizens Hospital, Diagnostic Pathology, Hiroshima, Japan; [5]Shikoku Cancer Center, Breast Oncology, Matsuyama, Japan; [6]Fukuyama Citizens Hospital, Breast and Thyroid Surgery, Fukuyama, Japan; [7]Kochi Health Science Center, Breast and Thyroid Surgery, Kochi, Japan; [8]Matsue Red Cross General Hospital, Breast Surgery, Matsue, Japan; [9]Kagawa Prefectural Center Hospital, Breast Endocrine Surgery, Takamatsu, Japan; [10]Kawasaki Medical School General Medical Center, Surgery, Okayama, Japan; [11]Kawasaki Medical School Hospital, Breast and Thyroid Surgery, Kurashiki, Japan*

Background: It has reported that the gut microbiota modulates the host immune system and may influence the efficacy of anti-cancer treatment. To elucidate the associations between gut microbiota and the efficacy of neoadjuvant chemotherapy (NAC), we conducted a multicenter prospective cohort study on breast cancer.

Material and Methods: Between October 2019 and March 2022, 197 patients were registered and received NAC as part of the Setouchi Breast Project-14 at eight institutions in Japan. All patients underwent standard therapies based on the Japanese Breast Cancer Society Clinical Practice Guidelines. Among 197 patients, 183 were available for final analysis. Fecal samples were collected prior to NAC, and metagenomic DNA was extracted. The bacterial community structure was determined by sequencing variable regions 3 (V3) and 4 (V4) of the 16S rRNA gene on the MiSeq Illumina technology platform. We investigated the associations between gut microbiota and pathological complete response (pCR) after NAC.

Results: All patients were female, with a median age of 52 years (25–77). Seventy cases (38%) were hormone receptor (HR)-positive/ human epidermal growth factor-2 (HER2)-negative, 59 (32%) were HER2-positive, and 54 (30%) were triple negative (TN). The pCR rate was 36% for all patients, 14% for HR-positive/HER2-negative, 62% for HER2-positive, and 24% for TN. α-diversity and β-diversity analysis showed no significant differences between the pCR and residual disease groups. A class comparison test between the efficacy of NAC and bacterial composition showed three bacteria (Victicallales: $p = 0.001$, Anaerolineales: $p = 0.001$, and Gemellales: $p = 0.002$) with significant associations.

Conclusions: Some bacterial composition demonstrated associations with the efficacy of NAC, although no diversity in gut microbiota was observed. Further studies are required to validate our findings.

No conflict of interest.

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81 (PB-081) Poster

Impact of anthracyclines use on pathological complete response to neoadjuvant treatment in HER2-positive breast cancer

C. Teixeira[1], M. Gonçalves[1], A.C. Valente[1], J. Reis[1], N. Tavares[1], I. Augusto[1], I. Sousa[1], D. Almeida[1], M.J. Ribeiro[1], M. Barbosa[1]. *[1]Centro Hospitalar Universitário São João, Medical Oncology, Porto, Portugal*

Background: The optimal chemotherapy regimen in the neoadjuvant setting for HER2-positive breast cancer (BC) is yet to be established. We intended to evaluate whether the use of anthracyclines (AC) would improve the pathological complete response (PCR) compared with a carboplatin-taxane (CT) regimen in our sample.

Material and Methods: Retrospective study of women with early HER2-positive BC from January/2018 to June/2023 who completed neoadjuvant treatment (NAT) with AC or CT based regimens. The primary endpoint was PCR. Survival analysis was performed using the Kaplan-Meier method and the log-rank test. Univariate and multivariate analyses, of predictors of response, were carried out using the chi-square test, Fisher's exact test, and logistic regression model, respectively.

Results: A total of 117 women with a median age of 48 years [26–78] were included. Median follow-up (FU) was 27 months [7–68]. 73 patients (62.4%) received AC and 44 (37.6%) CT. The PCR was significantly higher in the CT group (68.2% vs. 48.6%; $p = 0.039$). 6 patients (5.1%) had less than 50% tumor regression, of those 4 underwent AC regimen. Univariate analysis revealed that tumors HER2 positive IHC 3+ and postmenopausal women had higher PCR compared to HER2 IHC 2+ (63.9% vs. 46.3%, $p < 0.001$) and premenopausal women (67.4 vs. 48.6%, $p = 0.046$). However, no differences were verified in the multivariate analysis. No significant differences were observed in the occurrence of all grade adverse events. However, the AC group had a higher incidence of febrile neutropenia (8.2% vs. 4.5%, p = 0.046). Moreover, the AC group had a significantly greater decline in left ventricular ejection fraction (LVEF) (mean difference: –2.13%; CI95% 0.01–4.24; p = 0.048). During the FU, 1 patient died (AC group) and 12 relapsed (12.3% in AC group vs. 6.8% in CT group, p = 0.531).

Conclusion: In our sample, AC-based chemotherapy in HER2-positive BC NAT was associated with worse responses. Although no relevant differences in occurrence of adverse events, AC regimen was associated with a higher number of febrile neutropenia and a greater decline in LVEF. These results should be interpreted with caution due to short follow-up. Larger prospective trials with longer FU will be needed to clarify the benefits of using AC in this setting.

No conflict of interest.

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POSTER SESSION **20 March 2024** **9.00–18.30**

Rehabilitation/Survivorship/Follow up

82 (PB-082) Poster

Exploring associations between cognitive-emotional factors and healthcare use in breast cancer survivors with pain: a cross-sectional study

E. Roose[1], A. Lahousse[1], W. Cools[2], L. Leysen[1], K. Mostaqim[1], P. van Wilgen[1], D. Beckwée[3], A. Timmermans[4], R. Bults[1], J. Nijs[1], M. van Hoeij[5], C. Fontaine[5], E. Huysmans[1]. *[1]Vrije Universiteit Brussel VUB, Pain in Motion research group, Jette, Belgium; [2]Vrije Universiteit Brussel VUB, Core facility - Support for Quantitative and Qualitative Research SQUARE, Jette, Belgium; [3]Vrije Universiteit Brussel VUB, Rehabilitation Research research group, Jette, Belgium; [4]Universiteit Hasselt UH, REVAL research group, Diepenbeek, Belgium; [5]University Hospital Brussels, Breast Clinic, Jette, Belgium*

Introduction: Pain is among the most prevalent (34%) side effects seen in breast cancer survivors. Cognitive-emotional factors (CEF) are known to play a role in the mechanism behind pain. Both, pain and CEF, are known dynamics behind healthcare use behavior. However, associations between CEF and healthcare use in breast cancer survivors with pain before are lacking and thus explored in this cross-sectional study.

Methods: Dutch speaking breast cancer survivors with pain were recruited in 4 hospitals in Belgium. Healthcare use was assessed by the Medical Consumption Questionnaire and further categorized into medication use (opioid, psychological medication, cancer-related hormonal medication and other medication use), consulting behavior (physiotherapist, psychologist, other primary healthcare providers and secondary healthcare providers) and hospital stays. CEF were assessed by the Injustice Experienced Questionnaire (IEQ), Pain Catastrophizing Scale (PSC), Pain Vigilance and Awareness Questionnaire (PVAQ), Brief Illness Questionnaire (IPQ-B) and the Depression Anxiety and Stress Scale (DASS-21). Total scores of all CEF outcome measures were used. In addition, demographics and pain phenotypes were inventoried. The association between healthcare use and CEF are examined by logistic regression for medication use and by Poisson regression for consulting behavior.

Results: In breast cancer survivors with pain (n = 122), opioid use is associated with the PCS and DASS-21. Psychological medication is only related to the DASS-21. No CEF are associated with hormonal medication and other types of medication use. The number of visits to a general practitioner is related to the IEQ and DASS-21. However, whether someone visit a general practitioner is not related to CEF. The number of physiotherapy visits is related to the DASS-21 and PCS. Only DASS-21 is important in whether someone visits a physiotherapist. The number of psychological visits is related to the IEQ, PCS and PVAQ. Whether someone visits the psychologist is related to the PVAQ and DASS-21. The number of visits to other primary healthcare providers is related to the IEQ, PCS, IPQ, and DASS-21. Whether someone visits other primary healthcare providers is related to the same CEF, except the IPQ. Lastly, secondary healthcare provider visits are related to the PVAQ and DASS-21. However, visiting a secondary healthcare provider is not related to any CEF. Unfortunately, hospital stays could not be analyzed due to the low prevalence.

Conclusion: CEF are related to different types of medication use and visiting behavior in breast cancer survivors with pain. The results give a preliminary basis of the mechanism behind healthcare use and give potential for the development of innovative psychological therapy approaches targeting CEF in order to decrease the socio-economic burden of breast cancer survivors with pain.

No conflict of interest.

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83 (PB-083) Poster

Effect of mobile phone app-based intervention on quality of life in breast cancer survivors: A randomized controlled study

M. Kaur[1], B. Yadav[1], D. Dahiya[2], S. Kaur[3], A. Sharma[4], S. Ghoshal[1]. *[1]Postgraduate Institute of Medical Education and Research, Radiotherapy & Oncology, Chandigarh, India; [2]Postgraduate Institute of Medical Education & Research, General Surgery, Chandigarh, India; [3]Postgraduate institute of medical education & research, National Institute of Nursing Education, Chandigarh, India; [4]Postgraduate Institute of Medical Education & Research, Psychiatry, Chandigarh, India*

Introduction: Patients after breast cancer treatment experience multiple physical and psychological problems which often affect their quality of life (QoL). One of the most crucial aspects of caring for cancer patients is the proper control of these symptoms, which require ample interdisciplinary care. Self-management and education are two strategies for empowering patients to adapt to their disease conditions and solve problems on their own. The purpose of this study was to find the effect of mobile app-based training on the QoL, fatigue, sexual dysfunction and arm edema in women with breast cancer after completion of cancer treatment.

Methods: Breast cancer patients, after 3 months of completion of their treatment were randomized to routine care or routine care plus access to the mobile phone app–based training support for 6 months. QoL and symptom distress were measured at baseline, at 3 months and at 6 months of intervention. The mobile app-based training also provided basic information about breast cancer, symptoms diary and lifestyle recommendations (adequate and balanced nutrition, regular physical activity, exercises). QoL was assessed using EORTC QLQ-30, BR-23 scale. Visual CTCAE scale was used to measure fatigue and vaginal dryness. LENT-SOMA scale was used to measure lymphedema. Per protocol as well as intension to treat analysis was performed. A two tailed p value <0.005 was considered statistically significant. The protocol was cleared by the institute ethics committee and it was registered in CTRI (clinical trial registry of India CTRI/2018/06/014638).

Results: Total 170 breast cancer survivors were randomized, 85 each in the control and app the group. Demographics and clinical profile of the participants were comparable in both the groups except per capita income, age at diagnosis and duration of completion of treatment. At baseline all health-related outcome parameters were comparable in both the groups. At 3 months follow up, quality of life score was better in the app group compared to the control group. No significant difference was seen in fatigue and vaginal dryness in any of the groups at 3 months. At 6 months, app group demonstrated statistically significant improvement in all functioning scale (except for role functioning). Median quality of life score was 100 (IQR 83–80) in the app group as compared to 66 (IQR: 58–100) in the control group ($p = 0.000$). At 6 months, fatigue, lymphedema and vaginal dryness improved significantly in the app group. About the app, 90% users quickly learned how to use the application and 93% said that they would definitely recommend this app to other patients.

Conclusions: Mobile application for breast cancer survivors was effective in improving the quality of life, fatigue, lymphedema and vaginal dryness. Mobile app is an effective intervention for supportive care in women with breast cancer.

No conflict of interest.

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84 (PB-084) Poster

Evaluation of breast skin/nipple-areolar complex sensation and quality of life after nipple-sparing mastectomy followed by reconstruction

B. Polita[1], J. Maksimenko[2], J. Lapiņš[3], A. Ģīlis[3], A. Irmejs[4], J. Gardovskis[5]. *[1]Riga Stradiņš University- Pauls Stradiņš Clinical University Hospital, Breast Oncology Surgery, Riga, Latvia; [2]Pauls Stradiņš Clinical University Hospital, Breast Oncology Surgery, Riga, Latvia; [3]Pauls Stradiņš Clinical University Hospital, Plastic Surgery, Riga, Latvia; [4]Pauls Stradiņš Clinical University Hospital, General Surgery, Riga, Latvia; [5]Pauls Stradiņš Clinical University Hospital, Surgery, Riga, Latvia*

Objective: It is commonly assumed that following a nipple-sparing mastectomy (NSM) with implant/expander reconstruction, the sensation of the breast skin and the nipple-areolar complex (NAC) is diminished or not regained at all.

The purpose of this study is to evaluate postoperative 1 month-1 year breast skin/NAC touch pressure sensibility after NSM followed by reconstruction with implant/expander and patients' quality of life (QoL) consequent to this procedure, hypothesizing that sensibility may diminish after the procedure with small progressive return.

Methods: This was achieved by performing sensation tests using Semmes-Weinstein monofilaments in 9 predefined points of the breast and NAC, 2-point discrimination test in the 4 quadrants of the breast, and QoL assessment using the BREAST-Q.

We have evaluated 41 patients in Pauls Stradiņš Clinical University Hospital, with a total of 65 breasts, who underwent NSM between 2021 and 2023, performing the breast sensation tests before surgery, 1/3/6 months, and 1 year after surgery.

Inclusion criteria involved patients that have undergone NSM followed by reconstruction with an implant or expander; nipple has not been excised; able to provide written consent; able to answer questionnaire; over the age of 18 years old. While exclusion criteria were: sensibility examination cannot be performed; different surgical technique other than nipple-sparing mastectomy; if nipple was excised; patient doesn't meet inclusion criteria.

Results: Our results reflect a decline in breast skin and NAC sensation in the 1 month evaluation after NSM (Mean: 4.74) when compared to the assessment before surgery (Mean: 2.44), with a small progressive return reflected in the 3 months (Mean: 4.08), 6 months Mean: 3.61), and 1 year evaluation. The following were the mean scores obtained from BREAST-Q: Psychosocial Well-being (Mean: 41, IQR: 38–49), Sexual Well-being (Mean: 19.79, IQR: 16–24), Satisfaction with Breasts Pre-OP (Mean: 12.21, IQR: 11–14), Satisfaction with breast reconstruction (Mean: 41.5, IQR: 38.5–50), Satisfaction with Implants (Mean: 5.5, IQR: 4.25–6.75), Satisfaction with nipple reconstruction (Mean: 2.94, IQR: 2.5–3.5), Physical Well-being Chest/Abdomen/Back and shoulder, Adverse effects of radiation, and Satisfaction with Information/Surgeon/Medical Team/Office Staff.

Conclusions: This study confirms that sensibility diminishes after this procedure, as observed when comparing the sensation evaluation results before the operation with the 1-month evaluation, with small progressive retum reflected in the following months. The obtained conclusions from the sensibility evaluation combined with the questionnaire, will contribute further insight and evidence, therefore providing information to the medical community that may facilitate the improvement of the observed results.

No conflict of interest.

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85 (PB-085) Poster

Prevalence of depression, anxiety and stress and its associated factors among women with breast cancer in Sri Lanka

U. Jayarajah[1], J. Mithushan[2], W.P.H. Priyan[2], K. Peiris[2], H. Wijayalathge[2], T. Wijeratne[3], S. Gunasekera[4], S. Seneviratne[2]. *[1]National Hospital of Sri Lanka, Department of Surgery, Colombo, Sri Lanka; [2]University of Colombo, Department of Surgery, Colombo, Sri Lanka; [3]Queen's University- Canada, Department of Internal Medicine, Ontario, Canada; [4]National Cancer Institute, Department of Oncology, Maharagama, Sri Lanka*

Background: A diagnosis of cancer is known to cause high levels of stress, anxiety, and depression. Despite the existence of numerous international studies that have demonstrated the presence of clinically diagnosable depression, anxiety, and stress in breast cancer patients, no such evidence or research has been conducted in the Sri Lankan context. We aimed to evaluate anxiety, stress and depression and their associated factors in a cohort of Sri Lankan women with breast cancer (BC).

Materials and Methods: A randomly selected 300 women with BC who are being followed up at Apeksha Hospital, Maharagama were included. Depression, anxiety, and stress levels were assessed using validated, translated versions of DASS-21(depression, anxiety, stress scale-21) and BDI (Beck depression inventory) questionnaires. Factors associated with anxiety, stress and depression were analysed using parametric tests. Ethics approval for this study was obtained from the Ethics Review Committee (EC-17–068) of the Faculty of Medicine, Colombo, Sri Lanka.

Results: The mean age was 53 ± 11 years and the mean follow-up duration was 22 ± 17.9 months. Most of the patients (60.3%, n = 181) had undergone mastectomy and chemotherapy and radiotherapy were received by 57.7% (n = 173) and 52.7% (n = 158) respectively. Based on BDI, 45.3% (n = 136) had some degree of depression while 17% (n = 51) had moderate-severe depression. Based on DASS-21, 34% (n = 102), 32.3% (n = 97) and 41% (n = 123) had some degree of depression, anxiety and stress, respectively while 27.3% (n = 82), 24% (n = 72) and 34.3% (n = 103) had moderate-severe depression, anxiety and stress, respectively. Women with advanced stages of cancer (stage III-IV) and who underwent mastectomy versus breast conservation had significantly greater risks of depression ($p < 0.01$). Women educated up to secondary or lower had a greater risk ($p = 0.007$) for both depression and stress. Follow-up duration, marital status, monthly income, breast surgery type, radiotherapy, and chemotherapy were not significantly associated with depression.

Conclusion: A high prevalence of depression, anxiety, and stress was observed in Sri Lankan women with BRC. Identifying women at greater risk and screening all women with BRC for depression, anxiety and stress may help identify these women early. Early recognition and treatment will likely reduce the additional 'psychological burden' and may improve their treatment compliance and quality of life.

No conflict of interest.

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86 (PB-086) Poster

Quality of life following completion of treatment among Sri Lankan women with breast cancer

U. Jayarajah[1], H. Wijayalathge[2], K. Peiris[2], T. Wijeratne[3], S. Gunasekera[4], S. Seneviratne[2]. *[1]National Hospital of Sri Lanka, Department of Surgery, Colombo, Sri Lanka; [2]University of Colombo, Department of Surgery, Colombo, Sri Lanka; [3]Queen's University, Department of Internal Medicine, Ontario, Canada; [4]National Cancer Institute, Department of Oncology, Maharagama, Sri Lanka*

Background: Quality of life (QOL) of women with breast cancer is known to be affected by the disease itself and treatment. Being a developing country with contrasting social and cultural norms to the West, Sri Lankan women

may have a different experience on QOL following surgical treatment of breast cancer. This study was conducted to assess post-treatment QOL in women with breast cancer in Sri Lanka.

Materials and Methods: QOL was assessed among a randomly selected sample of 221 women with breast cancer undergoing follow-up at Apeksha Hospital, Maharagama. QOL was assessed using validated EORTC QLQ-C30 and QLQ-BR23 questionnaires. Non-parametric tests were used for statistical analyses. Ethics approval was obtained from the Ethics Review Committee of the Faculty of Medicine, University of Colombo, Sri Lanka (EC-17–126). All patients gave informed written consent before participating in this study.

Results: Mean age was 57.6 years (SD = 11.5). Mean follow-up duration was 31.5 months (SD = 18.6).

Mean global health score was 62.6. (SD = 23.4) Mean scores (greater scores better functioning) of physical functions, role function, emotional function, cognitive function, and social function were 70.7, 76.1, 79.8, 82.3 and 88.0, respectively. Mean scores for body image, sexual functioning, sexual enjoyment, and future perspective assessed in QLQ-BR-23 were 82.2, 14.8, 19.3 and 75.5 respectively.

Mean symptom scores (greater scores more symptomatic) for fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhoea, and financial difficulties were 32.9, 10.1, 33.9, 13.4, 27.9, 22.6, 16.9, 5.6 and 33.0, respectively. Side effects, breast symptoms, arm symptoms and upset by hair loss assessed in QLQ-BR-23 were 22.3, 16.7, 27.3 and 24.4, respectively.

No significant association was noted between functional or symptom scores with the type of surgery (i.e., mastectomy vs. breast conservation) in QLQ-C30 or QLQ-BR23 ($p > 0.05$).

Conclusions: Although the general QOL was found to be satisfactory, substantially poor QOLs were observed in areas of sexual functioning and sexual enjoyment. Severity of symptoms is minimal except fatigue and financial difficulties among patients on follow-up. Type of surgery did not appear to be associated with QOL. Measures should be implemented to help women with breast related symptoms especially sexual, arm and hair loss related symptoms which contribute significantly to poor QOL following surgery.

No conflict of interest.

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88 (PB-088) Poster

A multidisciplinary approach to the enhancement of quality of life of breast cancer patients in the South-west, Nigeria

B.O. Adebayo-Oke[1], C.C. Asuzu[2]. *[1]University of Ibadan, Nigeria, Counselling and Human Development Studies, Ibadan, Nigeria; [2]University of Ibadan, Counselling and Human Development Studies, Ibadan, Nigeria*

The primary clinical goal of healthcare in chronic health conditions and terminal diseases, such as breast cancer, is the enhancement and maintenance of quality of life and the control of symptoms. Despite the increase in breast cancer incidence and mortality rate worldwide, appreciable figure of breast cancer survivors and overall survival still exist with early diagnosis and treatment commencement. Therefore, paying close attention to the enhancement of survivors' quality of life becomes imperative, as the disease and its treatment short- and long-term side effect can pose negative impact on the survivors' quality of life. However, there is paucity of literature on experimental studies focusing on the use of multidisciplinary-based therapeutic interventions such as Cognitive behavioral therapy (CBT) and Nutritional counselling (NC) in enhancing the Quality of life (QoL) of breast cancer patients as globally campaigned for. The study assessed the effect of CBT and NC on the QoL of breast cancer patients in the South-west, Nigeria.

The study was anchored to the Bio-psychosocial model and adopted pre-test, post-test quasi experimental design. Three states were randomly selected out of the six states in the South-west and three hospitals were purposively selected based on the breast cancer patients turn out. The hospitals were randomized into two experimental (CBT and NC) and a control groups. Screening test was conducted on the women patients with breast cancer using Functional Assessment of Cancer Therapy-Breast (FACT-B) version 4, with the cut-off score of 74. Minimum of 30 participants per group, total of 92 participants formed the sample size of this study. Participants in the intervention groups were exposed to eight sessions of CBT and four sessions of NC, each session lasted for an hour. European Organization for Research and Treatment of Cancer (EORTC) version 3.0 of the QLQ-C30 and QLQ Br23 (r = 0.80) was administered pre and post intervention. The data were subjected to Analysis of Covariance, estimated marginal mean and Scheffe post-hoc analysis at 0.05 significance level.

There was a significant main effect of treatment ($F_{(2; 73)} = 61.098$; partial $\tilde{\eta} = 0.626$) on the quality of life of breast cancer patients. Post-test QoL mean score was significantly higher in both experimental groups CBT (100.19) and NC (109.17) compared with the control group (77.57). However, NC group obtained the highest post-test mean score (112.809) followed by the CBT (99.695^a) and the control group (77.808^a).

Both CBT and NC were effective in enhancing quality of life of breast cancer patients in the South-west, Nigeria. However, NC was more effective than CBT, therefore both should be integrated and/or scaled up in breast cancer care and management.

No conflict of interest.

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89 (PB-089) Poster

7 year follow-up of the Triple A study: outcome in ER+ breast cancer patients with a disputable indication to receiving adjuvant chemotherapy based on the 70-GS test result and based on the pre-test advice

E. Verreck[1], A. Kuijer[2], J.E.C. van Steenhoven[3], J. Volders[4], M.C. van Maaren[5], T. van Dalen[6]. *[1]Utrecht University, Medicine, Utrecht, Netherlands; [2]St. Antonius hospital, Surgery, Utrecht, Netherlands; [3]UMC Utrecht, Surgery, Utrecht, Netherlands; [4]Diakonessenhuis, Surgery, Utrecht, Netherlands; [5]Netherlands Comprehensive Cancer Organisation IKNL, Research and Development, Utrecht, Netherlands; [6]Erasmus MC, Surgery, Rotterdam, Netherlands*

Background: Gene expression profiles (GEPs) are used in addition to clinicopathological characteristics to refine the determination of prognosis and contribute to decision-making regarding the administration of adjuvant chemotherapy (CT) in early-stage breast cancer patients. A previous prospective study showed that the 70-Gene Signature (70-GS) changed the oncologists' CT advise prior to the 70-GS test result in half of the patients, resulting in less patients receiving CT [1]. Here, the latter study is complemented with oncological outcome data.

Material and Methods: Patients operated for early-stage ER+ breast cancer with a disputable CT indication had been prospectively included between 2013 and 2015 [1]. Outcome information was collected by the Dutch Comprehensive Cancer Organization. The primary endpoint of this study was distant metastasis free survival (DMFS) defined as being alive and free of DM. DMFS was stratified for the 70-GS risk score and the oncologists' pre-test CT advice.

Results: After a median follow-up of 7 years distant metastases were diagnosed in 23 of the 606 patients (3.8%) and 36 (5.9%) patients had died (table 1). The DMFS rate for the 357 70-GS genomic low risk patients was 94.2% (95% CI 91.2–96.2%) and 89.1% for the 249 genomic high risk patients (95% CI 84.3–92.4%; $P = 0.052$), while 3% of the low- and 80% of the high risk patients received CT. For the subgroups based on pre-test advice (no CT/CT/unsure) there were no differences in DMFS (89.8, 93.2 and 92.0%, respectively), while comparable proportions of patients had received CT. The disease free survival rate of all patients was 89.5% and not significantly different between subgroups.

Table 1: Summary of outcome events

Event	Overall	70-GS		Pre-test CT advice		
		Low genomic risk	High genomic risk	No CT	CT	Unsure
No. of patients (%)	606	357	249	100	259	247
Distant metastasis	23	10 (2.8)	13 (5.2)	4 (4.0)	11 (4.2)	8 (3.2)
Locoregional recurrence	14	8 (2.2)	6 (2.4)	1 (1.0)	8 (3.1)	5 (2.0)
Contralateral breast cancer	14	7 (2.0)	7 (2.8)	1 (1.0)	6 (2.3)	7 (2.8)
Death	36	18 (5.0)	18 (7.2)	8 (8.0)	12 (4.6)	16 (6.5)

Conclusions: In patients with ER+ early breast cancer in whom the indication to administer CT was considered disputable and the 70-GS had changed the pre-test advice in half of them, DMFS was better in the low- than in the high genomic risk group of whom the majority received CT. Outcome

did not differ between groups categorized by pre-test CT advise. It is sensible to deploy the 70-GS to better select patients for adjuvant CT. Further studies need to address the optimal interplay between clinical and genomic risk to better select patients who benefit from 70-GS use.

No conflict of interest.

Reference

[1] Kuijer A, et al. Impact of 70-Gene Signature Use on Adjuvant Chemotherapy Decisions in Patients With Estrogen Receptor–Positive Early Breast Cancer: Results of a Prospective Cohort Study. J Clin Oncol. 2017 Aug;35(24):2814–2819.

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90 (PB-090) Poster

Assessment of Quality of Life after breast cancer treatment using EORTC QLQ-C30 questionnaire

D. Dahiya[1], S.S. Kahlon[1], B.S. Yadav[1], A. Sharma[2], S. Irrinki[3], S. Satish[3].
[1]Postgraduate Institute of Medical Education & Research, General Surgery, Chandigarh, India; [2]Postgraduate Institute of Medical Education and Research, Psychiatry, Chandigarh, India; [3]PGIMER, General Surgery, Chandigarh, India

Objective: This study is aimed to assess QoL after breast cancer treatment using EORTC QLQ-C30 questionnaires.

Methods: This is a prospective observational study which included 100 BC patients who received treatment at PGIMER Chandigarh. QoL was assessed after three months of completion of treatment for BC using EORTC QLC-30 questionnaire. Descriptive analysis was made using parametric tests for continuous variables otherwise non-parametric tests were used. Pearson's correlation coefficient, Spearman's correlation coefficient and Multiple regression modelling were used wherever applicable.

Results: Mean age of study population was 51.02 ± 12.16 years and 61 patients were in stage I & II. Mean Global Health Score (GHS) QoL score was 55.17 ± 13.75 which was lower than EORTC reference value of 61.8 ± 24.6. Among functional scales, best score was for emotional functioning (91.00 [95% CI 88.77–93.22]) while social functioning scored the lowest (74.33 [95% CI 70.71–77.96]). Pain, insomnia and fatigue were most worrisome symptoms. Elder age negatively affected GHS, physical functioning, and cognitive functioning. Being married had a significant positive impact on GHS, physical functioning and role functioning. Living in a nuclear family and having an occupation has significant positive impact on GHS/QOL.

Conclusions: There were many factors which were related to lower quality of life including age, marital status, occupation status and type of family. This study highlights the women at risk of poorer quality of life after breast cancer treatment in Indian society.

No conflict of interest.

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91 (PB-091) Poster

Understanding patient experiences of early breast cancer treatment: informing future studies to reduce treatment burden

S. Potter[1], M. Mactier[2], K. Fairhurst[3], H. Stobart[4], J. Gath[4], S. McIntosh[5].
[1]University of Bristol, Bristol Medical School, Bristol, United Kingdom; [2]Queen Elizabeth University Hospital, Breast Surgery, Glasgow, United Kingdom; [3]University of Bristol, Bristol Centre for Surgical Research, Bristol, United Kingdom; [4]Independent Cancer Patients Voice, London, United Kingdom; [5]Queen's University Belfast, Patrick G Johnson Centre for Cancer Research, Belfast, United Kingdom

Background: Breast cancer treatment is multimodality, although not all patients benefit from each treatment. However, many patients experience significant morbidities substantially impacting quality of life. This survey aimed to understand patient experiences of their treatment, to inform future research which aims to reduce treatment burden while maintaining excellent oncological outcomes.

Methods: An online survey was co-developed with patient advocates to explore respondents' experiences of treatments. Questions included simple demographics, treatments received and views about omitting therapies if safe to do so. The survey was circulated via social media. Responses were summarised using simple descriptive statistics; free text was analysed thematically.

Results: Of 235 responses received, the majority were white (n = 225, 95.7%) and aged 40–60 (n = 158, 67.2%). Almost 60% (n = 134, 57.0%) lived in the UK, with additional respondents spread across Europe and North America. Treatments received were surgery (n = 211, 89.8%), radiotherapy (RT, n = 150, 63.8%), chemotherapy (CT, n = 139, 59.1%) and endocrine therapy (ET, n = 158, 67.2%).

Of 197 (83.8%) respondents expressing a preference, 79 (29.8%) would omit CT; 62 (26.4%) would omit ET; 41 (17.5%) would avoid surgery and 20 (8.5%) would omit RT if safe to do so.

Respondents opting to avoid CT highlighted 'brutal' short-term side effects and their profound impact on daily living. Hair loss was a common concern and was considered a 'very visible' sign of being a 'cancer patient'. Long-term effects such as peripheral neuropathy had lasting effects on activities of daily living.

Almost all respondents who would omit ET cited the profound impact of side effects (including joint/muscle pains, fatigue, hair loss, sleep disturbance and loss of libido) on quality of life.

Surgery was identified as having long-term impacts on respondents' physical and psychological well-being, with many wishing to avoid 'disfiguring' procedures affecting their relationships and quality of life. Respondents highlighted specific procedures they would seek to avoid including mastectomy due to the 'trauma' of losing a breast and axillary node clearance due to complications (e.g. lymphoedema).

Fewer women chose to avoid RT, but those choosing to do so cited both short and long-term side issues including chronic pain, difficulties travelling and attending for treatment over 5 weeks as reasons.

Several women however commented that survival was their 'absolute priority', and that high-quality evidence to support the safety of reducing treatments was required.

Conclusions: This survey confirms that different patients may wish to de-escalate different components of their therapy. Studies developing an evidence base for treatment personalisation with particular emphasis on reducing CT and ET are research priorities.

Conflict of interest: Advisory Board: SMcI reports advisory board and speaker honoraria from Roche, Asta Zeneca, Lilly, MSD and Novartis.

No other co-authors have any conflicts to declare.

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92 (PB-092) Poster

Adherence challenges in breast cancer: Evaluating tamoxifen and aromatase inhibitors in adjuvant hormone therapy

N. Camejo[1], D. Amarillo[1], C. Castillo[1], L. Argenzio[1], D. Santana[1], G. Herrera[2], L. Cabrera[3], M. Guerrina[1], C. Dörner[3], G. Krygier[1].
[1]Department of Clinical Oncology, School of Medicine, University of Uruguay, Montevideo, Uruguay; [2]Department of Quantitative Methods, School of Medicine, University of Uruguay, Montevideo, Uruguay; [3]Department of Clinical Oncology, Departmental Hospital of Soriano "Zoilo A. Chelle" - U.E. 30., Mercedes, Uruguay

Introduction: Adjuvant hormone therapy (HT) in breast cancer (BC) for patients with positive hormone receptors (HR) increases overall survival (OS). Previously, our group assessed adherence to HT in patients treated at the Mastology Unit (MU), finding a 30.5% reduction over five years, which could impact OS. Personalized interventions to improve adherence can only be implemented if patient subgroups at higher risk for suboptimal adherence are identified.

Objective: To identify risk factors for suboptimal adherence to adjuvant HT in BC patients treated at the MU of the Hospital de Clínicas and the Departmental Hospital of Soriano.

Materials and Methods: This retrospective, cross-sectional, descriptive study included stage I-III BC patients treated with HT for at least one year. Adherence was assessed using the Morisky-Green treatment adherence questionnaire. Statistical Analysis: Odds ratios (OR) for non-adherence were estimated in simple and multiple models, with a significance threshold set at $\alpha = 0.05$. Analyses were performed using R software version 4.0.4.

Results: Ninety-six patients were included, with sociodemographic characteristics detailed in Table 1 and treatments in Table 2. Non-adherence was found in 22.9% (n = 22) of patients. Potential predictors of non-

adherence identified in Table 3 showed that only the type of HT (tamoxifen) and cohabitation were predictors in the multivariate analysis. Although patients who received ovarian suppression therapy, chemotherapy, and radiotherapy were more adherent, this was not significant. Patients aged 46–70 were more likely to adhere in the simple model. Time since diagnosis was not associated with adherence.

Conclusion: We evaluated real-life adherence to HT; 22.9% of patients were non-adherent despite the known benefits in OS, good tolerance, and free provision of treatment. The potential predictors for non-adherence were tamoxifen use and cohabitation. Further studies with larger patient cohorts are needed to identify "real-life" patient subgroups with a higher probability of non-adherence to design intervention studies aimed at improving it.

No conflict of interest.

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93 (PB-093) Poster

Elevating breast cancer care in India: A focus on quality of life

L. Busheri[1], D. Muknak[2], N. Athavale[2], S. Nare[2], G. Thomas[3], R. Alhat[3], R. Navgire[3], B. Varghese[3], M. Pai[3], C. Deshmukh[3], M. Munshi[3], U. Dhar[3], R. Mishra[2], D. Kelkar[2], S. Joshi[2], C. Koppiker[3]. *[1]Prashanti Cancer Care Mission, Administration, Pune, India; [2]Prashanti Cancer Care Mission, Centre for Translational Cancer Research, Pune, India; [3]Prashanti Cancer Care Mission, Orchids Breast Health Centre, Pune, India*

Introduction: Breast cancer presents a mounting concern in India, characterized by escalating incidence rates. Annually, India reports nearly 200 K new breast cancer cases, and 90 K breast cancer-related deaths, reflecting a significant 50% mortality rate. While the country grapples with a lack of dedicated breast units, our unit identified this gap and worked towards bridging it. In 2009, we set-up a state-of-the-art comprehensive breast cancer centre, one of its kind in the region. The center delivers cutting-edge care through a specialized multidisciplinary team (MDT) including lead oncoplastic surgeon, medical oncologist, pathologist, radiologists, researchers, radiation oncologist and an extended MDT. The extended team provides holistic support services, including genetic counseling, yoga, nutrition and onco-psychology counseling focusing on preserving patients' quality of life (QoL). The unit also includes a thriving research arm and a strong focus on training and outreach.

Another challenge in breast cancer management in India is the limited adoption of breast conservation surgery (BCS) (10–30%), mainly due to the prevalence of locally advanced stages. In recognition of this, our approach emphasizes oncoplasty, which prioritizes oncological safety and aims to optimize aesthetic outcomes with BCS rates over 80%. Our practice has placed a significant focus on oncoplastic techniques to broaden the scope of breast conservation options, highlighting the role of the entire MDT in achieving oncoplastic excellence. Here we present our focus on the implementation of various systems to improve QoL and Patient-Reported Outcome Measures (PROMs) within the framework of our single-surgeon practice.

Methods: PROMs serve as a vital instrument in assessing patient health status, QoL, and intervention impact, enriching healthcare implementation with the patient's perspective. Since 2012, our center has employed BREAST-Q PROMs, with annual PROMs data collection post-surgery facilitated by skilled practitioners and oncopsychologists. These have also been translated into regional languages, bridging linguistic divides. These PROMs resound with our patients, where oncological safety converges with heightened self-esteem and body image confidence.

Results: PROMs analysis reveals satisfaction across all BREAST-Q domains. Patient testimonies echo with satisfaction rates, including breast (85%), physical (78%), sexual (73%), psychosocial well-being (87%), and overall outcomes (86%).

Conclusion: Our studies with BREAST-Q PROMs underscore the significance of assessing patient acceptance for oncoplastic procedures and understanding treatment impact on QoL. We advocate for the integration of PROMs analysis as standard practice in breast surgery across India. This approach empowers us to more effectively address the unique needs of breast cancer patients within our nation.

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94 (PB-094) Poster

Comparative survival analysis of infiltrating ductal carcinoma versus infiltrating lobular carcinoma of the breast

C. Huertas Burgos[1], L. Beltrán Parra[1], M.C. Sanz Ferrández[1], L. Álvaro Valiente[1], B. García Chapinal[1], M. Arroyo Vozmediano[1], M. Gallego Álvarez[1], M. Blanco Guerrero[1], S. Aragón Sánchez[1]. *[1]Hospital 12 de Octubre, Breast section, Madrid, Spain*

Background: The natural history and survival of breast cancer vary greatly among women due to the heterogeneity of this disease. Knowledge of prognostic factors allows for the calculation of the likelihood of recurrence and long-term survival. The main objective of the present study has been to determine whether the histological classification of breast cancer conditions the overall survival and disease-free survival of the patients under study.

Material and Methods: A comparative survival analysis was conducted, including a total of 848 patients diagnosed with Infiltrating Ductal Carcinoma (IDC) and Infiltrating Lobular Carcinoma (ILC) at a tertiary hospital between January 2013 and December 2017. Patients who underwent prophylactic surgery and those who had experienced a recurrence or a second ipsilateral primary tumor were excluded. Data on Overall Survival (OS), Disease-Free Survival (DFS), and recurrence location (local, nodal, or distant) were collected. Kaplan-Meier survival curves were used for statistical analysis.

Results: The mean follow-up was 90 months (minimum 76 months, maximum 130 months). The mean Overall Survival (OS) was 109 months for IDC and 108 months for ILC ($p = 0.745$). The mean Disease-Free Survival (DFS) until local, loco-regional, or distant recurrence was 113 months for IDC and 106 months for ILC ($p = 0.013$), with this difference being statistically significant. There were no significant differences between both groups in terms of local recurrence, ipsilateral nodal recurrence, and distant metastasis events ($p = 0.222$).

Conclusions: Our study did not find differences in overall survival between patients diagnosed with IDC and ILC. However, we observed statistically significant differences when comparing the time interval between the diagnosis of the primary tumor and the occurrence of both local and distant recurrence in both groups. Disease-free time is longer in patients diagnosed with IDC, potentially serving as a positive prognostic factor for survival in our cohort.

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95 (PB-095) Poster

The INFLUENCE 3.0 model: time-dependent risks of locoregional recurrence and contralateral breast cancer, now also including patients treated with neoadjuvant systemic therapy

M. van Maaren[1], T. Hueting[2], D. van Uden[3], M. van Hezewijk[4], L. de Munck[5], A. Zeillemaker[6], M. Schmidt[7], G. Sonke[8], C. Groothuis-Oudshoorn[1], S. Siesling[5]. *on behalf of the NABOR project group, [1]Technical Medical Centre, University of Twente, Department of Health Technology and Services Research, Enschede, Netherlands; [2]Evidencio Medical Decision Support, Evidencio Medical Decision Support, Haaksbergen, Netherlands; [3]Canisius Wilhelmina Hospital, Department of Surgical Oncology, Nijmegen, Netherlands; [4]Institution for Radiation Oncology, Radiotherapiegroep, Arnhem, Netherlands; [5]Netherlands Comprehensive Cancer Organisation IKNL, Department of Research and Development, Utrecht, Netherlands; [6]Alrijne Hospital, Department of Surgery, Leiden, Netherlands; [7]Netherlands Cancer Institute-Antoni van Leeuwenhoek, Division of Molecular Pathology, Amsterdam, Netherlands; [8]Netherlands Cancer Institute-Antoni van Leeuwenhoek, Department of Medical Oncology, Amsterdam, Netherlands*

Background: Individual risk prediction of locoregional recurrence (LRR) and contralateral breast cancer (CBC) supports decisions for personalized follow-up planning in patients who have been treated for primary breast cancer. This study aimed to improve a previously developed prediction tool by revising the underlying models and expanding them for patients who received neoadjuvant treatment.

Material and Methods: Data from the Netherlands Cancer Registry was collected of women diagnosed with nonmetastatic breast cancer between 2012 and 2016, treated with surgery. Two modelling approaches, Cox regression and Random Survival Forest were compared to predict LRR and CBC during the first five years since surgery. Separate models were developed for patients treated with neoadjuvant systemic therapy (NST).

Missing data was imputed using the *mice* package in the statistical software program R. The models were internally validated by 100 times bootstrap resampling to assess the discrimination using the Area Under the Curve (AUC) and the calibration using the Integrated Calibration Index.

Results: In total, 49,631 and 10,154 patients were included in the non-NST and NST group, respectively. There were 825 (1.7%) and 296 (2.9%) patients diagnosed with a LRR as a first event in the non-NST and NST group, respectively. CBC as first event was diagnosed in 1025 (2.1%) and 141 (1.4%) in the non-NST and NST group, respectively.

Age, mode of detection, histology, sublocalisation, differentiation grade, pT, pN, hormonal receptor status ± endocrine treatment, HER2 status ± targeted treatment, surgery ± direct reconstruction ± radiation therapy, and chemotherapy were identified as significant predictors for LRR and/or CBC in non-NST patients. The models developed for NST patients included the same variables, but excluding pT and pN status, and including axillary lymph node dissection and presence of pathologic complete response.

In the non-NST cohort, the Cox model was chosen as best performing model with an AUC of 0.77 (95%CI: 0.767–0.773) for prediction of LRR. The random survival forest model performed best for prediction of CBC, with an AUC of 0.68 (95%CI: 0.67–0.68). In the NST cohort, for both outcomes the random survival forest model performed best, with AUCs of 0.77 (95%CI: 0.76–0.78) and 0.73 (95%CI: 0.69–0.76) for LRR and CBC, respectively. Regarding calibration, ICI values were all <0.01 (observed-predicted difference was less than 1%).

Conclusions: This revised and expanded INFLUENCE model showed moderate to good performance in the prediction of LRR and CBC. INFLUENCE 3.0 has been made available as an online tool to enable clinical decision support regarding personalised follow-up strategies, also for patients treated with NST.

Conflict of interest:

Other Substantive Relationships: Tom Hueting declares employment at Evidencio, the website where INFLUENCE 3.0 will be hosted. In addition, this study is part of a by ZonMW funded project (10330032010001), in which the INFLUENCE model will be used in practice.

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97 (PB-097) Poster

Prognostic role of HER2 expression in patients with estrogen receptor positive/HER2-negative breast cancer. Results from a population-based cancer registry study

C. Tommasi[1,2,3], M. Corianò[1,2,3], O. Serra[1,2,3], B. Pellegrino[1,2], D. Zanoni[1,2], F. Faccini[4], M. Michiara[1,2], P. Sgargi[1], C. Giuliano[5], S. Ferretti[6], V. Grossi[7], A. Ravaioli[7], F. Zamagni[7], F. Falcini[7], A. Musolino[1,2,3]. *[1]Emilia Romagna Cancer Registry- Parma Unit, Medical Oncology and Breast Unit- AOU Parma, Parma, Italy; [2]Gruppo Oncologico Italiano di Ricerca Clinica, Goirc, Parma, Italy; [3]University of Parma, Medicine and Surgery, Parma, Italy; [4]Emilia Romagna Cancer Registry- Piacenza Unit, Public Health Department- AUSL Piacenza, Piacenza, Italy; [5]Emilia Romagna Cancer Registry- Modena Unit, Public Health Department- Local Health Authority, Modena, Italy; [6]Emilia Romagna Cancer Registry- Ferrara Unit, Local Health Authority- University of Ferrara, Ferrara, Italy; [7]Emilia Romagna Cancer Registry- Romagna Unit, IRCCS Istituto Romagnolo per lo Studio dei Tumori IRST "Dino Amadori", Meldola- Forlì, Italy*

Background: Estrogen Receptor (ER)-positive (+)/Human Epidermal Growth Factor Receptor 2 (HER2)-negative (-) breast cancers (BCs) express variable protein levels of HER2, which can influence prognosis.

Materials and Methods: This cohort study was conducted using data on all consecutive patients (pts) diagnosed with BC between 2005 and 2017, which were systematically and prospectively collected by the Emilia-Romagna Cancer Registry (Provinces of Piacenza, Parma, Modena, and Ferrara), Italy. The study included 13527 pts with ER+/HER2- BC. Tumors were classified by HER2 IHC score (0 [n = 7155], 1+ [n = 5186], or 2+ with negative FISH [n = 1186]). Comparisons of clinicopathologic characteristics and disease outcome were performed.

Results: BCs with late-stage diagnosis, high histological grade, or high proliferative rate were more likely to be HER2 1+ or 2+/FISH- in comparison with earlier stage, low-grade, or low-proliferative tumors (lower bounds of 95% confidence intervals [CIs] for odds ratios [ORs] > 1). BCs with high expression of ER (≥ 80% [n = 12383]) were more enriched with HER2 1+ (OR 1.39; 95%CI, 1.2–1.6) or 2+/FISH- tumors (OR 1.26; 95%CI, 1.0–1.6) than ER-low/moderate (1–79% [n = 1144]) ones. The 5-year overall survival (OS) for HER2 1+ BCs was lower than that for HER2 0 or 2+/FISH- tumors (P = 0.0018). This finding was confirmed also after stratification by ER status (low/moderate and high expression; P = 0.07 and 0.007, respectively). By multivariate logistic regression, the following variables were significantly associated with HER2 1+, or 2+/FISH- expression compared to HER2 0 tumors: age at diagnosis <50, high histological grade, ER expression ≥ 80% (lower bounds of 95% CIs for ORs > 1). Multivariate Cox's regression analysis showed that histological grades G2 and G3 were independently associated with poor survival vs. G1 tumors (HR 1.2; 95%CI, 1.1–1.3 and 1.3; 95%CI, 1.1–1.4, respectively). Furthermore, HER2 2+/FISH- status was significantly associated with better survival in comparison with HER2 0 tumors (HR 0.82; 95%CI, 0.7–0.9). This finding was confirmed also after stratification by ER status (ER 1–79% and ≥ 80%). No significant difference in OS was observed between HER2 1+ and 0 BCs.

Conclusions: The putative worse prognostic impact of HER2 expression in pts with ER-positive/HER2-negative BCs was not confirmed. The better outcome observed in pts with HER2 2+/FISH- BCs may be related to the known FISH-negative (HER2-non-amplified) status of this subgroup. These findings may help identify optimal patient inclusion criteria for clinical trials with novel anti-HER2 therapies in ER-positive/HER2-negative disease.

No conflict of interest.

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98 (PB-098) Poster

Effects of Dyadic Psychoeducational Intervention on Psychological Distress and Quality of Life among Breast Cancer Survivors in Nepal: A Randomized Controlled Trial

A. Sharma[1], A. Sriyuktasuth[2], W. Phligbua[2], N. Vongsirimas[3]. *[1]Mahidol University, Faculty of Nursing, Kathmandu, Nepal, Nepal; [2]Mahidol University, Faculty of Nursing, Department of Medical Nursing, Salaya, Thailand; [3]Mahidol University, Faculty of Nursing, Department of Mental Health and Psychiatric Nursing, Salaya, Thailand*

Background: Advancement in diagnostic and effective treatment modalities are successful in prolonging survival leading to the new phenomenon of survivorship among breast cancer patients. In the context of Nepal with focus being on screening, and treatment the concerns of survivors are yet to be addressed. The study was conducted with the aim of exploring the psychological distress and quality of life of breast cancer survivors and their spousal caregivers and evaluating the effectiveness of telephone delivered dyadic psychoeducational intervention in the context of Nepal.

Methods: A two-arm randomized controlled trial (RCT) was conducted. From the registry of Bhaktapur Cancer Hospital, 64 female breast cancer survivors and their spouse meeting the inclusion criteria participated in the study. Assessment was done at baseline (T0), T1 (T0+ 4 weeks) and T2 (T1+ 4 weeks). Dyads were assessed using sociodemographic and breast cancer related questionnaire, Hospital Anxiety and Depression Scale (HADS), Family Communication Subscale of Cancer Communication Assessment Tool for Patient and Families (CCAT-PF), Quality of life Instrument- Breast Cancer Patient Version (QOL-BC) and Caregiver Quality of Life Index (CQOLC). The intervention group received 8 sessions of intervention delivered biweekly over four weeks through telephone.

Results: There was no significant difference between the intervention group and control group in sociodemographic characteristics and study variables at baseline. The mean score for anxiety, depression, and quality of life of dyads differed significantly across three time points. The group and time interaction effect was found to be significant for mean score of anxiety, depression and quality of life of dyads. Further, among survivors mean anxiety score significantly decreased (F = 4.126, p = 0.047), while mean score for physical (F = 4.108, p = 0.047) and psychological (F = 4.165, p = 0.046) quality of life significantly increased among the intervention group compared to the control group at each measurement point. The anxiety and depression score significantly decreased while quality of life score significantly increased among the intervention group dyads from baseline to posttest.

Conclusion: Breast cancer survivors and their spouse in Nepal benefit from telephone delivered dyadic psychoeducational intervention. This intervention should be promoted which will broaden the scope of nursing practice and research for addressing concerns of breast cancer survivors in Nepal.

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99 (PB-099) Poster

The impact of personality traits on health-related quality of life in cT1-2N0 breast cancer patients treated with breast-conserving therapy: Three years patient-reported outcomes of the BOOG 2013-08 randomized controlled trial

V. Wintraecken[1,2], L. van Roozendaal[3], J. Simons[4,5], J. de Vries[6,7], S. van Kuijk[8], H. Sackey[9,10], M. Vane[2,4], T. van Dalen[11,12], J. van der Hage[13], L. Strobbe[14], S. Linn[15], M. Lobbes[4,16,17], P. Poortmans[18,19], V. Tjan-Heijnen[4,20], K. van der Vijver[21,22,23], H. Westenberg[24], C. Dirksen[8,25], H. de Wilt[26], L. Boersma[27], M. Smidt[2,4]. *On behalf of the BOOG 2013-08 study Trialists Group, [1]Maastricht University, GROW - School for Oncology and Developmental Biology, Maastricht, Netherlands; [2]Maastricht University Medical Centre+, Department of Surgery, Maastricht, Netherlands; [3]Zuyderland Medical Center, Department of Surgical Oncology, Sittard-Geleen, Netherlands; [4]Maastricht University, GROW - School for Oncology and Reproduction, Maastricht, Netherlands; [5]Erasmus Medical Centre, Department of Radiotherapy, Rotterdam, Netherlands; [6]Tilburg University, Department of Medical and Clinical Psychology, Tilburg, Netherlands; [7]Admiraal de Ruijter ziekenhuis, Board member Adrz, Goes, Netherlands; [8]Maastricht University Medical Centre+, Department of Clinical Epidemiology and Medical Technology Assessment, Maastricht, Netherlands; [9]Karolinska Institutet, Department of Molecular Medicine and Surgery, Stockholm, Sweden; [10]Karolinska Institutet, Department of Breast- Endocrine Tumors and Sarcoma, Stockholm, Sweden; [11]Diakonessenhuis Hospital, Division of Surgical Oncology, Utrecht, Netherlands; [12]Erasmus Medical Centre, Department of Surgery, Rotterdam, Netherlands; [13]Leids University Medical Center, Division of Surgical Oncology, Leiden, Netherlands; [14]Canisius-Wilhelmina Hospital, Division of Surgical Oncology, Nijmegen, Netherlands; [15]Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital, Division of Medical Oncology, Amsterdam, Netherlands; [16]Zuyderland Medical Center, Department of Medical Imaging, Sittard-Geleen, Netherlands; [17]Maastricht University Medical Centre+, Department of Radiology and Nuclear Medicine, Maastricht, Netherlands; [18]Iridium Network, Department of Radiation Oncology, Antwerp, Belgium; [19]University of Antwerp, Faculty of Medicine and Health Sciences, Antwerp, Belgium; [20]Maastricht University Medical Centre+, Division of Medical Oncology, Maastricht, Netherlands; [21]Ghent University Hospital, Department of Pathology, Ghent, Belgium; [22]Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital, Center for Gynecological Oncology Amsterdam CGOA- Department of Gynecology, Amsterdam, Netherlands; [23]Ghent University, Department of Diagnostic Sciences, Cancer Research Institute Ghent CRIG, Ghent, Belgium; [24]Radiotherapiegroep location Arnhem, Radiation Oncology, Arnhem, Netherlands; [25]Maastricht University, Care and Public Health Research Institute CAPHRI, Maastricht, Netherlands; [26]Radboud University Medical Centre, Division of Surgical Oncology, Nijmegen, Netherlands; [27]Maastricht Radiation Oncology MAASTRO clinic, Department of Radiation Oncology, Maastricht, Netherlands*

Background: The results presented originate from the BOOG 2013-08 study which investigates the oncological safety of sentinel lymph node biopsy (SLNB) omission in cN0 T1-2 breast cancer patients treated with breast conserving therapy (BCT). The aim of current study was to assess the impact of personality traits 'trait anxiety' (TA) and neuroticism (N) on HRQoL up to three years after study inclusion.

Material and Methods: The BOOG 2013-08 study is a non-inferiority randomized controlled multicentre trial that enrolled 1730 patients (NCT02271828). The patients underwent BCT with or without SLNB, followed by radiation therapy of the breast. A subgroup of 1055 participants were used for analysis.

Results: Analyses revealed that irrespective of treatment arm, patients with high TA or high N levels reported significantly more morbidity complaints and lower HRQoL scores compared to patients with low TA and N levels. Results from the linear mixed effect models for repeated measures confirmed these results and also showed that the impact of tumour characteristics, (neo) adjuvant treatment, and surgical procedure are limited (table 1).

Table 1: Results from linear mixed model analysis

Parameter	Regression coefficient (95% CI)	*P* value
Treatment arm	–.11 (–3.3–3.1)	.949
Age	–.08 (–.34–.18)	.554
Axillary treatment		
• No additional axillary treatment	–15.0 (–40.5–10.6)	.250
• ALND or Regional RT	–15.1 (–41.4–11.3)	.261
• ALND and regional RT	REF	
(Neo)adjuvant treatment		
• Chemotherapy	8.1 (–5.1–21.4)	.228
• Immunotherapy	–6.3 (–23.5–10.8)	.468
• Hormonal therapy	10.0 (–12.0–32.0)	.372
• Chemo- and immunotherapy	9.0 (–4.2–22.1)	.180
• Chemo- and hormonal therapy	8.6 (–5.3–22.5)	.224
• Chemo-, immune- and hormonal therapy	REF	
cT stage		
• cT1	–2.4 (–8.3–3.6)	.437
• cT2	REF	
pT stage		
• pT0	–9.7 (–32.1–12.7)	.392
• pT1	–3.5 (–18.4–11.4)	.642
• pT2	–3.1 (–18.6–12.3)	.689
• pTis	REF	
Personality		
• Low personality level	15.3 (3.3–27.4)	.013
• High TA level	13.9 (1.5–26.4)	.029
• High N level	REF	
Comorbidities	–2.9 (–4.0–1.8)	<.001
Educational level		
• Low educational level	1.3 (–2.6–5.1)	.517
• Moderate educational level	–4.4 (–8.6–.16)	.042
• High educational level	REF	
BMI	–.26 (–.57–.05)	.100
Smoking	–.57 (–.57–.05)	.521
Marital status		
• Single	4.6 (–4.9–14.2)	.346
• Married	4.2 (–4.4–12.7)	.337
• Divorced/widow(er)	5.9 (–3.5–15.3)	.218
• Living together	2.6 (–7.2–12.4)	.603
• Other	REF	
Children	–1.9 (–6.8–3.0)	.451
Employment status		
• No, no paid job	1.5 (–3.4–6.3)	.555
• No, retired	3.7 (–1.5–8.9)	.158
• No, disabled	–8.8 (–17.7–.1)	.052
• Yes, paid job	REF	

Conclusions: These results emphasize the importance of measuring and stratification of personality traits in order to accurately interpret patient-reported outcomes.

No conflict of interest.

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100 (PB-100) Poster

Quality of life of women with breast cancer after receiving home-based dance program in Taiwan: A pilot randomized controlled trial

Y.H. Yang[1], I.C. Hou[1]. *[1]National Yang Ming Chiao Tung University, School of Nursing, Taipei, Taiwan*

Background: During COVID-19, telecare replaces face-to-face contact to maintain social distance and reduce the spread of the virus. The current epidemic is coming to an end. However, breast cancer cases, no matter the treatment or survival stage, are facing physical and mental symptoms, such as "social isolation", which affects their quality of life. Studies have shown that

dance can help breast cancer cases improve depression and quality of life, but most of these dance programs are conducted face-to-face. Online dance helped breast cancer cases join the classes without the limitations of time, space, distance, and treatment status, but lacking enough evidence. The purpose of this study was to design a "home-based dance program" suitable for women with breast cancer in Taiwan and conduct a clinical trial on its feasibility in improving their quality of life.

Material and Methods: After receiving breast cancer women with stage 0 to III breast cancer, who were recruited from support groups all over Taiwan, were randomized 1:1 into intervention and control groups. The experimental group had received 12 sessions of the program, 1 session a week, 60 minutes per session, lasting 3 months. Each session included 15 minutes of warm-up, 30 minutes of dance choreography teaching, 15 minutes of cool down, and 5 minutes of final discussion. The control group only received usual care during this pilot study. Two questionnaires—the European Organization for Research and Treatment of Cancer (EORTC) Quality-of-Life Questionnaire Core 30 (QLQ-C30) and the EORTC Breast Cancer-Specific Quality-of-Life Questionnaire (QLQ-BR23)—were distributed to subjects in both arms before and after program.

Results: A total of 23 breast cancer patients were enrolled in the trial, 11 in the experimental group and 12 in the control group, allocated randomly. The average age is 49.6 ± 9.3 years old, most are diagnosed with stage II, and 31.1% (n = 9) are still in treatment. The results showed the experimental group had significant improvement over the control group in the physical function domain ($p = 0.05$) role function domain ($p = 0.04$) and breast symptoms domain ($p = 0.04$). The qualitative feedback from subjects in the experimental group was perceiving spiritual peacefulness, learning about their bodies more, and having social connections with others after the program.

Conclusions: The home-based dance program shows the improvement of physical and role function by releasing uncomfortable symptoms for women with breast cancer. The 3-month home-based dance program was feasible in Taiwan. Future studies can keep evaluating the effectiveness of home-based dance and expand the larger sample size.

No conflict of interest.

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101 (PB-101) Poster

Effectiveness and implementation of shared decision-making about post-treatment surveillance after breast cancer supported by information on risks of recurrence – Results of the SHOUT-BC study

S. Siesling[1], J. Ankersmid[2], L. Strobbe[3], C. van Uden[4], C. Drossaert[5]. *Santeon VBHC Breast Cancer Group, [1]Netherlands Comprehensive Cancer Organisation IKNL, Research and Development, Utrecht, Netherlands; [2]SANTEON and University of Twente, Value based health care, Utrecht, Netherlands; [3]Canisius Hospital, Surgery, Nijmegen, Netherlands; [4]SANTEON, Value based health care, Utrecht, Netherlands; [5]University of Twente, Psychology, Health and Technology, Enschede, Netherlands*

Background: In the Netherlands, 17,000 women per year are diagnosed with breast cancer. Although treatments are highly personalized, post-treatment surveillance remains one-size-fits-all: an annual mammogram and physical examination for at least five years. Given that risks for locoregional recurrence (LRR) and second primary (SP) cancers vary, patient preferences and burden differ, and sustainability of health care is under pressure, this approach is under debate. Personalized information on risks of recurrence can guide shared decision-making (SDM) about tailored surveillance. The SHOUT-BC study evaluated the acceptance and effectiveness of SDM with outcome information (on risks of LRRs and SPs) about post-treatment surveillance across eight Dutch hospitals.

Materials and Methods: The Breast Cancer Surveillance patient decision aid (BCS-PtDA) was developed in co-creation with patients, healthcare professionals and experts, incorporating the INFLUENCE 2.0-nomogram for personalized LRR and SP risk assessment. The BCS-PtDA consists of three components: 1) a paper handout visualizing personalized risks 2) a web-based deliberation tool with information on surveillance, value clarification exercises and a patient-reported outcome measure on fear of cancer recurrence, and 3) a summary of patient preferences on surveillanxe. Healthcare professionals received training in SDM supported by outcome information using the BCS-PtDA. The study followed a prospective multiple interrupted time series design in three phases: pre-implementation, implementation, and post-implementation. Study outcomes included patient involvement in decision-making, decisional conflict, role in decisions, quality of life, chosen care, and PtDA satisfaction. Female breast cancer survivors approximately one year after curative surgery were included.

Results: Of 507 participants (282 pre-implementation, 225 post-implementation), analysis showed increased patient involvement in decision-making post-implementation, with an estimated effect increase of 27.14 points on a 100-point scale. There was also increased engagement, less decisional conflict, and lower fear of recurrence post-implementation, along with a slight decrease in surveillance frequency. The PtDA was well-received.

Conclusions: Incorporating personalized outcome information into SDM for post-treatment breast cancer surveillance is promising. This approach empowers patients, reduces decisional conflict, and enhances care experiences. Providing comprehensive information and involving patients in decision-making allows for more personalized care. Continued research and enhancement of the BCS-PtDA, along with improved implementation, will advance SDM about surveillance after breast cancer.

No conflict of interest.

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102 (PB-102) Poster

Breast cancer follow-up: current state of personalization and opportunities for improvements

S. Siesling[1], A. Klaassen[2], C. Drossaert[3], A. Zeillemaker[4], J. Wiegersma[5], J. Korevaar[6]. *the NABOR study group, [1]Netherlands Comprehensive Cancer Organisation IKNL, Research and Development, Utrecht, Netherlands; [2]Netherlands Comprehensive Cancer Organosation IKNL and University of Twente, Research and Development and Health Technology and Services Research, Utrecht and Enschede, Netherlands; [3]University of Twente, Psychology- Health and Technology, Enschede, Netherlands; [4]Alrijne Hospital, Surgery, Leiden, Netherlands; [5]Flevo Hospital, Surgery, Almere, Netherlands; [6]The Hague University of Applied Sciences, Oncology, The Hague, Netherlands*

Objective: Breast cancer follow-up can be divided into surveillance and aftercare. The need for personalization of follow-up is widely recognized, but current guidelines on surveillance follow a 'one-size fits all' approach and lack specific recommendations on personalization of aftercare. As it remains unclear to what extent current clinical practice still follows a generic approach or already adopted personalization, this study investigates the extent to which current surveillance and aftercare is personalized to patients' individual needs and risks. Variations in needs assessments, information provision and decision-making on the surveillance and aftercare trajectory are assessed.

Method: Semi-structured in-depth group interviews were performed in fifteen Dutch hospitals, with in total 29 Health Care Practitioners (HCPs). A self-administered questionnaire including both closed and open questions was used as an interview guide. To describe variations and degree of personalization in follow-up, quantitative answers were supported by citations from transcripts, using a deductive approach.

Results: Surveillance was mostly guided by the national guideline and generally not based on patients' needs, preferences or risks on recurrence. HCPs exceptionally deviated from the guideline by providing more surveillance because of patients' distress and preference. In aftercare, patients' needs and preferences were taken into account in decisions on the intensity of consultations, but needs were not systematically assessed. Besides, hospitals varied in the intensity of consultations and use of measurements to assess patients' needs. Information provision was mostly the same for each patient. Aftercare plans were mostly either not used or used as standard summary form which was not tailored to the patients' specific situation. Current decision-making on the surveillance and aftercare trajectory is mostly controlled by HCPs with no or little involvement of patients, but HCPs preferred more shared decision-making.

Conclusions: Current follow-up is not structurally personalized to patients' prognoses, needs and preferences, and variations between hospitals in their aftercare suggest hospitals are independently searching for a way to personalize aftercare. Aftercare could be more personalized by systematic assessment of patients' needs and tailored information provision on effects of cancer and its treatment as well as on aftercare options. Guidance on shared decisions on the intensity of aftercare and needed support and personalization of the surveillance based on risk-estimations and needs-assessments is desirable. Also the use of tools like prediction

models and decision aids may support the implementation of personalized aftercare and surveillance in clinical practice.

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103 (PB-103) Poster

A multidisciplinary nurse-led service for the nipple-areola complex tattooing after breast cancer surgery: feasibility and piloting results of a complex intervention evaluation study

M. Guberti[1], D. Maselli[2], T. Livieri[3], G. Farioli[4], S. Lucchi[3], F. Castagnetti[5], G. Ferrari[5]. *ARCADE Research Team, [1]AUSL-IRCCS Reggio Emilia, Research and EBP Unit Health Professions Department, Reggio Emilia, Italy; [2]AUSL-IRCCS Reggio Emilia, Research Unit - Health Professions Department, Reggio Emilia, Italy; [3]AUSL-IRCCS Reggio Emilia, General Surgery Department, Reggio Emilia, Italy; [4]AUSL-IRCCS Reggio Emilia, infectious diseases service, Reggio Emilia, Italy; [5]AUSL-IRCCS Reggio Emilia, Breast surgery department, Reggio Emilia, Italy*

Background: The Nipple-Areola Complex (NAC) tattooing is a simple and safe nonsurgical reconstruction technique that restores the skin's appearance by introducing resorbable pigments into the dermis. The service is not always easily accessible for women, considering its significant costs. The project aims to evaluate the impact on professionals, patients, and organizations of a nurse-led clinic in the context of Reggio Emilia for the NAC tattooing on women who underwent breast cancer surgery.

Methods: The framework of the Medical Research Council for developing and implementing complex interventions in healthcare was followed. According to the results of a literature review (phase 1.a) and the context analysis (phase 1.b), an initial intervention was planned and modeled (phase 1.c). The plan was tested in a small-scale pilot (phase 1.d). A mixed-method study will evaluate the implementation of this intervention (phase 2).

Results: Here, we present the results of phases 1.b, 1.c and 1.d. Phase 1. b. The modeling of the intervention was conducted from June 202, identifying theories, context elements, and part of interests. Specifically, we: 1) Engaged the integrated Breast Unit and Research departments; 2) selected three nurse-tattooists 3) created informative material about the treatment; 4) Involved citizens and local associations with presentations and calls for proposals for the new clinic's name; 5) chose the setting and collected the necessary materials. Phase 1.c: The intervention plan was developed in November 2022 with meetings. We created and shared a monthly schedule of activities: patients with the specialist's indication for NAC tattooing were individually contacted by the case manager. Each treatment involves 3–4 sessions, 30–40 days apart, in an ambulatory setting. It consists of NAC project (shape and color), medical tattooing with a dermographer and sterile needles, result documentation, first dressing, and patient education. Instruments for materials tracking, waiting list management, and recording documentation were identified. Phase 1.d: The "ARCADE" clinic started its activities in January 2023. More than 40 dermopigmentation sessions have been scheduled, providing more than 100 tattoos. Over 30 women have completed the treatment without significant complications, expressing overall satisfaction. We noted that the management aspects were efficient. The time necessary to treat one NAC is, on average, one hour. The median material cost for each tattoo is 50 euros. All the elements of activities were continuously evaluated and refined.

Conclusion: Implementing free-of-charge multidisciplinary nurse-led clinics might provide this treatment with reduced cost and waiting time, ensuring patient safety and quality of life. Further steps of this project will focus on outcomes identification and measurement.

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104 (PB-104) Poster

Tattooing to reconstruct nipple-areola complex after oncological breast surgery: a scoping review

D. Maselli[1], M. Torreggiani[2], T. Livieri[3], G. Farioli[4], S. Lucchi[3], M. Guberti[2]. *[1]AUSL-IRCCS Reggio Emilia, Research Unit - Health Professions Department, Reggio Emilia, Italy; [2]AUSL-IRCCS Reggio Emilia, Research and EBP Unit Health Professions Department, Reggio Emilia, Italy; [3]AUSL-IRCCS Reggio Emilia, General Surgery Department, Reggio Emilia, Italy; [4]AUSL-IRCCS Reggio Emilia, Infectious diseases service, Reggio Emilia, Italy*

Background: The dermopigmentation of the Nipple-Areola Complex (NAC) is a safe non-surgical reconstruction technique that can restore psycho-physical integrity, representing the final step after oncological surgery. This scoping review aims to identify and synthesize the literature focused on medical tattooing for NAC reconstruction in women who underwent breast reconstruction after cancer surgery. Competence and training, outcomes, and organizational aspects were assessed as specific outcomes.

Methods: The Joanna Briggs Institute (JBI) methodology for scoping reviews was followed. MEDLINE, Embase, Cochrane Library, Clinical Key, Scopus, and Cinahl databases were consulted. After title (N = 54) and abstract (N = 39) screening and full-text review (N = 18), articles that met eligibility criteria were analyzed and narratively synthesized. We assessed the quality of studies with the Effective Public Health Practice Project (EPHPP) instrument.

Results: 13 articles were analyzed, with full texts (N = 11) and only abstract (N = 2). The designs and the methodology of the studies were not robust, affecting the overall quality of the literature (N observational studies = 11; N pilot experimental studies = 2). Nurses were the professionals mostly involved (N = 6), then medical staff (N = 4) and tattoo artists (N = 2). The professional training is poorly described in 6 papers. The most frequently assessed outcome was the satisfaction rate (N = 8). One study explored quality of life aspects with a validated questionnaire. The management of these services resulted variable. Nurse-led services were implemented in 2 studies.

Conclusion: Despite methodological weaknesses, NAC tattooing research is relevant because it helps women redefine their identity after demolitive cancer treatments.

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105 (PB-105) Poster

LIFE app – the digital approach to multidisciplinary care in breast cancer

M. Vasileva-Slaveva[1], V. Terziiska[2], E. Valerieva[3], A. Ivanova[4], M. Taushanova[5], M. Tareyn[6]. *[1]Bulgarian Breast Cancer Association, Breast surgery, Sofia, Bulgaria; [2]Bulgarian Breast Cancer Association, Survivorship, Sofia, Bulgaria; [3]Bulgarian Breast Cancer Association, Gynecology, Sofia, Bulgaria; [4]Bulgarian Breast Cancer Association, Nutrition, Sofia, Bulgaria; [5]MBAL "Nadezdha", Medical Oncology, Sofia, Bulgaria; [6]Acibadem Tokuda hospital, Psycho-oncology, Sofia, Bulgaria*

Background: Breast cancer (BC) care and respectively the patients' outcomes are improving in the last years, globally. Multidisciplinary approach in treatment is fundamental for this improvement. Still, there are countries where optimization of the available resources and processes is needed to achieve the survival and quality of life outcomes of patients living in the Western countries. Eastern Europe is a region with traditionally lower BC survival. Credible data on cancer epidemiology and treatment of BC patients is lacking. Multidisciplinary approach in treatment in Bulgaria is hardly applied, since there is not a single internationally certified breast cancer center, that covers all European requirements.

LIFE is a mobile and desktop application for patient's support and education. It collects verified information for the current treatment practices of BC patients and provides a platform for a multidisciplinary care. Here we report some results obtained from the first 294 registered active users of the app diagnosed and treated in different institutions throughout Bulgaria.

Methods and Materials: LIFE application is developed by the Bulgarian Breast and other gynecological Cancers Association/BBCA (non-profit) and was first launched in October 2022. It is freely available in Google play in Bulgarian and English (https://life.bbca.bg/). For patients LIFE serves as mobile diary and source of information. Patients are creating a profile and are further guided through the app by an assistant. Doctors from different oncological specialties, psycho-oncologist or nutritional specialists can use the app to follow up closely their patients.

Results: By 15 of November 2023 in the application there are 229 confirmed patients' profiles, 2 assistants, 4 doctors, 5 registered psycho-oncologist and 39 articles on different BC related topics. Registered patients

are diagnosed between 2008 and 2023 and are between 27 and 67 years old. They are from any stage at diagnosis as 38 of them are in stage IV.

Conclusion: LIFE platform is a digital tool for a multidisciplinary care. Patients in Bulgaria are often receiving different therapies in different institutions and are followed by different doctors. LIFE app is providing a continues care throughout the patient's pathway. Doctors can follow the adherence to treatment, physical activity and symptoms of their patients on a daily basis, which is improving patient-doctor communication and trust. LIFE is improving and supporting the education and activation of patients in seeking multidisciplinary evidence-based approaches in BC care.

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106 (PB-106) Poster

Lessons learned from COVID-19: improving breast cancer services from the patient perspective

C. Myers[1], K. Bennett[2], C. Cahir[2]. *[1]Royal College of Surgeons in Ireland, School of Population Health, Dublin, Ireland; [2]Royal College of Surgeons in Ireland, Data Science Centre, Dublin, Ireland*

Background: Globally, health services for breast cancer (BC) were significantly disrupted due to the coronavirus disease (COVID-19) pandemic and the recovery and adaptation of health services is widely unknown. The purpose of this study is to reflect on the health service experiences of women with a diagnosis of BC in Ireland during the pandemic and to propose patient-centered priorities and recommendations to improve BC services moving forward from COVID-19.

Methods: The study included semi-structured qualitative interviews (n = 28) with women who participated in a related mixed-methods cohort study. Women with a diagnosis of BC within 5 years in Ireland were initially enrolled and women were selected for interviews through stratified purposive sampling to ensure data was available on diverse cases. Interviews took place in early 2023 to reflect on perspectives from the COVID-19 government lockdown. Thematic analysis was conducted using NVivo software.

Results: Thematic analysis highlighted three main themes: unmet needs; patient priorities; and recommendations. Women discussed unmet needs such as routine care fall-out, mental well-being, and financial difficulties. Patient priorities included cohesion among multidisciplinary BC care, proper communication with BC health professionals, and self-empowerment in BC care. Lastly, women recommended improvements for the transition from active treatment, support services, and adaptation of telemedicine.

"I do think that any patient going through cancer treatments, it's not just breast cancer, any patient… there needs to be a little bit more support for the aftercare."

Conclusion: The pandemic has impacted BC services considerably, and this impact has accentuated unmet needs for women with BC in Ireland. Considering these unmet needs from varying backgrounds, patient- centred priorities and recommendations were proposed. To conclude, the patient voice should be prioritized when implementing changes for improvement to health services.

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107 (PB-107) Poster

Comparative analysis of overall survival according to TNM stage of IDC and ILC

H. Kim[1], F.J. Tongcos[1], C. Jung Whan[1], Y. Ji Young[1], J. Seung Pil[1], L. Eun-Shin[1]. *[1]Korea university Anam hospital, Breast Surgery, Seoul, South Korea*

Background: Invasive lobular carcinoma (ILC) is the second most common cancer and has many differences compared to invasive ductal cancer (IDC) in epidemiology, clinicopathology, and natural history. ILC is characterized by hormone receptor-positive, human epidermal growth factor receptor 2 (HER 2) negative, and low to intermediate histologic grade, respectively. Diagnosing ILC is not easy. This may be why ILC has poor long-term outcomes compared to IDC. This study aims to investigate the clinicopathological characteristics of ILC and IDC in Korea and evaluate their impact on overall survival (OS) of each TNM stage of ILC and IDC.

Material and Methods: The Korean Breast Cancer Society Registry was queried for breast cancer patients who underwent breast cancer surgery between January 2006 and December 2011. We selected 54,348 patients whose tumors were classified as IDC and ILC. Overall survival until December 2014 was analyzed according to TNM stage using Kaplan-Meier curves and Log-rank test. Clinicopathological factors at the time of initial operation, such as sex, age, menopausal status, estrogen and progesterone receptor (ER and PR) expression, HER2 status, Ki-67, surgical methods in breast and axilla and treatment trends, were compared between IDC and ILC.

Results: Of 54,348 patients, there were 52,927 (97.4%) in IDC and 1,421 (2.6%) in ILC from 2006 to 2011. As of December 2014, the number of surviving patients was 49,038 (92.7%) for IDC and 1,328 (93.5%) for ILC. In univariate analysis, overall survival was influenced by age, ER and PR status, HER2 status, Ki67 and treatment trends regardless of histology, IDC and ILC ($P < 0.001$). Mortality rates were 7.3% in IDC and 6.5% in ILC. Overall survival did not differ between IDC and ILC (HR = 0.88, 95% CI = 0.74 to 1.09; P = 0.252). Additionally, overall survival according for TNM stage shows similar results in IDC and ILC (stage\xE2\x85; P = 0.946, stage II; P = 0.147, stage III; P = 0.486, stage IV; P = 0.272). When limiting the analyses to ER positive only, overall survival tended to be similar to before the restriction (HR = 0.88, 95% CI = 0.71 to 1.09; P = 0.137).

Conclusion: When comparing IDC and ILC, there are no significant differences in overall survival in the same stage and estrogen receptor positive group.

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108 (PB-108) Poster

The effect of prehabilitation in cancer patients: A systematic review and meta-analysis

K. Mostaqim[1], A. Lahousse[1], E. Roose[1], J. Nijs[1], D. Beckwée[1], S. Demunter[1], H. Ghijselings[1], C. Barcellos[1], A. Timmermans[2], E. Rheel[1], E. Huysmans[1], L. Leysen[1]. *[1]Vrije Universiteit Brussel, Department of Physiotherapy, Human Physiology and Anatomy, Faculty of Physical Education and Physiotherapy, Brussels, Belgium; [2]Universiteit Hasselt, Department of Physiotherapy, Diepenbeek, Belgium*

Background: Cancer rehabilitation during and following oncological treatment is an integrated and evidence-based aspect of oncological care. Contrary to the body of evidence supporting the use of cancer rehabilitation, little is known about the potential effects of cancer prehabilitation. With prehabilitation starting to gain noteworthy acceptance in the field of oncology care, this systematic review with meta-analysis aims to evaluate the effect of prehabilitation interventions on biopsychosocial outcomes in people with breast, colon, lung, and prostate cancer before and after treatment.

Material and Methods: PubMed, Web of Science, and Embase were screened for randomized controlled trials that study prehabilitation interventions in cancer patients. The interventions had to consist of an exercise, nutritional or psychological intervention, or a combination. Meta-analyses were performed when $\geq$2 studies were pooled, and subgroup and sensitivity analyses based on intervention and cancer types were performed in case of heterogeneity ($I^2 > 50\%$).

Results: Forty-five studies (n = 3,699) were included.

Prehabilitation has a significant effect before the start of cancer treatment on maximal inspiratory pressure, peak VO_2, peak expiratory flow, VO_2 at anaerobic threshold, watt max, walking capacity, walking distance (WD), lower body strength (BS), and physical functioning (PF).

Also, immediately after cancer treatment, significant effects in favor of prehabilitation were found for depressive symptoms, mental health, PF, WD, upper BS, forced vital capacity, fat-free mass, insulin sensitivity, number of days with chest tubes, length of hospital stay, pneumonia, atelectasis, post-treatment complications, and other pulmonary complications.

Even after a longer period (±1 month) significant results were found for interferon-γ, tumor necrosis factor-α, physical activity, PF, WD, and quality of life.

Process evaluation: Recently, a new literature search was performed, including 15 new studies. This has led to more data and allows for meta-analyses on two new outcomes, pain and fatigue. The new analyses will be ready by the time of the presentation.

Conclusions: Prehabilitation is a promising new approach, showing a positive effect on biopsychosocial outcomes in cancer patients before and

after cancer treatment. However, more research is needed to determine the optimal content of a prehabilitation intervention for each cancer type, and on strategies to improve treatment compliance.

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109 (PB-109) Poster

Recurrence of breast cancer after reconstruction with macro-textured silicone breast implants

J. Spoor[1], F. Dieleman[1], E. Bleiker[2], M.J. Vrancken Peeters[3], M. Mureau[4], F. van Leeuwen[1]. *[1]Netherlands Cancer Institute Antoni van Leeuwenhoek, Epidemiology, Amsterdam, Netherlands; [2]Netherlands Cancer Institute Antoni van Leeuwenhoek, Psychosocial Research and Epidemiology, Amsterdam, Netherlands; [3]Netherlands Cancer Institute Antoni van Leeuwenhoek, Surgical Oncology, Amsterdam, Netherlands; [4]Erasmus MC Cancer Institute, Plastic and Reconstructive Surgery, Rotterdam, Netherlands*

Background: The recently established association between silicone breast implants (SBIs) and the rare entity of Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) has raised concerns about recurrence of breast cancer in patients with implant-based reconstructions. These concerns apply specifically to implants with a macro- textured surface. In this retrospective cohort study, we investigated the effect of breast reconstruction with textured SBIs on long-term oncologic outcomes of breast cancer patients.

Methods: This study was conducted in two large tertiary referral centres in the Netherlands. Patients who had been treated for primary breast cancer in one of the two centres between January 1st 2000 and December 31st 2015 were included. Data were acquired from prospectively maintained institutional- and nation-wide registries. In addition, patients' files were reviewed manually. Missing data was accounted for by multiple imputation by chained equations (MICE). Patients were categorized according to their base-line treatment, which was Breast Conserving Surgery (BCS) or mastectomy. Reconstruction with a silicone breast implant was analysed as a time-dependent variable. The outcomes of interest were loco-regional recurrence-free survival (LRRFS) and distant metastasis-free survival (DMFS). Hazard Ratio's (HRs) were calculated through multivariable Cox proportional hazard models.

Results: Of the 4,696 women who were eligible for inclusion, 2,400 had received mastectomy. Of these women, 1,196 had been reconstructed with an SBI. Only macro-textured implants had been used. Mean (standard deviation) follow-up time was 11.3 (5.0) years. Compared with women who had undergone a conventional mastectomy or autologous reconstruction, women with implant-based reconstructions did not differ significantly in LRRFS or DMFS after accounting for various confounding factors (HR 0.84 [95% CI 0.64–1.11] and HR 0.88 [95% CI 0.70–1.11], respectively).

Conclusion: Reassuringly, this cohort study did not find a difference in long-term oncologic outcomes between women who had undergone a conventional mastectomy or autologous reconstruction and women who had received a reconstruction with a macro-textured SBI.

No conflict of interest.

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110 (PB-110) Poster

Defining musical toxicity and its prevalence among patients with breast cancer

J. Burlile[1], J. Cameron[2], H. Gunn[2], N. Larson[2], J. Boughey[3], M. Mrdutt[3], F. Couch[4], J. Olson[2], J. Bradt[5], Y. Sharifzadeh[1], K. Ruddy[6], D. Shumway[1], C. Loprinzi[6], E. Cathcart-Rake[6]. *[1]Mayo Clinic, Department of Radiation Oncology, Rochester, USA; [2]Mayo Clinic, Quantitative Health Sciences, Rochester, USA; [3]Mayo Clinic, Department of Surgery, Rochester, USA; [4]Mayo Clinic, Department of Laboratory Medicine and Pathology, Rochester, USA; [5]Mayo Clinic, Department of Physical Medicine and Rehabilitation, Rochester, USA; [6]Mayo Clinic, Department of Medicine, Division of Medical Oncology, Rochester, USA*

Background: Oncology care teams are acutely aware of the high prevalence of cancer, but few may know that 50% of American households have at least one musician, or that in the UK, 43% of adults play an instrument. Despite the significant number of musicians diagnosed with cancer each year, the effect of cancer treatments on musicianship has not been well-studied. Musicianship requires a high degree of fine motor and sensory control, and we hypothesize that musicians experience unique manifestations of breast cancer treatment toxicities.

Material and Methods: A nine-item Musical Toxicity Questionnaire was designed and sent to participants who had previously consented to enrollment in the Mayo Clinic Breast Cancer Registry, which contains nurse-abstracted data. The survey was distributed electronically via REDCap and was approved by the Mayo Clinic IRB. Treatment details were collected retrospectively.

Results: Of the 4075 surveys that were distributed, 1871 were returned. After removing non-musicians and blank surveys, a total of 535 respondents reported 802 unique musical endeavors: hence 29% (535/1871) of respondents identified as musicians. For these musicians, the median time from diagnosis to survey was 5.2 years (range 0.2 to 22.3 years). Most respondents had stage I or II disease (71%), and 32% were node positive. The most commonly reported musical endeavor was singing (51% of unique musical responses) followed by keyboard instruments (31%) and plucked stringed instruments (8%). Over one quarter (27%, 144/535) of respondents reported acute musical toxicity (AMT), defined as new difficulty playing music or singing during cancer treatments. For 73% of this group, musical toxicity persisted for longer than one year after finishing treatments or never resolved.

Of those respondents with AMT who received chemotherapy, 71% reported it negatively impacted their abilities, while 34% of those who received radiation and 28% of those who underwent surgery found those treatments negatively impactful. Non-wind players found surgery more impactful than vocalists or wind players. When comparing mastectomy to lumpectomy, more patients who underwent mastectomy reported AMT; further analysis of confounding factors is ongoing.

The most commonly affected musical abilities were the ability to sing or play for a long period of time (64% of those with AMT), accuracy (44%), and singing or playing quickly (36%). For wind players and vocalists, playing or singing long notes was also difficult.

Conclusion: Musicians represent a large cohort who are under-represented in the medical literature. AMT affects over one in four musicians receiving treatment for breast cancer, and for most patients, this difficulty does not resolve. Further investigation is warranted to better understand optimal treatment options for musicians who value the preservation of their musical abilities.

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111 (PB-111) Poster

Sexual HEalth and therapy adherence of hormone-sensitive breast CANcer survivors on maintenance endocrine therapy – The SHE-CAN project at Mount Sinai Hospital, Canada

A. Remtulla Tharani[1], J. Smith[1], N. Salman[1], S. Nandakumar[1], A. Abbruzzino[1], N. Singh[1], E. Richard[1], E. Hu[1], T. Czerwoniak[1], A. Hrycyshyn[1], A. Lawryshyn[1], K. Signarowski[1], J. Elliott[1], M. Pankiw[1], T. Wertelecky[1], S. Rattansi[1], G. Watson[1], C. Elser[1], C. Brezden-Masley[1]. *[1]Mount Sinai Hospital, Medicine, Toronto, Canada*

Introduction: Endocrine therapy (ET) is the standard of care for hormone sensitive (HR) breast cancer. While these drugs are highly efficacious and patients remain on them for extended periods of time, there are many side effects (Burstein et al., 2014). It is estimated that 20–30% of women on ET stop early due to these side effects, most commonly due to gynecological symptoms of menopause (GSM) (Barron et al., 2007). The purpose of this study is to better understand the vaginal health, sexual health, quality of life, sexual dysfunction, and adherence to therapy for HR breast cancer patients treated with anti-estrogen therapy.

Methods: From August 2021 to October 2023, women from Mount Sinai Hospital's outpatient oncology clinic who presented with HR breast cancer and who were being treated with anti-estrogen agents for a minimum of three months, were invited to participate in the study. Participants were asked to complete a survey examining their treatment experience and adherence, occurrence and frequency of GSM, patient-provider communication, along with two validated measurement tools (Female Sexual Function Index (FSFI) and Menopausal Quality of Life (MENQOL)). Medical history was also

reviewed from the participant's medical chart. Analysis was conducted using Excel.

Results: Of the 175 participants surveyed, the median age was 57 years [IQR:50–66] with 166 participants (95.4%) presenting in the adjuvant setting versus 8 patients (4.6%) in the metastatic setting. At the time of diagnosis, 75 participants (42.9%) were pre-menopausal, 19 participants (10.9%) were peri-menopausal, and 70 participants (40.0%) were post-menopausal. When surveyed, 42 participants (24.0%) were on tamoxifen and 126 participants (74.0%) were on an aromatase inhibitor. Within six months prior to survey completion, 10 participants (5.7%) stopped taking their medication for a period of time. Within the past year, participants reported experiencing the following symptoms "all of the time": vaginal dryness (26.3%), hot flashes (28.6%), insomnia (21.1%), decreased sex drive (36.6%), and pain during intercourse/masturbation (20.0%). Only 61 participants (34.9%) reported that a healthcare provider had asked them about experiencing GSM. The mean FSFI score was 21.7 ± 7.3 among 57 sexually active participants. Of these 57 participants, 42 (73.7%) had a final score of 26.5 or less, the cut-point used to demonstrate female sexual dysfunction. A total of 172 participants completed some portion of the MENQOL. Symptoms captured in the MENQOL's vasomotor domain were found to be most bothersome.

Conclusion: In our study, breast cancer patients on ET have significant sexual dysfunction. Management of GSM and communication between patients and healthcare providers is required and should be prioritized to improve sexual dysfunction and treatment adherence.

Conflict of interest:

Advisory Board: Dr. Brezden-Masley has been involved as a consultant for Agendia Inc., Astellas, AstraZeneca, Bristol–Myers Squibb, Eisai, Eli Lilly Canada Inc., Gilead, Knight, Merck Sharp and Dohme LLC, Mylan, Novartis Pharmaceuticals Canada Inc., Pfizer Canada Inc., Roche, Sanofi, Seagen, and Taiho Pharma Canada Inc. Dr. Geoffrey Watson is on the advisory board for Novartis and received honoraria from Pfizer, Astra Zeneca, Knight Therapeutics, Novartis, and Boehringer Ingelheim.

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112 (PB-112) Poster

Psychometric validation of the Danish BREAST-Q reconstruction module

C.B. Willert[1], K. Bang Kristensen[2], P. Envold Bidstrup[3], L. Mellemkjær[3], N. Kroman[4,5], A.M. Axø Gerdes[6], L. Rosenkrantz Hölmich[1,5]. *[1]Copenhagen University Hospital- Herlev and Gentofte, Department of Plastic Surgery, Herlev, Denmark; [2]Section of Biostatistics, Department of Public Health, Copenhagen, Denmark; [3]Danish Cancer Institute, Center for Cancer Research, Copenhagen, Denmark; [4]Copenhagen University Hospital-Herlev and Gentofte, Clinic of Breast Surgery, Gentofte, Denmark; [5]University of Copenhagen, Department of Clinical Medicine, Copenhagen, Denmark; [6]Rigshospitalet, Department of Genetics, Copenhagen, Denmark*

Background: Breast reconstruction is a major surgical procedure that carries potential complications and lasting side effects. Patient-reported outcome measures (PROMs) are essential for assessing the impact of breast reconstruction on quality of life. PROMs collect subjective information directly from the patient and add to clinical and functional outcomes. The objective of using PROMs is to generate quantitative measures from unmeasurable subjective qualities. It is essential that a PROM is adequate and that it has been psychometrically validated for use in the relevant patient population.

The BREAST-Q is a validated questionnaire for breast surgery outcomes. This study reports a psychometric validation of the Danish BREAST-Q reconstruction module, which consists of 7 pre-operative scales and 15 post-operative scales. This validation study aims to evaluate the reliability, validity, and utility in clinical practice and research.

Material and Methods: Eligible women were included from January 2019 to June 2020. The BREAST-Q was administered electronically. Psychometric analyses examined reliability and validity using both Rasch Analyses and Classical Test Theory. Scales with more than 40 complete responses were eligible for psychometric validation. Measurements included test for local response dependence, item fit, differential item functioning, and more.

Results: We included 140 patients in the pre-operative group and 257 in the post-operative group. The response rate was 82% and 78% respectively, which gave 115 pre-operative and 201 post-operative complete responses. We validated four pre-operative and 11 post-operative scales. Missing data was below 5% in all scales except for the pre-operative *sexual well-being* scale, the post-operative *satisfaction with breast* scale, the post-operative *physical well-being: abdomen* scale, and the post-operative *satisfaction with abdomen* scale. Floor effects were found in 4 scales and ceiling effects in 6 scales. The Rasch analyses disclosed evidence of local response dependence for most of the BREAST-Q scales, but very little evidence of poor item fit and differential item functioning remained after considering the local response dependence. The estimated reliability was lower after adjusting for local response dependence.

Conclusion: The Danish version of the BREAST-Q reconstruction module is a valid instrument and most of the scales are well-targeted to our sample of Danish patients. The evidence of local response dependence and the floor and ceiling effects suggests that estimates of the reliability of the BREAST-Q scales should be interpreted with some caution. Thus, the validity of the instrument was confirmed by our analyses.

No conflict of interest.

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113 (PB-113) Poster

Patient-reported outcomes of clinical importance during five years after breast cancer diagnosis using real world data

S. Gernaat[1], D. Mink van der Molen[2], R. Gal[2], M. Batenburg[2], F. van der Leij[3], I. Baas[4], S. Siesling[5], L. Veenendaal[6], W. Maarse[7], M. Sier[8], E. Schoenmaeckers[9], D. Evers[10], C. van der Pol[11], A. Doeksen[12], C. Bargon[12], D. Young-Afat[13], H. Verkooijen[2]. *UMBRELLA, [1]University Medical Center of Utrecht, Trail Office, Division of Imaging and Oncology, Utrecht, Netherlands; [2]University Medical Center of Utrecht, Division of Imaging and Oncology, Utrecht, Netherlands; [3]University Medical Center Utrecht, Department of Radiation Oncology, Utrecht, Netherlands; [4]University Medical Centre Utrecht, Department of Medical Oncology, Utrecht, Netherlands; [5]Netherlands Comprehensive Cancer Organization IKNL, Department of Research and Development, Utrecht, Netherlands; [6]Alexander Monro Hospital, Department of Surgery, Bilthoven, Netherlands; [7]University Medical Center of Utrecht, Department of Plastic- Reconstructive and Hand Surgery, Utrecht, Netherlands; [8]Rivierenland Hospital, Department of Surgery, Tiel, Netherlands; [9]Meander Medisch Centrum, Department of Surgery, Amersfoort, Netherlands; [10]Ziekenhuisgroep Twente, Department of Surgery, Hengelo, Netherlands; [11]Alrijne Hospital, Department of Surgery, Utrecht, Netherlands; [12]St. Antonius Hospital, Department of Surgery, Utrecht, Netherlands; [13]Amsterdam University Medical Center, 14. Department of Plastic, Reconstructive and Hand Surgery, Amsterdam, Netherlands*

Background: Long-term patient-reported outcomes (PROs) from unselected breast cancer populations are scarce, but highly important to identify knowledge gaps and unmet needs among survivors. We investigated PROs of women during five years following treatment for invasive breast cancer or ductal carcinoma in situ (DCIS).

Material and Methods: Women referred to five Dutch hospitals for primary breast cancer treatment were systematically asked to participate in the Utrecht cohort for Multiple BREast cancer intervention studies and Long-term evaLuAtion cohort (UMBRELLA; 2013–2023). Women with at least one completed questionnaire during follow-up were included. The EORTC QLQ-C30 was used to evaluate functional outcomes and symptoms. Anxiety and depression were assessed with the HADS. Outcomes were collected at cohort enrollment, three and six months, and every six months thereafter. Thresholds for EORTC QLQ-C30 scales were used to identify patients with clinically important problems. A HADS score of ³8 indicated an increased risk of an anxiety or depressive disorder. Clinical and treatment data were provided by Netherlands Cancer Registry. PROs from the Dutch general population (N = 2309), matched on age-range and sex, were retrieved from the PROFILES registry. Age-adjusted logistic regression models of factors associated with clinically important PROs at five years were estimated in the breast cancer population.

Results: There were 2280 out of 5810 UMBRELLA participants who reached five years follow-up, and of these, 787 (35%) provided PROs. At that time, most functioning and symptom scales like emotional-, role- and social functioning, QoL, fatigue, pain, appetite loss, nausea and vomiting of women

with breast cancer were comparable to the general population. Though, a significantly higher proportion of women with breast cancer reported clinically important cognitive functioning (28% vs. 13%, p < 0,01), physical functioning (29% vs. 23%, p < 0,01) and dyspnea (27% vs. 19%, p < 0,01) compared to the general population. Factors significantly associated with clinically important cognitive functioning were chemotherapy (OR 1,70 95 CI 1,20–2,41) and lymph node involvement (OR 1,43 95CI 1,01–2,02). Lower education (OR 1,73 95CI 1,24–2,43) and T stage II (OR 1,95 95CI 1,09–3,49) or T stage III/IV disease (OR 6,74 95CI 2,35–19,30) versus T0/DCIS were associated with clinically important physical functioning. Clinically important dyspnea was associated with lower education (OR 1,74 95CI 1,24–2,43) and chemotherapy (OR 1,78 95CI 1,24–2,57).

Conclusions: Although most functioning and symptoms scales were comparable to the general population, almost one third of women with breast cancer had clinically important cognitive- and physical functioning, or dyspnea after five years. Chemotherapy, T stage, lymph node status and education level may be used to identify women at risk.

No conflict of interest.

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114 (PB-114) Poster

Patients' perception of breast reconstruction after mastectomy: From socio-cultural barriers to unmet information needs?

Z. Naimi[1], A. Riahi[1], M. Bohli[1], R. Ben Amor[1], A. Hamdoun[1], G. Bouguerra[1], R. Haddad[1], L. Kochbati[1]. [1]*Abderrahmen Mami Hospital Ariana, Radiation Oncology Department, Ariana, Tunisia*

Background: The aim of this study was to assess breast cancer patients' perception of breast reconstruction (BR) after mastectomy and to identify determinant factors for breast reconstruction decision making.

Materials and Methods: A cross sectional study including Tunisian breast cancer (BC) patients treated with radical mastectomy was conducted. Patients were asked to fill in a 16-item survey assessing patients' personal experience, perception and apprehension regarding breast reconstructive surgery. Statistical association between socio-demographic factors and the survey outcomes were analysed.

Results: A total of 99 BC patients were included in this study. Mean age was 46 years-old. Thirty-five percent of patients had a college degree, 57.6% underwent basic education and 7% were illiterate. Eighty-two patients were married. Seventy-six percent of patients were aware of BR's possibility after mastectomy. Reconstruction options were discussed by referent doctors in 63% of cases but only 34% of patients were actually referred for BR. Only 2 patients did undergo BR, both young with a college degree and previous awareness of breast reconstructive surgery. In both cases, BR was related to "better self-esteem" and "better body image." Fifteen percent of the study cohort expressed the desire to undergo BR, mainly young (<45 year-old in 80% of cases) and married patients (60%). Patients' apprehensions regarding BR were attributed to "unwillingness to undergo any further surgery," "financial difficulties," "insufficient provided information" and "fear of disease recurrence" respectively in 23%, 15%, 14% and 12% of cases. Twelve patients reported the "lack of BR's need" as "mastectomy did not affect their self-esteem." Only one patient expressed the "fear of society perception." On a 0–10 scale, patients' mean self-assessed knowledge score regarding BR was 2(0–10). Age negatively correlated with patients' knowledge score (Pearson coefficient = – 0.26, p = 0.009) as well as the desire to undergo BR (Pearson coefficient = – 0.2, p = 0.01). Educational level and previous awareness of BR were statistically related to higher patient's knowledge score with Pearson coefficient of 0.4 and 0.44 (p < 0.0001), respectively. The desire to undergo BR statistically correlated with previous awareness of breast reconstructive surgery and marital status (Pearson coefficient 0.24 and 0.27, p ≤0 .01, respectively).

Conclusion: This study showed low rate of BR among Tunisian breast cancer survivors with a significant lack of awareness and knowledge regarding breast reconstructive surgery. Efforts should be made to provide accurate information and implement referral pathways to plastic surgeons to better fulfil patient's unmet information needs and overcome misconception about BR.

No conflict of interest.

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115 (PB-115) Poster

A pragmatic approach to lymphedema surveillance – as easy as ABC

J. Hing[1], S.M. Tan[1]. [1]*Changi General Hospital, Division of Breast Surgery, Singapore, Singapore*

Background: To date, there is a lack of standardisation of a lymphedema surveillance strategy. Local rates of BCRL prevalence and risk factors were not previously described. We presented key findings and recommendations from our centre's lymphedema surveillance strategy that used patients' reported symptoms, standard arm circumference measurements and clinical assessment in the diagnosis of BCRL.

Materials and Methods: We conducted a cross-sectional study of 511 breast cancer patients to assess the prevalence of BCRL, and its associated risk factors. We defined BCRL prevalence rates based on 3 criteria
A- **A**rm circumference measurements
B- patients' self-reporting of **B**CRL associated symptoms,
C- **C**linical diagnosis based on the International Society of Lymphology staging.

Results: The median follow-up of patients was 88.8 months. The cumulative prevalence rate in the cohort was 30.9%. The cohort of BCRL patients were older at time of diagnosis, had higher mean BMI (27.7 v 25.2), more likely to have mastectomy (77% vs 64.3%), axillary clearance, less likely breast reconstruction, higher-grade tumour, more lymph node excised, more advanced nodal disease, undergone adjuvant chemotherapy.

However, clinically significant BCRL rate was only 6.5% (33/511). Proportion of clinically significant BCRL in patients undergoing sentinel lymph node biopsy was 1.7% compared to 9.9% in patients who undergone axillary clearance. Majority of the BCRL were subclinical or mild in severity.

Conclusion: Our study showed that our rates of breast cancer related lymphedema were comparable to international standards and highlighted similar patient profiles who were at risk of developing BCRL. Having a comprehensive lymphedema surveillance strategy is paramount to pave way for future studies.

No conflict of interest.

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POSTER SESSION **20 March 2024** **9.00–18.30**

Supportive and Palliative Care Including End of Life Treatment

116 (PB-116) Poster

Correlation of chemotherapy-induced alopecia and quality of life among breast cancer patients undergoing scalp cooling device during chemotherapy

W. Yeo[1], F. Mo[1], L. Li[1], T. Lau[1], H. So[2], D. Lui[2], H. Wong[2], E. Leung[2], D. Chan[2], H. Yeo[1], K. Lai[1], E. Pang[1], Y. Li[1], C. Kwok[2]. [1]*The Chinese University of Hong Kong, Clinical Oncology, Hong Kong, Hong Kong;* [2]*Princess Margaret Hospital, Clinical Oncology, Hong Kong, Hong Kong*

Background: Chemotherapy-induced alopecia is a highly worrisome side effect for patients undergoing chemotherapy. This prospective two-center study aimed to determine the effectiveness of scalp cooling system in preventing chemotherapy-induced alopecia, and the associated quality of life (QoL) among patients with different extents of hair loss.

Methods: Chinese breast cancer patients who were planning for taxane- and/or anthracycline- based (neo)adjuvant chemotherapy were consented to enroll to this study. The Orbis Paxman Hair Loss Prevention System for scalp cooling was provided to studied patients. Dean score, as determined by patients, was adopted to measure the extent of chemotherapy-induced alopecia 4 weeks after the completion of all cycles of chemotherapy; 0–2 score reflects hair loss of 50% or less, while 3–4 score reflects hair loss more than 50%. Patient-reported QoL based on EORTC QLQ Q30 at baseline and at the end of chemotherapy were collected; change in QoL were compared between those with Dean scores 0–2 vs 3–4.

Results: 46 eligible patients underwent scalp cooling. Of these, 3 did not undergo any assessments, resulting in 43 patients who were assessable for outcomes. At the end of chemotherapy, the extents of chemotherapy-induced alopecia, as defined by Dean scores, were 0–2 for 30.2% and 3–4

for 69.8% of patients. At the end of chemotherapy, some degree of changes in QoL were observed in the two groups of patients. However, these changes did not reach statistical significance between patients who had Dean score 0–2 versus (vs) those with Dean score 3–4 score on aspects of functioning domains including physical functioning, emotional functioning, role functioning, social functioning and cognitive functioning, as well as global QoL. On the other hand, in terms of symptom scales, patients who had Dean score 0–2 had significantly less deterioration in fatigue (higher value indicating worse QoL) than those with Dean score 3–4; the change in scores being +0.85 and +14.63 respectively ($p = 0.041$). For other items under symptom scales, patients with Dean score 0–2 had less deterioration in QoL than those with Dean score 3–4, although not reaching statistical significance.

Conclusion: The present scalp cooling system provided a low efficacy in preventing chemotherapy-induced alopecia in breast cancer patients undergoing chemotherapy. However, at completion of chemotherapy, patients who achieved less extent of hair loss had less deterioration in fatigue than those who had more extent of hair loss.

Acknowledgement: The scalp cooling system was provided by Orbis Paxman Hair Loss Prevention System.

No conflict of interest.

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117 (PB-117) Poster

Modified Delphi consensus on interventions for radiation dermatitis in breast cancer: A Canadian expert perspective

T. Hijal[1], M. Yassa[2], E. Chow[3], J.M. Bourque[2], D. Rodin[3], E.M. Wiebe[4], N. Logie[5], H.M. Dahn[6], J.M. Caudrelier[7], I. Kong[8], V. Théberge[9], P. Wright[10], V. Panet-Raymond[1], B. Bashir[11], C.H. Avella Bolivar[12], S. Marchuk[13], M. Sauder[14], J. Claveau[15], N. Dayeh[16], J.Q. Cao[5]. *[1]McGill University, Oncology, Montreal, Canada; [2]Université de Montréal, Radiation Oncology, Montreal, Canada; [3]University of Toronto, Radiation Oncology, Toronto, Canada; [4]University of Alberta, Oncology, Edmonton, Canada; [5]University of Calgary, Oncology, Calgary, Canada; [6]Dalhousie University, Radiation Oncology, Halifax, Canada; [7]University of Ottawa, Radiology- Radiation Oncology and Medical Physics, Ottawa, Canada; [8]University of British Columbia, Surgery, Vancouver, Canada; [9]Université Laval, Radiation Oncology, Quebec, Canada; [10]University of Saskatchewan, Radiation Oncology, Saskatoon, Canada; [11]University of Manitoba, Radiology, Winnipeg, Canada; [12]McGill University Health Centre, Radiation Oncology, Montreal, Canada; [13]University of British Columbia, Radiation Oncology, Vancouver, Canada; [14]University of Toronto, Dermatology, Toronto, Canada; [15]Université Laval, Dermatology, Quebec, Canada; [16]L`Oreal Canada, Dermatological Beauty Division, Montreal, Canada*

Background: Acute radiation dermatitis is a prevalent adverse effect of radiotherapy in patients with breast cancer, and there is a lack of high-quality data regarding its prevention and management. Furthermore, the lack of standardized care for acute radiation dermatitis necessitates a comprehensive evaluation of available interventions. This study employs a modified Delphi consensus process to compile the perspectives of Canadian dermatology and breast cancer radiation oncology experts, aiming to establish consensus-based recommendations for the prevention and management of acute radiation dermatitis in breast cancer patients.

Methods: A four-round modified Delphi consensus process was organized with the participation of 19 Canadian experts. The process involved a systematic review of existing literature on the prevention and treatment of acute radiation dermatitis in breast cancer, from January 1946 to July 2023. After review of the literature, participants first provided their opinions on the strength and quality of the evidence for the 59 identified interventions. A second round involved assessing the degree to which the intervention would be recommended in either low- or high-risk settings. A third and a fourth round were used to consolidate consensus, which was determined by achieving a minimum agreement threshold of 75%. Recommendations were formulated based on the degree of consensus reached.

Results: After the first round, consensus for evidence of recommendation or suggestion in support of use of a product was reached for 4 prevention interventions, whereas near-consensus was reached for 7 other preventative interventions. With regards to the management of acute radiation dermatitis, there was consensus about the strength of evidence for 1 product and near-consensus for another. However, a significant number of interventions did not receive recommendations for either prevention or management due to insufficient or conflicting evidence. Three subsequent rounds are currently being held, and final recommendations are planned for the spring 2024.

Conclusion: This pan-Canadian modified Delphi consensus initiative provides expert-reviewed and evidence-based recommendations for interventions to prevent and manage acute radiation dermatitis in breast cancer patients. The endorsed interventions offer valuable guidance for clinicians, highlighting areas where consensus among experts has been achieved. The identified gaps in evidence underscore the imperative for continued research efforts to refine the standard of care for acute radiation dermatitis in breast cancer patients undergoing radiotherapy.

Conflict of interest:
Advisory Board: L'Oreal Canada

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118 (PB-118) Poster

Self-efficacy for coping among Moroccan patients newly diagnosed with locally advanced breast cancer: insights from cohort study

M. Omari[1], L. Amaadour[2], A. El Asri[3], K. Kassab[4], C. Tachallait[4], Z. Benbrahim[5], N. Mellas[5], K. El Rhazi[6], M.E.A. Ragala[4], J. El Hilaly[7], K. Halim[8], B. Zarrouq[9]. *[1]Faculty of Sciences Dhar El Mahraz- Sidi Mohamed Ben Abdallah University, Laboratory of Natural Substances, Pharmacology, Environment, Modeling, Health & Quality of Life, Fez, Morocco; [2]Hassan II University Hospital, Fez, Morocco, Department of Medical Oncology, Fez, Morocco; [3]Ministry of Health and Social Protection, Higher Institute of Nursing Professions and Health Techniques, Fez, Morocco; [4]Teacher`s Training College Ecole Normale Supérieure, Sidi Mohammed Ben Abdallah University, Department of Biology and Geology, Fez, Morocco; [5]Hassan II University Hospital, Department of Medical Oncology, Fez, Morocco; [6]Sidi Mohammed Ben Abdallah University, Laboratory of Epidemiology and Research in Health Sciences- Faculty of Medicine and Pharmacy, Fez, Morocco; [7]Regional Center of Education and Training CRME F, Laboratory of Pedagogical and Didactic Engineering of Sciences and Mathematics- Regional Center of Education and Training CRME F of Fez, Morocco, Fez, Morocco; [8]Teacher`s Training College Ecole Normale Supérieure, Sidi Mohammed Ben Abdallah University, Department of Human and Social Sciences - Education Sciences, Fez, Morocco; [9]Teacher`s Training College Ecole Normale Supérieure, Sidi Mohammed Ben Abdallah University Department of Biology and Geology, Department of Biology and Geology, Fez, Morocco*

Background: Women with breast cancer vary in their self-efficacy to cope with their disease and its announcement: a variability that has proven to be associated with many factors. This study, carried out in 2023 among Moroccan women newly diagnosed with locally advanced breast cancer at the university hospital center Hassan II- Fez, aims to determine the association of their Self-efficacy with their sociodemographic, clinical, physical and psychological symptoms.

Methods: The data were collected using a questionnaire on the sociodemographic and clinical characteristics of patients, containing psychometric scales on the Cancer Behavior Inventory Brief Arabic and Memorial Symptom Assessment Scale Arabic and Hospital Anxiety and Depression Scale Arabic. Descriptive results were presented in percentages and mean after the normality check (Skewness and Kurtosis test), bivariate analysis (Mann-Whitney U test, H Kruskal-Wallis test, Spearman test), univariate and multivariate analysis (enter) were performed by SPSS V 25.0 software. This study was approved by the hospital-university ethics committee related to University of Sidi Mohamed Ben Abdellah (N°24/18).

Results: The results of this cross-sectional study involved 209 women diagnosed with breast cancer indicated that the Patients'mean age was 47.42 (9.45) years old and the mean score for self-efficacy for coping with breast cancer was 91.19 (22.45).

The results of the linear regression show that the self-efficacy to cope with locally advanced breast cancer was significantly associated with the monthly family income less than 250$ compared to patient living with family without monthly income ($B = 9,16$; $p = 0.016$; IC 95% [1,70; 16,61]), depression ($B = -2,591$, $p < 0.001$; CI 95% [−3,60; −1,57]), pain ($B = -2,43$; $p = 0.04$, CI 95% [−4,84; −,023]) and numbness/tingling in the hands ($B = 3,73$; $p = ,009$; CI 95% [0,92; 6,54]). The coefficient of determination (R2) was 0.30, which

indicates that 38.2% of Self-efficacy for coping with cancer was attributable to this model.

Conclusion: The mean score of self-efficacy for coping with breast cancer in this study was high. The latter among Moroccan women in university hospital center Hassan II- Fez was adequate among patients after diagnosis. Monitoring the fluctuation of this feeling is probably required to strengthen therapeutic management during and after neoadjuvant chemotherapy.

No conflict of interest.

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119 (PB-119) Poster

Depression, anxiety and psychological alterations in breast cancer patients under neoadjuvant therapy: A systematic review

M. Omari[1], L. Amaadour[2], A. El Asri[3], Z. Benbrahim[4], N. Mellas[4], K. El Rhazi[5], M.E.A. Ragala[6], J. El Hilaly[7], K. Halima[8], B. Zarrouq[6]. *[1]Faculty of Sciences Dhar El Mahraz- Sidi Mohamed Ben Abdellah University, Laboratory of Natural Substances, Pharmacology, Environment, Modeling, Health & Quality of Life, Fez, Morocco; [2]Hassan II University Hospital, Department of Medical Oncology, Fez, Morocco; [3]Higher Institute of Nursing Professions and Health Techniques, Ministry of Health and Social Protection, Fez, Morocco; [4]Hassan II University Hospital, Department of Medical Oncology, Fez, Morocco; [5]Sidi Mohammed Ben Abdallah University, Laboratory of Epidemiology and Research in Health Sciences- Faculty of Medicine and Pharmacy, Fez, Morocco; [6]Teacher's Training College Ecole Normale Supérieure, Sidi Mohammed Ben Abdallah University, Department of Biology and Geology, Fez, Morocco; [7]Regional Center of Education and Training CRME F, Laboratory of Pedagogical and Didactic Engineering of Sciences and Mathematics, Fez, Morocco; [8]Teacher's Training College Ecole Normale Supérieure, Sidi Mohammed Ben Abdallah University, Department of Human and Social Sciences - Education Sciences, Fez, Morocco*

Background: Locally Advanced Breast cancer (LABC) patients who are eligible for neoadjuvant therapy (NAT) present a disorder of psychological variables during this treatment. The aim of this systematic review is to understanding depression, anxiety and psychological alterations by examining their prevalence and their change during NAT in LABC.

Material and Methods: Quantitative and qualitative studies that reported to depression, anxiety and others psychological alteration during NAT in LABC were included. The Cochrane Library, PubMed, Science direct, Scopus, and Web of Science databases were consulted, up until July 30, 2023. Selection was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses guidelines. the protocol has been registered at PROSPERO under number: CRD42021230300.

Results: This systematic review included a total of 37 quantitative and 4 qualitative studies. Among the questionnaires most frequently used in these studies were the HADS, Beck Depression Inventory, Hamilton Depression Rating Scale, Beck Anxiety Inventory, Self-Rated Anxiety Scale and psychosocial or emotional subscales of quality-of-life scales. Before the start of NAT, the prevalence of depression was as high as 46%, while it ranged from 40% to 78.5% after the end of NAT. As for anxiety, its prevalence did not exceed 54% before NAT, and only one study showed a prevalence of 27% after the end of NAT. Three studies showed a significant reduction in psychological distress during NAT. Four studies observed an improvement in anxiety, while only one study found a significant reduction in depression levels during NAT. We found that these psychological alterations were associated with factors such as extended family life, perceived social support, delays in diagnosis or initiation of neoadjuvant treatment, and the impact of the Covid-19 pandemic.

Conclusion: These findings highlight the importance of considering psychological alterations in the context of locally advanced breast cancer (LABC), from the diagnostic phase to the end of neoadjuvant treatment. The results suggest the need for effective psychological interventions.

No conflict of interest.

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122 (PB-122) Poster

A randomized controlled trial evaluating the role of a "patient reported outcome"-based interactive supportive tool for breast cancer patients using adjuvant endocrine therapy

R. Vanhoudt[1], A. Coolbrandt[2], H. Wildiers[1], P. Neven[3], J. Swinnen[4], C. Weltens[5], A. Smeets[1], I. Nevelsteen[1]. *[1]University Hospital of Leuven, Department of Oncology, Multidisciplinary Breast Centre, Leuven, Belgium; [2]University Hospital of Leuven, Department of Oncology, Leuven, Belgium; [3]University Hospital of Leuven, Department of Gynaecology and Obstetrics, Multidisciplinary Breast Centre, Leuven, Belgium; [4]Catholic University of Leuven, Department of Oncology, Leuven, Belgium; [5]University Hospital of Leuven, Department of Radiotherapy, Multidisciplinary Breast Centre, Leuven, Belgium*

Background: Menopausal side effects of adjuvant endocrine therapy (AET) in early HR+ breast cancer (BC) affect quality of life (QoL) and treatment compliance. Supportive digital tools have shown to be useful in guiding self-management of side effects and coaching healthy lifestyle. Co'moon is a motivational interactive tool combining e-learning and daily life scenario's focusing on self-management, lifestyle and patient-reported outcome measures (PROMs). We present a study evaluating its use and effect in a consecutive series of women with HR+ early BC.

Materials and Methods: HR+ early BC patients were randomized into 2 groups, within 2 months after initiation of AET. Standard postoperative care was provided in both groups, combined with a monthly online PROMs (EORTC FACT-ES) until first follow-up. Additional access to Co'moon was provided in the intervention group (IG) via the electronic patient file (EPF) for 3–4 months. A summary of the PROMs was provided for the health care professional (HCP) at time of consultation. The course of consultation and use of Co'moon were assessed by patients using a self-reported questionnaire. The difference in QoL was assessed in a descriptive manner after use of Co'moon. Additionally, the perceived impact on improving side effects of AET by the patient itself was measured. Thirdly, the added value of PROMs in the EPF was evaluated at consultation.

Results: 82 patients were included: 41 in the IG using Co'moon and 41 in the control group (CG) with similar baseline demographics. In the IG, 70% patients used Co'moon with an average of 1.6 times (range 1–11) for 16.27 minutes (range 1′-59′), mostly in the first week of availability. No clear difference in PROMs/QoL was reported (mean IG: 134 vs CG: 137, p = 0.445). However, more frequent use of Co'moon was associated with a higher perceived impact on improving side effects by the patient itself and subsequently QoL. In addition, 85% of IG-patients indicated that Co'moon might be useful for all BC patients. 64.11% of IG reported that PROMs were discussed during consultation. 76% of HCPs rated the PROMs-summary in the EPF as an added value.

Conclusion: Our digital supportive tool Co'moon for BC patients using AET did not clearly improve PROMs at 3–4 months. Nevertheless, Co'moon was used by the majority of patients when available. It was also found to be useful for other BC patients by its users due to a higher perceived self-impact on self-management and improving side effects. As the reported study is rather small with a short follow-up, an additional efficacy study is necessary to draw final conclusions regarding the usefulness of Co'moon in supporting BC patients using AET.

No conflict of interest.

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POSTER SESSION **20 March 2024** **9.00–18.30**

Systemic Treatment Including Immunotherapy, ADCs, CDKs etc: Early Disease

123 (PB-123) Poster

A Multicountry Discrete Choice Experiment (DCE) to Understand Patients' Preferences for HR+/HER2– Early Breast Cancer (EBC) Treatments

V. Harmer[1], C. Ammendolea[2], M. Ryan[3], F. Boyle[4], G. Werutsky[5], D. El Mouzain[6], D. Marshall[7], C. Thomas[8], S. Heidenreich[9], H. Lu[8], J.C. Mora Payan[10], D. Aubel[11], A. Danyliv[12], P. Pathak[13], N. Harbeck[14].
[1]Imperial College Healthcare NHS Trust, Medical Oncology, London, United Kingdom; [2]Canadian Breast Cancer Network, and Jewish General Hospital, Montreal, Québec, Canada; [3]University of Aberdeen, Health Economics Research Unit, Aberdeen, United Kingdom; [4]Mater Hospital, Patricia Ritchie Centre for Cancer Care and Research, North Sydney, NSW, Australia; [5]Latin American Cooperative Oncology Group, and Hospital São Lucas, PUCRS University, Porto Alegre, Brazil; [6]Abu Dhabi Stem Cells Center, Medical Oncology, Abu Dhabi, U.A.E.; [7]Cumming School of Medicine- University of Calgary, Medical Oncology, Calgary, AB, Canada; [8]Evidera, Patient-Centered Research, London, United Kingdom; [9]Evidera, Patient Preference and Patient-Centered Research, London, United Kingdom; [10]Novartis Pharmaceuticals Corporation, Global Medical Affairs, East Hanover, USA; [11]Novartis Pharmaceuticals Corporation, Global Patient Engagement, East Hanover, USA; [12]Novartis Pharma AG, Health Economics and Outcomes Research HEOR, Basel, Switzerland; [13]Novartis Pharmaceuticals Corporation, Health Economics and Outcomes Research HEOR, East Hanover, USA; [14]LMU University Hospital, Breast Center, Department of Obstetrics and Gynecology, Munich, Germany

Background: As the HR+/HER2 – EBC adjuvant therapy landscape evolves, treatment decisions are increasingly complex and need to incorporate patient (pt) perspectives. This study quantified the trade-offs that pts are willing to make when presented with a choice of adjuvant therapy.

Materials and Methods: Women with HR+/HER2– EBC were recruited from eight countries for an online DCE. The DCE design was informed by qualitative pt interviews (N = 40), clinical data, and consultation with a global steering committee comprising healthcare professionals, pt advocates, and health economists. Within the DCE, respondents made 10 choices between two hypothetical treatment options described by six attributes: venous thromboembolism (VTE), neutropenia, diarrhea, fatigue (risk of each respective adverse event), 5-year invasive disease-free survival (5-y iDFS), and treatment type/duration (endocrine therapy [ET; 5 y] alone, ET + 2 y CDK4/6i, or ET + 3 y CDK4/6i). The levels of attributes were varied systematically to ensure respondents faced trade-offs. DCE data were analyzed using a mixed logit model. Clinically relevant relative attribute importance (cRAI), based on clinically observed or expected levels of the attributes, and minimum acceptable improvement in iDFS were calculated.

Results: A total of 866 respondents completed the DCE (US, n = 160; France, n = 119; Spain, n = 114; Canada, n = 113; UK, n = 111; Germany, n = 106; South Korea, n = 72; Australia, n = 71). The mean age was 57.7 years, 19.1% (n = 165) were premenopausal, 1.7% (n = 15) were ET naive, and 36.4% (n = 315) had prior chemotherapy; 29.2% (n = 253), 55.0% (n = 477), and 15.7% (n = 136) had stage I, II, and III disease respectively. Increasing 5-y iDFS was the most important attribute to respondents, followed by reducing the risks of VTE, neutropenia, and diarrhea (Table). Reducing the risk of fatigue and treatment type/duration were less important than the other attributes. For every percent increase in the risk of diarrhea, neutropenia, or VTE, respondents would require corresponding increases in 5-y iDFS of 0.04%, 0.10%, and 2.16%, respectively.

Table: Clinically Relevant Relative Attribute Importance

Attribute	Clinically Relevant Range	cRAI
5-year iDFS	75.4%–82.7%	38.40%
VTE	0.7%–2.5%	20.42%
Neutropenia	5.6%–46.0%	20.26%
Diarrhea	8.7%–83.5%	14.99%
Treatment Type/ Duration	(ET alone) to (ET + 3 y CDK4/6i)[a]	3.65%
Fatigue	18.0%–40.9%	2.28%

[a]Range includes: ET (5 y) alone, ET + 2 y CDK4/6i, and ET + 3 y CDK4/6i.

Conclusions: When selecting an adjuvant therapy, patients considered both symptomatic and asymptomatic AEs to be important in addition to the 5-y iDFS. These preferences indicate that adding a CDK4/6i to ET may be a preferred option for many pts for the increased efficacy, but also the type of CDK4/6i would matter given different adverse event profiles.

Conflict of interest:
Other Substantive Relationships:
V. Harmer has nothing to disclose. C. Ammendolea reports grants from Novartis for CBCN advocacy and education funding personal fees/honoraria from Novartis. M. Ryan has nothing to disclose. F. Boyle has nothing to disclose. G. Werutsky reports personal fees/honoraria from Novartis. D. El Mouzain has nothing to disclose. D. Marshall reports travel support from ISPOR and personal fees/honorarium from for teaching a methods course research grants to institution from Canadian Institutes of Health Research, Genome Canada, Arthritis Society, Alberta Innovates consulting services to Analytica and Novartis with fees paid to institution. C. Thomas reports employment from Evidera, a business unit of Thermo Fisher Scientific's Clinical Research group. Evidera received funding for conducting the work outlined in this submission. S. Heidenreich reports employment from Evidera stock from Thermo Fisher Scientific. H. Lu reports employment from Evidera. JC. Mora Payan, D. Aubel, A. Danyliv, P. Pathak report employment and stock ownership from Novartis. N. Harbeck reports personal fees for consulting from Novartis, Roche, Sandoz/Hexal, Gilead, Seagen person fees for lectures from Novartis, Lilly, Pfizer, AstraZeneca, Daiichi Sankyo, MSD, Pierre-Fabre, Roche, Gilead, Seagen co-director the West German Study Group

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124 (PB-124) Poster

Adjuvant endocrine therapy choices in premenopausal patients with estrogen receptor-positive early breast cancer: insights from the GIM23-POSTER study

L. Arecco[1,2], M.M. Latocca[1], E. Blondeaux[3], F. Riccardi[4], V. Guarneri[5,6], G. Bisagni[7], F. Puglisi[8,9], A. Ferro[10], V. Adamo[11], F. Giovanardi[12], S. Tamberi[13], S. Donati[14], E. Landucci[15], L. Biganzoli[16], V. Rossi[17], S. Pastorino[1], E. de Azambuja[2], F. Poggio[1], M. Lambertini[1,18], L. Del Mastro[1,18]. *Gruppo Italiano Mammella (GIM), [1]IRCCS Ospedale Policlinico San Martino, Clinica di Oncologia Medica, Genoa, Italy; [2]Institut Jules Bordet and Université Libre de Bruxelles U.L.B., Department of Medical Oncology, Brussels, Belgium; [3]IRCCS Ospedale Policlinico San Martino, Clinical Trial Unit, Epidemiologia Clinica, Genoa, Italy; [4]AORN Cardarelli, UOC Oncologia, Naples, Italy; [5]Università di Padova, DiSCOG, Padova, Italy; [6]Istituto Oncologico Veneto IRCCS, UOC Oncologia 2, Padova, Italy; [7]Azienda USL-IRCCS di Reggio Emilia, Department of Oncology and Advanced Technologies- Oncology Unit, Reggio Emilia, Italy; [8]Centro di Riferimento Oncologico di Aviano CRO IRCCS, Department of Medical Oncology- Unit of Medical Oncology and Cancer Prevention, Aviano, Italy; [9]University of Udine, Department of Medicine, Udine, Italy; [10]Rete Clinica Senologica- APSS, Medical Oncology, Trento, Italy; [11]Papardo Hospital- University of Messina, Department of Human Pathology, Messina, Italy; [12]Comprehensive Cancer Centre, AUSL-IRCS di Reggio Emilia, Medical Oncology, Reggio Emilia, Italy; [13]Area Vasta Romagna- Faenza Hospital, Department of Medical Oncology, Faenza, Italy; [14]Versilia Hospital- Azienda Usl Toscana Nord Ovest, Medical Oncology, Lido di Camaiore, Italy; [15]S. Chiara Hospital, Medical Oncology, Pisa, Italy; [16]Hospital of Prato, Medical Oncology, Prato, Italy; [17]S. Camillo-Forlanini Hospital of Rome, Breast Unit, Rome, Italy; [18]Università degli Studi di*

Genova, Dipartimento di Medicina Interna e specialità Mediche DIMI, Genoa, Italy

Background: The majority of premenopausal patients with early breast cancer (eBC) are diagnosed with luminal-like disease and therefore candidate to receive adjuvant endocrine therapy (ET); however, no standardized patient-level criteria for tailoring adjuvant ET currently exist.

Material and Methods: The GIM23-POSTER study, conducted across various Italian institutions affiliated with the Gruppo Italiano Mammella (GIM), is a multicenter, prospective, observational study including premenopausal estrogen receptor-positive eBC patients candidate to receive adjuvant ET. Patients may have received prior chemotherapy (CT) in the (neo)adjuvant setting but not previous ET. The study explores the characteristics and choices of adjuvant ET prescribed, with a focus in patients at high-risk of recurrence according to monarchE and NATALEE trials.

Results: Between October 2019 and June 2022, 600 patients were enrolled, with a median age of 46 years (Interquartile range (IQR) 41–49). Almost half (278, 46.4%) of the patients had stage I disease, while 245 (40.8%) and 66 (11.0%) patients had stage II and III, respectively; 67 (11.2%) patients had HER2-positive disease. Overall, 218 (36.3%) patients received prior CT, of whom 91 (41.9%) in neoadjuvant setting. Among the 593 (98.8%) patients with available data on adjuvant ET prescribed, 149 (25.1%) patients received adjuvant tamoxifen alone, 83 (14.0%) tamoxifen + ovarian function suppression (OFS), while 361 (60.9%) patients received aromatase inhibitors (AIs) + OFS. Patients treated with AIs + OFS had larger tumours, more nodal involvement, higher tumor grade and more often received CT. Among patients who received neoadjuvant CT (n = 91), those who achieved pathological complete response (pCR) received AIs + OFS in 69.7% of cases while among the 48 (52.7%) patients that did not achieve a pCR, 83.3% received AIs + OFS. According to the enrollment criteria of the monarchE and NATALEE trials, 233 (44.8%) out of 520 HER2-negative patients were considered at clinical high-risk of recurrence. Among them, 82 patients (15.8%) met the criteria of high-risk for monarchE, while 232 patients (44.7%) met the criteria of clinical high-risk for the NATALEE trial (Table 1). 89.1% of patients in the monarchE high-risk group received AIs + OFS as adjuvant ET, while NATALEE high-risk patients received AIs + OFS in 74.1% of cases.

Table 1: Concordance between patients included in non-high-risk and high-risk categories according to monarchE and NATALEE trials

	Non-high-risk monarchE n (%)	High-risk monarchE n (%)	Total n (%)
Non-high-risk NATALEE	287	1	288
n (%)	(55.2%)	(0.1%)	(55.3%)
High-risk NATALEE n (%)	151	81	232
	(29.0%)	(15.7%)	(44.7%)
Total n (%)	438	82	520
	(84.2%)	(15.8%)	(100%)

Conclusions: AIs + OFS is the most commonly prescribed adjuvant endocrine strategy in premenopausal patients, especially for those patients considered at higher risk of recurrence.

Conflict of interest:

Other Substantive Relationships:

VG reports personal fees for advisory board membership for AstraZeneca, Daiichi Sankyo, Eisai, Eli Lilly, Exact Sciences, Gilead, Merck Serono, MSD, Novartis, Pfizer, Olema Oncology, Pierre Fabre personal fees as an invited speaker for AstraZeneca, Daiichi Sankyo, Eli Lilly, Exact Sciences, Gilead, GSK, Novartis, Roche and Zentiva personal fees for expert testimony for Eli Lilly.

FP reports Honoraria for advisory boards, activities as a speaker, travel grants, research grants: Amgen - Astrazeneca - Daichii Sankyo - Celgene - Eisai - Eli Lilly- - Exact Sciences- Gilead - Ipsen – Menarini- MSD - Novartis - Pierre Fabre - Pfizer - Roche - Seagen - Takeda – Viatris, Research funding Astrazeneca – Eisai - Roche.

AF reports support for attending meeting from Gilead, MSD and Pfizer honoraria from Pfizer, Novartis, Daiichi Sankyo, Ely Lilly, Seagen, Gilead, Astra Zeneca.

VA reports consultancy/advisory role/speaker bureau: Amgen, Astra Zeneca, BMS, Gilead, Lilly, MSD, Novartis, Pfizer, Roche, Sandoz, Sanofi, Sevier, Takeda.

FG reports support for attending meeting from Daichii Sankyo, Gilead, Novartis, Pfizer, Lilly participation on advisory board from Seagen LB reports personal financial interests (Honoraria, consultancy or advisory role): Amgen, AstraZeneca, Boehringer-Ingelheim, Daiichi-Sankyo, Eisai, Exact Sciences, Gilead, Lilly, Novartis, Pfizer, Pierre Fabre, Roche, Sanofi, SeaGen Institutional financial interests: Celgene, Genomic Health, Novartis

EdA reports financial: Honoraria and/or advisory board from Roche/GNE, Novartis, SeaGen, Zodiac, Libbs, Pierre Fabre, Lilly, Astra-Zeneca, MSD, Gilead Sciences Travel grants from Roche/GNE and Astra-Zeneca Research grant to my institution from Roche/GNE, Astra-Zeneca, and GSK/Novartis, Gilead Sciences Non-financial: ESMO director of Membership 2023–2024 and BSMO President 2023–2026.

FP reports support for attending meeting from Daichii Sankyo, Gilead, Novartis and Pfizer participation on advisory board from AstraZeneca and fees or honoraria from Eli Lilly, Novartis, Pfizer and Gilead, outside the submitted work.

ML reports advisory role for Roche, Lilly, Novartis, Astrazeneca, Pfizer, Seagen, Gilead, MSD and Exact Sciences and speaker honoraria from Roche, Lilly, Novartis, Pfizer, Sandoz, Libbs, and Takeda, and Travel Grants from Gilead outside the submitted work.

LDM reports institutional research grant from Eli Lilly, Novartis, Roche, Daiichi Sankyo, and Seagen consulting fees from Eli Lilly honoraria from Roche, Novartis, Pfizer, Eli Lilly, AstraZeneca, Merck Sharp and Dohme, Seagen, Gilead, Pierre Fabre, Eisa, Exact Sciences, and Ipsen support from Roche, Pfizer, and Eisai and fees paid for participation on a data safety monitoring board or advisory Board from Novartis, Roche, Eli Lilly, Pfizer, Daiichi-Sankyo, Exact Sciences, Gilead, Pierre Fabre, Eisai, AstraZeneca, and Agendia.

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125 (PB-125) Poster

Effectiveness of online education in improving clinicians' knowledge and confidence in the management of hereditary breast cancer

Z. Fiske[1], E. Ballard[2], D. Grainger[3], J. Cohen[4], M. Piccart[5], N. Harbeck[6].
[1]Medscape Global, Clinical Strategy, London, United Kingdom; [2]Medscape Global, Medical Education, London, United Kingdom; [3]Medscape Global, Medical Education, Paris, France; [4]WebMD, Outcomes, Durham, USA; [5]Institut Jules Bordet, Scientific Director, Brussels, Belgium; [6]LMU University Hospital, Dept. of OB&GYN, Munich, Germany

Background: The available treatment options for patients with hereditary breast cancer have increased in recent years and treatment algorithms are thus getting more complex. The objective of this study was to assess the effect of an online continuing medical education (CME) activity on clinicians' knowledge in understanding the latest developments in adjuvant therapies and their confidence in offering tailored treatment for patients with early-stage hereditary breast cancer.

Methods: This CME activity consisted of a 15-minute video discussion between 2 expert faculty with synchronised slides. Educational effect was assessed using a repeated-pair design with pre-/post-assessment. 3 multiple choice questions assessed knowledge, and 1 question rated on a Likert-type scale assessed confidence, with each individual serving as their own control. A McNemar's test assessed significance of improvement in the percentage of correct responses to knowledge/competence questions from pre- to post-assessment. P values < .05 are statistically significant. The activity launched on 29th of March, 2023, with data collected through 9th June, 2023 being reported in the current study.

Results: 129 oncologists, 109 surgeons and 32 obstetricians/gynaecologists who answered all the assessment questions were included in this analysis. All three physician groups demonstrated a statistically significant improvement in knowledge across all 3 learning themes, as shown in the table.

Table

	Correct Responses from Oncologists (n = 129)			Correct Responses from Surgeons (n = 109)			Correct Responses from obstetricians/ gynaecologists (n = 32)		
	Pre-Activity	Post-Activity	P-value	Pre-Activity	Post-Activity	P-value	Pre-Activity	Post-Activity	P-value
Defining patients at high risk of disease recurrence	89%	95%	<.01	61%	81%	<.001	44%	72%	<.01
Efficacy of adjuvant therapy	81%	91%	<.001	70%	82%	<.01	59%	81%	<.01
Safety profiles of adjuvant therapy	36%	51%	<.001	27%	40%	<.01	31%	44%	<.05

Additionally, 42% of oncologists, 46% of surgeons and 44% of obstetricians/gynaecologists reported increased confidence in offering tailored treatment for patients with early-stage hereditary breast cancer, and that increase was, on average, 53%, 83% and 95% among the three physician groups, respectively.

Conclusions: This analysis demonstrates the positive educational impact of an online CME activity on the latest developments in hereditary breast cancer across three key physician learner groups. As new data emerges and guidelines are updated, it will be important to educate clinicians on these developments so that they feel confident and competent when applying them in their clinical practice.

No conflict of interest.

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126 (PB-126) Poster

Impact of an Online Educational Activity on Oncologists' Knowledge and Competence Regrading the Optimal Use of Adjuvant Treatment in Breast Cancer

Z. Fiske[1], D. Grainger[2], J. Habib[3], V. Mülle[4]. *[1]Medscape Global, Clinical Strategy, London, United Kingdom; [2]Medscape Global, Medical Education, Paris, France; [3]Outcomes, Web MD, New York, USA; [4]University Medical Center, Hamburg-Eppendorf, Department of Gynecology, Hamburg, Germany*

Background: The management of early breast cancer is evolving with the introduction novel adjuvant therapies. The objective of this study was to assess if an online continuing medical education (CME) activity could improve the knowledge and competence of oncologists regarding individualised, evidence-based treatment for patients with early breast cancer.

Methods: This educational activity consisted of a 30-minute video presentation with synchronized slides. Educational effect was assessed using a repeated-pair design with pre-/post-assessment. 3 multiple choice questions assessed knowledge/competence, and 1 question rated on a Likert-type scale assessed confidence, with each individual serving as their own control. A chi-squared test assessed significance of improvement in the percentage of correct responses to knowledge/competence questions from pre- to post-assessment. *P* values < .05 are statistically significant. The activity launched on 15th of March, 2023, with data collected through 10th May, 2023 being reported in the current study.

Results: The analysis set consisted of responses from oncologists (n = 105) who answered all assessment questions during the study period. Analysis of pre- vs post-intervention responses demonstrated a significant improvement in overall knowledge and competence of oncologists (*P* < .01). Overall correct responses increased from 50% pre- to 63% post-CME. Specific areas of improvement include:

- Knowledge of clinical trial data about novel adjuvant CDK 4/6 inhibitor in HR-positive/HER2-negative early breast cancer (pre 37%, post 60%; *P* < .01)
- Knowledge of clinical trial data about neoadjuvant/adjuvant immunotherapy in triple-negative breast cancer (pre 70%, post 83%; *P* < .01)
- Competence of offering appropriate adjuvant treatment for patients with early breast cancer harboring BRCA mutations (pre 45%, post 57%; *P* < .01)

After education, 26% of oncologists had a measurable increase in confidence in tailoring treatment for patients with early breast cancer, and that increase was, on average, 52%.

Conclusions: This study demonstrated the success of an online, 30-minute CME activity on improving the knowledge, competence and confidence of oncologists regarding optimising treatment approaches in early breast cancer.

No conflict of interest.

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127 (PB-127) Poster

This study evaluates the impact of metabolic syndrome on pathological response in young patients (≤45 years) with HER2-neu negative breast cancer after preoperative chemotherapy. The study includes the analysis of pathologic data to determine the relationship between metabolic status and treatment efficacy

O. Martyniuk[1], T. Tarasenko[2], V. Chekhun[3], I. Smolanka[4], M. Bondar[2], P. Shudrak[2]. *[1]National Cancer Institute, Chemotherapy of solid tumours, Kyiv, Ukraine; [2]National Cancer Institute, Chemotherapy of solid tumour, Kyiv, Ukraine; [3]R.E. Kavetsky Institute of Experimental Pathology, Oncology and Radiobiology, R.E. Kavetsky Institute of Experimental Pathology, Oncology and Radiobiology, Kyiv, Ukraine; [4]National Cancer Institute, Breast Surgery, Kyiv, Ukraine*

Background: This study aims to investigate the influence of metabolic syndrome on pathological response in young patients with HER2-neu negative breast cancer after preoperative chemotherapy (4ddAC-12Tweekly). Understanding the relationship between metabolic status and treatment efficacy is key to personalized care for cancer patients.

Materials and Methods: The results of the pathological report of 88 patients diagnosed with HER2-neu negative breast cancer of stage IC-IIIB who received a full course of preoperative chemotherapy were analyzed. 40 patients met three or more criteria for metabolic syndrome, including impaired glucose tolerance, insulin resistance, high blood pressure, abdominal obesity, body mass index over 30, and impaired fat metabolism. 48 patients had only 1 sign of MS or no signs of metabolic syndrome at all.

Results: It was found that a complete response was 1.4 times more likely to be achieved in the group of patients without signs of metabolic syndrome. Women with a greater number (4 or more) of signs of metabolic syndrome, complete pathomorphosis was observed less often than in women with 3 signs of MS. Also, when analyzing the timing of the chemotherapy cycle, the delay was 2.1 times more frequent in patients in the MS group, and side effects of chemotherapy were 2.9 times more frequent in the MS group. This emphasizes the possible negative impact of advanced metabolic status on chemotherapy outcomes and quality of life.

Conclusions: The results suggest that the number of signs of metabolic syndrome may be a prognostic factor for the effectiveness of chemotherapy in patients with HER2-neu negative breast cancer. This is important information for the development of individualized treatment strategies and support during therapy, improving outcomes in this group of patients.

No conflict of interest.

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128 (PB-128) Poster

Impact of Oncotype DX Recurrence Score and Nottingham Prognostic Index on adjuvant treatment in patients with axillary lymph node micrometastasis in early breast cancer

A. Mumtaz[1], S. Szoradov[2], H. Khout[3], S. Gilani[3]. *[1]Nottingham Breast Institute, Oncoplastic Breast surgery, Nottingham, United Kingdom; [2]Nottingham City Hospital, Oncology, Nottingham, United Kingdom; [3]Nottingham Breast Institute, Breast Surgery, Nottingham, United Kingdom*

Background: Early Breast cancer (pT1-2) patients diagnosed with lymph-node micrometastasis (N1mic) in sentinel node biopsy (SNB) are not considered for further axillary treatment in non-neoadjuvant setting as evidence support no impact of N1mic on overall and recurrence free survival. Concurrently, the Oncotype DX Recurrence Score (RS) has proven invaluable in guiding chemotherapy recommendations within the NHS. In this study, we investigate the potential correlation between micrometastasis and the need for adjuvant chemotherapy as determined by RS and NPI.

Methods: We conducted a retrospective analysis of breast cancer patients with micrometastasis who underwent RS assessment between 2015 and 2023.

Results: Based on NPI score 3.4–5.4,patients were classified as intermediate risk. They were offered RS testing. Micrometastasis in SNB was found in 79 patients.20 received chemotherapy,10 patients of these had a high RS score (>25), and further 10 received chemotherapy due to high risk factors for recurrence, such as young age, high grade and lymphovascular invasion despite having RS scores of 7–25.59 patients (74.6%) with RS <25 were not recommended for chemotherapy. Predict score was calculated on all 79 patients, as it indicates the percentage benefit of chemotherapy in 5 and 10 years.10 patients who had chemotherapy due to high RS (>25) had

median 5.9% and 10 patients who had chemotherapy based on high risk factors for recurrence (RS <25) had 4.2% benefit of chemotherapy in 5 years according to Predict tool. Similarly, 59 patients had no chemotherapy due to low RS and low risk factors for recurrence had median 2.5% benefit of chemotherapy in 5 years. On average follow-up duration of 42.6 months, all patients in the non-chemotherapy group remained disease-free. Conversely, 2/10 patients who received chemotherapy due to a high RS score developed metastatic disease, with a mean survival time of 40.5 months and an average disease-free interval of 12 months.

Conclusion: In this study we observed that Predict tool assessment and RS are concordant. For NPI we consider micro-metastasis as node positive disease. However if we consider it as node negative and re-calculate the NPI score, 59 patients of non-chemotherapy group had mean NPI of 3.2. We have also shown that micrometastasis, while contributing to elevated NPI score, do not mandate the administration of chemotherapy. The prognostic impact and clinical relevance of this minimal nodal burden is debatable. Meta-analysis and multi-centered studies will be required to consider any change in the TNM staging and NPI scoring as micrometastasis is still considered in N1 category even when we do not offer treatment to patients in non-neoadjuvant setting.

No conflict of interest.

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POSTER SESSION **20 March 2024** **9.00–18.30**

Systemic Treatment Including Immunotherapy, ADCs, CDKs etc: Advanced Disease

129 (PB-129) Poster

Insights into the biological effect of targeting CDK12 in advanced ER+ breast cancer

A. Allotta[1], S. Kalsi[1], M. Ola[1], S. Hickey[1], S. Cocchiglia[1], F. Bane[1], K. Sheehan[2], D. Vareslija[3], L. Young[1], D. Ottaviani[1]. *[1]Royal College of Surgeons in Ireland, Surgery, Dublin, Ireland; [2]Beaumont Hospital, Pathology, Dublin, Ireland; [3]Royal College of Surgeons in Ireland, The School of Pharmacy and Biomolecular Sciences, Dublin, Ireland*

Introduction: A better understanding of breast cancer progression to metastasis is critical for identifying new therapeutic targets. Preliminary data from our lab described the role of CDK12 in regulating the pro-tumorigenic signalling in advanced ER+ breast cancer, and showed evidence of CDK12 modulating ER and MED1 chromatin accessibility. In this work we extend and validate these findings in novel cellular models and explored the biological outcomes of targeting CDK12 in advanced ER+ breast cancer.

Material and Methods: By immunofluorescence, co-immunoprecipitation and immunoblotting studies we characterized the co-expression, co-localization and functional cooperation between CDK12, ER and MED1 proteins. Using a small molecule inhibitor (CT7116), we treated endocrine resistant and metastatic ER+ breast cancer cells (24 h) and characterized by western blot studies the expression of CDK12 and its transcriptional-associated partners. Furthermore, the expression of apoptotic and DNA-damage related proteins was investigated.

Results and Discussions: CDK12 protein was found to be co-expressed with ER and MED1 proteins in the nuclei of advanced ER+ breast cancer cells. By reciprocal immunoprecipitation we found that ER/MED1 interaction was disrupted when CDK12 was inhibited, providing a mechanistic explanation for CDK12 regulating estrogen signalling. We then used CT7116 to target CDK12 in our cells, and found that besides ER and MED1, CT7116 reduced the expression of CDK12 partners CDK13 and CCNK, as well as total and activated form of RNA Pol II. Previous RNA-seq investigations revealed that besides ER signalling, CDK12 regulated DNA-repair, apoptosis and cell cycle progression. Indeed, pharmacological targeting of CDK12 with CT7116 led to a loss of RAD51 and gain of γH2AX expression, indicative of DNA damage. Likewise, the treatment resulted in increased expression of the apoptotic marker cPARP protein and CDKN1A, a potent cyclin-dependent kinase inhibitor, which overexpression results in cell cycle arrest. Finally, we explored the use of CT7116 in combination with standard-of-care therapies for ER+ advanced breast cancer (fulvestrant and ribociclib) for which our cell models were resistant to. By drug synergistic experiments, we ratified the sensitivity of our models to the use of CT7116, and defined the combo treatment to be likely additive.

Conclusion: Altogether, our data defined the functional effects of targeting CDK12 in advanced ER+ breast cancer, supports previous findings and encourage further studies on CDK12 transcriptional mode of action in endocrine resistant and metastatic breast cancer.

No conflict of interest.

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130 (PB-130) Poster

Effective anti-diarrhea strategies for pyrotinib (PYR) plus trastuzumab (H) and docetaxel (T) in patients (pts) with HER2+ metastatic breast cancer (mBC): a multicenter, phase 1 trial (PHAENNA)

H. Yao[1], Y. Shi[2], Y. Yao[3], H. Li[4], H. Zhou[5], S. Wang[6], Q. Qin[7], W. Li[8], C. Geng[9], M. Wang[10], X. Wang[11], Y. Cao[12], Z. Yu[13], C. Du[14], W. Zhao[15], S. Wu[16], Y. Cui[17], P. Liu[18], J. Lin[18], E. Song[1]. *PHAENNA, [1]Sun Yat-sen Memorial Hospital- Sun Yat-sen University, Phase I Clinical Research Center, Guangzhou, China; [2]Tianjin Medical University Cancer Institute and Hospital, Phase I Clinical Research Department, Tianjin, China; [3]Sun Yat-sen Memorial Hospital- Sun Yat-sen University, Department of Breast Surgery, Guangzhou, China; [4]The First Affiliated Hospital of Bengbu Medical College, Surgical Oncology, Bengbu, China; [5]The First Affiliated Hospital of Bengbu Medical College, Clinical Trial Research Center, Bengbu, China; [6]Xiangya Hospital Central South University, Breast Surgery, Changsha, China; [7]Xiangya Hospital Central South University, National Agency for Clinical Trial of Medicines, Changsha, China; [8]The First Hospital of Jilin University, Oncology Department, Changchun, China; [9]The Fourth Hospital of Hebei Medical University, Mammary Center, Shijiazhuang, China; [10]The Fourth Hospital of Hebei Medical University, Phase I Clinical Research Laboratory, Shijiazhuang, China; [11]Henan Key Laboratory of Cancer Epigenetics, Cancer Hospital, The First Affiliated Hospital, College of Clinical Medicine, Medical College of Henan University of Science and Technology, Department of Oncology, Luoyang, China; [12]The Affiliated Hospital of Qingdao University, Phase I Clinical Research Center, Qingdao, China; [13]The Affiliated Hospital of Qingdao University, Department of Oncology, Qingdao, China; [14]Shenzhen Hospital- Cancer Hospital, Chinese Academy of Medical Sciences, Medical Oncology, Shenzhen, China; [15]The First Affiliated Hospital of Shandong First Medical University Shandong Provincial Qianfoshan Hospital, Phase I Clinical Trial Laboratory, Jinan, China; [16]Peking University First Hospital, Department of Chemotherapy Oncology, Beijing, China; [17]Peking University First Hospital, Early Phase Clinical Trials Laboratory, Beijing, China; [18]Jiangsu Hengrui Pharmaceuticals Co., Ltd., Department of Clinical Development, Shanghai, China*

Background: PYR (an irreversible pan-HER inhibitor) plus H+T has promising anti-tumor activity for HER2+ BC, both in the neoadjuvant and 1L settings. Similar to other HER2i, diarrhea is the most common side effect with PYR. Here, we report the outcomes of different anti-diarrhea strategies when HER2+ mBC pts were treated with PYR plus H+T.

Material and Methods: Eligible pts received PYR (from C1D7, QD, oral) plus H (8 mg/kg in C1 and 6 mg/kg from C2, IV) and T (75 mg/m^2, IV) on D1 of each 21-day cycle. This study consisted of 5 cohorts. Cohort 1: pts received 400 mg PYR, without loperamide prophylaxis; Cohort 2: pts received 400 mg PYR, with loperamide prophylaxis; Cohort 3: pts received 320 mg PYR, with loperamide prophylaxis; Cohort 4: pts received 320 mg PYR, with use of loperamide for diarrhea management; Cohort 5: PYR dose escalation from 320 mg in the first 3 cycles to 400 mg thereafter was planned, with loperamide prophylaxis. Loperamide for primary prophylaxis of diarrhea was given in the first 2 cycles (C1D7, 4 mg TID; and then 2 mg QID).

Results: Totally, 97 pts were enrolled, with 14, 20, 20, 20, and 23 in each cohort. Of them, 0, 35.0%, 30.0%, 15.0%, and 26.1% had received prior anti-tumor therapy(ies) in the m setting, respectively. Incidence of G3 diarrhea in cohorts with loperamide use was lower than that in the cohort without loperamide prophylaxis (8.7–35.0% in Cohorts 2 to 5 vs. 64.3% in Cohort 1; Table 1). In the 3 cohorts with loperamide prophylaxis, dose escalation of PYR seemed to reduce the incidence of G3 diarrhea compared with a fixed dose of PYR (8.7% in Cohort 5 vs. 30.0% in Cohort 3 and 35.0% in Cohort 2). No G4 or G5 diarrhea was reported. ORR in all pts with measurable lesion was 80.0%, with 85.7%, 83.3%, 78.9%, 80.0%, and 73.7% in Cohort 1 to 5, respectively.

Table 1: Characteristics of diarrhea following PYR plus H+T

	Cohort 1 (N = 14)	Cohort 2 (N = 20)	Cohort 3 (N = 20)	Cohort 4 (N = 20)	Cohort 5 (N = 23)
Dose of PYR/Loperamide	400 mg/ No	400 mg/ Yes	320 mg/ Yes	320 mg/ Yes	320–400 mg*/Yes
PYR exposure, mo	14 (4–18)	12 (5–14)	5 (5–19)	9 (6–10)	6 (5–7)
G3 diarrhea	9 (64.3)	7 (35.0)	6 (30.0)	3 (15.0)	2 (8.7)
– Time to first episode, d	15 (12–16)	14 (10–17)	13.5 (12–22)	15 (12–218)	17 (17–17)
– Duration of episode, d	1 (1–2)	1 (1–2)	1 (1–1)	1 (1–1)	1 (1–1)
– Cumulative duration, d	2 (1–4)	1 (1–5)	1.5 (1–3)	1 (1–1)	5.5 (4–7)
Dose hold of PYR	2 (14.3)	2 (10.0)	2 (10.0)	0	1 (4.3)
Dose reduction of PYR	1 (7.1)	1 (5.0)	1 (5.0)	0	2 (8.7)
Discontinuation of PYR	0	0	0	0	0

Data are median (IQR) or n (%). *17 pts escalated to 400 mg in the 4th cycle.

Conclusions: The 320–400 mg dose escalation strategy of PYR and the use of loperamide are effective anti-diarrheal strategies while taking PYR plus H+T.

Conflict of interest:

Other Substantive Relationships: H.Yao, Y. Yao, S.Wang, Q. Qin, W. Li, Y. Cao, Z. Yu, and E. Song received research grants from Jiangsu Hengrui Pharmaceuticals. P. Liu and J, Lin are employees of Jiangsu Hengrui Pharmaceuticals.

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131 (PB-131) Poster

Trends of Absolute Lymphocyte Count and Neutrophil/Lymphocyte Ratio across Times among Breast Cancer Patients using Eribulin

M.X. Su[1], H.W. Lin[2], H.T.H. Nguyen[3], T.C. Lin[2], C.J. Chen[1], H.C. Wang[1], C.T. Wu[1], Y.C. Wu[1], G.Y. He[1], L.C. Liu[1], C.H. Huang[1]. *[1]China Medical University Hospital, Surgical Department, Taichung, Taiwan; [2]China Medical University, School of Pharmacy and Graduate Institute, Taichung, Taiwan; [3]Hanoi University of Pharmacy, Department of Clinical Pharmacy, Hanoi, Vietnam*

Background: Given inflammation plays an important role in cancer development and responses to therapy, an increasing number of studies exploring the associations of survival outcomes and the common inexpensive inflammatory biomarkers (e.g., absolute lymphocyte count [ALC] and the neutrophil-to-lymphocyte ratio [NLR]) for cancer patients. This study aimed to examine the ability of the ALC and NLR across different times after initiation of eribulin among patients with advanced/metastatic breast cancer (A/MBC) in predicting survival outcomes of A/MBC patients receiving eribulin. Accordingly, we hypothesized that the changes in the ALC and NLR across times after eribulin initiation would facilitate clinicians making better decisions to predict a patient's outcomes regardless concurrent use of eribulin or not.

Methods: We retrospectively reviewed A/MBC patients treated with eribulin from 2015 to 2019 at our institution. Patients' inflammatory biomarkers (ALC, NLR) were assessed and compared for the data prior to starting eribulin (baseline), and at 1, 3, and 6 months after initiating eribulin. We choose the following cut-offs to classify the enrolled patients into ALC and NLR high and low groups: 1000/μl for ALC and 3 for NLR. Given ALC and NLR trends were defined as increasing or decreasing by comparing the data in the later timing with the initial data. We further grouped patients into four groups upon their ALC/NLR trends (which was compared to its corresponding cut-off point) and its ratio as high/high[H/H], high/low[H/L], low/high[L/H], and low/low[L/L] trends in different timing. The Cox Proportion Hazard Regression analysis of progression-free survival (PFS) and overall survival (OS) were performed to explore the associations between the survival outcomes and ALC and NLR trends among four groups across times.

Results: Of 136 A/MBC patients treated with eribulin, 60 patients with complete blood tests were compared. Controlling for the age, number of metastatic sites and/or off/on treatment with eribulin, patients with low ALC versus high NLR at 3-month-test tended to increase their PFS and OS significantly as compared to those with high ALC versus low NLR (Hazard ratio; 95%CI = 2.5; 1.1-5.8 and 2.8; 1.2-6.9, respectively).

Conclusion: Accordingly, those A/MBC patients with low ALC versus high NLR at three month after eribulin initiation was statistically associated with patients' worse survival outcomes than those with high ALC versus low NLR but not for that at 1- or 6-month. In this case, it is sure that those widely available and inexpensive markers, i.e., ALC and NLR as compared to cut-off points at three month could be helpful indicators to identify individuals who potentially benefit from eribulin, as well as to predict their response and prognosis.

No conflict of interest.

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132 (PB-132) Poster

Single center analysis of safety profile and survival outcomes of intracranial radiation therapy in combination with trastuzumab-emtansine (T-DM1)

C. Mattioli[1], V. Salvestrini[1], C. Becherini[1], L. Visani[1], I. Desideri[1], D. Greto[1], E. Olmetto[1], E. Scoccimarro[1], M. Mangoni[1], A. Peruzzi[1], C. Orsatti[1], G. Frosini[1], I. Bonaparte[1], L. Burchini[1], M. Valzano[1], I. Meattini[1], L. Livi[1]. *[1]Azienda Ospedaliero Universitaria Careggi, Radiation Oncology Unit, Florence, Italy*

Background: Brain metastasis development is still an open issue for HER2-positive advanced breast cancer, with an incidence of about 50% among metastatic patients (pts). Radiotherapy (RT), either stereotactic radiosurgery (SRS) or whole brain radiotherapy (WBRT), is the standard of care for brain metastases. Despite the development and the widespread use of new HER2 target agents, strong data are missing relative to the combination of systemic therapies and RT.

In this single center experience, we aim to evaluate the safety profile and survival outcomes of combining the antibody drug conjugate Trastuzumab emtasine (TDM-1) with intracranial RT in metastatic breast cancer (MBC) pts.

Materials and Methods: We retrospectively collected data of patients treated with intracranial RT, both SRS or WBRT, at our center from January 2014 to June 2023. Characteristics of pts, brain metastases and treatment were recorded. Toxic effects were scored according to Common Terminology Criteria for Adverse Events (CTCAE v5.0). Statistical analysis of overall survival from intracranial RT (OS), progression-free survival from intracranial RT (PFS) and local control of treated brain metastasis were performed by the Kaplan Meier method.

Results: A total of 26 consecutive pts with HER2-positive MBC were treated for brain metastasis at our institution and included in the analysis. The median age was 51 years [range 31–81 years]. Single fraction (15–24 Gy) SRS was performed in 17 pts while 3 pts received hypofractionated (25Gy in 5 fractions) SRS. Gamma Knife-SRS, CyberKnife-SRS and Volumetric Modulated Arc Therapy (VMAT) were performed in 9 (34%), 7 (27%) and 4 (15%) pts. Six out of 26 (26%) pts underwent WBRT. The median time interval between T-DM1 administration and RT (both SRS/WBRT) was 16 days [range 3–27 days]. The median PFS from the first course of SRS/WBRT was 13 months [95% CI 7,5–18,5 months], whereas the median OS was not reached. The local control rate of brain lesions treated with SRS was 83% at 1 year and 75% at 2 years. Four pts out of the 20 pts treated with SRS, had acute toxicity; we reported grade (G) 1 amnesia (1pt), G2 visual deficit (1 pt), G2 dizziness (1 pt) and G2 brain oedema (1 pt). Radionecrosis developed in only 1 case (4%): the pt experienced G3 radionecrosis after 8 months from SRS, that required hospitalization and corticosteroid treatment. No chronic side effects were observed. Among pst treated with WBRT, we observed only a case of G2 brain oedema one month after RT.

Conclusion: To date, there is still a lack of prospective studies investigating the safety of combination between T-DM1 and intracranial RT. In this retrospective study, we observed a low incidence of G≥3 adverse events, but caution is still advised when combining T-DM1 with intracranial RT.

No conflict of interest.

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133 (PB-133) Poster

Temporal evolution of breast cancer brain metastases treatments and outcomes

M. Bottosso[1], G. Griguolo[1], F. Miglietta[1], M.C. Guarascio[1], A.C. Cattelan[1], C. Zurlo[1], V. Aldegheri[2], M. Marino[1], F. Zanghi[1], C.A. Giorgi[3], G. Vernaci[3], F. Girardi[3], M.V. Dieci[1], V. Guarneri[1]. *[1]University of Padova, Department of Surgery- Oncology and Gastroenterology, Padova, Italy; [2]Istituto Oncologico Veneto IRCCS, Radiology Department, Padova, Italy; [3]Istituto Oncologico Veneto IRCCS, Division of Oncology 2, Padova, Italy*

Background: Brain metastases (BM) are a common complication of advanced breast cancer (BC), typically associated with poor prognosis. The management of BM has significantly evolved over time, both in terms of locoregional and systemic therapies; however, the clinical impact of these changes remains partially unexplored.

We here evaluate the evolution of treatments and outcomes of BC patients (pts) with BM over two decades.

Material and Methods: Pts diagnosed with BCBM at Istituto Oncologico Veneto between 2000 and 2021 were included in 3 groups according to year of BM diagnosis: 2000–2007 (group A), 2008–2014 (group B) and 2015–2021 (group C). Clinicopathological features and treatments were collected from medical charts. BC subtype was defined according to hormone-receptor (HR) and HER2-status assessed on primary BC by clinical practice. Overall survival (OS) was defined as time from BM diagnosis to death or last follow-up. Prognostic factors were evaluated using log-rank test and univariate/multivariate Cox regression models.

Results: We included 343 pts: 50 in group A, 123 in group B and 170 in group C. Median age at BM diagnosis was 55 years (range 23–84). BC subtype at diagnosis was: HER2+ BC for 132 (38.5%), HR+/HER2- BC for 130 (37.9%) and HR-HER2- BC for 66 pts (19.2%).

While no differences in neurosurgery use ($p = 0.434$) were observed over the three time periods, a significant increase in stereotactic radiotherapy ($p < 0.001$) and a concomitant decrease in whole-brain radiotherapy use was observed over time ($p = 0.010$).

Regarding systemic therapies, among HR+ BC pts, a significant increase in endocrine therapy use after BM diagnosis was observed (18.2%, 33.4%, 43.5% in group A, B, C, respectively; $p = 0.026$). Among HER2+ BC pts, significantly more received anti-HER2 therapy after BM diagnosis in recent years (28.0%, 74.4%, 84.4% in group A, B, C, respectively; $p < 0,001$), with more recent pts also receiving a higher number of anti-HER2 therapy lines ($p = 0.002$).

No significant OS improvement over time was observed in the overall study cohort (median OS 6.4 months, 7.6 months, 7.9 months in group A, B, C, respectively; $p = 0.145$). A significant OS improvement was selectively observed only in patients with HR-/HER2+ BC (median OS 6.2 months, 7.6 months, 23.6 months in group A, B, C, respectively; $p = 0.005$). While HER2-positivity was not prognostic in group A ($p = 0.221$ at univariate analysis), it became a significant prognostic factor in group C ($p = 0.006$ at multivariate analysis).

Conclusions: Over two decades, locoregional and systemic therapy of pts with BCBM has significantly changed. However, in this large real-world cohort, a significant improvement in OS was only observed in pts with HR-/HER2+ BCBM, probably due to the increased availability of anti-HER2 therapies with intracranial activity.

Conflict of interest:

Advisory Board: GG reports personal fees as advisory boards for Gilead, Seagen and Menarini FM reports personal fees for advisory role from MSD MVD reports personal fees for consultancy/advisory role from Eli Lilly, Pfizer, Novartis, Seagen, Gilead, MSD, Exact Sciences, AstraZeneca, Roche, Daiichi Sankyo, Roche VG reports personal fees for advisory board membership for AstraZeneca, Daiichi Sankyo, Eisai, Eli Lilly, Exact Sciences, Gilead, Merck Serono, MSD, Novartis, Pfizer, Olema Oncology, Pierre Fabre.

Other Substantive Relationships: GG reports personal fees as invited speaker from Eli Lilly, Novartis and MSD FM reports personal fees from Roche, Novartis, Seagen, Pfizer, Lilly, Gilead and MSD CAG reports personal fees from Novartis, Lilly and AstraZeneca FG reported personal fees as honoraria from AstraZeneca and Lilly VG reports personal fees as an invited speaker for AstraZeneca, Daiichi Sankyo, Eli Lilly, Exact Sciences, Gilead, GSK, Novartis, Roche and Zentiva personal fees for expert testimony for Eli Lilly.

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134 (PB-134) Poster

A Prospective, Single arm, Multicentre, Post-marketing Study (Phase IV) to evaluate effectiveness of Dr. Reddy's Trastuzumab (DRL_TZ) in Patients with HER2-Positive Advanced Breast Cancer

S. Nag[1], C. Deshmukh[2], M. Jain[3], P. Reddy[4], N. Reddy[5], N. Maharaj[6], R. Desai[7], V. Natarajan[7], K. Gaurav[8]. *[1]Sahyadri Super Speciality Hospital, Medical Oncology, Pune, India; [2]Deenanath Mangeshkar Hospital and Research centre, Medical Oncology, Pune, India; [3]Noble Hospital Pvt. Ltd, Medical Oncology, Pune, India; [4]Dr. Reddy`s Laboratories, Biostats and data management, Hyderabad, India; [5]Dr Reddy`s Laboratories, Medical and Regulatory Affairs, Hyderabad, India; [6]Dr Reddy`s Laboratories, Clinical Development, Hyderabad, India; [7]Dr. Reddy`s Laboratories, Medical Affairs, Hyderabad, India; [8]Dr Reddy`s Laboratories, Medical Affairs, Hyderabad, India*

Background: Dr. Reddy's Trastuzumab (DRL_TZ) is a biosimilar to reference trastuzumab (Herceptin®), with established pharmacokinetics, efficacy and safety similarity. Post-approval studies are necessary for understanding these drugs in clinical settings. This post-marketing study evaluated the effectiveness of DRL_TZ in HER2-positive Advanced Breast Cancer (HER2+ ABC).

Materials and Methods: This prospective, single-arm, multicenter (14 Indian centers) phase IV study (Feb 2019 - July 2021) evaluated DRL_TZ's effectiveness in female HER2+ ABC patients (≥18 years). Eligible patients with confirmed HER2+ ABC (IHC 3+ or 2+ with FISH confirmation), who had not received taxane & trastuzumab treatment before for metastatic disease with at least 1 measurable lesion as per the RECIST 1.1 were enrolled. Patients received DRL_TZ (loading dose 8 mg/kg and 6 mg/kg for subsequent cycles) as a 3 weekly-regimen in combination with either paclitaxel or docetaxel for up to 8 cycles. The effectiveness endpoint was Progression-free survival (PFS) and Best Overall Response Rate (ORR) at completion of 8 cycles or at end-of-study (EOS).

Results: One hundred and sixty-two patients with HER2+ ABC with a mean (±SD) age of 50.4 (11.33) years, were enrolled in the study. One hundred and thirty-nine (85.8%) patients had IHC3+. ECOG status of 0, 1 and 2 was noted in 22 (13.6%), 139 (85.8%) and 1 (0.6%) patient, respectively. One hundred and ten patients (67.9%) of HER2+ ABC (95% CI: 60.12, 75.01) demonstrated a PFS at EOS. The best ORR is 56.2%, observed in 91 patients of ABC (95% CI: 48.17, 63.95). Seven (4.3%) patients (CI: 1.75, 8.70) showed Complete Response. Partial response was observed in 84 (51.9%) patients of HER2+ ABC (95% CI: 43.88, 59.76).

Conclusions: This PMS demonstrated real-world effectiveness of DRL_TZ in HER2+ ABC to be consistent with literature.

Conflict of interest:

Other Substantive Relationships: Dr Shona Nag, Dr Chetan and Dr Minish Jain were PIs for the study. Others are employed by DRL.

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135 (PB-135) Poster

A Prospective, Single arm, Multicentre, Post-marketing Study (Phase IV) to evaluate safety and immunogenicity of Dr. Reddy's Trastuzumab (DRL_TZ) in Patients with HER2-Positive Advanced Breast Cancer

S. Nag[1], C. Deshmukh[2], M. Jain[3], P. Reddy[4], N. Reddy[5], N. Maharaj[6], R. Desai[7], V. Natarajan[8], K. Gaurav[8]. *[1]Sahyadri Super Speciality Hospital, Medical Oncology, Pune, India; [2]Deenanath Mangeshkar Hospital and Research centre, Medical Oncology, Pune, India; [3]Noble Hospital Pvt. Ltd, Medical Oncology, Pune, India; [4]Dr Reddy`s Laboratories, Biostats and data management, Hyderabad, India; [5]Dr Reddy`s Laboratories, Medical and Regulatory Affairs, Hyderabad, India; [6]Dr Reddy`s Laboratories, Clinical Development, Hyderabad, India; [7]Dr Reddy`s Laboratories, Medical Affairs, Medical Affairs, India; [8]Dr. Reddy`s Laboratories, Medical Affairs, Hyderabad, India*

Background: Dr. Reddy's Trastuzumab (DRL_TZ), a biosimilar to reference trastuzumab (Herceptin®), was evaluated for the safety & immunogenicity in HER2-positive Advanced Breast Cancer (HER2+ ABC) as part of post-marketing surveillance (PMS).

Material and Methods: This prospective, single-arm, multicenter (14 Indian centers) phase IV study (Feb 2019 - July 2021) evaluated DRL_TZ safety and immunogenicity in female HER2+ ABC patients (≥18 years).

Eligible patients had HER2+ ABC (IHC 3+ or 2+ with FISH confirmation), who had not received taxane & trastuzumab treatment before for metastatic disease and had at least 1 measurable lesion as per the RECIST 1.1. Patients received DRL_TZ (loading dose 8 mg/kg and 6 mg/kg for subsequent cycles q3w) in combination with either paclitaxel or docetaxel for up to 8 cycles. Safety endpoints were incidence of adverse events (AEs), serious adverse events (SAEs), LVEF decrease/LV dysfunction and Infusion Related Reactions (IRRs). Immunogenicity was assessed by studying anti-trastuzumab antibodies (ADA).

Results: One hundred and sixty-two patients with HER2+ ABC were enrolled in the study. One hundred and twenty-six patients (77.8%) experienced 352 Treatment-emergent adverse events (TEAEs). Grade ≥3 TEAE were noted in 8 (4.8%) patients. Eight (4.8%) patients experienced AE that led to permanent discontinuation of study drug or withdrawal from the study. SAE noted in 7 (4.3%) patients [3 (1.85%) was related to study drug]. One (0.6%) patient had fatal SAE due to COVID-19 and was not related to the study drug. Common TEAEs (%) included alopecia (37.7), asthenia (12.3), urinary tract infection (12.3), peripheral neuropathy (11.7), anemia (11.7), diarrhea (8.6) and back pain (8). IRR was noted in 3 (1.9%) patients. LVEF decline [n (%)] of <5%, 5–10% and ≥10% was noted in 18 (11.1), 14 (8.6) and 1 (0.6) patient, respectively. Confirmatory assay 2 for ADA was positive in 3 (3.9%) patients (3.9%) at end-of-study and 1 (1.3%) patient was positive for neutralizing ADA; none had corresponding AE.

Conclusion: This PMS demonstrated real-world safety & immunogenicity of DRL_TZ in HER2+ ABC to be consistent with literature.

Conflict of interest:

Other Substantive Relationships: Dr Shona Nag, Dr Chetan and Dr Minish Jain were PIs for the study. Others are employed by DRL.

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136 (PB-136) Poster

Clinical outcome of treatment rechallenge with HER2-directed antibody-drug conjugate in metastatic breast cancer: a single-centered real-world experience

M. Ando[1], T. Shimoi[2], T. Imai[2], Y. Kojima[2], K. Sudo[2], K. Yonemori[2].
[1]Perpetual Succour Hospital, Cebu Cancer Institute, Cebu, Philippines; [2]National Cancer Center Hospital, Department of Medical Oncology, Tokyo, Japan

Background: The advent of antibody-drug conjugates (ADCs) has revolutionized the therapeutic landscape of HER2-positive metastatic breast cancer (mBCa). ADCs are a novel biopharmaceutical drug class that contains an antigen-specific antibody backbone coupled with a potent biologically active cytotoxic payload, resulting in improved patient outcomes. In the DESTINY-Breast01 trial, trastuzumab deruxtecan (TDxd) demonstrated a response rate of 64% among patients who received trastuzumab emtansine (T-DM1). Results from the phase 3 DESTINY-Breast02 study revealed a statistically significant improvement in progression-free survival (PFS) and overall survival compared with the physicians' choice in the post-T-DM1 setting. This study aims to evaluate the clinical efficacy of ADC rechallenge (T-DM1 to TDxd) in heavily treated mBCa through its best response rates and progression-free survival (PFS) benefit in the real-world setting.

Methods: We retrospectively identified 25 patients with heavily treated mBCa who received ADC rechallenge treated between January 2019 to March 2023 at the National Cancer Center Hospital, Tokyo, Japan. Patients' clinical characteristics, response rates, and survival were evaluated. PFS2/PFS1 ratio was evaluated where PFS2 was the PFS for ADC rechallenge and PFS1 was the PFS for a prior line of treatment. PFS2/PFS1 ratio >1.3 was defined as treatment benefit in non-homogenous heavily pre-treated patients.

Results: Median number of previous lines of therapy received was 6 (range: 4 to 12). ADC rechallenge with TDxd led to an objective response rate of 72% and a clinical benefit rate of 80% with a median progression-free survival of 7.2 months (95% CI, 2.13 to 12.28). Toxicities that led to TDxd discontinuation included interstitial lung disease (ILD) (24%) and grade 3 transaminitis (4%). The median time to the first ILD event was 7.0 months (range: 2.80 to 12.83). A PFS2/PFS1 ratio of >1.3 was observed in 56% of the ADC rechallenge population.

Conclusion: ADC rechallenge may achieve disease control and appears to be a reasonable option for patients with HER2-positive mBCa who have received multiple treatment lines. Further studies are needed to focus on identifying biomarkers predictive of benefits with ADC rechallenge.

No conflict of interest.

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137 (PB-137) Poster

Clinically locally advanced breast cancers: the EUSOMA experience

P. Van Dam[1], M. Tomatis[2], A. Ponti[2], L. Marotti[3], C. Aristei[4], M.J. Cardoso[5], K.L. Cheung[6], G. Curigliano[7], J. de Vries[8], D. Santini[9], F. Sardanelli[10], I.T. Rubio[11]. *On behalf of the Eusoma Working Group, [1]University Hospital Antwerp, Oncology Dept., Edegem, Belgium; [2]European Society of Breast Cancer Specialists EUSOMA, Eusoma Datacentre, Florence, Italy; [3]EUSOMA, Head Office, Florence, Italy; [4]University of Perugia, Department of Medicine and Surgery, Perugia, Italy; [5]Champalimaud Clinical Center, Breast Unit, Lisbon, Portugal; [6]School of Medicine and University of Nottingham, Academic Unit for Translational Medical Sciences, Derby, United Kingdom; [7]European Institute of Oncology, Division of New Drugs and Early Drug Development for Innovative Therapies, Milan, Italy; [8]University Medical Center Groningen, University Medical Center Groningen, Groningen, Netherlands; [9]IRCCS Azienda Ospedaliero-Universitaria di Bologna, Pathology Unit, Bologna, Italy; [10]IRCCS Policlinico San Donato, Unit of Radiology, San Donato Milanese, Mi, Italy; [11]Clinica Universidad de Navarra, Breast Surgical Oncology, Madrid, Spain*

Background: The aim of the present study was to assess the frequency, clinical and pathologic characteristics and treatment modalities used for clinically locally advanced breast cancers (LABCs). Comparisons were made between cT4d and cT4abc LABCs.

Materials and Methods: The European Society of Breast Cancer specialists (EUSOMA) data warehouse, created in 2006, contains over 200,000 BC cases. For the present analysis, we searched for T4a-d cases in the last decade (2013–2022).

Results: We identified 977/96000 cases of IBC (T4d) and 2427/96000 cases of T4abc, of which 542 (55.4%) and 251 (10.3%) had metastatic disease at presentation, respectively ($p = 0.054$). Median age of the cT4d and cT4abc patients respectively was 59 (range 20–100) and 73 (24 – 100) years ($p < 0.001$). IBC was significantly more frequent of aggressive molecular subtypes (HR-/HER2-, HR+/Her2+, HR-/HER2, $p \leq 0.010$). Complete pathology reporting was less demanding and lower for cT4d and dT4abc cases for the period 2013–2017 (61.7% and 48.7%) but improved significantly for 2018–2022 (96.1% and 95.1%; $p < 0.001$). Neo-adjuvant treatment, chemotherapy, endocrine treatment in cT4d/HR+ and radiotherapy were respectively given in 76.2%, 79.4%, 85.2% and 80.7% of cT4dM0 cases compared to 31.7%, 45.9%, 89.5%, and 61.4% of cT4abcM0 cases (all $p < 0.001$). In the patients with non-metastatic disease at presentation, 83.2% of cT4d patients received mastectomy, 5.5% breast conserving surgery and 11.2% no surgery, compared to 72.5% ($p < 0.001$), 17.4.% ($p < 0.001$) and 9.9% (not significant, NS) of cT4abc patients, respectively. Patients with HER2+ disease were treated with chemotherapy and anti-HER2 biological drugs in 98.0% of cT4d and 97.1% and cT4abc cases (NS). Patients with T4d tumors with metastatic disease at the time of diagnosis were treated with mastectomy, chemotherapy, endocrine treatment and radiotherapy in cT4d/HR+ in 32.1%, 71.4%, 85.2% and 30.2% compared to 36.4% (NS), 47.3% ($p < 0.001$), 89.5% (NS), and 25.2% ($p < 0.001$) in T4abcM0 cases.

Conclusions: Given that the preferred treatment sequence for cT4dM0 patients according to the ESMO and NCCN guidelines is neoadjuvant chemotherapy followed by mastectomy, radiotherapy and, if relevant, adjuvant endocrine and/or targeted treatment, it is striking that in the current real-life analysis these treatment modalities seem to be underused (except for anti-HER therapy). In order to optimize the outcomes of patients with cT4dM0 BC, audit and quality indicators should specifically focus on the use of this multimodality treatment. Administration of endocrine therapy in ER +/M1 patients may also be an area for improvement. Particularly in patients with cT4abc LABC, patient preference and comorbidities often drive decisions on the treatment trajectory, making assessment of quality of care more complicated.

No conflict of interest.

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138 (PB-138) Poster

Efficacy and safety of abemaciclib in the treatment of HR+ HER2- advanced breast cancer: real world data

K. Cankar[1], E. Matos[1], T. Ovčariček[1], M. Auprih[1], N. Režun[1], K. Dejanovic[1]. [1]*Oncology Institute of Ljubljana, Department of Medical Oncology, Ljubljana, Slovenia*

Background: Abemaciclib (abema) is a iCDK4/6 approved for treatment of HR+HER2- ABC. Randomised clinical trials have shown promising results in terms of PFS and OS. This combination is associated with additional toxicity and cost, as many patients can achieve durable disease remission with ET alone. Objective of the study was to evaluate clinical experience with the drug in terms of efficacy and safety.

Materials and Methods: *R*etrospective analysis of pts treated with abema from Nov 2019 to Febr 2022 was performed. Pts information were obtained from the Slovenian National Institute of Public Health and the Slovenian Cancer Registry. EHR were used to collect treatment characteristics. Primary objective was rwPFS; secondary were OS and safety. Descriptive statistical methods were used to describe the cohort, Kaplan-Meier method was used to calculate FU time, rwPFS and OS. Cox regression models were used for univariate and multivariate analyses.

Results: Between Nov 2019 and Feb 2022, 134 pts were treated with abema at the Institute of Oncology Ljubljana. Median age at treatment initiation was 62 years. 51.1% of pts received abema with ET as 1L for ABC, 68.1% in combination with AI, 31.9% with fulvestrant. 23.9% of pts were treated with abema in the 2L and 24.6% in 3L+. mFU was 24 mos. mrwPFS in 1L was 23.0 mos (95% CI;13.3–32.7), 20.0 mos in 2L (95% CI; 6.4–33.6) and 7.0 mos (95% CI; 4.2–9.8) in 3L+. mOS was NR for 1L and 2L and was 26.0 mos 3L+. Liver mets significantly impact rwPFS and OS, identified as only independent adverse prognostic factor. mOS from the diagnosis of metastatic disease for the whole group of pts was 83 mos. AEs were reported by 97.7% of patients, with common AEs including diarrhoea, anaemia, increased serum creatinine, neutropenia and fatigue. Grade 3/4 AEs were noted in 21.6% of pts. Abema dose reductions occurred in 44.0% of pts, primarily due to diarrhoea (32.2%). Most patients (70.9%) discontinued abema, due to disease progression or death (47.0%) and AE (17.2%).

After progression on 1L abema, 80.8% pts were treated with ChT, and 71.6% after progression on 2L. Following discontinuation due to AEs, 7 pts continued with ET monotherapy, for 14 pts iCDK4/6 was switched (ribociclib or palcociclib), 2 pts were followed until progression or death.

Conclusions: Abemaciclib demonstrated notable efficacy according to our analysis, irrespective of treatment line, aligning with pivotal trial results. Despite the selective pt population, a median OS of over 5 years from metastatic disease diagnosis highlights the significant benefit of incorporating iCDK4/6 inhibitors into HR+HER2- ABC treatment. Safety data aligned with the established profile of abema, with no new AEs identified. As the drug is approved for adjuvant use, effective management of AEs and ensuring pts compliance are imperative.

No conflict of interest.

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139 (PB-139) Poster

Can metastatic breast cancer be cured? Long-term follow up of patients diagnosed from 2001–2012

Z. Zhang[1], R.H.Z. Sim[1], S. Zhou[2], N. Phyu[3], M. Wong[1], F.Y. Wong[4], Y.S. Yap[1]. [1]*National Cancer Centre Singapore, Medical Oncology, Singapore, Singapore;* [2]*National Cancer Centre Singapore, Clinical Trial Office, Singapore, Singapore;* [3]*National Cancer Centre Singapore, Cancer Informatics, Singapore, Singapore;* [4]*National Cancer Centre Singapore, Radiation Oncology, Singapore, Singapore*

Background: The survival outcomes of metastatic breast cancer (MBC) patients have been improving with the availability of new treatments, especially with targeted therapies for the HER2-positive (HER2+) subtype. We aimed to study whether "cure" is possible with long-term follow-up of MBC patients diagnosed from 2001–2012 at the National Cancer Centre Singapore (NCCS).

Material and Methods: Patients diagnosed with de novo MBC or metastatic relapse of previous breast cancer (BC) from 2001 to 2012 were identified from the prospectively maintained registry of patients at our institution. Patient and tumor characteristics, including immunohistochemical subtype, as well as treatment details and survival status were evaluated, with focus on the HER2+ subtype.

Results: The cohort of 1713 MBC patients diagnosed and seen at NCCS comprised 856 (50.0%) de novo MBC, and 857 (50.0%) metastatic relapse. Median follow-up estimated using reverse Kaplan-Meier method was 14.5 years (IQR: 12.8–17.4 years). Median overall survival (OS) was 1.9 years (95% CI: 1.8 to 2.1 years). The 10-yr OS rate for hormone receptor positive (HR+) HER2 negative (HER2-) (n = 704), HER2+ subtype (n = 508) and triple negative (TNBC) subtype (n = 368) were 7.3%, 6.0% and 2.2% respectively. The data cutoff date was August 1, 2023. Among the 50 MBC survivors who were still alive with follow-up visits over the preceding 12 months, 21 (42.0%) had HER2+ MBC, with 10 (47.6%) patients in complete remission (CR), defined as no evidence of active cancer on imaging modality performed at least within 12 months from the last follow-up date. None of the 27 HR+HER2- and 2 TNBC MBC patients were in CR. Independent predictors of improved OS in HER2+ MBC included HR positivity (HR 0.74, p = 0.002), receipt of trastuzumab in first line setting (HR 0.58, p < 0.001), whilst the presence of visceral metastasis (HR 1.37, p = 0.003) and age above 65 (HR 2.22, p = 0.027) were negative predictors of survival on multivariable analysis.

Conclusion: "Cure" or long-term complete remission appears achievable in a small percentage of HER2+ MBC, even in the pre-pertuzumab era. In contrast, while there are long term survivors with HR+HER2- and TNBC MBC, cure appears less likely.

No conflict of interest.

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140 (PB-140) Poster

Real-World Comparison of Overall Survival in Female Patients with HR+/HER2- Metastatic breast cancer receiving endocrine therapy, endocrine therapy plus palbociclib, or chemotherapy

U. Rizwan[1], R. Hussain[1], G. Kanagala[2]. [1]*West Virginia University, Internal Medicine, Parkersburg, USA;* [2]*New York City Health and Hospitals Corporation, Internal Medicine, New York City, USA*

Background: Hormone receptor-positive (HR+)/human epidermal growth factor receptor 2-negative (HER2-) metastatic breast cancer (MBC) accounts for most MBC cases (1). Endocrine therapy (ET) is the standard of care. Palbociclib, a cyclin-dependent kinase 4/6 inhibitor, has been shown in recent clinical trials, including PALOMA-2, PALOMA-3, PEARL, MONALEESA-7, and MONALEESA-3 to significantly improve overall survival (OS) when combined with ET.

This study aimed to compare the overall survival (OS) of patients with HR +/HER2- MBC metastatic to visceral organs treated with ET, ET + palbociclib (ET + P), or chemotherapy using real-world data.

Materials and Methods: We conducted a retrospective cohort study using the TriNetX database, with the data of 50 million patients from 80 healthcare organizations. Over 2,800 patients with HR+/HER2- MBC metastatic to visceral organs diagnosed between January 1, 2000 and November 14, 2023 made three cohorts: ET only, ET + P, and chemotherapy only. ET was any aromatase inhibitors, selective estrogen receptor modulators or fulvestrant. Chemotherapy included anthracyclines, taxanes, gemcitabine, capecitabine or vinorelbine. To ensure comparability, baseline characteristics such as age, race, lab findings, comorbidities, and cancer stage were matched. Kaplan-Meier curves and paired log-rank tests were employed for cohort comparisons.

Results: Assumption of proportionality was not rejected. There was a statistically significant difference in the survival curves of the three groups. The median survival, log-rank test results are summarized in Table 1. The hazard ratio for OS was significantly lower for both ET and ET + P compared to chemotherapy. This supports the use of ET and ET + P as the standard of care for first-line treatment of this patient population.

Conclusion: We used a large, real-world database to compare the OS of patients with HR+/HER2- MBC metastatic to visceral organs treated with ET, ET + P, or chemotherapy. Our study provides further evidence that ET and ET + P are the standard of care for first-line treatment of HR+/HER2- MBC metastatic to visceral organs.

No conflict of interest.

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Table 1: (abstract: 140 (PB-140)): Summary of multiple Kaplan-Meier, multiple log-rank, hazard ratio and proportionality tests

	Patients	Mortality	Median Survival	Survival probability	Log-rank test	X2	1.958	Hazard ratio	0.893	Proportionality	x2	3.912
Palb	301	98	2475	49.89%		df	1	CI	0.656,1.074		df	1
ET no P	556	179	–	52.31%		p	0.1617				p	0.0479
	Patients	Mortality	Median Survival	Survival probability	Log-rank test	X2	33.733	Hazard ratio	0.498	Proportionality	x2	0.874
Palb	301	98	2475	49.89%		df	1	CI	0.391,0.633		df	1
Chemo	439	213	501	30.98%		p	<0.0001				p	0.35
	Patients	Mortality	Median Survival	Survival probability	Log-rank test	X2	24.908	Hazard ratio	0.605	Proportionality	x2	2.073
ET no P	556	179	-	52.31%		df	1	CI	0.496,0.739		df	1
Chemo	439	213	501	30.98%		p	<0.0001				p	0.1499

141 (PB-141) Poster

Evaluate the impact of HER2 status on the response to CDK4/6 inhibitors in advanced breast cancer

M. Veloso Gonçalves[1], C. Teixeira[1], A.C. Valente[1], J. Reis[1], N. Teixeira[1], I. Sousa[1], D. Almeida[1], I. Augusto[1], M. Barbosa[1], S. Meireles[1]. *[1]Centro Hospitalar Universitário de São João, Oncologia Médica, Porto, Portugal*

Background: HER2-low breast cancer (IHC 1+ or 2+ with negative SISH) has been studied as a biologically distinct subtype. To date, its role in defining the therapeutic strategy is still limited, being treated as HER2 negative (IHC 0). In metastatic breast cancer with positive hormone receptors and negative HER2 (IHC 0, 1+, 2+ with negative SISH), the first-line systemic treatment, in the absence of visceral crises, is CDK4/6 inhibitors. Despite the current investigation of the efficacy of anti-HER2 therapies in HER2-low tumors, the association between HER2-low status and the outcome of treatment with CDK4/6 inhibitors has not yet been established.

Material and Methods: A retrospective study of patients with HRpMBC undergoing treatment with CDK4/6 inhibitors from 01/01/2017 to 31/12/2021. Survival analysis was performed using the Kaplan-Meier method and the log-rank test. The prognostic impact was assessed using the Cox regression model.

Results: A total of 137 patients were enrolled, all female, with a median age at diagnosis of 52 years [22–85] and 53.3% (73) were in postmenopausal status. Around 35.8% (n = 49) were metastasized at diagnosis and 62% (85) had metastasis in 3 or more locations.

Regarding HER2 expression, 65% (89) had IHC 0 and 35% (48) IHC 1+ or 2+ (SISH negative). Around 65.7% (90) took CDK4/6 inhibitors as first-line therapy, while 34.3% (47) took it as a subsequent line. The majority of patients started treatment with palbociclib (59.1%, 81), 32.1% (44) with ribocilib and 8.8% (12) with abemaciclib. Grade 3 toxicity is described in 62.3% (84) of patients, the majority of which were hematological with neutropenia (51.8%, 71). There was a need to postpone treatment in 70.8% (97) of cases and to reduce the dose in 34.3% (47). Around 62.8% (86) showed disease progression under CDK4/6 inhibitors. The median follow-up was 24 months (3–143).

There was no statistically significant impact on OS and PFS of HER2-low status in patients treated with CDK4/6 inhibitors in HRpMBC in univariate analysis (median PFS HER2 0 vs HER2-low: 28 months, 95% CI 21.49–34.51 vs 27 months, 95% CI 11.87–42.13, p = 0.477; median OS HER2–0 vs HER2-low: 149 months, 95% CI 67.23–230.77 vs 158 months, 95% CI 120.08–195.93, p = 0.907). HER2-low status was not identified as an independent prognostic factor for the outcomes studied (PFS: HR 0.85, 95% CI 0.47–1.54, p = 0.587; OS: HR 1.03, 95% CI 0.48–2.23, p = 0.931).

Conclusions: In our sample, it was found that HER2-low status did not have a statistically significant impact on the efficacy of CDK4/6 inhibitors, in terms of progression-free survival and overall survival. This result supports that, to date, there is no data demonstrating the need to change the therapeutic line depending on HER2-low expression in patients with HRpMBC. More prospective studies with more significant samples are needed to validate these conclusions.

No conflict of interest.

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142 (PB-142) Poster

Trastuzumab deruxtecan's safety profile – a real life study

F. Pereira[1], C. Vieira[1], A. Ferreira[1]. *[1]Instituto Português de Oncologia do Porto, Medical Oncology, Porto, Portugal*

Background: The DESTINY-Breast trials with trastuzumab deruxtecan (T-DXd) showed positive outcomes in patients with both HER2-positive and HER2-low metastatic breast cancer, which changed the treatment scenario for many patients with metastatic breast cancer. When it comes to adverse effects, the most reported are nausea, fatigue/ asthenia, alopecia, neutropenia, anemia. Pneumonitis is commonly a reason for discontinuation of therapy and its surveillance is essential. With this study, we aim to evaluate the safety profile of T-DXd in women being treated in IPO Porto and compare it to the literature.

Material and Methods: The patients included are women with metastatic breast cancer that are followed in IPO Porto, who initiated treatment with T-DXd between October 2021 and November 2023. The data relates to demography, the extension of the disease, previous treatments, adverse effects, and response to treatment. The data was obtained retrospectively through Vision, a software of Business Intelligence that integrates clinical and administrative information from multiple databases with hospital data, and manually through the patient's clinical process. The analysis was done through descriptive statistics and statistical inference, using R studio and Microsoft Office Excel.

Results: 32 patients with HER2 low or HER2 positive disease were included. In most cases, T-DXd is the fourth or further line of treatment (56.3%). The Clinical Benefit Rate for HER2 positive patients was 66.6% and 14.2% for HER2 low patients (most of these patients haven't reached the first response evaluation or 6 months of therapy yet). Regarding the safety profile, 78.1% of patients presented at least one adverse effect, and most of them grade 1. The reported effects were emesis (40.6%), asthenia (34.4%), hepatic toxicity (21.9%), pneumonitis (12.5%), alopecia (12.5%), neutropenia (12.5%), mucositis (9.4%), thrombocytopenia (9.4%) and diarrhea (3.1%). There were 2 cases of grade 3 adverse effects – asthenia and pneumonitis (steroid refractory). 13 patients (40.6%) ceased treatment, 4 of them (12.5%) for toxicity (pneumonitis, thrombocytopenia, and emesis) and the rest for disease progression.

Conclusion: T-DXd improves treatment outcomes in women with metastatic HER2 low or HER2 positive disease. Our analysis shows a favorable safety profile, with manageable adverse effects, that rarely require treatment interruption. The most common adverse effect was emesis, there was less cases of neutropenia when compared to the DESTINY-Breast trials, and there were no reports regarding anemia or cardiac toxicity. It is important to state that the data was obtained from clinical records, so some mild effects might be overlooked, and also that we are still learning and perfecting the management of these effects.

No conflict of interest.

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POSTER SESSION **21 March 2024 9.00–17.30**

Local Regional Treatment - Radiotherapy

143 (PB-050) Poster

MR-guided adaptive partial breast radiotherapy in low-risk breast cancer: a phase II study

C. van Vliet[1], D. van den Bongard[1], S. Tetar[2], S. van der Velde[3], B. Slotman[1], F. Lagerwaard[1], A. Bruynzeel[1]. *[1]Amsterdam UMC, Location VUmc, Radiation Oncology, Amsterdam, Netherlands; [2]Catharina Ziekenhuis, Radiation Oncology, Eindhoven, Netherlands; [3]Amsterdam UMC, Location VUmc, Surgery, Amsterdam, Netherlands*

Background: The majority of breast cancer patients are treated with breast-conserving surgery followed by postoperative whole (WBI) or partial breast irradiation (PBI). Previous studies on PBI demonstrated similar ipsilateral breast tumor events (IBTE) compared to WBI, however conflicting data on toxicity and cosmetic outcomes were reported. This study investigates the feasibility of stereotactic MR-guided adaptive radiotherapy (SMART) for PBI, with emphasis on toxicity and cosmetic outcomes.

Material and Methods: Patients with low-risk breast cancer suitable for PBI as defined by ESTRO guidelines were included after tumor board consensus. SMART was delivered in supine position in a two-week course of 5 fractions of 6 Gy, or 6.5 Gy in case of Bloom-Richardson grade 3 or triple negative tumors. Toxicity and patient- and physician-reported cosmetic outcomes were scored at 3, 9, 18 and 36 months postoperatively at regular follow-up consultations (at 36 months patient-reported cosmetic outcome only).

Results: Between 2017–2020, 50 patients were included. Five patients did not receive SMART: due to severe claustrophobia (n = 3), extensive postoperative hematoma (n = 1), and poor visibility of surgical cavity on MRI (n = 1).

Median age was 66 years (50–86), median tumor size was 1.2 cm (0.3–2.6). Most tumors were Bloom-Richardson Grade 1 (55.6%), estrogen receptor positive (95.6%), progesterone receptor positive (77.8%) and Her2 receptor negative (100%). The majority of patients did not receive adjuvant hormonal therapy (77.8%) or chemotherapy (95.6%).

The highest grade acute toxicity within three months was grade 3 fatigue in one patient, grade 2 toxicity was seen in 9/45 patients (20%), of which fatigue was reported mostly (n = 5). At 18 months, four patients (9%) reported grade 2 toxicity, consisting of fibrosis (n = 1) and fatigue (n = 3). No grade 3 or higher late toxicity was recorded.

At 9 and 18 months, 86.4% of patients were (very) satisfied with the cosmetic outcome. General appearance of the treated breast scored little to no difference compared to the contralateral breast by 95.5% and 90.9% of patients at 9 and 18 months, respectively. Physicians scored 66% and 74% good general appearance at the same follow-up time points. At 36 months 84.2% of patients were (very) satisfied with the cosmetic outcome.

With a median follow-up of 38 months (34–62), five ipsilateral breast tumor events (IBTE) occurred. Four of these were qualified as true local recurrences, one was considered a second primary tumor. Median time to IBTE was 37 months (26–51). Two patients presented with regional recurrences, one patient developed distant metastasis at 2.5 years.

Conclusion: MR-guided adaptive PBI for patients with low-risk breast cancer was feasible and leads to low rates of both early and late toxicity. Good to excellent cosmetic outcomes were reported after a follow-up of 3 years.

No conflict of interest.

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144 (PB-051) Poster

Characteristics of breast radiotherapy patients experiencing breast oedema at a UK tertiary centre

F. Wilson[1], K. Clark[2], C. Anandadas[2]. *[1]University of Manchester/Christie NHS Foundation Trust, Radiotherapy Related Research, Manchester, United Kingdom; [2]Christie NHS Foundation Trust, Clinical Oncology, Manchester, United Kingdom*

Background: Breast oedema can occur following breast conserving treatment and is associated with breast pain, reduced quality of life and poor body image. The incidence and risk factors for breast oedema are much less well studied than arm lymphoedema, and it may go under-recognised by clinicians and under-reported by patients. The UK FASTforward study reported a higher incidence of moderate/marked breast oedema with 26Gy in five fractions compared with 40Gy in 15 fractions with a five year cumulative incidence of 7.5% vs 5.5%. We aimed to describe the characteristics of patients under the breast oedema service who received radiotherapy for breast cancer at a tertiary centre, and to assess any impact of the introduction of 26 Gy in five fractions on breast oedema referrals.

Materials and Methods: Patients were identified from attendance at specialist physiotherapy services for management of breast oedema at two hospitals. All had been treated with radical radiotherapy for adjuvant treatment of breast cancer, following breast conserving surgery, at a tertiary centre. Demographics, clinical and treatment data were extracted from electronic clinical records and radiotherapy plans.

Results: 73 patients were identified, of which 11 had co-existing arm lymphoedema. 12 were current smokers. 46 patients received radiotherapy after the introduction of the 26 Gy regimen, of these 17 (37.0%) received 26 Gy.

Table 1: Demographics and treatment parameters for breast oedema caseload patients. Numbers may not add up to 100% due to small amount of missing data

Metric	n = 73
Median BMI kg/m^2 (IQR)	29.9 (27.2–33.8)
Median age at radiotherapy (IQR)	56 (50–64)
Post menopausal	48 (65.8%)
Sentinel lymph node biopsy	40 (54.8%)
Axillary lymph node dissection	33 (45.2%)
Chemotherapy	33 (45.2%)
Post-op complications (seroma, infection)	22 (30.1%)
Dose and fractionation	
26 Gy/5#	17 (23.2%)
40 Gy/15#*	44 (63.3%)
40 Gy/15# + sequential boost	12 (16.4%)
Breast only radiotherapy	66 (90.4%)
Breast + supraclavicular fossa	5 (6.8%)
Breast + supraclavicular fossa + internal mammary chain	2 (2.7%)
6MV photons	44 (60.3%)
10MV photons	26 (35.6%)
Mean (range) breast separation, cm	22.3 (16.4–28.7)
Median (IQR) PTV evaluation volume** (cc)	1335 (908–1513)

*Includes 8 patients who had dose reduced to 38Gy due to hot spot concerns
**Surrogate for irradiated breast volume

Conclusions: Most patients with breast oedema did not have co-existent arm lymphoedema. A high proportion were overweight or obese. Patients treated with 26Gy did not appear to be over-represented in this group. Further research is required to identify risk factors for development breast oedema, to allow appropriate patient counselling and to facilitate targeted follow up for those at highest risk.

No conflict of interest.

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145 (PB-052) Poster

Preoperative accelerated partial breast irradiation in locally recurrent breast cancer patients

T. Snellen[1], F. van Duijnhoven[1], I.M. van der Ploeg[1], M.J.T.F.D. Vrancken Peeters[1], A.N. Scholten[2]. *[1]Netherlands Cancer Institute - Antoni van Leeuwenhoek hospital, Surgical oncology, Amsterdam, Netherlands; [2]Netherlands Cancer Institute - Antoni van Leeuwenhoek hospital, Radiation oncology, Amsterdam, Netherlands*

Introduction: Currently, standard local treatment for ipsilateral recurrent breast cancer is a salvage mastectomy. However, repeat breast conserving therapy, consisting of breast conserving surgery combined with re-irradiation, has been shown to be a feasible alternative for a selected

group of patients. In the primary setting, accelerated partial breast irradiation (APBI) is an international accepted treatment for a subset of breast cancer patients. Preoperative APBI results showed low complication rates, limited fibrosis and induration, and good to excellent cosmetic results, compared with results reported after postoperative APBI. This led to the current PAPBI-3 pilot study assessing the feasibility of repeat breast conserving therapy with preoperative APBI followed by breast conserving surgery in patients with locally recurrent or second primary breast cancer. Primary outcome is acute post-treatment toxicity up to 3 months after local treatment. Secondary outcomes involve the occurrence of fibrosis and/or induration, quality of life, and cosmetic outcome 3 months after end of local treatment.

Methods: A total of 31 women aged ≥51 years with invasive, unifocal, hormone receptor-positive, Her2Neu-negative ipsilateral recurrent or second primary low risk (<3 cm, N0M0) breast cancer will be enrolled in the study and treated with preoperative APBI followed by repeat breast conserving surgery. Radiation therapy consists of 5 × 5.2 Gy to the tumor with a 20 mm margin. The surgical intervention will consist of wide local excision of the breast tumor and a sentinel node procedure. Acute post-treatment toxicity will be scored using the CTCAE v5.0. Quality of life is to be scored using the QLQ-C30 and QLQ-B45 patient questionnaires. Cosmetic outcome is going to be determined by the BCCT.core software program and a patient questionnaire. Patients will be followed up until 3 months after treatment.

Results: Patient accrual is expected to start early 2024.

Outcome: The PAPBI-3 pilot study aims to determine whether preoperative APBI followed by repeat breast conserving surgery is a feasible treatment for patients with ipsilateral recurrent or second primary breast cancer. In case of a favorable outcome, this pilot study will be followed by a larger, multicenter clinical trial focusing on long term cosmetic outcome.

No conflict of interest.

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146 (PB-053) Poster

The radiotherapy omission within the Sinodar One protocol: Survival and Relapse Outcomes and dosimetric analysis

R. Spoto[1], A. Bertolini[1], D. Franceschini[1], L. Dominici[1], F. Lobefalo[1], C. Tinterri[2], M. Scorsetti[3]. *[1]IRCCS Humanitas Research Hospital, Department of Radiotherapy and Radiosurgery, Rozzano, Italy; [2]IRCCS Humanitas Research Hospital, Breast Unit, Rozzano, Italy; [3]Humanitas University, Department of Biomedical Sciences, Pieve Emanuele, Italy*

Background: We conducted a re-analysis of the data from the SINODAR-ONE phase III randomized trial, focusing on the omission of radiotherapy. The primary objectives of the study were overall survival (OS) and locoregional relapse (LRR). We performed a dosimetric analysis of the dose to the axilla.

Materials and Methods: Patients with T1-2 breast cancer and 1–2 macrometastatic sentinel lymph nodes were randomly assigned in a 1:1 ratio to either undergo removal of ≥10 axillary level I/II non-sentinel lymph nodes followed by adjuvant radiotherapy (ARM 1) or receive no further axillary treatment (ARM 2). We collected radiotherapy data and compare the outcomes. We contoured retrospectively all four axillary levels and internal mammary chain in order to perform a dosimetric analysis of the dose distribution to that regions.

Results: From 2015 to 2020, a total of 889 patients were enrolled and randomized. The median follow-up period was 34.0 months. Radiotherapy data were available for 355 patients. In study arm, no axillary dissection was performed, and locoregional radiotherapy was administered 17pts that represent a major deviation. In ARM 1 and ARM 2, we observed 0 and 2 deaths, and the relapse were 2 and 4, respectively. Statistical analysis did not reveal any significant differences between the two arms. The dosimetric analysis performed on 72 pts (56 treated with VMAT and 16 treated with 3D conformal technique) revealed that the median mean dose to the first level of axilla is half of prescription dose.

Conclusion: In T1-2 breast cancer patients with 1–2 macrometastatic sentinel lymph nodes treated with sentinel lymph node biopsy alone, the 3-year survival and relapse rates were not inferior to those of patients treated with axillary lymph node dissection plus or minus locoregional radiotherapy. The dose to axilla can't influence these results.

No conflict of interest.

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147 (PB-054) Poster

An innovative technique in partial volumetric modulated arc therapy for treating node-positive left-sided breast cancer

H.C. Park[1], K. Hyojung[1], W. Jeong[1]. *[1]Chonnam National University Medical School, Department Radiation Oncology, Gwang Ju, South Korea*

Background: The study was designed to reveal the advantages of novel partial arc volumetric modulated arc therapy (np-VMAT), an innovative radiotherapy planning technique, over traditional VMAT and static intensity-modulated radiation therapy (s-IMRT) for advanced left breast cancer that requires nodal irradiation.

Methods: The treatment plans were prepared using the Monaco15 radiation treatment planning (RTP) system and four methods: s-IMRT with six fields, half-arc VMAT (h-VMAT) with two arcs, tangential-based VMAT (p-VMAT) with four partial arcs, and np-VMAT with six arcs. We added two-half arcs with p-VMAT, including the whole breast and supraclavicular lymph node (SCL), for 20 cases of left breast cancer. Target coverage and organs at risk (OAR) dose were compared via the SPSS 28 independent *t*-test.

Results: The dose coverage of p-VMAT was less than the targeted 95% coverage, whereas the other three methods showed better coverage without any significant difference. The dose (including the volumes V5Gy, V20Gy, and V30Gy, and the mean dose value) irradiated on the left lung dose during np-VMAT was lower than those irradiated during h-VMAT and p-VMAT. In contrast, the right lung was exposed to a higher dose in the arc plan than in s-IMRT, although the administered dose was negligible. The dose received by the heart was similar in all the four treatment methods, and that received by the esophagus was significantly low in np-VMAT.

Conclusions: In large-field radiotherapy with nodal positives, the target coverage and OAR dose reduction facilitated by the np-VMAT method are superior to those allowed by the other three methods (s-IMRT, h-VMAT, and p-VMAT). We expect that the np-VMAT method can be used effectively in the large-field radiotherapy of left-sided breast (and SCL) cancer.

No conflict of interest.

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148 (PB-055) Poster

Implementing the UK NICE guidance (NG101), the safe omission of breast radiotherapy – a regional service evaluation

N. Roberts[1], E. Macinnes[2]. *[1]Leeds Cancer Centre, St James's University Hospital, Radiotherapy, Leeds, United Kingdom; [2]St James's University Hospital, Breast Surgery, Leeds, United Kingdom*

Background: In response to data from several randomised controlled trials, in 2018 the UK National Institute for Health & Care Excellence (NICE) updated its guidance to include the safe omission of post-operative radiotherapy for certain low risk cohorts of breast cancer patient as defined by: their age, tumour pathology and immunohistochemical profile (IHC). As well as strict patient selection criteria, the guidance also stipulates how this recommendation should be discussed with the patient to help inform their treatment decision. Since this time all Cancer Units across the West Yorkshire region have aimed to deliver this change.

Materials and Methods: The aim of the evaluation was to establish any practice variation across the region and explore how the guidance had been implemented in each unit, with the intention of improving practice and thereby patient care. A retrospective data trawl of the local patient record system was performed for patients meeting the NICE eligibility criteria for omission of radiotherapy who had their first definitive treatment between Jan-June 2022. The initial data trawl by each Cancer Unit was followed up by individual patient level data queries undertaken by the Clinical Oncologist at each unit.

Results: 50 patients met the eligibility criteria for omission of radiotherapy across the region which represents 29% of the total referral population for post operative breast radiotherapy in this age group. Only 17% of this total (30 patients) actually omitted treatment. There was a wide range in the proportion of eligible patients omitting treatment across the units from 25%–77%. Differences were also seen across and within units for multi-disciplinary team meeting (MDTM) recording terminology of the treatment decision for radiotherapy and the specialty of healthcare practitioner having the 'discussion' with the patient. 100% of patients omitting radiotherapy commenced endocrine treatment, as stipulated in the guidance.

Conclusion: All units across the West Yorkshire region are omitting radiotherapy for NICE NG101 eligible patients. Variation exists in the implementation of this guideline between units which could impact on the proportion of eligible patients omitting radiotherapy regionally.

Recommendations have been made to improve consistency in practice across the region and for a follow up evaluation.

No conflict of interest.

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149 (PB-056) Poster

Post-operative Radiation In Early Breast Cancer with N1 Disease: 10 year follow up

E.L.S. Tang[1], M.Y.P. Chan[2], J.C.J. Chen[2], E.Y. Tan[2]. *[1]Woodlands Health, General Surgery, Singapore, Singapore; [2]Tan Tock Seng Hospital, General Surgery, Singapore, Singapore*

Background: Definitive recommendations for post-operative nodal radiation in post-menopausal women with N1 disease (1 to 3 nodes involved) are still awaiting the SUPREMO trial. Although locoregional control is improved, overall survival benefit has not been consistently demonstrated. We have reviewed post-menopausal women diagnosed with early breast cancer and N1 disease at our unit and have evaluated the clinical benefit of post-operative nodal radiation over 10 years. The primary end point of this study is overall survival, and the secondary end point is to evaluate for factors affecting overall survival and disease free survival.

Material and Methods: A retrospective review of 191 post-menopausal women diagnosed with N1 disease from 2004 to 2011 was performed. Demographics, post- operative histology, adjuvant treatment, survival as well as disease free recurrence were evaluated.

Table 1: Patient demographics and tumour characteristics in those who received radiotherapy (RT) compared to those who did not receive radiotherapy (RT)

	RT (N = 95)	No RT (N = 96)	P Value
Median Age (years)	56 (50 to 79)	65 (50–90)	<0.001
Ethnicity			
Chinese	78	83	0.636
Indian	3	5	
Malay	12	4	
Others	2	4	
Co-morbidities			
Yes	68	71	0.747
No	27	25	
Number of involved nodes			
1	47	65	0.004
2	25	21	
3	23	10	
Histology			
Invasive ductal carcinoma	91	88	0.331
Invasive lobular carcinoma	2	5	
Other histologies	2	3	
Median tumour size (mm)	23 (5–50)	25 (2–45)	0.941
Tumour grade			
1	7	9	0.001
2	24	51	
3	63	35	
Lymphovascular invasion			
Present	44	22	0.001
Absent	45	68	
ER status			
Positive	66	80	0.025
Negative	29	15	
HER2 status			
Positive	20	16	0.246
Negative	44	57	
Triple Negative			
Yes	11	6	0.127
No	53	67	
Type of surgery			
Wide local excision	47	9	<0.001
Mastectomy	48	87	

Results: Post-operative radiation was given to 95 of 191 women (49.7%); and was part of breast conservation therapy in about half (49.5%). Younger age at diagnosis (P < 0.001), a greater number of involved nodes (P = 0.004), lymphovascular invasion (LVI) and a higher tumor grade (P = 0.001) were more frequently found in women who received post-operative radiation. Nodal radiation did not improve 10-year recurrence-free (P = 0.084) or overall survival (P = 0.203).

Post-operative nodal radiation was associated with significant improvement in 10-year overall survival in women who were already receiving hormonal therapy (P = 0.047). However, this additional benefit was not seen in those receiving chemotherapy and targeted therapy.

Conclusions: Women with unfavourable risk factors were more likely to receive post-operative radiation, likely because they were deemed to be at higher risk of recurrence. Nodal radiation did not significantly improve 5-year, 10-year recurrence-free or overall survival. However, in those who were only on hormonal therapy, radiotherapy is beneficial in improving overall survival.

No conflict of interest.

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150 (PB-057) Poster

Intensification with HDR-Brachytherapy boost in locally advanced breast cancer after neoadjuvant chemotherapy

I. Martinez Montesinos[1], I. Visus[2], N. Fuentemilla[3], P. Jablonska[2], S. Flamarique[2], E. Burillo[2], P. Lorenzana[2], M.U. Ruiz[2], M.I. Martínez[2], A. Sola[2], R. Villanueva[4], N. García[4], E. Villafranca[2]. *[1]Hospital Universitario de Navarra, Radiation Oncology in Breast cancer and Brachytherapy, Pamplona, Spain; [2]Hospital Universitario de Navarra, Radiation Oncology, Pamplona, Spain; [3]Hospital Universitario de Navarra, Radiation Oncology Physicist, Pamplona, Spain; [4]Hospital Universitario de Navarra, Radiation Oncology Nurse, Pamplona, Spain*

Background: Locally advanced breast cancer patients are at high risk of local and systemic relapse. The aim of our study was to analyze the impact of intensification using HD-BTboost delivered to the tumor bed in patients with LABC, who underwent neoadjuvant chemotherapy (NACT) followed by conservative breast surgery and adjuvant RT in terms of local control, regional control and overall survival.

Material and Methods: Patients with LABC who received NACT followed by BCS (with ALND or SLNB) and adjuvant RT plus HD-BT boost in our institution were retrospectively reviewed. NACT schemes:EC+taxol with or without anti-HER2 therapy. The majority of patients received adjuvant systemic treatment (ET and/or CT/anti-HER2 therapy). Main radiation therapy schemes: 50Gy/25 fractions (until 2016) and from 2016 onwards, moderate hypofractionation. Interstitial MC-HD-BT was used in all patients (15Gy in 3 twice-daily fractions over 2 days. For late toxicity we relied on CTCAEv.5 scales.

Study endpoints: 5- and 8-year ipsilateral breast recurrence (IBR)-free survival, regional recurrence (RR)-free survival, distant metastases (DM)-free survival, PFS and OS.

Kaplan-Meier and Log-rank tests were used. For statistical analysis: SPSSv.25.

Results: A total of 144 patients(p) between September 2008-April 2022 were included. Median follow-up: 63 months(3–169). Mean age: 49.7 years. Clinical stage: 51p(35.42%) had T1 tumours, 71p(49.31%) T2, 21p T3 (14.58%) and 1p(0.7%) T4. 69p(47.9%) were N0, 62p (43.06%) N1, and 13p (9%) N2 or more, at diagnosis. 36p(25%) had TN; 30% Luminal-HER2; 12.5% HER2,the rest were Luminal. 5.5%(8p) grade 1, 41.6%(60p) grade 2 and 52.8%(76p) grade 3.

Brachytherapy dosimetric results: median D90-PTV:106.83%PD(72.99–115.77), median V100-PTV:94.9%PD(52.28–99.58), median CI:1.67 (V100 implant/V100PTV)(1.01–2.83) and IH (V150implant/V100implant):29.95 (20.7–42.6), respectively. After NACT 44p(30.5%) had pCR.

Events: 9 IBR, 8 RR, and 22 DM. 5 and 8-year IBR-FS was 94.2 and 90.4%; 5 and 8-year RR-FS was 97.5 and 90%; 5 and 8-year DM-FS were 87.2 and 82.3%: 5 and 8-year PFS were 85.6 and 77.8; 5 and 8-years OS and 90.3 and 84.1%, respectively.

We analysed the association between OS and prognostic factors. To highlight, there was a statistically significant association between the presence of pCR and higher rates of PFS and OS. No statistically significant differences were seen between the pCR versus partial response and the LC rate. 9p and 2p presented G2 and G3 fibrosis, respectively.

Conclusion: Intensification with HDR-BT boost in patients with LABC provides excellent LC rates, despite the presence of poor prognostic factors such as TN phenotype, high histological grade and/or the presence of

residual disease after NACT. HD-BT boost could be considered for selected patients in this clinical scenario.

No conflict of interest.

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151 (PB-058) Poster

Predictive factors of incidental internal mammary chain irradiation in breast cancer radiotherapy

Z. Naimi[1], A. Riahi[1], M. Bohli[1], R. Ben Amor[1], A. Hamdoun[1], G. Bouguerra[1], R. Haddad[1], L. Kochbati[1]. *[1]Abderrahmen Mami Hospital Ariana, Radiation Oncology Department, Ariana, Tunisia*

Background: This study aimed to assess the incidental radiation dose delivered to internal mammary chain (IMC) in breast cancer radiotherapy (RT) and to analyse its association with patient's anatomic factors and technical parameters.

Materials and Methods: Data of 100 breast cancer patients were analysed. All patients underwent hypofractionated 3D conformal radiotherapy with a prescription dose of 40 Gy/15 fractions +/– an additional boost of 13.35 Gy to the tumor bed/thoracic wall. Radiotherapy was delivered by tangential beams +/– supraclavicular field. The IMC was not initially included in target volumes, but retrospectively contoured according to ESTRO guidelines. The following dosimetric parameters to IMC were assessed: Dmean, V30Gy and V40 Gy. Patient's anatomic features were evaluated including: breast/chest wall volume and breast index (largest axial distance between CTV's medial and lateral borders). Incidental doses to IMC were statistically analysed with regards to patient's anatomic features, type of surgery, tumor bed location and RT target volumes.

Results: The left/right ratio was 1.27 with 56% of left-sided breast cancer patients. The tumor bed was external in 71% of cases. Radical mastectomy was performed for 51 patients whereas 49 patients underwent breast conservative surgery. An additional boost to tumor bed/thoracic wall was prescribed for 50% of patients. Supraclavicular lymph nodes irradiation was performed for 50% of the study cohort. The mean Dmean to IMC was 9.39 (1.71–37.38) Gy. Dmean to IMC >15 Gy was found in 14% of cases. The mean V30 Gy and V40 Gy were 5.68% (0–100%) and 1.2% (0–54%) respectively. Breast cancer laterality did not statically impact incidental doses to IMC. Neither breast/chest wall volumes nor breast index correlated with doses to IMC ($p > 0.2$). Statistical significant positive correlation was found between type of surgery and Dmean to IMC (Pearson coefficient = 0.2, $p = 0.04$). Dmean to IMC was statistically higher in chest wall RT when compared to breast RT. Internal tumor bed location was statically related to higher incidental doses to IMC. No statistical association was found between doses to IMC and supraclavicular irradiation.

Conclusion: This study showed a wide range of incidental doses to IMC highlighting the variability of IMC coverage in 3D conformal breast cancer RT. The main predictive factors of incidental IMC irradiation were radical mastectomy and internal tumor location. Nonetheless these incidental doses remain below the consensual prophylactic range.

No conflict of interest.

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152 (PB-059) Poster

Radiotherapy of breast cancer in BRCA1 and BRCA2 carriers

T. Marinko[1], A. Jerala[2], M. Krajc[3]. *[1]Institute of Oncology Ljubljana, Radiation Oncology Department, Ljubljana, Slovenia; [2]University of Ljubljana, Medical Faculty, Ljubljana, Slovenia; [3]Institute of Oncology Ljubljana, Department of Clinical Cancer Genetics, Ljubljana, Slovenia*

Background: Studies have shown that breast cancer patients with germline *BRCA1* and *BRCA2* (*BRCA 1/2)* pathogenic/likely pathogenic variants (P/LPV) treated with mastectomy have the same overall survival as patients treated with breast-conserving surgery followed by radiotherapy (breast conserving therapy – BCT). However, patients treated with BCT have significantly more local and regional recurrences (LRR). We aimed to verify these results in our own population and analyse which type of surgery is most frequently chosen by our patients.

Material and Methods: In this retrospective study we used medical records to collect the data of all patients with primary breast cancer, who tested positive for germline *BRCA1/2* P/LPV at the Institute of Oncology Ljubljana between 2016 and 2021. 354 patients were included in the study. Statistical analysis was conducted using SPSS.

Results: Patients whose *BRCA1/2* positive status was known prior to surgery (83 out of the total 354 patients) opted for the recommended mastectomy significantly more frequently than for BCT (79 out of 83 (95.2%) vs. 4 out of 83 (4.8%); $p < 0.0001$). There was no significant difference in overall survival between patients treated with BCT and those treated with mastectomy with or without radiotherapy (HR = 1.508; 95% CI [0.627–3.623], $p = 0.355$). Patients treated with BCT had significantly higher rates of LRR than patients treated with mastectomy ($p = 0.0011$).

Conclusions: Patients who were aware of their *BRCA1/2* positive status before surgery were significantly more likely to choose mastectomy as a treatment option; overall survival of patients, treated with BCT, and those treated with mastectomy did not differ significantly; although those treated with BCT had significantly higher incidence of LRR.

No conflict of interest.

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153 (PB-060) Poster

Toxicity and cosmetic outcome after Intraoperative Radiotherapy with Electrons (IOERT) to the partial breast during breast conserving surgery of breast cancer patients in early stages: First results of a prospective single-center registry trial

G. Fastner[1], R. Reitsamer[2], C. Gaisberger[1], M. Stana[1], C. Fussl[1], M. Mattke[1], B. Grambozov[1], F. Zehentmayr[1], A. Sir[2], N. Annon-Eberharter[1], F. Röder[1]. *[1]University Hospital Salzburg, Landeskrankenhaus, Paracelsus Medical University, Salzburg, Austria, Department of Radiotherapy and Radio-Oncology, Salzburg, Austria; [2]University Hospital Salzburg, Landeskrankenhaus, Paracelsus Medical University, Salzburg, Austria, Department of Gynecology, Salzburg, Austria*

Background and purpose: Partial breast irradiation (PBI) has been established as an effective de-escalation strategy for the treatment of early stage breast cancer. The aim of this single-center, registry base, observational study is to assess the effect of intraoperative electron radiation (IOERT) as a full dose treatment to the partial breast during breast conserving surgery (BCS), in terms of acute/late toxicity and cosmetic outcome.

Material and Methods: Recruitment for this prospective trial (415-E/2464/5-2019) began in November 2018 and consists of BCS patients who received a full dose IOERT with 21 Gy (90% isodose) to the partial breast. Only low risk breast cancer patients (age $\geq$ 50 years, unifocal tumors <2 cm, no grading 3, R0, Luminal A, KI 67 $\leq$ 25%, N0) were considered. Acute/late toxicity and cosmesis were evaluated by validated scorings systems.

Results: 257 eligible patients were screened, of which 31 were excluded and the remaining 226 analyzed in November 2023. After a median follow-up (FUP) of 25 months (range 0.7–61), for acute effects CTCAE-score 0/1 was noted in 98.5% in week 1 and 98% in week 4, respectively. Late toxicity Grading 0/1 (mean values of all qualities, ranges) by LENT-SOMA criteria was observed in 96.5% (85.5–100) at 4/5 months and remained unaltered with 96.1% (81–100) at 4 years. Baseline cosmesis (week 1) after wound healing was scored as excellent/good in 91% of cases by subjective (patient) and in 84% by objective assessment by a radiation oncologist, with no impairment thereafter. Thus far, no locoregional recurrence has been detected, 2 patients developed metastases and 2 died.

Conclusions: Acute and late treatment tolerance of full dose IOERT to the partial breast in early breast cancer stages is excellent in short-term assessment and comparable to the current literature. Postoperative cosmetic appearance is not impaired after 4 years FUP.

No conflict of interest.

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154 (PB-061) Poster

Cold heart: active breathing coordinator-assisted deep inspiration breath hold leads to a safer heart sparing approach to early and locally advanced breast cancer treatment

E. Bonzano[1], L. Squillace[1], A. Lancia[1], L. Mantovani[2], A. Francia[2], M. Cavallari[2], A.R. Filippi[1]. *[1]IRCCS San Matteo Polyclinic Foundation, Radiation Oncology, Pavia, Italy; [2]IRCCS San Matteo Polyclinic Foundation, Medical Physics, Pavia, Italy*

Background: Cardiac toxicity resulting from radiation therapy (RT) for left-sided breast cancer (LBC) is recognized as dose-dependent. This prospective analysis aimed to assess the efficacy of RT utilizing the moderate deep inspiration breath-hold (mDIBH) technique assisted by the Active Breathing Coordinator (ABC) in reducing the mean heart dose (MHD) and mean/maximum doses to the left descending coronary artery (LAD). We examined the feasibility of this technique across different doses and treatment volumes.

Material and Methods: Data were prospectively collected from patients (pts) with LBC stages 0-III undergoing RT with the ABC/mDIBH technique. Inclusion criteria encompassed eligibility for left-sided RT, tolerance to mDIBH, willingness to undergo device training, and the ability to maintain a 20-second breath-hold. Primary endpoints included dose reduction to the heart and LAD, procedural success rate across different treatment schedules and target volumes. Further analyses involved comparing ABC-assisted dosimetry with free-breathing plans, focusing on MHD and mean/maximum LAD doses.

Results: A total of 207 pts with stages 0-III LBC were enrolled (November 2020–July 2023). Of these, 195 underwent RT with ABC, achieving a procedural success rate of 94%. Doses ranged from 26 Gy in 5 fractions (ultrahypofractionated) to 50 Gy in 25 fractions (conventional fractionation) and 40 Gy in 15 fx (standard fractionation). In the ultrahypofractionated scheme, the Heart Dmean was 0.73 Gy, while the LAD mean and max were 1.83 and 5.49 Gy, respectively. Shifting focus to conventional fractionation, the doses were as follows: Heart Dmean 2.84 Gy, LAD Dmean 5.25 Gy, and LAD Dmax 11.68 Gy. Lastly, in the standard fractionation scenario, the Heart Dmean was 0.90 Gy, and the LAD mean and max were 2.29 Gy and 8.98 Gy, respectively. A comparison with the same fractionation in free-breath demonstrated a significant reduction in MHD from 1.23 ± 0.64 Gy (free-breathing) to 0.90 ± 0.32 Gy (mDIBH) ($p < 0.0143$). Additionally, notable LAD sparing was observed, with a decrease in Dmax from 20.63 ± 12.42 Gy (free-breathing) to 8.98 ± 5.10 Gy (mDIBH) ($p < 0.0001$) and a decrease in Dmean from 4.64 ± 4.55 Gy (free-breathing) to 2.29 ± 0.86 Gy (mDIBH) ($p < 0.0073$). For pts receiving 50 Gy with breast reconstruction (20 pts), the mean heart dose was 1.347 Gy, indicating remarkable dose sparing. No adverse events were reported across all doses or volumes.

Conclusions: This study reinforces previous findings that mDIBH with the ABC device significantly reduces the cardiac dose. In our clinical practice, mDIBH with the ABC device stands as the preferred approach for cardiac sparing in LBC patients, demonstrating feasibility and safety in all treatments. Only a minimal proportion (5%) of enrolled patients faced ineligibility due to device tolerability issues and severe hearing impairment.

No conflict of interest.

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155 (PB-062) Poster

Utility of clinical-pathological parameters for exclusion of BRCA1/2 mutation carriers as candidates for partial breast irradiation

R. Bernstein Molho[1], N. Abu-Shehada[2], E. Gal-Yam[3], Z. Zippel[4], T. Menes[4], M. Sklair-Levy[5], S. Galper[6], O. Kaidar-Person[7]. *[1]Sheba Medical Center, Oncogenetics and Oncology, Ramat Gan, Israel; [2]Sheba Medical Center, Oncogenetics, Ramat Gan, Israel; [3]Sheba Medical Center, Oncology, Ramat Gan, Israel; [4]Sheba Medical Center, Surgery, Ramat Gan, Israel; [5]Sheba Medical Center, Meirav breast imaging center, Ramat Gan, Israel; [6]Sheba Medical Center, Breast Radiation Unit & Oncology Institute, Ramat Gan, Israel; [7]Sheba Medical Center, Breast Radiation Unit, Oncology Institute, Ramat Gan, Israel*

Background: Several international groups published guidelines to identify low-risk breast cancer (BC) patients that are eligible for partial breast irradiation (PBI). These include the American Society for Radiation Oncology (ASTRO), the European Society for Radiotherapy and Oncology (ESTRO) and ESTRO subgroups such as IORT Task Force and GEC-ESTRO. Only ASTRO guidelines recommend against the use of PBI in known carriers of germline pathogenic variants (PVs) in *BRCA1* or *BRCA2*. As genetic testing might be time consuming, the aim of this study was to evaluate the proportion of BC patients, subsequently found to be *BRCA1/2* mutation carriers that would be eligible for PBI based on clinical-pathological criteria of the above international guidelines.

Patients and Methods: Data were extracted from the medical records of consecutive BC *BRCA1/2* PV carriers treated at a single institution between 2006 and 2023. Data included patient demographics, tumor characteristics, treatment, and disease outcomes.

Results: Overall, 514 patients were identified, 20 of them presented with synchronous bilateral disease. After excluding 16 patients with metastatic de novo disease, 498 patients with 518 primary tumors were analyzed. Of these, 282 (12 of them with synchronous bilateral disease) presented with unknown genetic status at diagnosis, these formed the study cohort. Median age at diagnosis was 42.7 years (range 23.8–77.9). Based on the recent ASTRO guidelines (not including conditionally recommended criteria), 19/294 (6.5%) of the tumors would be eligible for PBI, including 1 triple-negative tumor, 3 Her2-positive tumors, and 7 patients diagnosed between ages 40–49. Using the ESTRO IORT and the ACROP-ESTRO PBI criteria, 9/294 (3%) would be eligible, whereas the GEC ESTRO low risk criteria would miss 31/294 (10.5%) of the carriers, and their intermediate risk criteria would miss an additional 8.2% (overall 18.7%) of the carriers.

Conclusions: Explicit clinical-pathological criteria identify low risk BC patients who have a low likelihood (3–11%) of being *BRCA1/2* PV carriers.

No conflict of interest.

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156 (PB-063) Poster

Safety of trastuzumab deruxtecan and radiation therapy combination in HER2-positive metastatic breast cancer patients

L. Visani[1], I. Ratosa[2], D. Ribnikar[3], C. Becherini[1], N. Bertini[1], I. Bonaparte[1], D. Stefanovski[3], N. Dobnikar[2], I. Desideri[1], C. Mattioli[1], M. Valzano[1], M. Banini[1], V. Salvestrini[1], M. Bernini[4], C. Tommasi[4], J. Nori[5], L. Orzalesi[4], S. Bianchi[6], L. Livi[1], I. Meattini[1]. *[1]Azienda Ospedaliero-Universitaria Careggi, Radiation Oncology Unit, Florence, Italy; [2]Institute of Oncology, Division of Radiotherapy, Ljubljana, Slovenia; [3]Institute of Oncology, Division of Medical Oncology, Ljubljana, Slovenia; [4]Azienda Ospedaliero-Universitaria Careggi, Breast Surgery Unit, Florence, Italy; [5]Azienda Ospedaliero-Universitaria Careggi, Diagnostic Senology Unit, Florence, Italy; [6]Azienda Ospedaliero-Universitaria Careggi, Pathology Unit, Florence, Italy*

Background: Trastuzumab deruxtecan (T-DXd) currently represents the standard of care for the treatment of patients with metastatic HER2-positive (HER2+) breast cancer (BC) after disease progression to first line containing taxanes and trastuzumab. Radiation therapy (RT) is frequently required in the metastatic setting, either with palliative or ablative intent in case of oligometastatic or oligoprogressive disease. The aim of our study is to evaluate the safety of the use of T-DXd and concomitant RT in a consecutive series of HER2+ BC patients.

Material and Methods: We retrospectively evaluated patients diagnosed with metastatic HER2+ BC, treated at two leading European institutions (University of Florence, Italy and Institute of Oncology, Ljubljana) who started treatment with T-DXd between May 2021 and August 2023, receiving RT or not. Primary outcome of the study was the association between RT and any adverse events (AEs) > grade (G)2.

Results: Data of 52 consecutive patients treated with T-DXd with or without RT were retrospectively evaluated. Sixteen patients received RT immediately before (within a month) or during T-DXd, for a total of 17 RT treatments, while 36 patients did not. Median age was 54 years old (range 34–88). At a median follow up of 6 months (range 1–24), 3 patients (18.8%) had died in the RT group, while 5 patients (13.9%) in the no-RT group. Twenty-one patients (40.4%) received T-DXd as fourth or further line of systemic anti-HER2 treatment, while 16 (30.8%) in third line and 13 (25.0%) in second line. Two patients (3.8%) with early metastatic disease relapse (<6 months after adjuvant or neoadjuvant anti-HER2 therapy completion) received T-DXd as first line treatment. Median total RT dose prescription was 30 Gy (range 8–48) with a median number of fractions of 3 (range 1–15). Median EQD2 dose was 50 Gy (range 16–104) and median BED 60 Gy (24–149). The most frequently treated site was bone (47.1% of cases; N = 8/17) followed by brain (29.4%; N = 5/17). A chi-square test of independence was performed to examine the relation between RT administration and the

development of >G2 toxicity. The relation between these variables was not significant (p = 0.83). Regarding toxicities of special interest for T-DXd, 3 cases of G3 fatigue have been reported in no-RT group with 1 case in the RT group. Overall, only 1 case of G3 nausea was observed (in the no-RT group). Grade 2 interstitial lung disease (IDL), that led to T-DXd discontinuation, was observed in 1 case in RT group and in 2 cases in no-RT group. No radionecrosis events were observed among the 4 patients treated with intracranial RT.

Conclusions: Our first data are encouraging regarding the potential safety of this combination, showing that concurrent RT did not increase severe acute toxicity. Data from larger series are needed to confirm these results.

No conflict of interest.

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157 (PB-064) Poster

The continuous thermal dose-effect relationship in locoregional recurrent breast cancer patients treated with postoperative re-irradiation combined with hyperthermia

P. Tello Valverde[1], K. Pateras[2], A. Bakker[1], W. Kolff[1], G. van Tienhoven[1], P. Kok[1], B. Slotman[1], H. Crezee[1]. *[1]Amsterdam UMC, Radiation Oncology, Amsterdam, Netherlands; [2]University of Thessaly, Faculty of Public and One Health- Laboratory of Epidemiology & Artificial Intelligence, Karditsa, Greece*

Background: Mild hyperthermia (39–43°C) combined with re-irradiation can improve complete response rate compared with re-irradiation alone in locoregional recurrent (LRR) breast cancer. Observational studies analyzing a dichotomized hyperthermia thermal dose (TD) parameter showed in various tumor sites that higher hyperthermia TD was associated with better tumor response rate compared with a lower TD. However, analyzing the TD-effect relationships utilizing a continuous TD parameter is more powerful and less sensitive to false positive results. This has never been done so far, so we investigated the effect of a continuous TD parameter on locoregional control (LRC) in patients with LRR breast cancer treated with postoperative re-irradiation and hyperthermia.

Methods: In this study, we retrospectively analyzed the data of 112 women with LRR breast cancer treated in 2010–2017 with postoperative re-irradiation 8 × 4 Gy (n = 34) or 23 × 2 Gy (n = 78), combined with 4–5 weekly hyperthermia sessions guided by invasive thermometry. Among possible parametrizations of CEM43 (cumulative equivalent minutes at 43°C), including the TD parameter based on time-temperature exposures, the logarithm of the session with the highest invasively measured dose CEM43T50 (median CEM43) was selected based on univariate and stepwise regression analyses. The best fitted recurrence-free survival model was further analyzed under a Bayesian paradigm, assuming three informative priors (continuous highest CEM43T50, tumor location breast/chest wall and lymph node involvement).

Results: Twenty-four patients (21.4%) developed an infield recurrence; the median time to recurrence was 3.4 years (interquartile range (IQR) 2.7–4.6 years). Median highest session CEM43T50 was 7.2 minutes (equivalent to a median temperature T50 of ∼40.5°C), with an IQR between 2.4–15.9 minutes. Continuous TD parameter analysis showed that a higher TD was significantly associated with an increasing LRC ($P = 0.001$). Univariate and multivariate regression analysis showed that a twofold increase of TD (equivalent to a ∼0.5°C temperature increase) was associated with a 0.69 times (31%) and 0.79 times (21%) increase in hazard ratio for LRC, respectively. Bayesian survival regressions lead to a range of comparable decreasing hazard ratios of recurrence when TD increased. These findings were robust under both an optimistic and a skeptic informative prior assumption on the effect of TD.

Conclusion: Twofold increase of hyperthermia TD was associated with a significant increase in LRC over the continuous TD range during hyperthermia treatment and postoperative re-irradiation in LRR breast cancer. This result has implications for treatment delivery and is suggestive for a therapeutically relevant molecular hyperthermia effect in treatment with re-irradiation and hyperthermia.

No conflict of interest.

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POSTER SESSION **21 March 2024** **9.00-17.30**

Local Regional Treatment - Surgery

158 (PB-065) Poster

The incidence of non-sentinel nodal disease in patients undergoing a completion axillary node clearance after a positive sentinel node biopsy

S. Khawaja[1], S. Mehdi[1], Y. Sharaiha[1], A. Munir[1], S. Khan[1], A. Huws[1]. *[1]Prince Philip Hospital, Peony Breast Care Unit, Llanelli, United Kingdom*

Background: The presence of non-sentinel lymph node disease is affected by the age of the patient, the number of sentinel nodes retrieved; the size of the tumour, and the Her 2 status. Our retrospective study aimed to identify the incidence of non-sentinel nodal positivity in patients who underwent a completion axillary node clearance.

Materials and Methods: All the patients undergoing a sentinel node biopsy between January 2022 to July 2023 in the Hywel Dda University Health Board, Southwest Wales were included. Patients found to be sentinel node positive for macro metastases were identified and their axillary nodal burden was assessed. Other data collected for this cohort of patients were if the tumour was screen-detected or symptomatic; the tumour characteristics and the type of surgery performed.

Results: 504 patients underwent breast cancer surgery during the above time period. 418 of these patients had a sentinel node biopsy. 362 (87%) of the latter subgroup was node negative. 56 of the 418 patients (13%) were positive with macro-metastases out of which 46 underwent a completion axillary node clearance. Six patients received radiotherapy to the axilla. Two patients refused any axillary treatment. One patient was found to have lung metastases in the post-operative setting and did not have any further axillary treatment. One patient is awaiting staging investigations before undergoing the planned completion axillary node clearance.

Within the cohort who underwent a completion axillary node clearance, 13 patients had non-sentinel lymph node positivity with macro metastases. Eight patients had only one more positive lymph node. Thirty-one patients had no further axillary disease, while 2 final histology results are still awaited.

In the 13 patients who had more axillary disease, the mean age of the patients was 63 years with a mean tumour size of 52.7 mm. 84.6% were grade 2 and 61.5% were invasive ductal cancers. The tumours in 11/13 were ER positive, 12/13 were PR positive and all 13 were Her 2 negative.

71% of the tumours in this group were detected in the symptomatic setting.

Conclusion: On reviewing the results, 72% of the patients undergoing a completion axillary node clearance did not have any further axillary disease. The mean tumour size was 31.18 mm in the patients who had no non-sentinel nodal positivity. Therefore, tumours under 30 mm in size, ER positive and Her 2 negative with at least two sentinel nodes being retrieved and showing only one positive node can be considered for radiotherapy to the axilla rather than a completion axillary node clearance.

No conflict of interest.

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159 (PB-066) Poster

10-year survival outcomes of following ultrasound-guided targeted axillary surgery in breast cancer patients after neoadjuvant chemotherapy

J. Park[1], H. Keum[1], B. Kang[1], J.H. Jung[1], H.Y. Park[1], J. Lee[1]. *[1]School of Medicine- Kyungpook National University- Kyungpook National University Chilgok Hospital, surgery, Daegu, South Korea*

Background: Neoadjuvant treatments in node-positive breast cancer may lead to the regression of both breast cancer and lymph nodes. However, when complete regression is achieved, it can be challenging to identify traces of the previous tumor site or lymph nodes, making accurate surgery difficult. The authors conducted ultrasound-guided targeted axillary surgery (TAS) to ensure precise pathological evaluation of axillary lymph nodes and aim to present 10-year oncological outcomes.

Methods: From 2013 to 2017, ultrasound-guided TAS was conducted on 111 patients with node-positive breast cancer at a single center. 83 patients underwent charcoal tattooing, and 28 patients had clip insertions at the time of diagnosis. While 77 patients underwent sentinel lymph node biopsy (SLNB) or axillary sampling (AS), 34 patients received axillary lymph node dissection (ALND). Clinicopathological factors, including the type of axillary targeting, type of breast surgery, pathological tumor size, total and metastatic lymph node count, immunohistochemistry type, and margin status, were analyzed. Survival outcomes related to locoregional recurrence, distant metastasis, and death were also evaluated.

Results: The mean number of removed axillary lymph nodes was significantly different between the two groups (5.18 for TAS, and 14.65 for ALND; $p < 0.001$). Moreover, the mean number of metastatic axillary lymph nodes was significantly different between the two groups (0.57 for TAS, and 3.88 for ALND; $p < 0.001$). Meanwhile, there were 7 cases (9.09%) of locoregional recurrence in the TAS group, and 2 case (5.88%) in the ALND group. The incidence of distant metastasis was 12 cases (15.58%) in the TAS group and 7 cases (20.59%) in the ALND group. Additionally, 7 cases (9.09%) resulted in death in the TAS group, compared to 2 cases (5.88%) in the ALND group. The average recurrence-free survival, metastasis-free survival, and overall survival for the TAS group were 82.46, 77.32, 84.10 months, and 82.57, 74.34, 84.04 months for the ALND group. There were no statistical differences in locoregional recurrence, distant metastasis, and overall survival between the TAS and ALND groups ($p = 0.567$, $p = 0.552$, and $p = 0.579$, respectively).

Conclusion: In node-positive breast cancer, the 10-year survival outcomes showed no significant differences between TAS group and ALND group. Therefore, it may be considered acceptable to perform TAS with relatively few complications if a targeting method for metastatic axillary lymph nodes are available.

No conflict of interest.

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160 (PB-067) Poster

Risk of upstaging after a core biopsy diagnosis of classic, pleomorphic and non-classic lobular carcinoma in situ, a nationwide study

P. Westenend[1], C. Meurs[2], C. Kerkhoven[1], M. Menke-Pluijmers[3], S. Siesling[4]. *[1]Laboratory of Pathology, Pathology, Dordrecht, Netherlands; [2]CMAnalyzing, CMAnalyzing, Zevenaar, Netherlands; [3]Albert Schweitzer Hospital, Surgery, Dordrecht, Netherlands; [4]University of Twente, Department of Health Technology and Services Research, Enschede, Netherlands*

Background: There is a wide variation in reported upstage rate for both classic and non-classic LCIS, probably due to the small size of the series and selection bias. The uncertainty in the upstage rate may affect treatment decisions, mainly the choice between surgery or surveillance. In general surveillance is recommended for classic LCIS and surgery for non-classic LCIS. We studied the upstage rate in a large nationwide population.

Material and Methods: Dutch women with a biopsy-proven primary diagnosis of LCIS in 2011 to 2020 were selected from the national Dutch Pathology Archive (PALGA). Patients were only included if LCIS was the main diagnosis. Patients with DCIS or invasive carcinoma in the same biopsy or in another biopsy from the same breast were excluded. LCIS was coded as classic, pleomorphic or non-classic (not otherwise specified). Data on subsequent breast biopsies and surgical specimen were also available. Surgery within 3 months of the biopsy was regarded as related to the biopsy.

Results: 1178 patients were diagnosed with LCIS, on average 118 per year; 1018 (86%) were classic LCIS, 129 (11%) pleomorphic LCIS, and 31 (3%) non-classic LCIS not otherwise specified. The upstage rate was 33% for classic LCIS, 32% for pleomorphic LCIS and 31% for non-classic LCIS. However, the surgery rate was widely divergent; low for classic and high for pleomorphic and non-classic LCIS. Follow up of patients that were not operated within 3 months after the biopsy revealed 6 patients with ipsilateral DCIS and 28 patients with ipsilateral invasive cancer within 2 years after biopsy.

Conclusions: A biopsy diagnosis of LCIS only is rare. Taking the low surgery rate for classic LCIS into account and the low number of events at follow up, this study supports the use of surgery for classic LCIS; surgery is only warranted in selected patients. The data supports the use of surgery in pleomorphic LCIS and non-classic LCIS. For comparison of the upstage rate between studies or subtypes of LCIS, it is important to report the surgery rate.

No conflict of interest.

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162 (PB-069) Poster

De-escalating Axillary Lymph Node Dissection: can it be avoided in patients undergoing mastectomy for positive sentinel node-breast cancer?

R. Guevara-Peralta[1], C. Ortega-Exposito[1], C. Falo-Zamora[2], M. Campos-Delgado[1], A. Benitez[3], A. Petit[4], H. Perez-Montero[5], J. Ciria-Puigpinós[6], J. Jimenez[7], J. Ponce i Sebastià[1], M. Pla-Farnós[1], A. Garcia-Tejedor[1]. *[1]Hospital Universitari de Bellvitge, Gynecology Department, Barcelona, Spain; [2]Institut Català d'Oncologia, Oncology Department, Barcelona, Spain; [3]Hospital Universitari de Bellvitge, Nuclear Medicine Department, Barcelona, Spain; [4]Hospital Universitari de Bellvitge, Pathology Unit Department, Barcelona, Spain; [5]Institut Català d'Oncologia, Radiotherapic Oncology Department, Barcelona, Spain; [6]Universitat de Barcelona, Medicine Faculty, Barcelona, Spain; [7]Hospital Universitari de Bellvitge, Radiology Department, Barcelona, Spain*

Background: The indications for Axillary Lymph Node Dissection (ALND) have evolved in recent years following the release of findings from ACOSOG Z001 and EORTC 10981-22023 AMAROS. The initial trial revealed that this surgical procedure could be omitted in the primary surgery for patients with tumors smaller than 5 cm, patients with conservative surgery, and those with less than 3 macrometastases in the sentinel node (SN) without worsening survival. The second trial expanded its scope to include mastectomy patients; however, there is a lack of specific studies demonstrating the safety of omitting ALND in individuals undergoing mastectomy.

Objective: To determine the need for Axillary Lymph Node Dissection in patients undergoing mastectomy and macrometastasis at SN after primary surgery and its impact on the incidence of lymphedema.

Material and Methods: We designed an Observational Retrospective Cohort Study of patients undergoing mastectomy as primary surgery for breast cancer with 1 or 2 macrometastasis in the SN between the years 2013–2023. The sample was divided into two groups based on the performance of ALND. Kaplan-Meier curves were performed to estimate the disease-free survival (DFS) and overall survival (OS) of both groups and log rank to determine if there were significant differences between them. The Chi-square test was used to compare the incidence of lymphedema in both groups.

Table 1: (abstract: 160 (PB-067)):

	All		Classic		Pleomorphic		Non-classic		p-value
	N	(%)	N	(%)	N	(%)	N	(%)	
Upstage									
All	*319*		*186*		*107*		*26*		0.954
No	216	(68)	125	(67)	73	(68)	18	(69)	
DCIS	24	(7)	16	(9)	7	(7)	1	(4)	
Invasive BC	79	(25)	45	(24)	27	(25)	7	(27)	
Surgery									
All	*1178*		*1018*		*129*		*31*		<0.001
No	859	(73)	832	(82)	22	(17)	5	(16)	
Yes	319	(27)	186	(18)	107	(83)	26	(84)	

Results: Of the 328 patients in our study, 63 patients (19%) underwent mastectomy. Lymphadenectomy was performed in 44 (70%) of these patients. In the ALND group, between 1 and 2 positive sentinel nodes were found in 27 cases (61.4%), while 17 were negative (38.6%). The mean follow-up of our population was 47 months (SD 32). DFS at 5 years of follow-up in the ALND group was 89% (95% CI 79–99%), while in the group that did not undergo ALND it was 100% (p 0.273). The OS in the ALND group was 84% (95% CI 86–100%), while in the group that did not undergo ALND it was 100% (p 0.402). The incidence of lymphedema was 61% in the control group (ALND) and 5% in the study group (without ALND) (p < 0.001). It is important to note that within the control group (ALND) only 11% developed a severe grade of lymphedema, while there were no cases of severe lymphedema in the study group.

Conclusions: In patients diagnosed of breast cancer who have undergone mastectomy as primary surgery and who present less than 3 macrometastases in the sentinel lymph node, performing ALND does not have an impact on recurrences, or survival. Additionally, this type of surgery increases significantly the risk of lymphedema.

No conflict of interest.

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163 (PB-070) Poster

The role of a patient with breast cancer in a multidisciplinary team – from making a decision to changing the treatment option

Z. Maksimovic[1], R. Ljubisavljević[1], I. Simović[1], G. Veličanin[1], A. Ćurčić[1], A. Banjanac[1], S. Đikić[1], E. Karisik[2], D. Aleksandrovic[3], J. Tanasijevic[3], D. Petković[3], S. Vatricevic[4], Z. Babic[4], N. Rsovac[4], K. Kundovic[4], M. Misic[5], S. Mitrovic[5], Z. Mihajlovic[5], J. Vukasinovic[5]. *[1]Health center Studenica Kraljevo, Surgery, Kraljevo, Serbia; [2]Health center Novi Pazar, Surgery, Novi Pazar, Serbia; [3]Health center Studenica Kraljevo, Oncology, Kraljevo, Serbia; [4]Health center Studenica Kraljevo, Pathology, Kraljevo, Serbia; [5]Health center Studenica Kraljevo, Radiology, Kraljevo, Serbia*

The task of the multidisciplinary team (MDT) is to make the best decision for the treatment of the oncology patients based on the modern accepted medical doctrines. The focus is on the patient who must be informed with all the facts regarding the disease and agree to the proposed diagnostic and therapeutic procedures. The aim of this paper is to show how important the patient's opinion is for making the first decision of the MDT, as well as which factors lead to a change in the treatment plan before the start of the first treatment modality.

We took data from electronic medical records and a questionnaire conducted with 196 patients operated for breast cancer at the Studenica Kraljevo General Hospital from January 2022 to September 2023. All patients were seen at the MDT before the start of treatment, 190 personally attended the conference and decision making and 6 was not present due to comorbidity. We analyzed age, cTNM at the time of diagnosis, pathohistological and IHC findings after biopsy, first MDT decision, non-acceptance of the first MDT decision by the patient and the reasons for it, change of the patient's opinion before starting the first treatment modality and the reasons for it change of the operative modality and reasons for it. The data show that 36 patients (18%) did not accept the first proposal of MDT, there were 29 who did not accept the recommended sparing operation but required mastectomy, 4 did not accept mastectomy but required sparing surgery, 3 did not accept neoadjuvant therapy. The most common reason for not accepting the proposal MDT was of a personal nature, in 22 there was fear, malignancy in personal or family history, in 8 the key factor was the influence of the environment and in 6 patients the advice of doctors who were not competent members of MDT.

The intended type of treatment was changed before the operation in 44 patients,19 of them due to personal reasons, fear, the influence of the environment and the doctor's advice, and in 25 the surgeon changed the planned operative modality before the operation.

Analyzing the data we found that in as many as 83 patients (42%) the initial decision of the MDT was changed At the request of 55 patients the initial decision was changed before starting treatment with surgery, of which only 4 patients wanted a sparing breast operation instead of a mastectomy, and all the others requested a mastectomy. instead of sparing surgery, most often due to bad personal experience, malignancy in the family (48%),advice from the environment (24%) advice from doctors who are not competent members of the MDT (28%)

In conclusion-as the patient is at the center of consideration of the MDT, all decisions of the MDT must be made in the presence and agreement with the patient and with her consent in order to avoid or implement changes to the treatment plan

No conflict of interest.

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164 (PB-071) Poster

Prospective trial on cryosurgery for early breast cancers without subsequent tumour excision

A. Kwong[1], M.T.H. Co[1], T. Shek[2], E. Fukuma[3]. *[1]The University of Hong Kong, Surgery, Hong Kong, Hong Kong; [2]The University of Hong Kong, Pathology, Hong Kong, Hong Kong; [3]Kameda Medical Center- Japan, Breast Centre, Kamogawa, Japan*

Introduction: Cryosurgery is a minimally invasive percutaneous ablative breast cancer treatment. Early pilot studies have shown its effectiveness in treating selected early breast cancers.

Methods: This is a single arm prospective trial on cryosurgery on early breast cancers with ethical approval. Inclusion criteria include In-situ or invasive ductal carcinoma with size <=1.5 cm in the largest dimension. Patients were screened pre-operatively with PET/MRI scans for size eligibility. Eligible patients were treated by cryosurgery by a breast specialist. Axillary surgery such as sentinel lymph node biopsy were performed in the same setting.

PET/MRI scans were repeated at 6-week post-cryosurgery, and systematic image-guided core needle biopsy were performed at 8-weeks post-cryosurgery, for documentation of any residual breast cancers. Tissues from anterior, posterior, superior, inferior, medial, lateral and central areas were biopsied by one single breast surgical specialist for post-cryosurgery evaluation of tumor viability by specialist pathologist.

Results: 43 patients were recruited into the study. 16 patients were excluded after multifocality/multicentricity found by MRI or MRI size fallen outside inclusion criteria. 27 patients received cryosurgery.

The median size of the tumor was 11 mm (Range 5–15 mm). Tumor histology include one ductal carcinoma in situ and 26 invasive ductal carcinoma. All patients had positive hormonal receptor (ER and PR) status. None of them were HER-2 enriched. Median cryosurgery procedure time was 45.5 minutes (Range 20–141 minutes).

6-week Post-cryosurgery PET scan of all 27 patients showed metabolically quiescent post-ablation lesion. 6-week Post-cryosurgery MRI scan of all 27 patients showed residual post-treatment cavity with median size of 42 mm (Range 28–54 mm). Post-cryosurgery surgery systematic biopsy at 6 weeks showed no evidence of residual viable tumor in all patients, which correlates with the post-cryosurgery PET/MRI findings. None of the 27 patients developed surgical complications. All patients had at least 12 weeks of follow-up and remained well.

Conclusion: Cryosurgery resulted in complete ablation of all early breast cancers treated in this cohort. This cohort showed significantly better ablative results when compared to previously published retrospective studies where cryosurgery on larger tumors tend to be associated with increased risk of residual tumors. The authors believe strict size inclusion criteria in this study plays an important role in this. Pre-cryosurgery PET and MRI also allowed much more accurate estimation of the tumor size which is reflected by the large number of patient exclusion after PET and MRI in this cohort.

Conflict of interest:

Other Substantive Relationships: Cryoprobes and ProSense system were donated by WKK Medical Equipment Company Ltd.

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165 (PB-072) Poster

Predictors of upstage for invasive breast cancer in women with ductal carcinoma in-situ

P. Chan[1], E.J. Sim[2], L.W. Khin[3], E.Y. Tan[1]. *[1]Tan Tock Seng Hospital, Breast Unit, Singapore, Singapore; [2]Tan Tock Seng Hospital, General Surgery, Singapore, Singapore; [3]Tan Tock Seng Hospital, Clinical research and Innovation office, Singapore, Singapore*

Background: Ductal carcinoma in-situ (DCIS) is often detected through screening and its prevalence has increased with greater screening uptake and it now accounts for approximately 20% of all new breast cancers. Although 20-year breast cancer-specific mortality is 3.3%, surgery is often done when DCIS is diagnosed on percutaneous biopsy because of possibility of undiagnosed invasive foci in the rest of the lesion (invasive upstage). We therefore aim to identify predictors of upstage of DCIS to invasive carcinoma and build a logistic regression model to predict upstage.

Material and Methods: A retrospective study was carried out on 910 women pulled from 3 different institutions with histologically confirmed DCIS on needle biopsy from 1 January 2006 through to 31 December 2015. Women with micro-invasive component in the biopsy specimen or did not undergo definitive surgery were excluded from analysis. Patient demographic, clinical, pathological, radiological variables, treatment data and outcomes were collected from the electronic medical records and evaluated to identify possible predictors of invasive upstage and recurrence. Bivariate analysis was conducted for categorical variables using Fisher's exact test or Pearson's Chi-square test, as appropriate. Covariates that showed statistical significance from the bivariate analyses, and other important clinical covariates, were included in the multivariable logistic regression model.

Results: Overall, 274 (30.1%) women with DCIS were found with an upstage to invasive breast cancer at surgery. Bivariate analyses found radiological tumour size and progesterone receptor (PR) status to be significantly associated with invasive upstage. Larger lesions (P < 0.001) were more often found with an invasive component. PR negative tumours were 1.7 times more likely to have an invasive upstage. Of note, there was no significant association with estrogen receptor (ER) status. On multivariable logistic regression, radiological lesion size (adjusted OR 1.018, 95% CI 1.008–1.029, P = 0.004), and PR tumour status (adjusted OR 1.66, 95% CI 1.47–1.92, P = 0.016) emerged as independent predictors of invasive upstage. A shrinkage factor of 1.33 was calculated to account for the small number of variables in our model. After accounting for this, the calibrated risk score for PR-tumour status and radiological lesion size was 0.6 and 0.03 (per 1 mm increase) respectively. While there is no difference in hazards for recurrence between those with invasive upstage and those without, PR-negative tumours showed a worse overall survival.

Conclusions: This study found 30.1% of DCIS diagnosed at biopsy were found with an upstage of invasive cancer. Independent predictors were larger radiological size and PR-negative status. Tumour PR status appeared to have prognostic significance in DCIS tumours that upstaged to invasive cancers.

No conflict of interest.

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166 (PB-073) Poster

Can we omit intraoperative frozen-section biopsy during breast-conserving surgery in selected patients?

S.H. Kang[1], H.T. Noh[1], H. Hong[1], M.H. Lee[1], J. Cho[1], H.J. Lee[1], S.Y. Kwon[2]. *[1]Keimyung University School of Medicine, General Surgery, Daegu, South Korea; [2]Keimyung University School of Medicine, Pathology, Daegu, South Korea*

Background: Many surgeons in Korea routinely perform intraoperative frozen-section biopsy (IFS) for evaluating the resection margin during breast-conserving surgery (BCS) for patients with breast cancer. Most surgeons expect a lower margin positive rate and lower re-excision rate while performing IFS. However, some surgeons have questioned the effectiveness of IFS, because in some cases, it necessitates re-excision after the first surgery because of false-negative results despite a longer operation time and additional usage of resources. This study aims to evaluate whether the use of IFS correlates with the positive margin rate and re-excision rate.

Material and Methods: We collected data from patients who underwent BCS for invasive breast cancer between August 2018 and December 2021. The patients were treated either by two surgeons who routinely performed IFS for evaluating the resection margin (IFS group) or by another surgeon who did not perform IFS and performed specimen ultrasonography or mammography for evaluating the resection margin (no-IFS group). We analyzed the correlation between the use or non-use of IFS and the positive margin rate and re-excision rate. We further evaluated factors influencing the resection margin, namely, microcalcification, non-mass enhancement (NME) on MRI, and multifocality.

Results: In the IFS group (n = 186), 20 patients were found to have tumor involvement on the resection margin on undergoing IFS and further excision was performed during the surgery. Moreover, 11 patients (5.9%) had tumor involvement on the resection margin of the permanent-section biopsy specimen and 8 (4.3%) underwent re-excision. In the no-IFS group (n = 162), 24 patients underwent additional intraoperative excision depending on the result of specimen ultrasonography or mammography. Moreover, 9 patients (5.6%) had tumor involvement on the resection margin of the permanent-section biopsy specimen and 7 (4.3%) underwent re-excision. The positive margin rate and re-excision rate showed no significant differences between the two groups (P > 0.999 and P > 0.999). Among the factors that could influence the resection margin, only NME on MRI showed a correlation with the positive margin rate (P = 0.009) and re-excision rate (P = 0.03).

	Intraoperative frozen section biopsy		p value
	no (n = 162)	yes (n = 186)	
Positive margin on permanent section biopsy	9 (5.6%)	11 (5.9%)	>0.999
Re-excision	7 (4.3%)	8 (4.3%)	>0.099

Conclusion: This study revealed no significant differences in the positive margin rate and re-excision rate during BCS with or without IFS. Therefore, we could consider omitting IFS during BCS in a selected group of patients with breast cancer who undergo margin evaluation using specimen ultrasonography or mammography. These results also suggest that surgeons should be cautious when performing BCS for patients with NME on MRI.

No conflict of interest.

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167 (PB-074) Poster

Characteristics and clinical outcomes of breast cancer patients under different modalities of breast-conserving surgery and lymph node management in China

T. Pan[1], C. Zheng[2], C. Xu[3], J. Ding[4], J. Liu[5], W. Wu[6], Y. Chen[1], O. Wang[2]. *[1]The Second Affiliated Hospital- Zhejiang University School of Medicine, Department of Breast Surgery, Hangzhou, China; [2]The First Affiliated Hospital of Wenzhou Medical University, Department of Breast Surgery, Wenzhou, China; [3]Affiliated Jinhua Hospital, Zhejiang University School of Medicine, Department of Breast and Thyroid Surgery, Jinhua, China; [4]Ningbo Medical Center Lihuili Hospital, Department of Breast and Thyroid Surgery, Ningbo, China; [5]Hangzhou First People's Hospital, Department of Breast Surgery, Hangzhou, China; [6]The Third Affiliated Hospital of Wenzhou Medical University, Department of General Surgery, Wenzhou, China*

Background: In China, oncoplastic breast reconstruction surgery (OPS) has not been popularized, and axillary lymph node dissection (ALND) might still be overused. The objective of this study is to describe characteristics and compare clinical outcomes between different breast-conserving surgery (BCS) types and axillary lymph node managements in Chinese breast cancer (BC) patients.

Material and Methods: All BC female patients treated with BCS at 6 hospitals of China between January 2014 and December 2019 were included in this study. The type of BCS, axillary lymph node management, and other clinical data were collected. The outcome included local recurrence (LR), distant metastasis (DM) and invasive margins (IM). Surgical complication was also collected.

Results: A total of 2195 patients were enrolled, of whom 2123 undergoing BCS alone, 68 received OPS by autologous flap, and 4 by implant. The characteristics of the patients were shown in the table. There were 2040 (96.1%) patients received sentinel lymph node biopsy and 400 (18.2%) received ALND. No statistically significant difference was observed with LR (50 [2.4%], 2 [2.9%], 0; P = 0.705), DM (65 [3.1%], 4 [5.9%], 0; P = 0.264) and IM (45 [2.1%], 2 [2.9%], 1 [25.0%]; P = 0.085) among the three kinds of breast-conserving procedure. In patients who had multiple lesions (number of lesions >1), those who received ALND (n = 33) compared with those who did not (n = 131) showed no significant advantage in terms of LR (2 [6.1%] vs 4 [3.1%], P = 0.348) and DM (1 [3.0%] vs 1 [0.8%], P = 0.363). Even in patients with combined 1–2 sentinel lymph node metastases, there was no statistically significant difference in LR (1 [1.8%] vs 8 [2.5%], P > 0.999) and DM (2 [3.6%] vs 7 [2.1%], P = 0.623) in patients who received ALND (n = 55) compared to those who did not (n = 326). Among all patients, the incidence

of surgical complications was 1.5% (32 patients), and the most common were seroma formation (0.5%) and incision infection (0.2%).

Variables	N = 2195
Age, median (interquartile range)	50.8 (44.0, 59.0)
Clinical stage at diagnosis, n (%)	
0	71 (3.2)
I	1334 (60.8)
II	737 (33.6)
III	18 (0.8)
Unknown	35 (1.6)
Number of lesions, n (%)	
1	2015 (92.5)
2	137 (6.3)
≥3	27 (1.2)
Unknown	16 (0.7)
Number of sentinel lymph node metastases, n (%)	
0	172 (8.2)
1	91 (4.3)
2	286 (13.6)
≥3	1561 (74.0)
Unknown	85 (3.9)

Conclusions: The different breast-conserving surgeries have shown similar clinical outcomes for resectable BC, but the current acceptance of OPS in China still needs to be improved. Furthermore, the use of ALND did not show benefit for the improvement of clinical outcomes, while overuse of ALND still exists in China.

No conflict of interest.

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168 (PB-075) Poster

Avoiding a visible scar in peripherally located UIQ tumors: Comparative study of Aesthetic and Surgical outcomes of the Modified Vs Standard Matrix Rotation Technique

K. Wijesinghe[1], T. Abeywickrama[2], T. Saanthepan[2], K. Lakmal[3], M. Chandraguptha[3], S. Kalaiyukam[3], N. Ganesharajah[3], U. Jayarajah[2], A. De Silva[2]. *[1]Consultant General and Breast surgeon, Department of Surgery, Faculty of Medical Sciences, University of Sri Jayawardenepura, Colombo, Sri Lanka; [2]National Hospital of Sri Lanka, Surgery, Colombo, Sri Lanka; [3]Colombo South Teaching Hospital, University Surgical Unit, Colombo, Sri Lanka*

Background: Oncoplastic breast conserving surgery assists in achieving a good aesthetic outcome in breast cancer surgery. However, tumors located in the upper inner quadrant (UIQ) still pose a challenge to the surgeon giving rise to visible scars and deformities especially if peripherally located. Due to this reason we introduced the modified approach to the matrix rotation technique to avoid a visible scar in the UIQ. This modified approach utilized a de-epithelialized dermo-glandular flap to fill the defect. This study aims to compare the aesthetic and surgical outcomes after the standard Vs modified technique.

Materials and Methods: This is a prospective study of 32 patients diagnosed with peripherally located UIQ breast cancer at two tertiary care hospitals during 2022. All patients were operated by two breast surgeons following multi-disciplinary decision. Aesthetic outcomes were measured at 12 months by an independent observer and by the patient with regard to breast volume, shape, symmetry, scars, nipple areola complex and global judgement using the aesthetic item scale. This consisted of a Likert scale from 0 to 10, where 0 means the worst aesthetic outcome and 10 the best. Surgical and flap related morbidities were classified using the Clavien–Dindo classification system.

Results: 16 patients were in the modified group and 16 patients in the standard group. There was no statistically significant difference in both groups in terms of age, tumour size and breast size. The mean operative time was 64 minutes and 68 minutes in standard and modified group respectively with no significant difference. No surgical complications were reported in both groups such as wound dehiscence, infection, flap necrosis or re-excisions.

Patient reported aesthetic outcome demonstrated good response to breast volume, shape, symmetry and nipple areola complex in both groups. However, lower aesthetic outcome was reported in scar visibility and global judgement in the standard group compared to the modified technique group with $p < 0.01$. Similar observation was seen in the independent observer rating with significant lower aesthetic outcome in scar visibility. Among the patients who scored low for global aesthetic judgment, 94% stated the restriction in the choice of clothing due to visible scar and 90% had low self-esteem with the standard technique.

Conclusions: Our preliminary results demonstrate superior aesthetic outcome with the use of the modified matrix technique for UIQ tumors. Whilst long term studies with a larger sample size is needed, we believe that modified matrix technique is a good option to avoid a visible scar in the breast in appropriately selected patients.

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169 (PB-076) Poster

Machine learning model predicting axillary pathologic response after neoadjuvant chemotherapy for clinically node-positive breast cancer

A. Matsumoto[1], M. Sugimoto[2], S. Naruse[1], Y. Isono[1], Y. Maeda[1], A. Sato[1], M. Yamada[1], T. Ikeda[1], H. Jinno[1]. *[1]Teikyo University School of Medicine, Department of Surgery, Tokyo, Japan; [2]Keio University, Graduate School of Media and Governance, Kanagawa, Japan*

Background: Neoadjuvant chemotherapy (NAC) has eradicated axillary lymph node metastasis in approximately 40% of patients. These patients could avoid complications by omitting axillary dissection (ALND). This study aimed to evaluate clinicopathological factors and imaging characteristics by MRI and ultrasound (US) and predict axillary pathologic complete response (ypN0) after NAC by using machine learning, which enables the identification of candidates for ALND omission in patients with clinically node-positive disease.

Material and Methods: We identified 202 patients with clinically node-positive breast cancer who received NAC from March 2006 to April 2022. All patients underwent MRI and US before and after NAC. Patients were judged node-positive when they had cytologically proven nodal disease by fine-needle aspiration or suspicious lymph nodes by diagnostic imaging. All patients were randomly divided into a learning cohort of 152 cases and a validation cohort of 50 cases. In the validation cohort, the association between ypN0 status and clinicopathological and imaging characteristics was assessed by multivariate logistic regression (MLR) analysis and machine learning (ADTree method, ensemble learning). The area under the receiver operating characteristic (ROC) curve (AUC) was used to evaluate discrimination by the model. The model was further evaluated in the validation cohort.

Results: The median age was 54.0 (range, 22–82) years, and the median tumor size was 3.8 (range, 0.9–15.0) cm. Of 202 patients, 104 (51.5%) had luminal, 53 (26.2%) had HER2-positive, and 45 (22.3%) had triple-negative disease. Overall, 88 (43.6%) patients achieved ypN0. Independent predictors of ypN0 status were the absence of lymphadenopathy after NAC (odds ratio [OR]: 19.52, $p < 0.001$), clinical stage N1 (OR: 5.87 vs. cN2–3, $p = 0.012$), HER2 positivity (OR: 5.09, $p = 0.006$), ≥70% breast tumor reduction by MRI (OR: 3.04, $p < 0.001$), hormone receptor negativity (OR: 2.94, $p = 0.041$), and nuclear grade (NG)3 (OR: 2.86 vs. NG1-2, $P = 0.034$). In a MLR model using these predictors, the AUC was 0.902 (95% confidence interval (CI): 0.854–0.949, $p < 0.001$). The sensitivity and specificity of the model were 84.6% and 83.7%, respectively. In the validation cohort, the AUC was 0.890 (95% CI: 0.798–0.981, $p < 0.001$), and the sensitivity and specificity were 81.8% and 78.6%, respectively. Using the ADTree method, the AUC was 0.975 for the training cohort and 0.933 for the validation cohort. When ensemble learning was further adapted, the AUC was 0.977 for the training cohort and 0.947 for the validation cohort.

Conclusions: By constructing a ypN0 prediction model using machine learning, it was possible to make more accurate predictions than conventional MLR models, suggesting the possibility of individualizing axillary surgery after NAC.

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170 (PB-077) Poster

Prepectoral breast reconstruction with tissue expander covered by acellular dermal matrix: results and outcomes after the first 94 procedures

M. Bernini[1], D. Cassetti[1], C. Tommasi[1], I. Gaggelli[1], G. Gigliucci[1], L. Arlia[1], F. Manetti[1], I. Meattini[2], L. Livi[2], V. Salvestrini[2], L. Visani[2], G. Bicchierai[2], J. Nori Cucchiari[3], D. De Benedetto[3], F. Di Naro[3], S. Bianchi[4], L. Orzalesi[1]. *[1]Azienda Ospedaliero-Universitaria Careggi, Chirurgia della Mammella, Florence, Italy; [2]Azienda Ospedaliero-Universitaria Careggi, SODc Radioterapia Oncologica, Florence, Italy; [3]Azienda Ospedaliero-Universitaria Careggi, Diagnostica Senologica, Florence, Italy; [4]Azienda Ospedaliero-Universitaria Careggi, Istologia Patologica e Diagnostica Molecolare, Florence, Italy*

Background: Reconstructive options after conservative mastectomy, either skin-, nipple-sparing or skin reducing, entail a variety of safe methods to recreate the natural shape and aesthetics of the breast. Tissue expanders (TE) are usually placed in a retropectoral position. The purpose of this study is to evaluate the feasibility and safety of two-step reconstruction with TE in prepectoral position covered by acellular dermal matrix (ADM), thus taking advantage of a more prudent two-stage approach while still maintaining the benefits of a prepectoral reconstruction.

Material and Methods: Between January 2021 and October 2023, 79 patients with BRCA 1/2 mutations or early breast cancer were deemed suitable for a two-stage procedure. All patients underwent conservative mastectomy with immediate preprectoral reconstruction using TE covered with a specific ADM, designed as an internal bra, followed by a second surgery for TE replacement. Demographic, histological, oncological data and surgical complications were recorded. Moreover, in five cases a capsule sample was harvested during second stage and microscopically evaluated.

Results: A total of 94 conservative mastectomies were performed. In terms of short terms complications, 3 patients developed hematoma and 1 patient developed seroma. 2 patients showed wound dehiscence, both healed after conservative treatment. No case of necrosis of skin or nipple has been observed. As for failure rate, in 3 patients (3.7%) complications were found that required reintervention with temporary prosthetic implant removal. All these 3 complications were late, after three months and were infections in 2 cases and TE rupture in the remaining. All five capsule samples analyzed at hematoxylin-eosin histology showed a complete integration of the ADM with the native mastectomy flap, displaying neo angiogenesis, signs of adipocites regeneration and a synovial metaplasia at TE surface.

Conclusions: Not all patients are candidates to a DTI, especially in the prepectoral setting, in selected cases it may be necessary to perform a delayed breast reconstruction after conservative mastectomy, in order to minimize the mastectomy flap microvessels tension and therefore the use of TEs can be chosen, still keeping the prepectoral strategy. The placement of temporary implants in prepectoral position can be achieved by means of adequate ADM devices that cover completely the TE securing its position, while guaranteeing a progressive expansion with time due to the biological interaction with native tissue and a complete reabsorption. Such an approach represents a novel trend in the two-stage reconstruction scenario and this is the largest series in literature with this type of technical feature. Authors report optimistic results of prepectoral reconstruction with TE entirely covered by ADM, which is a safe, practical and reproducible method.

No conflict of interest.

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171 (PB-078) Poster

Ductal carcinoma in situ of the breast, lessons learned after more than 10 years follow-up of a cohort of patients from a large western cancer centre

M. Bernini[1], D. Cassetti[1], C. Tommasi[1], I. Gaggelli[1], F. Manetti[1], G. Gigliucci[1], L. Arlia[1], I. Meattini[2], L. Livi[2], V. Salvestrini[2], L. Visani[2], G. Bicchierai[2], J. Nori Cucchiari[3], D. De Benedetto[3], F. Di Naro[3], S. Bianchi[4], L. Orzalesi[1]. *[1]Azienda Ospedaliero-Universitaria Careggi, Chirurgia della Mammella, Florence, Italy; [2]Azienda Ospedaliero-Universitaria Careggi, SODc Radioterapia Oncologica, Florence, Italy; [3]Azienda Ospedaliero-Universitaria Careggi, Diagnostica Senologica, Florence, Italy; [4]Azienda Ospedaliero-Universitaria Careggi, Istologia Patologica e Diagnostica Molecolare, Florence, Italy*

Background: Ductal carcinoma in situ (DCIS) of the breast is not necessarily precursor of invasive breast carcinoma (IBC). DCIS represents an intraductal lesion of the breast characterised by increased epithelial proliferation with cellular atypia not invading the basement membrane of the ductal lobular unit. Since the advent of widespread mammography has become clear that DCIS is a non-lethal problem and its main threat relates to the subsequent occurrence of IBC. The purpose of this study is to evaluate the characteristics of DCIS population, the rate of upgrading to IBC immediately at final pathology report after surgery and the rate of locoregional recurrence (LRR) either as DCIS or as invasive cancer after a long period of follow-up in a cohort of women submitted to surgery for DCIS in a large western cancer centre.

Material and Methods: We performed a retrospective analysis of all consecutive patients admitted between 01/01/2010 to 31/12/2012 whose initial diagnosis was DCIS at our centre. The patients were treated with breast conserving surgery (BCS), radical mastectomy or conservative mastectomy. Demographic data, histological evaluation and surgical technique were recorded. Endpoints included the rate of LRR and the rate of IBC upgrading.

Results: Overall, 210 patients were included in the study, most with cluster of microcalcifications as the primary radiological lesion (75%). Median age was 52.5 years (mean 54.7; interquartile range [IQR] 31–79 years). Median follow-up was 102 months (IQR 1–142 months). In 75 (35.7%) cases we recorded an upgrade to IBC on postoperative pathology. Thirty-eight upgraded lesions (50.6%) were G3 and forty-five (60%) were multicentric. Eventually, twelve out of 75 upgraded cases (16%) subsequently developed a LRR. Similarly, thirty-six (17.1%) patients with definitive pathological report of DCIS subsequently developed a LRR. The median time to recurrence was 80 months (IQR 28–126 months). No cases of death were registered.

Conclusions: In literature, DCIS represents some 25% of all BC diagnoses, death for breast carcinoma after a diagnosis of DCIS is rare: 1.1% after 10 years of diagnosis. Despite concerns surgery remains the mainstay of treatment with adjuvant radiotherapy reducing by half LRR of DCIS or the development of invasive disease after BCS. In our study, the upgrade rate to IBC was found to be 35.7%. In literature, there is great variability in this rate. After a 10 year follow-up we observed a similar recurrence rate for upgraded IBC cases (16%) and for the pure DCIS cases (17.1%). As a matter of fact, surgery is still needed in every case of DCIS due to a quite high rate of upgrading to IBC and to a not negligible rate of recurrence. As a consequence of that, follow-up is also mandatory in order to detect recurrences and avoid any mortality rate for this type of breast carcinoma.

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172 (PB-079) Poster

The role of the certified surgeon-oncologist in improving the diagnosis and operative treatment of patients with breast tumors

R. Ljubisavljević[1], Z. Maksimovic[1], A. Curcic[1]. *[1]Health center Studenica Kraljevo, Surgery, Kraljevo, Serbia*

In most cases, breast cancer surgery is performed by general surgeons. The aim of this paper is to show that a certified oncologist surgeon contributes significantly to the better treatment of breast cancer patients by introducing modern diagnostic and surgical procedures. In this retrospective analysis, which included 1408 patients, operated on in Studenica KV General Hospital for breast tumors from 2008 to 2014. yr., the data were obtained from the hospital information system. The age of patients, type of biopsy (preoperative CORE or intraoperative ex Tempore), number of operated benign lesions, type of anesthesia, number of operated malignant lesions and scope of operative procedures, axillae dissection and SLNB, length of post-operative hospitalization were analyzed. Data were analyzed using descriptive statistics and descriptive statistical methods.

We divided the research period into two parts. The first from 2007 to 2010 and the second from 2011 to 2014 which coincides with the subspecialty studies of our general surgeon. in the first period, only 14 patients out of a total of 779 (1.8%) had a true cut biopsy performed preoperatively. In the second period, out of 599, 276 (46.1%) had the specified biopsy.

The beginning of the use of SLNB in order to decide on the extent of possible ALND coincides with the second period of our research, that is, with the beginning of our surgeon's training. Before 2012, this surgical-diagnostic procedure was not used in our institution and was performed in only 4.17% of patients. While in 2013 it was done in 48% and in 2014 in 44.52% of operated patients.

During the observed period, there was an increase in the number of patients who underwent BCS compared to MRM.

In the first period of our research, 13.2% of tumorectomies were performed under local anesthesia, while 86.8% of them were performed under general anesthesia. In the second period, which coincides with the training of our general surgeon, tumorectomy was performed under local anesthesia in 54% of patients, while 46% of the same operation was performed under general anesthesia. This reduced the time of hospitalization from 4 to an average of 2 days.

All previously mentioned research results will be presented in the form of tables and graphs.

A certified surgeon-oncologist significantly contributes to the improvement of quality in the diagnosis and treatment of patients with breast tumors, which can be seen in the increase in the number of preoperative core biopsies of the breast, the reduction in the number of operations for benign breast tumors under general anesthesia, the reduction in the volume of axillary surgery, ALND vs SLNB and the increase in the number of sparing breast cancer surgery.

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173 (PB-080) Poster

Inflammatory breast cancer: A clinical syndrome requiring multidisciplinary management

L. Scardina[1], A. Di Leone[1], A. Franco[1], E. Biondi[1], F. De Lauretis[1], E. Petrazzuolo[1], A. D'Angelo[2], D. Terribile[1], R. Masetti[1], G. Franceschini[1]. *[1]Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Woman-Child and Public Health Department, Rome, Italy; [2]Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Dipartimento Di Diagnostica Per Immagini, Rome, Italy*

Background: Inflammatory breast cancer (IBC) is an unfrequent and aggressive subtype of breast cancer and it accounts for only 2–4% of all breast tumors. The NCCN Guidelines state that current treatment include: neoadjuvant chemotherapy (NAC), modified radical mastectomy and radiation therapy. Further systemic adjuvant therapies will also have to be performed subsequently based on the molecular profile of the tumor and the residual disease after NAC. For these reasons IBC definitely requires a multidisciplinary approach with the application of evidence-based medicine for improvement of oncological results. A multidisciplinary model was developed at Gemelli Hospital in Rome in an effort to optimize treatment and ease the application of evidence-based oncologic protocols. Our interdisciplinary team includes breast surgeon, medical oncologist, breast pathologist, radiation oncologist, breast radiologist, geneticist, psycho-oncologist, breast care nurse. During multidisciplinary meetings (MDM), the case of every patient is discussed and an individualized treatment plan is programmed in adherence to the latest practice guidelines. The MDM allows IBC patients to access not only the most appropriate evidence-based chemotherapy regimen, but also specific interventions aimed at protecting their quality of life. In this setting patients are also evaluated for enrollment in clinical trials, but the rarity of the disease makes conduction of specific, large prospective clinical trials more difficult. International guidelines still state that surgical treatment in IBC is a radical mastectomy regardless of response to NAC, breast conserving surgery (BCS) is currently not recommended. However, thanks to the increased rate of pathological complete response after NAC, there is a rising question whether it is possible to perform a BCS in IBC patients.

Materials and Methods: The ConSIBreC trial is a prospective non-inferiority randomized study aimed to assessing the use of BCS in IBC patients that achieve clinical complete response after NAC. Primary endpoint is LR rate at 24 months, and secondary endpoints are the rates of LR-free survival and OS.Patients fulfilling all eligibility criteria are randomly assigned to either modified radical mastectomy or BCS.

Results: Patient enrolment is planned to begin in January 2024 and will continue until a total of 300 patients. The ConSIBreC Trial was presented in October 2023 at 42nd Congress of the ESSO in Florence and received the best clinical trial award.

Conclusion: MDM for IBC patients plays a fundamental role, allowing patient-centered optimal treatment, standardization of care and ensure transparent surgical decision making. This may drive to studying the potential of BCS in IBC after NAC and to gain knowledge from prospective randomized controlled studies to consider surgical de-escalation, as the ConSIBreC trial will do.

No conflict of interest.

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174 (PB-081) Poster

MELODY: A prospective non-interventional multicenter cohort study to evaluate different imaging-guided methods for localization of malignant breast lesions (EUBREAST-4/iBRA-NET, NCT 0555941 1)

N. Cabıoğlu[1], M. Banys-Paluchowski[2], T. Kühn[3], Y. Massannat[4], A.A. Esgueva[5], G. Karadeniz Cakmak[6], B. Gulluoglu[7], N. Ditsch[8], N.Z. Cantürk[9], M.L. Gasparri[10], D. Murawa[11], M. Kontos[12], I.T. Rubio[13], T.H.F. Tvedskov[14], M.M. Khan[15], L.P. Rebaza[16], A. Lowery[17], O.D. Gentilini[18], W.P. Weber[19], J. Harvey[20]. *and MELODY Study Group, [1]Istanbul University Istanbul Faculty of Medicine, Department of General Surgery, Istanbul, Turkey; [2]University Hospital Schleswig-Holstein, Campus Lübeck, Department of Gynecology and Obstetrics, Lübeck, Germany; [3]Breast Cancer Center, Die Filderklinik, Breast Cancer Center, Filderstadt, Germany; [4]Aberdeen Breast Unit, Aberdeen Royal Infirmary, Aberdeen Breast Unit, Aberdeen, United Kingdom, [5]aesgueva@unav.es, Breast Surgical Oncology, Madrid, Spain; [6]BreZonguldak BEUN The School of Medicine, Breast and Endocrine Unit, General Surgery Department, Zonguldak, Turkey; [7]Marmara University School of Medicine and SENATURK Turkish Academy of Senology, Istanbul, Turkey, Department of Surgery, Breast Surgery Unit, Istanbul, Turkey; [8]University Hospital Augsburg, Germany, Breast Cancer Center, Augsburg, Germany; [9]Kocaeli University School of Medicine and SENATURK Turkish Academy of Senology, Department of Surgery, Kocaeli, Turkey; [10]Ospedale Regionale di Lugano EOC, Department of Gynecology and Obstetrics, Lugano, Switzerland; [11]General Surgery and Surgical Oncology Department, Collegium Medicum, University in Zielona Gora, General Surgery and Surgical Oncology Department, Zielona Gora, Poland; [12]University of Athens, Laiko Hospital, Department of Surgery, Athens, Greece; [13]Clinica Universidad de Navarra, Breast Surgical Oncology, Madrid, Spain; [14]University of Copenhagen, Herlev & Gentofte University Hospital, Department of Breast Surgery, Copenhagen, Denmark; [15]Khyber Medical College & Khyber Teaching Hospital, Breast Care Service, Department of Surgery, Peshawar, Pakistan; [16]Clinica Oncosalud Auna, Clinica Oncosalud Auna, Lima, Peru; [17]University of Galway, Department of Surgery, Galway, Ireland; [18]San Raffaele University and Research Hospital, Department of Breast Surgery, Milan, Italy; [19]Basel University Hospital, Division of Breast Surgery, Department of Surgery, Basel, Switzerland; [20]Manchester University NHS Foundation Trust & Faculty of Biology, Medicine and Health, University of Manchester, The Nightingale and PREVENT Breast Cancer Centre, Manchester, United Kingdom*

Background: In the last decades, the proportion of breast cancer patients receiving breast-conserving surgery has increased, reaching 70–80% in developed countries. In case of non-palpable lesions, surgical excision requires some form of breast localization. While wire-guided localization has long been considered gold standard, it carries several limitations, including logistical difficulties, the potential for displacement and patient discomfort, and re-excision rates reaching 21%. Other techniques (radioactive seed or radio-occult lesion localization, intraoperative ultrasound, magnetic, radio-frequency and radar localization) have been developed with the aim of overcoming these disadvantages. However, comparative data on the rates of successful lesion removal, negative margins and re-operations are limited. In the majority of studies, the patient's perspective with regard to discomfort and pain level has not been evaluated. The aim of MELODY (MEthods for LOcalization of Different types of breast lesions) is to evaluate different imaging-guided localization methods with regard to oncological safety, patient-reported outcomes, and surgeon and radiologist satisfaction.

Prospective Clinical Trial Design: The EUBREAST and the iBRA-NET have initiated the MELODY study to assess breast localization techniques and devices from several perspectives (NCT05559411, http://eubreast.org/melody).

Specific Aims: Primary outcomes are: 1) Intended target lesion and/or marker removal, independent of margin status on final histopathology, and 2) Negative resection margin rates at first surgery.

Secondary outcomes are among others: rates of second surgery and secondary mastectomy, resection ratio (defined as actual resection volume divided by the calculated optimum specimen volume), duration of surgery, marker dislocation rates, rates of marker placement or localization failure, comparison of patient-reported outcomes, rates of "lost markers" and diagnostician/radiologist's and surgeon's satisfaction as well as the health economic evaluation of the different techniques.

Statistical Methods: The study is defined as a non-inferiority study with two primary endpoints and six comparisons for each endpoint. Each localization device/method will be compared to the wire-guided localization considered standard. Each commercially available device will be analyzed in a separate cohort.

Target accrual: 7,416 patients. Enrollment started in January 2023. The study will be conducted in 30 countries and is supported by the Oncoplastic Breast Consortium, AWOgyn, AGO-B, SENATURK and Korean Breast Cancer Study Group. Financial support will be provided by Endomag, Merit Medical, Sirius Medical and Hologic.

Contact information:
PD Dr. Maggie Banys-Paluchowski
Email: melody@eubreast.com
Prof. Dr. med. Thorsten Kühn
Email: info@eubreast.com

Conflict of interest:

Corporate-sponsored Research: EndoMag, Mammotome, Sirius Medical, Gilead, ExactSciences, Endomag, Merit Medical, Holigic.

Other Substantive Relationships: Roche, Novartis, Pfizer, pfm, Eli Lilly, Onkowissen, Seagen, AstraZeneca, Eisai, Amgen, Samsung, Canon, MSD, GSK, Daiichi Sankyo, Gilead, Sirius Medical, Syantra, resitu, Pierre Fabre, ExactSciences.

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175 (PB-082) Poster

The role of macrophages in hormone positive breast cancer

G. Oner[1], C. Van Berckelaer[1], M. Praet[2], N.Z. Canturk[3], S. Altintas[1], W. Tjalma[1], B. Zwi[4], M. Peters[1], P. Pauwels[2], P.A. van Dam[1]. *[1]Antwerp University Hospital, Multidisciplinary Oncologic Centre Antwerp, Antwerp, Belgium; [2]Antwerp University Hospital, Department of Histopathology, Antwerp, Belgium; [3]Kocaeli University, Department of General Surgery, Kocaeli, Turkey; [4]Antwerp University Hospital, Department of Hematology, Antwerp, Belgium*

Background: Tumor-associated macrophages (TAMs) constitute an important part of the tumor microenvironment of breast cancer and they play an essential role in tumor progression and metastasis. However, the role of TAMs in neoadjuvant chemotherapy (NAC) is unclear and need to be identified in estrogen receptor positive (ER+)/HER-2 negative breast cancer (BC). The aim of this study is to investigate the role of TAMs in the response to NAC in ER+/HER-2 negative BC.

Methods: Expression of TAMs was examined immunohistochemically, pre- and post- NAC in a cohort of 50 ER+/ HER-2 negative BC patients. All the patients received 4 to 8 cycles of NAC and the treatment consisted of anthracycline- and taxane-based regimens. Following NAC, mastectomy or breast conserving surgery were performed. Immunohistochemical staining with monoclonal antibodies for CD68 and CD163 were performed. All staining procedures were done according to validated protocols and scoring was done by a pathologist specialized in breast cancer. Positivity was defined as staining > 1% in stromal tissue compartments. Response to NAC was evaluated according to tumour size change on imaging and Ki-67 change.

Results: The median age was 57.2 (31–73) years. Diameter of tumour size decreased with a mean of 7.3 mm (−76mm–37 mm) ($p < 0.001$) during NAC and the value of Ki-67 value decreased with a median of 12 after NET ($p < 0.001$). CD-68 expression decreased after NAC, but this was not statistically significant. On the other hand, CD163 expression after NAC significantly decreased ($p < 0.001$) and a decrease in tumour size was found to correlate with the change in CD163 expression. In addition, a higher number of CD163 tumour-associated macrophages before NAC was associated with a better NAC response.

Table 1. Patient and tumour characteristics of the study population. TNM: tumour node metastasis classification

Patients Characteristics (N = 50)		Before NAC n (%)	After NAC n (%)
Median age	57.2 years (31–73 years)		
Menopausal status	*Premenopausal*	19 (38)	
Postmenopausal	31 (62)		
Tumour size (TNM – cT- ypT)	*T0*	–	3 (6)
T1	–	20 (40)	
T2	26 (52)	16 (32)	
T3	19 (38)	10 (20)	
T4	5 (10)	1 (2)	
Nodal status (TNM – cN- ypN)	*N0*	20 (40)	25 (50)
N1	23 (46)	23 (46)	
N2	6 (12)	2 (4)	
N3	1 (2)	–	
Nuclear Grade	*G1*	13 (26)	
G2	24 (48)		
G3	7 (14)		
Unknown	6 (12)		
sTIL	<10% (category 1)	36 (72)	41 (82)
≥10–40% (category 2)	9 (18)	6 (12)	
≥ 40% (category 3)	5 (10)	–	
Residual Cancer Burden Category	RCB-pCR		3 (6)
RCB-I		4 (8)	
RCB-II		26 (52)	
RCB-III		15 (30)	

Conclusion: TAMs may play an important role in the NAC response in ER+/HER-2 negative BC. Further research is imperative to improve our understanding of the clinical usefulness of TAMs particularly in the ER+/ HER-2 negative BC subtype.

No conflict of interest.

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176 (PB-083) Poster

Early outcomes of volume replacement using paste-type micronized acellular dermal matrix for oncoplastic breast conserving surgery

Y. Cha[1], E. Park[2]. *[1]Dong-A University College of Medicine, Dong-A University Hospital, Surgery, Busan, South Korea*

Background: Surgical approaches in breast cancer have been changing to ensure both oncologic safety and cosmetic results. Oncoplastic breast-conserving surgery (BCS) was developed to compensate for the cosmetic disadvantage of the conventional BCS and is widely used in breast cancer patients. Although the concept of "oncoplastic breast surgery" has been accepted for decades, breast surgeons have been striving to develop more advanced surgical skills that ensure non-inferior oncologic outcomes with better cosmetic outcomes. In Asian women, the size of the breast is relatively small, whereas the size of the tumor is large. Therefore, volume displacement with the patient's own breast tissue only is difficult to achieve cosmetically satisfying results. In this study, we investigated the post-operative outcome and safety in oncoplastic BCS as volume replacement using injectable Acellular dermal matrix (ADM).

Material and Methods: Patients: From February 2021 to May 2023, 176 female breast cancer patients who underwent breast conserving surgery were in a single institution. Patients were divided into two groups. BCS only 101 patients, BCS with volume replacement using micronized ADM 75 patients. By reviewing medical reports, we investigated patients' demographic characteristics, operation time and postoperative outcome.

Surgical technique: The partial breast tissue was removed including tumor and cavity margins were confirmed by frozen section biopsy. If the resection margin was clear, surgeon decide whether to use ADM or not. Surgeon rearrangement of the breast parenchyma to correct volume loss. Nevertheless, an appropriate amount of ADM is used if the breast shape is expected to be cosmetically unsatisfaction. The ADM was used as Megafill® (L & C BIO, Seongnam, Korea) or CG realloputty (CGBio Corp., Seongnam, Korea). Inject the ADM into breast defect site after breast parenchymal repositioning.

Results: As a result of retrospective research using medical records, total 176 patients, 101 patients underwent BCS only, and 75 patients underwent BCS using ADM. The mean patient age was 56 years (range = 21–84 years), 52.4 (range = 33–72 years), respectively. The average operation time was 78 min (range = 33–137 min), 83 min (range = 42–145 min), respectively. Minor complications occurred in 4 and 3 patients, respectively. However, most patients were satisfied with the shape of their breast when they underwent BCS with ADM. Also, the satisfaction of the surgeon who performed the reconstruction with ADM was significantly better in patients compared to the BCS only.

Conclusions: The oncoplastic BCS with volume replacement using ADM can considered useful method with safety and cosmetic advantage. Breast reconstruction using ADM can be an easy and convenient way to create a better shape of the breasts after BCS and will also have advantage in follow-up observation.

No conflict of interest.

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177 (PB-084) Poster

Expanding the use of Oncoplastic Surgery in Invasive Lobular Breast Cancer: long-term results of 476 patients treated with three different surgical approaches

E. Biondi[1], L. Scardina[1], A.M. Sanchez[1], F. Moschella[1], S. D'Archi[1], B. Carnassale[1], E. Di Guglielmo[1], E. Petrazzuolo[1], E. Savia[1], R. Masetti[1], G. Franceschini[1]. [1]*Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Woman, Child and Public Health Department, Rome, Italy*

Background: Invasive lobular carcinoma (ILC) of the breast is the second most common histologic subtype of breast cancer. Specifically due to the lack of e-caderine, ILC has the tendency to be multifocal/multicentric and bilateral with a diffuse growth pattern. Moreover, one of the main challenges is obtain clear margins despite the under/overestimation of the lesions on mammography and US, while breast MRI has been widely recognized as the most reliable imaging method for surgical planning. Data about best surgical treatment remains conflicting for ILC and mastectomy has traditionally been chosen as the safest treatment. The aim of this retrospective study is to affirm that level I and II oncoplastic surgery (OPS) is a safe and effective treatment in patients with ILC accurately studied with MRI.

Methods: All patients who had undergone surgery for ILC at Gemelli Hospital between January 2004 and January 2022 were reviewed. A retrospective analysis of 476 patients was conducted. A complete radiological study including MRI was performed in all cases. Descriptive statistics were computed on the cohort, particularly, Kaplan-Meier curves were extracted, and log-rank tests were applied.

Results: Mean age was 55 years. According to MRI, 233 patients (48.9%) had multifocal disease while 243 patients (51.1%) had a single focus. Patients underwent breast conserving surgery (BCS) in 150 cases (31.5%), BCS with OPS (level I and II) techniques in 165 cases (34.7%) and mastectomy in 161 cases (33.8%). Patients undergoing OPS were more likely to have multifocal and larger tumors compared to BCS population ($p < 0.0001$, $p < 0.0001$). Overall, the positive margin rate (PMR) was 10%. Multivariate analysis showed large tumor size, multifocality and surgery technique as independent risk factors for positive margins. Therefore, PMR was higher in women undergoing BCS (18%) compared to patients undergoing OPS (7.86%) ($p = 0.002$). Regarding the MRI pre-operative study, the average mean difference between histological and radiological size ("DeltaR") was +/–1.71 mm. Furthermore, the dimensional difference between radiological and histological measurements was progressively higher as the histological dimensions of the tumors increase. The concordance of MRI and histological measurement for tumor greater than 20 mm was low. Median FUP was 90 months. There were no significant differences in terms on OS and LR-DFS between the groups.

Conclusion: ILC represents a challenge for a correct surgical treatment. Nowadays, MRI is a useful tool in surgical planning, allowing a more appropriate prevision of oncological safe resections. In this study, we showed that OPS should be considered in selected patients ensuring better local control especially in ILC greater than 20 mm, without disadvantage in terms of OS, DFS and D-DFS.

No conflict of interest.

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178 (PB-085) Poster

Optimising Breast Cancer Care: A groundbreaking digital health initiate significantly shortens time from diagnosis to treatment initiation

A. Fatima[1]. [1]*Shaukat Khanum Cancer Hospital, Surgical Oncology, Lahore, Pakistan*

Background: An an extended period from core needle biopsy to the start of treatment is linked to a gradual decline in overall survival. This impact is particularly notable in stage I and II breast cancer cases, with a hazard ratio of 1.09–1.16 ($p < 0.001$). These stages, expected to have better survival rates, are also the largest population, making any survival reduction less acceptable due to potential increased healthcare costs.

Aims: To address this concern, our aim was to evaluate an innovative digital health platform's ability to decrease the time from positive core needle biopsy to the initiation of breast cancer treatment. We compared this to a historical cohort of patients treated at the same facility over the preceding 6 months.

Methods: The study focused on women assessed at a specific breast imaging center for inconclusive (Bi-RADS 0) and suspicious (Bi-RADS 4 & 5) mammograms, ultrasound, and/or breast MRI. Time to treatment (TTT) calculations were limited to patients diagnosed with in situ and invasive breast cancer by core needle biopsy. Our primary goal was to achieve a greater than 50% reduction in historical TTT, with a secondary goal of reducing TTT to under 30 days.

Results: From January 2023 to August 2023, 462 patients were enrolled in the quality improvement initiative and managed on the digital health platform. Among the 196 patients with suspicious imaging findings (Bi-RADS 4 or 5), all underwent a diagnostic core needle biopsy. Of these, 62 were diagnosed with invasive or in situ breast cancer and were referred for surgery or medical oncology. The average TTT was 31 days with the digital health platform, compared to 71 days in the historical cohort—a statistically significant 55% reduction, surpassing the 50% reduction goal. While the study did not achieve the secondary goal of an average TTT below 30 days, this was primarily due to three patients who chose to delay cancer therapy for personal or health reasons. Excluding these cases would have resulted in an average TTT of 28.75 days, meeting our goal.

Conclusion: In conclusion, this quality improvement initiative showcased the effective implementation of a novel digital health platform, achieving a 57% reduction in the time from a positive core needle biopsy to breast cancer surgery or the initiation of systemic therapy. The initiative successfully eliminated any delay in the start of cancer therapy that could compromise patients' overall survival.

No conflict of interest.

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179 (PB-086) Poster

The Lowmag Trial: Magnetic procedure for sentinel lymph node detection and metastasis evaluation in breast cancer patients

A. Christenhusz[1], A. Dassen[1], M. van der Schaaf[2], S. Salamzadeh[3], M. Brinkhuis[4], B. Ten Haken[3], L. Alic[3]. [1]*Medisch Spectrum Twente, Surgery, Enschede, Netherlands;* [2]*Medisch Spectrum Twente, Radiology, Enschede, Netherlands;* [3]*University of Twente, Magnetic Detection and Imaging, Enschede, Netherlands;* [4]*Laboratorium Pathologie Oost Nederland Labpon, Pathology, Hengelo, Netherlands*

Background: Primary tumour biology and axillary lymph node status are crucial prognostic factors in breast cancer treatment. The LowMag trial introduced a magnetic sentinel lymph node biopsy (SLNB) procedure using a Superparamagnetic Iron Oxide (SPIO) tracer and handheld magnetometer as a radiation-free alternative for axillary staging. The objective of this clinical pilot study was to assess a low-dose magnetic tracer for non-invasive

preoperative evaluation of lymph node metastases and intraoperative SLN detection to achieve accurate imaging in the diagnostic phase. This may save axillary surgery in 80% of patients without lymph node metastases.

Methods: Patients with confirmed invasive breast cancer or ductal carcinoma in situ, eligible for SLNB, were included in the LowMag trial (NTR 4858, http://www.trialregister.nl) consisted of radioactive and magnetic SLNB. The SLNs were perioperatively detected by Sentimag® (counts were documented), and inked to keep track of spatial orientation between MRI and histopathology. Amount of iron was estimated post-surgery using two magnetic devices: SPaQ and Sentimag®. Additional ex vivo MRI was acquired using low-field MRI system (Pure Devices). After buffered in formalin fixation, the LN were lamellated perpendicular to the MRI planes, and consecutively sectioned at 2 μm distance and stained with H&E, Perls Prussian blue, CK8/18 and CD68.

Results: In an interim assessment of 20 LNs (nine patients) two LNs from two patients contained a metastasis. The analysis revealed good concordance of uptake between magnetic and radioactive tracer. Median amount of iron trapped in the LN was 19.21 μg (ranging from 0.1 pg to 109 μg). In pathology, iron particles were observed in both the subcapsular space and sinusoids of healthy LNs, with macrophages located in proximity. In the metastatic LNs, tumour cells were observed in both subcapsular and parenchymal regions, primarily situated in the central area. There was limited infiltration into the adjacent adipose tissue, and sinusoids. Regions occupied by tumour cells show no iron infiltration.

In MRI, healthy LN with low iron content shows a centrally located fatty region without iron uptake. Healthy tissue regions within metastatic LNs exhibit a behaviour similar to that of the healthy LNs. In the metastatic sites, there was a reduced presence of iron contrast.

Conclusion: The MRI images clearly differentiate between fat, nodal tissue and SPIO tracer (either in signal intensity or in texture), demonstrating a potential of LN imaging using a low-field MRI system.

No conflict of interest.

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180 (PB-087) Poster

Trends in localization of non-palpable breast lesion: a 10 year analysis in the Dutch population

A. Christenhusz[1], S. Siesling[2], J. Simanowski[3], J. van der Palen[4], M. Brinkhuis[5], M. van der Schaaf[6], B. Ten Haken[3], L. Alic[3], A. Dassen[1]. *[1]Medisch Spectrum Twente, Surgery, Enschede, Netherlands; [2]Netherlands Comprehensive Cancer Organisation IKNL, Research and Development, Utrecht, Netherlands; [3]University of Twente, Magnetic detection and imaging, Enschede, Netherlands; [4]Medisch Spectrum Twente, Epidemiology, Enschede, Netherlands; [5]Laboratorium Pathologie Oost Nederland, Pathology, Hengelo, Netherlands; [6]Medisch Spectrum Twente, Radiology, Enschede, Netherlands*

Background: In 2020, 67% of primary breast cancer patients in the Netherlands underwent breast conserving surgery (BCS). Current standard-of-care for image-guided localization (IGL) of non-palpable breast cancer includes e.g. iodine seed (IS), wire guidance (WG), radio-guided localization (ROLL), ultrasound guidance (US), magnetic marker (MM) and radio-frequency (RFID). However, there is limited comparative data regarding oncological safety. Therefore, the aim of this retrospective population-based study is to assess oncological safety of non-palpable breast lesions regarding surgical margins and re-excision rates for various IGL techniques.

Methods: This study included 59,990 patients documented by the Netherlands Cancer Registry who underwent BCS with IGL between 2013 and 2022. The evaluation of resection margins (clear, focally positive, or more than focally positive) followed Dutch guidelines for re-excision. The relation between IGL technique and resection margin status was evaluated by a multinominal logistic regression, conducted separately for invasive cancer and ductal carcinoma in situ (DCIS). The odds ratio (OR) was calculated using iodine seed as reference.

Results: Large variation in the IGL methods employed by Dutch hospitals was observed over the years. The utilization of IS, MM and RFID consistently increased, while WG experienced a decline. Regarding surgical margins, there were no significant differences between the IGL techniques for patients with invasive carcinoma. For DCIS patients, MM had highest probability of a focally positive margin status (OR = 1.94) while US had the highest probability of a more than focally positive margin status (OR = 1.80). Regarding re-excision rate, both invasive carcinoma (OR = 1.37) and DCIS (OR = 1.45) showed an elevated likelihood of re-excision in cases involving WG. (A correction was made for confounders).

Table 1: Multivariate analysis with respect to surgical margins.

	Invasive carcinoma Total Number of patients n = 47637	Focally irradical n = 2681 OR	> Focally irradical n = 1272 OR	In Situ Carcinoma Total Number of patients n = 12353	Focally irradical n = 1428 OR	> Focally irradical n = 680 OR
IS	26567	1492 ref = 1	703 ref = 1	6064	677 ref = 1	280 ref = 1
WG	16310	908 OR 1.05	410 OR 1.02	5341	**650*** **OR 1.18**	**335*** **OR 1.46**
ROLL	1660	111 OR 1.11	71 OR 1.36	504	54 OR 0.95	30 OR 1.10
US	1370	78 OR 0.85	42 OR 0.86	212	18 OR 0.76	**22*** **OR 1.80**
MM	1183	70 OR 1.11	29 OR 0.92	123	**22*** **OR 1.94**	5 OR 0.85
RFID	547	22 OR 0.98	17 OR 1.20	109	7 OR 0.87	8 OR 1.19

*Significant difference to reference IS

Conclusion: Regarding surgical margins in patients with invasive carcinoma, no significant differences were identified. With respect to focal irradical margin status in DCIS-patients, MM and WG performed inferior to IS. In case of a more than focal irradical margin status WG and US performed inferior to IS. Regarding the re-excision rate, WG performed inferior to IS for both invasive carcinoma and DCIS.

No conflict of interest.

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181 (PB-088) Poster

Versatility of chest wall perforator flaps and radiological findings at follow up

K. Valasiadou[1], D. Dragoumis[1], M. Al-Attar[2]. *[1]University Hospitals Leicester, NHS Trust, Breast Surgery, Leicester, United Kingdom; [2]University Hospitals Leicester, Breast Imaging, Leicester, United Kingdom*

Background: Partial breast reconstruction using chest wall perforator flaps (CWPF) is offered as an option of volume replacement after breast conservation (>20%) for partial breast reconstruction (PBR) or after mastectomy in eligible patients. CWPF are versatile fascio-cutaneous pedicled flaps that could be based on either lateral intercostal artery (LICAP), branch of lateral thoracic artery (LTA), thoracodorsal artery (TDAP) or anterior intercostal artery (AICAP) perforators.

They enable provide local means of volume replacement with acceptable donor site scarring, help reduce mastectomy rates, do not usually require symmetrization procedures, are safe, quick, and allow sparing of the latissimus dorsi muscle, have minimal donor site morbidity, offer excellent aesthetic result and improve quality of life. We hereby present a prospective database of all CWPF performed in a UK University Hospital 2014–2023 and evaluate the impact of CWPF on clinical and mammographic follow-up.

Methods: Seventy-four consecutive patients were identified, median follow-up: 47.6 months (3–116), 2 delayed LICAPs after previous lumpectomy and radiotherapy, 6 LICAPs as autologous immediate reconstruction after mastectomy. All mammograms at >1-year after surgery/annually performed and double reported.

Results: The flap was visible on the mammogram in 55% of the patients, seven mammograms showed calcifications, three mammograms showed fat necrosis, no patients were recalled from mammographic surveillance for further imaging or biopsy of flap related abnormality. Six patients attended the clinic with symptoms, had further imaging, with normal findings, therefore no biopsy was required. There were no interval cancers or locoregional recurrence. One patient died from non-breast cancer related cause (DCIS).

Conclusion: Our series demonstrates that versatile autologous CWPF produce characteristic mammographic features that differ from those after

standard BCS or therapeutic mammoplasty. Surveillance mammograms after PBR + CWPF are accurate with low recall (no recall in these series) and biopsy rates.

No conflict of interest.

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182 (PB-089) Poster

Risk of locoregional recurrence after breast cancer surgery by molecular subtype – A systematic review and network meta-analysis

L. Nolan[1,2]. [1]*University of Galway, Surgery, Galway, Ireland;* [2]*Royal College of Surgeons in Ireland, Dublin 2, Ireland*

Background: The prevention of locoregional recurrence (LRR) is crucial in breast cancer, as it translates directly into reduced breast cancer-related death. Breast cancer is subclassified into distinct intrinsic biological subtypes with varying clinical outcomes.

Aims: To perform a systematic review and network meta-analysis (NMA) to determine the rate of LRR by breast cancer molecular subtype.

Methods: A NMA was performed as per PRISMA-NMA guidelines. Molecular subtypes were classified by St Gallen expert consensus statement (2013). Analysis was performed using R and Shiny.

Results: Five studies were included including 6,731 patients whose molecular subtypes were available. Overall, 47.3% (3,182/6,731) were Luminal A (LABC: estrogen receptor (ER)+/human epidermal growth factor receptor-2 (HER2)-/progesterone receptor (PR)+ or Ki-67<20%), 25.5% (1,719/6,731) were Luminal B (LBBC: ER+/HER2-/PR– or Ki-67≥20%), 11.2% (753/6,731) were Luminal B-HER2+ (LBBC-HER2: ER+/HER2+), 6.9% (466/6,731) were HER2+ (HER2 ER-/HER2+), and finally, 9.1% (611/6,731) were triple-negative breast cancer (TNBC: ER-/HER2-). The median follow-up was 74.0 months and the overall LRR rate was 4.0% (271/6,731). The LRR was 1.7% for LABC (55/3,182), 5.1% for LBBC (88/1,719), 6.0% for LBBC-HER2 (45/753), 6.0% for HER2 (28/466) and 7.9% for TNBC (48/611). At NMA, patients with TNBC (odds ratio (OR): 3.73, 95% confidence interval (CI): 1.80–7.74), HER2 (OR: 3.24, 95% CI: 1.50–6.99), LBBC-HER2 (OR: 2.38, 95% CI: 1.09–5.20) and LBBC (OR: 2.20, 95% CI: 1.07–4.50) were significantly more likely to develop LRR compared to LABC.

Conclusion: TNBC and HER2 subtypes are associated with the highest risk of LRR. Multidisciplinary team discussions should consider these findings to optimise locoregional control following breast cancer surgery.

No conflict of interest.

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183 (PB-090) Poster

Comparison of wire and non-wire localization techniques in breast cancer surgery: a review of the literature and recent advancements with pooled analysis

S. Shirazi[1], H. Hajiesmaeili[2], M. Khosla[2], S. Taj[2], T. Sircar[2], R. Vidya[2]. [1]*Princess Royal University Hospital, King's College Hospital NHS Foundation Trust, Breast Surgery, Orpington, London, United Kingdom;* [2]*New Cross Hospital, The Royal Wolverhampton NHS Trust, Breast Surgery, Wolverhampton, United Kingdom*

Background: Wide local excision is a common procedure in the treatment of breast cancer. Wire guided localization has been the gold standard for many years however, several issues have been identified with this technique and therefore, wire free techniques have been developed. We reviewed and synthesised the available literature comparing wire guided localization with newer wire-free techniques used in breast conserving cancer surgery.

Material and Methods: Multiple databases including Pubmed and MEDLINE were used to search articles between 1 January 2000 and 31 December 2022. Terms included "breast neoplasms", "margins of excision", and "reoperation". In total, 34 out of 256 papers were selected for review. Comparisons were made between positive margins and re-excision rates of wire guided localization (WGL) with wire-free techniques; specifically, RADAR localization (SAVI SCOUT®), magnetic seed localization (Magseed®), radio occult lesion localization (ROLL), and radioactive seed localization (RSL). Pooled p-values were calculated using chi-square testing to determine statistical significance.

Results: Pooled analysis demonstrated statistically significant reductions in positive margins and re-excision rates when SAVI SCOUT®, RSL, and ROLL were compared with WGL. When SAVI SCOUT® was compared to WGL, there were fewer re-excisions {(8.6% vs. 18.8%; p = 0.0001) and positive margins (10.6% vs. 15.0%; p = 0.0105)}, respectively. This was also the case in the ROLL and RSL groups. When compared to WGL; lower re-excision rates and positive margins were noted {(12.6% vs. 20.8%; p = 0.0007), (17.0% vs. 22.9%; p = 0.0268)} for ROLL, and {(6.8% vs. 14.9%), (12.36% vs. 21.4%) (p = 0.0001)} for RSL, respectively. Magseed® localization demonstrated lower rates of re-excision than WGL (13.44% vs. 15.42%; p = 0.0534), but the results were not statistically significant.

Conclusions: SAVI SCOUT®, Magseed®, ROLL, and RSL techniques were reviewed. Pooled analysis indicates wire-free techniques, specifically SAVI SCOUT, ROLL, and RSL, provide statistically significant reductions in re-excision rates and positive margin rates compared to WGL. However, additional studies and systematic analysis are required to ascertain superiority between techniques.

No conflict of interest.

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184 (PB-091) Poster

Validation Study on the OSCAR score for Treatment Decision Planning for Low-risk DCIS patients

M. Co[1], A. Kwong[1]. [1]*The University of Hong Kong, Surgery, Hong Kong, Hong Kong*

Background: Ongoing prospective trials are underway to evaluate the oncologic safety of conservative treatment for selected low risk DCIS patients. However, oncologic safety is not the only concern in the treatment decision making. OSCAR score (Oncologic safety, Symptom, Costs, Anxiety, Risk) was proposed in 2021 to allow comprehensive assessment on treatment decision making. A dedicated online computer program was developed to calculate the score. The link of the online calculator can be found on the public website (https://poetic-pastelito-f1b352.netlify.app/). This study aims to validate its correlation to patient satisfaction/regret.

Material and Methods: This is a study on all DCIS patients treated between January 2021 and June 2023. OSCAR scores of surgery versus conservative treatment (OS-M vs OS-C) were calculated. Patients were then counselled by specialist breast surgeon for treatment. Low risk DCIS patients (as defined by LORIS trial, UK), with higher OSCAR score for conservative treatment were advised for conservative treatment, and vice versa. Differential OSCAR score (DOS) was defined as the numerical difference between OS-M and OS-C. Patient satisfaction towards treatments were assessed in a Likert scale of 0–10. Decision regret was evaluated by the validated decision regret scale (0–100, 0 represents no regret).

Results: 61 patients were recruited into the study with 24 low, 24 intermediate and 13 high grade DCIS. Median age was 44 (Range 20–73). All patients underwent surgery with 27 mastectomies and 34 lumpectomies. One patient has higher OS-C score but decided for surgery eventually, OSCAR score to treatment decision concordance rate was 98.3%.

Median DOS was 32 (Range 1–57). Median patient satisfaction was 7 (Range 6–9). Median decision regret scale was 19.5 (Range 2–66).

Positive linear correlation between DOS and patients' satisfaction was demonstrated (Pearson test = 0.737). While negative linear correlation between DOS and patient regret scale was also demonstrated (Pearson test = –0.615).

Conclusions: OSCAR score correlates well with post-treatment patient satisfaction/regret.

No conflict of interest.

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185 (PB-092) Poster

Cerenkov Luminescence Imaging and Flexible AutoRadiography – a first-in-human novel imaging study for intra-operative margin assessment in women undergoing breast-conserving surgery for cancer

A. Sinha[1,2], H. Jeffery[1,2], Z. Peterson[1,2], B. Shifa[1,2], P. Jurrius[1], S. Allen[3], E. Lee[3], M. Azmat[3], R. Barrass[3], K. Adamson[3], V. Karydakis[2], M. Thorat[2], G. Bitsakou[2], E. Shaari[2], H. Hisham[2], S. Pinder[1,4], G. Cook[1,3], J. Thomas[2], A. Kothari[1,2], A. Purushotham[1,2]. *[1]King's College London, School of Cancer and Pharmaceutical Sciences, London, United Kingdom; [2]Guy's and St Thomas' NHS Foundation Trust, Breast Surgery, London, United Kingdom; [3]Guy's and St Thomas' NHS Foundation Trust, Nuclear Medicine, London, United Kingdom; [4]Guy's and St Thomas' NHS Foundation Trust, Breast Pathology, London, United Kingdom*

Background: In all, 70% of women with breast cancer who require surgical intervention undergo breast-conserving surgery (BCS). Of these 20–25% of patients will require a further surgical procedure due to close or involved histopathological margins. Therefore, there is a clinical need for novel imaging techniques to assess resection margins intraoperatively.

This interventional study aimed to apply two novel imaging techniques, Cerenkov Luminescence Imaging (CLI) directly detecting light emitted by a radiotracer and Flexible AutoRadiography (FAR) by applying a thin, flexible scintillating film to detect emitted activity indirectly to assess excision margins intra-operatively in women undergoing BCS.

Method: A single-arm interventional study was designed to evaluate the diagnostic accuracy of these dual-modality imaging techniques in conjunction with 18-Fluorodeoxyglucose (18F-FDG) to assess tumour margins in women undergoing BCS. Axillary surgery was performed as standard of care. CLI-FAR imaging was performed using the LightPath system, an *in vitro* diagnostic device designed to locate and identify positron-emitting radionuclides within surgically excised specimens.

The study included patients with invasive breast cancer who were over 18 years old, no previous surgery or radiotherapy to the ipsilateral breast, weren't pregnant, lactating and no known 18F-FDG hypersensitivity. Patients were injected with 250MBq +/- 10MBq of 18F-FDG 90–180 minutes before surgery and imaging of the specimen intraoperatively. The surgically excised tumour was initially imaged using an x-ray machine, and margins of suspicion were then imaged using CLI-FAR. Any suspicious margin underwent an immediate re-excision in the form of cavity shavings. The CLI-FAR margin and re-excision data were compared with final histopathology. A margin of 1 mm of healthy tissue for invasive cancer and associated DCIS were defined as a clear margin. The histopathologists were blinded to the results of CLI-FAR.

Results: In all, 52 specimens were imaged in 50 patients with a total of 100 margins reviewed using CLI-FAR.

These results showed a margin specificity of 98.9% and sensitivity of 76.9%. The positive predictive value was 90.9% and negative predictive value 96.6%. In all, 10 margins in 8 patients were identified as positive on CLI-FAR imaging, which was acted upon intraoperatively. In these patients, all initial margins were also positive on histopathology, but cavity shavings were benign on 7 and therefore these patients avoided a second operation.

True Positive	10
False Positive	1
True Negative	86
False Negative	3
Total number of margins assessed	100

Conclusion: CLI-FAR imaging presents a promising, technique for intraoperative assessment of tumour margins in BCS. Future work will examine this novel imaging approach in women undergoing breast-conserving surgery for pure ductal carcinoma *in situ.*

Trial number: REC15/LO/0029

No conflict of interest.

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186 (PB-093) Poster

A comparative study of outcome of axillary lymph node dissection vs axillary radiotherapy in early breast cancer patients with positive sentinel lymph node

A. Bandi[1], K. Pujj[1], M. Sharma[1]. *[1]Gujarat Cancer Research Institute, Surgical Oncology, Ahmedabad, India*

Background: To compare axillary recurrence rate between Axillary Lymph node dissection (ALND) and Axillary Radiotherapy (ART) groups in sentinel node positive early breast cancer patients.

Methodology:

- Study Type: Observational Prospective study
  Patient Enrolment: Operated between Jan 2018–Dec 22
  Follow-up period: Upto July 2023.
  Conducted at: Gujarat Cancer and Research Institute, Ahmedabad, Gujarat, India
  Inclusion Criteria
- All patients of Early breast cancer undergoing upfront sentinel node biopsy and having positive SLNs were included.
  - Positive sentinel LN includes both micromets & macromets.
  - Patients with positive sentinel node(s) underwent either ALND or ART (except cases with ITCs in SLN)
  - Exclusion Criteria(s)
  - Previously underwent axillary surgery or radiation for any other indication.
  - Patients who underwent Neoadjuvant systemic therapy (NACT).
  - Statistical Analysis
  - Statistical analysis was done using SPSS version 25.
  - Quantitative and qualitative data analyzed by descriptive statistics.

Intention to treat analysis was done for ART group.

Results: A total of 594 SLNB procedures were conducted during the study period.188 patients with positive sentinel lymph node were included in the study. Out of these, 117 patients were in the ALND group opposed to 71 in the ART group. Out of the 71 patients intended to take radiotherapy, 13 patients defaulted the treatment and 4 had only isolated tumour cells in the sentinel node hence were exempted. Finally, 54 patients received axillary radiotherapy. Axillary Recurrence rate was 0.9% (1 patient) in ALND vs 1.5% (1 patient) in ART group.

Table: Comparison of ALND and ART group

	ALND group	ART group	P Value
Number of patients	117(62.2%)	67 (36.4%)	
Mean Age (range)	51.1 (24–80)	49.8 (28–75)	0.285
Median No of Positive nodes	2	1	<0.001
Range of +ve nodes harvested	1–6	1–3	
IQR (interquartile Range)	1–2	1–1	
T1	21 (17.9%)	7 (11.7%)	0.33
T2 or Higher	96 (82%)	60 (88%)	0.74
BCS	23 (19.6%)	18 (25.3%)	0.22
LVI (+)	47 (40.1%)	31 (45%)	0.63
PNI (+)	49 (41.8%)	23 (33.8%)	0.195
ER/PR (+)	78 (66.6%)	38 (55.8%)	0.09
Her2 (+)	54 (46.1%)	24 (35.2%)	0.137
Axillary Recurrence	1 (0.9%)	1 (1.5%)	0.699
Median of Follow-up (Interquartile Range)	16 months (6–35 months)	11.5 months (6.5–24 moths)	0.03

Extranode positivity was seen in 70 of 117 patients in the ALND group. Subgroup analysis of these group showed >2 positive nodes in SLNB to be a statistically significant factor for predicting extra positive nodes in completion ALND.

Conclusion: Axillary lymph nodal dissection and Axillary RT both provide a comparable outcome in Early breast cancers with positive Sentinel Node biopsy. However, a multicentric RCT can provide a more definitive answer for the applicability of the results of AMAROS trial in the developing world where

high dropout rates and poor compliance are significant factors in treatment decisions.

No conflict of interest.

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187 (PB-094) Poster

Empowering Breast Cancer Patients: Enhancing Pre-Surgery Decision-Making through 3D Animated Videos

S. Murali-Nanavati[1], G. Chitkara[1], N. Bardeskar[2], H. Tongaonkar[3].
[1]*Nanavati Max Super Speciality Hospital, Breast Oncology, Mumbai, India;* [2]*Nanavati Max Super Speciality Hospital, Research Officer, Mumbai, India;* [3]*Nanavati Max Super Speciality Hospital, HOD Surgical Oncology, Mumbai, India*

Background: Breast cancer is highly prevalent among Indian women, complicating the choice of a surgical approach based on tumor characteristics and cosmetic concerns. This complexity often leaves patients and families in a state of confusion. This study investigates the transformative role of 3D animated videos in empowering breast cancer patients to make informed surgical decisions.

Methods: Patients received comprehensive education about surgical methods, their benefits, limitations, outcomes, and cosmetic implications. They then watched a concise yet informative animated video illustrating these options. After their surgeries, patients completed an online questionnaire to evaluate their experiences with counseling and the video. The questionnaire assessed whether the video helped them envision cosmetic results and their overall satisfaction with the decision-making process. Data was analyzed using Microsoft Excel 2016.

Results: In the survey, 93 women participated, with most in the 40–50 age group (29.03%). Common comorbidities included diabetes mellitus (13.98%) and hypertension (15.05%), while nearly half had no comorbidities (47.31%). Sixteen had locally advanced breast cancer, 76 had operable breast cancer, and 1 had oligometastatic breast cancer. Of the 83, only 13 had undergone neoadjuvant chemotherapy. After counseling and the animated video, 44.09% chose breast-conserving surgery, 29.03% opted for oncoplastic breast-conserving surgery, and 25.81% selected modified radical mastectomy. Counseling significantly increased awareness of surgical options, with all aspects exceeding 90% agreement. Patients felt actively involved in the decision-making process and found preoperative counseling exceedingly helpful. The animated video aided 93.55% in understanding surgical nuances, enhancing the overall counseling session. It also significantly reduced anxiety levels (88.17%) and garnered high satisfaction (89.25%) with scar placement as shown in the video.

Conclusions: This study underscores the revolutionary impact of animated videos in enhancing patient understanding, reducing preoperative anxiety, and elevating expectations regarding breast cancer surgery options. These videos empower patients to make well-informed decisions, ultimately leading to greater confidence and satisfaction as they embark on their breast cancer treatment journey.

No conflict of interest.

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188 (PB-095) Poster

Usefulness of submammary adipofascial flap to cover breast implants: A viable option in resource limited setting

K. Wijesinghe[1], T. Abeywickrama[2], S. Theivaagar[2], G. Niruban[3], M.R. Chandraguptha[3], K. Lakmal[3], K. Sathasivam[3], A. De Silva[2].
[1]*Consultant General and Breast surgeon, Department of Surgery, Faculty of Medical Sciences- University of Sri Jayawardenepura, Colombo, Sri Lanka;* [2]*National Hospital of Sri Lanka, Surgery, Colombo, Sri Lanka;* [3]*Colombo South Teaching Hospital, University Surgical Unit, Colombo, Sri Lanka*

Background: Sub-pectoral silicone implants are often used in immediate breast reconstruction following mastectomy for breast cancer patients. Pectoral muscle is usually not sufficient for complete coverage of the implant and acellular dermal matrix is commonly utilized to fill the defect which is, however expensive and not freely available in resource limited countries. Limited studies have been performed to describe use of the submammary adipofascial (SMAF) flap to provide adequate soft-tissue coverage of the implant. It is in this setting we describe the aesthetic and surgical outcomes and quality of life (QoL) with implant-based breast reconstruction utilizing the SMAF flap in patients diagnosed with breast cancer.

Materials and Methods: This is a prospective study of 21 patients diagnosed with breast cancer over a 4-year period (2018–2022). All patients were operated by two breast surgeons following multi-disciplinary decision. Surgical and flap related morbidities were classified using the Clavien–Dindo classification system. QoL was assessed using the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast-23 (QLQ-BR23) and aesthetic outcomes were measured by an independent observer with regard to breast volume, shape, symmetry, scars, and nipple areola complex using the aesthetic item scale.

Results: The mean age was 43 years with majority of patients having T2 breast cancer. All patients underwent nipple sparing mastectomy and sub-pectoral implant with SMAF flap reconstruction. The median vertical length of the flap was 8 cm (range 6–12 cm). The median bra cup size was B and the median size of the silicone implant was 180cc. The mean follow-up was 12 months. Mean operative time 132 minutes. All patients had suction drains that were removed in several days. All implants were adequately covered with SMAF. No complications were reported such as flap necrosis, wound infection and implant removal. The median hospital stay was 4.2 days (range 3–6 days). In QLQ-BR23 QoL assessment, breast and arm symptoms, body image and future perspective showed higher scores. Hair loss, systemic therapy side effects and sexual functioning showed lower scores. In 90.4%, superior aesthetic outcomes were reported (>8/10) in breast symmetry, shape, volume, nipple position and scar visibility.

Conclusions: SMAF flap is a good technique that provides soft tissue coverage for sub-pectoral implant reconstruction in small to medium size breast with good aesthetic outcomes, minimal morbidity and minimal cost, making it a good alternative for breast surgeons in resource limited settings. Thus, we consider this procedure to be useful and a viable option for implant-based breast reconstruction in carefully selected patients.

No conflict of interest.

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189 (PB-096) Poster

Multicenter study to evaluate the efficacy and standardize radiofrequency ablation therapy for early breast cancer

T. Kinoshita[1], S. Takayama[2], M. Takahashi[3], T. Fujisawa[4], T. Shien[5], M. Takahashi[6], K. Aogi[6], T. Ohnishi[7], H. Tsuda[8], M. Yoshida[9], N. Yamamoto[10], RAFAELO Study Group. [1]*NHO Tokyo Medical Center, Division of Breast Surgery, Tokyo, Japan;* [2]*National Cancer Center Hospital, Dept. of Breast Surgery, Tokyo, Japan;* [3]*Hokkaido University, Dept. of Breast Surgery, Sapporo, Japan;* [4]*Gunma Prefectural Cancer Center, Dept. of Breast Surgery, Ohta, Japan;* [5]*Okayama University Hospital, Dept. of Breast and Endocrine Surgery, Okayama, Japan;* [6]*NHO Shikoku Cancer Center, Dept. of Breast Surgery, Matsuyama, Japan;* [7]*National Cancer Center Hospital East, Dept. of Breast Surgery, Kashiwa, Japan;* [8]*National Defence Medical College, Dept. of Pathology, Tokorozawa, Japan;* [9]*National Cancer Center Hospital, Dept. of Pathology, Tokyo, Japan;* [10]*Chiba Cancer Center, Dept. of Breast Surgery, Chiba, Japan*

Background: Early-stage breast cancer is increasingly detected by screening mammography, and we aim to establish radiofrequency ablation therapy (RFA) as a minimally invasive, cost-efficient, and cosmetically acceptable local treatment. In our Phase I study, localized tumors with a maximum diameter of 2 cm, preoperatively diagnosed by imaging and histopathology, were treated with RFA. A 90% complete ablation rate was confirmed histopathologically. Our phase II multicenter study of RFA without resection for early breast cancer will evaluate the long-term safety and efficacy of RFA as well as its cosmetic results, which are a perceived advantage of this technique.

Materials and Methods: From Nov. 2009 to Nov. 2012, 58 patients with early-stage breast cancer received non-surgical RFA therapy. Patients had localized solitary N0 tumors with a maximum diameter of 1 cm. In our experimental therapy, a radiofrequency electrode needle is inserted through the skin into the breast lesion under imaging guidance, followed by thermal ablation with radiofrequency waves. RFA will be conducted under general anesthesia. The Cool-tip™ RF Ablation Single Electrode Kit (Medtronic, CO, USA) will be used to standardize the evaluation of the ablation effect. They underwent RFA and SNB under general anesthesia and adjuvant therapy

and breast radiation. Follow-up evaluation for residual tumor at 3, 6, and 12 months after RFA included clinical examination, diagnostic imagings and vacuum-assisted biopsy. Surgical resection was recommended for patients with suspected residual disease or incomplete ablation. The primary endpoint was the frequency of adverse events. Secondary endpoints included the complete ablation rate and ipsilateral breast relapse-free rate.

Results: The follow-up period ranged from 15 to 109 months (median, 85 months). The 57 patients completed the non-surgical RFA procedure and underwent diagnostic imaging and needle biopsy after 3 months. Seven patients with suspected incomplete ablation underwent surgical resection; incomplete ablation was confirmed in 5 (8.6%, 2 with invasive and 3 with non-invasive ductal carcinoma). During subsequent follow-up, 1 patient each was diagnosed with contralateral breast cancer and ipsilateral breast tumor relapse. No distant recurrence was documented. Cosmetic results were excellent in 94% of patients.

Conclusions: Our phase II multicenter study of RFA without resection for early breast cancer will evaluate the long-term safety and efficacy of RFA as well as its cosmetic results, which are a perceived advantage of this technique.

No conflict of interest.

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190 (PB-097) Poster

A comparative study of surgical, oncological and aesthetic outcomes in conventional breast-conserving versus oncoplastic breast-conserving surgery for excision of breast tumour

A. Bhattacharya[1], D. Maitra[2]. *[1]Apollo Cancer Centre, Surgical Oncology, Kolkata, India; [2]Medical College Kolkata, Breast and Endocrine Surgery, Kolkata, India*

Background: Conventional breast-conserving surgery (BCS) has served as the standard of care for a long time as a safer alternative to mastectomy. Nevertheless, inherent challenges such as positive surgical margins, the requirement for subsequent surgeries and less than satisfactory cosmetic results have prompted exploration into alternative methods. Oncoplastic breast surgery (OBS) emerges as a promising technique, poised to enhance both oncological safety and patient's satisfaction. The aim of this study is to compare BCS and OBS in terms of surgical, pathological and oncological outcomes, supplemented by an assessment of cosmesis and quality of life of patients.

Materials and Methods: A retrospective single-centre study where we compared two groups of patients with primary non-metastatic breast tumours – group A (n = 131), in which BCS was performed versus group B (n = 114), in which OBS was performed. The two groups did not vary substantially in age, breast size, type of axillary surgery, tumour grade and receptor status. The procedures were performed by the same surgical team, from January 2021 to January 2023. The lead surgeon is specially trained in breast surgery. The OBS procedures included the round block technique of Benelli, Grisotti flap mammoplasty, Lejour mammoplasty, batwing, hemi-batwing mastopexy and mini latissimus dorsi (LD) flap. We assessed the outcome in terms of resection margins, need for re-excision, frequency of complications, initiation time of adjuvant therapy, aesthetic outcome and quality of life (EORTC BR23). To compare the data, statistical analyses were performed.

Results: The mean follow-up time of both the groups was 14 months. Invasive carcinoma > 2 cm ($p = 0.03$), multifocality ($p = 0.02$), ductal carcinoma in situ ($p = 0.03$), clinically positive axilla ($p = 0.01$) and greater weight of the excised breast tissue ($p = 0.004$) were more frequent in the oncoplastic group. Positive margins were found in 14 patients in group A (11%) and none in group B (0%) ($p = 0.0003$). The overall complication rate (4% vs 7%) and the initiation time of adjuvant therapy (3.1 weeks vs 3.4 weeks) did not vary significantly. The scores for cosmetic outcome and quality of life were significantly higher in the OBS group. The mean operating time was higher in the OBS group, however, not significantly.

Conclusion: Oncoplastic surgery showed promising results as a safe tool to deal with large tumours and in difficult anatomical locations. It facilitated removal of substantial volumes of breast tissue, yielding enhanced cosmetic results without impeding the timely administration of adjuvant therapy. Importantly, oncoplastic surgery exhibited no incidence of positive margins, eliminating the necessity for re-excision. Upon subsequent follow-up, OBS exhibited superior oncological outcomes, albeit with a longer operating time compared to conventional BCS.

No conflict of interest.

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191 (PB-098) Poster

Carpe diem: a new era for daycase mastectomies?

E. Carrington-Windo[1], U. Ali[2], S. Mohamed[1], E. Curtis[2], G. Lilley[2], K. Gomez[1]. *[1]Neville Hall Hospital, Breast Surgery, Abergavenny, - Wales, United Kingdom; [2]Neville Hall Hospital, Anaesthesia, Abergavenny, Wales, United Kingdom*

Objectives: Daycase surgery aims to optimise patient care and resource utilisation. It is frequently utilised in general surgery for procedures e.g. hernia and laparascopic cholecystectomy.

Advances in surgery, anaesthesia, and postoperative care have resulted in increasing availability of daycase procedures to mastectomy patients. This offers several advantages, including reduced hospital stay, decreased healthcare costs, better patient satisfaction, and minimised risk of hospital-acquired infections.

Currently, no national or international consensus exists on the need for an overnight stay post mastectomy. This study aims to evaluate the safety and efficacy of changing practice from overnight stays to same-day discharge in a rural District General Hospital.

Methods: A retrospective analysis of 53 consecutive patients recorded as undergoing mastectomy between January 2020 and April 2023 was performed. Data was collected on patient demographics, tumour size and biology, anaesthetic time, length of hospital stay and successful discharge criteria.

Results: Of the 53 eligible patients. 35 were true daycase procedures, 14 stayed from 1–3 days and 4 stayed >3 days. Daycase vs non daycase mean age was 58.5 vs 59.4. Mean BMI was 28.3 vs 30.9. Daycase vs non daycase ASA 1 was 40% vs 5.6%, ASA 2 was 54.3% vs 55.6% and ASA 3 5.7% vs 39%. Mean operation time was 96 vs 118 mins and mean time in anaesthetic room 33 vs 39 mins. Mean use of opioid was 127.7mcg vs 150.4mcg fentanyl, and 8.6 mg vs 11.9 mg morphine.

Mean breast weight for daycase vs non daycase was 838 g vs 634 g. Procedures performed included mastectomy alone or with additional SLNB, ANC or immediate reconstruction. 10 daycase patients (29%) underwent ANC and 2 (6%) underwent bilateral mastectomy. 4 non day case patients (22%) underwent ANC, one patient (6%) underwent bilateral mastectomy. No patient in either group suffered an early complication. 6 patients experienced delayed complications including seroma formation, haematoma and cording. One patient, who was discharged as a daycase, presented to the ED with a seroma. No patients required re-admission to hospital or a return to theatre.

	Daycase	Non Daycase
No. of patients	35	18
Mean age	58.5	59.4
ASA	ASA 1: 14 (40%), ASA 2: 19 (54%), ASA 3: 2	ASA 1: 1, ASA 2: 10, ASA 3: 7
Complications	5	1
Representations	1	0
Number of ANC	10 (29%)	4 (22%)
Number of bilateral mastectomies	2 (6%)	1 (6%)

Conclusions: In conclusion, day case mastectomy can be viable for selected patients. However, careful patient selection, thorough preoperative assessment and adequate postoperative support are crucial for successful implementation. Further improvements in the process, such as a digital discharge package or an out-of-hours telephone advisory service could provide greater reassurance for patients experiencing minor complications e.g. seroma.

No conflict of interest.

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192 (PB-099) Poster

Factors influencing surgical approach in breast cancer patients post neoadjuvant systemic therapy at the Latvian Oncology center

V. Garascenko[1], E. Meistere[2], Z. Al Jamal[2], A. Hegmane[1], J. Eglitis[1], K. Arcimovica[1]. [1]*Riga East Clinical University Hospital, Latvian Oncology center, Riga, Latvia;* [2]*University of Latvia, Faculty of medicine, Riga, Latvia*

Background: Breast cancer (BC) is a widespread malignancy among women globally. The evolution of BC management includes the integration of neoadjuvant systemic therapy (NST) as a crucial component. The choice of the surgical approach post-NST is a multidisciplinary decision, dependent on diverse clinical and pathological factors. Our study aimed to explore factors influencing surgical decisions in BC patients after NST and their correlation with overall pathological complete response (pCR) outcomes.

Methods: A total of 309 BC patients who received NST and underwent surgical treatment at Riga East Clinical University Hospital from 2019 to 2023 were enrolled in the study. The study encompassed the assessment of clinical, histopathological characteristics, and the choice of surgical procedure. Statistical analysis was conducted using SPSS software.

Results: 309 BC patients after NST were enrolled. BC aggressive subtypes (n = 185;60%) were more prevalent compared to less aggressive subtypes (n = 124;40%) among those receiving NST. Breast conserving surgeries (BCS) were performed in 150 (48.5%) cases while mastectomies (MS) were performed in 159 (51.5%) cases. Early-stage patients primarily underwent BCS (n = 102;33.01%), while MS was the most common choice for locally advanced BC (n = 102;33.01%). Type of surgery was significantly associated with the cancer stage ($p < 0.001$). After NST, 50 (60.2%) patients from early stage group achieved pCR. Among these, 34 (68%) patients underwent BCS, while 16 (32%) patients underwent MS. Among early breast cancer pCR patients who underwent BCS, 31 (n = 34) had aggressive subtypes. The majority (87%) had unifocal lesions, with 3 exhibiting asymmetry, 5 presenting microcalcifications and 2 showing deformity. In the early breast cancer pCR group where MS was performed, 12 (n = 16) patients had aggressive subtypes and 8 of them had mammography-detected microcalcifications.

From all BC patients after NST most common subtypes to achieve pCR were HER2+ and TNBC subtypes (n = 25;n = 27) ($p < 0.001$), particularly within the early-stage group (n = 16;n = 19) ($p < 0.001$). Among early-stage HER2+ BC patients who achieved pCR the most common type of surgery was BCS (n = 12;75%), while less common (n = 4;25%) was MS. Notably, all MS patients (n = 4) in this group had microcalcifications. Among early-stage TNBC patients (n = 18) who achieved pCR the most common type of surgery was BCS (n = 16, 88.8%). Among them,17 had unifocal lesions.

Conclusion: Aggressive subtypes predominated in breast cancer patients undergoing NST. Surgery choice correlated with cancer stage, favoring BCS for early-stage cases and mastectomy for locally advanced patients. Decision-making was influenced by factors like disease extent and mammographic findings. A higher rate of pCR was observed in HER2+ and TNBC subtypes, especially in the early-stage group.

No conflict of interest.

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193 (PB-100) Poster

Assessment of breast reconstruction outcomes at Riga East Clinical University Hospital

E. Meistere[1], V. Garascenko[2], J. Eglitis[2], K. Arcimovica[2]. [1]*University of Latvia, Faculty of Medicine, Riga, Latvia;* [2]*Riga East Clinical University Hospital, Latvian Oncology Center, Riga, Latvia*

Background: Breast reconstruction program is government reimbursed in Latvia since January 1, 2022. Reconstruction after mastectomy is a significant part of treatment among breast cancer affected women. The results of the study would outline the experience of the breast reconstruction program in the Riga East Clinical University Hospital.

Material and Methods: The data of 206 patients who underwent 321 breast reconstruction surgeries at Riga East Clinical University Hospital between 2022 and 2023 were collected from a database. Statistical analysis was conducted using SPSS software.

Results: This study analyzed 321 breast reconstruction procedures on 206 patients. The age of patients ranged from 32 to 75 years, with an average age of 49. Among all breast reconstruction surgeries analyzed, the majority were immediate surgeries 149 (46.4%) and 37 (11.5%) were delayed. 112 (34.9%) cases constituted a second stage surgery involving the expander change to implant from previous years and remaining 23 (7.2%) included other procedures. Most surgeries were two-stage (n = 254; 79.1%), with fewer one-stage (n = 44; 13.7%). Reconstruction materials included implant-based reconstruction (n = 278;86.6%), autologous reconstruction (n = 25; 7.8%), combination of both (n = 9; 2.8%) and 9 (2.8%) other surgeries related to breast reconstruction where no additional material was used. Complications occurred in 29 (9%) cases, with hematoma (n = 11; 40.7%) being the most common. Breast symmetrisation during this period was performed in 57 (17.8%) of all cases.

Among the 206 patients, 162 (84.8%) had early-stage breast cancer, 29 (15.2%) had locally advanced breast cancer. 54 (26.2%) patients received neoadjuvant systemic therapy.

The study found a significant association between the stage of surgery and complications- two-stage reconstructions had less complications than one-stage. Neoadjuvant chemotherapy did not significantly affect the likelihood of complications during breast reconstruction.

Conclusions: Most surgeries were two-stage which highlights a thorough approach to reconstruction and lower count of complications as well. Implant-based surgery was the dominant reconstruction method. The increase in the number of breast reconstruction procedures highlights the demand for a state-funded program among breast cancer patients.

No conflict of interest.

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194 (PB-101) Poster

Preshaping surgery of ptotic breasts prior prophylactic nipple-sparing mastectomy and immediate reconstruction: A single-center five-year retrospective study

D. Gudaviciene[1], T. Maciulaitis[2], N. Jakutis[1], R. Venciute-Stankevice[3], S. Mazeika[1], I. Kastyte[1]. [1]*Vilnius University Hospital Santaros klinikos, Department of Plastic and Reconstructive Surgery, Vilnius, Lithuania;* [2]*Vilnius University, Faculty of Medicine, Vilnius, Lithuania;* [3]*Vilnius University Hospital Santaros klinikos, Department of Plastic and Reconstructive Surgery, Vilnius, Lithuania*

Background: The Vilnius University Hospital Santaros Klinikos Center of Plastic and Reconstructive Surgery has observed a notable increase in the number of nipple-sparing prophylactic mastectomies (NSM) with immediate reconstruction in mutated patients with increased risk of breast cancer over the past five years, catering to both therapeutic and prophylactic purposes. A subset of patients seeking these procedures, despite not meeting traditional anatomical selection criteria for NSM, are resolute in preserving their Nipple-Areola Complex (NAC). In response, a two-stage surgical approach was introduced in clinical praxis.

Material and Methods: Our study placed a unique emphasis on a subset of patients who did not conform to the traditional anatomical criteria for a one-stage approach involving nipple-sparing mastectomy (NSM) and immediate breast reconstruction. Instead, we adopted a two-stage surgical strategy. In the initial stage, patients with macromastia and ptotic breasts underwent preshaping mastopexy or reduction procedures to prepare them for subsequent procedures involving nipple-sparing mastectomy and direct-to-implant or direct-to-flap reconstruction, which took place within a 3 to 13 months timeframe. We compiled comprehensive data encompassing surgical techniques, perioperative results, and follow-up records and discussed our experience.

Results: The study involved 36 patients in whom preshaping mastopexy or reduction. 22 of them had a second-stage procedure - nipple-sparing mastectomy (NSM) and immediate breast reconstruction. 21 patients opted for NSM and implant-based reconstruction, while one case involved bilateral NSM with immediate free TRAM flap reconstruction. The initial stage required an average hospital stay of 3.39 days, with the second stage averaging 9 days. The mean interval between the two stages was 7.7 months, ranging from minimum 3 to maximum 13 months. The superomedial pedicle was predominantly employed in the first stage, closely followed by the inferior pedicle. Among the 21 patients who received breast implants, surgical mesh was used in 16 cases. The majority reported high levels of satisfaction. The complications, including hematoma or infection, observed in only 2 cases.

Conclusions: Our findings support the adoption of this two-stage surgical methodology as the standard of care in challenging cases, offering favorable

outcomes in the context of NSM and immediate reconstruction. This research adds valuable insights to enhance reconstructive options available for a diverse patient population.

No conflict of interest.

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195 (PB-102) Poster

A prospective comparative study of indocyanine green, radioisotope, and methylene blue for sentinel lymph node detection in early breast cancer: Evaluating sensitivity, oncological safety, and patient quality of life

E. Angelidou[1]. [1]*Euromedica General Clinic Dodecanese, Breast Unit-Gynecological Department, Rhodes, Greece*

Background: This prospective study aimed to assess the sensitivity and oncological safety of indocyanine green (ICG) imaging in the sentinel lymph node (SLN) identification in breast cancer. A comparison was made with the conventional methods of methylene blue (MB) and the golden standard of radioisotope (RI). Additionally, our study evaluated the impact on the quality of life of patients undergoing these procedures.

Materials and Methods: 200 patients with primary breast cancer and clinically node negative axilla were prospectively enrolled from December 2018 to December 2021. Axillary sentinel lymph node biopsy (SLNB) was performed using ICG, MB, and RI. The primary observation factor was the positivity of ICG versus MB and RI in axillary SLNB. Secondary indicators included axillary SLN detection rate, mean number of axillary SLNs detected, mean number of metastatic SLNs detected, safety, and patient quality of life. The BREAST-Q questionnaire was distributed to the 200 patients at least 1 year after surgery and completing of their treatment and their prospectively collected database was reviewed. BREAST Q software generated scores for Lymphedema, physical, emotional, and sexual wellbeing, which were evaluated. Statistical analyses were conducted using SPSS Statistics, version 25.0 (IBM Corp., Armonk, NY, USA). P values <0.05 were considered statistically significant.

Results: Axillary SLNs were found in all 200 patients, totalling 644 detected axillary SLNs. Pathological examination confirmed metastatic axillary SLNs in 45 patients. The SLN detection rates were 100%, 98%, and 80% for ICG, RI, and MB, respectively. Positivity, SLN detection rates, detection rates of metastatic SLNs, and the number of metastatic SLNs detected with ICG and RI were comparable with no statistically significant difference but were superior to MB. The mean number of axillary SLNs detected was significantly higher with ICG than with RI or MB (3.22 vs. 1.52 vs. 1.25, $p < 0.05$). No tracer-related adverse events occurred with ICG or RI, while a long-lasting skin blue colouring or reaction was observed in 5% of MB cases. No patient developed lymphedema, and all patients experienced high levels of quality of life, except for the 5% of women with persistent blue coloration from MB.

Conclusions: ICG proves to be a very safe, reliable, sensitive, and effective axillary SLN tracer with high levels of quality of life, offering a feasible alternative to RI in imaging for axillary SLN in breast cancer and demonstrating superiority over MB.

No conflict of interest.

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196 (PB-103) Poster

Same-day complex breast cancer surgery: key points of an enhanced recovery after surgery protocol

M. Medarde Ferrer[1], O. Aparicio Rodriguez[1], I. Viader Barraca[2], A. Placeres Gago[3], L. Mora López[1]. [1]*Hospital Universitari Parc Taulí, Surgery, Sabadell, Barcelona, Spain;* [2]*Hospital Universitari Parc Taulí, Anesthesia, Sabadell, Barcelona, Spain;* [3]*Hospital Universitari Parc Taulí, Nursing, Sabadell, Barcelona, Spain*

Background: Same day surgery in complex breast cancer surgery is safe and effective due to ERAS protocols. Nevertheless, routine practice is hospital admission nowadays. Probably due to the difficulty in implementing protocols that include a high number of actions, some of them of technical complexity (thoracic paravertebral block). We present the design of an ERAS protocol based on three basic pillars with the objective of finding out the success rate of same day surgery in complex oncological breast surgery in our environment.

Material and Methods: Prospective observational study including all patients who underwent a mastectomy, mastectomy with sentinel node, lumpectomy with axillary lymphadenectomy, and mastectomy with axillary lymphadenectomy from September 2018 to September 2021. The three key points of the protocol are: preoperative visit with the specialized nurse; prevention of nausea and vomiting; pain control, by performing the BRILMA interfascial block.

Demographic, clinical, anthropometric variables, operative and process times, type of intubation, quantification of pain using the VAS (Visual analogic scale) were collected at PACU (Post-anesthetic Resuscitation Unit), at RR (Recovery Room) and at home, analgesics administered and rescue at PACU, at RR and at home, drainage days and anesthetic and surgical adverse effects. We evaluated the success rate, unexpected admission rate, readmission rate, frequent visits to the emergency room, telephone consultations, complications, and patient satisfaction (by patient reported outcome measures, PROM).

Results: A total of 89 patients were included. The success rate was 94% (84 patients) and the unexpected admission rate 6% (5 patients). The reasons for unexpected admission were nausea and vomiting in 3 patients, pain in 1 patient, and hematoma of the wound in 1 patient. Only 3 of the 89 patients didn't complete the protocol due to not performing BRILMA block. The mean VAS were 1.1 (standard deviation SD 1.4) at the PACU, 0.7 (SD 0.7) at the RR, 1.3 (SD 1.1) on the first day and 1.2 (SD 1) on the second day. The emergency room visit rate was 3.4% (3 patients) and telephone consultations was 3.4% (3 patients). The complications were: seroma, hematoma, and wound infection. No patient was readmitted or reoperated. 97.6% of patients would recommend the process to a relative or friend.

Conclusions: The application of a specific ERAS protocol for same-day complex breast cancer surgery that includes our key action points allows a high accomplishment, a high success rate, and a low rate of unexpected admissions.

No conflict of interest.

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197 (PB-104) Poster

Comparison of treatment results between invasive lobular and invasive ductal carcinoma of the breast

L. Beltrán Parra[1], C. Huertas Burgos[1], L. López Marín[1], C. Garrido López[1], M.C. Sanz Ferrández[1], L. Álvaro Valiente[1], M. Blanco Guerrero[1], M.L. Arroyo Vozmediano[1], S. Aragón Sánchez[1]. [1]*12 de Octubre Hospital, Gynecology and Obstetrics, Madrid, Spain*

Background: Invasive ductal carcinoma is the most common histological type of breast cancer (80%), followed distantly by invasive lobular carcinoma (10%), which differs in epidemiology, presentation, treatment response, and recurrence behaviour. The aim of this study was to conduct a comparative analysis of primary treatment and pathological characteristics between invasive ductal carcinoma (IDC) and invasive lobular carcinoma (ILC).

Materials and Methods: A cross-sectional study was conducted, including women diagnosed with ILC and IDC between 2013 and 2017 in a tertiary hospital. Patients with prophylactic surgery and those with recurrence or a second ipsilateral primary tumor were excluded. Data on the type of primary treatment, breast and axillary surgery, tumor size, lymph node involvement, margin involvement, reconstruction, lymphovascular invasion (LVI), and histological grade were collected. In the neoadjuvant subgroup, the correlation between clinical response via nuclear magnetic resonance and pathological response in the breast and axilla was analysed. Chi-square was used for statistical analysis.

Results: Of the 848 included patients, 88.21% had IDC, and 11.79% had ILC. Patients with ILC had a larger tumor size ($p < 0.001$), more involved margins ($p = 0.03$), less LVI ($p = 0.05$), and a lower histological grade ($p < 0.01$). In both groups, the most common primary treatment was surgery (66.2% in IDC and 74% in ILC), followed by neoadjuvant chemotherapy in IDC (31%) and hormone therapy in ILC (10%). More radical surgery ($p < 0.001$) and reconstruction ($p = 0.03$) were performed in ILC. The most frequently performed axillary surgery was selective sentinel lymph node biopsy (69.9% in IDC and 68.9% in ILC). No significant differences were found in lymph node involvement in those whose primary treatment was surgery, with both groups more likely to have no lymph node involvement. In the neoadjuvant subgroup, ILC showed a lower complete clinical response (p

= 0.05) and lower pathological response, both overall (p = 0.02) and in the breast (p = 0.02) and axilla (p = 0.02).

Conclusions: Patients with ILC present larger tumors at diagnosis and lower rates of response to neoadjuvant chemotherapy, factors that likely influence the significantly more frequent use of radical surgical approaches in ILC compared to IDC in our population.

No conflict of interest.

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198 (PB-105) Poster

Comparison of the clinicopathological features between invasive lobular and invasive ductal carcinoma of the breast

L. Beltrán Parra[1], C.G. Huertas Burgos[1], J. Izquierdo de la Fuente[1], C. Garrido López[1], M.C. Sanz Ferrández[1], M. Gallego Álvarez[1], M. Blanco Guerrero[1], M.L. Arroyo Vozmediano[1], L. Álvaro Valiente[1], B. García Chapinal[1], S. Aragón Sánchez[1]. *[1]12 de Octubre Hospital, Gynecology and Obstetrics, Madrid, Spain*

Background: The most common histological type of breast cancer is invasive ductal carcinoma (IDC) (80%), followed by invasive lobular carcinoma (ILC) (10%), which differs in terms of epidemiology, clinical presentation, and long-term evolution. The objective of this study was to conduct a comparative analysis of the clinical and histological characteristics of patients diagnosed with IDC and ILC of the breast.

Materials and Methods: A cross-sectional study was conducted, including patients diagnosed with IDC and ILC and treated at a tertiary hospital between January 2013 and December 2017. Patients with prophylactic surgery, recurrence, or a second ipsilateral primary tumor were excluded. Age at diagnosis, tumor location, TNM clinical classification, histological grade, and immunohistochemical characteristics were compared between the two groups. Chi-square was used for statistical analysis.

Results: A total of 848 patients were included, with 88.21% diagnosed with IDC and 11.79% with ILC. There were no differences between the groups regarding age (mean of 60.4 years) or menopausal status. Bilateral or multifocal tumor findings did not differ, but multicentricity was more frequent in IDC (p = 0.002). In both groups, the most frequent tumor location was the superoexternal quadrant (37%). Concerning TNM classification, clinical size was significantly smaller (T1-T2) in IDC (88.1%, p = 0.024), with no differences in clinical involvement of regional lymph nodes or distant metastasis. Histological analysis of tumor samples obtained through pre-surgery core needle biopsy showed higher histological grade in IDC (25.2% grade 3, p < 0.001). According to molecular classification, luminal A or B phenotype was more common in ILC (91.9%), while HER2-positive and triple-negative phenotypes were more common in IDC (33.9%) (p < 0.001).

Conclusions: The results demonstrate that IDC and ILC are entities with different clinical behaviour and biological phenotypes. A better understanding of breast cancer subtypes is essential for providing individualized treatment for our patients.

No conflict of interest.

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199 (PB-106) Poster

Safety and effectiveness of acellular dermal matrix (Megaderm) in breast conserving surgery of breast cancer

H. Shin[1]. *[1]Myongji Hospital, Breast and Thyroid Surgery, Goyang-si, South Korea*

Breast cancer treatment has evolved from mastectomy to breast-conserving surgery, including innovative approaches for T2 and T3 stages. Maintaining breast shape and nipple symmetry poses challenges, prompting exploration of acellular dermal matrix (ADM) use. ADM, derived from human skin tissue, has been proven safe in breast reconstruction but lacks comprehensive evaluation in breast-conserving surgery. This study (2017–2019) involved 50 cases, ages 49.9 on average, with stages 0–3C. ADM insertion aimed to address wide defect areas impacting aesthetics. Surgery times averaged 119 minutes, with various ADM sizes. Complications (partial necrosis, hematoma, seroma) were transient, resolving with antibiotics. Pain (VAS score ~3) was reported in 15 cases. Surgeon-rated aesthetic satisfaction averaged 8.79, while patients rated 7.6. Follow-up ultrasounds at 6 and 12 months showed successful integration and shape maintenance, without inflammation. The study affirms that ADM effectively fills mega-sized defect areas (Tis to T2) in breast-conserving surgery, ensuring high aesthetic satisfaction and safety, even after radiation therapy.

No conflict of interest.

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200 (PB-107) Poster

The INFLUENCE II study: identification of sentinel lymph nodes in breast cancer patients through non-invasively fluorescent imaging using indocyanine green: an international multicentre implementation study protocol

T. Dinger[1], B. Jansen[1], C. Bargon[1], E. Postma[1], D. Young-Afat[2], H. Verkooijen[3], A. Doeksen[1], INFLUENCE II Collaborative. *[1]St. Antonius Hospital, Surgical Oncology, Nieuwegein and Utrecht, Netherlands; [2]St. Antonius Hospital, Plastic- Reconstructive and Hand Surgery, Utrecht, Netherlands; [3]University Medical Centre Utrecht, Division of Imaging and Oncology, Utrecht, Netherlands*

Background: Identifying lymphatic metastases is an important prognostic factor in the survival rate of breast cancer and the presence of lymphatic metastases carries consequences for further treatment. Currently, the golden standard for obtaining the SLN in patients with breast cancer is radio guided surgery with radioisotope technetium (^{99m}Tc). However, the use of ^{99m}Tc-nanocolloid is logistically challenging for both patient and caregiver and presents adverse effects. A recently proven effective and safe alternative is fluorescent imaging using Indocyanine Green (ICG). In this study we aim to evaluate the international implementation of ICG fluorescent imaging for SLN mapping.

Methods: INFLUENCE II is an international, multi-centre, pre- and post-implementation study. Patients >18 years with DCIS, invasive T1-T3 breast cancer confirmed by biopsy, clinical node-negative status confirmed by preoperative axillary ultrasound with an indication for breast surgery with SLN procedure via axillary incision will be included. Phase I (pre-implementation): standard SN procedure using 99mTc-nanocolloid, which implies ^{99m}Tc injection the day or the morning before surgery. Phase II (transition period): patients receive dual injection with ^{99m}Tc-nanocolloid and ICG. Surgeons will use both techniques until they feel confident with the single use of ICG. Phase III (post-implementation): 5 mg (2 ml) ICG will be injected periareolar after administration of general anesthesia and before incision. The sentinel lymph node will be visualized by fluorescent imaging using a fluorescence camera.

Study endpoints: The primary endpoint is the identification rate of SLNs achieved by ^{99m}Tc-nanocolloid or the fluorescent signal of ICG. Secondary endpoints are total number of LNs removed, detection time, total operative time, complications and (serious) adverse events, loco regional recurrence after 1 year follow-up, pre-implementation expectations regarding ICG, post-implementation experiences regarding ICG including barriers and success factors, and the learning curve for participating surgeons.

Discussion: In this era, ICG is increasingly used in various surgical fields, providing real-time visual feedback to surgeons. It serves as a safe and accurate alternative to technetium in SLN mapping, addressing logistical challenges and reducing costs. This will be the first multicentre prospective study, implementing and upscaling a novel diagnostic technique for SLN mapping through fluorescent imaging using ICG in an international setting.

Conclusion: This study will be the first to upscale a novel technique for SLN mapping using ICG in breast cancer surgery, facilitating controlled implementation and providing future guidelines.

No conflict of interest.

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201 (PB-108) Poster

Italian National Survey on Axillary Surgery after neoadjuvant therapy (NAT) in initially node-positive breast cancer with pathologic complete response (PCR)

S. Alessandrini[1], L. Alberti[2], A. Polizzi[3], S. Bovani[4], R. Cabula[5], S. Grendele[6], A. Macolino[7], R. Bellochi[1], G. Lolli[1]. *[1]San Giovanni Battista Hospital, Breast Surgery, Foligno, Italy; [2]Vittorio Emanuele III Hospital, Breast unit of ULSS8 Berica, Montecchio Maggiore, Italy; [3]European Institute of Oncology, Breast Surgery, Milan, Italy; [4]Santa Maria della Misericordia Hospital, Breast Unit, Perugia, Italy; [5]Cagliari Hospital, Breast Surgery, Cagliari, Italy; [6]Alto Vicentino Bassano del Grappa Hospital, Breast Unit of AULSS7, Santorso, Italy; [7]B. Ramazzini Hospital, Breast Unit AUSL Modena, Carpi, Italy*

Background: Worldwide there is no consensus on axillary management after neoadjuvant therapy (NAT) in patients with clinically node-positive (cN+) breast cancer converting to ycN0 after NAC. The aim of our survey is to analyse Italian surgical practice in this setting.

Materials and Methods: In October 2023, the survey was sent by email to the 151 Italian Breast Unit's Directors. It was composite of a clinical scenario regarding a Breast Cancer patient cN+ undergone NAT with an axillary PCR (ycN0), and three key questions about the surgical treatment:

1. Which is the axillary surgical treatment in your Breast Unit?
2. Do you always remove initially metastatic lymph node/s? Which is your detection technique?
3. If you recommend sentinel lymph node's dissection, do you use single or double tracer? Which one? How many lymph nodes do you remove on average?

Results: We recorded answers from 46 Italian Breast Units. The most common surgical treatment is targeted axillary dissection (TAD) (45%), followed by sentinel lymph node biopsy (SLNB) (41%) and axillary lymph node dissection (ALND) (14%). No one performs targeted lymph node biopsy. Italian results are more encouraging than European ones published by EUBREAST in terms of de-escalation in axillary surgery maybe thanks to the famous data published by European Institute of Oncology. In TAD the most common tracers, holding the same place, are carbon nanoparticles (33,3%) and clip (33,3%), followed by "magnetic seed (Magseed®)" (27,8%) and "miniature radiofrequency identification seed (LOCalizer®)" (5,6%). In SLNB detection, dual tracers are not the common practice (32%). The most common tracer is radioactive (Tn99) combined with Blu dye mainly. Number of removed lymph node varies from an average of 3 in SLND to 17 in ALND.

Conclusions: There is wide heterogeneity in this field. The lack of guidelines should be update with evidences. Many international studies like AXANA, NEONOD2, NSABP B-51 and Alliance A11202 will probably confirm that de-escalation of axillary surgery is the right choice in PCR scenario.

No conflict of interest.

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202 (PB-109) Poster

Omission of axillary clearance in early breast cancer with positive sentinel node undergoing breast conservation: preliminary results of Z0011 criteria application in clinical practice

G. Cisternino[1], R. Di Micco[1], V. Zuber[1], A. Pellegrini[2], M. Serra[2], S. Baleri[1], M. Rampa[1], S.P. Corona[1], F. Calabretto[1], N. Rotmensz[1], A. Critelli[1], M. Taffurelli[2], O.D. Gentilini[1]. *[1]IRCCS San Raffaele Scientific Institute, Breast Surgery Unit, Milan, Italy; [2]IRCCS Azienda Ospedaliero-Universitaria di Bologna, Breast Surgery Unit, Bologna, Italy*

Background: Axillary lymph node dissection (ALND) in presence of sentinel lymph node (SLN) metastases has been the surgical standard of care for treating breast cancer (BC) patients for decades. In 2017, results from the ACOSOG Z011 trial showed that in patients with T1-2 invasive BC, no palpable axillary adenopathy and 1–2 metastastic SLNs, 10-year overall survival (OS) for patients treated with sentinel node biopsy (SLNB) alone was noninferior to overall survival after ALND. Today, due to the widespread application of these findings and the increasing knowledge of BC biology, ALND has become restricted to a dwindling group of patients with clearly metastatic axillary nodes. The aim of this study was to evaluate results from the application of Z0011 criteria in clinical practice in two Italian high-volume Breast Surgery Units.

Material and Methods: This was a prospective observational study including patients operated in IRCCS Policlinico Sant'Orsola in Bologna and IRCCS San Raffaele Research hospital in Milan between the 1st of November 2020 and 31st of July 2023. Inclusion criteria were: cT1-2 cN0 BC undergoing breast conserving surgery (BCS), preoperative negative axillary ultrasound, metastases in 1 or 2 SLN at histopathological examination, omission of ALND. Exclusion criteria were: presence of 3 or more metastatic SLN, negative SLNB, ALND performed. Primary endpoint was OS. Secondary endpoints were disease free survival (DFS) and locoregional recurrence. All procedure followed standard clinical practice. All patients were discussed in the multidisciplinary breast meeting for deciding the adjuvant treatment.

Results: A population of 795 cT1-2 cN0 BC patients underwent BCS and SLNB during the study period. 705 women fulfilled exclusion criteria (672 negative sentinel node biopsy, 33 ALND) and were excluded. Ninety patients were included.

Population, n	90
Age (years), median (IQR), n (%)	
≤50 y	60 (52–68)
>50 y	19 (21%)
	71 (79%)
Clinical stage, n (%)	
T1	75 (83%)
T2	15 (17%)
Tumor size, median (IQR), mm	16 (11–19)
Receptor status, n (%)*Luminal A	50 (55%)
Luminal B	35 (39%)
Luminal Her2 +	1 (1%)
Her 2+	1 (1%)
TN	3 (4%)
Number of histologically positive nodes, n (%)	
1	81 (90%)
2	9 (10%)
Total number of lymph node s removed, Median (IQR)	2 (1–3)
Radiotherapy, n (%)	
No	0
Yes	90 (100%)
Adjuvant Chemotherapy, n (%)	
No	73 (81%)
Yes	17 (19%)
Oncotype DX, n (%)RS Low (0–25), n	33 (37%)
RS High (26–100), n	29
	4
Endocrine Therapy	
No	6 (7%)
Yes	84 (93%)

At a median follow-up of 19 months (IQR 13–23) OS and DFS were 100%. No loco-regional recurrence was observed.

Conclusion: The preliminary results of our study confirm that omitting ALND in patients meeting Z011 criteria is oncologically safe and should be the standard of care in all breast units. However, in the modern context of personalization of BC treatment, each decision should be based on a case-by-case multidisciplinary discussion.

No conflict of interest.

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203 (PB-110) Poster

Uptake of post-mastectomy immediate breast reconstruction in older women – A real-world analysis from the European Society of Breast Cancer Specialists (EUSOMA) certified breast centres

R. Lee[1,2], R. Parks[2,3], L. Marotti[4], A. Ponti[5], M. Tomatis[4], C. Aristei[6], G. Curigliano[7,8], J. De Vries[9], D. Santini[10], F. Sardanelli[11,12], P. Van Dam[13], I.T. Rubio[14], M.J. Cardoso[15], K.L. Cheung[2,3], EUSOMA Working Group. *[1]Nottingham University Hospitals NHS Trust, General Surgery, Nottingham, United Kingdom, [2]University of Nottingham, Nottingham Breast Cancer Research Centre, Nottingham, United Kingdom, [3]University of Nottingham,*

School of Medicine, Nottingham, United Kingdom, [4]European Society of Breast Cancer Specialists EUSOMA, European Society of Breast Cancer Specialists EUSOMA, Florence, Italy, [5]CPO Piemonte- Turin and European Society of Breast Cancer Specialists EUSOMA, CPO Piemonte- Turin and European Society of Breast Cancer Specialists EUSOMA, Florence, Italy, [6]University of Perugia and Perugia General Hospital Sant'Andrea delle Fratte Perugia, Radiation Oncology Section- Department of Medicine and Surgery, Perugia, Italy, [7]European Institute of Oncology, IRCCS, Division of New Drugs and Early Drug Development for Innovative Therapies, Milan, Italy, [8]University of Milano, Department of Oncology and Hemato-Oncology, Milan, Italy, [9]University Medical Center Groningen, University Medical Center Groningen, Groningen, Netherlands, [10]IRCCS Azienda Ospedaliero-Universitaria di Bologna, Pathology Unit, Bologna, Italy, [11]Università degli Studi di Milano, Department of Biomedical Sciences for Health, Milan, Italy, [12]IRCCS Policlinico San Donato, San Donato Milanese, Unit of Radiology, Milan, Italy, [13]Antwerp University Hospital, Multidisciplinary Oncologic Center, Edegem, Belgium, [14]Clinica Universidad de Navarra- Cancer Center Universidad de Navarra, Breast Surgical Oncology, Madrid, Spain, [15]Champalimaud Clinical Center/Champalimaud Foundation- and Lisbon University Faculty of Medicine, Breast Unit, Lisbon, Portugal

Background: The population of older women living with breast cancer is increasing worldwide. Despite the demonstrable benefits of post-mastectomy immediate breast reconstruction (PMIBR) in improving patients' quality of life and psychosocial well-being, some studies concluded that there is a lower uptake of PMIBR in older women versus younger women. This study uses real-world prospectively collected data from the European Society of Breast Cancer Specialists (EUSOMA), to explore whether there is such disparity seen in recent data, how we can attempt to overcome this, and to see if the disparity was influenced by the COVID-19 pandemic.

Methods: Data was retrieved and analysed from the EUSOMA database on primary breast cancer cases diagnosed and treated in certified European Breast Centres. Female patients who had undergone mastectomy for primary breast cancer from 2017 to 2021 were included.

Results: A total of 16614 women who underwent mastectomy for primary breast cancer between 2017 and 2021 were included, of which 73.5% (12204) were aged <70 years and 26.5% (4410) were ≥70 years old. Overall, 70.1% (8560/12204) of younger women underwent PMIBR, while only 14.4% (636/4410) of older women underwent PMIBR ($p < 0.001$, adjusted OR 0.06). The majority of women (73.8%) did not receive any neoadjuvant treatment, 23.5% received neoadjuvant chemotherapy (NACT) and 2.8% neoadjuvant endocrine therapy (NAET). At the multivariable analysis, radiotherapy ($p < 0.001$, OR 0.52) was an independent predictor for younger women not undergoing PMIBR. Overall, the percentage of PMIBR in both older and younger women decreased as breast cancer stage increased from cTIS to cT4. Tumour characteristics and treatment related factors were not significantly associated with the uptake of PMIBR in both age groups. During the COVID-19 pandemic in 2020–2021, the PMIBR rate was 52.9%, compared to 65.7% in 2017–2019. There was no significant impact of COVID-19 on the disparity in uptake of PMIBR in older women compared to younger women.

Conclusion: Our study is the only study currently available which provides statistical evidence that there is disparity in uptake of PMIBR between older and younger women. However, the underlying reasons remain inadequately understood. It is imperative that further research is performed, including conducting qualitative interviews to explore patient and physician factors, and refining the EUSOMA quality indicators to capture patients' comorbidities and preferences. These may allow us to understand the disparity in uptake of PMIBR between older and younger women.

No conflict of interest.

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204 (PB-111) Poster

Is there a difference in quality of life, among women diagnosed with breast cancer, after tumor localization with magnetic clip compared to guidewire? A study based on the randomized MAGTOTAL study

S. Ferding[1], A. Jazrawi[1], E. Pantiora[2], H. Olofsson[3], A.F. Hersi[4], F. Wärnberg[5], A. Karakatsanis[2], S. Eriksson[1]. *[1]County Council of Vastmanland, Kirurgkliniken, Vasteras, Sweden; [2]Uppsala Akademiska sjukhus, Kirurgkliniken, Uppsala, Sweden; [3]County Council of Vastmanland, Klinisk patologi, Vasteras, Sweden; [4]Sahlgrenska Universitetssjukhus, Plastikkirurgiska kliniken, Gothenburg, Sweden; [5]Sahlgrenska Universitetssjukhus, Kirurgkliniken, Gothenburg, Sweden*

Background: The incidence of non-palpable breast cancer is increasing due to earlier detection. Localization of these lesions before breast conserving surgery (BCS) has been a challenge. Today's conventional methods, such as guidewire, comes with several drawbacks. Recently, a magnetic clip has been developed to localize tumors.

The aim of this study was to evaluate the patient´s perceived quality of life and well-being after receiving either magnetic clip or guidewire as localizer.

Methods: The study population is extracted from the MagTotal study where 426 patients with non-palpable breast cancer were included from Vasteras, Gothenburg, and Uppsala hospitals in Sweden. In the present study only patients from Vasteras are reported. The women were randomized to either magnetic clip (Magseed®) or guidewire. All patients got SPIO (Magtrace®) for sentinel lymph node localization and were asked to respond to the lifestyle questionnaire BreastQ at four different occasions: pre-operative, post-operative, six months, and one-year post-operative.

Results: In all, 108 patients (54 clips/54 wire) were invited and 15 declined to fill in the questionnaire. This resulted in 51 women receiving magnetic clip and 42 women guidewires. There was no statistical significant difference between the two groups in terms of quality of life or well-being during the one-year follow-up period: psychosocial well-being $p = 0.063$, sexual well-being $p = 0.111$, visual experience of breast $p = 0.115$, physical experience of breast $p = 0.176$, chest pain $p = 0.517$, and chest function $p = 0.151$.

Conclusion: Magnetic clip is a well-functioning tumor localization method regarding the women's quality of life and well-being before and after surgery. The main advantage with the magnetic clip is facilitating logistics for the patient as well as for the surgeon and pathologist. The magnetic clip should be considered for tumor localization in the future.

No conflict of interest.

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205 (PB-112) Poster

Inflammatory response to neoadjuvant endocrine therapy in hormone receptor-positive breast cancer

G. Oner[1], C. Van Berckelaer[1], M. Praet[2], N.Z. Canturk[3], S. Altintas[1], W. Tjalma[1], Z. Berneman[4], M. Peeters[1], P. Pauwels[2], P.A. van Dam[1]. *[1]Antwerp University Hospital, Multidisciplinary Oncologic Centre Antwerp, Antwerp, Belgium; [2]Antwerp University Hospital, Department of Histopathology, Antwerp, Belgium; [3]Kocaeli University, Department of General Surgery, Kocaeli, Turkey; [4]Antwerp University Hospital, Department of Hematology, Antwerp, Belgium*

Background: The presence of tumor infiltrating lymphocytes (TILs) is associated with a favourable clinical outcome in triple negative breast cancer (TNBC) and HER-2 positive breast cancer (BC). However, the prognostic role of TILs in estrogen receptor-positive (ER+)/HER-2 negative BC and the effect of neoadjuvant endocrine therapy (NET) on TILs is controversial. This study elucidates the interaction of TILs and NET. Moreover, it addresses the problem that the Residual Burden of Cancer (RCB) index is not an efficient way to assess NET response.

Methods: We retrospectively analysed stromal and intratumoral TIL levels pre- and post- NET and peripheral immune markers (neutrophils, lymphocytes, neutrophil- lymphocyte ratio, platelet- lymphocyte ratio) in a cohort of 56 ER+/HER2- BC patients of which pre-treatment core biopsy and post NET surgical resection specimens were available. They were treated with tamoxifen (N = 16), an aromatase inhibitor (N = 40) or a combination of an aromatase inhibitor with a PI3K inhibitor (N = 11) for a median duration of 6 months (range 1–37) months. Response to NET was evaluated using the Residual Cancer Burden (RCB) index. We performed a univariate analysis of all clinicopathological parameters and peripheral blood parameters to investigate the impact on TILs before and after NET.

Results: In the stroma, the number of infiltrating TIL decreased with a mean of 2.03% (range: –45 to 30) during NET ($p = 0.06$). Intratumoral TIL (iTIL) concentration decreased with a mean of 1.16% ($p < 0.0001$) during NET. There is a strong correlation between iTIL and Ki-67 values before and after NET ($p = 0.04$, $p < 0.0001$, respectively). Pre-treatment stromal TILs were positively associated with Platelet- lymphocyte Ratio value before NET ($p = 0.02$).

Table: The fraction (%) of HR (+) patients (n = 56) showing stromal TILs and intratumoral TILs before and after NET

Patients	Stromal TILs (Before NET) (n = 56)	Intratumoral TILs (Before NET) (n = 55)	Stromal TILs (After NET) (n = 55)	Intratumoral TILs (After NET) (n = 54)
TILs <10% (category 1)	40 (71%)	46 (84%)	44 (80%)	51 (94%)
TILs ≥10–40% (category 2)	13 (24%)	9 (16%)	9 (16%)	2 (6%)
TILs ≥ 40% (category 3)	3 (5%)	-	2(4%)	-

Conclusion: After NET, the number or TILs decrease both intratumoral and in the stroma. However, the distribution and composition of these TILs is heterogeneous in the ER (+) breast cancer microenvironment and subsets of TILs in the immune infiltrate may have an impact on TILs' response to NET. The RCB index is not effective in determining the prognosis for HR (+) BC after NET.

No conflict of interest.

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206 (PB-113) Poster

RADIOSO Milan Trial: Clinical and Organizational Benefits of SCOUT® Radar Localization system for non-palpable lesions

A. Polizzi[1], G. Pagani[1], E.A. Alloggio[1], L. Nicosia[1], A. Latronico[1], C.A. Sangalli[1], E. Cassano[1], P. Veronesi[1], V.E. Galimberti[1], Unità di Senologia IEO. [1]*Istituto Europeo di Oncologia - IEO, Breast Unit, Milan, Italy*

Background: SCOUT® RADAR Localization (Merit Medical) is a wire-free localization system for non-palpable breast lesions. The RADIOSO Milan Trial is a prospective observational study aimed to evaluate the impact of SCOUT® RADAR Localization system on patients undergoing breast-conserving surgery at IEO, Milan.

Material and Methods: 300 breast cancer patients with non-palpable lesions will be enrolled from March 2023 to December 2024.

Primary endpoint is the rate of successful localization procedures with SCOUT®. Key secondary endpoints include the migration rate, the percentage of cases with negative margins, and the re-excision rate. Data on patient demographics, medical history, breast cancer characteristics, surgical details, pathological findings will be collected and analyzed. Patient, radiologist and surgeon satisfaction will be evaluated through a questionnaire.

Results: Preliminary data from March to October 2023 have already been collected. 194 SCOUT-reflectors were placed in 179 patients, with the majority (97%) placed under ultrasound guidance. The indication for SCOUT placement was made mainly by breast surgeons (46%), followed by medical oncologists (33%) and radiologists (21%). The overall re-excision rate was 0%. Margins specimens: 95.5% were negative (≥10 mm), 2.25% were negative (≤ 1 mm), and 2.25% were unassessable. The radiologists reported a 100%successful SCOUT localization rate with no migration, and the surgeons reported a 100%successful SCOUT retrieval rate.

Conclusion: The preliminary results of RADIOSO Milan Trial suggest that SCOUT® Radar Localization technology could implement the IEO internal treatment option for patients undergoing non-palpable breast lesion localization. SCOUT® may bring added value in the following cases: • BI-RADS 5 patients suspected of ductal carcinoma in situ (DCIS) and eligible for conservative surgery could undergo reflector placement in the same procedure of biopsy. • Neoadjuvant chemotherapy patients due to the long-term positioning and minimal MRI artifact. • Placement of multiple reflectors, or use of both SRL and ROLL in patients with multifocal or multicentric neoplasia referred for conservative surgery.

Conflict of interest:
Corporate-sponsored Research: Merit Medical

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207 (PB-114) Poster

The impact of advanced oncoplastic surgery on breast-conserving surgery rates: a retrospective study of 4,500 breast cancer procedures at a tertiary referral centre

A. Reid[1], R. Thomas[1], A. Pieri[1], A. Critchley[1], L. Kalra[1], J. Carter[1], H. Cain[1]. [1]*Royal Victoria Infirmary, Breast Unit, Newcastle Upon Tyne, United Kingdom*

Background: As the focus of cancer survivorship shifts from solely improving oncological endpoints to a more holistic approach, greater weight is being placed on cosmetic and psychological outcomes. Reducing mastectomy rates improves patients' quality of life in numerous areas following breast cancer treatment. The advent and adoption of advanced oncoplastic techniques, particularly utilising therapeutic mammoplasty (TM) and chest wall perforator flap (CWPF) procedures, allows successful breast-conserving surgery (BCS) to patients who otherwise would have required a mastectomy. The aim of this study is to ascertain if the adoption of these procedures has assisted in the reduction of mastectomies performed.

Methodology: We evaluated the Office of Population Censuses and Surveys (OPCS) data that included all procedures involving breast cancer surgery at the centre between April 2016 and July 2023. This revealed a dataset of 4,549 procedures, with each entry returning the procedure date, patient hospital number and all recorded OPCS codes. The data was filtered by searching for specific OPCS codes to identify procedures that involved: BCS, mastectomy, CWPFs, mastopexy, mammoplasty and total reconstructions. R Studio (®) was used to explore statistical analysis and data visualisation.

Results: 4,130 patients were treated for breast cancer over this time period. The BCS rate increased from 60.3% in 2016 to 75.3% in 2023. Using a linear regression model, we can see that the BCS rate over time demonstrates a positive correlation, with the rate increasing by 1.9% each year (coefficient = 1.94, p-value = 0.0086, multiple R-squared = 0.71). Between 2017 and 2022, which is the time period in which we had complete years of operative data, the number of oncoplastic procedures increased by 114%, from 76 to 163 procedures per year (n = 738). Conversely, the number of total reconstruction procedures in the same period decreased by 42%, from 148 procedures in 2017 to 86 procedures in 2022 (n = 612).

Conclusion: Having reviewed the data of over 4,500 breast cancer procedures, we can see that the BCS rate at this centre has seen a statistically significant increase over the past eight years. Over the same time period, we have seen an increase in the frequency of advanced oncoplastic procedures. There have been concerns raised that many of these procedures, particularly the TM, are performed for "onco-cosmetic" reasons rather than to offer BCS to patients requiring a mastectomy. The corresponding reduction seen in total reconstructions following mastectomy dispels this concern. These oncoplastic techniques allow for adequate tumour resection whilst maintaining breast cosmesis, which consequently leads to improved psychosocial results like body image and self-esteem in the long term compared to a mastectomy even when reconstruction is performed.

No conflict of interest.

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208 (PB-115) Poster

Breast conserving therapy in patients with multiple ipsilateral breast cancer in the era of neoadjuvant therapy – a nationwide population based study

E. Heeling[1], J.H. Volders[2], W.K. de Roos[3], R.R.J.P. Van Eekeren[4], I.M.C. van der Ploeg[1], M.J.T.F.D. Vrancken Peeters[1]. [1]*Netherlands Cancer Institute - Antoni van Leeuwenhoek, Surgical Oncology, Amsterdam, Netherlands;* [2]*Diakonessenhuis, Surgical Oncology, Utrecht, Netherlands;* [3]*Ziekenhuis Gelderse Vallei, Surgical Oncology, Ede, Netherlands;* [4]*Rijnstate, Surgical Oncology, Arnhem, Netherlands*

Background: For many years, multiple ipsilateral breast cancer (MIBC) was considered a relative contraindication for breast conserving surgery (BCS) because of concerns regarding oncological safety. In the current era where neoadjuvant systemic treatment (NST) is increasingly being used, the de-escalating trend in the surgical treatment of breast cancer (BC) might be continued in patients with MIBC disease. This study aims to provide an up-to-date overview of the trends and factors influencing the choice for BCS in patients with MIBC over a period of ten years.

Methods: Nationwide, real time data were used from the Netherlands Cancer Registration (NCR). All women of 18 years and older diagnosed with invasive BC between 2011 and 2021 in the Netherlands were included. Multifocal and multicentric BC are registered by the NCR as the same entity and are both defined in this study as MIBC. The primary endpoint was the trend in type of surgery for MIBC over the years 2011 to 2021. Secondary endpoints were factors influencing the use of BCS in MIBC and overall survival (OS).

Results: We included 147,825 patients: 83% (n = 122,675) had unifocal BC and 17% (n = 25,150) had MIBC. The use of BCS for MIBC increased from 29% in 2011 to 41% in 2021. In total, 2,718 of the MIBC patients underwent BCS (38%) and 4,410 of the MIBC patients were treated with mastectomy (62%) after NST (n = 7,128). In multivariate analyses, younger age, invasive lobular carcinoma, and more advanced clinical tumor- and nodal stage were significantly associated with less frequent BCS, as well as NST. Overall pCR rates were 32% for unifocal BC and 25% for MIBC. In patients with MIBC, pCR was observed in 28% of patients treated with BCS and in 23% of patients that underwent mastectomy. With a median follow-up of 54 months (IQR 27–93) the OS of patients with MIBC was 92% after BCS and 87% after mastectomy (log-rank p = < 0.01).

Conclusion: This study shows the de-escalation trend in surgical treatment of patients with MIBC over the past ten years with excellent five-years OS.

No conflict of interest.

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209 (PB-116) Poster

Effect of breast cancer molecular subtype on axillary treatment strategies based on baseline 18F-FDG PET/CT findings

F. Van Amstel[1], C. de Mooij[2], J. Simons[3], C. Mitea[4], P. Van Diest[5], P. Nelemans[6], C. Van der Pol[7], E. Luiten[8], L. Koppert[9], M. Smidt[2], T. van Nijnatten[4]. *[1]Maastricht University Medical Centre +, Department of Radiology and Nuclear Medicine, Maastricht, Netherlands; [2]Maastricht University Medical Centre+, Department of Surgery, Maastricht, Netherlands; [3]Erasmus Medical Centre- Rotterdam, Department of Radiotherapy, Rotterdam, Netherlands; [4]Maastricht University Medical Centre+, Department of Radiology and Nuclear Medicine, Maastricht, Netherlands; [5]University Medical Centre Utrecht, Department of Pathology, Utrecht, Netherlands; [6]Maastricht University Medical Centre+, Department of Epidemiology, Maastricht, Netherlands; [7]Alrijne Hospital, Department of Surgical Oncology, Leiderdorp, Netherlands; [8]Amphia Hospital Breda, Department of Surgery, Breda, Netherlands; [9]Erasmus Medical Centre, Department of Surgical Oncology, Rotterdam, Netherlands*

Background: In clinically node-positive (cN+) breast cancer patients treated with neoadjuvant systemic therapy (NST), axillary disease extent on baseline ^{18}F-FDG PET/CT combined with pathologic axillary response to NST has been proposed to guide axillary treatment de-escalation. Nevertheless, axillary pathologic complete response (pCR) was found to strongly depend on breast molecular subtype. This study aimed to assess whether axillary disease extent on baseline ^{18}F-FDG PET/CT and breast molecular subtype are predictors for axillary pCR.

Materials and Methods: cN+ patients treated with NST in the prospective Radioactive Iodine Seed placement in the Axilla with Sentinel lymph node biopsy (RISAS) trial (NCT02800317) who underwent ^{18}F-FDG PET/CT at baseline were included. Baseline ^{18}F-FDG PET/CT exams were centrally reviewed to differentiate between limited (1–3) and advanced axillary disease (≥4 hypermetabolic axillary lymph nodes). After NST, all patients underwent the RISAS-procedure followed by completion axillary lymph node dissection. Axillary pCR rates were stratified by axillary disease extent on baseline ^{18}F-FDG PET/CT, and subsequently by hormone receptor (HR)+/HER2- HR+/HER2+, HR-/HER2+ and triple negative (TN) molecular subtype.

Results: A total of 185 patients were included: 62.7% with limited and 37.3% with advanced baseline axillary disease. Overall axillary pCR rate was 29.7% (7% for HR+/HER2-, 52.6% for HR+/HER2+, 75% for HR-/HER2+, and 34.1% for TN; $p < 0.001$). Overall and within the molecular subtypes, axillary pCR rates did not significantly differ between limited versus advanced baseline axillary disease. Breast molecular subtype was found to be a significant predictor of axillary pCR, with odds ratios up to 40 for HR-/HER2+ compared to HR+/HER2-.

Conclusions: Axillary pCR rates were not significantly different between limited and advanced axillary disease on baseline ^{18}F-FDG PET/CT, and this finding was consistent within each of the breast molecular subtypes. Therefore, breast molecular subtype should be considered more important than baseline axillary disease extent in axillary treatment strategies in cN+ patients treated with NST to further improve axillary treatment de-escalation.

No conflict of interest.

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210 (PB-117) Poster

Correlation between radiologic complete response of the breast and axillary pCR in breast cancer patients treated with neoadjuvant systemic therapy – a single center retrospective analysis

F. Van Amstel[1], R. van Mierlo[1], S. Engelen[2], J. Houwers[1], S. Siesling[3], M. Smidt[2], T. van Nijnatten[1]. *[1]Maastricht University Medical Centre +, Department of Radiology and Nuclear Medicine, Maastricht, Netherlands; [2]Maastricht University Medical Centre +, Department of Surgery, Maastricht, Netherlands; [3]Comprehensive Cancer Center the Netherlands, Netherlands Cancer Registry, Utrecht, Netherlands*

Background: Previous studies demonstrated a strong correlation between breast- and axillary pathologic complete response (pCR) in breast cancer patients treated with neoadjuvant systemic therapy (NST). This study aimed to assess whether radiologic complete response (rCR) of the breast on imaging (MRI) can predict absence of axillary lymph node metastases (ypN0) in breast cancer patients treated with NST for different cN-status and breast molecular subtypes.

Material and Methods: Patients treated with NST and those who underwent baseline and mid- or post-NST MRI between 2012 and 2020 were retrospectively included from the Netherlands Cancer Registry. Patients were categorized into either radiologic complete response of the breast (breast rCR) or radiologic residual disease (breast non-rCR) and were compared to histopathologic results of surgical specimen. Multivariable regression evaluated clinicopathological variables correlated with ypN0. Odds ratio's (ORs) with 95% confidence intervals (CIs) were calculated.

Results: Of 307 included patients, 27.4% achieved breast rCR. Of these patients, 83.3% had ypN0 compared to 57.8% without breast rCR ($p < 0.001$). Of the clinically node negative (cN0) patients with breast rCR, 89.1% had ypN0 compared to 81.7% without breast rCR ($p = 0.247$). Of the clinically node positive (cN1-3) patients with breast rCR, 76.3% had ypN0 compared to 35.1% without breast rCR ($p < 0.001$). In case of breast rCR, patients with the estrogen receptor (ER)+ subtype were less likely to achieve ypN0 compared to those with HER2+ and triple negative (TN) subtypes (OR: 0.38, 95% CI: 0.06–2.58, $p = 0.032$).

Conclusions: Breast rCR on imaging is significantly associated with ypN0, especially in cN1-3 patients and patients with HER2+ and TN subtypes.

No conflict of interest.

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211 (PB-118) Poster

The CINDERELLA APProach: Future Concepts for Patient Empowerment in Breast Cancer Treatment with Artificial Intelligence-Driven Healthcare Platform

T. Schinköthe[1], E.A. Bonci[2], K.P. Orit[3], H. Cruz[2], R. Di Micco[4], O. Gentilini[4], J. Heil[5], P. Kabata[6], M. Romariz[7], T. Gonçalves[7], H. Martins[8], B. Ludovica[9], M. Mika[10], A. Pfob[5], N. Romem[3], G. Silva[11], M. Bobowicz[12], M.J. Cardoso[2]. *[1]University of the Bundeswehr Munich, Research Center Smart Digital Health, Neubiberg, Germany; [2]Champalimaud Foundation, Breast Unit-Champalimaud Research and Clinical Centre, Lisbon, Portugal; [3]Sheba Medical Center, Breast Cancer Radiation Therapy Unit, Ramat Gan, Israel; [4]San Raffaele University and Research Hospital, Breast Surgery Unit, Milan, Italy; [5]Heidelberg University Hospital, Department of Obstetrics & Gynecology, Heidelberg, Germany; [6]Medical University of Gdańsk, Department of Surgical Oncology, Faculty of Medicine, Gdańsk, Poland; [7]INESC-TEC, Institute for Systems and Computer Engineering, Technology and Science, Porto, Portugal; [8]ISCTE, Instituto Universitário de Lisboa, Lisbon, Portugal; [9]SDA Bocconi University, Center for Research on Health*

and Social Care Management CERGAS, Milan, Italy; [10]CANKADO, Research, Cologne, Germany; [11]Universidade de Lisboa, CEAUL - Centro de Estatística e Aplicações- Faculdade de Ciências, Lisbon, Portugal; [12]Medical University of Gdańsk; 2nd Division of Radiology, Faculty of Health Sciences with the Institute of Maritime and Tropical Medicine, Gdańsk, Poland

Background: The CINDERELLA trial (NCT05196269) is designed to determine the efficacy of the CINDERELLA APProach, an innovative cloud-based healthcare platform, in enhancing the shared decision-making process for breast cancer patients facing locoregional treatments. This study evaluates the influence of the Artificial Intelligence (AI)-driven platform on several key aspects: alignment of pre-treatment patients' expectations with post-treatment ones, aesthetic results, patient contentment, body image satisfaction, utilization of health resources, and overall quality of life. A significant challenge encountered was the integration of diverse functionalities into a multi-lingual platform.

Materials and Methods: The CINDERELLA APProach is integrated with the CANKADO electronic health record (EHR) system. Healthcare providers access the application via the web, while patients use a dedicated smartphone app. The professional portal encompasses comprehensive patient access management, case report form (eCRF) functionalities, patient image management, and a direct link to the BreLO-AI tool (Breast Locoregional Outcome AI system for aesthetic evaluation and prediction). For patients, it provides educational materials and captures electronic Patient-Reported Outcomes (ePRO). The system facilitates randomization and allows study monitors to oversee all participating centers and patient activities in real time. The platform is currently accessible in English, Portuguese, German, Polish, Italian, and Hebrew.

Results: Initiated in August 2023, the study has engaged four out of six centers, enrolling 88 of the intended 1030 patients. Among these, 43 (49%) were assigned to the intervention group, while 45 (51%) were placed in the control group. Patients in the intervention group actively use the smartphone app in four different languages.

Conclusions: The CINDERELLA trial is a pivotal step towards integrating technology with patient care in breast cancer treatment. Preliminary recruitment and engagement data indicate good platform acceptance across multiple languages and cultural contexts. While full results are pending, the potential for the CINDERELLA APProach to revolutionize patient engagement and treatment optimization in breast cancer care is promising. The trial's completion will provide valuable insights into the role of digital health solutions in improving patient outcomes and streamlining healthcare processes.

Conflict of interest:
Ownership: Timo Schinköthe

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212 (PB-119) Poster

Oncoplastic innovation: immediate prepectoral reconstruction using Braxon® – our experience

E. Marrazzo[1], V. Zanella[1], M.A. Placucci[1], O. Jaber[2], G. De Salvia[2], P.A.G. Bisagni[1]. *[1]Ospedale Maggiore di Lodi, General Surgery, Lodi, Italy; [2]Ospedale Maggiore di Lodi, Plastic Surgery, Lodi, Italy*

Background: Immediate reconstruction after mastectomy with prepectoral implants associated with acellular dermal matrix (ADM) is a technique that, in recent years, has allowed for sparing the mobilization of the pectoralis major muscle. In this retrospective study we evaluated the outcome of patients undergoing immediate prepectoral reconstruction with ADM.

Material and Methods: The analysis included all patients who underwent nipple-sparing mastectomy and immediate prepectoral ADM breast reconstruction for breast carcinoma between 2020 and 2023. Exclusion criteria for the use of the prepectoral technique included: prior radiation therapy, comorbidities leading to high risk of flap necrosis (such as diabetes, connective tissue diseases and smoking), and the intraoperative surgeon's decision based on evidence of vascular compromise of mastectomy flaps.

Results: Out of 163 patients who underwent mastectomy between 2020 and 2023, 41 patients reconstructed with ADM Braxon® were included in the analysis. Post-operative complications recorded were: 2 instances of skin flap necrosis resulting in subsequent prosthesis removal; 3 cases of skin necrosis near the margins subsequently re-debrided without compromising the reconstruction; 1 resolved seroma with antibiotic therapy; 1 seroma case treated conservatively with subsequent skin necrosis requiring debridement without the need for prosthesis removal; 1 case of implant infection resolved with intravenous antibiotic therapy. Most complications occured in 2020 with a decreasing trend during years.

Conclusions: The prepectoral technique has been effective and safe, with a complication rate in line with broader case studies. The reduction in complications over the years is linked to the specialists' learning curve. Patient selection for this type of reconstruction was bound by adequate vascularity and uniform flap thickness, always respecting oncological principles. In an effort to reduce the risk of skin necrosis, we opted to remove the wound flaps used for surgical access.

No conflict of interest.

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213 (PB-120) Poster

Management of Phyllodes tumors: a Dutch population-based retrospective cohort between 1989 and 2022

J. Van Olmen[1], S.A.L. Bartels[1], A.W.J. Beerthuizen[1], E.M. Bekers[2], A.N. Scholten[3], C.A. Drukker[1], M.J.T.F.D. Vrancken Peeters[1], F.H. van Duijnhoven[1]. *[1]Netherlands Cancer Institute Antoni van Leeuwenhoek Hospital, Surgical Oncology, Amsterdam, Netherlands; [2]Netherlands Cancer Institute Antoni van Leeuwenhoek Hospital, Pathology, Amsterdam, Netherlands; [3]Netherlands Cancer Institute Antoni van Leeuwenhoek Hospital, Radiotherapy, Amsterdam, Netherlands*

Background: Phyllodes tumors (PT) are rare tumors of the breast. Controversy about the optimal treatment for PT remains. The aim of our study is to analyze patterns in treatment and outcome in a population-based series of patients with benign, borderline and malignant PT.

Material and Methods: We performed a retrospective analysis of data on all patients from 1989 to 2022 with a benign, borderline or malignant PT extracted from the Dutch nationwide pathology databank (Palga). For borderline and malignant PT patients data were extracted from the Netherlands Cancer Registry as well. Cumulative incidence rates of local recurrence and of distant metastasis were estimated using the one minus Kaplan-Meier estimator. A multivariable cox regression analysis was performed to evaluate the relationship between possible risk factors and local recurrence. For the multivariable cox regression analysis borderline and malignant PT were combined.

Results: We included 2829 patients (benign PT n = 1908, borderline PT *n* = 452 and malignant PT *n* = 469). Benign and borderline PT patients more often had breast-conserving surgery (BCS) as final surgery (95% vs. 81 *vs.* 46%). In malignant PT adjuvant radiotherapy was administered in 14.7%; this rate increased over time (OR: 1.07 per year, 95%CI 1.02–1.13, *P* = 0.012).

The 5-year cumulative incidence of local recurrence was 5.2% (95% CI: 4.1–6.3) for benign PT, 8.7% (95%CI 6.0–11.4) for borderline PT and 11.7% (95%CI 8.6–14.8) for malignant PT.

For benign PT, local recurrence was related to positive margins (HR: 2.3, 95%CI: 1.3–4.7, p = 0.007). In case of positive margins the 5-year cumulative incidence remained low: 7.5% (95%CI: 4.6–10.4).

In patients with malignant or borderline PT, local recurrence was related to tumor size ≥ 20 mm (HR: 10.6, 95%CI: 1.5–76.8, p < 0.001) and positive margins (HR: 3.4, 95%CI: 1.8–6.2, p < 0.001), but not to negative margin width (HR: 1.4, 95%CI: 0.8–2.5, p = 0.350). The 5-year cumulative incidence of local recurrence in borderline and malignant PT in case of positive margins was high: 15% (9.7–20.3).

Distant metastasis occurred only in malignant PT with a 5-year cumulative incidence of 4.7% (95%CI 3.3–6.1).

Conclusion: In patients with benign PT local recurrence was related to positive margins. However, as local recurrence rates remained low in case of positive margins, there is no indication for re-excision in case of positive resection margins.

In patients with borderline or malignant PT we identified BCS, larger tumor size and positive final margins as risk factors for local recurrence. As margin width did not influence recurrence rate, any negative margins should be accepted.

No conflict of interest.

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214 (PB-121) Poster

Optimum Resection Volume in breast conserving surgery: time for an update

A. Esgueva[1], S. Diaz-Botero[1], C. Sobrido[2], E. Díez-Uriel[2], M.J. Lucena[2], S. García-Patos[3], V. de Miguel[3], I.T. Rubio[1]. *[1]Clínica Universidad de Navarra, Breast Surgical Unit, Madrid, Spain; [2]Clínica Universidad de Navarra, Breast Imaging Unit, Madrid, Spain; [3]Clínica Universidad de Navarra, Registered Nurse, Breast Surgical Unit, Madrid, Spain*

Background: The Optimum Resection Volume (ORV) is a method used to assess the excess of healthy breast tissue excised in breast conserving surgery (BCS). It is calculated as the spherical tumor volume plus a 1 cm margin of healthy breast tissue. Following the consensus on margin width after BCS (no ink on tumor for invasive carcinoma or 2 mm for ductal carcinoma in situ (DCIS)) a margin of 1 cm is probably no longer necessary to define an ideal resection volume.

The aim of the study is to propose a new method to evaluate the excess of healthy breast tissue resected according to the consensus margin width for breast cancer.

Material and Methods: A dataset of different tumor diameters was created. The tumor volume, ORV and Ideal Resection Volume (IRV) for each tumor size have been calculated. IRV for invasive cancer is defined as the spherical tumor volume plus a 1 mm margin of healthy breast tissue and IRV for DCIS is analogous to IRV for invasive but with 2 mm margin to meet the DCIS margin width consensus. The increased calculated rate (ICR) shows the excess of healthy breast tissue between ORV and IRV. (ORV/IRV), it has been calculated for invasive and in situ carcinoma. Comparison for excess of healthy breast tissue was performed using a paired t-test. Generalized logarithmic/linear models have been used for correlation evaluation.

Results: A dataset of 5 tumor diameters ranging from 5 to 50 mm was created (Table 1). The adoption of the ORV generates significant larger resection volumes compared to the IRV for invasive and IRV for in situ in all cases ($p = 0.03$). However, there is not a statistically significant difference between IRV in invasive and in situ ($p = 0.08$). Both ICR shows increasing excess of breast tissue for the smaller tumor sizes ($p < 0.001$) compared to ORV. For a 10 mm tumor the ORV means a surgical specimen that is 15.6 times larger than the calculated by IRV for invasive 9.8 times for IRV in situ.

Table 1.

Tumor size (mm)	Tumor volume (mm^3)	ORV (mm^3)	IRVinv (mm^3)	IRVdcis (mm^3)	ICRinv	ICRdcis
5	65.4	8181.2	179.6	381.7	45.5	21.4
10	523.6	14137.2	904.8	1436.8	15.6	9.8
20	4188.8	33510.3	5575.2	7238.2	6	4.6
25	8181.2	47712.9	10306	12770.1	4.6	3.7
30	14137.2	65449.9	17157.3	20579.5	3.8	3.2
50	65449.85	179594.4	73622.18	82448	2.4	2.2

Conclusion: The use of IRV instead of ORV contributes to smaller resection volume, in concordance with internationally accepted margin width guidelines for invasive and in situ cancer. As there is no statistically significant differences between IRV in invasive and in situ cancer, it can be unified in IRV for 2 mm margin. This new IRV would be helpful in surgical planning and for updating ongoing or future clinical studies regarding surgical resection volumes in BCS.

No conflict of interest.

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215 (PB-122) Poster

Congruence of Tumor Characteristics between Preoperative Biopsy and Surgical Excision Specimen for Small Breast Tumors: CONSCIENCE

S. Wooldrik[1]. *[1]Franciscus Gasthuis & Vlietland, Surgery, Rotterdam, Netherlands*

Introduction: Due to nationwide screening, 50% of breast cancer cases are small, with favorable prognoses. Minimally invasive techniques like thermal ablation or vacuum-assisted excision offer potential benefits, but their drawback is the lack of surgical specimens for adjuvant therapy decisions. This retrospective study aims to assess the risk of therapy indication misjudgement in small tumors, focusing on concordance between surgical specimens and preoperative imaging and biopsy to improve precision in patient selection for minimally invasive interventions.

Material and Methods: A retrospective monocenter cohort study included women treated for T1 breast carcinoma from 2020 to 2022. Exclusions comprised lobular tumors, HER2 overexpression, triple-negative tumors, and neoadjuvant treatment. Histological assessments, including tumor grade and tumor size, were compared between preoperative biopsy and surgical specimens. Statistical analyses, including Cohen's kappa, positive and negative predictive values, and percentages of agreement, were employed to evaluate concordance.

Results: After exclusions, 353 tumors were analyzed. The overall agreement for tumor grade was 80% (95% CI [0,75–0,84]) with a Kappa of 0.61 ($p < 0.001$). The agreement for tumor size was 68% (95% CI [0,63–0,73], K 0.4 ($p < 0.001$), in case of ultrasonography and 58% (95% CI [0,49–0,67], K 0.29 ($p < 0.001$) in case of MRI. Ultrasound measurements had a higher likelihood of underestimating tumour size (19% vs. 13%) whereas in case of MRI the likelihood of overestimating the tumor size was higher (29% vs. 5%).

Conclusion: Our study demonstrates moderate concordance in both tumor grade and tumor size between preoperative imaging and biopsy, and the surgical excision specimen in small tumors. Overall, there is a greater risk of underestimation than overestimation of tumor grade and size, except in the case of MRI scans, where there is a higher likelihood of overestimating the tumor size. This information is crucial for proper patient selection for minimally invasive techniques.

No conflict of interest.

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Table: (abstract: 215 (PB-122)):

		Pathology			K	Agreement (%[95%CI])	Underestimation (%)	Overestimation (%)
Tumor size US (cm)		**≤1**	**1,1–2**	**>2.1**		68 [0,63–0,73]		
≤1		92	37	1	0.55 ($p < 0.001$)	70		26
1,1–2		29	137	13	0.37 ($p < 0.001$)	76	19	13
>2.1		4	26	0				
Tumor size MRI (cm) (n = 117)		**≤1**	**1,1–2**	**>2.1**		58 [0,49–0,67]		
≤1		24	3	0	0.5 ($p < 0.001$)			49
1,1–2		16	44	4	0.27 ($p = 0.002$)		5	29
>2.1		7	19	0				
Tumor grade biopsy stage	**In situ carcinoma**	**Grade 1**	**Grade 2**	**Grade 3**				
In situ carcinoma	0	2	8	0				
Grade 1	2	116	22	0	0.7 ($p < 0.01$)	80 [0,75–0,84]	1	17
Grade 2	1	24	147	10	0.6 ($p < 0.01$)		12	1
Grade 3	0	0	3	4	0.39 ($P < 0.01$)		71	

216 (PB-123) Poster

Targeted Axillary Dissection post primary chemotherapy: data analysis from a single multidisciplinary unit in South Africa

C. Benn[1], D. van Loggerenberg[2]. [1]*Breast Care Centre of Excellence - South Africa, Department of surgery, Johannesburg, South Africa;* [2]*Breast Care Centre of Excellence - South Africa, Research, Johannesburg, South Africa*

Background: Global breast cancer management trends have shown a de-escalation in surgical treatment as a more biological management approach driven by primary oncology; specifically NAC and a decrease in axillary lymph node dissection. In keeping with this, a total of 2558 newly diagnosed cancer patients were seen at our unit from 2016–2020, of which between 36 and 42% per year receive primary/neoadjuvant chemotherapy as their initial treatment for breast cancer. Standard of care post-NAC has traditionally required an axillary dissection. Recently, targeted axillary dissection has been postulated and studied in many academic units.

Materials and Methods: 953 patients who underwent NAC and subsequent targeted axillary node sampling between January 2016 to December 2020 were included. Data was anonymised and a secondary record analysis was performed.

A subset of patients had nodal clipping and localizing prior to NAC; and all patients had dual tracer prior to surgery (magtrace and blue dye). All patients received radiation therapy. Patients were followed up with serial mammograms and/or ultrasounds for a period of 1 to 5 years.

Conclusions: No patients presented with recurrence following targeted axillary sampling after having received neoadjuvant chemotherapy, surgery and radiation. Thus, targeted axillary node dissection"sampling" is shown to be safe in this cohort of patients with no nodal recurrences documented thus far on routine radiological follow-up.

No conflict of interest.

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217 (PB-124) Poster

Metaplastic Breast Cancer: Treatment and Prognosis in a University Hospital over a 20 year period

K. Valasiadou[1], P. Kohli[2]. [1]*University Hospitals Leicester NHS Trust, Breast Surgery, Leicester, United Kingdom;* [2]*University Hospitals Leicester, Breast Surgery, Leicester, United Kingdom*

Background: Metaplastic breast cancer (MBC) is a rare, aggressive form of breast cancer which is therapeutically challenging. These are adenocarcinomas with squamous and/or mesenchymal tumor features usually triple negative disease. The prognosis is much worse compared to non-MPC triple negative breast cancer. With sparse literature there are no current treatment guidelines for MBC and the standard of care remains the same as for invasive breast cancer. The aim of this study was to evaluate the patient characteristics, pathological features, treatment and clinical outcomes of non-metastatic MBC in a UK University Hospital.

Materials and Methods: Histologically confirmed 51 MBC from January 2000 to December 2020 were identified from our electronic database. Demographic, staging, treatment, recurrence and survival details were collected reviewing the medical records. The Kaplan-Meier method was used to assess overall survival (OS) and Cox regression analysis was used to assess the impact of covariates on OS.

Results: A total of 51 patients were identified, 6 (11.8%) screening detected. The median age of presentation was 49 years (range 41–90 years). Twelve patients (23.5%) presented with clinical T3/T4 disease, 42 (82%) with Grade 3 tumors. Axillary nodal involvement was detected in 7 patients (13.73%) at presentation. Only one case was estrogen receptor positive and there were no HER2 positive cases. As these tumors are usually refractory to chemotherapy, only 6 (11.7%) patients received neo-adjuvant chemotherapy followed by surgery. None of these showed complete pathological response, 2 showed partial response and 1 had disease progression. Twenty-three patients (45.1%) had chemotherapy, 36 (70.6%) had radiotherapy. Twenty-two patients (43.1%) had breast conserving surgery. One mastectomy patient had immediate breast reconstruction. At a median follow-up of 26 months, 50.9% (n = 26) had a recurrence. Lung was the most common site of metastasis (20, 39.2%) followed by brain (9, 17.6%), bone (7, 13.7%), liver (2, 3.9%) while 3 (5.9%) had local recurrence. The median overall survival (OS) was 52.4 months. Age, tumor size more than 5 cm, nodal positivity, grade, differentiation, NACT were not predictive of OS or disease-free survival.

Conclusion: MBC is an infrequent entity. The diagnosis of MBC is difficult and requires the use of immunohistochemistry. Most of the cases in our study presented with a larger tumor size; however, they displayed a relatively lower incidence of nodal involvement as well as hormone receptor negativity. Being a rare and heterogeneous disease, multi-centre studies are essential for better understanding and management of these tumors.

No conflict of interest.

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218 (PB-125) Poster

Do the results of the SOUND trial necessitate a paradigm shift in our approach to axillary staging in patients undergoing a mastectomy for DCIS?

N. Garg[1], M. Thorat[1], A. Kothari[1]. [1]*Guy's & St. Thomas' NHS Foundation Trust, Breast Surgery, London, United Kingdom*

Background: Results from the SOUND trial demonstrate the oncological safety of omitting sentinel lymph node biopsy (SLNB) in patients with T1 invasive breast cancer and negative axilla on preoperative ultrasound. Consequently, we hypothesised that patients with pure ductal carcinoma *in situ* (DCIS) on pre-operative needle biopsy undergoing a mastectomy could potentially also be spared an SLNB if the probability of upgrading from T*is* to T2 invasive breast cancer is negligible.

Material and Methods: We conducted a retrospective cohort study, by reviewing the electronic hospital records of all patients that underwent a mastectomy following the diagnosis of DCIS on needle biopsy at a single-institution between 2016 and 2023. All patients had normal findings on preoperative axillary ultrasound. The clinical and pathological features of these cases were recorded.

Results: Of 133 patients with a preoperative diagnosis of DCIS, 29(22%) were upgraded to invasive breast cancer on final histology. The median size of DCIS was 60 mm [Interquartile range (IQR) 35–75 mm]. The median size of invasive disease in those that were upgraded was 5.5 mm (IQR 4–11 mm). In 1 patient (0.8%) the invasive tumour size was 22 mm, within 90 mm of DCIS. Two out of 3 sentinel lymph nodes (SLNs) showed micrometastasis in this patient. Out of the 106 patients that underwent a synchronous SLNB, 11 (10.4%) showed axillary nodal metastasis, 5/11 had only micrometastasis in the nodes while 6/11 harboured micrometastatic disease. The grade of DCIS on core biopsy was not associated with the probability of SLN metastasis ($p = 0.63$). Interestingly, SLN metastases were seen in only ER positive DCIS patients in this cohort ($p = 0.033$). With each centimetre (cm) increase in the size of DCIS, the probability of SLN metastasis increased by 21% [Odds Ratio (OR) = 1.21; 95% Confidence Interval (95%CI) 1.01–1.44; $p = 0.040$). In the DCIS subgroups of size - smaller than 50 mm, 50–100 mm and >100 mm, SLN metastasis rate was 3%, 13% and 19% respectively.

Conclusions: Less than 1% of patients that undergo a mastectomy for DCIS show a focus of invasive disease > 2cms. Therefore, based on the results of the SOUND trial, these patients could potentially avoid any form of synchronous axillary staging. Based on the findings of our study, we recommend this would be a safe approach in most patients undergoing a mastectomy for DCIS, except when the extent of DCIS > 100 mm on preoperative imaging. This is because the rate of SLN metastasis in patients with DCIS > 100 mm was 19% in our cohort which is considerably higher than the SLN metastasis rate for patients that underwent SLNB in the SOUND trial (13%).

No conflict of interest.

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219 (PB-126) Poster

Comparison of wire-guided versus Magseed localisation for impalpable breast lesions: Single centre initial experience

Z. Taraki[1], E. Haxhiaj[1], H. Amin[2], A. Hamid[2], D. Betal[1]. [1]*University College London Hospital NHS Foundation Trust, Women's Health, London, United Kingdom;* [2]*University College London Hospital NHS Foundation Trust, Radiology, London, United Kingdom*

Background: The breadth of breast conserving surgery has expanded and the accurate localisation of impalpable breast cancer is critical. Techniques have evolved to improve surgical planning and cosmesis. The aim of this

study is to compare safety and effectiveness of wire and Magseed localisation techniques.

Methods: This retrospective cohort study analysed consecutive patients undergoing breast conserving surgeries from 2018 to 2020 in a single centre. The primary outcome was accurate localisation and removal of the index lesion. Secondary endpoints included specimen weight, re-excision rates rate for positive margins. infection rate and outline planning for the surgery.

Results: Data was collected from 100 patients with 50 patients in each group. All patients underwent breast conserving surgery with or without axillary surgery. The distance of the marker from the lesion were closer in the Magseed localisation compared to the wire localisation group (1.5 mm, range 0–13 mm versus 4.5 mm, range 0–24 mm; $p < 0.01$). There was no significant difference in the comparison of Magseed to wire localisation for specimen weight (2–43.5 g vs 2.64–38.5 g; $p > 0.05$), margins and re-excisions (8 vs 9 re-excisions, $p > 0.05$), or infections (2 vs 4 patients, $p > 0.05$). Surgical planning and workflow was improved as 82% of Magseeds were inserted days prior to the surgery whilst 100% of the wires were inserted the same day of the surgery.

Conclusion: Our study showed that Magseed provided more accurate localisation of impalpable breast cancers compared to wire and provided the opportunity to be inserted days before the day of the surgery to improve workflow. There were no significant differences in specimen weight, margins, re-excision, or infection rates between the two techniques.

No conflict of interest.

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220 (PB-127) Poster

Comparative study between using ultrasound dissecting device or electrocautery in modified radical mastectomy

G. AbouElnagah[1]. [1]*Alexandria Faculty of Medicine, Surgical Oncology Unit, General Surgery Department, Alexandria, Egypt*

Background: The ultrasound dissection & blood sealing device is a recent surgical instrument that allows intra-operative cutting and coagulation at the same time. The aim of this study was to compare between the usage of ultrasound dissection & blood sealing device or electrocautery in modified radical mastectomy operation.

Material and Methods: This study included eighty patients with operable breast cancer. They were randomized into two equal groups to do modified radical mastectomy either using ultrasound dissection & blood sealing device (group A) or using conventional electrocautery (group B). The total operative time, the time of axillary dissection, the time for raising the flaps and the time of breast dissection were calculated. The days of drainage and the total drainage volume were also recorded.

Results: Calculating the time needed for axillary dissection revealed a significantly shorter time in patients operated on by ultrasound dissection & blood sealing device. ($p = 0.004$). The mean total draining volume in group (A) was lower than in in group (B). The difference was statistically significant. ($p = 0.02$). 15% of cases in group (A) and 25% of cases in group (B) suffered from postoperative seroma, the difference was statistically insignificant ($p = 0.677$).

Conclusions: The use of ultrasound dissection & blood sealing device in MRM shortening the axillary dissection time and decrease drainage volume, drainage day and hospital stay.

No conflict of interest.

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221 (PB-128) Poster

Comparative study of role of indocyanine green (ICG) combined with methylene blue dye versus methylene blue dye alone in sentinel lymph node biopsy (SLNB) in post-neo adjuvant chemotherapy breast cancer patients

K. Gaurav[1], A. Anand[1], G. Charan[1], A.A. Sonkar[1]. [1]*King George's Medical University, General Surgery, Lucknow, India*

Background: Sentinel lymph node biopsy by dual dye method (radioisotope + blue dye) is standard of care for axillary staging in breast cancer patients. But there is no final consensus on the role of SLNB technique in post-NACT breast cancer patients. This study compares the efficacy of Methylene blue (MB) dye alone versus (ICG + MB dye) in SLN detection in post-NACT breast cancer patients undergoing MRM.

Material and Methods: A prospective observational study was performed, which included 61 patients undergoing MRM with SLNB (n = 39 patients for MB dye alone and n = 22 patients for combination method) from 2019 to 2021. SLN identification rate (IR) and positive detection rate (PDR) were compared between the two groups.

Results: SLNB was done with 61 post-NACT patients undergoing MRM. A total of 242 SLNs were identified with the median number of SLNs detected by MB alone and ICG+MB method being 3.66 ± 2.11 and 4.5 ± 2.32 respectively. Both methods showed an SLN identification rate (IR) of 100% in each case. The SLN positivity detection rate (PDR) of MB and ICG+MB samples were 69.2% and 83.3% respectively. Among 39 patients enrolled for MB dye alone, 143 blue nodes were sampled, of which 18 showed metastases (12.58%) and among 22 patients enrolled for the combination method; 99 double-positive nodes were sampled, of which 35 showed metastases (35.35%).

Conclusion: The usage of ICG+MB combination exhibits greater potential to detect SLN when compared to using MB dye alone, without the involvement of radioactive isotopes, and also the SLN positivity identification is also greater with the use of a combination of dyes.

No conflict of interest.

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222 (PB-129) Poster

Results of ex vivo biopsies on explanted breast tissue

H. Thunqvist[1], P. Hellman[2], A. Karakatsanis[2], A. Zouzos[3], P. Hedén[4], V. Thurfjell[5]. [1]*Uppsala university, Student in Engineering Physics, Uppsala, Sweden;* [2]*University Hospital Uppsala, Department of Surgical Sciences, Uppsala, Sweden;* [3]*Karolinska Institute, Department of Oncology-Pathology, Stockholm, Sweden;* [4]*Karolinska Institute, Akademikliniken, Stockholm, Sweden;* [5]*Uppsala University Hospital, Department of Immunology, Genetics and Pathology, Uppsala, Sweden*

Background: Mammogram, ultrasound and tissue biopsy are the current standard of care for diagnosis of breast cancer. Methods that obtain more bioptic material, such as vacuum assisted biopsy/ excision (VAB/VAE), gradually overlap with surgical excision, that is continuously de-escalating, but the current challenge is verification of intact lesion removal and accurate margin assessment. Resitu® Medical has developed a novel device enabling biopsy and minimally-invasive removal of smaller breast lesions in one procedure, enabling removal of smaller breast lesions in one procedure.

Materials and Methods: Instrument diameter is intended to range between 9–18 mm, to cover the majority of screening-detected lesions. Under ultrasonographic guidance, the lesion is vacuumed into the tube and an in-built diathermy hook releases the biopsy from the surrounding tissue with concomitant haemostasis. The instrument has been used on explanted human breast tissue from individuals undergoing surgery for breast reduction. Tissue were either frozen or handled freshly. Settings of diathermia and optimization of technique has been performed. Explanted pieces of tissue were fixed in formalin and sectioned in 5um slices, and stained with hematoxylin and eosin. A pathologist (VT) reviewed all glasses (n = 40).

Results: There is a learning curve when using the instrument. Tissue which had been frozen and thawed and then biopsied turned out to be of bad quality and were dismissed for further analyses. Initially, the diathermic power was too high or low, leading to thermal damage and crush artifacts. With diathermic setting stable, there was minor thermal damage. Fragmentation occurred especially in very fatty tissue. In more dense fibrotic breasts less fragmentation occurred, and one whole piece were mostly retrieved. Crush artefacts also occurred after the attempts on frozen tissue, which was a part of the experiment. Assessment of the overall quality for diagnosis led to a success in 18 out of 19 of cases. Of these the quality was evaluated with the results shown in the table below.

Quality of sample	Thermal damage	Fragmentation	Crush artifacts
Poor	1	9	0
Good	6	4	3
Very good	12	6	16

Conclusions: The tests have shown that with a good technique and appropriate diathermic setting the Resitu instrument can be used to extract good samples for pathologic evaluation. With very fatty tissue, there is a lot of fragmentation, but overall this would not impede the pathological evaluation of extracted lesions. The thermal damage can cause parts of the extracted tissue to be hard to diagnose, but it is limited and primarily located on the part of the sample where it is released from surrounding tissue, and further from the part of the sample that the intended target is located

No conflict of interest.

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POSTER SESSION **21 March 2024** **9.00–17.30**

SCREENING

224 (PB-131) Poster

Evaluating performance of an AI-enabled radiation-free test for detection of breast cancer in women younger than 45 years: A meta analysis of three prospective studies

S.T. Kakileti[1], S. Sampangi[2], G. Manjunath[3]. *[1]Niramai Health Analytix Pvt Ltd, Machine Learning Research, Bengaluru, India; [2]HealthCare Global, Breast Radiology, Bengaluru, India; [3]Niramai Health Analytix Pvt Ltd, CEO and Founder, Bengaluru, India*

Background: Recent change in mammography reporting guidelines by US FDA highlights the need for an additional supplemental screening modality for women with dense breasts. Furthermore, American College of Radiology updated its screening guidelines recommending annual screening beginning at age 40 for women of average risk and even earlier for women at higher-than-average risk. Even European Guidelines suggest not implementing mammography screening for asymptomatic average-risk women aged 40 to 44 due to breast density issues. A supplemental screening with Breast MRI is not affordable for many countries.

In this paper, we evaluate the efficacy of Thermalytix, a low-cost artificial intelligence-based screening test for its potential to be a supplemental screening modality for women younger than 45 years. Thermalytix involves computer-aided analysis of high resolution thermal scans using machine learning to quantify high thermal activities and asymmetric vascularity in the breast region.

Material and Methods: For this evaluation, we pooled the output of Thermalytix for 1187 women from three independent prospective clinical studies. All three studies had the same protocol schema, namely, participants underwent Thermalytix test followed by the standard of care (SoC) tests comprising mammography and ultrasound followed by biopsy for radiologically positive patients. This combined SoC diagnosis was used as a reference result for computing sensitivity and specificity.

Results: Out of 1187 women, 162 women were diagnosed for breast malignancy. The sensitivity and specificity of Thermalytix on the whole population was found to be 88.3% (95CI: 83.3%–93.2%) and 84.7% (95CI: 82.5%–86.9%), respectively. Out of 1187 women, 463 were younger than 45 years and 43 of them were diagnosed to have a breast malignancy as per SoC. In this cohort, Thermalytix showed a sensitivity of 90.7% (95CI: 82.0%–99.4%) and specificity of 82.14% (95CI: 78.5%–85.8%).

Conclusion: Thermalytix demonstrated good sensitivity and specificity in women under 45 years as well as on the overall population analyzed. This sensitivity and specificity obtained with Thermalytix is comparable to sensitivity (86.9%) and specificity (88.9%) reported with mammography in the Breast Cancer Surveillance Consortium (BCSC) study. Furthermore, Thermalytix has better user experience over conventional screening as it is non-contact, non-invasive, radiation-free, affordable and privacy aware. Thus, Thermalytix has the potential to be a promising modality for breast cancer screening on women younger than 45 years. Large scale studies are however needed to evaluate the test on women with different ethnicities.

Table: Performance of Thermalytix Breast Cancer Screening Test

	True Negatives	True Positives	False Negatives	False Positives	# Women
Study I	157	52	11	38	258
Study II	323	71	7	69	470
Study III	388	20	1	50	459
Total	868	143	19	157	1187

Conflict of interest:

Advisory Board: Dr. Sudhakar Sampangi is an advisor for Niramai Health Analytix.

Board of Directors: Dr. Geetha Manjunath is CEO and Founder of Niramai Health Analytix.

Other Substantive Relationships: Dr. Siva Teja Kakileti is an employee of Niramai Health Analytix.

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225 (PB-132) Poster

The Punjab breast cancer AI-digital project: Implementing Artificial Intelligence-based triaging at scale for population-level screening of breast cancer

S.S. Gill[1], A. Gupta[1], A. Trikha[2], K. Adapa[1], T. Kaur[3], R. Gupta[4], U. Ummul[5], V. Nanda[6], S. Upadhyay[7], H. Madhu[8], S.T. Kakileti[9], S. Collison[5], G. Manjunath[9]. *[1]Government of Punjab, Department of Health & Family Welfare, Chandigarh, India; [2]Government of Punjab, Secretary Health & Family Welfare-cum-Mission Director NHM Punjab, Chandigarh, India; [3]Niramai Health Analytix Pvt Ltd, Screening Ops, Bengaluru, India; [4]Roche, Health Care Partner, Chandigarh, India; [5]Niramai Health Analytix Pvt Ltd, Clinical Research, Bengaluru, India; [6]Niramai Health Analytix Pvt Ltd, Business Development, Delhi, India; [7]Niramai Health Analytix Pvt Ltd, Business Development, Bengaluru, India; [8]Niramai Health Analytix Pvt Ltd, Product Engineering, Bengaluru, India; [9]Niramai Health Analytix Pvt Ltd, Machine Learning Research, Bengaluru, India*

Background: Many Low and Middle Income Countries (LMICs) still use Clinical Breast Examination (CBE) as a population level screening test for breast cancer as conventional imaging modalities are not affordable and feasible to implement at scale. This is a prominent reason for high mortality rates of >50%. Thermalytix, a novel combination of thermal imaging and artificial intelligence, is emerging as a low-cost, portable and automated test for detection of breast cancers. This study presents preliminary findings of a collaborative effort between the technology innovation team and the government for implementing Thermalytix AI-based triaging as a population level screening method.

Materials and Methods: A pilot project was undertaken by the Government of Punjab to screen women using AI-based Thermalytix test at different Primary/Community Health Centers and District Hospitals from June 2022 to September 2023. Two portable units of Thermalytix were used to screen women across the centers in 15 districts. HCWs were trained to conduct breast cancer awareness programs and mobilize women for the screening camps. High risk symptomatic women were given priority in a screening camp. High school graduates were trained to perform Thermalytix screening in the camps. For all women, Thermalytix generated an automated B-score ranging from 1 (low likelihood of malignancy) to 5 (high likelihood of malignancy). Women with high B-Scores of 4 and 5 (referred as “RED”) were counseled and recommended for a follow-up diagnostic imaging test in a tertiary care hospital.

Results: In total, 12,227 women with age varying from 20 to 80 years (Median age: 41 years) undertook the Thermalytix test during the study period. 15% of the total participants had at least one breast complaint. Thermalytix classified 386 women as RED with a test positivity rate of 3.16%. 248 women were followed up with additional imaging tests or clinical exam and suspicious cases sent for histopathology. 22 of these women were diagnosed with a breast malignancy on histopathology, giving a PPV of 8.9% for confirmed diagnosis. A considerable percentage of asymptomatic women who were test positive were ruled out in a followup clinical exam and were not sent for histopathology - a limitation of this study, which if addressed in future could possibly increase this PPV for Thermalytix.

Conclusion: This is the first ever large scale field study of an AI-based screening test in India, and the preliminary results demonstrate the potential of such automated analysis to triage patients in LMICs. The success of the

project can be seen in two ways (i)Low skilled technicians were employed to perform the screening test (ii)22 cancers (CDR: 0.18%) were detected with Thermalytix. This CDR is 3x better when compared to the 30 cancers detected among 50,366 women (CDR: 0.059%) with CBE in an earlier study conducted in India.

Conflict of interest:

Board of Directors: Dr. Geetha Manjunath and Mr. Himanshu are on the board of Directors of Niramai Health Analytix.

Other Substantive Relationships: Ms. Taranjit Kaur, Dr Uzma Ummul, Mr. Vicky Nanda, Mr. Somdev Upadhyay, Dr Siva Teja and Dr Sathiakar Collison are employees of Niramai Health Analytix.

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226 (PB-133) Poster

Testing the European quality assurance scheme for breast cancer services

S. Baldacchino[1], L. Neamţiu[2], M. Garcia Escribano[1], L. Stănică[1], E. Riggi[1], G.P. Morgano[1], T. O'Grady[1], A. Janusch-Roi[1]. *[1]Healthcare Quality Group on Cancer, European Commission - Joint Research Centre (JRC), Ispra, Italy; [2]Institutul Oncologic "Prof. Dr. Ion Chiricuta" Cluj-Napoca, Romania*

Background: The European Commission Initiative on Breast Cancer (ECIBC) aims to provide evidence-based recommendations and a voluntary quality assurance (QA) scheme for breast cancer services (BCS) across Europe, covering the entire care pathway from breast cancer screening to palliative care. The European QA scheme defines a set of evidence-based requirements to ensure quality and continuity of care throughout the entire care pathway. The scheme is developed with the support of the Quality Assurance Scheme Development Group (QASDG), a multidisciplinary expert group that includes patients.

Materials and Methods: The European QA scheme for breast cancer services has been tested to collect feedback and improve on feasibility and practicability in real healthcare settings across Europe. Testing was done in two phases:

1. A *feasibility exercise* involving 8 volunteer BCS from 6 European countries who self-assessed their compliance to the service requirements listed in the Manual for Breast Cancer Services, using supporting tools made available by ECIBC, and provided feedback.
2. The *pilot exercise* tested third-party auditing and the accredited certification approach of the scheme. The pilot exercise was carried out in collaboration with the European co-operation for Accreditation (EA) and involved 18 entities (BCS, certification bodies, national accreditation bodies and other entities) from 8 European countries.

Results: The main findings include feedback received on the feasibility of service requirements; the importance of training and guidance for the auditors and the BCS; and the benefits of fostering a culture of continuous improvement and learning. Feedback was evaluated with the QASDG experts yielding streamlined requirements, a better presentation of the scheme and improvements on its universal feasibility. Overall, the requirements were found to be clearly described, useful and have the potential to lead to quality improvement. Importantly, as a first step, the European QA scheme was found to be 'fit-for-purpose' by the EA.

Conclusions: The testing phase has led to optimisation of the scheme and demonstrated its potential for quality improvement. The final version will undergo formal validation by EA. The European QA scheme for breast cancer services will subsequently be publicly available and interested services across Europe and beyond will be able, if interested, to implement the service requirements, self-assess, and later on apply for accredited certification.

No conflict of interest.

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227 (PB-134) Poster

2023–2024 Update of the European breast cancer guidelines on screening and diagnosis

E. Riggi[1], G.P. Morgano[1], E. Parmelli[2], S. Baldacchino[1], M. Garcia Escribano[1], T. O'Grady[1], L. Stănică[1], A. Janusch-Roi[1]. *[1]Healthcare Quality Group on Cancer, European Commission - Joint Research Centre (JRC), Ispra, Italy; [2]Humanitas University, Clinical Epidemiology and Research Center, Department of Biomedical Sciences, Pieve Emanuele, Italy*

Background: The European Guidelines for Screening and Diagnosis of Breast Cancer are evidence-based and developed within the European Commission Initiative on Breast Cancer (ECIBC). They are developed by a multidisciplinary group (GDG) of selected experts following the 'GRADE' approach and include the use of 'Evidence to Decision' frameworks.

Methods: To ensure that the recommendations in the European Breast Guidelines are kept up to date, a structured updating strategy is followed at regular intervals. This strategy consists of four phases (prioritisation, surveillance, updating, publication), it considers if new evidence may affect existing recommendations and allows the introduction of new Healthcare Questions (HQs).

Results: The fourth update of the European Breast Guidelines for 2023–2024 commenced in December 2022. The GDG prioritised the update of recommendations concerning imaging modalities for screening women and the use of artificial intelligence (AI) in mammography reading. To date, the GDG assessed new evidence pertaining to five recommendations and modified two on digital breast tomosynthesis. No changes were made to the recommendations for using AI. The forthcoming GDG discussion will focus on the use of magnetic resonance imaging, contrast-enhanced mammography, and ultrasound for tailored screening of women with dense breasts.

Conclusions: The updating strategy allowed for the structured identification of priority topics where new, high-impact evidence is available, thus ensuring the European breast cancer guidelines remain valid and up-to-date.

No conflict of interest.

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228 (PB-135) Poster

Correlation between plasma D-Dimer and Factor VIII levels with clinical stage and axillary lymph node status in patients presenting with operable breast cancer

A. Biswas[1], H. Saha[2], D. Maitra[1]. *[1]Kolkata Medical College, General Surgery, Kolkata, India; [2]IPGMER & SSKM Hospital Kolkata, Gastrosurgery, Kolkata, India*

Background: An attempt to evaluate the role of D-dimer and Factor VIII levels in carcinoma breast to predict lymph node involvement and to look for relationship of these markers with histopathologic parameters. Most of the previous studies were done on western population however very few studies have been done on Indian population. This study aims to show that increased D-Dimer and factor VIII levels are important markers of clinical stage, lymphovascular invasion (LVI), lymph node involvement and tumor metastasis in operable breast carcinoma patients.

Material and Methods: An institution based prospective observational study conducted on indoor patients admitted with operable breast carcinoma in the Department of Surgery, Medical College, Kolkata. 80 patients admitted for MRM/ BCS from March 2020 to May 2021 were included and subjected to certain investigations followed by surgery and then followed up as per the protocol of this study.

Operable breast carcinoma- Stage 1,2 & 3A disease (up to T3N1M0).

Result: Correlation of the duration and size of the breast lump with plasma D-Dimer and Factor VIII levels were not statistically significant. The increase in these two markers were statistically significant for clinical T stage but not for pathological T stage. No correlation between the pathological type and hormone receptor status with these two markers were found. The increase of plasma D-Dimer level with the increase of grade was found to be statistically significant. The increase in Factor VIII level with the increase of grade was found to be not statistically significant. The correlation of plasma D-Dimer and Factor VIII levels with pathological N stage were found to be statistically significant. A positive correlation was found between LVI and plasma D-Dimer and Factor VIII levels. The increase in the median of plasma D-Dimer and Factor VIII levels were not statistically significant for clinical TNM stage.

Conclusion: D-dimer and factor VIII levels directly correlated with the extent of lymph node involvement, number of positive lymph nodes but not with tumor size, ER, PR status.

These may be used as prognostic markers.

Can act as surrogate markers of LVI in early breast cancer and presence of metastasis in axillary nodes.

In cases of clinically node negative axilla with raised plasma D-dimer and factor VIII levels, negative SLNB reports may be false negative.

May be used as predictors of response to NACT.

Significant postoperative decrease may provide objective criteria to assess completion of surgery.

Recurrence after completion of treatment may be indicated by resurgence in plasma D-dimer and factor VIII factor.

D-dimer may prove to be a non-invasive, safe, convenient and easily available biomarker which can be combined with SLNB.

Targeted therapy based on D-Dimer and Factor VIII levels may be contemplated if suitable options are available.

No conflict of interest.

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229 (PB-136) Poster

Breast cancer knowledge and screening practices among women in Uruguay

N. Camejo[1], D. Amarillo[1], C. Castillo[1], M. Bernate[1], F. Burguez[1], E. Darino[1], A. Deleón[1], T. Milwa[1], B. Maria[1], G. Krygier[1]. [1]*School of Medicine, Department of Clinical Oncology, University of Uruguay, Montevideo, Uruguay*

Introduction: In Uruguay, breast cancer (BC) is the most common and deadly cancer among women. The WHO maintains that up to 30% of BC cases are preventable through health promotion targeting modifiable risk factors such as physical inactivity, obesity, alcohol consumption, radiation, and smoking, the latter being disputed. In our country, nearly half of the women may present at least one risk factor for breast cancer.

Objective: To evaluate the knowledge of Uruguayan women on breast cancer screening.

Materials and Methods: This is an observational, descriptive, cross-sectional study. A survey was conducted among women, disseminated via social networks. Informed consent was requested at the beginning of the survey as an exclusive requirement to participate. Anonymity of the respondents was maintained in the statistical analysis, and approval was obtained from the Ethics Committee of the Hospital de Clínicas.

Results: A total of 1859 women participated. The average age of the participants was 38.7 years (SD: 11.55; range 18–80). 73% (1357) resided in Montevideo. Regarding education level, 46.4% (863) had completed tertiary education, 45% (836) secondary, while 8.4% (156) primary. In terms of health coverage, 89.3% (1660) had private insurance, 9.7% (180) public health, and 1% (19) had no health coverage. 75.1% (1396) recognized BC as the deadliest cancer for women. 52% (967) believe that 3 out of 10 women are at risk of developing BC, and 18.4% (342) are unaware of its prevalence. 60.2% (1119) acknowledge mammography as a test that has reduced BC mortality. 64.2% (1193) believe it should start at age 40. Regarding frequency, 60.5% (1125) consider it should be done annually. The most considered risk factors for developing BC were smoking (60.9%, 1132), obesity (57%, 1060), and physical inactivity (56.8%,1056).

Conclusions: Our results show that respondents are adequately informed about the importance of BC and mammographic screening to prevent it; however, 74.3% (1381) believe that screening should start at 40 years of age.

No conflict of interest.

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230 (PB-137) Poster

Performance evaluation of artificial intelligence as a third reader in breast cancer screening

G. Logue[1], A. Talwalkar[1], F. Singh[1], R. Tuano-Donnelly[1], S. Iram[1], H. Bailey[1]. [1]*South Lancashire Breast screening programme. Wrightington, Wigan and Leigh NHS Foundation Trust, Radiology, Wigan, United Kingdom*

Background: Women between the ages of 50–70 are invited for screening mammograms every 3 years within the UK National Breast Cancer Screening Programme. Two views of each breast are obtained which undergo standard double reading (SDR) with consensus for discordant readings by human expert readers to decide whether patients are recalled for further assessment (RA) or routinely recalled in the next screening interval (RR).

Artificial intelligence (AI) has a potential role in breast cancer detection. The UK National Screening Committee continues to examine AI's performance, benefits and harm before it is included in guidelines. The purpose of this ongoing retrospective evaluation is to compare the performance of human SDR and an independent silent AI reader in recall outcomes and cancer detection. This simulates AI as a third reader in the screening programme.

Materials and Methods: 4381 women attended 3 breast screening units in the Lancashire region over a 6-week period. Patients with a complete set of four mammograms were included in the study, excluding those with breast implants or previous mastectomy. The data set included 4298 patients. All mammograms underwent routine human SDR.

The commercially available AI platform, Mammography Intelligent Assessment (Mia), was utilised in this study as an independent third reader. Images were retrieved from local Picture Archiving and Communications Systems 2 weeks following the screening mammogram. Mia's output was not available during the human SDR process. Based on the software's predetermined algorithms each mammogram was interpreted and binary outputs were created (RA or RR). At 6 weeks, 4 human expert readers reviewed cases with discordant outputs determining the need for patient follow up.

Results: 3752 cases had negative concordance outcomes (both human SDR and MIA outputs matched as RR) and 56 had positive concordance outcomes (both human SDR and MIA outputs agreed as RA).

416 cases had positive discordance outcomes (both outputs disagreed = MIA output was RA and human SDR output was RR). No patients were recalled for further assessment during the discordance review.

74 cases had negative discordance outcomes (both outputs disagreed = human SDR output was RA and MIA output was RR). Of those requiring further investigation, 28 cases had benign and 1 had malignant cytology results. Overall, 73 of these cases that were not recalled by MIA were referred back for routine screening with 1 being a screen-detected cancer.

Conclusion: The overall performance of Mia shows a promising negative predictive value with potential to reduce unnecessary recalls in the workflow. This evaluation is in early stages and so extrapolation of results are limited by the small sample size. A foreseeable challenge is Mia's high recall rate which will unlikely change as it does not compare images with other views or previous mammograms.

No conflict of interest.

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231 (PB-138) Poster

Is awareness the most important factor in increasing breast cancer screening uptake?

B. Celik[1], K. Karabulut[2], M. Manay[2], A.N. Yashar[2], E. Dilege[1]. [1]*Koc University, School of Medicine, General Surgery, Istanbul, Turkey;* [2]*Koc University, School of Medicine, Istanbul, Turkey*

Background: Breast cancer (BC) is the most common cancer among women in the world and Turkey. Screening mammography (MG) is still the most effective method for early diagnosis. According to the Turkish Health Literacy Survey, the rate of MG in women of screening age is 28.7%.

In this study, we aim to analyze the level of BC awareness at different sociocultural levels and genders to find the associated factors to increase awareness and define a way to increase screening uptake. We will share the preliminary results of the surveys we have conducted.

Material and Methods: This is one arm of a multicentric designed study in Istanbul. The online or black-white questionnaire was done after obtaining informed consent from anyone above 18 years admitted to Koç University Hospital outpatient clinics except breast, gynecology, and obstetrics clinics and healthcare workers. Anyone having a diagnosis of BC was excluded.

Twenty-eight question survey for women and men cover sociodemographic characteristics, health literacy scale, knowledge about BC, risk factors, warning signs/symptoms, breast self-examination (BSE) practice, and breast cancer screening (BCS).

Results: Two hundred seventeen women and 107 men participated in the questionnaire so far. The sociodemographic characteristics of the

respondents are shown in Table 1. There is no statistically significant difference between knowledge of BCS age between those who graduated from high school or above and those who were primary school graduates and literate (p: 0.17) *or* between those with high or low income *(p:0.84)*. Higher-educated women have significantly more BCS than lower-educated ones *(p:0.017)*. Monthly income *(p:0.5)* and occupation *(p:0.11)* had no effect. The rate of undergoing MG for responders aged 40 and above with a family history of breast cancer was found to be 77.4%. In contrast, for those without a family history, the rate was determined to be 66.2%. Also, the rate of undergoing MG among individuals with breast cancer in their surroundings was 75%, whereas for those without such proximity, the rate of undergoing MMG was observed to be 24%. When asked, "Where do you get information about BC and screening?" the most common answer is 70% from health workers, 47% from family, and 45% from social media.

Table 1 The sociodemographic of the responders

-	Women *(n:217)*
Age, years, median	39 (18–73)
Education	
Literate - Primary School	38
High school-University-Higher	179
Monthly Income	
No Income-26500TL	187
Over 26500TL	30
Anyone with breast cancer	
In the family	68 ***(31%)***
Between friends	119 ***(54%)***
Self-breast examination habit	168 ***(77%)***
Getting a mammogram at least once (>40)	81 ***(%75)***

Conclusion: A woman diagnosed with BC increases awareness of other women. There is still a significant task for healthcare professionals in raising screening. Social media and the internet may be used more effectively to raise BC awareness.

No conflict of interest.

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232 (PB-139) Poster

Multi-modal AI-based imaging for improving breast cancer screening across breast densities: A pilot study

B. Govindaraju[1], S.T. Kakileti[1], S. Sampangi[2], G. Manjunath[1]. *[1]Niramai Health Analytix Pvt Ltd, Machine Learning Research, Bengaluru, India; [2]HealthCare Global, Breast Radiology, Bengaluru, India*

Background: Mammography based breast cancer screening has proven to reduce mortality in women, but is found to be less effective in women with dense breasts. Due to this, different regulatory bodies insisted on the need for having density information on mammography reports in recent years. On the other hand, Thermalytix, a computer aided breast cancer detection system with thermal imaging, is emerging as a new Artificial Intelligence (AI)-based functional imaging that is showing promising results on dense breasts. We propose a multi-modal AI based screening modality that uses both X-Ray mammograms and thermal scans. This is the first ever pilot study that leverages the complementary nature of two imaging modalities.

Materials and Methods: 181 women were invited to undergo both mammography and Thermalytix imaging in 2 sites. Mammography images were analyzed by the MammoAI module to predict the likelihood of malignancy. Likewise, Thermalytix analyzed thermal images using AI to generate the likelihood of malignancy based on suspicious high thermal activities and vascular patterns. To determine the output of the multi-modal modality, mammography results were considered when the breast tissue density was fatty and Thermalytix result was considered when tissue density is dense. Blinded to these AI results, participants underwent standard of care (SoC) procedures involving mammography and/or ultrasound followed by biopsy if radiologically positive. This SoC diagnosis was used as ground truth for obtaining the performance metrics.

Results: Out of 181 women, 20 women were diagnosed with breast malignancy as per SoC. When mammoAI alone was used, it resulted in a sensitivity and specificity of 70.0% and 98.76%, respectively. When Thermalytix AI alone was used, it resulted in a sensitivity and specificity of 95% and 75.16%, respectively. When multimodal imaging was considered, the sensitivity and specificity were found to be 85% and 89.44%, respectively. These findings indicate an enhancement of around 4% compared to Thermalytix alone and a 6% improvement compared to mammoAI alone when sensitivity+specificity was chosen as the metric. Specifically on dense breasts (n = 71), this improvement with multi-modality was 27% when compared to mammoAI alone and 12% when compared to radiologist interpreted mammograms.

Conclusion: This first ever pilot study showed the benefit of multi-modal imaging of mammography and Thermalytix to improve overall breast cancer detection. The proposed multimodal imaging included AI based analysis for both the modalities to alleviate subjectivity. This pilot study shows the potential of combining AI and multimodality to address the gap in early detection of breast cancer in dense breasts by combining radiation-free functional imaging with X-Ray imaging to provide high sensitivity and specificity for all women with minimal additional cost.

Conflict of interest:

Advisory Board: Dr. Sudhakar is on advisory board of Niramai Health Analytix.

Board of Directors: Dr. Geetha Manjunath is on Board of Directors of Niramai Health Analytix.

Other Substantive Relationships: Dr. Siva T and Mr. Bharath G. are employees of Niramai Health Analytix.

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233 (PB-140) Poster

Management of B3 lesions in screening population; review of South Lancashire breast screening unit

S. Rehman[1], A. Talwalkar[1], S. Hilton[1], M.K. Hindley[1]. *[1]Wrightington, Wigan and Leigh Teaching Hospitals NHS Foundation Trust, Breast Screening Unit, Thomas Linacre Centre, Wigan, United Kingdom*

Background: B3 lesions are defined as 'lesions of uncertain malignant potential' that may provide benign histology on core biopsy, but either are known to show heterogeneity or to have an increased risk of associated malignancy. NHS Breast screening program (BSP) provides recommendations regarding standardized management of B3 lesions without resort to first line diagnostic excision. Vacuum-assisted excision (VAE) is recommended by NHS BSP for managing all B3 lesions, except papilloma with atypia, spindle cell lesions and fibroepithelial lesions. Aim of this audit is to assess incidence of screen detected B3 lesions in South Lancashire breast screening unit, to evaluate further assessment (using VAE versus diagnostic surgical biopsy) and to determine tumor upgrade rate.

Material and Methods: Retrospective data collection was performed using National breast screening system (NBSS). 30,281 ladies had screening mammograms in 2022. 1,072 patients were recalled to assessment clinic and 585 invasive procedures were performed on 496 patients.

Results: 48 patients (8.89%) patients had B3 outcome on initial biopsy. Majority of lesions were papillary lesions (14), Atypical intraductal epithelial proliferation (AIDEP)/atypical ductal hyperplasia (ADH) (11), Flat epithelial atypia (9) and lobular neoplasia (8). Smaller number of lesions included cellular fibroepithelial lesion, radial scar, spindle cell lesion and mucocele like lesion. 16 patients had B3 lesions without atypia and out of these 12 were eligible for VAE (by excluding 2 patients with stromal lesions and 2 patients with synchronous B5 lesions). 10 patients underwent VAE, and 1 cancer was diagnosed in this group (7.1%). 32 patients had B3 lesions with atypia. Out of these 24 were eligible for VAE (by excluding papillary lesions without atypia and spindle cell lesion/fibroadenoma. 2 patients with synchronous B5 lesions underwent mastectomy and were not assessed). Out of these 24 patients 20 had VAE, 4 underwent diagnostic surgery. By excluding 2 patients with synchronous B5 lesions, 11 out of remaining 30 patients had tumor upgrade with PPV of 36.6%. AIDEP/ADH was associated with highest upgrade to malignancy (36.36%). Overall, 83% of B3 lesions eligible for VAE were appropriately assessed with VAE and diagnostic surgery was performed for <25% patients with tumor upgrade rate of 7.1 to 36.67%.

Conclusions: Management of B3 lesions requires multidisciplinary approach and radiological-pathological concordance. VAE is safe alternative to diagnostic surgery allowing preoperative diagnosis of cancer and

avoidance of surgery in benign lesions. This pathway ensures adequate sampling to exclude coexistent in situ or invasive carcinoma.

No conflict of interest.

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POSTER SESSION **22 March 2024** **9.00–14.30**

Basic Science and Translational Research

234 (PB-050) Poster

Evaluation of Prostate Specific Membrane Antigen (PSMA) immunohistochemical expression in early-stage breast cancer subtypes

N. Andryszak[1], P. Kurzawa[2], M. Krzyżaniak[2], M. Nowicki[3], M. Ruchała[4], D. Iżycki[5], R. Czepczyński[4]. *[1]Poznan University of Medical Sciences, Department of Endocrinology- Metabolism and Internal Medicine, Poznan, Poland; [2]Poznan University of Medical Sciences, Department of Oncological Pathology University Clinical Hospital in Poznan, Poznan, Poland; [3]Poznan University of Medical Sciences, Department of Histology and Embryology, Poznan, Poland; [4]Poznan University of Medical Sciences, Department of Endocrinology Metabolism and Internal Medicine, Poznan, Poland; [5]Poznan University of Medical Sciences, Department of Cancer Immunology, Poznan, Poland*

Background: Breast cancer, known for its diverse subtypes, ranks as one of the leading causes of cancer-related deaths. Prostate-specific membrane antigen (PSMA), primarily associated with prostate cancer, has also been identified in breast cancer, though its role remains unclear. The aim of our study was to evaluate PSMA expression in early-stage breast cancer and assess its distribution across breast cancer subtypes. Additionally, we have investigated the correlation of immunohistochemical factors related to breast cancer with PSMA expression.

Material and Methods: This study aimed to evaluate PSMA expression in breast cancer subtypes: luminal A, luminal B, HER2-positive, and triple-negative breast cancer (TNBC). Immunohistochemical evaluation was performed on early-stage breast cancer patients' tumor specimens, and PSMA expression was assessed in tumor cells and vessels. The study included the analysis of the Ki67 proliferation index, estrogen receptor (ER) expression, progesterone receptor (PR) expression, and HER2 status in conjunction with PSMA expression.

Results: This retrospective study included 98 early-stage breast cancer cases. PSMA expression was examined in both tumor cells and tumor-associated blood vessels. The analysis revealed PSMA expression in tumor-associated blood vessels in 88 cases and in tumor cells in 75 cases. Ki67 expression correlated positively with PSMA expression in blood vessels ($p < 0.0001$, R Spearman 0.42) and tumor cells ($p = 0.010$, R Spearman 0.26). The estrogen and progesterone receptor expression correlated negatively with PSMA levels in blood vessels ($p = 0.0053$, R Spearman −0.26 and $p = 0.00026$, R Spearman −0.347, respectively). HER2 status did not significantly impact PSMA expression. We did not detect any statistically significant differences between breast cancer subtypes.

Conclusions: Our study confirms the presence of PSMA expression in breast cancer cells, particularly in tumor-associated blood vessels. The analysis reveals a correlation between higher PSMA expression and aggressiveness of breast cancer cells, suggesting its potential involvement in angiogenesis and the formation of metastases. These findings provide novel information that may have some future implications for breast cancer imaging and treatment strategies. Triple-negative breast cancer, characterized by its poor prognosis, high aggressiveness and PSMA overexpression, could particularly benefit from innovative therapeutic approaches.

No conflict of interest.

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235 (PB-051) Poster

AKT1, ERBB2, ESR1, KRAS, PIK3CA and TP53 alteration detection by a new ctDNA assay in plasma of patients with hormone receptor positive (HR+)/HER2- advanced Breast Cancer treated with hormonal therapy and CDK4/6 inhibitors

A. Virga[1], C. Gianni[2], M. Palleschi[2], F. Merloni[2], R. Maltoni[2], P. Ulivi[1], U. De Giorgi[2], G. Martinelli[3], S. Bravaccini[1]. *[1]IRCCS Istituto Romagnolo per lo Studio dei Tumori IRST "Dino Amadori", Bioscience Laboratory, Meldola, Italy; [2]IRCCS Istituto Romagnolo per lo Studio dei Tumori IRST "Dino Amadori", Medical Oncology, Meldola, Italy; [3]IRCCS Istituto Romagnolo per lo Studio dei Tumori IRST "Dino Amadori", Scientific Directorate, Meldola, Italy*

Background: Metastatic breast cancer (mBC) patients with hormone receptor positive (HR+)/HER2- tumors are usually treated with hormonal therapy (HT) plus CDK4/6 inhibitors (CDK4/6i). However, a majority of these patients experience disease progression (PD), underscoring the necessity to identify resistance mechanisms to CDK4/6i. The primary aim is to evaluate the precision and feasibility of a novel multi-gene target panel NGS assay for detecting genomic alterations of *AKT1*, *ERBB2*, *ESR1, KRAS, PIK3CA*, and *TP53* on circulating tumor DNA (ctDNA) in the plasma of women undergoing HT (letrozole/fulvestrant) in combination with CDK4/6i. Additionally, our aim is to investigate the association between genomic profiling and clinical outcomes.

Material and Methods: Plasma samples were collected at 2 time points (at baseline and at the 3/6 months after starting CDK4/6i treatment) from 16 patients with advanced HR+/HER2- BC, enrolled in IRCCS IRST (B114 protocol). Starting from 2 ml of plasma, ctDNA was isolated and libraries were prepared by using Plasma-Seqsensei (PqS)® Breast Cancer IVD kit (Sysmex Inostics, GmbH)® and sequenced by Illumina NEXTSEQ550 platform. NGS data were analysed by Plasma-SeqSensei™ IVD Software®. PqS technology utilises an internal quantifier, which allows robust quantification of tumour-specific sequences over a broad dynamic range down to a limit of detection of 6 mutant molecules.

Results: On the total of 16 enrolled patients, 8 were analysed: 4 had PD, 3 partial response (PR) and 1 stable disease (SD), during follow-up after 3 months of CDK4/6i treatment. The analysis of the other 8 patients is ongoing. Out of the 4 patients with PD, 1 was wild-type for the analyzed genes and 3 presented *PIK3CA* mutations at baseline. Among the 3 *PIK3CA* mutated PD patients, 2 showed a higher mutant allele frequency (MAF) in the second time point sample (1 of them presented the same trend in terms of MAF improvement for both *PIK3CA* and *ERBB2* mutations), while in 1 patient, somatic *PIK3CA* alteration was absent in the sample collected during treatment. In the patients with PR, the 3 alterations detected (*AKT1, TP53* and *PIK3CA*) dramatically dropped during treatment.

Conclusions: The liquid biopsy analysis by PqS is feasible and accurate and the mutations found show a good correlation with the patients' outcome in our preliminary analysis. In accordance with literature data, the *PIK3CA* alterations were seen in patients who developed CDK4/6i's resistance. The lack of mutations in the PD patient could be explained by the presence of a lobular carcinoma, characterized by several other gene alterations not investigated with this assay. The decrease of *AKT1, TP53* and *PIK3CA* MAF alterations detected on plasma collected at 3 months during follow-up, was associated with the PR to CDK4/6i and could be useful in disease monitoring.

No conflict of interest.

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236 (PB-052) Poster

Enhanced cancerous properties of breast cancer cell and brown adipocyte co-cultures compared to their fused cells

S. Hu[1], S.K. Tey[2], V.Y. Shin[2], Z. Ni[2], T. Zou[2], A. Kwong[2]. *[1]The University of Hong Kong, Breast Surgery, Hong Kong, Hong Kong; [2]LKS Faculty of Medicine, The University of Hong Kong, Breast Surgery, Hong Kong, Hong Kong*

Background: The unique microenvironment of breast cancer (BC) surrounded by adipose tissue plays a critical role in tumorigenesis and metastasis. However, the underlying mechanisms of BC progression driven by various types of adipocytes are not fully elucidated. This study aims to understand the role of BC-adipocyte interaction in cancer invasiveness at cellular and molecular levels.

Material and Methods: Preadipocytes (3T3L1 cell line)-derived mature adipocyte-like adipocytes (AL), brown adipocytes (BAT), white adipocytes (WAT) as well as adipose-derived stem cell (ASC) were labeled with red fluorescence cell tracker and were co-cultivated with green cell tracker-tagged hormone receptor-positive breast cancer cell (MCF7) respectively. The alteration of cells at morphological, genomic and numerical levels at serial time points were examined by time-lapsed confocal laser scanning microscopy, DNA fluorescence in situ hybridization (FISH), and flow cytometry. The invasiveness of cancer cells was investigated in terms of their proliferation, migration, and invasiveness. Furthermore, the functional role of adipocytes on BC was explored in a xenograft tumor mouse model. In addition, the underlying mechanism was explored regarding the role of mitochondrial function and relevant molecular signaling.

Results: MCF7 co-cultured with all types of adipocytes showed a higher tumor activity than MCF7-BAT co-cultivation was the highest (4-fold increase in MTT and migration assay, $p < 0.0001$). Furthermore, the tumorigenic potential of the co-cultivated cells was also observed in the xenograft tumor mouse model, in which the in vivo tumor growth of co-cultivated cells was significantly higher than that of the MCF7 alone. Morphologically, MCF7-adipocyte cell-cell fusion was observed in all types of co-cultivation, and the fused cell proportion was significantly higher in MCF7-BAT than in other co-cultivation. Mechanistically, the transcriptional levels of empirical cell fusion and adipogenic metabolism molecules were substantially higher in co-cultivated cells. In addition, the cancer cells co-cultured with BAT showed higher intracellular mitochondrial content and were positively associated with more aggressive cancerous behavior. However, fused MCF7-BAT cells per se did not show superior invasiveness compared with other fused cells and the whole co-cultivation systems.

Conclusion: Various adipocytes can spontaneously fuse with breast cancer cells without special induction or stimulation. Both co-cultures and fusion hybrid cells consistently displayed an obvious change towards a more malignant phenotype. Brown adipocyte has the strongest effect of promoting breast cancer invasiveness by increasing the mitochondrial content of the cancer cells independent of cell fusion.

No conflict of interest.

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237 (PB-053) Poster

The prognostic significance of disseminated tumor cells detected in bone marrow on the prognosis after breast carcinoma treatment: A long-term, retrospective study

L. Dirix[1], A. Prové[2], P. Vermeulen[3]. *[1]Sint-Augustinus, Iridiumkankernetwerk, Antwerp, Belgium; [2]Sint-Augustinus, Medical Oncology, Wilrijk-Antwerp, Belgium; [3]Sint-Augustinus, Medical Oncology, Wilrijk-Antwerp, Belgium*

Background: The main cause of death in breast cancer patients is metastatic spread of tumor cells. The presence of disseminated tumor cells (DTCs) in the bone marrow at diagnosis has been suggested as a predictor for late metastasis and increased mortality after they awake from a state of dormancy.

Methods: This is a retrospective case-control study of 125 female patients successfully treated for localised breast cancer, with a mean follow-up time of 117 months. The patients that developing distant metastasis after therapy were compared to the control group who did not. Data of bone marrow samples was gathered through real time-polymerase chain reaction (RT-PCR). Markers of DTCs: cytokeratin 19 (CK) and mammaglobin (MAM), were used. The aim of this study is to confirm the association between DTC s and Disease-specific survival (DSS).

Results: CK positivity had a significant ($p = 0,045$) negative influence on DSS at a hazard ratio (HR) of 1,906 (1,049–3,462). However, MAM positivity did induce a significant risk increase ($p < 0,001$) with a HR of 3,202 (1,721–5,956). Patients with a BM positive for both CK and MAM had a HR for DSS of 7,294 (2,917–18,240). Different combinations of positivity/negativity led to the assumption that MAM is a better predictor for DSS.

Conclusion: This study confirms the role of DTCs as a negative, prognostic factor in breast cancer patients during long-term follow-up. Use of a combination of CK and MAM to identify increased risk or a preference for either of these markers could be object of further studies to help predict the prognosis of breast cancer at time of diagnosis.

No conflict of interest.

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239 (PB-055) Poster

Luminal breast cancer cells growth is sustained by lipoaspirate components obtained specifically from the abdomen

M. Truffi[1], I. Rybinska[2], F. Piccotti[1], L. Signati[1], F. Bianchi[3], S.M. Pupa[2], E. Tagliabue[2], F. Corsi[4], T. Triulzi[2]. *[1]Istituti Clinici Scientifici Maugeri IRCCS, Nanomedicine and Molecular Imaging Lab, Pavia, Italy; [2]Fondazione IRCCS Istituto Nazionale Dei Tumori, Dept. of Experimental Oncology, Milan, Italy; [3]Università degli Studi di Milano, Dept. of Biomedical Science for Health, Milan, Italy; [4]Istituti Clinici Scientifici Maugeri IRCCS, Breast Unit, Pavia, Italy*

Background: Lipofilling (LF) is a widely employed technique for breast reconstruction following surgery in breast cancer (BC) patients. However, recent research has shed light on a potential tumorigenic role of adipocytes and adipose-derived stem cells (ASCs), prompting concerns on the safety of LF for cancer patients.

Materials and Methods: Lipoaspirate was obtained from the subcutaneous adipose tissues, either from the abdomen or loin, of 28 patients undergoing LF after BC surgery. Adipocytes and cells of the stromal vascular fraction were isolated from lipoaspirates and cultured in a transwell system, either alone or with luminal MCF7 or triple negative (TN) MDA-MB-231 BC cells for 7 days. Additionally, indirect co-culture with conditioned media of lipoaspirate components was performed with both luminal and TNBC patient-derived organoids (PDO). Tumor cell proliferation was evaluated through cell count and CellTiter-Glo® 3D cell viability assay, respectively. Culture media conditioned by adipocytes and ASCs were analyzed by multiplex Luminex assays to characterize cell secretome.

Results: Characterization of adipocytes and ASCs secretome identified two and three clusters of adipocytes and ASCs, respectively, with peculiar production of inflammatory molecules or growth factors. These clusters were not associated with body mass index and other patient features but, rather, with the site of lipoaspirate sampling. Indeed, adipocytes and ASCs releasing higher levels of inflammatory molecules were mainly derived from loins.

Proliferation of both MCF7 and MDA-MB-231 cells was significantly increased by co-culture with adipocytes and ASCs. In 3D cell culture condition, only luminal PDO viability, and not that of TNBC PDO, was supported by conditioned media from both adipose tissue cell types. Notably, in both 2D and 3D cell culture conditions, induction of luminal BC cell growth was significantly higher when co-cultured with adipose tissue cells derived from the abdomen than with those obtained from loin lipoaspirate.

Conclusions: Overall, our data support the existence of heterogeneity in the phenotype of adipocytes and ASCs, mainly explained by the site of lipoaspirate sampling. In addition, our findings identified a pro-tumor crosstalk between abdominal lipoaspirate cell components and luminal BC cells that deserves further investigation.

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No conflict of interest.

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242 (PB-058) Poster

Triple-negative breast cancer cells that survive ionizing radiation exhibit an Axl-dependent aggressive radioresistant phenotype

Q. Gu[1], J. Ji[2]. *[1]Zhejiang Cancer Hospital, Department of Radiation Oncology, Hangzhou, China; [2]Zhejiang Cancer Hospital, Department of Nuclear Medicine, Hangzhou, China*

This study aimed to investigate the aggressive behavior of triple-negative breast cancer (TNBC) cells that had survived ionizing radiation and explore the potential targets of TNBC combination treatment. Consistent with the previous literature, Axl was highly expressed in TNBC and closely associated with the degree of malignancy based on immunohistochemical staining. Using a gradient irradiation method, the ionizing radiation-resistant mouse TNBC cell line4T-1/IRR was established. It was found that Axl expression was upregulated in 4T-1/IRR cells. After irradiation by X-ray, the cell viability

and colony formation ability of 4T-1/IRR cells were significantly increased when compared with the 4T-1cells. Combined radiotherapy with Axl inhibition by treatment with R428 and small interfering RNA lentivirus targeting Axl infection significantly reduced cell viability, colony formation ability, DNA double-stranded break repair, and the invasive and migratory ability of 4T-1/IRR cells. In vivo, the small animal radiation research platform was applied to precisely administer radiotherapy of the tumor-bearing mice. R428 treatment combined with 6 Gy X-ray significantly inhibited the growth of 4T-1/IRR cells-derived xenograft tumors in the BALB/c mouse. The results of western blotting showed that the critical molecular mechanism involved in the radio resistance of TNBC cells was the PI3K/Akt/mTOR signaling pathway induced by Axl activation. Thus, it is hypothesized that targeted Axl therapy combined with radiotherapy may have significant potential for the treatment of TNBC.

No conflict of interest.

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244 (PB-060) Poster

High human leukocyte antigen class I expression correlates with poor prognostic features in receptor-positive, Her2Neu-negative breast cancer

M. Vernet-Tomas[1], I. Vazquez[2], F. Olivares[2], D. Lopez[3], J. Yelamos[4], N. Argudo[5], M. Jimenez[5], A. Martinez[5], P. Nicolau[6], P. Maso[6], R. Alcantara[7], N. Arenas[7], S. Vidal-Sicart[8], Y. Aguilar[8], R. Valhondo[8], M. Algara[9], J. Sanz[9], A. Noguera[10], M.J. Lopez-Camenforte[10], L. Comerma[2]. *[1]Hospital del Mar, Breast Unit, Barcelona, Spain; [2]Hospital del Mar, Breast Unit, Pathology, Barcelona, Spain; [3]Hospital del Mar, Pathology, Barcelona, Spain; [4]Hospital del Mar, Immunology, Barcelona, Spain; [5]Hospital del Mar, Breast Unit, General Surgery, Barcelona, Spain; [6]Hospital del Mar, Breast Unit, Gynaecology, Barcelona, Spain; [7]Hospital del Mar, Breast Unit, Radiology, Barcelona, Spain; [8]Hospital del Mar, Nuclear medicine, Barcelona, Spain; [9]Hospital del Mar, Breast Unit, Radiotherapy, Barcelona, Spain; [10]Hospital del Mar, Breast Unit, Breast Care Nurse, Barcelona, Spain*

Background: The purpose of this phase of the MUltimodal Targeted Axillary Surgery trial (ClinicalGov NCT04039893, July 31 2019) was to determine whether HLA-I expression and NK cell tumor infiltration in breast cancer are related to axillary tumor burden and other prognostic features.

Material and Methods: We analyzed 35 diagnostic biopsy samples, taken from 35 breast cancer patients with axillary node involvement and upfront surgery. HLA-I H-score and the number of NK cells × 50 high power fields (HPF) were correlated with clinical (age, body mass index) and pathological variables (number of infiltrated lymph nodes, tumor size, histological type, the presence of ductal carcinoma in situ, focality, histological grade, necrosis, lymphovascular and perineural invasion, Her2Neu status, and the percentages of tumor-infiltrating lymphocytes (TILs), estrogen receptor, progesterone receptor, ki67, and p53).

Results: Most patients in this cohort showed a Luminal Her 2 negative phenotype (33/35). No correlation was found between HLA-I H-score and NK cells × 50 HPF with the number of infiltrated lymph nodes. A positive correlation was found between HLA H-score and TILs and Ki67 expression ($p = 0.00$ and $p = 0.00$, respectively). HLA H-score increased with histological grade and was higher in unifocal than in multifocal disease ($p = 0.044$ and $p = 0.011$, respectively). No correlation was found between NK cells × 50 HPF and any other variables.

Conclusions: High HLA-I H-score values correlated with features of poor prognosis in this cohort of breast tumors, but not with axillary tumor burden. This finding highlights the differences between breast cancer and cancers in other locations, in which low HLA-I expression tends to be associated with poor prognostic features.

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246 (PB-062) Poster

The potential role of Collagen type VII in breast cancer proliferation

S. Perez Diaz[1], J. Lindberg[1,2], P. Kingham[1], M. Sund[3], G. Rask[2], J. Svensson[4], M. Jansson[2], R. Wiberg[1,2]. *[1]Umeå University, Department of Integrative Medical Biology, Section of Anatomy, Umeå, Sweden; [2]Umeå University, Department of Surgical & Perioperative Sciences, Surgery, Umeå, Sweden; [3]University of Helsinki and Helsinki University Hospital, Department of Surgery/CLINICUM, Helsinki, Finland; [4]Umeå Univeristy, Department of Statistics, Umeå School of Business, Economics and Statistics, Umeå, Sweden*

Background: Breast cancer has a good 5-year survival rate, but still there is a 10% relapse rate 10 years after primary treatment. Cancer cells can persist in the primary site as disseminated tumor cells surviving in a prolonged quiescent state for years and then become activated. To better understand the molecular mechanisms leading to relapse, the role of the tumor cell microenvironment is an important research area. Extracellular matrix proteins are relevant factors in modulating the tumor microenvironment. Low gene expression of type VII collagen (ColVII) has been associated with poor 5-year survival in breast cancer. This study aims to investigate the role of ColVII in breast cancer dormancy and aggressiveness.

Methods: A human estrogen-receptor (ER) positive breast cancer cell line (MCF7) and adipose-derived mesenchymal stem cells (AdMSC) were exposed to hypoxia using cobalt chloride. ColVII expression was evaluated at gene and protein level using qRT-PCR and immunoassays. Subpopulations of AdMSC expressing high levels of ColVII (ColVII-AdMSC$_{High}$) were isolated using immunomagnetic selection. Proliferation and cell migration of MCF7 cells were evaluated with and without recombinant ColVII as well as in a 3D spheroid model using ColVII-AdMSC$_{High}$ or ColVII-AdMSC$_{Low}$ cells. Human tissue was immunohistochemically stained for ColVII in a cohort of seven ER-positive and eight triple negative breast cancer (TNBC) patients. The tumor area was measured and the percentage of intratumoral ColVII expression was calculated.

Results: The expression of ColVII in MCF7 cells was increased in the hypoxic group at gene level, which was also confirmed at protein level. AdMSC expressed 5–6 times more ColVII protein compared with MCF7 cells. MCF7 cells had a significantly lower Ki67 expression when cultured in the presence of recombinant ColVII, compared with culture in the absence of recombinant ColVII. In the 3D model MCF7 cells expressed lower Ki67 in ColVII-AdMSC$_{High}$ spheroids compared with ColVII-AdMSC$_{Low}$ spheroids. In line with the in vitro data, expression of intratumoral ColVII was significantly associated to low Ki67 ($p = 0,028$) in human tissue samples. Furthermore, high ColVII expression was associated with lower nuclear grade ≤ 2 ($p = 0,007$) and less aggressive breast cancer subtype, with ColVII being expressed in 7/7 of the ER-positive cases and 2/8 of the TNBC cases.

Conclusion: The in vitro results showed that ColVII is associated with reduced proliferation of an ER-positive cell line, and ColVII expression is correlated with a less aggressive tumor type (ER-positive vs TNBC), lower Ki67 expression and lower nuclear grade in human breast cancer tissue. Thus, ColVII may be a positive prognostic marker in breast cancer as well as have an important role in maintaining breast cancer dormancy.

No conflict of interest.

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247 (PB-063) Poster

SARS-CoV-2 M-protein promotes malignancy of breast cancer cells and alters interaction in breast tumor microenvironment

T.H.N. Nguyen[1], M. Usuda[1], S. Park[1], C.K. Vuong[1], T. Yamashita[1], O. Ohneda[1]. *[1]University of Tsukuba, Institute of Medicine, Tsukuba city, Japan*

Background: The spread of the COVID-19 pandemic significantly influences cancer patients, not only in terms of cancer care but also cancer progression after SARS-CoV-2 viral infection. Although patients could recover from COVID-19, post-COVID-19 syndrome remains a concern. However, there is little work on the impact of SARS-CoV-2 infection on cancer cells and its mechanism. Therefore, our study aims to investigate the impacts of SARS-CoV-2 proteins on breast cancer cells (BCCs) and their consequences on the tumor microenvironment.

Material and Methods: In this study, we investigated the direct impacts of proteins from SARS-CoV-2 on the characteristics and malignancy of different types of BCCs, aggressive BCCs (MDA-MB-231 cells) and non-aggressive

BCCs (MCF7 cells). In addition, the impacts of SARS-CoV-2 protein-induced BCCs on tissue stem cells that were involved in the facilitation of tumor microenvironments, such as adipose tissue mesenchymal stem cells (ATMSCs) and endothelial progenitor cells (EPCs) were also examined.

Results: Our results showed that SARS-CoV2 membrane protein (M-protein) promoted the endothelial-mesenchymal transition and lung metastasis of aggressive BCCs MDA-MB-231 via the activation of NF-κB pathway and STAT3 pathway. In addition, the subsequent interaction between M-protein-induced aggressive BCCs and tissue stem cells via extracellular vesicles (EVs) was investigated. The results demonstrated that after being internalized with EVs secreted from M protein-induced aggressive BCCs, ATMSCs acquired characteristics of tumor-associated MSCs with the improved potential to support angiogenesis and cancer progression via their secretome. Furthermore, EVs derived from M-protein-induced aggressive BCCs prompted EPCs to exhibit features of tumor endothelial cells, which enhanced BCC malignancy. Interestingly, although nonaggressive BCCs MCF7 did not show significant direct responses to M-protein induction, EVs derived from M-protein-induced aggressive BCCs promoted the cancer stemness of non-aggressive BCCs via the Wnt-β-catenin-ALDH pathway, which facilitated their drug resistance, tumor-initiating capacity, and metastasis.

Conclusions: Taken together, the above findings imply that breast cancer patients who recovered from COVID-19 are at risk of not only worsening cancer progression and metastasis but also relapse after treatment, indicating that they require extra monitoring in the long term. These findings also suggested several signaling pathways that can be targeted for the treatment of breast cancer patients with post-COVID-19.

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248 (PB-064) Poster

CAIX and related genes predict poor survival outcomes in hormonal receptor-negative breast cancer

W. Numprasit[1,2], J. Edwards[1], J.A. Quinn[1], C. Thuwajit[3], S. Shamis[1], W. Rooney[4], E. Mallon[5]. *[1]Wolfson Wohl Cancer Research Centre, School of Cancer Sciences, College of MVLS, University of Glasgow, Glasgow, United Kingdom; [2]Faculty of Medicine Siriraj Hospital, Mahidol University, Division of Head Neck and Breast Surgery, Department of Surgery, Bangkok, Thailand; [3]Faculty of Medicine Siriraj Hospital, Mahidol University, Department of Immunology, Bangkok, Thailand; [4]BioClavis Ltd, BioClavis Ltd, Glasgow, United Kingdom; [5]Department of Pathology, Queen Elizabeth University Hospital, Glasgow, United Kingdom*

Background: Hypoxia drives tumour aggression at least partly through pH regulation and metabolic alteration. Carbonic anhydrase IX (CAIX) is a hypoxia-induced transcription gene that responds to hypoxia and acidic environment by hydrating extracellular CO_2 to produce HCO_3^- to buffer intracellular pH. Moreover, CAIX is involved in tumour cell proliferation and migration. Hormonal-receptor (HR) negative breast cancer including HER-2 overexpression and triple-negative subgroups has a poorer prognosis than luminal breast cancer. This study aims to investigate the role of CAIX in HR-negative breast cancer.

Material and Methods: A cohort of 197 HR-negative breast cancer patients was included in a tissue microarray to evaluate the correlation between CAIX expression by IHC and survival outcomes. Of those 131 FFPE samples, the TempO-Seq® human Whole Transcriptome panel was used to perform whole transcriptomic analysis. Gene set enrichment analysis (GSEA) was used for identifying significant signalling pathways. Breast cancer cell lines MDA-MB-231, SKBR3 and MCF-7 were experimented in western blot analysis to determine the expression of interested genes under normoxia and hypoxia conditions (1% O_2).

Results: High CAIX expression was found in 64 cases (32.5%) while low CAIX expression was found in 133 cases (67.5%). High CAIX had significantly inferior cancer-specific survival (CSS) to low CAIX expression (log-rank p = 0.029). Four genes were significantly upregulated, and 18 genes were downregulated in high CAIX cases compared to low CAIX cases. GSEA revealed high CAIX phenotype enriched in 5 pathways particularly hypoxia and glycolysis pathways (FDR q-value = 0.07 and 0.05, respectively). *NDRG1*, *PPFIA* and *VEGFA* mRNA levels were related to unfavourable CSS. In addition, protein levels of these genes were upregulated under hypoxic condition compared to those in normoxic condition.

Conclusions: CAIX and related genes are at least prognosticators for HR-negative breast cancer patients. The mechanism and relevant function of the interested gene require further exploration.

No conflict of interest.

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249 (PB-065) Poster

Predicting response to neoadjuvant chemotherapy in breast cancer by biomechanics quantified with Magnetic Resonance Elastography

A. Sinha[1,2], P. Jurrius[1,2], O. Darwish[3], B. Shifa[1,2], Z. Peterson[1,2], H. Jeffery[1,2], K. Welsh[3,4], A. Metafa[5], J. Spence[4], A. Kothari[2], H. Hamed[2], G. Bitsakou[2], K. Vasileios[2], M. Thorat[2], E. Shaari[2], A. Sever[4], A. Rigg[6], S. Pinder[1,7], S. Ralph[3,8], A. Purushotham[1,2]. *[1]King`s College London, School of Cancer and Pharmaceutical Sciences, London, United Kingdom; [2]Guy`s and St Thomas NHS Foundation Trust, Breast Surgery, London, United Kingdom; [3]King`s College London, School of Biomedical Engineering & Imaging Sciences, London, United Kingdom; [4]Guy`s and St Thomas NHS Foundation Trust, Breast Radiology, London, United Kingdom; [5]King`s College Hospital NHS Foundation Trust, Breast Radiology, London, United Kingdom; [6]Guy`s and St Thomas NHS Foundation Trust, Breast Oncology, London, United Kingdom; [7]Guy`s and St Thomas NHS Foundation Trust, Breast Pathology, London, United Kingdom; [8]University Paris Diderot, LVTS-Inserm U1148, Paris, France*

Background: Patients with breast cancer undergoing neoadjuvant chemotherapy (NACT) are monitored using Magnetic Resonance Imaging (MRI) with Dynamic Contrast Enhancement (DCE) as the gold-standard imaging technique to assess tumour response. MRI has a sensitivity of 80–90% and a specificity of 37–97%. Therefore, it is essential to identify alternative, non-invasive imaging biomarkers which show promise in identifying/predicting response to neoadjuvant chemotherapy.

The objective of this study is to investigate the hypothesis whether biomechanics quantified over time via MR-Elastography (MRE) can identify complete pathological response in patients undergoing NACT and potentially predict response at an earlier timepoint.

Materials and Methods: Tissue Stresses of Cancer IRAS: 204546 REC:16/LO/1303. Patients with breast cancer undergoing NACT underwent 5 MRE scans in addition to MRI scans. DCE and elastography findings were compared to the post-operative histopathology results. Changes in biomechanics quantified within the tumour footprint between pre-NACT and post-NACT were used to investigate the ability of MRE to identify a complete or partial histopathological response.

Results: In all, forty-one patients (205 MRE scans) were included in the analysis as they had completed their neoadjuvant chemotherapy and surgery and passed all data quality checks.

Between pre-NACT and post-NACT, patients with a complete pathological response showed a drop in elasticity, whereas those with a partial response had a constant or increased elasticity. Pathological response depended on tumour type, with a complete pathological response more likely in TNBC and HER2+/ERPR- breast cancer (Chi^2 test – p = 0.004).

At the early timepoint 1.1 (shortly after the first cycle of chemotherapy), response/resistance correlated with a corresponding rise/drop in phase angle. It is important to remember that response/resistance is determined via histopathology at end-NACT. As such, it is intriguing that the relative change in phase angle carries such early predictive information (p < 0.0001).

Conclusion: Integrating MRE in a routine MRI scanner and using a combined biomarker approach (DCE+MRE) is promising to predict complete pathological response at the end of NACT in breast cancer patients. Although both DCE-MRI and MRE have good sensitivity and specificity individually, DCE-MRI and MRE combined have a sensitivity of 94.4% and a specificity of 95.7% in predicting complete pathological response, which could be a beneficial non-invasive diagnostic tool when considering de-escalation in surgery. Furthermore, it was noted that the phase angle predicts early in the treatment cycle whether a patient will have a complete pathological response at the end of their treatment.

No conflict of interest.

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250 (PB-066) Poster

PD-L1 and IRF1 expression is associated with improved therapy response in the prospective randomized neoadjuvant ABCSG 34 trial

U. Heber[1], D. Hlauschek[2], C. Singer[3], D. Egle[4], R. Greil[5], R. Helfgott[6], E. Müller-Holzner[7], C. Hauser-Kronberger[8], M. Rudas[9], G. Pfeiler[3], F. Fitzal[10], S. Lax[11], M. Filipits[12], M. Gnant[13], Z. Bago-Horvath[14], ABCSG. *[1]Medical University of Vienna, Department of Pathology- Comprehensive Cancer Cancer, Vienna, Austria; [2]ABCSG, Statistical Department, Vienna, Austria; [3]Medical University of Vienna, Department of Obstetrics and Gynecology, Vienna, Austria; [4]Medical University of Innsbruck, Department of Gynecology and Obstetrics, Innsbruck, Austria; [5]Paracelsus Medical University, Department of Internal Medicine III with Hematology, Medical Oncology, Hemostaseology, Infectiology and Rheumatology, Salzburg, Austria; [6]Ordensklinikum Linz, Department of Surgery and Breast Health Center, Linz, Austria; [7]deceased, Austria; [8]Zytolabor Kronberger, Zytolabor, Salzburg, Austria; [9]Medical University of Vienna, Department of Pathology, Vienna, Austria; [10]Breast Practice Fitzal, Breast Surgery, Vienna, Austria; [11]Johannes Kepler University- Hospital Graz II, Department of Pathology, Graz, Austria; [12]Medical University of Vienna, Center for Cancer Research, Vienna, Austria; [13]Medical University of Vienna, ABCSG, Comprehensive Cancer Center, Vienna, Austria; [14]Medical University of Vienna, Department of Pathology, Comprehensive Cancer Center, Vienna, Austria*

Background: The role of PD-L1 expression in predicting pathological response in patients with early breast cancer treated with neoadjuvant systemic therapy remains unclear. Besides PD-L1, other immune related biomarkers might improve prediction of therapy response. In this study, we evaluated the expression of PD-L1 and the associated biomarkers STAT1 and IRF1 as prognostic factors for outcome in neoadjuvant endocrine therapy or chemotherapy in patients with early HER2 negative breast cancer within the prospective randomized ABCSG 34 trial.

Patients and Methods: Tumor samples of 223 of 400 patients within the ABCSG 34 trial were evaluated. 150 and 63 patients received neoadjuvant chemotherapy and endocrine therapy, respectively. Pre-therapeutic core biopsy samples were immunohistochemically stained with antibodies against PD-L1 (Immune Score, IC: SP142 clone, Ventana; Combined Positivity Score, CPS: SP263 clone, Ventana), STAT1 and IRF1 (both Cell Signaling Technology). Protein expression levels were correlated with clinicopathological parameters and quantified with Spearman rank correlation. Univariate ordinal logistic regression models were used to assess the association with residual cancer burden (RCB) at surgery. All study procedures were approved by the Institutional Review Board of the Medical University of Vienna.

Results: Based on clinicopathological parameters, the immunohistochemical sample cohort was representative of the entire ABCSG 34 patient cohort. In the chemotherapy cohort, PD-L1 was evaluated in 133 cases: IC and CPS were positive in 47.4% *vs.* 18.0% (n = 63 *vs.* 24), respectively. Both higher IC and CPS were associated with lower RCB (IC: OR 1.12, 95% CI 1.05–1.19; p = 0.0002; CPS: OR 1.03, 95% CI 1.00–1.07; p = 0.03). Expression of STAT1 in tumor cells or tumor infiltrating lymphocytes (TILs) was not associated with RCB (tumor cells: OR 1.12, 95% CI 0.75–1.67 p = 0.59; TILs: OR 1.25, 95% CI 0.71–2.22; p = 0.44). IRF1 was assessed in 88 cases and was positive in 88.6% of cases in tumor cells (n = 78) and in 72.7% in TILs (n = 64). IRF1 expression in tumor cells as well as in TILs was prognostic for lower RCB (tumor cells: OR 1.23, 95% CI 1.03–1.47; p = 0.024; TILs: OR 1.76, 95% CI 1.32–2.34; p = 0.0001).

In the endocrine therapy cohort, PD-L1 was evaluated in 59 cases. IC and CPS were positive in 18.6% and 3.4% (n = 11 *vs.* 2), respectively. No association of IC, CPS as well as STAT1 and IRF1 expression with RCB was found (p > 0.05), which might be attributed to the much smaller sample size compared to the chemotherapy cohort.

Conclusion: Higher PD-L1 and IRF1 expression are associated with a better response to neoadjuvant systemic therapy indicated by lower RCB score in the ABCSG 34 study. Combining PD-L1 and IRF1 immunohistochemistry seems to improve neoadjuvant therapy response prediction.

Conflict of interest:

Advisory Board: GSK, MSD, Astra-Zeneca, Novartis, PharmaMar, Stemline, Daiichi Sankyo, Amgen, Eli Lilly, EPG Health, EQVIA, PierreFabre, Veracyte.

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251 (PB-067) Poster

XIAP overexpressing Inflammatory Breast Cancer Patients have high Infiltration of immunosuppressive subsets and increased TNFR1 signaling targetable with Birinapant, a pan- IAP antagonist

G. Devi[1], C. Van Berckelaer[2], S. Van Laere[3], J. Geradts[4], S. Lee[5], M. Morse[6], L. Dirix[7], M. Kockx[8], F. Bertucci[9], P. Van Dam[10]. *[1]Duke University School of Medicine, Duke Cancer Institute, Surgery, Pathology, Duke Consortium for Inflammatory Breast Cancer, Durham, NC, USA; [2]Antwerp University Hospital UZA, Molecular Imaging. Pathology. Radiotherapy. Oncology MIPRO, Antwerp, Belgium; [3]University of Antwerp, Center for Oncological Research CORE, Integrated Personalized and Precision Oncology Network IPPON, Antwerp, Belgium; [4]East Carolina University, Pathology, Greenville, USA; [5]Duke University, Surgery, Durham, USA; [6]Duke University School of Medicine, Duke Cancer Institute, Medicine, Duke Consortium for Inflammatory Breast Cancer, Durham, USA; [7]GZA Hospitals, University of Antwerp, Oncology, Antwerp, Belgium; [8]CellCarta, CellCarta, Antwerp, Belgium; [9]Aix-Marseille Université, Institut Paoli-Calmettes, Predictive Oncology team- Centre de Recherche en Cancérologie de Marseille CRCM, Inserm, CNRS, Marseille, France; [10]Multidisciplinary Breast Clinic-Antwerp University Hospital UZA, Molecular Imaging, Pathology, Radiotherapy, Oncology MIPRO, Faculty of Medicine and Health Sciences, Antwerp, Belgium*

Background: Increased inflammatory, immune, and oxidative stressors in the mammary gland have been reported as risk factors for inflammatory breast cancer (IBC) along with presence of macrophages in the normal tissue from IBC patients. However, mechanistic studies identifying the cellular stress response signaling in the tumor microenvironment are lacking. Our previous studies have demonstrated a dual role for X-linked inhibitor of apoptosis protein (XIAP) in regulating programmed cell death during cellular stress. Therefore, we investigated how the tumor immune microenvironment (TiME) modulates XIAP in IBC and nIBC patients and conducted preclinical studies to evaluate Birinapant, a pan XIAP/IAP antagonist in clinical trials, for its ability to modulate immune-stress signaling.

Method: Spatial localization of immune subsets, XIAP, and PDL1 expression in IBC and nIBC (n = 142) pretreatment tumors conducted using immunohistochemistry. Validation performed by gene expression analysis of patient tumors along with in silico modelling and TNFR1 signaling studies in the presence of an IAP antagonist in a co-culture model simulating immune stress.

Results: Gene set enrichment analysis identified cellular stress response- and inflammation-related genes in high-XIAP IBC tumors. Spatial immunophenotyping of the high-XIAP IBC tumors (37/81) identified increased CD163+ tumor-associated macrophages (TAMs), low CD8/CD163 ratio in both tumor stroma (TS) and invasive margins (IM). To further evaluate paracrine interactions between cancer cells and M2 macrophages that govern XIAP overexpression, tissue biopsies (n = 68) with cancer cell fractions exceeding 80% to mitigate effect of stroma were analyzed for genes associated with XIAP activation score obtained from IBC cell lines with stable XIAP overexpression and knock-out. Heat diffusion analysis using the scaled virtually inferred protein activity scores of the XIAP master regulators revealed high TNFRSF1A. Indeed, induction of TNFR1 and XIAP was observed when patient-derived treatment naïve IBC cells were co-cultured with human macrophage-conditioned media simulating TAMs, further demonstrating that the TNF-a signaling pathway is a likely candidate governing TAM-induced XIAP overexpression in IBC cells. Treatment with a pan-IAP antagonist, Birinapant, that has the ability to disrupt TNFR1 prosurvival signaling, induced cell death.

Conclusions: To the best of our knowledge, this is the first study revealing an interplay between increased TAMs, TNF-a signaling, and XIAP activation during (immune) stress in IBC. These data also demonstrate the potential of IAP antagonists as immunomodulators to improve IBC therapeutic regimens.

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252 (PB-068) Poster

Breast cancer patients' communication needs and wishes for an explainable Artificial Intelligence prediction model for lymphedema

C. Roumen[1], J. Rainbird[2], K. Verhoeven[3], G. Bologna[4], A. Bombezin-Domino[5], T. Rattay[2], J. van Soest[6,7,8], A. Dekker[7], M. Joore[9], A. Pannison[10], A. Perotti[10], B.L.T. Ramaekers[9], S. Rivera[11,12], A. Romita[6], A. Traverso[7,13], A.J. Webb[14], I. Koutsopoulos[15], C.J. Talbot[14], G. Cortellessa[16], F. Fracasso[16]. *[1]Maastricht University, Department of Health Services Research, Care and Public Health Research Institute CAPHRI, Faculty of Health Medicine and Life Sciences, Maastricht, Netherlands; [2]University of Leicester, Leicester Cancer Research Centre, Leicester, United Kingdom; [3]GROW School for Oncology and Reproduction, Maastricht University Medical Centre+, Department of Radiation Oncology, MAASTRO, Maastricht, Netherlands; [4]University of Applied Sciences and Arts of Western Switzerland, Hes-so, Geneva, Switzerland; [5]Therapanacea, Research, Paris, France; [6]Medical Data Works B.V., Research, Maastricht, Netherlands; [7]GROW School for Oncology and Reproduction- Maastricht University Medical Centre+, Department of Radiation Oncology, MAASTRO-Maastricht, Netherlands; [8]Maastricht University, Faculty of Science and Engineering, Brightlands Institute for Smart Society, Heerlen, Netherlands; [9]Maastricht University Medical Center+, Department of Clinical Epidemiology and Medical Technology Assessment, Maastricht, Netherlands; [10]CENTAI Institute, Research, Turin, Italy; [11]UNICANCER, Research, Paris, France; [12]Institut Gustave Roussy, Research, Paris, France; [13]Università Vita-Salute San Raffaele, School of Medicine, Milan, Italy; [14]University of Leicester, Department of Genetics and Genome Biology, Leicester, United Kingdom; [15]Athens University of Economics and Business, Department of Informatics, Athens, Greece; [16]Consiglio Nazionale delle Ricerche CNR, Istc, Rome, Italy*

Background: Lymphedema can be a side effect of surgery and loco-regional radiotherapy (RT) in breast cancer (BCa) patients, and has the potential to have a major impact on the quality of life. Predicting the personalized risk of lymphedema can guide a more tailored treatment and provide (lifestyle) advice (in case of high risk) to reduce the risk and severity of lymphedema. In the ongoing multi-centre Horizon Europe collaborative study, PRE-ACT (Prediction of Radiotherapy side Effects using explainable AI for patient Communication and Treatment modification), explainable Artificial Intelligence (AI) is used to predict lymphedema and other side effects (toxicity) from RT in BCa patients. For the development of a clinical trial using the AI prediction model, it is imperative that it fits the needs of BCa patients.

Material and Methods: Onsite and online focus groups were held in the Netherlands (n = 6) and in the United Kingdom (n = 4). Former BCa patients were recruited via the radiation oncology clinic Maastro and the Breast Cancer Foundation in the Netherlands, and in the United Kingdom via advertisements on social media and the Breast Cancer Now Voices group. Questions regarding the *kind of information* patients need about their personalized risk of developing lymphedema, *how* the information should be given to them and *when* the information is needed, were asked. The focus groups were recorded (with audio and transcription) and coded memos were used. Qualitative data were transcribed verbatim and analysed following a conventional content analysis.

Results: BCa patients wanted to be knowledgeable on the representativeness of the AI model for their personal situation and the possible side effects and impact of lymphedema. Support was warranted, not only from physicians, but also from high quality information, differentiated to what a BCa patient needs and is able to handle. Although BCa patients preferred digital and visual information on the risk of obtaining lymphedema, they preferred a physical consultation to discuss treatment options and supportive measures. Specifically in the Netherlands, BCa patients preferred two consultation moments in order to process information and make an informed decision. The order was not specifically stated, e.g. (1) first consult, then read/discuss at home and then decision consult or (2) first information with instruction, then read/discuss at home and then decision consult.

Conclusions: BCa patients have a clear view on what, when and how they would like to receive information of an explainable AI prediction model, highlighting representativeness and impact on their personal situation and processing of high quality information. These needs are incorporated into a digital communication package, which is tested in a clinical trial, to facilitate risk communication and value elicitation during shared decision-making.

No conflict of interest.

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253 (PB-069) Poster

High fiber diet to counteract early signs of heart damages: an ultrastructural morphological study to pioneer new strategies for management of cardiotoxicity in breast cancer

F. Arnaboldi[1], N. Gagliano[1], M. Di Modica[2], A. Stacchiotti[1], T. Triulzi[2], M. Iorio[2], L. Sfondrini[1], V.M. Le Noci[1], E. Tagliabue[2], S.M. Pupa[2], F. Bianchi[1,3]. *[1]University of Milan, Biomedical Sciences for Health, Milan, Italy; [2]Fondazione IRCCS Istituto Nazionale Tumori, Department of Experimental Oncology, Milan, Italy; [3]IRCCS Policlinico San Donato, Laboratorio di Morfologia Umana Applicata, Milan, Italy*

Background: Among comorbidities that can affect care and clinical outcomes of breast cancer (BC) patients, cardiovascular diseases (CVDs) are the most frequent and relevant. BC and CVDs are multifactorial, with highly overlapping risk factors and a direct mutual effect. Of note, in patients with early-stage BC, most of post-treatment recurrence and cancer-specific deaths are related to CV events. Recent clinical and experimental evidence in human microbiota studies shed light on the contribution of gut microbiota alteration to the development and progression of CVDs, but also suggests diet intervention as a potential strategy to mitigate anti-cancer therapy side effects.

In this context, we recently investigated in an *in vivo* experimental model of HER2-positive BC the effects of gut microbiota homeostasis alteration, induced by antibiotic dissolved in drinking water, on the cardiac muscle tissue, and the eventual protection of high-fiber diet toward heart damage.

Material and Methods: Groups: untreated (CT), treated with vancomycin followed after by administration of normal (VAN) or high fiber diet (HFiber) Friend leukemia virus B (FVB) mice, subcutaneously injected with HER2+ BC cells. Heart tissue structure and ultrastructure have been analyzed by light and transmission-electron microscopy (TEM), respectively; mitochondria dynamics have been assessed by Real-time PCR and proteomic approaches (FT-Orbitrap).

Results: Light microscopy analysis did not reveal any morphological alteration induced by VAN. Image analysis of digitalized TEM images of cardiomyocytes showed that the regular arrangement of myofibrils was preserved, but mitochondria in the VAN group were significantly larger and more elongated compared to CT. The number of preserved mitochondria was lower, whereas the number of partially and totally damaged mitochondria was higher, in the VAN group compared with the CT. No significant alteration has been detected in the HFiber group. Molecular characterization of mitochondria dynamics indicated that oral antibiotics administration induced upregulation of expression of genes driving mitochondria fusion, such as OPA1, DNM1, MFS1, and a trend of reduction of biogenesis related-genes such as NRF1 and PPRargc1, is consistent with the observed size increase in the group of dysbiotic mice. Moreover, elevation of SOD2 expression, the major enzyme involved in detoxification pathways, confirms ongoing oxidative damage.

Conclusions: Vancomycin treatment induces early ultrastructural alterations of intermyofibrillar mitochondria in cardiomyocytes; (ii) TEM analysis is useful to detect ultrastructural alterations in absence of evident histological tissue damage; (iii) Hfiber diet can counteract the detrimental effect triggered by dysbiosis induced by antibiotics administration. Analysis of immune profile and BC features are ongoing.

No conflict of interest.

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254 (PB-070) Poster

Targeting proprotein convertase subtilisin/kexin type 9 (PCSK9), through an innovative virus-like particles (VLP)-based vaccine, enhance the antitumoral activity of a HER-2-VLP vaccine in a preclinical model of HER-2 positive breast cancer

F. Ruzzi[1], L. Scalambra[1], M.S. Semprini[1], O.M. Pittino[1], C. Cappello[1], S. Angelicola[1], A. Palladini[2], P. Nanni[1], C. Fougeroux[3], L. Goksøyr[3], A.F. Sander[3], P.L. Lollini[1]. *[1]University of Bologna, Department of Medical and Surgical Sciences, Bologna, Italy; [2]University of Pavia, Department of Molecular Medicine, Pavia, Italy; [3]University of Copenhagen, Centre for Medical Parasitology, Copenhagen, Denmark*

Background: A virus-like particles (VLP)-based vaccine against HER-2 (HER-2-VLP) showed promising therapeutic activity in human HER-2 transgenic mouse models, by significantly inhibiting tumor growth, without totally eradicating it (OncoImmunology, 7: e1408749).

Proprotein convertase subtilisin/kexin type 9 (PCSK9) is primarily known for its role in cholesterol metabolism, but recent studies showed that it may be involved in cancer progression.

To improve HER-2-VLP vaccine therapeutic efficacy, we evaluated a combined approach with PCSK9-VLP vaccine in a preclinical mouse mammary carcinoma model.

Material and Methods:

HER-2-VLP and PCSK9-VLP vaccines. AP205 phage capsid VLP are conjugated with catcher-HER-2 ECD or PCSK9 (in AddaVax adjuvant 1:1).

Cells. MamBo89 cells, derived from a FVB human HER-2 transgenic mouse mammary carcinoma, was used for in vivo studies. Human HER-2+ breast cancer cell lines, BT-474 and its trastuzumab-resistant clone BT-474 C5, were used for in vitro assay.

Mice. FVB female mice were used for therapeutic studies. Experimental protocols were approved by the Italian Ministry of Health with letter 714–2017.

ELISA. Anti-HER-2, anti-PCSK9 antibodies and PCSK9 protein levels were tested by ELISA.

Results: The therapeutic activity of HER-2-VLP vaccine was evaluated alone or combined with PCSK9-VLP vaccine on FVB mice challenged with MamBo89 cells i.m.f.p. Starting from 2 weeks after cell injection, mice received 6 biweekly vaccinations.

Compared to untreated group, PCSK9-VLP vaccine alone caused an initial significant ($p < 0.05$) slowdown in tumor growth at day 50 after cell injection, without totally blocking it. HER-2-VLP and combined HER-2-VLP+PCSK9-VLP treated mice showed tumor regression in 83% of mice starting from day 40 after cell challenge. While 60% of HER-2-VLP vaccinated mice relapsed 3 months later, 100% of mice treated with vaccine combination were tumor free 5 months later. The 83% of the mice treated with the combined approach were tumor free 8 months after cell challenge compared with only 33% of mice treated with HER-2-VLP alone.

PCSK9-VLP vaccine alone elicited a 137-fold increase in anti-PCSK9 antibody response and a significant reduction in PCSK9 serum level, while the combination treatment showed a reduced anti-PCSK9 response, probably due to the immunodominance of HER-2. HER-2-VLP alone and the combination elicited comparable anti-HER-2 antibody levels (0.1 mg/ml).

The antibodies elicited by HER-2-VLP and HER-2-VLP+PCSK9-VLP inhibited the 3D growth of human breast cancers cells. Antibodies elicited by the combined vaccination were more effective than those elicited by the HER-2-VLP vaccine alone in the inhibition of C5, a trastuzumab resistant clone of BT-474.

Conclusions: PCSK9-VLP vaccine showed adjuvant activity if combined with HER-2-VLP vaccine, enhancing its therapeutic efficacy against HER-2+ breast cancer.

No conflict of interest.

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256 (PB-072) Poster

Investigation of the metabolic switch in a triple-negative breast cancer brain metastasis mouse model

J. Marin[1], N. Kindt[1], S. Boutry[2], L. Larbanoix[2], R. Morandini[1], F. Journe[1,3], G.E. Ghanem[1], A. Awada[1,4]. [1]*Laboratory of Clinical and Experimental Oncology LOCE - Hôpital Universitaire de Bruxelles HUB - Jules Bordet Institute, Université Libre de Bruxelles, Brussels, Belgium;* [2]*Center for Microscopy and Molecular Imaging CMMI, University of Mons, Gosselies, Belgium;* [3]*Laboratory of Human Biology & Toxicology, Faculty of Medicine and Pharmacy, University of Mons, Mons, Belgium;* [4]*Department of Medical Oncology - Hôpital Universitaire de Bruxelles HUB - Jules Bordet Institute, Université Libre de Bruxelles, Brussels, Belgium*

Background: Breast cancer (BC) is the second leading cause of central nervous system (CNS) metastases, which include leptomeningeal metastasis (5% of CNS metastases) and parenchymal brain metastasis (95% of CNS metastases). The triple-negative breast cancer (TNBC) is one of the most aggressive subtypes of BC with a higher risk of developing breast cancer brain metastases (BCBM). Brain metastases (BM) occur in approximately 10–30% of patients with advanced metastatic BC and are associated with poor prognosis. Recently, studies have revealed changes in the metabolism of cancer cells once they are established in the brain. However, these metabolic switch processes remain obscure. In this study, we will compare the metabolic signatures of brain-derived TNBC cell lines by targeting the expression of key genes involved in several metabolic pathways. The final aim is to find new therapeutic targets in order to develop more effective treatments capable of limiting the progression of metastatic brain tumours.

Materials and Methods: The emergence of new therapeutic strategies depends on understanding how cancer cells modify their metabolic activity, enabling them to proliferate in brain tissue. To provide information in this field, we established a mouse model of brain metastasis by injecting human TNBC cells (MDA-MB-231 cells) into the brain of immunodeficient mice. Our breast cancer brain metastasis mouse model enables us to obtain, after several injections, brain-derived cell lines adapted to the cerebral environment. The changes in the metabolic activity of these cells will first be studied by real-time quantitative PCR (RTqPCR). The panel of genes studied included: ACOX1, ACADL, CD36, CPT1A, ACOT2, FABP12, PPARA, G6PD, 18S (non-exhaustive list).

Results: Cell lines generated by serial intracranial injections increase the aggressiveness of the model as the cells acquire an increased proliferative advantage in the brain, with a significant decrease in mouse survival (Log-rank test, $p < 0.001$). Brain-derived cells show changes in gene expression related to cellular metabolism. The transcriptomic study revealed, among other things, a significant increase in the expression of certain genes involved in the beta-oxidation pathway (Student t-test, $p < 0.05$). This suggests a switch to fatty acid metabolism during tumour development in the brain parenchyma.

Conclusion: These metabolic modifications could therefore be associated with a marked increase in the proliferation of tumour cells in the brain microenvironment. To validate that adaptation of tumour cell metabolism is a key feature of BCBM progression, further investigation is required. This could lead to the development of a new approach for the treatment of BM by targeting metabolic pathways.

No conflict of interest.

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257 (PB-073) Poster

Metronomic treatment significantly enhanced cytotoxicity in palbociclib-resistant ER-positive breast cancer cell lines

N. Sherif[1], A. Ilari[1], N. Cordani[1], E. Grassilli[1], M.E. Cazzaniga[1], M. Lavitrano[1], M.G. Cerrito[1]. [1]*Università degli studi di Milano Bicocca, School of medicine and surgery, Monza, Italy*

Background: Breast cancer accounts for approximately 30% of all cancers diagnosed in women across all age groups, of which 70% are of the ER-positive (ER+) subtype. Despite the significant progress made in recent years in treating the disease, a large percentage of patients develop resistance to endocrine therapy limiting its benefits. In ER+ advanced breast cancer, the use of cyclin 4/6-dependent kinase inhibitors (CDK4/6) in combination with hormonal therapy has had considerable importance. Despite the improvement in disease management that CDK4/6 inhibitors offer to patients with ER+ breast cancer, not all patients respond to these drugs, and most patients initially responding to CDK4/6 inhibitors develop acquired resistance. However, there remains an unmet need to develop new therapeutic approaches and drugs for targeted therapies for this subtype of advanced breast cancer.

In the present study, we aimed to assess the effect of metronomic treatment (mCHT, administration of drugs at low doses, without periods of free-break) treatment with 5-fluorouracil (5-FU) plus vinorelbine (VRL) in two breast cancer cell lines ER+, MCF7 and T47D palbociclib resistant (MCF7 pR5 and T47D pR5).

Material and Methods: After IC50 assessment, both cell lines were exposed to the treatment every 24 hours for 96 hours and cell viability was detected by MTS assay. Colony formation and migration/invasiveness assay was used to evaluate the effect of the mCHT treatment with 5-fu plus VNR. By western blot, was analyzed the expression of different proteins involved in the apoptotic pathway, such as Bcl-XL, Bax, Mcl-1, Bax and Bim. The residual ability to form spheroids after mCHT treatment of the MCF7 pR5 and T47D pR5 was also assessed.

Results: The results show that mCHT treatment significantly inhibits cell viability of MCF-7 and T-47D pR5, synergistically. Moreover, in both cell lines pR5, clonogenic, migration/invasiveness capacity shows a significant decrease after mCHT treatment.

Interestingly, the pro- and anti-apoptotic proteins expression are differently regulated in MCF-7pR5 and T47D after mCHT treatment suggesting two different mechanisms of death in palbociclib-resistant cell lines. Furthermore, results show that the mCHT treatment inhibits the ability to form spheroids.

Conclusions: mCHT treatment with VRL plus 5-FU shows anti-proliferative and anti-clonogenic effects through different molecular mechanisms in two palbociclib-resistant ER+ cell lines. These results could improve our present and prospective understanding of recent medical treatments

representing an important step towards a new possible therapeutical approach for patients who develop intrinsic or acquired resistance to CDK/6 inhibitors.

No conflict of interest.

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259 (PB-075) Poster

Metronomic treatment with 5-fluorouracil plus vinorelbine inhibits the expression of markers of stemness in stabilized and primary cell lines of triple-negative breast cancer

A. Ilari[1], N. Sherif[2], E. Grassilli[2], M. Silva[3], M. Lavitrano[3], M.E. Cazzaniga[4], M.G. Cerrito[3]. *[1]Univesità degli Studi Milano-Bicocca, School of Medicine and Surgery, Monza, Italy; [2]Università degli Studi Milano-Bicocca, School of Medicine and Surgery, Monza, Italy; [3]Università degli Studi di Milano-Bicocca, School of Medicine and Surgery, Monza, Italy; [4]Università degli Studi Milano Bicocca, School of Medicine and Surgery, Monza, Italy*

Background: Triple-negative breast cancer (TNBC) is an aggressive subtype of breast cancer characterized by the absence of the estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor amplification/overexpression 2 (HER2). TNBC is biologically heterogeneous with different clinical behaviors, frequently related to short disease-free survival (DFS) and overall survival (OS). There is still a lack of specific targeted therapy for TNBC, so finding an effective treatment for patients is strictly required. In this scenario, metronomic therapy (mCHT, low doses of drugs without interruptions) could be effective.

Material and Methods: IC50 values for 5-fluorouracil (5-FU) and vinorelbine (VNR) were determined in both metronomic (mCHT) and standard (STD) regimes for stabilized and primary cell lines using the ATP assay. Then, combined drugs were used to treat both cell lines and primary culture. After treatments, spheroids were generated using a medium containing 2% matrigel. Once the spheroids were formed, they were disaggregated to obtain second-generation spheroids. Real-Time PCR, Western Blot, and immunofluorescence analyses were conducted for specific stemness-related genes: CD44, CD133, C-MYC, EPCAM, FZD7, NANOG, and NOTCH1.

Results: Our work shows a significant reduction of the expression of stemness genes in the spheroids treated with metronomic therapy compared to the STD treatment and the control. These results are confirmed by the Western blot, where the expression of stemness-related proteins, in particular CD44, CD133, C-MYC, and NOTCH1, are decreased in both first and second-generation of spheroids. Furthermore, throughout the analysis of the NOTCH1 pathway, we notice a substantial reduction of the expression of p21 (DNA repair gene) in spheres mCHT treated derived from the primary cell line. Immunofluorescence shows significant hypoexpression of the proteins mentioned above in the first- and second-generation of spheroids treated with mCHT compared to STD and the control.

Conclusions: Evidence suggests that the accumulation of therapy-resistant tumor stem cell (CSC) populations in TNBC contributes to poor clinical outcomes. These CSCs are increased in TNBC compared to non-TNBC breast tumors. Our results show that mCHT treatment significantly reduces stemness markers related to drug resistance and metastasis rates. These data and others previously obtained with mCTH, integrated with the results obtained in clinical practice, suggest that metronomic treatment can be used as a first-line treatment in TNBC and not only as a last chance. This could represent an excellent treatment strategy for patients under ineffective treatment regimens.

No conflict of interest.

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260 (PB-076) Poster

Adherence to clinical practice guidelines: a population-based study of socio-economic inequalities in breast cancer

D. Petrova[1], D. Redondo Sánchez[2], M. Rodríguez-Barranco[2], M. Carulla[3], M. Guevara[4], A. López de Munain[5], A. Vizcaíno[6], R. Marcos-Gragera[7], E. González-Flores[8], M. Sant[9], M. Pollán[10], M.J. Sánchez-Pérez[2]. *[1]University of Granada, Andalusian School of Public Health, Granada, Spain; [2]Andalusian School of Public Health, Cancer Registry of Granada, Granada, Spain; [3]Hospital Universitari Sant Joan de Reus, Tarragona Cancer Registry, Tarragona, Spain; [4]Registro de Cáncer de Navarra, Registro de Cáncer de Navarra, Pamplona, Spain; [5]Registro de Cáncer de Gipuzkoa, Registro de Cáncer de Gipuzkoa, San Sebastian, Spain; [6]Registro de Cáncer de Castellón, Registro de Cáncer de Castellón, Castellón, Spain; [7]Registro de Cáncer de Girona, Registro de Cáncer de Girona, Girona, Spain; [8]Hospital Universitario Virgen de las Nieves, Medical Oncology, Granada, Spain; [9]Istituto Nazionale per lo Studio e la Cura dei Tumori, Epidemiology Unit, Milan, Italy; [10]Instituto de Salud Carlos III, Centro Nacional de Epidemiología, Madrid, Spain*

Background: Breast cancer survival is lower among women with lower socioeconomic status and differences in the care received could be contributing to these disparities. This study investigated possible socio-economic inequalities in adherence to clinical practice guidelines for the diagnosis and treatment of breast cancer in Spain.

Materials and Methods: We conducted a retrospective, high-resolution, population-based study of 3,253 incident cases of invasive breast cancer (C50 according to ICD-O-3), diagnosed between 2010–2014 in women residing in six Spanish provinces covered by population-based cancer registries (Castellón, Gipuzkoa, Girona, Granada, Navarra, and Tarragona). Socioeconomic status was measured using a small-area-based deprivation index, developed by the Spanish Society of Epidemiology based on the 2011 Spanish census, and divided in quintiles from the most deprived (Q5) to the least deprived (Q1). Adherence to clinical practice guidelines was measured with 13 indicators based on recommendations for breast cancer diagnosis and treatment of the European and Spanish Societies of Medical Oncology and 2 indicators on the timeliness of care based on regional Spanish guidelines. Adherence levels were compared between the quintiles of socioeconomic deprivation.

Results: Adherence on the different indicators varied from 34% to 94%. There were no significant differences between the socioeconomic groups on the indicators evaluating the type of treatment received overall or as a function of tumor characteristics. However, women living in the most deprived areas were less likely to receive a sentinel node biopsy overall (58% vs. 69%, $p < 0.001$) and when the axillary lymph nodes were clinically negative (73% vs. 82%, $p = 0.003$), but were more likely to undergo lymphadenectomy when the sentinel lymph nodes were positive (84% vs. 71%, $p = 0.053$). Women living in the most deprived areas were also less likely to receive timely treatment, such as undergoing surgery within 30 days after pathological diagnosis (26% vs. 40%, $p < 0.001$) or starting adjuvant treatment within six weeks after surgery (29% vs. 41%, $p = 0.010$).

Conclusions: Despite the overall coverage of the Spanish Health system, women living in more deprived areas were less likely to receive care consistent with the clinical practice guidelines valid at the time. It is important to know the reasons behind these inequalities and their impact on patients' survival.

No conflict of interest.

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261 (PB-077) Poster

Clinical and experimental investigation showed varied expression of ANP32a isoform in subtypes of breast cancer and role in metastatic and chemo-resistance in TNBCs

F. Malik[1], S. Mir[2]. *[1]Indian Institute of Integrative Medicine, Pharmacology and Cancer Research, Srinagar, India; [2]Indian Institute of Integrative Medicine, Pharmacology, Srinagar, India*

Background: Metastatic TNBCs aggressively disseminates to distant organs and eventually become non-responsive to current chemotherapeutic options. Interestingly, few reports have shown contentious role of ANP3aA through its divergent expression in various cancers. It is shown to act as an oncogene in CML, pancreatic, colorectal, hepatocellular and oral carcinoma, whereas displayed as tumor suppressor in prostate, lung, breast cancers. Keeping in view of this ambiguity, it was interesting to explore the expression of ANP32A in across the subtypes of breast cancer using BC patient samples, cell lines, further unraveling role in metastasis and therapeutic response in TNBC models.

Methodology: In this study, we performed the proteomic profile of TNBCs clinical samples to understand the differential protein expression in subtypes of breast cancer. We examined the protein expression pattern and net effect of ANP32A isoforms in TNBCs by modulating the expression of the gene

using CRISPER/case9. Role of ANP32a was evaluated for invasion, metastasis and chemotherapy response using various human and Mice TNBC cell lines, mice xenograft models and clinical samples.

Result: During the comprehensive analysis of various factors, it was observed that the expression of an isoform of ANP32a was poorly expressed in TNBCs compared to other subtypes of BC clinical samples. To further explore the role of ANP32a in TNBCs, modulated expression of the ANP32a in human MDAMB231, BT549 and mouse 4T1 cells demonstrated over expression of ANP32a led to decreased proliferative, invasive and migratory potential and poor response to chemotherapies. Anp32a over expression diminished the stemness, EMT and metastatic abilities of TNBC. Further, mice xenograft experiment showed that ANP32a expressing cells were unable metastasize to distant organs. The MS based proteomics studies depicted that Anp32a is interacts and stabilizes tumor suppressor AXIN-1, a part of destruction complex β-Catenin pathway thus inhibiting its activation. Further, ANP32a bearing mice tumor xenografts showed better response towards cisplatin and paclitaxel treatments compared to control and ANP32a knockdown cells.

Conclusion: In conclusion, our study demonstrated the expression of ANP32a in subtypes of BC is inconsistent with lowest in TNBCs. Further experimental analysis confirmed that loss of the expression of ANP32a isoforms is associated with enhanced stemness, invasiveness and metastatic abilities, along with poor response towards the cisplatin and Paclitaxel treatment in cellular and animal xenograft models. Our results demonstrated that ANP32a interacts and stabilizes tumor suppressor AXIN-1, thus inhibiting the activation of β-Catenin stream. This study reveals that ANP32a acts as tumor suppressor in breast cancers and isoforms can be predictive marker for the treatment choice of cisplatin and Paclitaxel.

No conflict of interest.

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262 (PB-078) Poster

Efficacy and oncological outcomes of sustained endocrine monotherapy for elderly breast cancer patients

T. Dinger[1], E. Postma[1], J. Volders[2], H. Kelder[3], A. Doeksen[1], T. van Dalen[4].
[1]St. Antonius Hospital, Surgical Oncology, Nieuwegein and Utrecht, Netherlands; [2]Diakonessenhuis Utrecht, Surgical Oncology, Utrecht, Netherlands; [3]St. Antonius Hospital, Research and Statistical Analysis, Nieuwegein and Utrecht, Netherlands; [4]Erasmus Medical Centre, Surgical Oncology, Rotterdam, Netherlands

Background: Endocrine monotherapy (EMT) is used as a substitute for surgical treatment in frail elderly breast cancer patients to obtain local control during their remaining lifespan. The aim of this study was to assess the efficacy and oncological outcomes of EMT as primary treatment in elderly patients with ER positive breast cancer without metastases.

Methods: Elderly patients (≥70 years) with estrogen receptor-positive breast cancer who received initial treatment with EMT between 2008 and 2015 at two Dutch hospital were identified through the Netherlands Cancer Registry. Primary outcomes were clinical response (RECIST criteria) and invasive local treatment (radiotherapy or salvage surgery) for different time intervals after initiation of EMT. Secondary outcomes were overall- and breast cancer-specific survival (OS and BCSS).

Results: Out of the 122 patients (median age 86 years) in this study, 100 (82%) received EMT as definitive treatment, whereas 22 received endocrine therapy as a ''bridge to surgery.'' Most patients were clinically node negative (84.7%) and 111 patients (91%) received an aromatase inhibitor as initial endocrine treatment. Median follow up was 47 months [IQR 27–62]. The median overall survival was 4.8 years [IQR 4.1–5.5]. The results are presented in table 1 for different time intervals.

Conclusion: In elderly breast cancer patients, sustained EMT can be discussed as a safe and effective alternative to surgery during their remaining lifespan. The results of our study can contribute to a more customized application of EMT and optimize follow-up frequency.

No conflict of interest.

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263 (PB-079) Poster

Multiomic profiling reveals predictive molecular characteristics of response to neoadjuvant antibody-drug conjugate versus chemotherapy and dual HER2 blockade in HER2 positive breast cancer

T. Foukakis[1], K. Wang[1], I. Zerdes[1], Y. Zhu[1], E. Sifakis[1], N. Tsiknakis[1], G. Manikis[1], D. Salgkamis[1], L. Harbers[2], J. Bergh[1], H. Johansson[1], N. Crosetto[2], J. Lehtiö[1], A. Matikas[1], T. Hatschek[1], Swedish Breast Cancer Group. *[1]Karolinska Institutet, Department of Oncology, Pathology, Stockholm, Sweden; [2]Karolinska Institutet, Department of Microbiology, Tumor and Cell Biology, Stockholm, Sweden*

Background: The PREDIX HER2 trial (n = 202) compared neoadjuvant docetaxel, trastuzumab, and pertuzumab (DHP) vs. trastuzumab emtansine (T-DM1) in HER2-positive breast cancer, resulting in similar pathologic complete response (pCR) rates.

Methods: Fresh-frozen pre-treatment biopsies were used for RNA, DNA and protein extraction and subsequent RNA-sequencing (n = 187), shallow whole-genome sequencing (n = 179), exome sequencing (n = 190) and mass spectrometry-based proteomics (n = 170). Tumor intrinsic molecular features and microenvironment components were quantified and associated with pCR in each arm using logistic regression. Predictive value was evaluated by adding the interaction term between biomarker and arm. In addition, a machine learning analysis was conducted with a treatment-stratified ensemble of 3 classifiers (Logistic Regression, Random Forest and SVM) trained on clinical and omics data for predicting pCR.

Results: We identified associations between molecular features and response to anti-HER2 treatments some of which were differentially predictive across DHP and T-DM1 arms (Table).

Biomarker	DHP arm		T-DM1 arm		P for interaction
	OR (adjusted)	P	OR (adjusted)	P	
DNA-based					
ERBB2 gene copy ratio	2,09	<0,001	1,3	0,25	0,15
BRCA2 deletion	0,85	0,43	2,21	0,01	0,01
TP53 mutation	0,93	0,73	1,59	0,03	0,09
COSMIC Signature 15	0,78	0,24	1,47	0,11	0,05
CIN CX2	1,45	0,12	0,73	0,13	0,03
LOH Deletion burden	1,32	0,21	0,58	0,02	0,01
Subclone percentage	0,84	0,43	1,32	0,18	0,13
TMB (clone)	2,57	0,06	0,91	0,66	0,06
TMB (LOH)	3,62	0,05	0,76	0,36	0,03
RNA-based					
ERBB2 expression	3,08	<0,001	1,42	0,12	0,04
ESR1 expression	0,59	0,06	0,4	0,01	0,47
PGR expression	0,95	0,82	0,54	0,02	0,14
HER2-enriched subtype (PAM50)	1,78	0,02	1,53	0,09	0,72
HER2DX (research version)	1,46	0,12	0,73	0,13	0,03
Taxane response score	1,64	0,03	1,07	0,77	0,19
Neutrophils*	0,85	0,46	0,54	0,01	0,16
Mast cells*	0,99	0,95	0,57	0,02	0,09
Cancer associated fibroblasts#	0,96	0,86	0,67	0,08	0,25
Endothelial cells&	0,67	0,06	1,15	0,55	0,1

LOH = loss of heterozygosity, TMB = tumor mutational burden
Calculated using method by Danaher et al*, TIDE#, MCPcounter&

Interestingly, patients with low HER2DX score had better pCR rates with T-DM1 ($OR_{T\text{-}DM1vsTHP,\ HRadj}$ = 2,61, p = 0,06), while patients with high score benefitted from DHP ($OR_{DM1vsTHP,\ HR\ adjusted}$ = 0,29, p = 0,004). In the HR-positive subset, patients with low CIN CX2 score had better responses with T-DM1 ($OR_{DM1vsTHP}$ = 3,02, p = 0,05), while the opposite was seen for high CIN CX2 ($OR_{DM1vsTHP}$ = 0,32, p = 0,04). In the machine learning model, the

mean AUC score was 0,81 ± 0,1 and 0,68 ± 0,14 for the T-DM1 and DHP arms respectively.

Conclusion: Using multiomics analysis in a randomized trial, we show that T-DM1 and standard dual HER2 blockade harbor strikingly distinctive biomarkers of response. Further validation in prospective biomarker-driven studies, integrated multimodal predictive models and studies with novel antibody-drug conjugates are warranted.

Conflict of interest:

Advisory Board: Novartis.

Other Substantive Relationships: consultancy to Astra Zeneca, Affibody, Pfizer, Novartis, Veracyte, Exact Sciences, Gilead Sciences and Roche honoraria from UpToDate research funding to institution from Pfizer, Astra Zeneca, Novartis, Veracyte.

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264 (PB-080) Poster

Adiponectin affects breast cancer stem cells behavior in hormone-resistant mammospheres

G.D. Naimo[1], M. Forestiero[1], F. Giordano[1], M.L. Panno[1], S. Andò[1], L. Mauro[1]. *[1]University of Calabria, Department of Pharmacy, Health and Nutritional Sciences, Rende, Italy*

Background: Tumor microenvironment (TME) exerts a critical role in regulating the complex interaction between stromal and epithelial cells through the secretion of cytokines and growth factors. The most abundant cellular component of stromal mammary microenvironment is represented by adipocytes. The unbalanced adipokines secretion, occurring in obesity condition, is characterized by low level of adiponectin (adipo), which affects breast cancer growth and progression. Breast cancer stem cells (BCSCs) have been recognized as the leading cause of tumor progression, metastasis formation and resistance against chemotherapy due to their self-renewal and multi-lineage differentiation ability in response to conventional drugs and TME stimuli. Thus, the aim of the present study was to evaluate the effects of low adipo level on BCSCs behavior in hormone-resistant mammospheres.

Methods: MCF-7 wild type (WT) and tamoxifen-resistant (TR) cells have been grown as mammospheres. Mammospheres Forming Efficiency (MFE) and cell viability maintenance (self-renewal) have been measured by mammospheres count. qRT-PCR to quantify mRNA levels of epithelial mesenchymal transition (EMT), stemness, proliferation and cell cycle markers. Flow cytometry analysis to evaluate $CD44^+/24^-$ cell ratio, ALDH expression, ROS production, cell cycle and apoptosis. DNA quantitation, Western Blotting (WB) and migration assays to investigate proliferation and invasiveness.

Results: Our results demonstrated an enhanced MFE and self-renewal capacity in adipo-treated TR-MCF-7 cells. The presence of BCSCs into mammospheres has been identified through measurement of specific markers by flow cytometry. Data showed an enrichment of $CD44^+$ and $ALDH1^+$ cells in adipo-treated TR-MCF-7 mammospheres, concomitant with a reduction of cell subpopulation expressing the differentiation marker CD24 and ALDH1, not observed in WT MCF-7 cells. qRT-PCR analysis confirmed the CD44 and CD24 expression profile in both cell lines and revealed an increased mRNA level of stemness and EMT markers in hormone-resistant mammospheres. Moreover, cell cycle and Annexin V assay showed a G1/G0 arrest and an apoptosis reduction in hormone-resistant cells, in the presence of low Ki67 level, compared to WT cells. Notably, flow cytometry analysis of ROS production, correlated with DNA damage-induced cell death, evidenced a reduction of their levels in adipo-treated TR-MCF-7 mammospheres. Finally, TR-MCF-7 cells obtained from II generation mammospheres showed low proliferation rate concomitant with low Ki67 level and reduced cell motility, sounding a cellular state of quiescence compared to WT-MCF-7 cells.

Conclusions: Here we demonstrated that low adipo level favors stem-like features in TR-MCF-7 cells, sustaining tumor progression.

No conflict of interest.

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265 (PB-081) Poster

Clinical validation of an Artificial-intelligent (AI) enabled digital test using the patients diagnostic breast biopsy to predict invasive breast cancer recurrence within 6-years

M. Donovan[1], G. Fernandez[2], J. Zeineh[3], A. Sainath Madduri[4], R. Scott[5], M. Prastawa[5]. *[1]PreciseDx, Clinical, Miami, USA; [2]PreciseDx, Chief Scientific Officer, New York City, USA; [3]PreciseDx, Chief Technology Officer, New York City, USA; [4]PreciseDx, Computational Biology, New York City, USA; [5]PreciseDx, Image Analysis Engineer, New York City, USA*

Background: Invasive Breast cancer (IBC) has surpassed lung cancer as the leading diagnosed cancer worldwide, representing some 15.5% of all cancer deaths. There remains an outstanding need to improve the current standard of care at diagnosis including a reproducible and quantitative assessment of histologic grade and biological phenotype. We previously validated a digital laboratory developed test to predict breast cancer recurrence (BCR) using the surgical resection specimen. We now present the same approach for the diagnostic biopsy, providing a risk of recurrence earlier in the treatment planning and decision process.

Methods: 1559 patients from 2004–2016 (Mount Sinai Health System, NY, NY, USA) with 6-years median follow-up divided 3:1, training (surgical cohort, 14% event rate) and validation (biopsy cohort, 13% event rate). H&E Whole slide Images (WSI), 40X magnification (Philips, Netherlands) were deconstructed with an AI- generated, precision medicine 'morphology feature array' (MFA) designed to extract tumor cell and tissue architectural features. Both cohorts were predominantly early-stage, ER/PR+ve, Her2-ve. Only age at diagnosis was utilized for biopsy model development. Recurrence events were classified as locoregional, distant metastasis and overall survival. C-index/AUC curves, Kaplan-Meier, hazards ratio, sensitivity, specificity, NPV, and PPV were used to assess risk discrimination.

Results: Surgical training model (n = 1559), age (mean 60 years) combined with 7 imaging features representing an AI-(grade) yielded a C-index of 0.75 (95% CI, 0.73–0.77) vs. clinical (age) 0.62 (95% CI, 0.59–0.65). A risk score of 59 (scale 0–100) stratified patients as low- or high-risk, HR 4.9, P value <0.001, with a sensitivity 0.71, specificity 0.71, NPV 0.94, and PPV 0.27 for predicting BCR within 6 years. In the diagnostic biopsy validation cohort (a subgroup of the surgical training cohort, n = 570), the model produced a C-index of 0.76 (95% CI, 0.72–0.80) vs. age only 0.65 (95%CI, 0.59–0.71). When patients were stratified by a risk score of 59, the HR was 4.9, P value <0.001), sensitivity 0.76, specificity 0.67, NPV 0.96, and PPV of 0.22 for predicting BCR.

Conclusion: We developed and validated a breast biopsy AI-enabled digital platform which successfully predicted early-stage BC recurrence within 6 years using only the H&E-stained image and age at diagnosis. The test is designed to assist in the characterization of clinical risk and the overall management of patients at the time of diagnosis. Additional studies are underway to further refine impact on treatment selection.

Conflict of interest:

Ownership: founders: MD, GF, JZ employees: GF, ASM, RS, MP consultants: MD, JZ.

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266 (PB-082) Poster

Systematic profiling of primary invasive lobular breast carcinoma defines distinct candidates for PD-1/PD-L1 targeting immunotherapy

H. Böhm[1], B. Lenoire[2], N. Wilhelm[2], I. Zörnig[1,2], D. Jäger[1,2], P. Sinn[3], C. Fremd[1,2]. *[1]National Center for Tumor Diseases, Medical Oncology, Heidelberg, Germany; [2]German Cancer Research Center, Clinical Cooperation Unit Applied Tumor Immunity, Heidelberg, Germany; [3]University Hospital Heidelberg, Pathology, Heidelberg, Germany*

Background: Invasive lobular breast cancer (ILC) has long been considered to be immunologically inert. It remains not well understood, if and to what extend immunogenicity qualifies ILC for immune checkpoint inhibition (ICI). This study aims to profile ILC tumor microenvironment (TME) with the overall aim to better select ILC patients for immunotherapy.

Methods: Across a comprehensive cohort of 141 early breast cancer patients, pathologically diagnosed with ILC, immune infiltration (CD3, CD8, CD20, CD68), tertiary lymphoid structures (TLS), antigen presentation (MHC1) and programmed death receptor 1 ligand (PD-L1) were analyzed by standard histological assessment and machine learning guided whole slide tissue imaging (HALO). Single cell counts after segmentation were combined

to quantify immune cell densities in biologically relevant compartments of the TME to determine distinct immune phenotypes. These phenotypes were correlated with PD-L1 expression, TLS counts, clinicopathological parameters and survival. Moreover, exceptional responders to ICI as well as biomarkers positive non-responders were profiled by immunogenomics as well as multiplexed single cell analysis.

Results: We observed an extensive spectrum of T cell infiltration, measuring CD3+ cell counts from 40 up to 2967 cells per mm² tumor area. Higher T cell counts were linked to antigen presentation by MHC1 expression. However, tumors demonstrating dense T cell infiltrates without tumor cell MHC1 expression were observed as well as tumors with strong MHC1 staining in up to 98% of tumor cells without any T cell infiltrate. Mean PD-L1 expression was modest with a neural network trained median combined positive score (CPS) of 0.17, with few patients (6.35%) exhibiting PD-L1 expression above clinically meaningful cut-offs (CPS>10). Applying a stepwise approach, 49.22% of patients defined an "immune desert" phenotype featured by poor T cell infiltration. In turn, 14.84% of patients (n = 19) defined an "inflamed" phenotype, with >500/mm² CD8+ T cells. This phenotype showed significanty higher PD-L1 expression ($p < 0.001$), MHC1 expression ($p = 0.032$) and TLS counts ($p < 0.001$). Nevertheless, none of the aforementioned phenotypes differed in progression free or overall survival. Exploring clinical responses to PD-1 or PD-L1 directed ICI in advanced lobular breast cancer patients on the single patient level did not correlate well with immune phenotypes or established biomarkers. Multiplex analysis of TME as well as deep immunogenic profiling in index patients of exceptional response will be presented at the meeting.

Conclusion: Here, we identify a small but meaningful subgroup of ILC patients with an excellent pre-existing anti-tumor immunity, who may be excellent candidates for ICI.

No conflict of interest.

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267 (PB-083) Poster

Unravelling tumor heterogeneity in patients with HER2-low hormone receptor-positive breast cancer using spatial transcriptomics

D. Fimereli[1], M. Serra[1], M. Rediti[1], F. Lifrange[2], N. Occelli[1], L. Collet[1], D. Vincent[1], G. Rouas[1], L. Craciun[3], D. Larsimont[3], D. Venet[1], M. Vikkula[4], F.P. Duhoux[5], F. Rothé[1], C. Sotiriou[1]. *[1]Institut Jules Bordet, Breast Cancer Translational Research Laboratory J-C Heuson, Brussels, Belgium; [2]University Hospital Center of Liege, Department of Pathology, Liege, Belgium; [3]Institut Jules Bordet, Laboratoire d'Anatomie Pathologique, Brussels, Belgium; [4]de Duve Institute, Human Molecular Genetics, Brussels, Belgium; [5]Institut Roi Albert II- Cliniques universitaires Saint-Luc and Institut de Recherche Expérimentale et Clinique pôle MIRO, Department of Medical Oncology, Brussels, Belgium*

Background: The current binary distinction between HER2-positive and HER2-negative breast cancer (BC) has recently been challenged by the emergence of the HER2-low entity. Antibody-drug conjugates targeting HER2 have shown efficacy in both HER2-positive and HER2-low BC, while some preliminary evidence showed efficacy also in patients with HER2-zero BC. Here, by combining spatial transcriptomics (ST) and morphological annotation, we aimed to investigate the inter- and intra-tumor heterogeneity of ERBB2 expression in relation to breast cancer IHC subtypes.

Material and Methods: We performed ST (Visium 10X Genomics) on frozen tumor samples from 106 patients with hormone receptor positive (HR +) ductal BC with HER2 IHC staining and FISH. Hematoxylin/eosin slides were morphologically annotated integrating manual and machine learning-based approaches reaching single-cell resolution (QuPath software). The relative histomorphological categories composition of each spot across the ST slide was computed as percentage of pixels. Spots were defined as tumoral if the percentile of pixels in that spot surpassed the 80th percentile of all the tumor spots in the cohort.

Results: Our cohort consisted of 56 HER2-zero (IHC 0), 30 HER2-low (IHC 1+) and 20 HER2-positive (IHC 2+/FISH positive or IHC 3+) samples. HER2-zero samples contained a significantly higher percentage of acellular stroma spots compared to HER2-low ($pvalue = 0.04$), while no other morphological annotation showed a difference, including tumor spots. Only tumor spots were retained for downstream analysis. A difference in the ERBB2 gene expression was found at the spot level, with a higher expression in HER2-low samples compared to HER2-zero samples (median expression 0.4, 0.7 and 3.1 in HER2-zero, HER2-low and HER2-positive, respectively). Inter-sample heterogeneity was observed, with 27% of the HER2-zero samples having equal or higher mean ERBB2 expression that the mean ERBB2 expression of the HER2-low cohort. Variability within individual samples was observed, revealing two distinct peaks in ERBB2 expression, one characterized by low levels and the other by medium-high levels. This pattern was frequently observed in samples classified as HER2-zero and HER2-low, indicating the existence of tumor spots with diverse ERBB2 expression.

Conclusions: Our results revealed inter- and intra-tumor heterogeneity of ERBB2 expression in HER2-zero and HER2-low BC. The use of spatial transcriptomics can provide more details of the spatial distribution of ERBB2. Further validation is warranted.

Conflict of interest:

Other Substantive Relationships:

Francois P Duhoux: Fondation belge contre le cancer (Post-doctoral research grant) Roche (Consulting fees, travel) Pfizer (Consulting fees, travel)AstraZeneca (Consulting fees, travel) Lilly (Consulting fees) Novartis (Consulting fees) Amgen (Consulting fees, travel) Daiichi Sankyo (Consulting fees, travel) Pierre Fabre (Consulting fees) Gilead Sciences (Consulting fees, travel) Seagen (Consulting fees) MSD (Consulting fees) Teva (travel).

Christos Sotiriou: ASTELLAS (Grants) CEPHEID (Grants) VERTEX (Grants) SEATTLE GENETICS (Grants) PUMA (Grants) AMGEN (Grants) Merck & Co.Inc (Grants) EISAI (Payment or honoraria for lectures, presentations, speakers bureaus) PRIME ONCOLOGY (Payment or honoraria for lectures, presentations, speakers bureaus) TEVA (Payment or honoraria for lectures, presentations, speakers bureaus) EXACT SCIENCES (Payment or honoraria for lectures, presentations, speakers bureaus) ROCHE (travel) GENENTECH (travel) PFIZER (travel).

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POSTER SESSION **22 March 2024** **9.00–14.30**

Genetics

268 (PB-084) Poster

Impact of establishing a genetic clinic in conjunction with clinical practice in India

L. Busheri[1], Y. Thakur[2], J. John[2], N. Athavale[2], S. Nare[2], G. Thomas[3], R. Navgire[3], C. Deshmukh[3], M. Munshi[3], U. Dhar[3], M. Kulkarni[2], D.A. Kelkar[2], S. Joshi[2], R. Mishra[2], C.B. Koppiker[3]. *[1]Prashanti Cancer Care Mission, Administration, Pune, India; [2]Prashanti Cancer Care Mission, Center for Translation Cancer Research - A joint initiative of IISER Pune and Prashanti Cancer Care Mission, Pune, India; [3]Prashanti Cancer Care Mission, Orchids Breast Health Centre, Pune, India*

Background: Breast cancer is one of the most common cancers afflicting women worldwide today. Approximately 5–10% of all breast cancer occurrences are hereditary, caused by germline mutations in breast cancer pre-disposing genes. As a result, genetic testing and counselling are critical components of diagnosis and therapy, especially for patients with a family history of breast and ovarian cancer. However, despite expansion of guidelines by international agencies such as NCCN, the uptake of genetic testing is still low in the Indian population. Very few studies have determined the prevalence of germline mutations in breast cancer patients in India, and the burden of hereditary breast cancer in India is as yet not well-established. To mitigate this gap Prashanti Cancer Care Mission (PCCM) established its Genetic Clinic in 2017 providing free genetic counselling and subsidized genetic testing to breast cancer patients.

Methods: The PCCM Genetic Clinic recommends breast cancer patients for genetic testing as per National Comprehensive Cancer Network (NCCN) guidelines. If NCCN criteria are met by a breast cancer patient, they are advised by the doctor to undergo genetic counseling and testing. Patient is provided with complementary pre-test counseling before the genetic test, to emphasize the need for and importance of testing and post-test counseling once the reports arrive to explain the result and give surveillance and therapy options.

Results: We present data for 280 breast cancer patients who visited the PCCM genetic clinic and underwent genetic testing. Of the 280 patients tested, 47.14% (132/280) did not harbour any germline mutation while 52.86% (148/280) harboured atleast one mutation in breast cancer predisposing genes. We also tested unaffected family members of germline positive patients, with family members of 21 patients undergoing cascade testing. All individuals who underwent cascade testing were counselled regarding options and precautions to be undertaken in view of their germline test. Patients testing positive for pathogenic germline mutations were recommended appropriate modifications in their treatment regimen. An ongoing project is also assessing the perception of genetic counseling and testing among breast cancer patients.

Conclusion: The PCCM Genetic clinic has provided genetic counseling to over 300 patients with over 280 patients tested. The availability of complementary genetic counseling and subsidized genetic testing at the clinic is an effort towards increasing accessibility to genetic testing in an LMIC like India. Our efforts at the centre are also focused on increasing the awareness of the genetic basis of breast cancer. It is essential that other centres across the country also incorporate such a genetic clinic within their clinical practice and enable optimal healthcare availability to high-risk patients.

No conflict of interest.

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270 (PB-086) Poster

Comparative study of gene mutations between Japanese and Lithuanian BRCA1/2 pathological variant carriers

K. Taruno[1], B. Dominyka[2], T. Mieko[1], I. Mayuko[1], S. Rasa[3], L. Olga[3], U. Jurgita[4], N. Seigo[1]. *SICORP (Strategic International Collaborative Research Program) of the Japan Agency for Medical Research and Development (AMED) [1]Showa University, Breast Surgical Oncology, Tokyo, Japan; [2]National Cancer Institute of Lithuania, Genetics, Vilnius, Lithuania; [3]National Cancer Institute, Genetic Laboratory, Vilnius, Lithuania; [4]National Cancer Institute, Radiology, Vilnius, Lithuania*

Background: In October 2021, the Japan-Lithuania Collaborative Research Program (SICORP: Strategic International Collaborative Research Program) of the Japan Agency for Medical Research and Development (AMED) began a collaborative study to compare hereditary breast cancer in Japan and Lithuania. This study focuses on the genetic characteristics of hereditary breast cancer, along with evaluating the effectiveness of breast MRI to detect hereditary breast cancer radiomic features. Despite the close historical ties between Japan and Lithuania, their geographical and genetic background differ significantly. The aim of this report is to compare the *BRCA1/2* mutation between the Japanese population of hereditary breast and ovarian cancer (JOHBOC) HBOC registry and Lithuanian NCI (National Cancer Institute) patients with breast cancer and their associated family members from 2017 till 2022 period.

Material: For analysis we used Japanese data from HBOC registry. This registry documented 3530 cases with pathological variant-positive *BRCA*1/2 individuals from 2017 through August 2022. The majority of the *BRCA1/2* pathological variant holders (*BRCA1*: 1529cases, *BRCA2*: 2001cases) were enrolled in the registry and the calculation was based on these data. Similarly, data for Lithuanian *BRCA*-positive individuals came from the Genetic diagnostic laboratory of National Cancer Institute which included 454 individuals, who were *BRCA* pathological variant holders (*BRCA1*: 325cases, *BRCA2*: 129cases).

Result: The percentages of *BRCA1/2* positives were 44% for *BRCA1*, 56% for *BRCA2* in Japan, and 71.6% for *BRCA1* and 28.4% for *BRCA2* in Lithuania. The gene mutations were 266 for *BRCA1* and 293 for *BRCA2* on the Japanese side, and 24 for *BRCA1* and 28 for *BRCA2* in Lithuania. Only 3 gene mutations (c.181T > G, c.1687C > T, and c.4327C > T) in *BRCA1* and 2 gene mutations (c.5645C > A, and c.9117G > A) in *BRCA2* were common.

Conclusion: Japan and Lithuania are geographically and racially different, and have little in common in terms of *BRCA1/2* gene mutations, the most common causative gene of hereditary breast cancer. Further analysis of the causative genes of other hereditary tumors will be conducted in the future to further examine the differences in genetic mutations between the two countries.

Funding for this study: Study is carried on as the part of the AMED Japan-Lithuania project.

No conflict of interest.

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271 (PB-087) Poster

Mutation spectrum of homologous recombination repair genes in early triple-negative breast cancer: association with clinicopathological factors, immune infiltration, and prognosis

Y. Lu[1], Z. Wang[1], M. Han[1], A. Li[2], M. Ruan[2], C. Wang[2], X. Zhang[3], C. Zhu[4], K. Shen[1], X. Chen[1]. *[1]Ruijin Hospital- Shanghai Jiao Tong University School of Medicine, Department of General Surgery, Comprehensive Breast Health Center, Shanghai, China; [2]Ruijin Hospital, Shanghai Jiao Tong University School of Medicine, Department of Pathology, Shanghai, China; [3]Amoy Diagnostics Co., Ltd, Department of Translational Oncology, Xiamen, China; [4]Amoy Diagnostics Co., Ltd., Department of Translational Oncology, Xiamen, China*

Background: The frequency and clinical relevance of tumor mutations in homologous recombination repair (HRR) genes in early triple-negative breast cancer (TNBC) are not well established. Furthermore, the association between HRR mutation, immune infiltration, and prognosis in TNBC is unknown. The aim of this study was to evaluate the mutation spectrum of HRR genes and its association with clinicopathological factors, immune infiltration, and prognosis in TNBC.

Methods: TNBC patients (434 patients from Ruijin cohort) were evaluated with targeted next-generating sequencing for mutations in HRR genes. The frequencies of mutations were compared with public reference cohorts (320 TNBC patients from METABRIC, 105 from TCGA, and 225 from MSKCC 2018). Associations between mutation status and clinicopathological factors, immune infiltration, and prognosis were analyzed.

Results: HRR genes mutations were seen in 21.89% of 434 patients, with *BRCA1/2* mutations significantly enriched in tumors with breast/ovarian cancer family history ($P = 0.025$) and high Ki-67 levels ($P = 0.018$). The pathological variation (PV) prevalence of *BRCA1* was higher in Ruijin cohort (10.60%), than other public cohorts (2.67% to 2.86%), whereas the PV prevalence of *BRCA2* in our study (3.92%) and MSKCC 2018 (4.44%) outnumbered that of TCGA (0.95%) and METABRIC (0.63%). HRR genes mutations were not related with recurrence-free survival (RFS) (adjusted $P = 0.070$) and overall survival (OS) (adjusted $P = 0.318$) for TNBC patients, regardless of carboplatin treatment or not ($P > 0.05$). Moreover, immune infiltration and PD-L1 expression was positively associated with HRR or *BRCA1/2* mutation (all $P < 0.001$). Patients with both HRR mutation and high $CD8^+$ T cell counts had the best RFS and OS compared with other groups, whereas patients with no HRR mutation and low $CD8^+$ T cell counts had the worst outcomes ($P < 0.001$ for RFS and $P = 0.019$ for OS).

Conclusion: High frequency of tumor mutations in HRR genes was found in early TNBC patients, but showed no significant association with survival outcome. Immune infiltration and PD-L1 expression was positively associated with HRR mutation, and both HRR mutation and high $CD8^+$ T cell infiltration levels were associated with superior disease outcome.

No conflict of interest.

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272 (PB-088) Poster

Association between prognosis, carboplatin treatment response and homologous recombination deficiency status in early triple-negative breast cancer

Z. Wang[1], Y. Lu[1], M. Han[1], A. Li[2], M. Ruan[2], Y. Tong[1], X. Zhang[3], C. Zhu[3], K. Shen[1], L. Dong[2], X. Chen[1]. *[1]Ruijin Hospital, Shanghai Jiao Tong University School of Medicine, Department of General Surgery, Comprehensive Breast Health Center, Shanghai, China; [2]Ruijin Hospital-Shanghai Jiao Tong University School of Medicine, Department of Pathology, Shanghai, China; [3]Amoy Diagnostics Co. Ltd., Department of Translational Oncology, Shanghai, China*

Background: Frequency and clinical significance of homologous recombination deficiency (HRD) in early triple-negative breast cancer (TNBC) are not well understood. The aim of this study was to assess HRD status and its correlation with clinicopathological factors, gene mutation status, carboplatin treatment response, and prognosis in TNBC.

Methods: Formalin-fixed paraffin-embedded (FFPE) tumor tissues from consecutive 225 TNBC patients, including 60 patients who received neoadjuvant chemotherapy (NAC), were evaluated with HRD complete panel. HRD positivity was defined as high HRD score and/or BRCA1/2 pathogenic or likely pathogenic mutation. Somatic tumor homologous recombination repair (HRR) associated genes were also tested in enrolled patients. Associations between HRD status and clinicopathological factors, carboplatin treatment response, and prognosis were analyzed.

Results: HRD was found in 53.3% of 225 patients, with HRD positivity significantly related to high Ki-67 levels ($P = 0.001$). *BRCA* mutation carriers had significantly higher HRD scores compared to *BRCA* wild type (77.90 ± 12.40 vs 45.35 ± 6.59, $P < 0.001$) or non-*BRCA* HRR genes-mutated group (46.29 ± 24.32, $P < 0.05$). HRD positivity was associated with favorable distant metastasis-free survival (hazard ratio [HR] 0.49, 95% confidence interval [CI] 0.26–0.90, $P = 0.022$) and overall survival (HR 0.45, 95%CI 0.20–0.99, $P = 0.049$), irrespective of carboplatin treatment. In patients who received NAC, HRD positivity ($P = 0.005$) or high HRD score ($P = 0.003$) was significantly associated with higher pathological complete response (pCR) rate.

Conclusion: TNBC patients with *BRCA* mutation have higher HRD score than patients with other non-BRCA HRR gene mutations or the wild-type group. HRD positivity was associated with better prognosis and higher neoadjuvant pCR rate in early TNBC patients, irrespective of carboplatin treatment, warranting further clinical validation.

No conflict of interest.

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273 (PB-089) Poster

Effect of pharmacogenomic polymorphism on hormone therapy for breast cancer patients: systematic review and meta-analysis

C.Y. Kuo[1], Y.Z. Chou[2], C.S. Ho[2], K.C. Cheng[2], O. R. Mafruhah[5], M.X. Su[1], L.C. Liu[3], H.W. Lin[4]. *[1]China Medical University Hospital, Surgical Department, Taichung, Taiwan; [2]China Medical University, School of Pharmacy, Taichung, Taiwan; [3]China Medical University, School of Medicine, Department of Surgery, Taichung, Taiwan; [4]China Medical University, School of Pharmacy and Graduate Institute, Taichung, Taiwan; [5]Universitas Islam Indonesia, Department of Pharmacy, Indonesia*

Background: The effectiveness of a same hormone therapy medication were various from patients to patients due to either genetic polymorphisms or other factors for those breast cancer (BC) patients with Estrogen receptor (ER) positive. There is a consensus of CYP450 polymorphism on Tamoxifen but unknown the extent. None of consensus of genetic polymorphisms on aromatase (AIs) and/or CDK4/6 inhibitors was available yet. Our study aimed to investigate the associations and extent of pharmacogenetic polymorphisms on the effectiveness and safety of hormone therapies for BC patients.

Material and Methods: A comprehensive systematic literature review was performed on PubMed and EMBASE for the English publications by December 2021. The databases of human genetic variation on drug response (i.e., PharmGKB) was utilized d to confirm the corresponding phenotypes. Designed standardized data form was used to collect and organize the extracted data from the available literature. Four authors cross reviewed and validate the risk of bias using Newcastle-Ottawa Scale and Version 2 Cochrane tool. Further meta-analysis was performed for the sufficient extracted data classified by the medications, type of genetic variation and survival outcomes.

Results and Discussion: There were totally 1,005 hits retrieved either from Embase or PubMed, but only 22 studies met our eligible criteria (tamoxifen accounts for 77%, aromatase inhibitors were 18% and only one exploring CDK4/6, i.e., Palbociclib). Although almost half of the studies were conducted in Europe and explored Caucasian, 14% were in Asian countries. Given survival outcomes didn't show statistically significant difference among different genetic polymorphisms, BC patients with poor metabolism of CYP2D6 and CYP2C19 taking Tamoxifen seemed less effective. BC patients treated with AIs were influenced by TCL1A and CYP19A1 and seemed more likely to encounter AI-Associated Musculoskeletal Syndrome (i.e., arthralgia). As for subgroup analysis, BC patients with poor metabolism of CYP2D6 were less likely to encounter BC specific survival outcomes but was influenced by prior chemotherapies or not.

Conclusion: Although certain types of genetic variants of CYP2D6 and CYP2C19 seemed associated with the effectiveness of Tamoxifen and safety of AIs for BC patients, almost no statistically strong enough associations with pharmacogenomic variations was found due to small sample size. Nevertheless, early detection of these germline gene polymorphism is helpful to guide the treatment options for hormone positive breast cancer while avoiding the unexpected adverse reactions and facilitate effectiveness enhancement in clinical practice in the future.

No conflict of interest.

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274 (PB-090) Poster

Clinical performance and agreement with immunohistochemistry of RT-qPCR-based early breast cancer subtyping: the Mammamark experience

D. Tormen[1], M.R. Biasin[1], I.M. Montagner[1], V. Mourmouras[1], A. Scapinello[1], G. Mora[2], G. Sgarbossa[3], D. Napetti[3], S. Lonardi[3], S. Frezzini[3]. *[1]Veneto Institute of Oncology IOV – IRCCS- Padua- Italy, Anatomy and Pathological Histology Unit, Padua, Italy; [2]Veneto Institute of Oncology IOV – IRCCS- Padua- Italy, Breast Surgery 2 Unit, Padua, Italy; [3]Veneto Institute of Oncology IOV – IRCCS- Padua- Italy, Medical Oncology 3 Unit, Padua, Italy*

Background: RT-qPCR is a novel assay with reliable reproducibility in breast cancer (BC) subtyping, based on ER, PgR, Ki67, and HER2 key biomarkers. Our aim was to assess the agreement between RT-qPCR and routine immunohistochemistry (IHC) and *in situ* hybridization (ISH) techniques either in the assessment of HER2 equivocal results, Ki67 intermediate range, or in the risk prediction of recurrence score (RS) groups, and the clinical performance of RT-qPCR and IHC-based subtypes in predicting prognosis.

Material and Methods: Expression of ESR1, PGR, MKI67, and HER2 by RT-qPCR (Mammatyper® test) was performed on RNA extracted from the 119 archival FFPE samples of operable BC patients treated between 2019 and 2023. IHC assessed the biomarker protein levels and ISH the HER2 amplification. The BC subtypes were defined based on the St. Gallen expert panel with predefined cutoffs. The concordance rates between IHC/ISH and RNA data were reported. The correlation of continuous RS values with RNA-based and IHC-based PgR and MKI67/Ki67, respectively, was compared by linear regression analysis. All the results were correlated with relapse-free survival (RFS).

Results: A total of 119 early BC samples were included. A good agreement between RT-qPCR-based and IHC-based biomarker assessment was found. As expected, discordance rates were significantly higher in the Ki67 intermediate range group (20% cutoff), opposed to the low- and high range groups (5% and 30% cutoffs, respectively). As regards HER2, most (75%) of the discrepancies belonged to the IHC 2+ group, with over two thirds (76%) of IHC 2+/ISH-positive cases found to be HER2-low by RT-qPCR. The majority of them were reclassified as luminal B HER2- subtypes. Regarding the correlation with RS, a negative trend of RS values and PgR levels, opposed to a positive trend of RS values and Ki67/MKI67 levels, was found. All the patients with PgR negative levels had a RS ≥25, compared to the PR negative cases having a 11–25 RS, and all those with high (≥20%) Ki67 value had a RS ≥25. Both ER/ESR1 and PR/PgR positive results were associated with good prognosis for RFS (log-rank $p < 0.001$ and $p < 0.001$, respectively) while HER2/ERBB2 status had no influence on RFS. In multivariate analysis, a high (≥30%) Ki67 value was the only independent prognostic factor for RFS ($p = 0.05$).

Conclusions: RT-qPCR may provide a complementary assay to IHC/ISH to stratify hard-to-reach BC groups including HER2-low, that impact subtyping and treatment plan. Of note, PgR and Ki67 levels may better correlate with the high-risk RS cases and thus chemotherapy benefit,

compared to IHC. The clinical performance of RT-qPCR-based and IHC-based BC subtyping with regard to the prognosis was almost similar.

No conflict of interest.

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275 (PB-091) Poster

Genomic and transcriptomic characterisation of endocrine therapy-resistant breast cancers: a single-institution longitudinal study

C. Martinez-Perez[1], C. Kay[1], L. Renshaw[2], J.M. Dixon[2], A.K. Turnbull[1].
[1]Institute of Genetics and Cancer, University of Edinburgh, Edinburgh, United Kingdom; [2]NHS Lothian, Edinburgh Breast Unit, Edinburgh, United Kingdom

Background: Endocrine therapy (ET) is an essential tool for the treatment of the ER-positive (ER+) subtype of breast cancer (BC). However, about 40% of patients develop acquired endocrine therapy resistance (ETR). This leads to relapse and, potentially, the development of metastatic disease, which accounts for the majority of BC-related deaths.

Materials and Methods: We have performed multiomics assessment of a cohort of patients (n = 109) with ER+/HER2- BC treated at the Edinburgh Breast Unit. All patients received ET and developed a BC recurrence after an initial period of response. We collected clinical information and long-term follow-up and obtained sequential FFPE tissue.

This work included profiling of matched longitudinal and/or synchronous samples sets: 70 cases with baseline and recurrence tumours samples, 20 of which also included profiling of co-occurring lesions in the breast and axillary lymph nodes. We also profiled a subset of cases (n = 17) who developed multiple recurrences (up to 7 consecutive relapses) under different lines of ET.

We performed targeted DNA sequencing and whole-transcriptome profiling for all samples.

Results: 97% of samples carried mutations in genes associated with ETR, with an average of 4 driver variants in each tumour. Commonly altered genes included *TP53*, *PIK3CA*, *RUNX1*, *MAP3K1* and *GATA3*. Interestingly, the top 2 most mutated genes (*TP53* and *PIK3CA*) exhibited different mutation rates between early (with 5 years) and later (>5 years) recurrences. *RUNX1* aberrations were significantly more common in recurrent lesions, compared to matched baseline tumours.

In sub-analysis of matched samples, we observed a trend of conserved mutational profiles, with half of the variants typically being sustained both over time (primary and recurrence) and across sites (synchronous local and node tumour). Most conserved variants exhibited stable or increasing variant allele frequencies (VAFs). Gene expression analysis showed differential activity of pathways including proliferation, ER, HER2, AKT and RAS.

Further integrative analysis of the mutational information alongside the transcriptomic data is underway and will be presented, including a focused, case-specific assessment of those cases with multiple consecutive recurrences.

Discussion: This study has generated a unique multiomics dataset for the study of acquired resistance in ER+ BC. Preliminary analysis has evidenced the broad range of mechanisms involved in the development of ETR. Study of longitudinally matched tumours has provided insight into how key aberrations found at baseline which are linked to a more resistant phenotype are selected to undergo clonal expansion. A better understanding of these underlying driver mechanisms of resistance and the identification of actionable biomarkers will be essential to improving our management of the critical unmet challenge of ETR.

No conflict of interest.

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POSTER SESSION **22 March 2024** **9.00–14.30**

Optimal Diagnosis

276 (PB-092) Poster

Epidemiology of HER2-low breast cancer in Lithuania

A. Cesas[1], L. Poskiene[2], R.B. Valkiuniene[3], L. Radvinskiene[4], I. Lege[5].
[1]Klaipeda University Hospital, Department of Oncology, Klaipeda, Lithuania; [2]Lithuanian University of Health Sciences, Department of Pathology, Kaunas, Lithuania; [3]National Centre of Pathology, Department of Breast Pathology, Vilnius, Lithuania; [4]Klaipeda University Hospital, Department of Pathology, Klaipeda, Lithuania; [5]AstraZeneca, Baltic Medical & Regulatory Department, Vilnius, Lithuania

Background: According to internationally published data, 35.2–64.4% of breast cancer cases are with HER2-low expression (Gampenrieder et al., 2021; Miglietta et al., 2021; Horishawa et al., 2021) out of all the breast cancer cases with identified HER2 expression (HER2 0, HER2 1+, HER2 2+, HER2 3+). This study aimed to determine HER2-low breast cancer epidemiology data in Lithuania and compare it with officially published data from clinical trials and epidemiologic studies.

Material and Methods: The biological data of 1882 breast cancer cases were analyzed by the pathology laboratories of the National Centre of Pathology, the Hospital of Lithuanian University of Health Sciences Kaunas Clinics, and Klaipeda University Hospital. It quantified the overall frequency of breast cancer patients with a HER2-low subtype that was defined by an immunohistochemistry score of HER2 1+ or HER2 2+ /ISH–.

Results: The results of the HER2 breast cancer expression demonstrated that there were 955 (50.7%) HER2-negative (HER2 0), 648 (34.4%) HER2-low (HER2 1+ and HER2 2+/ISH-), and 279 (14.9%) HER2-positive (HER2 2 +/ISH+ and HER2 3+) breast cancer samples. Based on the extrapolated data for metastatic breast cancer samples, 63 out of the 179 cases were HER2-low metastatic breast cancer (35.2%).

Out of 1882 evaluable breast cancer cases, 1774 had identified both HER2 and hormone-receptor (HR) status. Among them, 921 (51.9%) were HER2-negative, 603 (34.0%) were HER2-low, and 250 (14.1%) were HER2-positive. Low HER2 expression was more frequent in the HR-positive group than in the hormone-receptor-negative group (84.0% vs. 9.1%).

Table 1

	All N (%)	HER2 negative N (%)	HER2 low N (%)	HER2 positive N (%)
Cases with identified HER2 status	1882 (100)	955 (50.7)	648 (34.4)	279 (14.9)
Cases stratification by location of samples				
Tumor	1663 (86.8)	NE	569 (87,8)	NE
Distant metastases	179 (9,5)	NE	63 (9,7)	NE
Lymph nodes/unidentified	70 (3,7)	NE	16 (2,5)	NE
Cases stratification by hormone receptor status				
HR+ cases	1416 (75.2)	721 (72.5)	544 (84.0)	151 (54.1)
HR- cases	358 (19.0)	200 (20.1)	59 (9.1)	99 (35.5)
Unknown HR status	108 (5.8)	34 (3.4)	45 (6.9)	29 (10.4)

NE- not evaluated.

Conclusions: The comparative analysis of the results demonstrates that the data provided by the national pathology laboratories aligns with the officially published data of the clinical trials and the epidemiological studies. The results of the analysis on the epidemiology of HER2-low breast cancer in

Lithuania, provided by the national pathology laboratories, are reliable for predicting the numbers and percentages in the distribution of HER2 expression in Lithuania.

Acknowledgments: This work was funded by AstraZeneca, Lithuania. The medical writing support was provided by GuruMA, Lithuania.

No conflict of interest.

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277 (PB-093) Poster

HER2-low and tumor infiltrating lymphocytes in triple negative breast cancer: are they mutually connected?

X. Baez Navarro[1], N.S. van den Ender[1], A. Nguyen[1], R. Sinke[2], P. Westenend[3], J.B. van Brakel[4], C. Stobbe[2], J. Westerga[2], C.H.M. van Deurzen[1]. *[1]Erasmus MC, Pathology, Rotterdam, Netherlands; [2]Pathan, Pathology, Rotterdam, Netherlands; [3]PAL Dordrecht, Pathology, Dordrecht, Netherlands; [4]Skåne University Hospital, Pathology, Malmö, Sweden*

Background: Most patients with triple-negative breast cancer (TNBC) are not candidates for targeted therapy, leaving chemotherapy as the primary treatment option. Recently, immunotherapy has demonstrated promising results in TNBC, due to its immunogenicity. In addition, a novel antibody-drug conjugate, namely, trastuzumab-deruxtecan (T-DXd), has shown effectiveness in TNBC patients with low HER2 expression (HER2-low). These novel treatment options raise the question about the potential association between the density of stromal tumor-infiltrating lymphocytes (sTILs) and the level of HER2 expression.

Aim: To evaluate the association between the level of HER2 expression (HER2-low versus HER2-0) and density of sTILs in TNBC patients, and how they impact the response to neoadjuvant chemotherapy (NAC).

Methods: This is a retrospective multicenter study including all TNBC patients diagnosed between 2018 and 2022. Central pathology review included sTILs percentages and level of HER2 expression. Tumors were reclassified as either HER2-0 (HER2 IHC 0) or HER2-low (IHC 1+ or 2+ with negative reflex test). Various clinicopathologic characteristics, including sTILs density, and response to NAC were compared between HER2-0 and HER2-low cases.

Results: In total, 753 TNBC patients were included in this study, of which 292 patients received NAC. Interobserver agreement between the original pathology report and central review was moderate (77% had the same IHC status after reclassification in either HER2-0 or HER2-low; k = 0.45). HER2-low TNBC represented about one third (36%) of the tumors. No significant difference in sTILs density or complete pathologic response rate was found between HER2-0 and HER2-low cases ($p = 0.476$ and $p = 0.339$ respectively). The density of sTILs ($\geq$10% sTILs versus <10%) was independently associated with achieving a cPR ($p = 0.011$).

Conclusion: No significant association was found between HER2-low status and density of sTILs nor response to NAC. Nonetheless, sTILs could be an independent biomarker for predicting NAC response in TNBC patients.

Conflict of interest:

Advisory Board: C. van Deurzen was involved in an advisory board of AstraZeneca/Daiichi Sankyo and received research funding from AstraZeneca.

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278 (PB-094) Poster

A comparison between immunohistochemistry and mRNA expression to detect HER2-low breast cancer

X. Baez Navarro[1], M.R. van Bockstal[2], A. van der Made[1], C.H.M. van Deurzen[1]. *[1]Erasmus MC, Pathology, Rotterdam, Netherlands; [2]Cliniques Universitaires Saint-Luc, Pathology, Brussels, Belgium*

Background: Tumors with low levels of HER2 expression (HER2-low) have become a targetable subset of breast cancer (BC) thanks to the efficacy of novel anti-HER2 antibody-drug conjugates like trastuzumab deruxtecan (T-DXd). HER2 immunohistochemistry (IHC) is the current recommended assay for HER2 classification in daily clinical practice. However, this essay is associated with limited interobserver agreement concerning the diagnosis of HER2-low BC. We investigated whether mRNA expression quantified via qRT-PCR could serve as a valuable complementary and more objective method to IHC for detecting HER2-low BC.

Methods: Twenty-four biopsy cases were randomly selected from our previously published interobserver study of non-overexpressing HER2 BC. In this study, each case underwent HER2 IHC evaluation by 16 pathologists to establish a consensus on the IHC scores. In addition, fluorescence in situ hybridization (FISH) was performed on all cases. For this current study, mRNA was extracted from microdissected invasive tumor cells of formalin-fixed paraffin-embedded material. qRT-PCR was employed for quantitative evaluation of HER2 using the cut-off values of the essay, resulting in the following MammaTyper® classes: HER2-0, (including HER2-0 and ultralow), HER2-low and HER2-positive. We compared the mRNA expression levels with the consensus IHC scores (IHC 0, 1+, 2+), the HER2 subcategories: HER2-0 (IHC 0) and HER2-low (IHC 1+ and 2+/FISH negative).

Results: Based on the IHC consensus, 5 cases were HER2-0 and 19 were HER2-low, while MammaTyper® identified 4 cases as HER2-0 or ultralow, 17 as HER2-low, and 3 as HER2-positive, resulting in a concordance of 75%. Two discordant cases had a IHC consensus score of 0 and were classified as HER2-low by MammaTyper®. One case had a consensus IHC score of 2+ and was identified as HER2-0 or ultralow by MammaTyper®. Three MammaTyper® HER2-positive cases were scored as IHC 2+ without amplification as determined by FISH. The mRNA levels strongly correlated with the consensus IHC scores ($r = 0.585$, $p = 0.003$) and the HER2 subcategories ($r = 0.547$, $p = 0.006$). When comparing mRNA levels within HER2 subgroups, a significant difference in mean mRNA expression was found between HER2-0 and HER2-low ($p = 0.03$).

Conclusion: Our findings indicate a strong correlation between mRNA expression quantified by MammaTyper® RT-qPCR and HER2 IHC consensus scores, but there was a substantial proportion of discordant HER2-results between both methods. Additional research with larger numbers including clinical outcome is needed to determine its added value.

Conflict of interest:

Advisory Board: C. van Deurzen is part of the Advisory Board of AstraZeneca.

Other Substantive Relationships:

Sysmex Nederland B.V. is the subsidizing party of this project by providing the PCR kits. However, they have no involvement in the processing, analysis or interpretation of the results or the writing of the abstract.

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279 (PB-095) Poster

Reassessment of HER2 Status in Invasive Micropapillary Carcinoma of the Breast - Recommendations for Improvement of 2023 ASCO/CAP Guideline on HER2 Testing

Y. Li[1], M. Zhang[1], M. Yue[1], X. Yuan[2], C. Liu[2], X. Li[2], Y. Liu[1]. *[1]The Fourth Hospital of Hebei Medical University, Department of Pathology, Shijiazhuang, China; [2]Shuwen Biotech Co. Ltd, R&D center, Hangzhou, China*

Background: Invasive micropapillary carcinoma (IMPC) is a specific subtype of breast cancer with cell polarity reversal. This distinct morphology of IMPC can affect the immunohistochemical (IHC) staining of human epidermal growth factor receptor-2 (HER2), and tumor cells usually show an incomplete membranous staining pattern.

Material and Methods: Using the 2023 American Society of Clinical Oncology and the American College of Pathologists (ASCO/CAP) Guideline on HER2 testing, IHC results for HER2 were retrospectively reassessed in 281 consecutive patients with IMPC who were admitted in the Fourth Hospital of Hebei Medical University from January 2015 to June 2023. Since most cases were mixed breast cancers with invasive micropapillary components ranging from 10% to 100%, only the HER2 status of the invasive micropapillary region was reassessed. With reference to the hematoxylin and eosin-stained sections of each case, other types of invasive breast cancer and ductal carcinoma in situ components were removed from its formalin-fixed paraffin-embedded (FFPE) tissue blocks. ERBB2 mRNA level of all processed FFPE samples were detected by MammaTyper® (Cera Biotech GmbH, Berlin), a quantitative real-time polymerase chain reaction (RT-qPCR) kit for breast cancer subtyping, and fluorescence in situ hybridization (FISH) was performed for HER2 IHC 2+ cases.

Results: According to the 2023 ACSO/CAP Guideline, 162 were HER2 IHC negative (0/1+), 89 were equivocal (2+), and 30 were positive (3+). Regarding the integrity of HER2 IHC staining, 75% (211/281) showed a basolateral membrane staining pattern, 11% (30/281) were completely stained, while 14% (40/281) were not stained at all. Among 106 HER2 IHC 1+ cases, 27 cases showed faint and 79 cases showed weak staining of the basolateral membrane, while the positive rates of MammaTyper® ERBB2 RT-qPCR were 0% (0/27) and 16% (13/79), respectively. Among the 89 cases of HER2 IHC 2+, 63 had moderate and 26 had intense staining of the basolateral membrane, and the positive rates of ERBB2 RT-qPCR were 33% (21/63) and 96% (25/26), respectively. The amplification rates by FISH were 35% (22/63) and 100% (26/26), respectively. The positive rate of ERBB2 RT-qPCR in HER2 IHC 3+ cases was 100%.

Conclusion: The characteristic of IMPC HER2 IHC is staining of the basolateral membrane. The MammaTyper® ERBB2 RT-qPCR and FISH detection suggest that IHC staining interpretation should focus on staining intensity rather than integrity. We believe that for IMPC, intense basolateral membrane staining in $\geq$ 10% of invasive tumor cells indicates HER2 positivity, which can be directly interpreted as 3+; moderate to weak staining of the basolateral membrane in $\geq$ 10% of invasive tumor cells should be classified as 2+, and FISH or MammaTyper® detection should be performed to determine HER2 status.

No conflict of interest.

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280 (PB-096) Poster

Multi-institutional predictive model for axillary nodal involvement using the EUSOMA database

S. Steyaert[1], B. Bussels[2], I. Kindts[3], A. Roelstraete[4], P. Poortmans[5], P. Vermeulen[5], C. de Beukelaar[6], K. Van Varenbergh[7], S. Goossens[8], P. De Jaeger[1], The BreaCS consortium. *[1]AZ Delta, RADar Learning & Innovation Centre, Rumbeke, Belgium; [2]AZ Delta, Department of Radiotherapy, Rumbeke, Belgium; [3]AZ Groeninge, Department of Radiotherapy, Kortrijk, Belgium; [4]OLVZ Aalst, Department of Radiotherapy, Aalst, Belgium; [5]GZA, Department of Oncological Research, Antwerp, Belgium; [6]AZ Groeninge, Clinical Trial Center, Kortrijk, Belgium; [7]OLVZ Aalst, Clinical Trial Center, Aalst, Belgium; [8]Endare, Clinical Innovation, Ghent, Belgium*

Background: Accurate assessment of axillary nodal involvement is essential for effective clinical management of breast cancer patients. We developed a novel multi-institutional predictive model to estimate the patient-specific risk of axillary nodal involvement based on pre-operative clinico-pathological features in clinically node-negative patients.

Material and Methods: Clinicopathological data from the European Society of Breast Cancer Specialists (EUSOMA) database from four Belgian EUSOMA-certified hospitals were collected, which resulted in a dataset of approximately 2500 patients. To create our predictive model, we divided the dataset into a training set (80%) and a test set (20%). Leveraging artificial intelligence-based techniques, multiple models were trained on the training set using a cross-validation approach, and their performance was assessed and compared.

Results: The area under the receiver operating characteristic curve (AUC) on the test set for our predictive modelling ranged between 0.70 and 0.79. This indicates a promising level of predictive accuracy for the risk of axillary lymph node involvement in early breast cancer.

Conclusions: Our multi-institutional approach leveraged a substantial patient cohort and diverse clinical data sources, contributing to the robustness and generalizability of our predictive model. The development of such models holds significant potential for improving clinical decision-making and subsequent patient outcomes in breast cancer management.

No conflict of interest.

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281 (PB-097) Poster

Digital multidisciplinary meetings enable regional specialist oncology treatment

C. Benn[1], D. van Loggerenberg[2]. *[1]Breast Care Centre of Excellence - South Africa, Department of Surgery, Johannesburg, South Africa; [2]Breast Care Centre of Excellence - South Africa, Research, Johannesburg, South Africa*

Background: The technological revolution within the medical field spurred on by the global pandemic has resulted in changes in the possible medical landscape. Within the South African medical infrastructure, the differences in medical care provided to patients due to specialist availability vary between different regions within the country drastically. Using a full digital support system resulted in a new service provision of MDM expertise offered to various allied health professionals independent of the region and thus improved MDM access to a greater range of patients.

Methodology: Existing treatment plans provided for patients attending the centre from outside of the reasonable treatment range (3–6 hour travel) were provided via a written report to allied healthcare providers for treatment remotely.

Post-digitalisation, the existing service offering was expanded to include Multidisciplinary meetings with recorded treatment discussion, radiological review and pathological support, coupled with interactive treatment decisions provided by tier academic specialists in the surgical oncological and radiation fields, allowing for treatment support of regional patients to be provided by the centralised digital MDM team.

Further inclusion of controlled cloud patient database sets, including Clinical, radiological and pathological diagnostic information coupled with outlined treatment plans, provided members with a reference database for treatment and research collaborations.

Results: An increase in regional referrals of patients, both digitally and in-person, the number of patients seen over the SARs pandemic and an increasing number of specialists joining the MDM has been seen due to an increased relationship being developed between the MDM team and regional healthcare providers.

Assessments from 2020 to 2022 show a 46%increase in MDM capacity for specialists (23 members to 35) and a 17% increase in weekly newly diagnosed patients associated explicitly with regional members (exceeding 100 new patients per annum)

Conclusion: Digital MDM enables specialist centres to support regional allied healthcare providers, enabling top-quality guideline-based care for a wider demographic of patients usually excluded due to logistical and resource limitations. Standardisation and implementation of Regionally supportive digital MDT meetings would enable treatment support without increasing costs to centres or patients.

No conflict of interest.

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282 (PB-098) Poster

Breast implant–associated anaplastic large cell lymphoma (BIA-ALCL): A mass but no fluid

S. Rehman[1], F. Singh[1], A. Talwalkar[1], S. Iram[1], K. Zacharioudakis[2]. *[1]Wrightington, Wigan and Leigh Teaching Hospitals NHS Foundation Trust., Breast Screening Unit, Thomas Linacre Centre, Wigan, United Kingdom; [2]Wrightington, Wigan and Leigh Teaching Hospitals NHS Foundation Trust, Breast Surgery, Wigan, United Kingdom*

Background: BIA-ALCL is a rare but emerging distinctive type of T cell Non-Hodgkin Lymphoma that arises around textured breast implants years after they are placed either for reconstructive or cosmetic reasons. It can present with more common pattern of peri-implant effusion or with less common mass forming disease.

Material and Methods: 59-year-old female patient with history of bilateral breast augmentation 19 years ago presented to symptomatic breast clinic with a lump in upper inner quadrant of left breast. She underwent imaging for further assessment.

Results: Bilateral mammograms including Eklund views were normal.

Ultrasound revealed an underlying soft tissue mass with internal vascularity in left breast upper inner quadrant behind the edge of the breast implant. The patient underwent a technically difficult core biopsy.

Histopathology showed cores containing small B-lymphocytes (CD20, CD79 and PAX-5 positive) along with a conspicuous population of atypical small to medium to occasional large neoplastic bF1 positive CD4

preponderant T-lymphocytes, which show strong diffuse CD30 expression. These features were regarded to be compatible with BIA-ALCL.

Breast MRI with contrast and silicone specific sequences showed a lobulated heterogeneously enhancing lesion behind left breast implant with restricted diffusion extending into the pectoralis muscle. No peri-implant fluid or implant rupture seen, incidental right sided intracapsular rupture was noted.

FDG PET-CT showed a metabolically active lobulated mass lying posterior to the medial aspect of the left breast implant infiltrating the underlying pectoral muscles, demonstrating high intensity uptake of FDG. Focal FDG uptake was also noted within the left L3 vertebral body. This was further assessed with MRI spine that demonstrated focal T1 hypointense STIR hyperintense L3 vertebral lesion with involvement of pedicles and spinous process in keeping with metastatic lesion.

The patient was referred to lymphoma MDT as per breast MDT discussion. She was started on chemotherapy. Follow up PET-CT done after 3 cycles of chemotherapy showed complete metabolic response in terms of decrease in FDG uptake in left breast mass and resolution of uptake in L3 vertebra (Deauville 2). Patient will undergo surgical excision of residual mass along with complete excision of implant capsule after finishing her chemotherapy.

Conclusions: BIA-ALCL can present with increased peri-implant fluid alone, a mass with fluid or a mass alone without peri-implant fluid as was the case here. Increased awareness of BIA-ALCL and its varied clinical and imaging presentations may aid early detection and improved prognosis through integrated clinical and multimodality imaging evaluation and multidisciplinary management.

No conflict of interest.

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283 (PB-099) Poster

Ten-year follow-up results of the Lavender Way, Lavender Procedure in the diagnosis and treatment of breast cancer

P. Bretz[1], D. Mantik[1], R. Lynch[2], B. Djordjevic[1]. *[1]Visionary Breast Center, Research, La Quinta, USA; [2]Visionary Breast Center, Clinical Research, La Quinta, USA*

Background: The purpose of this study in patient care was to use the combined experience of over 120 years of the intradisciplinary team to exploit the value of a genetic test that not only tells a woman's risk for breast cancer but also when that risk will likely manifest within a ten-year period. If a woman is deemed high risk, multiple non-radiation diagnostic modalities are used in an accelerated fashion to diagnose nascent tumors before they have attained the capacity to metastasize, ideally less than 1 cm. This is the Lavender Way that portends the Lavender Procedure (cryoablation). The Lavender Procedure is a 20-minute in-office procedure with all patients resuming normal activity immediately with the breast basically looking untouched.

Material and Methods: A clinical trial investigating steroid hormone pathway genes has identified and confirmed age-specific genetic associations with breast cancer risk for SNPs in four genes. An example is The C/C genotype of cytochrome P450 X1B2 (CYP11B2) was associated with decreased risk at younger ages (30–40) but increased risk at older ages (55–69), a so-called "flipper" gene. This test is done at baseline and future imaging is dictated by the results. If a patient is deemed high-risk, accelerated imaging is carried out using multiple non-radiation modalities including modified military infrared, a pressure-sensing device, ultrasound, and liquid biopsy. The goal is to find nascent tumors amenable to cryoablation itself eliminating the need for any surgery, chemotherapy, or radiation.

Results: A total of 25 procedures on 21 patients were carried out starting in January 2014. The patients were divided into three groups. Group 1 were ideal patients e.g. less than 1 cm with ideal genetics. Group 2 was less than ideal including ductal carcinoma in-situ. Group 3 was strictly palliative. Ten years out except for 2 and one lost to follow-up, all patients in Groups 1 and 2 are alive and breast cancer-free, treated with no surgery, no chemotherapy, and no radiation. The two deaths were a result of a fall and the other from an aggressive primary lung cancer five years from treatment.

Conclusion: The Lavender Way and Lavender procedure have surmounted problems that have plagued mankind for millennia in the diagnosis and treatment of breast cancer. To name a few, keeping women returning for appropriate imaging year after year, having their body image remain intact, the significant other allowed into the procedure room, and eliminating the dread, fear, and anxiety of breast cancer diagnosis and treatment. All this is done with much dramatically lowered cost and is available to all women globally if the situation arises. It also solves the problem of how and when to image a high-risk woman that traditional methods like mammography and MRI can't as insurance companies won't pay for in spite of the need for repeat exams.

No conflict of interest.

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284 (PB-100) Poster

IHC-based and mRNA-based subtyping for Triple-negative breast cancer

S. Zhao[1], C. Tong[2], F.J. Qian[2], X.Y. Yuan[3], Q. Zhang[3], X.M. Li[2], W.T. Yang[4], Z.M. Shao[1]. *[1]Fudan University Shanghai Cancer Center, Breast Surgery, Shanghai, China; [2]Shuwen Biotech Co. Ltd., Research and development center, Hangzhou, China; [3]Shuwen Biotech Co. Ltd., Medical Affairs, Hangzhou, China; [4]Fudan University Shanghai Cancer Center, Pathology, Shanghai, China*

Background: Triple-negative breast cancer (TNBC) is a heterogeneous disease. T-DXd shows efficacy in the HER2-low TNBC subgroup patients, but its side effects need be more carefully monitored. Molecular subtyping for TNBC provides insight into precision treatment strategies for TNBC patients. It has been reported that TNBC may be classified into LAR, IM, BLIS and MES subtypes based on gene expression profiles ("Fudan Subtyping"). This subtyping was further simplified in an IHC method with the AR, CD8, FOXC1, and DCLK1 biomarkers. Subtyping-based therapy has been shown to provide clinical benefits for TNBC patients in the FUTURE trial. Here we validate novel IHC-based and mRNA-based assays for Fudan subtyping in a TNBC cohort and explore the distribution in HER2-low versus HER2-0 in different subtypes.

Materials and Methods: 129 Formalin-fixed paraffin-embedded (FFPE) TNBC samples were collected from Fudan University Cancer Hospital, between 2019 and 2023. These samples were subtyped by IHC according to previously reported method. Freshly cut FFPE sections with 4∼5 um thickness were stained using Wenfuxi® (Shuwen Biotech) on a Leica Bondmax automatic stainer. An mRNA-based subtyping approach using RNA-Seq was developed on DNBSEQ-T7 platform and the expression of target genes were determined by log2 (FPKM +1).

The overall percent agreement (OPA), positive percent agreement (PPA), negative percent agreement (NPA) and Cohen's kappa was calculated to measure the agreement among the two assays and the previously reported IHC method. Chi-square statistics was also used to analysis the data.

Results: The OPA of TNBC subtyping between the novel IHC-based assay and previously reported IHC- method was 98.4%, and the Cohen's kappa coefficient was 0.980 (95% CI 0.949–1.000, $P < 0.001$). The expression of AR, CD8, FOXC1 and DCLK1 by the novel IHC assay show highly concordant with the previously reported IHC method. The OPA of the four biomarkers are all over 99%.

When comparing the mRNA-based assay to the novel IHC-based assay, the OPA of TNBC subtyping was 72.2%. For AR, the NPA was 95.1% and PPA was 83.3%. The OPA for CD8 and FOXC1 was 85.7% and 88.8%, respectively. Similar results were shown when compared with previously reported IHC-based approach.

According to the results of Wenfuxi®, LAR subtype was significantly higher in HER2-low than in HER2-0 TNBC ($P < 0.05$).

Conclusions: This study suggests that Wenfuxi® is a novel sensitive and specific IHC-based approach for triple-negative breast cancer subtyping. The mRNA-based also has acceptable concordance. Moreover, LAR enrichment in HER2-low TNBC should be further evaluated.

No conflict of interest.

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285 (PB-101) Poster

Malignancy upgrade risk in B3 lesions: do they all require excision biopsy?

J. Su[1], E.J. Sim[1]. [1]*Tan Tock Seng Hospital, General Surgery, Singapore, Singapore*

Introduction: Breast B3 lesions have a heterogenous biological behavior with varying risks of upgrade to malignancy and most lesions undergo open excision after initial biopsy due to this.

Objective: We hypothesized that some of these B3 lesions have low malignancy upgrade risk. We were also interested in the patterns of malignancy upgrade of each B3 lesion as well as whether some low risk B3 lesions can be managed with vacuum assisted excision or surveillance imaging.

Methods: We collected data from our prospective database and identified patients who underwent radiologically guided breast biopsy showing B3 lesions from 1st January 2016 to 1st March 2023. Demographic data, clinical and pathological data were obtained for these patients.

Results: 545 patients with a mean age of 52 years (23–87) underwent breast biopsy with 470 of them diagnosed with B3 lesions. There were a total of 635 B3 lesions noted with overall upgrade risk of 20.2% (95 patients). Majority of them were Chinese (85.9%) with atypical ductal hyperplasia (ADH) being the most common lesion (40.6%). The rest of the B3 lesions included flat epithelial atypia (FEA - 23.3%), intraductal papilloma (IDP - 15.7%), radial scar (8.8%), lobular neoplasia (4.6%) and papillary lesions (4.4%). Highest upgrade rates were noted in papillary lesions (53.6%), radial scars (30.4%) and ADH (27.5%). Majority of papillary lesions which had upgrade were diagnosed to have ductal carcinoma-in-situ (DCIS - 28.6%) and invasive ductal carcinoma (14.3%). The presence of atypia increased the risk of upgrade for most lesions as well. Low upgrade rates were noted in FEA (7.4%) and IDP (3%). Further subgroup analysis revealed that DCIS was the most common malignancy upgrade for all B3 lesions. Low DCIS upgrade rates were again noted for FEA (6.8%) and IDP (2%). In particular, the risk of malignancy upgrade in IDP without atypia was extremely low at 1.3%.

Conclusion: Most B3 lesions have significant risk of malignancy upgrade. However, in select patients with FEA and IDP, this risk is low, and they may benefit from vacuum assisted excision or surveillance instead of open excision biopsy.

No conflict of interest.

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286 (PB-102) Poster

Multidisciplinary pain clinic

S. Grosfeld[1], A. Pijl[2], M. Lauret[3], J. Vlieger[2], M. Ernst[2]. [1]*Alexander Monro Hospital, Utrecht, Horssen, Netherlands;* [2]*Alexander Monro Ziekenhuis, Utrecht, Bilthoven, Netherlands;* [3]*Edema and oncology physiotherapy Oofu, Utrecht, Bilthoven, Netherlands*

Background: After a breast cancer diagnosis, surgery usually follows. The pain after surgery generally disappears on its own. However, in 20–50% of people this pain persists for a longer period of time.

There are different types of pain: acute or chronic pain, including myofascial pain or neuropathic pain.

Material and Methods:

1. 2 months after surgery, patients receive standard pain questionnaires, namely the SF12 and the BPI (Brief Pain Inventory). These pain questionnaires are intended to inventory pain complaints.
2. The Multidisciplinary pain consultation is intended for patients who experience chronic pain complaints that affect daily life. The patient is seen in one afternoon by a clinical nurse specialist; an anesthesiologist-pain specialist; an oncological physiotherapist and a masseur from the “massage by cancer” network. Before the visit, the patient completes the PDI (Pain Disability Index). The patient is then discussed in a multidisciplinary meeting and provided with advice. The clinical nurse specialist looks at what advice the patient can receive in the area of the 6 aspects of positive health. Almost every patient immediately receives exercises and advice from the oncological physiotherapist to help them get started in their own environment; the anesthesiologist discusses for example trigger point treatment. The final massage allows the patient to immediately experience the effect of massage on pain complaints. An evaluation moment with the patient follows after 8 weeks.
3. Pain consultation for other pain complaints as a result of the breast condition and possible treatment therefor by the anesthesiologist-pain doctor.

Results: New insights are being gained into the treatment of pain. These new insights make the patient more self-reliant to act on advice, resulting in less pain and more functional recovery of ADL activities. In addition, the patient is able to regain control over the (pain) complaint. Patients feel taken seriously and 75% of the patients report fewer or no more pain complaints due to recommended interventions.

Conclusion: Through a multidisciplinary approach, multiple insights into the cause and treatment of pain complaints. Knowledge and explanation helps reduce pain complaints.

No conflict of interest.

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287 (PB-103) Poster

The microbiome of patients with breast cancer; observational study on the microbiome composition of breast cancer patients and the effects of chemotherapy treatment on the microbiome

S. Grosfeld[1], M. Ernst[2]. [1]*Alexander Monro Hospital, Utrecht, Horssen, Netherlands;* [2]*Alexander Monro Ziekenhuis, Utrecht, Bilthoven, Netherlands*

Background: Research into the role of bacteria in an individual’s health and the role they play in the development of inflammation and cancer has not yet led to a full understanding of them. It is important to gain more clarity about which bacteria play a role in maintaining health.

Recent research among a group of women (n = 32) concluded that the bacteria of women with breast cancer differed from those of healthy women. The results seem to indicate that certain bacteria may be associated with the development of cancer and different responses to treatment. Even though there appears to be a relationship between the composition of the microbiome and breast cancer, it is still unclear whether the composition (disruption) of the microbiome is the reason for the cancer or only contributes to the disease.

Material and Methods: This study was conducted with 15 patients from the Alexander Monro Hospital diagnosed with breast cancer with ER/PR positive and HER-2 negative disease and receiving neoadjuvant chemotherapy (NAC; ddAC followed by Paclitaxel). The enrolled patients were asked to take a stool sample at two times (before and 1weeks after NAC) to have their microbiome checked.

Results: 14 women had abnormal immunogen-acting bacteria pre-chemotherapy. In 13 patients, these bacteria were moderately to severely reduced. This is striking because these bacteria mainly cause complaints when they are present in increased numbers. Most women (13) had a reduced presence of Equol-promoting bacteria. Equol can bind to the estrogen receptors ERa and ERb. It has antioxidant, immune-stimulating and anti-inflammatory properties. If you have enough Equol-promoting bacteria in the stool (>5.0 × 1^9), it can have a protective effect in developing breast cancer. After chemotherapy, the immunogenic bacteria were increased in 2 women, the significance of this must be further investigated. The amount of Equol-promoting bacteria was normalized in two women. In the woman with a complete remission after chemotherapy the microbiome was better after chemotherapy.

Conclusions: It is striking that the Equol-promoting bacteria were reduced in a large proportion of patients. As a result, these patients may have missed the protective effect against developing breast cancer. Microbiome composition appears to be improved with complete remission. The immunogenic bacteria appear to have little influence on the course of the disease in the population studied. Research will soon be conducted in a larger group of women who receive neo-adjuvant chemotherapy, at the same time a group of women without breast cancer will also have their microbiome analyzed.

No conflict of interest.

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288 (PB-104) Poster

Clinical-pathological characteristics and progression of breast cancer at the Hospital de Clínicas mastology unit

N. Camejo[1], D. Amarillo[1], C. Castillo[1], M. Mengui[1], S. Miraglia[1], I. Siécola[1], V. Mustafá[1], N. Vila[1], M. Gonzalez[1], G. Krygier[1]. [1]*School of Medicine, University of Uruguay, Department of Clinical Oncology, Montevideo, Uruguay*

Introduction: In Uruguay, breast cancer (BC) is the leading cause of cancer incidence and mortality among women. It is a multifactorial disease associated with genetic inheritance, estrogenic hormonal history, lifestyle, environmental, and cultural factors.

Objectives: To investigate the clinical-pathological characteristics of patients diagnosed with BC at the Hospital de Clínicas and to assess the overall global survival (OGS) according to the biological subtype.

Materials and Methods: Data related to the clinical-pathological characteristics and evolution of patients treated for BC between January 1, 2011, and December 31, 2020, at the Mastology Unit of the Hospital de Clínicas were collected. Overall survival (OGS) was calculated for all patients, globally, and according to biological subtype.

Results: A total of 390 patients were included. Clinical-pathological characteristics were: ductal carcinoma: 83%, stage: in situ (1.8%), I (27.7%), II (29.7%), III (23.6%), IV (12.6%). Regarding the biological profile: 235 tumors (60.3%) were HR+/HER2−, 88 tumors (22.6%) were HER2+, while another 41 tumors (10.5%) were classified as triple-negative (TN). The OGS median for all patients was 92 months. The 2- and 5-year OGS rates for luminal tumors were 92% and 64%; in TN tumors, the OGS rate at 24 months was 69%, with a 5-year rate of 53.3%, and for HER2+ 76.6% and 67.3%, respectively.

Conclusions: Most tumors were diagnosed at early stages, consistent with data reported in national studies. The frequency of HR+/HR−tumors was slightly lower than the 70% reported in previous national studies, while the prevalence of HER2+ and TN tumors was similar to that reported in European, North American, and Latin American studies, where the prevalence found is around 20%.

No conflict of interest.

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289 (PB-105) Poster

Breast Pain: Optimal clinical pathway

A. Munir[1], A. Huws[1], K. Nelson[1], S. Khan[1], N. Javed[1], Y. Sharaiha[1], S. Khawaja[1]. [1]*Prince Philip Hospital, Breast Surgery, Llanelli, United Kingdom*

Introduction: One third of the referrals to a symptomatic breast units in United Kingdom are due to breast pain. There is a very low risk of detecting breast cancer in patients who present with breast pain only and clinically do-not have a lump or another red flag signs.

Aims: The aim of this service improvement project was to identify the risk of detecting breast cancer in patients referred with pain only.

Methods: All patients referred by GP with complaint of breast pain were triaged by one of four senior clinicians. These patients were seen in a dedicated clinic by a trained advanced nurse practitioner. They all had a mammogram and an US was done by a senior clinician only if dictated by clinical exam or mammogram findings.

Results: In 18 months, 124 patients were seen in these clinics. Ultrasound was deemed necessary in 42/124 patients (based on mammographic density/physical findings). 7/124 patients had biopsies done based on clinical or radiographic findings. Only one patient was diagnosed with grade 1 IDC 10 mm, who required a vacuum assisted biopsy for calcifications. The rate of cancer detection in patients with breast pain only and no palpable lump was 1/124 (0.8%).

Recommendation: Our initial experience indicates that stratifying patient referrals and seeing these patients in a dedicated clinic is safe and may reduce the workload and improve waiting time for Urgent Suspected Cancer cases in symptomatic breast clinic.

No conflict of interest.

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290 (PB-106) Poster

Improving the accuracy of breast cancer diagnosis in multi-protein signature markers using artificial intelligence algorithms

Y. Kim[1], S.S. Kim[2], C.S. Yoon[1], J.M. Park[1], W. Han[3], D.Y. Noh[1]. [1]*CHA Gangnam Medical Center, CHA University School of Medicine, Department of Surgery, Seoul, South Korea;* [2]*Bertis. Inc, Manufacturing and Technology Division, Yongin-si, South Korea;* [3]*Seoul National University College of Medicine, Department of Surgery and Cancer Research Institute, Seoul, South Korea*

Background: In our previous study, we developed a 3-protein signature blood marker using a proteomics technique for early diagnosis of breast cancer. This study is to evaluate the breast cancer diagnosis performance of a newly developed 7-protein signature blood marker with artificial intelligence techniques by adding candidate proteins to existing blood markers to improve breast cancer diagnosis.

Material and Methods: A total of 323 breast cancer patients and 221 health control blood samples were analyzed. From July 2022 to October 2023, 221 breast cancer patients and 121 health controls were prospectively enrolled. In addition, 101 blood from breast cancer patients and 100 blood from health control groups were provided from other institutions and included in the analysis. In previous studies, peptides that are optimal for MS/MS detection were selected through the development of the PepQuant library, a biomarker detection library. The selected proteins were chemically synthesized and then quantified by a multi-reaction monitoring (MRM) method. After discovering and verifying breast cancer biomarkers, algorithms were developed using five machine learning (ML) models for seven types of plasma analysis proteins (APOC1, CHL1, FN1, vWF, PRG4, CLU, and MMP9) and nine types of serum analysis proteins (FN1, VWF, PRG4, MMP9, CLU, PRDX6, PPBP, APOC1, and CHL1). As there was no significant difference in performance between ML models, it was found that the biomarker properly distinguished breast cancer and healthy control samples. Among ML models, the deep learning model showed slightly higher performance with an average AUC of 0.9000. To evaluate the performance of breast cancer diagnosis, performance evaluation was conducted based on sensitivity, specificity, accuracy, false positive rate, false negative rate, positive predicted value, and negative predicted value.

Results: The sensitivity, specificity, and accuracy of the 3-protein signature developed in the previous study were similar to the previous results. The sensitivity, specificity, and accuracy of the multi-protein signature analyzed using a new machine learning model were 84.6%, 70.0%, and 77.9%, respectively, which outperformed the previous markers. The false positives and false negatives were 30% and 15.4%, indicating a 23% improvement in false negatives over previous markers. In addition, positive and negative predictions were also recognized to be improved to 74.2%, 83%.

Conclusions: Breast cancer diagnosis using a multi-protein signature developed with AI models showed that breast cancer diagnosis can be significantly improved compared to before.

Conflict of interest:

Ownership: Dong-young Noh is Co-CEO of Bertis Inc.

Board of Directors: Sung-soo Kim is paid as a chief researcher at the Bertis Inc.

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291 (PB-107) Poster

Characteristics of mammogram occult breast cancer – Retrospective review in single center in Singapore

C.P.C. Ng[1], E.Y. Tan[2,3], M.Y.P. Chan[2]. [1]*Woodlands Health, Department of Surgery, Singapore, Singapore;* [2]*Tan Tock Seng Hospital, Department of General Surgery, Singapore, Singapore;* [3]*Lee Kong Chian School of Medicine, Surgery, Singapore, Singapore*

Background: Mammogram (MMG) has been used as the screening tool for breast cancer in Singapore. However, breast density in Asian population is generally higher and may lower the sensitivity of cancer detection. The aim of this study is to evaluate the clinical, radiological and pathological characteristics of MMG occult cancer.

Material and Methods: All female patients with histologically proven breast cancer in Tan Tock Seng Hospital from 2012 to 2022 were included in this retrospective study. Relevant clinical, radiological and pathological data were collected and analyzed from the hospital breast cancer database.

Patients with incomplete clinical data or incomplete radiological assessment (only MMG or ultrasound performed) were excluded. Statistical analysis was performed using SPSS 25.0 (IBM®).

Results: 2688 patients were included for analysis. 2563 patients (95.3%) with breast cancer could be detected by either MMG alone (N = 240) or in combination with ultrasound (N = 2323) (MMG detectable), while 125 patients (4.7%) with breast cancer had a normal MMG (MMG occult).

Patients with MMG occult cancer were younger with a median age of 54 years old, compared to 60 years old in patients with MMG detectable cancer ($p < 0.01$).

57 patients (45.6%) with MMG occult cancer were asymptomatic, while 923 patients (36.0%) were asymptomatic with MMG detectable cancer ($p = 0.036$). The most common presenting symptom was breast lump in both groups (73.5% in MMG occult cancer and 92.1% in MMG detectable cancer).

In patients with MMG occult cancer, 50.4% had dense breast (score C) and 12% had extremely dense breast (score D). The proportion of patients with dense or extremely dense breast was higher in MMG occult cancer comparing to MMG detectable cancer (95.1% vs 86.2%, $p = 0.019$).

Majority of the patients were diagnosed to have invasive ductal carcinoma in both groups (57.6% in MMG occult and 68.2% in MMG detectable cancer). Among patients with invasive cancer, the proportion of early invasive cancer (T1) was higher in MMG occult cancer (66.0% vs 43.9%, $p < 0.01$). There was also a higher proportion of carcinoma in-situ detected among patients with MMG occult cancer comparing to those with MMG detectable cancer. (24.8% vs 17%, $p = 0.029$). The overall proportion of early invasive cancer and carcinoma in-situ were higher in the MMG occult cancer group compared to the MMG detectable cancer group ($p < 0.01$).

Conclusions: Whilst MMG is a sensitive tool in detecting breast cancer, the addition of ultrasound may further improve the detection rate with MMG occult cancer, in particular young patients with dense breast.

No conflict of interest.

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292 (PB-108) Poster

Predictive value of contrast enhanced spectral mammography (CESM) and mammotome guided biopsy of clipped tumour in determining pathological complete response following neoadjuvant chemotherapy in breast cancer patients

S.S.H. Phua[1], P.M.Y. Chan[1], E.Y. Tan[1], J. Chen[1], E.J. Sim[1]. [1]*Tan Tock Seng Hospital, General Surgery, Singapore, Singapore*

Background: Breast cancer is the top cancer in female globally. Neoadjuvant chemotherapy (NAC) is an established approach in certain groups of breast cancer patient. Pathologic complete response (PCR) following NAC has been suggested to be a good prognostic factor with potential better disease-free survival and overall survival. In fact, there are ongoing studies evaluating the outcomes of avoiding breast surgery on patients with predicted PCR. Having a good technique to predict PCR will help us identify these potential patients. Our study aims to evaluate the predictive value of contrast enhanced spectral mammography (CESM) and mammotome biopsy of clipped tumour in determining PCR following NAC.

Material and Method: 37 patients who were undergoing neoadjuvant chemotherapy for breast cancer were prospectively studied between November 2019 to September 2023. These patients underwent contrast enhanced spectral mammogram (CESM) pre and post neoadjuvant chemotherapy to evaluate the mass as seen on CESM. In addition, a vacuum assisted biopsy (VAB) is done intraoperatively, just prior to the tumour resection surgery.

Results: We prospectively reviewed 37 patients. Despite 94.6% (35/37) of the women having dense breast on mammogram, 97.3% (36/37) of the tumour could be picked up with contrast enhancement, with majority showing intense enhancement prior to NAC. All tumours showed reduction in enhancement following NAC. 29.7% (11/37) achieved PCR following NAC. Regardless of PCR status, patients who underwent NAC may show total resolution of tumour enhancement on CESM. However, those with PCR have a higher likelihood of showing complete resolution of tumour enhancement. 15.3% (4/26) of the tumours which did not achieve PCR showed no further enhancement in the post NAC CESM, while 54.5% (6/11) of the tumours which achieved PCR showed no further enhancement in post NAC CESM. In correlating mammotome guided biopsy of clip prior to formal surgical resection, 82.8% (29/35) of the patients showed concordance between the mammotome biopsy and final tumour specimen histology.

Conclusion: Mammotome guided biopsy of clip appears to have high predictive value in determining PCR following NAC. This will have a remarkable impact in the management of breast cancer as a significant group of patients may potentially avoid the morbidity of a surgery. Further studies can be performed to determine if (I) more experience will improve mammotome technique and further increase its predictive value, and (ii) incorporating artificial intelligence helps to improve the predictive value of CESM.

No conflict of interest.

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293 (PB-109) Poster

Contrast-enhanced mammography (CEM) with magnetic tracer as an alternative to MRI

C. Benn[1], D. van Loggerenberg[2]. [1]*Breast Care Centre of Excellence - South Africa, Department of surgery, Johannesburg, South Africa;* [2]*Breast Care Centre of Excellence - South Africa, Research, Johannesburg, South Africa*

Aim: The use of a superparamagnetic iron oxide versus Technetium-99 m and blue dye for sentinel lymph node biopsy (SLNB) in patients with early-stage breast cancer is viable, reliable, and non-inferior method of detection. Concerns around the impact on the quality of radiological assessments post magtrace injection resulted in a comparative trial between contrast-enhanced mammography (CEM) imaging and MRI and the radiologist's ability to determine the extent of disease.

Method: A total of 55 patients with biopsy-proven breast cancer patients and assessed as axillary metastatic node negative on imaging were reviewed. Histologically confirmed diagnosis and clinically and radiologically cT0-4 N0 breast cancer due for Mx/Lx + SLNB/TAD were injected with 2 ml of Magtrace and underwent radiological tests (Contrast-enhanced Mammogram and MRI) to assess the amount of interference or image artefacts due to Magtrace injection and the ability to assess the extent of disease.

Results: Assessment on CEM the Magtrace did not impact the image nor the interpretation in all subjects.

Nodal information from the CEM was obtained.

Patients' experience, based on VAS pain score, showed a return to normal pain levels within 5 minutes of Magtrace injection; a significant pain increase was seen in less than 10% of study participants.

Conclusion: The usage of Magtrace in conjunction with CEM does not negatively impact the diagnostic capabilities of the radiologist and can be considered a non-inferior alternative to traditional blue dye. Where a longer-term tracking of axillary SLNB is beneficial, such as those patients requiring primary chemotherapy, Upfront magtrace injection provided information about nodal drainage to the axillary as well as the internal mammary basin. This provides further useful insight as to which patients may be eligible for de-escalation of radiation treatment or a more focused radiation planning.

Patients with contraindications to blue dye or severe medical or psychological aversions to MRI - can have a diagnostically equivocal option with the use of Magtrace and CEM.

No conflict of interest.

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294 (PB-110) Poster

Preoperative ultrasonic guided lymph node tattooing of clinically negative axilla may boost sentinel node biopsy. Initial results

O. Hussein[1], E. Elnaghi[2], S. Elbalkah[1]. [1]*Mansoura University Oncology Center, Surgical Oncology, Mansoura, Egypt;* [2]*Mansoura University, Radiology and Diagnostic Imaging, Mansoura, Egypt*

Introduction: Sentinel lymph node biopsy (SLNB) has become a standard of care in patients with clinically negative axilla. In its simplest form, SLNB using the methylene blue dye successfully identifies the sentinel node in 88–94% of cases. Various methods have been investigated to increase the identification rate and decrease the false negative rate of SLNB. Ultrasonography is an established tool for preoperative axillary staging.

In this study, the investigators perform preoperative ultrasonographic axillary evaluation and tattooing of suspicious lymph nodes followed by SLNB with methylene blue technique. Head-to-head and node-to-node comparison of ultrasonographic and surgical staging is conducted. The

objective is to test whether preoperative ultrasonographical tattooing can compensate for the non-identification rate of methylene blue dye technique of SLNB.

Methods: Preoperative ultrasonographic evaluation of clinically negative axilla. Nodes with either round shape, cortical thickness >3 mm, or with eccentric hilum are tattooed with sterile charcoal. Sentinel node biopsy is performed with peri-areolar subdermal injection of 3 ml methylene blue 5%. All blue, enlarged and /or tattooed nodes are separately biopsied and labelled as SLN and/or tattooed node.

The study is prospectively registered (ClinicalTrials.gov Identifier: NCT04644848). Institutional ethical approval and informed consent of all participants have been obtained.

Results: Of 16 patients, 11 had negative both sentinel and tattooed nodes, two patients had negative sentinel nodes that were also tattooed, and one patient had positive both sentinel and tattooed nodes. Interestingly, two patients with negative sentinel nodes had positive tattooed nodes.

Conclusions: Contrary to hypothetical expectations, preoperative ultrasonography did not localize the exact sentinel node(s) in 75% of cases. In most patients, charcoal tattoo and blue dye did not stain the same nodes. However, head-to-head concordance was 87.5%. Moreover, false negative sentinel node biopsy was rescued with ultrasonographic tattooing in 12.5% of cases.

No conflict of interest.

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295 (PB-111)

Breast cancer in Morocco: A comprehensive review of clinical and radiological features

F. Aboulhoda[1], O. Erefai[1], F. Bejja[1], A. El Maroudi[2], C. Telfine[3], A. Soulaymani[1], A. Mokhtari[1], H. Hami[1]. *[1]Laboratory of Biology and Health-Faculty of Science, Ibn Tofail University, Kenitra, Morocco; [2]Béclère, Radiology Center, Kenitra, Morocco; [3]Abou El Kacem Zahraoui, Hospital, Ouezzane, Morocco*

Background: Breast cancer is the leading form of cancer among women worldwide, and it remains a significant issue in Morocco. This study aims to provide a detailed description of the clinical and radiological characteristics of breast cancer cases in a Moroccan setting.

Material and Methods: We conducted a retrospective study on patients diagnosed with breast cancer at the Reference Center for Reproductive Health in Kenitra over a 6-year period (2013–2018). Patient profiles, including clinical presentations and radiological findings, were meticulously evaluated.

Results: In a cohort of 973 women diagnosed with breast cancer, we analyzed 891 radiological reports derived from mammography and ultrasonography. The mean age at diagnosis was 51.3 ± 12.4 years, and 67% of the patients were married. The initial pregnancy age averaged at 23.8 ± 6.8 years, coupled with an average of 4.3 ± 2.4 pregnancies, resulting in 3.75 ± 2.3 live births per patient. The cohort showed a predominance of postmenopausal individuals (53%), and 55% had histories of hormonal contraceptive usage for an average of 9 years. A family history of breast cancer was reported in 89 patients, 43% of whom were related to a sister lineage. Notably, 97% of the examined patients were assigned a BI-RADS classification of 4 or 5, with the left breast being involved in 50% of cases. Lesions predominantly displayed spiculated or irregular margins (87%) and dense breast tissue was identified in 34% of the cases as type 3 or 4. Microcalcifications were detected in 31% of the participants. Lesion localization was primarily in the superior-external quadrant (36%), with the majority characterized as hypoechoic (99%) and attenuating (76%). Axillary adenopathy was noted in 60% of cases, and the mean tumoral dimension was recorded at 29.3 ± 17.3 mm.

Conclusions: The integration of mammography and ultrasonography is critical for the accurate diagnosis of breast cancer and provides valuable information for characterizing and classifying abnormal findings. This binomial imaging approach is essential for directing clinical decision-making toward further pathological evaluation or vigilant monitoring.

No conflict of interest.

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POSTER SESSION **22 March 2024** **9.00–14.30**

Precision Medicine

296 (PB-112)

Geriatric-8 as a screening tool in elderly breast cancer patients for prediction of mortality in Indian cohort

S. Sable[1], T. Wadasadawala[1], R. Sarin[1], R. Pathak[1], R. Krishnamurthy[1], S. Ghosh[1], T. Shet[2], J. Bajpai[3], S. Joshi[4], P. Popat[5], S. Gulia[3]. *[1]Tata Memorial Centre- Homi Bhabha National Institute, Radiation Oncology, Mumbai, India; [2]Tata Memorial Centre- Homi Bhabha National Institute, Pathology, Mumbai, India; [3]Tata Memorial Centre- Homi Bhabha National Institute, Medical Oncology, Mumbai, India; [4]Tata Memorial Centre- Homi Bhabha National Institute, Surgical Oncology, Mumbai, India; [5]Tata Memorial Centre- Homi Bhabha National Institute, Radiodiagnosis, Mumbai, India*

Background: The PROTECT study (CTRI/2021/07/034792) aimed to assess the accuracy of different geriatric assessment tools for prediction of cumulative incidence of 1-year mortality. The Geriatric-8 (G8) was one of the tools used in this study. It is a short screening tool containing eight-items, and is derived from comprehensive geriatric assessment tool.

Material/Methods: The study sample comprised of 300 newly diagnosed breast cancer patients aged ≥65 years who were treatment naïve at the time of initial evaluation. Patients were accrued from July 2021 to November 2022. Geriatric assessment was done before treatment initiation. G8 captures age, food intake, weight loss, mobility, neuropsychological problems, body mass index, drugs and health status. It is an interviewer-based assessment and takes approximately 5 minutes to complete. It is scored between 0–17 and score ≤14 is considered to have considerable vulnerabilities. The data was locked in 31st October 2023 for purpose of survival analysis. The overall survival rate was calculated using Kaplan-Meier survival analysis. The log-rank test was used to know prediction of survival rate by prognostic factors and G8. Multi-variate analysis was done using Cox regression and hazards ratio.

Results: The median age was 70 years. About half (51%) of the patients had co-morbidities. There were 234 (78%) non-metastatic patients and 66 (22%) metastatic patients. The median follow-up time for the current analysis was 15 months (CI 14–15.8), by reverse Kaplan-Meier method. We documented 38 (12.6%) patients as dead. The cumulative incidence of mortality was 14.6%. Several prognostic factors were analysed to study correlation with mortality. We observed a significant association with survival rate for stage (metastatic vs non-metastatic group [p = 0.00]) and hormone receptor status (positive vs negative [p = 0.01]). A significant association of low G8 score (score ≤14) with survival rates (p = 0.00) was observed. No association was seen with other factors like WHOPS and presence or absence of co-morbidities. On multivariable analysis, presence of metastatic disease (HR 2.2, CI 1–4.5) and low G8 score (HR 2.48, CI 1.2–5) showed a significant difference in survival, whereas no difference was seen for hormone receptor status (Table 1)

Table 1: Results of survival analysis for prognostic factors and G8 score

Factors		2 yr-survival (%)	p-value*	Hazard Ratio*
Metastatic disease	No	88.6	0.001	Ref
	Yes	74.8		2.2
Hormone receptor	HR+	90.3	0.05	Ref
	HR-	72.6		1.9
G8 score	>14	92.5	0.02	Ref
	≤14	76.4		2.48

*from multivariate analysis

Conclusion: Low G8 scores (≤14) predicts poor survival. Patients with metastatic disease and hormone receptor negative status have low survival. Geriatric-8 seems a promising baseline screening tool offering the potential to aid in the identification of vulnerable patients.

No conflict of interest.

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297 (PB-113) Poster

Insights into HER2-Low Status and the Breast Cancer Immune Microenvironment: A 20-Gene Signature Study

S. Di Cosimo[1], S. Pizzamiglio[2], C.M. Ciniselli[2], V. Duroni[2], A. Blanda[2], V. Cappelletti[1], L. De Cecco[3], C. De Marco[1], M. Silvestri[1], J. Cortes[4], A. Llombart-Cussac[5], M.C. De Santis[6], A. Vingiani[1], B. Paolini[7], R. Orlandi[8], M.V. Iorio[8], G. Pruneri[1], P. Verderio[2]. *[1]Fondazione IRCCS Istituto Nazionale dei Tumori, Department of Advanced Diagnostics, Milan, Italy; [2]Fondazione IRCCS Istituto Nazionale dei Tumori, Bioinformatics and Biostatistics Unit, Department of Epidemiology and Data Science, Milan, Italy; [3]Fondazione IRCCS Istituto Nazionale dei Tumori, Molecular Mechanisms Unit, Department of Research, Milan, Italy; [4]International Breast Cancer Center IBCC, Pangaea Oncology, Quironsalud Group, Barcelona, Spain; [5]Hospital Arnau de Vilanova-Liria, Clinical and Molecular Oncology Laboratory, Valencia, Spain; [6]Fondazione IRCCS Istituto Nazionale dei Tumori, Radiation Oncology 1, Breast Unit, Milan, Italy; [7]Fondazione IRCCS Istituto Nazionale dei Tumori, Department of Pathology, Milan, Italy; [8]Fondazione IRCCS Istituto Nazionale Dei Tumori, Molecular Targeting Unit, Milan, Italy*

Background: HER2 antibody-drug conjugates are reshaping the conventional HER2 status dichotomy, heightening expectations in the realm of HER2 status assessment and its associated molecular characterization. In this context, we have tasked gene expression profiling (GEP) with accurately identifying HER2-low tumors and exploring variations in tumor-infiltrating immune cell (TIIC) composition according to HER2-low GEP-based scores.

Materials and Methods: GEP data from primary tumors of newly diagnosed breast cancer patients (n = 304) were collected from institutional databases INT1 (n = 125), INT2 (n = 84), and INT3 (n = 95), and used for the generation of a specific HER2-low signature and for the deconvolution of TIICs by CIBERSORTx. The association between HER2-low signature scores and TIICs was analysed using Spearman correlation coefficient (r), with a 95% confidence interval (CI) calculated through bootstrap methods. In silico analyses were performed using data from The Cancer Genome Atlas Research Network (TCGA, n = 783).

Results: A 20-gene HER2-low signature, derived through the analysis of differentially expressed genes across HER2 immunohistochemistry categories, effectively discriminated HER2-low tumors (showing high scores) from those classified by immunohistochemistry as HER2 0 or 3+ (showing low scores). Notably, the signature scores demonstrated the capability to differentiate between 1+ versus 0, and 2+ versus 0 categories, regardless of hormone receptor status. In all INT datasets and in the TCGA, a negative correlation was found between the fraction of M1 macrophages and the 20-gene HER2-low signature scores. Similarly, a negative correlation of CD8+ T cells and activated memory CD4+ T cells with the 20-gene HER2-low signature scores was observed in INT3 (r = −0,32; 95%CI − 0.49; −0.11 and r = −0,43; 95%CI −0.59; −0.24) and TCGA (r = −0,38; 95%CI −0.44; −0.32 and −0,36; 95%CI −0.42; −0.29) datasets. These correlations remained consistent across both positive and negative hormone receptor status. In contrast, monocytes exhibited a positive association with the 20-gene HER2-low signature scores (r = 0.25; 95% CI 0.02; 0.45), but this relationship was limited to triple negative breast cancer.

Conclusions: The increase in the score of a specific 20-gene signature adept at accurately identifying HER2-low is associated with progressive depletion of M1 macrophages, thereby extending the prior observation of reduced T-cell fraction. The enrichment of monocytes within triple negative tumors suggests heterogeneity among HER2-low breast cancer, emphasizing the impact of hormone receptor status. This emerging data holds implications for better identifying HER2 status and understanding the mechanisms underlying the action and resistance of new drugs including antibody-drug conjugates.

No conflict of interest.

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298 (PB-114) Poster

Changes in treatment recommendations for patients with ductal carcinoma in situ using a 7-gene predictive biosignature: Analysis of the Australian PREDICT registry

Y. Zissiadis[1], K. Kirkham[2], A. Driver[3], L. Donnelly[2], S. Shivers[4], T. Bremer[4], B. Mann[5], M. Dreosti[6]. *[1]Genesiscare, Hollywood Private Hospital, Perth, Australia; [2]Genesiscare, Australia, Melbourne, Australia; [3]Genesiscare, Australia, Sydney, Australia; [4]PreludeDx, Laguna Hills, California, USA; [5]Royal Women's Hospital, Surgery, Melbourne, Australia; [6]Genesiscare, Australia, Adelaide, Australia*

Background: The role of adjuvant radiotherapy (RT) following breast-conserving surgery (BCS) for ALL women with ductal carcinoma in situ (DCIS) remains controversial. Although there is Level 1 evidence supporting the use of RT to reduce the risk of local recurrence, prognostic and predictive tools are needed to better stratify individual risks and benefits of RT. Historically clinical and pathological features have been used to guide the use of RT following breast conserving surgery in these patients. The 7-gene predictive DCIS biosignature provides a validated score (DS) for women receiving BCS that assesses 10-year risk of DCIS and invasive cancer recurrence with and without adjuvant RT. This study reports the impact of this biosignature on treatment decisions for this group of women with DCIS treated with breast conserving surgery in Australia.

Materials and Methods: The PREDICT study is a prospective, multi-institutional registry for patients who received DCISionRT testing as part of their routine care. The registry includes females 26 and older who are diagnosed with DCIS and are candidates for BCS and eligible for RT. Treating physicians completed treatment recommendation forms before and after receiving test reports to capture surgical, radiation and hormonal treatment (HT) recommendations and patient preferences.

Results: This planned interim analysis was performed in 442 patients with complete data treated at 43 clinical sites in Australia. 14% of women were 50 or younger, nuclear grade was high in 50%, and tumour size was 2.5 cm or greater in 15%. Overall, RT recommendation (yes/no) was changed for 42% of women after testing with a net reduction in recommended RT of 15% (66% pre-assay to 51% post-assay $p < 0.001$). Of patients recommended to receive RT pre-test, 43% were recommended to not receive RT post-test and of the patients recommended to not receive RT pre-test, 40% were recommended to receive RT post-test. The post-test RT recommendation rate increased with increasing DS score (< 2, 2–4, >4), with 9% of patients recommended RT for DS< 2, 63% for DS 2–4, and 100% for DS 4–10. The use of the test resulted in different RT recommendations than with clinicopathology alone, where RT recommendations were changed for 48%, 37%, and 35% for women of age< 50 years, with Grade 3 DCIS, or with DCIS > 2.5 cm, respectively. Collectively, this suggests that physicians had a high confidence in the test results when making their final treatment recommendations with the test results.

Conclusions: This analysis demonstrates that the use of the 7-gene predictive biosignature resulted in significant changes in recommendations to add or omit RT in this study of 442 women. The integration of DCISionRT into the clinical decision-making processes has a substantial impact on recommendations to personalize care and prevent over- or under-treatment.

No conflict of interest.

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299 (PB-115) Poster

Improved Chemosensitivity Prediction for HR+HER2- Breast Cancer Patients with MammaPrint High2 risk group in the FLEX Trial

J. O'Shaughnessy[1], A. Sonnenblick[2], S. Strulov Shachar[3], S. Kümmel[4], L.A. Fischer[5], D. Rezek[6], D. Pronin[7], A. Menicucci[8], W. Audeh[8]. *[1]Baylor University Medical Center, Texas Oncology, Dallas, USA; [2]Tel Aviv Sourasky Medical Center, Devision of Oncology, Tel Aviv, Israel; [3]Tel Aviv Sourasky Medical Center, Division of Oncology, Tel Aviv, Israel; [4]Kliniken Essen-Mitte, Breast Unit, Essen, Germany; [5]Municipal Hospital Holweide, Breast Cancer Center, Cologne, Germany; [6]Marien-Hospital, Breast Cancer Center, Wesel, Germany; [7]Agendia NV, Medical Affairs, Amsterdam, Netherlands; [8]Agendia Inc., Medical Affairs, Irvine, USA*

Background: Hormone receptor-positive (HR+), HER2-negative early-stage breast cancer (EBC) is known for its heterogeneity and varying responses to neoadjuvant chemotherapy (NCT)s. Genomic profiling has emerged as a valuable tool to guide pre-operative treatment decisions in EBC by predicting the likelihood of a pathological complete response (pCR) or chemosensitivity. The 70-gene MammaPrint (MP) test has been instrumental in classifying patients with EBC into Low or High Risk categories of developing distant metastasis. Further stratification of the MP High Risk group into High 1 (H1) and High 2 (H2) category has shown significantly improved pathologic complete response (pCR) rates, following NCT or targeted agents including immunotherapy, in MP H2 tumors compared MP H1. This analysis assesses the utility of MP H1/H2 risk stratification as a

biomarker for chemosensitivity in patients with HR+HER2- EBC enrolled in the real-world FLEX Trial.

Methods: The FLEX Trial (NCT03053193) is an ongoing prospective, observational study involving patients who underwent MP testing, with or without molecular subtyping using BluePrint, and consented to comprehensive genome data collection. This analysis includes patients with HR+HER2-, MP High Risk tumors with available treatment response data. Patients were further categorized into H1 (MP index 0.000 to −0.569) and H2 (MP index −0.570 to −1.000) groups. BluePrint classified tumors as Luminal-, HER2-, or Basal-Type. pCR was assessed in a subset of patients treated with NCT (n = 260).

Results: Among patients with MP High Risk tumors, 64% (n = 166) had a MP H1 tumor and 36% (n = 94) had a MP H2 tumor. Menopausal status, tumor stage, and lymph node status were comparable between both groups. A substantial 75% (71) ($p < 0.001$) of tumors within the H2 group were categorized as Grade 3; this observation suggests a higher prevalence of aggressive tumors within this group. This also highlights that H2 can be present across various tumor grades. Nearly all (97%) H1 tumors were Luminal-Type, while for H2 tumors, 46% were Luminal-Type, and 54% were Basal-Type. A significantly higher *proportion of patients achieved pCR in the MP* H2 *group* (27/94; 28.7%) vs. MP H1 (11/166; 6.6%) ($p < 0.001$). Among Basal-Type tumors, H2 tumors exhibited the highest pCR rate (38.8%) compared with H1 tumors (20%) ($p = 0.02$). In Luminal-Type tumors, H2 tumors had a significantly higher pCR (16.6%) compared with H1 tumors (6.3%) ($p = 0.033$).

Conclusion: These findings indicate the utility of MammaPrint in predicting pCR following NCT in patients with HR+HER2- EBC. Tumors with MammaPrint H2 demonstrated higher chemosensitivity than H1 tumors. H2 biomarker stratification can aid in identifying Luminal B tumors that are more likely to benefit from NCT.

No conflict of interest.

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300 (PB-116) Poster

Real-world analysis of genomic signature indications and impact on adjuvant chemoendocrine therapy (CET) decisions: experience from the French LISE cohort (n = 301)

B. Cutuli[1], C. Charles[2], F. Bancheri[3], Y. Caron[1], D. Coeffic[1], P. Colin[1], P.H. Dorangeon[3], S. Ferrand[3], N. Gavillon[3], C.G. Hemery[1], N. Jovenin[1], L. Krebs[1], A.R. Majidi[3], F. Mallet[1], W. Mina[1], K. Prulhiere-Corviole[1], P. Terrosi[3], A. Theillier[3], I. Veron-Leclercq[3], G. Yazbek[1]. *[1]Centre Icone, Radiotherapie-Oncologie, Bezannes, France; [2]Scilink, Clinical research, Biarritz, France; [3]Polyclinique de Courlancy, Chirurgie, Reims-Bezannes, France*

Background: We aimed to assess real-world indications of the Oncotype DX® assay in early-stage breast cancer (BC) pN0/1 patients (pts) and its impact on adjuvant CET use.

Methods: LISE is an ongoing observational study comprehensively evaluating BC characteristics, management practices and outcomes in 3,367 pts (including 2,929 invasive cases) diagnosed from Jan 2010 to Nov 2023 at Courlancy Cancer Institute & Centre Icone (Reims, France).

Results: A first interim analysis from 1,512 eligible HR+/HER2- pts showed Oncotype DX testing in 301 tumors (19.9%, 2014–2023). Pt baseline characteristics were: age distribution at diagnosis, ≤50 years (y) 33.9%, 51–70 y 55.1%, >70 y, 11.0%; menopausal status, 63.8% postmenopausal, 36.2% premenopausal. Clinicopathological features were: pathological tumor size, pT1a 1.0%, pT1b 13.0%, pT1c 58.5%, pT2 26.6%, pT3–4 1.0%; tumor grade, SBR I 13.6%, SBR II 67.4%, SBR III 18.9%; main histological subtypes, invasive ductal carcinoma 81.7%, invasive ductal carcinoma 13.7%; molecular subtypes, luminal A 32.9%, luminal B HER2- 67.1%; Ki67 ≥20% in 64.7%; node status, pN0 72.4%, pN1mi 9.0%, pN1 18.7%.

The most common indication for Oncotype DX testing was for discordant or intermediate histoprognostic factors (50.8%). Other reasons included the need to confirm endocrine therapy only or CET indication (24.3% and 20.3%, respectively). Cases with unjustified testing (n = 14; e.g. prescribed prior to cancer review board) were retrospectively confirmed (4.7%).

The impact of Oncotype DX on adjuvant CET use is reported in the table. Oncotype DX testing demonstrated major changes in therapeutic choices, with a 70.1% reduction in CET indications in our cohort. In pN0–N1mi and pN1 pts, CET indication was reduced by 67.6% and 78.5%, respectively. The highest de-escalation rates were observed in ≤50y pN1 pts, 51–70 y pN1 pts and premenopausal pts, while the lowest were in post-menopausal pN0/N1mi pts and >70 y pN1 pts.

Table: De-escalation rates, based on therapeutic indications before/after Oncotype DX testing.[a]

CET indication	All pts	≤50 y	51–70 y	>70 y	Premenopausal pts	Post-menopausal pts
All pN, n	287	99	156	32	105	182
Pre-test (%)	74.6	62.6	79.5	87.5	64.8	80.2
Post-test (%)	22.3	13.1	26.9	28.1	10.5	29.1
% decrease	−70.1	−79.1	−66.2	−67.9	−83.8	−63.7
pN0/pN1mi, n	231	83	128	20	88	143
Pre-test (%)	70.6	59.0	75.7	85.0	61.3	76.2
Post-test (%)	22.9	14.5	28.9	20.0	10.2	30.8
% decrease	−67.6	−75.4	−61.8	−76.5	−83.4	−59.6
pN1, n	56	16	28	12	17	39
Pre-test (%)	91.1	81.3	96.5	91.6	82.3	94.9
Post-test (%)	19.6	6.2	17.9	41.7	11.8	23.1
% decrease	−78.5	−92.4	−81.4	−54.5	−85.7	−75.7

[a]After excluding 14 unjustified tests (clear indication of ET or CET).

Conclusions: Oncotype DX testing was justified in 95.3% of cases and allowed for considerable therapy de-escalation in our cohort, including in specific pt subpopulations. Our results confirm the utility of the test to refine management strategies and avoid overtreatment in our center.

No conflict of interest.

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301 (PB-117) Poster

Integrating isolation using label-independent microfluidics and advanced staining for comprehensive Circulating Tumor Cell Analysis

M. Ciccioli[1], D. Greaves[1], A. Young[1], A. Cottingham[1], R. Bourne[1], A.S. Pailhes-Jimenez[2]. *[1]ANGLE Europe Limited, Cell Biology and Imaging, Guildford, United Kingdom; [2]ANGLE Europe Limited, Research and Development, Guildford, United Kingdom*

Background: In the realm of cancer diagnostics, liquid biopsy emerges as a transformative tool, enabling routine and repetitive characterization of cancer at genetic, transcriptional, and protein levels. Notably, the isolation of Circulating Tumor Cells (CTCs) from blood samples holds immense potential for cancer screening, management and monitoring. However, the prevalent reliance on epitope-dependent CTC capture systems, primarily focused on epithelial markers, poses limitations in detecting mesenchymal CTCs. Tumor cells undergoing epithelial-to-mesenchymal transition (EMT) during metastasis remain elusive with traditional platforms. Addressing this gap, our research introduces the use of ANGLE's Portrait$^+$ CTC staining kit leveraging epithelial and mesenchymal markers for identification and phenotyping of CTC isolated through the Parsortix® PC1 system, a label-independent microfluidic device able to isolate CTCs from metastatic breast cancer (MBC) patient blood based on size and deformability.

Methods: Peripheral blood was drawn into Streck Cell-Free DNA tubes from 8 MBC patients and processed on Parsortix® PC1 systems within 144 hours after collection. Harvested CTCs were cytospun on ANGLE's CellKeep™ slides to maximize the retention of cells. Slides were immunofluorescently stained using ANGLE's Portrait$^+$ CTC staining kit (Research Use Only), a freeze-dried antibody mixture, comprising a nuclear dye (Hoechst) and antibodies against epithelial markers (FITC), mesenchymal markers (Cy3), and blood lineage markers (Cy5) including antigens expressed by blood cells such as lymphocytes, macrophages, granulocytes, monocytes, fibroblasts, and cells of megakaryoblastic potential. Stained slides were imaged using a BioView DeNovo imaging system.

Results: CTCs were identified in four (50%) out of the eight MBC patients, with a median of 6 and mean of 16 CTCs identified per patient. CTC clusters harvested by the Parsortix® PC1 system were observed in the majority (75%)

of the CTC-positive patients. Cluster size ranged from 2–15 CTCs per cluster, and the number of clusters per patient ranged from 1–14. Phenotypically, three of the positive donors presented only mesenchymal CTCs, while the remaining donor presented a combination of both epithelial and mesenchymal CTCs.

Conclusions: This research underscores the significance of incorporating mesenchymal markers in CTC characterization as most captured CTCs expressed mesenchymal markers, suggesting that an epithelial-only approach would have missed a substantial proportion of harvested CTCs. ANGLE's Portrait^{+} CTC staining kit to identify and phenotype CTCs, combined with ANGLE's Parsortix® system, provides an efficient, easy to use and standardized solution for the harvesting and characterization of multiple CTC phenotypes.

Conflict of interest:

Other Substantive Relationships: All authors are employees at ANGLE Europe Limited.

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302 (PB-118) Poster

Correlation between weight and Recurrence Score in a cohort of HR+ve/HER2-ve early breast cancer patients: a retrospective analysis

G. Di Grazia[1], R. Signorelli[2], F. Martorana[2], P. Vigneri[2]. [1]*University of Messina, Department of Human Pathology "G. Barresi", Messina, Italy;* [2]*University of Catania, Department of Clinical and Experimental Medicine, Catania, Italy*

Background: OncotypeDX® is a validated tool to define the risk of recurrence of patients with HR+ve/HER2-ve early breast cancer (BC) and identify those who can safely forgo chemotherapy. Increased body weight and body mass index (BMI) are directly associated with the risk of BC among postmenopausal women and represent unfavorable prognostic markers for BC patients. We retrospectively assessed the potential correlation between weight/BMI and Recurrence Score (RS) obtained from OncotypeDX® in a cohort of patients with HR+ve /HER2-ve BC.

Material and Methods: From January to September 2023, patients with stage I-III, HR+ve /HER2-ve invasive BC were enrolled at a single Institutions. Clinical records and informative OncotypeDX® test result had to be available. Linear regression was used to assess correlations between RS as a continuous outcome, body weight and BMI; logistic regression was used considering RS as a binary outcome (RS < 25 and RS ≥ 25). Statistical analyses were performed using STATA v.17.

Results: A total of 43 women were enrolled, of whom 33 (77%) had a RS < 25 and 10 (23%) a RS ≥ 25. Only 10 women were premenopausal while the remaining 33 were post-menopausal. Almost 70% of tumors were NST, predominantly pT1N0, G2, ER+ve, Pg+ve, and with a Ki67 ≥ 20%. Median BMI was 26.37 (range 19.43–41.96), while median body weight was 65.8 Kg (range 44–87). 17 (39.5%) patients were overweight, while 12 (27.91%) were obese.

Body weight was inversely related to RS (p 0.016), as its value tended to decrease as weight increased. However, the correlation lost its significance when considering RS as a binary outcome (p 0.064). Similarly, a statistically significant association emerged between BMI and RS as a continuous outcome (p = 0.024), but not as a binary outcome (p = 0.125). No disease recurrence or deaths occurred in our cohort due to the short follow-up.

Table: Baseline demographic and histological characteristics of patients

Total patients population = 43		
Characteristic	Value	
	RS < 25 (33)	RS ≥ 25 (10)
Median age–yr (range)	61 (43–77)	55 (47–69)
Median BMI–no. (range)	26.64 (19.33–41.96)	25.34 (20.08–31.61)
BMI category–no. (%)		
Normal weight	10 (30.30)	4 (40)
Overweight	12 (36.36)	5 (50)
Obesity	11 (33.33)	1 (10)
Menopausal status–no. (%)		
Premenopausal		
Postmenopausal	9 (27.27)	1 (10)
	24 (72.73)	9 (90)
pT–no. (%)		
1b	5 (15.15)	3 (30)
1c	16 (48.48)	4 (40)
2	12 (36.36)	3 (30)
pN–no. (%)		
X	1 (3.03)	0 (0)
0	26 (78.79)	9 (90)
1	6 (18.18)	1 (10)
Grading–no. (%)		
1	3 (9.09)	0 (0)
2	23 (69.70)	4 (40)
3	7 (21.21)	6 (60)
Ki67 positivity–no. (%)		
<20%	11 (33.33)	1 (10)
≥20%	22 (66.67)	9 (90)

Conclusions: According to previous evidence, conflicting data exist about the association between RS and weight/BMI. Here we showed an inverse correlation between these parameters. The precise nature of this relationship remains incompletely elucidated, indicating the need for further comprehensive investigations.

No conflict of interest.

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303 (PB-119) Poster

An ultrasensitive assay for estrogens and all third-generation aromatase inhibitors

B.E. Bertelsen[1]. [1]*Haukeland University Hospital, Department of Medical Biochemistry and Pharmacology, Bergen, Norway*

Background: The study introduces an ultrasensitive assay capable of simultaneously quantifying sub-picomolar levels of estrogens and all third-generation aromatase inhibitors (AIs), setting a new standard in sensitivity, measuring range and clinical applicability.

Material and Methods: Utilizing a robotic mixing procedure for easy, precise, and high-throughput sample flow, all sample preparation steps were automated. Extraction was performed in 96-well plates using hexane:MTBE, followed by the addition of a novel separation solvent, consisting of hexane: IPA. This ensured distinct separation of the two liquid phases, yielding clean extracts without compromising extraction efficacy. Analytes were chromatographically separated using two serially coupled columns (Phenyl – C8) and subjected to MS/MS in ESI mode using a QTRAP 6500+ (SCIEX). The method was rigorously validated and is traceable to two accredited estrogen methods.

Results: The developed method exhibited a wide measurement range and unparalleled sensitivity (Table 1). All analytes demonstrated accuracies within 100 ± 8% and R^2 values ≥ 0.997. Symmetrical and narrow peaks were observed even at low concentrations.

In a clinical utility test involving 51 postmenopausal breast cancer patients on AI therapy, Letrozole emerged as the most efficient AI, suppressing E1 and E2 to sub-picomolar levels in all but one patient. Exemestane showed measurable E1 levels in all but one patient, while Anastrozole exhibited quantifiable E1 levels in all patients. A strong correlation was observed between Exemestane and its main active metabolite, 17-hydroxy-exemestane, with a mean ratio of 6:1.

Table 1: Measuring range for the assay.

	LOD pmol/L	LLOQ pmol/L	ULOQ pmol/L
E1	0.17	0.2	12 000
E2	0.56	0.8	13 000
17HEXE	2.3	8.0	125 000
EXE	5.8	13	203 000
LET	9.8	14	701 000
ANA	32	95	1 500 000

LOD, limit of detection; LLOQ, lower limit of quantification; ULOQ, upper limit of quantification; 17HEXE, 17-hydroxyexemestane; ANA, anastrozole; E1, estrone; E2, estradiol; EXE, exemestane; LET, letrozole.

Conclusion: To our knowledge, this method is the world's most sensitive assay for quantifying estradiol, estrone, all third-generation AIs, and 17-hydroxy-exemestane. It sets a new standard in both sensitivity and clinical applicability, offering a cost-effective tool for monitoring AI therapy and individual dosing. The heightened sensitivity also enables nuanced studies of therapeutic drug monitoring and reduced AI dosage or frequency, holding significant potential to impact personalized treatment regimens and enhance patient care.

PMID: 34958096

No conflict of interest.

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305 (PB-121) Poster

Prediction of HER2 positive breast cancer patients' response to anti-HER2 therapy using mRNA level

N. Atallah[1], S. Makhlouf[1], X.M. Li[2], Y. Zhangy[2], E. Rakha[1], Cerca Biotech Germany. [1]*Nottingham University, Histopathology, Nottingham, United Kingdom;* [2]*Cerca Biotech, GmbH, Berlin, Germany*

Introduction: HER2-positive (HER2+) breast cancer (BC) constitutes 10–15% of BC cases. To date, HER2+ status evaluated through immunohistochemistry (IHC) (score 3+) or IHC 2+ with evidence of HER2 gene amplification, determines the eligibility to anti-HER2 therapy. However, about 40% of HER2+ BC patients experience recurrence following adjuvant anti-HER2 therapy, raising concerns about the reliability of current HER2 assessment methods and their ability to define HER2 positivity. MammaTyper® assay (Ref CC01010, Cerca Biotech GmbH) is a RT-qPCR BC subtyping platform based on the mRNA expression of *ERBB2*, *ESR1*, *PGR*, and *MKI67*. This study aims to evaluate the accuracy of the MammaTyper® assay in predicting the response of HER2+ patients to therapy.

Material and Methods: A well characterised HER2+ BC cohort of 256 cases, diagnosed at Nottingham University hospitals between 2006 and 2018, was included. The cohort was divided into 2 groups: a treated group (n = 143) who received adjuvant anti-HER2 therapy, and a non-treated group where the patients were diagnosed before approval of anti-HER2 therapy and received chemotherapy only (n = 113). Tumour clinicopathologic characteristics were matched between the two groups. RNA extraction was carried out with RNXtract® Kit (Ref CC01011, Cerca Biotech GmbH) using formalin-fixed paraffin-embedded (FFPE) sections with at least 20% tumour content. RT-qPCR was performed using the MammaTyper® kit to measure *ERBB2, ESR1, PGR*, and *MKI67* mRNA levels. Expression results were calculated by MammaTyper® Report Generator (Ref CC05000). A BC subtype was diagnosed based on predefined validated cutoffs. Correlation between MammaTyper® results and IHC status was analysed. The endpoint was 15-years BC free survival and distant metastasis free survival.

Results: MammaTyper® assay identified 221/256 (86.3%) cases as HER2+, 11.7% (30/256) as HER2 low and 2% (5/256) as HER2 negative. Using MammaTyper® assay, HER2+ patients treated with anti-HER2 therapy had significantly prolonged DFS and DMFS (HR = 0.56, p = 0.006 and HR = 0.57, p = 0.012, respectively) with less risk of recurrence compared to those who were treated with chemo only, while the IHC-defined HER2+ patients had less significant results (HR = 0.62, p = 0.023 and HR = 0.66, P = 0.04, for DFS and DMFS, respectively). Conversely, MammaTyper® HER2 negative patients did not show survival difference between the group of patients who were treated with trastuzumab and those who were treated with chemotherapy only (p > 0.05).

Conclusion: Compared to the semi-quantitative IHC approach, MammaTyper® assay is more accurate in defining and identifying HER2+ BC patients that would benefit from anti-HER2 therapy.

No conflict of interest.

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306 (PB-122) Poster

Investigating the Effectiveness of CDK 4/6 Inhibitor loaded 4-Carboxy Phenyl Boronic acid Conjugated pH Sensitive Chitosan Lecithin Nanoparticles in the management of Breast Cancer

N. Rajana[1], S. Yeruva[1], N. Mehra[1]. [1]*National Institute of Pharmaceutical Education and Research NIPER - Hyderabad, Department of Pharmaceutics, Hyderabad, India*

Background: Over the past few decades, anti-cancer drugs have been suffering from off-target toxicity and non-specific effects in preclinical, and clinical setups; targeting the specific cancer tissue is the main approach to triumph this burdensome. Recently, many receptors are known to be overexpressed in cancer and are explored as docking sites for targeting tumor tissues.

Materials and Methods: Palbociclib (PALB), Chitosan, lecithin, 4-carboxy phenylboronic acid (4- CPBA), MCF-7 cells. A 4-carboxy phenylboronic acid (4- CPBA) conjugated Palbociclib (PALB) loaded pH-sensitive chitosan lipid nanoparticles (PPCL) were fabricated by an ionic gelation method.

Results: 4-CPBA was conjugated to chitosan by carbodiimide chemistry and the formation of the conjugate was confirmed by 1HNMR, ATR-FTIR spectroscopic techniques. The ionic-gelation method was used for the fabrication of PPCL and particle size, PDI, and zeta potential was found to be 226.5 ± 4.3 nm, 0.271 ± 0.014 and 5.03 ± 0.42 mV. Presence of pH-sensitive biological macromolecule, i.e., chitosan in the carrier system provides pH-senstivity to PPCL and sustainedly released the drug up to 144 h. The PPCL exhibited approximately 7.2, 6.6, and 5- fold reduction in IC50 values than PALB in MCF-7, MDA-MB-231 and 4T1 cells. Receptor blocking assay concluded that the fabricated nanoparticles were internalized into MCF-7 cells might be through sialic acid-mediated endocytosis. PPCL caused extensive mitochondrial depolarization, enhanced ROS generation, apoptosis (DAPI nuclear staining, acridine orange/ ethidium bromide dual staining), and reduced % cell migration than pure PALB.

Conclusion: Thus, it reported that delivering PALB by 4-carboxy phenyl boronic acid conjugated chitosan lipid nanoparticles provides an optimistic approach to treatment of breast cancer.

No conflict of interest.

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307 (PB-123) Poster

Interrogating HER2 status in Circulating Tumor Cells isolated using the Parsortix® System from Metastatic Breast Cancer patients

A. Young[1], L. Vlietinck[1], D. Greaves[1], M. Ciccioli[1], A.S. Pailhes-Jimenez[2]. [1]*ANGLE Europe Limited, Cell Biology and Imaging, Guildford, United Kingdom;* [2]*ANGLE Europe Limited, Research and Development, Guildford, United Kingdom*

Background: Diagnosis and treatment of breast cancer patients is guided by evaluation of human epidermal growth factor receptor 2 (HER2) status in tissue biopsies. Extracting tissue biopsies is invasive, with little opportunity for repeat testing. However, monitoring of circulating tumor cells (CTC) isolated from blood can be made possible through minimally invasive liquid biopsy techniques. In this study, ANGLE's Parsortix® PC1 system, an epitope-independent microfluidic device that isolates and harvests CTCs from blood based on size and deformability, was combined with a Research Use Only (RUO) downstream Immunofluorescence (IF) assay for HER2 protein identification on CTCs isolated from blood of metastatic breast cancer (MBC) patients collected at multiple timepoints.

Methods: Contrived samples were derived from healthy volunteers' blood drawn in Streck Cell-Free DNA tubes, spiked with HER2+ (SKBR3 and HCC1954) and HER2- (MCF-7, T47D and Hs 578T) cancer cell lines and separated on Parsortix® PC1 instruments within 144 hours post-draw.

Harvests were spun onto positively charged slides and stained using ANGLE's Portrait HER2 IF panel for CTC identification, consisting of a nuclear dye, epithelial and mesenchymal markers, blood lineage markers, and an antiHER2 protein antibody. Slides were imaged on a BioView Allegro Plus imaging system. The workflow was used to harvest CTCs from 26 MBC patients. Six patients had HER2-positive primary tumour and were receiving HER2 targeted therapy (Group 1), while 20 patients had HER2-negative primary tumour and were not receiving HER2 targeted therapy (Group 2). From each patient, two to six blood draws were obtained, with at least one month between subsequent draws.

Results: In contrived samples, analytical specificity and sensitivity of the assay was 97.3% and 96.9%, respectively. In the patients' cohort, ≥1 CTC was identified in at least one draw in 66% of Group 1 patients (range 1–36, median: 2, mean: 5) and in 90% of Group 2 patients (range 1–393, median: 7, mean: 35), with ≥1 CTC overexpressing HER2 observed in 25% and 28% of the CTC positive patients in the two groups, respectively. HER2 status changed in 27% of CTC positive donors across multiple draws, with similar rate between the two groups.

Conclusions: Results obtained in this study on HER2 expression in CTCs match published data for similar patients' cohorts, indicating robustness of the assay. Interestingly, more CTCs were harvested from HER2- donors than HER2+ donors on targeted therapy. Taken together, this study demonstrates the frequency of discordance of HER2 status between primary tumours and CTCs (observed in 44.5% of CTC positive donors), with CTCs being potentially more representative of tumour evolution over time and highlights the advantages of liquid biopsy for regular monitoring and guiding treatment decisions in MBC patients.

Conflict of interest:
Other Substantive Relationships: All co-authors are employees at ANGLE Europe Limited.

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308 (PB-124) Poster

Metabolomic profile as a biomarker in early breast cancer patients candidate to neoadjuvant therapy

V. Martini[1], B. Ruffilli[2], S. Di Lascio[1], F. D'Avanzo[1], V. Rossi[1], S. Gobbato[2], F. Vezzoli[2], L. Negrini[2], R. Alsati[2], R. Ben Ayed[2], G. Tarantino[3], V. Guarneri[4], G. Griguolo[4], R.L. Boldorini[2], C. Branni[2], L. Matera[2], N. Sala[2], E. Barberis[2], M. Manfredi[2], A. Gennari[2]. *[1]AOU Maggiore della Carità, Oncology Department, Novara, Italy; [2]University of Eastern Piedmont, Translational Medicine, Novara, Italy; [3]Pharmanutra Spa, Scientific Officer, Pisa, Italy; [4]University of Padova, Dept of Surgery, Oncology and Gastroenterology, Padova, Italy*

Background: Pathological complete response (pCR) after neoadjuvant therapy (NAT) is strongly related to improved outcomes. Overall, 50–60% of patients obtain a pCR after NAT. Therefore, novel approaches must be developed to implement new therapeutic strategies in patients with residual disease (RD).

Metabolomics is an innovative approach that can provide information on dynamic changes occurring during cancer development and progression and may represent an innovative method to identify host related factors correlated with treatment outcome.

In this study, we aimed to identify a metabolomic signature associated with treatment response and long-term outcome, through the use of untargeted metabolomics analysis in early breast cancer (EBC) patients undergoing NAT.

Material and Methods: An untargeted metabolomic approach was applied: plasma samples were collected at baseline. Small molecules were isolated from the plasma, derivatized and evaluated through two-dimensional gas chromatography/mass spectrometry (GCxGC-MS). The metabolomic profiling was then related to treatment response (pCR versus RD). On a training set of 55 samples, a machine learning strategy with Boruta features selection algorithm paired with genetical algorithm was constructed and validated on the remaining 29 examples.

Results: 113 EBC patients were enrolled between 12/2020 and 06/2023. Of these, 96 (84.9%) underwent surgery, with an overall pCR of 51% (ER +16.7%, Her2+ 56.7%, TN 55.6%); of them 84 (74.3%) were included in the present analysis (18 ER+, 30 HER2+, 36 TN). Among 445 small molecules, 61 were differentially expressed in patients with pCR versus RD ($p < 0.05$ and Fold Change FC >1.3). By multivariate analysis, patients with RD showed higher levels of unsaturated fatty acids, such as eicosatrienoate (FC = 12, p 0.02), 9-decenoic acid (FC = 2.09, p 0.0001), and 17-octadecynoic acid (FC = 2.2, p 0.02), and lower levels of fatty acids, such as 9-hexadecenoic acid (FC<0.01, p <0.001), doconexent (FC = 0.01, p < 0.001), 9,11-conjugated linoleic acid (FC = 0.2, p < 0.001), glucose (FC = 0.01, p < 0.001), and glucopyranose (FC = 0.02, p < 0.001).

Conclusions: Our data indicate that host related metabolomic signatures may identify patients with EBC failing to achieve a pCR after NAT. We identified several fatty acids, aminoacids and small molecules that can be modulated through dietary supplementation. Possible effects by BC subtype are being investigated.

No conflict of interest.

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309 (PB-125) Poster

Cryoablation in Breast Cancer Care – an analysis from a Single Multi-Disciplinary Unit in Southern Africa

C. Benn[1], D. van Loggerenberg[2]. *[1]Breast Care Centre of Excellence - South Africa, Department of surgery, Johannesburg, South Africa; [2]Breast Care Centre of Excellence - South Africa, Research, Johannesburg, South Africa*

Background: Cryoablation or cryosurgery is a minimally invasive technique that serves as an alternative to surgical excision of solid tumors. It is a process whereby cancerous cells are destroyed using subfreezing temperatures. In recent years, cryoablation has been used to manage both early and metastatic breast cancer. However, its uses are rarely described within the African context. We aim to describe cryoablation's short-term benefits and outcomes in breast cancer care as used in a South African multidisciplinary breast unit.

Materials and Methods: This study is a retrospective cohort study. A total of 55 female patients were included. All patients presented with early-stage breast cancer with a tumor size of 25 mm or less. 36 patients (90%) presented with luminal A breast cancer and a ki67 of less than 15% as per unit protocol. However, 4 patients (10%) had non-luminal A cancer. Of these, 2 had stage 4 cancer with an unknown subtype; 1 had severe dementia with PCR post primary chemotherapy for a triple negative breast cancer and 2 had HER2 positive cancer. Total ages ranged from 40 to 89 years (median = 75 years). Cancer stage, tumor size, comorbidities and dates of follow up were also recorded.

All patients underwent cryoablation between January 2020 to May 2022 with initial follow up of a limited mammogram 6 weeks post-procedure and, thereafter, serial mammograms and ultrasounds for up to 3 years.

Results: Of the 55 patients, 54 (97.5%) underwent cryoablation. One procedure was aborted due to frostbite mid-procedure. Follow-up imaging showed complete tumour ablation in 97.1% of patients, all of whom had Luminal A breast cancer longest follow-up up currently at at 36 months. However, 2 patients had recurrence; one had a different tumour biology and was judged as a new primary the other was remote from the site of the original tumour. Recurrence also occurred in bothHER2-positive cancer-presenting patients, although initial cryoablation was successful. Finally, 2 patients developed mild frostbite post-cryoablation that resolved spontaneously. No other side effects were noted.

Conclusions: When looking at short-term outcomes, cryoablation is a successful alternative to surgical intervention in elderly patients who present with early-stage, luminal A breast cancer. It is a less invasive intervention, and follow-up imaging has shown its success. This study also proves a role for cryoablation in resource-constrained settings, particularly in Southern Africa, where timeous surgical management is not always available. Further investigations are required to determine cryoablation's long-term benefits and outcomes in breast cancer care within our context.

No conflict of interest.

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310 (PB-126) Poster

Breast tissue segmentation in MR images using deep-learning

Y. Forghani[1,2], R. Timotoe[1,2], M. Figueiredo4[3], T. Marques[1], E. Batista[4], F. Cordoso[4], M.J. Cardoso[4], J. Santinha[1], P. Gouveia[1,2]. *[1]Champalimaud Clinical Centre, Champalimaud Foundation, Digital Surgery Lab, Lisbon, Portugal; [2]Faculdade de Medicina de Lisboa, Caml, Lisbon, Portugal; [3]Instituto Superior Técnico, Universidade de Lisboa, Instituto de Telecomunicações, Lisbon, Portugal; [4]Champalimaud Clinical Centre, Champalimaud Foundation, Breast Unit, Lisbon, Portugal*

Background: Breast cancer is a pressing global health concern, with approximately 2.3 million new cases diagnosed annually. Treatment often involves breast-conserving surgery combined with radiotherapy, accounting for 50–70% of cases in the USA and 70–85% in the EU. Precise segmentation (annotation) of breast tissues, especially for non-palpable tumors, is crucial for effective diagnosis and treatment. Automatic methods are indistinguishable from manual segmentation and are currently considered the best option by avoiding intra- and inter-observer variability. This research leverages advanced image processing and AI-assisted tools to improve segmentation accuracy and efficiency.

Material and Methods: Our objective was to segment breast tissues, including breast, fibroglandular tissue (FGT), and arteries, in dynamic contrast-enhanced MR images from 100 patients randomly selected from the Duke-Breast-MRI dataset. We assessed several U-Net architectures, including 2D and 3D models with full and low resolution, as well as a 3D cascade U-Net. To evaluate the models, we used 5-fold cross-validation. Mean dice coefficients were computed by comparing the output of these models to manual segmentations conducted by experienced radiologists.

Results: Breast, FGT, and arteries mean dice coefficients of each Unet model are presented in the Table for different U-net models. Our study demonstrated that all U-Net architectures achieved high mean dice coefficients for breast segmentation, indicating their clinical relevance. Notably, the 3D low-resolution U-Net exhibited lower performance in FGT segmentation, likely due to challenges related to small arteries. Full-resolution U-Net architectures outperformed other models in arteries segmentation.

Table: Breast, FGT, and arteries mean dice coefficients of different Unet models

Unet model	Breast mean dice coefficient	FGT mean dice coefficient	Arteries mean dice coefficient
2D	0.96	0.80	0.39
3D full resolution	0.96	0.79	0.51
3D low resolution	0.97	0.75	0.39
3D cascade full resolution	0.96	0.78	0.51

Conclusions: This research highlights the potential of AI-driven approaches in achieving clinically relevant breast tissue segmentation. However, for improved FGT and arteries segmentation, we recommend incorporating T2-weighted MR images and exploring the creation and assessment of trained model ensembles.

No conflict of interest.

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311 (PB-127) Poster

Deregulated gene expression in relation with DNA methylation profiles associated with Estrogen Receptor (ER) status and breast cancer molecular subtypes

L. Addou Klouche[1], D. Birnbaum[2], M. Chaffanet[2]. *[1]Laboratory of Nutrition, Pathology, Agro Biotechnology and Health. UDL-Sba, Molecular pathology, Cancer and Therapeutic, Sidi-Bel-Abbes, Algeria; [2]Paoli Calmettes Institute, Molecular oncology laboratory, Marseille, France*

Background: Breast cancer (BC) is the most frequent and the most deadly cancer among women worldwide. Different classifications of disease (anatomoclinical, pathological, prognostic) are used for guiding the management of patients. Unfortunately, they fail to reflect the whole clinical heterogeneity of the disease. Because the phenotype of tumors is dependent on many genes, a large-scale and integrated molecular characterization of the genetic and epigenetic alterations should allow the identification of new molecular classes clinically relevant, as well as among the altered genes and/or pathways, the identification of new therapeutic targets. We focused on luminal B breast cancer molecular subtype whose clinical course is particularly pejorative and for which no targeted therapy exists.

Material and Methods: To further define molecular alterations associated within the luminal B tumors we studied, with high-Throughput molecular analysis (array-comparative genomic hybridization aCGH, human promoter arrays and DNA microarrays), copy number aberrations, DNA promoter methylation and gene expression profiles in 117 primary breast cancer samples. An integrated analysis of gene profiling and DNA promoter methylation profiling has contributed to the identification of candidate genes.

Results: Frequent copy number aberrations (CNAs) were found in luminal B tumors. The luminal B/luminal A comparison showed that 8p11-p12 amplification and gains of distinct regions are more frequent in luminal B tumors. Different DNA methylation patterns were variably associated with ER expression ($p = 5.6 \times 10^{-7}$), SBR grade, molecular subtype ($p = 5 \times 10^{-4}$, and TP53 status ($p = 1.2 \times 10^{-3}$). The supervised analysis comparing methylation score data of ER+ and ER- tumors identified 3,484 gene promoters with methylation differences between the two groups (t test, FDR,0.05). Among them, gene promoters including those of *APC, CAV1*, *CCND2*, *CDCA7*, *CDH3*, *CDKN2A*, *CDKN2B*, *HEY2*, *RASSF1*, *RECK* had a DNA methylation level higher in the ER+ group (t-test, FDR,0.05). BC subtypes have specific methylation profiles. Luminal B was reported as the most frequently methylated, High DNA methylation level associated with the luminal B subtype targeted *CITED4, SP100*, *SAMD9L*, *DCR1*, *FBXO32*, *ASS1*, *FAM78A* and *STAT5A* genes previously reported as tumor suppressor genes or associated with tumor progression.

Conclusions: This refined molecular dissection of luminal breast cancers has pointed new specific candidates. we have reported luminal B candidate genes associated with the development and tumor progression of this aggressive subtype. Seven of the luminal B candidate oncogenes we have identified could be targeted and lead to the development of targeted therapies.

No conflict of interest.

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POSTER SESSION **22 March 2024** **9.00–14.30**

Risk Factors

312 (PB-128) Poster

Lipid metabolite levels associated with the risk of breast cancer: a Mendelian randomization study

W. Zhang[1], D. Zhao[1], H. Huang[1], H. Uddin[2], Y. Zhang[3], H. Yang[1]. *[1]Fujian Medical University, School of Public Health, Fuzhou, China; [2]Fujian Medical University, Overseas Education College, Fuzhou, China; [3]Peking University, School of Public Health, Beijing, China*

Background: In recent years, the incidence of breast cancer has been increasing, making it the most common cancer worldwide. It has had a serious impact on women's physical and mental health. Several studies have found a strong association between lipid-related metabolites and breast cancer, but the causal relationship between these has not been clearly elucidated.

Methods: We conducted a two-sample Mendelian randomization analysis using the summary statistics from genome-wide association studies to obtain information on lipid metabolites (n = 115,078) and breast cancer (n = 228,951). The primary analysis method utilized the inverse variance weighting (IVW) method to identify metabolites that were significantly associated with the risk of breast cancer (false discovery rate <0.05) and to investigate their associations with different subtypes of breast cancer. A feature selection based on LASSO was performed to select the most important metabolites from the associated lipid metabolites. These metabolites were then studied in the sensitivity analysis using MR-Egger regression, weighted median and MR-PRESSO methods to ensure the accuracy and stability of the results. Meanwhile, multivariate Mendelian randomization (MVMR) was used to account for the effects of BMI and alcohol consumption.

Results: Our study identified a potential causal relationship between 35 lipid metabolites and the risk of breast cancer. 14 of them were associated with an increased risk of breast cancer, while 21 lipid metabolites may be

associated with a decreased risk. All 35 of these lipid metabolites were strongly associated with Luminal A breast cancer, but not with Luminal B breast cancer. After LASSO regression, HDL_CE (OR = 1.09, 95% CI 1.04–1.15, *P* = 0.0004), L_HDL_PL_pct (OR = 0.92, 95% CI 0.87–0.97, *P* = 0.0035), L_VLDL_TG (OR = 0.93, 95% CI 0.88–0.98, *P* = 0.0076), and M_VLDL_C_pct (OR = 1.07, 95% CI 1.02–1.13, *P* = 0.0077) were identified as the most important lipids with independent effects on breast cancer risk. Sensitivity analysis suggested no substantial difference in the results obtained from different models. However, MVMR analysis adjusting for BMI and alcohol consumption only confirmed the significant associations between HDL_CE, M_VLDL_C_pct, and breast cancer.

Conclusion: HDL_CE and M_VLDL_C_pct may be causally associated with breast cancer, and the result is robust. This finding may provide valuable insights into the pathogenesis of breast cancer and could be considered in the risk assessment for the disease.

No conflict of interest.

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313 (PB-129) Poster

Predictive factors of micro and macrometastasis in sentinel lymph node in invasive lobular carcinoma

C. Julià[1], M.R. Sanchez-Mateos Enrique[2], C.M. Capó Pons[1], G. Tena Vivó[1], A.M. Petit Montserrat[3], A. Rodríguez Gasén[4], C. Falo Zamora[5], A. Garcia-Tejedor[6]. *[1]Hospital de Viladecans, Gynecology, Vicladecans, Spain; [2]Hospital Clínico Universitario Virgen de la Arrixaca, Gynecology, Murcia, Spain; [3]Hospital Universitario de Bellvitge-Instituto Catalán de Oncología, Anatomical Pathology, Hospitalet de Llobregat, Spain; [4]Hospital Universitario de Bellvitge-Instituto Catalán de Oncología, Nuclear Medicine, Hospitalet de Llobregat, Spain; [5]Hospital Universitario de Bellvitge-Instituto Catalán de Oncología, Medical Oncology, Hospitalet de Llobregat, Spain; [6]Hospital Universitario de Bellvitge-Instituto Catalán de Oncología, Gynecology, Hospitalet de Llobregat, Spain*

Background: While the axillary effects of invasive ductal carcinoma (IDC) have been thoroughly investigated, the relatively lower incidence of invasive lobular carcinoma (ILC) has led to a substantial gap in our understanding of its impact on the axillary level.

Study aims to analyze risk factors (RF) for metastasis in ILC's sentinel lymph node (SLN) and assess if axillary involvement in clinically node-negative (cN0) ILC patients is similar to IDC in the AMAROS trial.

Material and Methods: An observational, retrospective and bicentric study of patients diagnosed of cT1-T3 ILC between 2007–2020 who underwent to primary surgery and SLN biopsy (SLNB) was performed.

We compared our results with those published in AMAROS trial in the axillary lymph node dissection (ALND) group, considering that our hospital avoids ALND in macrometastasis in SLNB since 2012.

To identify the RF of metastasis in SLN, patients with isolated tumor cells were grouped with negative SLN and we performed uni- and multivariate analyses (MA) (logistic regression) of the most relevant diagnostic variables. Moreover, we have conducted a MA to explore the RF for macrometastasis in SLN of ILC.

Results: 270 patients were evaluated. ALND was performed in 36/66 (54.5%) of macrometastasis. In our series of cT1-2, 19.3%(6/31) of ALND had >4additional positive lymph node(LN) compared with the 8%(52/672) described in the AMAROS trial (p = 0.03), in a sample of 80% of IDC.

The significant RF (p < 0.05) are described in Table1. In the MA analysis remains as significant RF: age (OR0.96 IC95%0.9–0.99), MRI size (OR1.04 IC95%1.01–1.07), histological subtype (OR0.26 IC95%0.1–0.7), and pathological size (OR1.05 IC95%1.03–1.08). In the MA of RF for macrometastasis histological subtype (OR0.3 IC95%0.1–0.8) and pathological size (OR1.03 IC95%1.01–1.05) emerged as significant contributors.

	pN0(n = 159)	pN+(n = 111)
Age, mean ± SD	59,7 ± 10	55,6 ± 9,2
Menopausal status, n(%)		
Menopause	121(63%)	70(37%)
Premenopause	38(48%)	41(52%)
cT, n(%)		
T1	95(66%)	48(34%)
T2	52(49%)	5(51%)
T3	12(60%)	8(40%)
Quadrant location, n(%)		
External	87(62%)	54(38%)
Internal	33(66%)	17(34%)
Central	34(50%)	34(50%)
Multicentric	2(50%)	2(50%)
MRI size(mm), mean ± SD	23.0 ± 14.1	29.2 ± 19.5
Pathological size(mm), mean ± SD	23,1 ± 19.4	33.7 ± 20.5
Lymphovascular invasion, n(%)		
Yes	7(29%)	17(71%)
No	147(62%)	91(38%)
Histological subtype, n(%)		
Pleomorphic	19(40%)	29(60%)
Others	140(63%)	82(37%)
Type of surgery, n(%)		
Conservative	122(63%)	72(37%)
Mastectomy	37(49%)	39(51%)

Conclusions: ILC cN0 may exhibit a higher number of affected LN than IDC. This could lead to an underestimation of axillary staging in ILC cases, which have different prognoses. It suggests the potential need for tailored management approaches for these distinct tumor entities. The pleomorphic histological subtype and a larger pathological size emerge as the most significant RF associated with the involvement of SLN in macrometastasis.

No conflict of interest.

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316 (PB-132) Poster

Factors relating to late presentation of locally advanced breast cancer patients

N. Kuntaraksa[1], C. Suebnukarn[1]. *[1]Surin Hospital, Surgery, Surin, Thailand*

Background: Locally advanced breast cancer (LABC) is a major problem and high incidence in developing countries. Late presentation is a key factor that relating to locally advanced breast cancer patients. The goals of this study needed to find the factors that relating to late presentation of LABC and plan for created a proper strategy to reduce the late presentation rate especially in LABC.

Material and Methods: A study design was a prospective cohort observational study conducted at Surin hospital from January 2020 to December 2021. New cases of breast cancer patients were approached and interviewed before treatment, observed during treatment and followed 1 year after diagnosed.

Results: 141 patients were diagnosed with breast cancer in 2020, 20 patients were excluded. A total of 121 patients were approached, the mean age at diagnosed was 52.92 ± 12.06 years. 56 patients (46.3%) were locally advanced stage, all patients presented with breast mass. Fear of treatment is factor relating to late presentation of breast cancer patients (P = 0.040). Late presentation patient was associated to LABC (P = 0.001). Factor relating to late presentation of locally advanced breast cancer patients were Khmer ethnicity (P = 0.002), history of breast cancer screening (P = 0.033), and presence of angiolymphatic invasion (P = 0.032). Multivariate analysis shown Khmer ethnicity(P = 0.043), Menarche(P = 0.045) and history of breast cancer screening were factors relating to late presentation of locally advanced breast cancer patients (P = 0.042).

Conclusions: Late presentation of breast cancer patient was associated to locally advanced stage. Fear of treatment is factor relating to late presentation of breast cancer patients. Ethnicity, menarche and history of breast cancer screening were factors relating to late presentation of locally advanced breast cancer patients. Appropriate breast cancer screening

protocol may reduce late presentation of locally advanced breast cancer patients.

No conflict of interest.

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317 (PB-133) Poster

Linking the dots of breast cancer modifiable risk factors in pre- and post-diagnosis period among breast cancer patients in India

S. Ranjan[1], R. Thakur[1]. [1]*Indian Institute of Technology Mandi, School of Humanities and Social Sciences, Mandi, India*

Background: In India, there is little research on how lifestyle factors affect the prognosis of breast cancer (BC). This study looked at the association and variability in BC modifiable risk factors during the pre-and post-diagnosis period among diverse socio-demographic variables in the country.

Methods: 355 BC patients from Punjab, India, participated in this cross-sectional study. 106 (29.86%) patients were interviewed purposefully at the Advanced Cancer Institute in Bathinda, whereas 249 (70.14%) were interviewed at the Homi Bhabha Cancer Hospital in Sangrur. The study's results were calculated using descriptive analysis and logistic regression.

Results: Among total BC patients, the mean (SD) age at diagnosis was 49.36 (11.28) years, consisting of 324 (91.27%) women and 31 (8.73%) men cases. Women BC patients were significantly 2.26 times more likely than men to have non-normal BMI, 5.55 times more likely to have non-normal sitting time per day, and 8.24 times more likely to not have a balanced diet in the pre-cancer diagnosis period. Similar findings were observed for post-cancer diagnosis, although the BMI result was not statistically significant. Pre-cancer diagnosis modifiable BC risk factors were correlated with the post-cancer diagnosis modifiable BC risk factors.

Conclusions: In this study, we conducted an experimental analysis of BC modifiable risk factors during pre- and post-diagnosis. Our study found that BMI, sedentary lifestyle, and imbalanced diet intake were all connected with a higher risk of BC in India. The findings will aid policymakers in better understanding the problem of modifiable risk factors in BC patients.

No conflict of interest.

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318 (PB-134) Poster

Prognostic impact of non-alcoholic fatty liver disease and non-alcoholic steatohepatitis-related liver fibrosis on postoperative long-term outcomes of breast cancer

K.T. Hwang[1]. [1]*Seoul National University College of Medicine, Seoul Metropolitan Government Seoul National University Boramae Medical Center, Surgery, Seoul, South Korea*

Introduction: Obesity has shared a correlation with fatty liver disease and breast cancer. However, previous studies on the relation between fatty liver and breast cancer have shown conflicting results on the impact of fatty liver on the survival and recurrence of breast cancer patients. In this study, we attempted to investigate the prognostic value of nonalcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH) related liver fibrosis in patients with breast cancer undergoing surgery, using noninvasive tools like liver-to-spleen attenuation (L/S) ratio and Fibrosis-4 (FIB-4) score, respectively.

Materials and Methods: A total of 933 patients diagnosed with primary invasive breast cancer between April 2006 and December 2019 were included. The patients with stage IV breast cancer were also excluded. 821 patients were divided into two groups according to the L/S ratio of 1 measured by the preoperative low-dose computed tomography: 89 patients (10.8%) with a L/S ratio<1 vs. 732 patients (89.2%) with a L/S ratio≥1. They were also divided into two groups based on the FIB-4 score of 2.67: 788 patients (96.0%) with a FIB-4 score<2.67 vs. 33 patients (4.0%) with a FIB-4 score≥2.67.

Results: Patients with NAFLD were older and higher BMI, and had a higher proportion of mastectomy, and hyper-transaminasemia. Patients with NALFD showed worse overall survival and disease-free survival compared to those without NAFLD ($p = 0.003$ and 0.044 (Log-Rank)). However, no significant differences in local recurrence-free, regional recurrence-free, systemic recurrence-free, and contralateral breast cancer-free survivals. ($p = 0.501$, 0.498, 0.064, and 0.472, respectively (all, Log-Rank)) The survival outcome of breast cancer doesn't show any relationship with NASH-related fibrosis (overall survival; $p = 0.011$ (Log-Rank), but $p = 0.075$ (Breslow), disease-free survival; $p = 0.561$ (Log-Rank)). After stratified by the subtypes of breast cancer, the L/S ratio remained a significant predictor of overall, disease-free, local recurrence-free, and regional recurrence-free survivals in the hormone receptor (HRc)+/HER2- subtype only ($p = 0.002$, 0.005, 0.004 and <0.001, respectively), but not in other subtypes. The FIB-4 score was also not a significant predictor of breast cancer when analyzed by molecular subtype. NAFLD was a significant risk factor for mortality in multivariable analysis (HR, 2.08; 95% CI, 1.052–4.102; $p = 0.035$). NASH-related fibrosis was not a significant risk factor for mortality in multivariable analysis (HR, 1.73; 95% CI, 0.702–4.286; $p = 0.233$).

Conclusions: NAFLD is significantly associated with decreased overall survival in patients with breast cancer especially the HRc+/HER2- subtype, unlike NASH-related fibrosis. Therefore, NAFLD should be assessed in the preoperative setting for predicting long-term prognoses of breast cancer patients.

No conflict of interest.

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319 (PB-135) Poster

Dietary acid load and breast cancer risk: a role for methionine intake

A. Ronco[1], J.M. Calderón[2], W. Martínez-López[3]. [1]*Pereira Rossell Women's Hospital, Unit of Radiotherapy and Oncology, Montevideo, Uruguay;* [2]*University of Montevideo, Biomedical Sciences Center, Montevideo, Uruguay;* [3]*Instituto de Investigaciones Biológicas Clemente Estable, Genetics Department and Biodosimetry Service, Montevideo, Uruguay*

Background: Scarce epidemiologic evidence links Cancer risk to dietary acid load (DAL) and methionine intake. DAL contributes to metabolic acidosis, which is closely related to cancer development. Besides, methionine is the main acidogenic amino acid and involves epigenetic influences. Therefore, DAL and methionine deserve to be further epidemiologically analyzed concerning breast cancer.

Material and Methods: A case-control study was performed on 572 breast cancer cases and 2294 matched controls, women drawn from Uruguayan public hospitals. Participants were interviewed through a specific questionnaire. Food-derived nutrients were calculated from available databases. DAL was calculated based on validated measures, including Potential Renal Acid Load (PRAL) and Net Endogenous Acid Production (NEAP) scores. Odds ratios (OR) were estimated by logistic regression, adjusting for potential confounders.

Results: We found significant and direct associations between breast cancer risk (Q5 vs. Q1) and PRAL (OR = 3.33 [2.12–5.22]), NEAP (OR = 3.61 [2.13–6.15]), and methionine intake (OR = 4.94 [3.42–7.13]). Trends were significant ($p < 0.001$). PRAL showed the highest ORs among fiber low-eaters compared to high-eaters (OR = 9.96 vs. OR = 1.32, respectively). PRAL displayed higher ORs among subsets with a positive family history of cancer compared to a negative one (OR = 6.16 vs. OR = 2.80, respectively).

Conclusions: Results confirm that an acidogenic dietary style may increase the breast cancer risk. Our findings suggest that methionine intake, displaying comparable ORs as the scores themselves, might be an independent factor influencing the risk linked to acid-base disbalance, which turns into metabolic stress.

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320 (PB-136) Poster

Variations in time to breast cancer treatment initiation and survival across ethnoracial groups: a DAGs based approach to systematic review

P. Mokhtarihesari[1], D. Lizotte[2], G. R. Bauer[3]. *[1]Western University, Epidemiology and Biostatistics, London, Canada; [2]Western University, Department of Computer Science, London, Canada; [3]University of Minnesota Medical School, Institute for Sexual and Gender Health, Minnesota, USA*

Background: While many social determinants of health associated with racial disparity are well-known, they do not act in isolation, and the causal structure of their influence on outcomes has not been established in breast cancer. The aim of this review is to apply causal analysis to systematically review the existing evidence on racial/ethnic disparities in initiation of treatments and their impact on breast cancer patients' survival in the U.S.

Materials and Methods: A comprehensive systematic search of databases was performed. Studies on cohorts of female breast cancer patients who were diagnosed with stage I-III in the US were included. A modified checklist for applying the evidence synthesis for constructing directed acyclic graphs (ESC-DAGs) method was used to describe causal relationships between ethnoracial group membership and time to treatment initiation and overall survival outcomes identified in the studies.

Results: Among the 30 studies that met the inclusion criteria, 20 investigate time to surgery. Most of these reported significant variation across ethnoracial groups in the timing of breast-conserving surgery and mastectomy procedures and their subsequent impact on survival. The review identified three primary covariate groups used to adjust analyses, which are shown in the accompanying figure: individual and sociodemographic attributes, tumor-specific characteristics, and the quality of healthcare services. Studies identified a variety of unmeasured variables with potential impacts on treatment initiation time resulting from data limitations and study design. Most studies did not directly explore the mediational effect of time to treatment, leaving a gap in causal reasoning within the literature. Important covariates, such as socioeconomic status during patients' early life and throughout their breast cancer journey, were not considered, potentially leading to a lower estimated causal interpretation of observed disparities across racial/ethnicity groups.

Conclusions: This review applied causal analysis to understand this complexity and create actionable knowledge that supports efforts to redress health inequity in breast cancer. The studies primarily focused on readily accessible factors affecting the timing of treatment initiation, suggesting the need for methodologically rigorous research in this area. We suggest the existing literature consider the impact of essential factors such, mental health, health-related quality of life, and other social determinants on the initiation of prescribed treatments for patients. We advocate for using a causal framework to consider race/ethnicity together with other covariates to better understand its impact on inequalities in breast cancer care.

No conflict of interest.

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322 (PB-138) Poster

The incidence of male breast cancer in Klinefelter's syndrome and its proposed mechanisms

B. Cook[1], S. Nayar[1]. *[1]King's College London, FoLSM, London, United Kingdom*

Background: 70% of men with Klinefelter's Syndrome (KS) are diagnosed through a fertility pathway. These patients have been previously reported to have an increased risk of Male Breast Cancer (MBC) (Brinton, 2011). This systematic review provides the latest information regarding the incidence of MBC in the KS population compared to the standard male population and identifies proposed mechanisms by which MBC may develop in KS.

Materials and Methods: Papers were collected based on the PRISMA protocol of study size (>100 participants) and study type (cohort studies). Data from each study was summarised by country and compared with national data on MBC incidence. 3 papers were included out of 405 screened. A literature review was conducted for cancer mechanism identifying the most recent papers available. 11 papers were included out of 229 screened.

Results: 3 papers with 5046 total KS patients were included. Overall incidence of MBC in KS was significantly higher than the general population (8.69 vs 0.48 per 100,000 patient years $p < 0.01$). Standardized incidence ratios (SIR) were calculated across the UK, Danish and Swedish KS populations (below).

Population (KS patients)	Incidence (KS)*	Incidence (Normal)*	SIR (95% CI)	P-Value
Denmark (832)	17.54	0.54	32.48 (6.50 to 100.13)	<0.001
UK (3518)	10.11	0.50	20.22 (5.30 to 55.07)	<0.001
Sweden (696)	0.00	0.4	∞ (N/A)	N/A

*Per 100,000 patient-years

The largest cohort study showed an incidence significantly higher than that of the national UK average. A smaller cohort study in Denmark similarly showed a statistically significant increase in incidence. In Sweden, the data was inconclusive due to no cases of MBC in KS being reported in the trial.

Data on the aetiology behind MBC in KS is sparse but mechanisms are likely hormonal and genetic. These include decreased miRNA (MIR-3648) expression (known to be associated with ER-receptor +ve breast carcinoma), increased oestrogen/progesterone receptor expression and exogenous androgen use. However, exact mechanisms remain to be established.

Conclusions: KS significantly increases the risk of MBC, but more data is needed to identify the true risk that KS poses to breast cancer development. The proposed hormonal and genetic aetiology of MBC additionally requires a much larger data set to confirm. There is a need for an accurate and recent study of MBC incidence in KS to define the current risk.

No conflict of interest.

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