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## Abstracts for oral presentation at the Association of Breast Surgery Conference, 16<sup>th</sup> & 17<sup>th</sup> May 2016, Manchester Central

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### Monday 16th May 2016, Session 3: Submitted papers. 09:00 to 10:30

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#### 1. Identifying risk factors for low patient satisfaction with aesthetic outcome after Breast Conserving Surgery (BCS)

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**Introduction:** Poor cosmetic outcome is associated with psychological morbidity. The BREAST-Q is a validated PROM with nine domains designed to evaluate patient satisfaction and quality of life. A new module has been designed for patients undergoing BCS but to date there are no published studies. Our aim was to investigate risk factors for low score for the 'Satisfaction with breast' domain of the BREAST-Q.

**Methods:** Ethical approval was obtained. Consecutive women who had unilateral BCS were invited to complete the BREAST-Q as part of a wider study of outcome. Clinicopathological data was collected independently of the BREAST-Q results. Satisfaction with breast score was dichotomised by median score. Univariate binary logistic regression analysis was undertaken. All variables with  $p < 0.1$  were taken forward to multivariate analysis.

**Results:** 200 women participated. Median age was 64.7 years (IQR, 55.6–71.5). Median satisfaction score was 68 out of 100 (IQR, 55–80). BMI, type of axillary surgery, size of tumour on ultrasound, weight of specimen, nodal status and delayed wound healing were all significant on univariate analysis. Boost radiotherapy, re-excision of margins, age and time since surgery did not show significance. On multivariate analysis, increasing BMI (<25, 25–30, >30 kg/m<sup>2</sup>) and ultrasound size (<10, 10–20, >20 mm) were independently associated with lower satisfaction.

**Conclusion:** High BMI and USS tumour size are associated with lower satisfaction. Percentage breast volume excised has previously been associated with satisfaction but we are the first to demonstrate that high BMI is associated with lower satisfaction. These findings may help surgeons to plan their surgical strategy and manage patient expectations.

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#### 2. Immediate lipofilling following breast conserving surgery for breast cancer is associated with improved patient reported cosmetic outcome

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**Introduction:** Immediate lipofilling can potentially improve the cosmetic outcome following breast conserving surgery (BCS) and

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radiotherapy. This study evaluates the outcome of BCS and immediate lipofilling.

**Methods:** Between May 2011 and December 2014, patients who had undergone BCS and immediate lipofilling, and a matched control group of similar age and treatment period who had BCS but no lipofilling were identified. A modified Breast-Q<sup>TM</sup> questionnaire was completed by 32 lipofilled and 39 control patients. Statistical analysis was by  $\chi^2$  test and differences considered significant at  $P < 0.001$ .

**Results:** There were no local recurrences at median follow-up (36 months). Median age was 49y for lipofilled vs 54y for non-lipofilled, and median tumour size was 21mm vs 16mm. Patient satisfaction with appearance showed a significant shift towards greater satisfaction in lipofilled patients. This was reported for appearance in the mirror clothed (87.5% lipofilled vs 59% non-lipofilled patients were very satisfied) and unclothed (40.6% vs 25.6% very satisfied), shape of breasts in bra (81% vs 59% very satisfied), size of breasts (71.8% vs 43.6% very satisfied), ability to wear fitted clothing (71.9% vs 51.3% very satisfied), equality of size of breasts (46.9% vs 30.8% very satisfied) and how closely matched the breasts are (53.1% vs 28.2% very satisfied).

**Conclusions:** This is the first and largest study to report outcomes after immediate lipofilling following BCS. Significantly higher levels of satisfaction with appearance were seen after lipofilling when compared to patients of a similar age and follow-up with smaller cancers that did not have lipofilling.

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#### 3. Extreme oncoplastic surgery: Extending the boundaries of breast conservation

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**Background:** The boundaries of oncoplastic breast-conserving surgery are being extended, allowing breast conservation for more patients traditionally treated by mastectomy. The term 'extreme' oncoplastic surgery (eOBCS) has been recently proposed to describe these more extensive resections<sup>1</sup> but the clinical, oncological and patient-reported outcomes are largely unknown.

**Methods:** A group of 73 patients treated by eOBCS for tumours  $\geq 50$ mm was identified from a prospectively collected database of 333 OBCS procedures. Data collected included patient and tumour characteristics, clinical outcomes including early complications requiring intervention, additional surgical procedures and local recurrence (LR). Levels of

patient-reported satisfaction and well-being were assessed using the validated 'Breast Q' questionnaire.

**Results:** Seventy three patients underwent eOBCS (52 LD mini flaps and 21 therapeutic mammoplasties) between 1995–2015 for tumours  $\geq 50$ mm (tumour diameter 67 [50–177] mm, specimen weight 257 [73–975] gm, follow-up 64 [2–175] months). Radial margins  $\geq 2$ mm were reported in 86% and multifocality in 25% of specimens. Two cases (2.7%) of LR were observed after eOBCS and radiotherapy, within national guidelines of  $<3\%$  LR rate within 5 years<sup>2</sup>. Breast Q scores in all domains compared favourably with patients undergoing total mastectomy and reconstruction.

**Conclusion:** This study confirms the clinical utility and oncological safety of eOBCS as an alternative to mastectomy and reconstruction. High levels of patient satisfaction and good local control can be achieved alongside conservation even for large, multifocal tumours

1. Silverstein MJ et al *The Breast Journal* 2015 <http://dx.doi.org/10.1111/tbj.12356>

2. Surgical guidelines for the management of breast cancer, *Eur J Surg Oncol* (2009) <http://dx.doi.org/10.1016/j.ejso.2009.01.008>

<http://dx.doi.org/10.1016/j.ejso.2016.02.023>

#### 4. Impact of proximity to plastic and reconstructive services on the geographical variation in immediate breast reconstruction practices in the United Kingdom

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**Background:** This study aimed to investigate the impact of proximity to the nearest specialist plastic and reconstructive services on the geographical variation in the volume of immediate post-mastectomy breast reconstruction (IBR) using the national English administrative record Hospital Episode Statistics (HES). Our prediction was an inverse relationship between the volume of autologous breast reconstruction and the distance to plastic surgical services.

**Methods:** HES data was interrogated to derive 10-year [2004–2013] rates of expander implant-only, autologous latissimus dorsi (ALD), LD-implant and autologous (non-LD) IBR by UK NHS Trust. For each NHS Trust, the distance to specialist plastic and reconstructive surgery services was computed from the available data on the BAPRAS website. Data were observed to be non-parametric. For each procedure, bivariate spearman correlation analysis was conducted between 10-year reconstruction volume and distance to plastic reconstructive services (significance  $p < 0.05$ ).

**Results:** An inverse relationship was observed between distance and IBR volume for all procedures. However, the strength of the inverse relationship varied according to procedural subtype and was not significant for LD-implant ( $Rho = -.134$ ,  $p = 0.084$ ) moderately significant for implant-only ( $Rho = -.161$ ,  $p < 0.05$ ) but highly significant for autologous LD ( $Rho = -.254$ ,  $p < 0.001$ ) and free-flap reconstructions ( $Rho = -.377$ ,  $p < 0.001$ ).

**Conclusion:** As predicted, the inverse relationship between proximity and IBR volume and the strength of this association especially for autologous and free-flap procedures suggests that distance to plastic and reconstructive service may in part explain some of the geographical variation in post-mastectomy breast reconstruction. The implications are that patients with easier proximity to plastic surgeons may receive more complex IBR procedures. Policy changes may be required to address equity of access to autologous IBR.

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#### 5. Patients are more satisfied after oncoplastic breast conservation than total autologous breast reconstruction

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**Introduction:** Oncoplastic breast-conserving surgery (OBS) avoids mastectomy for larger tumours, but patient-reported outcomes following OBS are unknown.

**Methods:** The BREAST-Q<sup>®</sup> questionnaire<sup>1</sup> was distributed to 333 women treated by therapeutic mammoplasty or LD mini flap since 1991 (tumour diameter 32.5[5–100]mm). BREAST-Q<sup>®</sup> software generated scores/100 for breast appearance, physical, emotional and sexual well-being. These were compared with National Mastectomy and Breast Reconstruction Audit (NMBRA)<sup>2</sup> scores following Immediate Autologous Reconstruction (IAR).

**Results:** 150 (45%) women returned questionnaires (age 52 [30–83]yr, follow up 84 [4–281] months). 89% rated OBS better than mastectomy, and  $>80\%$  expressed no regrets, recommending it to others. Only 16% reported unplanned outcomes. Scores following OBS were higher in all domains than following IAR (breast appearance 66 v 65, physical wellbeing 78 v 74, emotional wellbeing 77 v 71, sexual wellbeing 55 v 51), with high scores persisting beyond 15yr. The operated breast was described as soft/normal, pain-free and lump-free by 61%, 60% and 72%, respectively, and  $>90\%$  enjoyed unrestricted daily activities. Additional procedures included nipple reconstruction (9%), tattooing (5%), surgery for wound complications/fat necrosis (12%), lipofilling (5%), and symmetrisation (23%). Overall, better surgical outcomes were reported following OBS v IAR (excellent/very good/good results 91% v 85% respectively).

**Conclusion:** Patient-reported outcomes following OBS compare favourably with those following IAR.

<sup>1</sup>Pusic A et al. Development of a New Patient-Reported Outcome Measure for Breast Surgery: The BREAST-Q. *Plast Reconstr Surg* 2009;124:345–53.

<sup>2</sup>Jeevan R et al. Findings of a national comparative audit of mastectomy and breast reconstruction surgery in England. *J Plast Reconstr Aesthet Surg* 2014;10:1333–44.

<http://dx.doi.org/10.1016/j.ejso.2016.02.025>

#### 6. New possible surgical approaches for the submammary adipofascial flap based on its arterial supply

**Ehab Elzawawy**, **Melad Kelada**, **Ahmed Alkarmouty**

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**Introduction:** Submammary adipofascial flap (SMAF) is a valuable option for replacement of the inferior portion of the breast. It is particularly useful for reconstruction of partial mastectomy defects. It is also used to cover breast implants. Little is known about the vascular supply of this flap. Most surgeons base this flap cranially on the submammary skin crease, reflecting it back onto the breast. The blood vessels supplying this flap are not well defined, and the harvest of the flap may be compromised due to its uncertain vascularity. The aim of the work was to identify perforator vessels supplying SMAF and define their origin, site, diameter and length.

**Materials and methods:** The flap was designed and dissected on both sides in 10 female cadavers. SMAF outline started upwards at the submammary skin crease (upper border) and extended downwards for 10 cm (length) and started medially 2cm from midline and extending laterally for 7cm (width). The flap was raised carefully from below upwards to identify the perforator vessels supplying it from all directions. These vessels were counted and the following measurements were taken using Vernier caliper: diameter, total length, length inside the flap and distance below the submammary skin crease. The Data was collected and statistical analysis was done using SPSS/version 20 software. For comparison

between groups, ANOVA-test was used followed by post hoc test and Waller-Duncan method.

**Conclusions:** The perforators at the lateral part of the flap took origin from the lateral thoracic, thoracodorsal and intercostal vessels. They were significantly larger, longer, more numerous and of multiple origins than those on the medial part of the flap and this suggests that laterally based flaps will have better blood supply, better viability and more promising prognosis. Both approaches, medially based and laterally based SMAF carry a better prognosis and lesser chance for future fat necrosis than the classical cranially based flap.

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### 7. Recurrence and complications after volume replacement oncoplastic breast conservations

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**Introduction:** Volume replacement oncoplastic conservation is less frequently applied than volume displacement techniques, and less relevant data available therefore. Hence recurrences and complications were analysed after volume replacement oncoplastic conservation.

**Methods:** a retrospective analysis of patients treated with volume replacement oncoplastic conservation between 2010 and 2014 were carried out.

**Results:** 205 oncoplastic breast conservation surgeries were carried out altogether. Of those 30 patients (14.6%) were treated with volume replacement conservation for mainly ductal (23) and lobular (5) cancer. The mean tumour size was 25 mm (9–45). 13 patients had grade 2 and 3 cancer, respectively. 23 patients had hormone sensitive and four had HER-2 positive cancer. Seven patients' nodes were positive. Five (16.6%) had incomplete margins and all underwent re-excision. All patients had radiotherapy, 22 had adjuvant hormonal therapy. 14 had adjuvant and two had neoadjuvant chemotherapy. Four patients received Herceptin. During a median follow-up time of 44 months (11–61) no local recurrence was detected. One patient only developed regional recurrence involving the brachial plexus. Six patients were smokers, one had diabetes, four patients were

immunosuppressed, and one patient was anti-coagulated. Mean BMI was 28. Patients were treated using thoracoepigastric flap (13), LICAP flap (5), TDAP flap (2), LTAP flap (1), matrix rotation (8) and crescent flap (1). 7 patients (23.3%) had some degree of postoperative complications including seroma (2), partial flap failure (2), hematoma (1) fat necrosis (1) and cellulitis (1). Of those, two (6.7%) required further surgery for complications.

**Conclusion:** Volume replacement oncoplastic surgery is a relatively safe option, since no local recurrence was detected and complication rate is low.

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### 8. Evaluation of the early post-operative effectiveness of a novel muscle-sparing breast reconstruction technique using Braxon<sup>®</sup> (acellular dermal matrix) – Multicentre European experience

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**Introduction:** We report initial results of a prospective audit of novel muscle-sparing subcutaneous implant breast reconstruction technique using a new Braxon<sup>®</sup> ADM. This was carried out in UK and Europe.

**Methods:** All patients who underwent muscle-sparing breast reconstruction since 2014 were included in the study. The pre-shaped Braxon<sup>®</sup> ADM completely wraps the implant after rehydration in saline for 5 minutes. The ADM with the implant is placed on the muscle, without detaching the pectoralis major.

**Results:** A total of 110 patients had Braxon<sup>®</sup> ADM plus implant reconstruction. 70 patients had unilateral and 20 patients had bilateral procedures. Complications included an implant loss of 1.8%; wound necrosis of 0.9% and 3.6% wound dehiscence. The short-term outcomes have been excellent, with high patient satisfaction, less pain, a more natural shape and feeling and good cosmetic outcomes.

**Conclusion:** The initial experience appears highly satisfactory, although long-term follow-up is required.

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## Monday 16th May 2016, Session 5: BJS prize papers. 11:00 to 12:30

### 9. Defining & characterising cells derived from human lipoaspirate tissue – Does the anatomical harvest site make any difference?

Mandana Pennick<sup>1</sup>, Nicholas Bryan<sup>3</sup>, Sandra Fawcett<sup>2</sup>, Mysore Chandrashekar<sup>1</sup>, Geraldine Mitchell<sup>1</sup>, John Hunt<sup>2</sup>

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**Introduction:** Use of autologous fat transfer is increasing to correct deformities after breast conserving surgery, improve tissue quality and aid wound healing. It is likely that adipose derived stem cells (ASCs) contained within lipoaspirate are responsible for these extended uses. Clinically, one anatomical harvest site may appear 'better' than another however this has not been reproduced *in-vitro*. We wished to characterise the cells cultured from lipoaspirate from different anatomical locations to understand the fundamental properties of the cells we re-inject in vivo.

**Methods:** Human lipoaspirate tissue from 20 subjects has been digested and cells extracted cultured to confluence. Experimentation

included flow cytometry, differentiation, cell metabolism and DNA proliferation studies.

**Results:** Flow cytometry confirmed CD markers commonly found on ASCs. Plasticity of cells was proven with both adipogenic and osteogenic differentiation. Proliferation studies to date suggest no difference in DNA quantification or cell metabolism between anatomical sites. However cells from lower abdomen have shown earlier differentiation in both adipogenic and osteogenic media.

**Conclusions:** Results from flow cytometry suggest cells being cultured are ASCs. Their ability to differentiate down both adipogenic and osteogenic lineages confirms plasticity. Results so far do not show a difference between phenotype or concentration of cells as a function of anatomical harvest site. Cells harvested from the lower abdomen may have greater plasticity than those from other anatomical sites. Ongoing work will confirm or refute these initial findings.

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### 10. Development of a treatment pathway to improve quality of care in the management of breast abscess and mastitis

Sarah Eshelby<sup>2</sup>, Findlay MacAskill<sup>2</sup>, Kaiyumars Contractor<sup>2</sup>, Omar Asha<sup>2</sup>, Paul Thiruchelvam<sup>2</sup>, Sally Curtis<sup>2</sup>, Deborah Cunningham<sup>2</sup>, Ragheed Al-Mufti<sup>2</sup>, Dimitri Hadjiminis<sup>2,1</sup>, Daniel Leff<sup>1,2</sup>

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**Introduction:** The Guidelines and Audit Implementation Network (GAINS) guidelines (2009) for the management of breast abscess and mastitis, include the timing and choice of antibiotic therapy, use of ultrasound guided needle aspiration and need for specialist follow-up. A prospective audit in 2011 observed sub-optimal practice, non-uniform prescribing (6 different antibiotics), higher than anticipated rates of incision drainage (20%) and protracted length of stay (mean=2.21 days). Consequently, a 'best practice' proforma and treatment algorithm was developed in consultation with surgeons, radiologists, microbiologists and emergency physicians, and was adopted following quality and safety board review. The aim of this study was to demonstrate quality improvement.

**Methods:** A 'Mastitis and Breast Abscess Pathway' was introduced across four acute NHS London teaching hospitals and a loop-closing audit was conducted to assess practice improvement. Prospective data was collected for all cases of "mastitis"/"breast abscess" between January and September 2015, to capture proforma uptake, ensure admissions were fully justified, record antibiotic compliance, monitor imaging guided aspiration versus surgical drainage, and assess rates of specialist follow-up.

**Results:** 50 patients presented with mastitis/abscess. Improvements in care included uniform antibiotic prescribing (81% vs. 42%), increased uptake of US guided aspiration (90% vs. 50%), reduced rates of incision drainage (0% vs. 20%), reduced admissions (23% vs. 31%), reduced hospital stay (mean: 1.9 vs. 2.21 days), and improved follow-up (90% vs 43%).

**Conclusions:** The introduction of a mastitis and breast abscess best practice pathway has improved the management of mastitis and breast abscesses, reduced hospital admissions and saved valuable hospital resources.

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### 11. The oncological safety of non-surgical management of close anterior margins in breast conserving surgery

George Boundouki, Joseph R.W.S. Hee, Natalie Croghan, Cliona C. Kirwan, James R. Harvey

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**Introduction:** The management of patients with margin involvement after breast conserving surgery remain controversial. While it is known that histologically involved margins lead to higher local recurrence rates, the surgical management of involved anterior margins may be less important than that of radial margins. In addition, re-excision surgery entails an increased risk of poor cosmetic outcome. Our aim was to investigate the safety of not re-excising close anterior margins.

**Methods:** A retrospective review was undertaken of the records of all patients who underwent breast conserving surgery for breast cancer between 2000 and 2008 at a single unit where excision of close anterior margins was not routinely undertaken. A close margin was defined as disease within 2 millimetres of the resection margin.

**Results:** Two thousand and 567 patients underwent breast conserving surgery of whom 273 (10.6%) had a close anterior margin with all other margins being clear. Follow-up data was available for 258 patients. Two hundred and thirty (89.1%) patients did not have re-excision surgery. Of those, 53 had disease at the margin. Average follow-up was 6.2 years (range 6 months to 14.3 years). The 5 year local recurrence rate was

2.6% (6/230). For those with disease at the margin, the 5 year recurrence rate was 1.9% (1/53).

**Conclusions:** Non-surgical management of close/involved anterior margins is safe with low rates of local recurrence when combined with good adjuvant therapy. Re-excision of solely close anterior margins may therefore lead to poor cosmetic outcomes with little potential oncological benefit.

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### 12. A comparison of two digital mammography systems at Breast Test Wales – More or less accurate?

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**Introduction:** The Welsh breast screening service (Breast Test Wales) converted to wholly digital technology in 2012. This study aims to compare performance of two newly introduced digital mammography technologies (Sectra/Philips and Hologic); specifically, are there differences in the number, type, size and grade of tumour identified?

**Method:** This is a retrospective study of a prospectively collected database of 50,000 consecutive screening episodes from 2012; clients aged 49–88 (mean 61.9) performed at Breast Test Wales South East division. All studies were double blind read by two readers. All tumours identified in the two arms of the study were detailed and compared. Performance was analysed for any statistically significant differences.

**Results:** 500 cancers were found with no significant difference in invasive cancer detection nor between ductal or lobular subtypes. Hologic detected 267 tumours, 71 (26.59%) were DCIS (2.88 per 1000), compared to Sectra with 233 cancers overall including 34 (14.59%) DCIS (1.44 per 1000). The difference in DCIS detection was significant  $p < 0.001$  with both showing 53% High Nuclear Grade (HNG) lesions yet Hologic found proportionately more Low Nuclear Grade (LNG) (23% vs Sectra 9.5%). Sectra radiation dose was significantly less (0.7mGy) compared to Hologic (1.6mGy) for 60mm breast thickness.

**Conclusions:** Population breast screening is criticised for identifying lesions irrelevant to long term outcomes or life expectancy. Whilst Hologic and Sectra/Philips seem comparable in terms of invasive cancer detection, we show a statistically significant difference of DCIS detection, not reported in previous studies. This is a contentious issue as identifying more DCIS has potential to overdiagnose screened patients leading to increased morbidity, higher 'cancer detection rates,' longer cancer waiting times and reduced psychological well-being. Sectra delivers similar invasive detection delivering a lower dose mammogram, important in limiting overall population radiation dose. Further work to ascertain if difference in cancer detection rates are *clinically* significant long term are required.

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### 13. Should we MRI the contralateral breast in lobular cancer? A study from a teaching hospital and a District General Hospital

Jessica Tan<sup>1</sup>, Claudia Pisarek<sup>2</sup>, Daniel Cocker<sup>1,2</sup>, Michael Williamson<sup>1</sup>, Ekambaram Babu<sup>1</sup>, Daniel Leff<sup>2</sup>

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**Introduction:** Invasive lobular carcinomas (ILC) account for 5–15% of breast cancers. They are characterised by non-cohesive cells, which grow in a single file (termed 'Indian filing'). There is a reportedly higher incidence of bilateral involvement in ILC (20–29%) as compared with other breast cancers. MRI has been shown to be more sensitive for ILC as compared with ultrasound (US) and mammography. It also appears to be more accurate in assessing extent of disease, and therefore used

primarily in aiding surgical planning for breast conserving surgery. Additionally, MRI may be used in cases where neo-adjuvant chemo/radiotherapy is given, in order to assess response to treatment. However, it has been reported that in 7% of cases, MRI has picked up contralateral malignancies not seen using other modalities. London Cancer Alliance guidance suggests that MRI can help plan breast-conserving surgery, but does not mention that for patients choosing mastectomy that MRI scanning can identify contralateral synchronous tumours.

We ask if there is a potential to miss contralateral cancers by not performing MRI on all patients presenting with ILC.

**Methods:** Collected data on all patients presenting to a District General Hospital (DGH) and a large central Teaching Hospital (TH) with ILC between 1<sup>st</sup> January 2011 and 31<sup>st</sup> December 2014.

**Results:** 199 patients presented with ILC (90 to DGH, 109 to TH). 130 patients had an MRI (41 at DGH, 89 at TH). 6 were known to have had bilateral cancers on presentation. 19/124 were found to have contralateral abnormalities. 0/19 of these were contralateral ILCs. Therefore all malignancies were picked up clinically or on mammography.

**Conclusion:** From this dataset, there is no evidence to indicate the use of routine MRI in patients with ILC considering unilateral mastectomy.

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#### 14. The REQUITE-AB study: Validating predictive models and biomarkers of radiotherapy toxicity to reduce side-effects and improve quality of life in breast cancer patients

**Tim Rattay<sup>1</sup>, Kerstie Johnson<sup>1</sup>, Samuel Lavers<sup>1</sup>, David Azria<sup>3</sup>, Akke Botma<sup>2</sup>, Jenny Chang-Claude<sup>2</sup>, Susan Davidson<sup>5</sup>, Dirk De Ruyscher<sup>6</sup>, Sara Gutiérrez Enrí quez<sup>9</sup>, Phillipe Lambin<sup>10</sup>, Tiziana Rancati<sup>11</sup>, Barry Rosenstein<sup>12</sup>, Christopher Talbot<sup>1</sup>, Hubert Thierens<sup>13</sup>, Ricardo Valdagni<sup>11</sup>, Ana Vega<sup>14</sup>, Adam Webb<sup>1</sup>, Frederik Wenz<sup>2</sup>, Catharine West<sup>8</sup>, Tom Burr<sup>4</sup>, Alison Dunning<sup>7</sup>, R. Paul Symonds<sup>1</sup>**

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**Background:** Clinically significant side-effects from radiotherapy affect around a quarter of breast cancer patients and may have a considerable impact on outcomes from breast surgery. An increasing number of replicated genetic associations for radiotherapy-induced adverse effects are being reported. The purpose of the EU-funded REQUITE consortium is to validate genetic markers and known clinical factors implicated in radiotoxicity to personalise cancer care in the future. The aim of the REQUITE-AB project is to develop an integrated set of predictors for radiotherapy side-effects in breast cancer patients as the primary component of a decision-making tool for clinicians and patients.

**Methods:** As part of the REQUITE multi-centre observational cohort study >1,900 patients eligible for adjuvant breast radiotherapy will be recruited in nine centres across Europe and North America between April 2014 and August 2016, with centralised data management, biobanking and two years' prospective follow-up using a standardised protocol. Primary endpoints of the REQUITE-AB project are acute skin toxicity (CTC-AE v4.0) and change in patient-reported outcome (PRO) scores on

completion of radiotherapy and at 3 months from start of radiotherapy. Secondary endpoints are late side-effects including fibrosis.

**Results:** 1,206 breast cancer patients have been recruited to date with standardized documentation of toxicity and PROs. On completion of radiotherapy, 22.5% of patients recruited so far developed grade 2 skin toxicity (brisk erythema) with a further 1.7% displaying grade 3 toxicity (moist desquamation). PRO questionnaire completion rates at baseline and end of treatment are 85.8% and 88.6%, respectively.

**Conclusion:** The REQUITE study includes the largest radiogenomics cohort of breast cancer patients recruited to date under a single standardised protocol. Genotyping will take place in 2016. The ability of clinical and genetic variables to predict both clinical outcomes and PROs will be examined. Findings of the REQUITE-AB project are likely to inform the development of future interventional biomarker trials in breast cancer care and breast reconstruction.

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#### 15. Axillary lymph nodes downstaging by neo-adjuvant chemotherapy for breast cancer

**Samiya Al-Hattali, Andy Evans, Douglas J.A. Adamson, Jayaram Mohanamurali, Colin A. Purdie, Douglas C. Brown, E. Jane Macaskill**  
 Ninewells Hospital, Dundee, UK

**Introduction:** Surgical management of axilla in patients with breast cancer (BC) after neoadjuvant chemotherapy (NAC) remains a clinical challenge. The aim of this study was to explore the effects of NAC on axillary lymph nodes to identify a subset of patients who may be spared axillary node clearance (ANC).

**Method:** A retrospective analysis of all patients with BC who received neoadjuvant chemotherapy from 2010 to 2015 and who subsequently underwent ANC. All patients had a pre-treatment biopsy confirming axillary metastases.

**Results:** Of 110 patients, of median age 50 years (range 24–79), 29 patients (26%) received anthracycline based NAC, 7 patients (6%) received taxanes only NAC and 74 patients (67%) received an anthracycline and taxane regimen. Twenty patients (18%) had pathological complete response (pCR) in the primary tumour. The median number of axillary nodes removed was 17 (range 7–34). Forty-one patients (36%) had no macrometastasis and 23 patients (20%) had only 1 positive node. A negative ANC (no macrometastasis) was found in 18 of 20 (90%), 13 of 25 (52%), 9 of 51 (17%) and 1 of 14 (7%) of patients who had a pCR, near complete, partial and no or minimal response respectively (P<0.0001). A total of 56 patients (49.6%) showed pathological evidence of axillary downstaging.

**Conclusion:** Contemporaneous NAC regimens have a significant impact on axillary nodes metastasis. Sentinel node biopsy should be considered as primary surgical management of axilla in the setting of NAC where there is evidence of good response to treatment.

<http://dx.doi.org/10.1016/j.ejso.2016.02.035>

#### 16. Long term recurrence outcome of patients undergoing oncotype Dx testing for ER positive and node negative early breast cancer

**Asma Munir, Sujatha Udayasanka, Daniel Thomas, Anita Huws, Gill Dazeley, Yousef Sharaiha, Saira Khawaja, Simon Holt**  
 Prince Philip Hospital, Llanelli, UK

**Background:** We have previously reported on the impact of oncotype Dx testing in decision making for adjuvant therapy in early stage breast cancer patients with oestrogen receptor (ER)-positive and axillary lymph node-negative disease. The primary objective of this study was to determine the long term recurrence outcome in these patients.

**Methods:** Between 2009 to 2012, 86 patients with estrogen receptor (ER)-positive and axillary lymph node-negative breast cancer underwent

the Oncotype Dx test. Clinical and pathological variables, treatment with chemotherapy, and follow-up for local and distant recurrences were evaluated.

**Results:** The median age of the patients was 58 years with a range of 38 years to 76 years. Concerning the oncotype Dx results, 51 patients (59%) had a low recurrence score; 24 (28%) had an intermediate result; and 11 (13%) had a high recurrence score. Only 24 patients (27.9 %) were treated with chemotherapy plus endocrine therapy. This included all the patients in the high recurrence group and 13 in the intermediate group. The remaining 62 (72.1%) were treated only with endocrine therapy. The median follow up was 50 months. Only one patient in the total

cohort had developed both a local recurrence and distant disease (lung metastases). Her RS was 39, and she had received chemotherapy and endocrine therapy.

**Conclusions:** Our data indicate that the actual recurrence rate for our cohort was 1.18%. Our study confirms that oncotype Dx is reliable in predicting the recurrence rate in node negative early breast cancer patients and avoids unnecessary chemotherapy.

<http://dx.doi.org/10.1016/j.ejso.2016.02.036>

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## Monday 16th May 2016, Session 9: Submitted papers. 14:30 to 16:00

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### 17. Local recurrence in young women with invasive breast cancer: The POSH study

**Tom Maishman, Ramsey Cutress, Aurea Hernandez, Sue Gerty, Ellen Copson, Lorraine Durcan, Diana Eccles**

Cancer Sciences Academic Unit and Southampton Clinical Trials Unit, University of Southampton, Southampton, Hants, UK

**Introduction:** POSH (MREC:00/06/69) is a prospective cohort study of 3024 women aged 18–40 with breast cancer. Randomised controlled trials suggest equivalent survival between mastectomy and breast conserving surgery (BCS), however emerging data suggests a possible survival advantage for mastectomy in gene mutation carriers, and young age may be a predictor of higher rates of local-recurrence.

**Methods:** Summary statistics were used to describe the cohort by surgery (mastectomy or BCS). Endpoints were local-recurrence interval, distant disease-free interval and overall survival. Cumulative hazard and Kaplan-Meier plots were used to describe survival data. Univariate and multivariate analyses were carried out using Flexible Parametric and Cox proportional hazards models.

**Results:** Of 2882 patients analysed, 1464 underwent mastectomy, 1395 BCS; and lymph node surgery only in 23. Patients undergoing mastectomy had significantly larger tumours and higher proportions of positive Family History, ER+, PR+, and/or HER2+ tumours. Local events only accounted for 15% of recurrences. Local-recurrence rate was similar at 18 months but higher for BCS compared to mastectomy at 5- and 10-years (1.0% v 1.0%: HR=1.43, p=0.348; 5.3% v 2.6%: HR=3.39, p<0.001; and 11.7% v 4.9%: HR=5.27, p<0.001, respectively). Similar results were found in the adjusted model. Conversely, distant-metastases and death events were significantly lower for BCS but not after adjusting for prognostic factors.

**Conclusions:** In the short term, there is no difference in local-recurrence between BCS and mastectomy in young women. Longer term local-recurrence is higher in BCS, but there is no difference in survival between surgical groups after adjusting for known prognostic factors.

**Acknowledgements:** Data collection/analysis funded by CRUK (grants:A7572, A11699, C1275/A15956). Sponsored by UHS NHS Foundation Trust.

<http://dx.doi.org/10.1016/j.ejso.2016.02.037>

### 18. Managing the ‘Angelina Jolie effect’ with tea and biscuits Douglas Macmillan, Nicky Scott, Nottingham Breast Institute Research Team (L. Brock, M. Akerlund, C. Otieno)

Nottingham Breast Institute, Nottingham, UK

**Introduction:** After the actress announced her prophylactic surgery in 2013, the Nottingham Breast Institute (NBI) had a 100% increase in new referrals, with similar effects across the country. As other studies have

shown, the trend appears long-lasting. To manage the increased demand on the service and support women diagnosed as gene positive, a forum was set up to enable women to access information and support via a larger network.

**Method:** NBI launched the first ‘Tea Party’ – an information evening for gene positive women in 2014. Genetic counsellors; breast surgeons and gynaecologists gave short presentations on their speciality followed by question and answer sessions. Women at different stages of their treatment were invited: recently diagnosed / pre-surgery breast + oophorectomy / post-surgery breast + oophorectomy.

A private closed Facebook group was set up and only those invited to the group that had signed a disclaimer could participate.

**Results:** The Tea Party now runs every two months and the first event had 21 attendees; we now have on average of 18 attendees. NBI has hosted nine events so far, one of them included partners. Each session has been evaluated with 100% of participants saying they found the ‘Tea Party’ useful.

The Facebook group has 40 members and is busy with comments, support and people sharing their stories.

**Conclusion:** Group sessions with clinical staff have demonstrated alternative ways to manage the exponential increase of the support required for women with high risk family history.

<http://dx.doi.org/10.1016/j.ejso.2016.02.038>

### 19. First results of a pre-planned interim analysis of a national multicentre Patient Reported Outcome Study (PRO-Bra) in breast reconstruction following mastectomy with titaniferously coated polypropylene mesh (TilooBra)

**Stefan Paepke<sup>1</sup>, Anna Jäger<sup>1</sup>, Evelyn Klein<sup>1</sup>, Marion Kiechle<sup>1</sup>, Ralf Ohlinger<sup>2</sup>, Christine Ankel<sup>3</sup>, Andree Faridi<sup>3</sup>, Annette Meir<sup>4</sup>, Jens Blohmer<sup>5</sup>, Christine Gerber-Schäfer<sup>6</sup>, Christine Mau<sup>7</sup>, Marc Thill<sup>8</sup>**

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<sup>7</sup> Brustzentrum des Helios Klinikums Berlin Buch, Berlin, Germany

<sup>8</sup> Brustzentrum des Agalesion Krankenhauses Frankfurt/Main, Frankfurt/Main, Germany

**Introduction:** In the majority of interdisciplinary breast centres of Germany, implant based, mesh-supported operations constitute a total of

approximately 50-60% of reconstructive techniques. The vast majority of mesh-supported plastic reconstructive breast operations were performed with the titanized polypropylene mesh TiLoop®Bra [ Zoche H; 2014]. The BreastQ [Pusic AL; 2006] is the most valid and reliable measurement of quality of life aspects in important domains used in clinical routine.

**Material and Method:** Because the patient reported outcome is the most relevant factor reflecting the overall satisfaction from a patient perspective, a prospective single arm non-randomized surveillance study with BreastQ-scales at 12 months as primary endpoint was conducted (2013). Overall 205 breasts of 153 pts. were treated between 12/2013 and 9/2015. A pre-planned analysis of the first 60 pts. with completion of the BreastQ after 6 months (secondary endpoint) was done.

**Results:** Most frequent indication was BC. Almost all surgeries were primary reconstructions (96.6%) and nipple-skin-sparing mastectomies (97.1%). An expander exchange is planned for 20 pts. The most frequent incision was inframammary (n= 115), followed by T-shaped (n= 45). The average of the pts. was 50 y (19–77); BMI was 22 (17–33), 77.3% were non-smokers. Percentage of neoadjuvant chemotherapy was 23%, of prior radiotherapy was 12%. Radiotherapy showed no significant influence of the BreastQ. Severe events occurred in 46 cases. The most frequent complications were necrosis (n= 12), hematoma (n= 12); 9 pts. dropped out. The mean score of BreastQ was equal pre- and postoperative after 6 months (67+/-16 to 65+/-15); satisfaction with breast from 67+/-22 to 61 +/-14; psycho-social well-being from 71+/-17 to 73+/-18; sexual well-being from 62+/-17 to 60+/-19; satisfaction with outcome was 75+/-18 and satisfaction with surgeon 90+/-15. 88.3% were very satisfied, 10.0% somewhat satisfied, only 1.7% somewhat dissatisfied, 0% very dissatisfied.

**Conclusion:** The first analysis of the PROBra-study shows positive results in all outcome parameters. The study will continue until the complete recruitment of the pre-planned 267 pts. within a follow up of at least two years.

<http://dx.doi.org/10.1016/j.ejso.2016.02.039>

## 20. Electrochemotherapy for skin metastases in advanced breast cancer: Experience from the London Cancer Network

**Shramana Banerjee<sup>1</sup>, Jackie Newby<sup>1</sup>, Graeme Moir<sup>2</sup>, Virginia Wolstenholme<sup>2</sup>, Caroline Footitt<sup>2</sup>, Diane Whittaker<sup>1</sup>, Mohammed Keshtgar<sup>1</sup>**

<sup>1</sup>Royal Free London NHS Foundation Trust, London, UK

<sup>2</sup>Royal London Hospital NHS Foundation Trust, London, UK

**Aims:** Electrochemotherapy (ECT) combines the administration of poorly permeable chemotherapeutic agents with electroporation. This allows electrical pulses to form pores within the cell membrane to facilitate drug delivery into the cells. This study assessed how breast cancer patients were benefited and identified potential problems following treatment at London Cancer Network centres.

**Methodology:** Patients referred within the London Cancer Network for cutaneous metastases from breast cancer were included. Patients who fulfilled the NICE UK (National Institute of Health and Care Excellence) and local guidelines were offered treatment. Gabapentin was given prior to general anaesthesia. An intravenous Bleomycin 15,000IU/m<sup>2</sup> was given as a bolus. Treatment was commenced 8 minutes later with Cliniporator™. Electrical pulses were delivered via an electrode inserted through the skin surface. Treatment response, disease progression free duration, post-operative symptoms and length of in-patient stay (LOS) were recorded.

**Results:** 28 patients were referred for ECT and 23 patients received 28 treatments from 2011–2015 with Median LOS 3 days. Median follow up was 6 months (range 3–18). 15 patients had complete response (65%) and 8 patients had partial response. There were no deaths or immediate adverse events from ECT. 5 Patients (21%) with extensive diffuse chest wall disease reported persistent discomfort post treatment requiring extended period of post treatment analgesia.

**Conclusions:** ECT is effective in the treatment of breast cancer cutaneous metastases. Appropriate patient selection for treatment is essential in order to maximise the benefits and minimise potential side-effects particularly in extensive chest wall disease.

<http://dx.doi.org/10.1016/j.ejso.2016.02.040>

## 21. An Exploration of Clinical Decision-Making in Advanced Nursing Practice

**Suzanne Halliday<sup>1,2</sup>, Grace Lucas<sup>1</sup>, Theresa Wiseman<sup>1</sup>, Jacquie Woodcock<sup>1</sup>**

<sup>1</sup>The Royal Marsden NHS Foundation Trust, Sutton, UK

<sup>2</sup>Brighton and Sussex NHS Trust, Brighton, UK

**Introduction:** This study explores clinical decision-making in advanced level nurses. Areas of interest include the influences of education and experience in addition to contrasts between simple and complex decision-making.

**Methods:** A grounded theory methodology was used for data collection. Data were obtained from eleven clinical nurse specialists in a South of England NHS Trust. Trust research and development and committee for clinical research approval was gained. Following consent, face-to-face, semi-structured interviews were conducted. Emerging categories relating to advanced nurses' experiences of clinical decision-making were identified.

**Results:** Results indicated clinical decision-making in advanced nursing was informed by the previously identified elements of ethical practice, knowledge, relationships, reflection and self-awareness. In addition to the aforementioned elements this professional group were shown to employ further elements including attitude to service provision, knowledge utilization, team work, nurse/patient relationship, self-belief and patient-care. This highlights that clinical decision-making in advanced nursing practice may be more complex than previously acknowledged.

**Conclusions:** Study findings support current literature relating to clinical decision-making in advanced nursing practice. New, disparate theoretical categories also emerged from the data, contributing to the known understanding of clinical decision-making in this population.

**Recommendations:** Findings indicate this population would benefit from a continued requirement for mentorship and supervision. The significance of theoretical knowledge in clinical decision-making also endorses the need for clinical support and teaching in the workplace to optimize the extensive decision-making repertoire advanced practice nurses utilize when making clinical decisions.

<http://dx.doi.org/10.1016/j.ejso.2016.02.041>

## 22. International validation of the EORTC Patient-Reported Outcome Measure (PROM) in breast reconstruction (BRR): Evaluating health related quality of life (HRQL) and clinical effectiveness

**Zoe Winters<sup>1</sup>, Maryam Afzal<sup>1</sup>, Gerhard Rumpold<sup>2</sup>, Bernhard Holzner<sup>2,3</sup>, Anne Oberguggenburger<sup>3</sup>, Renee Da Costa Vieira<sup>4</sup>, Susan Hartnup<sup>5</sup>, Kathy Filcroft<sup>6</sup>, Vesna Bjelic-Radisic<sup>7</sup>, Marie Panouilleres<sup>8</sup>, Maria Rydevik-Mani<sup>9</sup>, M.T. King<sup>10,11</sup>, C. Rutherford<sup>10</sup>**

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<sup>11</sup>Sydney Medical School, Sydney, Australia

**Introduction:** PROMs are integral to assessing clinical effectiveness after BRR. The European Organization for Research and Treatment of Cancer (EORTC) BRR questionnaire (QLQ-BRR24) was developed for use alongside the EORTC PROMs: QLQ-C30 (cancer) and QLQ-BR23 (breast cancer).

**Methods:** Patients (n=514) from 9 countries covering 6 languages self-reported the EORTC QLQ-C30, QLQ-BR23 and the QLQ-BRR24 before and after BRR including a debriefing questionnaire/interview. Prospective patients (n=274) completed the QLQ-BRR24 at baseline (before mastectomy and BRR) and at 5–8 months after (response to change analysis, RCA). Cross-sectional patients (n=240) were at 1–5 years after BRR to capture long-term HRQL effects and test-retest reliability through two rounds of QLQ-BRR24 completion (3–8 weeks apart). Scale convergent validity was tested using Pearson's correlations.

**Results:** Patient groups: implant alone (n=204), donor flap (n=215) and control (mastectomy or staged-delayed, n=88). Six HRQL scales: i) sexuality; ii) treatment side effects; iii) donor symptoms; cosmetic [iv] breast; v) nipple; vi) surgery satisfaction] and 4 single questions (well-fitting bra, loss or preserve nipple, donor scars satisfaction) were psychometrically tested. Patients did not report difficulties. Good reliability of QLQ-BRR24 scales, except for treatment-related arm symptoms (tingling and fullness) and poor test-retest of two single questions (nipple loss and donor-satisfaction). Significant ( $p < 0.01$ ) correlations (convergent validity) between conceptually related scales of QLQ-BRR24 and QLQ-C30, QLQ-BR23. Clinically significant effects-sizes (Cohen's d: 0.37–0.54) and RCA were demonstrated for sexuality, treatment side effects and well-fitting bra.

**Conclusions:** EORTC-QLQ-BRR24 is internationally validated for BRR in breast cancer patients. Future studies should consider comparing it to the BREAST-Q.

<http://dx.doi.org/10.1016/j.ejso.2016.02.042>

### 23. Breast Clinical Nurse Specialist perspective of decision support interventions

**Karen Collins<sup>2</sup>, Lynda Wyld<sup>1</sup>, Maria Burton<sup>3</sup>, Kate Lifford<sup>1</sup>, Fiona Armitage<sup>1</sup>**

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<sup>3</sup>Cardiff University, Cardiff, UK

**Introduction:** Treatment protocols for older women with breast cancer may vary from standard to accommodate co-morbidity and frailty. Supporting decision-making in older women may be challenging due to lack of informational resources and research evidence. We report development of tools to support shared decision making in older women from the perspective of the Clinical Nurse Specialist (CNS).

**Method:** The information preferences of older women were studied using a multi-source intervention. CNS's, oncologists, surgeons, patients and healthy volunteers were recruited for questionnaires, audio recorded consultations, telephone and face to face interviews to determine the information needs of older women. Data were used to develop a series of decision support interventions (DESI's) to aid older women making breast cancer

treatment decisions. These DESI's comprised patient booklets, a web based algorithm allowing clinicians to establish individual risks and option grids. User feedback on the tools was obtained to refine them further.

**Results:** This abstract reports a re-interpretation of the data collected from a CNS perspective of the decision supports using framework analysis to identify common themes in the feedback to further refine the DESI's to facilitate clinical utility, acceptability, ease of use, practicality and facilitators and barriers to routine clinical practice.

**Conclusions:** The decision tools were well received by CNSs whose feedback directed further amendments and addition of a 'frequently asked questions' section related to the sources and validity of underpinning data. This tool will now be tested as part of the Age Gap randomised trial.

<http://dx.doi.org/10.1016/j.ejso.2016.02.043>

### 24. Comparison of treatment variations in old age breast cancer in two units of a metropolitan city in the United Kingdom

**Laszlo Romics<sup>1</sup>, Gillian Bentley<sup>2</sup>, David Kipgen<sup>3</sup>, Elizabeth Mallon<sup>3</sup>, Sheila Stallard<sup>4</sup>, Julie Doughty<sup>4</sup>**

<sup>1</sup>New Victoria Hospital, Glasgow, UK

<sup>2</sup>West of Scotland Managed Cancer Network, Glasgow, UK

<sup>3</sup>Queen Elizabeth University Hospital, Glasgow, UK

<sup>4</sup>Gartnavel General Hospital, Glasgow, UK

**Background:** Treatment of patients with old age breast cancer depends on tumour biology and stage, patients' comorbidities, frailty, patients' and physicians' preference. We have retrospectively compared the management of old age patients with breast cancer in two neighbouring breast units in a metropolitan city.

**Methods:** Pathological characteristics and treatment provided for patients with old age breast cancer diagnosed between 2009 and 2013 were compared. Two-tailed Z-test was used for statistics.

**Results:** 3850 patients were treated with breast cancer in the two units during this five-year period of time. 954 patients were 70 years or older at the time of diagnosis. 718 patients (75.3%) had ER positive / Her-2 negative combination of cancer, with no significant differences within the two units. Similar number of patients with old age breast cancer was treated in the units (487 and 471). Unit 1 treated significantly lower proportion of old age breast cancer patients with hormonal therapy only (94; 19.3%) than Unit 2 (161; 34.2%) ( $p = 0$ ). Similarly, Unit 1 operated significantly more patients with old age breast cancer (371; 76.2%) than Unit 2 (289; 61.3%) ( $p = 0$ ). When patients underwent surgery, mastectomy rates were almost identical in between the two units (50.1% and 51.2%).

**Conclusion:** Significant variation of treatment in old age breast cancer was found in two neighbouring breast units. Since these two units work in close geographical proximity it is unlikely that co-morbidity, frailty or deprivation would be significantly different. Decision-making on the multidisciplinary meetings should be examined in the future.

<http://dx.doi.org/10.1016/j.ejso.2016.02.044>

## Tuesday 17th May 2016, Session 14: Submitted papers. 09:00 to 10:30

### 25. Validation of the use of radioactive iodine-125 seed localisation of breast carcinoma in patients undergoing breast conservation surgery in the United Kingdom

**Robert Milligan, Adam Critchley, Stewart Nicholson, Henry Cain**  
Royal Victoria Infirmary, Newcastle, UK

**Introduction:** We are the first breast unit in the UK to introduce radioactive seed localisation (RSL) using iodine-125 seeds as an alternative to guidewire localisation (GWL). The aim of this study was to evaluate and compare the efficacy of RSL and GWL in breast conservation surgery with wide local excision (WLE).



**Methods:** Data were collected prospectively on the last 100 patients undergoing GWL WLE prior to the introduction of RSL, and the first 100 patients undergoing RSL WLE. Patients with non-palpable and histologically proven invasive carcinoma were included. Exclusion criteria were: multiple guidewires, therapeutic mastectomy, diagnostic excision biopsy and pathological complete response after chemotherapy. Incomplete resection margins were considered less than 1mm for invasive disease and less than 2mm for pre-invasive carcinoma. Data collected included tumour type, size and grade, total excision weight and margin positivity. Statistical analysis was performed using Unpaired Student T-Test.

**Results:** Both groups showed similar tumour characteristics of type, grade and receptor status. Mean total tumour size was similar between groups measuring 19.44mm (5–55) in the GWL group compared with 18.61mm (3.8–59) in the RSL group ( $p=0.29$ ). Mean total specimen excision weights were significantly lower in the RSL group compared with the GWL group, weighing 31.55g (4.5–112) and 37.42g (7.8–157.1) respectively ( $p=0.02$ ). 13 patients had positive margins in the RSL group compared with 15 in the GWL group (13% vs 15% respectively,  $p=0.34$ ).

**Conclusion:** RSL using iodine seeds is a safe and reliable alternative to GWL for localisation of non-palpable invasive breast carcinomas in the UK.

<http://dx.doi.org/10.1016/j.ejso.2016.02.045>

## 26. Locoregional recurrence following breast cancer surgery in the trastuzumab era: A systematic review by subtype

Andrew McGuire<sup>1</sup>, Aoife Lowery<sup>1</sup>, Malcom Kell<sup>2</sup>, Michael Kerin<sup>1</sup>, Karl Sweeney<sup>1</sup>

<sup>1</sup>NUI Galway, Galway, Ireland

<sup>2</sup>Mater Misericordiae University Hospital, Dublin, Ireland

**Introduction:** There is increasing evidence that molecular subtype influences locoregional recurrence (LRR) of breast cancer. Previous systematic reviews evaluating the quantitative influence of subtype on LRR predated the use of Trastuzumab. This study was undertaken to systematically assess the impact of subtype on LRR in a contemporary treatment era.

**Methods:** A comprehensive search for all published studies assessing LRR according to breast cancer subtype was performed using Medline and cross-referencing available data. Only studies where patients were treated with Trastuzumab were included. Relevant data was extracted from each study for systematic review. Primary outcome was LRR related to breast cancer subtype.

**Results:** In total 8,894 patients were identified from 10 studies. There was a significantly lower risk of LRR in patients with luminal A subtype of breast cancer when compared to luminal B (OR 0.54; 95%CI= 0.42 to 0.70), HER2/neu over-expressing (OR 0.46; 95%CI= 0.35 to 0.60) and triple negative breast cancers (OR 0.28; 95%CI= 0.23 to 0.35). HER2/neu over-expressing tumours treated with Trastuzumab were significantly less likely to develop LRR than triple negative cancers (OR 0.7; 95%CI= 0.55 to 0.96). There was no significant difference in LRR between the Her2-positive Luminal B and Her2/neu over-expressing breast cancers (OR 0.86; 95%CI= 0.62 to 1.18).

**Conclusion:** Luminal A tumours are associated with the lowest rates of LRR. Luminal B and HER2/neu over-expressing subtype tumours treated with Trastuzumab exhibit comparable LRR rates, which are significantly lower than in the triple negative subtype. This highlights the positive impact of targeted breast cancer treatment.

<http://dx.doi.org/10.1016/j.ejso.2016.02.046>

## 27. Sentinel Lymph Node Analysis Pre and Post-Introduction of One Step Nucleic Acid Amplification (OSNA): Cost evaluation

Madelaine Gimzewska, Sophie Allen, Matthew Tambling, Omotayo Johnson, Manish Kothari

Ashford & St Peter's NHS Foundation Trust, Chertsey, UK

**Introduction:** One Step Nucleic Acid Amplification (OSNA) for intra-operative analysis of sentinel lymph nodes (SLNs) in breast cancer reduces the need for a second operation for axillary lymph node dissection (ALND) in patients with SLN metastases.

**Primary outcome:** Operating time and cost of SLN assessment comparing conventional post-operative histopathological evaluation (group 1) with intra-operative analysis using OSNA (group 2). Secondary outcomes: 1) Rate of macro and micrometastases; 2) Rate of axillary clearance; 3) Overall SLN yield.

**Methods:** Retrospective data were collated on consecutive patients 9 months pre ( $n=96$ ) and post ( $n=90$ ) OSNA introduction. Level 1&2 ALND was performed for macrometastases. Those with negative SLN or micrometastases did not undergo further axillary surgery. Costs were calculated as 'overall cost to the Trust per year'.

**Results:** Median duration of surgery for groups 1 and 2 was 75.5 and 104.5 minutes respectively ( $p<0.05$ ). Total operating time per 100 patients was 61 hours longer in group 2 compared with group 1, despite patients with macrometastases in group 1 requiring a second operation for ALND. The cost of SLN analysis using OSNA compared to histopathology was £38,000 more expensive per annum.

Micrometastasis detection was higher in group 2 (24% vs 7%,  $p<0.01$ ), with no difference in rate of macrometastases ( $p=0.3$ ) or negative SLNs ( $p=0.07$ ). ALND rate was 6% and 16% in groups 1 and 2 respectively ( $p<0.05$ ). There was no difference in SLN yield.

**Conclusion:** Intra-operative OSNA is not time or cost effective when compared with conventional histopathological analysis for assessment of SLN metastases.

<http://dx.doi.org/10.1016/j.ejso.2016.02.047>

## 28. OPTIMA (Optimal Personalised Treatment of early breast cancer using Multi-parameter Analysis): A prospective trial to validate the predictive utility and cost-effectiveness of gene expression test-directed chemotherapy decisions

Adele Francis<sup>1</sup>, Robert C. Stein<sup>2</sup>, Andrea Marshall<sup>3</sup>, Daniel W. Rea<sup>4</sup>, David A. Cameron<sup>5</sup>, Iain R. Macpherson<sup>6</sup>, Helena M. Earl<sup>7</sup>, Christopher J. Poole<sup>8</sup>, Peter S. Hall<sup>5</sup>, John M.S. Bartlett<sup>9</sup>, Leila Rooshenas<sup>10</sup>, Adrienne Morgan<sup>11</sup>, Victoria Harmer<sup>12</sup>, Jenny Donovan<sup>10</sup>, Claire Hulme<sup>13</sup>, Christopher McCabe<sup>14</sup>, Sarah E. Pinder<sup>15</sup>, Luke Hughes-Davies<sup>16</sup>, Andreas Makris<sup>17</sup>, Janet A. Dunn<sup>3</sup>

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**Introduction:** Multi-parameter gene expression assays (MPAs) are used to estimate individuals' residual risk and guide chemotherapy use in hormone-sensitive HER2-negative node-negative early breast cancer. OPTIMA aims to prospectively validate the use of MPAs to predict chemotherapy sensitivity in a largely node-positive breast cancer population.

**Methods:** Eligible patients are men or women aged  $\geq 40$  years with resected early stage ER-positive, HER2-negative breast cancer, who have either 1–9 involved nodes or tumours  $\geq 30$ mm. Randomisation is to standard management (chemotherapy then endocrine therapy) or MPA-directed treatment. Those with a tumour categorised as “high-risk” by the test have standard management whilst those at “low-risk” have endocrine therapy alone. The preliminary phase (OPTIMA-prelim) evaluated the performance of MPAs for use in the main efficacy trial; and assessed the feasibility and acceptability of a large trial. OPTIMA-prelim used Oncotype DX as the primary discriminator; OPTIMA will use Prosigna (PAM50). Co-primary outcomes are invasive disease free survival and cost-effectiveness. A 4500 patient study allows the demonstration of 3% non-inferiority of test-directed treatment with 5% significance and 85% power. Addition of OPTIMA-prelim patients allows assessment of non-inferiority with 2.5% significance.

**Results:** OPTIMA-prelim demonstrated that a large-scale UK study is feasible. It showed that research on MPA-directed therapy, especially with Prosigna, should be of substantial value to the NHS.

**Conclusion:** OPTIMA is a large prospective trial validating test-directed therapy in node-positive hormone-sensitive early breast cancer and will have a global impact. OPTIMA opens to recruitment in February 2016.

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### 29. London Cancer Alliance: Development of a metastatic breast cancer service model and service specification

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**Introduction:** There are approximately 35000 UK patients with metastatic breast cancer (MBC). 5 year survival is 20% from diagnosis of metastatic disease with median overall survival approaching 2 years. Although national drivers mandate care for these patients there is minimal information on MBC standards and no guidance on best practice service delivery models.

**Method:** A London Cancer Alliance (LCA) audit showed variation in MBC service delivery. The LCA Breast Cancer Pathway group developed a MBC model service specification detailing 3 metastatic breast service models. They reflect the variation of patient caseloads amongst Trusts and are underpinned by 6 standards.

LCA MBC standards:

1. Dedicated metastatic clinic(s), including CNS led lists
2. A specialist breast metastatic nurse
3. Dedicated MDT slots to discuss metastatic patients, either as a metastatic MDT or as a dedicated part of the MDT meeting
4. Database of metastatic patients

5. Robust communication between metastatic breast teams, acute oncology and community palliative care services. Agreed pathways to drains, bloods transfusions and supportive procedures can minimise emergency admissions and improves patient experience

6. Access to MBC trials

**Results:** Management of MBC requires the above multidisciplinary and holistic approach supported by healthcare professionals experienced and trained in this area.

**Conclusion:** Underpinned by the six LCA best practice standards, implementation of the LCA Breast Metastatic Service Model Standards and Specification provides a feasible and practical approach to addressing the gaps in provision of care, reducing variation in practice, improving standards, patient experience, treatment, support and care of these patients.

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### 30. Screen-detected lobular neoplasia of the breast: Findings from the Sloane Project

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**Introduction:** The Sloane Project is a national UK prospective audit of ductal carcinoma in situ and atypical epithelial lesions including lobular neoplasia (LN), a collective term for atypical lobular hyperplasia and lobular carcinoma in situ. The number of women diagnosed annually with LN has increased as a result of mammographic screening but the radiological features, diagnosis and management are poorly documented.

**Methods:** Ethical approval was not required. 371 women with pure LN diagnosed between 2003 and 2013 were identified from the Sloane Project database. Demographic and radiological features and diagnostic and therapeutic procedures were analysed.

**Results:** Non-pleomorphic LN was diagnosed in 355 women and was most frequent among women aged 50 to 54, most commonly in the left breast (57.7%;  $p=0.004$ , chi square test), in the upper outer quadrant and confined to one site. The predominant radiological feature was microcalcification, most commonly granular, and this increased in frequency with increasing breast density. Casting microcalcification increased in frequency with increasing lesion size (Kruskal-Wallis test;  $p=0.034$ ). 312/355 (87.9%) women underwent surgery: 17 underwent more than one operation, five had mastectomy and five had axillary surgery. One woman had radiotherapy and 15 were prescribed endocrine treatment. Pleomorphic lobular carcinoma in situ presented as granular microcalcification in eight of 16 cases. Two women had mastectomy and four had radiotherapy.

**Conclusions:** Screen-detected LN is predominantly non-pleomorphic and is typically associated with granular microcalcification in

radiographically dense breasts of relatively young women. Surgical and non-surgical management is highly variable. Evidence-based management guidelines are required.

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### 31. Our initial experience of digital breast tomosynthesis guided vacuum assisted breast biopsies and the patient's perspective: A single centre experience

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**Introduction:** Digital breast tomosynthesis (DBT) helps analyse the breast in 1mm sections and has resulted in a decrease in the recall rate. With the advent of this latter radiological modality, some lesions will be detected with DBT. We present our first experience of DBT guided vacuum assisted breast biopsies (VABB).

**Material and Methods:** Our study duration is from June 2014 to July 2015. Previously, the prone table was being used. The procedure was performed by one of three trained personnel using the 9 gauge needle. A clip was placed post biopsy. The indication of the procedure, complication rate, correlation of imaging and pathologic findings and outcomes of the patients were assessed.

**Results:** A total of 88 patients were biopsied. The mean age was 57 years with a range between 30 to 80 years. The mean size of the lesion was 13mm. The primary lesion targeted was microcalcifications. 40 patients had benign lesions confirmed histologically and were discharged. 22 patients had indeterminate (B3) lesions out of which 6 had open benign biopsies. Two had B4 lesions, and 24 had B5 lesions. No complications were encountered. Patient satisfaction confirmed the procedure to be faster and less painful compared to stereotactic core biopsies.

**Conclusion:** DBT guided VABB has proven to be accurate with a lesser radiation dose being used, a shorter procedure time, safe and convenient to the patient. It is a new and promising technology.

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### 32. Thrombin Inhibition Preoperatively (TIP) in Early Breast Cancer (EBC), the first clinical trial of NOACs as an anti-cancer agent: Trial Methodology

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**Introduction:** Breast cancer is associated with a 3-4 fold increased risk of venous thromboembolism (VTE). These patients have a 4-fold lower survival than those remaining free of VTE, implying VTE is a surrogate marker for aggressive cancer. Tumour expression of thrombin pathway markers are increased in ERneg, high Ki67 breast cancer subtypes. In *in vitro* and *in vivo* studies, the thrombin pathway promotes cancer growth and metastases, highlighting the potential role of the thrombin pathway as a therapeutic target in cancer. Rivaroxaban is an oral direct Factor Xa inhibitor which inhibits conversion of prothrombin to thrombin.

**Aim:** To determine whether 14 days of preoperative Rivaroxaban in ERneg EBC patients results in inhibition of tumour proliferation as determined by a reduction in tumour Ki67 from baseline (pre-treatment) to 14 days post treatment (surgical excision).

**Trial methodology:** A multi-centre phase II preoperative 'Window-of-Opportunity' RCT of Rivaroxaban compared to no treatment in ERneg, stage I-III EBC. Patients will be randomised 1:1:1 (Rivaroxaban 20mg od: Rivaroxaban 10mg od: no treatment) and receive 14 (+/-3) days of treatment in the window between diagnosis and surgery. Primary analysis will be on the combined two Rivaroxaban arms to form a Rivaroxaban:no treatment, 2:1 trial design, with change in Ki67 from baseline (pre) to post Rivaroxaban/no treatment (post) being the primary endpoint. The no treatment arm is a reference group. Subgroup analysis of the Rivaroxaban arm (20mg od:10mg od) will allow dose-response assessment.

#### Conclusions:

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