THE AMERICAN SOCIETY OF BREAST SURGEONS

2018 ANNUAL MEETING

OFFICIAL PROCEEDINGS, Volume XIX

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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Contents

Scientific Oral Presentations I

Friday, May 4, 2018 2:15 pm–3:30 pm
Moderators: Judy Boughey, MD; Mahmoud El-Tamer, MD

403081 - Lymph node status does not predict tumor biology

Danielle Bello[1], Christy Russell[2], Debbie McCullough[2], Marni Tierno[2], Monica Morrow[1]

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Background/Objective: Lymph node status in breast cancer has historically been considered the most important prognostic factor determining disease-specific and overall survival, but in the modern era, genomic profiling has become an increasingly important prognostic tool. The 21-gene Oncotype DX® Breast Recurrence Score® (RS) assay has been validated as both a prognostic and predictive tool in node-negative estrogen receptor positive (ER+)/HER2- breast cancer in multiple large datasets, including prognostic validation in the prospective TAILORx and WSG PlanB trials. Information on RS distribution and its prognostic and predictive value in node-positive breast cancer is more limited. In this study, we compared RS results among patients with lymph node negative (N0), micrometastatic (N1mi), and macrometastatic (N+) breast cancer to determine if nodal metastases are associated with more aggressive biology as determined by RS result.

Methods: The study included 610,350 tumor specimens examined by the Genomic Health clinical laboratory from 2/2004 to 8/2017. Histology was classified centrally, using a single hematoxylin and eosin slide and World Health Organization criteria. Lymph node status was determined locally. RS results based upon quantitative reverse transcription polymerase chain reaction gene expression were calculated for each specimen. RS distribution (Low <18; Intermediate 18-30; High 31) was compared by nodal status.

Results: Eighty percent (n=486,013) of patients were N0, 4% (n=24,325) were N1mi, 9% (n=56,100) were N+, and 7% (n=43,912) had unknown lymph node status. Median patient age was 60 years (interquartile range [IQR] 51-67) in N0 and N1mi patients, and 62 years in N+ (IQR 53-70) and unknown nodal status patients (IQR 52-68). Mean RS was 18 in N0 patients, 16.7 in N1mi patients, 17.3 in N+ patients, and 18.8 in the indeterminate group. The majority of patients in all nodal subgroups had low RS results (Table). High RS were seen in 9.8% of N0 patients, 6.9% of N1mi patients, and 8.1% of N+ patients. When the high RS result threshold was decreased from 31 to 25, as used in the TAILORx and RxPONDER trials, only 14.8% of N+ patients and 16.9% of N0 patients had a high RS result. The likelihood of a high RS in N1mi and N+ patients varied with tumor histology, with only 2% of patients with classic infiltrating lobular cancer having a high RS result compared to 7-8% of those with ductal carcinoma. A high RS result was rare in N+ tubular (0.8%) and mucinous cancers (4%), but was seen in 11% of papillary cancers; findings similar to those in the N0 population (Table).

Conclusions: Recurrence Score® results among N0, N1mic, and N+ patients are similar, suggesting that just as the RS identifies a spectrum of biology and predicts benefit of chemotherapy among ER+, HER2- N0 patients, the same biologic spectrum exists within patients with nodal metastases. Although it is possible that our findings reflect selection of more favorable N+ patients for testing, the large sample

size and consistency of results across tumor subtypes suggest that there are a significant number of women with node-positive disease at low risk for recurrence after treatment with endocrine therapy alone. If the RxPONDER trial demonstrates a predictive benefit for the RS result in N+ women, our findings indicate that substantial numbers of patients could avoid the burden of chemotherapy.

Table: Recurrence Score results

Nodal Status	Recurrence Score (RS) Risk Group (n=610,350)				Mean RS by Histology					
		Low (<18)	Intermediate (18-30)	High (≥ 31)	Ductal, NOS (n=504,362)	Lobular, Classic Type (n=49,819)	Lobular, Other Variants (n=5069)	Mucinous Carcinoma (n=16,116)	Papillary Carcinoma (n=4159)	Tubular Carcinoma (n=3599)
N0 (n=486,013)		286,504 59.0%	152,913 31.5%	46,596 9.6%	18.5	16.3	18.2	14.9	11.1	14.5
N1mi (n=24,325)		15,463 63.6%	7,212 29.7%	1,650 6.8%	17.0	15.3	18.9	14.8	10.6	14.6
N+ (n=56,100)		34,603 61.7%	17,021 31.3%	4,476 8.0%	17.6	15.7	17.9	15	12.5	15.2
Unknown (n=43,912)		25,004 56.9	13,603 31.0%	5,305 12.1%	19.4	16.9	18.1	15	9.8	14.8

403956 - Local recurrence rates after breast-conserving therapy in patients receiving modern era therapy

Heather Neuman[1], Jessica Schumacher[1], Bret Hanlon[1], Stephen Edge[2], Kathryn Ruddy[3], Ann Partridge[4], Jennifer Le-Rademacher[3], Menggang Yu[1], David Vanness[1], Dou-Yan Yang[1], Jeffrey Havlena[1], Caprice Greenberg[1]

[1]University of Wisconsin School of Medicine and Public Health, Madison, WI, [2]Roswell Park Cancer Center, Buffalo, [3]Mayo Clinic, Rochester, [4]Dana Farber Cancer Institute, Boston

Background/Objective: Multiple randomized controlled trials have demonstrated equivalent survival between breast conservation and mastectomy, albeit with a higher local recurrence rate after breast conservation. However, the absolute rates of local recurrence have been declining as a result of multi-modality treatment. We sought to evaluate the local recurrence rates after breast-conserving surgery in a cohort of patients receiving modern-era therapy within the context of a clinical trial, and to evaluate variation in rates of recurrence by molecular tumor subtype.

Methods: Data were included from nine Alliance for Clinical Trials in Oncology legacy clinical trials that enrolled women diagnosed with Stage I-III breast cancer between 1997-2011. Women who had undergone breast-conserving surgery and modern-era systemic and radiation therapies (n=6,927) were included. Five-year rates of local recurrence were estimated from Kaplan-Meier curves. Patients were censored at time of distant recurrence, death, or last follow-up. Multivariable Cox proportional hazards models were used to identify factors associated with time to local recurrence, including patient age, tumor size, lymph node status, and molecular tumor subtype.

Results: The overall rate of local recurrence at 5 years from trial registration was 4.2% (95% CI 3.7-4.8%). Rates were lowest for patients with ER/PR+ HER2neu+ disease (3.0%, 95% CI 1.9-4.8%), and highest for patients with ER/PR- HER2neu- disease (6.9%, 95% CI 5.6-8.4%). On multivariable analysis, ER/PR-HER2neu- disease and more positive lymph nodes were associated with higher risk of local recurrence. ER/PR+ HER2neu+ disease tumors and older age were associated with a lower risk of local recurrence (Table).

Conclusions: In the modern era, the rate of local recurrence in a cohort of patients treated and followed within the context of a clinical trial was quite low. These modern-era estimates can be used to inform discussions between patients and surgeons regarding breast conservation versus mastectomy.

Table: Local recurrence rates after breast-conserving therapy in patients receiving modern-era therapy

Table. Multivariable Cox Proportional Hazards Model Assessing Factors Associated with Time to Local Recurrence			
	Demographics (N, %)	Cox Proportional Hazards Model for Local Recurrence (HR, 95% CI)	
Risk group			<0.0001
ER/PR+ Her2neu-	63.1% (4,370)	Reference	
ER/PR- Her2neu-	1,467 (21.2%)	1.9 (1.4-2.6)	
ER/PR+ Her2neu+	631 (9.1%)	0.5 (0.3-0.9)	
ER/PR- Her2neu+	459 (6.8%)	0.9 (0.6-1.4)	
Tumor Size			0.5
0-=2 cm	3,975 (57%)	Reference	
2-=5cm	2,704 (39%)	1.0 (0.8-1.3)	
>5 cm	235 (3.4%)	1.5 (0.8-3.0)	
Node status			<0.0001
Negative	4,451 (71.5%)	Reference	
0-3+	1,391 (22.4%)	2.5 (1.9-3.4)	
>3+	382 (6.1%)	3.8 (2.5-5.6)	
Age (years)			0.006
<50	2,355 (34%)	Reference	
50 - <60	2,353 (34%)	0.6 (0.4-0.8)	
60 - <70	1,508 (21.8%)	0.7 (0.5-1.0)	
=70	711 (10.3%)	0.8 (0.5-1.2)	

403265 - Chronic pain after breast surgery: A prospective observational trial

Tara Spivey[1], Emily Gutowski[2], Nantthasorn Zinboonyahgoon[3], Tari King[3], Laura Dominici[3], Mehra Golshan[3], Kristin Schreiber[3]

[1]Massachusetts General, Brigham and Women's, and Dana-Farber Cancer Institute, Boston, MA, [2]Harvard Medical School, Boston, [3]Brigham and Women's Hospital, Boston

Background/Objective: Persistent post-operative pain is an important outcome in breast surgery in a significant minority of patients, yet few previous studies have comprehensively assessed surgical, medical, demographic, and phenotypic factors predictive of this entity in a prospective manner. Identification of patients at risk before surgery could improve pre-operative counseling, and allow targeted intervention and peri-operative planning aimed at preventing persistent post-operative pain. We prospectively sought to determine characteristics associated with post-operative pain 6 months after breast surgery, with an emphasis on aspects of surgical technique and management.

Methods: Between 2014 and 2017, 221 patients undergoing breast surgery at our institution were enrolled before surgery, and assessed for demographic, baseline pain, and psychosocial characteristics. Anxiety, depression, and pain catastrophizing were evaluated using validated questionnaires (PROMIS short forms, and Pain Catastrophizing Scale). Surgically related pain was quantified as the Pain Burden Index (PBI) using the Breast Cancer Pain Questionnaire, which queries pain severity and frequency in the surgical area (breast, axilla, chest wall, and ipsilateral arm), both pre-operatively, and also post-operatively out to 6 months. Breast surgery was categorized into 3 basic subgroups for the purpose of evaluating extent of surgery: breast-conserving surgery, mastectomies without reconstruction, mastectomies with reconstruction. In addition, further detailed data regarding surgical factors including axillary dissection, surgical complications, and subsequent surgeries as well as anesthetic and adjuvant treatments were assessed. Kruskal-Wallis Test was used to analyze group differences, and Mann-Whitney U Test was used to evaluate the impact of axillary dissection and late opioid use on persistent pain. Spearmans correlations were used to assess associations between PBI and demographic and psychosocial factors.

Results: Two hundred twenty-one subjects reported on pain outcomes including the PBI, which takes into account severity, frequency, and area of pain. There was no significant difference in PBI at 6 months between subjects who underwent breast-conserving surgery vs. mastectomies without reconstruction vs. mastectomies with reconstruction. Additionally, longer duration of surgery did not correlate with increased PBI. However, PBI was significantly higher in those who underwent axillary dissection ($p=0.037$). Younger age (<0.001) and higher BMI ($p=0.021$) correlated with higher PBI. Similarly, higher pre-operative anxiety ($p=0.018$), depression ($p=0.001$), and catastrophizing scores ($p=0.012$) were associated with higher PBI at 6 months. In addition, women who reported continued use of opioid medications for surgical pain at 2 weeks after surgery had significantly higher PBI scores at 6 months ($p<0.001$).

Conclusions: The extent and duration of breast surgery was not associated with persistent post-operative pain at 6 months, with the notable exception of axillary dissection. Psychosocial characteristics including higher anxiety, depression, and pain catastrophizing before surgery were associated with higher persistent post-operative pain at 6 months, suggesting that these, in conjunction with demographic factors including younger age and higher BMI, may help to screen for at-risk patients in the pre-operative setting. Those taking narcotic pain medications at the 2-week mark also had significantly higher PBI, suggesting that this could be used as a post-operative risk factor to identify

patients at risk of pain persistence. Further prospective studies along with longer longitudinal follow are required to validate these findings.

404340 - HBOC patients who do not meet Medicare criteria for genetic testing have similar rates of clinically actionable findings as those who do meet criteria

Jennifer Axilbund, Erin O'Leary, Scott Michalski, Shan Yang, Robbie Evans, Stephen Lincoln, Robert Nussbaum, Edward Esplin

Invitae, San Francisco, CA

Background/Objective: More than 275,000 patients are diagnosed with breast or ovarian cancer every year. An estimated 5-10% are due to hereditary causes, such as hereditary breast and ovarian cancer syndrome (HBOC). Medicare, the third-party payer that covers 44 million patients in the US, has implemented a set of clinical criteria to determine coverage of testing the BRCA1 and BRCA2 genes. Other insurance providers policies often mimic Medicare. Current Medicare BRCA1/2 genetic testing criteria require a personal diagnosis of cancer, and often need additional family history of cancer. However, the efficacy of these widely utilized clinical testing criteria has not been established. Additionally, current criteria were developed to identify carriers of BRCA1/2 variants and have not been evaluated in the panel testing era. In a series of patients insured by Medicare undergoing genetic testing, we evaluate the efficacy of Medicare genetic testing criteria in identifying patients with hereditary risk.

Methods: We studied a consecutive series of Medicare patients where the testing indication was a personal and/or family history of breast and/or gynecological cancer, and the order included at least the BRCA1 and BRCA2 genes. Ordering clinicians completed a brief checklist indicating whether patients did or did not meet Medicare criteria for BRCA1/2 genetic testing. Genetic test outcomes were compared between the in-criteria and out-of-criteria groups for different sets of genes. Positive outcomes were pathogenic (P) or likely pathogenic (LP) variants; uncertain results were identification of 1 or more variant of uncertain significance (VUS); and negative outcomes were findings of only benign or likely benign variants. Patients in families with known P/LP variants were excluded from the primary analysis.

Results: Among all 1990 unique patients in this cohort, 1516 (76.2%) met Medicare testing criteria and 474 (23.8%) did not meet criteria. When only results from BRCA1 and BRCA2 are considered, the positive rate of the in-criteria group is 1.43 fold as that of the out-of-criteria group (3.3% vs. 2.3%), a difference that is not statistically significant (p=0.35). When all the genes ordered for each patient are considered, the positive rates between the 2 groups are also similar (9.6% vs. 7.8%, p = 0.27). Rates of VUS did not differ substantially between the 2 groups. The in-criteria group on average ordered slightly fewer genes than out-of-criteria group (average panel size 18.6 genes vs. 22.5 genes), but the difference was not significant (Z = 0.21).

Conclusions: The rate of LP/P variants was similar among patients who did and did not meet Medicare criteria for BRCA1/2 genetic testing. The current criteria specifically reflect the historically severe presentation of high-penetrant BRCA1/2 variants, and do not adequately capture the range of clinical presentations commonly seen. Additionally, carriers of clinically actionable variants in genes other than BRCA1/2 are just as likely to fall outside of current criteria. Almost half of Medicare patients with actionable variants will be missed if testing is restricted to those meeting current criteria. This is likely to be true for other insurance providers who follow Medicare genetic testing criteria

Table: Results

outcome	in-criteria: *BRCA1/2* alone	out-of-criteria: *BRCA1/2 alone*	In-criteria: Larger HBOC panels ordered	out-of-criteria: Larger HBOC panels ordered
positive	3.3%	2.3%	9.6%	7.8%
uncertain	2.8%	3.8%	18.7%	20.9%
negative	93.9%	93.9%	71.8%	71.3%

402910 - Are genetic testing guidelines still relevant?

Peter Beitsch[1], Pat Whitworth[2], Rakesh Patel[3], Paul Baron[4], Barry Rosen [5], Gia Compagnoni[5], Rache Simmons[6], Dennis Holmes[7], Linda Ann Smith[8], Michael Kinney[9], Karen Barbosa[10], Ian Grady [11], Cynara Coomer[12], Lisa Curcio[13], Eric Brown[14], Linsey Gold[14], Antonio Ruiz[15], Patricia Clarke[16], Heather MacDonald[17]

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Background/Objective: Pathogenic genetic mutations are estimated to occur in 10-15% of all breast cancer patients, with BRCA 1/2 accounting for 40-50% of pathogenic/likely pathogenic (P/LP) mutations. However, it is estimated that <30% of breast cancer patients harboring a BRCA 1/2 mutation have been identified, with the percentage being much less for the ~20 other breast cancer-associated genes. Our failure to identify patients with P/LP mutations is multifactorial and includes physician education, insurance road blocks, and most importantly, confusing and restrictive testing guidelines. We created a community-based registry to determine the incidence of P/LP mutations in patients with breast cancer who meet and do not meet the NCCN 2017 genetic testing criteria.

Methods: An IRB-approved multicenter prospective registry was initiated with 18 community and academic breast physicians experienced in cancer genetic testing and counseling. Eligibility criteria included patients with a breast cancer diagnosis who had not previously had genetic testing. Patients were consented and underwent an 80-gene panel test (InVitae Multi-Cancer Panel). Recruitment goals were 500 patients who met NCCN genetic testing criteria and 500 who did not, with the objective of identifying if there was a statistically significant difference in P/LP mutation rate between these 2 patient cohorts. The non-inferiority study was powered to detect a difference in positive/LP mutation rate of 4 percentage points with statistical significance ($p<0.05$, Fisher's exact test). HIPAA-compliant

electronic case report forms collected information on patient diagnosis, test results, and physician recommendations made after test results were received. IRB approval and oversight was provided by WIRB (Puyallup, WA) or via a local IRB.

Results: Six hundred two patients have been registered as of November 6th, 2017, data from 364 patients have been reviewed (48% met NCCN criteria, and 52% did not), and we have genetic mutation data on 235 patients to date. Median age for the enrolled patients is 62. Median age for patients who met NCCN criteria is 60; those who did not, have a median age of 64.5. There were 60.8% of patients recently diagnosed with breast cancer. Of these, 46.6% met NCCN criteria; 53.3% did not. Of those not recently diagnosed, 49.7% met NCCN criteria; 50.3% did not. Eleven percent of patients had a history of a prior non-breast cancer, 46.3% of those met NCCN criteria, and 53.7% did not. There were 12.4% of patients who met NCCN criteria and had test results with a P/LP mutation, while 11.5% of patients who did not meet criteria had a pathogenic mutation. The difference of positive cases among the 2 groups is not statistically significant (p= 0.84). The spectrum of mutated genes varied between the 2 groups, with some overlap.

Conclusions: Patients who did not meet NCCN genetic testing guidelines had a similar percentage of pathogenic/likely pathogenic mutations compared to patients who met NCCN guidelines. Expanded panel testing yields more pathogenic hereditary mutations than BRCA 1/2 or breast cancer panels with 5-7 genes. More than 42% of patients with P/LP mutations may be missed if NCCN guidelines are required for genetic testing. Current guidelines are detrimental to identifying patients with P/LP mutations and should be abandoned.

Table: Genetic testing mutation rate in non-NCCN/NCCN breast cancer populations

NCCN criteria designation (**235** with reported test results/mutation data)	#/% who have P/LP mutations	% who do not have P/LP mutations
Patients who meet current guidelines	**14/113** (**12.4%**)	**99/113 (87.6%)**
Patients who do not meet guidelines	**14/122 (11.5%)**	**108/122 (88.5%)**

Scientific Oral Presentations II

Saturday, May 5, 2018 2:00 pm–3:15 pm
Moderators: Judy Boughey, MD; Roshni Rao, MD

403418 - Axillary nodal evaluation in elderly breast cancer patients: Potential effects on treatment decisions and survival

Nina Tamirisa, Samantha Thomas, Oluwadamilola Fayanju, Rachel Greenup, Laura Rosenberger, Terry Hyslop, Shelley Hwang, Jennifer Plichta

Duke University Medical Center, Durham, NC

Background/Objective: Recent studies suggest that surgical lymph node evaluation may be omitted in select elderly patients with breast cancer, due to the lack of impact on planned adjuvant therapy. To evaluate differences in receipt of adjuvant therapy and subsequent impact on survival, we compared outcomes in clinically node-negative (cN0) elderly patients with and without axillary surgery.

Methods: Using the National Cancer Database (2004-2014), we identified patients age 70 with clinical stage T1-3 (cT1-3) and cN0 invasive breast cancer and divided them into 2 cohorts - those with surgical lymph node evaluation (1 node removed) and those without (0 nodes removed). Propensity score matching was used to match patients based on age, year of diagnosis, tumor grade, cT stage, estrogen receptor (ER) status, and Charlson/Deyo co-morbidity score using a GREEDY method. Patients who did not undergo surgical nodal evaluation were matched with at least 1, but up to 4 patients who did. All analyses were stratified by match. Unadjusted median overall survival (OS) was estimated using the Kaplan-Meier method, and differences between groups were calculated using the log-rank test. A Cox proportional hazards model was used to estimate the effect of lymph node surgery on OS after adjustment for known covariates.

Results: Of the 133,898 matched patients, median age was 80 (IQR 76-84) and median tumor size was 1.4 cm (IQR 0.9-2.1). There were 76.3% patients who had a co-morbidity score of 0 (18.2% score=1 and 5.5% score 2), and median follow-up was 56.8 months (95% CI 56.4-57). Nodal surgery was performed in 102,338 patients (76.4%) with distribution of final nodal pathology (pN) as follows: 83.6% pN0 (n=85,537), 11.6% pN1 (n=11,833), 1.7% pN2 (n=1790), 0.7% pN3 (n=696), and 1.8% pNx (n=1797). Patients with nodal surgery were more likely to receive chemotherapy (pN1-3: 22.2%, pN0: 5.9%, cN0-no nodal surgery: 2.8%, p<0.001), radiation (pN1-3: 49.7%, pN0: 47.5%, cN0-no nodal surgery: 26%, p<0.001), and endocrine therapy (pN1-3: 72%, pN0: 58.5%, cN0-no nodal surgery: 46.4%, p<0.001). The unadjusted 5-year OS was higher for patients undergoing axillary surgery than those who did not (76.6% vs 59.7%, log-rank p<0.001). After adjustment for known covariates, patients who did not undergo nodal surgery had a worse OS (HR 1.63, 95% CI 1.58-1.67). In the adjusted analysis (Table), factors associated with an improved OS included receipt of chemotherapy (HR 0.86, 95% CI 0.81-0.91), radiation (HR 0.67, 95% CI 0.65-0.69), endocrine therapy (HR 0.77, 95% CI 0.75-0.79), and mastectomy (HR 0.94, 95% CI 0.91-0.97); a worse OS was associated with male gender (HR 1.31, 95% CI 1.17-1.45) and progesterone receptor-negative status (HR 1.12, 95% CI 1.08-1.16). In a subgroup analysis of patients with cT1, grade 1/2, ER+ disease, the unadjusted 5-year OS results remained significant (nodal surgery: 81.3% vs no nodal surgery: 66.9%, log-rank p<0.001).

Conclusions: In cN0 breast cancer patients 70 years old, positive nodes were identified in 14% of those undergoing axillary surgery. In an overall healthy population, axillary surgery was associated with higher

rates of adjuvant therapy and improved OS, demonstrating that it remains an important component of surgical therapy. A selective approach to the omission of nodal surgery should be considered in these patients with node-negative breast cancer, as the surgical outcome may influence subsequent treatment decisions and long-term outcomes.

Table: Estimated effect of select variables on adjusted overall survival using Cox proportional hazards modeling; hazard ratios (HR) reported. (N=118,826)

	HR (95% CI)	P-Value	Overall P-Value
Study Group			<0.001
Lymph Node Surgery	REF	<0.001	
No Lymph Node Surgery	1.628 (1.583-1.674)		
Gender			<0.001
Female	REF		
Male	1.305 (1.174-1.450)	<0.001	
Race			<0.001
White	REF		
Black	1.068 (1.012-1.127)	0.02	
Other	0.760 (0.677-0.855)	<0.001	
Progesterone Receptor (PR) Status			<0.001
PR+	REF		
PR-	1.115 (1.075-1.156)	<0.001	
Treatment with Chemotherapy			<0.001
No	REF		
Yes	0.861 (0.814-0.912)	<0.001	
Treatment with Radiation			<0.001
No	REF		
Yes	0.668 (0.646-0.690)	<0.001	
Treatment with Endocrine Therapy			<0.001
No	REF		
Yes	0.768 (0.746-0.791)	<0.001	
Surgery Type			<0.001
Lumpectomy	REF		
Mastectomy	0.938 (0.909-0.968)	<0.001	

403819 - The feasibility of breast-conserving surgery for multiple ipsilateral breast cancer: An initial report from ACOSOG Z11102 Alliance trial

Kari Rosenkranz[1], Linda McCall[2], Karla Ballman[3], Charlotte Kubicky[4], Laurie Cuttino[5], Huong LePetross[6], Kelly Hunt[6], Judy Boughey[7]

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Background/Objective: Early retrospective studies have reported increased risk of local recurrence in the multiple ipsilateral breast cancer (MIBC) population undergoing breast-conserving therapy (BCT). More recent retrospective data, however, support the feasibility of breast conservation in appropriately selected patients with acceptable recurrence rates. The American College of Surgeons Oncology Group (ACOSOG) Z11102 was designed to assess the feasibility and safety of breast conservation in MIBC with a primary endpoint of local recurrence rate. Herein we report the feasibility of breast conservation and assess factors associated with conversion to mastectomy.

Methods: ACOSOG Z11102 is a prospective, single arm, non-inferiority trial designed to assess the feasibility of breast conservation in women with 2 or 3 sites of malignancy in a single breast, separated by >2 cm or more. Patients were accrued to the study either pre- or post-operatively. Statistical analysis was performed using chi-square and Fisher's exact tests.

Results: Two hundred twenty-three eligible patients were enrolled, of whom 197 enrolled pre-operatively and make up the cohort for this analysis of successful BCT, with a median age of 62 years. The majority of patients (188, 95.4%) had 2 foci of disease, while 9 (4.6%) had 3 foci identified pre-operatively. Median size of the largest single focus of tumor was 1.5 (range 0.04-7.0cm). The majority of patients had at least 1 tumor that was ER+ (95.4%) and PR+ (91.4%). A HER2+ tumor was present in 10.4% of the study cohort. Forty-nine patients (25.0%) had node-positive disease. On final pathology, 4.1% of the patients had a single contiguous lesion rather than MIBC. Fifty-seven patients (28.9%) underwent resection as a single lumpectomy, 137 (69.5%) as 2 separate lumpectomies, 3 (1.5%) as 3 lumpectomies. Fourteen patients (7.1%) converted to mastectomy after attempted BCT, with 13 converted to mastectomy due to persistently positive margins, and the remaining patient opted for mastectomy. Of the 183 (93%) patients who successfully completed BCT, the total number of operations needed to obtain negative margins for BCT was 1 in 132 (73.3%), 2 in 42 (23.3%), 3 in 5 (2.8%), 5 in 1 (0.6%) patient, and unknown in 3.

Conclusions: Breast conservation is feasible in women with MIBC, with 67% of patients achieving a margin-negative excision in a single operation, and 7% of patients requiring conversion to mastectomy due to positive margins. No factors associated with conversion to mastectomy were identified. Long-term follow-up to assess local recurrence rates is awaited.

Table

		All patients enrolled preoperatively (n=197)	Completed BCS (n=183)	Converted to mastectomy (n=14)	p-value
Patient Age					0.097
	Median (range)	62 (40 – 87)	63 (40 – 87)	57.5 (42 – 76)	
Patient had pre-op MRI					0.57
	Yes	186 (94.4%)	173 (94.5%)	13 (92.9%)	
	No	11 (5.6%)	10 (5.5%)	1 (7.1%)	
Number of lesions (preop imaging)					0.21
	1	3 (1.5%)	3 (1.6%)	0	
	2	185 (93.9%)	173 (94.5%)	12 (85.7%)	
	3	9 (4.6%)	7 (3.8%)	2 (14.3%)	
Number of lesions (preop biopsy)					0.49
	2	188 (95.4%)	175 (95.6%)	13 (92.9%)	
	3	9 (4.6%)	8 (4.4%)	1 (7.1%)	
Number of lesions (path)					0.44
	0	1 (0.5%)	1 (0.6%)	0	
	1	10 (5.1%)	10 (5.5%)	0	
	2	169 (86.7%)	158 (86.8%)	11 (84.6%)	
	3	14 (7.2%)	12 (6.6%)	2 (15.4%)	
	4	1 (0.5%)	1 (0.6%)	0	
Size of largest lesion (preop)					0.97
	Median (range)	1.7 (0.8 – 5.0)	1.7 (0.8 – 5.0)	1.6 (0.8 – 4.5)	
Size of largest lesion (path)					0.17
	Median (range)	1.5 (0.04 – 7.0)	1.4 (0.04 – 6.5)	2.1 (0.1 – 7.0)	
Min distance between lesions (preop)					0.84
	Median (range)	3.7 (2.0 – 14.0)	3.8 (2.0 – 14.0)	3.4 (2.2 – 8.0)	
Her2 positive disease					0.37
	Yes	20 (10.4%)	20 (11.2%)	0	
	No	172 (89.6%)	158 (88.8%)	14 (100%)	
	Not done	5	5	0	
Histology					0.64
	Ductal	116 (58.9%)	108 (59.0%)	8 (57.1%)	
	Lobular	15 (7.6%)	14 (7.7%)	1 (7.1%)	
	Ductal/DCIS	43 (21.8%)	41 (22.4%)	2 (14.3%)	
	Lobular/DCIS	3 (1.5%)	3 (1.6%)	0	
	Ductal/Lobular	20 (10.2%)	17 (9.3%)	3 (21.4%)	

404366 - The impact of post-mastectomy chest wall radiation on prepectoral implant-based breast reconstruction

Catherine Sinnott[1], Anke Ott Young[2], Sarah Persing[2], Danielle Bertoni[2], Mary Pronovost[2], Christine Hodyl[3], Daniel McConnell[1]

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Background/Objective: Radiation is a well-known risk factor for complications after implant-based breast reconstruction. Prepectoral implant-based breast reconstruction with local de-epithelialized dermal flap and acellular dermal matrix (ADM) placement is a new and less invasive alternative to the traditional subpectoral approach. The purpose of this study is to evaluate the impact of post-mastectomy chest wall radiation on outcomes after prepectoral implant-based breast reconstruction compared to subpectoral immediate implant-based reconstruction.

Methods: A database was collected identifying patients who underwent prepectoral or subpectoral Wise pattern or modified-Wise pattern implant-based breast reconstruction with ADM placement performed by the senior surgeon from 2010 to 2017. Two hundred eighty-five patients (428 breasts) underwent prepectoral reconstruction, and in this group, 242 patients (373 breasts) were not exposed to radiation, while 43 patients (55 breasts) were exposed to post-mastectomy chest wall radiation. Eighty patients underwent subpectoral reconstruction, and in this group, 62 patients (97 breasts) were not exposed to radiation, while 18 patients (20 breasts) were exposed to post-mastectomy chest wall radiation. Outcomes were assessed by comparing complication rates between prepectoral and subpectoral groups, including infection, flap necrosis, dehiscence, capsular contracture, seroma, hematoma, rippling, implant loss, local recurrence, and metastatic disease.

Results: Post-operative outcomes were similar in patients who underwent prepectoral or subpectoral reconstruction who did not receive post-mastectomy chest wall radiation. As expected there was a higher rate of capsular contracture in prepectoral reconstruction patients with post-mastectomy chest wall radiation compared to prepectoral reconstruction patients who did not receive radiation (12.7% vs. 3.2%; p=0.006). Similarly, there was a higher rate of capsular contracture in subpectoral reconstruction patients who received post-mastectomy chest wall radiation compared to subpectoral patients who did not receive radiation (50.0% vs. 2.1%; p<0.001). However, the capsular contracture rate was nearly 4 times higher in subpectoral reconstruction patients who received post-mastectomy chest wall radiation compared to prepectoral reconstruction patients receiving radiation (50.0% vs. 12.7%; p=0.001). In addition, 10 out of the 11 cases of capsular contracture in the subpectoral reconstruction patients who received radiation were more severe (Baker Grade III and IV) contractures compared to prepectoral reconstruction patients receiving radiation, where only 2 out of 7 cases of capsular contracture were Baker Grade III, and the remaining were Baker Grade II contractures. All other complication rates were similar between prepectoral and subpectoral reconstruction patients who received post-mastectomy chest wall radiation, as well as between all other comparison groups.

Conclusions: Patients undergoing subpectoral implant-based breast reconstruction who received post-mastectomy chest wall radiation had a capsular contracture rate 4 times greater than patients receiving post-mastectomy chest wall radiation who underwent prepectoral implant-based breast reconstruction. Patients who underwent subpectoral reconstruction who received post-mastectomy chest wall radiation had more severe (Baker Grade III and IV) contractures compared to prepectoral reconstruction patients receiving post-mastectomy chest wall radiation. Prepectoral implant-based breast reconstruction may be a viable option for patients who need post-mastectomy chest wall radiation.

404138 - Long-term patient satisfaction after nipple-sparing mastectomy and conventional mastectomy with reconstruction does not differ significantly

Anya Romanoff, Emily Zabor, Michelle Stempel, Virgilio Sacchini, Andrea Pusic, Monica Morrow

Memorial Sloan Kettering Cancer Center, New York, NY

Background/Objective: Nipple-sparing mastectomy (NSM) is increasingly used for breast cancer risk reduction and treatment. Despite the risk of retained breast tissue associated with NSM, small retrospective studies, which have not all controlled for baseline characteristics and treatment differences among patients with and without NSM, suggest superior patient satisfaction with NSM. The aim of this study was to compare patient satisfaction following NSM and total mastectomy (TM) with expander/implant reconstruction utilizing the BREAST-Q patient reported outcome measure in a well-characterized patient population with available baseline breast satisfaction data.

Methods: Patients undergoing mastectomy at a single institution from 2007-2017 were identified by retrospective review of a prospectively maintained database. Eligibility included either NSM or TM with tissue expander/implant reconstruction, completion of a pre-operative, and at least 1 post-operative BREAST-Q survey. Baseline characteristics were compared using Fisher's exact test and Wilcoxon rank sum test. BREAST-Q scores were compared in 4 domains: satisfaction with breasts, psychosocial well-being, sexual well-being, and satisfaction with overall outcome; and at 4 time points: pre-operative, 6 months and 1 year post-operative, and at most recent follow-up. Multivariable linear regression models were fit for each domain at each time point.

Results: Of 967 eligible patients, 126 (13%) underwent NSM, and 841 (87%) underwent TM. Median patient age was 47 (range 20-77). Demographic and disease characteristics and BREAST-Q scores are compared in the table. Patients having NSM were younger, had lower BMI, more often had bilateral mastectomies, were more likely to have prophylactic surgery, and were less likely to have chemotherapy and radiation than those having TM. Women who underwent NSM had significantly higher pre-operative BREAST-Q satisfaction with breasts (66.5 vs. 58, p=0.004) and sexual well-being (63 vs. 60, p=0.006) scores. Six months and 1 year post-operatively, NSM patients reported significantly higher scores in all analyzed BREAST-Q domains. With longer follow-up (median 3.4 years from surgery, range 1.5-6.5 years), scores for all domains were similar between groups. On multivariable analysis after controlling for age, laterality, chemotherapy, radiation, and pre-operative BREAST-Q scores, only psychosocial well-being (p=0.025), and satisfaction with overall outcome (p=0.022) at 6 months remained significantly higher in the NSM group. Satisfaction with breasts (p=0.076) and sexual well-being (p=0.077) scores at 6 months were higher in the NSM group, but this difference was not statistically significant. There were no significant differences between groups in any BREAST-Q domain at 1 year or most recent follow-up (all p>0.05).

Conclusions: Patients undergoing NSM differed significantly from those undergoing TM, and had higher levels of satisfaction prior to intervention, which persisted in early post-operative follow-up. After adjusting for baseline factors, there was no significant difference in satisfaction at most recent follow-up in patients who underwent NSM compared with those who underwent TM. In spite of the perceived advantages of NSM, we found no clear long-term advantage of NSM based on patient reported outcomes information which should be discussed with patients during the decision-making process.

Table

	Nipple-sparing Mastectomy n=126	Total Mastectomy n=841	p-value
Age *(median, range)*	43 (28, 63)	48 (20, 77)	**<0.001**
Body mass index *(median, range)*	22.3 (17, 34)	24.7 (16, 63)	**<0.001**
Race *(n, %)*			0.073
White	105 (83.3)	667 (79.3)	
Black	2 (1.6)	59 (7)	
Hispanic	0 (0)	5 (0.6)	
Asian	12 (9.5)	53 (6.3)	
Other	2 (1.6)	16 (1.9)	
Unknown	5 (4)	41 (4.9)	
Marital Status *(n, %)*			0.317
Single	23 (18.3)	141 (16.8)	
Married/partnered	94 (74.6)	625 (74.3)	
Divorced	9 (7.1)	61 (7.3)	
Widowed	0 (0)	14 (1.7)	
Mastectomy *(n, %)*			**0.001**
Unilateral	102 (81)	557 (66.2)	
Bilateral	24 (19)	284 (33.8)	
Indication *(n, %)*			**0.014**
Cancer	110 (87.3)	789 (93.8)	
Prophylactic	16 (12.7)	52 (6.2)	
Stage *(n, %)*			0.091
0	20 (15.9)	108 (12.8)	
1	58 (46)	402 (47.8)	
2	23 (18.3)	192 (22.8)	
3	3 (2.4)	67 (8)	
N/a	22 (17.5)	72 (8.6)	
Axillary procedure *(n, %)*			0.121
Yes	107 (84.9)	780 (92.7)	
No	19 (15.1)	61 (7.3)	
Chemotherapy *(n, %)*			**0.009**
Yes	38 (30.2)	357 (42.4)	
No	88 (69.8)	484 (57.6)	
Radiation *(n, %)*			**0.005**
Yes	18 (14.3)	215 (25.6)	
No	108 (85.7)	626 (74.4)	
Complications *(n, %)*			0.091
Major	6 (4.8)	28 (3.3)	
Minor	17 (13.5)	69 (8.2)	
None	103 (81.7)	744 (88.5)	
Pre-op BREAST-Q *(median, range)*			
Satisfaction with breasts	66.5 (0, 100)	58 (0, 100)	**0.004**
Psychosocial well-being	73 (37, 100)	67 (23, 100)	0.077
Sexual well-being	63 (18, 100)	60 (0, 100)	**0.006**
6 month post-op BREAST-Q *(median, range)*			
Satisfaction with breasts (n=272)	71 (50, 100)	64 (27, 100)	**0.015**
Psychosocial well-being (n=271)	83 (43, 100)	70 (26, 100)	**0.013**
Sexual well-being (n=265)	57 (0, 100)	52 (0, 100)	**0.023**
Satisfaction with overall outcome (n=271)	75 (21, 100)	71 (27, 100)	**0.017**
1 year post-op BREAST-Q *(median, range)*			
Satisfaction with breasts (n=390)	71 (27, 100)	65 (0, 100)	**0.018**
Psychosocial well-being (n=388)	79 (46, 100)	76 (28, 100)	**0.022**
Sexual well-being (n=377)	63 (0, 100)	53 (0, 100)	**0.023**
Satisfaction with overall outcome (n=389)	75 (21, 100)	75 (0, 100)	**0.020**
Last follow-up BREAST-Q *(median, range)*			
Satisfaction with breasts (n=238)	71 (27, 100)	64 (20, 100)	0.175
Psychosocial well-being (n=238)	92 (33, 100)	76 (26, 100)	0.161
Sexual well-being (n=230)	63 (22, 100)	52 (0, 100)	0.124
Satisfaction with overall outcome (n=237)	75 (0, 100)	75 (0, 100)	0.422

404290 - Is age trumping genetic profiling in clinical practice? Relationship of chemotherapy recommendation and Oncotype DX recurrence score in patients <50 versus >50 and trends over time

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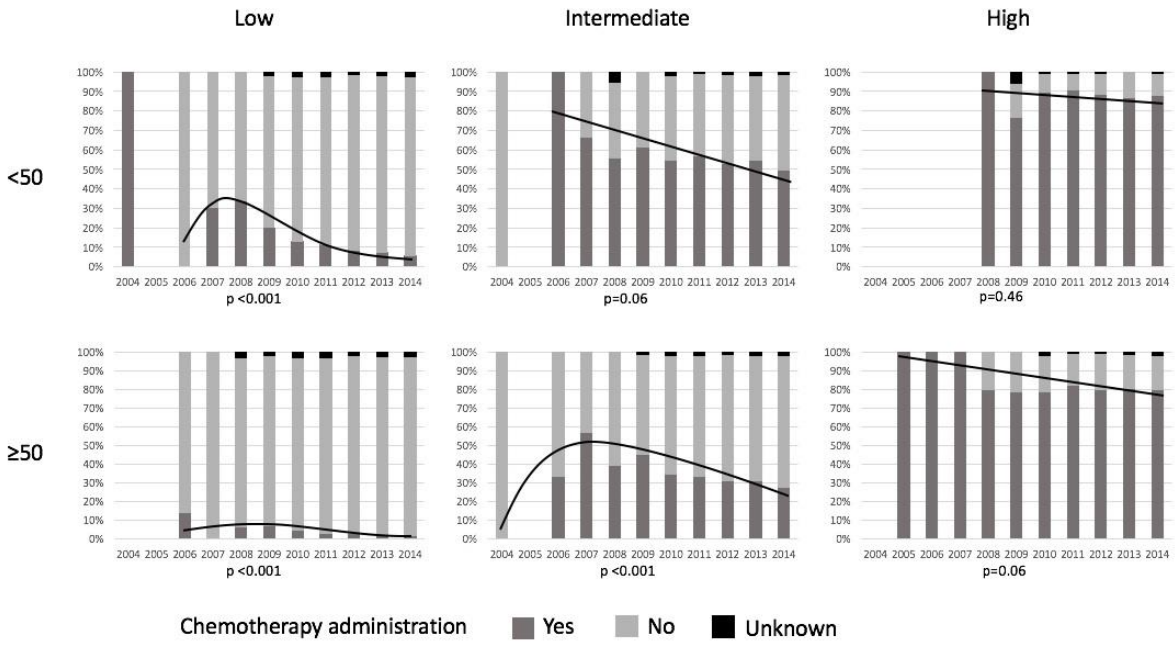
Background/Objective: The 21-gene assay Oncotype DX (oDX) is used as a tool to predict recurrence and indicate response to chemotherapy in patients with early-stage breast cancer. The NCCN does not stratify recommendation by age or menopausal status; therefore, it should be applied to all patients who fit the criteria. Studies suggest that this patient population has more aggressive biological factors, the oDX recurrence score (RS) has been shown to be reflective of 10-year distant recurrence risk for all patients despite age and should be used to guide chemotherapeutic recommendations. Despite this, the use in <50 patient population in clinical practice and trends over time compared to patients >50 is a topic of interest. The relationship between age, RS, and chemotherapy use was evaluated and trends of oDX testing over time was assessed.

Methods: Using the National Cancer Database, we identified women with T1 or T2, N0, estrogen receptor-positive and HER2/neu-negative breast cancer from 2004 to 2014. Pre-menopausal women were classified as <50 years old, and RS was classified as low <18, intermediate 18-30, or high>30. The number of patients from 2004-2014 who had oDx testing was evaluated. Comparisons of RS and chemotherapy use for patients <50 and > 50 were made and management trends over time were assessed.

Results: There were 380,308 breast cancer cases that met eligibility criteria for oDX testing. Of those 115,281 (30.3%) patients had oDX performed of which 24,556 (21.3%) were <50 years old. When stratified by RS, the majority of patients had a low RS in both groups (<50-59.0% and >50-59.1%), were white (<50-83.7% and >50-88.4% >50), and had T1N0 disease (<50-78.3% and >50-77.4%). Patients in the low RS group <50 were more likely to get chemotherapy or be recommended chemotherapy than patients >50 (16.9% vs 10.8%, p=<0.001) but a similar number of patients with a low RS refused chemotherapy. In the intermediate RS group, 64.4% patients <50 received or were recommended chemotherapy vs 46.3% of patients >50 (p=<0.001). There was also a significant difference in patients who were not recommended chemotherapy in the intermediate RS group (<50- 32.0% vs >50-48.6%; p=<0.001), with older patients being more likely to not be recommended chemotherapy. The high RS group had similar results, with a significant difference in the rates of chemotherapy recommendation (93.1% of patients <50 vs 88.6% >50; p=<0.001). Additionally, within the high RS group, 6.0% patients <50 were not offered chemotherapy vs 9.4% >50 (p<0.001). We further stratified the data by year (Figure) and noted an increasing trend in utilization of oDX, specifically in 2010 likely related to NCCN guideline changes. There was a decreasing trend in chemotherapy recommendations in patients with low RS in both age groups (p=0.001) and a downward trend towards no chemotherapy in intermediate RS patients, with only the >50 reaching statistical significance (p=0.06 and <0.001, respectively). No significant changes in chemotherapy use was seen in patients with high RS (p=0.46 and 0.06, respectively).

Conclusions: The testing of oDX in breast cancer has significantly increased since first implemented. With time, we continue to see higher rates of chemotherapy use in patients <50 years old despite oDx recurrence score. Additional studies should be done to shed light into the disparity between recommendations from genomic profiling by oDX and clinical practice patterns.

Figure: Chemotherapy administration



Quickshot Presentations

Saturday, May 5, 2018 12:00 pm – 1:30 pm
Moderators: Jill Dietz, MD; Henry Kuerer, MD

402997 - Oncotype DX® recurrence score as a predictor of response to neoadjuvant chemotherapy

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Background/Objective: The Oncotype DX® 21-gene assay is one of the most widely used and best validated assays for predicting response to adjuvant chemotherapy in breast cancer. However, the use of this test for predicting chemosensitivity in the neoadjuvant setting in patients with estrogen receptor-positive, HER2-negative breast cancer is not yet established.

Methods: This is a retrospective review of the National Cancer Database. The population for this study consisted of women with T1-T3, hormone receptor-positive, HER2-negative primary invasive breast cancer who were diagnosed and received neoadjuvant chemotherapy (NCT) between 2012 and 2015. Only patients with a recorded Oncotype DX® recurrence score were included; their results were defined as low (<18), intermediate (18-30), or high (>30). Patients were then identified as having achieved a pathologic complete response (pCR) or not following NCT. pCR was defined as no remaining invasive disease in breast or axillary nodes on pathologic review. Unadjusted analyses were performed to determine the association between the achievement of pCR and clinically relevant variables, including tumor size, regional lymph node involvement, tumor grade, and Oncotype DX® recurrence score. Multivariable regression analysis was then performed to determine adjusted associations of these variables with the achievement of pCR.

Results: Nine hundred eighty-nine women with an Oncotype DX recurrence score who received chemotherapy in a neoadjuvant setting were evaluated for their response to NCT. Of these, 227 (23.0%) had a low recurrence score; 450 (45.5%), an intermediate recurrence score; and 312 (31.5%), a high recurrence score. The mean age for the cohort was 54 years. In this cohort, 431 (43.6%) patients had a T1 tumor; 451 (45.6%), T2; and 107 (10.8%), T3. In addition, 757 (76.5%) had N0 disease while 232 (23.5%) were N+. The cohort included 123 (12.4%) patients with a grade 1 tumor, 517 (52.3%) with grade 2, and 349 (35.3%) grade 3. pCR was achieved by 42 patients from our cohort (4.3%). Unadjusted modeling for the occurrence of pCR revealed an association with clinical tumor size, grade, and Oncotype DX recurrence score. T1 tumors showed a decreased pCR rate when compared to T2/T3 tumors (OR, 0.21; 95% CI, 0.09-0.49). In contrast, high-grade tumors (OR 3.01; 95% CI, 1.56-5.83) and high recurrence risk score (OR 6.73; 95% CI, 2.92-15.54) were found to have a positive association with pCR. Multivariable logistic regression analysis confirmed the significant relationship between increased rates of pCR and high recurrence risk score (OR 6.73; 95% CI, 2.92-15.54), while smaller tumors were again found to correlate with a decreased pCR rate (OR 0.20; 95% CI, 0.08-0.48). Regional lymph node involvement did not demonstrate to be a significant predictor of pCR (OR 0.44; 95% CI, 0.18-1.08).

Conclusions: Our findings demonstrate a positive association between Oncotype DX high recurrence risk score and chemosensitivity in the neoadjuvant setting. Prospective studies are warranted to further validate and support the use of recurrence score to predict response to neoadjuvant chemotherapy in estrogen receptor-positive, HER2-negative patients.

404086 - Association of 21-gene recurrence score results with surgical intervention received after neoadjuvant hormonal therapy: Secondary endpoints of the TransNEOS validation study

Hiroji Iwata[1], Norikazu Masuda[2], Yutaka Yamamoto[3], Tomomi Fujisawa[4], Tatsuya Toyama[5], Masahiro Kashiwaba[6], Shoichiro Ohtani[7], Naruto Taira[8], Takehiko Sakai[9], Yoshie Hasegawa[10], Rikiya Nakamura[11], Hiromitsu Akabane[12], Yukiko Shibahara[13], Hironobu Sasano[13], Takuhiro Yamaguchi[14], Kentaro Sakamaki[15], Debbie McCullough[16], Naoko Sugiyama[16], Calvin Chao[16], Yasuo Ohasahi[17]

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Background/Objective: Neoadjuvant (NA) therapy for locally advanced breast cancer may improve surgical outcomes without affecting the survival advantages of adjuvant therapy. Because not all patients with estrogen receptor-positive (ER+) breast cancer respond equally to NA chemotherapy (CT) or hormonal therapy (HT), the ability to select patients more likely to benefit from NAHT would represent progress in clinical management of ER+ breast cancer. The 21-gene Oncotype DX Breast Recurrence Score® (RS) test is validated to predict adjuvant CT benefit in patients with node-negative (N0) ER+ breast cancer. NEOS is a randomized phase 3 study assessing long-term prognosis of ER+ primary breast cancer with/without adjuvant CT following 6 months of NA letrozole (UMIN 000001090, http://www.umin.ac.jp/). Here we report secondary endpoints of a translational study of the NEOS study (TransNEOS), in which the association of the 21-gene RS result with surgical intervention received (breast-conserving surgery [BCS] or mastectomy) was evaluated in patients treated with NAHT.

Methods: NEOS enrolled 904 postmenopausal patients with ER+, HER2-negative, clinically N0 breast cancer to evaluate the effect of adjuvant CT on patients who responded to NAHT. The TransNEOS study included samples from patients with tumors 2 cm, with the intention to evaluate 300 samples from NEOS. Archived biopsy samples were sent for 21-gene RS testing. Response to NAHT was recorded as complete/partial response (CR/PR), or stable/progressive disease (SD/PD). Pre-NAHT surgical candidacy and post-NAHT actual surgery received were recorded. Endpoints of the TransNEOS study were to evaluate the relationship between RS results and response to NAHT (primary), between RS results and rate of BCS after NAHT (secondary), and between single-gene results of the RS test and rate of BCS after NAHT (secondary). Association between RS result and surgical intervention was tested by the profile likelihood test for continuous RS result, and chi-square or Fisher's exact test (as appropriate) for RS group categories.

Results: The analysis included 294 patients. Median age was 63 years. Median tumor size was 2.5 cm. Most (66%) tumors were grade 1, 20% were grade 2, 9% were grade 3, and 5% were unknown. The 21-gene test results were RS <18 in 156 (53.0%), RS 18-30 in 83 (28.6%), and RS 31 in 54 (18.4%). Rates of clinical response to NAHT (CR/PR) were 54% for RS <18, 42% for RS 18-30, and 22% for RS 31. Rates of

pre-NAHT BCS candidacy were 62% for RS <18, 57% for RS 18-30, and 63% for RS 31 (p=.97). Rates of post-NAHT BCS received were 79% for RS <18, 67% for RS 18-30, and 60% for RS 31 (p=.006). Among 77 patients who were originally candidates for mastectomy, 58% of patients with RS <18 received BCS, compared with 35% with RS 31 (p=.045). Conversely, among 119 patients who were originally candidates for BCS, 8% of patients with RS <18 received mastectomy, compared with 21% of patients with RS 31 (p=.039). In a univariable analysis, RS results, ER and PR by RT-PCR, and ER gene group score were each significantly associated with post-NAHT BCS received (p=.01, p=.001, p<.001, and p<.001, respectively). In a multivariable model adjusting for age, tumor size, and grade, RS results were not a significant (p=.06) predictor of post-NAHT BCS received. In similar models with ER and PR by RT-PCR, and ER gene group score were significant (p=.01, p<.001, and p<.001, respectively).

Conclusions: Use of core biopsy samples for 21-gene Oncotype DX Breast RS testing was feasible. Univariable analysis validated the RS result as a predictor of clinical response to NAHT in postmenopausal patients with ER+, HER2-negative, clinically N0, primary early breast cancer. Additionally, RS <18 was significantly associated with post-NAHT surgical intervention received, and change from pre-NAHT candidacy to surgical intervention received. Multivariable analyses suggest that hormone receptor status by RT-PCR underlies the association between RS results and surgical intervention received.

403780 - Utility of expedited hereditary cancer testing in surgical management of newly diagnosed breast cancer patients

Kristin Theobald[1], Lisa Susswein[2], Maegan Roberts[2], Megan Marshall[2], Jessica Mester[2], Darrow Speyer[2], Ravin Williams[2], Sara Knapke[2], Patricia Murphy[2], Rachel Klein[2], Kathleen Hruska[2]

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Background/Objective: Knowledge of a germline pathogenic variant may inform cancer treatment decisions for newly diagnosed breast cancer patients. Genetic testing for BRCA1/2 has been shown to impact surgical decision-making, while similar data for multi-gene hereditary cancer panel testing are lacking. We aim to describe the clinical utility of expedited genetic testing (RUSH) for patients with newly diagnosed breast cancer.

Methods: Genetic test results were reviewed for 7,255 newly diagnosed female breast cancer patients undergoing RUSH multi-gene cancer panel testing between 2013 and 2017. This testing included BRCA1/2 analyses and up to 60 additional cancer predisposition genes. We calculated the yield of Pathogenic/Likely Pathogenic variants (collectively, PV). Mosaic PVs and MUTYH heterozygous PVs were not considered positive. The NCCN Guidelines (Version 1.2018) were evaluated to determine if management recommendations were published for each of the genes in which PVs were identified.

Results: A multi-gene panel was ordered as initial or only testing (i.e., no prior BRCA1/2 testing) in 70.7% (7,255/10,258) of RUSH cases, and the positive yield among this group was 9.5% (689/7,255). Within this group, 712 PVs were identified in 689 women, with 3.2% of all positive women having more than 1 PV. While the yields for BRCA1 and BRCA2 were 2.1% (149/7,255) and 2.3% (167/7,255) respectively, 55.6% (396/712) of PVs were identified in genes other than BRCA1/2, with CHEK2, ATM, and PALB2 being the most common (Table.). The NCCN guidelines recommend surveillance, medical, and/or surgical management for 96.9% (690/712) of PVs identified. Among women testing positive, 47.4% (327/689) had at least 1 PV in a gene with NCCN guidelines recommending the option of risk-reducing mastectomy. An additional 45.6% (314/689) had at least 1 PV in PALB2, ATM, CHEK2, CDH1, NBN, or NF1

for which NCCN indicates that while evidence is insufficient, risk-reducing mastectomy may be considered based on family history. In addition, 51.1% (352/689) of positive women had at least 1 PV in a gene with NCCN Guidelines recommending surgical options for organs or tissues other than breast.

Conclusions: More than half of PVs were identified in genes other than BRCA1/2. A majority of newly diagnosed patients were potential candidates for surgical intervention according to NCCN guidelines and many of these would have been missed if only BRCA1/2 testing had been ordered. Nearly half of patients had PVs in moderate risk genes, such as PALB2, for which surgical management recommendations may be evolving. Of note, while published data regarding outcomes for prophylactic surgery in patients with moderate risk genes are lacking, recent case-control series confirm a significantly increased risk for breast cancer in association with PALB2 (OR= 6.56-7.46). Expedited multi-gene hereditary cancer panel testing should be considered as a first-line order when surgical decision-making is pending to provide comprehensive information for acute cancer management.

Table: PV identified in women undergoing Panel RUSH testing without prior BRCA1/2

Actionable Gene by NCCN	Number of PVs identified and Yield (%) Per Gene^	Risk Reducing Mastectomy recommended based on NCCN Guidelines	Risk Reducing Mastectomy based on family history per NCCN	Non-breast prophylactic surgery options recommended per NCCN
CHEK2	190/6,415 (3.0%)		X	
BRCA2	167/7,255 (2.3%)	X		X
BRCA1	149/7,255 (2.1%)	X		X
ATM	63/6,380 (1.0%)		X	
PALB2	51/7,024 (0.7%)		X	
NBN	13/4,277 (0.3%)		X	
BRIP1	10/4,466 (0.2%)			X
TP53	10/6,920 (0.1%)	X		
PMS2	9/4,677 (0.2%)			X
MSH6	5/4,677 (0.1%)			X
PTEN	4/6,894	X		X
NF1	4/259 (1.5%)		X	
RAD51C	3 /4,466			X
RAD51D	3 /4,466			X
MLH1	3/4,677			X
MSH2	2/4,678			X
CDH1	2/6,666		X	X

^ Yields were calculated based on unique women undergoing testing for each gene, therefore the denominator per gene will vary.

402616 - Patient preferences for DCIS treatment strategies: A discrete-choice experiment

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Background/Objective: Ductal carcinoma in situ (DCIS), a nonobligate precursor of breast cancer, is often aggressively managed with multimodal therapy. However, there has been little research into patients preferences for acceptable tradeoffs when treatment-related outcomes such as breast appearance, side effects, and invasive cancer risk are considered. In such preference-sensitive settings, a discrete-choice experimental design (DCE) has been helpful in eliciting the relative importance of different treatment-related attributes within a given patient population.

Methods: Women presenting for screening mammography were invited to participate in an online survey. Respondents were provided educational content regarding DCIS, then were asked to answer 10 DCE questions addressing different treatment trade-offs. Each question presented 2 health states resulting from different treatment options. Health states were defined by 5 attributes, each with 3 or 4 levels: breast appearance (no surgery, lumpectomy, mastectomy, mastectomy with reconstruction), severity of infection within the first year (none, mild, moderate, severe), chronic pain (none, 1 year, 5 years), hot flashes (none, 1 year, 5 years), and risk of developing breast cancer/dying from breast cancer within 10 years (2%/0.2%, 5%/0.5%, 10%/1%, 20%/2%). Log-odds relative-importance weights for attribute levels were obtained by random-parameters logit and then proportionally weighted on a scale from 0-10, with 10 representing the most important attribute.

Results: One hundred fifty women completed the survey. Forty-seven participants (31%) dominated on the risk of invasive breast cancer, always selecting the health state with the lowest cancer risk and thus indicating that they were unwilling to make any tradeoff that resulted in increased cancer risk. After excluding those women who dominated on risk only, breast cancer risk was still the most important factor (10) followed by chronic pain (5.9 [95% CI 4.3-7.7]) and infection (5.6 [95% CI 4.1-7.5]). Thus, conditional on the levels represented, chronic pain was 59% as important as the greatest reduction in the risk of cancer offered, and infections were 56% as important. Responses from non-risk dominators also provided information on acceptable tradeoffs between surgical treatment outcomes at variable levels of breast cancer risk (Table). On average, non-risk dominators reported that they would trade lumpectomy for no surgery at a 2.2% absolute future breast cancer risk; mastectomy for no surgery at 2.9% absolute risk; mastectomy with reconstruction for no surgery at 3.5% absolute risk; and mastectomy for lumpectomy at 2.7% absolute risk. There was variability in acceptable tradeoffs depending on surgical outcome, with tolerable breast cancer risk levels ranging from 2.2% to 3.5%.

Conclusions: Although almost one-third of women were unwilling to accept any increase in cancer risk in exchange for less invasive DCIS management, the majority of participants (69%) were willing to accept some increase in breast cancer risk or side-effect burden to minimize changes in their appearance as a result of surgery. In order to achieve the optimal preference-based treatment decision, clinicians must recognize that there exists heterogeneity in how women prioritize breast cancer risk and treatment-related side effects, and that treatment options should be presented to patients within this context.

Table: Patient-reported acceptable risk tradeoffs for surgical treatment outcomes

From	To	Acceptable Absolute 10-year Breast Cancer Risk (%)
Reconstructed breast, large scar	No surgery	3.5 (2.4, 4.7)
Reconstructed breast, large scar	Normal, small scar	3.4 (2.5, 4.2)
Reconstructed breast, large scar	No breast, large scar	2.6 (1.9, 3.4)
No breast, large scar	No surgery	2.9 (1.9, 3.8)
No breast, large scar	Normal, small scar	2.7 (1.9, 3.6)
Normal, small scar	No surgery	2.2 (1.6, 2.7)

403256 - Predicting non-sentinel lymph node metastases in patients with a positive sentinel lymph node after neoadjuvant chemotherapy

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Background/Objective: Current standard of care for patients treated with neoadjuvant chemotherapy (NAC) who have a positive sentinel lymph node (SLN) after NAC is to proceed to completion axillary lymph node dissection. Many breast cancer care providers utilize widely available nomograms in patients who have not received NAC to predict likelihood of additional non-SLN metastases in patients found to have a positive SLN, to help with decision-making regarding further axillary management. The goal of this study was to develop a nomogram for the prediction of additional nodal disease in patients found to have a positive SLN after NAC.

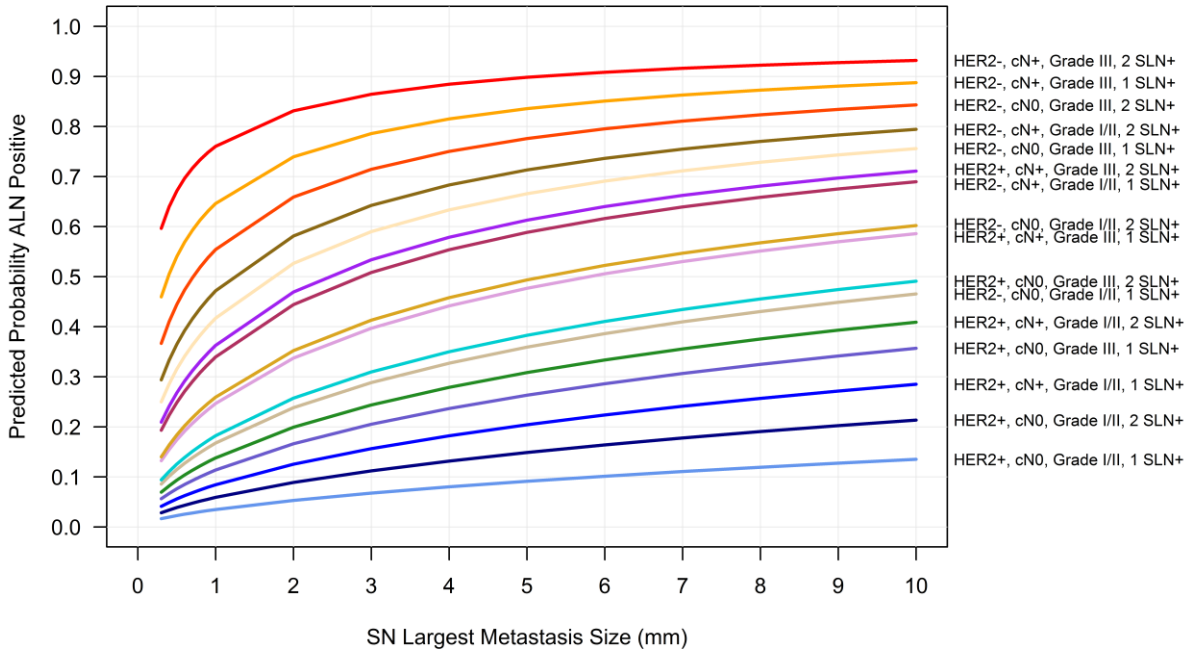
Methods: With IRB approval, we reviewed all patients 18 years of age with invasive breast cancer treated with NAC followed by SLN surgery with a positive SLN and completion axillary lymph node dissection (ALND) from 2006-2017 at our institution. Clinicopathologic data was reviewed including clinical and pathologic tumor size, histology, grade, tumor biology [categorized as Hormone Receptor (HR)+/HER2-, triple negative breast cancer (TNBC), HER2+], number of SLNs removed, number of positive SLNs, size of largest SLN metastasis, presence of lymphovascular invasion (LVI), and extranodal extension. Factors predictive of positive non-SLNs were analyzed using univariate and multivariable logistic regression.

Results: One hundred twenty patients with positive SLN after NAC and completion ALND were identified. Median age was 51 with 30.8% clinically node negative and 69.2% clinically node positive prior to NAC. Tumor biology was 20.0% HER2+, 66.7% HR+/HER2- and 13.3% TNBC. Additional nodal disease was found on ALND in 63.3% of patients. On univariate analysis, factors predictive of positive non-SLNs were: biologic subtype (TNBC and HR+/HER2- compared to HER2+, $p<0.001$), higher tumor grade ($p=0.047$), higher pathologic T category ($p=0.02$), presence of SLN extranodal extension ($p=0.04$), larger SLN metastasis size ($p<0.001$), and higher number of SLNs positive ($p=0.02$). Factors significant on multivariable analysis included number of SLNs positive, grade III vs grade I/II, HER2+ vs HER2-, cN+ vs cN-, and largest SLN metastasis size; the resulting model showed excellent discrimination (AUC=0.82; 95% CI: 0.74-0.90) and good calibration (Hosmer-Lemeshow $p=0.54$). Model-predicted probability of

additional non-SLN metastasis as a function of SLN metastasis size by tumor biology, clinical nodal status, grade and number of positive SLNs is shown in the Figure.

Conclusions: The likelihood of positive non-SLNs in a patient with a positive SLN after NAC varies by biologic subtype, grade, clinical node status, size of the largest SLN metastasis, and number of SLNs positive. A clinical prediction model incorporating these factors can help physicians and patients estimate likelihood of additional nodal disease and may be useful to guide decision-making regarding axillary management.

Figure: Model-predicted probability of additional non-SLN metastasis as a function of SLN metastasis size by tumor biology, clinical nodal status, grade and number of positive SLNs



404038 - Prospective evaluation of quality of life for patients with breast cancer treated with breast-conserving surgery, mastectomy alone, and mastectomy with immediate breast reconstruction

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Background/Objective: To evaluate the change in satisfaction and quality of life between early breast cancer patients treated with breast-conserving surgery (BCT), mastectomy alone (MA), or mastectomy with immediate breast reconstruction (IBR) at 1 year after surgery using the BREAST-Q.

Methods: All early-stage (Stage 0-II) breast cancer patients treated at a single tertiary care center between 2015 and 2017 were enrolled. Their quality of life and satisfaction outcomes were compared using the BREAST-Q breast satisfaction (BS) and psychosocial wellbeing (PSW) scales at 12 months. A multivariate linear regression was performed to assess changes in BS and PSW scores between baseline and 12 months. Clinically relevant and statistically different baseline factors were incorporated in the multivariable model; these include patient's age, income, education, ethnicity, cancer stage, and procedure laterality.

Results: A total of 242 early-stage breast cancer patients (Stage 0-II) were prospectively enrolled; 107 underwent BCT, 56 MA, and 79 IBR. Patients in the BCT group were older at baseline (60 +/- 11 years old) compared to MA (52 +/-12 years) or IBR (49 +/-10 years) ($p<0.0001$). The majority of IBR cases were bilateral (66%), whereas they comprised only 32% of MA and 5% of BCT ($p<0.0001$). Education, income, and ethnicity were comparable between groups at baseline. The 3 groups had similar baseline BS and PSW scores ($p=0.17$ and $p=0.71$). At 12 months, BCT had the highest BREAST-Q scores, with 68/100 for BS and 79/100 for PSW ($p<0.0001$), compared to, respectively, 57 and 65 for IBR, and 48 and 57 for MA. After multivariable regression accounting for patients age, income, education, ethnicity, cancer stage, and laterality, BS BREAST-Q change from baseline to 12 months was not statistically different for BCT and IBR ($p=0.0662$), while MA patients experienced lower BS compared to BCT ($p<0.0001$). IBR patients had no different BS when compared to MA ($p=0.16$). With regard to PSW, similar patterns were present. IBR patients had no different PSW than BCT ($p=0.25$), while MA patients experienced lower wellbeing compared to BCT ($p<0.0001$). IBR had higher PSW compared to MA ($p=0.0039$).

Conclusions: This large prospective study highlights that changes in breast satisfaction and psychosocial wellbeing at 12 months for BCT and IBR are no different in early-stage breast cancer patients, but are significantly reduced in MA. This study is the first to compare BREAST-Q outcomes between BCT, MA and IBR, and provides important evidence to support the use of BCT and IBR to optimize long-term quality of life and breast satisfaction for early-stage breast cancer patients.

Table: Linear multivariable regression model adjusted for age, income, education, ethnicity, cancer stage and laterality comparing BREAST-Q at 12 months for BCT, mastectomy, and IBR

Predictor	Unadjusted beta coefficient (95% CI)	p value	Adjusted beta coefficient (95% CI)	p value
Breast Satisfaction				
Model 1				
BCT	Ref (0.0)	-	Ref (0.0)	-
Mastectomy	-18.4 (-28.0 - -8.9)	0.0002	-25.2 (-37.1 – -13.2)	<0.0001
IBR	-7.6 (-16.8 – 1.7)	0.11	-14.1 (-29.2 – 1.0)	0.0662
Model 2				
BCT	18.4 (8.9 – 28.0)	0.0002	25.5 (13.6 – 37.4)	<0.0001
Mastectomy	Ref (0.0)	-	Ref (0.0)	-
IBR	10.9 (0.2 – 21.6)	0.0467	10.1 (-4.0 – 24.3)	0.16
Psychosocial well-being				
Model 1				
BCT	Ref (0.0)	-	Ref (0.0)	-
Mastectomy	-14.7 (-21.3 - -8.2)	<0.0001	-20.9 (-29.2 – -12.5)	<0.0001
IBR	-5.3 (-11.7 – 1.1)	0.1045	-6.1 (-16.6 – 4.4)	0.25
Model 2				
BCT	14.7 (8.2 – 21.3)	<0.0001	20.9 (12.5 – 29.2)	<0.0001
Mastectomy	Ref (0.0)	-	Ref (0.0)	-
IBR	9.5 (2.1 – 16.8)	0.0121	14.8 (4.8 – 24.7)	0.0039

Legend: BCT: Breast Conserving Surgery, IBR: Immediate Breast Reconstruction

404025 - No change in contralateral prophylactic mastectomy rates after implementation of a patient educational handout based on the 2016 ASBrS consensus statement: An ongoing quality improvement initiative

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Background/Objective: Nationally, rates of contralateral prophylactic mastectomy (CPM) have increased. In 2016, an American Society of Breast Surgeons (ASBrS) consensus statement advised against routine CPM in average-risk patients with unilateral breast cancer (BC). This statement specifically recommends that surgeons provide patients with detailed information about CPM and make a recommendation for or against CPM. Based on the statement, our breast center drafted a CPM educational handout, distributed it to appropriate patients, and encouraged surgeon utilization during

consultation with newly diagnosed BC patients. We examined if CPM rates were impacted after introducing this educational handout.

Methods: We reviewed mastectomies for BC at a single breast center, offering comprehensive reconstruction options, from 9/2015-4/2017. Exclusions were: males, bilateral BC, BRCA+, and personal history of BC. We analyzed CPM rates before and after the educational handout was introduced in 9/2016. We used multivariate analysis to examine if CPM rates differed before vs. after the educational handout, after controlling for patient differences in the 2 time periods. Factors associated with CPM on univariate analysis were selected for multivariate analysis.

Results: We identified 172 patients undergoing mastectomy for a unilateral BC, of whom 89 (51.7%) had CPM. In the CPM group, 89.9% (n=80) had immediate reconstruction vs. 55.4% (n=46) in the non-CPM group ($p<0.0001$). Unadjusted CPM rates were similar before and after educational handouts were available (52.3% vs. 50%, $p=0.79$). When individual surgeons rates were examined, no surgeons CPM rate changed significantly after introducing the handout. Factors associated with increased CPM rate on univariate analysis were young age, surgeon, IR, N0 status, and married status. Factors not associated with CPM were history of atypia, MRI, T-size, family history of BC, and multicentricity. Baseline characteristics were similar in the before vs. after groups, except for mean BMI (29.0 vs. 26.9, $p=0.04$). On multivariate analysis, IR and N0 status remained significant predictors of CPM, and time period (before vs. after the handout) was not predictive of CPM.

Conclusions: At our institution, surgeon awareness of the ASBrS CPM statement and a simple intervention did not affect CPM rates. This suggests that patient factors leading to CPM are complex, and that a multi-faceted method may be more effective in influencing CPM decisions. In response, we have implemented a 4-step approach for further quality improvement. First, surgeons created an acronym (RiSCC) covering 4 key points during counseling (Ri: quantify the RISK of contralateral BC; S: CPM will not alter SURVIVAL; C: CHEMOTHERAPY, e.g. CPM will not alter recommendations for adjuvant therapy except for pure DCIS; C: CPM will double the risk of surgical COMPLICATIONS). Second, nurse navigators now use the same acronym for reinforcing these points for patients who choose CPM. Third, surgeons are providing written and verbal recommendations for or against CPM. Finally, a modified educational handout is being distributed to emphasize pros vs. cons of CPM. Breast centers that choose to look at trends surrounding CPM as an internal quality review should control for known predictors of CPM, and should consider a multi-faceted approach to quality improvement efforts.

Table: Multivariate analysis of factors associated with CPM (n=172)

	Odds Ratio (of Yes vs. No)	Effect Likelihood Ratio *p*-value
Age: >55 (vs. ≤55)	 0.72	0.40
Surgeon: 2 (vs. 1) 3 (vs. 1) 4 (vs. 1)	 0.85 1.23 0.25	0.09
Immediate reconstruction: Yes (vs. No)	 5.75	0.0001
Married: Yes (vs. No or Unknown)	 1.41	0.37
Nodal status: N0 (vs. N1-3)	 0.47	0.05

404031 - Multidisciplinary margin assessment reduces number of positive margins

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Background/Objective: Successful breast conservation surgery requires achieving negative margins. Re-operation impacts cosmesis and results in increased costs and delays to adjuvant therapy. There are varied strategies for reducing positive margins. At our institution, the whole surgical specimen is imaged, then serially sectioned with repeat imaging performed. There is then evaluation and discussion between surgeon, pathologist, and radiologist regarding the need for excision of additional margins. The goal of this study was to determine the benefit of each component of this approach in reducing the number of positive margins.

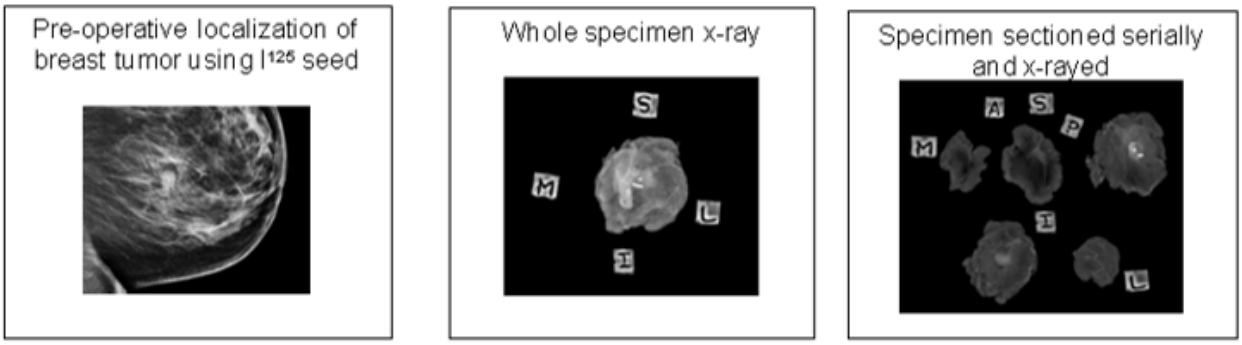
Methods: This was a single-institution prospective study including 10 breast surgical oncologists. Before discussing the intra-operative evaluation with pathology and radiology, surgeons completed a survey. The survey assessed whether they would have taken additional margins based on intra-operative findings and their review of whole specimen images (WSIR) alone and whether they would have taken additional margins based on their review of the serially-sectioned images (SSIR). These results were compared to the multidisciplinary decisions (MDD) and the pathology results. Margins were classified based on consensus guidelines. For invasive cancer, margins were considered positive if tumor was found on ink. For DCIS with no associated invasive carcinoma, margins were positive if DCIS was on ink and close if margins < 2 mm. Comparisons were made using Fisher's exact test with significance level of 0.05.

Results: One hundred surveys were completed. Localization was guided by an I125 seed in 74, wire in 23, and palpation in 3 cases. Tumor histology was classified as invasive ductal in 65, invasive lobular in

10, and DCIS in 25. Margins of the original specimen were close or positive in 21%. After WSIR, surgeons reported they would have taken additional margins in 26 cases, which would have reduced the number of close or positive margins from 21% to 13% (p<.001). After SSIR, 52 would have taken additional margins, however the number of close or positive margins remained 13%. MDD resulted in additional margins taken in 56 cases reducing the number of close or positive margins to 7% (p<0.001 compared to SSIR). In 66 cases with lesions < 2 cm on imaging, margins would have been close or positive in 11 (16.7%) of the original specimens, 7 (10.6%) after WSIR, 7 (10.6%) after SSIR, and 4 (6.1%) after MDD. In 30 cases with lesions 2-5 cm, a close or positive margin would have occurred in 9 (30%) cases based on the original specimen, 5 (16.7%) after WIR, 5 (16.7%) after SSIR, and 2 (6.7%) after MDD. In the 81 cases that had a mass, the proportion of cases with close or positive margins would have been 19.8% (n=16) with the original specimen, 11.1% (n=9) after WSIR or SSIR, which reduced to 4.9% (n=4) after MDD. In the 40 cases with calcifications (either with mass or alone) on imaging, the number of close or positive margins would have been 17.5% (n=7) based on the original specimen, 12.5% (n=5) after WSIR or SSIR, and 10% (n=4) after MDD.

Conclusions: While surgeon review of specimen radiographs can decrease the number of close or positive margins from 21% to 13%, more rigorous multi-disciplinary intra-operative margin assessment reduces the number of close or positive margins to 7%.

Figure: Intra-operative specimen imaging



403777 - Litigation for breast cancer care: Delay in diagnosis continues to top the chart

Brittany Murphy[1], Mohamed Ray-Zack [1], Pooja Reddy[1], Asad Choudhry[1], Martin Zielinski[1], Elizabeth Habermann[1], Louis Jakub[2], James Jakub[1]

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Background/Objective: General surgery, which includes breast surgery, is regarded as a specialty with high legal risk. Fifteen percent of general surgeons practicing in the United States face a medical malpractice suit each year for a variety of reasons. In early 2000, delay in breast cancer diagnosis was the leading cause for litigation in breast care, but recent trends are unknown. We sought to determine if cases show the same patterns in litigation for breast cancer care over the following 15 years by reviewing a public legal database.

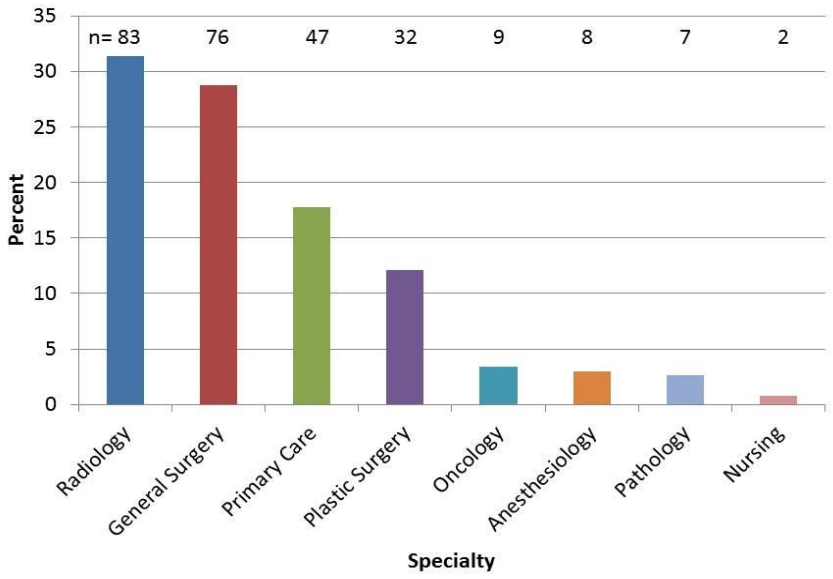
Methods: We queried the Lexis Nexis legal database using the search terms medical malpractice and a comprehensive list of terms related to breast cancer, identifying all cases from 2000-2016. Data on state and federal jurisdiction were abstracted and included patient and case characteristics, alleged reason for

litigation, procedure performed, pre-operative and post-operative diagnosis, along with case outcomes and award payouts. Descriptive analyses were performed.

Results: Our search revealed 490 cases, of which 264 met inclusion criteria. Excluded cases were those not directly related to breast cancer care. The mean (± SD) patient age at time of incident was 46.9 ± 9.6 years and 263 (99.6%) patients were female. Failure to timely diagnose breast cancer was the most common reason for litigation (n= 164, 62.1%), followed by failure to obtain adequate informed consent regarding the procedure and potential complications (n=26, 9.8%). The defendant specialties most frequently named in lawsuits were radiology (83, 31.4%), general surgery (76, 28.8%), and primary care (47, 17.8%), [Figure]. When a general surgeon was the defendant, the most common allegation was failure to provide adequate treatment (34, 44.7%), followed by unnecessary or incorrect procedure performed (9, 10.8%), and failure to obtain adequate informed consent (9, 10.8%). When a plastic surgeon was the defendant (32, 12.1%), the most common reason for litigation was failure to obtain adequate informed consent (15, 46.9%) followed by deformity/disfigurement (7, 21.9%). The vast majority of lawsuits alleged that negligence occurred in the pre-procedural period (200, 75.8%), followed by post-procedural period (41, 15.5%). Eighteen (6.8%) cases were related to intra-operative complications: improperly performed procedure (6, 33.3%), intra-operative injury (5, 27.8%), anesthesia related (3, 16.7%), retained foreign object (2, 11.1%), and wrong site surgery (2, 11.1%). Mortality associated with alleged negligence occurred in 42 (15.9%) cases, usually related to delay in diagnosis. One hundred and forty-five cases reached a verdict in favor of the defendant (54.9%), 60 (22.7%) cases had a verdict in favor of the plaintiff, whereas 59 (22.3%) reached a settlement out of court. The median [IQR] award payout in cases with a plaintiff verdict was $1,300,000 [$535,750-$2,725,000] or settlement $750,000 [$362,500-$1,425,000].

Conclusions: Failure to timely diagnose breast cancer continues to be the most common reason for litigation related to breast cancer care. General surgeons were the second most common specialty facing litigation and by identifying the most common reasons why, we may help decrease this rate and improve the patient experience. While half of cases ruled in favor of the defendant, when the plaintiff received a payout, the amount was often substantial.

Figure: Specialties associated with breast cancer care litigation



404018 - Reducing breast cancer-related lymphedema (BCRL) through prospective surveillance monitoring using bioimpedance spectroscopy (BIS) and patient-directed self-interventions

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Background/Objective:
Breast cancer related lymphedema (BCRL) is a chronic progressive disease that can result from necessary nodal surgery for breast cancer staging and treatment and can cause significant impact in quality of life as well as a profound cost burden to the patient and health care industry. Current NCCN guidelines support baseline measurements with prospective assessment of breast cancer patients to allow for early diagnosis and treatment of BCRL. We sought to determine if baseline measurement with Bioimpedance spectroscopy (BIS) followed by serial postoperative evaluations provide early detection that is amenable to conservative interventions providing a reduction in BCRL.

Methods:
Breast cancer patients from a single institution were prospectively evaluated from November 2014 to December 2017, with unilateral disease undergoing treatments high-risk for BCRL. High-risk treatments were defined as axillary lymph node dissection (ALND) with regional nodal irradiation (RNI) and/or Taxane chemotherapy. All patients received baseline BIS measurements prior to surgery followed by serial post-operative measurements in a routine surveillance model, with all individuals having at least 1 year post-operative follow-up. Patients with subclinical lymphedema diagnosed by a BIS result of 2 standard deviations above baseline from preoperative assessment (10+points) were started on at home conservative interventions of a compression sleeve garment and patient directed self-massage for a period of 4-6 weeks. Post-intervention measurements were taken to assess for improvement.

Results:
One hundred forty-six patients undergoing high-risk treatment for the development of BCRL were evaluated. A total of 49 (34%) patients developed subclinical lymphedema by elevated BIS scores with self-directed treatment initiated. Of these, 40 (82%) had resolution of elevated measurements (return to normal range for their baseline) at last follow-up. Nine patients had continued elevated measurements that required referral to outpatient complete decongestive therapy (CDT) for a clinically persistent BCRL incidence of 6%. Patients with persistent BCRL had significant nodal burden on final surgical pathology with 8 of the 9 (89%) having N2 or N3 disease. Of these 9 patients, 6 have since died secondary to breast cancer.

Conclusions:
Our results demonstrate that prospective monitoring utilizing BIS elevation with conservative early intervention results in significantly lower rates of BCRL requiring CDT in a high-risk group of breast cancer patients. Historically, rates of clinical BCRL in these patients have ranged from 20-40%. These findings support early prospective screening and intervention for BCRL. Early detection with patient directed interventions for subclinical and early lymphedema can improve patient outcomes and decrease the risk of chronic irreversible lymphedema.

Top 12

403787 - Can PREDICT and BOADICEA scores help identify patients that would benefit from risk-reducing mastectomy?

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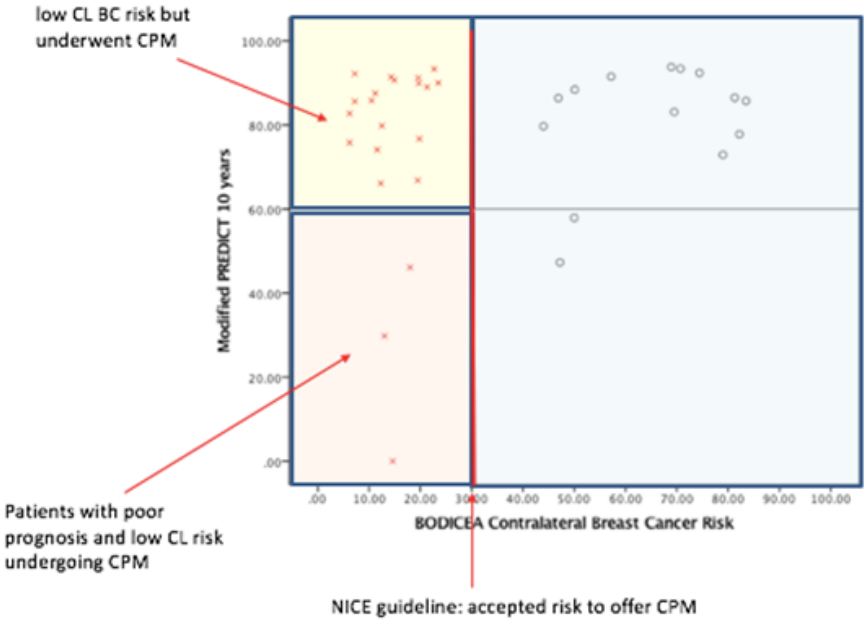
Background/Objective: For patients with sporadic breast cancer (BC), rates of contralateral cancer are low (0.7%/annum), and there is no evidence to suggest contralateral prophylactic mastectomy (CPM) offers survival advantage. Furthermore, CPM with autologous reconstruction has major resource implications. Despite this, the rate of CPM performed in the USA and UK is rising. The aim of this study was to review the implications of bilateral reconstructive surgery in patients with unilateral BC and to determine means of prospectively identifying patients who would benefit from CPM.

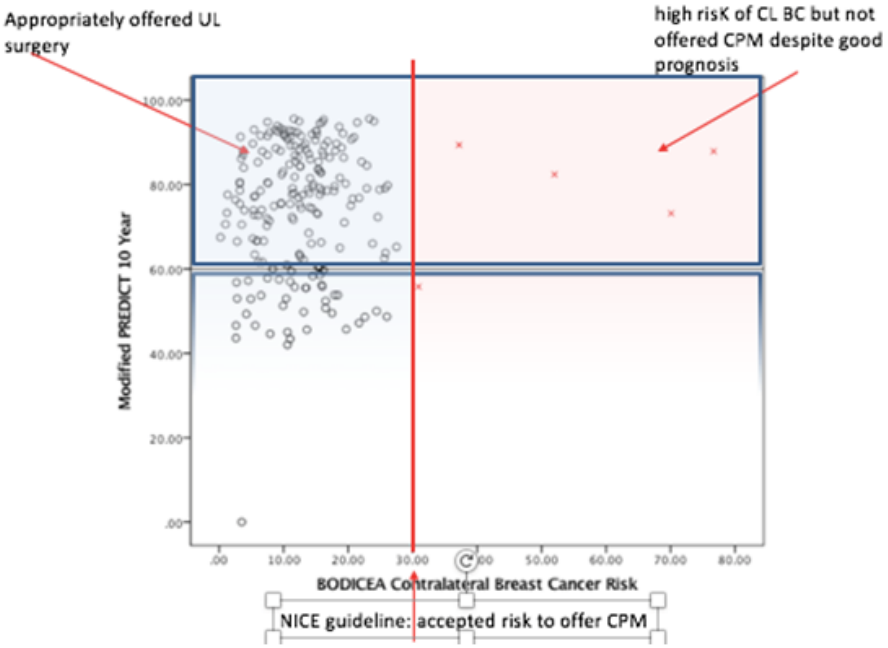
Methods: Based on age, diagnostic mode and histopathological factors, PREDICT scores were retrospectively calculated for n=257/293 consecutive patients undergoing mastectomy and autologous reconstruction. Patients undergoing bilateral mastectomy for bilateral disease were excluded. Modified PREDICT scores were subsequently calculated based on the treatment individual patients received. Family history and tumor biology were used to calculate the contralateral BC risk using the web-based BODICEA risk calculator. Data were analyzed using SPSS (v20) to correlate modified PREDICT versus BODICEA scores to identify the proportion of patients with a contralateral risk of >30% and 5-year survival of >80% (i.e., UK National Institute of Clinical Excellence criteria for offering CPM).

Results: Of 293 consecutive patients, 250 had unilateral mastectomy and autologous reconstruction, 43 had bilateral surgery. Of the total, n=20 patients had a contralateral risk score of >30% and of those who underwent unilateral surgery (n=250), only n=5 patients had a contralateral score of >30% and would have fulfilled NICE criteria for CPM. There was no correlation between BODICEA and PREDICT scores (5/10 years p=0.735). Interestingly, of patients undergoing bilateral surgery (n=43), n=5 was for bilateral disease, n=15 had BRCA/P53 mutation, n=2 had BODICEA score of >30% but no gene testing, and n=21 had a BODICEA score of <30% [mean BODICEA score=14.3%, range 6.2-23.5%]. The majority of CPM was performed at patient request with limited justification (n=6), non-significant family history of BC or variant of unknown significance on testing in n=6 and the remainder were patients with local recurrence or previous contralateral disease (n=8).

Conclusions: In the absence of prospective contralateral risk scoring, certain patients with low risk of contralateral disease are undergoing CPM and reconstruction, and a smaller proportion of patients with good prognoses and substantial contralateral risk are not offered CPM. Prospective calculation of contralateral risk and predicted survival could improve decision-making in patients undergoing CPM. Further work is required to develop a quick and convenient surrogate score that can be calculated in clinic, in the absence of the final histology to aid decision-making.

Figure: Scatter plot showing BOADICEA score of CL BC risk vs. 10 year modified PREDICT scores for patients who underwent CPM (top) and ULM (bottom)





404284 - Multi-gene panel testing increases yield of surgically actionable results among breast cancer patients

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Background/Objective: Genetic testing for BRCA1/2 is widely accepted following a breast cancer diagnosis to assist with impending surgical management decisions. With multigene panel tests (MGPT) becoming more commonplace, National Comprehensive Cancer Network (NCCN) guidelines have evolved to include surgical management considerations for additional breast cancer susceptibility genes due to significantly increased cancer risks. This study aims to determine the likelihood of a surgically actionable result based on NCCN guidelines beyond BRCA1/2 when using a breast cancer-specific MGPT at 1 commercial laboratory.

Methods: We performed a retrospective analysis in our cohort of female patients with a breast cancer diagnosis who had testing with a 17-gene breast cancer-specific MGPT (ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, MRE11A, MUTYH, NBN, NF1, PALB2, PTEN, RAD50, RAD51C, RAD51D, TP53) between June 2012 and December 2016. The frequency of likely pathogenic and pathogenic variants was calculated for each gene. NCCN guidelines (Version 1.2018) were used to determine surgically-actionable findings for breast and other cancers.

Results: Of 29,568 breast cancer cases tested, 9.14% (n=2702) were identified to carry a likely pathogenic or pathogenic variant (excluding MUTYH carriers). There were 2.69% (n=794) of patients who were positive for either BRCA1 or BRCA2, and 1908 patients (6.45%) tested positive for mutation(s) in genes beyond BRCA1/2. Based on these results, risk-reducing mastectomy (RRM) could be considered for an additional 83 patients based on identification of a mutation in PTEN or TP53 (3.07% of mutation carriers). As indicated by NCCN, RRM could be considered for an additional 1465 patients (54.22% of mutation carriers) with mutations in ATM, PALB2, CHEK2, CDH1, NF1 or NBN in the context of a significant family history of breast cancer. Importantly, an additional 194 patients (7.18% of mutation carriers) had a surgically actionable finding for sites beyond breast, including consideration of risk-reducing Salpingo-Oophorectomy (n=159, BRIP1, RAD51C, RAD51D), gastrectomy (n=18, CDH1), and hysterectomy (n=17, PTEN).

Conclusions: Expanding testing beyond BRCA1/2 for breast cancer patients with clinical histories suggestive of inherited cancer predisposition increased the identification of surgically actionable mutations for breast and other cancers. These findings highlight MGPT as an efficient and effective approach to identify more patients for whom discussion of cancer risk management options is warranted, including the risks and benefits of various cancer prevention options.

403820 - Impact of screening mammography interval on stage and treatment in women diagnosed with breast cancer

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Background/Objective: Screening mammography has shown to significantly reduce breast cancer mortality(1-3). After the increase in screening mammography uptake in the late 20th century, compliance plateaued in the past decade: in 2015, only 65% of women over 40 had a mammogram within the prior 2 years (4). The age to start screening has also been controversial citing risk of overtreatment and false positive findings outweighing benefit in younger age groups. However, studies focusing only on reduction in mortality from screening mammography do not take into account other potential benefits of early detection such as the minimization of medical and surgical treatment patients need or receive to optimize survival rates. We aimed to evaluate the influence of screening mammography on subsequent treatment in women diagnosed with breast cancer.

Methods: Patients > 40 years old diagnosed with breast cancer from Sept 2008 to May 2016 at a single institution were included. They were divided into 2 groups according to the time interval between breast cancer diagnosis and prior screening: patients with screening within 24 months of diagnosis (1-24 months) and patients with screening 25+ months including those who never had a mammogram. Logistic regression models were used to assess the association between the two groups and clinical factors including receipt of chemotherapy, node status, tumor size, and receipt of mastectomy or axillary dissection (AD). Analyses of lymph node status and tumor size were stratified by whether a patient underwent upfront surgery or neoadjuvant chemotherapy. Subgroup analysis was then performed based on age group at diagnosis: 40-49 years, 50-59 years, 60-69 years, and ≥70 years.

Results: 1125 breast cancer patients with information on screening interval were included. Of these, 819 (73%) had screening 1-24 months prior to diagnosis, and 306 (27%) had screening 25+ months including 65 (6%) who never had a mammogram. Overall, those screened 25+ months were significantly more likely to receive chemotherapy (OR (95% Confidence Interval - CI): 1.51, (1.14, 1.99), p=0.0040), undergo mastectomy (OR (95% CI): 1.32 (1.00, 1.72), p=0.0465), and require AD (OR (95% CI): 1.66 (1.17, 2.35), p=0.0045) than patients who underwent screening 1-24 months prior to diagnosis. Among those who underwent upfront surgery (1045/1125, 93%), patients with screening 1-24 months had significantly smaller tumors than those with mammogram 25+ months (mean: 12.5 mm vs 14.5 mm, p=0.0225), with the subgroup never screened having the largest mean tumor size of 20 mm. On subgroup analysis by age groups, patients aged 40-49 years who never had a mammogram (n=29) were significantly more likely to require chemotherapy (OR(95%CI): 2.52(1.10,5.77), p=0.0287), have positive nodes (OR(95%CI): 4.52(1.64,12.42),p=0.0035), have larger tumors (mean 23 mm vs 13 mm,p=0.0417), undergo mastectomy (OR(95%CI): 3.44 (1.41,8.43),p=0.0068), and undergo AD (OR(95%CI):4.64(2.05,10.52), p=0.0002) compared to those screened within 24 months (n=197). These effects were seen to varying degrees across other age groups as well.

Conclusions: Breast cancer screening is associated with decreased stage at diagnosis, as well as decreased receipt of more extensive medical and surgical treatment. This was evident in the 40-49 year age group as well, where controversy still exists on whether screening is even necessary. Decision making regarding the use of screening mammography should not only take into account survival advantage, but other endpoints including potential for less aggressive treatment.

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398829 - A potential role for peripheral natural killer (NK) cell activity induced by pre-operative chemotherapy in breast cancer patients

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Background/Objective: Tumor-infiltrating lymphocytes are an important predictive factor for achieving complete pathologic response (pCR) after neoadjuvant chemotherapy in human epidermal growth factor receptor 2 (HER2)-positive and triple-negative (TN) breast cancer patients. NK cells can directly recognize and kill cancer cells according to innate immunity, and lower levels of peripheral NK cells are associated with an increased risk of death from breast cancer. We assessed peripheral NK cell activity for potential associations with pathologic therapeutic response and cancer subtype following pre-operative chemotherapy in breast cancer patients.

Methods: Thirty-nine patients with Stage II-IV breast cancer received pre-operative chemotherapy from July 2012 to August 2017 in our clinic as indicated: Nab-paclitaxel (nab-PTX)/fluorouracil/ epirubicin/cyclophosphamide (FEC), 9 cases; nab-PTX/FEC/trastuzumab (HER), 2 cases; FEC/nab-PTX, 7 cases; FEC/nab-PTX/HER, 9 cases; docetaxel (DTX)/FEC, 3 cases; FEC/DTX, 2 cases; FEC/DTX/HER, 1 case; FEC/PTX, 2 cases; EC/nab-PTX, 1 case; EC/PTX, 1 case; EC/DTX, 2 cases. By subtype: Liminal-A (L-A), 5 cases; L-B, 18 cases; L-HER2, 9 cases; HER2, 3 cases; TN, 4 cases. Peripheral NK cell activity was measured by flow cytometry using blood samples from the patients before and after chemotherapy.

Results: Increased NK cell activity was observed in 24 patients, but was decreased in 15 patients after chemotherapy, as compared to the results before chemotherapy (p=0.0005). Six factors were recorded and evaluated in univariate analyses: Median age, stage, Grade 2 response (marked changes in 2/3 of the cancer cells), disappearance of axillar lymph node metastasis (Ax+), nuclear grade, and Ki-67-positivity. Increased NK cell activity following pre-operative chemotherapy was found to be significantly associated with disappearance of Ax+ (p=0.0235). Based on univariate analysis, 2 key factors, Grade 2 response and disappearance of Ax+, involved in pathologic therapeutic response to pre-operative chemotherapy were further evaluated in a multivariate analysis. Increased NK cell activity was significantly associated with the disappearance of Ax+ (odds ratio = 5.41, 95% confidence interval = 1.19-24.52, p=0.0283) (Table). Increased NK cell activity was not associated with any cancer subtype.

Conclusions: Increased peripheral NK cell activity induced by pre-operative chemotherapy was associated with disappearance of Ax+, suggesting that the activation of NK cell-mediated immune surveillance by pre-operative chemotherapy plays a key role in eradicating metastatic tumors in breast cancer patients irrespective of subtype. The mechanism for the peripheral NK cell activation that leads

to disappearance of Ax+ following pre-operative chemotherapy needs to be elucidated and is currently under investigation.

Table: Univariate and multivariante analyses of changes in peripheral NK cell activity and clinicopathologic factors in 39 breast cancer patients receiving pre-operative chemotherapy

	Univariate analysis			Multivariate analysis		
Variable	Changes of NK cell activity (%)		P-value	OR	95% CI	P-value
	Increased NK cell activity (n=24)	Decreased NK cell activity (n=15)				
Pre-chemo (mean±SE)	25.0 ± 2.5	34.0 ± 4.4	0.0638*			
Post-chemo (mean±SE)	39.7 ± 2.6	22.6 ± 3.8	0.0005*			
Median age, y (range)	51.5 (27–67)	59.0 (38–69)	0.1330+			
Stage						
II	10	8				
III	10	6	0.2819+			
IV	4	1				
≥ Grade 2 response	12/24 (50.0%)	6/15 (40.0%)	0.5422**	—	—	—
Disappearance of Ax+	13/19 (68.4%)	4/14 (28.5%)	0.0235**	5.41	1.19–24.52	0.0283
Nuclear grade						
1	2	0				
2	2	3	0.8967+			
3	20	12				
Ki-67-positivity (%)						
< 15	7	1				
15–35	4	5	0.4014+			
> 35	13	9				

Chemo, chemotherapy; SE, standard error; Ax+, axillary lymph node metastasis; *, Student's *t*-test; +, Mann-Whitney test; **, Chi-Square test. OR, odds ratio; CI, confidence interval

403876 - Phase II open-label trial investigating percutaneous laser ablation for treatment of early-stage breast cancer: MRI, pathology, and outcome correlations

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Background/Objective: An IRB-approved, multicenter clinical trial (NCT01478438) was designed to determine the efficacy and outcome of percutaneous laser ablation (PLA) in treatment of invasive ductal breast carcinoma. Secondarily, post-ablation MRI was evaluated as an alternative to surgical pathology in predicting residual post-ablation invasive cancer and ductal carcinoma in situ.

Methods: Patients with a single focus of biopsy-proven infiltrating ductal carcinoma measuring 20 mm or less by pre-ablation MRI were treated with image-guided PLA using an 805 nominal nanometer

wavelength laser diode source. Thermal ablation was documented with thermal sensors placed at the tumor periphery, measuring predefined temperature levels indicating complete ablation. Patients were evaluated at 4 weeks post-ablation with mammogram, ultrasound and MRI, after which they underwent surgical resection. Cell viability criteria were applied to pathology specimens by evaluation of pre- and post-ablation H&E, CK 8/18, Ki-67 and estrogen receptor (ER) staining patterns. Complete tumor ablation was defined pathologically as no residual viable breast cancer cells at the targeted ablation site. Patients were seen in follow up at designated intervals.

Results: Sixty-one patients (60 evaluable) (ages 42-77, mean age 64 years) treated with PLA were reported in this series (June 2012 - May 2015). Ablation was considered complete by the treating physician in all cases. The mean tumor size was 11.3 mm. The mean laser time was 15.8 minutes. There were no serious adverse events. Post-ablation cell viability was determined by MRI and changes in H&E, CK 8/18, Ki-67 and ER staining patterns. Complete tumor ablation was confirmed in 51 patients (85.0 %) by both post-ablation MRI and pathologic analysis. Nine patients (15.0%) were found to have residual cancer by both post-ablation MRI and pathologic analysis. A post-ablation discordance between MRI and pathology was found in evaluation of 8 patients, with 4 patients (6.7%) being false positive and 4 patients (6.7%) being false negative. The negative predictive value (NPV) of MRI for all patients was 92.2% (95% CI 71.9 91.9). Forty-six of the 47 patients (97.9%) with pre-ablation tumors 15mm or less were completely ablated using PLA. The NPV of MRI for cancers 15mm or less was 97.7% (95% CI 86.2 99.9). Good to excellent patient satisfaction with cosmesis was reported by 56 of 58 patients (96.6%) 4 weeks following PLA, with patients reporting higher functional and lower symptomatic scores than the EORTC mean for breast surgery patients completing the EORTC QLQ-C30 and BR23 questionnaires. Two recurrences were noted in follow-up (mean follow-up: 43 months). Both patients had complete ablations documented by post-ablation MRI findings and pathologic analysis. One patient (8.5 mm ER positive tumor) declined any additional treatment following PLA and excision. At 3 years, a recurrence was documented 25 mm from the original PLA site. A second patient (11.5 mm triple negative tumor) was treated with chemotherapy plus whole-breast radiation following PLA and resection. A skin recurrence was noted in the lumpectomy incision at 3-year follow-up. There were no PLA-associated sequelae.

Conclusions: Percutaneous laser ablation is a possible alternative to traditional breast cancer conservation surgery for treatment of early-stage invasive breast cancer. A strong correlation exists between post-ablation MRI findings and pathologic alterations in H&E, CK 8/18, Ki-67, and ER staining. Clinical trials which evaluate PLA efficacy and outcome in the absence of subsequent surgical resection are necessary to further determine the potential of this breast cancer therapy.

403423 - 'Driving' rates down: A population-based evaluation of travel time to radiation center on the use of mastectomy for breast cancer

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University of Calgary, Calgary, AB, Canada

Background/Objective: Higher-than-national-average mastectomy rates have been observed in Alberta, Canada. Driving time to radiation centers has been shown to be associated with mastectomy use. To improve access to radiation therapy, several new radiation centers opened in Alberta after 2010. However, the impact of these new centers on mastectomy rates is unknown. Therefore, we sought to

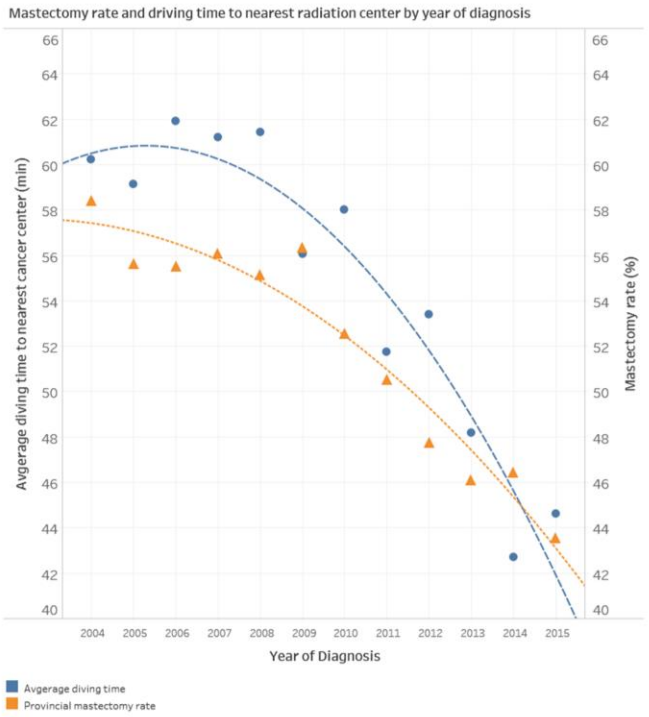
better understand the effect of opening new radiation centers on mastectomy rates for breast cancer patients under a single-payer universal health care system.

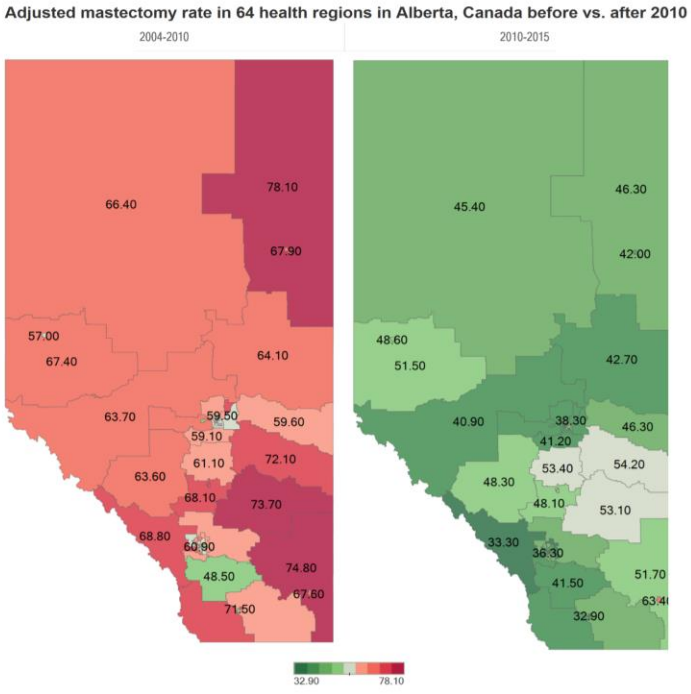
Methods: In Alberta, Canada, all incident breast cancer patients (excluded Stage IV) who underwent surgery from 2004 through 2015 were identified from the Alberta Cancer Registry (ACR). Individual patient data were obtained from the ACR and other administrative data sources. Driving times to the nearest radiation center were derived through Google API (Application Programming Interfaces). Mastectomy rates for 64 pre-defined health areas in the province over the study timeframe were calculated after adjusting for patient and tumor factors. Mastectomy rates were compared before and after 2010. Logistic regression was performed to determine the association between driving time from patient residence to nearest radiation center and mastectomy in entire cohort and subgroups (including age, TNM stage, radiation center, and adjuvant treatment subgroups).

Results: We identified 21,872 incident breast cancer patients who underwent surgery. The proportion of patients with driving time to the nearest radiation center >2 hours significantly decreased after the opening of the new radiation centers (17.5% vs. 9.0%, $p<0.0001$). The provincial adjusted mastectomy rate decreased from 53.4% before 2010 to 47.0% after 2010 ($p<0.0001$). The adjusted mastectomy rates among the 64 areas significantly decreased from 48.0-78.1% before 2010 and 32.9-63.4% after 2010, respectively. Factors associated with mastectomy included age ($p<0.0001$), higher Charlson co-morbidity index ($p<0.0001$), lobular histology ($p<0.0001$), higher T stage ($p<0.0001$), lymph node involvement ($p<0.0001$), higher tumor grade ($p<0.0001$), hormone status ($p<0.0001$), institute type ($p=0.005$), year of diagnosis ($p<0.0001$), and greater driving time to nearest radiation center ($p<0.0001$). The effect of driving time to nearest radiation center on mastectomy was consistent across subgroups.

Conclusions: Opening of radiation centers reduced driving time to the nearest cancer center for women with breast cancer and was associated with a reduction of rates and geographic variation of mastectomy in our province. This implied that distance to special care did affect patients treatment choice, and modifiable system factors such as driving time to radiation center should be addressed to provide optimal care for women with breast cancer.

Figure: Mastectomy rate and driving time to nearest radiation center





404003 - Impact of breast reconstruction on time to definitive surgical treatment, adjuvant therapy, and breast cancer outcomes

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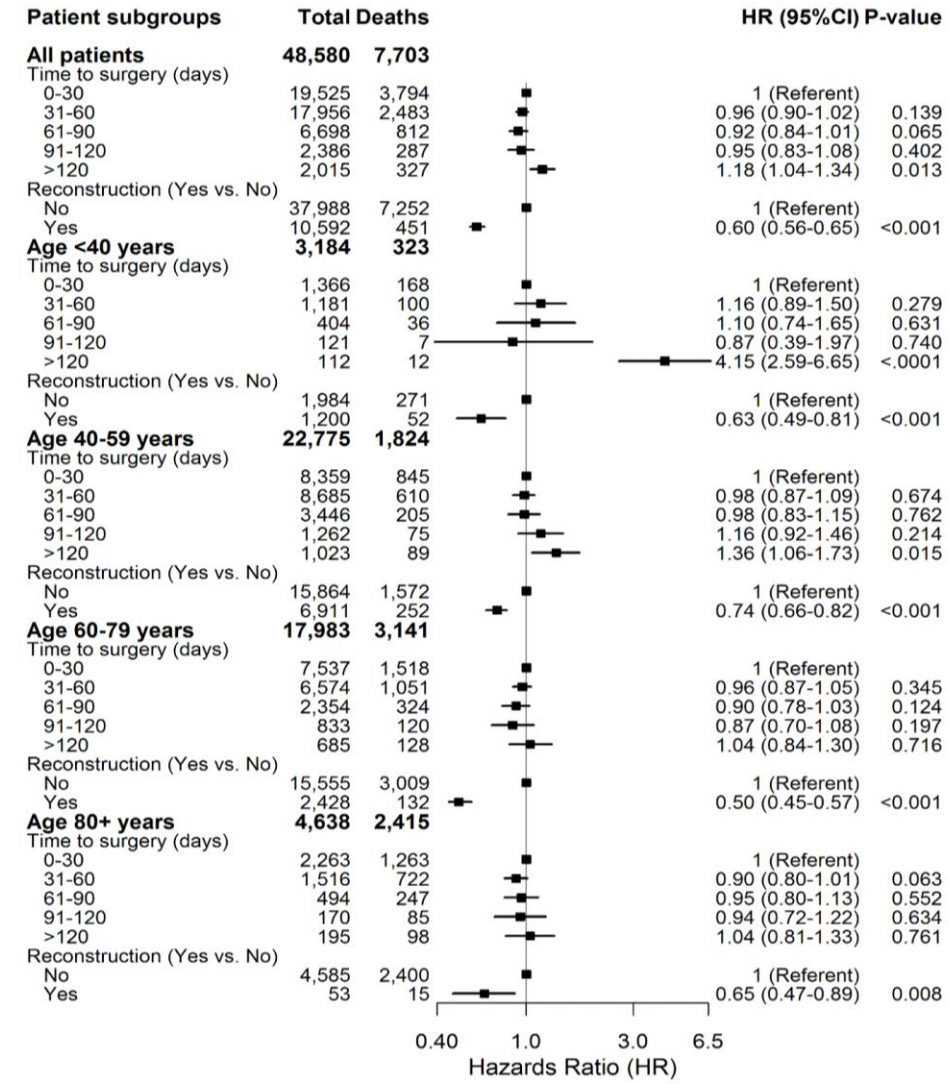
Background/Objective: Recent studies have shown that the time interval between breast cancer diagnosis and surgery is rising and that incremental delays in surgery and adjuvant treatment are associated with decreased survival. The added complexity of immediate breast reconstruction (IBR) has been suggested as a causative factor in prolonged time to treatment. This study aims to investigate time to treatment and survival outcomes in breast cancer patients undergoing IBR.

Methods: We performed a retrospective cohort review of women diagnosed with Stage 0-III breast cancer undergoing mastectomy with and without IBR from 2004-2014 in the California Cancer Registry. Time to treatment (surgery, systemic therapy excluding neoadjuvant chemotherapy, and radiation) by reconstruction status and Cox proportional overall mortality hazards ratios (HR) were assessed. Propensity score matching to diminish selection bias adjusted for age, race/ethnicity, socioeconomic status (SES), marital status, stage, grade, hormone receptor status, Commission on Cancer (CoC) accreditation, co-morbidity, receipt of chemotherapy, hormone therapy, or radiation therapy, and removal of contralateral uninvolved breast. Subgroup analyses were conducted within age group strata (<40, 40-59, 60-79, and 80+ years) to minimize the impact of age at diagnosis on survival findings.

Results: Of 56,782 patients, 13,738 (24.2%) underwent IBR with median follow up 68.8 months. The mean (SD) age of those with IBR was 51.4 years (0.4) and without IBR was 61.0 years (SD 14.1). Median time between diagnosis and surgery was increased for patients with IBR compared to those without (49 (interquartile range (IQR) 34-73) vs. 35 (IQR 21-56) days; p<0.001). The mean time from diagnosis to definitive surgery was increased by 34% with IBR (vs. without) (95% CI 1.32-1.36) and by 5% in patients with > 1 co-morbidities (vs. none) (95%CI 1.03-1.06). Compared to non-Hispanic white patients, mean time from diagnosis to surgery was prolonged by 11% for Hispanic (95% CI 1.09-1.13) and by 26% for non-Hispanic black (95% CI 1.22-1.30) patients, and by 14% with age 40-59 years (95% CI 1.11-1.18) compared to age <40 years. The mean time from diagnosis to surgery was decreased by 17% with Stage II (95% CI 0.82-0.84) and 24% with Stage III (95% CI 0.74-0.77) as compared to Stage I, and by 7% in hospitals without CoC accreditation (vs. with CoC accreditation) (95% CI 0.91-0.94). IBR (with vs. without) did not affect the median interval from surgery to adjuvant chemotherapy (41 (IQR 30-55) vs. 40 (IQR 30-54) days; p=0.2) or surgery to adjuvant radiation (175 (IQR 138-210) vs. 174 (IQR 123-216) days; p=0.6), but slightly prolonged time to endocrine therapy (71 (IQR 30-166) vs. 66 (IQR 27-164) days; p=0.01). Adjusted overall mortality HR demonstrated lower survival when time to surgery exceeded 120 days [HR 1.18 (1.04-1.34)] and improved survival with IBR [HR 0.60 (0.56-0.65)]. In the subgroup survival analyses, the benefit of reconstruction persisted for all age groups, while surgical delay did not affect those older than 60 years.

Conclusions: While IBR is associated with prolonged time to definitive surgery, initiation of post-operative adjuvant therapy is not substantially affected by IBR. Patients and providers should be reassured that surgical delays due to coordinating IBR do not affect survival outcomes, but should attempt to address other risk factors associated with delays to ensure surgery is performed within 4 months of diagnosis.

Figure: Forest plot for adjusted overall mortality hazards ratios among patients with Stage I-III breast cancer



Propensity score adjusted for race/ethnicity, socioeconomic status, marital status, stage, grade, estrogen receptor, progesterone receptor, laterality, Commission on Cancer accreditation, comorbidity, receipt of chemotherapy, hormone therapy or radiation therapy, and contralateral prophylactic mastectomy.

403817 - Evaluation of Oncotype DX as a predictor of nodal burden in clinically node negative breast cancer patients

Sarah Tevis, Isabelle Bedrosian, Roland Bassett, Elizabeth FitzSullivan, Carlos Barcenas, Funda Meric-Bernstam, Kelly Hunt, Abigail Caudle, Henry Kuerer, Elizabeth Mittendorf, Alastair Thompson, Mediget Teshome, Anthony Lucci, Sarah DeSnyder, Shon Black, Ko Un Park, Rosa Hwang

MD Anderson Cancer Center, Houston, TX

Background/Objective: Oncotype DX 21-gene recurrence score (RS) has been found to predict distant recurrence and disease-free survival in patients with node-negative, estrogen receptor-positive breast cancer. Although an association between RS and locoregional recurrence (LRR) has also been reported, whether RS is useful to guide locoregional therapy decisions is unclear. We sought to evaluate the relationship between RS and lymph node burden in women with clinically node-negative breast cancer.

Methods: Patients with invasive breast cancer who underwent sentinel lymph node dissection (SLND) and with an Oncotype DX RS were identified from a retrospective review of a prospectively maintained comprehensive academic cancer center database from 2010 to 2015. Patients were excluded if they were clinically or biopsy-proven node-positive or if they underwent neoadjuvant chemotherapy. RS was classified as low risk (<18), intermediate risk (18-30), or high risk (>30). We evaluated the association between RS and the presence and number of pathologically positive nodes, the presence of extranodal extension, maximum lymph node metastasis size, and disease recurrence. Statistical analyses were performed in R version 3.4.0 with p value <0.05 considered significant.

Results: Of the 1,121 patients who met inclusion criteria, 168 (15%) had a positive SLN. Of the patients with a positive SLN, 84 underwent completion axillary lymph node dissection, and the remaining 84 patients had 1-2 positive SLNs and did not undergo further axillary surgery. RS was low risk in 58.5% of patients, intermediate risk in 32.6%, and high risk in 8.9%. As demonstrated in the Table, RS was not associated with positive SLN, number of positive lymph nodes, maximum lymph node metastasis size, or extranodal extension. The median follow-up period of the study population was 23 months. High-risk RS was significantly associated with distant recurrence (p=0.0015), but not significantly associated with locoregional recurrence (p=0.07).

Conclusions: Oncotype DX RS is not associated with a positive SLN or nodal burden in women with clinically node-negative breast cancer. These results suggest that RS is not useful to guide decisions regarding axillary surgery for these patients.

Table: Lymph node status and Oncotype DX recurrence score

	No. of patients	RS < 18	RS 18-30	RS >30	p-value
Total (%)	1121	656 (58.5)	365 (32.6)	100 (8.9)	n/a
SLN status					
Positive (%)	168 (15.0)	98 (58.3)	61 (36.3)	9 (5.4)	
Negative (%)	953 (85.0)	558 (58.6)	304 (31.9)	91 (9.5)	0.12
Number of positive LN (mean, range)	168	1.3 (1-7)	1.3 (1-3)	1.4 (1-3)	0.36
Maximum LN metastasis size (mean)	168	3.3 mm	3.3 mm	4.5 mm	0.97
Presence of ENE (% of + LNs)	26	18 (69.2)	7 (26.9)	1 (3.8)	0.53

RS, Oncotype DX recurrence score; LN, lymph node; ENE, extranodal extension

403976 - Deep learning through convolutional neural networks using a breast MRI tumor dataset can predict axillary neoadjuvant chemotherapy response

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Background/Objective: We hypothesize that convolutional neural networks (CNN) can be used to predict axillary response to neoadjuvant chemotherapy (NAC) using a breast MRI tumor dataset prior to initiation of chemotherapy.

Methods: An IRB-approved, retrospective review of our database from 1/2009 to 6/2016 identified 127 locally advanced breast cancer patients who: 1) underwent breast MRI prior to the initiation of NAC; 2) successfully completed Adriamycin/Taxane-based NAC; and 3) underwent surgery including sentinel lymph node evaluation/ axillary lymph node dissection with available final surgical pathology data. Patients were classified into 2 groups based on their NAC response confirmed on final surgical pathology: pathologic complete response (pCR) of the axilla (group 1), and non-pCR of the axilla (group 2). For deep learning, cases were randomly separated into a training set [80%] and test set [20%]. For each breast MRI, tumor was identified on first T1 post contrast dynamic images and underwent 3D segmentation using an open source software platform 3D Slicer. A 32x32 patch was then extracted from the center slice of the segmented tumor data. A CNN was designed for neoadjuvant class prediction based on each of these cropped images. In brief, CNN consisted of 4 convolution layers, max-pooling layers, and dropout of 0.25 after each convolution layer. For each breast tumor, a final softmax score threshold of 0.5 was used for 2 class classification. Two class neoadjuvant prediction model was evaluated. Code was implemented in open source software Keras with TensorFlow on a Linux workstation with NVIDIA GTX 1070 Pascal GPU.

Results: Two class neoadjuvant prediction model of the axilla was evaluated for the 2 patient groups. Group 1 consisted of 49 patients with pCR of the axilla. Group 2 consisted of 78 patients with non-pCR of the axilla. The CNN achieved an overall accuracy of 83% with sensitivity of 93% and specificity of 77%. Area under the ROC curve (0.93).

Conclusions: Current deep CNN architectures can be successfully trained with relatively small-sized medical data sets to predict NAC treatment response of the axilla from breast MRI data obtained prior to initiation of chemotherapy. Larger data set will likely improve our prediction model.

404081 - Extent of axillary surgery in women with Stage IV breast cancer

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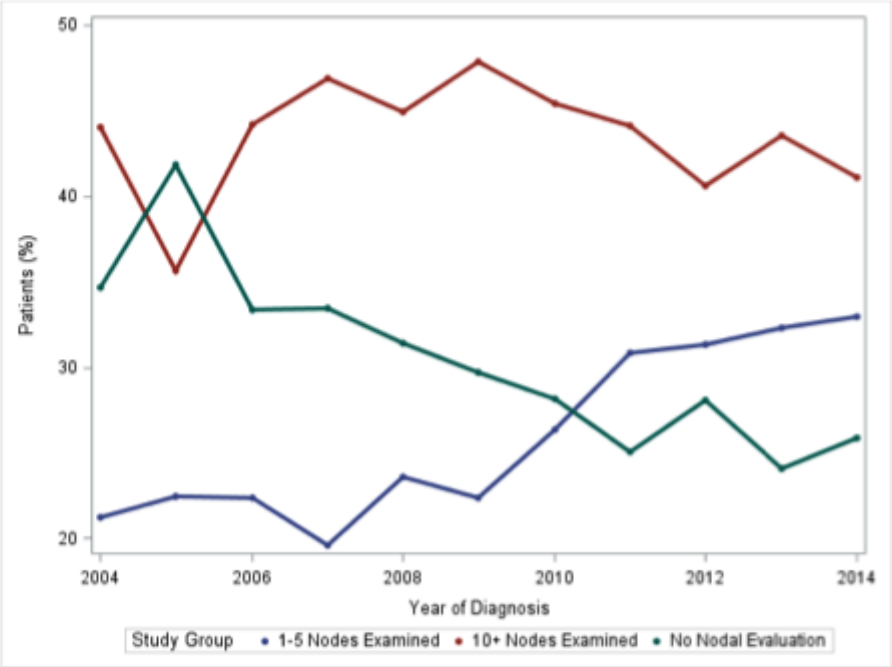
Background/Objective: Surgical resection of the primary tumor remains controversial among women with Stage IV breast cancer, and little is known about appropriate management of the axilla. We investigated contemporary national practice patterns and the association of axillary surgery with survival among women with de novo Stage IV breast cancer.

Methods: Using the National Cancer Database from 2004-2014, we identified female patients with de novo Stage IV breast cancer who underwent surgical resection of the primary breast cancer following receipt of chemotherapy, endocrine, and/or radiation therapy. We compared women based on number of lymph nodes removed. Sentinel lymph node biopsy (SLNB) was defined as removal of 1-5 nodes and axillary lymph node dissection (ALND) as removal of 10 or more nodes. Unadjusted median overall survival (OS) was estimated using the Kaplan-Meier method and compared between groups using the log-rank test. A Cox Proportional Hazards Model was used to estimate effect of nodal evaluation on OS after adjustment for patient demographic, clinical, and treatment-related covariates.

Results: There were 8,165 subjects identified (median age=55, IQR 47-64); 27% (2,201) who underwent SLNB, 43.7% (3,572) who underwent ALND, and 29.3% (2,392) who did not undergo axillary surgery. Use of SLNB increased over time from 21.2% in 2004 to 33% in 2014, while rates of ALND remained constant across the study period (44% in 2004 vs. 41.1% in 2014) (Figure). The majority of patients were ER+ (n=5,488, 67.2%), PR+ (n=4,327, 53%) or HER2- (n=3,089, 66.3%); presented with visceral, brain, or lung metastasis (76%); and received a mastectomy (n=6,677, 81.8%). The majority received chemotherapy (n=6,976, 85.4%) and radiation therapy (n=4,627, 56.7%) as part of their initial treatment. Of those with ER+/PR+ disease, the majority received endocrine therapy (n=4,293, 76.3%). Unadjusted median OS was similar for those undergoing SLNB (52.1 months; 95% CI 48.4-56.3) and ALND (52.9 months; 95% CI 49.9-55.2), and OS in both groups was better than in those undergoing no axillary surgery (45.3 months; 95% CI 42.6-47.4, log-rank p<0.001). After adjustment for known covariates including surgery type, there was a statistically significant improvement in OS among patients undergoing ALND compared to no axillary surgery (HR 0.89; 95% CI 0.82-0.97, p=0.01) but no improvement in survival for those undergoing SLNB when compared to no axillary surgery (HR 0.92; 95% CI 0.83-1.01, p<0.08) or ALND (HR 1.03; 95% CI 0.94-1.13).

Conclusions: Surgical resection of the primary tumor is associated with high rates of axillary surgery among women with Stage IV breast cancer, and we observed a small but significant improvement in survival among those undergoing ALND, but not SLNB. Further, axillary staging with SLNB adds little to prognosis, and can arguably be avoided in women undergoing surgery with Stage IV disease.

Figure:



Nodal Evaluation	Year of Diagnosis										
	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
1-5 Nodes	82 (21.2%)	94 (22.5%)	104 (22.4%)	120 (19.6%)	178 (23.6%)	195 (22.4%)	262 (26.4%)	298 (30.8%)	317 (31.3%)	299 (32.3%)	252 (33%)
10+ Nodes	170 (44%)	149 (35.6%)	205 (44.2%)	287 (46.9%)	339 (45%)	417 (47.9%)	451 (45.4%)	426 (44.1%)	411 (40.6%)	403 (43.6%)	314 (41.1%)
None	134 (34.7%)	175 (41.9%)	155 (33.4%)	205 (33.5%)	237 (31.4%)	259 (29.7%)	280 (28.2%)	242 (25.1%)	284 (28.1%)	223 (24.1%)	198 (25.9%)

403837 - Low mutant allele tumor heterogeneity (MATH) is associated with activation of the immune response and improved survival of breast cancer patients

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Background/Objective: Tumor heterogeneity arises from differences among cancer cells that are inherited during cell division. It implies the coexistence of sub-populations of cancer cells that differ in their genetic, phenotypic, or behavioral characteristics. The makeup of cancer cells, within the same tumor or between a given primary tumor and its metastasis, can be diverse. Several studies have documented a role for intra-tumor heterogeneity in driving tumor progression and treatment resistance in breast cancer. Studies have used mutant-allele tumor heterogeneity (MATH) as a quantitative measure of intra-tumor heterogeneity. MATH is based on differences among mutated loci in the mutant-allele fractions determined by gene sequencing of tumor DNA. Elevated MATH has been associated with worse survival in multiple cancers, including breast. However, genetic heterogeneity is not well examined. In this study, we aim to correlate tumor heterogeneity to immune gene signatures. We hypothesize that low MATH is associated with immune responsiveness and improved survival in breast cancer.

Methods: Genomic data, including gene mutations, was collected from breast cancer patients in the Cancer Genome Atlas (TCGA) and used to calculate MATH scores. The patients were divided into low and high MATH groups. MATH was then correlated with clinical characteristics, expression of immune response genes, and attraction of immune cells via CIBERSORT. The correlation between MATH and immune response gene expression was shown using box plots. Survival analysis was demonstrated using Kaplan Meir curves.

Results: Low MATH was associated with improved overall survival (OS) while high MATH demonstrated worse survival (n High=548, n Low=411; p=0.049). Subgroup analysis revealed that ER+ (n High=376, n Low=325; p=0.011) and non-triple-negative tumors (n High=435, n Low=361; p=0.01) with low MATH scores had better survival compared to other biomarker signatures of breast cancer. Although not significant, low MATH was associated with improved OS in luminal cancers (n High=125, n Low=150; p=0.083). Mutations generate antigens that can be recognized by the immune system. We found that low MATH was associated with the infiltration of anti-tumor CD8 ($p<0.013$) and CD4 T cells ($p<0.00024$), and less tumor promoting Tregs ($p<4e-04$). On the other hand, high MATH was associated with increased composition of Tregs ($p<4e-04$) and less CD8 ($p<0.013$) and CD4 T cells ($p<0.00024$). MATH is associated with the expression of tumor response genes. PD-L1, the ligand for Programmed death-1, is thought to play an important role in the antitumor immune response to breast cancer. We found that low MATH correlated to high PDL-1 expression ($p<0.0031$), providing the link between tumor heterogeneity and tumor biology.

Conclusions: By utilizing a large dataset with sufficient statistical power, we found that low MATH was associated with enhanced immunogenicity and is prognostic of improved survival in breast cancer. Our study offers a unique perspective by correlating tumor heterogeneity to immunity and genomics, which may have future implications for targeted therapies.

404183 - High androgen receptor expression tumors have worse overall survival in ER-positive breast cancer

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Background/Objective: Androgen receptor (AR) is a member of the steroid nuclear receptor family, which includes estrogen receptor (ER) and progesterone receptor (PR). In breast cancer, AR is expressed in 5080% of tumors, cross-talks with ER in luminal subtype, and is related to the resistance to hormonal therapies. High AR to ER ratio was reported to associate with a favorable prognosis. Multiple publications reported that high AR expression was associated with better survival in breast cancer; however, how they determined the level of expression were somewhat arbitrary. In fact, there is a criticism in the field that the data are incompatible between the studies due to lack of standardized staining method of AR. Indeed, some reported that high AR expressed tumors showed significantly shorter survival. Given this controversy, we investigated the association of AR expression and patient survival using gene expression data of the publicly available large cohort.

Methods: Clinical and RNA-sequence data were obtained from The Cancer Genome Atlas (TCGA) through cBioportal. High or low expression of AR was determined by automated scanning and selecting the threshold yielding the lowest p-value of overall survival (OS). Utilizing same cutoff point, survival analysis and Gene set enrichment analysis (GSEA) were conducted between AR high and low expression group in subgroup based on ER status.

Results: Among 1093 TCGA breast cancer cohort, there were 805 ER-positive patients (73.7%) and 237 ER-negative patient (21.7%). AR expression were significantly higher in ER-positive tumors compare to ER-negative tumors (0.16+1.08 vs -0.58+0.93, $p<0.001$). The largest difference in OS between AR expression high vs low was achieved at the cutoff point of 820 and 270 patients; however, the difference was not significant in whole cohort (5-year OS rates: 81.4% vs 83.5%, $p=0.085$). On the other hand, AR high expression group showed significantly worse OS in ER-positive patients (5-year OS rates: 84.2% vs 93.8%, $p=0.007$), whereas there was no significant difference in ER-negative patients (5-year OS rates: 74.8% vs 76.5%, $p=0.572$). To explore the underlying mechanism of worse survival in AR high expressed tumor in ER-positive patients, GSEA was conducted between AR high- and low-expression group in ER-positive patients. GSEA demonstrated that high expression of AR tumors enriched gene set that down-regulated in response to ultraviolet (UV) radiation (Normalized enrichment score; NES=1.98, $p=0.033$) and low AR expressed tumors enriched gene set that up-regulated in response to UV radiation (NES=-1.50, $p=0.027$). Our result may implicate that ER-positive breast cancer with AR high expression tumors have worse OS because they respond less to radiation therapy.

Conclusions: In conclusion, according to our analysis, high expression of AR showed worse OS in ER-positive, but not in ER-negative breast cancer patients. Our data implicated that response to radiation therapy may be one possible mechanism.

Poster Session I

Benign

402780 - Idiopathic granulomatous mastitis - A 10-year review on a region-wide, multi-center database

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Background/Objective: Idiopathic granulomatous mastitis (IGM) is an uncommon, chronic inflammatory breast disease with elusive etiology, simulating malignancy clinically and radiologically. Here we present our 10-year review on a region-wide multi-center IGM database.

Methods: A retrospective study was performed on a prospectively maintained database from 3 University affiliated hospitals in Hong Kong and Shenzhen, China. All patients with biopsy-proven IGM were included, while patients with positive tuberculosis growth were excluded. Disease recurrence rate and its prognosticators were evaluated.

Results: One hundred two patients were included between January 2007 to December 2017. Median age was 33 years old (Range 20 - 54). Most patients presented with painful mass (n=57), median size at presentation was 37mm (6 - 92mm). Sixty-three patients had bacterial culture performed on the pus sample, including 8 Corynebacterium Kroppenstedii and 4 diphtheroid species. Seventy-seven (75.5%) patients received conservative treatment with oral corticosteroid (+/- antibiotics) and drainage only, while 25 (24.5%) patients received breast lump excision after initial medical treatment. Twelve (11.8%) patients developed disease recurrence after median follow-up interval of 14 months (4 51 months). Univariate analysis revealed abscess on presentation, history of smoking, positive bacterial culture, and presence of Corynebacterium Kroppenstedii as significant prognosticators for disease recurrence. Subsequent multivariate analysis with logistic regression found that abscess on presentation, positive bacterial culture (any species), and isolation of Corynebacterium Kroppenstedii were independent risk factors for disease recurrence ($p<0.01$). Conclusion recurrent IGM is not uncommon. Infective presentation and isolation of bacterial growth were independent factors of recurrence.

Conclusions: Recurrent IGM is not uncommon. Infective presentation and isolation of bacterial growth were independent factors of recurrence.

404085 - Re-evaluating if observation continues to be the management of idiopathic granulomatous mastitis

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Background/Objective: Idiopathic granulomatous mastitis (IGM) is an uncommon disease process in the breast. Its presentation can mimic more serious conditions such as infection and breast cancer. Therefore, awareness of the condition is important for surgeons. Disfiguring surgical procedures, including bilateral mastectomies, have been used to treat this benign process. The current series is the largest IGM study to date.

Methods: Retrospective chart review of patients treated at a county safety-net hospital in Arizona was conducted. Cases were identified from January 2006 to August 2017. Sociodemographic information, clinical history, management, and outcomes were collected.

Results: There were 101 occurrences of IGM among 87 women. Eighty-one of 87 patients were Hispanic born outside the United States. The average age was 35 years (range 16-60 years). Nearly all patients 95% were parous with an average of 3 pregnancies. Ninety-one percent of patients presented with a palpable mass, and 2 presented with nipple retraction. Forty-four of the masses were at least 5cm at presentation. Three patients had known prolactinomas that were not being treated at the time of their IGM development, 8 patients were pregnant, and 2 patients were breast feeding. Early in the time studied, 5 patients underwent excision of the masses. The remaining 82 underwent planned observation after biopsy confirmation of the diagnosis. Five patients were lost to follow-up, 6 are recently diagnosed and improving, and the other 71 patients with IGM resolved spontaneously, including 11 recurrent episodes. One of the second episodes and 2 third episodes are under current observation. Surgical procedures in the group undergoing observation were restricted to core biopsy for diagnosis and drainage of fluid collections. Average time to resolution was 5.9 months (range 0-20).

Conclusions: IGM is a self-limited, benign condition that waxes and wanes and eventually resolves without resection. After diagnosis, medications are unnecessary, and operations can be limited to drainage procedures for fluid collections. Watchful waiting should be employed for these patients, and it should be explained that time to resolution varies.

404100 - Flat epithelial atypia: Are we being too aggressive?

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Background/Objective: Flat epithelial atypia (FEA) is a form of non-malignant atypical hyperplasia of the breast. Historically, patients with FEA on breast needle core biopsy have been advised to undergo open surgical excision to rule out an underlying in-situ or invasive carcinoma. According to the literature, the malignant upgrade rate of FEA diagnosed on core needle biopsy varies between 0-30%. Excision versus observation with radiological follow-up for these lesions remains controversial. Furthermore, the increasing use of vacuum-assisted biopsy is changing the way in which FEA is managed - with fewer patients being subjected to surgery in favor of larger-volume, image-guided biopsy and close radiological surveillance. Our study determined the local rate of malignant upgrade when pure FEA is seen on needle

core biopsy in Edmonton, Alberta. We also evaluated clinical features that may predict which patients are at higher risk of malignant upgrade.

Methods: This study was a retrospective review of a prospectively-collated provincial pathology database. One hundred one female patients were diagnosed with FEA alone on needle core biopsy between 2006-2016. Patients who had FEA present together with either in-situ or invasive carcinoma within the same biopsy cores were excluded. Along with patient demographics, the size of the lesion on pre-operative imaging, the method of extraction and the presence of co-existing benign and malignant pathology on final excision biopsy were analyzed.

Results: The local rate of malignant upgrade when pure FEA is diagnosed on a breast needle core biopsy is 13%. Age at time of diagnosis, size of original lesion on mammogram, presence of atypical ductal hyperplasia or atypical lobular hyperplasia on core needle biopsy, and the use of vacuum-assisted biopsy did not significantly correlate with malignant upgrade risk. In our center, the use of vacuum-assisted biopsy and radiological follow-up is overtaking the somewhat historical practice of open surgical excision when pure FEA is diagnosed on initial needle core biopsy. Of the 21 patients who had radiological follow-up, none have gone on to be diagnosed with either in-situ or invasive malignancy (average follow-up - 36 months).

Conclusions: This study shows that open surgical excision could be avoided in patients with pure FEA diagnosed on breast needle core biopsy, given the low malignant upgrade rate and the low risk of developing malignancy with radiological follow-up.

404205 - Treatment of breast asymmetry improves quality of life in adolescents and young women

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Background/Objective: Although common during puberty, persistent breast asymmetry beyond skeletal maturity of at least 1 cup-size difference is associated with poor self-esteem and emotional wellbeing. This longitudinal cohort study measures the impact of surgical correction of breast asymmetry on adolescent health-related quality of life.

Methods: The following validated surveys were administered to skeletally mature females with breast asymmetry undergoing surgical correction and comparably aged female controls: Short-Form 36v2 (SF-36), Rosenberg Self-Esteem Scale (RSES), and Eating-Attitudes Test-26 (EAT-26). Cohorts completed surveys at baseline and post-operatively/follow-up at 6 months, 1 year, 3 years, and 5 years.

Results: The mean ages of breast subjects (n=39) at surgery and controls (n=125) at baseline were 18.2 and 16.7 years, respectively. All asymmetry forms were included. The most frequent size difference was 2 cups, with a mean volume difference of 204 mL. At baseline, asymmetry subjects performed significantly worse than controls in 3 SF-36 domains (general health, social functioning, and role-emotional), and on the RSES and EAT-26. By the first post-operative year, asymmetry subjects experienced significant improvements in 2 SF-36 domains (social functioning and role emotional). These results largely did not vary by age, BMI category, and asymmetry severity. Within the first year, post-operative asymmetry patients performed equally to controls in all SF-36 domains, and on the RSES and EAT-26.

Conclusions: Surgical correction of asymmetry in adolescents and young women is associated with improved psychosocial wellbeing, unaffected by age, BMI category, or severity. Post-operatively, breast

patients performed comparably to unaffected controls. Providers should be aware of the psychosocial improvements surgery can provide adolescents with persistent, distressing asymmetry.

403174 - Surgical treatment of gynecomastia improves quality of life in adolescents and young men

Joseph Firriolo, Laura Nuzzi, Carolyn Pike, Brian Labow

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Background/Objective: Adolescent gynecomastia is associated with psychosocial deficits, and disordered eating thoughts and behaviors. This longitudinal cohort study measures the impact of surgical correction of gynecomastia on adolescent health-related quality of life.

Methods: The following validated surveys were administered to adolescents and young men with persistent gynecomastia (>3 years) undergoing surgical correction and male controls of comparable ages: Short-Form 36v2 (SF-36), Rosenberg Self-Esteem Scale (RSES), and Eating-Attitudes Test-26 (EAT-26). Cohorts completed surveys at baseline and post-operatively or at follow-up at 6 months, 1 year, 3 years, and 5 years.

Results: Forty-two gynecomastia and 68 control subjects were included in analyses. The majority of breast subjects had either grade II or III gynecomastia. Mean ages of breast subjects at surgery and controls at baseline were 17.0 and 18.7 years, respectively. Pre-operatively, gynecomastia subjects performed significantly worse than controls in 5 SF-36 domains (general health, vitality, social functioning, role-emotional, and mental health), and on the RSES and EAT-26. Gynecomastia patients demonstrated significant post-operative improvements in 5 SF-36 domains (physical functioning, role-physical, bodily pain, vitality, social functioning). These results largely did not differ by age and BMI category. Within 1 year, post-operative gynecomastia patients performed similarly to controls in all SF-36 domains and on the RSES.

Conclusions: Surgical correction of gynecomastia in adolescents and young men yielded measurable improvements in physical, social, and emotional wellbeing, largely unaffected by age and BMI category. Within 1 year, post-operative breast subjects performed comparably to unaffected controls. Providers should be aware of the physical and psychosocial improvements surgery can provide young men with gynecomastia. Concerns regarding patient age and BMI should not constitute absolute contraindications to surgery.

404363 - Management of breast cancer risk in patients with atypia: Variability in a single academic institution

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Background/Objective: Atypical (ductal or lobular) hyperplasia (AH) and lobular carcinoma in situ (LCIS) are associated with a 4- to 8-fold increase in breast cancer risk. It is unclear how often finding these lesions on workup of abnormal imaging influences patients breast cancer risk management. We examined the management of patients with AH/LCIS found on core needle biopsy (CNB) or excisional biopsy at a single academic institution.

Methods: The institutional pathology database was queried for pathology reports describing AH (ductal or lobular) or LCIS without cancer found on CNB or excisional biopsy from 2013-2016. A chart review was performed for patient demographics, imaging findings and management recommendations. Univariate and multivariate analysis examined factors predicting management changes.

Results: Fifty-eight women were identified with AH/LCIS. Fifty-seven were found on CNB of an imaging abnormality and 1 on excision of a radial scar found on screening mammogram. Excisional biopsy were performed in 81% (47/58), and 3 were found to have ductal carcinoma in situ (6.4%). Of the remaining 55 patients without cancer, 13 had LCIS, and 42 had AH. Most were evaluated in the breast surgery clinic 54/55 (98.2%). Breast cancer risk was calculated using a model in 47%. The average lifetime risk was 34.71±15.91%. Medical oncology (Med-onc) referral for consideration of antiestrogen therapy (AE) was recommended in 44 (80%) patients, and 25 (45%) saw a medical oncologist. Twenty-one of those patients (38%) were recommended to take AE. Of these, only 5 accepted (9.1%). Patients were more likely to be recommended AE by the Med-onc if they had a risk model calculated (mean lifetime risk 40.6% vs 28.3%, yes vs no, p=0.0419) and if they underwent surgical excision of their core needle biopsy (p=0.025). On multivariate analysis, the only predictor of acceptance of AE was the level of lifetime risk (51.0% vs 32.7%, yes vs no, p=0.0583). Twenty patients had a family history of breast cancer and 9/55 (16.4%) met criteria for genetic counseling. Testing was performed in 6 patients, 1 of whom had a CHEK2 genetic mutation. Two patients underwent prophylactic mastectomy (PM) for LCIS. PM was associated with strong family history (p=0.030), having other known risk factors for breast cancer (such as mantle cell radiation and prior breast biopsies, p=0.024) and receipt of genetic testing (p=0.024). MRI screening was recommended for 21/55 patients (38.1%) and 17/21 (81%) accepted it, while 4 patients opted for automated whole breast ultrasound. Recommendation of MRI screening was more likely for patients with increased mammographic breast density (p=0.031), strong family history (p=0.031), other known risk factors for breast cancer (p=0.013), and genetic testing (p=0.013).

Conclusions: Identification of atypia on core needle biopsy of an imaging abnormality without upstaging resulted in changes in risk management recommendations for 70.9% (39/55) of all patients, although only 1.27% ultimately opted for risk-reducing medication or surgery. Although most patients are being appropriately referred for clinical evaluation, there exist opportunities for optimization of risk management, including routine use of models for risk calculation.

404129 - A hospital-based, case-control study with the objective of identifying biomarkers of breast cancer risk in benign breast biopsy samples

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Background/Objective: History of prior benign breast disease (BBD) on biopsy, particularly if atypical, is associated with increased risk of subsequent breast cancer. The identification of biomarkers of breast cancer risk in BBD samples will very likely improve risk stratification and management of these women. We have assembled a case-control population with a BBD history for this purpose. However, known breast cancer risk factors may not be distributed as expected in a population selected for a documented history of BBD.

Methods: The Enterprise Data Warehouse of Northwestern Medicine was queried for women with procedure codes of breast biopsy and diagnosis codes of breast cancer, including duct carcinoma in situ. Women with a breast cancer diagnosis (cases) and an antecedent benign breast biopsy (BBB) at least 1

year prior were contacted and consented for participation. They were matched by age (± 2 years) and race, to controls with BBB and no breast cancer up to the time of consent (verified again in 2017). Participants completed a survey detailing major breast cancer risk factors. The BBB blocks were retrieved from the NM pathology archives and reviewed by a breast pathologist for classification as benign/non-proliferative, proliferative without atypia, and atypical hyperplasia. Odds radio (OR) and 95% confidence interval (CI) for individual risk factors were estimated using logistic regression.

Results: Our study population consists of 847 women (422 cases and 425 controls) with a mean age of 50.8 (SD 11.0) years in cases and 51.4 (SD=10.8) years in controls. Interval from BBB to cancer diagnosis was 6.80 years (SD 4.58), and follow-up duration was 12.8 years (SD 6.55) for controls. Most known risk factors showed non-significant trends in the expected direction. Women with early menarche (OR 1.40, CI 0.97-2.03) and family history of male breast cancer (OR 3.04, CI 0.82-11.32) had increased ORs for subsequent breast cancer diagnosis. The family history of at least 1 female relative with breast cancer was similar in cases and controls (OR 1.08, CI 0.67, 1.74). Obesity, defined as BMI 30, increased the risk of breast cancer (OR 1.28, CI 0.88-1.84). Age at first-term pregnancy >30 was significantly different in cases and controls (OR 1.67, CI 1.15-2.41); parity was non-significantly protective. Smoking, alcohol use, or the presence of atypical hyperplasia were not associated with increased risk of breast cancer in this BBD population. BBD histology was similar between cases and controls: normal/nonproliferative in 178 cases and 164 controls, proliferative change in 129 cases and 150 controls, and atypical proliferation 53 cases and 55 controls. The mean interval between BBB and breast cancer diagnosis was 6.8 (SD 4.58) years. During the follow-up period, 2.1% (9/425) controls have developed breast cancer after a mean interval of 16 years (range 9-21 years, median 17 years).

Conclusions: The risk factor profiles in this population conform to reports of populations unselected by BBD status in most respects; notable exceptions are family history of breast cancer and presence of atypical hyperplasia. Some of these differences may relate to selection biases of a hospital-based study, but the similarity of the cases-control population may be an advantage in isolating the effects of molecular changes in breast cancer cases. These differences are important to identify, since they may affect the interpretation of results. They also point to the importance of future validation of biomarkers discovered in these BBD samples.

404116 - Patients diagnosed with radial scar after core needle biopsy for mammographic asymmetry have a higher upstage rate than other imaging findings

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Background/Objective: Radial scar often presents as a spiculated mass on mammogram and ultrasound warranting a core biopsy, histology of which resembles a flame-shaped fibrotic lesion. Although benign, the upstage rate of radial scar upon surgical excision ranges anywhere from 0-40%. The association of imaging and clinical characteristics with upstage rate has not been clearly defined. We sought to determine the upstage rate and to determine the imaging and clinical characteristics associated with malignancy in a contemporary, single-institution patient cohort between 2012 and 2014.

Methods: After obtaining approval from our IRB, we used natural language software to query our electronic medical records and identified 595 patients with a diagnosis of radial scar with or without other concurrent breast pathology between 2008 and 2014. A preliminary analysis of a subset patient

cohort included 308 patients with any diagnosis of radial scar between 2012 and 2014. Pathology reports were reviewed, and a group of 54 patients who were diagnosed with solitary radial scar on core needle biopsy were identified, of whom 45 went on to subsequent excision. The clinical and imaging characteristics associated with malignancy of this group were then compared.

Results: The mean follow-up time for this pilot cohort (n=45) was 1.7 years, and the average age at diagnosis was 51.3 years. The overall upstage rate was 11.1% (n=5). Patients presenting with mammographic asymmetry or density were significantly more likely to be upstaged to malignancy than those presenting with mammographic calcification, MRI enhancement, palpable lesion or nipple discharge (22.7% vs 0%, respectively p=0.02). Of the 9 patients (16.6%) who did not undergo subsequent excision, 3 patients declined the procedure per surgeons report, and the core biopsy results of the remaining 6 patients were deemed benign and concordant by our radiologists.

Conclusions: In this pilot study, excision after radial scar seen on core biopsy yielded an overall upstage rate of 11.1%. All 5 patients who were upstaged had abnormal mammogram with asymmetry/density. To validate our findings, we will include the 595 patients from 2008-2014. This final study cohort will be one of the largest contemporary patient cohorts to be examined.

Table 1. Upstage Rate of Radial Scar Patients

Radiologic Target	Total (n)	Subsequent Excision	Pathologic Upgrade (n)	Rate of Upgrade (%)	P
Mammographic Calcification	23	19	0	-	
Mammographic Density	25	22	5	22.7%	
MRI Enhancement	2	2	0	-	0.02
Palpable Lesion	4	2	0	-	
Nipple Discharge	0	0	0	-	
All Targets	54	45	5	11.1%	

403969 - A retrospective review of idiopathic granulomatous mastitis in the Southwest Native American population

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Background/Objective: Idiopathic granulomatous mastitis (IGM) is an unusual, benign inflammatory breast disease of unknown etiology. There are a limited number of reported cases in the literature and no consensus on optimal treatment. We will present our institutions' experience as well as summarize our treatment interventions and outcomes.

Methods: Over an 18-year period, 85 patients with a diagnosis of granulomatous mastitis were identified. A retrospective chart review identified patient demographics, reproductive and lactation status, concurrent or subsequent erythema nodosum and/or polyarthralgias, presenting symptoms, laboratory and pathologic results, and subsequent treatments.

Results: Eighty-five patients with a diagnosis of granulomatous mastitis were seen at our institution from December 30, 1999- September 17, 2017 with median follow-up 36.8 months (0-176.1 months). The median age at presentation was 30 years old (range 18-46 years). Ninety-six percent of the patients had been or were pregnant at the time of diagnosis. The median time from last pregnancy was 3 years. In the 62 patients with documented lactation history, 47 (76.8%) breast-fed their last infant. Presenting symptoms were a mass in 75 (87%) patients and abscess in 27 (32%) of patients. The average size of the

breast mass on presentation was 6 cm (0.5 to 15 cm). Twenty-one patients (20%) experienced disease in both breasts during their course. Twelve patients (14%) had concurrent or subsequent erythema nodosum, and 25 (29%) had a concurrent or subsequent diagnosis of polyarthralgia. Breast symptoms resolved within a median time of 6 months (Range 0.7-58 months). Recurrences occurred in 18 (21%) of patients. Treatment varied from antibiotics, incision and drainage, aspiration, intralesional steroid injection, and systemic immunosuppression. The results are summarized in the table.

Conclusions: IGM is a rare disease that may have an increased prevalence in the Native American population. Due to the relatively frequent occurrence of IGM in our breast clinic, we have evaluated a multitude of therapeutic interventions but have not found a conclusive therapeutic algorithm.

Table: Comparison of IGM therapeutic modalities

Treatment	Intra-lesional steroid	No intra lesional steroid	Intra-lesional steroid with aspiration	Aspiration alone	Open Incision and Drainage	No open Incision and Drainage	Antibiotic therapy	No antibiotic therapy	Systemic immune suppressive therapy	No systemic steroid therapy
Number of patients	44	38	33	19	43	40	51	25	28	55
Median length of symptoms	6 months	5 months	8 months	8 months	7 months	4.5 months	6 months	4 months	8 months	5 months
# patients with recurrence*	12 (27.3%)	3 (7.9%)	10 (30.3%)	1 (5.3%)	11 (25.6%)	3 (7.5%)	11 (21.6%)	3 (12%)	8 (28.6%)	5 (9.1%)

*Recurrence is defined as recurrence of disease after resolution of symptoms for 6 months or longer.

403790 - Upstaging of pseudo-angiomatous stromal hyperplasia (PASH) to ductal carcinoma in situ (DCIS) or invasive breast cancer: A single institution review from 2012-2014

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Background/Objective: Pseudo-angiomatous stromal hyperplasia (PASH) is a benign histological diagnosis characterized by dense stromal fibrosis with blood vessel-like channels lined by myofibroblasts, usually occurring in women of reproductive age. The management of PASH found on percutaneous core biopsy has remained controversial since the upstage rate in surgical excision after core biopsy has been reported to range between 0% to 13.3%. The association of imaging and clinical characteristics with upstage rate has not been defined. We sought to determine the upstaging rate and to determine the imaging and clinical characteristics associated with malignancy in a contemporary retrospective cohort of patients (n=138) treated at a single institution in 2012-2014.

Methods: After obtaining IRB approval, we used natural language software to query our electronic medical records and identified 472 patients with a diagnosis of PASH between 1/1/2008 12/31/2014. We performed chart review on 257 patients who had undergone core needle biopsy either by ultrasound or mammographic guidance at our institution between 2012-2014 and identified 152 patients with a diagnosis of PASH. Of the 152 patients, 14 were found to have PASH on initial excisional

biopsy. Our study cohort was comprised of the remaining patients (n=138) who were found to have PASH on core needle biopsy. Data on clinical and imaging characteristics among those (n=33) who were upstaged to malignancy were compared.

Results: The median follow-up time of our study cohort was 3.3 years. The median age was 43.7. Most women (n=105) did not undergo surgical excision because the imaging results were deemed benign and concordant. Of the 33 patients (23.9%) who underwent surgical excision following core biopsy, the overall upstage rate was 12.12%. Patients with mammographic calcifications were more likely to be upstaged to malignancy (22.22%) than those presenting with mammographic density (13.33%) (p=0.4862, 1-tailed Fisher's exact test). Interestingly, MRI enhancement or palpable findings were not associated with an increased upstage rate to malignancy on excision.

Conclusions: In this pilot study, we identified an overall upstage rate of 12.12% in a small pilot cohort of patients who had undergone excision after core biopsy revealing PASH. We found that mammographic calcifications were more likely to yield malignancy upon excision (22.2%) although the difference was not statistically significant. To validate our findings, we will include the 472 patients from 2008-2014. This final study cohort will be one of the largest contemporary patient cohorts to be examined.

Table 1: Upgrade rate of PASH patients

Radiologic Target	Total (n)	Subsequent Excision (n)	Pathologic Upgrade (n)	Rate of Upgrade (%)
Mammographic Calcification	23	9	2	22.22%
Mammographic Density or Architectural Distortion	90	15	2	13.33%
MRI Enhancement	19	7	0	0.00%
Palpable Lesion	6	2	0	0.00%
All Targets	138	33	4	12.12%

400404 - Atypical breast lesion upgrade rate to carcinoma at a community center

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Background/Objective: Current recommended management of atypical breast lesions (ABL) includes surgical excision and pathologic review for possible associated malignancy. However, a large majority of these lesions are not found to have associated malignancy on post-operative pathology. Several retrospective chart reviews from large academic centers have shown that close observation with repeat imaging may be appropriate and spare the patient a surgical procedure. Here we examine the upgrade rates at a community center.

Methods: Retrospective chart review of female patients undergoing surgery for ABLs at a single center identified by surgery CPT codes for excisional breast biopsy, lumpectomy, or mastectomy from January 2012 through June 2017 was conducted. Exclusion criteria were: previous ipsilateral cancer, surgeries involving lymph nodes, or male patients. Atypical lesions included were atypical ductal hyperplasia (ADH), atypical lobular hyperplasia (ALH), intraductal papilloma (IP), sclerosing adenosis, (SA), radial scar, lobular carcinoma in-situ (LCIS), and flat epithelial atypia (FEA). Pre-operative and post-operative pathologies were examined.

Results: There were 1,942 patients identified by CPT code. All patients were female. Two hundred seven patients had an ABL identified on pre-operative core needle biopsy (CNB) and underwent subsequent

surgery. Median age was 56 years (18-85 years), and median BMI was 30 (range 17-70). Sixty-one percent of patients had no family history of breast or ovarian cancer (n=126), 23% had family history of breast cancer (n=48), 2% had family history of ovarian cancer (n=5), and 14% had unknown family histories (n=28). Fifty-five percent of ABLs were identified on screening mammogram. One hundred thirty patients (63%) underwent CNB by ultrasound-guidance, and 37% by stereotactic mammography (n=77). Seventy-one percent of specimens contained only 1 ABL (n=147), and 29% contained more than 1 ABL (n=60). The total ABL upgrade rate to carcinoma was 9.7% (n=20). The majority of upgrade pathology was DCIS (65%, n=13) and there were 7 patients upgrade to invasive carcinoma (35%, n=7). Most upgraded lesions contained multiple ABL 40% (n=8). Other upgraded lesions contained single lesions: atypical ductal hyperplasia (35%, n=7), 15% sclerosing adenosis (n=3), 15% intraductal papilloma (n=3), and LCIS 5% (n=1). Four hundred one patients were excluded due to lack of pre-operative biopsy. This was due to 3 reasons: 43% surgeon recommendation to undergo excisional biopsy (n=174), 42% patient preference to undergo excisional biopsy, and 15% radiologist recommendation due to lesion characteristics. Identification of malignancy in non-biopsied patients was 11% (n=46).

Conclusions: While this community center data is concordant with larger academic centers, the upgrade rate to malignancy remains close to 10%. Determining which lesions would be more likely to harbor malignancy could spare up to 90% of women a surgical procedure. Further characterization of ABLs to risk-stratify them may allow identification of subgroups more appropriate for imaging surveillance. Additional studies examining lesion- or patient-specific characteristics more associated with malignancy are warranted.

403041 - Select choices in benign breast disease

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Background/Objective: Up to 50% of all women encounter benign breast problems during their lifetime. In contrast to the treatment of breast cancer, high-level evidence from randomized clinical trials is not available to guide treatment decisions for benign breast disease. Subsequently, management is largely based on individual physician experience or training. In 2012, The American Board of Internal Medicine (ABIM) initiated its Choosing Wisely campaign to promote conversations between patients and physicians about challenging the use of commonly performed tests or procedures which may not be necessary. The American Society of Breast Surgeons (ASBrS) Patient Safety and Quality Committee (PSQ) chose to participate in this campaign by creating a list of practices that physicians and patients should question in regard to the management of benign breast disease.

Methods: The PSQ solicited candidate measures for the Choosing Wisely campaign that addressed benign breast disease. PSQ surgeons represent a wide variety of practice patterns that include academic and private practices across the country. The resulting list of appropriateness measures of care was ranked by a modified Delphi appropriateness methodology. Two rounds of ranking were performed to achieve the final list, which was subsequently approved by the ASBrS Board of Directors and endorsed by the ABIM.

Results: The final 5 measures are as follows: (1) Don't routinely excise areas of pseudoangiomatous stromal hyperplasia (PASH) of the breast in patients who are not having symptoms from it. (2) Don't routinely surgically excise biopsy proven fibroadenomas that are smaller than 2 centimeters in size. (3) Don't routinely operate for a breast abscess without an initial attempt to percutaneously aspirate or drain it. (4) Don't perform screening mammography in asymptomatic patients with normal exams who have less than 5-year life expectancy. (5) Don't routinely drain non-painful, fluid-filled cysts.

Conclusions: The ASBrS Choosing Wisely measures that address benign breast disease management are easily accessible to patients via the internet. Consensus was reached by the group regarding these recommendation, likely reflecting broad applicability of these measures. These measures provide guidance for shared decision-making for patients and physicians.

402840 - Prevalence and management of mastalgia in breast clinic patients

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Background/Objective: Due to higher ratio of breast cancer in Southeast Asia, mastalgia or breast pain is a common cause of related fear and anxiety in females. Mastalgia is the most frequent condition in women visiting doctors for treatment. The objective of this study was to evaluate the prevalence of mastalgia and role of diet changes, analgesia, and evening primrose oil (EPO) in management of mastalgia.

Methods: This prospective descriptive study was conducted at the breast surgery department of our institute. All female patients were enrolled from January 2017 to June 2017. Performa was designed for the purpose by the medical officer. All patients presenting with breast pain, heaviness, burning sensation, and tenderness were included in the study. Patients were initially interviewed at the time of presentation and then after 6 months of treatment.

Results: Overall, 78 female patients had shown positive response to the given treatment. Although very uncommon, 1 male patient also reported bilateral mastalgia without any other underlying causes and relieved symptoms with treatment. Out of the total number of female patients (n=93) who presented with mastalgia, 8 patients had BIRADS 4 lesion on their mammography and diagnosed with breast cancer on stereo-tactic biopsy. Details of results are shown in the table.

Conclusions: Careful and thorough evaluation of mastalgia is necessary to rule out any underlying pathology. In most of patients with mastalgia without any other pathology reassurance, dietary modifications, analgesia (local/oral), and EPO are beneficial to relieve their symptoms with the least side effects. Further research regarding psychosocial and other associated factors is needed for persistent cases.

Table: Mastalgia

Age Range	Below 50 years : 84 Above 50 years : 09
Premenopausal	71
Postmenopausal	22
Unilateral Mastalgia	56
Bilateral Mastalgia	38
Mild to moderate Pain	63
Severe Pain	31
Cyclic Mastalgia	37
Non Cyclic Mastalgia	57
Associated Nipple Discharge	21
Family H/O Ca Breast	16
Clinical Examination	
Negative	42
Scattered Nodularity	54
Breast Imaging	
Negative	39
Benign	46
Suspicious	08
Treatment Given	
Analgesia + dietary modifications	42
Analgesia + dietary modifications+ EPO	51

404263 - How often is final pathology upgraded after surgical excision for fibroadenoma?
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Background/Objective: Fibroadenomas are common benign breast lesions that are frequently found on physical exam or imaging. These lesions are usually excised because they are symptomatic or because they have increased in size, which may be concerning for a more ominous pathology. Most of the time, however, if the imaging and initial core biopsy are consistent with fibroadenoma, then the final pathology is also fibroadenoma. We examined a series of patients who had lesions excised with characteristic imaging and pathologic features of fibroadenoma to determine the rate of upgrade on final pathology. We hypothesized that the rate would be very low.

Methods: We conducted a retrospective chart review of patients with a pre-operative pathologic diagnosis of fibroadenoma, who underwent subsequent surgical excision, from October 2013 to December 2015. For all cases, pre-operative and post-operative pathology were reviewed. In addition, we reviewed the pre-operative radiologic findings, as well as the reason for excision. Pre-operative radiology was identified as typical or atypical. If ultrasound findings included at least 1 of the words, circumscribed, lobulated, or hypoechoic, then the findings were considered a typical radiologic appearance. If the ultrasound findings lacked all of these words, or included a description of an irregular mass or indistinct margins, then the findings were considered an atypical radiologic appearance.

Results: A total of 39 cases were identified with a pre-operative biopsy of fibroadenoma. Cases were excluded if pre-operative pathology was not consistent with a pure fibroadenoma, such as fibroepithelial lesion or another pathology arising within a fibroadenoma. All included cases had a typical radiologic appearance. Several of the excluded cases had an atypical radiologic appearance. After surgical excision, the final pathology for 38 of the cases was fibroadenoma. One case was upgraded to benign phyllodes tumor (2.6%). Twenty-two cases (56%) were excised for increase in size only. Ten cases (26%) were excised because the lesion was symptomatic only. Five cases (13%) were excised because the lesion was both symptomatic and had increased in size. Two cases (5%) were excised because the patient was already undergoing breast surgery for another reason. The 1 lesion that was upgraded on final pathology was excised because it was symptomatic. In total, 27 cases (69%) were excised for an increase in size. The change in size ranged from 13-111%. The average change in size was 39%. None of these cases had an upgrade on final pathology.

Conclusions: All of our patients had a pre-operative biopsy consistent with fibroadenoma and all of the lesions had a typical radiologic appearance. In our small set of patients, only 1 had an upgrade on final pathology, corresponding to 2.6%. We suspect that this percentage would be even lower with a larger sample size. The majority of lesions were excised because of an increase in size. In the setting of characteristic pre-operative pathology and imaging, even large increases in size do not seem to confer an increased risk of upgrade on final pathology. This suggests that increase in size may not be a useful indication for fibroadenoma excision and further studies with a larger sample size could help confirm this.

Complications

375965 - Risk-reduction surgery in BRCA mutation-carrier patients: an analysis of the National Surgical Quality Improvement Program (NSQIP) database

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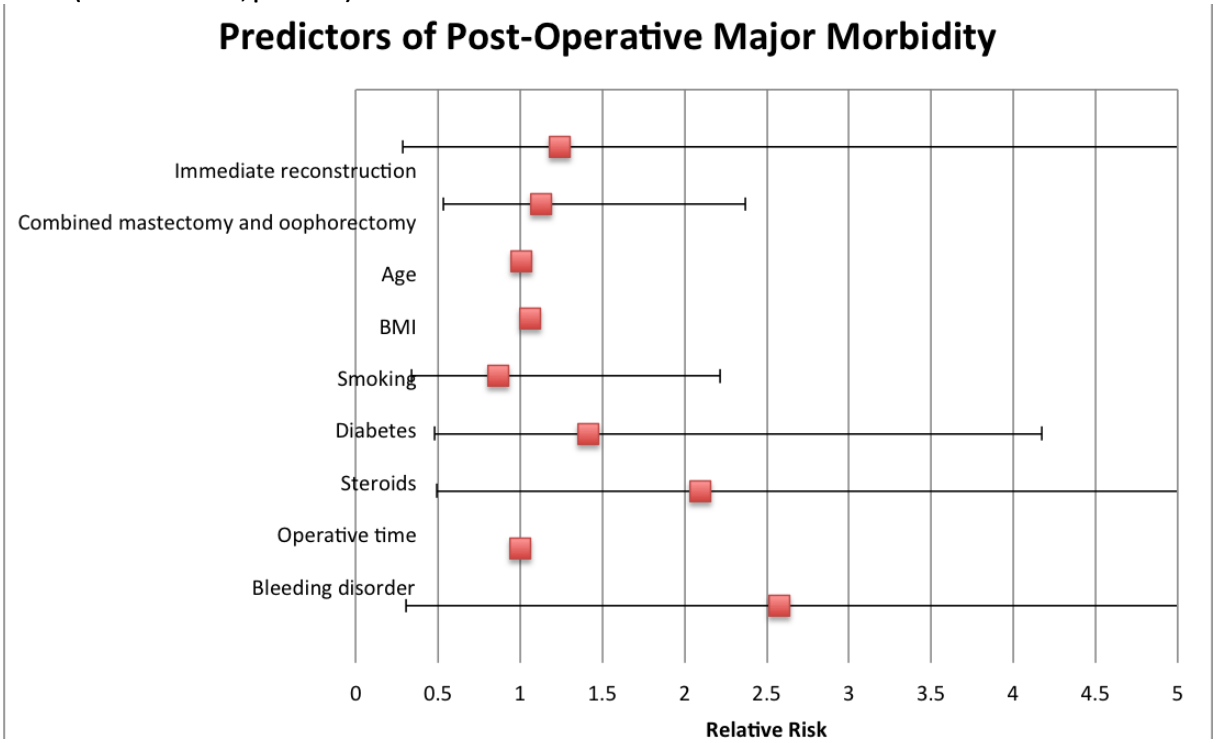
Background/Objective: Patients with a genetic susceptibility to breast and ovarian cancer are eligible for risk-reduction bilateral mastectomy and bilateral salpingo-oophorectomy (BSO). We examined the post-operative complication rates in patients undergoing risk-reduction breast surgery using a large, multi-national surgical outcomes database. We hypothesize that concurrent prophylactic procedures do not result in additional morbidity.

Methods: A retrospective cohort analysis was conducted between 2011 and 2015 using the American College of Surgeons National Surgical Quality Improvement Program database. All females with genetic susceptibility to breast and/or ovarian cancer undergoing risk-reduction surgery were identified. Primary outcome was 30-day post-operative major morbidity associated with prophylactic mastectomies. A multivariate analysis was performed to determine predictors of post-operative morbidity following risk-reduction mastectomy, and to measure the adjusted effect of a concurrent BSO on major morbidity. Predictor variables were selected a priori and included age, body mass index, smoking, diabetes, steroid use, operative time, pre-existing bleeding diathesis, immediate breast reconstruction, and concurrent BSO.

Results: Of the 3658 included patients, 3590 (98.1%) had prophylactic mastectomies, and 2743 (75.0%) underwent immediate breast reconstruction. One hundred five (2.9%) patients underwent concurrent mastectomy and BSO. Median age at the time of surgery was 46.4 +/- 11.2 years. Overall, the rate of major morbidity and wound infection were 2.4% and 2.3%, respectively. On multivariate analysis, body mass index was the only covariate associated with post-operative major morbidity (relative risk (RR) 1.1; p=0.0002). Immediate breast reconstruction (RR 1.2; p=0.78) or concurrent BSO (RR 1.1; p=0.75) were not associated with increased post-operative complications.

Conclusions: Analysis of this large prospective cohort showed that women with a genetic susceptibility to breast and/or ovarian cancer are electing to have surgery at a later age than recommended. Addition of prophylactic BSO at the time mastectomy was not associated with additional morbidity. Concomitant prophylactic mastectomy and BSO is currently not the standard of care in the US and Canada, but may be considered for this patient population.

Figure: Forest plot depicting the predictors of major morbidity. Only body mass index was found to be associated with post-operative major morbidity following risk-reduction surgery in women with genetic susceptibility to breast and/or ovarian cancer (relative risk: 1.1; p=0.0002).



403173 – Peri-operative ketorolac and post-operative hematoma formation in adolescent reduction mammaplasty: A single surgeon experience of 500 consecutive cases

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Background/Objective: The opioid crisis is a growing public health concern in the United States. Ketorolac is proven to help manage post-operative pain and decrease the amount of required opioids; however, its use is limited due to concerns of post-operative bleeding and hematoma formation. This study explores the relationship between hematoma formation and administration of peri-operative ketorolac in adolescent females undergoing reduction mammaplasty.

Methods: We reviewed the records of 500 consecutive patients undergoing reduction mammaplasty.

Results: Five-hundred patients were included in our analyses. The average age at the time of operation was 18.0 ± 2.2 years. Three hundred eighty-nine (77.8%) patients received intravenous ketorolac in the peri-operative period. Seven (1.4%) patients developed a post-operative hematoma: 3 were drained under local anesthesia, and 4 underwent surgical drainage in the operating room. Hematoma formation was not associated with intra-operative ketorolac use (p=0.999), post-operative ketorolac use (p=0.432), or any peri-operative ketorolac use (p=0.654). The mean age, total resection mass, and intra-operative/ post-operative ketorolac dose of patients did not significantly differ by hematoma status (p>0.05, all). Intra-operative use of ketorolac was associated with lower total dosing of intra-operative fentanyl (p<0.001) and morphine (p=0.009). Post-operative use of ketorolac was associated with lower total dosing of post-operative morphine (p<0.001).

Conclusions: Ketorolac use in our patient sample was associated with decreased perio-perative opioid use, but not with hematoma formation. Ketorolac may be safe to use in adolescent reduction mammaplasty without increasing the risk of hematoma formation.

403798 - Effect of surgical complications on health-related quality of life outcomes in adolescents and young women following reduction mammaplasty

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Background/Objective: Although reduction mammaplasty is associated with improved health-related quality of life (HRQOL), surgical treatment for younger patients remains controversial. This study measures complications following reduction mammaplasty in adolescents and young women, and the impact of surgical complications on HRQOL outcomes.

Methods: Clinical evaluations were performed, and the following validated surveys were administered to skeletally mature patients undergoing reduction mammaplasty: Short-Form 36v2 (SF-36), Rosenberg Self-Esteem Scale (RSES), Breast-Related Symptoms Questionnaire (BRSQ), and Eating-Attitudes Test-26 (EAT-26). Subjects completed surveys at baseline and post-operatively at 6 months, 1 year, 3 years, and 5 years.

Results: Three-hundred thirty subjects were included in analyses. The mean age of subjects at the time of surgery was 17.9 years. Less than 1% of subjects experienced a major complication, and roughly 20% experienced at least 1 minor complication, commonly: hypertrophic scarring, minor infection or wound dehiscence, or persistent altered breast sensation. Complication rates did not vary by BMI category, age, or amount of tissue resected. Patients demonstrated significant post-operative improvements in all SF-36 domains (physical functioning, role-physical, general health, bodily pain, vitality, social functioning, role-emotional, mental health), and on the RSES, BRSQ, and EAT-26. HRQOL outcomes largely did not vary by complication status.

Conclusions: Although major complications following reduction mammaplasty are rare in adolescents, minor complications are common. Complication rates in this sample did not vary by age, BMI, or resection mass. When complications occurred, patients experienced significant and similar HRQOL gains post-operatively as those patients without complications. Providers should be aware of the benefits reduction mammaplasty can provide younger macromastia patients, regardless of complication status.

458678 – Pre-operative indocyanine green fluorescence angiography (SPY Elite) mapping improves outcomes for skin- and nipple-sparing mastectomy

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Background/Objective: Ischemic complications of skin- and nipple-sparing mastectomies negatively impact patient recovery and may delay adjuvant treatment. Intra-operative indocyanine green angiography (ICGA) has been used by plastic surgeons to assess flap perfusion following mastectomy. With limited penetrance of 5-7 millimeters, we hypothesized that pre-incision ICGA would allow breast surgeons to identify the dominant vasculature to the skin flap and prevent vascular injury during mastectomy. Improved vascularity may reduce ischemic compromise during skin envelope-sparing mastectomy.

Methods: In this prospective, IRB-approved study, women undergoing skin- or nipple-sparing mastectomy underwent pre-operative ICGA immediately prior to mastectomy and again post-mastectomy, prior to reconstruction. Pre-operative ICGA provided a temporary map of the superficial breast vasculature allowing surgeons to mark dominant vessels on the skin surface. Post-operative imaging documented the number of vessels preserved and percentage of mastectomy flap perfusion. Patient risk factors including BMI, smoking history, and uncontrolled diabetes were assessed. A standardized follow-up tool was used to assess complications within the 30-day post-operative period for all patients. Fisher's exact test was used to measure outcome significance.

Results: Forty women undergoing skin- or nipple-sparing mastectomy agreed to participate in this study. ICG was administered after the induction of anesthesia. Vessel identification occurred synchronously for all visible vessels within 15-25 seconds. Zero to 5 vessels were pre-operatively marked on 40 breasts, for a total of 113 vessels with 83 oriented toward the nipple. Three patients were noted to have a diffuse vascular pattern without mappable dominant vessels. Of the 113 mapped vessels, 71 (62.8%) were preserved as documented by post-mastectomy ICGA. Perfusion scan demonstrated that 38 (95%) mastectomy flaps had perfusion of 90% of the total flap following mastectomy. The complication rate for all patients was 17.5%. Discriminated by percent flap perfusion, those with 90% compared to those with <90% had a significantly lower complication rate of 13.1% vs 100%, respectively (p=0.027). When comparing the 90% group to the <90% group, infection requiring antibiotics occurred in 5/5 (100%) vs. 2/2 (100%), wound breakdown occurred in 2/5 (40%) vs. 1/2 (50%), and return to the OR was required in 1/5 (20%) vs. 1/2 (50%), respectively. Comparing vessel preservation in those with perfusion 90% with and without complications, fewer vessels to the nipple were preserved (7/9 (77.8%) vs 64/72 (88.9%)), respectively. In the 2 patients with perfusion <90% with complications, 1 had a diffuse pattern, and in the other, both mapped vessels were not preserved. The only 2 active smokers both had complications, regardless of residual perfusion (90% vs 75%). Turning to former smokers, if at least half of vessels were preserved, there were no complications. In those where the vessels could not be mapped or preserved, 2/3 (66.7%) had complications.

Conclusions: The ability to provide a skin flap with perfusion 90% greatly diminishes the likelihood of post-operative complications. In this study, pre-operative ICGA allowed breast surgeons to map vessels in 92.5% of patients and to preserve 62.8% of mapped vessels. Further, increasing vessel preservation correlated with reduced complications. This is amplified in current and former smokers and may prove to be relevant in other high-risk groups as well. Pre-operative ICGA utilized by breast surgeons

decreased complications and improved patient outcomes. In facilities with ICGA technology, this may provide a useful adjunct in teaching and evaluating mastectomy techniques.

404027 - Breast fibromatosis: Are they all created equal?

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Background/Objective: Fibromatosis of the breast is a rare, benign tumor, lacking metastatic potential, but can be aggressive and lead to failure of loco-regional control if not adequately treated. The consensus on treatment remains wide local excision; however, other therapies have been described. Fibromatosis has been well documented in previous surgical scars of young women especially around pregnancy; however, the etiology of breast fibromatosis has not been well established. We describe a series of patients with primary and secondary fibromatosis of the breast after previous surgery and/or radiation. We propose the classification of primary and secondary breast fibromatosis.

Methods: We present a case series of the patients with breast fibromatosis at a single institution from 2003-2017. Demographics, presentation, previous surgery or radiation, treatment modalities, and outcomes are discussed. A patient was considered to have primary fibromatosis if she had not undergone surgery or radiation to her breast.

Results: A total of 16 women were included; 14 of the 16 patients were treated surgically. The majority were treated with wide local excision including lumpectomy (8), mastectomy (1), and mastectomy or lumpectomy with chest wall excision including ribs (2). The remaining patients were treated with a chest wall excision after prior mastectomy or implant placement (3). Eight patients had positive margins on initial resection and required re-excision with negative margins on final pathology. These patients often were misdiagnosed on their initial core biopsy with a myofibroblastoma or spindle cell lesion. The average follow-up time was 65 months. There were 2 patients who had a recurrence. The first was originally managed with a lumpectomy and recurred 1.5 years later. At that time, she had a second lumpectomy with partial resection of the left pectoral muscle and rib periosteum. She recurred again 2 years later and was managed with a radical mastectomy. The second was also managed initially with a lumpectomy and recurred 2 years later, and was treated with a re-excision. None of the patients treated with aggressive surgical management initially had a recurrence. Nine patients were categorized as having secondary fibromatosis with a previous history of surgery; 6 patients had prior implants. Eight of 9 patients had either radiation or an implant. Of these, 4 had radiation to the chest after a breast cancer surgery, and 1 had radiation for cosmetic reasons. Although the data are limited, it would appear that secondary breast fibromatosis is associated with previous radiation or implant surgery.

Conclusions: Secondary breast fibromatosis may be hard to diagnose, as it is often mistaken for surgical scars or other benign pathologies. It is often more aggressive then primary fibromatosis. It often develops on the chest wall or around the capsule of implants. And when managed inappropriately, it will recur. For this reason, we advocate an aggressive surgical treatment for this disease process. However, management should employ a multi-disciplinary approach. Radiation therapy and anti-estrogen therapies have been described as potential treatment strategies, but their effectiveness may be limited. Secondary fibromatosis can be insidious and is often misdiagnosed. Vigilance for this disease process is crucial in avoiding missing this tumor in patients with prior surgeries and radiation as part of their breast cancer treatment.

401479 - Implementation of a venous thromboembolism prophylaxis protocol using the Caprini risk assessment model in patients undergoing mastectomy

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Background/Objective: The risk for peri-operative venous thromboembolism (VTE) in cancer patients is multi-factorial. Although breast surgery is generally considered low risk for VTE, guidelines for prophylaxis in breast cancer patients are not well-established. We adopted a formal VTE prophylaxis protocol for patients undergoing mastectomy +/- implant-based reconstruction using the Caprini risk assessment model. Here we report our experience with implementation of this protocol during the first year.

Methods: In August 2016, all breast surgeons (n=10) and breast reconstructive surgeons (n=11) at our institution agreed to implement the following VTE prophylaxis protocol for patients undergoing mastectomy +/- implant-based reconstruction (tissue expander or direct-to-implant placement). Patients undergoing autologous reconstruction were excluded. The Caprini score, a validated individualized assessment tool for risk of peri-operative VTE, was calculated for each patient. Patients with a score of 5 received a single dose of pre-op subcutaneous (SQ) heparin and post-op SQ heparin every 8 hours while hospitalized. Patients with scores 8 were additionally discharged on enoxaparin daily for 2 weeks. All patients had lower extremity pneumatic compression devices intra- and post-op until ambulating. VTE events and bleeding complications were captured in a prospectively maintained database. Additional patient and treatment variables were obtained from the medical record. We assessed 30-day incidence of VTE and bleeding events and protocol compliance.

Results: Five hundred twenty-two mastectomies +/- implant-based reconstruction were performed from August 2016-17; 10 patients were ineligible for the VTE protocol due to medical contraindications. Median patient age was 51 years [range 19-95], BMI was >25kg/m2 in 285 (54.5%) patients. Caprini scores ranged from 2 to 11; 431 (82.6%) patients had a score from 5-7. Procedures included: unilateral mastectomy (UM) (n=120, 30.0%), UM with reconstruction (n=168, 32.2%), bilateral mastectomy (BM) (n=52, 10.0%) and BM with reconstruction (n=182, 34.8%). Four hundred eighty-six (93.1%) patients had active malignancy. Median procedure length was 222 min [range 82-784], and median length of hospital stay (LOS) was 1 day [range 0-5]. Overall protocol compliance was 60.5%, with improved compliance in the second half of the study period (53.6% vs 68.6%, $p<0.001$). Non-compliance included complete omission of peri-op heparin in 59 (11.3%) patients and partial omission in 124 (23.8%). Compliance with pre-op heparin administration was better than with post-op heparin administration (76.8% vs. 69.7%, $p=0.01$) and also varied by breast surgeon ($p<0.01$) and plastic surgeon ($p=0.05$). Improved compliance was associated with use of reconstruction ($p=0.03$), bilateral procedures ($p=0.02$) and longer procedure length ($p<0.001$), and a trend was seen for higher BMI ($p=0.06$). Events included 1 (0.2%) non-fatal VTE despite appropriate prophylaxis per protocol, 14 (2.7%) re-operations for hematoma, and 4 (0.8%) non-operative hematomas. Median LOS was 2 days in patients with a bleeding event.

Conclusions: During the first year of protocol implementation, more than 80% of patients undergoing mastectomy +/- implant-based reconstruction had Caprini scores between 5 and 7, suggesting a 1.8-4.0% risk of VTE. Overall protocol compliance was associated with breast and plastic surgeon, use of reconstruction, bilateral procedures and length of procedure, and importantly, improved over the study

period. The incidence of VTE and bleeding events were low and in line with historical rates for breast surgical procedures. Continued evaluation of the risks and benefits of a Caprini-based protocol for pharmacologic VTE prophylaxis in breast cancer patients is warranted.

404145 - Overall health at diagnosis predicts the risk of complications within the first year after breast cancer diagnosis and treatment

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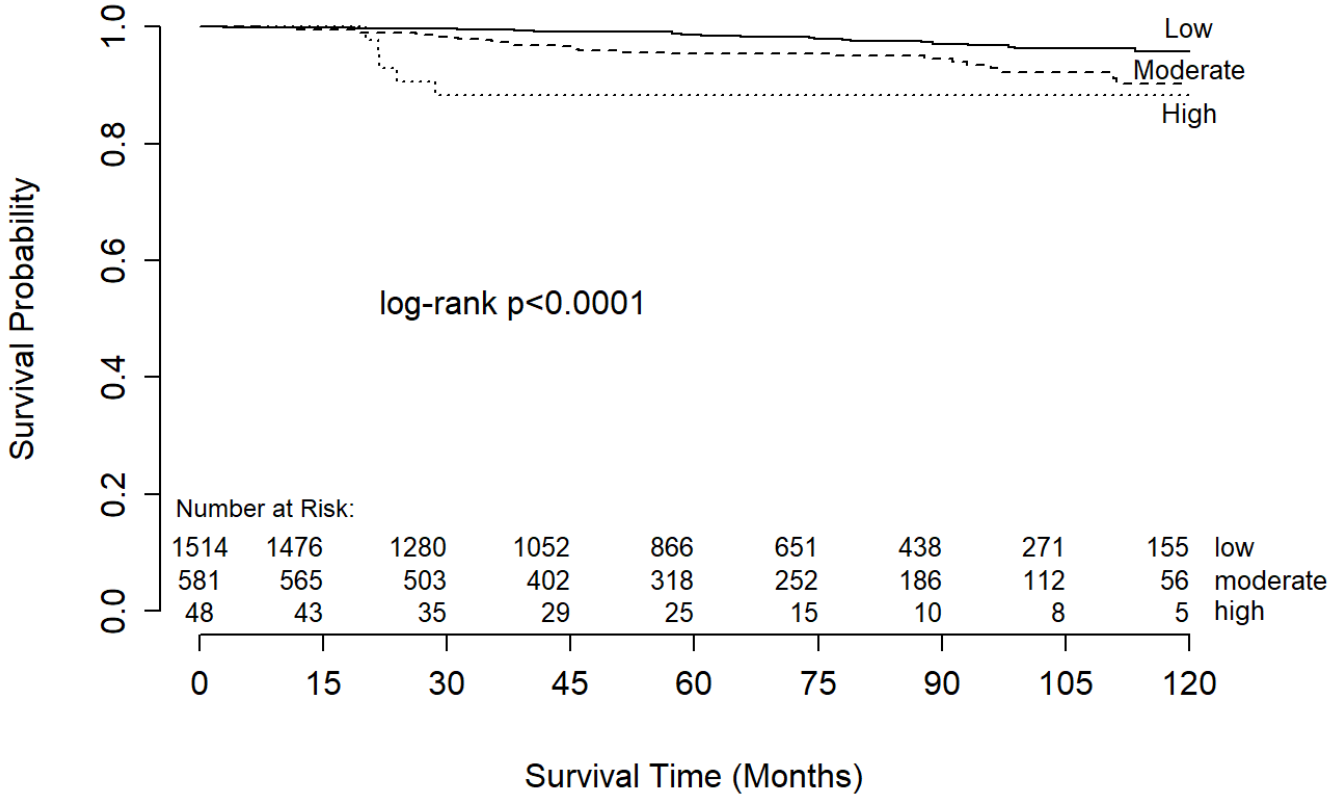
Background/Objective: Multimodal therapy for breast cancer is not without side effects or harm, and women with pre-existing co-morbidities may be at higher risk of treatment-related complications. We sought to determine the association of overall health at diagnosis with adverse sequelae within the first year after breast cancer treatment.

Methods: We identified women 40-90 years old in our institutional registry with Stage I-II invasive breast cancer who underwent surgical resection of their primary from 2005 to 2014. Health status at diagnosis was defined by pre-existing co-morbidities including congestive heart failure (CHF), diabetes, morbid obesity (BMI >35), other concurrent cancers, smoking, renal insufficiency, and liver disease. Adverse sequelae occurring within 1 year of surgery were captured including pneumonia, venous thrombotic event (VTE), cardiac complications, renal failure, urinary tract infection (UTI), and surgical site infection. Recursive partitioning with bootstrapping stratified patients by risk of treatment-related sequelae based on their co-morbidities. A p-value of 0.1 was the criterion for stratification. Based on their co-morbidity profiles, women were stratified as having a low, moderate, or high risk for post-treatment sequelae. Univariate summary statistics were calculated. Unadjusted overall survival (OS) was estimated using the Kaplan-Meier method and compared between risk groups using the log-rank test. A Cox proportional hazards model was constructed to estimate the association of risk group with OS after adjusting for covariates including age, surgery type, and hormone receptor status.

Results: There were 2,143 women included in our analysis. Of these, 83% had estrogen receptor-positive disease. Sixty-five percent underwent lumpectomy, 35% underwent mastectomy, 49% underwent radiotherapy, and 35% underwent chemotherapy. More than half of women had at least 1 co-morbidity, of which hypertension (39%), other cancers (20%), and diabetes (12%) were the most common. Sequelae within 1 year of surgery included UTI (15%), pneumonia (14%), cardiac complications including arrhythmia (12%), cellulitis (9%), renal insufficiency (4%), and VTE (3%). The low-risk group included those with no co-morbidities or hypertension only. The moderate-risk group comprised those with combinations of the examined co-morbidities except for CHF, which alone or in combination with other conditions determined the high-risk category. Type of surgery and use of endocrine or radiation therapy did not differ among groups (all $p>0.05$); however, the use of chemotherapy differed significantly among high-, moderate-, and low-risk women (27% vs 39% vs 33%, $p=0.04$). Women at high risk of complications had lower 10-year OS compared to those at moderate or low risk (88% vs 90% vs 96%, log-rank $p<0.001$). After adjustment, undergoing mastectomy (HR 1.66, $p=0.042$) and being at moderate (HR 2.30, $p=0.001$) or high risk (HR 5.22, $p=0.003$) of adverse sequelae were associated with reduced OS, while positive hormone receptor status was associated with improved OS (HR 0.43, $p<0.001$).

Conclusions: Women with overall poorer health at the time their breast cancer treatment is initiated are at higher risk of adverse sequelae within 1 year of treatment, and have decreased 10-year OS. In this population, tailored management plans should account for this increased morbidity and inform shared decision-making discussions between patients and providers.

Figure: Kaplan-Meier curve depicting 10-year overall survival by risk group



404345 - The efficacy of single breast incision for both breast and axillary surgery on the post-operative pain and range of movement

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Background/Objective: Axillary surgery still maintains a therapeutic role in treatment for breast cancer patients as well as a staging tool for the axilla and has traditionally performed using a separate axillary incision. Single incision in the breast away from the axilla to do the SLNB or to clear the axilla is a better option to minimize post-operative pain and improve range of movement.

Methods: Between June 2015 and August 2017, 240 patients with Stage I breast cancer were enrolled in our study, and were assigned to 1 of the 2 groups - single incision is done in the breast to perform lumpectomy and to approach the axilla or 2 separate incisions. Operative time and surgical complications were compared between the 2 groups.

Results: There were 168 patients who underwent single incision, and 72 patients who underwent axillary separate incision. There was no significant difference in the average operative time ($p>.05$). There was a significantly greater difference in pain score between both groups with higher incidence of pain and limited range of movement in the separate incision group ($p<.05$) compared to the single incision group.

Conclusions: The axillary surgery through the single breast incision is feasible and offers a post-operative axillary pain-free life and comfortable range of arm movement.

403211 - Impact of lumpectomy operative time on DVT risk

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Background/Objective: Peri-operative deep venous thrombosis (DVT) is a potentially preventable disease that is associated with significant morbidity and mortality, and while malignancy is a risk for DVT formation, breast cancer has a lower association with DVT formation than other cancers. Peri-operative DVTs during breast surgery are rare, with a reported rate of 0.23% for patients undergoing mastectomy, and while specific risk factors for peri-operative DVTs during mastectomy have been well characterized, risk factors for development of DVTs during lumpectomy are not well established.

Methods: We utilized the ACS-NSQIP database to retrospectively compare the incidence of DVT requiring intervention in patients after lumpectomy, comparing patients who had lumpectomy operative times less than or equal to 90 minutes against patients whose case took longer than 90 minutes. DVT formation within 30 days of lumpectomy were included in this comparison. Statistical analysis was performed using either chi-squared test or 2 tailed t-test.

Results: Overall, there were 15 cases of DVT requiring therapy identified from 12,779 patients undergoing lumpectomy, resulting in an overall DVT incidence of 0.12%. There were 10,248 lumpectomy cases with operative times below 90 minutes, associated with 9 episodes of DVT compared to 2,531 lumpectomy cases with operative times greater than 90 minutes which was associated with 6 episodes of DVT (0.09% vs 0.24%, $p=0.049$). Increased operative times was also associated with increased patient BMI (29.5 vs 30.8, $p<0.001$) and decreased patient age (61.4 vs 60.3, $p<0.001$).

Conclusions: Increased lumpectomy operative time was associated with increased peri-operative DVT incidence requiring therapy. Obesity, another known risk factor for DVT formation, is also associated with increased lumpectomy operative times and may contribute to this association seen in our patient cohort. While the incidence of DVT in patients undergoing lumpectomy was lower compared to mastectomy, when lumpectomy operative times exceed 90 minutes, the observed DVT rate was similar to that of mastectomy. Overall, the incidence of DVT during lumpectomy remains very low, but similar to mastectomy, certain high-risk groups of patients may benefit from increased peri-operative DVT prophylaxis.

Table: Characteristics of patients undergoing lumpectomy compared by operative time

	Total	Operative Time		p
		<= 90 min	> 90 min	
n	12,779	10,248	2,531	
Age	61.2 ± 13.2	61.4 ± 13.6	60.3 ± 11.7	**<0.001**
BMI	29.7 ± 7.2	29.5 ± 7.1	30.8 ± 7.4	**<0.001**
Race				
American Indian	61 (0.5)	50 (0.5)	11 (0.4)	**<0.001**
Asian	503 (3.9)	419 (4.1)	84 (3.3)	
Black	1386 (10.8)	1107 (10.8)	279 (11.0)	
Pacific Islander	43 (0.3)	31 (0.3)	12 (0.5)	
Unknown	1422 (11.1)	1226 (12.0)	196 (7.7)	
White	9364 (73.3)	7415 (72.3)	1949 (77.0)	
Comorbidities				
Smoking	1483 (11.6)	1199 (11.7)	284 (11.2)	0.5
Diabetes	1687 (13.2)	1340 (13.3)	347 (13.7)	0.4
Hypertension	5813 (45.5)	4650 (45.5)	1163 (45.9)	0.6
COPD	431 (3.4)	360 (3.4)	71 (2.8)	0.08
Chronic kidney disease	34 (0.3)	28 (0.3)	6 (0.2)	0.75
DVT requiring therapy	15 (0.12)	9 (0.09)	6 (0.24)	**0.05**
Days to DVT development	13.9 ± 7.3	14.9 ± 7.3	13.5 ± 6.2	0.73

CPM

380122 - Reframing the conversation about contralateral prophylactic mastectomy: Preparing women for post-surgical realities

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Background/Objective: A growing number of women with early-stage unilateral breast cancer and no known genetic risk choose to have contralateral prophylactic mastectomy (CPM), a decision not supported by evidence-based guidelines. This trend perplexes and concerns many surgeons because CPM increases a patients risk for surgical complications while offering little, if any, clinical benefit. The objective of this study was to explore the emotional effects of CPM including its impact on women's self-confidence, sense of femininity, sexual intimacy, and long-term peace of mind. Currently, there are few published studies that have conducted in-depth interviews with women who had CPM to explore the aftermath of their surgeries. This topic lends itself to a qualitative approach because the open-ended nature of this methodology allows for a full exploration of these issues.

Methods: We conducted hour-long telephone interviews with 42 women diagnosed with unilateral, early-stage breast cancer at low risk for contralateral disease, who elected to undergo CPM in the last 10 years. Participants were recruited through study flyers posted at breast cancer centers, on national websites for breast cancer survivors, or directly by their surgeons. Using an open-ended topic guide, we explored their perspectives on having CPM and the short- and long-term impacts they experienced as a result of the surgery. Interviews were audio-recorded and transcribed, and we used a grounded theory approach for our qualitative analysis.

Results: In reflecting back on their experience, almost all of the women said they were told by their surgeons (and believed) that they had only a slim chance of getting breast cancer in their healthy breast. Yet this statistically small likelihood did not discourage them from CPM; many expressed that they had already been a statistic by getting breast cancer and thus feared they could be unlucky again. Many of the patients reported being unprepared for the emotional impact of CPM such as negative effects on their self-confidence, sense of self, and intimate sexual relationships. Most could not recall being aware of critical information about the potential harms of CPM at the time of decision-making and assumed that, although they would experience some difficulties for the first year, after their recovery, they would return to life as they knew it. Unexpectedly, some benefits that the women believed they would obtain from CPM did not materialize, and they experienced certain life-altering sequelae they did not anticipate. The majority (70%) said they never found the peace of mind they sought, as they continued to experience persistent worries about cancer. Those who had reconstruction found it more difficult than anticipated, and for most (89%), the results fell short of their expectations, and their new breasts never became a part of their sexual identity. Disappointing reconstruction outcomes took an additional toll on their sexual relationships, more because of how the women viewed themselves than how their husbands responded to their new bodies. Numbness in their breast area was worse and more impactful

than anticipated, and most lamented the loss of an erogenous zone. Despite experiencing these unexpected negative outcomes, 38 of 42 women said they would make the same decision again.

Conclusions: Participating women reported having felt confident in their choice to opt for CPM at the point of decision-making, although many did not have complete knowledge of potential long-term impacts before surgery. Contrary to previous hypotheses that women would decline CPM if sufficiently educated, women in this study were well aware of their low risk of contralateral breast cancer, but nevertheless elected to undergo CPM. These findings highlight the opportunity for physicians to communicate with patients about their surgical options, by reframing the conversation to focus on the patient experience of both emotional and physical tradeoffs of CPM. This shift in focus may allow patients to make decisions that are better informed and more preference-based; however, it is unknown whether such information would dissuade patients from making the choice for CPM, or would merely allow them to have more realistic expectations.

403927 - Prevalence of contralateral breast procedures and associated factors, a retrospective descriptive study

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Background/Objective: Despite evidence that contralateral prophylactic mastectomy (CPM) for unilateral breast cancer has no overall mortality benefit, the prevalence has increased 3-fold in the U.S. The proportion of patients who elect to undergo a contralateral procedure, the reasons, and the sociodemographic, hereditary, and tumor factors associated with this decision have not been fully described in our institution. Furthermore, there is a paucity of research on contralateral procedure utilization in lumpectomy for unilateral breast cancer. We sought to determine the prevalence and distribution of contralateral procedures performed at our institution and the cited reasons for the procedure. We then sought to compare demographic variables and post-operative outcomes between persons who did and did not have a contralateral procedure.

Methods: A retrospective review of 486 patients who underwent surgery for breast cancer between October 2014 and April of 2017 at our institution was conducted; 425 unique adult patients with unilateral breast cancer met inclusion criteria for this study. Patient demographic information, reasons for contralateral procedure, and surgical outcomes were compared for those patients who chose to undergo a contralateral procedure versus those who did not; sub-group analyses were then performed by surgery type (mastectomy or lumpectomy). Additionally, reason for procedure was stratified by age group.

Results: Our study population underwent more lumpectomies (n=237, 56%) than mastectomies (n=188, 44%); breast-conserving rate 56% (237/425). Contralateral procedures were performed on 25.2% (n=107) patients undergoing surgery for unilateral breast cancer; more in mastectomy patients (n=97, 51.6%) compared to lumpectomy patients (n=10, 4.1%). For mastectomy patients, the most common contralateral procedure was simple mastectomy (n=38), followed by skin- and nipple-sparing mastectomy (n=25); for lumpectomy patients, it was breast reduction (n=3). The most common cited reason for performing a contralateral procedure was symmetry, with no difference between mastectomy and lumpectomy patients or patient age group. Overall, patients who elected to undergo a contralateral procedure were younger (mean 55 years of age versus 65) and lumpectomy patients who

underwent a contralateral procedure were less likely to be obese. There was no increase in adverse post-operative outcomes overall, or in mastectomy patients, but lumpectomy patients who underwent a contralateral procedure were more likely to have a breast hematoma or re-operation.

Conclusions: Performance of contralateral procedures was common at our institution. Patients undergoing mastectomy were more likely to have a contralateral procedure performed than those undergoing lumpectomy. The most commonly cited reason was symmetry, regardless of breast cancer surgery type. Patients who were younger were more likely to undergo a contralateral procedure. While the sample size of lumpectomy patients undergoing contralateral procedures was small, they had a significant increase in prevalence of breast hematoma and re-operation. The mastectomy population with contralateral procedures did not show any increase in adverse post-operative outcomes, differing from the published literature which reports about a 2-fold increased complication rate.

395256 - Contralateral prophylactic mastectomy as treatment for breast cancer increasing in the state of New Jersey

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Background/Objective: The rate of contralateral prophylactic mastectomy (CPM) in women with unilateral, early-stage breast cancer is increasing with no plateau. No study to date has examined changes in surgical treatment of women with early-stage breast cancer in New Jersey. The objective of this study was to improve the understanding of patient- and tumor-related factors that influenced the choice of mastectomy with CPM, as treatment for early-stage breast cancer, in New Jersey.

Methods: A retrospective analysis of 10 years of breast cancer data including 52,254 women ages 40-80, treated in New Jersey from 2004 through 2014. Bivariate analyses examined associations between covariates and type of surgery utilized: breast conservation surgery (BCS), unilateral mastectomy (UM), or mastectomy with contralateral prophylactic mastectomy. Logistic regression models identified possible associations between type of surgery and various patient and tumor-related characteristics.

Results: Women who were treated with CPM were more likely to be young (14.9% of women ages 40-49) and White (7.8%), as compared to 6.8% of Asian women, 4.9% of African American women and 6% of Hispanic women, and privately insured (p<.0001). CPM rates increased from 3.74% of all cases in 2004 to 11.2% of all cases in 2014, while breast-conservation surgery rates remained stable. Factors that predicted CPM included: race (both White (OR 1.90, CI 1.613-2.238) and African American women [OR 1.244, CI 1.009-1.533] were more likely to undergo CPM, when compared to Asian women), and payer (women who were uninsured were more than 30% less likely to undergo CPM [OR .675, CI .490-.930], and women with private insurance were almost 30% more likely to receive CPM [OR 1.290, CI 1.056-1.577]). Level of education was predictive in that as the education level increased the likelihood of receiving CPM increased as well (OR1.027, CI 1.020-1.033). Disease-related factors that were predictive of CPM included immediate reconstruction and stage at diagnosis. Women who underwent immediate reconstruction were more than twice as likely to undergo CPM (OR 2.363, CI 2.175-2.568). Women with lower-stage tumors at diagnosis were also more likely to opt for CPM when compared to women with Stage III tumors (in situ [Stage 0] [OR 1.317, CI 1.149-1.509] and local [Stage I] [OR 1.270, CI 1.128-1.430]). Additionally, year of surgery was predictive of CPM, in that the rate of CPM increased from 2004-2014 (OR 1.126, CI 1.111-1.140).

Conclusions: The rate of CPM as a treatment for unilateral breast cancer continues to rise; however, this decision seems to be relatively independent of tumor-related factors and clinical evidence of efficacy. These results, which are consistent with most if not all studies of CPM, are further evidence that this change in treatment paradigm has been widely accepted into practice although lacking clinical efficacy and without an improvement in disease-specific survival for most women with sporadic breast cancer. Further research into physician practice patterns and level of knowledge about CPM indications is needed in that clinical recommendations are apparently not being heeded by many surgeons in the United States.

404346 - Regional location predicts high bilateral mastectomy rates among Medicare providers

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Background/Objective: The rise in bilateral mastectomy (BM) for newly diagnosed breast cancer patients has been associated with multiple patient factors, but few studies have examined whether BM rates vary by surgeon. The objective of this study was to examine variation in BM rates among Medicare providers.

Methods: The SEER-Medicare linked database was used to identify women age 65 or older who underwent surgery for AJCC Stage 0-III unilateral breast cancer from 2007-2011. Using a 6% cutoff point based on receiver operating curve (ROC) analysis of median surgical volume and proportion of bilateral mastectomy (BM) in the Medicare dataset, surgeons who performed BM as 6% or more of their total cases were classified as high-proportion providers. Multivariate analyses were used to determine predictors of surgeons who were high-proportion providers of BM after adjusting for provider, facility, patient, and tumor factors.

Results: There were 13,299 breast surgeries performed by 293 surgeons. Of these, 9,926 (74.6%) underwent lumpectomy, 2,761 (20.8%) unilateral mastectomy, and 612 (4.6%) bilateral mastectomy. The median number of surgeries performed by a provider was 38 (range 25-156). 8705 (65.5%) of cases done by high-volume surgeons (>38 cases). There wre 1,744 (13.1%) surgeries performed by Surgical Oncologists, and 11,555 (86.9%) were performed by General Surgeons. There were 5,794 (43.6%) surgeries performed in the West region of the country, 1,425 (10.7%) in the Midwest, 3,266 (24.6%) in the Southeast, and 2,814 (21.2%) in the Northeast. Ninety-one surgeons were classified as high-proportion providers of BM. The number of cases was similar between the high-proportion providers (median 37, IQR 30-48) compared to the low-proportion providers (median 38.5, IQR 29-55, p=0.50). Compared to low-proportion surgeons, high-proportion surgeons were more likely to perform unilateral mastectomies (24.2% vs 19.4%, p<0.01), more likely to be Surgical Oncologists compared to General Surgeons (14.4% vs 12.6%, p<0.01), to be located in a rural area (8.2% vs 6.0%, p<0.01), and to be located in the West region (55.8% vs 38.6% p<0.01). High-proportion surgeons were less likely to be located in the Northeast (2.8% vs 28.6%, p<0.01). Multivariable analysis was performed adjusting for surgeon, facility, patient, and tumor factors to identify predictors of high-proportion providers of BM [Table 1]. Location outside the Northeast region was the most significant predictive factor of a high-proportion surgeon (OR 13.6 [CI 11.0-16.8] for the Southeast region, OR 12.1 [9.6-15.1] for Midwest region, and OR 15.08 [12.3-18.4] for West region; all p<0.01). The only other variables predictive of high-proportion providers of BM were lower-volume surgeons (OR 0.73 [0.67-0.79], p<0.01) and a diagnosis

in 2011 (OR 1.16 [CI 1.00-1.35], p=0.04). Patient factors (age, race, marital status) and tumor factors (histology, grade, tumor size, stage, ER status) were not associated with high-proportion providers of BM.

Conclusions: Variation in BM performance even in women >65 years old exists, and region of the country was the strongest factor associated with higher BM rates. Institutional bias and regional practice patterns may further explain these findings but cannot be studied in this database. Further study is needed to better understand these findings.

Table: Predictors of high-proportion providers of bilateral mastectomy

Variable	Univariable Odds Ratio (95% CI)	Multivariable Odds Ratio (95% CI)	Multivariable P-value
Surgeon Factors			
High surgeon volume (ref: low)	0.73 (0.67-0.79)	0.73 (0.67-0.79)	<0.01
Surgical oncologist (ref: general surgeon)	1.17 (1.05-1.30)	0.99 (0.88-1.11)	0.88
Southeast (ref: Northeast)	13.18 (10.73-16.19)	13.60 (11.04-16.75)	<0.01
Midwest (ref: Northeast)	11.94 (9.56-14.91)	12.06 (9.64-15.08)	<0.01
West (ref: Northeast)	14.63 (11.98-17.86)	15.08 (12.34-18.44)	<0.01
Rural area (ref: metropolitan/urban)	1.39 (1.21-1.61)	1.02 (0.87-1.18)	0.84
Patient Factors			
Age 70-74 (ref: 65-69)	0.94 (0.85-1.04)	0.95 (0.86-1.06)	0.38
Age 75-79 (ref: 65-69)	0.84 (0.76-0.94)	0.88 (0.79-0.99)	0.04
Age 80-84 (ref: 65-69)	0.86 (0.76-0.97)	0.90 (0.79-1.02)	0.11
Age >85 (ref: 65-69)	0.83 (0.72-0.96)	0.91 (0.77-1.06)	0.23
Diagnosis in 2011 (ref: 2007)	1.13 (0.99-1.31)	1.16 (1.00-1.35)	0.04
Tumor Factors			
Stage II (ref: I)	1.03 (0.95-1.12)	--	
Grade 2 (ref: grade 1)	0.85 (0.78-0.93)	0.95 (0.93-1.02)	0.14
Grade 3 (ref: grade 1)	0.85 (0.76-0.94)	0.92 (0.81-1.04)	0.17
ER negative (ref: positive)	0.92 (0.82-1.02)	--	

404268 – A prospective study of decision-making for contralateral prophylactic mastectomy

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Background/Objective: Retrospective studies have shown that multiple different patient and tumor factors are associated with a patient's decision to undergo contralateral prophylactic mastectomy (CPM). However, few studies have examined factors that influence patient decision-making in real time.

Methods: This was a single institution prospective study of newly diagnosed breast cancer patients with unilateral breast cancer from 2015-2017. Those with a pathologic gene mutation or who underwent a mastectomy without reconstruction were excluded. Participants completed an ad hoc survey after consultation with their breast surgeon but before undergoing surgery. The survey assessed patients' discussions with their surgeons, known decisional factors for CPM, shared decision-making, and anxiety. Logistic regression was used to evaluate which decision-making factors were most strongly associated with CPM versus breast conservation (BCT) and unilateral mastectomy (UM).

Results: Two hundred of 205 patients completed surveys (113 BCT patients, 47 UM patients, and 40 CPM patients; response rate 97.6%). The mean age of respondents was 59.0 years, and the majority (76%) had Stage 0-I tumors. CPM patients were almost twice as likely to have made the final decisions for surgery mostly or totally by themselves (83% CPM vs. 44% non-CPM, $p<0.001$) but were not more likely to be very confident in these decisions (67% CPM vs. 78% non-CPM, $p=0.38$). They were also less likely to have perceived a definitive recommendation from their surgeon for which surgery to undergo (64% CPM vs. 90% non-CPM, $p<0.001$). After adjustment for age and tumor stage, the strongest independent predictors for CPM were: worry about cancer recurrence (aOR=3.47, $p=0.002$), how much they had discussed the benefits of CPM with their surgeon (aOR=2.95, $p<0.001$), worry about contralateral breast cancer (aOR=2.52, $p<0.001$), and avoiding additional screening tests (aOR=2.49, $p<0.001$). Concern about the difficulty of surgery and general anxiety levels were not significantly associated with choice for CPM ($p=0.46$ and 0.37, respectively).

Conclusions: Women who choose CPM do so mainly on their own, possibly due to a perception of surgeon ambivalence regarding the best treatment. However, discussion of CPM is an independent predictor of CPM choice which highlights an opportunity for surgeons to be more assertive in their recommendation for or against CPM.

403891 – Practitioner opinion on contralateral prophylactic mastectomy: How do we steer a patient-driven discussion?

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Background/Objective: Contralateral prophylactic mastectomy (CPM) is increasing despite a recent statement paper from The American Society of Breast Surgeons discouraging average-risk women with unilateral breast cancer (BC) from undergoing CPM. The objective of our study was to conduct a needs assessment of BC health practitioners to gather information about their opinions, attitudes, and experiences surrounding CPM.

Methods: The Ottawa Decision Support Framework was the theoretical framework for the development of the interview guide. Semi-structured interviews were conducted until data saturation with a convenience sample of BC practitioners, including oncologic and reconstructive surgeons, medical oncologists, and nurse navigators. Practitioners were sampled from both academic and community practice settings.

Results: From July 2016 until July 2017, a sample of 16 BC practitioners was interviewed in Ontario, Canada. Practitioners interviewed were 62.5% female and from various BC disciplines. Included in the sample were 11 surgeons (oncologic and reconstructive), 3 medical oncologists, and 2 nurses. Half of practitioners practiced in an academic setting (8/16) and the other half from a community practice. Nearly all practitioners (15/16) identify the discussion regarding CPM as patient initiated. The majority of practitioners (13/16) describe their role as supporting the patient in the decision-making process. Practitioners described educating patients on the lack of survival benefit and in general discouraging CPM. I address the questions and that sometimes people have a fear of recurrence. And, that fear is actually not really founded based on current management. Because, we've improved. And, I talk about the fact that some people feel that anxiety related to recurrence of breast cancer even in the setting of contralateral mastectomy, is not always relieved. The main described advantages and disadvantages to CPM are outlined in the Table. Practitioners agreed that most patients demonstrate decisional conflict (11/16) as a barrier to decision-making, and it is a challenge to realign patients understanding and expectations. I think it’s just the competing information they have from the world and family and friends, and what their medical practitioners are telling them and also their own experience with their body, and journey. Almost all practitioners (15/16) identified a need for information materials to help educate patients on the risks and benefits of CPM and to help realign expectations.

Conclusions: Practitioners have identified CPM in average-risk women with unilateral breast cancer as a patient-driven phenomenon that is on the rise, despite highlighting the increased risk of complications and lack of survival benefit. Our practitioner needs assessment identifies the need for a dynamic decision aid to help guide the shared decision-making process for practitioners and patients. A decision aid would potentially enhance patient knowledge and understanding of the benefits and risks of CPM while helping to realign patient expectations.

Table: Advantages and disadvantages of CPM

Practitioner responses	No. (%)
Advantages	
Reduced anxiety	15 (93.8%)
Improved symmetry and cosmesis	9 (56.3%)
Reduced contralateral breast cancer risk	5 (31.3%)
Ability to use smaller prosthesis	1 (6.3%)
Disadvantages	
Increased surgical complications	15 (93.8%)
Lack of survival advantage	7 (43.8%)
Impact on psychological well-being and body image	7 (43.8%)
Increased operative time and costs	3 (18.8%)
Losing ability to breast feed	1 (6.3%)

404235 - Comparison of mastectomy rates by facility type and region

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Background/Objective: There is increasing concern about rising rates of mastectomy and prophylactic contralateral mastectomy (CPM) performed over the last decade without obvious survival benefit. Various oncologic organizations have issued guidelines recommending more limited extent of surgical resection. The purpose of this analysis is to determine the patterns of practice by facility type and geographic region using the National Cancer Database (NCDB).

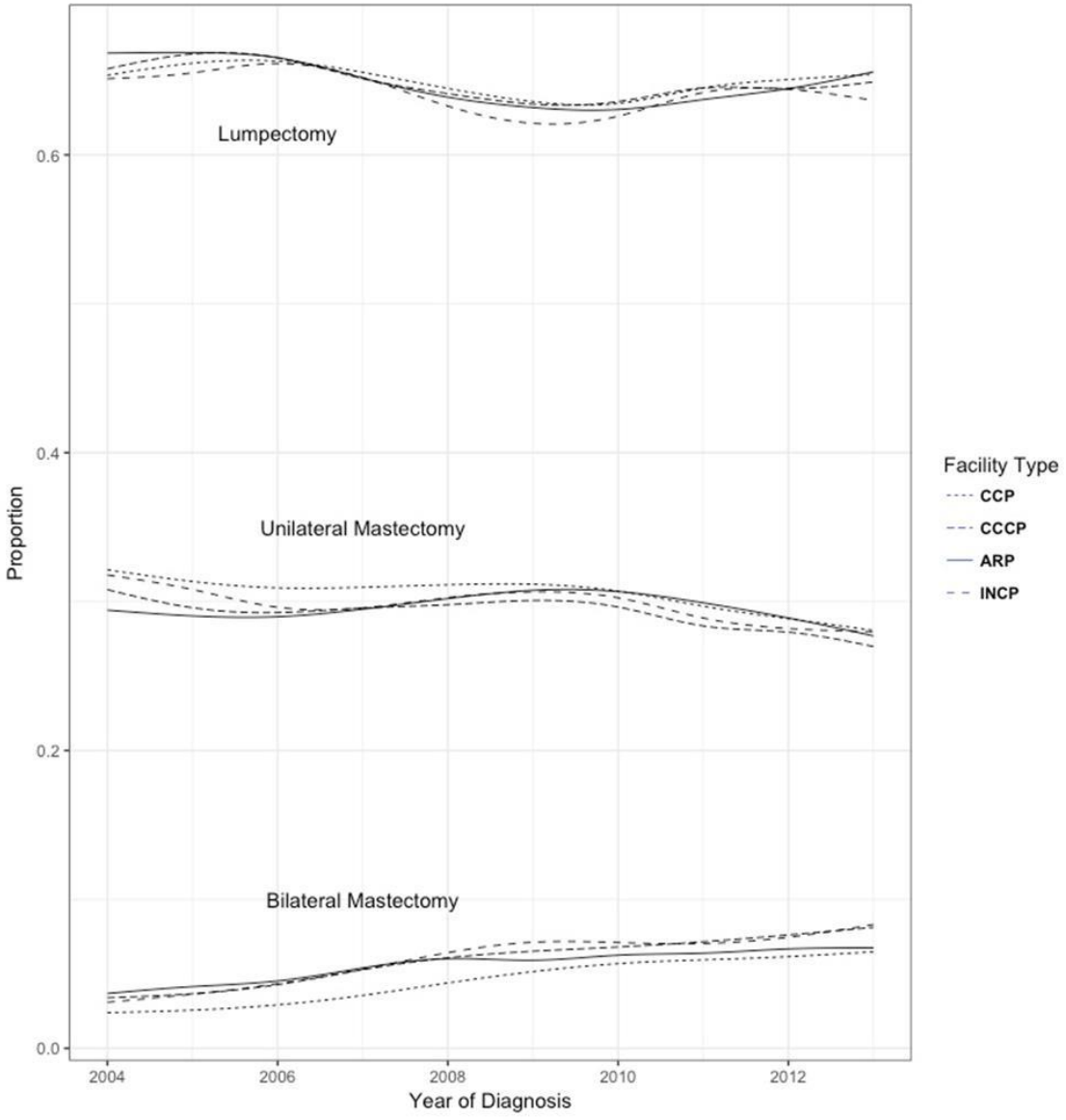
Methods: Women undergoing breast conservation therapy with lumpectomy, unilateral mastectomy, and bilateral with prophylactic contralateral mastectomy from 2004 to 2013 were included. Women with contralateral mastectomy for known disease were excluded. Centers were categorized as Academic/Research Program (ARP), Comprehensive Community Cancer Program (CCCP), Community Cancer Program (CCP) and Integrated Network Cancer program (INCP). Regions were Midwest, Northeast, South and West. Odds ratios of bilateral mastectomy were calculated by facility type (reference ARP) and geographic region (reference South).

Results: In analysis of 1,229,435 women, lumpectomy, unilateral mastectomy and bilateral mastectomy were performed in 64.8% (796874), 29.4% (361946), and 5.7% (70615) of patients respectively. The majority of women were white (75.42%) with mean age of 62.13 years old and presented with Stage IA (51.42%) with moderately differentiated (39.98%), ER-positive (82.82%) and PR-positive (72.33%) breast cancers. There were 35.7% of women from the South, 25.11% from the Midwest, 21.68% from the Northeast, and 17.51% from the West. There were 51.93% treated at CCCP, 29.00% treated at ARP, 11.39% at CCP, and 7.67% treated at INCP. Co-morbidity index was 0 in 85.01%, 1 in 12.43%, and greater than 2 in 2.56%. Overall, 53.1% were privately insured, and 38.2% were covered by Medicare. Odds ratios of undergoing bilateral mastectomy by region compared to the South: Midwest 0.88 (95%CI 0.87-0.92) p<0.01; Northeast 0.59 (95%CI 0.57-0.60), p<0.01; West 1.00 (95%CI 0.98-1.02), p 0.82. Odds ratios of undergoing bilateral mastectomy by facility compared to ARP: CCCP 1.06 (95%CI 1.04-1.08) p<0.01;

CCP 0.80 (95%CI 0.78-0.83) p<0.01; INCP 1.07 (95% CI 1.04-1.11) p<0.01. Lumpectomy and unilateral mastectomy decreased slightly over time and bilateral mastectomy increased slightly over time (OR per year respectively 0.99, 0.99, and 1.09, all p<0.01).

Conclusions: Using the NCDB to compare rates of CPM by facility type and region, overall trends were identified. Patients in the Midwest and Northeast were overall less likely to undergo CPM compared to the West and South. Patients were also less likely to have CPM at CCP in comparison to larger centers. Over time, the rates of lumpectomy and unilateral mastectomy slightly decreased while CPM increased. These results show that rates of bilateral mastectomy continue to increase over all geographic regions and facility types despite guidelines suggesting more limited surgery.

Figure:



DCIS

404154 - Validation of the Mayo model for pre-operative prediction of upstaging of ductal carcinoma in situ (DCIS) to invasive breast cancer

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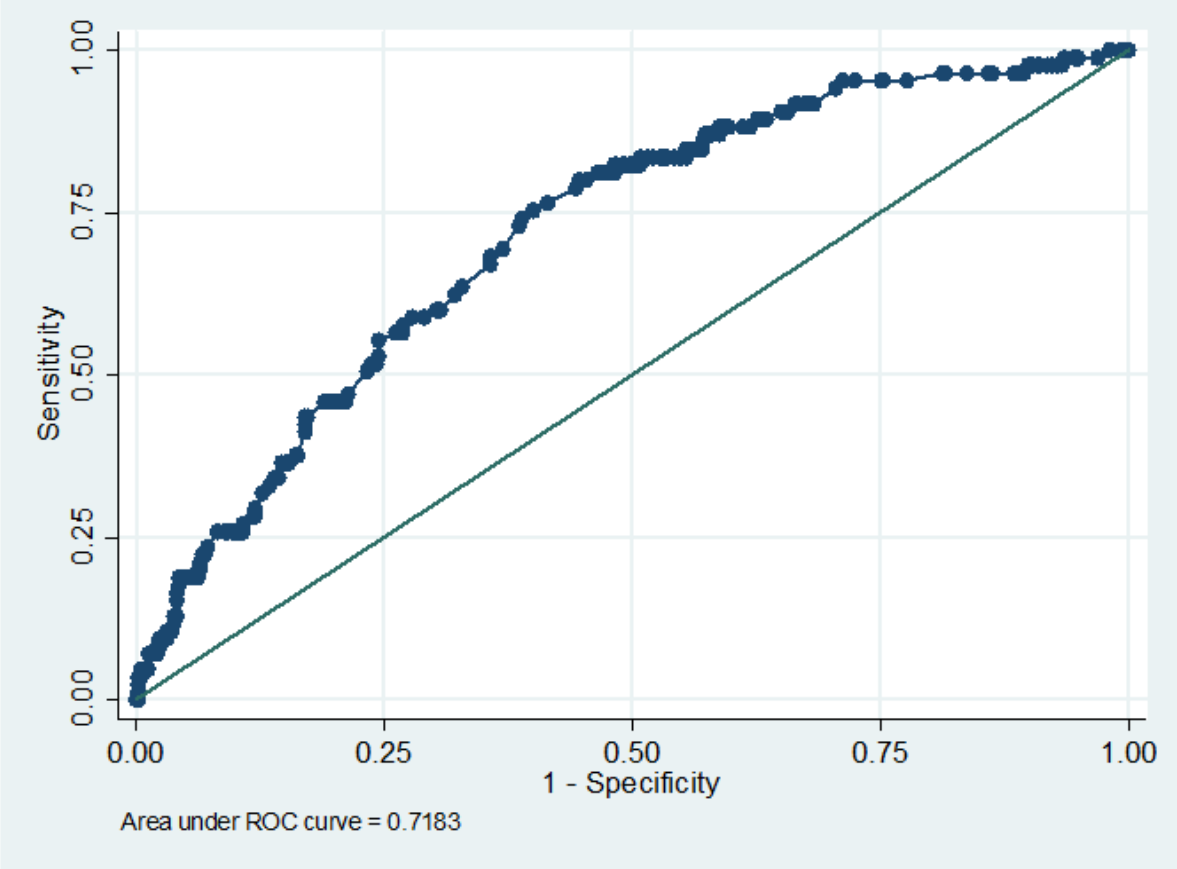
Background/Objective: The upstage rate of DCIS found on core needle biopsy (CNB) to invasive breast cancer (IBC) varies from 10-60% in published studies. This prediction has acquired importance with the increased interest in less therapy for selected patients with DCIS. The Mayo Model (Jakub JJ 2017, DOI 10.1245) uses 4 predictive factors with a reported c-statistic of 0.71. We have performed an external validation study of this model, using the same parameters

Methods: We identified 641 patients diagnosed with screen-detected DCIS on CNB between January 1, 2007 and December 31, 2012, through a query of the Enterprise Data Warehouse of Northwestern Medicine. A wide range of clinical and pathologic features were confirmed by manual medical record review. Patients with suspicion of microinvasion were included. Multivariable logistic regression was used to evaluate the combined value of the 4 predictors in the Mayo model (mammographic size, grade, presence of mass, and multicentricity). This was used to generate the area under the curve (c-statistic) using receiver operating characteristic (ROC) analysis.

Results: The mean age of the study population (n=641) was 56.54 years (SD 12.57), of whom 17.9% were upstaged on surgical excision. The mean size of the calcifications on imaging was 2.42 cm (SD 2.6); 73 (11.6%) of the patients had multicentric lesions, and 57 (9%) had a mass on imaging. The grade distribution was: 13.46% grade 1, 40.5% grade 2, and 46% grade 3. The multivariable logistic model revealed significant odds ratios (ORs) for 3 features: the presence of a mass (OR 4.9, 95% CI 2.2-10.9), grade (OR 2.5, 95% CI 1.6-3.9), and greatest dimension of calcifications per mm increase (OR 1.1, 95% CI 1.0-1.2). Multicentricity was not a statistically significant parameter (OR 1.4, 95% CI 0.7-3.0). The ROC curve resulting from this model has an AUC (c-statistic) of 0.71 (95% CI 0.66, 0.78), similar to that published by the Mayo group.

Conclusions: Our study confirmed the predictive ability of the model developed by Jakub et. al., even though we included patients with suspicion of microinvasion on CNB. However, improvements are clearly needed if patients are to be counseled regarding the wisdom of a watchful waiting approach to DCIS management based on such models.

Figure: ROC curve for validation of the Mayo model upstaging of DCIS to invasive breast cancer



404152 - Local recurrences in patients with close or positive margins without post-mastectomy radiation for pure DCIS: A systematic literature review

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Background/Objective: Although many patients with ductal carcinoma in situ (DCIS) are successfully treated with breast-conserving surgery, up to 30% of pure DCIS patients still undergo mastectomy. Utilization of post-mastectomy radiation (PMRT) in patients with DCIS with close margins (CM) or positive margins (PM) remains controversial. This systematic review aims to explore the local recurrence rates (LR) of patients who underwent mastectomy for DCIS without PMRT.

Methods: A systematic literature review identified peer-reviewed articles in PubMed evaluating patients with pure DCIS who underwent mastectomy with close margins (CM) or positive margins (PM). We selected studies that reported margin status and local recurrence (LR) and conducted descriptive statistical analysis.

Results: The search yielded 317 articles; 11 met the inclusion criteria and collectively evaluated 1,055 patients with a mean age of 45.8 years over a mean follow-up 79.4 months (range 22 144; SD 41.7). Among all 1,055 patients, 371 (35.2%) had PM and 560 (53.1%) had CM. Nine studies reported specific margins in agreement with current margin recommendations of 2 mm for negative margins among 866 patients; 367 (42.4%) of these patients had PM defined as tumor on ink, and 499 of these patients (57.6%) had CM, including 213 (24.6%) with <1mm margins, and 286 (33.0%) with <2mm margins. The weighted average for LR was 3.7% (Range 0-16.1%, SD 5.1%) among all patients with a median time to recurrence of 60 months (24-114 months, SD 47.6).

Conclusions: This study is the largest comprehensive literature review to date on PMRT for pure DCIS with close or positive margins. Our systematic review reveals low LR, thereby demonstrating the oncologic safety of sparing PMRT in patients with Stage 0 breast cancer with close or positive margins. In the future, validation in a large-scale study is warranted to bring clarity to this important clinical question.

Table: Study Characteristics

Study	Country	Study Years	Number of Patients *(n)*	Median Follow Up *(months)*	Mean Age *(years)*	No. of Patients with Positive Margins *(n)*	No. of Patients with Margins <1mm *(n)*	No. of Patients with Margins <2mm *(n)*	No. of Patients with Margins <5mm *(n)*	Median Time to Local Recurrence *(months)*	Local Recurrence *(%)*
Carlson et al.	USA	1991-2003	19	82.3	44.3	0	19	-	-	-	10.5
Chadha et al.	USA	1997-2002	24	55.2	-	5	19	-	-	114	8.3
Chan et al.	USA	1985-2005	59	96	47	4	-	28	55	24	1.7
Childs et al.	USA	1998-2005	44	91.2	52	21	-	23	0	-	4.5
FitzSullivan et al.	USA	1996-2009	94	33.6	-	5	89	-	-	-	4.2
Godat et al.	USA	1995-2006	20	44.4	-	0	20	-	-	-	0
Glorioso et al.	USA	2006-2017	43	57	-	-	-	43	-	-	11.2
Klein et al.	Canada	1994-2003	649	121.2	-	305	-	220	-	-	2.3
Owen et al.	Canada	1990-1999	66	144	-	31	35	-	-	-	4.5
Rashtian et al.	USA	1994-2002	31	22	-	0	31	-	-	42	16.1
Spiegel et al.	USA	1985-1994	6	126	40	-	-	-	-	-	0

404261 - Removing the term carcinoma when discussing a diagnosis of ductal carcinoma in situ does not affect decisions about surgical treatment

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Background/Objective: The terminology of ductal carcinoma in situ (DCIS) has received national recognition due to its possible effects on patient anxiety in the setting of a favorable prognosis. However, alternative terminology such as ductal intraepithelial neoplasia (DIN) has not been widely adopted in favor of DCIS in the clinical setting. The purpose of this pilot study was to assess whether replacing the term DCIS with DIN in discussions of treatment options would alter patient decision-making.

Methods: Women with a normal mammogram and no personal history of DCIS or breast cancer were recruited to discuss treatment for a hypothetical breast lesion. Exclusion criteria included a first-degree relative with breast cancer/DCIS and a history of genetic susceptibility to breast cancer. Participants were interviewed about treatment options for DCIS/DIN. Identical scripts were used for interviews with the exception of the term DCIS/ DIN and scripts were randomly assigned. At the conclusion of the interview the State-Trait Anxiety Inventory was administered. Statistical analysis was conducted with the Fisher's Exact test. Qualitative analysis was performed to assess the rationale for treatment choice.

Results: Of the 25 participants, the majority had > high school education (54%), were African American (63%) and had an average income of <$50,000 (58%). The mean age was 62 years. The majority of participants chose surgical treatment (72%) over surveillance with a preference for breast conservation (83%). There was no difference between DCIS and DIN groups in choosing surgical treatment versus surveillance or in type of surgery (Table). However, of those choosing treatment, only 33% of the DIN group agreed to preventive endocrine therapy versus 87% of the DCIS group (p=0.08). The average reported anxiety levels were elevated (DCIS = 47, DIN = 45) with no difference between the groups (p=1). There were no independent predictors of treatment choice. On qualitative analysis, the most common theme regarding treatment choices in both groups was the desire to alleviate anxiety induced by the diagnosis.

Conclusions: This study suggests that avoiding the term carcinoma does not affect surgical treatment decisions for DCIS in this patient population. However, removing carcinoma from these discussions may result in fewer patients choosing chemoprophylaxis. The driving factor in treatment decisions appeared to be anxiety about a DCIS diagnosis although removing the term carcinoma did not affect reported anxiety levels. Further research is needed to define the optimal terminology for discussing DCIS with patients to minimize anxiety and enhance informed decision-making.

Table: Treatment choices with DCIS and DIN terminology

Intervention	DCIS (N=13)	DIN (N=12)	Total	P value
Surveillance	4 (31%)	3 (25%)	7 (28%)	1
Treatment	9 (69%)	9 (75%)	18 (72%)	
Type of treatment	**DCIS (N=9)**	**DIN (N=9)**		
Lumpectomy with Radiation	8 (89%)	7 (78%)	15 (84%)	0.6
Mastectomy	1 (11%)	2 (22%)	3 (16%)	
Chemoprophylaxis	7 (78%)	3 (33%)	10 (55%)	0.08

403973 - Distinguishing atypical ductal dysplasia from ductal carcinoma in situ: Convolutional neural network-based machine learning approach using mammographic image data

Simukayi Mutasa[1], Eduardo Pascual[2], Priya Jadeja[3], Jenika Karcich[1], Christine Chin[1], Ralph Wynn[1], Bret Taback[1], Sachin Jambawalikar[1], Richard Ha[1]

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Background/Objective: Current management of ADH is surgical excision, largely due to possible upgrade to DCIS. We hypothesize that convolutional neural networks (CNN) can be used to predict ADH from DCIS in order to stratify patients who warrant surgical excision.

Methods: Following IRB approval, retrospective review of our database was performed between January 2012 and January 2016. Patients diagnosed with ADH by stereotactic guided biopsy of calcifications and subsequent surgical excision yielding ADH without upgrade to DCIS was included in the ADH group. Patients diagnosed with DCIS on either stereotactic biopsy of calcifications or surgical excision were included in DCIS group. Two standard mammographic magnification views (CC and ML/LM) of the calcifications were used for analysis. For deep learning, for each patient, group of calcifications that were targeted for biopsy underwent 3D segmentation in both CC and ML/LM views using an open-source software platform 3D Slicer. Each image was scaled in size based on the radius of the segmentations and resized to fit a 32x32 pixel bounding box. A 14 hidden layer topology was used to implement the neural network. The network architecture contained 5 residual layers and dropout of 0.25 after each convolution. For each breast tumor, a final softmax score threshold of 0.5 was used for 2 class classification. Cases were randomly separated into a training set [80%] and test set [20%] with utilization of 5-fold cross validation. Code was implemented in open source software Keras with TensorFlow on a Linux workstation with NVIDIA GTX 1070 Pascal GPU.

Results: In total, 380 unique images representing ML and CC magnification views of calcifications from 190 patients were used for CNN algorithm. One hundred thirty-eight images from 69 patients in the ADH

group and 242 images from 121 patients in the DCIS group were used. The network was trained for 1200 epochs. Aggregate 5-fold cross validation area under the receiver operating curve (AUC) was 0.82 ± 0.07 for the validation set. Aggregate specificity and sensitivity was 90% (95% CI, ± 10) and 75% (± 12) respectively. Accuracy was measured at 79% (± 8.3).

Conclusions: Current deep CNN architectures can be successfully trained with relatively small-sized imaging data set to distinguish pure ADH from DCIS. Larger data set will likely improve our prediction model and has potential to be applied in a clinical setting to treat patients less aggressively for ADH.

404036 - Invasive recurrence after DCIS: Characteristics after initial BCT vs mastectomy

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Background/Objective: Invasive local recurrence after treatment of DCIS with BCT is more common than after initial mastectomy, but it is unclear if characteristics and patterns of invasive recurrence vary based on initial surgical therapy. The purpose of this study was to examine the differences among patients with DCIS who experienced invasive recurrence based on initial treatment with BCT vs. mastectomy.

Methods: An IRB-approved, retrospective review identified patients with invasive recurrence after treatment for DCIS from 1984-2014 at a single institution. Patients with an initial DCIS recurrence, and a subsequent invasive recurrence were included, but only data on the invasive recurrence were recorded. Age at diagnosis and characteristics of the invasive recurrence, including subtype approximated by immunohistochemistry (hormone receptor positive/HER2 negative [HR+/HER2-], triple negative [TNBC], HER2 positive [HER+]), and pattern of first invasive recurrence (local, regional or metastatic) were compared between groups. Age differences were assessed using the Kruskal-Wallis test. Categorical variables were compared using Fisher's exact test.

Results: There were 452 patients identified with an invasive recurrence after surgery for DCIS: 367 (81%) treated with initial BCT and 85 (19%) with mastectomy. Patients who had undergone BCT were older at diagnosis than those who had undergone mastectomy (median age of 52 vs. 42, p<.001), and had a higher proportion of TNBC invasive recurrences (10% vs. 1.2%) and a lower proportion of HER2+ (17% vs 21%) and HR+/HER2- (65% vs 68%) (p=.01). A higher proportion of first invasive recurrences after BCT were local, whereas a higher proportion of first invasive recurrences after mastectomy were regional or distant (p<.001)(Table). Median time to local and regional recurrence was similar for the 2 surgical groups. However, the median time to distant recurrences was significantly longer in the BCT group compared to the mastectomy group (p=.02).

Conclusions: There are significant differences in characteristics and patterns of invasive recurrence after BCT and mastectomy for initial treatment of DCIS, with a higher proportion of regional and distant recurrence (as compared to local recurrence) among patients initially treated with mastectomy. Future studies are needed to examine this group of patients within the context of all patients diagnosed with DCIS to gain a better understanding of the significance of these findings.

Table: Pattern and median time to invasive recurrence after DCIS by surgery type

Type of surgery	Local recurrence (%)	Median years since surgery	Regional recurrence (%)	Median years since surgery	Distant recurrence (%)	Median years since surgery
BCT	345 (94%)	6.2	5 (1.4%)	7.1	17 (4.6%)	11.5
Mastectomy	10 (12%)	7.4	53 (62%)	4.9	22 (26%)	6.3

403999 - Mastectomy with close or positive margins for pure DCIS. Do we need to radiate?

Sylvia Reyes[1], Austin Williams[2], Renee Arlow[2], Julia Tchou[2], David Anderson[2], Stacy Ugras[2], Ari Brooks[2], Dahlia Sataloff[2], Lucy De La Cruz[2]

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[2]*University of Pennsylvania, Perelman School of Medicine, Philadelphia, PA*

Background/Objective: Approximately one-third of patients with ductal carcinoma in situ (DCIS) undergo mastectomy. Margin status is a well-established risk factor of local recurrence (LR) in patients with DCIS treated with breast conservation. However, in the setting of mastectomy, it is a topic of controversy. The purpose of this study was to evaluate our institutional LR in patients treated with mastectomy for pure DCIS without post-mastectomy radiation (PMRT) in the setting of close or positive margins (PM) and compare them with those who had negative margins.

Methods: We performed a retrospective review of patients chart and identified those with pure DCIS treated with mastectomy without radiation from 2010-2013. We defined close margins at <2mm and positive as ink on tumor. The primary endpoint was LR, defined as recurrence to chest wall. Secondary endpoints were distant or regional recurrences. We analyzed outcomes according to margin status (<2mm/positive), nuclear grade, comedonecrosis, receptor status (estrogen/progesterone), types of mastectomy and reconstruction, and receipt of hormonal therapy. Local recurrence was compared among patients with close/positive margins and those with negative margins.

Results: We identified 129 patients who met our inclusion criteria. Thirteen (10%) patients had DCIS identified on both breasts after bilateral mastectomy for a total of 142 total cases. Median age was 50 (range 21-81) with a median follow-up 127 months (range 4-228). Of these 142 cases, 19 (13.4%) cases had close or positive margins with a median age of 50 (range 30-79) and median follow-up of 128 months (range 4-198). There were no significant differences in demographics or tumor characteristics between those with close/positive margins compared to those with negative margins (Table). Close margins were twice as likely to occur in the anterior or posterior margins compared to the remaining borders. Local recurrence was seen in 3 cases overall (2.1%). Patients with close/positive margins were significantly more likely to have LR (n=2, 10.5%) compared to those with negative margins (n=1, 0.8%), p=0.006. When comparing these 2 groups, the time to LR was significantly longer in the negative margin group, 73 months, compared to 14.5 months in the close/positive margin group, p=0.05. Both close margin LR cases occurred at the posterior margin and the negative margin LR case occurred in the axilla. One (0.7%) case with a close margin (<1mm) developed distant recurrence at 196 months.

Conclusions: In our series, the risk of LR is significantly increased in DCIS patients with close or positive margins after mastectomy, 10.5% compared to <1% with negative margins. Validation in a large-scale study is warranted to better assess the utility of post-mastectomy radiation in DCIS.

Table: Characteristics and local recurrence in DCIS post-mastectomy patients

	Total	Negative	Positive/Close	p
n	142	123	19	--
Mean Age *(years)*	50.7 ± 12.4	50.9 ± 12.1	49.9 ± 14.4	0.76
Age				
<40	24 (14.7)	19 (15.4)	5 (26.3)	0.36
40-70	109 (79.1)	97 (78.9)	12 (63.2)	
>70	9 (6.3)	7 (5.7)	2 (10.5)	
Race				
White	93 (65.5)	83 (67.5)	10 (52.6)	0.23
African American	37 (26.1)	30 (24.4)	7 (36.8)	
Asian	5 (3.5)	3 (2.4)	2 (10.5)	
Latina	2 (1.4)	2 (1.6)	0 (0.0)	
Other/unknown	5 (3.5)	5 (4.1)	0 (0.0)	
Genetic Mutation				
BRCA	6 (4.2)	5 (4.1)	1 (5.3)	0.66
Li Fraumeni (p53)	5 (3.5)	5 (4.1)	0 (0.0)	
None	131 (92.3)	113 (91.9)	18 (94.7)	
Laterality				
Unilateral	116 (81.7)	101 (82.1)	15 (78.9)	0.74
Bilateral	26 (18.3)	22 (17.9)	4 (21.1)	
Sentinal Lymph Node Biopsy	135 (95.1)	117 (95.1)	18 (94.7)	0.94
Initial surgery				
Breast conserving	21 (14.5)	18 (14.6)	3 (15.8)	0.3
Unil(Total	40 (28.2)	32 (26.0)	8 (42.1)	
Bilateral mastectomy	81 (57.0)	73 (59.3)	8 (42.1)	
Type of Mastectomy				
Nipple-sparing	20 (14.1)	17 (13.8)	3 (15.8)	0.16
Skin-sparing	108 (76.1)	92 (74.8)	16 (84.2)	
Total	19 (13.4	19 (15.4)	0 (0.0)	
Reconstruction				
None	15 (10.6)	15 12.2)	0 (0.0)	0.24
Autologous	54 (38.0)	45 (36.6)	9 (47.4)	
Implant	73 (51.4)	63 (51.2)	10 (52.6)	
Receptor Status				
Estrogen				
Positive	20 (14.1)	18 (14.6)	2 (10.5)	0.39
Negative	102 (71.8)	86 (69.9)	16 (84.2)	
Unknown	20 (14.1)	19 (15.4)	1 (5.3)	
Progesterone				
Positive	31 (21.8)	25 (20.3)	6 (31.6)	0.34
Negative	91 (64.1)	79 (64.2)	12 (63.2)	
Unknown	20 (14.1)	19 (15.4)	1 (5.3)	
HER2/neu				
Positive	32 (22.5)	28 (22.8)	4 (21.1)	0.88
Negative	11 (7.7)	9 (7.3)	2 (10.5)	
Unknown	99 (69.7)	86 (69.9)	13 (68.4)	
Comedonecrosis	58 (40.8)	53 (43.1)	5 (26.3)	0.23
Grade				
1	13 (9.2)	10 (8.1)	3 (15.8)	0.48
2	64 (45.1)	58 (47.2)	6 (31.6)	
3	59 (41.5)	49 (39.8)	10 (52.6)	
Unknown	6 (4.2)	6 (4.9)	0 (0.0)	
Margin				
Negative	123 (86.6)			--
Positive	4 (2.8)			
Close (<2mm)	15 (10.6)			
Local Recurrence	3 (2.1)	1 (0.8)	2 (10.5)	0.006
Time to Local Recurrence *(months)*	34.0 ± 33.9	73.0 ± 0.0	14.5 ± 3.5	0.047
Mean Follow Up *(months)*	46.2 ± 22.8	46.3 ± 23.2	45.4 ± 21.0	0.9
Distant recurrence *(%)*	1 (0.7)	1 (5.2)	0	

NAC

404011 - Association between histological markers and pathologic complete response after neoadjuvant chemotherapy

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Background/Objective: Neoadjuvant chemotherapy (NAC) has emerged in the treatment of breast cancer. Recently, several NAC trials have shown that patients with complete pathological response (CPR) have better long-term outcomes and improved survival. The purpose of this study is to determine if the biological markers of breast tumors are associated with CPR after NAC.

Methods: This is a cross-sectional study including 449 women with invasive ductal carcinoma treated with NAC in a single institution between March 2006 and March 2017. Histological grade (HG), hormonal receptor status (estrogen and/or progesterone), proliferation marker (KI 67), human epidermal growth factor receptor 2 expression (HER-2), and angiolymphatic invasion (ALI) status of the tumors were retrieved from pre-treatment biopsies. All patients received anthracyclines and taxanes as their NAC treatment before surgery. Women with HER2 overexpression also received trastuzumab. CPR was defined as no invasive or in situ residuals in either the breast or nodes in the surgical specimen. The associate between the candidate predictor and CPR was assessed with Pearson chi-square test and logistic regression models. Predictors that reached a pre-determined p of 10% were used in a multivariate logistic regression model.

Results: The median age of the sample was 49 years (range: 24 to 82). PCR were observed in15.3% of the specimens. The univariate analysis is presented in the table. All analyzed markers were associated with PCR in univariate analysis. Every 10% increase in KI67 expression was associated with a 24% increase in the odds of PCR (p<.0001). In the multivariate analysis, a statistically significant association between HR, HER2 status and KI67 was observed (HR: OR=.38; IC95%= .18-.83; p=.02 / HER2: OR=2.5; IC95%=1.1-5.6; p=.02; Ki67: OR:1.26 for an increase of 10%; IC95%= 1.1-1.5;p=.01).

Conclusions: Our results have shown that HG, hormonal receptor, HER-2, KI 67, and ALI MRI are biologically predicted markers for PCR in both univariate and multivariate analysis, and can be used as criterion to define the cases that could benefit from NAC.

Table: Univariate association between biological markers of breast tumors and CPR

		Negative n (%)	Positive n (%)	
Overall (n=449)		380 (84.63)	69 (15.37)	
Histological grade	1	16 (3.56)	2 (0.44)	p 0.029
	2	166 (36.97)	19 (4.23)	
	3	162 (36.08)	40 (8.90)	
ER and/or PR	Positive	272 (60.57)	31 (6.90)	p 0.0000
	Negative	107 (23.83)	38 (8.46)	
HER-2	Positive	101 (22.49)	31 (6.90)	p 0.0086
	Negative	249 (55.45)	38 (8.46)	
Angiolymphatic invasion	Positive	191 (42.53)	1 (0.22)	p 0.0000
	Negative	176 (39.19)	63 (14.03)	

403768 - Recurrence in patients who achieved pathological complete response by neoadjuvant chemotherapy

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Background/Objective: Recent studies have indicated that patients who achieved a pathological complete response (pCR) by neoadjuvant chemotherapy (NAC) have better long-term outcomes than those who did not. Recently, the pCR rate is approaching 50%, particularly in patients with hormone-receptor-negative disease. If the disease is not recurred locally in cases with pCR, and pCR could be accurately diagnosed pre-operatively, it may be possible to treat some population of patients without surgery after chemotherapy. We analyzed the outcomes of patients who had achieved pCR by NAC with special attention to local recurrence and risk factors of recurrence.

Methods: We investigated disease-free survival in 395 patients who were identified as having a pCR from 1599 patients with primary operable breast cancer treated by NAC in 4 institutions (pCR rate of 24.7%; 395/1599). As for subtypes in 395 cases, pCR cases were 50 in Luminal type (pCR rate of 7.2%), 98 in Luminal-HER2 type (32.1%), 116 patients in HER2 type (52.5%), and 131 in triple-negative (TN) type (34.2%).

Results: The median follow-up was 41 months. Recurrent diseases including local recurrence or distant metastasis was found in 5.80% (23/395). According to subtypes, these were 2.00% (1/50) in Luminal type, 4.08% (4/98) in Luminal-HER2 type, 10.3% (12/116) in HER2 type, and 4.58% (6/131) in TN type. Local recurrence was found in 1.2% of all cases (5/395). It was prominent that brain metastasis was frequently observed in HER2 type (12/116). Clinical stage as tumor size and nodal status before NAC were found as a risk factor of recurrence in the univariate and multivariate analysis.

Conclusions: Except HER2 type, recurrence was not frequent in cases obtained pCR, particularly in cases with an early clinical stage. Local recurrence was rarely observed in any subtype. Based on this result, we think that it is possible to omit surgery in patients with highly expected pCR. We have already conducted a multicenter feasibility study to treat without surgery. For cases diagnosed as clinical complete response after NAC by contrast-enhanced magnetic resonance imaging, ultrasound-guided core needle biopsy (CNB) is performed before starting the surgery. The concordance of pathological results between CNB and surgical specimen is examined. The enrollment was completed recently.

404209 - Axillary management after neoadjuvant chemotherapy for N1 breast cancer: Is axillary lymph node dissection always necessary?

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Background/Objective: Neoadjuvant chemotherapy (NACT) utilization has increased in breast cancer, resulting in the conversion of many patients with clinical N1 (cN1) disease to N0, with a small proportion having a pathological complete response (pCR). However, it is difficult to reliably predict the patients who will have a cPR. The overall aim of this study is to describe practice patterns and survival in NACT patients with cN1 disease and to determine factors associated with pCR in NACT patients.

Methods: All women diagnosed with cN1 breast cancer in Alberta who underwent NACT between January 2012 and December 2014 were identified from an existing retrospective, population-based dataset. Patient demographics, pre- and post-NACT clinical stage, final post-operative tumor and node characteristics, margin status, surgical treatment of breast (breast-conserving surgery (BCS) vs. mastectomy) and axilla (sentinel lymph node biopsy (SLNB), SLNB plus axillary lymph node dissection (ALND), or planned ALND), recurrence, and cause of death were obtained from primary chart review. Descriptive statistics were used to characterize treatment patterns between axillary treatment groups, with actual recurrence-free survival (RFS) and overall survival (OS) reported. Multivariable analysis was used to identify factors associated with pCR.

Results: A total of 237 patients with cN1 breast cancer were treated with NACT during the study period. There were 34 patients (14.3%) who underwent SLNB alone, 26 patients (11.0%) who underwent SLNB plus ALND, and 177 (74.7%) patents who underwent ALND. Nodal stage, complete clinical response, pCR are summarized in the table. Rates of positive nodes in the ALND, SLNB plus ALND, and SLNB groups were 64.4%, 23.5%, and 69.2%, respectively. There were negative lymph nodes on final pathology in 35.6% and 30.8% of the ALND and SLNB plus ALND groups, respectively. There were no differences between axillary groups with respect to age, tumor histology, clinical response to tumor, surgical procedure, or tumor focality. There was no difference in 5-year RFS between those who had ALND (93.8%), SLNB followed by ALND (96.2%), or SLNB alone (91.2%) (p=0.56). Patients with pCR after NACT were more likely to have smaller tumors (p<0.001) and HER2+ breast cancer, compared to non-pCR patients. On multivariable analysis, predictors of pCR after NACT were complete clinical response (OR=10.9, 2.4-11.2), HER2+ tumor (OR=6.0, 2.9-12.4), and other (i.e., metaplastic) histology (OR=2.4, 1.0-5.6). Factors that were not associated with pCR include triple-negative or hormone-positive tumors, tumor multifocality, T stage, and age <40.

Conclusions: While most patients underwent ALND after NACT during the study period, SLNB alone and SLNB plus ALND was being used even in the setting of pre-treatment cN1 disease, with no significant differences in overall survival. There were no positive lymph nodes identified on final pathology for 35.6% and 30.8% of the ALND and SLNB plus ALND groups, respectively, and ALND could have been avoided in this setting. This represents the potential for significant unnecessary morbidity, where patients may experience pain, paresthesia, and lymphedema. Patients who may be more likely to have pCR and avoid ALND after NACT may be patients HER2-positive tumor, complete clinical response, and other (i.e., metaplastic) histology.

Table: Nodal stage, complete clinical response, pCR

	ALND (n=177)	SLNB plus ALND (n=26)	SLNB (n=34)
Preoperative Clinical N Stage			
cN1	172 (97.2%)	25 (96.2%)	34 (100.0%)
cN2	5 (2.8%)	1 (3.8%)	0 (0.0%)
Postoperative Pathological N Stage			
pN0	63 (35.6%)	8 (30.8%)	26 (76.5%)
pN1	59 (33.3%)	10 (38.5%)	8 (23.5%)
pN2	55 (31.1%)	8 (30.8%)	0 (0.0%)
Complete Clinical Response	32 (18.1%)	10 (38.5%	20 (58.8%)
Pathological Complete Response	63 (35.6%)	8 (30.8%)	26 (76.5%)

403447 - Lymph node ratio as an alternative to pN staging for predicting prognosis after neoadjuvant chemotherapy in breast cancer

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Background/Objective: Axillary nodal status is one of the most important prognostic factors in breast cancer. The lymph node ratio (LNR), defined as the ratio of involved nodes to dissected nodes, has been suggested as an independent prognostic factor because the number of dissected and involved lymph nodes might differ across institutions. Neoadjuvant chemotherapy (NAC) has been the preferred treatment method for reducing tumor mass in the breast and axillary area. However, NAC can reduce total number of excised lymph nodes compared with upfront surgery. Therefore, an emerging question is whether axillary nodal status and LNR following NAC can accurately predict prognosis. We evaluated the prognostic value of axillary nodal status and LNR after NAC.

Methods: A total of 236 patients between 2006 and 2015 were enrolled. Patients were divided into 4 groups according to the following cut-off values for LNR : 0 (n=107), 0.01-0.20 (n=68), 0.21-0.65 (n=50), and >0.65 (n=11).

Results: Pathologic complete responses were observed in 16.9% of the overall cohort. In univariate analysis, pathologic N stage was a significant prognostic factor of disease-free survival (DFS, p=0.013) and overall survival (OS, p=0.004). However, in multivariate analysis, hormone receptor status (p=0.043) and LNR (p=0.028) were significantly associated with DFS and LNR (p=0.017) showed statistical significance for OS; however, pathologic N stage was no longer significantly associated with DFS or OS.

Conclusions: Traditional nodal staging has been accepted as an important prognostic factor; however, our results indicated that the nodal ratio could be an alternative to pN staging as a prognostic factor after NAC in breast cancer.

404320 - Tumor biology and tumor size are predictors of complete pathologic response following neoadjuvant chemotherapy in the National Cancer Database

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Background/Objective: Tumor size and lymph node status have historically been used to stage breast cancer and guide treatment recommendations. However, there is increasing recognition of the major role tumor biology plays in long-term outcomes. This is evidenced by the recently released 8th edition AJCC guidelines for cancer staging that incorporate receptor status in addition to tumor size, nodal status, and metastatic disease. No large studies have examined the relative roles of tumor size and receptor status on response to neoadjuvant chemotherapy (NAC) in the breast. We hypothesized that tumor size would not be associated with whether a patient experienced a complete pathologic response (pCR) to NAC once receptor status was taken into account.

Methods: We queried the National Cancer Database for women >18 years old who underwent NAC and surgery for unilateral Stage I-III invasive breast cancer from 2003-2013. Women with T4 disease were excluded due to an inability to evaluate tumor size. Patients without complete information for clinical tumor stage, pathologic tumor stage, and receptor status were excluded. Multivariable logistic regression models assessed sociodemographic, diagnosis, and treatment factors including time to starting NAC associated with pCR. Predicted probabilities for time to starting NAC in monthly increments were calculated from the multivariable model. Monthly increments were chosen based on the average time to starting NAC in this cohort.

Results: The 40,670 women included in this study had a mean age of 52 years with a majority presenting with Stage II disease (62%). Patients predominantly had ER/PR+ HER2- (45%) or triple-negative (28%) disease. Overall, 19% of patients had a pCR following NAC. In multivariable models (Table), increasing tumor size was independently associated with lower pCR rates ($p<0.0001$). Receptor status had the largest effect of any variable tested ($p<0.001$), with ER/PR-HER2+ patients most likely to have a pCR. Overall ER/PR- patients were more likely to experience pCR than ER/PR+ patients. An additional finding was that longer time to NAC initiation was independently associated with a lower pCR rate ($p<0.0001$). Patients starting NAC 4 weeks after diagnosis had a predicted probability of pCR of 20.1% (CI 0.20-0.22), starting NAC 4-8 weeks after diagnosis had a 19% (CI 0.18-0.19) probability, and greater than 8 weeks had a 14% (CI 0.13-0.15) probability.

Conclusions: In contrast to our initial hypothesis, tumor size is independently associated with pCR following NAC after controlling for receptor status, although the effect of receptor status is stronger than that observed for tumor size. These data reinforce the importance of including receptor status, a surrogate for tumor biology, in the AJCC staging and treatment of breast cancer. An unexpected outcome from this analysis was the identification of potential disparities in outcomes for patients with a delay in the start of NAC, an area for further cancer care delivery research.

Table: Multivariable analysis of the association between clinical T stage, receptor status, and time from diagnosis to NAC initiation with pCR (n=40,510)

		OR	95% CI		p-value
Clinical T Stage	1	REF			<0.0001
	2	0.93	0.87	0.99	
	3	0.61	0.56	0.66	
Receptor status	ERPR+HER-	REF			<0.0001
	ERPR+HER+	2.94	2.72	3.17	
	ERPR-Her-	3.82	3.57	4.09	
	ERPR-HER+	6.22	5.72	6.76	
Time to starting NAC	≤4 weeks	REF			<0.0001
	5-8 weeks	0.86	0.81	0.91	
	>8 weeks	0.60	0.56	0.65	

*Variables in multivariable model in addition to those listed above include the following factors measured at diagnosis: age race, ethnicity, clinical N stage, insurance, facility type, income, education, comorbidities, distance to treatment facility, geographic location.

402585 - Effect of breast conservation following neoadjuvant chemotherapy vs mastectomy with adjuvant chemotherapy in operable breast cancer

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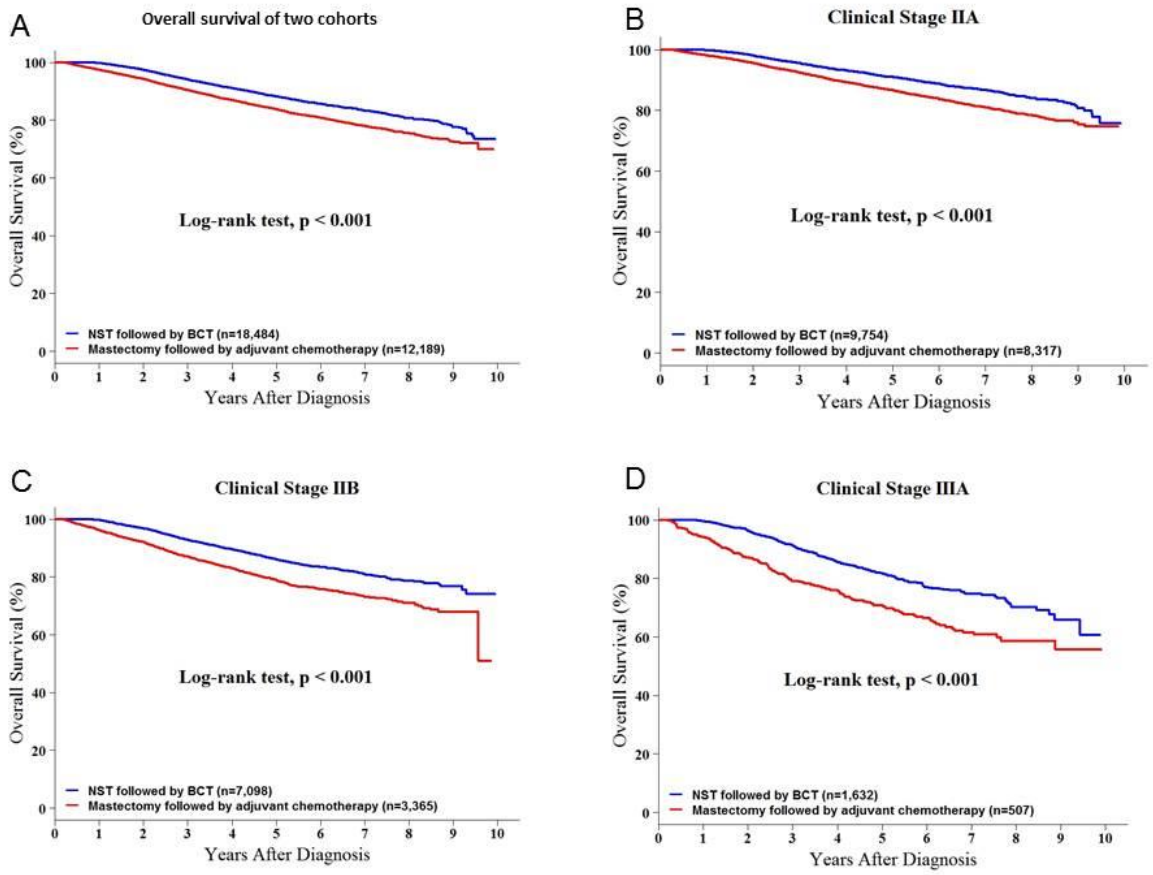
Background/Objective: Multiple clinical trials have demonstrated the ability of neoadjuvant systemic therapy (NST) to downstage breast tumors and facilitate breast conservation therapy (BCT) without compromising overall survival (OS). Additionally, individual trials comparing BCT to mastectomy demonstrate equivalent OS. However, no studies have directly compared the OS of women with operable Stage II-III breast cancer (BC) that had NST followed by BCT to women treated with mastectomy followed by adjuvant chemotherapy (AC).

Methods: Female patients >18 years of age with operable clinical Stage II and III breast cancer were identified from the National Cancer Database between 2006 and 2014. Two cohorts were created according to treatment approach: NST followed by BCT and mastectomy followed by AC. Cox proportional regression was used to compare OS for the 2 cohorts.

Results: Of the 30,673 patients who met inclusion criteria, 18,484 (60.3%) received NST followed by BCT, and 12,189 (39.7%) with mastectomy and AC without radiotherapy. The 5-year and 7-year OS were significantly different between the groups: 88.2%/83.8% for patients treated with NST followed by BCT, and 83.3%/78% for mastectomy and AC (both $p<0.01$) (Figure A). Kaplan-Meier survival analysis of patients stratified by treatment and initial clinical stage demonstrated higher survival for patients who received NST followed by BCT (Figure B-D). After controlling for significant demographic and tumor features, patients treated with mastectomy and AC had an increased risk of death (HR 1.8, 95%CI 1.66-1.96, $p<0.001$) compared to patients undergoing NST and BCT.

Conclusions: Women with operable clinical Stage II-III breast cancer treated with NST followed by breast conservation therapy may achieve an improved OS compared with those treated with mastectomy and AC. This may reflect a benefit derived from early administration of systemic therapy and adjuvant radiotherapy. Further prospective validation is warranted.

Figures: Kaplan-Meier survival analysis in both cohorts (A) and stratified by clinical stages (B-D)



403115 - Neoadjuvant trastuzumab in HER2-positive breast cancer, is pathological complete response enough?

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Background/Objective: Patients with HER2-positive (HER2+) breast cancer in II-IIIA stages treated with neoadjuvant chemotherapy plus trastuzumab (NCT), increased pathological complete response (pCR) to 65.2%; in local advanced breast cancer (LABC) including inflammatory carcinoma, is reported in 38%. Disease-free survival (DFS), and overall survival (OS) is better, and pCR is considered as a good prognostic factor. pCR is greater in pure HER2+ subtype (50%) compare to Luminal/HER2+ (31%). Central nervous system (CNS) metastases could occurred in 30-50% over time, with median survival of 2 years. The objective of the study was to identify patients with HER2+ breast cancer who could relapse, especially in CNS even with pCR after NCT.

Methods: A retrospective cross-sectional study was conducted, including patients with HER2+ breast cancer I-III stages treated with NCT. Inclusion years were from 2009 to 2014, with at least 18 months of follow-up. pCR was defined as absence of invasive carcinoma in surgical specimen. OS was calculated

since first chemotherapy and DFS since surgery. Surrogate molecular subtypes were classified. Proportions test and logistic regression were used for analysis as appropriate. P value <0.05 was considered statistically significant (2-sided).

Results: We included 302 patients with age of 51 years; LABC were documented in 90.7%, with tumor size of 5.4 cm; the mean pre-operative trastuzumab applications were 5 doses. Conservative surgery was done in 17.2%, and mastectomy in 82.6%. Luminal/HER2+ were reported in 141 (46.7%), and pure HER2+ in 161 (53.3%). Pure HER2+ have some differences compare to Luminal/HER2+ cases (p<0.05): have less early stages (6.2% vs. 12.8%), more inflammatory carcinomas (26.7% vs. 13.5%), higher Ki67 expression (30% vs. 20%), less conservative surgeries (10.75% vs. 24.82%), and more pCR (57.4% vs. 34%). Appropriated pathological evaluation was done in 299 cases. pCR were reported in 138 (46.1%), and non-pCR in 161 (53.8%). Differences between patients are shown in the table. No pCR were identified in Stage I or grade-1 tumors. There were more pCR (p<0.05) with higher the grade, IIB clinical stage, pure HER2+, lower hormonal receptor, and higher Ki67 expression. Inflammatory carcinomas developed pCR in 45.9%. OS were 34 months (18-76), similar between groups. Recurrence occurred in 17.7%, 6 months earlier in pure HER2+ compared to Luminal/HER2+ (17 vs. 23, p=0.267). Visceral recurrences were more frequent. CNS was the first site of visceral relapse, more frequent in pure HER2+; it occurred in 50.9% of all patients with any type of recurrence over time. Risk factors associated with recurrence were pure HER2+ (OR 2.48, 95%CI= 1.26 4.86, p=0.008), and the presence of extracapsular invasion (OR 6.54, 95%CI= 3.21 4.86, p=0.008). The only risk factor associated to OS was relapse (OR 28.89, 95%CI= 9.27 -89.99, p<0.001).

Conclusions: pCR in HER2+ LABC was little higher with known factors to pCR development. Visceral recurrence was more frequent, especially to CNS, the 1 occurred in <2 years from first chemotherapy, and affected 50% of all relapsed patients over time, regardless the first site of recurrence. Patients with pure HER2+, and with extracapsular invasion, need to be follow-up closer to opportunely identify CNS relapse, and evaluate the integration of routinely CNS computed tomography or magnetic resonance as part of follow-up studies even in presence of pCR.

Table: Clinical, histological, and outcome features of pathological response

VARIABLE	No pCR*	pCR*	*p*
Patients	**161**	**138**	
Clinical stage			*0.018*
I	4 (100%)	0	
IIA	12 (50%)	12 (50%)	
IIB	18 (34.6%)	34 (65.4%)	
IIIA	56 (58.3%)	40 (41.7%)	
IIIB	58 (59.8%)	39 (40.2%)	
IIIC	13 (50%)	13 (50%)	
Histology			*0.491*
Ductal	158 (54.1%)	134 (45.8%)	
Lobular	1 (50%)	1 (50%)	
Micropapillary	2 (50%)	2 (50%)	
Lymphovascular invasion	36 (51.4%)	34 (48.6%)	*0.614*
Grade 1	3 (100%)	0	*0.032*
Grade 2	85 (60.3%)	56 (39.7%)	
Grade 3	67 (47.9%)	73 (52.1%)	
Intraductal association	44 (53%)	39 (47%)	*0.872*
Luminal /HER2+ subtype	93 (66%)	48 (34%)	*0.000*
Pure HER2+ subtype	68 (43%)	90 (57%)	
Estrogen receptor (percentage of inked cells) in Luminal cases, n= 141	37.3%	17.9%	*0.000*
Progesterone receptor (percentage of inked cells) in Luminal cases, n= 141	13.7%	6.6%	*0.000*
Ki-67 (percentage of expression in inked cells)	20 (4 – 88)	30 (5 – 85)	*0.002*
Initial tumor size (mm)	55 (15 – 230)	51 (12 – 200)	*0.050*
Relapse, n= 53	36	17	*0.122*
First site of recurrence (visceral)	22 (61.1%)	14 (82.4%)	
First site of recurrence (non-visceral)	14 (38.9%)	3 (17.6%)	
First site of recurrence, n= 53			*0.279*
Locoregional	9 (25%)	1 (5.9%)	
Bone	5 (13.9%)	2 (11.8%)	
Lung or mediastinum	6 (16.6%)	1 (5.9%)	
Liver	4 (11.1%)	1 (5.9%)	
CNS	12 (33.3%)	12 (70.6%)	
CNS relapse during follow-up in patients with any recurrence, n = 53	15 (41.7%)	12 (70.6%)	*0.049*
CNS relapse from first chemotherapy (months), n= 29	16	21	*0.250*

**Mean ± SD, median (range), or number of cases with percentage.*
pCR= pathological complete response; CNS= central nervous system.

404167 – Non-operative management for invasive breast cancer after neoadjuvant treatment. Is less more?

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Background/Objective: Improved imaging and neoadjuvant therapy (NAT) have led to higher pathologic complete response rates (pCR) in patients with invasive breast cancer. This has questioned the necessity of surgery and axillary lymph node (ALN) dissection in these patients. Prospective clinical trials are implementing extensive core biopsies of the tumor bed of patients with image based pCR as a means to identify and spare them breast surgery. In addition, it is anticipated that patients with pCR are most likely going to have no or minimal disease in ALN as well. To verify the feasibility of these trials, we performed a pathologic analysis of all our patients who have undergone NAT from 2009 to present.

Methods: Using a single institution pathology database, we identified 312 patients. Clinical and pathologic information including gross and microscopic descriptions as well as biomarker status was gathered.

Results: pCR was 50% for patients with negative ALN pretreatment but only 26% for patients with positive ALN at diagnosis. Despite achieving pCR in the breast, up to 10% of patients with positive ALN and 1% with negative ALN had persistent disease. Interestingly up to 13% of patients who were presumed to have no ALN disease either clinically and or by imaging were found to have metastatic carcinoma in ALN. The metastases were predominantly (80%) <5mm, and missed on physical exam and or due to biopsy sampling error. pCR in breast and ALN directly correlated with tumor size, ALN disease, HER2 positivity, and triple negativity.

Conclusions: All invasive carcinomas decrease in size either by concentric shrinking or satellite loss of tumor foci. The latter phenomenon was mostly seen in tumors <1cm. This raises the potential of core biopsy sampling error of tumor beds in small tumors, which can falsely downstage to pT0. Further study is warranted to define selection criteria for potential candidates to avoid breast/axillary intervention post neoadjuvant chemotherapy.

Table: Breast carcinomas treated with NAC classified by stage and biomarker status

AJCC	ALN (+) =50%	Her2+/triple(-) (%)	ALN (-) =50%	Her2+/triple(-) (%)
pT0N0	26	75	49	82
pT0N1	10	60	1	0
pT1N0	10	50	25	60
pT1N1	26	35	3	50
pT2N0	1	0	10	20
pT2N1	21	10	9	8
pT3N0	0	0	3	50
pT3N1	6	40	0	0

402904 - Major reduction in axillary lymph node dissections after neoadjuvant systemic therapy in node-positive breast cancer by combining PET/CT and the MARI procedure (Marking Axillary lymph nodes with Radioactive Iodine Seeds)

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Background/Objective: Axillary lymph node dissection (ALND) is still frequently performed in node-positive (cN+) breast cancer patients, regardless of the response to neoadjuvant systemic treatment. Combining PET/CT pre-NST and the MARI-procedure (Marking Axillary lymph nodes with Radioactive Iodine seeds) after neoadjuvant systemic therapy (NST) has the potential to avoid unnecessary ALNDs. In the present study, we present the results of the implementation of this strategy.

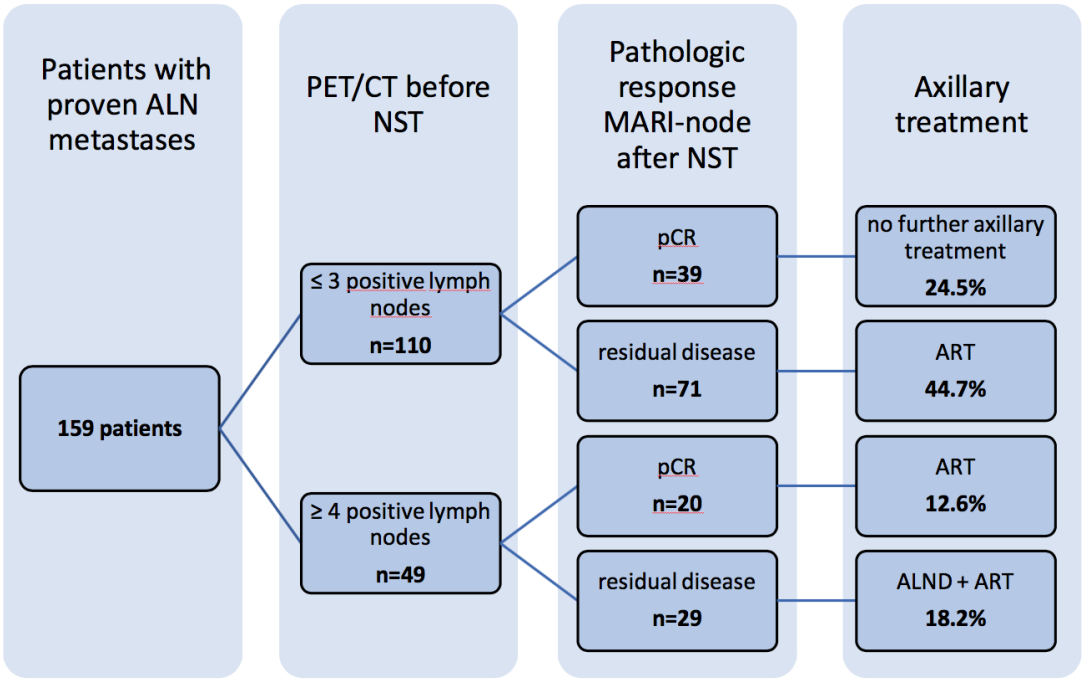
Methods: All breast cancer patients treated with NST at the Netherlands Cancer Institute who underwent a PET/CT and MARI-procedure from July 2014 until July 2017 were included. All patients underwent tailored axillary treatment according to a protocol based on the combined results of the PET/CT pre-NST and the MARI-procedure. In this protocol, patients with 1-3 FDG-avid axillary lymph nodes (ALNs) on PET/CT (cN<4) and a tumor-negative MARI-node receive no further axillary treatment. cN(<4) patients with a tumor-positive MARI-node receive local-regional radiotherapy, as well as patients with 4 FDG-avid ALNs (cN(4+) and a tumor-negative MARI-node after NST. An ALND is only performed in cN(4+) patients with a tumor-positive MARI-node.

Results: Data from 159 patients who received a PET/CT pre-NST and a MARI-procedure post-NST were analyzed, of whom 110 patients had 1-3 and 49 patients had 4 FDG-avid ALNs on PET/CT prior to NST. ALND was omitted in 130 patients (82%). Local-regional radiotherapy was administered in 91 patients (57%) and 39 patients (25%) received no further axillary treatment (Figure).

Conclusions: In an era of possibilities of de-escalation of loco regional treatment due to excellent response on neoadjuvant systemic treatment, we now present a method resulting in a major reduction of 82% of ALNDs in cN+ breast cancer patients by combining pre-NST axillary staging with PET/CT and post-NST staging with the MARI-procedure.

Figure: Results of tailored axillary treatment of N plus patients who received neoadjuvant systemic treatment

NST neoadjuvant systemic therapy, *PET/CT* positron emission tomography combined with computed tomography, *MARI* Marking the Axilla with Radioactive Iodine Seeds, *ALN* axillary lymph node, *pCR* pathologic complete response, *ALND* axillary lymph node dissection



NSM

403573 - The impact of neoadjuvant chemotherapy on complications following nipple-sparing mastectomy

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Background/Objective: As the demand for nipple-sparing mastectomy (NSM) increases and surgeons expand the eligibility criteria, a subset of patients may become candidates following neoadjuvant chemotherapy (NC). However, the impact of NC on post-operative complications remains unclear, as the limited literature is discordant. The purpose of this study is to better characterize the effects of NC on surgical complications following NSM.

Methods: A single-institution, retrospective chart review was performed on patients undergoing NSM from 1989 to 2015. Patient demographics, surgical intervention, systemic treatment, and complication rates were collected. Primary outcomes were rates of post-operative complications including nipple areolar ischemia and necrosis, skin flap ischemia and necrosis, implant loss, infection, wound dehiscence, hematoma, and seroma. A secondary outcome was the number of unintended operations following initial NSM. Each breast was considered independently for analysis, and subgroups were delineated into those receiving either NC, adjuvant chemotherapy (AC), or no chemotherapy. Univariate logistic regression was used to determine odds of developing surgical complications.

Results: A total of 636 breasts were identified for review. Of these, 44 received NC, 213 received AC, and 379 did not receive chemotherapy. Overall complication rates were 45.5%, 38.0% and 31.4%, respectively. Those receiving NC were significantly more likely to have skin flap ischemia (OR 3.28, 95% CI 1.34 - 8.00, $p<0.01$) than patients who had adjuvant chemotherapy and significantly more likely than patients not having chemotherapy (OR 4.02, 95% CI 1.72 - 9.36, $p<0.01$; Table). Patients with flap ischemia were subsequently more likely to undergo an additional, unintended operation (OR 4.35, 95% CI 2.31 8.17, $p<0.01$). There was no difference in nipple areolar necrosis, wound dehiscence, or infection for patients undergoing chemotherapy (adjuvant vs. neoadjuvant). Patients undergoing AC had significantly increased odds of developing an infection compared to patients not receiving chemotherapy (OR 2.44, 95% CI 1.26 4.71, $p<0.01$). The odds of a hematoma or seroma was significantly reduced in both the adjuvant (OR 0.45, 95% CI 0.19 1.05, $p=0.05$) and neoadjuvant groups (no occurrences, $p<0.01$) compared to the no chemotherapy group.

Conclusions: Post-operative complication rates in NSM patients undergoing NC are comparable to those receiving adjuvant chemotherapy. Patients undergoing NC have significantly increased rates of flap ischemia following NSM compared to both AC and no chemotherapy patients. However, there is no additional risk for nipple areolar complex necrosis, wound healing, or implant loss with NC prior to NSM.

Table: Odds ratio (OR), 95% confidence intervals (CI), and p-values (*p*) compared to patients with no chemotherapy

	Neoadjuvant chemotherapy		*Adjuvant chemotherapy*	
Surgical complications	OR (95% CI)	*p*	OR (95% CI)	*p*
Skin flap ischemia	4.02 (1.72, 9.36)	0.003	1.22 (0.65, 2.33)	0.537
Skin flap necrosis	0.47 (0.06, 3.67)	0.429	1.19 (0.56, 2.54)	0.640
Nipple ischemia	0.83 (0.24, 2.84)	0.767	1.51 (0.88, 2.61)	0.132
Nipple necrosis	0.70 (0.16, 3.08)	0.623	0.98 (0.50, 1.93)	0.958
Hematoma / seroma	**	<0.001	0.45 (0.19, 1.05)	0.049
Infection	1.69 (0.47, 6.04)	0.443	2.44 (1.26, 4.71)	0.008
Implant loss	1.65 (0.72, 3.79)	0.254	1.07 (0.65, 1.75)	0.802
Wound dehiscence	1.01 (0.12, 8.14)	0.996	1.60 (0.61, 4.21)	0.345
Any complication	1.82 (0.97, 3.42)	0.063	1.34 (0.94, 1.91)	0.102

**No events occurred in this group.

404206 - Prophylactic nipple-sparing mastectomy: Characteristics of Brazilian patients

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Background/Objective: Nipple-sparing mastectomy (NSM) has been successfully performed for the treatment of breast cancer and for women at high risk for developing breast cancer. Approximately 40-50% of the hereditary breast and ovarian cancer syndromes are associated with mutations in the BRCA1 and BRCA2 genes, while only 10% is related to mutations in other genes, such TP53, PTEN, PALB2, CHECK2, and STK11. Women with mutations in these genes have a significant lifetime risk for developing breast cancer and can opt for risk-reduction mastectomy. Women with a positive family history of cancer also can opt for prophylactic surgery as prevention method. Current studies showed reduced risk to breast cancer after the use of prophylactic nipple-sparing mastectomy. Despite the good aesthetic and clinical outcomes, one of the concerns regarding NSM is the safety of nipple-areola complex preservation. Some authors demonstrated increased risk of breast cancer recurrence after NSM; however, others identified no difference in overall survival and local recurrence comparing NSM with skin-sparing mastectomy or conventional total mastectomy. Complication rates for NSM have been reported to be 16-22% and included nipple-areolar complex necrosis, hematoma, and implant infection.

Methods: Patient data were reviewed retrospectively for patient characteristics, cancer recurrence, and complications rates. Descriptive statistics were utilized to summarize these findings. All patients were operated by the same breast surgeon in 3 different institutions in Brazil. Patients with completed medical records were included in our study.

Results: The mean patient age was 42,64 years (range, 23-64) and 13 (31%) patients aged 35 years. Twenty-two patients (52,4%) who underwent bilateral prophylactic NSM were BRCA mutation carriers, 1 presented Li-Fraumeni syndrome (TP53 mutation), and 1 presented ATM gene mutation. Most of the patients reported a history of breast cancer in the family (83,3%), and 10 presented ovarian cancer in the family. Nine patients presented previous breast cancer, and 1 patient reported uterine cancer. There were 3 (7%) incidental diagnosis of CDIS, 1 patient was BRCA 1 mutation carrier with family history of breast and ovarian cancer, and the other 2 were negative for genetic mutations; however, presented family history of breast cancer. There was 1 newly diagnosed breast cancer in the 42 patients undergoing prophylactic NSM at a mean follow-up of 18.7 months. This patient was BRCA2 mutation carrier with family history of breast cancer and developed unilateral breast cancer with lymph node micrometastasis. Hematoma and dehiscence occurred in 2 patients (4,7%).

Conclusions: Our findings demonstrated efficacy and safety to perform NSM as prophylactic surgery with good outcomes and low complication rates at short-term follow-up.

403045 - Nipple-sparing mastectomy at a single institution: Should tobacco use be a contraindication?

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Background/Objective: Nipple sparing mastectomy (NSM) is a cosmetically pleasing alternative to simple or skin-sparing mastectomy in the appropriately selected patient. The aim of this study was to review our experience with NSM including recurrence rates and complication rates, and to identify variables that increase risk for complications.

Methods: Patients who underwent NSM at our institution from September 2008 to August 2016 were identified after IRB approval. Data collected included patient age, tobacco use, tumor size, hormone receptor status, lymph node status, radiation and chemotherapy treatment, incision type, and reconstruction type. Statistical analyses were performed using an ANOVA test for numerical co-variates and a chi-squared test for categorical variables.

Results: From September 2008 to August 2016, a total of 238 patients underwent 431 NSM, of which 81% percent were bilateral, and 19% were unilateral. Thirty-one percent of NSM were performed for breast cancer prophylaxis during the study period. A total of 297 (69%) NSM were performed due to a cancer diagnosis, including Stage 0 (27.6%), I (45.4%), II (24.7%) and III (2.3%) breast cancer. Five patients required nipple-areola complex (NAC) resection due to positive margins (2.9%). The overall rate of wound complications in our cohort was 15.6%, which resulted in at least 1 additional surgical intervention in greater than 90% of patients. However, only 6 (1.4%) patients required NAC resection due to nipple necrosis. Patients using tobacco at the time of surgery had significantly increased rates of complication (33.3% vs. 13.7%, $p<0.001$; Table), as were those who required adjuvant radiation therapy after NSM (28.6% vs. 14.3%, $p=0.026$; Table). NSM performed for hormone receptor-negative cancers had a higher rate of complications than those performed for HER2-positive and hormone-positive cancers, and significantly higher rates of complications than those performed for breast cancer prophylaxis (37.5% vs. 13.1%, $p=0.018$; Table). Only 1 patient had a local chest wall recurrence during the follow-up period and, to date, no patients are known to have distant recurrence.

Conclusions: Performance of NSM at our institution has increased over the last 8 years, and the majority of procedures are performed in patients with malignancy. The oncologic safety is confirmed by the

exceedingly low rate of local chest wall recurrence. Tobacco use and adjuvant radiation therapy remain the most significant risk factors for post-operative complications. These findings highlight the need for careful patient selection and patient counseling regarding modifiable risk factors and expected outcomes. Whether patients who are actively using tobacco products should be offered a NSM remains a topic of debate.

Table: Nipple-sparing mastectomy complication risk factors

		Complications		P-value
		No (N=362)	Yes (N=67)	
Smoking	No	334 (86.3%)	53 (13.7%)	< 0.001
	Yes	28 (66.7%)	14 (33.3%)	
Radiation	No	335 (85.7%)	56 (14.3%)	0.026
	Yes	25 (71.4%)	10 (28.6%)	
Hormone Receptor Status	Prophylactic	218 (86.9%)	33 (13.1%)	0.018
	Positive	113 (83.7%)	22 (16.3%)	
	Her2+	8 (80%)	2 (20%)	
	Negative	15 (62.5%)	9 (37.5%)	

403936 - Prophylactic nipple-sparing mastectomy: Indications, complications, and oncologic outcomes

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Background/Objective: Nipple-sparing mastectomy (NSM) is increasingly performed for risk reduction in high-risk groups. There are limited data regarding complications and oncologic outcomes in women undergoing bilateral prophylactic NSM. We reviewed our institutional experience with prophylactic NSM and examined the indications, rates of post-operative complications, incidence of occult malignant disease, and subsequent breast cancer diagnosis.

Methods: From 2000-2016, women undergoing bilateral prophylactic NSM were identified from a prospectively maintained database.

Results: There were 192 patients who underwent bilateral risk-reducing NSMs. Indications were BRCA1 or BRCA2 mutations in 117 (60.9%) patients, family history of breast cancer in 35 (18.2%), lobular carcinoma in situ (LCIS) for 29 (15.1%), and other reasons in 11 (5.7%). Immediate breast reconstruction was performed in 191 patients. There were 176 (91.7%) patients who underwent tissue expander/implant based procedures. Out of 384 breasts, 116 (30.2%) had some evidence of skin necrosis at follow-up, and most resolved spontaneously, with only 24 (6.2%) breasts requiring debridement. Other complications included wound infection in 16 breasts (4.2%), expander/implant removal in 8 breasts (2.1%), and hematoma in 5 breasts (1.3%). There was an incidental finding of ductal carcinoma in situ (DCIS) or invasive carcinoma in 14 (3.6%) and 6 (1.6%) breasts, respectively. The nipple

areolar complex (NAC) was entirely preserved in 378 mastectomies. There were a total of 6 (1.6%) nipple excisions, of which 3 (0.8%) were performed due to incidental DCIS at the nipple margin. At median follow-up of 36.8 months (range, 1.3-194), there were no known cases of local recurrences in those with incidental invasive breast cancer or DCIS, and no new diagnosis of breast cancer in the prophylactic cases.

Conclusions: Our institutional experience supports the use of prophylactic NSM in high-risk patients. The majority of patients were able to preserve their nipples, post-operative complication rates were low, and, with limited follow-up, there were no new cases of breast cancer.

402896 – Nipple-sparing mastectomy is safe in BRCA mutation carriers

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Background/Objective: There are limited data evaluating the oncologic and peri-operative safety of nipple-sparing mastectomy (NSM) in patients with BRCA genetic mutations. The aim of this study was to identify recurrence rates and peri-operative complications in BRCA mutation carriers undergoing NSM.

Methods: Following IRB approval, we interrogated a prospectively collected institutional database of breast surgery procedures. Patients who tested positive for BRCA1 or BRCA2 mutation undergoing skin sparing mastectomy, wherein the nipple-areolar complex (NAC) was preserved, were identified. Patient characteristics, peri-operative details, and recurrences were evaluated.

Results: From August 2009 to May 2016, 44 patients (n=1 with both BRCA 1 and 2 mutation) with BRCA1 (n=20) or BRCA2 (n=23) mutation underwent 85 NSMs, including 41 bilateral operations. The mean age at NSM was 41.5 years, and 2 patients were male. The majority were risk-reduction surgeries (68 NSMs, 80%), of which incidental cancer was found in 1 (1.5%) patient. Of the 85 NSMs, 24 were single-stage reconstruction (18 autologous), 57 2-stage reconstruction (56 implant-based, 1 autologous), and the 2 male patients underwent bilateral NSM without reconstruction. The median follow-up was 30.9 months (range 34 days 100 months). There were no locoregional recurrences in either prophylactic or therapeutic patients. One patient who underwent total mastectomy of the affected breast and contralateral prophylactic NSM was found to have pulmonary metastasis and died of disease at 21 months' follow-up. The overall complication rate was 19/85 operations (22.4%), and 7 patients (10 NSM, 11.8%) required re-operation: 4 for flap debridement (2 bilateral), 3 tissue expander explant or exchange (2 bilateral), 3 hematoma evacuation (1 bilateral), and 1 autologous flap microvascular venous thrombosis. There were 6 (7.1%) partial nipple necrosis, 2 (2.4%) total NAC loss, 4 (4.7%) breasts with partial thickness, and 7 (8.3%) with full thickness mastectomy flap necrosis. There were no statistically significant difference on demographic features, pathology findings, or operative features between surgeries with and without complications.

Conclusions: This single institution experience confirms the recent literature that NSM in BRCA1 or BRCA2 mutation carriers is associated with acceptable peri-operative complication and low early locoregional recurrence rates. Although follow-up is ongoing, NSM appears to be an oncologically safe option for female and male BRCA1 or BRCA2 mutation carriers.

402776 – Nipple-sparing mastectomy after neoadjuvant chemotherapy: Identifying patients at high risk for complications

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Background/Objective: Indications for nipple-sparing mastectomy (NSM) have expanded over time. Neoadjuvant chemotherapy (NACT) has, historically, been a contraindication to NSM due to concerns of increased surgical morbidity following cytotoxic chemotherapy. The aim of this study was to identify factors associated with post-operative complications in patients undergoing NSM after NACT.

Methods: Under IRB approval, we interrogated a prospectively maintained skin-sparing mastectomy institutional database. Patients who had received NACT undergoing NSM with breast reconstruction, wherein the nipple-areolar complex (NAC) was preserved at the conclusion of the operation, were evaluated. Patient characteristics and post-operative complications were examined. Patients with and without complications were compared, and Fisher's exact test was used to compare associations between covariates.

Results: From August 2009 to May 2016, 38 patients underwent 56 NSMs after NACT, of whom 18 patients (1 male) underwent bilateral concurrent NSM, and 6 contralateral prophylactic NSM. The mean follow up was 35.2 months (median 30 months, range 27 days 90 months). Of the 56 NSMs, 10 underwent single stage reconstruction (4 autologous), 44 2-stage reconstruction (all tissue expander/implant), and the single male patient underwent bilateral NSM without reconstruction. There were 5 (8.9%) patients noted to have partial nipple necrosis, no total NAC loss, 3 (5.4%) breasts with partial thickness, and 6 (10.7%) with full thickness mastectomy flap necrosis. The overall complication rate was 15/56 operations (26.8%), and 6 patients (7 NSM) required re-operation: 3 tissue expander explantation (1 bilateral), 2 flap debridement, and 1 hematoma evacuation. Considering risk factors for complications after NACT, only smoking (60% with a complication were smokers versus 12.2% of those without, $p<0.001$) was associated with complication. Age, body mass index, ptosis, breast size, surgical technique, and location of incision were not associated with complications. Although there was a trend towards more complications with use of acellular dermal matrix, this was not statistically significant (60% with complication had acellular dermal matrix versus 39% without complication, $p=0.22$).

Conclusions: NSM after NACT carries comparable complications to that reported for patients undergoing primary surgery by NSM, with smoking a significant risk factor.

Table: Factors associated with peri-operative complication

	With complication (N= 15)	Without complication (N=41)
Age (years, range)	45.6 (36-65)	43.6 (32-65)
BMI (average, range)	25.7 (21-33)	24 (20-38)
Days between last chemotherapy and surgery (average, range)	42.6 (19-105)	67.5 (13-336)
Concurrent bilateral NSM	7 (46.7%)	29 (70.7%)
Malignancy ‡	12 (80%)	20 (48.8%)
Previous breast surgery ‡	3 (20%)	26 (63.4%)
Ptosis (average grade, range)	1.2 (0-3)	1.3 (0-2)
Breast volume (average cc, range)	742.4 (189-1794)	647.3 (232-1799)
Bra cup size C or greater	5 (33.3%)	21 (51.2%)
Smoking (former and current)	9 (60%)	5 (12.2%)
Single stage reconstruction (N, %)	2 (13.3%)	8 (19.5%)
Surgical instrument for flap development		
Plasmablade	6 (40%)	18 (43.9%)
Electrocautery	9 (60%)	23 (56.1%)
Sharp dissection	4 (26.7%)	10 (24.4%)
Incision		
Inframammary fold	8 (53.3%)	26 (63.4%)
Lateral	2 (13.3%)	13 (31.7%)
Peri-areolar	3 (20%)	2 (4.9%)
Vertical	2 (13.3%)	0
Initial reconstruction type		
Tissue expander (TE) with acellular dermal matrix (ADM)	9 (60%)	16 (39%)
TE without ADM	4 (26.7%)	15 (36.6%)
Implant	0	6 (14.6%)
Autologous	2 (13.3%)	2 (4.9%)

‡ In the breast that is being undergoing operation

Oncoplastics

399983 - Comparing conventional breast-conserving surgery with the minimally invasive approach technique to treat early breast cancer - a retrospective case control study

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Background/Objective: The objective of the study was to compare the oncological safety and aesthetical results between the minimally invasive technique and the conventional breast-conserving surgery. Breast-conserving surgery was developed to avoid mastectomy and has become the standard of care in early-stage breast cancer. Patient concerns with aesthetics have led to the development of oncoplastic surgical approaches. It has been demonstrated that the aesthetic success in breast cancer surgical treatment leads to improved sexual and social recovery. In patients who have no desire or no need for associated mammoplasty, minimally invasive treatments allow the maintenance of the breast pre-surgical appearance. The minimally invasive technique is an oncoplastic surgery aimed to remove both the breast tumor and the sentinel lymph node through 1 incision, thus providing better aesthetic results than the conventional breast conservative 2-incision technique.

Methods: We retrospectively evaluated 2 cohorts of 60 consecutive early breast cancer patients (invasive breast cancer measuring no more than 25mm and clinically axillary negative lymph nodes) operated by either conventional breast-conserving surgery (n=26) or 1 incision surgery (n=34). We selected patients who have no desire or no need for associated mammoplasty. We compared the mammary volume tissue removed; surgical time; number of dissected lymph nodes; surgical complications such as seroma, infection, and dehiscence of the surgical wound; and deformities, retractions, and subsequent aesthetic sequelae.

Results: In the minimally invasive technique group, the breast volume removed was significantly lower than in the conventional surgery technique group as was the surgical time and the number of dissected lymph nodes (Table). No cases required enlargement of the margins, and aesthetical results were better in the minimally invasive technique with only incision group.

Conclusions: The minimally invasive approach to treat early breast cancer was shown to be similar to the conventional breast-conserving surgery in terms of oncologic outcomes but providing better cosmetic result.

Table: Demographics and surgical results

	Minimally invasive surgery (n=34)	Conventional surgery (n=26)	P value
Age			0.241
Medium	53.9 (11.4)	57.4 (11.3)	
Range	33 – 76	34 – 85	
Disease stage			0.482
I	30 (88.2)	21 (80.8)	
II	4 (11.8)	5 (19.2)	
Incision			>0.99
Axilla	1 (3.1)	0 (0.0)	
Periareolar	21 (65.6)	17 (65.4)	
Sulcus	10 (31.3)	9 (34.6)	
Breast dissected volume			<0.001
Medium	16.3 (8.5; 26.7)	42.4 (14.4; 112.2)	
Range	2 – 90	5 – 270	
Dissected lymph nodes			<0.001
medium (IIQ)	2 (1 – 5)	4 (1 – 13)	
Range	1 – 18	1 – 31	
Surgical time (min)			0.010
Medium	130 (105; 170)	180 (110; 240)	
Range	30 – 220	50 – 275	

403416 - Oncoplastic neoareolar reduction with nipple reconstruction: Improving cosmesis for centrally located cancers

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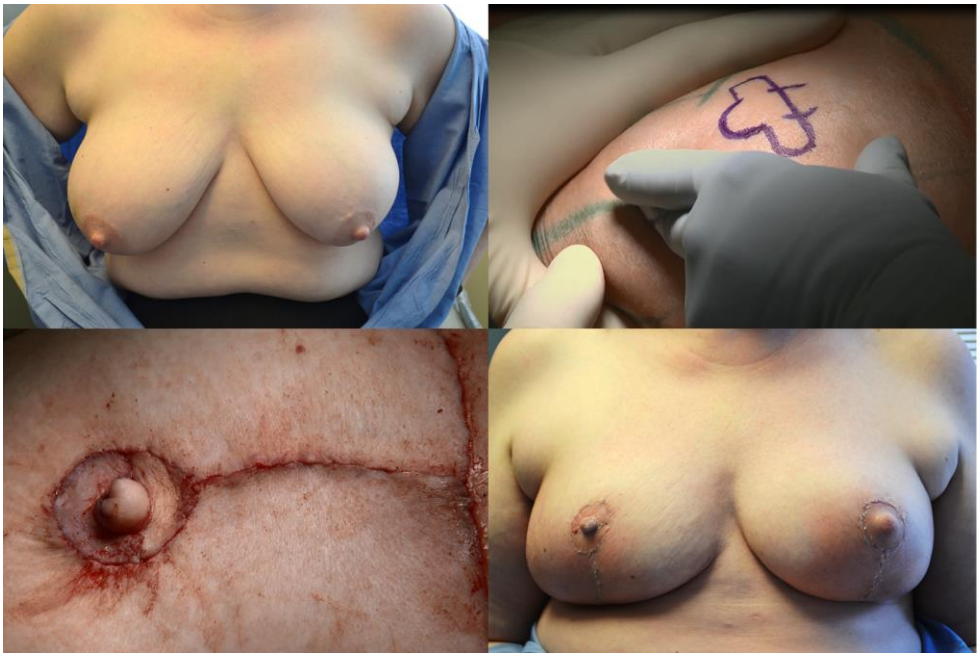
Background/Objective: Patients with breast cancers that abut the nipple-areolar complex are frequently advised to undergo mastectomy because of concern for poor cosmetic outcomes associated with central resections. Neoareolar reduction mammoplasty with immediate nipple reconstruction is a novel technique that may minimize the number of operations required for reconstruction. We hypothesized that this technique would allow for breast conservation and excellent cosmetic outcomes in patients with centrally located breast cancers.

Methods: This is a single-institution, retrospective review of patients with centrally located breast cancers who underwent central partial mastectomy reconstructed with neoareolar reduction mammoplasty and immediate nipple reconstruction with contralateral reduction mammoplasty for symmetry. Patients were offered this procedure regardless of presence of obesity, medical co-morbidities, or smoking history. Cosmesis scores were assigned by the operating surgeon at 6 months post-op based on objective criteria. Patient demographics, imaging and pathology size, margin width, mastectomy and re-excision rates, and cosmesis were evaluated.

Results: Thirteen patients underwent central partial mastectomy with neoareolar reduction mammoplasty and immediate nipple reconstruction with contralateral reduction mammoplasty for symmetry between January 24, 2017 and October 05, 2017. Average patient age was 61.8±9.5 years, and average BMI was 29.4±5.9 kg/m2. Average lesion size was 52.8±47.7mm on pre-operative imaging, and average disease span on final pathology was 54.7±48.6mm. Five patients (38.4%) had recent smoking histories, and 1 patient (7.7%) had diabetes. No ink on tumor was achieved in 12 (92.3%) patients. Five (38.4%) patients had inadequate margins, all for DCIS; 4 of them underwent re-excision, and 1 (7.7%) patient underwent mastectomy. Cosmesis scores were assigned to 9 patients, with 8 (88.9%) achieving good to excellent cosmetic results. Complications occurred in 5 (38.4%) patients, including 1 patient with minor incision separation, 1 patient with a small seroma, and 3 patients who had nipple-areolar complex ischemia of the reconstructed nipple. One patient required debridement of the nipple-areolar complex and delay of her adjuvant radiation therapy. No other complications required interventions or delays in initiation of adjuvant therapies. Four of the 5 patients with complications had cosmetic outcomes reported, and all 4 were good to excellent.

Conclusions: Central partial mastectomy with reconstruction using a neoareolar reduction mammoplasty with nipple reconstruction as a single-stage operation can allow for successful breast conservation with excellent cosmetic outcomes in patients with centrally located tumors. This technique allows patients to avoid mastectomy and to minimize the number of operations required for reconstruction. In this cohort, presence of extensive DCIS resulted in significant need for re-excision; however, re-excision can be successfully performed without compromising cosmetic outcomes. Although complications occurred in 38.4% of cases, the majority of complications were minor, did not require any intervention, did not delay initiation of adjuvant therapies, and did not significantly impact the final cosmetic result.

Figure: Photos of a 56-year old woman with extensive right breast DCIS abutting the nipple-areolar complex who underwent right central partial mastectomy with neoareolar reduction and immediate nipple reconstruction and contralateral mammoplasty reduction for symmetry: pre-operative photo (a), intra-operative marking of new nipple (b), immediate post-operative appearance of reconstructed nipple (c), and 2 weeks post-operative (d)



404210 - Addressing increased adiposity, patient satisfaction, and functionality with the angel wings technique

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Background/Objective: The Angel Wings Incision (AWI) developed at our institution is a novel concept aimed to address the management of increased adiposity along the lateral latissimus border and lateral chest wall, otherwise known as the dog-ear deformity, in patients undergoing total mastectomy. The objective of this study was to examine post-operative surgical outcomes, after use of the AWI, including patient assessment of pain, functionality, cosmesis, and overall satisfaction.

Methods: This is an IRB-approved, cross-sectional hybrid design study with a retrospective chart review, and assessment of patient perception of the AWI by survey. Included in the study population are female subjects ages 18 years and older who underwent mastectomies with tissue rearrangement and the AWI at our institution from March 2014 to January 2017. A survey was distributed to qualifying patients with questions addressing symptoms and satisfaction during the past week. The patients received 3 questionnaires, a validated measure of body image (10-item EORTC Body Image Scale), a subscale regarding arm symptoms from a validated measure of breast cancer related quality of life (3-item EORTC QLQ-BR23 arm symptom scale), and 6 items derived specifically for this study (formatted in the same manner as the EORTC QLQ-BR23 items, with the same response scale). To interpret findings for body image, we referenced scores from a study published in the *European Journal of Cancer* of 202

mastectomy patients assessed at varying times since surgery. To interpret the arm symptom scores, we used reference scores from a study involving 170 Dutch, 168 Spanish, and 158 American breast cancer patients surveyed at varying phases of treatment covering symptoms and side effects related to different treatment modalities, body image, sexuality, and future perspective. The data were analyzed with descriptive statistics.

Results: A total of 136 patients underwent mastectomy with AWI at our institution during the aforementioned timeframe. Of the 136 surveys distributed, 17 were returned. We examined the proportion of patients who reported at least moderate problems in each of 5 areas (i.e., scoring 3 or 4 on a 0-4 response scale, corresponding to quite a bit or very much). At the time of the survey, few patients indicated dissatisfaction with the appearance of skin under the arm (11.8%, n=2) or wished that additional skin or tissue had been removed from under the arm (11.8%, n=2). Very few participants reported having difficulty with pain under the arm (5.9%, n=1), problems with daily activities (5.9%, n=1), or perceptions that their breast prosthetic or brassiere did not fit well (5.9%, n=1). The great majority indicated that they would recommend this type of incision to other mastectomy patients (88.2%, n=15); 2 were undecided. For the questions regarding EORTC Body Image Scale (e.g., feeling self-conscious about your appearance, find it difficult to look at yourself naked, dissatisfied with the appearance of your scar, etc.), at the time of the survey, patients reported mean body image scores of 6.53 (SD=7.62). On average, these scores were notably better than those of a reference group of mastectomy patients; the effect size for this difference was large. For the EORTC QLQ-BR23 Arm Symptom scale (i.e., pain in your arm or shoulder, swollen arm or hand, difficult to raise your arm or move it sideways), at the time of the survey, patients reported mean arm symptom scores of 23.53 (27.18). On average, these scores were comparable to the level of arm problems reported by a reference group of breast cancer patients; the effect size for this difference was negligible.

Conclusions: The AWI appears to be a safe and reproducible technique during mastectomy. The resulting tissue flaps create a smooth lateral body contour upon incision closure that is aesthetically pleasing and eliminates dog-ear deformity without compromising functionality.

404270 - Oncoplastic surgery with the 3-D tissue implant maintains post-lumpectomy breast contour

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Background/Objective: Survivorship beyond breast cancer treatment includes both function and appearance of the breast after cancer surgery. A radiated surgical defect in the breast negatively impacts cosmesis and survivorship. Oncoplastic procedures bring surrounding tissues into the lumpectomy cavity to lessen the appearance deficit. Yet, advancing tissue from 1 site to another adds no volume and thins the depth of the breast. Recent use of a 3-dimensional tissue implant used for targeting radiation has the additional benefit of adding volume to the breast at the site of lumpectomy. This volume is similar to the excised tumor volume and enhances the overall cosmetic appearance. We

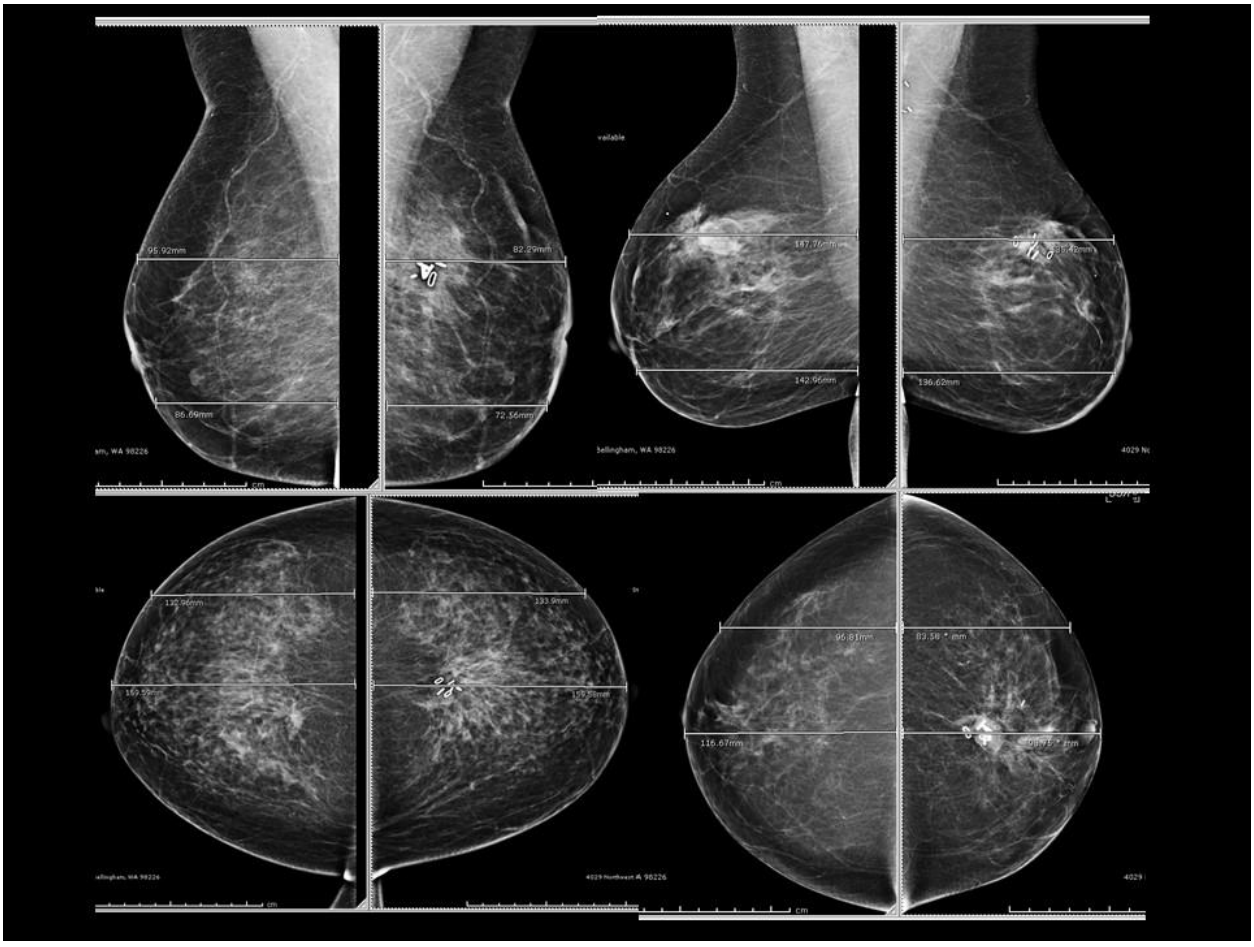
have used the 3-D tissue implant for more than 3 years and have initial 2-year data on the cosmetic appearance of treated patients.

Methods: Between May 2014 and October 2017, we implanted a 3-D tissue implant marker in 157 patients at the time of lumpectomy for breast cancer, often combined with oncoplastic reconstruction and followed by radiation treatment. All patients had serial interviews, physical exams, and serial mammograms to evaluate their cosmetic appearance. Both physician and patient assessed their appearance. We also objectively measured and compared the pre-treatment mammogram and the 2-year, post-treatment mammogram for symmetry and size using each breast as its own control. We compared the relative anterior-posterior measurement of the quadrant bearing the implant as well as the non-cancer quadrant to the similar locations of the pre-treatment mammogram (Figure). Both mammogram positioning and radiation effects would balance. We compared the relative change from baseline in the non-cancer portion of the breast to the change from baseline in the cancer portion of the breast as a percent difference.

Results: All 157 patients were treated with lumpectomy, oncoplastic reconstruction, and placement of a 3-D tissue implant. Three implants were removed due to positive margins. No implants were removed for any other reason. There have been no cancer recurrences. Overall, radiation oncologists felt the 3-DM was useful for treatment planning in 85% of patients. Of the 20 consecutive patients who have completed at least 2 years of follow-up, cosmesis was rated as excellent/good by clinicians (96%) and patients (94%). Mammograms taken at 2 years were closely examined. Both MLO and CC views were examined for changes in forward projection in the quadrant of the cancer, compared with forward projection in the non-cancer bearing quadrant. Whole-breast radiation effect varied among patients. Some had significant shrinkage while others had none. On average, we found that there was a slight decrease in forward projection in the MLO view of 2.4%, while in the CC view there was an increase in forward projection of 0.8%. These changes were not large enough to visualize clinically. Our use of the 3-D implant and oncoplastic tissue advancement maintained the pre-operative contour of the breast after lumpectomy.

Conclusions: The cosmetic appearance of the breast post-lumpectomy and radiation is often complicated by retraction and volume loss. We found that using a combination of oncoplastic surgery combined with a 3-D tissue implant, the forward projection of the breast at the lumpectomy site was preserved and patient satisfaction was good to excellent. Further investigation of the long-term cosmetic effects of breast cancer surgery should be encouraged.

Figure: Example of measured projection same breast pre-surgery (on left) and 2 years' post-surgery (on right). One film is reversed for better comparisons.



404272 - Extreme oncoplasty: Breast conservation for patients who traditionally require mastectomy

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Background/Objective: Extreme oncoplasty is a breast-conserving operation, using oncologic principles and plastic surgery techniques, in a patient who, in most physicians' opinions, requires a mastectomy. Women with lesions >50 mm, with multicentric, or multifocal disease are usually recommended to undergo mastectomy. We believe that extreme oncoplasty can be used to successfully resect T3 (>50 mm), multifocal or multicentric lesions with clear surgical margins, while maintaining or improving the cosmetic outcome.

Methods: There were 194 patients with lesions > 50 mm (often multifocal, multicentric, or locally advanced) identified in a prospective database who underwent breast conservation using a standard or split reduction pattern. They were categorized as the extreme oncoplasty group. These patients were compared to 503 patients in the standard oncoplasty group, comprising patients with unifocal lesions spanning 50 mm. Oncoplastic resection utilizing a reduction incision was followed by whole-breast

radiation therapy. Chemotherapy and hormonal therapy was determined on an individual basis by a medical oncologist. Data collected included tumor span, resection weight, margin width, re-excision rate, rate of conversion to mastectomy, and recurrence rates.

Results: There were 697 patients treated for breast cancer using oncoplastic reduction techniques. Of these, 194 (28%) were considered extreme oncoplastic cases, while 503 (72%) were categorized as standard oncoplastic cases. There was a clear difference between groups in resection weight, tumor span, and tumor margins. With a median follow-up of 28 months, there have been 16 (3.2%) local recurrences in the standard group. Thirty-one (6%) patients in the standard group underwent re-excision, and 5 (1%) opted for mastectomy. With a median follow-up of 20 months, there have been 8 (4%) local recurrences in the extreme group. Twenty (10%) patients in the extreme group required re-excision, and 5 (2.6%) opted for mastectomy.

Conclusions: Patients with tumor span 50 mm treated by standard oncoplastic reduction, as expected, fared better. They achieved the current standard of no ink on tumor 97% of the time compared with 88% for extreme cases. The rates of re-excision and conversion to mastectomy was higher for extreme cases compared with the standard group, but relatively low. Using current standards, 100% of extreme cases would have undergone mastectomy. In our series, only 2.6% of extreme patients underwent mastectomy, and 10% underwent re-excision. The benefits of breast preservation, using extreme oncoplasty techniques, should still be considered for patients who exceed the guidelines established by the prospective randomized trials.

Table: Characteristics of the standard and extreme oncoplastic cohorts

Variable	Standard Oncoplasty	Extreme Oncoplasty
N	503	194
Median Sample Weight	101 Grams	150 Grams
Median Tumor Span	19 mm	65 mm
No Ink on Tumor	97%	88%
Margin ≥ 1 mm	90%	61%
Re-Excision	6%	10%
Mastectomy	1%	2.6%
Median Follow-Up	28 Months	20 Months
Any Local Recurrence	3.2%	4%

404004 - Patient satisfaction and experience after level II oncoplasty and contralateral symmetry surgery performed by a single surgical oncologist

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Background/Objective: Level II Oncoplasty, as originally described by Clough, involves the use of sophisticated mammoplasty techniques to minimize post-operative deformity after breast-conserving surgery. This also most commonly involves contralateral symmetry surgery in the form of a mastopexy or reduction. This surgical approach most routinely involves 2 surgical teams involving both surgical oncology and plastic surgery. We sought to evaluate quality of the patient experience after surgery performed by a fellowship-trained breast surgical oncologist without plastic surgery assistance.

Methods: Fifty consecutive patients who underwent breast conserving treatment using level II oncoplasty techniques and contralateral symmetry surgery completed a 13-item survey with a 5-point Likert-type scale (strongly disagree: 1, disagree: 2, neutral: 3, agree: 4, strongly agree: 5) post-operatively to assess their experience and outcomes after surgery performed by a single breast surgical oncologist.

Results: Our survey revealed that patients felt that an oncoplastic approach in no way limited their ability to be cured of breast cancer (mean score 4.9). Most patients agreed that their post-operative aesthetic result was improved through the use of oncoplastic surgery (mean score 4.5) and would choose this type of surgical approach again (mean score 4.6) and were very satisfied with their experience and care (mean score 4.6). Patients agreed oncoplastic surgery facilitated normalcy without a daily aesthetic reminder of their diagnosis of breast cancer (mean score 3.9). Most patients agreed they would have undergone an additional reconstructive surgery if a single-stage operation could not be performed (mean score 3.9). Patients felt it best that 1 surgeon performing both the resection and reconstruction (mean score 4.7) as well as the importance of both operations being performed simultaneously (mean score 4.8). Patients were comfortable with the lack of a plastic surgeon involved in their care (mean score 4.4). Patients agreed they would recommend other patients seek surgeons with both skills in surgical oncology and reconstruction (mean score 4.6) and that all breast surgeons should be dually trained (mean score 4.9). Patients were not surprised 1 surgeon could perform both cancer resection and reconstruction (mean score 4.2). The primary reason patients stated for choosing oncoplastic surgery was to prevent deformity (mean score 4.1).

Conclusions: Patient satisfaction is high after level II oncoplasty and symmetry surgery performed by a breast surgical oncologist without plastic surgery assistance. Patients expect that their breast surgeon should be capable of both removing their breast cancer and reconstructing their breast and would recommend other seeks surgeons with these skillsets. Breast surgical oncology training programs in the United States should strive to produce surgeons dually trained in oncological and reconstructive surgery as they do in other parts of the world to meet these expectations. While this may be less critical in larger urban centers with an abundance of plastic surgeons, patients in less populated areas with less access would benefit from this new breed of oncoplastic surgeon.

403814 - Skin reduction nipple-sparing mastectomy: Safe and feasible in large volume or ptotic breasts

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Background/Objective: Nipple-sparing mastectomy (NSM) has been increasingly utilized for oncologic treatment and prophylactic risk reduction. Traditionally, patients with very large and/or ptotic breasts have been excluded from consideration of NSM due to concerns regarding excess skin, necrosis, and poor cosmetic outcomes. Skin-reduction NSM (SR-NSM) addresses the problem of excess skin while preserving the nipple areolar complex (NAC), but may result in increased rates of post-operative complications. We describe our early outcomes with SR-NSM in 27 patients (42 breasts).

Methods: Technique for SR-NSM included Wise-pattern de-epithelization around the NAC and on the inferior flap with creation of a new inframammary ridge and auto-dermal flap. Skin reduction was accomplished by imbricating the dermal blood supply with epidermal closure. Patients who underwent SR-NSM at a single institution were identified using a prospectively maintained database. Patient demographics, indications for surgery, procedures, complications, and follow-up were recorded. Minor complications evaluated included cellulitis, seroma requiring aspiration, and superficial wound dehiscence. Complications were considered major if they resulted in hospitalization or re-operation.

Results: Forty-two SR-NSM were performed in 27 patients (median age 52, range 33-69) between October 2014 and October 2017. Nineteen patients had SR-NSM for early-stage breast cancer, of which 9 (47%) also underwent contralateral prophylactic mastectomy (CPM). Six patients with BRCA mutations or a strong family history of breast cancer underwent bilateral prophylactic mastectomy (BPM); 2 additional patients had SR-NSM for contralateral risk-reduction. No incidental cancers were diagnosed in prophylactic mastectomy cases, though LCIS was found in 2 CPM specimens on final pathology. Mean breast weight was 751 g (range 422-1520 g), and mean patient BMI was 26.5 (range 17.3-43.9). All patients had immediate reconstruction with tissue expanders (TEs). Three patients (11%) underwent subsequent elective autologous reconstruction. Fifteen patients (63%) have completed Stage II implant reconstruction, and the remainder are undergoing tissue expansion. Minor complications occurred in 16.7% (7/42) of SR-NSM breasts. Of these, 2 were cellulitis treated with topical or oral antibiotics, 2 were seromas requiring aspiration, and 2 were superficial wound dehiscences. Re-operation was required secondary to infection in 2 cases (4.8%). One required TE removal, and the second occurred after elective revision of an autologous reconstruction. Both patients who required re-operation had a history of prior breast surgery, and 1 was also a former smoker. To date, only 4 patients (14.8%) have elected to undergo an additional operative procedure for cosmetic revision. No patients experienced flap or nipple necrosis requiring operative debridement, and none required NAC excision secondary to positive nipple margins on final pathology. At median follow-up of 17.8 months (range 0.2-35.5), there have been no local or regional recurrences in the 19 breast cancer patients.

Conclusions: Early outcomes for SR-NSM demonstrate a low rate of complications, the majority of which were minor and treated in the outpatient setting. Careful patient selection and modification of known risk factors may further decrease complication rates. No patients required excision of the NAC or re-operation for flap necrosis. In this series, SR-NSM was safe and feasible in patients with large volume and/or ptotic breasts for both oncologic treatment and risk reduction. The addition of skin reduction to NSM expands the eligibility of women who can benefit from preservation of the NAC. Furthermore, skin

reduction in this patient population may lead to improved cosmetic outcomes, as evidenced by the low rate of elective revisions in this series.

404006 - Limited resources and oncoplastic surgery: Initial experience in a low-/middle-income country

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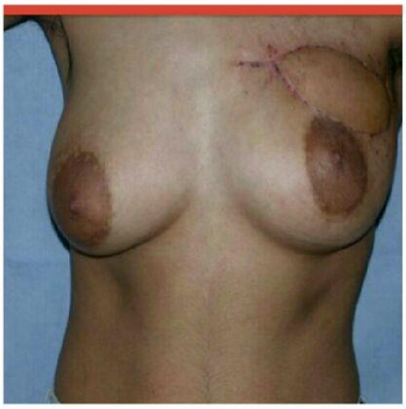
Background/Objective: The aim of this study is to share initial experience of oncoplastic surgery with limited resources in a low-/middle-income socioeconomic country working in absence of proper training in breast surgery working on the principle of see one and do one.

Methods: It is a retrospective case series done in the breast clinic of a teaching hospital in a third-world country. Data were collected from patients presenting in breast clinic over a period of 4 years. Forty-six patients meet the criterion including surgical planning and reconstruction of breast after established diagnosis of carcinoma breast by a breast surgeon.

Results: Oncoplastic surgeries were done in 46 patients over a period of 4 years. Mean age was 45 years. Out of the patients having T1, T2, and T3 tumors were 13 (28.2%), 27 (58.6%) and 6 (13.0%) respectively. Implants were placed in 25 (54.3%). Round Block Mammoplasty was done in 15 (32.6%). Grisotti procedure was done in 3 (6.5%). Contralateral mastopexy was done along with oncoplastic surgery in 27 (58.6%). Latissimus Dorsi flap was done in 2 (4.3%). According to short-term initial results, no recurrence was noted in 1 year of follow-up. Seroma was found in 12 (26.0%), wound infection in 6 (13.0%). No flap necrosis and no implant removal was done in this series.

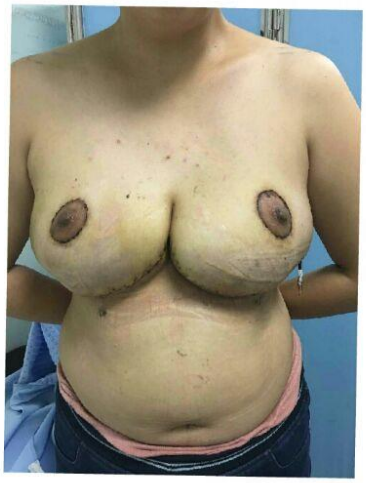
Conclusions: In this era of aesthetics, oncoplastic surgery is emerging as a new approach for breast conservation and minimizing breast deformities being a blend of oncology, plastic, and breast reconstructive surgery. Oncoplastic surgery with limited resources is real challenge.

Figure: Our experience in oncoplastic surgery

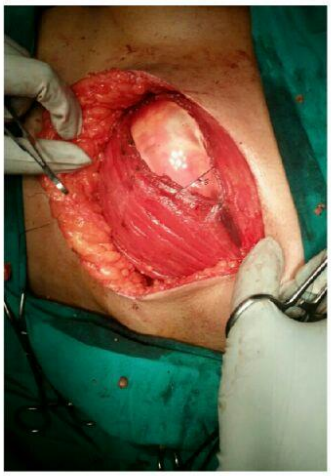


LD flap

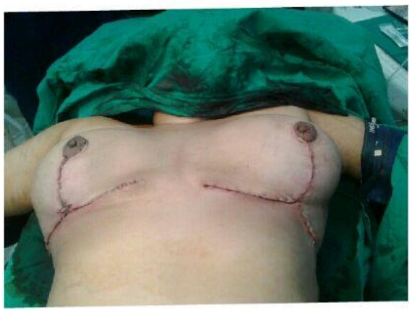
Breast conservation



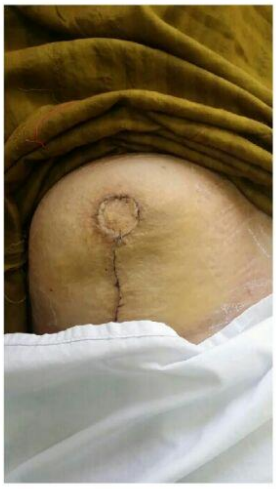
Round block mastopexy



Implant placement



Wise pattern mammoplasty



Grisotti procedure

401027 - A systematic review of utility score assessments in the breast surgery cost-analysis literature

Alexander Yoon[1], Laura Bozzuto[2], Andrew Seto[1], Carla Fisher[3], Abhishek Chatterjee[4]

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Background/Objective: Cost utility analysis is a tool that investigates cost-effectiveness assessment or value pertaining to surgical interventions. Specifically, it asks whether the added clinical effectiveness of an intervention is worth the cost compared to the status quo. An intervention's clinical effectiveness is the quality-adjusted life years (QALYs), which are formed by assessing utility scores of varying health states or clinical outcomes. Specifically, the product of a utility score and life years spent in a particular health state creates the QALYs for that health state. Hence, these utility scores are critically important in determining the cost utility of the surgical intervention being investigated, yet few articles exist in the breast surgery literature providing an educational description of what they represent. In this analysis, we critically reviewed the cost-effectiveness literature to collect existing utility scores related to breast surgery to create a repository of existing utility scores to serve as a resource for future analyses, to address their methodological standardization, and to understand potential gaps in the current research.

Methods: We used PRISMA guidelines and searched MEDLINE and EconLit for all studies that reported utility scores using the terms breast cancer surgery, reconstruction, and surgical treatment of breast cancer. References of included studies were screened for additional eligible publications. Two reviewers independently assessed trial quality and abstracted data related to the type of utility score assessment tool used (e.g., visual analog scales, time trade off, etc.), the population surveyed, and the utility scores for each health state. Utility scores ranged from 0 (death) to 1 (perfect life).

Results: Twenty articles from 8 countries between 1991-2017 met search criteria describing 119 unique health states. Health state assessments were most often made by physicians or health professionals (57.3%). Five common health states encountered by breast surgeons are described as examples in the Table with associated utility scores, survey tools used, and populations surveyed. As expected, breast conservation generally had higher utility scores than mastectomy operations (with or without reconstruction). Flap reconstruction had higher utility scores compared to implant reconstruction. Additionally, there was substantial methodologic variation in the acquisition of utility scores not only in the type of assessment tools utilized, but also in the populations surveyed (patients, surgeons, etc.). There were no studies that reported on oncoplastic operations or cost-utility measurements in the type of mastectomy performed.

Conclusions: In order to reliably perform cost utility analyses in breast surgery, established standards in the assessment of health states must be used. We reviewed the current body of literature and have summarized utility scores to aid in future cost study analyses. Present utility score data show a limited range of utility measurements in a relatively small area of breast surgery underscoring the need to further study health states and associated utilities focused on patient perspectives and newer reconstructive techniques. Our results demonstrate a significant opportunity for improvement in the methodologic rigor and standardization of utility assessments in breast surgery.

Table: Health states with associated utility scores

Health State	Utility Score Mean (SD)	Average Weighted Utility Score	Assessment Tool	Population Assessed
Breast Conserving Surgery				
De Koning, 1991	0.93		VAS	Clinicians and public health experts
De Koning, 1991	0.91		VAS	Clinicians and public health experts
Hall, 1992	0.8		TTO	General population
Kim, 2015	0.914 (0.888)	0.89	EuroQoL	Ambulatory breast surgery patients
Knuttel, 2017	0.8		VAS	Women
Knuttel, 2017	0.9		TTO	Women
Norum, 1997	0.87		EORTC [Tariff]	Not specified
Successful mastectomy, no reconstruction				
Hall, 1992	0.77		TTO	General population
Kim, 2015	0.915 (0.888)		EuroQoL	Ambulatory breast surgery patients
Kim, 2017	0.669 (0.199)		VAS	Patients
Kim, 2017	0.79 (0.265)	0.79	SG	Patients
Knuttel, 2017	0.8		VAS	Women
Knuttel, 2017	0.9		TTO	Women
Norum, 1997	0.84		EORTC [Tariff]	Not specified
Mastectomy with implant reconstruction				
Grover, 2013	0.74		VAS	Plastic surgeons
Knuttel, 2017	0.7		VAS	Women
Knuttel, 2017	0.85	0.77	TTO	Women
Krishnan, 2013	0.74		TTO & VAS	Plastic surgeons
Krishnan, 2014	0.7		TTO & VAS	Plastic surgeons
Krishnan, 2014	0.66		TTO & VAS	Plastic surgeons
Mastectomy with successful flap reconstruction				
Chatterjee, 2013	0.85		TTO & VAS	Plastic surgeons
Chatterjee, 2015	0.85		VAS	Reconstructive surgeons
Grover, 2013	0.83		VAS	Plastic surgeons
Grover, 2013	0.85	0.85	VAS	Plastic surgeons
Grover, 2013	0.74		VAS	Plastic surgeons
Thoma, 2003	0.87		VAS	Plastic surgeons
Thoma, 2004	0.87		VAS	Plastic surgeons
Implant failure with implant removal				
Krishnan, 2013	0.655		TTO & VAS	Plastic surgeons
Krishnan, 2014	0.585	0.61	TTO & VAS	Plastic surgeons
Krishnan, 2014	0.585		TTO & VAS	Plastic surgeons

VAS: visual analog scale; **TTO**: time trade off; **SG**: standard gamble; **EuroQoL**: quality of life survey; **EORTC**: quality of life survey

Ongoing Clinical Trials

403230 - Contraceptive use patterns among unaffected BRCA mutation carriers

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Background/Objective: Due to increased availability and prevalence of testing for hereditary cancer syndromes, more patients are being identified as carriers of hereditary breast cancer mutations. BRCA 1 and 2 gene mutations are the most common and place the carriers at high lifetime risk of both breast and ovarian cancers, and many of these carriers are diagnosed premenopausally. Due to the young age of diagnosis of these conditions, many patients are faced with challenging reproductive choices. While there are studies on the potential risks and benefits of hormonal contraception as well as recommendations on prophylactic procedures, there is limited evidence on what these patients and their providers choose for contraception for those who wish to maintain their fertility. In addition, there is little evidence on how the timing of prophylactic breast procedures may influence the decision-making of patients regarding contraception. Due to the complexity of the decision-making and concern for development of cancer, these patients may be at higher risk of being underserved in the safe provision of contraceptive care. In order to better understand current practices, this study will assess unaffected BRCA mutation carriers use of contraception before and after genetic testing, as well as after any prophylactic procedures.

Methods: Aim 1: Assess unaffected BRCA carriers use of contraception compared to national averages Aim 2: Assess if contraceptive use changes after these patients undergo prophylactic mastectomy

Results: Target accrual is 125 patients.

Conclusions: All BRCA mutation carriers at a single institution cancer center seen since 2007 will be contacted to participate.

402869 - Improving quality of life for patients with breast cancer invading the chest wall: A prospective trial for patients undergoing full thickness chest wall resection

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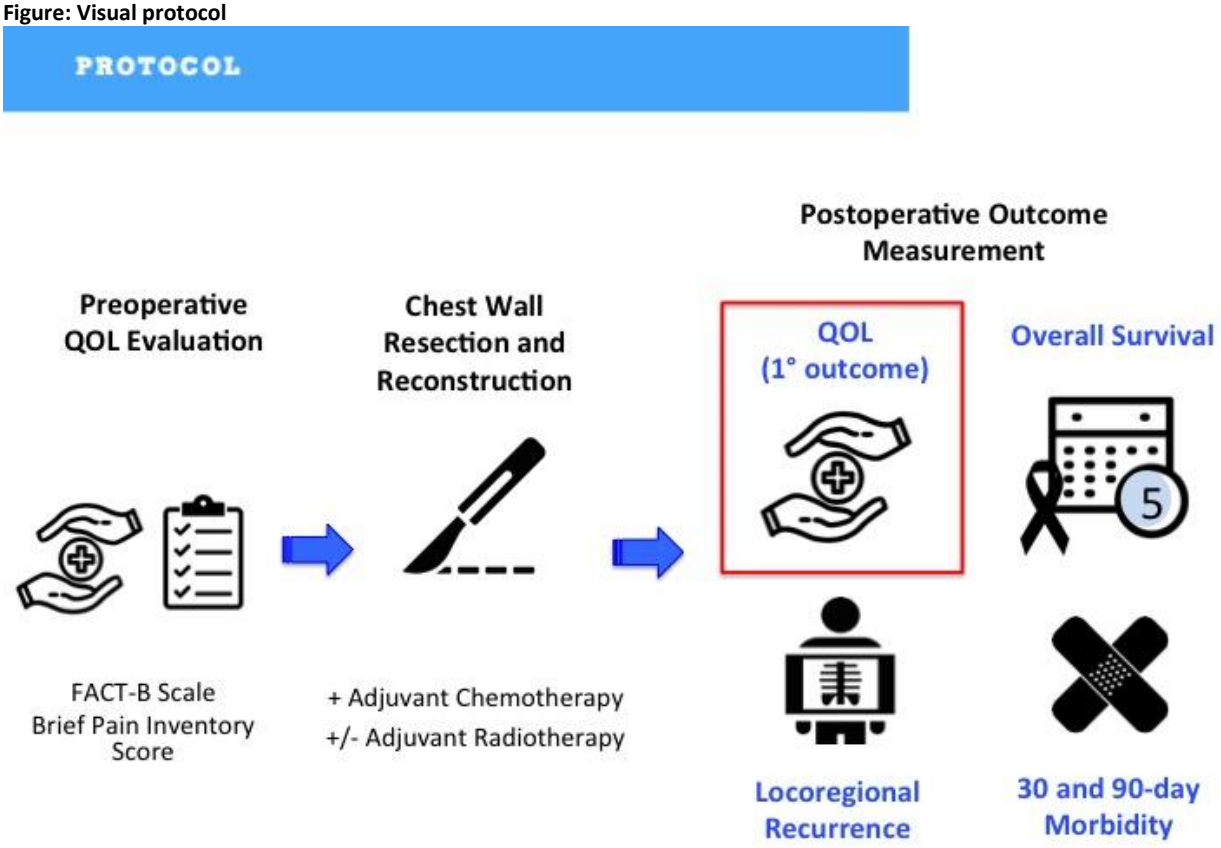
Background/Objective: The role of full-thickness chest wall resection (FTCWR) for breast cancer recurrence in the chest wall is controversial. No prospective evidence exists to evaluate the utility of FTCWR for these patients in improving health-related quality of life (HRQOL), nor have prospective studies evaluated objective measures of overall survival (OS), disease-free survival (DFS), locoregional recurrence (LRR), and short-term morbidity and mortality. Primary outcomes include HRQOL measured with the Functional Assessment of Cancer Therapy - Breast (FACT-B) scores pre- and post-operatively (2 weeks pre, and 1 month, 3 months, 6 months and 1 year).

Methods: Secondary outcomes measured at 1, 2, 3, and 5 years include OS, LRR, DFS and pre- and post-operative pain scores using the Brief Pain Inventory (BPI). Morbidity and mortality will also be measured at 30 and 90 days.

Results: Anticipated accrual is 104 patients over 3 years, with 27 patients in each of 4 analytic subgroups (curative intent patients, patients resected for palliative indications, primary tumors that invade the chest wall and do not respond to chemo- and radiotherapy, and patients refusing surgery).

Conclusions: University Health Network and Princess Margaret Cancer Centre, Toronto, Ontario, Canada

Figure: Visual protocol



Other

375516 - AJCC-7th anatomic stage, AJCC-8th prognostic stage groups, and Bioscore: (Dis)agreement between classification and prognostic ability: Have we improved our predictive skills?

Felipe Andrade, Sr.[1], Rebeca Heinzen[2], Fábio Augusto Arruda[2], Thamyse Fernanda de Sá Dassie[2], Max Mano[2], Larissa Cabral Marques[2], Lincon Jo Mori[2], Danubia Ariana Andrade[2], Karina Braga Ribeiro[3], Alfredo Carlos Simões de Barros[2]

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Background/Objective: Historically, anatomical extension based on tumor size, node status, and distant metastasis has been the cornerstone of breast cancer staging. Biological factors such as grade, hormone receptors, and HER2 expression, as well as genomic panels have been proven as prognostic factors and recently incorporated into AJCC 8th edition. The aim of our study was to verify the agreement between anatomic staging based on AJCC-7th edition (AJCC-7-AS) and prognostic stage groups based on AJCC-8th edition (AJCC-8-PSG) and to compare the prognostic ability of Bioscore (proposed by Mittendorf et al) and AJCC-8-PSG in a cohort of Brazilian women with non-metastatic breast cancer.

Methods: This is a retrospective cohort study, with a sample comprising 209 women with invasive ductal carcinoma initially treated with surgery at Hospital Sírio Libanês, São Paulo, Brazil, between 2005 and 2011. All patients received the standard adjuvant therapy according to recent guidelines. Medical charts were reviewed by 1 researcher, and both new AJCC-8-PSG as well as Bioscore were assigned to each case. Bioscore included 4 parameters (pathologic stage, ER status, HER2 status, and nuclear grade). Weighted Cohens kappa was used to verify the agreement between AJCC classifications. Five-year overall survival rates (5y-OS) were estimated using Kaplan-Meier method, and survival gradient was calculated subtracting 5y-OS from lowest highest stage.

Results: An AJCC-8-PSG could not be assigned to 31 patients because combination was not previewed by the classification. One hundred seventy-eight women were classified in both editions (AJCC-7-AS: IA, 41.6%; IIA, 37.6%; IIB, 12.4%; IIIA, 4.5%, IIIB, 3.9%; AJCC-8-PSG: IA, 35.4%; IB, 30.9%; IIA, 10.7%; IIB, 3.9%; IIIA, 7.3%, IIIB, 3.9%; IIIC, 7.9%). There was a moderate agreement between AJCC-7-AS and AJCC-PSG (weighted kappa=0.52, 95%CI 0.48-0.58). Stage migration has occurred more frequently in the following situations: 33 patients were downstaged from IIA to IB (18.5%), while 14 were upstaged from IA to IB (7.9%). Thirty-nine patients were either downstaged (n=15) or upstaged (n=24) 2 or more AJCC categories. The majority of patients presented Bioscore <3 (55%). Five-year OS according to AJCC-8-PSG and Bioscore are presented in the Table. Bioscore has shown a higher survival gradient (28.4%) compared to AJCC-8-PSG (17.7%), showing a better prognostic discrimination.

Conclusions: There was only a moderate agreement between AJCC-7-AS and AJCC-8-PSG. Our results have validated the prognostic utility of the Bioscore, which has shown a better survival contrast compared to AJCC-8-PSG, suggesting that the incorporation of the Bioscore into clinical practice should be considered.

Table. Five-year overall survival (95% CI) according to AJCC-8-PSG and Bioscore

AJCC-8-PSG/Bioscore	Classification			
	AJCC-8-PSG		Bioscore	
	n	5y-OS (95% CI)	n	5y-OS (95% CI)
IA/IB or Bioscore≤1	118	95.6 (89.9-98.2)	41	95.1 (81.9-98.8)
IIA or Bioscore=2	19	100	57	98.2 (88.2-99.7)
IIB or Bioscore=3	7	100	44	90.4 (76.5-96.3)
IIIA or Bioscore=4	13	100	17	100
IIIB or Bioscore=5	7	57.1 (17.2-83.7)	13	83.9 (49.4-95.7)
IIIC or Bioscore≥6	14	77.9 (45.9-92.3)	6	66.7 (19.5-90.4)
Survival gradient		17.7		28.4

403439 - Invasive pleomorphic lobular carcinoma and non-pleomorphic: Is the prognosis different?

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Background/Objective: Invasive non-pleomorphic lobular carcinoma and invasive pleomorphic lobular carcinomas exhibit differences in microscopic patterns of histopathology and immunohistochemistry. It has traditionally been believed that patients with invasive pleomorphic carcinomas have a worse prognosis. The aim of this study was to compare the oncologic evolution after treatment in women with invasive pleomorphic lobular carcinomas and invasive non- pleomorphic lobular carcinoma.

Methods: This was a retrospective cohort study comprising all women with invasive lobular carcinoma included in our database from 1987 to 2016 (n=195). The patients were treated according to contemporary protocols at the time of diagnosis. The disease-free survival and overall survival (Kaplan-Meier method and log rank test) were investigated for the oncologic outcome.

Results: Overall, there were 171 (87.7%) cases of invasive non- pleomorphic lobular carcinoma and 24 (12.3%) invasive pleomorphic lobular carcinoma. One hundred seventy-two cases remained alive without the disease, and 10 cases alive with the disease (distant or local). There were 11 cases of death from breast cancer and 2 from unrelated causes. The invasive pleomorphic lobular carcinoma immunohistochemistry indicated that 68.4% were ER-positive/HER2-negative, 15.7% were ER-positive/HER2-positive, 10.5% were ER-negative/HER2-positive, and 5.2% were ER-negative/HER2-negative. The prognostic evolution data are shown in the Table. The respective disease-free survival (p=0.53) and overall survival curves did not show statistically significant differences (p=0.91).

Conclusions: In this series, patients were treated in a personalized way according to their staging and immunohistochemically characteristics, and the prognosis of patients with invasive non-pleomorphic lobular carcinoma and invasive pleomorphic carcinoma was similar.

Table: Outcomes

	Non- Pleomorphic n (%)	Pleomorphic n (%)
Free of disease	151 (88,3)	21 (87,5)
Local recurrence	0 (0)	1 (4,2)
Distant recurrence	8 (4,7)	1 (4,2)
Deaths from breast cancer	10 (5,8)	1 (4,2)
Deaths from other causes	2 (1,2)	0 (0)

402927 - A qualitative assessment of physician-perceived factors influencing the decision-making of elderly women with breast cancer

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[1]University of Toronto, Richmond Hill, ON, Canada, [2]University of Toronto, Toronto, Canada

Background/Objective: Elderly women receive different breast cancer treatment options than younger women. Although studies have explored the effectiveness of various treatments in the elderly population, the impact of physicians on treatment decision-making has not previously been addressed. The main objective of this study was one-on-one semi-structured in-depth interviews conducted on purposively selected breast cancer specialists (surgeons, radiation oncologists, and medical oncologists) at a tertiary academic cancer center in Toronto, Ontario, Canada. Interviews were carried out between January and November 2017. The interviews were audio-recorded and professionally transcribed verbatim. Transcripts were independently coded and analyzed by 2 authors using a theoretical framework to identify themes associated with perceived patient experiences, attitudes, strategies, and obstacles involved in treatment decision-making, and to identify the physician-perceived attitudes and values related to treatment decision-making in elderly women (70 years old) with breast cancer.

Methods: One-on-one semi-structured in-depth interviews were conducted on purposively selected breast cancer specialists (surgeons, radiation oncologists, and medical oncologists) at a tertiary academic cancer center in Toronto, Ontario, Canada. Interviews were carried out between January and November 2017. The interviews were audio-recorded and professionally transcribed verbatim. Transcripts were independently coded and analyzed by 2 authors using a theoretical framework to identify themes associated with perceived patient experiences, attitudes, strategies, and obstacles involved in treatment decision-making.

Results: Twenty physicians were eligible to participate, of which 10 (50%) contributed. Distribution by specialty was as follows: radiation oncology (n=5), medical oncology (n=3), and surgical oncology (n=2). All physicians dedicated 50 to 100% of their practice to breast cancer. Women above the age of 70 were viewed as a diverse group with respect to physical health and expectations of breast cancer therapy.

Treatment side effects, length of treatment, impact on quality of life, and minimal survival benefit were perceived to strongly influence women to decline treatment. Physicians perceived that patients frequently declined treatment also because they did not perceive breast cancer as a life-threatening ailment compared to other medical co-morbidities. Breast reconstruction was generally not discussed, as it was considered unlikely to be important to elderly women. Additional factors that were perceived to influence treatment decision-making included lack of time for thorough assessment and treatment discussion, variable family/support, impact of treatment on family dynamics, caretaker responsibilities, misinformation about the disease and treatment options, and difficulty with language and cultural barriers. Physicians suggestions to improve the decision-making process included a dedicated primary care nurse for the treatment journey, longer time for consultation, and improvement in geriatric frailty assessment either through a formal geriatrics clinic or using clinical decision-aids.

Conclusions: Breast cancer treatment decision-making in elderly women is perceived to be a complex process. Ensuring that breast cancer experts have a comprehensive understanding of the factors that influence patients treatment choices may facilitate shared decision-making and improve educational strategies for elderly breast cancer patients. Future research will concentrate on integrating physician-based perceptions with patient-reported experiences.

404336 - The pre-treatment albumin-globulin ratio (P-AGR) as a predictor of long-term overall survival among triple-negative breast cancer patients

Basem Azab, Julia Amundson, Alessia Cioci, Igor Macedo, Ali Avisar, Danny Yakoub

University of Miami, Miami, FL

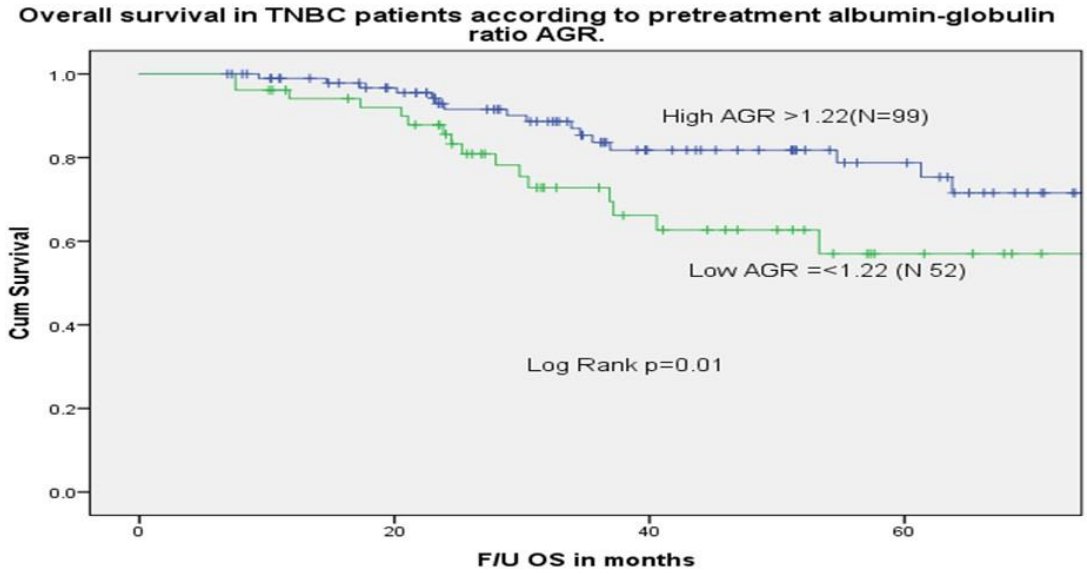
Background/Objective: Prior studies have demonstrated the prognostic value of pre-treatment albumin globulin ratio (P-AGR) in breast cancer; however,r the impact of P-AGR on overall survival (OS) among triple-negative breast cancer (TNBC) patients has not been elucidated. The aim of this study was to assess the predictive value of P-AGR on OS in TNBC.

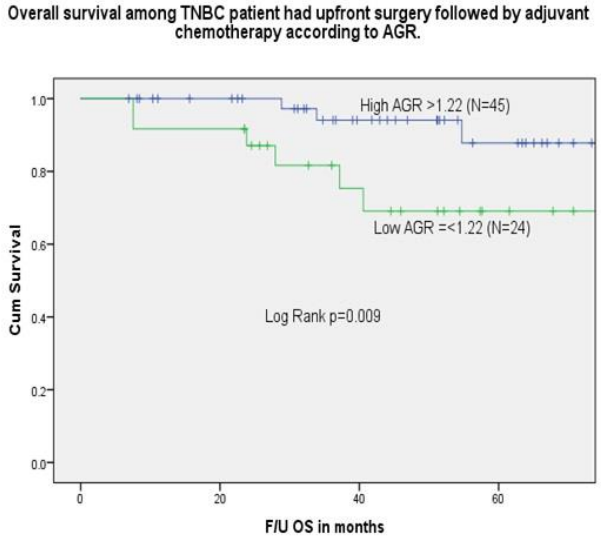
Methods: This retrospective study used a cohort of 151 non-metastatic TNBC patients who had documented total protein and albumin levels prior to their initial treatment modality. Survival status was obtained from our cancer registry. The P-AGR 1.22 cutoff was used as per our previous paper. All patients had surgery and chemotherapy (neoadjuvant or adjuvant).

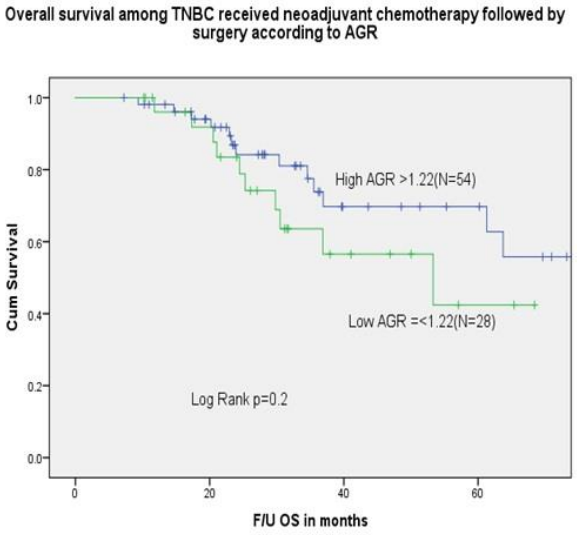
Results: The high P-AGR group (AGR >1.22, n=99) had a superior 5-year OS compared with those in the low P-AGR group (=<1.22, n=52), (OS=84% vs. 67%, p=0.01). After adjusting for age, T and N cancer stage, low P-AGR remained a significant predictor of mortality (HR 2.1, 95% CI=1.1-4.3, p=0.03). When TNBC patients were stratified according to their chemotherapy status, only those who had up-front surgery followed by adjuvant chemotherapy showed worse OS with low P-AGR compared to high P-AGR group (OS=71 vs. 93%, p=0.009). However, those that had neoadjuvant chemotherapy had no statistical significant difference in mortality (Low vs. high P-AGR: OS=76% vs. 64%, p=0.2).

Conclusions: Low pre-treatment AGR is an independent predictor of poor survival in TNBC. This negative impact of low P-AGR is ameliorated with neoadjuvant chemotherapy in contrast to those with up-front surgery. Further studies are needed to evaluate the utilization of P-AGR in TNBC treatment planning.

Figure: The overall survival among TNBC according to pretreatment albumin globulin ratio







402907 - Cost savings of surgeon performed intra-operative specimen ink with reduction of re-excision lumpectomies in breast conservation surgery

Astrid Botty Van den Bruele, Laila Samiian, Bharti Jasra, Carmen Smotherman, Marie Crandall

University of Florida - Jacksonville, Jacksonville, FL

Background/Objective: A key factor in breast conservation therapy (BCT) is obtaining a negative surgical margin. Nationally, re-excision rates for clear margins are reported to be 20-40%. Recent ASTRO-SSO margin guidelines define a negative margin as no tumor at the inked margin for invasive cancer, and 2mm from the ink for ductal carcinoma in situ (DCIS). Discordance between the surgeon and the pathologist interpretation of specimen orientation has been reported to be as high as 31% and could influence margin accuracy. This study examined whether the addition of surgeon performed intra-operative inking of the lumpectomy specimen could reduce re-excision rates and thus, decrease health care costs.

Methods: A retrospective review of a single institution prospective surgical database was performed from August 2009-May 2017. It included patients who had initial lumpectomy with pre-op diagnosis of invasive breast carcinoma or DCIS. Intra-operative specimen inking of all initial lumpectomy specimens were performed by the surgeon after Nov 2015. Re-excision rates after initial lumpectomy were compared across 3 time periods: before margin guideline publication (Jan 2014), after guideline publications (Jan 2014-Oct 2015), and after the addition of intra-operative surgeon performed specimen inking (Nov 2015-May 2017). The cost of 1 re-excision lumpectomy was calculated to be $25,654 per case, which included physician professional fees as well as hospital, operating room, and equipment costs. The cost of 1 specimen ink kit was $100 used only for initial lumpectomy, which was subtracted from the calculated cost savings. Re-excision specimens were not inked in the OR.

Results: A total of 400 initial lumpectomies for DCIS and invasive carcinoma were evaluated. Overall re-excision rate was 21% (n=84). Patients with DCIS were nearly 3 times more likely to undergo re-excision for margins as compared to patients with invasive carcinoma (OR 2.8, 95%CI 1.67-4.63, $p<0.001$). While we observed a trend toward decreasing re-excisions over time, this was not statistically significant. The cost of re-excision lumpectomy per 100 patients was $512,480 for the invasive group and $948,088 for the DCIS group prior to margin guidelines. Adoption of margin guidelines reduced re-excisions, decreasing the costs of surgical care by 25% for invasive breast cancer and 11% for DCIS. The addition of intra-operative specimen ink further reduced re-excision rates and provided another 18% cost savings for invasive breast cancer and 5.5% for DCIS.

Conclusions: Re-excision rates after initial lumpectomy remain significantly higher for DCIS than for invasive disease. Although margin guidelines improved re-excision rates, the addition of surgeon performed intra-operative inking of the lumpectomy specimen provided further reduction in re-excisions, resulting in an additional 18% cost savings for invasive cancer and 5.5% cost savings in DCIS.

Table: Cost of re-excision, DCIS vs IDC

Group	Invasive carcinoma*	In situ carcinoma*	Total	Cost of re-excision per 100 patients		
				Invasive	DCIS	Total
Prior to Margin Guidelines						
Re-excision, yes	23 (20%)	13 (37%)	**36 (24%)**	$513,080	$949,198	$615,696
Re-excision, no	93 (80%)	22 (63%)	**115 (76%)**	NA	NA	
Total	**116 (77%)**	**35 (23%)**	**151 (100%)**	-	-	
Margin Guidelines						
Re-excision, yes	13 (15%)	10 (33%)	**23 (20%)**	$384,810	$846, 582	$513,080
Re-excision, no	72 (85%)	20 (67%)	**92 (80%)**	NA	NA	
Total	**85 (74%)**	**30 (26%)**	**115 (100%)**	-	-	
COST SAVINGS				$128,270 (25%)	$102,616 (10.8%)	$102,616 (16.7%)
Additional of IOP Specimen Ink						
Re-excision, yes	10 (12%)	15 (31%)	**25 (19%)**	$307,848	$795,274	$487,426
Re-excision, no	75 (88%)	34 (69%)	**109 (81%)**			
Total	**85 (63%)**	**49 (37%)**	**134 (100%)**	-$8,500 ink kit	-$4,900 ink kit	-$13,400 ink kit
ADDED COST SAVINGS				$68,462 (18 %)	$46,408 (5.5 %)	$12,254 (2.4 %)

* p=0.536 (Chi-square test)

404359 - Viral infections associated in breast cancer patients in a Latin American cancer institute

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Background/Objective: Perú is a developing country, and the first causes of disease are infections. We consider it important to evaluate the presence of viral infections and asses the association with breast cancer. Our objective was to evaluate the presence in breast cancer patients: Hepatitis A virus (HAV) , hepatitis B virus (HBV), Epstein Barr Virus (EBV), HTLV 1-2, Citomegalovirus (CMV), Papilloma Virus (PVH), Herpes Virus I, Herpes Virus II, Immunodeficiency Human Virus (HIV).

Methods: Fifty patients from the Peruvian Cancer Institute were included. In peripheral blood was performed for serological markers; methodology and serological markers are described in the Table. PVH detection was realized by DNA extraction and was performed from samples of paraffin tissue from patients with breast cancer after selection of the tumor area by macrodissection and making cuts of 5-10 microns in diameter with new blades. The COBAS DNA sample preparation kit was used for the extraction of DNA in the paraffined samples.

Results: The average age was 50.6 years old, 75% (33) had between 1 and 2 sexual partners, 90.9% of patients did not had harmful habits such as alcohol or tobacco consumption, 81.8% (36) had no history

of mastitis, the average tumor size was 4.97 cm (0.8-16), locally advanced clinical stages and the presence of infiltrating ductal carcinoma in 88.7% predominated (39) with positive estrogen and progesterone receptors. The frequency of positive serology for Epstein Barr Virus, Hepatitis A and CMV was 100%, 89% HSV-I, HSV-II 39%, 0% HTLV-1, HIV 0%, 0% Chronic Hepatitis B, Hepatitis B old 9%, Hepatitis C 0%. Of the 50 selected tissue samples, only 44 were suitable for PCR study for HPV, 6 were discarded due to scarce tumor tissue in the sample; therefore, the study group was reduced to 44 patients who were also studied. The DNA concentrations obtained were in the range of 4 to 26 ng/ul, making adjustments for final concentrations of 20ng of DNA. The figure shows the polyacrylamide gel with the molecular amplification bands corresponding to the 450 bp of the L1 consensus region of the HPV. The band corresponding to the L1 gene region (450 bp) was detected in 17/47 (36%) of the samples studied.

Conclusions: It can be observed that there is a non-association between breast cancer and HCV, HBV, HTLV and HIV, or with active disease by HAV, HBV, HVS I-II; however, it was possible to find 3 cases of active EBV status, 3 with HVS type I, and 1 with HVS-II, which could translate a state of immune compromise associated with breast cancer, so that the need arises to make such markers in a control group and evaluate significant differences. Independently of the association or not with breast cancer, the high prevalence of exposure to these viruses (HAV, CMV, HSV I-II) in the Peruvian population can be observed. In relation to the presence of HPV genome in tumor tissue, in this study, we demonstrated that the presence of HPV virus is not uncommon in the Peruvian population with breast cancer studied (36%). An important observation is the presence of multiple oncogenic virus in the breast tissue prior to the subsequent development of breast cancer and could be a key criterion when assessing causation for the potential roles in human breast cancer development.

Table: Methodology and serological markers

CODIGO	ANALITO	METODO	MARCA	EQUIPO	
250310	CITOMEGALOVIRUS IgG Anti.	ELECTROQUIMIOLUMINISCENCIA	ROCHE	COBAS e601	AUTOMATIZADO
250311	CITOMEGALOVIRUS IgM Anti.	ELECTROQUIMIOLUMINISCENCIA	ROCHE	COBAS e601	AUTOMATIZADO
250316	HEPATITIS A: IgM	ELECTROQUIMIOLUMINISCENCIA	ROCHE	COBAS e601	AUTOMATIZADO
250317	HEPATITIS A TOTAL	ELECTROQUIMIOLUMINISCENCIA	ROCHE	COBAS e601	AUTOMATIZADO
250318	HEPATITIS B: ANTIGENO DE . DE SUPERFICIE	ELECTROQUIMIOLUMINISCENCIA	ROCHE	COBAS e601	AUTOMATIZADO
250319	HEPATITIS B:ANTICUERPO ANTIAUSTRALIA	ELECTROQUIMIOLUMINISCENCIA	ROCHE	COBAS e601	AUTOMATIZADO
250320	HEPATITIS B: ANTICUERPO ANTICORE IgM	ELECTROQUIMIOLUMINISCENCIA	ROCHE	COBAS e601	AUTOMATIZADO
250321	HEPATITIS B: ANTICUERPO ANTICORE TOTAL	ELECTROQUIMIOLUMINISCENCIA	ROCHE	COBAS e601	AUTOMATIZADO
250322	HEPATITIS B: ANTIGENO e (EPSILON)	ELECTROQUIMIOLUMINISCENCIA	ROCHE	COBAS e601	AUTOMATIZADO
250323	HEPATITIS B: ANTICUERPO. ANTIEPSILON	ELECTROQUIMIOLUMINISCENCIA	ROCHE	COBAS e601	AUTOMATIZADO
250325	HEPATITIS C: (ANTI HCV)	ELECTROQUIMIOLUMINISCENCIA	ROCHE	COBAS e601	AUTOMATIZADO
250309	HERPES 1 IgG	ELECTROQUIMIOLUMINISCENCIA	ROCHE	COBAS e601	AUTOMATIZADO
251202	HERPES 1 IgM	ELISA	VIRION SER	POWER WAVE S2	MANUAL
250371	HERPES 2 IgG	ELECTROQUIMIOLUMINISCENCIA	ROCHE	COBAS e601	AUTOMATIZADO
251201	HERPES 2 IgM	ELISA	VIRION SER	POWER WAVE S2	MANUAL
250326	Hiv 1-2, Anticuerpos	ELECTROQUIMIOLUMINISCENCIA	ROCHE	COBAS e601	AUTOMATIZADO
250328	HTLV	QUIMIOLUMINISCENCIA	ABBOTT	ARCHITECT	AUTOMATIZADO
250313	EPSTEIN BARR VIRUS CAPSIDE VIRAL (VCA) IgM	ELISA	VIRION SER	POWER WAVE S2	MANUAL
250312	EPSTEIN BARR VIRUS CAPSIDE VIRAL (VCA) IgG	ELISA	VIRION SER	POWER WAVE S2	MANUAL
251204	EPSTEIN BARR VIRUS ANTIGENO NUCLEAR (EBNA) IgG	ELISA	VIRION SER	POWER WAVE S2	MANUAL
251203	EPSTEIN BARR VIRUS ANTIGENO TEMPRANO (EA) IgG	ELISA	VIRION SER	POWER WAVE S2	MANUAL

401455 - The value of diagnostic second opinions in breast cancer patients referred to a cancer center with a multidisciplinary breast tumor board

Denise Garcia[1], Laura Spruill[1], Abid Irshad[2], Denise Kepecs[1], Jennifer Wood[1], Nancy Demore[1]

[1]Medical University of South Carolina, Charleston, SC, [2]Radiology, Charleston, SC

Background/Objective: The purpose of this study was to investigate the potential benefits and changes in patient outcomes associated with acquisition of radiologic, pathologic, and genetic second opinions in diagnosed breast cancer patients referred to an institution with a sub-specialized, multi-disciplinary tumor board.

Methods: After IRB approval, a retrospective analysis was performed on breast cancer patients diagnosed at an outside facility and referred to our cancer center for a second opinion between 8/2015 and 3/2016. The imaging and pathology slides of all second-opinion patients were reviewed by local fellowship-trained breast radiologists and pathologists and then discussed at a multi-disciplinary tumor board. Outside radiology, pathology, and genetic reports were compared with the re-interpretations at our institution, and differences were noted. The parameters analyzed for radiology were change in tumor size, additional views, biopsies and ultrasounds performed, as well as additional cancer found in the breast, and new node-positive disease discovered as a result of radiology work-up. The pathology data were assessed for change in histology, tumor grade, tumor size, and ER, PR or HER2/neu status. We also assessed whether or not genetic testing was made available to patients who met NCCN guidelines. Change in outcome was defined as identification of genetic mutation not previously identified at outside institution. Second-opinion cases were categorized as no changes, additional findings with no outcome changes, additional findings with change in outcome. Change in outcome was defined as change in surgical, chemotherapy, or radiation intervention.

Results: Out of a total of 225 patients, 70 (31%) were referred for diagnostic second opinions. Of the second opinions, a significant amount (75%) had additional images, or lesions discovered (Table 1). We found that most of the additional findings of second-opinion review were a result of radiologic differences or recommendations. The most frequent radiologic variation was the recommendation for additional views with about 40% resulting in a change in management. There were 33 additional biopsies obtained with 48% resulting in discovery of a new cancer (Table 2). Pathology variations on review for second opinions represented a smaller number of variations within second opinions, but a significant proportion resulted in change in outcome. Several pathologic variations included changes from invasive to non-invasive cancer, or in 1 instance, a change from sarcoma to phyllodes. The changes in management observed included change in timing of surgery, type of surgery offered, and surgery being removed as an option. No changes were observed between ER/PR and HER2/neu re-analyses, and no significant outcome changes resulted due to genetic testing.

Conclusions: Diagnostic second opinion at a cancer center resulted in a clinically significant number of additional breast cancers and positive nodes detected pre-operatively with a major change in the management outcome. Similarly, pathologic second opinion also resulted in a clinically significant number of cases where management was changed. Overall, our findings emphasize that referral for second opinion to an institution with a sub-specialty, multi-disciplinary tumor board is potentially beneficial and impacts outcomes for many patients.

Tables:

Second Opinion Variation	Radiology			Pathology		
	#Variation	# change in outcome	% change in outcome	# Variation	# change in outcome	% change in variation
	43	19	44%	12	7	58%

Table 1: Variations observed in radiology and pathology second opinions and resulting changes in outcomes. Total second opinions: N=70

Type of Additional Biopsy	# of patients	# Biopsies positive for cancer	% Biopsies positive for cancer
Ipsalateral	13	7	53.8
Contralateral	5	1	20.0
Ipsalateral calcifications	8	3	37.5
Axillary lymph node	7	5	71.4
Totals	33	16	48.5

Table 2: Additional biopsy locations as a result of radiology recommendations on second opinion review and corresponding cancer findings.

393799 - Bilateral mastectomy: Has the time for co-surgeons arrived? Results from the ASBrS Survey

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Background/Objective: The number of bilateral mastectomy (BM) operations being performed in the United States is rapidly increasing. Traditionally, BM operations are performed by a single surgeon. We have previously described an alternative 2-attending co-surgeon (CS) technique for BMs with the potential for reducing operative time. We sought to assess national BM practice patterns to better elucidate the current and potential future role for the CS technique.

Methods: An electronic questionnaire was sent to the 2446 members of the American Society of Breast Surgeons (ASBrS) in November of 2016. Data collected included practice type/location, years in practice, number of surgical partners, BM annual case load, reconstruction utilization, and information on surgeons familiarity and interest in, as well as anticipated benefits and drawbacks of, CS technique. Comparisons of categorical variables were made using a Fisher's exact test, a Pearson chi-squared test, or a mean score test where appropriate.

Results: Of the 2466 surveyed surgeons, 636 responded (26%); of these, 570 completed the questionnaire. Among the respondents who completed the survey, 82% (n=468) never, 16% (n=92) sometimes, and 2% (n=10) always use CS technique. Those using (always and sometimes) CS technique were more likely to perceive it decreasing operative time than those never using it (98% vs 85%, p<0.001). Time savings (71%, n=72) and opportunity to learn new techniques (35%, n=36) were most common benefits reported by CS technique users. Among the surgeons currently not using CS technique (n=491), 33% (161) would consider using it in the future. Compared to the group who would not consider CS technique, the group that would consider its use were: more likely to be in practice for fewer years, in smaller practices (<10 surgeons) (99 % n=160 vs. 92% n=305, p<0.001), and to perceive time savings of the CS technique over the single-surgeon method (97 %, n=157 vs 80%, n=264, p<0.001). Opportunity for learning new techniques (44%, n=71) and mentoring a junior surgeon (27%, n=44) were other commonly reported reasons for interest in the CST. Lack of sufficient time savings (48%, n=158) and insufficient reimbursement (30%, n=99) were most common reasons for disinterest in the technique; inability to find another surgeon (42%, n=138) and personal preference to work alone (33%, n=108) were also commonly reported.

Conclusions: Currently most breast surgeons perform BM operations using the traditional one-surgeon method, however up to 18% of surgeons surveyed use the CS technique as an alternative approach. A significant minority of surgeons (33%) are interested in learning more about and using the CS technique in the future. Time savings, mentorship, and opportunity to learn techniques are potential advantages of this approach; however, the perception of insufficient degree of time savings and financial reimbursement are potential barriers to CST implementation. Further studies on CS technique are warranted to determine if patient-centered outcomes can be improved in breast cancer surgery.

404179 - MRI demonstration of distribution and extent of residual breast tissue in skin-sparing mastectomy with immediate reconstruction

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Background/Objective: The balance between maximal resection of breast tissue and maintenance of viable flaps needs to be kept in skin-sparing mastectomy with immediate reconstruction. The presence of residual breast tissue might affect the risk of cancer recurrence. This study aims to describe the amount and distribution of residual breast tissue after skin-sparing mastectomy and immediate reconstruction, and to find correlation between patients' body mass index (BMI) and pre-sternal tissue thickness and flap thickness.

Methods: Women who underwent skin-sparing and nipple-sparing mastectomy and immediate reconstruction between 2014-2015, and underwent a breast MRI as part of their post-operative follow up were included. Flap thickness was measured as seen in breast MRI (pre contrast T1 sequence): At the midpoint of the maximal anterior to posterior distance in the axial projection, a perpendicular line was drawn to the edges of the implant. Flap thickness was measured 90° to this line in the lateral and medial aspects. Anterior flap and pre-sternal thickness were measured in the same level. Patient and tumor clinical and pathological characteristics were drawn from the hospital's medical records.

Results: Sixty-one women were included in the study. Four of them underwent bilateral, nipple-sparing mastectomy. Residual flap and pre-sternal thickness measurements are presented in the table. Mean

patient age was 45.7 (range 28-68). Mean BMI was 26.7 (range 16.2-40.4). Of the tumors, 68.8% were T1 or T2. Seventy percent of patients were N0. Thirty percent of surgeries were bilateral, 70% of patients had sentinel lymph node biopsy, and 63% were not treated with chemotherapy. There was a significant correlation between residual flap thickness, BMI, and pre-sternal thickness. There was no consistent correlation between stage of disease, type of axillary surgery, or implant type to flap thickness. In bilateral mastectomy cases, residual flap thickness did not differ between the cancer affected and the normal breast.

Conclusions: Care should be taken when performing skin-sparing mastectomy in order to minimize residual breast tissue, especially in the medial aspect of the breast. BMI and pre-sternal thickness are correlated with mastectomy flap thickness.

Table: Residual flap and pre-sternal thickness measurements

		Mean thickness (mm)	Range (mm)	Standard Deviation
Anterior flap (skin sparing mastectomy only)	L	3.3	2-18.9	0.34
	R	3.5	2-11.7	0.28
Medial flap	L	5.6	2-16.9	0.37
	R	6.5	2-23.5	0.47
Lateral flap	L	4.1	2-14.3	0.39
	R	5.2	2-25.9	0.51
Pre-sternal thickness		11.2	0.9-26	0.58

403990 - NCCN Guidelines for breast cancer: How compliant are we?

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Background/Objective: The National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines®) have been used to institute standards of care for the treatment of breast cancer since 1996. Though these guidelines have been present for over two decades, the reporting of institutional compliance with the NCCN guidelines is virtually absent in the literature. We sought to evaluate our institutional compliance with the NCCN Breast Cancer guidelines, at a Department of Defense (DoD) health care facility, with the goal of identifying areas for quality improvement.

Methods: A retrospective review of our institutional cancer registry database was performed identifying all patients diagnosed with invasive breast cancer during the dates of 1 Jan 2010 to 1 Jan 2016. The patient population consists of military beneficiaries, retirees, veterans and active duty service members. We excluded all patients who were male, clinical stage IV, pregnant, diagnosed or treated at an outside facility, and those with recurrent breast cancer. After identification, paper and electronic medical records were queried for all information pertaining to surgical compliance within the NCCN guidelines. We included only objective level 2A and higher evidence (initial work-up, index cancer operation, and lymph node evaluation). Nonspecific recommendations that were subjective, optional, or based on symptoms were not evaluated. We accounted for the triannual updates of NCCN guidelines. Compliance was measured for each patient and presented as a percentage of institutional compliance.

Results

Table: Compliance with NCCN guidelines by year

	Overall (%)	**2010 (%)**	**2011 (%)**	**2012 (%)**	**2013 (%)**	**2014 (%)**	**2015(%)**
Initial Workup	**49.57**	36.84	27.78	68.18	40.00	66.67	52.00
H&P	**98.29**	94.74	94.44	100.00	100.00	100.00	100.00
CBC	**74.36**	63.16	72.22	81.82	86.67	88.89	60.00
LFT	**50.43**	42.11	27.78	68.18	40.00	66.67	52.00
Bilat Mammo	**99.15**	100.00	100.00	95.45	100.00	100.00	100.00
Path Review	**100.00**	100.00	100.00	100.00	100.00	100.00	100.00
ER/PR status	**100.00**	100.00	100.00	100.00	100.00	100.00	100.00
Breast Surgery	**99.15**	100.00	100.00	100.00	100.00	94.44	100.00
LN Surgery	**99.15**	100.00	100.00	100.00	100.00	94.44	100.00

Conclusion: Compliance with NCCN breast cancer guidelines was high within our DoD institution. There are currently no other studies to compare our findings with a national compliance rate. We specifically identified a deficiency in our pre-operative laboratory evaluation. Based on the findings of this study, we are implementing a quality improvement project. We look forward to reevaluating our progress. We encourage all institutions that follow NCCN breast cancer guidelines to evaluate their compliance.

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402297 - A validated algorithm for the identification of a new outcome measure from administrative data: The Breast Cancer Recurrence Project

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Background/Objective: Cancer recurrence is an important clinical outcome measure, particularly for cancers with low mortality rates. It is not routinely reported in cancer registries or other large administrative datasets that are generally service specific. We conducted a retrospective cohort validation study to determine the feasibility of creating an algorithm to identify cases of breast cancer recurrence from provincial level administrative data linked around individual patients and across the cancer journey.

Methods: From the Ontario Cancer Registry, we identified all cases of primary breast cancer Stage 0-III diagnosed between January 2009 and December 2012, and alive 6 months from diagnosis. We developed clinical rules that were applied iteratively to data from provincial death, billing, treatment, and hospital inpatient and outpatient records during the period of observation until December 2013. Stage-related rates of recurrence determined by the algorithm were reviewed for validity by a clinical expert panel. We validated the algorithms ability to identify individual instances of recurrence in a structured sample of 3265 patient charts from 2 large regional cancer centers. Chart abstractors were trained, and an adjudication process guided by a set of agreed-upon rules was applied to cases in which the clinical outcome was unclear. Instances of contralateral cancer were not considered recurrences but were recorded to inform subsequent iterations of the algorithm.

Results: The overall rate of recurrence determined by the algorithm was 15% (14.3-15.7). Local, regional, and distant recurrence rates by stage at diagnosis are presented in the Table. Validation by chart audit showed an overall accuracy of the algorithm in predicting recurrences/non-recurrences of 0.89 (sensitivity 0.78, specificity 0.91, positive predictive value 0.55, negative predictive value 0.97). Treatment data were more effective than hospital data in improving the sensitivity of the algorithm with little effect on specificity.

Conclusions: Linking administrative data across the cancer journey for identification of new outcome measures is feasible and provides sufficient accuracy for system monitoring. Discrepant cases identified by the chart audit are being reviewed to update the algorithm and optimize performance.

Table: Local, regional, and distant recurrence by stage at diagnosis

Stage	N	Local Recurrence N (%, 95% CI)	Regional Recurrence N (%, 95% CI)	Distant Recurrence N (%, 95% CI)
0	1452	34 (2.3, 1.7-3.0)	0 (0, 0-0)	15 (1.0, 0.6-1.5)
1	13138	514 (3.9, 3.1-4.7)	36 (0.3, 0-1.0)	269 (2.1, 1.4-2.7)
2	11691	979 (8.4, 7.2-9.5)	118 (1.0, 0-2.3)	907 (7.8, 6.5-8.9)
3	4419	749 (17.0, 15.4-18.5)	89 (2, 0.3-3.8)	905 (20.5, 18.5-22.2)
Total	30700	2276 (7.4, 7.1-7.7)	245 (0.8, 0.7-0.9)	2083 (6.8, 6.5-7.1)

401245 - Quality of life and body image as a function of time from mastectomy

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Background/Objective: As treatment for breast cancer improves, quality of life (QoL) and body image after mastectomy becomes an increasingly important metric for both patients and providers. Few studies, however, have evaluated QoL and body image as a function of time after mastectomy.

Methods: Female patients with unilateral breast cancer undergoing mastectomy at a large academic institution were queried regarding their body image and QoL using validated instruments. The Body Image After Breast Cancer Questionnaire (BIBCQ) is a validated instrument measuring perceived vulnerability (to cancer), body stigma, limitations (in daily functioning), body concerns, transparency (obviousness of effect of cancer on appearance), and arm concerns in the context of breast cancer. The Functional Assessment of Cancer Therapy Breast (FACT-B) survey was used to assess QoL. Data were analyzed using non-parametric statistics (SPSS version 24).

Results: Ninety-four of the 109 patients approached completed both surveys (86.2% response rate). The median patient age of respondents at the time of surgery was 49.5 (range 29-82); the survey was administered at a median of 14.2 months post-operatively (range 0.3-192.1 months). Seventy-four patients (78.7%) had reconstruction, and 52 patients (55.3%) chose to undergo contralateral prophylactic mastectomy. Patients who reported an above-average overall body image perception on the BIBCQ tended to be further out from their surgery than those who reported a below-average perception (median 20.9 vs. 8.1 months, respectively, p=0.009). Reconstruction (p=0.450), contralateral prophylactic mastectomy (p=1.000), disease stage (p=0.413), race (p=0.485), education (p=0.718), insurance type (p=0.162), income (p=0.380), marital status (p=0.673), employment status (p=0.295), and age at surgery (p=0.120) were not correlated with BIBCQ scores. Patients who reported above-average QoL overall on the FACT-B also tended to be further out from their surgery compared to those with below-average overall QoL (median 21.8 vs. 6.4 months, respectively, p=0.004). Similar to BIBCQ scores, overall FACT-B scores were not correlated with reconstruction (p=1.000), contralateral prophylactic mastectomy (p=0.211), disease stage (p=0.306), race (p=0.087), education (p=0.619), insurance type (p=0.508), income (p=0.811), marital status (p=0.721), employment status (p=0.708), and age at surgery (p=0.087).

Conclusions: Better body image perception and higher QoL were associated with being further out from surgery. These findings suggest that body image and QoL may improve with time, as patients acclimatize to their new normal.

403967 - Hidden incision tunneled central venous access catheter placement: A comparison of a trans-axillary port placement (TrAPP) to traditional chest wall technique

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Background/Objective: Tunneled central venous catheters (CVC) allow patients undergoing chemotherapy a more consistent form of vascular access. For patients undergoing breast surgery, there is an increased motivation to optimize cosmesis without compromising oncologic success. Typically, tunneled CVC are placed on the chest wall for port placement, which is clearly visible to the patient. This novel technique involves placement of the pocket for the port in a hidden location in the axilla. The goal of this study was to evaluate complications and success in CVC placement in patients undergoing Trans-Axillary Port Placement (TrAPP) placement compared to traditional placement.

Methods: Single-institution, IRB-approved, HIPAA-compliant retrospective review of the electronic medical record identified patients undergoing tunneled CVC placement by a single surgeon was conducted. Complications were defined as surgical site infections (SSI), pneumothorax, deep venous thrombosis, or those requiring surgical revision. Complications were compared among the TrAP group and traditional group. Chi-squared analysis was utilized and 2 tailed p-value <0.05 was defined as significant.

Results: Two hundred two patients were identified who underwent tunneled CVC placement, with 89 (44.0%) undergoing TrAPP and 113 (56%) undergoing traditional placement. Mean age was 49.8 years (range: 27-75 years) with a mean BMI of 26.8kg/m2 (range: 17.3 42.4 kg/m2) in the TrAPP group and 55.2 years (range: 21-83 years) with a mean BMI of 29.1 kg/m2 (20-58.1 kg/m2) in the traditional group. One patient failed CVC placement in both groups, (1.12% vs. 0.88%, p=1.0). Complication rates were similar among both groups, with 14 (15.7%) patients experiencing any complication in the TrAPP group and 8 (7.0%) patients experiencing any complication in the traditional group, p=0.07. Specifically, more patients required port revision/removal in the TraPP group then the traditional group: 9 (10.1%) patients vs. 2 (1.8%) patients; p=0.006, due to port inversions or DVT. No pneumothoraces occurred in the TrAPP group vs 2 (1.75%) in the traditional group.

Conclusions: Trans-Axillary port placement (TrAPP) CVC technique is feasible and safe with no difference in overall complication rates when compared to conventional chest wall placement. In addition, it allows for a more inconspicuous location with a hidden scar that is cosmetically more appealing to the patient.

403561 - Do ACGME case logs reflect general surgery resident breast surgery training?

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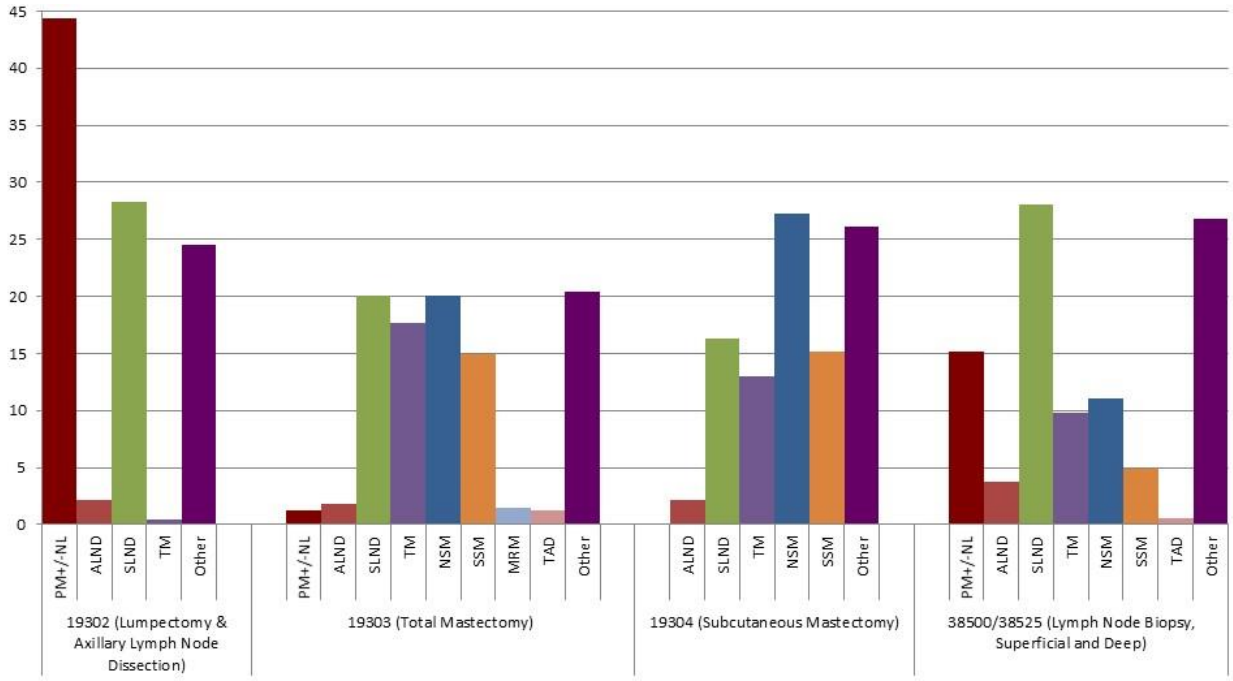
Background/Objective: Breast surgical indications and techniques are increasingly nuanced. The Accreditation Council for Graduate Medical Education (ACGME) mandates that minimum case requirements are recorded in the Resident Case Log System using a single Common Procedural Terminology (CPT) code per case. We hypothesized that general surgery training according to Surgical Council on Resident Education (SCORE) guidelines and documentation in ACGME case logs do not accurately reflect breast surgery training experience among general surgery residents.

Methods: ACGME case logs with CPT codes matching SCORE curriculum core breast operations (axillary sentinel lymph node biopsy (SLND) and lymphadenectomy (ALND), breast biopsy with or without needle localization, duct excision, partial mastectomy (PM), simple (TM), modified radical (MRM), and radical mastectomy (RM) were compared to procedures documented in operative reports. Breast surgical procedures were classified as partial mastectomy/excisional biopsy (PM) with or without needle/seed localization (NL), ALND, SLND,TM, nipple-sparing mastectomy (NSM), skin-sparing mastectomy (SSM), MRM, RM, targeted axillary dissection (TAD), subcutaneous mastectomy (SCM), and other (lactiferous duct procedure, incision and drainage, hematoma evacuation, debridement, plastic surgical procedure (implant removal, capsulectomy, scar revision, flap advancement, mastopexy), skin lesion excision, port procedure, ultrasound use).

Results: From 2011 to 2017, 619 breast cases were logged by 37 residents under 31 attending surgeons at 3 hospitals. CPT codes reported in case logs included 19301 (lumpectomy) in 176 (28.4%); 19303 (TM), 108 (17.5%); 19302 (lumpectomy and ALND), 78 (12.6%); 38500 (lymph node (LN) biopsy, superficial), 56 (9.1%); 38525 (LN biopsy, deep), 53 (8.6%); 19307 (MRM), 35 (5.7%); 19304 (SCM), 28 (4.5%); 19125 (excision breast lesion with radiologic marker), 26 (4.2%); 19120 (excision breast lesion), 23 (3.7%); 38745 (axillary lymphadenectomy, complete), 15 (2.4%); 19020 (mastotomy for abscess), 7 (1.1%); 19110 (nipple exploration), 6 (1.0%); 38740 (axillary lymphadenectomy, superficial), 2 (0.3%); 19305 (HRM), 2 (0.3%); 19112 (excision lactiferous duct fistula), 2 (0.3%); 19300 (mastectomy for gynecomastia), 1 (0.2%); and 19306 (extended HRM), 1 (0.3%). Comparison of procedures performed according to operative report for common CPT codes logged are shown in the Figure. Per case log, the corresponding operative note documented that 2 procedures were performed in 404 (65%) patients; 3, in 266 (42%); 4, in 121 (19%); 5, in 18 (3%); and 6, in 5 (1%). Of procedures requiring localization, 4 used radioactive seed localization (RSL) (coded as 19301 (N=2), 38500 (N=1), and 38525(N=1)), and 2 TAD were performed, 1 with wire localization (coded as 19303) and 1 with RSL (coded as 38525).

Conclusions: While some incorrect logging may be attributed to resident error, modern breast procedures are not represented accurately by quantity (multiple procedures counting as 1 case) or quality (lack of CPT code specific for procedure, e.g., CPT 19303 TM used for NSM). Discrepancies noted between cases logged and actual procedures performed demonstrate that the ACGME case log system and SCORE curriculum core requirements lack granularity in describing current breast surgical practices and should be refined to more precisely document the residents' level of breast surgical training.

Figure: CPT codes of cases logged by residents compared to procedures performed in operative report



PM: Partial mastectomy, NL: Needle localized, ALND: Axillary lymph node dissection, SLND: Axillary sentinel lymph node dissection, TM: Total mastectomy, NSM: Nipple sparing mastectomy, SSM: Skin sparing mastectomy, MRM: Modified radical mastectomy, TAD: Targeted axillary dissection, SCM: Subcutaneous mastectomy. Other category included: Lactiferous duct procedure, including duct excision and fistulectomy; incision and drainage; hematoma evacuation; debridement; plastic surgical procedure, including implant removal, capsulectomy, scar revision, flap advancement, mastopexy; excision of skin lesion; port placement or removal; use ultrasound guidance.

402416 - Patterns of care and efficacy of adjuvant therapies in skin involved breast cancers of all sizes

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Background/Objective: Invasive breast cancers with skin involvement are automatically classified as T4b (Stage III) under the AJCC (American Joint Committee on Cancer) 7th edition staging system, irrespective of their tumor size, and considered unresectable, having neoadjuvant chemotherapy recommended. The management of small skin-involved (SI) breast cancers, however, is controversial because prior data of ours and others have shown that their prognosis is far better than the Stage III category to which they are grouped. Moreover, the patterns of care and most optimal treatment for small SI tumors remain unknown. This study was undertaken to determine how SI lesions are being treated in the US, and to discern the benefit of systemic and radiation therapy on SI primaries of all sizes.

Methods: Patients diagnosed with Stage I-III breast cancer in the National Cancer Database between 2004 and 2011 were reviewed. Patients were excluded if they had in situ, metastatic, or inflammatory breast cancer, or a prior breast cancer. Patterns of treatment in patients having SI lesions were reviewed to determine what was administered, and overall survival (OS) was assessed, adjusting for patient, tumor, and treatment variables. Groups were compared using Chi-square tests and Wilcoxon rank sum tests. Multivariable logistic regression was used to identify predictors of receipt of chemotherapy and receipt of radiation. Propensity score matching was used to adjust for differences in the SI and non-SI groups, and differences in treatment by group were examined using logistic regression. Overall survival was analyzed using Cox proportional hazards models.

Results: There were 3,485 patients with SI and 456,287 patients with non-SI breast cancers fulfilling inclusion criteria. Median SI and non-SI patient ages were 64 and 59 years, while median tumor sizes were 5.0 and 1.5 cm, respectively. Chemotherapy was administered to 68.5% and 45.9% of SI and non-SI tumors, respectively ($p<0.001$) with 77.2% of SI and 33.3% of non-SI tumors <2 cm receiving chemotherapy ($p<0.001$). After adjusting for patient and tumor characteristics, SI patients overall were 16.6% more likely to receive any chemotherapy than non-SI patients (OR 1.17; 95% CI=1.06, 1.29; $p=0.002$). The subset of SI primaries <2cm were also more likely to receive chemotherapy than non-SI tumors (OR 1.97; 95% CI=1.45, 2.69). Neoadjuvant chemotherapy was given more frequently for SI than non-SI tumors overall; 45.8% vs 8.1% ($p<0.0001$). For SI primaries, neoadjuvant vs adjuvant chemotherapy was administered in 46.1% vs 31.2% of tumors <2 cm; in 42.6% vs 24.8% of tumors 2-5 cm; and in 48.4% vs 19.3% of tumors >5 cm. Radiotherapy was given to 61.1% and 64.3% of SI and non-SI tumors, respectively ($p<0.001$), while 65.6% of SI and 66.5% non-SI tumors <2 cm underwent radiation ($p=0.711$). After adjusting for patient and tumor characteristics, SI patients were 79.7% more likely to receive radiation therapy than non-SI patients (OR 1.80; 95% CI = 1.65, 1.95; $p<0.001$). Chemotherapy provided an OS benefit for Stage II and III SI and non-SI tumors ($p<0.001$ for all), but there was no difference in the magnitude of that benefit whether SI was present or not ($p=0.167$ and 0.601 in Stage II and III, respectively). Radiotherapy also provided an OS benefit for Stage II and III SI and non-SI tumors ($p<0.001$ for all), with the only differential benefit found to be greater in SI Stage II tumors versus their non-SI counterparts ($p=0.002$).

Conclusions: Despite controversy regarding staging and prognosis of small SI tumors, the majority of patients are given systemic therapy and radiotherapy, even when tumor size is small. There is an equally protective effect of chemotherapy and of radiotherapy on SI and non-SI primaries with a survival benefit seen in Stage II and III tumors whether SI was present or not. Meanwhile, the distribution of neoadjuvant vs adjuvant chemotherapy administration for SI tumors suggests that the definition of an unresectable tumor is not uniformly agreed upon, and further treatment guidance and standardization are required.

402630 - The impact of the Affordable Care Act on breast cancer care in the USA: A multi-institutional analysis

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Background/Objective: The Affordable Care Act (ACA, or Obamacare) was signed into law in 2010. As of February 2016, an estimated 20 million adults, including 9.5 million adult females, gained health insurance coverage under the ACA. The ACA eliminated cost sharing for preventive care such as mammograms. To date, there is little data available on the effect of the ACA on breast cancer care beyond the screening level. This study examined this effect across all levels of breast cancer care: prevention, treatment, and surveillance.

Methods: A retrospective database and chart review of patients at institutions participating in the Integrated Cancer Repository for Cancer Research (iCaRe2) Breast Cancer Collaborative Registry (BCCR) was completed for the timeframes before (2005-2010) and after (2011-2016) implementation of the ACA. A total of 13 sites from 9 states participated in this study. Fisher's exact test and t-tests were used for statistical analysis.

Results: There were 2078 breast cancer patients (366 diagnosed pre-ACA and 1712 diagnosed post-ACA) analyzed. Post-ACA patients were diagnosed at a later age than pre-ACA patients (54.4 years vs. 58.3 years, $p<0.001$). As well, a larger proportion of urban residents were diagnosed after compared to before ACA (63.9% vs. 57.1%, $p=0.015$). In the post-ACA setting, there was an increase in the number of non-Caucasian patients who accessed care. This trend approached but did not achieve statistical significance (5.9% pre- vs. 9.0% post-ACA, $p=0.059$). A shift in the distribution of insurance status was seen post-ACA, with an increased number of Medicaid patients noted (1.5% pre- vs. 4.7% post-ACA, $p=0.015$). No difference in use of screening mammogram was demonstrated; however, increased use of MRI (16.9% vs. 26.2%, $p=0.002$) and ultrasound (35.8% vs. 50.7%, $p<0.001$) were noted post-ACA. Fewer late-stage cancers (AJCC Stage III or IV) were diagnosed in the post-ACA group (20.6% vs. 13.3%, $p<0.001$). There was a trend towards fewer patients presenting with palpable masses post-ACA; however, this did not reach significance (44.7 pre- vs. 38.5 post-ACA, $p=0.072$). A trend towards increased use of genetic testing post-ACA was also seen, but did not achieve significance (23.8% vs. 30.0%, $p=0.059$).

Conclusions: The overall number of patients accessing breast cancer care increased post-ACA. Within this group, patients were older, more urban, and more likely to be insured through Medicaid compared to the pre-ACA group. Increased use of investigational imaging was noted after implementation of the ACA, and these patients were less likely to be diagnosed with later-stage breast cancers. These results

suggest that the ACA may have had a positive effect on breast cancer care. However, more time may be needed to reflect its true impact. This serves to reinforce the importance of affordable insurance coverage for all breast cancer patients.

402929 - Prognostic features and management implications for lobular intraepithelial neoplasia

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Background/Objective: Lobular intraepithelial neoplasia (LIN) refers to a spectrum of lesions ranging from atypical lobular hyperplasia (ALH) to lobular carcinoma in situ (LCIS). Since these lesions are usually not radiologically detectable, they are often found incidentally on core biopsies performed for other coexisting mammographic or clinical findings. An association has been found nevertheless between LIN and an increased risk of invasive carcinoma, of both lobular and ductal subtypes. Several studies have linked LCIS with a higher risk of malignant upgrade than ALH (8,4% vs 2,4%). Despite the fact that LIN is being considered a non-obligate precursor to invasive carcinomas, there is still much controversy surrounding its management, ranging from surgical excision to close surveillance. Through this study, we wish to shed more light on the prognostic features of LIN regarding its upgrade to invasive carcinoma and its implications on management.

Methods: We have retrospectively accessed our institutions prospectively maintained breast cancer database, collecting the records of patients with LIN treated between January 2009 and May 2017. Clinical and demographic data were collected, including imaging results, pathological features of the lesion, and treatments received. We have included patients with a diagnosis of LIN-spectrum lesions on breast biopsy, excluding patients with a concurrently-diagnosed invasive cancer or ductal carcinoma in situ (DCIS). With the help of our institutions breast pathologist and radiologist, we have reviewed and collected pathology and radiology reports. The main study outcome was lesion upgrade rate, defined as the finding of invasive breast cancer at surgery in the setting of a biopsy showing LIN. Patients with other diagnosed malignancies were excluded from the study. Statistical analysis was performed using the R statistical software. Our study protocol was approved by our institutions ethics review board.

Results: A total of 164 patients were identified fitting our inclusion criteria, of which 24 (14.6%) had an upgrade to invasive carcinoma at the time of surgery. The strongest predictors of upgrade were a personal history of breast cancer (79%) and the presence of a palpable mass (65%) ($p<0.001$). Conversely, patients not fulfilling these criteria had an upgrade rate of 3.9%.

Conclusions: Our findings identify personal history of breast cancer and the presence of a palpable mass as predictors of upgrade to invasive carcinoma in patients with LIN spectrum lesions. On the basis of our findings and of previous reports, we recommend surgical resection for patients presenting with these features, while close observation is an acceptable alternative for the remainder of patients with LIN.

403429 - Specialist trainee experiences in axillary lymph node dissection in a post-Z11-era survey indicates declining exposure and confidence

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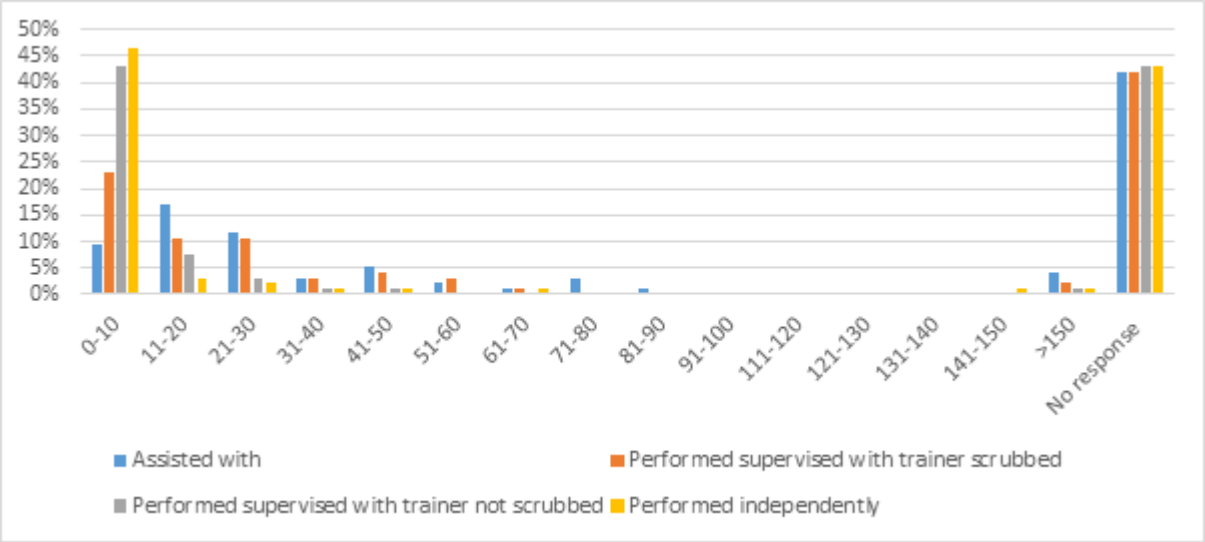
Background/Objective: Axillary lymph node dissection (ALND) is an essential procedure in the surgical management of breast cancer patients. In recent years, studies such as the ACOSOG Z0011 trial have led to a change in clinical practice and a well-documented reduction in the number of ALND procedures. We, therefore, hypothesize that resident exposure has dramatically decreased, impacting resident experience and confidence. To this end, a national survey of UK specialist breast surgical residents was conducted to assess experience, exposure and confidence in ALND.

Methods: A survey was developed by a team including a breast surgeon attending, residents, and a senior research fellow in surgical education. It consisted of 12 open and closed questions, pertaining to level of training, experience participating in and performing ALNDs, confidence in performing the procedure, and methods in which they felt training could be improved. Data on resident opinion regarding the effect of the Z0011 trial on ALND rates were also collected. The survey was administered to breast surgery residents at a Deanery level and through the Mammary Fold using an electronic survey tool, Qualtrics. Data were collected between April and August 2017.

Results: A total of 95 residents or recent attending appointees responded. The majority of respondents had performed only 1-10 ALNDs thus far in their career either with a trainer scrubbed, trainer present but not scrubbed, or independently (23%, 43% and 46% respectively) (see Figure), with a large proportion reporting that they lack confidence in performing the procedure independently. Only 24% of respondents felt they had enough opportunity to gain competence by the end of training. Just over half (51%) felt that ALND numbers had decreased significantly since Z0011 trial publication. Trainees reported that further opportunities would be beneficial, and these could be delivered via lab-based simulation.

Conclusions: UK surgical residents are failing to gain adequate exposure to ALNDs, which is affecting confidence and skill acquisition. Further training opportunities are therefore critical. Given the declining number of ALNDs being performed, simulation training with the new advancements in simulator fidelity and availability could bridge the gap and complement extant training opportunities. High-fidelity simulation is being increasingly recognized as a valuable adjunct to time spent in the operating theatre, and has been successfully developed in breast surgery for SLNB and wide local excision. A high-fidelity ALND surgical simulator has been developed at our center with expert input from a multidisciplinary team, and current preliminary data are promising regarding the simulators validation for skills training and assessment.

Figure: Total number of ALNDs assisted with, performed supervised with trainer scrubbed, performed supervised with trainer not scrubbed, and performed independently



403933 - Conditional survival in women with breast cancer: An analysis of 12,154 patients from a single institution

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Background/Objective: The aim of the study was to examine a conditional survival analysis in women with breast cancer and compare it to more traditional analysis of survival in order to develop more meaningful information for patients and their families.

Methods: A retrospective query of a prospective database was used to abstract patients diagnosed with breast cancer during the years 1988-2017. Patients were stratified by stage of disease at diagnosis. Data were generated based on 5-year disease-free survival (DFS) and overall survival (OS) from the date of diagnosis, as well as 5-year DFS and OS if patients survive 1,2,3, 4 and 5 years without recurrence or death (conditional survival [CS]). Denominators for recurrence and death rate calculations for each interval of CS were determined by the number of patients in the database who had survived or were disease-free at the 1-,2-,3- and 4-year mark from diagnosis. All deaths in the series were from metastatic breast cancer. The best prognosis groups, Stage 0 and I, were compared to life tables of survival for the normal US population. There were a total of 12,154 breast cancer patients in the study who received their care from the University of South Florida and Drs. Cox and Reintgen. The distribution of patients according to the stage of disease at diagnosis included for Stage 0, I, II, III and IV breast cancer, 21.0%, 44.2%, 27.9%, 5.3% and 1.6%, respectively.

Results: For all stages of disease as patients with breast cancer were followed without recurrence or death, the prognosis improved. For Stage I and II patients, 5-year DFS was not affected by survival during the follow-up period; however, for Stage III and IV patients, 5-year DFS increased as patients survived without recurrence during the follow-up period. For instance, for Stage III patients, a 5-year DFS at diagnosis was 53.6%, but this increased significantly to 75% if they survived 4 years without recurrence.

In regard to 5-year overall survival (OS), similar trends were noted. For Stage III patients at diagnosis, the 5-year OS was 44.6%, but this increased to 54.5% if they survived 4 years without recurrence. Five-year OS at any period of time during the recurrence-free follow-up period for Stage I patients was (85.8%, 87.8%, 90.2%, 93.1%, and 96.3%) as patients survive their disease without recurrence. The 5-year OS for patients with Stage II disease rose from 70.9%, 74.1%, 80.1%. 86.4%, and 93.3% as patients survive 1-4 years without recurrence. Stage IV patients improved their 5-year OS from 14.9% to 54.4% if they had no progression for 4 years of follow-up, but numbers were small. The best prognostic groups, those patients with Stage 0 and I breast cancer who survive without recurrence for the first 4 years of follow-up, continued to have an increased death rate compared to the normal population.

Conclusions: Prognosis improves for breast cancer patients if they survive during the follow-up period without recurrence. This was observed for all stages of disease, but particularly for Stage III and IV patients. For all women with breast cancer who survive without recurrence during their follow-up period, DFS and OS approach a common point for Stage 0-III disease. These data provide more meaningful recurrence and survival information for patients and their families, for clinicians, for lawyers in the medical/legal system, and for the insurance industry.

404330 - Endocrine medical treatment in breast cancer: Is that enough?

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Background/Objective: Endocrine treatment has been in the management of hormone receptor breast cancer for a few decades, but never as the first line of treatment. Now in the biomolecular era, we are able to select patients for whom endocrine treatment can be considered the first line of treatment.

Methods: During the months of May 2011 until June 2017, patients with ductal/lobular, in-situ, and invasive cancer were treated medically with endocrine treatment as first choice of treatment (Tamoxifen/AI), due to medical morbidity or as requested by patients. The use of biomolecular assays helped to support the treatment decision. The infrastructure of ABC as a comprehensive center with all the modalities for diagnostic and interventional breast imaging center allow us to do all the follow-up with the same health professionals. The assessments of the follow-ups were based on clinical, imaging (MRI, ultrasound, and mammogram), and pathological responses. We use the term "complete clinical response" on patients for whom the clinical history and the physical examination demonstrate complete improvement of the breast cancer. "Complete imaging response" is referred to those patients who, before treatment, had a breast MRI with enhancement lesions and in the follow-ups show no more enhancements. "Complete pathological response" refers to patients who had no residual cancer on the surgical specimen.

Results: We followed a total of 32 patients for an average period of 20.12 months (range=2-63 months), and an average age of 69.69 (range=45-86). Twenty-six of these patients (81.2 %) had Invasive Ductal Carcinoma, 6 patients (18.7%) had DCIS, 23 of the patients (71.88%), were only treated with endocrine treatment. Nine patients (28.13%) were treated with endocrine therapy plus surgery. The decision for surgery was a personal request of the patient, not a failure of the endocrine treatment. The 32 patients (100%) had a complete clinical response. Twenty-five patients (78.13%) presented a complete imaging response. From the patients who had surgery, 1 patient (11.11%) presented a complete pathological response, 6 patients (66.67%) presented down staging of the tumor, and 2 patients (22.22%) presented no change. Twenty-nine of the 32 patients (90.63%) were able to obtain the recurrence score by

Twenty-one Genes. Twenty-four of those had a low recurrence score, 4 had an intermediate score, and 1 patient had a high recurrence score. Even though this is a small group of patients, there was no failure of treatment, mortality, or progress of the disease. It demonstrated that on selective patients, the effectiveness of endocrine treatment is possible, and can be used as the first-line treatment. The selection of those patients was supported with the use of the 21 genes.

Conclusions: Endocrine treatment, based on clinical and biomolecular assays, can be considered safe to use as the first line of treatment for invasive and non-invasive breast cancer for those patients who refuse surgery or chemotherapy.

396513 - Experiences with a non-narcotic protocol in ambulatory breast surgery: Narcotics are not necessary, and use is surgeon-dependent

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Background/Objective: Surgeons write 1.8% of all prescriptions and 9.8% of all opiate prescriptions. Even small doses prescribed for short-term use can lead to abuse, thus surgeons are uniquely able to combat the opiate epidemic by changing prescribing practices. As part of a department-wide performance improvement project, we initiated a non-narcotic protocol for all ambulatory breast surgery patients. Our objectives were to determine whether post-operative pain could be managed without narcotics, and to describe our experiences with the protocol.

Methods: The non-narcotic protocol began in June 2016, and we reviewed the charts of all ambulatory breast surgery patients from July 2016-July 2017. The protocol suggested pain management expectation counseling and prescriptions for acetaminophen and ibuprofen. Follow-up included a secure message or phone call on post-operative day 1 and a clinic visit after 1-2 weeks. Of the patients who received the protocol, failure was measured by narcotics prescribed within 14 days of PACU discharge. Since the protocol was not strictly enforced, a group of patients were still prescribed narcotics; these patients were further analyzed to improve protocol adherence.

Results: One hundred eighty consecutive charts were reviewed. Ages ranged from 18-95 years (median 63). Procedures were lumpectomy only, lumpectomy with sentinel node biopsy (SLN), or lumpectomy with SLN and intra-operative radiation (IORT). There were 3 complications (all hematomas requiring takeback); 2 (1.6%) received the non-narcotic protocol, and 1 (1.9%) did not. One hundred twenty-seven (70.6%) patients received the non-narcotic protocol, of whom 3 (2.4%) failed. Fifty-three (29.4%) did not receive the protocol. Protocol adherence was surgeon-dependent and not associated with patient characteristics including age, ethnicity, surgery, or history of chronic narcotics (Table). Interestingly, when our more adherent surgeons strayed from the protocol, further chart review showed the narcotics were often prescribed by a resident not familiar with the protocol.

Conclusions: Non-narcotic protocols are one way to limit opiate prescriptions in ambulatory breast surgery patients. While studies have shown that narcotics are over-prescribed in ambulatory surgery, we believe this is the first evaluation of a non-narcotic protocol. While many surgeons are concerned about the bleeding risk associated with NSAIDs, our protocol was safe with no significant complications. Surgeons decisions, rather than patient characteristics, primarily drove the choice of pain management

in our study. We believe our protocol can be improved with stricter implementation and education, which must be balanced with provider independence.

Table: Characteristics

Variable	Non-Narcotic Protocol n=127	Against Protocol n=53	*p*
Surgeon			
Surgeon 1	7	8	
Surgeon 2	18	26	
Surgeon 3	0	8	*<0.01*
Surgeon 4	0	3	
Surgeon 5	9	4	
Surgeon 6	80	1	
Surgeon 7	13	3	
Surgery			
Lumpectomy Only	39	14	*0.18*
Lump+SLN	55	31	
Lump+SLN+IORT	33	8	
Age			
<30	3	1	
30-39	2	1	
40-49	13	5	*0.83*
50-59	34	13	
60-69	41	17	
70-79	27	14	
>80	7	2	
Ethnicity			
Asian/Pac Islander	6	17	
Black/African Am.	10	24	*0.49*
Hispanic/Latin Am.	5	7	
Other/Unknown	2	9	
Caucasian/White	30	70	
Chronic Pain			
Chronic Rx	2	5	*0.74*
No Chronic Rx	51	122	

396612 - Effect of diabetes mellitus on breast cancer prognosis

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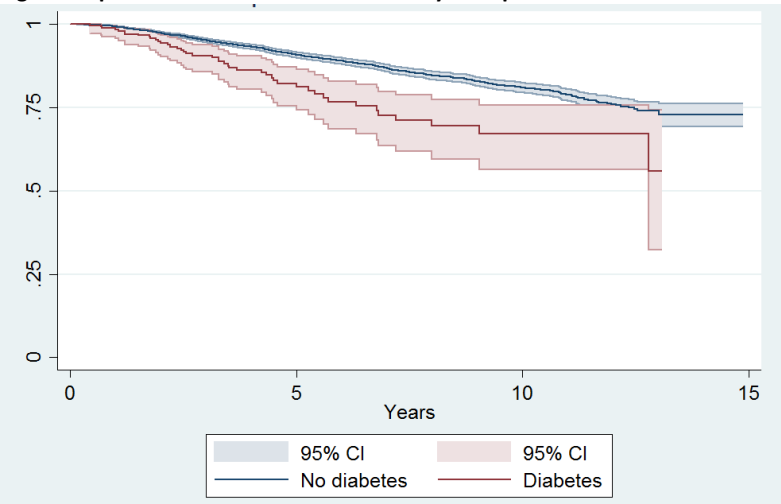
Background/Objective: Recent studies suggest that women with diabetes mellitus (DM) tend to be at higher risk for developing breast cancer (BC). However, the role of DM in BC prognosis remains controversial. We sought to evaluate the association between diabetes and cancer recurrence and survival in patients with BC.

Methods: We analyzed survival data from a prospectively-kept institutional BC registry, comparing patients with or without diabetes. We built Kaplan-Meier curves for both groups, comparing unadjusted survival statistics using Log-rank test. We used Cox Proportional Hazards to adjust for potential confounders.

Results: From 2003-2015, 6,280 women treated for BC were included in our institutional registry; 255 (4%) were diagnosed with DM. Five-year survival rates were 91% (95%CI: 90-92%) for the non-DM cohort and 82% (95%CI: 75-87%) for the DM cohort. Cox proportional hazards showed a negative association of DM with survival, which was statistically significant for the unadjusted (Hazard Ratio, HR=2.0, 95%CI [1.47-2.71], p<0.001) but not for the adjusted (HR=1.41, 95%CI [0.93-2.13], p=0.101) analysis. Predictors of worse survival within the DM cohort were smoking status (HR=2.52, 95%CI [1.30-4.90], p=0.006), and cancer stage (p<0.001), while receipt of chemotherapy provided survival benefit (HR=0.16, 95%CI [0.03-0.79], p=0.02). Adjusted analysis showed a negative but not statistically significant association between DM and cancer recurrence (HR=1.82, 95%CI [0.91-3.62], p=0.087). Predictors of recurrence within the DM cohort were cancer stage (p<0.001) and indication for axillary lymph node dissection (HR=35.42, 95%CI [1.16-1080.2], p=0.041).

Conclusions: Our findings indicate that after adjusting for patient and treatment characteristics, DM is not significantly associated with lower 5-year survival rates in BC patients. Although our results are not in agreement with studies previously published, we believe that appropriate control of DM might contribute to these negative results. Future studies should take into account levels of HbA1c as a marker of successful DM management.

Figure: Kaplan-Meier curve for survival analysis of patient with and without DM



403187 - Incidental breast cancer diagnosed after reduction mammaplasty despite pre-operative mammography

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Background/Objective: Reduction mammaplasty is a common operation performed on healthy women. There are varying estimates of the incidence of non-invasive and invasive breast cancer diagnosed at the time of reduction mammaplasty (0.1-2.3%), and there is limited information on these patients' pre-operative care. At minimum, all women over the age of 50 should have a pre-operative mammogram according to a 2016 publication of the American Society of Plastic Surgeons on evidence-based care for reduction mammaplasty. The purpose of this study was to determine the incidence of incidental breast cancer identified during reduction mammaplasty and to characterize the pre-operative imaging performed prior to reduction mammaplasty.

Methods: Women >18 years old who underwent reduction mammaplasty from 2013-2015 were identified from the Truven Health MarketScan® databases. Patients with a prior diagnosis of breast cancer were excluded. Patients were categorized as having incidental breast cancer found at time of reduction mammaplasty if there was a breast cancer diagnosis 0-30 days after the operation. Pre-operative mammography was defined as mammography within 1 year prior to reduction mammaplasty. Descriptive statistics were calculated.

Results: There were 18,969 women who underwent reduction mammaplasty in our cohort with a mean age of 42.5 years old. One hundred eighty-six women (0.98%) were found to have incidental breast cancer. Of those with incidental breast cancer, 78.0% (n=134) had invasive breast cancer, and 22.0% (n=52) had carcinoma in situ. Patients found to have incidental cancer were older than patients without cancer (50.8 vs. 42.5 years respectively, $p<0.001$). Overall, 58.2% of patients had mammography prior to reduction mammaplasty; rates were higher (84.3%) for patients over the age of 50 years. Of those over the age of 50 who were diagnosed with breast cancer at the time of reduction mammaplasty, 79.3% received pre-operative mammography.

Conclusions: Incidental breast cancer diagnosed at time of reduction mammaplasty is uncommon. Importantly, the majority of women older than 50 years old appropriately received pre-operative mammography. However, incidental cancers were still identified despite the receipt of mammography. These data can be used to guide pre-operative patient counseling to manage patient expectations on the potential for incidental breast cancer identified at reduction mammaplasty even with pre-operative mammography.

Table: Pre-operative mammography by age and presence of incidental breast cancer

	Mammography All Reduction Mammaplasty (N=18969)	**Mammography** Incidental Breast Cancer (N=186)
Total	58.2%	76.3%
Age: < 40	18.2%	27.3%
≥ 40 and <50	83.0%	90.6%
≥ 50	84.3%	79.3%

404262 - Breast cancer subtype phenotype is often not preserved in recurrent disease after Her-2/neu targeted therapy

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Background/Objective: Since its initial approval in 2006, trastuzumab has become the standard of care adjuvant therapy for HER-2/neu (HER2) overexpressing breast cancer. Whether the use of targeted therapy such as trastuzumab alters the receptor status of recurrent tumors is unclear. We hypothesize that recurrent tumors may lose HER2 expression after treatment with trastuzumab.

Methods: After obtaining IRB approval, we used natural language software to query our electronic medical records (EMR) and identified 411 patients with a diagnosis of recurrent invasive breast cancer between 5/1/2008 and 8/31/2017. We collected demographic, pathology, and treatment data and identified a subset of 321 women with recurrent breast cancer in whom receptor status of both the primary and recurrent tumor were available. For this study, we included only those with primary breast cancer which was HER2+ (n=32). We compared the tumor characteristics of the recurrent tumor of our study cohort stratifying by those who received a full course of trastuzumab (n=15) vs. partial or no treatment with trastuzumab (n=17).

Results: Of the 17 patients in the partial or no treatment subgroup, 11 patients never received trastuzumab. The remaining 6 patients had interrupted courses related to noncompliance or toxicity. There were no significant differences between the 2 subgroups in patient demographics, primary tumor characteristics, time to recurrence, sites of tumor metastasis, and disease outcome. Eight of 15 patients (53.3%) in the full trastuzumab course subgroup had a HER2- recurrent tumor, while only 2 of 17 patients (11.8%) in the partial/no trastuzumab subgroup were HER2- (p=0.01).

Conclusions: Here we demonstrate that recurrence in patients with HER2+ breast cancer treated with HER2-targeted therapy were more likely to be of HER2- subtype. Our results suggest that HER2+ breast cancer may be phenotypically heterogeneous and that targeted therapy may have selectively suppressed the clonal emergence of HER2+ tumor cells. Further studies are needed to evaluate the effectiveness of combination therapy in preventing recurrence of various breast cancer subtype, especially those with the poorest prognoses such as triple-negative breast cancer.

Table: Patient and tumor characteristics stratified by trastuzumab therapy

	Total	Received full course of trastuzumab		p
		Yes	*No*	
n	32	15	17	
Age at first diagnosis (years)	49.0 ± 12.6	49.3 ± 13.6	48.8 ± 12.1	0.89
Race				
White	25 (78.1)	13 (86.7)	12 (70.6)	0.07
Black	3 (9.4)	0 (0.0)	3 (17.6)	
Other	2 (6.3)	2 (13.3)	0 (0.0)	
Unknown	2 (6.3)	0 (0.0)	2 (11.8)	
Initial histology				
Hormone receptor				
Positive	20 (62.5)	10 (66.7)	10 (58.8)	0.83
Negative	4 (12.5)	2 (13.3)	2 (11.8)	
Unknown	8 (25.0)	3 (20.0)	5 (29.4)	
HER2				
Positive	32 (100.0)	15 (100.0)	17 (100.0)	1.00
Initial T stage				
1	15 (46.9)	6 (40.0)	9 (52.9)	0.78
2	7 (21.9)	3 (20.0)	4 (23.5)	
3	3 (9.4)	2 (13.3)	1 (5.9)	
Unknown	7 (21.9)	4 (26.7)	3 (17.6)	
Initial N stage				
0	7 (21.9)	0 (0.0)	7 (41.2)	0.8
1	12 (37.5)	8 (53.3)	4 (23.5)	
2	2 (6.3)	1 (6.7)	1 (5.9)	
3	2 (6.3)	1 (6.7)	1 (5.9)	
Unknown	9 (28.1)	5 (33.3)	4 (23.5)	
Adjuvant therapy				
Radiation	14 (43.8)	7 (46.7)	7 (41.2)	0.83
Chemotherapy	19 (59.4)	11 (73.3)	8 (47.1)	0.21
Trastuzumab course				
None	11 (34.3)	0 (0.0)	11 (64.7)	<0.001
Partial	6 (18.8)	0 (0.0)	6 (35.3)	
Full	15 (46.9)	15 (100.0)	0 (0.0)	
Time to recurrence (months)	49.3 ± 37.6	44.8 ± 38.2	51.7 ± 35.2	0.22
Site of recurrence				
In breast	17 (53.1)	8 (53.3)	9 (52.9)	0.25
Subcutaneous	4 (12.5)	3 (20.0)	1 (5.9)	
Chest Wall	3 (9.4)	2 (13.3)	1 (5.9)	
Axilla	3 (9.4)	0 (0.0)	3 (17.6)	
Distant	3 (9.4)	2 (13.3)	1 (5.9)	
Unknown	2 (6.3)	0 (0.0)	2 (11.8)	
Recurrent histology				
Hormone receptor				
Positive	18 (56.3)	9 (60.0)	9 (52.9)	0.12
Negative	13 (40.6)	6 (40.0)	7 (41.2)	
Unknown	1 (3.1)	0 (0.0)	1 (5.9)	
HER2				
Negative	10 (31.3)	8 (53.3)	2 (11.8)	0.01
Positive	22 (68.8)	7 (46.7)	15 (88.2)	
Mean follow-up (months)	83.5 ± 48.8	74.5 ± 48.5	95.0 ± 52.8	0.81
Vital status				
No evidence of disease	2 (6.3)	2 (13.3)	0 (0.0)	0.46
Alive with disease	9 (28.1)	4 (26.7)	5 (29.4)	
Died of disease	8 (25.0)	3 (20.0)	5 (29.4)	
Died of other causes	13 (40.6)	6 (40.0)	7 (41.2)	

404975 - Feasibility of a simulator for breast surgery training

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Background/Objective: Over time, breast cancer surgical treatment has evolved, and oncoplastic breast surgery has been integrated and become a gold standard in breast surgery. To indicate and to perform the best potential of those techniques is crucial training. The aim of this study is to present and discuss the feasibility of mastotrainers. Simulators, made of neoderm, developed to improve surgical skills in breast surgery.

Methods: A breast surgery course was organized during 6 modules. Four kinds of mastotrainer were used for practicing different surgical techniques. Most of the techniques were never used in the simulator before. The first with small breast is ideal to train conservative mastectomies and additive mammoplasty. The model 2 is able to train different breast oncoplastic techniques as well as inferior pedicle, superior pedicle, and round block techniques. The model 3, medium size breast, is good for training asymmetry corrections and to practice mastopexy techniques. The fourth model, the last version, is perfect to allow different techniques specially for reduction mammoplasty and several different oncoplastic breast surgeries techniques. It is possible to simulate tumors at different sites of the breast. At the end, a survey was applied to the attendees to receive a feedback regarding this training experience.

Results: After 6 modules, the participants were able to perform various techniques of oncoplastic breast surgery: round block technique, dermo-glandular flaps, upper pedicle, inferior pedicle, super medial pedicle, lateral pedicle, lumpectomies, conservative mastectomies, total muscle pocket for implants, muscular partial pocket for implants, use of expanders, use of definitive expanders, use of silicone implants, use of mesh for tissue reinforcement, use of adhesive suture, local flaps for nipple reconstruction, additive mammoplasty, and finally, with model association biological, they could practice the technique of fat grafting. The survey revealed the high level of achievement and satisfaction of the participants.

Conclusions: The use of mastotrainer is safe and feasible. It allows the practice of many techniques. It is strongly able to help breast surgeons to develop and to improve their surgical skills.

Patient Education

403542 - Projected cost of lifelong high-risk screening in BRCA mutation carriers versus prophylactic mastectomy with reconstruction: A cost-savings analysis

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Background/Objective: Awareness of value-based, quality care has become an increasingly important issue for health care. Patients with a BRCA mutation have a lifetime risk of developing breast cancer, up to 87% by age 70. The option of high-risk screening versus risk-reducing surgery is a physical, emotional, and financial decision. Given the significant expense associated with lifetime screening for BRCA 1 and 2 patients, surgery may not only be an option to prevent cancer but may reduce health care cost as well. To date, there are no cost analyses of surgery versus screening from the patient perspective. We designed a study to compare the expense of lifelong screening versus prophylactic mastectomy with reconstruction for BRCA 1 and 2 patients to evaluate potential cost-saving benefits.

Methods: We performed a projected cost analysis based on an estimate of lifelong, high-risk screening compared to prophylactic bilateral mastectomy with Deep Inferior Epigastric Perforator (DIEP) flap reconstruction. We utilized National Comprehensive Cancer Network (NCCN) recommendations to define lifelong high-risk breast screening. The screening included the cost of 1 additional office visit per year, an annual breast Magnetic Resonance Image (MRI), and an annual mammogram. Costs were calculated from average expenses charged to patients as well estimates from the billing hotline at our institution. The final estimates are after all discounts have been taken by the hospital and are representative of the final out-of-pocket fee that is paid. The high-risk screening cost was compared to the cost of a bilateral prophylactic mastectomy with DIEP flap reconstruction. Included in this surgery cost was the operating room fees, plastic surgeon fees, anesthesia fees, and the hospital stay. The patient costs were estimated based on a hypothetical insurance plan with a deductible of $1,000, an 80/20 copay, and a $5,000 annual out-of-pocket maximum.

Results: When comparing the total expenditures, we found that the estimated annual cost for screening is $2,611. The patient out-of-pocket cost is then calculated to be $1,322 annually. Thus, if a patient has no events, biopsies, or cancers, high-risk screening will cost an estimated $59,490 over the patient's lifetime. The insurance company will pay an estimated $1,289/year with a lifetime total of $58,005. The total lifetime screening cost is $117,495 paid by both the patient and insurance company. The bilateral prophylactic mastectomy with DIEP reconstruction cost was estimated at $111,426. Of this cost, the patient will pay her out-of-pocket maximum for the year, but will not have further charges associated with high-risk screening. If an insurance plan has an out-of-pocket maximum of $5000, the patient has the potential of a lifetime savings of $54,490 with the added benefit of a significant cancer risk-reduction. Additionally, as the total out-of-pocket cost for the patient is additive, it is most financially beneficial for the patient to have surgery at a younger age. The insurance provider pays $58,005 for screening and $106,426 for prophylactic surgery. Although the insurance provide ultimately pays more for surgery in this model, the benefit is in the reduction of cancer and its associated costs

Conclusions: Patients with a BRCA mutation will save more than $50,000 over their lifetimes by choosing to undergo early risk-reducing prophylactic mastectomy with reconstruction. Therefore, the

surgery option not only reduces cancer risk, but also has a significant lifetime cost savings. Patient cost perspectives have not previously been published, and we feel that's what makes this novel and an asset to future patient conversations.

Phyllodes

399222 - Local recurrence after breast-conserving therapy for phyllodes tumors: A 15-year retrospective review

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Background/Objective: Phyllodes tumors (PT) account for <1% of all breast tumors. There are sparse data regarding long-term outcomes of patients with PT following breast-conserving surgery without or without radiation therapy (RT). We performed a retrospective study of our tertiary cancer center's experience to examine how margin status and radiation therapy (RT) would affect rates of local recurrence and other outcomes.

Methods: This IRB-approved review included 70 patients diagnosed with PT from 1/1/2000 through 6/30/2015; none underwent mastectomy. Central pathologic review was conducted. Data are presented as proportions or medians and interquartile range. We used Fisher's exact and Chi-square tests for testing significance of differences for categorical variables and the Kruskal-Wallis test for continuous variables. A p-value less than 0.05 was considered statistically significant.

Results: The median age at presentation of patients with benign primary PT was 42.6 years (36.652.2) as compared to 45.1 years (40.653.9) in the borderline group and 56.8 years (50.459.6) in the malignant group (p=0.02). Median tumor size on physical examination (for palpable lesions) was dissimilar among the histologic groups: benign, 2.3 cm (2.03.5); borderline, 4.0 cm (3.05.3); and malignant, 6.0 cm (4.07.0) (p=0.009). Image-guided core needle biopsy demonstrated PT in 6% (of 34) of the benign group, none (of 11) of the borderline group, and 33% (of 6) of the malignant group (p=0.06). RT was known to have been received by 4% (2) of patients with benign PT, 21% (3) of patients with borderline PT, and 38% (3) of patients with malignant PT). Local recurrence occurred in 4% (2) of patients with benign PT, 7% (1) of patients in the borderline group, and 38% (3) of the malignant group (p=0.02). Local recurrence developed in 0/2 irradiated and 2/44 unirradiated patients with benign PT; 0/3 irradiated and 1/10 unirradiated patients with borderline PT; and 0/3 irradiated and 2/3 unirradiated patients with malignant PT. (Patients with unknown RT status were excluded.) Two of 27 (7%) of patients with margins <1 mm or positive with benign PT had local recurrence, compared to none of 21 patients with margins 1 mm or wider. Margin status was confounded with RT use for patients with borderline and malignant PT. One patient with malignant PT developed distant recurrence without local recurrence. Of those patients with benign PT, 96% remain alive without evidence of disease, compared to 93% in the borderline group, and 63% in the malignant group (p=0.02). No statistically significant association was demonstrated between disease-free survival and either margin status or RT received across all types of PT when subgroup analyses were performed. All patients who received RT (n=8) were PT-free at follow up. Only 1 patient expired of nonmalignant cause.

Conclusions: Patients with malignant PT generally presented at an older age and with clinically larger tumors than their benign and borderline counterparts. Core biopsy tended to demonstrate fibroepithelial pathology in all lesions, but PT pathology was more common in core biopsy of malignant lesions. RT was given with greater frequency to patients in the malignant group. A statistically significant association between locoregional recurrence and PT subtype was identified, with more than one-third of malignant PT demonstrating locoregional recurrence as compared to a small minority of benign and

borderline PT. Neither margin status nor receipt of RT demonstrated significant association with DFS in any PT subtype, which however may reflect the small number of cases in subgroups rather than their intrinsic importance.

404000 - Trends in the diagnosis of phyllodes tumors and fibroadenomas before and after release of WHO Classification Standards

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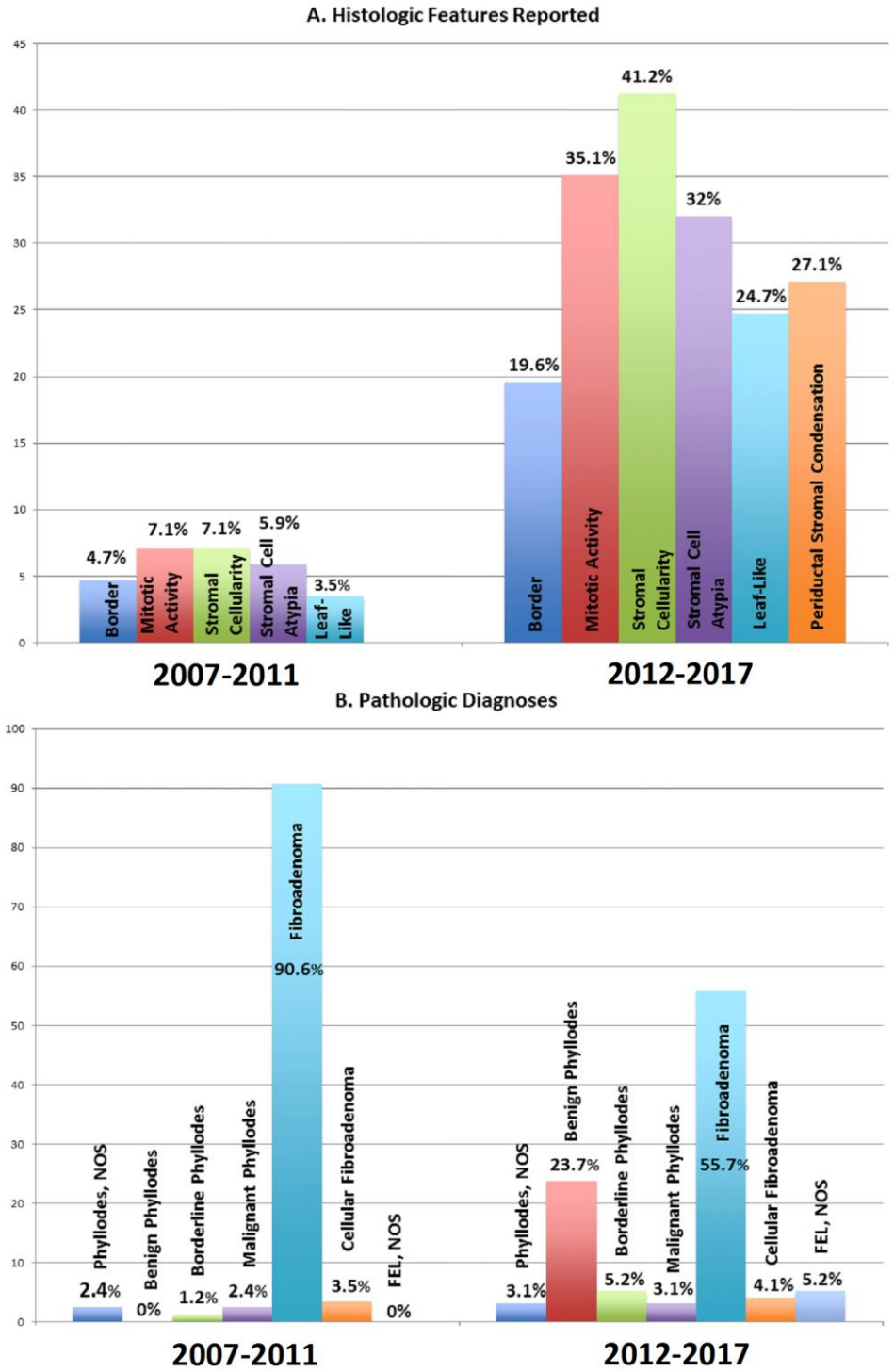
Background/Objective: Despite significant differences in clinical behavior and management, current literature has established the difficulty and inter-observer variability in diagnosing phyllodes tumors and fibroadenomas. In 2012, the World Health Organization (WHO) released criteria for the diagnosis and grading of phyllodes tumors based on histological features. We sought to examine the application of WHO criteria and changing epidemiology of fibroepithelial tumors.

Methods: A text search for "phyllodes tumor" and "fibroadenoma" in the diagnostic line, comment, or history section of all pathology reports from a single tertiary care pathology department was conducted from January 2007 to June 2017. Data for surgically excised tumors regarding histological features in the WHO criteria (tumor border, stromal cellularity, stromal cell atypia, and mitotic activity), as well as traditional descriptors (leaf-like architecture, periductal stromal condensation) were collected from surgical pathology reports. Demographic and clinical data were collected from medical records. Variables from diagnoses before and after 2012 were compared to evaluate the impact of WHO Breast Tumor Classification standards.

Results: During the study period, 182 surgically removed fibroepithelial tumors had pathologic data available for review. The mean (SD) age was 31.9 (17.4) years. Non-Hispanic white patients comprised 39.6% (70) of the study population, followed by 33.3% (59) Hispanic, 11.3% (20) Asian/Pacific Islander, 8.5% (15) non-Hispanic black, and 7.3% (13) other race ethnicity. Where presenting symptom was available, 65% (78) noted a mass, 20.8% (25) were found on screening imaging, and 5% (6) presented with pain. Overall, the final pathologic diagnoses were phyllodes NOS (5 (2.5%)), benign phyllodes (23 (12.6%)), borderline phyllodes (6 (3.3%)), malignant phyllodes (5 (2.8%)), fibroadenoma (131 (72.0%)), cellular fibroadenoma (7 (3.9%)), and fibroepithelial lesion NOS (5 (2.8%)). When comparing cases diagnosed before and after 2012, there were no significant differences in mean (SD) age (33.4 (17.7) before vs. 30.5 (17.2) after, p=0.1) or race ethnicity (p=0.5). When comparing recent data to that of the earlier time period, there were statistically significant increases in reporting of WHO and non-WHO histologic features. Analysis of final pathologic diagnoses demonstrated a significant increase in diagnoses of benign phyllodes tumors (0/85 (0%) before vs. 23/97 (23.7%) after) and decrease in diagnoses of fibroadenoma (77/85 (90.6%) before vs. 54/97 (55.7%) after) ($p<0.0001$). (See Figure.)

Conclusions: Since the release of the 2012 WHO Breast Tumor Classification standards, there has been an increase in reporting of specific histologic criteria as well as traditional descriptors of fibroepithelial lesions. The expanding use of these discrete criteria have been accompanied by an increased frequency of diagnoses along the fibroepithelial spectrum with the exception of a marked decrease in diagnoses of fibroadenomas. Whether the rising incidence of benign phyllodes tumors is due to reclassification of historically described fibroadenoma with use of WHO criteria or other factors requires further research. As fibroepithelial diagnoses become more distinct, evidence based management recommendations for less virulent phyllodes diagnoses should be developed.

Figure: Comparison of proportions A. Reporting WHO and traditional histologic features and B. Pathologic diagnoses before and after 2012



Comparison of percent reporting WHO and traditional histologic features 2004-2011 vs. 2012-2017 for all variables, p value <0.0001, except for Border, p value=0.003. Comparison of pathologic diagnoses 2004-2011 vs. 2012-2017, p value <0.0001.

404216 - Long-term outcomes after surgical treatment of malignant phyllodes tumors

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Background/Objective: Malignant phyllodes tumors (PTs) are rare, and little is known about their long-term prognosis. We sought to evaluate recurrence rates and identify factors predictive of local and distant failure.

Methods: From 1957 to 2017, we identified 124 patients with 125 malignant PTs. Patients with atypical or low-grade malignant PTs (also known as borderline) (=39) were included. Recurrence rates and survival were assessed using the Kaplan-Meier method and correlated with clinicopathologic factors using the log-rank test.

Results: Median patient age was 44 years (range 13-83). Median tumor size was 5 cm (range 0.9-35). Forty-three percent underwent mastectomy, and 57% underwent breast-conserving surgery. Adjuvant chemotherapy and radiotherapy were rarely used (1.6% and 0.8%, respectively). At a median follow-up of 7.8 years, 12 patients developed an isolated local (n=10), locoregional (n=1), or regional (n=1) recurrence, of which 11 occurred within 4 years of initial surgery. The 5- and 10-year locoregional recurrence-free survival was 90% (95% confidence interval [CI] 84-96). On univariable analysis, young age <40 (p=0.004), breast-conserving surgery (p=0.016), and close/positive margins (p=0.01) were associated with increased risk of locoregional recurrence (Table). Seven patients developed distant disease, 6 of which occurred within 18 months of initial surgery. All patients with distant disease had tumors with infiltrative borders, marked stromal overgrowth, marked stromal cellularity, and 10 mitoses per 10 hpf. Only 21 (17%) tumors had all of these characteristics; of these, 7 (33%) developed distant disease. Among the 104 (83%) that did not have uniformly poor features, none developed distant disease. Overall, the 5- and 10-year distant recurrence-free survival was 95% (95% CI 91-99) and 94% (95% CI 89-98). The 10-year disease-specific survival (DSS) was 95% (95% CI 91-99), and overall survival was 90% (95% CI 83-96).

Conclusions: Malignant PTs treated with surgical resection have an excellent prognosis with a 10-year DSS of 95%. The presence of uniformly poor pathologic features occurred in 17% of malignant PTs and predicts for a poor prognosis; efforts should be directed toward new treatment approaches for these tumors.

Table: Factors associated with locoregional recurrence

Characteristic	10 yr LRR free survival (95% CI)	Hazard ratio (95% CI)	p-value
Age			0.004
< 40	79% (67% - 93%)	1.00	
≥ 40	96% (92% - 100%)	0.18 (0.05 - 0.68)	
Histology			0.5
Low grade	89% (79% - 100%)	1.00	
Malignant	90% (83% - 97%)	0.71 (0.22 – 2.22)	
Stromal cellularity			0.5
Marked	88% (79% - 98%)	1.00	
Mild/moderate	91% (83% - 100%)	0.63 (0.16 - 2.45)	
Stromal overgrowth			0.8
Marked	95% (88% - 100%)	1.00	
Uniform	NA	2.02 (0.18 - 23.08)	
Stromal expansion	92% (85% - 100%)	1.72 (0.31 - 9.39)	
Borders			0.5
Circumscribed	NA	1.00	
Pushing	83% (71% - 98%)	0.98 (0.12 - 8.27)	
Infiltrative	91% (84% - 99%)	0.49 (0.06 - 4.19)	
Mitosis			0.2
< 10	96% (89% - 100%)	1.00	
≥ 10	88% (81% - 95%)	3.68 (0.47 - 28.66)	
Necrosis			0.2
No	92% (86% - 98%)	1.00	
Yes	68% (38% - 100%)	2.65 (0.52 - 13.43)	
Surgery			0.02
BCS	84% (76% - 94%)	1.00	
Mastectomy	97% (93% - 100%)	0.12 (0.02 - 0.95)	
Final margin			0.01
Close/positive	74% (56% -100%)	1.00	
Negative	93% (88% - 99%)	0.23 (0.07 - 0.78)	

LRR, locoregional recurrence; CI, confidence interval; BCS, breast-conserving surgery

Reconstruction

400897 - The use of serratus anterior fascial flap in integrated mastectomy and implant reconstruction

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Background/Objective: Tissue reinforcement with acellular dermal matrix (ADM) in single-stage (direct-to-implant) implant-based breast reconstruction contributes to a complete coverage of the implant, and thus avoids its direct exposure to skin incision. Nevertheless, the increased risks of infection, seroma formation, and even concomitant implant loss are not negligible. Our integrated technique makes use of the in-situ serratus anterior fascia as the inferior and lateral support of the implant following mastectomy, which serves the same purpose of ADM in terms of aesthetic outcomes, but minimizes the hazard of infective complications.

Methods: We retrospectively reviewed all the nipple-sparing mastectomy with direct-to-implant immediate reconstruction in Hong Kong Sanatorium and Hospital from 2012 to 2016. They included breast cancer patients requiring mastectomy and women undergoing prophylactic mastectomy. The authors made use of the serratus anterior fascial flap as an autologous implant coverage. Incision was determined by factors like tumor location, skin involvement, previous scars, etc. Skin flap was raised along the subcutaneous plane over the whole breast. Prepectoral fascia was incised at its upper border in infraclavicular region. Breast parenchyma was reflected for posterior dissection from superolateral to inferomedial direction reaching nipple level. Subpectoral pocket was raised by splitting pectoralis major muscles over the fourth or fifth intercostal space. Elevation of this subpectoral pocket was extended laterally beyond the pectoral muscles, raising also the serratus anterior fascia, while keeping the breast in-situ as a support for dissection. The pocket was developed by a combination of blunt dissection with gauze packing and sharp dissection with diathermy. The remaining inferior part of the breast was then dissected off the underlying pectoralis major muscles and serratus anterior fascia. After delivery of the breast specimen, textured anatomical gel implant was placed in the subpectoral pocket, which was then closed by approximating pectoral muscle fibers. Consequently, the implant would be completely covered by autologous tissues, i.e., pectoral muscles superomedially and serratus anterior fascial flap inferolaterally.

Results: Among the 51 women included, primary breast cancers account for 91.8% of our indications for these 61 procedures of integrated mastectomy and implant reconstruction, and the vast majority had an early disease stage. The remaining 5 (8.2%) were performed as contralateral prophylactic mastectomy. Almost three-quarters of the patients had a bra cup size of B or below. Clinical characteristics and histopathology results are summarized in the Table. After a mean follow-up of 31.6 months, there was no reported post-operative complication of skin flap or nipple-areola complex necrosis, or infection or extrusion of implant.

Conclusions: Our series support that the serratus anterior fascial flap could provide autologous coverage in place of ADM in implant-based breast reconstruction, especially in small- and medium-sized breasts. The short-term results were promising with minimal post-operative morbidities. Appropriate patient selection based on body habitus and disease status, as well as meticulous surgical technique, are critical for its success.

Table 1: Patient demographics, operative details, and histopathology results of 61 procedures of integrated mastectomy and implant reconstruction

	Number	(%)
Number of patients	*51*	
Mean age, years (range)	41.3	(23-64)
Mean body mass index, kg/m^2 (range)	19.9	(16.6-27.3)
Bra cup size		
A	17	(33.3)
B	20	(39.2)
C	8	(15.7)
D or above	3	(5.9)
Number of breasts	*61*	
Mean breast specimen weight, gram (range)	231.8	(70-510)
Mean implant volume, ml (range)	244.7	(95-400)
Pathological stage (AJCC Grouping)		
0	25	(41.0)
I	15	(24.6)
II	12	(19.7)
III	3	(4.9)
IV	0	(0)
Others (including prophylactic mastectomy)	6	(9.8)

403555 - The impact of NCCN guidelines for PMRT on reconstructive modality choice

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Background/Objective: Autologous reconstruction is preferred when patients require post-mastectomy radiation therapy (PMRT). The purpose of this study is to evaluate national trends for immediate reconstruction in the setting of PMRT.

Methods: Female patients who underwent mastectomy for non-Stage IV breast cancer between 2010 and 2013 were identified in the Surveillance, Epidemiology, and End Results (SEER) database. The patients were grouped based on the National Comprehensive Cancer Network (NCCN) guidelines regarding PMRT. The rate and type of reconstruction, when known, was determined for each of the groups.

Results: A total of 110,137 patients underwent mastectomy for non-Stage IV breast cancer between 2010 and 2013. The rate of immediate reconstruction was 21.8% when NCCN recommended PMRT, 31.1% when PMRT should be considered, and 37.4% when it is not recommended ($p<0.001$). However, within each subgroup, the rate of reconstruction was not impacted by the decision to actually proceed with PMRT. Of all reconstructions, 28.8% were autologous, 36.6% implant, 13.2% combined autologous and implant, and 21.5% unknown. The percent of autologous reconstructions, including combined autologous and implant and excluding unknowns, was not correlated with NCCN recommendation for, or the actual receipt of, PMRT.

Conclusions: Overall rates of immediate breast reconstruction correlated with NCCN guidelines for PMRT, but interestingly, not with the decision to adhere to these recommendations. In this cohort, the recommendation for PMRT did not lead to higher use of immediate autologous reconstruction.

Table: Rates of post-mastectomy radiation, any reconstruction and autologous reconstruction between 2010 and 2013

NCCN Radiation Recommendation N (%)	Post-mastectomy Radiation Therapy given N (%)		Any Reconstruction N (%)	Autologous Reconstruction* N (%)
Recommended 19891 (18.1%)	Yes	11778 (59.2%)	2784 (23.6%)	1187 (52.6%)
	No	8113 (40.8%)	1551 (19.1%)	700 (59%)
	Total	19891	4335 (21.8%)	1887 (54.8%)
Consider 19612 (17.8%)	Yes	6410 (32.7%)	2106 (32.9%)	801 (48.2%)
	No	13202 (67.3%)	3999 (30.3%)	1691 (53.4%)
	Total	19612	6105 (31.1%)	2492 (51.6%)
Not Recommended 70634 (64.1%)	Yes	3494 (4.9%)	1198 (34.3%)	475 (55.2%)
	No	67140 (95.1%)	25221 (37.6%)	10,578 (53.3%)
	Total	70634	26419 (37.4%)	11053 (53.4%)

* includes combined autologous and implant and excludes about 21% where type of reconstruction was unknown

403977 – Same-day mastectomy with staged, sub-pectoral reconstruction: 30-day outcomes and cost analysis

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Background/Objective: Recent data show a national trend in favor of mastectomy with implant-based reconstruction (IBR) over breast conservation for patients with breast cancer. An increase in contralateral prophylactic mastectomy (CPM) accounts significantly for the increased number of reconstructive procedures in the U.S. Traditionally, mastectomies with or without reconstruction were performed as inpatient procedures. With an increased demand for higher-cost IBR procedures, health care budgets face increasing financial constraints. Literature supports the safety of same-day mastectomy (SDM). We sought to determine the impact of implementing an enhanced recovery protocol (ERP) for SDM and sub-pectoral IBR, compared to planned overnight admissions (POA) on 30-day complication rates and overall costs.

Methods: An IRB-approved, retrospective review of all nipple-sparing mastectomy (NSM) and skin-sparing mastectomy (SSM) with sub-pectoral IBR within a university system in women 18 years of age for the time period 2014-2016 was performed. Demographic and clinical characteristics were compared between the stay types (SDM vs. POA). Complication rates and overall costs (direct and indirect) were calculated using descriptive statistics by stay types. Individualized direct and indirect cost and payment data from the hospital accounting system (Soarian and Invision) was sought. Post-operative complications requiring intervention, readmissions, ER visits, urgent care visits within the 30-day post-operative window were recorded. We used 2-sided t-test, exact Pearsons Chi-square test, and one-way ANOVA for stay type group comparisons.

Results: We identified 68 patient encounters for 63 patients. There were 36 SDM patient events (50% bilateral) and 32 POA patients (41% bilateral). There were 6 SSM patients, 1 patient with both SSM and contralateral NSM. There was a significant difference in mean age (Std Dev) between SDM and POA patients, 45 (11 SD) vs. 50 (10 SD) years of age respectively, p=0.03. There was a significant difference in

patients with POA due to social factors that included issues such as travel distance >60 miles, absence of social support, and patient request, 0/36 vs. 7/32, p=0.004. There was no difference in stay between patients based on BMI, presence of obstructive sleep apnea, diabetes, coronary artery disease, or renal dysfunction, unilateral vs. bilateral procedures, mental health diagnoses such as depression or anxiety, or surgical indications. There was a non-significant difference in the 30-day complication rate between groups, 5.1% for SDM compared to 15.1% in the POA group, p=0.27. There were 3 post-operative hematomas, the treatment of which did not change the admission pathway, 4 cellulitis events, 2 in each group, and 1 urinary retention event. There were no readmissions for pain, ER visits, or notable events for the SDM group. Cost data analysis revealed the mean direct costs for SDM and POA were $14,112 and $19,255 respectively, a 27% reduction, p=0.002. We showed a reduction in total cost (direct and indirect) of 30%, p=0.0003.

Conclusions: Using an enhanced recovery pathway, SDM with IBR can be performed safely without an increase in short-term complication rates. Additionally, there is a favorable financial impact on health care costs when appropriate patients are treated in an ambulatory setting.

403916 - Trends in reconstructive breast surgery following mastectomy at a single institution between 2011 and 2015

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Background/Objective: Studies show that same-day breast reconstruction after oncologic breast surgery is increasing, yet the data to support this increase in incidence are lacking. How does the presence of malignancy influence a woman's decision to choose reconstructive surgery? Does the evolving field of oncoplastics correlate with a rise in the number of reconstructive surgeries following oncologic mastectomy? This study is intended to examine the timing and type of reconstructive surgery following mastectomy at a community hospital between 2011 and 2015. We hypothesize that the majority of women will choose immediate reconstruction following mastectomy and that the number of reconstructive surgeries will increase from 2011 to 2015.

Methods: This retrospective review evaluates the numbers of breast reconstruction cases following mastectomy, whether for in situ or invasive breast disease, the timing of reconstructive surgery following oncologic surgery, and the type of reconstructive surgery at a single, community-based institution. All patients undergoing mastectomy between 2011 and 2015 were included in this study.

Results: This study consisted of 579 patients ages 21 to 76 years old (average age=55 years). Of those 579 patients, only 129 patients underwent reconstructive surgery following their mastectomy (22%). The number of reconstructive surgeries following mastectomies did not change over time as predicted (average number of cases per year=26). Our study showed that 70.5% of women underwent bilateral mastectomy for unilateral disease, while the remainder (29.5%) of women underwent unilateral mastectomy. Ninety-eight percent of patients had immediate reconstruction following mastectomy (same-day surgery procedure) while 2% had delayed reconstructive breast surgery. Of those that underwent breast reconstruction, the majority of patients elected for tissue expanders when compared to musculocutaneous flaps (98% vs. 2%).

Conclusions: This study did not demonstrate an overall increase in reconstructive surgeries between 2011 and 2015. This study did show an increase in bilateral mastectomies followed by bilateral reconstructive surgery for unilateral breast disease compared to unilateral oncologic and reconstructive

procedures. In addition, the majority of patients underwent immediate reconstructive breast surgery and more often with tissue expanders and implants compared to flaps. These trends of immediate reconstruction with tissue expanders compared to delayed reconstruction with tissue flaps mirror that of the National Cancer Database (NCDB) of the American College of Surgeons and the American Cancer Society. We conclude that while the overall rate of breast reconstruction after mastectomy has not changed, the increase in bilateral mastectomies for unilateral disease may reflect the increasing popularity of oncoplastics as well as benefits of immediate reconstruction including time, cost savings, and positive body image.

403177 - Impact of socioeconomic status on the receipt of immediate post-mastectomy breast reconstruction in Wisconsin

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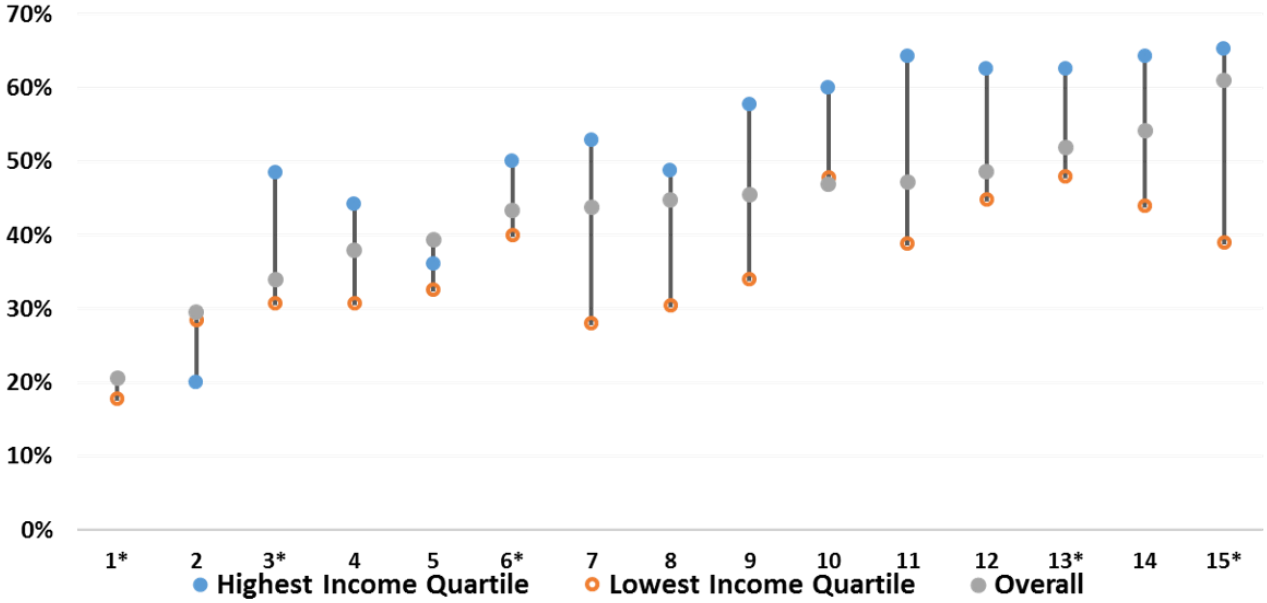
Background/Objective: Reconstruction after mastectomy is a critical component of comprehensive, high-quality breast cancer care, and is associated with higher quality of life. Although the use of reconstruction has increased steadily over the past decade, disparities persist for socioeconomically disadvantaged patients. The objective of this study was to examine the association between immediate reconstruction and socioeconomic status in the state of Wisconsin.

Methods: We used the Wisconsin Cancer Reporting System to identify women with Stage 0-III breast cancer who underwent mastectomy between 2009 and 2014. We excluded patients >75 years of age as very few of these women underwent reconstruction (<3%). We calculated the proportion of patients who underwent immediate reconstruction after mastectomy for the state as a whole, and within 15 distinct geographic regions defined by the Wisconsin Area Health Education Centers (AHEC). Chi-square tests evaluated differences in rates of reconstruction across regions. We categorized patient household income into quartiles and compared rates of reconstruction between the highest and lowest income quartiles within each region. Multivariable logistic regression was used to assess the relationship between receipt of reconstruction and patient income, controlling for other patient demographic and clinical variables known to impact receipt of reconstruction.

Results: Of the 6,696 patients comprising this cohort, the majority (54%) were under the age of 55, had early-stage breast cancer (17% DCIS and 35% Stage I), and were privately insured (54%). Overall, 46% of patients underwent immediate breast reconstruction after mastectomy. Rates of reconstruction varied significantly based on the geographic region of the state where patients lived, ranging from 21 to 61% ($p<0.0001$). Disparities in reconstruction by income was observed for most geographic regions (Figure). On multivariable analysis, lower income, higher stage, receipt of unilateral (versus bilateral) mastectomy, older age, receipt of radiation, not having private insurance, and earlier year of diagnosis were associated with lower rates of reconstruction. Region of the state remained significantly associated with reconstruction.

Conclusions: In this observational study in Wisconsin, we observed gaps in receipt of reconstruction based on income across most geographic regions of the state. Future work will focus on understanding the factors and processes that limit socioeconomically disadvantaged patients receipt of reconstruction in Wisconsin in order to identify opportunities to intervene.

Figure: Variation in rates of reconstruction after mastectomy across Wisconsin



394593 - Toradol® use in breast reconstruction: Risk of hematoma and benefit of post-operative pain control

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Background/Objective: Toradol® is a nonsteroidal anti-inflammatory used with increased frequency due to its success in post-operative pain control and subsequent decreased need for narcotics. Its use has been limited in plastic surgery for fear of post-operative bleeding and hematoma formation. The purpose of our study is to investigate whether Toradol® has an increased risk of hematoma in patients undergoing breast reconstruction and its efficacy in post-operative pain management.

Methods: We performed a retrospective review of patients undergoing implant-based breast reconstruction after mastectomy between January 2012 and December 2016. Other risk factors, such as chronic anticoagulation, aspirin, or coagulopathies, were documented as well.

Results: There were 202 patients who met our inclusion criteria. Our results show a post-operative hematoma rate of 4.5% in implant-based breast reconstruction. Of the patients who received Toradol®, 2.5% developed a hematoma compared to 2% in patients who did not receive Toradol®. This is not statistically significant with a p-value of 0.31. Patients who received Toradol® had a shortened length of stay, 1.89 days compared to 2.11 days in patients who did not receive Toradol®. This trended towards significance with a p-value=0.059. Patients who received Toradol® used less narcotics than those who did not, 80.3 mg compared to 108.6 mg. This was statistically significant with p-value of 0.002.

Conclusions: Generous narcotic prescribing has received greater scrutiny in recent years. Aside from the risk of increased narcotic availability in the community, the side effects of nausea, pruritis, and constipation delay patient recovery. Toradol® is a controversial drug in post-operative pain control due to the potential risk of bleeding. The results from our study show no significant increase in hematoma

formation in patients who received post-operative Toradol®. Our data also show that patients who received Toradol® have a decreased length of hospital stay and lower narcotic use. This is the largest study to date demonstrating a low risk for post-operative hematoma in implant-based breast reconstruction as well as its value in post-operative pain control.

402759 - Outcomes of autologous fat grafting in mastectomy patients following breast reconstruction

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Background/Objective: Autologous fat grafting (AFG) is used for improvement of the cosmetic appearance and composition of the breast following reconstructive surgery. Due to its historically controversial nature regarding risk of cancer recurrence, AFG has been utilized with widespread regularity only within the last decade. Though the oncological safety of the procedure has been established, limited data exist on other outcomes of AFG. Fat necrosis (FN), a known, benign complication of AFG, often presents as a palpable lump, raising suspicion of malignancy and requiring further evaluation to rule out recurrence. The aim of this study was to determine the incidence of FN in patients who have undergone AFG after mastectomy and reconstruction, and to identify patient and physician factors which may contribute to the development of FN.

Methods: A retrospective chart review was conducted of all patients who received AFG following mastectomy and reconstruction at our institution between 2011 and 2016, with a minimum 6-month follow-up period. Patient records were reviewed for demographics, BMI, smoking status, co-morbidities, reconstruction type, receipt of radiation, details and timing of AFG, development of FN, and incidence of cancer recurrence.

Results: Of 620 patients who underwent mastectomy followed by reconstruction during this time period, a total of 171 patients received AFG (128 implant-based, 43 autologous-based reconstruction) at our institution, and were included in this study. AFG procedures were performed by 7 surgeons. Patients received an average of 1.18 treatments, and the average follow-up time was 26 months. There were no immediate complications reported from the AFG procedures. Eighteen patients (10.5%) who received AFG subsequently developed FN an average of 3.4 months (range: 0.6 to 5.7 months) following the procedure. Patient factors such as age, BMI, smoking status, reconstruction type, timing of AFG after surgery, and receipt of radiation did not differ between those who developed FN and those who did not. Plastic surgeon, volume of fat injected, and number of AFG procedures did not differ significantly between both groups. Of the patients who developed FN, 12 received implant-based reconstruction, and 6 received autologous reconstruction. FN was initially identified by a patient-identified palpable abnormality in 12 patients, on physician exam in 5 patients, and by screening mammogram in 1 patient. Imaging confirmed FN in all 18 patients. Core needle biopsy was performed in 7 patients, and excision was performed in 2 patients. During this time period, local cancer recurrence was 1.7% for all patients, with no patients experiencing recurrence in the AFG cohort.

Conclusions: Fat necrosis is common in breast surgery patients following autologous fat grafting. There were no patient- or physician-associated factors identified that increased the risk of developing FN. AFG is an oncologically safe technique utilized following mastectomy and reconstruction. Patients should be counseled on the 10.5% incidence of FN presenting as a palpable abnormality, and the approximately 5% chance of requiring biopsy or excision.

SLN

403441 - Factors associated with false-negative rate of sentinel lymph node biopsy in breast cancer patients

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Background/Objective: Sentinel lymph node biopsy (SLNB) has become the routine surgical procedure for axillary nodal staging. The reported false-negative rate have varied widely from 0 to 33%. Contraindications to SLNB are still debated. Weighing the benefit of the minimally invasive technique versus the risk of understaging the patient has important implications for adjuvant therapy and the possibility of persistent axillary nodal disease.

Methods: Patient data were obtained from the clinical records of our institution from January 2005 to December 2016.The patients diagnosed with breast cancer underwent SLNB using methylene blue dye injected at the peritumoral, dermal, subdermal, periareolar, or subareolar locations prior to the operative procedure followed by completion axillary lymph node dissection. Sentinel lymph nodes and non-sentinel lymph nodes were then submitted to pathology for examination using H&E stains. Clinical factors, tumor characteristics, and sentinel lymph node characteristics were included in the study.

Results: There were 558 patients who underwent SLNB with completion axillary lymph node dissection. There were 178 (31.9%) cases of true positive SLNB, 331 (59.3%) cases of true-negative and 45 (8.1%) cases of false-negative SLNB, with an overall false-negative rate of 20.18%. Age, gender, tumor palpability, lymph node palpability, laterality, location, clinical stage, menopause, tumor size, histopathology, lymphovascular invasion, Nottingham grade, and hormonal status did not demonstrate any statistical significance. Univariate analysis showed statistical significance in FN rates in patients who underwent neoadjuvant chemotherapy (14.77%), <3 SLN harvested (13.66%), <10 non-sentinel lymph node harvested (20%), 1-3 positive non-sentinel lymph node (34.29%) and pathologic stage IIB (22.89%). Multivariate analysis confirmed that less than 3 SLN harvested and 1 to 3 positive non-sentinel lymph node are independent significant predictors of having a false negative SLNB.

Conclusions: Currently, this is the only study showing predictive factors in the Filipino population. Significant factors predictive of false-negative rate were identified. Similar to other studies, identification of multiple sentinel nodes and increased number of positive non-sentinel lymph nodes resulted to improved false-negative rate. However, other factors included such as age, tumor size, tumor palpability, hormonal status, and neoadjuvant chemotherapy were found to have conflicting results in other studies and was not significant in this study. Other factors that may have contributed to the high FN rate in this study but were not included are the surgeons' experience, biopsy technique, and type of dye used. Injection of radioactive colloid in combination with blue, dye improves the ability to identify multiple sentinel nodes compared with the use of blue dye alone. In this study, blue dye alone was used which may also account for the high FN rate.

403978 - A retrospective analysis of compliance with sentinel node biopsy alone vs axillary dissection among patients with invasive breast cancer and sentinel node metastasis: Are we applying the ACOSOG Z0011 Trial in community practice?

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Background/Objective: Results from The American College of Surgeons Oncology Group Z0011 (ACOSOG Z0011) trial were initially reported in 2005, concluding that Sentinel Lymph Node Dissection (SLND) alone did not result in inferior survival compared to Axillary Lymph Node Dissection (ALND) in patients with clinical T1-T2 invasive breast cancer, no palpable lymphadenopathy, and 1 to 2 positive sentinel lymph nodes (SLN). Patients enrolled in the trial were all treated with breast-conserving therapy and received whole-breast radiation. Positive SLNs were identified by frozen section, touch preparation, or permanent section. ALND was defined as anatomic level I and II dissection, including at least 10 lymph nodes. Patients were excluded, or considered ineligible, if they were pregnant or lactating, if they were treated with neo-adjuvant chemotherapy or hormonal therapy, if they were found to have bilateral or multicentric disease, if they had extranodal disease at the time of SLND, if they were found to have extracapsular extension, or if they were found to have 3 or more involved SLNs. Recent follow-up found that 10-year overall survival for patients treated with SLND alone was non-inferior to overall survival compared to those treated with ALND. This retrospective review aims to determine if surgeons at 1 community setting have tailored their practice to meet compliance with the ACOSOG guidelines.

Methods: We conducted a retrospective chart review of 233 patients who presented with invasive breast cancer and positive lymph nodes at 1 community center between January 2009 and June 2016. Pathology reports and operative reports were analyzed to ensure patients met the ACOSOG Z0011 inclusion criteria of T1-T2 disease, no palpable lymphadenopathy, and 1-2 positive SLNs. Patients were excluded using the ineligibility criteria noted above.

Results: Upon initial review of 233 cases, 131 (56.2%) patients were excluded due to primary surgical treatment with mastectomy, 7 (3.0%) patients were excluded due to neoadjuvant therapy, 5 (2.1%) patients were excluded for clinically positive axilla or biopsy confirmed axillary metastasis, 3 (1.2%) patients were excluded for bilateral disease, 6 (2.5%) patients were excluded for having 3 or more positive SLN, 25 (10.7%) patients were excluded due to extranodal extension, and 1 (0.4%) patient was excluded for having an incidental LN included in the specimen that contained metastasis. The remaining 55 (23.6%) patients met ACOSOG Z0011 criteria; 43 (78%) patients were treated with SLND alone, and 12 (21.8%) patients received ALND despite having less than 2 positive SLN.

Conclusions: Our goal was to assess for compliance with ACOSOG Z0011 guidelines in the community setting. After conducting a retrospective review of patients with invasive breast cancer and positive axillary nodes at 1 community center, we found that only 55 (23.6%) breast cancer patients met ACOSOG Z0011 criteria. A majority of eligible patients 78% (43 patients) were treated with SLND alone, while 21.8% (12 patients) were treated with ALND after discovery of 1-2 positive SLN. This study indicates that compliance with ACOSOG Z0011 guidelines in eligible patients remains less than optimal in a community setting.

403389 - Effect of primary breast tumor location on axillary nodal positivity

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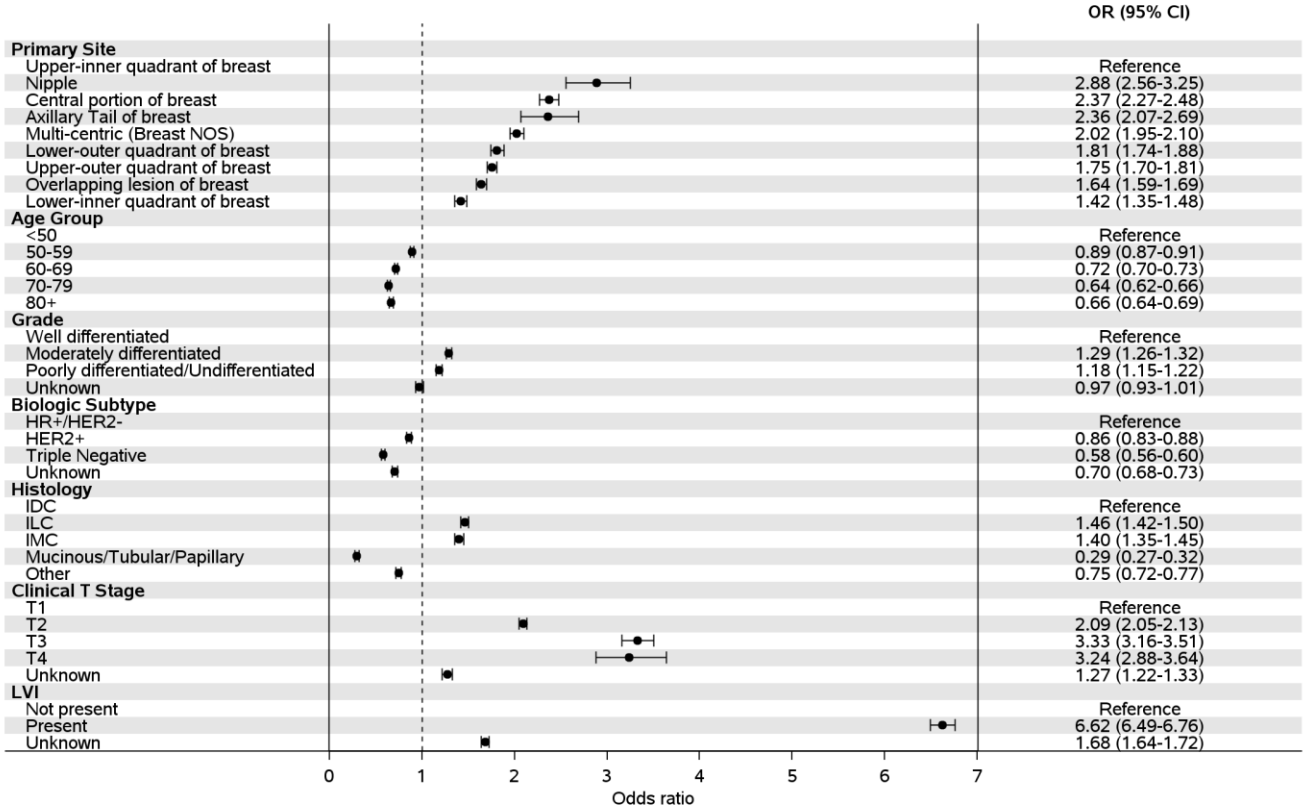
Background/Objective: Nomograms have been developed to predict likelihood of axillary nodal positivity in the pre-operative setting. Tumor size, histology and grade, tumor biology, presence of lymphovascular invasion (LVI), and patient age have been shown to affect the likelihood of nodal positivity at time of surgery. The aim of this study was to determine whether the location of a primary invasive breast cancer in the breast is associated with the likelihood of nodal positivity.

Methods: Women with invasive breast cancer undergoing surgery with axillary staging from 2010 to 2014 were identified from the National Cancer Database. Patients with inflammatory breast cancer and Stage IV disease were excluded. Rates of axillary nodal positivity by primary tumor locations were compared, and multivariable analysis was performed using logistic regression to control for factors known to impact nodal positivity.

Results: A total of 599,722 patients met inclusion criteria, of which 31.3% had positive lymph nodes overall. The greatest frequency of primary tumors were located in the upper outer quadrant (35.5%) followed by overlapping quadrants (22.5%), upper inner quadrant (12.2%), and multi-centric disease (11.2%). The likelihood of nodal positivity was greatest with primary tumors located in the nipple (43.8%) followed by multi-centric disease (40.8%), central breast (39.4%), and axillary tail lesions (38.4%), compared with lower incidence (20.4-31.8%) for outer and inner quadrant tumors ($p<0.001$). Other factors associated with nodal positivity included patient age, tumor grade, biologic subtype, histology, clinical T category, and LVI. On multivariable analysis adjusting for all these variables, tumor location remained independently associated with nodal positivity with odds ratios (compared to the upper inner quadrant) of 2.8 for tumors in the nipple (95% CI 2.5-3.1), 2.2 for the central breast (95% CI 2.2-2.3), and 2.7 for the axillary tail (95% CI 2.4-2.9). Limiting to the 430,949 patients with clinically node-negative disease treated with primary surgery, of which 18.8% were pathologically node-positive, factors associated with identification of positive axillary nodes at surgery remained tumor location, patient age, tumor grade, biologic subtype, histology, clinical T category, and LVI. Incidence of positive nodes was again highest for tumors in the nipple (30.0%), followed by central breast (26.1%), multicentric disease (23.2%), and axillary tail lesions (22.7%), compared with lower incidence (12.3-19.9%) for outer and inner quadrant tumors ($p<0.001$). On multivariable analysis (Figure), tumor location remained significant with largest effects for tumors located in the nipple OR 2.9 (95% CI 2.6-3.3), followed by central breast OR 2.4 (95% CI 2.3-2.5), and axillary tail OR 2.4 (95% CI 2.1-2.7).

Conclusions: Patients with invasive breast cancer located in the nipple, central breast, and axillary tail have the highest risk of positive axillary lymph nodes independent of patient age, tumor grade, biologic subtype, histology, and size. This relatively straightforward factor, available at time of diagnosis, should be taken into account along with other factors in pre-operative counseling and decision-making regarding plans for axillary lymph node staging.

Figure: Effect of primary tumor location on nodal positivity-Desai



403168 - No superior tracer for axillary sentinel lymph node biopsy: A single institution's experience

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Background/Objective: Axillary sentinel lymph node (SLN) biopsy is the gold standard for triaging lymph node metastasis, which is an important prognostic factor for patients with invasive breast cancer. Our investigation aims to determine trends in the axillary SLN biopsies performed at our institution. We hypothesize that the use of both radiotracer and either methylene blue or Lymphazurin blue (dual tracer) as well as the timing of the radiotracer injection impacts the ability to identify the SLN.

Methods: After IRB approval, we retrospectively reviewed our database of patients who underwent SLN biopsy from May 2012 to May 2017 at our institution. One hundred twenty-five patients were initially identified. Patients were excluded if they had bilateral disease or if they did not have a true SLN biopsy. The type of tracer used, location of radiotracer injection, the operative time, as well as the number of total nodes and positive nodes removed were noted. The post-graduate year of the resident involved in the case was also noted. Additionally, the surgeon was classified as Senior versus Junior faculty, with more than 15 years and less than 15 years of practice respectively. Statistical analysis was performed using Minitab Release 14 Statistical software (Minitab Inc., State College, PA). Analysis of Variance

(ANOVA) and Chi-Square were used to identify various relationships in our dataset. A statistical significance was accepted for $p<0.05$.

Results: We identified 107 analyzable patients who met our inclusion criteria. Six (5.6%) underwent SLN biopsy with radiotracer alone, 16 (15.0%) with methylene blue alone, 10 (9.3%) with Lymphazurin blue alone, and 75 (70.1%) with both radiotracer and either methylene or Lymphazurin blue. The average number of lymph nodes removed in each case was 1.8 (range 1-4), 3.8 (range 1-15), 1.6 (range 0-6), and 2.7 (range 1-12), respectively, which was not statistically significant ($p=0.136$). The average operative time (minutes) was 182 (range 139-234), 134 (range 69-188), 138 (range 99-196), and 158 (range 72-339), respectively. There was no statistical difference in length of case based solely on type of tracer used ($p=0.66$). In comparing biopsies in which the radiotracer was injected in Nuclear Medicine on the day of surgery versus in the pre-operative holding area by the surgeon, there was no difference in operative time ($p=0.66$) or number of nodes removed ($p=0.136$). There were not enough data points to analyze the impact of intra-operative injection. Of the biopsies performed, 65 (60.7%) were performed by our Junior faculty, while 42 (39.3%) were performed by our Senior faculty. There was no significant difference in the length of case based on surgeon type ($p=0.466$). However, our Senior faculty removed more total nodes than Junior faculty ($p=0.014$), while our Junior faculty tended to use a dual tracer method in comparison to our Senior faculty ($p=0.011$), which were both statistically significant. While there was no statistical difference in total number of nodes removed by resident year ($p=0.391$), chief residents were found to remove more positive lymph nodes ($p=0.008$).

Conclusions: Currently at our institution, there is no difference in success rates for axillary SLN biopsy based on tracer type used or years of practice for the operating surgeon. Additionally, our current data demonstrate that same-day injection (in Nuclear Medicine versus in the pre-operative holding area) has no impact on operative time or ability to identify the SLN. However, our current practice has begun to shift, in that we have begun to inject the radiotracer intra-operatively. We plan to further analyze this change in practice to determine if intra-operative injection radiotracer impacts the ability to identify the SLN and/or if it improves patient satisfaction by eliminating an injection into the breast in an awake patient.

404271 - Treatment patterns of low-risk post-menopausal breast cancer patients

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Background/Objective: Data from a single trial inform the recommendations from Society of Surgical Oncology (SSO)/Choosing Wisely Campaign (CWC) and Cancer and Leukemia Group B (CALGB) to forego sentinel lymph node biopsy, and to consider the omission of radiation therapy, respectively, for patients over age 70 with Stage I estrogen-receptor (ER) positive and Herceptin 2 receptor (HER2) negative breast cancer. Despite these recommendations, many patients are overtreated. This study evaluates patients over age 70 with Stage I, ER-positive, HER-2-negative breast cancer in order to define changes in treatment patterns since publication of SSO/CWC and CALGB guidelines.

Methods: We performed a retrospective cross-sectional analysis of 376 consecutively treated patients in 2016 over the age of 70 with Stage I, ER-positive, HER-2-negative breast cancer at KNC as part of a quality improvement project. In order to characterize practice patterns, patients were stratified by treatment type, including type of surgery, radiation therapy, hormone therapy, or absence of treatment.

Results: Two-hundred eighty patients in total underwent sentinel node biopsy (74%), of which 235 also received endocrine therapy. One-hundred sixty-nine patients (45%) underwent radiation therapy in conjunction with lumpectomy, of which 15 (4.0%) also received endocrine therapy. Sixty-four patients (17%) underwent mastectomy. Among those who underwent mastectomy, 53 received endocrine therapy, and 52 underwent sentinel node biopsy. Three-hundred forty-six patients (92%) received endocrine therapy. Eighteen patients out of 376 (4.8%) declined surgery, of which 14 (3.7%) underwent endocrine therapy only, and 4 (1.1%) declined all treatment. Fifteen patients (4.0%) were treated with lumpectomy and endocrine therapy only.

Conclusions: A majority of low-risk, post-menopausal patients with Stage I breast cancer treated at KNC are overtreated according to guidelines from SSO/CWC, and data published by CALGB. There is limited financial incentive to encourage unnecessary therapeutic intervention within an HMO structure, such as that found within KNC. Factors driving overtreatment may be patient or physician preference, rather than financial, and require further study.

403579 - Axillary management in mastectomy patients with sentinel lymph node metastasis

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Background/Objective: Axillary management in the multidisciplinary treatment of breast cancer has changed considerably in the past few years. With the publication of recent prospective, randomized trials, it is now agreed upon that a positive sentinel lymph node biopsy (SLNB) in select patients no longer mandates a completion axillary lymph node dissection (ALND), as a survival benefit has not been shown. Axillary radiotherapy has comparable regional control to ALND, with potentially less morbidity. Our objective is to compare trends in the management of regional metastasis detected following SLNB in clinically node-negative patients undergoing mastectomy.

Methods: In this retrospective review of the National Cancer Database, the population consisted of women with T1-2, primary invasive breast cancer diagnosed and treated in 2015 who were clinically node negative but found to have a positive SLNB at the time of a mastectomy. Patients were evaluated based on clinically significant demographic characteristics and the subsequent axillary treatment strategies of ALND alone, PMRT alone, combined ALND + PMRT (combination therapy), or no further treatment (NFT).

Results: There were 4,445 women identified with a positive SLNB at the time of mastectomy. Of these, 1,361 (31%) proceeded to have an ALND, 707 (16%) PMRT, 1,507 (34%) combination therapy, and 870 (19%) received NFT. Compared with patients <70 years of age, patients >70 were more likely to receive ALND alone (36% vs. 29%) or NFT (25% vs. 18%), and less likely to receive combined therapy (25 vs. 36%). Patients with a co-morbidity index 1 most often received ALND alone (36%), while patients without co-morbidities most often received combination therapy (34%). Regardless of proximity to treatment facility, patients living >50 miles away more frequently received NFT compared to those living within 50 miles (24% compared to 19%).

Conclusions: Significant practice variation is present in the management of axillary metastasis identified following SLNB in patients undergoing mastectomy. Many patients receive no further axillary management, which according to current guidelines, may represent undertreatment in these patients. Few patients received adjuvant radiation therapy without ALND, which may reflect a lack of adoption of recent clinical trial data and potentially unnecessary overtreatment of the axilla. Although further

delineation into these practice patterns is required, the findings suggest a need to enhance the adoption of evidenced-based clinical protocols in order to improve quality of care.

403957 - Mastectomy in early-stage breast cancer: The burden of axillary lymph node dissection

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Background/Objective: Management of the axilla in patients undergoing breast-conserving surgery has dramatically evolved, often with sentinel lymph node (SLN) biopsy alone as a sufficient approach. However, patients undergoing mastectomy as up-front treatment are still subject to axillary lymph node dissection (ALND) in the setting of a positive SLN. Although recent trends indicate more patients opting for mastectomy, particularly for early-stage disease, the burden of ALND has not been evaluated in this context. The aim of this study was to evaluate SLN and non-sentinel node (NSN) positivity among a contemporary cohort of early-stage breast cancer patients undergoing mastectomy.

Methods: Single-institution, IRB approved, retrospective review of clinically node-negative patients undergoing mastectomy as first-line treatment was conducted. Patients in the favorable subset (hormone receptor positive, T1/T2, without lymphovascular invasion or multicentricity) were compared to patients in the unfavorable subset based on primary tumor histopathologic features. Clinicopathologic features, number and positivity of SLNs and NSNs were recorded. Two tailed p-value <0.05 was defined as significant.

Results: Six hundred sixty patients underwent mastectomy with SLNB as first-line treatment for breast cancer, with 262 (39.7%) patients in the favorable subset and 398 (60.3%) patients in the unfavorable subset. Age, tumor size, and histologic subtype were comparable between both groups. In the unfavorable subset, 79 (19.8) patients demonstrated ER and PR loss, 191 (47.7%) LVI, and 121 (30.4%) multicentricity. SLN positivity occurred significantly less frequently in the favorable subset (13.7% vs. 41.0%, p=0.0001). The majority (80%) of patients underwent completion ALND for a positive SLN, with NSN positivity occurring less frequent in the favorable subset (28.6% vs. 45.8%, p=0.14). At a minimum, among SLN only positive patients 91 (60.5%), 72% in the favorable and 54% in the unfavorable subset, may have avoided ALND if they had undergone breast-conserving surgery. At a mean 42-month follow-up, recurrences were equal between both groups: 10 (1.5%) patients with local recurrences, 8 (1.2%) with distant recurrences, and no axillary recurrences.

Conclusions: A majority of early-stage clinically lymph node-negative patient, regardless of favorable or unfavorable tumor characteristics who elect for mastectomy may avoid ALND by choosing breast-conserving surgery. This factor must be discussed in patient treatment decisions.

403984 - Impact of omitting sentinel lymph node biopsy in elderly patients with clinically node-negative, ER-positive breast cancer

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Background/Objective: Based on randomized control trials demonstrating no survival benefit of axillary surgery in elderly breast cancer patients, the SSO/Choosing Wisely campaign recommends against the routine use of sentinel lymph node biopsy (SNB) in clinically node-negative (cN0) patients age 70 with hormone receptor positive breast cancer. However, axillary staging may influence adjuvant therapy decisions, and therefore, some advocate a role for SNB in this population. At our institution, axillary radiation is typically offered in the setting of 1 or more positive nodes. We sought to evaluate current patterns of axillary surgery in elderly breast cancer patients and identify predictors of sentinel node positivity to ultimately determine the impact of this guideline on our population.

Methods: Using our institution's prospective surgical database, we identified all patients age 70 who underwent breast surgery for Stage I-III breast cancer from 2012-2016. Patients with isolated DCIS, recurrent breast cancer, or palliative surgical intent were not included. Demographics, pre-operative tumor characteristics, and surgical treatment variables were abstracted from the surgical database and provincial cancer registry. In the cN0, ER+/HER2- subset of patients not treated with neoadjuvant therapy (NAT), we compared those with axillary surgery versus none. Univariate and multivariate analysis was used to identify factors associated with a positive sentinel lymph node.

Results: We identified 513 patients 70 years of age treated with surgery for breast cancer during the study period. Of these, 149 (29.0%) were excluded from analysis due to 84 (56.0%) ER- or HER2+, 59 (39.3%) node-positive at presentation, and 6 (4.0%) who received neoadjuvant therapy. Of the remaining 364 patients, the median age was 75 years [range 70-102). On pre-operative assessment, most patients had unifocal tumors (n=323, 88.7%) that were <2cm in size (n=230, 63.2%%). Histology was primarily ductal (n=322, 88.5%) and of low/intermediate grade (n=311, 85.4%). No axillary surgery was performed in 33 (9.1%) patients; these patients tended to be older (median age 80 vs. 75, p<0.001) and treated with breast-conserving surgery compared to mastectomy (81.8% vs. 57.5%, p=0.007). Twelve (36.3%) patients in the no axillary surgery group had been upstaged to invasive malignancy following excision for DCIS (n=5) or high-risk lesion (n=7), which was significantly greater than the proportion of patients with this presentation in the axillary surgery group (3.6%, p<0.001). In the 331 (90.9%) patients with SNB performed, 75 (22.7%) were histologically node-positive, and 11 (3.3%) underwent completion ALND. On univariate and multivariate analysis, only larger pre-operative T-stage (p=0.002) was significantly associated with a positive sentinel node, with a trend seen on univariate analysis for multifocal disease (p=0.07). Age (p=0.42), histologic type (p=0.27), and histologic grade (p=0.31) were not found to be associated. Absolute rates of sentinel node positivity were as follows: T1a 0/20 (0%), T1b 11/84 (13.1%), T1c 24/102 (23.5%), T2 37/110 (33.6%) and T3 3/11 (27.3%).

Conclusions: Sentinel node biopsy was performed in >90% of elderly patients in our cohort with clinically node-negative, ER+ HER2- breast cancer. There were 22.7% of patients who had a positive sentinel lymph node, and larger T-stage was the only predictive pre-operative variable. Significant rates of sentinel node positivity were observed even in patients with tumors <2cm in size pre-operatively (cT1). While overall rates of completion ALND were low for sentinel node positive patients, further study is needed to assess the effect of nodal positivity on the use of adjuvant radiation and systemic therapy,

as our findings suggest that a substantial proportion of patients may be impacted by the staging information gained from SNB.

404269 - Trends in regional treatment for micrometastatic breast cancer: A National Cancer Database review

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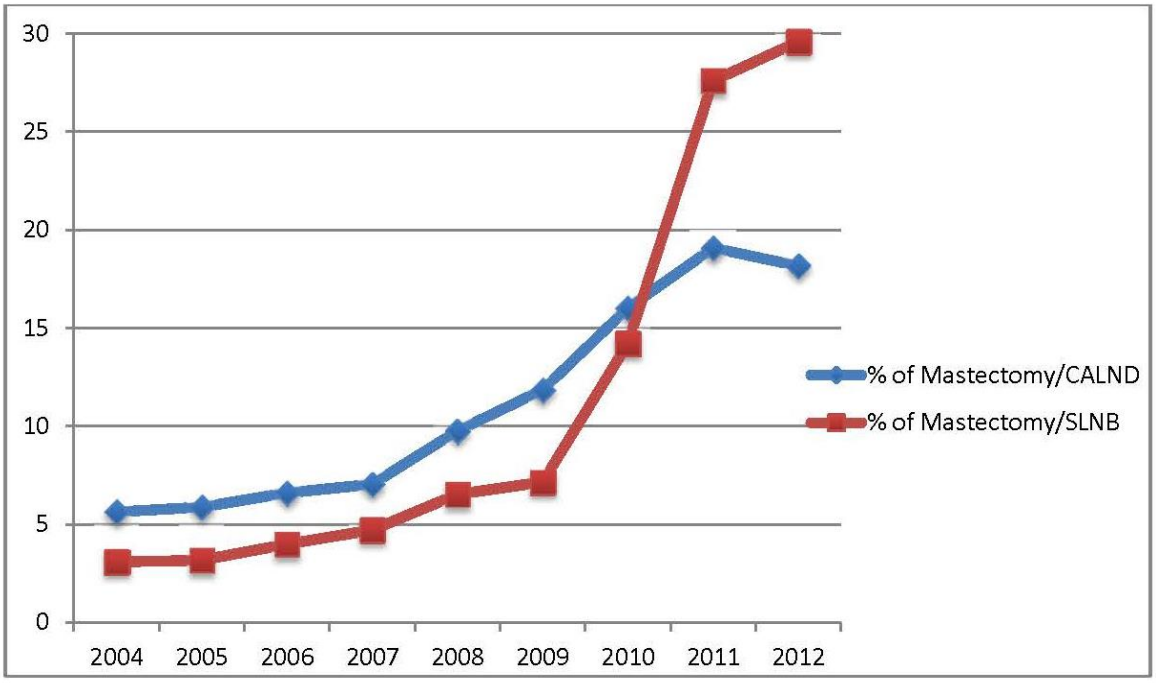
Background/Objective: The use of complete axillary lymph node dissection (CALND) for the presence of micrometastases in a sentinel lymph node (SLN) has been recently debated. Several institution-based studies have reported that a CALND for micrometastases does not impact survival or recurrence and there continue to be areas of uncertainty in its benefit. It is unclear what additional factors are associated with the clinical significance of micrometastases and if patients with micrometastases are being overtreated with a CALND or undertreated with only a SLN. The National Cancer Database provides a large nationwide dataset to study national trends.

Methods: Using the National Cancer Database (NCDB), we examined women who had micrometastasis after breast surgery for Stage I-III disease and what treatment was received including SLN biopsy and CALND. Patients treated with neoadjuvant chemotherapy were eliminated. We categorized removal of 4 nodes as a SLN biopsy and 10 nodes as CALND because the NCDB does not define SLN biopsy and CALND.

Results: Of 462,154 node-positive breast cancer patients in the NCDB from 2004-2014, 43,458 (9.4%) had micrometastic breast cancer in their lymph nodes. Cases were identified based on micrometastatic disease after final surgical pathology; 35,083 (81.1%) were Caucasian, 4,428 (10.2%) were African American, 1582 (3.7%) were Asian. Among molecular subtypes, 2285 (9.2%) were triple-negative, 32,311 (76.5%) cases had hormone-responsive disease, and 3,576 (14.4%) had HER2neu amplified tumors. A small majority of cases (23,930 or 55.1%) had tumors <2cm. Of women with micrometastatic disease, 21,574 (49.1%) had a SLN biopsy versus 15,013 (34.2%) who had a CALND. Rates of CALND significantly decreased after 2012, supporting the adoption of ACOSOG Z-0011. Interestingly, this was noted for patients receiving both breast conservation as well as mastectomy. Among mastectomy patients, more women had radiation after CALND (2,750 or 27.1%) than SLN (1,913 or 24.3%); use of post-mastectomy radiation among women with SLN as well as CALND steadily increased over time. There was a notable difference in use of ALND by geographic region ($p<0.001$), with patients in Mountain and New England regions receiving fewer CALND. Cancer center size affected ALND rates, with centers >20,000 patients trending to lower CALND use ($p<0.001$).

Conclusions: Use of CALND for micrometastatic disease is decreasing over time and diminished markedly after 2012. Patients treated in Mountain and New England regions or large cancer centers were less likely to receive CALND, especially after 2012. Post-mastectomy radiation use increased over time among women with SLN as well as CALND, and was observed more frequently in patients receiving CALND. Aggressive regional therapy in the micrometastatic population merits further investigation due to concerns for overtreatment.

Figure: Use of postmastectomy radiation over time among N1mi patients



404244 - Pathological confirmation of pre-chemotherapy biopsied and tattooed axillary lymph nodes

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Background/Objective: Tattooing is an alternative modality for marking biopsied axillary lymph nodes before the initiation of neoadjuvant chemotherapy (NAC). This may be performed by a radiologist or surgeon using ultrasound guidance or palpation. Detection of the black ink intra-operatively relies on surgical visualization of the axilla, much like is done for sentinel node biopsy when blue dye is utilized. Ideally, histopathological examination confirms the presence of tattoo.

Methods: Informed written consent was obtained for tattooing of biopsied axillary lymph nodes from women with newly diagnosed breast cancer undergoing fine needle aspiration or core needle biopsy of the node. Tattooing was carried out with 0.1-1.0 ml of black ink (GI-SPOT ink) injected into the nodal cortex and perinodal soft tissue after sampling was completed. Blue dye and Tc-sulfur colloid were used for sentinel node mapping. We focus on the histopathological findings after NAC.

Results: Forty-three tattooed patients were treated with NAC. Of these, 33 (77%) were node-positive before, and 12 (28%) remained node-positive after neoadjuvant therapy. The average number of days from tattoo to surgery was 150 days (71 to 257 days). The tattooed node(s) were visually identified in all cases as black tattoo pigment staining the surface of the node or in the adjacent perinodal fat. In 15 (35%) patients, more than 1 axillary lymph node had black ink within the lymph node on histologic evaluation despite pre-NAC tattoo of only 1 lymph node. All of these patients had nodal disease documented by either pre-NAC biopsy or final pathology. Of the 21 patients whose nodes were initially positive and were subsequently down-staged as node-negative following NAC, 2 (9%) were found to have a non-sentinel lymph node containing black tattoo pigment. In both cases, histologic treatment

effect was demonstrated within these nodes. In 1 of the patients, it was the only node demonstrating treatment effect. Of the 12 patients whose nodes remained positive following NAC, 6 (50%) were found to have additional black tattoo pigment within their axillary dissection nodes. Five of those patients did have additional involved lymph nodes within the dissection, and at least 2 patients had black tattoo associated with malignant nodes.

Conclusions: Tattoo of suspicious axillary lymph nodes at the time of biopsy prior to NAC adds to nodal staging accuracy at surgery. It is easily identifiable and can help detect lymph nodes that would not otherwise be sampled during sentinel node biopsy. The observed migration of tattoo pigment also affords a more inclusive localization than clip placement alone while decreasing patient discomfort and hospital costs.

403499 - Decrease in extent of axillary surgery in patients with early-stage breast cancer undergoing mastectomy: A National Cancer Database analysis

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Background/Objective: The American College of Surgeons Oncology Group Z0011 trial was practice changing in patients with early-stage breast cancer (ESBC) undergoing breast-conserving surgery. However, since mastectomy patients were not included in this trial, management of the axilla in this group has been more challenging. More recent trials have provided support for less extensive axillary surgery in patients undergoing mastectomy. We examined factors impacting the extent of regional lymph node surgery in patients with ESBC undergoing mastectomy.

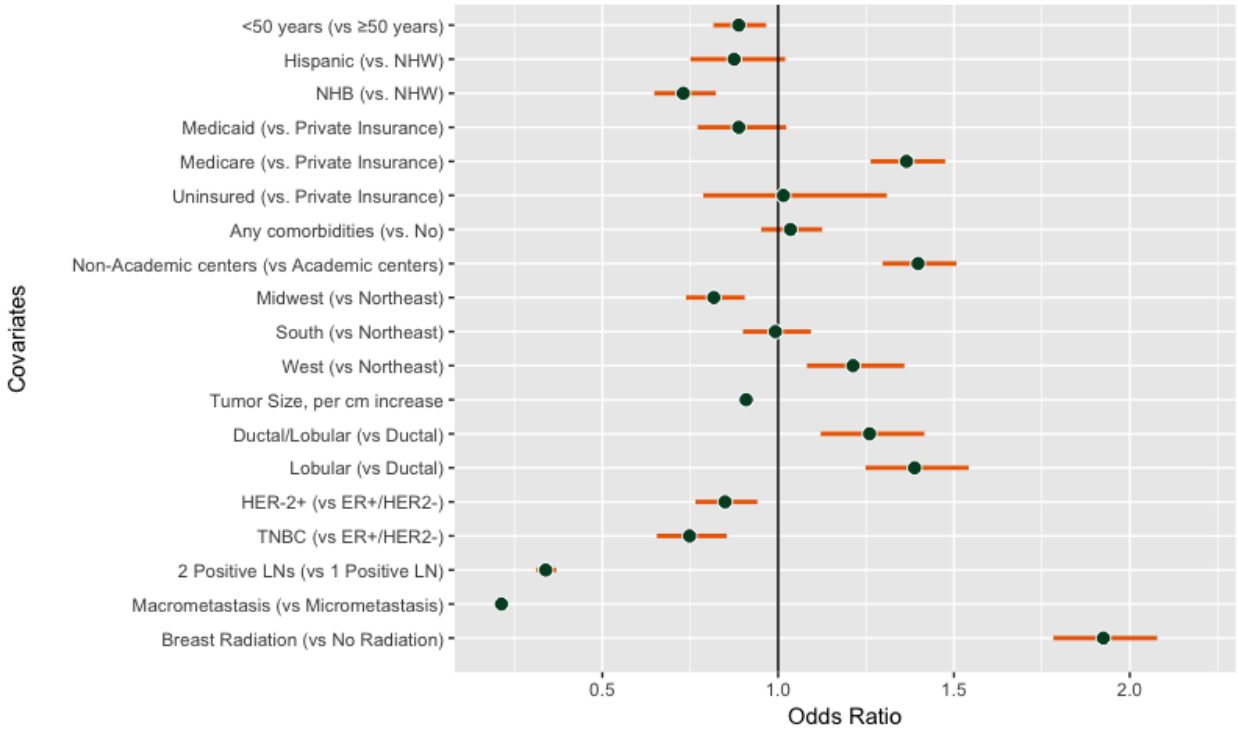
Methods: Women with clinical T1/2 N0 M0 invasive breast cancer who underwent mastectomy with 1 or 2 positive LNs on final pathology were selected from the National Cancer Database (2004-2015). Type of axillary surgery was defined by number of regional lymph nodes examined: 1-5 LNs sentinel lymph node dissection (SLND) and 10 LNs axillary lymph node dissection (ALND). Breast cancer subtypes were categorized as luminal (Estrogen receptor (ER)+/Human epidermal growth factor receptor-2 (HER-2)-), HER-2+, and triple-negative breast cancer (TNBC). The association between clinical characteristics and type of axillary surgery was assessed using multivariable binary logistic regression modeling.

Results: A total of 41,353 patients were included, 41% treated from 2004-2010 and 59% from 2011-2015. Mean age was 58 years, the majority of patients were non-Hispanic whites (81%), had clinical T1 tumors (58%), 1 positive LN (75%), and luminal subtype (75%, patients diagnosed after 2009). Adjuvant chemotherapy was given to 53% of patients and hormonal therapy to 78% of patients with ER+ tumors. Overall, 13,821 patients had SLND (34%), 20,422 had ALND (49%), and 7,110 had between 6-9 LNs removed (17%). From 2004-2015, a significant increase in SLND was observed. The percentage of patients having SLND was stable from 2004-2010 (range 20-26%), increasing to 35% in 2011 and 45% in 2015 ($p<0.0001$). A similar trend was observed in patients with micrometastatic LN involvement, SLND range 40-47% between 2004-2010, increasing to 57% in 2011 and 66% in 2015 ($p<0.0001$). In patients undergoing SLND, the use of adjuvant radiation therapy (RT) also increased from 9% in 2004 to 35% in 2015 ($p<0.0001$). On multivariable analysis evaluating patients treated between 2011-2015, independent factors associated with increased use of SLND were Medicare insurance, treatment at non-academic centers, Western region, lobular or mixed ductal/lobular histology, and adjuvant RT; factors associated with decreased use of SLND were younger age (<50 years), non-Hispanic black race, Midwest

region, increasing tumor size, HER2+ and TNBC subtypes, 2 positive LNs, and macrometastatic LN disease. (Figure).

Conclusions: Utilization of SLND in patients with early-stage breast cancer undergoing mastectomy has significantly increased. Decisions regarding axillary surgery were influenced by multiple patient (age, race, insurance), tumor (BC subtype, burden of LN disease), and treatment factors (location, adjuvant RT).

Figure: Adjusted logistic regression predicting use of SLND



403822 - Axillary staging trend in women age 70 or older with breast cancer between 2005 and 2012: Is omission of axillary staging gaining traction?

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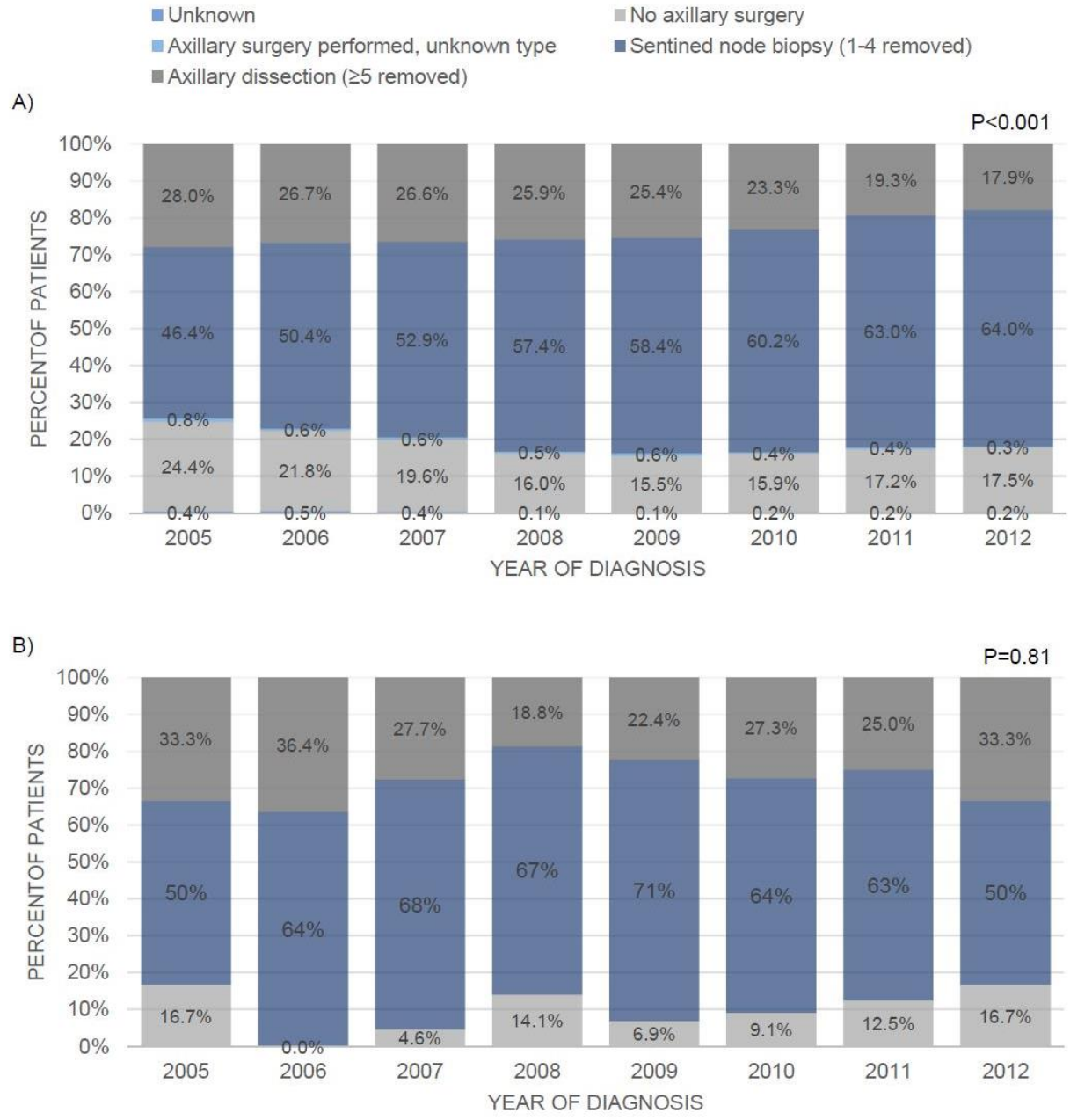
Background/Objective: The management of older women with breast cancer (BC), in particular those with favorable subtypes, should take into account patients performance status, co-morbidities, and life expectancy. Axillary nodal information may play a lesser role. In the Choosing Wisely campaign in 2016, the Society of Surgical Oncology (SSO) recommended not routinely performing sentinel node biopsy (SNB) in clinically node-negative women older than age 70 with hormone receptor positive (HR+) BC. In this study, we evaluated the practice patterns of axillary surgery (AS) in this population nationally and within our institution between 2005 and 2012. We hypothesized that AS for older women with T1, HR+ BC has been on the decline in more recent years, reflecting the SSO recommendation.

Methods: The National Cancer Database (NCDB) on BC and an institutional database were used for analysis. After obtaining approval from our IRB, we collected clinical data from women diagnosed with BC and treated at our institution between 2005 and 2012 (n=8,535). The study cohorts comprised of women age 70 or older diagnosed with T1, HR+, Stage I to III BC during this time period. Percentages of patients who underwent SNB, axillary dissection (AD), and no AS were calculated. Removal of 1 to 4 nodes and 5 nodes were used as surrogates for SNB and AD, respectively, as type of surgery was not recorded. Statistical analyses were performed using R and SPSS Statistics software. Comparisons were made using Chi-squared test. Using NCDB data, after excluding patients for whom variables were unknown, logistic regression was used to identify variables associated with AS.

Results: We identified 136,429 patients in NCDB and 246 patients at our institution who matched study criteria. Nationally, the percentage of patients who did not undergo AS decreased from 24.4% to 15.5% between 2005 and 2009, but increased again to 17.5% by 2012 ($p<0.001$). During this time period, SNB became increasingly common, with 46.4% of patients undergoing SNB in 2005 and 64.0% in 2012. AD decreased accordingly from 28.0% in 2005 to 17.9% in 2012. A similar but more variable trend was found at our institution that did not reach statistical significance. The rate of omission of AS decreased from 16.7% to 6.9% between 2005 and 2009, and increased again to 16.7% in 2012 ($p=0.81$). In multivariate analysis using NCDB data (n=128,823), increasing age (Odds Ratio (OR) 0.98, 95% Confidence Interval (CI) 0.98-0.98, $p<0.001$), increased co-morbidities (Charlson score 2 vs. 0 or 1) (OR 0.95, 95% CI 0.94-0.96, $p<0.001$), and treatment at an academic center (vs. community program or integrated cancer network) (OR 0.96, 95% CI 0.96-0.96, $p<0.001$) were negatively correlated with patients undergoing AS. Tumor grade 3 (OR 1.02, 95% CI 1.02-1.03, $p<0.001$) and more recent year of diagnosis (OR 1.01, 95% CI 1.00-1.01, $p<0.001$) were associated with patients undergoing AS.

Conclusions: Nationally and within our institution, the omission of AS in older women has not been readily adopted. However, even as the less invasive option of SNB became more common, there has been a slight annual increase nationally in the rate of AS omission in more recent years (2009 to 2012). Our results indicate that treatment de-escalation is slowly being adopted, but further education is needed to increase awareness and acceptance among physicians and patients to avoid overtreatment.

Figure: Patterns of axillary surgery by year of diagnosis, 2005 to 2012, A) nationally (n=136,429) and B) at our institution (n=246)



403922 - Axillary surgery is not associated with improved locoregional outcomes in women with small, estrogen receptor-positive breast cancers

Carlie Thompson[1], JoAnna Hunter-Squires[2], Kjirsten Carlson[2], Farin Amersi[2], Armando Giuliano[2], Alice Chung[2]

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Background/Objective: The role of axillary staging in the management of early breast cancer is evolving. The purpose of this study was to determine if women with small, estrogen receptor (ER)-positive breast cancers who undergo axillary surgery have improved locoregional outcomes than those who do not.

Methods: A prospectively maintained database was reviewed. There were 587 patients identified with T1a or b, ER-positive breast cancers. Clinicopathologic data regarding age at diagnosis, histology, tumor size, grade, receptor status, surgery, and adjuvant therapy were collected for these patients. The primary outcome was locoregional recurrence (LRR). Univariate analysis was carried out using a Cox proportional hazards model.

Results: Of 587 women, 505 underwent axillary staging and 82 did not. Women who did not undergo axillary staging were significantly older (median age 73.5 vs. 60 years; $p<0.001$), more frequently underwent breast-conserving surgery (85.4% vs. 68.3%; $p=0.006$) and less frequently received chemotherapy (3.7% vs. 10.8%; $p=0.046$), radiation therapy (41.3% vs. 59.6%; $p=0.003$), and hormone therapy (50.7% vs. 69.1%; $p=0.001$). Women who underwent axillary staging were found to have positive nodes in 2.18% (11/505) of cases. Median follow-up was 7.19 years. LRR rates were not significantly different between patients who did and did not undergo axillary staging (1.6% vs. 2.4%; $p=0.64$). In univariate analysis, only receipt of hormone therapy was associated with improved LRR (0.84% vs. 4.0%; $p=0.019$).

Conclusions: Women with small, ER-positive breast cancers who did not undergo axillary staging were older and received less aggressive surgical and adjuvant therapies. This approach was not associated with worse locoregional outcomes.

404373 - Intra-operative injection of 99m-Tc sulfur colloid for sentinel lymph node biopsy: Can the pre-operative injection procedure be eliminated?

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Background/Objective: Sentinel lymph node biopsy (SLNB) is the routine method to evaluate axillary lymph nodes in breast cancer patients with a clinically negative axilla. However, the process typically involves a separate appointment in Radiology to undergo injection of the radiocolloid tracer (RT) the day of or prior to surgery, which can lead to disruptions in scheduling and possible delays. Furthermore, the patient must endure an additional invasive procedure under local anesthesia alone. Intra-operative injection of the RT has been previously shown to be equally as effective as pre-operative injection. With the recent development of fully implantable localization devices that can be placed up to a month pre-operatively, eliminating the need for a pre-operative injection of the RT for SLNB would be ideal. This study evaluates our experience with intra-operative injection of the RT.

Methods: A retrospective review of all patients who underwent SLNB between June 2010 and June 2017 was performed. Per standardized protocol, all patients were injected immediately following intubation with both the technetium 99m-labeled sulfur colloid RT and 3mL 1% methylene blue dye (MBD) diluted in 2mL of normal saline unless contraindicated. Operative records and pathology reports were analyzed to determine whether sentinel lymph nodes (SLN) were identified and whether gamma counts were detected. Prior axillary procedures, use of neoadjuvant chemotherapy, and body mass index were also recorded

Results: In the 7-year study period, 453 SLNBs were performed in 435 patients. There were 365 (81%) done for invasive cancer, and 119 (26%) done after neoadjuvant chemotherapy. There were 448 (99%) in which sentinel lymph nodes were detected. In 17 (3.8%) cases, SLNs were undetectable with the gamma probe. In the 5 cases where SLNs were not detected, all 5 patients had a prior ipsilateral lumpectomy and SLNB. The mean number of SLNs harvested was 3.5 nodes. Ninety-eight patients (22%) had a positive SLN.

Conclusions: Intra-operative injection of sulfur colloid radiotracer is effective in the detection of sentinel lymph nodes in patients with clinically node-negative breast cancer. Eliminating the need for a pre-operative injection just prior to SLNB can avoid scheduling conflicts and decrease patient morbidity.

SLN/NAC

404214 - Improved false negative rates with intra-operative identification of clipped nodes in patients undergoing SLNB after neoadjuvant chemotherapy

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Background/Objective: Identification and resection of clipped node was shown to decrease the false-negative rate of sentinel lymph node biopsy (SLNB) after neoadjuvant chemotherapy (NAC) in patients presenting with initially node-positive breast cancer.

Methods: Between March 2014 and March 2016, a prospective trial was performed in 98 patients with axilla-positive locally advanced breast cancer (T1-4, N1-3), to assess the feasibility and efficacy of placing clips into most suspicious biopsy-proven node to reduce the false negative rate of SLNB after neoadjuvant chemotherapy. All nodes which are blue, radioisotope active, and suspicious palpable were considered SLN, and all patients underwent axillary dissection.

Results: The sentinel lymph node identification rate was 89.8%. Of those with a SLNB (n=87), median age was 44 (range, 28-66). Of those, 77 had cT1-3 disease (88.4%), and 10 had cT4 disease (11.6%). The majority of patients had cN1 (n=66, 76.7%), whereas 21 patients (23.3%) had cN2 and cN3. Median SLN number was 2 (1-7). Combined method was performed in 49 patients (43%), whereas blue dye alone was used in the remaining patients (57%). Fifty-eight patients (68.4%) were found to have 2 and more SLNs. Interestingly, the clipped node could not be found among SLNs or axillary lymph node specimen owing to the clip migration to the fatty tissue in a patient (1.1%) that was detected post-operatively by radiologic imaging. Of the remaining 86 patients, the clipped node was the sentinel lymph node in 70 patients (81.4%), whereas the clipped node was the non-sentinel lymph node in 16 patients (18.6%). Pathological examination of clipped nodes revealed metastases in 48% (n=42), regressional fibrosis in 25% (n=21), reactive changes in 22% (n=19), and fibrohyalinization in 5% patients (n=4). The overall false negative rate (FNR) was 11.4% (4/35), whereas the FNR was estimated to be 6.7% for patients presenting with cN1. Among patients with cN1 before neoadjuvant chemotherapy, the FNR was found to be 4.2% (1/24), when the clipped node was identified as sentinel lymph node. However, the FNR was determined to be high as 16.7% (1/6) among patients with cN1 before NAC, when the clipped node was found as the non-sentinel lymph node.

Conclusions: Our results demonstrate that marking suspicious nodes with clips before NAC seems to be a feasible technique since the clipped nodes could be retrieved as SLN or non-SLNs in almost all patients. In concordance with previous reports, our results also suggest that axillary dissection could be omitted in patients with initially presenting N1 disease and with a clipped node as SLN after NAC owing to the low FNR. Targeted axillary dissection may be required for those patients with a clipped node as non-SLN.

404246 - The impact of the American College of Surgeons Oncology Group Z0011 Trial on axillary lymph node dissection cases worldwide: A systematic review

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Background/Objective: Axillary lymph node dissection (ALND) is a fundamental procedure in the management of breast cancer patients. In 2011, the ACOSOG Z0011 trial demonstrated a subset of sentinel node-positive patients with low-volume disease derive no oncological benefit from ALND. Our hypothesis is that adoption of Z0011 findings into guidelines for practice is manifest as a significant reduction in ALND procedures in patients with low-volume axillary disease in the sentinel nodes. A systematic review was conducted to identify to what extent any reduction in procedures has been reported in the literature.

Methods: A systematic review was performed of Medline and EMBASE library databases for English language articles between 2011 and November 2017. Abstracts from conferences were also reviewed, and a cited reference search of the Z0011 paper was performed. Literature was sought that identified the number of ALND procedures performed before and after publication of Z0011.

Results: A total of 13 papers were identified from 4 countries (USA, Canada, Netherlands, Ireland) describing 10 single- or multi-center studies, and 3 national database studies of the National Cancer Database (USA) (2 papers), and the Eindhoven Cancer Registry (Netherlands). All studies reported a reduction in ALND procedures in the population studied. Ten studies had sufficient reporting rigor to isolate data from patients fitting Z0011 criteria. The mean absolute reduction in ALND after publication of Z0011 in Z0011-criteria patients was 49.5% (SD=17%). The range of absolute reduction was 14.5% to 73.4%. In 1 center, only 2.9% of patients meeting Z0011 criteria underwent completion ALND. Two papers studied other patient groups: patients having partial mastectomy and patients having neoadjuvant chemotherapy, and reported 6.1% and 14.5% absolute reduction in ALND respectively. One study of the Eindhoven Cancer Registry (Netherlands) studied all primary breast cancer patients and found an absolute reduction in ALND of 17%.

Conclusions: This review confirms a trend towards less extensive axillary surgery since the publication of Z0011, which whilst minimizing morbidity of ALND on the one hand, may create a new challenge for surgical training based on reduced exposure in residency.

403950 - Ultrasound-guided targeted sentinel lymph node biopsy using hydrogel-encapsulated clip localization in breast cancer patients with complete nodal response following neoadjuvant systemic therapy

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University of Florida, Gainesville, FL

Background/Objective: Axillary nodal status is one of the most important prognostic factors in breast cancer outcomes. Currently, sentinel lymph node biopsy (SLNB) is standard of care in patients with cN0 disease at presentation. Patients with clinical evidence of nodal disease are not candidates for SLNB and undergo axillary node dissection (ALND). However more often, neoadjuvant systemic therapy is used to down-stage both in breast and axillary disease. Recent studies demonstrate the use of SLNB rather than ALND in women who become clinically node-negative (cN0) following neoadjuvant treatment, particularly when the previous biopsy proven lymph node is removed during the sentinel lymph node procedure. In our study, we investigate the utility of ultrasound targeted SLNB using a hydrogel-encapsulated (HydroMARK) biopsy clip in women who undergo SLNB for post-neoadjuvant therapy cN0 disease. We propose that this method is feasible and effective in identifying the previously biopsied lymph node, and provides a means for targeted lymph node surgery following neoadjuvant therapy.

Methods: This is a retrospective review of all patients who underwent ultrasound targeted sentinel lymph node biopsy following neoadjuvant chemotherapy for Stage II and Stage III invasive breast cancer using hydrogel-encapsulated clip localization between January 2014 and April 2017. Data on pre-operative clip detection, concordance of targeted lymph node and sentinel lymph node status, and radiographic evidence of clip removal was investigated.

Results: Twenty-one patients underwent ultrasound targeted SLNB following neoadjuvant chemotherapy for invasive breast cancer using hydrogel-encapsulated clip localization between January 2014 and April 2017. Patient demographics and clinicopathologic features are detailed in the Table. Ninety-one percent of patients underwent successful pre-operative ultrasound localization. One patient underwent wire localization as the clip was unable to be identified with ultrasound. The clipped node was deemed a sentinel lymph node by either blue dye or technetium sulfur colloid uptake in 100% of cases. Specimen radiographs demonstrated previously clipped node to be removed in all cases.

Conclusions: Ultrasound-guided targeted SLNB using a hydrogel-encapsulated biopsy clip is a feasible and effective method in identifying previously biopsied lymph nodes in patients with cN0 disease following neoadjuvant systemic therapy. This technique will increase accuracy and lower false-negative rates in women undergoing SLNB following neoadjuvant therapy for node-positive disease.

Figure: Clinicopathologic features

Mean Age (years)	49.5
Tumor Histology	
Ductal	19 (90)
Lobular	2 (10)
Clinical Stage	
I	0
II	20(95)
III	1 (5)
IV	0
Tumor Marker Profile	
HR+/HER2-	6 (29)
HR+/HER2+	7 (33)
HR-/HER2+	3 (14)
HR-/HER2-	5 (24)
Type of Surgery	
Breast Conserving	11 (52)
Mastectomy	10 (48)
Average SLN Removed	4.6
Residual Nodal Disease	13 (62)
ALND Performed	12 (57)

402935 - Axillary nodal management following neoadjuvant chemotherapy for node-positive breast cancer

Carolina Ponce[1], Martin Loza[2], Pablo Mandó[2], Africa Pineiro[2], Mora Amat[2], Victoria Costanzo[2], Adrian Nervo[2], Daniel Mysler[2], Jorge Nadal[2], Federico Coló[2], José Loza[2], Reinaldo Chacón[2]

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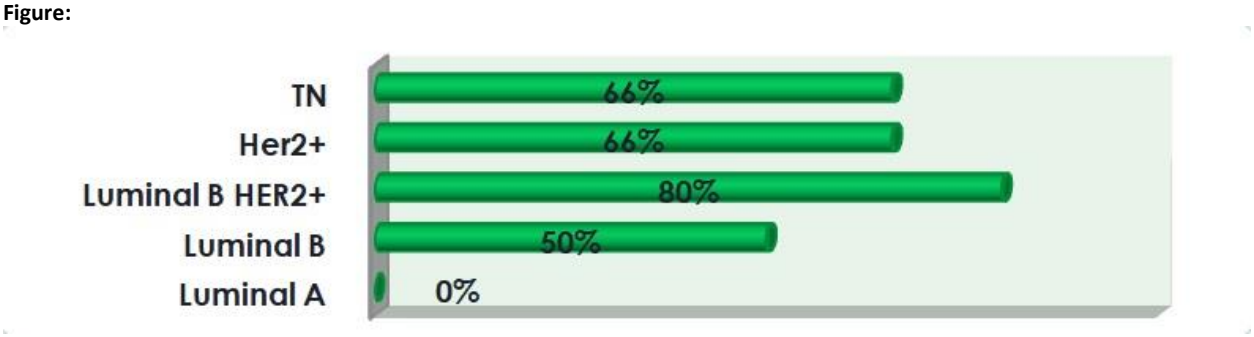
Background/Objective: The use of neoadjuvant chemotherapy (NAC) in breast cancer has increased in recent years, extending its use, even when conservative surgery is possible. Sentinel lymph node biopsy (SLNB) has been widely accepted in the context of the initial surgical management of breast cancer, but its application in the context of NAC has raised controversy, especially in those patients with positive axillary lymph nodes at the time of diagnosis. The aim of this work is to present our experience with SLNB after NAC in patients with clinically positive starting axilla.

Methods: This was a retrospective study of patients surgically treated between January 2007 and June 2017, who underwent NAC. In all the patients, diagnosis was made by core biopsy with immunohistochemical study (IHC) for ER, PR and HER2 (in case of equivocal result, FISH was performed). Initial axillary status was documented by physical examination and/or by core biopsy, and by physical examination at the end of NAC. In our practice, we can identify 2 different moments in terms of the choice of surgical treatment in patients who clinically negativized the axilla: until the end of 2013, SLNB was systematically performed in association with axillary lymph node dissection (ALND) in all patients; since 2014, ALND was reserved for those patients with positive SLN, and axillary radiotherapy was indicated in those with negative SLN. The SLNB after NAC was carried out in compliance with the recommendations: use of combined technique and removal of more than 2 lymph nodes. Additionally, since 2015, the charcoal tattooing of the positive axillary lymph node at diagnosis was incorporated to identify and remove it during surgery.

Results: We identified 99 patients who underwent NAC followed by surgery during the defined period of time. Fifty-nine patients with axilla + of onset were selected. Axillary clinical evaluation was performed after NAC: ALND for those patients with persistent positive axilla and SLNB for those who became negative, followed or not by LA. After NAC, ALND was planned on 39% (n=23) of the patients, SLNB + ALND on 29% (n=17), and only SLNB on 32% (n=19). Our identification rate of SLNB after NAC was 94.2%, and the false-negative rate was found to be 5.8%. Selecting exclusively the 27 patients with axillary core biopsy before NAC, we observed that 51.85% patients (n=14) negativized the axilla after NAC (66% of the triple-negative, 66% of the HER2+, 80% of the Luminal B HER2+, 50% of the Luminal B HER-, and 0% of Luminal A breast cancer).

Conclusions: In our experience, SLNB after NAC in patients with initially positive lymph nodes has acceptable identification rates and false-negative rates. When combined technique is used, more than 2 SLN are obtained, and accuracy is improved with the use of charcoal tattooing. The axillary complete response rate is even higher than in the breast. In this context, the application of SLNB post NAC allows avoidance of ALND and its morbidities in many patients. More studies and follow-up are required to evaluate the long-term implications of these results.

Figure:



Tumor Genetics

403867 - Novel use of a precision medicine tool in the neoadjuvant setting

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Background/Objective: Molecular genomic profiles can be used to guide treatment for refractory cancers and are on the forefront of personalized medicine for select patients. The neoadjuvant chemotherapy (NAC) setting provides an opportunity to compare genomic profiles to pathologic response. We report comprehensive molecular profiles and response in 40 patients in a multi-center NAT registry.

Methods: An ongoing, IRB-approved prospective registry at 8 community breast practices submitted tumor samples prior to treatment for genomic/proteomic analysis (110 genes, Paradigm, Phoenix AZ) Tumor response and associated profiles were analyzed.

Results: Forty patients completed their treatment and definitive surgery and have reported data. All patients received established chemotherapy regimens. Fifteen patients had a complete response, and 4 patients had minimal residual disease. The remaining patients (21) had partial response, stable, or progressive disease. Nine of 15 patients achieving a pCR overexpressed ERBB2 and received chemotherapy plus trastuzumab +/- pertuzamab. The remaining 6 pCR patients were all ERBB2 normal, but had high PARP1 RNA expression, a potential surrogate for rate of cell division, in the absence of other aberrations. The 21 patients who had a partial response or worse outcome had multiple molecular aberrations with unique markers that were not present in the 15 patients with a pCR. These included markers of known/possible drug resistance, poor prognostic markers, biomarkers of response to approved adjuvant treatments, and novel targets that warrant study in this setting. Some of these markers include: mutations: PIK3CA, TP53; copy number gains: EMSY, FGF, FGF4, MYC, SMAD4 and CCND1; high mRNA expression: SSTR, APRIL, KIT, AREG, TYMP, PARP1, HENT1 and IGFR1; abnormal protein expression: CA IX, HENT1, PTEN and MGMT.

Conclusions: Comprehensive genomic testing may predict resistant biology and additional targets for treatment or clinical study. Patients who do not achieve pCR through standard neoadjuvant protocols may harbor a known resistance marker or multiple genomic aberrations that may be a marker for response to immunotherapy. Advanced genomic analysis earlier in the patients' care path may improve response rates by suggesting targeted clinical trials or modifications in standard treatment protocols. Data are being accrued in the registry including whether these results are valuable in directing adjuvant therapy for non-complete responders and improving longer-term outcomes including recurrence.

Figure: PCDx variations found

	Partial Biomarker List					
	CNV Gain	CNV Gain	DNA Mutation	High Protein Expression	Low/Loss of Protein Expression	High MRNA Expression
	"pCR(complete response, w/ or w/o residual DCIS)"					
1				AR, ERBB2	CA IX	ERBB2, TYMP
2	HER2 (ERBB2)			AR, ERBB2, HENT1, TP	CA IX	ERBB2
3	TOPO IIa			AR, ERBB2, HENT1, TP		SSTR2
4	HER2 (ERBB2)			AR, ERBB2	CA IX	ERBB2
5	HER2 (ERBB2)		TP53	AR,ERBB2, HENT1, TP		ERBB3
6	HER2 (ERBB2)	MYC		AR		VEGFA
7	HER2 (ERBB2)	TOPO IIA		AR, ERBB2, TP		SSTR2
8				AR, HENT1, TP		
9	HER2 (ERBB2)			AR,ERBB2, HENT1, TP		ERBB2
10				AR, HENT1, TP	CA IX	AR, IGFR1, MGMT, PARP1, TYMP
11			EP300 (c.4662G>GA p.K1554N)	HENT1, TP		PARP1, TYMP
12				AR, HENT1, TP		PARP1, TYMP
13				HENT1, TP		AREG, PARP1, TYMP
14				HENT1, TP		PARP1, TYMP
15				HENT1, TP		PARP1, TYMP
	Minimal residual (scattered microscopic invasive disease-no individual areas >5mm)					
16				AR	CA IX	AR, PARP1
17				HENT1		MET, PARP1
18	CCND1	FGF4		AR, HENT1	CA IX, PTEN	PARP1
19				AR	CA IX	
	"PR(partial response, >1cm shrinkage in max diameter"					
20					CA IX	
21			PIK3CA (c.1633G>A p.E545K)	AR, HENT1	CA IX, PTEN	ADRA2, SSTR2
22					CA IX	TYMP
23				HENT1, TP	CA IX	PARP1, TYMP
24			PIK3CA (c.1633G>A p.E545K)	AR, TP	CA IX, PTEN	AREG
25				AR, TP		AREG, ERBB2, PARP1
26				AR, HENT1		SSTR2
27	EMSY (C11orf30)	SMAD4	PIK3CA (c.1633G>A p.E545K)	AR, HENT1, TP	CA IX	AR, PARP1, SSTR2, TYMP
28				HENT1	PTEN	PARP1, VEGFA
29	FGFR1			AR, HENT1	CA IX	FGFR1
30				HENT1, TP	CA IX	ERBB2, SSTR2, VEGFA
31				HENT1	PTEN	PARP1, TYMP
32				HENT1, TP	CA IX	MET, TYMP
33	MYC			HENT1, TP		APRIL, EPHA2, ERBB2, MET, MGMT, PARP1, TYMP, VEGFA
34				AR, HENT1, TP	CA IX	AR, ERBB2, PARP1
35					PTEN	
	Stable disease (no meaningful change)					
36			PIK3CA (c.3140A>G p.H1047R)	AR, HENT1, TP		AR, PARP1, TYMP
37			PIK3CA (c.1633G>A p.E545K)	AR, HENT1, TP	CA IX	AR, PARP1, TYMP
38	HER2 (ERBB2)			AR,ERBB2, HENT1, TP	CA IX	ERBB2, IGFR1, PARP1
39					CA IX, PTEN	APRIL, ERBB3, KIT, PARP1, SSTR2, TYMP
	Progressive (>1 cm increase in max diameter)					
40				AR, TP	CA IX	

400960 – Triple-negative apocrine carcinoma: A rare pathologic subtype with a better prognosis than other triple-negative breast cancers

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Background/Objective: Apocrine adenocarcinoma is a rare subtype of breast cancer on which relatively minimal data have been reported. We sought to compare the characteristics of patients diagnosed with triple-negative apocrine adenocarcinoma, as well as their long-term survival, to those of patients diagnosed with triple-negative invasive ductal carcinoma.

Methods: Using data from the National Cancer Database (NCDB) between 2004-2013, a total of 70,524 eligible patients with triple-negative breast cancer were identified including 566 patients with apocrine adenocarcinomas and 69,958 patients with invasive ductal carcinoma. Descriptive statistics for each variable were reported. The univariate association between each covariate as well as study cohorts were assessed using the chi-square test for categorical co-variates and ANOVA for numerical covariates. Cox proportional models were used to calculate hazard ratios.

Results: Triple-negative apocrine adenocarcinomas had a better overall 5-year survival than triple-negative invasive ductal carcinomas, 77.4% (95% CI 72.0-81.8%) vs 73.2% (95% CI 72.7-73.6%). Patients with triple-negative apocrine tumors were also more likely to be white, have Medicare, and have well or moderately differentiated tumors. Patients with triple-negative apocrine tumors were also less likely to receive chemotherapy, were diagnosed at an older age, and had smaller tumor sizes. When comparing months survived from diagnosis, apocrine adenocarcinomas did better (HR 0.67, 95% CI 0.54-0.83, p<.001) compared to intraductal carcinomas.

Conclusions: Triple-negative breast cancers are an aggressive subset of breast cancer with earlier recurrences and poorer survival than hormone-receptor positive cancers. Apocrine adenocarcinomas are a rare subtype of triple-negative breast cancer that has a modestly improved long-term survival when compared to triple-negative invasive ductal cancers. Based on the Cox proportional model, this survival benefit will likely persist as more long-term survival data becomes available. The fact that our data demonstrated that apocrine tumors are also more likely to be moderately or well-differentiated, diagnosed at a later age, and be smaller in size, corresponds with this improved survival. Further study of apocrine adenocarcinomas is warranted, particularly as the majority are androgen-receptor positive, which may serve as a unique focus for targeted therapies.

Figure: Apocrine adenocarcinoma vs invasive ductal carcinoma

Variable		Apocrine Adenocarcinoma N= 566	Intraductal Carcinoma N= 69958	Parametric P-Value
Race	White	444 (78.45%)	51133 (73.09%)	<.001
	Black	86 (15.19)	15594 (22.29)	
	Other	36 (6.36)	3231 (4.62)	
Primary Payor	Uninsured/Unknown	12 (2.12)	3129 (4.47)	<.001
	Private	222 (39.22)	37273 (53.28)	
	Medicaid	45 (7.95)	7376 (10.54)	
	Medicare	287 (50.71)	22180 (31.7)	
Laterality	Right	303 (53.53)	33938 (48.51)	0.045
	Left	263 (46.47)	35937 (51.37)	
Grade	Well Differentiated	33 (5.83)	1071 (1.53)	<.001
	Moderately Differentiated	303 (53.53)	10874 (15.54)	
	Poorly Differentiated	196 (34.63)	53897 (77.04)	
	Unknown	34 (6.01)	4116 (5.88)	
Lymph Node Positivity	No	340 (60.07)	42326 (60.5)	0.332
	Yes	179 (31.63)	20717 (29.61)	
	Unknown	47 (8.3)	6915 (5.88)	
Lymphovascular Invasion	No	326 (57.6)	39762 (56.84)	0.211
	Yes	115 (20.32)	12785 (18.28)	
	Unknown	125 (22.08)	17411 (24.89)	
Chemotherapy	No	231 (40.81)	14905 (21.31)	<.001
	Yes	313 (55.3)	53764 (76.85)	
	Unknown	22 (3.89)	1289 (1.84)	
Surgical Margin	Negative	521 (92.05)	62038 (88.68)	0.027
	Positive	17 (3)	2402 (3.43)	
	Unknown	28 (4.95)	5518 (7.89)	
Age at Diagnosis	Mean	67.61	58.61	<.001
	Median	67	58	
	Min	24	20	
	Max	90	90	
Tumor Size	Mean	2.29	2.77	.002
	Median	1.6	2.1	

403996 - Utility of HER2 retesting of histologic grade 3 invasive breast carcinomas

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Background/Objective: American Society of Clinical Oncology (ASCO) and College of American Pathologists (CAP) guidelines recommend repeat evaluation of human epidermal growth factor receptor 2 (HER2) status on surgical specimens from patients diagnosed by core needle biopsy with grade 3, HER2-negative invasive tumors of the breast. Although these guidelines were designed to improve the accuracy of HER2 identification, there are limited data to support reflexive testing. Revised guidelines are pending further study.

Methods: We evaluated 78 patients from Kaiser Permanente Northern California who were diagnosed between 2015-2017 by core biopsy with grade 3, HER2-negative invasive carcinoma of the breast to compare HER2 status on core biopsy versus excisional biopsy. HER2 status was determined by immunohistochemistry, fluorescent in situ hybridization, or both. All patients were retested for HER2 status on surgical specimen based on ASCO/CAP guidelines. Those who received neoadjuvant chemotherapy were excluded.

Results: One of the 78 patients evaluated demonstrated negative-to-positive status discordance between core biopsy and surgical specimen, and was ultimately treated with trastuzumab. One patient was HER2-negative by core biopsy and HER2-equivocal by both immuno-histochemical and fluorescent in situ hybridization evaluation of the surgical specimen. Seventy-six patients demonstrated concordant HER2 status between core biopsy and surgical specimen.

Conclusions: The rate of clinically significant HER2 status discordance between core biopsy and surgical specimen in patients with grade 3 breast carcinoma is low. However, given the dramatic improvement in overall and disease-free survival conferred by use of trastuzumab, our findings support reflex HER2 testing of surgical specimens for patients diagnosed by core biopsy with HER2-negative carcinoma of the breast.

403286 - Molecular alterations in secondary breast cancers

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Background/Objective: Breast cancer in patients with a prior history of malignancy (SBC) is associated with decreased survival compared to patients with primary breast cancer (PBC). Genomic and epigenomic alterations have been identified for many tumors that predict tumor aggressiveness, prognosis, and response to treatment. However, no such evaluation has been performed specifically on SBCs. The aim of this study is to identify transcriptomic and epigenomic signatures in a homogenous group of patients with SBC.

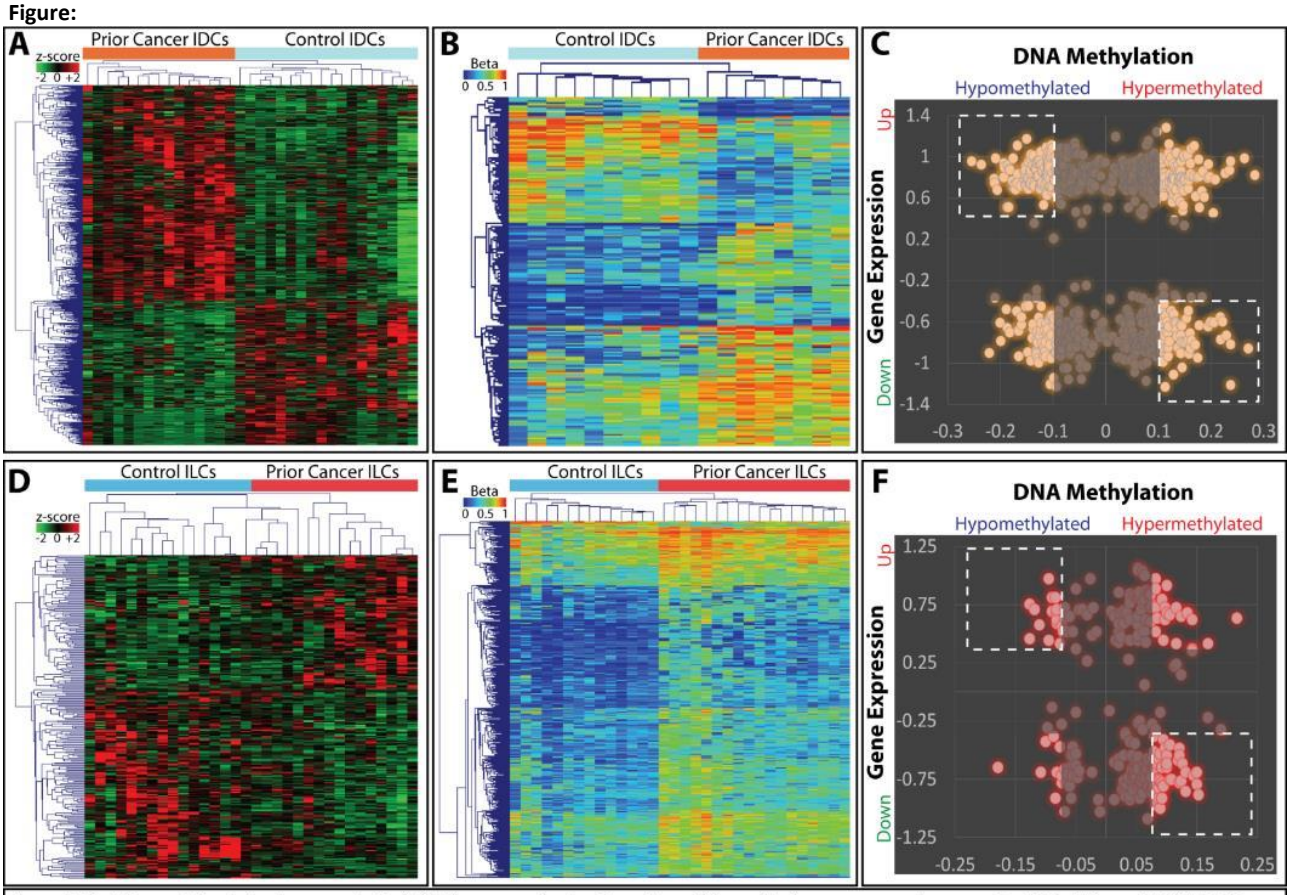
Methods: Molecular profiles of non-BRCA mutation carriers with estrogen receptor-positive, progesterone receptor-positive, HER2-negative invasive ductal (IDC) and invasive lobular (ILC) tumors were identified in the Cancer Genome Atlas (TCGA) project. Cases of SBCs were matched 1:1 to PBC controls by age, histology, and stage to create 2 independent cohorts of IDC (n=36) and ILC (n=40). TCGA RNA next-generation sequencing (RNA-seq) data were used to identify differentially expressed genes in each cohort. Genome-wide DNA methylation profiles of each tumor specimen included in the

transcriptional analysis were normalized. A Wilcoxon rank sum test (p-value<0.01) followed by a nearest Shrunken Centroid classification algorithm was used to identify differentially methylated genomic regions with classification potential. DNA methylation and gene expression signatures were then integrated to identify epigenetically regulated abnormal gene networks in tumors from patients with SBC.

Results: In the IDC cohort, 727 significantly (p<0.05) differentially expressed genes (434 upregulated, 293 downregulated) were identified; in the ILC cohort, 261 genes (108 upregulated, 153 downregulated) were identified (Figure A and D). In IDC SBCs, 105 genes were upregulated and hypomethylated (Figure C, upper dashed box), including genes encoding factors for mammary luminal cells proliferation (ESR1 (estrogen receptor alpha)) and regulators epigenomic stability (TET2, involved in tumor initiation and refractory disease progression). Seventy-three genes were downregulated by DNA hypermethylation (Figure C, lower dashed box), including genes involved in antigen presentation (HLA-E, HLA-DMA, and HLA-DRB5), interferon signaling (IRF8), and NF-B response (RELA). In ILC SBCs, hypomethylation in the upregulation of genes affected 17 genes (Figure F, upper dashed box), including the upregulation of anti-apoptotic genes (DAD1) and factors involved in tagging proteins for degradation (TRIM8, TRIM41, and UBTD1). DNA hypermethylation and downregulation of 46 genes were identified (Figure F, lower dashed box), including key differentiation breast factors such as CD44 antigen. Gene expression signatures of SBC closely corresponded with each histological subtype; only 1.51% of the genes overlapped between the 2 subtypes.

Conclusions: Differential gene expression and DNA methylation signatures are seen in both IDC and ILC SBC, including genes in each cohort that are relevant to tumor growth and proliferation. The differences seen in gene expression signatures corresponding with each histological subtype emphasize the importance of performing disease subtype specific evaluations of molecular alterations. Further studies are needed to validate these findings in a larger cohort of patients and to evaluate the impact of molecular alterations on survival.

Figure:



A and D: Hierarchical cluster analysis (HCL) generated using the differentially expressed genes in IDC **(A)** and ILC **(D)** from patients with a prior cancer. **B and E:** Heatmaps showing the HCL of genomic regions differentially methylated in IDC **(B)** and ILC **(E)** from patients with a prior cancer. **C and F:** Starburst plots showing the integrative analysis of differentially expressed **(Y-axis)** and differentially methylated **(X-axis)** genes in in secondary IDC **(C)** and ILC **(F)** tumors.

404022 - Comparison of Oncotype Dx and Mammprint in a community breast surgical practice: Implications from the MINDACT, TAILORx, and PROMIS Trials

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Background/Objective: Genomic analysis is essential to the management of Stage I/II estrogen-receptor positive, Her- negative (ER+HER2-) breast cancer. Results from several prospective clinical trials - MINDACT, TAILORx, and PROMIS - has provided high-level evidence to inform a choice of available genomic analyses for management and treatment planning.

Methods: We conducted a retrospective review of prospectively collected data in our breast cancer database between Jan. 2003 and Sept. 2017. Women with Stage I/II, ER+ HER2- breast cancer who had genomic testing performed were selected for analysis. We incorporated the findings from recent prospective trials of genomic analyses to determine optimal selection of a genomic test for patient care.

Results: There were 1324 new diagnoses identified of invasive breast cancer treated by the author . Seventeen (1%) were omitted due to incomplete data. Of these, 1082 (83%) were Stage I/II, and 832

(64% of total) were ER+HER2- and selected for analysis. Four hundred twenty genomic analyses were performed in 414 (50% of cohort) patients. Oncotype Dx was performed in 177 (42%), Mammaprint Analysis was performed in 243 (58%). See Tables 1&2 for a summary of results.

Conclusions: Both Oncotype Dx and Mammaprint analyses identify significant subsets of women who do not benefit from chemotherapy based on the highest level of evidence from clinical trials. However, in our review, which is consistent with the published literature, Mammaprint provided actionable results based on the highest-level evidence for the greatest percentage of patients. Additionally, evidence from the PROMIS trial would suggest that approximately 45% of women with Intermediate Oncotype Dx results will be found to be low risk by Mammaprint and thus, have high-level evidence supporting a specific treatment recommendation. Given the American Society of Clinical Oncology guidelines relative to performance of a single test, Mammaprint analysis should be the initial genomic analysis ordered. If Oncotype Dx is performed, reflex to Mammaprint analysis should be done for any intermediate results.

Tables 1& 2: Summary of results

Oncotype DX				
UltraLow <=11	35	20%	87	49%
Low 12-17	52	29%		
Intermediate - Low	49	28%	70	40%
Intermediate - High	21	12%		
High	20	11%		
Total	**177**			

Table 2

Mammaprint				
UltraLow	41	17%	149	61%
Low	108	44%		
High	93			38%
QNS	1			
TOTAL	**243**			

403032 - Clinical application of Oncotype Dx for early breast cancer in a private hospital in Peru: Surgical oncologists handling genomics tests

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Background/Objective: In our private hospital setting, early breast cancer treatment is almost always affordable through private health insurance, including Oncotype Dx ("ODX"), which was commercially released in Peru in early 2012, 8 years later than in the US. These companies started financing the test since 2014. In addition, there were 2 major caveats for its fluent application: from a clinical perspective, the great majority of patients are not detected at an early stage, thus making them ineligible for the genomics test. From a financial point of view, the cost of the test is 3 times more expensive in our country. We estimate about 500 ODX reports have been issued for the Peruvian population between 2012-2016. There are no published data regarding surgeons handling genomics tests in our population.

Methods: We reviewed our 3 surgical oncologists Genomic Health´s online accounts for ODX reports. Based on these records, we searched for their medical charts and built a database regarding demographics, menopausal status, tumor size, histologic grade and type, molecular subtypes by IHC biomarkers, surgical treatment, RS, adjuvant therapy, and follow-up. All samples were prepared by the same pathologist in a kit sent for the signatures headquarters. All patients were classified by AJCC 7th edition. We excluded patients with incomplete data in medical charts.

Results: We found 80 ODX records. Only 72 patients met our inclusion criteria. All patients were Peruvian females, no Caucasians. Mean age at diagnosis was 54.5 years (range 30-78), and 43 patients (59.7%) were post-menopausal. All patients underwent SLNB. Lumpectomy was performed in 41 patients (56.9%), 28 had total mastectomies (38.9%) and because of positive sentinel nodes, 3 underwent modified radical mastectomy (4.2%). The great majority of patients (88.9%) had invasive ductal carcinoma NOS, 6.9% were lobular, 2.8% mucinous and 1.4% micropapilar carcinoma. More than half of the patients had intermediate histologic grade (51.4%), low grade was found in 17 cases (23.6%), high grade in 9 cases (12.5%) and 9 cases (12.5%) had a Not Applicable label. Luminal A was the most frequent with 48 cases (66.7%) as opposed to Luminal B with 24 cases (33.3%), 2 of the latter resulting to be Her 2 enriched by gene RT-PCR. Clinical-pathologic stage I in 70.8% of patients, Stage IIA in 25% and Stage IIB in 4.2% of patients by final pathology. Between 2010 and 2014, only 27.8% of the cases were submitted for ODX vs. years 2015-2017 in which 73.6% has had the test, mainly because of private insurance started coverage since 2014. When reviewing the Recurrence Score (RS), we found 65.3% of patients with low RS, 27.8% with intermediate RS, and only 6.9% with high RS (RS range 0 to 53). These findings helped the surgical oncologist tailor the treatment decisions. All 5 patients with high RS received adjuvant CT. Of the 20 intermediate RS patients, the decision was taken with the clinical oncologists, and 15 went to adjuvant CT. The remainder 69.4% of the patients escaped systemic CT overtreatment and only had HT. Discrepancies: 2 of low-risk patients ended up receiving CT. One patient had contralateral breast cancer of a different molecular subtype for which she underwent systemic treatment, and 1 patient had axillary recurrence, treated with completion axillary lymph node dissection (3/22 with previous 0/3 SLNB) and adjuvant CT. Both are free of disease today. No distant recurrence or disease progression as of today. Mean follow up was 41.5 months (range 1-84 months).

Conclusions: Our patient population shows great benefit from the application of ODX, tailoring treatment decisions and avoiding chemotherapy overtreatment in almost 70% of patients. This practice should be extensively encouraged and adopted nationwide whenever the test is affordable.

Poster Session II

Age Extremes

403924 - Increasing omission of radiation therapy and sentinel node biopsy in elderly patients with early stage, hormone-positive breast cancer

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Background/Objective: There is increasing evidence that there is limited benefit of axillary staging with sentinel lymph node biopsy (SLNB) or radiation therapy (RT) in patients over age 70 with clinical Stage I ER+ breast cancer who undergo breast conserving surgery. In spite of this evidence, management guidelines regarding adoption of these practices and the clinical impact of this literature is in evolution. We hypothesize that omission of SLNB and RT has increased over time in patients over age 70 with early, ER+ breast cancer receiving breast-conserving surgery, and that patient and tumor characteristics can predict when RT is used in this patient population.

Methods: A retrospective analysis of a prospectively maintained single academic center tumor registry database was queried for all patients over age 70 with ER+ clinical T1N0 invasive breast cancer from 2009-2017 who underwent breast conservation treatment. A total of 141 patients were identified. Date of treatment, patient age, tumor characteristics (size and grade), use of SLNB, and use of RT were evaluated. The trend of treatment strategy (lumpectomy without SLNB or RT compared to lumpectomy with additional intervention) was evaluated over timing using the Exact Cochran-Armitage Trend Test. Multivariable logistic regression analysis was performed on the subgroup of patients (n=84) receiving care after publication of the long-term follow-up CALGB 9343 data to assess patient characteristics associated with omission of radiation therapy.

Results: The proportion of patients undergoing treatment with omission of RT and SLNB increased over the study period (Figure, p=0.0006). Patients who did not receive radiation therapy were older (78.76 years old +/- 5.48 v. 73.37 +/- 3.63, p<0.01). There was no difference between histologic grade or tumor size between those who did or did not receive RT. On multivariable analysis of patients who were treated after publication of the CALGB 9343 data (2014-2017), only age was predictive of being treated with RT (OR 0.77, 95% CI 0.67, 0.88).

Conclusions: Omission of both RT and SLNB are increasing in clinical practice in appropriately selected patients. The likelihood that patients are offered omission of these interventions increases with age. Tumor grade and size were not predictive of omission of RT or SLNB in this group of low-risk patients. Long-term data on patient outcomes are needed as these approaches are more widely adopted in clinical practice.

Figure: Trends of breast cancer management over time

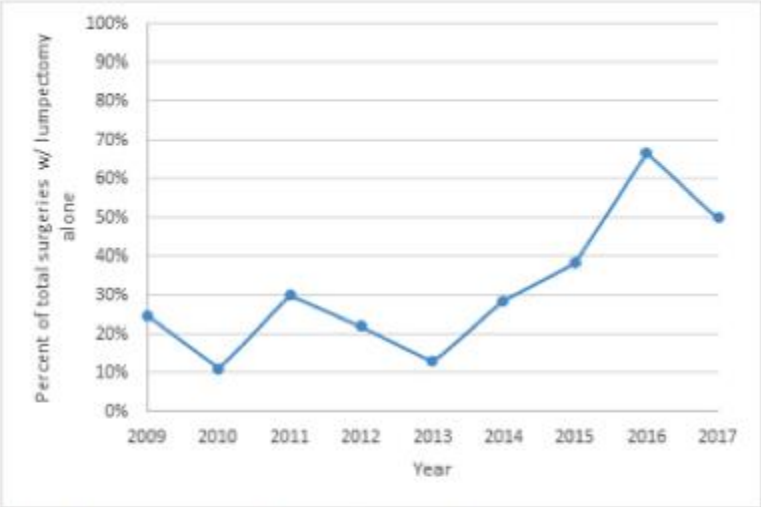

Figure 1: Trends of breast cancer management over time

Year	2009	2010	2011	2012	2013	2014	2015	2016	2017
Lumpectomy Alone	1	1	3	2	3	6	10	14	9
Lumpectomy + Other treatment	3	8	7	7	20	15	16	7	9
Total	4	9	10	9	23	21	26	21	18

403398 - Are providers and patients following hormonal therapy guidelines for patients over the age of 70? The influence of CALGB 9343

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Background/Objective: Elderly breast cancer patients are unique, and while few studies have determined what is optimal therapy, Hughes et al. published long-term follow-up results of CALGB 9343, which studied patients over the age of 70 with T1N0M0, estrogen- and/or progesterone-positive, HER2Neu-negative tumors. The authors found that in patients who underwent breast conservation therapy and omitted local radiotherapy, if they received 5 years of hormonal therapy, there was no difference in overall survival, distant disease-free survival, or breast preservation. Our study examined our institution's practices in this subset of patients.

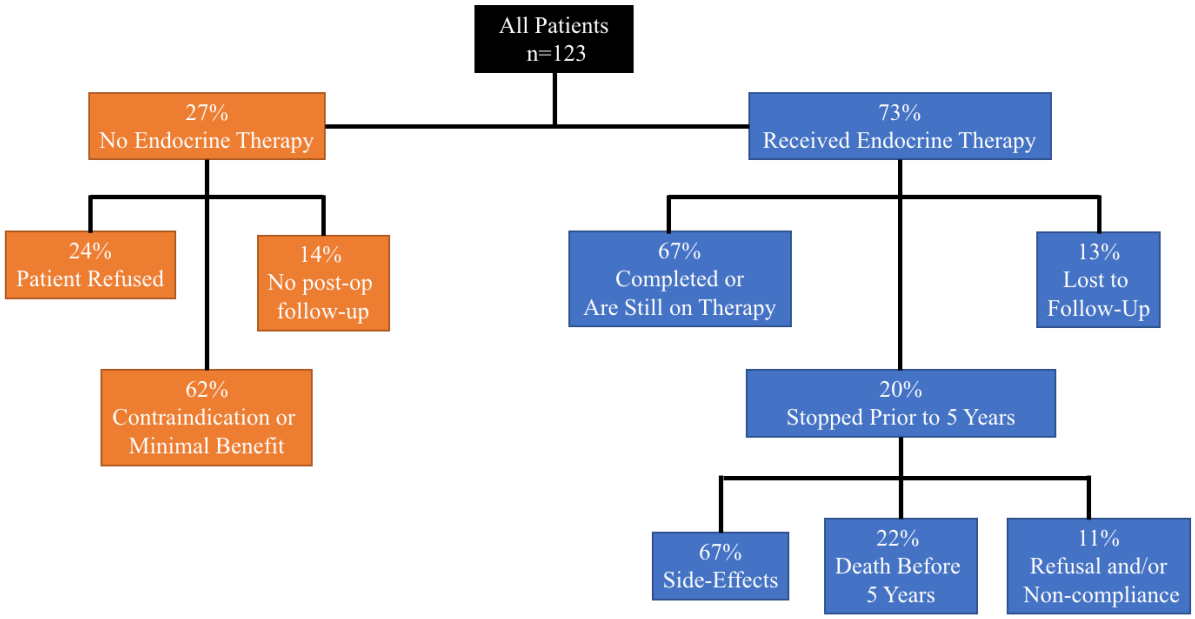
Methods: We performed a retrospective chart review on patients age 70 or older with T1N0M0 estrogen- and/or progesterone-positive, HER2Neu-negative tumors at our institution between April 2010 and October 2015. Factors analyzed included age, and if radiotherapy and/or endocrine therapy was received. If patients received hormonal therapy, we examined compliance and factors that contributed to discontinuation of recommended therapy. We also examined which factors contributed to providers recommending against endocrine therapy. Statistical analysis was performed using SPS software.

Results: There were 123 patients who met inclusion criteria. Overall, 46% received radiotherapy and 73% received hormonal therapy. Those who received hormonal therapy had a mean age of 76.2 years, while those who did not had a mean age of 80.2 years ($p < 0.001$ t-test). In patients who did receive

hormonal therapy (73%), the mean age at time of diagnosis for those that completed 5 years of therapy was 75.5 years as opposed to those who stopped therapy early, which was 77.6 years of age. For those who received endocrine therapy but stopped prior to 5 years, reasons for cessation included side-effect profile (67%), death (22%), and patient refusal and/or noncompliance (11%) (see Figure). Of the 27% of patients who did not receive hormonal therapy, 62% were not offered therapy by providers either because of minimal benefit or medical contraindications, 24% of patients refused to receive therapy, and 14% were lost to post-operative follow-up. Provider decisions to not recommend hormonal therapy were based on validated online risk assessment tools and/or performance status score. Medical contraindications included pre-existing renal, liver, and adrenal dysfunction, and osteoporosis.

Conclusions: To receive the full benefit of hormonal therapy in patients over 70 with T1N0M0 estrogen and/or progesterone positive, HER2Neu-negative tumors, especially in the setting of radiotherapy omission, it is imperative for patients to receive a full 5 years of therapy. Increasing patient age showed significant association to not receiving endocrine therapy. Contraindication to hormonal therapy and providers assessment of minimal patient benefit are the most common reasons why the patients are not prescribed hormonal therapy. In those patients who are offered and agree to receive hormonal therapy, short-term assessment of compliance should be performed, so that if patients are non-compliant, radiotherapy can be reconsidered. The decision for radiotherapy and endocrine therapy further emphasizes the significance of multidisciplinary care and the need for patient education. Further long-term and multi-institutional studies are needed to examine what other patient characteristics are associated with incomplete duration of therapy.

Figure: Results



399193 – Post-operative complications from mastectomies do not increase with advanced age

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Background/Objective: The decision about whether to perform mastectomies in elderly patients can be challenging due to concerns for increased risk of post-operative complications. The purpose of this study is to determine if there is an increased risk of complications following mastectomies associated with advanced age.

Methods: The National Surgical Quality Improvement Program (NSQIP) Database was queried from the years 2010 to 2015 using a primary CPT code for mastectomy with or without sentinel lymph node biopsy. All patients had a primary diagnosis of breast cancer. Patients with disseminated cancer, pregnant patients, and emergency cases were excluded. Nineteen relevant 30-day post-operative complications and 30-day mortality defined by the NSQIP database were identified and combined for a composite number for each patient. Univariate analyses using chi-squared tests were performed using a binary outcome variable (complication present or not) by age decade (decade 2 = age 18-29, 3 = 30-39, 4 = 40-49, etc.). Thirty-day mortality was also investigated independently using a chi-squared test by age decade. Univariate analyses using chi-squared tests were then performed using age decade by co-morbidities and demographic data including gender, BMI, diabetes, smoking, dyspnea, functional status, history of COPD, hypertension, dialysis, ASA classification, and steroid use. A multivariable logistic regression analysis was performed on incidence of post-operative complication compared by age decade using decade 6 (age 60-69) as the reference group. Co-morbidities of interest were controlled for and entered into the multivariable model if the univariate test produced a p-value <0.1 (= 0.1). A p-value <0.05 was considered statistically significant.

Results: A total of 4,932 patients met inclusion criteria. Age range was 18 to 90+. Univariate analyses performed for the presence of post-operative complications by age decade showed no statistically significant difference (p=0.67). A chi-squared test investigating 30-day mortality across age decades showed no statistically significant difference (p=0.15). After adjusting for co-morbidities and demographic data, there was no statistically significant difference between age decade and presence of post-operative complications, including 30-day mortality (p=0.94) and no difference between age decade and 30-day mortality (p=0.66). The odds of having 1 or more post-operative complications is 1.42 times higher in current smokers than in nonsmokers (p=0.0091, 95% CI: 1.09 1.85). The odds of having 1 or more post-operative complications is 3.88 times higher in patients who are not of a fully independent functional status than of those who are (p<.0001, 95% CI: 2.59 - 5.8) (Table).

Conclusions: After adjusting for co-morbidities, there is no increased risk for post-operative complications within 30 days of mastectomies due to the age of the patient, even in those older than 90. Our study suggests elderly breast cancer patients should not be excluded from undergoing a mastectomy solely based on their age.

Table: Logistic regression model for presence of post-operative complications by age decade after mastectomy

Predictors	Adjusted OR (95% CI)	p-value (*significant if p<0.05)
Decade 2 Ages 18-29 (N=20)	0.48 (0.06 – 3.63)	0.47
Decade 3 Ages 30-39 (N=174)	0.74 (0.41 – 1.35)	0.33
Decade 4 Ages 40-49 (N=649)	0.85 (0.61 – 1.19)	0.35
Decade 5 Ages 50-59 (N=1070)	0.96 (0.73 – 1.26)	0.76
Decade 6 Ages 60-69 (N=1285, reference group)	-	-
Decade 7 Ages 70-79 (N=1030)	0.91 (0.69 – 1.21)	0.50
Decade 8 Ages 80-89 (N=612)	0.87 (0.62 – 1.22)	0.41
Decade 9 Ages 90+ (N=92)	0.98 (0.51 – 1.90)	0.96
Age Decade (Overall)	-	0.94
Smoker	1.42 (1.09 – 1.85)	**0.0091***
Functional Status	3.88 (2.59 – 5.80)	**<.0001***

403430 - Primary endocrine therapy for breast cancer: A regional retrospective review, 2010 2015

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Background/Objective: Patients with estrogen receptor (ER)-positive breast cancer may be treated with primary endocrine therapy (PET) if they wish to avoid an operation or are deemed unsuitable for a general anesthetic. Surgery, chemotherapy, and radiotherapy may reduce overall quality of life without improvement in survival, particularly if treatment complications occur. The aim of PET is to prevent progression of disease, so that these patients die with, rather than from, breast cancer.

Methods: All patients with ER-positive breast cancer who received primary endocrine therapy between April 2010 and December 2015 were identified from the a regional breast cancer database, which covers a population of 488, 300 (Statistics New Zealand, 2015). Electronic notes were retrospectively reviewed for each patient. Outcomes assessed were mortality, breast cancer-specific mortality, and disease response. Outcomes were assessed as of 30 June 2017 to allow a minimum follow-up period of 18 months.

Results: Sixty-three patients were included. Less than half of patients treated with PET died of breast cancer (39%). Nine patients (14%) had progressive disease whilst on PET. In response to disease

progression, 5 patients changed PET agent, 2 proceeded to surgery (1 wide local under local anesthetic, 1 mastectomy under general anesthetic), and 2 received radiotherapy. Complete clinical response was observed in 20.6% and partial response in 54%.

Conclusions: For patients with breast cancer treated with PET, less than half die of breast cancer and only a small number have disease progression requiring surgery or radiotherapy. With an aging population, use of PET may become more prevalent. This is the only study in New Zealand on the clinical outcomes of patients being treated with PET. We are now able to provide population-specific prognostic information to patients who are unfit for surgery or decline surgery and wish to pursue PET as an alternative form of treatment.

Table: Breast cancer deaths vs non-breast cancer deaths

	Breast cancer deaths	Non breast cancer deaths	p value
Number	13	20	
Age at diagnosis (years)	86.0 (65 – 92)	87.5 (67 – 99)	0.51
Time from diagnosis to death (months)	12.6 (2.3 – 38.1)	26.2 (1.0 – 55.2)	0.005
Values provided are means with ranges in parentheses			

403887 - Comparison of breast cancer incidence, clinicopathologic features, and risk factor prevalence in women aged 20-29 at diagnosis to those aged 30-39

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Background/Objective: Breast cancer arising in women younger than 40 demonstrates unique biology and carries a worse prognosis than that diagnosed after 40. However, in studies of this population, women aged 20-29 are often combined with patients up to 45 years old at diagnosis, possibly obscuring characteristics inherent to the youngest patients when they are grouped with older patients. The incidence of breast cancer in women younger than 40 has been reported to be stable for the previous 4 decades; however, it is unclear if this is true of the very young group, 20-29, when examined independently. This study seeks to determine whether differences in incidence and risk factor prevalence exist between women aged 20-29 at diagnosis and those aged 30-39, and whether they exhibit similar clinicopathologic features.

Methods: The Surveillance Epidemiology and End Results (SEER) 9 registries of the National Cancer Institute were used to determine incidence rates of breast cancer in white, black, and American Indian/Alaskan native/Pacific Islander/Asian women aged 20-29, 30-34, and 35-39 from 1975-2014. In order to obtain specifics of patient demographics, tumor characteristics, and risk factor prevalence, a retrospective review was conducted of all women that presented to a single institution between 2005 and 2017 with invasive breast cancer and were aged 20-39 at diagnosis. Patients were identified by query of the electronic medical record (EMR) for ICD-9 code 174 or ICD-10 codes C50.0-C50.9. Univariate analysis and linear and polynomial regression of both national and institutional data were then performed using SPSS and JMP.

Results: The SEER database revealed 656,598 women diagnosed with breast cancer between 1975 and 2014, of which 3,834 were aged 20-29 at diagnosis. The incidence in women aged 20-29 was significantly lower than in women aged 30-34 or in women aged 35-39 (4.82 vs 26.23 vs 61.68 per 100,000, respectively, p<0.0001). Linear and polynomial regressions revealed a significant increase in the rate of breast cancer diagnosis from 1975 to 2014 in women aged 20-29 (R= 0.376 and R=0.542, p=0.010 and p=0.006, respectively), but there was no significant increase during that time in women aged 30-34 (p=0.222) or 35-39 (p=0.583). Of those aged 20-29 at diagnosis, incidence in black women remained stable over time (p=0.372), but the incidence in white women and American Indian/Alaskan native/Pacific Islander/Asian women increased significantly after 2009 (p<0.0001 and p=0.007, respectively). There were 566 patients at a single institution identified by EMR query, of whom 424 were eligible for inclusion. Sixty-three (14.9%) were aged 20-29 at diagnosis. Comparison of risk factors in those aged 20-29 with those aged 30-34 revealed a significantly younger age of first birth (22.5 vs 25.1, p=0.003), lower rate of oral contraceptive use (54.3% vs 76.1%, p=0.017), and lower rate of alcohol use (47.5% vs 63.8%, p=0.037). Comparison with those aged 35-39 at diagnosis revealed a lower BMI at diagnosis (25.4 vs 27.3, p=0.017) and higher rate of positive family history of ovarian cancer (18.3% vs 8.4%, p=0.026) as well as a similarly lower age at first birth (22.5 vs 26.8, p<0.0001), lower rate of oral contraceptive pill use (54.3% vs 74.8%, p=0.016), and younger age of menarche (11.0 vs 12.5, p=0.023). Additionally, those 20-29 had had fewer pregnancies and births at time of diagnosis than those aged 30-34 (0.85 vs 1.94, p<0.001, and 0.76 vs 1.36, p=0.001) or 35-39 at diagnosis (0.85 vs 2.1, p<0.001, and 0.76 vs 1.6, p<0.001) and were more likely to note a palpable mass prior to diagnosis than those aged 30-34 (96.3% vs 85.8%, p=0.043) or 35-39 (96.3% vs 85.6%, p=0.033). Further examination of risk factor prevalence in women aged 20-29 showed a significantly higher rate of first-degree relatives with breast cancer (p=0.042), a personal history of other cancers (p=0.016), and current tobacco use (p=0.004) after 2009.

Conclusions: Women with breast cancer aged 20-29 at diagnosis demonstrate unique attributes when compared with the other age groups with whom they have been traditionally combined. Given the finding of an increasing incidence in this population in addition to the well-known poor prognosis of breast cancer in this age group, it is imperative that a greater understanding of the unique biological attributes of these tumors be obtained.

398815 - Should we treat our Chinese elderly breast cancer patients with surgery or primary hormonal therapy?

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Background/Objective: Primary hormonal therapy has been used as an alternative to primary surgery for elderly with estrogen receptor-positive breast tumors. Such practices are less commonly performed in Asian countries, and the response to primary hormonal therapy in Chinese cohort is still lacking. This study aims to evaluate the clinical outcome of primary hormonal therapy and compared that to those who received primary surgery in Chinese elderly patients.

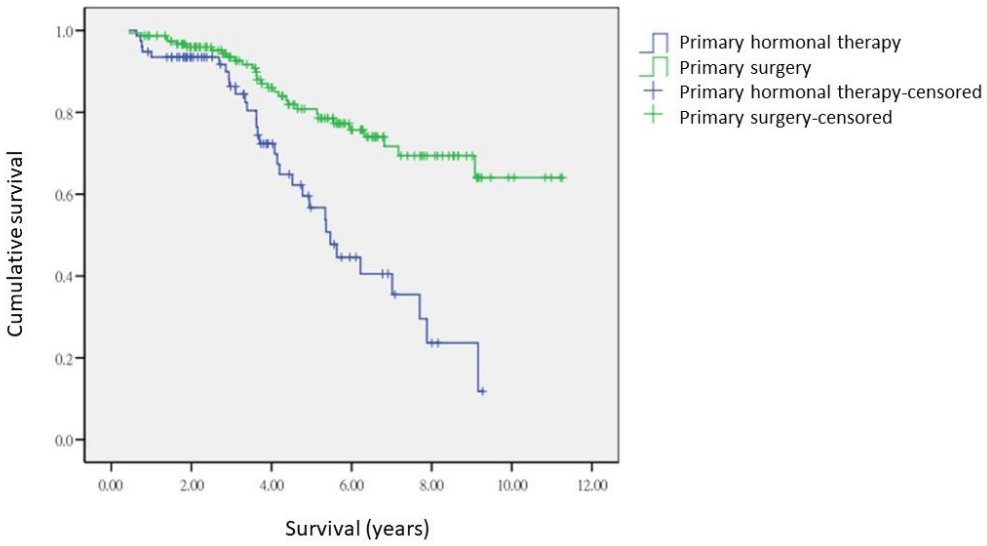
Methods: Chinese patients aged 70 and above with Stage I to III, estrogen receptor-positive breast cancer treated in a university-affiliated hospital from 2006 to 2015 were retrospectively reviewed. A 1:2 case match comparison of the overall survival of patients treated with primary hormonal therapy to

those who were treated surgically was performed, using propensity score case-match analysis to adjust for confounding factors. The time to response and time to progression of primary hormonal therapy was also recorded.

Results: There were 334 patients who fulfilled the inclusion criteria during the study period. Of these, 249 patients received primary operation followed by adjuvant therapy if indicated, whereas 85 patients were treated by primary hormonal therapy. The mean follow-up time was 56.5 months. Those patients treated with primary hormonal therapy were older (mean age 84.22 vs 75.87, p=0.000) and presented with larger tumors (T1 32.5% vs 62.3%, T2 52.0% vs 31.7%, T3 9.1% vs 2.4%, T4 6.5% vs 3.6%, p=0.000) than the operated group. There is no difference in terms of N stage, grading, and HER2 status. A 1:2 case match analysis was performed adjusting the confounding effect of age and T stage. In the first 2 years after treatment, the 2 groups had similar survival (p=0.367). The survival curves diverged after 3 years. Those patients with operation performed had a significantly better outcome than those treated with primary hormonal therapy (p=0.002) [Figure]. Among the 85 patients treated with primary hormonal therapy, 7 patients (8.2%) had clinical complete response. Twenty-nine patients (34.1%) had partial response, and 45 patients (52.9%) had stable disease. The median time to response is 4 months (range 1-15 months). A total of 41 patients (48.2%), with or without prior response, eventually had progression of disease. The median time to progression is 24 months (range 3-68 months). There was no significant difference in time to response and time to progression between patients on tamoxifen or aromatase inhibitor.

Conclusions: For frail elderly patients with limited life expectancy of less than 2 years, primary hormonal therapy alone may be appropriate since equivalent survival can be achieved for primary hormonal therapy with or without surgery. Those patients with longer life expectancy may gain survival benefits from local treatment. A comprehensive geriatric assessment is useful to predict the survival probability and guide the optimal treatment.

Figure: The overall survival curves comparing patients on primary hormonal therapy with primary surgery, 1: 2 case matching for age and T stage



403970 - Age disparities in breast cancer management: A multi-institutional study

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Background/Objective: Delay in diagnosis and treatment has been linked to poorer breast cancer outcomes. Young women with breast cancer are more likely to have aggressive disease and present with advanced disease; this may be compounded by delays in diagnosis and treatment. The purpose of this study is to assess the association between age and delays across the continuum of care in a cohort of multi-ethnic breast cancer patients in 3 large, academic New York City hospitals.

Methods: From 2008 to 2011, data were abstracted retrospectively from medical records of women ages 18 and above who presented with abnormal mammograms at 3 large hospitals in NYC. The 2 outcome variables were (1) diagnostic delay, a period of 60 or more days between diagnosis of abnormal mammogram and biopsy, and (2) treatment delay, a period of 90 days between biopsy and treatment. Patients with Stage IV cancer were excluded. Patients were designated as older (above age 45) or younger (under 45), and advanced stage (Stages II-III) or early stage (Stages 0-I). Chi-square analysis was used to compare characteristics of older and younger patients. Logistic regression models were used to assess the association between age and delays across the continuum of care, controlling for age, race, insurance status, treatment, stage, and nativity.

Results: A total of 614 patients were included in the study. Of these, 16.9 % (104 patients) were Caucasian, 34.5% (212 patients) were Black, 27.9% (171 patients) were Hispanic, and 18.9% (116 patients) were Asian. Younger women were proportionally more likely to present with advanced-stage cancer (64.5 % versus 57.5%, p=.02). Younger women were more likely to undergo mastectomy, while women over 45 were more likely to undergo lumpectomy (p=.04). There were no differences between the younger and older groups in terms of race, insurance status, nativity, or years in the US. Non-white patients were 3 times more likely to experience delays in diagnosis (OR 3.03, p<.05, CI 1.3- 6.7). Younger patients were less likely to experience diagnostic delays compared to older women (OR 0.41, p<.05, CI 0.2- 0.7). Age, race, insurance status, nativity, and years in the US were not predictors for treatment delay.

Conclusions: Despite presenting with higher stage at diagnosis, young age at diagnosis was not a significant predictor for diagnostic delay or treatment delay. There may be disparities in care for older women with a new diagnosis of breast cancer, and early intervention could potentially improve time to diagnosis and therefore improve prognosis.

Table: Adjusted relative risk for predictors of diagnostic and treatment delay

	Diagnostic Delay	Treatment Delay
	$n = 431$	$n = 513$
Race		
Non-white vs. White	3.038 (1.358 – 6.794)*	0.739 (0.385 – 1.418)
Age		
Younger vs. Older	0.418 (0.228 – 0.764)*	1.280 (0.756 – 2.168)
Nativity		
Foreign Born vs. US Born	0.958 (0.577 – 1.590)	0.714 (0.424 – 1.204)

Disparities

403776 - Analysis of the Oncotype DX-21 individual gene assay using RT-PCR in African-American women compared to Caucasian women with ER-positive breast cancer

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Background/Objective: Recent trends have found that breast cancer mortality is higher in African-Americans (AA) compared to Caucasians women. Multiple studies have looked at various factors that may contribute to this disparity. The aim behind this study was to explore if there was a difference in the 21-Gene Oncotype Dx Recurrence Score (RS) and expression of single genes by RT-PCR and to try to determine if there are differences in AAs versus Caucasians that may explain the adverse outcomes noted in AA.

Methods: This is a retrospective chart and tissue review. The study was conducted at Georgetown University Hospital (GUH). AA patients who had estrogen receptor (ER)-positive invasive breast cancer were identified and matched with Caucasian patients with ER-positive breast cancer of similar breast cancer stage and had not had an Oncotype performed as part of their care. They were contacted by telephone and consented by mail for their tissue to be sent for further analysis. Genomic Health conducted analysis of the tissue blocks. ER level was assessed by Allred score, as well as the 21-gene RS assay; individual genes was assessed by RT-PCR

Results: A total of 94 individuals were analyzed, 45 Caucasians and 49 AA. Both groups were of similar age and TNM distribution. The overall mean survival time for both races was 12.8 years. There was a significant difference between AA and Caucasians in overall survival. There was no significant difference between AA and Caucasian patients in their average RS. Further analyses of the individual proliferative genes in the Oncotype assay showed that there were no statistically significant differences between AA and Caucasians. However, specific Ki67 expression was found to have a significant positive correlation with Oncotype Dx recurrence score (correlation coefficient=0.52; $p<0.0001$), but it was not different when compared to race.

Conclusions: In the era of personalized medicine and the advent of genetic assay panel, we conclude that there is no difference in recurrence score between AA and Caucasians when match for stage and therefore, Oncotype Dx can be reliable used in AAs. Further studies are needed to clearly identify the factors contributing to the disparities in the outcomes of early-stage, hormone-positive breast cancer.

403730 - Demographic characteristics affect the rate of 21 gene recurrence score testing and chemotherapy administration

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Background/Objective: The 21 gene recurrence score (RS) is widely used to help determine the benefit of chemotherapy in patients with early-stage breast cancer. We hypothesize that the use of the RS and the use of systemic chemotherapy (in those with a recurrence score 18) is similar across the United States when adjusted for age, T and N stage, and co-morbidities. To address our hypothesis, we use data from the National Cancer Database (NCDB) to determine if certain demographic characteristics affect the utilization of RS testing as well as subsequent chemotherapy administration.

Methods: Using NCDB, we identified all breast cancer patients from 2004 to 2014 with the following tumor subtypes: T1 to T3, N0 to N1, ER-positive and Her-2/neu-negative. Patients were stratified according to whether or not they had RS testing performed. For patients with an intermediate- to high-risk recurrence score (18), we then determined whether or not they received chemotherapy. We compared the demographic and clinical characteristics of these groups using chi-square, independent t-test and ANOVA.

Results: Using NCDB, we identified 470,284 RS-eligible patients (T1 to T3, N0 to N1, ER-positive and Her-2/neu-negative). Of the RS-eligible patients, only 28% (131,596 patients) underwent testing. Of those who underwent RS testing, 41% (53,470 patients) had an intermediate- to high-risk score (18). Chemotherapy was administered to approximately 47% of those with an intermediate- to high-risk score. We noted a statistically significant difference in terms of the number of patients who underwent RS testing across all demographic areas. With the exception of urban versus rural setting and Charlson/Deyo score, there was a statistically significant difference in all other examined variables in the use of RS testing. Among those with an intermediate to high score, all demographic areas showed a statistically significant difference in the rate of chemotherapy administration, with the exception of the patients' level of education and urban versus rural setting.

Conclusions: This study suggests nationwide disparities in the rate of RS testing and subsequent chemotherapy administration based on race, socioeconomic status, and other demographic factors in patients with T1 to T3, N0 to N1, ER+ breast cancer. Further work is needed to narrow this treatment gap. The prognostic value of tumor biology (e.g., 21 gene recurrence score) is more important than anatomic tumor staging as reflected in the new AJCC 8th edition tumor staging manual. Therefore, results from patients with T3 and N1 disease, not previously included in other studies, will provide insight into practice pattern in these patients who were previously thought to be ineligible for 21 gene recurrence score testing.

Table:

	21 Gene Recurrence Score Eligible Patients (N)[1]	21 Gene Recurrence Score Preformed N (%)[2]	P Value[2]	21 Gene Recurrence Score ≥18 N (%)[3]	P Value[3]	Chemo Given N (%)	Chemo Not Given N (%)	Chemo Status Unknown N (%)	P Value
N	470,284	131,596 (28.0)		53,470 (40.6)		25,132 (47.0)	28,102 (52.6)	236 (0.4)	
Age (Years)	62.0 ± 12.4	58.8 ± 10.5	<0.001	58.6 ± 10.7	<0.001	55.9 ± 10.4	61.1 ± 10.3	61.4 ± 11.4	<0.001
Race/Ethnicity			<0.001		<0.001				<0.001
White	404828	114930(28.4)		46194(40.2)		21355 (46.2)	24655 (53.4)	184(0.4)	
Black	41028	9966 (24.3)		4566 (45.8)		2377 (52.1)	2162 (47.3)	27 (0.6)	
Other	20367	5554 (27.3)		2273 (40.9)		1183 (52.0)	1068 (47.0)	22 (1.0)	
Unknown	4061	1146 (28.2)		437 (28.2)		217 (49.7)	217 (49.7)	3 (0.7)	
Facility Location			<0.001		<0.001				<0.001
New England	28771	8253 (28.7)		3313 (40.1)		1476 (44.6)	1824 (55.1)	13 (0.4)	
Middle Atlantic	70684	24202 (34.2)		9461 (39.1)		4549 (18.8)	4826 (19.9)	86 (0.4)	
South Atlantic	100081	27884 (27.9)		11410 (40.9)		5116 (18.3)	6259 (22.4)	35 (0.1)	
East North Central	79780	24090 (30.2)		9659 (40.1)		4579 (19.0)	5056 (21.0)	24 (0.1)	
East South Central	26899	5980 (22.2)		2396 (40.1)		1107 (18.5)	1281 (21.4)	8 (0.1)	
West North Central	34648	10705 (30.9)		4351 (40.6)		2052 (19.2)	2297 (21.5)	2 (0.02)	
West South Central	31118	5721 (18.3)		2395 (41.9)		1052 (18.3)	1308 (22.9)	35 (0.6)	
Mountain	23557	7401 (31.4)		2948 (39.8)		1307 (17.7)	1633 (22.1)	8 (0.1)	
Pacific	60387	13588 (22.5)		5594 (41.2)		2456 (18.1)	3121 (23.0)	17 (0.1)	
Facility Type			<0.001		<0.001				<0.001
Community Cancer Program	48108	11623 (24.2)		4632 (39.9)		2106 (45.5)	2500 (54.0)	26 (0.6)	
Comprehensive Community Cancer Program	218796	59315 (27.1)		23675 (39.9)		10698 (45.2)	12872 (54.4)	105(0.4)	
Academic/Research Program (includes NCI-designated comprehensive cancer centers)	139110	42588 (30.6)		17528 (41.2)		8325 (47.4)	9123 (52.0)	80 (0.5)	
Integrated Network Cancer Program	49911	14298 (28.6)		5962 (41.7)		2565 (43.0)	3110 (52.2)	17 (0.3)	
Primary Insurance			<0.001		<0.001				<0.001
Not Insured	7451	1800 (24.2)		764 (42.4)		389 (50.9)	374 (49.0)	1 (0.1)	
Private Insurance / Managed Care	240211	80960 (33.7)		33100 (40.9)		17340 (52.4)	15627 (47.2)	133(0.4)	
Medicaid	25259	6606 (26.2)		2858 (43.2)		1523 (53.3)	1322 (46.3)	13 (0.5)	
Medicare	187406	39612 (21.1)		15703 (39.6)		5377 (34.2)	10249 (65.3)	77 (0.5)	
Other Government	4557	1321 (29.0)		497 (37.6)		256 (51.5)	240 (48.3)	1 (0.2)	
Insurance Status Unknown	5400	1297 (24.0)		548 (42.3)		247 (45.1)	290 (52.9)	11 (2.0)	
Educational Attainment for Patient's Area of Residence			<0.001		0.007				0.07
21 % or more	61983	14113 (22.8)		5796 (41.1)		2756 (47.6)	3002 (51.8)	38 (0.7)	
13 – 20.9 %	107218	27561 (25.7)		11416 (41.4)		5355 (46.9)	6005 (52.6)	56 (0.5)	
7 – 12.9 %	157269	45150 (28.7)		18199 (40.3)		8482 (46.6)	9642 (53.0)	75 (0.4)	
Less than 7%	142472	44433 (31.2)		17906 (40.3)		8472 (47.3)	9367 (53.3)	67 (0.4)	
Income			<0.001		0.012				0.01
Less than $38,000	62526	14989 (24.0)		6136 (40.9)		2851 (46.5)	3254 (53.0)	31 (0.5)	
$38,000 - $47,999	97246	25498 (26.2)		10568 (41.4)		4878 (46.2)	5652 (53.5)	38 (0.4)	
$48,000 - $62,999	126346	35429 (28.0)		14271 (40.3)		6624 (46.4)	7582 (53.1)	65 (0.5)	
$63,000 +	182655	55285 (30.3)		22322 (40.4)		10704 (48.0)	11517 (51.6)	101(0.5)	
Urban / Rural			<0.001		0.23				0.2
Metro	397363	111396 (28.0)		45259 (40.6)		21280 (47.0)	23776 (52.5)	203(0.4)	
Urban	54902	15145 (27.6)		6164 (40.7)		2887 (46.8)	3248 (52.7)	29 (0.5)	
Rural	6922	1881 (27.2)		741 (39.4)		343 (46.3)	398 (53.7)	0 (0)	
Charlson/Deyo Score			<0.001		0.13				<0.001
Charlson Score of 0	391411	112035 (28.7)		45632 (40.7)		21659 (47.5)	23778 (52.1)	195(0.4)	
Charlson Score of 1	64771	16523 (25.5)		6647 (40.2)		3008 (45.3)	3606 (54.3)	33 (0.5)	
Charlson Score of 2 or more	14102	3038 (21.5)		1191 (39.2)		465 (39.0)	718 (60.3)	8 (0.7)	
T Stage			<0.001		<0.001				<0.001
T1	347967	98313 (28.3)		38514 (39.2)		16752 (43.5)	21597 (56.1)	165(0.4)	
T2	109913	31489 (28.6)		14284 (45.4)		8021 (56.2)	6194 (43.4)	69 (0.5)	
T3	120523	109913 (91.2)		672 (0.6)		359 (53.4)	311 (46.3)	2 (0.3)	
N Stage			<0.001		<0.001				<0.001
N1	386373	116550 (30.1)		47609 (40.8)		21685 (45.5)	25709 (54.0)	215(0.5)	
N2	83911	15046 (17.9)		5861 (39.0)		3447 (58.8)	2393 (40.8)	21 (0.4)	

[1] 21 gene recurrence score eligible patients had the following tumor subtypes: T1 to T3, N0 to N1, ER positive and Her2 negative.
[2] P-value calculated by comparing patients who had an 21 gene recurrence score performed with those who did not have 21 gene recurrence score performed(column not shown).
[3] P-value calculated by comparing patients who had a 21 gene recurrence score ≥18 with those whose 21 gene recurrence score was <18 (column not shown).

404001 - Differences in initial presentation of Asian women aged 44 and younger compared to other ethnicities

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Background/Objective: Currently, the American Cancer Society recommends that average-risk women begin yearly mammograms by age 45, and can change to having mammograms every other year beginning at age 55. The guidelines also state that women should have the choice to start screening with yearly mammograms at age 40 if they so desire. It is estimated that more than 46,000 cases of breast cancer will be diagnosed in women under 45 years old in 2017 in the United States. In order to determine if adhering to the current recommendations of later onset of screening would adversely affect our population of patients, we sought to identify characteristics of women younger than 45 who presented to our institution with breast cancer. Data shows that different ethnicities have varied incidence of breast cancer and varied outcomes. In particular, we sought to identify how Asian patients presented with breast cancer, as we see a high proportion of Asian patients at our institution.

Methods: In this retrospective, IRB-approved chart review, we queried our prospective breast cancer database for patients who presented with breast cancer aged 44 and younger from 2005-2016. We evaluated various clinicopathologic features, including age at diagnosis, stage, histology, method of presentation, and race. In our database, race and ethnicity are self-reported.

Results: Of the 394 patients in our database, 57 self-reported as being of Asian ethnicity. The data revealed that Asian patients presented more frequently with an abnormal mammogram at diagnosis, with 43.8% of Asian patients presenting with abnormal mammography versus 36.8% of all other ethnicities, (p=.50). Asian patients presented with lower stages of breast cancer. Of the Asian women, 40.3% (23/57 patients) presented with DCIS (Stage 0) vs 20.1% (79/394) of all other races, (p=.012). With regard to mammographic findings for women with invasive cancer, Asian patients were more likely to have mammographic calcifications, 26.3% versus 23.7% in the other races, (p=.74). The median age at diagnosis was 41 and was the same between the Asian population and other ethnicities. Of note, 9.4% (37/394) of the entire data set were found to have mammographically occult breast cancer.

Conclusions: Asian women under the age of 45 with breast cancer present more frequently with an abnormal mammogram, and at an earlier stage of disease as compared to other racial subgroups. The difference in stage at presentation for Asian patients was statistically significant. In general, the majority of the women in this data set presented with an abnormal mammogram younger than age 44. These findings suggest there is a benefit in women in general, but particularly in the Asian population, to begin screening mammograms at an age earlier than that recommended currently by the American Cancer Society. This study was limited by its relative small sample size, and retrospective nature. Further studies will be needed to further reinforce these findings.

404111 - Racial disparities of differential expression of microRNA in triple-negative breast cancer

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Background/Objective: The incidence of breast cancer varies widely between ethnic populations in the United States. Several studies suggest that breast cancer subtypes also vary by race and age. Premenopausal African American (AA) women are more likely to develop triple-negative breast cancer (ER/PR-negative, HER2-negative), and less likely to develop luminal A breast cancers than their post-menopausal and Caucasian (CA) counterparts. The underlying reasons for this disparity are not well understood, although existing evidence implicates important genetic components. While it has been argued that racial variation may be largely due to lifestyle, dietary, socioeconomic, or clinical factors, these cannot fully explain the discrepancy. Studies of the pathology of tumors in AA and CA women have suggested that racial differences in the biology of triple-negative breast cancer may explain observed differences in outcome.

Methods: We investigated differentially expressed microRNAs from isolated from tissue sections of triple-negative breast cancer (TNBC). A total of 28 cases were examined, including 11 AA and 17 CA patients using the Taqman OpenArray microRNA Profiling. In order to selectively identify differentially expressed microRNAs from tumor cells, we isolated 500,000 um2 of tumor cells using laser capture microdissection (PALM) from paraffin-embedded sections. Total RNA (100ng) was purified and analyzed using the OpenArray technology.

Results: Statistically significant difference in microRNA expression was identified between AA breast tumors as compared to Caucasian breast tumors from laser captured microdissected tumor cells. African American TNBC had the highest expression of microRNAs 30a-3p, 95, 302c, 367, 372, 520b, and 601 and overall greater differential expression as compared to Caucasian TNBC tumors ($p<0.001$). Conversely, Caucasian TNBC tumors had greater expression of microRNAs 19a, 192, 206, 211, 302a, 335, 548d, 367c, let7g, and 645 ($p<0.001$).

Conclusions: While differential expression of microRNAs between TNBC tumors of African American and Caucasian patients has been evaluated in whole tumor tissue, we have identified microRNAs that are specific to the microdissected tumor cells. This result may aid in the understanding of racial differences in the biology of TNBC.

403569 - The impact of financial barriers on access to breast cancer care

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Background/Objective: Persistent socioeconomic disparities are evident in the delivery of health care. Patients with lower household incomes and poor insurance coverage consistently demonstrate worse clinical outcomes in comparison with patients in higher socioeconomic brackets. Despite previous research on health disparities, the extent of the effect of these inequalities in the management of breast cancer is not well understood. The purpose of our study is to perform a national cohort assessment of the impact of financial factors on specific aspects of breast cancer treatment.

Methods: This is a retrospective study using data from the National Cancer Database. The population consisted of female patients with primary breast cancer diagnosed between 2011 and 2015. Patients were then identified based on income and insurance status. Outcomes investigated were stage at diagnosis, use of breast conservation therapy, administration of systemic therapy for Stage III-IV disease, and rates of immediate reconstruction following mastectomy. Unadjusted and multivariable analyses were performed to determine significant associations between specific economic factors and clinical outcomes.

Results: There were 684,568 women identified and evaluated. Multivariable regression analyses revealed that stage of presentation was significantly associated with socioeconomic factors; specifically, patients with lower income (HR, 1.23) and no insurance (HR, 1.64) were more often diagnosed with advanced stage disease at presentation (Stage 0-I vs II-IV). Patients with lower income (HR, 1.08) and no insurance (HR, 1.05) had lower rates of breast conserving surgery. Out of the patients who underwent a mastectomy, patients with lower income (HR, 0.51) and no insurance (HR, 0.27) were less likely to receive immediate breast reconstruction. Administration of systemic therapy in patients with Stage III-IV disease was less frequent in patients with lower income (HR, 0.90) and no insurance (HR, 0.52).

Conclusions: Our findings demonstrate prevailing disparities in the delivery of care among patients with limited economic resources, which pertains to some of the most important aspects of breast cancer care. The full etiology of the observed disparities is complex and multifactorial, and a better understanding of these issues offers the potential to close the existing gap in quality care.

404238 - Physician attitudes towards physical exam in the evaluation of obese breast cancer patients: A national survey of surgical oncologists

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Background/Objective: The effect of obesity on the accuracy of physical examination in breast cancer patients has been previously reported by our group and others. Currently available studies have shown that there is no difference in the accuracy of physical examination of obese versus non-obese patients during the clinical staging of breast cancer patients. The objective of this study was to report surgeons perceived effectiveness of their own physical examination in the evaluation of obese breast cancer patients.

Methods: We developed and administered an online survey to a national sample of surgical oncologists. The survey was designed to evaluate provider attitudes, beliefs, and practices associated with the care of obese cancer patients. Within this survey, there was a subset of questions related to providers perception of the utility of physical examination in obese patients. Data were tabulated, and descriptive statistics performed.

Results: A total 172 providers accessed the online link, and 157 providers completed some or all of the survey (completion rate: 91.3%). In response to the following statement: When examining obese patients, I believe physical exam is less accurate and/or reliable, nearly all (96%) providers who completed this item responded yes (52/75, 69.3%) or maybe (20/75, 26.7%), suggesting a strong sense that physical exam in general is negatively impacted by obesity. When asked about accuracy of breast exams specifically, 117 respondents who routinely perform breast exams provided a response to the following statement: When examining obese patients, breast exams are less accurate. Only 22.2% of providers disagreed with this statement, while an overwhelming 77.8% replied either somewhat agree or strongly agree that breast exams are hindered by patient obesity. When asked the same question

about lymph node exams (When examining obese patients, lymph node exams are less accurate), 134 providers responded that they routinely perform lymph node exams and provided a response to the preceding statement. Only 3.7% of respondents did not agree with the above statement with regard to accuracy of lymph node exams, while 96.3% of providers somewhat or strongly agreed that lymph node exam is less accurate in obese patients. Additionally, among providers who reported routinely performing either breast or lymph node physical exam survey items, we asked evaluated responses to the following statement: When performing a cancer operation of the skin, soft tissue or breast the following intra-operative factors are affected by patient obesity. Operative time and surgeon comfort/ergonomics were both perceived to be significantly affected by patient obesity, with only 14.9% and 11.6% reporting little or no effect of obesity on these intra-operative parameters, respectively. Conversely, blood loss and ability to achieve an adequate cancer resection were both perceived by providers as much less affected by obesity, with 70.9% and 73.5% of respondents reporting little or no impact of obesity on these respective parameters.

Conclusions: In our previously reported experience, the discordance between physical exam and axillary ultrasound, as well as between physical exam and results at sentinel lymph node biopsy, did not differ between obese and non-obese patients. However, providers in our sample reported a strong perception that physical examination, specifically breast and lymph node exams, were in fact less accurate in the obese patient population. Further work to educate providers about the utility of physical examination to accurately stage breast cancer irrespective of body habitus should be emphasized going forward.

404324 - Regional variation in compliance with national accreditation program for breast center quality measures

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Background/Objective: Compliance with quality indicators has become an important indicator of the quality of care delivered at a facility. We examined regional variation in compliance with NAPBC (National Accreditation Program for Breast Centers) quality measures utilizing the National Cancer Database (NCDB).

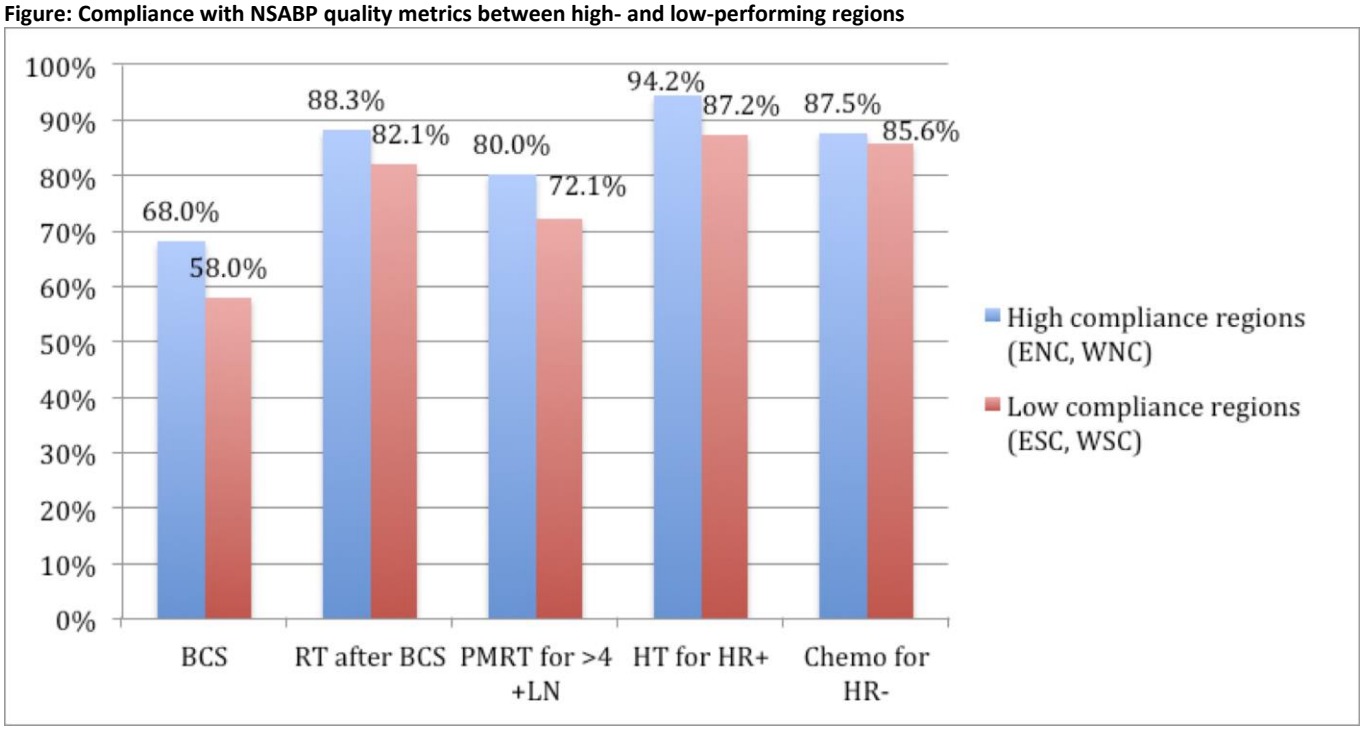
Methods: NCDB data was used to identify women who underwent surgery for AJCC Stage 0-III unilateral breast cancer from 2013-2014. Five NAPBC standards were measured: (1) breast-conserving surgery (BCS) rate for clinical AJCC Stage 0-II breast cancer, (2) radiation therapy within 365 days of diagnosis for women <70 y/o who underwent BCS, (3) post-mastectomy radiation within 365 days of diagnosis for women with 4 positive regional lymph nodes, (4) hormone therapy within 365 days of diagnosis for women with AJCC Stage IB-III hormone receptor positive (HR+) cancer, (5) combination chemotherapy within 120 days of diagnosis for women <70 y/o with AJCC Stage IB-III HR negative (HR-) cancer. Chi-square and multivariable analyses were used to examine regional compliance and predictors associated with non-compliance of each of these measures.

Results: There were 319,433 women who underwent surgery for Stage 0-III breast cancers at 1,228 contributing institutions in 9 regions of the country. Of 279,509 women with clinical Stage 0-III breast cancers, 65.8% had BCS (ranging 57.7% to 76.7% between regions, $p<0.01$). Of 145,419 women <70y/o who underwent BCS, 84.1% had radiation within 365 days (range 78.9% to 90.5% between regions, $p<0.01$). Of 13,370 women who underwent mastectomy with 4 positive lymph nodes, 76.6% had post-

mastectomy radiation therapy (range 70.5% to 81.9% between regions, p<0.01). Of 182,620 patients with HR+ stage IB-III cancer, 91.3% had hormone therapy within 365 days (range 84.5% to 96.0% between regions, p<0.01). Of 36,308 patients <70y/o with HR- stage IB-III cancer, 87.2% had chemotherapy within 120 days (range 84.8% to 88.6% between regions, p<0.01). Two regions (East North Central, West North Central) were identified as consistently having the highest compliance, and 2 (East South Central, West South Central) were identified as consistently having the lowest compliance regions. The Figure demonstrates the differences in rates of the 5 NABPC quality measures between the high and low compliance regions, all p-values <0.01. Multivariable analyses adjusted for facility, patient, and tumor factors were done to identify predictors of non-compliance for each of the NAPBC quality measures. Regional location was the only predictor of non-compliance that was statistically significant amongst all quality measures. Low-compliance regions had a 1.5-fold increased odds of not having BCS (OR 1.51, 95% CI 1.46-1.55), a 1.7-fold increased odds of not having radiation after BCS (OR 1.68, 95% CI 1.58-1.78), a 1.4-fold increased odds of not having post-mastectomy radiation (OR 1.40, 95% CI 1.21-1.62), a 2.1-fold increased odds of no hormone therapy (OR 2.13, 2.01-2.26), and a 1.3-fold increased odds of no chemotherapy for HR- tumors (OR 1.26, 95% CI 1.12-1.41), all p-values <0.01.

Conclusions: Regional location was the only significant independent factor associated with low or high compliance for all 5 NAPBC measures. These findings suggest that targeted efforts in certain areas of the country may help improve performance on these NAPBC measures.

Figure: Compliance with NSABP quality metrics between high- and low-performing regions



403944 - Understanding disparities driving breast cancer survival and reconstruction outcomes: A population-based analysis

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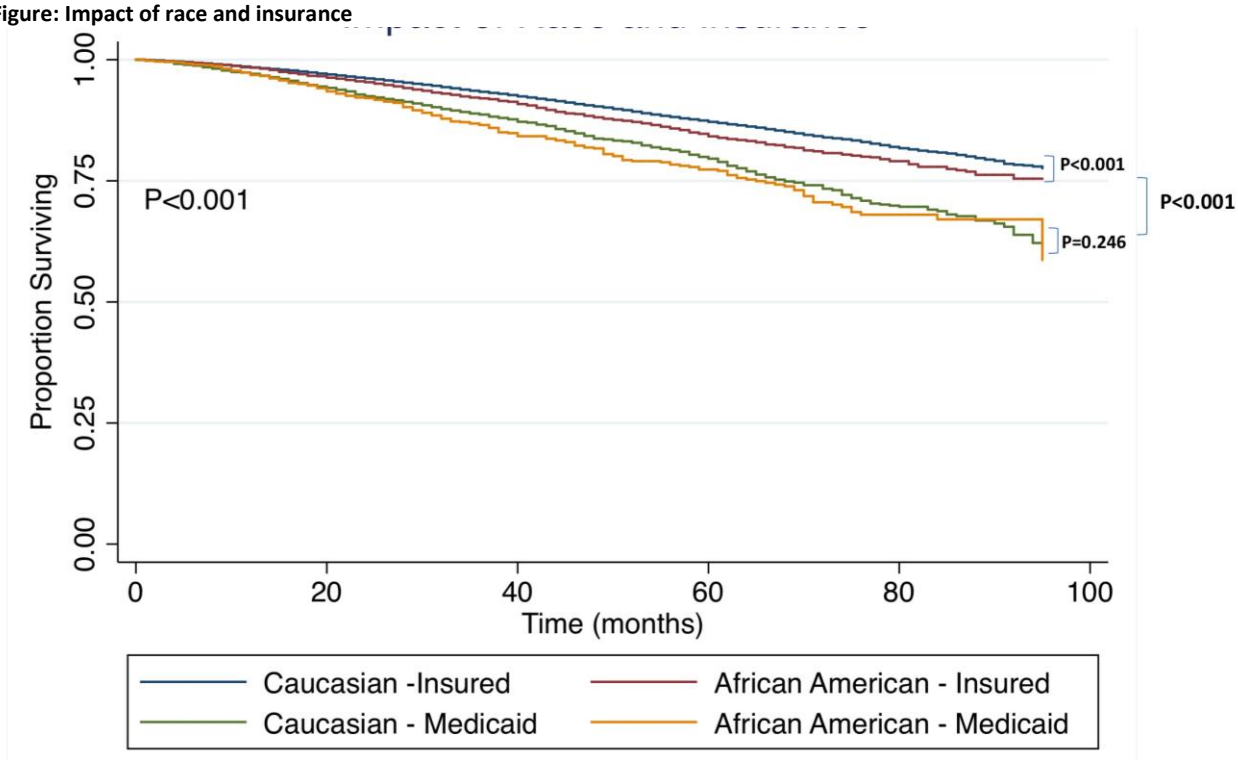
Background/Objective: Although African American women (AAW) have a lower incidence of breast cancer, survival remains poor among AAW compared with Caucasian women (CW). While tumor biology, hormonal receptor status, and genetics are established factors associated with survival, socioeconomic and racial factors influencing outcomes remain poorly understood. The objective of our study is to evaluate the impact of race and type of health care coverage on survival and receipt of reconstruction in a contemporary cohort of patients with breast cancer.

Methods: Patients who underwent breast-conserving surgery or mastectomy for invasive ductal and lobular carcinoma from 2007 to 2014 were identified using the Surveillance Epidemiology End Results (SEER) registry. Patients were stratified into 4 groups based on race and insurance status: CW-Insured, AAW-Insured, CW-Medicaid, and AAW-Medicaid. Overall and disease-specific survival was calculated using Kaplan-Meier method and compared using log-rank test. Multivariate Cox regression was performed to identify predictor of survival. Multivariate logistic regression was performed to identify factors associated with breast reconstruction following mastectomy.

Results: A total of 65,168 patient underwent surgery for breast cancer, 10% of whom were AAW, and 7% of whom had Medicaid health care coverage. The median age was 64 years. Stratified by race and insurance status, post-mastectomy reconstruction was more commonly performed among CW-insured compared with AAW-insured, CW-Medicaid, and AAW-Medicaid (44% vs. 37% vs. 30% vs. 27%, respectively; p<0.001). Similarly, incrementally higher T-stage and N-stage were observed among AAW-Medicaid and CW-Medicaid compared with the other groups. On the other hand, HER+ and ER+ tumors were more common among CW compared with AAW regardless of type of insurance status (p<0.001). The 5-year survival was significantly higher among CW-Insured compared with AAW-Insured (87.2% vs. 84.2%; p<;0.001) while CW-Medicaid had worse 5-year survival compared with AAW-Insured (79.6% vs. 84.2%; p<0.001). Furthermore, the 5-year survival was comparable between CW-Medicaid and AAW-Medicaid groups (79.6% vs. 77.3%, p=0.246). On multivariate survival analysis after adjusting for age, stage, and tumor factors, both race and insurance status were independent predictors of poor disease-specific survival (AAW-Insured HR 1.34, CW-Medicare HR 1.61, and AAW-Medicare HR 1.79, all p<0.001). Multivariate logistic analysis revealed that both race and type of health care coverage were the strongest independent risk factors associated with no breast reconstruction post-mastectomy.

Conclusions: This study demonstrates that access to care is an important prognostic factor in determining mortality among patients with a diagnosis of breast cancer as well as in the ability to obtain post-mastectomy reconstruction. Adequate health care coverage is vital in order to improve the quality of care delivered to breast cancer patients.

Figure: Impact of race and insurance



402262 - Obesity does not influence management of advanced breast cancer in the elderly

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Background/Objective: Breast cancer is prevalent among patients over age 70, and treatment in this age group frequently deviates from standard protocols. According to the National Center for Health Statistics, obesity is becoming increasingly more common in the elderly population, and it adds to the complexity of treatment decisions. We aimed to investigate whether body mass index (BMI) affects care in this subset of patients.

Methods: We performed a retrospective chart review on patients diagnosed with breast cancer who were age 70 or older with pathologically proven positive axillary lymph node or metastatic disease from April 2008 through September 2016. Patients were group into 5 categories: normal weight, overweight, class I, class II, and class III obesity (defined by health-risk and BMI). Mean and standard deviations of BMI were calculated for each category, and BMI was compared to treatment received, clinical stage, and hormone receptor status.

Results: In total, 118 patients (116 women and 2 men) met inclusion criteria. Thirty-four percent of patients had normal weight (BMI <25), while 32% were overweight (BMI 25-30), 20% were class I obesity (BMI 30-35), 10% were class II obesity (BMI 35-40), and only 3% were class III obesity (BMI >40). BMI was compared to if chemotherapy, radiation therapy, or axillary surgery was performed, and there was no statically significant difference. The mean BMI for patients who received chemotherapy was 28.1, and those who did not receive chemotherapy was 28.8 (p=0.51). Those who had radiation therapy had a BMI of 27.9 compared to 28.9 for those that did not (p=0.40). The BMI for patients who had axillary surgery was 27.9 ,and the BMI for those who did not, it was 28.8 (p=0.41). Clinical stage was also

analyzed in relation to BMI. While there was a trend for increasing clinical stage to be associated with a lower BMI, this was not statistically significant (p=0.06). Controlling for obese versus non-obese patients using a BMI of 30 as opposed to the previously stated categories, all analysis remained statically non-significant.

Conclusions: There were no statistical differences in BMI and treatment patterns in elderly patients with advanced cancer at our institution. Furthermore, neither stage or hormone receptor status is associated with a patient's BMI. Therefore, obesity does not appear to influence treatment decisions in patients over the age of 70. Breast cancer providers should turn to other patient and clinical factors when deciding treatment plans in this patient population. In the United States, the percentage of the population that is obese increases yearly, and further investigation is needed to examine how obesity influences tumor biology, diagnosis, and treatment decisions.

Table: Mean (standard deviation of BMI by therapy

	BMI mean (sd)	*p-value*
Chemotherapy		0.51
No	28.1 (6.3)	
Yes	28.8 (6.1)	
Radiation Therapy		0.40
No	27.9 (6.2)	
Yes	28.9 (6.2)	
Axillary Dissection		0.41
No	27.9 (6.0)	
Yes	28.8 (6.3)	
Operation Type		0.12
Lumpectomy	32.4 (5.9)	
Lumpectomy and sentinel node biopsy	29.4 (6.4)	
Lumpectomy and axillary dissection	29.5 (4.8)	
Mastectomy	31.8 (4.4)	
Mastectomy and sentinel node biopsy	29.0 (6.9)	
Mastectomy and axillary dissection	28.5 (6.9)	
No surgery	24.9 (3.9)	
Axillary dissection only	21.0 (NA, n=1)	

404333 - Avoiding lymphadenectomies for breast cancer: Does Z0011-eligibility make a difference at a Los Angeles County hospital?

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Background/Objective: Z0011-eligibility has made avoiding lymphadenectomies possible for many breast cancer patients; nonetheless, the impact of Z0011-eligibility in an underserved patient population is unclear. We sought to determine how many patients would meet Z0011-eligibility and the percentage of patients who would be able to avoid lymphadenectomy in an underserved Los Angeles County Hospital breast cancer patient population.

Methods: A retrospective chart review was performed. Patients with a new breast cancer diagnosis from January 2011 to December 2012 were identified from a clinical database prior to our adoption of Z0011 guidelines. The patients were divided into 4 groups - patients who underwent modified radical mastectomy (MRM), simple mastectomy (SM) with sentinel lymph node biopsy (SLNB), lumpectomy with SLNB, and lumpectomy with axillary lymph node dissection (ALND). The number of patients who were Z0011-eligible was then determined.

Results: Between 2011 and 2012, 223 total patients were identified, and the median age of the cohort was 54. Hispanic women were the largest ethnic group comprising 45% (n=101) of the total patients while the second- and third-largest ethnic groups were African-Americans comprising 28% (n=62) and Asians comprising 14% (n=32) of the cohort respectively. Caucasian patients comprised 10% (n=22) of the cohort, and 3% (n=6) were unknown. The most common surgical operation was MRM (Table). Out of the 223 patients, 42% (n=95) received a lymphadenectomy and 10 of those patients would have been Z0011-eligible. If the Z0011-eligible patients had avoided lymphadenectomy, 38% (n=85) of patients would have received a lymphadenectomy resulting in a 4% (n=10) decrease in the rate of lymphadenectomy.

Conclusions: If Z0011-eligible patients had avoided lymphadenectomy in the study time period, only 4% of patients would have been able to avoid lymphadenectomy in our cohort. The relatively modest decrease suggests that in the underserved population Z0011-eligibility may be uncommon, thus, decreasing the potential impact of the study. Further studies will need to be performed to clarify why Z0011-eligibility is low in our underserved patient population in order to make improvements that could broaden the impact of Z0011-eligibility and decrease the morbidity of lymphadenectomy.

Table: Operations performed

Surgical Operation Performed	2011-2012 N=223
MRM	78 (35%)
SM with SLNB	67 (30%)
Lumpectomy with SLNB	61 (27%)
Lumpectomy with ALND	17 (8%)

403385 - Black race and distant recurrence after neoadjuvant or adjuvant chemotherapy in breast cancer

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Background/Objective: Chemotherapy given in the neoadjuvant setting in mouse mammary carcinoma models, and in a subset of patients with residual breast cancer after completion of chemotherapy, creates a pro-metastatic tumor microenvironment characterized by an increase in the density and activity of cancer cell intravasation sites called TMEM (Tumor Microenvironment of Metastasis). TMEM is composed of an invasive cancer cell in direct physical contact with a pro-angiogenic macrophages and an endothelial cell. Interestingly, the breast cancer microenvironment in black race patients has a higher microvascular density and a higher density of pro-angiogenic macrophages. Therefore, we hypothesized that black race may be associated with the development of a chemotherapy-induced pro-metastatic response. We evaluated the association between race, distant recurrence, and adjuvant or neoadjuvant chemotherapy in localized or locally advanced breast cancer.

Methods: We evaluated DRFS in 1,211 patients treated with systemic adjuvant chemotherapy (AC) or neoadjuvant chemotherapy (NAC), including 704 black, 416 white, 63 Hispanic, and 28 women with

other or mixed race. The association between chemotherapy type (AC or NAC) and distant recurrence-free survival (DRFS) was examined using multivariate Cox proportional hazard models that included race, age, stage, estrogen receptor (ER) status, and triple-negative status.

Results: Features associated with worse DRFS included: Stage III disease (hazard ratio [HR]=3.69, p<0.001), age<50 years (HR=1.67, p<0.01), ER-negative disease (HR=2.28, p<0.01) and use of NAC (p<0.001), but not black race (p=0.06). NAC was associated with worse DRFS compared to AC in black (HR=3.14; 95% CI=2.12-4.59; p<0.001) but not in white women (HR=1.48, 95% CI=0.61-3.09; p=0.34).

Conclusions: Black race was associated with a worse distant recurrence-free survival when treated with neoadjuvant chemotherapy as compared to adjuvant chemotherapy. These clinical and biologic effects of neoadjuvant chemotherapy for breast cancer in black women are further being evaluated.

404148 - Rural-urban differences in time to radiation among breast-conserving surgery patients

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Background/Objective: Observed rural-urban disparities in the treatment and outcomes of breast cancer care may be explained by structural and organizational characteristics of health care systems. We examined the role of surgical care facilities characteristics and distance to care in an attempt to explain rural-urban variation in timing of initiation of guideline-recommended radiation therapy after breast-conserving therapy.

Methods: An observational study was conducted using the National Cancer Database to explore rural-urban differences in time to radiation initiation following surgery among women had breast-conserving surgery between 2003 and 2007. These years were used to allow for at least 5 years of follow-up after diagnosis. We included only women with Stage I or II, node-negative cancers who received adjuvant radiation and breast-conserving surgery. Women who received any chemotherapy or neoadjuvant radiation were excluded. We calculated percentages and frequencies of demographic characteristics of rural-urban patients. Time to radiation (TTR) was defined as the number of days between surgery and initiation of radiation. We then used Chi-Square tests for independence and Wilcoxon Rank Sum tests to compare rural-urban differences in TTR for all cases and stratified by U.S. Census Region. We constructed Kaplan-Meier curves stratified by TTR to compare rural-urban differences in survival. Finally, Cox Proportion Hazard models were constructed to further assess survival differences after adjusting for relevant demographic, facility, and clinical characteristics.

Results: Our analysis included 55,700 patients. Rural and urban populations varied by demographics including race, insurance status, household income, and education. Rural patients lived a media of 26.4 miles from their treatment center, compared to 6.5 miles for urban patients. The median time to radiation was significantly less for rural women than urban women (53 days vs 56 days; p<0.001). A greater percentage of rural patients (38.9%) initiated radiation within 45 days of breast-conserving therapy compared to urban patients (33.7%). In 5 regions, rural patients had shorter median times to radiation than urban patients ranging from 2 to 9 days. All other regions had no statistically significant differences. Both our unadjusted and adjusted analysis demonstrated no statistically significant differences between rural and urban survival (Table).

Conclusions: Timing of radiotherapy in breast-conserving therapy is highly important in relation to survival. Our results indicated rural patients initiated radiation earlier than urban patients. We refuted

our hypothesis that rural patients would have decreased survival, demonstrating no difference between rural-urban survival. Our findings suggest that rural care is of equal quality to that of urban care.

Table: Time to radiation in rural and urban breast cancer patients by region

	All	Rural	Urban	Change in Median	p-Value†
New England					
Mean (SD)	75.9±56.8	65.8±45.9	76.8±54.8		
Median	57 (41-87)	53 (39-75)	58 (39-75)	-5	<0.001
Middle Atlantic					
Mean (SD)	84.2±66.2	76.4±64.1	84.8±66.3		
Median	62 (43-100)	54 (38-84)	63 (43-102)	-9	<0.001
South Atlantic					
Mean	81.5±64.8	76.3±59.1	82.3±65.7		
Median	56 (39-106)	55 (38-93)	57 (40-109)	-2	0.003
East North Central					
Mean	77.7±74.4	77.1±75.7	77.8±74.2		
Median	54 (38-94)	51 (35-96)	54 (38-94)	-3	0.01
East South Central					
Mean	83.2±66.5	84.2±65.3	82.8±66.5		
Median	54 (35-124)	55 (35-123)	53 (35-124)	2	0.66
West North Central					
Mean	73.4±56.1	73.1±56.3	73.6±56.0		
Median	51 (35-91)	49 (35-91)	51 (35-91)	-2	0.44
West South Central					
Mean	87.6 ±76.9	91.1±73.6	87.0±77.5		
Median	56 (36-132)	56 (35-140)	55 (36-132)	1	0.48
Mountain					
Mean	76.0±62.7	67.3±55.5	77.6±63.8		
Median	49 (35-96)	47.5 (35-72.5)	50 (34-106)	-2.5	0.15
Pacific					
Mean	84.2±65.4	76.9 ±57.2	84.7±65.9		
Median	58 (41-116)	55 (40-91)	58 (41-118)	-3	0.03

† Wilcoxon Sum Rank Test

403935 - A study on intra-operative radiation therapy in breast cancer patients: Does socioeconomic status or race correlate with cure?

Jennifer Son, Laurel Mulder, Jennifer Poirier, Parul Barry, Andrea Madrigrano

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Background/Objective: Minority women with breast cancer more commonly have poorer outcomes and survival rates. There are many aspects to the treatment of breast cancer patients, and radiation therapy is an essential part of the treatment plan to prevent local tumor recurrence. In particular, intra-operative radiation therapy (IORT) is becoming increasingly more common with its ability to deliver radiation directly to the tumor bed. It is possible that poor outcomes in minority groups are related to aspects of care such as IORT. Our study aims to explore whether minority groups who received IORT vs. external beam radiation therapy (EBRT) have poorer outcomes in comparison to non-minorities. This is a retrospective review of de-identified data from the National Cancer Database in which we looked at breast cancer patients who received intra-operative radiation therapy (IORT) and compare them to those who had external beam radiation therapy (EBRT). We hypothesize that minorities do not choose IORT, and in patients who receive IORT, minorities have a poorer outcome compared to non-minorities.

Methods: A retrospective review of data from the National Cancer Database was conducted on breast cancer patients who received IORT and EBRT. A total of 1,186,535 cases were examined. Of these

patients, 4,583 had IORT, and 1,181,952 had non-IORT beam radiation or radioactive implants. Baseline variables included age, race, insurance status, income (2000 and 2012), education (2000 and 2012), geographical location (2003 and 2013), Charlson score, tumor grade, tumor size, and whether regional nodes were positive. Outcomes variables included readmission within 30 days, 30-day mortality, 90-day mortality, and long-term survival. To determine whether there were any differences between the 2 groups (IORT and non-IORT radiation), Chi-square tests were conducted on categorical variables and Wilcox Mann Whitney tests were conducted on ordinal variables. Kaplan Meier analysis was used to examine whether there were differences in survival between patients who received IORT and those who did not.

Results: Patients who underwent IORT were generally older (median=66) than those who underwent non-IORT radiation (median=60; $p<0.001$). Furthermore, race played a role, with fewer black patients and more white patients undergoing IORT ($p<0.001$). Fewer patients with government insurance (including Medicare and Medicaid) underwent IORT compared to patients with private insurance undergoing IORT ($p<0.001$). Patients who underwent IORT lived in ZIP codes with higher incomes when compared to those who underwent non-IORT radiation; this was true with the 2000 cohort as well as the 2012 cohort ($p<0.001$ for both). Patients who underwent IORT lived in ZIP codes with higher educational attainment when compared to those who underwent non-IORT radiation; this was true with the 2000 cohort as well as the 2012 cohort ($p<0.001$ for both). However, there was no significant difference between patients who underwent IORT and those who underwent non-IORT radiation on 30-day or 90-day mortality, ($p>0.99$ and $p=0.45$, respectively).

Conclusions: Educational and economic disparities still persist in the United States, leading to certain groups having limited access to health care, which ultimately leads to worse health care outcomes. Our results of the National Cancer Database showed that disparities still exist in treatment of breast cancer. Race, education, and socioeconomic status all appeared to play a role in the choice of IORT vs. EBRT. However, it does not appear that this affected mortality. In spite of marked advances in breast cancer, disparities persist in access to these modalities. Breast cancer requires a multidisciplinary team collaboration, and thus we must ensure that all minorities have equal access. It is increasingly important to address disparities as the population becomes more diverse and to understand the wide range of factors that contribute to them such as socioeconomic and educational status. Further studies are necessary to address other disparities that exist in the treatment of breast cancer and how we can work to provide equal care for all.

402937 - Does more aggressive treatment in Chinese women with invasive breast cancer lead to increased overall survival compared to Caucasian women?

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Background/Objective: Breast cancer is the sixth leading cause of cancer-related death in Chinese women. Previous studies have shown that Chinese women present at younger age and with more aggressive breast cancer compared to Caucasians; however, they have better overall survival. It is still in debate whether the ethnicity or treatment options may affect this disparity. The problem is further aggravated by the fact that most studies have been conducted either in China or based on national registries with heterogeneous populations. Therefore, we chose to compare the disease distribution,

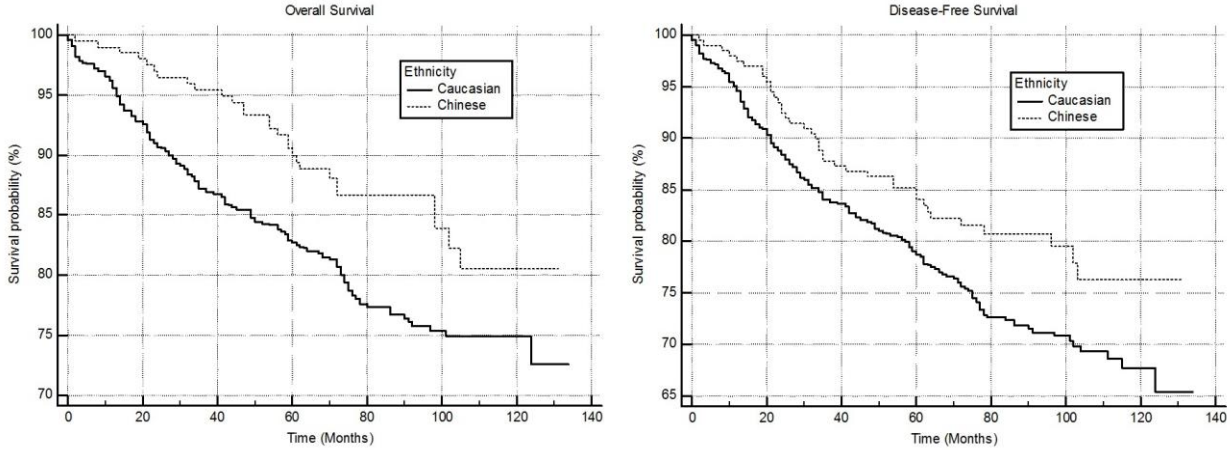
management and outcomes of Chinese females with invasive breast cancer to Caucasian counterparts in a single-center study, thus minimizing effects of the environmental exposure and accessibility of therapeutic resources.

Methods: We performed a single-center, retrospective review of Chinese and Caucasian females diagnosed with invasive breast cancer (invasive ductal or lobular carcinoma) between 2005 to 2015. Clinicopathologic characteristics, treatment modalities are compared between the 2 ethnicities using Chi-square and student T-test. The Kaplan-Meier method estimated overall survival (OS) and disease-free survival (DFS), and the log-rank test was used for comparisons.

Results: A total of 1089 female patients in our institution with invasive breast cancer were reviewed; 868 (79.7%) and 221 (20.3%) were self-identified as Caucasian and Chinese, respectively. Chinese patients were significantly younger than Caucasians (56 yrs vs 65 yrs, p<0.0001). There was no difference in the distribution of staging between the 2 groups. However, the Chinese group had fewer hormonal receptor-positive tumors (69% vs 78%, p=0.0003). Chinese patients were more likely to undergo total mastectomy (39% vs 19%, p<0.0001) and less likely to forego surgery (17% vs 26%, p<0.0001) across all stages. Similar distribution is seen when subdivided by stage of disease with statistical significance in Stage I and Stage II diseases. They were also more likely to receive chemotherapy (p=0.0122). Overall, the Chinese group had significantly better OS (117.7 months vs 110.7 months, Logrank p=0.01) and DFS (111 months vs 105 months, Logrank p=0.0305) than the Caucasian group (Figure).

Conclusions: Despite the younger age of initial diagnosis and less hormonal receptor positivity, Chinese women at our institution had a better overall and disease-free survival compared to Caucasian patients with invasive breast cancer. This might be attributed to more aggressive treatments in the same stage of the disease, as manifested by higher rate of mastectomies and chemotherapy among Chinese females.

Figure: Kaplan Meier for OS and DFS



404254 - Differences in patterns of surgical management in breast cancer patients after neoadjuvant chemotherapy: Comparing a private hospital to a safety net hospital

Lisa Winton, Rachel Warren, Caitlin Hester, Virginia Bailey, Rachel Wooldridge, Deborah Farr, James Huth, Marilyn Leitch

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Background/Objective: Neoadjuvant chemotherapy (NAC) has been used to increase the rates of breast conservation eligibility and with improvements in systemic therapy, pathologic complete response (pCR) has increased. Despite increasing rates of NAC and pCR over the last decade, rates of breast conservation are decreasing with more patients choosing to undergo a bilateral mastectomy. The aim of this study was to assess the rates of breast conservation and bilateral mastectomy among racial groups, and to assess variables that influence rates of immediate post-mastectomy reconstruction.

Methods: Women (898) who received neoadjuvant chemotherapy for a newly diagnosed breast cancer from 2010 to 2017 were identified from institutional tumor registries at both a private university hospital and a safety-net institution. Patient demographics, insurance status, tumor grade, histology, lymphovascular invasion, tumor hormonal profile, TNM stage, residual cancer burden, and surgical procedures were compared after women were stratified by race.

Results: Within the white patient cohort, the majority of women pursued either breast conservation therapy (33.8%) or bilateral mastectomy (34.4%) over a unilateral mastectomy (31.5%). Conversely, within the black and Hispanic patient cohorts, the majority of women underwent unilateral mastectomy (44.5% and 55.9% respectively). Bilateral mastectomy was the least performed procedure in both the black and Hispanic patient cohorts (15.7% and 14.1% respectively). Of all women undergoing mastectomy, white women were far more likely to receive immediate reconstruction when compared to racial minorities (64 vs 29%; $p<0.001$). Multivariate analysis revealed that age greater than 60 years (odds radio [OR], 0.26; 95% CI, 0.13-0.51; $p<0.001$) and patients requiring adjuvant radiation (OR 0.266; 95% CI 0.16-0.45; $p<0.001$) were associated with a lesser likelihood of immediate reconstruction. White women (OR 1.84; 95%, CI 1.10-3.08) and women treated at a private institution (OR 3.56; 95% CI, 2.28-5.67; $p<0.001$) had an increased likelihood of reconstruction.

Conclusions: Comparison of white women to racial/ethnic minorities shows that there is a statistically significant difference in treatment hospital and insurance status, with racial/ethnic minorities more likely to be uninsured or underinsured, and thus treated at a safety net hospital. Despite no significant difference in stage at presentation or rate of pathologic complete response following neoadjuvant chemotherapy, minority women have a different pattern of surgical treatment then white women. Both black and Hispanic women were more likely to have a unilateral mastectomy than breast conservation or bilateral mastectomy. Black and Hispanic women, however, did not pursue or were less likely to be eligible for immediate reconstruction. Given this difference between racial/ethnic groups in both pattern of surgical choice and reconstruction, further research is needed to assess the reasons for these differences and to ensure appropriate access to all surgical options, regardless of race.

Genetics

403874 - A polygenic risk score can refine breast cancer risk in unaffected women referred for hereditary cancer testing

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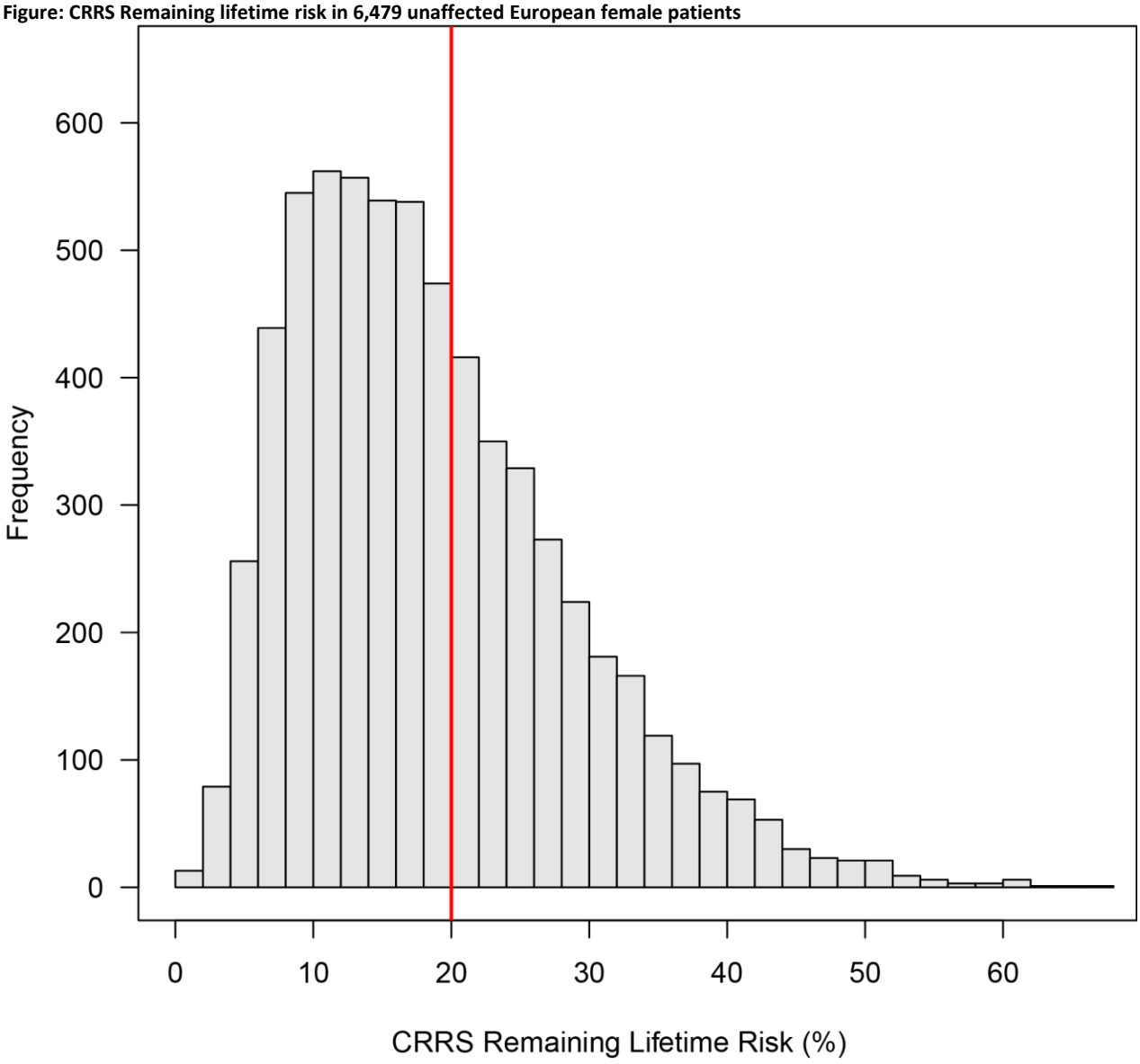
Background/Objective: Unaffected women with a family history of breast cancer who have a remaining lifetime risk of developing disease exceeding 20% using known risk models like Tyrer-Cuzick are appropriate for increased surveillance. Utilizing the Tyrer-Cuzick model with an 86 SNP molecular score, we developed a combined residual risk score (CRRS) that takes into account clinical, family, and genetic variables. The CRRS was applied to women who tested negative for pathogenic mutations in 11 genes associated with hereditary breast cancer to determine how the addition of molecular SNP data impacts risk stratification compared to the Tyrer-Cuzick model alone.

Methods: Patients were assigned a CRRS based on Tyrer-Cuzick v7.02 and 86-SNPs which were identified by Next Generation sequencing. Female patients were eligible for study inclusion if they were 18-84 years of age at the time of hereditary cancer testing, and reported White/Non-Hispanic and/or Ashkenazi Jewish ancestry. Patients were excluded from the study if they tested positive for a pathogenic mutation in a gene associated with hereditary breast cancer (BRCA1, BRCA2, TP53, PTEN, STK11, CDH1, PALB2, CHEK2, ATM, NBN, BARD1, BRIP1); if they reported a personal history of ductal carcinoma in situ, lobular carcinoma in situ, hyperplasia, unknown benign breast disease, or invasive breast cancer; if they did not indicate an ancestry or indicated an ancestry other than White/Non-Hispanic or Ashkenazi Jewish; or if they submitted for testing from states that do not allow for use of clinical samples after completion of genetic testing.

Results: We identified 6,479 patients who matched the study selection criteria. The average age at hereditary cancer testing was 44 years (interquartile range 34 years to 53 years). Nearly three-quarters (74%) of women reported an invasive breast cancer diagnosis in a first- or second-degree relative. CRRS remaining lifetime risk estimates ranged from 0.88% to 66.4% with an average of 18.7%. Tyrer-Cuzick estimates ranged from 1.1% to 42.8% with an average of 18.1%. 3,994 (61.6%) women had estimates 20% when using Tyrer-Cuzick alone. After applying the molecular SNP data, the risk for 15% (584/3,994) of them increased to greater than 20%.

Conclusions: The CRRS provides unaffected women who test negative for mutations in hereditary breast cancer genes with a precise measure of breast cancer risk. This new risk stratification tool enables clinicians to improve patient care through more effective allocation of screening and prevention strategies.

Figure: CRRS Remaining lifetime risk in 6,479 unaffected European female patients



404083 - Impact on the timing of BRCA1/2 genetic testing on the type of surgical resection for breast cancer

Darcy Berry, Ahkeel Allen, Paul Dale

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Background/Objective: The results of BRCA1/2 (BRCA1 and BRCA2 genes) genetic testing can impact surgical decision-making for the treatment of breast cancer. This study sought to explore whether the timing of BRCA1/2 genetic testing affected the type of surgical resection that was completed.

Methods: A retrospective chart review was performed of female patients who received genetic counseling at the cancer genetics clinic of an academic medical center between January 1, 2014 and August 31, 2017. Patients with positive germline BRCA1/2 genetic testing results were studied to

determine the timing with which their test results were disclosed in relation to their breast surgical excision.

Results: Of 814 new patient visits, there were 28 female patients with a BRCA1/2 mutation (Table). At the genetic counseling appointment, 57% (16/28) of patients were affected with breast (15) or ovarian (1) cancer, and 43% were unaffected. Among the 15 patients affected with breast cancer (included invasive breast cancer and DCIS), there were 19 metachronous breast cancers and, therefore, 19 separate breast excisions were completed. One patient and 1 breast excision was excluded from analysis secondary to the inability to determine the timing of genetic testing upon chart review. Eight breast resection were performed on patients who had received their positive genetic testing results prior to their surgery, and 10 breast resections were performed on patients who received their genetic testing results after resection. There were 2 unilateral mastectomies (25%) performed for patients with their genetic testing results available prior to surgery (Figure). However, 1 of these 2 unilateral mastectomies was performed on a patient who had previously had a unilateral mastectomy on the opposite breast, and the other was performed was on a patient diagnosed with liver metastasis.

Conclusions: Our results are concordant with previous studies and indicate that patients who are unaware of their mutation status compared to patients with prior genetic testing were more likely to undergo lumpectomy or unilateral mastectomy (90% and 25% of patients, respectively). Therefore, in our cancer genetics clinic, timing of genetic test result disclosure appeared to have a great impact on surgical decision-making. In future, genetic test results should be available to patients diagnosed with breast cancer meeting the NCCN Guidelines for BRCA1/2 genetic testing prior to their breast surgery when genetic test results could influence the type of surgical excision performed.

Table 1. Demographics of Patients with Positive Genetic Testing

Characteristic	**N (%)**
Number of Patients with *BRCA1/2* mutation	28
Patients *BRCA1+*	13 (46%)
Patients *BRCA2+*	15 (54%)
Age Range	18- 69
Ethnicity*	
Caucasian	17 (61%)
African American	10 (36%)
Hispanic	1 (4%)
Cancer Diagnosis	
Affected	16 (57%)
Unaffected	12 (43%)
BSO Prior to Genetic Testing	
Yes	6 (21%)
No	22 (79%)

*Percentages that do not equal 100% are due to rounding. Abbreviation: BSO, bilateral salpingo-oophorectomy.

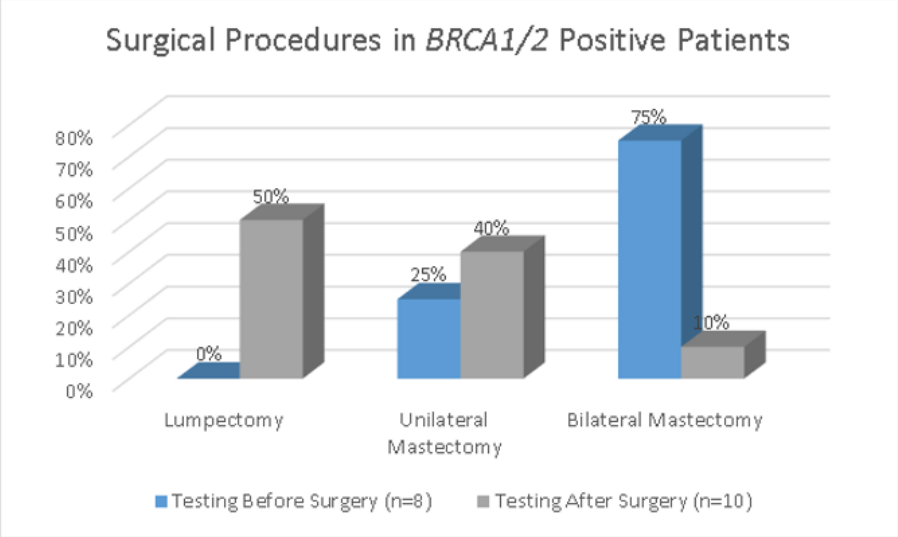

Fig. 1. The type of surgical procedure that was performed depending on whether *BRCA1/2* genetic testing results were disclosed prior to or after breast surgery.

404347 - Impact of variant of uncertain significance in breast cancer multigene germline panel testing on patient decision-making

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Background/Objective: As multigene germline panel testing has become more widely utilized, identification of variants of uncertain significance (VUS) in genes associated with increased breast cancer risk has increased. Approximately 2.5% of reclassified variants initially reported as uncertain significance are upgraded to likely pathogenic or pathogenic. Therefore, there is insufficient evidence that risk-reducing surgery should be performed when a VUS is initially identified. This study aimed to identify decisions made by high-risk and breast cancer patients found to have VUS in breast cancer-associated genes of varying penetrance.

Methods: A single-institution, clinical genetics database of all 1344 women who underwent multigene germline panel testing between 1/2013 and 12/2016 was queried for all patients found to have VUS in breast cancer-associated genes. Genes were classified as moderate risk (2- to 3-fold relative risk [RR] increase in breast cancer): ATM, CHEK2, NBN, NF1; high risk (3- to 5-fold RR increase): PALB2, CDH1, PTEN, STK11; highest risk (10-fold RR increase): BRCA1, BRCA2, TP53. Patient management choices were evaluated.

Results: We identified 163 (12%) patients who had 193 VUS identified. A total of 137 (84%) patients had a diagnosis of cancer, with 78 (48%) of these patients having breast cancer. Of the breast cancer patients, 12 (15%) underwent mastectomy with contralateral prophylactic mastectomy (CPM). One patient (1%) who did not have a history of cancer but VUS for BRCA2 underwent bilateral prophylactic mastectomy; lifetime breast cancer risk was 25.5% by Tyrer-Cuzik (IBIS) model and 15.9% by Gail model. Pathogenic mutations in related genes were identified in 116 (8.6%) patients, with 66 (57%) having breast cancer. CPM was performed in 46 (70%) patients with breast cancer, and 3 (6%) patients without breast cancer had bilateral prophylactic mastectomy. The rate of CPM in breast cancer patients with pathogenic mutation was expectedly higher than for patients with VUS identified (70% vs. 15%, $p<0.001$).

Conclusions: Patients with VUS may elect to undergo CPM. However, it is important for the physician and/or genetic counselor to discuss the significance and true risk of developing breast cancer in the context of a VUS. The high rate of VUS identification also highlights the need for comprehensive variant databases and functional studies to allow for better future classification of these variants.

Table: Incidence of VUS and pathogenic mutations in cohort

	Moderate risk gene	High risk gene	Highest risk gene	Total
Breast cancer diagnosis with VUS identified	40	19	19	78
Prophylactic contralateral mastectomy for breast cancer with VUS identified	6 (15%)	2 (11%)	4 (21%)	12 (15%)
Breast cancer diagnosis with pathogenic mutation	19	4	43	66
Prophylactic contralateral mastectomy for breast cancer with pathogenic mutation	11 (58%)	4 (100%)	31 (72%)	46 (70%)

403394 - Factors influencing choice of bilateral prophylactic mastectomies versus surveillance in unaffected carriers of inherited breast cancer syndromes in the Inherited Cancer Registry (ICARE)

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Background/Objective: Although there is a rising trend towards prophylactic mastectomy with increased awareness of inherited breast cancer, some unaffected carriers choose surveillance over risk-reduction surgery. We sought to identify differences among women electing bilateral prophylactic mastectomies (BPM) versus high-risk surveillance.

Methods: This is a single-institution, IRB-approved, international database of subjects recruited from genetics clinic, external referrals, and social/media outlets enrolled from 11/2000-1/2017 who received voluntary questionnaires at study entry. Subjects with a deleterious/pathogenic (including low penetrance), variant suspected deleterious, or likely pathogenic, in >1 of 11 genes associated with increased lifetime risk for breast cancer (per 2017 NCCN guidelines) were identified. Women with a previous history of breast cancer and males were excluded. Respondents who already received BPM versus those electing surveillance at the time of questionnaire were compared. Demographic and response data were collated. Wilcoxon and Pearsons Chi-square analyses were used to test differences between groups.

Results: There were 304 unaffected mutated genetic carriers identified; 22 men were excluded. There were 113/282 (40%) who underwent BPM. Among BPM patients, 94/113 (83%) had reconstruction. There was no significant difference between groups with regard to age, race, marital status, completion of high school, or family history of breast cancer (Table). There was significant difference between groups for higher education, low income, history of ovarian cancer, prior pregnancy, and worry about

getting cancer in the prior month. Women with higher education and previous pregnancy were more likely to undergo BPM. Women with lower incomes were more likely to choose surveillance. Ovarian cancer survivors were less likely to choose BPM, which is concordant with guideline recommendations. What is more, women who underwent BPM were less likely to worry about developing cancer in the month prior. There were no significant differences with regard to understanding implications of genetic mutations.

Conclusions: BPM is a common but not universal choice among unaffected genetic carriers of inherited breast cancer syndromes. Completion of childbearing, education, finances, history of ovarian cancer, and fear of future cancer play significant roles in these decisions. Further prospective investigation is warranted.

Table: Comparison of bilateral prophylactic mastectomy and surveillance groups

	Prophylactic (n=113, 40%)	Surveillance (n=169, 60%)	p-value
Median Age (range)	44 (21-73)	43 (17-76)	0.25
Completed High School, n (%)			0.96
YES	2 (1.8%)	3 (1.8%)	
NO	110 (97.4%)	165 (97.7%)	
UNKNOWN	1 (0.9%)	1 (0.6%)	
College Education or Higher, n (%)			0.006
YES	104 (92%)	149 (88.2%)	
NO	5 (4.4%)	20 (11.8%)	
UNKNOWN	4 (3.5%)	0	
Income <$50,000/year, n (%)			0.036
YES	17 (15%)	45 (26.6%)	
NO	86 (76.1%)	105 (62.1%)	
UNKNOWN	10 (8.9%)	19 (11.2%)	
History of Ovarian Cancer, n (%)			0.009
YES	6 (5.3%)	26 (15.4%)	
NO	107 (94.7%)	143 (84.6%)	
Response to "An individual who has an altered inherited cancer gene has a higher cancer risk for specific cancers", n (%)			0.25
TRUE	111 (99.1%)	162 (95.9%)	
FALSE	1 (0.9%)	1 (0.6%)	
I DON'T KNOW	0	5 (3%)	
MISSING	0	1 (0.6%)	
Response to "All individuals who have an altered inherited cancer gene get cancer", n (%)			0.27
TRUE	4 (3.6%)	6 (3.6%)	
FALSE	107 (95.5%)	154 (91.1%)	
I DON'T KNOW	1 (0.9%)	8 (4.7%)	
MISSING	0	1 (0.6%)	
Prior Pregnancy, n (%)			0.0005
YES	97 (85.8%)	114 (67.5%)	
NO	16 (14.1%)	55 (32.5%)	

403407 - Clinical outcomes according to BRCA status in breast cancer patients: Can the BRCA mutation be used as a prognostic factor for breast cancer?

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Background/Objective: BRCA mutations occur frequently in breast cancer (BC), but their prognostic impact on outcomes of BC has not been determined. BRCA1, 2+ and unverified variation (UV) patients were identified. According to BRCA mutation, we investigate the differences in pathologic features, overall survival, and disease-free survival.

Methods: From 2000 to 2016 July, we analyzed 93 patients who underwent BRCA gene testing among 1000 patients treated for breast cancer. Statistical analysis was performed using SPSS 14.0. The survival rate was measured using the Kaplan-Meier method. The association of each other was measured using linear by linear association test.

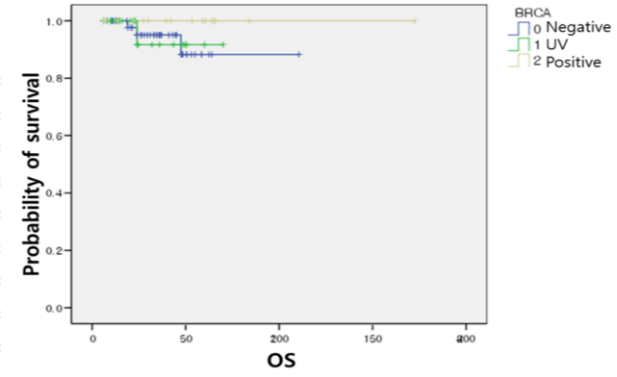
Results: The mean age of BRCA gene tested breast cancer patients was 39.7±4.2 years. Fifty-two patients (55.9%) had BRCA non-carrier patients. Twenty-five patients (26.9%) had BRCA UV. Sixteen patients (17.2%) had BRCA gene mutation. BRCA 1-positive was 10 patients (10.5%), and BRCA 2-positive was 6 patients (6.5%). Twelve patients (12.9%) had family history of breast cancer or ovarian cancer. Three patients (3.2%) were UV group, and 3 patients were BRCA-positive group. OS and DFS do not show statistically significant difference with BRCA gene mutation. There was no significant difference in BRCA and T stage, but N stage was statistically significant (p=0.01). Of the 93 patients, 23 (24.7%) had triple-negative breast cancer (TNBC). Six patients (60%) of BRCA 1-positive 10 patients were found to TNBC, but not in BRCA 2 group.

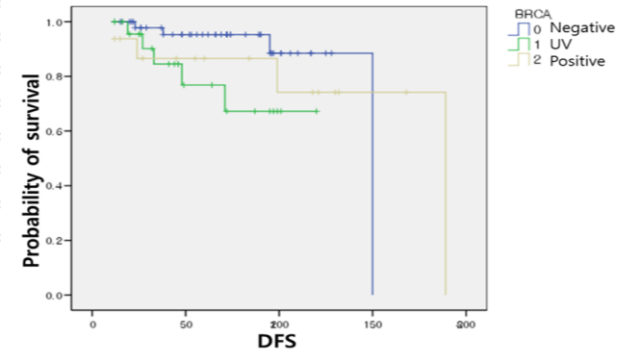
Conclusions: There was no significant difference in OS and DFS associated with BRCA gene mutation. The pathologic features showed only statically significant correlation with N stage. It is considered that the treatment should be maintained in accordance with pathological differences of BRCA1,2.

Table and Figure: Clinical outcomes according to BRCA status in breast cancer patients. Can the BRCA gene mutation be used as a prognostic factor for breast cancer?

Characteristics	BRCA negative(%)	BRCA UV(Unverified Variation)(%)	BRCA positive(%)	*p* value
T stage				0.101
Tis	6(11.5%)	2(8%)	0	
T1	30(57.7%)	12(48%)	7(43.8%)	
T2	14(26.9%)	10(40%)	9(56.2%)	
T3	2(3.9%)	1(4%)	0	
N stage				0.003
N0	41(78.8%)	14(56%)	5(31.3%)	
N1	5(9.6%)	6(24%)	4(25%)	
N2	3(5.8%)	4(16%)	4(25%)	
N3	3(5.8%)	1(4%)	3(18.7%)	
Hormone receptor				0.346
Positive	38(73.1%)	16(64%)	10(62.5%)	
negative	14(26.9%)	9(36%)	6(37.5%)	
HER2				0.515
0-1+	35(67.3%)	15(60%)	13(81.3%)	
2+	6(11.5%)	2(8%)	2(12.5%)	
3+	11(21.2%)	8(32%)	1(6.2%)	
Ki-67(Median)	20(1-98)	20(2-95)	35(1-95)	0.041
Stage				<0.01
Stage 0	5(9.6%)	2(8%)	0	
Stage 1	27(51.9%)	9(36%)	1(6.2%)	
Stage 2	13(25%)	8(32%)	8(50%)	
Stage 3	7(13.5%)	6(24%)	7(43.8%)	

Characteristics	BRCA negative(%)	BRCA UV(Unverified Variation)(%)	BRCA positive(%)	*p* value
Surgical treatment*				0.544
Breast conserving	43(82.7%)	18(72%)	8(50%)	
Total mastectomy	9(17.3%)	7(28%)	8(50%)	
Chemotherapy				0.056
Yes	40(76.9%)	23(92%)	15(93.8%)	
No	12(23.1%)	2(8%)	1(6.2%)	
Radiotherapy				0.550
Yes	44(84.6%)	20(80%)	15(93.8%)	
No	8(15.4%)	5(20%)	1(6.2%)	
Endocrine therapy				0.962
Yes	37(71.2%)	16(64%)	12(75%)	
No	15(28.8%)	9(36%)	4(25%)	
Recurrence				0.054
No	48(92.7%)	20(80%)	12(75%)	
Loco-regional	2(3.9%)	1(4%)	0	
Distant	2(3.9%)	4(16%)	4(25%)	
Death				0.333
Yes	3(5.8%)	1(4%)	0	
No	49(94.2%)	24(96%)	16(100%)	





402267 - Increased total and LDL-cholesterol in association with BRCA1 mutation

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Background/Objective: Deregulation of lipid and other metabolic pathways contribute to the pathogenesis and progression of breast cancer. The BRCA1 gene is not only important in the regulation of cell cycling, DNA repair, and cellular apoptosis, but also plays a significant role in lipid and glycemic homeostasis in reproductive, as well as major metabolic, tissue. Presently, there are limited data as to effects of a BRCA 1 mutation on circulating markers of lipid and glycemic status. In this study, we have examined the metabolic profiles of BRCA1 mutation carriers and their age-, weight- and gender-matched non-affected controls.

Methods: The study population consisted of 27 BRCA1 female mutation carriers and 29 controls with no known BRCA1 mutation nor family history of breast or ovarian cancer. Exclusion criteria included diabetes and glucose-lowering medications, diagnosed dyslipidemia on medication, or chemotherapy within the previous year. Study outcomes were: a) metabolic profiles (total cholesterol, LDL, HDL, triglyceride, fasting blood glucose, % HbA1c), b) anthropometrics (weight, BMI, lean and fat mass, % body fat, waist circumference), and c) self-reported survey information pertaining to demographics, BRCA1 testing, menopausal status, cancer history, previous surgeries, current marital status, parity, health (physical and psychological issues, medications), physical activity (frequency, duration, intensity), sleep (duration, perceived quality), and the use of alcohol, tobacco, and caffeine.

Results: Survey results found no significant ($p>0.05$) differences in age, demographics, marital status, or parity between the BRCA1 mutation carriers and controls. Anthropometrics also did not significantly differ between the BRCA1 and control groups, although there was a trend ($p<0.06$) toward greater body fat among the BRCA1 mutation carriers. Glycemic status (fasting blood glucose, HbA1c) was statistically similar ($p>0.05$) between the study groups as were total triglyceride and HDL-cholesterol. However, total and LDL cholesterol levels were significantly ($p<0.001$) higher for the BRCA1 mutation carriers than for their non-affected controls, i.e., total cholesterol = 222.1 ±10.0 vs. 176.7±6.3; LDL = 131.1±8.9 vs. 91.6±5.7, respectively. The higher cholesterol levels of the BRCA1 mutation carriers vs. controls did not occur secondary to differences in lifestyle, i.e., physical activity, sleep, alcohol/tobacco/caffeine use. Total- and LDL-cholesterol levels were also unrelated to health status, although a significantly ($p=0.0007$) greater percentage of those who were BRCA1-positive had diagnosed depression and were on antidepressants. Menopausal status was not a significant effector of cholesterol levels despite significant differences between the groups in the proportion of individuals who were pre- and post-menopausal. Data from multiple modeling analyses found that none of study variables (measured, categorical, self-reported) were significant predictors of the elevated cholesterol of the BRCA1 mutation carriers.

Conclusions: The results of the study suggest that a BRCA1 mutation may adversely affect lipid metabolism to increase total and LDL-cholesterol. Larger investigative studies are needed to substantiate these findings and to identify the impact elevated cholesterol in BRCA1 mutation carriers may have on cancer occurrence and cardiovascular disease risk.

403492 - Genetic structure of breast cancer and lymph node involvement among Senegalese women

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Background/Objective: Many genomic alterations are known in breast cancer. Few of them can be correlated with clinico-pathological and prognostic parameters. The objective of this study is to find a correlation between the genetic structuring of malignant breast tumors and ganglionic involvement.

Methods: One hundred twenty surgical samples of malignant breast tissue were used. Two mitochondrial genes (Cytochrome b and D-Loop) and a nuclear gene (Beta-fibrinogen) were amplified and sequenced. The genetic structuring of tumors according to node invasion was investigated by an analysis of molecular variance (AMOVA: Analysis of Molecular Variance) using the ARLEQUIN version 3.0 software. The genetic differentiation values per pair of cancer tissue populations (FST) as well as the associated probabilities were estimated using the same software.

Results: Molecular variance analysis revealed that the clinical heterogeneity of tumors was a function of the number of nodes invaded (N0-N1: Fst=0.119, p=0.035, N0-N2: Fst=0.148, p=0.002).

Conclusions: This finding highlights in our population a link between the importance of node invasion and the genetic heterogeneity of tumors.

403884 - Compliance with risk management strategies in female patients with BRCA gene mutation unaffected by breast cancer: A single-institution study

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Background/Objective: Women who are positive for the BRCA gene mutation have a higher lifetime risk of developing breast cancer. This warrants close clinical surveillance along with enhanced screening alternating between annual mammograms and MRIs every 6 months. Another option is prophylactic surgery with risk-reducing mastectomy (RRM) and/or bilateral salpingo-oophorectomy (BSO). However, it is unclear what the degree of adherence is over time when patients choose clinical surveillance over risk-reducing surgery. In this retrospective study, we examined patient compliance with follow-up visits and imaging recommendations over a 4-year period based on the type of breast cancer risk management strategy they opted to pursue.

Methods: All unaffected BRCA 1/2 mutation carriers who were identified at our institution between June 1, 2011 to May 31, 2013 were included in this study. Patients with male gender, a recent history of any stage of breast cancer, locally advanced or metastatic ovarian cancer, or bilateral mastectomies prior to genetic testing were excluded. Primary endpoints included length of follow-up (as defined by date of genetic testing to date of last documented oncology visit) and frequency of clinic visits during that time period. Secondary endpoints include number of imaging studies (mammograms, MRIs, and ultrasounds) and percutaneous biopsies per year, as well as time to bilateral RRM or BSO, if performed.

Results: Six hundred twenty-three patients were evaluated by a genetic counselor at our institution. Of these, 66 patients were found to be gene-positive for a BRCA mutation. Thirty-one patients were included in the final analysis in this study after excluding 35 patients based on the above criteria. From this cohort, 54.8% (17/31) of patients opted to undergo risk-reduction surgery - 41.9% (13/31) underwent a RRM, 48.4% (15/31) underwent BSO, and 35.5% (11/31) underwent both surgeries. The average time to RRM and BSO surgery was 14.36 and 13.45 months, respectively. Of these, 38.7% (12/31) were lost to follow-up within the first year of their genetic test date; the remaining patients (19/31) averaged a mean follow-up length of 40.0 months (range 14.0-62.6 months) and a frequency of 3.26 clinic visits per year. However, these 19 patients had a higher frequency of clinic visits in the first 2 years, and slightly more than half (10/19) were lost to follow-up within the first 4 years. They also had a frequency of 0.74 mammograms and 0.71 MRIs per year, which resulted in subsequent 0.37 ultrasounds and 0.35 biopsies per year. Specifically, patients who underwent surgery had a significantly longer follow-up duration (48.02 months) and more frequent visits (3.75 clinic visits per year) compared to those who did not (22.7 months and 2.19 clinic visits per year, p=0.0029). Patients who did not undergo any surgery had a lower compliance to annual mammograms and MRIs compared to their counterparts who eventually underwent surgery.

Conclusions: Patients with the BRCA gene mutation unaffected by breast cancer have the option of clinical surveillance with only imaging studies versus prophylactic surgery, but very few studies have compared patient compliance to the recommendations associated with each strategy. A non-surgical strategy for risk management may result in suboptimal compliance with the recommended guidelines. Our study highlights the importance of channeling institutional resources to increase patient compliance in the non-surgical cohort.

404019 - Genetic risk evaluation services for breast cancer patients in Nigeria: A call to action

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Background/Objective: The aim of this study was to determine what proportion of Nigerian breast cancer patients fulfill the criteria for genetic risk evaluation according to the 2018 NCCN Clinical Practice Guidelines in oncology for Genetic/Familial High-Risk Assessment: Breast and Ovarian, V1. 2018. Some breast cancer patients have genetic predisposition to breast cancer. Guidelines exist as a pointer to which set of patients to be referred for genetic counseling and testing. In Nigeria, genetic counseling and testing is not readily available for breast cancer patients. We believe that the proportion of Nigerian breast cancer patients is high enough for there to be a call to action for the provision of this service to Nigerian breast cancer patients.

Methods: Pathologic records of the immunohistochemistry report of patients who have been diagnosed with breast cancer in a Nigerian private pathology laboratory were accessed and reviewed. Data extracted were age, sex, estrogen, progesterone, and HER-2 receptor status. These were used to evaluate the patients who fulfilled the criteria for genetic risk evaluation according to the 2018 NCCN Guidelines Clinical Practice Guidelines in oncology for Genetic/Familial High-Risk Assessment: Breast and Ovarian, V1. 2018. The proportion of patients who fulfilled each of the criteria were extracted.

Results: A total of 151 patients with breast cancer were evaluated. Age range was 26 to 82 years with a mean age of 47 years, median 49 years, and mode of 45 years (sd 17.8) One hundred forty-eight

patients (98%) were females, and 3 (2%) were males. One hundred thirty-eight patients had invasive ductal carcinoma, 3 each had invasive lobular carcinoma and DCIS, 2 each had medullary, mucinous, and papillary carcinoma, while the last patient had Comedo Carcinoma. Sixty-two patients (41.1%) were ER-positive, while 89 (58.9%) were negative, 34 (22.5%) were PR-positive, while 117 (77.5%) were negative, 133 (88.1%) were Her-2-negative, while 18 (11.9%) were positive. Luminal types were as follows: Luminal A, 59 (39.1%), triple-negative, 74 (49%) Luminal B, 1 (.7%), Her 2 14 (9.3%), triple-positive, 3 (2%). The following patients met the criteria for further genetic risk evaluation according to the 2018 NCCN Guidelines Clinical Practice Guidelines in oncology for Genetic/Familial High-Risk Assessment: Breast and Ovarian, V1. 2018. Eighty-six patients were <50 years old, 18 patients who were >50 years but <60 years with triple negative-breast cancer, and 2 male patients (the third male patient was 50 yrs old). According to data available to us, 106 (70.2%) patients in the study population fulfilled the criteria for genetic risk evaluation.

Conclusions: A very high proportion of Nigerian breast cancer patients fulfill the criteria for genetic risk evaluation according to the 2018 NCCN Guidelines Clinical Practice Guidelines in oncology for Genetic/Familial High-Risk Assessment: Breast and Ovarian, V1. 2018. Unfortunately, there is not much focus on this aspect of care probably due to concerns about funding. It is therefore important that steps are taken to make this service available to Nigerian breast cancer patients. Population-based studies should also be performed to evaluate whether the criteria for genetic risk evaluation according to the 2018 NCCN Guidelines Clinical Practice Guidelines in oncology for Genetic/Familial High-Risk Assessment: Breast and Ovarian, V1. 2018 is appropriate in the Nigerian breast cancer population.

403925 - Genetic counseling in breast cancer: Experience in a private Argentine center

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Background/Objective: Genetic counseling is a process and not an isolated medical act, in which the personal and family risk of hereditary cancer susceptibility is evaluated, adapting surveillance strategies and reducing risk. While breast cancer (BC) is mostly sporadic (70-75%), the hereditary breast/ovarian cancer syndrome is the most common hereditary predisposition to cancer, and the main known genes linked to this syndrome are BRCA 1 and BRCA 2. The correct identification of carriers, especially in patients under 50 allows offering individualized advice and optimizing the available prevention resources. The objective of this study is to show our experience in genetic counseling and the characteristics of the population of patients under 50, diagnosed with breast cancer and BRCA mutation detected.

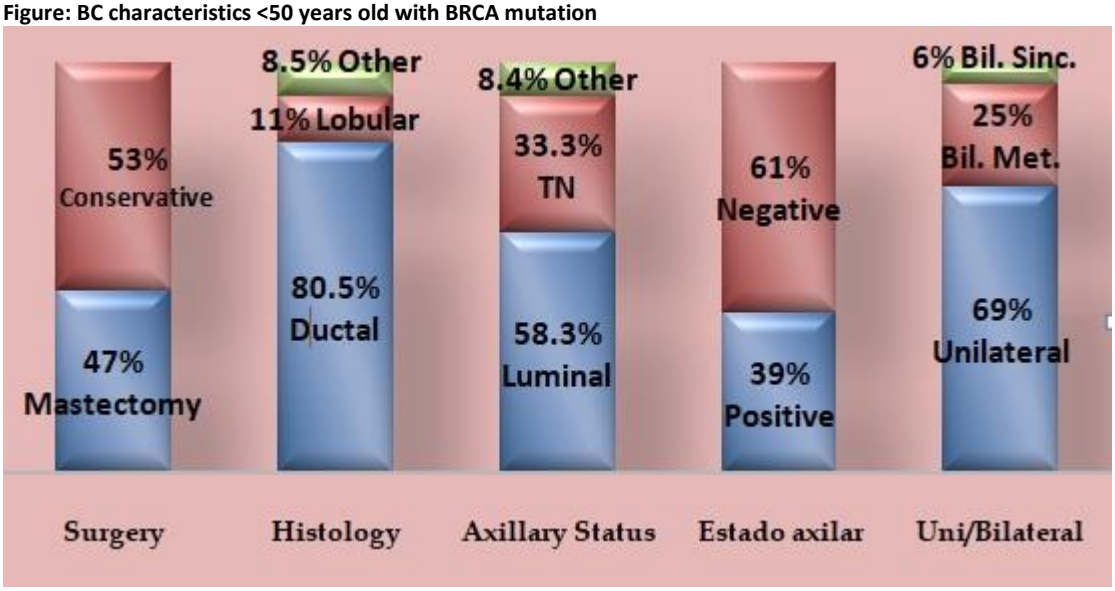
Methods: Retrospective analysis of the patients evaluated in our genetic counseling unit from August 2013 to June 2017.

Results: There were 1010 consultations registered, 84% (n = 850) from patients with personal and/or family history of breast cancer. The reasons for referral were: personal history 78%, family history 17%, family mutation 5%. Seven hundred six test requests were generated, 661 linked to BRCA mutations. Fifty-five percent of the tests were normal, 4% VUS, 29% pending/not done, and 12% of the tests were

positive for BRCA mutation: 67% BRCA1 and 37% BRCA2. In 44 breast cancer patients with BRCA mutation, the average age of presentation was 42 years, and 36 patients were less than 50 years old at the time of diagnosis (range 26-49), with an average tumor size of 2.3cm. During the specified time, 994 surgeries for breast cancer were performed in our institution, 36% (n=363) in patients under 50 years, BRCA mutation was confirmed in 3.6% of those patients.

Conclusions: Our statistics are similar to those described in the international literature. Genetic counseling is considered an essential part of oncological care, for the identification of individuals at risk, early detection, and correct management of the disease; but in our country, we have limited access to genetic tests. Priorities for the future should include strategies for the correct detection of patients who are potential mutation carriers and their referral to specialized professionals in the field of oncology genetics for testing and recommendations.

Figure: BC characteristics <50 years old with BRCA mutation



404232 - Early comprehensive genomic profiling of high-risk cancers results in early treatment changes

Linda Smith

Albuquerque, NM

Background/Objective: Comprehensive genomic profiling in cancer care has advanced quickly. Integrating this information into patient management may have the potential for both prevention and treatment. DNA sequencing of tumor and normal tissue, as well as RNA sequencing of tumor tissue, can identify somatic and germline genomic events, which may have biological significance or clinical utility. Sequencing can provide data complementary to hot spot sequencing, FISH, and IHC methodologies that can affect diagnosis, prognosis, and therapeutic targeting. Additionally, from germline testing and within the context of genetic counseling, high-risk families can have access to early MRI, colonoscopy, and other preventive measures. Within the Prospective Breast Registry Symphony Trial, of the 53 breast cancer patients tested, 22% were reclassified.

Methods: Fifty-three patients with high-risk tumors underwent clinical sequencing that includes tumor and normal tissue specimens. The normal tissue specimen is sequenced via next-generation sequencing within the protein coding regions of 1714 genes to identify germline variation. Tumor tissue is

sequenced within 1714 genes for DNA as well as whole transcriptome for mRNA and using the germline sequence as a reference, single nucleotide variants, insertions and deletions, copy number variations, and structural rearrangements are detected. Thirty-eight patients were luminal B, 6 HER2-positive, and 9 either triple-negative or FISH +2.

Results: Of the 38 Luminal B patients, 2 were found to carry BRCA germline mutations, and 1 a BRCA2 somatic mutation, qualifying all 3 for PARP inhibitor treatment. Germline MSH6 and 1 germline gene (DSP) for right-sided cardiac failure each changed treatment in those patients. Four of the 38 luminal B patients were identified as hormone resistant. Eighteen patients showed target for PIK3CA, which may be a critical defect for Luminal B patients. Two patients were found to be HER2-positive on RNA determination. All but 3 patients had active genes for potential trials, 1 of which has already entered a trial based on CCND1 alteration. Of the 6 HER2 patients, 1 was found to be somatic BRCA+. Of the 9 triple-negative patients, 2 were FISH+, but HER2 functional. All HER2 and triple-negative patients had other genomic features suggesting potential targeted therapy.

Conclusions: Comprehensive genomic profiling has evolved to a point of allowing testing so that the surgeon and the medical oncologist can best choose treatment options. Luminal B patients may only see a 7% response to prep op chemo, with poor long-term survival. By sequencing tissue specimens early in the course of treatment, options for changes in patient care can be visited, as well as increasing enrollment in trials to expedite chemo selections. In triple-negative and HER2-positive tumors, other targets were identified, again opening better chemo options with hopes of CPR at surgery in the future. Early integration of comprehensive genomic profiling has great potential to affect changes in early breast cancer management.

404215 - Exploring transcriptome expression profiling in breast cancer patients for informing clinical decisions

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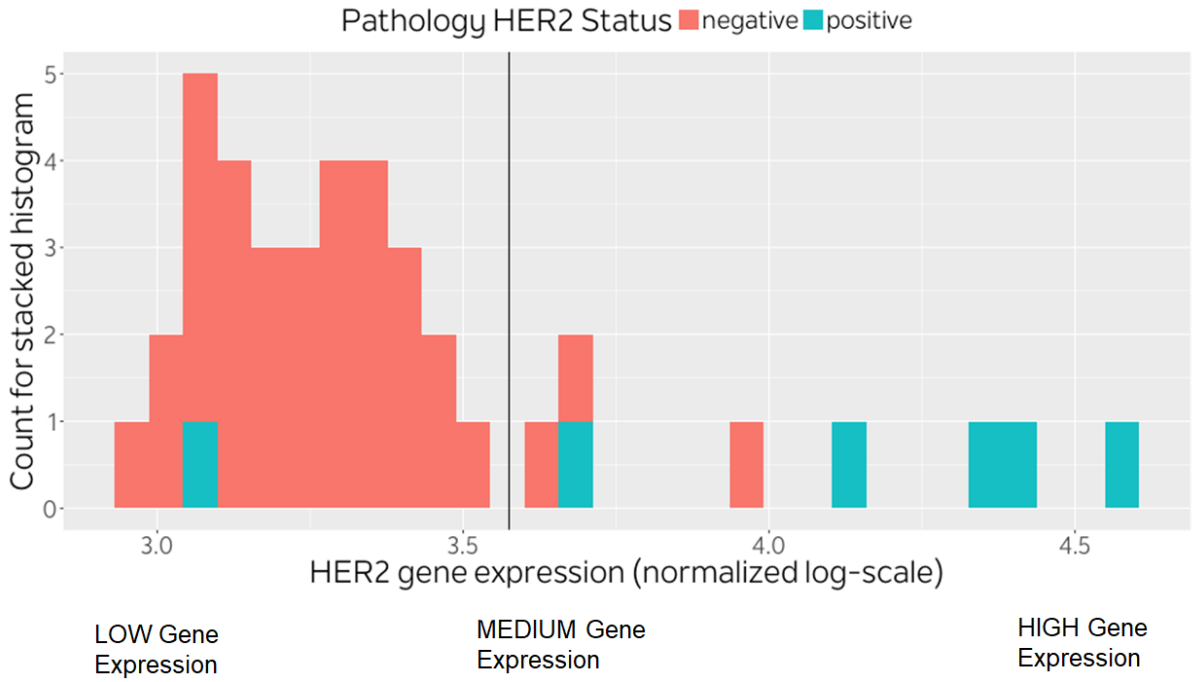
Background/Objective: Gene expression profiling can be a powerful tool in classifying cancer patients; however, there are multiple technology platforms and clinical testing assays relevant to gene expression both directly and indirectly. We examined the use of transcriptome gene expression levels for informing clinical decisions in 2 situations. The purpose of this study was to examine the concordance between the HER2 states from a pathology report with that from the gene expression levels of ERBB2 as well as to use whole transcriptome gene expression profiles to look for possible subgroups in high-risk luminal breast cancer patients defined by gene expression based clinical assays.

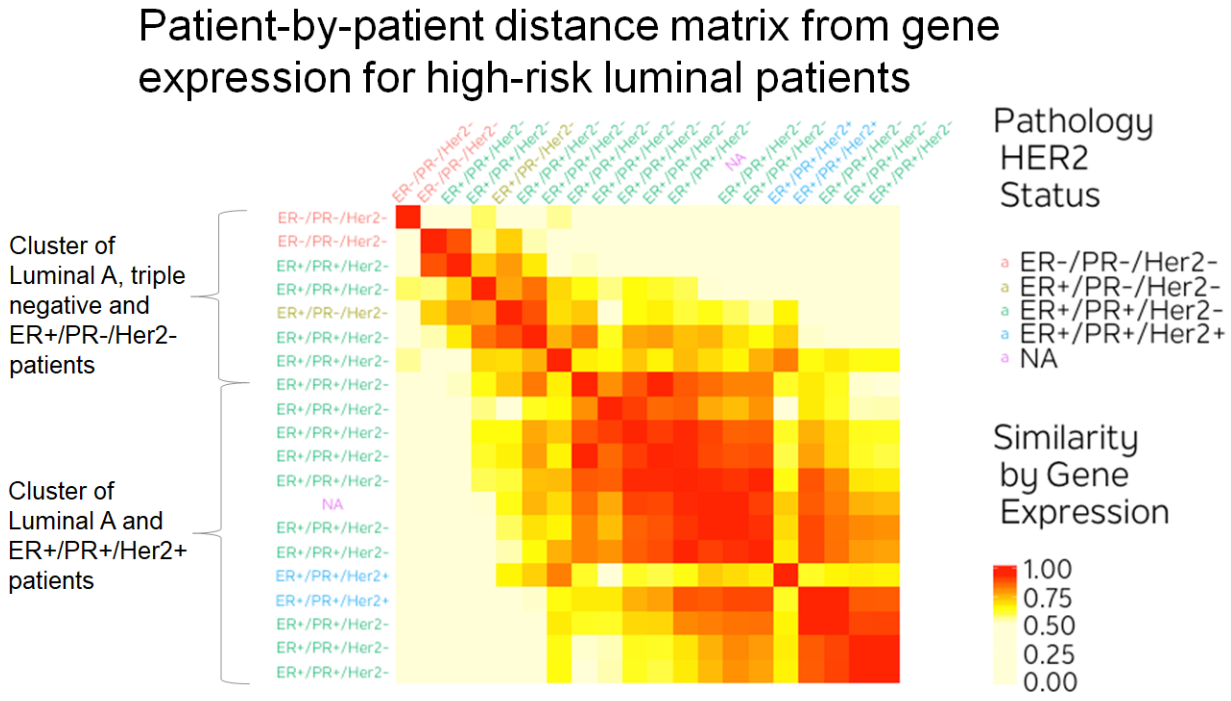
Methods: For 48 patients, we examined the concordance between the HER2 states from a pathology report with that from the gene expression levels of ERBB2 as determined via RNAseq. Additionally, using whole transcriptome gene expression in a subpopulation of 20 high-risk luminal breast cancer patients (as defined by positive Mammaprint and Blueprint tests), we used custom normalization and clustering approaches, which stratified luminal B patients.

Results: In comparing HER2 state with ERBB2 expression levels, we saw high-level agreement when gene expression levels where high, and some interesting cases of disagreement at lower levels of ERBB2 gene expression (Figure). And in high-risk luminal breast cancer patients we found 2 distinct sub-

populations, 1 of which is more like triple-negative patients, and the other subgroup is more like triple-positive (ER+/PR+/HER2+) patients (Figure).

Conclusions: This study was performed to show the utility in comparing the overlap and distinctions in orthogonal platform testing. The field of precision medicine is nascent, and comparing testing modalities and the putative biological and clinical implications will provide perspective for future clinical and research endeavors. We look forward to future analyses to expand on these preliminary analyses.





404348 - Hereditary cancer risk assessment: Refining a comprehensive safety net in a large multi-specialty group

Ames Smith

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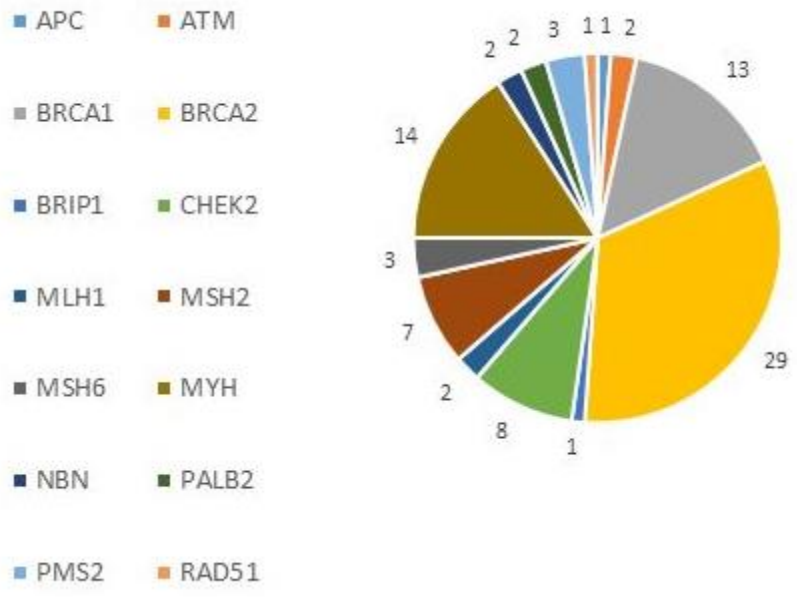
Background/Objective: In the United States, it is estimated that 1 in 400 individuals will harbor a deleterious mutation in BRCA1/2 genes associated with hereditary breast and ovarian cancer (HBOC). In addition, approximately 1 in 440 individuals will have a predisposition to early-age colon, uterine, gastric, and ovarian cancer associated with Lynch syndrome and polyposis (MLH1, MSH2, MSH6, PMS2, EPCAM, and APC genes). Benefit has been demonstrated for both oncology and unaffected patients through detection of mutations with impact on surgical, surveillance, and chemoprevention options. The purpose of this study was to highlight our practice-based model across specialties to integrate assessment and testing for hereditary cancer within a 200-physician multi-specialty group.

Methods: In June 2012, our breast surgery program implemented a simple process to identify, screen, and evaluate patients for hereditary cancer using a sustainable workflow with the following components: A hereditary cancer risk assessment (HCRA) questionnaire was created and evaluated based on NCCN guidelines for HBOC, Lynch, and polyposis syndromes. HCRA forms were given out to all incoming surgery and mammography patients. HCRA forms were reviewed by trained nurses; patients with history that met NCCN criteria were offered risk assessment and hereditary cancer testing when appropriate. All patients were provided with pre-test risk assessment and informed consent. Test results were reviewed by physician, and a detailed patient-specific management plan was communicated to the patient and primary care physician. Upon presenting results, consultation with a certified community-based genetic counselor was offered to patients and families. In 2014, we expanded our testing to include panel testing and expanded our screening process to other departments. Preparation prior to process implementation included observation of patient flow, training on hereditary cancer syndromes, and commitment to continued process improvement.

Results: In the 18 months prior to implementation, 4 patients received testing, and 1 was positive for a deleterious mutation. Testing results in the 65 months post-implementation (through October 2017) revealed 88 deleterious mutations out of 943 tested patients, which represents 9.33% of tested patients (see Figure). This is consistent with rates seen in other studies. Among these harmful mutations, 47.7% were positive for a BRCA mutation and 17% for a Lynch syndrome mutation. We also detected a patient who carries an APC mutation. The systematic nature of this process allows a platform for ongoing quality improvement. Since implementation, we have developed more testing sites within the Internal Medicine and OB/GYN groups.

Conclusions: Comprehensive screening with a systematic process for evaluating hereditary cancers has allowed us to identify and manage a large number of patients with deleterious mutations. This is potentially life-saving for these as well as for close blood relatives. In the first 65 months of this process, we were able to identify 88 deleterious mutations (9.33% positive rate) and provide personalized cancer risk management to all 943 patients. This approach could be easily implemented in other similar practice environments.

Figure: Testing results



403838 - Variation in genetic mutations in breast cancer patients meeting NCCN criteria vs those who do not

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Background/Objective: NCCN guidelines for genetic testing were established many years ago to identify patients with BRCA 1/2 mutations at a prevalence that seemed economically acceptable. However, the cost of genetic testing has plummeted, and now multi-gene panel testing is becoming the standard. We undertook the creation of a registry, testing all breast cancer patients with a multi-gene panel whether they met NCCN criteria for testing or not. The primary objective of this registry is to determine if providing all breast cancer patients with broad multi-gene panel genetic testing yields additional clinical value by identifying other actionable genetic mutations beyond BRCA 1/2 and if there was any differences in genetic mutations in those patients whom meet NCCN guidelines and those who do not.

Methods: An IRB-approved, multi-center prospective registry was initiated including 18 community-based and academic breast physicians experienced in cancer genetic testing and counseling. Sites were selected to insure geographic and ethnic diversity. Enrollment goal is 1000 patients. Consecutive patients ages 18-90 with a current or previous breast cancer who had never had genetic testing (either single or multi-gene panel) were offered testing with an 80-gene panel test and consented to be a part

of the registry. HIPAA-compliant electronic case report forms collected information on patient diagnosis, test results, and physician recommendations made after test results were received. IRB approval and oversight was provided by WIRB (Puyallup, WA) or via a local IRB.

Results: There were 602 patients registered as of November 6th, 2017, data from 364 patients has been reviewed (48% met NCCN criteria and 52% did not), and we have genetic mutation data on 235 patients, which constitutes our study population. Median age for the enrolled patients is 62 and ranges from 29 to 86. Median age for patients who met NCCN criteria is 60; those who did not, have a median age of 64.5. There were 60.8% of patients recently diagnosed with breast cancer. Of these, 46.6% met NCCN criteria; 53.3% did not. Of those not recently diagnosed, 49.7% met NCCN criteria; 50.3% did not. Elevent percent of patients had a history of a prior non-breast cancer, 46.3% of those met NCCN criteria and 53.7% did not. There was a similar rate of P/LP mutation rates in the 2 cohorts (12.4% of patients who met NCCN criteria and 11.5% of patients who did not meet criteria with a p-value of 0.84). However, the spectrum of mutated genes varied between the 2 groups, with some overlap. All of the identified mutations have clinical management guidelines, including some with implications for acute treatment as well as those with surveillance recommendations for patients and their unaffected family members. (See Table.)

Conclusions: Expanded panel testing yields more pathogenic hereditary mutations in patients who meet and who do not meet NCCN criteria for testing. There is variation in mutations between the cohorts, but many of these are actionable with present knowledge today. Expanded panel testing can provide information that may present additional treatment and follow-up options for all breast cancer patients, including clinical trials, not only those who meet criteria for testing.

Table: Variation in mutations between NCCN and Non NCCN breast cancer populations

P/LP mutations found (Based on analysis of 235 patients to date. 28 patients with one or more mutations found.)	Patients meeting NCCN guidelines for testing	Patients who did not meet NCCN guidelines
BRCA1/2	3	2
TP53	1	0
PALB2	3	0
CHEK2	2	1
ATM	0	2
Others	MYUTH RAD51C WRN HOXB13 BARD1 FH VHL	MYUTH (2) RAD51D (2) MSH2 MSH6 DI53L2 RECQL4 RET

404128 - A 13-year analysis of a preventive care program for BRCA 1/2-positive patients at a large academic institution

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University of Alabama at Birmingham, Birmingham, AL

Background/Objective: Outcomes for breast cancer patients have significantly improved through early detection and improved treatments. Guidelines suggest that surveillance recommendations should be tailored to the individual patients risk of developing breast cancer and objectives of care. At our institution, the Preventive Care Program for Womens Cancers was started in 2003 for women at increased risk of developing breast cancer based on genetic susceptibility, family history of breast cancer, or histologic precursors to breast cancer diagnosed on prior biopsy. In this study, we report on asymptomatic patients with BRCA 1 and BRCA 2 deleterious mutations who enrolled in our prevention program.

Methods: The clinic provides risk assessment, surveillance recommendations, genetic counseling and testing, opportunities for diagnostic and prevention clinical trials, and recommendations for preventive interventions from lifestyle modifications to chemoprevention and prophylactic surgery. Patients are referred through primary care providers, gynecologists, and word of mouth. Since the initiation of the clinic, 2,126 patients have been enrolled in an IRB-approved database. A retrospective cross-sectional study was conducted using this population of patients. From February 2003 through September 2017, women identified as increased risk for developing breast cancer were recruited for enrollment in the study. Upon enrollment, demographics, family history of cancers, and genetic testing data were collected. Additionally, events regarding prophylactic surgery, chemoprevention treatments, and cancer diagnosis were recorded.

Results: Of the 2,126 participants enrolled in the database, complete records were available for 117 patients with deleterious mutations in BRCA1 and/or BRCA2 who were asymptomatic at enrollment and with no prior cancer diagnosis. Mean age at enrollment of BRCA-positive cases was 38.0 +11.2 years (BRCA1 36.3 +10.6 years and BRCA2 39.5 +11.7 years). Of the BRCA1- and BRCA2-positive patients, 54 (46.1%) elected to undergo a prophylactic mastectomy and 7 BRCA2-positive (12.3%) individuals elected to begin chemoprevention. Forty-nine patients (86.0%) elected active surveillance of physical exam and imaging with MRI and mammography. Reasons for not utilizing chemoprevention include 3 (5.2%) had contraindications; 24 (42.1%) were not candidates due to age, desire for childbearing, or use of hormone therapy; and 22 (38.5%) declined for other non-specified reasons. Of the 55 patients who were undergoing active surveillance, 5 (4.3%) patients received a cancer diagnosis (Stage 0 or Stage I) as a result of screening with MRI. Four of these patients were BRCA2-positive, and 1 was BRCA- positive. For 3 of these patients, it was their first screening MRI. A sixth patient (BRCA 1 positive) presented in between screening with a palpable mass that was Stage IIa.

Conclusions: Breast cancer prevention clinics aim to improve detection and outcomes in high-risk breast cancer patients. The majority of patients undergoing active surveillance have been diagnosed at Stage 0 or Stage I and were diagnosed using MRI. With long-term follow-up of a significant number of high-risk individuals, this study highlights the unique and important role of breast prevention clinics to educate and survey high-risk patients allowing opportunities for breast cancer prevention and early detection.

Imaging

402971 - The Impact of the Dense Breast Notification Law on patterns of screening in a rural population in New York

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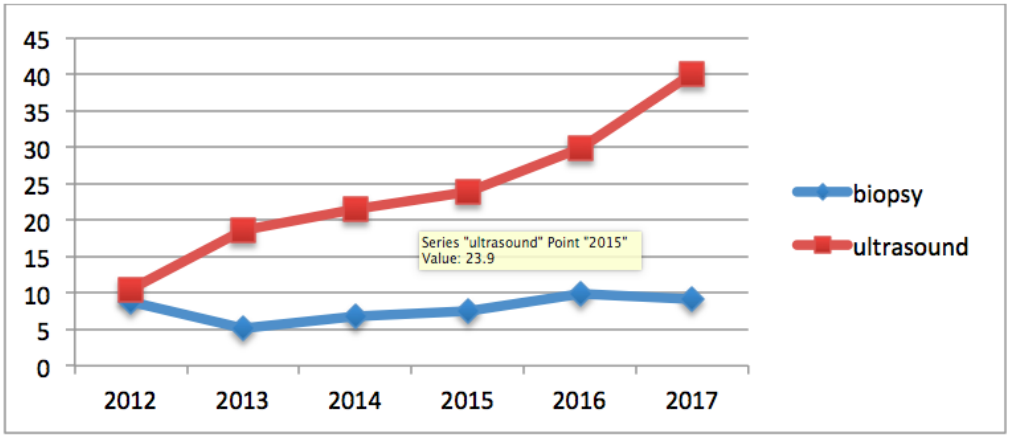
Background/Objective: Higher breast density is recognized as an independent risk factor for the development of breast cancer. Dense breasts are defined on mammogram as heterogeneously dense or extremely dense. A recent study in New York City demonstrated 74% of women in their 40s have dense breasts, and this decreases with age to 36% of women in their 70s. Breast cancer is 4-6 times higher in patients with extremely dense breasts as compared to patients with fatty breasts. Mammograms without additional imaging modalities such as ultrasound or MRI potentially miss more than half of breast cancers in patients with dense breasts. In 2013, New York was the one of the first states to mandate that patients be informed in writing if their mammograms showed dense breast. Then, in 2017, New York mandated that insurance pay for additional imaging for dense breast. This study evaluates whether screening practices have changed since the institution of the dense breast law and whether the change resulted in a change in clinical intervention.

Methods: Retrospective analysis of both pathology and radiology data was performed on all patients who received either screening or diagnostic mammograms from 2 major imaging centers in Middletown, NY from January 2012 to December 2016. The percentage of those with dense breasts who underwent ultrasound, as well as the number of patients who underwent breast biopsy, was determined by year. Basic demographic and socioeconomic factors, as well as risk factors for breast cancer, breast atypia or cancer, and status of surgical intervention were collected.

Results: Sixty percent of women age 40-49 were classified as having dense breasts compared to 27% of women aged 70-79. Evaluation of the data has demonstrated a steady increase in the number of breast ultrasounds performed on patients with dense breasts in the greater Middletown, NY area since 2013. However, this has not lead to a statistically significant increase in biopsies.

Conclusions: This study evaluates the impact of the dense breast notification law on the number of patients undergoing screening ultrasound in the greater Middletown, NY area and its effect on intervention. Although the number of annual screening ultrasounds has increased steadily in this population, only about 61% of women who qualified for additional screening underwent bilateral ultrasound in 2017, an increase from 22% in 2012. Interestingly, the number of biopsies has not significantly changed over time. Other studies have also questioned the utility and effectiveness of blanket screening based on density alone.

Figure and Table: Percentage of patients who underwent biopsy and percentage of patients who underwent ultrasound by year



Percentage of Patients Who Underwent Biopsy and Percentage of Patients Who Underwent Ultrasound by Year

	# heterogeneously dense	# extremely dense	# mammos	# mammos+sonos (%)	# biopsies (%)
2012	2682	951	7627	805 (10.5)	667 (8.74)
2013	2438	941	7621	1428 (18.7)	391 (5.13)
2014	2313	902	7148	1546 (21.6)	481 (6.73)
2015	2317	789	7064	1690 (23.9)	534 (7.56)
2016	2716	813	6695	2003 (29.9)	661 (9.87)
2017	2448	660	5586	1897 (40.0)	512 (9.17)

(1/1/17-10/31/17)

402401 - Intra-operative specimen radiograph is routinely indicated during mastectomy for breast cancer

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Background/Objective: Specimen radiograph is considered standard of care after breast conservation; however, mastectomy rates are increasing, and there are no data related to use of specimen radiograph after mastectomy done for breast cancer. The purpose of this study is to define the rate at which mastectomy specimen radiograph changes intra-operative management, in order to determine if routine practice is indicated. We hypothesize that this simple intervention is important to confirm that all cancer has been removed at the time of mastectomy.

Methods: A retrospective review was performed over a 9-month period (after the purchase of the hospitals intra-operative specimen radiography system) from February to October 2017. All mastectomies performed during this time by a single fellowship-trained breast surgeon with 10 years of experience were evaluated. There were a total of 37 mastectomies performed, of which 25 were for cancer. The remaining 12 were either contralateral prophylactic mastectomies or genetic mutation carriers.

Results: In the 25 mastectomies done for cancer, specimen radiograph demonstrated all expected clips in 23 cases. There were 2 cases (8%) where the expected number of biopsy clips was not seen on initial mastectomy radiograph. In 1 case, the single clip had migrated subcutaneously and was embedded in the skin. This patient was undergoing mastectomy for multifocal DCIS, and a small focus of invasive lobular carcinoma was unexpectedly found in the tissue adjacent to the clip (in the skin flap). The second patient had a multifocal invasive ductal cancer with long-standing breast implants in place, with 1 focus of cancer in the axillary tail. After the implant was removed, the axillary tail focus fell back into the axilla and was not within the standard boundaries of mastectomy. Because the mastectomy radiograph was done intra-operatively, identification of only 1 clip enabled removal of the second cancer focus with appropriate margin at the time of initial surgery.

Conclusions: The 8% rate of unidentified clips prompting further intra-operative evaluation is quite startling, and warrants consideration of standardization of this practice in the setting of mastectomy done for cancer. In this small series, both cases with retained clips were associated with residual foci of disease adjacent to the clips. This affected adjuvant treatment recommendations in both cases. The implication of a retained clip could be devastating for both the patient and the surgeon, particularly if cancer remains in the body after mastectomy. In centers that have intra-operative specimen radiograph capabilities, the practice of mastectomy radiograph adds no time (since it is done by the circulating staff in the operating room) or cost to the procedure. Identifying the absence of a clip allows the surgeon to take measures intra-operatively, including searching in the mastectomy/axillary cavities, as well as imaging the suction canister and lap sponges, to locate it. In addition, this practice facilitates closer histologic sectioning of the areas of concern in the mastectomy specimen by the pathologist. This small study is the first to investigate the practice of specimen radiograph for mastectomy. If the findings are corroborated in larger studies, specimen radiograph should be performed routinely in the setting of mastectomy for breast cancer. Consideration should be given by our national societies to defining this as a quality of care measure after mastectomy for breast cancer (similar to lumpectomy).

404338 - Screening versus staging magnetic resonance imaging-guided core needle breast biopsies upstage frequency and lesion characteristics for high-risk lesions

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Background/Objective: The latest recommendations from the American Cancer Society, the American College of Radiology, and the Society of Breast Imaging support annual breast magnetic resonance imaging (MRI) screening for high-risk patients (>20% lifetime). MRI has higher sensitivity than mammogram and ultrasound but decreased specificity, which leads to an increased number of biopsies and an increased incidence of pathology atypical lesions. The aim of this study was to investigate whether the malignancy upstage frequency for high-risk lesions (atypical ductal hyperplasia (ADH), atypical lobular hyperplasia (ALH) and lobular carcinoma in situ (LCIS)) identified via MRI-guided core breast biopsies varied based on indication: high-risk screening versus malignancy staging.

Methods: A retrospective review of all MRI-guided core needle breast biopsies performed at a single institution from January 2012 to June 2017 was completed. Patient demographics, MRI features, histopathologic findings from core biopsy, and excisional pathology were assessed. Statistical analysis (descriptive statistics and 2-way, 2-sample T-tests) were performed.

Results: A total of 203 MRI-guided biopsies were performed (10 diagnostic, 54 high-risk screening, 62 contralateral screening and 77 ipsilateral staging), and 29 (14.3%) high-risk lesions (ADH, ALH, LCIS) were observed. Surgical excision pathology was available and attributed to core biopsy site for 22 of 29 high-risk lesions. Five of 22 lesions (22.3%) were upstaged to invasive malignancy or ductal carcinoma in situ (DCIS). One-third (3/9) of lesions found during contralateral screening were upstaged, though no significant differences were observed by MRI indication. No differences were found in the upstage rate by MRI enhancement, size, or past history of breast cancer.

Conclusions: High-risk lesions identified via MRI-guided core biopsies were associated with an overall upstage rate to malignancy of 22.3%. Some variation was observed by indication, although this was not significant. As adoption of breast MRI annual screening continues, further evaluation of the upstage rate by clinical indication will be critical to inform the risk and benefits of surgical excision of ADH, ALH, and LCIS.

Table: Upstage rate by histologic and imaging characteristics

Characteristic	Upstaged to Malignancy		Unable to Classify[1]	T-test P-value
	Yes	No		
Total (n=29)	5	17	7	
Histologic Type[2]				
ADH (n=8)	1	4	3	0.44
ALH (n=17)	5	8	4	0.02
LCIS (n=14)	4	8	2	0.11
Indication for breast MRI				
High-risk screening (n=6)[3]	1	3	2	0.46
Ipsilateral staging (n=11)[4]	1	8	2	0.17
Contralateral screening (12)[5]	3	6	3	0.15
MRI enhancement				
Focal/homogenous (n=8)	1	4	3	0.44
Heterogeneous (n=9)	2	5	2	0.34
Linear/ductal (n=11)	2	7	2	0.48
MRI lesion (cm)				
<1 (n=18)	1	7	3	0.21
≥1 (n=11)	4	10	4	
Prior history of breast cancer				
Yes (n=8)	1	3	4	0.46
No (n=21)	4	14	3	

Two-sample, two-way T-tests were performed using STATA, p-value <0.005
ADH = Atypical ductal hyperplasia; ALH = Atypical lobular hyperplasia; LCIS= lobular carcinoma *in situ*

[1]Excisional pathology was not available for 7 high-risk lesions: no surgery secondary to patient preference, failed biopsy and excisional site matching and transfer of care to another institution
[2]Histologic classifications are not exclusive; 10 of 29 high-risk lesions met histologic criteria for multiple classifications
[3] High-risk screening refers to patients undergoing breast MRI screening secondary to high lifetime risk (>20%) for development of breast cancer, as consistent with the latest recommendations by the American Cancer Society, the American College of Radiology and the Society of Breast Imaging
[4] Ipsilateral staging refers to comprehensive MRI assessment of a breast with proven malignancy
[5] Contralateral screening is a component of our institution's breast cancer staging protocol and refers to MRI screening of the contralateral breast in patients with pathology proven malignancy

404043 - Frequency of development of breast cancer after normal breast MRI in patients without genetic mutations

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Background/Objective: MRI has a better sensitivity and equal or better specificity than mammograms for the detection of breast cancer. However, the time interval between a normal MRI of the breast and subsequent development of radiographically or clinically detectable breast cancer is unknown. We therefore conducted a single-center retrospective study in patients with a variety of risk factors for breast cancer to evaluate the time between a normal MRI and development of breast cancer.

Methods: We retrospectively studied all patients without known breast cancer risk-enhancing genetic mutations who underwent MRI of their breast(s) at our medical center between 2006 and 2012. Patients were included in this study if an MRI of 1 or both of their breasts were interpreted as BIRADS 1 or BIRADS 2, or if they had a recent diagnosis of breast cancer that was completely resected, and the contralateral breast did not have any pathology detectable on MRI. Patients with at least 2 years and up to 10 years of follow-up were included. The time intervals for development of radiologically or clinically detectable cancer following a normal MRI were analyzed in various risk groups of patients, including those with a family history or personal history of breast cancer, patients with dense breasts, and in patients without known risk factors.

Results: There were 801 breasts in 463 patients with normal MRI finding followed from 2 to 10 years (mean follow-up 5.9 ± 2.1 years, median follow-up 6 years). Following normal MRI of the breast in 4797 breast-years (2741 patient years) follow-up of the entire study population, 9 patients (1.9% of the patients and 1.1% of the studied breasts) developed breast cancer. However, in 5 years after the initial normal MRI, 5 of 463 patients (1.08%) and 5 of 801 breasts (0.62%) developed cancer. Approximately 1% (1.12%) of the patients (0.66% of breasts) with normal-density breasts, and 0% of patients without any other risk factors, developed cancer in 5 years following a normal MRI. There was no statistically significant difference for development of breast cancer within 5 years following a normal MRI of the breast in patients with dense breast compared to normal-density breasts ($p>0.05$), patients with strong family history compared to weak or no family history ($p>0.05$), patients with personal history of breast cancer compared to no personal history of breast cancer (p 0.05), and patients with no risk factors compared to patients with 1 or more risk factors ($p>0.05$).

Conclusions: Routine annual imaging for early detection of breast cancer within 5 years after a normal MRI has low yield across all risk groups without genetic mutations. Eliminating routine screening studies, including annual mammograms and other imaging studies, will lead to fewer unnecessary diagnostic studies and biopsies, and reduced cost.

Table: Frequency of development of breast cancer after normal breast MRI in patients without genetic mutations: Results

RF s	Patients (n/%)	Breasts (n/%)	F/U time in 10 years (Br*Yrs)	# of Ca detected	F/U time per Breast CA	p	F/U time with-in 5 years (Br*Yrs)	# of Ca in 5 years	F/U time per Breast CA in 5 years	p
All Pts	463	801	4797	9	533		3648	5	730	
DenseBr						>0.05				>0.05
Yes (+)	106/22.9	192/24.0	1266	1	1266		927	1	927	
No (-)	357/77.1	609/76.0	3531	8	441		2721	4	680	
Family Hx						>0.05				>0.05
No	258/55.7	436/54.4	2563	3	854		1953	3	651	
Weak	134/29.0	232/29.0	1398	2	699		1070	1	1070	
Strong	71/15.3	133/16.6	836	4	209		625	1	625	
Hx of Ca						0.006				>0.05
Yes (+)	215/46.4	336/41.9	2054	8	257		1524	4	381	
No (-)	248/53.6	465/58.1	2743	1	2743		2124	1	2124	

404223 - Accuracy of pre-surgical imaging to guide surgical resection in patients with invasive breast cancer treated with neoadjuvant chemotherapy

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Background/Objective: Surgical resection of invasive breast cancer (BC) in patients who receive neoadjuvant chemotherapy (NAC) is frequently guided by pre-surgical imaging. The purpose of this study was to determine which imaging modality (mammogram (MMG), ultrasound (US) and MRI) performed either prior to NAC (pre-NAC) or after NAC (post-NAC) correlated most with residual tumor burden on pathology.

Methods: A prospectively maintained database identified 82 women diagnosed with invasive BC between 2009-2017 who had imaging before and after NAC. Intra-class correlation coefficients (ICC) were calculated to examine the agreement between imaging findings with tumor size on final pathology. Sub-analyses were performed for radiologic response.

Results: Pre-NAC imaging in the 82 patients included MRI in all patients, MMG in 67 (81.7%) patients, and US in 70 (85.4%) patients. Post-NAC imaging consisted of MRI in all patients, MMG in 37 (45.1%), and US in 20 (24.4%). Median (IQR) duration of NAC was 115 (100-135) days. Four (5.1%) had no radiologic response, 51 (64.6%) had a partial radiologic response, and 24 (30.4%) had a complete radiologic response. Median (IQR) tumor size on final pathology was 0.85cm (0-2cm). Thirty-three (40.2%) achieved pathologic complete response; 9 (27.2%) of those patients had residual DCIS on final pathology. Overall, pre-NAC imaging had poor agreement with final tumor size (ICC for pre-NAC MMG, US, MRI: 0.00, 0.27, 0.06 respectively). Of the post-NAC imaging modalities, MMG had the lowest agreement with final tumor size (ICC 0.16), while USs agreement was also poor post-NAC (ICC 0.27). Post-NAC MRI was the most reliable imaging modality (ICC 0.62); however, it became less reliable in

patients with non-mass enhancement on MRI (ICC 0.27), multifocal disease (ICC 0.48), and a radiologic complete response (ICC 0.26).

Conclusions: Post-NAC MRI is the most reliable imaging modality with respect to residual tumor burden. MRI performed after NAC may be used to guide surgical resection in patients with invasive BC who have received NAC. However, MRI may be less reliable in the presence of non-mass enhancement, multifocal disease and a radiologic complete response.

404009 - Specialist follow-up may improve compliance for BIRADS 3 patients: A single institution's review

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Background/Objective: The Breast Imaging Reporting and Data System (BIRADS) Lexicon was first developed in 1985 as a way homogenize radiological interpretations of breast imaging. However, there are some limitations, mainly that it is strictly a radiological classification. This study aims to analyze the patterns of radiological and provider follow-up for our BIRADS 3 patients in our institution to determine any trends that will allow us to optimize a protocol and improve outcomes for our patients classified as BIRADS 3.

Methods: After IRB approval, we retrospectively identified patients who had mammography performed from January 2, 2015 April 30, 2015 at our institution. There were 2769 mammograms performed during the 4-month period. Patients were only included if they were classified as BIRADS 3 during this time frame. Demographic data, prior breast imaging, and surgery, as well as radiological and clinical follow-up visits were noted. Statistical analysis was performed using 2-tailed t-tests. A statistical significance was accepted for $p<0.05$.

Results: We identified 92 (3.3%) unique patients classified as BIRADS 3. Seventy-two (77.4%) had prior breast imaging at our institution, of which 17 (23.6%) were previously classified as BIRADS 3. The majority of the mammograms were ordered by primary care physicians (PCP) (63.0%), while only 6.5%, ordered by a breast surgeon (Table). All of the patients were recommended to have short-term follow-up (6 months), of which 62 (67.4%) had repeat imaging, 63 (68.5%) were seen by a provider, and 30 (32.6%) were lost to follow-up (Table). Of the 62 patients who underwent repeat imaging, 18 (29.0%) remained classified as BIRADS 3. Twelve (70.6%) of these patients had repeat imaging, 13 (72.2%) were seen by a provider, and 6 (33.3%) were lost to follow-up (Table). Finally, of the 12 patients who had a second follow-up image, 8 (66.7%) remained classified as BIRADS 3. Only 3 (37.5%) were seen by their PCP, and 3 (37.5%) were seen by their obstetrician-gynecologist (OB-GYN), while no patients were seen by a breast surgeon, and 2 (25%) were lost to follow-up (Table). Overall, patients were more likely to follow up after being classified as BIRADS 3 if they were initially seen by a breast surgeon versus a PCP ($p<0.0000001$) or versus an OB-GYN ($p=0.02$), or initially seen by an OB-GYN versus a PCP ($p=0.005$). Additionally, 100% of patients seen initially by a breast surgeon were seen in follow-up after classified as BIRADS 3, while 83.3% and 67.8% followed-up if seen initially by OB-GYN or a PCP respectively.

Conclusions: Currently at our institution, there is no standardized protocol for provider follow-up for patients classified as BIRADS 3 on breast imaging. Although our study was limited in numbers, our data

indicate that patients classified as BIRADS 3 were more likely to follow up with a provider if they were seen by a specialist, and most likely to follow up if seen by a breast surgeon. We plan to incorporate a protocol in which all BIRADS 3 patients are referred to a breast surgeon in hopes of limiting loss to follow-up and improve compliance for these patients.

Table: BIRADS 3 Follow-up demographics

		Initial Mammogram (N=92)	First Follow-Up (N=62)	Second Follow-Up (N=12)
Time to Follow-up				
	Average (range; SD)		9 months (3-26; 4.8)	7 months (6-13; 2.5)
Ordering Physician				
	Primary Care Physician	58 (63.0%)	40 (64.5%)	7 (58.3%)
	Obstetrician-Gynecologist	25 (27.2%)	15 (24.2%)	4 (33.3%)
	Breast Surgeon	7 (7.6%)	6 (9.7%)	1 (8.3%)
	Radiologist	2 (2.2%)	1 (1.6%)	0
Recommendations				
	Further imaging	0	0	0
	Short term follow-up (6-months)	92 (100%)	17 (94.4%)	8 (100%)
	One-year follow-up	0	1 (5.6%)	0
	Biopsy	0	0	0
Follow-up				
	Primary Care Physician	49 (53.3%)	8 (44.4%)	3 (37.5%)
	Obstetrician-Gynecologist	13 (14.1%)	4 (22.2%)	3 (37.5%)
	Breast Surgeon	6 (6.5%)	2 (11.1%)	0

404315 - Socioeconomic influences of follow-up for patients classified as BIRADS 3: A single institution's review

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Background/Objective: Breast cancer remains a universal concern, with 1 out of 8 women diagnosed with breast cancer in their lifetime. Increased screening with the use of mammography has allowed for earlier detection and increased survival rates. The Breast Imaging Reporting and Data System (BIRADS) initially developed to standardize breast imaging reporting has helped aid decision-making for patients with abnormal imaging. The loss of follow-up in our patients, especially among those classified as BRIADS 3, has remained a concern due to the potential for a missed cancer diagnosis. This study aims to analyze race and socioeconomic influences on loss of follow-up in our patients classified as BIRADS 3.

Methods: After IRB approval, we retrospectively identified patients who were classified as BIRADS 3 on breast imaging from January 2, 2015 April 30, 2015. Demographic data, including race, insurance type, as well as radiologic follow-up were noted. Statistical analysis was performed using a 2-sample t-test. A statistical significance was accepted for $p<0.05$.

Results: We identified 92 patients who met our inclusion criteria. Of our analyzable patients, 47 (51.1%) were African American, 39 (42.4%) were Caucasian, 2 (2.2%) were Asian, and the remaining 4 (4.3%) identified as Other. The average age of our cohort was 57 (range 23 85; SD 13.5). Forty-three (46.7%) were publicly insured, 40 (43.5%) were privately insured, 4 (4.3%) had a combination of public and private insurance, and 5 (5.4%) were uninsured. Of the 92 patients initially classified as BIRADS 3, 62 (67.4%) underwent repeat short-term imaging as recommended. Thirty (32.6%) patients were lost to follow-up, of which 43.3% identified as African American, 46.7% as Caucasian, and 10% as Other. The majority (66.6%) of these patients were either publicly insured or uninsured. Of the 62 patients who did undergo repeat imaging, more than half (54.8%) identified as African American and were almost evenly split between publicly and privately insured (43.5% versus 48.4%). Of our initial cohort, a higher proportion of those with private insurance returned for repeat imaging in comparison to those with public insurance (Table). Additionally, a higher percentage of African Americans returned for follow-up, compared to Caucasians (Table).

Conclusions: Breast cancer prevention and early detection remain significant public health concerns, despite continued advances in community awareness of screening recommendations. Although limited by sample size, our data highlight that a significant number of patients are lost to follow-up after being classified as BIRADS 3 and do not undergo the recommended close surveillance. Our data demonstrate that within our patient population, insurance payer classification and race are closely associated with loss of follow-up. Our data demonstrate that those with private insurance are more compliant with the recommended follow-up than those with public insurance. These data will help guide our future efforts at decreasing loss of follow-up rates and promoting adherence to the recommended imaging guidelines in our patient population.

Tablr: BIRADS 3 Follow-up demographics

		Total Patients (N)	Follow-Up (N)	Loss to Follow-Up (N)	p value
Race					
	African American	47	34 (72.3%)	13 (27.7%)	0.0003
	Caucasian	39	25 (64.1%)	14 (35.9%)	0.0047
	Asian	2	2 (100%)	0	0.158
	Other	4	1 (25%)	3 (75%)	0.563
Insurance Type					
	Public	43	27 (67.5%)	16 (37.2%)	0.0558
	Private	40	30 (75%)	10 (25%)	0.0003
	Self-Pay	5	1 (20%)	4 (80%)	0.1762
	Public and Private	4	4 (100%)	0	0.0449

400935 - Breast cancer screening among medically underserved women in New Mexico: Comparing and LOwering recall rates with digital breast tomosynthesis (3-D) VErsus full-field digital (2-D) mammography: The LOVE New Mexico study.

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Background/Objective: Research suggests that screening digital breast tomosynthesis (3D mammography) decreases recall rates and improves cancer detection rates. Recall, requiring a second visit to an imaging center, poses a unique challenge to medically underserved, rural women. Consequently, this technology has potential far-reaching implications for breast screening compliance and a favorable financial impact particularly in medically underserved populations. We hypothesize that the use of 3D mammography decreases the screening recall rate among women in New Mexico, a state with a disproportionately high rate of poverty, widespread language barriers, and a large rural population. Secondary objectives include cancer detection rates and biopsy positive predictive values.

Methods: We conducted a retrospective study utilizing PENRAD, the mammography information system used at our facility at the University of New Mexico (UNM) Comprehensive Cancer Center. We identified a total of 35,147 screening standard 2D and combination 2D/3D screening mammograms performed through the UNM Health Sciences Center between 2013-2016 using data abstracted through the PENRAD database. Recall rates, biopsy positive predictive values (PPV), and cancer detection rates were compared using descriptive statistics and relative risk (RR along with 95% Confidence Interval) by the Cochran-Mantel-Haenszel method. A subset of the women screened in 2016 were medically underserved, defined as age 40 and over meeting eligibility criteria for Medicaid or the Breast and Cervical Cancer Prevention Program (BCC), or lacked insurance coverage. A state-funded program called "Free 3D" was created with a planned enrollment of approximately 1000 women. Demographic

information of interest for the subgroup of 1030 women who enrolled in the State-funded "Free 3D" program was evaluated through a companion quality improvement project.

Results: When compared to 2D, 3D mammography resulted in a considerably lower recall rate, at 8.4% vs 11.1% ($p<0.0001$). The difference in recall rates became more pronounced over the study period. The relative risk of a "call-back" was reduced by 43% (RR: 1.43, 95% CI: 1.30-1.58%). There was no significant difference in PPV between mammography modes, although there was a trend towards a higher PPV with 3D mammogram compared to the benchmark value of 4.4% over the study period, at 4.8% with 3D vs 6.0% with 2D mammogram (RR: 0.69, 95% CI: 0.46, 1.03%, $p=0.07$). There was no difference in the cancer detection rate (5.3 vs. 5.1 per 1000 women, $p=0.82$) with 2D and 3D mammography. Demographic analysis of the subgroup receiving state aid revealed Hispanic participants numbered 63% of the total. Insurance data analysis showed that 54% of women screened were enrolled in Medicaid, followed by 27% referred through New Mexico BCC.

Conclusions: In New Mexico, women undergoing screening mammography between 2013 and 2016 experienced a significant 43% relative reduction in recall rate with the use of 3D mammography compared to conventional 2D imaging. This difference was most notable in the last year of the study. These findings are pertinent to centers that similarly serve large numbers of women from minority, rural, financially constrained, and medically underserved patient populations. Recall after screening mammogram in such populations represents a major potential barrier to comprehensive breast cancer screening. The benefit of 3D mammography as a screening method for breast cancer is currently under evaluation in multiple large population-based studies. However, the results of this study provide novel and previously unpublished insights regarding the unique value of incorporating 3D mammography into cancer care delivery for medically underserved women. Lastly, we are conducting a qualitative companion study to examine patient and primary care provider perspectives on factors influencing uptake and decision-making for 3D mammography.

403519 - Breast density increases after bariatric surgery

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Background/Objective: Obesity and breast density are both independent risk factors for the development of breast cancer. Bariatric surgery is a safe and effective treatment for morbid obesity, with sustainable weight loss and a reduction in overall cancer incidence. Breast density is known to decrease with increasing patient age; however, the impact of bariatric surgery on breast density remains unclear as recent studies have shown conflicting results on both qualitative and quantitative measures of breast density. We sought to evaluate changes in both qualitative (BI-RADS) and quantitative (Volpara automated score) breast density, and hypothesized breast density would increase following bariatric surgery.

Methods: All 2,232 women who underwent bariatric surgery between 1990 and 2015 at a single academic medical center were identified. Patients were excluded if they did not have a mammogram performed both before and after bariatric surgery at the same institution. Changes in body mass index (BMI), time between mammograms and surgery, and BI-RADS density scores were assessed on all patients. When available, Volpara automated software was used to calculate changes in volumetric

breast density (VBD), fibroglandular volume (FGV), and total breast volume. Differences between pre- and post-surgery values were assessed.

Results: The study cohort included 180 women who underwent bariatric surgery with pre- and post-surgery mammograms available. Median age at time of surgery was 50.0 (44.0-55.0) years, with 8.8 (4.4-14.7) months between the pre-surgery mammogram and bariatric surgery and 62.3 (28.5-116.4) months between surgery and the post-surgery mammogram. BMI was significantly reduced at the time of post-surgery mammogram [46.0 (42.0-51.8) kg/m2 vs. 35.4 (30.8-41.1) kg/m2; p<0.001]. No change in BI-RADS density scores was seen in 117 (65.0%) women from pre- to post-surgery mammograms, with 25 (13.9%) more women going up in density score and 38 (21.1%) decreasing in score (p=0.06). Eighteen women had sufficient Volpara data available. While VBD increased in these patients, FGV and total breast volume both decreased following bariatric surgery (Table).

Conclusions: Morbidly obese women were found to have increased VBD but decreased FGV and total breast volume following bariatric surgery and subsequent weight loss. No differences were detected in quantitative breast density, highlighting the discrepancy between BI-RADS and Volpara breast density measurements. Data from this study demonstrate an increase in breast density and decrease in volume following bariatric surgery. These findings may have implications on breast cancer risk.

Table: Breast density changes following bariatric surgery

	Preoperative Mammogram	Postoperative Mammogram	p value
Right breast VBD (%)*	3.5 (2.7-5.0)	4.3 (3.7-5.2)	0.007
Right breast total volume (cm^3)*	2108.7 (1702.4-2388.2)	1388.5 (758.5-1455.2)	0.0002
Right breast FGV (cm^3)*	66.1 (58.1-85.7)	52.8 (47.2-62.2)	0.005
Left breast VBD (%)	4.6 (2.6-5.8)	4.9 (3.8-6.4)	0.04
Left breast total volume (cm^3)	2113.4 (1616.4-2569.7)	1272.8 (567.0-1700.0)	<0.001
Left breast FGV (cm^3)	81.9 (61.3-114.0)	60.1 (44.6-79.4)	0.01

*Data not available for all patients
VBD = volumetric breast density; FGV = fibroglandular volume

404141 - Initial surveillance imaging after breast conservation therapy: Are recall rates for screening mammograms acceptable?

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Background/Objective: Most breast cancer treatment guidelines recommend annual mammography for breast cancer surveillance following breast conservation therapy (BCT). However, the recommendation for initial type of post-operative imaging modality, namely screening (sc-M) versus diagnostic mammogram (dx-M), is not specified. As a result, there is wide variability in breast imaging obtained after BCT. One reason for this discrepancy could be the desire to order a dx-M to prevent a recall in a patient previously diagnosed with a breast cancer. Per the American College of Radiology (ACR), a recall rate (RR) of 5-12% is acceptable for a routine sc-M. In this study we sought to determine the RR for patients (pts) who had sc-M as initial post BCT surveillance. A secondary aim was to compare the differences in outcomes between those undergoing sc-M versus dx-M with attention to biopsy recommendations and cancer detection rates.

Methods: A prospectively-maintained cancer registry at a high-volume tertiary care academic center was retrospectively reviewed for patients who underwent BCT from January-December 2015. Demographics, clinicopathologic features, breast density, imaging type, bx, and pathology results were recorded. Patients were excluded if they required a completion mastectomy or did not have imaging within a year. Patients were classified into either the sc-M or dx-M group. The primary endpoint was RR in the sc-M group. Secondary endpoints included number of bx and their subsequent pathology results. Statistical analysis was performed using chi-square, Fisher's exact, and t-test, where appropriate.

Results: In 2015, 584 patients underwent BCT, and 498 (85%) had surveillance imaging within 11.5+2.9 months of BCT. Thirty-two percent (n=160) and 68% (n=338) of patients had sc-M and dx-M, respectively. The 2 cohorts were similar in terms of age, clinical and pathological AJCC stages, phenotype, and breast density (all p>0.05) (Table). RR in the sc-M cohort was 12% (n=19). Supplemental tomo was performed in 59% of sc-M and 68% of dx-M (p=0.04). RR among sc-M with tomosynthesis (tomo) was 13% (12 of 95 patients). In the sc-M cohort, 1% (n=2) were advised to undergo a biopsy whereas 4.4% (n=15) of the dx-M cohort were so advised (p=0.07). In the dx-M cohort, 1 patient refused biopsy, and 1 patient did not have follow-up to receive a biopsy. Malignancy 1 year after BCT was identified in 0.4% (n=2) in the entire study cohort. No patients (0%) in the sc-M group and 2 pts (<1%) in the dx-M group were diagnosed with malignancy (p=1). Of note, both malignant lesions were in the same quadrant of the ipsilateral breast.

Conclusions: As recommended, the majority of patients completed some form of mammography within a year of BCT. An acceptable RR of 12% for sc-M was demonstrated, suggesting that sc-M is reliable as initial surveillance imaging 1 year post-BCT. There was, however, a trend towards more biopsies in the dx-M group compared to sc-M, but the overall identification of a new malignancy was low.

Table: Post-BCT surveillance – screening (sc-M) vs diagnostic (dx-M)

	sc-M	*dx-M*	*P Value*
Number of Patients (n=498)	160 (32%)	338 (68%)	
Median Age in Years (range)	63 (28-89)	64 (30-90)	0.31
AJCC Stage Pathologic			0.55
Stage 0	9 (6%)	12 (4%)	
Stage 1	109 (68%)	235 (69%)	
Stage 2	36 (24%)	83 (25%)	
Stage 3	6 (4%)	8 (2%)	
Density			0.92
Fatty Replaced	6 (4%)	10 (3%)	
Scattered Fibroglandular elements	82 (51%)	173 (51%)	
Heterogeneously dense	70 (44%)	149 (44%)	
Homogeneously dense	2 (1%)	6 (2%)	
Tomo/Additional Views			
Tomosynthesis	95 (59%)	232 (68%)	0.04
Magnification	30 (19%)	89 (26%)	0.06
Compression	0 (0%)	31 (9%)	
US	0	63 (19%)	
Screening Recall	19 (12%)	N/A	
# bx recommended	2	15	0.07
# bx performed	2	13	
Ipsilateral bx	1	7	
Contralateral bx	1	6	
Benign	1	10	
Malignant	0	2 (Ipsilateral)	1.00
High Risk	1	1	
Average time between surgery and first imaging months (SD)	11.5 ±2.9	11.5 ±2.9	

bx=biopsy, SD=standard deviation, tomo=tomosynthesis

403568 - The utility of interval MRI after benign and concordant MRI-guided breast biopsy

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Background/Objective: MRI-guided breast biopsy has emerged as a valuable technique for sampling of lesions seen exclusively on MRI and may prevent the need for surgical intervention. When these biopsy results are benign and concordant with the imaging findings, follow-up MRI may be suggested to confirm accuracy of the biopsy. However, there is currently no standard for follow-up MRI after an MRI-guided biopsy. This retrospective study evaluates our own practice of short-term follow-up MRI after benign and concordant MRI-guided biopsies and looks at the utility of this practice in decreasing the rate of missed cancers.

Methods: A retrospective review evaluating 285 lesions that underwent MRI-guided breast biopsy and marker placement at a single institution between 2012 and 2016 was performed. Of these, 64 lesions had benign pathology that was concordant with the imaging and underwent a follow-up MRI within 24 months. The lesions with benign and concordant pathology were further analyzed for the timing of follow-up MRI, change in lesion characteristics or size at follow-up, BIRADS category at follow-up MRI, and the results of any subsequent biopsies or imaging.

Results: Of the 64 MRI-guided biopsies that were benign and concordant, 23.4% (15/64) had their first follow-up MRI performed in months 3 to 5 after biopsy, 67.2% (43/64) had follow-up MRI in months 6-12, and 9.4% (6/64) were done between 13-24 months. Thirteen patients (20.3%, 13/64) underwent a second biopsy during the study period as a result of findings on their follow-up MRI. Of these, 3 patients (4.7%, 3/64) were found to have cancer. All 3 of the malignancies were found in the same location as the initial benign biopsy, and all had a final pathology of invasive ductal carcinoma. One was diagnosed by US-guided core needle biopsy (CNB) and the other 2 by excisional biopsy. Two of these cancers were detected at a 6-month follow-up MRI, and the third was detected at 12 months. The 10 other patients that underwent a repeat biopsy during the study period had various benign findings. Seven of these patients developed new suspicious lesions on follow-up MRI and underwent either MRI-guided biopsy (6/7) or US-guided CNB (1/4). Two patients had suspicious findings at the original biopsy site on follow-up imaging and proceeded to either wire-localized excisional biopsy or US-guided CNB.

Conclusions: In this cohort, the false-negative rate of MRI-guided biopsy is 4.7% with 2 of those being detected at 6 months. Therefore, our data suggest that short-term follow-up MRI after benign and concordant MRI-guided biopsy is beneficial in these patients in order to detect missed cancers.

403039 - Routine axillary ultrasound for patients with T1-2 breast cancer does not increase the rate of axillary lymph node dissection, based on predictive modeling

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Background/Objective: Axillary ultrasound (AUS) for cN0 breast cancer (BC) may identify nodal metastasis in patients who may have only 1-2 positive sentinel lymph nodes (SLN) and could have avoided axillary lymph node dissection (ALND), based on Z0011 results. We hypothesized that routine AUS for newly diagnosed BC could decrease the number of ALND (compared to not performing AUS), if some patients with a positive node detected by AUS were still considered candidates for SLNB (SLN biopsy). Patients unlikely to have >2 positive nodes on SLNB, and those unlikely to have a nodal pathologic complete response to neoadjuvant chemotherapy (NAC), could undergo primary surgery (no NAC) with SLNB (with radiographic documentation of a retrieved clipped positive node), despite biopsy-proven nodal metastasis. To test this hypothesis, we evaluated hypothetical management algorithms for treatment of BC with AUS-detected, needle biopsy-confirmed, nodal metastasis to determine whether any algorithm increased or decreased the number of ALND, compared to no pre-operative AUS.

Methods: We assessed the expected number of ALND in T1-2, cN0 breast cancer with strategies of routine AUS versus no AUS. For routine AUS, we analyzed 5 hypothetical management algorithms (Table). Decision-tree analysis assessed the likelihood of ALND with each algorithm, using probabilities from the literature and an institutional database for each branch point (e.g., suspicious vs non-suspicious AUS, 1 vs >1 suspicious node on AUS, negative- vs positive-node needle biopsy (NNB), likelihood of nodal pathologic complete response based on tumor biology, etc.). We assumed that those with NNB-proven nodal metastasis and a positive SLN after NAC would undergo ALND. To estimate the number of ALND under a hypothetical strategy of no AUS, we relied on previously published data showing that, with positive NNB, 50% of those with 1 AUS-suspicious node and 70% with >1 AUS-suspicious node have >2 positive nodes and likely require ALND.

Results: With a strategy of no pre-operative AUS, analysis showed that 10% of patients would undergo ALND. For a strategy of routine AUS, the expected rate of ALND was 14% if all patients with a positive NNB underwent ALND and 11% if all such patients underwent NAC (Table). For the algorithms using a strategy of patient selection for NAC based on tumor biology and the number of suspicious nodes, the predicted rate of ALND was 10%, regardless of the algorithm used (Table). Using routine pre-operative AUS, 29% of T1-2 BC with no palpable adenopathy would have suspicious AUS. Of those, 62% would have 1 suspicious node with 35% having positive NNB. Thirty-eight percent would have >1 suspicious node, with 45% having a positive NNB.

Conclusions: Some surgeons argue against pre-operative AUS in clinically node-negative BC due to concern that it will increase ALND rates. We showed that routine AUS for patients with non-palpable nodes can achieve ALND rates similar to that of no AUS. The only algorithm (1) resulting in increased ALND rates was the inadvisable strategy of not administering NAC to any group of node-positive patients. Although we did not find that any algorithm incorporating routine AUS decreased the predicted number of ALND, pre-operative diagnosis of non-palpable axillary metastasis may aid in selecting appropriate patients for NAC and help predict need for post-mastectomy radiation, which may influence surgical choice in patients motivated for mastectomy in order to avoid radiation.

Table: Description of 5 algorithms for management of a positive node detected by axillary ultrasound and proven by needle biopsy. The predicted ALND rate is shown for reach algorithm. The predicted rate of ALND without AUS was 10%.

Algorithm	Algorithm rationale	% predicted to undergo ALND
1. All patients with a biopsy-positive node, detected by AUS, undergo ALND.	We would not recommend this algorithm. This was used as a comparison group.	14%
2. All patients with a biopsy-positive node, detected by AUS, undergo NAC, followed by axillary re-imaging and SLNB if imaging has normalized.	We would not recommend this algorithm. This was used as a comparison group.	11%
3. > 1 suspicious node *or* 1 suspicious node *and* ER neg or HER2 pos disease → NAC, SLNB if axillary re-imaging normalizes 1 suspicious node *and* ER pos/HER2 pos → SLNB.	More than 1 suspicious node has been shown to predict N2-3 disease on ALND. These patients were selected for NAC since they are more likely to require ALND if SLNB is undertaken without neoadjuvant therapy. ER negative and HER2 positive disease have higher rates of nodal pCR. Patients with even 1 suspicious node, if ER negative or HER2 positive, are recommended for NAC as there a greater likelihood of achieving nodal pCR and avoiding ALND.	10%
4. > 1 suspicious node → NAC, SLNB if axillary re-imaging normalizes. 1 suspicious node → SLNB.	See the rationale for algorithm 3.	10%
5. > 1 suspicious node *and* ER neg or HER2 pos → NAC, SLNB if axillary re-imaging normalizes. All others → SLNB	See the rationale for algorithm 3.	10%

NAC, neoadjuvant chemotherapy. SLNB, sentinel lymph node biopsy (for purposes of this table, SLNB should be assumed to include targeted and retrieval of the positive node, marked by a clip). ALND, axillary lymph node dissection. pCR, pathologic complete response.

403419 - The effect of legislation requiring notification of patients with mammographically dense breasts

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Background/Objective: Mammographic breast density has been identified as an independent risk factor for the development of breast cancer. In the last 2 years, multiple states have introduced legislation that mandates disclosure of breast density on mammography (including Michigan in 2015). The law requires the following information to be provided to the patient: disclosure of dense breast tissue and its increased risk for breast cancer, information that dense breast tissue may obscure mammography findings, and recommendation to talk to a physician regarding this information and the potential for further screening. There are multiple issues regarding the disclosure of this information to patients. First, the prevalence of dense breast tissue in American women is high, approximately 43% (inversely related to age and body mass index). Additionally, there is currently no consensus among physicians regarding the need for supplemental imaging or the imaging modality of choice for women with dense breast tissue. Furthermore, there is no research reviewing the effect on patients or change in practice after legislation. We surveyed women with dense breasts identified on mammography, and reviewed changes in practice at our community hospital.

Methods: We performed a retrospective review of adult women (18 years of age) who had a mammogram during the years 2014 (pre-legislation) and 2016 (post-legislation) at a community hospital. Because there are >8,000 mammograms performed each year at our institution, we chose a random sample for each cohort (367 subjects). Data collected included: demographics, mammogram findings, and additional imaging ordered following mammography to evaluate rates of dense breasts in our community and differences between pre- and post-legislation care. Surveys were also sent in the mail to a random sample of 367 subjects who were identified as having heterogeneously or extremely dense breast tissue on an otherwise normal mammogram during the year of 2016. Exclusion criteria included women with any abnormality on mammogram, women with a history of breast cancer or previous breast biopsy/surgery, and known genetic mutation predisposing them to breast cancer. Subjects were asked questions regarding their knowledge of breast density, and any anxiety or stress this information caused them.

Results: Retrospective review demonstrated that more breasts were classified as dense in 2014 than 2016 (38.4% versus 28.5%, Chi-square, p=0.012). There were also more subjects identified as high risk (by National Cancer Institute's Breast Cancer Risk Assessment) for breast cancer in 2014 (22.8% of cases compared to 15.9% in 2016, Chi-square, p=0.029). Patients were older in the 2014 group (mean +/- SD: 61.4 +/-11.4 years) than 2016 (57.0 +/- 10.7, t-test for independent groups p<0.0005). Having an additional ultrasound following mammogram finding of dense breasts was also higher in 2014 (3.3% vs 1.0% in 2016, Chi-square, p=0.089). Unfortunately, survey participation was limited. Of 29 respondents, 90% (n=26) reported that they understood that dense breasts may make mammogram more difficult to interpret, but only 52% (n=15) reported that they understood it was a risk factor for breast cancer. Only 45% (n=13) of respondents discussed these findings with their physician. In total, 28% (n=8) reported they experienced some anxiety or stress because of the notification of dense breasts; however, 100% (n=29) stated they believed that women should be notified of their breast density. Additional survey results are still forthcoming.

Conclusions: This study demonstrates no increase in the rate of women identified as having dense breasts or change in care after the passing of legislation in the state of Michigan. Our survey study was

limited by small sample size, but suggests that women may not fully understand the ramifications of having dense breasts, and do experience stress or anxiety related to the disclosure of breast density. However, respondents still want to be notified of breast density. The full implications of this legislation are still to be determined. Clearly, more research is needed regarding the care of patients found to have dense breasts on mammogram, as well as to determine the recommended management of these patients.

Localization

395442 - Comparison of radioactive seed localization and wire localized excision of non-palpable breast lesions: A retrospective review of a community hospital's experience

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Background/Objective: Wire localized excision (WLE) is the standard procedure to treat non-palpable breast lesions. Radioactive seed localized excision (RSLE) was developed as an alternative technique. Most data comparing RSLE and WLE derives from large academic institutions with very limited data from community hospitals. The primary objective was to compare the rate of positive resection margin between WLE and RSLE.

Methods: Retrospective chart review of patients who underwent WLE or RSLE at a Canadian community hospital (January 1, 2011 July 31, 2017) was conducted. Patients from our center were identified from the Cancer Care Ontario Annual Report Database. Positive margin was defined as ink on tumor [ductal carcinoma in situ (DCIS) or invasive]. Group characteristics were compared using T test and Chi-square and statistical significance was set as $p<0.05$.

Results: A total of 2,602 breast surgery procedures were identified, of which 747 (28.9%) and 577 (22.6%) were WLE and RSLE, respectively. Frequency of invasive tumors were similar between both groups (RSLE 76.8% versus WLE: 73.1%, p=0.1). The overall (DCIS and invasive) positive margin rate was significantly lower with RSLE than WLE (9.9% versus 13.7%, p=0.04). The DCIS positive margin rate was lower with RSLE than WLE (7.9% versus 11.3%, p=0.07). The invasive margin rate was lower with RSLE than WLE (5.4% versus 6.8%, p=0.4).

Conclusions: RSLE technique was associated with lower positive margin rate in comparison to WLE. RSLE is an effective technique to excise non-palpable breast lesions in the community setting.

403975 - Comparison of margin and re-excision rates following radar reflector localization to wire localization in patients with invasive breast cancer

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Background/Objective: Alternatives to wire localization (WL) for non-palpable breast lesions have emerged to increase patient comfort and alleviate the imaging department coordination constraints. With the incorporation of radar reflector localization (RRL) to our institutional practice, we sought to evaluate our margin and re-excision rates with this new technology.

Methods: A single-institution, retrospective, IRB-approved study was conducted on all lumpectomies performed by 6 surgeons with WL or RRL for invasive breast cancer from January 2016 September 2017. Patients with ductal carcinoma in situ, an oncoplastic reduction, or bracketed lumpectomy were excluded. Demographic and clinical-pathologic data were collected. Surgical outcomes to include intra-

operative margin status, final pathology margin status and re-excision rate were collected, and then analyzed for each group using Fisher's Exact test, Wilcoxon Rank Sum Test, Pearson's Chi-Square Test and Pearson Residual.

Results: There were 363 patients who underwent localization for lumpectomy, 284 WL (78%) and 79 RRL (22%). There were no significant differences between age, histologic subtype, ER status, HER2/neu status, pathologic tumor size, specimen volume, or lymph node involvement in either group (Table). There was a 100% pre-operative localization rate using mammogram, ultrasound or MRI. The median number of days RRL was placed prior to surgery was 7 days (0-30). All lesions were successfully localized intra-operatively and confirmed with specimen radiograph. There was a significant difference in intra-operative gross positive margins between WL and RRL (11.9% vs 21.5%, p=0.048). There was no significant difference in positive margins on final pathology between WL and RRL (6.6% vs 2.5%, p=0.25). However, there was a significantly higher re-excision rate in the WL group compared to the RRL group (16.5% vs 3.8%, p=0.002).

Conclusions: In our single institution series, we found RRL to result in more intra-operative positive margins but no difference in final positive margins in lumpectomy specimen. However, RRL had fewer re-excisions than WL. These findings suggest factors other than margin status affect re-excision rate in our cohort, which requires further investigation in future studies. Overall, RRL is comparable to WL and offers more flexibility in scheduling and less concern of wire migration prior to surgery.

Table: Comparison of wire localization to radar reflector localization groups

	Wire (n=284)	Radar Reflector (n=79)	p-value
Median Age	65	65	0.99
Invasive Histology Ductal Lobular Other	 86.6% 8.8% 4.5%	 84.8% 8.8% 6.3%	0.77
ER+	85.5%	91.1%	0.33
HER2/neu+	5.2%	6.3%	0.86
Extensive Intraductal Component (>25% DCIS)	11%	8%	0.12
Lymph node involvement	15.8%	13.9%	0.72
Median Pathologic tumor size, pT (range)	12mm (0-90)	15mm (0-40)	0.28
Median Specimen Volume (mm^3)	41,580 (3,600-2,187,000)	52,500 (5,832-477,750)	0.08
Intraoperative positive margins	11.9%	21.5%	0.04
Median intraoperative margin re-excisions (range)	2(0-6)	2 (0-6)	0.16
Final pathology positive margins	6.6%	2.5%	0.25
Re-excision rate	16.5%	3.8%	0.002

402928 - Radioactive seed localization vs. wire-guided localization lumpectomy: Which has a better outcome in rural Tennessee?

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Background/Objective: Wire-guided localization (WGL) has been the gold standard for surgical excision of non-palpable breast lesions for many years. The problems with WGL include: (1) delayed operating room start times that are frequently due to scheduling conflicts between the surgeons and radiologists, (2) positive margins, which require further surgery and loss of healthy breast tissue, (3) dislodged/displaced wires, (4) difficulty in confirming the actual site of the breast lesion, as the wire tip may be distant from the entry site, resulting in excision of excess healthy breast tissue (5) patient discomfort. Radioactive seed localization (RSL) is a technique that uses titanium seeds containing 125I. Its half-life is about 60 days, which makes it more convenient for the patient to have it done prior to the day of surgery. The aim of this study was to compare WGL to RSL, to determine if there was an improved outcome with RSL in regards to decreasing the likelihood of positive margins and the need for re-excision in Johnson City, Tennessee, a town where patients from the rural areas of Tennessee, Virginia, and North Carolina are treated.

Methods: A retrospective review of data from Mountain States Health Alliance (MSHA) from 2007-2015 was performed. Patients who had non-palpable lesions with core biopsies demonstrating breast cancer (including ductal, lobular and papillary) and ductal carcinoma in situ (DCIS) that underwent I-125 seed localization and wire-guided localization lumpectomy were studied. The tumor size, histology, and margin status were obtained from the pathology results. Positive and close margins are defined as less than 1mm from the dyed resection margin. Negative margins are defined as greater than or equal to 1mm from the dyed resection margin. The number for re-excisions and the length of surgery were also obtained. Chi-squared statistical analysis was used to compare group re-excision % expressions, and a p value <0.05 was considered statistically significant.

Results: A total of 177 patients data was collected, of these 157 were included in the study. The table demonstrates the re-excision rates for RSL and WGL groups, which was not statistically significant. There was no significant difference in the re-operation for each tumor type in the either the WGL or RSL groups. Additionally, there was no difference in the operative times between the WGL and RSL groups.

Conclusions: Our study demonstrates that RSL did not have an improved outcome in regard to re-excision rates; both RSL and WGL had comparable rates of re-excision and similar operating room times. Our results in rural Tennessee are similar to the results of larger institutions in bigger cities. Despite not having improved margin and re-excision outcomes, RSL affords the ability to perform localization on a day prior to the surgery date, providing the opportunity for efficiency of the operating room, and has other benefits in regard to patient comfort and surgeon preference.

Table: Re-excision rates for RSL and WGL lumpectomy

	WIRE Group		SEED Group		
Description	N	Re-excision (%)	N	Re-excision (%)	P-value
All Patients	102	27 (26.4)	55	12 (21.8)	0.520
DCIS	36	10 (27.8)	19	4 (21.1)	0.586
IDC	43	10 (23.3)	12	3 (25.0)	0.900
IDC/DCIS	22	6 (27.3)	22	5 (22.7)	0.728
ILC	1	1	1	0	NA
Papillary CA	0	0	1	0	NA

Note: N = number of patients, entry in Re-excision column = number (%), the Chi-square procedure for comparing two percentages was used to determine the P-level. NA = sample size too small for statistical comparison.

403885 - Favorable outcomes with oncoplastic partial breast reconstruction using BioZorb®: An interim registry report on 662 enrolled patients

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Background/Objective: Up to 30% of women report poor cosmetic outcomes following breast-conserving surgery (BCS). Unfortunately, repair of these post-treatment deformities is difficult. While partial breast reconstruction with oncoplastic tissue re-arrangement can help improve these outcomes, it introduces imaging ambiguities that can complicate radiation targeting and future follow-up. To improve identification of the tumor bed for radiation targeting and planning, a 3D implantable marker was designed and has been studied in the setting of partial breast reconstruction within an IRB-approved registry. Ensuring clear visibility of the tumor bed differentiates the appropriate target tissues from surrounding mobilized oncoplastic tissue flaps and unrelated interstitial seroma fluid. The following interim report from a US-based clinical registry examines visibility of the device, its utility as judged by radiation oncologists, and the overall impact on cosmesis as reported by surgeons and patients. Demographic information, complication rates, and tumor characteristics are also analyzed.

Methods: Following informed consent, a total of 662 patients were enrolled in a multi-center clinical registry (14 centers over 3 years with 526 patient follow-ups). Eligible patients undergoing BCS were

implanted with the 3D implantable marker (BioZorb, Focal Therapeutics, Inc Aliso Viejo, CA). 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 irradiation planning and/or treatment targeting.

Results: Data on 526 patients with mean follow-up 12.3 months ranging from 6.3 to 53.4 months (FU: 58% 0-12 months, 28% 12-24 months, 13% 24-48 months) were collected and analyzed for this study. Median age was 63 years, 81% of women were post-menopausal. Breast size was evenly distributed between cup size B (27%), C (33%) and >D (36%). Cancers were in-situ (20%) and invasive (80%) measuring T1 (58%) and T2 (16%). Oncoplastic partial breast reconstruction with the implantable marker was concomitantly performed on 95% of patients (34% with minor mobilization of local tissue flaps, 61% with moderate/extensive tissue rearrangement). Re-excision with removal of implant (including mastectomy for extensive disease) occurred in 2.1% of patients. Patients having any sign of erythema, inflammation or infection of the breast or axilla was 1.96%. One cancer recurrence was reported. Radiation oncologists reported improved accuracy (93%) and easy visualization (95%) when planning and/or targeting the boost using the device. Our study shows long-term excellent or good cosmesis as judged separately by both physicians (90% good/excellent) and patients (88% good/excellent).

Conclusions: This interim report of 662 patients enrolled in a multi-center registry covering 12 states suggests good/excellent cosmesis can be achieved in the vast majority of patients following oncoplastic partial breast reconstruction using a 3D implantable marker. Improved identification of the radiation tumor bed combined with the space occupying structure of the device are likely factors contributing to the excellent cosmesis reported in these patients. Ongoing study of this group of patients will further clarify the value of using a 3D implantable marker.

403994 - Assessment of a new method for localization of non-palpable breast lesions

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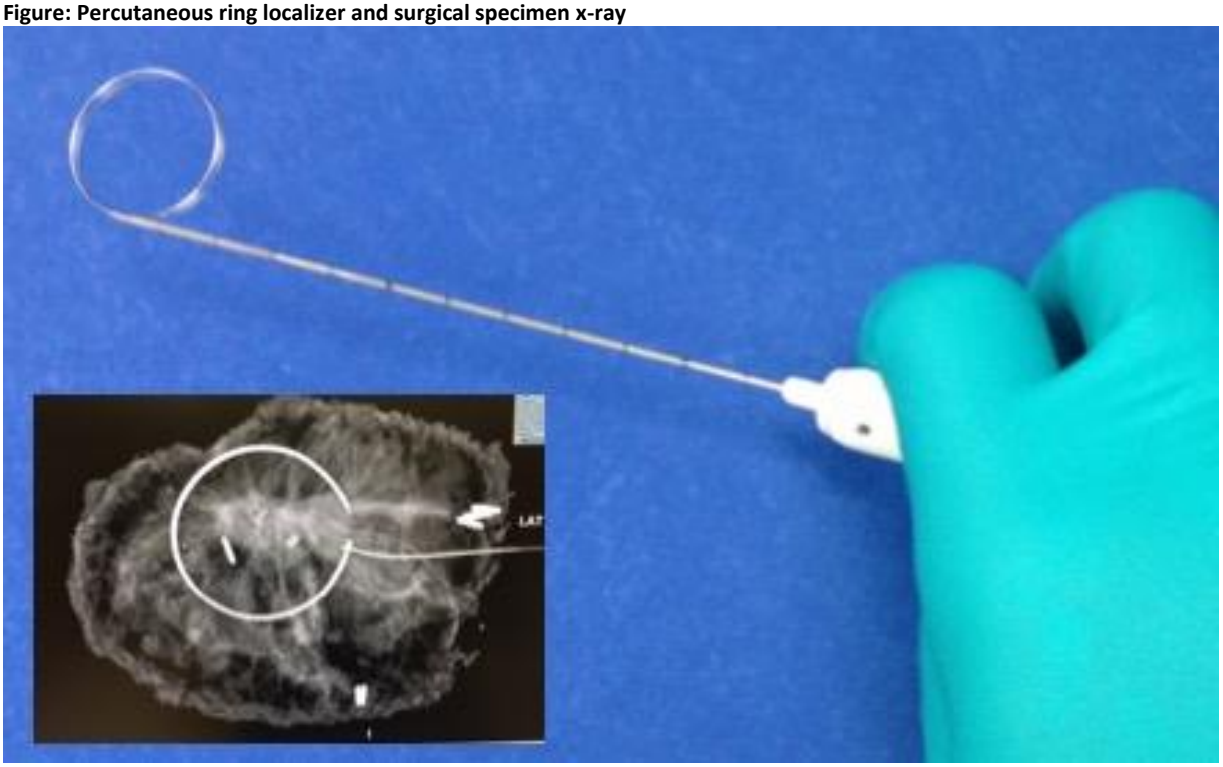
Background/Objective: Wire localization has long been the standard of care to assist surgeons with accurately locating and excising non-palpable lesions of the breast. However, difficulties associated with the procedure have prompted development of alternative technologies. The challenges to address include scheduling conflicts, accuracy in targeting the lesion, dislodgement of the wire, delays in surgery start time, and overall inconvenience for patients and clinicians. Valuable features of wire localization for the surgeon include tactile and visual cues during dissection however, these benefits are lost with the new platforms being introduced. Also, these new devices are costly, as they are complex consisting of an implantable percutaneous marking device, and a required complex intra-operative detection system. In this pilot series of patients, we examined an alternative approach that encircles the suspected lesion providing a perimeter to visually and palpably guide the surgeon during dissection, allowing placement of remote incisions and a more familiar and cost-effective procedure. The device is based on a simple needle deployment platform which may occur days before the procedure. In this study, we examine the utility of this new method of percutaneous localization.

Methods: Following informed consent, 26 patients undergoing partial mastectomy for a non-palpable lesion in the breast were evaluated in a prospective manner. The localization device consists of a needle cannula that houses a nitinol ring. The needle is advanced into the breast under ultrasound guidance, and the ring is manually deployed into the breast forming a circle around the target lesion, leaving a highly flexible tail portion emerging from the skin. The deployed nitinol ring encircles the lesion as opposed to penetrating the center or localizing a single point near the edge of the lesion. Performance data of the device were collected for both the placement and surgical removal in 26 patients. Two patients had more than 1 lesion localized prior to surgery.

Results: Surrounding the lesion in this manner provided visual and tactile cues for the surgeon while the shape of the nitinol ring and flexible tail portion provided protection against migration or discomfort when placed prior to surgery. Four patients had the device placed more than 24 hours prior to surgery. Fourteen of 28 placements were performed by the surgeon, and 14 of 28 were placed by the radiologist. All placements were performed using ultrasound guidance with an average placement time of 6.7 minutes. All deployments were accurately situated at the intended target with no evidence of migration or hematoma. Complete excision with negative margins on final histologic examination occurred in 28 of 28 lesions. No re-excisions were necessary. The average time from skin incision to completion of surgery was 22 minutes. There were no complications associated with placement or removal of the device.

Conclusions: This pilot study describes a novel method of localization for non-palpable breast lesions. The ring can be placed up to 30 days prior to surgical removal allowing for flexibility in scheduling for both surgeons and radiologists. Further evaluation of this unique device is warranted.

Figure: Percutaneous ring localizer and surgical specimen x-ray



405148 - A new era of pre-operative breast lesion localization

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Background/Objective: This study evaluates the new non-wire localization technologies for detection of nonpalpable breast lesions that could replace the traditional WL and eliminate its disadvantages. Radioactive seed localization (RSL) became popular by overcoming many of the disadvantages of WL. However, its strict safety procedures for handling the radioactive materials limit the use of RSL at some institutions and outpatient centers. The disadvantages of WL and RSL have led to the development of other types of pre-operative localization procedures that are recently cleared by US Food and Drug Administration. This study evaluates a radar reflector using micro-impulse radar (SAVI SCOUT, Cianna Medical Inc, Aliso Viejo, California), a magnetic seed (Magseed, Endomagnetics Inc, Austin, Texas), and a radiofrequency tag (Faxitrons LOCalizer, Faxitron Inc, Tucson, Arizona) in detection of nonpalpable breast lesions.

Methods: This study evaluates the patients scheduled to have breast-conserving surgery of a nonpalpable breast lesion from August 2016 to August 2017. The patients were selected from Johns Hopkins Bayview Medical Center in Baltimore, Maryland, and they were consulted about the different non-wire devices. Eighteen patients were consented to use the non-wire devices, and these patients were divided into SAVI SCOUT, MAGSEED, and FAXITRON groups. The patients had the non-wire reflectors placed up to 7 days before surgery, and placement was confirmed by mammography or ultrasonography. The presence of the implanted reflectors was confirmed by radiography on the day of the surgery, and the reflectors were detected by the headpieces during the surgery, excised, and sent for routine pathology.

Results: The reflectors for each non-wire localizers were successfully placed in 6 patients. All the 18 lesions and reflectors were successfully removed during surgery and were reported with clear margins. The OR delays for all patients in each group were recorded, and using the hospital database, these recorded delays were compared to the OR delays in WL patients within the same timeframe. The average OR delays for WL was reported to be 60 minutes in the same medical center, and the non-wire localization patients had significantly decreased or negligible OR delays.

Conclusions: Non-wire nonradioactive localization techniques provide a reliable and effective alternative method for the localization and surgical removal of nonpalpable breast lesions. Comparing to WL, the non-wire localization allows image-guided placement before the day of the surgery resulting in improved workflow and lowered OR delays that are often a noticeable disadvantage of WL. These techniques also avoid the bothersome protruding wires and risk of wire dislodging in WL and the strict nuclear regulatory requirements for RSL.

404170 - Ultrasound localization for breast conservation surgery: A safe and efficacious alternative to wire localization

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Background/Objective: Mammographic or sonographic guided wire localization is the standard method of tumor localization for patients undergoing breast conservation surgery (BCS). These techniques require an added percutaneous procedure prior to the operation without the use of general anesthesia, causing discomfort and stress for the patient. Wire localization may also pose scheduling challenges for surgeons and operating rooms. Migration of the wire between placement and the operation has also been reported. In hopes of alleviating some of these challenges, percutaneously placed radio-sensitive implants have become an alternative to wire localization. These costly novel implants may provide convenience in scheduling; however, it does not eliminate the separate percutaneous procedure and the associated patient discomfort nor are long-term data available on its safety. In light of these issues, this study investigates the efficacy of intra-operative ultrasound (IUS) localization for BCS. Ultrasound machines are widely available, easy to use, and pose minimal discomfort or risk to the patient. This modality has been examined previously in several smaller studies, but to our knowledge, this is the largest cohort of patients to be analyzed.

Methods: A single-institution, retrospective review of all patients undergoing oncoplastic BCS between January 2012 and January 2017 was conducted. Patients were categorized according to the method of localization as either intra-operative ultrasound (IUS) or wire localization (WL). IUS was selected for localization if the lesion was visible sonographically on pre-operative workup. The ability to localize the index lesion, margin status, and re-excision rates as recommended by a multidisciplinary tumor board were compared for each group. Chi-square test was used to compare the cohorts and $p<0.05$ was considered significant.

Results: There were 867 cancers treated between Jan 1, 2012 and Jan 30th, 2017 by 2 breast surgeons at a single institution: 105 underwent mastectomy, while 762 elected for oncoplastic BCS. Of the patients undergoing BCS, 51 did not require any localization. Among the 711 localized BCS patients, 335 (47%) were localized with IUS, and 376 (53%) were localized with pre-operative WL. In the IUS group, 223 (67%) had IUS performed by US technician and surgeon with pre-operative maximum dimension ranging from 4mm to 68mm with an average of 16.3mm. One hundred twelve (33%) had ultrasound performed by surgeon only with pre-operative maximum dimension ranging from 6mm to 77mm with an average of 16.2mm. In the WL group, 339 (90%) underwent mammographic WL, and 37 (10%) underwent ultrasound guided WL. All target lesions were identified at the time of surgery regardless of localization method. The re-excision rate was 20% in the IUS groups compared to 30.6% in the WL ($p=0.0014$). There was no tumor on ink in 90.7% of the IUS group and 83% of the WL group ($p=0.0028$). Histology in the WL groups was more predominately purely in situ disease (40.2%) than the IUS group (2.4%).

Conclusions: Although microcalcifications are not reliably visible on ultrasound, this study shows that a significant number of breast cancer patients have sonographically visible lesions. With improved technology, even small lesions or post-biopsy changes can be utilized as a sonographic target. IUS is a safe and effective localization method for patients undergoing BCS and should be considered as an alternative to invasive wire localization when planning for BCS.

Table: Ultrasound lesion characteristics

Sonographic Size of Lesion	≤ 10mm	>10mm, ≤20mm	>20mm
	Range 4mm-10mm	*Range 11mm-20mm*	*Range 21mm-77mm*
Ductal carcinoma in situ	2 (2%)	4 (3%)	3 (4%)
Invasive ductal carcinoma	72 (67%)	116 (75%)	48 (66%)
Invasive lobular carcinoma	11 (10%)	16 (10%)	7 (10%)
Other histology *	22 (21%)	19 (12%)	15 (21%)
No tumor on ink	99 (93%)	144 (93%)	61 (84%)
Re-excision	17 (16%)	33 (21%)	18 (25%)
Total	107 (32%)	155 (46%)	73 (22%)

*Other histology includes: mucinous, papillary, ductal and lobular features, and metaplastic

404316 - Cutting healthcare costs with hematoma-directed ultrasound-guided (HUG) breast lumpectomy

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Background/Objective: Health care reform aims to simultaneously reduce health care costs and improve patient experience without negatively impacting quality of care. Value-based reimbursement in oncology will force providers to play an active role in cutting expensive cancer care. Localization of non-palpable breast lesions for breast-conserving surgery (BCS) remains highly variable across the country and includes needle/wire localization (NL), radioactive seed localization, radar localization, and hematoma-directed ultrasound-guided (HUG) lumpectomy. The superiority of HUG lumpectomy over NL has been demonstrated repeatedly in terms of safety, accuracy, low positive margin rates, cosmesis, and patient satisfaction. Here, we evaluate the cost-effectiveness of HUG lumpectomy over NL for non-palpable breast lesions.

Methods: We performed a retrospective review of 432 patients who underwent both core needle biopsy and lumpectomy at our comprehensive cancer center between May 1, 2014 and October 31, 2017. Lumpectomies were stratified by localization technique: wire/needle localization versus hematoma-directed ultrasound-guided. Cost estimates were calculated for each procedure and compared. A cost-savings estimate was determined for the HUG localization technique, and a total amount of dollars saved over the entire study period was calculated.

Results: There were 432 lumpectomies performed in patients who underwent CNB at our institution during the nearly 3 ½-year study period: 61 (14.1%) via NL (CPT 19125) and 371 (85.9%) via HUG (CPT 19301 and 19120). Intra-operative ultrasound (CPT 76998) was used in 429 operations (99.3%). Of the lumpectomies performed by HUG, 166 lesions (44.7%) were visible only on mammogram or breast MRI prior to diagnostic core-needle biopsy (CNB). At our institution, the cost of pre-operative needle

localization by a radiologist (CPT 19281) is $497.00. Cost estimates comparing HUG lumpectomy with NL demonstrated an average cost savings of $497.00 per procedure, which amounted to a total of $82,502.00 for the entire 3 ½-year study period.

Conclusions: Hematoma-directed ultrasound-guided lumpectomy is safe, accurate, and has a low positive margin rate when compared to needle/wire localization. The initial CNB serves as both the diagnostic and localization procedure, thus saving time and a painful second procedure on the day of operation. In keeping with health care reform goals, HUG lumpectomy reduces health care costs, betters patient experience, and improves the quality of care surrounding surgical excision of non-palpable breast lesions.

404137 - Comparison of radioactive seed localization, wire localization, and intra-operative ultrasound guidance in breast-conserving surgery for non-palpable breast cancer at a single institution

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Background/Objective: More than one-third of breast cancers are not palpable at diagnosis, and accurate localization is essential for complete resection. Current literature does not favor 1 localization technique. We evaluated margin status after use of 3 localization techniques in breast-conserving surgery for non-palpable breast cancer.

Methods: We performed a retrospective review of women undergoing breast-conserving surgery for non-palpable invasive breast cancers and ductal carcinoma in situ (DCIS) at a single, high-volume institution between 1/1/2008 and 9/2/2015. Patients underwent wire-guided localization (WGL), radioactive seed localization (RSL), or intra-operative ultrasound (IOUS) based on surgeon practice. Data evaluated included demographics, histology, tumor size, sentinel node status, hormone receptor status, specimen volume, resident involvement, surgeon, additional margin excision at index operation, pre-operative imaging, and operative duration.

Results: A total of 696 procedures (690 patients) were analyzed. Most patients were Caucasian (95.3%). The groups significantly differed ($p<0.05$) in age, pre-operative imaging with tomosynthesis, resident involvement, specimen volume, and operative time. Significantly more WGL and RSL procedures had positive margins compared to IOUS (Table). Operative time and specimen volume were significantly higher for IOUS than for WGL or RSL. When controlling for age, specimen volume, additional margins at index operation, resident involvement, operative time, localization technique, pathology, pre-operative MRI, and surgeon, IOUS had the lowest positive margin rate. WGL procedures were 5.5 more likely to be associated with positive margins (OR: 5.5; 95% CI: 1.5 - 20.4), and RSL procedures were 5.8 times more likely to be associated with positive margins (OR: 5.8; 95% CI: 1.4 - 24.4) compared to IOUS procedures.

Conclusions: Localization with IOUS resulted in significantly fewer positive margins than WGL and RSL on both univariate and multivariate analyses. Notably, this was not impacted by many factors thought to affect margin positivity. Further studies would be beneficial in determining if our results at a single institution are reproducible.

Table:

	WGL	RSL	IOUS	p-value
Age (years)[#]	64.3±10.4[a,b]	62.5±11.3[a,c]	65.8±10.0[b,c]	0.164[a], 0.362[b], 0.027[c]
Receptor Status				
ER+	90.0%	91.4%	89.7%	0.848
PR+	80.2%	83.2%	86.2%	0.296
HER2+	7.7%	6.1%	8.1%	0.793
Screening Results				0.372
Mass	66.7%	69.6%	73.5%	
Calcification	33.3%	30.4%	26.5%	
Pre-op Imaging				
Tomosynthesis	18.3%	56.7%	33.6%	<0.001
Ultrasound	65.6%	73.8%	70.7%	0.124
MRI	51.1%	54.5%	50%	0.677
Resident Involvement	45.5%	39.8%	2.6%	<0.001
Additional margin excision	45.6%	35.5%	40.4%	0.064
Total Specimen Volume (cm^3)*	64.2 (9.7 – 551.9)[a,b]	53.5 (8.4 – 296)[a,c]	150 (28.1 – 900.1)[b,c]	0.011[a], <0.001[b,c]
Operative Time (min)*	61 (19 – 243)[a,b]	58 (20 – 249)[a,c]	127 (47 – 288)[b,c]	0.547[a], <0.001[b,c]
Pathologic Diagnosis				0.646
DCIS	31.3%	32.6%	30.2%	
IDC	59.8%	58.8%	64.7%	
ILC	7.1%	5.3%	4.3%	
other invasive cancers	1.8%	3.2%	0.9%	
Positive margin^	13.5%[a,b]	16.6%[a,c]	5.2%[b,c]	0.323[a], 0.014[b], 0.003[c]

[#]Data are shown as the mean±SD
*Data are shown as median (min-max)
^Significance was set at p<0.017 due to multiple comparisons, all others set at p<0.05
MRI = Magnetic Resonance Imaging
IDC = invasive ductal carcinoma
ILC = invasive lobular carcinoma

404276 - Is SAVI SCOUT localization as accurate as needle-localization in obtaining negative margins at time of breast conservation?: A single institutional experience

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Background/Objective: The purpose of this study was to evaluate the efficacy of initial implementation of the SAVI SCOUT (Cianna Medical) localization technique at time of lumpectomy for breast cancer, compared to use of wire- or needle-localization, as determined by margin positivity rate at a single institution.

Methods: A retrospective chart-review was performed from July 2016 to March 2017, on the initial 127 consecutive female patients who underwent SAVI SCOUT intra-operative localization at a single institution. All patients had biopsy-proven DCIS or invasive breast histology, and underwent partial mastectomy after percutaneous biopsy with stereotactic or ultrasound guidance. The outcomes of these patients were compared to 308 consecutive cases of biopsy-proven cancer, from January-December 2015, who underwent needle- or wire-localization at time of lumpectomy.

Results: Using the SAVI SCOUT system for tumor localization, 13/127 (10.2%) patients had a positive margin on final pathology. This included 3/38 (7.9%) patients who underwent pre-operative MRI scanning. In 1 case, the SAVI SCOUT failed to localize the cancer, necessitating intra-operative wire localization. Using the standard needle-localization, 52/308 (16.9%) patients had positive margins on final pathology, including 15/77 (19.5%) who had pre-operative breast MRI. At time of initial resection, 49/127 (38.6%) patients who underwent SAVI SCOUT localization had separate margins sent for permanent pathology, compared to 86/308 (27.9%) of patients who underwent needle localization.

Conclusions: Intra-operative localization of non-palpable breast cancer using SAVI SCOUT for breast conservation optimizes the surgeons ability to achieve negative resection margins, even during initial implementation, compared to the standard needle-localization method.

Table: Positive margin rate based on pathology and localization method

SAVI SCOUT		
	Positive margin	**Percent positive margin**
Total cases	**13/127**	**10.2%**
invasive	**8/88**	**9.1%**
DCIS	**5/39**	**12.8%**
Needle Localization		
Total cases	**52/308**	**16.9%**
Invasive	**46/249**	**18.9%**
DCIS	**6/59**	**10.2%**

LRR

404021 - The 21-gene recurrence score assay as a predictor of locoregional recurrence

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Background/Objective: The National Comprehensive Cancer Network and the American Society of Clinical Oncology include the 21-gene Recurrence Score (RS) Assay in their guidelines for evaluation of early-stage, ER-positive, HER2-negative, node-negative breast cancer, accepting that this tool accurately predicts the likelihood of distant recurrence (DR) and benefit of chemotherapy in this population. The association of RS with locoregional recurrence (LRR), and its use in selecting patients for omission of radiotherapy is less well studied.

Methods: Clinicopathological factors as well as outcome data were examined for 271 consecutive patients with newly diagnosed breast cancer who underwent RS testing between 2006 and 2017. Descriptive statistics were used to compare the RS with LRR and DR rates.

Results: A total of 271 patients had RS ordered for a newly diagnosed breast cancer between 2006 and 2017. Median patient age was 57, mean 56. All patients were female. All patients were ER+. One hundred ninety-five (72%) were white, 29 (10.7%) were African American, 34 (12.5%) were Hispanic, 11 (4.1%) were Asian, and race was not available for 1 patient. Two hundred four had node-negative disease, and 60 had at least 1 positive lymph node. Nodal status was not available for 7 patients. Twenty-five percent of patients had histologic grade 1 tumors; 58% and 17% had grade 2 and grade 3 tumors, respectively. Seventy-nine percent of patients had had tumors 2cm. Median follow-up was 66 months. Nine patients had LRR, and 12 patients developed DR. Recurrence Score Results Median RS was 17. Fifty-two percent of the patients had RS <18, 36% had RS 18-30, and 12% of patients had RS >30. There was no difference in the distribution of RS in relation to whether patients developed LRR. There was also no difference in mean RS in relation to LRR. The mean RS for patients with no LRR was 19. Mean RS for patients with LRR was 20. There was a significant difference in mean RS for patients with DR versus those without recurrence. The mean RS for patients with no DR was 19, and mean RS for patients with DR was 30 ($p<0.001$).

Conclusions: RS results are now included in prognostic stage group in the 8th edition of the American Joint Commission of Cancer staging manual. It is clear that this assay will continue to guide adjuvant therapy decisions in breast cancer. Our study confirmed RS as predictive of DR in hormone receptor positive breast cancer, correlating with the current literature. In our population, RS was not associated with LRR. Our findings suggest that RS is not a useful tool in selecting patients for omission of radiotherapy.

404131 – Long-term effective local control in patients presenting with T4 disease and treated with breast-conserving therapy after neoadjuvant chemotherapy

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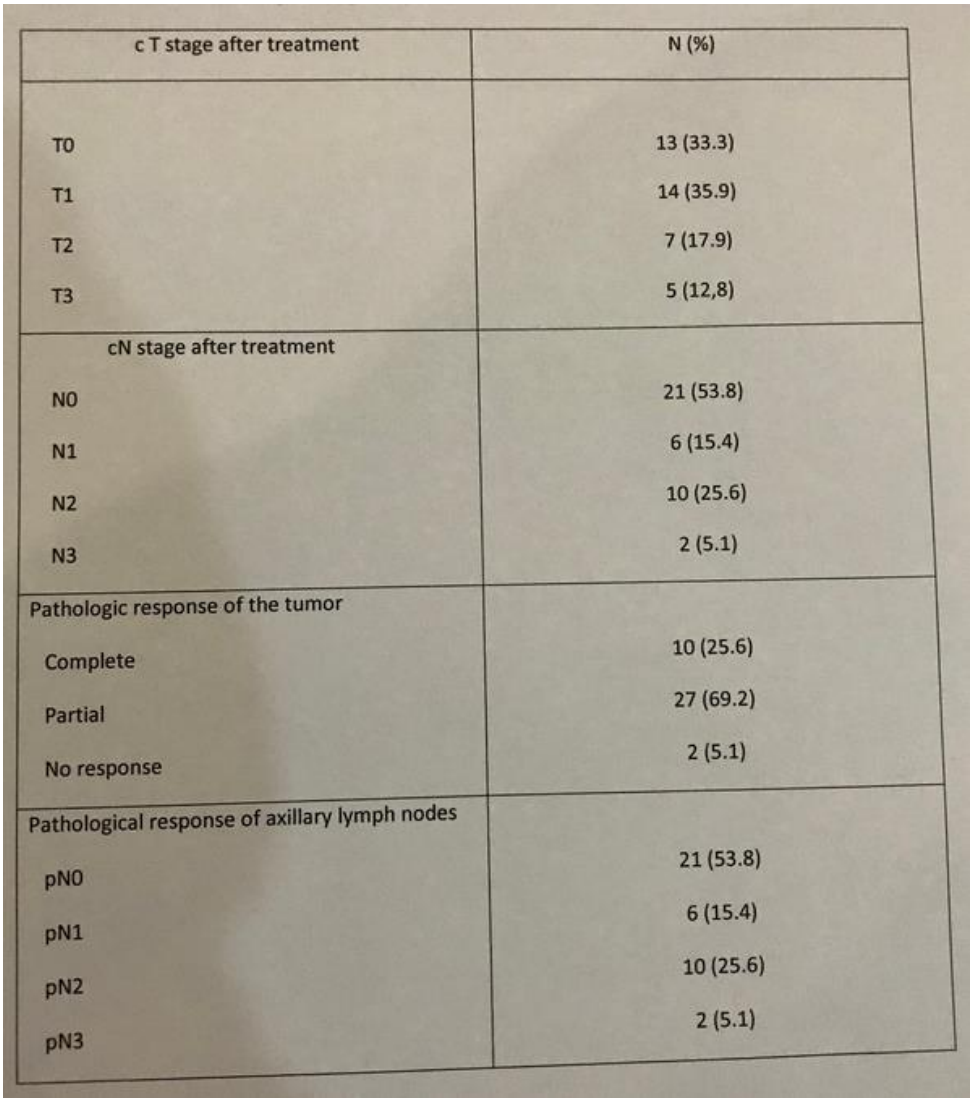
Background/Objective: T4 locally advanced breast cancer is associated with a relatively higher local recurrence that may be a contraindication for breast-conserving therapy (BCT) even after neoadjuvant chemotherapy. After implementation of new drugs and targeted therapies, the pathologic complete and partial response rates were improved with contemporary management by increasing survival rates in all patients. This study aimed to evaluate the long-term local control obtained in patients who initially present with T4 breast cancer involving the skin and treated with BCT after neoadjuvant chemotherapy at our institution.

Methods: Between May 1999 and May 2015, of 570 patients, 39 patients (7%) with T4 breast cancer underwent BCT following neoadjuvant chemotherapy and/or hormonotherapy, and long-term local recurrence rates were investigated. Patients with skin findings including diffuse erythema and peau d'orange were excluded from the study. Clinicopathologic factors, locoregional and distant recurrence were investigated.

Results: All patients had a localized T4 disease as defined localized skin involvement, including localized erythema, and/or skin edema, and/or skin invasion. Median age was 49 (28-88) years. Twenty-one patients (51.3%) were under 50 years of age. The immunohistological staining revealed that 26 tumors (66.7 %) were luminal type, 8 tumors (20.5 %) had HER2-neu overexpression, and 5 tumors (12.8 %) were triple-negative. The clinical and pathological breast complete response rates were 33.3% and 25.6%, respectively (Table). Post-treatment tumor features and pathologic response rates were summarized in the Table. The median follow-up time was 80.8 months (12-153). Local recurrence was seen only at the 27th month as ipsilateral breast cancer recurrence of a patient with triple-negative tumor. The actuarial ipsilateral breast cancer recurrence rate was 4.2% at 5 years. Furthermore, 5- and 10-year disease-free survival were 90% and 61%, respectively, whereas 5- and 10- year disease-specific survival rates were 96% and 75%, respectively.

Conclusions: These results suggest that patients initially presented with T4 disease can be safely treated with BCT if negative surgical margins can be achieved after neoadjuvant chemotherapy. Carefully selected patients have excellent long-term local control and survival with contemporary management. Mastectomy is not warranted for all patients with breast cancer who present with skin involvement.

Figure: Tumor clinical and pathologic responses



c T stage after treatment	N (%)
T0	13 (33.3)
T1	14 (35.9)
T2	7 (17.9)
T3	5 (12,8)
cN stage after treatment	
N0	21 (53.8)
N1	6 (15.4)
N2	10 (25.6)
N3	2 (5.1)
Pathologic response of the tumor	
Complete	10 (25.6)
Partial	27 (69.2)
No response	2 (5.1)
Pathological response of axillary lymph nodes	
pN0	21 (53.8)
pN1	6 (15.4)
pN2	10 (25.6)
pN3	2 (5.1)

Lymphedema

404072 - Efficacy of evidence-based professional education on strategies for lymphedema prevention in post-operative breast cancer patients

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Background/Objective: Lymphedema remains a significant source of morbidity among post-operative breast cancer patients, a fact highlighted by the American Society of Breast Surgeons 2017 Lymphedema Panel. While lymphedema prevention remains a critical element of mitigating some risk for development in post-operative patients, preventive measure are numerous and enjoy widely varying degrees of support from the peer-reviewed literature. The objectives of this study were to assess health care worker perceptions regarding strategies for lymphedema prevention in patients who had undergone surgery for breast cancer and determine the efficacy of an educational intervention in changing perceptions regarding such strategies.

Methods: A 13-question survey focused on the management of breast cancer related lymphedema was drafted and distributed electronically to attending physicians, resident physicians, and nurses. After responses had been collected, an evidence-based lecture addressing content relevant to lymphedema risk factors, prevention, and management was given to each group, and a post-session survey with content identical to the pre-education session survey was then distributed. Combined responses to the pre- and post-educational session surveys were compared to determine the efficacy of this educational session in changing perceptions regarding lymphedema prevention.

Results: A total of 88 individuals responded to the pre-education session survey (PRE), and 48 individuals responded to the post-education survey (POST). Most were surgeons (66% PRE, 83% POST) and had been in practice for 10 years or fewer (71% PRE, 85% POST). Between 27% (POST) and 38% (PRE) of respondents specialized in some form of oncology. Respondents correctly identified axillary lymph node dissection as conferring a higher risk for lymphedema than sentinel lymph node biopsy both before and after the educational session (91% PRE vs. 89% POST, $p=0.77$). There were no significant differences in correct identification of risk factors for developing lymphedema namely increased body mass index (77% PRE vs. 79% POST, $p=0.83$) and radiation therapy (94% PRE vs. 98% POST, $p=0.42$). After the educational session, respondents more often correctly noted a 3-year window post-operatively within which most patients who develop lymphedema begin to manifest symptoms (44% POST vs. 9% PRE, $p<0.001$). After the educational session, respondents were more likely to allow use of blood pressure monitoring or tourniquet placement on the arm on the side of previous axillary surgery (mean 3.2 POST vs. 2.3 PRE (scale 1-5), $p<0.001$), more likely to allow blood draws or IV access on the arm on the side of previous axillary surgery, and more likely to allow aerobic exercise and weight training in patients with a history of breast surgery (mean 3.3 POST vs. 2.2 PRE (scale 1-5), $p<0.001$). The majority of respondents believed that an education session would be able to change their current practice before and after the session (mean 3.8 PRE, 4.0 POST (scale 1-5)).

Conclusions: A lecture-based educational session regarding lymphedema risk factors, prevention, and management can help improve understanding of the evidence surrounding these topics and change clinician perceptions about effective strategies for prevention. Larger-scope, multi-disciplinary intervention may facilitate improved, evidence-based lymphedema care in post-operative breast cancer patients.

403232 - Correlation of bioimpedance spectroscopy with risk factors for the development of breast cancer-related lymphedema

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Background/Objective: We reviewed our institutions' experience performing serial L-Dex measurements to quantify the relationship between changes in these scores over time based upon a patients clinical risk for developing breast cancer-related lymphedema (BCRL).

Methods: From April 2010 through November 2016, 505 patients were prospectively evaluated with bioimpedance spectroscopy (BIS) in a structured BCRL surveillance protocol. Patients received pre- and post-operative L-Dex measurements at regular intervals and were categorized based upon the use of sentinel lymph node biopsy (SLNB), axillary lymph node dissection (ALND), taxanes, regional nodal irradiation (RNI), having an elevated body mass index (BMI) or various combinations of risk features. Differences in changes in L-Dex scores (magnitude and time) based upon high-risk features were analyzed.

Results: The change in L-Dex was associated with the type and number of risk factors. Both ALND and RNI were associated with a greater change in L-Dex ($p<0.001$). The median, maximal change in L-Dex for patients treated with ALND/RNI/Taxane was 16.7 versus 5.2 for ALND alone and 3.7 for SLNB alone ($p=0.016$). The effects of risk factors were additive. In a multiple linear regression model using all 4 risk factors to predict the maximal change in L-Dex, ALND and RNI still remained significantly associated with greater maximum change ($p<0.05$). The time required to reach the maximal change in L-Dex was also shorter in patients treated with ALND or RNI. (the time for 25% of patients achieving an L-Dex 7 was 4.3 months for ALND/RNI/Taxane patients versus 30.8 months for SLNB alone patients).

Conclusions: Risk factors for the development of BCRL were associated with both the magnitude of change in L-Dex scores and the time to reach maximal changes. These findings demonstrate the utility of serial L-Dex measurements in providing an objective assessment of a patients lymphedema status and the value of L-Dex serial measurements to assist in monitoring patients for the development of BCRL.

Male Breast Cancer

403898 - Atypical ductal hyperplasia in men with gynecomastia: What is their breast cancer risk?

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Background/Objective: Atypical ductal hyperplasia (ADH) significantly increases the risk of breast cancer in women. However, little is known about the implications of finding ADH in men having surgery for gynecomastia.

Methods: Review of 1093 male breast pathology reports from January 1987-September 2017 was performed using natural language processing to identify cases of ADH. Male ADH cases were then manually reviewed, and patients were excluded if ADH was upgraded to ductal carcinoma in situ or invasive cancer on excision, or if they were diagnosed with previous or concurrent contralateral breast cancer. Subsequent clinician notes and pathology reports were evaluated to determine if any male with ADH developed breast cancer.

Results: Eighteen male patients were diagnosed with ADH from June 2003-September 2017. Fifteen patients had bilateral gynecomastia, and 3 patients had unilateral gynecomastia. Pre-operative imaging included mammography in 7 patients and both mammography and ultrasound in 2 patients; 9 patients had no pre-operative imaging. Cause of gynecomastia was listed as anabolic steroids in 1, alcohol abuse in 1, low testosterone in 1, obesity in 1, possibly trauma in 1, and unknown/idiopathic in 13 patients. Description of surgical procedure was subcutaneous mastectomy in 7 patients and excision or reduction in 11 patients. No patient had their nipple areola complex removed, although 1 required a free nipple graft. Median patient age at ADH diagnosis was 25 years (range: 18-68 years). Of the 15 patients with bilateral gynecomastia, 12 had bilateral ADH, and 3 had unilateral ADH. Two cases of ADH were described as severe ADH, bordering on ductal carcinoma in situ. No patient reported a family history of breast cancer. No patient took tamoxifen. At a median follow-up of 85 months (range: 1-168 months), no patient developed breast cancer. One patient developed recurrence of gynecomastia with benign pathology on excision.

Conclusions: To our knowledge, this is the first study evaluating the risk of breast cancer in men diagnosed with ADH. With a median follow-up of 7 years, no patient developed breast cancer. This suggests that ADH in men does not pose the same risk as ADH in women, although longer follow-up is necessary for confirmation.

403892 - The surgical treatment of male breast cancer: An analysis of the National Surgical Quality Improvement Program (NSQIP) database

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Background/Objective: Male breast cancer is a rare malignancy, and gender-specific treatment guidelines and outcomes are lacking. We examined the treatment patterns and post-operative complication rates in male patients undergoing oncological breast surgery using a large multi-national surgical outcomes database.

Methods: A retrospective cohort analysis was conducted between 2011 and 2015 using the American College of Surgeons National Surgical Quality Improvement Program database (NSQIP). We identified all men undergoing breast surgery for the treatment of invasive or in situ carcinoma of the breast. We sought to describe the clinical characteristics, demographics, and surgical treatment plan most frequently used for this population. Our secondary aim was to assess the 30-day post-operative complication rates in the surgical treatment of male breast cancer. Major morbidity was defined as having 1 or more of the following post-operative 30-day complications: wound infection, pneumonia, pulmonary embolus, re-intubation or prolonged mechanical ventilation, renal failure, sepsis, myocardial infarction, cardiac arrest, and cerebral vascular accident.

Results: A total of 526 patients were included. Mean age at the time of surgery was 65.3 years old (Standard deviation (SD): 12). The majority of patients were Caucasian (72%) or African American (14%). Mean body mass index was 30.4 (SD: 6.6). Of the 526 patients, 93 (23%) had a diagnosis of in situ breast cancer. Surgical management: 79 (15%) underwent lumpectomy or partial mastectomy, 400 (76%) had a simple mastectomy, 5 (1%) subcutaneous mastectomy, and 16 (3%) modified radical mastectomy. Overall, the rate of major morbidity and superficial skin infections were both 1.9%; 19 (3.6%) patients had to undergo re-operation within 30 days.

Conclusions: Analysis of this large, prospective, multi-institutional cohort showed that the complication rates are low and comparable to what has been described in the literature for female breast cancer population. In some cases, men are undergoing breast-conserving surgery for the treatment of their breast cancer. This study adds to the literature regarding surgical treatment for this uncommon malignancy in men.

404153 - Breast cancer surgery in men: Characteristics, outcomes, and trends

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Background/Objective: Breast cancer is the most common noncutaneous cancer among women in the United States, but male breast cancer is a rare entity. To analyze differences between men and women undergoing surgery for breast cancer, we queried the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) database.

Methods: Patients of both genders who underwent resection of breast cancer between 2010 and 2014 were included in this study. Demographic data, peri-operative variables, and 30-day morbidity were analyzed and compared between male and female patients. Differences in group characteristics were calculated using Stata IC, Version 14. Chi-square tests and Students t-tests were used to compare

categorical and continuous variables, respectively, between genders. Adjusted logistic regression was performed for differences in outcomes variables.

Results: We identified 81,351 patients who met inclusion criteria, of which 1,049 (1.3%) were male. The observed proportion of male patients decreased significantly over the 5 years (from 1.8% in 2010 to 1% in 2014, p<0.001). Men were slightly older (61.2 vs 60.0 years, p=0.001) and had higher BMI (29.9 vs 28.9, p=0.001) when compared with women. Male patients were also less likely to undergo partial mastectomy (15.1 vs 44.4%, p=0.001). We observed a higher prevalence of diabetes (18.9 vs 12.5%, p=0.001), daily alcohol use (3.4 vs 1.2%, p=0.001), COPD (4.8 vs 2.9%, p=0.001), CHF (0.5 vs 0.3%, p=0.04), hypertension (51.3 vs 44.0%, p=0.001), dialysis dependence (1.0 vs 0.3%, p=0.001), history of TIA (3.2 vs 1.8%, p=0.01), and bleeding disorder (3.7 vs 1.7%, p=0.001) among male patients. Men were less likely to have had chemotherapy within a month before operation (2.2 vs 6.6%, p=0.001). Outcomes were similar between groups, with the exception of an increased risk of superficial surgical site infection among men (2.7 vs 1.7%, p=0.02). After adjusting for age, BMI, and diabetes, this difference remained significant with a risk increase of 52% among male breast cancer patients (OR=1.52, CI 1.042.22, p=0.03).

Conclusions: In this analysis of a nationwide cohort of breast cancer patients, several significant differences between male and female patient populations were observed. Despite the differences in co-morbidities, post-operative outcomes were similar between both groups, with the exception of a significantly higher risk of superficial surgical site infection among men.

403879 - Outcomes after mastectomy for breast cancer, males versus females: An ACS NSQIP study

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Background/Objective: Male breast cancers are often diagnosed at more advanced stages than women. The purpose of this study was to compare patient demographics and post-operative outcomes between males and females who underwent mastectomies for breast cancer, to determine if males had worse outcomes since they are diagnosed later.

Methods: Patients with breast cancer who underwent mastectomies between 2010-2015 codified in the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) database were identified using CPT codes for simple mastectomy, radical mastectomy, or modified radical mastectomy. Chi-square tests and Poisson regression were performed using STATA 14.0. The threshold for statistical significance was set at 0.05.

Results: Upon inquiry of the NSQIP database over 2010-2015, 1,198 (1.9%) men and 62,619 women were identified who had undergone mastectomies. The patient demographics are shown in Table 1. Males were older, had significantly higher ASA class, and were more likely to be obese (BMI >30), diabetic, and/or on hemodialysis at time of surgery. Post-operative outcomes are shown in Table 2. Males were less likely to require blood transfusions and had statistically significant shorter lengths of stay. Other outcomes were not significantly different between males and females undergoing mastectomies.

Conclusions: This is one of few studies comparing males and females, demographics, and post-operative complications for those undergoing mastectomies for breast cancer utilizing the ACS NSQIP database over an extended time period (2010-2015). Pre-operative patient characteristics show that males have

more co-morbidities than females. However, despite this, males overall did just as well as females post-operatively. In addition, they required fewer transfusions and had a slightly shorter length of stay. These results demonstrate that males have similar outcomes to females after mastectomy. This is important for peri-operative planning and patient counseling.

Tables: Pre-operative demographics and outcomes

Category	Males, n (%)	Females, n (%)	P-value
Procedure			
Simple Mastectomy	763 (64)	42,068 (67)	
Radical Mastectomy	29 (2)	1,273 (2)	
Modified Radical Mastectomy	406 (34)	19,278 (31)	
Age			
18-30	67 (5.7)	841 (1.4)	
31-50	190 (16)	18,058 (29)	
51-70	560 (47.3)	30,638 (49.4)	
71-90	368 (31)	12,493 (20.1)	
Ethnicity			
White	827 (70.5)	42,672 (69.7)	
Black	150 (12.8)	6,628 (10.8)	
Asian	28 (2.4)	3,415 (5.58)	
Native American	7 (0.6)	665 (1.1)	
Hispanic	50 (4.3)	3,814 (6.2)	
Unknown	111 (9.4)	4,014 (6.6)	
Diabetic	236 (19.7)	7,632 (12.2)	**<0.001**
ASA class			**<0.001**
I,II	635 (53)	39,206 (62.7)	
III	518 (43.3)	22,352 (35.7)	
IV	44 (3.7)	1,006 (1.61)	
Dialysis- Dependent	14 (1.17)	197 (0.31)	**<0.001**
BMI >30	513 (43.2)	22,314 (36)	**<0.001**
Smokier	145 (12.1)	7,962 (12.7)	NS

Table 1: The preoperative demographics of patients who underwent a mastectomy for breast cancer. **NS = not significant**

Outcome	Males, n (%)	Females, n (%)	P-value
Death	2 (0.17)	97 (0.15)	NS
Any Morbidity	315 (26)	15,659 (25)	NS
Surgical Site Infection	45 (3.8)	2,387 (3.8)	NS
Blood transfusion	9 (0.75)	1,116 (1.8)	**0.007**
Length of Stay			
0-3 days	1,155 (96.4)	58,807 (93.9)	**<0.001**
4-14 days	37 (3.1)	3,649 (5.8)	
>14 days	6 (0.5)	158 (0.26)	
DVT/PE	8 (0.67)	261 (0.4)	NS

Table 2: The post-operative outcomes after patients underwent a mastectomy for breast cancer.

404309 - Male breast cancer: The experience of a single academic institution

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Background/Objective: Although male breast cancer comprises less than 1% of all breast cancer diagnoses, recent data have demonstrated that its prevalence is increasing. In addition, there is paucity of information regarding the most effective treatment approach. We sought to evaluate outcomes of our male patients with breast cancer.

Methods: We analyzed data from a prospectively collected single-institutional breast cancer registry in order to identify male patients treated for breast cancer at our institution between 2003-2015. We extracted demographic information, clinicopathologic characteristics, and surgical and survival outcomes for these patients. We finally employed descriptive statistics.

Results: We identified 47 eligible patients. Mean age at diagnosis was 63. Of these, 31.9% of patients had a family history of breast cancer. Overlapping lesions were most common with a predominance of left-sided tumors. Grade II and III tumors were significantly more common than others while stage varied. Infiltrating ductal carcinoma was the predominant histological diagnosis. Modified radical mastectomy and total mastectomy were the most common surgical treatments. Three men had reconstructive elements to their surgeries. Complications occurred in 27.7% of patients and included hematoma, seroma, and infection. The majority of patients received adjuvant chemotherapy and hormone therapy, while only on1e patient received immunotherapy. Metastasis occurred in 31.9% of cases with the most common site being bone. Recurrences rates were 6.4%. Overall mortality was 27.7% for our follow-up.

Conclusions: Although our results are limited by the retrospective nature of the study, our study provides helpful insight into the clinicopathological characteristics of this rare disease and the experience of the patients who are affected by it.

Table:

Characteristics	n (%)
Race	
White	37 (78.7)
Black	10 (21.3)
Asian Indian or Pakistani	1 (2.1)
Age	
Mean +/- SD	63 +/- 12.6
Family History of Breast Cancer	15 (31.9)
Primary Tumor Site	
Nipple	3 (6.4)
Upper-inner	1 (2.1)
Lower-inner	1 (2.1)
Upper-outer	5 (10.6)
Lower-outer	1 (2.1)
Axillary tail	1 (2.1)
Overlapping lesion	15 (31.9)
NOS	10 (21.3)
Laterality	
Right	19 (40.4)
Left	28 (59.6)
Grade	
Grade I – Well differentiated	1 (2.1)
Grade II – Moderately differentiated	20 (42.3)
Grade III – Poorly differentiated	19 (40.4)
Grade IV = Undifferentiated, anaplastic	7 (14.9)
Stage	
0	5 (10.6)
I	5 (10.6)
IA	4 (8.5)
IIA	9 19.1)
IIB	7 (14.0)
IIIA	5 (10.6)
IIIB	1 (2.1)
IIIC	2 (4.3)
IV	7 (14.0)
UNK	1 (2.1)
Adjuvant Chemotherapy	
None	11 (23.4)
Systemic therapy before surgery	1 (2.1)
Systemic therapy after surgery	28 (59.6)
Systemic therapy both before and after surgery	1 (2.1)
Unknown	6 (12.8)
Hormone Therapy	33 (70.2)
Unknown	1 (2.1)
Immunotherapy	1 (2.1)
Surgery type	
Modified radical mastectomy	15 (31.9)
Modified radical mastectomy with removal of uninvolved contralateral breast	2 (4.3)
Total mastectomy	15 (31.9)
Total mastectomy with removal of uninvolved contralateral breast	1 (2.1)
Mastectomy, NOS	1 (2.1)
Lumpectomy or excisional biopsy	6 (12.8)
No surgery	7 (14.0)
Reconstruction	
Free nipple graft	1 (2.1)
Tissue transfer	2 (4.3)
Complications of surgery	
Seroma	5 (10.6)
Hematoma	4 (8.5)
Infection	4 (8.5)
Histology	
Infiltrating duct carcinoma	32 (68.1)
Adenocarcinoma	3 (6.4)
Papillary carcinoma	1 (2.1)
Lobular carcinoma	2 (4.3)
Infiltrating duct and lobular carcinoma	3 (6.4)
Intraductal carcinoma mixed with other types of carcinoma in situ	1 (2.1)
Intraductal carcinoma	4 (8.5)
Metastases	
Bone	4 (8.5)
Brain	1 (2.1)
Liver	2 (4.3)
Lung	3 (6.4)
Lymphovascular invasion	5 (10.6)
Recurrence	
No recurrence	30 (63.8)
Never disease free	9 (19.1)
Distant recurrence of invasive tumor	3 (6.4)
Unknown	5 (10.6)
Overall Mortality	13 (27.7)

394584 - Comparison of surgical outcomes between breast-conserving surgery and modified radical mastectomy in male breast cancer in the United States (NSQIP)

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Background/Objective: Male breast cancer (MBC) is a rare entity comprising only 1% of all incident breast cancers diagnosed in the United States. Modified radical mastectomy (MRM) remains the standard of care for virtually all MBC. Breast-conserving surgery (BCS) in MBC has been coming to the forefront as a reasonable treatment option. We elected to compare surgical outcomes between BCS and MRM in male breast cancer.

Methods: The National Surgical Quality Improvement Program (NSQIP) database was analyzed for 2015. We reviewed all male breast cancer surgical patients. Partial mastectomy (with and without) axillary lymph node biopsy were compared to MRM. Chi-square and independent t-tests were used to compare the 2 variables for demographics, co-morbidities, and post-operative complications.

Results: A total of 175 patients were analyzed. BCS was performed on 101 males (57.7%), and MRM was performed on 74 (42.29%). Patients who underwent MRM were older than patient who underwent BSC (57 versus 66 years, respectively) ($p<0.0001$). Co-morbidities and patient demographics were overall similar in both groups. Post-operative complications were overall not statistically different. Patients who underwent BS had shorter length of hospital stay ($p<0.0001$) and were more likely to have been operated on under MAC or IV sedation (14.85% vs 0%) ($p<0.0001$).

Conclusions: BSC in male breast cancer is commonly performed in the United States with similar surgical outcomes and shorter length of stay compared to MRM. More studies are needed to determine outcomes on survival between BSC and MRM in male breast cancer.

Table: Comparison of demographics and surgical outcomes between BSC and MRM in male breast cancer patients in the United States in 2015

Variables	BSC (n=101)	MRM (n=74)	Column1
	Mean (SD)	Mean (SD)	P-Value
Age	57.01 (16.50)	65.82 (12.92)	<0.0001
Total Operation Time (mins)	60.96 (45.70)	106.69 (46.73)	<0.0001
Length of Total Hospital Stay (Days)	0.2 (0.68)	1.34 (1.8)	<0.0001
Weight in lbs	195.45 (71.60)	203.78 (50.75)	0.393
	n (%)	n (%)	P-Value
Asian	1 (1.00)	1(1.35)	0.155
Black or African American	11 (10.89)	17 (22.97)	0.155
Unknown/Not Reported	12 (11.88)	10 (13.51)	0.155
White	77 (76.24)	46 (62.16)	0.155
Inpatient	7 (6.9)	26 (35.14)	<0.0001
Outpatient	94 (93.1)	48 (64.86)	<0.0001
General Anesthetic	86 (85.15)	74 (100)	<0.0001
MAC/IV Sedation	15 (14.85)	0 (0)	N/A
Current smoker within one year	13 (12.87)	12 (16.21)	0.34
DM2	7 (6.93)	7 (9.46)	0.119
CHF	2 (1.98)	2 (2.70)	0.556
HTN Requiring Medication	44 (43.56)	42 (56.75)	0.058
ESRD	0 (0.00)	1 (1.25)	N/A
Disseminated Cancer	1 (1.0)	5 (6.8)	0.05
Open Wound Infection	1 (1.0)	3 (4.1)	0.204
Chronic Steroid Use	3 (2.97)	2 (2.70)	0.664
Bleeding Disorder	2 (1.98)	3 (4.1)	0.356
Return to the OR Required	3 (2.97)	4 (5.4)	0.332
Any Readmission Required	3 (2.97)	3 (4.1)	0.504
Superficial SSI	2 (1.98)	5 (6.76)	0.115
Transfusion Intraoperatively/Postopoperatively	0 (0.00)	1 (1.25)	N/A

Margins

404118 - Achieving tumor-free margins: Intra-operative pathology consultation to lower re-excision rates at a community hospital

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Background/Objective: Achieving tumor-free margins in a single surgical procedure is the primary goal for breast-conserving therapy. However, it is not uncommon for these patients to undergo more than 1 operation. Positive margins increase the patients risk of local recurrence and reduced quality of life with multiple procedures. Based on anecdotal data within our patient population, lumpectomy specimens requiring re-excision had gross pathological findings that could have potentially warranted further margin excision at the index surgery, avoiding re-excision all together. Objective: To evaluate the number of re-excision lumpectomies that could have been avoided with intra-operative pathology consultation for grossly positive margins.

Methods: There were 579 patients who underwent lumpectomy who were reviewed retrospectively from 2010 to 2017. Of these patients, 478 were cases of DCIS and invasive ductal carcinoma, which were included in the study. Ninety-two patients underwent re-excision. The gross pathology of each re-excision case was reviewed. Gross findings that came within 2mm margins for DCIS and ink on tumor for invasive ductal carcinoma were considered potentially avoidable re-excisions. Thirty-four cases of the 92 re-excision lumpectomies were found to have positive margins on gross pathologic evaluation at the index surgery.

Results: Of the 478 lumpectomy cases for DCIS and invasive ductal carcinoma, 92 of them underwent re-excision from 2010-2017. The re-excision rate over this time period was calculated to be 19%, with an average of 11 women each year requiring re-excision. Of all 92 cases of women who underwent re-excision surgery, 37% (n=34) of them had gross pathologic findings correlating with positive margins and were potentially avoidable re-excisions. The potentially avoidable re-excision rate according to types of histopathology was 28% in DCIS, 55% in invasive ductal carcinoma, and 53% in combined DCIS with invasive ductal carcinoma.

Conclusions: Based on the Society of Surgical Oncology-American Society for Radiation Oncology Consensus Guideline on margins, the re-excision rate for breast-conserving therapy is 25% in the US. Re-excision surgery has the potential for added discomfort, surgical complications, increased health care cost, and additional unnecessary emotional stress for patients and their families. Our re-excision rate could have been reduced from 19% to 12% if intra-operative pathology consultation had been utilized. By implementing intra-operative pathology consultation for lumpectomies, the re-excision rate can be reduced by more than one-third with the highest impact in patients with invasive ductal carcinoma and combined DCIS-invasive ductal carcinoma.

403908 – Intra-operative gross pathologic inspection can reduce the need for margin re-excision after breast-conserving surgery regardless of surgeon experience

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Background/Objective: Return to the operating room for re-excision of positive or close margins in breast-conserving surgery (BCS) confers a significant emotional and financial cost to patients undergoing surgery for breast cancer. Various techniques have been described in order to decrease the rate of re-excision after BCS. At our institution, immediate gross inspection with intra-operative pathologic consultation and specimen radiograph is used as a real-time method of margin assessment. We hypothesized this practice results in a low re-excision rate after BCS regardless of the surgeon's experience or practice volume.

Methods: A retrospective review of 673 consecutive female patients undergoing BCS for invasive ductal cancer (IDC), invasive lobular cancer (ILC), and ductal carcinoma in situ (DCIS) from January 2014 to July 2017 was conducted. A total of 4 surgeons operated during this timeframe at a single institution. The 4 surgeons had 25 years, 10 years, 2 years, and 1 year of experience respectively. All cases underwent specimen radiograph evaluated by the surgeon, as well as formal gross evaluation, including inking and slicing, by the pathologist with the surgeon in attendance. Additional targeted shave margins were taken based off these assessments. Criteria for return for re-excision were defined as ink on tumor for IDC/ILC and by multidisciplinary consensus for DCIS prior to April 2016 and within 2mm after this date. The de-identified data was queried for population characteristics and re-excision rates. All statistical tests were 2-tailed, and a p-value of 0.05 was considered statistically significant in these analyses.

Results: Our total re-excision rate was 6.1% (n=41). The mean patient age was 61.8 years (± 12.0). Our population included 16.4 % (n=111) of patients who underwent neoadjuvant therapy. Neither diagnosis (IDC, ILC or DCIS), nor surgeon, significantly differed among those who had re-excisions and those who did not. The average distance of negative margins was 8.7mm. The rate of re-excision by surgeons experience level was 5.7% for 25 years, 8.0 % for 10 years, 8.5 % for 2 years and 5.7 % for 1 year. The proportion of re-excisions did not significantly differ among those with DCIS after the SSO/ASCO/ASTRO consensus statement on DCIS margin >2mm in April 2016.

Conclusions: By utilizing a combination of formal gross inspection with the pathologist intra-operatively, and specimen radiograph, all surgeons were able to achieve a similar re-excision rate, well below previously published rates. Our average negative margin length was also within 1cm, demonstrating that unnecessarily large specimens were not removed. This combination of methods for margin assessment is easily implemented by many practices, and is an excellent tool for surgeons to help reduce return to the operating room after BCS. It may be particularly helpful for younger surgeons as they start their careers.

403890 - Impact of intra-operative macroscopic assessment of lumpectomy margins on re-excision rate: A community hospital experience

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Background/Objective: Accurate evaluation of surgical margins has become an essential part of successful local treatment of breast cancer (BC). There is a wide range of re-excision rates reported in literature from 10-50%. The optimal technique for intra-operative margin assessment in patients with BC has yet to be defined. At our institution, it is standard practice to have intra-operative macroscopic margin analysis (IOMA) by pathologist. The aim of this study is to evaluate the utility of IOMA of BCS margins in a community hospital setting.

Methods: After IRB approval, we retrospectively analyzed all breast cancer patients treated with breast conservation surgery (BCS) from January 2016-October 2017 at our institution. Demographics, tumor characteristics, intra-operative macroscopic assessment results, additional shave margins (SM), re-excision rates, and presence of residual disease were recorded. Descriptive statistical analysis was performed.

Results: We identified 151 patients, of whom 146 (96.6%) had IOMA of lumpectomy specimen. Patient mean age was 59.2 (range 29-90), the most common histology was invasive ductal carcinoma seen in 117 (80.1%) patients, with a mean tumor size of 1.4cm (0-7cm) and mean specimen size of 3.2 cm2 (range 1.2- 11.5cm2) (Table). Eight (5.2%) patients had positive margins on final pathology, and 6 (3.9%) needed additional surgery for re-excision. We then analyzed patients who had SM excised based on IOMA. Shave margins were taken in 64 (43.8%) patients based on IOMA, of which 11 (17.2%) had negative margins due to SM, and 4 (6.3%) patients had positive margins despite additional SM. One had a completion mastectomy, and 3 patients had surgery for re-excision of margins. Only the mastectomy patient had residual disease. Of the 146 patients, 9 (6.2%) patients did not have SM removed despite IOMA recommendations. Of those, 2 (22%) patients had additional surgery for positive margins. Both patients had completion mastectomy, with 1 having 1.6cm of residual disease.

Conclusions: This study strongly suggests that IOMA is an efficient method of obtaining a high proportion of negative margins and optimum resection volumes in patients undergoing BCS. This method has considerable promise, and validation in a large-scale study is warranted.

Table:. Patient demographics

	n=146
Mean Age (years)	59.5
Histology (%)	
IDC	117 (80.1)
ILC	10 (6.8)
DCIS	24 (16.4)
Receptor Status (%)	
ER+	116 (79.5)
PR+	100 (68.5)
HER2+	20 (13.7)
Mean Tumor Size (cm)	1.4
Mean Specimen Size (cm2)	3.2

IDC-Invasive Ductal Carcinoma; ILC- Invasive Lobular Carcinoma; DCIS- Ductal Carcinoma In Situ; ER+- Estrogen Receptor Positive; PR+- Progesterone Receptor Positive; HER2+- Human Epidermal Growth Factor 2 Positive.

403025 - American Society of Breast Surgeons' practice patterns following publication of the SSO-ASTRO-ASCO DCIS consensus guideline on margins for breast-conserving surgery with whole-breast irradiation

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Background/Objective: The recently published SSO-ASTRO-ASCO consensus guideline on margins for breast-conserving surgery with whole-breast irradiation in ductal carcinoma in situ (DCIS) concluded that a 2mm margin should be considered the standard for an adequate negative margin width. However, the impact of this guideline on clinical practice is unknown. This study was undertaken to determine clinician practice both before and after publication of the guideline.

Methods: A survey was sent by electronic mail to 3,081 members of the American Society of Breast Surgeons (ASBrS). Questions evaluated members clinical practice type and duration, familiarity with the recently published guideline, and preferences for additional margin excision based on margin status both before and after guideline publication. Descriptive statistics were used. Additional analyses were conducted using SAS 9.4 (SAS, Cary, NC) software.

Results: Of those surveyed, 767 (24.9%) ASBrS members responded. Of those who responded, 533 (69.9%) were in private practice, and 230 (30.1%) were in an academic practice setting. A total of 416 (54.5%) respondents indicated that their practice focused only on breast diseases, while 347 (45.5%) perform breast surgery as a part of their practice. Most (709/767, 92.4%) indicated familiarity with the

guideline. Surgeons whose practice focused only on breast diseases were more likely to indicate familiarity with the guideline compared to those who perform breast surgery as part of their practice (96.9% versus 87%, p<0.0001). Of those respondents familiar with the guideline, re-excision when DCIS extended to the inked margin remained the same (594/629, 94.4% pre-guideline versus 593/629, 94.3% post-guideline). However, following guideline publication, surgeons were more likely to avoid re-excision to achieve a margin wider than 2mm (518/629, 82.4% pre-guideline versus 550/629, 87.4% post-guideline). Following guideline publication, more surgeons performed re-excision for pure DCIS and a close (1mm) margin (162/626, 25.9% pre-guideline versus 229/627, 36.5% post-guideline) and for DCIS with microinvasion and a close (1mm) margin (256/629, 40.7% pre-guideline versus 329/629, 52.3% post-guideline). For patients with extensive intraductal component and a close (1mm) margin, surgeons were more likely to avoid re-excision (322/629, 51.2% pre-guideline versus 347/629, 55.2% post-guideline). When analyzing responses by practice pattern, surgeons whose practice focused only on breast diseases were more likely to avoid re-excision to obtain a margin greater than 2mm both before and after the guideline compared to their colleagues who perform breast surgery as a part of their practice (328/375 (87.5%) versus 188/251 (74.9%) pre-guideline, p=0.0001; 344/375 (91.7%) versus 203/251 (80.9%) post-guideline, p=0.0001).

Conclusions: Since the publication of the SSO-ASTRO-ASCO guideline concluding that a 2mm margin should be considered standard for patients with DCIS undergoing breast-conserving therapy, surgeons are less likely to perform re-excision to obtain a margin greater than 2mm, more likely to perform re-excision to obtain a 2mm margin for both pure DCIS and for DCIS with microinvasion, and more likely to avoid re-excision to obtain a 2mm margin for extensive intraductal component.

404298 - Does partial mastectomy volume and tumor size predict margin positivity in breast cancer patients?

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Background/Objective: Since NSABP B-06 established the acceptability of partial mastectomy as primary therapy for early-stage breast cancer, reported rates of margin positivity (MP) have been from 20-70%. We sought to determine if specimen volume and/or tumor size influence probability of MP for invasive and non-invasive breast cancer patients.

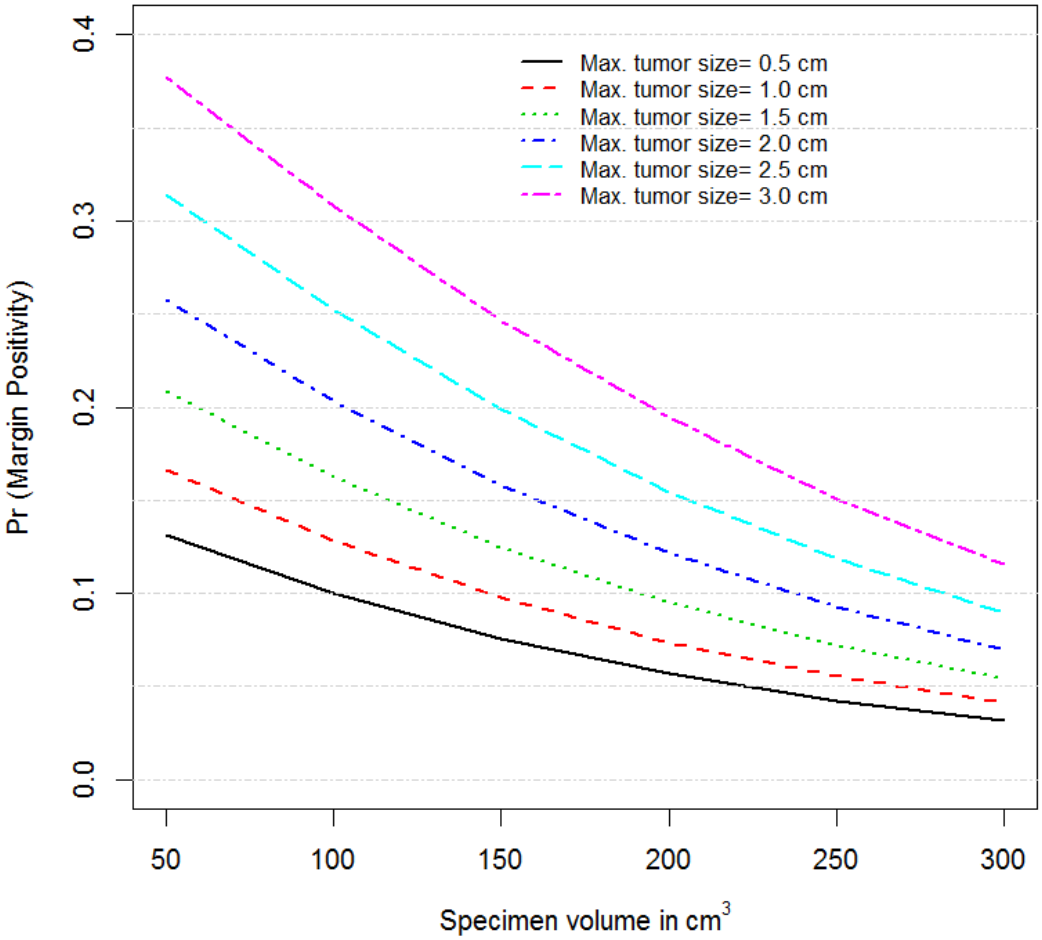
Methods: A retrospective review of pathology records was completed of patients having partial mastectomy for invasive and non-invasive breast cancer within our network. Data were reviewed regarding specimen volume, tumor size, age, histology, MP rates, and receipt of neoadjuvant chemotherapy. Logistic regression models were applied to determine what factors were significantly related to the probability of MP.

Results: From January 2015 through March 2017, 418 patients with partial mastectomy were reviewed. Of these, the overall MP rate was 17.2%. The MP rate was 12.0% for patients with invasive carcinoma and 22.4% for patients with DCIS. The MP rate was 10.6% in 46 patients who had neoadjuvant chemotherapy. For patients with invasive ductal carcinoma, the MP rate was 13.1% compared to 21.2% for patients with invasive lobular carcinoma. Full covariate data was available to calculate specimen volume in 371 patients. The MP rate in this group was 17.8%. Maximum tumor size and specimen volume were significantly related to the probability of MP (p<0.001 and p=0.038, respectively). Age had

a non-significant effect on MP and was excluded from the model. The Figure illustrates the relationship between specimen volume, tumor size, and likelihood of positive margin.

Conclusions: The relationship between tumor size and specimen volume predict margin positivity in breast conservation surgery. Surgeons can tailor their resection volumes based on expected tumor size and predicted MP rates. Further study is in process to examine other factors for variability in margin positivity.

Figure: Plot of predicted probabilities of MP by specimen volume and maximum tumor size



403250 - The relationship of breast density with positive margins after lumpectomy

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Background/Objective: Several recent reports have suggested that increased breast density may lead to an increased risk for positive lumpectomy margins during breast-conserving surgery. A positive margin after breast-conserving surgery (BCS) is a significant predictor for cancer recurrence and re-excisions. The MarginProbe is an FDA-approved device for intra-operative assessment of lumpectomy margins, and has been associated with a reduction in the need for re-excision surgery. The purpose of this study was to evaluate the relationship of breast density and other clinicopathologic characteristics with margin status in a population of women undergoing breast-conserving surgery with intra-operative use of the MarginProbe.

Methods: Our institutional database was queried for patients who had BCS with MarginProbe device from 2013-2017. We excluded all patients who underwent neoadjuvant chemotherapy. Variables of interest included breast density, patient and tumor characteristics, the results of pre-operative breast imaging, and the margin status of the main and final lumpectomy specimen. Mammographic breast density (MBD) was defined as less dense (BIRADS A&B) and more dense (BIRADS C&D). A positive margin was defined as <1mm. Statistical analyses included Pearsons Chi-square Tests and logistic regression.

Results: Out of a total of 332 patients with BCS and MarginProbe, 168 patients had complete data on MBD and main lumpectomy specimen margin status. The median age was 63 years (range 35-93). Patients with higher breast density were younger (p=0.003), included a higher proportion of Asians (p=0.004) and had lower BMI (p=0.021). Breast density did not differ between patients on the basis of histology, tumor size, or the presence of a positive margin in the main or final specimen (Table). Of the 168 patients, 89 (53%) had at least 1 positive margin on the main lumpectomy specimen. Intra-operative MarginProbe interrogation and directed re-excision of margins left only 24 patients (14.3%) with a persistently positive margin. Of these 24 patients, density was not significantly different in the DCIS vs. invasive breast cancers (p=0.754). Four of these 24 patients had negative main specimen margins, but disease was identified at the margin of re-excision specimens. Persistently positive margins were associated with older age (p 0.046), larger tumor size (p=0.011), and discordance with pre-operative breast imaging.

Conclusions: In this study of patients undergoing breast-conserving surgery, we found that the density of the breast tissue was not correlated with the likelihood of a positive margin. Seventy-three percent of patients with positive main lumpectomy margins were converted to final negative margins after MarginProbe-directed re-excisions. The presence of persistently positive lumpectomy margins was associated with older age and more extensive disease. Pre-operative breast imaging that does not accurately reflect the extent of disease may be a risk factor for positive margins despite the use of intra-operative margin assessment.

Table:

Variable	Total (N=167)	%	Less Dense (N=92)	%	More Dense (N=75)	%	P-Value
Age							0.003
Median (range) (years)	63 (35-93)		65 (41-88)		58 (35-93)		
Race							0.004
White	125	74.9	70	75.3	55	74.3	
Black	16	9.6	14	15.1	2	2.7	
Asian	14	8.4	3	3.2	11	14.9	
Hispanic	12	7.2	6	6.4	6	8.1	
BMI							0.021
Underweight (<=18)	1	0.6	0	0	1	1.3	
Normal (18-24)	61	36.5	26	28.3	35	46.7	
Overweight (25-29)	49	29.3	26	28.3	23	30.7	
Obese (30+)	56	33.5	40	43.5	16	21.3	
Histology							0.665
DCIS	29	17.3	15	16.1	14	18.7	
Invasive	139	82.7	78	83.9	61	81.3	
Size							0.317
<1 cm	57	34.1	36	39.1	21	28.0	
1-2.5 cm	87	52.1	44	47.8	43	57.3	
>2.5 cm	23	13.8	12	13.0	11	14.7	
Main Specimen Margins							0.345
Positive	89	53.3	46	50.0	43	57.3	
Negative	78	46.7	46	50	32	42.7	
Final Margins							0.730
Positive	24	14.4	14	15.2	10	13.3	
Negative	143	85.6	78	84.8	64	86.7	

404002 – Patient-level costs in margin excision for breast-conserving surgery

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Background/Objective: High re-operation rates (20%) following breast-conserving surgery (BCS) for positive margins are associated with increased physical and psychological morbidity and represent a likely significant and yet unknown cost burden to the NHS. Our aim was to compare financial costs between patients undergoing successful BCS versus re-operative breast surgery.

Methods: Financial data was retrieved for patients receiving BCS +/- re-operation between April 2015 and March 2016 using patient-level information and costing systems. Statistical analysis was conducted

using STATA 14.2, including descriptive statistics, ordinary least squares (OLS), and Propensity Score Matching Analysis (PSMA).

Results: The total cost of BCS (n=212) was £841,395 (IQR: £2021, range £836-£28,705). Overall, the median cost of BCS and re-operation was £4,511 (n=59), an additional £2,136 per patient compared to the median cost of £2,375 of definitive BCS (n=153) ($p<0.001$). Fifty-one percent (42%, 1 and 9%, 2 re-operations) of the total BCS costs were attributed to 28% of patients (59/212) whom underwent re-operation (24%, n=51/212 for 1 and 4%, n=8/212 for 2 re-operations). The results of the OLS and PSMA suggest that nodal metastasis (positive) and microcalcification (negative) impact total costs significantly (5% level).

Conclusions: This study is the first cost comparison between definitive BCS and re-operative surgery in the UK, interrogating direct patient-level costs. Re-operation has significant cost implications, and implementation of intra-operative margin assessment technologies could result in both quality improvement and substantial savings to the NHS.

403997 - Lower re-excision rates following breast conservation surgery in high-volume surgeons: More accurate, or just more breast tissue?

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Background/Objective: Breast-conserving surgery (BCS) is the preferred surgical approach for the majority of patients with early-stage breast cancer. With BCS, there are frequently concerns regarding the pathologic margin status, with population-based studies reporting re-operation rates between 17% and 35%. While re-operations are inevitable, the significant variability in the literature suggests that this is a quality of care issue. Surgeon volume has been identified as 1 of the factors influencing re-operation rates, with higher-volume surgeons having a decreased need for re-operation. Understanding the reason for this disparity is important in efforts to minimize unnecessary re-operations and improve the quality of care breast cancer patients are receiving. We aimed to determine whether a decreased need for re-operation among higher-volume surgeons could be attributed to larger tissue volumes being resected at the time of initial BCS.

Methods: A retrospective analysis of all patients referred to our cancer center over a 3-year period (January 1, 2011 to December 31, 2013) was performed. Patients undergoing initial breast-conserving surgery for either ductal carcinoma in-situ, or T1 and T2 breast cancers were included. Patients with an unknown tissue resection volume or an unknown tumor size were excluded. Factors considered for analysis included: surgeon case volume, tumor grade, histology, markers, tumor size, and volume of tissue resected (expressed as CRR - calculated resection ratio). Surgeon volume was treated categorically based on surgeon cases per year as: low (1-5), intermediate (6-10), high (11-24), and very high (25 or more) volume. Two multivariate logistic regression analyses were performed, 1 adjusting for tumor size only and another adjusting for both tumor size and CRR. The latter was used to determine whether surgeon volume was confounded with the volume of tissue excised (i.e., higher-volume surgeons excise larger volumes of tissue). The Generalized Estimating Equations method was applied to account for the correlation between patients operated on by the same specific surgeon.

Results: Tumor size had the largest influence on the need for re-excision in our patient cohort. After adjusting for tumor size, a trend to increased need for re-operation was noted as the surgeon volume decreased, and patients having surgery performed by intermediate volume surgeons were significantly more likely to have a re-excision compared to those having surgery performed by very high-volume surgeons (OR: 2.23; 95% CI: 1.15-4.32). The same trend and difference in re-excision rates remained significant even after adjusting for both tissue resection volume and tumor size (OR: 2.25; 95% CI: 1.13-4.51), suggesting that lower re-excision rates were not at the expense of larger resection volumes.

Conclusions: Tumor size was the most influential factor on re-operation rates in our population. Reduced re-excision rates with increase surgeon volume were not attributed to a larger volume of tissue resected at the time of attempted BCS.

404228 - Re-operative rates before and after 2014 SSO ASTRO Invasive Breast Cancer Margin Consensus Guidelines: A single institution retrospective review

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Background/Objective: The SSO (Society of Surgical Oncology) - ASTRO (American Society for Radiation Oncology) Consensus Guidelines for Stage I and II Invasive Breast Cancer Margins were released in 2014 to define acceptable margins. For invasive breast cancer, negative margins were defined as no tumor on ink. Wider margins than no tumor on ink did not lower the risk of ipsilateral breast tumor recurrence in the era of multimodality therapy. The purpose of this study was to evaluate re-operative rates in an 850 bed community hospital before and after consensus guidelines were published,

Methods: A retrospective review was performed on 449 Stage I-II breast cancer patients who underwent lumpectomy. Patients were stratified into 2 cohorts by time period: pre-SSO ASTRO (June 2012-December 2013; n=225) and post-SSO ASTRO (January 2016-August 2017; n=224). In the pre-SSO ASTRO group, 110 patients had invasive breast cancer versus 150 patients in the post-SSO ASTRO group. For the patients with invasive breast cancer, clinicopathologic patient data, tumor specific data, and re-operative rates were compared between the pre- versus post-SSO ASTRO groups. Statistical analysis was performed using Fischers exact and Chi-square tests. Significance was set at p=0.05.

Results: There were no differences between the 2 cohorts in regards to tumor-specific characteristics: T1 and T2 (p=0.06), hormone status (ER, p=0.4143; PR, p=1.0), and HER2Neu-negative (p=1.0). In the pre-SSO ASTRO cohort, 22 patients (20%) underwent reoperation for margin re-excision or mastectomy, while the post-SSO ASTRO cohort had 20 patients (13.4%) (p=0.17). The true positive margin (tumor on ink) rates were similar in pre- and post-SSO ASTRO cohorts, (8.2% vs 8.7%, p=1.0). In the post-SSO ASTRO group, 7 of the 20 patients who underwent reoperation had negative invasive cancer margins. Three were deemed to be close margins by the surgeon, and the other 4 required re-excision for residual DCIS.

Conclusions: There was a downtrend in re-operative rates from 20% to 13% after the 2014 SSO ASTRO consensus guidelines were published. However, this change was not statistically significant due to a lack of power in our study as the true positive margin and re-operation events were lower than expected. Data collection will be continued prospectively to further power this study. Interestingly, there are surgeons who still re-excise margins greater than no tumor ink for invasive breast cancer at our institution. This study brings into light the importance of surgeon education in an era of ever-changing guidelines for treatment of breast cancer patients.

404233 - Role of routine cavity shave margins in breast-conserving surgery: An institutional review

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Background/Objective: Adequate resection of the tumor is imperative to reduce recurrence in breast cancer (BC) patients receiving breast-conserving surgery. Clinical trials have demonstrated the role of routine cavity shave margins in reducing the rates of positive margins and re-excision. However, the generalizability of these findings to the larger early-stage BC population outside of a clinical trial remains in question.

Methods: A retrospective case-control study was conducted, which compared outcomes of patients receiving routine cavity shave margins resection (shave) and those undergoing directed margin resection/no additional margin resection (no shave) after partial mastectomy from October 2014 - October 2017 at our institution by 3 surgical oncology- or breast surgical oncology-trained surgeons. Positive margins were defined as invasive tumor touching the edge of the inked specimen or ductal carcinoma in situ (DCIS) present within 2mm of the edge of the inked specimen (without associated invasive tumor). The primary endpoints were final margin status at index surgery, rates of re-excision and complication rate. Comparisons between the 2 groups were made using Fisher's Exact tests and t-tests.

Results: A total of 379 patients were included in the analysis; 199 in the shave group and 180 in the no shave group. The rate of positive margins was 8% in the shave group and 24% in the no shave group (p=.0006). Sixteen percent of shave patients underwent a re-excision compared to 35% in no shave group (p<.0001). The complication rate in the shave group was 33% compared to 37% in the no shave group (p=NS). The positive margin rate in patients with neoadjuvant chemotherapy was 18% in the shave group and 25% in the no shave group (p=NS). There were no statistically significant differences in size, presence of DCIS, tumor specimen ratio, and receptor status between the shave and no shave groups. There was a significant difference in histology between shave and no shave groups, with invasive lobular histology associated with more cavity shaves and DCIS being associate with fewer compared to pure invasive ductal histology (p=.02).

Conclusions: Routine cavitary shaving decreased the rates of positive margins by more than 60% among patients receiving partial mastectomy. Our study provides additional evidence that routine cavity shaving provides adequate tumor resection, with no increase in complications, minimizing the need for additional surgery and its subsequent impact on cosmetic outcome, surgical morbidity, delay in adjuvant therapy, and health care costs.

404071 - Evaluation of 2014 Margin Guidelines on breast-conserving re-excision and recurrence: A multi-institution retrospective study

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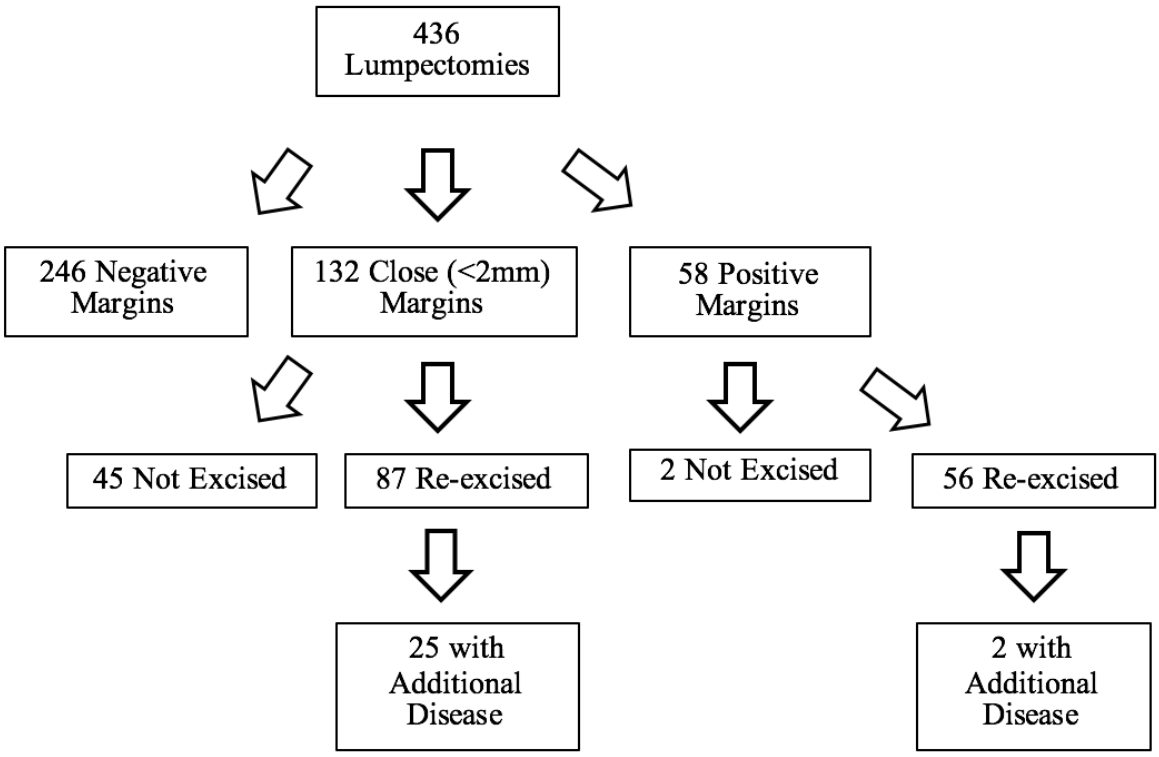
Background/Objective: The 2014 consensus statement from the Society of Surgical Oncology and American Society for Radiation Oncology supported the use of no tumor on ink as an adequate margin for breast-conserving therapy (BCT). This study evaluates the effect of this statement on surgical practices and outcomes in a multi-institution cohort.

Methods: A retrospective review of women treated with BCT at 3 comprehensive cancer centers was performed. Women age >18 receiving BCT for T1-2 breast cancer from 2008-2011 were included. Prior to the no tumor on ink guideline, all sites considered 2mm a negative margin. Estimated change in reoperation rate with 2014 guidelines was calculated, and factors predictive of re-excision were analyzed.

Results: There were 430 patients undergoing 436 lumpectomies who met eligibility criteria. Using a 2mm margin standard, 32.8% of patients underwent re-operation (Figure). This would have decreased to 13% using 2014 guidelines ($p<0.0001$). Both tumor size ($p=0.002$) and T stage ($p=0.005$) were predictive of re-excision. Patients who had additional intra-operative margins obtained (either directed or whole-cavity shave) were less likely to need re-excision ($p=0.014$). The total recurrence rate for this cohort, including local and distant presentations, was 7.1%; the mean time to recurrence was 43 months (range 2 to 95 months). When the re-excised subgroup was examined, 3/56 (5.4%) patients re-excised for a positive margin still experienced local recurrence despite subsequent margin clearance. In the group undergoing reoperation for a close margin, 5/87 (5.7%) later presented with local failure. Finally, of particular interest in this study, among patients with a close, but negative, margin who were not re-excised (n=45), 2 had local recurrences (4.4%). Recurrence rates among these 3 groups were not statistically different.

Conclusions: Use of 2014 margin guidelines would have dramatically reduced re-excision rates. Larger tumor size, greater number of involved margins, and DCIS at the margin were predictive of re-excision. Shave cavity margins decreased the need for re-excision. There was no difference in the rate of local recurrence for patients who were re-excised for a close margin and those who were not.

Figure: Flowchart of breast lumpectomy procedures and pathology findings (n=436)



404285 - Local control practices in early-stage breast cancer after publication of the 2014 SSO Invasive Breast Disease Guidelines

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Background/Objective: The principles of breast-conserving therapy include both surgical excision and radiation treatment to achieve adequate local control in early-stage breast cancer. After surgical margin recommendations were published by the 2014 SSO-ASTRO guidelines for invasive breast cancer, the majority of subsequent data revealed decreases in surgical re-excision practices at many institutions. In addition to surgical excision, the use of whole-breast irradiation has been shown to improve local control and survival. An additional radiation boost to the surgical cavity can also be administered to patients with various risk factors for recurrence. There are limited data that reviews concurrent re-excision and radiation practices following the new surgical guidelines. The purpose of our study was to review our institution's surgical re-excision and simultaneous radiation practices in patients receiving radiation boost before and after publication of the 2014 SSO-ASTRO guidelines for invasive breast cancer.

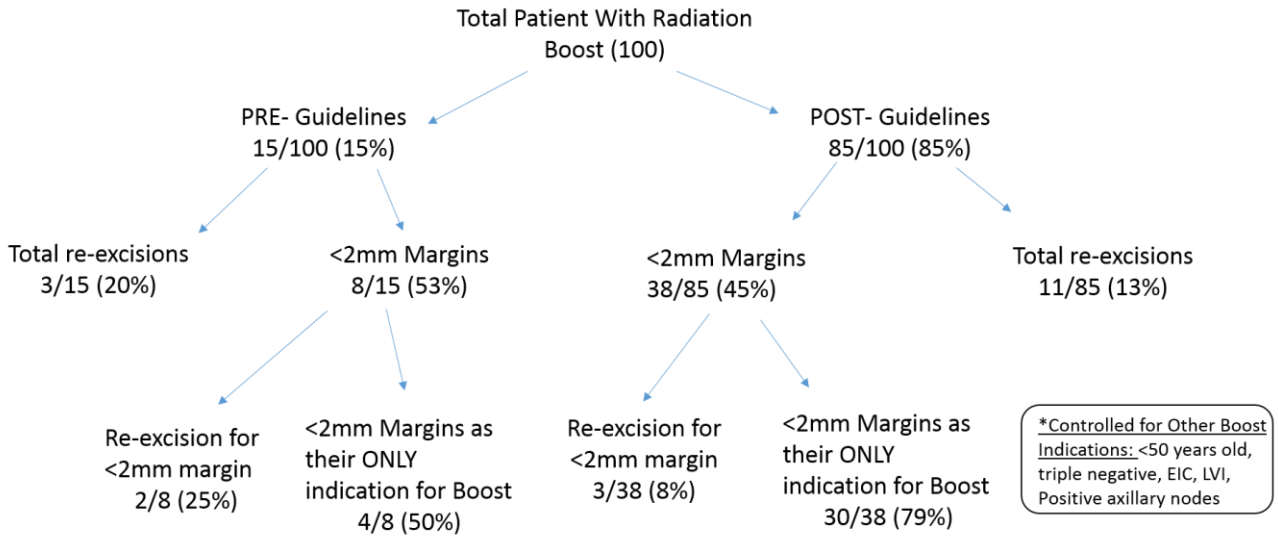
Methods: A retrospective review from Nov 2012-June 2015 identified 100 early-stage (I-II) breast cancer patients who underwent breast-conserving surgery (BCS) and adjuvant hypo-fractionated whole-breast irradiation plus boost. Patients who had multi-focal disease, neoadjuvant chemotherapy, or incomplete operative or pathologic reports were excluded. Tumor size, presence of high-risk features (e.g., lympho-

vascular invasion [LVI], extensive intraductal component [EIC]), hormonal receptor status, presence of HER2 neu protein, pathologic stage, final margin status <2mm, and number of surgical re-excisions were recorded. Boost indications, including young age, triple-negative disease, LVI, EIC, positive axillary lymph nodes, and <2mm margins were identified. Patients were divided into pre- and post-2014 SSO guideline groups. Relationships between clinical data were evaluated using unpaired T-tests.

Results: A total of 100 women, ages 45-88, were evaluated. Fifteen patients (15%) received radiation boosts prior to the 2014 SSO guideline publication, (PRE). Eighty-five patients (85%) received radiation boosts post-guideline publication, (POST). Eight PRE cohort patients (53%) had <2mm margins. Two of these PRE patients (25%) had a re-excision. After controlling for other indications for boost, 4 (50%) PRE patients who received a boost had <2mm margins as their only risk factor. In the POST cohort, 38 (45%) patients had <2mm margins. Three of the POST patients (8%) received a re-excision, and 30 POST patients (79%) who received a boost had <2mm as their only risk factor. Comparisons between PRE and POST cohorts with <2mm margins on final pathology revealed a 25% re-excision rate PRE vs. an 8% re-excision rate POST (p=0.166), and in patients with a <2mm margin as the only risk factor for boost, our data revealed a 50% radiation boost rate PRE vs. a 79% radiation boost rate POST, (p=0.093).

Conclusions: After evaluation of patients with radiation boost, our data raise the possibility that surgical re-excision rates have decreased and that there has been a synchronous rise in the delivery of radiation boost; however, due to limitations in our dataset, this association remains unclear. More data are needed to investigate the relationships between local control modalities in early breast cancer treatment.

Figure: Local control practices in early-stage breast cancer



403449 - The use of intra-operative ultrasonography to evaluate specimen margins

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Background/Objective: In our community hospital, intra-operative biopsy (IOB) is not always available, and when it is, it uses a significant amount of operating room (OR) minutes. With only 1 pathologist working in IOB outside the OR, availability and time spent in IOB are concerning issues. Our primary objective is to evaluate whether measuring specimen margins with intra-operative ultrasonography (US) could be performed faster than IOB and even replace IOB when this is not available. The second aim is to improve surgical accuracy of palpable and non-palpable breast cancer excision in order to obtain clear margins.

Methods: Female patients undergoing breast-conserving surgery (BCS) for palpable or non-palpable T1 or T2 invasive breast cancer were recruited. Patients with pre-operatively diagnosed primary or associated ductal carcinoma in situ (DCIS), multifocal disease, a history of neoadjuvant therapy, previous surgical treatments, or radiotherapy of the affected breast were excluded. All surgical procedures were performed between August 2016 and October 2017. A breast surgeon with 3 years of experience in US-guided breast procedure performed all the surgeries. Data included patient demographics, tumor localization and biology, and US tumor diameter measured in the OR prior to surgery. Once the tumor was excised, the margins of the 6 faces of the specimen were measured and registered with US. All specimens were oriented by sutures placed by the surgeon. The IOB tumor diameter and histological margin status of each surface were documented. Time was recorded since the specimen left the OR until the pathologist reported results. Margin length results were compared among the records provided by US, IOB, and the final pathology report.

Results: Twenty six patients underwent US-guided lumpectomy for cancer. Five cases were wire-guided localization in non-palpable breast cancer. The average size of the tumor was 1.9 cm measured by US and 1.8 cm at the final pathology. All patients had negative margins at final pathology. A total of 154 margins were finally evaluated, since in 2 cases, the anterior face was the skin. Five margins (3,2%) were positive, and 47 borders (30.5%) had 3 mm or less of clear margin found with US, which coincides with IOB results. In these cases, an additional margin shaving was performed. Eight margins seemed closer with US rather than with IOB. None were negative with US and positive with IOB. An average of 22 minutes was spent with IOB compared to 3.5 minutes of US specimen measuring in the OR. Of the borders where shaving was not performed (102), 6mm was the average measured by US and 7.5mm by IOB.

Conclusions: The use of intra-operative US to measure specimen margins optimizes surgical accuracy, saves OR time when the pathologist is not present in the OR, and moreover, it can be use when IOB is not available. Margin status was improved, and re-excision was not needed. The technique is effective, simple, and non-invasive, requiring no additional resources for obtaining adequate resection margins.

404184 - Evaluation of surgically excised breast tissue microstructure using wide-field optical coherence tomography (WF-OCT)

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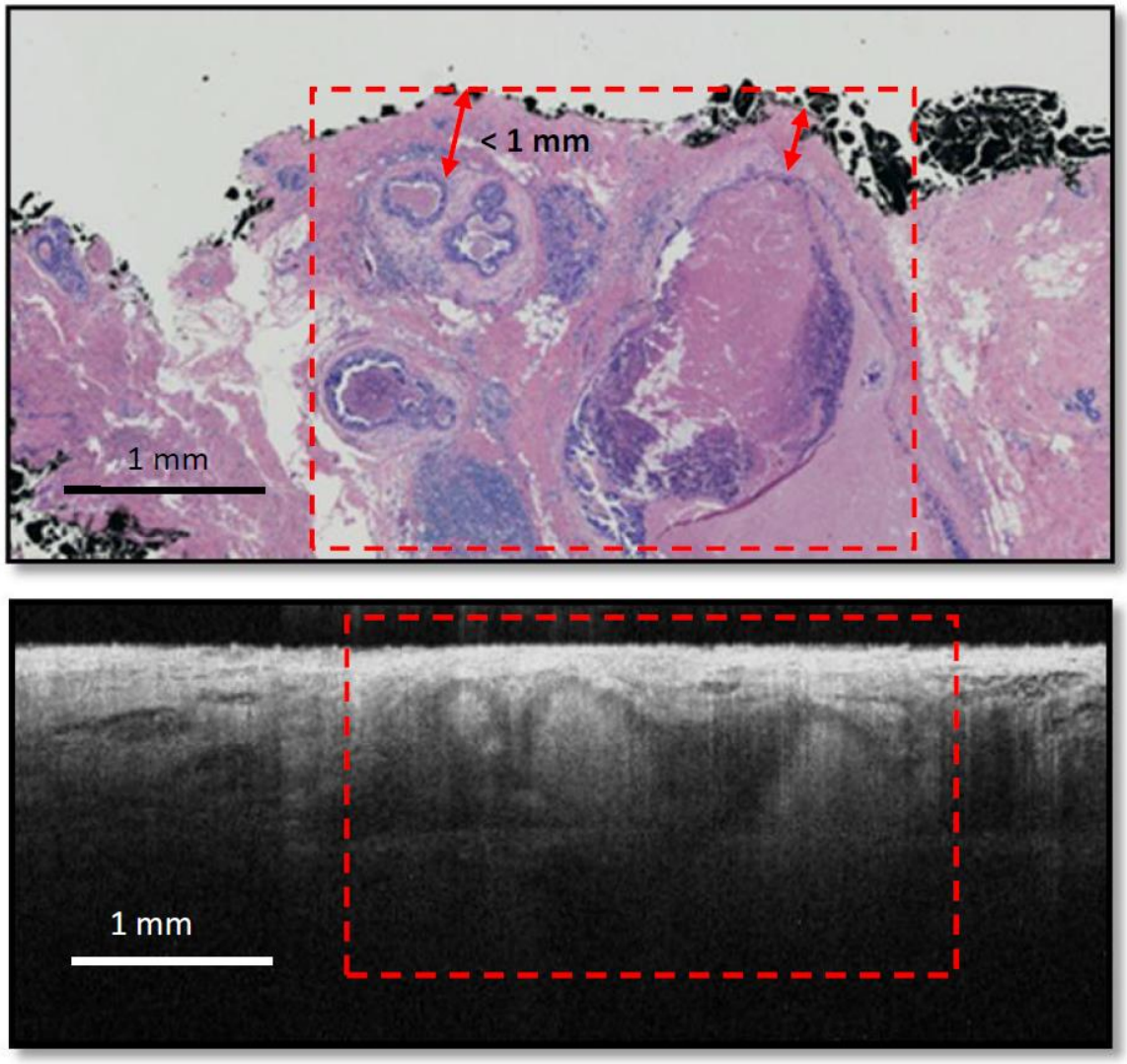
Background/Objective: Currently, effective intra-operative lumpectomy imaging tools do not exist. Lowering the surgical re-excision rate for breast-conserving surgery (BCS) can potentially be accomplished by introducing an innovative intra-operative imaging tool for tissue visualization of margins. The goal of this research is to demonstrate the concept of WF-OCT for tissue microstructure visualization in lumpectomy specimens with the ultimate goal of providing an adjunct imaging tool to aid in real-time surgical decision-making during BCS.

Methods: This IRB-approved, prospective, single-center study included women with biopsy-proven invasive or in situ carcinoma scheduled for primary BCS. Standard medical care was preserved in the study, including specimen processing. Using an investigational wide-field optical coherence tomography (WF-OCT) near-infrared based imaging technique, lumpectomy specimens and any final/shaved margins were imaged immediately prior to standard histological processing. The WF-OCT technology used in this study provided wide-field, 2-dimensional, cross-section, real-time depth visualization of the margin widths around excised specimens. A volume of images were captured up to a 10 cm x 10 cm tissue surface at high-resolution (~15 m) down to a 2 mm tissue depth. Integrated interpretation was performed incorporating the final pathology report linked with the WF-OCT image data for correlation.

Results: WF-OCT was performed on 113 specimens in 30 subjects. Patients ranged in age from 39-82 years with an average of 62.1 years. Of the 30 subjects evaluated, diagnosis was IDC in 8, DCIS in 8, IDC/DCIS in 12, ILC in 1, and additionally, sarcoma in 1. In 17/113 specimens, the carcinoma was either close to (<2mm), including 4 DCIS, 5 IDC/DCIS, and 1 sarcoma, or at ink (positive), including 3 DCIS, 2 IDC/DCIS, and 2 IDC. WF-OCT was concordant with final pathology margin status in 106/113 tissue samples with an overall accuracy of 93.8%. Of the 7 discordant specimen, 2 were IDC, 3 were DCIS, 1 was IDC/DCIS, and 1 sarcoma. Of note, in 2/7 discordant cases the carcinoma (microscopic DCIS) was seen close to/at the margin histologically, but not on WF-OCT.

Conclusions: The ability of WF-OCT to demonstrate 93.8% concordance with histology for tissue margins demonstrate the potential of this technology as a real-time, adjunct, intra-operative imaging tool for margin assessment. These initial results support that WF-OCT could help facilitate complete excision of the tumor while minimizing removal of any benign tissue. Further studies are needed for comprehensive evaluation of this technology in the intra-operative setting.

Figure: Histology image of DCIS (dashed box) located less than 1mm from the inked margin correlated to the WF-OCT cross sectional image from the corresponding region



403520 - SSO/ASTRO consensus leads to significant reduction in unnecessary re-excisions

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Background/Objective: In 2014, the Society of Surgical Oncology (SSO) in collaboration with the American Society of Radiation Oncology (ASTRO) released a consensus statement for the desired lumpectomy surgical margin, which was defined as no ink on tumor. Our objective is to evaluate surgeons' practice patterns following the guidelines in our community, multi-hospital setting. The management of the close margin is hypothesized to be the category with the most practice change.

Methods: This is an IRB-approved, retrospective chart review of our multi-hospital systems cancer registry. This study includes patients treated with breast-conservation surgery from January 1, 2012 to

December 31, 2016. The data were gathered from 11 hospitals within the system. Our inclusion criteria are females, age >18, with invasive breast cancer, Stages I-III, who underwent breast-conservation therapy. Pre-consensus is defined as January 2012-January 2014, while post-consensus is defined as February 2014-December 2016. Patients who underwent neoadjuvant chemotherapy or who had Stage 0 or IV breast cancer are excluded. Data points include the date of surgery, reason for re-excision, and re-excision rates. Close margins are defined as margins less than or equal to 2mm.

Results: This study included a total of 1886 lumpectomies. Of those, 186 lumpectomies were ultimately re-excised for a re-excision rate of 9.8%. Overall the re-excision rate changed from pre-consensus to post-consensus; the percentages were 10.9% and 9.3% respectively (p=0.26). Most importantly, we found that when faced with a close margin, those lumpectomies were re-excised at a rate of 25% pre-consensus, which decreased to 8.8% post-consensus (p=0.01). This demonstrates a 65% reduction in the patients who were re-excised for close surgical margins following the consensus statement.

Conclusions: The SSO/ASTRO consensus statement has created a significant treatment change in our multi-hospital system. The pre-consensus re-excision rate for the close margin was reduced by 65%, thus eliminating many unnecessary returns to the operating room. These findings meet our objective to evaluate a pattern change. This is unique as these data have not been reported for a community setting, and the specific close margin re-excision rate has not been evaluated before.

404101 - Selective shave margins does not decrease positive margin or re-excision rates for patients undergoing breast-conservative therapy for ductal carcinoma in situ

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Background/Objective: The selective shave margin technique (SSM) in breast-conservative surgery (BCS) has been shown to decrease re-excision rates without increasing recurrence for invasive carcinoma. While the guidelines for invasive cancer necessitate no ink on tumor, those for ductal carcinoma in situ (DCIS) recommend a 2mm margin width. The purpose of this study was to evaluate whether SSM decreases rates of positive margins and re-excision in patients undergoing lumpectomy for DCIS.

Methods: Patients who were diagnosed with DCIS and underwent BCS between January 2010 and January 2017 were identified from a prospectively maintained database. Patients were separated into 2 groups: SSM vs those treated with conventional lumpectomy (CL). Patients were defined as having SSM if additional breast tissue, measuring approximately 1x1x2cm, was excised from the margins of the lumpectomy cavity. Clinicopathologic characteristics, volume of resection, re-excision rates, and outcomes were compared between the 2 groups.

Results: Of the 91 total patients identified, 42 (46.2%) underwent CL, while 49 (53.9%) underwent SSM. Patients who underwent SSM were of similar age and race as those with CL (61.3± 11.6 years SSM vs 58.6±10.4 years CL, p=0.253; 76.6% white SSM vs 80.0% white CL, p=0.702). Both groups had similar rates of hormone receptor positivity and overexpression of HER2 (84.4% estrogen-receptor (ER) SSM vs 90.2% ER CL, p=0.421; 60% progesterone receptor (PR) SSM vs 73.2% PR CL, p=0.197; 29.6% HER2 SSM vs 29.4% HER2 CL, p=1.000). There were no differences between SSM and CL with respect to size of DCIS (1.5cm, Interquartile range (iQR): 0.3-3.0cm SM vs 1.8cm, IQR: 0.3-3.0cm CL, p=0.211) and overall volume of resection (45.23cm3, IQR: 25.93-101.2 cm3 SSM vs 49.25 cm3, IQR: 25.93-101.2cm3 CL,

p=0.638). Patients who underwent SSM or CL had a similar number of positive margins (42.86% SSM vs 50.0% CL, p=0.50) and re-excision rates (34.1% SSM vs 31.7% CL, p=0.815). Similarly, there were no differences in rates of re-excision with mastectomy between the 2 groups (8.16% SSM vs 16.67% CL, p=0.14). On univariate analysis, younger age (Odds ratio (OR): 0.93, 95% Confidence Interval (CI): 0.89-0.98, p=0.003), larger size of DCIS (OR: 1.74, 95% CI: 1.31-2.30, p<0.001), and lower-grade tumors (grade 2 vs. 3; OR: 0.18, 95% CI: 0.05-0.72, p=0.015) were associated with re-excision. On multivariable analysis only younger age (OR: 0.92, 95% CI: 0.86-0.97, p=0.002) and larger size of DCIS (OR: 1.88, 95% CI: 1.36-2.59, p<0.001) were associated with re-excision, while surgical technique was not. With median follow-up of 52.0 months (95% CI: 47.4-57.0), there was no difference between the 2 groups with respect to overall survival (OS) or recurrence (5-year OS rate: 100% SSM vs 91.8% CL, p=0.14; 5-year disease-free survival rate: 95.3% SSM vs 88.5% CL, p=0.28).

Conclusions: SSM did not result in higher volumes of excision compared to CL. SSM is not associated with either decreased rates of positive margins or rates of re-excision.

404242 - Should ductal carcinoma in situ (DCIS) within 2mm of a lumpectomy margin be managed differently in patients with pure DCIS versus patients with DCIS and invasive tumor?

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Background/Objective: Breast-conserving surgery (BCS) has low rates of local recurrence if adequate margins are achieved. The 2013 SSO/ASTRO lumpectomy margin guidelines for invasive cancer suggested that no ink on tumor (invasive or DCIS) is an adequate margin width. However, the 2016 SSO/ASTRO lumpectomy margin guidelines for DCIS recommended that a minimum 2mm margin should be obtained. Thus, under current guidelines, for a margin with DCIS within 2mm (but not on ink), re-excision is recommended for patients with a primary diagnosis of pure DCIS but not for those with a primary diagnosis of invasive cancer with DCIS. We compared rates of residual disease in patients with pure DCIS and invasive cancer plus DCIS who had DCIS >0 but <2mm of a margin.

Methods: Lumpectomies with complete shaved cavity margins (SCMs) at our institution from 2004 to 2006 were reviewed. Patients were divided into 2 groups: those diagnosed with invasive cancer +/- DCIS and those with pure DCIS. Margin widths were measured on the lumpectomy specimen and tumor in SCMs were used as a surrogate for residual disease in the cavity. Rates of residual disease when DCIS was >0-2mm to the final lumpectomy margin were determined.

Results: There were 446 patients identified who underwent lumpectomy with complete (4) SCMs. Of these, 124 patients had a primary diagnosis of pure DCIS, and 322 had invasive cancer +/- DCIS. In the pure DCIS group, 63 patients were found with DCIS >0-2mm from the final lumpectomy margin; 33 (52%) of these patients had residual disease in their SCMs. In patients with invasive cancer, 85 were found with DCIS (with or without invasive cancer) >0-2mm from the final lumpectomy margin; 41 (48%) patients had residual disease in their SCMs. There was no statistically significant difference in rates of residual tumor in patients with an initial diagnosis of pure DCIS versus those with invasive cancer plus DCIS (p=0.74).

Conclusions: Rates of residual disease in lumpectomy patients with DCIS close to the margin are similar for patients with pure DCIS and for those with invasive cancer plus DCIS, but management

recommendations differ under the current guidelines. Further studies are needed to determine the clinical impact of residual disease in these patients in the setting of current multi-modality treatment.

Other

404035 – Opioid-free anesthesia for patients undergoing mastectomy with reconstruction

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Background/Objective: Post-operative pain and nausea are common complications following general anesthesia for breast surgery patients. Patients undergoing surgery with opioid-free anesthesia (OFA) may have lower narcotic requirements in the post-operative period. The American Pain Society and the American Society of Anesthesiologists recommend multimodal pain control for patients undergoing procedures as a way to minimize the use of narcotic medications. Mastectomy, especially with reconstruction or axillary dissection, often requires narcotics for effective post-operative pain management along with high rates of post-operative nausea and vomiting (PONV). Despite the potential for OFA to limit overall narcotic use, no studies have examined this effect in patients undergoing surgical management of breast cancer. This pilot analyzed the effects of OFA on post-operative narcotic use, pain levels, and PONV in mastectomy patients compared to usual anesthesia care.

Methods: Following IRB approval, 48 patients undergoing mastectomy with tissue expander or implant based reconstruction at a single academic institution were retrospectively identified from 2015 to 2017. Patients were given either conventional anesthesia (CA) with the use of intra-operative narcotic medications or anesthesia without narcotic medications as part of a pilot program at the discretion of the anesthesia team. Records were reviewed for age, BMI, co-morbidities, prior surgical history, pain levels, and medication administration records. Mastectomy patients who received OFA were compared with age- and cancer stage-matched controls receiving CA. Sample size was calculated to detect a 20% difference in narcotic usage between groups. Primary endpoints were post-operative narcotic and antiemetic use, as well as self-reported visual analog pain scores. All narcotic use values were calculated in oral morphine equivalents (OME). Chi-square and Fisher's exact tests were used for categorical variables and students t- test was used for continuous variables.

Results: During the study period, 24 patients who underwent mastectomy with OFA were matched with 24 patients receiving CA. Among patients who had intra-operative narcotics, fentanyl was most commonly used (mean dose=264.4 mcg, SD=99.6). Patients in the t2wo groups had no differences in body mass index, American Society of Anesthesiologists risk class, history of smoking, or prior history PONV. Narcotic use did not differ between groups in the first 2 hours of the post-operative period (OFA 24.6 mg OME vs CA 21.1 mg OME, $p>0.10$) or when assessed over the entire length of the hospital stay (OFA 54.1 mg OME vs CA 48.3 mg, $p>0.10$). Mean pain scores were not significantly different between the groups during the first 2 hours of the post-operative period (OFA 5.2 vs CA 5.4, $p>0.10$) or when assessed throughout the entire length of hospital stay (OFA 4.7 vs CA 4.9, $p>0.10$). Antiemetic use was not significantly different throughout hospital stay ($p>0.10$).

Conclusions: This small pilot study demonstrated that use of opioid-free anesthesia for patients undergoing mastectomy with immediate reconstruction did not result in significantly decreased narcotic use, pain scores, or antiemetic use in the post-operative period. Obtaining a larger sample of patients

may help identify a subset of patients who may particularly benefit from OFA during breast cancer surgery.

402801 - Outcomes of surgical treatment of pleomorphic lobular carcinoma in situ of the breast

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Background/Objective: Pleomorphic lobular carcinoma in situ (PLCIS) is an uncommon, high-grade in situ carcinoma with some features of classic lobular carcinoma in situ, namely discohesion and absence of e-cadherin expression. First described in 1996, there are limited data on the natural history of PLCIS and no evidence-based consensus guidelines for management. Our aim was to evaluate upgrade rates at surgical excision and patient outcomes following surgical resection.

Methods: After IRB approval, we identified patients with a diagnosis of PLCIS between 6/2004 and 7/2017 from our prospectively maintained institutional pathology and breast surgery databases. We excluded patients with a concurrent pre-operative diagnosis of DCIS or invasive breast cancer. We analyzed patient, tumor, and treatment variables and outcomes following operation.

Results: We identified 18 patients with pure PLCIS (15 diagnosed with PLCIS on core needle biopsy (CNB), 2 upgraded to PLCIS at operation for CNB findings of atypical lobular hyperplasia, and 1 diagnosed after excisional biopsy without a preceding CNB). Median patient age was 52 years (range 48 to 74 years). All cases were screen-detected. Mammographic findings were calcifications in 77.8%, asymmetric density in 16.7%, and both calcifications and asymmetry in 5.5%. Of 8 patients with a pre-operative ultrasound, 5 (62.5%) demonstrated an associated hypoechoic mass. Of the 15 patients with PLCIS on CNB, 3 (20%) were upgraded to invasive lobular carcinoma at operation. Operations for PLCIS included mastectomy in 7 patients, all resected with negative margins, and wide local excision (WLE) in 11 of which 10 had negative margins and 1 patient had a focally positive margin. Post-operatively, of the 11 patients with a final diagnosis of PLCIS treated with WLE, 2 (18.2%) received adjuvant radiation therapy, and 6 (54.5%) received adjuvant endocrine therapy (4 for estrogen receptor (ER)-positive, 1 for ER-negative, and 1 with unknown receptor status PLCIS). With 47 months of mean follow-up, 2 patients developed ipsilateral breast recurrence. The solitary patient with ER-negative PLCIS with a focally positive margin following initial WLE and adjuvant raloxifene recurred with PLCIS 16 months later. She subsequently was treated with re-WLE and adjuvant radiation therapy (RT). The second patient recurred following WLE and adjuvant RT, but no adjuvant endocrine therapy, for ER-positive PLCIS excised with margins of 1cm; she developed node-negative invasive lobular carcinoma 87 months later and was treated with mastectomy and adjuvant endocrine therapy.

Conclusions: For this uncommon entity, we observed overall excellent outcomes following surgical treatment with negative pathologic margins. We noted an upgrade rate of 20% for PLCIS on pre-operative CNB to invasive cancer. Local recurrence at 16 months in the solitary patient with a focally positive margin suggests a benefit to margin negative resection. Ipsilateral invasive lobular carcinoma in 1 patient with ER-positive PLCIS >7 years after initial treatment including RT indicates close follow-up for future breast events and consideration of endocrine therapy may be of value as for other ER-positive breast neoplasms. While further and larger study with longer-term follow-up is needed, these data suggest wide local excision with negative margins, and consideration of adjuvant endocrine therapy for ER-positive disease, is a reasonable treatment strategy for patients with PLCIS.

404231 - ICE3 Trial: Cryoablation of low-risk, early-stage breast cancers 1.5 cm: An evaluation of local recurrence - An interim update

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Background/Objective: Genomic profiling has led to a better understanding of tumor biology, providing more individualized patient treatment. Minimalizing the approach to treatment for a select group of patients with favorable tumor biology should be considered. Cryoablation is shown to be effective for small breast cancers as shown in the ACOSOG Z1072 trial. The ICE3 Trial is a post-marketing study aimed to evaluate efficacy and safety of cryoablation without lumpectomy on low-risk, early-stage breast cancer in women 60 years or older. Efficacy measures are local recurrence and long-term survival. Cryoablation is an office procedure that percutaneously destroys lesions by exposing them to extremely low temperatures. Cryoablation may be followed by whole-breast radiation and, if appropriate, adjuvant pharmacologic treatment. Cryoablation offers patients participating in this study an alternative to surgical treatment (partial mastectomy) for their breast cancer; avoiding the potential risks associated with surgery.

Methods: This study is a multi-centered, single-arm, non-randomized clinical trial. The ICE3 trial is currently enrolling patients at 17 sites nationwide. This trial should enroll up to 200 patients. The criteria to include patients to the study are: competent to sign informed consent, diagnosis of invasive ductal breast carcinoma by core needle biopsy, meeting the following criteria - unifocal primary disease, tumors less than or equal to 1.5cm in size, estrogen and/or progesterone receptor-positive, HER2-negative, women aged 60 and older, breast size adequate for safe cryoablation. The lesion must be sonographically visible at the time of treatment. The procedure of the cryoablation is performed under ultrasound guidance and only local anesthesia is necessary. The entire cryoablation process is 20-40 minutes, depending on lesion size, and requires no sutures.

Results: Thus far, 143 total patients enrolled, 3 screen failed, 140 procedures performed with 100% success rate, 1 imaging and clinical recurrence, 97 patients (67%) have been followed for 6 months, 79 patients (55%) for 12 months of follow-up, 23 patients (16%) for 24 months of follow-up, and 1 patient for 36 months. Seventy-eight of 79 patients with at least 12 months of follow-up post-ablation showed no recurrence = 98.7%. The mean age is: 75, with range of 58-94; the mean tumor size is: 7.5mm Transverse, with range of 2.8mm-17mm and 8.6mm Sagittal, with range of 0mm-17mm. The results to date show no significant device-related adverse events or complications reported. Most of the adverse events reported were minor (ex: edema, bruising, minor bleeding from needle insertion, minor local hematoma); 2 patients (1.4%) had moderate skin burn that were topically treated. Adjuvant treatment is at the discretion of the treating physician, according to protocol. Twenty patients have undergone adjuvant radiation, and 1 patient received chemotherapy. Seventy-six patients receive endocrine therapy. Sentinel node biopsy is at the discretion of the treating surgeon. Nine patients have undergone sentinel biopsy. One patient had positive sentinel nodes. This patient had radiation and endocrine therapy. The 24-month follow-up visit occurred in April 2017. The patient is currently still clinically negative for a recurrence. All of the patients were released home on the day of the procedure. Most (76%) of them returned to their full daily activities 48 hours post-procedure. More than 95% of the patients reported satisfaction from the cosmetic results during the follow-up visits. More than 98% of the physicians reported satisfaction from the cosmetic results during the follow-up visits.

Conclusions: According to this interim review of the data for the ICE3 trial, cryoablation offers relatively small sub-procedure risks to the subjects with the benefits of a minimally invasive alternative to surgical treatment of early-stage, low-risk breast cancer. Continued enrollment of patients in ICE3 trial to a goal of 160-200 participants will be the largest validated breast cancer, liquid nitrogen-based cryoablation database with long-term follow-up in this population.

403101 – Multi-disciplinary clinic discussion associated with decreased performance of breast MRI and increased eligibility for breast conservation

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Background/Objective: The management of breast cancer benefits from a multi-disciplinary approach as this leads to better adherence to management guidelines. There is much variability in the utilization of MRI in the management of breast cancer. This study examines the effect of implementation of a multi-disciplinary clinic (MDC) on the utilization of MRI and breast-conserving therapy (BCT).

Methods: We conducted a retrospective review of patients who were diagnosed with invasive breast cancer 1 year prior to and after the implementation of an MDC at our institution. We examined various clinical factors including age, sex, tumor characteristics, radiologic studies, surgical and medical treatment, and rates of BCT. We performed univariate analysis to compare differences among rates of pre-treatment MRI and BCT between patients who were and were not presented at the MDC.

Results: A total of 539 patients were eligible for the study. There were 122 patients who were diagnosed prior to MDC, and 419 patients discussed at MDC. There was no difference in the average age (59.9 vs 62.2, p=0.1). There were no differences between the non-MDC and MDC patients among rates of BCT offered if eligible (96.8% vs 96.7%, p=0.95) and BCT performed if eligible (98.8% vs 93.9%, p=0.07). There was, however, a significant difference between the 2 groups in rates of pre-treatment MRI performed (32.2% vs 14.4%, p<0.001). When comparing the groups that did not have a pre-treatment MRI and those that did, there was a decrease in the rate of BCT eligibility (82% vs 72.9%, p=0.02), BCT offered (98.6% vs 87.0%, p<0.001), but not in the rates of BCT performed if eligible (95% vs 94.2%, p=0.82).

Conclusions: Having a pre-treatment MRI resulted in patients more likely to be considered ineligible for BCT, and also less likely to be offered BCT. Having lower rates of BCT offered is a negative repercussion that may be mitigated through an MDC approach because patients are less likely to have a pre-treatment MRI when presented at MDC. Further research is warranted, and more detailed conclusions may be obtained through prospective trials such as the ALLIANCE-MRI trial.

403901 - Breast biopsy during post-treatment surveillance of early breast cancer patients yields high rates of benign findings

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Background/Objective: Physical examination every 4-12 months and annual mammography is recommended for surveillance of breast cancer survivors treated with breast-conserving surgery.

Organized Canadian breast screening programs for patients with no history of breast cancer have an associated 16% core biopsy rate, 1.7% surgical biopsy rate, and a benign to malignant biopsy ratio of 1.9 to 1. However, the impact of clinical and imaging surveillance following treatment for breast cancer on invasive breast procedures is not known. We sought to characterize the incidence of breast biopsy and rates of subsequent breast surgery during routine surveillance of early breast cancer survivors.

Methods: We identified all patients in Alberta, Canada who underwent breast-conserving surgery for screen-detected invasive breast cancer or ductal carcinoma in situ (DCIS) from 2010-2014. Patients with <90 days follow-up were excluded. The cohort was identified from a population-based prospective surgical database, which captures breast cancer surgeries from 14 institutions in academic/urban and community settings. Patient, tumor, and treatment variables were also abstracted. Invasive breast procedures including core biopsy, surgical biopsy, lumpectomy, or mastectomy were identified using provincial physician claims data, with medical chart review for details pertaining to all surgical procedures. Multivariable regression analysis was performed to identify factors associated with invasive breast procedures.

Results: A total of 2,065 patients met inclusion criteria; 1,650 (79.9%) were treated for invasive disease and 428 (20.6%) for DCIS. Most patients with invasive cancer had Stage I disease (1386 patients, 84.0%). Median age at initial surgery was 62 years, median follow-up was 3.82 years. Adjuvant treatment data were available for 1,853 patients; 1,686 (90.1%) completed whole-breast irradiation, 254 (13.7%) received chemotherapy, and 63.0% (973/1,545) of hormone-receptor positive patients received endocrine therapy. During surveillance, core biopsies were performed in 304 patients (14.7%). Of these, 224 (73.7%) core biopsies yielded benign pathology, and 80 (26.3%) identified malignancies, with a benign-to-malignant ratio of 2.8 to 1. Surgical biopsies were performed in 11 patients (0.5%); 10 (90.9%) were benign, and 1 (9.1%) malignant. Additional breast surgery after biopsy was performed in 101 patients (4.9%); 36 (1.8%) had local recurrence/ipsilateral breast cancers, 42 (2.0%) developed contralateral breast cancers, and 2 (0.1%) had ipsilateral angiosarcoma. Only 21 patients (1.0%) had surgery for other benign indications, most commonly risk reduction (n=10) or chronically infected seroma/hematomas (n=5). Overall, 58 patients (2.8%) had subsequent unilateral (n=36) or bilateral (n=22) mastectomy during surveillance. On multivariate analysis, factors associated with any invasive breast procedure included younger age (p=0.004), earlier year of surgery (p<0.0001), shorter driving time to nearest cancer center (p=0.01), surgery at an academic institution (p=0.03), higher number of breast imaging tests in the preceding year (p=0.01), final margins <2mm (p=0.01), and adjuvant radiation therapy (p<0.001).

Conclusions: In our population of women treated with breast-conserving surgery for screen-detected breast cancers, subsequent core and surgical biopsy rates during surveillance were 14.7% and 0.5% respectively. The benign to malignant core biopsy ratio was higher than reported rates in the average-risk screened population, suggesting a more liberal biopsy approach in breast cancer survivors. The ipsilateral breast cancer rate was 1.8%, contralateral breast cancer rate was 2.0% and subsequent breast surgery rate was 4.9%. While breast biopsy is frequently an anxiety-provoking procedure for breast cancer survivors, patients can be reassured that the majority of biopsies yield benign pathology, and rates of recurrence, contralateral breast cancers, and subsequent breast surgery are low.

401308 - Validation of a formalin-fixed paraffin embedded nanostring assay for breast cancer

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Background/Objective: Estimation of breast cancer risk is of great interest, but validated risk assessment tools do not incorporate molecular factors. Our goal is to validate the use of a 76-gene, microarray-based clinical assay (Malignancy Risk signature, MR) on a commercially available, NanoString platform using formalin-fixed paraffin-embedded (FFPE) tissue. The MR signature was developed from Affymetrix microarray in fresh frozen (FF) tissue and was previously validated to distinguish malignant from benign FF breast and lung lesions. Our primary aim was to validate the use of the MR NanoString in FFPE breast tissue compared to FF.

Methods: After IRB approval, institutional tissue and databanks were queried for breast cancer cases with banked FF and FFPE benign and tumor tissues with associated clinical data. After macrodissection of benign and malignant lesions (if needed), automated RNA extraction was performed. All specimens were quantified by Qubit and were screened for quality on the Agilent TapeStation. A custom NanoString nCounter CodeSet for the MR signature and 18 housekeeping genes was developed; hybridizations were performed in randomized FF/FFPE groups. The NanoString cartridges were scanned at 555 fields of view, and statistical analysis included background correction by mean + 2 of standard deviation of negative controls and normalization by geometric mean of housekeeping genes during data processing. To evaluate batch effect, ANOVA test was applied to estimate the difference of the endogenous genes and housekeeping genes across batches. Principal component analysis was used to generate MR signature score based on the first principal component.

Results: One hundred thirty-seven samples had adequate RNA quantity and quality to undergo NanoString analysis. Twenty-eight cases were identified with all 4 tissue specimens (112 NanoString); an additional 8 cases had at least 1 paired specimen (FF/FFPE tumor or FF/FFPE benign). The expression of 18 housekeeping genes had lower variation across all samples (CV%: 17 ~ 23) and no batch effect was noted based on ANOVA test for 18 housekeeping gene expression across the batches before normalization ($p>0.05$). Normal tissue samples were noted to have poor cellularity and low RNA yield for both FF and FFPE tissues, with FF benign samples having the lowest RNA yields (range 0.05ug-7.13ug; average 0.64ug). Pearson correlation coefficient between FF tumor and FFPE tumor was good at 0.67 ($p<0.001$). Poor correlation was noted between FF normal and FFPE normal specimens at 0.25 ($p=0.203$). Across all 137 specimens, Pearson correlation coefficient for MR loading coefficient was 0.99 between FF and FFPE ($p<0.001$), supporting the validity of the FFPE assay compared to FF.

Conclusions: Good correlation was identified between FFPE and FF specimens on NanoString, validating the use of this platform in reproducing the gene signature, and specifically its utility in FFPE. Poor correlation in benign tissue samples is likely due to poor cellularity of benign breast tissue specimens and is a potential limitation of this approach.

Table: Frequency table for nanostring breast cancer tissue samples

Type	FF	FFPE	Total
Normal	30	36	66
Tumor	35	36	71
Total	65	72	137

403242 - SBR score correlates with nodal positivity and distant recurrence

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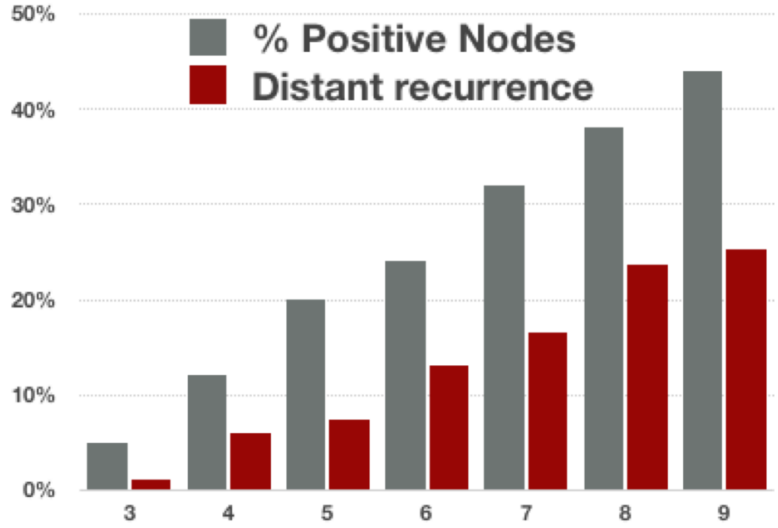
Background/Objective: The Scarff-Bloom-Richardson score is calculated by adding a score of 1 (best) to 3 (worst) for nuclear grade, tubule formation, and mitotic count, yielding a total score that ranges from 3 (best) to 9 (worst). SBR scores of 3 to 5 are grouped as grade 1 (low-grade), scores of 6 and 7 are considered grade 2 (intermediate-grade) and scores 8 and 9 are grade 3 (high-grade). We analyzed nodal positivity and distant disease probability by individual SBR score to determine whether both increased as SBR score increased and to determine whether the current groupings were appropriate.

Methods: We used a prospective database to find 2,985 patients with invasive ductal carcinoma with axillary nodal status and all data to calculate SBR scores. Nodal positivity was analyzed by SBR score. N0(i+) was considered node-negative. P-values between each SBR group were calculated using 2x2 tables. The probability of distant recurrence was determined by Kaplan-Meier Analysis. The difference between curves was analyzed by the log-rank method.

Results: As the SBR score increased, so did nodal positivity and the probability of distant recurrence (Figure). The rate of nodal positivity appeared to be appropriately categorized by low, intermediate and high grade when the patients were grouped SBR 3, 4 (less than 15%) versus 5, 6 (less than 30%), versus 7, 8, 9 (less than 45%). Distant disease, however, conformed best when grouped SBR 3, 4, 5 versus 6, 7, versus 8, 9 as in the standard grouping pattern.

Conclusions: There was excellent correlation between SBR score and nodal positivity and the probability of distant disease. As SBR score increased, nodal positivity increased but it did not conform to the standard grouping pattern. When distant recurrence was the endpoint, our data confirmed the currently accepted grouping pattern. While SBR scores of 3, 4 and 5 are considered low-grade, there is substantial risk of nodal metastases and distant disease in patients with SBR scores of 4 and 5. The only true low-grade lesions are those that score 3, and they represent only 5% (138/2985) of patients.

Figure: Correlation between SBR score, nodal positivity and distant recurrence



404293 - The impact of mitotic score versus pleomorphic subtype on disease-free survival in invasive lobular carcinoma of the breast

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Background/Objective: Pleomorphic invasive lobular carcinoma (pILC) is thought to have worse outcomes than classic invasive lobular carcinoma, and is therefore treated more aggressively with higher rates of chemotherapy use. However, currently available data are sparse and show conflicting results regarding the significance of pILC. We sought to determine whether or not pleomorphic subtype is an independent predictor of poor outcomes in a large cohort of ILC cases, adjusting for all components of grade, stage, and estrogen receptor (ER)/progesterone receptor (PR)/HER2 status.

Methods: We queried a prospectively maintained surgical database and identified 614 cases of ILC treated at our institution from 1995-2016. We reviewed records to determine tumor grade and its component scores, clinical outcomes, and follow-up time. Local or distant recurrences were included as diseas- free survival (DFS) events. We excluded 10 cases of de novo metastatic ILC, and 38 cases of mixed invasive ductal/ILC, leaving 566 for analysis. Data were analyzed in STATA 14.2, using the chi-squared test for categorical variables, t-test for continuous variables, Kaplan Meier disease-free survival estimates, and a Cox regression model.

Results: Average age at diagnosis was 59.4 years (range 28-91), and mean follow-up time was 6 years (range 0.5-30), with the majority of cases being grade 2 (62%), and ER+PR+HER2- (76%). Pleomorphic subtype was seen in 59 cases (10.4%), and was significantly associated with higher grade, higher stage, increased lymphovascular invasion, and receptor status (Table). On univariate analysis, pILC cases had significantly worse DFS. However, worse DFS was also significantly associated with overall grade, higher nuclear score, higher mitotic score, higher stage, and receptor status other than ER+PR+HER2-. After adjustment for these factors in a Cox regression model, pleomorphic subtype was no longer significantly associated with DFS. However, high mitotic count was an independent predictor of poor outcome, and tumors with mitotic score of 3 had significantly worse DFS than those with mitotic count of 1 (hazard ratio 3.6, CI 1.01-12.82, p=0.047). Receptor status remained a significant predictor of DFS.

Conclusions: The poor outcomes seen in pILC are likely driven by higher mitotic rate seen in these tumors, as well as the increased proportion of PR-, triple-negative, and HER2+ tumors. Nuclear pleomorphism does not appear to be an independent predictor of poor outcome, therefore calling into question the clinical utility of this subtype designation. Mitotic count may be more useful in ILC, and future work should explore its impact.

Table:

	Pleomorphic ILC (n = 59)	Classic ILC (n = 507)	p value
Mean age at diagnosis (years)	59	59.5	p=0.137
Tumor subtype (n=488)			p<0.0001
ER+PR+Her2-	49%	78%	
ER+PR-Her2-	15%	17%	
ER-PR-Her2-	15%	2%	
Her2+	21%	3%	
Stage (n=566)			p<0.0001
1	39%	67%	
2	37%	21%	
3	24%	12%	
Lymphovascular invasion (n=533)	23%	7%	p<0.0001
Overall Grade (n = 537)			P<0.001
1	0%	37%	
2	70%	62%	
3	30%	1%	

401030 - Social stigma and issues of femininity among Pakistani women breast cancer patients

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Background/Objective: There are some cultural factors that shape women's experience of breast cancer. Goffman (1963) explains disease stigma by saying that people who possess a socially undesirable characteristic have spoiled identity that leads to social discrimination and devaluation. Although there are many quantitative studies done on the subject, an ethnographic study was needed to understand the breast cancer experience holistically. This study aims to understand the experience of a breast cancer patient taking into consideration the gendered and social relations of patients and caregivers and the underlying issues of breast as a symbol of femininity.

Methods: This qualitative study uses the 6 dimensions of stigma (Jones et al, 1984) viz. concealable, course of the action, disruptiveness, aesthetics, origin, and peril, as a theoretical framework to look at the social stigma women patients diagnosed with breast cancer have to experience. Face-to-face in-depth and conversational interviews were conducted with 35 married women breast cancer patients in a cancer clinic, recruited via non-probability convenience and purposive sampling. The women were housewives from rural or urban settings, 40-60 years of age, and only 5 of them had family history of breast cancer.

Results: Thematic analysis showed that many breast cancer patients perceive that once their cancer is revealed to others, people treat them differently. Women feel cancer is less concealable because of the chemotherapy and associated alopecia, which increases the visibility of the disease. The physical pain and fatigue accompanied with the treatment brings with it vulnerabilities, which the caregivers have to address. The patients felt that their duties as mothers and homemakers were disrupted or shifted to the caregivers, which made them feel less feminine. Also, disclosure to friends and relatives was difficult because in most cases, the patient was held responsible for the disease, the primary reasons being the dietary patterns, contraceptive measures, or religious causes. The labels used by friends and family had connotations with helplessness and powerlessness.

Conclusions: The stigma surrounding breast cancer patients acts as a barrier to care and may lead to negative health outcomes. Patients often express feelings of being misunderstood, avoided, feared, or pitied (Parekh & Childs, 2016, p. 151). Therefore, health professionals may support appropriate coping strategies to deal with the stigma.

403986 - Atypical ductal hyperplasia identified on core needle biopsy should be excised

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Background/Objective: The management of atypical ductal hyperplasia (ADH) of the breast identified on core needle biopsy (CNB) has evolved and routine excision of all ADH is being questioned. Upstage rates to malignancy following excision of ADH on CNB are reported between 7-45%. Studies have attempted to define a low-risk group that can avoid surgical excision, but upstage rates in contemporary studies remain significant. The purpose of this study was to evaluate the presence of malignancy

following excision of CNB diagnosed ADH at our regional center and to evaluate factors predictive of malignancy. The secondary goal was to determine the upstage rate in patients meeting criteria for low-risk lesions to see if that group may be spared surgery.

Methods: Patients having excision of high-risk breast lesions at our regional breast surgical center were identified from OR lists, and chart review was performed to identify patients with ADH identified on CNB between 2014 and 2017. Diagnostic work-up was performed at 10 regional breast diagnostic imaging facilities, with core needle biopsy pathology performed at 7 regional hospitals. All surgery and surgical pathology was performed at our regional center. The primary endpoint was rate of upstage to malignancy. The association of age, palpability, discharge, clinical exam size, imaging size, family history of breast cancer, and type of CNB with upstage to cancer was evaluated.

Results: There were 1193 patients having surgery for high-risk lesions identified, with 294 having CNB diagnosis of ADH. Two hundred sixteen patients presented with an image-detected abnormality and the remainder with breast symptoms (mass 17, discharge 6, pain 7, not specified 48). Eighty-eight percent of core biopsies were performed with stereotactic techniques, while 12% were ultrasound-guided biopsies. Five had excision of palpable lesions, and the remainder had image-guided excision. Sixty-three patients were upstaged to malignancy (21.4%), with 11 having invasive cancer, 1 encapsulated papillary carcinoma, and 51 with DCIS (4 with microinvasion). Following excision, 129 patients had atypia, 13 had other high-risk lesions, and 92 had benign diagnoses. Of the patients diagnosed with invasive malignancy, the average tumor size was 7.9mm. Nine patients had invasive ductal carcinoma, 2 patients had tubular carcinoma, and no patients had lobular carcinoma. Of the patients diagnosed with DCIS, the average size was 20.1mm, 41.2% had grade 1 DCIS, 39.3% had grade 2 DCIS, 11.7% had grade 3 DCIS, and 7.8% had DCIS with microinvasion. The presence of a palpable mass or nipple discharge was not associated with upgrade to malignancy. There was a trend towards an association of larger physical exam size ($p=0.097$), larger imaging size ($p=0.090$), and family history of breast cancer ($p=0.084$) with upstage to malignancy. Patients with malignancy were older (60.7 vs 56.4 years, $p=0.005$), but 11 patients upstaged to malignancy were under 50 (2 invasive, 1 microinvasive, 8 DCIS) with a similar upstage risk (22% over 50, 18.6% under 50, $p=0.56$). Patients having an ultrasound-guided core biopsy were more likely to be diagnosed with malignancy (40%) than those having stereotactic core biopsy (20.5%), $p=0.0008$). Of the 63 patients who had malignancy at surgical excision, 10 (16%) had imaging lesions less than 6mm in size and upstaged to invasive carcinoma (n=1.3mm) and DCIS (9-mean size 14.9mm, microinvasion=1, grade 3=2, grade 2=2, grade 1=4) at surgical excision. Fifteen (24%) patients with malignancy had imaging lesions between 6 and 9mm (invasive (4) and DCIS (9)).

Conclusions: The upstage rate to malignancy after excision of ADH at our center is 21.4%, and we recommend ongoing excision of ADH when found on CNB. Patients who may have been considered low risk due to small lesion size and younger age still upstaged to malignancy. Further study is needed to better define a low-risk group before we can offer follow-up to patients with ADH at our center.

399385 - High Cole relaxation frequency measured by electrical impedance may indicate poor outcomes for invasive breast cancer patients

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Background/Objective: The EPET I study (Electrical Property Evaluation Technology) [1] evaluated the bioelectrical impedance of excised benign and malignant breast tissue. It demonstrated that the Cole relaxation frequency [2] (CRF, the rate at which the electrical charge re-distributes across the cell membrane) for malignant tissue is up to 1000 times that of benign tissue. Can the CRF give us further information regarding patient outcomes? In other words, could specific ranges of CRF values indicate a worse or better prognosis?

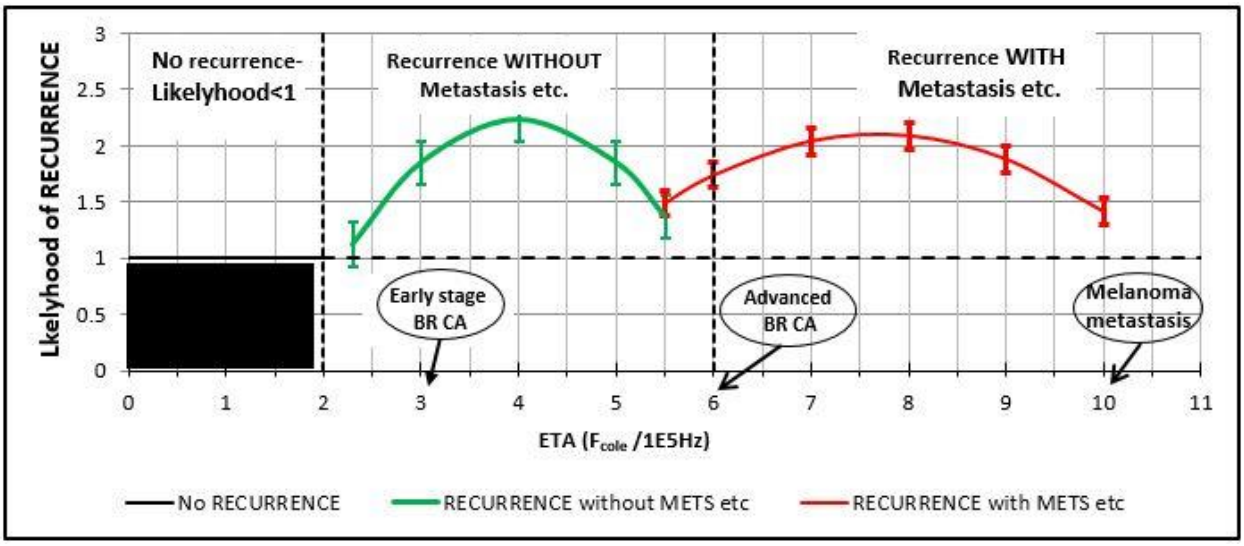
Methods: One hundred forty-five patients with 150 cancers who all had impedance measurements taken with the same apparatus [1], had outcome information available from a Cancer Registry, and (as a data quality control criterion discussed in [1]) had measurements that fit to the Cole Function with a Pearson Correlation Coefficient (PCC)>0.96, were reviewed. Twenty-seven patients had benign disease, 81 patients had cancer but no recurrence, 20 patients recurred, and of those, 15 patients developed metastases or were Stage IV before surgery (we call this metastasis etc.). These CRF measurements can be expressed as the ratio of CRF to 100 kHz. We call this dimensionless ratio the Electronic Transformation Age (ETA), since the working hypothesis developed in Reference [1] is that the cells increase in CRF due to increased nano-architecture transformation disorder as the cells transform from benign to malignant. With this definition, benign tissues have an ETA less than 1, and cancerous greater than 1. Ten-year follow-up is now available for these patients and was used to answer the question posed in the Objective.

Results: The figure shows the comparison for ETA values 1 to 10 of the Likelihood (L) of recurrence compared to non-recurrence for 3 outcomes: no recurrence, recurrence with metastasis UNLIKELY (shown in green), and with metastasis LIKELY (shown in red) with Standard Error shown for each; no recurrence (L<1) for an ETA < 3, non-metastasis recurrence for an ETA of 3 to 6, and recurrence with metastasis for ETA>6. Comparatively, while all of the cases of recurrence, with and without metastasis etc., were predicted by the ETA, the group of patients with metastases included patients with initial path Stage I-III, 2 patients with triple-negative disease, 1 patient with ER PR-negative but HER2 +, the rest had hormone receptor-positive, HER2-negative disease. Only 4 patients had grade 3 tumors. Thus, not all of the patients had Stage III disease, poorly differentiated, negative hormone receptors, or HER2-positive disease. Oncotype Dx was not performed.

Conclusions: ETA is a new and predictive parameter that compares well to breast cancer cell line suspensions data [3] (ovals in the figure are cell line findings). ETA measurements, easily obtained at the time of surgical excision, may be an independent prognostic factor to be used for planning treatment and follow-up. This is a very small study, however, and this finding should be investigated with a larger, prospective trial that compares the ETA with other prognostic markers and tumor genetic markers.

[1]The Cole relaxation frequency as a parameter to identify cancer in breast tissue. Med Phys 39(7): 4167-74 (2012). doi: 10.1118/1.4725172. PubMed PMID: 22830750. [2] Electrical physiology: electrical resistance and impedance of cells and tissues. Med Phys 1: 344-348 (1944). [3] Electrical properties of breast cancer cells from impedance measurements of cell suspensions. Journal of Physics: Conference Series: 245(1) (2010)

Figure: Likelihood (L) analysis of 3 outcomes: (1) no recurrence, (2) recurrence without metastasis etc., and (3) recurrence with metastasis etc.



403198 - A randomized controlled trial evaluating receipt of decision aid and patients perception of information conveyed during surgical consultation

Heather Neuman[1], Jennifer Tucholka[1], Jordan Bruce[2], Nicole Steffens[3], Jessica Schumacher[1], Caprice Greenberg[1], Lee Wilke[1], Jennifer Steiman[4]

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Background/Objective: To make an informed decision about breast cancer surgery, it is important for patients to hear about the benefits and risks of the surgical options. In a prior study, a significant proportion of breast cancer patients (41%) reported that their surgeon did not discuss all surgical options with them; further, more patients reported discussing lumpectomy than mastectomy. We hypothesized that providing patients with high-quality information prior to the surgical consultation would prepare them for the consult and increase the likelihood that they would report both options being discussed. The objective was to examine the impact of pre-consult information on patients perception of information conveyed during their surgical consultation.

Methods: In this randomized control trial, Stage 0-III breast cancer patients were prospectively randomized to an email link to standard websites (National Cancer Institute, American Cancer Society, Breastcancer.org) versus a decision aid. Patients seeking second opinions, diagnosed by excisional biopsy, or without an email address were ineligible. Patients completed a survey following surgical consultation that assessed perceptions of the information conveyed (n=211). Univariate statistics used to compare findings between study arms. Multivariable logistic regression models were used to assess the association between patients perception of information conveyed and age, education, stage, and surgeon. The change in pseudoR2 estimated the proportion of the variance in patients perception that was attributable to patient factors versus the surgeon.

Results: The median age was 60 years (range 27-80), 98% were white, 55% had Stage I cancer, and 87% had at least some college education; demographics were similar between study arms (p=NS). There was

no association between study arm and reported discussions for either lumpectomy or mastectomy. Overall, 94% of patients reported that their surgeon discussed lumpectomy as an option for them versus 76% for mastectomy (Table). Seventy percent reported that their surgeon discussed both options. The individual surgeon that a patient saw was a strong predictor of patients perceptions of whether mastectomy was discussed as an option for them (p=0.0001), whether reasons to have a mastectomy were discussed (p=0.004), and whether reasons not to have a lumpectomy were discussed (p=0.03). Of the patient factors, only stage was associated with information conveyed, with patients with higher-stage cancers more likely to report that their surgeon discussed reasons to have a mastectomy (p=0.01).

Conclusions: Overall, the majority of patients reported hearing about both lumpectomy and mastectomy as options for them from their surgeon. Importantly, this included a balanced discussion around the reasons for and against a given procedure. Our high rates as compared to prior studies may be because patients received information prior to the consultation or may reflect the timing of assessment (immediately after surgical consultation to minimize recall bias). However, patients were still less likely to describe having mastectomy discussed as an option for them, with surgeon seen explaining most (73%) of this variation. This emphasizes the significant influence of provider discussions in this preference-based decision. Further work will evaluate patient-surgeon communication directly to identify opportunities to intervene.

Table: Patient perceptions of information conveyed during surgical consultation

	% (N)
Did any of your health care providers talk about lumpectomy as an option for you?	94%
Did any of your health care providers talk about mastectomy as an option for you?	76%
Did you and your health care providers talk about reasons to have a lumpectomy?	94%
Did you and your health care providers talk about reasons **not** to have a lumpectomy?	69%
Did you and your health care providers talk about reasons to have a mastectomy?	83%
Did you and your health care providers talk about reasons **not** to have a mastectomy?	80%
**As there were no differences between study arms, the data presented represents the overall cohort*	

402453 – Breast enhanced recovery after surgery: Improvement of patient experience

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Background/Objective: The aim of the breast enhanced recovery after surgery (ERAS) pathway was to evaluate factors that could optimize the recovery of breast surgery patients. The outcomes of interest were decreased post-operative nausea, vomiting, and pain.

Methods: A multidisciplinary approach was taken to establish and implement an ERAS protocol for breast patients. We performed a post-operative survey for 3 months prior and for 3 months after the initiation of the ERAS pathway. Patients received ERAS information at the time of surgery decision, at pre-anesthesia clinic, and on the day of surgery. Patients were pre-operatively administered scopolamine patches, celecoxib, and gabapentin. Intra-operatively, they received intravenous anti-emetics and pectoral blocks. The survey participants were patients who had undergone breast surgery including: excisional biopsy, partial mastectomy, mastectomy, and any axillary procedure. These

patients were asked to complete surveys at their first post-operative visit, assessing their experience with nausea and pain immediately after surgery, at the 24-hour, 48-hour and 1-week marks. They were asked to rate these on a scale of 1 through 5 (1=none, 5=very bad). We also asked patients when they stopped requiring narcotics. Mann-Whitney U tests were used to compare post-operative pain, nausea levels, and narcotic usage between the pre-ERAS and post-ERAS patient groups.

Results: Generally, post-operative pain and nausea levels improved with the implementation of a breast ERAS protocol (Table). Pain immediately after surgery was significantly lower in the post-ERAS group compared to the pre-ERAS group (p=0.001). For 24 hours to 1 week post-operation, pain levels were not significantly different between the pre- and post-ERAS groups ($p \geq 0.06$). With respect to nausea, there was no significant difference between the pre-ERAS and post-ERAS patient groups for any post-operative time point (p>0.579). For narcotic usage, there was no significant difference between the pre- and post-ERAS groups (p=0.318).

Conclusions: After implementing ERAS, we saw a statistically significant reduction in immediate post-operative pain. The proposed protocol will benefit from continued evaluation and study to create a better post-operative experience for our patients. Overall trends toward improvement in nausea and pain in this series are a promising outcome. Future areas of interest will be a direct measure of impact on rates of post-operative admission for same day surgery.

Table: Post-operative nausea and pain levels among patients, median (average ± standard deviation)

		Pre-ERAS (n=147)	ERAS (n=154)
Pain	Immediately	3.0 (2.87 ± 1.20)	2.0 (2.42 ± 1.21)
	At 24 hrs	3.0 (2.87 ± 1.10)	3.0 (2.65 ± 1.19)
	At 48 hrs	3.0 (2.47 ± 1.10)	3.0 (2.53 ± 1.15)
	At 1 wk	2.0 (2.14 ± 1.07)	2.0 (2.18 ± 1.08)
Nausea	Immediately	1.0 (1.65 ± 1.21)	1.0 (1.50 ± 0.90)
	At 24 hrs	1.0 (1.40 ± 0.90)	1.0 (1.30 ± 0.72)
	At 48 hrs	1.0 (1.23 ± 0.63)	1.0 (1.25 ± 0.80)
Note: Abstentions were excluded from analyses			

401534 - The natural history of undiagnosed invasive breast cancer in the modern era

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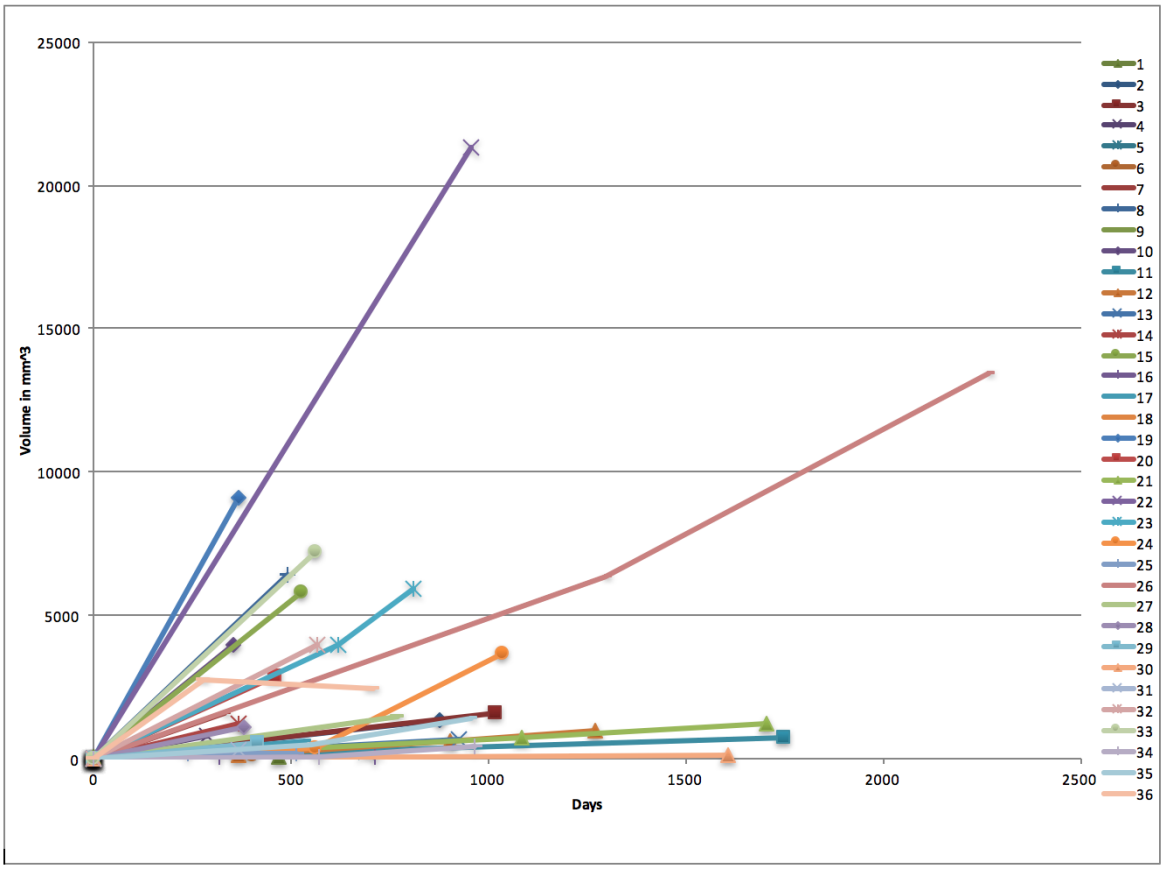
Background/Objective: Traditionally, the growth of breast cancer has most commonly been estimated using overly simplistic, inaccurate mathematical models of tumor doubling time. The authors describe the progression of undiagnosed, untreated breast cancer missed on serial mammograms in a large metropolitan area. Tumor growth velocity of a homogeneous subset of breast cancers was correlated to patient and tumor characteristics to determine if the speed of progression could be predicted.

Methods: Women with biopsy-proven breast cancer presented to a nationally-accredited breast center in Brooklyn, New York between February 2011 and June 2017. Prior imaging was reviewed, and patients whose breast cancers were found to have been missed on previous serial mammograms at outside urban breast screening centers were included in the study. Patient and tumor characteristics were collected. Two attending radiologists reviewed the mammograms to record tumor dimensions at different time points. The volume was calculated using the formula for an ellipsoid if 3 dimensions were available, and an oblate spheroid if only 2 dimensions were available. Rates of change in volume, or tumor growth velocities, were calculated in mm^3/day. Medians, Kruskal-Wallis (H), and Spearman Rho statistics were employed to correlate tumor volume growth velocity to patient age, stage at presentation, grade, pathologic tumor size, Oncotype Dx, and spheroid-ellipsoid discrepancy (SED).

Results: Seventy-two tumors were identified in 64 patients, and 4 women were excluded due to benign pathology or missing measurements on secondary review. In the 6 patients with 2 tumors, the largest was chosen. Fourteen were DCIS-only, leaving 46 invasive tumors. Of those, 36 estrogen receptor-positive and Her-2-negative invasive tumors were identified and included in the analysis. Median age was 70 (range 44-83). Eight percent of patients presented with pain, and 11% presented with a palpable mass. Nineteen percent were eventually found to have axillary nodal metastases. Median Oncotype Dx score was 14 (range 1-55). The volume measurements were plotted over time, with the slope of each line representing the rate of growth (Figure). Ninety-four percent of tumors increased in volume over time. Tumor growth rates varied widely, but 63.9% of tumors at least doubled in volume over a median follow-up of 689 days (range 287-2267), and the median growth velocity was 0.8mm^3/day (range -0.4-24.3) among all tumors. Tumor grade, pathologic invasive tumor size, and pathologic tumor stage (pT of TNM) were positively correlated to tumor growth velocity (H=6.2, p=0.04; rho=0.54,p=0.001; and H=11.9, p=0.04 respectively). Age, pathologic nodal positivity, Oncotype Dx score, follow-up time, and spheroid-ellipsoid discrepancy (SED) were not related to tumor growth velocity in this sample.

Conclusions: Contrary to the assumptions of prior math models, the growth rates of a homogeneous group of invasive breast cancers varied widely and could not be predicted. Therefore, when a patient presents with breast cancer in a clinical or medicolegal context, it is impossible to predict at what time point the cancer became clinically or radiologically apparent. Difficult-to-measure biologic factors such as tumor microenvironment may play a more significant role in tumor growth rates than traditional clinicopathologic characteristics.

Figure: Tumor growth velocity over time in a homogeneous subset of estrogen receptor positive, HER-2 negative invasive cancers



404258 - A pilot study of a breast surgery enhanced recover after surgery (ERAS) protocol to eliminate narcotic prescription at discharge

Kristin Rojas[1], Donna-Marie Manasseh[1], Solomon Agbroko[2], Nicole Bilbro[2], Patrick Borgen[1]

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Background/Objective: The use of opioid-sparing analgesia in enhanced recovery after surgery (ERAS) protocols can provide exceptional peri-operative pain control while minimizing adverse side effects such as somnolence, nausea, and the potential for addiction. We sought to implement an ERAS protocol in breast surgery patients undergoing lumpectomy or mastectomy without reconstruction.

Methods: A multidisciplinary team was assembled to develop a 10-step ERAS protocol that would apply to patients undergoing a lumpectomy or mastectomy without reconstruction: 1) Enhanced pre-operative counseling of peri-operative expectations and non-narcotic pain control 2) Clear liquids up to 2 hours pre-operatively 3) Pre-operative holding area medication: 975mg acetaminophen, 300mg gabapentin 4) Intra-operative maintenance of euvolemia, normothermia 5) Antiemetic protocol upon induction 6) Long-acting local analgesia prior to incision (1:1 mixture of 20cc 1.3% bupivacaine liposome suspension with 20cc 0.5% bupivacaine hydrochloride in lumpectomy, or 1:2 mixture of 20cc 1.3% 20cc bupivacaine liposome suspension with 40cc 0.25% bupivacaine hydrochloride in mastectomy) 7) 15mg

ketorolac at incision closure 8) At least 20cc of liposomal bupivacaine mixture (skin, subcutaneous, chest wall, axilla, and drain site) 9) Early cessation of intravenous fluids, early ambulation, and unrestricted diet 10) Ibuprofen 600mg q6 hours alternating with 650mg Tylenol at discharge A pilot study of 30 patients of 2 attending surgeons was planned. Patients were excluded if they did not receive the pre-operative medication (2 patients) or if they were administered a pre-operative neuraxial block by anesthesia (1 patient). In-hospital and discharge prescription of morphine milligram equivalents (MMEs) of the study group were compared to a control group of similar patients receiving usual care. Post-operative day 1 and week 1 pain scores were collected from patients at the post-operative visit.

Results: There were 29 surgeries in 27 patients who received the ERAS protocol. The mean age of patients in the ERAS group was 56. In the ERAS group, there were 19 needle-localized lumpectomies, 4 excisional biopsies, and 2 re-excisions totaling 25 lumpectomies. There were 4 mastectomies without reconstruction. Fourteen patients had breast cancer. Pain scores were available for 13 lumpectomies and 4 mastectomies without reconstruction. Median post-op day 1 score in the lumpectomy group was 1 (range 0-5). Median post-op week 1 score was 1 (range 0-3). Within the mastectomy without reconstruction (n=4), median post-op day 1 score was 2.5 (range 0-4), and median post-op week 1 score was 0.5 (range 0-1). No ERAS patients required narcotic pain medication after discharge. Only 1 mastectomy patient required an opioid overnight while in-house, and this was 6 MMEs. All lumpectomy patients went home on POD 0, and all mastectomy patients went home on POD 1 except for 1 in the study group who went home on POD 0. In contrast, in a control group of 13 lumpectomies, the average number of MMEs per patient at discharge was 45.6 (median 50, range 0-83.3). There were 4 mastectomies without reconstruction, and the average number of MME prescribed at discharge per patient was 66.3 (median 66.1, range 41.6-83.3).

Conclusions: A multidisciplinary, comprehensive ERAS protocol employing opioid-sparing techniques successfully eliminated post-operative narcotic prescription and while improving patient satisfaction. Incorporation of a comprehensive opioid-sparing multimodal analgesic regimen can minimize the contribution that surgeons make to the epidemic that kills 91 Americans every day.

396771 - Optimal post-operative antibiotic prophylaxis after breast surgery: A meta-analysis

Charalampos Siotos, Michael McColl, Mohamad Sebai, Stella Seal, Michele Manahan, Mehran Habibi, Carisa Cooney, Gedge Rosson

Johns Hopkins University, Baltimore, MD

Background/Objective: Current clinical guidelines dictate the use of prophylactic antibiotics after breast surgery for the prevention of surgical site infections (SSI). However, there is no agreement among physicians whether post-operative prophylaxis after clean surgeries, like breast surgery is necessary nor for the duration of the prophylaxis. We sought to evaluate systematically the current literature regarding the optimal use and duration of post-operative antibiotic prophylaxis in plastic breast surgery.

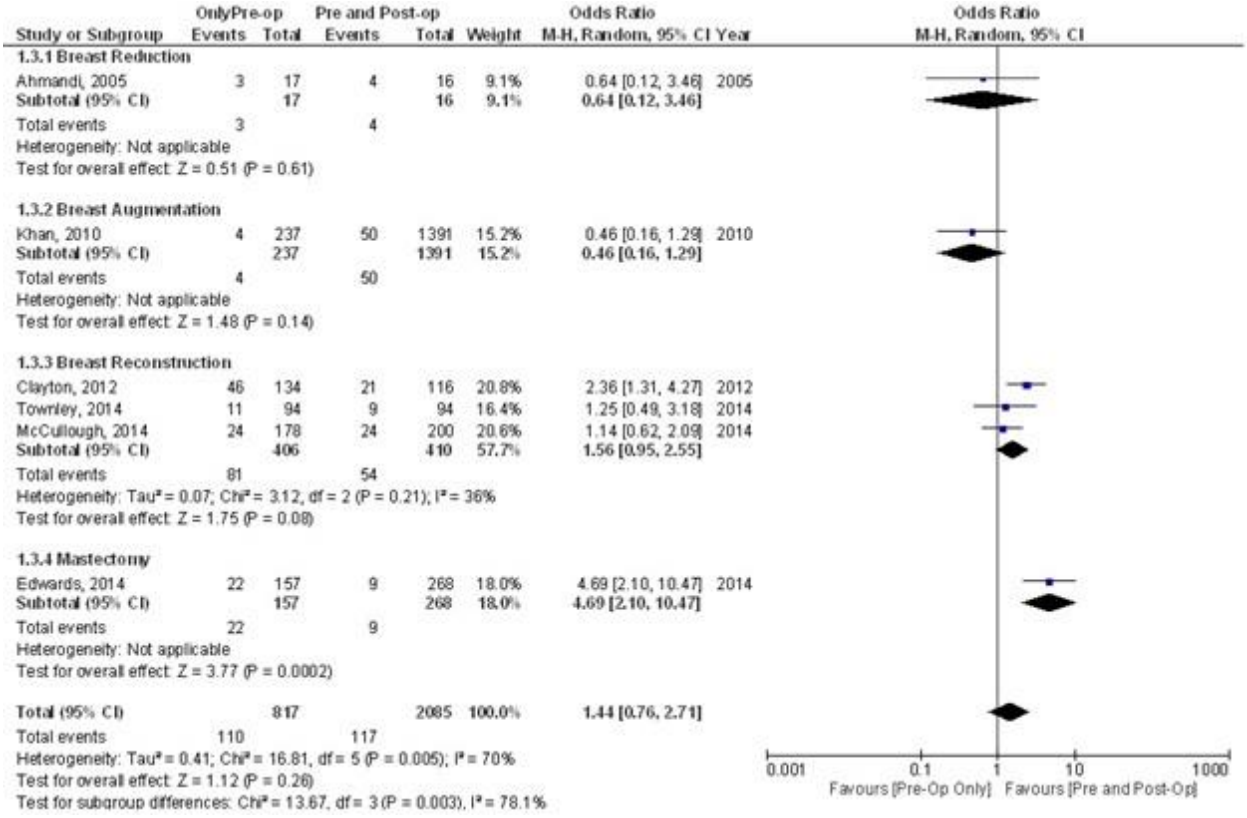
Methods: We systematically searched the PubMed, Embase, Cochrane, and Web of Science databases for relevant articles published until January 2017. We performed meta-analysis employing Random Effects Model and the RevMan software.

Results: Our search revealed 727 articles, which were screened based on their title and abstract. Of them, 56 were screened based on the full text. Following the screening process, 10 studies (1 randomized trial, 1 observational prospective, and 8 retrospective) met our criteria. Overall, 4,354 patients were included who underwent mastectomy, breast reconstruction, breast reduction, or breast

augmentation. Meta-analysis of 6 studies showed that pre-operative only use of antibiotics was associated with higher risk for SSI, although not at a statistically significant level (2,902 patients, OR=1.54, 95%CI [0.87-2.74], p=0.31, I2=64%). The results of our second meta-analysis indicates that short duration (24 hours) of post-operative antibiotics was statistically significantly associated with higher odds of SSI (5 studies, 2,843 patients, OR=1.59, 95%CI [1.02-2.46], p=0.04, I2=28%).

Conclusions: According to the results of our meta-analyses, prolonged (>24 hours) duration of prophylactic antibiotics after breast surgery might prevent surgical site infections more effectively than short duration course of antibiotics. However, limited data are currently available. Further prospective studies are necessary to establish the optimal duration of post-operative prophylactic antibiotics, balancing the benefit of infections prevention and the risk of related complications and cost.

Figure: Pre- and post-operative antibiotics versus pre-operative antibiotics only and SSI



402895 - Trends in quality indicators in the Dutch Breast Cancer Registry: What can we learn from more than 90,000 breast cancer patients registered between 2011 and 2017?

Marie Jeanne Vrancken Peeters[1], Pauline Spronk[2], Erik Heeg[2]

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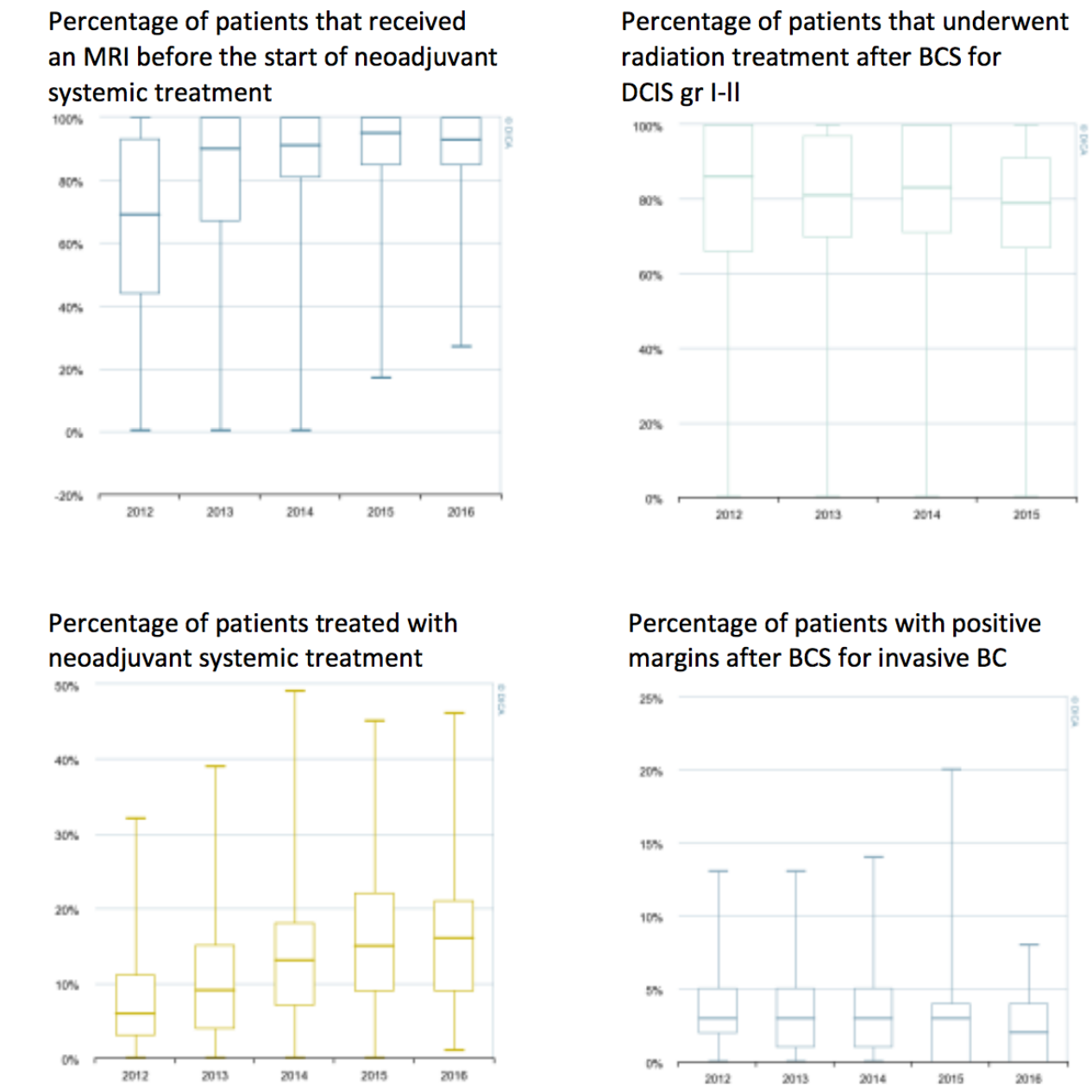
Background/Objective: Improving quality of care starts with measuring the quality of the care we give. For this purpose, the NABON Breast Cancer Audit (NBCA) was instituted in 2011 as a nationwide audit to address quality of breast cancer care and guideline adherence in the Netherlands. To developed meaningful quality indicators as a means of quality assurance, we have defined a set of potential quality indicators and have analyzed them over the last few years.

Methods: Clinical and pathological characteristics as well as information regarding diagnosis and treatment of more than 90,000 new patients diagnosed with invasive breast cancer or in situ carcinoma (DCIS) were collected in all hospitals (n=92) in the Netherlands and registered in the NBCA. Thirty-two quality indicators measuring care structure, processes, and outcomes were compared between hospitals. Furthermore, trends in indicators were analyzed for their use in improvement of quality of breast cancer care.

Results: The NBCA contains data of about 90,000 patients. Thirty-two quality indicators were being analyzed from 2012-2016. Different trends were found indicating the relevance of a particular indicator for quality improvement. The Figure shows an example of 4 different trends that were observed regarding the change in the median and the variation over the years. An increase of the median in combination with a decrease in variation represents a definite improvement of quality of care as being shown in the indicator showing the use of MRI before the start of NST (1A). An increase of the median in combination with a stable variation as being shown in the indicator showing the use of NST (1C) represents an increase in quality of care, but moreover shows that the definition being used for this indicator might not cover what we would like to know to really improve quality of care. The other 2 indicators (1B and 1D) didn't show that much change over time in both the median and the variation, indicating that quality of care is at its top level or that the definition of the indicator should be sharpened to really measure quality of care.

Conclusions: Measuring the quality of our care is very important to further improve the care we give. Quality of care is very difficult to measure, however. In the Netherlands, we started a national database consisting of all diagnostic and treatment parameters of new breast cancer patients in order to measure quality of care by defining so-called quality indicators. With the present results, we show that analyzing these indicators over time is essential to really judge a particular indicator on its value for quality improvement.

Figure: Trends in quality indicators over the past 5 years in the Netherlands, data obtained from more than 90,000 new BC patients registered in the NABON breast cancer audit (the Dutch national BC registry).



403965 - Does obtaining a larger sample of breast tissue lead to decreased HER2-equivocal diagnoses?

Yancey Warren, Jr.[1], Deba Sarma[1], April Phantana-Angkool[1], Lejla Hadzikadic-Gusic[1], Amy Voci[1], Terry Sarantou[1], Meghan Forster[1], Chad Livasy[1], I'sis Perry[1], Paul Andrews[2], David Tyson[2], Richard White[1]

[1]Levine Cancer Institute at Carolinas Medical Center, Charlotte, NC, [2]University of North Carolina School of Medicine, Chapel Hill, NC

Background/Objective: The 2013 ASCO/CAP (American Society of Clinical Oncology/College of American Pathologists) Guidelines for defining the HER2 receptor status of a breast cancer are currently utilized to determine who gets HER2-targeted therapy. There is substantial benefit to receiving HER2-targeted therapy for HER2-positive breast cancer, but it is unclear how those diagnosed with HER2-equivocal cancer should be managed. The goal of this study is to determine if undergoing up-front surgery when diagnosed with a HER2-equivocal breast cancer provides more definitive HER2 status, thereby allowing more tailored therapy.

Methods: We performed a retrospective review of HER2-equivocal core biopsies diagnosed and treated at our institution from 2014-2017. We then identified patients who had surgery up front. We defined specimens as HER2-equivocal using those standards set forth by the 2013 ASCO/CAP guidelines: IHC 2+ and dual-probe HER2/CEP17 ratio <2.0 with an average HER2 copy number 4.0 and <6.0 signals/cell. Exclusion criteria included positive or negative reflex test, positive or negative repeat test on a different core biopsy from the same specimen, patients with metastatic disease, patients not considered for surgery or chemotherapy for varying reasons, and biopsy at a site other than the breast.

Results: Forty (82%) patients found to be HER2-equivocal on core biopsy received up-front surgery. Twenty-nine (73%) underwent breast-conserving therapy (BCT), and 11 (28%) underwent mastectomy. Twenty (50%) patients were demonstrated to be either HER2-positive or negative on final surgical specimen, and 20 (50%) remained HER2-equivocal on final surgical specimen. Of the 40 patients, 5 (13%) received HER2-targeted therapy based on demonstrated change to HER2-positive disease. Of the 20 (50%) patients who remained HER2-equivocal, 4 (20%) received HER2-targeted therapy.

Conclusions: Our results showed that 50% of patients remained HER2-equivocal on final surgical specimen. Therefore, in half the patients presented here, additional tissue did not resolve the dilemma of HER2-equivocal findings. We therefore recommend the ASCO/CAP 2013 Guidelines for HER2 status be revised to better define HER2-positive, -negative, and -equivocal to facilitate the best patient treatment.

	Final HER2 Surgical Specimen Pathology			
	Equivocal	Positive	Negative	Total
BCT	16	6	7	29
Mastectomy	4	3	4	11
Received HER2 Targeted Tx	4	5	0	9

Table: Results of final surgical specimen pathology and subsequent administration of HER2-targeted therapy

403868 - Management of HER2-equivocal breast cancer

Yancey Warren, Jr.[1], Deba Sarma[1], April Phantana-Angkool[1], Lejla Hadzikadic-Gusic[1], Amy Voci[1], Terry Sarantou[1], Meghan Forster[1], Chad Livasy[1], I'sis Perry[1], Edward Hardison[2], Richard White[1]

[1]Levine Cancer Institute at Carolinas Medical Center, Charlotte, NC, [2]University of North Carolina School of Medicine, Chapel Hill, NC

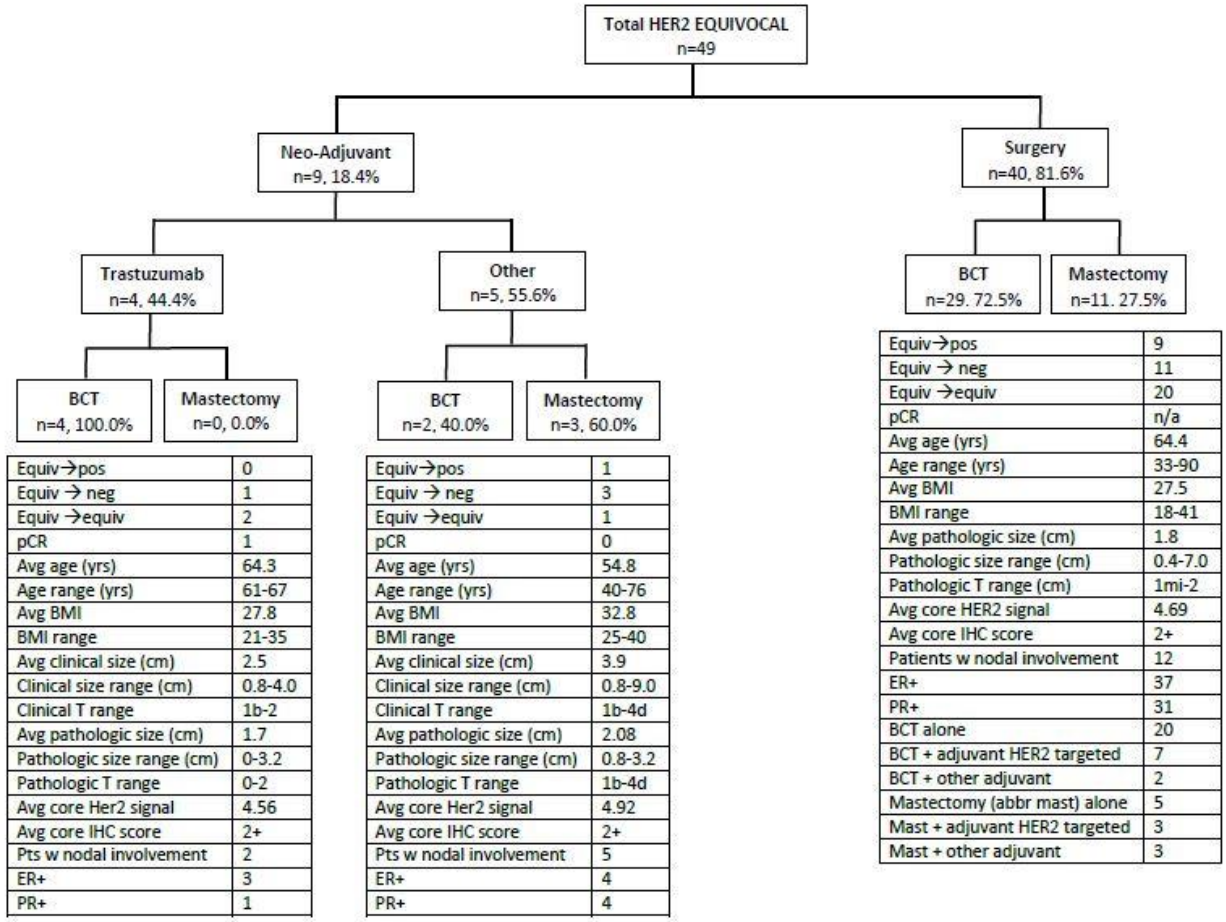
Background/Objective: The benefits of HER2-targeted therapy in the treatment of human epidermal growth factor receptor 2 (HER2)-positive breast cancer have been well studied. Large clinical trials such as NSABP B47 are attempting to analyze the potential benefit of this therapy even for HER2-negative breast cancers. There is currently no standard of care in the treatment of HER2-equivocal breast cancers. The goal of this study is to compare differences in therapy for those patients diagnosed with HER2-equivocal breast cancer on initial core needle biopsy at our institution from 2014-2017.

Methods: We performed a retrospective review of all HER2-equivocal core biopsies diagnosed and treated at our institution from 2014-2017. We defined specimens as HER2-equivocal using standards set forth by the 2013 ASCO/CAP guidelines: IHC 2+, dual-probe FISH average HER2 copy number 4.0 and <6.0 signals/cell, or dual-probe HER2/CEP17 ratio <2.0 with an average HER2 copy number 4.0 and <6.0 signals/cell. Exclusion criteria included positive or negative reflex test, positive or negative repeat test on a different core biopsy from the same specimen, patients with metastatic disease, patients not considered for surgery or chemotherapy for varying reasons, and biopsy at a site other than the breast.

Results: A total of 49 HER2-equivocal core biopsies were identified. Nine (18%) patients underwent neoadjuvant treatment, while 40 (82%) patients received up-front surgery. In the neoadjuvant group, 4 (44%) underwent neoadjuvant HER2-targeted therapy. In the group that received upfront surgery, 9 (45%) patients were demonstrated to be HER2-positive on final pathology, 11 (55%) were shown to be HER2-negative, and 20 (50%) remained equivocal. Five (56%) of HER2-positive patients received adjuvant HER2-targeted therapy. Four (20%) of the HER2-equivocal patients received adjuvant HER2-targeted therapy. No HER2-negative patients received adjuvant HER2-targeted therapy.

Conclusions: Offering HER2-equivocal patients up-front surgery enabled our institution to better select those individuals who would benefit from HER2-targeted therapy and prevent the overtreatment of those who would not benefit from HER2-targeted therapy. In those who remained equivocal, few received HER2-targeted therapy.

Figure: Various approaches to the management of patients with HER2 equivocal breast cancer at a single institution from 2014-2017 with patient characteristics and final demonstrated pathology



Equiv→pos	0
Equiv → neg	1
Equiv →equiv	2
pCR	1
Avg age (yrs)	64.3
Age range (yrs)	61-67
Avg BMI	27.8
BMI range	21-35
Avg clinical size (cm)	2.5
Clinical size range (cm)	0.8-4.0
Clinical T range	1b-2
Avg pathologic size (cm)	1.7
Pathologic size range (cm)	0-3.2
Pathologic T range	0-2
Avg core Her2 signal	4.56
Avg core IHC score	2+
Pts w nodal involvement	2
ER+	3
PR+	1

Equiv→pos	1
Equiv → neg	3
Equiv →equiv	1
pCR	0
Avg age (yrs)	54.8
Age range (yrs)	40-76
Avg BMI	32.8
BMI range	25-40
Avg clinical size (cm)	3.9
Clinical size range (cm)	0.8-9.0
Clinical T range	1b-4d
Avg pathologic size (cm)	2.08
Pathologic size range (cm)	0.8-3.2
Pathologic T range	1b-4d
Avg core Her2 signal	4.92
Avg core IHC score	2+
Pts w nodal involvement	5
ER+	4
PR+	4

Equiv→pos	9
Equiv → neg	11
Equiv →equiv	20
pCR	n/a
Avg age (yrs)	64.4
Age range (yrs)	33-90
Avg BMI	27.5
BMI range	18-41
Avg pathologic size (cm)	1.8
Pathologic size range (cm)	0.4-7.0
Pathologic T range (cm)	1mi-2
Avg core HER2 signal	4.69
Avg core IHC score	2+
Patients w nodal involvement	12
ER+	37
PR+	31
BCT alone	20
BCT + adjuvant HER2 targeted	7
BCT + other adjuvant	2
Mastectomy (abbr mast) alone	5
Mast + adjuvant HER2 targeted	3
Mast + other adjuvant	3

Radiation

401243 - Does molecular subtype matter in breast cancer patients receiving intra-operative radiation therapy (IORT)?

Jessica Burgers[1], Melinda Epstein[2], Sadia Khan[3], Peter Chen[4], Brian Kim[4], Kevin Lin[4], Lincoln Snyder[3], Colleen Coleman[3], January Lopez[5], Lisa Guerra[3], Ralph Mackintosh[4], Melvin Silverstein[3]

[1]Keck School of Medicine, University of Southern California, Glendale, CA, [2]Department of Research, Hoag Memorial Hospital Presbyterian, Newport Beach, CA, [3]Department of Surgery, Hoag Memorial Hospital Presbyterian, Newport Beach, CA, [4]Department of Radiation Oncology, Hoag Memorial Hospital Presbyterian, Newport Beach, CA, [5]Department of Radiology, Hoag Memorial Hospital Presbyterian, Newport Beach, CA

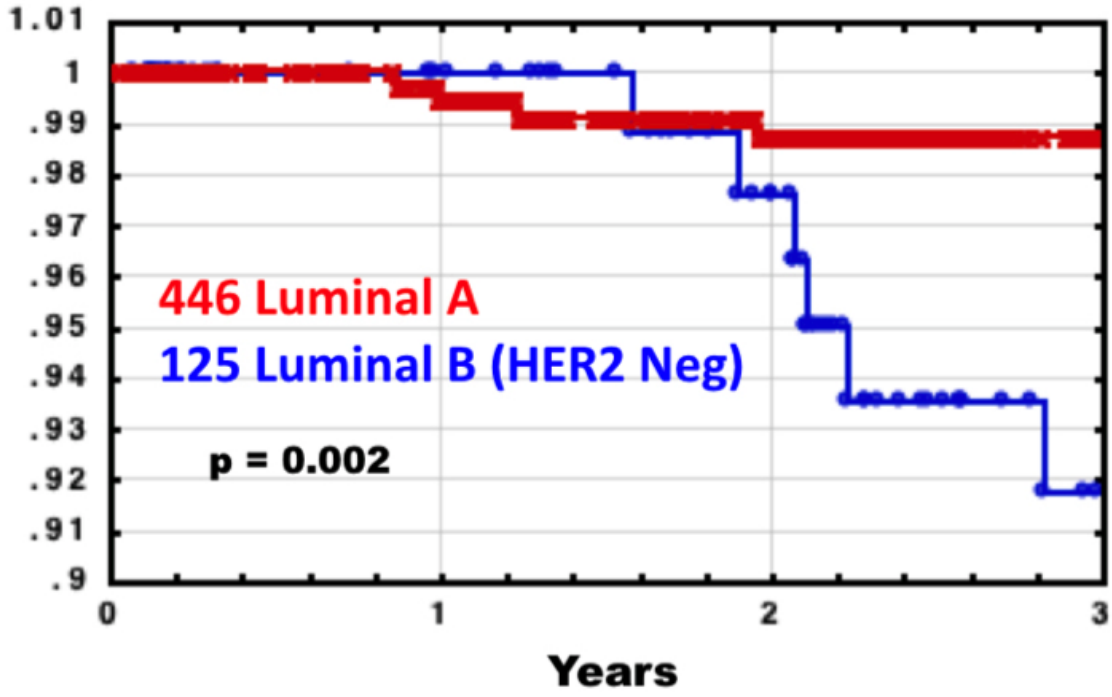
Background/Objective: Luminal A tumors (ER-positive and usually low grade) and Luminal B HER2-negative tumors (ER-positive and typically higher grade) are 2 molecular subclasses of breast tumors that have varied prognoses and different responses to therapy. To date, no data have been published regarding the comparison of these subgroups to intr-aoperative radiotherapy (IORT). To address these lack of data, we instituted a study to compare local recurrence rates in patients with these tumor subtypes treated with IORT.

Methods: There were 557 patients with invasive ductal carcinoma, Luminal A or Luminal B HER2-negative molecular subtypes, and treated with excision plus IORT included in the study. Patients who received whole-breast radiation in addition to IORT were excluded from this analysis. Immunohistochemical analysis was used as a surrogate for molecular subtyping. Luminal A patients were ER- and/or PR-positive, HER2-negative, and had a Ki67 less than 15%. If Ki67 was 15-19%, then PR had to be more than 20% positive. The Luminal B HER2-negative tumors were defined as ER- and/or PR-positive, HER2-negative, and had a Ki67 20%. Patients with a Ki67 of 15-19% and PR <20% positive were also included in this group. Any ipsilateral breast tumor event was considered a local recurrence, regardless of location. Kaplan-Meier analysis was used to predict local recurrence probabilities.

Results: With a median follow-up of 32 months, there were 6 local recurrences among 446 Luminal A patients compared to 8 among 125 Luminal B HER2-negative patients. At 3 years, the predicted local recurrence rate for Luminal A tumors was significantly lower (p=0.002) than for Luminal B HER2-negative tumors (1.3% vs. 8.2% respectively) (Figure). Patients who were Luminal A and ASTRO suitable had no local recurrences.

Conclusions: Our data demonstrate that following IORT as the full course of radiation therapy, Luminal A patients have a lower local failure rate (1.3%) than Luminal B HER2-negative tumors (8.2%) (p=0.002). The current published radiation oncology guidelines do not consider molecular subtype when determining suitability for IORT. Given the short length of follow-up in our study, it is difficult to draw a definitive conclusion about the role of tumor molecular subtyping in the selection of patients for IORT alone. However, the preliminary results suggest that the patient and the physician may want to consider tumor molecular subtype when selecting IORT as the only radiation therapy.

Figure: Kaplan-Meier curve of local recurrences luminal A versus luminal B (HER2-negative) invasive ductal carcinoma receiving IORT alone without WBRT



404029 - Prepectoral versus retropectoral implant-based reconstruction following nipple-sparing mastectomy and adjuvant radiation therapy

Solange Cox[1], Laura Bozzuto[2], Alex Bartholomew[3], Michael Sosin[4], Troy Pittman[4], Shawna Wiley[4], Eleni Tousimis[4]

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Background/Objective: Anatomic location (prepectoral or retropectoral) of implant-based reconstructive early complications following nipple-sparing mastectomy (NSM) and radiation therapy (XRT) have not been well studied. This study aims to compare implant-related complications between patients undergoing pre- vs. retropectoral reconstruction following NSM and adjuvant radiation therapy.

Methods: A retrospective chart review was performed for all patients who underwent NSM with prepectoral reconstruction followed by adjuvant radiation therapy. Data points including patient demographics, tumor subtype, and surgical management were obtained and used to identify age- and stage-matched controls with retropectoral reconstruction. The primary outcome was the rate of rippling, clinically relevant contracture (grade 3 or 4), and secondary outcomes included surgical complication rates defined as presence of hematoma, infection, flap ischemia or necrosis, nipple ischemia or necrosis, and implant loss.

Results: A total of 10 patients were identified in the prepectoral group and 10 retropectoral reconstructed patients were matched based on age, stage, and ethnicity. Overall mean follow-up time was 33.9 (SD: 25.8) months for all patients (prepectoral=13.90 months (SD:4.39), retropectoral=54.01

months (SD:22.2) p<0.001). Clinically relevant contracture rates (grade 3 or 4) were comparable in prepectoral vs. retropectoral groups, 30% vs. 70%, p=0.179, respectively. Grade 4 contractures rates were increased in the retropectoral group (30% vs. 0%, p=0.210) without reaching statistical significance. There was an increased trend of breast rippling in the prepectoral group (40% vs. 0%, p=0.08). Aside from implant-related deformity, overall complication rates differed significantly between the pre- and retropectoral groups (0% vs 50% respectively, p=0.030).

Conclusions: Prepectoral implant-based reconstruction following NSM and adjuvant radiation therapy is associated with increased levels of implant rippling, but lower rates of grade 3 and 4 contracture, and reduced rates of overall surgical complications compared to retropectoral implant-based reconstruction.

403113 - Acute and chronic complications associated with x-ray intra-operative radiation: The first 1000 patients from a single center

Melinda Epstein, Sadia Khan, Peter Chen, Brian Kim, Kevin Lin, Lincoln Snyder, Colleen Coleman, January Lopez, Lisa Guerra, Ralph Mackintosh, Melvin Silverstein

Hoag Memorial Hospital Presbyterian, Newport Beach, CA

Background/Objective: X-ray intra-operative radiation therapy (IORT) is a promising new treatment modality for the delivery of post-excision breast irradiation. It is associated with a low risk of significant complications. We present data regarding local effects and complications associated with IORT treatment in 1000 patients with a median follow-up time of 32 months.

Methods: One thousand patients were treated with IORT delivered using the Xoft Axxent Electronic Brachytherapy (eBx) System. Data were collected at 1 week, 1 month, 3 months, 6 months, and 1 year post-operatively. Thereafter, data were collected yearly. Acute complications were defined as those occurring within the first month. Chronic complications were those that persisted at 6 months. Grade 3 or greater complications were considered significant.

Results: Currently, 88% of our patients were followed more than 6 months. The Table details patient demographics as well as acute and chronic complications. The most common acute complication was erythema, seen in 20% of patients. The most common chronic complication was fibrosis observed in 9.1% of patients. However, only 4% of patients experienced significant grade III complications. The majority of patients who had complications experienced more than 1.

Conclusions: IORT is a promising treatment modality that greatly simplifies the delivery of post-excision radiation therapy. Only a small percentage of IORT patients experienced significant acute (4%) or chronic complications (2.4%), which appears more favorable than the acute dermatitis reactions and potential long-term complications related to whole-breast radiation. These data are consistent with previously published studies, providing further evidence of the low rate of significant complications associated with IORT. Addendum: A flexible tungsten rubber shield was used during the first 27 IORT cases to protect the internal organs from radiation therapy. Tungsten particles from these shields were identified in all 27 patients when they underwent their first post-operative mammography at 6 months. This was immediately reported to the FDA, and the IORT Program was halted until a stainless-steel shield was available 9 months later. All 27 patients were immediately advised and referred to appropriate consultants. No significant illnesses have been reported to our knowledge secondary to tungsten exposure. This complication is not included in the Table.

Table: Acute and chronic complications of IORT in a 1000-patient cohort

Variable	N (%)
N	1000
Median Age (Range)	65 yr. (40-92 yr.)
Median Follow-Up (Range)	32 mo. (1-89 mo.)
Acute Hematoma (Required Drainage)	10 / 1000 (1%)
Acute Seroma (Required Drainage ≥ 3 times)	6 / 1000 (0.6%)
Infection (Required Antibiotic or Surgery)	13 / 1000 (1.3%)
Necrosis (Required Surgery)	13 / 1000 (1.3%)
Acute Erythema: Severity Grade I/II Severity Grade III	**198 / 1000 (20%)** 196 / 198 (99%) 2 / 198 (1%)
Chronic Seroma (Present at 6 mo.)	23 / 1000 (2.3%)
Chronic Fibrosis (Present at 6 mo.): Severity Grade I/II Severity Grade III	**88 / 1000 (9.1%)** 87 / 88 (99%) 1 / 88 (1%)
Chronic Hyperpigmentation (Present at 6 mo.): Severity Grade I/II Severity Grade III	**69 /1000 (6.9%)** 69/ 69 (100%) 0/ 69 (0%)
Patients with Significant Acute Complications (Grade III)	40 /1000 (4%)
Patients with Significant Chronic Complications (Grade III)	24 / 1000 (2.4%)

403080 - Eliminating Intention-to-treat bias: A more accurate assessment of 1000 IORT patients

Melinda Epstein, , Sadia Khan, Peter Chen, Brian Kim, Kevin Lin, Lincoln Snyder, Colleen Coleman, January Lopez, Lisa Guerra, Ralph Mackintosh, Melvin Silverstein

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Background/Objective: Two trials of X-ray intra-operative radiation therapy (IORT), TARGIT-A and TARGIT-R, have shown IORT to be a safe alternative to whole-breast radiation therapy (WBRT) with a low local recurrence rate. In both trials, patients with adverse findings on histopathology received WBRT in addition to IORT (15% for TARGIT-A and 27% for TARGIT-R). Since data from these trials were reported by intention to treat, patients who received IORT alone or in combination with WBRT were combined into a single cohort. The probability of local recurrence was reported for the entire cohort. Since patients who receive WBRT with IORT as a boost recur at lower rate than patients who receive IORT

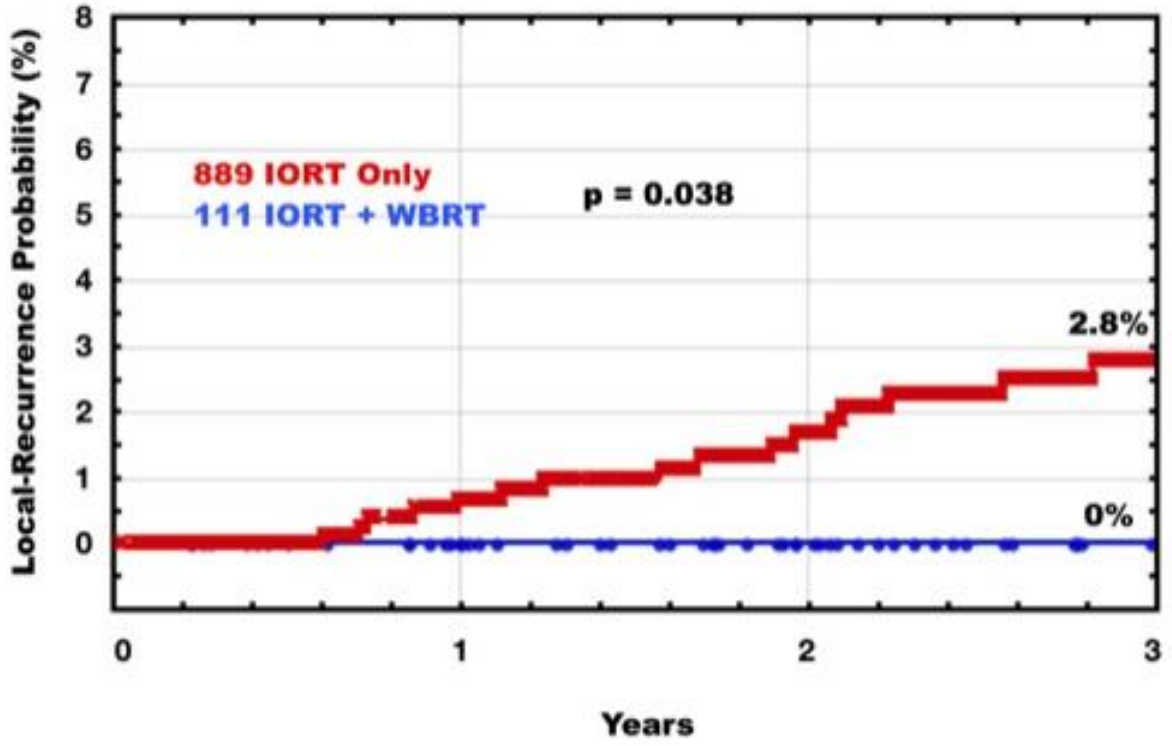
alone, combining these groups resulted in an artificially improved recurrence curve. To more accurately assess the local recurrence rate with IORT alone, we analyzed data from a prospective, non-randomized IORT trial by treatment delivered, separating those who received IORT alone from those who received IORT plus WBRT.

Methods: One thousand patients received X-ray IORT as part of a prospective study from June 2010 to September 2017. All patients had tumor spans 30mm 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 30mm, tumor margins 2mm, no extensive lymphovascular invasion, and negative lymph nodes (N0(i+) acceptable). Patients who did not meet all criteria were advised to receive supplemental WBRT. Kaplan-Meier analysis was used to estimate local recurrence probability for each group. All local events, regardless of which quadrant they occurred, were included in the analysis.

Results: There were 889 patients treated with IORT as their sole form of radiation therapy. One hundred eleven patients received IORT plus WBRT. There have been 23 IBTEs, 14 at or near the IORT treatment site and 9 in different quadrants. There have been 2 regional recurrences, 2 distant recurrences, and no breast cancer-related deaths. All 27 events occurred among 25 patients. None of the recurrences occurred in patients who received IORT plus WBRT. With a median follow-up of 32 months, Kaplan-Meier analysis predicted that 2.8% of patients treated with IORT alone and 0% of patients treated with IORT plus WBRT will recur locally at 3 years (Figure). This difference is statistically significant (p=0.038).

Conclusions: The local recurrence rate for 889 patients treated with IORT alone was 2.8% at 3 years compared to 0% in the 111 patients with adverse pathologic findings who received both IORT and WBRT (p=0.038). When the 2 treatment groups were combined into 1 cohort, the local recurrence rate dropped from 2.8% to 2.4%, a difference of 0.4%. Combining patients who received IORT alone with those treated with IORT plus WBRT results in an improved recurrence curve. The greater the percentage of patients treated with additional WBRT, the more the recurrence curve improves. Thus, in studies that have a high percentage of patients treated with WBRT, such as TARGIT-A and TARGIT-R, the difference is likely to be greater. Combining the 2 groups into a single curve gives an overall picture of what an IORT program can accomplish, but it is equally as important to understand what IORT can accomplish when used as the only adjuvant radiation therapy, without the contamination effects of additional WBRT.

Figure: Local recurrence rates in patients treated with IORT vs. IORT plus WBRT



402189 - Implementation of a breast intra-operative radiation therapy (IORT) program is associated with a reduction in mastectomy rate

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Background/Objective: Intra-operative radiation therapy (IORT) reduces the number of radiation fractions and shortens treatment time in selected breast cancer patients. We hypothesized that IORT would lessen the obstacles and access to post-operative radiotherapy and make more patients amenable to breast conservation. In this study, mastectomy rates were examined before and after IORT was implemented at a single institution.

Methods: Patients with newly diagnosed breast cancer presenting for surgery over an 8-year period at a single Institution with cTis, cT1, or cT2 and cN0 disease were analyzed and divided into 2 groups, pre-IORT vs. post-IORT. The pre-IORT group consisted of 683 patients presenting from January 2009 to August 2012, and the post-IORT group comprised 940 patients presenting from August 2012 to March 2017. IORT was implemented at our institution in August 2012. Patients were excluded from analysis if they had a contraindication to breast conservation or had clinically positive nodes.

Results: In the patients treated after the implementation of IORT (post-IORT group), 346/940 (36.8%) actually received IORT as a single treatment or as a boost. The overall mastectomy rate in the post-IORT group was 31.8%, compared to 39.5% in the patients treated prior to the implementation of IORT (pre-IORT group) (p=0.001, Pearson Chi-Square). The mastectomy rate for each clinical tumor stage is seen in the Table below, with a significant decrease in mastectomy rate seen in the cT1 patients (32.9% vs.

26.1%, p=0.021). When analyzed by the distance from our institution's radiation center and pre-IORT vs. post-IORT mastectomy rate, there was a significant decrease in the mastectomy rate in patients with clinical stages Tis and T1 living 0-24 miles from the center (cTis: 45.8% vs. 27.2%, p=0.019; cT1: 29.2% vs. 20.1%, p=0.029).

Conclusions: The implementation of an IORT program was associated with a significant reduction in the mastectomy rate in this study population, suggesting that IORT reduces the barriers of post-operative radiation therapy and allows eligible patients to undergo breast conservation. Larger studies will be required to validate this finding.

Table: Mastectomy rates

Mastectomy Rate Based on Clinical Stage			
Clinical Stage (Total #pts)	Pre-IORT	Post-IORT	p value
Tis (397)	40.9% (61)	32.3% (80)	0.08
T1 (982)	32.9% (139)	26.1% (146)	0.021
T2 (244)	63.1% (70)	54.9% (73)	0.197
Overall (1,623)	39.5% (270)	31.8% (299)	0.001
Mastectomy Rate Based on Clinical Stage and Distance from Institution			
Clinical Stage: Distance from Institution (Total #pts)	Pre-IORT	Post-IORT	p value
Tis: 0-24 Miles (151)	45.8% (27)	27.2% (25)	0.019
Tis: 25+ Miles (246)	37.8% (34)	35.3% (55)	0.692
T1: 0-24 Miles (428)	29.2% (58)	20.1% (46)	0.029
T1: 25+ Miles (554)	36.2% (81)	30.3% (100)	0.149
T2: 0-24 Miles (69)	61.5% (24)	56.7% (17)	0.683
T2: 25+ Miles (175)	63.9% (46)	54.4% (56)	0.209

404327 - Investigation into the utilization of accelerated partial breast irradiation in early-stage breast cancer patients

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Background/Objective: Accelerated partial-breast irradiation (APBI) is an acceptable alternative to whole-breast irradiation in appropriately selected patients with early-stage breast cancer. Despite the existence of risk-stratified guidelines, APBI may be underutilized in the treatment of this select group of patients. Recent data used the Surveillance, Epidemiology, and End Results Program (SEER) database to quantify early-staged breast cancer patients who may have been eligible for APBI using 4 different APBI guidelines. Unfortunately, the SEER database does not provide information on important clinical and pathological features that may render a patient ineligible for APBI. Our study aims to improve upon the accuracy of patient selection and eligibility for APBI using the National Cancer Database (NCDB) and to compare these findings to current APBI practices.

Methods: Women treated for early-stage (I-II) breast cancer who underwent breast-conserving surgery (BCS) were identified in the NCDB from 2009-2014. Tumor characteristics (size, histology, stage, grade,

and hormone status) and patient characteristics were analyzed for APBI eligibility using the following 4 national and international guidelines: the 2009 American Society for Radiation Oncology [ASTRO], the 2009 Groupe Europeen de Curietherapie of European Society for Therapeutic Radiotherapy and Oncology [GEC-ESTRO], the 2013 American Brachytherapy Society [ABS], and the 2012 Intensity Modulated and Partial Organ Radiotherapy following Breast Conservation Surgery for Early Breast Cancer trial [IMPORT LOW]. Patients with bilateral breast cancers, previous malignancy of any kind, mastectomy patients, and patients receiving neoadjuvant chemotherapy were excluded. Using the patient selection criteria designated by each APBI guideline, the number of patients eligible for APBI was determined. The number of APBI-eligible patients using the NCDB were then compared to those numbers obtained by the SEER database and to the number of NCDB patients who actually received ABPI. Statistics were performed using unpaired t-tests.

Results: A total of 304,150 early-stage breast cancer patients treated with BCS were identified from the NCDB. Out of these patients, 275,587 (90.6%) received whole-breast radiation and 28,563 (9.4%) received APBI. Using 4 guidelines, the percentage of patients eligible for APBI in the NCBD and SEER databases, respectively, were: 15.1% vs 41.2% [ASTRO], 18.8% vs 74.6% [GEC-ESTRO], 38.8% vs 74.6% [ABS], and 52.4% vs 75.0% [IMPORT LOW]; (all p<0.0001). Out of the patients in NCDB who were eligible for APBI, the percentage of patients who actually received APBI were: 15.2% [ASTRO], 15.0% [GEC-ESTRO], 12.3% [ABS], and 12.4% [IMPORT LOW]. Information regarding which institutions have limited or no access to partial-breast irradiation modalities could not be elicited from the NCDB, nor does the NCDB give information about patient preference.

Conclusions: Previous reports on patient eligibility for APBI using SEER data are overestimated, largely due to the unavailability of important patient and tumor characteristics not captured within the SEER database. Moreover, our analysis of NCDB data reveals a potential underutilization of APBI in appropriately selected patients. Additional studies are needed to account for the role of randomized clinical trial results, institutional capability to offer APBI, and patient preference.

Table: Investigation into the utilization of APBI in early-stage breast cancer patients

Database	NCDB		SEER Database		
Total Number of Patients Studied	304,150		108,484		
Years Treated	2009-2014		2010-2012		
Eligibility for APBI	**Eligible Patients Based on Criteria**	**%**	**Eligible Patients Based on Criteria**	**%**	**P-value**
ASTRO	45,862	15.1%	44,797	41.2%	**<0.0001**
GEC-ESTRO	57,249	18.8%	81,020	74.6%	**<0.0001**
ABS	117,919	38.8%	81,020	74.6%	**<0.0001**
IMPORT LOW	159,347	52.4%	81,459	75.0%	**<0.0001**
Out of APBI Eligible Patients in NCDB	**Number of Patients Who Received APBI**	**%**			
ASTRO	6989	15.2%			
GEC-ESTRO	8580	15.0%			
ABS	14470	12.3%			
IMPORT LOW	19804	12.4%			

459444 - Target study: The use of a radiopaque hydrogel during breast-conserving surgery with full-thickness closure to improve target definition of breast radiotherapy

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Background/Objective: During (oncoplastic) breast-conserving surgery (BCS), the surgical cavity is closed in multiple layers to reduce seroma formation and to improve cosmetic outcome. This creates challenges for tumor bed delineation at the time of adjuvant radiotherapy planning because of reduced post-operative seroma size and lower cavity visibility. Our team showed that target definition using surgical clips has poor inter-observer agreement in patients following breast-conserving surgery with full-thickness closure, with a median conformity index (Cx) of 0.44. This potentially leads to a geographical miss with consequent risk of local recurrence or toxicity. We hypothesize that the injection of a radiopaque hydrogel in the lumpectomy cavity before closure can improve inter-observer agreement of radiotherapy target definition.

Methods: A prospective intervention study was performed in women undergoing oncoplastic (level 1) BCS with an indication for adjuvant radiotherapy from July 2017 to February 2018. In the interventional group, 3 to 9 ml of iodined Polyethylene Glycol hydrogel and clips were used to mark the surgical cavity. CT images of patients having received BCS with standard clips only were used as control group, matched on resected specimen weight, maximum distance between clips, and age. Patients received a CT-scan just after surgery, at 4 weeks, and at 2.5 months. Four radiation oncologists delineated the tumor bed volume on the CT-scans and rated the cavity visualization score (CVS, 1-5 score). The primary endpoint was the Conformity Index (Cx) as a measure of agreement between the observers target volumes. Secondary endpoints were median target volumes, median CVS, feasibility of the intervention, adverse events, and usability (System Usability Scale (SUS, 0-100)).

Results: Twenty-four patients were included in the interventional group, with 3 patients lost to follow-up due to positive margins and need for relumpectomy. The 1:1 matched control group included 21 patients for analysis. Feasibility of the intervention was high, in 21/21 (100%) patients the hydrogel was identified in the surgical cavity on both the post-operative and 4-week CT-scan. Median CVS was higher in the intervention group (4 IQR[2-5]) than in the control group (2 IQR[2-3]), $p<0.05$. Median target volumes were not different between groups (intervention group 26ml [17-46] vs. control group 28ml [17-31], p=NS. Median Conformity index was higher in the intervention group (Cx=0.70 [0.58-0.76]) than in the control group (Cx=0.34 [0.26-0.46]), $p<0.05$. Usability of the hydrogel intervention was high, with a mean SUS score of 97. Two patients in the intervention group developed a surgical site infection, and 3 patients had symptomatic seroma formation. Adverse event rates were not significantly different between groups. In the 3 cases requiring a relumpectomy, the hydrogel was identified, being solidified in the surgical cavity. The product was easy to remove.

Conclusions: The use of a radiopaque hydrogel during breast-conserving surgery improves target definition for boost or partial breast radiotherapy, compared to standard clips only. The intervention is feasible and safe. The benefit of the hydrogel is most prominent in cases with FTC that could lead to low CVS. This might increase patient eligibility for partial-breast irradiation treatment modalities, in which accurate target definition is critical. Also, in both partial and boost radiotherapy the chance of a geographical miss and subsequent risk of local recurrence could be reduced by improved treatment

accuracy. Future research should aim to optimize timing and to better select patients who benefit from this intervention.

404008 - Use of a subcutaneous spacer for skin protection during breast brachytherapy: A pilot study on mastectomy specimen

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Background/Objective: Partial-breast irradiation following breast-conserving surgery has shown equal effectiveness as whole-breast irradiation in a selected group of early-stage breast cancer patients. Brachytherapy is the most frequently used technique with the longest experience and highest level of evidence. One side effect of all forms of breast brachytherapy is skin toxicity and subsequent cosmetic deterioration, with dose to the skin as the main risk factor. Spacers have been previously investigated in prostate brachytherapy to move away the rectum wall from the high-dose area. We hypothesize that the injection of an inert/biodegradable spacer between the dermis and the most superficial layer of the planned target volume (PTV) could reduce the dose to the skin in breast brachytherapy. This pilot study evaluates the proof of principle of a subcutaneous spacer injection in human breasts and predicts the dosimetric brachytherapy consequences.

Methods: A pilot study of an ultrasound guided spacer injection was performed on mastectomy specimens, using either hyaluronic acid (HA) (Barrigel TM) or iodined Polyethylene Glycol (PEG)(TraceIT TM). Success of the intervention was defined as creating a subcutaneous space 5mm with a 20mm radius. Possibility of hydrodissection was recorded and ease of use was measured with the System Usability Scale (SUS, 0-100 score). CT-scans were made pre- and post-injection. Brachytherapy planning was performed on a simulated Clinical Target Volume (CTV) and dosimetry was calculated with and without spacer. V100, V200 were calculated as quality assurance of the planning. Dose to small volumes (D0.2cc and D0.05cc) and the existence of a hot spot on 1 cm2 of the skin 85% were calculated as measures for skin toxicity risk.

Results: Twenty-two mastectomy specimen were used for spacer injection; 11 HA, 11 PEG. Success of the intervention was 100% for HA and 90.9% for PEG ($p>0.999$). Median injected volumes were 8ml (IQR [6-9.5]) for HA and 7ml (IQR [6-8]) for PEG ($p=0.193$). Hydrodissection was possible in 81.8% with HA and 63.6% with PEG ($p=0.635$). Median SUS score was 97.5 (IQR [95.0-97.5]) for HA and 82.5 (IQR[72.5-87.5]) for PEG ($p<0.001$). Mean V100 was 95.9% (SD=1.1%) without spacer and 94.3% (SD=2.5%) with spacer ($p=0.001$). Mean V200 was 22.5% (SD=2.6%) without spacer and 28.1% (SD=6.3%) with spacer ($p<0.001$). Mean D0.2cc was 80.8Gy with and 53.5Gy without spacer ($p<0.001$). Mean D0.05cc was 78.1Gy with and 52.4Gy without spacer ($p<0.001$). Skin isodose 85% was present in 13/22 (59.1%) specimen without spacer and 1/22 (4.5%) specimen with spacer ($p<0.001$).

Conclusions: This pilot study shows a high success rate of a subcutaneous spacer injection for skin protection during breast brachytherapy. A spacer thickness of 5mm reduces the skin dose dramatically. HA appears superior to PEG. This intervention could protect the skin with several forms of brachytherapy and clinical evaluation of the skin protection is currently underway.

404275 - Optimizing timing of free-flap reconstruction after post-mastectomy radiation therapy can lead to improved outcomes

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Background/Objective: The most significant threat to successful autologous free-flap breast reconstruction is flap failure, and return to the operating room (OR) can cause significant increased morbidity to patients. Many patients pursuing autologous free-flap reconstruction have advanced-stage breast cancer and require post-mastectomy radiation therapy (PMRT). PMRT has known undesirable outcomes in autologous breast reconstruction, and the ideal time for free-flap reconstructive surgery after PMRT is not well established. The objective of this study was to determine whether different time intervals from PMRT to reconstruction surgery correlates with surgical complication risks.

Methods: A single institution prospectively maintained database was reviewed, and women who underwent free-flap breast reconstruction after PMRT between 2009 and 2016 were selected for analysis. Patients having PMRT (n=109) were then categorized into discrete time intervals between PMRT and surgery (<6 months, 6-12 months and >12 months; <12 months and >12 months). Flap complication rates were compared between groups. Major complications were defined as flap failure and return to OR. Co-morbidities that could potentially affect surgical complication risks, including smoking history, hypertension (HTN), diabetes mellitus (DM), and autoimmune disease were compared among the groups. The chi-square test or Fisher's exact test were used as appropriate for categorical variable comparisons using SAS 9.4 software. All tests were 2-sided and p-value <0.05 were considered significant.

Results: Of 109 patients with prior PMRT, there were 36 (33%) patients in <6 months group, 38 (35%) patients in 6-12 months and 35 (32%) patients in >12 months group. The co-morbidities of the 3 cohorts were compared, and there was no statistical difference in rates of HTN, DM, or autoimmune disease. Patients in the >12 month cohort were less likely to have a smoking history (14.29% vs 41.67% and 39.47% respectively; p=0.023). Return to the OR during the same hospital admission was 13.9 %, 0% and 5.7% (p=0.03), and major complication rates were 13.9%, 0%, and 8.6% respectively for patients who underwent reconstructive surgery <6 months, 6-12 months, or >12 months after PMRT. Patients undergoing surgery at 6-12 months had the lowest major complication rate compared to the other 2 cohorts (0% vs 11.4%, p=0.049). Interestingly, patients undergoing surgery >12 months after PMRT had increased rate of post-operative hematomas (8.6% vs 0% (<6 months) and 0% (6-12 months); p=0.03). Remarkably, no patients who underwent surgery 6-12 months after PMRT were returned to the OR, and none had flap failure. There was no statistically significant difference between cohorts for minor complications including infection, open wounds, small areas of flap necrosis, seroma formation, or post-operative hematoma.

Conclusions: Timing from radiation to surgical intervention affects major surgical complication risks in delayed autologous free-flap reconstruction. A 6-12 month interval between completion of PMRT and flap reconstruction appears to be optimal based on our institution's experience, and should be incorporated into surgical planning.

374015 - Effect of BioZorb® surgical marker placement on post-operative radiation boost target volume

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Background/Objective: BioZorb® is a tumor bed marker placed during partial mastectomy for targeted post-operative radiation. This study was designed to evaluate BioZorb® effect on radiation boost clinical target volume (CTV), planning target volume (PTV), ipsilateral lung radiation (Gy), and heart irradiation in left-sided cancers.

Methods: Data were collected via a case-controlled, retrospective study with 2 study arms: BioZorb® intra-operative placement versus no BioZorb® placement. Patients were stratified by BMI, age, tumor laterality, and cancer stage. Mean, standard deviation, median, range of cubic centimeters of clinical and planning target volume, cardiac dose in left-sided cancers, ipsilateral lung dose, and volume of ipsilateral lung receiving 20 Gy were reported.

Results: Of 143 patients, median CTV (cm3) was 8.7 and 14.2 (p=0.0048), median PTV (cm3) was 53.2 and 79.6 (p=0.0010), median ipsilateral lung Gy was 7.53 and 6.74 (p=0.0099) and volume (cc) of ipsilateral radiation lung at 20 Gy was 13.4 and 12 in BioZorb® and non-BioZorb® arms respectively (p=0.008). Patients with BMIs of 25-30 had CTV medians of 7.8 and 11.1 in BioZorb® and non-BioZorb® arms respectively (p=0.0293).

Conclusions: The BioZorb® arm showed statistically significant reductions in CTV, PTV, but not ipsilateral lung or heart irradiation. These results support and expand upon the small studies that have previously been performed and help surgeons inform and guide their patients' multidisciplinary decisions in breast-conserving therapy.

Stage IV

403396 - Why has the incidence of Stage IV breast cancer not decreased?

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Background/Objective: Breast cancer is the most common cancer in women worldwide, and de novo Stage IV comprises up to 5% of cases in the United States. Despite the widespread adoption of screening mammography over the past several decades, the incidence of Stage IV breast cancer is not decreasing; in fact, studies suggest that incidence of Stage IV is increasing, in the U.S. and abroad. Recently, we used the Surveillance, Epidemiology, and End Results (SEER) database to show that many breast cancers are small, not because they are detected early, but because they have favorable biology. This supports the idea of breast cancer not as a single disease entity diagnosed at different points along a continuum, but as a group of diseases with distinct biological behaviors that dictate different presentations and natural histories. The purpose of this study is to characterize the biology of breast cancer that presents as Stage IV in order to highlight what makes this disease subset unique, and to compare it with the biology of cancers most commonly found on screening mammography.

Methods: Invasive breast cancers diagnosed in women over 18 years of age between 2001 and 2014 were identified in the SEER database. The cohort was divided into 3 previously validated prognostic groups based on estrogen receptor (ER), progesterone receptor (PR), and grade. Groups included favorable, intermediate, and unfavorable tumor biology. The distribution of these 3 biological groups was then compared across tumor stages. Logistic regression was also performed on Stage IV cases, testing demographic variables including age, race/ethnicity, and marital status, as well as disease variables including histology, biology, size, and nodal status.

Results: Out of 654,706 patients with known receptor status, grade, and stage, 21.6% had favorable biology, 54.9% intermediate biology, and 23.5% unfavorable biology. As shown in the Table, the distribution of biological category varied tremendously by tumor stage. Patients presenting with Stage IV disease had 35% unfavorable and only 7.5% favorable tumors, whereas Stage I patients had only 16.3% unfavorable and 31.6% favorable tumors. ($p<0.001$) Among 167,550 patients with tumors less than or equal to 1cm, the vast majority of which were found by screening mammography, 38.0% were favorable and only 14.2% were unfavorable. Unfavorable tumor biology remained significantly associated with Stage IV disease in multivariate models when adjusted for race, age, marital status, T stage, N stage, and tumor histology (OR 1.48 95%CI 1.40-1.57).

Conclusions: Although hormone receptors and grade represent only primitive measures of tumor biology, the distribution patterns found here would probably apply to more sophisticated measures, and likely explain why screening has not led to a reduction in Stage IV disease.

Table: Distribution of tumor biology across Stages I-IV breast cancer

Biology	Stage			
	I	II	III	IV
Favorable	101,335 (31.6%)	32,272 (14.1%)	5,813 (7.3%)	1,915 (7.5%)
Intermediate	167,363 (52.2%)	131,345 (57.5%)	45,943 (57.4%)	14,586 (57.4%)
Unfavorable	52,167 (16.3%)	64,727 (28.3%)	28,346 (35.4%)	8,893 (35.0%)

402973 - Presentation, diagnosis, and management of locally advanced breast cancer: Is it different in low-/middle-income countries (LMICs)?

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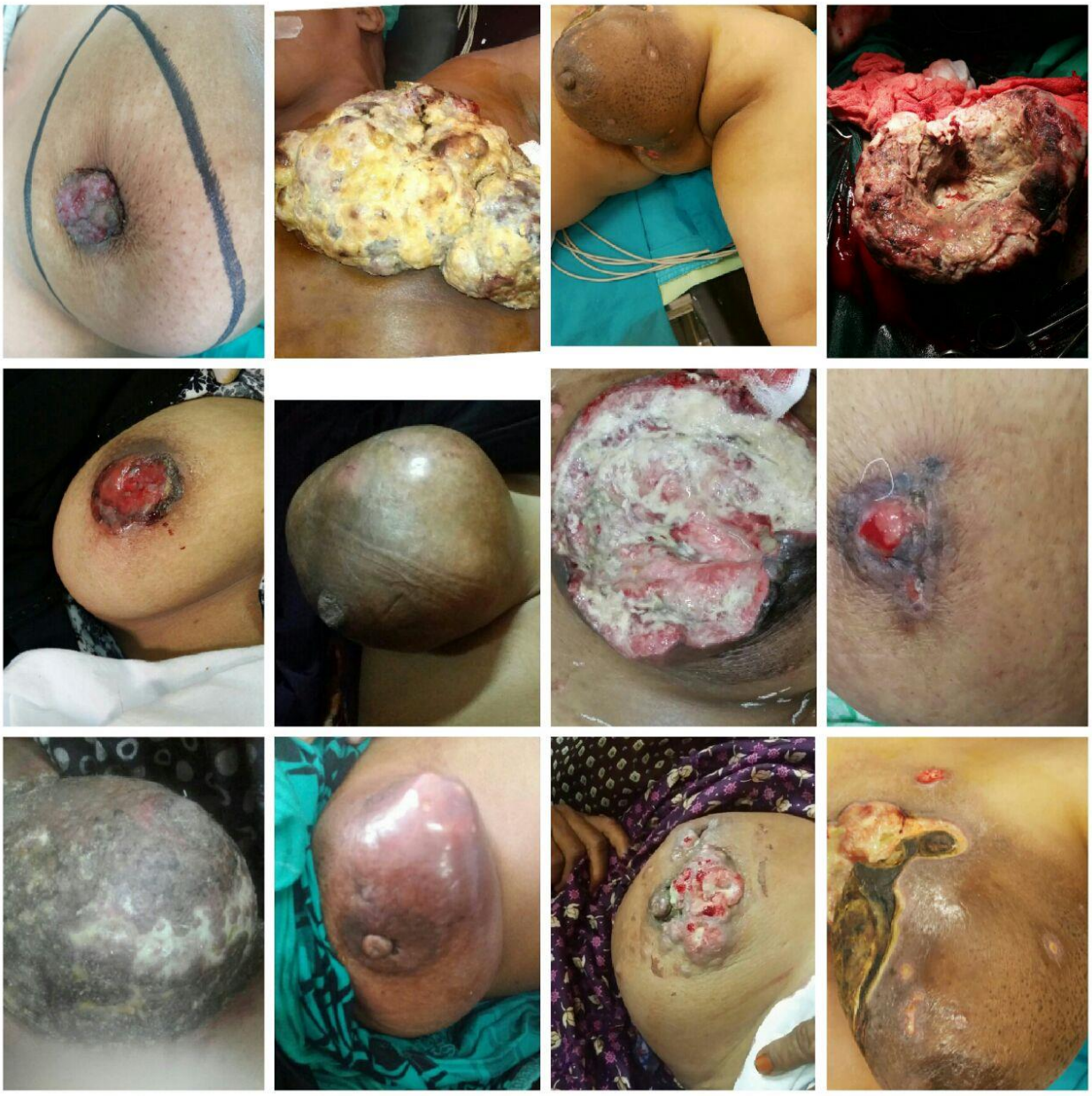
Background/Objective: Breast cancer incidence is increasing, and it is highest in low-income countries. More than half of the patients presents to us have LABC. The main challenge is regarding awareness, screening, late presentation, and its management in a developing country. Our aim of study is to share the experience with various presentations, diagnosis and management of LABC in a third-world country

Methods: This is a retrospective case series done in surgical ward of a teaching hospital in a third-world country. Data were collected of patients presenting in breast clinic over a period of 3 years. A total of 172 patients with breast cancer were managed in the breast clinic over 3 years. Our study included 112 patients, i.e., 65% of total patients, who presented with LABC based on their clinical presentation confirmed by histopathological diagnosis and followed by surgical management. Data were recorded and analyzed for frequency, mean, and percentages.

Results: One hundred twelve patients presented with LABC over a period of 3 years. All but 2 were female. Mean age was 52 years. Out of 112 patients, 103 (91.9%) patients have tumor of 5cm. Seventy-seven (68.7%) patients presented with skin involvement. Seventeen (15.2%) patients have fungating mass. Discharging sinus presented in 14 (12.5%). Nipple excoriation noted in 19 (16.9%). Involvement of axilla was in 86 (76.7%). Chest wall was involved in 22 (19.6%). Total T3 and T4 were 71 (63.3%) and 41 (36.6%) respectively. Diagnosis of all patients was confirmed by histopathology. Neoadjuvant therapy was given to all patients. According to receptor status, ER/PR was positive in 46 (41.1%) and negative in 66 (58.9%). HER-2/neu-positive in 31 (27.6%) and negative in 81 (72.3%). On staging, breast carcinoma was metastatic in 13 (11.6%) with liver, lung, and bone in 4 (3.5%), 3 (2.7%), and 6 (5.3%) respectively. Breast conservation was done in 6 (6.1%) patients, modified radical mastectomy was done in 86 (86.9%), radical mastectomy in 3 (3.03%), total mastectomy in 4 (4.045), and 13 (11.6%) patients were not operated on.

Conclusions: In our series, 65% of all breast cancers are LABC at presentation. In low-/middle-income countries, a high percentage of LABC at presentation results in high metastatic disease, poor prognosis, and limits conservation of the breast. Awareness and education about breast cancer can have long-term impact to reduce the suffering and improve outcomes.

Figures: Common presentations of LABC in our breast clinic



Time to Treatment

404024 - In-office biopsy by surgeon: A fast-track to breast cancer treatment

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Background/Objective: Timely treatment of patients with breast cancer (BCa) is associated with improved outcomes. A delay in diagnosis after abnormal imaging or clinical examination not only leads to a delay in treatment but also patient anxiety. The National Quality Measures for Breast Centers (NQMBC) guidelines recommend a time from initial abnormal finding to biopsy and treatment of 7 and 28 days, respectively, in order to expedite definitive management. At our breast center, surgeons perform core needle biopsies (CNB) at the initial visit, compared to the national standard of referral to a radiologist for biopsy. We sought to determine if same-day office biopsy reduces time to treatment in BCa patients.

Methods: We retrospectively analyzed all patients evaluated at our breast center from September 2013 to September 2017 from a prospectively maintained database. We identified patients who presented with abnormal imaging studies or suspicious physical findings and not yet undergone biopsy prior to their first encounter. We compared time from abnormal findings to biopsy and abnormal findings to first treatment modality (surgery or systemic therapy) between 2 cohorts: patients who received a same-day office biopsy (OB) and those referred to radiology for biopsy (RB).

Results: Ninety-four patients met inclusion criteria and were seen by a breast surgeon at our breast center for abnormal findings; 66 (70%) in the OB cohort and 28 (30%) in the RB cohort. All patients were female. Median age was 61 years. Overall, 89 (95%) of patients were diagnosed on imaging and the remaining 5 (5%) on clinical examination. On CNB histology, 25 (27%) were DCIS, and 69 (73%) were invasive carcinoma. No patients required repeat CNB for an inadequate initial sample. Overall, first treatment modality was surgery (57, 61%), neoadjuvant chemotherapy (15, 16%), definitive chemotherapy (15, 16%), or hormonal therapy (7, 7%). Time from abnormal findings to CNB (10d (IQR 4-28) vs. 34d (IQR 22-49), p=0.0011) and abnormal findings to first treatment (40d (IQR 29-57) vs. 71d (IQR 50-85), p=0.0393) were both significantly shorter in the OB cohort. Neither cohort met NQMBC targets; however, OB was closer on both metrics.

Conclusions: Same-day office biopsy by breast surgeons at our institution was associated with a significant decrease in time from abnormal findings to both CNB and treatment with no repeat CNB for inadequate samples. As long as adequate training is provided, this offers an expedited pathway to BCa diagnosis and treatment.

403910 - Delayed surgical resection impacts disease recurrence in patients with invasive breast cancer

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Background/Objective: For patients with invasive breast cancer, the optimal timing of surgery after diagnosis is unknown. Some recent studies have suggested that a longer time to surgery negatively impacts both disease-free and overall survival, while others have not found timing to treatment to be a significant factor in patient outcomes. The aim of our study was to evaluate the association between timing of surgery following diagnosis of breast cancer and disease-free survival (DFS) and overall survival (OS) within a comprehensive, community health system.

Methods: Women diagnosed and treated for Stage I to Stage III breast cancer at our institution in 2012 were retrospectively identified from a prospectively maintained dataset. Patients with a prior diagnosis of breast cancer and those who received neoadjuvant chemotherapy were excluded. Time from diagnosis to surgery was calculated. Analysis groups included patients who underwent resection <30 days from diagnosis versus >30 days, as well as patients who underwent resection at <60 days versus >60 days. Survival outcomes were estimated using the Kaplan-Meier method and compared by log rank test.

Results: One hundred five patients met inclusion criteria. Average age was 64. There were 87.5% diagnosed with invasive ductal carcinoma and 12.5% with invasive lobular carcinoma. The median time to surgery after diagnosis was 26 days (range 2 to 134 days). Median follow-up was 61.2 months. Five-year DFS was 96% for patients with surgery <30 days and 94% for patients with surgery >30 days after diagnosis. Five-year OS was 97% for patients with surgery <30 days and 94% for patients with surgery >30 days after diagnosis. There was no difference in DFS (p=0.7) or OS (p=0.95) between patients who had surgery <30 days or >30 days. Five-year DFS was 96% for patients with surgery <60 days and 75% for patients with surgery >60 days after diagnosis. Five-year OS was 97% for patients with surgery <60 days and 97% for patients with surgery >60 days after diagnosis. A surgery date of >60 days after diagnosis was associated with shorter DFS (p=0.03) but did not adversely affect overall survival (p=0.72).

Conclusions: A delay of more than 60 days between the diagnosis of breast cancer and resection influenced recurrence outcomes but did not affect OS. Our findings suggest that efforts should be made to avoid an extended interval between diagnosis and appropriate surgical resection in breast cancer patients, and that surgery should be undertaken no later than 60 days after diagnosis to avoid negatively impacting disease-free survival.

403592 - Delayed adjuvant hormonal therapy and its impact on morbidity and mortality in women with breast cancer

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Background/Objective: Adjuvant hormonal therapy (HT) has been a significant addition to the arsenal of treatment modalities for hormone-sensitive breast cancer. These oral therapies, which include tamoxifen and aromatase inhibitors, have shown significant efficacy in decreasing cancer recurrence, prolonging survival, and decreasing mortality rates when prescribed 5 years or longer. While their benefits have been well characterized in the literature, the timeliness of the initiation of adjuvant HT and the effects of delayed initiation of treatment have not been analyzed. Much of breast cancer therapeutic research has focused on the efficacy of intercepting cancer recurrence. The purpose of this study was to characterize delays to HT and assess the impact they have on clinical outcome.

Methods: A retrospective analysis of cases in the National Cancer Database was performed. The study cohort consisted of female patients with invasive ductal and/or lobular, hormone receptor-positive breast cancer diagnosed between 2010 and 2015 who received adjuvant HT following surgical management. Initiation of HT greater than 6 months (180 days) after surgery was defined as a delay. Unadjusted and multivariable logistic regression modeling was performed to establish associations between delayed HT and demographic factors such as facility type, facility volume, age, ethnicity, insurance coverage, and co-morbidity index; and clinical factors including tumor grade and size, regional lymph node involvement, type of surgery received, unplanned readmission within 30 days of surgery, and final status of surgical margins. Survival analysis was performed using the Kaplan-Meier estimation and Cox proportional hazards regression to evaluate 5-year overall survival differences between timely and delayed HT, adjusting for age, co-morbidity index, tumor grade, tumor size, regional lymph node involvement, unplanned readmission, and final status of surgical margins.

Results: Of 234,216 women assessed, 3.4% had a delay in the initiation of adjuvant HT. Positive demographic-related risk factors were younger age (age <40: OR, 2.13; 7% delayed HT; delayed mean of 271 days to HT), ethnic minority groups (non-Hispanic black: OR, 1.63; 6% delayed HT; delayed mean of 256 days to HT), and uninsured or non-private insurance (uninsured: OR, 1.30; 6% delayed HT; delayed mean of 251 days to HT; Medicaid: OR, 1.42; 6% delayed HT; delayed mean of 262 days to HT). Clinical factors significantly associated with delayed initiation of adjuvant HT were high grade tumor (grade 3/4: OR, 1.43; 5% delayed HT; delayed mean of 260 days to HT), larger tumor size (pT3: OR: 1.85; 7% delayed HT; delayed mean of 253 days to HT), greater lymph node involvement (pN3: OR: 2.98; 9% delayed HT; delayed mean of 257 days to HT), having an unplanned readmission within 30 days of surgery (OR, 1.21; 4% delayed HT; delayed mean of 247 days to HT), and positive final surgical margins (OR, 1.38; 5% delayed HT; delayed mean of 258 days to HT). Adjusted survival analysis showed a survival disadvantage of delayed initiation of HT (HR, 1.29; $p<0.01$).

Conclusions: Risk factors for delayed initiation of HT specific to demographic and clinical characteristics were identified. Delayed initiation of HT was associated with a survival detriment. Efforts should be made to further delineate and address these barriers in clinical management in order to ensure timely patient treatment and optimal oncologic outcomes.