THE AMERICAN SOCIETY OF BREAST SURGEONS

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ANNUAL 18TH MEETING

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2017 ANNUAL MEETING

OFFICIAL PROCEEDINGS, Volume XVIII

Scientific Session Abstracts

Scientific Session Awards

Abstracts presented at the Society's annual meeting will be considered for the following awards:

- The **George Peters Award** recognizes the best presentation by a breast fellow. In addition to a plaque, the winner receives $1,000. The winner is selected by the Society's Publications Committee.

  The award was established in 2004 by the Society to honor Dr. George N. Peters, who was instrumental in bringing together the Susan G. Komen Breast Cancer Foundation, The American Society of Breast Surgeons, the American Society of Breast Disease, and the Society of Surgical Oncology to develop educational objectives for breast fellowships. The educational objectives were first used to award Komen Interdisciplinary Breast Fellowships. Subsequently the curriculum was used for the breast fellowship credentialing process that has led to the development of a nationwide matching program for breast fellowships.

- The **Scientific Presentation Award** recognizes an outstanding presentation by a resident, fellow, or trainee. The winner of this award is also determined by the Publications Committee. In addition to a plaque, the winner receives $500.

- All presenters are eligible for the **Scientific Impact Award**. The recipient of the award, selected by audience vote, is honored with a plaque.

All awards are supported by The American Society of Breast Surgeons Foundation.

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Scientific Oral Presentations I

Friday, April 28, 2017 2:15 pm–3:15 pm
Moderators: Sarah Blair, MD; Judy Boughey, MD

257342 - The influence of breast density on preoperative MRI findings and outcome in patients with a known diagnosis of breast cancer

E. Alexa Elder, Alyssa Ferlin, Laura Vallow, Zhuo Li, Tammeza Gibson, Sarah McLaughlin
Mayo Clinic, Jacksonville, FL

Background/Objective: Many cite breast density as an indication for preoperative breast MRI for surgical planning in patients with a known diagnosis of breast cancer. However, the utility and value of MRI in this setting is unknown. We sought to analyze MRI outcomes including differences in preoperative biopsy rates, new lesion identification, and recurrence in breast cancer patients according to breast density.

Methods: We performed a retrospective review of newly diagnosed breast cancer patients at our institution from 2007-2011 who underwent preoperative MRI screening. We obtained clinical and pathological data and grouped patients by breast density based on mammographic determination with BIRADS density 1 and 2 considered low density (LD) and 3 and 4 as high density (HD). Continuous variables were compared between density groups with Wilcoxon rank sum test, and categorical were compared using Chi-squared test or Fisher's exact test. Kaplan-Meier method was use to estimate freedom from recurrence at 8 years, and log-rank test was used to compare freedom from recurrence between density groups. All statistical tests were two-sided with alpha level set at 0.05 for statistical significance.

Results: Overall, 682 women with breast cancer underwent preoperative MRI of which 454/682 (67%) had dense breasts (HD) and 228/682 (33%) had BIRADS density 1 or 2 (LD) breasts. Patients with dense breasts were younger (59 years old vs 67 years old, $p < 0.0001$), had larger tumors (1.7 vs 1.5cm, $p=0.02$), lower BMI (25 vs 29, $p < 0.0001$), and were more likely to pursue mastectomy (47% vs 31%, $p=0.0001$) or bilateral mastectomy (17% vs 10%, $p=0.02$). More HD patients had additional ipsilateral MRI findings than did LD patients [193/454 (43%) vs 72/228 (32%), $p=0.005$]; however, the rate at which second site biopsy was recommended when an additional abnormality was identified was similar [HD: 123/193 (63%) vs LD: 47/72 (62%), $p=0.85$]. Among those having second site biopsy, the likelihood of finding an additional foci of cancer was also similar with 48/98 (49%) HD patients and 14/40 (35%) LD patients ($p=0.19$) having a positive biopsy. Interestingly, 52/62 (84%) additional cancers occurred in patients with BIRADS density 2 or 3 MMGs, while 9 occurred in extremely dense (BIRADS 4 density) breasts, and only one in BIRADS 1 density breasts. Second cancers in LD patients were more likely to be IDC (78%), while in HD, they were equally split between DCIS (43%) and IDC (43%). In the contralateral breast, the same trends existed with more HD patients having MRI abnormalities (25% vs 14%, $p=0.0009$), but with similar rates of recommended second site biopsy ($p=0.98$) and incidence of contralateral cancer found (HD: 5% LD: 0%, $p=0.57$). After MRI workup, 157/183 (86%) LD patients eligible for breast-conserving surgery (BCS) chose BCS while 242/307 (79%) HD patients chose BCS. With a median follow up of 84 months and similar rates of adjuvant chemo/endocrine and radiation therapy,

no difference in local recurrence rates existed when stratified according to density subtype (HD:6.8% vs LD:8.1%, p=0.40).

Conclusions: Patients with dense breasts are more likely to have additional areas of MRI abnormality in either breast, but this does not translate into finding more second-site cancers. However, breast density may influence patient's surgical decision-making. Local recurrence occurred equally in those with HD and LD breasts. These data suggest preoperative MRI is not more valuable in patients with dense breasts, and outcomes are similar regardless of density.

254421 - Contralateral breast cancer (CBC) risk in women with ductal carcinoma in situ (DCIS): Is it high enough to justify bilateral mastectomy?

Megan Miller, Shirin Muhsen, Cristina Olcese, Sujata Patil, Monica Morrow, Kimberly Van Zee
Memorial Sloan Kettering Cancer Center, New York, NY

Background/Objective: Women with ductal carcinoma in situ (DCIS) are increasingly choosing bilateral mastectomy. Our goal was to quantify the contralateral breast cancer (CBC) rate in women with DCIS treated with breast-conserving surgery (BCS), to compare CBC with ipsilateral breast tumor recurrence (IBTR) risk, to identify factors associated with the risk of CBC, and to determine if risk factors for IBTR were the same as those for CBC.

Methods: A prospectively maintained database of DCIS patients undergoing BCS from 1978-2011 was used to identify all women with a contralateral breast at risk. Patients who had CBC prior to or synchronous with the index DCIS diagnosis and those who had synchronous CBC and IBTR were excluded. The outcome of interest was the first breast event, either CBC or IBTR, defined as diagnosis of either DCIS or invasive cancer. Associations of patient, tumor, and treatment factors with CBC and IBTR were evaluated using cumulative incidence curves and competing risk regression (CRR).

Results: 2759 patients were identified. Median follow-up was 6.8 years (range 0-30 years); 645 were followed for ≥10 years. Of these patients, 328 (11.9%) had IBTR and 127 (4.6%) had CBC as their first breast event. Cumulative incidence of IBTR at 5 and 10 years was 7.8% and 14.3%, compared to 2.8% and 5.6% for CBC, respectively. Univariately, premenopausal women had higher overall IBTR rates than postmenopausal women (p=0.001, 10-yr rate 17.4% vs 12.7%), but there was no difference in overall CBC rates (p=0.4, 10-year rate 5.5% vs 5.7%). Similarly, while the IBTR cumulative incidence was greater in patients <40 years old compared to those aged 40-79 years and ≥80 years (p=0.0008, 10-year rate 26.3% vs 13.9% vs 6.7%), CBC rates were similar across age groups (p=0.5, 10-year rate 1.4% vs 5.9% vs 2.3%). Women presenting with clinical findings (palpable mass, nipple discharge, Paget's disease) had a higher IBTR cumulative incidence than screen-detected (p=0.001, 10-year rate 20.1% vs 13.5%). In contrast, they had a lower CBC cumulative incidence (p=0.01, 10-year rate 2.3% vs 6.1%). Interestingly, neither family history of breast cancer nor nuclear grade was significantly associated with IBTR or CBC. Women treated in more recent years had a lower cumulative incidence of IBTR (p < 0.0001, 10-year rate 12.9% for ≥1999 vs 19.3% for ≤1998) but no lower risk of CBC (p=0.08, 10-year rate 6.4% vs 4.0%). Among those treated with endocrine therapy, the cumulative incidence of both IBTR and CBC was about half of that seen in those without (p < 0.0001 for IBTR, 10-year rate 7.8% vs 16.3%; p=0.2 for CBC, 10-year rate 3.2% vs 6.4%). Women receiving radiation (RT) had lower IBTR rates (p < 0.0001, 10-year rate 10.3% RT vs 19.3% no RT); CBC rates were not significantly different (p=0.1, 10-year rate 6.3% RT vs 4.9% no RT). In multivariable CRR, women who were postmenopausal, diagnosed radiographically or ≥1999,

had low nuclear grade, or received endocrine therapy or RT had a lower risk of IBTR (Table 1). However, no factors were significantly associated with risk of CBC.

Conclusions: Rates of CBC were low across all patient groups, irrespective of age, family history, and characteristics of initial DCIS, and were not associated with factors that increase IBTR risk. For a woman undergoing BCS for DCIS, the 10-year IBTR rate is 2.5-fold higher than the CBC rate, and for a woman not receiving RT, the IBTR rate is 4-fold higher than CBC rate. Identification of factors associated with higher IBTR risk may be important in decision-making between BCS and unilateral mastectomy, but should not prompt contralateral prophylactic mastectomy for DCIS.

	Cumulative incidence curves (univariate analysis)				Competing risk regression (multivariate analysis)			
	10-yr cumulative incidence				Hazard ratio			
	CBC	p-value (Gray's test)	IBTR	p-value (Gray's test)	CBC	p-value	IBTR	p-value
Menopausal status		0.4		0.001		0.5		0.003
Pre	5.5%		17.4%		1.00		1.00	
Post	5.7%		12.7%		1.14		0.68	
Age, yrs		0.5		0.0008				
<40	1.4%		26.3%		1.00		1.00	
40-79	5.9%		13.9%		1.12	0.8	0.77	0.2
≥80	2.3%		6.7%		0.73	0.7	0.42	0.1
Presentation		0.01		0.001		0.07		0.02
Clinical	2.3%		20.1%		1.00		1.00	
Radiologic	6.1%		13.5%		2.04		0.68	
Family history		0.3		0.5		0.6		0.7
No	5.2%		14.0%		1.00		1.00	
Yes	6.2%		14.7%		1.11		1.05	
Grade		0.4		0.2		0.5		0.002
Low	5.2%		12.7%		1.00		1.00	
Intermed/high	6.0%		14.3%		1.18		1.70	
Year of surgery		0.08		< 0.0001		0.1		0.03
≤1998	4.0%		19.3%		1.00		1.00	
≥1999	6.4%		12.9%		1.42		0.74	
Radiation		0.1		< 0.0001		0.8		<0.0001
No	4.9%		19.3%		1.00		1.00	
Yes	6.3%		10.3%		1.08		0.44	
Endocrine Tx		0.2		< 0.0001		0.07		0.003
No	6.4%		16.3%		1.00		1.00	
Yes	3.2%		7.8%		0.61		0.58	

10-year cumulative incidence rates and competing risk regression hazard ratios by patient characteristic for contralateral breast cancer (CBC) vs ipsilateral breast tumor recurrence (IBTR)

254910 - A validated nomogram to predict upstaging of ductal carcinoma in situ to invasive disease

Brittany Murphy[1], Alexandra Gonzalez Juarrero[1], Amy Conners[1], Tara Henrichsen[1], Santo Maimone, IV[2], Michael Keeney[1], Beiyun Chen[1], Tashinga Musonza[1], William Harmsen[1], Amy Degnim[1], Judy Boughey[1], Tina Hieken[1], Elizabeth Habermann[3], Harsh Shah[1], Sarah McLaughlin[2], Barbara Pockaj[4], James Jakub[1]
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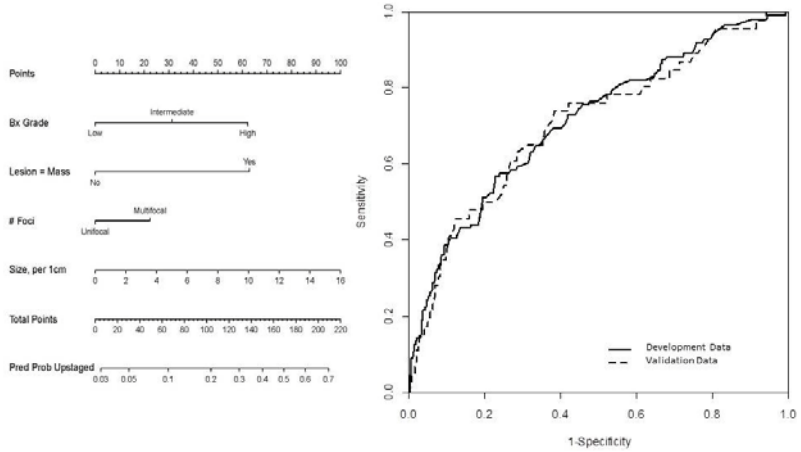
Background/Objective: Approximately 20% of patients with a core needle biopsy (CNB) diagnosis of ductal carcinoma in situ (DCIS) may be upstaged to invasive disease. Patients with invasive disease are recommended to undergo axillary nodal staging, most often requiring a second operation. We developed and validated a nomogram to preoperatively predict percent risk for upstaging to invasive cancer.

Methods: With IRB approval, we reviewed 827 patients with pure DCIS on CNB who underwent 834 operations at one institution between 1/2004-10/2014. We evaluated method of detection of DCIS and

tumor characteristics on CNB and used a multivariable model to create a nomogram to predict the risk of upstage from DCIS to invasive cancer. This nomogram was validated with an external dataset of 466 patients with DCIS on CNB between 11/1998-9/2016 from 2 other large academic sites. An area under the ROC (AUC) curve was constructed to evaluate nomogram discrimination.

Results: The rate of upstaging to invasive disease was 118/834 (14%). On multivariable analysis, grade on CNB, mass lesion on imaging, multifocal/centric disease, and linear dimension were associated with upstage to invasive disease, c-statistic 0.71 (95% CI 0.66-0.77). For every 1-cm increase in largest linear dimension on preoperative imaging, the rate of pathologic upstage increased by 20% (p=0.0001). A nomogram was constructed to calculate the preoperative predicted probability of upstaging (Figure). In the external validation dataset, 46/466 (9.9%) patients were upstaged to invasive disease. Application of our nomogram in this dataset had nearly identical discrimination with a c-statistic of 0.71 (95% CI 0.63-0.79, Figure). When estimates from the development model were applied to the validation dataset, 56 upstages were predicted, and 46 were observed.

Conclusions: For patients with a CNB diagnosis of DCIS, a high-grade lesion on biopsy, mass lesion on imaging, multifocal/centric disease, and large linear dimension were risk factors for upstage to invasive disease. This validated nomogram may be used for preoperative assessment of risk of upstage to invasive disease and counseling patients regarding axillary staging at the time of definitive surgery.



Performance of a validated nomogram to predict the probability of upstage to invasive disease for patients with dcis on core needle biopsy

253118 - Cost and complication burden of oncoplastic breast conservation compared to other treatment options in women with breast cancer

Rosa Hwang[1], Jing Jiang[2], Stacey Carter[3], Tina Shih[2], Scott Oates[2], Charles Butler[2], Henry Kuerer[4], Gildy Babiera[5], Elizabeth Mittendorf[6], Anthony Lucci[7], Abigail Caudle[8], Isabelle Bedrosian[8], Alistair Thompson[2], Sarah DeSnyder[8], Donald Baumann[2], Mark Clemens[9], Patrick Garvey[9], Mark Schaverien[2], Thomas Buchholz[2], Sharon Giordano[10], Kelly Hunt[4], Benjamin Smith[2]
[1]University of Texas MD Anderson Cancer Center, Houston, TX, [2]University of Texas MD Anderson Cancer Center, Houston, TX, [3]Baylor University, Houston, TX, [4]University of Texas MD Anderson Cancer Center Department of Breast Surgical Oncology, Houston, TX, [5]University of Texas MD Anderson Cancer Center Morgan Welch Inflammatory Breast Cancer Research Program and Clinic, Houston, TX, [6]University of Texas MD Anderson Cancer Center and Morgan Welch Inflammatory Breast Cancer Research Program and Clinic, Houston, TX, [7]Department of Breast Surgical Oncology, University of Texas MD Anderson Cancer Center and Morgan Welch Inflammatory Breast Cancer Research Program and Clinic, Houston, TX, [8]University of Texas MD Anderson Cancer Center, Houston, TX, [9]Plastic Surgery, The University of Texas MD Anderson Cancer Center, Houston, TX, [10]University of Texas MD Anderson Cancer Center, Houston, TX

Background/Objective: Lumpectomy with oncoplastic reconstruction followed by whole breast irradiation (Lump+Recon+WBI) is an increasingly popular treatment approach for patients with breast cancer. It is as oncologically safe when compared to Lump+WBI without oncoplastic reconstruction or mastectomy with or without post-mastectomy breast reconstruction (Mast+Recon, Mast alone). The aim of this study was to analyze the costs and complications associated with Lump+Recon+WBI in comparison to other surgical options.

Methods: Cases of incident, invasive female breast cancer diagnosed from 2000 to 2011 were identified from the MarketScan Commercial Claims and Encounters Database. This data source is a convenience sample of health insurance claims amalgamated from private insurers and self-funded companies. Patients were included if they were diagnosed in 2000-2011 and treated with Lump+WBI with or without oncoplastic surgery, Mast Alone, or Mast+Recon. Patients receiving post-mastectomy radiation or neoadjuvant chemotherapy were excluded. Claims determined type of treatment, total cost within 2 years of diagnosis, and complications within 2 years of diagnosis including wound complication, local infection, seroma/hematoma, fat necrosis, breast pain, pneumonitis, rib fracture, and implant removal. Modified Poisson regression tested associations of local treatment with complication risk adjusted for clinical factors such as age, comorbidity, chemotherapy, and axillary surgery. Adjusted cost was calculated using generalized linear regression (log link function, gamma distribution) adjusted for relevant baseline covariables.

Results: Of 39,518 patients, treatment was as follows: 40% Lump+WBI (n=15,953), 2% Lump+Recon+WBI (n=747), 30% Mast Alone (n=11,432), and 29% Mast+Recon (n=11,386). The proportion of patients per year treated with Lump+Recon+WBI was 0% in 2000, surpassed 1% in 2007, and rose to 4% in 2011. Risk of any complication was 29% with Lump+WBI (referent), 37% with Lump+Recon+WBI (aRR=1.26, 95% CI 1.14-1.39), 25% with Mast Alone (aRR=0.89, 95% CI 0.86-0.93), and 54% with Mast+Recon (aRR=1.88, 95% CI 1.82-1.93). Total adjusted cost within 2 years of diagnosis was $66,217 (95% CI $64,584-$67,850) for Lump+WBI, $69,781 (95% CI 63,977-$75,585) for Lump+Recon+WBI, $48,767 (95% CI $47,174-$50,361) for Mast Alone, and $89,187 (95% CI $86,549-$91,825) for Mast+Recon. The adjusted cost for Lump+Recon+WBI was significantly different compared to each of the other 3 local treatment options ($p < 0.0001$).

Conclusions: Oncoplastic lump+WBI confers a toxicity profile and total cost which is much better than Mast+Recon and similar to Lump+WBI without oncoplastic surgery. For patients who are marginal candidates for Lump+WBI due to large anticipated post-operative tissue defect, incorporation of oncoplastic surgery with lumpectomy may offer a better value than Mast+Recon.

	Adjusted Costs		
	Total	Complication	Non-complication
Treatment	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)
Lump+WBI	$66217 (64584-67850)	$1300 (1130-1470)	$64517 (62942-66091)
Lump+Recon +WBI	$69781 (63977-75585)	$2242 (1242-3241)	$67075 (61591-72560)
Mast alone	$48767 (47174-50361)	$1881 (1565-2198)	$47307 (45777-48838)
Mast+Recon	$89187 (86549-91825)	$10662 (8989-12336)	$78271 (75989-80554)

Adjusted costs for local therapy options

257382 - Oncogenic microRNA expression in earlier-stage breast cancer may confer survival advantage

Sara Kim[1], Tsutomu Kawaguchi[1], Li Yan[2], Jessica Young[1], Kazuaki Takabe[1]
[1]Roswell Park Cancer Institute, Buffalo, NY, [2]Department of Biostatistics and Bioinformatics, Roswell Park Cancer Institute, Buffalo, NY

Background/Objective: MicroRNAs (miRNAs) have been identified to play a critical role in carcinogenesis and progression of breast cancer (BrCa). Some miRNAs, such as miR21 and miR155 have been reported to have oncogenic properties promoting cell growth, proliferation and invasion; whereas miR-205 has been found to have both oncogenic and tumor suppressive roles. Although the clinical relevance of MiR-744 is unknown, it has been reported to promote cell proliferation in vitro. We hypothesized that overexpression of oncogenic miRNAs would be associated with a worse survival based on their known functions.

Methods: All data was obtained from The Cancer Genome Atlas (TCGA). Expression of 4 miRNAs: miR-21, miR-155, miR-205, and miR-744 were retrieved from the GDC data portal for analyses. After miRNA-specific thresholds were derived from the data and used to group the patients into either a high-expression or low-expression group, survival data was calculated using the Cox proportional hazard model. Further sub-analyses separating the patients based on receptor status and presence of metastases were also compared using the same method.

Results: Among the 1097 breast cancer samples logged in TCGA, 1053 samples were found to contain both clinical data and microRNA-seq datasets on the miRNAs of interest. Surprisingly, high expression levels of miR-21 and miR-155, the 2 miRNAs that are well known as “oncogenic” miRNAs demonstrated

significantly better prognoses (p=0.038 and 0.049, respectively). This association was significant in ER-negative and Stage 1 cancer patients for both miRNAs. High expression of miR-205, the miRNA that is reported to have both oncogenic and suppressive roles in breast cancer, demonstrated significantly better prognosis (p=0.034), which was significant in ER/PR-positive and lymph node-negative patients. MiR-744, which has been reported to be oncogenic in vitro only, was associated with a significantly better prognosis when highly expressed (p=0.013), which was significant in ER/PR-positive, HER2-negative and lymph node negative patients.

Conclusions: By utilizing a big dataset (TCGA) with sufficient statistical power, we found that high expression of miR-21, miR-155, and miR-744 in the breast tumor samples were all significantly associated with better overall survival. We were able to clarify that miR-205 has a positive impact on survival in ER/PR-negative patients, despite reports of their oncogenic functions. We conclude that is necessary to further evaluate the roles of these miRNAs and how their expression affects survival in breast cancer patients.

Scientific Oral Presentations II

Saturday, April 29, 2016 2:15 pm–3:15 pm

Moderators: Judy Boughey, MD; E. Shelley Hwang, MD

257057 - Factors influencing management and outcome in patients with occult breast cancer with axillary lymph node involvement: Analysis of the National Cancer Database

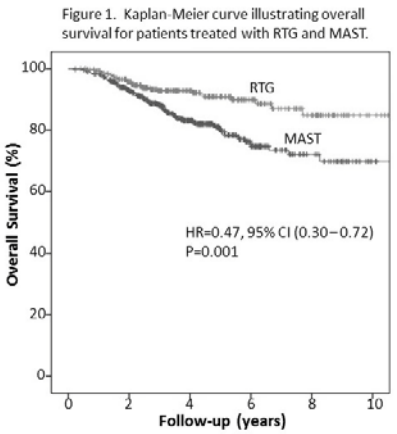
Lindsay Hessler[1], Jason Molitoris[1], Emily Bellavance[2], Elizabeth Nichols[2], Paula Rosenblatt[2], Katherine Tkaczuk[2], Steven Feigenberg[2], Soren Bentzen[2], Susan Kesmodel[2]
[1]University of Maryland Medical Center, Baltimore, MD, [2]University of Maryland School of Medicine, Baltimore, MD

Background/Objective: Occult breast cancer (BC) is a rare presentation that accounts for 0.1% of all BC cases. While small series have demonstrated similar outcomes between mastectomy and breast conservation + radiation therapy (RT), the optimal management has not been defined. In this study, we examine factors associated with treatment type and outcome in patients with occult BC.

Methods: Female patients with cT0N1/2M0 BC were selected from the National Cancer Database (2004-2013). Patients were categorized into 4 treatment groups: MAST = Mastectomy + Axillary lymph node dissection (ALND) +/- RT; RTG = No breast surgery + RT + ALND; ALND = No breast surgery + No RT + ALND; OBS = No breast surgery + No RT + No ALND. ALND was defined as regional LN surgery with removal of ≥ 4 nodes. Patients who received neoadjuvant therapy were included. Chi square analysis and logistic regression multivariable analysis (MVA) were used to compare treatment groups and identify independent factors associated with management with MAST rather than RTG. Cox regression MVA was used to identify independent factors associated with overall survival (OS). Kaplan-Meier analysis was used to examine the impact of treatment on OS.

Results: Of 2.03 million BC cases, 1853 females (0.09 %) with cT0N1/2M0 disease were identified and 1278 patients were managed with one of 4 strategies: MAST = 597, RTG = 343, ALND = 107, OBS = 231. Patients treated with MAST and RTG were similar in cN and pN stage, race, income, insurance, estrogen receptor status, comorbidities, and year of diagnosis. Patients were more likely to be treated with RTG if at an academic center (47.2% vs. 31.8%, P < 0.001) and living in an urban area (38.8% vs. 29.8%, P=0.041) and more likely to have MAST than RTG if younger than age 40 (80.0% vs. 20.0%, P=0.013). On MVA, the only factor associated with treatment type was care at an academic center, with a higher likelihood of RTG (odds ratio 1.93, 95% confidence interval [CI] 1.43-2.59, P < 0.001). Multivariable survival analysis showed that RTG was independently associated with OS (hazard ratio [HR] 0.51, 95% CI 33-0.79, P=0.003), as were fewer comorbidities, use of chemotherapy, number of positive nodes, and number of nodes examined. Univariate survival analysis demonstrated that patients treated with RTG had a significant OS improvement compared to patients treated with MAST (Fig 1; HR 0.47, 95% CI 0.30-0.72, P=0.001). The 5- and 10-year estimates of OS after RTG were 90.8% +/- 2.9% and 84.8% +/- 3.6% and after MAST 80.0% +/- 2.1% and 69.8% +/- 3.8%, respectively.

Conclusions: Patients with occult BC were more likely to be treated with RTG if at an academic center. Patients treated with RTG had a significantly better OS than those treated with MAST even after adjusting for other covariates. This analysis supports the use of RTG as a treatment approach for patients with occult BC.



Kaplan-Meier survival analysis RTG vs. MAST

257239 - The use of sentinel lymph node dissection after neoadjuvant chemotherapy in clinically node-positive patients: Practice patterns of members of the American Society of Breast Surgeons

Abigail Caudle[1], Isabelle Bedrosian[1], Denai Milton[1], Sarah DeSnyder[1], Henry Kuerer[2], Kelly Hunt[2], Elizabeth Mittendorf[3]
[1]University of Texas MD Anderson Cancer Center, Houston, TX, [2]University of Texas MD Anderson Cancer Center Department of Breast Surgical Oncology, Houston, TX, [3]UT MD Anderson Cancer Center and Morgan Welch Inflammatory Breast Cancer Research Program and Clinic, Houston, TX

Background/Objective: Recent trials have reported on the accuracy of sentinel lymph node dissection (SLND) for staging the axilla in clinically node-positive patients who receive neoadjuvant chemotherapy (NAC). This survey was designed to assess dissemination and uptake of these trial findings in surgical practice. Secondary goals were to: 1) evaluate patient characteristics surgeons use in determining candidacy for SLND, and 2) identify technical factors considered important for accuracy.

Methods: American Society of Breast Surgeons members were invited by e-mail to complete an anonymous online survey. Of those, 642 members responded representing 21% of 3090 eligible members. Results were collected and summarized as proportions based on the number of members who responded to each specific question. Comparisons were made using Fisher's exact test.

Results: Practice settings were categorized as private or community practice focusing on breast (35%), private or community general practice (30%), academic breast practice (23%), or academic general practice (11%). Respondents indicated knowledge of the Z1071 (86%), SENTINA (57%), and SN-FNAC (39%) trials. The false negative rate (FNR) of these trials was correctly reported by 53% (336/638) of respondents as 10-15%. Before the trials, 45% (285/636) offered SLND compared to 85% (543/638) after the trials. In the 556 respondents who reported knowledge of at least one trial, 310 (56%) offer SLND to > 50% of patients, 175 (31%) offer to < 50%, and 70 (13%) routinely perform ALND. Surgeons who report knowledge of the trials but have not incorporated SLND into practice were more likely to identify the correct FNR of the trials (70%, 48/69) than those that offer SLND (57%, 278/484) (p=0.07). Respondents who reported knowledge of the trials but did not change their practice to incorporate SLND (n=67) cited concerns over lack of outcome data (64%), worries about FNR (42%), lack of resources (34%), or objections from radiation oncologists (25%), medical oncologists (18%), or other surgeons (7%).

Respondents that reported knowledge of the trials and have incorporated SLND into their practice (n=485) consider nodal response on US (64%), number of abnormal nodes at diagnosis (63%), plans for adjuvant radiotherapy (63%), patient age (42%), tumor receptor profile (36%), and tumor size (21%) in their decision to offer SLND. Technical features considered critical for SLND by those with who have incorporated SLND into practice and expressed knowledge of the trials were dual tracer technique (88%), removal of the clipped node (83%), removal of ≥2 SLNs (72%), removal of ≥ 3 SLNs (64%), use of immunohistochemistry (50%), and normalization of US (51%). Sixty-seven percent (373/559) of all respondents routinely place clips in biopsied nodes and 74% (276/373) localize and remove them at surgery.

Conclusions: The publication of trials evaluating SLND in clinically node-positive patients who receive NAC has resulted in changes in practice in a majority of surgeons. However, there is considerable variation in considerations for patient selection and technical features thought to be critical for accuracy. Concerns over the FNR and lack of outcome data limit incorporation of SLND into practice by some surgeons.

256627 - Model for predicting nodal positivity in women age ≥ 70 with hormone receptor positive cancer to aid incorporation of a recently released Society of Surgical Oncology Choosing Wisely guideline into clinical practice

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Background/Objective: The Society of Surgical Oncology (SSO) recently announced its Choosing Wisely guidelines, including one recommendation not to routinely use sentinel lymph node (SLN) surgery in clinically node-negative (cN0) women ≥ 70 years of age with hormone receptor (HR)-positive invasive breast cancer. However, identification of node positivity in women ≥ 70 years still impacts treatment decisions for regional nodal irradiation and duration of systemic hormone therapy. Therefore, there is great need for a model using readily available clinical pathological factors to predict the likelihood of nodal positivity in this group of patients - to identify patients at low risk of nodal positivity where SLN surgery can be eliminated.

Methods: We queried the National Cancer Database (NCDB, 2010-2013) for all women ≥ 70 years with HR+ cT1-4, cN0 invasive disease with axillary surgery performed. A stratified random sample of 2/3 of the cohort was used for model development, and the remaining 1/3 was used as an independent validation set. Stratification factors were balanced between the 2 sample sets and included calendar year, age, clinical T stage, grade, HER2 status, and histology. Patient and tumor characteristics were assessed with multivariable logistic regression to determine which factors predicted positive lymph node(s). Model discrimination was estimated with the area under the curve (AUC).

Results: We identified 36,890 women age ≥ 70 meeting the criteria for this study, of which 5,942 had positive axillary nodes (16.1%). On univariate analysis, factors associated with increased risk of nodal positivity were increased clinical T stage, higher grade, and invasive lobular or invasive mammary histology. Both increasing age and HER2 positivity were significant in univariate analysis; however, after adjustment for other factors in a multivariable model, neither of these factors remained significant ($p=0.57$ and $p=0.32$, respectively) and were thus not included in the final model. All other variables remained significant (each $p < 0.001$) in multivariable analysis (see Table). The resulting model had an

AUC of 0.706 (95% CI: 0.699-0.713) and identified a total of 14,245 (38.6%) women with predicted probability of positive nodes < 10%, of whom 949 (6.7%) had positive nodes. Performance in the independent validation set [n = 15,423 women, 2,408 (15.6%) node positive] was similar with an AUC 0.702 (95% CI: 0.692-0.713). Nodal positivity rate was 6.2% for the subset with predicted probability < 10% and 21.4% when the predicted probability was >=10%. This yielded a 3.5 (95% CI: 3.1-3.9) relative risk for nodal positivity when the model predicted ≥ 10% versus < 10% probability.

Conclusions: Tumor size, grade, and histology impact nodal positivity in women age ≥ 70 with HR+ invasive breast cancer, while HER2 status did not have an independent effect on nodal positivity in multivariable analysis. We have established a model that can be used to predict risk of nodal involvement for women included in the new Choosing Wisely guideline (age ≥ 70 with HR+ invasive breast cancer) and might provide guidance on who might safely omit axillary surgery. Conversely, for women identified to be at a 3.5-fold increased risk for nodal positivity, axillary nodal staging may be important to inform adjuvant treatment decisions (e.g., radiation and extended hormone therapy).

Model Development		
	Odds Ratio (95% CI)	**p-value**
Clinical T stage		<0.001
cT1mic/cT1a	1.0 (Reference)	
cT1b	1.28 (1.09-1.50)	
cT1c	2.71 (2.33-3.16)	
cT2	5.60 (4.81-6.51)	
cT3	11.02 (8.98-13.51)	
cT4a-c	11.97 (8.57-16.73)	
cT4d	37.67 (12.81-110.77)	
Grade		<0.001
Well differentiated	1.0 (Reference)	
Moderately differentiated	1.40 (1.30-1.51)	
Poorly differentiated	1.65 (1.51-1.81)	
Histology		<0.001
IDC	1.0 (Reference)	
ILC	1.13 (1.04-1.23)	
IMC	1.40 (1.25-1.56)	
Mucinous	0.20 (0.15-0.26)	
Other	0.63 (0.56-0.70)	
Model Performance		
Predicted Node Positivity	**Actual Node Positivity**	**Relative Risk**
< 10%	6.2%	3.5 (95% CI: 3.1-3.9)
≥ 10%	21.4%	

Multivariable model predicting nodal positivity in women age ≥ 70 with HR+ cN0 invasive breast cancer

256621 - Radioactive seed localization versus wire localization for breast-conserving surgery: Which is more costly?

Yimeng Zhang[1], Erin Cordeiro[2], Jean Seely[3], Joshua Hefler[4], Kednapa Thavorn[5], Mukta Mahajan[6], Susan Domina[7], Jon Aro[8], Andrea Ibrahim[9], Angel Arnaout[2], Denis Gravel[10], Carolyn Nessim[2]
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Background/Objective: Radioactive seed localization (RSL) is a potentially less costly alternative to wire-guided localization (WGL) for localization of non-palpable breast lesions, but there exists limited literature information on the cost and resource utilization differences between the procedures. The purpose of this study is to compare the cost outcomes and resource utilization between the first-year implementation of RSL with WGL from the previous year for breast conserving surgery (BCS) for patients with non-palpable breast cancer at a large Canadian tertiary center.

Methods: This is a retrospective cohort study. Data pertaining to treatment costs, resource utilization, and patient outcomes were collected for patients who underwent BCS with RSL from April 1, 2015 – March 31, 2016 and patients who underwent BCS with WGL from April 1, 2014 – March 31, 2015.

Results: We compared 153 patients who underwent WGL with 153 patients who underwent RSL and confirmed there were no significant demographic differences between the cohorts other than a lower rate of diabetes mellitus for the RSL cohort (6.54% vs 13.73%, p=0.037). The average cost per patient for RSL was $219.17 vs $365.10 for WGL ($p < 0.001$). As a result of the implementation of the RSL program, there was an increase of dedicated allocated radiology appointments to RSL (9/day) and a requirement of fewer radiologists for these procedures per day. Moreover, patients were transported to the OR more quickly for RSL procedures (120 min vs 254 min, $p < 0.001$). There were no significant differences observed for average surgery times, volume of specimen removed, rate of intraoperative margin re-excisions, and rate of positive margins between the 2 procedures. Patients were less likely to experience vasovagal reactions after localization with insertion of the radioactive seed vs the wire (8 incidences vs 1 incidence, $p < 0.05$). There were no significant differences in complication rates including hematoma, seroma requiring drainage, and cellulitis.

Conclusions: We have successfully compared the annual resource utilization and costs for patients with early-stage breast cancer undergoing RSL vs WGL for breast-conserving surgery. This is the first North American study directly comparing costs between the 2 localization procedures in a public payer system. RSL is a significantly less costly procedure than WGL and allowed for more efficient use of radiology and scheduling with shorter wait times for patients on the day of the surgery. Although we did not find significant clinical differences in patient outcome, we suggest that RSL should be utilized in place of WGL given the cost, decreased need of human resources, and efficiency benefits.

252257 - A single institution retrospective study of once daily external beam fractionation accelerated partial breast irradiation compared to whole-breast irradiation in evaluation of local recurrence and toxicity symptoms with minimum five-year follow-up

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Background/Objective: Studies have demonstrated low rates of local recurrence with accelerated partial breast irradiation (APBI) for early-stage breast cancer; however, reports of long-term recurrence rates and toxicities are still limited. In 2002, our institution adopted a 3-week regimen of external-beam partial-breast irradiation administered in 16 fractions of 2.7 Gy, resulting in a total dose of 43.2 Gy for early-stage breast cancer patients. We herein report our institution's local recurrence rate and toxicity symptoms of an APBI cohort compared to a cohort of patients who underwent whole-breast irradiation (WBI).

Methods: This is a single institution retrospective study that compared recurrence and toxicity between a cohort of 290 patients that underwent APBI to a cohort of 304 patients who underwent WBI from 2002-2012. Median follow up was 6.1 years for the WBI cohort and 8.0 years for the APBI cohort. Patients were evaluated for acute toxicity symptoms based on common terminology criteria for adverse events (CTCAE) v3.0 where levels ranged from 0 which indicated no acute toxicity symptoms to greater than 3 which indicated severe symptoms.

Results: The median age at treatment for WBI was 63 (range, 30 – 89) and for APBI was 69 (range, 42 – 89). More patients in the APBI cohort had lobular tumors (10.3% vs 4.9%), tumors < 1.0cm (62.8% vs 45.7%), estrogen and progesterone receptor-positive tumors (89.7% vs 70%), and did not receive adjuvant chemotherapy (98.6% vs. 70.8%). A higher proportion of WBI patients had grade III tumors (39.1% vs. 16.2%). The overall recurrence rate for the WBI group was 10.5% (32 recurrences) and 8.6% (25 recurrences) for the APBI cohort. The locoregional recurrence (LRR) rate for the WBI cohort was 2.63% versus 8.3% for the APBI cohort and the in-breast failure (IBF) rate for WBI was 0.98% compared to 7.6% for the APBI cohort. Sixty-six percent of IBF in the WBI group were elsewhere IBF failures versus 64% of APBI IBF. The time to locoregional recurrence was 31.1 months for the WBI cohort compared to 60.2 months for the APBI cohort. The IBF rates among IDC, ILC, and DCIS were 9.0%, 6.6%, and 3.1% for the APBI cohort compared to 1.1%, 0.0%, and 0.0% for the WBI group. Toxicity was also evaluated. One hundred thirty-six patients (44.7%) stated that fatigue was moderate in the WBI cohort versus only 31 patients (10.7%) in the APBI cohort. Likewise, desquamation was present in 59 (19.4%) WBI patients versus 0 (0%) APBI patients, and moderate erythema was present in 185 (60.9%) WBI patients compared to 19 (6.6%) APBI patients.

Conclusions: Locoregional recurrences were twice as high in the APBI group compared to the WBI group despite less aggressive tumor features in the APBI group, but these recurrences rates were all under 10% with 8 years of follow-up. Toxicity was less in the APBI group. Clinicians will need to decide if the trade-off of lower toxicity is worth a slightly higher locoregional failure rate when making radiation therapy treatment recommendations for early-stage breast cancer patients.

Quickshot Presentations

Saturday, April 29, 2017 12:30 pm – 1:30 pm

Moderators: Jill Dietz, MD; Jan Wong, MD

257384 - Association of annual mammography screening with healthcare costs following breast cancer diagnosis

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Background/Objective: Nearly a quarter of a million women in the United States are predicted to be diagnosed with breast cancer in 2016. The economic impact of breast cancer management is estimated to exceed $20 billion by 2020. Routine screening mammography has become the standard of care for women at average risk of breast cancer, but significant debate continues to surround an appropriate frequency of screening and starting age. Overuse of screening mammography can lead to critical consequences of overdiagnosis and potential overtreatment, compounding the problem of inappropriate allocation of healthcare resources. We investigated the association between adherence to annual screening mammography (ASM) and healthcare costs in the first year following breast cancer diagnosis in a retrospective cohort of commercially-insured U.S. women.

Methods: Using the Truven Health Analytics|MarketScan®|Database from 2006-2013, we conducted a retrospective review of screening mammography frequencies in women aged 45-60 during the 5 years prior to primary invasive breast cancer diagnosis in 2011-2012. Patient demographics, family history, and clinical characteristics were extracted from the database. We excluded women with a prior history of breast cancer, a genetic predisposition to breast cancer, missing cost data, or diagnosis of ductal carcinoma in situ (DCIS). Adherence to ASM was defined as mammography at least every 14 months during the 5 years before diagnosis. Healthcare and prescription costs were assessed for one year following breast cancer diagnosis by accounting for total payments from the insurance plan made to providers. Unadjusted univariate and adjusted multivariable analyses using a generalized linear model with log-link and gamma variance function were performed. All statistical tests were 2-sided, and statistical significance was assessed at alpha=0.05.

Results: Of 1,876 women diagnosed with breast cancer in 2011-2012, mean age at diagnosis was 53.7 ± 4.3 years, and only 307 (16.4%) were adherent to annual screening during the 5-year time period prior to diagnosis. No statistically significant difference in mean total healthcare cost in the first year following breast cancer diagnosis was demonstrated when comparing annual screeners to non-annual screeners ($82,432 vs. $89,255, p=0.086). However, when controlling for type of surgical treatment, adjuvant chemoradiation, metastatic disease status, Romano-Charlson comorbidity score, geographic region, employment demographics, and HMO status, adherence to ASM was significantly associated with decreased total healthcare cost (p=0.044). Utilizing this estimated equation to predict total healthcare costs for a hypothetical 54-year-old patient undergoing partial mastectomy with needle localization and subsequent radiation therapy, we found a $3,836 difference – if the patient was an annual screener prior to diagnosis, her total healthcare costs in the first year following diagnosis would be $51,171; however, if she was not an annual screener prior to diagnosis, her total healthcare costs in the first year following diagnosis would increase to $55,007.

Conclusions: Annual screening mammography prior to breast cancer diagnosis significantly decreases healthcare costs in the first year following diagnosis for commercially-insured women. Recent updates in screening mammography guidelines and recommendations for biennial screening may provide even greater cost savings to primary payers. Future models will investigate the cost-effectiveness of varying screening intervals and individual treatment algorithms to establish optimal screening age, screening frequencies, and care pathways for women at average risk of breast cancer.

257126 - A ten-year experience with mastectomy and tissue expander placement to facilitate subsequent radiation and reconstruction

Zeina Ayoub[1], Eric Strom[1], Valentina Ovalle[2], George Perkins[1], Wendy Woodward[3], Welela Tereffe[1], Benjamin Smith[1], Simona Shaitelman[1], Michael Stauder[1], Karen Hoffman[1], Sarah DeSnyder[4], Patrick Garvey[5], Mark Clemens[5], Carlos Barcenas[6], Henry Kuerer[7], Steven Kronowitz[8]
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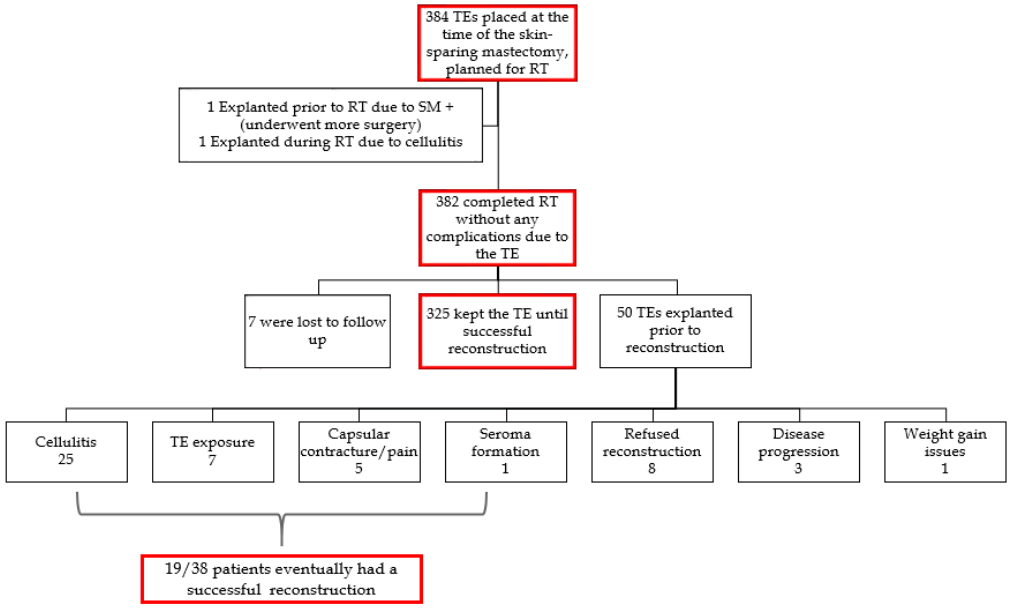
Background/Objective: Skin-sparing mastectomy and immediate reconstruction is favored by patients and surgeons due to its one-step process and favorable cosmetic results. However, in patients who need post-mastectomy radiotherapy (PMRT), we previously showed that immediate reconstruction can result in compromised radiotherapy plans. To combine these 2 approaches, we have offered breast cancer patients undergoing a total mastectomy and expected to require PMRT a delayed-immediate approach. This consists of placing a tissue expander at the time of skin-sparing mastectomy, which is deflated prior to radiotherapy, and completing reconstruction several months after the end of radiotherapy. The aim of this study was to assess the primary outcomes and complication rates of this strategy.

Methods: Between September 2002 and August 2013, a total of 384 reconstructions (4 with bilateral disease) had a tissue expander placed at the time of mastectomy and subsequently underwent PMRT. Rates and causes of tissue expander explantation prior to, during, and after radiotherapy were collected. Details about the final stage of reconstruction as well as subsequent complications were collected. Kaplan-Meier survival times were calculated using date of diagnosis as time zero.

Results: Median follow-up after diagnosis was 5.6 years (range, 1.3-13.4 years). In the study cohort, 364 patients (94.8%) had stage II-III breast cancer, and 7 patients (1.8%) had locally recurrent disease. There were 324 patients (84.4%) with clinically or pathologically positive lymph nodes, and 244 patients (63.5%) received neoadjuvant chemotherapy. The 5-year rates of actuarial locoregional control, disease-free survival, and overall survival were 99.2%, 86.1%, and 92.4%, respectively. The intended delayed-immediate reconstruction was subsequently completed in 325 of 384 mastectomies (84.6% of the study cohort). Of the remaining 59 tissue expanders, 1 was explanted prior to radiotherapy, 1 during radiotherapy, and 7 patients (1.8%) were lost to follow-up. There were 50 patients (13.0%) who required explantation after radiation but prior to their planned final reconstruction, mainly due to cellulitis, exposure of the expander, disease progression, and patient preference among others (see figure for

detailed breakout). An additional 19 of these 50 patients (4.9% of the total cohort) were eventually able to have a classic delayed reconstruction after explantation. In all, the total rate of completed reconstructions was 89.6%. The median time from placement of the tissue expander until reconstruction was 12 months (interquartile range, 9-15 months). The most common type of reconstruction was abdominal-based autologous reconstruction (45.5%), followed by latissimus dorsi-based reconstruction (29.0%), and exchange of the tissue expander with an implant alone (21.5%).

Conclusions: Tissue expander placement at skin-sparing mastectomy in patients who require radiotherapy is a highly successful approach. Nearly all patients can safely undergo radiation therapy with a tissue expander in place, and up to 90% of patients eventually complete the 2-stage approach with an autologous or implant based reconstruction. Considering that immediate reconstruction may compromise radiotherapy plans, placing tissue expanders during mastectomy is a useful approach for women who require radiotherapy. This large study provides comprehensive data for discussing the risks and benefits of this approach with patients.



TE: Tissue Expander

256902 - Contralateral prophylactic mastectomy with reconstruction increases health care utilization and cost

Judy Boughey[1], Stephanie Schilz[2], Zhu Lin[3], Elizabeth Habermann[4], Valerie Lemaine[1]
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Background/Objective: Rates of contralateral prophylactic mastectomy in women with unilateral breast cancer continue to rise in the United States, especially in women undergoing immediate breast reconstruction (IBR). The aim of this study was to compare 2-year health care utilization between

unilateral mastectomy and reconstruction (UM+IBR) and bilateral mastectomy with reconstruction (BM+IBR).

Methods: We utilized administrative claims data from a large U.S. commercial insurance database (OptumLabs) to identify privately insured and Medicare Advantage-insured women age 18+ years who underwent IBR between 1/2004 and 12/2013. We compared 2-year total costs of care and unadjusted utilization rates between the UM+IBR and BM+IBR both for implant-based and autologous reconstruction. Comparisons were tested using t-test, and differences in cost were estimated with Wilcoxon rank sum test.

Results: 11,728 women undergoing mastectomy with IBR were identified; 7,693 with implant reconstruction (2,090, 27% UM and 5,603, 73% BM) and 4,035 with autologous reconstruction (1,754, 43% UM and 2,281, 57% BM). The mean (sd) hospital length of stay at initial surgery was similar between BM+IBR and UM+IBR (2.5 (1.8) vs 2.5 (2.1), p=0.21). Overall rate of office visits was similar in both BM+IBR and UM+IBR (2384.0 per 100 women vs 2384.1, p=0.54); however, rate of ER visits was higher for BM+IBR (34.2 per 100 women vs 30.2, $p < 0.0001$). Focusing on patients with implant reconstruction the mean (sd) hospital length of stay at initial surgery was higher for BM+IBR compared to UM+IBR (2.0 (1.4) vs1.7 (1.5), p= < 0.0001). Rate of office visits was similar in both BM+IBR and UM+IBR (2411.6 per 100 women vs 2439.3, p=0.21); however, rate of ER visits was higher for BM+IBR (34.0 per 100 women vs 29.9, $p < 0.001$). In patients with autologous reconstruction, the mean (sd) hospital length of stay at initial surgery was higher for BM+IBR compared to UM+IBR (3.7 (1.9) vs 3.5 (2.2), p=0.0011). However, the rate of ER visits was higher for BM+IBR than UM+IBR (34.7 per 100 women vs 30.6, p=0.006), and the rate of inpatient admission was also higher in BM+IBR (28.0 vs 23.4, p=0.001). Total 2-year cost of care for implant reconstruction was higher for BM+IBR than UM+IBR for commercial insurance ($106,469 vs $96,689, $p < 0.001$); however, the difference was not significant for Medicare Advantage. For autologous reconstruction, total Medicare Advantage 2-year cost of care was higher for BM+IBR than UM+IBR ($57,602 vs $37,713, p=0.027), with even greater differences seen in commercial insurance.

Conclusions: Bilateral mastectomy with autologous reconstruction was associated with increased ER visits and inpatient admissions resulting in higher total cost of care over 2 years compared to unilateral mastectomy. Bilateral mastectomy with implant reconstruction was associated with more ER visits and higher total cost of care for commercial insurance; however, the difference was not statistically significant for Medicare Advantage. Patients with unilateral disease considering contralateral prophylactic mastectomy should be counseled on the additional risks and costs associated with bilateral mastectomy with reconstruction.

	Implant reconstruction (n=7,693)			Autologous reconstruction (n=4,035)		
Outcome	UM	BM	P value	UM	BM	P value
Inpatient admission	30.6	29.9	0.5564	23.4	28.0	0.0010
Office visits	2439.3	2411.6	0.2134	2318.3	2316.3	0.5265
ER visits	29.9	34.0	0.0007	30.6	34.7	0.0059
Commercial Insurance						
N Patients	1984	5481		1716	2245	
Reconstruction Cost	$18,903 (12,135)	$27,052 (18,241)	<0.0001	$26,215 (21,543)	$43,180 (35,007)	<0.0001
Post Reconstruction Cost	$77,786 (79,296)	$79,417 (79,982)	0.0835	$61,458 (63,428)	$71,354 (81,872)	<0.0001
Total Cost of Care	$96,689 (83,205)	$106,469 (86,212)	<0.0001	$87,672 (70,053)	$114,535 (93,447)	<0.0001
Medicare Advantage						
N Patients	103	121		37	35	
Reconstruction Cost	$8,790 (3,020)	$10,039 (4,356)	0.0273	$11,029 (7,043)	$14,521 (10,291)	0.0209
Post Reconstruction Cost	$30,153 (27,726)	$38,821 (56,704)	0.2055	$26,684 (27,337)	$43,081 (35,268)	0.0305
Total Cost of Care	$38,943 (28,720)	$48,860 (58,084)	0.0971	$37,713 (29,863)	$57,602 (40,289)	0.0265

Costs shown are Mean (SD)

Comparison of 2-year costs and unadjusted utilization rates per 100 women with IBR

257374 - Minimally-invasive, sutureless, image-guided, definitive lumpectomy and excisional biopsy in an outpatient setting

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Background/Objective: Despite advances in technologies characterizing breast cancer biology, indolent lesions cannot be identified. Many indolent breast cancers and ductal carcinoma in situ (DCIS) are overtreated to avoid undertreatment of life-threatening cancers. In addition, many high-risk lesions are also taken to the operating room. We seek to validate a minimally invasive approach to treating small cancers and high-risk lesions that may reduce use of specialty resources.

Methods: 281 women ages 31-86 had removal of small DCIS and invasive cancers or HRL using a 15- or 20-mm radiofrequency basket-capture with imaging guidance. Tissue elasticity permitted removal through a 12-mm incision. A second 20-mm basket-capture was used to obtain shaved margins for patients diagnosed with cancer on core biopsy. Incisions were closed with Steri-Strips™. Procedures were conducted under local anesthesia and with P.O. sedation. Patient tolerance scores were recorded. Standard radiologic evaluation (specimen and breast) and histologic criteria were applied in all cases. Patient data are registered prospectively in a HIPAA-compliant registry and reported with informed consent.

Results: Final histologic size for ranged from 1-20 mm. Of 52 DCIS and 73 invasive lesions, 23 (18.4%) had positive margins by histologic standards; 17/22 with reported results (77.3%) had no residual lesion after open surgery. A total of 26 patients had open re-excision; 6 despite clear margins at intact (one of these patients chose mastectomy). 95 patients went on to complete accelerated partial- (72) or whole-breast (23) radiation. Pain scores for patients with cancer averaged 1.55 out of 10 (range 0-7). All 156 high-risk lesions were definitively removed. Twelve patients had their high-risk pathology change from the original core biopsy pathology; 4 were upgraded within the HRL categories, and 8 were actually

downgraded. Two patients went on to open excisional biopsy because of physician discomfort with margin status; both patients were upgraded within the HRL category, but cancer was not found. Patient-reported pain scores averaged .93 out of 10 (range 0-6).

Conclusions: For small DCIS, invasive cancers, and high-risk lesions, image-guided, minimally invasive lumpectomy/excisional biopsy can be accomplished in an outpatient setting, either in the physician's office or imaging suite. The Intact specimen permits standard of care histologic analysis of lesions and margins. Because image-guided targeting requires less tissue removal via small incisions that do not require sutures, this lumpectomy/excisional biopsy approach reduces morbidity, distress, discomfort, and expense associated with overtreatment of small breast cancers, and it is particularly appealing to certain subsets of patients for whom surgical risks may be increased.

257264 - A patient-specific 3-D printed form accurately transfers supine MRI-derived tumor localization information to guide breast-conserving surgery

Richard Barth, Jr.[1], Venkat Krishnaswamy[2], Keith Paulsen[3], Timothy Rooney[1], Wendy Wells[1], Elizabeth Rizzo[1], Christina Angeles[1], Jonathan Marotti[1], Rebecca Zuurbier[1], Candice Black[1]
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Background/Objective: Wire-localized excision of non-palpable breast cancer is an imprecise technique, resulting in positive margins approximately 30% of the time. We evaluated whether a new device, the Breast Cancer Locator (BCL), could transfer tumor localization cues derived from an individual's supine MRI breast exam into the surgical field to facilitate accurate tumor resection.

Methods: Patients undergo pre-operative MRI in the supine (surgical) position. A radiologist outlines the tumor edges on consecutive images, enabling the formation of a 3- dimensional image of the tumor in the breast. Using 3-D printing, a bra-like plastic form (the BCL) is fabricated with built-in features which allow a surgeon at the time of surgery to: 1) mark the edges of the tumor on the breast surface, 2) inject blue dye into the breast tissue to define the edges of the resection margin and 3) place a wire in the tumor center. Blue dye markings are placed at 4 locations: 1 cm medial, cranial, caudal and lateral to the MR-defined tumor edges. Interactive 3D images of the tumor in the breast are also available to the surgeon in the OR and are used to ascertain distances from the tumor edge to the skin and chest wall. We tested the accuracy of patient-specific BCLs in patients with palpable cancers. Our main outcome measure was the distance from the center of the blue dye to the tumor edges. BCL localization was considered accurate if all blue-dye injections were outside of the pathologic tumor edges.

Results: Fifteen patients underwent partial mastectomy after placement of surgical cues using patient-specific BCLs. Cues were placed in < 5 minutes in all patients. No adverse events occurred. The mean pathologic tumor diameter was 3.3 cm, range 1.3 – 7 cm. Tumors were located in the following quadrants: upper outer 47%, upper inner 27%, lower inner 20%, lower outer 7%. The BCL accurately localized 14/15 cancers. In the 14 accurately localized cases, a total of 52 blue-dye injections were made, and all were outside of the tumor edges. The median distance from the center of the blue dye to the tumor edge was 1.1 cm. Three of 52 (6%) injections were < 5 mm from the tumor edge, 75% were between 0.5 – 2.0 cm from the edge, and 19% were > 2 cm from the tumor edge. The clinical pathologic margins were negative in all 15 patients. Specimen mammography identified the wire in the middle of

the tumor in 13/14 cases with accurate dye injections. In one case, the wire tip on specimen mammogram was located slightly superficial to the tumor.

Conclusions: Information on breast cancer location and shape derived from a supine MRI can be transferred to patients in the operating room using a 3D printed form. The form is easy to use and is safe. The cues generated by the form accurately identified the tumor edges in vivo.

257052 – Breast cancer-related lymphedema risk is related to multidisciplinary treatment and not surgery alone – Results from a large cohort study

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Background/Objective: Breast-cancer related lymphedema (BCRL) is a significant complication in women undergoing treatment. In this study, we aim to assess BCRL incidence and risk factors over up to 22 years follow up among a large population-based cohort.

Methods: We utilized the Olmsted County Rochester Epidemiology Project Breast Cancer Cohort, a population-based sample of all incident breast cancer cases diagnosed in Olmsted County, MN residents in 1990-2010. Charts were electronically and manually reviewed to ascertain definite or probable breast-cancer related lymphedema (BCRL). Time to BCRL was calculated from definitive breast surgery to date of diagnosis of BCRL. Variables collected included type of breast and axillary surgery, receipt of radiation and chemotherapy, cancer stage, and baseline BMI. The cumulative incidence estimator was used to estimate the rate of BCRL diagnosis while accounting for the competing risk of death; competing risks regression was used for multivariable analysis assessing risk factors for BCRL, which are reported with hazard ratios (HRs) and 95% confidence intervals (CIs).

Results: A total of 1794 patients with stage 0-3 breast cancer with a median of 10 years follow-up were included. Median age at cancer diagnosis was 60 years; 44% were overweight or obese at index. Stage distribution was 17% stage 0, 47% stage I, 28% stage II, and 7% stage III. A majority (58.5%) underwent lumpectomy, 28% unilateral mastectomy, and 13% bilateral mastectomy. Most patients underwent axillary staging surgery (44% axillary dissection (ALND), 40% sentinel lymph node biopsy (SLNB), 16% no axillary surgery) and 57% received radiation (RT). The median number of lymph nodes examined was 3 for SLNB only and 16 in ALND. The cumulative incidence of BCRL diagnosis within 5 years was 9.1% (95% CI: 7.8-10.5%). Overall mastectomy vs lumpectomy was not associated with higher rates of BCRL ($p=0.42$) among patients with any axillary surgery. All patients with BCRL within 5 years had undergone axillary surgery. The 5-year incidence of BCRL was 5.3% in SLNB only and 15.9% in ALND patients ($p < 0.001$). Adjuvant RT did not impact BCRL rates in SLNB only patients (6.3% with RT vs 3.6% without, $p=0.15$), however it did in ALND patients (22.2% vs 7.8%, $p < 0.001$). In patients treated with surgery only (no radiation and no chemotherapy) BCRL rates were not different between ALND versus SLNB ($p=0.36$). In multivariable analysis among patients with any axillary surgery, ALND and adjuvant RT remained significantly associated with BCRL with adjusted HRs of 2.0 (95% CI: 1.3-3.1) for adjuvant RT and 2.7 (95% CI: 1.9-3.9) for ALND vs SLNB only. Chemotherapy was also significantly associated with BCRL (HR 1.8, 95% CI: 1.2-2.8), as was advanced stage disease [stage III (HR 2.2, 95% CI: 1.2-3.7) vs stage 0/I disease]. Patients with BMI≥35 (HR 1.9, 95% CI: 1.0-3.3) or BMI 25-34.99 (HR 1.5, 95% CI: 1.1-2.0) had higher rates of BCRL than those with BMI < 25, $p < 0.01$.

Conclusions: BCRL is a sequelae of multimodal breast cancer treatment that affects some breast cancer survivors. The risk of lymphedema was multifactorial and not impacted by axillary surgery alone. BCRL rates were higher in patients receiving chemotherapy, radiation, ALND, more advanced stage of disease, and higher BMI. Adjuvant RT carried a higher risk of lymphedema development in patients undergoing ALND but not SLNB.

Table 1. Cumulative incidence of BCRL diagnosis by patient and clinical factors among breast cancer patients undergoing axillary staging surgery (n=1547)

	N	2-year cumulative incidence	5-year cumulative incidence	Univariate p-value
Baseline BMI				<0.001
<25	866	5.7%	8.3%	
25-29.99	408	10.9%	14.6%	
30-34.99	192	11.0%	13.2%	
≥35	76	17.1%	18.5%	
Stage				<0.001
0/I	919	3.3%	5.6%	
II	514	11.7%	14.7%	
III	114	32.7%	39.1%	
Surgery				<0.001
BCS+SLNB	454	5.7%	6.6%	
BCS+ALND	365	9.3%	14.4%	
Mastectomy+SLNB	285	3.5%	5.0%	
Mastectomy+ALND	443	12.9%	16.9%	
Radiation Therapy				<0.001
No	646	4.4%	6.4%	
Yes	901	11.0%	14.4%	
Chemotherapy				<0.001
No	1030	4.1%	6.3%	
Yes	517	16.6%	20.8%	

257074 - Improved locoregional control in a contemporary cohort of nonmetastatic inflammatory breast cancer patients undergoing surgery

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Background/Objective: Inflammatory breast cancer (IBC) is an aggressive form of breast cancer characterized by rapid progression and early metastatic dissemination. The purpose of this study was to assess contemporary rates of local regional recurrence (LRR) in the era of trimodality therapy for non-metastatic IBC, and identify risk factors leading to local failure.

Methods: One hundred fourteen patients with non-metastatic IBC receiving trimodality therapy(neoadjuvant chemotherapy(NCT), surgery, and radiation therapy) were identified from a prospectively collected database from 2007-2015 and outcomes analyzed.

Results: Median age at diagnosis was 52 years and the median follow-up was 3.6 years. Sixty-three (55%) patients presented with N2 IBC and 52 patients (45%) presented with N3 IBC. A LRR was observed during follow-up for 4 patients; 25 died, and 85 were censored at last follow-up. Surgical margins were negative in 99% of patients (n = 113). The 2-year probability of LRR was 3.19% (95% CI 1.03%, 9.90%). Five-year overall survival for this cohort was 69.14%. Competing risk analysis identified improvement in DFS among patients with HER2+ subtype, clinical stage IIIB, complete or partial radiologic response to NCT, pathologic complete response, and lower nodal burden on presentation.

Conclusions: Locoregional recurrences were rare at a median of 3.6 years follow-up in a contemporary cohort of IBC patients treated with trimodality therapy. Though longer follow-up is needed, aggressive surgical resection to negative margins in the frame of trimodality therapy with curative intent can lead to LRR rates that mirror non-IBC rates.

257285 - Management of benign phyllodes tumors of the breast: Is wide local excision still indicated?

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Background/Objective: Phyllodes tumors of the breast are rare heterogeneous fibroepithelial neoplasms classified as either benign, borderline, or malignant. There is no clear consensus regarding the necessity of obtaining wide surgical margins for the treatment of benign phyllodes tumor (BPT). In this study, we sought to describe surgical treatment patterns of these tumors and their associated outcomes.

Methods: All women diagnosed with BPT who underwent core biopsy or surgical excision between January 2010 and December 2014 were identified from a prospectively maintained, city-wide pathology dataset of all breast core biopsies and surgical excisions. Patient demographics, pre-operative biopsy pathology, final tumor characteristics, margin status, surgical treatment with the surgeon's margin intent (marginal vs wide local excision), recurrence, and cause of death were obtained from primary chart review. Descriptive statistics were used to characterize treatment patterns as well as recurrences and survival.

Results: We identified 123 women treated and followed for BPT in our region from the pathology database. The mean age was 39.4 years old (+/-14.4 years). Most patients (121 patients; 98%) had an initial ultrasound guided core biopsy. However, only 24 (20%) had an initial diagnosis of BPT on the core biopsy. Of the remaining 97 patients, core biopsy revealed fibroepithelial lesions in 48 (40%), fibroadenomas in 46 (38%) and other pathologies in 3 (2%). The majority of patients (100 patients; 81%) were diagnosed with BPT after the initial surgical excision. The most common practice at the initial surgical excision was to marginally excise (shell out) the lesion with no intent at a wide local excision (83 patients 68% marginal excision vs. 38 patients 31% wide local excision). Therefore, margins of the excisions were often positive (60 patients 49% with tumor on ink and an additional 27 patients 22% with less than 2-mm margin). For patients with positive margins for BPT, only 33 (27%) underwent a second surgery for re-excision to obtain a negative final margin. Of those that did, the majority of patients (28/33 patients; 85%) yielded no residual disease. After a median follow up of 59 months, disease recurred in 6 patients (5%). Of these, all had positive margins after initial marginal excision / "shelled out," of which only one went on to wide local re-excision. All 6 patients had WLE for recurrent BPTs. The new margins were only positive in 1 patient, and she has not undergone further re-excision. Overall on follow up, 2/123 patients died for reasons unrelated to phyllodes tumor.

Conclusions: Phyllodes tumor of the breast is a rare entity often confused with fibroadenoma and frequently treated with marginal excision, resulting in close/positive margins. In this study, we found that re-excisions of BPT in order to obtain wider/negative margins did not reveal additional tumor. Recurrence of benign disease was low (5%) and successfully treated with re-excision, supporting a conservative approach to these tumors.

Top 10 Posters
Friday, April 28 and Saturday, April 29, 2017

254928- Excision alone for low risk ductal carcinoma in situ using University of Southern California/Van Nuys Prognostic Index

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Background/Objective: Numerous prospective randomized trials have proven that whole breast radiation therapy (WBRT) following excision for ductal carcinoma in situ (DCIS) decreases the rate of ipsilateral breast tumor recurrence (IBTR). However, it does not improve overall survival and may represent overtreatment in some low-risk patients. The University of Southern California/Van Nuys Prognostic Index (USC/VNPI) is an algorithm that quantifies 5 measurable prognostic factors (tumor size, margin width, nuclear grade, age, and comedonecrosis) to aid in predicting local recurrence in conservatively treated patients. The aim of this study was to determine IBTR rates based on treatment type for the most favorable subgroup of patients, those with USC/VNPI scores of 4, 5, or 6.

Methods: A prospective database was queried for patients with pure DCIS and a USC/VNPI score of 4, 5, or 6. Patients were divided into 3 groups based upon treatment (mastectomy, excision plus WBRT, and excision alone) and analyzed for IBTR rate and overall survival. IBTR was defined as any ipsilateral breast event, in any quadrant, including DCIS and/or invasive breast cancer. Treatment was not randomized. Treatment decisions were based upon patient preference after full disclosure and discussion of available data, including risks, benefits, and all treatment alternatives. No patients received chemotherapy. Endocrine therapy was used at the discretion of the medical oncologist.

Results: A total of 461 patients met study criteria: 55 patients were treated with mastectomy, 82 patients were treated with excision plus WBRT, and 324 were treated with excision alone. Median follow-up for all patients was 73 months. The table shows the 10-year IBTR probability and overall survival as computed by Kaplan-Meier analysis. There were no IBTR events in the mastectomy group. There were 4 IBTRs in the excision plus WBRT group and 16 in the excision alone group. There was no significant difference in overall survival across the 3 treatment groups (p=NS). While radiation therapy reduced the IBTR rate by approximately 50%, there was no significant difference in the 10-year probability of IBTR, regardless of breast-conserving treatment (p=NS). The absolute risk reduction offered by WBRT is 4.5% at 5 years and 3.8% at 10 years. A total of 26 patients would need to be treated with WBRT to prevent 1 IBTR at 10 years.

Conclusions: Adjuvant WBRT may be safely omitted in patients with low-risk, USC/VNPI 4, 5, or 6 DCIS, as there is no significant difference in the probability of IBTR or overall survival.

TREATMENT	N	10-Year IBTR	10-Year Overall Survival
Mastectomy	55	0%	92.6%
Excision plus WBRT	82	3.5%	94.7%
Excision Alone	324	7.3%	92.2%

IBTR probability and overall survival based on treatment

257059 - Factors influencing use of hormone therapy for ductal carcinoma in situ: A National Cancer Database study

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Background/Objective: A majority of ductal carcinoma in situ (DCIS) cases are hormone receptor positive (HR+). Prospective clinical trials have demonstrated that adjuvant hormonal therapy (HT) reduces the risk of invasive and non-invasive recurrence and the risk of contralateral breast cancer; however, this benefit is only observed in HR+ DCIS and HT does not improve survival. Prior SEER data suggested that the use of HT for DCIS decreased over time. The purpose of this study was to assess national practice patterns and the influence of type of surgical resection on the use of adjuvant HT for HR+ DCIS patients using the National Cancer Database (NCDB).

Methods: Data on all patients with DCIS diagnosed from 2004-2013 were extracted from the NCDB. Patients were classified as either estrogen receptor (ER) positive or negative and according to whether HT was received as part of the first course of treatment. Factors associated with receipt of HT were assessed using chi-square tests for univariate analysis and logistic regression for multivariable analysis.

Results: A total of 156,048 DCIS patients were included, of which 129,844 (83.2%) were ER+ and 26,204 (16.8%) were ER-. Among the ER- patients, 2,093 (8.0%) were treated with HT. Among ER+ patients, 59,170 (45.6%) were treated with HT. Use of HT increased over the time period from 42.2% in 2004 to 47.7% in 2013 ($p < 0.001$). Focusing on the ER+ patients 129,041 (99.4%) were women, 803 (0.6%) were men, and median age was 58.0. ER+ DCIS was well differentiated in 19.3%, moderately differentiated in 44.3%, and poorly differentiated in 36.4%. Median size of ER+ DCIS was 9.0 mm (IQR 5.0, 17.0). Surgical treatment was breast-conserving surgery (BCS) in 78.5%, unilateral mastectomy in 13.9%, and bilateral mastectomy in 7.6%. HT use varied by type of surgery with rates of 52.7% among those undergoing BCS, 30.7% for unilateral mastectomy, and 8.1% for bilateral mastectomy patients ($p < 0.001$). Among patients treated with BCS, HT use was higher in those who received adjuvant radiation therapy (RT) than in those treated without RT (61.6% vs 27.5%, $p < 0.001$), and treatment combinations included BCS+HT+RT in 44,749 (45.6%), BCS+RT in 27,854 (28.4%), BCS+HT in 7,011 (7.1%), and BCS only in 18,521 (18.9%). Males treated with BCS were significantly less likely than females to receive HT (41.2% vs 52.8%, respectively, $p < 0.001$). In the BCS subset, multivariable analysis (see Table) showed more recent calendar year (OR 1.5, 95% CI: 1.4-1.6 for 2012-2013 vs 2004-2005), younger age (OR 2.7, 95% CI: 2.5-2.9 for age 50-59 vs ≥ 80; OR 1.6, 95% CI: 1.5-1.7 for age 50-59 vs 70-79), female gender (OR 1.4, 95% CI: 1.1-1.7), and use of RT (OR 3.9, 95% CI: 3.8-4.1) were associated with increased likelihood of use of HT.

Conclusions: Adjuvant HT use in DCIS varies widely across patients and has increased over time. HT use is greatest in patients with ER+ DCIS undergoing BCS and highest within the BCS subset that receive adjuvant RT. Men with ER+ DCIS treated with BCS were less likely to receive HT. Adjuvant HT is used in 30.7% of patients treated with unilateral mastectomy, where the main role is to decrease contralateral breast cancer. Our observations that HT was utilized in approximately 3000 patients with bilateral mastectomy or ER- DCIS identifies an opportunity for education.

	Odds Ratio (95% CI)	p-value
Calendar Year		
2004-2005	1.0 reference	
2006-2007	1.13 (1.08, 1.19)	<0.001
2008-2009	1.16 (1.11, 1.22)	<0.001
2010-2011	1.26 (1.21, 1.32)	<0.001
2012-2013	1.49 (1.42, 1.55)	<0.001
Age		
<40	0.70 (0.63, 0.77)	<0.001
40-49	0.98 (0.94, 1.02)	0.23
50-59	1.0 reference	
60-69	0.87 (0.84, 0.90)	<0.001
70-79	0.62 (0.60, 0.65)	<0.001
≥80	0.38 (0.35, 0.40)	<0.001
Sex		
Female	1.37 (1.12, 1.69)	0.003
Male	1.0 reference	
Charlson-Deyo Score		
0	1.0 reference	
1	1.05 (1.0, 1.09)	0.05
2+	0.91 (0.82, 1.01)	0.08
Tumor Size		
<10 mm	1.0 reference	
≥ 10 mm	0.94 (0.91, 0.98)	<0.001
Unknown	1.01 (0.98, 1.04)	0.50
Grade		
Well differentiated	1.0 reference	
Moderately differentiated	0.93 (0.89, 0.97)	<0.001
Poorly differentiated	0.93 (0.89, 0.97)	<0.001
Unknown	0.92 (0.88, 0.96)	<0.001
Radiation therapy		
No	1.0 reference	
Yes	3.95 (3.82, 4.08)	<0.001

Multivariable analysis of factors associated with HT use in ER+ DCIS patients treated with BCS

257375- Surgical resection of the primary tumor in women with stage IV breast cancer: Contemporary practice patterns and survival analysis

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Background/Objective: Among women with stage IV breast cancer, surgical resection of the primary tumor has remained controversial. We sought to determine national practice patterns of primary site resection and the impact of surgery on mortality among a contemporary cohort of metastatic breast cancer patients.

Methods: Using the National Cancer Database, women diagnosed with stage IV breast cancer were identified from 2003-2012. Subjects with an intact primary breast cancer alive at least 12 months after diagnosis were included. Treatment was categorized into the following groups: surgery prior to systemic therapy, surgery following systemic therapy, and systemic therapy alone. Multivariate logistic regression models were used to estimate the association of treatment sequence with receipt of mastectomy or breast conservation therapy after adjustment for known covariates. Hazard ratio for overall survival was estimated using a Multivariate Cox proportional hazards model.

Results: In total, 24,015 subjects were identified. Of those, 24.8% underwent surgery following systemic therapy, 19.0% underwent surgery prior to systemic therapy, and 56.2% underwent systemic therapy alone. Surgery following systemic therapy was associated with a higher rate of mastectomy when compared to patients who underwent surgery first (OR 1.49; 95% CI 1.36-1.64; $p < 0.001$). Unadjusted median overall survival (OS) differed by treatment sequence: 37.5 months for systemic therapy alone, 49.4 months for surgery first, and 52.8 months for surgery following systemic therapy (log-rank $p < 0.001$). After adjustment for known covariates, OS was improved in the surgery following systemic therapy (HR 0.56; 95% CI, 0.52-0.61; $p < 0.001$) and surgery prior to systemic therapy (HR 0.68; 95% CI, 0.62-0.73; $p < 0.001$) groups.

Conclusions: Surgery of the primary tumor is associated with improved survival. Unlike prior data, we demonstrate that treatment sequence impacts outcomes with improved OS with surgery following systemic therapy. However, pending results of the ECOG 2108 trial, treatment of stage IV patients should involve multidisciplinary teams to maximize benefits and minimize harm.

256763 - Positive ultrasound-guided lymph node needle biopsy in breast cancer may not mandate axillary lymph node dissection

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Background/Objective: The ACOSOG Z0011 (Z11) trial demonstrated that, for select patients with clinically nonpalpable axillary lymph nodes (LN) and 1-2 positive sentinel lymph nodes (SLN), axillary

lymph node dissection (ALND) is unnecessary. The Z11 trial did not address findings on preoperative axillary ultrasound (axUS), which in many centers is now part of the standard work-up of a newly diagnosed breast cancer patient. Currently, it is not known whether the Z11 trial findings can be applied to patients without palpable adenopathy, but who have been diagnosed with LN metastasis preoperatively by axUS-guided LN needle biopsy (axUS-LNNB).

Methods: A retrospective analysis was performed of newly diagnosed invasive breast cancers from June 2009 to October 2015 with (1) no palpable lymphadenopathy, (2) abnormal axUS (as determined from radiology report), (3) axillary LN metastasis confirmed preoperatively by axUS-LNNB, (4) no neoadjuvant therapy, and (5) underwent ALND. LN disease burden was dichotomized as N1 (1-3 positive nodes) vs. N2-3 (≥ 4 positive nodes). The univariate relationship between clinicopathologic factors and LN disease burden was examined. Specific abnormalities on axUS were also separately analyzed for a relationship to LN disease burden. A single radiologist (DP) reviewed preoperative imaging to determine the best preoperative estimate of tumor size; for 7 cases in which images were not available, image size from outside radiology report was used.

Results: Of 81 included cases, 39 had N1 disease (48%) and 42 had N2-3 disease (52%). On univariate analysis, T size > 2 cm on preoperative imaging and ≥ 2 abnormal LN on axUS were associated with N2-3 disease (Table). In addition, axillary US showing loss of fatty hilum, replaced appearing LN, or round LN (characteristics demonstrated in previous studies to be most strongly associated with positive axUS-LNNB) was also associated with N2-3 disease. Age, tumor quadrant, histologic type, ER/PR/HER2 status, grade, lymphovascular invasion on core biopsy, and LN size or cortical thickening on axUS were not significantly associated with N status. For patients meeting all 3 criteria associated with N1 disease (T size on imaging ≤ 2 cm, 1 abnormal LN on axUS, and no evidence of loss of fatty hilum/replaced LN/round LN on axUS) only 25% of patients had N2-3 disease, although the number of cases meeting all 3 criteria was small (n=16, 20% of the cohort).

Conclusions: The results of this study are similar to recent studies demonstrating that approximately half of patients without palpable adenopathy but with preoperative US-guided, biopsy proven axillary LN metastases have N1 disease. Our analysis identified several characteristics that were significant predictors of N2-3 disease (T size > 2 cm on imaging, ≥ 2 abnormal LN on axUS, and loss of fatty hilum/replaced/round appearing LN on axUS). In contrast, on subset analysis, 75% of cases that lack these characteristics had N1 disease. We therefore conclude that patients with positive axUS-LNNB who would otherwise qualify for Z11 management and have only a single suspicious node on axUS may reasonably undergo attempt at SLNB (including retrieval of the needle-biopsied node). Patients meeting the 3 criteria specified are particularly unlikely to have ≥ 3 positive SLNs and require subsequent ALND.

Imaging features	N1 n=39	N2-3 n=42	*p*
Tumor size on imaging ≤ 2 cm > 2 cm	 20 (64.5%) 19 (38.0%)	 11 (35.5%) 31 (62.0%)	 0.020
Number of abnormal lymph nodes on axillary ultrasound 1 ≥ 2	 28 (58.3%) 11 (33.3%)	 20 (41.7%) 22 (66.7%)	 0.026
Axillary ultrasound showing loss of fatty hilum, replaced node, or round node Yes None of these characteristics	 1 (12.5%) 38 (52.0%)	 7 (87.5%) 35 (48.0%)	 0.024
Subset defined from above characteristics: • Tumor size on imaging ≤ 2 cm & • 1 abnormal lymph node on axillary US & • axillary ultrasound DOES NOT show loss of fatty hilum or replaced node/round node Rest of cohort	 12 (75.0%) 27 (41.5%)	 4 (25.0%) 38 (58.5%)	 0.015

Significant imaging factors associated with nodal status, p values are chi-squared likelihood ratios. The final row demonstrates a subset at low risk for harboring N2-3 disease

257322 - Implementation of findings of ACOSOG Z1071 into clinical practice for breast cancer patients (T0-4, N1-2) undergoing neoadjuvant chemotherapy

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Background/Objective: It has been widely recognized that it commonly takes many years for the results of clinical trials to be incorporated into clinical practice. ACOSOG Z1071 assessed the feasibility and false negative rate of sentinel lymph node biopsy (SLNB) performed after neoadjuvant chemotherapy (NAC) in patients presenting with clinical T0-4, N1-2 breast cancer. The false negative rate (FNR) was reported to be 12.6% overall. However, the FNR was further reduced to 10.8% or less if dual-tracer technique was used and 3 or more sentinel lymph nodes were examined. Our aim was to analyze how the findings of ACOSOG Z1071 influenced our clinical practice and whether surgeons followed appropriate techniques.

Methods: A retrospective review of institutional tumor registries identified 140 female patients who had T0-4 and N1-2 breast cancer and underwent NAC prior to definitive surgical management from May 2013 to September 2016. Data collected included: demographics; attending surgeon; clinical presentation including tumor location, histology, receptors and clinical stage at diagnosis; radiographic studies performed; type of NAC; type of breast and axillary surgery performed; technical aspects SLNB and final pathologic features, including retrieval of a clipped axillary lymph node, the finding of biopsy site change and final pathologic stage. Patients were determined to be eligible for SLNB based on the criteria of ACOSOG Z1071. The primary endpoint was compliance with offering eligible patients SLNB. Secondary endpoints included analyses of the SLNB technique and methods employed in order to reduce the FNR of the procedure. Kruskal-Wallis and Fischer's Exact tests were performed.

Results: Of 140 patients identified, 127 were determined to be eligible for SLNB. Compliance in offering

eligible patients SLNB increased rapidly over time. This increase in rate of adoption of Z1071 was statistically significant when analyzed by half-year increments and as a function of continuous time (p= 0.0003). Statistically significant differences in approach to implementation of Z1071 existed among surgeons (p < 0.0001), between University and County hospital facilities (p < 0.0001), according to race (p=0.0095) and according to insurance status (p=0.0002). Of 86 patients undergoing SLNB, appropriate technique for minimizing FNR was performed in 94.2%. Positive axillary lymph nodes were clipped in 39.5% of patients undergoing SLNB. Of these, retrieval was confirmed in 73.5%.

Conclusions: Implementation of the findings of clinical trial ACOSOG Z1071 into clinical practice increased rapidly in the first 2 years following presentation, achieving a high rate of acceptance. Despite high acceptance, there appear to be factors influencing surgeon application of Z1071 that warrant further study. Surgeons have been careful to use the recommended SLNB techniques shown by Z1071 to reduce the FNR. Furthermore, many have taken additional steps intra-operatively to improve upon this reduction. Further study to assess methods for minimizing false negative SLNB results, such as clip placement at nodal biopsy or preoperative localization of known positive nodes, is needed.

	n/Total (%)	*p*
Time		0.0003*
May-Jun 2013	4/12 (33.3%)	
Jul-Dec 2013	13/27 (48.1%)	
Jan-Jun 2014	21/29 (72.4%)	
Jul-Dec 2014	21/22 (95.5%)	
Jan-Jun 2015	18/21 (85.7%)	
Jul-Dec 2015	18/24 (75.0%)	
Jan-Mar 2016	4/5 (80.0%)	
Surgeon		<0.0001
1	20/36 (55.6%)	
2	1/1 (100.0%)	
3	25/25 (100.0%)	
4	25/26 (96.2%)	
5	7/13 (53.8%)	
6	2/3 (66.7%)	
7	19/36 (52.8%)	
Hospital		<0.0001
County	37/71 (52.1%)	
University	62/69 (89.9%)	
Race		0.0095
African-American	16/26 (61.5%)	
Hispanic	31/53 (58.5%)	
Caucasian	42/49 (85.7%)	
Other	10/12 (83.3%)	
Insurance		0.0002
Medicare/Medicaid	24/37 (64.9%)	
County/None	21/41 (51.2%)	
Private	54/62 (87.1%)	

*Kruskal-Wallis test for singly ordered categorical comparison used. All other p-values from Fisher's Exact test.

Compliance rate by clinical parameters

256737 - High Ki-67 is associated with an increased likelihood of a pathologic complete response in patients with estrogen receptor positive breast cancer

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Background/Objective: Response to neoadjuvant chemotherapy (NAC) differs based on breast cancer (BC) phenotype, with overall low pathologic complete response (pCR) rates in patients with estrogen receptor positive, HER2-neu negative (ER+/HER2-) BC compared to other phenotypes. Predicting which patients in this subset are most likely to achieve pCR may help streamline treatment decision-making. We hypothesize that patients with ER+/HER2- BC and a high Ki-67 are more likely to achieve a pCR compared to those with lower Ki-67. This may allow the ability to identify patients who would require less extensive breast or axillary surgery at the end of treatment.

Methods: A retrospective chart review was performed on a prospectively maintained NAC database at a single institution from 2010-2015. Patients with ER+/HER2- BC were identified. Patient demographics, clinicopathologic information, surgical plans, and outcomes pre- and post-NAC were collected.

Statistical analysis was performed using Stata/SE v.14.1 (2016). A p value < 0.05 was considered statistically significant.

Results: Of 651 patients treated with NAC, 153 had ER+/HER2- BC. Mean age was 51. Eighty-four 84 (55%) were pre-menopausal. One hundred thirty-three (87%) had invasive ductal carcinoma. At diagnosis, 144 (94%) had clinical AJCC stage II or III disease, and 97 (63%) had a positive lymph node biopsy (LN+). Ninety-four (61%) had ER H-score > 200. Forty-seven (31%) had Ki-67 26-50% categorized as high proliferation index. Fifty-three (35%) had Ki-67 > 50% categorized as very high proliferation index.

Only 15 (10%) patients were candidates for breast conservation therapy (BCT) pre-NAC, based on tumor-to-breast ratio. One hundred thirty-six (89%) completed NAC, and most, 132 (86%), received doxorubicin, cyclophosphamide, and paclitaxel. Fifty-eight (38%) were BCT candidates post-NAC.

Twenty-one (14%) achieved pCR both in breast and axilla. Twenty-one (14%) had pCR in breast. Sixty-nine (45%) had pCR in axilla. Of the 21 patients with pCR both in breast and axilla, 10 (48%) had ER H-score ≤100. Five (24%) had high Ki-67 > 26-50%, and 15 (71%) had very high Ki-67 > 50% (OR 5.3, p=0.0013).

Conclusions: This study suggests that patients with ER+/HER2- BC and a very high Ki-67 are more likely to achieve a pCR compared to those with lower Ki-67. A larger sample of patients is needed to confirm these results. The significance of achieving a pCR in this subset of patients would be helpful in the prediction of those who may undergo less extensive surgery at the end of treatment.

N = 153	Age (mean)	51 (range 24-78)	
MENOPAUSAL STATUS	Post-menopausal	69	45%
	Pre-menopausal	84	55%
HISTOLOGY	Invasive ductal carcinoma	133	87%
	Invasive lobular carcinoma	20	13%
Estrogen Receptor H score	1-100	29	19%
	101-200	30	20%
	201-300	94	61%
Ki-67	Low (1-10%)	19	12%
	Moderate (11-25%)	27	18%
	High (26-50%)	47	31%
	Very High (>50%)	53	35%
Pre-NAC Clinical AJCC Stage	I	9	6%
	II	84	55%
	III	60	39%
NAC	Completed NAC	136	89%
	Type of NAC: ACT	132	86%
PATHOLOGIC RESPONSE (TVR%)	100%	21	14%
	51-99%	78	51%
	0-50%	45	29%
BREAST SURGERY	BCT Candidate pre-NAC	15	10%
	BCT Candidate post-NAC	58	38%
AXILLARY SURGERY	LN+ Pre-NAC	97	100%
	LN+ downstaged to LN- Post-NAC	34	35%
pCR SUBGROUP ANALYSIS		N=21	
pCR in breast and axilla		21	14%
pCR in breast		21	14%
pCR in axilla		69	45%
Estrogen Receptor H score	1-100	10	48%
	101-200	3	14%
	201-300	8	38%
Ki-67	Low (1-10%)	1	5%
	Moderate (11-25%)	0	0%
	High (26-50%)	5	24%
	Very high (>50%)	15	71%
pCR and Ki-67 >50%		Ki-67 > 50%	Ki-67 ≤ 50%
	pCR (N=21)	15 (71%)	6 (29%)
	No pCR (N=123)	37 (30%)	79 (64%)
	OR 5.338 (95% CI 1.92-14.86)	P-value = 0.0013	

AJCC American Joint Committee on Cancer, **NAC** neoadjuvant chemotherapy, **ACT** doxorubicin/cyclophosphamide/paclitaxel, **TVR** tumor volume reduction, **pCR** pathologic complete response, **LN+** positive lymph node biopsy, **LN-** negative lymph node biopsy, **SLNB** sentinel lymph node biopsy, **ALND** axillary lymph node dissection, **BCT** breast conservation therapy, **OR** odds ratio, **95% CI** 95% confidence interval

257146 - Validation of a NSQIP-based prediction model for surgical site infections after breast reconstruction

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Background/Objective: The Breast Reconstruction Risk Assessment (BRA) Score is a model developed to predict the risk of surgical site infections (SSI) within 30 days after breast reconstruction. This was derived from the National Surgical Quality Improvement Program (NSQIP) database, where the average risk of SSI was 3.75%. We aim to externally validate this model in our cohort of patients who have undergone total skin-sparing mastectomy (TSSM) with immediate breast reconstruction.

Methods: We reviewed all cases of TSSM with immediate breast reconstruction between 2005-2013 performed at our institution. SSIs in our cohort were defined as any infections requiring oral antibiotics, intravenous antibiotics, or procedures for resolution. The BRA Score variables included type of reconstruction, age, BMI, ASA class 3+, bleeding disorder, prior PCI or cardiac surgery, diabetes, active smoking, dyspnea, and hypertension. We compared the BRA Score model with models derived from our own dataset. We generated a new model using variables associated with complications after breast reconstruction, including age, BMI, diabetes, incision, lymph node dissection, prior radiation, and acellular dermal matrix

Results: We identified 746 patients who had undergone TSSM with immediate breast reconstruction, with an overall 30-day SSI risk of 5.2%. The 1-year SSI risk was 16.4% in the 684 patients who underwent prosthetic breast reconstruction. The BRA Score for 30-day SSI did not fit our data well (C-statistic 0.509). We generated a risk prediction model using specific variables associated with breast reconstruction, and 10-fold cross-validation yielded improved discrimination for overall 30-day risk of SSI (C-statistic 0.583) and 1-year SSI risk in prosthetic breast reconstruction (C-statistic 0.625).

Conclusions: Many risk prediction models have been published, but few are used clinically due to lack of validation or relevance to the population studied. The BRA Score model does not incorporate several important variables associated with breast reconstruction outcomes, such as lymph node dissection status, prior radiation, and the use of acellular dermal matrix. Our new model with these variables achieves better discrimination with our data but requires external validation. An improved SSI risk model could be developed using a larger cohort, with variables specific to breast reconstruction.

Reconstruction	30-day SSI	1-year SSI
Prosthetic (684)	35 (5.1%)	112 (16.4%)
Pedicle TRAM (36)	1 (2.8%)	n/a
Free flap (22)	3 (12%)	n/a
Latissimus (1)	0 (0%)	n/a

Incidence of SSIs

256558 - Impact of compromised pulmonary function on 30-day outcomes after breast cancer resection

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Background/Objective: Pulmonary comorbidities have been associated with inferior outcomes after many surgical interventions. We aim to identify the impact of compromised pulmonary function, defined as active smoking status and underlying lung disease, on 30-day outcomes after resection of breast cancer.

Methods: All patients who underwent resection for invasive breast cancer between 2007 and 2012 were identified in the American College of Surgeons (ACS) National Surgical Quality Improvement Program (NSQIP) database using Current Procedure Terminology (CPT) and International Classification of Diseases, Version 9 (ICD-9) codes. Pulmonary compromise was defined for all patients with a history of COPD, active smoking status, preoperative ventilator dependence and concurrent pneumonia. Active smoking status in NSQIP is defined as having smoked any number of cigarettes within one year prior to surgery. Outcome variables were compared between groups and adjusted for patient age, body mass index, and procedure type.

Results: A total of 71,294 patients who met inclusion criteria were identified. Of these, 10,855 patients (15.2%) had compromised pulmonary function. There were 9,594 active smokers and 1,986 patients with a history of COPD. Twelve patients had concurrent pneumonia, and 10 patients were ventilator dependent preoperatively. Average number of packyears in this group was 28.2 (SD 28.7; range 0-200). Overall complications after resection for breast cancer were low in the dataset (3.321 patients, 4.6%). After adjusting for body mass index, age, and type of procedure, patients with pulmonary compromise had higher postoperative risk of superficial surgical site infection (2.6 vs 1.7%, OR=1.6, $P < 0.001$), wound dehiscence (0.7 vs 0.3%, OR 2.3, $P < 0.001$), wound infection (1.0 vs 0.6%, OR=1.6, $P < 0.001$), pneumonia (0.2 vs 0.1%, OR=2.6, $P < 0.001$), reintubation (0.2 vs 0.1%, OR=2.6, P=0.001), failure to wean from a ventilator (0.1 vs 0.0%, OR 2.8, P=0.005), flap failure (0.5 vs 0.3%, OR 1.7, P=0.001), sepsis (0.5 vs 0.3%, OR 1.7, P=0.003), and septic shock (0.1 vs 0.0%, OR 3.1, P=0.001). Overall 30-day morbidity was increased by 43% among patients with pulmonary compromise (6.2 vs 4.4%, OR 1.4, $P < 0.001$). There was no significant difference in risk of death between groups (0.18 vs 0.12%, P=0.17).

Conclusions: Pulmonary disease has a significant impact on postoperative morbidity of patients undergoing resection for breast cancer, especially on infectious and pulmonary complications. Meticulous attention to improved preoperative planning and early smoking cessation may help to optimize outcomes.

257188 - Intraoperative radiation therapy: A treatment option for patients with invasive cancers

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Background/Objective: Breast conserving surgery (BCS) with adjuvant whole breast radiation therapy (WBRT) is standard treatment for patients with early stage breast cancer. The TARGIT trial reported similar rates of local recurrence when IORT, a single dose of radiation therapy targeted at the tumor bed delivered at the time of partial mastectomy, was compared to WBRT. Patient selection for IORT is a challenge since true extent of disease is not known until days after surgery. This study evaluates preoperative clinical factors used to identify appropriate patients for IORT, perioperative complications, and disease recurrence in patients treated with IORT.

Methods: This is a nested case-control study derived from a prospective non-randomized study including all women with invasive breast cancer undergoing BCS from February 2011 to October 2016. Patients with unifocal tumors < 3 cm on imaging, no evidence of nodal disease, and absence of lymphovascular invasion on core needle biopsy were offered IORT at the time of partial mastectomy. Patients with final pathology meeting the inclusion criteria were treated with IORT only (IORT). Those who did not meet all inclusion criteria were recommended to undergo additional therapy (AT) including whole breast radiation with or without re-excision or mastectomy. Systemic therapy was given when appropriate. Patient and tumor characteristics, disease recurrence, complications and survival were compared between IORT and AT groups. Multivariable-adjusted odds ratios were estimated with logistic regression.

Results: 238 patients with 243 invasive breast cancers were treated with IORT from 2011 to 2016. 164 cancers met the criteria for single dose IORT (IORT group) with pathology showing unifocal cancer, negative sentinel nodes, margins >2mm and no evidence of lymphovascular invasion. 79 cancers did not meet the criteria and therefore patients were advised to have additional therapy (AT group). No difference in patient age (IORT 63.6 years vs AT 62.0 years, p=0.20), tumor size on mammogram, ultrasound, or MRI (IORT 1.1 cm vs AT 1.2 cm, p=0.36 on mammogram, IORT 1.1 cm vs AT 1.0 cm, p=0.82 on ultrasound, and IORT 1.4 cm vs AT 1.6 cm, p=0.28 on MRI) were observed between the 2 groups. Presence of lobular histology was not associated with a need for additional therapy (p=0.87). No factors, including tumor grade and hormone receptor status, were associated with a need for AT (Table 1). No patients had major perioperative complications. The IORT group was associated with fewer minor complications such as hyperpigmentation and fibrosis compared with the AT group (IORT 10% vs. AT 28%, p=0.001). There was no significant difference in recurrence after an average of 29 months of follow up (IORT 1.2% vs AT 1 1.3%, p>0.99). One patient in the IORT group died of an unrelated cancer.

Conclusions: IORT is associated with a low risk of local recurrence in early breast cancer. No preoperative factors, including the presence of lobular histology, were shown to be associated with the need for additional therapy based on our inclusion criteria. Although long term outcomes are yet to be determined, however IORT is associated with a low risk of local recurrence in this study. In well selected patients, IORT is an effective treatment option for patients with invasive breast cancer.

	IORT n=164	AT n=79	P
Age, years	63.6 ± 8.8	62.0 ± 8.8	.20
BMI, cm/m2	27.5 (23.9 – 33.3)	26.1 (23.3 – 31.2)	.15
Tumor Size, cm			
Mammogram	1.1 (0.8 – 1.6)	1.2 (0.8 – 1.8)	.36
Ultrasound	1.1 (0.7 – 1.6)	1.0 (0.8 – 1.6)	.82
MRI	1.4 (1.0 – 1.9)	1.6 (1.1 – 2.0)	.28
Histology, n			
IDCA	125 (76.2)	61 (77.2)	.53
IDLCA	29 (17.7)	10 (12.7)	
ILCA	7 (4.3)	6 (7.6)	
Other	3 (1.8)	2 (2.5)	
Any lobular histology, n	36 (22.0)	16 (20.3)	.87
Grade, n			
1	64 (39.0)	25 (31.7)	.46
2	82 (50.0)	46 (58.2)	
3	18 (11.0)	7 (8.9)	
Receptor status, n			
ER+	153 (93.3)	74 (93.7)	> .99
PR+	135 (82.3)	64 (81.0)	.86
Her2-	155 (94.5)	73 (92.4)	.57
Recurrence, n	2 (1.2)	1 (1.3)	> .99
Survival, n	163 (99.4)	79 (100.0)	> .99

Normally-distributed, continuous data displayed as mean ± standard deviation and compared with the t-test; non-normally distributed continuous data displayed as median (interquartile range) and compared with the Wilcoxon rank-sum test; categorical data as count (proportion) and compared with the Fisher exact test. BMI, body mass index. MRI, magnetic resonance imaging. IDCA, invasive ductal carcinoma. IDLCA, invasive carcinoma with ductal and lobular features. ILCA, invasive lobular carcinoma. ER, estrogen receptor. PR, progesterone receptor.

a. Among 216 patients with ultrasound measurements

b. Among 222 patients with MRI measurements

c. Excluding 1 patient with indeterminate grade

Clinical characteristic of cancers treated with IORT alone (IORT) and cancers treated with IORT and additional therapy (AT)

256282 - Who should be offered contralateral prophylactic mastectomy? A Canadian consensus statement using Delphi methodology

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Background/Objective: In the last decade, the number of average-risk women with unilateral breast cancer undergoing a therapeutic mastectomy and a contralateral prophylactic mastectomy (CPM) is increasing. Amongst North American surgeons, a formal and evidence-based statement from a surgical association to guide the appropriate use of CPM is needed. The goal of this project is to create a nationally endorsed Canadian consensus statement for CPM in women with unilateral breast cancer using Delphi consensus methodology.

Methods: The Modified Delphi method utilizes a panel of experts to systematically assess and synthesize evidence, and to anonymously evaluate statements about a topic of interest incorporating several rounds of feedback. A nationally representative panel of general surgeons, radiation oncologists, plastic/reconstructive surgeons, medical oncologists, a psychologist, and relevant policy stakeholders were invited to participate in consensus statement generation. A systematic quantitative and qualitative review was completed and summarized for panelists. Thirty-one statements were created in 5 topic domains: pre-disposing risk factors for breast cancer, tumour factors, reconstruction/symmetry issues, patient factors, and other factors. Panelists were asked to rate statements on a 7-point Likert scale in the context of provided medical evidence. Two electronic rounds of iterative rating and feedback were anonymously completed, followed by an in-person meeting for discussion and consolidation of included statements. Consensus for each statement was reached when there was 80% agreement amongst panelists

Results: The panel included 15 females and 11 males (19 general surgeons, 2 plastic surgeons, 2 medical oncologists, 2 radiation oncologists, 1 psychologist) from across Canada. Consensus was reached for all statements. Overall, CPM was not recommended by the panel for average risk woman with unilateral breast cancer. Tumor and patient factors, including receptor status, multifocality, grade, subtype, stage, method of detection, and patient/family anxiety, should not affect the decision to recommend CPM. Patients should have appropriate access to supportive care services and accurate information to help cope with anxiety about breast cancer recurrence and death. The panel recommended CPM for women with previous Mantle field radiation. The panel agreed that CPM could be considered on an individual basis in: women with unilateral breast cancer and with a genetic mutation in one of BRCa1/2/CHEK2/PTEN/p53/PALB2/CDH1 genes, and in women with unilateral breast cancer who may have significant difficulty achieving symmetry after unilateral mastectomy. However, multidisciplinary consultation and discussion of alternatives to achieve symmetry are advised.

Conclusions: CPM is rarely medically recommended for women with unilateral breast cancer. However, discussion to provide appropriate supports is advocated.

	*cancer (LABC: > 5cm (T3), extensive palpable nodes (N2,N3), chest wall and/or skin involvement)** *CPM is not recommended if the patient has unilateral multifocal or multicentric disease** *CPM is not recommended if the patient has high grade breast cancer** *CPM is not recommended if the patient has a contralateral indeterminate or benign breast imaging finding* *CPM is not recommended if the patient has a lobular breast cancer* *CPM is not recommended if the initial cancer was only identified on MRI imaging* *CPM (with or without reconstruction) is not recommended, but may be considered, in a woman in whom breast symmetry may be a major issue after unilateral mastectomy (with or without reconstruction)* *CPM is not recommended based on timing (immediate or delayed) or type (implant or tissue-based) of reconstruction*** *CPM is not recommended based solely on patient anxiety around developing a contralateral breast cancer, distant metastases, breast cancer related death, and/or ongoing breast surveillance ** *CPM is not recommended even if the patient's non-medical sources of information strongly advocate for CPM**
CPM is recommended	*CPM is recommended in women who had Mantle field radiation*
CPM can be considered	*There is insufficient evidence to recommend for or against CPM and therefore CPM may be considered on an individual basis for women with early stage breast cancer and a genetic mutation in CHek2/ PTEN/ P53/ PALB2/CDH1 genes* *CPM (with or without reconstruction) is not recommended, but may be considered, in a woman in whom breast symmetry may be a major issue after unilateral mastectomy (with or without reconstruction*

*Met consensus in either first or second round of the Delphi survey (prior to in-person meeting)

** Part of this statement met consensus in first or second round of Delphi survey (statement was re-worded at in-person meeting)

Summary of recommendations for contralateral prophylactic mastectomy

Poster Session and Reception I

Friday, April 28, 2017

Benign

255300 - Quality of life is adversely affected by the diagnosis of proliferative breast lesions

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Background/Objective: The adverse impact of an abnormal mammogram on quality of life (QOL) is well-known; however resultant diagnoses that affect breast cancer risk may also impact QOL. We investigated the impact of a proliferative breast lesion with atypia diagnosis on QOL. Patients with a benign breast biopsy, family history of breast cancer, or a deleterious gene mutation were comparison groups.

Methods: The Breast Molecular Epidemiology Resource (BMER) is a prospectively maintained single-institution database of tissue samples and patient reported QOL data since 2010. QOL is assessed using the Functional Assessment of Cancer Therapy-Breast (FACT-B) at time of study enrollment, which consists of the FACT-General (FACT-G) plus Breast Cancer Subscale (BCS). FACT-G subscales include Physical Well-being (PWB), Functional Well-being (FWB), Emotional Well-being (EWB), and Social Well-being (SWB). BMER was queried for all patients without breast cancer, excluding those without FACT-B questionnaires. Patients were grouped into 4 categories: benign breast lesion without atypia (BB), proliferative breast lesion with atypia (PBL) (atypical ductal hyperplasia, atypical lobular hyperplasia and lobular carcinoma in situ), family history of breast cancer (FH), and deleterious genetic mutation (GM). Patients with a deleterious mutation were placed in GM regardless of BB, PBL or FH. Patients were categorized as BB if they did not have PBL, FH, or GM. Co-morbidities, risk factors, and interventions were obtained through chart abstraction. Statistical analysis was performed using Stata 13.1. Baseline characteristics and QOL metrics were compared between groups. Finally, the relationship of QOL scores and interventions was examined

Results: 323 patients met initial criteria; the final study population comprised 223 patients with completed FACT-B. Of these, we identified 28 patients with BB, 39 PBL, 97 FH, and 59 GM. PBL patients were older with a mean age of 52.6 ($p < 0.001$) and had a higher rate of comorbid pulmonary and liver disease. PBL patients had more percutaneous biopsies (mean = 1.1) and surgical excisions (mean = 0.96) than other groups ($p < 0.001$). PBL patients were more likely to be offered anti-estrogen therapy than FH or GM patients (48.7% vs 21.6% vs 22.0%) but were also more likely to decline therapy (28.2% vs 2.1% vs 5.0%, $p < 0.001$). GM patients had a higher rate of prophylactic mastectomy (57.6%) compared to PBL (5.1%) & FH (2.1%) ($p < 0.001$). Results of QOL metrics are summarized in Table 1. The FACT-G score, PWB, and self-reported QOL (single question item) were highest in BB and lowest in PBL (p=0.0456, p=0.0359, and p=0.0207 respectively). On multivariate analysis correcting for age, number of biopsies, depression, tobacco and alcohol use and comorbidities, FACT-G scores continued to be lower in PBL (β= -8.25, p=0.03) and GM (β=-12.16, p=0.002) compared to BB or FH patients, although the self-reported QOL was not longer different. Excluding BB patients, QOL or FACT-G score did not predict if patients opted for MRI screening follow up in high risk clinic, anti-estrogen risk reducing therapy or prophylactic mastectomy.

Conclusions: Patients with proliferative breast lesions report worse quality of life compared to patients with a benign breast biopsy or a family history of breast cancer, as do patients with a deleterious genetic mutation. QOL did not impact treatment choice. Opportunities exist to develop strategies for improving QOL in this large group of patients.

	Benign Lesion without Atypia (BB)			Proliferative Lesion with Atypia (PBI)			Family History of Breast Cancer (FH)			Genetic Mutation (GM)			
	Mean	Std.Dev	#*	Mean	Std.Dev	#*	Mean	Std.Dev	#*	Mean	Std.Dev	#*	p
Age	48.3	12.8	28	52.6	8.4	39	50.6	14.4	97	43.2	12.0	59	**0.001**
Overall QOL	8.6	1.5	28	7.6	1.8	39	8.4	1.6	97	8.4	1.4	59	**0.046**
Overall Spiritual Well-Being	8.3	1.6	28	7.7	2.1	39	8.3	1.6	96	8.5	1.4	59	0.124
PWB score	26.0	1.5	27	22.8	5.7	39	24.5	4.6	94	23.6	5.0	59	**0.036**
SWB score	23.9	4.7	27	21.5	6.6	39	23.6	5.3	92	23.0	4.8	59	0.216
EWB score	19.4	3.5	27	17.6	5.4	39	19.5	5.2	91	17.7	5.4	59	0.068
FWB score	23.4	4.6	27	20.5	6.7	39	23.2	5.7	90	22.0	5.6	59	0.072
FACT G total score	92.7	10.9	27	82.4	19.0	39	90.5	15.4	88	86.3	16.4	59	**0.021**
BC score	27.6	4.9	16	28.3	6.1	23	30.3	5.3	14	24.4	4.6	11	0.070
FACT B total	119.4	14.6	16	113.3	23.8	23	128.6	9.8	13	110.4	15.5	11	0.054

Table 1: Quality of life (QOL) metrics based on risk category (Higher score=higher QOL).

*: Number of patients that filled each section of the questionnaire

PWB: Physical Well-being; SWB: Social Well-being; EWB: Emotional Well-being; FWB: Functional Well-being; FACT-G: Functional Assessment of Cancer Therapy - General; BC: Breast Cancer; FACT-B: Functional Assessment of Cancer Therapy - Breast

Quality of life metrics based on risk category

257379 - Evaluating the incidence of upgrade to malignancy following surgical excision of high-risk breast lesions identified by core needle biopsy

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Background/Objective: Excision of high risk breast lesions (HRL) (i.e. papilloma, atypical ductal hyperplasia, atypical lobular hyperplasia, lobular carcinoma in situ, and ductal carcinoma in situ) identified by image guided core needle biopsy continues to be standard of care. Previous studies have shown a HRL will be upgraded to carcinoma in situ (CIS) or invasive carcinoma (IC) in up to 20% of cases at re-excision. It is thought that with better biopsy methods such as vacuum-assisted or ultrasound guided core biopsies, the incidence of discordance will decrease. This study aimed to determine the rate of upgrade of high risk lesions identified on stereotactic or ultrasound-guided biopsy upon excisional biopsy.

Methods: A retrospective review of our medical chart database was performed to identify patients diagnosed with a high-risk lesion at core needle biopsy between 2014-2016. Histological features between core needle biopsy and surgical excision were recorded. The type of high risk lesions diagnosed at core needle biopsy and the rate of upgrade to malignancy following surgical excisions were studied.

Results: 857 patients who underwent core needle biopsy following detection of suspicious lesions on BI-RADS IV mammograms were identified. High risk lesions warranting subsequent surgical excision were found in 137 of 857 patients (16.0%). 39 (4.5%) patients underwent work-up at outside institutions and were not available for follow-up on this study, leaving 98 patients with a total of 103 biopsies available for evaluation. There were 73 (74.4%) patients with pathology reports that showed HRL concordance on surgical excision. The other 25 (25.5%) patients had discordance and upgraded to carcinoma in situ or invasive carcinoma on surgical excision. Overall, 103 high risk lesions were identified: 53 DCIS (51.5%), 21 ADH (20.4%), 3 ALH (2.9%), and 26 (25.2%) papillomas. 29 of the 103 HRL samples (28.1%) were upgraded to carcinoma in situ (CIS) or invasive carcinoma (IC). Specifically in regards to DCIS, 12 were upgraded to IDC (22.6%), 10 ADH were upgraded to CIS or IC (47.6%), and 7 papillomas were upgraded to CIS or IC (26.9%).

Conclusions: Core needle biopsy is a useful method for retrieval of suspicious breast lesions detected on BI-RADS IV mammography reports. However, the core needle biopsy method may not always identify malignancy within the small sample of tissue that is removed. Associated occult malignancy within the surrounding tissue may go undetected unless an excisional biopsy is completed. This study reveals an increased incidence (28.1%) of HRL upgrade on surgical excisional biopsy at our local academic medical center. Vacuum-assisted and large bore biopsy needles did not reduce the rate of upgrade upon surgical excision compared to historic rates. We recommend continued use of surgical excision following diagnosis of a high-risk breast lesions on core needle biopsy.

256491 - Atypical ductal hyperplasia on percutaneous biopsy: Do all need surgically excised?

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Background/Objective: NCCN guidelines currently recommend surgical excision after diagnosis of atypical ductal hyperplasia (ADH) on percutaneous biopsy. Rate of upgrade to ductal carcinoma in situ (DCIS) or invasive cancer ranges from 7-87% in the literature. Significant improvements have been made in imaging technology and biopsy techniques. We aimed to identify our institution's upgrade rate in order to identify radiographic and pathologic features associated with upgrade and stratify which patients could benefit from observation over surgical excision.

Methods: A retrospective review identified all women diagnosed with ADH on stereotactic biopsy performed at our institution from 2008-2015 who were treated with surgical excision. Patients with ipsilateral breast cancer or ADH associated with another lesion were excluded. Dedicated breast radiologists reviewed all breast imaging for size of the lesion and residual calcifications after biopsy. Breast pathologists reviewed the biopsy slides for number of ADH foci, individual cell necrosis, and micropapillary features. Chi-square and Fisher's exact tests were used to describe and test for associations between categorical demographic, clinical, radiologic, and pathologic characteristics of subjects. T tests and Wilcoxon tests were used to describe and test for associations between continuous characteristics.

Results: During the study period, 82 women underwent 84 stereotactic biopsies at our institution followed by surgical excision. Underlying malignancy was identified at the time of excision in 14 breasts

(9 DCIS and 5 invasive cancer) for an upgrade rate of 16.7%. Age at time of biopsy, breast density, or having a personal or family history of breast cancer was not associated with upgrade to malignancy. The biopsy needle gauge or number of cores removed was not associated with upgrade. Features associated with higher risk of upgrade included lesions larger than 2cm, < 50% of the lesion removed by biopsy, presence of 3 or more foci of ADH, and lesions with individual cell necrosis.

Conclusions: Advances in imaging and biopsy techniques have resulted in upgrade rates from ADH to malignancy lower than historically quoted. This provides an opportunity for more conservative management. Thorough radiologic and pathologic correlation can identify patients at low risk for upgrade who may be able to avoid surgical excision.

	Upgraded to DCIS/IBC (n=14)	No upgrade (n=70)	p-value
Lesion size (mean, SD)	2.4 cm (2.6)	1.5 cm (1.9)	0.0621
< 50% lesion removed	6 (44%)	12 (17%)	0.0544
≥ 3 foci ADH present	12 (86%)	43 (61%)	0.0591
Individual cell necrosis	5 (36%)	9 (13%)	0.0514
Micropapillary features	7 (50%)	18 (26%)	0.1068

252287 - Treatment of fibroadenoma with ultrasound guided focused ultrasound ablation (USgFUSA); Toxicity and early results from the first United States feasibility study, IDE-G130252

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Background/Objective: Current management of patients with fibroadenoma includes observation or surgical excision. The objectives of this study were to evaluate the safety and feasibility of Ultrasound guided High Intensity Focused Ultrasound (USgHIFU) delivered by the Echopulse device (Theraclion, Paris) for treatment of breast fibroadenomas. Patient safety, cosmetic outcome, tumor response and patient experience were assessed.

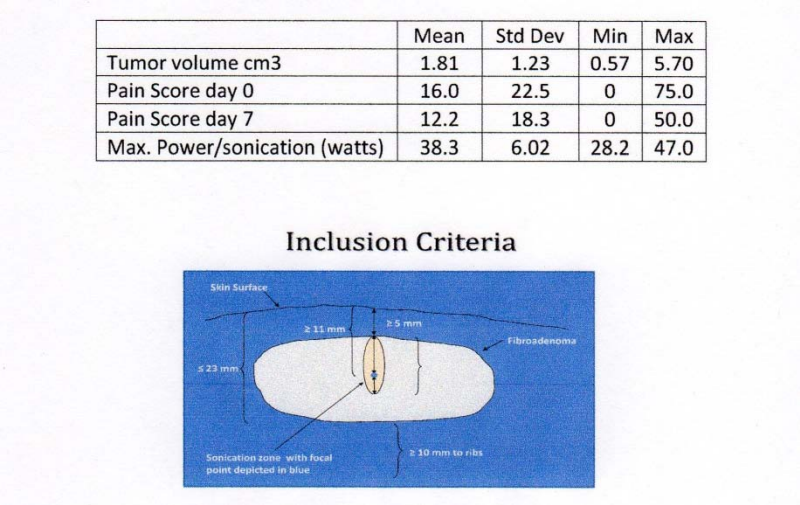
Methods: Twenty female patients with a palpable breast fibroadenoma 1cm or larger were enrolled in a single arm treatment study and underwent USgFUSA of their tumor utilizing the Echopulse device. Optimal energy per sonication was individually established for each patient by determining the minimal energy setting found to produce tissue boiling within the lesion as observed on real-time B-mode ultrasound. Subjects experience of the treatment and toxicity were ascertained via standardized instruments. Patient experience, toxicity, cosmesis, and change in tumor size on both physical examination and ultrasound measurement were obtained immediately after treatment as well as 3, 6 and 12 months post-treatment.

Results: Enrolment is complete with 20 of 20 (100%) of patients successfully completing therapy. Mean tumor volume was 1.8cc (SD = 1.23, Range 0.57 – 5.7). Mean patient age was 35.2. Forty percent of patients were Caucasian, 40% Latino, and 20% were Black. Fifty percent reported a painful mass prior to

treatment. Mean power/sonication = 38.3 watts. Mean number of sonication sites treated/patient = 34.3. All adverse events were grade 1 or 2. No skin burns, nor other major toxicities were observed at day 0, 7, or 3 months post-treatment. The most common adverse event observed was pain, reported by 15/20 (75%) of patients during treatment, and 14/20 (60%) at day 7. Mean pain score during treatment = 16 on a scale from 0 to 100 (100 = worst pain). Mean pain score at day 7 = 12.2. Patient satisfaction from those completing 3 months follow-up to-date was 4.4 on a scale of 1-5 (5 = most satisfied) and likelihood they would recommend it to a friend or family member was 4.7 (5 = strongly agree).

Conclusions: To date, in study IDE #G130252, Ultrasound guided Focused Ultrasound Ablation for treatment of fibroadenoma was well tolerated, and resulted in minimal toxicity. Early data on efficacy will be available at the time of presentation.

	Mean	Std Dev	Min	Max
Tumor volume cm3	1.81	1.23	0.57	5.70
Pain Score day 0	16.0	22.5	0	75.0
Pain Score day 7	12.2	18.3	0	50.0
Max. Power/sonication (watts)	38.3	6.02	28.2	47.0



Inclusion criteria and results

256535 - Impact of chemoprevention indication score (CIS) on uptake of preventive therapy

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Background/Objective: We developed the Chemoprevention Indication Score (CIS) to enhance the uptake of chemoprevention by eligible patients via evidence-based risks/ benefit calculation in an efficient manner. This study demonstrates the impact of the use of CIS score in a high-risk clinic on patient uptake of preventive therapy.

Methods: A retrospective analysis of a prospectively maintained database was performed. Data from patients from the Texas Tech University Health Sciences Center Breast Center of Excellence, Risk Assessment and Prevention Program (RAPP) from January 2010 to December 2014 was cross-tabulated using CIS scores and rates of uptake of chemoprevention.

Results: Between January 2010 to December 2014, 157 patients were enrolled in RAPP. Thirty-one patients were under the age of 35 which precluded the calculation of Gail score. The remaining 126 patients underwent Gail score and CIS calculation followed by counseling using visual CIS card regarding chemoprevention. 5-year Gail score distribution was as follows: 1.66-2%= 11 (13.1%); >2-3% = 32 (37.6%); >3% = 42 (49.3%). The CIS score and prevention uptake is depicted in the table. Overall, 51/126

(40.8%) started chemoprevention treatment [39 (76.47%) patients took Tamoxifen, and 12 (23.53%) took Raloxifene].

Conclusions: The Chemoprevention Indication Score (CIS) enhances the uptake of chemoprevention by patients. Results of our study show promise for use in counseling women at risk for breast cancer. It can be utilized as a quick and easy tool to aid health care providers in counseling women at high risk regarding chemoprevention.

CIS score:	Neither % (N)	Ral % (N)	Tam % (N)		Ral or Tam % (N)	
<4	100.0 (17)	0.0 (0)	0.0 (0)	p <0.00001	0.0 (0)	P <0.00001
4 – 5	68.9 (42)	19.7 (12)	11.5 (7)		31.2 (19)	
6+	31.9 (15)	0.0 (0)	68.1 (32)		68.1 (32)	
All	59.2 (74)	9.6 (12)	31.2 (39)		40.8 (51)	

CIS and prevention uptake

257079 - The influence of psychiatric health on breast abscesses in the non-lactating patient: A community hospital's experience

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Background/Objective: Puerperal mastitis and abscesses are well described in the literature; however, there is little data exploring the causes of nonpuerperal abscesses. Diabetes mellitus, smoking and obesity have been suggested as potential risk factors since they predispose patients to all soft tissue infections. This study examines the characteristics of patients who presented to our community hospital with breast abscesses and aims to identify possible risk factors in the development of nonpuerperal breast abscesses.

Methods: After institutional review board approval, we retrospectively reviewed our database of all patients who presented to our institution with a diagnosis of breast abscess from June 1, 2009 to May 30, 2016. Six hundred and forty-five patient encounters were initially identified. Encounters were excluded if the record was unable to be located within the electronic medical record (EMR), if it was an abscess recurrence, or if it was not a true diagnosis of breast abscess. The basic demographics, comorbidities, procedures performed, laboratory and microbiology data, as well as length of stay and recurrences for each patient were noted. Statistical analysis was performed using SPSS version 22.0. Pearson's correlations were used to examine associations between demographics and comorbidities of patients with breast abscesses.

Results: We identified 190 unique patients with a true diagnosis of a primary breast abscess (Mean age 36.0, range 11 – 75). Of these patients, the majority were non-lactating (93%), non-diabetic (83%), obese (60%), African American (90%) women (95%) who were smokers (57%) (Table 1). We had a large percentage of patients (29%) with a co-existing psychiatric diagnosis. Twenty-one patients (11%), 38 patients (20%) and 12 patients (6%) had a co-existing diagnosis of anxiety, depression and bipolar respectively. Patients on psychotropic medications were significantly more likely to have drainage performed in the Operating Room as opposed to in the Emergency Department (35% compared to 25%,

p < 0.01), as well as a significantly longer length of stay (p < 0.01) (Table 1). In addition, patients with a co-existing psychiatric diagnosis were significantly more likely to have a recurrence of their primary breast abscess in comparison to the general population (p = 0.017).

Conclusions: Our study suggests that psychiatric co-morbidities and/or psychotropic medications may be potential risk factors for the development of nonpuerperal abscesses. This has not previously been reported. Interestingly, the majority of patients in our study with nonpuerperal breast abscesses were non-diabetics, which contradicts current literature. Limitations of our study include incomplete psychiatric histories, lack of patient follow-up, and a small patient population size. Further studies must be done to explore this relationship amongst psychiatric diagnoses, psychiatric pharmaceuticals and the development and/or recurrence of non-puerperal abscesses. A future aim will be to explore the use of a patient navigator in the management of our patients, particularly to assist in the establishment of care for treatment of our patients' psychiatric co-morbidities.

Table 1: Results

	N (%)	Mean (Range)
Gender:		
Female	181 (95)	
Male	9 (5)	
Age:		36.0 (11-75)
BMI:		
Underweight (<18.5)	2 (1)	
Normal (18.5–24.9)	37 (19)	
Overweight (25–29.9)	36 (19)	
Obese (30 or greater)	114 (60)	
Unknown	1 (1)	
Race:		
African American	172 (90)	
Hispanic	3 (2)	
Caucasian	14 (7)	
Other	1 (1)	
Lactating:		
Yes	4 (2)	
No	185 (97)	
Pregnant	1 (1)	
Smoker:	109 (57)	
Psychiatric diagnosis:	55 (29)	
Anxiety	21 (11)	
Depression	38 (20)	
Bipolar	12 (6)	
Prescribed psychiatric medication(s):	30 (16)	
Psychiatric diagnosis, what was done:		
I&D in ED	14 (25)	
I&D in OR	19 (35)**	
Antibiotics only	11 (20)	
None	4 (7)	
Other	7 (13)	
Length of hospital stay:		
Prescribed psychiatric medication:		0.51 (0-8)**
General population:		0.34 (0-8)
Recurrence of same breast abscess:		
Psychiatric diagnosis:	11 (20)*	
General population:	27 (14)	

*p < 0.05; **p< 0.01

Results

252149 - Reduction mammaplasty improves quality-of-life in adolescents with macromastia: A longitudinal cohort study

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Background/Objective: Macromastia, the benign overgrowth of one or both breasts, is a common condition with a well-documented negative impact on mental and physical health, self-esteem, and social functioning. Reduction mammaplasty during adolescence is relatively controversial; the psychological effects of treatment in this age group are largely unknown. This study seeks to measure changes in health-related quality-of-life (HRQOL) and breast-related symptoms following reduction mammaplasty in adolescents, and explore the effects of age and BMI category at time of surgery on postoperative quality-of-life outcomes.

Methods: In this longitudinal cohort study, our group administered the Short-Form 36v2 (SF-36), Rosenberg Self-Esteem Scale (RSES), Breast-Related Symptoms Questionnaire (BRSQ), and Eating-Attitudes Test-26 (EAT-26) to 102 adolescents with macromastia and 84 unaffected female controls, aged 12 to 21 years. Patients with macromastia completed surveys preoperatively and postoperatively (at 6 months, 1 year, 3 years, and 5 years). Control subjects completed baseline and follow-up surveys at the same intervals. Higher scores in the SF-36, RSES, and BRSQ are associated with a better HRQOL, global self-esteem, and fewer/less severe breast-related symptoms, respectively. Higher scores in the EAT-26 are indicative of disordered eating thoughts and behaviors.

Results: Mean age at the time of reduction mammaplasty was 17.9 ± 1.7 years. Patients with macromastia demonstrated significant score improvements postoperatively from baseline on the RSES, BRSQ, and in 7 out of 8 SF-36 domains (Table 1; $p < 0.001$). Postoperative subjects scored significantly higher than controls at follow-up on the RSES and in 4 SF-36 domains (physical functioning, bodily pain, social functioning, and mental health), when controlling for differences in baseline BMI category ($p < 0.05$, all). Follow-up scores on the EAT-26, BRSQ, and in 4 SF-36 domains (role-physical, general health, vitality, and role-emotional) did not differ between the 2 groups ($p \geq 0.05$, all). Following reduction mammaplasty, the proportion of patients experiencing pain, bra strap grooving, inframammary intertrigo, and difficulty participating in sports and finding properly fitting bras/clothing was significantly lower than at baseline ($p < 0.001$, all), with postoperative rates similar to those seen in control subjects ($p \geq 0.05$, all). Both younger (< 18 years, n=54) and older patients (≥18 years, n=48) had significant postoperative improvements in RSES and BRSQ scores. On the SF-36, only older patients experienced a benefit in the mental health subscale ($p < 0.001$). When the macromastia group was stratified by BMI category, both healthy-weighted (n=38) and overweight/obese patients (n=64) had significant postoperative improvements on the RSES and BRSQ, and 6 SF-36 domains. Unlike their healthy-weighted counterparts, overweight/obese patients did not have improvements in SF-36 general health ($p=0.65$).

Conclusions: Reduction mammaplasty was significantly associated with improvements in HRQOL and breast-related symptoms of adolescent patients. Postoperatively, patients report levels of well-being similar to, if not higher than, unaffected age-matched females. These results largely do not vary by BMI

category or age. Patients and providers should be aware of the potential benefit of reduction mammaplasty for adolescents with symptomatic macromastia.

	Macromastia Postop-Preop Difference[A] Mean (95% CI)	*p*-value**	Control F/U-Baseline Difference[B] Mean (95% CI)	*p*-value**
SF-36* Domains				
Physical Functioning	22.3 (16.4 to 28.2)	**<0.001**	-2.7 (-6.8 to 1.5)	0.21
Role-Physical	27.0 (21.2 to 32.7)	**<0.001**	4.3 (0.7 to 8.0)	**0.02**
Bodily Pain	32.7 (27.4 to 38.1)	**<0.001**	1.3 (-2.6 to 5.3)	0.51
General Health	1.7 (-2.1 to 5.5)	0.37	-3.7 (-7.7 to 0.3)	0.07
Vitality	11.9 (7.8 to 16.0)	**<0.001**	-3.2 (-6.7 to 0.4)	0.08
Social Functioning	22.6 (10.2 to 23.5)	**<0.001**	-0.5 (-4.8 to 3.9)	0.84
Role-Emotional	16.8 (10.2 to 23.5)	**<0.001**	-0.2 (-5.1 to 4.7)	0.93
Mental Health	8.5 (4.1 to 12.8)	**<0.001**	-3.3 (-7.0 to 0.3)	0.07
RSES*	3.7 (2.4 to 4.9)	**<0.001**	-1.3 (0.5 to -2.3)	**0.01**
BRSQ*	58.2 (54.1 to 62.2)	**<0.001**	-4.1(-7.7 to -0.5)	**0.03**
EAT-26*	-1.3 (-3.1 to 0.5)	0.15	1.0 (-0.8 to 2.7)	0.28

A: Mean within Macromastia subjects difference between preoperative to postoperative survey scores; positive change in mean indicates preoperative to postoperative increase in score.

B: Mean within Control subjects difference between baseline to follow-up survey scores; positive change in mean indicates baseline to follow-up increase in score.

*: **SF-36**: Short-Form 36v2, **RSES**: Rosenberg Self-Esteem Scale, **BRSQ**: Breast-Related Symptoms Questionnaire, **EAT-26**: Eating-Attitudes Test-26.

**: *p*-value for dependent *t* test for paired samples.

Comparisons of baseline and follow-up survey scores for patients with macromastia who underwent reduction mammoplasty and healthy adolescent females followed over time

255583 - The treatment conundrum for idiopathic granulomatous mastitis

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Background/Objective: Idiopathic Granulomatous Mastitis (IGM) is an uncommon benign inflammatory breast disease, for which the etiology and treatment are unclear. It is characterized by noncaseating granulomata with microabscesses confined to breast lobules. The prevalence of IGM is unknown, and what few parameters exist for treatment have been derived from anecdotal evidence and small retrospective studies. Thus, there is need for further study of the risk factors, pathogenesis, and treatment for IGM. While no standardized treatment protocol exists at our institution for IGM, the treatment algorithm has consisted of a stepwise approach starting with conservative management, reserving methotrexate and surgical intervention for persistent or severe disease.

Methods: A pathology database was retrospectively queried for diagnoses of granulomatous disease on breast biopsy or fine needle aspiration from January 2008 to October 2013. Patients with cultures positive for fungal infections and tuberculosis were excluded. Medical charts were reviewed for

demographic information, clinical presentation, treatments, and clinical outcomes (including resolution and recurrence). Univariable and multivariable models were employed, and outcomes were analyzed by the Kaplan-Meier method.

Results: Of the 209 patients who met criteria for IGM, 192 (92%) were Hispanic. The mean age was 36 years, and nearly all were overweight or obese with a mean BMI of 30 (SD+/- 6.5). One hundred eighty-four (88%) patients had at least one prior pregnancy, and 173 (83%) had >1 prior live birth. There were 132 (63%) patients who had complete resolution of disease, with median time to resolution of 22 weeks. For the 36 (17%) patients who received expectant management alone, median time to complete resolution was 17 weeks. Prolonged times to complete resolution were observed with the use of glucocorticoids (HR 0.61, p = < 0.001), antibiotics (HR 0.65, p = 0.002), and/or methotrexate (HR 0.50, p = 0.004). Of note, 70 (33%) patients were lost to follow up. For those who achieved complete resolution of disease, the overall risk of recurrence was 12.4% and did not appear to be related to the method of medical management. Incision and drainage and/or surgical intervention were the only factors associated with an increased rate of recurrence (HR 2.24, p = 0.02).

Conclusions: For patients with milder forms of disease, expectant management alone resulted in complete resolution of disease in 4-5 months. For patients with more severe forms of disease who received medical management, there were increases in time to resolution. It was not clear that any form of management resulted in improvements in the rates of resolution of disease. Irrespective of treatment strategy, the majority of patients in our study achieved complete resolution, and recurrence of symptoms was infrequent.

257053 - 12,000 breast biopsy clips and counting: Current and future implications of breast biopsy marker placement accuracy

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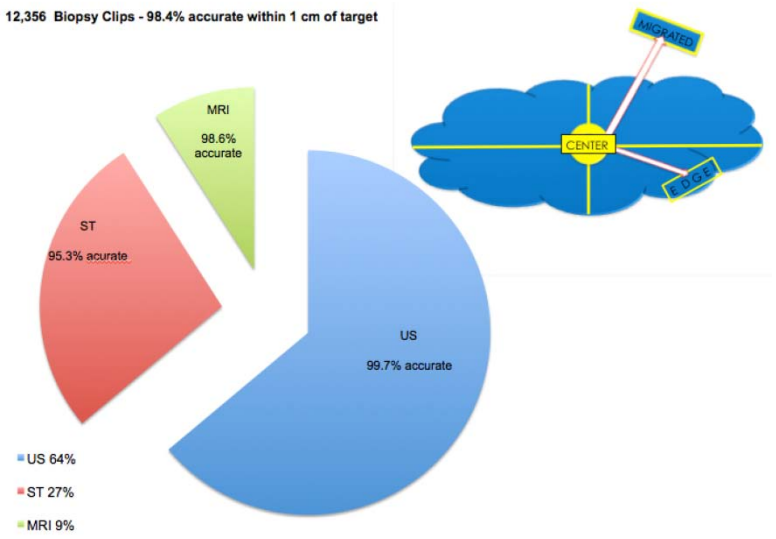
Background/Objective: Breast biopsy clips help verify correct site surgical excision on specimen x-ray. Most radiologists describe accurate clip placement as being within 1 cm of the target. However, it is unclear whether this refers to 1 cm distance is measured from the center of the target lesion or 1 cm from the edge of the target. The 2014 consensus panel led by the Society of Surgical Oncology redefined clear surgical margins for a subset of invasive cancer specimens as “no ink on tumor”. This updated definition may decrease re-excision rates, improve cosmetic outcomes, and decrease treatment costs. A refined description of clip placement accuracy from the center of the target lesion may be more consistent with the updated surgical margin definition. Since non-wire localization devices (Seeds, SCOUT, MAGSEED, RFID), are deposited similar to biopsy clips, center placement could help achieve clear surgical margins and decrease re-excision rates.

Methods: For each breast biopsy clip placement procedure 2011, 2012, 2013, 2015, and Q1-3 2016, the radiologist, imaging modality, clip type, and placement accuracy were recorded. Accurate clip placement was defined as the clip localized 0 - 10 mm from the target on post biopsy mammography. For each migrated clip, the radiologist assessed whether an additional clip placement was needed (e.g. lack of residual target or if clip placement would impact decisions based on neoadjuvant treatment plans).

Review of all images of migrated clips was used to provide performance feedback to radiologists and to update the clip/marker inventory.

Results: 12,356 clip placements (64% US, 27% ST, 9% MRI) showed clip migration of 1.6% overall. US guidance was the most accurate modality 99.7%, followed by MRI 98.6%, and ST 95.3%.

Conclusions: Clip marker placement, currently described as placement within 1 cm of the target lesion, is 95-100% accurate in most patients. A refined Radiology description of breast biopsy clip placement where distance is measured from the center of the target may be more consistent with the updated surgical margin definition and further: 1) Standardize published results 2) Establish goals for preoperative non-wire localization device placement 3) Establish feasibility for future image-guided placement of one-step procedures with one device that is placed at biopsy and serves as both clip marker - localization device and potential therapy delivery devices.



Accuracy of clip placement using ultrasound, stereotactic, MRI guidance and varied placement at the center, edge, and outside the target may all be described as accurate placement. A refined description of clip placement accuracy, that measures distance from the center of the target lesion, may be more consistent with the updated surgical margin definition.

257094 - Confidence in uncertainty: A survey of breast health recommendations for high-risk benign breast disease

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Background/Objective: Nearly one-third of all breast biopsies demonstrate a high-risk benign breast lesion; however, the management of these lesions has changed dramatically over the past few years, ranging from routine surgical incision to imaging surveillance. The aim of this study is to determine current practice patterns and comfort levels of breast health professionals managing patients with high-risk benign breast lesions.

Methods: A web-based survey link was sent to members of the Canadian Society of Surgical Oncology, Canadian Association of General Surgery and Canadian Association of Radiologists. The survey presented 5 detailed case-based scenarios, each describing a patient with a high-risk benign breast lesion including: classical lobular carcinoma in situ (cLCIS), atypical ductal hyperplasia (ADH), papilloma without atypia, radial scar and flat epithelial atypia (FEA). Participants were asked their recommended management strategy for each case. Respondents were also asked their estimates of future breast cancer risk and the role of chemoprevention for both cLCIS and ADH. Responses were collected between August 2nd, 2016 and September 10th 2016. Participants who did not complete the 5 case-based questions were excluded from analysis.

Results: Forty-one respondents answered the demographic and case-based survey questions. Nineteen (46%) were surgeons and 22 (52%) were radiologists. Most participants had been in practice for more than 15 years, worked in an academic setting and dedicated 15-50% of their practice to breast patients. The median overall comfort level in managing high-risk benign breast disease was 4.0 (out of a maximum of 5), with surgeons being more comfortable than radiologists (4.0 vs. 3.5, p=0.003). When asked about the role of surgery following a percutaneous biopsy revealing cLCIS, 44% of respondents felt a lumpectomy was indicated while 51% felt that follow-up was appropriate. When presented with a case of a papilloma on percutaneous biopsy, 27% of respondents recommended a lumpectomy, while 68% recommended imaging follow-up. For a percutaneous biopsy indicating FEA, 49% of overall respondents recommended follow-up and 46% recommended surgery; surgeons were slightly more likely to recommend surgery than radiologists (63% vs. 32%, p=0.08). Even for ADH there was no consistent recommendation, with 56% of respondents recommending surgery and 42% observation. The greatest consensus came from a case demonstrating a radial scar, where 65% of respondents who felt the biopsy was concordant, recommended surgery. When asked what the lifetime breast cancer risk associated with cLCIS and ADH was, both surgeons and radiologists vastly under-estimated, with the majority indicating a lifetime risk of 15-20% for cLCIS and 10-15% with ADH. Most breast health professionals did not refer patients with either cLCIS or ADH for a discussion of chemoprevention.

Conclusions: This survey demonstrates that even though breast health professionals feel quite confident in their knowledge of high-risk benign breast disease, there is no consensus regarding the treatment. We also demonstrated that most breast health professionals vastly underestimate the lifetime risk associated with both cLCIS and ADH and neglect to refer for discussion of chemoprevention. The results highlight the current gaps in knowledge and demonstrate that evidenced-based guidelines are urgently needed to ensure more uniform practice and to reduce confusion for our patients.

257072 - Intraductal papilloma on core biopsy: To excise or not excise?

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Background/Objective: Intraductal papillomas (IDP) are tumors that form in the lactiferous ducts of the breast. IDPs with atypia, large size, palpable, or are symptomatic are typically excised due to a risk of malignancy. However, the presence of a benign IDP without atypia does not confer increased risk of breast cancer. The aim of our study was to evaluate whether excision of IDP might be overtreatment based on quantifying the rates of upgrade in a consecutive patient population where all IDPs were routinely excised.

Methods: We retrospectively reviewed the records of patients treated for IDP at our institution from 2009-2016. We identified 157 core needle biopsy (CNB) proven IDPs that underwent surgical excision. We reviewed pathology reports to determine the rates of atypia, invasive or in situ malignancy. Univariate analysis was performed using the Fisher's Exact Probability Test.

Results: The median age of the patients was 56 years with a median length of follow up of 15.5 months. All patients had radiographic abnormalities and the median size of IDPs was 1.3cm. Fifty-five patients (35%) had palpable findings compared to n=85 (54%) with mammographically detected lesions, which was the most common method of detection. Thirty-seven patients (24%) presented with symptoms of nipple discharge with n=16 (10%) having symptoms of bloody nipple discharge. All 157 patients underwent surgical excision after CNB. Fourteen patients (9%) had atypia (n=11 had atypical ductal hyperplasia and n=3 were not further classified in the pathology reports). Malignancy was found in n=10 patients (6%), in which n=7 patients had in situ carcinoma (70%) compared to n=3 who had invasive malignancy (30%). Of the invasive carcinomas, 100% were invasive ductal or invasive lobular carcinoma. None of the invasive malignancies were invasive papillary carcinoma. No association with upgrade rate was found when evaluating subsets of patients based on nipple discharge, imaging features, lesion location (distance from the nipple), family history or use of oral contraceptives. The median size of IDPs showing invasive malignant features was 1.35cm, in situ malignant features was 1.2cm and atypical features was 1.3cm. Therefore, size was not a significant predictor in upgrade rate of IDPs.

Conclusions: IDPs found on CNB have a low chance of harboring an occult malignancy. However, the upgrade rate in our institutional consecutive series of surgically excised CNB-proven IDPs, 9% had atypia and 6% had upgrade to malignancy, with 70% in situ and 30% invasive malignancy. Surgical excision should be considered for IDP found by CNB given the relatively high rate of upgrade and the lack of clinical features predicting for upgrade.

256575 - Upstaging of papillary lesions to carcinoma in African American women

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Background/Objective: Management of papillary lesions has been controversial with studies showing different rates of upstaging to malignancy. This has led to variable management consisting of either resection or serial imaging. Differences across studies suggests that there may be inherent differences between papillary lesions among different populations. Thus far, there has been a paucity of investigation into papillary lesions with regard to race. The aim of this study was to look at the incidence of papillary lesions across a predominantly African American population and to identify if there are any identifiable risk factors associated with upstaging of papillary lesions.

Methods: This was a retrospective chart review of patients treated at the Hospital and Medical Center. Eligible patients were selected by CNB pathology records with the descriptor "papillary" or "papilloma." Biopsies with synchronous DCIS or with "papillary type" DCIS were excluded. The lesions were categorized into groups of: papillary lesion or papilloma; papillary hyperplasia and papillary lesion with atypia. The final excisional pathology diagnosis as well as radiographic and patient factors were recorded and then analyzed to compare each factor with the rate of upstaging.

Results: 123 biopsies were identified that met inclusion and exclusion criteria which accounted for 6% of all breast core needle biopsies performed. 63% of the patients were African American. Atypical papillary lesions were most likely to be upstaged to malignancy at a rate of 27.7%. The odds ratio was 3.3, P=.05. Papillary lesions and papillary lesions with hyperplasia were also upstaged to cancer at a lower rate of 8.3% and 12.5% respectively. A multivariate analysis of all papillary lesions demonstrated a higher likelihood of upstaging based on BIRADS classification (P=.04). There was no association between race, age, size of lesion and radiographic features. An analysis of only the atypical lesions also demonstrated an association with higher BIRADS classification (P=.04). In addition, cases with distortion were significantly more likely to be upstaged to malignancy (OR = 2.67, P = 0.04, 95% CI 1.03-6.89). No other patient or radiographic characteristics were associated with upstaging.

Conclusions: There was a 6% incidence of papillary lesions found on CNB in this predominantly African American population compared to the 2-4% incidence reported by other studies. This difference may reflect an inherent predisposition for the development of papillary lesions in African Americans. However, upon further analysis there did not appear to be a higher risk of upstaging to malignancy among this group of women. It is important to note that in this study we investigated the rate of upstaging to malignancy. We did not investigate the clinical course of the woman diagnosed with cancer. African American woman when compared to Caucasian women have been found to have more advanced disease at diagnosis of breast cancer, as well as a higher likelihood of ER negative status and higher risk of recurrence. This may also be the case with papillary cancer in this group of women, however this is yet to be studied in depth. The rate of upstaging atypical lesions to malignancy was 27.7% which was within the range of other studies. In our analysis, pure papillary lesions and those with hyperplasia were also found to have a rate of upstaging along an increasing gradient. Similar to other studies, there were no identifiable patient or radiographic risk factors that increased the likelihood of upstaging, with the exception of BIRADS classification. Our study reflects what has been observed before; that papillary lesions are extremely variable without any readily identifiable risk factors to suggest upstaging. Currently there is no indication that African American race is associated with a higher risk of upstaging.

255593 - Efficacy and safety of ductal lavage for non-lactational idiopathic granulomatous mastitis: A retrospective case series study

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Background/Objective: For non-lactational patients with pathologically diagnosis of idiopathic granulomatous mastitis (IGM), the current treatments include antibiotics and/or corticosteroids, surgery, or observation alone. In this retrospective case series study, we reported the efficacy and safety outcomes of the ductal lavage as the first-line treatment for IGM female Chinese patients.

Methods: We retrospectively reviewed our database and identified 20 IGM patients that had received ductal lavage as the first-line treatment. The inclusion and exclusion criteria include: 1) 18-65 years old female patients; 2) Mastitis occurred at least 1 year after the cessation of the very recent lactation.3) Received ductal lavage as first-line treatment. 4) Pathologically diagnosed as IGM; 5) Pregnant women, or women with breast carcinoma were excluded; 6) Patients with systemic lupus erythematosus(SLE), rheumatic disorders, or tuberculosis were excluded. For the ductal lavage, we inserted the infusion cannula (21-23G) into 4-5 lactiferous ducts from the nipple under local anesthesia, and pump 10ml

irrigation solution (2% Lidocaine 5ml, Triamcinolone acetonide 40mg, 0.9% saline 10ml and ceftriaxone 1.0g) into the ducts. The patient returns to the clinic the next day, with the irrigation solution staying in the lactiferous ducts overnight, and receives breast massage. Repeat the infusion and massage procedure every other day, for 2 weeks. We reviewed the charts and information of these patients, and obtained the follow-up information by telephone and face-to-face visit at clinic. Complete response (CR) is defined as the disappearance of palpable mass and all related symptoms (redness, tenderness, etc.). Partial response (PR) was defined as significant relief of symptoms, but does not reach the CR criteria. Stable and progressive diseases (SD/PD) were defined as unchanged and progressive symptoms, respectively, indicating the ineffectiveness of the treatment.

Results: A total of 20 patients were identified as eligible. The median age was 34.5 (15-53) years old. The median (range) size of the mass by palpation was 6.25(1.5-12) cm. There were 12 patients had a history of breast feeding and one of them had lactational mastitis during the breast-feeding period. With a median follow-up of 5.7 months. There were 9 patients achieved CR. The median (range) months to CR was 1.8 (0.7-6.3) months. These patients did not receive any further treatments. There were 10 patients achieve PR. Among them, 2 received surgical treatment, and one received steroid treatments. The others did not receive any further treatment. There was one patient who had SD/PD, and received surgical treatment. The procedure of the ductal lavage is safe and painless, without any adverse events.

Conclusions: This retrospective study suggested the efficacy and safety of ductal lavage used as the first-line therapy for non-lactational IGM patients. A prospective, single arm study with more data collected was registered (NCT02794688) and initiated, to confirm the result of this study.

246845 - Upgrade rates to ductal carcinoma in situ (DCIS) or cancer when atypical ductal hyperplasia is found on core biopsy: Does size matter?

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Background/Objective: Atypical ductal hyperplasia (ADH) on core needle biopsy of the breast is an indication for excision to rule out ductal carcinoma in situ (DCIS) or cancer in the vicinity. The upgrade rate in the literature ranges from 15% - 30% or higher. Excisional biopsy is unpleasant for the patient and costly ($8,500 or more) to the system. There is some evidence that upgrade rates are lower with vacuum assisted large bore core needle biopsies than with small bore core needle biopsies. Our hypothesis was that a combination of core biopsy associated variables, such as needle size and target characteristics, might be used to define a subset of ADH on core patients for whom excisional biopsy might safely be omitted.

Methods: This is a single institution retrospective study of189 patients from 2011 to 2013 with atypical ductal hyperplasia on core needle biopsy who then underwent a surgical resection. Patients with a diagnosis of ductal carcinoma in situ or invasive carcinoma on core biopsy were excluded. The primary objective was to identify the upgrade rates from ADH found on needle core biopsy after surgical excision; the secondary objectives were to identify aspects associated with upgrade status including size of biopsy probe, imaging target and patient age.

Results: A comparison analysis between the upgraded group and the non-upgrade group showed a lower upgrade rate associated with a larger core (9g, vacuum assisted) when compared with smaller core needles (13g) (10% vs 20%, p=0.0521). The overall upgrade rate was 15%.

Conclusions: Because of the historically high upgrade rates after findings of atypical ductal hyperplasia on core needle biopsy, surgical excision has been the standard of care. This study aimed to delineate factors associated with a lower rate in order to potentially identify a group for whom excision might safely be omitted. This study showed that a large bore needle (9g, vacuum assisted) was associated with a smaller percentage upgrade (n=9, 10% vs. n=20, 20%; p=0.0521) when compared to a smaller bore needle (13g, both automated gun and vacuum assisted). In contrast to previous studies which found that 9g and 11g core biopsy needles have a similar upgrade rate, this study compared 9g needles to 13g needles and found a lower upgrade rate with the larger bore needle. However, even the 9g vacuum assisted device had a 10% upgrade rate to DCIS or cancer when excisional biopsy was subsequently performed. Our data do not support omission of excisional biopsy after ADH is found on core, regardless of core needle size or target lesion characteristics.

256305 - A single institutional review of papilloma found on core biopsy from 2008-2015

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Background/Objective: The management of papilloma found on percutaneous core biopsy traditionally requires an open surgical biopsy to rule out additional disease such as DCIS or invasive cancer, i.e., an upgrade. Upgrade rates range between 2-44% in the published literature. While numerous predictors of upgrade have been examined, identifying patients for whom the core biopsy is sufficient (and therefore not requiring a surgical biopsy) remains controversial. We conducted a review of our own patients with a benign papilloma diagnosed by core biopsy examining numerous factors which may be used to delineate those requiring further surgical biopsy.

Methods: A retrospective chart review was completed for patients found to have a benign papilloma on initial core biopsy over a 7-year period from 2008 to 2015 at a single institution.

Results: Out of 129 patients with papilloma on initial core biopsy, 127 underwent surgical excision. In the 'upgrade' group, 8 patients had an invasive cancer or DCIS. The 'non-upgrade' group consisted of 119 patients of whom 15 patients with ADH and 1 patient with LCIS were included. Patients in the upgrade group were older, at an average age of 67 years old, compared to the non-upgrade group at an average age of 54 years old. Four out of the 8 patients (50%) in the upgrade group had atypia on initial core biopsy, compared to 23 out of 119 patients (19%) in the non-upgrade group. Patients in the upgrade group were more likely to have had their biopsy with a 14-gauge needle at 87%, compared to the non-upgrade group at 41%.

Conclusions: At our institution, patients found to have upgrade in disease (invasive cancer and DCIS) after excision of a benign papilloma diagnosed by percutaneous core biopsy were older in age, more likely to have had their biopsy with a 14-gauge needle, and with atypia on initial pathology compared to the non-upgrade group. Based on these findings and those of previously published studies, these factors may be used to better manage patients found to have a benign papilloma on core biopsy.

CPM

256635 - Selective use of sentinel lymph node surgery in patients undergoing prophylactic mastectomy using intraoperative pathology

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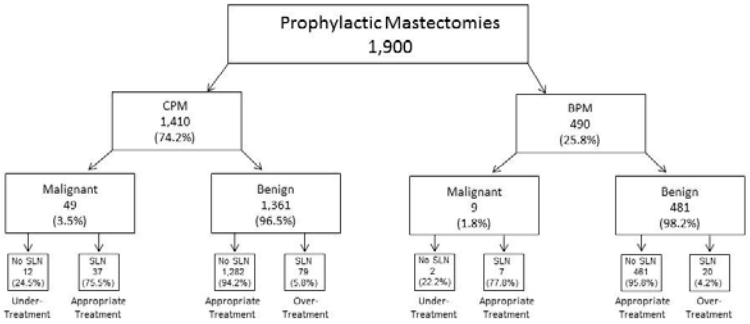
Background/Objective: Routine sentinel lymph node (SLN) surgery in patients undergoing prophylactic mastectomy (PM) is unnecessary as the vast majority of PMs do not have cancer. However, in the rare case where final pathology shows invasive cancer, PM patients who did not have SLN surgery may require a second operation for axillary staging. Our institution utilizes intraoperative pathology to guide surgical decision for resection of SLNs in PM. The aim of this study was to review the outcomes of this approach.

Methods: We identified all women ≥ 18 years who underwent bilateral PM (BPM) or contralateral PM (CPM) at our institution from 1/2008-7/2016. Each breast was counted as one case. Most patients underwent preoperative radiocolloid injection in PM. We evaluated the frequency of SLN resection and rate of occult breast cancer (DCIS or invasive disease) identified in the PM. We used the following definitions: over-treatment - SLN surgery in patients without cancer; under-treatment - no SLN surgery in patients with cancer; appropriate treatment - no SLN in patients without cancer or SLN surgery in patients with cancer.

Results: PM was performed on 1,900 breasts: 1,410 (74.2%) CPMs and 490 (25.8%) BPMs. Overall, SLN surgery guided by intraoperative pathology resulted in appropriate treatment of 1,787 (94.1%) cases: 1,319 (93.5%) CPMs and 468 (95.5%) BPMs. Cancer was identified in 58 (3.0%) cases (32 invasive disease and 26 DCIS) on final pathology. Concurrent SLN surgery was performed in 44 of these cases, due to intraoperative pathology in 43 (cancer identified in 39 and atypia in 4) and in one case a SLN was resected within the axillary tail of the breast. Four patients (9.1%) had a positive SLN and 2 had completion axillary dissection performed at the same operation. In 8 cases, cancer/atypia was identified on intraoperative pathology but no SLN was resected (4 patients were not preoperatively injected with radiocolloid and one pre-operatively declined SLN surgery). In 6 cases, cancer/atypia was not identified intraoperatively and found on final pathology (3 invasive and 3 DCIS); no patients returned to the operating room for axillary surgery. Invasive disease found on intraoperative pathology was larger than that seen only on final pathology (6.4 mm versus 3.8 mm, p=0.05). SLN surgery was appropriately performed in PM cases with intraoperative identification of cancer in 39 cases (2.0%). SLNs were removed due to atypia in the PM in 18 cases and in 81 breasts with benign pathology. SLN surgery directed by intraoperative pathologic analysis allowed appropriate treatment in 1,787/1,900 (94.1%) breasts, by avoiding SLN in 1,743 cases (91.7%), and performing SLN in cases with cancer in 44 (2.3%); compared to over-treatment in 97% if routine SLN surgery is performed in all PM patients and under-treatment in 3% if SLN is not performed in any PM patients.

Conclusions: Intraoperative pathology to direct SLN surgery in patients undergoing prophylactic mastectomy allowed the vast majority of patients to have appropriate SLN staging in one operation. This approach minimizes over-treatment from routine SLN at time of PM and minimizes under-treatment from avoiding SLN in PM for those cases where malignancy is identified.



	Over-treatment	Appropriate treatment	Under-treatment
Routine SLN in all PM	97.0%	3.0%	0%
No SLN at time of PM	0%	97.0%	3.0%
Intraoperative pathology directed SLN	5.2%	94.1%	0.7%

Sentinel lymph node surgery guided by intraoperative pathology in patients undergoing prophylactic mastectomy

257197 - Morbidity and quality of life outcomes of breast reconstruction for unilateral mastectomy vs. additional contralateral prophylactic mastectomy: A cohort study of 211 breast reconstruction patients

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Background/Objective: The rates of contralateral prophylactic mastectomy at the time of therapeutic mastectomy for unilateral breast cancer have more than tripled in the past decade, reaching 12.7% of cases. This is despite the lack of evidence for survival benefit associated with these procedures. Indeed, there is a lack of published data on postoperative outcomes for cases of contralateral prophylactic mastectomy followed by bilateral breast reconstruction (CBR) compared to unilateral mastectomy and breast reconstruction (UR). We performed the current study to investigate potential differences in morbidity and patient-reported quality of life (QoL) outcomes between these 2 groups.

Methods: Using our IRB-approved, prospectively collected breast reconstruction patient registry, we queried pre- and post-operative data from patients who underwent CBR or UR at our institution. Data included patient demographics, comorbidities, surgical history, cancer treatment, pre-operative and 12-month post-final reconstruction Breast-Q© scores, breast reconstruction treatment, and post-operative complications. We used simple and multiple linear regression to compare morbidity and QoL changes between the study groups (CBR vs. UR). Satisfaction with abdomen domain was not included in the analyses due to the heterogeneity of reconstruction types, however, type of reconstruction was adjusted for in the adjusted analysis.

Results: Between 2010 and 2015, 211 patients underwent CBR (n=86, 40.8%) or UR (n=125, 59.2%). While the unadjusted surgical morbidity was significantly higher for the BR group at 60 days post-tissue expander placement ($p < 0.001$), it was not significantly different between groups immediately before final reconstruction, at 60 days post-final reconstruction, or at 1 year post-final reconstruction. After adjusting for age, BMI, type of reconstruction, timing of reconstruction, chemotherapy, radiotherapy,

and previous breast surgery, CBR patients did not have a statistically significant difference in pre- to post-reconstruction changes of QoL when compared to UR in the domains of Satisfaction with Breast (p=0.62), Psychosocial Well-being (p=0.71), Sexual Well-being (p=0.85), and Chest Physical Well Being (p=0.09).

Conclusions: Our findings suggest that performing a contralateral prophylactic mastectomy at the time of therapeutic mastectomy and bilateral breast reconstruction for unilateral breast cancer is not associated with higher QoL compared to unilateral mastectomy and breast reconstruction. While there was no increased morbidity at 1 year post-final breast reconstruction, there was a higher rate of short-term (60-day) complications for staged breast reconstruction following tissue expander placement for the CBR group. These results would help in counseling patients interested in undergoing contralateral prophylactic mastectomy and bilateral breast reconstruction for unilateral breast cancer.

255995 - Contralateral prophylactic mastectomy in early breast cancer: A systematic qualitative review and theoretical framework

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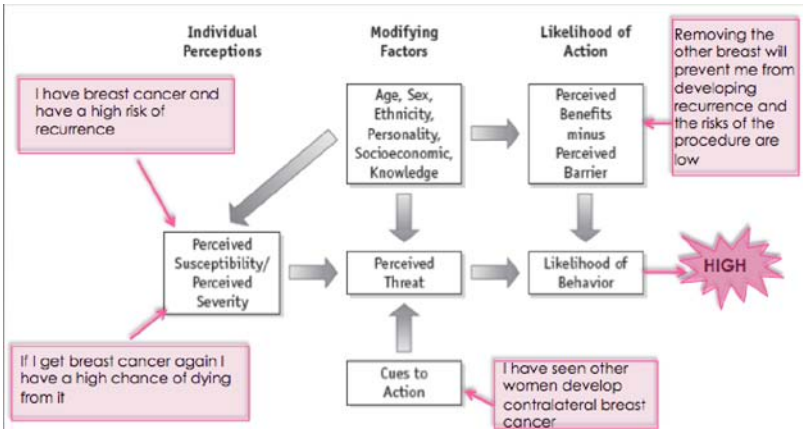
Background/Objective: Rates of contralateral prophylactic mastectomy (CPM) in North America have been increasing significantly. Numerous studies have demonstrated that CPM has no survival benefit in the average risk population and it is not recommended. In our previous work, we determined that women predominantly choose CPM because they overestimate their risk of contralateral breast cancer, breast cancer recurrence as well as their risk of dying from breast cancer. The purpose of this study was to complete a systematic review of the international qualitative literature to understand why women chose CPM and develop a theoretical framework to explain this phenomenon

Methods: We performed a systematic review of the literature using Medline, EMBASE, and Cinahl databases between 2004-2015. We included studies if patients were older than 18 years, had non-BRCA, unilateral breast cancer and underwent a contralateral prophylactic mastectomy and had qualitative data. Abstracts were reviewed for relevance and 2 independent reviewers reviewed all articles meeting criteria for inclusion. All articles were assessed for quality using the Standards for Reporting Qualitative Research: A Synthesis of Recommendations. Thematic analysis was performed.

Results: Our initial search yielded 432 abstracts, of which 23 were reviewed in full. Sixteen were met the inclusion and exclusion criteria. Study design was inhomogeneous and included purely qualitative date, survey data and both. Study quality was variable. We identified 2 major themes. The overarching theme was that women choose CPM because of fear of death and recurrence and to take control of their cancer. The second major theme was that although women were satisfied with their decision to pursue CPM, many had some dissatisfaction with the result, especially those who had breast reconstruction. The Health Belief Model (HBM) was then used as a framework to understand how these factors contribute to a woman's decision to pursue CPM. Many women have an elevated sense of threat (high perceived vulnerability and severity). There are few perceived barriers to this procedure and women see CPM as providing a significant benefit (risk reduction). Furthermore, many women cite experiences of friends or family which act as 'cues to action.' All of these factors strongly influence women to choose CPM.

Conclusions: A systematic review of the international literature confirmed that women choose CPM because of fear of recurrence and death from breast cancer even when that risk is low. Understanding this process in terms of the Health Belief Model may allow healthcare providers to provide meaningful guidance to women seeking CPM.



Health Beliefs Model Framework

257157 - Contralateral prophylactic mastectomies: Correlations between primary tumor and histological findings of contralateral breast

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Background/Objective: In Italy in 2015 48,000 new cases of breast carcinomas were diagnosed. Women who are diagnosed with breast cancer have a significant risk of developing contralateral breast cancer during the rest of their lives and this risk is closely associated to the family history, to the onset of breast cancer at a young age and is expressed at about 0.5 to 1% of metachronous tumors per year. The purpose of this work was to evaluate which and how many neoplastic lesions were seen in the contralateral breast that underwent prophylactic mastectomy and to understand what factors predict the appearance of such lesions.

Methods: 169 bilateral mastectomies were analyzed in patients with an average age of 47 years, carried out from July 2008 to April 2016, at the Breast Unit of the Sant'Andrea Hospital. We considered women of any age suffering from unilateral breast cancer without either clinical or radiological evidence of a malignant lesion in the contralateral breast and negative for mutations of the BRCA1-BRCA2 genes test. Of the 169 bilateral mastectomies 35 patients were excluded from the study because they underwent neoadjuvant chemotherapy, another 35 patients because they were suffering from a bilateral neoplasia and 7 cases because they had mutated BRCA1 or BRCA2 genes. Therefore, the remaining 92 patients were included in the study.
Results: Both the histological features of the primary tumor and any lesions found in the contralateral prophylactic breast were analyzed. Histological examination of the main breast showed 60 cases of invasive ductal carcinoma (IDC), 17 cases of invasive lobular carcinoma (ILC), 9 cases of in situ ductal

carcinoma (ISDC), 3 microinvasive ductal, 1 invasive tubular carcinoma, 1 in situ lobular and 1 widespread in situ. In the contralateral breast, the definitive histological examination revealed that 47 patients had an occult lesion in the prophylactic contralateral breast; in particular, 2 cases of LIN 1, 7 cases of LIN2, 6 cases of lobular carcinoma in situ, 26 between DIN1A/DIN1A-B/DIN1B, 4 cases of carcinoma in situ and 2 cases of invasive ductal carcinoma. In our experience, the data analysis showed that 47 patients had occult lesions in the prophylactic breast. The correlation obtained from the observation of the main tumor has shown that in a total of 60 invasive ductal carcinomas 32 have a contralateral occult lesions and in a total of 17 cases of invasive lobular carcinoma 9 have an occult lesion in the prophylactic breast. Of these lesions, the multicentric relationship is that 50% of invasive ductal and invasive lobular carcinoma of the main breast have a contralateral lesion.

Conclusions: In conclusion, we would like to remind, as demonstrated by our follow-up data and as the literature reiterates, that this surgery does not improve patient survival. Certainly, patients with unilateral breast cancer have many surgical therapies to be able to deal with not only having a bilateral mastectomy. The endpoint of this work is try to understand the risk factors of having a contralateral breast lesion to reduce the probability of a metachronous cancer.

254180 - Influence of socioeconomic factors on the rates of contralateral prophylactic mastectomy, a NCDB study

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Background/Objective: A patient's surgical choice may be influenced by more than the stage, grade or type of tumor. We evaluated the association between insurance status, race and distance to a treatment center on use of contralateral prophylactic mastectomy (CPM).

Methods: The National Cancer Data Base (NCDB) was used to identify women over 18 with a non-metastatic primary breast cancer (BC) of ductal, lobular or mixed histology and known surgery and insurance status diagnosed between 2004 and 2013 (Stage 0-III). Chi-squared tests were used to assess unadjusted differences between rates of CPM and socioeconomic factors including insurance status, race, ethnicity, and distance to treatment center. Multivariable logistic regressions were used to assess the influence of socioeconomic factors on CPM while controlling for confounding factors such as patient and tumor characteristics including non-surgical treatment, grade, ER/PR/HER2 status, stage, comorbidities, facility type, tumor size, year of diagnosis, education, income and age.

Results: We identified 864,105 patients of which 56,334 (6.5%) had a CPM. CPM rates for in situ disease were about half of that for invasive disease, 3.4% and 7.0% respectively. The mean age was 59 years, the majority of patients were white (84.1%) and 5.2% identified as Hispanic. The majority of patients traveled < 20 miles to a TC (79.5%) and most patients had private insurance or Medicare (58.3% and 33.4%, respectively). Size of tumor, age, race, ethnicity, insurance status and distance to hospital were all associated with the rates of CPM for invasive BC ($P < .05$). In general, younger, white, non-Hispanic patients with private insurance residing far from a treatment center (TC) were most likely to undergo a CPM. Hispanic women underwent fewer CPM than non-Hispanic (6.3% vs. 7%). For patients with invasive disease, the rates of CPM among white, black, and Hispanic patients increased for those who lived farther away from a TC. However, distance from TC impacted CPM rates for black and Hispanic patients more than white and non-Hispanic patients. The absolute rate increase for patients >100 miles

from a TC compared to those < 20 miles was observed to be greatest for Black and Hispanic patients (3.5% and 3.9%) compared to White and Non-Hispanic populations (2.5% and 2.6%). The highest observed rate was up to 10% for Hispanic patients >100 miles from a treating hospital. For all patients with invasive disease the rates of CPM were significantly different between insurance groups, with rates highest in the privately insured (8.8%) and lowest in the non-insured and Medicare (7.2% and 3.8% respectively, P < 0.001). All unadjusted associations with CPM were significant independent predictors on multivariable analysis. Compared to patients with private insurance, those with Medicaid (OR 0.655), Medicare (OR 0.447) and non-insured (OR 0.168) were significantly less likely to have a CPM (P < .001).

Conclusions: Utilizing the NCDB, we found that insurance status and distance to hospital were independently associated with CPM between 2004 and 2013. Additionally, increased distance to treating facility disproportionately affects and increased the rates of CPM for Black and Hispanic patients. As CPM rates continue to rise, it is increasingly important that we continue to try to identify reasons for this trend and look beyond tumor characteristics to find other potential influences on a women's choice.

	Prophylactic Mastectomy	No Prophylactic Mastectomy	Unadjusted Chi Square P-Value	Multivariable Logistic Regression Odds Ratio (95% CI)*
Insitu (n=118,952)				
Age				
18-35	118 (9.7%)	1102 (90.3%)	<0.001	***
36-50	1716 (4.8%)	33746 (95.2%)		(reference)
51-65	1605 (3.2%)	48352 (96.8%)		0.74 (.699-.800)
66-75	508 (2.4%)	20921 (97.6%)		0.48 (.417-.556)
76+	129 (1.2%)	10755 (98.8%)		0.166 (1.34-.206)
Race				
White	3619 (3.6%)	95,919 (96.4%)	<0.001	(reference)
Black	280 (2.1%)	12842 (97.9%)		0.52 (.448-.596)
Other	177 (2.8%)	6115 (97.2%)		0.71 (.603-.845
Ethnicity				
Non-Hispanic	3929 (3.5%)	109152 (96.5%)	<0.001	(reference)
Hispanic	147 (2.5%)	5724 (97.5%)		0.63 (.522-.754)
Distance to Hospital				
<20 miles	2989 (3.1%)	91918 (96.9%)	<0.001	(reference)
21-50 miles	666 (4.3%)	14820 (95.7%)		1.16 (1.052-1.271)
51-100 miles	214 (5.3%)	3848 (94.7%)		1.21 (1.035-1.416)
>100 miles	122 (6.2%)	1850 (93.8%)		1.38 (1.123-1.691)
Insurance Status				
Private Insurance	3075 (3.9%)	75092 (95.4%)	>0.001	(reference)
Medicaid	155 (3.1%)	4470 (96.9%)		0.80 (.734-1.054)***NS*
Medicare	793 (2.3%)	32989 (97.7%)		1.06 (.625-1.793) ***NS*
Not Insured	53 (2.6%)	2025 (97.4%		0.64 (.469-.875)
Invasive (n=745,153)				
Age				
18-35	3928 (19.8%)	15922 (80.2%)	<.001	***
36-50	20852 (11.5%)	160303 (88.5%)		(reference)
51-65	19381 (6.6%)	272796 (93.4%)		0.66 (.644-.675)
66-75	6215 (4.2%)	142762 (95.8%)		0.45 (.432-.470)
76+	1882 (1.8%)	101112 (98.2%)		0.17 (.157-.177)
Race				
White	45867 (7.3%)	581188 (92.7%)	<0.001	(reference)
Black	4109 (5.1%)	76189 (94.9%)		0.52 (..498-.539)
Other	2282 (6%)	35518 (94%)		0.68 (.646-.715)
Ethnicity				
Non-Hispanic	49807 (7.0%)	656685 (93%)	<0.001	(reference)
Hispanic	2451 (6.3%)	36210 (93.7%)		0.66 (.625-.694)
Distance to Hospital				
<20 miles	37802 (6.5%)	539459 (93.5%)	<0.001	(reference)
21-50 miles	8892 (8.4%)	97200 (91.6%)		1.13 (1.097-1.160)
51-100 miles	2860 (9.5%)	27322 (90.5%)		1.20 (1.150-1.262)
>100 miles	1543 (9.6%)	14517 (90.4%)		1.228 (1.155-1.306)
Insurance Status				
Private Insurance	37458 (8.8%)	388199 (91.2%)	<0.001	(reference)
Medicaid	3942 (8.1%)	44496 (91.9%)		0.78 (.746-.812)
Medicare	9687 (3.8%)	245141 (96.2%)		0.90 (.864-.928)
Not Insured	1170 (7.2%)	15059 (92.8%)		0.66 (.616-.713)

*Significance for Logistic Regression determined based on 95% Confidence Intervals (CI) controlling for Grade, Year of Diagnosis, ER/PR/HER2 status, facility type, clinical stage, age, radiation/chemo/hormonal treatment, Charlson-Deyo score, tumor size, race, ethnicity, insurance status and distance to hospital. ** NS=Non significant as 95% CI crossed 1. ***Numbers too small for Logistic Regression.

DCIS

256748 - Is it possible to predict upstaging in DCIS? Yes, with a simple score!

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Background/Objective: Approximately 30% of patients with an initial diagnosis of ductal carcinoma ductal in situ of the breast (CDIS) presents stromal invasion in the final surgical specimen, which requires axillary staging using sentinel lymph node biopsy (SNB). This study aimed to describe the prevalence of upstaging among women with an initial diagnosis of pure DCIS and also to identify predictive factors of invasion in order to better select patients that would have benefit of receiving SNB at the time of primary surgery.

Methods: This is a cross-sectional study including 169 consecutive patients with an initial diagnosis of unilateral CDIS established through needle core (14- or 16-gauge) or vacuum-assisted biopsy (9- or 10-gauge) from January 2006 to January 2016. All patients were submitted to surgical excision. Demographic characteristics, clinical, radiological, and pathological variables were analyzed. Chi-square test was used to verify the association between those variables and invasion. Poisson model with robust variance was used to estimate prevalence ratios (PR) (crude and adjusted) and corresponding 95% confidence intervals (95% CI). Final regression coefficients were used to build the risk score for upstaging, using an alpha error=5%.

Results: Fifty-three patients presented upstaging for invasive carcinoma (31.4% [95% CI 24.4-38.9]). In the univariate analysis, the following variables were significantly associated with IBC at final diagnosis: age < 46 years (crude PR=1.71, p=0.023) and the presence of a palpable mass (crude PR=2.08, p=0.001), type of biopsy (core biopsy, crude PR=2.57, p < 0.001), nuclear grade (grade 2, crude PR=2.19; grade 3, crude PR=4.79, p < 0.001), and comedonecrosis (crude PR=4.61, p < 0.001). The frequency of upstaging did not vary according to the size of the lesion (p=0.058) or menopausal status (p=0.176). In the multivariate analysis, only the type of biopsy (adjusted PR=2.21, 95% CI) 1.52-3.22 and the presence of comedonecrosis (adjusted PR=4.19, 95% CI 2.19-8.03) remained as independent predictors of invasion. Our score attributed specific points according to the type of biopsy and the presence of comedonecrosis, ranging from 0 to 2.5, showing a very good predictive ability (area under ROC curve=0.799, 95% CI 0.729-0.869) (Table 1).

Conclusions: We were able to identify that the type of biopsy and comedonecrosis are predictive factors of stromal invasion among women with DCIS. The proposed score has shown a good predictive ability and its utilization in the clinical practice can improve therapeutic planning.

Comedonecrosis	Type of biopsy	Score	Upstaging prevalence (%)
Absent	Vacuum-assisted	0	9.4
Absent	Core biopsy	1	16.7
Present	Vacuum-assisted	1.5	35.6
Present	Core biopsy	2.5	82.1

Score points and upstaging prevalence for each category of type of biopsy and comedonecrosis

220838 - Ductal carcinoma in situ – A long-term survival and risk analysis

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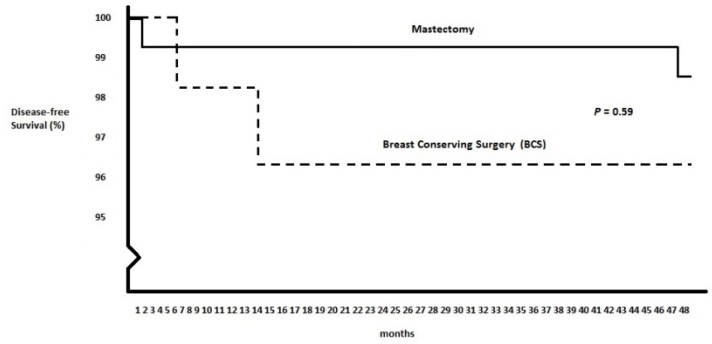
Background/Objective: Ductal Carcinoma in situ (DCIS) is more frequently encountered in the last decade due to better patient education and breast screening protocol. The mainstay of treatment of DCIS is surgery, be it mastectomy or lumpectomy. However, there is an on-going debate that if we are over-treating DCIS with extensive surgeries. Here we look into the clinical outcomes of DCIS in a tertiary referral unit using a prospective database.

Methods: Baseline demographic, clinical, radiological and pathological data from patients diagnosed with DCIS on resectional specimens were retrieved from a prospectively maintained database. Multivariate analysis was performed to evaluate the risk factors for involved surgical margin and patient survival. Survival analysis was performed with Kaplan-meier curve and log-rank tests. P-value of < 0.05 is considered statistically significant.

Results: From 1st May 1999 – 31st July 2015, 176 female patients were treated for DCIS. The median age of diagnosis was 52 years-old. 69 (39.2%) of them were detected by screening mammogram. 35（19.9%） were low grade DCIS, 71 (40.3%) were intermediate grade while 70 (39.8%) were high grade. 172 (97.7%) had pure DCIS and 4 patients (2.3%) had microinvasive component. More than half of our patients were hormonal receptor positive (N = 93) 120 (68.2%) patients received mastectomy and the remaining received breast conserving surgery (BCS); surgical margins were involved in 12 patients who received BCS and 1 patient who received skin-sparing-mastectomy; all patients were re-operated for a clear margin. Multivariate analysis found that intrinsic tumor factors like DCIS size and grade are not associated with risk of margin involvement. The only independent risk factor for surgical margin involvement is being treated with BCS (P = 0.004). Although BCS is associated with increased risk of margin involvement, with adequate follow-up treatment to ensure a clear final resection margin, the 5-year Disease-free-survival (DFS) was comparable to that of the mastectomy group. (Mastectomy 98.3%, BCS 96.4%, P-value = 0.59) After a median follow-up of 60 months, the overall survival (OS) was 97.7%. Breast cancer specific survival was 100% in pure DCIS group, and that in microinvasive DCIS was 75% (P = 0.023). Microinvasive DCIS is the only independent risk factor for DCIS mortality in our study (Hazard ratio 42.5, P = 0.002).

Conclusions: BCS is associated with increased risk of margin involvement but it does not affect the long-term survival in DCIS. Microinvasive DCIS is the only independent risk factor for DCIS mortality.



Survival curve analysis showing the disease-free survival of mastectomy vs. BCS

Survival curves of breast cancer specific survival in DCIS patients with or without microinvasion

Survival curves of DCIS

257404 - Management of ductal carcinoma in situ in women ≥ 65: A single institution experience

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Background/Objective: Ductal carcinoma in situ (DCIS) constitutes approximately 30% of all newly diagnosed breast cancers (BC) with majority (almost 60%) of cases diagnosed at age 65 or older. Despite this, in many studies, women in this age group are underrepresented and optimal management can be controversial. Compared to younger patients, the tumor biology of DCIS in older women is considered less aggressive with a higher rate of hormone-receptor positive tumors and lower grade disease. The current treatment guidelines for DCIS may therefore lead to overtreatment and under treatment in patients in this patient population. Given interest in appropriate treatment strategies for these women, we aimed to analyze the treatment trends at a single institution in patients with a diagnosis of DCIS that are > 65 years old.

Methods: After institutional board review approval, we performed a retrospective review of all patients with a diagnosis of DCIS treated at a single institution from 2010-2013. We excluded patients < 65 years

old, those who did not receive treatment, or those without treatment information available. Standard diagnostic metrics were computed.

Results: We identified 104 patients that met our inclusion criteria. The mean age of our study cohort was 71.8 with a range of 65-91 years. The majority of patients were white (62.5%) with estrogen-receptor positive (79.8%) and intermediate grade DCIS (40.4%). Less commonly were low grade (24.0%) and high grade (33.7%) DCIS. Mean size of DCIS was 1.0 (0.1-11) cm. The majority of patients were surgically treated with partial mastectomy (PM) (78.8 %) and the remaining 22 (21.2%) patients had mastectomy (unilateral mastectomy 14.4 % and bilateral mastectomy 6.7 %). Of those patients treated with PM, 21 (25.6%) patients received adjuvant radiation (XrT), 16 (19.5%) patients received adjuvant endocrine therapy (HT), 19 (23.1%) patients had combination HT and XrT, and 15 (18.3%) patients underwent PM alone. Nine (40.9%) patients underwent reconstruction following mastectomy (66.6% autologous and 33.3% implant based). Forty-two (40.4%) patients in this group received HT with a mean treatment time of 37 (2-60) months.

Conclusions: Our study shows the heterogeneity of the surgical and adjuvant treatment of DCIS treatment in patients > 65 years old at a large academic institution. As cancer centers integrate pathways development into their treatment plans, this heterogeneity needs to be acknowledged and discussed. Future research should evaluate the clinical effectiveness of treatment for DCIS in this patient population and taken into consideration functional status, life expectancy, patient preference and impact of therapy on function.

257413 - A validated model for prediction of upgrade to invasive breast cancer following core biopsy diagnosis of DCIS

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Background/Objective: The diagnosis of screen-detected DCIS is confirmed by core needle biopsy, but the surgical pathology may reveal an upgrade to invasive disease. The frequency of upgrade is variable, but the probability is related to features identifiable on imaging and core biopsy. Such upgrades have implications for clinical management and for the design of clinical trials. We have analysed our experience with DCIS upgrades to develop a predictive model of upgrade.

Methods: Women receiving surgical therapy at Northwestern Medicine for DCIS diagnosed on core biopsy were included. The training set (340 women) was accrued from 2007 to 2010, and the validation set (163 women) was accrued between 2010-2012. Women with microinvasive cancer in the core biopsy ≤ 1 mm in size were included. Their clinical, imaging and pathologic characteristics were retrospectively examined using pathology and imaging reports. Univariate logistic regression was used to identify factors for inclusion in a multivariate model that would forecast the finding of invasive carcinoma in the surgical specimen that was >1 mm in size. The starting variables included age, race, nuclear grade of DCIS, hormone receptor (HR) status, presence of comedo necrosis (CN) (present, absent, or focal), lobular extension (LE), size on mammography, and presence of mass on mammography or ultrasound. Receiver-operating characteristic (ROC) curve/area under the curve (AUC) analysis was used to estimate model accuracy and select a parsimonious model. The final model was then tested in the validation set using cross validated parameter estimates from the training dataset.

Results: The training set consisted of 340 patients, and the validation set included 163 patients. Key characteristics of the 2 groups are showed in the Table below. In the training set, univariate analysis identified predictors of invasion: age, presence of CN, LE, presence of mass on imaging, size on mammography, and nuclear grade of DCIS. Multivariate analysis reduced these to: age, presence of LE, mass on imaging, and grade III DCIS, with an AUC of 0.76. The overall upgrade rate in the test set was 13% and was 12% in the validation group. The ROC curves created by applying the cross validated parameter estimates from the training set on the both the training and validation sets yielded and estimated AUCs of 0.76 for the test set and 0.67 for the validation set.

Conclusions: We have identified a combination of factors that predict the presence of invasive carcinoma when a core biopsy shows DCIS, and have confirmed the predictive ability of our model in an independent validation set. Such models, particularly if refined for greater accuracy, will be useful in guiding decisions about clinical care and will be useful for design of clinical trials in the future.

Mean Age (years)	% hormone receptor positive	% grade III	% with comedo necrosis	% with lobular extension	Mean mammographic size (cm)	% with mass on mammogram or US
56	87%	47%	51%	31%	3.0	19%
57	84%	41%	49%	42%	2.4	25%

Characteristics of the women in the training and validation sets

257324 - Percutaneous biopsy negatively affects the ability of MRI to accurately depict the extent of disease among patients with DCIS

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Background/Objective: The impact of percutaneous biopsy on the ability of MRI to accurately depict the extent of disease in patients with DCIS has not been evaluated. The aim of this study was to compare the MRIs performed before versus after percutaneous biopsy for accuracy in predicting the pathologic extent of DCIS. Our hypothesis is that MRI performed after percutaneous biopsy will negatively impact the MRI results.

Methods: After an IRB waiver was obtained, retrospective review was performed of patients who underwent surgical treatment of DCIS only and had preoperative MRI. MRI results were re-reviewed by 2 radiologists for this study (A.M. and Y.L). Patients were excluded if they did not have images for review or documented size of lesion on MRI or surgical pathology. Descriptive statistics were used for

demographic data and Pearson's correlation coefficient was used to determine the relationship between pathologic specimen size and MRI size.

Results: A total of 54 patients met inclusion criteria. All patients were female with a mean age 59 ± 10.8 years (range 41 to 83). The majority of patients had high-grade DCIS (46%, n=25) or intermediate-grade (44%, n=24) while low-grade (9%, n=5) was infrequent. Pre-biopsy MRI was performed in 30% (n=16) of patients, while post-biopsy MRI was performed in 70% (n=38) of patients. In 15/38 patients (39%) who underwent a post-biopsy MRI, the post-biopsy artifact significantly limited MRI evaluation for the reading radiologists not allowing for accurate measurements to be drawn. Twenty patients (37%) had breast conserving therapy (BCT) while 34 (63%) underwent mastectomy. Fourteen patients (30%) had their surgical approach changed because of the MRI results, and, of these, 11 (20% of entire cohort) underwent mastectomy. Mean lesion size on preoperative MRI was 3.6 ± 1.9 cm while mean lesion size on pathologic specimen was 1.6 ± 1.9 cm. Pre-biopsy MRI more strongly correlated with surgical specimen ($r=0.561$, $p < 0.001$) whereas post-biopsy MRI did not significantly correlate with actual size of tumor on surgical specimen ($r= 0.028$, $p=0.921$). Only 2 patients had a local recurrence (3.7%), both of whom underwent mastectomy after post-biopsy MRI.

Conclusions: Percutaneous biopsy significantly limits the ability to accurately interpret the extent of DCIS on preoperative breast MRI by overestimating extent of disease. Surgeons should be aware that in patients with a post-biopsy MRI, tumor size may be different than anticipated which may affect surgical decision-making and potentially cosmetic results.

257174 - Evaluating the upstaging risk of HER2-positive DCIS to invasive breast cancer: A matched cohort

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Background/Objective: Ductal carcinoma in situ (DCIS) rates have increased over the last 2 decades owing to the widespread use of mammography. Pathologically, there are subgroups of invasive breast cancer (IBC) that behave more aggressively, including those with human epidermal growth factor 2 (HER2). HER2 overexpression in IBC is an independent poor prognostic factor; however, the significance of HER2 overexpression in DCIS is not well defined. Some propose that HER2-positive DCIS (HERposDCIS) on core needle biopsy (CNB) may have higher rates of progressing to or co-existing with IBC on final pathology, and thus, a potential indication for sentinel lymph node biopsy. The present study assessed correlation of HER2posDCIS with upstaging rate to IBC on final pathology.

Methods: After institutional review board approval, we retrospectively reviewed data of patients with a diagnosis of DCIS on CNB at our institution from 2007-2016. Patients with micro-invasive disease on CNB and without treatment or histologic data available were excluded. We performed a matched cohort study using STATA14c for statistical analysis. Multivariate analysis was performed using logistic

regression. For the age-related comparisons, data were analyzed using 2-sample t-tests. A p-value of < .05 was used to assign statistical significance.

Results: We identified 319 patients who met our inclusion criteria, 130 had HER2posDCIS (40.8%). After definitive surgery, 85 (26.6%) patients with DCIS on CNB were upstaged to IBC, of which 45 (52.9%) had HER2posDCIS. We compared HER2 positive versus HER2 negative DCIS patients after matching for age, race, grade, and treatment. We found that HER2posDCIS had significantly higher rates of upstaging to IBC on final pathology (OR 1.89; p=0.012). When comparing our matched cohort among the 4 most common breast cancer receptor subgroups, we found that triple-positive, estrogen/progesterone receptor (ER/PR) and HER2 positive disease on CNB were more than 2 times as likely to have IBC on final pathology (OR = 2.5, p=0.01), whereas patients with ER/PR positive/HER2 negative on CNB were half as likely to have IBC on final pathology (OR=.5, p=0.04). There was a strong trend toward significance in patients with ER/PR negative, HER2 positive DCIS (OR: 1.67 p=0.085) and no difference in upstaging to IBC for patients with triple (ER/PR/HER2) negative (OR: 0.89 p=0.8). Additionally, patients with HER2posDCIS were significantly younger regardless of ER/PR status (p=0.03).

Conclusions: Our study demonstrated that HER2 overexpression in patients diagnosed with DCIS on CNB were at increased risk of having IBC on final pathology compared to those who did not. For institutions where HER2 testing may be performed on DCIS, consideration should be given to sentinel lymph node biopsy at the time of surgery and/or patients should be counseled appropriately about risk of upgrade to IBC.

	All HER2pos (n = 130)	**Triple Negative (n=25)**	**Triple Positive (n=46)**	**ER/PRpos/HER2neg (n = 117)**	**ER/PRneg/HER2pos (n=66)**
Mean Age at Diagnosis in Years (SD)	54.2 (10.4)	61.9 (12.1)	53.4 (10.3)	56.8 (11.8)	53.7 (10.4)
Race (%)					
White	90 (69.2)	15 (57.6)	29 (63)	69 (59.0)	46 (70.8)
Black	26 (20.0)	9 (34.6)	12 (26.1)	38 (32.5)	10 (15.4)
Asian	5 (3.9)	1 (3.9)	3 (6.5)	2 (1.7)	2 (3.1)
Other/unknown	7 (6.9)	1 (3.9)	2 (4.2)	8 (6.8)	7 (10.7)
Grade on Core Biopsy (%)					
Low	3 (2.3)	1 (3.9)	1 (2.2)	15 (12.8)	1 (1.5)
Intermediate	38 (29.2)	3 (11.5)	19 (41.3)	66 (56.4)	13 (20.0)
High	89 (68.5)	22 (84.6)	26 (56.5)	36 (30.8)	51 (78.5)
XrT (%)	46 (37.1)	8 (30.77)	16 (34.8)	44 (37.6)	25 (39.7)
Definitive Surgery (%)					
Lumpectomy	80 (61.1)	16 (61.5)	31 (67.4)	83 (70.9)	35 (53.0)
Mastectomy	30 (22.9)	6 (23.1)	8 (17.4)	20 (17.1)	19 (28.8)
Bilateral Mastectomy	21 (16.0)	4 (15.4)	7 (15.2)	14 (12.0)	12 (18.2)
Invasive Cancer on Final Pathology (%)	45 (34.35)	6 (23.1)	18 (39.1)	23 (19.7)	23 (34.9)
Likelihood of Invasion on Final Pathology by Receptor Profile					
Odds Ratio	1.89	0.89	2.5	0.49	1.67
95% CI	1.15 - 3.09	.34 - 2.37	1.23 - 5.19	.25 - .96	.93 - 2.96
P-value	0.01	0.8	0.01	0.04	0.085

HER2- Human Epidermal Growth Factor; **Triple Negative:** Estrogen/Progesterone/HER2 negative; **Triple Positive:** Estrogen/Progesterone/HER2 positive; **ER:** Estrogen Receptor; **PR:** Progesterone Receptor; **DCIS:** Ductal Carcinoma in Situ; **XrT:** Radiation; **pos:** Positive; **neg:** Negative.

Patient characteristics and matched cohort analysis

256193 - Outcome after local invasive recurrence: The impact of original diagnosis of DCIS versus invasive cancer

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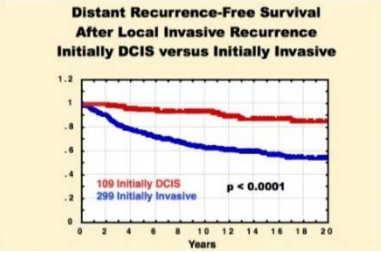
Background/Objective: The outcome following an invasive local recurrence after treatment for breast cancer is variable but generally assumed to be a negative prognostic indicator, regardless of the original diagnosis. The aim of this study was to determine the prognostic impact of an invasive local recurrence following an original diagnosis of DCIS versus an original diagnosis of invasive breast cancer.

Methods: A prospective database of 6,833 patients treated from 1979-2016 was queried for all patients who developed a local recurrence after treatment for breast cancer. All ipsilateral breast tumor events were counted as a local recurrence, regardless of time to local recurrence or breast quadrant location. Patients were stratified by whether the original cancer was DCIS or invasive and then by whether the local recurrence was DCIS or invasive. Kaplan-Meier analysis was used to determine distant disease-free survival. Curves were compared using the log rank test.

Results: Five hundred sixty-eight patients experienced an ipsilateral breast tumor event. Three hundred thirty-seven (59%) had an original invasive diagnosis, while 231 (41%) had an original DCIS diagnosis. One hundred thirty-one (23%) developed a distant recurrence. Median follow-up was 9.8 years. Of those who developed a distant recurrence, 118 (90%) had an original invasive cancer with invasive local recurrence, 12 (9%) had an original invasive cancer with DCIS local recurrence, and 1 (1%) had an original DCIS with invasive local recurrence. No patients with an original DCIS and a DCIS recurrence had a distant recurrence. The probability of developing distant metastases after a local invasive recurrence was significantly higher at 42% in the original invasive group compared to 12% in the original DCIS group ($p < 0.0001$). Ten- and 15-year distant disease-free survival was 100% for all patients with a DCIS recurrence, regardless of original diagnosis. Ten- and 15-year distant disease-free survival were 94% and 88% for original DCIS with invasive recurrence. In those with original invasive cancer with invasive recurrence, ten- and 15-year survival were 64% and 58%. This was shown to be statistically significant ($p < 0.0001$), Figure.

Conclusions: Patients with an original diagnosis of invasive breast cancer have a higher probability of developing an invasive local recurrence when compared to patients with an original diagnosis of DCIS (42% versus 12%). In addition, they have a significantly shorter recurrence-free survival at all follow-up times. The outcome after local invasive recurrence is significantly worse if the original diagnosis is invasive breast cancer rather than DCIS.



Disparities

257304 - Continued disparities in breast cancer stage at diagnosis and survival by race and socioeconomic status

Dalliah Black[1], Jiangong Niu[2], Vivian Bea[1], Ana Refinetti[1], Mediget Teshome[1], Kelly Hunt[1], Henry Kuerer[1], Sharon Giordano[3]
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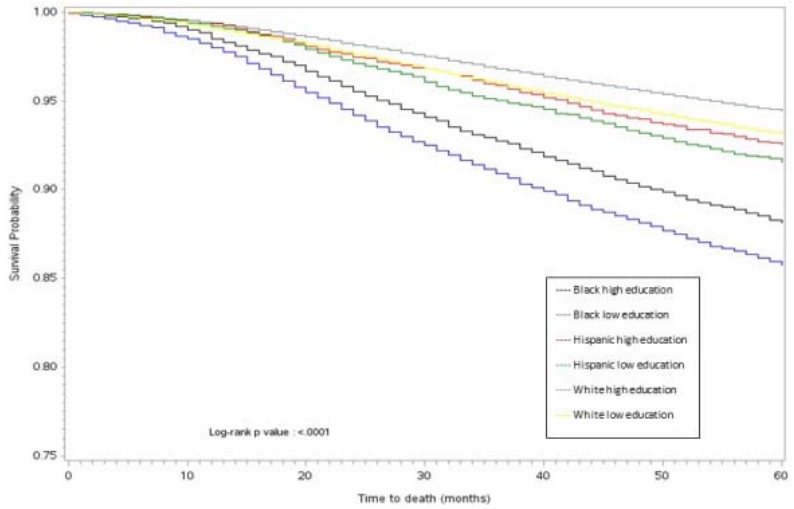
Background/Objective: Breast cancer disparities such as advanced stage at diagnosis and lower survival in minority and low socioeconomic populations are multifactorial and partly due to delays in diagnosis and limited access to treatment. Since the early 2000s, changes in national and state policies provide women of low socioeconomic status access to mammogram screening and breast cancer treatment. The aim of this study is to determine if there have been improvements in earlier breast cancer stage at diagnosis and survival in disparate populations as healthcare policies have been implemented.

Methods: The Surveillance, Epidemiology and End Results (SEER) database was used to identify women ≤ 80 years of age diagnosed with stage 1 - 3 breast cancer between 2000 - 2013. Race, stage at diagnosis, and year of diagnosis were collected. Poverty level was defined by quartile of percentage of poverty in the census region the patient resides. Education status was defined by quartile of percentage of non-high school graduates in the region the patient resides. Five-year overall mortality and 5-year cancer specific mortality rates were determined. A p-value < 0.05 is considered significant.

Results: Of 486,972 women, 378,161 (78%) were white, 54,685 (11%) were black, and 54,126 (11%) were Hispanic. Black patients were more likely to be in the highest poverty level (34%) compared to whites (24%) and Hispanics (22%) ($p < 0.001$). More black patients resided in regions with lower education status (36%) compared to whites (23.4%) and Hispanics (23.5%) ($p < 0.001$). Patients with the highest poverty and lowest education status did not have increases in stage 1 breast cancer diagnosis over the study period (48.9% in 2000 to 49.1% in 2013 and 48.3% in 2000 to 48.5% in 2013, respectively). White patients residing in high educated regions and those residing in low educated regions were more likely to be diagnosed with stage 1 breast cancer (55% and 52%, respectively) followed by educated Hispanic patients (46%). Hispanic patients of low socioeconomic status and blacks of high and low socioeconomic status were similarly least likely to be diagnosed with stage 1 disease (41%), and this was statistically significant compared to the other 3 groups ($p < 0.001$). Over time, black patients with both high and low socioeconomic status persistently had a higher 5-year overall mortality rate (22 %) and 5-year cancer specific mortality rate (10.2%) compared to all Hispanic (13.7% and 5.9%) and all white patients (15.5% and 4.7%) ($p < 0.001$) (Figure).

Conclusions: Since implementation of healthcare policies in the early 2000s to improve access to breast cancer screening and treatment, women of lower socioeconomic status have not had improvements in earlier diagnosis and survival. A racial disparity also persists with black women of all socioeconomic levels being less likely diagnosed with early-stage breast cancer and having worse survival outcomes compared to white and Hispanic women. Strategies to improve the effectiveness of policies providing access to care for underserved women and interventions addressing racial disparities are needed for achieving improvements in breast cancer outcomes in vulnerable populations.



Five-year disease-specific survival by race and education status

256184 - Young minority patients with breast cancer present with primarily hormone receptor-positive tumors

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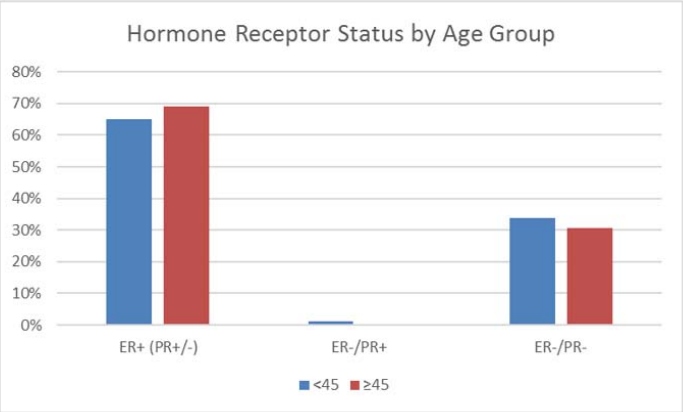
Background/Objective: Poor clinical and prognostic outcomes of breast cancer in young minority patients have largely been attributed to hormone receptor negative tumors. In our predominantly minority patient population, we demonstrate that patients younger than 45 years of age are presenting at more advanced clinical stages with primarily hormone receptor positive tumors.

Methods: This is a retrospective review of the breast cancer tumor registry from an urban tertiary care cancer center. Cases between January 2000 and December 2015 were abstracted for demographics, receptor status, pathology, and American Joint Committee on Cancer (AJCC) stage at diagnosis. Patients were stratified by age: at or below 44 and 45 years or above. Receptor status was based on immune-histochemical assay using the Refine detection system from Leica™. Hormone receptor positivity was determined by estrogen receptor (ER) and/or progesterone receptor (PR) staining >5%. HER2-neu staining was not considered in this study.

Results: There were 776 breast cancer patients diagnosed and treated at our institution who met criteria for this study. A primarily minority population was served: 53% African American and 31% non-White Hispanic. Average age of the cohort was 55 (15 to 95) years of age. Twenty-three percent of patients diagnosed with breast cancer were under the age of 45. Total number of patients with hormone receptor positive tumors was 533/776 (69%). The number of patients under the age of 45 with hormone receptor positive tumors is 118/178 (67%), and the number of patients 45 and above with hormone receptor positive tumors is 415/598 (69%) (p=0.38; Figure). When comparing the groups by clinical stage at presentation, 70% of women under 45 presented with stage II or higher, versus 55% in women over the age of 45 (p=.0007).
Conclusions: Our data suggest that, irrespective of age, the majority of breast cancers in minority patients are hormone receptor positive. Additionally, women under 45 years presented with a

significantly higher rate of advanced stage breast cancer. Therefore, the aggressive nature of the tumors seen in young, minority women may not only be related to hormone receptor status.



257180 - Racial disparities among DCIS patients

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Background/Objective: There is extensive research describing racial and ethnic disparities among patients with invasive breast cancer; however, few studies examine disparities among patients with ductal carcinoma in situ (DCIS). DCIS identifies patients who are at increased risk of developing invasive cancer, and disparities in this group could impact the disparities observed in patients with invasive cancer. We examined DCIS patients at Wake Forest Baptist Hospital to detect differences between racial/ethnic groups that could affect breast cancer outcomes.

Methods: This is a retrospective analysis of 207 patients diagnosed with DCIS at a medical center from 2008 to 2015. Clinical and pathologic features were evaluated among white, African American, and Hispanic patients to detect differences in presentation, use of endocrine therapy, adherence to endocrine therapy, and pathologic features. Clinical features included age at diagnosis, palpable versus non-palpable lesion at time of diagnosis, receipt of and adherence to endocrine therapy, and development of breast cancer within the follow-up period. Pathologic features included prevalence of estrogen-receptor-positive (ER+) DCIS among the groups.

Results: The average age at diagnosis with DCIS was 58 years in both white (W) and African American (AA) women and 50 years in Hispanic (H) women (n=161 W, 39 AA, 5 H). The difference in age at diagnosis between groups did not reach statistical significance (p=0.228). There was a significant difference in presentation with a palpable versus non-palpable lesion, where 40% of Hispanic and 15% of African American women presented with a palpable lesion as compared to 8% of white women (p=.004). In the overall sample, 9.2% of all women terminated endocrine therapy early, however, adherence differed by race/ethnicity as 40% of Hispanic women terminated therapy early compared to 8.7% of white and 5.1% of African American women (p=.027). There was no significant difference between racial/ethnic groups in ER+ cases, receipt of endocrine therapy, or development of breast cancer during the follow-up period.

Conclusions: As they do in invasive breast cancer, racial and ethnic disparities exist in patients with DCIS. More African American and Hispanic women presented with palpable lesions when compared with white women, and Hispanic women were more likely to terminate endocrine therapy earlier than recommended. Further studies should identify the reasons behind these findings, and efforts should be targeted at increasing routine screening mammography as well as compliance with adjuvant endocrine therapy. This data suggest that racial and ethnic disparities could affect patients with DCIS and put them at higher risk for development of invasive breast cancer in the future.

257346 - Patterns of incidence and stage at diagnosis of breast cancer in Sri Lanka, 1985-2010

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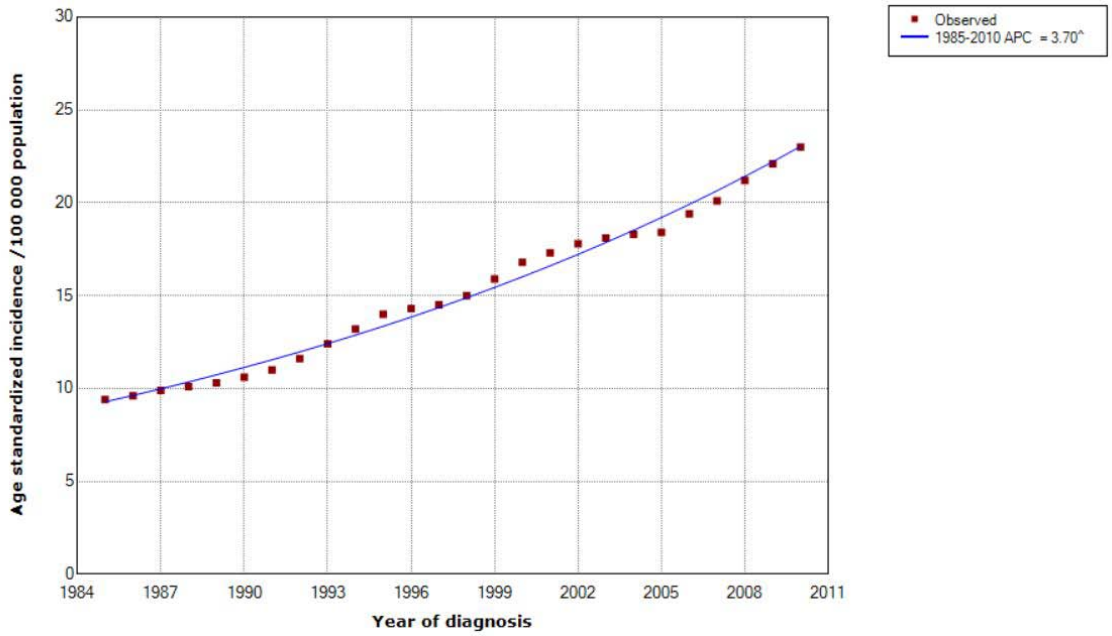
Background/Objective: A gradual decline in the incidence of breast cancer is documented in developed countries, especially over the last 10 to 15 years, while in developing countries, the incidence continues to rise. In general, increasing cancer incidence is typically interpreted as an increase in the true occurrence of disease but may also reflect better reporting or increased diagnostic scrutiny. We conducted this study to examine trends in incidence and stage at diagnosis of breast cancer in a developing country, Sri Lanka.

Methods: A retrospective cohort evaluation of patients with breast cancer during 1985-2010 was performed using population based data from the Sri Lanka National Cancer Registry. Trends in incidence were analyzed overall and by age group using joinpoint regression analysis.

Results: The age standardized incidence of female breast cancer has increased from 9.4 to 23.1 per 100 000 from 1985 to 2010 - a 2.46-fold increase (95% confidence interval [CI 2.16-2.78]; $p < 0.001$ for trend, estimated annual percentage change [EAPC] 3.7%, 95% CI 3.5-3.9) (Figure). In contrast, the breast cancer incidence among males has essentially remained unchanged over this period (from 0.2 to 0.3 per 100 000). Highest incidence of breast cancer was seen among women of 60- to 64-year age group, which has increased from 68 to 100 per 100,000 population over a 10-year period from 2001 to 2010 (EAPC 4.6%, 95% CI 3.9-5.2, $p < 0.001$ for trend). A gradual increase in the stage recording in the national cancer registry was noted which has increased from 42% in 2007 to 57% in 2010. A majority of breast cancers are diagnosed at an advanced stage (stage III and IV), which however appears to be declining gradually; from 55% in 2007 to 51% in 2010.

Conclusions: A gradual increase in the incidence of female breast cancer is noted in Sri Lanka while no such change was observed among males. A majority of breast cancers are advanced at diagnosis, which however appears to be declining. A greater emphasis needs to be placed on earlier diagnosis of breast cancer in order to reduce the burden of breast cancer in Sri Lanka in the future.



Joinpoint regression analysis of trends in breast cancer incidence in Sri Lanka from 1985 to 2010 (APC – annual percentage change

257353 - Ethnic disparities in breast cancer survival in New Zealand: A quantitative analysis?

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Background/Objective: Ethnic disparities in cancer survivals are well known among many populations for a variety of cancers. Underlying reasons for these disparities are complex and poorly understood, but include patient, tumour, and healthcare system factors. We investigated the breast cancer survival disparity between Indigenous Māori and European women in New Zealand and quantified the relative contributions of patient, tumour, and healthcare system factors towards this survival disparity.

Methods: All women with newly diagnosed breast cancer in the Waikato, New Zealand between 1999 and 2012 were identified from the Waikato Breast Cancer Register. Cancer-specific survival between Māori and NZ European women was compared using Kaplan-Meier survival curves while contributions of different factors towards the survival disparity were quantified with Cox proportional hazard modelling.

Results: Of the total of 2,791 women included in this study, 2,260 (80.1%) were NZ European, and 419 (15%) were Māori. Māori had a significantly higher age-adjusted, cancer-specific mortality (hazard ratio [HR] =2.02, 95% confidence interval [CI], 1.59-2.58) with significantly lower 5-year (76.1% vs. 86.8%, $p < 0.001$) and 10-year (66.9% vs. 79.9%, $p < 0.001$%) crude cancer-specific survival rates compared with NZ European women. Stage at diagnosis explained approximately 40% of the survival disparity, while screening, treatment, and patient factors (i.e., comorbidity, obesity, and smoking) contributed by approximately 15% each towards the survival disparity. The final model accounted for almost all of the cancer survival disparity between Māori and NZ European women (HR=1.07, 95% CI, 0.80-1.44) (Table).

Conclusions: Māori women experience an age-adjusted risk of death from breast cancer, which is more than twice that for NZ European women. Lower screening coverage, delay in diagnosis, inferior quality of treatment and greater patient comorbidity appear to be important factors contributing to survival disparity between Māori and NZ European women.

Characteristics	Overall HR (95% CI)	Stage I & II HR (95% CI)	Stage III & IV HR (95% CI)
Unadjusted	1.81 (1.43-2.30)	0.99 (0.62-1.58)	1.96 (1.47-2.61)
Model A (Baseline - adjusted for age and year of diagnosis)	2.02 (1.59-2.58)	1.20 (0.75-1.93)	2.09 (1.56-2.80)
Model B (Model A + Screening status)	1.86 (1.46-2.37)	1.14 (0.71-1.93)	2.00 (1.49-2.67)
Model C (Model B + Cancer stage at diagnosis)			
Tumour, Lymph nodes & Metastasis	1.48 (1.15-1.93)	1.08 (0.67-1.74)	1.67 (1.23-2.27)
Model D (Model C + Cancer biological factors)			
ER/PR, Grade & HER-2	1.40 (1.09-1.81)	1.15 (0.71-1.88)	1.49 (1.09-2.05)
Model E (Model D + Treatment)			
Completion of definitive local therapy	1.31 (1.01-1.69)	1.18 (0.72-1.92)	1.40 (1.02-1.93)
Use of systemic therapy [a]	1.26 (0.97-1.64)	1.12 (0.69-1.83)	1.35 (0.98-1.87)
Delay in surgery or adjuvant therapy [b]	1.25 (0.96-1.63)	1.13 (0.69-1.85)	1.41 (1.01-1.95)
Model F (Model E + Patient factors)			
Comorbidity index score	1.20 (0.92-1.57)	1.08 (0.66-1.78)	1.33 (0.95-1.86)
Smoking	1.16 (0.88-1.53)	1.10 (0.66-1.85)	1.24 (0.88-1.76)
BMI	1.11 (0.83-1.48)	1.12 (0.66-1.90)	1.16 (0.81-1.66)
Model G (Model F + Healthcare access factors)			
Socioeconomic deprivation	1.10 (0.83-1.47)	1.07 (0.63-1.84)	1.16 (0.81-1.67)
Urban / rural residency	1.09 (0.82-1.46)	1.08 (0.63-1.84)	1.16 (0.80-1.67)
Public / private treatment	1.07 (0.80-1.44)	1.12 (0.65-1.93)	1.11 (0.77-1.61)

[a] chemotherapy and endocrine therapy, [b] delay in surgery or delays in initiating chemotherapy or radiation therapy

Hazard ratios for breast cancer-specific mortality risk in Māori compared with NZ European women with stepwise adjustment

257028 - Influence of age on treatment and outcomes in black women with invasive breast cancer

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Background/Objective: Young age at diagnosis has a negative prognostic impact on outcome in patients with breast cancer, and breast cancer in African American women presents at a younger age than in white women. In addition, despite recent advances in the treatment of breast cancer, African American race has been associated with a worse survival. The aim of this study was to evaluate the impact of age on management and outcomes of black women with invasive breast cancer.

Methods: We performed a retrospective review of black women treated for invasive breast cancer at our institution between January 2005 and December 2010. Findings were compared by age using Fisher's exact test. The Kaplan- Meier method estimated overall survival (OS) and breast cancer disease free survival (DFS), and the log-rank test was used for between-group comparisons. Multivariable Cox regression included factors determined a priori.

Results: There were 674 patients with 682 cancers comprising our cohort. Median age was 55 (range: 22–91), and median tumor size was 1.55 cm (range: 0.09–22 cm). The majority of patients were ER+ (66%). The median body mass index (BMI) was 30 (range: 17.2–56.5). Patients were stratified by age as < 50 (n=239; 35%) versus ≥ 50 (n=443; 65 %). One hundred thirty-six (56.9%) of the young women had mastectomy compared to 176 (39.7%) ($p \leq 0.001$). Younger patients were more likely to have an axillary node dissection (p=0.006) (table shows clincopathologic characteristics among both groups). The younger cohort had significantly lower BMI ($p < 0.001$) and was significantly more likely to have lymphovascular invasion (LVI) (p=0.004) and positive lymph nodes ($p < .001$). In addition, the younger women were more likely to receive chemotherapy ($p \leq 0.001$). With a median follow-up of 5.8 years

(range 0–11.5), 5-year OS was 88% (95% confidence interval [CI]: 86–91%) and 5-year DFS was 82% (95% CI: 79-85%). No statistically significant difference in DFS (p=0.398) or OS (p=0.308) on the basis of age was seen. On multivariable analysis, ER status, nodal positivity, and stage were predictors of DFS, but not age.

Conclusions: Young age was associated with more adverse pathologic factors among black women including LVI and nodal positivity. Younger women also required more aggressive treatment including chemotherapy, but age was not a significant predictor of outcomes.

Age	Overall, % (n)	<50, % (n)	>50, % (n)	p
Tumor size (median (range))	1.55cm (0.9 – 2.4)	1.8cm (0.9 – 2.5)	1.5 (0.9 – 2.3)	0.144
ER				0.798
Negative	225 (33%)	81 (33.9%)	144 (33%)	
Positive	449 (66%)	157 (66%)	292 (66%)	
NA	8 (1%)	1 (0.4%)	7 (1.6%)	
Her 2 +				0.108
Equivocal	9 (1%)	5 (2%)	4 (1%)	
Negative	537 (79%)	183 (77%)	354 (80%)	
Positive	106 (16%)	45 (19%)	61 (14%)	
NA	30 (4.4%)	6 (3%)	24 (5%)	
Nodal Status				<0.001
Negative	403 (59%)	117 (49%)	286 (65%)	
Positive	277 (41%)	121 (51%)	156 (35%)	
NA	2 (0.3%)	1 (0.4%)	1 (0.2%)	
LVI				0.004
No	450 (66%)	142 (59%)	308 (70%)	
Yes	205 (30%)	89 (37%)	116 (26%)	
NA	27 (4%)	8 (3%)	19 (4%)	
BMI (mean (range))	30 (26 – 35)	28.9 (25 – 33)	30.4 (27 – 35)	<0.001
Chemotherapy				<0.001
No	241 (35%)	48 (20%)	193 (44%)	
Yes	441 (65%)	191 (80%)	250 (56%)	
Endocrine therapy				0.805
No	265 (39%)	91 (38%)	174 (39%)	
Yes	417 (61%)	148 (61%)	269 (61%)	
Radiation therapy				0.611
No	237 (35%)	86 (36%)	151 (34%)	
Yes	431 (63%)	147 (62%)	284 (64%)	
NA	14 (2%)	6 (2%)	8 (2%)	

Clinicopathological characteristics

Age Extremes

257263 - Postoperative complications in elderly women with breast cancer: An analysis of the NSQIP database

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Background/Objective: Data on postoperative complication rates for elderly women undergoing breast cancer surgery are lacking. These data would help determine the safety of breast oncological surgery in this population. This study aimed to compare the postoperative complication and mortality rates of young (40-69 years old) and elderly (≥70 years old) women with breast cancer.

Methods: Analysis of the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) database was performed. Patients with breast cancer who underwent surgery at NSQIP-

affiliated hospitals from 2004 to 2014 were included. Exclusion criteria included in situ tumors, male patients, and simultaneous reconstruction. Primary outcome was a composite of 30-day postoperative complications and mortality. Surgery was categorized as breast-conserving surgery (BCS) and mastectomy. Age groups were compared by univariate analysis as well as with multivariable analysis in order to adjust for known confounders. Comorbidity defined as American Society of Anesthesiology (ASA) score was considered an effect modifier and was assessed using a stratifying logistic regression.

Results: We identified 118,267 patients of which 84,055 met the study criteria. Distribution of patients by age groups was 58,014 young (69%) and 26,041 elderly (31%) patients. Significant differences at baseline were observed between age groups (Table). Compared to younger women, elderly women were more likely to undergo mastectomy, have ASA score ≥3, and have higher frequency of comorbidities. However, elderly women were less likely to receive neoadjuvant chemotherapy. In the unadjusted analysis, the 30-day composite of postoperative complication and mortality rate was higher among the elderly (3.8% vs 3.2%, $p < 0.0001$). Significant differences in postoperative complications were observed between age groups (Table). After adjusting for type of surgery, chemotherapy, steroid use, and smoking, elderly women remained at increased risk of developing postoperative complications or dying (odds ratio 1.26, 95% confidence interval 1.13–1.41). The effect of age on the outcome is dependent on the ASA score. Nonetheless, in a stratifying model, age category was no longer associated with the primary outcome.

Conclusions: Our study demonstrates the low perioperative morbidity and mortality rates after breast cancer surgery in elderly women. However, this population is at high risk of developing complications and dying after adjusting for confounders. This finding is dependent on the effect of comorbidities. These data support the safety of breast cancer surgery in elderly patients. Preoperative risk assessment tools could be used to determine patients at higher risk of adverse outcome.

Variable	Young (40-69y) N= 58,014	Elderly (≥70y) N= 26,041	P Value
Comorbidities			
Diabetes mellitus	6,569 (11.3%)	4,757 (18.3%)	<0.0001
Smoking	9,249 (15.9%)	1,666 (6.4%)	<0.0001
Alcohol consumption	511 (1.6%)	173 (1.3%)	0.023
Chronic obstructive pulmonary disease	1,346 (2.3%)	1,468 (5.6%)	<0.0001
Congestive heart failure	95 (0.2%)	144 (0.6%)	<0.0001
Myocardial infarction	29 (0.1%)	30 (0.2%)	<0.0001
Dialysis	144 (0.3%)	93 (0.4%)	0.006
Cerebrovascular disease	250 (0.8%)	365 (2.8%)	<0.0001
Steroid use	1,134 (2%)	605 (2.3%)	0.0005
Bleeding disorders	767 (1.3%)	920 (3.5%)	<0.0001
American Society of Anesthesiology (ASA) score ≥3	17,015 (29.4%)	13,183 (53.8%)	<0.0001
Treatment			
Breast conserving surgery	35,544 (61.3%)	15,066 (57.9%)	<0.0001
Mastectomy	22,470 (38.7%)	10,975 (42.1%)	<0.0001
Chemotherapy 30 days before surgery	2,414 (7.1%)	257 (2%)	<0.0001
30-day postoperative complications			
Superficial surgical site infection	933 (1.6%)	409 (1.6%)	0.7
Deep surgical site infection	242 (0.2%)	75 (0.2%)	0.3
Organ space surgical site infection	112 (0.4%)	41 (0.3%)	0.005
Pneumonia	37 (0.06%)	41 (0.16%)	0.0001
Reintubation	24 (0.04%)	30 (0.12%)	0.0001
Pulmonary embolism	32 (0.06%)	29 (0.11%)	0.005
Urinary tract infection	133 (0.2%)	139 (0.5%)	0.0001
Stroke	12 (0.02%)	36 (0.1%)	0.0001
Cardiac arrest	12 (0.02%)	12 (0.05%)	0.04
Myocardial infarction	13 (0.02%)	31 (0.1%)	<0.0001
Deep venous thrombosis	49 (0.08%)	46 (0.18%)	0.002
Bleeding requiring transfusion	258 (0.4%)	145 (0.6%)	0.03
Death	32 (0.06%)	58 (0.22%)	<0.0001

Patient comorbidities and postoperative complications

256897 - Is the current Breast Imaging-Reporting and Data System (BI-RADS) score applicable to the pediatric population?

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Background/Objective: Identifying breast masses in pediatric and adolescent population causes tremendous concerns to both parents and physicians because of the prevalence of malignant potential in the adult population. The spectrum of breast lesions in children and adolescents varies greatly from that of adults, with the pediatric lesions being overwhelmingly benign. The American College of Radiology Breast Imaging Reporting and Data System (BI-RADS) is widely accepted for risk stratification in the adult population, yet no study to date has demonstrated the validity of BI-RADS for usage in the pediatric population. The aim of the study is to compare BI-RADS classification with pathology to assess the applicability of the scoring system in the pediatric population.

Methods: We performed a retrospective review of pediatric patients less than 21 years of age with a palpable breast mass or abnormal ultrasound obtained from January 2010 to September 2016. We further compared and analyzed the demographic data, imaging, and surgical biopsy results according to the current BI-RADS classification.

Results: We reviewed 161 patients that either had a clinically palpable breast mass or abnormal ultrasound in the study. There were a total of 105 patients that had pathologic correlates, but only 96 had associated BI-RADS grading. Overall, 77 (73%) biopsies were fibroadenomas, and 67.5% of the fibroadenomas received a BI-RADS 4 classification. Of note, 9 of the patients that were classified as BIRADS 4 with biopsied results underwent elective surgical excision. The surgical specimens included 7 fibroadenomas, 1 gynecomastia, and 1 granulomatous mastitis, all of which correlated with the biopsy diagnosis. All 105 patients with biopsied or surgically excised lesions were benign with an overwhelming majority being fibroadenomas. The average age of the patients in the BI-RADS 4 group is 17.4 years old, which had no statistical significance in the average age between each BI-RADS groups.

Conclusions: Having a biopsy or undergoing surgery is not a benign process, as it comes with complications and potentially further testing. It can be stressful and extremely exhausting especially in this young susceptible population. To date, there are no valid studies or guidelines regarding the application of BI-RADS scoring in pediatric patients, making the decision in management of these lesions challenging. In the adult population recommendations are that BI-RADS 4 lesions undergo biopsy. With adherence to these guidelines, 70/78 (90%) of the pediatric patients underwent biopsy, of which all were benign. Our current scoring system compounded with cultural anxiety surrounding breast malignancy results in undue emotional and financial burdens on the patients from an overestimation of cancer risk in this population. Taken together, we propose to further analyze the current algorithm and to assess the necessity for a revised or novel scoring system specific to the pediatric population.

BI-RADS US CATEGORY	Biopsy Results	(n=105)
BI-RADS 1	No biopsy result available	0
BI-RADS 2	6 fibroadenomas	6
BI-RADS 3	15 fibroadenomas, 1 cyst, 2 benign breast tissue, 1 lymph node, 1 fibrosis	20
BI-RADS 4	52 fibroadenomas, 1 abscess, 1 tubular adenoma, 1 cyst, 4 benign breast tissue, 2 galactocele, 2 biphasic, 1 GM†, 1 fibromatosis, 1 chronic inflammation, 1 PASH‡, 1 gynecomastia, 1 LA§, 1 fibroepithelial lesion	70
BI-RADS Not Obtained	4 fibroadenomas, 1 benign squamous papilloma, 2 cyst, 1 chronic inflammation, 1 adenosis	9

†Granulomatous mastitis ‡Pseudoangiomatous stromal hyperplasia §Lactating adenoma

BI-RADS US categories in 105 pathology specimens

257327 - Impact of age on the presentation and management of breast cancer: A National Cancer Database analysis

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Background/Objective: Age is a significant risk factor for breast cancer with previous reports suggesting that patients diagnosed at a younger age may have poorer prognosis. Much of this literature, however, consists of historical single center experiences. Here we present a population-based study that examines differences in national trends of breast cancer presentation and treatment based on patient age.

Methods: The American College of Surgeons National Cancer Database was queried for patients diagnosed with breast cancer (n=2,032,209) from 2003 – 2013. Patients were grouped according to age at diagnosis, either between 15 – 39 years old (n=92,910) or greater than 39 years old (n=1,939,299). These 2 groups were compared with regard to patient demographics, disease characteristics, stage at presentation, and type of treatment received.

Results: Patients diagnosed with breast cancer at ages 15 – 39 compared to those diagnosed at 40 years or older were more likely to be non-white (25% vs. 15%, $p < 0.01$) and to have private insurance (78.6% vs. 53.3%, $p < 0.01$). In both groups, a majority of patients were treated at metropolitan as opposed to urban or rural centers (89% vs. 87%). Younger patients appeared to present at more clinically advanced stages when compared to the older age cohort (57% vs. 33% stages 2-4, $p < 0.01$). Additionally, younger patients were more likely to have HER2+ receptor status (9% vs. 5%, $p < 0.01$) or triple-negative disease (7.5% vs. 4.1%, $p < 0.01$). Rates of surgical intervention (92.6% vs. 92.8%) and radiation therapy (49% vs. 51%) were clinically similar between both groups, though younger patients were significantly more likely to receive chemotherapy (69.6% vs. 32.5%, $p < 0.01$).

Conclusions: Younger breast cancer patients present with more advanced clinical stage disease, exhibit less favorable receptor status, and receive higher rates of adjuvant chemotherapy when compared to older patients. Further investment is needed to develop and deliver personalized and age appropriate cancer care to these differing patient populations.

Characteristic	*Age 15 - 39* (n = 92910)	*Age > = 40* (n = 1939299)	P *value*
Clinical Stage			<0.0001
Stage 0	14.9%	23.2%	
Stage 1	27.7%	43.6%	
Stage 2	37.9%	22.2%	
Stage 3	13.2%	6.2%	
Stage 4	6.2%	4.8%	
Pathological Stage			<0.0001
Stage 0	13.8%	18.7%	
Stage 1	29.6%	44. 2%	
Stage 2	38.0%	26.3%	
Stage 3	15.4%	8.8%	
Stage 4	3.2%	2.0%	
Surgical Treatment			0.0052
Yes	92.6%	92.8%	
No	7.2%	7.0%	
Unknown	0.2%	0.2%	
Radiation Therapy			<0.0001
Yes	48.5%	51.0%	
No	49.3%	47.2%	
Unknown	2.1%	1.8%	
Chemotherapy			<0.0001
Yes	69.6%	32.5.7%	
No	27.6%	63.7%	
Unknown	2.3%	3.8%	
Hormone Therapy			<0.0001
Yes	44.7%	51.9%	
No	49.5%	42.8%	
Unknown	5.8%	5.3%	

256984 - Characteristics of younger patients with breast cancer pursuing fertility preservation

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Background/Objective: Young women diagnosed with breast cancer who have not started or completed childbearing often have concerns regarding fertility. This study describes the characteristics and choices of women referred to a fertility nurse specialist (FNS) to receive education and help with referrals to reproductive endocrinologists and infertility (REI) specialists.

Methods: We performed an IRB-approved retrospective review of a database of women with stage 0-III breast cancer counseled by our FNS from 2009 to 2015. Clinicopathologic characteristics, referring service, treatment, and outcome from referral (REI consult accepted, declined, undecided) were

collected. Between-group comparisons were made with the Kruskal-Wallis test for continuous variables and Fisher's exact test for categorical variables.

Results: Three hundred forty-nine women with 356 breast cancers (7 bilateral) were identified; median age at diagnosis was 35 years (range: 20-53). Three hundred twenty-six (91.6%) cancers were invasive ductal, 271 (76.1%) ER positive, and 69 (19.4%) HER2 positive. Stage distribution was stage 0 (3.9%), stage I (36%), stage II (46.1%), stage III (13.4 %), and unknown (0.6%). Two hundred twenty-six women (63.5%) had a mastectomy, with 141 (39.4%) having a contralateral prophylactic mastectomy. Sixty-four (18.3%) patients received neoadjuvant chemotherapy, 206 (59.0%) adjuvant chemotherapy, and 254 (72.8%) endocrine therapy. The majority of women (57.6%) were referred to FNS by their surgeon prior to surgery. FNS consultations were performed in clinic with 67 (19.2 %) women and over the phone with 282 (80.8%). Prior to their breast cancer diagnosis, 101 (28.9%) women had at least one child, and 144 (41.3%) were married. Two hundred forty-two (69.3%) had used oral contraceptives, and 28 (8%) had attempted prior fertility treatment. Two hundred fourteen (61.3%) women agreed to follow-up consultations with REI, 57 (16.3%) declined, and 58 (16.6%) were undecided. Factors examined for association with FNS outcome are shown (Table). Nulliparous women ($p < .001$) and those referred by their breast surgeon ($p=0.04$) as an early referral are more likely to accept REI referrals. Women pursuing REI are more likely to receive adjuvant chemotherapy ($p=0.002$) and endocrine therapy ($p=0.021$), while women declining REI were more likely to receive neoadjuvant chemotherapy ($p < 0.001$).

Conclusions: Early referral to a FNS program may allow young women with breast cancer an opportunity to discuss and pursue fertility preservation options. Women who are nulliparous or referred by their surgeon were more likely to agree to an REI consultation. The timing of planned treatment may influence a woman's choice, as those who accepted referral were more likely to receive adjuvant chemotherapy and/or endocrine therapy and those who declined were more likely to receive neoadjuvant chemotherapy. Further research into decision-making, as well as uptake of fertility preservation options after REI referral, is planned.

	Overall (n=341)	No REI referral (n=124)	REI referral (n=217)	p-value
Median age	35 (32,39)	36 (32,39)	35 (31,38)	0.078
Marital status				
Not married	205 (58.7%)	66 (55%)	126 (58.9%)	<.001
Married	144 (41.3%)	54 (45%)	88 (41.1%)	
Parity				
0	248 (71.1%)	68 (56.7%)	168 (78.5%)	<.001
1	73 (20.9%)	39 (32.5%)	31 (14.5%)	
≥2	28 (8%)	13 (10.8%)	15 (7%)	
Referring service				
Breast Medicine	144 (41.3%)	58 (48.3%)	76 (35.5%)	
Breast Surgery	201 (57.6%)	60 (50%)	136 (63.6%)	0.04
Genetics, GYN	3 (0.9%)	1 (0.8%)	2 (0.9%)	
N/A	1 (0.3%)	1 (0.8%)	0 (0%)	
Neoadjuvant chemotherapy				
No	285 (81.7%)	80 (66.7%)	191 (89.3%)	<.001
Yes	64 (18.3%)	40 (33.3%)	23 (10.7%)	
Adjuvant chemotherapy				
No	142 (40.7%)	63 (52.5%)	75 (35%)	0.002
Yes	206 (59%)	56 (46.7%)	139 (65%)	
N/A	1 (0.3%)	1 (0.8%)	0 (0%)	
Endocrine therapy				
No	93 (26.6%)	42 (35%)	49 (22.9%)	0.021
Yes	254 (72.8%)	77 (64.2%)	164 (76.6%)	
N/A	2 (0.6%)	1 (0.8%)	1 (0.5%)	

Factors associated with outcomes of FNS consultation

256795 - Surgical treatment of adolescent breast disorders: Institutional experience and national trends

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Background/Objective: While most adolescent breast disorders are benign and cosmetic in nature, their surgical treatments are not without potential for morbidity and may require multiple operations. We sought to describe our institutional experience with these procedures, including the number of operations needed to correct various deformities, and comment on the recent trend of breast surgery in adolescents across the United States.

Methods: We identified children and adolescents aged 0-20 who underwent a breast procedure using Current Procedural Terminology (CPT) and International Classification of Disease-9th Revision (ICD-9) diagnoses from 2 data sources: an academic institution from 1/2000 to 7/2016 and the Kids' Inpatient Database (KID) from 1/2000 12/2012. In the institutional cohort, conditions were categorized into common and complex breast disorders. The average number of procedures needed to correct common and complex breast disorders was compared using an unequal Variance T-test. A trends analysis was performed for breast procedures from the KID with weighted data to reflect the United States as a whole using a Rao-Scott Chi Square test.

Results: At our institution, 241 patients underwent a breast procedure: 181 females and 60 males. Median patient age was 18 (IQR 16-19) at the time of his or her first operative intervention. Common breast disorders treated included: bilateral breast hypertrophy in 123 (51.0%), benign lesion excision in 78 (32.4%), breast asymmetry in 14 (5.8%), and bilateral breast hypoplasia in 6 (2.5%). Complex breast disorders included: Poland's Syndrome in 8 (3.3%), tuberous breast deformity in 7 (2.9%), complex breast asymmetry secondary to conjoined twinning in 2 (0.8%), excision of malignant lesions in 2 (0.8%), and congenital bilateral amastia in 1 (0.4%). Common breast disorders were corrected with a median of 1 procedure by lesion excision, breast reduction, or augmentation procedures. One patient with breast asymmetry was corrected with 2 treatments of fat grafting alone. Complex breast disorders were corrected with a median of 2 procedures. Congenital bilateral amastia and Poland's syndrome were treated initially with autologous flap and tissue expander placement and required subsequent operations for implant exchange, fat grafting for symmetry, or nipple revision. Tuberous breast deformities were treated initially with implant reconstruction or mastopexy and required subsequent operations for symmetry. The 2 patients who underwent resection of malignant tumors required an average of 4.5 procedures to correct utilizing bilateral skin-sparing mastectomies and implant-based reconstructive techniques. In the KID, the weighted data approximated 7,231 patients were hospitalized for a breast procedure between 2000 and 2012. This decreased from 1,661 in 2000 to 1,078 in 2012, $p < 0.001$.

Conclusions: Common adolescent breast disorders may be surgically corrected with one operation, while complex disorders including malignancy often require multiple operations to correct. Inpatient treatment of adolescent breast disorders has been decreasing in recent years, likely reflecting a trend to outpatient procedures.

256466 - Are women ≥70 years old receptive to decreased breast cancer screening?

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Background/Objective: There is currently no consensus on when to stop mammographic screening. The US Preventive Services Task Force (USPSTF) recommends bi-annual mammogram screening for women 50-74. Both the American Congress of Obstetricians and Gynecologists (ACOG) and The American Cancer Society (ACS) recommend annual screening mammography for women ≥40 with no upper age limit. Due to this lack of consensus, many patients will continue screening indefinitely. Both physician recommendation and patient attitudes have been cited as significant factors predicting screening behavior. The purpose of this study was to examine the role of physician recommendation, perceived health benefits of annual screening mammography, and history of breast cancer in determining screening behavior.

Methods: Between 9/2015-4/2016, an anonymous survey was distributed to female patients ≥70 presenting for screening mammogram. Responses were stratified by breast cancer history. Chi-square analysis was performed to relate having a history of breast cancer to patient views on screening.

Results: Five hundred sixty-one women completed the survey. Eighty-seven percent had annual screening mammograms. Ninety-one perceont saw a physician at least 1-2 times/year. Thirty-three percent had a history of breast cancer. Overall, 89% believed mammographic screening benefited their health, and 81% believed early detection was important for successful treatment. Sixty-five percent believed that stopping mammograms would negatively impact their health, and when asked at what age they would feel comfortable stopping mammograms, 67% of the group answered “never.” Stratified by breast cancer history, women with a history of breast cancer were less likely to feel comfortable stopping mammograms at any age, even if recommended by a physician, compared to women without a history of breast cancer (57% vs. 71%, respectively, p=0.002). Women without a history of breast cancer were more comfortable receiving mammogram screening every 2+ years compared to women with a history of breast cancer (59% vs. 36%, respectively, $p < 0.001$). Neither group felt comfortable with clinical breast exam alone (81% vs. 85%; p=0.137).

Conclusions: The majority of women ≥ 70 surveyed believed that yearly mammograms benefited their health. Most women with a history of breast cancer would not change their screening routine regardless of physician recommendation; however, those without a history were more likely to accept recommendations for less frequent screening. These findings suggest that patient perceptions regarding the benefits of breast cancer screening play a major role in determining screening behavior.

257359 – Ten-year and lifetime risk to stratify women ages 40-44 for screening mammography: A single NAPBC accredited center experience

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Background/Objective: The American Cancer Society revised recommendations for screening mammography for average risk women in 2015. The new recommendations advised to start screening at age 45 for average-risk women. We sought to calculate the risk of screen detected breast cancer

patients at our institution to determine if these women would have been identified as appropriate for screening mammogram based on risk assessment only.

Methods: The breast program leadership approved a quality assurance review of breast cancers diagnosed at our NAPBC center for the years 2010-2014. All screen detected cancers detected in women aged 40-44 were included for review. The tumor registry presented the committee with de-identified data for analysis and review. Ten-year and lifetime risks were calculated using the online IBIS Breast Cancer Risk Evaluation Tool – version 7 (available at http://www.ems-trials.org/riskevaluator/).

Results: Fifty-two women between the ages 40-44 were diagnosed with breast cancer during the time interval. Nineteen cancers were screen detected and the patients determined to have no symptoms prior to mammography. Only 15 charts were complete with information required for the online calculator and were included in the analysis. The average lifetime risk was 16.29% (median 13.20%) while the average 10-year risk was elevated at 2.65% (median 1.80%). Five of the patients (33.33%) reported a family history and when these women were excluded, the average lifetime risk was lower at 11.55% (median 11.80%), and the average 10-year risk was not elevated at 1.70% (median 1.70%). Being overweight or obese (BMI >24.9) was identified in 11 (73.33%) patients. Two patients had evidence of surgical menopause, and 1 was using hormones for 4 years prior to diagnosis. Otherwise, all patients were premenopausal. One patient had a history of a benign biopsy. Three patients were nulliparous and all stated menarche from ages 12-14. There was no Ashkenazi Jewish ancestry within this population.

Conclusions: The IBIS calculator is helpful to identify women's risk for breast cancer by calculating 10-year and lifetime risk. Within our population, those without a family history were found to have average lifetime and 10-year risk calculations. All patients with family history of breast cancer were found to have elevated lifetime and/or 10-year risk calculations. Being overweight or obese (BMI >24.9) was identified in many of the patients. We conclude that the risk calculator used would fail to identify 9 women within our center over a 5-year period with screen detected cancers. Based on the current ACS recommendations, these 9 women would be identified as average risk and would have the opportunity to have annual screening.

Genetics

257405 - Current variant of unknown significance rates in multigene panel testing

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Background/Objective: As information regarding familial genetic syndromes increases, more patients are undergoing genetic testing. With the introduction of panel testing (ranging from 5-43 genes), the incidence of variants of unknown significance (VUS) identified at our institution is increasing; however, this has not been well documented in the literature. The lay press has described VUS as a "medical mystery" with "implications entirely uncertain." We sought to define the VUS rates at our institution, hypothesizing that the non-BRCA VUS rate is higher than what is currently reported in the literature (13.4%).

Methods: Of a total of 890 patients seen by 2 genetic counselors at our community hospital from July 2013 to October 2016, 351 patients underwent genetic panel testing. A retrospective review was

performed using an institutional database to determine incidence of mutations and VUS in BRCA as well as non-BRCA genes.

Results: Genetic panel testing identified BRCA mutations in 2.8% of patients (10/351). The total BRCA VUS incidence was 4.3% (15/351), consistent with published reports. Non-BRCA mutations were identified in 17 patients (4.8%), with the most common being CHEK2 (4 patients), ATM (2 patients), MLH1 (2 patients), and TP53 (2 patients). There was 1 patient each with a mutation in BARD1, MSH2, NBN, PALB2, PTEN, RAD51C, and SDHB. The total non-BRCA VUS rate was 34% (120/351). The genes most frequently demonstrating VUS included APC (n=14), ATM (n=14), CHEK2 (n=12), CDH1 (n=9), PMS2 (n=9), and PALB2 (n=8). VUS were also identified in BARD1 (n=6), BRIP1 (n=6), MSH6 (n=5), NBN (n=5), BMPR1A (n=5), CDKN2A (n=4), MSH2 (n=4), RAD51C (n=3), MLH1 (n=2), MRE11A (n=2), MUTYH (n=2), RAD50 (n=2), STK11 (n=2), PTEN (n=1), POLD1 (n=1), POLE (n=1), RAD51D (n=1), SMAD4 (n=1), and TP53 (n=1).

Conclusions: The incidence of VUS at our institution (combining both BRCA and non-BRCA genes) was high (39%) with panel testing. Myriad has previously reported that for the BRCA gene, with time as more diverse populations are tested the rate of VUS has dropped (12.8% in 2002 to 2.9% in 2012 for all comers, with highest initial incidence and drop in patients from African and Latin American ancestry). Our institution does have a large proportion of African American and Hispanic patients, which may contribute to our high VUS rate. A limitation of our study is that a small subset of the patients identified to have a VUS were already tested by the oncologists or primary physicians and then referred to the genetic counselors after the variant was identified, which would also partially account for the high incidence we report. Our hope is that demonstrating the high rate of VUS will dissuade both clinicians and patients from making clinical decisions based on a variant result. Furthermore, the importance of testing diverse populations is essential to further characterize these variants and cancer risk.

257048 - Adhering to the guidelines: Rates of BRCA mutation using NCCN genetic testing criteria

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Background/Objective: BRCA high-risk assessment is recommended by the National Comprehensive Cancer Network (NCCN) in patients with breast cancer who meet one of 11 criteria. Limited data are available regarding the likelihood of detecting a mutation when these criteria are followed. Awaiting test results to inform surgical planning may result in a delay to therapy of several weeks, which has been shown to impact long-term outcomes. This study reviews genetic testing at a single institution to find the rate of BRCA mutation in our breast cancer patients, and identify which NCCN guideline criteria are most predictive of a positive result.

Methods: All subjects who underwent BRCA1/BRCA2 genetic testing between January 2008 and December 2015 at a single institution were reviewed, and 368 were identified, 199 of whom had breast cancer prior to testing. Patients underwent genetic counseling and testing based on NCCN guidelines identified at their clinic visit or at multidisciplinary breast tumor board. A retrospective chart review examined patient and tumor characteristics, NCCN criteria were applied, and BRCA testing results and

associations among these were analyzed using Pearson's chi-squared test and Fisher's exact test. Multiple combinations of testing criteria were examined for predictive value.

Results: Nineteen (9.5%) patients were found to have a BRCA abnormality, 7 (3.5%) with a variant of unknown significance (VUS), and 12 (6.0%) with a deleterious mutation (BRCA+). Adherence to NCCN guidelines was confirmed in 98.5% of subjects. The reasons for testing are found in the Table. High-risk family history was the reason for testing in 140 patients (70.4%), young age (< 50y) at diagnosis in 128 (64.3%), and high-risk cancer [triple-negative breast cancer (TNBC), or 2 primaries] in 50 (25.1%). The rate of BRCA+ was not significantly different among these 3 groups (7.8%, 7.8%, 6.4% p=0.877). The subjects who met all 3 reasons for testing (8.5%) had a BRCA+ rate of 15%. In the study cohort of 199, patients tested because of young age with TNBC had a BRCA+ rate of 10.5%, while the rate for those tested because of young age, TNBC, and family history was 11.1%. These increases in rate of BRCA+ result were not significant compared to those tested because of young age alone (p=0.811). BRCA+ vs BRCA- subjects were more likely to be ER negative (52.6% vs 24.4%, p=0.001), have grade 3 cancer (63.2% vs 31.7%, p=0.007), and have more reasons for testing (mean number of reasons 3±1.4 for BRCA+ vs. 2±1 for BRCA- (p=0.001). Fifty-five (28%) patients had only 1 reason for testing, and only 3 of these were BRCA+ (5.5%). The only individual testing criteria associated with a significantly higher incidence of BRCA+ were known genetic mutation in the family (p < 0.001) and personal history of ovarian carcinoma (p=0.008). Rate of BRCA positivity only increased significantly when the patient had ≥ 4 criteria for testing compared to ≤3 (p=0.002). Twelve (6.0%) patients had ≥4 criteria and 5 were BRCA+ (41.7%).

Conclusions: Using NCCN guidelines for genetic high-risk assessment, a deleterious BRCA mutation was detected in only 6% of breast cancer patients. Criteria associated with a higher chance of BRCA+ were identified but were present uncommonly. Delaying surgical therapy to await genetic testing results does not appear warranted in most patients.

Reason for testing: Personal history of breast cancer and…	Subjects meeting criterion*: Total N (%)	No BRCA Mutation N (% of BRCA-)	BRCA mutation N (% of BRCA+)	*p* value
Individual from a family with a known genetic mutation	8 (4%)	5 (3%)	3 (25%)	<0.001
Diagnosed < 50 years of age	128 (64%)	114 (61%)	10 (83%)	0.113
Diagnosed < 60 years of age with triple negative breast cancer	37 (19%)	34 (18%)	3 (25%)	0.552
Two breast cancer primaries	17 (8%)	16 (9%)	1 (8%)	0.979
≥1 close relatives with breast cancer diagnosed at ≤50 years of age	73 (37%)	66 (35%)	7 (58%)	0.108
≥1 close relatives diagnosed with ovarian carcinoma	42 (21%)	38 (20%)	4 (33%)	0.284
≥2 close relatives diagnosed with breast or pancreatic cancer at any age	79 (40%)	74 (40%)	5 (42%)	0.885
From a population at increased risk (Ashkenazi Jewish)	6 (3%)	6 (3%)	0 (0%)	0.528
Personal and/or ≥3 close relatives with breast, pancreatic, prostate, melanoma, sarcoma, adrenocortical carcinoma, brain, diffuse gastric, colon, thyroid, kidney cancers, hamartomatous polyps of GI tract, dermatological manifestations or macrocephaly	34 (17%)	32 (17%)	2 (17%)	0.968
Personal history of ovarian carcinoma	2 (1%)	1 (0.5%)	1 (8%)	0.008
Personal history of male breast cancer	1 (0.5%)	1 (0.5%)	0 (0%)	0.799

*Patients may have more than one reason for testing

Version 1.2017 NCCN Guidelines for genetic assessment in breast cancer: Distribution of patients with and without BRCA

248497- Anxiety in BRCA mutation carriers: The impact of prophylactic breast surgery

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Background/Objective: Deleterious BRCA mutation carriers (BrMC) face choices in managing cancer risk which may impact their quality of life. Our study aims to assess anxiety of BRCA mutation carriers without cancer who have and have not undergone prophylactic bilateral mastectomy.

Methods: An anonymous, cross-sectional survey was conducted electronically. The survey was emailed to the BrMC identified from our genetic counseling database and included the Hospital Anxiety and Depression Scale (HADS) as well as investigator-generated questions regarding demographics and prophylactic choices with respect to mutation and surgery. Non-responders received 2 additional survey invitations. Statistical analysis was performed using Fisher's exact and the Wilcoxon rank-sum tests. Respondents were analyzed in total, and divided into 2 subgroups, those who underwent prophylactic surgery versus those managed by high risk screening.

Results: Out of our database of 432 BrMC, 170 valid email contacts were identified. Sixty-six BrMCs completed the survey (39% response rate) with a median age of 50 (range 18 - 79). 30.8 % were under the age of 40. Twenty-three percent of respondents were pre-menopausal. Of the 32 unaffected BrMCs, 7 (6 BRCA1, 1 BRCA2) had prophylactic mastectomy with reconstruction, and 25 had no surgery (8 BRCA1, 17 BRCA2). The HADS scores did not differ significantly between the prophylactic mastectomy and no surgery group. When asked specifically about their BRCA mutation and anxiety, the patients who elected to undergo prophylactic bilateral mastectomy reported an increased level of anxiety with respect to their mutation as compared to those who did not undergo surgery (p=0.033). Following surgery, the prophylactic bilateral mastectomy group had decreased anxiety regarding getting breast cancer. Of those who did not undergo surgery, 11 (44%) felt that prophylactic surgery would not make them feel less anxious.

Conclusions: Unaffected BrMC had no difference in overall anxiety regardless of the decision to undergo prophylactic bilateral mastectomy. This information may be important for physicians counseling BrMC on prophylactic and surveillance options.

248539 - Sexual function in BRCA mutation carriers: Impact of surgery and timing?

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Background/Objective: Deleterious BRCA mutation carriers (BrMC) face choices in managing cancer risk, which may impact their quality of life. Our study aims to compare the surgical choices and sexual function of BrMC with and without breast cancer.

Methods: An anonymous, cross-sectional survey was conducted electronically. The survey was emailed to the BrMC identified from our genetic counseling database and included the Female Sexual Function Index (FSFI) as well as investigator-generated questions regarding demographics and prophylactic choices with respect to mutation and surgery. Non-responders received 2 additional survey invitations. Statistical analysis was performed using Fisher's exact and the Wilcoxon rank-sum tests. Respondents were analyzed in total, and divided in to 2 subgroups, those with and without a breast cancer diagnosis.

Results: Out of a database of 432 BrMC, 170 valid email contacts were identified. Sixty-six BrMCs completed the survey (39% response rate) with a median age of 50 (range 18 - 79). Postmenopausal status was reported in 77.2%, bilateral salpingo-oophorectomy (BSO) reported in 81.2%, and history of ovarian cancer in 11.5%. These were evenly distributed among subgroups. In the 32 BrMCs without breast cancer, prophylactic nipple-sparing mastectomy was chosen by 21.9%, which was significantly higher for BRCA1 vs BRCA2 carriers (42 vs. 6%; p=0.048). Overall, FSFI was not significantly different between those choosing prophylactic mastectomy versus high-risk screening (30.75 vs 26.2, p=0.25). Notably, median FSFI was higher in the prophylactic mastectomy group compared to BrMCs undergoing mastectomy with a cancer diagnosis (30.75 vs 23.6; p=0.16). Finally, there was not a significant difference in the role of the chest during intimacy between those choosing prophylactic surgery and high-risk screening.
Conclusions: In a small sample size, choice of prophylactic surgery or high-risk screening was not associated with a significant difference in sexual function or the chest as part of intimacy. However, sexual function was much lower in patients with a cancer diagnosis than those choosing prophylactic surgery. These results may help physicians counsel patients regarding decision-making in the timing and receipt of prophylactic surgery.

257294 - Differences among a modern cohort of BRCA mutation carriers choosing bilateral prophylactic mastectomies compared to breast surveillance

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Background/Objective: Women with a deleterious BRCA mutation have a 40-80% lifetime risk of breast cancer and can reduce their risk by >90% with risk reducing surgery. We sought to compare a modern cohort of women with a BRCA mutation choosing bilateral prophylactic mastectomies (BPM) vs breast surveillance to better elucidate factors impacting decision making among this high-risk group.

Methods: We retrospectively identified women with a known BRCA 1 or 2 mutation from a prospectively maintained single-institution database. The surveillance cohort (n=313) consisted of women seen in a high-risk clinic for physical exam and imaging between 2014-2016 and the surgery cohort (n=142) consisted of mutation carriers who underwent BPM between 2010-2016. Women with a previous breast cancer diagnosis or a variant of unknown significance were excluded. Clinical and familial factors were compared between the 2 groups. To test for differences, the Kruskal-Wallis test was used for continuous variables and Fisher's exact test for frequency and percent with categorical variables.

Results: Women choosing surgery were more likely to have a BRCA1 than a BRCA2 mutation compared to the surveillance group (57% vs 43%, p=0.015) and were less likely to have a personal history of ovarian cancer (10% vs 20%, p=0.01). There was no difference in the age at genetic testing between the groups (40 vs 39 years, p=0.6). Median age at BPM was 43 years (range 21-67); median age at last surveillance visit 46 years (range 21-87). Women undergoing BPM were more likely to be married (78% vs 62%, p=0.01), to have more children (median 2 vs 1, $p < 0.001$), and to have undergone a prior prophylactic oophorectomy (61% vs 37%, $p < 0.001$). In regards to family history, women choosing BPM had more first-degree relatives with a history of breast cancer (63% vs 48%, p=0.01) or a sister with breast cancer (23% vs 14%, p=0.02), and were more likely to have a young family member with ovarian cancer. Nearly all women in both groups have had MRI screening (96%), although those in surveillance

have had more recent breast MRI and more MRIs recommending short-term follow-up (32% vs 20%, p=0.005). Women in the surgery cohort were more likely to have had an MRI recommending additional imaging to evaluate a suspicious finding (9% vs 2%, p=0.02). There was no difference in the number of prior breast biopsies, history of atypia/LCIS, or current/prior use of chemoprevention. Significant findings are shown in the Table.

Conclusions: A significant number of women with BRCA mutations choose to undergo surveillance rather than prophylactic surgery. Marital status, personal history, and family history of cancer appear to be important factors in decision-making. Overall, the decision appears multifactorial, and emotional experiences and relationships rather than breast abnormalities are likely the main driving factors.

Variable	Surveillance (N=313)	Surgery (N=142)	P-Value
Personal Characteristics			
Genetic Mutation			0.015
BRCA1	140 (45%)	81 (57%)	
BRCA2	173 (55%)	61 (43%)	
Marital Status (n=441)			0.01
Married	194 (62%)	111 (78%)	
Divorced/separated/ widowed	23 (7%)	5 (4%)	
Single	83 (27%)	25 (18%)	
Parity, median (range)	1 (0, 6)	2 (0, 5)	<0.001
Personal history of ovarian cancer	62 (20%)	14 (10%)	0.01
Personal history of prophylactic oophorectomy	115 (37%)	86 (61%)	<0.001
Age at prophylactic oophorectomy, median (range)	49 (32, 69)	43 (31, 65)	0.001
BMI, median (range)	23.8 (16.3, 48.5)	25.0 (18.1, 47.4)	0.022
Family History			
Number of first degree relatives with breast cancer (n=453)			0.011
0	161 (51%)	52 (37%)	
1	130 (42%)	79 (56%)	
>1	21 (7%)	10 (7%)	
Sister with breast cancer (n=453)	45 (14%)	33 (23%)	0.022
Relative with ovarian cancer diagnosed under age 40 (n=451)	11 (4%)	12 (9%)	0.027
Imaging			
MRI ever recommending short term follow-up	99 (32%)	28 (20%)	0.005
MRI ever recommending additional imaging	6 (2%)	13 (9%)	0.002

Significant differences among BRCA mutation carriers undergoing breast surveillance vs risk reducing surgery

257134 - Breast surgeon consultation with remote genetic counselor improves clinical decision-making

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Background/Objective: Breast surgeons have been ordering and counseling patients for BRCA1/2 testing for 20 years, but genetic testing is rapidly expanding – both in demand and the genes tested. ASBS Consensus guidelines recognize that breast surgeons are ideally positioned to provide access and counseling, but acknowledge that support by genetic counselors is beneficial in some circumstances. Genetic counselors (GCs) are an invaluable but limited resource with variable supply across the country. This study is designed to determine if remote GC access impacts physician decision-making for appropriate patient selection, genes tested, and clinical management.

Methods: A multi-center prospective study involved 14 community-based breast cancer physicians experienced with hereditary cancer counseling, testing, and interpretation of the results and who did not have a genetic counselor as part of their practice. Physicians identified genetic testing candidates and discussed each case with a remote GC to evaluate appropriate patient selection and appropriate gene panels ordering. Physicians could review cases with GCs after test results were received and prior to conducting patient counseling. Pre- and post-test surveys were completed for each patient by the testing physician. Data gathered included utilization of guidelines, change in genes tested after GC consult, and reasons for post testing GC consultation. A standard pricing fee regardless of panel size or genes selected was employed for this study.

Results: A total of 249 patients were evaluated with a median age of 51. A recent diagnosis of breast cancer was reported in 61% of the patients. Reasons for genetic testing included: surgical planning (42%), management of family members (45.3%), and a family history of cancer (69.8%). Risk assessment was performed on 97% of patients. NCCN genetic testing guidelines were utilized in 66% of patients. A gene panel of > 20 genes was used 55% of the time. Physicians changed their test selection after conferring with GC 18% of the time including: 26% ordering larger panels due to family history; 23% after better understanding of testing options; 51% comfort with appropriateness of panel (larger or smaller). Physicians sought post-test consultations 41% of the time: 28% for management plans; 27% for implications of variants of uncertain significance; 26% for issues related to negative findings. Post-test remote GC consultation resulted in a meaningful change in patient management 16% of the time.

Conclusions: Community-based breast specialists are assessing risk and generally using guidelines to select appropriate patients for genetic testing. Remote genetic counseling support helps physicians choose the best gene panel test, aids in counseling challenging cases, and impacts clinical management. Remote genetic counseling appears to be an efficient use of this valuable resource and may provide a model for “as needed” or “on demand” genetic counseling as genetic testing volume and use of expanded panels grows rapidly.

257142 - Hereditary cancer risk: A growing body of evidence supporting broader testing

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Background/Objective: Breast surgeons play an active role in genetic counseling and testing of both affected and unaffected patients at increased risk for breast cancer. Traditionally, NCCN guidelines have been the primary reference for selecting appropriate patients to test for hereditary breast cancer. The recent lower cost of testing and the availability of multigene panels have increased the willingness of patients to be tested. We undertook a study to determine the current genetic testing practices of community breast surgeons and the impact of physician access to remote genetic counselor (GC) consultation. While the goal of this study was to understand if physician access to remote clinical consultation with a genetic counselor would impact identification of candidates for testing, incidental findings raise the question about the current validity of NCCN guidelines. Results indicate that the use of traditional NCCN guidelines may underestimate those at risk for deleterious mutations.

Methods: A multi-center prospective data collection was performed that included 14 community-based breast cancer physicians experienced with genetic counseling and testing. Patients were identified as candidates for genetic testing based on patient's perceived and actual risk for hereditary breast cancer as part of standard of care. Surveys were completed before and after testing. Surveys included questions about utilization of guidelines and test results. A standard pricing fee regardless of panel size or genes selected were employed for this study, which eliminated cost as an issue in gene panel selection.

Results: A total of 249 patients were tested, with a median age of 51. Risk assessment for breast cancer and genetic mutations was done on 97% of patients utilizing various models including Tyrer-Cusick, BRCAPRO, Hughes Risk App, and NCCN guidelines. Genetic testing was considered because of a recent diagnosis of breast cancer (61%), to guide treatment decisions (42%), and/or strong family history of breast cancer (69%). Patients met NCCN guidelines for genetic testing 66% of the time, and the majority of patients (55%) were tested for > 20 genes (3% BRCA1/2 only testing). Patients under 50 had deleterious mutations 14.7% of the time; patients over 50, 12.6% of the time. In patients < 50 there was a higher percentage of patients with BRCA1/2 mutations (47% vs 37.5%). Looking at the entire group, 14% had a positive result for a deleterious mutation, 26% had a variant of uncertain significance (VUS), and 61% were negative. The most common positive findings were BRCA1, BRCA2, and CHEK2. Among the patients who met NCCN criteria for testing, 12.7% had deleterious mutations (50% of which were BRCA1/2), while of patients who did not meet NCCN criteria, 11.3% had deleterious mutations (33% of which were BRCA1/2).

Conclusions: Patients who did not meet NCCN genetic testing guidelines had a similar percentage of deleterious mutations as the patients who met the guidelines. This could be partially accounted for by the expanded numbers of genes tested since there were a higher number of BRCA1/2 deleterious mutations in the patients who met the guidelines. With the decrease in testing costs, perhaps guidelines for genetic testing should be re-evaluated, expanded, or completely removed. The downstream benefit to the many relatives of an affected individual should also be a consideration. A large study testing all patients who present with breast cancer is underway.

257069 - Preoperative panel testing for hereditary cancer syndromes does not significantly impact time to surgery for newly diagnosed breast cancer patients as compared to BRCA1/2 testing

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Background/Objective: Genetic testing is an important component of the preoperative work-up in patients at high risk for hereditary breast cancer and has been incorporated into NCCN guidelines. Options for genetic testing include multi-gene panels as well as traditional BRCA 1/2 assays. This study seeks to determine if there is a delay in time to surgery for newly diagnosed breast cancer patients undergoing panel testing as compared to traditional BRCA1/2 testing.
Methods: A retrospective review was performed of all women newly diagnosed with breast cancer who underwent genetic evaluation for hereditary cancer syndromes using our institution's Genetic Counselor Database from January 2013 to August 2015. The data was reviewed for date of pathologic diagnosis of breast cancer, date of genetic evaluation, and date of surgery. Type of surgical procedure (breast conservation vs mastectomy) as well as cancer stage was also recorded. Patients were excluded if they were male, pathologic/surgical information was unavailable, if the patient underwent neo-adjuvant chemotherapy, or genetics evaluation was performed after the surgical date.

Results: Of the 649 patients in our database, 138 patients met inclusion criteria. During the time period studied, the use of genetic panels increased from 7.7% of patients tested in 2013 to 48.3% in 2015 ($p=0.002$). The time from diagnosis to surgery for BRCA1/2 test patients was 43.5 days compared to 51.0 days in the panel group ($p=0.186$). Age, tumor stage, and use of preoperatively MRI was not statistically significant different between groups. The rate of mastectomy was not statistically significant between the 2 groups (BRCA1/2 -31.4% vs panel group- 37.7%, $p=0.322$). Turnaround time for genetic testing decreased during the time period studied, and was approximately 6 days longer for panel testing than BRCA1/2 testing. On average, it took 12.2 days for BRCA 1/ 2 results and 18.9 days for the panel ($p < 0.01$). In 2014 and 2015, the turnaround time for BRCA1/2 testing was 12.4 and 10.5 days respectively, whereas for panel testing the turn around time was 20.5 and 18.2 days respectively ($p= < 0.001$). In the BRCA 1/2 group there were 2 (2.3%) positive tests (BRCA1 X1 and BRCA2 X1) and 3 (3.5%) VUS (BRCA2 X 3 patients). In the panel group, there was 1 (1.9%) positive test (BRCA1+), and 8 VUS were seen in 6 patients (11.5%). A multiple linear regression analysis was performed looking at factors associated with time to surgery including tumor stage, MRI, use of mastectomy, and type of genetic test performed. Regression analysis significantly predicted time to surgery ($R2=.07$, $F(4,132) = 3.431$, $p < .01$). Of the 4 variables included, only mastectomy significantly contributed to the model ($B=.29$, $p < .001$).

Conclusions: In our cohort, panel genetic testing did not statistically delay time to surgery compared to BRCA 1/2 testing alone. The use of panel testing for hereditary cancer syndromes has increased over time, and the lab turnaround time has also decreased for panel testing. Surgeons should not be discouraged from use of genetic panel testing preoperatively as there is no clinically significant delay in surgical timing.

Preoperative Panel vs BRCA 1/2 testing for Genetic Predisposition to Cancer					
	BRCA 1/2	Percentage	Panel Test	Percentage	p value
Number of patients					
2013	24	92.3%	2	7.7%	
2014	32	59.3%	22	40.7%	0.002*
2015	30	51.7%	28	48.3%	
TOTAL	86		52		
Tumor stage					
0	22	25.6%	9	17.3%	
1	40	46.5%	29	55.8%	
2	23	26.7%	11	21.2%	0.228
3	1	1.2%	3	5.8%	
Mastectomy rate					
	27	31.4%	20	37.7%	0.322
MRI performed					
	63	73.3%	31	59.6%	0.113
Time to surgery (days)					
	43.5		50.9		0.186
Lab test turnaround time (days)					
2014	12.4		20.5		
2015	10.5		18.2		
TOTAL	12.2		18.9		<0.001*

*p value <0.05

257368 - Expanded gene panel utilization in women with breast cancer: Identification and intervention beyond breast cancer risk

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Background/Objective: Clinicians ordering multi-gene panels to assess hereditary breast cancer risk face a growing variety of testing options ranging from pre-curated panels organized by cancer type to large, comprehensive panels. Although BRCA1 and BRCA2 (BRCA1/2) testing for hereditary risk among patients with breast cancer is well established, many panels include lesser known breast cancer genes or genes associated with other cancer types. Some of these genes lack established medical management guidelines, which raises challenges for patient counseling and care. We hypothesized that the use of broader gene panels results in improved identification of clinically relevant findings in genes not known to be related to personal or family history. Using a series of female breast cancer patients for whom next-generation sequencing panel testing through a commercial laboratory identified pathogenic (P) or likely pathogenic (LP) variants in cancer genes other than BRCA1/2, we sought to define clinician ordering patterns and compare the rates of P/LP findings in genes with established medical management guidelines.

Methods: We reviewed 1,085 sequential cases of women with breast cancer who had P/LP findings in genes other than BRCA1/2. De-identified personal and family history information provided by ordering clinicians was analyzed, and 3 subgroups were created by test order type: (A) breast-cancer-associated genes only, (B) genes associated with commonly assessed cancer types (including breast, gynecologic, and gastrointestinal), and (C) large, comprehensive panels with expanded tumor types. Within each group, we determined how often P/LP findings occurred in genes with professional society management guidelines and whether the findings were consistent with the reported personal and family histories.

Results: Among the 1,085 cases reviewed, 1,131 P/LP variants were identified, with 44 patients having 2 or more variants. The table shows the number of patients tested within each panel type (group A, B, or C). These data compare variants identified in genes associated with breast and non-breast cancers for which management guidelines exist. Interestingly, a substantial proportion of P/LP variants were

identified in genes for which patients had no associated personal or familial histories. Overall, 92.3% of variants identified in this cohort were in genes associated with medical management guidelines.

Conclusions: In our cohort of 1,085 breast cancer patients, 85.6% were tested with broader panels addressing risk for multiple cancer types (Groups B and C). Expanded panel testing allowed for improved identification of hereditary cancer risk in patients and their family members. While others have shown that pathogenic variants in non-BRCA genes are rare, our data show the majority of these variants are associated with medical management guidelines which may alter clinical care. Additionally, breast cancer-specific panels may miss clinically actionable findings in genes associated with hereditary predispositions for other cancers. Further analysis is needed to determine the clinical impact and patient outcomes associated with the identification of P/LP variants in non-BRCA1/2 genes.

	Group A: Breast cancer-only panels	Group B: Common cancer panels (incl. breast, gyn, GI)	Group C: Expanded panels (incl. all/rare tumor types)
Patients (n)	156	788	141
P/LP variants	Total: 158	Total: 825	Total: 148
Breast mgmt. guidelines	154 (97.5%)	525 (63.6%)	74 (50%)
Other mgmt. guidelines		235 (28.5%) 110 (46.8%) (unrelated to personal/fam hx)	47 (31.8%) 22 (46.8%) (unrelated to personal/fam hx)
P/LP variants in genes without medical management guidelines	4 (2.5%)	65 (7.8%)	27 (18.2%)

Comparison of variants identified by test order type. LP, likely pathogenic; mgmt., management; P, pathogenic

257091 - Molecular receptor profiles in male mutation carriers with breast cancer

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Background/Objective: The importance of cancer genetic testing in patients with breast cancer is growing, and its significance extended with the discovery that inherited mutations are now targets for therapeutic interventions. BRCA2 mutations have been previously reported to predominate among men with breast cancer. Recently, sequencing tests have expanded to cover a large panel of genes. We analyze here tumor molecular profiles of 40 men with breast cancer who also underwent germline genetic testing and counseling for inherited mutations in breast cancer susceptibility genes.

Methods: Our institutional Cancer Genetics Research Database was queried for cases of breast cancer in men. All patients were consented prior to undergoing genetic testing. A variety of commercial tests were used, some including massively parallel sequencing of breast cancer-associated genes including ATM, BRCA1, BRCA2, CDH1, CHEK2, NBN, NF1, PALB2, PTEN, STK11, and TP53. The associated pathology records of these patients were reviewed to abstract the molecular profile (ER, PR and HER2 receptors) of each of these cancers.

Results: Ten (25%) of the 40 cases identified were found to carry deleterious germline mutations. BRCA2 mutations occurred in 5, with 1 man having bilateral metachronous cancers. All BRCA2-associated

cancers were strongly ER-positive/PR-positive/HER2-negative, except for 2 that were PR-negative and 1 case with equivocal HER2 expression (2+ by immunohistochemistry, IHC). Two men harbored ATM mutations, and their associated cancers were also ER-positive and PR-positive, with 1 HER2-negative another HER2-equivocal (2+ IHC). Of the 2 BRCA1-associated cancers, molecular biomarker data was only available in 1, with a triple-negative profile. Interestingly, 1 male carrier of a CDH1 mutation was diagnosed with an ER-positive/PR-positive/HER2-negative invasive lobular cancer, as is typical of women with CDH1 mutations.

Conclusions: Inherited mutations are highly prevalent among men with breast cancer who present for clinical genetic testing. These are predominantly BRCA2 and are associated with an ER-positive/PR-positive/HER2-negative molecular receptor profile.

256628 - Clinical decision-making in patients with variant of unknown significance in BRCA 1 or 2 genes

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Background/Objective: How diagnosis with a variant of unknown significance (VUS) in a BRCA gene impacts clinical decision-making is not well known. Limited prior studies have shown VUS patients experience less cancer distress reduction than BRCA negative patients. We sought to explore surgical decision-making in patients diagnosed with BRCA VUS and evaluate factors influencing this.

Methods: With IRB approval, we identified all patients who underwent genetic testing at our institution and tested positive for a VUS in the BRCA 1 or BRCA2 genes between 2004 and 2016. Retrospective chart review was performed to obtain clinical data. We further queried the commercial genetics public databases for BRCA1 and BRCA2 variants including ClinVar, BRCA Exchange, and BRCA1 and BRCA2 LOVD, all of which adhere to ENIGMA consortium rules for variant classification. Groups were compared using Wilcoxon rank-sum and chi-square tests.

Results: We identified 97 patients (95 female, 2 male) with BRCA VUS. At the time of VUS identification, 20 had no current or prior breast or ovarian cancer, 67 had current or prior breast cancer, 9 had ovarian cancer, and 1 both breast and ovarian cancer. In the 20 patients without current or prior breast or ovarian cancer at time of VUS identification, the median Tyrer-Cuzick (IBIS) lifetime breast cancer risk score was 27% (range: 16-62%), and median Gail score (lifetime risk) was 20% (range: 7-43%). The median number of relatives with breast cancer was 3 (range 1-6) with 16/20 (80%) patients having a mother or sister with breast cancer. Management in 7 (35%) VUS carriers was by bilateral prophylactic mastectomy (BPM) (1 before and 6 after VUS were identified), 1 (5%) by chemoprevention, 3 (15%) by additional screening with MRI or MBI, and 9 (45%) by routine surveillance. Additionally, 5 (25%) opted for risk-reducing bilateral salpingo-oophorectomy (BSO) (1 before and 4 after VUS were identified). Choice for BPM was significantly associated with IBIS score (median 32% vs 24%, p=0.02) and first-degree family history (44% versus 0%, p=0.05) but not Gail score or number of family members with cancer. Of 67 patients who had breast cancer, VUS was known prior to initial surgery in 10 patients – 5 (50%) elected lumpectomy, 2 (20%) unilateral therapeutic mastectomy (TM), 2 (20%) TM and contralateral prophylactic mastectomy (CPM), and 1 (10%) underwent bilateral TM for bilateral cancer. In the 57 patients with breast cancer surgery preceding VUS identification, 24 (42%) had lumpectomy,

10 (18%) unilateral TM, 17 (30%) TM+CPM, 1 (2%) lumpectomy converted to TM+CPM, 4 (7%) bilateral TM for bilateral cancer, and 1 (2%) had no breast surgery (due to stage IV disease). Thus, rate of CPM at initial surgery did not differ significantly between those where the VUS was identified prior to versus after surgery (20% vs 32% respectively, p=0.45). An additional 3 patients underwent delayed CPM after VUS identification; 2 initially underwent lumpectomy but required delayed TM for margin control and had CPM at that time, and 1 who initially underwent TM opted for delayed CPM after VUS identification. Additionally, 18/67 (27%) breast cancer patients opted for risk reducing BSO (2 before and 16 after VUS identification). Breast cancer patients with VUS had a median of 2 family members with breast cancer (range 0-9), and 45% had a mother or sister with breast cancer. Choice for CPM after VUS was not significantly associated with number of relatives with breast cancer (p=0.62) or presence of first-degree family history (40% vs 49%, p=0.71). No patient with ovarian cancer underwent prophylactic mastectomy. Of the 97 mutations initially identified as VUS, 20 (21%) have been subsequently reclassified to benign or likely benign and 1 (1%) to pathogenic or likely pathogenic.
Conclusions: Patients with BRCA VUS had strong family history and elevated IBIS and Gail risks. BRCA VUS carriers with cancer elected surgical choices similar to average-risk breast cancer patients. VUS carriers without cancer had high rates of BPM, and this appeared to be influenced by first-degree family history and IBIS score. Over time, a significant proportion of BRCA VUS were reclassified, the majority as benign, illustrating the advances in knowledge and importance of appropriate counseling regarding VUS.

Imaging

256553 - Assessment of skin involvement in breast cancer: Preoperative ultrasound and anatomopathological correlation

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Background/Objective: The removal of the overlying skin carcinoma is often unnecessary and can compromise the aesthetic result of breast surgery. In the presence of an anterio- located breast carcinoma, the distance between the lesion and skin is an important factor in the decision to remove or preserve the skin overlying the tumor. Ultrasound (US) could be a good tool for this purpose; however, the shrinkage observed in this method is difficult to properly assess the obtained measures. Objectives: To correlate the tumor-skin distance obtained from ultrasound and pathological (Path) examinations and establish a relationship between these parameters.

Methods: This study was a prospective correlational study of 39 consecutive women presenting 41 breast tumors who were diagnosed with invasive cancer and were candidates for conservative or radical surgery. The distance between the tumor and skin was measured using preoperative US examinations and an anatomopathological evaluation. US examination was performed independently by 2 breast surgeons specializing in breast cancer diagnosis. Each observer performed 3 different measurements of the area, and the average of these 3 distances was recorded as the final value, just as done in Path evaluation. All patients underwent surgery which invariably included the removal of the skin overlying the tumor.

Results: The mean distance between the tumor and skin obtained from the US examinations was 0.8 cm, with a minimum of 0.15 cm and a maximum of 2.43 cm. The Path examinations yielded a mean

distance of 2.21 cm, with values ranging from 0.5 to 5.0 cm. The Pearson correlation coefficient between the methods was r = 0.75.

Conclusions: The tumor-skin measurements obtained from US examinations correlated well with those obtained from Path examinations. The distance obtained by sonography was consistently less than that obtained from a pathology specimen, and the average difference was 3.1-fold. Overall, the Path distance between the tumor and skin can be estimated using the following model: Dpathology = 0.69 + 1.89 x DUS, where D is distance.

Coefficients	Estimate	Standard Error	95% Confidence interval	p
Intercept	0.69	0.24	[0.21; 1.17]	0.006
US	1.89	0.27	[1.36; 2.43]	< 0.001

N = 41

Results of the simple linear regression model to estimate the histological distance between the tumor and the skin

256719 - View for view, 3-D specimen tomosynthesis provides more data than 2-D specimen mammography

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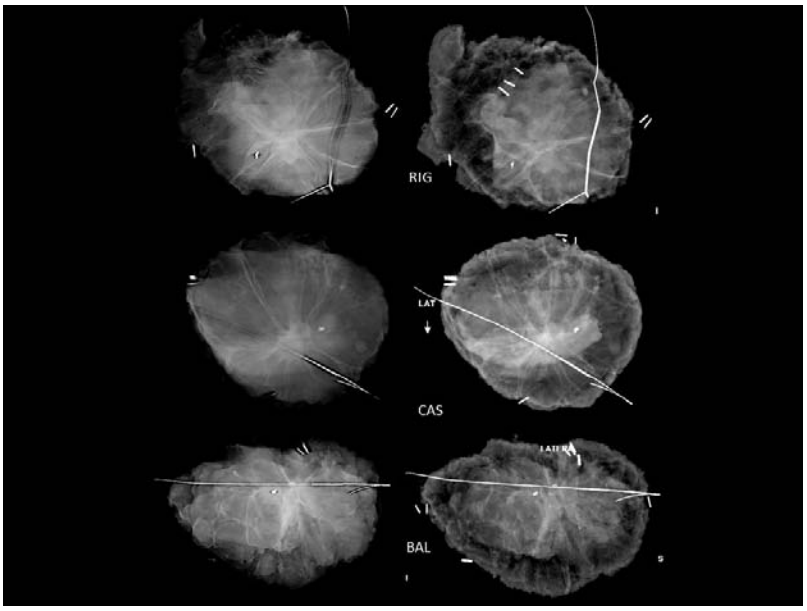
Background/Objective: Intraoperative digital specimen mammography (IDSM) has become the standard confirmation method to ensure an image-guided procedure has removed the targeted breast lesion. We've seen improvements in camera acuity, faster processing, and larger fields of view to facilitate the surgeon's identification of non-palpable cancers. To obtain the so-called three-dimensional view (3-D), routine use of 2 orthogonal images has been utilized as a 3-D view. Yet in screening mammography, true 3-D mammography has now arrived as tomosynthesis, not simply 2 orthogonal MLO and CC views of the breast. Likewise, for specimen imaging, true 3-D mammography is specimen tomosynthesis, not 2 orthogonal views using a 2-D machine. We report our current findings on the enhancement of specimen imaging provided by true 3-D intraoperative specimen tomosynthesis (IDST).

Methods: Between April 2015 and October 2016, we have obtained specimen imaging on 210 consecutive image-guided breast lumpectomies using 2 specimen imaging machines. One provided IDSM, and the other provided IDST. Two orthogonal views of each specimen were taken with each machine. For patient management, intraoperative review of all images was available to the operating surgeon for their immediate action as appropriate. Comparison data was accumulated as to ease of use, time to first image, handling issues, re-excisions, mechanical issues, as well as image comparisons. Images of breast lesions were categorized into 3 groups by their dominant findings: 1) densities, 2) calcifications and 3) clips. All images were forwarded from the operating room to the radiologists and permanent recording via standard PACS system.

Results: The circulating nurse received the specimen from the surgeon and placed it sequentially in each of the machines in the exact same orientation. For equal comparisons, 2 orthogonal views were taken with each device, although the use of tomosynthesis obviates the need for 2 orthogonal images since the Z-axis is visible on a single image. Functionality of the 2 machines were very similar. Time to first image was prompt although there was a difference in the developing time for the IDST, being almost twice as long as IDSM (65 seconds vs. 32 seconds). Of the 210 patients, specimen images were classified into 61% densities, 26% clips, and 13% calcifications. The primary difference in imaging was found in the

density group. In 70% of patients with densities or spiculated lesions, the IDST provided more information than the IDSM. It was possible to see the target lesion more often with IDST than IDSM. Comparing the same image orientation, overlapping tissue was avoided and spiculations could be seen more easily using IDST (see Figure). Looking at all 210 lesions as a group, IDST was more precise in 43% of all lesions examined. This was reflected over the time of the study as surgeons would only look at the IDST to assess their intraoperative excision accuracy and need for immediate re-excision.

Conclusions: Use of specimen tomosynthesis in the operating room has improved the accuracy of intraoperative imaging in 43% of cases. By improved visualization of the cancer, surgeons can be sure they have removed the target lesion and not only the clip. Further use by others should validate these early findings.



Compare each pair and identify the 2-D vs.the 3-D image

256730 - Risk factors for volume and surface asymmetry after breast-conserving therapy as measured using 3-dimensional surface imaging

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Background/Objective: Previous studies have shown that post-treatment psychological well-being is associated with aesthetic outcome after breast-conserving therapy (BCT). Surgeons and radiation oncologists must provide patients with the best quality care and information. Understanding the risk factors for a poor aesthetic outcome is crucial in planning the surgical strategy and managing patient expectations. Risk factors have been identified in the past with patient satisfaction and panel assessment of photographs as the outcome measures, but these both have limitations. The advent of 3-D-surface imaging (3-D-SI) allows objective measurement of appearance such as symmetry of volume

and surface shape. Hypothesis: Risk factors for poor volume and surface symmetry can be identified using 3-D-SI Aim: To identify risk factors for poor volume and shape symmetry after BCT as measured by 3-D-SI.

Methods: Ethical approval was obtained. Two hundred women who had unilateral BCT 1-6 years ago were recruited at the time of surveillance mammogram. Participants underwent 3-D-SI. Volume symmetry was calculated by dividing the volume of the smaller breast volume by the larger breast and expressing as a percentage. Surface symmetry was calculated by reflecting the 3-D image of 1 breast onto the other through the sagittal midline plane. The root mean squared of the distances between the 2 images was calculated. Univariate linear regression analysis was used to identify clinicopathological variables with a p-value < 0.1 which were entered into a multivariate model with a 5% significance level.

Results: During the study period, 649 women had mammography. Of these, 342 (52.7%) were eligible and visited at a time when the main investigator was available. They were invited by letter. It was not possible to contact 109 (31.9%) women to confirm participation. Twenty-seven (11.6%) declined, and 6 women did not attend. In total, 200 women participated. Mean age was 64.2 years (SD 10.1), mean time from surgery to participation was 35.5 months (SD 17.7). One hundred eighty-six (93%) were Caucasian British, mean BMI was 27.5kg/m2 (SD 5.4), mean ultrasound size of tumour was 13.9 mm (SD 8.6), median specimen weight was 32.5 g (IQR 20-49). Median volume symmetry was 87% (IQR 78-93) and surface symmetry was 5.87 mm (IQR 4.23-7.95). On multivariate analysis, independent factors for poor volume symmetry were specimen weight and experience of operating surgeon. Independent factors for poor surface symmetry were specimen weight, BMI, and pathological tumour size (Table).

Conclusions: This is the first study to use objective 3-D objective measurements to identify risk factors for poor volume and shape after BCT. These results concur with previous studies in which volume excised (or its surrogate such as tumour size, specimen weight) has been identified as a risk factor. Our findings confirm the importance of this risk factor and remind surgeons that carefully planned, targeted excision is essential. We believe that high BMI may be a risk factor either because larger-breasted women suffer from greater radiation-induced fibrosis and shrinkage or because these women may have been dissatisfied with their appearance prior to treatment, but a longitudinal study is required to assess this. We believe less experienced surgeons may take larger specimens, particularly for impalpable lesions because they have not yet fully developed their 3-D orientation and may be more risk averse regarding positive margins. Closer supervision may, therefore, improve outcome.

Variable	Constant (95% CI)	Coefficient (95% CI)	P value
VOLUME SYMMETRY (%)			
Weight of specimen (g)	87.6 (85.1 – 90.1)	-0.05 (-0.08 - -0.01)	**0.010**
Level of operating surgeon			
Consultant			
Trainee supervisor scrubbed		-6.27 (-10.24- -2.3)	**0.010**
Overall			**0.005**
SURFACE SHAPE SYMMETRY (mm)			
Weight of specimen (g)	1.9 (0.0 – 3.8)	0.02 (0.02 – 0.03)	**<0.001**
BMI at time of surgery (kg/m2)		0.10 (0.03 – 0.17)	**0.003**
Pathology size (mm)		0.04 (0.01 – 0.06)	**0.014**

Multivariate analysis results for the independent risk factors for poor volume and surface shape symmetry

257038 - The added value of radiologic reviews: Additional cancers and avoiding false positives

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Background/Objective: It is standard practice at our institution to review all breast imaging performed at outside institutions prior to patients undergoing image-guided biopsies or surgery. To date, there is limited data in the literature examining the change in management as a result of these reviews. This study was undertaken in order to examine the effect of these radiology reviews on clinical management.

Methods: A retrospective chart review of all imaging consultations from January 1, 2013 to October 30, 2016 was performed. This study includes 540 women who had outside mammograms and breast ultrasounds re-read by dedicated breast imagers at our institution. With respect to the initial outside report, the consultation reports were then classified as concordant, with no further work up needed, or as discordant, with additional imaging and/or biopsy recommended. If a biopsy was performed, the results were then grouped based on the final pathology findings. Patients were excluded if their imaging review or surgical consultation was not complete.

Results: A total of 540 women were included in this study. Of these women, 452/540 (83.7%) had no change in their management and 88/540 (16.3%) had a change in their work-up. This included 39 (7.2%) women who were initially BIRADS 4, and after additional imaging, were spared an image-guided biopsy. An image-guided biopsy was performed in 17 women (3.1%), and pathology was benign. Additional imaging followed by an image-guided biopsy with a high-risk finding was diagnosed in 12 women (2.2%). New or additional areas of breast cancer were identified in 20 women (3.7%) who underwent a biopsy, based on our additional imaging and recommendations. A total of 25 biopsies were performed in these 20 women, and 6 had a new diagnosis of contralateral breast cancer. In addition, 4 were found to have axillary metastases after additional work-up upon review of their imaging.

Conclusions: Based on official review of breast imaging and additional evaluation, 42 (7.8%) patients did not have a biopsy as originally recommended by an outside facility. This avoided a false positive finding in a substantial number of women. Additional areas of breast cancer were diagnosed in 3.7% of these women. Of the women with a new diagnosis of breast cancer in this study, review of outside breast imaging led to a diagnosis of contralateral breast cancer in 6/20 patients (30%). Review by dedicated breast imagers should be strongly considered and incorporated into practice based on the fact that overall management was changed in 16.3% of women.

234341 - Implementation of a community-based screening program for women at high risk for breast cancer

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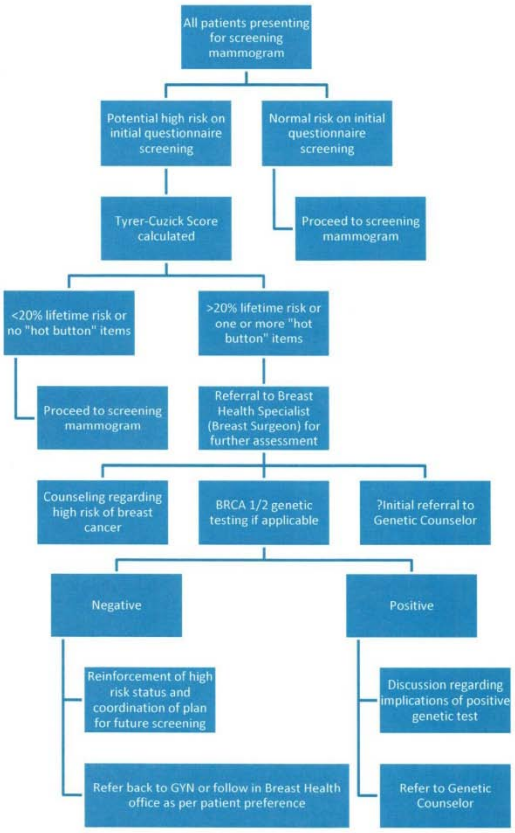
Background/Objective: Formal and enhanced screening programs for women at high risk for breast cancer have become prevalent across the country. These programs take many different forms but are usually located within and sponsored by larger academic cancer centers. The majority of susceptible women, however, present to community centers and hospitals, so that seems a reasonable site for such initial comprehensive screening. Nevertheless, such programs at the community level are relatively rare.

The current analysis describes the development and inauguration of such a program at a community health system in Philadelphia, PA.

Methods: In April 2016, a comprehensive program was initiated at at Aria-Jefferson Health System in Philadelphia, PA. This was formally structured to include multidisciplinary input and was organized and coordinated by the Surgical Breast Health Office under the direction of the Medical Director for Breast Health (a dedicated breast surgeon). Formal protocols and routing procedures were established and communicated prior to initiation of the program. Initial data were gathered for the first 6 months after initiation, which included number of patients screened, number of patients deemed high risk, percentage response from contacted patients, and cancellation rate for follow-up visits.

Results: Between April 1, 2016 and September 30, 2016, 5,715 patients were given an initial screening questionnaire to assess applicability for further testing. Of these, 842 (14.7%) were deemed applicable by initial screen and went on to formal Tyrer-Cuzick screening using a readily available and free online risk calculator. Two hundred fifty-two patients (29.9% of those screened by Tyrer-Cuzick) had a lifetime risk of greater than 20% or had a “hot button” risk item (e.g., personal history of breast or ovarian cancer at a young age; 2 or more first-degree relatives with breast cancer, 1 of which was at a young age). Initial attempt was made to contact this cohort of patients by phone; there was a 52.4% success rate in actually speaking with the patient. Of these, 64 patients (25.4% of those deemed to be at risk) agreed to be seen by the Breast Health Specialist (one of 2 dedicated breast surgeons). Unfortunately, 35.9% of those with appointments either cancelled or did not show for a variety of reasons. Those seen by the breast surgeon had genetic testing performed in the office, and after initial counseling, applicable patients were referred to a geneticist for further consultation.

Conclusions: There is a large cohort of patients presenting to a community health system who are potentially at increased risk for breast cancer. Thus, a comprehensive and inclusive screening program is essential at the community level. This functions well as a surgeon-led, multidisciplinary effort. The key to success in such a program is to assure that patients follow through with evaluation and testing as indicated, and that is best accomplished with the help of a dedicated Breast Health Navigator.



Screening protocol

256344 - Anxiety is not a barrier to screening mammography in younger women

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Background/Objective: Every year, a significant number of women under the age of 50 die of breast cancer, accounting for approximately 20% of all breast cance- related deaths. However, in 2009 the U. S. Preventive Service Task Force updated their criteria for women aged 40-49 to not recommend routine annual screening mammography in this population. Several organizations now recommend that imaging be delayed under the pretense that earlier screening will lead to more false positive tests, unnecessary biopsies, and significantly increased patient anxiety. False-positive mammography can cause anxiety, distress, and other psychological effects, but these findings have been documented to be transient. This study was designed to evaluate the anxiety caused by false positive mammography and to determine if it is a barrier to breast cancer screening. We plan to quantitatively measure the distress caused by having an abnormal screening mammogram and breast biopsy. Then we will determine whether the anxiety caused by a false positive mammogram and/or benign breast biopsy will become an obstacle to future screening mammography in those affected women.

Methods: The study cohort consisted of symptomatic and asymptomatic females recommended for breast biopsy at one of our 11 imaging sites. IRB approval was received and data was collected from May 1 – October 31, 2016. Using the National Comprehensive Cancer Network (NCCN) Distress Thermometer, the anxiety of each patient was quantified at 3 predetermined times during the breast biopsy process: 1. in person, after imaging, when a biopsy is recommended by a radiologist; 2. in person, just prior to biopsy which occurs after the patient has had a consultation with a breast surgeon; 3. via telephone, after pathology results are revealed to the patient by the breast surgeon. Finally, the patients were asked if they would have undergone screening mammogram, knowing they would have a benign biopsy. The inclusion criteria are females age 18 or older, breast biopsy recommended by a physician, any level of breast symptoms, BIRADS category 3, 4, or 5. Patients with a current diagnosis of breast cancer (BIRADS 6), personal history of breast cancer, history of dementia, or those who did not complete the biopsy process were excluded. Comparisons were done using two-sample t-tests, Wilcoxon rank sum tests, and chi-square tests. Statistical significance was defined as $p < 0.05$.

Results: The sample population included 166 patients out of the 1,349 biopsies performed at our health system. All of these patients underwent screening mammogram, diagnostic imaging, and eventual biopsy; 89 were found to have benign results. After patients received the benign biopsy results, anxiety levels returned to baseline for almost every patient. The vast majority of these patients (84%) stated they plan to continue future screening mammograms even after experiencing a false positive mammography. The patients age 40-49 were evaluated (33), and the results were the same. Regardless of the transient anxiety they experienced, the majority (87%) would have still undergone screening mammography knowing they would require a biopsy.

Conclusions: Routine screening recommendations for younger women have recently undergone changes due to the high rate of false positive screening mammography and the concern for increased patient anxiety. This study confirms patients have increased anxiety with an abnormal mammogram. However, 84% of patients evaluated state they will continue to undergo screening mammogram even after having an abnormal mammogram leading to a benign biopsy. We were also able to assess the

transient anxiety caused by an abnormal screening mammogram and eventual benign breast biopsy, as the anxiety levels returned to normal after biopsy results are known. Based on these findings, anxiety is not a barrier to breast cancer screening in women 40-49. Future recommendations for women 40-49 should reconsider routine annual screening mammography, as patients' anxiety does not appear to be a barrier and mortality remains comparatively high.

256576 - Comparison of preoperative ABUS and MRI in newly diagnosed women with breast cancer

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Background/Objective: Women with newly diagnosed breast cancer may harbor additional sites of malignancy that are missed by mammography (MMG) in either the affected or contralateral breast. Supplemental imaging modalities, such as magnetic resonance imaging (MRI) or hand-held, whole-breast sonogram (US), add diagnostic value to MMG, but have many disadvantages that limit their widespread implementation. In women without a known diagnosis of breast cancer, automated whole breast sonography (ABUS), in addition to MMG, has been shown to double the detection rate for breast cancer as compared to MMG alone. The purpose of this study was to compare the overall sensitivity and specificity of ABUS to MRI for detection of ipsilateral and contralateral occult breast cancer in newly diagnosed breast cancer patients. ABUS has potential to provide a relatively inexpensive and well-tolerated alternative to MRI in women with newly diagnosed breast cancer.

Methods: This is a prospective single institution study enrolling women > 18 years of age from 2013-2016 with a new diagnosis of breast cancer. Participating women underwent both MRI and ABUS (Arm 1) or ABUS alone (Arm 2) if MRI was contraindicated or not tolerated. Occult lesions seen on supplemental imaging were evaluated by experienced breast radiologists and clinical correlation was used to determine the need for additional biopsy to document extent of disease, or change in the surgical plan to include excision of the additional lesion. We anticipated ABUS would identify at least 75% of the occult lesions identified by MRI.

Results: A total of 110 women diagnosed with breast cancer consented to receive supplemental imaging with either MRI+ABUS (Arm 1, n=91) or ABUS alone (Arm 2, n=19). There were 49 occult breast lesions detected by either ABUS or MRI (39 ipsilateral and 10 contralateral). Of the 49 occult lesions, 30 underwent additional percutaneous biopsy to document extent of disease. The remaining 19 were either presumed malignant or surgical excision with mastectomy was already planned, and further sampling was not clinically necessary. The sensitivity of ABUS and MRI to detect occult lesions was determined using McNemar's test. The sensitivity of ABUS to detect additional occult breast cancer in a woman with a known diagnosis of breast cancer is 18.2% (95% CI 7-64%). None of the occult lesions identified by ABUS alone that underwent a biopsy were malignant (n=3). Of the 14 biopsy-proven occult breast cancers found on MRI, only 2 were also seen on ABUS.

Conclusions: MRI is far superior to ABUS in the detection of occult foci of breast cancer when a woman has a known diagnosis of breast cancer. Many of the additional occult foci detected on MRI were not seen on ABUS. If MRI is contraindicated in a woman with a known cancer, ABUS could be used for supplemental imaging if indicated. However, the sensitivity of ABUS for occult breast cancer is significantly lower than MRI, and ABUS should not replace MRI for women who can tolerate that exam.

	Occult Lesions	ABUS		Total
		Detected/Positive	Not-detected/Negative	
MRI	Detected/Positive	2	38	40
	Not-detected/Negative	9	0	9
	Total	11	38	49

256736 - Accuracy of the MRI in the assessment of axillary lymph node involvement in women with breast cancer after neoadjuvant chemotherapy

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Background/Objective: Lymph node assessment after neoadjuvant chemotherapy (NeoCT) is important for the preoperative planning, particularly for cases with axillary metastases downstaging. This study aimed to estimate diagnostic accuracy of clinical examination (CE) and magnetic resonance imaging (MRI) in the prediction of lymph node status in women with breast cancer submitted to NeoC.

Methods: This is a cross-sectional study including 207 women with invasive ductal carcinoma treated between January 2006 and April 2016. Hormonal receptors and HER-2 status were determined by imunohistochemistry. All women were submitted to NeoCT with anthracyclines and taxanes concomitantly with by trastuzumab for those overexpressing HER2 and axillary lymphadenectomy. At the end of the treatment, all patients were clinically evaluated (CE) by 2 breast surgeons and post-chemotherapy MRI was performed in all patients (double reading by specialized radiologists in all cases). For both CE and MRI, we have estimated sensitivity (Se), specificity (Sp), positive (PPV) and negative predictive values (NPV), as well as overall accuracy (A) in prediciting lymph node status after neoadjuvant chemotherapy using pathology evaluation as the gold standard. Area under ROC curve and corresponding 95% confidence intervals (95% CI) were calculated for the entire group and also according to molecular subtypes.

Results: Age ranged from 25 to 79 years (median=49) and most women were Caucasian (64.7%). Most of patients presented with T2 tumors (44.4%), and 151 women (73%) had clinical N+ at baseline. Overall, CE had significantly lower Se than MRI, but higher Sp. However, both PPV and NPV were similar. In the stratified analysis according to molecular subtype, it was possible to notice that MRI had better diagnostic performance in the group of women with triple-negative breast cancer (PPV=81.8% and NPV=74.2%), being superior to CE in the prediction of lymph node involvement (MRI= area under ROC curve=0.725; CE=0.509) (Table).

Conclusions: Our results have shown that MRI is superior to clinical exam in the assessment of lymph node status in women with triple-negative breast cancer submitted to neoadjuvant chemoterapy. In the remaining subtypes, both CE and MRI presented similar results (low Se, area under ROC curve close to 0.50), showing that neither method is satisfactory to predict axillary lymph node status after neoadjuvant chemotherapy.

Category	Exam	Se (%) (95% CI)	Sp (%) (95% CI)	PPV (%) (95% CI)	NPV (%) (95% CI)	A (%)	Area under ROC curve (95% CI)
Overall (n=207)	CE	7.0 (3.1-14.4)	98.1 (92.7-99.7)	77.8 (45.2-93.7)	53.0 (46.1-59.8)	58.4	0.526 (0.497-0.554)
	MRI	30.0 (21.4-40.1)	85.0 (76.5-90.9)	65.2 (49.7-78.2)	56.5 (48.5-64.2)	54.1	0.575 (0.519-0.632)
Triple Negative (n=42)	CE	5.9 (0.3-30.8)	96.0 (77.7-99.8)	50.0 (9.5-90.5)	60.0 (44.6-73.6)	59.5	0.509 (0.439-0.579)
	MRI	52.9 (28.5-76.1)	92.0 (72.5-98.6)	81.8 (47.7-96.8)	74.2 (55.1-87.5)	76.2	0.725 (0.591-0.858)
Luminal (A or B) (n=77)	CE	7.8 (2.5-19.7)	96.1 (78.4-99.8)	80 (37.5-96.4)	34.7 (24.7-46.2)	37.7	0.520 (0.467-0.573)
	MRI	19.6 (10.3-33.5)	92.3 (73.4-98.6)	83.3 (50.9-97.1)	36.9 (25.5-49.8)	44.2	0.559 (0.484-0.635)
Luminal HER2+ (n=46)	CE	6.7 (0.3-33.9)	100.0 (86.3-100)	100.0 (5.5-100.0)	68.9 (53.2-81.4)	69.6	0.533 (0.468-0.599)
	MRI	26.7 (10.3-33.5)	77.4 (73.4-98.6)	36.4 (50.9-97.1)	68.6 (50.6-82.6)	60.9	0.520 (0.382-0.658)
HER-2 pure (n=21)	CE	12.5 (4.4-64.4)	100.0 (71.6-100.0)	100.0 (20.6-100.0)	65.0 (43.3-81.9)	66.7	0.562 (0.440-0.685)
	MRI	25.0 (4.4-64.4)	69.2 (38.9-89.6)	33.3 (6.0-78.6)	60.0 (32.9-82.5)	52.4	0.471 (0.264-0.678)

MRI and CE diagnostic accuracy measures according to molecular subtype

257448 - Breast cancer outcomes following MRI-based selection for mastectomy

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Background/Objective: Women who receive breast MRI for surgical planning for breast cancer are more likely to undergo mastectomy than women whose treatment plans are based on conventional imaging. Whether MRI-based selection for mastectomy is associated with better cancer outcomes is unknown. We performed a retrospective evaluation of preoperative MRI use and outcomes for women undergoing mastectomy.

Methods: The Enterprise Data Warehouse of Northwestern Medicine was searched for women diagnosed with breast cancer who underwent mastectomy. The use of preoperative MRI, clinical and therapy details, and outcomes data were extracted. Chest wall recurrence and distant recurrence were evaluated with Cox proportional hazards model, adjusting for tumor and treatment variables.

Results: There were 1992 women with invasive cancer or DCIS who underwent mastectomy between 2005-2015 (919 with preoperative MRI and 1039 without). With the exception of young age, the factors significantly associated with MRI use in multivariate analysis indicated favorable disease (white race, node negativity, and HER2 negativity). Mean follow-up time was similar (MRI group 56 months, no-MRI group 57 months, p=0.53). Postmastectomy RT use was higher in the MRI group than in the no-MRI group, (51.8% v 48.2%). Eighty-one women experienced a chest wall recurrence; the crude 5-year rate was 4.5% for the MRI group and 4.1% for the no-MRI group (p=0.041). The crude distant recurrence rate was 9.2% for the MRI group and 10% for the no-MRI group (p=0.78). In multivariate models that included key biologic and treatment variables, MRI use was not significantly associated with chest wall recurrence with HR=1.5, 95% CI 0.95, 2.37 (p=0.08), or with distant recurrence: HR=0.87, 95%CI 0.63, 1.19 (p=0.37).

Conclusions: The outcomes of women undergoing mastectomy following MRI are comparable to those who did not undergo MRI, despite apparently favorable profiles. Prospective data with long-term follow-up are needed to define the most appropriate utilization.

249342 - MRI mammography for evaluation of residual disease after excisional biopsy for breast cancer

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Background/Objective: Approximately 10% of patients with early breast cancer present to our institute after initial excisional biopsy performed at another hospital. The T stage and margin status are often not available. In this setting we sought to assess the utility of breast MRI in evaluating residual disease in patients after excisional biopsy on basis of morphology and kinetics

Methods: The medical records of 114 patients who underwent surgery for early breast cancer post-lumpectomy status from September 2010 to December 2014 were reviewed retrospectively. Sixty-seven patients underwent contrast-enhanced MRI before surgery and subsequently underwent either re-excision lumpectomy or mastectomy with histopathological correlation.

Results: About 67 patients were found eligible for study. The mean age of onset was 44.97 years [Range 28-70]. The ratio of Left: Right were 30:37. Thirty-eight patients were positive for residual disease on MRI - 27 underwent MRM or mastectomy, and 11 underwent BCS. Three patients were found to have multifocal and multicentric disease on MRI and none had a contralateral disease. Twenty-nine patients were negative for residual disease on MRI – 8 had residual disease on final histopathology report. The sensitivity and specificity of MRI for detecting residual disease were 77.14% and 65.62%. The positive predictive value of MRI was 71.05 and negative predictive value was 72.41.

Conclusions: Although post-surgical changes challenge assessment of residual disease, MR mammography is still useful in prediction of residual lesion after excisional biopsy for breast cancer. Hence, it should be considered in patients post-excisional biopsy

257345 - Impact of breast MRI use on surgical treatment of breast cancer

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Background/Objective: Studies have examined the utility of breast MRI in the management of breast cancer patients, and most found breast MRI increases the rate of mastectomy. Data is lacking as to whether MRI improves patient outcomes. The purpose of this study was to evaluate the effect of pre-operative breast MRI on the surgical management of breast cancer patients at a high-volume breast care center.

Methods: A retrospective chart review of breast cancer patients at Beaumont Health Royal Oak Breast Care Center from January 2007 – December 2015 was performed. Data was collected including, age, histology, laterality, type of biopsy, performance of MRI, lymph node surgery, and surgical treatment. We evaluated whether breast MRI had an impact on surgical treatment of patients with either ductal carcinoma in situ (DCIS), invasive ductal carcinoma (IDC), invasive lobular carcinoma (ILC), or a combination of IDC/ILC. We excluded patients who received neoadjuvant chemotherapy, with LCIS and missing information on MRI status, histology, or surgical treatment.

Results: A total of 3,572 patients with a diagnosis of breast cancer were evaluated. The average age was 60.9 years; 33.2% of patients had mastectomies, and 45.4% had preoperative breast MRIs. There were 905 patients in DCIS group, 2,320 in IDC group, 282 in ILC, and 65 in IDC/ILC group. The data is consistent with a common effect of breast MRI on mastectomy rates across the 4 histology levels [Breslow-Day p-value=0.7; OR 1.68; 95% CI for OR: (1.45, 1.94)]. Mastectomies were more common in women with breast MRIs compared to women without breast MRIs for DCIS (41.2% vs. 29.6%; OR=1.67: 95% CI: 1.25, 2.22) and IDC patients (38.3% vs. 26.4%; OR=1.74: 95% CI: 1.45, 2.08). Mastectomy rates were higher for patients with breast MRIs compared to patients without breast MRIs for both the ILC group (42.0% vs. 36.6%; OR=1.27: 95% CI: 0.67, 2.15) and IDC/ILC group (48.3% vs. 33.3%; OR=1.87: 95% CI: 0.61, 5.75).

Conclusions: Breast MRI increased mastectomy rates relative to patients without breast MRI controlling for histology. An analysis of the relationship between breast MRI and surgical treatment controlling for other variables should be performed.

255523 - Sensitivity and specificity of three-sequence MRI for breast cancer screening of high-risk, asymptomatic women

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Background/Objective: Women whose estimated lifetime risk of breast cancer exceeds 20% are designated “high risk,” for whom current screening recommendations include bilateral mammogram and breast MRI. Compared to mammography, breast MRI is substantially more expensive, time-consuming, and complex to interpret. These disadvantages could be minimized if shorter sequence MRI could be used for initial screening, with full-sequence MRI only when initial findings were suspicious. We therefore evaluated the sensitivity and specificity of a three-sequence bilateral breast MRI for breast cancer screening.

Methods: A retrospective series of breast MRIs was assembled from asymptomatic women who met criteria for “high risk” (personal history of breast cancer, chest irradiation, atypical ductal or lobular hyperplasia, or mutation predisposing to breast cancer) and had undergone screening bilateral breast MRI between October 2007 and June 2015. Breasts that had undergone mastectomy or had incomplete or indeterminate images were excluded from study. MRIs were limited to 3 sequences (T1 pre-contrast, T1 post-contrast, T2), stripped of patient identifiers, and placed in random order before review by a fellowship-trained breast radiologist who assigned a BIRADS designation.

Results: A series of 296 breasts from 146 women, including 8 women imaged twice 1-4 years apart, was studied. Full-sequence MRI had rated 92 breasts as at least suspicious for tumor. For detecting such breasts, three-sequence MRI yielded 65.2% (95% confidence interval, CI: 55.1-74.2%) sensitivity, 97.1% (93.7-98.7%) specificity. Among suspicious breasts, 28 carried tumors subsequently confirmed by biopsy: 26 unilateral tumors and 1 bilateral case. For detecting breasts with confirmed tumor, three-sequence MRI yielded 89.3% (72.8-96.3%) sensitivity, 84.3% (79.5-88.2%) specificity. Sensitivity of three-sequence MRI for detecting breasts originally rated as at least suspicious was higher when tumor was subsequently confirmed (25/28, 89.3%) than when tumor was not present (35/64, 54.7%). (Table)
Conclusions: In this first evaluation, a three-sequence screening MRI (omitting sequences providing kinetics data, retaining sequences providing morphology data) has very good sensitivity (89.3%) for

identifying breasts with tumor present and high specificity (97.1%) for excluding breasts not suspicious for tumor per full-sequence MRI. Our findings add to the growing body of evidence that abbreviated breast MRI is not inferior to standard full-sequence breast MRI as a screening modality. Studies are needed to compare the sensitivity, specificity, and inter-rater reliability of published 2, 3, and 4-sequence breast MRI protocols for screening high-risk, asymptomatic women.

257311 - Screening Breast Magnetic Resonance Imaging: What are the costs?

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Background/Objective: MRI can detect breast cancers not visualized on either mammogram or ultrasound. Thus, breast MRI is recommended for screening in women at high risk for breast cancer. When compared with mammography, MRIs are significantly more costly with unknown benefit in women who are not BRCA mutation carriers, thus its use remains controversial. The purpose of our study was to evaluate the efficacy and utility of screening MRIs in terms of false positive rates and downstream procedural costs both in the high risk and general population.

Methods: All outpatient claims from 1/2008-1/2011 in the MarketScan database were queried for women >18 years old who underwent screening breast MRI. Patients with prior diagnosis of breast cancer were excluded. The frequency of patients who underwent surgery, biopsies, or neither following MRI was evaluated (Fig. 1). The rate of false positives was defined by patients who underwent MRI and subsequent biopsy but did not receive surgery. A sub-analysis was performed on women with BRCA mutations. The cost of biopsies and surgical procedure following MRI were also assessed and were presented from the perspective of a third party payer.

Results: 48,121 women were included in our analysis. 10.8% underwent surgery immediately following MRI. 2.9% underwent biopsy and 86.1% received no additional treatment after index MRI. For those who underwent breast biopsy (N=1,391) 28.7% underwent surgery and 71.3% received no treatment. The cohort who did not undergo further treatment was defined as the false positive group. Thus the rate of false positive following screening MRI was 15.2%. 2.3% (N=1,124) of the patients in our study were found to have BRCA mutations with 6.6% false positive rate. The mean cost for biopsies following MRI was $2,456 per patient (95% CI: $2,315-$2,603). Cost of biopsies for each patient with false positive MRIs was $2,183 (95% CI: $2,033-$2,359). This cost totaled $2,165,536 for all those with false positive MRIs in our patient cohort.

Conclusions: For patients who underwent screening MRI for breast cancer, the false positive rate was 15.2%. In those with BRCA mutations, the rate of false positives was significantly reduced when compared with patients without the mutations (6.6%). The associated costs of biopsies from false positive MRIs were $2,183 per patient or $2,165,536 for all patients within the cohort. These results support the current recommendation for the use of screening MRIs in women who are BRCA positive. However, the relatively high false negative rate and the associated downstream biopsy costs suggest that screening MRIs should be used judiciously in the patients without BRCA genetic mutations.

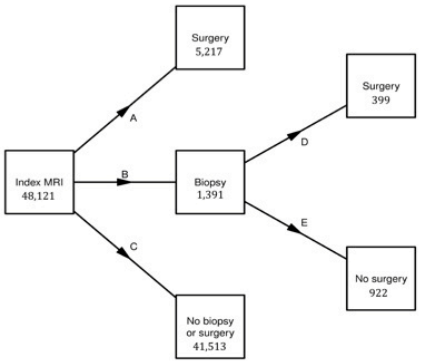

Figure 1. The model shows the different paths a patient may follow after index MRI. After the initial index MRI, patients may receive surgery, biopsy or no treatment within 3 months. Patients who undergo a biopsy after the index MRI can have surgery or no surgery within 6 months of the biopsy.

In the model, transitions labeled A, B and C were required to occur within 3 months of the date of the index MRI. Transitions D and E were required to occur within 6 months of the date of biopsy.

256706 - Invasive lobular carcinoma- Correlation between imaging and final pathology: Is MRI better?

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Background/Objective: Invasive lobular carcinoma (ILC) is associated with high re-excision rates in breast cancer patients following breast-conserving surgery (BCS). Previous studies suggest that MRI may be better at estimating tumor size than other imaging modalities and the use of MRI could lower re-excision rates. The correlation between lesion size on different imaging modalities and final pathology tumor size has not been well characterized.

Methods: We reviewed a prospectively maintained database of patients with unilateral stage I-III patients undergoing BCS at a single institution between 2006 and 2014. Pearson correlation analysis was used to evaluate the relationship between tumor size on ultrasound (US) and MRI compared with final pathology. Re-excision rates in patients with and without MRI were compared.

Results: Of 1190 patients who underwent BCS, 119 patients (10%) with ILC were identified. Mean patient age was 67 years (range 31-96). Of these patients, 90 (77.6%) had an imaging abnormality on mammography; however, only 23 (25.6%) patients had the size of the lesion documented and mammographic data was therefore excluded from analysis. Mean tumor size was 1.51 cm on US (range 0.1- 4.7cm), 2.53 cm on MRI (range 0.6- 14.7cm) and 2.68 cm on final pathology (range 0.2-15.9cm). For the 66 patients (65.3%) with a preoperative US, the correlation coefficient between US size and pathology size was 0.31. For the 61 patients (84.7%) with preoperative MRI, the correlation coefficient between MRI size and pathology size was 0.52. 36 patients (30.2%) underwent both an US and MRI. The correlation between the two imaging modalities together was 0.71. MRI underestimated the final size by more than one cm in 16/61 (26.2%) cases and US underestimated the final size in 36/66 (55.6%) of cases. Overestimation rates by more than 1 cm were 7/61 (11.5%) and 2/66 (3.0%) for the sizes on MRI and US, respectively. 41/119 (34.5%) patients underwent re-excision after BCS. Patients with a preoperative MRI had a re-excision rate of 33.3% versus 36.2% in the patients without MRI (p=0.84). Patients in the MRI group were overall younger than in the no- MRI group (mean age 63.3 years [range 31-91] vs. 72.8 years [range 36-96], respectively, p< 0.0001). There was no significant difference in mean

tumor pathology size between the two groups (MRI 2.48 cm ± 1.91 vs. no-MRI 2.98 cm ± 2.76, p=0.25). 11 of 61 (18.0%) patients had multifocal disease seen on MRI. Of those, 5/11 (45.5%) had re-excision versus 19/61 (31.1%) patients without multifocal disease on MRI (p=0.49).

Conclusions: MRI provides a better estimate of tumor size than US for ILC, however the size of the tumor on imaging, regardless of modality, weakly correlated with final pathology. MRI or US appear to underestimate final pathology size in a significant number of patients, and does not provide a way to avoid re-operation for negative margins.

256661 - Clinical Utility of Sonographic Elasticity Imaging in the Evaluation of Breast Lesions

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Background/Objective: Strain and shear wave elastrography is a relatively new ultrasound technique that has been shown to have high sensitivity and specificity for characterizing benign versus malignant breast lesions. In strain elastography, a compression and release force is applied to the breast with the transducer. The breast is different than other soft tissues in that tumor size differs between the B-mode image and the elastogram. Lesions that are soft deform more than those that are stiff. Shear-wave elastrography uses ultrasound push pulse (acoustic radiation force impulse) to generate shear waves perpendicular to the push pulse.

Methods: A cohort of 578 women scheduled for sonographically-guided biopsy of breast lesions were recruited from 6 sites under an IRB-approved protocol. All participants received an elastogram which displayed both the B-mode and elasticity images in real time. We also performed a retrospective review of patients with breast lesions and had a diagnosis of breast cancer by image-guided or surgical biopsy was performed.

Results: A total of 635 lesions were imaged and biopsied. There were 222 (35%) malignant or borderline lesions and 413 (65%) benign lesions. Of the 222 malignant lesions, 219 had an elasticity imaging/B-mode rain of at least 1.0. Of the 413 benign lesions, 361 had an elasticity imaging/B-mode ratio less than 1.0. These results corresponded to an overall sensitivity of 98.6% and overall specificity of 87.4%.

Conclusions: Sonographic elasticity imaging has high sensitivity in characterizing malignant lesions of the breast. Furthermore, elasticity imaging on strain elastrography is related to tumor grade.

254871 - High Resolution Breast PET Imaging (BPI) in Evaluating Axillary Lymph Node Status Prior to Surgery

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Background/Objective: The purpose of this study was to evaluate the ability of Breast PET Imaging to assess the axillary nodal status prior to surgery in patients diagnosed with breast cancer. The premise was that high-resolution Breast PET Imaging, based on metabolic activity at the cellular level, would provide more precise information than other imaging modalities or clinical exam.

Methods: A retrospective review of newly diagnosed breast cancer patients was performed with evaluation of their high-resolution Breast PET Imaging, including their axillary views. The determination

of abnormal nodes was based on visible radiotracer uptake and lesion to background ratio measurements with malignant nodes tending to show > 2X the uptake as compared to normal background tissue.

Results: Table 1 Breast PET Imaging (BPI) + 11/130 SLNB/ALND + 24/130 Breast PET Imaging (BPI) - 109/130 SLNB/ALND - 109/130 Sensitivity 46.0% Specificity 99.1% PPV 91.6% NPV 89.3% FP rate 1.0%

Conclusions: Conclusions: The high specificity and low false positive rate demonstrated in our initial work indicate that Breast PET could play a role in the pre-surgical assessment of the axilla in patients diagnosed with breast cancer. The low sensitivity demonstrated could be improved upon with ongoing efforts to optimize system geometry and post reconstruction algorithms. Of note, almost 1/4 (23%) of the undetected lesions in our study were lobular cancers which may prove to be inherently more difficult to visualize. Lobular tumor cells tend to spread out compared to ductal cells which form clumps or masses. The shape of the lesion and its spatial layout may also affect the resultant lesion detection in the axilla. Clinical evaluation of the axilla is an area of increasing interest in managing breast cancer. Axillary lymph node status is a critical prognostic indicator. Physical exam has proven to be inadequate, with some studies demonstrating error rates as high as 41% and false positive rates as high as 53%. Studies performed using Ultrasound and MRI have shown inconclusive and/or discrepant results. Current standard of care is trending toward optimizing preoperative techniques that can inform the surgical and treatment approach. The study presented here is part of ongoing work directed at improving methods to achieve this goal. Larger, multi-center studies evaluating the use of breast PET imaging (BPI) with Fluorodeoxyglucose 18F (18F-FDG) to assess axillary lymph nodes prior to surgery are needed.

Localization

257245 - Efficiency impact of radar localization

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Background/Objective: Patient satisfaction and improved efficacy/efficiency are tied to hospital reimbursement. An 11-site clinical study examined the efficacy of the SCOUT radar localization (RL) system, a zero-radiation, wire-free approach to breast tumor localization and surgical guidance. The objective of this abstract is to assess the impact of radar localization on radiology and operating room efficiency as compared to wire localization.

Methods: A multi-center clinical evaluation of SCOUT in patients with non-palpable breast lesions was performed and previously reported. At the conclusion of the study, radiologists and surgeons across the 11 participating centers completed evaluation forms inclusive of questions comparing their radar localization experience during the study with their previous wire localization experience. Placement of the radar reflector occurred on or before the day of localization surgery.

Results: A total of 154 radar localizations were performed utilizing the SCOUT radar localization system. Fourteen radiologists and 13 surgeons completed the evaluation forms. Of the 10 radiologists who answered the query about workflow improvements with radar localization compared to wire localization, 90% indicated an improvement with radar localization. Reasons cited included the ability to

schedule localization appointments at the convenience of the patient and radiology department. A summary of the surgeon evaluations is shown in Table.

Conclusions: Radar localization offers workflow efficiency improvements compared to wire localization. The ability to perform the localization procedure up to 30 days before surgery effectively uncouples radiology and surgery schedules. Radiology can now eliminate early-morning schedules previously reserved for same-day wire localizations. Surgeons found that radar localization allowed earlier surgery start times, decreased patient wait times, and reduced operating room delays due to the localization procedure. Surgeons who, on average, had reflectors placed 2.8 days before surgery noted greater efficiency gains than those with placements occurring on the day of or the day before surgery. Additional studies are needed to establish cost savings due to improved radiology and OR efficiencies.

	Number of Surgeons	Days RL Occurred Before Surgery	Avg. # Cases/ Surgeon	Earlier Surgery Start Times*	Decreased Patient Wait Times*	Reduction in OR Delays*
All surgeons	13	2.2	11	4.9	4.3	4.4
Surgeons for whom RL performed on avg > 1 day before surgery	9	2.8	9	5.0	4.4	4.6
Surgeons for whom RL performed on avg within 1 day of surgery	4	0.6	15	4.7	4	3.7

* Likert scale of 1-5, where 3 = same as WL, <3 = worse than WL, >3 = better than WL
RL = Radar Localization

Surgeon evaluation surveys

256688 - SCOUT RADAR localization improves breast surgery operating room start times compared with wire localization

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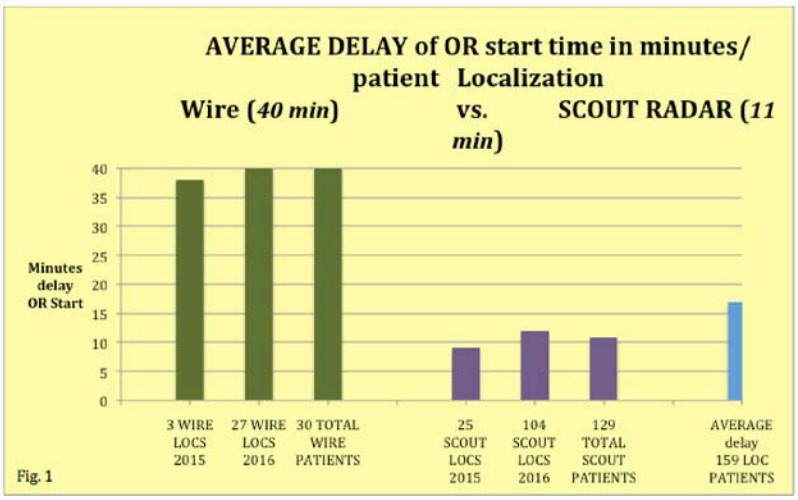
Background/Objective: Operating Room (OR) delays can be costly. There is an initial OR set-up fee and an additional charge per minute throughout the operation. US Midwest estimates a basic OR room set-up fee of $3,147 and $56/minute charge. Eastern US estimates $80/minute and a $3,000 fee for a same-day cancellation of surgery. Therefore, improvements that minimize OR start time delays or cancellations, including those attributed to pre-operative breast radiology procedures, can yield cost savings. Prior to June 2015, breast radiology provided only same day pre-operative wire breast localization. After that date, pre-operative localization with a non-wire SCOUT RADAR (SCOUT) device became an available option. The surgeon can opt to schedule non-wire localization 0 - 30 days prior to surgery. This uncouples the Radiology and Surgery department schedules, minimizing OR delays or cancellations encountered with same day pre-operative breast procedures.

Methods: OR start time delays were recorded at one hospital for 2 breast surgeons prior to and after the implementation of SCOUT. From January 1, 2015 to October 1, 2016, the number of minutes of delayed start time for any cause was recorded. Minutes of delay per patient were compared for pre-operative wire and SCOUT.

Results: Between January 1, 2015 and October 1, 2016, 2 experienced breast surgeons performed 287 SCOUT guided surgeries. The OR start time delays for these 2 surgeons operating on non-palpable breast lesions were recorded at one hospital for 159 patients (30 wire localization and 129 SCOUT localization) with an average OR start delay of 17 minutes for any reason. OR start delays in patients with pre-operative localization averaged 40 minutes in wire patients and 11 minutes in SCOUT patients (Figure). The 29-minute difference was statistically significant (95%CI $p < .001$). No delay or same-day cancellation was attributed to SCOUT localization.

Conclusions: Use of non-wire SCOUT localization for non-palpable breast lesions improved OR start times compared with wire localization in one hospital for 2 breast surgeons. Improved OR start time may result in cost savings, could favorably impact patient and physicians' (surgeon, anesthesiologist, radiologist) satisfaction, and may impact price transparency. OR costs may vary by geography.



Comparison of average OR start time delays (in minutes) of 159 patients at one hospital. Patients underwent either wire or SCOUT RADAR pre-operative localization of non-palpable breast lesions during study period January 1, 2015 - September 30, 2016.

256691 - SAVI SCOUT RADAR – A non-wire non-radioactive localization device can be used for axillary lymph node surgery

[Abstract Retracted]

256662 - Single-institution comparison of wire versus radioactive seed localization for non-palpable breast tumors

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Background/Objective: Localization for non-palpable breast tumors has widely been performed with a needle or wire localization (WL). Newer methods have been sought to try and improve on localization and decrease complications associated with wire placement. Radioactive seed localization (RSL) is one

method that involves deployment of a radioactive seed under imaging guidance. A gamma probe is used intraoperatively to locate the seed and excise the area; this allows for feedback during the excision. The feedback received is believed to lead to more accurate excisions in regards to margins while simultaneously allowing for a smaller volume of normal breast tissue to be removed. The aim of this study was to compare these 2 techniques (WL vs RSL) for localization with regard to margin status, need for re-excision, length of procedure, and complications related to localization technique.

Methods: An institutional electronic health record (EHR) was queried for individuals who had undergone excisional breast biopsy or partial mastectomy using RSL or WL between February 2012 and 2015. During the 3-year study period, our institution began using RSL in September of 2013.The patients were grouped into those who underwent RSL, those who underwent WL during the same time period RSL was being performed, and a comparative group of WL performed one-and-a-half years before the introduction of RSL. The comparative group of WL was used to evaluate for differences over time. The EHR was reviewed for localization technique, lesion pathologic margins, volume of tissue removed, OR time, need for re-excision, and complications. WL that occurred concurrently with RSL was compared. Statistics were reported using SPSS.

Results: A total of 1272 patients underwent localization procedures during the study period. There were 551 patients in the comparative WL group (February 2012-September 2013). During the time (September 2013-February 2015) when WL and RSL were being performed concurrently for localization, 572 patients underwent WL, and 147 underwent RSL. In the RSL group, 11 patients had positive margins that required re-excision (7.4%) vs 43 patients (7.5%) in the group of WL that occurred concurrently. There was no difference between the groups in regards to positive margins or re-excisions (p=0.360 and p=0.614 respectively). There were 7 complications in RSL group (4.8%) vs. 20 in the concurrent WL group (3.5%), with the majority of complications being hematomas related to localization procedure (57.1 %). There was a significant difference in OR time between the WL and RSL (82.4 vs. 104.4 minutes, p=0.000, average difference of 22 minutes). Volume of tissue removed was significantly less in the RSL (38.3 cm3) vs. WL group (40.0 cm3, p=0.011). When comparing the WL groups before and after September 2013, there was no significant difference in positive margins, re-excision, complications volume of tissue removed, or OR time.

Conclusions: In this retrospective single institution study RSL and WL were comparable techniques for localization of non-palpable breast lesions. Operative time favoring WL and volume of tissue removed favoring RSL were the only significant differences between groups. Differences in operative time may be related to learning curve of a new technique. The difference in volume of breast tissue is an advantage for the RSL technique as it may improve cosmetic outcomes for patients. This, as well as possible facilitation of scheduling with RSL, requires further study.

257381 - Utilization of multiple SAVI SCOUT surgical guidance system reflectors in the same breast: A single-institution feasibility study

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Background/Objective: SAVI SCOUT Surgical Guidance System has been shown to be a reliable and safe alternative to wire localization in breast surgery, but little is known about the use of multiple reflectors. This study evaluated the use of multiple reflectors in the same breast.

Methods: An IRB-approved, HIPAA-compliant, single institution retrospective review of 127 patients who underwent breast lesion localization and excision using percutaneously inserted non-radioactive, infrared-activated, electromagnetic wave reflectors (SAVI SCOUT Surgical Guidance System, Cianna Medical) between June 2015 and October 2016 was performed. Targets and reflectors were localized intraoperatively utilizing an infrared light/electromagnetic wave emitting handpiece. We evaluated a subset of these 127 patients in whom more than 1 reflector was placed in 1 breast. Specimen radiography and pathology verified target/reflector removal. In bracketed cases, the maximum distance between the 2 reflectors was recorded as measured on the mammogram and specimen radiograph. Final surgical pathology was reviewed, and margin status, re-excision rates, and complications were recorded.

Results: Of 127 patients, 22 patients had more than one reflector placed in 1 breast (total of 47 reflectors), 19/22 (86.4%) patients had a total of 2 ipsilateral reflectors, and 3/22 (13.6%) patients had a total of 3 ipsilateral reflectors. There were 18/22 (81.8%) patients with malignancy, 2/22 (9.1%) patients had high risk lesions, and 2/22 (9.1%) patients had benign lesions. The indications for multiple reflector placement in the same breast included multiple separate lesions (n=10) and bracketing of large lesions (n=12). Among patients with bracketing reflectors, the mean distance between the reflectors was 41 mm (SD 21 mm). The closest distance between the 2 reflectors was 25 mm and the farthest was 93 mm. Removal of the targeted lesion and retrieval of reflector was successful in all cases. One hundred percent of bracketed lesions were removed as a single specimen with a 100% retrieval rate within the first specimen obtained. There were 2/18 (11.1%) patients with malignancy who had close margins (< 1 mm) on surgical pathology. There were 2/18 (11.1%) patients who had positive margins and required re-excision. No complications were recorded.

Conclusions: The use of multiple SAVI SCOUT reflectors for localizing multiple lesions in the same breast or bracketing large lesions is feasible and safe.

257358 - Two-year experience of radioactive seed localization versus wire localization for nonpalpable breast lesions at a large community hospital

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Background/Objective: Several large academic institutions have shown radioactive seed localization (RSL) to be a safe and effective alternative to wire localization (WL) for localization of nonpalpable breast lesions. However, few community hospitals have adopted this technique. The surgical and oncologic superiority of RSL over WL is not well established. This study's objective is to describe the initial 2-year experience of RSL versus WL at a large community hospital.

Methods: This study is a retrospective chart review using both the electronic health record and the hospital's cancer registry to examine surgical and oncologic parameters in patients who underwent RSL

or WL for breast-conserving surgery from November 1, 2013 to November 31, 2015. The data in this study were examined for difference in continuous variables using the two-sample t-test. Differences in categorical variables were assessed using Pearson's Chi-square test or Fisher's exact test.

Results: The total number of lesions examined was 382. RSL was utilized in 205 (54%) lesions, WL was used in 155 (41%), and both techniques were used in 22 (6%) lesions. The average time from seed placement to surgery was 3.2 days. Pathology was benign in 182 (48%) lesions. Of the 200 (52%) malignant lesions, DCIS was present in 41 (21%) lesions, invasive disease in 52 (26%) lesions, and both in 107 (54%) lesions. Final pathologic diagnosis, nuclear grade, hormone receptor status, mean cancer size, and stage were similar between single RSL and single WL. Mean specimen weight was 27 g for the RSL group and 33 g for the WL group (p=0.008). For malignant lesions, mean specimen size was 36 g for the single RSL lesions and 35 g for single WL lesions (p=0.90). For benign lesions, mean specimen size was 17 g for single RSL and 22 g for single WL (p=0.017). Negative margins were defined as "no ink on tumor" for invasive cancer and > 2 mm for DCIS. Re-excision for margin clearance was required for 17 (17%) of malignant lesions in the RSL group and 20 (22%) in the WL group (p=0.31). Re-excision was required for 11 of 41 (26%) of DCIS lesions, 5 of 52 (9.6%) of invasive lesions, 25 of 107 (23%) lesions with both DCIS and invasive component. When comparing re-excision rates for invasive cancers alone and any cancer with a DCIS component, re-excision rates were higher for cancers involving DCIS (p=0.039), regardless of localization technique. When examining single RSL versus single WL technique, the mean operative time was 66 minutes versus 56 minutes (p=0.035). For malignant lesions, mean OR time was 86 minutes for single RSL versus 70 minutes for single WL (p=0.014). For benign lesions, mean OR time was 46 minutes for single RSL versus 40 minutes for single WL (p=0.09). Of the 89 malignant lesion excised with single RSL, 75 had nodal evaluation (84%), versus 47 of 58 lesions excised with single WL (81%). Operations requiring SLNB or ALND were significantly longer (90 minutes versus 50 minutes, $p < 0.0001$). Single RSL use increased over time, with 26% (31/119) first quarter utilization versus 68% (67/98) in the fourth quarter.

Conclusions: This is the largest single institution community-based study comparing RSL to WL for excision of nonpalpable breast lesions. For benign lesions, RSL allows for excision of smaller specimens, though this did not remain true for malignant lesions. Though there was a trend toward fewer re-excisions using RSL, re-excision rates were overall similar between RSL and WL. Cancers involving DCIS had higher re-excision rates regardless of localization technique. Malignant lesions required longer OR time for single RSL, though this was not significant for benign lesions. For RSL lesions, the mean OR time did not significantly change over the study period, nor did the need for nodal evaluation. According to our experience, we believe RSL to be a viable option in the community setting.

NAC

257230 - Time from completion of neoadjuvant chemotherapy to surgery: Effects on outcomes in breast cancer patients

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Background/Objective: Limited data exist on the optimal timing between the completion of neoadjuvant chemotherapy and definitive surgery in patients with breast cancer. This study sought to determine the relationship between time interval from completion of neoadjuvant chemotherapy to surgery and locoregional recurrence and 5-year overall survival in an attempt to define a best practice.

Methods: A retrospective analysis of all patients undergoing neoadjuvant chemotherapy for stage I-III breast cancer from 1998-2010 was undertaken. Clinicopathologic factors were examined. Patients undergoing stratified into groups based upon 2-week intervals from the start of neoadjuvant chemotherapy to definitive surgery.

Results: Three hundred eighty-eight patients received preoperative neoadjuvant chemotherapy during the study period. The median age was 50 (61.9% white, 33.8% black and 4.3% other). There were 2.8% of patients with stage I, 57.2% stage II, and 40% stage III. Median follow-up was 85 (range 3.8 - 247.2) months. Pathologic complete response (pCR) was achieved in 20.6%, partial in 67.8% and no response or progression in 11.6%. Overall, 32 (8.2%) patients experienced a local recurrence, and 108 patients died (27.8%) during the study period, 16 patients (4.1%) unrelated to their breast cancer. The interval from chemotherapy to surgery was divided into 2-weeks blocks, with 3.6% receiving therapy within 0-2 weeks, 25.3% >2-4 weeks, 42.8% >4-6 weeks, 16% >6-8 weeks, and 12.4% >8 weeks. The 5-year overall survival (OS) for each time interval was 71.42%, 79.73%, 82.79%, 82.28%, and 79.98%, respectively (p=0.82). Further analysis revealed an increased 5-year overall survival for patients receiving surgical intervention 4-8 weeks following neoadjuvant chemotherapy versus any other time intervals (82.64% versus 79.01%) (p=0.67).

Conclusions: Breast cancer patients undergoing surgical intervention during a period between 4 and 8 weeks following neoadjuvant chemotherapy may have a higher overall 5-year survival.

255947 - Impact of neoadjuvant chemotherapy on breast cancer subtype: Does subtype change and, if so, how?

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Background/Objective: Background breast cancer subtype, as determined by the expression of estrogen receptor (ER) and progesterone receptor (PR), together defined as hormone receptor (HR) status, and the HER2/neu receptor (HER2), is important in predicting prognosis and guiding therapy. Knowledge regarding how tumors evolve during treatment and whether subtype is influenced by neoadjuvant chemotherapy (NAC) is limited. The aim of this study was to compare the HR and HER2 status between core needle biopsy and residual tumor after surgery of breast cancer patients treated with NAC, and also to evaluate the impact of status change on therapeutic management.

Methods: After institutional review board approval, we performed a retrospective review of all patients with a diagnosis of breast cancer who received NAC and had their initial biopsy and post-NAC surgical specimens evaluated for tumor subtype between January 2009 and December 2014 at our institution. Immunohistochemistry (IHC) of ER, PR, HER2, and fluorescence in situ hybridization (FISH) for HER2 expression, when indicated, was performed using identical technique and measured by a single pathologist who specializes in breast pathology. Pre- and post-NAC subtype was cross-tabulated to assess change. Standard diagnostic metrics were computed.

Results: Fifty patients with 54 cancers were identified to have their initial biopsy and post-NAC surgical specimens evaluated for tumor subtype in identical fashion. There was a complete pathologic response

after NAC in 23 cancers (42.6%). Residual disease was noted in 31 cancers (57.4%). Five of these (16.1%) had a change in tumor subtype, of which 4 changes were based on IHC. One tumor was HR negative/HER2 negative based on IHC and post-NAC FISH testing was positive, changing tumor subtype to HR negative/HER2 positive. The most unstable subtype was HR positive/HER2 positive, as subtype changed after NAC in 2 of 4 cases (50%). Subtype change led to treatment changes in all 5 cases, with either the addition or discontinuation of adjuvant therapies.

Conclusions: Patients with breast cancer may experience alterations in their tumor subtype after NAC. At our institution, this led to a change in adjuvant treatment in 100% of such patients. This implies that re-testing receptor status of residual tumors after NAC may be considered in order to tailor adjuvant therapy after NAC.

		Post-NAC (n)		
		HR pos/HER2 neg	*HR pos/HER2 pos*	*HR neg/HER2 pos*
Pre-NAC (n)	*HR pos/HER2 neg*	15	1	0
	HR pos/HER2 pos	1	2	1
	HR neg/HER2 pos	0	1	1
	HR neg/HER2 neg	0	0	0

HR: Hormone Receptor; HER2: Human Epidermal Growth Factor Receptor 2; pos: positive; neg: negative; Pre-NAC: Pre-Neoadjuvant Chemotherapy; Post-NAC: Post-Neoadjuvant Chemotherapy

Change in receptor status

256901 - Neoadjuvant chemotherapy is not associated with improved survival for estrogen receptor positive/negative breast cancer

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Background/Objective: Neoadjuvant chemotherapy (NAC) for breast cancer does not have a clear impact on overall survival, although some data suggest a benefit for women with hormone receptor negative tumors. We sought to determine whether treatment with NAC as opposed to adjuvant chemotherapy (AC) resulted in improved overall survival for women with estrogen receptor positive (ER+) or negative (ER-) tumors.

Methods: Using the National Cancer Database, we identified women with clinical stage I-IIIC breast cancer who were treated with surgery and chemotherapy between 2004-2006, the most recent years with available survival data. We compared demographic and clinicopathologic characteristics between women receiving NAC vs AC and performed Kaplan-Meier analysis to determine differences in survival. Cox multivariate regression was performed to evaluate whether timing of chemotherapy was associated with survival for women with ER+ vs. ER- tumors. HER2 status was not available for analysis. Bonferroni correction was used to maintain overall alpha level of 0.05 for multiple hypothesis testing.

Results: We identified 51,957 women who met inclusion criteria. Women who received NAC (n=11,577) as opposed to AC (n=40,380) were significantly younger [mean ± SD; 50±11 vs. 54±11 years, $p < 0.005$), ER- (42% vs. 33%, $p < 0.005$), black (18% vs. 12%, $p < 0.005$), with high-grade tumors (58% vs 50%, $p < 0.005$). Patients receiving NAC were significantly more likely to receive radiation therapy (70% vs 64%, $p < 0.005$), less likely to receive endocrine therapy (47% vs 55%, $p < 0.005$), and more likely to undergo mastectomy (61% vs 44%, $p < 0.005$) and axillary lymph node dissection (65% vs 57%, $p < 0.005$). Kaplan-Meier analysis demonstrated no difference in overall survival for women undergoing NAC vs. AC for ER+ tumors [median survival months (95% CI): 74.8 (74.3-75.3) vs 74.5 (74.3-74.7), p=0.61). Cox multivariate regression for both ER+ and ER- tumors is shown in the Table. For ER+ tumors, NAC was not

independently associated with survival. For ER- tumors, while NAC was associated with diminished overall survival on Kaplan Meier analysis [median survival months 74.1 (73.5-74.6) vs 74.5 (74.1-74.8), p=0.003], it was not independently associated with survival following multivariate regression. Other clinicopathologic variables including histology, progesterone receptor status, surgical margins, extent of primary surgery, primary payor, and facility type were not significant predictors of survival.

Conclusions: In a large cohort of women who received surgery and chemotherapy for breast cancer, NAC is associated with younger age, more aggressive tumor characteristics, and more aggressive surgical therapy. Whether women have ER+ or ER- disease, treatment with NAC as opposed to AC does not have a significant impact on overall survival.

	ER+		ER-	
	HR (95% CI)	**p-value**	**HR (95% CI)**	**p-value**
Age >50	1.01 (0.98, 1.04)	0.43	1.01 (0.97, 1.06)	0.56
Race				
White	1	-	1	-
Black	0.88 (0.81, 0.96)	0.003	0.82 (0.72, 0.93)	0.002
Other	1.02 (0.99, 1.06)	0.13	0.87 (0.76, 0.99)	0.04
Clinical T stage (I vs II vs III)		0.09		0.46
Clinical N stage (0 vs I vs II vs III)		0.56		0.12
Breast Conserving Surgery (vs Mastectomy)	1.02 (0.98, 1.05)	0.43	0.98 (0.93, 1.04)	0.49
# Lymph nodes sampled				
0	1	-	1	-
1-5	1.04 (0.94, 1.15)	0.47	1.23 (1.08, 1.39)	0.001
>5	1.07 (1.04, 1.11)	1×10^{-5}	1.12 (1.07, 1.18)	5×10^{-7}
Neoadjuvant Chemotherapy (vs Adjuvant)	1.00 (0.96, 1.05)	0.87	1.05 (1.00, 1.11)	0.08
Radiation Therapy Omitted	1.10 (1.06, 1.14)	2×10^{-6}	1.09 (1.03, 1.15)	0.005
Endocrine Therapy Omitted	1.24 (1.20, 1.29)	1×10^{-30}	1.03 (0.95, 1.12)	0.47

Cox multivariable analysis of overall survival

256696 - Neoadjuvant therapy and nodal pathologic complete response affects node counts at axillary node dissection in breast cancer

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Background/Objective: Recommendations for number of lymph nodes removed during axillary lymph node dissection (ALND) are based on a mathematical model that was created in the 1990s. This number has been used as a quality indicator in the surgical management of breast cancer. The management of the axilla has evolved dramatically over the years with less invasive techniques (sentinel node biopsy) and increased use of regional radiotherapy. The use of neoadjuvant therapy (NAT) has also changed the landscape of breast cancer treatment and is becoming common practice in the management of node-positive breast cancer. Our objective is to characterize the effect of NAT and nodal pathologic complete response (pCR) on number of nodes retrieved at ALND in patients with breast cancer. Increased understanding of this effect may improve management of the axilla and alter quality indicators in breast cancer surgery.

Methods: A retrospective review of a prospectively maintained breast cancer database at Mount Saint Joseph Hospital was conducted to identify patients with invasive breast cancer who underwent ALND between January 1, 2012 and March 31, 2016. Lymph node yield at the time of ALND in patients treated with NAT was compared to patients that underwent surgery first. In the NAT group, patients with a

nodal pCR were compared to those with residual disease. Statistical analysis was performed using an unpaired t-test with Welch's correction; a p-value of < 0.05 was considered significant.

Results: A total of 313 patients with node-positive invasive breast cancer requiring ALND were identified. One hundred eighty-five (59%) had surgery first, and 128 (41%) were treated with NAT (chemotherapy, hormonal therapy, or a combination) followed by ALND. The average number of nodes removed in the surgery first group was 11.5 compared to 9.5 nodes in NAT group (Figure, p=0.0105). The average number of positive nodes at ALND in the surgery first group was 3.9 compared to 2.6 in the NAT group (p=0.0285). In the NAT group, 54% had positive nodes while 46% had nodal pCR. In the NAT group, node harvest number in residual axillary disease was 12.0, significantly higher than the average of 6.5 nodes when there was a nodal pCR (Figure, $p < 0.0001$).

Conclusions: While further characterization of the effect that NAT has on axillary nodes is needed, these findings demonstrate that NAT has a significant impact on the number of nodes removed at ALND. This seems to significantly affect those patients who achieve a nodal pCR. This questions the utility of node number as a quality indicator for ALND in the setting of NAT especially when patients achieve a nodal pCR.

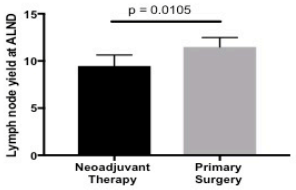

Figure 1. Axillary lymph node yield at time of ALND in patients with node-positive breast cancer treated with neoadjuvant therapy (n=128) or primary surgery (n=185). P-value calculated using an unpaired two-tailed t-test with Welch's correction. Whiskers indicate 95% confidence intervals.

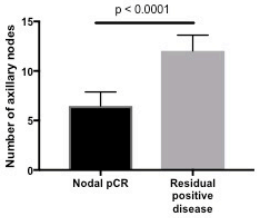

Figure 2. Node harvest number in individuals treated with neoadjuvant therapy in patients with residual axillary disease compared to nodal pathologic complete response (pCR). P-value calculated using an unpaired two-tailed t-test with Welch's correction. Whiskers indicate 95% confidence intervals.

Neoadjuvant therapy and nodal pathologic complete response affects node counts at axillary node dissection in breast cancer

255630 – High-resolution breast PET imaging (BPI) to assess tumor response to neoadjuvant chemotherapy for breast cancer

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Background/Objective: The objective of this study was to evaluate the ability of high-resolution breast PET imaging (BPI) with Fluorodeoxyglucose 18F (18F-FDG) to predict response to neoadjuvant chemotherapy (NAC) prior to surgery. Our hypothesis was that metabolic imaging with BPI would demonstrate high sensitivity and specificity in predicting response to NAC when compared with final

surgical pathology results. Pathologic response to NAC can serve as an individual strong prognostic indicator for risk of recurrence.

Methods: Patients undergoing NAC for breast cancer were imaged with a high-resolution BPI system before (baseline) and after completion (restaging) of NAC. The median time delta between exams was 30 weeks (14-31). Tumor size and maximum uptake value (PUV max) measured from BPI images were compared with extent of residual disease at surgery.

Results: Sixty-two patients completed imaging and proceeded to surgical resection after NAC. Average patient age was 52.17 years. Using Breast PET to characterize tumor size in largest dimension and lesion maximum uptake value (PUV max) pre- and post-NAC. Tumor size post-NAC was then correlated with final surgical pathology measurements. Breast PET imaging (BPI) results are presented in the Table.

Conclusions: This study demonstrates that high-resolution breast PET imaging (BPI) with Fluorodeoxyglucose 18F (18 F-FDG) has value in predicting response to NAC prior to definitive surgery. Changes in tumor size and tumor maximum uptake value (PUV max) on BPI imaging performed at initiation of NAC and upon completion of NAC were highly accurate in predicting the presence or absence of residual disease when compared to final surgical pathology results. Estimation of tumor size post-NAC from BPI appears to correlate better with pathological tumor size than mammography, ultrasound, MRI, or clinical assessment. Over the past decade, we have seen changes in neoadjuvant treatment guidelines that make it a standard option for primary operable disease for patients who are candidates for adjuvant systemic chemotherapy, irrespective of the size of the tumor. Neoadjuvant chemotherapy has shown similar long-term survival benefit as adjuvant therapy. Neoadjuvant treatment of breast cancer is well established as a safe and effective therapeutic approach for primary and locally advanced breast cancer. The neoadjuvant approach offers the advantages of downstaging the disease, potentially reducing the extent of surgery, and in an era of personalization of therapy, testing the efficacy of therapy administered to patients. Since these results demonstrate that the use of high-resolution breast PET imaging with Fluorodeoxyglucose 18F (18F-FG) is highly accurate in assessing tumor response to neoadjuvant chemotherapy in breast cancer patients, we recommend that it be considered in the work-up of patients undergoing such treatment. In the future, our analysis can be expanded to assess differences in response based on tumor type, receptor, and HER2 status.

Partial Response	Pathology BPI	40/62 37/62
Complete Response	Pathology BPI	20/62 21/62
No Response	Pathology BPI	2/62 4/62
Mean Baseline PUVmax	6.16 (.96-15.2)	
Mean Restaging PUVmax	1.36 (0-15.5)	
Mean Baseline Tumor Size (largest dimension cm)	5.06 (1.3-8.0)	
Mean Restaging Tumor Size (largest dimension cm)	2.22 (0-4.3)	
Mean Pathology Tumor Size (largest dimension cm)	2.47 (0-5.4)	
Sensitivity	90.69%	
Specificity	94.73%	

257369 - Preoperative ultrasound following pertuzumab-based neoadjuvant therapy for breast cancer: A novel modality to predict fewer lymph nodes retrieved on axillary lymph node dissection

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Background/Objective: In HER2-positive breast cancer, neoadjuvant pertuzumab has led to improved pathologic complete response (pCR) rates. However, limited data exist evaluating the number of axillary lymph nodes retrieved in patients who had a pCR after neoadjuvant chemotherapy. We sought to determine if pre-neoadjuvant and preoperative axillary disease burden in breast cancer patients correlated with the number of axillary lymph nodes retrieved in an axillary lymph node dissection (ALND) following neoadjuvant chemotherapy with or without pertuzumab.

Methods: Patient demographics and clinical data were collected in all breast cancer patients diagnosed from January 2012 to September 2016 who received neoadjuvant chemotherapy and subsequently underwent ALND. Ultrasound evaluation of the axilla prior to and following neoadjuvant chemotherapy was noted where available in order to assess the initial and subsequent burden of axillary metastatic disease. Pathologic outcomes in patients who received neoadjuvant chemotherapy with and without pertuzumab were analyzed using a Student's t-test for continuous variables and Fisher's exact test for categorical variables.

Results: The mean age of the 117 patients who met inclusion criteria was 51.8 ± 10.7 years; all were female. Pre-neoadjuvant ultrasound was performed in 115 patients, and pre-operative ultrasound was performed in 109 patients. There was no significant difference in nodal disease burden between the 2 groups before neoadjuvant therapy ($p=0.13$); however more patients in the pertuzumab group had resolution of their axillary disease on post-chemotherapy ultrasound ($p < 0.01$). Patients who received neoadjuvant chemotherapy with pertuzumab had a higher rate of pCR when compared to patients who did not receive pertuzumab ($p < 0.01$). In patients who had sonographic resolution of their axillary metastatic disease, ALND yielded fewer lymph nodes in the pertuzumab group (7.3 ± 3.5 nodes) compared to the no pertuzumab group (15 ± 6.6 nodes) ($p < 0.01$) and more frequently yielded fewer lymph nodes than the national standard of 10 ($p < 0.01$). When patients had sonographic resolution of a heavy axillary disease burden as well as a a pCR, 6.4 ± 3.3 lymph nodes were recovered in the pertuzumab group while 15.6 ± 6.2 were recovered in the no pertuzumab group ($p < 0.01$).

Conclusions: This study suggests that breast cancer patients who have a high burden of axillary metastatic disease at diagnosis and subsequently receive neoadjuvant pertuzumab have decreased lymph nodes retrieved in the pathologic specimen. Furthermore, those patients who had a pCR after receiving pertuzumab have even fewer lymph nodes identified in ALND specimens, possibly due to obliteration of the nodes after neoadjuvant treatment. Post-neoadjuvant but pre-operative ultrasound can select patients who are more likely to have decreased lymph node number reported after pertuzumab and ALND and may not meet the current guidelines of a minimum of 10 axillary lymph nodes recovered in pathologic specimen. This suggests that in this patient group less than 10 axillary lymph nodes in the final pathologic specimen is not a signifier of poor quality of surgery but rather an indicator of response to neoadjuvant pertuzumab.

Patient Demographics	Neoadjuvant without Pertuzumab (n=96)	Neoadjuvant with Pertuzumab (n=21)	p-Value
Replaced Axillary Lymph Nodes			
Pre-Neoadjuvant Ultrasound	80 (85.1%)	14 (66.6%)	0.13
Post-Neoadjuvant Ultrasound	40 (45.5%)	3 (14.3%)	< 0.01
Pathologic Outcomes			
Average Number of Axillary LN	15.1 ± 6.6	11.5 ± 6.9	0.04
Less than 10 Axillary LN	19 (19.8%)	10 (47.6%)	0.01
Complete Pathologic Response	26 (27.1%)	12 (57.1%)	< 0.01

257367 - Mastectomy in patients eligible for breast-conserving therapy following neoadjuvant chemotherapy

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Background/Objective: Breast-conserving therapy (partial mastectomy followed by radiation; BCT) provides equivalent overall survival compared to mastectomy for breast cancer. However, there is a noticeable trend toward mastectomy following neoadjuvant chemotherapy (NAC), even in BCT-eligible patients. The aim of the study is to identify rates and influential factors in receipt of mastectomy in BCT-eligible patients having undergone NAC.

Methods: Retrospective review of academic institutional tumor registries, belonging to private and county hospitals, identified patients who received NAC followed by surgery for breast cancer from 2001 to 2013. BCT-eligible patients were divided into 2 groups: 1) those who received BCT and 2) those who proceeded with mastectomy. The primary endpoint was receipt of mastectomy in BCT-eligible patients. Data regarding demographics, clinical presentation, tumor characteristics, and treatment were collected and analyzed.

Results: A total of 414 female patients underwent NAC followed by surgery. Two hundred fifteen patients were deemed eligible for BCT following completion of NAC. Of these, 145 underwent BCT (group 1), and 70 proceeded with mastectomy (group 2). The mean age at diagnosis was 49.7 ± 10.3 years. Univariate analysis demonstrated no statistically significant difference between study groups with regard to age, race, tumor location, stage, histology, and receptor status. Analysis using a multivariable logistic regression model revealed insurance status to influence the type of definitive surgery received. When compared to the uninsured county hospital patients, those with private insurance were more likely to receive mastectomy [57.1% versus 15.7%, p=.01; odds ratio (OR) = 2.7, 95% confidence interval (CI) 1.3-6.0]. Likewise, when compared to the uninsured county hospital patients, those with Medicare or Medicaid were more likely to receive mastectomy (27.1% versus 15.7%, p= 04; OR=2.5, 95% CI 1.0-6.0).

Conclusions: Insurance status influenced the receipt of mastectomy over BCT in BCT-eligible patients following NAC. Given the lack of survival benefit of mastectomy in BCT-eligible patients, further studies evaluating surgical decision making are warranted.

256703 - Role of neoadjuvant chemotherapy for surgery in locally advanced Korean breast cancer: A single center study

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Background/Objective: One of aims of neoadjuvant chemotherapy for locally advanced breast cancer is downstaging and facilitation of surgical resection. The preoperative prediction for response is very important. This study aimed to analyze several kinds of preoperative factors of good responders among locally advanced breast cancer.

Methods: Between October 2011 and April 2016, 54 patients with locally advanced breast cancer were enrolled and preoperatively treated with an anthracyclin-based (anthracyclin and cytoxan and/or taxol) regimen.

Results: Fifty patients (92.5%) had invasive ductal carcinomas. Twenty-eight (51.9%) showed partial remission, and 9 patients (16.6%) shows pathologic complete remission (pCR) or near pCR. Downstaging occurred in 69% (37), and conservative surgical method instead of mastectomy was performed for them. Initial HER2 positive subtype (ER- PR- Her2+) and PR negative status were significant factors for achieving pCR and near pCR (p=0.002, p=0.018). Prediction rate for downstaging with post-chemotherapy MRI was 61%.

Conclusions: Neoadjuvant chemotherapy for locally advanced breast cancer in Korean women can be downstaged and converted to conserving surgery. HER2+ subtype and PR negative status were important factors for good response with neoadjuvant chemotherapy. So far, MRI can be a relatively accurate tool for responders, but omission of surgery after neoadjuvant chemotherapy is not yet possible.

Patient Education

257176 - Impact of health literacy on surgical treatment of breast cancer

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Background/Objective: Health literacy refers to the ability to obtain, appraise, and integrate health-related knowledge. Low health literacy (LHL) is a critical indicator of adverse health outcomes, and previous research has demonstrated that patients with LHL are less likely to undergo cancer screening. The purpose of this study is to describe the association between patient health literacy and breast cancer diagnosis and treatment trends at an academic tertiary care medical center.

Methods: From June 2015 through September 2016, a health literacy questionnaire was administered to all new breast cancer patients and all breast cancer patients seen in follow-up. The health literacy questionnaire is a valid and reliable 3-item self-report screening tool with ranges in score from 3-15 (higher scores represents lower health literacy). Pertinent clinical outcomes related to the diagnosis and treatment was obtained for all patients with a health known health literacy score. Descriptive statistics were calculated to describe health literacy and patient characteristics, and linear and logistic regressions were calculated to determine the relationship of health literacy on stage at presentation and surgical treatments.

Results: A total of 512 breast cancer patients were included in this analysis. 12.1% of the patients identified as having the lowest level of health literacy (limited health literacy), and 13.5% were identified as having marginal health literacy. Therefore, 25.6% of the patient population have levels of health literacy (limited and marginal) that are considered to be LHL. There was a significant difference in health literacy based on stage of presentation with LHL corresponding to higher stage at presentation (p=0.02). Patients who presented with stage IV disease had a 1.45 point-lower health literacy average (i.e., higher score) than any other stage at presentation. There was no statistical significance in the relationship of health literacy to surgical treatment (breast conservation versus mastectomy) (p=0.82), or on the use of contralateral prophylactic mastectomy (p=0.06). In a multivariate model, after controlling for age at diagnosis and cancer stage, there was a statistically significant relationship between health literacy and utilization of breast reconstruction following mastectomy with those reporting lower levels of health literacy less likely to undergo reconstruction (aOR 0.783, p=0003).

Conclusions: LHL is known to be associated with adverse outcomes and poor adherence to treatment recommendations. Health literacy is not well defined in the breast cancer patient population and is relevant to the diagnosis and treatment counseling of breast cancer patients. Our findings shown that LHL is associated with higher stage at presentation and decrease use of breast reconstruction. Patients with LHL represent an understudied breast cancer patient population with unique counseling and education needs. Tailored interventions are needed to combat disparities in cancer treatment associated with LHL.

252392 - What do women really think? Patient understanding of breast cancer risk

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Background/Objective: Patient perception of modifiable and nonmodifiable risk factors has not been well delineated. Studies have shown that women with a history of breast cancer have a higher perceived risk for developing contralateral breast cancer. On the other end of the spectrum, women with limited knowledge have been found to have lower rates of screening. The objective of this study was to identify disparities in patient knowledge pertaining to breast cancer risk estimation across groups of adult women. With this information, clinicians will be able to address educational gaps which may help with patient decision- making.

Methods: This was a single institution, cross-sectional study of women with diverse backgrounds. All adult women who presented to the Breast Center were invited to complete an anonymous survey. The

survey was designed to measure patient characteristics such as ethnicity, education, and lifestyle factors as well as to assess patient opinions of breast cancer risk.

Results: There were 2,511 patients participating in the study. Sixty percent believed that breast cancer cannot be prevented, or did not know if breast cancer can be prevented. Ninety-four percent believed that a family history of breast cancer increases risk. With regard to modifiable factors, greater than 40% believed that smoking, obesity, lack of exercise, OCP use, or hormone therapy use increases the risk of breast cancer. There was a smaller proportion who believed that wearing an underwire bra (7%), using deodorant (16%), or consuming red meat (23%) increases breast cancer risk. Factors which women believed to decrease breast cancer risk included breastfeeding (47%), exercise (62%), and weight loss (39%). Eighty-two percent of women did not believe that a medication can be given to decrease breast cancer risk. On multivariate analysis, factors that were associated with believing that breast cancer cannot be prevented included: family history of breast cancer (p=.002), personal history of breast cancer (p=.003) and personally identifying as being high risk (p=.04). Women who do not consume alcohol (p < .001) and women with less education (p=.001) were more likely to think that breast cancer can be prevented. Having a history of a breast biopsy and smoking status did not correlate with being more or less likely to think that breast cancer is preventable. Fifty-seven percent of patients surveyed believed that breast cancer risk can be estimated. In a multivariate analysis, women with a personal history of breast cancer (p= < .001) and higher education (p=.002) were significantly associated with being more likely to believe that risk can be estimated. Family history, personally identifying as being high risk, history of biopsy, smoking, and alcohol use were not statistically significant. Eighty percent of women surveyed believed that a genetic test can estimate risk. Of the 2,312 patients who responded to this question, only 28 (1.2%) disagreed that a genetic test can estimate risk. Women with a personal history of breast cancer were more likely to agree (p=0.02). There were no other statistically significant associations when controlling for the other variables.

Conclusions: Patients were more likely to believe that nonmodifiable risk factors have a greater impact on cancer development, especially those patients who had already developed breast cancer and who identified as being high risk. Patients did not have high confidence in physician ability to estimate their risk, with only 57% believing that risk can be estimated. This follows previous trends that have been observed with patient overestimation of contralateral breast cancer development. Very few women were aware that tamoxifen can decrease the risk of breast cancer development, and this deserves attention and explanation by physicians, as patients with and without a history of breast cancer responded similarly to this question. This survey did show that women believe that there are modifiable factors which influence the development of breast cancer; however, there were misconceptions identified, such as the use of underwire bras, deodorant, and OCPs contributing to increasing risk. While deodorant and underwire bra avoidance may not cause harm to the patient, OCP avoidance can result in unwanted pregnancy in patients that perhaps would have otherwise used OCPs. In summary, this study revealed opportunities for physicians to reach out and educate patients, both in a primary care setting, as well as in the breast center after the development of a breast cancer has occurred.

246080 - Implementation of Well Follow-up Care Initiative improves health resource utilization and adherence to surveillance imaging guidelines in breast cancer survivors

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[1]University of Toronto, Toronto, ON, Canada, [2]Cancer Care Ontario, Sunnybrook Research Institute, Toronto, ON, Canada, [3]McMaster University, Juravinski Cancer Centre, Hamilton, ON, Canada, [4]Cancer Care Ontario, Toronto, ON, Canada, [5]Ontario Institute for Cancer Research, Toronto, ON, Canada, [6]Institute for Clinical Evaluative Sciences, Toronto, ON, Canada, [7]HOPE Research Centre, Sunnybrook Health Sciences Centre, Toronto, ON, Canada, [8]Institute of for Clinical Evaluative Sciences, Toronto, ON, Canada, [9]University of Toronto, Cancer Care Ontario, Toronto, ON, Canada

Background/Objective: Breast cancer survivors are increasing in number and despite clear guidelines for ongoing surveillance, underuse of yearly surveillance mammography, contrasted by an overuse of distant imaging for metastatic disease, is common. Between 2010 and 2013, Cancer Care Ontario (CCO) initiated the development and implementation of models to transition the follow-up care of breast cancer survivors to primary care. These models involved discharge from routine oncology follow-up, provision of surveillance guidelines to patients and primary care providers, and a mechanism for facilitated re-entry to the cancer system as required. Our study assesses the impact of these new models on surveillance imaging utilization and the number of specialist visits after transition.

Methods: Breast cancer survivors transitioned between 2010 and 2013 were matched to controls using propensity score matching for age, cancer stage, year of diagnosis, socioeconomic status, local health integration network (LHIN), aggregated diagnosis score (ADG), and resource utilization band (RUB). Administrative health databases were used to determine number of medical visits and imaging studies performed between the date of patients' transition and the date of last follow-up or death. In addition to the breast, body sites for distant imaging included the thorax, abdomen, pelvis, and skeleton. Utilization was compared between the cohort and control groups.

Results: A total of 2,324 breast cancer survivors from the pilot cohort were matched to a control. Patients' transition to primary care occurred after a mean of 59.4 months from their initial diagnosis; the average duration of follow-up was 26.2 months. A greater proportion of transitioned patients received surveillance mammograms when compared to controls (83 vs 73%, $p < 0.001$). The rate of mammography per patient-year was consistently higher in the transitioned group. This difference between the 2 groups increased with the number of years of follow-up after transition: rates of mammogram per patient-year were of 0.85 vs 0.79 at 2 years and 0.82 vs 0.59 at 5 years for transitioned patients vs controls. Imaging with bone scan, thoracic, abdominopelvic, and brain CT was significantly lower among transitioned patients (Table). Use of plain X-rays was not different between the groups. Transitioned patients had fewer visits to medical oncology and radiation oncology specialists during the follow-up period, while visits to general practitioners or other specialists were similar (Table).

Conclusions: Well-communicated plans for discharge to community care after successful completion of breast cancer treatment are associated with improved adherence to breast cancer surveillance guidelines and reduced utilization of specialty services without affecting utilization of unrelated health care resources. Longer follow-up data are required to determine impact on clinical and patient-reported outcomes.

	Cases (n=2324)	Controls (n=2324)	p-value
Breast Imaging			
Mammogram	1,920 (82.6)	1,698 (73.1)	<.001
Ultrasound	486 (20.9)	479 (20.6)	0.8
MRI	109 (4.7)	131 (5.6)	0.145
Distant Imaging			
Bone Scan	270 (11.6)	340 (14.6)	0.002
Thoracic CT	291 (12.5))	377 (16.2)	<.001
Abdominopelvic CT	342 (14.7)	443 (19.1)	<.001
Head CT	289 (12.4)	340 (14.6)	0.029
Brain MRI	120 (5.2)	139 (6.0)	0.224
PET-CT	< =5	8 (0.3)	0.248
X-ray	1,315 (56.6)	1,321 (56.8)	0.859
Medical visits			
Emergency Medicine	1,140 (49.1)	1,202 (51.7)	0.069
General Surgery	1,000 (43.0)	990 (42.6)	0.767
General Practitioner/ Family medicine	2,276 (97.9)	2,261 (97.3)	0.15
Medical Oncology	418 (18.0)	926 (39.8)	<.001
Radiation Oncology	257 (11.1)	491 (21.1)	<.001
Other Physicians	2,067 (88.9)	2,050 (88.2)	0.433

Imaging tests and physician visits after transition

257249 - Discussion about surgery on an online health community peaks in March and October

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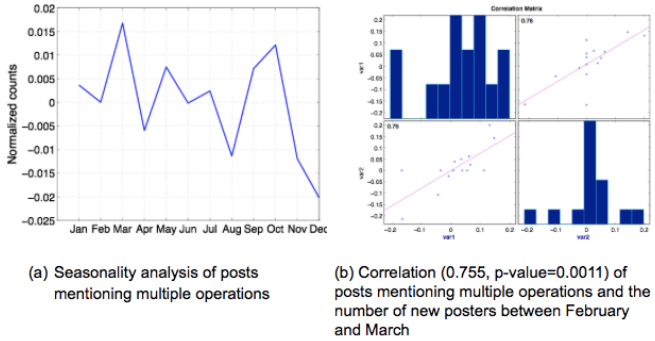
Background/Objective: Prior research has demonstrated that Google searches about breast cancer peak each year in October, despite the fact that there are biannual peaks (in the fall and spring) of new breast cancer diagnoses. It is currently unknown if online social network activity regarding breast cancer surgery exhibits a seasonal pattern. Knowledge of seasonal activity surrounding breast cancer surgery can help to disseminate information at a time when patients will be most receptive to it.

Methods: We downloaded 16 years (2000-2016) of posts (n=326,000) and the dates of creation from a publicly available online breast cancer community. We utilized keyword searches to identify posts mentioning more than 1 breast cancer operation (n=23,189). Posts mentioning more than 1 operation (e.g., lumpectomy and mastectomy) were chosen for analysis because they have been previously described to correlate with discussion about surgical decision-making. We then performed a seasonality analysis of the posts based on their date of creation, first using a 5-degree polynomial curve to estimate the seasonality, then applying a seasonal filter to the detrended series. Lastly, we performed deseasonalization by subtracting the seasonal component from the original time series. Finally, we performed a content analysis of 25 randomly selected posts from peak months to identify factors driving the observed trends.

Results: The greatest number of new members entered the community each March, and the majority of posts in March were authored by new members. Seasonality analysis revealed the peak prevalence of posts mentioning more than 1 operation to be both March and October (Figure). Correlation analysis showed a significant relationship between new posters and posts mentioning multiple operations in March (p=.0011). Content analysis revealed that in both October and March, increased discussion about surgery is driven by posters with new diagnoses of breast cancer seeking information, with replies from long-time posters explaining the benefits and disadvantages of the various operations.

Conclusions: We demonstrated that online social network activity in a breast cancer community reflects seasonal patterns around diagnosis. Online social network data can be used to identify time periods when patients may have an increased interest and motivation to learn about surgery.



(a) Seasonality analysis of posts mentioning multiple operations

(b) Correlation (0.755, p-value=0.0011) of posts mentioning multiple operations and the number of new posters between February and March

Seasonality analysis and correlation test with new posters in March

255896 - Seeing eye to eye: Do newly diagnosed breast cancer patients and their surgeons agree on the role played in decision-making?

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Background/Objective: Decisions about breast cancer surgery should be based, in part, on patient preferences, but the role patients want to play in these decisions varies. Some patients want to make the decision for themselves, some want the doctor to make the decision, and some want to collaborate with their doctor. We often assume that providers are adept at perceiving what role the patient is playing, but there are no data on how often surgeons and patients agree about which role the patient played and the impact this may have on outcomes. Also, prior studies have shown that many patients do not achieve their desired role, but prospective data are lacking. This has been shown to affect decisional outcomes such as decision regret and satisfaction.

Methods: As part of an ongoing study, we surveyed 50 newly diagnosed breast cancer patients about their preferred role in decision-making prior to their consultation with a surgeon. Preferred role was obtained using the Patient Preference Scale (based on the Control Preference Scale). This scale includes 5 roles: most passive (“I prefer to leave all decisions regarding my treatment to my doctor.”), passive (“I prefer that my doctor make the final decision about which treatment will be used but seriously consider my opinion.”), collaborative (“I prefer that my doctor and I share responsibility for deciding which treatment is best for me.”), active (“I prefer to make the final selection of my treatment after seriously considering my doctor's opinion.”), and most active (“I prefer to make the final selection about which treatment I will receive.”) Following their consultation with 1 of 4 surgeons, we asked the patient and the surgeon to select what role they thought the patient played using the Patient Perception Scale and the Provider Perception Scale. Data were analyzed for concordance between the role preferred and the role achieved and the patient’s and provider’s perceptions using the Wilson Score interval approach with 95% confidence intervals.

Results: Forty-six percent (23) of patients preferred the collaborative role. Forty-four percent (22) preferred an active role, but only 1 patient preferred the most active role. Ten percent (5) of patients preferred a passive role, but none preferred the most passive role. After the consultation, the provider's and patient's perceptions about the exact role the patient played were not concordant, κ=0.033 (0.024, 0.0406). Patient's perceived a low concordance with their exact preferred role, κ=0.408 (0.378, 0.439). If the 2 active and 2 passive roles were grouped, concordance improved. Using these groupings, concordance with the provider's perceptions improved, κ=0.800 (0.774, 0.824) and the patient's perceptions of the role they achieved were concordant, κ=0.966 (0.953, 0.976).

Conclusions: Newly diagnosed breast cancer patients prefer a range of roles in the surgical decision-making process. This prospective data confirms that many do not achieve their exact preferred role and further, shows that the provider's perception of the role the patient played is often different from the patient's perception. It is not clear how patients view the differences between the different roles and how meaningful it is if they achieve a close, but not exact role. It is not known how disagreement between the provider and patient on the role the patient played may impact outcomes. Future work will analyze decisional outcomes and quality of life based on concordance and a communication intervention to improve role and perception concordance.

257101 - Impact of the receipt of pre-consultation web-based material on patients' value-concordant decision-making for type of breast cancer surgery

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Background/Objective: The decision for breast cancer surgery should consider patient preference, and a high-quality decision should be concordant with patients' values. We hypothesized that receipt of a web-based breast cancer surgery decision aid (DA) prior to a surgeon visit would enhance communication between the patient and surgeon by prompting patients to consider their values and preferences a priori. We used a novel implementation strategy to deliver 2 different types of web-based information to patients prior to the surgical consultation, and compared the impact on patients' baseline preferences for surgical type.

Methods: We prospectively randomized stage 0-3 breast cancer patients to be emailed a link to a web-based decision aid versus standard web sites (National Cancer Institute, American Cancer Society, Breastcancer.org). Prior to meeting the surgeon, patients completed the Breast Cancer Surgery Decision Quality Instrument, which elicits patients' values relevant to surgical decision-making. Patients were asked their baseline preference for type of surgery. Concordance between patients' values and baseline preference for surgery was calculated by developing a multivariable logistic regression model of their baseline preference for surgery, including the elicited patient values as predictors. The model-predicted probability of a baseline preference for mastectomy versus breast conservation was then calculated for each patient. Patients were considered concordant if they had a stated preference for mastectomy with a predicted probability of ≥ 0.5, or breast conservation with predicted probability of < 0.5. The proportion concordant was compared between the 2 randomization arms using chi-square (and Fisher's exact test where appropriate).

Results: Two hundred forty-four patients were randomized and electronically received the web-based material; 222 answered the values and preference questions and are included in this analysis. Participants' median age was 58 (27-80), 99% were white, and 66% had at least a college degree; these demographics were consistent across study arms ($p > 0.05$). After receiving the web-based material but before meeting the surgeon, 44% of patients reported uncertainty regarding their preferred surgery; 38% stated a preference for breast conservation and 18% for mastectomy (distribution similar across study arms, $p=0.4$). Patients stated a preference for surgery type concordant with their reported values in 90% of cases. Likelihood of concordance was statistically different between study arms ($p=0.04$, DA 85% [n=9 discordant] vs standard websites 96% [n=3 discordant]). For those patients that reported uncertainty regarding their baseline preference for surgery, the vast majority (94%, n=89) had a model-predicted probability based on their values that suggested a strong preference for either mastectomy (23%, n=22) or breast conservation (69%, n=67).

Conclusions: In our randomized study, there was a statistically but likely not clinically significant difference in the likelihood of patients having a values-concordant baseline preference for surgery based on the type of web-based information received. Importantly, most patients who state a preference for surgery are doing so in concordance with their values. Although a large proportion of patients stated they were uncertain which surgical procedure they preferred, most answered questions about key values relevant to breast cancer surgery in a way that suggested a baseline preference for type of surgery. Using this type of survey to elicit patients' baseline values and preferences for surgery prior to meeting the surgeon is feasible and may enhance patient-surgeon consultations by providing surgeons important insights into how their patients are approaching decision-making.

SLN

254629 - Sentinel lymph node biopsy after initial lumpectomy (SNAIL study)

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Background/Objective: Recommendations for sentinel lymph node biopsy (SLNB) in women presenting to an oncology center with recent prior lumpectomy are based on retrospective studies; however, prospective data is still sparse. Periareolar injection is a validated technique for SLNB, based on the theory that lymphatics from all quadrants of the breast draining to peri-areolar plexus, then through 1 or 2 afferent lymphatic channels to axillary sentinel nodes. We report a prospective observational study evaluating the feasibility and accuracy of SLNB in patients diagnosed with breast cancer after lumpectomy

Methods: The study was carried out from January 2015 to October 2016 in Tata Medical Center (TMC), India, approved by the institutional review board (EC/TMC/36/14). We included a consecutive series of 50 patients who presented after lumpectomy with a definitive post-operative histological diagnosis of invasive breast cancer. All patients had periareolar methylene blue injection for SLN identification, followed by validation axillary dissection. Analysis was done by SPSS 23.

Results: The median lumpectomy size before SLNB was 2.4cm (IQR 1.8, 4). SLNs were identified in 46 of 50 patients (identification rate: 92%). The median number of SLNs was 2 (IQR 1,4), with > 1 SLN identified in 29 out of 46 patients (63%). Fourteen patients (28%) had a positive SLN, and in 7 of these

(50%), the SLN was the only positive node. Twelve SLNs had macro-metastases, and 1 each had micro-metastasis and isolated tumor cells (ITC). Of 32 patients with negative SLNs, axillary dissection confirmed negative LNs (pN0) in 30 patients. Two patients had a single positive non-sentinel lymph node. Taking all nodal disease including ITC as positive, the false negative rate (FNR) was 12%, and if ITC was considered negative, it was 13.3%. Central rather than peripheral location of the initial tumor, based on the site of the operative scar, was predictive for false negativity, as both patients had central tumors with periareolar surgical scars (Fisher's exact test=5.1, p=0.02). The sensitivity of SLNB in this group was 87.5%, and accuracy was 96.5%. Comparing the "detection failure" and the "detection success" groups, we found that tumor location or tumor size at prior lumpectomy had no impact on the identification rate. The interval between the 2 surgeries was shorter in the "detection failure" group than the "success"' group (34±5 vs 40±17 days), but not statistically significant. There were no methylene blue-related complications.

Conclusions: The accuracy of SLNB is not affected by prior excision of palpable lumps for breast cancer. In this series, a short interval between surgeries did not result in a lower SLN identification rate. FNR may be high after excision of central tumors with periareolar scars, and the procedure should be approached with caution in this group.

257067 - Does omission of lymph node evaluation in women 70 years of age or older with clinically node negative hormone receptor positive breast cancer affect survival?

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Background/Objective: The Society of Surgical Oncology, in its 2016 "Choosing Wisely" guidelines, suggested that lymph node (LN) evaluation should not be routinely performed in women ≥ 70 years of age with clinically LN negative (-), hormone receptor (HR) positive (+) breast cancer. We sought to determine the impact of omission of LN evaluation in this population on survival.

Methods: Patients ≥ 70 years of age diagnosed with clinically LN-, HR+ breast cancer between 2004 and 2012 were identified in the National Cancer Database (NCDB). Overall survival analyses were performed using SPSS.

Results: There were 161,993 eligible patients with survival data identified in the NCDB. Whether lymph node evaluation was performed or not was unknown in 387 patients; the remaining 161,606 patients formed the cohort of interest. Median patient age was 77 (range; 70-90), and the median tumor size was 14 mm. There were 129,137 patients (79.9%) who had regional LN surgery; of these, the median number of LNs examined was 2 (range; 0-88). There were19,225 (14.9%) who were found to be LN+; the median number of positive LNs was 1 (range; 1-57). With a median follow up of 41.6 months, there was a significant difference in overall survival between those who had LN evaluation and those who did not (median survival 119.6 vs. 67.3 months, $p < 0.001$). Patients who had LN evaluation were more likely to be younger, with smaller tumors, White, with private insurance, fewer comorbidities, and tumors that were higher grade, and were more likely to have undergone surgery, radiation, chemotherapy, and/or hormonal therapy for their disease (see Table). Taking these potential confounders into account, including patient age, race, ethnicity, income, insurance, community size, region, comorbidities

(Charlson-Deyo score), tumor size, grade, receipt of surgery, radiation, chemotherapy, and/or hormonal therapy, on Cox multivariate survival analysis, patients who had LN evaluation had a significantly lower hazard rate of death than those who did not have LN evaluation (HR=0.628; 95% CI: 0.608 – 0.649, log rank p < 0.001).

Conclusions: Only about 20% of patients who are ≥ 70 years of age with clinically LN-, HR+ breast cancer did not have LN evaluation in keeping with the new "Choosing Wisely" guidelines. In our analysis, patients compliant with this guideline had a worse overall survival when controlling for sociodemographic, pathologic, and treatment variables. Although the absence of data on breast cancer-specific survival limit interpretation of this finding, it is likely that these findings are, in part, attributable to selection biases which cannot be accounted for. These data suggest that the "Choosing Wisely" guidelines for LN evaluation have not been uniformly followed in the past; surgeons may be performing sentinel LN biopsy in patients they feel would benefit from this low-risk staging procedure, contributing to significant overall survival differences.

	Bivariate analysis of factors associated with LN evaluation			Multivariate Survival Analysis	
Factor	No LN Evaluation	LN Evaluation	Bivariate p-value	Cox HR	Cox p-value
LN evaluation				0.628	<0.001
Median patient age (years)	83	76	<0.001	1.079	<0.001
Mean tumor size (mm)	18.2	16.8	<0.001	1.004	<0.001
Race:			<0.001		0.001
White	89.6%	90.6%		Referent	
Black	7.6%	6.4%		1.017	
Other	2.8%	3.1%		0.833	
Hispanic Ethnicity	2.8%	3.2%	0.002	0.784	<0.001
Median income:			<0.001		<0.001
< $30,000	10.6%	10.5%		Referent	
$30,000 - $35,999	15.5%	17.0%		0.980	
$36,000 - $45,999	27.4%	28.8%		0.923	
$46,000+	46.5%	43.7%		0.897	
Insurance:			<0.001		0.269
Uninsured	0.4%	0.3%		Referent	
Private insurance	9.5%	11.1%		1.088	
Medicaid	1.2%	1.0%		1.252	
Medicare	88.6%	87.3%		1.093	
Other government	0.3%	0.3%		1.033	
Community description/size:			<0.001		<0.001
Metro area; > 1 million (M)	57.8%	52.2%		Referent	
Metro area; 250,000 – 1 M	22.0%	22.3%		1.088	
Metro area; < 250,000	8.6%	10.6%		1.146	
Urban area; 20,000+	5.3%	5.8%		1.1063	
Urban area; 2500 – 19,999	5.2%	7.4%		1.035	
Rural area; < 2500	1.1%	1.7%		1.009	
Region:			<0.001		<0.001
New England	11.8%	5.7%		Referent	
Middle Atlantic	17.8%	15.3%		1.012	
South Atlantic	19.3%	20.6%		1.022	
East North Central	20.1%	19.1%		1.090	
East South Central	4.7%	5.8%		1.059	
West North Central	6.3%	8.4%		1.139	
West South Central	5.1%	7.1%		1.003	
Mountain	3.6%	4.8%		0.998	
Pacific	11.3%	13.1%		0.881	
Charlson-Deyo Score:			<0.001		<0.001
0	76.4%	78.3%		Referent	
1	17.2%	17.5%		1.521	
2	6.3%	4.2%		2.455	
Tumor grade:			<0.001		<0.001
1	36.3%	34.7%		Referent	
2	50.0%	51.3%		1.141	
3	13.8%	14.0%		1.456	
Surgery type:			<0.001		<0.001
None	22.7%	0.1%		Referent	
Lumpectomy	61.6%	64.2%		0.472	
Mastectomy	15.8%	35.7%		0.499	
Radiation therapy received	21.2%	52.3%	<0.001	0.691	<0.001
Chemotherapy received	2.8%	8.9%	<0.001	1.092	<0.002
Hormonal therapy received	54.2%	72.5%	<0.001	0.751	<0.001

Factors associated with LN evaluation, and multivariate Cox regression survival analysis

256771 - First experience with hybrid tracers (radioactive-fluorescent) in breast sentinel node and roll procedures in Uruguay's National Cancer Institute

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Background/Objective: Uruguay exhibits one of the highest rates of breast cancer in Latin America, similar to those of developed nations. For this reason, many surgeries are performed daily by breast lesions that require identifying sentinel node or non-palpable lesions. Uruguay's National Cancer Institute (INCA) has introduced breast sentinel lymph node biopsies (SLNB) and radioguided occult lesion localization (ROLL) procedures many years ago. Recently, we have incorporated the hybrid tracer 99mTc nanocolloid-indocyanine green (99mTc NC-ICG) to these procedures. The aim of our work is to describe our first experience with the hybrid tracer in SLNB and ROLL procedures at Uruguay's National Cancer Institute (INCA).

Methods: Ten female patients had SLNB procedures performed with 99mTc NC-ICG. Patients were injected approximately 14 hours before surgery periareolary subcutaneous in the same quadrant of the lesions. Scintigraphic and SPECT-CT images were later acquired. During the SLNB, a gamma probe and near infrared (NIR) visualization system (Fluvir) was used to localize the SLN. These combinations allowed us to guide to the SLN using the acoustic cue provided from the gamma probe and the images from the NIR visualization system. Once found, the nodes were removed and examined histopathologically. Patients who had positive SLNB underwent axillary dissection. Also 5 patients had ROLL procedures performed. These patients were injected with 99mTc NC-ICG under mammography, and 1 hour later, patients were in the operating room where with the aid of the gamma probe and NIR visualization system, lesions were removed for histopathology examination. All procedures were approved by the Ethics Committee.

Results: SLNB with 99mTc NC-ICG allowed us to use their complementary fluorescent and radioactive properties in order to find the SLN. In this way, the gamma probe guided us to the region where the node was, and fluorescence made it easy to remove it and spare the rest of surrounding tissue. In this way, we could remove XXX nodes, being xxx positive. All radioactive nodes were fluorescent. In ROLL procedures, using gamma probe and fluorescent information allowed us to better delineate where the tracer was placed. Margins were free from disease.

Conclusions: INCA successfully started to work with hybrid tracers in breast SLN and ROLL procedures. These procedures did not have an adverse effect on patients, being safe and have the potential to add a visual cue to these kind of procedures, which aids in SLN and lesion localization and removal.

256856 - Prospective study of the feasibility of sentinel lymph node biopsy in the setting of inflammatory breast cancer

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Background/Objective: Inflammatory breast cancer (IBC) is the most aggressive form of breast cancer. The majority of patients with IBC have axillary nodal involvement at the time of presentation. Advances in neoadjuvant chemo therapy (NACT), in particular HER2-targeted therapy, have been shown to improve rates of pathologic complete response. However, current standard of care for all patients with IBC, regardless of nodal status, includes axillary lymph node dissection (ALND). Although 2 previous studies have evaluated sentinel lymph node biopsy (SLNB) for IBC patients, neither used dual tracers to attempt sentinel lymph node (SLN) identification, and neither assessed nodal response before and after NACT with axillary imaging. The purpose of this study was to prospectively determine false negative rates of SLNB in IBC patients using dual tracer mapping, and to correlate nodal pathology findings with preoperative axillary nodal basin imaging.

Methods: Sixteen patients with IBC were prospectively enrolled in our IRB-approved protocol. All patients presented with T4d disease. Seven patients had N1, 2 had N2, and 7 had N3 disease. Four patients were hormone receptor (HR) positive and HER2 negative, 2 were both HR and HER2 positive, 5 were HR negative/HER2 positive, and 5 were both HR and HER2 negative. Patients underwent clinical axillary staging with both physical examination and axillary ultrasound both before the initiation of their preoperative chemotherapy and prior to surgery. At surgery, all patients underwent SLNB followed by ALND. Both blue dye and radioisotope were used for SLNB in all patients.

Results: SLN mapping was successful in only 4 of the 16 patients (25%), and 3 of these 4 (75%) had a pathologic complete response (pCR) within the axilla. The 1 patient who mapped but was not found to have a pCR in the axilla had a positive SLNB with additional nodal disease identified after ALND. Two of the patients who mapped successfully had HER2 positive disease, and 2 had triple-negative disease. Of the patients with successful mapping, 2 had N1 disease at diagnosis, and 2 had N3 disease. All patients who successfully mapped had presumed residual nodal disease on preoperative axillary ultrasound. Twelve of the 16 patients (75%) did not drain tracer into the axilla. Ten of these remaining 12 patients (83%) had pathologically proven axillary disease after neoadjuvant chemotherapy.

Conclusions: The great majority of IBC patients did not have successful SLNB after completion of neoadjuvant chemotherapy. A small subset of patients who have pCR might undergo successful SLNB, but axillary imaging failed to reliably identify these patients. ALND at the time of mastectomy should remain standard of care for all IBC patients.

257386 - Is there a role for axillary ultrasound to clinically stage the axilla in obese breast cancer patients?

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Background/Objective: Obesity is a major health epidemic in the United States and has been reported to affect more than a third of the adult population. The role of obesity in all dimensions of medical care is an area of great interest among researchers and clinicians alike. There is some data to suggest physiologic and prognostic differences in obese versus non-obese breast cancer patients. We propose that the relationship between obesity and malignancy is multi-dimensional and may affect the diagnostic methods that are traditionally used, including physical exam and radiographic studies. Recent research has suggested that metastatic lymph nodes at sentinel lymph node biopsy (SLNB) in clinically node negative (cN0) patients did not differ based on body mass index (BMI). We sought to determine if axillary ultrasound may be a useful adjunct to physical exam in obese breast cancer patients during clinical staging. To date, there are no studies to suggest that obese patients warrant any additional evaluation of their lymph node status than usual and standard care.

Methods: A single institution cancer registry was used to identify patients with T1/T2 breast cancers who had undergone axillary ultrasound prior to initiation of neo-adjuvant therapy over a 5-year period. Patient demographics including age, BMI, stage, clinical node status, and results of axillary ultrasound were all reported. Additional information on axillary biopsy as well as findings at SLNB was also collected. Patients with a BMI of 30 or above were considered obese. Discordance between physical exam and ultrasound was determined based on pre-treatment evaluation of each domain. Discordance was defined as a clinically positive physical exam with a negative axillary ultrasound or a negative physical exam with a positive ultrasound. Statistics were reported using SPSS.

Results: Two hundred fifty-six patients were identified for analysis. Patients with stage 2 disease made up 71.1% of our population, while 8.6% had stage 1 disease, and the remaining 20.3% of patients had stage 3 or 4 disease. The average BMI was 29.3, and 93 (36.3%) patients met the definition for obesity. A total of 83 (32.4%) patients had discordant physical exam and ultrasound results. Among discordant patients, the overwhelming majority (91.6%) had a negative physical exam with a positive ultrasound. Obese patients were found to have discordant results in 31/93 (33.3%) patients, compared to 52/163 (31.9%) of non-obese patients. This difference was not statistically significant by X-square test of independence ($X^2=0.055$, $p=0.814$).

Conclusions: In our experience, there is not a difference in the number of obese patients determined to have discordant physical exam and ultrasounds compared to non-obese patients. These results corroborate recent reports that suggest that obese patients deemed cN0 by physical exam were no more likely to have a positive sentinel lymph node biopsy than non-obese patients. Although many clinicians may surmise that physical exam is less reliable in obese patients, our results support that physical exam is as reliable in obese patients as in non-obese patients for determination of clinical nodal status in our population of patients. Based on this data, there is not a unique role for additional axillary evaluation for obese patients in the absence of other clinical indications to pursue additional imaging studies.

256992 - Novel sentinel nodal stations are highly predictive of axillary nodal disease volume in breast cancers

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Background/Objective: Despite sentinel lymph node biopsy (SLNB) being the gold standard procedure in early breast cancer, the precise anatomical location of sentinel lymph nodes (SLN) is still unknown.

Methods: We have identified 2 novel sentinel nodal stations (SNS) in relation to the intercostobrachial nerve (ICB) and the medial pectoral neurovascular bundle (MP) within the axilla. Consecutive patients undergoing breast cancer surgery with SLNB using blue dye alone were prospectively studied and analyzed.

Results: A total of 300 SLNB were performed on 298 patients using blue dye tracer alone. The identification rates of sentinel lymph nodes at the ICB and MP SNS were 98.0% (294 of 300) and 91.7% (275 of 300) respectively. Both ICB and MP sentinel lymph nodes were found in 91.7% (275 of 300) of the cases. The median number of ICB and MP nodes harvested was 1 respectively. The non-identification rate of sentinel lymph node was 2% (6 of 300 cases). Twenty percent (60 of 300) of cases were found to have metastases in the sentinel lymph nodes, and subsequently underwent axillary clearance. Of the 58 cases (96.7%) that had node positive disease at the ICB SNS, 18 (31.0%) were also found to have nodal metastases at the MP SNS. Conversely, only 2 cases (3.3%) showed nodal metastases at the MP SNS without involvement of the ICB SNS. In patients with only ICB SNS positive disease, there was a median of 1 additional positive non-sentinel lymph node found on axillary clearance. Taken together, these results strongly suggest that lymphatic channels flow in a Haldstedian fashion from the breast first to the ICB SNS, and hence to the MP SNS. Significantly, the positive predictive value of MP SNS for heavy nodal disease (N2 or 3) was 85.0% (95% CI 61.13 – 96.04). Furthermore, the probability of N1 disease based on the negative predictive value was 98.2% (95% CI 95.65 – 99.34).

Conclusions: Our report represents the first description of 2 novel SNS based on readily identifiable anatomical structures within the axilla. This has led to a high identification rate during SLNB. By minimizing the amount of dissection done, this technique could also potentially reduce the duration of surgery as well as the risk of injury to vital structures within the axilla. Finally, our data suggest that the MP SNS is highly predictive of further nodal disease burden.

257828 - Sentinel node frozen section correlates with unnecessary axillary dissection

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Background/Objective: The aim of our study was to evaluate the adoption of the proposed ACOSG Z11 protocol in a major cancer center in Brazil, and what its first impact for the patients and surgeons would be. Traditionally, Brazilian and South American surgeons had some difficulty adopting the Z11 protocol.

Methods: In July 2014, after a multidisciplinary meeting in a major Brazilian cancer center, the breast surgeons staff decided to adopt the Z11 protocol. The patients who had criteria for inclusion in Z11 were included. After approval from the Ethics Committee, a retrospective database was constructed to evaluate the preliminary results of one year of this new protocol. The criteria for inclusion and exclusion were the same as proposed in the ACOSOG Z11 trial.

Results: After one year, 200 patients had clinical and pathological criteria for inclusion in the Z11 protocol (T1-2, N0, no neoadjuvant chemotherapy, and only those candidates for breast-conserving surgery, followed by radiotherapy). The median age was 61 years old (30-90 years old), median tumor size was 16 mm (1-37 mm). All patients received sentinel node biopsy, and 2 no planned groups were formed, according to the surgeons' preference for who conducted the cases. In group A, N =70 patients, the surgeons used frozen section routinely to evaluate lymph node status (LN). In Group B, N -130, no frozen sections were performed. No difference between age, size, type of tumour, number of sentinel nodes identified, ER, or HER-2 were registered between groups. The only registered difference between them were positivity for PR (0.002) and percentage of axillary dissection (p=0.003). In Group A, 58 patients had negative SNB and 12 were positive (11/12 had axillary dissection, 7/11 (63%) had no residual disease, and 4/11 (37%) had only one positive node). In Group B, 110 patients had negative nodes (75%), and 20 (25%) had positive nodes. Only 5/20 patients had axillary dissection in this group. The criteria for axillary dissection used were extranodal disease or > 3 positive nodes. All of these patients had other positive LN in axillary dissection.
Conclusions: The rouine use of sentinel node frozen section correlates with greater chance of unnecessary axillary dissection. In all patients whose frozen sections were used to decide about axillary clearance, this procedure resulted in a negative axillary dissection. The adoption of Z11 protocol should reduce drastically our complications related to lymphedema, pain, and other complications. These patients are being surveyed for disease-free survival, overall survival, and main major complications.

257314 - Practice patterns of axillary staging of hormone-positive breast cancers: a report from the National Cancer Database

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Background/Objective: The decision to expose elderly women, who have increased rates of comorbidities, to the potential morbidity and mortality of a breast cancer surgery is complicated by the fact that their overall mortality due to breast cancer is similar to their age-based non-cancer mortality. The Choosing Wisely campaign has made a recent recommendation that sentinel lymph node (LN) biopsy in clinically node negative women 70 and older with hormone receptor positive invasive breast cancer be avoided. The rationale is that hormonal therapy is standard for all patients with hormone receptor positive invasive breast cancer, and that locoregional recurrence is not impacted by axillary staging in this population. This recommendation has the opportunity to optimize medical and surgical treatments while minimizing their morbidity and mortality. Our aim is to assess practice patterns related

to axillary staging in women 70 and older and elucidate the challenges related to the implementation of this recommendation.

Methods: From a group of 2.2 million women with diagnoses of invasive breast cancer or ductal carcinoma in situ between the years of 2004 and 2014 from the National Cancer Database (NCDB), a cohort of 615,435 patients 70 years of age and greater with invasive cancer were identified. From this cohort, 313,704 patients were identified who underwent initial treatment with hormone therapy, which was used as a surrogate for hormone receptor-positive cancers since hormone receptor status is not available in the NCDB. Patient demographics, hospital type, axillary staging procedures, numbers of axillary nodes evaluated and positive, and tumor size were evaluated using descriptive statistics, one-way ANOVA and chi-square analyses.

Results: Sentinel LN biopsy was performed in 49% of the patients in this cohort and some staging procedure was performed in 75.9%. The mean age at diagnosis is 77.2 years, which, along with race, was not significantly associated with the number of positive axillary LN ($p = 0.24$ and 0.69, respectively). The mean number of LNs examined during axillary staging surgery was 10.9; the mean number of positive nodes was 3.69, and there is a positive correlation between the number examined and the number of positive LNs ($p = 0.002$). Larger tumors and those with a higher grade also correlated with larger numbers of positive LNs ($p < 0.001$) The highest number of axillary staging procedures were performed at Comprehensive Community Cancer Centers (49.5%, $p < 0.001$). Community Cancer Programs performed the lowest percentage of sentinel LN biopsies, the highest percentage of primary axillary dissections and ipsilateral axillary dissections performed during the same procedure as a sentinel LN biopsy (See Table 1, $p < 0.001$.) Academic/Research Cancer Centers treated the highest number of patients without regional LN surgery ($p < 0.001$).

Conclusions: The practice of axillary staging, especially sentinel LN biopsy, in elderly women with hormone-receptor positive invasive breast cancer is very prevalent. Higher rates of axillary dissection in the community setting may reflect late adoption of sentinel LN biopsy, and may highlight a target area for education related to new staging recommendations. Analysis of changes in locoregional recurrence and survival are necessary after full implantation of this recommendation.

	Overall	Community Cancer Program	Comprehensive Community Healthcare Program	Academic/Research Program	Integrated Network Cancer Program
n	72697	8842 (12.0%)	36476 (49.5 %)	20372 (27.6%)	8007 (10.9%)
No regional LN surgery	23.8	22.2	22.5	26.9	23.3
LN biopsy or aspiration	1	0.6	0.9	1.3	1.1
SLN biopsy	49	46.5	50.1	47.1	51.3
Axillary dissection	13.2	17.2	13.2	12.3	10.9
Unknown LN removed	0.1	0.2	0.1	0.1	0
1-3 LN removed	3.9	5	3.7	4	3
4 or more LN removed	9.2	12	9.4	8.1	7.9
SLN biopsy + axillary dissection	12	12.3	12.3	11.2	12.2
SLN biopsy followed by axillary dissection	0.9	0.9	0.8	0.9	0.9
Unknown	0.3	0.2	0.2	0.4	0.2

Table 1. Percent of patients undergoing axillary staging procedures at different types of institutions

257318 - Multidisciplinary management of the axilla in patients with cT1-2N0 breast cancer undergoing mastectomy: results from a prospective single institution series

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Background/Objective: The AMAROS trial concluded that for patients with clinical T1-2 N0 primary breast cancer and 1-2 positive sentinel lymph nodes (SLN), axillary radiotherapy (AxRT) provides equivalent local regional control and a lower incidence of lymphedema as compared to axillary lymph node dissection (ALND). Although these findings are easily implemented in patients receiving breast conservation, the impact of these results for patients undergoing mastectomy remains unclear. We prospectively assessed how often ALND could be replaced by AxRT in a consecutive cohort of patients undergoing mastectomy for clinical T1-2 N0 breast cancer.

Methods: Beginning in November 2015 our multidisciplinary group agreed to omit routine intraoperative evaluation of the SLN in clinical T1-2 N0 patients ≤ 60yo undergoing upfront mastectomy who would otherwise be eligible for consideration of post-mastectomy radiation therapy (PMRT). For patients > 60yo intraoperative evaluation of the SLN was also omitted in the presence of other high risk features (lymphovascular invasion or hormone receptor negative disease). Patients with 3 or more positive SLN on final pathology were returned to the OR for ALND. Patients with 1-2 positive SLN on final pathology were reviewed by our multidisciplinary group to determine if PMRT + AxRT was an appropriate alternative to ALND.

Results: From Nov 2015 - Oct 2016, 123 patients with cT1-2 N0 breast cancer underwent primary mastectomy; of these 75 met all criteria for our multidisciplinary consensus strategy. 13 (17%) patients were > 60 years old without high risk features and underwent intraoperative evaluation of the SLN per standard care, all were node negative intraoperatively and 2 were positive on final pathology. Among the remaining 62 patients without intraoperative evaluation of the SLN, 47 (76%) patients had negative SLNs on final pathology and 15 (24%) had at least one positive SLN. 2 (3%) had ≥ 3 positive SLN on final pathology and were returned to the OR for ALND; neither of these 2 patients had additional positive nodes. Among the remaining 13 patients with 1-2 positive SLN on final pathology, 10 (77%) received PMRT + AxRT, 2 were returned the OR for ALND (no additional positive nodes were found) and 1 patient was observed.

Conclusions: Our multidisciplinary consensus strategy for patients with cT1-2 N0 breast cancer undergoing mastectomy demonstrates that omission of intraoperative evaluation of the SLN resulted in return to the OR for ALND in only 4 patients (6.5%); 2 had ≥3 positive SLN and 2 did not otherwise meet criteria for PMRT. ALND was avoided in 10/13 (77%) patients with 1-2 positive SLN in favor of PMRT + AxRT. These data demonstrate that with appropriate multidisciplinary consensus strategies intraoperative evaluation of the SLN can be safely omitted in patients meeting AMAROS criteria who would otherwise be eligible for PMRT.

257212 - Are Lymph Node Characteristics on Axillary Ultrasound Associated with Multiple Positive Lymph Nodes in Patients Managed by ACOSOG Z0011 Criteria?

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Background/Objective: Axillary ultrasound (AUS) with biopsy has a positive predictive value (PPV) nearing 100% and is used to identify suspicious nodes during breast tumor evaluation. A positive biopsy eliminates patients from being managed by ACOSOG Z0011 criteria, which identified nodal positivity based on clinical, not radiographic, evaluation. A positive AUS biopsy cannot reliably determine the need for an axillary lymph node dissection (ALND), thus questioning the utility of AUS biopsy prior to clinical evaluation in cN0 patients. Several lymph node characteristics are associated with nodal positivity. We sought to determine if specific abnormal lymph node characteristics, rather than solely lymph node positivity on AUS biopsy, were associated with the likelihood of having multiple positive nodes on final pathology. If characteristics associated with multiple positive nodes can be identified, patients can be stratified into groups that can benefit from biopsy and those that should avoid biopsy and be managed according to Z0011 criteria.

Methods: A retrospective review of a prospectively maintained database identified cT1-2N0 patients who underwent AUS and received BCT (breast conserving therapy) between 2010-2015. Clinicopathologic factors and ultrasound characteristics on AUS were compared between patients with 0-1 and multiple (≥2) positive lymph nodes on final pathology.

Results: From 2010-2015, 208 patients with cT1-2N0 breast cancer underwent preoperative AUS and BCT. Median age was 64 years. 74.5% of tumors were T1, 92.8% of ductal histology, and 80.8% were estrogen positive. On final axillary surgical pathology, 94.7% and 5.3% had 0-1 and multiple (≥2) positive lymph nodes, respectively. On univariate analysis, multiple positive lymph nodes on final pathology was associated with visualization of multiple LN on AUS (OR=5.153, p=0.034), loss of fatty hilum (OR=5.152, p=0.017), and presence of lymphovascular invasion (LVI) (OR=11.448, $p < 0.001$). Variables approaching significance for multiple positive LNs were: round LN shape (OR=3.397, p=0.059), greater cortical thickness (OR=1.189, p=0.056), and tumor multifocality (OR=4.031, p=0.055). On multivariate analysis, only the presence of LVI was found to be associated with multiple positive LNs (OR=8.374, $p = 0.010$).

Conclusions: In patients meeting Z0011 criteria who underwent preoperative AUS, LVI was associated with the presence of multiple positive LNs and thus the potential need for ALND. No specific lymph node characteristics were found to be associated with the need for ALND, although several characteristics were significant on univariate analysis. A limited number of patients in the study population had ≥2 positive lymph nodes on final pathology, likely contributing to the lack of variables that remained significant on multivariate analysis. With a larger sample of patients with ≥2 positive lymph nodes, perhaps other AUS characteristics may be associated with multiple positive nodes. It remains difficult to determine which group of cN0 patients should undergo biopsy preoperatively and which patients should undergo clinical evaluation first, so as to remain candidates for ACOSOG Z0011. Although ultrasound has a high PPV for the presence of axillary metastases, qualitative details about LN abnormalities may not be sufficient to determine the presence of multiple positive LNs and the need for ALND.

		Univariate		Multivariate	
Characteristic	Categories	Odds ratio	P	Odds Ratio	P
Loss of fatty hilum	Yes vs. No	5.152	**0.017**	5.339	0.214
Number of abnormal LN on AUS	Multiple vs. none	5.153	**0.034**	4.500	0.307
LVI [a]	Yes vs. No	11.448	**<0.0001**	8.374	**0.010**
LN shape	Round vs. elliptical	3.397	0.059*	0.430	0.500
Cortical thickness (mm)	Continuous	1.189	0.056*	0.967	0.828
Multifocality	Yes vs. No	4.031	0.055*	3.986	0.127
Age (yrs)	Continuous	0.985	0.575	0.976	0.443

* approaching significance
[a] lymphovascular invasion

Table 1: Univariate and multivariate analysis of variables associated with ≥2 positive lymph nodes on final pathology

256751 - The Impact of Axillary Surgery on Women with N2-N3 Invasive Breast Cancer

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Background/Objective: Among women with node-positive breast cancer, low volume axillary disease can be safely managed with sentinel lymph node biopsy (SLNB) and radiation; however, surgical lymphadenectomy has remained the standard of care for women with advanced nodal disease. We sought to determine the impact of axillary surgery on overall survival (OS) in patients with N2-N3 invasive breast cancer.

Methods: Women (18-90 years) with clinical N2-3 invasive breast cancer who underwent axillary surgery were identified from the American College of Surgeons National Cancer Data Base (NCDB) between 2004-2013. Axillary surgery was categorized as SLNB alone or axillary lymph node dissection (ALND). SLNB was defined as removal of 1-5 lymph nodes and ALND was defined as removal of ≥10 nodes. Patients who had removal of 6-9 lymph nodes, metastatic disease, or did not undergo primary breast surgery were excluded. Patient clinicopathologic and hospital-level variables were collected and summarized for SLNB alone vs. ALND. The log-rank test was used to compare OS between LN surgery groups, and Cox proportional hazards models were used to estimate the effect of ALND vs. SLNB alone after adjustment for known covariates. An interaction term was included in a subsequent model to determine if the effect of LN surgery on OS differed for cN2 vs. cN3 patients

Results: A total of 22,156 patients met inclusion criteria. Median age of the cohort was 56 years (IQR 47-66). Median tumor size was 8.7 cm (4.1-18.4). The majority of patients were hormone receptor positive (53.9% ER+, 65.7% PR+). In total, 27% of women underwent lumpectomy, 73% mastectomy, 86.4% chemotherapy, 74% radiation, and 54.4% received endocrine therapy. 68.5% of all women had clinical N2 disease and 31.5% had clinical N3 disease at diagnosis. 2,190 (9.9%) underwent SLNB alone, and 19.966 (90.1%) underwent ALND. The median number of nodes removed in the SLNB group was 3, and 17 in the ALND group. SLNB alone vs. ALND was associated with private insurance (59.9% vs. 55.1%),

grade 3 disease (61% vs. 54.1%), invasive ductal cancer (90.5% vs. 86.6%), and lumpectomy (36% vs. 26%, all p values < 0.001). SLNB patients were less likely to be treated with radiation (71% vs. 74.4%) or endocrine therapy (45.7% vs. 55.4%, both p's < 0.001) compared to ALND patients. After adjustment for known covariates including radiation, chemotherapy, endocrine therapy, receptor status, histology and breast surgery type, ALND was associated with an improvement in survival compared to SLNB (HR 0.68, p < 0.001). The effect of ALND vs. SLNB on survival did not differ between cN2 vs. cN3 patients. (LN Surgery*cN-Stage interaction p=0.23).

Conclusions: Compared with SLNB alone, ALND was associated with improved survival among women with N2-N3 invasive breast cancer. Though omission of ALND is safe in patients with low volume axillary nodal disease, surgical lymphadenectomy should continue as standard of care for women with N2-N3 invasive breast cancer outside a clinical trial.

257320 - Potential for Targeted Axillary Dissection in Patients Who Do Not Receive Neoadjuvant Chemotherapy

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Background/Objective: ACOSOG Z0011 showed that patients with < 3 positive sentinel nodes (SLN) may safely omit axillary node dissection (ALND). There is debate about the role of needle biopsy if < 3 abnormal nodes are seen on US since a positive result defines the patient as clinically node positive, thus requiring ALND. The goal of this study was to determine the proportion of patients with low volume nodal disease on US that are confirmed to have < 3 pathologically positive nodes (p+LN).

Methods: Patients with clinical T1-2 breast cancer with < 3 abnormal nodes seen on US with biopsy-confirmed nodal metastases marked with a clip were identified from a prospective registry database. All patients underwent ALND. Patients who had < 3 p+LN were compared to those with ≥3 p+LN.

Results: Twenty-eight patients were included- 26 (93%) had 1 abnormal node on US and 2 (7%) had 2 nodes. Surgical pathology confirmed < 3 p+LN in 18 (64%). Subjects with < 3 p+LN were less likely to have high nuclear grade (3/18, 17% vs. 6/10, 60%, p=0.03) and had smaller pathologic tumor size (2.5 vs 3.7 cm, p=0.04). There were no differences between the group with < 3 p+LN to those with ≥3 p+LN in clinical tumor size (2.4 vs 3 cm, p=0.2), node size on US (1.8 vs 1.7 cm, p=0.6), proportions with ductal histology (16/18, 89% vs. 7/10, 70%, p=0.4), ER positive tumors (16/18, 89%, vs. 9/10, 90%, p=0.9), or HER2+ tumors (0/18 vs 1/10, p=0.4). In patients with < 3 p+LN, the mean nodal focus was 13 mm (range 0.7 – 36) of which 94% (17/18) were macrometastases. Nine patients underwent targeted axillary dissection (TAD) with removal of the clipped node in addition to SLND. All clipped nodes were retrieved as SLNs.

Conclusions: The majority of patients with small volume disease on US will have < 3 p+ LNs. Instead of avoiding biopsy of these abnormal nodes, TAD may allow for thorough nodal evaluation and potential omission of ALND although further work is required to determine if these patients could safely omit ALND when pathology confirms involvement of < 3 nodes.

257100 - Patient age and tumor subtype predicts adherence to ACOSOG Z0011 recommendations: Analysis of national practice patterns

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Background/Objective: In 2010, the American College of Surgeons Oncology Group Z0011 (ACOSOG Z0011) trial established the safety of omitting axillary lymph node dissection among women undergoing lumpectomy and radiation with 1-2 positive sentinel lymph nodes. We sought to determine the contemporary application of ACOSOG Z0011 criteria based on patient age and tumor subtype.

Methods: Using the National Cancer Data Base, we identified patients with clinical stage I or II breast cancer and at least 1-2 positive lymph nodes treated with lumpectomy and radiation from 2009-2013. Extent of axillary surgery was categorized as SLNB (1-5 nodes removed) or ALND (≥10 nodes). Women who had removal of 6-9 lymph nodes or who received neoadjuvant chemotherapy were excluded. Tumor subtype was categorized as luminal (ER+ or PR+), HER2+, or triple negative breast cancer (TNBC). Patient demographics and treatment variables were collected and evaluated. Logistic regression was used to estimate the odds of receiving SLNB versus ALND after adjustment for demographic factors, treatment characteristics, and facility-level variables. A molecular subtype*age interaction was also modeled.

Results: A total of 22,974 patients met our inclusion criteria. Median patient age was 60 years (IQR 52-68). 72.8% (16,723) of patients had stage I disease, and 27.2% (6,251) had stage II disease. 60.7% (13,945) of women underwent SLNB and 39.3% (9,029) received ALND. 60.9% (13,992) of the total cohort received adjuvant chemotherapy, including 7,156 (51.3%) of the SLNB group and 6,836 (75.7%) of the ALND group. On multivariate analysis, compliance with Z0011 increased over time for all patient groups (OR=1.79 per year, p < 0.001). Furthermore, receipt of SLNB vs ALND did not differ between younger (< 40) versus older (>70) patients (OR 0.94, p=0.54). On individual pairwise comparison, the odds of receiving SLNB only was most strongly impacted by the combination of patient age and tumor subtype (overall p=0.02). The groups most likely to receive SLNB only were HER2+ patients ≥70 years of age (adjusted proportion 0.74 [95% CI 0.68-0.79]) (Table 1). Women treated at community cancer centers were less likely to receive SLNB alone (and were thus more likely to proceed to ALND) compared to those treated at academic centers (OR=0.72, p < 0.001).

Conclusions: Among eligible women with early stage breast cancer, compliance with Z0011 increased over time in all patient groups. Women >70 with HER2+ invasive breast cancers and those treated at academic institutions were more likely to receive only SLNB when compared to other patient groups. Adherence to Z0011 was most strongly predicted by age and tumor subtype.

	Age	Molecular Subtype	Adjusted Proportion (95% CI)	Pairwise Differences	Overall Interaction p-value
1	<40	HER2+	0.633 (0.531 - 0.724)		0.02
2		Luminal	0.663 (0.607 - 0.716)		
3		TNBC	0.623 (0.506 - 0.727)		
4	40-69	HER2+	0.654 (0.613 - 0.693)	7	
5		Luminal	0.643 (0.61 - 0.675)	7	
6		TNBC	0.66 (0.618 - 0.7)	7	
7	≥70	HER2+	0.74 (0.683 - 0.789)	4 5 6 8	
8		Luminal	0.647 (0.609 - 0.683)	7	
9		TNBC	0.717 (0.654 - 0.772)		

Note: numbers listed in "Pairwise Differences" column denote the age*subtype groups that are significantly (p<0.01) different from each other when conducting individual pairwise tests.

Table 1: Adjusted Interaction Results for Age * Molecular Subtype (N=20,169)

257098 - Number of nodes in sentinel lymph node biopsy for breast cancer: are surgeons still biased?

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Background/Objective: It has been shown previously that surgeons may be biased at sentinel lymph node biopsy (SLNB) for breast cancer, removing more nodes in high-risk breast cancer patients despite evidence that removing >4 nodes does not improve diagnostic accuracy and risks increased morbidity. The purpose of this study was to assess the number of lymph nodes removed at SLNB for breast cancer and what factors may alter SLNB technique. Our hypothesis is that despite increased comfort with the use of SLNB there will exist significant differences in the number of lymph nodes harvested at SLNB in certain high-risk groups, which may be attributed to surgeon bias.

Methods: A prospectively maintained breast cancer database was reviewed. All patients that had a SLNB for primary treatment of breast cancer between January 2012 and March 2016 were included. Patients with known positive axillary nodes, inflammatory breast cancer and prophylactic mastectomy were excluded. Patient demographics, clinical and imaging findings, tumour biology, neoadjuvant therapy and pathology were reviewed. Groups were compared using t-test with Welch's correction, and one-way ANOVA for multiple comparisons.

Results: 1603 patients met inclusion criteria. The average number of SLNs, non-SLNs and total LNs was 2.53±1.51, 0.54±1.24, 3.08±2.00, and, respectively (mean ± SD). Table 1 contains average numbers of SLN, non-SLN and total LN for each subgroup. Significantly more LNs were removed in certain groups, including: Age < 40 vs. Age >40, Invasive vs. DCIS, Grade III vs. Grade II, T2 vs. T1 and ER- vs. ER+.

Conclusions: Our study identified a significant difference in the number of lymph nodes removed at SLNB in certain groups. This may be attributed to surgeon bias when treating higher risk patients such as: younger age, higher grade, larger tumour size and invasive disease. This bias is similar to what has been reported previously; however the overall averages fall within the generally accepted range of 1-4 LNs. While average node removal is low reflecting increasing experience and comfort with the technique of SLNB, there are still cases in which more than the recommended number of nodes are being removed, which can subject patients to unnecessary morbidity with minimal benefit. Surgeons must be cognizant of this potential bias, especially when performing SLNB on higher risk patients. Further comparison of node positivity, subsequent axillary management and the use of adjuvant therapy in high-risk groups is warranted to fully elucidate the clinical impact of this bias.

Table 1: Mean number of lymph nodes removed by patient/tumor characteristics

Patient/Tumor Characteristics	Patients (n = 1603)	SLN	Non-SLN	Total LN
Age <40	78	3.13**	0.60	3.73*
Age > 40	1525	2.51**	0.54	3.04*
DCIS	179	2.4	0.33**	2.73***
Invasive	1439	2.55	0.57**	3.11***
Grade I	380	2.53	0.52	3.05
Grade II	645	2.44**	0.55	2.99**
Grade III	388	2.76**	0.66	3.42**
T1	993	2.47*	0.49	2.96*
T2	438	2.69*	0.71	3.4*
T3	29	2.72	0.38	3.1
ER+	1143	2.5	0.55	3.05*
ER-	152	2.77	0.68	3.45*
HER2+	177	2.68	0.72	3.39
HER2-	1072	2.51	0.54	3.06
NAT	65	2.83	0.62	3.45
No NAT	1538	2.52	0.54	3.06

SLN indicates sentinel lymph node; DCIS, ductal carcinoma in situ; NAT neoadjuvant treatment
Non-parametric 2-way T-test: * p < 0.05, ** p < 0.01, *** p < 0.001.

Table 1: Mean number of lymph nodes removed by patient/tumor characteristics

257360 - Patterns of Care and Decision Making in Mastectomy Patients after ACOSOG Z0011

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Background/Objective: INTRO ACOSOG Z0011 showed that axillary dissection (ALND) can be avoided in breast cancer patients with 1-2 positive sentinel lymph nodes (SLNs) who undergo breast conserving surgery and whole-breast radiation (XRT). Our aim was to assess our practice and factors influencing decision making for mastectomy patients with positive SLNs after the publication of Z0011.

Methods: 427 medical records were reviewed from 2010-2016, to find patients with T1-T2 breast cancer, clinically node negative, having mastectomy with positive SLN biopsy. We collected data on demographics, comorbidities, tumor and nodal factors, and adjuvant therapy. Patients with and without ALND were compared by t-test for continuous measures and Chi-square test for categorical measures.

Results: 116 patients met inclusion criteria, 55 patients without ALND (group 1, mean age 53) and 61 with ALND (group 2, mean age 56). There was no difference in comorbidities, clinical stage, multifocality, hormonal status, or Ki67. Both groups had average of 3.2 SLNs. Group 2 had more positive nodes (1.6 vs. 1.0 in group 1; $p< 0.001$), larger mean nodal metastasis (9.5mm vs. 2.2 mm; $p < 0.0001$). MSKCC nomogram prediction of positive non-SLNs was higher in group 2 than 1 (mean 51% vs. 14%, $p < 0.0001$). 85% of group 2 had positive SLN intraop and completion ALND; 15% had a negative touch prep but positive final pathology with delayed ALND. In group 1, 95% had negative touch prep and 5% had deferred nodal pathology evaluation. 30% of group 1 were presented in tumor board vs. 8% in group 2 ($p=0.0018$). 36% of group 1 received XRT to the axilla vs. only 2.7 % in group 2 ($p=0.0014$).

Conclusions: When SLNs were positive intraop, completion ALND was performed. When intraop pathology was negative and nodes positive on permanent section, surgeons were less likely to do ALND.

More often they presented the patient in tumor board, advised adjuvant radiation or observation, used nomograms, and were influenced by data from Z0011 and AMAROS trial when justifying no ALND. These findings reflect the need for clinical trials to address management of mastectomy patients with positive sentinel nodes.

257354 - Clinical Node Positive Disease is a High Predictor of Pathologically Positive Nodes: Report from the National Cancer Data Base

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Background/Objective: The concordance of clinically-positive node staging with pathologically-positive node staging is controversial and not well studied. This information can be helpful in the neoadjuvant setting, particularly for radiation planning of the chest wall and regional nodes.

Methods: Using the National Cancer Data Base, we identified 39,653 female patients with clinical N1 (cN1) or N2 (cN2) breast cancer who underwent surgery without neoadjuvant chemotherapy from 2010-2013. We examined the proportion of cN1 and cN2 patients with tumor-positive nodes on pathologic staging and factors associated with having four or more tumor-positive nodes or more then one tumor-positive node using univariate and multivariate regression analysis.

Results: There were 34,124 (86.1%) patients staged as cN1 and 5,529 (13.9%) as cN2. Lumpectomy was performed in 35.6% of patients and mastectomy was performed in 63.4%. Overall, 93.5% of clinically node-positive patients were pathologically node-positive; 94.1% of cN1 patients had tumor-positive nodes and 98.1% of cN2 had tumor-positive nodes. Of the cN1 patients, 26.2% were upstaged to pN2 or pN3, 7.1% were downstaged to pN0, and 66.7% had no change in stage. Of the cN2 patients, 11.3% were upstaged to pN3, 9.6% were downstaged to pN0 or pN1, and 79.1% had no change in stage. For the cN1 group, 66.6% of patients had 1-3 pathologically positive nodes and 27.5% had 4 or more positive nodes; 35.4% had only one tumor-positive node. For the cN2 group, 9.2% had 1-3 pathologically positive nodes, 76.8% had 4-9 positive nodes and 12.2% had 10 or more positive nodes. Multivariate analysis demonstrated that lobular or mixed histology, larger tumor size, higher grade, presence of lymphovascular invasion (LVI) and Her2-positive tumors were independent predictors of having 4 or more positive nodes and of having more than one positive node (Table 1). LVI was the strongest predictor of node positivity beside tumor size and grade for 4 or more positive nodes (OR 2.31; 95% CI 2.19-2.44, $p < 0.0001$) and for more than one positive node (OR 1.99; 95% CI 1.89-2.09, $p < 0.0001$). Triple-negative breast cancers were less likely to have 4 or more positive nodes and more than one positive node, OR 0.89 (95% CI 0.82-0.97, $p < 0.0050$) and OR 0.82 (95% CI 0.76-0.88, $p < 0.0001$) respectively.

Conclusions: Over 90% of patients with clinically node-positive disease have pathologically tumor-positive nodes. Factors associated with greater than one pathologically tumor-positive node or 4 or more positive nodes are similar. Our group is currently looking into how these factors can be utilized in a model to predict how many nodes are tumor-positive prior to initiating neoadjuvant therapy.

Table 1. Summary of independent predictors of more than one positive node on adjusted analysis

Variable	*Odds ratio*	*95% CI*	*p-value*
Age 70-90	0.90	0.84-0.96	0.0012
Lobular histology	1.31	1.18-1.45	< 0.0001
Mixed ductal and lobular histology	1.48	1.35-1.61	< 0.0001
Tumor size			
1.1-2.0 cm	1.40	1.28-1.54	< 0.0001
2.1-3.0 cm	1.94	1.77-2.12	< 0.0001
3.1-4.0 cm	2.60	2.34-2.88	< 0.0001
> 4.0 cm	3.43	3.10-3.80	< 0.0001
Grade II	1.33	1.23-1.44	< 0.0001
Grade III	1.49	1.37-1.63	< 0.0001
LVI* present	1.99	1.89-2.09	< 0.0001
Triple negative	0.82	0.76-0.88	< 0.0001
HR-**, Her2+	1.19	1.06-1.32	0.0021

*LVI = lymphovascular invasion; ** HR+ = hormone receptor-positive

256764 - ACOSOG Z0011: Impact After 5 Years

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Background/Objective: ACOSOG Z0011 demonstrated that patients with clinical T1-2, N0 breast cancer undergoing breast conserving therapy (BCT) may safely omit axillary lymph node dissection (ALND) when they have < 3 positive sentinel lymph nodes (SLN). We have previously reported that in the year following publication of the Z0011 trial results, ALND was performed in 24% of patients meeting Z0011 eligibility criteria at our institution compared to 85% in the year prior to Z0011 publication.(1) The goal of this study was to determine if that rate had further decreased after 5 years. (1)Caudle et al. Ann Surg Onc. 2012

Methods: This is a single institution review of patients with clinical T1-2, N0 invasive breast cancer undergoing BCT between 9/1/2015 and 8/31/2016. Patients had negative nodes by clinical and ultrasound exam. Patients with ≥3 positive SLNs and patients who had neoadjuvant chemotherapy were excluded. Clinicopathologic data were recorded to include factors impacting surgical management of the axilla. Comparisons were made using the student's t-test or Fisher exact test as appropriate with a significance level of 0.05.

Results: A total of 396 patients were evaluated. None of the patients had intra-operative assessment of SLNs performed. SLNs were negative in 347 (88%) and positive in 48 (12%). Of the 48 SLN-positive patients, 28 (58%) had T1 tumors and 20 (42%) had T2 tumors. Tumor receptor subtype was characterized as hormone receptor (HR) positive/HER2 negative in 42 (88%), HER2+ in 4 (8%), and HR-/HER- in 2 (4%). 8% (4/48) of SLN-positive patients underwent ALND. Patients who underwent ALND were more likely to have 2 positive SLNs (50%, 2/4) than the non-ALND group (2%, 1/44) (p=0.02). The

ALND group also had a higher proportion of nodal metastases with microscopic extranodal extension (75%, 3/4) than the non-ALND group (18%, 8/44) (p=0.03). Patients who underwent ALND had a higher predicted probability of having additional positive non-SLNs by a published nomogram (53%, range 37-70%) than those that did not have ALND (22%, range 1-57%) (p=0.0002).There were no differences in pathologic tumor size, mean number of SLNs removed, mean size of nodal focus, or proportion of those with micrometastasis. There was a nonsignificant trend seen in tumor histology with 75% (3/4) of the ALND group having ductal histology and 25% (1/4) with lobular compared to the non-ALND group which was 96% (42/44) ductal, 2% (1/44) lobular, and 2% (1/44) mixed (p=0.09). One (25%) patient in the ALND group had additional positive SLNs.

Conclusions: The current study indicates that surgeons at our institution have become more comfortable with the Z0011 trial data 5 years after report of the study results. In the year following publication, we performed ALND in 24% of Z0011-eligible patients1 which dropped to 8% in the most recent year. Importantly, surgeons still individualize their approach to patients by assessing pathologic variables to determine whether to perform ALND. The use of intra-operative SLN assessment, which adds cost and time, has been abandoned.

SLN NAC

257160 - Do we need to stage the axilla prior to neo adjuvant chemo? Analysis of clinically and radiologicaly negative (N0) breast cancer patients from a single centre

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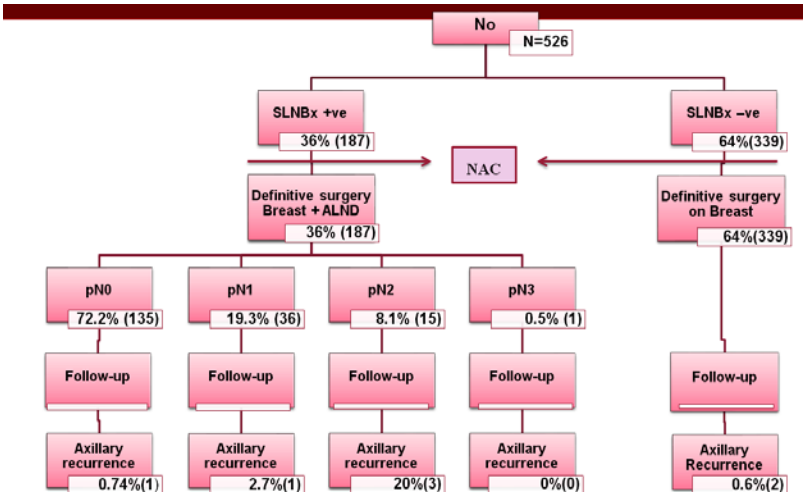
Background/Objective: Staging the axilla via sentinel node biopsy (SLNBx) is a standard technique for clinically and radiologicaly negative patients. The timing to do the SLNBx before or after neoadjuvent chemo (NAC) is controversial. The aim of the study is to see the outcomes of SLNBX in our patients who underwent NAC in clinically and radiological negative axilla.

Methods: Retrospective analysis of all patients from 2009-2013 were included with clinically and radiologicaly node negative axilla, requiring NAC to downstage their breast disease. Patients' data were retrieved via hospital information system and the following variables were taken for analysis on a preset proforma: age, gender, tumor type, site, and size, grade of tumor, receptor status, type of surgery, type of chemotherapy, treatment completion date, number of lymph nodes found positive on staging, and number of lymph nodes found positive on axillary lymph node dissection (ALND) post neoadjuvant chemotherapy (NAC). The patients' records were followed up for 3 years to check for axillary recurrence. Data was analysed on SPSS V 19, and statistical analysis was done. Median (IR range) was computed for numerical variables. Frequency and percentage was used for categorical variables.

Results: A total of 560 patients were selected for the study, and 34 were excluded, so a total of 523 patients' data was analysed. All patients underwent SLNBX and 64.4% (334) were found to be negative on staging, whereas only 35.5% (187) were found to be negative. All patients were then given NAC. Patients who were SLNBx +ve were subjected to ALND in addition to the definitive surgery to the breast.

Out of 187 patients who underwent NAC, 72.2% (135) turned out to be node negative (pN0), 19.3% (36) were found to have pN1, 8.1% (15) were pN2, and 0.5% (1) was found to be pN3. Patients who were SLNBx negative underwent definitive surgery to the breast and followed up for 3 years. Only 0.6% (2) developed axilary nodal recurrence.

Conclusions: SLNBx is a day case procedure that is done under general anesthesia, and the chemotherapy is delayed for at least 2 weeks after SLNBx so as to give time for wound healing. Our study shows that 64% patients are negative with a 35% false negative rate but after neoadjuvant chemo, 72.2% (135) of the patients were found to be node negative on ALND. So rather than doing SLNBX before chemo, it might be safe to do the SLNBx after NAC to avoid the delay in chemo and avoid unnecesary ALNDs and morbidity associated with it. We conclude that sentinel lymph node biopsy (SLNBx) after neoadjuvant chemo (NAC) is an effective way of dealing with axillary staging and treatment. We recommend SLNBx after NAC at the time of definitive surgery in order to prevent another general anesthesia and utilization of resources. By following this protocol, we can send the patients early for chemotherapy without any delay. A randomized controlled trial is required to validate the results and to establish guidelines in this regard.



256740 - Localizing the clipped node in patients with node-positive breast cancer treated with neoadjuvant chemotherapy – early learning experience and challenges

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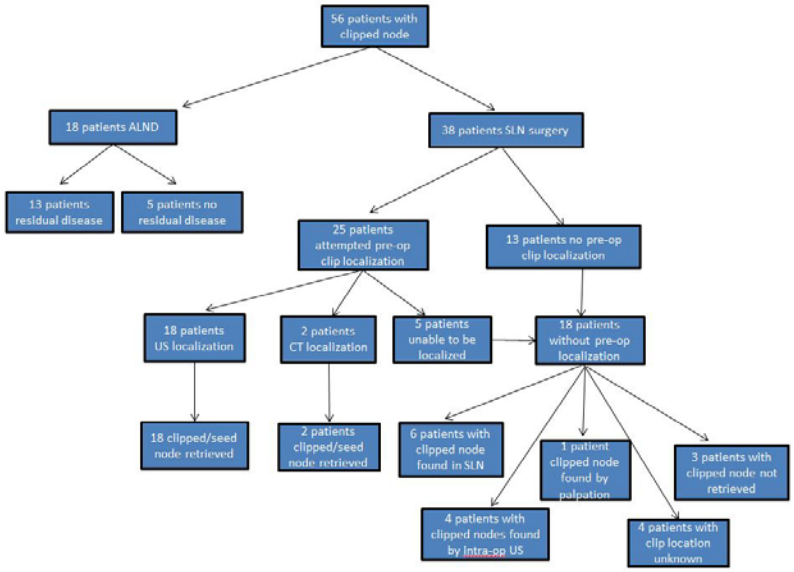
Background/Objective: Sentinel lymph node (SLN) surgery can be used to stage the axilla after neoadjuvant chemotherapy (NAC) in patients who present with node-positive breast cancer. Placement of a clip in the positive node with resection of the clipped node at SLN surgery improves the accuracy of the procedure. We sought to evaluate our experience with SLN surgery and resection of the clipped node since introduction into our practice of clip placement in these patients.

Methods: With IRB approval, we reviewed all patients with breast cancer from our institution who had undergone percutaneous biopsy identifying metastatic disease in an axillary lymph node, had a clip placed in the positive lymph node, and underwent neoadjuvant chemotherapy followed by surgery.

Results: A total of 56 node-positive patients who had the positive node clipped and were treated with NAC were identified. In 18 patients (32.1%), the patient and surgeon elected to proceed directly to axillary dissection (ALND) after neoadjuvant chemotherapy without SLN surgery. Thirteen of these patients were node positive, and 5 were node negative. Thirty-eight patients underwent SLN surgery (18 SLN surgery alone and 20 had SLN + ALND). In 25 patients, preoperative localization of the clipped node with an I-125 radioactive seed was attempted. In 18 cases (72%), localization was performed by ultrasound guidance. In 7 cases (28%), the clipped node was not visualized sonographically; in 2 cases (8%), CT-guided seed localization was performed, and in 5 cases no preoperative localization was performed. In all 20 cases with seed localization, the seed and the clipped node were resected along with additional SLNs. In 13 patients, preoperative seed localization was not requested/attempted. Of the 18 cases without preoperative seed localization (13 not attempted and 5 unable to be localized), the clipped node was resected intraoperatively in 11 cases (61%). It was identified by palpation in 1 patient, by intraop ultrasound in 4 patients, and as 1 of the SLNs in 6 patients (identified by blue dye only in 2 patients, radioactive colloid only in 2 patients, both blue dye and radioactive colloid in 2 patients). Overall, the clipped node was resected in 31/38 (82%) of cases. Of the remaining 7 cases, in 3 patients, the clipped node was not found despite an attempt at retrieval intra-operatively and SLN surgery was performed, and in 4 patients, early in our experience, the clipped node was not localized and SLN surgery was performed without an attempt to identify or document the clipped node. Three patients had a positive SLN and proceeded to ALND, and 4 patients had negative SLNs and no further axillary surgery.

Conclusions: Identification of the clipped node after neoadjuvant chemotherapy is feasible and can be performed several ways. Preoperative localization of the clipped node with ultrasound was successful in 72% of cases. Alternative options include CT guided seed localization, intraoperative ultrasound, and intraoperative palpation as well as SLN surgery. In cases without preoperative localization, the clipped node is frequently still identified intraoperatively.



Flowchart clipped node

257414 - Evaluation of radiological response in axilla and need of completion axillary surgery after neoadjuvant chemotherapy in biopsy-proven, node-positive breast cancer patients. Single center study of 768 patients

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Background/Objective: Axillary status has a very vital role in the prognosis of breast cancer patients. Locoregional spread of breast cancer usually occurs by lymphatics1. With the advancements in axillary surgery and the development of sentinel node biopsy, the need to do completion axillary surgery has reduced. Completion surgery of axilla carries lots of morbidity. Advances in the field of radiology and better knowledge of axillary response can also help in segregating patients for completion ALND vs no ALND.

Methods: A total of 768 patients with CN1 axillary status and who underwent neoadjuvant chemotherapy and were candidates for breast-conserving surgery were selected for this study. These patients were enrolled in the hospital from 1st January 2006 till 31st December 2013. Retrospective data was extracted from the system. The demographics of patients, pathological characteristics of tumors, stage at presentation, receptor status, nodal stage on ALND post-chemotherapy, radiological response in axilla post chemotherapy, and follow-up details for axillary recurrence were extracted from the hospital database. Neoadjuvant treatment was offered to all patients to downstage the disease. All patients were biopsy (FNAC)-proven, node-positive patients. After neoadjuvant chemotherapy, all underwent ultrasound of their breast and axilla to assess the response to chemotherapy. All patients finally underwent complete axillary node dissection.

Results: All patients in this study are females. Median age was 45 years (range 22-71 years). We categorized the patients in stages according to TNM staging system. A total of 0.5% (n=4) patients had stage 0 disease, 0.3% (n=2) patients had stage I disease, 53.4% (n=410) patients had stage II disease, 44.8% (n=344) had stage III disease, while 1.0% (n=8) had stage IV disease. We found that 81.8% patients had invasive ductal carcinoma, and 15.9% of patients had mixed invasive ductal carcinoma with DCIS. Only 1.0% had invasive lobular carcinoma. There were 45.1% of patients with grade II and 52.3% of patients with grade III tumors. There were 63.5% of patients who were estrogen receptor positive, and 53.6% were progesterone receptor positive, while 33.3% of patients were HER-2-Neu positive, and 21.4% of patients had triple-negative disease. Combined radiological and pathological complete response was seen in 41.92% of patients, while 4.6% of patients showed partial response on sonography but actually were pathologically N0 on ALND. There were 22.13% of patients who showed radiological complete response but actually had N1 disease on ALND, and 4.6% of patients with radiological complete response who showed involvement of more than 4 nodes on ALND, while 9.89% of patients showed true partial response both radiologically and pathologically. There were 13% of patients with partial radiological response who had more than N1 disease on ALND, and 3.64% of patients had stable disease both radiologically and pathologically. Local recurrence in axilla was seen in 2.6% of patients. Out of this, 0.7% belong to complete response group, and 1.8% belong to partial response group.

Conclusions: We conclude from our study that by carefully selecting patients on the basis of sonography we can save many patients from the morbidity of completion ALND. Combining this with sentinel node biopsy post neoadjuvant chemotherapy with a removal of minimal 3 sentinel nodes, we can achieve

even better and accurate results in terms of less false negatives. Further prospective studies are needed to validate the results of this retrospective analysis.

Time to Treatment

257042 – Patient-related factors associated with delays in time to surgery in breast cancer patients

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Background/Objective: There has been increasing awareness and interest in time from diagnosis to definitive surgery (TTS) as a quality indicator in breast cancer care. In this regard, emphasis had been placed on optimizing processes of care in an effort to reduce delays in treatment. In this study, we hypothesize that patient-related factors are an important contributor to TTS and aim to identify the impact of patient-related factors on TTS in newly diagnosed breast cancer patients.

Methods: Sixty-five consecutive patients with newly diagnosed breast cancer undergoing surgery in 2016 were included in the study. Patients with stage IV disease, those undergoing neoadjuvant therapy, and patients who are non-operable candidates were excluded. The date of breast cancer diagnosis was defined as the date of initial biopsy. A delay in treatment was defined as any factor that resulted in prolonging TTS beyond the initially offered operative date. Patient demographics, clinicopathological information, type of surgery, TTS, and reasons for delay in TTS were documented and analyzed.

Results: All patients were female. The median time from initial breast biopsy to first clinic visit (TTC) was 11 days (range, 2-84). Of the total patients, 33.8% (n=22) were external referrals seen at our institution for a second opinion [median TTC 20 days (range, 7-84)]. Of all patients, 49.2% (n=32) had a patient-related delay in TTS [median, 41 days (range, 19-120)]. Reasons for delays included personal issues/patient choice in 17 patients (53.1% of patient-related delays), time taken obtaining a second opinion in 7 patients (21.8% of patient-related delays), delays related to genetic testing in 4 patients (12.5% of patient-related delays), patient co-morbidity requiring further work-up or optimization in 3 patients (9.3% of patient related delays), and insurance issues in 1 patient (3.1% of patient-related delays). Patient choice delays included vacation, work-related issues, family commitments, and additional time needed to consider treatment options. In patients without a patient-related delay, the median TTS was significantly shorter: 16 days for those undergoing no reconstruction (range, 8-48), 26 days (range, 14-62) for cases with immediate reconstruction, and 31 days (range, 19-33) for cases of intraoperative radiation therapy.

Conclusions: Minimizing TTS in breast cancer, although important, must be balanced with patient concerns. Almost half of patients have delays in TTS as a result of patient-related factors. It is critical to consider patient-related factors when considering TTS as a quality metric in breast cancer care.

256030 - Factors associated with prolonged time to treatment completion in triple-negative breast cancer

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Background/Objective: Time-to-treatment studies in breast cancer (BC) care have focused on time from diagnosis to surgery and have not stratified by receptor status. For aggressive types of breast cancer, such as triple-negative breast cancer (TNBC), multimodality therapy is very important to optimize outcomes for patients. Thus, it's important to consider the time to completion of all treatment modalities, not just time to the initial operation, when assessing barriers to care. The goal of this study was to understand patient factors which are associated with prolonged time to completion of all treatment modalities (TTC-ATM), specifically in triple-negative breast cancer (TNBC).

Methods: The National Cancer Database (NCDB) was accessed to obtain patient information. TNBC patients were selected as these individuals most commonly need all 3 treatment modalities (surgery, chemotherapy, and radiation) for appropriate BC care. Patients with a new BC diagnosis from 2010-2011 were included as this is the earliest available HER2 status recorded in NCDB. Patients who had stage IV disease at diagnosis or outliers in treatment duration (< 6 or > 18 months) were excluded. Patients were divided into tertiles relative to completion of all treatment as follows: shortest TTC-ATM (lowest terile), middle TTC-ATM (mid tertile), and longest TTC-ATM (upper tertile). The tertiles were compared to determine any factors which differed between groups.

Results: Overall 17,717 patients met inclusion criteria, with 34.1% stage I, 48.2% stage II, and 17.9% stage III disease. Most patients had breast conservation (69.2%), and 36.7% had neoadjuvant chemotherapy. Average TTC-ATM was 270±52.7 days. When dividing into tertiles, lowest-tertile patients completed treatment in < 243 days (n=5,913), mid-tertile patients completed treatment in 243-284 days (n=5,879), and upper-tertile patients completed treatment in > 284 days (n=5,925). When comparing patient characteristics, the tertiles differed significantly in age ($p < 0.001$), race ($p < 0.001$), stage ($p < 0.001$), and comorbitidity score ($p < 0.001$). Patients in the lowest tertile (fastest TTC-ATM) were older with a higher rate of stage I disease, more commonly Caucasian, and healthier (lower Charlson-Deyo Score). Patients in the lowest tertile were also more likely to have breast conservation ($p < 0.001$). Patients in the upper tertile (longest TTC-ATM) were more likely to have neoadjuvant chemotherapy ($p < 0.001$), a reflection of stage of their disease.

Conclusions: This study importantly analyzes factors associated with increased TTC-ATM for a specific subtype of breast cancer, TNBC. Some factors associated with longer TTC-ATM are likely a result of treatment protocols (stage, type of operation, neoadjuvant use). However, the association with longer TTC-ATM in younger, African American, and Hispanic patients demonstrates potential barriers to care which warrant further investigation.

	Lowest Tertile Tx Dur <243 d N=5913	Mid Tertile Tx Dur 243-284 d N=5879	Upper Tertile Tx Dur >284 d N=5925	p-value
Age at Diagnosis	56.0±11.4	53.2±11.0	53.3±11.4	<0.001*
Race				
Caucasian	4165 (74.3%)	3769 (67.5%)	3107 (54.8%)	<0.001*
African American	1025 (18.3%)	1306 (23.4%)	1894 (33.4%)	
Hispanic	244 (4.1%)	310 (5.6%)	472 (8.3%)	
Other	174 (3.1%)	198 (3.5%)	201 (3.5%)	
AJCC Stage				
Stage I	2907 (49.1%)	1798 (30.6%)	1343 (22.7%)	<0.001*
Stage II	2392 (40.4%)	2969 (50.5%)	3160 (53.3%)	
Stage III	614 (10.3%)	1112 (18.9%)	1422 (24.0%)	
Surgery Type				
BCS	4764 (80.6%)	3990 (67.9%)	3492 (59.0%)	<0.001*
Mastectomy	1146 (19.4%)	1886 (32.1%)	2429 (41.0%)	
Charlson-Deyo				
0	5134 (86.8%)	5130 (87.3%)	4992 (84.3%)	<0.001*
1	672 (11.4%)	644 (11.0%)	783 (13.2%)	
2	107 (1.8%)	105 (1.8%)	150 (2.5%)	
Neoadjuvant Chemo-therapy	1283 (21.7%)	2322 (39.5%)	2899 (48.9%)	<0.001*

Factors which differed significantly between the tertiles. Tx Dur = treatment duration, in days. *p-value <0.05 is considered significant. BCS = breast conservation surgery. Charlson-Deyo = comorbidity score, where 0 is healthier and comorbidities increase with increasing score.

257402 - Time to treat for breast cancer: Impact of patient characteristics and preferences on time from breast cancer diagnosis to first surgical appointment

Yitian Liu[1], Stephanie Valente[2], Nancy Greve[2], Lisa Park[2], Ashley Simpson[2], Stephen Grobmyer[3]
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Background/Objective: Studies have shown significantly increasing times to treatment of breast cancer (from time of initial diagnosis to definitive treatment) over recent years with concern that increasing delays may lead to worse oncologic outcomes. Often, the delay in time to treatment begins with delay to initial surgical consultation (SC). We sought to identify patient reasons for delay in time from initial core needle biopsy diagnosis to first SC.

Methods: A prospectively collected database of women diagnosed with breast cancer at our institution from 2015-2016 was reviewed. Patient time to first surgical appointment as well as documented patient preferences regarding the appointment were gathered through a prospectively collected nurse navigation tool. Additional patient variables such as patient age, race, marriage status, number of children, employment status, breast surgical history, and type of cancer were also analyzed using multivariate analysis.

Results: A total of 564 women identified as newly diagnosed with breast cancer at our institution during this timeframe were surveyed under our nurse navigator-driven protocol. Of these, 154 (27.3%) women opted for the earliest available appointment while 410 (72.7%) chose a later available date. The average time from diagnosis to SC was 8.52 days (ranging from 0-37 days). Patients who accepted a first available appointment waited an average of 5.65 days, while those who deferred a first appointment waited 9.60 days ($p < 0.001$). Among patients who chose to forgo the earliest available appointment, the primary reason(s) for doing so were preference for location (56.8%), followed by surgeon preference

(35.9%), day of week (8.3%), travel plans (3.2%), gender of surgeon (2.0%), or “other reason” not specified for 5.9% of those who deferred a first appointment. Additionally, significant patient characteristics affecting overall time to appointment included age, history of previous breast cancer, and prior breast surgical intervention.

Conclusions: Among women newly diagnosed with breast cancer, there is a substantial group that chooses to defer the first available surgical consultation appointment for patient preference. Patient factors and preferences are extremely important in considering evaluation of time-related metrics for breast cancer care, and these should be considered in efforts to optimize patient-centered care. Future investigation will seek to determine whether these factors affect time to definitive treatment, outcomes, and survival of breast cancer patients.

Tumor Genetics

257283 - The 12-gene Oncotype DX® Breast DCIS Score™ assay: A summary of clinical evidence and commercial experience

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Background/Objective: Most patients with ductal carcinoma in situ (DCIS) receive radiation therapy (XRT) after breast-conserving surgery (BCS) to reduce local recurrence (LR) rates, despite no improvement in disease-specific survival. While risk models based on clinicopathologic factors (eg, Van Nuys Prognostic Index or MSKCC nomogram) can help assess a patient’s risk of recurrence, they are based on population averages and may lose precision when applied to individual patients. The 12-gene DCIS Score assay is the first multigene assay that provides individualized estimates of 10-year LR risk and invasive LR risk. Here we summarize both the clinical evidence supporting the use of the DCIS Score assay and the routine practice assessed in the commercial database.

Methods: Peer-reviewed articles and presentations were reviewed to identify studies that generated clinical evidence on the validation and utility of the 12-gene DCIS Score assay. DCIS Score assays performed by Genomic Health from Jan 2012 to Oct 2016 were analyzed.

Results: The DCIS Score assay was prospectively developed. Clinical validation was established in 2 prospectively designed retrospective studies (total N=1,587) that each demonstrated the prognostic utility of the assay for patients with DCIS who had BCS alone or BCS + XRT. Risk estimates for DCIS Score groups were similar between validation studies despite differences in clinicopathologic characteristics. For patients who had BCS + XRT, the absolute benefit of XRT was less for patients with low DCIS Score results than for patients with high results. Two decision-impact (DI) studies (total N=242) showed that assay results change treatment recommendations ~30% of the time, with an overall reduction in XRT recommendations. Moreover, patients reported reduced decisional conflict and state-anxiety after receiving DCIS Score results. As of October 2016, 11,350 DCIS Score assay results have been delivered for clinical practice. Average patient age was 60 years (SD 11.2 years). DCIS Score distributions were similar between the studies and the commercial database (Table).

Conclusions: The 12-gene DCIS Score assay is the first clinically validated multigene assay that provides individualized LR risk information for patients with DCIS—information based on tumor biology and

independent of clinicopathologic features. This information is actionable and useful to physicians and patients alike when making XRT decisions, and may reduce the overtreatment of patients with low-risk disease. Analysis of samples assayed in clinical practice showed that real-world, contemporary patients are overall similar to patients who were enrolled in clinical studies of the DCIS Score assay.

	N	DCIS Score Distribution, n (%)		
		Low	Intermediate	High
E5194 validation	327	230 (70)	53 (16)	44 (14)
Ontario BCS validation	571	355 (62)	95 (17)	121 (21)
Ontario BCS + XRT validation	689	332 (48)	155 (22)	202 (29)
DI study #1	115	72 (63)	24 (21)	19 (17)
DI study #2	127	84 (66)	25 (20)	18 (14)
GHI commercial database	11350	7424 (65)	1934 (17)	1992 (18)

256500 - Appropriate use of Oncotype DX in breast cancer patients: An NCDB analysis

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Background/Objective: Oncotype DX is a 21-gene assay designed to predict cancer recurrence and utility of adjuvant chemotherapy in addition to hormonal therapy for patients with early-stage estrogen receptor (ER) positive and HER2/neu nonamplified breast cancer. In an era of rising health care costs and the need for a cost-conscious practice, we examined the trends in clinical use of Oncotype DX in breast cancer patients and appropriate use of the assay.

Methods: The NCDB was used to query women ages 18 and over from 2004-2013 with primary breast cancer stages 0-III who had an Oncotype DX recurrence score (0-100). Patient demographics, socioeconomic factors, and treatment data were collected. Chi-squared test and multivariate analysis were used for statistical assessment. The cost of the Oncotype DX assay as provided by the manufacturer, Genomic Health, is $4,620.

Results: 76,281 patients were identified as having stage 0-III breast cancer with an Oncotype DX recurrence score of 0-100. The median age at diagnosis was 59 [18-90+]; the majority were white (87.3%), Charleson-Deyo score of 0 (85.6%), pathologic T1 (73.1%) or T2 (24.2%), pathologic N0 (81.9%), ER positive (98.9%) and progesterone receptor (PR) positive (89.5%), HER2/neu non-amplified (94.1%), and underwent partial mastectomy (68.8%). Chemotherapy was administered to 20,253 patients (26.6%). HER2/neu amplification was noted in 1,847 (2.4%) of the population. Adjuvant hormonal therapy was recommended in 72,697 (95.3%), and 69,341 (90.9%) patients received the recommended adjuvant hormonal therapy. The recommended adjuvant hormonal therapy was not received by 2,302 patients (3%). Adjuvant hormonal therapy was not recommended in 3,304 (4.3%) of these patients. The Oncotype DX assay was, therefore, inappropriately ordered in 4.3% of patients who were not recommended adjuvant hormonal therapy as well as 2.4% of patients who had HER2/neu amplification. A cost analysis reveals that $8,533,140 was spent on inappropriately ordered assays for patients with HER2/neu amplified tumors and $15,264,480 on patients for whom hormonal therapy was not recommended.

Conclusions: This study shows that the Oncotype DX 21-gene assay was inappropriately ordered in 1,847 (2.4%) patients with known HER2/neu amplification, and 3,304 (4.3%) patients tested for whom endocrine therapy was not recommended. This resulted in at least $23,797,620 in unnecessary health care costs. Inappropriate use of the assay represents an area of clinical practice where health care dollars could be better utilized.

	Frequency	Percentage
ER Status		
Negative	779	1.0%
Borderline	12	0.0%
Positive	75409	98.9%
Unknown	81	0.1%
HER2/NEU Status		
Non-amplified	71785	94.1%
Borderline/equivocal	1264	1.7%
Amplified	1847	2.4%
Unknown	1385	1.8%
Chemotherapy received		
Yes	20253	26.6%
No	56028	73.4%
Hormone therapy		
Recommended	72697	95.3%
Received	69341	90.9%
Not Received	2302	3.0%
Unknown if Received	1054	1.38%
Not Recommended	3304	4.3%
Unknown	280	0.37%

Analysis population (n=76281)

257522 - Clinical utilization of the Breast Cancer Index for prediction of endocrine benefit in early stage ER+ breast cancer

Brock Schroeder, Theresa Operana, Cathy Schnabel
Biotheranostics, Inc., San Diego, CA

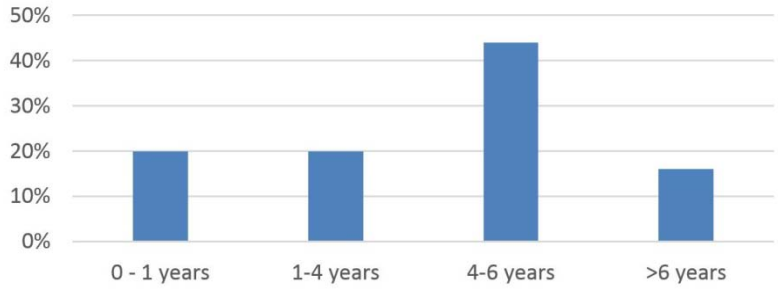
Background/Objective: Randomized trials have demonstrated a significant, but modest (3-5%), absolute benefit from extended (10 years) endocrine therapy vs 5 years in patients with early-stage ER+ breast cancer. However, patients are also exposed to risks of serious toxicities (e.g., endometrial cancer and thromboembolic events with tamoxifen, and fractures with aromatase inhibitors). Breast Cancer Index (BCI) is a gene expression-based test that is validated for quantification of risk of late (>5 years) distant recurrence and predictive of likelihood of benefit from extended endocrine therapy. The objective of this study was to better understand the clinical utility and utilization patterns of genomic classification with BCI in the context of extended endocrine therapy decision-making by breast surgeons.

Methods: Descriptive analyses were performed using data from The BCI Clinical Correlative Database, containing demographic information, clinical and pathologic characteristics, utilization patterns, and test results for cases submitted for BCI testing in clinical practice. In this study, patient characteristics, utilization patterns based on potential indication of use, and clinical results for BCI Predictive (HoxB13/IL17BR; H/I) were analyzed for cases submitted by breast surgeons.

Results: Nine hundred and seven patients, submitted by 75 breast surgeons, were included in this analysis. The mean age was 58 years (range: 32 years - 92 years; 90% ≥ 50 years). Surgeons utilized BCI across a range of intervals from time of diagnosis: 20% < 1 years; 20% ≥ 1 to < 4 years; 44% ≥ 4 to < 6

years; and 16% ≥ 6 years. BCI identified 42% of patients with a high likelihood vs. 58% with a low likelihood of benefit from EET based on the H/I ratio.

Conclusions: Findings from this study, utilizing a large retrospective analysis, help characterize the role of BCI in the clinical practice of breast surgeons for patients with early-stage, ER+ breast cancer. The majority of cases were submitted more than 4 years' post-diagnosis, demonstrating the long-term follow-up and management of endocrine regimens in early stage ER+ patients. However, one-fifth of cases were submitted near the time of diagnosis, indicative of test use to inform a long-term endocrine therapy management plan at the time of diagnosis. BCI stratification of patients with endocrine responsive disease and high likelihood of benefit from extended endocrine therapy may facilitate selection of patients for prolonged regimens.



BCI utilization patterns (years from diagnosis)

257389 - A comparison of tumor biology based on genomic health Oncotype DX recurrence scores in a private cancer center versus a public safety-net hospital

Julie Wecsler[1], Roksana Karim[2], Yanling Ma[3], Maria Nelson[1], Stephen Sener[1], Christy Russell[4], Darcy Spicer[4], Janice Lu[4], Julie Lang[1]
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Background/Objective: Oncotype DX recurrence score (RS) is used in the clinical setting to guide treatment decisions for the role of chemotherapy in addition to endocrine therapy. We hypothesized that differences might exist in the RS in 2 different populations after controlling for other relevant factors.

Methods: We included stage I-III estrogen receptor positive breast cancer patients with an Oncotype DX performed January 1, 2007-December 31, 2015 at adjacent hospitals treated by the same faculty. Data were collected on patient demographics, tumor biology, and treatments. Logistic regression models evaluated the association between RS and demographic, tumor, and treatment factors.

Results: Three hundred fifty-four patients met inclusion criteria. Two hundred twenty-five (64%) were from the cancer center (CC), and 129 (36%) from the public hospital (PH). Mean age at diagnosis was 55.7 years. In the PH, 74% of patients were Hispanic, and 9% of patients were Caucasian in comparison

to the CC, where 12% of the patients were Hispanic, and 67% were Caucasian ($p < 0.001$). Three hundred forty (96%) patients received endocrine therapy. At the CC, 72% had T1 tumors versus 59% at the PH ($p=0.02$). Mean RS was 18.7 for the CC and 17.1 for the PH ($p=0.17$). Mean follow-up was 3.4 years. One hundred eighty-eight patients had a RS of < 18 (55%), 125 patients had an RS of 18-30 (36%), and 33 patients had a RS of > 30 (9%). The distribution of RS did not differ between the CC and the PH ($p=0.31$). Fifteen patients (4%) were found to have a recurrence of any kind. Three of the 6 patients with distant recurrence received adjuvant chemotherapy. Multivariate analyses identified PR positivity, grade, and chemotherapy as the significant correlates of RS. When stratified by institute, only PR positivity and chemotherapy were significant predictors of RS at the CC, whereas grade and chemotherapy were the significant correlates for RS at the PH.

Conclusions: The recurrence rate was 4% at a mean follow-up of 3.4 years. While great differences exist between these 2 populations, the recurrence scores were similar, suggesting that tumor biology is consistently represented across diverse populations after controlling for relevant covariates.

Poster Session and Reception II
Saturday, April 29, 2017

Clinical Trials

254218 - First clinical experience with insterstitial laser therapy (ILT) ablation for stage I breast cancer

Danielle Martin[1], Afonso Nazário[2], Silvio Eduardo Bromberg[1], Rodrigo Gobbo Garcia[1], Angela Flavia Logullo Waitzberg[3], Monica Rudner[1]
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Background/Objective: Screening programs are changing the scope of breast cancer with a growing number of patients diagnosed at an early stage. Current standard treatment (breast conservation and radiation therapy) offers an excellent prognosis to these patients. Besides tumor removal, other techniques can be used to destroy a mass in place. A range of minimally invasive techniques holds promise on local breast tumor ablation (i.e., thermotherapy, cryotherapy, and irreversible electroporation). Previous studies with ILT for breast cancer report ablation rates between 33-70%. Most common cited causes for this failure are equivocal tumor size estimation, inadequate technique, and learning curve. OBJECTIVE: Improve ILT technique and acquire better ablation rates by the evaluated procedure.

Methods: A prospective study with 20 patients with stage I, invasive breast cancer presented as a unique lesion as inclusion criteria will be evaluated. MRI and US will estimate primary tumor volume and roll out multicentric/multifocal disease. ILT ablation will performed by an Echolaser unit (Elesta) through percutaneous laser optical fibers with a US-guided insertion in the lesion center. All procedures will be held under local anesthesia and sedation. The image post procedure reevaluation comprises an US immediately after the ablation and a new MRI about 3 hours after the procedure. The definitive proposed surgical treatment should be realized 8-13 days after the ILT ablation. We describe in this paper the results from the 2 firsts patients and what is planned to be done to improve the results.

Results: see attached table

Conclusions: The laser beam has destroyed nearly 90% of neoplastic tissue. Consequences of laser therapy were visible in smaller intensity in surrounding tissue. These preliminary results suggest that laser therapy can eliminate viable neoplastic tissue in vivo, without affecting too much non-neoplastic adjacent tissue. Trying to achieve better results, there are some technique points to be improved for next cases: patients with associated DCIS should be excluded, 2 optic fibers should be used for tumors greater than 2 cm. There are several advantages of ILT for breast cancer treatment, including preserving the structure and function of breast, no bleeding, no scarring, and no radiation. The aim of this study is to refine the technique allowing ILT to be an eligible option to treatment in stage I breast cancer.

Patient		1	2
Age		65	66
Tumor Size (cm)		1,1	1,7
Pathologic Features		IDC, G2, ER +, PR +,HER-2 negative, Ki67 20%	IDC + extensive DCIS, G2, ER +, PR +,HER-2 negative, Ki67 10%
Initial Image		solitary lump	solitary lump + pleomorphic micro calcifications
ILT	n. of fibers	1	2
	total dose	(1500 + 1500J)*; 5W	(2000J + 2000J)* ; 5W
	total time (min)	10 minutes	7, 2
post- ILT US		small architectural distortion	unspecific echo texture alteration.
post- ILT MRI		edema area of 11 x 6 x 5 cm	edema area of 12 x 6 x 4 cm and an irregular homogeneous enhancement with 1,5 x 0,8 cm in the under lateral ablation local.
Pathologic Data		Fulguration and total necrosis in 50% of primary tumor. Partial ablation on 90% of tumor bed.	Extensive areas of necrosis and degeneration on 90% of primary tumor bed. Ductal carcinoma in situ foci around the main area.

* the optic fibers have been repositioned at the middle time of procedure to ablate a larger area.

Results

257111 - Intraoperative radiotherapy for management of ductal carcinoma in situ of the breast: A single center experience

Elizabeth Carlson, Angelena Crown, Debra Wechter, Janie Grumley
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Background/Objective: Intraoperative radiation therapy (IORT) has been shown to be effective in the treatment of breast cancer and may eliminate the need for post-operative external beam radiation therapy in well selected patients. To date, the majority of patients treated with IORT have been diagnosed with invasive ductal histology. The use of IORT in patients with ductal carcinoma in situ (DCIS) has not been well documented. This study was designed to assess the predictability of current imaging studies to select appropriate patients with DCIS for treatment with IORT, perioperative complications, and local recurrence in patients treated with IORT.

Methods: This single institution prospective non-randomized study enrolled women diagnosed with DCIS on core biopsy between February 2012 and July 2016. All patients who elected breast conservation (BCS) were assessed for IORT. Pre-operative imaging included bilateral digital mammography and contrast enhanced magnetic resonance imaging (MRI). Patients over the age of 44 years old with unifocal DCIS and lesion measurement ≤ 3.0 cm by imaging or exam were eligible for IORT. Patients underwent BCS with IORT at the initial operation. If final pathology showed extent of DCIS ≥ 3cm and/or margins ≤2 mm, additional therapy was advised. Patients are followed for complications and disease recurrence at 3, 6, 12, and 18 months, then annually.

Results: Fifty-seven patients were enrolled in the study. Seven patients (12.3%) were found to have invasive carcinoma on their final pathology and were excluded from further analysis in this study. Nine patients (18.0%) with DCIS had margins ≤ 2 mm on final pathology. One patient had a posterior chest wall margin less than 2 mm, so further treatment was not recommended. The remaining 8 patients (16%) were recommended to have additional treatment (AT). Three patients elected for mastectomy. Five had re-excision and were advised to have whole-breast irradiation. Forty-two patients (84.0%) with DCIS on final pathology were treated with IORT only. There were no statistical differences in clinical

factors between the group receiving IORT alone and those in the AT group (see Table). One patient in the IORT group developed cellulitis and wound dehiscence 5 months post-operatively after receiving chemotherapy for treatment of contralateral invasive ductal carcinoma. Seventeen patients reported hyperpigmentation at the treatment site. There were no local recurrences at a mean follow up of 31 months (range 4-56 months).

Conclusions: Bilateral digital mammography and breast MRI are good predictors of extent of DCIS and suitability for IORT. No other statistically significant predictors were identified to aid in the selection of patients for IORT. IORT with BCS may be an effective treatment for appropriately selected patients with DCIS. Further studies are needed to assess long-term outcome.

	IORT alone n=42	IORT plus AT n=8	p-value
Age (range)	58.7 (46.8-73)	60.1 (47-74)	0.681
BMI (range)	27.2 (10.45-40.16)	28.2 (21-48.4)	0.78
Clinical size (cm) (range)	1.5 (0.3-3.0)	1.1 (0.4-2.0)	0.152
MMG size (cm)	1.1 (0.2-3.1)	0.9 (0-1.8)	0.268
MRI size (cm)* (range)	1.3 (0-3.0)	0.9 (0-2.4)	0.399
Biopsy nuclear grade			
High (3)	18 (42.9%)	7 (87.5%)	0.107
Intermediate (2)	17 (40.5%)	1 (12.5%)	
Low (1)	7 (16.7%)	0 (0%)	
ER status			
Positive	40 (95.2%)	8 (100%)	>0.999
Negative	2 (4.8%)	0 (0%)	
Pathological size	0.90 (0.0-2.6)	2.13 (0.2-6.0)	0.122

*MRI results reported as post-biopsy changes/hematoma/seroma are not included in the final analysis

Comparison of patient groups

256607 - SHAVE2: A multicenter trial of cavity shave margins

Elizabeth Dupont[1], Adam Berger[2], Theodore Tsangaris[2], Ricardo Martinez[3], Carlos Garcia-Cantu[3], Andrew Fenton[4], Marissa Howard-McNatt[5], Eileen Consorti[6], Sonali Pandya[7], Eric Brown[8], Sharon Lum[9], Kristalyn Gallagher[10], Eric Whitacre[11], Meghan Butler[12], Tara McPartland[13], Anees Chagpar[12]
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Background/Objective: A recent single-center randomized trial, published in the *New England Journal of Medicine*, demonstrated that resection of cavity shave margins can reduce positive margin and re-excision rates in patients undergoing partial mastectomy. The current trial seeks to validate these findings in a larger multicenter study across many practice settings.

Methods: Inclusion/Exclusion Criteria: The targeted total sample size across all sites is 400 patients. All patients who had a core biopsy for diagnosis of stage 0-3 breast cancer for which a partial mastectomy is planned, including any who received neoadjuvant therapy, are eligible. Exclusion criteria include metastatic disease, plan for total mastectomy, excisional biopsy for diagnosis, previous or concurrent history of another breast cancer in the ipsilateral or contralateral breast, and plan for intraoperative radiation therapy. Methods: After local institutional review board approval, sites undergo a remote site initiation visit (SIV) with the coordinating center (CC). Source documentation, including signed informed consent, is reviewed centrally at the CC and eligibility confirmed. At the time of surgery, surgeons are instructed to perform their standard partial mastectomy, including the excision of selective shave margins on the basis of intraoperative imaging or gross analysis. Intraoperatively, a phone call is made to the CC, who confirms patient identification and that the surgeon is ready to close. The patient is randomized 1:1 to either have additional circumferential cavity shave margins taken ("shave") or to close ("no shave"). Local sites send source documentation to the CC where data collection, entry and analysis is performed. The research associate at the CC will contact patients at 1 and 5 years for patient-reported outcomes.

Results: Outcome Measures: Primary outcome measures are positive margin and re-excision rates. Positive margins are defined as tumor at ink for patients with invasive disease and margins of < 2 mm for those with DCIS. Secondary outcome measures include volume of tissue excised, patient-reported outcomes including quality of life and cosmesis, time to adjuvant therapy, and recurrence rates. Patients will be followed for 5 years' post-surgery.

Conclusions: To be determined -- trial in progress

Site	Location	SIV	Accrual (as of 11/5/16)
Watson	Lakeland, FL	7/20/16	27
Thomas Jefferson	Philadelphia, PA	7/6/16	11
Renaissance	Edinburg, TX	6/23/16	6
Akron General	Akron, OH	9/22/16	0
Wake Forest	Winston-Salem, NC	11/30/16	
Alta Bates	Berkley, CA	Regulatory	
Women's and Infants	Providence, RI	Regulatory	
Summit Medical Group	Berkeley Heights, NJ	Regulatory	
William Beaumont	Troy, MI	Regulatory	
Loma Linda	Loma Linda, CA	Regulatory	
UNC Chapel Hill	Chapel Hill, NC	Regulatory	
Breast Center of S. Arizona	Tucson, AZ	Regulatory	

SHAVE2 sites and accrual

256376 - Real time, near-infrared detection of breast cancer using BLZ-100 in patients undergoing surgical tumor resection

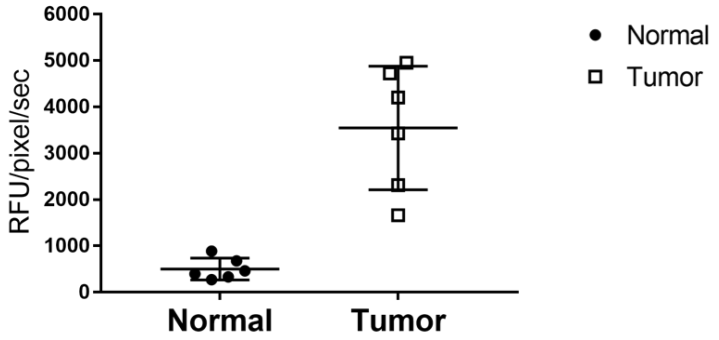
Kristi Harrington[1], Lennart Tan[1], Dennis Miller[2], Laura Ishak[2], Stacey Hansen[2], Julia Parrish-Novak[2], Kristine Calhoun[3], Benjamin Anderson[3], Sara Javid[3], Suzanne Dintzis[3]
[1]Overlake Hospital Medical Center, Bellevue, WA, [2]Blaze Bioscience Inc., Seattle, WA, [3]University of Washington Medical Center, Seattle, WA

Background/Objective: Breast-conserving surgery is commonly used for early-stage breast cancer patients, but carries a risk of positive margins. The ability to determine margin status of the excised tissue and to identify areas of residual disease in the surgical cavity in the operating room could reduce the rate of positive margins and decrease re-excision rates. BLZ-100 is an investigational peptide-fluorophore conjugate that has been shown in preclinical studies to have uptake in breast tumors. This clinical study provides safety and clinical proof of principle data for BLZ-100 to detect breast carcinoma intra-operatively and ex vivo. Ultimately, the goal is to use BLZ-100 and NIR imaging to detect positive margins on excised tissue and in the surgical bed in real time in the operating room. We hypothesize that near-infrared (NIR) imaging using a tumor-targeting imaging agent, BLZ-100, could aid in the detection of tumor containing tissue in real time.

Methods: Subjects with adequate liver and kidney function and biopsy-confirmed in situ and/or invasive breast carcinoma scheduled for surgical excision were eligible to participate. Twelve subjects received an IV bolus dose of 12 mg of BLZ-100 at least 2 hours before surgery. Subjects were monitored for adverse events, changes in vital signs, and laboratory measures for up to 7 days' post-dose. A total of 13 specimens were available from 9 lumpectomies and 4 mastectomies (3 nipple-sparing). NIR imaging was performed with 2 systems, the SIRIS from TealLight Surgical and the SPECTRUM from Quest Medical Imaging.

Results: There were no BLZ-100-related adverse events, vital sign changes, nor alterations in laboratory measures in any of the 12 subjects treated. Initially, ex-vivo imaging of specimens from 6 subjects was performed to assess the degree of BLZ-100 uptake and to facilitate correlation with histopathology. Tissue slices from all size specimens showed increased fluorescence in tumor (2 DCIS, 4 IDC) compared to normal breast tissue. Quantitative image analysis performed on pathologically confirmed IDC and normal regions showed an approximate 7-fold difference in fluorescent signal (range 5-10) as displayed in the Figure. NIR imaging of the surgical cavity and the excised tissue in the OR was subsequently added to the study and included 6 cases. Of these cases, one subject with IDC had a clinically close margins that showed increased fluorescence in the gross lumpectomy specimen in the OR, fluorescence near the edge of a tumor-containign slice, and fluorescence in the patent's resection cavity. Additional resection in this region generated a specimen with DCIS and notable fluorescence.

Conclusions: BLZ-100 uptake and subsequent enhanced fluorescence of pathologically confirmed regions of tumor (DCIS and IDC) has been demonstrated in this study. These data suggest BLZ-100 and NIR imaging have the potential to aid surgeons and pathologists to assess adequacy of surgical margins in real time.



Fluorescent signal in breast tissue sections

256759 - Freezing instead of resection of small breast tumors (FROST Trial): A study of cryoablation in the management of early-stage breast cancer

Emily Ho[1], Dennis Holmes[2]

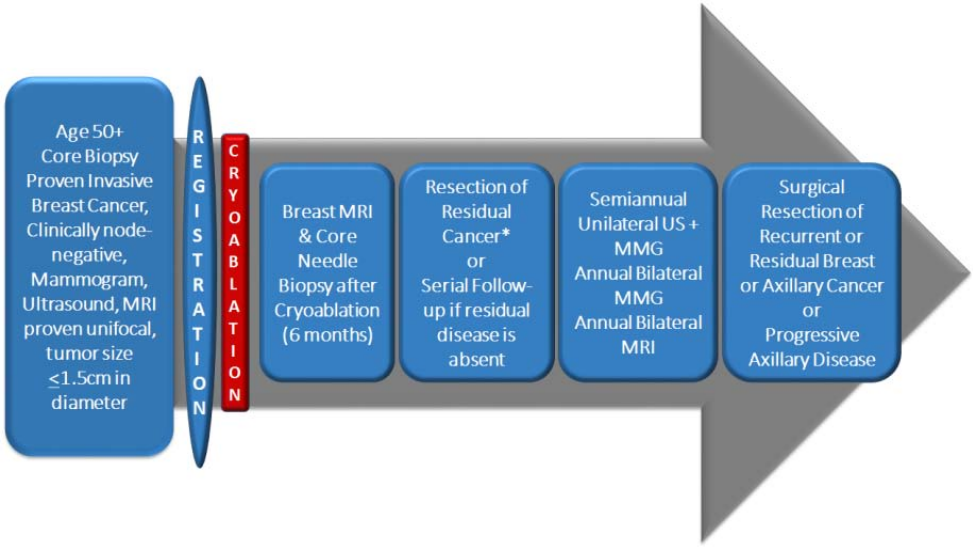
[1]John Wayne Cancer Institute, Santa Monica, CA, [2]John Wayne Cancer Institute Providence Saint John's Health Center, Santa Moncia, CA

Background/Objective: ACOSOG Z1072 demonstrated complete target tumor ablation in 92% of stage I invasive breast cancers treated with cryoablation prior to resection. We hypothesize that cryoablation can achieve complete tumor ablation and adequate local control in a selected population of women with early stage invasive breast cancer managed with cryoablation alone, without planned surgical resection.

Methods: The FROST trial is a phase II, single-arm, multicenter study open to women age 50 and older with core needle biopsy-proven clinical stage I, T1, clinically node negative (N0), unifocal, hormone receptor positive, HER2/neu-negative invasive ductal carcinoma measuring ≤ 1.5 cm by mammography, ultrasound, and contrast-enhanced MRI. Following registration, all subjects will undergo ultrasound-guided cryoablation followed 6 months later by an ultrasound-guided core biopsy of the cryoablated lesion to document the absence of residual viable disease. Subjects who have no residual disease will go on to receive a 5-year (minimum) course of adjuvant endocrine therapy and serial mammography, ultrasound, and contrast-enhanced MRI. Breast radiotherapy will be optional for subjects age 70 and older (low risk stratum) and mandatory for women age 50 to 69 (moderate risk stratum). Sentinel node biopsy is optional in both cohorts. All subjects found to have residual or recurrent disease will undergo standard surgical resection. The FROST trial was activated in June 2016. The study is currently open at 3 sites with 20 sites planned. A total of 110 eligible subjects will be enrolled in each stratum for total accrual goal of 220. Enrollment is planned over 3 years followed by 5 years of follow-up.

Results: The primary endpoint of the study will be to determine the rate of complete tumor ablation in patients treated with cryoablation, defined as absence of residual viable invasive or in situ carcinoma detected by core needle biopsy of the ablation site performed 6 months post-cryoablation. The secondary endpoint will be to determine the 5-year ipsilateral breast tumor recurrence rate in patients treated with cryoablation without subsequent resection. Local recurrence will be defined as recurrence of cancer within the index quadrant confirmed histologically by core needle biopsy. Breast cosmesis (assessed by BCCT.core) and adverse events will also be evaluated.

Conclusions: If the FROST trial is successful at achieving complete ablation in greater ≥ 80% of study subjects, the trial will provide an important foundation for establishing cryoablation as an alternative to conventional therapy in selected women with early stage invasive breast cancer.



FROST study schema

256219 – Progesterone-estimated timing of oophorectomy predicts better survival in premenopausal hormone receptor sensitive incurable breast cancer

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Background/Objective: In premenopausal incurable breast cancer, hormone therapy is the first line of treatment. Many hormones and growth factors influence recurrence and survival. Meta-analysis of previous results reveal luteal phase timing of surgical oophorectomy in the menstrual cycle favourably influenced better outcomes. However, few data report worse survival than in follicular phase surgery. There are possibilities that anovulatory luteal phase oophorectomy may influence survival. Progesterone-estimated timing of surgery may avoid the hazards of oophorectomy at anovulatory cycle. In this study, we evaluated whether the effect of progesterone-estimated timing on oophorectomy had better outcomes in incurable breast cancer patients.

Methods: One hundred fifteen premenopausal women of incurable ER and PR positive breast cancer were recruited for this trial. They were selected after estimation of progesterone hormone to confirm follicular (Progesterone < 2ng/ml) and luteal (Progesterone ≥5ng/ml) phase. Randomisation was done after laboratory confirmation of serum progesterone level. Surgical oophorectomy followed by oral tamoxifen was given in each patient with at least 3 years' follow-up for overall survival (OS) and progression-free survival (PFS). The 2 groups were analyzed by Kaplan-Meir methods and log-rank test.

Results: Progression-free survival (PFS) was better in the follicular phase group, but overall survival (OS) demonstrated no significant differences in the 2 groups. Median progression-free survival (PFS) for

follicular phase was 0.98 and for luteal phase was 0.72. Overall survival (OS) was 2.3 and 2.29 in the luteal and follicular phase group respectively.

Conclusions: Timing of oophorectomy did not influence OS, but PFS was better in follicular phase oophorectomy. The study suggests the estimation of serum progesterone before planning oophorectomy would better survival in incurable premenopausal hormone receptor sensitive breast cancer.

257408 - Referral patterns from primary care services to a metropolitan safety net hospital

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Bellevue Hospital, NYU Langone Medical Center, New York, NY

Background/Objective: Safety net hospitals provide an important role in the care of women diagnosed with breast cancer who may lack insurance or rely on public insurance. While many of these women may present at late stages, more attention has been paid to primary care services and increasingly, the number of women who are referred for breast cancer management come through primary care. We look at our volume to assess our referral pattern and how our patients are referred to our breast clinic.

Methods: A retrospective chart review of the EMR for breast cancer patients newly diagnosed from 2012-2013 was performed using the tumor registry at Bellevue Hospital Center. Patients with recurrent breast cancer, stage IV breast cancer, and those that weren't managed surgically at our institution were excluded from the study. Data including patient demographics, established relationship with PCP, and SM and palpable mass at presentation were obtained and analyzed using SPSS Statistics Software.

Results: One hundred seventy-three patients were included in the study, of which 5 presented with bilateral breast cancer (n=178). The majority of the patients seen at our institution were from minority groups, primarily Hispanic (34%) and Chinese (23%). One hundred twenty-nine patients (72%) had a PCP at the time of diagnosis versus 49 patients (28%) without a PCP. Patients without a PCP were more likely to have a palpable breast mass at presentation, compared to patients with a PCP (73% vs. 42% respectively, $p < 0.05$). While fully a third (33%) of our patients were referred from within our institution (internal medicine, gynecology, and geriatrics), another 27% came from our local community ambulatory care center. The remaining patients were referred from outside institutions or self-referred. Twenty percent were referred to our institution due to lack of insurance.

Conclusions: PCPs play a valuable role in breast cancer screening and detection. Given that our institution, a tertiary referral center, has double the volume of our ambulatory care center, the primary care doctors at the latter center have more time to engage the patient in health-promoting behaviors. By engaging more of the PCPs and educating them on the changing landscape of breast screening guidelines, there is an opportunity to make gains in patient outcomes.

256225 - Multicentric randomized Italian trial: Axillary dissection or not in sentinel node macrometastasis of breast cancer

Corrado Tinterri, Emilia Marrazzo, Andrea Sagona, Wolfgang Gatzemeier, Erika Barbieri, Alberto Testori, Valentina Errico, Carlo Rossetti, Marco Eboli, Arianna Rubino, Giuseppe Canavese
Humanitas Cancer Center, Milan, Lombardia, Italy

Background/Objective: Sentinel lymph node (SLN) staging is currently used to avoid complete axillary lymph node dissection (ALND) in breast cancer (BC) patients with negative SLN without jeopardizing survival or regional control. International guidelines keep recommending ALND in the presence of positive (+) SLN. However, SLN is the only site of axillary metastasis (MTS) in many cases (60%). Retrospective studies have also shown a low risk of locoregional relapse in patients with SLN+ not receiving ALND. The aim of this trial is to confirm that performing only SLNB does not affect survival or relapse risk in patients with 1-2 SLNs+. This procedure could reasonably be introduced in the clinical management of this patient subgroup, providing them also with a better quality of life due to a reduction of morbidities associated with ALND.

Methods: This multicenter clinical trial randomizes 2,000 patients distributed in 2 arms: standard treatment of axillary dissection in patients with metastatic SLN vs no axillary dissection. The study will close in 3 years. Eligibility criteria are: age 40-75 years, primary invasive T1-T2 tumor, axillary nodes clinically N0, no more than 2 SLNs within macroMTS at intraoperative or definitive histological evaluation, no distant MTS, no neoadjuvant therapy, no previous invasive BC, and signed informed consent. Exclusion criteria are: DCIS, inflammatory, contralateral BC, presence of only microMTS in the SLN, pregnancy or breastfeeding, and comorbidity impeding adjuvant therapy. Follow-up controls foresee: clinical examination every 6 months for 5 years and yearly thereafter, annual mammography and breast echography, annual axillary echography for patients in the SLNB arm, and additional laboratory and instrumental surveys in case of suspected onset of distant MTS.

Results: This study started in January 2016. The active centers are 32 different hospitals in Italy. We have recruited 152 patients, 79 in the standard arm (sentinel lymph node biopsy plus axillary dissection) and 73 in the sperimental arm (only sentinel lymph node biopsy). The enrollment will finish in 2 years. We await the final results.

Conclusions: If the results of this trial confirm that abstention from ALND in certain patients with 1-2 metastatic SLN proves suitable, its introduction into clinical practice would be determine a significant reduction in complications associated with ALND, improving the quality of life without compromising survival or the risk of locoregional recurrence.

257313 - Reducing the burden of breast cancer in young women (RUBY): A prospective, pan-Canadian cohort study

May Lynn Quan[1], Kristin McBain[2], Nancy Baxter[3], Christine Friedenreich[4], Kelly Metcalfe[5], Ellen Warner[6], Antoine Bouchard-Fortier[1], Susan Isherwood[4], Ivo Olivotto[4], Steven Narod[5]
[1]University of Calgary, Calgary, AB, Canada, [2]St. Michael's Hospital, Toronto, ON, Canada, [3]St Michael's Hospital, Toronto, ON, Canada, [4]Alberta Health Services, Calgary, AB, Canada, [5]Women's College Hospital, Toronto, ON, Canada, [6]Sunnybrook Health Sciences Centre, Toronto, ON, Canada

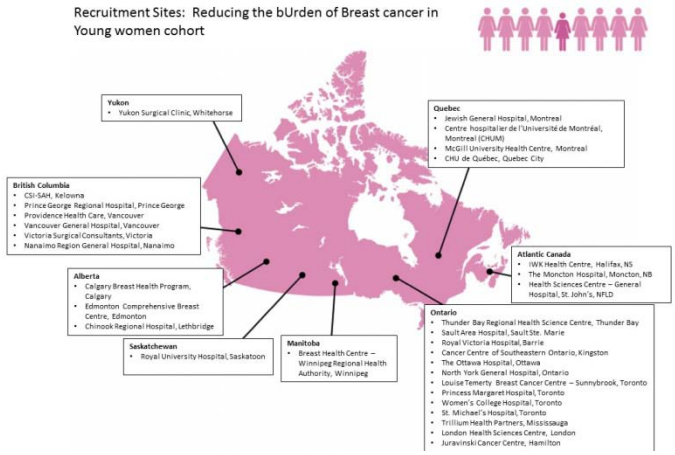
Background/Objective: Despite known differences in breast cancer outcomes and tumour phenotypes in young women compared with older women, there is limited understanding of the basic biology, epidemiology, and optimal therapeutic strategies for breast cancer in young women. We present the RUBY study, a prospective cohort designed to examine predictors, treatment, quality of life, and outcomes from time of diagnosis for this unique population. We are creating a comprehensive repository of data, biospecimens, and patient-reported outcomes in women age 40 and younger with breast cancer from a diverse range of practice settings across Canada. The initial RUBY cohort will address 4 separate subprojects: 1. Genetics: Evaluate the contribution of 25 genes linked to breast cancer causation; 2. Lifestyle/modifiable risk factors: Explore associations between increased breast cancer risk and outcomes for young women and the impact of lifestyle (physical activity, caloric, phytoestrogen, and micronutrient intake) on outcomes; 3. Fertility: 1) assess oncofertility knowledge among surgeons and develop a fertility tool kit for young women; and 2) determine pre-treatment predictors of premature ovarian failure; 4. Initial therapy: 1) document the spectrum of treatments received, 2) evaluate the impact of treatment delay, 3) develop and disseminate a strategy for providing pre-treatment, multi-disciplinary care across jurisdictions, and 4) evaluate patient pre-treatment knowledge and preferences for treatment including surgery.

Methods: The RUBY study will enroll 1,200 newly diagnosed, incident women with breast cancer aged 18 - 40 from 32 sites across Canada, over 4 years. Recruitment is through surgeons, prior to treatment. Patients consent to release of medical information and optionally 1) complete validated, online patient-reported outcome (PRO) questionnaires, 2) contribute baseline, 1-, 2- and 3-year blood samples, 3) provide access to formalin-fixed, paraffin-embedded tissue (FFPE) for TMAs, and 4) provide permission to be contacted for future research. Reassessments with questionnaires, +/- blood samples, occur at 3 months, at the completion of active treatment, and at 12, 24 and 36 months from diagnosis. The RUBY site PIs will function as knowledge translation units to bring findings to clinical practice.

Results: RUBY activated July 1, 2015 at a single site. Additional sites continue to activate. As of November 8, 2016, 230 participants with an age range of 25 to 40 years have been recruited from 25 sites in 8 provinces and the Yukon. Twenty-five to 30 patients are being recruited per month. Provider oncofertility knowledge assessment has been completed, and a multidisciplinary pre-treatment checklist has been developed through an integrated knowledge translation strategy and has been disseminated and will be evaluated for clinical effectiveness and adoption.

Conclusions: RUBY is on schedule to meet target accrual of newly diagnosed women ≤40 with breast cancer during our 4-year recruitment period in a pan-Canadian, multisite, cohort study. In addition to addressing key determinants of outcomes including genetics, expanded lifestyle factors, delivery and use of treatments, as well as their impact on fertility, we are creating a clinical network to develop and disseminate new knowledge into practice. This legacy cohort of patient-reported outcomes, clinical

data, and biospecimens is the first of its kind in Canada and will serve as a valuable resource for future research.



Recruitment sites

257287 - Feasibility of diagnostic interstitial ex-vivo mammary autofluorescence microendoscopy

Dena Monjazebi[1], Alexandre Douplik[1], Wey Leong[2], Susan Done[3], Supriya Kulkarni[2], Brian Wilson[4], Alexandra Easson[2]
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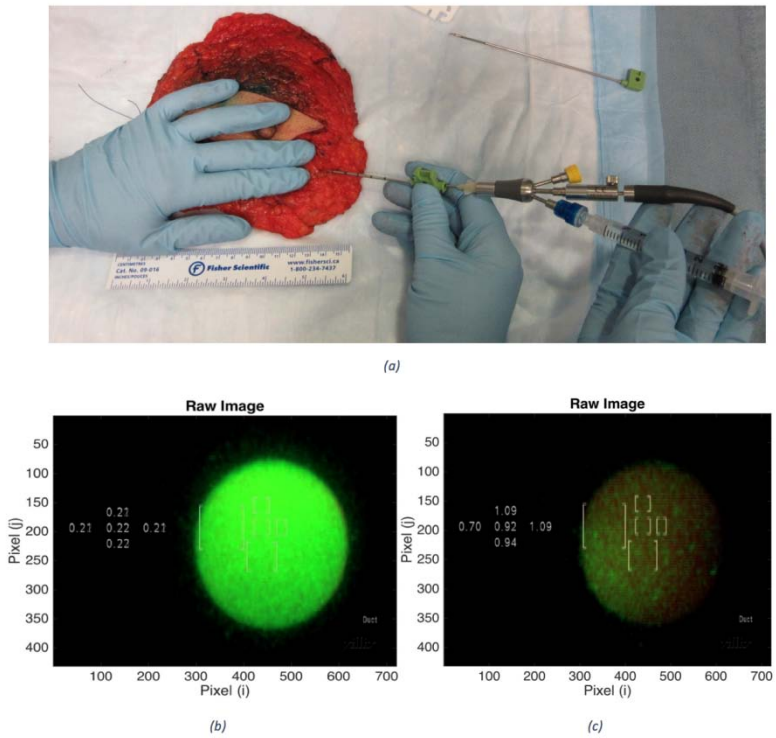
Background/Objective: This is a feasibility study to explores the ability and safety of the autofluorescence (AF) microendoscope to discriminate between cancer and normal tissue when inserted interstitially into the excised breast. When coupled with core tissue biopsy, success in this approach has the potential to aid the diagnostic radiologist in determining the risk of malignancy during breast cancer work-up and could significantly reduce the number of required biopsies and considerably impact patients.

Methods: After institutional approval, 5 women with clinically palpable breast cancer planned for curative mastectomy were recruited for the study. Immediately after mastectomy, the breast specimen was taken to the pathology and assessed within 20 minutes. A standard 14-gauge (BARD) biopsy trocar was inserted through the breast into the palpable breast tumor, the internal cannula withdrawn, leaving a hollow passage directly into the cancer. A 550-micron outer-diameter, high-resolution (6000 pixel) microendoscope (Polydiagnost, Germany) coupled to AF imaging was inserted into the hollow needle, and white light and autofluorescent images were taken (Figure). The AF illumination wavelength range was 390 to 450 nm. The endoscope was removed, the biopsy needle was reinserted, the biopsy gun attached, and a core needle tissue biopsy was taken from the tissue imaged by the endoscope. This was repeated into a normal area of breast in the same patient. The biggest obstacle was the inflow of blood into the working channel; however, sufficient quality images could be obtained upon saline rinsing. The specimen was passed to pathology for standard processing.

Results: The 5 patients had invasive ductal carcinoma that included the spectrum of pre- and post-menopause, grades II/III, and ER, PR and HER2-neu positivity. AF imaging demonstrated 100% sensitivity

and specificity to differentiate between the pathologically proven cancer and normal tissue. A green for normal and reddish image for malignancy could be clearly discriminated (Figure). One patient had a persistent palpable mass after neoadjuvant chemotherapy. AF images of the palpable tissue was in the normal range; biopsy showed only fibrosis (a true negative). The mean numerical color value (NCV) for cancer was 1.22, and normal tissue was 0.14. No adverse consequences occurred for the pathology assessment because of our intervention.

Conclusions: We demonstrated that the AF microendoscopy can accurately distinguish between cancer and normal tissue when inserted interstitially. Additionally, we developed a reliable, feasible and safe biopsy coupled method to obtain AF images and correlative tissue biopsies. Our next step is to explore the use of this technology in a larger sample size and in the clinical diagnostic radiology setting to explore the ability of AF microendoscopy to discriminate across the spectrum of breast pathology. An AF microendoscopy coupled with image-guided biopsy could potentially reduce the number of biopsies that the patients undergo, aid in the screening of high-risk patients, and simplify the diagnostic work-up of women with cancer in the presence of multiple lesions. This can potentially be a new diagnostic tool.



(a) Data acquisition-Participant no. 1. Cross signifies the location of the tumor. A sample of autofluorescence imaging of normal (b) versus malignant tumor (c). The field of view has a diameter of approximately 2 mm. For all study cases, the cancer appeared as a domination of red color and the normal as a vivid green color.

256713 - Seroma formation after early drain removal in patients undergoing breast cancer surgery: A randomized controlled trial (CTRI/2014/01/004362)

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Background/Objective: Seroma is the most frequent postoperative complication after breast cancer surgery. Drainage of the chest wall and axilla is the standard method of preventing seroma formation. Traditionally, drains are removed once the drainage is reduced to about 30-50 ml in 24 hours, which may take several days. This can delay discharge from hospital, require repeated visits to the hospital, and may delay initiation of adjuvant treatment. In an earlier study on seroma prevention, we found a suggestion that drain removal 7 days after did not influence seroma formation (*Breast J*. 2013; 19:478–484). Since this was a post hoc analysis, to test this hypothesis, we carried out the present randomized controlled trial.

Methods: Two hundred patients admitted for breast cancer surgery in the Department of Surgery, PGIMER, Chandigarh, India from July 2013-Dec 2014 were enrolled. Ninety-four patients were randomized to early drain removal (EDR) and 106 patients to standard drain removal (SDR). In EDR, drains were removed when the drain volume was less than 100 ml or 7 days after surgery, whichever was earlier. In SDR, the drains were removed when the drain volume fell below 30 ml/24 hours. The primary endpoint of the study was seroma formation. A seroma was defined as any palpable fluid collection in the axilla or chest wall. Secondary outcomes included daily drain output, cumulative drain output, duration of drainage, drain fluid infection, lymph node status, and wound complications. The study was approved by the Institutional Ethics Committee and registered with the Clinical Trials Registry-India (CTRI). Statistical analysis was performed using SPSS 17. Descriptive statistics like mean, median, percentage, standard deviation, and range were calculated. Hypothesis testing was performed using independent t test, Wilcoxon rank sum test, and Chi Square test. A p-value of 0.05 was considered significant.

Results: Twelve patients were excluded from the EDR group because they withdrew consent. Thus 82 patients in the EDR group and 102 in the SDR group were analyzed. Both groups were similar for age, BMI, type of surgery performed, stage, and lymph node involvement. The drains were removed after a mean of 8 days (range 5-8) in EDR and 20 days (range 5-30) in SDR group. The mean cumulative drain output was 987 ml (range 315-3000) in EDR group and 1747 ml (range 380-4460) in SDR group. In the EDR group, 31 patients (37.8%) developed seroma compared to 6 patients (5.7%) in the SDR group ($p < 0.0001$). All patients with seromas underwent aspirations till resolution. In the EDR group 42 (51.2%) patients showed drain output < 200 ml on the first day, among those only 10 (12.2%) patients developed seroma. Forty patients showed drain output ≥ 200 ml and among those 21 (25.6%) patients developed seroma ($p < 0.007$). In the EDR group, 50 patients showed cumulative drain output of < 1000 ml. Among those, 12 (24%) patients developed seroma. Thirty-two patients showed cumulative drain output > 1000 ml, among those 19 (59.4%) patients developed seroma ($p < 0.001$). In the EDR group, seroma developed in 13 (28.3%) patients with pN0 status compared to 18 (50%) patients with pN1-2 status ($p < 0.04$).

Conclusions: Early drain removal was associated with a significantly higher incidence of seroma formation. Within the EDR group, a first-day drain output of < 200 ml, a cumulative drain output of <

1000 ml, and pN0 status was associated with a lower incidence of seroma formation. These factors may be used to select patients for early drain removal.

257172 - The intelligent knife for detection of invasive breast cancer at radial margins: An intraoperative feasibility trial

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Background/Objective: High rates of re-operative intervention for positive margins following attempted breast-conserving surgery are common in both the UK and USA (national average rates ~20%). There is a need for a rapid and reliable technique to better optimise intraoperative margin control. Rapid evaporative ionisation mass spectrometry (REIMS) analyses surgical aerosols produced as a by-product of routine electrosurgical use. This prospective intraoperative feasibility study aims to evaluate the capability of REIMS to characterise breast tissues at the “inked” radial margin.

Methods: Electrosurgical aerosol produced during cutting and coagulation mode was aspirated from ex-vivo fresh and frozen, normal/benign, or cancerous breast tissues into a modified mass spectrometer (Xevo G2-XS-Q-TOF). Spectra were assigned a diagnosis based on post-REIMS histopathology and multivariate statistical methods were used to create a classification model of normal versus cancer. Tandem mass spectrometry (MS) analysis of significant peaks was performed to identify biochemical differences between the classes. Diagnostic accuracy of the model was confirmed using leave 1 patient out cross validation. This ex-vivo classification model was used for the interpretation of intraoperative spectra. Intraoperative REIMS data was acquired during breast surgery by continuous aspiration of electrosurgical aerosol. Time synchronised operative video recordings of the surgical scene were performed to co-register spectral data to the location of the iKnife in relation to excision margins. Diagnostic accuracy of the iKnife in the determination of positive and negative margin status (invasive tumour or normal breast on ink) was compared to final histopathology.

Results: A dataset of ex-vivo tissue types was created using 1,606 sampling points (normal n=1,121, tumour n=485) from 836 breast specimens (normal n=467, tumour n=369). The tumour database was composed of 476 sampling points from invasive disease (98.1%) and 9 sampling points from ductal carcinoma in situ (DCIS) (1.9%). Univariate analysis combined with tandem MS identified 63 phospholipids and 6 triglycerides species responsible for 24 spectral differences between normal and tumour tissue type. A multivariate statistical model was created and was 90.9% sensitive for the classification of tumour and 98.3% specific for the classification of normal breast tissues. This model was used with specific thresholds for the intraoperative iKnife recognition. The iKnife was used during 85 operations (n=52 wide local excisions, 12 mastectomies, 9 oncoplastic excisions, 12 re-excision of margins). High-intensity spectra were obtained throughout the entire operation. Spectral results were presented onscreen (surgeon blinded) within 2 seconds of electrosurgical activation. The smoke was analysed at a rate of one spectra per second. Data was obtained from 505 margins. The primary outcome measure for the detection of invasive tumour margins demonstrated a sensitivity of 77.8% (7/9 margins) and a specificity of 92.8% (449/484 margins) for the identification of negative margins. In the operations with false positive results, tumour spectra accounted for a mean of 1.2% (65 out of 5,357 spectra) of the total electrosurgical activation time. Detection of DCIS at the margin was a secondary

outcome measure due to the under powering of the ex-vivo model for DCIS; however, with this model 4/12 positive DCIS margins were correctly classified.

Conclusions: REIMS has been optimised for the rapid analysis of heterogeneous breast tissue. Tumour-associated changes in the breast lipidome have been identified by REIMS tandem MS. A classification model with high diagnostic accuracy has been built from spectra acquired from ex-vivo normal and cancerous breast tissue. Intraoperative results demonstrate that surgical aerosol can be analysed throughout BCS with results presented in real time. Initial data suggest that the iKnife is capable of identifying positive invasive tumour margins with high diagnostic accuracy. The classification model was significantly underpowered for DCIS; however, diagnostic accuracy is expected to improve as we build on our classification models and further optimise instrumentation. Future work will involve expanding the classification dataset as well as clarifying the diagnostic accuracy of REIMS as part of a clinical trial [REI-EXCISE, CRUK CRC Trial, CRUK/16/021].

256724 - Adenomammectomy and recostruction without prosthesis in breast cancer

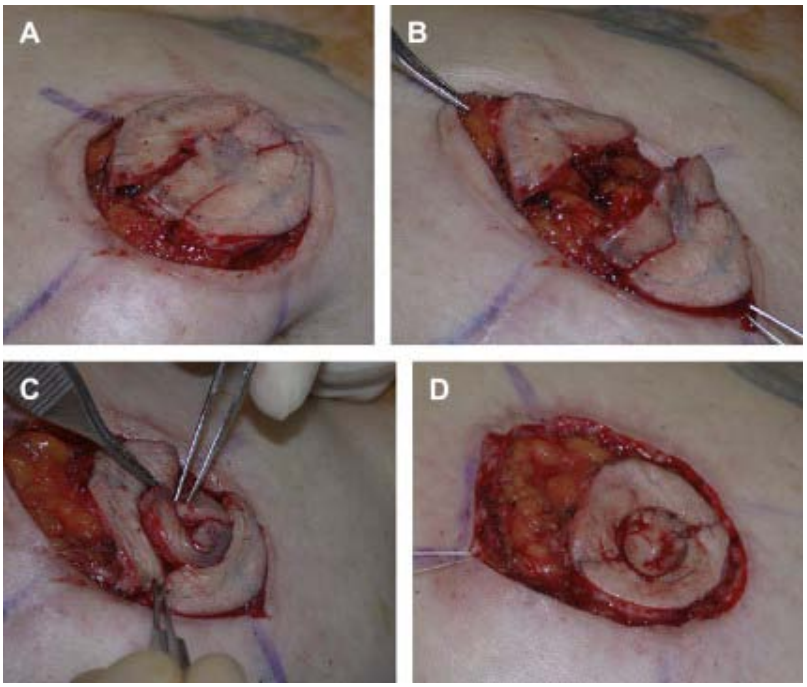
Angela Strazzanti, Giuseppe Garozzo, Santi Gangi, Claudio Trovato
Ospedale Vittorio Emanuele, Catania, Sicilia, Italy

Background/Objective: This study aims to show how is possible to do reconstruction without prosthesis after mastectomy and adenomammectomy using fat and soft autologous tissue (not a lipofilling procedure).

Methods: We perform many mastectomy and adenomamectomy procedures for cancer, and in the same operation, we do the reconstruction. We have 2 different groups of patients: patients who have adenomamectomy and reconstruction with prosthesis and those without prostesis (use of autologous fat and soft tissue naturally present in breast). Patients who have reconstruction without prosthesis have earlt recovery, and we can do this procedure in women with major morbilities because the risk is less than with prosthesis.

Results: The use of autologous fat tissue (not lipofilling) that is naturally in the breast can recreate the natural shape that looks likes as a prosthesis. This procedure is useful in prophylactic mastectomy in patients with high risk for cancer.

Conclusions: We would like to demonstrate how it is possible to do reconstruction in patients with major morbities but reduce the risk of implant prostesis. Our procedure is new, because many surgeons have used the autologous tissue of the breast only in breast-reducing surgery. With this technique, we have a glandular residual tissue less than 5%, and we can advise the use of this as a prophylactic procedure in patients with a risk of breast cancer.



256868 - Single-blinded, randomized assessment of post-mastectomy analgesia using exparel (liposomal bupivacaine) versus standard bupivacaine or placebo (saline)

Eleni Tousimis[1], Stuti Tambar[2], Arjun Kanuri[1], Ryan Mathis[3], Shawna Willey[1], Sulakshana Seevaratnam[1], Bridget Oppong[1], Troy Pittman[1]
[1]Medstar Georgetown University Hospital, Washington, DC, [2]Georgetown University, Washington, DC,

Background/Objective: Primary Objective: Post-operative pain scores (determined using a validated questionnaire from the American Pain Society) and amount of narcotics required (determined using EMR documentation from nursing staff). Secondary Objective: Length of stay

Methods: Target Accrual: 100 patients. Site the trial is open at: MedStar Georgetown University Hospital

Results: Date of activation 11/1/2016. Anticipated Study Length: 5 years

Conclusions: Trial Design: This is a randomized, single-blinded placebo-controlled trial. Inclusion criteria will be all female patients over 18 undergoing bilateral therapeutic or prophylactic skin or nipple-sparing mastectomy at MedStar Georgetown University Hospital with immediate reconstruction consisting of either tissue expander placement or direct implant placement at the time of mastectomy. Patients will be randomized to one of 3 arms: (1) injection of liposomal bupivacaine at the end of the mastectomy, (2) injection of standard bupivacaine (SB) at the end of the mastectomy, or (3) saline injection at the end of mastectomy. All patients will be able to receive IV and oral narcotic medications in the post-operative period on an as-needed basis. Patients randomized to LB arm will receive 266 mg of liposomal bupivacaine (LB) in 20 cc of solution. This will be expanded with various amounts of normal saline to cover the appropriate surgical field. Our routine expansion for a bilateral mastectomy is to add 60 mL of saline to 20 mL (266 mg) of LB. In our practice, we use an 18-gauge needle to inject the medication in a "field-effect" encompassing all 4 quadrants of the chest muscles (pectoralis and serratus) subfascially

above inferior aspect of ribs. This occurs prior to reconstruction. Patients randomized to the SB arm will receive weight-based dosing of bupivacaine, administered in the same manner as the LB arm. Patients who are in the placebo arm will receive a similar volume of saline in same manner as the LB arm. Postoperatively, all patients will be admitted for overnight stay and discharged on post-operative day 1 if they meet discharge criteria. Total length of stay will be documented. They will all have the option of receiving IV morphine injections as well as oral acetaminophen-hydrocodone as needed for additional pain control. The administration of these additional medications will be recorded for each patient by nursing staff. On post-operative day 1, each patient will be administered the American Pain Society Outcome Questionnaire while in the hospital. After discharge from the hospital, we will call the patient on post-operative day 2, 3, 5 and 7 to assess pain and satisfaction scores, using the same questions each time. For any patients staying in the hospital longer than 1 day, the questionnaire will be administered in the hospital on the same post-operative days. Subject participation only lasts for these 7 days of follow-up.

256896 - Nipple sensitivity after therapeutic or prophylactic nipple-sparing mastectomy

Eleni Tousimis[1], Stuti Tambar[2], Sulakshana Seevaratnam[1], Aiste Gulla[1]
[1]Medstar Georgetown University Hospital, Washington, DC, [2]Georgetown University, Washington, DC,

Background/Objective: Primary Objective: To determine the percentage of women who retain nipple or skin sensation post nipple-sparing mastectomy for breast cancer or prophylaxis, specifically to the nipple-areola complex, and to determine if sensation to heat, cold, vibration, and light touch are equally maintained. Secondary Objective: To determine if adjuvant treatments such as radiation, chemotherapy, or endocrine therapy affect retention of sensation to the nipple-areolar complex. To determine if type of incision used for nipple-sparing mastectomy has any effect on post-operative nipple sensitivity. To determine if there is a difference in the amount of retained sensitivity in diabetic patients versus non-diabetic patients and smokers versus non-smokers. To determine if there is a difference in the amount of retained sensitivity related to bra/cup size or body mass index. To determine if there is a difference in nipple sensation related to type of reconstruction- implant based versus autologous. To determine if tumor size or tumor proximity to nipple has any effect on nipple sensation.

Methods: Target Accrual: 50 patients. Site the trial is open at: MedStar Georgetown University Hospital

Results: Date of Activation 4/1/2016 Anticipated Study Length: 5 years

Conclusions: Design: This is a non-randomized prospective cohort study. Patients will be recruited from a population of women who have been diagnosed with breast cancer or high risk for breast cancer and plan to undergo therapeutic or prophylactic nipple-sparing mastectomy for treatment of their cancer. Inclusion Criteria: Women age 18 or older. Primary nipple-sparing mastectomy for therapeutic or prophylactic purposes, without prior breast surgery (lumpectomy, excisional biopsy). May have had prior ipsilateral needle biopsy. Breast surgeon and plastic surgeon must agree that the patient is a suitable candidate for nipple-sparing mastectomy based on oncologic safety and expected reasonable cosmetic outcome. Tis-2, N0-1, M0 Stage 0-2 Any ER, any PR, any HER2 status. Prophylaxis for high-risk condition including: confirmed BRCA-1 or BRCA-2 mutation carrier, first-degree relative of a BRCA 1 or 2 mutation carrier, biopsy proven ADH, ALH, LCIS, FEA. Exclusion Criteria: Women < 18 years of age. Non-English speaking patients. Pregnant women. Women lactating < 6 months prior to surgery. Ipsilateral breast or nipple surgery prior to nipple-sparing mastectomy (does not include needle biopsy). Ipsilateral

breast with previous radiation. Neoadjuvant chemotherapy. History of past or current nipple piercing. Postive nipple margin, or need for excision of nipple-areolar complex. Inflammatory breast cancer. Pagets disease. T3-4, N2-3, M1 Stage 3-4. Each woman will be tested preoperatively and at 1 week, 1 month, 3 months, 6 months, and 12 months post-operatively. Testing will occur in 12 locations on the ipsilateral breast: nipple: superior, inferior, medial, and lateral; distal areolar border: superior, inferior, medial, and lateral: and breast skin 5 cm from the border of the areola: upper outer quadrant, lower outer quadrant, upper inner quadrant, lower inner quadrant. The patient will be blind-folded during testing. All testing will be completed by a single researcher when possible. Light touch sensation will be evaluated using the Semmes-Weinstein Monofilament mini-kit. Each site will be tested by depressing the monofilament on the site until it bends and holding for 2 seconds. This will be repeated a total of 3 times per monofilament. The thinnest filament felt by the patient will be recorded. Vibration will be evaluated using 30Hz and 256Hz tuning forks. Each site will be tested by holding the end of the tuning fork to the site for 5 seconds. This will be repeated a total of 3 times at each site per tuning fork frequency. Vibratory sensation will be recorded as perceived or not perceived for each frequency in each location. Heat sensation will be evaluated with a metal probe kept at a constant 50C via a hot water bath held to the skin for 5 seconds. This will be repeated a total of 3 times at each site. Heat sensation will be recorded as perceived or not perceived in each location. Cold sensation will be evaluated with a metal probe kept at a constant 10C via an ice bath held to the skin for 5 seconds. This will be repeated a total of 3 times at each site. Cold sensation will be recorded as perceived or not perceived in each location.

257226 - Novel intraoperative magnetic resonance system for margin assessment in breast-conserving surgery: MRI margin-to-margin clinical study

Christine Teal[1], J. Michael Dixon[2], Tami Karni[3], Tanir Allweis[4], Moshe Papa[5], V. Suzanne Klimberg[6]
[1]The George Washington University, Washington, DC, [2]Western General Hospital, Edinburg, Scotland, United Kingdom, [3]Assaf Harofeh Medical Center, TZrifin, Israel, [4]Kaplan Medical Center, Rehovot, Israel, [5]Assuta Medical Center, Tel-Aviv, Tel Aviv, Israel, [6]University of Arkansas for Medical Sciences, Little Rock, AR

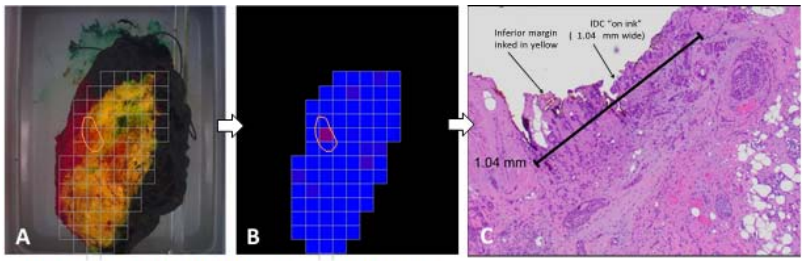
Background/Objective: Re-excision rates in breast-conserving surgery (BCS) are reported as being between 21 and 50%. For women undergoing BCS, margin status is recognized as one of the most important predictors of local recurrence regardless of subsequent radiotherapy. The ClearSight™ system (Clear-Cut Medical Ltd., Rehovot, Israel), is a mobile, magnetic resonance (MR) imaging system for the OR environment. The ClearSight™ system applies diffusion-weighted (DW) imaging to create parametric maps reflecting the spatial distribution of diffusion properties of tissues in the margins of excised lumps. The study objective was to evaluate the performance of the ClearSight™ MRI system in margin assessment during BCS.

Methods: A multi-center, single arm, blinded study was conducted in 6 sites worldwide: USA (George Washington University Hospital and University of Arkansas for Medical Sciences), UK (Western General Hospital), and Israel (Assuta Medical Center, Kaplan Medical Center, and Assaf Harofeh Medical Center). The study was conducted in 2 main phases: system validation (parameters exploration and adjustment) followed by feasibility evaluation. All surgeries were performed per site standard of care. Following BCS, the specimen was inked intraoperatively, and multiple margins were scanned. The ClearSight™ generated a 2-D map representing the diffusion properties in each aspect (Figure). Finally, the excised tissue was sent to histopathology for routine assessment. Both surgeons and pathologists were blinded

to the system outcome. Comparison was made between the standard histopathology findings and the system measurements for evaluating its performance in differentiating between cancerous and non-cancerous tissue on a margin-to-margin basis.

Results: Overall, 220 female patients are being enrolled the study since October 2015 to January 2017. Study recruitment and data analysis is ongoing. Previously published clinical data demonstrated the high accuracy of the ClearSight™ system when compared to histopathology findings on a point-to-point basis.

Conclusions: The ClearSight™ system shows potential of being an effective, intraoperative MR margin assessment tool, which may assist the surgeons in reducing re-excision rates in BCS.



A. Optical image B. Surface MR diffusion map C. Histopathology finding

ClearSight™ specimen scan

257149 - Primary Radiotherapy And DIEP flAp reconstruction: The PRADA study

Paul Thiruchelvam[1], Dimitri Hadjiminas[2], Susan Cleator[2], Simon Wood[3], Daniel Leff[1], Navid Jallali[2], Stuart James[4], Fiona MacNeill[4]
[1]Imperial College, London, England, United Kingdom, [2]Imperial College NHS Trust, London, England, United Kingdom, [3]Imperial College NHS Trust, London, Northern Ireland, United Kingdom, [4]The Royal Marsden Hospital, London, England, United Kingdom

Background/Objective: The aim of this study is to determine the surgical outcomes of radiotherapy prior to surgery at 2 sites - The Royal Marsden Hospital and the Imperial College NHS Trust, London. The study seeks to determine if radiotherapy (RT) prior to mastectomy with immediate DIEP flap reconstruction: • Is feasible with equivalent acute complications rates to standard mastectomy and immediate DIEP flap reconstruction performed prior to RT • Will improve the long-term aesthetic outcome of mastectomy and immediate DIEP flap reconstruction in patients requiring radiotherapy • Avoids delays to radiotherapy after surgery because of wound healing issues • Will ultimately increase immediate reconstruction rates

Methods: Women with breast cancer who have been recommended by the breast multidisciplinary team to undergo both mastectomy and adjuvant radiotherapy and who are suitable for DIEP flap reconstruction will be invited to take part in this study at their surgical planning consultation between their fifth and sixth chemotherapy cycles, when it usually becomes apparent they will require mastectomy and axillary clearance/sentinel node biopsy or if they have failed breast conservation. If they wish to proceed in the study, they will be invited to a clinical oncology consultation at which time adjuvant radiotherapy will be discussed. If the patient remains happy to participate in the study, consent will be taken prior to radiotherapy and surgery. Radiotherapy will be initiated between 3-4 weeks following the final cycle of chemotherapy. Patients will be treated according to departmental protocol,

40Gy/15 fraction/3 weeks, 50Gy/25 fractions/5 weeks or 42.72Gy/16#/3.2 weeks. Where indicated, 5mm-10mm wax bolus will be applied to the skin of the breast for at least half of the planned treatments. Patients will proceed to mastectomy, axillary nodal clearance, or sentinel node biopsy and immediate DIEP flap reconstruction at 2-6 weeks following completion of radiotherapy. This range of timings allows for surgery to be planned beyond the peak of the skin reaction but prior to development of skin/ subcutaneous tissue fibrosis. Patients will be reviewed at 2, 4, 8 and 12 weeks' post-surgery. Patients will undergo 3-D-surface imaging*, 2-D-photography and applanation tonometry at 12 weeks and 12 months post-surgery. Patient-reported outcome measures will be assessed at the same time points using the Breast-Q. Primary Endpoint • Presence of open breast wound at 4 weeks after mastectomy & DIEP flap reconstruction (open wound defined as wound requiring a dressing />1 cm Secondary Endpoints • Presence of an open breast wound at 8 and 12 weeks after mastectomy & DIEP flap reconstruction • Relationship between pre- and intra-operative factors and likelihood of open wound at 4 weeks • DIEP flap loss rate • Difference in volume and symmetry between the reconstructed and non-reconstructed breast using 3-D-surface imaging at 3 months and 12 months after surgery • Patient satisfaction (as measured using the BREAST-Q reconstruction module) before, 3 months after, and 12 months after surgery • Difference in breast compressibility between the reconstructed and non-reconstructed breast using applanation tonometry at 3 months and 12 months following surgery. Number of patients = 20 total to be accrued over 18 to 24 months.

Results: This trial has been actively recruiting since January 2016, and is listed on ClinicalTrials.gov Identifier number: NCT02771938

Conclusions: The surgeons and clinical oncologists from Imperial College and the Royal Marsden have begun to develop a limited experience of mastectomy and DIEP reconstruction 14 days following completion of RT (20 cases, no significant post-operative complications). This non-randomised phase II study sets out to formally evaluate the safety of reversing the order of mastectomy plus immediate DIEP flap reconstruction and adjuvant RT, with a view to a subsequent randomised controlled trial testing local control and cosmetic outcomes.

256939 - Testing the ability of pembrolizumab to alter the tumor immune microenvironment of high-risk DCIS

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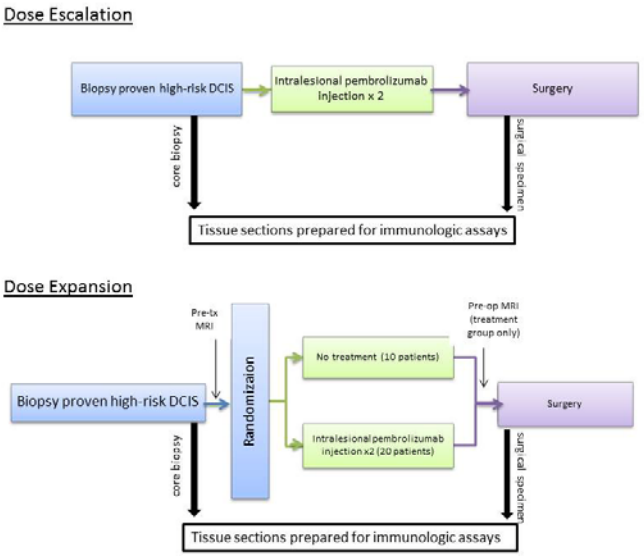
Background/Objective: Ductal carcinoma in situ (DCIS) of the breast represents a heterogeneous collection of lesions. The risk for invasive breast cancer varies, as does the type of cancer that develops (estrogen receptor positive, triple-negative, or HER2-positive cancer). We have previously shown that high-risk DCIS (large size, high grade with comedo necrosis, palpability, HER2 positivity, and hormone receptor negativity) are characterized by a high proportion of macrophages and inactivated T cells, an environment that today may be reversible. Thus, these DCIS may provide an opportunity to prevent cancer. The focus of this trial is to see if the tumor immune environment can be changed with short-term local exposure to an immunomodulating agent, pembrolizumab, a monoclonal antibody that blocks the interaction between PD-1 and its ligands. PD-1 receptor and ligand interactions are a pathway that tumors use to suppress immune control. This trial uses surgical excision to learn whether there is evidence of an immune response. If this is observed, a trial could be designed to use this approach as a means of preventing progression of high-risk DCIS.

Methods: Subjects will need biopsy-proven DCIS with at least 2 high-risk features – high grade (grade 2 or 3), palpable mass, HER2 positive, estrogen receptor negative, young age (< 45 years old), large size (>5 cm) – to be eligible. This study comprises intralesional administration of pembroluzimab, starting with dose escalation in 3 cohorts (2 mg, 4 mg, and 8 mg). A dose-expansion cohort will be conducted at the maximum tolerated dose. In the dose escalation phase, 3 subjects will be enrolled into each cohort unless a dose-limiting toxicity is observed. Eligible subjects will be offered 2 doses of pembrolizumab injected intralesionally 3 weeks apart followed by surgery as determined by the subject and surgeon 3 weeks after the second dose. The dose-expansion cohort will have target accrual of 30 subjects, randomized to either the control group or treatment group. Ten subjects, randomized to the control group, will proceed to surgery alone. Twenty subjects, randomized to the treatment group, will receive 2 doses of pembrolizumab 3 weeks apart followed by surgery 3 weeks after the seconnd dose. All subjects in the dose-expansion cohort will have a baseline MRI, and the treatment group will have a second pre-operative MRI. Tissue from the core biopsy and surgical specimen will undergo immunologic assays to characterize changes in the immune environment. The primary objectives of the dose-escalation phase are to determine the maximum tolerated dose for the expansion cohort and to define the dose-limiting toxicities, tolerability, and feasibility of intralesionally administered pembolizumab. The primary objectives of the dose-expansion phase are to determine the response rate to intralesional pembrolizumab as measured by an increase in intralesional CD8+ T cells (baseline versus post treatment) compared to the control group. Exploratory objectives include characterizing changes in the immune environment of DCIS and to determine whether changes are seen in tumor volume on MRI imaging following intralesional pembrolizumab. We are targeting accrual of 9-18 subjects in the dose-escalation cohorts and 30 subjects for the dose-expansion cohort for a total of 39 – 48 subjects. We hope to meet our accrual goals within 24 months of opening. This trial is scheduled to open at University of California, San Francisco on December 1, 2016.

Results: N/A

Conclusions: N/A



High-risk DCIS pembrolizumab trial schema

Complications

257167 - The impact of obesity on outcomes for patients undergoing mastectomy using the ACS-NSQIP dataset

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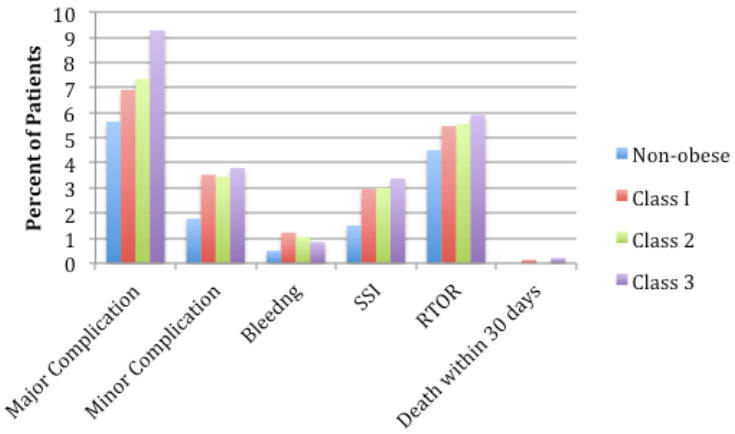
Background/Objective: According to the World Health Organization, 34.7% of females in the United States are obese (BMI ≥ 30), compared to 32.5% in 2010. As patients become more obese, it is important to better characterize how surgical outcomes change with increasing BMI. Previous research has demonstrated high BMI as an independent risk factor for surgical complications after breast surgery. We sought to examine whether increasing obesity had an effect on outcomes of women who received a unilateral mastectomy without breast reconstruction.

Methods: The study reviewed the 2007-2012 ACS-NSQIP database and identified all patients who underwent a unilateral mastectomy without reconstruction. Patients were then categorized and compared according to the World Health Organization obesity classification. Data were analyzed for surgical complications, minor complications (e.g., UTI and SSI), and major complications (e.g., renal failure, sepsis, deep vein thrombosis, return to operating room [RTOR], cardiac arrest).

Results: A total of 7207 women were identified. The median BMI was 27.3 kg/m2. Thirty-five percent were normal weight, and 29.7% had a BMI 25-29.9. Thirty-four percent of patients were obese (BMI > 30 kg/m2), of which 1390 (19%) were Class I (BMI = 30–34.9 kg/m2), 667 (19%) were Class II (BMI = 35–39.9 kg/m2), and 474 (6.5%) were Class III (BMI > 40 kg/m2). From the cohort, 453 patients (6.29%) had a major complication, and 173 patients (2.40%) had a minor complication. Fifty-three (0.74%) had bleeding complications, 148 (2.05%) had a surgical site infection (SSI), 352 (4.88%) RTOR, and 7 (0.01%) died within 30 days. Major complications ($p=0.005$) and minor complications ($p < 0.001$) significantly increased as BMI increased. Surgical sight infections and RTOR had increasing trends, but were not statistically significant.

Conclusions: This study characterizes the risk of postoperative complications in women receiving unilateral mastectomies and shows that increasing obesity class is associated with major and minor postoperative complications. Our finding highlights the need for careful preoperative risk assessment and counseling of obese patients.



Percent of patients with complications after mastectomy based on BMI

219647 - Does the indication for breast surgery impact surgical outcomes? A contemporary analysis of the ACS-NSQIP database

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Background/Objective: There is limited data about whether perioperative outcomes differ based on the indication for breast surgery. Herein we aim to assess if breast surgery for prophylaxis, compared to that for malignancy, impacts surgical outcomes.

Methods: All women who underwent simple or subcutaneous mastectomy were identified from the 2007-2012 ACS-NSQIP database. Patients were identified by their ICD-9 codes and categorized into 2 groups. Group 1 consisted of patients diagnosed with breast cancer or carcinoma in situ; group 2 consisted of patients diagnosed with a genetic predisposition to malignant neoplasm of the breast (i.e., BRCA mutation). Demographic and preoperative variables were compared between groups and outcome variables. Outcome variables were analyzed using age- and operative time-adjusted logistic regression models.

Results: There were 30,803 patients identified. Group 1 consisted of 30,644 (99.5%) patients diagnosed with malignancy; group 2 consisted of 159 (0.5%) who underwent prophylactic surgery. Those undergoing prophylactic surgery were significantly younger and white ($p < 0.01$). When adjusted for age and operative time, the prophylactic group demonstrated a greater risk of DVT ($p = 0.03$). There were no differences in mortality, superficial/deep/organ space infections, UTI, wound dehiscence, or MI.

Conclusions: In this analysis of a national cohort of breast surgery patients, those undergoing prophylactic surgery due to a genetic predisposition had a greater likelihood of developing a postoperative DVT. This contradictory finding should be used to properly educate and manage those undergoing prophylactic surgery. Further work into the pathogenesis of the current finding is indicated.

256731 - Bilateral mastectomy without reconstruction is not associated with increased surgical complications

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Background/Objective: There has been a recent increase in breast cancer patients choosing contralateral prophylactic mastectomy (CPM) concurrently with a total mastectomy (TM). Surgical complication rates are reported to be increased when a bilateral mastectomy (BM) is performed compared to a unilateral mastectomy (UM), particularly with immediate reconstruction. The purpose of this study is to determine if patients undergoing a BM by 2 attending surgeons experience a higher surgical complication rate than patients undergoing a UM by single surgeon, if no reconstruction is performed.

Methods: A retrospective review of the case logs of 6 dedicated breast surgeons at a single institution was performed to identify patients who underwent a UM by single surgeon or BM by 2 surgeons without reconstruction. Demographic and clinicopathologic information, operative details, and surgical complications were recorded. Complications included: hematomas requiring reoperation, infections requiring antibiotics or incision and drainage (I&D), seromas requiring ≥ 1 aspiration or drain re-insertion, skin ischemia (excoriations or blisters treated conservatively) or necrosis (full-thickness, resulting in eschar formation requiring debridement). Statistical analysis was performed using SPSS to calculate chi-square and one-way ANOVA. A p-value of < 0.05 was considered statistically significant.

Results: Of 546 patients treated with TM, 205 (38%) had BM and 341 (63%) UM. The median follow-up was 14 months. Age, BMI, and bra cup size between the 2 groups were not significantly different ($p > 0.05$). Three hundred fifty-six (65%) patients had diagnosis of invasive ductal carcinoma. Fifty-four (27%) and 96 (28%) patients in BM and UM groups were treated with neoadjuvant chemotherapy. In the BM group, 138 (79%) underwent CPM. In the UM group, 6 (2%) underwent prophylactic UM after treatment of contralateral breast cancer previously. More patients in BM group underwent axillary lymph node dissection: 61 (30%) in BM and 62 (18%) in UM ($p= < 0.01$). There were no statistical differences in complications between the 2 groups ($p > 0.05$). The most common complication was infection occurring in 34 (17%) and 45 (13%) patients in BM and UM, which required antibiotic treatment or I&D. Hematoma occurred in 10 (5%) and 22 (7%) patients in BM and UM. All of the patients with hematoma required reoperation except for 1, treated conservatively. Seroma occurred in 20 (10%) and 31 (9%) patients in BM and UM. Skin ischemia developed in 8 (4%) and 8 (2%) in BM and UM. Skin necrosis occurred in 7 (3%) and 8 (2%) in each group. Overall, 9 (4%) and 24 (7%) patients in BM and UM groups required reoperation. The average operative time was 86+32 and 87+31 minutes in BM and UM, respectively. Ninety-nine percent of patients had intraoperative blood loss < 50 ml.

Conclusions: The surgical complication rate for patients undergoing 2-surgeon BM is similar to those who have a UM if done without immediate reconstruction. Our results are different than data reported in NSQIP with a 2-fold increase in complications for BM vs UM. Although CPM is not routinely recommended for patients who will not derive a significant benefit from the procedure, for patients electing BM, 2-surgeon surgery may improve operative outcomes.

	Bilateral Mastectomy	Unilateral Mastectomy	P-value
N =546	205	341	
AGE in years mean±SD (range)	63.5±13.5 (21-100)	61.5±13.3 (25-95)	0.10
BODY MASS INDEX mean±SD (range)	29.4±7.1 (17-56)	28.8±6.8 (16-53)	0.32
OPERATING TIME in minutes mean±SD (range)	86.3±31.7 (20-215)	87.1±31.4 (25-211)	0.77
BRA SIZE			0.42
≤A	16 (8.9%)	26 (8.9%)	
B	58 (32.4%)	86 (29.4%)	
C	48 (26.8%)	94 (32.1%)	
D	31 (17.3%)	53 (18.1%)	
>D	24 (13.4%)	34 (11.6%)	
HISTOLOGY			0.47
Invasive ductal carcinoma	129 (64.8%)	227 (66.8%)	
Invasive lobular carcinoma	31 (15.6%)	45 (13.2%)	
Ductal carcinoma in-situ	27 (13.6%)	39 (11.5%)	
Other	12 (6.0%)	28 (8.2%)	
GENETIC TESTING			0.48
Not indicated	155 (76.7%)	225 (74.0%)	
Positive	19 (9.4%)	25 (8.2%)	
Negative	28 (13.9%)	54 (17.8%)	
NEOADJUVANT CHEMOTHERAPY	54 (26.6%)	96 (28.3%)	0.67
PROPHYLACTIC SURGERY	138 (68.7%)	6 (1.7%)	<0.01
AXILLARY SURGERY			<0.01
No axillary staging	25 (12.4%)	59 (17.2%)	
Sentinel lymph node biopsy	116 (57.4%)	222 (64.7%)	
Axillary lymph nodes dissection	61 (30.2%)	62 (18.1%)	
COMPLICATIONS			
Reoperation	9 (4.4%)	24 (7.0%)	0.21
Hematoma	10 (4.9%)	22 (6.5%)	0.45
Infection	34 (16.6%)	45 (13.2%)	0.28
Seroma	20 (9.8%)	31 (9.1%)	0.79
Skin ischemia	8 (3.9%)	8 (2.3%)	0.30
Skin necrosis	7 (3.4%)	8 (2.3%)	0.46
ESTIMATED BLOOD LOSS			0.31
≤50 ml	202 (99.0%)	337 (98.8%)	
>50 ml	1 (0.5%)	4 (1.2%)	
FOLLOW UP in months mean±SD (range)	21.3±18.6 (1-73)	23.5±18.6 (1-74)	

257159 - Post–operative complications in combined gynecologic and breast surgery: An analysis from NSQIP

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Background/Objective: Previous studies have identified no difference in complication rates in breast cancer or high-risk patients who undergo coordinated gynecologic surgery at the time of their breast surgery. Recent literature has however highlighted both the increased operative complication rates for patients undergoing the addition of a contralateral prophylactic mastectomy and the survival detriments for delays in initiating adjuvant therapy in the cancer population. We therefore sought to examine in a modern national surgical dataset, the outcomes after breast and gynecological surgery alone and those operations performed simultaneously to determine the impact of the additional surgical procedures on perioperative complications.

Methods: We utilized the National Surgery Quality Improvement Program (NSQIP) database to identify patients who underwent breast surgery between 2011-2015. Patients without axillary surgery were excluded to identify those with primary breast cancer. We also extracted patients who underwent prophylactic oophorectomy with or without hysterectomy as a comparison group. Descriptive statistics were performed for patient comorbidity, operative time, and length of stay by procedure type. Chi square analysis was used to assess outcomes including complications, readmission, reoperation, and discharge to higher level of care. Independent t tests were utilized to assess continuous variables. All statistics were performed in SPSS v. 24.

Results: We identified 77,030 patients who underwent breast surgery during the study timeframe and a second cohort of 124 patients who underwent prophylactic oophorectomy alone or in combination with a hysterectomy. Patients who underwent breast surgery alone were found to be older and to have more comorbid conditions. More than 40% of patients who underwent breast surgery alone were > 65 years of age compared with < 1% of patients who underwent a simultaneous gynecologic procedure ($p < 0.001$). Patients who underwent simultaneous gynecologic procedures were found to have significantly longer length of stay, higher complication rates, readmission, and reoperation rates ($p < 0.001$ for all) as compared with patients who underwent breast surgery alone (Table). The addition of any operative procedure to the breast surgery, either gynecologic or plastic reconstructive, resulted in significantly higher complication rates but were equivalent to gynecologic surgery alone ($p=0.897$) Total length of stay, defined as length of stay during initial operation plus length of stay of any readmissions, was also significantly longer in patients who underwent any coordinated operations ($p < 0.001$).

Conclusions: We found that healthier patients were more likely to undergo coordinated gynecologic and breast/reconstructive surgery. However, patients who underwent gynecologic surgery at the time of partial or complete mastectomy for breast cancer were found to have worse post-operative outcomes which were similar to the outcomes for solitary gynecologic procedures. Limitations of this study are lack of certainty for the gynecologic diagnoses and a small cohort size of combined procedures. Higher complication rates in breast cancer patients who have coordinated operations may lead to delays in adjuvant therapy and discussions regarding the need for the combined approach are recommended.

	All Patients N = 77,030	Breast N= 55,765	Gyn alone N = 124	Breast + Plastics N=21,055	Breast + Gyn N = 136	Breast + Plastics + Gyn N = 75	P value
Operative Time (avg)	141.0 min	103.15 min	106.45	127.9 min	240.7 min	349.0 min	<0.001
Length of Stay (avg)	1.07 days	0.77 days	1.27 days	1.84 days	1.76 days	2.34 days	<0.001
Total LOS (avg)	1.65 days	1.28 days	1.46 days	2.61 days	3.10 days	3.28 days	<0.001
Complication	3,781 (4.9)	2,331 (4.2)	9 (7.3)	1,434 (6.8)	9 (6.7)	7 (9.5)	<0.001
DC to Higher Level of Care	583 (0.8)	487 (0.9)	1 (0.8)	95 (0.5)	1 (0.7)	0 (0)	<0.001
Readmission	2,698 (3.5)	1,768 (3.2)	3 (2.4)	915 (4.3)	10 (7.4)	5 (6.8)	<0.001
Reoperation	3,154 (4.1)	1,579 (2.8)	3 (2.4)	1,566 (7.4)	5 (3.7)	4 (5.4)	<0.001
Mortality	61 (0.1)	57 (0.1)	0 (0)	4 (0)	0 (0)	0 (0)	0.008

Post-operative outcomes across procedure types

257370 - Impact of patient and operative factors on 30-day revisits following outpatient mastectomy

Jennifer Yu, Margaret Olsen, Amy Cyr, Julie Margenthaler
Washington University School of Medicine, St. Louis, MO

Background/Objective: Improvements in perioperative care and communication have increasingly shifted breast cancer surgery into the outpatient setting. Despite this trend, most women who undergo mastectomy are still admitted as inpatients, and little data exist characterizing outcomes following outpatient mastectomy. We sought to analyze patient and operative factors associated with 30-day revisits following outpatient mastectomy in women with breast cancer.

Methods: We used the Healthcare Cost and Utilization Project State Ambulatory Surgery Database from 2006-2013 to create a cohort of women aged 18 and older who underwent outpatient mastectomy for invasive breast cancer, breast cancer in situ, or history of breast cancer. Descriptive statistics and logistic regression were used to analyze associations between clinical factors, defined by ICD-9-CM and CPT codes and the Elixhauser comorbidity classification, and 30-day revisits.

Results: Of 3,944 women with outpatient mastectomy, 694 (18%) had an inpatient or outpatient encounter within 30 days postoperatively. Mean age was 56.8±13.3 years. Ninety-four percent (650/694) had undergone unilateral mastectomy, with the majority either simple (344, 53%) or modified radical mastectomy (295, 45%). The most frequent complications requiring revisit were surgical site infection (64, 9%), hematoma (40, 6%), and seroma (23, 3%), and the majority of revisits were ambulatory surgery or observation stays (434, 63%). Multivariable logistic regression demonstrated significantly increased odds of 30-day revisit with any reconstruction (OR 1.25, 95% CI 1.05-1.5), diabetes (OR 1.64, 95% CI 1.21-2.21), and regional disease (OR 1.64, 95% CI 1.22-2.18). No significant differences were found in odds of 30-day revisit for race, unilateral vs. bilateral procedures, or other comorbidities.

Conclusions: All-cause revisits within 30 days following outpatient mastectomy are infrequently related to surgical complications. Women undergoing outpatient mastectomy were younger with relatively few comorbidities. Analysis of outpatient interventions and unscheduled visits may provide additional information regarding management trends for complications after mastectomy.

LRR

256775 - Rates and timing of local-regional recurrence in young women with breast cancer in the modern era

Cory Donovan, Lerna Ozcan, Farin Amersi, Xiao Zhang, Armando Giuliano, Alice Chung
Cedars-Sinai Medical Center, Los Angeles, CA

Background/Objective: Historically, women under the age of 40 have had high rates of local recurrence following breast-conserving surgery (BCS). This may influence young women to choose mastectomy over BCS for early-stage breast cancer. Adjuvant treatment has improved significantly, but contemporary rates of local-regional recurrence (LRR) in this age group are not well characterized.

Methods: A prospectively maintained database for a single institution was reviewed for all women age ≤ 40 who underwent an operation for unilateral stage I-III breast cancer between 2000-2013. Rates of LRR were compared between patients who underwent BCS and mastectomy. Multivariable analysis was performed to evaluate factors influencing LRR rates.

Results: Data for 446 patients were analyzed. Mean patient age was 35 years (range 20-40). One hundred eighty-four patients had BCS, and 262 had mastectomy. Median follow-up was 79 months (m) (range 5-194). Sixty-four (14%) patients had identified genetic mutations. One hundred and four (23%) patients had triple-negative (TN) tumors, 99 (22%) tumors were HER2+, and 243 (45%) tumors were hormone receptor positive (ER/PR+) and HER2-. Three hundred twenty-seven (73%) patients underwent chemotherapy, 81 of 262 patients (33%) had post-mastectomy radiation, and 183 of 309 (59%) of ER+ patients had documented hormone therapy use. On analysis, 32 patients (7%) were found to have LRR. There was no difference in LRR rate between patients who underwent BCS and mastectomy (p=0.84, Table). Twelve patients (3%) had a nodal recurrence. Twenty-three (5%) patients had chest-wall or ipsilateral in-breast recurrence, of which 10 (5%) were noted in BCS patients and 14 (5%) in mastectomy patients. Three patients (< 1%) had both nodal and ipsilateral breast or chest-wall recurrence. Patients with TN tumors did not have a higher risk of LRR when compared to patients with hormone receptor positive tumors and patients with HER2+ tumors (p=0.54). The mean time to LRR in patients with TN tumors was 14 months (range 5-20). HER2+ tumors recurred local-regionally at a mean time of 20 months (range 5-35). Patients with ER+ tumors, however, had a mean time to LRR of 51 months (3-144). On multivariable analysis, hormone receptor status, presence of a genetic mutation, surgery type, histology, hormone therapy, chemotherapy, and radiation therapy were not associated with increased LRR rates. Lymph node positivity was the only positive predictor of LRR (p=0.05).

Conclusions: In this era, young patients who undergo BCS have similar LRR rates to patients who undergo mastectomy. Triple-negative and HER2+ tumors were found to recur within 2 years of diagnosis, while for ER+ tumors, the risk of local recurrence continues more than a decade after diagnosis.

	BCS		Mastectomy		Chi-Square p=value
	N=184	%	N=262	%	
Local chest wall and in breast Recurrence	9	5%	14	5%	1.00
Regional Nodal Recurrence	2	1%	5	3%	P=0.70
Distant Recurrence	21	11%	31	12%	1.00
Average Follow-up (m)	93		73		P<0.001
Average Tumor Size (mm)	22		27		P=0.01
LN Positive	63	34%	115	44%	P=0.53
ER +	135	73%	174	66%	P=0.12
TN	39	21%	64	24%	P=0.49
Her2+	40	22%	59	23%	P=0.91
Genetic Mutation +	13	7%	47	18%	P<0.001
Stage 1	76	41%	90	35%	P=0.13
Stage 2	90	49%	116	44%	P=0.34
Stage 3	15	8%	50	19%	P=0.002
Neoadjuvant Chemotherapy	13	7%	61	23%	P<0.001
Chemotherapy	123	67%	204	78%	P=0.01
Hormonal Therapy	74	40%	121	46%	P=0.25
Radiation	164	89%	87	33%	P<0.001

Local and regional recurrence rates, patient and tumor characteristics for women under the age of 40 who underwent BCS (Breast Conserving Surgery) compared to women who underwent Mastectomy.

Breast-conserving surgery vs. mastectomy in patients age 40 and younger

257006 - Locoregional recurrence rates among HER2neu-positive patients from 2003-2016: A retrospective review with 8 years of follow-up

Grace Hendrickson, Catherine Pesce, Gaurav Ajmani, Elizabeth Gray, Ermilo Barrera, David J. Winchester, Katharine Yao
NorthShore University HealthSystem, Evanston, IL

Background/Objective: In 2004, treatment with Herceptin (trastuzumab) became the standard of care for patients with human epidermal growth factor receptor 2 (HER2)-positive breast cancer, and several randomized trials have demonstrated improved overall survival for those patients who receive Herceptin compared to those who do not receive Herceptin. However, few studies have examined locoregional recurrence (LRR) rates among HER2-positive patients and how these rates vary by patient and tumor factors and surgery type.

Methods: Using an institutional database, the authors identified 312 female HER2-positive breast cancer patients who were diagnosed and treated between 2003 and 2016. LRR rates were reported for 3 cohorts: those undergoing neoadjuvant Herceptin, adjuvant Herceptin, or no Herceptin. For those patients who received adjuvant Herceptin, we examined LRR stratified by age, race, hormone receptor status, stage of disease, nodal status, surgery type, radiation given, and chemotherapy and hormone therapy given. Using chi-squared analysis, we compared these subgroup LRR rates between those patients who received adjuvant Herceptin and those patients who did not receive adjuvant Herceptin.

Results: Of 312 patients, 44 (14.1%) underwent neoadjuvant Herceptin, 146 (46.8%) underwent adjuvant Herceptin, and 122 (39.1%) did not receive Herceptin. Among the 44 patients who received neoadjuvant Herceptin, 5 (11.4%) experienced LRR with a median follow up of 4.8 years. Of 146 patients who underwent adjuvant Herceptin, LRR occurred in 10 patients (6.8%) versus 15 (12.3%) of the 122 patients who did not receive Herceptin at 8 years of median follow up (Table). LRR occurred in the breast, specifically, within 70% of the 10 patients who received adjuvant Herceptin and in 73% of the 15 patients who did not receive Herceptin. LRR rates between those receiving adjuvant Herceptin and those not receiving Herceptin were significantly different between patients < 54 years old and for stage I patients but were not significantly different by patient race, surgery type, nodal status, tumor stage, hormone receptor positivity, radiation, chemotherapy, or hormone therapy. LRR rates for those under 54 years old were 4% in the Herceptin group compared to 18% in the no Herceptin group ($p < 0.05$) and 0% and 13% respectively for stage I patients ($p < 0.05$). LRR rates for those receiving adjuvant Herceptin were 6% for those undergoing lumpectomy versus 8% for those undergoing mastectomy ($p > 0.05$), 5% for node negative patients versus 8% for node positive patients ($p > 0.05$), and 13% for hormone receptor negative patients versus 3% for hormone receptor positive patients ($p < 0.05$) (Table).

Conclusions: LRR rates were higher in the no Herceptin group compared to the adjuvant Herceptin group. LRR rates were approximately 10% or less among all subgroups that received adjuvant Herceptin and only varied significantly by hormone receptor.

Characteristic	# of Patients (No Herceptin)	LRR % (No Herceptin)	# of Patients (Adjuvant Herceptin)	LRR % (Adjuvant Herceptin)	p Value (Chi-Squared Test)
	15	12.3	10	6.8	0.127
Age					
<54	50	18	74	4	0.01
>54	72	8	72	10	0.77
p		0.11		0.18	
Race					
Nonwhite	13	0	22	0	NA
White	109	14	124	8	0.16
p		0.15		0.17	
Surgery					
Lumpectomy	78	10	81	6	0.35
Mastectomy	40	17	63	8	0.14
p		0.26		0.68	
Lymph Node +					
No	79	14	62	5	0.07
Yes	43	9	84	8	0.85
p		0.46		0.41	
Radiation Therapy					
No	44	14	43	5	0.15
Yes	74	11	100	8	0.53
p		0.65		0.47	
Hormone Receptor					
HR-	58	16	54	13	0.70
HR+	64	9	92	3	0.11
p		0.30		0.03	
Pathological Stage					
I	70	13	46	0	0.01
II	29	10	54	9	0.87
III	7	14	25	4	0.32
p		0.93		0.10	
Other Chemotherapy					
None	69	10	10	0	0.29
Adjuvant	45	16	136	7	0.10
p		0.93		0.10	
Hormone Therapy					
No	65	14	56	14	0.94
Yes	51	10	84	2	0.06
p		0.93		0.10	

LRR in patients that received no Herceptin versus patients that received adjuvant Herceptin

245105 - Do size and nodal stage affect time to recurrence?

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Background/Objective: Time to recurrence of breast cancer is important for determining need for extended hormonal therapy, appropriate follow-up time for clinical trials, and for prioritizing patient survivorship and aftercare concerns. Larger tumor size (T size) and greater number of positive nodes are associated with greater likelihood of breast cancer recurrence, but it is not clear whether these are also associated with shorter time to recurrence. This study examined the effect of clinicopathologic factors on time to recurrence.

Methods: From a database of breast cancer recurrences at one institution from 2000-2016, patients were selected with invasive breast cancer and local, regional, or distant recurrence. Exclusion criteria were male sex, stage IV disease at presentation, or ≤6 months from diagnosis to recurrence. We examined the relationship between initial ER, PR, HER2, T size, node status, grade, and stage and time to recurrence.

Results: Two hundred thirty-five patients were included. ER 0% (vs. ER 81-100%), PR 0% (vs. PR 1-100%), Grade III vs. (Grade I-II), and T size >4cm (vs. T size 2.1-4cm) were associated with shorter time to recurrence (Table). Number of positive nodes, stage, and HER2 status did not exhibit a relationship with time to recurrence. Whereas ER and PR levels exhibited stepwise relationships with time to recurrence, this pattern was not evident with T size or node status (Table). Node status (N0-2 vs. N3) was further examined within strata defined by ER and PR level to evaluate for confounding by hormone receptor status. In ER or PR positive tumors, N3 disease was not associated with shorter time to recurrence. However, for ER negative tumors, N3 disease was associated with shorter time to recurrence, compared to N0-2 disease (0.92 years vs 2.28 years). Similarly, for PR negative tumors, the time to recurrence was shorter for those with N3 disease, compared to N0-2 disease (1.5 vs. 2.6 years). For these analyses, the number of cases with N3 disease was too small to determine statistical significance.

Conclusions: The study demonstrates that tumor size and ER and PR negativity were associated with shorter time to recurrence. However, node status in ER/PR positive disease was not associated with shorter time to recurrence. This is important as it emphasizes the importance of tumor biology over anatomy and the decreasing clinical usefulness of the current staging system in determining prognosis.

	Number of Cases	Mean TTR (95% CI) (y)
ER staining		
0%	75	2.2 (1.9 - 2.6) [1]
1-20%	22	3.3 (2.4 - 4.2)
21-80%	44	3.8 (3.0 - 4.5)
81-100%	94	4.3 (3.7 - 4.8) [1]
PR staining		
0%	107	2.5 (2.2 - 2.8) [1]
1-100%	128	4.2 (3.8 - 4.7) [1]
HER2		
negative	188	3.5 (3.1 - 3.8)
positive	38	3.0 (2.3 - 3.7)
Grade		
I - II	96	3.8 (3.3 - 4.3) [1]
III	103	2.8 (2.4 - 3.1) [1]
Tumor size (cm)		
0-0.5	18	3.1[2]
0.6-1.0	13	3.8[2]
1.1-2.0	63	3.5 (2.9 - 4.0)
2.1-4.0	89	3.9 (3.3 - 4.4) [1]
>4	37	2.5 (1.9 - 3.2) [1]
Number positive nodes		
0	74	3.5 (3.0 - 4.0)
1-3	68	3.7 (3.1 - 4.4)
4-9	50	3.3 (2.7 - 4.0)
>9	22	2.4 (1.6 - 3.3)
TNM stage		
I	47	3.7 (3.1 - 4.4)
II	75	3.3 (2.8 - 3.8)
III	78	3.2 (2.6 - 3.7)

[1]statistically significant comparisons: ER 0% vs. ER 81-100%; PR 0% vs. PR 1-100%; Grade III vs. Grade I-II; T size 2.1 – 4.0 vs. T size > 4

[2]Too few cases to compute 95% CI

Time to recurrence

Lymphedema

248787 - Prospective evaluation of patients with axillary web syndrome after breast cancer surgery: Epidemiology, risk factors, and clinical aspects

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Background/Objective: Axillary web syndrome (AWS) is a common complication after breast cancer surgery with axillary approach, characterized by the presence of axillary cord, pain, and reduced range of motion (ROM). The main objective of this study is to describe cord frequency, characteristics, and risk factors.

Methods: This was a prospective cohort study of 173 women performed at the Breast Diseases division of a university in São Paulo between July 2014 and September 2015. The data concerning socio-demographic status, anthropometric values, ROM, comorbidities, pain, cord frequency, and characteristics (localization, number, thickness, if palpable and/or visible) in preoperative and 7, 15, 30, 60, 90, and 180 days after surgery were collected.

Results: Most cords appeared on the seventh post-operative day (66.1%) with a total incidence of 90.9% at the final evaluation (180 days). More than 70% of the cords occurred were palpable, and 80% occur only in the axilla in any evaluation time. A correlation was observed between cord occurrence and reduced flexion and abduction shoulder ROM ($p < 0.001$ and $p < 0.001$, respectively). Hypertension ($p=0.003$) and axillary lymphadenectomy ($p=0.029$) increased the risk of developing cords. Diabetes decreased the risk to less than 30% ($p=0.022$).

Conclusions: The first week after breast cancer surgery showed more frequent presence of AWS. The cords were palpable, thicker, and more frequent in the axilla. Limited shoulder ROM was also associated with the cords. Axillary lymphadenectomy and hypertension were the main risk factors for development the AWS; diabetes lowered the risk. A careful and specific AWS evaluation seen in this study should explain its high incidence. The association and significance of hypertension (positive) and diabetes (negative) with AWS should be evaluated in future researches.

256618 - Bioimpedence spectroscopy for the early detection of lymphedema after surgical axillary nodal staging

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Background/Objective: Lymphedema (LE) develops in up to 68% of women undergoing surgical axillary nodal staging (SANS) for breast cancer, resulting in decreased quality of life. Bioimpedence spectroscopy (BIS) is marketed as a method for early detection of LE, allowing early intervention to minimize its impact. We reviewed the use of BIS in patients undergoing SANS as part of their breast cancer treatment to determine its impact on LE detection.

Methods: All patients undergoing SANS had a baseline BIS prior to surgery with planned repeat testing at 1, 3, 6, 9, 12, and 18 months (mo) post-op. Any BIS increase of 10 or more (BIS+10) was considered to

indicate at least subclinical LE. Clinical (C) LE was defined as LE documented by a trained LE therapist by arm measurement (difference of 2 cm or more) or other volumetric measures. Each patient was also evaluated for subjective (S) LE by visual assessment of arm size and symptom review at each time point. Any patient with either BIS+10 or SLE was referred to a LE therapist for further evaluation, education, and treatment. Included patients had baseline BIS and at least one post-op BIS, and had at least 6 months' follow-up. Data collected included age, menopausal status, BMI, type of breast and nodal surgery, breast or nodal radiation, chemotherapy, pathologic findings, staging, BIS measures, SLE, and CLE. Associations were determined by univariate and multivariate analyses.

Results: One hundred and two patients met inclusion criteria. The average age was 60 (range 22-87). Mean follow up was 14 months (range 6-23). CLE developed in 11.7% of all patients undergoing SANS (SN 6.8%, AD 42.8%). Patients with and without CLE are compared in the table. Demographics were similar between those with and without CLE. The extent of nodal surgery, extent of nodal disease, LVI, BIS+10, and SLE were independent predictors of CLE. The time to BIS+10 and time to SLE were not significantly different (p=0.26). Of the 102 patients, 88 had sentinel node biopsy (SN) (86.3%), and 14 had axillary dissection (AD) (13.7%). BIS+10 was seen in 18 (17.6%) patients, (SN 10.2%, AD 64.3%). There were 66.7% of BIS+10 patients who had SLE, and 55.6% had CLE. Of the 6 patients with BIS+10 but no SLE, CLE was confirmed in 1 (16.7%). There were 44.4% of BIS+10 patients who did not have CLE. In 3 patients without BIS+10 or SLE, CLE was documented during the acute postoperative period when patient was referred for therapy for range of motion to facilitate radiation therapy, and subsequent BIS measures were not elevated.

Conclusions: BIS+10 is an independent predictor of CLE, making it a useful a tool for office assessment. Forty-four percent of the patients with BIS+10 never developed CLE during the observed time, suggesting that BIS testing, leading to further evaluation and education on LE precautions, may have prevented CLE in these patients. Cases with documented CLE without BIS+10 all had arm measurements done in the acute postoperative period, and none had subsequent problems with CLE or BIS+10, suggesting that documented increase in arm measurements during the postoperative period does not predict persistent problems with CLE. The lack of time differential between BIS+10 and the detection of SLE suggests that in many cases, it does not detect LE earlier than careful questioning and arm evaluation, although there is a significant detection bias as the BIS measures and SLE assessments were being done by the same provider at the same visit. BIS is an effective tool for office assessment of LE and may help prevent this complication by identifying patients most at risk.

TABLE 1		CLE	No CLE	Univariate	Multivariate
		Mean (Range) or %	Mean (Range) or %	Pvalue	Pvalue
		n=12	n=90		
Demographics	Age	61 (43-81)	60 (22-87)	NS	
	BMI>30	58.3%	33.3%	0.09	NS
	Postmenopausal	66.7%	75.6%	NS	
	FU Length (months)	14 (7-19)	14 (6/23)	NS	
Surgery	Breast Conserving Surgery	66.7%	60.0%	NS	
	Sentinel node Biopsy	50.0%	91.1%	<0.0001	
	Axillary Dissection	50.0%	8.9%	<0.0001	0.008
Other Therapies	Chemotherapy	58.3%	30.0%	0.05	NS
	Breast/Chest Wall Radiation	83.3%	73.3%	NS	
	Regional Nodal Radiation	33.3%	16.7%	NS	
	Neoadjuvant Systemic Therapy	8.3%	8.9%	NS	
Pathology	Tsize	40 (11-120)	24.4 (0-116)	0.02	NS
	# nodes removed	13.5 (1-31)	3.4 (1-22)	<0.0001	0.001
	#positive nodes	3 (0-12)	0.3 (0-8)	<0.0001	0.001
	Extranodal extension	100.0%	33.3%	0.01	NS
	Lymphovascular invasion	50.0%	13.3%	0.002	0.018
Pathologic staging	T0	0.0%	1.1%	NS	
	Tis	8.3%	10.0%		
	T1	41.7%	55.6%		
	T2	41.7%	27.8%		
	T3	8.3%	5.6%		
	N0	58.3%	84.4%	0.0009	NS
	N1	16.7%	14.4%		
	N2	8.3%	1.1%		
	N3	16.7%	0.0%		
	0	8.3%	11.1%	NS	
	1	33.3%	50.0%		
	2	33.3%	32.2%		
	3	25.0%	6.7%		
Lymphedema Metrics	BIS+10	75.0%	10.0%	<0.0001	<0.0001
	Multiple measures of BIS+10	50.0%	1.3%	<0.0001	0.000
	Time to BIS+10 (months)	4 (1-9)	8 (2-13)	0.014	
	Subjective Lymphedema	75.0%	7.8%	<0.0001	<0.0001
	TIME TO CLE (months)	5 (2-11)	NA	na	

Patients with CLE compared to patients without

Male Breast Cancer

256704 - Male breast cancer: A review of one Saudi institution experience

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Background/Objective: Breast cancer is a rare malignant tumor in males. This study aimed to investigate the clinicopathological characteristics of those patients in the Saudi population.

Methods: A 15-year retrospective review was conducted, including all males diagnosed with breast cancer at a single institution.

Results: Fifty-three cases were identified with a mean age of 58±14 years. The majorities were Saudi 47 (89%), married 48 (91%), and live in the central region of Saudi Arabia 33 (62%). Fifty-one (96.2%) cases presented with a palpable mass, and 2 (3.8%) cases presented with nipple discharge. The majority has IDC 52 (98%). ER was positive in 50 (94%) patients, PR was positive in 43 (81%) patients, and HER-2 was positive in 8 (15%) patients. Regarding the tumor stage, 31 (58.6%) had T4, 14 (26.4%) had T2, 5 (9.4%) had T1, and 3 (5.6%) had T3. Moreover, 39 (73.6%) had intermediate grades, 9 (17%) had high grades, and 5 (9.4%) had low grades. On presentation, 20 (37.7%) cases presented with distant metastases, which were mainly to bone in 9 (45%) cases, and to lung in 8 (40%) cases. Fifty-one (96.2%) received hormonal-therapy, 22 (41%) received chemotherapy, and 22 (45.3%) radiotherapy. Forty-three (81%)

patients underwent surgical intervention; among them, 35 (66%) were therapeutic, and 8 (15%) were palliative. Thirty-four (64%) patients underwent modified radical mastectomy, 8 (15%) underwent simple mastectomy and SLNB, and 1 (1.9%) patient underwent lumpectomy and axillary lymph node dissection. The local recurrence rate was 1.9% with a mean follow-up of 44.1±30.3 months.

Conclusions: Based on our data, in our population, the majority of males with breast cancer have IDC with positive estrogen receptors, and they usually present late.

Margins

257298 - Recurrence rates in triple-negative breast cancer utilizing cavity shave margins

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Background/Objective: Breast-conserving surgery (BCS) requires tumor excision with negative margins. Randomized controlled trials have demonstrated that routine cavity shave margins (CSM) decrease re-excision rates in breast cancer. Triple-negative breast cancer (TNBC) is known to have more aggressive tumor biology and high rates of early local and systemic recurrence. The aim of this study is to identify whether performing routine CSMs in TNBC reduced recurrence rates.
Methods: Three hundred eleven triple-negative breast cancers treated with BCS between 2005-2013 were reviewed. Patients underwent standard partial mastectomy (SPM) or CSM per surgeon practice patterns. Data collected included demographics, pathology, treatments, recurrence, and re-excision rates.

Results: Two hundred twenty-six SPMs were compared to 85 CSMs with a median follow-up of 4.5 years. Analysis between groups revealed no differences in stage, tumor pathology, demographics, or receipt of therapy. Average age at diagnosis was 54, and a majority (n=195, 63%) of patients were African-American or Hispanic. Overall re-excision rate was 20.6%. Most re-excisions (64.1%) were performed for tumor close to a margin (< 2 mm). Patients undergoing CSM were less likely to undergo re-excision (n=13, 15.3% versus n=51, 22.6% for SPM). Overall recurrence rate was 16.7% (n=52). Thirty-seven (16.4%) SPMs recurred versus 15 (17.6%) CSMs (p=0.27). Isolated loco-regional recurrence was equivalent between the 2 groups (p=0.9). The majority of recurrences in both groups were distant recurrences (SPM n=20, 54.1% vs CSM n=9, 60%).

Conclusions: In triple-negative breast cancer patients undergoing BCS, recurrence rates are not impacted by CSM technique.

257112 - Retrospective study of the adequacy of surgical margins post-breast conservation surgery in Manitoba

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Background/Objective: Breast conservation surgery (BCS) is the standard of care for the treatment of early-stage breast cancer. A margin of normal tissue around the cancer is required to ensure complete resection; however, there are currently no studies that confidently define what constitutes an adequate surgical margin. This controversy leads to increased rates of re-excision, and also raises concerns about the value of revision surgery. The objectives in this study are: 1) to identify the rate of re-excision for a positive or close margin in Manitoba after original lumpectomy for invasive or non-invasive breast cancer between 2009 and 2012, and 2) to identify factors that could potentially predict no residual disease found at revision surgery in patients with invasive cancer.

Methods: This retrospective cohort study included patients with invasive or noninvasive breast cancer who underwent a lumpectomy between 2009 and 2012, with a positive or a close (< 2 mm) margin that led to a re-excision. Patients were identified through the Cancer Care Manitoba Cancer Registry. Patient demographics, type of surgery, and tumour pathological details that include staging, receptor status, and surgical margins were identified from the Cancer Registry and operative and pathology reports. Each of the 6 anatomical margins was reported for margin status (focally positive, positive, close, negative, or unknown), as well as margin width (if close), and the pathology type at the margin (invasive or non-invasive). Univariate and multivariate analyses were conducted to determine the relationship of different variables of interest with the status of residual disease at second surgery.
Results: Of the 2,458 patients identified, 539 patients underwent a re-excision due to close or positive margins, resulting in a re-excision rate of 21.9%. Invasive cancer was present in 2,089 patients who underwent lumpectomy, including 410 cases undergoing re-excision. In our cohort, 37.3% of patients with invasive cancer had no residual disease identified on the revision surgery pathology report. On univariate analysis, the size of invasive component, grade of invasive component, nodal stage, and the number of positive margins were related to the status of residual disease at the second surgery (p-values < 0.05). Surprisingly, receptor status, lymphovascular invasion, and location were not found to be related to the presence of residual disease. With the exception of nodal stage, the same variables remained statistically significant on multivariate analysis.

Conclusions: The rate of re-excision in Manitoba for women with close or positive margins following BCS is 21.9%, which is lower than what has been previously reported in the literature for other jurisdictions. On multivariate analysis, size and grade of the invasive component and the number of positive margins are related to residual disease after re-excision. These results suggest an identifiable subgroup of patients who could potentially avoid unnecessary surgery, and could help to dramatically reduce the rates of revision procedures in the future.

257155 - Another issue challenging re-excision rate as a quality measure

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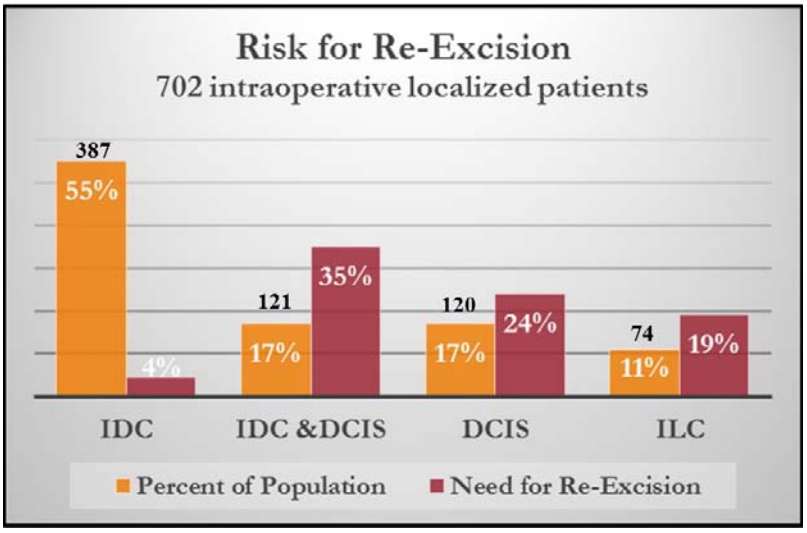
Background/Objective: In the quest of defining quality measures that accurately distinguish quality care, one obvious variable is the wide variety of re-excision rates in breast cancer surgery. Recent guidelines defining the margin width warranting re-excision may decrease the national re-excision rate as may the use of shaved margins at lumpectomy. Yet to embark on using surgical re-excision rate as a standard quality metric, there must be a uniform baseline to which all surgeons can be compared. To find a common baseline, we used a 10-year series of ultrasound-guided breast cancer lumpectomies to examine the consistency of re-excision rates in a single institution.

Methods: We reviewed 1,100 consecutive breast cancer patients seen from 2003 to 2012. Of these, 727 (66%) had intraoperative ultrasound localization (IOL) procedures, and we collected at least 96% (702) of the data points for this review. Our radiologists obtained a core needle biopsy in 96.2% and place an ultrasound visible clip for IOL. Our IOL protocol is typical of other reports, which include ultrasound visualization, guidewire placement, and image confirmation of the excised lesion. Positive margins were defined as tumor on ink most often followed by re-excision or mastectomy.

Results: Patients were on average 63 years old (range 25-94). Average size of breast cancer was 1.74 cm with grade evenly divided between grades 1, 2, and 3 (29%, 32%, and 23%). Histologic distribution was typical and included 55% IDC-invasive ductal carcinoma (387), 17% IDC with DCIS (121), 17% DCIS-ductal carcinoma in-situ (120), 11% ILC-invasive lobular carcinoma (74), and for this study, other histologies were included as IDC. Negative margins were achieved in 85% of patients with 71% of margins at least 2 mm at the initial procedure. The final surgical procedure was breast-conserving surgery in 93% and mastectomy in 7% of which 30% were bilateral. The overall positive margin rate was 14.8% (104/702) with an uneven distribution between histologies. Invasive ductal carcinoma (IDC) was the most common histology, yet there was only a 4% positive margin/re-excision rate. When the IDC had associated in-situ disease (17%), there was a 9-fold increase in positive margins and re-excisions. Similarly, only 17% of patients had pure DCIS, but 24% of those had re-excisions. Of the 11% of patients who had invasive lobular carcinoma, 19% had re-excisions (see Figure).

Conclusions: Granted that we have negative margin guidelines for no ink on tumor, but when specific histologic patterns are present, it is more likely to have ink on tumor than when they are absent. When (or if) we compare re-excision rates as a quality metric, we must be sure to look at the distribution of histologies in order to assess any specific level of quality. Positive margins and resultant re-excisions were disproportionately distributed among histologic types. A quality measure using re-excision rates or even positive margin rates may be inaccurate unless the histologic distribution of cases is similar.



Disproportionate distribution of re-excision risk according to histology

257223 - A comparison of margin width in DCIS patients treated with breast-conserving surgery plus whole-breast radiation therapy

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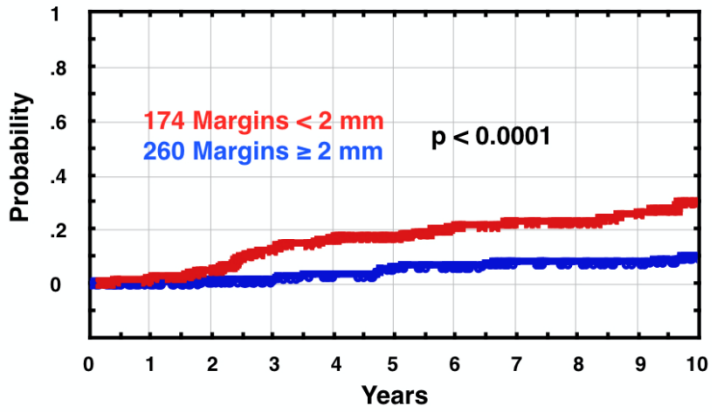
Background/Objective: In an effort to define adequate surgical margin width in patients diagnosed with ductal carcinoma in situ (DCIS), a consensus guideline was recently published supported by 3 major cancer societies: the Society of Surgical Oncology, the American Society for Radiation Oncology, and the American Society of Clinical Oncology. The guideline found that there are fewer ipsilateral breast tumor recurrences (IBTR) in DCIS cases whose margins were at least 2 mm at the time of breast-conserving surgery (BCS) followed by whole-breast radiation therapy (WBRT). The aim of this study was to validate these findings in our patient population.

Methods: We queried a prospective database for patients with pure DCIS (no invasion or micro-invasion) treated with BCS followed by WBRT. Four hundred thirty-four were stratified into 2 groups based on final margin width: 174 with margins < 2 mm (narrow margin group) and 260 with margins ≥ 2mm (adequate margin group). The primary endpoint was ipsilateral breast tumor recurrence. Any breast event, regardless of quadrant, was considered a local recurrence. Secondary endpoints were regional, distant recurrences, and mortality. Kaplan-Meyer analysis was used to determine local recurrence rates at 10 years. Differences in outcome were analyzed using the log-rank test.

Results: Median follow-up for the entire group was 95 months. The average age of both groups was 54 years. The median tumor span was 20 mm for the narrow margin group and 16 mm for the adequate margin group. The probability of an IBTR is shown in the graph. For patients with narrow margins, IBTR was significantly higher when compared to patients treated with adequate margins (31% vs 11% $p < 0.0001$). The median time to an IBTR was 70 months. There was no significant difference between distant recurrence or survival based on margin width.

Conclusions: Analysis of our data supports the Consensus Guideline: 2 mm is an appropriate minimal margin width for patients with DCIS treated with breast-conserving therapy plus whole-breast radiation therapy. Although there was a significant difference in local recurrence rates, we saw no difference in distant recurrence, overall survival, or breast cancer-specific survival. The narrow margins may be due to the slightly larger tumor span in that group. It is unclear why there is a higher percentage of invasive recurrences in the adequate margin group, and this requires further study.



434 DCIS treated with excision plus RT, local recurrence rate

256889 - Impact of utilizing a real-time, intraoperative radiofrequency probe for margin assessment in breast-conserving surgery

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Background/Objective: Breast conservation therapy is the standard option for patients with early-stage breast cancer. Obtaining negative margins to decrease local recurrence is the challenge of the surgeon. Re-excision rates vary substantially; however, the recently reported average across multiple institutions was 25%. Real-time assessment of margin status could aid in intraoperative clinical decision-making and decrease positive margin status improving oncologic and aesthetic outcomes, prevent delay in adjuvant treatment, and relieve additional stress for the patient. A device (Margin Probe; Dune Medical Devices, Caesarea, Israel) that uses radiofrequency spectroscopy to algorithmically analyze tissues and differentiate between normal and malignant tissue has been approved for use in the United States. The purpose of this study was to compare the re-excision rate before and after use of the device. Other variables assessed were the size of specimen and the number of additional shavings taken to further define the device's impact.

Methods: A single center retrospective chart review was preformed comparing 120 consecutive cases prior to use of the probe and 120 consecutive cases after institution of its use. Reliability of the device was determined by comparing postoperative pathology reports. Patients included were over 18 years of age, are candidates for breast conservation surgery, had not received neo-adjuvant therapy, and had no prior surgery or implants in the breast.

Results: Descriptive results are summarized in the Table. There was a significant difference in the total re-excision rate between the margin probe and historical comparison group. There was no significant difference between groups in the rate of positive margin on the main specimen. The mean number of shavings taken was higher in the margin probe group than in the historical comparison group. The 2 patient populations were similar in respect to the patient's age, tumor pathologic characteristics, and extent of disease. There was no difference in the volume of the specimen.

Conclusions: The use of the MarginProbe device with all other modalities employed in intra-operative decision-making during a lumpectomy allowed the surgeons to better refine the specimen. Significantly fewer final positive margins were observed with no effect on the size of the specimen. The MarginProbe shows great potential in improving re-excision rates benefiting the patient, surgeon, and the health system as a whole.

	Historical Comparison	Margin Probe	Impact
	(N = 120)	(N = 120)	
PM Main Specimen, N (%)	26 (21.7%)	35 (29.2%)	35% More
Re-Excision, N (%)			
Any Re-Excision	22 (18.3%)	11 (9.1%)	50% Less (*p=0.039*)
Re-Lumpectomy	18 (15.0%)	7 (5.8%)	61% Less
Mastectomy	4 (3.3%)	4 (3.3%)	No Difference
Shavings, Mean (SD)	0.5 (0.7)	2.0 (1.4)	1.5 More
Volume of Main Specimen	50.2 cc	41.3 cc	9 cc less
Total Volume	53.4	53.5	No Difference

Comparison of historical and marginprobe data

256600 - Does intra-operative margin assessment improve margin status and re-excision rates? A population-based analysis of outcomes in breast-conserving surgery for ductal carcinoma in situ

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Background/Objective: There has been longstanding controversy on optimal surgical margin width for women having breast-conserving surgery (BCS) for ductal carcinoma in situ (DCIS). Currently, up to 1 in 3 women undergo re-excision surgery for inadequate margins. The recent 2016 SSO/ASTRO/ASCO joint statement recommends ≥ 2-mm margins in BCS for DCIS. This is consistent with our provincial guideline from 2008. In addition to margin threshold, the use of intra-operative margin assessment techniques has been reported to reduce re-excision rates, though optimal methods remain unclear and practice varies widely. This study sought to: i) evaluate our province's experience and outcomes in BCS for DCIS using a 2-mm margin threshold and ii) describe our use of various intra-operative margin assessment techniques and determine if this practice has an effect on final margin status and re-excision rates.

Methods: We used a prospectively collected provincial dataset to identify all patients who underwent wire-localized BCS for pure DCIS from January 2010 to December 2014. Margin status and re-excision data were obtained from primary chart review. Descriptive statistics were used to evaluate surgical practice patterns and re-excision outcomes. Three intra-operative margin assessment techniques were studied: i) Single-view intact specimen mammography, ii) intra-operative ultrasound by surgeon, and iii) sliced specimen assessment by pathologist, often combined with sliced specimen mammography. Multivariable logistic regression analysis adjusting for confounders was used to determine the effect of

any intra-operative margin assessment on margin status and re-excision rates. A secondary analysis was performed to determine the relative effect of each individual technique on our primary outcomes.

Results: The analyzed cohort consisted of 588 patients. Using the ≥2-mm margin criteria, the overall positive margin rate was 52% (307 patients) with re-excisions performed in 75% (229 patients). Final margin status at initial surgery was "tumor-on-ink" in 117 patients (20%) of which 89% had a re-excision, "< 1 mm" in 117 (20%) of which 68% had a re-excision and "1-1.9 mm" in 73 (12%) of which 47% had a re-excision. Only 10 patients (2%) with margins ≥2 mm had further re-excision surgery. Following re-excision, additional disease was present in most cases performed for a "tumor-on-ink" margin (72%), and about half of cases performed for a margin < 1 mm or 1-1.9 mm (45% and 49% respectively). Nearly 1 in 5 patients required more than 1 re-excision procedure for margin clearance. Of all 229 patients requiring re-excision surgery, 140 (61%) had breast-conserving surgery as final treatment, 78 (34%) had unilateral mastectomy, and 11 (5%) had bilateral mastectomy for an overall mastectomy rate of 15% in the cohort. Of all 588 patients, intra-operative margin assessment was employed in 368 (63%). Two hundred and eighty-four patients (77%) had intact specimen mammography alone, 63 (17%) had sliced specimen assessment by pathologist usually combined with sliced specimen mammography, 17 (5%) had ultrasound, and 4 (1%) had another combination. There were significantly more intra-operative re-excisions when intra-operative margin assessment was performed (25% vs. 14%, p=0.001), especially in the sliced specimen assessment and mammography by pathologist group (43%). Adjusting for confounders, there was no difference in the odds of a positive margin or secondary excision with the use of any margin assessment technique as compared to wire localization alone (OR 0.75, p=0.202, 95%CI 0.49-1.16; OR 1.14, p=0.564, 95%CI 0.72-1.81). On secondary analysis, sliced specimen assessment by pathologist reduced the odds of a positive margin and secondary excision (OR 0.54, p=0.002, 95%CI 0.37-0.80; OR 0.61, p=0.036, 95%CI 0.39-0.97).

Conclusions: Positive margin rates for women with pure DCIS are high in our province, with a significant percentage of residual disease found in patients with margins less than 2 mm. Intra-operative sliced specimen assessment by pathologist commonly combined with sliced specimen mammography appears to significantly reduce the rate of positive margins by immediate intra-operative revision, thereby reducing the need for secondary excision.

256720 - Integration of MarginProbe in lumpectomy procedures with IORT

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Background/Objective: Achieving clear margin is an important aspect of breast conservation therapy. For patients undergoing intra-operative radiation therapy (IORT) clear margins are even more important. Having positive margins following the lumpectomy procedure IORT has significant implications, as it leads to the conversion to whole-breast radiation. We present our initial experience on the contribution of MarginProbe, a real-time, intra-operative margin assessment tool, to achieving clear margins during lumpectomy surgery with IORT.

Methods: The device was routinely used in lumpectomy cases with IORT. Lumpectomy was performed according to routine practice. MarginProbe was used intra-operatively on all 6 faces (margins) of the

main lumpectomy specimen, providing a positive / negative indication for each margin. Specimens were immediately sectioned and gross pathology evaluation was performed. Intraoperative imaging was performed for non-palpable lesions. Additional shavings were taken based on the information received from all the above modalities. IORT (INTRABEAM) was performed according to the established procedures.

Results: Between February 2014 and September 2016, 79 patients were treated. Average age was 70, average tumor size was 1.1 cm. Eight (10%, 8/79) cases had positive margins (tumor on ink) on the (main) lumpectomy specimen, but through a combination of device detection and gross pathology, 6 were corrected intraoperatively. In 4 (50%, 4/8) cases with positive margins, intra-operative of use of device led to the identification of all positive margins on the main specimen. Synergistically to device deployment, in 3 cases information from intra-operative gross pathology led to the final margins being clear. In 1 case, although all margins were detected, the margins were persistently positive in the new shaving. There were 2 re-excision procedures (2.5%, 2/79). Average volume of the specimens was 44 cc. There were, on average, 1.5 shavings with no cancer taken per case.

Conclusions: Intra-operative margin assessment contributes to achieving clear margins. The combination of MarginProbe and gross pathology resulted in 6 cases (7.6%, 6/79) being spared the need to come back for second surgery, and with it the need for whole-breast radiation. Further studies may include the use of the device on the shavings.

257135 - Routine shave margins are not necessary in early-stage breast cancer treated with breast-conserving surgery

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Background/Objective: Breast-conserving surgery (BCS) is considered standard of care for women with early-stage breast cancer. Between 20-50% of women treated with BCS will require re-operation for margins, and it has been suggested that routine cavity shave margins may reduce the frequency of re-operation. The purpose of this study was to review the rates of positive margins after BCS as well as the rates of re-operation after BCS and the presence of residual disease at re-operation after BCS.

Methods: A prospectively maintained breast cancer database was reviewed. All patients undergoing BCS for primary treatment of breast cancer between January 2012 and December 2015 were included. The incidence of positive and close margins, the rates and types of re-operations performed, as well as the frequency of residual disease among re-operative specimens were reviewed.

Results: Over a 3-year period, 2,096 patients had stage 0 – III breast cancer, with 1,224 (58%) undergoing BCS, and 872 (42%) undergoing mastectomy. Among the patients undergoing BCS, 128 (11%) had positive margins. Of these, 87 (68%) required re-operations, with 56 (64%) undergoing a revision of margins and 31 (36%) undergoing mastectomies. A remaining 41 (32%) of patients with positive margins did not require re-operation. Overall, 364 (30%) of all BCS patients had a second surgery; 87 (68%) for positive margins and 109 (25%) for close margins (0-2 mm). The remaining 171 (26%) re-operations were not related to margin status. In all 364 re-operation specimens, 183 (50%) had

no residual disease, 70 (19%) had residual invasive disease, and 111 (30%) had residual in-situ disease. No statistically significant relationship existed between positive margins and residual disease (p=0.5859), or close margins and residual disease (p=0.1341).

Conclusions: The rate of positive margins after BCS at our institution is 11%, with an overall re-operation rate after BCS of 30%. Among patients with positive margins, 32% did not require a second surgery. Margin status in our population was not related to the presence of residual disease. Routine shave margins would not be warranted at our institution and focus should be shifted instead to addressing the non-margin related reasons for re-operations as well as strategies to reduce re-operations among these patients.

257273 - Effect of intraoperative gross margin assessment on re-excision and local recurrence rates in patients undergoing breast conservation therapy for breast cancer

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Background/Objective: Margin status is a critical determinant of local recurrence (LR) in breast cancer. The role of routine intraoperative gross margin assessment (IGMA) continues to be debated. We sought to study the impact of IGMA on subsequent re-excision and recurrence rates.

Methods: IRB-approved retrospective review was performed on 233 consecutive patients who underwent lumpectomy for breast cancer between 2006 and 2010. Clinical, pathologic, and follow-up data were collected. IGMA and specimen radiograph was used. Resection of margins was done for close margins < 2 mm. Re-excision rates were noted and patients were followed up for recurrence.

Results: Patients were predominantly Caucasian (91.4%), post-menopausal 172 (78.9%), with intermediate grade tumors 103 (48.8%), and clinical stage 1- 82 (51.9%). All patients underwent intraoperative imaging; however, the IGMA was performed in 115/233 patients (53.7%). Immediate intraoperative re-excision of margins was performed in 81/233 patients (34.8%). On final pathology, 110 patients (47.4%) had positive margins of which 107 (97.3 %) underwent subsequent re-excision. IGMA was associated with lower rate of positive margins on final pathology (41.5% vs. 61.1%, p=0.007) and lower subsequent re-excision rates (35.7% vs. 59.6%, p < 0.001). No difference in re-excision rates was noted based on preoperative imaging modality used (p=0.79), as well as MRI (p=0.58). Most patients, 192 (94.6%) received adjuvant radiation therapy (XRT). Of the 145 patients (76.7%) who had whole breast XRT, 56.3% received a boost, and 41 (21.7%) patients had accelerated partial breast XRT. In a median follow-up period of 5.7 years, 15 patients recurred (6.4%), 5 were LR. Neither type of XRT (P = 0.45) nor re-excision (P=1.00) were statistically associated with LR.

Conclusions: Intraoperative margin assessment was significantly correlated with negative margins on final pathology and lower re-excision rates. We recommend the routine use of this technique to avoid additional surgeries in patients undergoing BCT for breast cancer.

Re-excision vs. Pre-operative imaging modality N (%)							
		Total	MRI	MMG	US	Palpation	P - value
Total re-excisions	No re-excision done	105 (64)	33 (67.4)	27 (58.7)	44 (64.7)	1 (100)	0.79
	Re-excised	59 (36)	16 (32.6)	19 (41.3)	24 (35.3)	0 (0)	
Intraoperative margin assessment vs. Post-operative margin status N (%)							
		Total	Yes	No	P - value		
Postoperative Margin Status	Negative	97 (49.5)	35 (38.9)	62 (58.5)	**0.007**		
	Positive	99 (50.5)	55 (61.1)	44 (41.5)			
Intraoperative margin assessment vs. Re-excision status N (%)							
		Total	Yes	No	P - value		
Re-excisions	No re-excision done	114 (53.3)	40 (40.4)	74 (64.3)	**< 0.001**		
	Re-excised	100 (46.7)	59 (59.6)	41 (35.7)			

(MRI – Magnetic Resonance Imaging, MMG – Mammogram, US – Ultrasound)

Correlation of preoperative imaging modality, intraoperative margin assessment with post-operative margin status, and re-excision rates in patients undergoing breast conservation therapy for breast cancer

257125 - Assessing variation in provider and institution-level re-excision rates: Opportunity for a statewide surgical collaborative to improve breast cancer care

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Background/Objective: Considerable variation exists in the rate of re-excision after breast-conserving surgery (BCS) in the U.S., with individual surgeon rates ranging from 0-70%. The optimal approach for reducing repeat surgical procedures for the 230,000 American women each year diagnosed with breast cancer is not known. However, new guidelines addressing optimal margins after BCS (which impact need for re-excision) were published by the Society of Surgical Oncology and American Society for Radiation Oncology (ASTRO) in 2014 for women with early-stage cancer undergoing radiation therapy as a part of first course treatment. Additionally, best practice guidelines for further decreasing the need for re-excision were published by the American Society of Breast Surgeons (CALLER toolkit) in 2015. The objectives of the current project were to use hospital discharge and administrative claims data to assess surgeon- and institution-level variation in re-excision rates across the state of Wisconsin and assess temporal trends given the recent introduction of guidelines.

Methods: De-identified Wisconsin Hospital Association (WHA) all-hospital discharge and Wisconsin Health Information Organization (WHIO) all-payer claims data (which captures insurance claims for 72% of the state population) from Q2 2013–Q1 2015 were extracted at the surgeon and institution level. Both data sources capture operations performed in inpatient, outpatient, and surgical center settings and can identify and link encounters for patients who undergo procedures at multiple facilities. Rates of breast-conserving surgery and re-excision (lumpectomy or mastectomy within 60 days of the index BCS) were calculated in 6-month increments between Q2 2013 and Q1 2015 for surgeons who perform a minimum of 10 breast-conserving procedures per year. This minimum was chosen because 1) it is the standard minimum number of observations that can be used to maintain de-identification; 2) it allows for stable re-excision rate estimates; and 3) it has been used as a low volume threshold in prior re-

excision studies. Women diagnosed with early-stage invasive breast cancer and DCIS were included in the patient cohort.

Results: Over the study period, 93 Wisconsin providers practicing at 56 unique facilities met eligibility requirements, including performing 10 or more BCS per year. The majority of breast-conserving surgeries (n=3,470) were performed in non-urbanized areas and in community hospitals as opposed to academic or comprehensive cancer center settings. Statewide average patient-level re-excision rates were consistent over time (19.4%, 18.5%, 18.7%, and 18.3%, respectively). The mean rate of re-excision across providers in the state was 18.7%, with significant variation at both the facility (5-66%) as well as provider (3-70%) levels.

Conclusions: In contrast to recent studies of other national and regional surgical quality improvement databases, there has been little change in re-excision rates in the broader Wisconsin community from 2013 to 2015, despite the publication of new guidelines and ASBrS educational materials (CALLER toolkit) that were made available in 2014 and 2015. In addition, variation in re-excision rates exist at both the surgeon and facility levels. These findings suggest further quality improvement initiatives are necessary to reduce the cost and patient burden of additional surgeries. Such interventions could include provider and facility-level benchmarked re-excision rate reports to ensure surgeons are aware of their performance relative to peers or other methods (e.g., didactic instruction, surgical coaching) to increase uptake of best practices across the diversity of practice and community settings. Such broad interventions can improve the quality of care for all patients with breast cancer without disrupting current practice and referral patterns.

257021 - Are 2-mm margins necessary for mixed in situ and invasive ductal carcinoma?

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Background/Objective: Recent consensus guidelines have been published for adequate margin widths in both invasive and non-invasive (DCIS) ductal carcinomas. These guidelines recommended “no ink on tumor” for invasive carcinoma but supported obtaining a minimum 2-mm margin width for DCIS. In cases with tumors involving both invasive carcinoma and DCIS, the recommendation was to follow the invasive guideline. We reviewed our data of patients with “mixed” invasive cancer and DCIS components in order to evaluate margin, recurrence, and re-excision rates.

Methods: An IRB-approved retrospective review of patients treated from 2008-2014 was conducted using our Tumor Registry. Of 3,660 patients undergoing breast conservation surgery, 412 (11.2%) had mixed tumors with margin data available. Tumor receptor, lymph node status, and recurrence rates were evaluated. Recurrence and survival times were calculated from time of last known mammogram.

Results: Of the 412 patients, those with DCIS margins < 2 mm and ≥2 mm were split evenly with 206 (50%) in each group. The overall recurrence rate was 1.2% (n=5), with 4/5 patients having DCIS margins < 2 mm. Of note, 1 of these patients refused primary radiation and endocrine therapy. At the time of surgery, all 5 patients were ER/PR (+), 4 were HER2 (+) (1 no data), and 3 patients had negative lymph nodes (2 patients had no nodes taken). Average time to recurrence was 18 months. Two of the recurrences were mixed tumors, and 3 of the recurrences were DCIS.

Conclusions: While the overall recurrence rate was very low, the majority of patients with mixed tumors and recurrence had DCIS margins < 2 mm. Further investigation is warranted to determine if wider margins are needed in the setting of mixed tumors.

NSM

257393 - Is it oncologically safe to perform nipple-sparing mastectomy in patients with tumor-nipple distance less than 2.0 cm?

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Background/Objective: There is a tendency to avoid nipple-sparing mastectomy (NSM) when the tumor-nipple distance (TND) is less than 2.0 cm due to the risk of occult nipple involvement. The purpose of the study is to determine whether the patients who undergo NSM with immediate reconstruction are oncologically safe when TND is less than 2.0 cm.

Methods: A retrospective review of patients who underwent NSM and immediate reconstruction for operable breast cancer between 2010 and 2015 was conducted. MRI was used to obtain TNDs to compare local-recurrence free and disease-free survival in group I (TND < 2.0 cm) and group II (TND ≥2.0 cm).

Results: Twelve patients who are diagnosed with only DCIS are excluded. Among the n=93 NSMs with invasive tumor diagnosis, TND was < 2.0 cm in n=29 (31.2%) cases and ≥2.0 cm in n=64 (68.8%) cases. The follow-up time was median 28 months (range; 3-72). In between group analyses, there were no significant differences in regards with ER, PR, and HER-2 status (p=0.41, p=0.36, and p=0.59; respectively). There was similar nodal involvement status between 2 groups (p=0.14). Group I had n=2 local recurrences, and the other group had n=2 local and n=2 distant metastases. There were no significant differences between the 2 groups with respect to disease-free survival (3-year DFS 91.7% vs. 97.3%; p=0.24).
Conclusions: Conclusion: It is oncologically safe to perform NSMs in patients with TNDs under 2.0 cm. Larger cohorts are needed to confirm the oncologic safety.

256580 - Indocyanine green (ICG)-based intraoperative angiography validates use of nipple delay for patients undergoing nipple-sparing mastectomies

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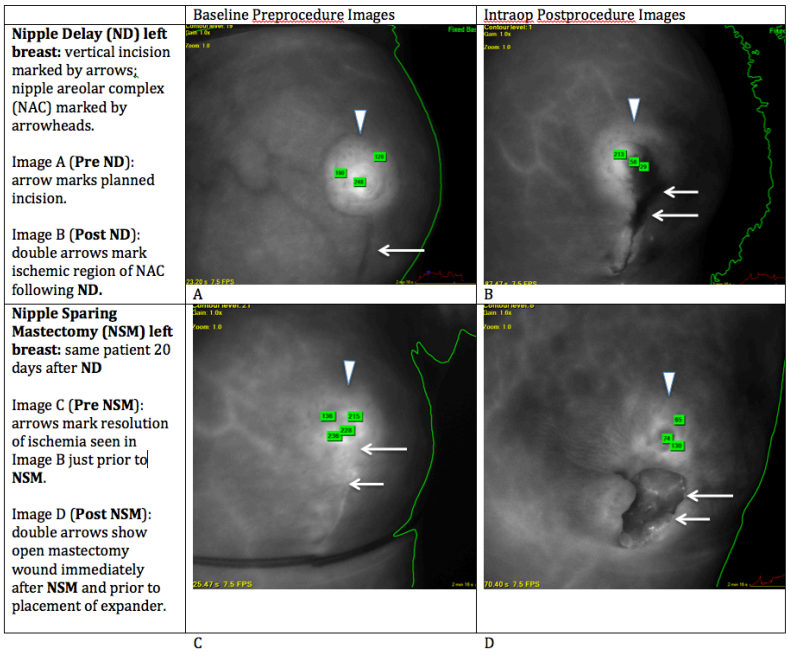
Background/Objective: Viability of the nipple areolar complex (NAC) is key to achieving an optimal aesthetic result from nipple sparing mastectomy (NSM) with reconstruction. Nipple delay (ND) has been described as a first stage surgical procedure in which the blood flow from the gland to the NAC is divided in order to increase the blood flow through the skin and subcutaneous tissue to the NAC and thereby decrease the risk of tissue loss from subsequent NSM. The purpose of this study was to use quantitative measurements from ICG angiography to determine if objective evidence can validate the merits of ND prior to NSM.

Methods: Patients underwent ND procedures through a portion of the planned NSM incisions 2 to 3 weeks prior to NSM. Imaging sequences were obtained intra-operatively with the SPY Elite (Novadaq Inc.) imaging system prior to and immediately following the ND and NSM. During retrospective review of the sequences the frame with the maximum fluorescence at the nipple was analyzed using the Spy quantification tool kit. Absolute values were placed at the maximum fluorescent point of the nipple, as well as the areola. The minimum value of the areola was also recorded. The absolute numbers represent the intensity of fluorescence at the area of interest. The pixel scale has values from 0-255 with 0 being the lowest intensity and 255 being the highest.

Results: Twelve breasts in 6 patients underwent bilateral ND followed by bilateral NSM an average of 18 days later. The average age for this group was 37; 5 had a BRCA 1 or 2 mutation, and 1 had invasive ductal cancer (IDC). The control group without prior ND had 10 breasts in 6 patients who underwent NSM. The average age for this group was 50.5; 1 had a BRCA 1 mutation, the other 5 had IDC. No patient in any group had full thickness loss of the nipple or areola. One in the ND group had a small area of epidermolysis of the nipple and one in the control group had an area of breast skin necrosis treated with debridement and hyperbaric oxygen. Both healed completely without any visible cosmetic deformity. The average absolute perfusion (AAP) of both nipples in patients undergoing nipple delay went from 170 to 105 between the start and end of the procedure; a decline of 38%. By the time the patient underwent NSM, the perfusion images had improved and the numbers increased (see example in figure). The AAP of both nipples in patients who had undergone a prior nipple delay had increased to a new baseline of 235 and dropped to 105 following NSM; a decline of 56%. The control group went from a lower baseline of 198 to 42; a decline of 79%. Thus, the ND patients had a 19% higher initial reading and 145% greater final value compared to those who did not undergo ND prior to NSM. Similar changes were seen in the readings from the areola. Those who underwent ND had a maximum areola value that was 42% greater and a minimum areola value that was 44% greater prior to NSM. Following NSM, the patients who underwent ND had a maximum areola value 60% greater and a minimum areola value 136% higher than those who had not undergone ND.

Conclusions: This study suggests that by using the SPY with ICG angiography, it is possible to collect objective data that ND can increase the blood flow to the NAC in patients planning to undergo subsequent NSM. This approach should lead to an increased likelihood of viability of the NAC following NSM. Nipple delay should be considered in any patient at risk of full thickness loss of portions of the NAC following NSM.



Intraoperative indocyanine green angiography

256681 - To dilate or not to dilate: Improved complication rates in skin-sparing and nipple skin-sparing mastectomies using the dilation technique

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Background/Objective: The use of skin-sparing mastectomies (SSM) and nipple skin-sparing mastectomies (NSSM) has increased in recent years as studies have demonstrated equivalent outcomes and recurrence rates compared to traditional simple mastectomies. Postoperative complications, such as skin and nipple ischemia or necrosis, wound dehiscence, and infection, are often related to the formation of large skin flaps required for these procedures. The flaps can be created using a variety of techniques, including sharp dissection, electrocautery, tumescence, and blunt dilation. We hypothesized that developing the dissection plane for the skin flaps using a serial dilation technique with cervical dilators significantly reduces postoperative complication rates in SSM and NSSM compared to non-dilation techniques.

Methods: This retrospective chart review analyzed data from 529 patients who underwent SSM or NSSM from 2001 to 2015 at a single institution to assess complication rates between dilation and non-dilation techniques for skin flap formation. The chi-square test was used to verify statistical significance.

Results: The 529 patients underwent SSM or NSSM via a dilation technique (406 patients, 761 breast surgeries) or a non-dilation technique (123 patients, 229 breast surgeries). Overall complication rates were 16.5% in the dilation group (67/406) and 37.3% in the non-dilation group (46/123) (p=0.0001). The dilation group had 17 (4.1%) cases of skin flap ischemia/necrosis and 4 cases of nipple necrosis (0.9%), compared to 12 cases (9.7%) and 3 cases (2.4%) respectively in the non-dilation group (flap necrosis

p=0.03, nipple necrosis p=0.43). Wound dehiscence occurred in 14 patients (3.4%) in the dilation group versus 13 patients (10.5%) in the non-dilation group (p=0.003). Observed infectious complications such as exposed tissue expander with expander infection (5 patients, 1.2% vs 5 patients, 4%; p=0.10) and cellulitis/ superficial wound infection (27 patients, 6.6% vs 13 patients, 10.5%; p=0.21) were also higher in the non-dilation set. Finally, complication rates were compared among dilation and non-dilation subgroups based on incision type, which included those involving the inframammary fold ("inverted T," inframammary, or wise pattern incisions) and those that did not involve the inframammary fold (radial, inferior vertical, elliptical, periareolar incisions). The incidence of ischemia, wound dehiscence, and infectious complications was greater in the non-dilation categories in both incision types, but was only statistically significant in the subgroup of patients with an incision involving the inframammary fold (p=.0001).

Conclusions: The dilation technique for creation of skin flaps in SSM and TSSM results in fewer ischemic and infectious postoperative complications compared to non-dilation techniques. The benefit of the dilation technique is further demonstrated by a lower incidence of complications between patient subgroups based on incision type.

257113 - Satisfaction with nipple-sparing mastectomy is greater for high-risk patients versus patients with breast cancer

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Background/Objective: Nipple-sparing mastectomy (NSM), whereby the nipple-areolar complex is preserved, is increasingly being offered to women who require mastectomy for either breast cancer (BC) or who desire prophylactic mastectomy for high-risk (HR) status. We sought to determine whether patient satisfaction varied between these 2 groups and the factors that may account for observed differences.

Methods: We prospectively queried 80 patients who underwent NSM with reconstruction between 2013-2016 utilizing the BREAST-Q tool post-operatively. BREAST-Q is a validated questionnaire that evaluates patient satisfaction in outcome and care using multiple domains. The responses were scored 0-100, with 100 being highest satisfaction. Groups were compared according to indication for mastectomy: BC (56 patients) versus HR (24 patients). The BREAST-Q data were analyzed within self-satisfaction domains (satisfaction with breast, psychosocial wellbeing, satisfaction with outcome and satisfaction with physical wellbeing) and satisfaction of care (satisfaction with surgeon, office staff, medical staff, and information). Median scores of overall satisfaction and domains were calculated and multiple comparison-corrected Mann-Whitney U tests were performed.

Results: Overall self-satisfaction was greater for HR group (Median=77) when compared to BC group (Median=68), p=0.012. Overall satisfaction with care was the same for HR (Median=100) and BC groups (Median=100), p=0.44. When comparing HR to BC groups, there was little difference between satisfaction with breast and psychosocial well-being domains. There was a moderate but insignificant difference between HR (Median=86) and BC (Median=75) groups for satisfaction with outcome, p=0.31. There was a moderate and significant difference between HR (Median=81) and BC (Median=71) groups for physical well-being, p=0.02. When comparing HR to BC groups, there was little difference in

satisfaction with information and no difference in sexual well-being nor satisfaction with surgeon and staff.

Conclusions: NSM provides high levels of satisfaction among all patients. However, HR patients have higher levels of satisfaction than BC patients following NSM. Higher satisfaction for HR over BC patients may be due to length of time patients have to consider their surgeon and procedure, risks of adjuvant therapy, number of biopsies and potentially higher complications associated with obtaining clear margins in the case of cancer. In an era of quality metrics, patient satisfaction must be included in the evaluation of success as techniques for NSM advance. As patient satisfaction is challenging to correlate to specific tangibles, it is important for future studies to attempt to determine why there are differences between the HR and BC patient populations.

256464 - Prospective study comparing surgeons' pain and fatigue associated with nipple-sparing vs. skin-sparing mastectomy

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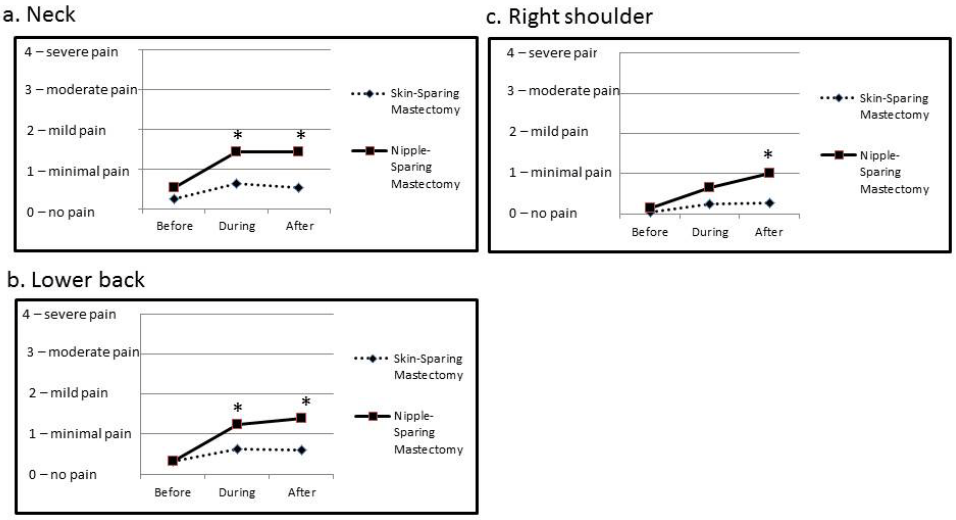
Background/Objective: Nipple-sparing mastectomy (NSM) eliminates the need for nipple-areola reconstruction and improves cosmetic and psychological outcomes, compared to skin-sparing mastectomy (SSM). The rate of nipple-sparing mastectomy (NSM) has increased dramatically in recent years. Although NSM benefits patients, it is widely recognized that NSM is more technically challenging for the surgeon than SSM. However, surgeon symptoms and fatigue related to performing NSM have not been investigated.

Methods: This was a prospective study comparing surgeon-reported physical symptoms and fatigue before, during, and after NSM vs. SSM. Surgeons also answered general questions about the performance of the operation. Questions were drawn from a comprehensive surgeon ergonomics survey (A. Park) and the NASA Task Load Index; original questions specific to mastectomy were also included. Patients provided written, informed consent, and surgeon responses were collected by electronic questionnaire. For bilateral cases, 2 surgeons performed simultaneous mastectomies and completed independent questionnaires.

Results: Questionnaires were submitted after 26 NSMs and 55 SSMs. Seven surgeons completed questionnaires: 4 attending surgeons completed questionnaires after 23 NSM and 43 SSM, and 3 fellows completed questionnaires after 3 NSMs and 12 SSMs. For NSM, pre-operative bra cup size was A-B in 42% (n=11), C in 46% (n=12), and >C in 12% (n=3). For SSM, preoperative bra cup size was A-B in 18% (n=10), C in 45% (n=25), and >C in 36% (n=20). For NSM, incisions were inframammary (85%, n=22) or peri-areolar (15%, n=4). For SSM, incisions used were an ellipse encompassing the nipple (65%, n=36) or Wise-pattern (35%, n=19). One hundred percent of NSMs and 96% of SSMs (n=53) were completed by right-handed surgeons. When the change in surgeon pain was compared, NSM was associated with a greater mean increase in surgeon neck pain (during vs. before, p=0.05; after vs. before, p=0.02), lower back pain (during vs. before, p=0.04; after vs. before, p=0.02), and right shoulder pain (during vs. before, not significant; after vs. before, p=0.02) (Figure). On a 10-point scale, surgeons rated NSM more mentally demanding (mean, 6.0 vs. 4.6, p=0.006), physically demanding (mean, 7.1 vs. 4.5, $p < 0.001$),

and difficult (mean, 6.8 vs. 4.6, $p < 0.001$) than SSM. On a 10-point scale, surgeons also reported that visualization was more difficult (mean, 5.7 vs. 3.2, $p < 0.001$) and fatigue was greater (mean, 6.0 vs. 3.2, $p < 0.001$) after NSM, compared to SSM. No difference was reported in satisfaction with the equipment available, the cosmetic outcome, or the oncologic/technical outcome of the procedures.

Conclusions: NSM was associated with greater surgeon neck, lower back, and right shoulder pain, as well as greater mental demand, physical demand, and fatigue, relative to SSM. Although symptoms reported were mild, chronic strain could lead to repetitive stress injury. There is a need for greater understanding of the ergonomic challenges surrounding NSM, as well as alternative approaches to improve surgeon ergonomics during NSM.



Mean surgeon pain reported before, during, and after operation, for nipple-sparing mastectomy vs. skin-sparing mastectomy. Body parts showing statistical differences (marked by *) by type of mastectomy are shown.

257014 - Nipple recurrence after nipple-sparing mastectomy: Biology not proximity

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Background/Objective: Nipple-sparing mastectomy (NSM) provides breast cancer patients an opportunity for an excellent aesthetic outcome without compromising oncologic outcome. Little data exist on the rate of local recurrence, especially in the form of nipple-areola complex (NAC) recurrence. The goal of this study is to report on nipple recurrence over a 10-year period in a single-surgeon experience.

Methods: We retrospectively reviewed 360 NSMs performed by a single surgeon from 2006 to 2016. Patients undergoing neoadjuvant chemotherapy, previous radiation therapy, or previous breast surgery were not excluded. Criteria for eligibility was no tumor in nipple core. Tumors close to, but not involving, the NAC were not excluded from selection for NSM. This analysis focused on local recurrence involving the nipple.

Results: In 200 patients, 360 NSM were performed. Of these, 80% were bilateral and 20% unilateral. Implant-based reconstruction was performed in 80% and autologous reconstruction in the remaining 20%. Indications for NSM included: stage 1 or 2 disease (40%), locally advanced (20%), DCIS only (20%), local-recurrence after breast conservation (10%), and risk reduction (10%). Of the 200 patients, we reviewed 180 cancer patients. In 180 patients over 10 years, there were 4 local recurrences and 3 systemic recurrences. Two local recurrences occurred elsewhere in the breast, and 2 occurred at the nipple (1.1%). Both recurrences presented with crusting. In both patients, the index primary was more than 3 cm from the nipple with negative skin/nipple margins. Patient 1 was age 51 at diagnosis of ER negative, PR weakly positive, high-grade DCIS; she received no adjuvant systemic therapy. Latency period between the index NSM and Paget's recurrence was 15 months. Patient 2 was age 54 at diagnosis of ER negative, PR negative, HER2 positive, high-grade, stage 1 invasive ductal carcinoma with DCIS. She received adjuvant chemotherapy and HER2 targeted therapy. Latency period was 48 months. Both patients underwent NAC removal with final pathology consistent with the original primary; they are both free of disease. This falls in line with data reported from the Electron Beam Intraoperative Radiotherapy (ELIOT) trial, where patients undergoing NSM received intraoperative NAC single fraction radiation. Lohsiriwat et al published that Paget's disease local recurrence occurred in 0.8% (n=7) of 861 patients; of these, 100% were ER negative and 86% HER2 positive.

Conclusions: Nipple recurrence after NSM is extremely rare. Even with liberal indications and without intraoperative NAC radiation, we found the incidence of nipple recurrence to be 1.1%. All reported cases involve ER negative disease. This suggests that tumor biology is more important than proximity of disease to the nipple as a potential risk factor for nipple recurrence. Potentially, many more patients with cancer near, but not involving, the nipple-areola complex can be safely considered for nipple-sparing mastectomy

252716 - Ultrasound localization of intercostal perforating vessels reduces post-operative wound complications from nipple-sparing mastectomy

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Background/Objective: Complications of nipple-sparing mastectomy (NSM) are well documented, particularly skin necrosis as a result of ischemia. The intercostal perforating vessels (IPV) have been demonstrated to provide a significant proportion of the blood supply to the nipple-areolar complex (NAC). We propose that localization of the IPV, utilizing intra-operative ultrasound (US), will reduce the incidence and severity of skin necrosis following NSM.

Methods: Prospective data collection was performed on 37 women undergoing NSM who provided consent for the study. This group was compared with 52 historical NSM controls performed in the preceding 12 months. US was performed using a Sonosite™ US, 5-12mHz transducer, using the Doppler mode. Data monitored included: success of localization, success of preservation of IPV during the procedure, rate, and severity of necrosis of the skin, or NAC as measured by the skin ischemic necrosis (SKIN) score.

Results: Thirty-seven NSMs were performed utilizing US localization of the IPV. Localization was successful in 100%. Preservation of the IPV vessels was 100% in these individuals. Notably, we found

significant variability in the location of the primary IPV, identified with nearly equal frequency in the second intercostal space (ICS) and third ICS. The groups were well matched for known risk factors: age, prior radiation therapy (RT), smoking, and body mass index (BMI). Complication rates and severity as measured by SKIN score are shown in the Table. The data indicates that fewer and less severe complications were observed in women with successful US localization and preservation of the IPV.

Conclusions: Our study provides preliminary evidence that US localization of the IPV can reduce skin necrosis complications in NSM. The findings are consistent with our hypothesis that localization of the IPV leads to preservation of the primary vasculature of the NAC and reduced complications. The observed variable location of the primary IPV may contribute to the value of localization. Surgeons facile with US can readily employ this technique to reduce skin necrosis and related complications.

SKIN Score	Study	Control
None (A1)	65%	42%
B2	22%	38%
B3	0%	12%
C2	9%	2%
C3	4%	0%
D3	0%	6%

Complications

256743 - Patient satisfaction following nipple-sparing mastectomy and assessment of nipple-areolar sensation

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Background/Objective: The number of patients undergoing nipple-sparing mastectomy (NSM) has been increasing as the indications for this procedure continue to grow. The goal of this study is to describe our experience with NSM in regard to aspects of overall patient satisfaction, quality of life, and particularly nipple sensation. We anticipated that overall patient satisfaction would be high but rates of post-operative nipple sensation would be low, especially in patients with a smoking history.

Methods: Eighty-nine women who underwent NSM since 2008 by a single surgeon were sent a survey administered between 2 to 9 years after surgery. Survey questions used a 5-point scale with questions pertaining to overall patient satisfaction, regrets regarding the procedure, recommending the procedure to another patient, and the preservation of nipple sensation. Demographic and clinical information were also collected from a patient database.
Results: Forty of 89 women responded to the survey. The mean patient age was 48 years. Thirty-five of the patients underwent bilateral NSM, with 80% undergoing immediate reconstruction with silicone implants, and 13 were BRCA positive. Overall, 70% of patients were very satisfied with their decision to undergo NSM, and 80% of patients rated their quality of life as content or very content post-operatively. Seventy-two percent of patients would encourage a friend to have a prophylactic NSM, and 70% have

never regretted undergoing the procedure. No patients had normal nipple sensation, but 35% did report having some level of sensation (5 very little, 7 some, 2 mostly normal) to the nipple. More specifically, women who reported a smoking history had lower rates of residual nipple sensation than those who did not smoke. Fifty-two percent (13/25) of non-smokers reported no nipple sensation compared to 87% (13/15) of smokers (p=0.04). Neither age at surgery nor time since surgery appeared to be related to preserved nipple sensation.

Conclusions: The majority of patients undergoing NSM are satisfied with their procedure, would recommend it to another patient, and rated their overall quality of life positively. Similar to other studies there was a low rate of residual nipple sensation following NSM. However, we also found decreased rates of nipple sensation in patients with a smoking history, which could impact pre-operative discussion with patients.

256656 - The use of hydrodissection in nipple-sparing mastectomy: A comparative study

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Background/Objective: Hydrodissection is a novel technique to create a tissue dissection plane by a combination of fluid pressure with needle dissection and can be applied to the mastectomy setting. We have used an infiltration of the subcutaneous and pre-pectoral breast planes with a mixture of 1 l of normal saline, 0.5 ml of 1:1000 adrenaline and 30 ml of 0.5% chirocaine, typically using 500 ml of fluid in each breast prior to the parenchymal resection with standard sharp dissection. Hydrodissection is thought to facilitate the exposure of the resection plane and therefore might result in reduced traction-related flap trauma. As even skin flaps can be created, it may also result in less need for secondary revision surgery. The aim of this study was to evaluate the use of hydrodissection in the setting of risk reducing nipple-sparing mastectomy (NSM) compared to standard operative technique.

Methods: The Risk Reduction Dataset, a prospectively collected database of patients having surgery for BRCA 1/2 gene mutations or strong family history of breast cancer, was used to identify patients who underwent bilateral risk reducing, NSM and immediate implant-based reconstruction through an inframammary crease incision (IMC), using hydrodissection (HD Group). This group was compared to a cohort of consecutive patients that underwent conventional NSM before the introduction of hydrodissection as the standard technique in the department (Control Group). All surgery was performed by the same surgical team in a single institution. Patient data from both groups were collected and compared using non-parametric statistical analyses on per case and per procedure basis.

Results: Twenty-two patients (comprising 44 NSMs) were included in the HD group, and 20 patients (a total of 40 NSMs) were included in the Control group. Patients' characteristics were similar for both groups (Table). Median length of hospital stay was significantly less for patient in the HD group (2 vs 2.5 days, p=0.016). Hydrodissection was associated with more events of partial-thickness nipple-areola complex (NAC) necrosis in the univariate analysis (25% vs 7.5%, p=0.032), but when a multivariate model including age, smoking status, body mass index (BMI) and size of used implant was performed, there was still a trend but did not reach statistical significance (p=0.053). Despite this observation,

hydrodissection was not associated with more re-admissions or need for further intervention (Table). Conversely, significantly fewer patients in the HD group required revision surgery in the form of Coleman fat transfer to improve the quality of the mastectomy flaps (4.5% vs 35%, $p < 0.001$) compared to patients in the Control group.

Conclusions: The introduction of hydrodissection in the setting of NSM and immediate implant-based reconstruction through a remote IMC incision in a consecutive cohort of patients resulted in a trend towards more minor complications in the form of partial thickness NAC necrosis but was also associated with significantly reduced length of hospital stay and less need for subsequent surgical revision with fat transfer.

256840 - Surveillance practices after nipple-sparing mastectomy

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Background/Objective: Standard of care for surveillance following mastectomy has traditionally been physical exam (PE) alone. With increasing use of nipple-sparing mastectomy (NSM), there is controversy whether patients who have had NSM should undergo surveillance breast imaging for local-regional recurrence (LRR). The objective of this study was to review the practice patterns and findings of surveillance after NSM.

Methods: We performed a single institution retrospective review of women over the age of 18 who underwent NSM from 2010-2015. Patient and tumor characteristics, surgical treatment, disease management, method of post-surgical surveillance, and detection of LRR were compared between those who had surveillance imaging (SI) and those who had PE alone. SI included screening breast MRI or mammogram following NSM. Patients who had diagnostic imaging for suspicious PE findings, but did not have screening imaging were categorized in the PE alone group.

Results: A total 209 of patients were identified and included in the analysis. The majority of patients had bilateral NSM (155, 74%), while 54 (26%) were unilateral. Breast center surgeons, those at our institution who specialize in breast surgery and practice in a high-volume multi-disciplinary setting, performed most cases (165, 79%). Mean age at time of NSM was 47.5 years. Fifty-two (25%) NSM were prophylactic. Among those with invasive cancer, 69 (53%) had stage 1 disease, 47 (36%) had stage 2, and 15 (11%) had stage 3 disease. Overall, 45 (22%) patients had a BRCA1 or BRCA2 mutation. Of the total patients, 79 (38%) had SI; 130 (62%) had surveillance with PE alone. Among the SI group, MRI was the most frequent form of SI used (69; 87%) while 10 (13%) had surveillance mammogram. There was no significant difference between the SI and PE groups when comparing age at diagnosis, tumor size, node status, margins, tumor biomarkers, chemotherapy, post-operative radiation, suspicious findings on PE, tumor histology, BRCA status, or type of reconstruction received. A significant predictive factor of postoperative surveillance imaging was breast center surgeon ($p < 0.01$). With median follow-up time of 13.5 months, there was no significant difference in LRR between SI and the PE groups (1.3% vs 0.8%, $p=0.99$). Overall, there were a total of 2 LRRs (1%): 1 chest wall recurrence in the SI group and 1 axillary recurrence in PE group. Both LRRs were detected by PE; none were detected by SI. The chest wall recurrence in the SI group presented as a palpable mass several weeks following a negative surveillance MRI.

Conclusions: LRR after NSM is a rare event that can be missed by SI. PE alone is an effective means of detecting LRR and is an appropriate method of surveillance following NSM.

257291 - Nipple areolar-sparing mastectomy in a community hospital setting: Report of an 11-year experience

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Background/Objective: Nipple areolar-sparing mastectomy (NSM) has emerged over the past decade as an acceptable surgical option for women needing or desiring mastectomy for breast cancer treatment and/or prevention. The literature supporting the oncologic and surgical safety of NSM has come almost exclusively from academic medical centers. This is a report on an 11-year experience with NSM at an urban, community hospital to demonstrate parity with the results reported from academic medical centers and to support the use of NSM in the community setting.

Methods: An IRB-approved retrospective chart review was performed on patients undergoing NSM from November 2004 to October 2015. Data collected included: patient demographics, co-morbidities, details of the surgical procedure, complications, neo/adjuvant therapies, pathology, staging, and recurrences.

Results: Three hundred sixty-five patients underwent a total of 607 NSM. The average age was 50.1 (range: 21-77 years). Race and ethnicity for 336 patients: Non-Hispanic whites (53%); Hispanic whites (19%); Asians (23%), Native Americans, African-Americans and other (5%). Co-morbidities included: smoking (11.5%), hypertension (19%), heart disease (4.4%), diabetes (3.6%), stroke/TIA (1.6%). One hundred seventy-eight patients had a family history of breast cancer with 35 patients (9.6%) having BrCa 1/2 genetic based risk. Neoadjuvant chemotherapy: 97/365 (26.6%) patients and adjuvant chemotherapy: 81/365 (22. 2%). There were 348 therapeutic NSM (57%) and 259 prophylactic NSM (43%). Pathologic staging: Stage 0 (29%), I (32%), II (30%), III (8%) and IV (1%). Patients may have had more than one complication. The overall complication rate (analyzed by patient) was 25.2%. This included significant complications: implant/expander explantation (4.6%); epidermolysis/partial thickness necrosis (9.2%); full thickness necrosis (4.6%); and infections (6.1%). Minor complications were ecchymosis (5.9%) and seromas (6.9%). Overall average follow-up was 2.5 years with oncologic specific follow-up of 2.8 years. Local/regional recurrences occurred in 14 patients having therapeutic NSM (4%). There was 1 nipple-areolar complex recurrence (0.3%) at 3.0 years, 9 additional local and 4 axillary recurrences. There were 5/14 recurrences (which includes the nipple-areolar complex recurrence case) in patients initially diagnosed with DCIS. Nine (2.5%) patients have died—4 NED and 5 of breast cancer.

Conclusions: NSM was developed to provide a greater sense of femininity following mastectomy for treatment and prevention. Over 80% of all cancer care in the US is provided in the community, non-academic setting. The race/ethnicity and stage distribution of this study's patient population combined with the high number of patients receiving neoadjuvant chemotherapy emphasizes the appropriate, yet widespread use of NSM. Low early recurrence rates in a high-risk population (neo/adjuvant chemotherapy in 49%), support the oncologic safety. Furthermore, this is emphasized with the single (1/348 at risk breasts) recurrence in the nipple-areolar complex. These results with NSM are on par with similarly reported large series from academic medical centers and support the use of NSM as a safe option for patients in the community setting.

256493 - Quality of life after nipple-sparing mastectomy: A prospective study of patients using the Breast Q

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Background/Objective: Nipple-sparing mastectomy (NSM) is an increasingly common procedure and considered oncologically safe for select patients. The objective of this study was to examine quality of life (QOL) and satisfaction domains for patients who have undergone NSM at our institution. We aimed to evaluate these domains by examining psychosocial, sexual, and physical well-being as well as satisfaction with breasts and with care after NSM using the BREAST-Q questionnaire.

Methods: After obtaining institutional review board approval, we performed a retrospective review of all patients who underwent NSM between July 2010 and June 2015 at our institution. Semi-structured telephone interviews were prospectively conducted using the BREAST-Q questionnaire, which measures outcomes in a scale from 0-100 points.

Results: We identified 43 patients who underwent NSM during our study period. The median age of our patients was 47 (range 30-64). Sixteen patients (37%) underwent NSM for prophylactic purposes, while 8 patients (19%) for DCIS, 17 patients (40%) for stage I, and 2 patients (4%) underwent NSM for stage II disease. Tumors with estrogen receptor positivity were the most common with 21 patients (49%), while 2 patients (5%) had HER2 positive disease. Thirty-six patients (84%) underwent an implant-based reconstruction, with 7 (16%) undergoing an autologous reconstruction. Fifteen patients (35%) had adjuvant endocrine therapy while 6 patients (14%) underwent adjuvant chemotherapy, and 1 patient (2%) underwent post-mastectomy radiation therapy (PMRT). Twenty-six out of 43 patients participated in our study with a response rate of 60%. Median overall satisfaction with breasts was 75 (scale 0-100). Psychosocial well-being and physical well-being scores were 80.5 and 81, while the median score for sexual well-being was 42. Overall satisfaction with care was very high, with median scores of 100 for satisfaction with surgeon, medical team, as well as the office staff.

Conclusions: This single center study shows that NSM provides patients with favorable results in domains of psychosocial, sexual, and physical well-being as well as high overall satisfaction. When patients are eligible for NSM from an oncologic safety standpoint, NSM should be considered as a favorable option particularly in domains of psychosocial and physical well-being.

	NSM Patients (n=43)
Median Age in Year	47
Indication for NSM (%)	
Stage 0 BC	8 (19)
Stage I BC	17 (40)
Stage II BC	2 (4)
Prophylactic	16 (37)
Receptor Status	
ER positive	21 (49)
PR positive	19 (44)
HER 2 positive	2 (5)
Reconstruction Technique	
Implant based	36 (84)
Autologous	7 (16)
Adjuvant Treatment	
Endocrine Therapy	15 (35)
Chemotherapy	6 (14)
PMRT	1 (2)

NSM: Nipple Sparing Mastectomy; **BC:** Breast Cancer; **ER:** Estrogen Receptor; **PR:**Progesterone Receptor; **HER2:** Human Epidermal Growth Factor 2; **PMRT**: Post-Mastectomy Radiation Therapy.

Study characteristics

257120 - A case-control study of nipple-sparing versus skin-sparing mastectomy with immediate reconstruction in a teaching hospital

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Background/Objective: Nipple-sparing mastectomy (NSM) for breast cancer or prophylaxis is technically more difficult than skin-sparing mastectomy (SSM). In this study, we sought to evaluate our surgical outcomes 5 years after introducing NSM in the setting of a teaching hospital with a surgical residency and breast fellowship.

Methods: An IRB-approved retrospective chart review was performed on all female patients who underwent mastectomy at UIHC between January 1, 2008 and January 1, 2016. Patient and tumor characteristics, type of mastectomy, indication for surgery, intra- and peri-operative details, complications, and time to adjuvant therapy were obtained with chart abstraction. These variables were then compared between patients who underwent SSM or NSM. Pearson chi squared test and two-sample t-test were used to evaluate associations. Data were abstracted at the breast rather than at the patient level. Intraoperative blood loss was reported for the mastectomy and reconstruction together.

Results: We identified 518 mastectomies within the study period: 135 simple mastectomies, 256 SSM, and 127 NSM. NSM increased from 2.9% to 48.5% of mastectomies with immediate reconstruction (M-IR) from 2011 to 2015. NSM patients were younger (mean age 44.8y vs 48.7y, $p < 0.0006$), had a lower BMI (25.3 vs 28.3, $p=0.0001$), smaller specimen weight (417.3gm vs 611.7gm, $p < 0.0001$) and were more likely to have surgery for prophylaxis than cancer (60% NSM vs 44.8% SSM, $p < 0.001$). Eighty-one percent of NSM were bilateral vs. 62.8% of SSM. The mean mastectomy time was significantly longer for NSM vs. SSM for patients without concomitant axillary surgery ($p=0.032$) and did not decrease over time. Bilateral mastectomies were performed simultaneously by 2 surgeons and did not have a longer operative time ($p=0.356$). Patients undergoing NSM had higher intraoperative blood loss compared to SSM (mean 245.8 cc vs. 156cc, $p=0.0003$), and were more likely to require blood transfusion (8.6% vs. 3.1%, $p=0.019$). Factors predicting higher blood loss for all patients with M-IR included age < 55y ($p=0.002$), ptosis ≥ grade 2 ($p=0.021$), surgeon ($p=0.046$), and bilateral mastectomy ($p < 0.001$) but not

BMI, receipt of neoadjuvant chemotherapy, specimen weight, reason for mastectomy, year of surgery, or mastectomy time. On multivariate analysis, only NSM (β =72.7, p < 0.001), bilateral surgery (β =56.7, p=0.01), and autologous reconstruction (β =74.9, p=0.046) remained significant predictors of blood loss. There was a significant decrease in blood loss between the first and second half of NSM cases (mean 298.8 vs 190.2cc, p=0.0134) but not for SSM patients over time (p=0.06). There was no significant difference between NSM and SSM in rates of infection (5.5% vs. 9.8%, p=0.157), skin flap necrosis requiring reoperation (9.4% vs. 7.4%, p= 0.053), post-operative hematoma (3.1% vs. 6.3%, p= 0.199), or seroma (7.8% vs. 12.8%, p= 0.167). The rate of skin flap necrosis decreased by more than 50% between the first and second half of NSM cases (p=0.031), while other short-term outcomes remained the same. The time from surgery to adjuvant chemotherapy (p=0.65) or adjuvant radiation (p=0.89) was not different between the 2 groups.

Conclusions: NSM was associated with higher blood loss and more transfusions than SSM. Other short-term results and time to adjuvant treatment for cancer patients were comparable. Refinement of surgical technique and patient selection resulted in less blood loss and lower flap necrosis rate over time, but no change in mastectomy time. NSM can be successfully introduced at a teaching institution, with careful attention to surgical outcomes.

Oncoplastic

256644 - A cost-utility analysis comparing large volume displacement oncoplastic surgery to mastectomy with single stage implant reconstruction in the treatment of breast cancer

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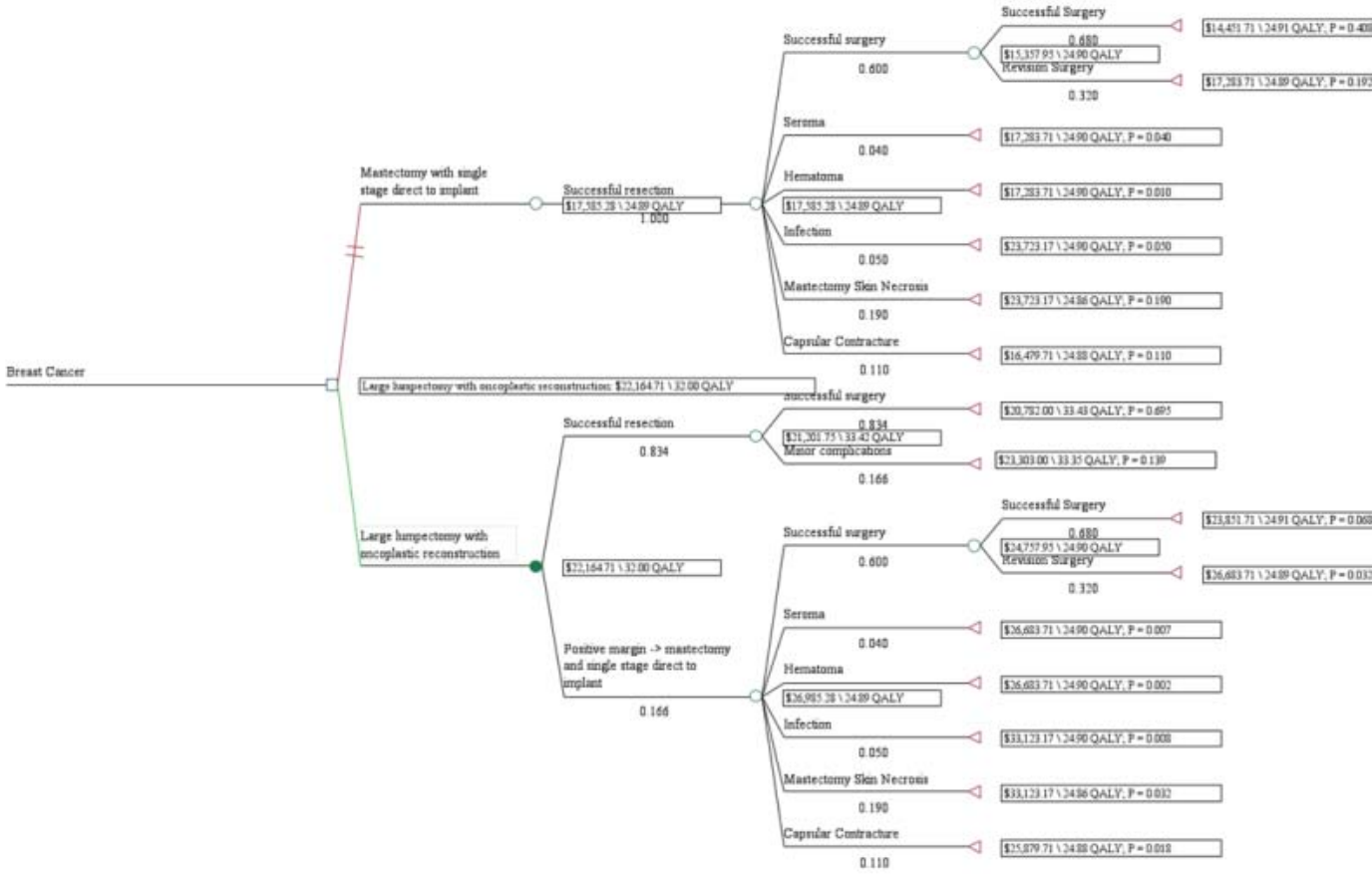
Background/Objective: For larger cancers in moderate- to large-breast sized women, breast surgical cancer treatment may include large volume displacement oncoplastic surgery (LVOS) or mastectomy with single stage implant reconstruction (SSIR). Often in the case of LVOS, reduction mammaplasty designs are used in the oncoplastic reconstructions with a contralateral symmetry operation. The goal of this study was to investigate the cost-utility between LVOS versus SSIR to determine which approach is cost-effective in the treatment of breast cancer. There has been no previous cost nor clinical effectiveness analysis comparing these techniques.

Methods: A review of the literature was performed to calculate probabilities for clinical outcomes for each surgical option (LVOS versus SSIR), and to obtain utility scores that were converted into quality-adjusted life years (QALYs) as measures for clinical effectiveness. For a cost assessment pertaining to outcomes in each surgical option, average national Medicare payment rates using DRG and CPT codes were used. Radiation was assumed as adjuvant treatment in the LVOS arm. A decision analysis tree was constructed comparing LVOS to SSIR (Figure 1) into which these probabilities, QALYs, and costs were placed. An incremental cost-utility ratio (ICUR) was calculated comparing the difference for both surgical options in costs by the difference in clinical-effectiveness to see which surgical option was more cost-effective. To validate our results, we performed one-way sensitivity analyses in addition to a Monte-Carlo analysis.

Results: The decision tree (Figure) shows the associated probabilities, QALYs, and costs for each clinical outcome arising from either the LVOS arm or the SSIR arm. An ICUR of $644/QALY favoring LVOS was calculated based on its clinical-effectiveness gain of 7.11 QALY at an additional cost of $4,579.43 (partly due to the additional costs of radiation treatment and the bilateral operation needed for LVOS compared to no radiation and unilateral surgery for SSIR). This proved that LVOS is a cost-effective surgical option given that a surgical approach is deemed cost-effective if its ICUR is less than $50,000/QALY. One-way sensitivity analyses underscored the degree by which LVOS was cost-effective. For example, LVOS became cost-ineffective when a successful LVOS cost more than $50,000 (more than twice its estimated cost shown in the figure). Similarly, probabilistic sensitivity analysis using Monte-Carlo simulation showed that even with varying multiple variables at once, results tended to favor our conclusion supporting the cost-effectiveness of LVOS.

Conclusions: For the appropriate patients with moderate- to large-sized breasts with breast cancer, large volume displacement oncoplastic surgery is cost-effective in breast cancer treatment compared to mastectomy with single-staged implant reconstruction. This provides yet another reasonable breast conservation surgical option for the breast cancer patient.



Oncoplastic surgery versus mastectomy with single stage implant reconstruction decision tree

257168 - Aesthetic outcome and complications encountered following oncoplastic breast surgery

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Background/Objective: Oncoplastic breast surgery (OBS), which demonstrates similar long-term survival to mastectomy on randomized trials, has become the preferred treatment option over mastectomy for suitable patients largely due to the aesthetic outcome. The aim of this paper is to analyze the occurrence of surgical complications as well as the aesthetic outcome after OBS in breast carcinoma patients with the intention of identifying areas that need improvement for better patient management.

Methods: Ninety-eight patients who underwent OBS in a single surgical unit in National Hospital of Sri Lanka from June 2015 to June 2016 were included in the study. Patients were followed up in the breast care clinic in the post-operative period and were assessed for early and late complications. Aesthetic outcome was evaluated based on scar visibility, breast size, breast retraction, and nipple position using the Harvard scale. Patients and surgeons made an independent score.

Results: The mean age was 46 years with a mean interval follow up period of 9 months post-treatment. The majority (70.4%) had T2 stage disease according to TNM classification. Level 1 OBS was performed in 73.4% of patients while the rest underwent level 2 OBS. Assessment by the surgeon reported a satisfaction level of good to excellent on "scar visibility" and "breast size," with a 69.3% and 72.4% recording respectively; compared to only 45.9% and 38.7% for nipple deviation and breast retraction. The majority of patients (87.7%) reported good to excellent satisfaction with the overall aesthetic outcome of OBS. Common early post-operative complications included seroma formation (42.8%), wound dehiscence (24.4%) and surgical site infection (9.1%). Positive margins were seen in 12.2% who needed re-operation. Among these patients with positive margins, 41.6% requested mastectomy for fear of re-positivity, and 58.3% expressed displeasure of re-surgery. There were 59.1% of patients who developed radiotherapy-induced skin reactions. Two patients presented with local recurrence. Multivariate analysis of factors affecting the aesthetic outcome demonstrated that post-operative wound dehiscence ($p < 0.01$) and re-operation ($p < 0.05$) were significantly associated with poor aesthetic outcome.

Conclusions: More emphasis is required on refining the surgical techniques to minimize nipple deviation and breast retraction, which were the main drawbacks in aesthetic outcome. The incidence of re-operation after OBS is favorable in comparison with global figures. However, the risk of re-operation should be emphasized to patients prior to embarking on OBS.

257326 - Can "extreme oncoplasty" results be replicated?

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Background/Objective: Certain centres develop a reputation for offering specific procedures, but it can be difficult to replicate in other units. "Extreme oncoplasty" refers to reduction mammoplasty with

immediate contralateral symmetrization for women with multicentric or large tumours (> 5 cm) who would otherwise require mastectomy, and has been shown to give acceptable rates of negative resection margins, conversion to mastectomy and local recurrence [Silverstein, 2015]. In the UK, oncoplastic procedures are routinely offered by breast surgeons yet tumours > 5 cm and multicentric disease remain at the limit of, or beyond, most surgeons' indications. Hypothesis: Bilateral reduction mammoplasty (BRM) offers the option of breast conservation, not only with acceptable oncological outcomes, but also with minimal serious surgical complications AND with a good aesthetic result. Aim: To report comprehensive outcome data on "extreme oncoplasty."

Methods: With institutional approval, data were collected on a consecutive series of women undergoing BRM for multicentric tumours or tumours >5 cm from June 2009 to November 2014. Data included clinico-pathological factors, surgical complications (according to Clavien Dindo Classification), oncological and patient-reported outcomes (using the BREAST-Q questionnaire).

Results: Fifty-one patients were eligible. Forty-eight had unilateral therapeutic mammoplasty with immediate symmetrisation, and 3 had bilateral cancer. The median follow-up was 36 months (IQR 27-52). All had grade 2 ptosis or more and a UK cup size of C to J pre-operatively. Mean age was 54.9 years (SD 9.1), median BMI was 29.9kg/m2 (IQR 25.5-34.9, range 22.3-49.2), and 22 patients (43%) had a smoking history. Median tumour size on imaging was 60 mm (IQR 54.5-70, range 50-170); 12 had multicentric disease. Twenty-four patients (47%) received neoadjuvant treatment, (17 chemotherapy, 7 endocrine); none achieved a complete clinical response. Median pathological tumour size was 38.5 mm (IQR 30-50). The median resection specimen weight was 267 g (IQR 183-412). Margin re-excision was required in 6 patients, 2 went on to mastectomy with autologous reconstruction and were excluded from further analysis. Twenty-one (41.2%) women experienced ≥ 1 complication, 18 (35.3%) were Clavien Dindo grade 1 (7) (e.g., delayed wound healing, minor skin necrosis, haematoma, seroma) or grade 2 (11) (e.g., wound infections), all treated non-operatively. Grade 3a complications were rare (3) and mainly on the therapeutic side ($p < 0.05$). Complications were associated with higher BMI, specimen weight, and longer time to radiotherapy ($p < 0.05$). Local recurrence occurred in 1 patient (2%), distant metastases in 3 (5.9%), and 1 has died. Ten patients were excluded from the analysis of satisfaction because of death, metastasis, or living abroad. The response rate to the BREAST-Q questionnaires among the remaining 41 was 48.8% (20 patients). The median score for the "satisfaction with the breast" domain was 75.5 out of 100 (IQR 56-91). Median scores for the other subscales were 89 for adverse effects of radiation, 72 for psychological well-being, 55 for sexual well-being, 64 for physical well-being, and 100 for information and staff.

Conclusions: These UK data closely reflect previous American reports, providing further evidence that BRM can give good local control. In addition, the rate of complications requiring surgical intervention was low. Patient satisfaction with breasts is notably high compared with published series of standard breast conservation (median 68) and breast reconstruction (median 75 for NSM with implant, mean 71.9 for flap reconstruction), perhaps reflecting patients' awareness that mastectomy was the only alternative, or new-found satisfaction with an improved breast appearance.

256541 - The specialist clinical masters qualification in oncoplastic breast surgery: A globally accessible degree supporting clinical excellence

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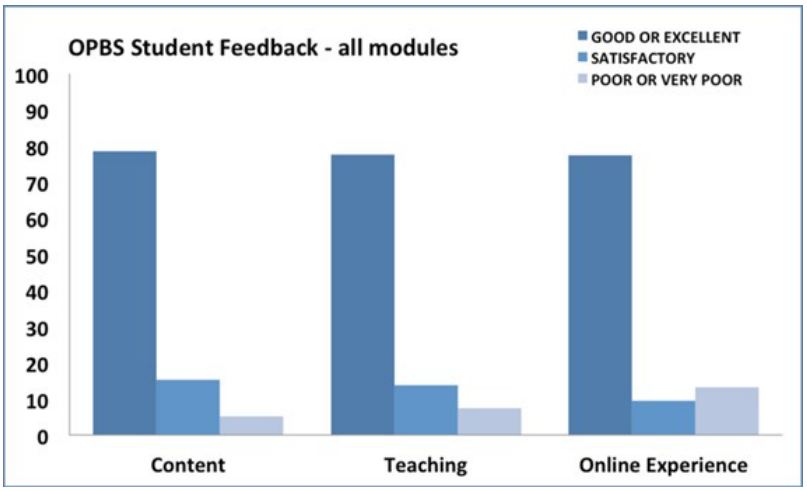
Background/Objective: In 2009, UK surgical trainees (residents) reported widespread dissatisfaction with their training programmes, in part due to new legal restrictions placed on their working hours. We identified a need for accessible and flexible specialist clinical education to complement practical on-the-job experience. The University of East Anglia (UEA), in partnership with the UK Association of Breast Surgery (ABS) and the British Association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS) launched the Specialist Clinical Mastership (SCM) degree in Oncoplastic Breast Surgery in 2010. This unique online course is available internationally to both training and established breast surgeons. A firm prior grounding in breast oncology surgery is required, as the course builds on this knowledge to develop specialist oncoplastic breast reconstruction practice. Clinical knowledge and decision-making is developed utilising problem-based, peer-group learning, enhanced by practical training sessions. Participation is asynchronous, facilitating learning that complements working practice. Now entering its seventh year of delivery, this paper provides an overview of the outcomes of this innovative course.

Methods: Student admissions data were obtained from the University of East Anglia's Admissions Department. Student outcomes were provided by the Learning and Teaching Hub. Student feedback was prospectively collected and analysed by the SCM e-technology team.

Results: To date, 124 students have enrolled in the Oncoplastic Breast Surgery Course, including 22 international students. Ninety-nine students enrolled in the full 3-year Masters course, and 25 in the 2-year Postgraduate Diploma. To date, 38 awards have been achieved: 16 Masters degrees in Oncoplastic Breast Surgery, 6 PG diplomas, and 6 PG certificates. Of the 124 students, 11 students have withdrawn for personal reasons and 7 due to failed assessments. Over 30% of course applications followed positive personal recommendations by a current student. Student feedback has consistently remained high for all aspects of the course (Figure: 2015 student cohort course feedback calculated across all online modules)

Conclusions: The SCM in Oncoplastic Breast Surgery won a Gold Award in 2013 at the annual UK e-learning awards for innovation and quality. Based on this successful model, further Mastership degrees were established in Regional Anaesthesia and Coloproctology. A new suite of specialist professional development (SPD) courses in breast surgery will launch at UEA in 2017. These will utilise the established online components of the SCM programme to provide globally accessible and quality-assured specialist accreditation in breast surgery, supporting appraisal and revalidation processes. For further information regarding SCM and SPD programmes: https://specialist.uea.ac.uk/



Student evaluation of master's degree

257201 - Challenges in utilizing oncoplastic techniques in breast-conserving surgery – A Canadian perspective

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Background/Objective: Oncoplastic breast surgery (OPS) allows for oncologically safe tumour resection while avoiding breast contour deformity and maintaining breast cosmesis. Despite this, these techniques are not routinely used in Canada. This study examines Canadian general surgeons' beliefs and utilization of oncoplastic techniques in breast conserving surgery (BCS).

Methods: A qualitative study exploring general surgeons' knowledge and utilization of OPS in BCS was completed. Purposive sampling identified general surgeons from across Canada who routinely treat breast cancer. Surgeons varied in length/location of practice, extent of training and gender. Data were collected via semi-structured interviews and focus groups. Constant comparative analysis identified key themes.

Results: Data saturation was achieved after 16 interviews. While most surgeons were interested in improving cosmesis and employing OPS, knowledge, beliefs, and access often limited their utilization of these techniques. Lack of knowledge about specific oncoplastic techniques and unfamiliarity with the difference between oncoplastic and reconstructive surgery were identified as limiting factors. Surgeon beliefs were also a factor, as some participants suggested that oncoplastics would not substantially alter patients' cosmetic outcomes. Other surgeons believed that patients are not concerned with cosmesis, therefore, utilizing OPS would not provide a substantial benefit. Many surgeons voiced concerns around the lack of acceptance by their fellow general surgeons, plastic surgeons, and radiation oncology colleagues, feeling unsupported in their attempts to offer OPS. Barriers to access were identified as a third key theme. Many surgeons described having limited access to hands-on training as well as minimal

support when adopting OPS into their practice. A minority of surgeons also expressed concerns around limited access to operating room time and appropriate reimbursement given the increased length of operative time and complexity for oncoplastic BCS.

Conclusions: This study identified multiple challenges faced by surgeons in introducing OPS. Key themes included educational, acceptability, and attitudinal barriers. Overall, most participants had an interest in performing oncoplastic techniques. However, they felt unprepared to utilize them in their surgical practice. Active educational and institutional strategies will be required to overcome the current challenges and improve provision of OPS in the management of breast cancer.

235931 - Estimated percentage of breast volume excision and its relationship with quality of life and satisfaction after breast conservation therapy for breast cancer

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Background/Objective: Breast conservation therapy (BCT) is the preferred surgical approach for patients with early-stage breast cancer. Cosmesis and satisfaction after BCT may be impacted when the estimated percentage of breast volume excised (EPBVE) is greater than 10%. In this study, patient reported satisfaction and quality of life (QofL) after BCT were evaluated for different EPVBE groups. We hypothesized that QofL and satisfaction will be negatively affected as EPBVE increases.

Methods: Patients from a prospectively maintained database treated with BCT (stages 0-III with at least 1 year follow-up), were evaluated after Institutional Review Board approval. Exclusion criteria included incomplete records, bilateral disease, recurrence, or death. Eligible patients were mailed the BREAST-Q BCT postoperative survey, which includes 9 satisfaction and QofL modules. A second mailing and phone call followed if the first survey was not returned. Responses were processed with the QScore software and transformed into summary scores ranging from 0-100. Breast volume (BV) was estimated with a previously validated formula from preoperative mammographic cranio-caudal view measurements (BV=1/3π radius^2 height). Excised breast volume (EBV) was estimated from surgical specimen weights or measurements converted to volume (EBV=4/3πr1r2r3). EPBVE was then calculated ((EBV/BV)x100). Patients were grouped based on EPBVE of < 10% and ≥ 10% and mean scores were compared. Univariate analysis (UA) was performed utilizing two sample T-test and chi-square tests. Analysis of variance (ANOVA) was used to determine the effect of each parameter for satisfaction with breasts. Study was funded by grants from the National Cancer Institute (R25-CA134283) and the American Society of Breast Surgeons Foundation (research grant 2016).

Results: Of 290 patients, 77 met exclusion criteria. Two hundred thirteen patients were mailed the BREAST-Q survey. Eighty-three (38.9%) responses were obtained. UA (EPBVE of ≥10%, n=52 vs. < 10%, n=32) showed that age, location in breast, side, stage, ER status, HER2 status, sentinel or axillary lymph node dissection, chemotherapy, or hormonal therapy use are independent of EPBVE groups. The ≥10% group had greater percentage of adjuvant radiation use (p=0.03), and margin re-excision (p < 0.01). UA demonstrated no significant differences among EPBVE groups' mean scores in all 9 modules: satisfaction with breasts (p=0.22), sexual satisfaction (p=0.32), satisfaction with radiation (p=0.29), psychological satisfaction (p=0.79), physical satisfaction (p=0.79), and satisfaction with information (p=0.31), surgeon (p=0.22), medical team (p=0.92), and non-medical staff (p=0.83). Sexual satisfaction had the lowest response rate of all modules at 32.5% (100% response rate for satisfaction with breasts). ANOVA

demonstrated no statistically significant effect from any of the variables (location, side, stage, chemotherapy use, radiation use, margin re-excision, or EPVBE) for satisfaction with breasts ($p > 0.05$).

Conclusions: In this study, EPVBE ≥10% does not appear to significantly impact satisfaction or QofL after BCT. These results differ from other studies suggesting a negative impact on satisfaction when the percentage of breast tissue resected during lumpectomy exceeds 10%. The relationship between EPVBE, QofL and satisfaction after BCT needs further analysis. Survey based analysis of satisfaction and QofL after BCT are limited by low response rates.

Parameters	EPBVE <10% Mean scores (± Std. dev)	EPBVE ≥10%. Mean scores (± Std. dev)	p Value
Breast Satisfaction	72.30 (20.90)	66.48 (20.85)	**0.22**
Sexual Satisfaction	63.84 (19.46)	58.90 (15.79)	**0.32**
Satisfaction with Radiation	85.76 (16.49)	89.52 (12.70)	**0.29**
Psychological Satisfaction	80.10 (19.10)	78.87 (20.75)	**0.79**
Physical Satisfaction	74.65 (22.64)	75.94 (18.53)	**0.79**
Satisfaction with Information	86.72 (18.06)	82.40 (18.51)	**0.31**
Satisfaction with Surgeon	94.90 (12.37)	89.93 (20.00)	**0.22**
Satisfaction with Staff	95.26 (13.05)	95.93 (13.50)	**0.83**
Satisfaction with Medical Team	94.45 (8.58)	97.70 (12.60)	**0.92**

Breast Q score analysis

256712 - Lateral oncoplastic breast surgery (LOBS) - A new approach: Description of technique and short-term results

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Background/Objective: Oncoplastic breast surgery is one of the most exciting developments in breast conservation surgery (BCS). The technique of current-day BCS is a paradigm shift from the old NSABP 1987 guidelines. New procedures are being described constantly, and only one's imagination can limit this. We describe the surgical technique and short-term results of a new approach to Level I Oncoplasty that we have named Lateral Oncoplastic Breast Surgery (LOBS).

Methods: Between January 1, 2013 and April 30, 2016, 106 females were selected to undergo LOBS in the Department of Surgery, PGIMER, Chandigarh, India. The cohort included patients diagnosed with breast cancer and phyllodes tumour on core biopsy. The selection criteria for BCS were standard and the selection for LOBS was based on tumor location (outer-quadrant tumors). In case of phyllodes tumors, the tumors could extend medially beyond the outer quadrants. Technique: The incision is marked along

the anterior axillary fold and moves downward curving around the breast mound and finishes in the inframammary crease. The lump is marked out, and the patient placed in the lateral decubitus position. The patient is supported in a way that the table can be tilted both anteriorly and posteriorly. The incision is developed along the marked line, and the lateral border of the Pectoralis Major is exposed. The breast is then elevated from the pectoral muscle well away from the tumor. The next mobilization is in the subcutaneous plane similar to elevation of mastectomy flaps. Thus a biplanar mobilization is performed. Tumor resection is carried out and is guided by bimanual palpation of the tumor. Marker clips are placed as standard. The residual defect is closed by direct approximation or by adjusting the residual breast tissue in to the defect ("swinging flaps"). The breast tissue is sutured to the lateral edge of the Pectoralis Major muscle to avoid medial displacement of breast tissue. Axillary clearance is performed through the same incision without changing the position of the patient.

Results: Of the 106 patients in the study, 93 (87.7%) had breast cancer, and 13 (12.3%) had phyllodes tumors. For patients with breast cancer, the median duration of follow-up was 12 months (range 3-30). The mean size of the lump was 2.751±1.37 cm, and the mean weight 70.2±32.42 gm. Three patients had a positive margin. In 2 patients, negative margins were achieved by re-excision while one patient opted for a mastectomy. Surgical site infection was present in 15 (16.12%) patients. Minor marginal necrosis was present in 2 patients. Fat necrosis was diagnosed in 3 patients. In the patients with phyllodes tumors, the median duration of follow-up was 20 months (range 16-23). The mean size of the lump was 8.89±2.01 cm, and the mean weight 359±134.59 gm. One (7.6%) patient suffered SSI. Superficial NAC necrosis occurred in 1 patient. There was no marginal necrosis, or need for re-excision in this group. All patients were satisfied with the cosmetic outcome. In the study duration, there was no local recurrence.

Conclusions: Early trend analysis of results suggests that the technique is oncologically equivalent to conventional BCS. The technique works well for both upper and lower outer-quadrant tumors. Bimanual palpation of tumour during resection allows better definition of tumour margins and minimizes the breast tissue excised. The cosmetic outcome is appreciated by the patient as the scar is not visible from the front in the sitting position. Larger tumors can be removed with this procedure, thus limiting the need for reconstruction by a volume replacement technique. If needed, a mini LD flap can be done without changing the position of the patient. This technique appears to be an easy and valuable addition to the repertoire of a breast surgeon.

257344 - Oncoplastic lumpectomy with accelerated partial breast irradiation for breast cancer care utilizing a cavity evaluation device: A novel surgical approach

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Background/Objective: Breast conservation therapy (BCT) has been described as an effective alternative to mastectomy for the treatment of breast cancer in select patients, and surgical approaches have evolved to include oncoplastic techniques to improve cosmetic outcomes. Oncoplastic reduction mammoplasty (ORM) is one such technique, which combines BCT with reduction mammoplasty. This procedure ultimately leads to unidentifiable surgical margins, often necessitating total mastectomy as salvage therapy in the event of positive margins following ORM. The purpose of the present study is to introduce a variation of ORM, which utilizes intraoperative balloon catheter (IOBC) placement during ORM to allow preservation of the lumpectomy cavity and future placement of a catheter for accelerated

partial-breast irradiation (APBI), if desired. The present study also aims to provide short-term data on the efficacy of this technique.

Methods: Following IRB approval, 78 patients undergoing ORM utilizing IOBC placement between September 2009 and July 2015 were retrospectively identified from the Breast Cancer Database maintained by the USF Breast Health Program. Chart review assessed the rate of positive margins on lumpectomy, negative margins on subsequent resection, and the need for total mastectomy. The secondary outcome of interest was the rate of postoperative wound complications. Data were analyzed using IBM SPSS Statistics 23.

Results: Of the 78 patients undergoing ORM with IOBC placement, 32 (41.0%) had close or positive margins, but only 28 required resection. Of those 28 patients, negative margins were ultimately achieved in 26 (92.9%) patients, and 2 (7.1%) patients required total mastectomy to achieve negative margins. Seventy-three of 78 (93.6%) patients went on to receive APBI. The length of follow-up ranged from 0 to 75 months with a median of 19 months. Local recurrence occurred in 5 patients, and distant metastasis occurred in one patient. Local wound complications occurred in 21 (26%) cases, and included 5 seroma formations, 3 occurrences of nipple necrosis, 7 surgical site infections, and 2 instances of epidermolysis. Thirteen patients required surgical revision due to wound complications.

Conclusions: ORM with CED placement is an improvement on ORM alone based on the short-term data presented. This allows patients to undergo additional direct-margin resection following the index operation without requiring salvage mastectomy. The addition of APBI to ORM did not result in severe wound complications and may be a viable alternative to whole-breast radiation. Long-term data on oncologic outcomes are necessary and will provide an avenue for further study.

	N	%
Margins at Index Operation		
Negative	46	58.9
Close	6	7.7
Positive	26	33.3
Margins on Revision		
Negative	26	92.9
Positive	2	7.1
Conversion to Mastectomy		
Yes	2	2.6
No	76	97.4
Surgical Complications		
Surgical site infection	7	9.0
Seroma	5	6.4
Nipple necrosis	3	3.8
Epidermolysis	2	2.6
Hematoma	3	3.8
Other	6	7.7
Received APBI		
Yes	73	93.6
No	5	6.4

Patient treatment

257183 - Oncoplastic breast surgery experience in a Latin American cancer institute

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Background/Objective: For the last 20 years, the trend for achieving a good cosmetic result following a breast-conserving therapy (BCT) has given rise to oncoplastic surgery (OPS), which combines plastic surgery techniques with oncological clear margins. It is a third surgical weapon for breast diseases besides mastectomy or BCT. In 2012, OPS was introduced as a surgical standard treatment for breast cancer and allied diseases at the National Cancer Center of Peru (INEN). Annually, we take care of 1,200 new cases, and only 5.6% are DCIS, having the great majority T2-T3 tumors. The goal of this study is to analyze a subgroup of patients treated with different OPS techniques between 2012-2015 at INEN.

Methods: We reviewed retrospectively the INEN database for breast cancer and allied diseases treated with OPS between January 2012 and December 2015. We collected demographics, tumor characteristics, OPS techniques, local and systemic adjuvant treatment, follow-up, complications, recurrency, and mortality rates for each case. Surgeries were performed only by breast surgeons properly trained under the OPS philosophy, including residents. In some cases, we did OPS after neoadjuvant chemotherapy. We excluded inflammatory carcinoma and breast-feeding at time of surgery. All patients were classified by AJCC 7th edition.

Results: Of 586 patients, we found 129 (22%) OPS cases. All patients were Peruvian females, no Caucasians. Mean age at diagnosis was 53 years (range 20-81), 58 patients (45%) were < 50 years old. Eighty-four cases (65%) were T2, and 45 cases (35%) were T1. ER (+) status in 90 patients (69.8%) and 37 patients (29.1%) had HER2 (+) status by IHQ. One hundred twenty-six patients (97.7%) had a diagnosis of carcinoma,and 3 patients (2.3%) had benign phyllodes tumor. Ninety-seven patients (75.2%) underwent surgery as primary treatment and then received standard systemic chemotherapy. Sixteen patients (12.4%) received neoadjuvant chemotherapy and then OPS. One hundred and six patients (82.2%) underwent complimentary radiation therapy. The OPS technique most frequently used was the round block in 55 patients (42.6%), followed by lateral mammoplasty with NAC re-centralization in 24 patients (18.6%), vertical mammoplasties in 22 patients (17.1), batwing in 8 patients (6.2%), the Grisotti technique in 8 patients (6.2%), centralectomy in 4 patients (3.1%), and adipofascial flap in 3 patients (2.3%). We found 5 patients (3.9%) had not-specified technique in the surgical report. With the aid of plastic surgeons, 11 patients (8.5%) had symmetrization surgery at the same time of OPS. We achieved clear margins in 117 patients (90.7%) in a single-time procedure, with less than 10% of patients requiring a second surgery: 5 patients underwent re-excision surgery, 3 patients underwent completion mastectomy, and 1 patient underwent modified radical mastectomy. Two patients (1.5%) had complications, 1 with surgical site infection and 1 with surgical wound dehiscence. In both cases, they were managed without further complications. Three patients (2.3%) recurred, 2 of them had >2cm primary tumor size, 2 of them were triple negative with high ki-67 index, and 1 of them had compromised margins. One patient died of disease progression. Mean follow-up was 20 months (range 1-65 months).

Conclusions: The OPS is a great surgical option when performed by trained breast surgeons in the properly selected patient, for achieving the oncologic and cosmetic results that most patients and surgeons expect, preserving good overall survival comparable with BCT and mastectomy.

Batwing with contralateral symmetrization with same pattern

Phyllodes

236904 - Association between recurrence and presence of residual tumor in patients with phyllodes tumors undergoing re-excision for close and positive margins

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Background/Objective: Phyllodes tumors (PT) are fibro-epithelial tumors of the breast for which wide local excision (WLE) has been recommended due to risk of local recurrence. Lesions not sampled prior to surgery or initially diagnosed as fibro-epithelial lesions (FEL) on core biopsy may have a diagnosis of phyllodes tumor on excision. Historically, re-excision for close or positive margins has been the standard of care. Re-excision can be problematic in some patients. This study examines the rate of residual phyllodes tumor in patients undergoing re-excision for close or positive margins and compares recurrence rates among patients undergoing re-excision versus observation.

Methods: From an institutional pathology database, we identified all patients with phyllodes tumor diagnosed between 2003 and 2013. A total of 246 cases were identified. Operative and surgical-pathology reports were reviewed to collect clinical, pathologic, and follow-up data.

Results: Among 246 cases, 144 (59%) had a documented core biopsy result, and 102 (41%) were operated for radiological or clinical breast lesions without core biopsy. Among patients who had core biopsy, the majority (72%) were initially diagnosed with FEL, 11 % PT and 12% fibroadenoma. Two hundred forty-three patients had WLE, and 3 patients had mastectomy. On final pathology, there were 216 (88%) benign PT and 30 (12%) borderline/malignant tumors. Among patients with benign PT

(n=216), margins were negative in 64 patients (29.6%), 50 (23%) had close margins, and 102 (47%) had positive margins. Of those with close margins, 22 (44%) underwent reexcision, and residual benign PT was found in 2 cases (9%). Among the patients with positive margins, 45 (44%) had re-excision, and residual benign PT was detected in 4 patients (8.8 %). After a median follow-up period of 35.5 months (range 0.16- 157.7), there were 4 (1.9%) recurrences among patients with benign PT. Two underwent re-excision for close and positive margins, and 2 recurred after initial excision with negative margins. There was no difference in recurrence among patients who had re-excision for positive or close margins versus observation (p=0.7 & 0.21) (Table). All recurrent cases were managed with wide excision.

Conclusions: The overall rate of residual benign phyllodes tumor in patients undergoing re-excision for close margins was 9% and positive margins 8.8%. Among patients with close or positive margins, there was no significant difference in disease recurrence between patients who underwent re-excision and those who were observed. It may be reasonable to manage these patients conservatively with close follow-up.

	Close margins n=50		Positive margins n=102		Negative margins n=64
	Re-excision		Re-excision		
	YES	NO	YES	NO	
N	22	28	45	57	
Recurrence	0	1	1	0	2
P-value	0.21		0.7		-

*Recurrence status was unknown for 6 patients with close margins and 22 patients with positive margins

Recurrence rate among patients with benign phyllodes tumor

256707 - Phyllodes breast tumors: A review of a single Saudi institution experience

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Background/Objective: Phyllodes tumors (PT) are rare fibroepithelial neoplasms, accounting for about 0.5% of all primary breast tumors. The study aimed to evaluate the local recurrence, distant metastasis, mortality, and overall survival rates of PT cases.

Methods: Retrospective analysis of the clinical, pathological, and therapeutic data of 45 patients with a PT who were treated between January 2000 and December 2015 at a single Saudi institution. Tumors were classified into benign (21 cases), borderline (6 cases), and malignant (18 cases) according to the criteria proposed by the World Health Organization.

Results: The median follow-up period was 35 (7-185 months). The median age was 37 (19-62 years). The median tumor size was 9.2 (2.3-25cm). Surgery consisted of wide local excision in 27 cases (60%), simple mastectomy in 14 cases (31.1%), and nipple-sparing mastectomy in 4 cases (8.9%). The surgical margins were positive in 12 cases (26.7%). While, the overall rate of local recurrence for the entire group was

8.9% (4 cases), it was 4.7% (1 case) for benign PT, and 16.6% (3 cases) for malignant PT. Distant metastasis developed in 5 patients with malignant PT; thus the distant metastasis rate was 11.1% for the entire group and 27.8% for the group with malignant PT. There were 2 mortality cases among those affected with malignant PT. Therefore, the mortality rate was 4.4% for the entire group and 11.1% for the group with malignant PT.

Conclusions: Our experience suggests that adequate surgery with negative margins is the treatment of choice.

257289 - Racial/ethnic disparities in malignant phyllodes tumors of the breast: Analysis of the National Cancer Database, 1998-2012

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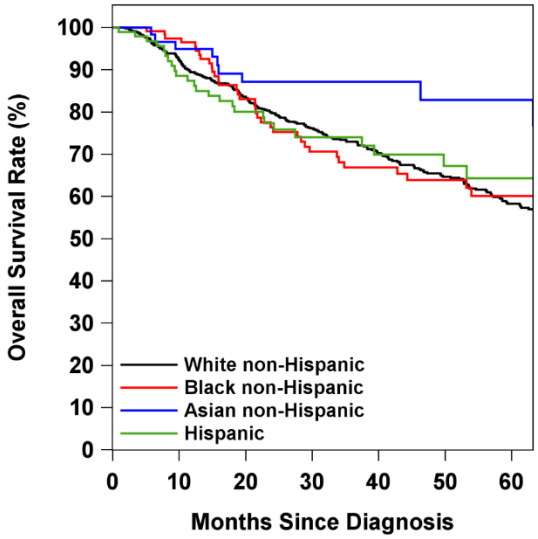
Background/Objective: Malignant phyllodes tumors (MPTs) are often excluded from studies examining racial/ethnic (RE) differences in breast cancer. Small-scale studies, representing limited geographic locations, suggest some RE groups have worse MPT-related outcomes. In this study, we hypothesized that large-scale RE disparities would not be evident in MPT presentation, treatment or overall survival (OS).

Methods: Using the National Cancer Database, RE differences in patient, geographic, tumor, and treatment characteristics were tested for among women diagnosed with MPTs of the breast during 1998-2012. Predictors of tumor size and disease stage at diagnosis, treatment regimen, time to treatment initiation, and OS were identified via stepwise variable selection using Poisson, cumulative logit, generalized logit, and proportional hazards models.

Results: Among 4,133 patients with MPTs, White non-Hispanics (WNH) were older at diagnosis (mean age 54.3 years) than all other RE groups (46.6-48.5 years). Black non-Hispanics (BNH) showed greater prevalence of comorbidities and, along with Hispanics (HIS), were more typically uninsured and residing in areas of lowest median income and highest high school dropout rates. Conversely, more Asian non-Hispanics (ANH) and WNH had private insurance and their majorities resided in areas of the highest income bracket. Significant predictors of tumor size at diagnosis included all 12 examined patient and geographic factors. Adjusted mean tumor size was 13-27% greater for ANH than BNH (1.13x, 95% confidence interval [CI] 1.10-1.16), WNH (1.20x, 95% CI 1.18-1.23), and HIS (1.24x, 95% CI 1.24-1.30) patients. Predictors of disease stage at diagnosis included insurance type, RE group, year of diagnosis and proximity to a metropolitan area. While disease stage did not significantly vary among WNH, BNH, and HIS patients, the probability of higher disease stage was 2x greater in ANH than WNH (OR 2.11, 95% CI 1.42-3.14), BNH (OR 1.96, 95% CI 1.25-3.07), and HIS (OR 2.04, 95% CI 1.28-3.23) patients. Predictors of treatment regimen (surgery, radiotherapy, and systemic therapy) included nodal status, tumor size, and RE group. ANH patients were 2x more likely to undergo total rather than partial mastectomy when compared to all other RE groups. In contrast, time to treatment initiation did not depend on RE group; significant effects included insurance status, nodal status, and population size (metropolitan area, urban, or rural). Patients with private insurance versus no insurance (HR 1.41, 95% CI 1.06-1.88) and living in an urban area versus living in a metropolitan area (HR 1.27, 95% CI 1.02-1.58) were more likely

to initiate treatment. Lastly, predictors of OS included nodal status, patient age, surgery (none, partial, or total mastectomy), tumor size, comorbidity index, radiotherapy, regional location of hospital facility, and RE group. Risk of death was 4x greater for BNH than ANH patients (HR 4.06, 95% CI 1.01-4.28). Reflecting this pattern, adjusted estimates of 3-year OS were 87.1% (95% CI 76.0-99.9%) for ANH, 74.0% (95% CI 58.2-94.3%) for HIS, 73.0% (95% CI 58.3-91.4%) for WNH, and 66.9% (95% CI 48.9-91.4%) for BNH patients.

Conclusions: Like breast cancers of epithelial origin, RE differences in presentation, treatment and outcome exist in women with MPTs. Determination of whether these differences are attributable to socioeconomic factors leading to later presentation versus tumor biology requires further investigation.



Racial/ethnic survival patterns for women diagnosed with malignant phyllodes tumors of the breast

Radiation

256806 - Impact of a 3-D bioabsorbable implant on the rate of breast-conserving surgery: Review of 1067 breast cancer patients in the private practice setting

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Background/Objective: Increasing use of oncoplastic procedures has helped to improve aesthetic outcomes with breast conservation surgery. However, relatively few surgeons are well versed in these techniques. Those who consistently do use tissue re-arrangement caution others about the difficulty this may create for radiation targeting. A novel 3-dimensional (3-D) absorbable device sutured to the margins of the tumor bed during lumpectomy facilitates use of oncoplastic techniques, provides an easily recognizable method for marking the tumor bed, and may help to increase the number of women eligible for breast conservation. We examined the number of women in our practice receiving Breast Conservation Surgery (BCS) in the 3 years prior to, and following the routine use of this implantable marker device in our practice.
Methods: One thousand and sixty-seven consecutive patients undergoing surgery for breast cancer were examined from Jan 1st 2011 through October 31, 2016 (70 months). Demographic information,

stage and type of disease, surgical treatment, re-excision rate, type of radiation therapy used, use of oncoplastic techniques, and cosmetic outcome were analyzed. BCS as a percentage of all breast cancer patients surgically treated at our practice was recorded. The BCS percentage for 2011-13 was compared to the BCS percentage for 2014-16 to determine whether the use of the bioabsorbable implant marker (introduced into our practice mid-2012) had any impact on the rate of BCS in our practice. The implantable marker device (BioZorb, Focal Therapeutics, Aliso Viejo, CA) was utilized in conjunction with oncoplastic techniques during surgery and was subsequently used by radiation oncologists for boost or PBI planning for radiation therapy. Method of radiation therapy delivered was also recorded.

Results: The rate of BCS for the 2011-2013 time period was 35.7%, whereas the rate of BCS for the 2014-16 time period was 45.6% (a 27.7% increase). Early reports regarding cosmetic appearance of the breast with use of the marker during BCS show a trend for excellent or good cosmesis in over 90% of patients, as judged by both physicians and patients. An increase in the routine use of hypofractionation in our BCS patients has also been noted with routine use of the device.

Conclusions: We found this device facilitated use of oncoplastic techniques by providing a 3-D structure with a degree of volume replacement that could support tissue flaps when sutured directly to the tumor bed margin. In addition, the marker provided a consistent method to clearly identify the tumor bed for radiation planning even after extensive tissue re-arrangement within the breast. The increased rate of BCS seen in our practice in the years following adoption and routine use of the device is likely a result of the favorable cosmetic outcomes achieved combined with the increased use of hypofractionated (shorter course) radiation therapy.

221000 - The use of hypofractionated radiation therapy in a large, multi-state community-based physician practice

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Background/Objective: Hypofractionated radiation therapy is a clinically efficacious short course of treatment for patients with early-stage breast cancer treated with breast-conserving surgery that is underused in the United States as compared to Canada and the United Kingdom. The purpose of this study was to examine the use of hypofractionated radiation therapy over time in a large, multi-state privately owned, community-based radiation oncology practice in the United States.

Methods: This cross-sectional study utilized a cancer database abstracted from patients' records, and maintained by a private, for-profit radiation oncology physician group. The sample of patients was restricted to women who met the criteria for hypofractionation as specified in ASTRO guidelines: age 50 and older, with negative lymph nodes, following BCS for early-stage invasive breast cancer or ductal carcinoma in situ (DCIS), and having had no chemotherapy treatment. The years 2004 through 2013 were included. Bivariate associations of patient, geographic location, and tumor variables were tested with the Pearson's chi square test. Covariates found through bivariate analysis to be associated with hypofractionation with p-values of < 0.5 were included in a multivariate logistic regression model, with the addition of tumor grade which is an important clinical finding that has been found to be associated with the effectiveness of hypofractionated RT. The logistic regression model was used to identify an association between covariates and the odds of receiving hypofractionation therapy.

Results: Of the 5,959 women in the database, 230 or 3.86% of the total cases received hypofractionated RT. The number of women that were treated with the shorter course of radiation increased over the study period, from 5 patients (1.4% of total patients) in 2004 to 55 patients in 2013 (8.76% of total patients) ($p < .001$). In the logistic regression model, the significant factors related to the use of the shorter course of treatment were age, with older women more likely to receive hypofractionation, particularly women over 80 years of age (OR 7.14; 95% CI 3.61- 14.1; $p < .001$), facility location, with the West as the area in which women were most likely to receive hypofractionation (OR 7.93; 95% CI 4.01-15.66; $p < .001$), and year of surgery with 2013 as the year in which a woman's chance of receiving hypofractionation was highest (OR 6.94; 95% CI 2.60-18.49; $p < .001$).

Conclusions: A significant majority of patients for whom hypofractionated RT would be appropriate received conventional RT throughout this study period. In regards to age, the shorter course of treatment was primarily used for women over the age of 80. This finding is consistent with that found in other recent US studies. The geographic variation that was found in this study is consistent with Wang and colleagues, in which the regions of the country with the greatest use of hypofractionation were the West and the Midwest. The increase in the use of the short course of treatment over the course of ten years is consistent with recent US studies, and is consistent with the typical diffusion of medical innovation which will show an increase over time. Given that the trend of hypofractionated RT use has been found to be slowly increasing in the US, future studies are needed to demonstrate the factors that are facilitating or impeding continued adoption of this medical innovation in the US.

Table 2 Odds ratios for receipt of conventional fractionation versus hypofractionation from the logistic regression model

Covariate	(reference)	OR	95% CI	P
Age	50-59			
60-69		1.32	.885-1.99	.170
70-79		2.77	1.86-4.12	<.001*
80+		7.14	3.61-14.10	<.001*
Marital Status	Divorced			
Married		.755	.470-1.21	.248
Widowed		.918	.534-1.57	.758
Single		.945	.520-1.71	.854
Unknown		.437	.202-.945	.036*
Median income quartile	<$30,000			
$30,000-$35,000		2.37	.704-8.00	.163
$35,001-$45,999		2.29	.689-7.60	.176
$46,000-$100,000		2.45	.756-7.94	.135
> $100,000		2.10	.538-8.22	.285
Facility location	Mid Atlantic			
Northeast		2.95	1.46-5.97	.003*
South		2.41	1.24-4.66	.009*
Midwest		5.55	2.76-11.11	<.001*
West		7.93	4.01-15.66	<.001*
Year of diagnosis	2004			
2005		.645	.184-2.25	.493
2006		1.13	.386-3.31	.821
2007		.928	.305-2.82	.896
2008		1.37	.499-3.76	.540
2009		2.88	1.08-7.68	.034*
2010		3.20	1.19-8.63	.021*
2011		2.50	.896-6.97	.080
2012		4.34	1.60-11.81	.004*
2013		6.94	2.60-18.49	<.001*
Grade	Unknown			
Well differentiated		1.11	.698-1.77	.650
Intermediate differentiation		.775	.493-1.21	.269
Poorly differentiated		.994	.607-1.62	.983
Undifferentiated		2.58	.853-7.82	.093
ER receptor	Unknown			
Negative		.979	.486-1.97	.955
Positive		1.07	.616-1.86	.806
Her2 result	Unknown			
Negative		.900	.617-1.31	.587
Positive		.202	.027-1.49	.117

Abbreviations: CI = confidence interval; OR = odds ratio; Other abbreviations as in Table 1

Odds ratio for receipt of conventional fractionation versus hypofractionation from the logistic regression model

256842 - Post-lumpectomy radiation therapy for DCIS: A single-institution's experience

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Background/Objective: In a time when clinicians are attempting to identify a cohort of patients with ductal carcinoma in situ (DCIS) who will benefit most from post-lumpectomy radiation therapy (RT), tools have been developed to quantify patients' risk for in-breast recurrence. These tools have not yet been integrated into standard use. At our institution, the recommendation for RT after lumpectomy for DCIS is guided by established clinicopathologic factors and reviewed by a multi-disciplinary group. The purpose of this study was to compare the clinicopathologic characteristics and outcomes of post-lumpectomy DCIS patients with and without RT at our institution.

Methods: The Institutional Breast Cancer Database was queried for all women who were diagnosed with DCIS from 2010-2016. Variables included age, method of presentation, risk factors, tumor and treatment characteristics, and ipsilateral breast tumor recurrence (IBTR). Statistical analyses included Pearson's Chi Square and Fisher's Exact Tests.

Results: Of 480 women with pure DCIS and no prior history of breast cancer, 350 (73%) underwent lumpectomy. The median follow-up was 4 years, and median age was 60 years. Two hundred thirty-six (67%) women underwent RT following lumpectomy. Compared to women who did not undergo RT, these women were younger (p=0.003), had larger tumor size (p=0.0008), higher grade (p=0.0006), and comedo features (p=0.03). Women who underwent post-lumpectomy RT had an IBTR rate of 2% vs. 4% (p=0.32) with no RT. The 10 patients with early IBTR in both groups were younger (median age 54 years), and all had intermediate- or high-grade DCIS. Of the 114 patients who did not undergo adjuvant RT, 70 (61%) met the RTOG 9804 criteria for omission of adjuvant RT. Of the 44 patients who did not receive adjuvant RT and did not meet RTOG 9804 criteria, 20 declined RT, and 24 were not referred.

Conclusions: Within a relatively short follow-up period, we found a very low overall rate (3%) of IBTR for our patients who underwent lumpectomy for DCIS. These results are consistent with previously published trials on post-lumpectomy RT in DCIS. RT at our institution is recommended based on well-established clinicopathologic factors and multidisciplinary care. Considering the low recurrence rates, we recommend continuing the current trend of using published criteria and multidisciplinary review. It remains to be seen to what extent the newly developed recurrence tools, such as Oncotype DX ® Breast DCIS Score™, will improve upon these short-term recurrence rates.

256175 - Four-year results of a single site X-ray IORT trial for early breast cancer

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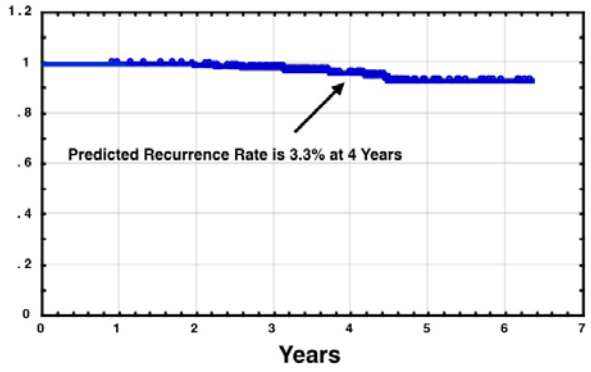
Background/Objective: Two prospective randomized trials, TARGIT-A and ELIOT, have shown intraoperative radiation therapy (IORT) to be a safe alternative to whole-breast radiation therapy following breast-conserving surgery for selected low-risk patients. However, minimal data are available about the clinical effectiveness of this modality of treatment using the Xoft® Axxent® Electronic Brachytherapy System® (Axxent System). To address the lack of data, we instituted a single site prospective IORT trial utilizing the Axxent system.

Methods: Two hundred and one patients with 204 distinct breast cancers were enrolled in a prospective X-ray IORT trial at Hoag Memorial Hospital Presbyterian from June 2010 to September 2013. Prior to surgery, all patients had tumor spans ≤ 30 mm in greatest extent as determined by mammography, ultrasonography, and MRI. All tumors were treated with breast-conserving surgery and IORT. To be eligible for IORT as the sole adjuvant radiation therapy, final pathology had to confirm tumor extent ≤ 30 mm, tumor margins ≥ 2 mm, no evidence of extensive lymphovascular invasion, and negative lymph nodes (isolated tumor cells were acceptable). Data were collected at 1 week, 1 month, 6 months, 1 year, and yearly thereafter.
Kaplan-Meier analyses were used to estimate recurrence-free survival.

Results: To date, there have been 7 ipsilateral breast tumor events (3 DCIS and 4 invasive), no regional or distant recurrences, and no breast cancer-related deaths. One ipsilateral breast tumor event was within the IORT field, 4 outside of the IORT field but within the same quadrant as the index cancer, and 2 were new biologically different cancers in different quadrants. Three of 7 events were in patients who deviated from the protocol criteria. With a median follow-up of 45 months, Kaplan Meier analysis projects 3.3% of patients will recur at 4 years. If only same quadrant recurrences are considered, the Kaplan Meier analysis predicts 2.7% of patients will recur at 4 years.

Conclusions: The recurrence rates observed in this trial were comparable to those of the prospective randomized TARGIT-A and ELIOT trials as well as the retrospective TARGIT-R trial. The low complication rates previously reported by our group as well as the low recurrence rate reported in this study supports the cautious use and continued study of IORT in selected women with low-risk breast cancer.



Local recurrence-free survival

257036 – 3-D implantable marker provides benefits for radiation targeting and cosmesis

Cary Kaufman[1], Michael Cross[2], Nayana Dekhne[3], Kiran Devisetty[4], Dave Edmonson[5], Jennifer Gass[5], Cathy Graham[6], Linsey Gold[7], Sharad Goyal[8], William Hall[9], Robert Hong[10], Scott Jones[11], Robert Kuske[12], Sonali Pandya[5], Rogsbert Phillips[13], Steven Schonholz[14], Linda Smith[15], Lorraine Tafra[16]
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Background/Objective: Post-lumpectomy deformities of the breast occur in more than 30% of patients. Post-treatment correction of these defects is difficult, thus, there is a true opportunity for new surgical and radiation techniques to help improve patient outcomes. Oncoplastic techniques have provided some improvement; however, the extensive tissue re-arrangement during these procedures can result in a negative impact on radiation targeting. A unique 3-D implantable marker was designed to provide improved targeting, some degree of volume replacement and function as a tool for permanent marking of the tumor bed for long-term surveillance. We studied the effect of the device on visualization of the lumpectomy tumor bed during radiation targeting, its impact on boost treatment volumes, and impact on cosmetic outcome over a 3-year follow-up period.

Methods: Following informed consent, eligible patients undergoing breast conservation with implantation of the bioabsorbable 3D implantable marker (BioZorb, Focal Therapeutics, Inc – Aliso Viejo, CA) were enrolled in a multi-center clinical registry. A total of 395 patients have been enrolled from 12 centers over the past 4 years (296 with follow-ups reported). Data include patient demographics, breast size, tumor characteristics, surgical and radiotherapy techniques, cosmesis, and follow-up. In each case, the device was sutured directly to the margins of the tumor bed during lumpectomy with or without oncoplastic closure techniques. The marker was utilized for boost or partial-breast irradiation (PBI) planning or treatment targeting.

Results: Data on 296 patients with median follow-up 10 months (FU: 42% 0-12 months, 23% 12-24 months, 10% 24-48 months) was collected analyzed for this study. Median age was 64 years, 82% of women were postmenopausal, and 58% had one or more comorbidities. Breast size was evenly distributed between cup size B (29%), C (32%) and >D (35%). Cancers were in-situ (20%) and invasive (79%) measuring T1 (59.2%) and T2 (19.1%). Oncoplastic rearrangement with the implantable marker was used on 92% of patients at the time of lumpectomy (20.7% with minor mobilization of local tissue flaps, 71.5% with moderate/extensive tissue rearrangement). Re-excision (including mastectomy for extensive disease) occurred in 8.9% of patients. Infections occurred acutely (0-6 wk) in 6 patients, and in 1 patient the device was removed during surgical debridement of the postoperative infection. No cancer recurrences have been reported. The device was utilized by radiation oncologists for boost or PBI planning and treatment. Early reports regarding cosmetic appearance show a trend for excellent or good cosmesis (93% and 93%, 0-12 months post-surgery) as judged separately by both physicians and patients.

Conclusions: These early findings suggest excellent cosmesis can be achieved in the vast majority (>90%) of patients undergoing BCS and implantation of this unique device. The combination of improved radiation planning and targeting to decrease treatment volumes and the 3D structure providing volume replacement and a mechanism for tissue ingrowth are likely factors contributing to the excellent cosmesis reported in these patients.

257122 – Long-term value of 3-D bioabsorbable tissue marker on radiation planning and targeting, cosmesis, and follow-up imaging

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Background/Objective: Early breast cancer is most often treated with breast-conservation lumpectomy followed by radiation therapy. With long-term survival, desired outcomes include both cancer survival and optimal cosmetic results. Despite oncoplastic surgery and focused radiation techniques, some patients will be left with less-than-optimal cosmetic results. Accurate radiation targeting may decrease the overall volume of breast tissue treated, helping to decrease the negative cosmetic effects of radiation. We used a 3-D bioabsorbable marker (3DM) to aid in radiation targeting and have followed the long-term results on cosmetic outcome and follow-up imaging.

Methods: Between May 2014 and September 2016, we implanted a 3DM in 79 patients at lumpectomy for breast cancer often combined with oncoplastic reconstruction (reconstructive lumpectomy). Radiation oncologists assessed impact on radiation planning and targeting. Of the entire group, 36 patients have been followed for at least 1 year with serial exams, follow-up mammograms, and assessment of cosmesis by clinician and patients.

Results: All 79 patients were evaluated for use of the 3DM. There were no cancer recurrences nor problems with the 3D requiring removal in any patient. Overall, radiation oncologists felt 3DM was useful for treatment planning in 85% of patients. The figure demonstrates the value in planning and targeting by radiation oncologists. Use of 3DM targeting for boost or partial-breast irradiation occurred in 69%. The 3DM allowed more exact targeting in patients receiving boost or partial-breast radiation, allowing treatment volumes to decrease by an average of 24% in partial-radiation patients. Of the 36 patients who have completed at least 1 year of follow-up, cosmesis was rated as excellent/good by clinicians (96%) and patients (96%). Mammograms taken at 1 year revealed minimal increase in fibrotic density in the area of the 3DM when compared with the similar area on the opposite breast.

Conclusions: Use of a 3DM bioabsorbable marker positively contributes to radiation treatment planning and targeting. This is followed by long-term excellent/good cosmetic results with minimal changes on mammograms. Use of 3DM is associated with a positive long-term effect on breast cancer patients receiving breast-conserving surgery. An ongoing registry study using 3DM may verify these findings in multiple centers.

OVERALL Evaluation	
Visibility	
Easily seen	100%
Useful for Treatment Planning	
Useful	85%
Useful in hypofraction regimen	
Very or fairly useful	65%
TARGETING for BOOST	
Easily seen	100%
Useful in boost planning	93% very or fairly
Accuracy improvement	100% useful
Useful for field in field	53% very or fairly
Useful during boost setup	60%
Overall benefit	Very useful 60%
	fairly useful 20%
	somewhat 13%
	not 7%
TARGETING for PBI	
Easily seen	100%
Useful in PBI planning	88% very or fairly
Reduce PTV	63% able to reduce
Percent reduction in PTV	24% average
Useful for hypo fx regimen	100%
BZ used for set up	100%
How Useful was BZ?	Very useful 100%
Cosmesis assessed by Provider @ 1 year	
Excellent	70%
Good	26%
Fair	4%
Cosmesis assessed by Patients @ 1 yr	
Excellent	70%
Good	26%
Fair	4%
Impact of 3DM on cosmesis @ 1 year	
Very important	35%
Significant	62%
None	3%
Palpable to patient @ 1 year	
No	76%
Barely	12%
Yes	12%
Tender to touch @ 1 year	
None	90%
Minimal	5%
Yes	5%

Radiation oncologist assessment and long-term results

257394 - Feasibility of intraoperative radiation therapy using CT-guided high-dose-rate brachytherapy without a fully integrated brachytherapy suite

Melissa Lazar[1], Adam Berger[2], Gina Petroni[3], Theodore Tsangaris[2], Pramila Anne[1], Nicole Simone[2], Bruce Libby[3], Timothy Showalter[3], Shayna Showalter[4]
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Background/Objective: Accelerated partial-breast irradiation (APBI) is becoming a popular choice as an alternative to whole-breast irradiation in patients with early-stage breast cancer. Intraoperative radiation therapy (IORT) is a form of APBI that allows for the delivery of a single fraction of radiation at the time of breast-conserving surgery (BCS). Currently available methods of IORT have been criticized due to lack of image-guided treatment planning and poor dosimetry resulting from the use of low-energy photons. At another institution that has an HDR brachytherapy suite and in-room computed tomography (CT), a novel form of breast IORT was developed. This allows for customized treatment

planning and delivery of a higher prescription dose. The procedure and IORT treatment all take place in a fully integrated brachytherapy suite. We sought to test the feasibility of this method of IORT at our institution that does not have a fully integrated brachytherapy suite.

Methods: A feasibility study at a second site was designed to be incorporated into an ongoing prospective Phase II trial. Eligibility criteria included patients 45 years or older with invasive or situ breast cancer with a tumor size < 3 cm and N0 disease. Patients were eligible before (pre-pathology) or within 30 days (post-pathology) of their BCS. BCS was performed in a same-day procedure unit. A multilumen brachytherapy balloon was placed in the lumpectomy cavity and filled to an appropriate volume. Cavity conformance was assessed using ultrasound. Following discharge from the same-day procedure unit, the patients walked to the radiation oncology department and underwent CT imaging, treatment planning, and HDR brachytherapy to a dose of 12.5 Gy (to 1-cm depth from the balloon surface) was delivered. Following treatment, the balloon was deflated, and the catheter was removed. The primary endpoints were feasibility and acute toxicity. Feasibility was defined as being able to deliver protocol treatment in 12 of the first 15 patients accrued to the study.

Results: Sixteen patients were consented for the study, and 1 was found to be ineligible. Fifteen patients were enrolled in the study. The median age of patients enrolled was 64 (range 49 to 72 years old). There were 7 Caucasian patients, 9 African American patients, and 2 Hispanic patients. Fourteen of the patients were treated in the pre-pathology cohort, and 1 was treated in the post-pathology cohort. All patients were able to receive protocol-directed therapy (95% CI 78, 100%), and thus the study was deemed feasible. Two patients had adverse events; 1 patient developed a seroma after surgery requiring oral antibiotics and aspiration, and 1 patient developed wound breakdown requiring local wound care.

Conclusions: For patients with early-stage breast cancer, HDR brachytherapy with CT guidance is feasible and safe in a setting without an integrated brachytherapy suite. Our novel approach to breast IORT incorporates image guidance and allows for a higher radiation dose than conventional IORT and is currently being evaluated in a prospective phase 2 trial.

227178 - Placement of the BioZorb® marker is associated with smaller irradiated tumor bed in patients receiving breast-conserving therapy

Kunal Sindhu, Jaroslaw Hepel, David Wazer, Theresa Graves, Charu Taneja, Doreen Wiggins, Kara Leonard
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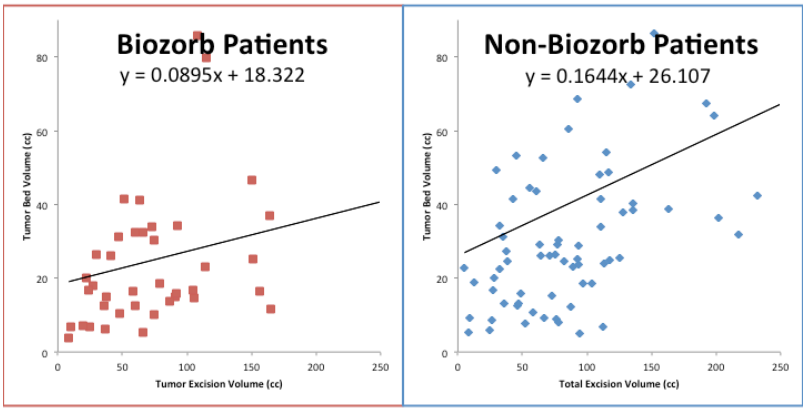
Background/Objective: The BioZorb® marker, produced by Focal Therapeutics, is a walnut-sized coil equipped with 6 titanium surgical clips that can be implanted in the tumor bed during breast-conserving surgery. By precisely defining the lumpectomy site in 3 dimensions, the device marks the surgical site for radiotherapy planning and is particularly helpful for boost planning. We aim to evaluate if patients with BioZorb® marker have smaller volume tumor bed than those with free clips or no clips.

Methods: Women diagnosed with breast cancer who were treated in the radiation oncology department at Rhode Island Hospital between May 1, 2015 and April 30, 2016 were retrospectively identified from an institutional database. Patients were classified as having had a BioZorb® placed or not having had a BioZorb® placed. Surgical pathology reports from all patients were examined to calculate

the total specimen volume excised during breast-conserving surgery. For all patients, 3 dimensions were reported for the lumpectomy specimen size and volume was calculated as a cube to represent the lumpectomy specimen volume. Tumor bed volume was determined based upon the contour established by the treating radiation oncologist in Philips© Pinnacle3 treatment-planning software. Linear regression analyses were performed to determine the relationship between excised surgical specimen volumes and tumor bed volumes in both patients who had and who had not received the implantable Biozorb® marker. The differences in the slopes of the 2 groups of patients were assessed for statistical significance using the t-test.

Results: A total of 117 women treated with breast radiation in our department during the defined time interval were identified; 42 women with implantable BioZorb® marker and 75 women without. Mean surgical specimen volume was 102.7 cc for women with BioZorb® and 104.2 cc for women without. Mean tumor bed volumes were 27.5 cc and 43.2 cc for women with and without BioZorb® placement, respectively. The figure demonstrates the linear relationship between excised surgical specimen volume and tumor bed volume in both groups of patients. The standard error among the group of patients who had received the Biozorb® marker was 23.739, compared to 46.474 in the non-Biozorb® group. A t-test for significance found that the difference in the slopes of the lines of best fit between the 2 groups was, in fact, statistically significant (t=0.001).

Conclusions: The BioZorb® implantable device is associated with smaller tumor bed volumes and as such, with smaller accelerated partial breast irradiation or boost irradiated volumes. These findings suggest that the Biozorb® system may offer an advantage in more precisely defining the lumpectomy site and in sparing larger volumes of healthy breast tissue from radiation. As these are early institutional data, the sample size is small, representing one limitation of the study.



Biozorb vs. non-biozorb

257173 - Intraoperative radiotherapy for breast cancer treatment in a rural community

Allison Lorenzen[1], Boris Kiriazov[1], James DeAndrade[1], Ingrid Lizarraga[2], Sonia Sugg[2], Carol Scott-Conner[1], Lillian Erdahl[2], Wenqing Sun[1], Ronald Weigel[2]
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Background/Objective: Access to quality health care poses particular challenges to patients living in rural communities. Multidisciplinary care for breast cancer patients in rural communities is further

complicated by an aging population and the distance patients must travel to treatment facilities. Single-dose intraoperative radiotherapy (IORT) offers a viable treatment alternative to traditional whole-breast radiation therapy (WBRT) for select patients. The purpose of this study was to analyze the utilization of IORT in patients undergoing breast-conserving surgery for breast cancer at a single academic institution located in a rural state.

Methods: A retrospective review of patient medical records was conducted for all patients at a single institution with a diagnosis of DCIS or invasive breast cancer from April 2012 to September 2014 who had undergone breast-conserving surgery in conjunction with either IORT or WBRT at the operating institution. Student's t-test or Fisher's exact test were used to make statistical comparisons

Results: Patients undergoing IORT (n=72) were significantly older than patients treated with WBRT (n=80) (66 vs. 58 years, $p < 0.001$) and had smaller tumors on pre-operative imaging and final pathology (1.1vs.1.6 cm, $p < 0.001$; 0.95vs.1.33, $p < 0.02$). IORT patients lived farther from the treating facility than WBRT patients (55 vs. 36 miles, $p < 0.03$; Table). To account for biases created in IORT selection criteria, subgroup analysis were performed for women receiving WBRT with similar characteristics (age > 50 years, tumors < 3 cm, and clinically node negative). While differences in age (66 vs. 63, $p < 0.05$) and tumor size by pathology (0.95 vs. 1.31, p=0.02) remained significantly different, tumor size by pre-operative imaging was no longer significant (1.1 vs. 1.4 cm, p=0.08). The distance patients traveled from their homes to the treating facility remained significantly higher for patients receiving IORT (55 vs. 29 miles, $p < 0.02$).

Conclusions: Eligible women at our institution electing to receive IORT tended to be older and live further from the treating facility than those choosing to undergo WBRT. Given that access to quality health care has been associated with challenges for patients living in rural areas, these data suggest that IORT is an attractive option for women from rural communities.

Patient Characteristics	All patients receiving IORT (n=72)	All patients receiving WBRT (n=80)		All patients receiving IORT (n=72)	Age/stage matched patients receiving WBRT* (n=44)	
Age (mean)	65.9	58.3	p<0.001	65.9	62.7	p=0.04
Distance traveled to treating facility (mi)	54.6	36.3	p=0.027	54.6	29.25	p=0.012
Mean tumor size imaging (cm)	1.1	1.6	p<0.001	1.1	1.4	p=0.077
Invasive breast cancer on pathology (%)	82	83	p=1.0	82	80	p=0.81
Patients receiving neoadjuvant therapy	0	13	p<0.001	0	0	p<0.001
Mean tumor size on final pathology (cm)	0.95	1.33	p=0.012	0.95	1.31	p=0.02
Hormone receptors						
ER positive (%)	93	70	p<0.001	93	70	p<0.01
PR positive (%)	86	61	p<0.001	86	61	p<0.01
HER2 positive	6.5	17	p=0.11	6.5	15	p=0.30
Patients with nodal metastases	6	17	p=0.040	6	4	p=1.0
Patients requiring re-excision	2	15	p<0.01	2	7	p=0.026

*including all patients ≥50 years of age, preoperative tumor size <3.5 cm, clinically node negative, no neoadjuvant therapy

Characteristics of patients receiving IORT vs. WBRT

257026 - MammoSite brachytherapy: A retrospective patient survey regarding perceived cosmesis, access to care, and overall satisfaction

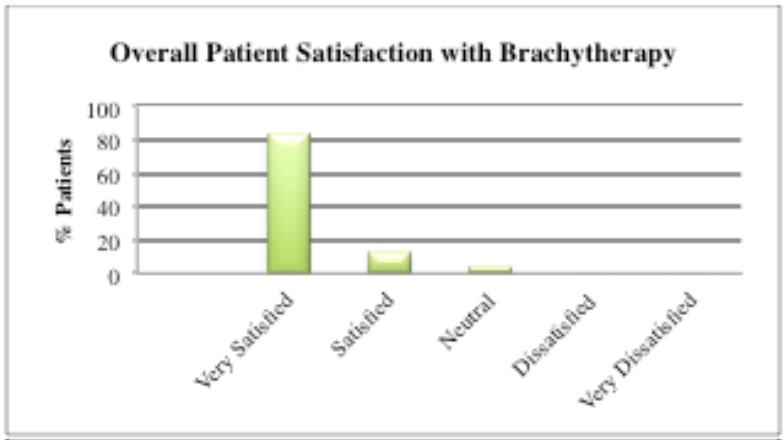
Jason Nealy, Constanze Rayhrer, Gosta Iwasiuk
Community Memorial Health System, Ventura, CA

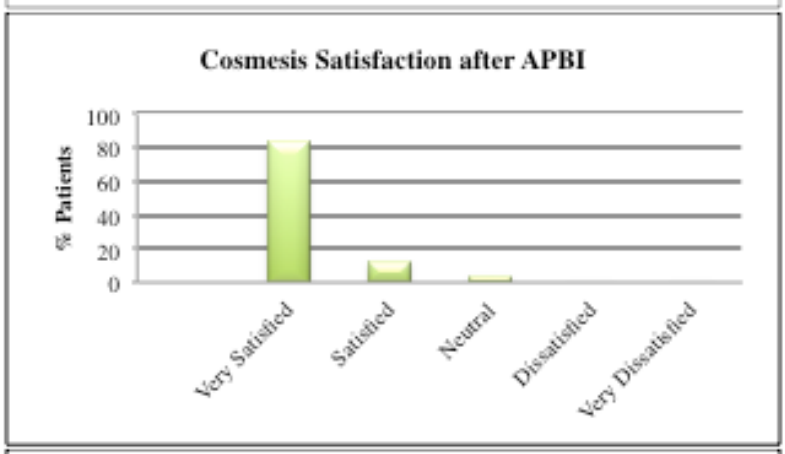
Background/Objective: For decades, whole-breast irradiation (WBI) has been used to reduce the risk of ipsilateral breast tumor recurrence (IBTR) after breast-conservation surgery (BCS) for early breast cancers. Accelerated partial-breast irradiation is a newer technology allowing an accelerated course of therapy while maintaining equivalent long-term patient survival. This study addresses patient-perceived cosmesis after therapy, access to care, and their overall impression of the accelerated course of radiation.

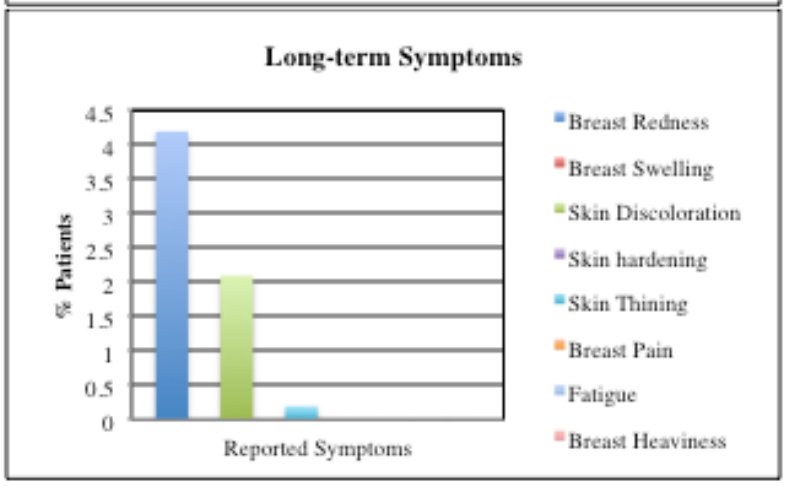
Methods: This is a retrospective study performed from a single center in Ventura, California. Appropriate patients were chosen using the American Society for Therapeutic Radiology and Oncology (ASTRO) consensus guidelines for APBI in 2009 that included age, BRCA status, tumor size, margins, LVSI, estrogen receptor status, multifocality/centricity, histology, nodal status, and receipt of neoadjuvant chemotherapy. Surveys were conducted on patients who underwent BCS between 2007 and 2012 on a voluntary basis. Fifty-four patients met inclusion criteria; 48 surveys were completed and returned.

Results: Overall, patient satisfaction with BCS followed by MammoSite brachytherapy is very high (98.8% very satisfied or satisfied, 4.1% neutral). Similarly, patient satisfaction regarding cosmesis mirrors overall satisfaction (98.8% very satisfied, 4.1% neutral). Breast redness (4.2%) and skin changes (2.3%) were the highest-reported, long-term sequelae following brachytherapy. Reported long-term complications were very low, 6.5%. If APBI were not offered and a complete course of WBI of 5 to 7 weeks was required after BCS, 85.5% of responders propose they could have completed this, while 14.5% respond that they would be unable to complete due to various obligations or geographic limitations.

Conclusions: Though APBI has demonstrated higher occurrences of local recurrence compared to WBI, a niche patient population exists who will benefit from APBI when the alternative is to forgo adjuvant therapy. This niche constitutes those who are unable to adhere to the course of radiation therapy for WBI. This study provides a clearer picture of the patient's perception of APBI with a focus on cosmesis and access to care. This unique perspective allows improved patient counseling of expectations during treatment and long-term outcomes following therapy. The emphasis on cosmetic outcomes following breast cancer treatment was highlighted; however, even those who reported "neutral" satisfaction to overall cosmesis recommend APBI in lieu of WBI or mastectomy alone. This may be a culturally adapted negative perception of mastectomy or may reflect the relative convenience of an accelerated course of therapy.


Overall Patient Satisfaction with Brachytherapy
% Patients
100
80
60
40
20
0
Very Satisfied
Satisfied
Neutral
Dissatisfied
Very Dissatisfied


Cosmesis Satisfaction after APBI
% Patients
100
80
60
40
20
0
Very Satisfied
Satisfied
Neutral
Dissatisfied
Very Dissatisfied


Long-term Symptoms
% Patients
4.5
4
3.5
3
2.5
2
1.5
1
0.5
0
Reported Symptoms
Breast Redness
Breast Swelling
Skin Discoloration
Skin hardening
Skin Thining
Breast Pain
Fatigue
Breast Heaviness

251483 - Clinical analysis of early results of the implementation of intraoperative radiotherapy with the Intrabeam device during breast-conserving surgery of early breast cancer in a private hospital

Yonina Tova, Moshe Papa
Assuta Medical Center, Tel-Aviv, Israel

Background/Objective: Results of TARGIT trials increased clinical interest in intraoperative radiotherapy (IORT) during breast-conserving surgery (BCS) in early breast cancer, and thus we have evidence of an increase in its use. At Assuta Medical Centers, we implemented this treatment in a private hospital setting where multiple surgeons use it. This report reviews surgical oncology guidelines, the protocol for the treatment, as well as the outcomes for breast cancer patients who received IORT as their sole radiation treatment at our hospital

Methods: From August 2014 to October 2016, 2,484 breast cancer patients underwent breast-conserving surgery at Assuta Medical Centers, Tel Aviv, Israel. One hundred thirteen early-stage breast cancer patients received BCS and IORT with the Intrabeam radiation device. Since there was a large diversity of surgeons, each patient, along with their radiological and pathological data, was presented to a multidisciplinary tumor board which included surgeons, radiation oncologists, medical radiologists, pathologists, and breast imaging radiologists. After approval, the patient received IORT. All surgeons had training as well as a supervision period prior to doing the procedure individually. Adjuvant therapy including EBRT, chemotherapy, or hormonal therapy was administered according to the final pathologic results and oncologic guidelines. Patients were followed to determine oncologic events, short-term toxicity, and overall cosmesis.

Results: Out of the 2,484 breast cancer patients, 159 cases (6.4%) were referred for IORT. One hundred thirteen patients (71%) were eligible and were treated with IORT by Intrabeam. With a median follow-up of 18.8 months (range 2 to 26 months), no patient developed local relapses. There were no metastases and no deaths. The average hospital stay was 1.2 days, and wound healing time was 7±2 days. Four patients (4.8%) developed postoperative infection, 2 of them (2.4%) had delayed infection, and one patient (1.2%) experienced a hematoma. Two patients needed surgical re-excision. There was no observed excess need for pain medication. The evaluation of cosmetic outcome showed that 82% of the patients graded as excellent or very good, while 18% patients graded it as good. Four patients (4.8 %) needed additional external radiation therapy. We analyzed the reasons for non-treatment in the 29% of referred patients. We found that 36% of these did not meet the eligibility criteria, 17% had positive SLN during surgery and IORT was aborted, 23% of the patients were eligible but the reason for non-treatment was economic due to insurance refusal to pay the cost, in 3% it was due to a technical problem in the Intrabeam machine, and in 14% it was due to miscellaneous reasons - mostly patient refusal due to media effect (Dr. Google).

Conclusions: For early-stage breast cancer patients, intraoperative radiotherapy after breast-conserving surgery in a private based center, if done according to a peer-reviewed protocol, is both safe and reliable and has resulted in very acceptable outcomes. With the larger emerging experience, patient selection for IORT should be less restrictive. Patient and physician education is needed in order to increase awareness of this modality. Insurers should be involved in the costs and benefits of this procedure.

257137 - A novel multi-lumen double balloon catheter for accelerated partial breast irradiation

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Background/Objective: A novel, double-balloon catheter for accelerated partial breast irradiation (APBI) allows a customized positioning of the inner treatment catheters away from the center channel (to improve dose coverage) and away from the balloon surface (to minimize hotspots within the breast tissue) relative to fixed geometry balloon systems. In this study, we assess the optimal radiation dosimetric capability and to compare target volume coverage (conformance) with ability to limit dose to the breast, skin, and chest wall.

Methods: A total of 10 consecutive patients that received APBI at our institution were treated with a new Best Double Balloon Multi-Catheter system following lumpectomy. All patients met the current ASBrS guidelines for patient selection and were treated with standard regimens of 34Gy in 10 fractions over 5 days with high-dose rate brachytherapy. The patients underwent 3D CT-based treatment planning and several key dosimetric parameters were collected and analyzed. These were compared to previous multi-lumen and single-lumen catheter systems (MammoSite and Contura MLB).

Results: The detailed results of our study cohort can be found in the attached table. The target coverage was excellent and similar to other balloon devices. However, there was significant improvement in the ability to reduce dose to the mean skin surface (92.5%) and the chest wall (109.9%) beyond conventionally accepted limits of 125% of the maximum prescription dose for varying skin to balloon surface distances. The mean hotspots within the breast tissue were also reduced with V150 (25.9cc) and V200 (6.4cc).

Conclusions: The enhanced ability to position the inner catheters at a variable distance from the center channel in a balloon catheter system allowed significantly improved ability to spare radiation dose to key avoidance structures that have shown to lead to toxicities in the literature including the skin surface, chest wall, and hotspots in the breast tissue. This in turn has the potential to increase the number of patients with anatomic constraints that may be technically eligible for a balloon-based APBI approach.

Parameter	Mean Value	Range
PTV-Eval (cc)	82.33	49.45-119.52
D90 of PTV Eval (%)	96.13	89.17-99.16
Max Skin Dose (%)	92.5	34.8-140.5
Max Chest Dose (%)	109.9	35.5-172.0
V150 Absolute (cc)	25.88	15.71-32.97
V200 Absolute (cc)	6.39	5.08-7.90
V300 Absolute (cc)	1.08	0-1.33
Inner Balloon Volume (cc)	5.58	2.93-7.89
Inner Lumen Surface to Center (mm)	7.9	6.3-9.7
Balloon Surface to Center (mm)	19.2	15.7-24.2
Skin to Balloon Surface (mm)	6.4	3.4-9.6
Chest Wall to Balloon Surface (mm)	6.7	0-22

253480 - Intra-operative versus external beam radiotherapy in breast-conserving oncologic surgery and the incidence of clinically symptomatic seroma formation requiring aspiration

Craig Smith[1], Lexie Vaughn[2], Eric Clayton[3], Aaron Pederson[1], Michael Hasselle[1], William Burak, Jr.[1], Elena Rehl[1]
[1]Memorial University Medical Center, Savannah, GA, [2]Mercer University School of Medicine, Savannah, GA, [3]Curtis & Elizabeth Anderson Cancer Institute, Savannah, GA

Background/Objective: Intraoperative radiotherapy (IORT) use in breast-conserving surgery (BCS) for oncologic breast surgery allows for direct, low-dose radiation therapy to the excision bed that potentially saves the patient and health care system time, money, and radiation complications as compared to external beam radiotherapy (EBRT). Symptomatic seroma formation in the lumpectomy bed is a bothersome complication of BCS. Our aim was to identify whether the type of postoperative radiotherapy IORT, IORT + EBRT, or EBRT alone would impact the rate of symptomatic seroma formation requiring aspiration.

Methods: We retrospectively compared 499 patients who underwent BCS at our tertiary center between 2011 to 2015. All patients who underwent IORT, IORT (as a boost) + EBRT, and EBRT alone were identified. Patient demographics and tumor characteristics were analyzed. We specifically identified patients that developed symptomatic seromas requiring aspiration.

Results: Of the 499 patients, 138 (27.7%) received only IORT, 95 (19.0%) IORT + EBRT, and 266 (53.3%) only EBRT. There was a total of 39 (7.8%) patients with symptomatic seromas requiring aspiration. Of these 39 aspirated seromas, 10 (7.2%) were IORT patients, 11 (11.6%) IORT+EBRT patients, and 18 (6.8%) were EBRT-only patients (p=0.311). Multivariate analysis was performed on demographic variables including, patient age, height, weight, along with tumor characteristic analysis. This analysis failed to show a significant correlation to symptomatic seromas requiring aspiration.

Conclusions: We found clinically symptomatic seroma formation requiring aspiration after BCS using IORT, IORT + EBRT, or EBRT alone to be statistically equivocal. We believe that the benefits bestowed on patients receiving IORT compared with EBRT, such as avoiding time-intensive outpatient radiotherapy, cost savings, and limited side effects of IORT, are not tarnished by an increased number of seromas requiring aspiration.

257272 - Factors predicting radiation therapy in early-stage breast cancer in patients > 70

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[1]University of Wisconsin School of Medicine and Public Health, Madison, WI, [2]University of Wisconsin, Madison, WI

Background/Objective: The Cancer and Leukemia Group B's (CALGB) study 9343 demonstrated that omission of radiation therapy (RT) in women ≥70 years of age undergoing breast-conserving surgery (BCS) for an early-stage estrogen receptor (ER) positive breast cancer resulted in a low rate of local regional recurrence (LRR) at 5 (4%) and 10 (10%) years. Although radiation consistently lowered these rates to 1% and 2%, respectively, the authors concluded avoidance of RT was a "reasonable choice." Prior studies have demonstrated that relatively high rates of radiation have persisted despite initial

publication of the trial data in 2004. We hypothesized that sustained RT use in this group may reflect tailored implementation of these results by patients and providers, based on patient life expectancy as well as the perceived risk of LRR due to tumor characteristics. The objective of this study was to determine the impact of patient-, tumor-, and system-level factors on the rate of RT in a contemporary cohort.

Methods: The National Comprehensive Database was used to identify women ≥ 70 years of age with Stage 1 ER+ breast cancer who underwent BCS from 2010-2013 (n=39,829). This time period was selected as it corresponded to the reporting of long-term follow-up data from CALGB 9343. Rates of first-course adjuvant RT over time were calculated, and trends in these rates were examined using Join-Point. Logistic regression was utilized to identify factors associated with the receipt of RT, controlling for patient, tumor, and system factors.

Results: During the study period, the overall rate of RT for patients ≥ 70 years of age was 68%. Use of RT decreased over the study period, and the rate of decline was more pronounced in older patients: annual percent change was -1.64% for women age 70-75 years and -7.76% for women greater than 85 years old. Those who had more comorbidities were also less likely to receive RT (Table). In regards to tumor characteristics, higher tumor grade and a positive margin status predicted RT, whereas HER2 Neu status did not. Geographic location and facility type were strongly associated with receipt or omission of RT. Among treating centers, the largest decline in RT over time was observed in academic programs.

Conclusions: Although rates of RT following BCS in patients over 70 are declining, higher rates persist in a subgroup of patients. Our findings suggest that patients and providers are using factors such as patient age and comorbidities (surrogates for life expectancy), as well as tumor characteristics (surrogates for recurrence risk without radiation) to guide decision-making for or against RT. Importantly however, there is also variation in RT by geographic location and facility type, suggesting future efforts should examine mechanisms driving this variation to ensure equitable care is received.

Predictors of RT	Odds Ratio (95% CI)	P Value
Time trends		
Year of Diagnosis		
2010	Ref	**<0.0001**
2011	0.96 (0.88-1.04)	
2012	0.83 (0.77-0.90)	
2013	0.70 (0.64-0.75)	
Patient Factors		
Race		
White	Ref	**NS**
Black	1.0 (0.90-1.1)	
Other	1.1 (0.88-1.3)	
Age		
65-70	Ref	**<0.0001**
70-75	0.26 (0.23-0.28)	
75-80	0.15 (0.13-0.16)	
80-85	0.07 (0.07-0.08)	
>85	0.03 (0.03-0.04)	
CDCC		
0	Ref	**<0.0001**
1	0.82 (0.76-0.88)	
2	0.58 (0.51-0.67)	
Tumor Characteristics		
Grade		
Well-differentiated	Ref	**<0.0001**
Moderately differentiated	1.3 (1.2-1.4)	
Poorly differentiated	1.7 (1.5-1.9)	
Her 2 Neu Status		
Negative	Ref	**NS**
Positive	1.0 (0.90-1.22)	
Margin Status		
Negative	Ref	**0.004**
Positive	1.3 (1.1-1.5)	
Facility Factors		
Location		
Northeast	Ref	**<0.0001**
South Atlantic	0.75 (0.69-0.82)	
Mid-West	0.98 (0.90-1.1)	
South	0.87 (0.78-0.96)	
West	0.81 (0.74-0.89)	
Facility Type		
Academic	Ref	<0.0001
Comprehensive Cancer Center	1.4 (1.3-1.5)	
Community	1.3 (1.2-1.5)	
Distance from Reporting Facility		
<10 miles	Ref	0.0001
10-20 miles	0.92 (0.86-0.99)	
20-50 miles	0.88 (0.81-0.97)	
50-100 miles	0.72 (0.61-0.84)	
>100 miles	0.76 (0.62-0.95)	
**model controlled for Hispanic, receipt of chemotherapy, receipt of lymph node surgery, private insurance in addition to Medicare, distance from radiation facility, rural/urban residence, medical income, and education*		

Factors predicting radiation therapy in early-stage breast cancer in patients > 70

257224 - Effect of radiation therapy on the satisfaction of patients with immediate, implant-based breast reconstruction

Eva Thiboutot[1], Carmen Webb[2], Claire Temple-Oberle[1]
[1]University of Calgary, Calgary, AB, Canada, [2]Tom Baker Cancer Centre, Calgary, AB, Canada

Background/Objective: Practice guidelines recommend delaying reconstruction until post-mastectomy radiation therapy (PMRT) is complete; however, the indication for PMRT is sometimes unanticipated. While the higher complication profile of implant-based reconstruction (IBR) after PMRT has been explored in non-randomized studies, there is less known with regards to patient-reported outcomes (PRO) in this setting.

Methods: We identified consecutive patients who underwent immediate IBR February 2012 to June 2015, from a prospectively compiled database, excluding patients who had prior radiation therapy to the chest. The validated Breast Reconstruction Satisfaction Questionnaire (BRECON-31©) was completed by patients as part of standard follow-up after reconstruction was finalized. Subscales were scored and compared between patients with and without PMRT for whom BRECON-31© results were available. Scores were also compared between radiated women whether the indication for radiation had been expected or not. Chi-Square and two-tailed Student T-test were used to compare proportions and continuous data respectively. A p-value less than 0.05 was considered significant.

Results: Sixty-four women met study criteria. Sixteen received PMRT, and 48 did not. Nine women (56%) had an unanticipated indication for PMRT. The PMRT group was similar to the no PMRT group with regards to age (43 vs. 48 years old, p=0.07), marital status (94 vs. 52% married, p=0.13), body mass index (28 vs. 26, p=0.13), tobacco use (0 vs. 8% smokers, p=0.18), and Charlson comorbidity index (88 vs. 69% score 0, p=0.64). Fewer patients in the group with PMRT underwent bilateral mastectomies (44 vs. 77%, p=0.01), and the indication for surgery was more likely to be invasive disease in that group (65 vs. 19%, p < 0.01). The patients in the PMRT group had larger tumors (23 vs. 14 mm, p=0.02), higher nodal disease burden (94 vs. 10% N+, p < 0.01), and were more likely to have received systemic therapy (100 vs. 23% had chemotherapy; 75 vs. 38% had endocrine therapy; both p < 0.01). Of minor and major complications, only capsular contracture rates differed between groups (13 with PMRT vs. 1.2%, p=0.01). There were 2 reconstruction losses in each treatment group (8.7 vs. 2.4% p=0.15). Of the 9 subscales, 7 showed no difference in satisfaction between the 2 groups. Radiated women scored lower in the arm concerns and breast appearance subscales. Scores for women expecting PMRT were similar to these for when it was unanticipated (mean total score 77 vs. 79, p=0.66).

Conclusions: Women with immediate IBR scored similarly to their non-radiated counterparts across 7 of 9 domains of satisfaction and quality of life (QoL). Arm concerns and breast appearance scores are lower with PMRT, likely secondarily to more extensive nodal procedures in higher-stage patients, and to the effect of radiotherapy on capsular contracture and risk of lymphedema. Our findings are in line with the few available studies using other PRO tools to evaluate the impact of PMRT on patient satisfaction, as well as studies objectively measuring the effect of PMRT on incidence of arm morbidity and cosmetic outcome of breast reconstruction. These issues will have to be balanced against the lower QoL caused by delaying reconstruction, in counseling women about their reconstructive options, especially when PMRT is a possibility. This is the first study using the BRECON-31 looking at satisfaction related to receipt of PMRT after immediate, implant-based breast reconstruction.

	No PMRT		PMRT		P value
	Number of Respondents (%)	Score (%) (±SD)	Number of Respondents (%)	Score (%) (±SD)	
BRECON total	48 (100)	83.4 (8.6)	14 (100)	78.2 (9.5)	0.06
Self image	48 (100)	88.3 (12.4)	14 (100)	81.7 (20.0)	0.14
Arm concerns	45 (93.8)	90.3 (16.5)	14 (100)	74.6 (19.5)	**0.004***
Intimacy	40 (83.8)	91.8 (10.4)	12 (85.7)	91.7 (6.9)	0.98
Satisfaction	48 (100)	89.3 (12.9)	14 (100)	84.1 (19.9)	0.24
Recovery	46 (95.8)	64.5 (14.8)	14 (100)	66.5 (17.8)	0.67
Self-consciousness	43 (89.6)	80.0 (18.0)	13 (92.9)	74.0 (16.5)	0.29
Expectations	48 (100)	87.2 (11.5)	14 (100)	84.2 (11.6)	0.41
Breast appearance	48 (100)	79.1 (13.4)	13 (92.9)	66.7 (21.3)	**0.01***
Nipple	32 (66.7)	73.9 (11.9)	3 (21.4)	63.2 (23.4)	0.18

BRECON-31© scores analysis by treatment group

257162 - Receipt of postmastectomy radiation improves survival regardless of time interval from diagnosis: Implications for the American College of Surgeons Commission on Cancer Breast Cancer Quality Metrics

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Background/Objective: To ensure optimal breast cancer care, the American College of Surgeons Commission on Cancer (ACS CoC) developed quality measures with respect to timing of radiation, endocrine, and chemotherapy. This study aims to evaluate nationwide compliance to the receipt of post-mastectomy radiotherapy (RT) in patients with ≥ 4 positive lymph nodes (LN) within 365 days of diagnosis (MASTRT) and to assess the impact of compliance to this measure on overall survival.

Methods: Women diagnosed with invasive breast cancer from 2004 to 2012 were identified in the National Cancer Database. Receipt of RT within 365 days from diagnosis was determined for patients with stage III (≥4 LN) disease following mastectomy to determine compliance with the MASTRT measure. Uni- and multivariate logistic regression was used to assess factors associated with non-compliance to the guideline. Uni- and multivariate Cox proportional hazard models were used to assess patient, tumor and treatment factors associated with improved OS.

Results: Of the 29,349 women with stage III disease (≥ 4LN) post-mastectomy, 66.9% received RT within 365 days, while 33.1% were non-compliant (2.2% received RT after 365 days, 30.9% did not receive RT). Compliance with timely RT (≤ 365days) was associated with improved OS compared to no RT (HR 0.69, 95% CI 0.66-0.72). Survival advantage persisted in patients who received delayed RT (> 365days) compared to no RT (HR 0.74, 95% CI 0.64-0.85). In multivariate analysis, factors associated with non-compliance to MASTRT were Medicaid (OR 0.72, 95% CI 0.66-0.78), Medicare (OR 0.80, 95% CI 0.73-

0.87) or no insurance (OR 0.63, 95% CI 0.55-0.72), distance to hospital >44 miles (OR 0.69, 95% CI 0.63-0.76), and ER negativity (OR 0.79, 95% CI 0.73-0.86), while adjuvant chemotherapy (OR 4.62, 95% CI 4.26-5.02) was associated with improved compliance.

Conclusions: The survival benefit of compliance with the ACS CoC quality measure MASTRT for post-mastectomy RT appears to be based on receipt of RT itself rather than the time to RT. Focus on some of the modifiable factors associated with non-compliance, such as insurance type and access to care, may lead to improved quality of care and ultimately overall survival.

Reconstruction

256605 - Grisotti flap reconstruction for retroareolar breast tumours: Single centre 10-year experience

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Background/Objective: Retroareola breast cancers were traditionally treated with mastectomy. Grisotti flap technique allows breast conservation using a dermoglandular volume displacement method. This study explores the oncoplastic safety of the procedure and complications over a 10-year period in a single centre.

Methods: Data was collected prospectively from January 2005 to January 2015. All patients underwent wide local excision for retroareola breast tumour requiring removal of the nipple-areola complex and immediate reconstruction with Grisotti flap reconstruction in a single centre. The primary aim was to identify the number of local and distant recurrences. Secondary aims were the number requiring further re-excision or mastectomy, wound complications, and mortality.

Results: Sixty-nine patients were operated on during the study period. Most of the patients were postmenopausal (94%) and had invasive cancer (64%) that was node negative (74%). Most patients had adjuvant radiotherapy (81%) and endocrine therapy (70%). Margins were involved in 10 patients (14%), 6 underwent mastectomy, of which 3 had residual in-situ disease. There were no local recurrences, but 3 distant recurrences, and one died of metastatic liver disease. There was 3 further deaths not related to breast cancer. There was no flap necrosis in our series, superficial infection in 7%, and infected seroma in 3%.

Conclusions: Grisotti flap technique can be used for a select group of breast cancer patients with retroareolar breast cancers with good oncoplastic safety and minimal complications. Our study represents one of the largest series of Grisotti flap reconstructions with results comparable with standard breast conserving surgery. Data is currently being collated regarding patient-reported outcome measures.

Patient and tumour characteristics	
Age ≤ 50	4 (6%)
Age > 50	65 (94%)
Mean Age (Range)	64 (43-87)
Invasive Cancer	44 (64%)
DCIS only	13 (19%)
Paget's only	3 (4%)
DCIS and Paget's	8 (12%)
Periductal mastitis	1 (1%)
Nodal Surgery	50
Node positive	13 (26%)
Node negative	37 (74%)
ER+	52 (75%)
ER-	13 (19%)
Unknown/not available	4 (6%)
HER2+	3 (4%)
HER2-	53 (77%)
Unknown/not available	13 (19%)
Margins Involved	
Re-excision of margins only	4 (6%)
Mastectomy	6 (9%)
Adjuvant Therapy	
Radiotherapy	56 (81%)
Chemotherapy	13 (19%)
Endocrine Therapy	48 (70%)
Herceptin	2 (3%)
Recurrence	
Local	0
Distant	3 (4%)
Death	
Breast cancer related	1 (1%)
Other causes	3 (4%)
Complications	
Flap necrosis	0
Superficial wound infection	5 (7%)
Seroma	2 (3%)
Wound dehiscence	1 (1%)

Grisotti flap reconstruction - Patient and tumour characteristics, further surgery, recurrence, mortality, and wound complications

257496 - Does response to neoadjuvant chemotherapy impact breast reconstruction?

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Background/Objective: Neoadjuvant chemotherapy (NAC) is administered for breast cancer for downstaging of disease. We sought to determine the impact of response to NAC (rNAC) on breast reconstruction.

Methods: A prospective database of NAC and mastectomy with or without reconstruction was reviewed with IRB approval. Univariable analyses were conducted using Kruskal-Wallis or Fisher's exact test. Multivariable logistic regression was used to adjust for potential confounders.

Results: We identified 283 cancers in 277 patients receiving NAC and mastectomy between 9/2013 and 5/2016. Median age was 49 years. The table gives clinicopathologic characteristics stratified into 2 groups: no pathologic complete response (NpCR, n=207) and pathologic complete response (pCR, n=76). The pCR group had smaller T-stage (p=0.003) and was more frequently HR- subtype (p < 0.001), but not different in N-stage (p=0.156). One hundred forty-five patients (51.2%) had unilateral mastectomy, and 138 (48.8%) had bilateral mastectomy (BM). Two hundred fifty (88%) were not candidates for BCS, 9

(3.2%) were considered high risk (family history or gene testing), and 15 (5.3%) had mastectomy by patient preference. Two had bilateral breast cancer. Reasons for mastectomy did not differ between groups (p=0.102). One hundred eighty-three patients had immediate reconstruction (IR), and 100 had no IR. On univariable analysis, younger age ($p < 0.001$), smaller T-stage at presentation ($p < 0.001$), BM ($p < 0.001$), and tumor subtype ($p = 0.006$) were significantly associated with higher rates of IR. On multivariable analysis assessing association of rNAC with IR, pCR (p=0.70) and tumor subtype (p=0.075) were not significantly associated with IR (p=0.70); patients with T4 tumors at presentation had lower odds of IR (OR 0.05, $p < 0.01$) even when accounting for rNAC. One hundred eighty-one patients received adjuvant radiation therapy; this was not associated with IR (p=0.07) or reconstruction type (tissue expander vs autologous, p=0.39).

Conclusions: In patients who have mastectomy after NAC, IR is influenced by age, T-stage at presentation, and choice of BM, but not by rNAC. A subset of patients who are young, with earlier T-stage and pCR are more likely to proceed with BM.

Factor	Overall (n = 283)	No pCR (n = 207)	pCR (n = 76)	p-value
Age, median (range)	49 (27, 87)	49 (27, 87)	49 (28, 85)	0.402
Tumor size, median (range)	4.2 (0.7, 15)	5 (0.7, 15)	3.6 (1.1, 15)	0.014
T stage at presentation				0.003
T1	26 (9.2)	15 (7.2)	11 (14.5)	
T2	132 (46.6)	94 (45.4)	38 (50)	
T3	74 (26.1)	65 (31.4)	9 (11.8)	
T4	50 (17.7)	33 (15.9)	17 (22.4)	
NA	1 (0.4)	0 (0)	1 (1.3)	
N stage at presentation				0.156
N0	82 (29)	55 (26.6)	27 (35.5)	
N1	167 (59)	127 (61.4)	40 (52.6)	
N2	18 (6.4)	11 (5.3)	7 (9.2)	
N3	16 (5.7)	14 (6.8)	2 (2.6)	
Clinical axillary node status (after NAC)				0.058
Negative	250 (88.3)	178 (86)	72 (94.7)	
Positive	33 (11.7)	29 (14)	4 (5.3)	
Breast cancer subtype				<0.001
ER-, PR-, HER2-	75 (26.5)	50 (24.2)	25 (32.9)	
ER-, PR-, HER2+	33 (11.7)	13 (6.3)	20 (26.3)	
ER/PR+, HER2-	119 (42)	110 (53.1)	9 (11.8)	
ER/PR+, HER2+	54 (19.1)	33 (15.9)	21 (27.6)	
NA	2 (0.7)	1 (0.5)	1 (1.3)	

Patient and disease characteristics by pCR

257031 - Comparing morbidity rates between wise pattern and standard horizontal elliptical mastectomy incisions in patients undergoing immediate breast reconstruction

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Background/Objective: Breast cancer patients with ptotic breasts who pursue mastectomy with immediate reconstruction can present reconstruction challenges. A wise pattern (inverted-T) mastectomy incision (WPM) has been suggested as an alternative to the standard horizontal elliptical mastectomy (EM) incision to reduce redundant skin and correct ptosis. However, it remains unclear if

WPM is associated with higher rates of complications. Herein, we sought to examine the differences in outcomes and morbidity between the 2 incision types.

Methods: We performed a retrospective review of all women undergoing mastectomy with immediate prosthetic reconstruction at our institution between June 2007 and January 2016. We compared those undergoing WPM to a control population of women undergoing EM during this same time period. Statistical analysis was performed evaluating clinical, pathological, and surgical outcomes variables according to patient and per breast. All tests were 2-sided with alpha level set at 0.05 for statistical significance.

Results: In total, 241 women underwent mastectomy and prosthetic reconstruction in 421 breasts, of which 78/241 (32%) women had WPM (149 breasts), while 163/241 (68%) had EM (272 breasts). Patients having WPM were similar in age, smoking status, diabetes, race, tumor type, and pathologic stage (all $p > 0.07$) as women having EM. More women having WPM received neoadjuvant chemotherapy (13% vs 5%, $p=0.03$), had bilateral procedures (94% vs 67%, $p < 0.0001$), and were obese (BMI: 29.3 vs 24.1, $p < 0.0001$) than EM patients respectively. Overall, WPM was associated with longer OR times ($p=0.002$) and increased overall rates of all complications (54% vs. 28%, $p=0.0001$). Skin flap necrosis was the most frequently encountered complication, occurring in 59/149 (39.9%) of WPM breasts and in 24/272 (8.9%) of EM breasts ($p < 0.0001$). Among breasts with skin necrosis, full thickness necrosis occurred more frequently in the WPM breasts [24/59, (41%) vs 7/24 (29%), $p < 0.001$]. However, there was no difference in the need for revisional procedures in the OR between the groups (WPM: 24.1% vs EM: 17.6%, $p=0.207$). The most common location of skin flap necrosis in the WPM group was at the central T-zone (39/59, 66%). There was no difference in rates of hematoma or breast seroma formation ($p=0.519$ and $p=0.887$, respectively) between the 2 groups. Multivariate analysis identified only older age and pectoralis major muscle division for creation of the tissue expander pocket as predictors of skin flap necrosis [OR 1.01 (95%CI 1.00, 1.02) and OR 1.32 (95%CI 1.12, 1.55), respectively].

Conclusions: Patients should be counseled that WPM is associated with higher rates of skin flap necrosis. However, this does not translate into higher rates of revisional procedures or return to OR. Technical aspects of WPM should be studied to help reduce rates of skin necrosis.

256697 - Non-clinical factors associated with post-mastectomy reconstruction in a contemporary cohort of breast cancer survivors

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Background/Objective: Rates of post-mastectomy reconstruction have increased over recent years. However, prior studies have suggested lower rates of reconstruction for subgroups of patients defined by factors such as race, income, and insurance status. Our objective was to determine contemporary rates of reconstruction in the United States and examine non-clinical factors associated with receipt of reconstruction.

Methods: The National Cancer Database was used to identify women with stage 0 or stage 1 breast cancer treated with mastectomy (n=297,121), as patients with early-stage disease are less likely to have

a tumor or treatment-related contraindication for reconstruction. Women >75 years of age were excluded due to the low rate of reconstruction observed in this cohort (4.6%). Trends in reconstruction rates between 2004-2013 were examined using Join-point regression analysis. A contemporary cohort of patients diagnosed between 2010-2013 (n=145,577) was created. Multivariable logistic regression was used to identify non-clinical factors associated with reconstruction, controlling for patient age, comorbidities, tumor, and treatment characteristics.

Results: Rates of reconstruction increased from 27% in 2004 to 48% in 2013 at an annual percent change of 5.8%. Controlling for clinical factors within our contemporary cohort of patients, race, income, education, type of insurance, location of residence, and type of treating facility were all strongly associated with receipt of reconstruction (Table).

Conclusions: Although rates of reconstruction have increased dramatically over the past decade, lower rates persist for subgroups of vulnerable patients. This gap in care quality is likely mediated by a mix of fixed and modifiable factors at the patient, provider, and system levels. Determining modifiable factors that negatively impact receipt of reconstruction and identifying interventions to address them is a critical step towards improving the quality of breast cancer care for vulnerable populations.

Race		
White	Ref	<0.0001
Black	0.87 (0.83-0.91)	
Other	0.61 (0.57-0.74)	
Facility type		<0.0001
Academic	Ref	
Comprehensive community cancer program	0.87 (0.84-0.89)	
Community	0.52 (0.5-0.55)	
Insurance		<0.0001
Private	Ref	
None	0.43 (0.39-0.47)	
Medicaid	0.54 (0.51-0.57	
Medicare or other government	0.65 (0.63-0.68)	
Place of residence		<0.0001
Metro	Ref	
Urban	0.72 (0.69-0.76)	
Rural	0.63 (0.57-0.71)	
Income (by quartile)		<0.0001
Highest-1	Ref	
2	0.74 (0.71-0.77)	
3	0.63 (0.61-0.66)	
Lowest-4	0.57 (054-0.60)	
Education level (by quartile)		<0.0001
Highest-1	Ref	
2	0.94 (0.91-0.97)	
3	0.91 (0.88-0.95)	
Lowest-4	0.88 (0.83-0.93)	
Controlling for patient age, comorbidities, stage, ER/PR status, Her2neu status, grade, receipt of radiation, receipt of chemotherapy, bilateral mastectomy, geographic region, year of diagnosis, distance from reporting facility		

Multivariable logistic regression of non-clinical factors associated with post-mastectomy reconstruction

255754 - Does surgical technique impact post-operative outcomes of breast reconstruction?

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Background/Objective: In 2015, approximately 106,338 breast reconstructions were performed in the US. Nearly 81% of these procedures were implant-based reconstructions. One of the more commonly used techniques in implant-based reconstruction is the dual plane (DP) technique, where the implant is placed under the pectoralis muscle, and reinforcement of the skin flap is achieved through the use of an acellular dermal matrix (ADM). A new surgical technique is the pre-pectoral (PP) technique which is a less invasive procedure and involves the placement of implant above the pectoral muscle with full anterior reinforcement using ADM. The goal of this study was to assess the impact of surgical technique on post-operative outcomes of breast reconstruction.

Methods: This was a single site, retrospective cohort study that included data on breast reconstruction procedures from June 2013 to March 2016. Variables collected included patient demographics, co-morbidities, chemotherapy and radiation exposure, surgical technique, the use of closed incision negative pressure therapy (ciNPT) and outcomes including length of hospital stay (LOS) and 90-day complications. Two-sided T-tests and Chi-square or Fisher's Exact tests were performed at $\alpha = 0.05$. General linear models and logistic regression models were also performed in order to control for possible confounding variables.

Results: The study included data on 176 patients (DP=117, PP=59) and 335 breasts (DP=225, PP=110). The PP group had a higher BMI (29.5 vs. 26.3 kg/m2; p=0.0017), and a significantly higher proportion of patients with diabetes (13.6% vs. 2.6%; p=0.0073), hypertension (35.6% vs. 17.1%; p=0.0061), and prior breast surgery (36.8% vs. 22.2%; p=0.0415). A higher proportion of PP patients received ciNPT (57.6% vs. 25.6%; $p < 0.0001$) compared to the DP group. There were no differences in complication rates between the 2 groups. The PP group had a significantly lower LOS compared to DP (mean: 1.1 vs. 1.8 days, $p < 0.0001$). Nearly 95% of PP patients were discharged after 1 hospital day compared to only 25.6% of the DP patients ($p < 0.0001$). Results of multiple regression models were similar to the univariate analyses after controlling for effects of age, BMI, ciNPT use, diabetes, hypertension, and prior breast surgery. No significant differences were found in the proportion of patient breasts with any complication (p=0.5875) whereas there was a significantly shorter LOS in the PP group ($p < 0.0001$) compared to DP group.

Conclusions: This is one of the first studies to explore the length of hospital stay between PP and DP groups. The shorter LOS in the PP group may be a result of less invasive nature of the technique; however, additional data are needed to support this finding. Complication rates were similar between the 2 groups even though the PP group had higher BMI and higher proportions of patients with diabetes, hypertension, and prior breast surgery. Studies with longer-term follow-up are needed.

	DP N = 225 n (%)	PP N = 110 n (%)	p-value
Any complication	22 (9.8%)	14 (12.7%)	0.4130
Surgical site infection	11 (4.9%)	2 (1.8%)	0.2343
Dehiscence	7 (3.1%)	6 (5.5%)	0.3672
Necrosis	9 (4.0%)	10 (9.1%)	0.0771
Seroma	7 (3.1%)	3 (2.7%)	1.0000
Hematoma	7 (3.1%)	3 (2.7%)	1.0000
Tissue expander exposure	3 (1.3%)	1 (0.9%)	1.0000
Return to operating room	10 (4.4%)	4 (3.6%)	1.0000

Complication rates across surgery types (breast-level)

256817 - Does closed-incision, negative-pressure therapy impact post-operative outcomes of breast reconstruction?

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Background/Objective: There is evidence that closed-incision management using negative-pressure therapy (ciNPT) may have clinical benefit in surgical applications including orthopedic, sternotomy, colorectal, and abdominal wall repairs by protecting surgical incisions, maintaining a closed environment and removing fluids and infectious materials. However, little evidence exists on the effect of ciNPT use after breast reconstruction procedures. Thus, the goal of this study was to compare post-operative outcomes among patients using ciNPT and standard of care (SOC) after breast reconstruction.

Methods: This was a single site, retrospective cohort study that included data for patients undergoing breast reconstruction from October 1, 2013 to March 31, 2016. Variables collected included patient characteristics, co-morbidities, chemotherapy and radiation exposure, surgical technique, ciNPT (as delivered by PREVENA™ Therapy) use, and outcomes such as number of drains, drain duration, and complication rates within 90 days. Two-sided T-tests and Chi-square or Fisher's Exact tests were performed at α=0.05. General linear models and multiple logistic regression models were also performed for continuous and categorical outcomes, respectively, in order to control for possible confounding variables.

Results: The study included data on 155 patients (ciNPT=117, SOC=91) and 294 breasts (ciNPT=125, SOC=169). There were no significant differences in age, BMI, proportion of smokers, and patients with hypertension between the groups. The ciNPT group had a significantly lower proportion of patients with diabetes (0% vs. 11%; p=0.0055) and prior breast surgery (17.7% vs. 38.5%; p=0.0061) compared to SOC. There was no difference in chemotherapy exposure between the groups; however, fewer ciNPT patients had radiation exposure compared to SOC (10.9% vs. 31.1%; p=0.0032). A higher proportion of ciNPT patients underwent the pre-pectoral technique of breast reconstruction (53.1% vs. 25.3%; p=0.0004) compared to SOC. The ciNPT group had lower rates of overall complications, infections, dehiscences, necroses, and returns to the operating room compared to SOC. All patients (100%) in the ciNPT group

had 2 drains compared to 81.7% of the SOC group ($p < 0.0001$). Moreover, the ciNPT group had significantly lower mean drain days per-drain (6.1 vs. 9, $p < 0.0001$) and total drain days (12.2 vs. 18.1, $p < 0.0001$) compared to SOC group. Results of general linear models and logistic regression were similar to the univariate analyses after controlling for effects of age, BMI, surgical technique, diabetes, hypertension, and prior breast surgery. The ciNPT group had significantly lower total drain days (11.9 vs. 17.8 days; $p < 0.0001$) and lower proportion of breasts with any complication compared to SOC (odds ratio for No ciNPT use vs. ciNPT use = 2.983, 95% confidence interval = 1.043-8.532; p=0.0416).

Conclusions: This study demonstrated significantly lower infection, dehiscence, necrosis rates, and drain duration among the ciNPT group. These results may translate to improved patient outcomes and efficient use of resources in a hospital setting. Further studies are needed to corroborate the findings in our study.

	SOC N = 169 n (%)	ciNPT N = 125 n (%)	p-value
Any complication	24 (14.2%)	7 (5.6%)	0.0176
Surgical site infection	10 (5.9%)	0 (0%)	0.0059
Dehiscence	11 (6.5%)	0 (0%)	0.0030
Necrosis	16 (9.5%)	1 (0.8%)	0.0016
Seroma	7 (4.1%)	1 (0.8%)	0.1442
Hematoma	4 (2.4%)	5 (4.0%)	0.5024
Tissue expander exposure	3 (1.8%)	0 (0%)	0.2643
Return to operating room	11 (6.5%)	0 (0%)	0.0003

Complication rates between ciNPT and SOC groups (breast-level)

257108 - Evolution of the Breast Reconstruction Risk Assessment Calculator: External validation and radiation correction factor

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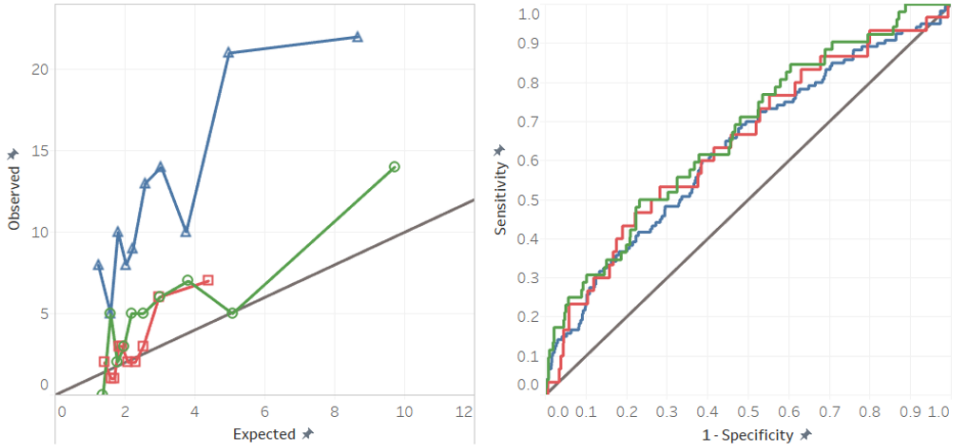
Background/Objective: As patients face an ever-growing set of options for breast reconstruction, an understanding of individualized risk can enhance surgical decision-making. The Breast Reconstruction Risk Assessment Score (BRA Score, www.brascore.org) is a risk calculator that provides patient-specific estimates of risk for surgical complications based on reconstruction modality and an individual's unique combination of pre-operative variables. We evaluate the performance of BRA Score models for surgical site infection (SSI), seroma, and explantation in patients undergoing prosthetic-based reconstruction from an independent, single-institution series of patients. Moreover, we introduce a correction factor to the models to account for the impact of radiation therapy on complications.

Methods: Data for validation of the BRA Score was obtained through review of all initiated tissue expander/implant reconstructions between January 2004 and December 2015 at a single institution. BRA Score inputs and primary outcomes were recorded for each patient. BRA Score-predicted risks for each outcome was then assessed against observed outcomes along 3 dimensions: calibration, discrimination, and accuracy. In addition, an adjunct risk assessment model for SSI was created using multivariate logistic regression on the validation cohort. A systematic review of the literature was performed to identify studies that investigated the impact of radiation on complications in prosthetic reconstruction. Meta-analysis was performed on the risk of surgical site infection associated with radiation therapy, and the summarized risk ratio was incorporated into the BRA Score regression model.

Results: Eight hundred fifty-five patients with a median follow-up time of 14.0 months were included for analysis. One hundred sixty-six patients (19.4%) experienced a surgical site infection, seroma, or explantation. Validation statistics are summarized in the figure below. Calibration and accuracy were best for seroma, whereas models for SSI and explantation tended to underestimate risk. All models had good discriminatory performance, meaning that they were effective in distinguishing low-risk patients from high-risk patients. The adjunct model for SSI incorporated key risk factors such as radiation therapy and chemotherapy, which were not available in the training database for the original BRA Score. This model demonstrated good calibration, discrimination, and accuracy when validated internally. A thorough systematic review of the literature yielded 1,820 references from which 15 were included for meta-analysis. Seven of these studies reported rates of infection, yielding a summarized relative risk of 2.61 (95% CI: 1.38 – 4.92) for infection related to post-mastectomy radiotherapy.

Conclusions: Current BRA Score models demonstrate the ability to distinguish low- and high-risk patients. Accuracy may be improved by re-calibration of model coefficients. We have introduced one method of re-calibration by appending a term for post-mastectomy radiation that was derived from meta-analysis of robust external data. Moving forward, this represents a novel method to account for risk factors and outcomes that are of particular interest to breast surgeons. In addition, we have illustrated how an adjunct model based on a single-center experience may help paint a more complete picture in risk assessment.

Figure. Calibration plot of observed and predicted events by risk-stratified deciles (left) and receiver-operator curve for predicted risk (right) based on BRA Score models for surgical site infection (SSI), seroma, and explantation. Key validation statistics for calibration (Hosmer-Lemeshow goodness-of-fit), discrimination (C statistic), and accuracy (Brier Score) are summarized below.



Line	Hosmer-Lemeshow P-value	Correlation Coefficient	C statistic (95% CI)	Brier Score
SSI	0.004	0.896	0.68 (0.60 – 0.75)	5.81%
Seroma	0.521	0.892	0.64 (0.54 – 0.73)	3.36%
Explantation	<0.001	0.873	0.67 (0.60 – 0.73)	12.82%
Reference	-	-	-	-

Calibration and discrimination plots

257352 - The integration of autologous DIEP flap reconstruction in a joint university-community hospital initiative

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Background/Objective: There are numerous reconstructive options available to patients after mastectomy. Autologous free-flap reconstruction has primarily been available only in major university centers for a variety reasons. These include specialty plastic surgery training, specialty equipment, length of procedure, reimbursement issues, and specialized nursing staff. Unfortunately, this limits the reconstructive options of many women who are having their surgery in a community setting. This IRB approved retrospective study reports outcomes in patients receiving free-flap reconstruction in a university hospital (UH) versus a community hospital (CH), done in a cooperative, integrative fashion by the same university plastic surgeons.

Methods: One hundred sixteen patients who underwent a deep inferior epigastric perforator (DIEP) flap reconstruction after mastectomy over 5 years (10/2010-5/2015) in our CH were compared to 116 age-matched patients done over 2 years (6/2013-6/2015) at the UH, ensuring that all patients had at least 1 year of follow up. Average age was 55.9 years in CH and 53.2 in UH. Three hundred nineteen flaps were evaluated. The operating microsurgeons were experienced and were primarily situated at the UH. All patient charts were reviewed and assessed for complications including return to the OR in an immediate or delayed fashion, delayed wound healing, and length of stay. The 2 groups were compared and analyzed.

Results: One hundred eighty-seven consecutive flaps in 116 patients were completed without any incidence of flap loss in the CH. The UH group had 1 flap lost (0.75%). Average length of stay was 4.45 days versus the 5.19 days at the UH (p-value =0. < 0.01). Delayed wound healing was the most common post-operative complication, with 21.3% at the CH versus 39.9 % at UH (p=0.183). Both the CH and the UH experienced an identical 3.7% rate of major complications which required return to the OR at any point during their 1-year post-op course.

Conclusions: The introduction of DIEP flap reconstruction in our community hospital in conjunction with a university hospital plastic surgical program was an initiative that provided a reconstruction option not previously available. Results produced at the CH were equivalent to those patients undergoing similar surgery at the UH. With required plastic surgical expertise and nursing training, autologous DIEP flap reconstruction can be accomplished in a cooperative collegial fashion in a CH.

256727 - Breast reconstruction using modified inferior dermal flap, implant, and nipple areola complex repositioning technique: Experience at MISR Cancer Center

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Background/Objective: Immediate breast reconstruction is routinely used for most of the mastectomy candidate patients at the MISR Cancer Center. Due to patient preferences and advanced professional patient care, more and more cosmetic expectations are demanded every other day. Inferior dermal flap with implant is widely practiced. We added modifications to this procedure using the autologous tissue as an inferolateral local sling, avoiding the costs in the low-resource setting and reducing the morbidity of lengthy operating time. After using this modification many patients avoided a second procedure for subsequent nipple reconstruction and re-positioning that will decrease further appointments and costs.

Methods: This study involved 24 patients (29 breasts) previously treated at our center from September 2014 to August 2016, excluding patients who are planned for preoperative radiotherapy, and T4 patients. Patients are counselled and attended the MDT meeting plus the plastic surgeon's meeting for preoperative planning and photographing. Skin markings and a suitable nipple areola complex position is suggested. Reconstruction was performed following a periareolar skin deepethelialization to obtain the new nipple areola complex position. A Wise pattern skin incision and an inferior deepithelialized dermal sling was sutured to the pectoralis major to form a pocket for a silicone implant. The nipple areola complex was sited at the time of reconstruction, with biopsies taken from retroareolar tissue before proceeding with the procedure.

Results: Patient average age was 51 years (range 38–64). Eleven mastectomies were for invasive carcinoma, 8 for ductal carcinoma in situ, 5 for lobular carcinoma, and 5 of 19 mastectomies were prophylactic (3 high risk and 2 atypical lobular hyperplasia). Average operative time was 150 min. There were no immediate complications requiring reoperation. All retroareolar biopsies were benign, and no locoregional recurrences have occurred. Four nipples had partial superficial necrosis of the lower pole but healed with conservative treatment. No patients required any subsequent procedures to their reconstructed breast.

Conclusions: The modified inferior dermal flap with implant and nipple areola complex re-positioning is an excellent one-stage reconstruction option. This method presents a potentially safe, trusted, and aesthetically accepted outcome for Egyptian women with large and ptotic breasts.

257416 - Racial and geographic disparities in post-mastectomy reconstruction: A SEER database analysis

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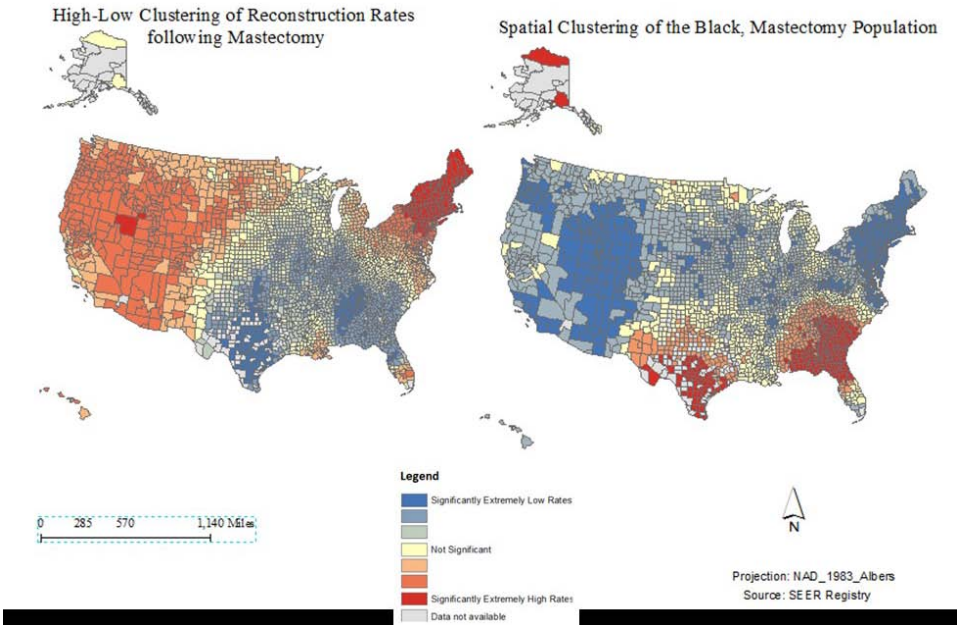
Background/Objective: There is concern about racial and geographic disparities in utilization of post-mastectomy reconstruction. The purpose of this study was to examine if racial disparities in post-mastectomy reconstruction varied by geographic region.

Methods: The SEER registry was queried for women who were diagnosed with breast cancer between 2000 and 2013 and underwent mastectomy excluding individuals who were diagnosed at autopsy, had unknown AJCC stage, or were in AJCC stage 4, or primary tumor (T) stage was not T0-T4 (n=78,400). Chi-square ($\chi 2$) test was utilized to assess significant differences in bivariate analysis. Binary Logistic Regression was utilized to assess racial (White, Black, Other) disparities in obtaining a reconstruction (Yes/No) after mastectomy, and regional disparities (Alaska, East, Northern Plains, Pacific Coast, Southwest) in obtaining a reconstruction. Regression models were adjusted for age, marital status, estrogen and progesterone receptor status, radiation treatment, histology, year of diagnosis, AJCC stage, rurality of residence, first malignancy, number of tumors, and grade. Finally, we conducted a crude hot-spot analysis to examine spatial variation of reconstruction rates following mastectomy throughout the United States compared to areas where there was a high percentage of thr Black population that underwent mastectomy. All analyses were conducted in software ArcGis and R, and all interpretations are reported at the 95% confidence interval.

Results: The overall reconstruction rate was 19.2%, ranging from 15.9-25.7% across United States counties. Reconstruction rate among Blacks was 10.7% ($p < 0.001$), compared to 82.3% among Whites, and 6.3% among individuals in the other category ($p < 0.001$). After adjusting for potential confounders, Blacks were significantly less likely to have a reconstruction compared to Whites ($p < 0.001$), and individuals residing in the Northern Plains compared to those residing in other regions were more likely to have a reconstruction following mastectomy ($p < 0.001$). Hot-spot analyses suggest that regions with a statistically higher population of Blacks undergoing mastectomy did not overlap with regions were reconstruction rates were significantly high; in fact, reconstruction rates appeared to be significantly lower in those regions (Figure 1).

Conclusions: Results indicate potential racial, spatial, and race by spatial variation for reconstruction after mastectomy. Black women utilize reconstruction less frequently than White women, and this disparity is pronounced in regions with higher mastectomy rates for Blacks. Further study is needed to determine causes of these disparities.



Spatial variation of the overall population having a reconstruction compared to clustering of the Black population undergoing mastectomy

257186 - Enhanced recovery after surgery pathway for microsurgical breast reconstruction: A systematic review and meta-analysis

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Background/Objective: Enhanced Recovery After Surgery pathways (ERAS) were introduced in 1997 as a multimodal approach to improve postoperative outcomes. ERAS pathways have become increasingly accepted and implemented for many procedures in several surgical specialties, which successfully improved postoperative pain control, reduced length of stay (LOS), and reduced costs. However, there is yet no widely accepted ERAS for microsurgical breast reconstruction. The purpose of this study is to conduct a systematic review of the current literature on ERAS for microsurgical breast reconstruction and to do a meta-analysis to determine whether the use of ERAS in microsurgical breast reconstruction cases is associated with any changes in LOS, or postoperative morbidity.

Methods: We searched PubMed, Embase, Cochrane, Scopus, and Web of Science for all randomized control trials, case-control, retrospective cohort, and prospective cohort studies published prior to June 2016 that contain original data investigating ERAS in microsurgical breast reconstruction in relation to postoperative LOS and morbidity. Studies found were screened using eligibility criteria previously agreed upon by the authors. Meta-analysis, odds ratio (OR), and 95% confidence interval (CI) were used to pool acquired data.

Results: The initial search identified 87 studies. Two independent screeners identified 4 original articles, with a pooled population of 676 patients who met the inclusion criteria. Of those, there were 3 retrospective studies and one prospective study. While LOS data was not homogenous enough to do a meta-analysis, ERAS LOS was reported in 3 studies to be lower when compared to the previous protocols, from 6.6 to 3.9 days ($p < 0.001$), 7.4 to 6.2 days ($p< 0.001$), and 6.2 to 3.1 days ($p< 0.001$). Two studies were pooled for the meta-analysis of postoperative morbidity, which suggested that ERAS was not associated with changes in 30-day postoperative morbidity; partial flap loss p=0.44 (OR 1.80, 95% CI: 0.41-7.95), total flap loss p=0.91 (OR 1.07, 95% CI: 0.35-3.23), breast hematoma p=0.69 (OR 1.15, 95% CI: 0.59-2.21), donor site infection p=0.53 (OR 1.29, 95% CI: 0.58-2.86), urinary tract infection p=0.29 (OR 0.37, 95% CI: 0.06-2.29), and pneumonia p=0.42 (OR 1.81, 95% CI: 0.43-7.66).

Conclusions: Our review suggests that ERAS in microsurgical breast reconstruction is associated with lower LOS. Meta-analysis suggests that ERAS is not associated with increased postoperative morbidity. The results of this review are limited by the low number of prospective and randomized controlled trials, the small number of patients and studies included, and the moderate heterogeneity of the groups evaluated within the included studies.

256899 - Surgical and oncologic outcomes after pre-pectoral breast reconstruction for mastectomy patients: The MedStar Georgetown University experience

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Background/Objective: Sub-pectoral (SP), implant-based breast reconstruction with acellular dermal matrix (ADM) has become an established technique for breast reconstruction after total mastectomy. Sub-pectoral placement of the implant with partial muscle coverage with ADM has achieved desirable cosmetic outcomes with less pain as compared to full muscle coverage. However, the disadvantages of this technique include infection, capsular contracture, postoperative pain, and animation deformity. With the widespread use of ADM, pre-pectoral (PP) prosthetic-based breast reconstruction has emerged as a new alternative to the partial or total SP approach. We reviewed our first patients who underwent PP implant reconstruction at MedStar Georgetown University Hospital between December 2015 and November 2016 and compared them to patients who underwent SP reconstruction during the same time period.

Methods: A retrospective chart review of patients undergoing either PP or retro-pectoral breast reconstruction at a single institution over 11 months was performed. Patient selection for PP reconstruction was based on surgeon preference of patients who were athletic and benefit from no animation deformity, low BMI, non-smokers, whose tumor was at least 1 cm from the overlying skin or nipple areolar complex, and no macromastia. Furthermore, the SPY Elite® image obtained intra-operatively showed adequate perfusion to the skin and nipple-areolar complex. Data was collected pertaining to patient demographics, tumor biology, reconstruction type, post-operative pain scores, narcotic use, and surgical and oncologic outcomes.

Results: Twenty-four patients were identified during the study period that underwent PP breast reconstruction. Age- and stage-matched control groups were obtained with 24 patients who underwent SP reconstruction in the same time period. Mean age of patients for PP was 50 years (range 32-71) and for SP was 48 years (range 32-74). Mean BMI was 22.3 for PP group (range 19-28) and 23 for SP group (range 18-35). The average breast size in the PP group was 35 with B and C cup being the most common (n=9,9). In the SP group, the average breast size was 35 with B being the most common (n=8). There were no D cups in the PP group, but there were 5 patients with D cups in the SP group. In the PP group, 64% of patients had invasive ductal cancer, 67% had in-situ ductal cancer, and 4% had invasive lobular cancer. In the SP group, 50% of patients had invasive ductal cancer, 63% had in-situ cancers, and 21% had invasive lobular cancer. In the SP group, 30% were stage 0, 37.5% were stage I and 33.3% were stage II which was equivalent to the PP group. Eighteen percent were BRCA positive in the PP group and 21% in the SP group. Ninety-one percent of patients in the PP group had nipple-sparing mastectomy, and 82% of them were bilateral procedures. Comparatively, 100% of patients in the SP group had NSM, and 83% were bilateral. The average pain score was 4.12 in the PP group (range from 2 to 7) and 5 in the SP group (range 2-7, p-value 0.08). Postoperative narcotic use was significantly lower in the PP group (p 0.02). There were 4 skin flaps with ischemia and 4 implant losses noted in the SP group. The PP group had significantly lower surgical complications including 1 skin flap with ischemia and 2 implant losses. Two patients in the SP group had nipple ischemia which progressed to full necrosis requiring removal of the NAC. No such patients were noted in the PP group. The median follow-up was 24 weeks for the PP group and 43 weeks for the SP group, and there were no local recurrences reported.

Conclusions: Pre-pectoral breast reconstruction is an emerging technique for immediate breast reconstruction after mastectomy. In carefully selected patients who are either undergoing prophylactic surgery or who have stage 1-2 cancer with low BMI, lack of macromastia, non-smokers, and have good flap perfusion intraoperatively with SPY technology were excellent candidates for this technique. Our study has shown that patients undergoing PP breast reconstruction had less postoperative complications with less narcotic use and equivalent oncologic outcomes as compared to the SP approach. Further prospective studies with longer follow-up are necessary to determine that PP reconstruction is associated with decreased post-operative pain, length of stay, animation deformity with improved aesthetic outcomes, and equivalent oncologic outcomes.

256397 - Optimizing opioid prescribing practices after mastectomy with immediate reconstruction

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Mayo Clinic, Rochester, MN

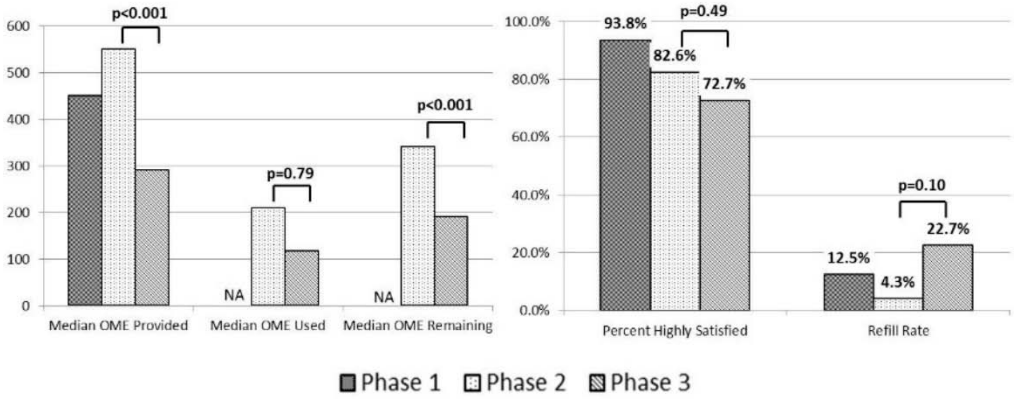
Background/Objective: Deaths as a result of drug overdose outnumber motor vehicle deaths in the United States. It is believed that over a third of opioid prescriptions are abused. As a result, the Surgeon General has recently made a call to action to address this epidemic. Anecdotal evidence suggests wide variations in current post-discharge prescribing practices in elective breast surgery patients. Therefore, a 3-phase initiative was conducted to provide evidence-based practice management guidelines for discharge prescribing practices.

Methods: Patients undergoing mastectomy with concurrent tissue expander reconstruction at a single institution participated in 1 of 3 phases of a quality initiative (11/15-9/16). Patients were surveyed at their first follow-up visit to determine post-discharge pain medication utilization, satisfaction with their pain management after discharge (scale 0-10, ≥9= highly satisfied), and refill rates. Discharge opioid prescriptions were converted to total oral morphine equivalents (OME). Based on phase I, guidelines for post-discharge acetaminophen, tramadol, and oxycodone prescriptions were developed for patients with average vs high-risk for post-operative pain (phase II-III). Descriptive statistics were used.

Results: During phase I, 16 patients who underwent mastectomy with subcutaneous tissue expander reconstruction were surveyed (11/15-12/15). Median 450 (IQR 347-551, range 225-925) OME were prescribed. Two patients required refills, and 93% were highly satisfied with their pain management. A guideline was subsequently developed to standardize post-discharge prescribing (550 OME prescribed average risk vs 900 OME high risk), and the survey was repeated (phase II, 3/16-5/16). Median 210 (IQR 0-303) OME were used. Of the 23 patients, one required refills, and 83% were highly satisfied. Six patients did not use any opioids after discharge, and 96% had left over opioids, resulting in 77% of opioids being un-used. Based on these findings, guidelines were revised to limit the number of opioids prescribed (290 OME average risk vs 450 OME high risk), and the survey was repeated (phase III, 7/16-9/16). A median of 118 (IQR 10-290) OME were used. Of the 22 patients, 5 required a refill, and 73% were highly satisfied. Three patients did not use any opioids after discharge, and 71% had leftover opioids, resulting in 53% of opioids being un-used. Comparison between phases is shown in Figure 1.

Conclusions: Routine post-discharge prescribing practices result in wide variability and may lead to significant over-prescription of opioids after elective breast surgery. Our experience suggests that guidelines can reduce the amount of opioids prescribed at discharge. However, while reducing excess

opioids available in the community is a noble goal, it must be done cautiously, as increased need for medication refills and decreased patient satisfaction can be an unintended consequence.



Comparison of OME, percent of patients highly satisfied with post-discharge pain management, and refill rates at each phase

Stage IV

257265 - Surgical and systemic management of stage IV breast cancer in the National Cancer Database (2009-2012)

Taiwo Adesoye[1], Jessica Schumacher[2], Caprice Greenberg[2], Jennifer Steiman[2], Heather Neuman[2], Lee Wilke[2]
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Background/Objective: There is ongoing debate regarding the use of primary tumor surgery for metastatic breast cancer. Current National Comprehensive Cancer Network guidelines recommend against this approach except for palliation. Several studies suggest a survival benefit. However, these are retrospective and subject to significant selection bias. We sought to examine current patterns of surgical and systemic treatment in patients presenting with metastatic breast cancer in a large contemporary dataset.

Methods: Using the National Cancer Database, we identified women who presented with stage IV breast cancer at diagnosis between 2009 and 2012. Receipt of breast surgery and surgical management of the axilla was determined over time. We compared sociodemographic factors between patients who did not receive surgery to those who did using chi square analysis. For patients undergoing surgery, we compared time to surgery relative to time to receipt of any systematic therapy (chemotherapy, immunotherapy and/or hormone therapy).

Results: Overall, 27,892 patients with stage IV disease at diagnosis were identified. Within this cohort, 9,729 (34.9%) underwent surgery, with the rate declining from 2,547 (38.1%) in 2009 to 2,270 (31.8%) in 2012. Compared to women who did not undergo surgery, those who received surgery were more likely to be younger, white, privately insured, without comorbidities and received care at a comprehensive community center ($p < 0.001$). Of those undergoing surgery, breast-conserving surgery was performed in

2,758 (28.4%) patients, and 6,971 (71.6%) received mastectomy. Nodal examination was performed in 11,650 (41.8%) patients. Compared to those who did not undergo surgery, more women who underwent surgery received chemotherapy (70.4% vs 49.6%, $p < 0.0001$) and any systemic therapy (91.8% vs 83%, $p < 0.0001$). Of 7,759 patients with known time to receipt of surgery and any systemic therapy, 3,226 (41.6%) received surgery prior to systemic therapy. 58.5% of patients who received surgery before systemic treatment received surgery within 30 days of diagnosis. Of these patients for whom surgery preceded systemic therapy the majority were ER/PR positive (77.8%) and had metastatic disease to only one of the following sites; brain, bone, liver, or lung (48.1%).

Conclusions: A substantial minority of patients presenting with stage IV breast cancer are undergoing breast surgery, with patients selected for surgery tending to be younger, privately insured, and without any comorbidities. Additionally, approximately 40% of patients were found to have surgery prior to systemic therapy, suggesting that some patients may have been diagnosed with stage IV disease after the primary breast surgery. Given the increasing body of evidence suggesting no survival benefit associated with primary breast surgery of stage IV disease with a large randomized trial result still pending, staging work-up for patients at risk for distant metastases prior to surgery may be warranted to spare patients' unnecessary surgery.

249836 - Stage IV breast cancer is increased by omitting screening mammography

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Background/Objective: Breast cancer is one of the most common cancers in the United States. Approximately 1 in 8 women will develop breast cancer in her lifetime. Mammography has been shown to be effective for early breast cancer detection and in decreasing incidences of late-stage breast cancer diagnoses. Many studies have shown that screening mammography has survival and prognostic benefits in breast cancer. Several national associations provide specific guidelines recommending early screening mammography. The American College of Radiology, National Comprehensive Cancer Network, and American College of Obstetrics and Gynecology continue to recommend screening mammograms starting at age 40. The American Cancer Society states that screening mammograms should start at age 45, but women have the choice to start annual mammograms at age 40-44. Recently the United States Preventive Services Task Force changed their recommendations to delay screening mammograms until age 50 and do not routinely suggest mammograms after age 75. Despite these recommended guidelines, 6-10% of newly diagnosed breast cancers are still diagnosed at Stage IV, or metastatic, at presentation. This study aims to review patients who present with stage IV breast cancer and the breast imaging they received in the 10 years prior to diagnosis. The purpose of this study is to elucidate if these patients were adherent to breast screening guidelines.

Methods: A retrospective chart review of all newly diagnosed stage IV breast cancer patients among 7 different hospitals in one health system over a 5-year interval (2011-2016) was initiated after IRB approval was obtained. All female patients age 40 and older who were diagnosed with stage IV breast cancer were included. Charts were reviewed to determine when the most recent breast imaging was performed in the 10 years prior to diagnosis.

Results: During the 5-year interval reviewed, 169 patients were diagnosed with stage IV breast cancer at our health system. Over 63% of newly diagnosed stage IV breast cancer patients had no dedicated breast screening imaging in the 10 years prior to diagnosis, specifically no breast ultrasounds, mammograms, or MRIs. The majority of patients (107/169 or 64.5%) had incidental findings on other imaging modalities such as CT scans, plain films, or non-breast MRIs that initiated their metastatic breast cancer workup. Many women presented with unrelated symptoms such as musculoskeletal or gastrointestinal complaints. The mean age of these patients was 63.8 years old. Of the women who presented with stage IV breast cancer, 23% were over the age of 75. The pathology of these cancers was most commonly invasive ductal carcinoma (65.7%) and hormone receptor positive, HER2 negative (59.2%). Interestingly, 76.9% of patients had a primary care physician listed at the time of diagnosis, and no patients were found to carry any genetic mutations.

Conclusions: The majority of the patients diagnosed with stage IV breast cancer had no breast screening imaging for over 10 years prior to their diagnosis. This demonstrates that most patients diagnosed with stage IV breast cancer were not compliant with any national breast screening guidelines. These findings suggest that routine screening mammography would have been beneficial in diagnosing breast cancer at an earlier stage. Also, most of the patients listed a primary care physician at the time of diagnosis which questions if physicians are adherent to breast screening guidelines or if this discordance is simply attributable to patient non-compliance. The results of this study also bring into question the United States Preventative Services Task Force recommendations to stop screening mammography for patients over age 75, as 23% of our stage IV patients were over the age of 75 at the time of diagnosis. The conclusions of this study continue to underscore the importance of breast cancer screening.

256597 - Patients with early-stage breast cancer still experience distant metastasis: The incidence and patterns of metastasis in early breast cancer patients

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Background/Objective: In recent decades, the rate of mortality in breast cancer patients has decreased due to early diagnosis and the advancement of treatment methods. However, despite multimodality treatment, about 20 – 30% of patients with early-stage breast cancer still experience distant metastasis. Patterns of metastatic failure by specific anatomic site and methods to predict which patients will experience metastasis have remained under-ascertained. For this reason, we evaluated the incidence and patterns of the development of metastasis at specific sites in early-stage breast cancer.

Methods: Eight hundred ninety-three patient with AJCC stage I or II who had breast cancer surgery were identified for this study from January 2004 to December 2014. We excluded women 1) with ductal carcinoma in situ (Tis), 2) with incomplete hospital electronic data and 3) who experienced local or distant recurrence within 6 months after surgery. Disease-free survival and the first metastatic sites were evaluated according to patients and tumor characteristics.
Results: Median follow up time was 76.5 months. Sixty-eight (7.6% of total patients) patients experienced systemic disease spread. Solitary metastasis was found in 39 patients and the others were experienced multiple distant metastases. Bone (41.0%), lung (25.6%) and liver (17.9%) were the 3 most common first metastatic sites. Using multivariate analysis, tumor size, nodal status, and molecular

subtype were independent risk factors for disease-free survival. In estrogen receptor-positive patients, long-term metastasis was more frequently found than receptor-negative patients.

Conclusions: The present study has demonstrated the site-specific risks of metastasis. Predicting the incidence and patterns of metastasis at specific sites could help physicians to perform more specific screening and prevention methods. These data could support clinical practice of screening for early breast cancer patients. Site-specific imaging should be added by concerning patient-specific site or symptoms.

257362 - Breast cancer patients with isolated disease to the lung: A single institution experience

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Background/Objective: The reported incidence of breast cancer presenting with isolated metastatic disease to the lung or pleura (IMLP) is approximately 12%. It usually represents systemic disease, and therefore no consensus exists on the best treatment modality between surgical intervention and systemic therapy. We performed this study to evaluate the median overall survival (OS) and 5-year OS rate of patients with metastatic breast cancer with IMLP disease treated at our institution.

Methods: We performed a retrospective review of data of 7971 patients with breast cancer treated between 1995 and 2013 at the Hospital of the University of Pennsylvania. We identified 119 patients with breast cancer and metastatic disease including lung/pleura. We excluded those with extra-thoracic disease. Treatment modalities involved operative and/or systemic therapy and their survival. In our study, we defined systemic therapy as chemotherapy and/ or endocrine therapy.

Results: Fourteen (11.8%) patients met our inclusion criteria, mean age was 58.9 years, most common tumor type was invasive ductal cancer (92.9%) and estrogen receptor positive (71.4%). Three patients (21.4%) underwent video assisted thoracotomy (VATS) for lobectomy in combination with systemic therapy, 8 (57.1%) had systemic therapy alone, 2 (14.3%) patients refused treatment, and 1 (7.14) received endocrine therapy alone. The mean number of nodules and nodule size was 3.25 nodules and 3.1 cm. The median OS and 5-year OS for all patients was 39.6 months and 64.3%, respectively. For those who underwent VATS and systemic therapy, the median OS and 5-year OS was 43 months and 66.6 % versus those treated with systemic therapy alone, was 36.4 months and 50.0% respectively (p-value = 0.742).

Conclusions: This retrospective analysis suggests that patients with IMLP disease who undergo both surgical intervention and systemic therapy have a more favorable median OS and 5-year OS. Generally, isolated metastatic disease offers the opportunity to gain local control and therefore potentially improve outcome. A multidisciplinary approach continues to be is essential in the decision-making to obtain local control and improve survival in selected patients with IMLP disease.

Study Subject	Age	Follow-up *(months)*	Race	ER Status	PR Status	HER2	Tumor Type	1ry Tumor size, largest *(cm)*	XRT	1ry BC treated with chemo	Adjuvant HT	Final Surgery	Systemic Therapy for Metastasis	Surgical Intervention for Metastasis	Number of Nodules *(n)*	Largest Nodule *(cm)*	Number of Lobes Affected *(n)*	Pleural effusion	Mediastinal Nodes	Hilar nodes	VATS margin R0
1	66	44.9	Black	Neg	Neg	Neg	IDC	2.3	No	No	No	M	Capecitabine	No	4	1.9	2	Yes	No	No	-
2	66	44.9	Black	Neg	Pos	Pos	IDC	3.5	No	No	No	BCT	Paclitaxel/ Trastuzumab	(VATS (Wedge LLL)	3	3.8	2	No	No	No	-
3	71	44.5	White	Pos	Pos	Neg	IDC/ILC				-	BCT	-	No	1	1.5	1	No	No	Yes	-
4	46	85.7	Black	Pos	Pos	Pos	IDC	0.2	Yes	Yes	Yes	M	Xeloda/ Lapatinib	VATS (wedge LUL)	1	0.9	1	No	No	No	Yes
5	36	80.7	Black	Pos	Pos	Neg	IDC	1.1	Yes	Yes	Yes	BCT	Taxol/Bevacizumab	No	2	0.4	2	Yes	No	Yes	-
6	68	66.7	White	Pos	Pos	Neg	IDC	0.5	No	No	Yes	M	Abraxane/Gemzar	VATS (wedge LLL)	3	3.3	3	Yes	Yes	Yes	Yes
7	39	61.1	White	Pos	Pos	Neg	IDC	8	Yes	Yes	Yes	M	Lupron/Ixabepilone/ Xeloda Ixabepilone/Xeloda	n/a	10	6.6	-	Yes	No	Yes	-
8	88	49.6	-	Neg	Neg	Neg	IDC	1.3	Yes	Yes	No	BCT	Xeloda	No	4	2.1	2	No	No	No	-
9	62	33.4	White	Pos	Pos	Neg	IDC	1.5	Yes	No	Yes	M	Tamoxifen	No	-	0.8	1	No	No	No	-
10	59	62.6	Black	Neg	Neg	Neg	IDC	2.8	Yes	Yes	No	M	Abraxane/Avastin	No	3	0.5	1	Yes	No	No	-
11	45	89.4	White	Pos	Pos	Neg	IDC	3.8	Yes	Yes	Yes	M	Xeloda/ Lupron/Denosumab	No	1	0.3	1	Yes	No	No	-
12	59	12.5	Black	Pos	Neg	Pos	IDC	2.7	No	Yes	Yes	BCT	Letrozole and Lapatinib--> changed to Anastrazole/ Faslodex	No	4	1.5	4	No	No	No	-
13	44	47.8	White	Pos	Pos	Neg	IDC	2.5	Yes	Yes	Yes	M	Letrozole --> Xeloda/Abraxane then >Faslodex/Denosumab/Eribulin	No	-	-	1	Yes	No	No	-
14	75	34.1	Black	Neg	Neg	Pos	IDC	3.6	Yes	Yes	No	M	Paclitaxel 75 mg/m2/Trastuzumab	No	3	3.4	3	Yes	No	No	-

***ER**: Estrogen Receptor; **PR:** Progesterone Receptor; **BC: Breast Cancer; Neg: Negative; Pos: Positive; HER2:** Human Epidermal Growth Factor Receptor 2; **IDC**: Invasive Ductal Carcinoma; **ILC**: Invasive Lobular Carcinoma; **XRT:** Whole Breast Radiation; **HT:** Hormonal Therapy; **M:** Mastectomy; **BCT**: Breast Conservation Therapy; **LLL**: Left Lower Lobe; **LUL**: Left Upper Lobe.*

Demographic and treatment details of study subjects

257211 - Comparative management of patients presenting with stage IV breast cancer across academic, private, and public institutions in the same metropolitan area

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Background/Objective: The management of stage IV breast cancer varies amongst different centers and regions of the country. Recent studies have pointed to a disproportionate rate of African American (AA) women presenting with stage IV disease. Further studies point to disparities in the type of therapies offered to this patient population. This is an observational survey in the care of patients presenting with stage IV breast cancer across 3 different hospital settings within the same hospital system in a large metropolitan area.

Methods: A retrospective examination of all patients presenting with stage IV breast cancer over a 12-year period was undertaken. Demographics and treatment information were compared between the 3 hospital settings. Statistical analyses were performed to identify care strategies of stage IV breast cancer patients across 3 treatment facilities.

Results: There were 500 patients identified with an initial presentation of stage IV breast cancer (173 academic, 151 private, and 176 public). The AA women represented 65.4% of the ethnic make-up of the entire system, but this varied between centers: 38.7%, 70.86%, and 86.93% at the academic, private, and public hospitals, respectively. When examining initial therapy for patients presenting with stage IV disease, 14.2% underwent surgical management, and 51.60% received chemotherapy across the entire system. Rates were similar between AA and Caucasian patients, surgery 15.5% versus 12.7% and chemotherapy 52.63% versus 47.0%. Surgical management varied between the facilities (11.8%, 21.2% and 10.2%), as did the use of chemotherapy (49.71%, 47.72%, 58.27%), when comparing academic, private and public facilities, respectively.

Conclusions: There were no clear ethnic disparities noted in rates of surgical or medical management of patients presenting with Stage IV breast cancer in this hospital system. But, there was a greater utilization of both treatment strategies at the private hospital in comparison with the academic or public hospitals. Further work will be explored to determine if this had a measurable impact on survival.

Other Topics

257177 - American Cancer Society 2015 guideline update affecting breast cancer detection rates at a community hospital compared to national incidence rates

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Background/Objective: There is a controversial recommendation published by the American Cancer Society in 2015 that women ages 40-44 should no longer receive annual routine mammogram screening. Based on anecdotal data within our patient population in Oakland County, Michigan, we suspected we would miss significant breast cancer diagnoses by not screening that age group. By looking systematically at screened female patients in our population, we have shown biopsy-proven and statistically greater incidence of breast cancer cases in the 40-44 age range when compared to the national incidence rates that the SEER (Surveillance, Epidemiology, and End Results) Program has published. Objective: To demonstrate the potential benefit of breast cancer screening of women ages 40-44 at St. Joseph Mercy Oakland Hospital in Oakland County, Michigan.

Methods: There were 48,006 screening mammograms reviewed retrospectively over the years 2009 to 2013 in women of ages 40-44 and 45-49. Incidence rates of biopsy-proven malignancy in these 2 age groups were calculated and compared. The incidence rate for women of ages 40-44 was found to be 0.0937% and 0.137% for women ages 45-49. The published incidence rates from the SEER Program over the exact same years for women of ages 40-44 and 45-49 were 0.0409% and 0.062%, respectively.

Results: The incidence rate for women of ages 40-44 in Oakland County, MI was found to be more than twice the incidence rate predicted by the national average. The difference in incidence rates between this population and the national average was found to be statistically significant ($p < 0.002$).

Conclusions: We found in our population that there is a greater-than-doubled detection rate of breast malignancies in women of ages 40-44 when compared to incidence rates nationally. This documents that local populations may be skewed and therefore, before adopting the recommendations, a study of local population incidence is warranted.

256692 - Talc seromadesis: Aspects to consider in order to improve the seromadesis technique following breast cancer surgery

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Background/Objective: Several techniques are available either to prevent or to treat breast seromas after undergoing a mastectomy. The lack of evidence does not justify not approaching the problem with innovative adapted techniques. A case series design was used to determine the effectiveness of the use of surgical talc for the treatment of persistent breast seromas. The purpose of this study is to describe an alternative technique using talc seromadesis.

Methods: A case series study on 6 female patients (ages 68 ± 7.9), 5 of whom were diagnosed with invasive ductal carcinoma (IDC) and one with ductal carcinoma in situ (DCIS), presenting a breast

serenoma resistant to common therapies were treated with adapted talc seromadesis. A solution was prepared with 5 g of surgical talc diluted in 90 ml of isotonic saline solution and 10 ml of a 1% solution of lidocaine hydrochloride (without epinephrine). An incision of approximately 1 cm was made next to the surgical wound in order to reach the subcutaneal dead space flap. Thirty milliliters of the solution was then injected and left for 5 minutes, after which a Biovac™ drain was secured. A compressive bandage was applied after the drain. This drain was left in each patient, who was sent home and asked to monitor the amount of fluid present in the drain on a daily basis until less than 20 ml of fluid per day was self-reported by the patient. To confirm the effectiveness of the procedure, a needle aspiration of less than 20 ml should be performed a week after the drain has been removed. The following variables were measured: Amount of drainage present before the seromadesis, amount of time the Biovac was present before being removed, and weekly fluid production after Biovac removal.

Results: Of the 6 patients participating in the study, 4 had a seroma for less than a month, while the other 2 had it for 6 and 12 months respectively. According to the medical histories, an average of 181.67 ± 121.71 ml of fluid per week was reported before the seromadesis. After the seromadesis, the Biovac was left for an average of 28.67 ± 15.34 days. At the follow-up session that took place a week after the procedure, an average of 7.5 ± 2.5 ml of fluid was extracted from the patients. After this initial follow-up one patient returned after 2 months with a new seroma producing around 260 ml per week. A second post-irradiated participant with concomitant uncontrolled DM2 presented an infected wound, which had to be healed by secondary intention.

Conclusions: Talc seromadesis proved to be an effective procedure in the treatment of resistant seromas. The presence of a concomitant pathology should be taken into consideration before performing this technique to avoid complications. It is important to use a diluted solution of surgical talc and to perform a local massage, so the substance is well distributed throughout the whole dead space. Additionally, the use of lidocaine is important in reducing the pain that the solution may cause. More research is needed to determine this modified talc seromadesis technique effectiveness and long-term results.

	Age	Type of Carcinoma	Weight (kg)	Height (cm)	BMI (kg/m^2)	DM2	High Blood Pressure	AINE	Chemotherapy	Pre-seromadesis production (ml)	Post-Drain removal production (ml)	Drain removal time (days)	Complications
Patient 1													
Patient 2													
Patient 3													
Patient 4													
Patient 5													
Patient 6													
Average													
St. Dev.	7.96		13.1	6.88	5.23					121.71	2.5	15.35	

Patient's characteristics and results pre- and post-talc seromadesis

257383 - Increased risk of secondary sarcomas in women with breast cancer: A 40-year analysis with SEER data

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Background/Objective: Second malignancies can develop as a consequence of cancer treatment. Several studies have described an association between radiation exposure and the development of soft tissue sarcoma. The aim of this study was to identify factors associated with increasing risk of sarcomas in women with breast cancer, with a particular focus on radiation field.

Methods: This is a retrospective cohort study comprising all women with microscopically confirmed in situ and invasive breast carcinomas included in the SEER-9 database from 1973 to 2013 (n=488,804) with information regarding the use of radiation therapy (RT) as part of the treatment. The development of subsequent sarcoma in the cohort was identified by querying the SEER database for all microscopically confirmed tumors with ICD-O-3 codes 880 through 958 that occurred in women in the cohort during the study period (1973-2013). Women with a diagnosis of sarcoma within 6 months of diagnosis of their breast cancer (n=136) were excluded from further analyses, in order to avoid the inclusion of synchronous malignancies. Results were stratified by location of sarcoma into in-field and out-of-field. In-field sarcomas were defined as those occurring at sites that would be included in the RT field, ie, thorax and ipsilateral upper extremity. Out-of-field sarcomas were those occurring at all other sites. Standardized incidence rations (SIR) and corresponding 95% confidence intervals (95% CI) were calculated. All analyses were performed using SEERStat version 8.3.2.

Results: During the study period, 1,373 women from the cohort developed 1,388 sarcomas within a median latent period of 105 months after the diagnosis of breast cancer (range, 7-417 months). One hundred sixty-two sarcomas were observed in-field (SIR=2.02, 95% CI 1.72-2.36) while 1,226 secondary malignancies were located out-of-field (SIR=1.35, 95% CI 1.28-1.43). Overall, mullerian mixed tumors (n=274), carcinosarcomas (n=229), and leiomyosarcomas (n=154) were the most frequent histological types. Radiation therapy increased the risk of secondary sarcomas both in-field (SIR=3.22, 95% CI 2.63-3.91) and out-of-field (SIR=1.46, 95% CI 1.33-1.59), while women not submitted to RT only presented increased risk of secondary sarcomas out-of-field (SIR=1.28, 95% CI 1.19-1.38). In the group of secondary sarcomas in-field, the most frequent secondary sarcomas were malignant fibrous hystiocitoma (n=21), leiomyosarcomas (n=18), and dermatofibrosarcomas (n=16). Risk of secondary sarcomas in-field for those women submitted to RT only started to increase significantly 5 years after the diagnosis of the first primary (6-11 months after first primary, SIR=0.61, 95% CI 0.02-3.41; 12-59 months, SIR=1.64, 95% CI 0.97-2.59, 60-119 months, SIR=4.72, 95% CI 3.43-6.34; 120 months and later, SIR=4.00, 95% CI 2.84-5.47).

Conclusions: An increased risk of secondary sarcomas was found for women with breast cancer submitted to RT, including tumors both inside and outside the radiation field. These findings can suggest the presence of cancer predisposition syndromes, with the RT possibly increasing even more the risk of sarcomas in this group of cancer-predisposed women. Our findings highlight the importance of the long-term follow-up of these patients in order to increase early detection of these secondary sarcomas, minimizing the consequent morbidity and mortality.

257073 - Impact of rural-urban status on survival after mastectomy without reconstruction versus mastectomy with reconstruction

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Background/Objective: Mastectomy with reconstruction has been proven to be comparable to mastectomy without reconstruction for overall survival. However, access to reconstruction in a rural compared to an urban setting may be limited due to lack of providers or centers specializing in this area. Recent studies have demonstrated time to surgery influences breast cancer survival. We hypothesize rural patients would have delayed time to surgery (TTS) if undergoing mastectomy with reconstruction compared to mastectomy alone, and poorer breast cancer survival compared to urban patients undergoing similar procedures.

Methods: We utilized data from the National Cancer Database to study 90,319 patients diagnosed with invasive, non-inflammatory, non-metastatic breast cancer who underwent mastectomy without reconstruction or mastectomy with reconstruction as initial treatment between 2003 and 2007, with follow-up available through 2012. Chi-square analysis and independent t-test were used to compare TTS by rural-urban status. Survival curves were constructed by rural urban status for surgery type. Cox regression analysis was used to calculate hazard ratios (HR) and 95% confidence intervals (CI) controlling for demographic, clinical, and treatment characteristics.

Results: Mastectomy without reconstruction comprised 82% of the cohort, and 18% of these patients were rural. Mastectomy with reconstruction comprised 18% of the cohort with 11% rural patients. Mastectomy without reconstruction patients were older, had higher comorbidity scores, were less often treated at an academic center, held less private insurance, were less educated, and were poorer. Mastectomy with reconstruction patients had lower stage at diagnosis. Mean TTS was 27±22 days for mastectomy without reconstruction vs 36±22 days for mastectomy with reconstruction patients. Time to surgery was longer in the urban group for all surgery types (~4 days longer). More patients underwent surgery within 30 days in mastectomy without reconstruction group compared to the mastectomy with reconstruction group (67% vs 46%). Poorer survival was noted in rural compared to urban patients in unadjusted analysis of mastectomy without reconstruction patients ($p < 0.001$). No survival difference was seen in the mastectomy with reconstruction group between rural and urban patients. However, adjusting for demographic, clinical, and treatment characteristics, there was no difference in survival by rural urban status for either mastectomy without reconstruction (HR 0.96; 95% CI 0.93-1.00), or mastectomy with reconstruction (HR 1.36; 95% CI 0.96-1.92).

Conclusions: Time to breast surgery was longer for mastectomy with reconstruction compared to mastectomy without reconstruction in both urban and rural cohorts. Adjusted analysis refutes our hypothesis and demonstrates no difference in survival for rural patients undergoing mastectomy with reconstruction even with a delayed time to surgery.

256906 - Body image and sexual function in breast cancer survivorship: The impact of time and surgical approach

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Background/Objective: Breast cancer survivors comprise the largest group of cancer survivors in the United States. Patients are living longer after their breast cancer treatment. As life expectancy increases, so does the longevity of the impact of surgical procedures. Our study aims to evaluate patient perceived body image as characterized by satisfaction with chest wall appearance and sexual function following treatment stratified by time and surgical modality.

Methods: An anonymous, cross-sectional survey of 585 patients in surveillance after breast cancer treatment at a single multidisciplinary breast cancer program was conducted over 18 months. Results were analyzed in the fields of appearance satisfaction of chest after surgery, interval from surgery, surgical modality, and sexual function measured by the Female Sexual Function Index (FSFI). Statistical analysis was performed using Fisher's exact and the Wilcoxon rank-sum tests or the Kruskal-Wallis test. Responses were divided based on interval from surgery and surgical modality. Time intervals were < 1 year, 1-2 years, 2-4 years, and greater than 4 years. Satisfaction was characterized as satisfied, equal or dissatisfied. Surgical modality included lumpectomy (L) and mastectomy with reconstruction (MR). MR was then divided into subgroups of non-nipple sparing mastectomy (MR-N) or nipple-sparing mastectomy (MR+N).

Results: Of the 585 respondents, 152 (76.4%) patients at 1-2 years from treatment described satisfaction with the appearance of their chest compared to 108 (61.4%) who were > 4 years from treatment (p= 0.05) Overall, patients undergoing L had a nearly significant higher rate of appearance satisfaction than those undergoing MR (76.2 versus 66.7, p=0.07). However, when MR is placed in subgroups, the difference in appearance satisfaction between L and MR+N is lost (76.2 versus 71.4% p=0.6), as compared to appearance satisfaction of L versus MR-N (76.2 vs 50, p=0.006). Sexual dysfunction (FSFI < 26) increased over time from surgery for L: 41.2% at 1-2 years, 45.6% at 2-4 years and 57.1% at > 4years (p=0.2). While not significant, MR patients' sexual dysfunction decreased over time: 42.3 at 1-2 years, 38.9 at 2-4 years, and 29.6 at >4 years (p=0.8).

Conclusions: Overall, our study shows that as breast cancer survivors move away from their diagnosis and treatment, they report decreasing satisfaction with the appearance of their chest. While we cannot account for evolving surgical technique, this may be a consequence of patients moving past the turmoil of initial diagnosis and into survivorship. Further, we find a trend to greater appearance satisfaction for those who kept their nipples whether by L or MR+N. These results suggest the importance of avoiding deformity, which may be improved by oncoplastic technique and neoadjuvant therapy. Finally, MR patients report a lowering rate of sexual dysfunction overtime, an opposite trend to the L group. This may be a consequence of age and other confounding factors. Overall these results may assist clinicians in counseling patients at diagnosis.

257336 - Given that provider-specific public reporting launches in 2016, it is time to engineer a 4-star rating system for patient stakeholders to compare surgeon performance for breast-conserving operations!

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Background/Objective: Previously limited to group practices and ACOs, the CMS public report-carding of individual providers begins in 2016 with a star system. Many patients seek information from online rating agencies that provide testimonials, but no procedure-specific data, to aid their search for destination of care for breast-conserving surgery for cancer (BCS). In this study, for 2 intuitively important patient-centered QM, reoperation rates (ROR) and cosmetic outcomes (COS), we aimed to provide the first step towards development of a CMS-type of star rating system to inform patients anticipating BCS. There is strong evidence for nationwide variability of ROR. There is very limited data on the variability or national performance of COS. To develop a rating system, we aimed to determine the interactions between surgeon, ROR, excisional volume, and COS within a single institution for internal quality improvement (QI) and as a first step towards public transparency and nationwide peer comparison. Given the recent rapid adoption of oncoplastic (OncP) lumpectomy techniques, we also aimed to challenge the historical assumption that surgeons who achieved low ROR did so by performing large volume lumpectomies with resulting worse COS.

Methods: After IRB approval, a retrospective review of a prospective breast center database was performed for all patients Stage 0-3 undergoing initial lumpectomy from 2010-2015 by 3 surgeons. A mailed survey was sent to each patient in 2016 to ask for their self-reported COS by the Harvard scale (excellent, good, fair, poor). Univariate and multivariate regression analysis was used to test for interactions between surgeon and multiple other independent variables known to influence ROR, for the outcomes of ROR and COS. For the star rating system, 4 performance levels each were created for ROR and COS, after literature review. For ROR: < 10%, 10-19%, 20-29%, >30% = 2, 1.5, 1.0, 0.5 stars, respectively. For % total patients reporting COS as excellent or good: >90%, 80-90%, 70-79%, < 70% = 2, 1.5, 1.0, 0.5 stars, respectively.

Results: The ROR in < 60 days for Stage 0-3 and Stage 1-3 patients were 12.3% of (54/438) and 10.4% (38/366), respectively. For 3 surgeons, the unadjusted ROR were 9.5%, 13.0% and 16.3% (p=0.18). Comparing to the surgeon with lowest ROR, the odds ratios (OR) for ROR for the other surgeons were 1.32 [CI 0.46-3.83; p=0.357] and 3.22 [1.45-7.16; p=0.004]. Level 1 OncP surgery was performed in 98 (22.4%) of 438 patients, ranging from 16%-32% by surgeon (p=0.047). Resection volume (3d) mean, median (range) were 196 mm3, 157 mm3 (7-1150 mm3). There was an inverse association between larger volume and lower ROR [odds ratio 0.995 (CI 0.992-0.998; p < 0.001)]. Excellent, good, fair, and poor COS were 55.3%, 32.2%, 8.6% and 4.0%, respectively (N= 152 respondents). There was no difference in COS by surgeon (p=0.295). OncP techniques were used more often in patients with higher volume resections (p=0.031). Surgeons A, B, and C had composite star scores of 4, 3, and 2.5.

Conclusions: In the setting in which 1 in 5 patients underwent OncP techniques, resection volume was not associated with COS. Furthermore, surgeons with statistically significant differences in reoperation rates did not have significant differences in cosmetic outcomes, challenging the historical assumption that linked a surgeon with a better ROR to a worse COS. A simple star rating system modeled after CMS public reporting was able to differentiate the performance between surgeons for 2 patient-centered

outcome measures of BCS. Next steps would follow accepted methods for composite measure development-- patient focus groups to establish the mathematical weighting of ROR/COS (reflecting patient values), reliability and validity testing, pilot studies to gather composite data from the ASBrS patient registry and survey, peer comparison with internal transparency, then a multi-stakeholder consensus conference to refine the star system prior to public transparency.

257029 - Breast cancer luminal subtypes and patient presentation

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Background/Objective: Previous studies have shown that mammogram-detected cancer has more favorable prognosis, at least in part because they are smaller and with less nodal involvement. We hypothesize that mammogram-detected cancers are also more favorable because they are more often diagnosed with a more favorable luminal subtype.

Methods: This is a retrospective review of a prospective database for operable invasive breast cancers diagnosed from 2008-2016. Patients were stratified using luminal subtype and presentation of abnormal findings leading to diagnosis. These variables were analyzed using chi square test. Five-year, distant, disease-free survivals (DDFS) were analyzed based on luminal subtypes and based on presentation. Luminal subgroups are defined as follows: luminal A ER+/HER2-; luminal B ER+/HER2+; HER2+ overexpressive ER-/HER2+; and basal ER-/HER2-. Invasive breast cancers were classified into the luminal subgroups A 570 (67%), B 95 (11%), HER2+ 57 (7%), and basal 129 (15%). Additional variables that were analyzed include tumor size, tumor differentiation, Ki-67, lymph node involvement, luminal subtypes, age, and race.

Results: Forty-eight percent (404) of the 846 patients presented with palpable masses, 41% were noted by the patients. After these 404 lesions were palpated, subsequent mammograms showed the lesion in 72%. Fifty-two percent (442) of the cancers were found with mammography: 71% were masses and 29% were calcifications. Sixty-seven percent (530) of the cancers were luminal A, 11% luminal B, 7% HER2 overexpressive, and 15% were basal. Palpable cancers were significantly ($p < 0.001$) more likely to be triple negative than cancers found on mammography. DDFS was related to both presentation and luminal subtype. Ninety-five percent of the patients with cancers detected on mammography were alive and disease-free at 5 years compared to 86% of patients with cancers palpated by physicians and 85% of patients with cancers first palpated by the patients.

Conclusions: These results indicate that cancers presenting as palpable masses are significantly more frequently triple negative than cancers presenting on mammography. This results in significantly poorer outcomes for palpable cancers. This supports the hypothesis that the poor outcome of palpable cancers is due to tumor biology in addition to tumor size and nodal status.

Presentation	Luminal A ER+/Her2-	Luminal B ER+/Her2+	Her2+ ER- Her2+	Basal ER- Her2-	Total N	Distribution	5 yr DDFS By presention
Mammo Mass	78%	9%	4%	9%	315	37%	95%
Mammo Calcifications	66%	14%	9%	11%	127	15%	95%
Pt Palpable	57%	13%	8%	23%	345	41%	85%
MD Palpable	76%	5%	5%	14%	59	7%	86%
Total N	570	95	57	129	N=846		
Distribution	67%	11%	7%	15%			
5yr DDFS By subtype	93%	94%	81%	84%			

DDFS by presentation and luminal subtype

252809 - Selective radio-guided axillary dissection (SeRAD): A prospective cohort study

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Background/Objective: In the staging of the axilla for clinically lymph node negative disease, sentinel lymph node biopsy (SLNB) has become the standard over the axillary lymph node dissection (ALND). In patients with T1-T2 invasive breast cancer, clinically node negative, and 1 or 2 metastatic sentinel lymph nodes, SLNB alone results in the same survival as ALND. Axillary selective radioguided dissection technique (SeRAD) is comparable to SLNB + 4 or 5 parasentinel lymph node dissection. The aim of our study is to compare SeRAD versus SLNB, in order to demonstrate that SeRAD reduces the rate of reoperation of patients (ALND).

Methods: The technique we developed for selective radioguided axillary dissection is based on the removal of a sentinel lymph node together with 4 or 5 parasentinel lymph nodes. This removal is performed following lymphatic flow, guided by decreasing radioactivity, highlighted with the aid of the gamma probe. Since June 2014 through May 2016, we operated for invasive breast cancer on 75 patients by SLNB and 145 patients by SeRAD technique. The average age of the patients was 55 (range 25-84).

Results: Of the 75 patients subjected to SLNB, 14 had metastatic sentinel lymph node, and in all 14 cases, ALND was needed. Of the 145 patients subjected to SeRAD, vice versa, 25 had metastatic sentinel and/or parasentinel lymph node, but only in 5 cases ALND was needed.

Conclusions: In our experience, SeRAD has revealed many advantages compared to ALND and SLNB. It removes both the SLN and a variable number of parasentinel lymph nodes, sufficient for oncological staging. This radio-assisted technique ensures the removal of the first lymph node that follows the lymphatic flow after the SLN (unlike the single first level lymphectomy, which cannot guarantee this) and allows its inclusion in the histologic specimen even in cases of “skip metastases.” It permits avoidance of the intraoperative histo-cytologic examination of the SLN, thus shortening operating times. It permits avoidance of the need to re-operate the patient in the presence of unfavorable histologic results, thus avoiding unnecessary lymphectomies with all its related complications. It reduces costs and surgical time, compared to more demolitive surgery. The performance of SeRAD is technically much easier and faster than ALND. Finally, it allows for shorter post-operative hospitalization periods (a post-operative stay of 1 or 2 days less) and is almost free of complications.

	SLNB	SeRAD
Surgery on N		
Number of patients (%)	75 (34,09%)	145 (65,90%)
Median age in years (range)	58,39 (34-86)	55,24 (23-85)
Mean lymph nodes removed (range)	1,34 (1-3)	4,8 (3-7)
pN+ patients (%)	14 (18,67%)	25 (17,24%)
Patients subjected to ALND	14 (17,24%)	5 (3,45%)
Primary tumor		
Palpable mass (%)	48 (64,00%)	84 (57,93%)
Mean diameter in cm (range)	1,28 (0,3-2,2)	1,58 (0,2-1,9)
Mean distance from resection margins in cm (range)	1,35 (0-4,1)	2,32 (0-3,4)
Histotype		
CDI (%)	33 (44,00%)	72 (49,66%)
CDIS (%)	16 (21,33%)	25 (17,24%)
CLI (%)	11 (14,67%)	18 (12,41%)
CLIS (%)	6 (8,00%)	11 (7,59%)
Other (%)	9 (17,33%)	19 (13,10%)
Surgery on T		
Quadrantectomy	54 (72,00%)	116 (80,00%)
Lumpectomy	11 (14,67%)	10 (6,90%)
SSM	4 (5,33%)	15 (10,34%)
NSM	6 (8,00%)	4 (2,76%)
Mammography (%)		
No abnormalities	6 (8,00%)	13 (8,97%)
Calcifications	53 (70,67%)	112 (77,24%)
Mass	9 (12,00%)	16 (11,03%)
Calcifications and mass	7 (9,33%)	4 (2,76%)
Ultrasound (%)		
No abnormalities (%)	9 (12,00%)	16 (11,03%)
Benign lesion (%)	4 (5,33%)	5 (3,45%)

SeRAD patients table

257228 – Minimally invasive, sutureless, stereo-targeted definitive lumpectomy in an outpatient setting

Pat Whitworth
Nashville Breast Center, Nashville, TN

Background/Objective: Despite advances in technologies characterizing breast cancer biology, indolent lesions cannot be identified. Many indolent breast cancers and DCIS are overtreated to avoid undertreatment of life-threatening cancers. Improving use of specialty resources to reduce overtreatment meets a high-priority need in modern breast cancer care.

Methods: One hundred twenty-five women ages 31-86 had removal of small DCIS and invasive cancers using a 20-mm radiofrequency basket-capture with stereotactic guidance. Tissue elasticity permitted removal through a 12-mm incision. A second 20-mm basket-capture was used to obtain shaved margins. Incisions were closed with Steri-Strips™. Procedures were conducted under local anesthesia and with P.O. sedation. Patient tolerance scores were recorded. Standard radiologic evaluation (specimen and breast) and histologic criteria were applied in all cases. Patient data are registered prospectively and reported with informed consent.

Results: Final histologic size ranged from 1-20 mm. Of 52 DCIS and 73 invasive lesions, 23 (18.4%) had positive margins by histologic standards, and 17/22 with reported results (77.3%) had no residual lesion after open surgery. A total of 26 patients had open re-excision, 6 despite clear margins at intact (One of these patients chose mastectomy.). Ninety-five patients went on to complete accelerated partial (72) or whole-breast (23) radiation. Patient pain scores averaged 1.55 out of 10 (range 0-7).

Conclusions: For small DCIS and invasive cancers, image-guided, minimally invasive lumpectomy can be accomplished in an outpatient setting, either the physician's office or imaging suite. The intact specimen permits standard-of-care histologic analysis of lesions and margins. Because stereo targeting requires less tissue removal via small incisions that do not require sutures, image-guided lumpectomy reduces morbidity, distress, discomfort, and expense associated with overtreatment of small breast cancers. And it is particularly appealing to some subsets of patients for whom surgical risks may be increased.

257329 - Image-guided definitive excision of high-risk breast lesions in the outpatient setting

Pat Whitworth
Nashville Breast Center, Nashville, TN

Background/Objective: In light of increasing pressure on health care resources, we seek to validate a minimally invasive, image-guided alternative to open surgical excision for high-risk breast lesions.

Methods: One hundred fifty-six women ages 31-78 had image-guided (stereotactic or ultrasound), minimally invasive, intact excision of high-risk lesions and surrounding tissue, using either a 15- or 20-mm radiofrequency basket-capture. Imaged lesion size was 3-12 mm. Thirty-seven percent were masses, 57% were microcalcifications, and the remaining were a combination of mass and microcalcifications. Tissue elasticity permitted removal through a 10- to 12-mm incision. Incisions were closed with Steri-Strips™. Procedures were conducted under local anesthesia and with P.O. sedation in the office or imaging department. Patient pain tolerance scores were recorded. Standard radiologic evaluation (intact specimen and breast) and histologic criteria were applied in all cases. Patient data are collected in an electronic HIPAA-compliant registry and reported with informed consent.

Results: All 156 lesions were definitively removed. Final histology is shown in the associated table. Twelve patients had their high-risk pathology change from the original core biopsy pathology; 4 were upgraded within the HRL categories and 8 were actually downgraded. Two patients went on to open excisional biopsy because of physician discomfort with margin status; both patients were upgraded within the HRL category but cancer was not found. Patient reported pain scores averaged .93 out of 10 (range 0-6).

Conclusions: All 156 lesions were definitively removed. Final histology is shown in the associated table. Twelve patients had their high-risk pathology change from the original core biopsy pathology; 4 were upgraded within the HRL categories, and 8 were actually downgraded. Two patients went on to open excisional biopsy because of physician discomfort with margin status; both patients were upgraded within the HRL category, but cancer was not found. Patient-reported pain scores averaged .93 out of 10 (range 0-6).

Final INTACT Histology	# of patients	% of total
ADH	37	24%
ALH	20	13%
LCIS	5	3%
Papillary Lesion with Atypia	9	6%
Papillary Lesion with No Atypia	47	30%
Radical Scar	19	12%
Other HRL	19	12%

Final intact histology

256753 - Significant discordance of lymphovascular invasion between breast cancer core biopsies and surgical specimens limits its role as a tool for preoperative prediction of nodal metastasis

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Background/Objective: Many breast cancer nomograms have been developed from resected tumor pathology, but are intended to be used preoperatively based on core biopsy results. Some of these nomograms use lymphovascular invasion (LVI) as one criterion to predict the likelihood of sentinel lymph node metastasis. In this study, we examined whether LVI on resected tumor pathology is accurately identified on core biopsy, and whether there is a difference in correlation of patients' sentinel node status between core biopsy and resected tumor LVI.

Methods: We reviewed cases of invasive breast cancer from February 2011 to September 2014, excluding those with neoadjuvant therapy, recurrent cancer, histology other than ductal/lobular/mixed, or stage IV disease. LVI was categorized as absent, present, or suspicious, as indicated in the pathology report, and compared on core biopsy vs. resected tumor. We also compared the percentage of patients who had a positive sentinel node biopsy between negative, suspicious, and positive LVI on core biopsy vs. resected tumor.

Results: We analyzed 614 cases for LVI discordance. Of 147 cases with positive LVI on resected tumor, 70 (55%) were negative for LVI on core biopsy (Table). Of cases with LVI present on core biopsy, 33.3% were negative for LVI on resected tumor. Of cases suspicious for LVI on core biopsy, LVI status on resected tumor was negative in 44.6%. When using core biopsy to define LVI, the percentage of patients with positive sentinel lymph nodes was not significantly different by LVI status (negative, suspicious, or positive). However, when using resected tumor to define LVI, there was a stepwise increase in the likelihood of having a positive sentinel lymph node with negative, suspicious, or positive LVI (Table). The likelihood of a positive sentinel lymph node was significantly higher for those with positive LVI on resected tumor, compared to those with negative LVI on resected tumor (48.2% vs. 12.5%, $p < 0.001$).

Conclusions: In some nomograms, the presence of LVI has been shown to increase the probability of having sentinel node metastasis by approximately 25%. However, the present study demonstrates that preoperative core biopsy misses the majority of cases of LVI. Furthermore, the percentage of patients with positive sentinel nodes was not significantly different between those with negative LVI and positive LVI on core biopsy, but was significantly increased in patients who had positive LVI on resected tumor vs. negative LVI on resected tumor. Postoperative data (e.g., pathology from resection) is often used to develop nomograms for preoperative use, on the assumption that the core biopsy information will correlate with the resected tumor. This study shows that LVI on core biopsy does not correlate well with resected tumor pathology, which translates into an inability to accurately predict sentinel node status preoperatively.

		Resected tumor			
		Negative for LVI (n=477)	Suspicious for LVI (n=10)	Positive for LVI (n=127)	% of patients with + SLN
Core Biopsy	Negative LVI (n=510)	434 (91%)	6 (60%)	70 (55%)	17.3% (CI 14.0-21.1%)
	Suspicious for LVI (n=74)	33 (7%)	3 (30%)	38 (30%)	23.0% (CI 13.5-36.8%)
	Positive for LVI (n=30)	10 (2%)	1 (10%)	19 (15%)	27.8% (CI 10.7-53.6%)
	% of patients with + SLN	12.5% (CI 9.7-15.9%)	37.5% (CI 10.2-74.1%)	48.2% (CI 36.8-57.9%)	

256995 - Circulating tumor DNA and burden of disease in breast cancer

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Background/Objective: Tumor somatic mutations can be detected in blood as circulating free DNA (cfDNA) that are concordant with mutations in the primary cancer. This non-invasive technology is emerging as a potential tool to dynamically monitor tumors response to treatment, potentially detect actionable molecular targets, and inform prognosis.

Methods: Between 2014 and 2016, we studied patients with newly diagnosed invasive stage I-IV breast cancer who underwent upfront surgery or chemotherapy and followed them serially (baseline, post-operative, 1 month, 3 months, 6 months, and 12 months) over a 12-month period. Guardant Health has developed a protocol (digital sequencing) for purification, targeting, sequencing, and analysis of cfDNA for the detection of single nucleotide variants (SNVs) in 54 genes and copy number alterations (CNAs) in 3 genes (ERBB2, EGFR, MET). Peripheral blood samples were collected in 2 10 mL tubes at baseline and subsequent time points. The lower limit of detection is 0.1% variant allele frequency (VAF) at each nucleotide position with analytic specificity for SNVs > 99.9999%. Here we report findings of baseline assessments in cfDNA tumor-related genetic alterations and their correlation with disease stage.

Results: Of 30 patients with breast cancer, 20 underwent upfront surgery and 10 upfront chemotherapy. According to subtype, 17 (57%) were ER+/PR+/HER2-, 10 (33%) ER+/PR+/HER2+, and 3 (10%) ER-/PR-

/HER2-. Stage distribution was as follows: Stage I= 10 (33.3%), Stage II = 13 (43.3%), Stage III 5 (16.6%), IV = 2 (6.6%). cfDNA alterations were detectable in 12 (40%) overall, including 20% stage I, 38% stage II, 60% stage III, and 100% stage IV. The rate of alterations in HER2+ patients at baseline testing was considerably higher, namely 50% stage I (n=2) and 75% stage II (n=3). Interestingly, 50% of these alterations were no longer detected in samples taken in the operating room post-surgical resection of the primary tumor.

Conclusions: In this pilot exploratory study, cfDNA was frequently detected in patients with newly diagnosed stage I-IV breast cancer. The evaluation of cfDNA analysis offers a non-invasive means to serially monitor a systemic component of disease.

257204 - The present of grossly palpable Level II axillary nodes during ALND is a strong predictor of level III axillary nodal involvement for breast cancer patients

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Background/Objective: The number of involved axillary lymph nodes is an important prognostic factor that guide selection of breast cancer patients who might benefit from adjuvant treatment. Current NCCN guidelines recommend ALND should include level III nodes only if gross disease is apparent. In reality, very few surgeons extend ALND to level III. And the necessity of level III dissection is still an issue of controversy. We aim to investigate the positive identification rate of level III nodal involvement when level II axillary nodes are grossly palpable during ALND for breast cancer patients.

Methods: We prospectively enrolled breast cancer patients with cT1-3N1 diseases. They all had multiple suspicious nodes on ultrasound and cytological proof positive nodes by ultrasound-guided nodes FNA. All patients underwent modified radical mastectomy and found grossly palpable level II axillary nodes during ALND and thus proceeded to do level III nodes dissection. Level III nodes is dissected by bluntly dividing the pectoralis major muscle at the level around 2 cm below the sterno-clavicular joint. All patients received post-op axillary and regional nodal radiation therapy and proper systemic therapy accordingly. We calculated positive identification rate of level III nodes in this setting, numbers of positive Level III nodes, rate of lymphedema, and disease-free survival rate.

Results: Between January 2010 and Jun 2015, 35 eligible breast cancer patients were enrolled. All patients were found grossly palpable level II nodes and underwent level III nodes dissection. Pathological results revealed that 31 patients had positive level III nodes, identification rate was 89%, and average number of positive nodes were 2.15 (ranged from 1-4). Patient-reported incidence at 12 months of moderate or severe lymphedema was 17.1%, which was similar to patients who underwent Level I and II dissection only at our institution. At a median of 3.5 years' follow-up, disease-free survival of this cohort of patients was 91.4%. Only 3 metastatic events were found, and no locoregional recurrence event was reported.
Conclusions: In conclusion, our study found that the present of grossly palpable Level II axillary nodes during ALND is a strong predictor of Level III axillary nodal involvement for cT1-3N1 breast cancer patients. Level III axillary dissection is recommended in this setting for more accurate staging and achieving great locoregional control.

257365 - Biodiversity of synchronous breast cancers and clinical management implications

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Background/Objective: Additional foci identified on breast imaging may change clinical decision-making. The purpose of this study is to evaluate the incidence and potential clinical significance of additional breast tumors identified by imaging.

Methods: An IRB-approved review of our database from 1/1/12 to 12/31/15, yielded 886 patients with breast cancer. Of 886 patients, 175 patients (19.5%) had pathology-proven 213 additional tumors. Both the primary and secondary tumors in these patients underwent the following evaluation: size, histologic subtype, hormone receptor and HER2 status, tumor grade, Ki-67, and type of imaging modality performed. Statistical analysis was performed (SPSS, version 24).

Results: In 175 patients, 213 synchronous additional tumors were present; one additional (142, 66.7%), 2 additional (26, 12.2%), 3 additional (6, 2.3%) and 4 additional tumors (1, 0.5%). Of 213 tumors, 112 were multifocal (52.6%), 60 were multicentric (28.2%), and 41 were contralateral cases (19.2%). The size of the 175 primary tumors was significantly larger (mean 2.07 cm, SD 1.43) than the 213 secondary tumors (mean 1.34cm, SD 0.93, $p < 0.001$). The primary tumor was significantly more likely to be invasive (90.3%, 158/175) compared to secondary tumors (74.6%, 54/213, $p < 0.001$). However, in 17 patients with primary tumor diagnosis of DCIS, unsuspected invasive tumor was identified in 6 secondary tumors (35.3%). In 18.3% (32/175) patients, secondary tumors were larger than the primary tumor. HER2 discordance between primary and secondary tumors was present in 3.8% and ER/PR discordance was present in 6.7%. Higher tumor grade was present in the secondary tumors in 17.7% of patients compared to the primary tumor. Fifty-two percent of these clinically significant findings were mammographically occult and identified on breast MRI.

Conclusions: Synchronous secondary breast cancers are biodiverse with the presence of unsuspected invasion, larger size, and higher grade as well as discordance in ER/PR/HER2 status. Over half of these cases are only seen at MR imaging and are likely to impact clinical management in these patients.

256025 – 15-year decrease in general surgery resident breast operative experience: Are we training proficient breast surgeons?

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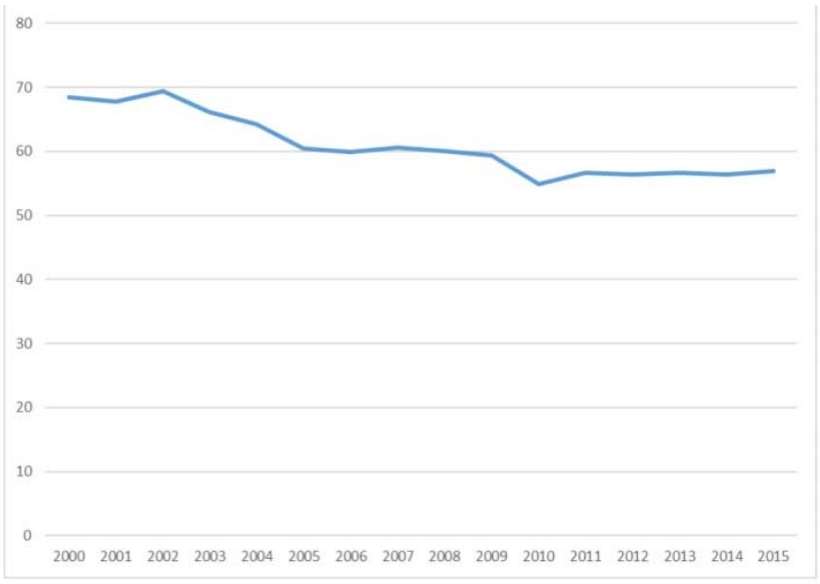
Background/Objective: With the institution of restricted general surgery resident duty hours, there has been a concern about the number of cases performed by graduating residents. While prior reports have focused on defining alimentary and intra-abdominal case numbers, details regarding resident operative experience for breast surgery cases have not been described. Breast cases are some of the most common operations performed by general surgeons in practice, so it is important to understand the experience of residents in training. The purpose of this paper is to evaluate trends in general surgery resident operative experience for breast cases over the last 15 years.

Methods: Accreditation Council for Graduate Medical Education (ACGME) case log system is the official method for recording operative experience during residency. Currently, no minimum required case numbers exist for breast-specific operations. The ACGME Case Logs Statistics reports for the graduating classes of 2000-2015 were reviewed for average breast-specific case numbers and trends over time.

Results: ACGME case log data was available for the following breast-specific categories: all breast cases, sentinel lymph node excision, breast excisional biopsy/lumpectomy, mastectomy – simple, and mastectomy – modified radical. There is no separate category for axillary dissection. Resident total case volume increased by 2% from 2000 to 2015, with the 2015 graduating class logging an average of 985.5 total cases (p=0.0159). Contrary to overall increased operative volume, the number of total breast cases decreased by 17.1% from 2000 to 2015. Subcategory analysis indicated that the largest drop in experience was in modified radical mastectomy (61.5% decrease, p=0.0001) with the 2015 gradates logging only 5.3 cases per resident over 5 years of training. The second largest drop was excisional biopsy/lumpectomy (25.8% decrease). On the other hand, resident experience in simple mastectomy increased from 6.0 to 10.8 cases (p=0.0001). Sentinel lymph node experience fluctuated over time, but has been down-trending in recent years (67.3% decrease 2010 to 2015, p=0.0001), with 2015 graduates logging only 4.6 sentinel lymph node procedures over 5 years of training.

Conclusions: General surgery resident experience in breast operations has decreased by 17% over the last 15 years, despite increase in overall operative volume. Residents have less experience in more complex cases, in particular, axillary management. Currently no minimum required case numbers exist for breast-specific operations in training, raising concern about the proficiency of graduating general surgery residents with respect to these procedures. It is reasonable to set a national minimum number of breast-specific operations residents must do in order to be considered appropriately trained to perform these cases in practice.



Total breast cases = all mastectomy, open excision/lumpectomy, and sentinel lymph node excision.
Total breast cases logged by residents over 5-year training

252724 – Same-day results from ultrasound-guided core needle biopsy of suspicious breast masses

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Background/Objective: Touch prep cytologic analysis of breast core biopsy specimens has been reported as a means to provide same-day results and improve care. We evaluated this approach in our community satellite breast center to demonstrate high concordance and improved quality care.

Methods: We prospectively performed touch prep cytology in addition to standard histology on all women receiving ultrasound-guided core needle biopsy of highly suspicious (ACR 4b,c and ACR 5) breast masses who provided written consent. Slides were prepared from 12 or 14 G core biopsy specimens using Papanicolaou technique and transported to our central pathology lab for review by the pathologist. The pathologist reported their findings verbally to the attending surgeon, and results were subsequently communicated by the surgeon to the patient on the same day. Results were categorized as suspicious, atypical, benign, or deferred. Data monitored included concordance of cytopathology to final pathology, patient satisfaction, and care enhancement as related to expedited genetic counseling, imaging, and medical/surgical oncology evaluation.

Results: Thirty-six women who met study criteria were offered same-day results. Six (17%) declined participation. In 30 consented patients, our findings are summarized in the Table.

Conclusions: Our findings are consistent with previously reported studies and show a high concordance in a select group of women with suspicious lesions. The high patient satisfaction found in our study likely stems from rapid turnaround of accurate results. Providing same-day results expedited the treatment plan for a significant number, further contributing to patient satisfaction. Prior studies have demonstrated that expedited care can contribute to reduced costs of care. We intend to continue to

monitor data while expanding the criteria to BI-RADS 4a lesions and make same day results a routine part of our breast care.

BIRADS Category	
4b	19%
4c	21%
5	60%
Concordance	100%
Patient Satisfaction	
Excellent	94%
Very Good	6%
Care Enhancement	31%

257097 - NSQIP analysis of axillary lymph node dissection rates for breast cancer: Implications for resident and fellow participation

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Background/Objective: The management of the axilla in breast cancer (BC) has shifted towards less radical surgery in the last 2 decades. Most recently, results from the American College of Surgeons Oncology Group Z0011 (Z11) trial demonstrated that not all patients with positive sentinel nodes require completion axillary lymph node dissection (ALND). We postulate that there has been a national downward trend in number of ALNDs completed since the publication of Z11, subsequently impacting surgical resident exposure to this procedure. Given this, we utilized the large, national ACS-NSQIP database to evaluate rates of ALND, as well as surgical resident and fellow involvement. There has been no prior study analyzing the impact of ALND trends on surgical trainee education.

Methods: All women diagnosed with invasive breast cancer (IBC) were identified in the ACS-NSQIP database from 2007-2014. Total number of procedures that included ALND were identified utilizing CPT codes for partial mastectomy with axillary lymphadenectomy, modified radical mastectomy, superficial axillary lymphadenectomy, and complete axillary lymphadenectomy. Given that the number of hospitals included in the database increased each year, we totaled these procedures and compared them to the number of IBC diagnoses using percentages. Cases involving resident participation were then identified and subsequently divided by training level: junior (post-graduate year [PGY] 1 to 2), senior (PGY 3 to 5) and fellow (PGY ≥6). Resident participation was compared between each year of data. Two tailed z tests were used to compare proportions, with significance determined when $p < 0.05$.

Results: From 2007-2014, a total of 128,372 women were identified with IBC, with a total of 36,844 ALNDs performed. Overall, ALND rates decreased by an average of 3.4% yearly from 2007-2014 (Figure). Total resident participation in ALND procedures significantly dropped in 2011, from 49.3% before (2007-2010 average) to 29.4% after (2011-2012 average; $p < 0.01$). Notably, junior residents experienced the greatest decrease in ALND cases (21.3% to 9.0%, $p < 0.01$), but senior residents were also affected (25.2% to 17.2%, $p < 0.01$). Fellow-level trainees experienced no change (2.8% to 3.1%, p=0.81) as the overall rates for ALND cases decreased.

Conclusions: There is a downward trend in the number of ALNDs being performed for women with IBC, with subsequent decrease in resident participation in ALND procedures. Although rates are decreasing for all level residents, this effect is greatest for junior-level trainees, with no significant change for fellow-level trainees. Acknowledgement of this trend is extremely important when creating future surgical curriculum changes for both general surgery and fellowship training programs.

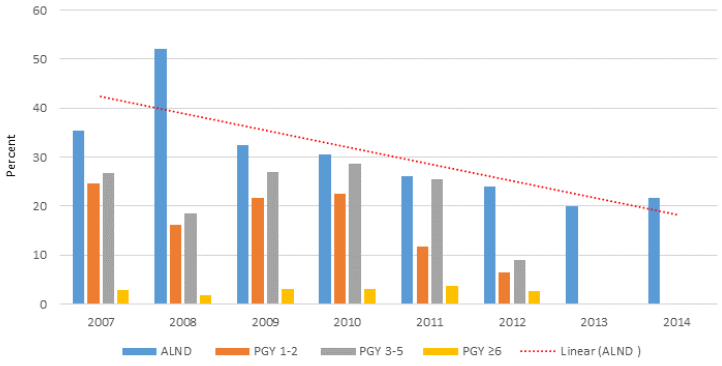

Figure. Rates of overall ALND and resident participation in ALND according to PGY level (2007-2014). *No resident data available for years 2013-2014. ALND, axillary lymph node dissection; PGY, post graduate year.

Rates of ALND and resident participation

256546 - Can objective measurements from 3-dimensional surface imaging replace subjective measures of outcome after breast-conserving therapy?

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Background/Objective: Aesthetic outcome is correlated with patients' psychological recovery after treatment. Currently, there is no gold standard for measuring the aesthetic outcome after breast-conserving therapy (BCT). Patient-reported outcomes measures and panel assessments of photographs are often used, but these are time-consuming, subjective, and difficult to standardize. An objective assessment tool is needed to provide a standardized, quick, and cost-effective aesthetic analysis to improve standards and for use in clinical studies evaluating new techniques in surgery and radiotherapy. Hypothesis: Objective volume and shape symmetry measurements are a useful tool in assessment of aesthetic outcome after BCT. Aim: To investigate whether breast volume and shape symmetry measured using 3-dimensional surface imaging (3D-SI) are associated with results of a patient satisfaction questionnaire (BREAST-Q-BCT) or panel assessment of images.

Methods: Ethical approval was obtained. Women who had unilateral BCT 1-6 years ago were recruited at the time of surveillance mammogram. Participants underwent 3-D-SI and completed the BREAST-Q BCT module. Volume symmetry was calculated by dividing the volume of the smaller breast by the larger breast and expressing as a percentage. Surface asymmetry was calculated by reflecting the image of one breast onto the other through the sagittal midline plane. The root mean squared (RMS) of the measured differences between the 2 surfaces was calculated. As the differences increase, the asymmetry increases and so does the RMS. The panel consisted of 2 breast surgeons, 1 radiation oncologist and 1 breast care nurse. The panel scored by consensus using the Harvard 4-point scale (1=poor, 2=fair, 3=good, 4=excellent). A Kruskal-Wallis ANOVA was used to investigate the relationship between volume symmetry, surface asymmetry, and panel outcome score. Patients were grouped according to their panel score, and the median volume and symmetry results were compared between groups. To identify where the differences lay, a post hoc pairwise comparison was performed using a Dunn Sidak test. Spearman's correlation was used to assess association between both volume and surface symmetry, and patient satisfaction.

Results: During the study period 649 women had mammography. Three hundred forty-two (52.7%) were eligible and visiting for mammography at a time when the investigator was available to carry out imaging. They were invited by letter. It was not possible to contact 109 (31.9%) women to confirm participation. Twenty-seven (11.6%) declined to attend, and 6 women did not attend, leaving 200 participants. Mean age was 64.2 years (SD 10.1), mean time from surgery to participation was 35.5 months (SD 17.7). One hundred eighty-six (93%) were Caucasian British, mean BMI was 27.5kg/m2 (SD5.4), mean ultrasound size of tumour was 13.9mm (8.6), median specimen weight was 32.5g (IQR 20-49). The median score for 'Satisfaction with breasts' was 68 (IQR 55-80). Median volume symmetry was 87% (IQR 78-93), and surface symmetry was 5.87mm (IQR 4.23-7.95). The median volume symmetry significantly differed between patients in groups given panel scores for 3-D images of fair and good, good and excellent. The median surface asymmetry also differed significantly according to patient panel groups. There were 4 significant pairwise comparisons between poor and good, poor and excellent, fair and good, fair and excellent panel scores. There was only a weak correlation of both volume symmetry and surface asymmetry with BREAST-Q scores for Satisfaction with breasts (correlation coefficients 0.187 ($p=0.008$) and -0.229 ($p < 0.001$) respectively).

Conclusions: Breast volume symmetry and surface asymmetry measured by 3-D imaging are both associated with panel assessment and patient satisfaction. The weak correlation with patient satisfaction indicates that patient satisfaction cannot simply be defined from 1 or 2 parameters. The objective volume and surface symmetry measures were strongly associated with results of a panel assessment of a 3-D image; hence a 3D-SI tool has potential as a quick and objective aesthetic evaluation to replace costly and time-consuming panel assessment. In the future, we envisage a core outcome set in breast cancer surgery incorporating oncological data, patient satisfaction, and objective aesthetic outcome analysis to enable global analysis of the patient breast cancer treatment experience.

245226 - Is a computerized risk assessment tool adequate to identify patients in need of further breast cancer risk stratification?

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Background/Objective: Formal and enhanced screening programs for women at high risk for breast cancer have become prevalent across the country. These programs are often multidisciplinary, and initial intake and evaluation is at the technician rather than the physician level. Online computerized risk assessment tools can be used to pre-screen such patients, though they may miss important items that increase a patient's risk of developing breast cancer. The current analysis was designed to examine whether or not such online tools are sufficient as an initial screening modality.

Methods: In April, 2016, a comprehensive breast cancer risk stratification program was initiated at Aria-Jefferson Health System in Philadelphia, PA. This was formally structured to include multidisciplinary input and was organized and coordinated by the Surgical Breast Health Office under the direction of the Medical Director for Breast Health. Initial screening was done in the Mammography Department and involved a patient questionnaire, followed by Tyrer-Cuzick (T-C) Risk Stratification using an online tool and calculator. A breast specialist (the breast surgeon) then reviewed all records and selected those requiring further evaluation and counseling. One hundred consecutive patients who were identified for high risk screening and counseling formed the test cohort. They were stratified based on Tyrer-Cusick Score (greater than 20% lifetime risk vs equal to or below 20%) and the presence of "red flags" prompting screening. The "red flags" were: family history of breast or ovarian cancer at age 45 or younger, personal history of ovarian cancer, 2 or more first-degree relatives with breast cancer, early menarche (before age 11), nulliparity, male breast cancer in self or a first-degree relative.

Results: Of the 100 consecutive patients, 51 (51%) had T-C scores over 20%. Approximately half of these (25) had other red flags, and half (26) did not. On the other hand, 49 (49%) of the cohort patients had one or more red flags in spite of T-C Scores below 20%; these, too, were selected for review in accordance with the protocol elucidated above and at the discretion of the breast surgeon. Therefore, if only red flags were used to define susceptible patients, 26 potentially high-risk patients (with higher T-C scores but without red flags) would have been missed. On the other hand, if only T-C scores were used, 49 potentially high-risk patients (with red flags but low scores) would have been missed in this analysis.

Conclusions: Tyrer-Cusick Risk Stratification Scores are useful tools in determining a patient's risk for developing breast cancer. This is not sufficient alone, however, to determine which patients should go on to further evaluation and testing. The T-C Score must be used in conjunction with routine screening and subjective evaluation of the record on the part of the breast specialist if potentially high-risk patients are expected not to slip through the cracks of a community comprehensive screening program.

257271 - The impact of receptor status on mastectomy rates in early stage invasive breast carcinoma

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Background/Objective: There is an established relationship between hormonal receptor (HR, estrogen and/or progesterone receptors) and human epidermal growth factor receptor (HER2) status and locoregional recurrence for patients treated with early-stage breast cancer. While many patient- and disease-related characteristics are considered for women when making a decision between mastectomy and breast-conserving surgery (BCS), available data do not support including HR and HER2 receptor status as key components when deciding upon surgical management of the disease. The purpose of this study was to analyze how HR and HER2 status influence the surgical management trends between mastectomy and BCS among women with early-stage breast cancer.

Methods: The National Cancer Database was queried for women with cT1-cT3, cN0, cM0 breast carcinoma from 2004-2012. Patients with unknown HR and/or HER2 status were excluded. Patients were grouped based on receptor status and surgical management (total mastectomy or BCS). Univariate and multivariate analyses were performed to investigate factors associated with mastectomy.

Results: 280,241 patients met inclusion criteria. After multivariable adjustment, the following factors were associated with the receipt of mastectomy: including younger age, Caucasian race, medical comorbidities, lower median household income, household distance from the treating center, larger tumors, invasive lobular histology, and higher tumor grade (each $p < 0.001$). Additionally, patients with HR+/HER+ and HR-/HER2+ tumors were the most likely to undergo mastectomy (OR 1.202 and 1.467 respectively compared to HR+/HER2- patients, each $p < 0.001$) while patients with HR+/HER2- tumors demonstrated similar mastectomy rates as HR-/HER2- ($p=0.599$).

Conclusions: While no prospective clinical data exist to suggest that surgical decision-making should be influenced by HR or HER2 receptor status, our data indicate that women are more likely to undergo a mastectomy if they test HER2+. The causes and clinical impact of this influence remain unclear, and further research will help to clarify this practice trend.

	Univariable	Multivariable			
	p-value	*p*-value	OR	lower 95%	upper 95%
Clinical Characteristics					
Age (yo)	<0.001	**<0.001**	**0.976**	**0.975**	**0.977**
Year of diagnosis	0.008	0.721	0.998	0.990	1.007
Race	<0.001	**<0.001**			
White			ref		
Black		**<0.001**	**0.814**	**0.791**	**0.838**
American Indian		**0.008**	**0.806**	**0.686**	**0.946**
Asian/Pacific		**<0.001**	**1.143**	**1.092**	**1.196**
Unknown		**<0.001**	**0.863**	**0.802**	**0.929**
Hispanic		**<0.001**	**0.925**	**0.888**	**0.963**
Charlson/Deyo Score	<0.001	**<0.001**			
0			ref		
1		**<0.001**	**1.253**	**1.224**	**1.282**
2		**<0.001**	**1.452**	**1.387**	**1.520**
Median income of zip	<0.001	**<0.001**			
<$38,000			ref		
$38,000–$47,999		**<0.001**	**0.951**	**0.925**	**0.978**
$48,000–62,999		**<0.001**	**0.926**	**0.901**	**0.951**
≥ $63,000		**<0.001**	**0.886**	**0.863**	**0.909**
Unknown		0.901	0.984	0.766	1.264
Payer	<0.001	**<0.001**			
Not Insured			ref		
Private		0.310	1.033	0.971	1.099
Medicaid		0.841	0.993	0.926	1.064
Medicare		**<0.001**	**1.247**	**1.169**	**1.330**
Government		0.056	1.105	0.998	1.224
Unknown		0.120	0.924	0.837	1.021
Distance to Hospital	<0.001	**<0.001**			
< 25 miles			ref		
25-100 miles		**<0.001**	**1.270**	**1.241**	**1.299**
>100 miles		**<0.001**	**1.334**	**1.265**	**1.406**
Unknown		0.787	0.964	0.739	1.257
Disease Characteristics					
Laterality	0.015	**0.031**			
Right			ref		
Left		0.946	1.001	0.985	1.017
Bilateral		0.439	1.507	0.533	4.256
Not reported		**0.004**	**1.839**	**1.215**	**2.784**
Clinical AJCC T-Stage	<0.001	<0.001			
cT1			ref		
cT2		**<0.001**	**2.100**	**2.061**	**2.139**
cT3		**<0.001**	**6.735**	**6.338**	**7.157**
Histology	<0.001	**<0.001**			
IDC			ref		
ILC			**1.702**	**1.658**	**1.747**
Receptor Status	<0.001	**<0.001**			
HR+/HER2-			ref		
HR+/HER2+		**<0.001**	**1.202**	**1.169**	**1.237**
HR-/HER2+		**<0.001**	**1.467**	**1.403**	**1.535**
HR-/HER2-		0.599	0.993	0.965	1.021
Grade	<0.001	**<0.001**			
1			ref		
2		**<0.001**	**1.291**	**1.265**	**1.318**
3-4		**<0.001**	**1.350**	**1.316**	**1.385**
Unknown		**<0.001**	**1.186**	**1.140**	**1.234**

Abbreviations: yo, years-old; AJCC, American Joint Committee on Cancer; IDC, invasive ductal carcinoma; ILC, invasive lobular carcinoma; HER2, human epidermal growth factor receptor 2; LVSI, lymphovascular space invasion.

Factors associated with receipt of mastectomy over lumpectomy (odds ratio values over 1.0 favor mastectomy over lumpectomy)

220595 – Patient-centered approach to percutaneous breast biopsy

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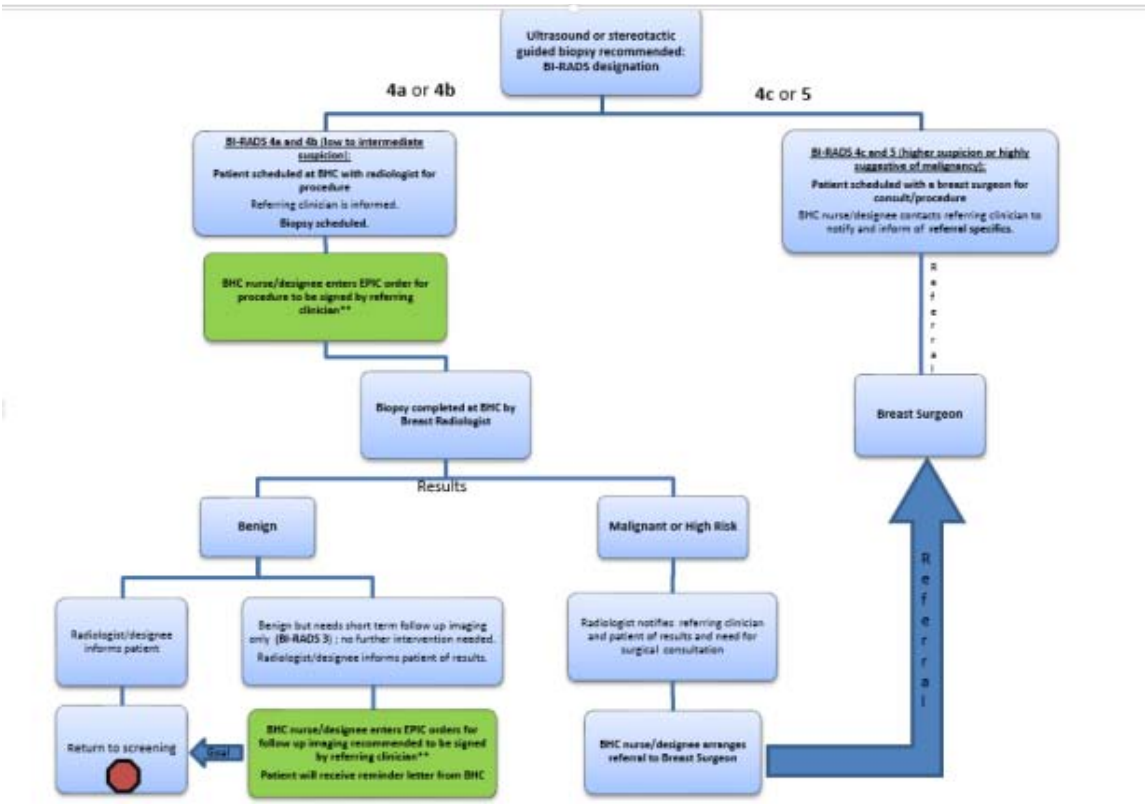
Background/Objective: The tug of war between radiologists and surgeons regarding the performance of percutaneous breast biopsies has flourished during the past decade. Multiple institutions have developed stringent rules prohibiting qualified surgeons from using the ultrasound machine and stereotactic table for performing biopsies. Rather than succumbing to a relationship of animosity, our radiologists and surgeons have developed a collaborative, patient-centered biopsy pathway that has improved access and ensured seamless delivery of care for the breast patient.

Methods: Four radiologists and 3 dedicated breast surgeons participate in the biopsy protocol. All surgeons are certified in ultrasound and stereotactic guided breast biopsy by the American Society of Breast Surgeons. Patients undergo BI-RADS categorization by the radiologist interpreting the initial mammogram/ultrasound. Patients with a BI-RADS category of 4a or 4b (low to intermediate suspicion for malignancy) receive their biopsy by the radiologist, whereas patients with a BI-RADS category of 4c or 5 (moderate to high suspicion for malignancy) are referred to the breast surgeon for biopsy. Goal is to improve time to percutaneous biopsy as well as surgeon access for patients who may have a malignancy.

Results: The biopsy protocol has reduced overall access to biopsy from 8 days to 6 days. Access to biopsies by radiologists decreased from 5.1 days to 3.9 days, whereas access to biopsies performed by surgeons improved from 8 days to 3.6 days.

Conclusions: Our patient-centered biopsy protocol improves overall access to percutaneous biopsy by utilizing all qualified personnel to perform the procedure. Patients who are likely to have benign pathology are able to undergo expedited biopsy and return to their primary care provider without involvement of the surgeon. Patients who are likely to have malignant pathology are introduced to the breast surgeon at the earliest opportunity and maintain continuity of care from diagnosis through treatment. The protocol ensures that primary care providers are informed and involved with every critical step of the process.



Breast biopsy pathway protocol

257241 - Clinical outcome of optimally treated HER2-positive and HER2-negative breast cancers

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Background/Objective: It is known that HER2-positive (HER2+) breast cancers are biologically more aggressive than HER2-negative (HER2-) tumors. The use of trastuzumab combined with adjuvant chemotherapy has become the standard of care since the publication of 2 landmark studies in 2005 that changed systemic therapy of patients with primary operable HER2+ breast cancer. This study is an update of the comparison between HER2+ and HER2- cancers after 2005. Our aim was to analyze tumor parameters and clinical outcomes between these 2 groups with the understanding that, per clinical guidelines, HER2+ patients receive trastuzumab. Additionally, we analyzed HER2+ tumors stratified by estrogen receptor (ER) status and hypothesized that ER-/HER2+ tumors would be associated with worse patient outcomes.

Methods: We conducted a retrospective cohort study and identified 1,287 patients from the electronic medical record who underwent primary breast cancer surgery at our institution between 2006 -2015. We excluded patients with HER2+ tumors who did not receive trastuzumab and patients without follow-up data or receptor data; 1,099 patients were included in the final analyses. Patients were stratified by HER2 status, and HER2+ patients were further subdivided by ER status. T-tests, ANOVAs, chi square tests, and Goodman-Kruskal's gamma analyses were used to compare clinical characteristics and patient

outcomes between HER2+ and HER2- tumors with a subgroup analysis of HER2+ tumors stratified by ER status.

Results: A total of 143 HER2+ patients were identified (13%), with 90 patients having tumors that were also ER+. The mean age at diagnosis of all patients was 64.8 years, with HER2+ patient being significantly younger at diagnosis (57.8 v. 65.9 years, $p < 0.001$). HER2 status was not associated with race, tumor size, frequency of recurrence, or overall survival. However, HER2+ tumors were associated with increased mean nodal involvement ($p=0.003$) and receptor-negative cancers (See Table, $p < 0.001$). Additionally, HER2+ patients had higher tumor grades ($G=0.464$, $p < 0.001$) and decreased time to metastatic disease compared to those with HER2- tumors (9.18 years vs. 8.56 years, $p=0.05$). In our subgroup analysis of the HER2+ cohort by ER status, there was no association between ER status and patient outcomes or tumor characteristics.

Conclusions: Our results are consistent with previous studies that have shown HER2+ tumors are associated with a more aggressive clinical phenotype with greater nodal involvement, higher tumor grade, and decreased time to metastatic disease. However, we found no difference in the frequency of recurrence and overall survival between patients with HER2- and HER2+ tumors. Our study confirms the greater clinical severity of disease in patients with HER2+ cancers but also reaffirms the utility of trastuzumab in the treatment of these patients.

		Overall	Her 2-	Her2+				Comparison of Her2- vs Her2+
				Overall	ER			
					ER+	ER-	p	p
n		1099	956	143	90	53	-	-
Mean age at diagnosis		64.83 ± 13.69	65.89 ± 13.61	57.75 ± 12.11	56.99 ± 12.13	59.05 ± 12.08	0.327	< 0.001
Race [n (%)]								
Frequency	Asian	26 (2.4)	23 (2.4)	3 (2.1)	0 (0)	3 (5.7)	0.174	0.58
	Black	328 (29.9)	290 (30.3)	38 (26.6)	22 (24.4)	16 (30.2)		
	Hispanic	19 (1.7)	17 (1.8)	2 (1.4)	1 (1.1)	1 (1.9)		
	White	680 (61.9)	583 (61.0)	97 (67.8)	65 (72.2)	32 (60.4)		
	Other	37 (3.4)	34 (3.6)	3 (2.1)	2 (2.2)	1 (1.9)		
	Not available	9 (0.8)	9 (0.9)	0 (0)	0 (0)	0 (0)		
Tumor size (cm)		1.98 + 1.76	1.97 + 1.71	2.07 + 2.04	2.00 + 1.65	2.20 + 2.61	0.576	0.54
Mean size	T1 (≤ 2 cm)	1.06 ± 0.50	1.06 ± 0.48	1.03 ± 0.59	1.07 ± 0.52	0.97 ± 0.69	0.44	0.65
	T2 (2.1 - 5 cm)	2.93 + 0.85	2.94 + 0.86	2.90 + 0.82	2.82 + 0.79	3.11 + 0.90	0.305	0.78
	T3 (> 5 cm)	7.89 ± 2.34	7.76 ± 2.30	8.50 ± 2.61	7.65 ± 1.75	9.35 ± 3.31	0.399	0.42
Frequency	T1 (≤ 2 cm)	626 (57.0)	542 (56.7)	84 (58.7)	52(57.8)	32 (60.4)	0.357	0.77
	T2 (2.1 - 5 cm)	325 (29.6)	282 (29.5)	43 (30.1)	31 (34.4)	12 (22.6)		
	T3 (> 5 cm)	47 (4.3)	39 (4.1)	8 (5.6)	4 (4.4)	4 (7.5)		
Tumor grade [n (%)]								
	I	206 (18.7)	197 (20.6)	9 (6.3)	8 (8.9)	1 (1.9)	0.062	< 0.001
	II	392 (35.7)	336 (35.1)	56 (39.2)	42 (46.7)	14 (26.4)		
	III	268 (24.4)	205 (21.4)	63 (44.1)	37 (41.1)	26 (49.1)		
	Not assessed	232 (21.1)	217 (22.7)	15 (10.5)	0 (0)	0 (0)		
No. of involved axillary nodes (mean)		1.25 ± 2.85	1.15 ± 2.77	1.91 ± 3.26	1.95 ± 2.963	1.83 ± 3.74	0.827	0.003
	0 [n (%)]	644 (58.6)	576 (60.3)	68 (47.6)	40 (44.4)	28 (52.8)	0.462	0.001
	1 to 3 [n (%)]	316 (28.8)	265 (27.7)	51 (35.7)	32 (35.6)	19 (35.8)		
	>3 [n (%)]	97 (8.8)	75 (7.8)	22 (15.4)	16 (17.8)	6 (11.3)		
	Not assessed	42 (3.8)	40 (4.2)	2 (1.4)	2 (2.2)	0 (0)		
Breast Cancer Subtypes [n (%)]								
	Any ER+ or PR+	876 (79.7)	781 (81.7)	95 (66.4)	-	-	-	< 0.001
	ER-/PR-	222 (20.2)	174 (18.2)	48 (33.6)	-	-		
	Not available	1 (0.1)	1 (0.1)	0 (0)	-	-		
Disease status (n)								
	No evidence of disease	885 (80.5)	772 (80.8)	113 (79.0)	72 (80.0)	41 (77.4)	0.28	0.02
	Alive with disease	81 (7.4)	63 (6.6)	18 (12.6)	13 (14.4)	5 (9.4)		
	Dead of disease	83 (7.6)	72 (7.5)	11 (7.7)	5 (5.6)	6 (11.3)		
	Dead of other causes	47 (4.3)	46 (4.8)	1 (0.7)	0	1 (1.9)		
Recurrence [n (%)]								
	Local	90 (8.2)	80 (8.4)	10 (7.0)	5 (5.6)	5 (9.4)	0.38	0.58
	Distant	144 (13.1)	118 (12.3)	26 (18.2)	17 (18.9)	9 (17.0)	0.78	0.05
Overall survival (mean in years)		9.91	9.91	9.47	9.65	8.57	0.16	0.94
Time to local recurrence (mean in years)		9.34	9.20	9.48	8.66	9.61	0.37	0.56
Time to metastatic disease (mean in years)		9.12	9.18	8.56	8.57	8.10	0.98	0.05

Patient and tumor characteristics for breast cancer cohort

257104 - Comparison between groups with and without adherence to breast screening in patients with small breast cancer (≤2 cm)

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Background/Objective: Breast screening programs have brought clinical benefit as early detection of breast cancer. Furthermore, it is well established that screening-detected breast cancer is associated with a better prognosis compared with symptom-detected breast cancer. In this study, we investigated whether breast screening would offer a clinical benefit even in small breast cancer, comparing the differences between 2 groups for adherence to breast screening or not in the populations with breast cancer equal to or less than 2 cm.

Methods: Patients diagnosed with invasive cancer with maximal tumor size not larger than 2 cm (T1) from January 2006 to December 2012 in Gangnam Severance Hospital were included in this study, excluding stage IV breast cancer, patients receiving neoadjuvant chemotherapy, and bilateral breast cancer. Total number of patients was 714, with screen-adherent group (N=459), non-adherent group (N=200), and unclassified (N=55). The adherence to breast screening was defined as receiving a breast screening within the last 2 years, while those who never had a breast screening and those who reported having a screening more than 2 years ago were defined as the non-adherent group. The recurrence-free survival (RFS) was compared by the adherence to breast screening.

Results: The non-adherent patients were significantly younger (49.5 vs 52.1, p=0.001) and were more likely to have larger size of tumor (1.42 vs 1.2cm, $p < 0.001$) than the screening-detected patients. The non-adherent patients had advanced nodal stage and higher histologic grade (p=0.006 and $p < 0.001$, respectively). In comparisons subtypes of tumor (p=0.007), the screening-detected patients have more favorable type than non-adherent patients (Luminal A 65.9% vs 54.8%), whereas they had less TNBC subtype than the symptom-detected patients (12.7% vs 15.1%). The RFS was significantly better in the screening group (p=0.010, the log-rank test). On multivariate analysis, the adherence to breast screening was a significant independent prognostic factor for the RFS, and the adjusted hazard ratios were 0.36 (95% confidence interval, 0.14-0.89; p=0.028).

Conclusions: Breast cancers detected under the adherence to breast screening are associated with favorable tumor biology and better prognosis than cancers detected outside of screening even in patients with small breast cancer. Our findings suggest that the adherence to breast screening may offer a clinical benefit in terms of tumor biology, as well as migration of stage.

Variables*	Comparison	Univariate (P)	Multivariate (P)	Hazard ratio
T stage		0.183		
	T1a /b			
	T1c			
Nodal status		0.009	0.417	
	Negative			Reference
	Positive			0.67 (0.26-1.73)
Estrogen receptor		0.816		
	Positive			
	Negative			
Progesterone receptor		0.161		
	Positive			
	Negative			
HER2		0.333		
	Negative			
	Positive			
Histologic grade		0.064	0.180	
	I and II			Reference
	III			0.51 (0.19-1.38)
Adherence		0.010	0.024	
	Adherence			Reference
	Non-adherence			0.38 (0.13-0.87)

Univariate P, the log-rank test
Multivariate P, the Cox-regression hazard model

Univariate and multivariate survival analyses for recurrence-free survival

231843 - Surgeon variability and factors predicting for reoperation following breast-conserving surgery

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Background/Objective: We investigated breast-conserving surgery (BCS) techniques at our cancer center to identify practice variability among high-volume surgeons and factors associated with reoperations.

Methods: We retrospectively identified consecutive patients with early stage I-II breast cancer who underwent BCS between January-December 2014 at our institution. Male patients and those who received preoperative therapy were excluded. Patient demographic, tumor, and surgical data were extracted from medical records, including reason for reoperation, procedure, number of reoperations, and pathology results for each specimen. A multivariate regression model was used to identify factors associated with reoperation.

Results: A total of 507 patients with stage I (n=415) and stage II (n=92) breast cancer were identified. Median invasive tumor size was 1.1 cm. Overall reoperation rate was 23% (n=116) and varied significantly amongst surgeons (range 15-40%). The reoperations included: re-excision (n=102; 88%), unilateral mastectomy (n=7; 6%), and bilateral mastectomy (n=7; 6%). Intraoperative margin techniques (global cavity or targeted shaves) were utilized in 258 cases (51%); no margin technique was utilized in 249 cases (49%). Median total specimen size (lumpectomy + margin size in cm3) varied among surgeons (median 66.0 cm3, range 29.3-164.73 cm3). Older patients were significantly less likely to undergo reoperation (OR =0.43, 95% CI=0.20-0.95). Patients with multifocal disease (OR= 4.70; 95% CI=1.87-11.82) were significantly more likely to undergo reoperation.

Conclusions: Examination of BCS demonstrated variability in reoperation rates and margin practices among our breast surgeons. Despite similar tumor sizes, large variations were seen in surgical volume resection without concomitant decrease in re-excisions with larger specimens. In this non-prospective study, shave margins was not associated with reduced need for re-excision. Further analysis of variation at the hospital and surgeon level for BCS operations are warranted.

	Lumpectomy alone (n=391) N (%)	Reoperation (n=116) N (%)	Adjusted OR (95% CI)
Age			
<40	2(0.5%)	2(1.7%)	1.40(0.16-12.68)
40-49	39(10.0%)	23(19.8%)	1.00
50-59	85(21.7%)	31(26.7%)	0.67(0.30-1.48)
60-69	135(34.5%)	28(24.1%)	**0.43(0.20-0.95)**
70+	130(33.2%)	32(27.6%)	0.65(0.25-1.71)
Insurance			
Private	232(59.3%)	75(64.7%)	1.00
Public	153(39.1%)	39(33.6%)	1.23(0.62-2.43)
Other	6(1.5%)	2(1.7%)	0.56(0.06-5.75)
Race			
White	332(84.9%)	86(74.1%)	0.81(0.37-1.76)
Non-White	40(10.2%)	20(17.2%)	1.00
Missing	19(4.9%)	10(8.6%)	1.30(0.38-4.49)
Grade			
I	132(33.8%)	29(25.0%)	1.00
II	170(43.5%)	54(46.6%)	1.19(0.63-2.24)
III	89(22.8%)	33(28.4%)	1.55(0.68-3.52)
Tumor Subtype*			
HR+/HER2-	317(87.1%)	92(82.9%)	1.00
HER2+	34(9.3%)	14(12.6%)	0.66(0.25-1.71)
HR-/HER2-	13(3.6%)	5(4.5%)	0.88(0.25-3.15)
Invasive Tumor Size	1.26(0.79)	1.35(0.89)	1.02(0.74-1.41)
Node Status			
Positive	43(13.3%)	19(19.6%)	1.46(0.74-2.88)
Negative	281(86.7%)	78(80.4%)	1.00
Lymph Node Procedure			
Axillary Node Dissection	7(1.9%)	1(0.9%)	0.17(0.006-4.77)
Sentinel Node Biopsy	315(83.3%)	95(83.3%)	0.55(0.04-6.85)
None	56(14.8%)	18(15.8%)	1.00
Multifocal			
Yes	18(4.6%)	18(15.5%)	**4.70(1.87-11.82)**
No	373(95.4%)	98(84.5%)	1.00
Shave Margin Technique **			
None	190(48.6%)	64(55.2%)	1.00
Global	131(33.5%)	28(24.1%)	0.67(0.37-1.23)
Targeted	70(17.9%)	24(20.7%)	1.07(0.50-2.27)
Surgery Site			
Site 1	196(50.1%)	50(43.1%)	0.77(0.44-1.34)
Site 2	195(49.9%)	66(56.9%)	1.00

*HR= Hormone receptor

** Median total specimen size (lumpectomy + margin size in cm^3) 66.0 cm^3. (Range 29.3-164.73 cm^3).

Factors associated with reoperation

256625 - Is axillary surgery needed for patients with adenoid cystic carcinoma?

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Background/Objective: Adenoid cystic carcinoma (ACC) is a rare breast cancer subtype generally reported to have a favorable prognosis and low rate of axillary nodal metastasis despite an estrogen and progesterone receptor-negative/low, HER2-negative phenotype. No consensus guidelines exist for axillary staging and treatment. We hypothesized that axillary surgery may not be necessary for all patients with ACC.

Methods: After IRB approval, we queried our breast pathology database for patients with ACC operated on at our institution between January 1994 and August 2016. Patient, tumor, and treatment variables were abstracted from the medical record after pathology review of each case to confirm the diagnosis of ACC as defined by tumor consisting of 2 main cell types: modified ductal and myoepithelial cells that typically have hyperchromatic and angular nuclei with clear cytoplasm arising in tubular, cribriform, or solid morphologic patterns.

Results: We identified 20 cases of pure ACC in 19 women, median age 59 years. Tumors ranged in size from 0.2 to 4.8 cm. Preoperative axillary ultrasound was performed in 13 patients (65%) and was normal in 10 and suspicious in 3. In all 3 patients with an abnormal axillary ultrasound, ultrasound-guided lymph node FNA was performed and negative. Twelve patients were treated by breast-conserving surgery and 8 by mastectomy. Axillary operation was sentinel lymph node (SLN) surgery in 15 cases (75%), while the remainder did not have any axillary surgery. All patients were node negative on final pathology. After 3.6 years median follow-up (range 0.2 to 38.6 years), 3 patients experienced a local recurrence at 2, 16, and 17 years respectively, and no patients developed regional nodal disease. Of the 3 patients with recurrence, the initial treatments were mastectomy, breast conservation with adjuvant radiation, and breast conservation without radiation in 1 patient each, respectively.

Conclusions: We observed no cases of nodal metastatic disease in 20 consecutive cases of pure ACC of the breast. Preoperative axillary ultrasound combined with fine-needle aspiration of any sonographically suspicious nodes accurately predicted pathologic nodal stage in our series. These data raise the question of whether axillary surgery might be safely omitted in patients presenting with pure ACC and a clinically negative axilla.

Year of Diagnosis	
1974-1990	1 (5%)
1991-2000	1 (5%)
2001-2010	8 (40%)
2011-2016	10 (50%)
Age at Diagnosis (years), median (range)	59 (22-78)
Presentation	
Screening Mammogram	10 (50%)
Palpable Mass	4 (20%)
Pain	4 (20%)
Incidental Finding at Surgery	1 (5%)
Missing	1 (5%)
Clinical Tumor diameter (cm), median (range)	1.5 (0.6 -5.3)
Clinical T stage	
Tis	1 (5%)
T1	12 (60%)
T2	3 (15%)
T3	1 (5%)
T4	0 (0%)
Missing	3 (15%)
Pathology Tumor diameter (cm), median (range)	1.8 (0.2-4.8)
Pathologic T stage	
Tis	0 (0%)
T1	10 (50%)
T2	9 (45%)
T3	0 (0%)
T4	0 (0%)
Unknown	1 (5%)
Grade	
1	12 (60%)
2	6 (30%)
3	0 (0%)
Missing	2 (10%)
Estrogen Receptor Status	
Negative (<1%)	13 (65%)
Low (1-10%)	3 (15%)
Positive (>10%)	1 (5%)
Missing	3 (15%)
Progesterone Receptor Status	
Negative (<1%)	13 (65%)
Low (1-10%)	4 (20%)
Missing	3 (15%)
HER2 Amplification	
Negative	13 (65%)
Positive	0 (0%)
Missing	7 (35%)
Axillary Ultrasound	
Normal	10 (50%)
Suspicious	3 (15%)
None	7 (35%)
Breast Operation	
Breast-conserving surgery (BCS)	12 (60%)
Mastectomy	8 (40%)
Axillary Operation	
Sentinel Node Biopsy (SLNB)	15 (75%)
Axillary Dissection (ALND)	0 (0%)
None	5 (25%)
Number of sentinel nodes removed, median (range)	2 (1-6)
SLN Pathology	
Positive	0 (0%)
Negative	15 (100%)

Patient, tumor, and treatment variables

257380 - Differences in breast cancer patients diagnosed and treated at various institution types: A report from the National Cancer Database

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Background/Objective: Several studies have examined the link between hospital and surgeon volume and the decrease in morbidity and mortality that such experience confers on breast cancer patients treated by them. Since breast cancer diagnoses continue to rise, so do the number of patients who are critically looking at hospital and physician attributes to determine where they would prefer to receive their treatment. Our aim is to analyze data from the National Cancer Database (NCDB) to describe the patterns of diagnosis and treatment of breast cancer among various institution types, and their impact on survival.

Methods: A cohort of 2.2 million women with diagnoses of invasive breast cancer (IBC) or ductal carcinoma in situ (DCIS) between the years of 2004 and 2014 from the NCDB was evaluated. Data were segregated based on the type of institution reporting the case: community cancer program (CCP), comprehensive community cancer program (CCCP), academic/research program (ARP), and integrated network cancer program (INCP). Patient demographics, including age, race, and great circle distance (the distance from the patient's home to the reporting institution) within each institution type were compared. Patient comorbidities on the Charleson/Deyo scale (0, 1 or 2 and greater comorbidities) were also analyzed. Patients were grouped according to whether they received their diagnosis and part or all of their treatment (or a decision not to treat) at the reporting institution or elsewhere. The frequencies for each group were compared for each institution type overall and for subgroups based on whether the pathologic diagnosis was DCIS or IBC.

Results: The mean age at diagnosis is 61.9 years, with patients reported by ARP being significantly younger than other institution types (60.7 years, $p < 0.001$). Patients reported by ARP were significantly more racially diverse than those at other centers ($p < 0.001$). The mean great circle distance for the entire cohort is 22.2 miles, with patients reported by ARP traveling a significantly longer distance for treatment (30.3 miles, $p < 0.001$). There were no differences in the Charleson/Deyo scale of comorbidities between institution types ($p=0.13$). When analyzing diagnosis and treatment at the reporting institution, significantly fewer patients were both diagnosed and treated at ARP (57.2%) than other institutions (range 65.8 to 70.8%, $p=0.002$), while significantly more patients reported by ARP (40.3%) were diagnosed elsewhere prior to being treated there (range 24.5 to 29.8%, $p < 0.001$). These results are similar when analyzing by DCIS or IBC subgroups, though more pronounced for patients with IBC (Table, $p < 0.001$). Mean overall survival was 117.8 months, and there was no significant difference in survival between institution types (range 116.5 to 118.6 months, $p=0.14$).

Conclusions: As the majority of breast cancer diagnoses are made in community cancer programs, it is important to understand the motivation of patients to be treated elsewhere. We found that those with more advanced stage disease (IBC) have an even stronger predilection toward seeking treatment elsewhere. Since survival is equivalent between center type, however, the quality of breast cancer care in the community is likely undervalued. Since the NCDB does not have individual surgeon data, further studies with a diverse collection of centers examining the impact of surgeon-specific characteristics would be useful in understanding and educating patients about the value of specialized centers in breast cancer care.

DCIS									
Diagnosis	Diagnosed at reporting institution					Diagnosed elsewhere			
Treatment at Reporting Institution	Total	All treatment	Part of treatment	Part or all of treatment	All treatment elsewhere	Total	All treatment	Part of treatment	Part or all of treatment
Community Cancer Program	79.3	18.3	11.1	44.6	5.3	20.6	2.1	6.7	11.8
Comprehensive Community Cancer Program	76.8	20.4	9.9	41.8	4.7	23.2	3.2	6.8	13.2
Academic/Research Program	68.6	23.3	5.7	36.8	2.8	31.3	6.4	7.8	17.1
Integrated Network Cancer Program	75.6	18	12.9	40.2	4.5	24.3	3.8	7.2	13.3

Invasive Cancer									
Diagnosis	Diagnosed at reporting institution					Diagnosed elsewhere			
Treatment at Reporting Institution	Total	All treatment	Part of treatment	Part or all of treatment	All treatment elsewhere	Total	All treatment	Part of treatment	Part or all of treatment
Community Cancer Program	74.7	15.2	13.6	41.2	4.7	25.4	1.9	9.6	13.9
Comprehensive Community Cancer Program	69.6	15.3	13	37.4	3.9	30.4	3	10.7	16.7
Academic/Research Program	57.2	16.7	7.2	30.9	2.4	42.7	7.3	12.9	22.5
Integrated Network Cancer Program	68.7	11.4	16.6	36.4	4.3	31.2	3.1	11.8	16.3

Percent of patients diagnosed and treated for DCIS and invasive breast cancer at different university types

257373 - Compliance and adherence to breast cancer treatment in a medically underserved population

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Background/Objective: Compliance and completion of treatment for breast cancer is associated with improved outcomes. It has been reported that patients may not complete treatment for several reasons including cost of treatment and side effects. We examine the rate of compliance and completion of treatment in a population of breast cancer patients treated at a safety net hospital

Methods: One hundred ninety-seven patients treated for breast cancer (stage 0-IIIC) were identified from the surgery and pathology records during 2011- 2014. The patients' medical records were retrieved and data analyzed retrospectively. The main outcome variables were compliance and completion of therapy. Additional variables examined included race, age at diagnosis, stage, and income.

Results: Median age was 52. Of this group, 36% were Asian, 17% African-American, 10% White, 37% Hispanic. The majority of patients presented early stage; however, blacks and Hispanics were more likely to be diagnosed at later stages (p=0.000). Sixty-four percent of the patients reported an income of ≤$15,000. Eighty-seven percent of patients offered chemotherapy accepted, 91% of these patients completed treatment. These patients did not differ significantly by race (p=NS). Ninety-four percent of patients offered radiation therapy accepted, and 99% completed radiation therapy, and these patients did not differ significantly by race (p=NS). Ninety percent of patients offered hormonal therapy accepted, and 95% adhered to therapy (p=NS).

Conclusions: There are many factors involved in patient compliance and early discontinuation of therapy particularly in safety net hospitals. We find that in our large safety net hospital, there is a higher acceptance of treatment for chemotherapy, radiation, and hormonal therapy as well as completion of treatment compared to most academic institutions, and this is independent of race. While the reasons for the high rates are unclear, we believe culturally competent care and enhanced patient navigation are

instrumental in patient compliance. Further prospective studies will need to be done to determine the main contributor of enhanced compliance and adherence to treatment.

256946 - Impact of Hydrocodone Schedule Change on Patients Undergoing Mastectomy

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Background/Objective: In October 2014, the Drug Enforcement Agency (DEA), in an effort to decrease the rate of prescription drug abuse and addiction, re-classified hydrocodone combination products (HCPs) from Schedule III to Schedule II. This change was meant to limit ready access to HCPs and prevents routine refills of HCPs. The impact of this change on breast surgery patients and breast surgeon practice patterns has not been studied. There was concern that this schedule change would increase hospital length of stay and potentially lead to increased refill rates of less potent alternatives that would have to be utilized. This is the first study to evaluate the impact of this schedule change on post-operative pain management in patients undergoing total mastectomy with expander-based reconstruction.

Methods: Three hundred patients undergoing mastectomy with expander reconstruction at an academic medical center before and after the HCP schedule change were identified by retrospective review. Factors evaluated included demographics, discharge medications, use of epidurals, length of stay, refills of medications, use of anxiolytics/muscle relaxants, electronic and telephone messages sent by the patient regarding inadequate pain control, and outpatient change in pain medication. Patients were excluded if they had a history of chronic pain medication use, underwent complete axillary lymph node dissection, or were re-admitted for complications unrelated to pain control.

Results: Sixty patients met final inclusion criteria, half prior to the schedule change (PSC) and half after the schedule change (ASC). No difference was noted between groups in regards to age, BMI, or receipt of neoadjuvant chemotherapy (Table). There was a significant reduction in the use of HCPs after the schedule change (< 0.0001) with a transition to utilization of tramadol (20% PSC vs 50% ASC) and codeine-containing agents (0% PSC vs 23% ASC). Length of stay, phone calls and electronic messages for pain control, as well as use of muscle relaxers was equivalent between groups. Epidurals were utilized in patients ASC, but not PSC. There was an increased need to change pain medications in the outpatient setting ASC, but this was not statistically significant.

Conclusions: In patients undergoing mastectomy with expander placement, the change in schedule of HCPs significantly altered prescribing patterns, with increased utilization of alternatives containing codeine as well as tramadol. This change did not increase hospital length of stay or interactions with medical staff regarding inadequate pain medication as an outpatient, although there was a trend towards having to change pain medications ASC. The impact of this change on rates of opioid abuse and rates of serotonin syndrome due to increased use of tramadol is an area of future investigation.

Table 1	Prior to schedule change N (%)	After schedule change N (%)	All	p-value
Age in years (median)	45	46.5	46	0.42
Body Mass Index (median)	23.4	27.9	26.5	0.07
Neoadjuvant chemotherapy	10(33)	9(30)	19(32)	0.99
Length of stay (days)	2.33	2.1	2.22	0.25
HCP used	**24(80)**	**8(26)**	**32(53)**	**<0.0001**
Muscle relaxer given	25(83)	29(97)	54(90)	0.19
Epidural used	0(0)	4(13)	4(6)	0.11
Pain medication refill	9(30)	10(33)	19(32)	0.99
Electronic message regarding inadequate pain control	5(17)	4(13)	9(15)	0.99
Telephone call regarding inadequate pain control	3(10)	1(3)	4(6)	0.61
Out-patient change in pain medication	2(6)	5(17)	7(12)	0.42

Impact of hydrocodone schedule change on patients undergoing mastectomy