THE AMERICAN SOCIETY OF BREAST SURGEONS



2019 ANNUAL MEETING OFFICIAL PROCEEDINGS, Volume XX 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.

Breast Surgeons

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Scientific Oral Presentations I

Friday, May 3, 2019 2:00 pm–3:30 pm Moderators: Sarah Blair, MD; Henry Kuerer, MD, PhD

581898 - Burnout and professional fulfillment in breast surgeons

Jennifer Zhang, Luis Riba, Leo Magrini, Aaron Fleishman, Ted James Beth Israel Deaconess, Boston, MA

Background/Objective: Physician burnout is a well-recognized problem in health care that negatively impacts physician well-being and decreases the quality of patient care. Rates of professional burnout in breast surgery are not well defined. We sought to better understand the degree of burnout among breast surgeons and identify factors that may influence levels of burnout and professional fulfillment.

Methods: All United States members of the American Society of Breast Surgeons (ASBrS) with a valid email address (2568 surgeon members) were surveyed in October 2017. Results were anonymous, and participants were blinded to the study hypothesis. The survey consisted of 39 questions including demographic characteristics, practice patterns, and elements of the Professional Fulfillment Index (PFI). The presence of professional fulfillment was set at a score of 3.0 or greater, and the presence of overall burnout was set at 1.33 or greater, as previously published. Multivariable linear regressions were performed for overall burnout and professional fulfillment.

Results: Of the 2,568 surveys delivered, 708 surveys were initiated, and 660 were completed. The mean age of surgeons was 51.5 years, 68.6% were female, 86.4% were in a partnered relationship, and mean years in practice was 18.5 years. The majority worked 40-60 hours per week (median days worked per week was 5). Surgeons spent an average of 80% of work hours on patient care, and 64.8% had a full-time breast surgery practice; 51.7% practiced in a private setting, and 44.3% practiced in a population of 500,001 or greater. Overall, 270 (41.3%) of surgeons had evidence of burnout, and 379 (57.5%) did not have professional fulfillment. On multivariable analysis, years in practice was negatively associated with burnout, and working >60 hours per week was positively associated with burnout. Years in practice was positively correlated with professional fulfillment and having <50% of practice dedicated to breast surgery correlated negatively with fulfillment.

Conclusions: We identified that 41% of breast surgeons had burnout, and 57.5% did not have professional fulfillment. Our data suggest that specific clinical practice conditions largely influence rates of burnout and professional fulfillment. The risk factors identified in our analysis may be useful in identifying breast surgeons who are particularly at higher risk for burnout, and designing targeted interventions focused on the clinical practice environment to promote professional sustainability.

575089 - Patient selection for non-operative management of HER2+ invasive breast cancer after neoadjuvant systemic therapy

Susie Sun, Raquel van la Parra, Gaiane Rauch, Cristina Checka, Audree Tradros, Anthony Lucci, Mediget Teshome, Dalliah Black, Rosa Hwang, Benjamin Smith, Savitri Krishnamurthy, Vicente Valero, Wei Yang, Henry Kuerer The University of Texas MD Anderson Cancer Institute, Houston, TX

Background/Objective: With recent advances in neoadjuvant systemic therapy (NST), patients with HER2-positive breast cancer and pathologic complete response (pCR) following NST may be candidates for non-operative management clinical trials. For patients to be eligible for these trials, they must have a pCR in both the invasive and DCIS components to ensure no nidus for recurrence remains. The purpose of this study was to identify unique clinicopathologic characteristics that are associated with finding residual disease after NST. A secondary outcome was to assess the effect of NST on the invasive and DCIS components of HER2-positive breast cancer.

Methods: Two hundred eighty patients with clinical T1-2N0-1 HER2-positive breast cancer treated with NST followed by surgical resection were identified. Clinicopathologic characteristics of those who achieved pCR in the breast and lymph nodes were compared with those who had residual disease. Multivariate analyses were performed to evaluate for predictors of residual disease.

Results: Of the 280 patients, 102 (36.4%) had pCR in the breast and lymph nodes after NST, and 50 (17.9%) had residual DCIS in the breast only. DCIS was a component on initial biopsy in 129 (46.1%) of patients. Patients with residual disease in the breast and nodes were more likely to have hormone receptor-positive tumors compared with negative tumors (73.4% vs. 50.8%; respectively, p<0.0001). Variables that were predictive of residual disease in the breast and nodes included incomplete radiologic response (OR 5.62, p=0.002) and hormone-positive status (OR 2.56, p<0.0001). Combined imaging modalities (MRI, mammogram, ultrasound) after NST had a sensitivity of 97.1% and negative predictive value of 70.6% in the detection of residual disease in the breast and lymph nodes. NST failed to eradicate the DCIS component in 64.3% of patients with in situ disease on initial core biopsy. Patients with invasive disease with DCIS on initial core biopsy were less likely than those without DCIS on initial core biopsy to achieve pCR in the breast (31% vs 43%, p=0.038).

Conclusions: Hormone receptor-positive tumors, radiologic evidence of residual disease, and DCIS on initial biopsy are associated with incomplete pathologic response after NST in HER2-positive breast cancer. The low negative predictive value of imaging after NST mandates the need for image-guided biopsy confirmation to rule out residual disease. These results help to delineate and identify unique characteristics associated with HER2-positive cancers for patients who may become eligible for inclusion in trials assessing non-operative management of exceptional responders after NST.

578685 - Perspectives on the costs of cancer care: A survey of the American Society of Breast Surgeons

<u>Rachel Greenup</u>¹, Christel Rushing², Laura Fish³, Whitney Lane⁴, Jeffrey Peppercorn⁵, Lisa Tolnitch¹, Terry Hyslop², Evan Myers¹, S. Yousuf Zafar¹, E. Shelley Hwang¹

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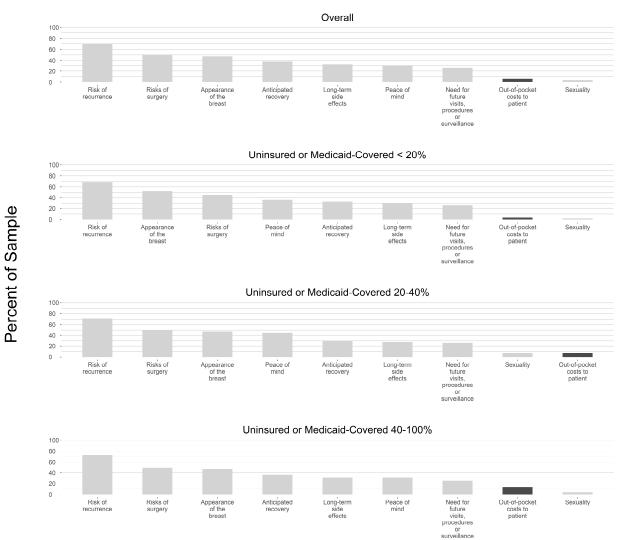
Background/Objective: Although financial toxicity is a well-recognized side effect of oncology care, anticipated health care costs are not routinely addressed in shared decisions as women face equally effective options for breast cancer surgery. We sought to characterize surgeons' attitudes and practice patterns around cost transparency when caring for women with breast cancer.

Methods: Members of the American Society of Breast Surgeons completed a 10-item survey between July-September 2018, focusing on attitudes and practices surrounding cost consideration and transparency when discussing surgical treatment options with patients.

Results: The survey was emailed to 2,405 surgeons, and 598 (25%) responded. Only 6% of surgeons believed that "out-of-pocket costs" was one of the most influential factors on decisions for breast cancer surgery and was more likely to be reported as important by surgeons with a higher population of uninsured/Medicaid-covered patients. Surgeons believed that "risk of recurrence" (70%), "appearance of the breast" (50%), and "risks of surgery" (47%) were the most important considerations for women. Although 50% of surgeons recognized that their patients considered health care costs in treatment decisions, the majority reported "infrequently" (43%) and "never" (16%) considering patient out-ofpocket costs when making medical recommendations. Surgeons who consistently considered costs in treatment recommendations did not differ by surgeon age, gender, practice setting, or years in practice, although those treating a higher percentage of Medicaid or uninsured patients were more likely to be cost conscientious (p=0.002). Overall, 36% of respondents "agreed" or "strongly agreed" that patient socioeconomic and insurance status influenced physician consideration of health care costs. Regardless of their personal practices around cost discussions, the overwhelming majority (87%) believed that patients should have access to health care cost information before making medical decisions, and only 3% disagreed. Only 20% reported feeling prepared to discuss the costs of cancer treatment with their patients. Even among those who reported routinely considering costs in treatment recommendations, only 48% reported feeling prepared to have cost discussions with patients. Although 32% acknowledged that nothing was preventing them from discussing costs, 20% feared that doing so might impact the quality of patient care. Surgeons reported that insufficient knowledge of costs or resources to have cost discussions (61%), inability to help with costs (24%), and inadequate time (22%) impeded cost conversations with patients. Overall, 38% of respondents agreed that if 2 treatment options were equally effective, the less expensive option should be recommended. Almost half (47%) of respondents agreed that doctors should consider how care of an individual patient impacts societal costs.

Conclusions: Breast cancer surgeons believed that women should have access to health care costs prior to making cancer treatment decisions, yet few considered patient out-of-pocket costs in medical recommendations, most reported feeling ill-prepared for cost discussions, and some worried about the impact on cancer care. Addressing barriers to cost transparency may improve shared decisions for women facing preference-sensitive choices for breast cancer surgery.

Tables: The proportion of uninsured or Medicaid-covered patients influences surgeon perceptions of cost as a factor in patient decisions for breast cancer surgery



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581304 - Interim analysis lymphedema "PREVENT" randomized trial

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Background/Objective: Breast cancer-related lymphedema (BCRL) represents a major source of morbidity amongst breast cancer survivors. Increasing data support the concept of early detection of subclinical BCRL followed by early intervention. A multi-site, international, randomized controlled trial is being conducted comparing lymphedema progression rates of those detected with using volume measurements derived from calculated from circumference using tape measure (TM) versus bioimpedance spectroscopy (BIS). We present results of a planned interim results.

Methods: Patients were enrolled pre-surgery and randomized to surveillance with either TM or BIS. Post-surgical inclusion criteria included Stage I-III invasive breast cancer or DCIS with at least 1 of the following: mastectomy, axillary treatment (axillary lymph node dissection (ALND), sentinel lymph node biopsy (SLNB) with greater than 6 nodes, axillary radiation), taxane-based chemotherapy. Additional post-surgical exclusion criteria included bilateral breast surgery. Patients who triggered intervention (change from pre-surgical baseline $\geq 5\%$ volume by TM; ≥ 6.5 L-Dex BIS) were prescribed a compression sleeve and gauntlet for 4 weeks and re-evaluated. The trial's primary endpoint is the rate of lymphedema progression requiring complex decongestive physiotherapy (CDP) with progression defined as a TM volume change in the at-risk arm $\geq 10\%$ above the pre-surgical baseline. This pre-specified interim analysis was performed when at least 500 trial participants had 12 months or greater follow-up.

Results: A total of 508 patients were included in this analysis who had been followed for least 12 months post-surgery (median=17.8 months, IQR=13-23). The median age was 58.8 years with 77% of patients (n=389) being white. Median Body Mass Index was 27.9 (IQR=24-33); the most frequently reported co-morbid conditions were cardiovascular in nature (44%, n= 223). A majority of patients were diagnosed with Stage I breast cancer (56.7%, n=288) with 39.0% (n=198) of patients having Stage II/III at baseline, the median baseline BIS measurement was 0.0 (IQR: -3 -+3.0) L-Dex units. Median arm volume in the atrisk arm at baseline was 1943.2 mL (IQR: 1685-2344) and 1949.6 mL (IQR: 1667-2335) in the non-atrisk-arm. Other than a single statistically significant difference in a history of digestive conditions, none of the key demographic, clinical, or baseline treatment characteristics differed between the groups. Of the 508, 109 (21.9%) triggered pre-threshold interventions (n=68 TM group, n=41 BIS group). Compared to TM, BIS had a lower rate of trigger (15.8% BIS vs. 28.5% TM, p<0.001) and longer times to trigger (9.5 months BIS vs. 2.8 months TM, p=0.002). Twelve triggering patients progressed to CDP including 10 in the TM group (14.7%) and 2 in the BIS group (4.9%) representing a 67% relative reduction and a 9.8% absolute reduction (p=0.130).

Conclusions: Interim results demonstrate that post-treatment surveillance with BIS reduced absolute rates of progression of BCRL requiring CDP by approximately 10% compared with TM, although not statistically significant. These results may support the concept of post-treatment surveillance with BIS to detect subclinical BCRL and initiate early intervention.

581545 - Transcriptomic changes in invasive residual cancer after neoadjuvant chemotherapy in patients with triple-negative breast cancer

Javier Orozco¹, Ayla Manughian-Peter¹, Francisco Gago², Grace Chang¹, Janie Grumley¹, Diego Marzese¹

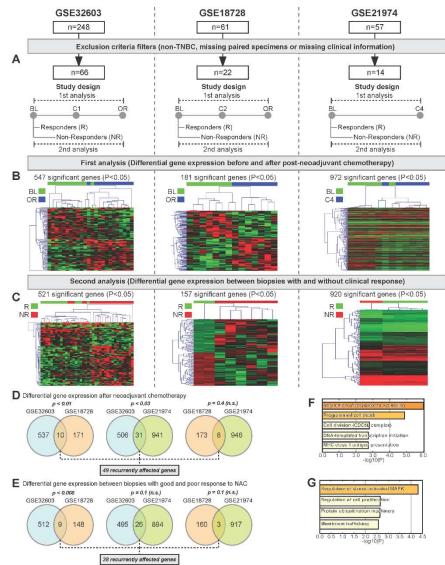
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Background/Objective: Invasive residual disease after neoadjuvant chemotherapy (NAC) is associated with a worse prognosis in patients with triple-negative breast cancer (TNBC). These remaining viable cells may reflect an inherent insensitivity or acquired resistance to NAC. Here, we aimed to measure gene expression changes induced by NAC, and to identify associations between the transcriptomic profile of the core biopsies with the likelihood to respond to NAC.

Methods: By surveying clinically annotated gene expression datasets (GSE32603, GSE18728, and GSE21974), we identified a cohort of 102 TNBC patients with paired core biopsies (baseline, BL) matched with post-NAC tissue (after the first cycle of NAC, C1; second cycle C2; fourth cycle, C4; and in surgical specimen, OR). First, we evaluated gene expression differences between BL and OR by applying paired Student's t-test (Fig. A: first analysis). Second, we evaluated gene expression differences between Core biopsies from patients that responded to NAC (R), defined as pathological complete response (pCR), and patients that did not respond to NAC (NR), defined by an incomplete pathological response (partial response, stable disease, or progressive disease; Fig. A: second analysis) by applying a non-paired Student's t-test. Hierarchical clustering and pathway enrichment analyses were employed to characterize relationships between differentially expressed genes and identify potentially affected gene pathways in TNBC.

Results: Initially, we identified 547, 181, and 972 genes differentially expressed (p<0.05) between BL and OR (or C4 biopsies) in GSE32603, GSE18728, and GSE21974 datasets, respectively (Fig. B). Of these, 49 genes were consistently altered in at least 2 independent studies (Fig. D). Additionally, 521, 157, and 920 genes showed significantly (p<0.05) different expression between responders and non-responders in the BL specimens in GSE32603, GSE18728, and GSE21974 datasets, respectively (Fig. C). Of these, 38 genes were differentially expressed in BL when comparing responders to non-responders (Fig. E). Of note, pathway enrichment and regulatory gene network analyses identified enhanced chemokine release, cell division and decreased programmed cell death in residual disease after NAC (Fig. F). In addition, we observed an upregulation of stress-activated mitogen-activated protein kinases (MAPK) cascade in non-responders compared to responders (Fig. G).

Conclusions: These results indicate the potential of NAC to influence the gene expression patterns of residual disease, most significantly impacting cell division and apoptosis mechanisms. Furthermore, it offers clues regarding the mechanisms affecting TNBC response to NAC and suggests the existence of intrinsic differences between TNBC tumors that achieve pCR and those that may be resistant or insensitive to NAC.



Figures: Transcriptomic changes associated with neoadjuvant chemotherapy

581640 - Physician knowledge of contralateral breast cancer and local recurrence risk is associated with increased recommendations for contralateral prophylactic mastectomy: A survey of physicians at NAPBC-accredited centers

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Background/Objective: Physician recommendation for contralateral prophylactic mastectomy (CPM) has been shown to significantly influence whether a patient chooses CPM. Few studies have explored physician knowledge about contralateral breast cancer (CBC) and local recurrence risk and whether this knowledge is associated with recommendation for CPM.

Methods: We conducted a cross-sectional survey of physicians at NAPBC-accredited breast centers across the United States. Physician knowledge levels of CBC and local recurrence risk were assessed and stratified by different physician and facility factors. Knowledge levels were then correlated with recommendation for CPM for average risk women and young women with breast cancer.

Results: There were 1,761 physicians surveyed, with a 67.9% response rate (n=1195). When asked about 10-year CBC risk, 982 (82.8%) physicians answered correctly for average risk women (5% or less), 638 (53.8%) for women with a first-degree relative with breast cancer (10% or less), and 605 (51.0%) for a women with a BRCA mutation (20-30%). For all 3 questions about CBC risks, there were significant differences in the proportion of physicians answering correctly when stratified by physician type; 279 (90.9%) radiation oncologists had the highest knowledge, and 179 (80.3%) plastic surgeons had the lowest knowledge (p < 0.001). Years in practice was also significantly associated with CBC risk knowledge for average risk women; 324 (87.8%) physicians in practice >20 years had highest knowledge vs. 131 (82.9%) for physicians <5 years in practice (p<0.001). There were no significant differences in knowledge when stratifying by facility factors such as practice setting, annual case load, or number of beds at the facility. Seven hundred twenty-eight (61.4%) physicians answered correctly that local recurrence risk was the same for estrogen receptor (ER) tumors, 545 (46.0%) for triple-negative breast cancer, and 728 (61.4%) for Her2neu-positive cancers. There were significant differences in the proportion of physicians answering correctly for ER-positive tumors when stratified by physician type; 203 (70.0%) medical oncologists had the highest knowledge vs. 115 (48.9%) plastic surgeons (p < 0.001). Gender was also significant - 353 (67.2%) female physicians vs. 368 (59.7%) male physicians had high knowledge (p=0.009), but facility factors were not significant. Compared to having higher knowledge, lower knowledge about local recurrence risk was significantly associated with favoring insurance coverage for CPM for average-risk women (51.5% vs. 39.1%, p<0.01) and favoring insurance coverage for all cases (39.1% vs 30.1%, p<0.01). Lower knowledge was also associated with physician opinion that CPM is strongly indicated in patients under 40 with breast cancer (23.2% vs 20.1%, p<0.01) and in young patients with ER-negative breast cancer (23.4% vs. 18.3%, p<0.01).

Conclusions: Physician knowledge about CBC and local recurrence risks could be improved. Lower knowledge is associated with higher physician recommendation for CPM and more favorable attitudes about insurance coverage for CPM. It is not clear if improving physician knowledge will change recommendation for CPM.

581645 - Implementation of post-mastectomy home recovery program in a large, integrated health delivery system

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Background/Objective: Nationwide, the incidence of mastectomy and reconstruction in an ambulatory setting has been increasing. Surgical home recovery permits the patient to recuperate in a familiar environment, reduces their risk of nosocomial infections, and optimizes utilization of inpatient resources for higher acuity patients. Studies have shown that in well-selected patient populations, same-day surgery for mastectomy is a safe option. A pilot project was initiated within a large, integrated health system to encourage home recovery of mastectomy patients, including patients undergoing implant-based reconstruction and bilateral mastectomies.

Methods: Surgical Home Recovery Program (SHRP) for mastectomy patients was implemented in October 2017 via a regional breast clinical performance team. The goal was to minimize practice variability across surgeons and medical centers in a large, integrated health care delivery system providing coverage to 4.3 million members. Specific measures included setting patient expectations at the initial consultation, educating patients about postoperative home care, using multi-modality pain management to decrease postoperative nausea and vomiting and pain, and timely post-discharge followup with patients by phone or e-mail. SHRP included the entire surgical team from breast care coordinators to post-anesthesia care unit recovery nurses. Providers received monthly reports on regional and medical center specific rates of home recovery following mastectomy, in order to share and implement best practices. All patients undergoing mastectomy, including those undergoing immediate implant-based reconstruction and/or double mastectomies, were included. Patients undergoing immediate autologous tissue reconstruction were excluded, as were patients who were hospitalized for >1 day following mastectomy. The primary endpoint was the rate of same day discharge. Chi-square analysis was used to compare the 2 mastectomy cohorts 6 months before and after the implementation period of October 2017 - March 2018. We also compared emergency department (ED) visits, reoperations, and readmissions within 7 days for SHRP patients vs patients who were admitted overnight.

Results: Twenty-one medical centers participated in the regional initiative. Prior to implementing SHRP, 164 of the 628 (26%) of the mastectomies were outpatient procedures. After the implementation period, 403 of the 620 (65%) mastectomies underwent home recovery (p<0.001) [Figure]. Despite the increased rate of outpatient mastectomy, there was no statistically significant differences in presentation to the ED (5.1% vs 5.66%, p=0.67), reoperation (1% vs 2%, p=0.72), or readmission (.8% vs 1.9%, p=0.08).

Conclusions: By implementing standard expectations and sharing best practices, there was a significant increase in the rate of home recovery for mastectomy without compromising quality of patient care. The successful implementation of this pilot program supports expansion of the surgical home recovery program for all patients undergoing mastectomy.

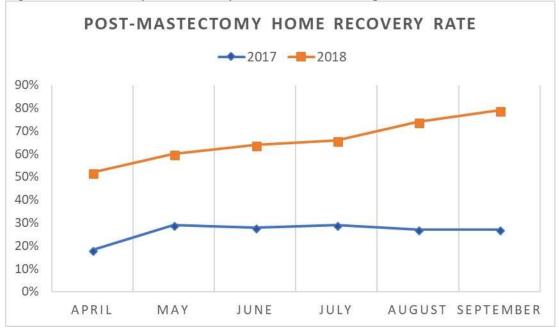


Figure: Post-mastectomy home recovery rate before and after regional initiative

580940 - Reducing narcotic prescriptions in breast surgery patients: A prospective analysis <u>Betty Fan</u>, Stephanie Valente, Sabrina Shilad, Zahraa Al-Hilli, Diane Radford, Chao Tu, Stephen Grobmyer

Cleveland Clinic, Cleveland, OH

Background/Objective: Recent studies have shown that narcotics prescribed for postoperative pain may be overprescribed and result in excessive unused pills that could lead to potential abuse. No clear standard regarding number or type of narcotics for adequate postoperative pain control have been established for breast surgery. In this study, we aimed to review our opioid prescribing patterns, implement a change to reduce and standardize our prescribing practices, and evaluate the utilization of these narcotics for patients who underwent breast surgical procedures. The goal was to optimize the practice of postoperative narcotic prescribing in breast surgery patients.

Methods: In order to establish baseline prescribing practice, a review of consecutive breast surgical patients treated in 2017 was performed to establish baseline postoperative narcotic prescribing patterns. The most common medications prescribed and the number of pills given for excisional biopsy/lumpectomy, simple mastectomy, and mastectomy with reconstruction were documented. The median and range numbers of narcotics prescribed were then used to educate surgeons about prescribing patterns. Starting in February 2018, the department implemented a planned change based on our findings and reduced the number of narcotic pills prescribed. We then prospectively collected data on prescribing patterns and recorded how many pain pills patients actually took of those prescribed after discharge. Data regarding changes in the amount of narcotics prescribed and patient use patterns were analyzed.

Results: Baseline narcotic prescribing patterns from 100 consecutive breast surgery patients identified that narcotic prescribing practices were not consistent in either the type or number of narcotics prescribed. Narcotics prescribed included Tramadol, Tylenol-3, Norco/Hydrocodone, and Percocet/Oxycodone and

ranged from 0-40 pills (Figure). The median number of narcotic pills given for excisional biopsy/lumpectomy was 15, mastectomy 20, and mastectomy with reconstruction 28. Following planned modification of prescribing patterns, review of 103 breast surgery patients identified a statistically significant reduction in the number of narcotic pills prescribed for excisional biopsy/lumpectomy (p<0.01) and mastectomy with reconstruction patients (p<0.01). Even after the prescribing reduction, the median number of narcotic pills taken by patients was significantly less than that prescribed for patients in all categories: 1 pill for excisional biopsy/lumpectomy, 3 pills for mastectomy and 18 pills for mastectomy with reconstruction (p<0.01, p<0.01, p<0.01 respectively). 40% of our sampled patients reported using zero prescribed narcotics after their operation.

Conclusions: A narcotic prescribing reduction program can be successfully implemented in breast surgery patients. Half of patients undergoing excisional breast biopsy, partial mastectomy and mastectomy without reconstruction used less than 3 pills after hospital discharge. These observations regarding narcotic use in breast surgery patients can be used to further optimize narcotic prescribing practices in these patients.



Figure: Reduction in opioid prescriptions and patient-reported usage

581033 - A randomized prospective trial of supine MRI-guided vs wire localized lumpectomy for breast cancer

<u>Richard Barth, Jr.</u>¹, Venkataramanan Krishnaswamy², Keith Paulsen³, Timothy Rooney¹, Wendy Wells¹, Christina Angeles¹, Rebecca Zuurbier¹, Kari Rosenkranz¹, Steven Poplack⁴, Tor Tosteson⁵ ¹Dartmouth-Hitchcock Medical Center, Lebanon, NH, ²CairnSurgical, Inc., Lebanon, NH, ³Thayer School of Engineering, Hanover, NH, ⁴Washington University, St. Louis, MO, ⁵Geisel School of Medicine, Hanover, NH

Background/Objective: Wire localized excision of non-palpable breast cancer is imprecise, resulting in positive margins 15-35% of the time. The goal of this study is to compare a new technique utilizing pre-operative supine MRI with intraoperative optical scanning and tracking (MRI) to wire localization (WL).

Methods: Women with a confirmed diagnosis of invasive breast cancer or ductal carcinoma in situ (DCIS) were randomized to MRI or WL-guided partial mastectomy. Women in group MRI had a 3dimensional image of the cancer in their breast created by fusing pre-operative supine MRI with intraoperative optically scanned images of the breast. The surgeon had access to this 3-D image in the operating room and used a hand-held optically tracked probe to draw the projected edges of the cancer on the breast surface; no wires were used. The main outcome measure was the positive margin rate. Secondary outcomes included specimen volume and imaging/pathologic relationships.

Results: One hundred thirty-eight patients were randomly assigned in a 1:1 ratio to group MRI or group WL. Sixty-six percent had invasive breast cancer and DCIS, 22% had invasive cancer, and 12% had DCIS. There were no differences in patient or tumor characteristics between groups. Mean patient age was 64 years. The mean (standard deviation, SD) pathologic tumor diameter in all patients with invasive cancer in group MRI vs group WL was 1.4 (0.8) vs 1.5 (0.9) cm; the mean tumor diameter in patients with pure DCIS was 1.9 (1.1) vs 2.2 (1.7) cm. The proportion of patients with positive margins in the MRI-guided surgery group was half that observed in group WL: 12% vs 23%, p=0.08. The mean (SD) specimen volumes in groups MRI and WL were not significantly different: 74 (34) vs 70 (25) ml, p=0.45. When compared to pathology, tumor diameters were underestimated by >2 cm in 4% of cases by MRI and in 9% of cases by mammography. Sixty-eight percent and 58% of the cases underestimated by >2 cm by MRI or mammography, respectively, had positive margins. In contrast, only 15% and 14% of cases that were not underestimated by MRI or mammography had positive margins.

Conclusions: This study is the first to demonstrate that supine MRI can be used to guide breastconserving excisions of non-palpable invasive breast cancer. Pre-operative supine MRI co-registered with intra-operative optical scanning and tracking enabled tumors to be resected with equivalent volumes when compared to wire localized partial mastectomy. There was a trend toward a lower positive margin rate in patients who had supine MRI-guided surgery. Margin positivity was more likely when imaging underestimated pathologic tumor size.

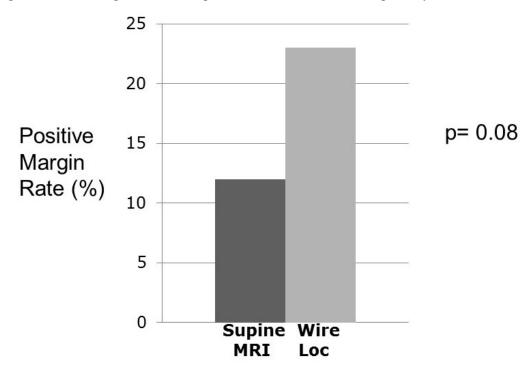


Figure: Positive margin rate after supine MRI or wire localized lumpectomy

Scientific Oral Presentations II

Saturday, May 4, 2019 1:30 pm–3:15 pm Moderators: Henry Kuerer, MD, PhD; Kimberly Van Zee, MD

581296 - A comparison of patient-reported outcomes after breast-conserving surgery and mastectomy with implant breast reconstruction

<u>Meghan Flanagan</u>¹, Emily Zabor², Anya Romanoff¹, Sarah Fuzesi¹, Michelle Stempel¹, Babak Mehrara³, Monica Morrow¹, Andrea Pusic⁴, Mary Gemignani¹

¹Breast Service, Department of Surgery, Memorial Sloan Kettering Cancer Center, New York, NY, ²Biostatistical Service, Department of Epidemiology and Biostatistics, Memorial Sloan Kettering Cancer Center, New York, NY, ³Plastic and Reconstructive Surgical Service, Memorial Sloan Kettering Cancer Center, New York, NY, ⁴Division of Plastic Surgery, Brigham and Women's Hospital, Boston, MA

Background/Objective: Many factors influence decisions regarding choice of breast-conserving surgery (BCS) versus mastectomy with reconstruction for early invasive breast cancer (BC). The purpose of this study was to compare patient satisfaction following BCS and mastectomy with implant reconstruction utilizing the BREAST-Q patient-reported outcome measure.

Methods: Women with stage I or II BC undergoing BCS or nipple-sparing (NSM)/total mastectomy (TM) with immediate tissue expander/implant reconstruction who completed a BREAST-Q from 2010 to 2017 were identified by retrospective review of a prospective database. Baseline characteristics were compared, and linear mixed models were used to analyze associations with BREAST-Q scores over time.

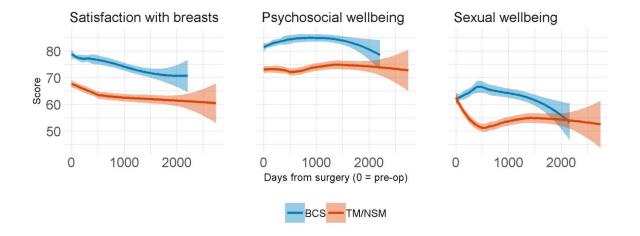
Results: Our study group comprised 3233 women; 2026 (63%) had BCS, 123 (3.8%) had NSM, and 1084 (34%) had TM. With BCS, 92% received radiation compared with 23% of NSM/TM (p<0.001). The median time from surgery to BREAST-Q was 205 days for BCS and 639 days for NSM/TM (p<0.001). The median age of the cohort was 53 years (range 23-97). Women who received BCS were older, more likely to have Stage I breast cancer and receive radiation therapy, and less likely to have chemotherapy (all p<0.001) compared with NSM/TM. Multivariable analysis included time from surgery, type of surgery, age, bilateral disease, any axillary procedure, path stage, chemotherapy, radiation, and conversion to mastectomy. Regardless of type of surgery, breast satisfaction scores decreased significantly over time (p<0.001) whereas psychosocial (p=0.001) and sexual (p=0.004) wellbeing scores increased significantly over time. BCS was associated with significantly higher scores over time as compared with NSM/TM across all subscales (all p<0.001) (Figure). Radiation was significantly associated with decreased scores over time across all subscales (all p < 0.05). Older age (p < 0.001) and Stage II vs I (p=0.001) were also associated with decreased breast satisfaction over time. Younger age (p=0.001) and Stage II vs I (p=0.031) were additionally associated with decreased psychosocial wellbeing over time. Chemotherapy (p=0.005) was associated with decreased sexual wellbeing over time. In a sensitivity analysis separating NSM and TM, NSM did not differ significantly from TM with respect to any of the subscales.

Conclusions: Although we noted significant differences in patient and disease characteristics among women who had BCS compared to mastectomy, on multivariable analysis, BCS was associated with significantly higher BREAST-Q scores. As expected, treatment-related factors such as radiation have a significant effect on breast satisfaction, and on psychosocial and sexual well-being. These findings may

help in counseling women who have a choice for surgical treatment. Breast satisfaction scores decreased over time in all women, highlighting the need for further evaluation with longer follow-up.

Figures: BREAST-Q subscale scores comparing NSM/TM and BCS adjusting for median time from surgery to completion of BREAST-Q

NSM, nipple-sparing mastectomy; TM, total mastectomy; BCS, breast-conserving surgery



580579 - Outcomes of >1300 nipple-sparing mastectomies with immediate reconstruction: The impact of expanding indications on complications

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Background/Objective: The enhanced aesthetics and demonstrated oncologic safety of nipple-sparing mastectomy (NSM) in well-selected patients has resulted in increased rates among patients with locally advanced breast cancer and those with risk factors such as obesity and prior radiation and surgery. Limited data exist on the complication and reconstruction success rates in a contemporary patient cohort with expanded indications for NSM. Thus, our aim was to evaluate these metrics over time as indications for NSM and patient selection criteria have evolved.

Methods: With IRB approval, patients treated with NSM from 2009 to 2017 were identified from our prospective breast surgery registry. Main outcomes were 30-day complication requiring treatment (surgical site infection, hematoma or seroma requiring operation, necrosis requiring debridement or hyperbaric therapy, unplanned reoperation) and one-year reconstruction failure rates. Patient, tumor and treatment variables of interest were analyzed. Cochran-Armitage trend tests were used to evaluate significance of changes over time; risk factors for complications and reconstruction failure were assessed using logistic regression.

Results: We evaluated 1302 breasts in 770 women undergoing cancer treatment (n=557) or risk reduction (n=745). Median patient age was 47 years (range: 21-77). The overall 30-day complication rate was 4.6% (60/1302 breasts) and declined from 13.5% in 2009 to 1.1% in 2017, p<0.001, despite a significant increase over the study period in the proportion of patients with obesity (p<0.001) and treatment with neoadjuvant chemotherapy (p<0.001) as shown in the table. Reconstruction success at 1 year was 96.5%

among 1176 evaluable breasts. Obesity was not significantly associated with either outcome after 2013. Prior radiation (OR 3.6, p=0.002) and recent/current smoking (OR 4.1, p<0.001) significantly increased the risk of 30-day complications. Only prior radiation was significantly associated with reconstruction failure at one year (OR 5.1, p<0.001).

Conclusions: We found decreasing 30-day complication rates of NSM, despite broadened indications among higher-risk patients over time. These data confirm a team learning curve with NSM and also demonstrate the nipple-sparing approach is suitable for appropriately selected higher-risk patients for both risk reduction and cancer treatment.

| Variable | Year | | | | | | | | P value | |
|-----------------|-------|-------|--------|-------|--------|---------|---------|---------|---------|--------|
| | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | |
| 30-Day | 7/52 | 12/84 | 6/104 | 6/90 | 3/130 | 12/188 | 9/254 | 3/222 | 2/178 | <0.001 |
| Complications | 13.5% | 14.3% | 5.8% | 6.7% | 2.3% | 6.4% | 3.5% | 1.4% | 1.1% | |
| Reconstruction | 46/52 | 74/80 | 96/99 | 76/83 | 99/106 | 120/129 | 250/253 | 222/222 | 152/152 | <0.001 |
| Success 1 Year | 88.5% | 92.5% | 97.0% | 91.6% | 93.4% | 93.0% | 98.8% | 100% | 100% | |
| BMI ≥ 30 | 7/52 | 9/84 | 10/104 | 6/89 | 14/127 | 35/187 | 34/254 | 44/222 | 38/178 | <0.001 |
| | 13.5% | 10.7% | 9.6% | 6.7% | 11% | 18.7% | 13.4% | 19.8% | 21.3% | |
| Recent/Current | 3/52 | 13/82 | 11/104 | 4/90 | 6/128 | 18/188 | 18/254 | 18/222 | 18/178 | 0.73 |
| Smoker | 5.8% | 15.9% | 10.6% | 4.4% | 4.7% | 9.6% | 7.1% | 8.1% | 10.1% | |
| Neoadjuvant | 0/52 | 5/84 | 6/104 | 3/90 | 18/130 | 24/188 | 32/254 | 48/222 | 37/178 | <0.001 |
| Chemotherapy | 0% | 6.0% | 5.8% | 3.3% | 13.8% | 12.8% | 12.6% | 21.6% | 20.8% | |
| Prior Breast | 10/52 | 16/84 | 17/102 | 16/89 | 36/130 | 52/188 | 56/254 | 37/222 | 38/177 | 0.84 |
| Surgery | 19.2% | 19.0% | 16.7% | 18% | 27.7% | 27.7% | 22.0% | 16.7% | 21.5% | |
| Prior Radiation | 0/52 | 0/84 | 2/99 | 7/90 | 11/130 | 17/188 | 11/254 | 8/220 | 2/177 | 0.95 |
| | 0% | 0% | 2% | 7.8% | 8.5% | 9% | 4.3% | 3.6% | 1.1% | |
| Node-positive | 8/23 | 12/35 | 7/35 | 6/22 | 10/56 | 17/60 | 24/91 | 32/84 | 16/64 | 0.74 |
| Breast Cancer | 34.8% | 34.3% | 20% | 27.3% | 17.9% | 28.3% | 26.4% | 38.1% | 25% | |
| (among breasts | | | | | | | | | | |
| with cancer) | | | | | | | | | | |

Table: Association of risk factors with 30-day and one-year outcomes of NSM

580617 - DCIS with microinvasion: Is it in situ or invasive disease?

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Background/Objective: Ductal carcinoma in situ (DCIS) with microinvasion (DCISM) comprises mainly non-invasive disease with a small component of invasive disease. Thus, DCISM can be a challenging entity to discuss with patients and to treat. Here, we compared DCISM to pure DCIS and small-volume invasive ductal carcinomas (IDC), as related to biology, treatment patterns, and outcomes.

Methods: Women ages 18-90 years with non-metastatic breast cancer who underwent breast surgery were identified from the SEER Database (2004-2015). Those with DCIS (no invasive disease), DCISM (invasive component ≤ 1 mm), or T1a (>1 mm and ≤ 5 mm) IDC were selected. Patient and tumor characteristics were compared. Multivariate logistic regression was used to estimate the association of diagnosis with the probability of undergoing mastectomy among all patients and radiation among lumpectomy patients after adjustment for known covariates. Overall survival (OS) and breast-cancer-specific survival (BCSS) were estimated with the Kaplan-Meier method. Cox proportional hazards

models were utilized to estimate the association between OS/BCSS and type of disease while adjusting for other covariates.

Results: Of the 134,569 women identified: 3.2% had DCISM (n=4,361), 70.9% had DCIS (n=95,393), and 25.9% had invasive disease (n=34,815). Median follow-up for all patients was 66 months. Women with invasive disease were slightly older than those with DCIS and DCISM (median 62 years for invasive vs 59 years for DCIS and DCISM, p<0.001). When reported, tumor grade and all biomarkers (ER/PR/HER2) were significantly different for DCISM compared to DCIS and invasive disease (all p<0.001). Compared to invasive disease, DCISM was less likely to be ER+ or PR+ and more likely to be HER2+. Although the majority of patients were node-negative for all groups, patients with DCISM were slightly more likely to have positive nodes than those with invasive disease (p<0.001). DCISM patients were the most likely to undergo mastectomy (43.5% vs 31.2% for DCIS and 36.2% for invasive; p<0.001), although this may be related to the extent of DCIS. Rates of chemotherapy receipt were similar for DCISM and invasive disease (10.9% vs 11.8%, respectively). After adjustment, DCIS and invasive patients were less likely to undergo mastectomy than DCISM patients (DCIS: OR 0.53, 95% CI 0.49-0.56, p<0.001; invasive: OR 0.86, CI 0.81-0.92, p<0.001). For those undergoing lumpectomies, the probability of radiation receipt was similar for DCISM and invasive patients (OR 1.04, CI 0.94-1.15, p=0.40), while lower for DCIS patients (OR 0.57, CI 0.52-0.63, p<0.001). Although there was a statistically significant difference, unadjusted OS and BCSS were clinically similar for all groups. After adjustment, OS was not significantly different between DCISM and invasive disease (HR 0.97, CI 0.87-1.08, p=0.59), while patients with DCIS had improved OS (HR 0.83, CI 0.75-0.93, p<0.001). However, BCSS was significantly different between DCISM and the other 2 groups (DCIS: HR 0.59, CI 0.43-0.8, p<0.001; invasive: HR 1.43, CI 1.04-1.96, p=0.03; Table).

Conclusions: Although DCISM is a distinct disease entity, current treatment patterns and prognosis for DCISM patients are comparable to those with invasive breast cancer. These findings may help providers counsel patients and determine appropriate treatment plans.

| | HR (95% CI) | P-Value | Overall P-Value |
|---------------------------|-----------------------|----------------|------------------------|
| Group | | | |
| DCISM | -REF- | | < 0.001 |
| In situ | 0.587 (0.428 - 0.804) | < 0.001 | |
| Invasive (1-5mm) | 1.426 (1.039 - 1.957) | 0.028 | |
| Age, continuous | 1.039 (1.033 - 1.046) | < 0.001 | < 0.001 |
| Race/Ethnicity | | | |
| White | -REF- | | < 0.001 |
| Asian or Pacific Islander | 0.8 (0.615 - 1.041) | 0.096 | |
| Black | 1.923 (1.628 - 2.27) | < 0.001 | |
| Hispanic | 1.226 (0.982 - 1.529) | 0.072 | |
| Other/Unknown | 0.544 (0.202 - 1.462) | 0.227 | |
| Insurance Status | | | |
| Any Medicaid | -REF- | | 0.051 |
| Insured/No specifics | 0.688 (0.516 - 0.918) | 0.011 | |
| Uninsured | 1.091 (0.504 - 2.362) | 0.824 | |
| Unknown | 0.733 (0.545 - 0.985) | 0.040 | |
| Grade | | | |
| 1 | -REF- | | < 0.001 |
| 2 | 1.452 (1.191 - 1.77) | < 0.001 | |
| 3 | 2.057 (1.66 - 2.55) | < 0.001 | |
| Unknown | 1.564 (1.214 - 2.016) | < 0.001 | |
| ER | | | • |
| Positive | -REF- | | 0.759 |
| ER-/Borderline | 1.079 (0.875 - 1.329) | 0.478 | |
| Unknown | 1.055 (0.729 - 1.529) | 0.776 | |
| PR | | | |
| Positive | -REF- | | 0.012 |
| PR-/Borderline | 1.326 (1.094 - 1.608) | 0.004 | |
| Unknown | 1.255 (0.88 - 1.789) | 0.209 | |
| HER2 | | | |
| Positive | -REF- | | 0.071 |
| HER2-/Borderline | 1.778 (1.064 - 2.973) | 0.028 | |
| Not 2010+ Breast | 1.454 (0.896 - 2.36) | 0.130 | |
| Unknown | 1.275 (0.752 - 2.161) | 0.367 | |
| Chemotherapy | | | |
| No/Unknown | -REF- | | < 0.001 |
| Yes | 2.584 (2.09 - 3.196) | < 0.001 | |
| Locoregional Treatment | | | |
| Mastectomy alone | -REF- | | < 0.001 |
| Lumpectomy + radiation | 0.606 (0.521 - 0.704) | < 0.001 | |
| Lumpectomy alone | 1.174 (0.995 - 1.386) | 0.058 | |
| Mastectomy + radiation | 2.359 (1.732 - 3.211) | < 0.001 | |
| Other/Unknown | 1.082 (0.653 - 1.795) | 0.759 | |
| Other Cancer | | | |
| Only Primary | -REF- | | < 0.001 |
| First of Multiple | 3.429 (3.021 - 3.892) | < 0.001 | |

581702 - Evaluation of hormonal profile of breast cancer using 16 A- 18 F-Fluro-Estradiol PET CT: A novel technique

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Background/Objective: Hormone receptor status has vital implications in prognosis and therapy of breast cancer. Immunohistochemistry (IHC) of core biopsy or excised specimen is the standard method of assessing Estrogen Receptor (ER) status in breast cancer. However, all ER+ tumours don't respond equally well to hormonal therapy. In addition, it is not possible to study ER status of metastasis at sites not amenable for biopsy. FDG PET can detect these metastases by their metabolic activity, but lacks specificity for ER receptors on breast tumours. Thus, there is need for a non-intervention technique that not only detects metabolic activity but also identifies ER expression in these situations. 16a-18F-fluoro-17b-estradiol (18F-FES PET CT) not only shows metabolic activity but also ER expression in breast cancer cells and may be useful in predicting response and studying ER status of metastatic sites, not amenable to biopsy. Our aim was to evaluate the role of 18F-FES PET CT in determining ER expression in breast cancer.

Methods: Our study design was a prospective study approved by the Institutional Review Board. Our inclusion criteria comprised patients above 18 years of age with early and locally advanced operable breast cancer consenting to take part in the study. Twenty-four patients with breast cancer were included in the study. For 18F-FES PET imaging, all imaging was performed on a GE Advance tomograph (Waukesah, WI). Standard PET CT protocol was used. Image acquisition and analysis was performed by one of the authors (RK) who was blinded to IHC results. ER expression was performed on core biopsy/ excision specimens by standard techniques. Slides were prepared and reported by one of the authors (SM). Appropriate surgical and adjuvant treatment was administered to all patients. In our analysis, ER expression on 18F-FES PET CT was done using SUV, SUV ratio (SUV ratio of lesion and mediastinal blood pool) and visual grading score (Grade 1 - no uptake; Grade 2 - uptake of lesion less than mediastinal blood pool; Grade 3 - uptake of lesion similar to mediastinal blood pool; Grade 4 - Lesion well defined, uptake more than mediastinal blood pool/similar to liver). ER expression on IHC was reported as Allred Score. Data were analysed using Stata 11.2. Correlation between lesion SUV, SUV ratio of lesion and mediastinal blood pool as well as visual grading score with ER expression on IHC was calculated using the Spearman's correlation coefficient. P-value of <0.05 was considered significant. The value of SUV ratio above which the lesion was considered ER-positive was calculated using the receiver operating characteristic curve (ROC curve).

Results: Sixteen out of 24 patients (66.66%) were ER+ on IHC. Results of 18F-FES PETCT with ER expression as determined by IHC are given in the Table. Assessment of ER expression on 18F-FES PETCT was performed using SUV, SUV ratio, and visual grading. Spearman's correlation coefficient for SUV, SUV ratio, and visual grading was 0.544 (p<0.006), 0.679 (p<0.0000) and 0.787 (p<0.0000) respectively with visual grading being the most accurate.

Conclusions: 18F-FES PETCT appears promising in evaluating ER expression in breast cancer. We propose use of visual grading for ER expression on 18F-FES PETCT as it has shown the strongest correlation with Allred score. It is non-invasive and has potential to assess receptor status of metastasis at sites not amenable for biopsy.

Table: Results of ER expression on FES PET/CT v/s IHC

| | IHC positive | IHC negative | |
|----------------------|--------------------|--------------|------------------|
| FES PET CT Positive | 14 (TP) | 0 (FP) | PPV= 100% |
| FESS PET CT Negative | 2 (FN) | 8 (TN) | NPV= 80% |
| | Sensitivity= 87.5% | | Accuracy= 91.66% |

581360 - Sexual dysfunction in survivorship: The impact of menopause and endocrine therapy

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Background/Objective: Sexual dysfunction is a common complaint for breast cancer survivors. Roughly one-fifth of breast cancers are diagnosed in premenopausal women, who are increasingly offered ovarian suppression and aromatase inhibitor therapy. We aimed to evaluate the association of menopausal status and the interaction of treatment modalities on sexual dysfunction.

Methods: We conducted a cross-sectional survey of breast cancer survivors at a single academic breast center. Eligibility criteria included women undergoing post-surgical treatment between 2000-2016. Participants were asked to complete an anonymous survey incorporating the Female Sexual Function Index (FSFI), demographic and treatment related questions. The results were analyzed using Kruskal-Wallis test for FSFI scores and Chi-square or Fisher's exact test for categorical data. Regression analysis was completed for associations and inclusive of interaction terms.

Results: Of 585 respondents, 278 (47.5%) had complete FSFI scores. Of these, 24 (8.6%) were premenopausal, and 80 (28.8%) were pre- or perimenopausal at the time of survey completion. All women reporting premenopausal status at survey completion were assumed to be premenopausal at diagnosis. Women reporting perimenopause, were assumed to be either premenopausal or perimenopausal at the time of diagnosis. The median FSFI scores for premenopausal (31.2, IQR 26.8-33.6) and pre/perimenopausal (29.2, IQR 25.9-32.2) were similar, while postmenopausal women (25.9, IQR 21.0-30.3) showed significantly lower FSFI scores (p=0.0007 and p=0.0002, respectively). Premenopausal women were significantly less likely to meet criteria for sexual dysfunction (FSFI score ≤ 26.55) when compared to postmenopausal women (21% vs 55%, p<0.0001). In premenopausal women, treatment modality (radiation, chemotherapy, tamoxifen, or aromatase inhibitors (AI)) was not significantly associated with median FSFI scores in univariate analysis (OR 0.32, 95% CI 0.18-0.56). Adjusting for treatment modality did not impact the significance (OR 0.43, 95% CI 0.23-0.80), but revealed that AIs

independently are associated with sexual dysfunction (OR 2.41, 95% CI 1.32-4.40). The interaction between menopausal status and AIs was not significant (p=0.24).

Conclusions: Our study demonstrates that menopausal status is significantly associated with sexual dysfunction in breast cancer patients. It further shows that sexual dysfunction in premenopausal women is not associated with treatment modality outside of aromatase inhibitor therapy. As more premenopausal breast cancer patients are treated with ovarian suppression following current American Society of Clinical Oncology guidelines, these data may guide clinicians in counseling all sexually active breast cancer patients in regard to sexual dysfunction and chosen treatment modalities.

581366 - The role of loco-regional treatment in long-term quality of life in de novo Stage IV breast cancer patients: Protocol MF07-01Q

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Background/Objective: Loco-regional treatment (LRT) is considered a treatment option in selected de novo Stage IV breast cancer (BC) patients. This is the first report of long-term quality of life (QoL) in a cohort of patients who were randomized to LRT and ST in the MF07-01protocol. We aimed to evaluate QoL using SF-12 Scale to evaluate the patients living at least 3 years since randomization.

Methods: SF-12 (V2) forms were filled during patients' visits who were living since 2015 and 36 months had passed since the randomization. We first calculated PCS-12 (Physical Health Composite Scale) and MCS-12 (Mental Health Composite Scale) Scores and compared the urban Turkish population score; then we compared these scores between the LRT and ST groups. Additionally, general health (GH), physical functioning, role functioning, bodily pain, vitality, mental health and social functioning were evaluated and compared between the groups. Considering age-related changes on QoL, we also compared PCS-12 and MCS-12 regarding age of 55. Four additional questions (compare your physical health/mental health/daily activities and energy current vs at diagnosis of BC) were asked and recorded considering the cultural differences.

Results: There were 81patients in this analysis; 68% of patients (n=55) had LRT, and 32% of patients (n=26) received ST. GH was good or very good in 62% (n=34) in the LRT group and 66% (n=17) in the ST group (p=0.63). Mean PCS-12 was 41.6+ 11.2, and mean MCS-12 was 44.6+ 9.3. PCS-12 and MCS-12 core difference was lower than the general Turkish population (PCS-12=49.3+ 12.8, and MCS-12= 46.8+ 13.0). Twenty-eight patients (51%) in the LRT group and 10 patients (38%) in the ST group reported below-average PCS-12 score (p=0.29). For MCS-12, 18 patients (33%) in the LRT, and 6 patients (23%) in the ST group reported below-average scores (p=0.37). There was no difference between the LRT and ST groups regarding PCS-12 and MCS-12 (p=0.34 and 0.54, respectively). Sixty percent of patients (n=49) were younger than 55, and PCS-12 and MCS-12 scores were similar in LRT and ST groups in patients younger and older than 55 years. Comparing current physical health/mental health/daily activities and energy vs at diagnosis of BC, all were similar (p>0.05).

Conclusions: The present study revealed that QoL scores were lower comparing the general population in patients with de novo Stage IV in long-term survivors. These results demonstrate that loco-regional treatment has no detrimental effect on QoL, but psychological distress of having metastatic cancer and

continued systemic treatment may be the cause of the lower scores of QoL compared to the general population.

| | LRT (n=55) | ST (n=26) | P |
|--|--|--|------|
| PCS-12, Mean±SD | 40.8±11.6 | 43.4±10.4 | 0.34 |
| MCS-12, Mean±SD | 44.2±9.9 | 45.6±8.1 | 0.54 |
| Age<55 | | | 2 |
| PCS-12, Mean±SD | 43.3±11.7 | 44.4±10.4 | 0.77 |
| MCS-12, Mean±SD | 43.2±9.9 | 47.0±6.6 | 0.19 |
| Age≥55 | | | |
| PCS-12, Mean±SD | 36.3±10.3 | 42.2±10.8 | 0.14 |
| MCS-12, Mean±SD | 46±9.9 | 43.8±9.6 | 0.55 |
| Current Physical health vs at diagnosis of BC | Same=49% (27) Better=11% (6) Worse=40% (22) | Same=50% (13) Better=23% (6) Worse=27% (7) | 0.27 |
| Current Mental health vs at diagnosis of BC | Same=55% (30) Better=20% (11) Worse=25% (14) | Same=42% (11) Better=31% (8) Worse=27% (7) | 0.49 |
| Current Daily activities vs at diagnosis of BC | Same=18% (10) Better=47% (26) Worse=35% (19) | Same=23% (6) Better=50% (13) Worse=27% (7) | 0.75 |
| Currently more Energy vs at diagnosis of BC | Yes=45% (25) No=55% (30) | Yes=50% (13) No=50% (13) | 0.7 |

Table: Physical and mental scores of patients living at least 3 years

581963 - Is routine oncotype testing in patients over 70 years of age warranted? An evaluation of the National Cancer Database after TAILORx

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Background/Objective: Oncotype testing in early-stage, hormone-positive breast cancers is used to predict the benefit of adjuvant chemotherapy for disease recurrence and overall survival (OS). Application of TAILORx results decreased the ambiguity of an "intermediate risk" recurrence score (RS) by stratifying scores into a binary classification system. Our aims were (1) to determine how women >=70 years with previously deemed intermediate RS were redistributed using post-TAILORx classification, in patients >=70 using a large national database.

Methods: Patients \geq =70 years with early-stage, node-negative, ER-positive, HER2-negative breast cancers who underwent oncotype testing in the National Cancer Database (2004-14) were included. Oncotype scores were defined in 2 ways: "pre-TAILORx" scores were classified into low (0-18), intermediate (19-30), and high risk (\geq 30) groups; "post-TAILORx" scores were classified into low (0-25) and high risk (\geq 25) groups.

Results: A total of 11,355 women were included. The average age was 74 years. Using pre-TAILORx classification, 61% (n=6967) were low risk, 31% (n=3546) were intermediate risk, and 7% (n=842) were high risk. Using post-TAILORx classification, 14% (n=1532) were high risk. Of the 3546 patients previously deemed intermediate risk, 81% (n=2856) were reclassified as low risk and unlikely to benefit from chemotherapy. As expected, only 11% (n=1217) of patients in this elderly cohort received chemotherapy. Of the patients classified as intermediate risk prior to TAILORx who received chemotherapy, 10% (n=289) would have been spared chemotherapy by being reclassified into the low-risk classification after TAILORx. The strongest predictor of post-TAILORx low-risk RS was tumor grade; 95% of well-differentiated tumors and 89% of moderately differentiated tumors had a low-risk RS, compared to 57% of poorly/undifferentiated tumors (p<0.001). Smaller tumor size was also predictive of low-risk RS. Age was not associated with RS (Table).

Conclusions: With new TAILORx criteria for oncotype stratification, the vast majority of patients \geq =70 can be classified as low risk and thus unlikely to benefit from chemotherapy. The majority of cancers in this cohort were well differentiated and associated with a low-risk RS. Given that this age group has a greater rate of chemotherapy associated complications, increasing the risks of unnecessary treatment, and considering increased health care costs associated with testing, reconsideration of routine oncotype testing in patients \geq =70, especially in those with well-differentiated tumors, is warranted. We propose that the decision to use oncotype testing be individualized in this elderly cohort. In addition to taking into account functional status and ability to tolerate chemotherapy, tumor grade and size may also better inform the decision to omit using oncotype score, especially in elderly patients with well differentiated tumors.

| Variable | Recurrence | e Score (RS) | p-value | |
|---------------------------|------------|--------------|---------|--|
| | Low (0-25) | High (>25) | | |
| Age | | | | |
| 70-74 | 6226 (87%) | 956 (13%) | 0.570 | |
| 75-79 | 2732 (86%) | 445 (14%) | 0.560 | |
| ≥ 80 | 825 (86%) | 131 (14%) | | |
| Grade | | | | |
| Well differentiated | 3000 (95%) | 158 (5%) | <0.001 | |
| Moderately differentiated | 5417 (89%) | 647 (11%) | | |
| Poorly/Undifferentiated | 914 (57%) | 677 (43%) | | |
| Tumor size | | | | |
| <1cm | 2672 (88%) | 363 (12%) | 0.001 | |
| 1-2 cm | 5854 (86%) | 926 (14%) | | |
| >2 cm | 1293 (84%) | 243 (16%) | | |

Table: Predictors of recurrence score

581969 - Same-day surgery for mastectomy patients in Alberta: A perioperative care pathway and quality improvement initiative

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Background/Objective: Despite evidence supporting same-day surgery (SDS) for mastectomy with no difference in wound complications, readmission and reoperation rates compared to those admitted overnight, uptake of early discharge remains low in Alberta. In addition to being safe, SDS has been shown to improve shoulder movement, reduce wound pain and decrease anxiety with high patient satisfaction and expedited psychological recovery. Moreover, overnight admissions following mastectomy in medically and socially fit breast cancer patients is an inefficient use of acute care resources. In response to a national performance review highlighting SDS for mastectomy at 1% in Alberta, we developed and implemented a SDS pathway to improve the quality of perioperative care for women undergoing mastectomy. The objective of this study is to describe the development, implementation, rate of SDS, and patient-reported experience (PRE) measures for a quality improvement initiative supporting SDS for mastectomy.

Methods: A multi-tiered perioperative pathway for SDS was conceived and designed in 2015 supporting 3 main groups: surgeons/nurse navigators, perioperative nurses, and patients/caregivers. Implementation was carried out via 5 regional committees, each composed of 6-8 local members: breast surgeon, nurse navigator, and operational leads for each of the following areas: pre-admission, day surgery, inpatient unit, operating room, and post-anesthetic recovery room. Local present- and future-state opportunities along the patient care experience were identified for each region where specific steps could be taken to improve the utilization, safety, and support for patients having SDS. Provincially branded materials for surgeons/nurse navigators included formal SDS presentations, order set templates, and "standard operating" procedures with early nursing contact and plan for assessment outside of emergency services if a post-operative issue were encountered. Two dedicated nurse educators provided in-service teaching for each perioperative team at 13 hospitals across the province. This included provision of standardized drain care and discharge teaching forms. A patient education booklet, group teaching classes, and online resources were developed for patients and families. A measurement framework was created, and data were collected on the number of same-day surgeries performed, emergency visits, and readmission rates. Patient-reported measures were collected using a voluntary online survey 1 week post-operatively using a validated PREs and recovery from surgery survey. Outcome measures were reported to the regional committees through an online provincial dashboard for feedback to clinical teams.

Results: Development of support materials, assembly of regional committees followed by implementation occurred across the province over 18 months, with final nursing in-services was completed in mid-2017. Regional modifications to aspects of the pathway were made in accordance with local patient population characteristics. Barriers to uptake include lack of surgery-specific nurse navigator support in smaller regions and surgeon preference for overnight admission. Since the initiation and implementation of the perioperative pathway, SDS rates for mastectomy in Alberta have improved from 1.2% to 40% in 2017-2018, releasing an estimated 1031 bed days. One hundred two patients voluntarily completed the PRE survey, with 91% of respondents indicating they felt "excellent or good" about how to take care of themselves once they were home, and 93% indicating they felt "excellent or good" about knowing who to contact or where to get support if there were issues. Subjective recovery 1 week following surgery was assessed using the Quality of Recovery (QoR-15) questionnaire with patients rating their recovery from 0 (poor) to 10 (excellent) across various domains (pain management, ability to eat, sleep, care for themselves, feel in

control, general well-being and return to work or usual home activities). The average response across categories 1 week following surgery was 7.9.

Conclusions: Development and regional implementation of a multi-tiered provincial perioperative pathway for breast cancer resulted in higher use of SDS for mastectomy in the early post-implementation period, with favourable patient reported experience measures.

582345 - Neoadjuvant endocrine therapy vs chemotherapy in node-positive invasive lobular carcinoma

<u>Oluwadamilola Fayanju</u>, Madeline Thornton, Hannah Williamson, Kelly Westbrook, Rachel Greenup, Jennifer Plichta, Laura Rosenberger, Anjuli Gupta, Terry Hyslop, Eun-Sil Hwang *Duke University, Durham, NC*

Background/Objective: Studies have suggested that patients with invasive lobular carcinoma (ILC) respond poorly to neoadjuvant chemotherapy (NACT), but neoadjuvant treatment is still recommended for many node-positive (LN+) ILC patients. Little is known about the comparative efficacy of neoadjuvant endocrine therapy (NET) vs NACT specifically in patients with hormone receptor-positive (HR+) ILC. We sought to compare long-term outcomes in patients with LN+ ILC who receive NET vs NACT.

Methods: Women with cT1-4c, cN1-3 HR+ ILC diagnosed 2004-2014 who underwent surgery and received either NET or NACT were identified in the National Cancer Database. Chi-square and t-tests were used to compare patient characteristics. Kaplan-Meier curves were used to estimate unadjusted overall survival (OS). Cox proportional hazards models were used to estimate the effect of neoadjuvant therapy on OS after adjustment for known covariates. P<0.05 was considered significant for all analyses.

Results: Of 5,942 patients identified, 855 received NET, and 5,087 received NACT. Patients who received NET were older (70 vs 54), had more comorbidities (Charlson/Deyo score \geq 1: NET 21.1% vs NACT 11.5%), lower cT stage (T3-4: NET 44.2% vs NACT 51%), lower rates of mastectomy (72.5% vs. 82.2%), and lower rates of both post-lumpectomy (73.2% vs 91.0%) and post-mastectomy (60.0% vs 80.8%) radiation vs NACT patients (all p<0.001). Only 126 NACT patients (2.5%) had pathologic complete response (pCR), and no NET patients had pCR. Despite having similar cN stage at presentation, NET patients had lower rates of nodal pCR (i.e., ypN0: NET 8.1% vs NACT 13.4%), more positive nodes on final pathology (median NET 4 vs NACT 3), and higher rates of breast (NET 10.5% vs NACT 7%) and nodal upstage (NET 35.6% vs NACT 29.4%) than NACT patients (all p<0.001). NACT patients had higher unadjusted 5-year OS vs NET patients (81.6% vs. 73.5%), but after adjusting for clinicopathologic characteristics, there was no significant difference in survival between NET and NACT patients (p=0.06; see Table). NET patients who received adjuvant chemotherapy (HR 0.63, 95% CI 0.44-0.90, p=0.01), and NACT patients who received adjuvant endocrine therapy (HR 0.59, 95% CI 0.48-0.72, p<0.001) had improved OS vs those who did not receive these systemic adjuvant treatments.

Conclusions: After adjusting for covariates, there was no significant difference between patients receiving NET and NACT, though larger prospective cohort studies with more balanced populations would be needed to confirm this finding. NET patients were older and almost twice as likely to have a Charlson-Deyo comorbidity score ≥ 1 , suggesting a greater burden of other health conditions at diagnosis. Additional research is needed to assess the potential efficacy of NET in younger, healthier patients and the optimal timing of endocrine therapy and chemotherapy in the management of locally advanced ILC.

| leoadjuvant endocrine therapy or chemother | HR (95% CI) | P-Value | Overall P-Value |
|---|--------------------|----------|-----------------|
| | | i -value | 0.06 |
| Treatment group Neoadjuvant chemotherapy | REF | | 0.00 |
| Neoadjuvant endocrine therapy | 0.76 (0.58 - 1.01) | 0.06 | |
| | 1.01 (1.00 - 1.02) | 0.004 | 0.004 |
| Age (years) | 1.01 (1.00 - 1.02) | 0.004 | 0.004 |
| White | REF | | 0.04 |
| | 1.18 (0.95 - 1.46) | 0.13 | |
| Black | | | _ |
| Other | 0.58 (0.33 - 1.03) | 0.06 | 0.02 |
| Ethnicity | DEE | | 0.02 |
| Hispanic | REF | 0.00 | |
| Non-Hispanic | 1.60 (1.08 - 2.37) | 0.02 | 0.04 |
| Charlson/Deyo comorbidity score | | | 0.01 |
| 0 | REF | | |
| 1 | 1.14 (0.92 - 1.41) | 0.22 | |
| ≥2 | 1.71 (1.19 - 2.44) | 0.003 | |
| Pathological T stage | DEE | | <0.001 |
| 1 | REF | | |
| 0 | 1.78 (1.11 - 2.86) | 0.02 | |
| 2 | 1.35 (1.09 - 1.68) | 0.006 | |
| 3 | 1.55 (1.24 - 1.93) | <0.001 | |
| 4 | 1.96 (1.42 - 2.71) | <0.001 | |
| X | 1.27 (0.79 - 2.02) | 0.32 | |
| Pathological N stage | | | <0.001 |
| 0 | 0.87 (0.65 - 1.16) | 0.34 | |
| 1 | REF | | |
| 2 | 1.53 (1.26 - 1.85) | <0.001 | |
| 3 | 2.80 (2.31 - 3.39) | <0.001 | |
| Х | 0.61 (0.38 - 0.98) | 0.04 | |
| Grade | | | <0.001 |
| 1 | REF | | |
| 2 | 1.30 (1.07 - 1.57) | 0.007 | |
| 3 | 1.70 (1.36 - 2.12) | <0.001 | |
| Surgery type | | | 0.64 |
| Lumpectomy | REF | | |
| Mastectomy | 1.11 (0.71 - 1.72) | 0.64 | |
| Treated with radiation post-lumpectomy | | | 0.02 |
| No | REF | | |
| Yes | 0.58 (0.37 - 0.92) | 0.02 | |
| Treated with radiation post-mastectomy | | | 0.003 |
| No | REF | | |
| Yes | 0.76 (0.64 - 0.91) | 0.003 | |
| Treated with adjuvant chemotherapy (neoadjuvant endocrine therapy patients only) | | | 0.01 |
| No | REF | | |
| Yes | 0.63 (0.44 - 0.90) | 0.01 | |
| Treated with adjuvant endocrine therapy (neoadjuvant chemotherapy patients only) | · · · | | <0.001 |
| No | REF | | |
| Yes | 0.59 (0.48 - 0.72) | <0.001 | |

Table: Adjusted overall survival, women with cT1-4c, cN1-3, HR+ invasive lobular carcinoma who received neoadjuvant endocrine therapy or chemotherapy, National Cancer Database, 2004-2014 (N=4452)

Hazard ratios (HRs), confidence intervals (Cls), and p-values are from a Cox proportional hazards model, stratified by year of diagnosis (2004-2009 and 2010-2014). A robust sandwich covariance estimator was used to account for correlation of patients treated at the same facility.

635483 - Preliminary results of a multi-center feasibility trial for real-time, intraoperative detection of residual breast cancer in lumpectomy cavity margins using the LUM Imaging System

<u>Barbara Smith</u>¹, Bridget Kelly¹, Kelly Hunt², Shelley Hwang³, Irene Wapnir⁴, Michele Gadd¹, Michelle Specht¹, Kevin Hughes¹, Conor Lanahan¹, Carson Brown¹, David Strasfeld⁵, Katherine Kacena⁵

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Background/Objective: Obtaining cancer-free margins is critical for local control in breastconserving surgery. Unfortunately, approximately 20-40% of patients have positive margins that require surgical re-excision. Our ongoing multicenter trial is evaluating the LUM Imaging System for real-time, intraoperative detection of residual cancer in patients undergoing lumpectomy for breast cancer. This system includes (1) LUM015, an intravenous agent activated to a fluorescent form by proteases at sites of tumor, (2) a handheld optical head for use in the lumpectomy cavity, and (3) image analysis software. Potential sites of residual tumor are identified within the lumpectomy cavity walls rather than on the surface of excised specimens, which we hypothesize may allow more accurate excision of residual cancer.

Methods: Women undergoing breast-conserving surgery for invasive breast cancer and/or ductal carcinoma in situ (DCIS) at 16 US hospitals received intravenous LUM015, a cathepsin-activatable fluorescent agent, at 1 mg/kg 4±2 hours prior to surgery. After the standard-of-care lumpectomy was completed, final cavity walls were assessed intraoperatively using the LUM Imaging System (Lumicell, Inc., Newton MA) to identify areas of fluorescence suspicious for residual cancer. Areas of fluorescent signal above a patient-specific detection threshold were excised and correlated with histopathology.

Results: The LUM015 imaging agent was administered preoperatively in 60 women with breast cancer, median age 61 years (range 41-74). Surgeons performed their standard of care lumpectomy, and the resulting lumpectomy cavity was imaged in vivo with the LUM Imaging System in 59 patients. Two hand-held circular optical heads with diameters of 1.3cm and 2.6cm, for use in smaller or larger incisions, allowed analysis of 1.33cm2 and 5.31cm2 areas within 1 second of tissue contact. Median tumor size was 1.9cm (range 0.1-7.8cm); 73% were invasive cancer +/- DCIS, and 27% were DCIS alone. The test set included images of 379 lumpectomy cavity margins. After standard-of-care lumpectomy and prior to imaging with the optical head, 14 of 59 (24%) lumpectomies had at least 1 pathology-confirmed positive final margin (<2mm for DCIS and "on ink" for invasive cancer). The LUM Imaging System detected cancer in the lumpectomy cavity walls in 11 of these 14 cases (78.6%). One subject, with a known allergy to other contrast agents, experienced an allergic reaction during LUM015 injection; she recovered and was discharged the following day. There were no other serious adverse events in the study population.

Conclusions: The LUM Imaging System allows real-time identification of residual cancer within the lumpectomy cavity of breast cancer patients. Accrual to this feasibility trial continues, and additional clinical trials and scientific evaluation of the system are planned.

Quickshot Presentations

Saturday, May 4, 2019 3:45 pm – 4:40 pm Moderators: Katherina Zabicki Calvillo, MD; Richard White, Jr., MD

580281 - Provider perspective: Fertility preservation discussions in premenopausal breast cancer patients

<u>Alex Bartholomew</u>¹, Maria Masciello², Shawndeep Tung³, Laura Bozzuto³, Ekaterini Tsiapali³ ¹Georgetown University, Mclean, VA, ²Georgetown University School of Medicine, Washington, DC, ³MedStar Georgetown University Hospital, Washington, DC

Background/Objective: Approximately 10% of new breast cancer diagnoses occur in premenopausal women annually. Oncologic management often involves treatment that can compromise or delay fertility. Thus, the importance of a fertility preservation discussion (FPD) prior to treatment intervention is paramount. Recent work at our institution highlighted a low rate (46%) of documented FPD. For this reason, we sought to better understand facilitators and barriers to FPD across a range of medical providers offering integrated care for breast cancer.

Methods: An electronic questionnaire was developed to assess factors influencing fertility preservation discussions and subsequent documentation in providers. This questionnaire was distributed to the departments of surgical oncology, medical oncology, and radiation oncology across a ten-hospital network via REDCap software. The questionnaire queried basic demographics about the provider and practice, as well as Likert scales assessing perceptions, documentation patterns, barriers, and patient factors influencing likelihood of FPD including age, stage of disease, patient desire, number of children, marital status, intended endocrine therapy, intended chemotherapy, and insurance status.

Results: The questionnaire was completed by 19 of 30 (63.3%) physicians, including 36.8% medical oncologists, 47.4% surgical oncologists, and 15.8% radiation oncologists. Physicians reported offering counseling to premenopausal women on fertility preservation 'always' (26.3%), 'frequently' (47.4%), 'sometimes' (21.1%), and 'rarely' (5.3%). Only 31.6% of physicians indicated they 'always' document these discussions and 10.5% of physicians indicated they 'always' have time for FPD in clinic. The majority (68.3%) of providers believed that the physician providing the therapy compromising fertility should be responsible for counseling. Significant differences existed for factors influencing the likelihood of having a FPD (p<0.001; 1 = least likely to 5 = most likely), with age (mean = 4.6) and patient desire (4.2) being ranked significantly higher, while marital status (1.6) and insurance status (1.2) were ranked significantly lower. Approximately 26% of physicians indicate they 'never' provide educational materials or online resources to patients interested in FPD, but 94.7% agreed that educational materials on fertility preservation would be helpful. In addition, 84.2% agreed that an electronic medical record reminder would facilitate fertility preservation discussions. After completing the questionnaire, 84.2% planned on improving both rates and documentation of FPD. Interestingly, just 63.1% of physicians believed that patients remembered the fertility discussions.

Conclusions: Fertility preservation in premenopausal patients is an integral aspect of breast cancer care that requires thorough and timely discussion and consistent documentation. Our physician questionnaire identified varying levels of counseling and inconsistent documentation. Barriers to FPD include lack of clinic time and physicians feeling that it is not their responsibility to counsel on fertility. Physicians indicated a need for educational materials in the clinic to increase discussion rates. Age and patient desire were identified to have the greatest impact on the likelihood of FPD. Following the survey, the majority

of physicians indicated plans to increase rates of counseling and documentation to improve the quality of care offered to patients.

580364 - Utility of second sentinel lymph node biopsy for patients with cN0 ipsilateral breast cancer recurrence after an initial sentinel lymph node biopsy

<u>Akiko Ogiya</u>, Ayaka Sato, Takehiko Sakai, Takuji Iwase, Tomo Osako, Rie Horii, Futoshi Akiyama, Takayuki Ueno, Shinji Ohno

Cancer Institute Hospital, Japanese Foundation for Cancer Research, Koto-ku, Tokyo, Japan

Background/Objective: In cases of cN0 ipsilateral breast cancer recurrence, performing a second sentinel lymph node biopsy (re-SLNB), after an initial SLNB, is becoming an accepted practice. However, there is variability in the rate of identification of sentinel lymph nodes (SNLs) during re-SNLB and still insufficient data on the accuracy of SLN diagnosis. Here we examined the clinical utility of re-SNLB by investigating patients with cN0 ipsilateral breast cancer recurrence, after an initial SNLB surgery, including an investigation of the prognosis for re-SNLB.

Methods: Of 136 patients diagnosed with cN0 ipsilateral breast cancer recurrence who underwent lymphoscintigraphy between April 2005 and December 2016 at our hospital, this study included 81 patients who underwent SLNB at the primary surgery. The median period of observation after re-SLNB was 61 months (8–155 months). Lymph node regions were categorized as ipsilateral axillary lymph nodes (AXLNs) (level I–III, Rotter), internal mammary lymph nodes (IMLNs), contralateral AXLNs, intramammary lymph nodes, and other lymph nodes. The number of nodes with radioisotope (RI) accumulation, number of nodes excised during re-SLNB, metastatic status of SLNs during re-SLNB, final lymph node procedure, and prognosis were investigated.

Results: Re-SLNB was performed using a combination of RI and dye in 72 patients and only RI in 9 patients. Lymphoscintigraphy revealed RI accumulation in SLNs in 77 patients (95%), where the region of accumulation was ipsilateral AXLNs in 68 patients (88%), ipsilateral IMLNs in 12 patients (16%), contralateral AXLNs in 14 patients (18%), intramammary lymph nodes in 6 patients (88%), and contralateral IMLNs in 1 patient (1%). The median number of SLNs with RI accumulation was 1 for ipsilateral IMLNs, ipsilateral IMLNs, and contralateral AXLNs. The rate of removed SLNs with RI accumulation out of the number of accumulated lymph nodes was 95% for ipsilateral AXLNs, 53% for ipsilateral IMLNs, and 63% for contralateral AXLNs. Some SLNs in ipsilateral IMLNs and contralateral AXLNs were not removed because of SLNs located behind the ribs, failure to identify nodes with accumulation during surgery and surgeon's decision. Of the 65 patients in whom RI accumulation was observed in ipsilateral AXLNs and in whom SLNs were removed during re-SLNB, 61 patients (94%) were negative for metastasis. Axillary dissection was omitted in 58 (95%) of these 61 patients, sampling was performed in 2, and dissection was performed in 1 patient. Of the 61 patients in whom axillary dissection was observed in the patients who underwent sampling and dissection.

Conclusions: Detection rate of SLNs was high in patients with cN0 ipsilateral breast cancer recurrence after a first SNLB (95%). Re-SLNB was performed most frequently in the ipsilateral AXLN region, and less frequently in the ipsilateral IMLN region and contralateral AXLN region. Lymphoscintigraphy was useful for re-SNLB. The rate of axillary recurrence after omitting dissection was low, indicating that re-SLNB is accurate and clinically useful.

580844 - National patterns of nipple-sparing mastectomy for breast cancer, 2005-2015 <u>Stephanie Wong¹</u>, Yoon Chun², Yasuaki Sagara¹, Mehra Golshan¹, Jessica Erdmann-Sager² ¹Dana Farber/Brigham and Women's Cancer Center, Boston, MA, ²Brigham and Women's Hospital, Boston, MA

Background/Objective: The oncological safety and indications for nipple-sparing mastectomy (NSM) are expanding. The objective of this study was to explore national patterns in the uptake of breast reconstruction with skin-sparing mastectomy and NSM, as well as examine clinical and demographic factors associated with its use.

Methods: We used the National Cancer Database to identify all women who underwent mastectomy for a first diagnosis of in situ or clinical Stage I-III invasive breast cancer between 2005-2015. Multivariable logistic regression was used to determine factors associated with receipt of reconstruction, and subset analyses then performed to determine trends and predictors of NSM in those who underwent mastectomy with reconstruction.

Results: Our cohort consisted of 395,815 women, of which 238,568 (60.3%) underwent mastectomy without reconstruction and 157,247 (39.7%) underwent mastectomy followed by reconstruction. On multivariable analysis, factors strongly associated with receipt of reconstruction included younger age at diagnosis, private insurance, academic/integrated network cancer center, higher income, and later year of treatment (all p<0.001). Among those receiving reconstruction during the study period, the use of NSM increased significantly, from 1.7% of reconstructive cases in 2005 to 14.3% in 2015 (p<0.001). The trend towards increasing use of NSM was seen in both early stage breast cancer and locally advanced disease, such that by 2015, NSM was performed in 15.3% of mastectomies with reconstruction for DCIS, 14.3% of mastectomies with reconstruction for Stage III breast cancer. In adjusted analyses, factors predicting receipt of NSM included younger age at diagnosis, lower clinical T stage, clinically node negative disease, use of neoadjuvant systemic therapy, and facility type (all p<0.001). Significant geographic variation and temporal trends were also noted, such that when compared to those treated in 2005, patients treated in 2015 were nearly ten-fold more likely to receive NSM (OR 9.67; 95% CI 7.32-12.76).

Conclusions: The use of breast reconstruction following mastectomy has increased four-fold over the last decade, while uptake of NSM has risen nearly ten-fold between 2005 and 2015. Further prospective studies evaluating oncologic outcomes of NSM in locally advanced breast cancer are warranted.

580928 - Distress: Characterizing what causes the thermometer to rise in patients with newly diagnosed breast cancer attending a multidisciplinary clinic

<u>Chelsey Ciambella</u>¹, Charu Taneja², Don Dizon², Doreen Wiggins², Christine Emmick², Kara Leonard², Mary Lopresti², Sabrina Witherby², Diana Cabral², Serena Snow², Theresa Graves² ¹Warren Alpert Medical School of Brown University/Rhode Island Hospital, Providence, RI, ²Lifespan Cancer Institute and Rhode Island Hospital, Providence, RI

Background/Objective: A diagnosis of breast cancer (BC) can result in multifactorial stress including emotional, financial, and physical aspects. If not properly addressed, distress can disrupt treatment and negatively impact outcomes. While screening for distress is common in medical oncology, the experience of patients with newly diagnosed BC has not been described. We characterize distress among new patients with BC in a multidisciplinary care (MDC) surgery-led clinic. The objectives of this study are to (1) determine the degree of distress at presentation (2) characterize the sources of distress and (3) evaluate

the impact of an MDC visit on distress scores. The degree and sources of distress along with what impact an initial evaluation in a multidisciplinary clinic (MDC) can have on distress have not been adequately studied. The objectives of this study are to (1) determine the degree of distress at presentation, (2) characterize the sources of distress, and (3) evaluate the impact of an MDC visit on distress scores.

Methods: Retrospective review of patients at the LCI MDC from January 1, 2015 to November 30, 2017. Charts were accessed for baseline demographics, tumor characteristics, and treatment data. Distress scores (DS) and sources of distress as captured using the NCCN Distress Thermometer were completed before evaluation by clinicians and in a subgroup of patients who were assessed after MDC visit. We investigated predictors of severe distress (DS \geq 4) using multivariable logistic regression. Paired t-test was used to determine the impact of an MDC visit on distress scores prior to and following MDC visit. All analysis was conducted with STATA 15.1.

Results: Three hundred fifty-one patients were analyzed. Mean initial DS (n=286) was 4.87 with 65% of patients presenting with severe distress. Sources of distress in >45% of patients included worry, nervousness, and fear. The most prevalent physical stressor was sleep issues in 33% of patients. Age <65 years was significantly (p<0.05) associated with higher DS at presentation. Among patients who were also queried pre- and post-MDC (n=86), a significant reduction in distress was identified 5.4 to 3.1 (p<0.05) as well as a reduction in severe distress (p<.005). There was no significant difference in mean scores when comparing neoadjuvant chemotherapy and operative treatment, lumpectomy or mastectomy.

Conclusions: This study demonstrates that more than half of patients recently diagnosed with breast cancer have severe distress with younger age associated with higher distress scores. Emotional stressors were the predominant factors accounting for distress at presentation. Also, conduct of a same-day MDC was associated with a significant reduction in DS. While this analysis is ongoing these data indicate the importance and feasibility for proactively screening patients. Our research lends support to the value of multidisciplinary evaluation in this setting.

562753 - Effect of surgery type on time to adjuvant chemotherapy and impact of delay on breast cancer survival: A National Cancer Database analysis

<u>Amanda Kupstas</u>, Tanya Hoskin, Courtney Day, Judy Boughey *The Mayo Clinic, Rochester, MN*

Background/Objective: There is a growing collection of data that suggests a delay in treatment of patients with breast cancer is detrimental to survival outcomes. In previous population-based registry studies the overall survival and breast-specific survival have been found to be affected if time to chemotherapy extended beyond 120 days of diagnosis. The aim of this study was to specifically evaluate the impact of the type of surgical treatment on time to adjuvant chemotherapy and subsequent impact of delay breast cancer survival in the National Cancer Database (NCDB).

Methods: A retrospective analysis of patients diagnosed with Stage I-III breast cancer from 2010-2014, treated with surgery and adjuvant chemotherapy, was performed using the NCDB. Delay in treatment was defined as greater than 120 days from diagnosis to first dose of chemotherapy. The effect of the type of breast surgery performed on time to chemotherapy was evaluated. Multivariate analysis was performed to assess factors associated with delay in treatment and the effect of delay on overall survival.

Results: Of 174,013 patients identified 155,625 patients (89%) initiated chemotherapy within 120 days of breast cancer diagnosis, including 92% of breast conservation surgery (BCS), 89% of mastectomy without reconstruction (M–IBR), and 85% of mastectomy with reconstruction (M+IBR) patients. Time

from diagnosis to first surgery was shorter in patients undergoing BCS than mastectomy overall (M-TOT) regardless of reconstruction (median 25 vs 30 days, p<0.001), and for those undergoing M–IBR versus M+IBR (median 26 vs 35 days, p<0.001). Although the time from first surgery to chemotherapy was also shorter, this did not seem clinically significant (43 days BCS vs 44 days M-IBR vs 44 days M+IBR, p<0.001). Thus, the time from diagnosis to first surgery accounted for the greatest portion of the delay from diagnosis to chemotherapy in patients with M-TOT (median 78 days) vs BCS (median 71 days), and M+IBR (median 84 days) vs M-IBR (median 74 days), see Table. The mastectomy group was further analyzed, and patient factors associated with a delay were increasing age, higher co-morbidity index, black race, Hispanic ethnicity, insurance status other than private insurance, each p<0.001. Patients with triple-negative or HER2+ tumors and those with higher-stage disease were less likely to have a delay in chemotherapy. After adjusting for these factors, the effect of reconstruction on delay remained significant (OR 1.7, 95% CI: 1.6-1.8, p<0.001). For all patients regardless of the type of surgery, after adjusting for patient, clinical, and treatment factors, delay of >120 days from diagnosis to chemotherapy was associated with worse OS (HR 1.25, 95% CI: 1.18-1.32, p<0.001).

Conclusions: Initiation of chemotherapy within 120 days of diagnosis is a reasonable goal that occurs for most patients. Initiation of chemotherapy beyond 120 days was associated with poorer overall survival. Time from diagnosis to surgery had the greatest impact on the time from diagnosis to chemotherapy, with reconstruction resulting in the longest delay to surgery. This reflects that access to plastic surgery is critical for optimal oncologic care.

| | BCS | M _{TOT} | M-IBR | M+IBR |
|---|---------------------------|------------------|------------------------------|--------------|
| | N=90,488 | N=83,525 | N=46,253 | N = 37,272 |
| Days from diagnosis to first surgery median (IQR) | 25 (15-37) | 30 (17-44) | 26 (15- 40) | 35 (22-50) |
| Days from first surgery to adjuvant chemotherapy start median (IQR) | 43 (33-58) | 44 (34-62) | 44 (34- 62) | 44 (34-62) |
| Days from diagnosis to adjuvant chemotherapy start median (IQR) | 71 (55-91) | 78 (61-101) | 74 <mark>(</mark> 57- 97) | 84 (65-106) |
| Delay > 120 days from diagnosis to adjuvant chemotherapy start n (%) | 7551 <mark>(</mark> 8.3%) | 10,837 (13.0%) | 5234 (11.3%) | 5603 (15.0%) |

Table: Effect of type of surgery on time to treatment

581764 - Are we overtreating hormone receptor-positive breast cancer with neoadjuvant chemotherapy? Correlating OncotypeDx® results with tumor response in patients undergoing neoadjuvant chemotherapy

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Background/Objective: Genomic testing on tumor tissue is frequently used to determine the need for adjuvant chemotherapy in hormone receptor-positive (HR+), Her2neu-negative (HER2-) breast cancer. A few small studies suggest that it may be a predictor of response to neoadjuvant chemotherapy (NAC). Our objective was to examine the frequency of genomic testing with OncotypeDx for newly diagnosed HR+HER2- breast cancer patients undergoing NAC and to examine the proportion of patients with an OncotypeDx score that does not predict benefit from chemotherapy.

Methods: The National Cancer Database was used to identify women with unilateral, AJCC 7th edition Stage I-III invasive HR+HER2- breast cancer. Patients with missing data on chemotherapy or surgical treatment were excluded. Trends and predictors of Oncotype in NAC patients were examined from 2010-2015 and adjusted for patient, facility, and tumor factors. Correlation of OncotypeDx results with pathological complete response was examined. Low recurrence score was defined as <11, intermediate as 11-25, and high as >25 as used in the TailorX trial.

Results: A total of 393.872 patients underwent surgery for Stage I-III HR+HER2- breast cancer from 2010-2015. OncotypeDx testing was sent in 42.6% of patients; 101,882 (47.2%) of patients that did undergo any chemotherapy, 29,588 (39.1%) that underwent adjuvant chemotherapy (AC), and 1,498 (7.1%) that underwent NAC. The utilization of OncotypeDx in patients who had NAC increased from 5.6% in 2010 to 8.6% in 2015 (p<0.01). The highest rates of OncotypeDx were in patients treated at integrated network cancer centers (8.3% vs 7.0% at community centers, p=0.01) and those treated in the East South Central (10.9%) region of the country (vs 5.7% in West South Central region, p<0.01). Independent predictors of testing with OncotypeDx included more recent year of diagnosis (OR 1.51 for 2015) and older age (OR 1.60 for age >70). Higher grade (OR 0.55 for grade 3) and more advanced stage (OR 0.09 for stage III) were associated with decreased use of OncotypeDx. Facility type and region were not significant predictors of OncotypeDx testing on adjusted analysis. Of the 1,498 NAC patients that had OncotypeDx testing, 82.8% had available recurrence score data; 88 (7.3%) were low risk for recurrence, 565 (47.0%) were intermediate risk, and 548 (45.6%) were high risk. Of 452 women <50 years old, 31 (6.9%) had a recurrence score of <11, 64 (14.2%) had a recurrence score of 11-15, 162 (35.8%) had a score of 16-25, and 195 (43.1%) had a recurrence score >25. 839 patients (69.9%) with OncotypeDx testing after NAC were clinically node negative, and 348 (29.0%) were clinically node positive. Recurrence score (OR 7.76, CI 2.76-21.87 for high-risk), grade (OR 4.40, CI 3.84-4.96 for grade 3) and age (OR 2.16, CI 156-2.99 for age <50) were all significant independent predictors of pathologic complete response on adjusted multivariable analysis.

Conclusions: The utilization of genomic testing with OncotypeDx in patients undergoing NAC is increasing and was an independent predictor of pCR. Nearly half of HR+HER2- patients had an OncotypeDx score that would not require chemotherapy in the adjuvant setting suggesting that some patients may be overtreated with NAC. Further study on the validity and clinical utility of genomic testing in the neoadjuvant setting are needed.

581789 - Exploring surgeon variability in recommendations for contralateral prophylactic mastectomy: What matters most?

Cindy Matsen¹, <u>Mark Taylor</u>², Chelsea Allen², Angela Presson², Morgan Millar² ¹Huntsman Cancer Institute at the University of Utah, Salt Lake City, UT, ²University of Utah, Salt Lake City, UT

Background/Objective: The decision to undergo contralateral prophylactic mastectomy (CPM) should be a shared decision between the patient and surgeon. The American Society of Breast Surgeons (ASBrS) released guidelines that state it is the responsibility of the surgeon to discuss the risks and benefits of CPM as they relate to the individual patient and give his/her recommendation regarding CPM. Many studies have investigated factors that affect a patient's decision to undergo CPM, but there are limited data on factors that affect surgeon recommendations for CPM. To address this, we conducted a survey of ASBrS members to evaluate the factors that affect surgeons' recommendations about CPM, their confidence in their recommendation, and their awareness and adoption of the ASBrS guidelines.

Methods: In February 2018, an electronic survey was sent to the ASBrS membership, assessing demographics and recommendations for CPM based on patient characteristics (patient age, breast cancer stage, receptor status, family history of breast cancer, and patient preference for CPM). Respondents were asked to estimate the patient's chance of developing contralateral breast cancer, whether they would recommend CPM, their confidence in this recommendation, their familiarity with the 2016 ASBrS guidelines on CPM discussions, their use of these guidelines, and the factors most important in their recommendations. Surgeon's recommendation of CPM was analyzed using generalized estimating equation (GEE) logistic regression, and confidence in this decision (5 levels) was analyzed using ordinal GEE regression where surgeons were treated as clusters. All patient characteristics and their pair-wise interactions were considered, and the final model for each outcome was selected using forward step-wise model selection. Odds ratios (ORs), 95% confidence intervals (CIs) and p-values were reported from the models.

Results: Five hundred thirty-six surgeons (21.9%) responded. Respondents had an average of 20 years in practice, were predominantly female, practiced in a community setting, and treated more than 100 breast cancer patients per year. Surgeons in a community setting were more likely to recommend CPM, OR 3.69 (1.48, 4.8), p<0.001. There was no difference in the confidence of this recommendation between community and academic surgeons. The odds of recommending CPM were lower for a 65-year-old patient than a 35-year-old patient, OR 0.09 (0.06, 0.14); higher for Stage III than Stage I, OR 2.88 (1.89-4.41); higher for HER2+, OR 2.67 (1.77-4.01), and triple-negative, OR 4.45 (3.01-6.56), compared to ER+; and lower without a family history of breast cancer, OR 0.59 (0.48-0.73); all p<0.001. There was no difference in the odds of CPM recommendation based on patient preference for CPM. There were similar findings for the confidence in the recommendation. The odds of recommending CPM increased by 13% (11%-15%) for each 1% increase in the estimated probability of contralateral breast cancer in the patient's lifetime. There were similar findings for the confidence in the recommendation. Nine percent of surgeons were not familiar with the ASBrS guidelines on CPM, and 19% were very familiar. Fifty-five percent of sampled surgeons either never use the guidelines or use them rarely. Thirty-eight percent use the guidelines most of the time or always. The surgeon's familiarity with and use of the ASBrS guidelines had no effect on the odds of a recommendation of CPM. The factors that respondents rated as the most important in their decision to recommend CPM to a patient were genetic testing results and lack of survival benefit from CPM. The factors ranked as the least important were increased number of future operations, permanent sensation changes, and negative impact on body image and sexuality.

Conclusions: While surgeons generally agree on the factors that are important in making a recommendation on CPM, there is variability in how strongly the different factors influence their recommendation and the confidence in their recommendation. In addition, while most surgeons were at

least a little familiar with the ASBrS guidelines, the majority do not routinely use them. These data provide insight into factors that may influence surgeon recommendations. More work is needed to understand how these interact with patient factors and preferences in the decision-making process.

581830 - Value of sentinel lymph node biopsy for microinvasive breast cancer <u>Amulya Alapati</u>, Joanne Szewczyk, Alessandra Mele, Ted James *Beth Israel Deaconess Medical Center, Boston, MA*

Background/Objective: Microinvasive carcinoma (DCISM), defined as DCIS was a focus of invasive carcinoma measuring <1 mm, can be managed similar to pure DCIS with breast-conserving surgery and radiation therapy. However, management of the axilla in DCISM has been the subject of debate, with reports in the literature differing on the utility and necessity of sentinel lymph node biopsy (SLNB) for DCISM. Although uncommon, SLNB is associated with increased risks of short-term and long-term morbidity. The aim of our study is to identify the factors associated with nodal disease in patients with microinvasive carcinoma, which can help in selecting patients for whom SLNB can be safely omitted.

Methods: The National Cancer Database was used to identify patients with microinvasive breast carcinoma (pT1mi), diagnosed from 2012-2015, who underwent sentinel lymph node biopsy (SLNB). Descriptive statistics and multivariable regression analysis were performed to determine the association between sentinel lymph positivity and clinically relevant variables of interest.

Results: Our cohort comprised 2659 patients with pT1mi who underwent SLNB. Of these, 114 (4%) were found to have positive sentinel lymph node metastasis on final pathology. Younger age (40-54 years) (n=50, 44%) and higher tumor grade (n=50, 44%) were associated with nodal metastasis (p<0.05). Multivariable regression analysis confirmed an increased incidence of sentinel node metastasis in patients under the age of 40 (OR 2.0, CI 1.1- 3.7), and in patients with high-grade tumors (OR 0.3 CI 0.2-0.6, p<0.05). Furthermore, patients with hormone receptor-negative and HER2-positive tumors were more likely to have sentinel node metastasis compared with tumors that were hormone receptor-positive and HER2 receptor-negative. (OR 0.4, CI 0.2- 0.8) (p<0.05).

Conclusions: In a large national cohort, the incidence of positive sentinel lymph nodes in patients with microinvasive carcinoma (DCISM) appears to be low (4%). Our study shows that younger patients, higher-grade tumors, hormone receptor-negative status, and HER2-positive tumors are associated with increased risk for nodal disease. SLNB should be considered in this patient population. Additionally, we may be able to identify low-risk patients with DCISM in whom SLNB can be avoided, limiting unnecessary morbidity and cost.

581837 - The 'Nipple Whipple'?! A pilot study to assess the ergonomic effects of nipplesparing mastectomy

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Background/Objective: Nipple-sparing mastectomies (NSMs) with reconstruction offer an improved cosmetic outcome compared to skin-sparing mastectomies (SSMs) with reconstruction. However, they are widely believed to be more difficult to perform, but there are little quantitative data to support this claim. This is a pilot study of electromyography (EMG) to assess physical strain of surgeons performing NSM and SSM.

Methods: This IRB-approved prospective study analyzed 4 surgeons performing mastectomies in a single university-affiliated health system. EMG electrodes placed on selected muscle groups on each surgeon were used to capture muscle exertion intraoperatively. After removal of artifacts from EMG, root-mean-square amplitude was taken every 100 msec and a histogram was created to find the 10th percentile, 50th percentile (median), and 90th percentile of root mean square (RMS) amplitude during the procedure. The amplitude was normalized by maximum exertion during isometric contraction, which was performed by the surgeon prior to each procedure. Demographic and exercise habit information was obtained from the 4 surgeons prior to their first case. Immediately following each mastectomy, data regarding musculoskeletal problems and surgery-specific workload were collected using a questionnaire comprising pertinent questions from the Nordic MusculoSkeletal Questionnaire, the Surgery Task Load Index, and questions specific to mastectomies. Analysis by breast of survey data was performed using the Wilcoxon rank-sum and Fisher's exact tests. EMG data were analyzed using repeated-measures ANOVA, controlling for surgeon, duration of procedure, left or right side, and first or second breast of the procedure.

Results: Interim analysis was performed after 32 mastectomies were completed. Of these surgeries, 23 were NSM (22 bilateral, 1 unilateral), and 9 were SSM (6 bilateral, 3 unilateral). Surgeons who routinely exercised were more likely to perform NSM than SSM (p=0.008). NSM were considered to be more mentally demanding (p=0.003) and physically demanding (p<0.001) than SSM. Visualization was deemed more difficult in NSM compared to SSM (p=0.003). Surgeons were more satisfied with the available equipment when performing SSM compared to NSM (p=0.032). After adjusting for surgeon, duration of procedure, left or right side, and first or second breast for bilateral procedures, the left cervical erector spinae muscle group worked significantly harder during NSM compared to SSM (p=0.019). The right cervical erector spinae, bilateral upper trapezii, bilateral anterior deltoid, and bilateral lumbar erector spinae muscle group exertion by surgeon, there was significant variability in the bilateral upper trapezii and bilateral lumbar erector spinae as well as the left cervical erector spinae and right anterior deltoid muscle groups. There was no difference in muscle activity for NSM vs. SSM when stratifying by laterality of the breast or sequence of the procedure. The duration of surgery did not affect muscle exertion in a significant manner.

Conclusions: Our pilot study shows that intraoperative EMGs can assess muscle activity for mastectomy operations and show a difference between NSM and SSM. This is the first study to provide quantitative data on muscle strain with NSM. Future studies could lead to the development of protocols or devices that could lessen muscle strain as well as physician-reported workload and musculoskeletal problems associated with NSM.

582323 - p16 as a biomarker to distinguish atypical ductal hyperplasia from ductal carcinoma in situ and to predict breast cancer progression

<u>Judy Tjoe</u>¹, Last Brittany², Jun Yin² ¹Advocate Aurora Health, Milwaukee, WI, ²Aurora Research Institute, Milwaukee, WI

Background/Objective: Clinical implications involving a diagnosis of atypical ductal hyperplasia (ADH) vs. ductal carcinoma in situ (DCIS) are very different. There exists a nearly 50% discordance rate in distinguishing cases of ADH from low-grade DCIS, potentially leading to overtreatment or missed treatment opportunities to prevent future development of invasive ductal carcinoma (IDC). Recent studies have documented the value of p16, COX-2 and Ki67 as prognostic biomarkers for locoregional invasive recurrences due to abrogated response to cellular stress (ARCS), but their association with cancer progression has not yet been evaluated. In the present study, we compared expression levels of the 3 ARCS markers in a large cohort of ADH and DCIS patients treated with contemporary standard of care and with >5-year follow-up to assess the ability of these markers to accurately distinguish ADH from DCIS and their associations with future breast cancer development.

Methods: Patients from a single multihospital health care organization initially diagnosed with primary pure ADH (n=61) and pure DCIS (n=94) from 1999 to 2013 were followed for their development of a subsequent clinically significant event (SCSE), defined as another diagnosis of atypia, DCIS, or IDC. Formalin-fixed paraffin-embedded tissue sections of initial event lesions and SCSE lesions were retrieved and stained for ER, PR, and HER2 expression by immunohistochemistry. If equivocal, HER2 amplification was assessed by silver in situ hybridization. Sequential sections were stained for p16, Ki67, and COX-2 using a novel multiplex immunohistochemical strategy, and expression was quantified in epithelial compartments using a software (inFormTM)-guided approach. For all comparisons among ADH, DCIS, and IDC, Wilcoxon-Mann-Whitney test was used.

Results: Initial diagnoses of ADH tended to occur at a younger age compared to DCIS (median age 52 vs. 62 years, p=0.004). The time interval between initial diagnosis and a SCSE is longer for an initial diagnosis of ADH than DCIS (39 vs 27 months, p=0.14). DCIS is less likely to be associated with a SCSE of ADH (13.3%) compared to an initial diagnosis of ADH developing into SCSE of ADH again (25%, p=0.038). However, DCIS is more likely to progress to a SCSE of IDC (44.4%) than ADH (37.5%, p=0.02). Moreover, DCIS shares more concordant ER/PR expression with its subsequent IDC than ADH (87.5% vs 66.6%, p=0.29). Additionally, high levels of p16 and low levels of COX-2 are significantly associated with low and intermediate (L/I) grade DCIS compared to ADH (p<0.001). High levels of p16 and Ki67 strongly correlate with a diagnosis of high-grade DCIS (p=0.011).

Conclusions: The ADH features of earlier initiation and greater predilection to be associated with a subsequent diagnosis of DCIS rather than IDC suggests ADH's role as precursor to some subtypes of DCIS. The significant elevation of p16 between ADH and L/I grade DCIS, and its further overexpression in high-grade DCIS indicates that p16 may play a role in ADH progression to DCIS and could potentially serve as a powerful biomarker to assist in distinguishing ADH from DCIS. Simultaneous increase in p16 and Ki67 expressions from L/I grade DCIS to high-grade DCIS supports our recent publication regarding the proposed functionalities of p16 and Ki67 in DCIS progression to IDC.

Poster Session I

Clinical Trials

581643 - Interim analysis of the DCISionRT PREDICT Study: Clinical utility of a biologic signature predictive of radiation therapy benefit in patients with DCIS

<u>Troy Bremer</u>¹, Pat Whitworth², Rakesh Patel³, Jess Savala¹, Peter Beitsch⁴, Charles Cox⁵, Steve Shivers⁵ ¹PreludeDx, Laguna Hills, CA, ²Nashville Breast Center, Nashville, TN, ³Good Samaritan Cancer Center, Los Gatos, CA, ⁴Dallas Surgical, Dallas, TX, ⁵University of South Florida, Tampa, FL

Background/Objective: In the US, over 60,000 women are newly diagnosed with ductal carcinoma in situ (DCIS) each year. Current diagnostic tools available to physicians treating patients with DCIS are largely considered inadequate to properly assess risk of recurrence, progression to invasive breast cancer or the benefit of adjuvant therapy required after surgery. When considered in the context of monetary, health-related, and quality-of-life costs associated with post-surgical adjuvant treatments, there remains a need for prognostic and predictive tools that help physicians assess risk and determine which patients may truly benefit from adjuvant and/or aggressive surgical therapy. DCISionRT, a biologic signature, provides DCIS risk assessment and predicts adjuvant radiation therapy benefit using individual tumor biology in conjunction with clinical and pathologic risk factors. The clinical impact of DCISionRT, a prognostic and predictive DCIS test, will be evaluated in the management of DCIS compared to traditional clinical and pathologic risk factors in physician's recommended treatment plan for patients with surgically treated DCIS.

Methods: A prospective post-market decision impact registry is being conducted to assess the impact of DCISionRT results in changing treatment recommendations for patients with DCIS before and after DCISionRT results with long-term follow-up. An interim analysis of the first 200 subjects was performed to assess decision change in aggregate (including changes in recommended radiation, adjuvant, and surgical treatment management). Additional analysis included decision change by patient age, tumor nuclear grade, and size. Eligible patients are women over age 25 who have been diagnosed with DCIS and are candidates for breast-conserving surgery and radiation or systemic treatment with sufficient tissue to generate DCISionRT results. Study Procedures/Data Collection Schedule: 1. Enrollment form completed—includes gender, age, race, other demographic and descriptive factors about the patient's diagnosis 2. Tissue sent for testing along with requisite information for analysis 3. Physician completes Pre-Report Survey—includes treatment plan recommendations prior to receiving results of DCISionRT test. 4. Physician completes Post-Report Survey—recommendations made after receiving DCISionRT test.

Results: The sample size will comprise up to 2,500 patients, obtained from 25 to 100 sites within the United States, enrolling 25 to 100 patients each.

Conclusions: The clinical impact of DCISionRT, a prognostic and predictive DCIS test, will be evaluated in the management of DCIS compared to traditional clinical and pathologic risk factors in physician's recommended treatment plan for patients with surgically treated DCIS. Decision changes will be assessed following the inclusion of the DCISionRT test into treatment management.

581738 - Eliminating narcotic use with institutional enhanced recovery after surgery (ERAS) Protocol in autologous breast reconstruction patients following mastectomy: A pilot study

<u>Christopher Mcgreevy</u>, Lucy De La Cruz, Suhail Kanchwala, Dahlia Sataloff, Ari Brooks, David Anderson, Alina Mateo *University of Pennsylvania*, *Philadelphia*, *PA*

Background/Objective: Autologous breast reconstruction following mastectomy in breast cancer patients has seen ever-evolving techniques in surgical approach. With each modification, attention is paid to maintaining the quality of reconstruction, surgical outcomes, and/or patient discomfort. Emphasis on more effective pain control while limiting opioid use, shorter hospital length of stay (LOS) and timely recovery following surgery are valuable targets many institutions strive to attain. By implementing our ERAS protocol, we aim to show how eliminating narcotic use does not compromise the quality, outcome, and patient experience of our mastectomy patients having autologous breast reconstruction at our institution.

Methods: After institutional review board approval, a prospective study is currently being conducted for mastectomy patients who are candidates for autologous breast reconstruction in our institution. Patients who meet criteria undergo mastectomy followed by two-staged free flap delayed repair. Pectoralis muscle blocks are performed prior to all operative cases. Patients are managed using a combination of Gabapentin and Tylenol pre-operatively and postoperatively, Tylenol and NSAIDs post-operatively with Tramadol as needed. Pre-oral hydration is encouraged up to 2 hours prior to surgery to limit intravenous fluid administration intraoperatively.

Results: Enrollment commenced September 2017. Eligible patients are women with in situ or invasive (Stage 0-III) breast cancer who are candidates for mastectomy with autologous breast reconstruction. Our study cohort will be matched to patients in our institution who have undergone an equivalent procedure during the study period but did not meet inclusion criteria or were not offered or declined enrollment in our ERAS protocol study. Patient demographics, comorbidities, neoadjuvant or adjuvant therapies are prospectively captured as well as pain scores and post-operative data such as wound infection and flap necrosis. Once we have accrued the desired 100 patients for this pilot study, outcomes will be controlled for factors such as body mass index, smoking status, cardiovascular history, diabetes, coagulopathies, autoimmune diseases, and corticosteroid use as well as neoadjuvant chemotherapy, radiotherapy, and endocrine therapy

Conclusions: Primary outcomes of interest are LOS, post-operative pain (based on patient-reported pain scale), and flap complications. Secondary outcomes will be time to adjuvant therapy from surgery.

581918 - Radioactive iodine seed localization in axilla with sentinel node biopsy (RISAS): A prospective trial on axillary staging after neoadjuvant chemotherapy in node positive breast cancer

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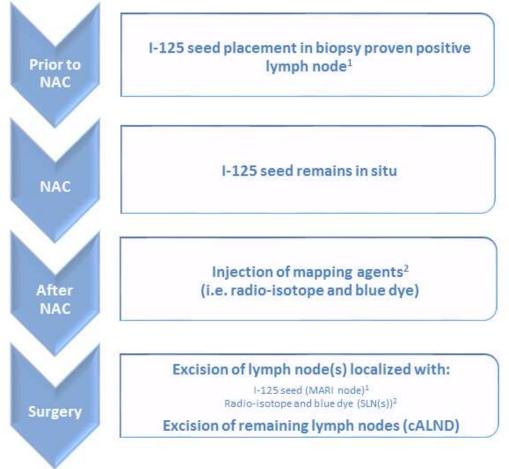
Background/Objective: As a result of neoadjuvant systemic therapy (NST), at least 1 out of every 3 patients with initial node-positive (cN+) breast cancer achieves an axillary pathologic complete response (ax-pCR). In case of ax-pCR, axillary lymph node dissection (ALND), which is the current standard treatment, can be regarded as overtreatment. This urges the need for a less invasive axillary staging method after NST, such as sentinel lymph node biopsy (SLNB) or MARI (Marking Axillary lymph nodes with Radioactive Iodine seeds). However, both MARI and SLNB cannot yet, as independent procedures, safely replace the traditional ALND, since residual axillary disease can be missed. Recent studies suggest that by combining these procedures, the accuracy of detecting residual axillary disease may be improved. We therefore developed the RISAS trial to validate the combination of MARI and SLNB (i.e., RISAS procedure) for axillary staging after NST in cN+ breast cancer with the potential to safely replace ALND.

Methods: In this currently recruiting prospective single-arm multicenter validation study, a total of 225 cN+ patients will be needed to test non-inferiority of RISAS compared to ALND. Fourteen Dutch hospitals are participating in this trial. The RISAS procedure consists of performing MARI and SLNB and is directly followed by completion ALND (Figure). All RISAS lymph nodes are compared to ALND specimen lymph nodes.

Results: Female patients, aged 18 years or older, with invasive breast cancer and pathologically proven axillary nodal metastasis are eligible. All patients have to provide written informed consent. Patients with (oligo)metastatic breast cancer, previous axillary surgery, or radiotherapy, and patients with periclavicular metastasis (cN3a or cN3c) are not eligible.

Conclusions: To test if the RISAS procedure is non-inferior to ALND for axillary staging after NAC in cN+ breast cancer patients.

Figure: RISAS procedure followed by completion ALND. The RISAS procedure consists of MARI(1) and SLNB(2)



577360 - Pre-mastectomy radiotherapy feasibility trial to facilitate immediate autologous breast reconstruction: A prospective cohort within a randomized clinical trial Puneet Singh, Karen Hoffman, Mark Schaverien, Benjamin Smith, Henry Kuerer MD Anderson Cancer Center, Houston, TX

Background/Objective: Women known to require post-mastectomy radiotherapy (RT) often must delay immediate reconstruction or when receiving immediate reconstruction have increased complications and poor cosmetic outcome, which results in psychological distress and multiple procedures. Neoadjuvant RT (NRT) is utilized in other cancer types with improved oncologic outcomes, and small numbers of studies administering breast NRT have been performed. We hypothesize that NRT will result in increased numbers of patients completing immediate autologous breast reconstruction following mastectomy, will be technically feasible, and will have minimal complications.

Methods: This NRT cohort is embedded within a randomized trial of hypofractionated (3 weeks) versus conventionally fractionated regional nodal irradiation (5 weeks; NCT02912312, PI: Karen Hoffman). The figure describes the NRT prospective cohort trial.

Results: Clinical stage T0-T3, N0-N3a; recommendation for NRT, planned mastectomy and desire for immediate breast reconstruction, does not have T4 disease/distant metastases/prior breast cancer/bilateral breast cancer.

Conclusions: The aims of the NRT trial include assessment of delays to surgery due to radiation skin or soft tissue effects; any technical intraoperative difficulties; the ability to perform targeted axillary dissection and sentinel node biopsy; abortion of reconstructive procedure due to radiation skin, soft tissue, or recipient vasculature effects with need to place implant/TE; evaluation of surgical and reconstructive complications as it relates to time between surgery and radiation and fractionation type; mastectomy skin flap necrosis requiring reoperation or debridement; complete or partial autologous flap loss; surgical recipient site delayed wound healing and infectious complications. The primary aim of the entire randomized trial is to compare the risk of lymphedema defined as a 10% increase in volume using perometer measurements between the affected and unaffected arms over 24 months. Additional endpoints are locoregional recurrence, distant metastases, disease-free survival, and overall survival.

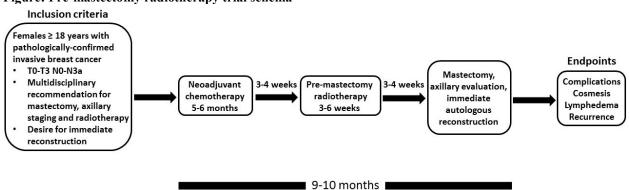


Figure: Pre-mastectomy radiotherapy trial schema

581737 - Can patients with multiple breast cancers in the same breast avoid mastectomy by having multiple lumpectomies to achieve equivalent rates of local breast cancer recurrence? A randomised controlled feasibility trial called MIAMI UK

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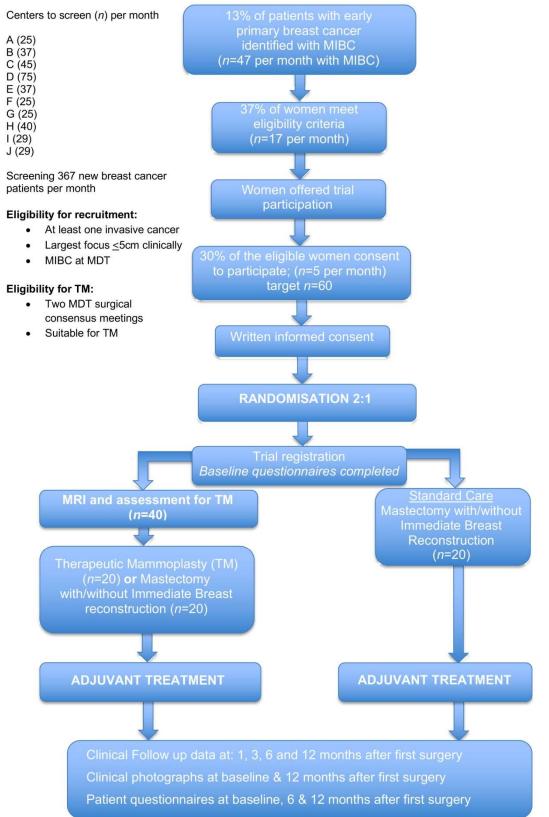
Background/Objective: Oncological safety of treating multiple ipsilateral breast cancers (MIBC) using therapeutic mammoplasty (TM) compared to mastectomy remains uncertain. A systematic review (Winters et al. BJS Open 2018, PMID: 30079385) showed poor to moderate quality evidence. The MIAMI feasibility phase randomized controlled trial (RCT) aims to demonstrate that sufficient numbers of eligible patients can be identified and accept randomization, and to determine why women accept or decline participation using qualitative methods. Herein, we report detailed screening logs evaluating the proportions of all MIBC, and those women with MIBC eligible for TM, in relation to all invasive breast cancers in participating hospitals. We describe factors influencing feasibility and potential recruitment barriers.

Methods: A two-armed, phase 3, open-label, prospective RCT will involve 16 UK centers. This feasibility study aims to recruit 50 women with MIBC aged >40 years randomized in a 1:1 ratio to multiple lumpectomies and TM compared to the standard of mastectomy +/- reconstruction. There are no limitations to numbers of cancer foci, with multifocal defined by a single lumpectomy and multicentric cancers by separate lumpectomies. Radiation therapy (RT) SOPs will mirror IMPORT HIGH (NCT00818051) and FAST FORWARD (ISRCTN19906132), with individualized case planning for dual lumpectomy RT boosts.

Results: Two centers have screened 230 invasive breast cancers (June - Oct 2018). MIBC were diagnosed in 29 women (12.6%). Most women were ineligible for the trial (n=23, 79%) with only 3 (10%) invited to participate. Ineligibility for TM was the commonest exclusion factor (n=9, 31%), followed by similar rates of bilateral breast cancer (n=4), previous breast cancer (n=3), neoadjuvant chemo (n=3), other cancers (n=3), less than 2 invasive foci (n=2) and exclusive DCIS (n=2). Rarely, reasons were compromised informed consent (n=1) and previous RT (n=1). All three women declined randomization, 2 preferring a mastectomy, and the other electing TM outside of MIAMI. Based on early results and detailed center feedback, the TMG proposed major amendments to the existing trial design such as changing the timing of randomization to follow the diagnosis of MIBC using standard imaging. Breast MRI will be restricted to women allocated to TM only, intending to evaluate TM ineligibility, and the independent role of MRI. The trial communication template will emphasize that TM should be offered within the trial. Furthermore, emphasis on TM over and above standard breast-conserving surgery followed by modern adjuvant treatments is important to iterate. In addition, a 2:1 randomization design has been proposed (Figure).

Conclusions: The MIAMI trial is the first multicenter UK clinical trial to investigate clinical and cost effectiveness of TM being equivalent to mastectomy +/-reconstruction in women with MIBC. The main trial requires a total of 2000 women based on a 2.5% 5-year local regional recurrence (LRR) using a 2% non-inferiority difference between TM and mastectomy. Five-year LRR will be the primary outcome for the main trial. Secondary outcomes comprise key components in core outcome sets for breast cancer and reconstruction. The feasibility phase will inform the design of the main RCT, and future clinical practice using guidelines for multidisciplinary team decision-making.

Figure: MIAMI Trial CONSORT flow



Genetics

581929 - Defining expectations of future biopsy and frequency of benign or malignant results of BRCA1/2-positive patients undergoing active surveillance

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Background/Objective: At our institution, the Preventive Care Program for Women's Cancers was started in 2003 for women at increased risk of developing breast cancer. When a woman is diagnosed with a genetic mutation known to be associated with breast cancer, she may elect to undergo active surveillance or prophylactic surgery. BRCA1 and BRCA2 are the most common genetic mutations, and women with these mutations are at the highest risk for developing breast cancer. In women who choose active surveillance, information regarding how frequently they can expect to undergo biopsy and frequency of a benign or malignant result is useful in defining realistic future expectations in this high-risk group. In this study, we report on the asymptomatic patient with BRCA1 and BRCA2 deleterious mutations, who enrolled in our prevention program, frequency of biopsies, rate of benign or malignant result, and decision for prophylactic surgery.

Methods: Since the initiation of the Prevention Care Program for Women's Cancers, 2,641 patients have enrolled in this IRB-approved database. A retrospective cross-sectional study was conducted using this population of patients. From February 2003 through August 2018, women identified as increased risk for developing breast cancer were recruited for enrollment in this study. Demographics, family history of cancers, and genetic testing data were collected. In addition, events regarding genetic mutations, method of detection of suspicious lesions, number of biopsies, results of those biopsies, prophylactic surgery, and cancer diagnosis were recorded.

Results: During the study period, 174 patients with asymptomatic BRCA1 and BRCA2 deleterious mutations were identified. Patients included for analysis where complete records existed and who had no prior breast cancer diagnosis. Mean age at enrollment was 38.7 (BRCA1 35.6 and BRCA2 41.8, p=0.004). Of those, 49 (32.3%) underwent prophylactic surgery, and 94 (63.1%) underwent active surveillance [BRCA1 39 (41.9%) and BRCA2 54 (58.1%), p=0.008]. Upon enrollment and initial evaluation with imaging and biopsy, 5 patients (3.4%) received a cancer diagnosis. In the prophylactic surgery group, 37 (75.5%) had no abnormal imaging or physical exam to warrant biopsy, 11 (22.4%) had abnormal imaging with subsequent biopsy with a benign result, and 1 (2.0%) had a biopsy with a malignant result. In the surveillance group, 66 (70.2%) had no biopsy recommended, 30 (31.9%) had a biopsy with a benign result, and 1 (1.1%) had a biopsy with a malignant result. Three women had more than 1 biopsy (100% benign). The median length of time to first biopsy from the time of enrollment for the surveillance group was 65 days and 102 days for the prophylactic surgery group. The median length of follow-up for the active surveillance group was 593.5 days and 1,208 days for the prophylactic surgery group. Method of detection of lesion requiring biopsy included 22 (47.8%) magnetic resonance imaging, 12 (26.1%) mammogram, 2 (4.4%) physical exam, and 1 (2.2%) ultrasound.

Conclusions: Women with BRCA mutations enroll in breast cancer prevention clinics to learn more about their breast cancer risk, methods of prevention, access to participation in surveillance, and early detection of breast cancer. With BRCA mutations being the most common genetic mutation in breast cancer, this study highlights the effectiveness of screening this high-risk population. While this group of women undergo biopsies more frequently due to increased screening, the majority do not require a biopsy during their surveillance. For those who do require a biopsy, this result is typically benign. This additional

information can be offered to women enrolling in prevention clinics to further allow them to make more informed decisions about pursuing surveillance in this high-risk group and establish realistic expectations of potential future need for tissue sampling.

581809 - Clinical management of high-risk breast cancer patients with variants of uncertain significance in the era of multigene panel testing

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Background/Objective: Multigene panel testing has become an increasingly common and critical component of care for patients at risk for breast cancer. With wide availability of next generation sequencing, rapid expansion of genetic panels has led to an increase in frequency of variants of unknown significance (VUS). The American College of Medical Genetics and Genomics states that clinicians should not make medical management decisions based on VUS findings. We sought to analyze the role VUS results play in the medical management of risk reduction and surveillance options for patients at increased risk of breast cancer.

Methods: All genetic testing reports from a single tertiary care institution from January 2015 – August, 2018 were reviewed. Cases were selected for indications of personal and/or family history of breast cancer. Genetic variants were grouped as 1) benign or likely benign, 2) VUS, or 3) pathogenic or likely pathogenic. Breast cancer associated genes included ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, MRE11A, MUTYH, NBN, NF1, PALB2, PTEN, RAD50, RAD51C, RAD51D, and TP53. Demographic and clinical data were collected from medical records. Clinical management (imaging, biopsy, type of breast surgery, prophylactic mastectomy, oophorectomy, and colonoscopy) performed after genetic testing was recorded. Patient, variant gene, and management characteristics were compared by pathogenicity of variant group classification (benign vs. VUS vs. pathogenic) for those who received surgery after panel testing.

Results: Of 692 genetic tests performed during the study period, 563 were undertaken for breast indications and had records available for review. The mean patient age was 53.9+13.3 years (range 21-92 years). The number of genes tested in each panel ranged from 1 to 81. Testing companies included Myriad (50.6%), Ambry (30.7%), and Invitae (18.5%). Among those tested, 44.8% had VUS: 29.7% had 1 VUS; 10.5%, 2; 3.6%, 3; and 1.1%, 4. Of 386 VUS identified, 31.4% were breast-specific variants, with BRCA2 (15.4%) and ATM (13.7%) the most frequent. Other breast-specific VUS frequencies were MUTYH (10.6%), CHEK2 (9.1%), BRCA1 (8.2%), BRIP1 (6.3%), PALB2 (6.3%), BARD1 (5.8%), CDH1 (5.3%), RAD50 (3.8%), RAD51D (3.8%), TP53 (2.9%), NBN (2.4%), RAD51C (2.4%), NF1 (1.9%), MRE11A (1.4%), and PTEN (1.0%). The most common non-breast VUS was APC (10.4%) and PMS2 (8.5%). A total of 61 (15.1%) variants were identified as pathogenic or likely pathogenic. Breast surgery was performed after genetic testing in 208 (36.9%) patients. In this patient group, pathogenic variants were more commonly observed in breast-specific genes (p<0.001). Comparison of patient demographics, breast-specific variant, and clinical management of those who underwent surgery after testing by variant classification group is shown in the table. No statistically significant differences were found in clinical management of surgical patients based on benign, VUS, or pathogenic findings on preoperative panel testing.

Conclusions: Previous reports that have shown that BRCA1/2 VUS may influence clinical decisionmaking raise concern that the increasing frequency of other VUS findings may change patient management decisions. The current study argues against VUS altering management decisions. In this high-risk patient population seeking panel testing, genetic factors help to inform, but not dictate, complex decision-making in surveillance and management.

| | | | N=208 WITH PRE-OPERATIVE PANEL TESTING | | | | |
|--------------------------------------|---------------------------|--------------------------------|--|---|---|-------------------------|--|
| | | OVERALL POPULATION N=563 | Benign/Likely Benign N=91 | Variant of Uncertain Significance N=96 | Pathogenic/Likely Pathogenic N=21 | p value for N=208 | |
| Age | 2 | 53.9 <u>+</u> 13.3 y | 55.0 <u>+</u> 13.1 y | 54.4 <u>+</u> 12.6 y | 50.9 <u>+</u> 14.3 y | 0.40 | |
| | Asian/Pacific Islander | 44 (7.82%) | 3 (3.30%) | 10 (10.42%) | 1 (4.76%) | | |
| Race/ethnicity | Hispanic | 122 (21.67%) | 23 (25.27%) | 22 (22.92%) | 4 (19.05%) | | |
| | Non-Hispanic black | 39 (6.93%) | 3 (3.30%) | 7 (7.29%) | 3 (14.29%) | 0.36 | |
| | Non-Hispanic white | 338 (60.04%) | 58 (63.74%) | 55 (57.29%) | 12 (57.14%) | | |
| | Other | 20 (3.55%) | 4 (4.40%) | 2 (2.08%) | 1 (4.76%) | | |
| Personal history of breast cancer | No | 203 (36.19%) | 2 (2.20%) | 7 (7.29%) | 0 (0.00%) | 0.14 | |
| (current or past) | Yes | 358 (63.81%) | 89 (97.80%) | 89 (92.71%) | 21 (100.00%) | 0.14 | |
| First degree | 0 | 278 (51.20%) | 58 (67.44%) | 59 (62.11%) | 9 (42.86%) | | |
| relatives with | 1 | 240 (51.20%) | 26 (30.23%) | 28 (29.47%) | 9 (42.86%) | 0.11 | |
| breast cancer | <u>>1</u> | 25 (4.60%) | 2 (2.33%) | 8 (8.42%) | 3 (14.29%) | | |
| Breast-specific | No | 386 (68.56%) | 91 (100.00%) | 35 (36.46%) | 3 (14.29%) | <0.001 | |
| variant* | Yes | 177 (31.44%) | 0 (0.00%) | 61 (63.54%) | 18 (85.71%) | ×0.001 | |
| | None | 143 (31.29%) | NA | NA | NA | NA | |
| Type of surgery | Breast conservation | 152 (33.26%) | 42 (46.15%) | 42 (43.75%) | 11 (52.38%) | 0.77 | |
| | Mastectomy | 162 (35.45%) | 49 (53.85%) | 54 (56.25%) | 10 (47.62%) | | |
| Deschula dia | None | 357 (76.94%) | 57 (62.64%) | 58 (61.05%) | 10 (47.62%) | | |
| Prophylactic mastectomy | Bilateral | 4 (0.86%) | 0 (0.00%) | 3 (3.16%) | 1 (4.76%) | 0.32 | |
| mustectomy | Contralateral | 103 (22.20%) | 34 (37.36%) | 34 (35.79%) | 10 (47.62%) | | |
| Post-test imaging | No | 227 (40.39%) | 32 (35.16%) | 40 (41.67%) | 9 (42.86%) | 0.61 | |
| Post-test imaging | Yes | 335 (59.61%) | 59 (64.84%) | 56 (58.33%) | 12 (57.14%) | 0.01 | |
| Post-test biopsy | No | 328 (58.78%) | 43 (47.78%) | 37 (38.54%) | 10 (47.62%) | 0.41 | |
| 1 OSC-LEST DIOPSY | Yes | 230 (41.22%) | 47 (52.22%) | 59 (61.46%) | 11 (52.38%) | 0.41 | |
| Post-test | No | 380 (96.94%) | 63 (96.92%) | 68 (97.14%) | 16 (94.12%) | 0.81 | |
| oophorectomy | Yes | 12 (3.06%) | 2 (3.08%) | 2 (2.86%) | 1 (5.88%) | 0.01 | |
| Post-test | No | 363 (91.21%) | 58 (87.88%) | 66 (92.96%) | 16 (94.12%) | 0.52 | |
| colonoscopy | Yes | 35 (8.79%) | 8 (12.12%) | 5 (7.04%) | 1 (5.88%) | 0.52 | |

| Table: Patient, variant gene, and management characteristics compared by pathogenicity of variant group |
|---|
| classification. N=563 overall and subset N=208 with pre-operative panel testing |

*ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, MRE11A, MUTYH, NBN, NF1, PALB2, PTEN, RAD50, RAD51C, RAD51D, TP53

581999 - Discrepancies between payer coverage and consensus guidelines for personalizing hereditary cancer risk

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Background/Objective: In hereditary breast and ovarian cancer (HBOC) genetic testing, the fast pace of advancements in technology have allowed clinical labs to offer multigene panel testing (MGPT), which is now the preferred genetic testing option of many clinicians. This trend has outpaced insurance coverage, thus limiting patient access to comprehensive diagnostic and genetic risk assessments. Little is understood about alignment of insurance company policy with published guidelines, which clinicians often rely on to guide the management of patients at increased risk for cancer. Here we compare National Comprehensive Cancer Network (NCCN) recommendations to HBOC genetic testing policies from three top US insurance companies and their impact on patient genetic testing results.

Methods: Management guidelines for breast and/or ovarian cancer were identified within NCCNv2.2019 for patients with mutations in 16 genes commonly found on MGPT (ATM, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, MSH2, MLH1, NBN, NF1, PALB2, PTEN, RAD51C, RAD51D, STK11, and TP53). MGPT orders were assessed for patients with insurer A, B, or C in the year 2017 at a single diagnostic testing laboratory.

Results: Among insurers A, B, and C, 6 (37.5%), 8 (50.0%) and 15 (93.8%) of the 16 genes were covered, respectively. On a patient level, limiting genetic testing to payer coverage resulted in unidentified mutations and missed opportunities to personalize cancer risk management in accordance with expert consensus. For example, among the 187 patients with Insurer A who were positive for a mutation in a gene with NCCN management guidelines, mutations for nearly half of patients (48.1%) would have remained unidentified had testing been limited to the genes covered by the insurer. This included multiple patients with mutations in syndrome-specific genes: CDH1 (1), STK11 (1), and NF1 (2). Mutations in PALB2 (14), ATM (28), BRIP1 (9), CHEK2 (25), NBN (4), and RAD51C/D (6) would have also been missed, all of which have a strong evidence base supporting their association with HBOC. Insurer B, with 118 patients, included coverage of PALB2 and CHEK2, increasing coverage to 80.5% of patients with a pathogenic mutation, and Insurer C offers coverage on all genes except NF1, which encompassed 96.9% of patients with a pathogenic mutation in a gene with NCCN management guidelines. With regard to management opportunities that would have been missed had the laboratory strictly followed testing for genes under the insurer's medical policy, 25.6% of patients who should consider breast MRI screening (range 3.4-45.1%, depending on insurer), and 10.5% (range 0-14%) of patients who should consider a risk-reducing salpingo-oophorectomy per NCCN, would not have been identified. However, all patients in which NCCN recommends a discussion of risk reducing mastectomy would have been identified, as all insurers cover BRCA1, BRCA2, PTEN, and TP53.

Conclusions: Ultimately, these data demonstrate a need for MGPT for patients at high risk for HBOC to provide risk assessments consistent with management guidelines. These data also highlight the discrepancies between insurance company policies and the influence they can have on access to care. Insurance companies should update their policies to be consistent with the most recent and relevant evidence-based medicine, which expert consensus panels translate into management options with sound clinical reasoning.

577316 - Prophylactic bilateral mastectomy and bilateral salpingo-oophorectomy in BRCA1/2 mutation carriers

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Background/Objective: Women with BRCA 1/2 mutations have an increased lifetime risk of developing breast cancer, and many choose prophylactic bilateral mastectomy to dramatically reduce their cancer risk. The purpose of this study is to determine the frequency of prophylactic mastectomy in BRCA1/2 mutation carriers, as well as to describe the characteristics of those pursuing surgery, patient experiences with high-risk screening, and reasons for not choosing prophylactic surgery.

Methods: A cross-sectional survey was conducted of BRCA1/2 mutation carriers identified from a database at a single academic institution. Inclusion criteria included women with a BRCA mutation who were 18 years of age or older and unaffected with cancer. The survey was administered electronically via email using REDCap. Three reminder emails were sent regardless of completion status. There were over 100 fixed-response questions that asked about 5 content areas: demographics, genetic testing, prophylaxis, childbearing, and partnering. Data were analyzed using SAS 9.4 (SAS Institute, Cary, NC) with Fisher's exact test to compare categorical responses; T-test or Wilcoxon rank-sum test for ordinal variables.

Results: Forty-one of 136 BRCA1/2 mutation carriers completed the survey (30% response rate). Of these 41, 36 met inclusion criteria, comprising 20 (56%) BRCA1 mutation carriers and 16 (44%) BRCA2 mutation carriers. Thirteen were 18-34 years of age, 18 were age 35-54, and 5 were age 55 or older. The majority of participants (65.9%) had 1 or 2 first- or second-degree relatives with a BRCA-related breast cancer, 31.7% had 3 or more relatives, and 1 had no relatives. The youngest age of diagnosis among relatives was: 25-34 years (12.5%), 35-44 years (45%), and 45 years or older (42.5%). Most (80%) women said that their health care provider offered them increased screening for the early detection of breast cancer. Of those offered increased screening, 82.1% underwent MRI, 78.6% had clinical breast exams, 71.4% had mammography, and 35.7% had ultrasound. Nearly all women (94.4%) reported that a health care provider discussed prophylactic mastectomy, but only 11 (30.6%) opted for the surgery. When the remaining 25 women were asked why they decided to not have surgery, 56% remained undecided, 40% said they were too young, 32% were delaying surgery to breastfeed, 24% wanted to avoid surgery, and 4% said their health care provider said it was not necessary. Those with 3 or more family members with breast cancer were no more likely to choose mastectomy (27%) than those with 2 or less (32%). Notably, there was a trend toward BRCA1 mutation carriers opting for mastectomy (40%) compared to BRCA2 mutation carriers (18.8%). With respect to their ovarian cancer risk, 7 (33.3%) reported that their breast surgeon recommended prophylactic bilateral salpingo-oophorectomy (BSO), 4 (21.1%) reported that their breast surgeon recommended hormone replacement (HR) following BSO, while 3 (15.8%) reported that their breast surgeon recommended against HR.

Conclusions: Our findings demonstrate that although the vast majority of female BRCA mutation carriers were offered prophylactic bilateral mastectomy by their health care providers, a minority of participants opted for the surgery. Reasons for not having the surgery included indecision, being too young, delaying to breastfeed, and wanting to avoid surgery. There was a trend towards BRCA1 mutation carriers being more likely to have prophylactic mastectomy than BRCA2 mutation carriers. Additionally, a minority of breast surgeons recommended prophylactic BSO and HR. Larger studies confirming our findings and exploring the perspectives of breast surgeons are needed.

580976 - Genetic risk and compliance with risk reduction in a high-risk breast population <u>Amy Pratt</u>, Lauren Cournoyer, Beverly Hay, Kathyrn Edmiston, Madhavi Toke, Anne Larkin, Jennifer LaFemina

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Background/Objective: While national guidelines exist regarding the role of genetic testing, surveillance, and risk-reducing therapies in women at an increased risk of breast cancer, prior data suggests that only approximately 50% of these patients are tested for pathogenic mutations. Data regarding compliance with subsequent recommendations is strikingly sparse in the literature. Herein, the aim is to assess the incidence of pathogenic mutations associated with breast cancer as well as compliance with screening and risk-reducing therapy recommendations within the context of an increased risk of breast cancer.

Methods: A retrospective analysis of subjects evaluated due to a possible increased risk of breast cancer was conducted from January 2013-August 2016. Variables including genetic testing recommendations and results as well as compliance with recommendations for clinical follow-up, radiologic screening, prophylactic surgery, and risk-reducing medication were assessed.

Results: A total of 1491 patients were evaluated during the study period. Fifty-eight percent (n=866) underwent genetic testing: 38% (n=79) were evaluated due to family history, 43% (n=89) due to personal history, and 19% (n=41) due to both family and personal history. Twenty-four percent (n=209) of those tested (14% of all subjects) were found to have a genetic mutation; 16% harbored pathogenic mutations associated with breast cancer. The most common deleterious mutations were BRCA1 (n=47; 22%), BRCA2 (n=32; 15%), MSH6 (n=16; 7%), MLH1 (n=10; 5%), APC and MUTYH (n=5 each, 2%), TP53 (n=4, 2%), and CHEK2 and MSH2 (n=3 each, 1%). Variants of uncertain significance (VUS) were identified in 33% of tests (n=72). Thirty-two percent (n=67) of subjects were lost to follow-up. After excluding this group, 93% (n=126/136; denominator for analysis indicates those who received such a recommendation) complied with recommendations for clinical follow-up, 88% (n=88/100) complied with radiologic surveillance, 88% (n=52/59) complied with prophylactic mastectomy, 73% (n=52/71) complied with prophylactic oophorectomy, and 95% (n=41/43) complied with risk-reducing medication.

Conclusions: The current report serves as one of the largest reports to date regarding compliance with recommendations within the context of increased risk of breast cancer. Data demonstrate that nearly 60% of subjects seen in this setting underwent genetic testing, yielding an appropriate 16% incidence of newly diagnosed pathogenic mutations associated with breast cancer, with BRCA1 and BRCA2 being the most common. VUS were identified in a third of cases. While nearly a third of subjects were lost to follow-up, those who did follow up demonstrated significant compliance with recommendations for screening and risk reduction. Given that a third of patients were lost to follow-up, further work is needed to identify barriers to compliance in this population, as well as insight into the outcomes associated with long-term compliance with such recommendations.

578732 - Choosing high-risk screening vs. surgery and the effect of treatment modality on anxiety and breast-specific sensuality in BRCA mutation carriers

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Background/Objective: We have previously shown that breast cancer surgery affects breast-specific sensuality, and that women who undergo mastectomy may have worse sexual function outcomes than those who undergo lumpectomy. It is less clear if patients who undergo prophylactic mastectomy are equally as affected as those with a cancer diagnosis. We sought to compare sexual function outcomes and their relationship to depression and anxiety between BRCA mutation carriers with and without cancer in order to guide surgical counseling and improve survivorship outcomes.

Methods: A confidential, cross-sectional survey was distributed electronically to BRCA mutation carriers (mBRCA) at least 18 years of age. The survey included investigator-generated questions, the Female Sexual Function Index (FSFI), and the Hospital Anxiety and Depression Scale (HADS) surveys. Responses were analyzed in total and divided into two subgroups: those with and without breast cancer.

Results: One hundred seventy email addresses were identified, and sixty-three mBRCA responded (37%). Approximately three-quarters of patients were postmenopausal. Although more than half of all mBRCA reported that the role of the breast in intimacy was important, most patients without cancer and all of those with cancer experienced an impressive decline in certain breast-specific sensuality parameters postoperatively. Among those without cancer, anxiety scores were not different between those choosing prophylactic mastectomy and high-risk screening. Sexual function as measured by the FSFI was negatively correlated with depression and anxiety in mBRCA. FSFI scores were not significantly different between those with and without cancer. However, the median FSFI of mBRCA with cancer, those undergoing high-risk screening, and those who underwent mastectomy (therapeutic or prophylactic) indicated sexual dysfunction

Conclusions: As the availability of genetic testing increases, more women are found to harbor BRCA mutations and must choose between high-risk screening and prophylactic surgery. Women with BRCA mutations, both with and without breast cancer, are susceptible to derangements in sexual function during the course of both screening or treatment, and this appears to be negatively correlated to depression and anxiety.

582132 - Genetic screening intervention: Identifying carrier status with a history of cancer Robin Sanders¹, Rebecca Urbanovsky², Erin Noel³

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Background/Objective: In 2016, a multidisciplinary team created a cancer genetic screening and highrisk breast cancer program. These programs were created to provide cancer risk assessment, genetic cancer screening, genetic cancer evaluation and testing, and development of a treatment plan with the patient in one location.

Methods: It was determined the breast center would provide the screening questionnaire and Tyrer-Cuzick score for each woman having a yearly mammogram or other breast exam. Each woman (or man) could opt out of the questionnaire. Each questionnaire would then be evaluated by a nurse practitioner (NP) in General Surgery for patient history who met National Comprehensive Cancer Network (NCCN) guidelines and insurance verification for genetic testing. The genetic evaluation guidelines as per NCCN Genetic/Familial High-Risk Assessment: Breast and Ovarian v1.2016 and NCCN Genetic/Familial High-Risk Assessment: Colorectal v.1.2016. If the patient met the above criteria, and their insurance allowed for testing, the patient was notified and could choose to speak to the NP for a genetic evaluation appointment. If the patient consented, testing could be performed the same day as consultation. Once the results were received, the patient was notified. If the patient had a positive genetic mutation, a referral was generated to the geneticist to develop a treatment plan. If the woman was high risk for breast cancer (Tyrer-Cuzick assessment of the lifetime risk of breast cancer to be greater than or equal to 20% or based on family history), she was referred to the cancer center to develop a high-risk breast cancer plan. This program began January 4, 2016. (Since the initiation of the program, we have created an NP-led, high-risk breast clinic in the breast surgery clinic.)

Results: The first year of the program demonstrated that our patient population is at a 5.7% risk of having a hereditary cancer predisposition. In addition, our program found a 7.2% high-risk breast cancer population. During the second year, we had a hereditary cancer predisposition of 6.6% and a high-risk breast cancer population of 9.4%. During this third year, our population of hereditary cancer predisposition is at 7.0% and a high-risk population of 6.4%. During the 2 years and 10 months of the program, a new question arose - how many patients who were positive for a genetic mutation had a personal diagnosis of a hereditary breast and ovarian cancer (HBOC)-classified cancer? An HBOC-classified cancer includes breast, ovarian, prostate, melanoma, and pancreatic cancers (CDC, 2015). A total of 69 positive mutations were identified. Of those, 26 patients had a personal history of a breast, ovarian, prostate, pancreatic, or melanoma cancer. This equates to 38% of our positivity rate associated with HBOC-classified cancer. Not all the mutations identified are associated with HBOC.

Conclusions: It is estimated 5-10% of all breast cancer can be attributed to a hereditary predisposition (National Institute for Health, 2017). A study in 2003 determined 9% of women with a significant family history warranted a genetic surveillance, lifestyle changes, medications, and/or surgeries to reduce their risk of cancer or ideally prevent cancer (Hughes, et al.). During the past few years, our program has evolved from bringing genetic evaluation to a genetically underserved area, to developing a program that includes cancer risk assessment, genetic cancer screening, genetic cancer evaluation and testing, and developing a treatment plan all in one location. In the population surveyed, we have found as high as 7.2% high risk for breast cancer women. Most general surgery offices treat breast cancer, and in some cases, treat women at increased risk for breast cancer. General surgery needs to spearhead genetic testing in the breast cancer population. As seen here, 38% of our positive mutations were found in patients with an HBOC-classified cancer. It is imperative to bring awareness for a genetics risk assessment to those who treat breast cancer - the surgical office. This program was developed to reduce the risk of breast

cancer in our community. A program using a multidisciplinary approach should be utilized in general surgery and breast care clinics to perform genetic risk assessments.

581461 - Clinical and pathological features of breast cancer among men and women with ATM and CDH1 mutations

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Background/Objective: Multigene panel testing for hereditary breast cancer has facilitated the identification of pathogenic non-BRCA1/2 mutations. We identify men with breast cancer-associated non-BRCA1/2 mutations and compare their clinical and pathological features to women with the same mutations.

Methods: The institutional cancer genetics research database was queried for men with breast cancer (MBC) who underwent genetic testing. Based on the non-BRCA1/2 pathogenic variants (PV) identified in MBC, we then queried the database for women with breast cancer (WBC) carrying those mutations. All patients consented for various multigene panel testing. Clinical data and histopathology were analyzed from patient records, and 95% confidence intervals were calculated for proportions.

Results: Thirteen of 47 (27.7%; 95% CI,16.8%-41.9%) MBC had deleterious germline mutations, of which 10 (76.9%; 95% CI, 49.1%-92.5%) were BRCA1/2, 2 (15.4%, 95% CI, 3.1%-43.5%) were ATM, and 1 (7.6%; 95%CI, 0.01%-35.4%) was CDH1. Among women, 28 and 4 were identified to be ATM and CDH1 mutation carriers, respectively. Median age at diagnosis of ATM-associated breast cancer was 45.5 years (women) versus 48.5 (men). Median age for women with CDH1-associated BC was 48.5 years. All men presented with palpable masses, while approximately half of women had screen-detected breast cancer. Of the 28 women with an ATM mutation, 2 presented with bilateral synchronous BC, and 1 had multicentric disease, each with different molecular profiles for a total of 31 tumors sampled in our female cohort and 2 in our male cohort. The primary pathology in WBC was invasive ductal carcinoma (IDC) [71.0%; 95% CI, 53.3-84.1%] and ductal carcinoma in situ (DCIS) [16.3%; 95% CI, 6.6%-33.1%]. Three [9.7%; 95% CI, 2.6%-25.7%] had invasive lobular carcinoma (ILC), which was bilateral and/or multifocal, and 1 [3.2%; 95% CI, 0.1%-17.6%] adenoid cystic carcinoma. Sixteen of the tumors in women were ER+/PR+. Two male ATM mutation carriers had ER+/PR+ IDC, 1 of which was HER2+, while 5 of the female ATM carriers had HER2+ disease. Three women had an additional PV in CHEK2, 1 of whom developed an ipsilateral breast recurrence. Another was BRCA2 positive. Seventy-five percent [95% CI, 28.9%-96.6%] of the double mutation carriers presented with Stage III disease and were younger at diagnosis (median age 36.5). Fifteen of the female ATM mutation carriers had breast conservation therapy, 6 underwent unilateral mastectomy, and 7 had bilateral mastectomies. 31% [7 of 27; 95% CI, 17.1%-49.4%] had lymph node disease. Of the 2 men with ATM-associated BC, 1 underwent breast conservation therapy, while the other had a unilateral mastectomy (see Table). All CDH1associated BC patients had ER+/PR+/HER2- ILC. Two female patients developed signet ring cell gastric adenocarcinoma after their BC diagnosis and underwent total gastrectomy, while the male carrier had a prior history of colorectal and prostate cancer. All women had bilateral mastectomies, while the man had a unilateral mastectomy.

Conclusions: Similar to nonhereditary BC, the majority of men and women with ATM-associated breast tumors are hormone receptor-positive IDC and those with a second pathogenic mutation present earlier with more advanced disease. Men with CDH1 may uniquely present with ILC of the breast, just like female CDH1 mutation carriers, which is otherwise extremely rare in men.

| NonBRCA1/2 mutation (n= total patients) | ATM (30 |)) | CDH | 11 (5) |
|--|-------------------|----------------|-----------------|-----------------|
| Patients (n=sampled tumors) | Female (n=31) | Male (n=2) | Female (n=4) | Male (n=1) |
| Median age at diagnosis | 45.5 | 48.5 | 48.5 | 80 |
| Initial presentation: % patients (95% CI) | | | | |
| Abnormal self-breast exam | 53.6 (35.8, 70.5) | 100 (29, 100) | 50 (15, 85) | 100 (16.8, 100) |
| Screen-detected breast cancer | 39.3 (23.5, 57.3) | 0 (0, 71.0) | 50 (15, 85) | 0 (0, 83.3) |
| Mean tumor size (cm ± SEM)* | 2.2 ± 0.36 | 2.9 ± 0.9 | 4 ± 1.6 | 1.4 |
| Lymph node disease (% known cases)** | 31 (17.1, 49.4) | 50 (9.5, 90.6) | 25 (3.4, 71.1) | 0 (0, 83.3) |
| Primary surgery (n=patients) | | | | |
| Unilateral mastectomy | 6 | 1 | | 1 |
| Bilateral mastectomies | 7 | | 4 | |
| Breast conservation | 15 | 1 | | |
| Primary histology: % sampled tumors (95% CI) | | | | |
| Ductal carcinoma in situ | 16.3 (6.6-33.1) | 0 (0, 71.0) | | |
| Invasive ductal carcinoma | 71.0 (53.3-84.1) | 100 (29, 100) | | |
| Invasive lobular carcinoma | 9.7 (2.6-25.7) | 0 (0, 71.0) | 100 (45.4, 100) | 100 (16.8, 100) |
| Other | 3.2 (0.01-17.6) | 0 (0, 71.0) | - | - |
| Hormone receptor profile: n=tumors | | | | Ś |
| ER+/PR+/HER2 - | 16 | 1 | 4 | 1 |
| ER+/PR+/HER2 not tested/unknown | 7 | | - | - |
| ER+/PR+/HER2+ | 3 | 1 | - | |
| ER+/PR-/HER2+ | 1 | | | |
| ER-/PR-/HER2 + | 1 | | - | |
| ER+/PR-/HER2- | 2 | | | |
| ER-/PR-/HER2 not tested/unknown | 1 | | | |

Table: Clinical and pathological features of ATM and CDH1-associated breast cancer

*Tumor size determined by final pathology after surgery. The largest span measurement was used. Of note, some tumors were treated neoadjuvantly. SEM=standard error of the mean.

**One unknown

582196 - Polygenic risk scores in breast cancer risk assessment: Clinical experience and management challenges

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Background/Objective: Polygenic risk scores (PRS) have recently been developed to enhance clinical breast cancer (BC) risk assessment with genetic testing laboratories employing this calculation in the germline cancer risk test setting. Current practice guidelines for breast management in high-risk patients rely on personal/family history risk-based models, such as a Tyrer-Cuzick (T-C). American Cancer Society (ACS) and National Comprehensive Cancer Network (NCCN) guidelines recommend women with a lifetime BC greater than 20%, as estimated by family history-based models, be offered high-risk breast surveillance (e.g., annual breast MRI in addition to mammography). However, these guidelines do not currently incorporate PRS. In the absence of guidelines, PRS BC estimates that vary significantly from those calculated by family history-based models present challenges to clinicians involved in breast management. The aim of the present study was to describe our institutional experience with PRS in a high-volume clinical cancer genetics program, with emphasis on cases with discrepant T-C and PRS risk estimates.

Methods: For this retrospective analysis, 4,586 patients seen for a cancer genetics evaluation between September 2017 and September 2018 were queried from our internal database. Eighty-three percent of the population (n = 3,807) was eligible for T-C calculation. Patients for whom T-C risk estimates were not calculated due to age (>85 years), male sex, or personal history of BC were excluded. Subgroup analysis

was performed for patients with a PRS calculation at a single outside reference lab. PRS was calculated concurrently with germline analysis. PRS-eligible patients included women of solely European ancestry without a personal history of BC, LCIS, hyperplasia, breast biopsy of unknown results, and were negative for mutation(s) in a BC risk gene. Chart review was performed to determine referral source. Follow-up management data was not available due to the analysis timeframe. Descriptive statistics consisting of frequencies and means were calculated.

Results: Thirty percent (n=1,118) of the study population had T-C estimates >20%. Three percent (n=105) of patients also had PRS calculated. The mean age for patients with discrepant risk estimates (n=27, 26%) was 46 (range: 21-59). Referral sources for these patients included OB/GYN (33.3%), breast surgery (22.2%), oncology (non-breast) (11.1%), general practice (7.4%), mammography clinic (7.4%), and other (18.6%).

Conclusions: In this cohort of patients who received a PRS, 26% had discrepant BC risk estimates as estimated by PRS and T-C. Discrepant BC risk estimates present challenges to clinicians in establishing a breast management regimen for patients and in communication of risk to patients. The majority of patients with discrepant BC risk estimates (18/27, 67%) had T-C estimates above 20% and PRS below 20%, raising potential concerns of unnecessary surveillance based on current guidelines. Further, a majority of discrepant patients (67%) were referred by providers other than breast specialists, who may not be aware of challenges presented by discrepant BC risk estimates. Further research is needed on BC outcomes in patients with discrepant risk estimates, and clinician management practices based on PRS.

| | Patients with PRS >20%, n (%) | Patients with PRS <20%, n (%) |
|---|-------------------------------|-------------------------------|
| Patients with T-C >20%, ฏ (%) | 34 (32.4) | 18 (17.1)* |
| Patients with T-C <20%, <u>n</u> (%) | 9 (8.6)* | 44 (41.9) |

Table: T-C and PRS calculations for cohort (n = 105)

*PRS and T-C risk estimates that were not both >20%, or both <20% were considered to be "discrepant"

Imaging

581630 - Cryoablation alone for breast cancer: Early results from the FROST Trial

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Background/Objective: Cryoablation has emerged as a minimally invasive approach for the treatment of early-stage breast cancer as an alternative to surgical resection. Cryoablation has the added advantage of being an image-guided percutaneous procedure that can be performed in the outpatient setting under local anesthesia. In the phase 2 trial ACOSOG Z1072, successful cryoablation was seen in 90% of all patients and in 100% of tumors smaller than 1 cm. All patients in this trial underwent surgical resection to determine the success rate of cryoablation. The FROST trial (Freezing instead of Resection Of Small breast Tumors) is an ongoing non-randomized phase 2 trial evaluating cryoablation alone for the management of early-stage breast cancer. We aim to summarize the early findings at our institution for patients enrolled in the FROST trial.

Methods: The first stratum of the FROST trial is limited to patients aged 70 and older with unifocal, clinical Stage I, T1 (1.5cm or smaller), N0, M0, hormone receptor-positive, HER2-negative invasive ductal cancers. All patients are assessed by mammogram, ultrasound, and MRI prior to undergoing cryoablation. Patient selection is limited to ultrasound-visible lesions. Patients are treated with ultrasound guided cryoablation followed by 5 years of endocrine therapy. No surgical intervention is performed. A second stratum expanded the age restriction to patients aged 50-69 years old. In this stratum, all patients will undergo Mammaprint testing on the core biopsy to determine risk of distant disease recurrence, and all will receive whole-breast radiation therapy post-ablation. Chemotherapy administration is left to the discretion of the treating medical oncologist. Patients are treated with ultrasound-guided cryoablation followed by 5 years of endocrine therapy. No surgical intervention is performed. The primary objective is to determine the rate of successful tumor ablation. The secondary objectives are to determine ipsilateral breast tumor recurrence rate, axillary recurrence rate, breast cosmesis after cryoablation, and adverse events in patients treated with cryoablation alone.

Results: Planned accrual is for 105 patients in each stratum with a total of 5 years of follow-up postablation. All patients at our institution to date have enrolled in stratum 1 of the study. Our institution has accrued 6 patients, 5 of whom have undergone ablation since May 2018. Two patients have reached 1 month of follow-up with no evidence of failure, recurrence, or adverse events. One patient has follow-up to 3 months without failure, recurrence, or adverse events. The remaining 2 patients have no follow-up to date. The sixth patient has not yet undergone ablation.

Conclusions: Cryoablation is a minimally invasive technique that can provide complete destruction of tumors, acceptable loco-regional control, good cosmesis, and minimal side effects in a selected population of women with early-stage hormone-positive breast cancer. The FROST trial is still in its early phase, but already demonstrates promising results with minimal failure, recurrence, or adverse events.

580846 - Predicting pathologic nodal response following neoadjuvant chemotherapy for invasive breast cancer utilizing sequential axillary nodal imaging techniques

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Background/Objective: Currently, there is no consensus regarding the appropriate method of imaging assessment of metastatic axillary lymph node response both during and at the conclusion of neoadjuvant chemotherapy (NCT) for invasive breast cancer (IBC). As post-neoadjuvant lymph node status frequently influences surgical management, understanding the role of various imaging modalities for preoperative lymph node assessment is increasingly valuable to surgeons. Our goal with this study was to determine which specific axillary imaging modalities (ultrasound (US), MRI, or CT) either individually or in sequence, were best to correctly identify the pathologic status of axillary lymph nodes after NCT.

Methods: A retrospective review of 86 tumors in 79 patients who underwent NCT for IBC at our institution was completed from January 2015 until April 2017. We documented imaging performed before, during, and after completion of NCT as well as the characteristics of the primary breast lesion and final lymph node pathological status. We used sensitivity, specificity, and logistic regression to assess how well different modalities predicted final pathologic lymph node status.

Results: In our study cohort, 50% of patients underwent partial mastectomies. The median number of lymph nodes surgically excised was 5 (range: 0-25). 33.7% of lymph nodes were found to be histologically positive on final pathology (range of 1 to 14 positive nodes). 58.1% of the primary cancers were ER-positive, 47.7% were PR-positive, 32.6% were HER-2-positive and 32.6% were triple negative. Clinically prior to NCT, 82 tumors had a median size of 2.65 cm (range: 0 - 14cm). On final pathology, 24 lymph node-positive patients had measurable metastasis size with a median value was 0.85 cm (range: 0 - 5.2cm). Prior to NCT, 55 (64.0%) MRIs, 78 (90.7%) US and 34 (39.5%) CT scans were evaluable. During NCT, 7 (8.1%) MRIs, 31 (36.0%) US and 1 (1.2%) CT scans were evaluable. Mid-treatment MRI had a sensitivity of 100% and specificity of 50% with US having a sensitivity of 80% and specificity of 33.3%. After completion of NCT, 52 (60.5%) MRIs, 28 (32.6%) US, and 5 (5.8%) CT scans were evaluable for lymph node assessment. Post-NCT US sensitivity was 88.9%, and MRI sensitivity was 88.2%. Specificities were 52.6% and 54.3%, respectively. Of the 86 tumors, 19.8% underwent both post-NCT MRI and axillary US assessment. Sensitivity was 100%, and specificity was 75% respectively for this cohort.

Conclusions: Both MRI and axillary ultrasound have an acceptably high sensitivity for detecting nodal positivity after completion of NCT for invasive breast cancer. In the absence of clinical concern for non-response, there is little value for mid-treatment imaging due to its low specificity. Most importantly, performing both post-NCT axillary ultrasound and MRI increases specificity by approximately 22%. This factor may allow for more patients to be considered for post-NCT sentinel lymph node biopsy and avoid unnecessary axillary dissection.

581700 - Moving breast MRI requests to primary care while avoiding unnecessary tests Cary Kaufman¹, Kimberlee Moses², Valerie Behrndt³

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Background/Objective: Controversy exists regarding the value and frequency of breast MRI in the evaluation of the breast cancer patient. Lack of clear guidelines used by all disciplines contributes to this problem. Currently, breast MRI is ordered only after the surgeon or other cancer physician sees the patient which creates a major delay in treatment. Although the radiologist is the clinician most likely to accurately judge the need for MRI after diagnosis, issues of self-referral prevent the radiologist from participating in this decision-making process. Our multidisciplinary team developed an agreed-upon set of indications for breast MRI that would be transmitted to Primary Care to proceed in ordering the breast MRI when indicated and avoiding the order when not indicated.

Methods: After several multidisciplinary meetings on this subject, a set of indications for breast MRI after the diagnosis of breast cancer were agreed upon. They consisted of women with invasive lobular cancer, women with dense breast tissue, women with cancers that were difficult to see the primary, women with multiple apparent primaries, and young women under 50 years old who were diagnosed with breast cancer. None of these guidelines were for women without a new diagnosis of breast cancer. This message was put on the biopsy report as a recommendation by the joint breast care committee's guidelines and sent to the primary care provider when they received the news of the biopsy results. When the primary care provider received the biopsy report with the committee's recommendation for a breast MRI, they would now order the breast MRI. If there were no recommendation, the primary care provider would simply refer to the surgeon. The goal was to facilitate prompt ordering of indicated breast MRIs and avoid breast MRI procedures without agreed upon indications. Prior to this mechanism, we measured how often the breast MRI was performed, who ordered the study, how many days before or after our first multidisciplinary meeting was the breast MRI, and how many days before or after surgical consultation was the study performed.

Results: Improvements were made in all directions. There were 30 patients evaluated prior to the initiation of this program and 31 patients evaluated afterwards. Before the program, breast MRI was obtained 12 days after our multidisciplinary meeting and 9 days after surgical consultation. Some breast MRIs were not recommended by our conference, yet the primary care provider ordered them anyway. That accounted for about 22% of ordered MRIs at baseline. After we instituted routine advice given on the biopsy report from the radiologists, immediate incorporation of the recommendations was noted. Now 80% of all breast MRIs were ordered by primary care when none were ordered previously. In addition, the non-indicated breast MRIs dropped from 22% to 8%, thus resulting in cost savings. In addition, the breast MRIs were timelier. They were obtained now 3 days PRIOR to the multidisciplinary meeting and 5 days prior to surgeon consultation.

Conclusions: We addressed issues with breast MRI including inconsistent indications, delays in obtaining the study, blanket overuse of breast MRI, and increased costs associated with all these items. By developing a set of breast MRI indication guidelines, and giving recommendations to primary care providers based on those guidelines, most of these problems have either resolved or have been significantly improved. Agreement on breast MRI guidelines is the first step in clarifying its use.

580448 - Detectability and usefulness of breast ultrasound in capsular contracture diagnosis

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Background/Objective: There is no precise diagnostic criteria for capsular contracture because only symptoms and physical examinations of the patient are used to diagnose the capsular contracture after breast augmentation with implant. The purpose of this study was to prospectively evaluate the detectability and usefulness of breast ultrasound in capsular contracture diagnosis.

Methods: Ultrasonography and pathology was used to determine the thickness of the capsule using ultrasonography in 26 patients who had undergone revision surgery after breast augmentation due to capsular contracture Baker grade III,IV and in 38 patients who underwent reoperation for other reasons with capsular contracture Baker grade I,II. The ultrasound equipment used is the Philips IU22 and the Canon aplio i600.

Results: Capsular thickness was measured from 0.6 mm on ultrasonogram. All 26 patients who underwent reoperation on Baker grade III and IV were able to observe capsular thickening by breast ultrasonography and pathology. The thickness was at least 0.6 mm and a maximum of 10 mm. In 38 patients who underwent reoperation for symptoms other than capsular contracture, a minimum of 0.3 mm and a maximum of 0.7 mm were measured ultrasound and pathology.

Conclusions: The diagnosis criteria of capsular contracture can be established more precisely by measuring the thickness and visibility using ultrasound rather than the Baker grade, which has been used to diagnose the capsular contracture for a long time.

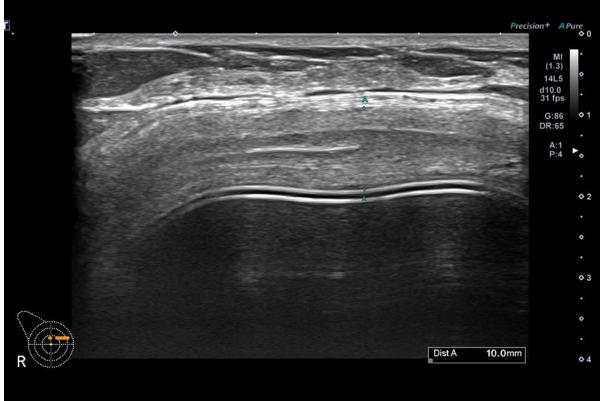


Image: Thickened capsule in ultrasound

579428 - Ultrasonographic evaluation with breast implant checklist after breast augmentation

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Background/Objective: As the number of breast augmentations and reconstructions using breast implants increased gradually during the recent decade, various breast implant-related complications and clinical conditions are made known including rarely reported Breast Implant-associated Anaplastic Large-Cell Lymphoma (BIA-ALCL) cases. Our objective was to study our check list for breast implant evaluation with ultrasound, as it can be important information in diagnosis and treatment for breast implant associated complications.

Methods: Ultrasonographic evaluation was done in women with breast implants who visited for a breast check-up from March, 2, 2017 to February, 28, 2018. Women were evaluated with high-resolution ultrasound (HRUS) plus the Breast implant Checklist which was first introduced by the Korea Breast Implant Society (KoBIS). High-frequency linear transducers of Philips IU-22 model was used. The sonographic and clinical findings of patients with breast symptoms were reviewed.

Results: A total of 540 patients had breast implants. Ages ranged from 20 to 55 years old (median 38), and 513 (95%) had breast augmentation for cosmetic purpose than reconstruction. Median follow-up duration from surgery was 14 months (range 1 months to 204 months). Breast implant were placed in submammary/subfascial (318, 61.9%) or subpectoral level (195, 37.1%). Implant types were saline (42, 7.8%) or silicone (498, 92.2%), implant shape was round (362, 67%) or anatomical (178, 32.9%). Two-hundred forty-five patients had unilateral or bilateral breast pain. One-hundred seventy-two (31.8%) were found with single or multiple breast implant-associated complications. Breast implant-associated complications in ultrasonographic finding included peri-implant fluid collection (107, 19.8%), capsular thickening (49, 9.1%), folding (55, 10.1%), focal or diffuse detachment (83, 15.3%), rupture sign (76, 14%), hematoma 21(3.8%), malrotation (59, 10.9%), and upside down of implant (31, 5.7%). Late seroma was found in 43 (7.9%) patients who had surgery 1 year ago or more, but none of the patients were diagnosed with BIA-ALCL so far. Breast pain and number of breast implant complication showed no significance (p>0.5).

Conclusions: Breast augmentation and reconstructions using breast implant are increasing, but a useful sonographic evaluation guideline is not suggested for breast implants. Therefore, we suggest a breast implant-associated complication check list and its definitions that can be used for breast ultrasonography for women with breast implants. More studies are in need including the checklist, which could help step towards thorough evaluation and diagnosis method for fewer misses of breast implant complication.

Table: Ultrasonic evaluation with breast implant checklist after breast augmentation

Table.1 Symptom at the time of follow up

| Symptom | | |
|---|-----|-------|
| Breast symptom negative | 231 | 42.7% |
| Breast symptom positive | 306 | 56.6% |
| Breast pain(unilateral, bilateral) | 245 | 45.3% |
| Other(implant related, skin irritation, nipple discharge) | 47 | 8.7% |
| Mass Palpable only | 3 | 0.56% |
| Palpable mass + pain | 8 | 1.48% |
| Palpable mass + pain + other | 3 | 0.56% |
| Unknown | 3 | 0.56 |

| Ultrasonographic Breast Checklist | Number of Patients (N) | % |
|--|---------------------------|--------------------------------|
| Breast Implant position Submammary/subfascial Subpectoral Unknown different level* | 318 195 26 1 | 58.8% 36.1% 4.8% 0.2% |
| Implant type Saline silicone | 42 498 | 7.8% 92.2% |
| Implant Shape Round (smooth, textured, micro-textured) Anatomical | 362 178 | 67.0% 32.9% |
| Implant-related complication Peri-implant fluid collection** | 107 | 19.8% |
| Focal/diffuse detachment | 83 | 15.3% |
| Rupture sign | 76 | 14% |
| Malrotation | 59 | 10.9% |
| Folding | 55 | 10.1% |
| Capsular thickening | 49 | 9.1% |
| Upside down of implant | 31 | 5.7% |
| Hematoma | 21 | 3.8% |
| Total | 172 | 31.8% |
| * Right subpectoral, Lt submammary ** includes late seroma (postop 1 yr or over) | 1 43 | 0.2% 7.9% |

Table.2 Result of Ultrasonographic Checklist

580531 - Impact of biennial versus annual mammography screening on breast cancer stage at diagnosis, after stratifying for risk

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Background/Objective: Breast cancer mortality has declined since 1990 due to earlier detection attributed to preventive screening programs. While annual screening is ostensibly a better method to identify tumors at earlier stages, potential harms include false-positive results, leading to unnecessary follow-up imaging, biopsies, and over-treatment. In 2015, the Breast Cancer Surveillance Consortium reported that 13.1% of pre-menopausal women who underwent biennial screening mammogram had increased proportions of stage IIB or higher tumors, larger tumor size, and less favorable prognostic characteristics compared with those screened annually. No difference was seen between postmenopausal women in either group. However, patients were not stratified into average- and high-risk groups. In this study, we aim to determine the effect of a biennial screening interval on stage of disease at diagnosis after stratifying for risk.

Methods: A retrospective cross-sectional analysis was performed for a random sample of female patients aged 40-75 diagnosed with breast cancer on biopsy after an abnormal digital mammogram, with a previous negative screening mammogram recorded in the mammography tracking system at our institution, between January 1, 2006 and June 1, 2016. This was done as a feasibility analysis in preparation for a larger study. The Tyrer-Cuzick model was used to calculate each patient's lifetime risk of developing breast cancer. They were then stratified into average (<20% personal lifetime risk) and high-risk groups (\geq 20%). Patient records were reviewed to determine the interval between most recent prior negative screening mammography and positive mammography, after which they were divided into annual (\leq 18 months) and biennial (>18 months) screening groups. Outcome variables included breast cancer stage at diagnosis, tumor size, cancer grade, as well as recurrence rate.

Results: Of the 90 eligible patients, 72 patients (80%) were average-risk, and 18 (20%) were high-risk. Of the average-risk patients, 43 (59.7%) had a prior screening mammogram within 18 months prior and 29 (40.3%) had a screening mammogram >18 months prior. Four (5.6%) patients in the average-risk group experienced a recurrence, while 2 (11.1%) did in the high-risk group. No disease more advanced than stage IIB at diagnosis was seen in either group. Among average-risk women, there was no significant association between biennial screening and higher stage or grade of disease at diagnosis. However, among high-risk patients, there was an association between biennial screening and having stage IIA or IIB disease at diagnosis (p=0.16) when using an alpha of 0.2. (See Table)

Conclusions: Given that there was no significant difference in stage of disease with the biennial screening group, this may be a reasonable interval for average-risk women while annual screening may be more preferable for high-risk patients. Additionally, this study captured patients with screening intervals of 15-22 months, a group previously not characterized according to prior definitions of annual (11-14 months) and biennial (23-26 months) screening. A larger study and sub-group analyses are indicated to further investigate these findings.

| | Average Risk | | | High Risk | | |
|-------------------------------|--------------|------------|---------|-----------|-----------|---------|
| | Annual | Biennial | p-value | Annual | Biennial | p-value |
| N | 43 | 29 | (:) | 9 | 9 | 2 |
| Mean age at diagnosis (Years) | 61.22 | 59.35 | | 53.02 | 49.39 | |
| Race | | | 0.72 | | | 0.77 |
| White | 32 (76.2%) | 23 (82.1%) | | 8 (88.9%) | 7 (77.8%) | |
| African-American | 2 (4.8%) | 3 (10.7%) | | 1 (11.1%) | 1 (11.1%) | |
| Other | 8 (19.0%) | 2 (7.1%) | ·) | 0 (0%) | 1 (11.1%) | <i></i> |
| Menopausal status | | | 0.77 | | | 1.00 |
| Pre-menopausal | 9 (22.0%) | 5 (19.2%) | | 4 (44.4%) | 5 (55.6%) | |
| Post-menopausal | 32 (78.0%) | 21 (80.8%) | | 5 (55.6%) | 4 (44.4%) | |
| Histologic diagnosis | | | 0.58 | | | 0.35 |
| DCIS | 24 (55.8%) | 19 (67.9%) | 0s | 7 (77.8%) | 4 (44.4%) | |
| Invasive ducal carcinoma | 29 (67.4%) | 19 (65.5%) | 9 | 3 (33.3%) | 3 (33.3%) | |
| Invasive lobar carcinoma | 4 (9.3%) | 3 (10.7%) | | 1 (11.1%) | 2 (22.2%) | |
| Adenocarcinoma | 0 (0%) | 0 (0%) | | 0 (0%) | 0 (0%) | |
| Mean tumor size (cm) | 1.71 | 2.52 | | 1.79 | 2.14 | |
| Tumor stage | | | 0.30 | | | 0.16 |
| Stage 0 | 10 (24.4%) | 7 (24.1%) | | 5 (55.6%) | 2 (25.0%) | |
| Stage IA | 22 (53.7%) | 13 (44.8%) | | 4 (44.4%) | 2 (25.0%) | |
| Stage IB | 1 (2.4%) | 0 (0%) | | 0 (0%) | 0 (0%) | |
| Stage IIA | 5 (12.2%) | 5 (17.2%) | | 0 (0.0%) | 3 (37.5%) | |
| Stage IIB | 3 (7.3%) | 4 (13.8%) | 0 | 0 (0.0%) | 1 (12.5%) | |
| Tumor grade | | | 0.43 | | | 0.40 |
| Grade 1 | 9 (28.1%) | 4 (16.7%) | | 2 (50.0%) | 2 (28.6%) | |
| Grade 2 | 19 (59.4%) | 12 (50.0%) | | 2 (50.0%) | 3 (42.9%) | |
| Grade 3 | 4 (12.5%) | 8 (33.3%) | | 0 (0.0%) | 2 (28.6%) | |

Table: Annual versus biennial screening by risk stratification

582074 - The effect of ultrasound screening on malignant breast lesions after implementation of the dense breast notification law

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Background/Objective: Mammography is an effective screening method that has been proven to reduce breast cancer mortality. However, mammograms in women with dense breasts are 50% less sensitive and may miss more potential cancers. In addition, breast density is a known risk factor for the development of breast cancer. The use of ultrasound has been shown to increase sensitivity of breast screening. In the ACRIN 6666 study, screening US had a sensitivity of 76% and a specificity of 84% when used in combination with mammography. Yet, the use of US and MRI are only reserved for women with a high risk of breast cancer and were not recommended for breast density alone. 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. The objective of this study is to evaluate whether the addition of ultrasound to breast cancer screening resulted in a decrease in the size of high-risk or malignant lesions when initially found on imaging. The surgical pathology is also evaluated for size.

Methods: Retrospective analysis of both pathology and radiology data was performed on all patients who received either screening or diagnostic mammograms and whether ultrasound was use in adjunct. All biopsy-proven high-risk or malignant lesions were then evaluated for size, and whether they appeared on mammography, ultrasound, or both. Surgical pathology was also evaluated to evaluate the size of the lesion. These sizes were compared to the imaging modalities for the year 2013- during which the notification law was implemented.

Results: Out of 371 total biopsies in 2013, 96 came back positive for high-risk or malignant lesions. In the group that only received mammography, the average size detected on imaging was 2.8cm, and the average size on surgical pathology was 1.62cm. In the group that received mammography/sonography, the average size detected on imaging was 1.88cm, and the average size on surgical pathology was 2.2cm. For all patients that underwent previously documented ultrasound surveillance, the average size detected on any imaging was 1.2cm, and the average size on surgical pathology was 1.675cm. For all patients that did not undergo documented ultrasound surveillance previously, the average size detected on any imaging was 1.17 cm, and the average size on surgical pathology was 1.44cm.

Conclusions: With the use of ultrasound as an adjunct to mammography, the detected size of biopsy proven malignant or high-risk lesions were significantly smaller detected on imaging compared to mammography alone. The sizes on pathology and imaging were the similar for biopsy-proven lesions for patients who were under sonographic surveillance compared to no previous ultrasound.

580685 - Breast cancer detection using multimodality breast cancer screening techniques is influenced by breast tissue density

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Background/Objective: Increased breast density is increasingly recognized as an independent risk factor for breast cancer leading to mandates in 36 states requiring supplemental screening in this patient population. We hypothesize that breast density influences the effectiveness of breast cancer detection when multimodality breast cancer screening techniques (ABUS in conjunction with 2D and 3D breast tomosynthesis) are used.

Methods: A retrospective review was conducted of all patients diagnosed with breast cancer at our institution between 2015 and 2016. All patients received a standard screening mammographic protocol of 2D and 3D breast tomosynthesis. At the time of screening mammogram, the images were reviewed by the technologist, and the breast density was determined according to a density algorithm. Breast density was assigned 1 of the following 4 categories: Category A. Fatty; Category B. Scattered fibro-glandular tissue; Category C. Heterogeneously dense; Category D. Extremely dense. Patients receiving a designation of either heterogeneously dense or extremely dense were offered ABUS examination. All mammograms and ABUS examinations were interpreted by board-certified, breast imaging radiologists. Radiographic findings were correlated with demographic information from the electronic medical record, as well as tumor registry data and pathology.

Results: A total of 389 patients were diagnosed with breast cancer during the study period. Breast density was assessed in 370 patients. Of those, 126 (34.1%) were identified as having dense breast tissue (category C and D). Ten patients (8%) had an ABUS examination, 4 of whom had mammographically occult breast cancers detected by ABUS alone, and were all heterogeneously dense. Increased breast density was associated with younger age, lower BMI, and white race.

Conclusions: The effectiveness of multimodality breast cancer screening may be influenced by breast density as well as clinical and demographic factors. Further studies are warranted to determine the value of each modality alone, and in combination in our patient population.

Table: Breast density

| | А | В | С | D |
|-------|-----------|------------|------------|----------|
| N (%) | 35 (9.5) | 209 (56.5) | 110 (29.7) | 16 (4.3) |
| Age | 63.54 | 62.49 | 54.41 | 47.12 |
| BMI | 35.37 | 32.25 | 27.95 | 22.46 |
| Race: | | | | |
| Black | 18 (51.4) | 92 (44.0) | 22 (20.0) | 6 (37.5) |
| White | 17 (48.6) | 111 (53.1) | 82 (74.5) | 9 (56.3) |

580961 – Low-dose molecular breast imaging (MBI) in the surgical setting: Initial clinical experience

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Background/Objective: The aim of this study was to retrospectively evaluate the potential benefits of low-dose molecular breast imaging (MBI) in the context of the diagnostic surgical setting to evaluate women with a prior history of breast cancer and/or equivocal mammography finding or positive mammography finding.

Methods: MBI was performed on 93 patients at our center between March 2017 and June 2018. Patients ranged in age from 30-79 years with an average age of 57.9 years. All of the patients underwent bilateral MBI scanning after intravenous injection of 8mCi Tc-99m- sestamibi. Imaging acquisition was initiated within 5 minutes using the LumaGEM dual head, planar, solid state digital system with cadmium zinc telluride (CZT) technology. Standard cranio-caudal and medio-lateral oblique views of each breast were obtained.

Results: We are reporting on 63 patients, 64 at the breast level (1 bilateral case). Thirty patients were excluded from this analysis because they do not yet have reference standard. Twenty-two subjects (35%) had a prior history of breast cancer. Breast density was reported by interpreting radiologist as C or D in 66.7% (42/63). Nineteen subjects (30.1%) had histologic confirmation of current breast cancer, 6 of these had biopsy prior to MBI. MBI was used to evaluate extent of disease in these patients. MBI was positive in 100% of pre-biopsy histologic confirmed cancers (13/13). Mammography was positive in 91.7% (11/13), and equivocal in 16.7% (2/13). MBI downgraded BIRADS in 10 cases (15.8%).

Conclusions: Low-dose MBI is an effective adjunct imaging modality in the surgical setting to evaluate patients who present with prior history of breast cancer or current mammographic findings. It is also a valuable tool to evaluate disease extent in newly diagnosed patients.

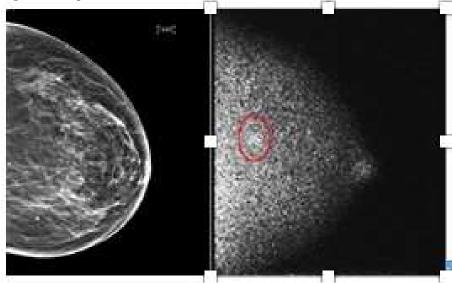


Figure: MBI pictures

581535 - Follow-up and diagnosis of breast incidentalomas on abdominal and chest MRI <u>Samantha Rios</u>¹, Kelsey Larson²

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Background/Objective: With the increasing use of imaging in medicine, it is important to not only report incidental findings, but also to make appropriate work-up recommendations as well. The aim of the study was to understand how often incidental breast findings are identified on MRI chest/abdomen protocols, how these findings are followed, and the final diagnosis (benign vs. malignant) of these lesions.

Methods: A single-institution retrospective review was performed of women who underwent abdominal or chest MRI from January 2007 – January 2017 for a non-breast cancer reason with a radiological report containing the key word "breast." Incidental breast findings were defined as lesions not known or suspected prior to imaging. For all patients where a breast lesion was identified, the radiologic reports, additional follow-up imaging and procedures, and final breast pathology were reviewed. Descriptive points were analyzed using counts and percentages versus mean with standard deviation where applicable.

Results: After review, 261 patients met inclusion and exclusion criteria with demographics in the Table. A majority of patients (92%) had a known or benign breast finding, but 8% (n=21) had a breast finding for which follow-up was recommended. Recommendation for follow-up included ultrasound (n=4), mammogram (n=8), per clinician (n=14), and breast MRI (n=2). Only 7/21 (33.3%) completed recommended follow-up: 86% (6/7) had normal follow-up imaging and return to yearly screening was recommended. However, 14% (1/7) had a new breast cancer diagnosed. Thus, the rate of new breast cancer diagnostic mammogram/ultrasound. Breast MRI as recommended in 2 patients did not add to cancer detection. Recommendation for specific imaging follow-up (56%) (mammogram/ultrasound/MRI) in the original MRI report was 39% more likely to be completed versus "per clinician" (17%) recommendation (p=0.15).

Conclusions: Although incidental breast findings on abdominal and chest MRI are uncommon, follow-up is important to exclude new breast cancer diagnosis. Incidental breast findings on abdominal/chest MRI are more likely to be benign lesions but it is important to recommend and follow up appropriately so as to not miss a new malignancy. Specific imaging recommendations (versus "per clinician") on the MRI reports appeared to improve rate of follow-up, with diagnostic mammogram/ultrasound being appropriate modalities to recommend. Although prior studies have documented incidental breast findings on CT, few have assessed breast incidentalomas on abdominal MRIs (Prabhu V.), with similar rates of new breast cancer diagnosis documented in our study. Prior studies assessing breast incidentalomas on chest MRIs are lacking. Going forward, multi-institutional studies may further define the rate of breast cancer diagnosis after breast incidentalomas identified on abdominal/chest MRI. In addition, studies focusing on improving follow-up imaging rates are important for patient safety and quality of care.

Table:

| Demographic | Ν | % of Total |
|---|-----------------|------------|
| Age | 56 +/- 11 years | N/A |
| Race | | |
| American Indian | 1 | 0.4 |
| Asian or Pacific Islander | 6 | 2.3 |
| African American | 18 | 6.9 |
| Caucasian | 18 | 6.9 |
| Unknown | 215 | 83.5 |
| Insurance | | |
| Medicaid | 10 | 3.8 |
| Medicare | 98 | 37.5 |
| Private | 142 | 54.4 |
| Unknown | 9 | 3.4 |
| Breast Cancer Status | | |
| History of breast cancer without current breast disease | 163 | 62.5 |
| No prior history of breast cancer | 98 | 37.5 |
| Type of MRI | | |
| MRI chest | 25 | 9.6 |
| MRI abdomen | 235 | 90.4 |
| Location of Imaging | | |
| Cancer Center | 74 | 28.4 |
| Main Campus (Tertiary Referral Center) | 106 | 40.6 |
| Suburban | 63 | 24.1 |
| Other | 15 | 6.9 |

581319 - Overuse of pre-operative staging in patients undergoing neoadjuvant chemotherapy for breast cancer

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Background/Objective: Overuse of pre-operative imaging to stage patients with breast cancer contributes to rising health care costs. National and international guidelines (ASCO, NCCN, ESMO) discourage the use of staging imaging for newly diagnosed early breast cancer (Stage I-II) regardless of nodal status. The purpose of this study was to evaluate pre-operative staging imaging rates among patients with Stage I-II breast cancer treated with neoadjuvant chemotherapy (NAC).

Methods: A total of 303 patients with Stage I-II breast cancer who had NAC from 2008 to 2016 were identified from a prospectively maintained database. Pre-operative staging imaging was examined. The primary outcome was rate of staging imaging performed.

Results: Of the 303 patients with Stage I-II breast cancer, mean age was 51 (range 26-87) years. Two hundred seventy-eight patients (92.4%) had invasive ductal cancer. One hundred sixty-seven patients (56.0%) had estrogen receptor-positive, 79 patients (26.5%) had triple-negative, and 126 patients (42.3%) had HER2-positive disease. A staging PET or CT scan was completed in 258 patients (85.2%), brain imaging in 94 patients (31.0%), and bone scans in 117 patients (38.6%). Forty-eight patients (15.8%) had all 3 imaging modalities completed, while only 37 patients (12.2%) had no imaging performed. Overall, 21 patients (8.1%) had a positive PET/CT scan for regional or distant lesions. One hundred thirty-nine

patients (n=139/228, 61.0%) had metastatic nodal disease or suspicious axillary nodal activity seen on PET/CT; Of these patients, 107 (107/139, 77.0%) had clinical N1 disease. Of the 21 patients with a positive PET/CT scan for distant disease, 15 patients (71.4%) were upstaged to Stage IV breast cancer, 4 patients (19.0%) were found to have a second primary malignancy: 1 with a contralateral breast cancer, while the remainder were biopsy-proven papillary thyroid, ovarian, and neuroendocrine tumors. Two patients (5.6%) had a resection of a suspicious liver lesion and anterior mediastinal mass with benign pathology. Importantly, there was no difference in ER-positive (p=0.796), HER2-positive (p=0.281), or triple-negative (p=0.369) receptor profiles for patients (4.3%) had a positive bone scan, and 3 of these patients (60%) had positive bone metastasis also seen on the PET/CT scan.

Conclusions: Despite guideline recommendations, there is a high rate of pre-operative staging imaging completed in patients with Stage I-II breast cancer who receive NAC with few positive results. Our findings suggest that pre-NAC staging is not necessary and contributes to higher costs in the management of clinically Stage I-II patients.

Localization

582194 - Reflector localized axillary lymph node biopsy: A novel aide in axillary staging after neoadjuvant chemotherapy for node-positive breast cancer

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Background/Objective: Neoadjuvant chemotherapy is being increasingly utilized, particularly in triplenegative or HER2-positive breast cancer, and has been shown to achieve axillary sterilization rates of over 45-55%. Alliance ACOSOG Z1071 demonstrated that the false-negative rate for sentinel lymph node biopsy after neoadjuvant chemotherapy in node-positive breast cancer can be reduced from 12.6% to 6.8% if the previously biopsied positive axillary lymph node is clipped and excised with a combined total of 3 or more sentinel lymph nodes identified with dual radioisotope and blue dye mapping. The aim of this study is to compare the efficacy of the axillary reflector device to axillary wire localization of the clipped previously biopsied lymph node (CPBLN) to aid in excision during definitive axillary staging after neoadjuvant chemotherapy.

Methods: Utilizing a prospectively maintained database of clinically node-positive breast cancer patients who underwent neoadjuvant chemotherapy, a retrospective analysis was conducted for patients treated between March 2016 and October 2018. Women over 18 who had clinical N1-3 breast cancer who underwent neoadjuvant chemotherapy for axillary down-staging and planned sentinel lymph node biopsy (SLNB) with axillary localization of the CPBLN were included. Exclusion criteria included patients with persistent clinically positive axillary adenopathy.

Results: Seventy women were identified who met study criteria. The majority of patients had cN1 disease (83%). Thirty-two patients underwent axillary wire localization (46%), and 36 women underwent axillary reflector localization (51%). Six patients had the reflector device placed during the initial weeks of chemotherapy (15.8%); median time between reflector placement and surgery was 137.5 days (range 87-176 days). All 6 of these patients had successful excision of the CPBLN. There were no differences in the successful localization of the CPBLN or successful excision of the CPBLN between the 2 modalities (wire versus reflector). Localization with either wire or reflector was the only means of CPBLN identification in 5 patients (7.1%) who had isotope and dye mapping failure. Positive CPBLN/SLNB requiring subsequent axillary lymph node dissection occurred in 30 patients (42.8%).

Conclusions: Use of the axillary reflector device is a new technique for localization and excision of the CPBLN at the time of SLNB after neoadjuvant chemotherapy for node-positive breast cancer. Unlike axillary wire localization, which requires same-day placement and removal, the axillary reflector can be placed into the grossly abnormal positive axillary node at the beginning of chemotherapy, which is more accurate, will still allow for successful identification of the CPBLN for excision months later at the time of definitive surgery, and can facilitate case flow on the day of surgery.

581771 - Does bracketing reduce positive margin rates in patients undergoing partial mastectomy?

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Background/Objective: With the advent of localization for non-palpable tumors, some have advocated bracketing with 2 or more devices to more accurately define the tumor extent and reduce positive margins. We sought to determine factors associated with the use of bracketing and its impact on margin positivity.

Methods: Data from a randomized controlled trial of patients undergoing partial mastectomy were used to determine the effect of bracketing and the number of wires used to localize non-palpable tumors on positive margin rate after partial mastectomy. Margins for this analysis were assessed based on the initial partial mastectomy (inclusive of any selective margins that were taken as a result of specimen radiography or surgeon gross assessment). A positive margin was defined as either invasive tumor at ink or DCIS within 2 mm. Non-parametric statistical analyses were performed using SPSS Version 24.

Results: A total of 216 patients underwent partial mastectomy with wire localization in this study; 31 (14.4%) had bracketing with 2 wires, and 5 (2.3%) had bracketing with 3 wires. Positive margin rates were 32.8%, 45.2%, and 40.0% in the 1-, 2- and 3- wire group, respectively (p=0.407). Factors associated with bracketing are shown in the Table. Patients who underwent bracketing tended to have larger tumors on imaging (p=0.042) and on final pathology (p=0.029); however, the extent of disease on final pathology tended to be underestimated by imaging. Those who were bracketed were also more likely to present with calcifications (p=0.009). Not surprisingly, bracketing with more wires resulted in a larger volume of tissue resected (p<0.001). Controlling for pathologic tumor size and presence of calcifications, the number of wires used to localize the tumor did not affect positive margin rate (p=0.600; OR for 2 wires vs. 1: 1.144; 95% CI: 0.469-2.791, p=0.768; OR for 3 wires vs. 1: 0.371; 95% CI: 0.046-2.994, p=0.352).

Conclusions: While bracketing tends to be used for larger tumors and those presenting with calcifications, the number of wires used to localize a tumor does not affect positive margin rates independent of these factors.

Table: Factors associated with bracketing

| Factor | Num | ber of wires (r | ı; %) | p-value |
|---|------------|-----------------|----------|---------|
| | 1 | 2 | 3 | |
| Median patient age; yrs | 61 | 60 | 74 | 0.357 |
| Race: | | | | 0.686 |
| White | 147 (81.7) | 22 (71.0) | 4 (80.0) | |
| Black | 17 (9.4) | 5 (16.1) | 0 (0) | |
| Asian | 2 (1.1) | 1 (3.2) | 0 (0) | |
| Other | 14 (7.8) | 3 (9.7) | 1 (20.0) | |
| Hispanic Ethnicity | 4 (2.8) | 2 (7.4) | 0 (0) | 0.467 |
| Palpable | 29 (16.1) | 6 (19.4) | 1 (20.0) | 0.890 |
| Mammographic mass | 113 (62.8) | 16 (51.6) | 1 (20.0) | 0.090 |
| Calcifications | 77 (42.8) | 17 (54.8) | 5 (100) | 0.009 |
| Presence of DCIS | 131 (72.8) | 23 (74.2) | 4 (80.0) | 0.924 |
| Extensive intraductal component | 113 (68.5) | 22 (75.9) | 4 (80.0) | 0.629 |
| Invasive tumor histology | | | | 0.247 |
| Ductal | 123 (87.9) | 13 (72.2) | 2 (66.7) | |
| Lobular | 11 (7.9) | 2 (11.1) | 1 (33.3) | |
| Other | 6 (4.3) | 3 (16.7) | 0 (0) | |
| Neoadjuvant chemotherapy | 3 (1.7) | 3 (9.7) | 0 (0) | 0.100 |
| Lymphovascular invasion | 15 (8.3) | 3 (9.7) | 0 (0) | 0.492 |
| Median tumor size by imaging, cm | 1.0 | 1.5 | 1.5 | 0.042 |
| Median pathologic tumor size, cm | 1.5 | 2.0 | 3.5 | 0.029 |
| Median volume of tissue resected; cm ³ | 65.2 | 113.4 | 136.5 | < 0.001 |

580274 - Radar localization for targeted excision of suspicious axillary lymph nodes

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Background/Objective: Preoperative localization and intra-operative guidance is advantageous for accurate resection of suspicious axillary nodes seen on imaging workup. SAVI SCOUT® enables pre-operative localization and real-time intraoperative guidance utilizing micro-pulse radar. The purpose of this study was to assess the effectiveness of the SAVI SCOUT® system in targeted excision of suspicious axillary nodes noted on preoperative ultrasound evaluation.

Methods: A single-institution, retrospective review of breast cancers from December 2016-October 2018 identified 50 patients with suspicious appearing axillary nodes on ultrasound imaging. All suspicious nodes underwent US guided core biopsy followed by SAVI SCOUT® reflector placement prior to surgery. Intraoperatively, the SAVI SCOUT® probe detected the reflector and guided axillary node excision with audible and numerical indicators from the console. Intraoperative radiographs confirmed the presence of the SAVI SCOUT® reflector within the axillary node. The axillary node specimen underwent intraoperative frozen section analysis followed by permanent pathologic sectioning. All 50 patients underwent concomitant sentinel node biopsy at the time of SAVI SCOUT® targeted axillary node excision.

Results: The average number of days from SAVI SCOUT® axillary node placement to surgery for neoadjuvant patients was 16, and for non-neoadjuvant patients was 4. Three patients had SAVI SCOUT® placement >100 days from surgery. Axillary node core biopsy pathology revealed metastatic disease in 35 of 50 patients (70%) with suspicious nodes on US imaging. Thirty patients (86%) with core biopsy-proven metastatic nodal disease received neoadjuvant chemotherapy. Twelve of 30 neoadjuvant patients (40%) had a complete pathologic response in the targeted axillary node. In the complete pathologic

response group, 4 patients were ER/PR/HER2-, 5 were HER2+ breast cancer (3 were ER-), and 3 were ER+/HER2-. One of the 30 neoadjuvant patients had isolated tumor cells in the SAVI SCOUT® node. Twenty-three of 35 patients (66%) with a core biopsy-proven metastatic node had positive nodal pathology at surgery. Eighteen of these 23 patients (78%) received neoadjuvant chemotherapy. Thirteen of these 18 neoadjuvant patients (72%) underwent completion axillary dissection. Eight of the 13 patients (62%) had 2 or more nodes (including the SAVI SCOUT® node) that were positive for metastatic disease (average number of positive nodes was 3). Fifteen of 50 patients (30%) with a negative axillary node core biopsy went on to SAVI SCOUT® localized node excision. Of this group, 8 patients had no metastatic disease in the SAVI node or sentinel nodes on final surgical pathology. Five of these 8 patients (63%) received neoadjuvant chemotherapy. Two of the 5 patients had loss of fatty hilum, 2 had 4mm cortical thickening, and 1 had a focally irregular cortex. Three of 8 patients not undergoing neoadjuvant chemotherapy were ER/PR+/HER2-, and had only 1 suspicious node seen on US with cortical thickening averaging 5.5 mm. Seven of 15 patients (47%) with a negative node core biopsy harbored metastatic nodal disease on final surgical pathology. All 7 patients were ER/PR+/HER2 - and were grade I-II. None received neoadjuvant chemotherapy, and had only 1 abnormal appearing node on US. One of 7 patients had isolated tumor cells on final surgical pathology. One patient had a 1mm micro-metastases in the SAVI SCOUT® node on surgical excision. One patient had necrosis/inflammation on axillary core biopsy whose node was subsequently positive on excision. The SAVI SCOUT® excised node was the sole node harboring disease in all 7 patients.

Conclusions: SAVI SCOUT® targeted nodal excision can benefit patients with abnormal appearing axillary nodes on US evaluation. Forty-seven percent of patients with a suspicious node on US assessment but with negative axillary node core biopsy were found harbor metastatic disease on targeted SAVI SCOUT® nodal excision. The targeted SAVI SCOUT® node was the only metastatic node in 100% of patients with a negative axillary node biopsy. In patients with core biopsy proven metastatic axillary nodal disease receiving neoadjuvant chemotherapy, 40% had a complete pathologic response. SAVI SCOUT® targeted nodal excision facilitates surgical axillary staging after neoadjuvant chemotherapy. This process allows for confident intraoperative assessment of treatment response in the axilla.

580284 - Management of focal mastectomy flap thickness in breast cancer patients: A novel approach

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Background/Objective: Maintaining the viability of the native breast skin envelope is crucial for successful aesthetic reconstructive outcomes in breast cancer mastectomy procedures. Balancing an acceptable oncologic procedure with optimal cosmetic results can present challenges due to lesion location, patient body mass, and other factors. The subcutaneous layer of the breast is variable and can contain islands of breast tissue. As such, the optimal mastectomy skin flap thickness remains to be defined. We evaluated the utilization of SAVI SCOUT® radar localization to facilitate precise targeted mastectomy flap dissection in patients undergoing skin-sparing and nipple-sparing mastectomies.

Methods: A single-institution retrospective review of breast cancer patients from January 2018-October 2018 evaluated patients undergoing skin-sparing or nipple-sparing mastectomies with SAVI SCOUT® localization of the core biopsy-proven sites of cancer. A SAVI SCOUT® reflector was placed within 7 days of surgery. Intraoperatively, the SAVI SCOUT® probe facilitated mastectomy flap dissection around the reflector with audible and numerical indicators from the console. Intraoperative radiographs and pathologic tissue sectioning confirmed the presence of the SAVI SCOUT® reflector within the specimen. On final mastectomy pathology, clear margins were designated as no tumor on ink for invasive disease and 2mm for in-situ disease.

Results: Ten patients undergoing mastectomies utilizing SAVI SCOUT® localization were evaluated. Of these cases, 7 underwent skin-sparing mastectomy with ellipse around nipple and areola, and 3 underwent nipple-sparing mastectomy via inframammary approach. Five patients had extremely dense breast tissue, 2 had heterogeneously dense breast tissue, and 3 had scattered fibroglandular densities. Six patients initially presented after palpating a new breast lump. Three patients had unifocal disease. Five patients had 2 lesions detected in the ipsilateral breast on imaging, and 2 patients had 3 lesions detected in the ipsilateral breast. Average lesion size detected on initial breast imaging workup was 2.33cm. Five patients had multicentric disease, 2 patients had multifocal disease, and 3 patients had unifocal disease. Seven patients had invasive ductal cancer, 1 had invasive lobular cancer, 1 had DCIS, and 1 had mucinous cancer. Six patients had N1 disease on final surgical pathology. Average closest margin was 3.5mm. Two patients were triple-negative, 1 patient was HER2+, and 7 patients were ER+/HER2-. Five patients underwent neoadjuvant chemotherapy. All 5 patients initially presented with palpable breast masses. Four of the 5 patients had extremely dense breast tissue. An average of 2 lesions were detected in the ipsilateral breast in this group of 5 patients with average lesion size of 2.45 cm. Three of the 5 patients had multicentric disease, 1 had multifocal disease, and 1 had unifocal disease. Average post-neoadjuvant lesion size on surgical pathology was 1.43 cm. All were invasive ductal cancers. Three of 5 patients were ER+/HER2-, 1 was triple-negative, and 1 was ER-/HER2+. Four of 5 patients had N1 disease on final post-neoadjuvant surgical pathology. One nipple-sparing patient with DCIS had an anterior surgical margin of <1 mm. One skin-sparing patient had residual cancer in an additional anterior margin, which as noted to contain the SAVI SCOUT® reflector on post-specimen imaging. Average closest margin with SAVI SCOUT® localization was 3.6 mm in these 5 patients.

Conclusions: Previous studies have evaluated the completeness of glandular tissue removal in skinsparing mastectomy procedures. Focal glandular tissue outside of the resection margin has been demonstrated in up to 38% of cases, of which up to 20% demonstrated residual carcinoma. Targeted lesion location with SAVI SCOUT® may facilitate adjustment of focal mastectomy flap thickness dissection in breast cancer patients with superficial lesions or patients with a thin subcutaneous mastectomy plane. This tool equips the surgeon with the means to accurately locate the non-palpable cancer during surgical mastectomy flap dissection, thereby enabling precise attention to margins in that focal area.

581780 - Utilizing business intelligence and lean system applications to improve efficiency in breast surgery

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Background/Objective: Over the past 30 years, the advancements in breast imaging and adaptations of screening programs have led to a large increase in surgeries for non-palpable breast lesions. Currently, the localization for the breast lesions is done with a small wire that is inserted via the skin under the guidance of mammogram or ultrasound prior to the surgery. With the addition of the need for injection in order to complete sentinel node biopsy in breast cancer cases, it adds further to the time needed for patients to be ready for surgery. The delays in the operating room cost hospitals and health systems millions of dollars each year. Optimizing the flow of the cases and ensuring a timely start of the surgeries would lead to a more successful health system by decreasing costs and increasing patient satisfaction. Each year, at hospitals across the enterprise, we perform approximately 736 breast procedures with needle localization, with or without sentinel node biopsies. Utilizing business intelligence applications, we have studied the collective breast surgery cases performed in the 5 hospitals of the enterprise. Tracking the flow of the patients through the process of steps needed to be ready, prior to the operating room, would help us measure the time needed for each case and help us identify the opportunities to make the process more efficient.

Methods: We used the "Perioperative Dashboard" created by the business intelligence group. This dashboard utilizes the Qlikview platform and analyzes all the events perioperatively for each case. We also employed patient tracking data, available in Epic, in order to track patient movements with timestamps on the day of their proposed surgeries. We measured the time spent at each step of the patient movement during the day of her surgery. We then performed simple statistics in order to gain a picture of the average amount of time that each patient spends on the day of the surgery, before she is ready to proceed to the operating room. After we had found significant delays in operating room start times associated with needle localization, we proposed a method to "un-couple" the process of tagging breast masses on the same operative day as lumpectomy by using wire localization with clips that can be placed up to weeks before the surgery. After implementation of this surgical strategy we once again re-evaluated the data using Qlikview to track patient movements on the day of their surgeries.

Results: We identified 55 patients who were undergoing breast lumpectomy that required mass localization. If the first case of the day was a breast resection with needle localization, late operating times were observed in 91.5% of the cases. This "first case delay" extends the delay for the entire room for the rest of the cases for that day 73.1% of the time, leading to a total minute delay of 17,000 in 1 year.

Conclusions: In our pilot intervention implementation, the time from patient check-in until she was brought back to the operating room decreased from an average of 3:27 to 2:38, and at the main hospital from 2:58 to 2:03. There was no observed statistically significant change in the time required to perform the wire localization using ultrasound guidance between our control and intervention groups. We plan to implement Lean practice principles to decrease the delay in 3 months by 30%.

579879 - Intraoperative ultrasound guidance with an US visible clip: A practical and costeffective option for breast cancer localization

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Background/Objective: For decades, wire localization has been the standard of care in breast cancer localization for partial mastectomy, but while reliable, wires are uncomfortable for patients and require an additional expensive, invasive procedure before resection. Our study evaluated the association between use of US-visible clips placed at time of biopsy and use of US for localization during resection; we hypothesized that US-visible clips would facilitate use of US-guided localization and reduce cost of care.

Methods: We enumerated a cohort of adult female breast cancer patients undergoing partial mastectomy at the University of Vermont Medical Center (UVMMC) between 2014-2016. We characterized the type of clip placed at time of core biopsy (US-visible vs. otherwise) and the localization method used during the resection procedure (wire localization vs. US). We fit robust-variance Poisson regression models to estimate the association between clip type and US localization. For cost-of-care evaluation, the total number of breast biopsies (both benign and malignant) was obtained from the Department of Radiology for 2014-2016. Cost analysis was performed with the use of institutional finances from the Departments of Surgery and Radiology.

Results: Of the 680 patients enrolled, 503 had complete data on localization method (excluding palpation) and clip type. Of these, 89% had the mass intraoperatively localized with US. The Table reports case characteristics, according to type of clip used. Placement of a US-visible clip at biopsy increased the likelihood of US-based localization during resection by 13% (95% CI: 5% to 21%). This association did not change substantially upon adjustment for surgeon, tumor size, and calendar year of operation. Cost analysis showed that in the 3-year study period, 2209 patients underwent breast biopsy at UVMMC. Placement of US-visible clips for these patients increased direct cost by \$17,500. Among those 2209 patients, 447 subsequently underwent partial mastectomy with intraoperative US, and of those 281 were facilitated by a US-visible clip. If those 281 patients had clips placed that were not localizable by US, they would have required wire localization, increasing direct cost by \$56,000 in radiology time and wire cost. The overall estimated direct cost savings from the placement of US-visible clips was therefore \$38,500 over 3 years.

Conclusions: Our study demonstrates that the use of US for tumor localization is both practical and cost effective when facilitated by US-visible clips. Our data show that 89% of breast cancer patients had tumor localization with US guidance at our institution and that there was no size difference in tumors resected with US versus wire localization. The novelty of this study is that US-localizable clips can be used to locate extremely small tumors. Upfront costs are more expensive for these clips; however, over 3 years, the overall cost is much lower with an US visible clip due to avoiding costs associated with wire localization. We recommend placement of a US-visible clip (e.g., Hydromark) at time of biopsy, and expect that the slight increase in initial treatment cost is more than offset by downstream cost savings.

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| Characteristics | US-Visible Clip n=302 | Other Clip Types n=201 | P-value t-test for continuous variables chi2 for categorical variables |
|---|---------------------------|--|--|
| Specimen size (g) mean±sd missing n | | 37.6±28.7 4 | 0.14 |
| Tumor size (cm) mean±sd missing n | | | 0.48 |
| Age of patient mean±sd | 63.9±11.4 | 62.7±11.6 | 0.21 |
| Year of Operation n (%) 2014 2015 2016 | 85(58.6%) | 60(41.4%) | |
| Surgeon n (%) A B C D E | 81 (62.8%) | 49 (37.2%) 23(47.9%) 3 (30%) 47 (29.4%) | |
| Localization method US (n=447) n (%) Wire localization (n=56) n (%) | 281 (62.9%) 21 (37.5%) | 1.0 1.5 | |

581815 - Results of a Phase I, prospective, non-randomized study evaluating a magnetic occult lesion localization instrument (MOLLI) for excision of non-palpable breast lesions <u>Nicole Look Hong</u>, Frances Wright, John Dillon, Mark Semple, Alexandru Nicolae, Ananth Ravi *Sunnybrook Health Sciences Centre, Toronto, ON, Canada*

Background/Objective: The primary objective of this first-in-human study was to evaluate the clinical feasibility of using a Magnetic Occult Lesion Localization Instrument (MOLLI) for localizing non-palpable breast lesions. MOLLI is a non-radioactive alternative for lesion localization.

Methods: A pilot study of 20 women who had non-palpable lesions visualized under ultrasound received a localized lumpectomy using the MOLLI guidance system - from August 2018 to present - was performed at a single institution. Patients were co-localized with magnetic and radioactive markers up to 3 days prior to lesion excision by a dedicated breast radiologist under ultrasound guidance. Both magnetic and radioactive markers were localized intraoperatively using dedicated hand-held probes. Radiographic and anatomical pathologic analysis was used to confirm marker excision both intraoperatively and

postoperatively. Demographic data, margin positivity, and re-excision rates are reported. Surgical oncologists, radiologists and pathology staff were surveyed for user satisfaction with the MOLLI guidance system using 5-point Likert scale questionnaires.

Results: As of November 7, 2018, follow-up data were available for 10 patients. Demographic data can be found in the Table. Post-radiological analysis: Post-implant mammograms verified that 9/10 markers were placed directly in the lesion center, and 10/10 had minimal or no migration. Radiologists reported that 100% of the marker implantations procedures were "easy" or "very easy" following a single training session. Post-surgical analysis: 100% of MOLLI markers were successfully removed with the specimen during surgical excision; no cases required final verification using the radioactive marker. Measurement of the distance of the MOLLI marker from anterior, posterior, superior, inferior, medial, and lateral aspects of the excised tissue specimen agreed with radiological imaging estimates to within 2 mm. In 9 /10 cases, surgeons ranked the MOLLI guidance system as "very easy" for lesion localization. Pathological analysis: 100% of patients had negative margins and did not require re-excision. One hundred percent of anatomic pathology staff ranked the MOLLI system as "very easy" to use and localize markers.

Conclusions: The MOLLI guidance system is a reliable, highly accurate, and non-radioactive method for localization and excision of non-palpable breast lesions. Further comparative evaluation of the MOLLI system in randomized trials with current standards of care would further demonstrate efficacy and patient-reported outcomes.

| | Average ± S.E. |
|----------------------------|-----------------|
| | (n = 10) |
| Age (years) | 62.9 ± 11.4 |
| Height (m) | 1.6 ± 0.1 |
| Weight (kg) | 67.7 ± 14.9 |
| Menopausal Status | |
| Pre | 2 (20%) |
| Post | 8 (80%) |
| Tumor Type | |
| DCIS | 2 (20%) |
| IDC | 7 (70%) |
| Other | 1 (10%) |
| Receptor Status | |
| ER / PR +, HER2 - | 9 (90%) |
| ER - / PR +, HER2 - | 1 (10%) |
| Largest Tumor Size (mm on | 16.9 ± 10.8 |
| imaging) | |
| BIRADS category | |
| 5 | 6 (60%) |
| 4 | 4 (40%) |
| Tumor Stage | |
| p2a | 4 (40%) |
| p1a | 5 (50%) |
| p0 | 1 (10%) |
| Tumor Grade | |
| 3 | 4 (40%) |
| 2 | 5 (50%) |
| 1 | 1 (10%) |
| Multifocal Disease | |
| Yes | 1 (10%) |
| No | 9 (90%) |
| Lymph node metastases | |
| Yes | 3 (30%) |
| No | 7 (70%) |

Table: Demographic data of enrolled patients to date

Abbreviations: BMI = Body Mass Index, DCIS = Ductal Carcinoma In-Situ,

ER = Estrogen Receptor, IDC = Invasive Ductal Carcinoma, PR = Progesterone receptor, S.E = Standard Error

582088 - Intraoperative wire needle localization of non-palpable lesions: Experience in a public hospital in São Paulo, Brazil

<u>Danielle Matsumoto</u>, Jonathan Maesaka Albert Einstein Israeli Hospital, São Paulo, Brazil

Background/Objective: As screening programs improve, as well chemotherapy treatments results, less invasive surgeries of non-palpable lesions become more frequent. Non-palpable lesions need to be submitted to some method of pre-operative localization to ensure proper resection with secure margins. The most used pre-operative localization methods are wire needle localization and radio-guided occult lesion localization (ROLL). The wire needle localization is a cheaper method but has as principal disadvantages the possibility of needle displacement between the time of insertion and surgery time and the surgical plan modification because of the point of insertion, which is usually determined by the radiologist. The ROLL, although it doesn't have the same disadvantages as the wire needle localization, is a much more expensive method, and requires the availability of nuclear medicine structure. In this study, we present the results of 5 cases of our practice in a public hospital in São Paulo, Brazil in which we've been performing the intra-operative wire needle localization of non-palpable lesions.

Methods: Five patients with non-palpable lesions, visible on ultrasound (nodules - 3 cases, or metal clip - 2 cases) underwent the intra-operative localization. After anesthesia, an ultrasound was performed for lesion identification and planning of the better incision in each case. Using ultrasound guiding, the wire needle was placed in the center of the lesion (in case of nodules) or touching the metal clip. These localization procedures were performed by the same surgical team, which has breast image experience.

Results: The mean procedure time for ultrasound and lesion localization was 9 minutes. In cases of metal clip, the specimens were submitted to mammogram to confirm clip removal. All the specimens underwent intra-operative pathological analysis of margin status, which confirmed adequate surgery approach. In 1 case, the margin needed to be expanded which happened immediately during surgery. All the patients answer a quality of life questionnaire and classified themselves as very satisfied with aesthetical results.

Conclusions: The intra-operative wire needle localization is a simple, low-cost technique, requiring just the breast surgery team training. The most important advantages are the minimal needle displacement risk and allowing most cosmetic incisions once it's located in the surgical plan area.

580503 - Radiofrequency identification tag localization is comparable to wire localization for non-palpable breast lesions

<u>Caroline McGugin</u>, Tara Spivey, Suzanne Coopey, Barbara Smth, Bridget Kelly, Michele Gadd, Kevin Hughes, Brian Dontchos, Michelle Specht *Massachusetts General Hospital, Boston, MA*

Background/Objective: Radiofrequency identification (RFID) tag localization (TL) is a technique of localizing non-palpable breast lesions that can be performed prior to surgery and does not require radioactive handling regulations. We sought to evaluate whether TL is comparable to wire localization (WL) in regard to specimen sizes, operative times, and re-excision rates.

Methods: A retrospective cohort analysis was performed on all localized excisional biopsies and lumpectomies with and without axillary surgery performed by 5 surgeons at 2 institutions. We identified all consecutive TL procedures performed from July 2018 through October 2018 and all WL procedures from initiation of the electronic medical record (April 2016) until adoption of alternative localization

methods (December 2016). Bilateral and multicentric lesions were excluded. Cases were stratified by surgery type (excisional biopsy, lumpectomy, lumpectomy with sentinel lymph node biopsy). Associations between localization technique and specimen volume, operative time, and re-excision rate were assessed by Savage, Wilcoxon rank-sum, and Chi-square tests, respectively. In order to control for the within-surgeon intra-class correlation, linear and logistic models were applied using generalized estimating equations.

Results: A total of 505 procedures were included; 147 were TL (29.1%), and 358 were WL (70.9%). TL and WL groups were similar in regard to surgeon, radiologist, number of wires/tags placed, surgery type, patient age, pathology, and lesion size. Nineteen (12.9%) RFID tags were placed before surgery, ranging 1-22 days. All intended targets were removed with TL and WL. Overall, TL had significantly smaller specimen volumes than WL (18.0 cm3 vs 23.9cm3; p=0.044) and longer operative times for lumpectomy (57 min vs 49 min; p=0.003), but these differences were not statistically significant when stratified by surgery type (Table). There was no difference in re-excision rate between TL and WL. After adjusting for surgeon, surgery type, pathology, and lesion size, localization technique was not associated with specimen size (p=0.736), operative time (p=0.125), or re-excision (p=0.465).

Conclusions: TL has similar surgical outcomes to WL with the added benefit of placement flexibility, improved operating room efficiency, and increased patient satisfaction. Tag localization is an acceptable alternative to wire localization and should be considered for non-palpable breast lesions.

| | Tag | Wire | |
|------------------------------------|-------------|-------------|---------|
| | N = 147 | N = 358 | p-value |
| Specimen volume (cm ³) | 18.0 (17.8) | 23.9 (28.9) | 0.044 |
| Excisional biopsy | 10.3 (8.0) | 15.9 (21.5) | 0.112 |
| Lumpectomy +/- SLNB | 22.8 (20.1) | 28.1 (31.4) | 0.218 |
| Operative time (min) | 56 (25.1) | 51 (24.5) | 0.020 |
| Excisional biopsy | 36 (11.9) | 34 (10.6) | 0.496 |
| Lumpectomy | 57 (19.5) | 49 (16.2) | 0.003 |
| Lumpectomy + SLNB | 73 (23.7) | 68 (25.5) | 0.054 |
| Re-excision rate | 23 (15.6%) | 41 (11.4%) | 0.090 |
| Lumpectomy | 10 (29.4%) | 14 (15.5%) | 0.082 |
| Lumpectomy + SLNB | 8 (13.3%) | 25 (17.6%) | 0.453 |

581631 - Hospital system rollout and initial experience with stainless steel magnetized seeds for breast and lymph node localization

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Background/Objective: Wire localization has been the standard technique for operative localization of non-palpable breast lesions for decades. Radioactive seed localization was recently introduced as an alternative method, although it is complicated by regulatory issues of tracking the radioisotope. Magseed is a 5 x 1 mm stainless steel seed placed under mammographic or ultrasound guidance from several months up to immediately before surgery. It is detected intraoperatively with the Sentimag probe, which generates a magnetic field to localize the temporarily magnetized seed. Using both auditory and visual feedback, the surgeon uses the probe to detect the Magseed location and thereby retrieve the lesion. This study reports the largest single institution experience of Magseed placement for operative localization of non-palpable breast lesions to date.

Methods: Patients who underwent Magseed placement for operative localization of breast lesions and/or lymph nodes from July 2017 to October 2018 were identified using a prospectively maintained database. Patient demographics, indications for surgery, and procedure type were recorded. Radiologic data included number and location of biopsy clips and Magseeds placed and retrieved, imaging technique used, and procedural complications. Pathology information included diagnosis at core biopsy and after surgery, and need for re-excision. Standard statistical analysis was performed using SAS 9.4, and a p-value <0.05 was considered statistically significant.

Results: Over an 18-month period, 578 Magseeds were placed in 455 patients by 9 radiologists and retrieved by 6 surgeons. Four hundred seventy seeds were placed in the breast for localization of 189 benign lesions and 257 malignant lesions. One hundred eight patients underwent localization of previously biopsied lymph nodes. The majority (70.5%) of Magseeds were placed with ultrasound guidance, and the remainder (29.5%) via stereotactic guidance. Three hundred seven (67.6%) patients were treated with partial mastectomy, 108 (23.8%) with excisional biopsy, and 39 (8.6%) with mastectomy. All Magseeds were removed for a 100% Magseed retrieval rate. The Magseed localization rate was 98.7% (95% CI: 97.1-99.5%), reflecting 6 cases in which the Magseed was not contained within the surgical specimen. In these cases, early in our experience, Magseeds were placed within the gel portion of the Hydromark biopsy clip, which can be dislodged from hydrostatic pressure during dissection, and were therefore identified outside the specimen at the time of excision. On 2 occasions an alternative method of intraoperative localization was required due to technical failure of the Sentimag probe. In 61 cases, the biopsy clip was not contained within the specimen, largely due to documented clip migration or dislodgement during dissection as described, yielding a clip localization rate of 86.4% (95% CI: 82.8-89.4%). Procedural complications from Magseed placement were observed in 7 patients (1.6%, 95% CI: 0.6-3.2%), the majority of which were hematomas. The overall re-excision rate following Magseed localization was 11.2% (95% CI: 8.5-14.5%).

Conclusions: The Magseed/Sentimag technique is safe, effective, and accurate for localization of nonpalpable lesions in the breast and lymph nodes for patients with both benign and malignant disease. Despite a learning curve for 9 radiologists and 6 surgeons at 7 locations, the Magseed retrieval rate was 100%. The low re-excision rate may reflect the accuracy of Magseed placement as a "second chance" localization procedure, especially in cases with biopsy clip migration. Unlike traditional same-day wire localization, Magseed placement has the advantage of uncoupling localization from the surgical procedure, which may increase operative efficiency and improve patient experience. We are currently comparing wire vs. Magseed localization at our institution to evaluate procedural cost and efficacy, and to assess patient and health system outcomes.

581650 - Prospective trial of magnetic seed localization of clipped nodes

Janine Simons, Marion Scoggins, Henry Kuerer, Aysegul Sahin, Ashley Snell, Isabelle Bedrosian, Joanna Lee, Kelly Hunt, Abigail Caudle *MD Anderson Cancer Center, Houston, TX*

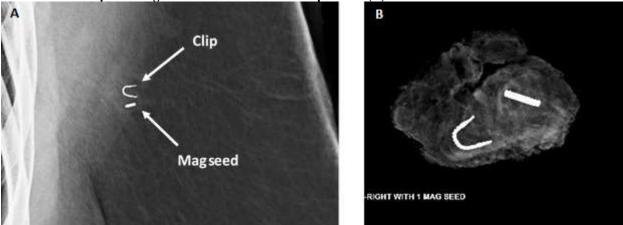
Background/Objective: Neoadjuvant chemotherapy (NAC) is often used in breast cancer patients presenting with nodal involvement. There has been recent interest in identifying patients who convert to node-negative status after NAC and may potentially avoid extensive axillary surgery. Placing clips in nodes with biopsy-confirmed disease and ensuring removal at the time of surgery has been shown to improve the accuracy of axillary staging over sentinel lymph node dissection (SLND) alone. Targeted axillary dissection (TAD), which involves localizing and removing clipped nodes in addition to removing sentinel nodes is 1 approach to assessing nodal response. However, localization techniques have been a challenge since the use of radioactive seeds carries extensive regulatory burden. Magseed® is a magnetic-based seed that can be placed under ultrasound guidance pre-operatively and detected intra-operatively using the Sentimag® probe. Our goal was to determine if magnetic seeds can be safely and effectively used to localize and remove clipped nodes at surgery.

Methods: This is a prospective registry trial enrolling patients with biopsy-proven nodal disease with a clip placed in the node and treated with NAC. The magnetic seed was placed under ultrasound guidance in the clipped node up to 30 days before surgery. All patients underwent TAD with selective removal of the clipped node and SLND.

Results: Seventeen breast radiologists placed magnetic seeds in 45 evaluable patients. All had successful seed placement on the first attempt with a mean time for localization of 6.7 minutes (range 2-30 m). The mean size of the clipped node after NAC was 1.5 cm (range 0.5-2.7 cm). The final position of the magnetic seed was within the node (n=39, 87%), in the cortex (n=3, 7%), or <3 mm from the node (n=2, 4%). The node was not well visualized in 1 case, but the seed was placed beside the clip (both were found within the node at surgery). The magnetic seed was retrieved at surgery in all cases. In 1 case, the seed and clip were found in different nodes. In all other cases, the clip and magnetic seed were retrieved in the same node (n=44, 98%). A mean of 1.4 nodes were removed in the specimen with the magnetic seed (range 1-6) reflecting the ability to selectively remove the clipped node. There were no device-related adverse events. The 9 surgeons that participated in the trial rated the ease of localization on a 5-point scale for each case. Transcutaneous localization was rated as easy (score of 1) in 89% (40/45) and difficult (score of 5) in 4% (2/45). Intra-operative localization was rated as easy in 84% (38/45) and difficult in 2% (1/45). The clipped node was an SLN in 35 cases (78%). Axillary node dissection was performed in 29 cases (64%) with no false-negative results (0/20).

Conclusions: Selective removal of clipped nodes can be accomplished safely and effectively using magnetic seed (Magseed®) localization. This technology allows for the convenience of seed localization without the regulatory burden associated with radioactive seeds.

Figures: Placement of magnetic seed within clipped lymph node (A) and specimen radiograph confirming removal of the clip and magnetic seed within 1 excised specimen (B)



581934 - SAVI SCOUT vs wire localization: Is one more efficient for OR utilization?

<u>Ashley Woodfin</u>, Jennifer Poirier, Rosalinda Alvarado, Andrea Madrigrano *Rush University Medical Center, Chicago, IL*

Background/Objective: Since the introduction of image-guided wire localization (WL) in the 1970s, this technique has prevailed as the gold standard for surgical excision of non-palpable breast lesions. However, this practice often requires coordinated preoperative wire placement on the day of scheduled surgical excision. This process can lead to inefficiencies in workflow, including surgical delays and longer wait times for patients. Replacing WL of non-palpable breast lesions with technology such as the SAVI SCOUT (SS) guidance system, offers a possible solution to workflow inefficiencies encountered with WL by uncoupling lesion localization with the day of surgery. Prior multi-center studies have established non-inferiority of the SS to WL in regard to effectiveness in excision of target, as well as need for re-excision. Given this advantage of the SS, the system may also be more effective than WL regarding OR utilization. We hypothesized that the use of the SS had positive impacts on our OR utilization by decreasing the incidence of operative delays, allowing on-time case starts, decreasing total operative time, and decreasing patient wait times in pre-op. We aimed to investigate this hypothesis using a query of our institution's EMR OR Datamart for comparison of case times between patients with SS versus WL guidance for partial mastectomy.

Methods: A query of the EMR OR Datamart at our institution was performed to collect OR information on patients undergoing partial mastectomies with image guidance in the form of pre-operative WL or SS localization between June 1, 2017 and October 2, 2018. Multiple procedure-related timing variables were examined, including delay in scheduled case start, time from patient arriving in pre-op area to OR, case duration, and whether the case started on time. Types of procedures were also recorded: partial mastectomy alone versus partial mastectomy with sentinel lymph node biopsy (SLNB). Welch's t-tests were used to look at differences in timing between the two groups (WL and SS) on delay in scheduled case start. Wilcoxon Mann Whitney tests were used to look at differences in timing between the 2 groups on time from patient arriving in pre-op area to OR, and case duration. Case duration was stratified by type of procedure prior to analysis (partial mastectomy and partial mastectomy + SLNB). The relationship between the type of localization procedure (SS or WL) and whether the case started on time was examined with a Fisher exact test. **Results:** A total of 392 patients were identified, with 127 in the SS group, and 265 in the WL group. When compared to the WL group, patients in the SS group had shorter delays (mean of 12.8 minutes vs. 31.5 minutes; p=0.001), shorter patient wait from pre-op area arrival to OR times (median of 92 minutes vs. 124 minutes; p=0.04), and shorter case durations during partial mastectomy + SLNB cases (median of 87 minutes vs. 104 minutes; p=0.001). In addition, SS cases were less likely to be delayed (p=0.03) when compared to wire localization cases. However, this did not remain true when looking at only the first start cases of the day, where there was no statistically significant difference between the 2 groups having on time or delayed starts (p>0.99).

Conclusions: The SS group was shown to have fewer delays to the OR overall, though these did not translate to more on time first-start-of-the-day cases. The SS cohort was also shown to have decreased wait times in pre-op. Presumably, both of these results would have a positive impact on patient satisfaction with decreased waiting/delays prior to surgery, although this endpoint was not directly studied in this project. In addition, the SS group had decreased case durations noted to be statistically significant when looking at partial mastectomy + SLNB. A higher percentage of on-time starts and decreased case durations point to the potential financial benefits of using SS over WL, secondary to improved OR utilization. Establishing the SS as more efficient for OR utilization when compared to the gold-standard of WL has valuable impacts in guiding cost-effective patient care: improving health care spending with the likely additional benefit of improved patient satisfaction.

Margins

581642 - Differences in re-excision rates for breast-conserving surgery using intraoperative 2D vs. 3D tomosynthesis specimen radiograph

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Background/Objective: Intraoperative specimen radiographs performed during breast conservation surgery for cancer have been shown to reduce the need for re-excision for positive margins. At our institution, surgeons review specimen radiographs in the operating room without radiologist consultation for margin assessment. We studied 2D vs. 3D image-guided cavity margin excision and compared it to final pathology and need for additional surgery.

Methods: We conducted a retrospective review of 514 partial mastectomies performed for cancer, with or without localization, from January 2016 through October 2018. Procedures were performed by 4 surgeons at a single tertiary institution with access, in the operating room, to 3D tomosynthesis at the private hospital and 2D digital radiographs at the safety net hospital. Data collected included demographics, intraoperative margin assessment, tumor histology, final pathology, and re-excision rates. We explored the association between 2D radiographs and 3D tomosynthesis using a multivariable logistic regression model.

Results: A total of 323 patients had 2D, and 191 had 3D specimen imaging (Table). The 2D group had a higher mean age and BMI (p<0.001). The 2D group had a higher percentage of Hispanic and Black patients compared to the 3D group, which had more White and Asian patients (p < 0.001). More patients had DCIS on core biopsy in the 2D group (p<0.001). In the 3D group, there was a higher percentage of patients with mammographically heterogeneous or extremely dense breasts (p < 0.02). There was a similar distribution of mammographic findings, such as presence of a mass and calcifications (p=0.205) and receipt of neoadjuvant chemotherapy (p=0.363). Most patients underwent radioactive seed-guided localization than wire localizations for non-palpable lesions in both groups (p<0.01). Fifty-nine percent of patients in the 3D group had additional imaging directed cavity margins excised based on surgeons' interpretation vs. 26% of patients in the 2D group (p<0.01). Thirty-eight patients (12%) in the 2D group had positive margins in main tumor specimen vs. 16 patients (8%) in 3D group (p=0.226). Re-excision rate for 2D group was 11% vs. 5% for the 3D group (p=0.016). On multivariable analysis, the use of 3D tomosynthesis compared to 2D imaging (Odds ratio=0.41, 95% [CI 0.19-0.89]) and invasive ductal carcinoma histology compared to ductal carcinoma in situ disease (Odds ratio=0.29, 95% [CI 0.15-0.57]) were independently associated with decreased re-excision rates.

Conclusions: Although both hospitals had significantly different patient populations, the re-excision rates after breast conservation are relatively low. Even after accounting for these differences, 3D tomosynthesis is independently associated with a lower re-excision rate (over 50% reduction). This technique can allow the surgeon to make a better assessment of margins to direct margin excision at the index operation. This translates into decreased return to the operating room, decreased anxiety levels, and lower costs for our patients. Use of 3D tomosynthesis may be considered to reduce rates of re-excisions.

| Table: (| Characteristics | of 2D | vs 3D | imaging groups |
|----------|-----------------|-------|-------|----------------|
|----------|-----------------|-------|-------|----------------|

| | 2D Specimen | 3D Specimen | |
|--|-------------|-------------|-----------------------------|
| | Radiograph | Radiograph | P- value |
| | (n=323) | (n = 191) | |
| | n (%) | n (%) | |
| Age, mean and standard deviation | 58 ± 10.9 | 62 ± 11.2 | 0.001 |
| BMI in kg/m ² , mean and standard deviation | 33 ± 7.0 | 27± 5.8 | 0.001 |
| Race | | | 0.001 |
| Asian | 8 (3) | 29 (15) | |
| Black | 133 (41) | 18 (10) | |
| Hispanic | 149 (46) | 8 (4) | |
| White | 33(10) | 136 (71) | |
| Core Biopsy | | | 0.003 |
| Ductal carcinoma in situ only | 93 (29) | 36 (19) | |
| Invasive ductal carcinoma | 210 (65) | 133 (70) | |
| Invasive lobular carcinoma | 13 (4) | 20 (10) | |
| Invasive mammary | 7 (2) | 2 (1) | |
| Mammographic Density | | | 0.019 |
| Almost entirely fatty | 11 (3) | 7 (4) | |
| Scattered fibroglandular | 204 (63) | 99 (52) | |
| Heterogenous dense | 106 (33) | 79 (41) | |
| Extremely dense | 2 (1) | 6 (3) | |
| Initial Mammographic Finding | | | 0.205 |
| Mass | 171 (53) | 102 (54) | |
| Focal asymmetry/density | 65 (20) | 47 (25) | |
| Calcifications | 87 (27) | 39 (21) | |
| Receipt of Neoadjuvant Chemotherapy | | | 0.363 |
| No | 253 (78) | 156 (82) | |
| Yes | 70 (22) | 35 (18) | |
| Lesion Localization | | | 0.001 |
| Wire | 80 (25) | 4 (2) | |
| Seed | 231 (71) | 183 (96) | |
| None (palpable lesion) | 12 (4) | 4 (2) | |
| Cavity Directed Margins Excised | | | 0.001 |
| No | 240 (74) | 79 (41) | 1982 - 2000 11 - C.1988 C.1 |
| Yes | 83 (26) | 112 (59) | |
| Positive Margins in Main Specimen | | | 0.226 |
| No | 285 (88) | 175 (92) | |
| Yes | 38 (12) | 16 (8) | |
| Re-Excision Performed | | | 0.016 |
| No | 288 (89) | 182 (95) | |
| Yes | 35 (11) | 9 (5) | |

581586 - Accuracy of intraoperative gross margin assessment in partial mastectomy

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Background/Objective: Partial mastectomy (PM) for breast cancer requires achieving clear margins while maximizing cosmesis. Positive margins mandate additional surgery. Wide variability exists in assessing intraoperative margins. We examined the accuracy of intraoperative gross margin assessment (IGM) in PM, and other factors that may affect final margin status. We hypothesized that both IGM was accurate and reliable when compared to the final histopathologic margin, and use of IGM assessment would ultimately result in a lower rate of second operations.

Methods: A retrospective study of patients with invasive breast cancer undergoing PM from January 2014 to December 2016 at the University of Vermont Medical Center was performed. Patients with in situ disease, neoadjuvant therapy, or prior ipsilateral breast irradiation were excluded. Five hundred two operations met inclusion criteria, where IGM was utilized in 307 of these cases. Data regarding reexcision rate, intraoperative/final histopathologic margin width, closest margin laterality, final margin positivity, change in margin status, localization method, specimen weight, histologic subtype/grade, tumor size, and nodal status were collected.

Results: Re-excision rate for patients who underwent IGM was significantly less than previously published conservative large series rates (12% vs 22%, p<0.001). No difference was detected between estimated closest IGM width and final closest histopathologic margin width (p>0.05). There was agreement between IGM and final closest pathologic margin laterality (total agreement 70%, p>0.05). Ten percent of patients who underwent IGM had positive final margins. Twelve percent of patients who underwent IGM had a change from positive to negative final margin status. Patients who underwent IGM had significantly more frequent changes in final margin status compared to patients who did not have IGM (p<0.001).

Conclusions: IGM demonstrated excellent accuracy when compared to final histopathologic margins, and resulted in fewer re-operations due to positive margins than would be expected based on previously published rates. We recommend IGM as a reliable tool for surgeons to enhance intraoperative decision making.

581967 - Can imaging-guided selective margin resection during lumpectomy for invasive breast cancer result in low re-excision rates?

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Background/Objective: Margin re-excision rates after lumpectomy for invasive breast cancer can be as high as 40%. Positive margins are associated with a two-fold increase in risk of ipsilateral breast tumor recurrence. Routine circumferential cavity shave margins have been reported to half the re-excision rate. The use of selective margin resection has limited and conflicting data. The objective of this study was to determine if selective margin resection guided by intraoperative imaging during lumpectomy can result in low margin re-excision rates.

Methods: Patients with invasive breast cancer treated with breast conservation therapy from November 2011 through May 2018 were identified using an institutional surgery database and retrospectively reviewed. Patient demographics, tumor characteristics, operative details, pathology results, complications, and survival were collected. Lumpectomy specimens were labeled using radiopaque markers on 6 sides and imaged with 2 view radiograph and/or ultrasound. Additional margins were resected at the discretion of the surgeon based on the imaging.

Results: A total of 175 female patients were included, and the median age was 56 years. Of those, 117 (67%) were clinical Stage I and 58 (33%) were clinical Stage II. Selective margins were resected in 102 (58%) patients, and the mean number of margins resected was 1.6. Twenty-seven (15%) patients had a positive margin on the lumpectomy specimen, and in 9 of those, the corresponding margin was selectively resected concurrently with only 1 persistently positive margin. Twenty (11.4%) patients required reoperation for margin re-excision. There was no difference in the mean total excised tissue volume between patients who did and did not have selective margins resected ($108 \pm 62 \text{ cm}3 \text{ vs } 98 \pm 55 \text{ cm}3$,

p=0.18). The mean volume of re-excision specimens was significantly larger than selective margin resection specimens ($16 \pm 22 \text{ cm}3 \text{ vs} 9 \pm 9 \text{ cm}3$, p=0.03). The rates of seroma and surgical site infection did not different between patients who did and did not have selective margins resected. The Kaplan-Meier 5-year recurrence-free survival and overall survival were 91% (95% CI 85-95%) and 96% (95% CI 92-98%), respectively.

Conclusions: Using imaging-guided selective margin resection, the rate of re-operation for margin reexcision was low at 11.4%. Selective margin resection did not significantly increase the total volume of tissue excised or the risk of seroma or surgical site infection. The re-excision rate was potentially reduced by half and is comparable to that reported for cavity shave margins.

581798 - MarginProbe use reduced positive margins and lumpectomy volumes

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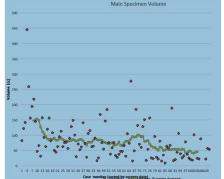
Background/Objective: The MarginProbe device (Dune Medical Devices, Ceasarea, Israel) has been utilized by some centers to decrease positive lumpectomy rates. We reviewed our outcomes using the device in respect to rates of positive lumpectomy margins and volumes of lumpectomy specimens.

Methods: We prospectively collected the data on our first consecutive 111 lumpectomies performed during the first 12 months of use of the device from April 2015 to March 2016. This was compared to a historical cohort of 87 consecutive lumpectomies performed during the 12 months just prior to this time period. The 2 groups were similar in patient characteristics and tumor types.

Results: In the historical control group of 87 lumpectomies, 9 (10.3%) cases of inadequate margins were identified. The margins were inadequate in 5 (4.5%) of the 111 lumpectomies performed where the MarginProbe was used (p=0.16 by 2-tailed Fisher's exact test). The mean specimen size in the control group was 132 +/- 19 cubic centimeters (95% CI) compared to 81+/- 13 cubic centimeters (95% CI) in the MarginProbe group (p<0.00001). We also observed a steady decrease in lumpectomy volume as experience was gained using the device (Figure).

Conclusions: These results were able to demonstrate favorable outcomes with the MarginProbe device for reducing positive margins while simultaneously reducing the size of the main lumpectomy specimen. Most centers using the device report a reduction in positive margins by about 50%. This study was unique in that it included the assessment of the lumpectomy volumes as well. Further studies with randomization to the use of this device versus other intraoperative methods of margin assessment would be valuable.

Figure: Main specimen lumpectomy volumes



581432 - Impact of consensus guidelines for breast-conserving surgery in DCIS

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Background/Objective: Until recently, there was no universal definition for negative margins in breast conserving surgery (BCS). In 2014, the SSO-ASTRO consensus guidelines for breast conservation therapy (BCT) recommended no ink on tumor as the standard for negative margins in patients with early-stage invasive breast cancer. In 2016, the SSO-ASTRO-ASCO consensus guidelines for BCT in DCIS recommended 2mm as the standard for negative margins. Both of these guidelines sought to standardize re-excision practices for BCS in order to decrease re-excision rates and health care costs, while minimizing the risk of ipsilateral breast tumor recurrence (IBTR). We previously reported on the potential impact of the 2014 guideline on our institution's practice, with an estimated reduction of over 5% in re-excision rates for invasive disease. We now evaluate the impact of the 2016 guidelines at our institution.

Methods: We identified all patients at our institution with pure DCIS who were initially treated with BCS from September 2014 to August 2018 using a prospectively-maintained institutional database. A retrospective chart review of these patients was performed to determine margin status and re-excision rates during the 2 years before and 2 years after the guidelines were published in order to determine the effect on our re-excision rates. Close margins were defined as <2mm.

Results: In the 2 years before the consensus guidelines were published, 180 patients with DCIS underwent initial BCS. Twenty-four patients had positive margins, and 22 underwent re-excision, including 3 mastectomies. Of the remaining 156 patients, 77 had \geq 2mm margins. The remaining 79 patients had close margins, and 45 (57%) of these patients underwent re-excision, including 1 mastectomy. Excluding the patients with positive margins, our re-excision rate was 28.8%. In the 2 years after the consensus guidelines were published, 156 patients with DCIS underwent initial BCS. Nineteen patients had positive margins, and 17 underwent re-excision, including 2 mastectomies. Of the remaining 137 patients, 82 patients had \geq 2mm margins. The remaining 55 patients had close margins, and 35 (63.6%) of these patients underwent re-excision, including 5 mastectomies. Excluding the patients with positive margins, our re-excision rate was 25.5%.

Conclusions: Our institution's re-excision rate did not change significantly during the 2 years before and after the publication of the SSO-ASTRO-ASCO consensus guidelines on margins for BCT in DCIS. An interesting trend was observed, however. Our overall re-excision rate decreased slightly; but, of the patients who had close margins, a larger proportion underwent re-excision after the guidelines were published. The guideline publication appears to have affected our institutional practices slightly, but not dramatically, as many of our surgeons' practices were comparable to the guideline recommendations prior to 2016. We continue to use clinical judgement based on patient and tumor characteristics in deciding which patients will benefit from margin re-excision.

581663 - The case for MarginProbe in the era of no ink on tumor - Impact on re-excision and tissue volume using radiofrequency spectroscopy post-consensus guidelines Rhonda Wachsmuth

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Background/Objective: In an effort to reduce national re-excision rates, in 2014, the Society of Surgical Oncology and the American Society for Radiation Oncology announced a Consensus Guideline of "No Ink on Tumor" to define positive margin for early-stage invasive cancer in patients undergoing breast-conserving therapy (BCT). Post Consensus Guideline adoption, our re-excision rate was 12.1%. We sought to determine if utilizing MarginProbe Radiofrequency Spectroscopy could further reduce positive margin and subsequent re-excision rate, without increasing excised tissue volume, in the "No Ink on Tumor" era.

Methods: We present a retrospective, observational review of 243 consecutive patients treated from January 2016 - April 2018. All patients were treated post-adoption of Consensus Invasive Guideline of "No Ink on Tumor" and represent the 157 consecutive patients directly before, and 86 consecutive patients directly after, implementation of MarginProbe for intraoperative margin assessment. Both groups comprised newly diagnosed invasive cancer or DCIS patients with consistent standard of care to include intraoperative ultrasound guided wire localization, intraoperative x-ray specimen imaging, and intraoperative margin color inking for orientation. Patients who received neoadjuvant chemotherapy were excluded from analysis.

Results: Utilization of MarginProbe produced a statistically significant relative reduction in re-excision of 71%. Re-excision rate in the historical group was 12.1% (19/157), with new re-excision rate in MarginProbe group of 3.5% (3/86, p=0.0334). Total tissue volume removed was decreased from 69cc to 59cc, a 14% decrease in the MarginProbe group. Additionally, in 10% (9/86) of the cases, malignant tissue (7 DCIS, 1 IDC, 1 ILC) was found in shavings directed by MarginProbe, for which histopathology reported main specimen clear. These cases represent disease that was identified and removed through MarginProbe directed shaving, which would have otherwise remained unknowingly in the breast as residual disease.

Conclusions: The 2014 Consensus Guideline of "No Ink on Tumor" to define positive invasive margin seeks to reduce national re-excision rates while consequently reducing cost to the health care system and improving quality of care and patient satisfaction. Multiple studies to date indicate a relative reduction in re-excision of 8-33% after adoption of the invasive margin guidelines. Implementing MarginProbe radiofrequency spectroscopy as standard of care further reduces rates of re-excision beyond those achieved with Consensus Guidelines alone, reaching low single-digit rates, and no increase in total volume of tissue removed. Additionally, malignant disease, both invasive and DCIS, which would have been previously unknown, can be identified and removed utilizing MarginProbe for directed shaves. Future studies should seek to determine if this identification and removal of residual disease will have a positive effect on local recurrence rates.

NAC

582099 - Impact of progesterone receptor status on response to neoadjuvant chemotherapy in oestrogen receptor-positive breast cancer patients: Should we be changing our approach?

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Background/Objective: Breast cancer patients respond differently to neoadjuvant chemotherapy (NAC) based on hormone receptor subtype. Oestrogen receptor positive/HER-2 receptor negative (ER+HER-) patients respond poorest but the effect of progesterone receptor (PR) status on response within this group has not been elucidated. The aim of this study was to assess the impact of PR status on response to NAC in ER+HER- breast cancer patients.

Methods: All patients receiving NAC over a 7-year period (2011-2017) were retrospectively identified from a prospectively maintained database within a specialised breast referral unit. Clinicopathological details were collated for all patients found to be ER+HER-. Primary outcomes including breast complete pathological response (PCR) rate and axillary PCR rate were compared between patients found to be progesterone receptor-positive and negative. Secondary outcomes including grade and presence of lymphovascular invasion were also assessed.

Results: A total of 206 patients were identified (151 in the ER+PR+HER- group and 55 in the ER+PR-HER- group). When compared with the PR+ group, patients found to be PR-negative were more likely to achieve a breast PCR (3.3% vs 25.4%; Chi Square test; p=0.001). In patients who were initially node-positive, PR negativity was associated with a higher rate of axillary nodal PCR compared to those found to be PR positive (12.2% vs 25.5%; Chi Square test; p=0.04). ER+PR-HER- patients were more likely to have higher-grade tumours but not LVI.

Conclusions: Over a quarter of ER+HER- patients who are PR-negative will have a complete pathological response to NAC in the breast and axilla. Such patients should be considered for NAC at diagnosis.

577632 - Is MRI an accurate predictor of nodal status after neoadjuvant chemotherapy? <u>Chandler Cortina</u>, Swati Kulkarni, Nadine Gottschalk, Ingolf Karst *Northwestern University Feinberg School of Medicine, Chicago, IL*

Background/Objective: Surgical management of the axilla after neoadjuvant chemotherapy (NAC) remains an area of uncertainty. Pre-operative imaging assessment of axillary nodes is essential in patient counseling and operative planning. We aimed to identify if magnetic resonance imaging (MRI) can be an accurate predictor of axillary nodal status after NAC.

Methods: Our IRB-approved and HIPAA-compliant proprietary prospective database was used to review all newly diagnosed breast cancer patients between August 2015 and March 2017 who received NAC at our institution. Post-NAC MRI findings and surgical pathology results were analyzed. The axillary nodal

status post NAC was evaluated on post-NAC MRI and compared to the final surgical pathology outcome to determine the positive and negative predictive value.

Results: In total, 114 patient received NAC during this time period, and 50 underwent post-NAC MRI prior to surgical intervention. The mean patient age was 46 years (range of 20-62). Thirty-eight percent were triple-negative, 28% were triple-positive, 20% were estrogen receptor (ER)-positive and human epidermal growth factor receptor 2 (HER2)-negative, and 12% were ER- and HER2+. In 35 patients with a negative nodal status on post-NAC MRI, 26 patients had a negative axillary result on final surgical pathology representing a negative predictive value (NPV) of 74.3% (26/35). In 15 patients with a positive nodal status on post-NAC MRI, 8 patients had a positive axillary result on final surgical pathology with a positive predictive value (PPV) of 53.3% (8/15).

Conclusions: Axillary imaging findings on post-NAC MRI do not predict pathologic outcome with adequate accuracy to replace post-NAC surgical pathologic evaluation of axillary nodes. Our findings are similar to that of previous studies evaluating prediction of axillary nodal status after NAC. This information can be valuable in patient counseling and surgical management of the axilla regarding the role of sentinel node biopsy after NAC.

| | | Pathology Outcome | | | | | Predictive Value | |
|---------------------------|----------|-------------------|-------|----------|-------|-------|------------------|-------|
| | | Positive | | Negative | | Total | | |
| | | N | % | N | % | Ν | PV | % |
| MRI Axillary Status | Positive | 8 | 53.3% | 7 | 46.7% | 15 | PPV | 53.3% |
| | Negative | 9 | 25.7% | 26 | 74.3% | 35 | NPV | 74.3% |
| | Total | 17 | | 33 | | 50 | | |

Table: NAC and MRI

577947 - Changes in surgical management over time in breast cancer patients treated with neoadjuvant chemotherapy

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Background/Objective: With advances in systemic and targeted therapies for breast cancer (BC), downstaging following neoadjuvant chemotherapy (NAC) has increased. Surgical management of both the breast and axilla has evolved with the increasing use of partial mastectomy and sentinel lymph node biopsy (SLNB). We examined our institutional experience with NAC and temporal trends in surgical technique over time.

Methods: From a prospectively maintained database, 352 women with Stage I-III BC were identified who underwent NAC followed by an operation between 2007-2017. Clinicopathologic factors and surgical management were assessed for the entire cohort. We then compared trends over time between 2 groups: early group (diagnosed 2007-2013) and recent group (diagnosed 2014-2017). Continuous and categorical variables were compared using the Welch t-test and Chi-square test. Median follow-up was determined by the reverse Kaplan-Meier method. Time-to-event analysis was compared using the log-rank test.

Results: The median age for the entire cohort was 50 years (IOR 41-60 years), and 194 (55.9%) patients had estrogen receptor (ER)-positive, 146 (42.1%) had HER2+, and 90 (25.9%) had triple-negative (TN) tumors. For staging, 257 (74.7%) patients had T1-2 tumors, 85 (24.7%) had T3-4 tumors, and 203 (58.5%) were cN+. Most patients underwent unilateral mastectomy (26.7%) or bilateral mastectomies (41.8%) compared to partial mastectomy (31.5%). For the management of the axilla, 170 (48.3%) patients had axillary lymph node dissection (ALND), 155 (44.0%) had SLNB, and 26 (7.4%) had both. Pathologic complete response (pCR) was seen in 113 (32.2%) patients. Of those patients with pCR, most had HER2+ (68.1%) or TN (24.8%) tumors. There was no difference in age, rate of ER+ and TN tumors, or clinical T stage between the early and recent groups. Compared to the early group, the recent group had more HER2+ tumors (53.1% vs 30.4%, p<0.001), were more often cN0 (52.3% vs 30.4%, p<0.001), and less likely to have staging imaging (75.4% vs 86.0%, p=0.017). For surgical management, the recent group was significantly more likely to have partial mastectomy (37.4% vs 25.4%, p=0.021) and SLNB alone (63.1% vs 24.3%, p<0.001) compared to the early group. There was no difference in postoperative complications between groups. There was a higher rate of pCR in the recent group (41.6% vs 22.5%, p < 0.001). With a median follow-up of 43.7 months, there was no significant difference between groups in breast recurrence (p=0.887), axillary recurrence (p=0.298), and distant recurrence (p=0.455).

Conclusions: Rates of breast-conserving surgery and SLNB following NAC significantly increased after 2013. The rate of pCR increased in more recent years likely due to improved therapies and patient selection. There was a low rate of locoregional recurrence overall with no increase in recurrence with less aggressive surgical management.

582126 - Time to initiation of neoadjuvant chemotherapy for breast cancer treatment does not influence patient survival: A National Cancer Database study

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Background/Objective: Delays in the initiation of adjuvant chemotherapy or radiation therapy are associated with worse outcomes in patients undergoing treatment for breast cancer. However, the impact of the time to initiation of neoadjuvant chemotherapy (NAC) on patient outcomes has not been previously studied. This question has gained clinical importance as more women undergo NAC. The purpose of this study was to determine if delays in NAC initiation impact patient survival.

Methods: We queried the National Cancer Database for women >18 years old who underwent NAC for Stage 1-3 invasive breast cancer from 2010-2011 and had known ER, PR, and HER2 receptor status. These years were chosen to ensure 5 years of follow-up. Due to their high 5-year survival rates, patients with ER/PR+ HER2- disease were excluded from the study. Additionally, patients who started NAC more than 180 days following their diagnosis (5.7% of cohort) were excluded from the study. Patients with triple-negative and HER2+ disease were analyzed separately. We dichotomized time to NAC based on an empirically based cutpoint identified by building Cox proportional models using 3, 4, and 5 weeks to determine the time point most likely to be associated with significance in our full model. Cox proportional hazard modeling was then used to evaluate the relationship between time to NAC, sociodemographic, diagnosis, and treatment factors with patient survival.

Results: The median age of the 12,080 women included in this study was 52 (range 21-90), with 51% presenting with Stage 2 disease. A total of 6,448 women had triple-negative, and 5,632 had HER2+ cancers. The median time to starting NAC was 4 weeks (range 0-26 weeks). Based on the optimal

cutpoint method, the cutoff for time to NAC was set to 4 weeks for triple-negative and 5 weeks for HER2+ cancers. Time to NAC initiation was not associated with a difference in survival in triple-negative (HR 1.10, p=0.15) or HER2+ cancers (HR 0.91, p=0.37).

Conclusions: Our findings demonstrate that the majority of women in the modern era start NAC in a timely fashion. We found that there was no effect of time to NAC on patient survival for triple-negative or HER2+ disease. This study supports continued efforts to deliver timely NAC, with limited evidence to suggest that delays in starting NAC impact long-term patient outcomes.

| | | Her2+ (cutoff 5 wk) | | Triple Negative (cutoff 4 wk) | | |
|------------------------|---|---------------------|---------|-------------------------------|---------|--|
| | | HR (95% CI) | p-value | HR (95% CI) | p-value | |
| T to NAC** | | 0.91 (0.74, 1.12) | 0.37 | 1.10 (0.97, 1.24) | 0.15 | |
| clining. | 1 | Ref | | Ref | | |
| Clinical | 2 | 1.00 (0.72, 1.40) | 0.98 | 1.09 (0.88, 1.36) | 0.42 | |
| Stage | 3 | 1.36 (0.94, 1.96) | 0.098 | 1.60 (1.27, 2.02) | < 0.001 | |
| | 4 | 1.70 (1.20, 2.41) | 0.003 | 2.4 (1.90, 3.03) | <0.001 | |
| Clinical N Stage | 0 | Ref | | Ref | | |
| | 1 | 1.38 (1.09, 1.75) | 0.008 | 1.89 (1.63, 2.20) | <0.001 | |
| | 2 | 1.83 (1.33, 2.53) | < 0.001 | 2.22 (1.82, 2.72) | <0.001 | |
| | 3 | 1.83 (1.23, 2.71) | 0.003 | 3.11 (2.51, 3.87) | <0.001 | |
| ER/PR- | t | 0.59 (0.48, 0.71) | < 0.001 | | | |

Table: Cox proportional hazard model of the association between time to NAC initiation and patient survival

* Other variables measured at the time of diagnosis and included in the model were: age, race, ethnicity, comorbidities, education, income, insurance type, facility type, geographic location and tumor grade

570881 - De-escalation of breast surgery after neoadjuvant therapy for breast cancer: Could we do better?

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Background/Objective: The use of neoadjuvant therapy (NAT) in breast cancer treatment has increased. Randomized control trials have shown no difference in disease-free or overall survival with neoadjuvant versus adjuvant therapy. Along with other advantages, NAT can increase surgical options converting mastectomy to breast-conserving surgery (BCS) or axillary lymph node dissection (ALND) to sentinel lymph node biopsy (SLNB). Our objective was to review the current surgical management of the breast following NAT, focusing on the tumour biology and surgical pathology to identify the success of BCS following NAT and missed opportunities to de-escalate breast surgery. We hypothesize that BCS after NAT is underutilized at our institution; however, when performed, it has a low failure rate.

Methods: A review of a prospectively maintained breast cancer database at Mount Saint Joseph Hospital was conducted to identify patients with invasive breast cancer who received NAT between January 1, 2012 and December 31, 2017. Analyses were done to determine rates of BCS versus mastectomy, indications for re-operation, rates of BCS failure, and histologic and hormone receptor profiles associated with pathologic complete response (pCR).

Results: A total of 278 patients were identified with invasive breast cancer who received NAT during the specified time period. Use of NAT increased significantly over the study period. Seventy-nine (28.4%) patients underwent BCS, and 199 (71.6%) underwent mastectomy or mastectomy and breast reconstruction. Rates of BCS following NAT also increased; in 2012, 10% of patients underwent BCS with this number increasing to 38% in 2016, with slightly less than this seen in 2017. Of the 79 patients that underwent BCS, 12 (15%) required re-operation with either revision of positive margin (8/12) or completion mastectomy (4/12), resulting in a BCS failure rate of 5%. pCR in the breast was achieved in 82 (29.3%) patients. Rates of pCR were higher in the BCS group 25/79 (31.6%) compared to the mastectomy group 57/199 (28.6%), although these results were not significant (p=0.36). Of the 57 patients who underwent mastectomy and achieved a pCR, 39 were identified as patients who would have been candidates for BCS, as these patients had unifocal disease with a good clinical response to NAT. pCR was achieved more often in hormone receptor-negative/HER2 receptor-positive (HR-/HER2+) patients (p=0.01). Of the 75 patients who had successful BCS after 1 or more surgeries, 17 (22.6%) were HR-/HER2+, and of the 39 patients deemed appropriate for BCS but had mastectomy, 12 (30.7%) were HR-/HER2+.

Conclusions: Rates of NAT are increasing at our institution as are the rates of BCS following NAT. Current methods of patient selection have proven successful given low rates of BCS failure and higher rates of pCR in BCS compared to mastectomy. Missed opportunities still exist to de-escalate surgical management of the breast. With further characterization of patient and tumour profiles associated with successful BCS and breast pCR, patient selection could be further optimized to select additional patients suitable for BCS following NAT, reducing the morbidity associated with more extensive breast surgeries.

577343 - Survival outcomes in patients with complete response following neoadjuvant chemotherapy: Is omitting surgery an option?

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Background/Objective: Neoadjuvant chemotherapy (NAC) is an accepted approach for locally advanced breast cancer (LABC) and for some early-stage breast cancer patients with biologically aggressive subtypes, such as HER2-positive and triple-negative disease. When pathologic complete response (pCR) is achieved in the axilla, select patients may de-escalate axillary surgery; however, there is a lack of evidence for how to minimize or even obviate surgery to the primary tumor site. The objective of this study was to evaluate the survival outcomes of patients with complete clinical response to NAC who did not undergo surgery to the breast.

Methods: The National Cancer Database (NCDB) was used to identify 83070 women with cT1-3, N0-3, M0 breast cancer who underwent NAC between 2010 and 2015. Patients with only in-situ cancer, more than 1 cancer over the lifetime, and did undergo surgery to primary site were excluded. Overall survival (OS) was determined. A matched group analysis was used to compare survival outcomes between patients who did and did not undergo surgery following NAC.

Results: Of the 350 NAC patients who did not undergo surgery, 45 (12.9%) had complete clinical response (cCR), 51 (14.6%) had clinical partial response (cPR), 241 (68.9%) had response but not recorded if complete or partial (R), and 13 (3.7%) had no response (NR) recorded to NAC. With a median follow-up of 30 months, 3-year OS rates were 96.8%, 86.2%, 81.7%, and 78.7% for the cCR, cPR, R, and

NR groups, respectively. When the OS of the cCR group was compared with the rest of the cohort, 5-year OS was better in cCR group (96.8% and 69.8%, p=0.004). Furthermore, Kaplan-Meier 3-year OS analysis of cCR patients without surgery (n=45, median follow-up 37 months) compared with similar group of patients who underwent surgery (n=3938, median follow-up 43 months) show no significant difference (96.8% and 92.5% respectively, p=0.18).

Conclusions: Although no surgery to the primary site after NAC is not a standard practice, studies are underway to determine if a subgroup of patients may not need surgery on the primary tumor when achieving a cCR. This retrospective cohort study demonstrated that in patients who achieve cCR following NAC, active surveillance or de-escalating therapy to the primary tumor site could be an option to consider in the future as these data do support the conduct of these studies.

581935 - Breast cancer with a higher proportion of tumor cells staining positive for HER2 is more likely to have complete pathologic response and better clinical outcome after neoadjuvant chemotherapy

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Background/Objective: Achievement of pathologic complete response (pCR) following neoadjuvant chemotherapy (NAC) is associated with favorable outcomes in patients with aggressive breast cancer subtypes such as HER2+. However, pCR rates are modest (20-50%), and accurate predictors of pCR in the treatment setting remain unclear. We propose that women with higher immunohistochemistry percentage (IHC%) staining for the HER2 receptor are more likely to have a pCR following NAC.

Methods: A single institutional database was queried to identify our study cohort (n=299) comprising all newly-diagnosed, stage 1-3, HER2+ breast cancer patients who received NAC between January 1, 2009 and September 4, 2018. We assessed the distribution of IHC% scores and noted that the distribution was negatively skewed (skew= -0.62), precluding the use of IHC% as continuous variable. A logit transformation was used to normalize the IHC% expression levels and values corresponding to one SD above the mean (4.59) comprised the "High IHC%" cohort. This normalized value correlated to a non-normalized IHC% value of 100%. Comparisons of covariates was performed using one-way ANOVA and Chi-Square tests. Univariate and multivariate logistic regression was employed to evaluate IHC% as a predictor of recurrence and outcome. Stata/SE 15.1 (StataCorp, College Station, TX) was used for all analyses.

Results: A total of 299 patients fit all eligibility criteria; however, 196 patients were excluded for having missing IHC%. A total of 103 patients were available for analysis. Patients with high IHC% were significantly more likely to have pCR (67.67% vs. 47.22%, p=0.05). Demographic information, clinical stage, ER/PR status, and surgery type did not differ between the 2 groups. Recurrence rates were significantly higher in the low IHC group (25% v. 6.45%, p=0.029), and most of these patients experienced distant metastasis (n=16, 88.89%, p=0.023). In univariate regression analysis, low IHC% was a predictor of both recurrence (OR: 4.83, p=0.043) and decreased overall survival (OR: 10.56, p=0.107). In a multivariate logistic regression analysis, low IHC% was trending towards significance as a predictor of both recurrence (OR: 4.03, p=0.084) and diminished overall survival (OR: 9.04, p=0.120) after controlling for clinical stage at diagnosis, age, and response to NAC. No other covariate served as a predictor of recurrence or survival during regression analysis.

Conclusions: In this single-institution investigation, high IHC% staining for the HER2 receptor protein was correlated with higher rates of pCR and favorable outcomes. Our results suggest clinical utility of

IHC% as a potential biomarker in predicting the benefits of NAC in the treatment of breast cancer. Given our limited sample size, further investigation to elucidate the mechanisms underlying this observation is warranted.

| | High IHC% | | Lov | p value | |
|--------------------|-----------|-----------|---------|-----------|-------|
| n=103, 100% | 31 | 30.10% | 72 | 69.90% | |
| Complete Response | 21 | 67.74% | 34 | 47.22% | 0.05 |
| Partial Response | 10 | 32.26% | 38 | 52.78% | 0.05 |
| BMI, mean ± SD | 27.9 | 5 ± 6.58 | 29.8 | 4 ± 8.37 | 0.313 |
| Age, mean ± SD | 46.83 | 5 ± 12.15 | 48.40 |) ± 11.54 | 0.534 |
| Race | | | | | |
| White | 21 | 67.74% | 51 | 70.83% | 1.000 |
| Black | 7 | 22.58% | 19 | 26.39% | 0.32 |
| Other | 3 | 9.68% | 2 | 2.78% | |
| HR Receptor Status | | | 1225.71 | | |
| ER+ | 16 | 51.61% | 44 | 61.11% | 0.37 |
| PR+ | 11 | 35.48% | 30 | 41.67% | 0.557 |
| Clinical Stage | | 2 | | | 24 |
| 0 | 2 | 6.45% | 2 | 2.78% | |
| 1 | 2 | 6.45% | 7 | 9.72% | 0.551 |
| 2 | 19 | 61.29% | 37 | 51.39% | 0.551 |
| 3 | 8 | 25.81% | 26 | 36.11% | |
| Definitive Surgery | | | | | |
| Lumpectomy | 11 | 35.48% | 30 | 41.67% | 0.486 |
| Mastectomy | 20 | 64.52% | 40 | 55.56% | 0.460 |
| Treatment | | | | | 34 |
| Hormone Therapy | 16 | 51.61% | 41 | 56.94% | 0.683 |
| Radiation Therapy | 13 | 41.94% | 48 | 66.67% | 0.012 |
| Recurrence | 2 | 6.45% | 18 | 25.00% | 0.029 |
| Deceased | 0 | 0.00% | 10 | 13.89% | 0.029 |

Table: Demographic, cancer, and treatment characteristics stratified by IHC%

576750 - Patterns in utilization of axillary operations in patients with node-positive breast cancer following neoadjuvant chemotherapy: A National Cancer Database (NCDB) analysis

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Background/Objective: American College of Surgeons Oncology Group (ACOSOG) Z1071 and Sentinel Neoadjuvant (SENTINA) trials published in 2013 demonstrated a significant false-negative rate of sentinel node mapping in the setting of node-positive breast cancer treated with neoadjuvant chemotherapy (NAC). There is controversy whether sentinel lymph node biopsy is appropriate in this patient population. The purpose of this study was to evaluate trends in axillary dissection and sentinel node biopsy before and after publication of the ACOSOG Z1071 and SENTINA trials.

Methods: Patients from National Cancer Database (NCDB) from 2012 to 2015 who had clinical T0 through T4, N1 through N2, M0 breast cancer and received NAC who had a sentinel lymph node biopsy (SNB) or axillary lymph node dissection (ALND) were examined. Patients were divided into 3 groups based on type of axillary operation: SNB, ALND, or both (SNB + ALND).

Results: A total of 32,036 patients with clinical T0 through T4, N1 through N2, M0 breast cancer who underwent axillary operations were identified. Of these, 5,565 patients had a SNB, 19,930 patients had an ALND, and 6,541 patients had both. Compared with the ALND group, patients in the SNB group were younger, less often Caucasian (74.5% vs. 75.0%, p=0.015), had higher rate of ductal cancer (86.7% vs. 81.0%, p<0.001), had a lower clinical T stage (p=<0.0010), and a higher rate of ductal cancer (86.7% vs. 82.3%, p<0.001). Patients in the SNB group had a higher rate of estrogen receptor-positive cancer (51.3% vs. 41.9%, p<0.001), lower rate of HER2-positive cancer (72.4% vs. 74.8%, p<0.001), but higher rate of triple-negative breast cancer (31.7% vs. 26.3%, p<0.001). For patients with N1 and N2 disease whose operative report was available, 5,157 (17.1%) had a SNB, 18.787 (62.3%) had a ALND, and 6,229 (20.6%) had both a SNB and ALND: pathologic complete response (PCR) rate was 66.5% in the SNB group (IQR 2-6), 13 for the ALND group (IQR 8-19), and 11 for both SNB and ALND group (IQR 6-17). Since 2013, the rate of ALND has decreased from 88.7% pre-trial to 77.1% post-trial across both community and academic institutions (p<0.001) [Table].

Conclusions: Since the ACOSOG Z1071 and SENTINA trials, national rates of ALND in node-positive breast cancer treated with NAC have decreased despite the higher false-negative rates seen in this setting.

| | Total | Community Cancer Program (CCP) | Comprehensi ve CCP (CCCP) | Academic/ Research Program | Integrated Network Cancer Program | |
|--------------------------|--|---|---------------------------------|----------------------------------|--|---------|
| | (N = 23,047) | (N = 2,084) | (N = 9,974) | (N = 7,986) | (N = 3,003) | P-Value |
| 2012 (pre- trial) | 5978 (88.7%) | 444 (86.5%) | 2524 (87.2%) | 2162 (91.2%) | 848 (87.8%) | <0.001* |
| 2013 (post -trial) | 5598 (85.7%) | 573 (87.2%) | 2392 (84.8%) | 1932 (87.5%) | 701 (82.9%) | |
| 2014 | 5678 (80.9%) | 548 (83.9%) | 2495 (80.3%) | 1895 (81.3%) | 740 (80.0%) | |
| 2015 | 5793 (77.1%) | 519 (76.8%) | 2563 (76.9%) | 1997 (78.7%) | 714 (74.1%) | |
| | tical significance mic/Research, ar | | | CP (p=0.037); To | tal, CCCP, | |

574500 - Impact of surgical timing on postoperative complications following neoadjuvant chemotherapy for breast cancer

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Background/Objective: Neoadjuvant chemotherapy (NAC) is increasingly used in the treatment of breast cancer. Prior studies have not shown an increased risk of postoperative complications following NAC; however, the timing of surgery in relation to the last dose of NAC can vary widely in practice. There is a recognized increase in the risk of wound complications when surgery is performed shortly after chemotherapy; however, the optimal time interval from last dose of cytotoxic chemotherapy to surgery (ICS) has not been studied in breast cancer. We reviewed our institutional experience with an eye towards the impact that ICS may have impact on postoperative complications and patient recovery.

Methods: A retrospective review of the prospectively maintained Legacy Health System Breast Cancer Database was performed for women treated with NAC from January 2011 through December 2016. Charts were reviewed for postoperative complications, and a multivariate analysis was performed accounting for patient age, surgeon, operation type (mastectomy versus lumpectomy), extent of lymph node dissection (sentinel lymph node biopsy versus axillary lymph node dissection), and ICS. Survival and recurrence data were also captured.

Results: There were 3571 patients diagnosed with breast cancer in the database during the study period. Of these, 455 patients were treated with NAC. On multivariate analysis, increasing age had the strongest association with the presence of any postoperative complication (p<0.0001); however, ICS of 28 days or less was also associated with the presence of any complication as well as non-seroma complications (p<0.05 for both). For complications requiring specific treatment, increasing age (p<0.001), mastectomy (p<0.05), and surgeon (p<0.01) were significantly associated, as was an ICS of 28 days or less (p<0.05). There was no difference in overall survival or disease-free survival between patients with ICS of 28 days or less when compared to an ICS of 29 days or greater at a median of 42 months of follow-up.

Conclusions: In the setting of NAC for breast cancer, an ICS of 28 days or less and increasing patient age are significant risk factors for the presence of any complication, non-seroma complications, and complications requiring additional treatment. The effect of ICS on postoperative complications has not previously been examined in the neoadjuvant setting, and the present findings should inform surgical planning. Surgeons should be cautious offering surgery 28 days or sooner following the end of NAC, especially with increasing patient age. Additional study on the effect of ICS on recurrence and survival is needed to further define the optimal timing of surgery after NAC.

NSM

578873 – Breast-specific sensuality and appearance satisfaction: A comparison of breastconserving surgery and nipple-sparing mastectomy

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Background/Objective: Nipple-sparing mastectomy (NSM) is an oncologically sound surgical option for many women with breast cancer. Yet its uptake in patients who are eligible for lumpectomy (L) continues to confound clinicians. We previously performed a pilot study that demonstrated that L had higher satisfaction with breast appearance, breast sensation, and better appreciation of the breast's role during intimacy over patients undergoing mastectomy with reconstruction (MR). These data were also used to define breast-specific sensuality (BSS).

Methods: A cross-sectional survey was offered to eligible breast cancer survivors in surveillance between 2014 and 2016. Eligible participants underwent surgery between 2000 and 2014, were >18 old, English speaking, and at least 1 year past surgery. The anonymous survey collected demographic information, treatment details, Female Sexual Function Index metrics, and investigator-generated questions regarding satisfaction and sensuality of the post-treatment breast.

Results: A total of 585 surveys were eligible for analysis. Surgical modality was divided between L: 406 (69.4%), mastectomy alone (M): 50 (8.5%), and mastectomy with reconstruction (MR): 129 (22.1%). Information on nipple preservation was available for 47 of the 129 patients who underwent MR, with 26 patients who underwent NSM and 21 who underwent non-nipple sparing mastectomy (nNSM). Two patients underwent NSM without reconstruction but were not included. Appearance satisfaction was significantly higher for L vs. M (76.2% vs. 38.8%, p=<0.0001), although not different for L vs. MR (p=0.073). When MR is compared by NSM vs. nNSM, L had similar appearance satisfaction with NSM (76.2% for L vs. 71.4% for NSM, p=0.64), but was less satisfied with nNSM (50%, p=0.0061). The chest remaining part of intimacy was significantly higher for L versus M or MR (65.4% for L, 46.8% for M, 45.2% for MR, p=<0.0001). Regarding partner comfort in the chest being seen undressed, L was significantly more comfortable than M or MR (82.4% for L vs. 53.8% for M, p=<0.001, and 64.4% for MR, p=0.0003). Feeling uncomfortable being seen undressed was reported by 10% of L compared to 35.9% and 22.9% of M and MR, respectively. When comparing NSM and nNSM only, those who underwent nNSM were less comfortable than L with their partner seeing their chest (p=0.0017). Pleasurable breast caress was reported by 66.2% of L patients vs. 16% of MR (p=<0.0001). When comparing NSM, 20% reported a pleasurable breast caress vs. 13% with nNSM, and 40% of NSM patients actually reported that the caress was unpleasant vs. 26.1% of nNSM, though these didn't reach significance (p=0.42).

Conclusions: These results confirm our original findings that L is superior to M and MR as reported by patients in comfort with partner seeing their chest, the breast as part of intimacy, and the pleasurable breast caress, all of which define BSS. NSM compares to L in appearance satisfaction, comfort with partner seeing the chest, and the role of the breast in intimacy, but has the highest rate of tactile displeasure. Counseling women regarding these survivorship outcomes will enhance the discussion regarding surgical options and will optimize patient expectations.

581255 - Three years of follow-up in 52 patients with nipple-sparing mastectomy after neoadjuvant chemotherapy

Leonardo Nissen, Cleverton Spautz, Cicero Urban, Rubens de Lima, Iris Rabinovich, Maira Doria, Karina Anselmi

Oncoclínica, Curitiba, Parana, Brazil

Background/Objective: Due the few published studies containing only data of nipple-sparing mastectomy (NSM) after neoadjuvant chemotherapy (NACT), we reviewed our oncological results and complications in this patient group.

Methods: All patients undergoing NSM at our service from March of 2012 to May of 2015 were selected. Patient demographics, oncological results, and surgical complications were collected, analyzed, and compared to results of current literature with the same study population. The analyzed data are included in the Table.

Results: A total of 52 patients were included during the study period, and the follow-up time was 37.2±18.8 months. Mean age was 42.5±9.6 years. The mainly initial anatomical stage was 2A, 46.2% (24 of 52), followed by IIB with 26,9% (14 of 52). Locoregional recurrence - not including recurrence in nipple areolar complex (NAC) - was presented in 5.8% (3 of 52). The NAC recurrence was presented in 7.7% (4 of 52) cases. The mean time relapse in NAC was 21.7±7.7 months, more than mean time of locoregional recurrence 14.17±7months (not including NAC). Systemic relapse was presented in 6 (11.5%) cases. The mean time for systemic relapse was 19.34±11 months. Total complications were presented in 25% (13 of 52) cases. There were 19.2% (10 of 52) of patients who needed hospital readmission, and 8 (15.4%) patients had implant loss. In the literature, few studies analyze separately the results in subgroup of patients who underwent neoadjuvant chemotherapy prior to surgery. Our results show a locoregional recurrence of 13.46% (7 of 52) in a meta-analysis with >5 years of follow-up. It appears as 11.4%, but it doesn't distinguish groups with or without NAC. The same study shows a recurrence in NAC of 3.4% - our recurrence in NAC was 7.7%. When we analyze the studies that specifying NSM results after NAC shows 6% of locoregional recurrence and no recurrence at NAC. We had 15.4% (8 of 52) implant loss, while other studies show 9.5% and 10% of loss in NACT groups. The minor complications (partial necrosis or desquamation) vary from 14.3% to 18%, while our study presents 27.8%.

Conclusions: We found a higher rate of local recurrence and complications. It is important to continue the follow-up of this specific group of patients because it is still a poorly detailed subgroup in the literature.

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Oncoplastics

580119 - Chest wall perforator flap for partial breast reconstruction: Value addition for oncoplastic techniques

Sanjit Agrawal, Shashank Nigam, Pooja Agarwal, Rosina Ahmed, Soumitra Shankar Datta Tata Medical Center, Kolkata, West Bengal, India

Background/Objective: Partial breast reconstruction techniques using chest wall perforator flap (CWPF) is novel and valuable addition for oncoplastic breast surgeons for lateral quadrant defect reconstruction in small non-ptotic breast cancer patients with large volume of excision (>20%). We report single-center experience of CWPF with regards to surgery details, complications, re-excision, and aesthetic outcomes.

Methods: This was a prospective, observational cohort study of patients who had undergone breast conservation surgery and reconstruction with CWPF from May 2017 to October 2018 at Tata Medical Center, Kolkata, India. All variables were recorded prospectively in institutional redcap database. The telephonic survey was done to analyze patient's satisfaction using a 4-point Likert scale, at about 6 months after completion of radiotherapy.

Results: We have performed 30 breast conservation surgeries with CWPF reconstructions over a period of 18 months. Median breast size was 34C. Breast ptosis was Grade 0 or 1 in 70% of patients. Chest wall perforators could be localized peri-operatively in all patients using handheld Doppler. Fifty-seven percent of patients had lateral intercostal artery perforator flap (LICAP), 7% had lateral thoracic artery perforator flap (LTAP), 33% had combined LICAP+LTAP, and 3% patients had anterior intercostal artery perforator flap. CWPF reconstruction was done for 86% of lateral quadrant tumor excision cavity defect, 10% of central quadrant, and 3% for medial quadrant defects. Median weight of excised specimen was 180 grams (140, 190). The operating time was 150 to 180 minutes. Median pathological tumor size was 4cm (2.5,4.8). Margin was positive as per SSO guideline in 3 patients, 2 required cavity shave, and 1 ended in mastectomy. The postoperative stay was 1 day only in all patients. The flap dimension harvested was generally 15(L) X 8(W) cm. One (3%) patient had complete flap loss out of 30 patients. Two patients developed hematoma, which was managed conservatively. Twenty-three of 30 patients have completed radiotherapy, out of which 14 responded to telephonic questionnaire. Ninety-three percent of patients were satisfied with surgical scar, and about 78% were satisfied with reconstructed breast compared to opposite breast. One hundred percent of patients were comfortable going to public places and in retrospect, felt that their decision for breast conservation with CWPF over mastectomy was right.

Conclusions: Lateral chest wall perforator flaps are additional options for breast surgery and may be used for partial breast reconstruction in small non-ptotic breasts with excellent outcome and high patient satisfaction scores.

582101 - Assessing the impact of a hands-on oncoplastic course on surgeons' practices

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Background/Objective: Oncoplastic surgery combines safe oncologic breast conservation with volume displacement or replacement techniques to improve cosmesis. Despite growing evidence confirming adequate disease-free and overall survival and patient satisfaction, oncoplastic surgery has not had the same level of uptake in North America as it has had across Europe. Many surgeons have started taking courses to acquire oncoplastic techniques, but the effect of these courses is unknown. This study aimed to assess the impact of a hands-on oncoplastic course on surgeon comfort with oncoplastic techniques, and rate of adoption of these techniques in their practices.

Methods: An online 10-question survey was developed and distributed to surgeons who had participated in a hands-on oncoplastic course offered in Ontario, Canada. Three solicitations were sent. Unique identifiers allowed a single response.

Results: Of 105 surveys sent out, 65 attending surgeons responded (response rate: 62%). All respondents stated cosmesis was of the utmost importance in breast-conserving surgery. The most common oncoplastic techniques they learned and currently use included glandular re-approximation (98.4%), undermining of skin (93.6%), undermining of nipple areolar complex (63.4%), and de-epithelialization and nipple areola complex repositioning (49.2%). More advanced techniques such as mammoplasty are being performed by 26% of participants. Sixty percent of surgeons reported they used oncoplastic techniques in at least 50% of their cases. Because of the course, 92% of respondents increased the amount of oncoplastic techniques in their practices. At least 70% of respondents said they would do another oncoplastic course. The main factors that facilitated the uptake of oncoplastic techniques was a better understanding of surgical techniques and planning.

Conclusions: This is the first study assessing whether an oncoplastic course helps surgeons incorporate these techniques into their practice. Our data show that there was a self-reported increase in the amount of oncoplastic procedures performed in course participants' practice. Oncoplastic courses provide a means for practicing surgeons to acquire technical skills, enabling them to deliver safe oncologic breast conservation with optimal cosmesis.

582104 - Oncoplastic surgery is not associated with increased complications when compared to standard breast-conserving surgery: An analysis of the NSQIP Database Fernando Angarita¹, Maryam Elmi², Erin Cordeiro³, David McCready¹, Tulin Cil¹

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Background/Objective: Although the oncologic safety and cosmetic outcome for early breast cancer patients who undergo oncoplastic surgery (OPS) is well described, data on postoperative complications are lacking. This study aimed to determine if there is a difference in overall postoperative complications (morbidity and mortality) associated with oncoplastic surgical techniques compared with standard breast-conserving surgery (BCS).

Methods: An analysis of the National Surgical Quality Improvement Program (NSQIP) database was performed. Adult women with ductal carcinoma in situ (DCIS) or invasive breast cancer who underwent BCS between 2005 and 20016 were included. Women who underwent concomitant BCS and soft tissue

transfer, mastopexy, or mammoplasty were categorized as having OPS. Women who underwent lumpectomy or partial mastectomy were categorized as BCS. The primary outcome was 30-day postoperative morbidity; the secondary outcome was 30-day all-cause mortality. A multivariable analysis was performed to evaluate the independent effect of OPS on postoperative complications.

Results: A total of 109,487 patients underwent BCS, of whom 9,126 (8.3%) also underwent OPS. The median age was 61 years old (IQR: 51-70). Twenty-two percent of patients had a postoperative diagnosis of DCIS. Within the OPS cohort, 2,381 (26.1%) had a tissue transfer of \leq 30 cm2, 1,657 (18.1%) had a transfer of 30.1 – 60.0 cm2, 1,779 (19.5%) had a transfer of >60 cm2, 1,649 (18.1%) had a mastopexy, and 1,660 (18.2%) had a mammoplasty. Women who underwent OPS were younger (58 years versus 61 years old, p<0.0001), had a lower body mass index (27.5 kg/m2 versus 32.1 kg/m2, p<0.001), were less frequently smokers (9.3% versus 12.6%, p=0.0001), used steroids less frequently (1.8% versus 2.6%, p<0.0001), and underwent neoadjuvant chemotherapy less frequently (0.7% versus 2.2%, p<0.0001). OPS had a significantly longer operative time compared to BCS (92.6 min versus 66.6 min, p<0.0001). The surgical morbidity rate (wound infection and/or dehiscence) was similar between both groups (OPS 1.7% versus BCS: 1.8%, p=0.06). The system-specific complication rate was similar between both groups. Thirty-day all-cause mortality was a rare event in either group. After adjusting for baseline differences, there was no difference observed in 30-day overall complications between women who underwent OPS compared to those who had standard BCS (OR 0.85, 95% confidence interval 0.64–1.23).

Conclusions: Despite longer operative times, OPS may be performed in breast cancer patients who are suitable candidates without increasing post-operative morbidity.

581107 - Initial experience of round block mammoplasty (RBM) for benign and malignant tumors: Is it the first step to advanced oncoplasty in low-/middle-income countries (LMICs)?

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Background/Objective: Our objective is to share an initial experience of oncoplasty and to highlight the outcomes in limited resources. As women's interest in cosmetic attractiveness increases, surgeons make attempts to minimize postoperative scars. Round block mammoplasty (RBM) can also be adapted for removal of tumors that are more centrally located, especially in breast cancer patients with small- to medium-sized breasts. Moreover, the doughnut technique, along with circumareolar incision, provides wider exposure for tissue resection and remodeling without sacrificing the cosmetic outcome with an advantage of inconspicuous post-operative scar and favorable aesthetic results. Oncoplastic breast-conserving surgery is more successful than standard wide local excision in treating larger tumors and obtaining wider radial margins, thus reducing the need for further margin excision, which delays adjuvant therapy.

Methods: We conducted a retrospective case series done in the breast clinic of a teaching hospital in Karachi, Pakistan over period of 6 years from January 2012 to January 2018. Ours is a public teaching hospital having 2 breast surgeons out of 23 general surgeons. The breast clinic was established in 2003, with 3 clinics and 3 OT lists per week, 2 by a senior surgeon and 1 by a junior surgeon. Visits included 150 cases per week in the clinic, 65% with locally advance breast cancer (LABC), 15% with phyllodes, and 15% were benign cases. A total 131 patients were selected because of strict selection criteria. Most of the patients complained of lump, pain, and discomfort. All patients were clinically examined, and breast ultrasound along with baseline investigations was done. Patients with benign lumps up to 6cm, age more than 14 years, and less than 45 years, and malignant lumps of <2.5cm at presentation were selected. The

number of complications were observed on follow-up. The data of different variables like age, postoperative hospital stay, and complications were collected. All patients underwent RBM, and histopathology was sent. Tumors were assigned group 1, and benign lumps were assigned group 2.

Results: Out of 131 patients who underwent RBM, 79 (60.3%) were benign, and 52 (39.7%) were malignant. Twenty-seven were carcinoma breasts, and 25 were phylloides. The mean age of group 1 was 31 years (range 18-44 years). Ten were T1, and 17 were T2. Six of the 27 were grade II, and 21 were grade III. Axillary lymph nodes were positive in 11. Nine were ER-positive, and 4 were HER-2 positive. Twenty-three patients received radiotherapy, and 11 patients received adjuvant chemotherapy. One received immunotherapy. Fourteen of 25 phyllodes were benign, 3 were malignant, and 8 were borderline. Group 2 mean age was 22 years (range 14-36 years). Size of lump removed was 4 cm, mean 2-6 cm. in group 1, 5 patients had positive margins, leading to margin re-excision in 4 and mastectomy in 1 patient. There was 1 recurrence noted for breast carcinoma in 2 years and 3 recurrence in phyllodes. Aesthetic outcomes of both groups 1 and 2, including ipsilateral shape, cleavage, scar visibility, dent visibility, and symmetry, were found satisfactory by patients.

Conclusions: RBM seems to have acceptable oncologic and cosmetic outcomes, and overall survival is comparable to mastectomy, so it can be adapted as an initial oncoplastic procedure in a wide range of patients in LMICs.

Figures: 26-year-old female with right breast fibroadenoma at 3 o'clock



Figure 1a: Skin Marking



Figure 1c: cavity after lumpectomy



Figure 1e: Excised lump



Figure 1b: De epithelization



Figure 1d: Closure



Figure 1f: final closure

581739 - Minimally invasive breast surgery through unique incision approach for early breast cancer: An analytical description of 94 cases

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Background/Objective: The objective of the study was to describe the characteristics of patients and breast tumours who were approached by minimally invasive technique conserving surgery. Breast-conserving surgery has become the standard of care in early-stage breast cancer. Today, with the development of oncoplastic surgical approaches, aesthetic incision and oncologic safety are in play. It has been demonstrated that the aesthetic success in breast cancer surgical treatment leads to psychological benefit and self-esteem for patients. In treatment of initial breast cancer, minimally invasive techniques with hidden and unique incision to approach the tumour and the sentinel lymph node allow the maintenance of the breast pre-surgical appearance without losing the oncological safety.

Methods: We retrospectively analyzed 94 early breast cancer patients (invasive breast cancer measuring no more than 30mm and clinically axillary negative lymph nodes) operated by unique incision surgery (inframammary or axillary or periareolar incision) for both tumour and sentinel lymph node, from 2015 until 2018. All surgeries were done by the same medical staff and at the same hospital. All selected patients had no desire or no need for associated mammoplasty or other type of surgery. We described place of incision, the mammary volume tissue removed, surgical time, number of dissected lymph nodes, surgical place in breast, and final aesthetic result.

Results: Among the analyzed cases, the mean age was 55 years, 71% had invasive ductal carcinoma, the mean of resected lymph nodes was 3.6, and the volume resected was 15.9 ml on average. Fity percent of the incisions were periareolar, and 45% were inframammary. The average time of surgery was 2 hours and 40 minutes. The type of incision varied with the location of the tumour. The number of lymph nodes and resected tissue volume had no statistical difference regarding the inframammary incision or others.

Conclusions: The minimally invasive technique through unique incision proved to be feasible and safe in the treatment of initial breast cancer with a very favorable aesthetic result.

563975 - Bilateral paravertebral nerve blocks are associated with reduced opioid use and pain scores after Level 2 volume displacement oncoplastic breast surgery

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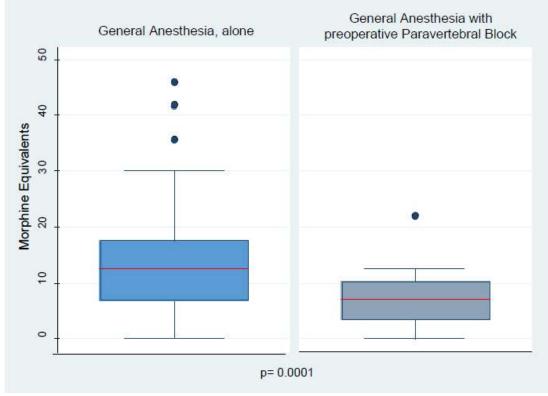
Background/Objective: As breast operations are increasingly performed in the ambulatory setting, opioid-sparing techniques are becoming more commonly used in an effort to decrease length of stay and reduce perioperative risks associated with narcotics. Several studies have demonstrated the benefits of preoperative paravertebral blocks (PVB) in breast reconstruction, but none to our knowledge have been performed in patients undergoing oncoplastic reconstruction and simultaneous contralateral symmetry mastopexy or mammaplasty. Therefore, we performed a retrospective study to explore associations between bilateral single-injection PVB and postoperative opioid use as well as pain scores in women undergoing Level 2 volume displacement oncoplastic breast surgery and immediate symmetry mastopexy or reduction mammaplasty.

Methods: We retrospectively reviewed women undergoing oncoplastic breast surgery with immediate symmetry mastopexy or reduction mammaplasty from August 6, 2015 to August 17, 2018, and compared those who received PVB prior to general anesthesia (GA) with those who received GA alone. The primary outcomes included postoperative opioid use in morphine equivalents (ME) and patient-reported pain score according to a verbal rating scale of 0-10, with 0 indicating no pain and 10 indicating the worst pain imaginable. The secondary outcome was the proportion of patients who had severe pain at discharge, defined as a score of \geq 5. Data were analyzed using the Wilcoxon rank sum test and multivariable logistic regression.

Results: Of 89 women, 38 (43%) received bilateral PVB prior to GA, and 51 (57%) received GA alone. Baseline characteristics were similar between groups. Patients who received PVB used significantly fewer median ME in the first 0-24 hours following surgery (12.5 vs. 6.7 ME, p=0.0001) and reported lower mean pain scores 0-8 hours post-operatively (8 vs. 7, p=0.0421) compared to those who received GA alone. Logistic regression predicting pain scores upon discharge showed that patients who received GA alone were 3.89 times more likely to experience severe pain upon discharge compared to those who received PVB prior to GA (OR = 3.89, 95% confidence interval 1.07-21.59).

Conclusions: Performing preoperative PVB was associated with a lower requirement for postoperative opioids and lower pain scores immediately after surgery as well as upon discharge. Given the ongoing opioid crisis, our results suggest the crucial role that PVB may play in optimizing recovery and minimizing narcotic use following oncoplastic reconstructive surgery. Additional studies are needed to further characterize this relationship.

Figure: Total morphine equivalents used during the first 24 hours after Level 2 volume displacement oncoplastic breast surgery according to type of anesthesia. Median morphine equivalents received are significantly less in those who underwent general anesthesia with preoperative paravertebral block compared to general anesthesia alone (p=0.0001)



581559 – Breast-conserving surgery with partial breast reconstruction or reduction mammoplasty followed by whole breast radiation therapy (WBRT)

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Background/Objective: More than half of women diagnosed with early-stage breast cancer undergo breast-conserving surgery. The 5-year survival rate of women with early-stage breast cancer is more than 98%; therefore, the cosmetic outcome is a very important quality of life issue. In patients undergoing breast-conserving surgery, volume loss is the most common cause of negative cosmetic outcomes in patients. In an effort to improve cosmesis, oncoplastic surgery at the time of partial mastectomy (BCS) \pm sentinel node surgery is more widely accepted. We are reporting our experience with patients who have undergone bilateral reduction mammoplasty or autologous flap partial breast reconstruction at the time of breast-conserving surgery prior to receiving whole breast radiation therapy. The objectives of this study were to evaluate for cosmetic outcomes and local control in this patient population in addition to examining the incidence of BIRADS 3 or 4 recommendations and fat necrosis on follow-up mammogram and ultrasound.

Methods: In this retrospective study, we identified 30 breast cancer patients, who at the time of BCS, either underwent partial breast reconstruction using autologous flap or had bilateral reduction mammoplasty. Postoperatively, all patients received WBRT to a dose ranging from 50.4Gy to 60Gy. Adjuvant systemic therapy was prescribed at the discretion of the treating oncologist. In follow-up, all patients were seen at regular intervals by the multidisciplinary team, and mammograms and directed ultrasounds were obtained at scheduled intervals.

Results: A total of 33 breasts in 30 patients (3 bilateral) are included in this review. The median followup is 63 months (range: 5 months to 134 months). The median age is 57 years (range: 37 to 77 years). The pathologic stage distribution was: 10 Stage 0, 14 Stage I, 5 Stage II, and 4 had Stage ypT0N0M0 having undergone BCS following neoadjuvant therapy. All but 1 patient had negative resections margins. Twenty patients underwent bilateral reduction mammoplasty, while 10 had either thoracodorsal artery perforator flap (TDAP), lateral intercostal artery perforator flap (LICAP), or other autologous free flaps. Twenty-six patients also received systemic chemotherapy and/or hormonal therapy. All 30 patients received whole breast radiation therapy post-operatively. Cosmetic results in the majority were excellent/very good. In follow-up, we observed that 4 patients underwent additional revisions for cosmetic indications, and 3 of the 4 patients were among those who had partial breast reconstruction using free-flaps. Follow up mammography noted recommendation of BIRADS 3 and 4 in 4/33 (12.1%) and 2/33 (6.1%) of breasts, respectively. Additionally, 6/33 (18.2%) had radiographic evidence of fat necrosis. To date, no patient has developed a local recurrence.

Conclusions: In the multidisciplinary care of breast cancer, the integration of oncoplastic procedures is increasingly being considered as an adjunct to breast-conserving surgery. We observed that partial breast reconstruction in addition to BCS prior to WBRT results in excellent cosmetic result and local control with the added benefit of avoiding a mastectomy by reconstructing volume loss. Radiographically, the incidence of fat necrosis was the most common finding, and the recommendation for BIRADS 4 was low. In select cases, partial breast reconstruction at the time of BCS prior to WBRT may be a reasonable approach to offset the volume loss of an extensive lumpectomy.

581592 - Evaluating need for additional imaging and biopsy after oncoplastic breastconserving surgery

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Background/Objective: Breast-conserving therapy (BCT) using oncoplastic surgery (OPS) allows for larger resections and improved aesthetics though volume redistribution and tissue rearrangement. The impact of OPS on surveillance imaging and need for additional biopsies has not been reported.

Methods: This is an observational cohort of patients undergoing BCT at a single institution from 2009-2018. Standard surgery (STS) was the predominant approach until OPS was introduced in 2012. We describe rates of imaging beyond standard diagnostic views, including additional views, diagnostic ultrasound, and short interval imaging, as well as rates of biopsy following both approaches.

Results: A total of 433 sequential patients were identified. The OPS group comprised 216 patients, and the STS group included 217 patients. Patient age (STS 60.4±11.8 years vs OPS 59.8±11.8 years, p=0.99) was similar between groups. Symmetry procedures were performed in 112 (51.2%) OPS patients. With an average follow-up of 79±27 months for the STS group and 40±17 months for the OS group, there was no difference in need for additional imaging between groups (STS 58 patients, 26.7% versus OPS 52 patients, 24.1%, p=0.66). When only the first 3 years of follow-up were considered, there was also no significant difference in need for additional imaging between groups (STS 39 patients, 18.0% versus OPS 50 patients, 23.1%, p=0.19). Additional imaging was required on the ipsilateral side in 35 (60.3%) STS patients compared to 23 (44.2%) OPS patients (p=0.12). Of the 29 OPS patients who had contralateral additional imaging, 14 (48.3%) had contralateral symmetry procedures performed at the time of their operation. Although there was a significant difference in re-excision rates, (STS 78 patients, 35.9% vs OPS 46 patients, 21.3%, p=0.001), re-excision following partial mastectomy was not associated with an increased need for additional ipsilateral imaging, p=0.78. Need for biopsy was higher in the STS group (STS 41 patients, 18.9%, with 47 total biopsies vs OPS 20 patients (9.3%) with 22 total biopsies, p=0.005) during the follow-up interval. The difference remained significant even when the follow-up was limited to the first 3 years (STS 25 patients, 11.5% vs OPS 18, 8.3%, p=0.05). Biopsy findings of malignancy were similar between groups with malignancy present in 25 (53.2%) of STS biopsies compared to 10 (45.5%) of OPS biopsies. Additional surgery was undertaken based on biopsy results in 22 (10.1%) STS patients compared to 9 (4.2%) OPS patients (p=0.03). Need for additional imaging, biopsy, and surgery declined with time in both groups.

Conclusions: Despite the use of tissue rearrangement techniques, OPS was not associated with an increased need for additional imaging compared to STS. STS was associated with an increased need for biopsy and additional surgery based on biopsy results compared to OPS. Concern for challenges with follow-up imaging should not factor into the decision to offer OPS and symmetry procedures to patients who meet criteria for BCT. Further study and longer-term follow-up are warranted to understand the trends in the need for additional imaging, biopsy, and additional procedures following OPS.

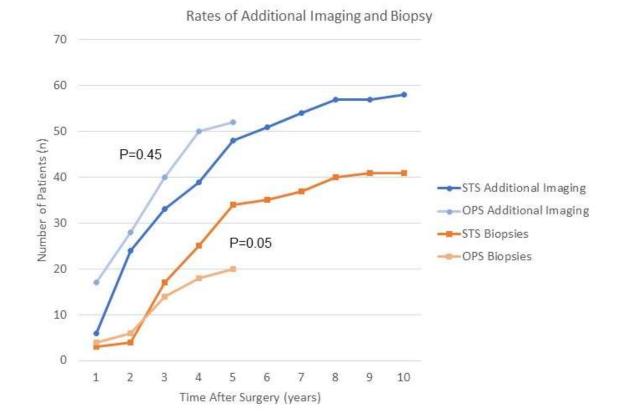


Figure: Cumulative patients requiring additional imaging and biopsy

581609 - Oncoplastic neoareolar reduction mammoplasty with immediate nipple reconstruction: Expanding indications for breast-conserving therapy

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Background/Objective: Breast-conserving therapy (BCT) has been associated with improved quality of life and cosmetic outcomes compared with mastectomy; however, centrally located breast cancers with close proximity to the nipple-areolar complex (NAC) present a unique cosmetic and oncologic challenge as removal of the NAC can cause significant cosmetic deformity. Oncoplastic neoareolar reduction mammoplasty with immediate nipple reconstruction is a novel technique that can permit BCT in these patients while also minimizing the number of operations required for reconstruction.

Methods: This is an observational cohort of breast cancer patients who underwent central partial mastectomy reconstructed with neoareolar reduction mammoplasty and immediate nipple reconstruction. Patients were offered this procedure regardless of presence of comorbidities or smoking history. Patient demographics, imaging and pathology size, margin width, mastectomy and re-excision rates, and cosmesis were evaluated.

Results: Twenty-three consecutive patients were identified;19 met traditional indications for mastectomy. Average patient age was 60.5±12.3 years, and average BMI was 29.9±6.0 kg/m2. Average lesion size was

 50.8 ± 43.9 mm (4-160 mm) on preoperative imaging, and average disease span on final pathology was 59.5 ± 45.2 mm (9-136 mm). Six patients (26.1%) had recent smoking histories, and 2 patients (8.7%) had diabetes. No ink on tumor was achieved in 21 (91.3%) patients. Thirteen (56.5%) patients had inadequate margins, 11 for DCIS and 2 for invasive cancer; 12 (52.2%) underwent re-excision, and 1 (4.3%) patient underwent mastectomy. All 13 achieved negative margins on final pathology. Cosmesis scores were assigned to 20 patients, with 19 (95.0%) achieving good to excellent cosmetic results. Complications occurred in 6 (26.1%) patients, including 3 patients who had NAC ischemia of the reconstructed nipple. One patient required debridement of the NAC and initiation of her adjuvant radiation therapy was delayed. No other complications required interventions or delays in initiation of adjuvant therapies. Five (83.3%) of the 6 patients with complications achieved good to excellent cosmetic outcomes. Of the 12 patients who underwent re-excision, 11 patients had cosmetic outcomes recorded, and 10 (90.9%) had good or excellent cosmetic outcomes.

Conclusions: Central partial mastectomy with reconstruction using a neoareolar reduction mammoplasty with nipple reconstruction as a single-stage operation can allow patients with cancers abutting the NAC to consider BCT. This technique allows patients to avoid mastectomy and to minimize the number of operations required for reconstruction while also maximizing cosmetic outcomes. In this cohort, presence of extensive DCIS frequently resulted in inadequate margins; however, re-excision can be successfully performed without significant compromise to cosmetic outcomes. Further study is warranted to examine the long-term oncologic and cosmetic results of this approach.

| | Patients n=23 | % |
|-----------------------------|---------------|---------|
| Patient Characteristics | | |
| Age (years) | 60.5 ± 12.3 | |
| BMI (kg/m2) | 29.9 ± 6.0 | |
| Smoking History | 6 | 26.1% |
| Diabetes | 2 | 8.7% |
| Tumor Characteristics | | |
| Size (mm) | 59.5 ± 45.2 | |
| Histology | | |
| Invasive Ductal Carcinoma | 15 | 65.2% |
| Invasive Lobular Carcinoma | 2 | 8.7% |
| Ductal Carcinoma-in-situ | 5 | 21.7% |
| Invasive Mucinous Carcinoma | 1 | 43% |
| Grade | | 9000030 |
| Grade 1 | 1 | 4.3% |
| Grade 2 | 12 | 52.2% |
| Grade 3 | 10 | 43.5% |
| Receptor Status | | |
| ER positive | 17 | 73.9% |
| PR positive | 10 | 43.5% |
| Her2 positive | 4 | 17.4% |
| Multifocal | 9 | 39.1% |
| LVI | 8 | 34.8% |
| Node positive | 10 | 43.5% |
| Surgery Characteristics | | |
| No tumor on ink | 21 | 91.3% |
| <2mm margins for DCIS | 11 | 47.8% |
| Re-excision | 12 | 52.2% |
| Mastectomy | 1 | 4.3% |
| Adjuvant Therapies | | |
| Chemotherapy | 13 | 56.5% |
| Radiation Therapy | 21 | 91.3% |
| Endocrine Therapy | 14 | 60.9% |

Table: Clinicopathologic characteristics

581953 - Patient satisfaction with breasts following single-stage oncoplastic reduction mammoplasty: Does radiation impact BREAST-Q?

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Background/Objective: Single-stage oncoplastic reduction mammoplasty has been used to improve cosmetic and functional outcomes for women with macromastia and to enable breast conservation in the setting of large tumors, but some patients undergo staged mammoplasty over concern about cosmetic results after radiation. Recent studies have provided normative data to enable comparison to women without cancer and women who undergo lumpectomy. Additionally, there is little known about the impact of radiation boost on patient satisfaction.

Methods: Using an institutional cancer database, patients were identified who underwent reduction mammoplasty following a cancer diagnosis from 2012-2016. Patient characteristics and treatment were gathered through chart review. Surveys including the BREAST-Q Reduction Post-operative v. 2.0 Satisfaction with Breasts module as well as questions addressing complications and nipple sensation were sent to identified patients.

Results: Seventy-six patients underwent oncoplastic reduction mammoplasty. Median patient age at diagnosis was 57 years (range 35-76). Average follow-up time was 49 months (range 21-79). Mean tumor size was 2.0 cm (0.2-10cm). Seven patients had a recurrence in the follow-up period (7.9%), with 2 local recurrences (2.6%), 2 axillary recurrences (2.6%), and 3 distant recurrences (3.9%). The survey response rate was 55% (42 patients). All but 1 of the patients had a single-stage reduction mammoplasty and lumpectomy prior to radiation therapy. Twelve women (28.6%) reported experiencing post-operative complications. Five patients underwent hypofractionated radiation, while the remaining patients underwent standard course radiation therapy. More patients were satisfied with their breast outcome than unsatisfied (64% vs 35%). When compared with normative data in the literature, BREAST-Q scores for satisfaction with breasts following oncoplastic reduction mammoplasty (mean 64, SD 23) compared favorably with patients in the literature who have not undergone surgery (mean score 58, SD 18) (p=0.03). While most patients were extremely satisfied with post-operative nipple sensation (45%), many patients were dissatisfied with their nipple sensation (36%). There was no difference in overall satisfaction between patients who underwent a boost to the lumpectomy bed and those that did not (p=0.50) (Table).

Conclusions: At an average of more than 4 years after cancer diagnosis, most patients are satisfied or very satisfied with their breast appearance following single-stage oncoplastic reduction. Patients should be informed that they may be dissatisfied with nipple sensation following surgery. Radiation (standard or hypofractionated, with or without boost) did not decrease satisfaction with breasts, impact patient feelings about symmetry, or increase complications following single-stage reduction.

| | Boost n=20 | No Boost n=22 | p-value |
|---------------------------------------|-------------------|------------------|---------|
| Age at diagnosis, years (range) | 58 (42-76) | 58 (44-72) | 0.79 |
| Tumor Size, cm (range) | 1.6 (0.4- 3.5) | 2.2 (0.6-8.5) | 0.31 |
| Overall Patient Satisfaction (IQR) | 62 (53-73) | 57 (52-83) | 0.95 |
| Complication (%) | 5 (25%) | 7 (32%) | 0.74 |

Table: Radiation boost vs. no boost following oncoplastic reduction mammoplasty

581340 - Intraoperative continuous ultrasonography-guided oncoplastic surgery: Margin assessment and selective cavity shaving

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Background/Objective: Oncoplastic surgery (OPS) is the preferred choice of treatment for breast cancer currently. The major aims are to achieve negative margins with the most acceptable cosmetic and oncologic outcome. The presence or absence of residual invasive cancer is one of the strongest prognostic factors for risk of recurrence, and the margin status is the other. Due to the excess tissue rearrangement, accurately predicting margin status intraoperatively is a must to avoid mastectomy during OPS, which is a challenge for the surgeon. The aim of the present study is to evaluate the efficacy of continuous intraoperative ultrasound-guided OPS (IUG-OPS) in terms of margin status and re-excision rate. The relationship between intraoperative assessment of gross macroscopic and ultrasonographic margins and cavity shavings results were also analyzed.

Methods: Between 2015 and 2018, IUG-OPS were performed on 118 patients. OPS procedures were decided according to patient and tumor characteristics. Tumor localization, breast/tumor volume ratio, glandular density, and patient preferences were the major factors to make selections. All of the patients underwent level I or II OPS with regards to the abovementioned factors. Surgeons performed continuous perioperative real-time sonographic margin assessment during resection, and macroscopic evaluation, specimen US including sonographic analysis of 6 faces of each specimen, and shaved cavity margins for permanent pathologic assessment were the standard steps of our methodology.

Results: The sensitivity of intraoperative ultrasound localization of the tumor was 100%. Patients were on average 49 years old (range, 34-72). There was no difference with respect to patient characteristics including age, menopausal status, personal-family history, oral contraceptive usage, body mass index, and tumor localization. Tumor-free margins were obtained by means of IUG-OPS in 95% of margins evaluated sonographically. Moreover, the involved margins were correctly identified by the surgeon via specimen sonography in 50% of the cases, which was confirmed by cavity shaving results. No frozen section analysis was performed, and macroscopic evaluation of the specimen predicted nothing significant. According to permanent section analysis of the resected specimens and cavity shavings, no further intervention was required due to margin positivity. IUG-OPS with real-time specimen sonography were unable to predict involved margins in cases confirmed to be invasive lobular carcinoma and ductal carcinoma in situ without evidence of residual cancer on pathological examination of cavity shavings. Accordingly, neither a second intervention, nor mastectomy, was required.

Conclusions: Continuous intraoperative ultrasound with specimen sonography and cavity scan after excision is an invaluable and effective modality to achieve negative surgical margins during OPS. Furthermore, meticulous sonographic assessment of specimen margins together with cavity shavings from tumor bed could be a feasible method to decrease re-excision rates without frozen section analysis leading to cost-effectiveness. However, the accuracy of sonography should be questioned in case of ductal carcinoma in situ and lobular histology.

581515 - Prepectoral one-stage breast reconstruction: Single-institution patient outcomes in 113 consecutive cases

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Background/Objective: Acellular dermal matrix (ADM)-assisted, one-stage direct-to-implant (DTI) breast reconstruction has revolutionised oncoplastic practice. The original technique describing ADM use as a lower pole cover for subpectoral implant placement had drawbacks leading to the evolution of prepectoral implant placement with ADM cover. The lack of muscle disruption in prepectoral reconstruction is potentially associated with reduced postoperative pain, faster recovery, elimination of animation deformity, and improved long-term comfort. Despite the described advantages of prepectoral implant reconstructions, uptake of this technique has been modest as ADM-assisted reconstructions have been implicated as a risk factor for higher rates of postoperative complications and reconstructive failure compared with traditional two-stage implant techniques. The aim of this study was to evaluate the outcomes of a consecutive series of ADM-assisted prepectoral breast reconstructions in a tertiary referral unit.

Methods: All patients who underwent prepectoral breast reconstructions between November 2016 to August 2018 were identified from electronic computer records. Data were collected on patient demographics (age, BMI, smoking history), adjuvant therapies, operative technique (nipple-sparing/skinsparing mastectomy, implant size, incision, drain output). All postoperative complications, length of stay, and secondary cosmetic procedures were recorded. During the study period, our institution used a biological ADM composed principally of fetal calf collagen III (SurgiMend PRS®). The 2 types of SurgiMend used were (i) Sheet fenestrated SurgiMend or (ii) Meshed SurgiMend. The rationale for using the newer meshed SurgiMend was easier intraoperative handling. Statistical analysis was performed using descriptive statistics, non-parametric tests, and logistic regression analysis **Results:** During the study period, 113 prepectoral breast reconstructions were performed in 57 patients (56.3% meshed SurgiMend). Median patient age was 42 (26-72) years, and median BMI was 22.2 (17.2-28.6). Only 7% of cases were performed on smokers. The indication for mastectomy was risk reduction in 63 cases (55.7%). Nipple-sparing mastectomy was performed in 80 cases (71%). The median mastectomy weight was 360(98 - 1099) gr, and the median implant volume used was 445(185 - 555) cc. The median length of hospital stay was 1 (1-9) day. Forty mastectomies had at least 1 complication (35.4%), but only 11 cases required surgical intervention (9.7%). Infection was observed in only 4 (3.5%) cases. Skin flap necrosis developed in 8 cases (7.1%). Of those who underwent nipple-sparing mastectomy, partial nipple necrosis occurred in 8 cases (10%). Of these, only 1 required surgical intervention, and the rest were managed conservatively. The implant loss rate was 1.8% (2 cases). Lipofilling as a secondary procedure was performed in 11.5 % of cases. The median follow-up for the study was 6 (1-16) months. Factors associated with an increased risk of post-operative complications on univariate analysis were patient BMI (p=0.01) and incision type (p=0.025), while implant size showed a trend towards statistical significance (p=0.054). Wise pattern incisions in nipple-sparing mastectomies were associated with the highest complication rates. However, on multivariate analysis, there were no independent predictors of complication.

Conclusions: Prepectoral DTI breast reconstruction using ADM provides a more natural, ptotic look in a single stage with faster recovery than subpectoral or traditional two-stage techniques. This study demonstrates that the complication and reconstructive failure rates following prepectoral implant placement with the use of ADM are low and comparable to traditional two-stage or subpectoral approaches. The use of the newer meshed ADM with easier intraoperative handling was demonstrated to be safe with no increased risk of complications. We believe previous reports highlighting higher complication rates using prepectoral techniques demonstrate the widely accepted learning curve for these procedures. Patient selection and meticulous surgical technique are particularly important during this learning curve.

581807 - Effectiveness and safety attributable to oncoplastic surgery as an adjuvant therapy for idiopathic granulomatous mastitis due to breast tuberculosis

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Background/Objective: Breast tuberculosis is one of the main etiologic differential diagnosis in patients with idiopathic granulomatous mastitis (IGM). However, the diagnosis of breast tuberculosis (BTB) is often established after surgery with most patients testing negative to standard TB diagnostics. Wide surgical resection has been recommended, but the treatment of choice for IGM with or without tuberculosis confirmation remain unclear. Furthermore, standard breast resection represents a disabling surgery, so there is a need for novel, effective, and safe treatment alternatives. Our aim was to assess the effectiveness and safety attributable to oncoplastic surgery as an adjuvant therapy to the anti-TB drug therapy for IGM due to BTB.

Methods: Using a cohort study design, we retrospectively evaluated each of the IGM cases diagnosed with BTB by Ziehl-Neelsen staining of a breast tissue sample during the years 2010-2016 in a social security hospital in Lima, Peru, the "Hospital de Emergencias Grau." Study outcomes included recurrence rates, corticosteroids use, and safety (defined as any wound, bleeding, or wound complication) during the first year of follow-up since starting the 9-month standard anti-TB drug therapy for BTB.

Results: We analyzed a total of 116 IGM cases due to BTB. Patients' age ranged from 19 to 80 years old, and most of them were female (99%), natural from Lima (79%), tested negative to PPD (91%), and had a negative history of pulmonary TB (91%). Most mastitis was located at the right breast (71%), in the upper external quadrant (75%), and classified as BI-RADS III by ultrasonography (91%). Most patients belong to the cohort of patients treated with standard drug therapy for BTB plus oncoplastic surgery (55%), while the rest belong to the cohort treated with standard drug therapy for BTB alone. The most frequent oncoplastic surgical pattern used were lateral (48%) and horizontal (27%). During the follow-up, we did not find differences between both cohorts in terms of recurrence rate (0% vs 2%; p-value=0.2440) or corticosteroids use rate (0% vs 2%; p-value=0.2440). Any adverse event was reported in the oncoplastic surgery cohort.

Conclusions: Oncoplastic surgery seems to represent an effective and safe adjuvant therapy to the standard anti-TB drug therapy for IGM due to BTB. However, further studies are needed to confirm these findings in a more rigorous way, like in a randomized clinical trial.

581040 - Interest in oncoplastic surgery within breast surgical oncology and plastic surgery <u>Yurie Sekigami</u>¹, Andrew Seto², Abhishek Chatterjee² ¹Tufts Medical Center, Cambridge, MA, ²Tufts Medical Center, Boston, MA

Background/Objective: The purpose of this study was to identify trends in presentations and publications accepted by plastic surgery (PS) versus breast surgical oncology (BSO) societies. Our hypothesis is that there is increasing interest in oncoplastic surgery within breast surgical oncology membership relative to that of plastic surgery.

Methods: A systematic review was performed restricted to oncoplastic surgery literature published between 2013-2017 available on PubMed. Publications were stratified to either PS or BSO categories based on the affiliation of the principal author listed as the last author. Oncoplastic surgery abstracts that were presented as poster presentations or oral presentations were obtained from 3 major PS conferences as well as 3 major BSO conferences between 2013-2017.

Results: A total of 153 publications and 65 abstracts related to oncoplastic surgery were included in this study. The majority of publications were from departments of BSO (68%, n=104) compared to PS (32%, n=49), and the majority of abstracts were presented at BSO conferences (83%, n=54) compared to PS conferences (17%, n=11). Compared to the field of PS, there has been a steady increase in interest in oncoplastic surgery in the field of BSO, represented by the increasing number of both publications and abstracts over the past few years (Figure). Publications focused on volume displacement techniques (n=55) were more common than volume replacement (n=34). Similarly, a higher number of abstracts focused on volume displacement (n=30) than volume replacement (n=8).

Conclusions: There is growing interest in oncoplastic surgery within the field of breast surgical oncology that seems to exceed that within plastic surgery. Through proper training and educational resources, oncoplastic techniques can be safely incorporated into a breast surgeon's practice. Future collaborations with professional plastic surgery organizations will develop competent breast surgeons, which will lead to improved oncologic and aesthetic outcomes for breast cancer patients.

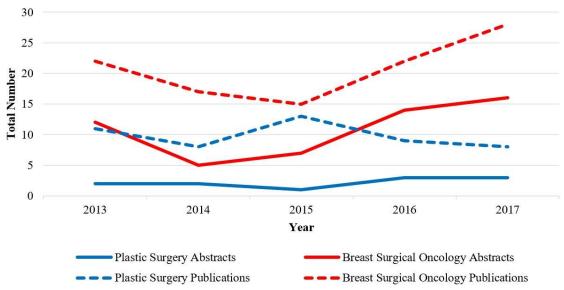


Figure: Oncoplastic surgery abstracts and publications yearly trend

573638 - Oncoplastic level 2 mammoplasty for large DCIS: Five-year results

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Background/Objective: DCIS often presents as ill-defined microcalcifications. Thirty percent will be treated by mastectomy, and 70% by breast conservative surgery, out of which approximately 1 in 3 undergo re-excision. Oncoplastic surgery (OPS) allows wider resections with immediate breast reshaping by mammoplasty. This study reviews our experience with level 2 mammoplasties in patients with histology-proven pure DCIS.

Methods: From a prospectively maintained database of 392 consecutive oncoplastic level 2 mammoplasties, 68 patients presented with pure DCIS. Involved margin rates and locoregional recurrence rates were calculated, with 76 months (0-166) median follow-up.

Results: The mean pathological tumour size was 34mm (median 26mm, range 0-106mm). The mean resection weight was 191 grams (median 131, range 40-1150). Margins were clear in 58 cases (85.3%) and involved in 10 cases (14.7%). Margins were involved in 1 out of 54 (1.9%) cases with a tumour size under 50mm, and in 9 out of 14 (64.3%) cases with a tumour size higher than 50mm (p<.001). On multivariable analysis, only tumour size >50mm (OR 95.400; p<0.001) was independently associated with involved margins. Seven patients had a mastectomy. The overall breast conservation rate was 89.4% and 100% for tumours less than 5cm. There were 3 local recurrences. The 5-year cumulative incidence for a local recurrence was 5.5% (0-11.5%).

Conclusions: OPS is a safe solution for large DCIS up to 50mm, with an involved margin rate of only 1.9% and can thus reduce the mastectomy rate in this group. As margin involvement significantly increases for tumours larger than 5cm, better preoperative localization and/or wider excisions are necessary in this group.

Patient Education

579398 - Evaluating effectiveness of a breast cancer survivorship program: Quality improvement pilot study

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Background/Objective: Survivorship programs aim to support the cancer patient transitioning from acute treatment to survivorship care in the community. Delivery of survivorship care has been recognised as an area of health care in need of development where current models may fail to meet the needs of survivors with little research in this field. Breast Cancer Care is the only UK-Wide charity providing specialist information and support for people affected by breast cancer supporting them in their day-to-day life management and emotional upheaval of breast cancer and health care professionals who care for them. The Moving Forward Course helps people to adjust to life after hospital-based treatment. It is provided in partnership with NHS trusts and health boards across the UK. Information and support encouraging self-management of ongoing physical and emotional issues is provided in 4 sessions over 4 weeks, sharing experiences with peers in a safe and caring environment. The aim of this pilot study was to evaluate the effectiveness of the Breast Cancer Survivorship Program and how to enhance it further.

Methods: All women who attended the Moving Forward Course between November 2015 and May 2018 were contacted by telephone with regards to evaluating the effectiveness of the impact of the course. Face-validated questionnaires were sent by post to those wishing to take part that focused on 4 aspects of cancer survivorship – physical, social, psychological, and spiritual well-being. Quantitative data were analysed using a 5-point Likert Scale and qualitative data through free text at the end of the questionnaire.

Results: Thirty-seven questionnaires were returned for analysis. Physical Well-being – the majority of women have kept physically active (95%), returned back to full activity (79%), and follow a balanced diet (86%). Most women are not in pain (67%) and are able to sleep (56%) but report fatigue (70%). Social Well-being - The majority of women were confident in their appearance (67%), have a good support network (86%), are able to speak to friends and family (81%), do not feel isolated (67%), and have confidence in their intimate relationships (51%). Psychological Well-being - Most patients had a good understanding of the side effects of treatment (86%), were confident in keeping breast aware (86%), and were aware of the signs and symptoms of recurrence (54%). Most are worried about cancer recurrence (97%), and are anxious of the future (65%). There was good knowledge of available support (94%), and they felt support was readily accessible (89%). Spiritual Well-being – the respondents did not feel more religious/spiritual (43%). Most understood the meaning of their diagnosis (75%) but felt uncertainty (57%). Some had gained inner strength (51%), most were hopeful of the future (73%), and their perspective of life had changed (75%). The main themes highlighted from the qualitative data was the establishment of an important support network course with fellow attendees. Some felt the course would have been useful when they were first diagnosed, others felt it would have been too much information at the time of diagnosis. Some felt the course could be adapted to account for age differences, for those that were working, and to have a program for partners. Others felt it would be useful to have a rolling program they could access as required.

Conclusions: This pilot study has shown that a breast cancer survivorship programme is effective for physical, social, psychological, and spiritual well-being even many months after the course. This forms the foundations for a larger focus group study to help implement and continually improve a programme that breast cancer survivors feel is effective and will be long-lasting.

581794 - Statin use at time of breast cancer diagnosis is associated with better outcomes Ann Chuang¹, Paul Tartter²

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Background/Objective: Statins (HMG-CoA reductase inhibitors) are lipid-lowering medications that block the conversion of HMG-CoA to mevalonic acid, and subsequently to estradiol. Statins have also been shown to possess anti-inflammatory properties. Studies have shown a correlation between obesity, cholesterol, estrogen, and breast cancer. We hypothesized that because of its cholesterol-lowering, anti-estrogen, and anti-inflammatory properties, statin use may be associated with presentation of invasive breast cancer and subsequent outcome.

Methods: Using our prospective breast cancer database, we performed a Level III retrospective cohort study to compare the incidence of breast cancer in statin users vs nonusers. We also examined age, number of pregnancies and completed births, age of statin use, tumor characteristics, and treatment modalities. We performed Chi square analysis for comparison of discrete variables between groups, and unpaired Student's T-test for comparison of continuous variables. Significance was set at p<0.05. IRB approval was obtained for this study.

Results: From our database, we found 137 statin users and 1391 nonusers who had invasive breast cancer. BMI was greater in the statin users than the nonusers (29.17 vs 27.03, p<0.01). There was no difference between age, number of pregnancies, number of births, and age of first birth between groups. There was a higher incidence of invasive lobular carcinoma (ILC) in the statin users than the nonusers (19.7% vs 10.8%, p=0.003) and a lesser incidence of invasive ductal carcinoma in the statin users than the nonusers (IDC, 80.3% vs 89.2%, p=0.003). There was no difference between tumor size and node positivity between groups. There was a lower proportion of moderate- and poorly differentiated invasive cancer in the statin users than the nonusers (0% vs 88%, p=0.038). There was no difference in tumor ER and HER2 status between groups. Statin users were more likely to undergo lumpectomy than mastectomy than nonusers (83% vs 80%, p=0.035). There was no significant difference between groups with regards to postoperative radiation therapy and tamoxifen use (p=0.145 and p=0.053). Statin users demonstrated less usage of postoperative chemotherapy than nonusers (27.0% vs 42.0%, p=0.001). Five-year local recurrence rates were also lower among statin users than nonusers (0% vs 5%, p=0.033).

Conclusions: Breast cancer patients taking statins at diagnosis had higher BMIs than nonusers. Statin users had better differentiated cancers, more frequently ILC, and more often had breast conservation. Both local and distant recurrence rates were also significantly lower among statin users. This suggests that statin use influences breast cancer biology and outcome. This may be attributed to the abovementioned anti-estrogen, cholesterol-lowering, and anti-inflammatory properties of the drug.

581276 - Contralateral prophylactic mastectomy: What's on the other side?

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Background/Objective: The rate of contralateral prophylactic mastectomy (CPM) has risen over the last 10 years. CPM and risk reduction surgery with bilateral prophylactic mastectomies (BPM) has shown a reduction of breast cancer development in certain populations (i.e., BRCA1/2 carriers), but it is still unclear if this translates to survival benefit, even in the highest-risk populations. Risk-reducing BPM or CPM in average-risk women is well documented to carry no survival benefit. We sought to evaluate pathologic findings in the unaffected breasts in both of these patient groups (BPM or CPM) to determine the rate of existing pathologic findings in the breast specimens being removed entirely for prophylaxis.

Methods: A retrospective review was performed of all patients who underwent a prophylactic mastectomy at a single NCI-designated comprehensive cancer center between January 2010 and October 2017. Patients undergoing BPM (without a cancer diagnosis) and patients undergoing CPM at the time of surgical treatment of a cancer diagnosis were evaluated. Clinical characteristics, risk status, prior medical treatment, type of surgical intervention, and final findings on pathology were collected and evaluated.

Results: A total of 886 women met inclusion criteria. There were 214 (24.2%) patients who had a known BRCA mutation and another 16 (1.8%) carrying a non-BRCA high-risk genetic mutation (HRGM) at the time of surgery. Among the patients with either BRCA/HRGM, 59.1% (n=136) had CPM compared to 81.8% (n=610) without BRCA/HRGM. Among patients with BRCA/HRG, 40.9% (n=94) had BPM compared to 18.2% (n=136) without BRCA/HRGM. When evaluating the prophylactic mastectomy specimens, 30.0% (n=239) had an abnormal finding on pathology, with 121 having multiple abnormal findings. Thirty-nine (10.8%) had DCIS, 15 (4.2%) had invasive cancer, 140 (38.9%) had atypical ductal hyperplasia, 48 (13.3%) had LCIS, 54 (15.0%) had radial scar, and 64 (17.8%) had intraductal papilloma. In addition, 5 (2.1%) specimens had a combination of DCIS and invasive cancer. There was no difference in incidental findings of DCIS or invasive cancer in CPM samples between those with BRCA/HRGM were less likely to have any abnormal finding in the unaffected breast than patients with BRCA/HRGM; 19.6% (n=45) vs. 29.6% (n=194) (p-value=0.003).

Conclusions: Overall, the likelihood of malignancy in the unaffected breast was low in both groups. Perhaps surprisingly, patients with a BRCA or other HRGM were less likely to have a non-malignant abnormal finding compared to patients without a genetic predisposition. This may have been due to a higher utilization of MRI in the BRCA/HRGM population, with biopsies of abnormal MRI findings excluding patients from being included in the study group. Although there were multiple prophylactic specimens with ADH, ALH, papilloma, and radial scar, the low risk of malignancy in both study groups supports judicious use of CPM and BPM. These data suggest that we must continue to educate our patients regarding the risks and benefits of these procedures and the increased risk and very limited benefit associated with prophylactic mastectomy.

580387 - Anxiety scores of women with an increased risk of breast cancer participating in facilitated group visits

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Background/Objective: Women with an increased risk of breast cancer are often anxious about their risk and may benefit from additional counseling related to their risk assessment, breast surveillance, and risk-lowering interventions. The purpose of the study was to examine self-reported anxiety before and after facilitated group visits for this population.

Methods: In conjunction with routine follow-up visits, women in a high-risk breast clinic were invited to attend a one-hour facilitated group visit. Based on the Centering model, the focus was on breast education and support, as well as health assessment. The small group sessions were facilitated by a breast surgery NP and consisted of 3-6 women each week. The structure of the session included check-in with a self-assessment sheet, which included a self-reported anxiety score using a validated tool (the Speilberger State-Trait Anxiety Inventory [STAI]). This 6-item survey asked about one's current anxiety state using Likert scale options (numeric scale 1-5). The self-reported categories (calm, tense, upset, relaxed, content, worried) were used to describe how they felt, "right now, at this moment." The check-in sheet also asked women to identify and rank potential topics of interest for discussion at the session. At the beginning of the session, women participated in an ice-breaker activity. Subsequently, a facilitated discussion ensued for 45 minutes, focusing on the topics identified by the women at that session. A variety of educational methods were used, ranging from myth busters Q&A, standing continuum of risk factors, or connecting with someone with a matching nutrition card. Breast models were used to practice breast self-awareness. At the end of each group visit, the STAI survey was repeated.

Results: Between March 1 and October 26, 2018, 87 women participated in the weekly group visits. Common topics of interest included genetics, nutrition, breast imaging, breast reconstruction, and exercise impact on cancer risk. All women were asked to complete the 6-question STAI survey before and after the session. Seventy-nine completed surveys (pre and post) were tabulated and analyzed, for a 91% completion rate. Mean values for each domain were calculated with a paired t test showing significant improvement in 5 of 6 domains. (See Figure - STAI pre-post means by domain. Comparing the pre- and post-surveys, women reported feeling calmer, more content, and more relaxed on the post-surveys (p-value<0.05). Women also reported feeling less worried and less tense by the end of the group session (p-value<0.05). The only category that did not change was feeling "upset;" however, this score was already low on the pre-survey (mean rating 1.25), and thus, did not change much after the session (mean rating 1.2).

Conclusions: For women with an increased risk of breast cancer attending a high-risk breast clinic, facilitated group visits appear to decrease self-reported anxiety. As such, facilitated group visits may offer women in a high-risk breast clinic a supplemental model of patient care, which provides additional education and support for women with increased anxiety.

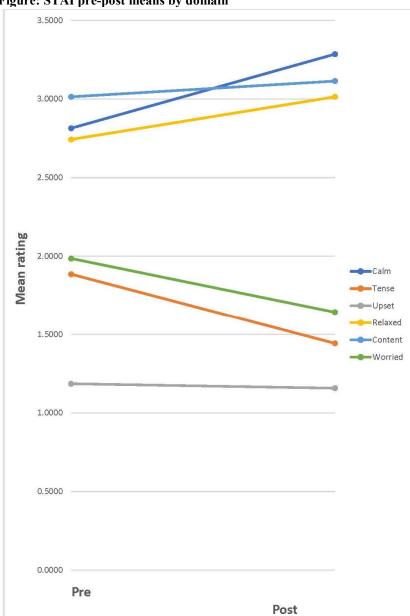


Figure: STAI pre-post means by domain

Phyllodes

580331 - Fibroepithelial lesions of the breast diagnosed on core needle biopsy: Do all patients require excision?

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Background/Objective: Fibroepithelial lesions of the breast represent a heterogeneous group of tumors with a wide range of clinical behavior. Due to their heterogeneity, the distinction between a cellular fibroadenoma and a benign phyllodes tumor can be challenging to make on core needle biopsy alone, resulting in a recommendation for surgical excision by the pathologist. In this study, we aimed to examine the population of patients diagnosed with an indeterminate fibroepithelial lesion on core needle biopsy, determine if there were any pre-operative characteristics that could predict upstaging to phyllodes tumor, and establish if there is a subset of patients who can be safely observed. We hypothesized that, of the patients who were surgically excised, more would have benefited from close observation.

Methods: An IRB-approved retrospective chart review was conducted on patients treated in our institution from January 2012 through September 2018. We identified patients by performing a search of core needle biopsy pathology specimens with a diagnosis of fibroepithelial lesion. We excluded patients who could be considered a member of a vulnerable population, patients with a personal history of phyllodes tumor or breast cancer, and patients with incomplete pathology records. We collected demographic, clinical, histological, and radiographic characteristics on each of the patients included in the study. We compared these characteristics between patients upstaged to phyllodes tumor on final surgical excision pathology and those who were not using Fisher's exact test for binary factors and Wilcoxon-Mann-Whitney test for continuous variables. Logistic regression models were constructed to model the likelihood of upstaging to phyllodes tumor as a function of the variables of interest.

Results: A total of 151 patients were identified who were diagnosed with an indeterminate fibroepithelial lesion on core needle biopsy during the study period. One hundred thirty-one patients met inclusion/exclusion criteria. Of those 131 patients, 16 (12.2%) were observed, and 115 (87.8%) went on to surgical excision. The final surgical pathology of the patients who were excised is summarized in the Table. There was no statistically significant difference between the group of patients who were upstaged to phyllodes tumor and those who were not with regard to race, menopausal status, or family history of breast cancer.

Conclusions: Our rate of upstaging to phyllodes tumor was 27%. This result is in keeping with the 18-42% rate of upstaging reported in previous studies. The only significant predictor of phyllodes tumor on final surgical pathology in our dataset was tumor size (p=0.0082), with larger tumors being more likely to be upstaged. Unfortunately, no other specific clinical, radiographic, or histological characteristics could predict upstaging to phyllodes tumor, although there seems to be some evidence that those who are premenopausal had a lower likelihood of upstaging (p=0.086). Our rate of upstaging may be used to counsel reliable patients after an indeterminate fibroepithelial lesion core needle biopsy result. In the setting of a breast center with readily available follow-up, close observation may be a reasonable option for patients with smaller tumors who wish to avoid surgery.

Table: Surgical excision pathology

| Tumor Type | Number of Cases | Percentage (%) | |
|----------------------------|-----------------|----------------|--|
| Malignant phyllodes tumor | 1 | 0.8 | |
| Borderline phyllodes tumor | 3 | 2.6 | |
| Benign phyllodes tumor | 27 | 23.5 | |
| Fibroadenoma | 76 | 66.1 | |
| Other benign lesion* | 8 | 7 | |

*Includes fibrocystic change, benign breast tissue, nodular adenosis, PASH, and lactating adenoma

Radiation

581161 - Can post-mastectomy radiation therapy be omitted in T1-2 clinically nodenegative breast cancer patients with a positive sentinel lymph node biopsy? <u>Kate Dinh¹</u>, Atilla Soran¹, Arda Isik¹, Priscilla McAuliffe¹, Emilia Diego¹, Efe Sezgin², Sushil Beriwal¹, Ronald Johnson¹ ¹University of Pittsburgh Medical Center, Magee-Women's Hospital, Pittsburgh, PA, ²Izmir Institute of Technology, Izmir, Turkey

Background/Objective: The AMAROS trial demonstrated that both axillary radiation and axillary lymph node dissection (ALND) provide excellent locoregional control in patients with clinically node-negative T1-2 breast cancers and a positive sentinel lymph node biopsy (+SLNB). In that study, 18% of patients underwent total mastectomy (TM). We evaluate survival outcome of TM patients who do not require additional axillary treatment after identification of a +SLNB.

Methods: A prospective breast cancer database at a single institution was retrospectively reviewed from 1/2013 to 12/2017 to identify patients with clinically node-negative T1-2 breast cancers who underwent TM, were found to have a +SLNB, and who did not undergo ALND. Demographics and clinicopathologic features were evaluated. We compared outcomes in those patients who received post-mastectomy radiation therapy (PMRT) to those who did not.

Results: A total of 72 patients were identified: 50 subsequently received PMRT, and 22 did not. All patients received systemic therapy (ST). More patients in the PMRT- group had tumor size \leq 20mm compared with the PMRT+ group (70% vs 44%, p=0.04). Although there was no difference in the number of lymph nodes identified, more patients in the PMRT+ group had >1 +SLNB (24% vs 5%; p=0.04). Extracapsular extension (ECE) was seen less in the PMRT- than PMRT + group (10% vs 32%, p=0.05). Micrometastasis was found in 73% of PMRT- patients and in 30% of PMRT+ patients (p=0.001). At median follow-up of 34 months, there were no loco-regional recurrences (LRR) in either group, and disease-free survival (DFS) was similar: 32.1 months in the PMRT+ group vs. 31.9 months in the PMRT- group.

Conclusions: PMRT is currently recommended + SLNB in cases where ALND is not done. With a limited number of patients, all of whom met AMAROS study criteria and received ST, our study showed that in selected cases with only one +SLNB, micrometastasis, no ECE and tumor size <2 cm, omitting axillary lymph node treatment did not increase LRR or decrease DFS in median 34 months follow-up.

| Table: N=72 | PMRT (+) | PMRT (-) | р |
|--------------------------------------|--------------|------------|-------|
| | | | Р |
| | N= 50 (69 %) | N=22 (31%) | |
| Age, mean ±SD | 53.3 ±12.8 | 56.2 ±14.5 | 0.38 |
| <70 years old | 46 (92%) | 17 (77%) | 0.08 |
| ≥70 years old | 4 (8%) | 5 (23%) | - |
| Tumor size; mm, mean ±SD | 26.6 ±24.0 | 17.6±9.1 | 0.11 |
| Tumor size $\leq 20 \text{ mm}$ | 21 (44%) | 14 (70%) | 0.04 |
| Tumor size > 20 mm | 27 (56%) | 6 (30%) | - |
| Follow up time, months, mean ±SD | 33.6±12.0 | 34.2±15.5 | 0.88 |
| Median follow-up (25%,75%) | 34 (24,42) | 34 (27,48) | 0.99 |
| Mean lymph nodes identified \pm SD | 3.6±1.9 | 3.7±1.7 | 0.86 |
| Lymph node positive =1 | 38 (76%) | 21 (95%) | 0.04 |
| Lymph node positive >1 | 12 (24%) | 1 (5%) | 1 |
| LNR (lymph node ratio) $\leq 15\%$ | 2 (4%) | 2 (9%) | 0.39 |
| LNR (lymph node ratio) >15% | 48 (96%) | 20 (91%) | - |
| LVI | 0 | 0 | |
| Micrometastasis | 15 (30%) | 16 (73%) | 0.001 |
| Macrometastasis | 35 (70%) | 6 (27%) | 1 |
| ECE (-) | 34 (68%) | 19 (90%) | 0.05 |
| ECE (+) | 16 (32%) | 2 (10%) | - |
| Triple negative | 3 (6%) | 2 (11%) | 0.49 |
| HER2 neu + | 4 (8%) | 1 (6%) | 0.72 |
| ER/PR (+) HER2 neu- | 42 (86%) | 15 (83%) | 0.81 |
| Loco-regional progression | 0 | 0 | |
| Distant metastasis | 3 (6%) | 2 (9%) | 0.65 |
| Death (breast cancer related) | 1 (2%) | 0 (0%) | 0.50 |
| Mean Disease free survival ±SD | 32.1±12.2 | 31.9±14.6 | 0.94 |

581950 - Nuclear grade: An important predictor of local recurrence in patients treated with intraoperative radiation therapy (IORT)

Melinda Epstein, Peter Chen, Brian Kim, Kevin Lin, Sadia Khan, Lincoln Snyder, Lisa Guerra, Colleen Coleman, Melvin Silverstein

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Background/Objective: IORT has been shown to be a safe alternative to whole breast radiation therapy (WBRT) with a low local recurrence rate for selected low-risk patients. In 2017, the American Society of Radiation Oncology (ASTRO) published a Consensus Statement with guidelines for selecting patients appropriate for IORT. Older age, negative lymph nodes, focal or no lymphovascular invasion, wider margins, smaller tumor size, and estrogen receptor positivity were among some of the tumor characteristics considered to decrease the risk of local recurrence and were utilized to divide patients in suitable, cautionary, and unsuitable categories. Nuclear grade, a prognostic factor known to be associated with local recurrence rates in breast cancer patients, was not considered a critical factor and was not included in these guidelines. We studied the effect of nuclear grade on local recurrence in patients receiving IORT to determine whether it should be included in the guidelines.

Methods: A total of 1100 patients received X-ray IORT using the Xoft Accent System as part of a prospective trial from June 2010 to July 2018. All tumors, including DCIS (n=235) and invasive (n=865) 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 \leq 30mm, tumor margins \geq 2mm, no extensive LVI, and negative lymph nodes [N0(i+) acceptable]. Patients that received IORT but did not ultimately meet all criteria were advised to receive supplemental WBRT. Nuclear grade was determined by pathologic examination. Kaplan-Meier analysis was used to estimate the probability of local recurrence for each nuclear grade individually and in groups (i.e., nuclear grades 1 and 2 versus nuclear grade 3). All local events, regardless of the quadrant in which they occurred, were included in the analysis. Groups were compared using the Log-Rank Test.

Results: The 4-year probability of local recurrence for high-grade lesions was 7%. Patients with nuclear grade 1 (n=135) and nuclear grade 2 (n=812) tumors had statistically similar probabilities of local recurrence at 4 years, 1.3% and 3.3% (p=0.53) and were grouped together as non-high-grade. When the local recurrence probabilities for non-high-grade and high-grade were compared, they were statistically different (p=0.036) (Figure). There were 31 local recurrences (9 in high-grade patients, 22 non-high-grade patients). Thirteen local recurrences were in different quadrants than the index cancer. Of the 31 local recurrences, 20 were invasive. One patient had a distant recurrence. There were no breast cancer-related deaths. Median follow-up was 40 months.

Conclusions: The use of X-ray IORT for the treatment of breast cancer continues to be controversial. ASTRO guidelines suggest that it only be used within a prospective registry or clinical trial and only in patients with tumors that exhibit low-risk characteristics. This study shows that nuclear grade is a statistically important predictor of local recurrence in patients that receive IORT. Consideration should be given to adding nuclear grade to the ASTRO criteria used for selecting patients appropriate for IORT.

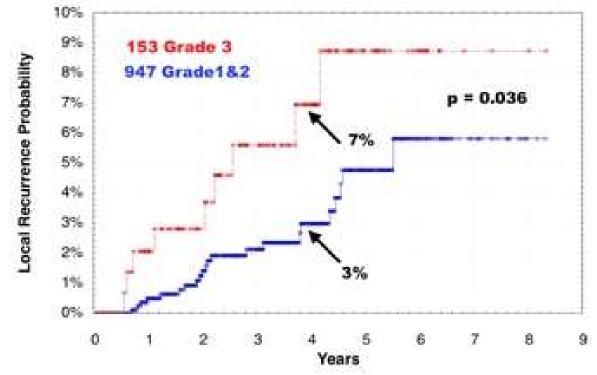


Figure: Probability of local recurrence in 1100 IORT patients by grade

580686 - Complication rates after intraoperative radiation therapy: Do applicator size and distance to skin matter?

Amani Jambhekar, Abby Wong, Bret Taback, Margaret Chen, Roshni Rao, Eileen Connolly, Lisa Wiechmann

Columbia University Medical Center, New York, NY

Background/Objective: Intraoperative radiation therapy has gained popularity for the treatment of earlystage breast cancer. Few studies have examined the relationship between complications and both demographic and technical factors. The objective of the current study was to determine if the distance from the applicator to the skin or applicator size were significant risk factors for complications.

Methods: Data were prospectively collected on patients who underwent lumpectomy followed by intraoperative radiation therapy (IORT) from November 1, 2013 to August 31, 2018. Patients were included if they underwent IORT with no further external beam radiation therapy. Exclusion criteria included any prior radiation exposure or personal history of breast cancer. Comorbid conditions such as body mass index, diabetes, and smoking, as well as technical specifications such as applicator size and distances to the skin were included for investigation. Student's t test, Fisher's exact test, and odds ratios were utilized for statistical analysis.

Results: The study comprised 219 patients, of which none developed clinically significant complications. 21.0% (n=46) had minor complications that did not require further intervention. The most common complication was a palpable breast seroma (n=37). The complications and no complications groups were similar in age and stage of disease (Table). Diabetes was the only comorbid condition that was a significant risk factor for complications (OR 3.2; 95% CI 1.3-7.5; p=0.008). The applicator sizes were

similar between groups (3.4+/- 0.4 vs 3.4 +/- 0.4 cm; p=0.5). Average skin distances were also similar between groups (Table). Surprisingly, the closest skin distance was not a significant risk factor for postoperative complications (1.4 +/- 1.6 vs. 1.4 +/- 1.9 cm; p=1.0).

Conclusions: Neither applicator size nor the closest skin distance were associated with increased complications after IORT. Additionally, traditionally described risk factors such as BMI and smoking were not predictive. Overall, complication rates of IORT remain low. Larger prospective studies are needed to examine technical risk factors so all providers may be optimally trained with outcome in mind.

| | Complications $(n = 47)$ | No Complications (n = 172) | All (n = 219) | p value |
|---------------------------------|--------------------------|-------------------------------|------------------|---------|
| Age | 65.4 +/- 8.8 | 65.4 +/- 10.0 | 65.2 +/- 9.7 | 1.0 |
| (Mean +/- SD; years) Stage I | 32 (68.1%) | 120 (69.8%) | 152(69.4%) | 0.8 |
| DM BMI | 11(23.4%) | 15(8.7%) | 26(11.9%) | 0.01 |
| (Mean +/- SD) | 30.0 +/- 7.9 | 28.6 +/- 5.9 | 28.9 +/- 6.5 | 0.2 |
| History of smoking | 8 (17.0%) | 42 (24.4%) | 50(22.8%) | 0.3 |
| Active smoker | 1 (2.1%) | 10 (5.8%) | 11(5.0%) | 0.5 |
| Distance to Skin | | | | |
| Superior | 1.9 +/- 2.4 | 2.0 +/- 2.6 | 2.0 +/- 2.6 | 0.9 |
| Inferior | 1.8 +/- 1.6 | 1.9 +/- 2.5 | 1.9 +/- 2.4 | 0.8 |
| Medial | 2.0 +/- 1.7 | 2.2 +/- 3.0 | 2.2 +/- 2.8 | 0.6 |
| Lateral | 1.8 +/- 1.7 | 2.0 +/- 3.1 | 1.9 +/- 2.8 | 0.6 |
| Closest | 1.5 +/- 1.6 | 1.5 +/- 1.8 | 1.5 +/- 1.8 | 1.0 |
| Applicator Size | 3.4 +/- 0.4 | 3.4 +/- 0.4 | 3.4 +/- 0.4 | 0.5 |

| Table: Demographic and | technical factors | associated with IORT |
|------------------------|-------------------|----------------------|
| Table, Demographic and | teennical factors | |

581514 - Twelve percent of SAVI catheters required explantation prior to completion of abbreviated partial breast irradiation (APBI) treatment in a mature community APBI program

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Background/Objective: More than 12% of strut-adjusted volume implant (SAVI) catheters were pulled in a 10-year period, totaling more than \$500,000 of cost in addition to the cost of subsequent whole breast radiation (WBI). This retrospective study seeks to identify the factors that impact the rate of failure, and to identify potential best practices to reduce the rate.

Methods: This retrospective study reviewed all cases of SAVI catheter insertion between 2007 and 2018 at a large community cancer center. Cases where a catheter was pulled prior to completion of radiation treatment were compared to those where APBI was completed. Factors studied included interval between lumpectomy and SAVI insertion, SAVI size, use of cavity evaluation balloon, neo-cavity creation versus percutaneous insertion, cavity size, BMI, patient age, mammographic density, lumpectomy specimen size, quadrant of breast, and strut inversion. Chi squared, and Mann-Whitney, Un-paired t-test and Fisher exact test were used to assess the effect of each factor on probability of catheter being pulled prior to completion of treatment.

Results: A total of 255 SAVI catheters were placed during study period, 33 (12%) of which were pulled prior to completion of treatment. Characteristics of the 33 catheter-pulled cases were compared to 185 randomly selected cases in which APBI was completed (the controls). Significant difference was seen

between the size of catheter used, (p=0.0001). Smaller catheters were more common among the controls. In an unplanned subgroup analysis, there was a trend towards discordance between the cavity length and the catheter size, suggesting that larger cavity size may increase risk of failure. None of the other factors studied impacted risk of explanation prior to completion of APBI.

Conclusions: The cost of inserting a SAVI device at our institution is \$17,960. If the SAVI catheter is explanted before APBI completion, the patient must then have whole breast irradiation. Such patients undergo an unnecessary operation (SAVI insertion), and incur significant financial and emotional cost, for a procedure from which they have derived no value. In our study, more than 12% of SAVI catheters were pulled in a 10-year period, totaling more than \$500,000 over and above the cost of the subsequent WBI. This retrospective study evaluated multiple factors to determine which might impact risk of SAVI catheter removal prior to completion of APBI. The only factor that correlated with increased risk of catheter explantation prior to completion between irregular cavity shape and explantation. APBI is a good alternative to WBI for selected patients, and avoids radiation effect on chest wall, lungs, and heart, but a 12% rate of explantation prior to completion of APBI is expensive, and the patient must still undergo WBI. These results indicate that CT prior to catheter insertion might identify irregular or large cavities not appropriate for SAVI. A multi-institutional study is indicated to investigate further ways to reduce risk that APBI catheters will be pulled prior to completion of irradiation.

582042 - A single-institution review of APBI using brachytherapy versus IORT: A patterns-of-care analysis

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Background/Objective: Our institution has always been on the forefront for offering accelerated partial breast irradiation to our patients. We acquired the Intrabeam system for Intraoperative Radiation Therapy (IORT) in September 2016 as a single-dose therapeutic option for select patients. We sought to perform a patterns of care analysis for patients undergoing breast brachytherapy to evaluate the usage of APBI with the introduction of IORT to the armamentarium of available APBI modalities at our institution.

Methods: An analysis of women with breast cancer treated with breast-conserving surgery and either breast brachytherapy or IORT between July 1, 2014 and October 31, 2018 was conducted. Age, histology (DCIS versus invasive disease), tumor size, estrogen receptor status, sentinel lymph node biopsy (SLNB) rate, nodal status, and Medicare reimbursements were compared between the patients who were treated with IORT versus the patients who were treated with catheter-based brachytherapy (CBB).

Results: Forty-nine patients with early-stage breast cancer received radiation therapy using CBB in the 28-month period (7/1/14-8/31/16) prior to the introduction of IORT at our institution (pre-IORT). Between September 1, 2016 and October 31, 2018 (post-IORT), a total of 83 patients were treated with APBI. Of the 83 patients treated with APBI during the post-IORT period, 40 (48.1%) patients were treated using IORT (one fraction) versus 43 (51.8%) patients treated using CBB. However, of the 43 patients in the CBB group, 20 were enrolled into the TRIUMPH-T trial with 3 fractions of brachytherapy; the remaining 23 patients received the full fractions. The overall increase of 43 additional APBI cases represents a 69.3% increase in the number of APBI cases between the pre-IORT and post-IORT period. The mean age for IORT patients was 73.0 years versus 67.6 years for CBB patients (p=0.0002). Thirty-eight (95.0%) patients had invasive carcinoma in the IORT group versus 40 (93%) in the CBB group. Thirty-nine (97.5%) IORT patients and 41 (95.3%) CBB patients had estrogen receptor-positive tumors.

Mean tumor size was 11.3 mm for IORT patients and 10.7 mm for CBB patients (p=0.604). Thirty-six (90%) patients in the IORT group had SLNB, and all lymph nodes were negative, while 39 (90.7%) patients in the CBB group had SLNB, all of which were also negative. Mean Medicare reimbursement for IORT was \$6978.30 versus \$8990.73 for CBB (p=0.0005).

Conclusions: Availability of IORT increased utilization of APBI at our institution. Moreover, the addition of IORT did not decrease our utilization rate of CBB. In the future we plan a continued analysis to assess the patterns of care of APBI-treated patients. This will include highlighting existing and potential barriers to either form of APBI but particularly that of IORT in the form of insurance denials, lack of surgical reimbursement, and logistics for coordinating multiple provider schedules.

578618 - Improved survival with breast conservation: Analysis of a large national database <u>Christopher Tokin¹</u>, Beiqun Zhao², Anne Wallace², Sarah Blair² ¹University of California, San Diego, Encinitas, CA, ²University of California, San Diego, La Jolla, CA

Background/Objective: Few large, population-based studies have compared breast conservation plus radiotherapy to mastectomy, and those that have focus on early stage tumors and exclude patients with more advanced stages or those that get mastectomy plus radiotherapy. While there is mounting evidence that there is a survival benefit to breast conservation over mastectomy in early-stage disease, we aimed to assess if this trend holds true in more advanced breast cancer, and whether radiotherapy when added to mastectomy allows for improved overall survival.

Methods: We queried the National Cancer Database (NCDB) for patients >18 years of age with a diagnosis of non-metastatic primary breast cancer. We compared lumpectomy with radiation versus mastectomy (with and without radiation) using univariable and multivariable Cox proportional hazard ratio analysis by controlling for age, Charlson/Deyo comorbidity scores, margin status, tumor size, number of positive lymph nodes, treatment at an academic center, neoadjuvant chemotherapy, and ER/PR/HER2 positivity.

Results: Of the more than 2 million breast cancer patients identified in the NCDB, the overall breast conservation rate was 44.6%. For smaller tumors where radiotherapy may be included in their treatment regimen (T2N1), there was an overall survival advantage to lumpectomy plus radiation when compared to mastectomy with or without radiation (p<0.01). In more advanced disease (T2-3, N1-3), there continued to be an overall survival advantage to breast conservation when compared to mastectomy alone; however, when radiation was added to the mastectomy treatment algorithm, survival rates were equivalent.

Conclusions: Breast conservation with radiotherapy portends improved survival rates compared to mastectomy alone for both early and more advanced staged disease, suggesting that breast conservation should be the preferred option if possible.

Table: Hazard ratios of lumpectomy + radiation when compared to mastectomy and mastectomy +radiation

| | Lumpectomy + XRT | Mastectomy Alone | 95% CI | Mastectomy +XRT | 95 % CI |
|------|---------------------|---------------------|-------------|--------------------|-------------|
| T2N1 | Reference | 1.68* | (1.58-1.80) | 1.15* | (1.07-1.24) |
| T2N2 | Reference | 2.86* | (2.52-3.14) | NS | |
| T2N3 | Reference | 2.56* | (2.22-2.96) | NS | |
| T3N0 | Reference | 2.05* | (1.67-2.54) | NS | |
| T3N1 | Reference | 2.25* | (1.81-2.81) | NS | |
| T3N2 | Reference | 2.81* | (2.14-3.71) | NS | |
| T3N3 | Reference | 2.14* | (1.61-2.86) | NS | |

*p<0.01

NS = not significant

Reconstruction

582082 - Enhanced recovery after surgery protocol demonstrates improved pain control and reduced opioid consumption for women undergoing mastectomy with immediate reconstruction

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Background/Objective: The management of patients undergoing breast cancer surgery continues to evolve. Our institution developed an evidence-based enhanced recovery after surgery (ERAS) protocol to facilitate recovery of patients undergoing mastectomy with immediate reconstruction. The protocol included preoperative patient education and nonopioid multimodal medications, intraoperative PECS blocks and opioid-sparing anesthetic, and postoperative-scheduled nonopioid multimodal medications. The aim of this study was to compare postoperative pain, opioid consumption, and antiemetic administration between traditional recovery after surgery (TRAS) and ERAS cohorts.

Methods: A retrospective comparison of TRAS and ERAS for patients undergoing mastectomy with immediate reconstruction surgery was designed. Total sample size, determined by an a priori power analysis was 102, with 51 in TRAS and ERAS cohorts. Subject inclusion was limited to a single breast surgeon in both cohorts. Cohorts were sequentially derived from the time period prior to ERAS implementation (May 2013 through May 2016) and post-ERAS protocol implementation in May 2016.

Results: No significant differences were found between the groups in terms of age, body mass index, chronic pain diagnosis, chronic opioid use, history of chronic substance abuse disorder, type of surgery (unilateral or bilateral mastectomy) or pain score on admission. Patients in the ERAS group had significantly decreased mean pain scores and total opioid consumption (measured by oral morphine equivalence) on post-operative Day 0 and Day 1. The ERAS cohort experienced less postoperative nausea and vomiting, required less antiemetic administration, and had a shorter hospital length of stay but differences were not statically significant.

Conclusions: Implementation of an ERAS protocol in the surgical management of patients undergoing mastectomy with immediate reconstruction resulted in significant reductions in postoperative pain and opioid consumption. This study reinforced the use of ERAS protocols in the breast surgery population. In addition, the study supports the use of ERAS protocols as opioid-sparing initiatives in this surgical setting and demonstrated successful multidisciplinary engagement in the implementation of the protocol.

| TRAS (n = 51) | ERAS (n = 51) | р |
|----------------------|--|--|
| 1.08 ± .27 | 1.02 ±.14 | .17 |
| 26 (51%) 25 (49%) | 34 (67%) 17 (33%) | .11 |
| 42 (82%) 9 (18%) | 48 (94%) 3 (6%) | .07 |
| 3.7 ± 1.3 | 2.2 ± 1.7 | <.001 |
| 3.5 ± 1.6 | 1.9 ± 1.8 | <.001 |
| 49.4 ± 25.9 | 20.9 ± 23.1 | <.001 |
| 35.1 ± 25 | 11.2 ± 13.7 | <.001 |
| | 1.08 ± .27 26 (51%) 25 (49%) 42 (82%) 9 (18%) 3.7 ± 1.3 3.5 ± 1.6 49.4 ± 25.9 | $1.08 \pm .27$ $1.02 \pm .14$ $26 (51\%)$ $34 (67\%)$ $25 (49\%)$ $17 (33\%)$ $42 (82\%)$ $48 (94\%)$ $9 (18\%)$ $3 (6\%)$ 3.7 ± 1.3 2.2 ± 1.7 3.5 ± 1.6 1.9 ± 1.8 49.4 ± 25.9 20.9 ± 23.1 |

Table: Mastectomy with immediate reconstruction TRAS and ERAS comparisons

Analysis & Level of Significance: chi-square, $p \le 0.05$, independent sample t-test with Boneferroni correction, $p \le 0.005$

580368 - Reoperation and postoperative outcomes for single-stage versus two-stage breast reconstruction following mastectomy: A meta-analysis

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Background/Objective: Implant-based breast reconstruction has become widely accepted as an appropriate reconstruction method following mastectomy for breast cancer. The 2 most common techniques include immediate reconstruction and implantation (single-stage procedure) or the use of a tissue expander with delayed insertion of implant and reconstruction (two-stage procedure). Using existing studies and available data, a meta-analysis was performed analyzing reoperation rates and postoperative complications between these 2 methods based on available literature.

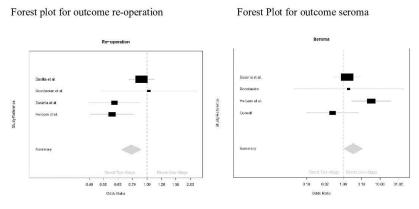
Methods: A literature search was performed by 2 individual investigators using the databases PubMed, Cochrane, and Medline. All articles comparing implant-based, single- and two-stage breast reconstructions outcomes between 2006 and 2016 were utilized. The primary endpoint of interest was reoperation rates. Secondary endpoints included postoperative complications such as infection, seroma, hematoma, and necrosis.

Results: A total of 5 studies met the inclusion criteria, for a total of 12,357 breast reconstructions. Of these, 2,281 breast reconstructions were single-stage, and 10,076 were two-staged. The primary endpoint of reoperation resulted in an increased reoperation rate in the single-stage breast reconstruction (see figures). Secondary endpoints demonstrated no statistical significance in infections (see figures), hematoma (see figures) and necrosis (see figures). However, there was an increased incidence of seroma formation in two-stage reconstruction (see figures).

Conclusions: Many studies have attempted to compare these 2 procedures; however, the debate remains on which procedure is best suited for breast reconstruction following mastectomy, and combined comparative large-scale studies are lacking. This meta-analysis attempts to combine comparative studies,

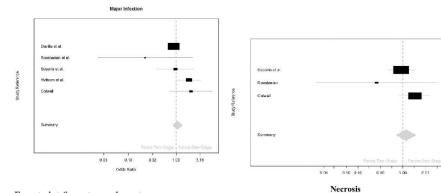
analyze reoperation rates and reconstruction outcomes between these 2 methods based on available literature. Our study met its aims and proved that single-stage reconstructions resulted in a significant increase in reoperation/revision rates. It also showed that single- and two-staged implant breast reconstructions had similar infection, hematoma, and necrosis rates. Given the statistically significant increase in reoperation/revision rates in a single-stage procedure, as well as increased risk for implant failure, we feel that the benefits of a single-stage procedure may not be substantiated in the patient with significant comorbidities. In the appropriately selected patient with low comorbid conditions, non-smoker, and normal BMI, there may be a role for this procedure. One must consider the quality of the mastectomy flap as well. A two-stage procedure, whether immediate or delayed, appears to be the safest option in those patients with thin flaps, comorbid conditions, smokers, and the general healthy population.

Figures: Forest plots for outcomes

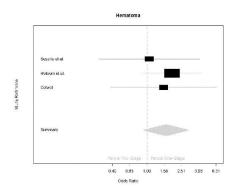


Forest plot for outcome major infection

Forest Plot for outcome necrosis



Forest plot for outcome hematoma





580703 - Evaluating patient satisfaction in autologous breast reconstruction vs. implant reconstruction

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Background/Objective: In the last decade, the rate mastectomies has increased by 36%, resulting in an increased need for breast reconstruction options. The goals of this study are to evaluate patient satisfaction in autologous and implant breast reconstruction and to determine if correlations exist between patient profile and reconstruction type.

Methods: Patient satisfaction surveys and demographic information collected via chart review were used to evaluate breast cancer patients ages 18-70 who had breast reconstruction between 2010-2017 at our institution. Multivariate logistic regression was used to determine demographic factors associated with reconstruction type. Multivariate linear regression was used to evaluate patient satisfaction with each type of reconstruction and to evaluate patient satisfaction related to time from first surgery.

Results: A total of 166 of 386 patients returned complete surveys; 146 from implant reconstruction patients and 20 from autologous reconstruction patients. All were between 2-7 years from initial breast reconstruction. Adjusted for patient profile, autologous reconstruction patients reported significantly higher natural/similar feeling of breasts compared to implant reconstruction patients (p<0.0001). There was no difference in satisfaction with appearance when undressed between the 2 groups (p=0.0795). However, the autologous group reported significantly higher satisfaction with both undressed appearance and natural/similar feeling of breasts at 3-7 years following first surgery (p<0.05 at all time points). Both increasing age (p=0.033) and having a college degree (p=0.049) were independently associated with significantly higher odds of having autologous reconstruction (p=0.011). Autologous reconstruction patients had 72% lower odds (OR 0.28) of discovering other reconstruction options after their surgery as compared to implant patients (p=0.045). Specifically, only 12% of autologous reconstruction patients found out about other options after their surgery as compared to implant patients (p=0.048).

Conclusions: These results offer patients and health care providers information about how demographics and time from surgery may affect outcomes. This warrants further investigation into complications during the follow-up period and how those may affect satisfaction.

| | All Patients (n = 166) | Autologous (n = 20) | Implant $(n = 146)$ | P-Value |
|--|---------------------------|------------------------|---------------------|---------|
| Are you satisfied with your decision to have breast reconstruction? | | | | |
| Mean (Standard Deviation) | 4.17 (1.12) | 4.45 (1.23) | 4.14 (1.11) | 0.243 |
| Are you content with the quality of your life now when compared to before | | | | |
| the surgery? | | | | |
| Mean (Standard Deviation) | 3.83 (1.22) | 4.10 (1.41) | 3.79 (1.19) | 0.282 |
| How high is your current concern for breast cancer? | | | | |
| Mean (Standard Deviation) | 3.33 (1.27) | 3.50 (1.47) | 3.31 (1.24) | 0.527 |
| How often do you experience intrusive thoughts about breast cancer? | 2.14 (1.04) | 2 10 (1 12) | 216(1.04) | 0.700 |
| Mean (Standard Deviation) | 3.16 (1.06) | 3.10 (1.17) | 3.16 (1.04) | 0.799 |
| Are you self-conscious about your appearance? Mean (Standard Deviation) | 2 07 (1 21) | 2 10 (1 20) | 2 07 (1 21) | 0.010 |
| Are you satisfied with your appearance when you are dressed? | 3.07 (1.31) | 3.10 (1.29) | 3.07 (1.31) | 0.919 |
| Mean (Standard Deviation) | 4.01 (1.13) | 4.30 (1.03) | 3.97 (1.14) | 0.216 |
| Are you satisfied with your appearance when you are undressed? | 4.01 (1.15) | 4.50 (1.05) | 5.97 (1.14) | 0.210 |
| Mean (Standard Deviation) | 2.81 (1.32) | 3.30 (1.17) | 2.75 (1.33) | 0.079 |
| With regards to your reconstruction, are you satisfied with your sex life? | 2.01 (1.52) | 5.50 (111) | 2.75 (1.55) | 0.077 |
| Mean (Standard Deviation) | 3.19 (1.35) | 3.25 (1.37) | 3.18 (1.35) | 0.824 |
| If you had a nipple-sparing mastectomy, has the sensation to your nipple | (1.00) | 0.20 (1.01) | 0110 (1100) | 0102 |
| been preserved? | | | | |
| Mean (Standard Deviation) | 1.34 (0.79) | 1.35 (0.75) | 1.34 (0.80) | 0.939 |
| Do your breasts feel natural and/or similar to how they felt before | | | | |
| mastectomy? | | | | |
| Mean (Standard Deviation) | 2.41 (1.20) | 3.60 (0.99) | 2.25 (1.13) | < 0.000 |
| Have you experienced any regret in having your surgery? | | | | |
| Mean (Standard Deviation) | 3.97 (1.27) | 4.20 (1.40) | 3.94 (1.25) | 0.388 |
| Did you feel fully informed and supported when choosing your breast | | | | |
| reconstruction? | | | | |
| Mean (Standard Deviation) | 4.25 (1.17) | 4.45 (1.05) | 4.22 (1.19) | 0.410 |
| How is your general health perception? | | | | |
| Mean (Standard Deviation) | 3.65 (1.08) | 3.65 (1.23) | 3.65 (1.07) | 0.997 |
| If you had to advise a friend who'd had a mastectomy, would you encourage | | | | |
| her to have breast reconstruction? Mean (Standard Deviation) | 4.10 (1.00) | 4.25 (1.18) | 1.06 (0.07) | 0.224 |
| Age at Date of Surgery | 4.10 (1.00) | 4.35 (1.18) | 4.06 (0.97) | 0.220 |
| Mean (Standard Deviation) | 51.42 (9.06) | 48.55 (9.17) | 51.81 (9.00) | 0.13 |
| How many total surgeries did you need? | 51.42 (5.00) | 40.00 (9.17) | 51.61 (5.00) | 0.15 |
| Mean (Standard Deviation) | 2.49 (1.08) | 2.65 (1.35) | 2.47 (1.05) | 0.49 |
| Adjuvant Treatment | 2.47 (1.00) | 2.05 (1.55) | 2.47 (1.05) | 0.47. |
| No Adjuvant Treatment | 80 (48.19%) | 6 (30.00%) | 74 (50.68%) | |
| Adjuvant Chemotherapy | 31 (18.67%) | 5 (25.00%) | 26 (17.81%) | |
| Adjuvant Radiation | 17 (10.24%) | 3 (15.00%) | 14 (9.59%) | 0.383 |
| Adjuvant Chemotherapy and Radiation | 38 (22.89%) | 6 (30.00%) | 32 (21.92%) | |
| Did you find out about other reconstructive options after your | | | | |
| reconstruction? | | | | |
| Yes | 51 (30.72%) | 3 (15.00%) | 48 (32.88%) | 0.10 |
| No | 115 (69.28%) | 17 (85.00%) | 98 (67.12%) | 0.104 |
| What is the highest level of education of you have completed? | | | | |
| High School Graduate | 19 (11.45%) | 7 (35.00%) | 12 (8.22%) | |
| College Graduate | 138 (83.13%) | 12 (60.00%) | 126 (88.30%) | 0.001 |
| I Prefer Not to Answer | 9 (5.42%) | 1 (5.00%) | 8 (5.48%) | |
| Race of Patient | | | | |
| White or Caucasian | 141 (84.94%) | 16 (80.00%) | 125 (85.62%) | |
| Black or African American | 10 (6.02%) | 1 (5.00%) | 9 (6.16%) | 0.600 |
| Other Race/Unknown | 15 (9.04%) | 3 (15.00%) | 12 (8.22%) | |
| Body Mass Index (BMI) | | | | |
| Underweight/Normal Weight | 64 (38.55%) | 4 (20.00%) | 60 (41.10%) | |
| Overweight | 48 (28.92%) | 6 (30.00%) | 42 (28.77%) | 0.15 |
| Obese | 51 (30.72%) | 10 (50.00%) | 41 (28.08%) | |
| Unknown Smarbing Status | 3 (1.81%) | 0 (0.00%) | 3 (2.05%) | |
| Smoking Status | 26 (16 666) | (/20 000/- | 20 /12 2001 | |
| Current or Former Smoker | 26 (15.66%) | 6 (30.00%) | 20 (13.70%) | 0.00 |
| Never Smoker | 87 (52.41%) | 12 (60.00%) | 75 (51.37%) | 0.03 |

Table: Descriptive statistics of cohort, overall and stratified by type of reconstruction

581826 - Reduced acute complications associated with implant-based prepectoral reconstruction after nipple-sparing mastectomy

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Background/Objective: Nipple-sparing mastectomy (NSM) has been associated with improved aesthetics and oncologic safety. Historically, reconstructive surgeons have performed subpectoral placement of implants. Prior to the advent of acellular dermal matrix (ADM), patients underwent total muscle coverage. The use of ADM allowed for partial muscle coverage. Both total muscular coverage and partial coverage have been associated with pain after surgery, as well as capsular contracture and animation deformity. Placing implants above the muscle in the prepectoral position may decrease these postoperative complications. Due to the paucity of data in the literature comparing complication rates amongst patients undergoing subpectoral versus prepectoral breast reconstruction, the aim of this study was to compare the complications rates in these 2 groups.

Methods: A retrospective review was conducted on all consecutive patients undergoing NSM with implant-based reconstruction with either prepectoral (PP) or subpectoral (SP) placement at our institution from November 2014 to January 2018. The primary outcome was acute 30-day postoperative complications including nipple-areola complex (NAC) necrosis, skin flap necrosis, wound dehiscence, infection, and hematoma/seroma. Secondary outcomes included nipple loss and rates of unintended reoperations. Each breast was considered independently for analysis. Chi square and multivariate logistic regression was used to control for age, body mass index (BMI), macromastia (cup size > C), and smoking, while evaluating outcomes based on implant location.

Results: A total of 230 patients (406 breasts) were included in the final cohort. All breasts underwent implant-based reconstruction, with 203 breasts in each of the PP and SP cohorts. The mean age was 46.1 years (SD=10.2), BMI was 24.1 (SD=4.3), 1.9% were current smokers, and 30.3% had macromastia. Overall complication rate for all patients was 8.9%, with a significantly increased complication rates in the SP compared to PP cohort (11.9% vs. 5.9%, p=0.033; Table). This remained when controlling for BMI, breast size, smoking, and age, resulting in a 2.6 times increased odds of complication for SP compared to PP (OR = 2.6, 95% CI 1.07-6.40, p=0.026). When examining individual complications, the SP reconstruction group had increased rates of skin flap necrosis (3.5% vs 0.5%, p=0.035), nipple areolar complex necrosis (6.9% vs 0.5%, p=0.001), hematoma/seroma (2.5% vs 2.0%, p=0.730), and wound dehiscence (3.5% vs 0%, p=0.007). However, infection rates were increased in the prepectoral reconstruction group (3.0% vs 0.5%, p=0.046). Rates of unintended reoperations were also significantly increased in the SP group (10.9% vs. 3.9%, p=0.006). Rates of nipple loss due to pathology, complications, or cosmesis did not differ significantly between the 2 groups (SP=3.9% vs. PP=1.5%, p=0.118).

Conclusions: Most patients undergoing NSM currently undergo subpectoral breast reconstruction. Our extensive experience with performing prepectoral breast reconstruction in a large series has shown that it is associated with significantly fewer overall acute postoperative complications and unintended reoperations compared to the traditional subpectoral implant reconstruction.

| | Subpectoral n = 203 | Prepectoral n = 203 | p-value | OR, 95% CI |
|----------------------------|------------------------|------------------------|---------|--------------------|
| Complication rate | 11.9% | 5.9% | 0.033 | 2.60 (1.07, 6.40) |
| Nipple loss | 3.9% | 1.5% | 0.118 | 2.74 (0.53, 14.26) |
| Unintended reoperations | 10.9% | 3.9% | 0.006 | 1.98 (0.83, 4.74) |

Table: 30-day postoperative complications based on implant location

Odds Ratio (OR) adjusted for age, BMI, macromastia, and smoking

581636 - Hyperbaric (HBO) treatment reduces the area of ischemic tissue in compromised flaps post-mastectomy

Tammy Ju, Cecilia Rossi, Kara Couch, Anita McSwain, Joanne Lenert, Christine Teal *George Washington University Hospital, Washington, DC*

Background/Objective: The use of hyperbaric oxygen treatments (HBO) has been found to improve oxygenation for flap perfusion. HBO treatments are becoming integrated into the treatment for post-mastectomy patients to reduce the risk of nipple and skin flap necrosis; however, its efficacy is not clear. The purpose of this study is to investigate the impact of hyperbaric treatments on the area of tissue ischemia after mastectomy with reconstruction.

Methods: A retrospective review was performed in 2016 from a single-institution breast care center. Adult female patients were identified who underwent mastectomy with reconstruction for a diagnosis of breast cancer or prophylaxis. Patients underwent HBO treatment if the breast flap or nipple areolar complex was deemed compromised based on SPY angiography. Pre-operative variables such as age, smoking, diabetes, obesity, prior radiation treatment, and breast weight were documented. Number of HBO treatments including pressure regimens and timing of treatments were recorded. Photos were taken of the compromised flaps before initial treatment and after last treatment, and compromised flap area measurements were recorded daily. Pre-operative variables, photos, and wound measurements were compared. Complications, such as necrosis, infection, and explantation within 60 days of surgery were also recorded. Statistical analysis using independent t-tests were used. A p-value <0.05 was considered statistically significant.

Results: Six patients were identified, and 11 breasts were examined. All patients underwent nipplesparing mastectomy with reconstruction (tissue expander vs implant). Average age of patients was 44. Average breast weight was 319 grams. All patients had no history of smoking, diabetes, obesity, or prior radiation. Two of 11 breasts ultimately underwent excision of necrotic tissue within 60 days, and there were no complications of infection or explantation. The average number of HBO treatments a patient underwent was 6.8. Photos and wound measurements were documented prior to and at the end of HBO treatment in 5 patients. The total area of compromised flap decreased consistently between initial photo and last documented photo for all 5 breasts from an average area of 13.2cm2 at initial treatment and 5.6cm2 at last treatment. These patients completed an average of 8.8 HBO treatments. An independent means student t-test comparing the volume of area before and after treatment resulted in a p-value of 0.12.

Conclusions: HBO treatments continue to be used as salvage therapy for flap or nipple necrosis after mastectomy. While HBO treatments are found to show clear and consistent decrease in compromised flap area with increased amounts of HBO treatments, the change in area was not statistically significant. These promising results suggest further larger studies are needed to determine the improvement in flap compromise after mastectomy with reconstruction due to HBO treatments.

581690 - Is your post-mastectomy patient missing something? The global success of Knitted Knockers

Cary Kaufman¹, Barbara Demorest² ¹University of Washington, Bellingham, WA, ²Knitted Knockers, Bellingham, WA

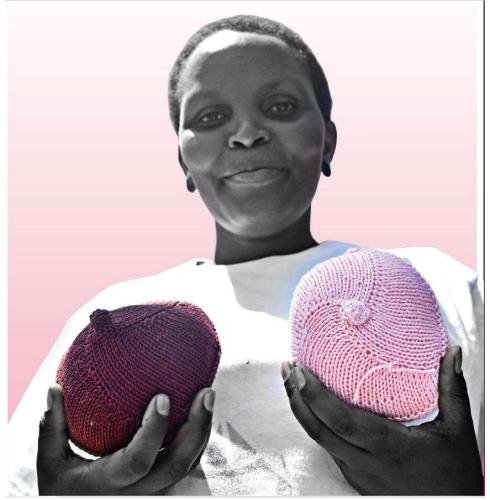
Background/Objective: About 35% of women with breast cancer undergo a mastectomy. Many of those women do not have immediate reconstruction, or if they do, it might be insertion of an expander. Besides being a traumatic life event, it is aggravated by having to appear in public in the immediate days and weeks after surgery without an easy acceptable painless prosthesis. Knitted Knockers are hand knitted light weight breast forms which fit into a normal bra allowing the recently operated patient a solution to her appearance. Plus, these are made by volunteers and given free of charge, shipping included.

Methods: Although not the originator of the Knitted Knocker, the leader started with her own need for the Knocker and visualized the same need multiplied thousands of times across the country and beyond. With no support and only her drive to get this message out, she networked with knitters. She invited knitters from clubs across the country to voluntarily download the pattern, purchase the yarn, knit the Knocker, and then to donate it to be given to the next mastectomy patient in any doctors' office or clinic. This volunteer organization is now 7 years old, and the leader continues to generate support for all Knitted Knockers to be free of charge and shipping.

Results: In the last 7 years, more than 50,000 Knitted Knockers have been mailed to patients. In addition, they have enlisted more than 1,200 other clinics covering all 50 states who similarly have volunteer knitters making and distributing Knockers to their medical communities. In the US, they have about 5,000 volunteers knitting and distributing in knitting clubs, yarn stores, and private homes. They send out more than 1,000 forms per month, postage in 2017 was \$58,000. In Rwanda and Kenya, where prostheses are unavailable, they taught a group of 30 Rwandans to knit the form who are teaching other women how to do so as well (see picture). Women were using newspapers, rags and anything to substitute for a form. The program has sent Knockers to centers in 30 different countries from Belgium to Uruguay. Their website provides the knit pattern, which has been downloaded more than 1 million times. They've had more than 500,000 views of their instructional video. In July 2018, they were awarded the "Best Documentary" at the California Women's Film Festival in Hollywood. They've been honored by the Susan Komen Foundation, the Rwanda Award, Loreal Women of Worth national finalist, on the TV podcast of the Today show, People Magazine, Inside Edition, Guideposts, PBS, and have received many other community service awards in the last 7 years.

Conclusions: There is a need in the medical community for a soft lightweight knitted breast form that fits in any bra for the early use by patients who have undergone mastectomy. Breast surgeons and patients should become aware of this useful post-mastectomy form, which is available to all patients in all 50 states.

Image: Rwandan knitter



582179 – Laparoscopic-assisted DIEP flap harvest improves breast reconstruction outcomes

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Background/Objective: Total extra-peritoneal laparoscopic-assisted (TEP-lap-assisted) harvest of the deep inferior epigastric (DIE) vessels permits a dramatic decrease of myofascial dissection in DIEP flap breast reconstruction. We present a reliable technique that further decreases donor site morbidity in autologous breast reconstruction.

Methods: Patients who underwent TEP-lap-assisted harvest of the DIE vessels were reviewed from March to October 2018. A supraumbilical camera port was placed at the medial edge of the rectus muscle to enter the retrorectus space. The extraperitoneal plane is developed using a balloon dissector and insufflation. Two ports are then placed through the infraumbilical linea alba to dissect the DIE vessels in the retromuscular plane. Muscle branches and the superior epigastric vessels are ligated. The DIE pedicle is ligated, and the vessels delivered through a minimal fascial incision.

Results: Twenty-four subjects totaling 40 flaps were included in the study. All flaps were single perforator DIEP flaps. The mean length of fascial incision was 1.9cm. Mean length of procedure for unilateral and bilateral reconstructions was 337.5 ± 91.3 and 442.9 ± 100.0 minutes, respectively, with patients in the latter half of the series undergoing significantly shorter harvest times. No subjects required narcotics during or after their hospitalization. Mean length of stay was 2.1 days. Successful flap salvage after venous congestion occurred in 1 subject. There was 1 pedicle transection during harvest that required perforator-to-pedicle anastomosis.

Conclusions: Total extra-peritoneal laparoscopic-assisted harvest of the DIE pedicle is a reliable method that dramatically decreases the pain and morbidity of autologous breast reconstruction.

581258 - The impact of post-operative prophylactic antibiotics in immediate two-stage prepectoral breast reconstruction

Jami Rothman, Michael Holland, Rachel Lentz, Clara Gomez-Sanchez, Rita Mukhtar, Jasmine Wong, Michael Alvarado, Laura Esserman, Cheryl Ewing, Hani Sbitany University of California, San Francisco, CA

Background/Objective: Immediate tissue expander placement remains the preferred method for breast reconstruction after mastectomy. Placement of the prosthesis in the prepectoral rather than submuscular plane is a relatively novel strategy to reduce post-operative pain and potential for animation deformity with overall equivalent cosmetic outcomes. Prophylactic post-operative antibiotic administration is a common practice for reducing reconstructive infection, but it raises concerns regarding indiscriminate and prolonged use of antibiotics. Additionally, this has not been studied specifically in the setting of prepectoral tissue expander placement. We sought to determine the impact of routine post-operative antibiotics on complication rates in patients undergoing prepectoral tissue expander placement.

Methods: We retrospectively identified all patients undergoing immediate prepectoral tissue expander placement following mastectomy by a single plastic surgeon from December 2015 to October 2018. We identified 2 cohorts of patients – 1 group that received prophylactic antibiotics at the time of discharge, and 1 group that did not. We collected treatment and outcomes data, and used IBM SPSS Version 23.0 to compare rates of post-operative complications. Our primary outcome was tissue expander loss, and secondary outcomes were infection, skin necrosis, and return to operating room.

Results: We identified 69 patients with 115 breasts who received prophylactic antibiotics upon discharge from the hospital, and 63 patients with 106 breasts who did not. There were no significant differences between the groups in terms of age, indications for mastectomy, or comorbidities. The group receiving antibiotics had significantly more patients who received neoadjuvant chemotherapy (42% vs. 28%; p=0.037) and underwent nipple-sparing mastectomies (88% vs. 79%; p=0.031). The antibiotic group had significantly lower rates of tissue expander loss, infection, and return to operating room (Table). There was no difference in skin necrosis rates.

Conclusions: No current guidelines exist to guide routine antibiotic use following immediate breast reconstruction with prepectoral tissue expanders. These data show a strong association between post-operative antibiotics and reduced post-operative complication rates in women undergoing prepectoral tissue expander placement, despite the antibiotic group having higher baseline risk for complications. As a result, our current practice is to prescribe all patients undergoing immediate prepectoral tissue expander placement a one-week course of antibiotics.

| Outcome | | No AntibioticsAntibioticsN = 106N = 115 | | | | |
|------------------------------------|----|---|----|--------|----------------------|---------|
| | N | % | N | % | OR (95%CI) | Р |
| Unplanned return to OR | 26 | 24.53% | 12 | 10.43% | 0.35 (0.17- 0.75) | 0.006 |
| TE Exposure | 6 | 5.66% | 0 | 0.00% | NC | 0.01 |
| TE Loss | 18 | 16.98% | 5 | 4.35% | 0.22 (0.08- 0.62) | 0.002 |
| Complete nipple loss | 2 | 1.89% | 2 | 1.74% | 0.92 (0.13- 6.65) | 0.934 |
| Skin Necrosis | 9 | 8.49% | 3 | 2.61% | 0.29 (0.08- 1.10) | 0.054 |
| Wound breakdown | 10 | 9.43% | 5 | 4.35% | 0.44 (0.14- 1.32) | 0.133 |
| Any infection | 26 | 24.53% | 8 | 6.96% | 0.23 (0.10- 0.54) | < 0.001 |
| Infection requiring IV antibiotics | 13 | 12.26% | 4 | 3.48% | 0.26 (0.08- 0.82) | 0.014 |
| Infection requiring operation | 11 | 10.38% | 2 | 1.74% | 0.15(0.03- 0.71) | 0.006 |
| Recurrent infection | 7 | 6.60% | 0 | 0.00% | NC | 0.005 |

Table: Outcomes between patients receiving prophylactic discharge antibiotics and not

582158 - Make your own DIEP: Perforator delay improves DIEP flap reliability

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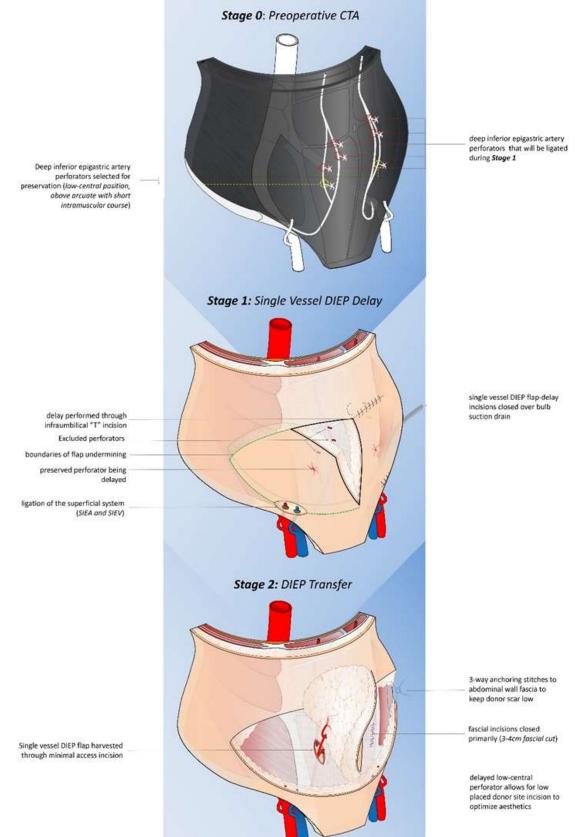
Background/Objective: We have applied the delay phenomenon to DIEP flap reconstruction in order to 1) reliably harvest single-vessel DIEP flaps without congestion 2) minimize abdominal wall morbidity, and 3) maximize aesthetics.

Methods: At the first stage, mastectomy and prepectoral expander placement is performed with abdominal perforator delay. We select a perforator with a short intramuscular course and low central location to minimize myofascial insult and to maximize a low scar placement. All other perforators are ligated along with the SIEA/V vessels. The reconstruction is then completed after a 2-week delay period. Any mastectomy skin flap necrosis is debrided prior to final flap inset minimizing postoperative wounds.

Results: Eight-five patients underwent 128 single-perforator DIEP flaps. Mean age and BMI was 50.9 years and 29.1 kg/m2. Two perforator complications occurred with 2 flap losses. Length of stay following flap transfer was 2.2 days. A total of 65.9% of patients avoided narcotics entirely. Operative breast complications included arterial thrombosis (0.8%), venous congestion (1.6%), and fat necrosis (1.6%). Operative abdominal complications included dehiscence (5.6%), seroma (2.4%), and skin flap necrosis (1.2%).

Conclusions: The two-stage delayed DIEP flap technique allows for selection of the ideal perforator based on location and course. This flexibility permits less dissection, less pain, and better scar location. Perforator delay mitigates the trade-off of blood supply and morbidity in free-flap breast reconstruction.

IMAGE:



580078 - Acellular dermal matrices as an adjunct to implant breast reconstruction: An evaluation of outcomes and complications

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Background/Objective: The uptake of post-mastectomy breast reconstruction is steadily increasing worldwide. Among reconstructive options, use of implants is the most commonly employed technique accounting for more than 80% of the cases. The use of acellular dermal matrices (ADM) is widespread in the setting of implant-based breast reconstruction (IBR) but there remains uncertainty in the existing literature with regard to the effect of ADM use on outcomes and complications. The aim of this study was to evaluate the outcomes and complication rates associated with the use of ADMs in IBR in a cohort of patients treated in a tertiary referral unit.

Methods: This was a retrospective cohort study of patients who underwent ADM-assisted IBR between 2008 and 2013. Cases were identified from a prospectively collected database including demographics, surgical indications, and procedural and adjuvant treatment details where applicable, as well as surgical complications and postoperative outcomes. Surgical complications included infection, inflammatory skin reaction (erythema), haematoma, seroma, skin necrosis, nipple necrosis, capsule formation, and implant loss. Categorical variables are presented as absolute numbers and percentages. Univariate binary logistic regression analysis was performed to identify potential factors associated with complications.

Results: A total of 110 patients comprising 175 mastectomies were identified and included in the analysis. The median age was 46 (19-75) years and the median BMI was 22.2 (16.2-41.5). Seventy-nine mastectomies were performed for therapeutic purposes. The median mastectomy weight was 244 (185-335) gr. The majority of reconstructions were performed with the use of fixed volume (n=115, 66%) or permanent expandable implants (n=53, 30%) as one-stage procedures. Forty mastectomies were associated with at least 1 complication. The infection rate was 2.3% (n=4), while the inflammatory skin reaction rate was 8% (n=14). Post-operative haematoma developed in 5 cases (2.9%), but only 2 required surgical interventions. Clinically detectable seromas developed in 15 mastectomies (8.6%) and was managed with drainage by needle aspiration in 2 cases. Three mastectomies were complicated by nipple necrosis (1.7%), 3 with skin necrosis (1.7%), and 9 with wound dehiscence (5.1%). Four mastectomies were associated with capsule formation (2.3%). Reconstruction failure with implant loss was observed in 3 cases (1.7%). Logistic regression analysis including age, BMI, smoking status and use of radiotherapy did not identify any factors associated with the development of complications.

Conclusions: This study shows that the complication rates following ADM-assisted IBR can be very low with careful patient selection and meticulous surgical technique. This supports the safety of using ADM in IBR as standard of care. Further research is warranted to assess the health economics of ADM use in IBR.

576324 - Aesthetic outcomes and patient satisfaction following nipple-sparing vs skinsparing, bilateral, risk-reducing mastectomies: An 18-year study

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Background/Objective: The incidence of bilateral risk-reducing mastectomies performed for carriers of a high-risk breast cancer predisposition is increasing. Preservation of the nipple-areolar complex in nipple-sparing mastectomies (NSM) represents a trend in modern breast reconstructive surgery, where oncologic and aesthetic outcomes are paramount. In risk-reducing surgery, NSMs are considered to be oncologically safe, whilst providing favourable results in patient satisfaction, psychosocial-and sexual wellbeing, as compared to the nipple-sacrificing mastectomies. Our aim was to objectively assess nipple symmetry following NSM against that of the reconstructed nipples achieved in nipple-sacrificing procedures. Secondary objective measures include the level of patient satisfaction with the native or reconstructed nipples.

Methods: This was a retrospective cohort study of 104 patients who had undergone risk-reducing mastectomies and immediate breast reconstruction at a single institution from 1997 to 2015. All patients over the age of 18 years were included, whilst any patients who developed breast cancer at any point during the study were excluded. Objective clinical assessment of bilateral nipple symmetry was evaluated using standardized reference points (i) sternal notch to nipple, (ii) nipple to infra-mammary fold, (iii) midline to nipple distance and (iv) nipple projection. Patient satisfaction was evaluated using validated, quantitative analysis.

Results: A total of 104 patients were recruited into the study with a median age of 43 years (27-56). 61 patients (59%) had nipple-sparing mastectomies (NSM group) and 43 had nipple-sacrificing mastectomies (non-NSM group). The majority of patients (n=93, 89%) had implant-based reconstruction. The median follow-up time from surgery was 8 years (2-17). There was no significant difference in the objective assessment comparing the 2 groups (NSM vs non-NSM). There was a significant difference with higher overall satisfaction (p=0.009), satisfaction with the nipple position (p=0.036), nipple projection (p=0.042), and nipple sensation (p<0.001) in favour of NSM.

Conclusions: The ability to achieve aesthetically acceptable results from nipple-sparing, risk-reducing mastectomies will encourage women to consider surgery for risk-management more favourably. Further studies to include validated outcome measurement tools are required.

582131 - The impact of shared decision-making on patient satisfaction following breast reconstruction

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Background/Objective: Breast reconstruction after prophylactic and therapeutic mastectomy is common, fueled by mandated insurance coverage and heightened patient education on reconstructive options. Procedural reconstruction has increased 39% since 2000. Risks and disadvantages of reconstruction make it a poor choice for some patients, and the growing "Go Flat" movement focuses on the option to not undergo reconstruction. With little published in the medical literature regarding non-reconstructed patients, we hypothesized that these patients may feel ostracized by conventional discussions of reconstruction options and lack appropriate decision-making aids to empower their ultimate choice. This

study explored the use of shared decision-making practices in breast reconstruction counseling and how they impact patient satisfaction with surgical outcomes after resection.

Methods: This is a de-identified retrospective review of prospectively collected online survey data. Consent was obtained from the group moderator of a closed breast cancer patient social media page containing a large contingent of women who elected not to reconstruct, and the survey was shared with all group members. Responses were voluntary, and participants were informed that responses were part of a study. We collected demographic information including age, social supports, and surgical indications. Patients ranked the degree to which they felt their reconstruction decisions were "entirely individual," exclusive of their health care provider, or "shared" with their provider. Patients rated and categorized decision aids used, and rated satisfaction after surgery using a Likert scale. The survey concluded with open-ended questions allowing patients to describe their experience.

Results: Among respondents (n=115), the average age was 50.2 years (+/-10.8 years). A majority of respondents (62.3%) had not undergone reconstruction, while 21.1% underwent reconstruction. 8.8% of respondents underwent reconstruction, which they later reversed. 57.6% of respondents reported their reconstruction choice was "entirely [their] decision," whereas only 6.4% described it as "entirely a shared decision." Patients ranked surgeons the most important contributors to shared decisions. 83.4% of individuals reported that they had made the right decision for themselves, but only 56% reported being satisfied with their outcome. Only 26 of the 51 patients who received material about surgical options rated the material helpful. However, 82.8% of patients who sought out images of real surgical outcomes independently reported those images helpful. Themes in open-ended responses included a desire for more information about reconstruction complications, the sense that providers did not support staying flat, and frustration with extra tissue after mastectomy.

Conclusions: In this majority non-reconstructed cohort, patients felt their providers did not support "going flat," leaving them to make their reconstruction decision independently. Patients felt available decision aids did not address opting out of reconstructing, and requested aids that described risks of reconstruction and contained images of common outcomes. These results convey a powerful message that we as providers are not delivering adequate information to empower our patients in navigating the difficult process of selecting a post-mastectomy reconstruction plan that best suits them. Shared decision-making results in better patient satisfaction, and current patient education does not adequately address the non-reconstructing cohort. Therefore, improvements offer opportunity for improved post-reconstruction satisfaction.

Time to Treatment

580155 - Screening mammograms in palpable breast cancers delays time to treat

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Background/Objective: In an effort to improve cancer care, time to treatment has been proposed to be included as a quality measure. Many factors contribute to delays in time to treatment in breast cancer, but there is no clear literature evaluating if the type of imaging, namely screening versus diagnostic mammograms, ordered initially for a palpable mass lengthens the time to biopsy and treatment. We designed a study to evaluate the type of mammogram ordered in the setting of a palpable breast mass and compare if patients who underwent a screening mammogram versus diagnostic mammogram had a difference in time to biopsy and treatment.

Methods: A retrospective chart review using the institution's tumor registry was performed at a large community hospital from January 1, 2016-December 31, 2016. Patients diagnosed with breast cancer with a palpable mass documented were reviewed. Dates of initial imaging, percutaneous biopsy, diagnosis, and initial first treatment were evaluated. Documentation of clinical breast exams appreciating the breast mass were also reviewed.

Results: Reviewing our tumor registry, 96 patients diagnosed with breast cancer in 2016 had a palpable breast mass noted on physical exam. When reviewing the patients with a palpable breast lump, 23 (24%) had a screening mammogram instead of a diagnostic mammogram that initiated their workup. Of these 23 patients, 6 (26%) patients had a known breast complaint at the time of their screening mammogram, which suggests an inappropriate imaging test was performed. The remaining 17 (74%) patients had no complaints at the time of their abnormal screening mammogram but were found to have a palpable breast abnormality during their breast exam with the breast surgeon and prior to any biopsies performed. When comparing median time to biopsy and initiation of treatment between patients who had diagnostic imaging versus screening mammogram that initiated their breast cancer workup, patients who underwent diagnostic imaging between streams had much shorter time delays. Median time to biopsy for diagnostic imaging patients was 3 days versus 19 days for patients who underwent screening (p<0.001). Similarly, median time to first treatment for diagnostic imaging patients was 36 days versus 52 days for those who underwent screening (p=0.002).

Conclusions: Our study shows that patients who had a palpable breast mass and underwent screening mammogram rather than diagnostic imaging had a statistically significant longer time to biopsy and treatment. This emphasizes the importance of appropriate initial imaging workup in breast cancer. We also found a large proportion of patients who had a palpable finding on physical exam when examined by the breast surgeon did not have any documented breast complaints or abnormal clinical breast exam findings prior to their abnormal screening mammograms. This may suggest patients and physicians are not performing clinical breast exams routinely, which could have expedited their diagnostic workup.

581493 - Single-day, single-site multidisciplinary approach for complex breast cancer

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Background/Objective: A delay in breast cancer treatment is associated with inferior survival outcomes. However, no clear guidelines exist defining the appropriate time frame from diagnosis to definitive treatment of breast cancer. Patients value timely diagnostic workup, and later stages at diagnosis and delayed treatment are contributory factors to poorer outcomes. A multidisciplinary approach for breast cancer treatment can minimize the time from diagnoses to first treatment. A great challenge in the management of cancer is the coordination required across specialties including surgical oncology, medical oncology, and radiation oncology. We hypothesized a one-day multidisciplinary clinic (MDC) approach will decrease time from initial diagnosis to first treatment for women with Stage II-III breast cancer.

Methods: We identified patients from our institute's Integrated Breast Cancer Research Database who had Stage II and III breast cancer, were at least 18 years of age, and were seen in the new single-day clinic (MDC) as well as those seen by specialists from varying disciplines on different days at regular clinic (non-MDC). Patients included are those who received treatment from start of MDC clinic (May 2015) until data collection (May 2017). Sixty patients saw at least 2 subspecialists (Surgical, Medical, or Radiation Oncology) in a single day (MDC cohort), and 194 were seen in the regular clinic (non-MDC cohort). Patients excluded from analysis were those seeking a second opinion, declined any treatment, received treatment in another facility, or had Stage IV disease.

Results: A total of 254 patients were included in analysis. There were 60 patients in the MDC cohort and 194 patients in the non-MDC cohort. The clinicopathological characteristics of patients in both groups (MDC and non-MDC) are similar. Comparisons between groups were performed using Fisher's exact test for discrete measures and t tests for continuous measures. The time from "first visit" to "first treatment" at MDC was 14 days (all 3 specialties) and 22 days (only 2 specialties) vs 30 days in non-MDC, indicating that single-day visit of all 3 specialty differs for NACT with half the time difference compared to standard treatment (Table). Probability of treatment by 14, 28, and 42 days from date of first visit further increases between MDC and non-MDC facility (Table).

Conclusions: A single-day clinic visit of MDC with coordination between of 2 or more specialty approach optimizes treatment and increases the likelihood of having a reduced diagnosis to treatment time. This short interval may prove to be significant in the effectiveness of managing complex breast cancer cases.

Table: Probability of treatment by 14, 28, and 42 days from date of first visit, median time to treatment, and hazard ratios [95% CI] for differences in time to treatment between patients seen at an MDC or non-MDC facility

| | N | Median TTT | 14d | 28d | 42d | HR 95% CL | P |
|--|---------------|----------------------------------|-------------------------------|---------------------------------|--------------------------|----------------------|--------|
| Whole Cohort | 254 | 27 [23, 30] | 21 [16, 26] | 54 [47, 60] | 72 [66, 77] | | |
| Non-MDC | 194 | 30 [27, 33] | 19 [13, 24] | 48 [40, 55] | 68 [60, 73] | | |
| MDC | 60 | 22 [16, 23] | 30 [17, 41] | 73 [59, 82] | 87 [75, 93] | 1.96 [1.7, 2.26] | <0.001 |
| | | | | | | , | |
| | | least two special | | | | | -0.001 |
| Same day MDC v MDC (at least two specialties) † | visit with at | least two special 22 [22, 31] | ties vs Same Mi 14 [2, 25] | DC with all 3 sp 69 [49, 81] | ecialties 83 [64, 92] | 1.47 [1.29, 1.68] | <0.001 |

581797 - Improving wait times and patient experience through implementation of a provincial early referral system for women with BI-RADS 5 breast lesions

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Background/Objective: Long diagnostic intervals from abnormal imaging to diagnosis are associated with patient anxiety and possibly poorer prognosis. While Canadian national targets exist for timely diagnostic assessment, recent review of breast screening programs found that only 55% of women receive a tissue diagnosis within the recommended interval. Furthermore, no population-based data extending beyond the biopsy to time of surgical consultation have been reported. To address the diagnostic interval from the patient perspective, we developed and implemented a province-wide clinical pathway for expedited work-up of BI-RADS 5 lesions coupled with early surgical referral (BI-RADS 5 Pathway). This study evaluates the effect of the BI-RADS 5 Pathway on wait times and the patient-reported experience (PRE).

Methods: The BI-RADS 5 Pathway was established in 2017 in collaboration with primary care physicians (PCP), radiology, and 2 breast health programs (BHP) in Alberta serving 80% of breast cancer patients provincially. All BI-RADS 5 imaging reports include an automated textbox prompting PCP to arrange immediate surgical referral, concurrently with the biopsy recommendation and an expedited biopsy date. A BHP nurse (RN) navigator receives all BI-RADS 5 reports, schedules a surgical consult 5 days post-biopsy, notifies the patient about her referral, and provides biopsy and pre-consult education. All patients in the pathway are added to a prospective BI-RADS 5 registry, and a measurement framework was developed to capture key diagnostic intervals. An electronic survey of PREs during diagnostic assessment was created using REDCap, which patients are invited to complete following surgical consult. This study includes consecutive patients managed under the BI-RADS 5 Pathway during its first year of implementation. We use descriptive statistics to evaluate diagnostic intervals and the PRE.

Retrospective chart review was performed of all BHP referrals with a BI-RADS 5 lesion over a 3-month period prior to pathway implementation to compare diagnostic intervals.

Results: A total of 935 patients had a BIRADS-5 breast lesion during the study period across 55 diagnostic imaging centres; 128 patients served as pre-pathway controls. Median duration from DI to biopsy and biopsy to pathology report was 6 and 5 days, respectively. Biopsy results were benign in 10%. One hundred sixty-one (17%) patients were referred to a surgeon outside of a BHP. Amongst 745 patients with a completed BHP surgical consult at time of analysis, median duration from DI to referral and DI to surgical consult was 7 and 15 days, versus 15 and 26 days respectively pre-pathway. PRE surveys were completed by 204 women. Regarding anxiety, most patients (92%) experienced at least 1 anxiety complaint during diagnostic assessment; 60% found it somewhat difficult to "work, take care of things at home, get along with others," and 18% found it very or extremely difficult. Prompt surgical consultation was the most commonly selected factor that reduced anxiety (88% of women). Multiple features of nurse navigator support also reduced patient anxiety including the ability to contact an RN with questions (80%), having an RN coordinate care appointments (63%), and RN pre-consultation education (60%). Regarding wait times, 68% were satisfied with the interval from DI to diagnosis. Regarding patient preferences, 52% stated that they would most prefer to receive a cancer diagnosis from a surgeon; however, only 32% and 4% in each BHP had their diagnosis communicated by a surgeon.

Conclusions: We successfully implemented a population-based pathway featuring expedited biopsy and early surgical referral for women with BI-RADS 5 lesions, which reduced diagnostic wait times. Through PRE data, we demonstrate that diagnostic assessment is highly anxiety-provoking for patients, but early surgical referral and nurse navigator support improve the patient experience.

578532 - Treatment times in breast cancer patients receiving neoadjuvant versus adjuvant chemotherapy: Is efficiency a benefit of preoperative chemotherapy?

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Background/Objective: Delays in the time to surgery, chemotherapy, and radiotherapy have each been shown to impair overall survival in breast cancer patients. Neoadjuvant and adjuvant chemotherapy confer equivalent survival, but it remains unknown which approach facilitates faster completion of treatment. If either setting were to result in a significant delay, it could have survival implications. In this study, we aimed to examine the time it takes patients to start and complete breast cancer treatment when undergoing neoadjuvant chemotherapy (NAC) versus adjuvant chemotherapy (AC).

Methods: Women \geq 18 years old with non-recurrent, noninflammatory, clinical Stage I-III breast cancer diagnosed from 2004-2015 whose treatment course included both surgery and chemotherapy were reviewed from the National Cancer Database (NCDB). Patients were divided into 2 groups; those undergoing NAC and those having AC, and stratified by whether they received radiotherapy and/or endocrine therapy. Comparisons between NAC and AC were performed using Student's t-test and Chi-square test. Propensity score-weighted logistic regression models were fitted. Treatment times were measured from biopsy to the date of first treatment, and from biopsy to the start of radiotherapy or endocrine therapy.

Results: There were 155,606 women who met inclusion criteria. Of these, 28,241 patients received NAC, and 127,365 patients received AC. Patients undergoing NAC had higher clinical T stage (35.8% T3/4 vs 4.9% T3/4) and higher clinical N stage (14.4% N2/3 vs 3.7% N2/3) compared to those having AC. Time to start treatment was longer in the NAC group (35.6 vs 33.4 days unadjusted, p<0.0001; 39.6 vs 38.4 days adjusted, p<0.0001). Time to radiotherapy was longer in patients undergoing NAC (243.2 vs 208.7 days unadjusted, p<0.0001; 253.0 vs 233.4 days adjusted, p<0.0001), and time to endocrine therapy was also longer in patients undergoing NAC (305.4 vs 268.3 days unadjusted, p<0.0001; 330.7 vs 309.4 days adjusted, p<0.0001). Average length of stay was similar in both groups (NAC 1.2 ± 4.1 days compared to AC 1.3 ± 6.2 days, p=0.002). In the NAC group versus AC group, rates of unplanned readmission (1.4% vs 1.7%, p=<0.0001), 30-day mortality (0.04% vs 0.00%, p=<0.0001), and 90-day mortality (0.33% vs 0.11%, p=<0.0001) were similar. NAC was not an independent predictor of increased length of stay, but was associated with a lower risk of readmission (OR 0.5, 95% CI 0.46-0.58) and a higher risk of 30- and 90-day mortality (OR 7.4, 95% CI 2.74-19.85 and OR 2.2, 95% CI 1.43-3.33).

Conclusions: Although NAC and AC confer equivalent survival in prospective randomized trials, NAC is not more efficient in getting patients through treatment when compared to AC, and NAC patients do not start treatment more quickly after diagnosis. While times from biopsy to radiotherapy and endocrine therapy are significantly longer in the setting of NAC, these times are not due to longer hospital stays or readmissions. Although there are clear indications for administering NAC versus AC, rapidity of treatment should not be considered a benefit of giving chemotherapy preoperatively.

581484 - The impact of time to first breast cancer surgery on survival

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Background/Objective: Although surgeons recognize the need for timely receipt of breast cancer surgery, decision-making and coordination of surgical treatment may take time. Prior studies have suggested that increased time to breast cancer surgery is associated with higher mortality. However, these studies did not account for receptor type and included patients diagnosed over a wide time range. The purpose of this study was to determine if time to first surgery impacts mortality in a modern era patient cohort treated with targeted therapies.

Methods: Through the National Cancer Database special study mechanism, medical records of 10 patients randomly selected from each of 1200 facilities were reviewed. These patients were from a stage-stratified sample of those diagnosed with Stage II or III breast cancer in 2006-2007 (n=11,391). Women who received neoadjuvant therapy, had inflammatory breast cancer, or had an estrogen receptor-positive tumor and no endocrine therapy were excluded. HER2-positive patients were also excluded due to low numbers. Women who had time to surgery equal to 0 days (16.5 %) or >13 weeks (1.2 %) were excluded. Stratified analysis was performed for ER/PR+HER2- (n=3681) and triple-negative (n=1037) disease. An empirically based time to first surgery cutpoint was identified using Cox proportional hazards models at 2, 3, 4, and 5 weeks to identify the smallest p-value, which corresponds to the cutpoint most likely to show a survival difference. Patients were then categorized as having surgery before or after the optimal cutpoint. The relationship of time to surgery and overall survival was analyzed using Cox proportional hazard models controlling for socioeconomic, disease, and treatment variables.

Results: Median time to surgery was 20 days (range: 0-282 days) before excluding patients with time to surgery equal to 0 days or >13 weeks. The optimal cutpoint for time to surgery was 3 weeks for

ER/PR+HER2- disease, with 1684 women undergoing surgery before 3 weeks and 1997 women undergoing surgery later than 3 weeks. The optimal cutpoint for time to surgery was 2 weeks for triple-negative disease, with 274 women undergoing surgery before 2 weeks and 763 women undergoing surgery at later than 2 weeks. Age, Charlson comorbidity score, number of positive lymph nodes, tumor size, grade, and receipt of adjuvant chemotherapy were associated with overall survival (Table). After controlling for clinical and socioeconomic variables, there was no statistical difference in overall survival between women who underwent surgery before or after the optimal cutpoint for ER/PR+HER2- (HR 1.15, p=0.06) or for triple-negative cancer (HR 1.04, p=0.77).

Conclusions: In this modern era cohort of Stage II and III breast cancer patients stratified by receptor status, we found no evidence to suggest time to surgery impacts overall survival. Further, most women in this national sample underwent timely surgery. Based on these data, there is not an urgent need to alter the current process of care for Stage II/III breast cancer patients considering surgery.

| | ER/PR+He | r2- | Triple Nega | tive |
|---|------------------|---------|------------------|---------|
| | HR (95% CI) | p-value | HR (95% CI) | p-value |
| Time to First Surgery After Cutpoint | 1.15 (0.99-1.33) | 0.06 | 1.04 (0.81-1.34) | 0.77 |
| Age | 1.05 (1.05-1.33) | < 0.01 | 1.02 (1.01-1.04) | < 0.01 |
| Charlson Score≥1 | 1.58 (1.30-1.92) | < 0.01 | 1.44 (1.11-1.87) | < 0.01 |
| <pre># Positive Lymph Nodes (ref=0)</pre> | | | | |
| 1-3 | 1.58 (1.30-1.92) | < 0.01 | 1.47 (1.12-1.94) | < 0.01 |
| ≥ 4 | 2.60 (2.12-3.19) | < 0.01 | 3.09 (2.34-4.08) | < 0.01 |
| Tumor Size (ref=< 2 cm) | | | | |
| 2-5 cm | 2.02 (1.67-2.45) | < 0.01 | 1.61 (1.17-2.20) | < 0.01 |
| >5 cm | 3.10 (2.41-3.99) | < 0.01 | 2.76 (1.88-4.06) | < 0.01 |
| Grade (ref=low) | | | | |
| Intermediate | 1.20 (0.97-1.47) | 0.09 | 0.83 (0.35-1.96) | 0.67 |
| High | 1.65 (1.31-2.06) | < 0.01 | 1.15 (0.50-2.64) | 0.74 |
| Received Adjuvant Chemotherapy | 0.68 (0.56-0.82) | < 0.01 | 0.41 (0.31-0.54) | < 0.01 |

Table: Cox proportional hazards model for overall survival

Table 1. Cox Proportional Hazards Models for Overall Survival.

*Also controlled for income, race, and insurance.

Tumor Genetics

581862 - Should the Oncotype DX DCIS assay be routinely used for shared decisionmaking for radiation following surgery in DCIS?

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Background/Objective: DCIS comprises up to 25% of mammographically detected breast cancers, with goals of treatment aiming to minimize the risk of local recurrence and invasive breast cancer while maximizing breast preservation. Since the landmark NSABP B-17 study, adjuvant radiation has been the standard treatment for DCIS following complete resection. While radiation has not been shown to increase overall survival, it has been shown to decrease the risk of an ipsilateral breast cancer by approximately 50%. As widespread mammographic screening detects smaller and lower-grade DCIS lesions, there currently exists greater acknowledgement that acceptable cancer control outcomes can be achieved with surgical excision alone or combined with hormonal therapy, with adjuvant radiotherapy reserved for patients with a higher risk of recurrence. The Oncotype DX Breast Cancer Assay for DCIS – also known as the DCIS Score (DS) – is a 12-gene assay that generates individualized estimates of 10-year risk of local recurrence (DCIS or invasive) following surgical excision. We present an IRB-approved retrospective study evaluating the use of the DS in recurrence risk stratification when deciding whether to undergo adjuvant radiation after surgical excision during consultation with both surgical and radiation oncology.

Methods: Retrospective data were collected on 58 consecutive patients diagnosed with DCIS who underwent surgical segmental resection and assigned a low-, intermediate- or high-risk DS using the DCIS Breast Cancer Assay. The patients were separated into 2 arms – those treated with adjuvant radiation and those who underwent surgical excision alone. Outcomes of local recurrence were determined after a mean interval follow-up of 3.8 years.

Results: Of the 58 patients, 50% (29) had a low-risk DS (<39), 31% (18) had an intermediate-risk DS (39-54), and 19% (11) had a high-risk DS (\geq 55). Of the 79% (46 patients) who had adjuvant radiation, 21 patients (ages 40-81) had a low-risk DS, 17 patients (ages 40-89) had an intermediate-risk DS, and 8 patients (ages 51-73) had a high-risk DS. Of the patients who received radiation, 1 53-year-old with an intermediate-risk DS had a local recurrence at mean interval follow-up – contributing to the 3% local recurrence rate of the entire cohort. Of the 12 patients (21%) who chose no radiation, 8 patients (ages 46-79) had a low-risk DS, 1 patient (age 72) had an intermediate-risk DS, and 3 patients (ages 55-86) had a high-risk DS. Of the patients who did not undergo radiation, one 86-year-old with a high-risk DS had a local recurrence at mean interval follow-up atients were ER+PR+, 20% were ER+PR-, and 14% were ER-PR-. All patients who were hormone receptor-negative underwent adjuvant radiation. The remaining patients (including all the patients who did not receive radiation) received anti-estrogen therapy after surgical excision.

Conclusions: The results of our study support that the DCIS Score is a useful tool when individualizing patient management– particularly when counseling patients regarding adjuvant radiation. Seventy-five percent of patients in our study who chose not to undergo further therapy with radiation had low- or intermediate-risk scores. To date, none of these patients have experienced an in-breast recurrence. Of the patients who chose to have adjuvant radiation even with a low-risk DS, 33% received partial breast irradiation instead of whole breast irradiation. This highlights that in addition to guiding the initial discussion of pursuing or avoiding radiation, the DS may also be used to help determine the length and modality of radiation given. In an era of personalized therapy and transparency, the DCIS Breast Cancer

Assay serves as a valuable tool when individualizing DCIS recurrence risk and facilitating shared decision-making between patients and clinicians.

581558 - Epigenetic subtyping of triple-negative breast cancers: Clinical and pathological implications

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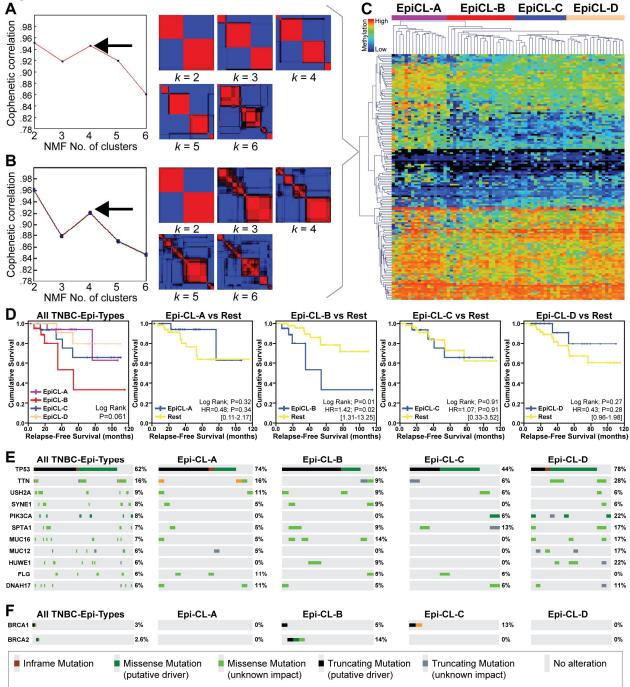
Background/Objective: Triple-negative breast cancer (TNBC) is defined by the absence of expression of estrogen receptor (ER) and progesterone receptor (PgR), and lack of amplification of the human epidermal growth factor receptor 2 (HER2). This definition has resulted in a heterogeneous collection of tumors with numerous differences including morphological characteristics, genetic makeup, immune-cell infiltration, response to systemic therapy, and overall prognosis. DNA methylation (DNAm) signatures are a robust tool to accurately identify disease-specific subtypes. The objective of this study is to generate an epigenetic sub-classification of TNBC tumors (TNBC-Epitypes) with utility for clinical decision-making.

Methods: Confirmed TNBC cases (n=163) from the Cancer Genome Atlas (TCGA) were classified according to the risk of relapse (high and low risk), and their gene expression TNBC subtype based on the Burstein et al. signature (Clin Cancer Res, 2015) into basal-like immuno-activator (BLIA), immuno-suppressor (BLIS), luminal androgen receptor (LAR), and mesenchymal-like (MES). Second, we selected TNBC DNAm profiles and used non-negative matrix factorization (NFM) machine learning approach to identify the optimal number of subtypes and the uncorrelated shrunken centroids (USC) method to select the most important genomic regions for each TNBC epitype. Kaplan-Meier curves with Log-rank test were generated to identify differences in relapse-free (RFS) survival rates and the Cox hazard models to assess hazard ratio (HR). Finally, the 'oncoprint' function on the R/Bioconductor package 'TCGAbiolinks' was used to explore the mutational background and gene expression profile of each TNBC epitype.

Results: The NFM analysis of the top 5,000 most significantly differentially methylated genomic regions suggested 4 TNBC epigenetic subtypes (higher cophenetic coefficient) when considering gene expression and risk of relapse (Fig. 1 A-B). These data were used to train USC classifiers using a 10-fold cross-validation strategy, which revealed that evaluation of only 149 regions accurately classified 75 TNBC tumors into 4 TNBC epitypes: Epi-CL-A, Epi-CL-B, Epi-CL-C, and Epi-CL-D (Fig. 1C). Importantly, patients with Epi-CL-B tumors showed a significantly shorter RFS (log-rank, p=0.009; HR =1.42, 95%CI [1.31-13.25; p=0.02]; Fig. 1D). Oncoprint profiling showed significant (Chi-square; p<0.05) differences in the mutation frequency of known breast cancer-related genes. Patients in epigenetic clusters B and C showed a significantly lower frequency of TP53 mutations, and patients in cluster D showed a significantly higher frequency of mutations in PIK3CA than the rest of the patients (Fig. 1E). The MUC16 gene, commonly known as cancer antigen 125 (CA-125), was frequently mutated in tumors from patients in cluster B, which showed a significantly shorter RFS. Finally, the mutational spectrum of BRCA1 and 2 varied greatly when comparing the TNBC cases in clusters A and D (0%) with cases on cluster C (13%) and in the poor prognosis cluster B (19%; Fig. 1F).

Conclusions: DNAm variations among TNBC tumors revealed distinct TNBC epitypes that exhibit significant clinical and genetic differences. These links between genetic make-up and epigenetic subtypes

open new avenues in the development of laboratory tests to more efficiently classify TNBC into potentially more targetable and clinically relevant subtypes.



Figures: Identification and characterization of triple-negative breast cancer epigenetic subtypes

581957 - Role of Oncotype DX® recurrence score in predicting nodal response after

neoadjuvant chemotherapy in breast cancer Alessandra Mele, Amulya Alapati, Ted James

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Background/Objective: The feasibility of sentinel lymph node biopsy (SLNB) in patients with clinically positive nodes undergoing neoadjuvant chemotherapy (NCT) has been evaluated in recent clinical trials. Patients who become clinically node-negative following NCT may be candidates for SLNB, provided that adequate nodal sampling is performed (i.e., at least 3 lymph nodes retrieved with the use of dual tracer). However, the appropriate selection of patients most suitable for this approach remains challenging. Previous studies have looked at factors predicting the likelihood of complete nodal pathologic response (pCR) after NCT. Studies are emerging exploring the role of Oncotype DX® in predicting response to neoadjuvant therapy; however, research to date is lacking specifically regarding the role of Oncotype DX® recurrence score (RS) in predicting nodal response after NCT. This study used the National Cancer Database (NCDB) to assess the association between low and high RS with nodal pCR.

Methods: The NCDB was used to identify patients with T1-T2, clinically N1/N2, ER-positive, HER2negative invasive ductal carcinoma of the breast diagnosed from 2010-2015 who underwent neoadjuvant chemotherapy and in whom an Oncotype DX® recurrence score (RS) was performed. RS was classified as low (<17), intermediate (18-30), and high (>31). Chi square analysis was performed to determine association between RS and nodal pCR.

Results: A total of 158 patients meeting inclusion criteria were identified. RS was low in 56 (35%), intermediate in 62 (39%), and high in 40 (25%) patients. Nodal pCR occurred in a greater proportion of patients with high RS, compared with intermediate or low RS (48% vs. 26%, and 26%, respectively, p-value=0.027)

Conclusions: Patients with high RS are observed to have greater rates of nodal pCR following NCT. Our study shows promise in utilizing Oncotype DX® RS to identify breast cancer patients with clinically positive lymph nodes in whom a significant response to NCT can be anticipated, and who would therefore be ideal candidates for SLNB as opposed to ALND.

582234 - ANXA1 expression was associated with worse progress in basal-like breast cancer <u>Maiko Okano</u>, Eriko Katsuta, Heather Poushay, Kazuaki Takabe *Roswell Park Cancer Institute, Buffalo, NY*

Background/Objective: Annexin A1 (ANXA1), a phospholipid-linked protein, is known to have multiple functions related to inflammatory pathways, cell proliferation, and the regulation of cell death signaling. ANXA1 was reported to have some association with cancer development, but the role of ANXA1 varies depending on cancer type. Recently, we reported that ANXA1 is associated with triple-negative breast cancer (TNBC) and its poor prognosis in 211 Japanese breast cancer cases. Similarly, some reports suggest that ANXA1 enriched breast cancer has poor survival. Conversely, some studies demonstrate opposite results, with high ANXA1 expression being associated with better outcome. It is speculated that the breast cancer subtype may be one of the reasons for these conflicting results. In this study, we investigated the association of ANXA1 mRNA/protein expression and patient survival for each breast cancer subtype using gene and protein expression data.

Methods: Clinical, RNA-seq and Reverse Phase Protein Array (RPPA) data were obtained from the Cancer Genome Atlas (TCGA) and METABRIC through cBioPortal. Overall survival (OS) and gene set enrichment analysis (GSEA) were conducted comparing high and low expression group.

Results: Basal-like breast cancer (BLBC) patients had significantly higher levels of ANXA1 expression compare to non-TNBC patients in both cohort (p<0.001). Among high mRNA expression of ANXA1 group of BLBC patients showed significantly worse OS in TCGA cohort (p=0.02) and worse DSS in METABRIC cohort (p=0.026). On the other hand, in ER-positive and HER2-positive patients, low mRNA expression of ANXA1 group had significantly worse OS (p=0.004, p=0.005, respectively) in TCGA cohort. In analysis using RPPA data in TCGA, OS was significantly lower in patients with high ANXA1 tumors among ER-positive patients and HER2-positive patients (p<0.001, p=0.016, respectively), but high ANXA1 group had worse OS in BLBC patients (p=0.0095). This was in agreement with transcriptome analysis. To explore the mechanism of these results, GSEA was conducted. In BLBC patients, high ANXA1 expression tumors were enriched EMT related genes (NES=2.02, p=0.011). On the other hand, in ER-positive patients, high ANXA1 expression tumors were enriched genes (NES=2.02, p=0.011). On the other hand, in ER-positive patients, high ANXA1 expression tumors were enriched genes (NES=2.02, p=0.011).

Conclusions: High expression of ANXA1 enriched EMT signaling related gene expression in BLBC patients is associated with worse OS. However, in ER-positive patients and HER2-positive patients, high ANXA1 expression was associated with better progression, and the possible reason of this outcome is the apoptosis and p53 pathway. This discrepancy between ER-positive breast cancer and BLBC on the effect of ANXA1 expression on patient survival may be attributed to the significantly different molecular/genetic backgrounds of these subtypes.

582290 - Low AR-expression tumors in ER-positive tumors were enriched DNA repair related gene, and it might be associated with patients' survival

Maiko Okano, Mariko Asaoka, Kazuaki Takabe Roswell Park Cancer Institute, Buffalo, NY

Background/Objective: The androgen receptor (AR) is expressed in 50–90 % of breast cancers, and its role in breast cancer is mechanistically complex and remains controversial. It was demonstrated that high AR expression related with resistance to tamoxifen and aromatase inhibitors. Also, it has been demonstrated that AR supports estradiol-mediated ER activity in both ER/AR positive breast cancer cells. In this study, we investigated the association of AR mRNA expression and patient survival using gene expression data of the publicly available large cohort.

Methods: Clinical and gene expression data were obtained from The Cancer Genome Atlas (TCGA) and METABRIC through cBioPortal. Disease-free survival (DFS), overall survival (OS), gene set enrichment analysis (GSEA), and CIBERSORT analysis were conducted comparing high- and low-AR expression groups.

Results: AR high- and low-expression group were 817 and 272 patients in the TCGA cohort and 1068 and 356 patients in the METABRIC cohort, respectively. AR mRNA and protein expression was significantly higher in ER-positive tumors compared to ER-negative tumors (p<0.001) in both cohorts. Correlation between AR mRNA and ER mRNA is weak (Pearson r=0.337). The expression of AR mRNA does not change depending on the menopausal state. There is weak correlation between AR mRNA and

ER mRNA in menopausal patients. The high-expression AR group showed significantly worse OS in ERpositive patients in the TCGA cohort (p=0.007). In the METABRIC cohort, the AR high-expression group showed significantly worse OS in Luminal B patients (p=0.007). To explore the mechanism of these results, GSEA was conducted. The protein secretion-related gene set (normalized enrichment score; NES=1.76, p=0.01) and the estrogen response-related gene set (NES=1.67, p=0.02) were significantly enriched with high-expression AR. On the other hand, DNA repair-related gene sets were significantly enriched in AR low-expressed tumors in ER+ tumors (NES=-1.75, p=0.01). In the CIBERSORT analysis, AR high-expression tumors were negatively associated with immune-eliminating cells, such as CD8 Tcells, Gamma-Delta T-cells, and memory B-cells (p>0.01). Cytolytic activity score (CYT) in AR lowexpression BC is higher than that in AR high-expression BC.

Conclusions: Low expression of AR showed better progress in ER-positive breast cancer. Low AR expression tumors in ER-positive tumors were enriched DNA repair related gene, and it might be associated with patients' survival.

581864 - Women with higher BMI do not have higher recurrence scores in a single-institution series

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Background/Objective: The Oncotype DX Recurrence Score (RS) has been widely adopted as a predictor of recurrence for ER+ or PR+, HER2-, axillary node-negative breast cancer patients. Additionally, obesity has been associated with higher rates of breast cancer recurrence and death. We sought to explore potential associations between RS, obesity, and outcomes in our 9-year, single-institution series of breast cancer patients. We hypothesize that tumors in women with higher BMI have a higher recurrence score.

Methods: We queried our IRB-approved, prospective breast cancer database and identified our study cohort (n=1429) comprising non-metastatic, Stage 1-3, ER+ or PR+, HER2-, axillary node-negative breast cancer cases diagnosed between January 1, 2009 and September 4, 2018. RS was stratified into 3 categories: low (RS 0-17), intermediate (18-30), and high (>30). Potential relationships were explored using BMI as both as a continuous and categorical variable (normal (18.5-24.9 kg/m2), overweight (25-30 kg/m2), and obese (>30 kg/m2) as per CDC guidelines. Chi-squared analyses were used to describe differences in use of RS across groups. Univariate and multivariate logistic regression was employed to evaluate BMI and RS as predictors of recurrence and survival outcome. Stata/SE 15.1 (StataCorp, College Station, TX) was used for all analyses.

Results: There was no correlation between RS and BMI when BMI was analyzed as a continuous or categorical variable (p=0.256 and p=0.707, respectively). As expected, pathological stage differed significantly across the 3 RS subgroups (p<0.001). High RS patients were more likely to receive adjuvant chemotherapy and less likely to receive hormone therapy (p<0.001) as part of first course treatment. Obesity was predictive of poor overall survival in univariate regression when analyzed both as a continuous (OR: 1.04, p=0.06) and categorical variable (OR: 2.38, p=0.05). In a multivariate logistic regression analysis, only RS remained predictive of both recurrence (OR: 3.36, p=0.005) and survival (OR: 4.78, p=0.001) when controlling for age, self-reported race, BMI, and pathological stage.

Conclusions: In this single-institution analysis, both high RS and obesity proved to be predictors of poor outcomes. However, despite the well-established relationships between obesity and breast cancer recurrence and survival, as well as the incorporation of RS as standard of care, we did not detect an association between obesity and RS in this single-institution series. Our results suggested that obesity and associated metabolic syndrome may affect expression of reporter genes other than those used in the 21-gene recurrence score assay. Future work is needed to elucidate the genetic and epigenetic effects of obese state on tumor progression.

| | Lo | w RS | Interm | ediate RS | Hi | gh RS | p-value |
|-----------------------|--------------|--------|--------------|-----------|--------------|---------|---------|
| n, % | 857 | 59.99% | 476 | 33.19% | 96 | 6.82% | |
| BMI mean ± SD | 27.77 ± 6.43 | | 27.65 ± 6.40 | | 28.87 ± 7.40 | | 0.228 |
| BMI Group | | | | | | | |
| Normal BMI | 325 | 37.92% | 190 | 39.92% | 34 | 35.42% | 0.75 |
| Overweight BMI | 258 | 30.11% | 140 | 29.41% | 26 | 27.08% | 0.75 |
| Obese BMI | 262 | 30.57% | 143 | 30.04% | 35 | 36.46% | |
| Age mean ± SD | 57.41 | ±10.28 | 56.64 | ± 10.83 | 56.37 | ± 12.40 | 0.354 |
| Race | 1410.00 | | | | | | |
| White | 689 | 80.40% | 382 | 80.25% | 70 | 72.92% | |
| Black | 123 | 14.35% | 77 | 16.18% | 21 | 21.88% | 0.284 |
| Other | 36 | 4.20% | 15 | 3.15% | 3 | 3.13% | |
| Pathological Stage | | | | | | 1.000 | |
| 1 | 722 | 84.25% | 391 | 82.14% | 65 | 67.71% | 0.000 |
| 2 | 130 | 15.17% | 84 | 17.65% | 29 | 30.21% | 0.002 |
| 3 | 4 | 0.47% | 0 | 0.00% | 0 | 0.00% | |
| Definitive Surgery | | | | | | | |
| Lumpectomy | 591 | 68.96% | 314 | 65.97% | 59 | 61.46% | 0.23 |
| Mastectomy | 266 | 31.04% | 162 | 34.03% | 37 | 38.54% | |
| Treatment | | | | | | | |
| Hormone Therapy | 804 | 93.82% | 457 | 96.01% | 84 | 87.50% | 0.035 |
| Radiation Therapy | 538 | 62.78% | 301 | 63.24% | 53 | 55.21% | 0.45 |
| Adjuvant Chemotherapy | 22 | 2.57% | 197 | 41.39% | 91 | 94.79% | < 0.001 |
| Recurrence | 22 | 2.57% | 9 | 1.89% | 10 | 10.42% | < 0.001 |
| Deceased | 17 | 1.98% | 11 | 2.31% | 9 | 9.38% | < 0.001 |

Table: Demographic, cancer, and treatment characteristics stratified by RS score

580452 - Association of a genomic index of sensitivity to endocrine therapy with locoregional recurrence of breast cancer

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MD Anderson Cancer Center, Houston, TX

Background/Objective: The sensitivity to endocrine therapy (SET) index is a genomic index measuring the transcriptional activity of 18 genes related to the estrogen and progesterone receptors (ER, PR) relative to 10 reference genes and adjusted for baseline prognostic index (cT, cN, RNA4). Hence, higher SET index is predictive of greater intrinsic tumoral sensitivity to endocrine therapy (ET). We hypothesized that high SET index would also be associated with lower risk of locoregional recurrence (LRR).

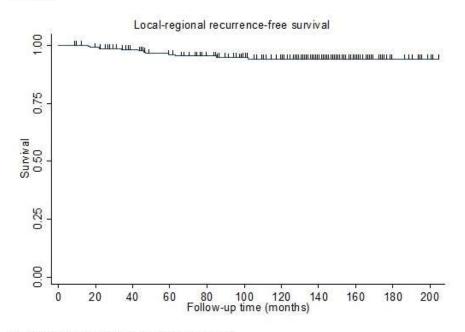
Methods: This was a single-institution, retrospective study of female patients ≥ 18 years diagnosed with hormone-receptor-positive (HR+), HER2-negative invasive breast cancer and treated with neoadjuvant chemotherapy (NACT) and adjuvant ET (Tamoxifen and/or aromatase inhibitor) diagnosed from 2000-2009. Patients were censored at time of last follow-up or death. All patients had a minimum 12 months of follow-up unless known to be deceased of distant metastatic disease or other cause within 12 months. SET index was defined as a binary (high vs low) variable based on a pre-defined cutpoint. Descriptive statistics were performed. Kaplan-Meier estimates of LRR-free survival and univariate analysis of factors associated with LRR were done.

Results: There were 212 subjects included with median age 50 (range 24-79) and median follow-up of 134 months (8-204). The majority of tumors were staged as cT2 (59.9%), and most subjects (69.3%) were clinically node-positive, with 1 in 5 women having either cN2 (6.6%) or cN3 (15.6%) disease. Ductal histology was most common (79.2%), and tumors were grade II or III in 94.3%. Two-thirds of the cohort underwent mastectomy, 83.0% had an axillary lymph node dissection, and 83.0% also received adjuvant radiation therapy. Residual cancer burden (RCB) index was pCR/RCB-0 in 8.0%, RCB-I in 9.0%, RCB-II in 53.3%, and RCB-III in 26.4%. SET index was high in 97 subjects (45.8%) and low in 115 (54.2%). Eleven LRRs were noted: 7 categorized as local, 3 as regional, and 1 as both. Ten-year overall survival was 79.5%, and 10-year LRR-free survival was 94.2%. Univariate analysis of factors associated with LRR including age, T-stage, N-stage, RCB index, and surgical procedure did not demonstrate any significant association. Although SET index was not statistically significantly associated with LRR-free survival, there was a trend that patients with SET index low were more likely to have LRR (HR 2.7, p=0.10; Figure) compared to those with SET index high.

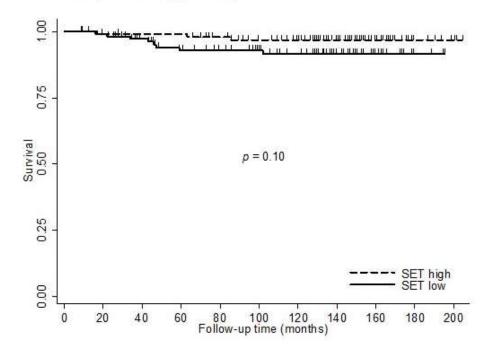
Conclusions: In this high-risk HR+/HER2-negative cohort of patients treated with NACT and adjuvant endocrine therapy, clinical and biologic factors did not appear to be associated with risk of local-regional failure, although the SET index showed a trend towards significance. Further evaluation with larger cohorts is indicated to determine whether SET index can help identify subsets of patients at high risk for local-regional failure.

Figures: Kaplan-Meier estimates of locoregional recurrence-free survival

A. Overall



B. Stratified by SET index (high vs low)



582079 - PLK1, polo-like kinase 1, is significantly associated with worse prognosis resulting from activated cell cycle and DNA repair deficiency in breast cancer

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Background/Objective: Polo-like kinase 1 (PLK1), the most investigated members of the PLK family, plays a pivotal role both in mitosis, especially in G2/M phase, and in the regulation of DNA damage repair. If PLK1 would play a pivotal role in cell-cycle regulation and DNA damage repair, overexpression of PLK1 is confirmed in breast cancer as well as various other cancers, which may have clinical implications. In fact, in breast cancer, it has been reported the clinical significance of PLK1 and the potential for clinical application of PLK1 inhibitors. However, compared to its well-characterized role in other cancers, little is known about clinical significance of PLK1 in a large breast cancer cohort.

Methods: The subjects of this study were a total of 1025 women from The Cancer Genome Atlas breast cancer cohort (TCGA) and a total of 237 women from the neoadjuvant (NAC) cohort. We developed bioinformatics analysis to verify the clinical significance of PLK1 mRNA expression in a large breast cancer cohort.

Results: In TCGA cohort analysis, high PLK1 mRNA expression was statistically significantly associated with more aggressive clinicopathological factors (higher age group, higher Nottingham Grade group, hormone receptor (HR)-negative, and triple-negative (TN). In Gene Set Enrichment Analysis, high PLK1 mRNA expression was significantly associated with cell cycle-related gene sets (G2/M check point, E2F targets), MTORC1 signaling, and MYC target gene sets. High PLK1 mRNA expression was also significantly associated with deficiency of homologous recombination (HR), which is one of the important mechanisms of DNA repair, and high expression of TP53, which is an intermediary to the HR of PLK1. In survival analysis, in the whole and in the HR-positive/human epidermal growth factor receptor 2-negative group, high PLK1 expression was a poor prognostic factor. Further, we verified the clinical significance as a therapeutic effect predictor of PLK1. HR deficiency (HRD) and tumor-infiltrating lymphocytes (TILs) are predictors of high sensitivity to chemotherapy. In CIBERSORT analysis, high PLK1 mRNA expression was correlated with high population of CD8+ T cell, high population of macrophage M1, and low population of macrophage M2. In addition, high PLK1 mRNA expression was associated with high immune cytolytic activity. However, in NAC cohort analysis, high PLK1 expression was not a predictor of chemotherapy.

Conclusions: We have demonstrated the clinical significance of PLK1 mRNA expression in TCGA breast cancer cohorts. Interestingly, it acknowledged the difference by subtype. Since high PLK1 expression correlated with HRD and TILs, target therapy for PLK1 and immunotherapy may be useful.

Poster Session II

Age Extremes

582034 - Treatment trends in early breast cancer in elderly women in the US between 2005 and 2015 using the NCDB

<u>Waed Alswealmeen</u>, Caitlin Hodge, Stefania Nolano *Abington Jefferson Health, Abington, PA*

Background/Objective: Breast cancer disproportionately affects older women, with the highest agespecific probability of developing invasive disease seen in women over 70. With our aging population, the upcoming decades will witness a larger cohort of elderly women both as newly diagnosed patients and survivors of breast cancer. Treatment of elderly women is largely extrapolated from literature focusing on younger women as elderly patients are largely underrepresented in clinical trials. We aim to look at treatment trends over a 10-year period in relationship to age.

Methods: We queried the National Cancer Database for all cases of invasive lobular and ductal breast carcinoma who were above the age of 18, unilateral, Stage 1-2 and HER-2 negative. Patients were divided into 2 groups based on age: below 50 and above 70 years of age. To account for covariates that can affect treatment decisions, patients from both groups were matched using propensity score matching based on race, income, insurance status, Charleson-Deyo score, stage, and tumor size. Analysis was done separately for hormone receptor-positive and hormone receptor-negative tumors. Chi-square and analysis of variance were used to compare categorical and continuous data respectively.

Results: The study identified 15,721 patients <50 years old with early breast cancer (Stage I and II) who were receptor-positive (ER+ and/or PR+). They were matched to 15,721 patients >70 years old. Baseline characteristics were not statistically significant after propensity matching. In early receptor-positive breast cancer, elderly women are less likely to receive full treatment. Seventeen percent of women over 70 received surgery alone compared to 7% of women <50. Only 42% of women over 70 received surgery, radiation, and chemotherapy, whereas 55% of women <50 received all 3 modalities. Overall survival was statistically higher but not clinically significant for younger women 42.58 vs 39.5 months (F-statistic: 178.7, p-value:<0.001). There were 2251 women with triple-negative breast cancer under age 50 who were matched to 2251 with triple-negative breast cancer above 70 years old. Surgery alone was offered to 46.47% of women >70 compared to 42.74% of women <50. Multimodality treatment consisting of surgery, radiotherapy, and chemotherapy was offered to 28.65% of women >70, whereas 51.49% of women <50 received full treatment. Again, overall survival was statistically higher but not clinically significant for younger women <20.57.81, p-value<0.0001).

Conclusions: Even though elderly women receive substandard treatment, there is no clinically significant difference in overall survival.

581577 - Comparing tumor characteristics and treatment among young women with breast cancer: Age <35 versus 35-40

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Background/Objective: Breast cancer is the most common cancer affecting young women. Five percent of all breast cancer occurs in women under the age of 40, and breast cancer is the most common cause of cancer-related death in women ages 20-39. Previous analyses have used different age criteria to define "young" patients for the comparison of tumor and patient characteristics and survival. Some compared patients <40 with those >/=40, while others compared patients <35. We sought to examine whether differences exist in patient and tumor characteristics between very young (VY) women who were <35 years of age versus young (Y) women who were 35 to 40. We examined cancer characteristics including stage at presentation, receptor status, grade, presence of lymphovascular invasion, invasive or in-situ disease, multifocality or multicentricity, patient demographics such as race and ethnicity, and treatment. Our hypothesis is that significant heterogeneity exists between the 2 groups and that VY patients inherently have more aggressive cancer biology. Additionally, we hypothesize that VY women present with later stage disease due to diagnostic delays secondary to a lower index of suspicion for malignancy.

Methods: We performed an IRB-approved, retrospective chart review of women between the ages of 18 and 40 years who were diagnosed with breast cancer from 2006 until 2016. All women were seen at a tertiary-level academic breast center. Patients were identified from the tumor registry. The following information was collected from the electronic medical record: age at time of diagnosis, demographics, cancer-specific details (receptor status, clinical stage at time of diagnosis), and treatment details (type of surgery performed on the breast and axilla, chemotherapy or endocrine therapy, and radiation therapy). Fisher's exact test was calculated using STATA 13. All p-values are two-tailed with p<0.05 considered statistically significant.

Results: A total of 262 women with invasive or in-situ cancer aged 18 to 40 at time of diagnosis were identified. Of these, 30.9% (n=81) were VY, with the youngest age being 21. There was no difference in race or ethnicity. There was also no difference in tumor grade, although 59.2% of the VY cohort had high-grade disease compared with 46.9% of Y (p=0.49). There was no difference in the histological tumor type with 90.9% ductal in the VY patients and 83.7% in Y. There was a significant difference in receptor status between the 2 groups - 64.9% of VY patients were estrogen receptor-positive compared with 81.8% of Y patients (p=0.005); 52.7% of VY were progesterone receptor-positive compared with 71.2% in Y patients (p=0.008). The VY cohort was also more likely to have triple-negative disease (24.3% vs. 12.4%, p=0.023), although there was no difference in HER2 receptor positivity (p=0.088). When AJCC 7 staging was utilized, most patients presented with Stage I or II disease (79.1% of VY vs. 89% of Y). However, the VY patients were more likely to present with Stage IV disease (6.2% vs. 1.1%, p=0.031). In regards to treatment, there was no difference in the administration of neoadjuvant chemotherapy, which was used in 43.2% of VY patients and 37.6% of Y patients (p=0.41). Adjuvant chemotherapy was administered to 48.2% of VY patients and 50.8% of Y patients (p=0.79). Ovarian suppression was performed in 22.2% of VY patients and 17.1% of Y patients (p=0.39). An analysis of surgical modalities is pending.

Conclusions: Patients aged 18-34 at the time of diagnosis were similar to those who were 35-40 in many regards including race and ethnicity, histologic type, neoadjuvant treatment, and adjuvant treatment. Though it appeared that VY women had a higher percentage of high-grade tumors, it did not reach statistical significance. There was, however, a higher rate of triple-negative breast cancer in VY women, and more patients presented with Stage IV disease supporting our hypothesis that VY patients have more aggressive cancer biology and a later disease presentation.

581459 - Quantifying the relationship between age at diagnosis and risk of breast cancerspecific mortality

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Background/Objective: Increasing age is positively associated with risk of breast cancer-specific mortality (BC-SM). However, there is a growing body of evidence that younger women have disproportionately poorer outcomes when controlling for stage and other prognostic variables. We sought to clarify the nature of the relationship between age at diagnosis and risk of BC-SM.

Methods: A retrospective population analysis of adult women diagnosed with invasive breast cancer between 2004 and 2015 registered in the SEER database was conducted. Multivariable Cox cause-specific hazards model was used to evaluate the association of age at diagnosis with risk of BC-SM. Functional relationship of age was assessed using cumulative sums of Martingale residuals and the Kolmogorov-type supremum test. Modeling results are adjusted for race, stage, grade, estrogen receptor (ER) status, progesterone receptor (PR) status, and year of diagnosis. Hazard ratios (HRs) and 95% confidence intervals (CIs) are provided as measures of strength of association and precision, respectively.

Results: A total of 162,022 women were eligible for study. Mean age at diagnosis was 59.7 ± 13.7 years. Most women (78.1%) were white, and 10.1% were black. About half (48.5%) had Stage I disease, 35.7% had Stage II, 11.4% had Stage III, and 4.4% had Stage IV disease. Tumor grade was I in 23.2% of the women, II in 42.5%, III in 33.8%, and IV in 0.4%. The majority of tumors were ER- or PR-positive (79.8% and 69.1%) with 18.3% and 28.6% being negative, respectively. Median follow-up was 63 months. During the study period, 13,708 women died from breast cancer, and 10,142 died from other causes. Cumulative incidence of BC-SM at 60 months post-diagnosis was 9.1% (95% CI=8.9%-9.3%). Plot of the cumulative sums of Martingale residuals demonstrates that age is quadratically related to the risk of BC-SM (supremum test: p<0.001). The final Cox model was fit with age included as a quadratic term. The vertex of the quadratic function occurs at approximately 43 years of age, which suggests that risk of BC-SM decreases from 18 to 43 years and then increases thereafter. This relationship is graphically displayed using age 43 as the reference for HR=1 (Figure). This model suggests that a 68-year-old woman has approximately the same risk of BS-SM (HR=1.55; 95% CI=1.12-2.15) as an 18-year-old (HR=1.57; 95% CI=1.22-2.01).

Conclusions: The relationship between age at diagnosis and adjusted risk of BC-SM is complex. The risk of BC-SM is highest at the extremes of age, consistent with a quadratic function. With the growing appreciation for breast cancer as a heterogeneous disease, it is essential to accurately address age as a prognostic risk factor in predictive models.

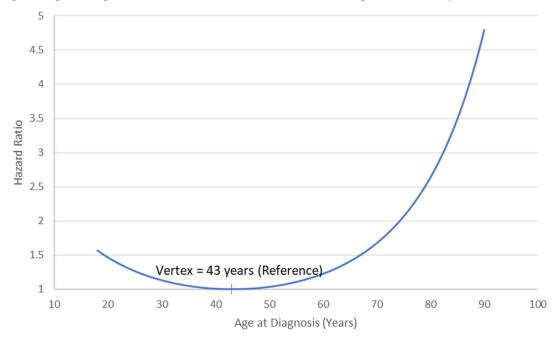


Figure: Age at diagnosis versus hazard ratio for breast cancer-specific mortality

580161 - A ten-year review of non-operative management for hormone-receptor positive breast cancer in elderly patients

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Background/Objective: Breast cancers are increasingly diagnosed in older patients; however, the majority will die of other causes. We reviewed the outcomes of non-operative management of hormone-receptor positive breast cancers diagnosed in patients greater than 80 years of age.

Methods: A retrospective review of all patients in a community health system, aged greater than 80 years, with Stage I-III hormone-receptor positive breast cancer, treated with hormone therapy only, was performed from 2005-2015.

Results: Nineteen patients treated with hormone therapy only were identified. Mean age at diagnosis was 89.6 \pm 0.3 years; median stage was IIA. Sixty-three percent of patients (12/19) were both estrogen and progesterone receptor-positive (ER/PR). All patients were HER-2neu negative. Mean duration of hormone treatment was 12.8 \pm 1.1 months. Forty-seven percent of patients (9/19) received anastrozole, 37% (7/19) received letrozole, and 16% received tamoxifen (3/19). At an average of 24.1 \pm 1.4 months follow-up, a minority of patients had died of breast cancer (5/19). Thirty-one percent (6/19) were alive with disease, and 42% (8/19) were dead of non-cancerous causes, most commonly sepsis (2/8) and stroke (2/8).

Conclusions: Here we demonstrate that women over age 80 with hormone receptor positive breast cancer can safely be treated with endocrine therapy only and avoid surgical intervention. Our findings are similar

to recent studies of nursing home residents undergoing non-operative care. This provides additional support for a non-operative approach in this population.

575735 - Screening mammography remains effective among older women

<u>Brittany Murphy</u>, Elizabeth Habermann, Amy Glasgow, Amy Conners, Judy Boughey, Amy Degnim, Lilia Finney Rutten *Mayo Clinic, Rochester, MN*

Background/Objective: The USPSTF recently concluded that there is insufficient evidence currently to assess the balance of benefit versus harm for screening mammography among women aged 75 years or older. The current CDC estimate of the average female lifespan in the USA is 81.1 years; therefore, suggesting individualized balance of benefit and harm based on life expectancy may be more appropriate. False-positive mammography results increase medical expense, unnecessary procedures, and patient anxiety, while false-negatives delay diagnosis. Given the lack of RCTs in older women, we pursued a retrospective review of the sensitivity and specificity of screening mammography in older women.

Methods: We identified all patients 50 years of age and older who underwent screening mammography between January 1, 2007 and January 1, 2017 at our academic institution using Current Procedural Terminology (CPT) and International Classification of Diseases (ICD)-9/10 codes. Outcomes included biopsy prompted by abnormal screening imaging (also identified by CPT and ICD-9/10 codes) and pathology results of benign, high-risk lesion (lobular carcinoma in situ, atypia), or malignant (ductal carcinoma in situ or invasive) disease. Mammography outcomes including biopsy, biopsy result, and mammography performance were compared by age through univariate analysis. Trends analyses over the age categories were performed using a Cochran-Armitage test. True positives were defined as an abnormal mammogram leading to a biopsy finding of a high-risk lesion or malignant diagnosis with a cancer diagnosis within 1 year of the screening mammogram; false-positive was an abnormal mammogram; true negative was a negative mammogram with no cancer diagnosis within 1 year of the screening mammogram with no cancer diagnosis within 1 year of the screening mammogram with no cancer diagnosis within 1 year of the screening mammogram with no cancer diagnosis within 1 year of the screening mammogram with no cancer diagnosis within 1 year of the screening mammogram with no cancer diagnosis within 1 year of the screening mammogram with no cancer diagnosis within 1 year of the screening mammogram with no cancer diagnosis within 1 year of the screening mammogram with no cancer diagnosis within 1 year of the screening mammogram.

Results: We identified 63,480 patients who underwent 242,263 screening mammograms during the study period. Following screening mammograms, frequency of biopsy was slightly but significantly lower for older patients - 1.3% in ages 75-79 and 1.2% in age 80+, compared to 1.4% in ages 50-69 and 70-74, p=.0009. Upon biopsy, malignant lesions were more often found in the older age groups: 20.2% 50-69, 32.1% 70-74, 34.0% 75-79, and 39.3% 80+ years, p<0.0001. False-positive results were greatest in the younger age categories, ranging from 54.9%-68.4% across the age groups, p<0.0001. Sensitivity remained stable across all age groups (94.7-97.3% for all age groups, p=0.27), and specificity was slightly higher in older patients (98.6-99.1% for all age groups, p<0.0001, Table). Positive predictive value improved with increasing age (p<0.0001), while negative predictive value was 100% for all age groups.

Conclusions: In older women (age 70+) who undergo mammographic screening and biopsy, a higher proportion have malignant findings compared to women ages 50-69, while mammographic sensitivity and specificity are consistent across age groups. While screening mammography remains effective in elderly patients, individual life expectancy should be considered when assessing benefit and harm for individual patient, as false-positive results are common.

Table: Mammography performance

| | Overall | Age 50-69 | Age 70-74 | Age 75-79 | Age 80+ | P-value |
|--|---------------|---------------|--------------|--------------|--------------|---------|
| N | 242263 | 169231 | 33130 | 22240 | 17862 | |
| Biop sy Performed | 3365 (1.4%) | 2426 (1.4%) | 448 (1.4%) | 285 (1.3%) | 206 (1.2%) | |
| Biopsy Result | | | | | | <0.0001 |
| Benign (False Positive) | 2196 (65.3%) | 1680 (68.4%) | 267 (59.6%) | 158 (55.4%) | 111 (54.9%) | |
| High Risk (True Positive) | 358 (10.6%) | 277 (11.4%) | 37 (8.3%) | 30 (10.5%) | 14 (6.8%) | |
| Malignant (True Positive) | 811 (24.1%) | 489 (10.2%) | 144 (32.1%) | 97 (34.1%) | 81 (39.3%) | |
| No Biopsy Performed | | | | | | |
| No can cer diagnosed within one year (True Negative) | 238204(98.3%) | 166324(98.3%) | 32601(98.4%) | 21866(98.4%) | 17393(99.0%) | 0.09 |
| Cancer diagnosed within one year (False Negative) | 3025 (1.3%) | 2292 (1.4%) | 348 (1.0%) | 231 (1.0%) | 156 (0.9%) | <0.0001 |
| Sen sitivity | 96.4% | 96.8% | 97.3% | 95.1% | 94.7% | 0.54 |
| Specificity | 98.8% | 98.6% | 99.0% | 99.0% | 99.1% | <0.0001 |
| Positive Predictive Value | 24.8% | 20.6% | 34.0% | 33.6% | 40.7% | <0.0001 |
| Negative Predictive Value | 100% | 100% | 100% | 100% | 100% | 0.06 |

581715 - Breast cancer biology, stage of presentation, and treatment in the extremes of age <u>Jennifer Plichta</u>¹, Samantha Thomas², Cosette DeChant¹, Oluwadamilola Fayanju¹, Laura Rosenberger¹, Anjuli Gupta¹, Terry Hyslop², E. Hwang¹, Rachel Greenup¹ ¹Duke University Medical Center, Durham, NC, ²Duke Cancer Institute, Durham, NC

Background/Objective: Among younger breast cancer patients, aggressive tumor biology, and advanced stage at presentation have warranted comprehensive evaluation and treatment, while de-escalation of therapy has been endorsed in older women with presumably favorable tumors. Given the changing demographics and treatment among women with breast cancer, we sought to compare contemporary biology, stage of presentation, and patterns of care, as well as survival trends in breast cancer patients at the extremes of age.

Methods: Adult patients with Stages 0-IV breast cancer from 2004-2015 in the National Cancer Database (NCDB) were selected. Patients were categorized by age as 18-45 years, 46-74 years, and \geq 75 years. Patient characteristics were compared using Chi-square and t-tests as appropriate. Kaplan-Meier curves were used to visualize unadjusted overall survival (OS). A Cox proportional hazards model was used to estimate the effect of age group, after adjustment for known covariates. A subset analysis of patients diagnosed in 2010 or later was conducted, including adjustment for tumor biology (hormone-receptor [HR]+/HER2-, HER2+, triple-negative [TN]).

Results: Of the 1,201,252 patients identified, 13% were \leq 45 years old (n=156,240) and 17.5% were \geq 75 years old (n=210,095). Median follow-up was 58.7 months. Clinical and pathological T/N stages were significantly different between all age groups (all p<0.001) and were generally more advanced in younger women (Table1). Older patients were more likely to be cN0 (87.7% vs 74.2%, p<0.001). Tumor grade was significantly different between younger and older patients (all p<0.001), with women \leq 45 years old more likely to have grade 3 disease when compared to women \geq 75 years old (48.6% vs older 27%, p<0.001). Notably, rates of de novo cM1 disease were comparable at the extremes of age (younger 3.7% vs older 3.5%, p<0.001). Tumor biology differed between older and younger patients, with HR+/HER2-tumors more likely in women \geq 75 years old (69.3% vs 51.3%), while HER2+ and TN tumors were more common in women \leq 45 years old (HER2+: younger 18.6% vs older 9.2%; TN: younger 14.9% vs older 8.2%). Younger patients were more likely to undergo mastectomy (vs lumpectomy, 56% vs 34%), receive chemotherapy (65.8% vs 10.2%), and receive radiation (56.2% vs 39.5%), while endocrine therapy was only slightly more common among younger patients (58.5% vs 56.5%) (all p<0.001). Unadjusted OS was worse in older patients and remained true after adjustment for all diagnoses (younger REF, older HR 2.94, CI 2.86-3.03), although the strength of the association weakened with increased disease severity (DCIS:

HR 7.19, CI 6.28-8.24; invasive non-metastatic: HR 3.06, CI 2.97-3.15; metastatic: HR 1.57, CI 1.5-1.66). Similar trends were observed in a subgroup analysis of patients where HER2 status was routinely reported.

Conclusions: Although significant differences in tumor biology and extent of treatment continue to exist between younger versus older breast cancer patients, the rarity of breast cancer in women over 75 years old was comparable to those under 45 years old. Importantly, elderly women were as likely to present with incurable metastatic disease as the very young. In a changing demographic of older women with breast cancer, thoughtful screening and treatment are important to prevent age-related disparities in breast cancer care.

| | Age C | aroup | P-value |
|-----------------------------|--------------------------------|---------------------------------|---------|
| | 18-45y (N=156240) | ≥75y (N=210095) | P-Value |
| Clinical T-Stage | | | <0.001 |
| T0/IS | 24558 (15.7%) | 25151 (12%) | |
| T1 | 63885 (40.9%) | 120054 (57.1%) | |
| T2 | 48677 (31.2%) | 47759 (22.7%) | |
| Т3 | 12914 (8.3%) | 7320 (3.5%) | |
| T4 | 6206 (4%) | 9811 (4.7%) | |
| Clinical N-Stage | | | < 0.001 |
| NO | 115957 (74.2%) | 184318 (87.7%) | |
| N1 | 30770 (19.7%) | 18989 (9%) | |
| N2 | 5973 (3.8%) | 4701 (2.2%) | |
| N3 | 3540 (2.3%) | 2087 (1%) | |
| Clinical M-Stage | | | < 0.001 |
| M0 | 150439 (96.3%) | 202831 (96.5%) | |
| M1 | 5801 (3.7%) | 7264 (3.5%) | |
| Grade | | | < 0.001 |
| 1 | 19825 (12.7%) | 54390 (25.9%) | |
| 2 | 60558 (38.8%) | 98974 (47.1%) | |
| 3 | 75857 (48.6%) | 56731 (27%) | |
| ER Status | | | < 0.001 |
| ER+ | 116531 (74.6%) | 179920 (85.6%) | |
| ER- | 39709 (25.4%) | 30175 (14.4%) | |
| PR Status | | | < 0.001 |
| PR+ | 106235 (68%) | 154745 (73.7%) | |
| PR- | 50005 (32%) | 55350 (26.3%) | |
| HER2 Status* | | | < 0.001 |
| HER2+ | 17104 (18.6%) | 11891 (9.2%) | |
| HER2- | 60976 (66.2%) | 99793 (77.5%) | |
| Tumor Biology* | | | < 0.001 |
| HR+/HER2- | 47241 (51.3%) | 89285 (69.3%) | |
| HER2+ | 17104 (18.6%) | 11891 (9.2%) | |
| TNBC | 13735 (14.9%) | 10508 (8.2%) | |
| Surgery Type | | | < 0.001 |
| Mastectomy | 87566 (56%) | 71444 (34%) | |
| Lumpectomy | 61367 (39.3%) | 120029 (57.1%) | |
| Other | 140 (0.1%) | 122 (0.1%) | - |
| No Surgery | 7167 (4.6%) | 18500 (8.8%) | - |
| Treatment with Chemotherapy | /10/ (4.070) | 10000 (0.070) | < 0.001 |
| No | 53512 (34.2%) | 188703 (89.8%) | 20.001 |
| Yes | 102728 (65.8%) | 21392 (10.2%) | |
| Yes | 102728 (03.8%) | 21392 (10.2%) | < 0.001 |
| | 69421 (42.99() | 127040 (60 50() | <0.001 |
| No | 68431 (43.8%) | 127040 (60.5%) | - |
| | 87809 (56.2%) | 83055 (39.5%) | .0.001 |
| Treatment with Endocrine | 04007 (11 10) | 01474 (10 50() | <0.001 |
| No Yes | 64627 (41.4%) 91613 (58.6%) | 91471 (43.5%) 118624 (56.5%) | |

Table: Patient characteristics

578799 - Sentinel lymph node biopsy in the elderly patient with breast cancer: Who needs it?

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Background/Objective: Current surgical treatment of breast cancer includes a sentinel lymph node (SLN) biopsy, and 1 way to potentially reduce morbidity amongst the patients \geq 70 years old is to omit a SLN biopsy. Previous studies have shown the reliability as well as the prognostication of a SLN biopsy in patients \geq 70 years old. Recently, The American Joint Committee on Cancer (AJCC) recently developed a new staging system for breast cancer to include grade and receptor status to more accurately clinically stage breast cancer. The goal of this study is to apply the AJCC 8 staging system to evaluate the need for SLN biopsy in women \geq 70 years old and determine a safe subset to reduce treatment without jeopardizing outcomes.

Methods: This is an Institutional Review board (IRB)-approved, retrospective chart review in our 11hospital system's cancer registry. Patients included were treated from January 1, 2012 to December 31, 2016. Inclusion criteria were female patients \geq 70 years old with Stage 1 - 3 invasive breast cancer. Patients diagnosed with Stage 0 or 4 disease were excluded. Other data points included date of diagnosis, stage of disease, type of surgery performed (mastectomy versus breast conservation), type of axillary surgery performed (if any), axillary node pathologic results, local or systemic recurrence, date, and cause of death (if applicable). If a patient had bilateral cancers, the cancers were analyzed independently.

Results: There were 490 patients that met our criteria: 377 were clinical Stage 1A, 10 were Stage 1B, 64 were Stage 2A, 17 were Stage 2B, 14 were Stage 3A, 4 were Stage 3B, and 4 were Stage 3C. Of the Stage 1A cancers, the majority (n=282) of patients had a SLNB performed, 88 patients had SLN biopsy excluded, and an axillary lymph node dissection was completed in 7 patients. None of the patients with Stage 1A breast cancer had metastatic lymph node involvement. In that same patient population, there were 11 recurrences (4 local and 7 systemic) and 18 deaths (2 deaths attributed to breast cancer).

Conclusions: Our goal was to evaluate the need for SLN biopsy in women \geq 70 years old to identify a subset of patients that could safely receive reduced treatment without jeopardizing outcomes. For patients \geq 70 years old with Stage 1A breast cancer, a very low percentage of patients will experience metastatic lymph node involvement; therefore, SLN biopsy can safely be excluded. Our data confirm there are few patients with a positive SLN in early-stage disease and few regional or systemic failures. Therefore, the morbidity of axillary surgery, competing causes for mortality, and estimated life expectancy need to be discussed openly when counseling patients in this age group, and consideration should be made to omit SLN biopsy.

580246 - Are we overtreating young women with early-stage breast cancer who elect mastectomy over breast-conservation surgery?

<u>Audree Tadros</u>, Tracy-Ann Moo, Michelle Stempel, Emily Zabor, Atif Khan, Monica Morrow Memorial Sloan Kettering Cancer Center, New York, NY

Background/Objective: Since the ACOSOG Z0011 trial, rates of axillary lymph node dissection (ALND) have declined among women electing breast conservation surgery (BCS). However, in young women (<50 years) electing mastectomy, indications for ALND are unchanged. For node-positive patients, young age (<50 years) is associated with increased use of post-mastectomy radiation. We

examine the axillary management of young women with early, clinically node-negative breast cancer found to have a positive sentinel lymph node (SLN) who elect BCS vs. mastectomy.

Methods: From 2010 to 2016, women, age <50 years, with clinical T1-T2N0 breast cancer having upfront surgery and found to have a positive SLN were identified from a prospective institutional database. Receipt of ALND and/or nodal radiation therapy (NodalRT) were compared between the 2 groups.

Results: A total of 192 women undergoing BCS and 165 women undergoing mastectomy were identified. Median age was 44 years. The majority of tumors were hormone-positive with invasive ductal histology. Rates of lymphovascular invasion and extracapsular extension were not statistically different between cohorts. The median number of SLNs excised in both groups was 3. All patients in the BCS group had <3 positive SLNs; 7 patients in the mastectomy group had 3 positive SLNs. The rate of micrometastasis did not differ significantly between groups (67%-mastectomy vs 68%-BCS). There were 5.2% (10/192) of women undergoing BCS who had an ALND (7 for ECE, 2 based on surgeon clinical judgement, and 1 for patient preference) versus 87% (144/165) of women undergoing mastectomy (p<0.01). There were 65% (36/55) of women in the mastectomy group who had micrometastatic nodal disease on SLN biopsy and underwent ALND based on surgeon clinical judgement. Nodal RT was given to 48% (78/165) of mastectomy patients compared to 30% (55/192) of BCS patients (p<0.01). Of the 75 mastectomy patients with 1-2 total lymph nodes with macrometastatic disease after completion ALND, 44% received NodalRT. Women undergoing BCS (45% vs 6%, p<0.01). At a median follow-up of 3.7 years, 2 isolated locoregional recurrences have occurred in the BCS group and 1 in the mastectomy group.

Conclusions: Clinically node-negative young women electing mastectomy have a significantly higher likelihood of receiving both ALND and nodal radiation than those who elect BCS. If the need for PMRT is clear with the finding of 1-2 SLN metastases, ALND and its associated morbidity could be avoided in women undergoing mastectomy.

| | BCS (N=192) | Mastectomy (N=165) |
|--------------------------------|-------------|--------------------|
| Age (median) | 45 | 43 |
| Clinical Tumor Stage | | |
| T1 | 120 (63%) | 83 (50%) |
| T2 | 72 (37%) | 82 (50%) |
| Histology | | |
| Ductal | 172 (90%) | 130 (79%) |
| Lobular | 11 (6%) | 20 (12%) |
| Mixed ductal/lobular | 8 (4%) | 13 (8%) |
| Other | 1 (<1%) | 2 (1%) |
| Grade | | |
| Low | 8 (4%) | 0 (0%) |
| Intermediate | 93 (49%) | 78 (58%) |
| High | 87 (46%) | 56 (42%) |
| Unknown | 4 | 31 |
| Subtype | | |
| HR+/HER2- | 153 (79%) | 121 (73%) |
| HER2+ | 28 (15%) | 34 (20%) |
| Triple negative | 11 (6%) | 11 (7%) |
| No. excised SLNs (median) | 3 | 3 |
| No. positive SLNS | | |
| 1. | 145 (76%) | 118 (72%) |
| 2 | 47 (24%) | 40 (24%) |
| 3 | 0 | 7 (4%) |
| Size of largest SLN metastasis | | |
| Micrometastasis | 61 (32%) | 55 (33%) |
| Macrometastasis | 131 (68%) | 110 (67%) |
| LVI present | 125 (65%) | 119 (73%) |
| ECE present | 51 (27%) | 41 (27%) |
| Pathologic Tumor Size (median) | 1.6 | 1.9 |
| Pathologic Nodal Stage | | |
| N1 | 189 (98%) | 144 (87%) |
| N2 | 2 (1%) | 19 (12%) |
| N3 | 1 (<1%) | 2 (1%) |
| Adjuvant Chemotherapy | 171 (90%) | 154 (94%) |
| Adjuvant Endocrine Therapy | 169 (88%) | 141 (85%) |
| Unknown | 1 | 6 |
| ALND | 10 (5%) | 144 (87%) |
| NodalRT | 55 (30%) | 78 (48%) |
| No ALND/ No NodalRT | 126 (68%) | 16 (10%) |
| No ALND/ + NodalRT | 49 (27%) | 5 (3%) |
| ALND/No NodalRT | 3 (2%) | 70 (43%) |
| ALND/ + NodalRT | 6 (3%) | 73 (45%) |

Table: Clinicopathologic and treatment characteristics by type of surgery

581617 - Effect of hospital volume on overall survival after surgery in elderly breast cancer patients

Sam Thalji¹, Julia Frebault¹, Youngjoo Cho², Abigail Thorgerson², Carmen Bergom³, Chiang-Ching Huang², Amanda Kong¹

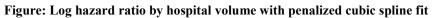
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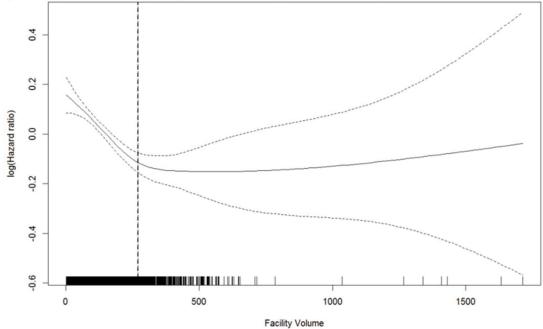
Background/Objective: Higher hospital volume has been shown to be associated with improved outcomes and increased overall survival following treatment for certain cancers. There remains a paucity of data examining treatment-related outcomes specifically in breast cancer patients age 80 or older. The primary aim of this study is to determine the association between hospital volume and mortality following surgery for breast cancer in patients 80 years of age or older. The secondary aim is to elucidate patient and treatment-related characteristics associated with high-volume centers.

Methods: The National Cancer Database was queried for women aged 80 years and over who underwent surgery for Stage I-III invasive breast cancer between 2005 and 2014. Hospital volume was defined as the average number of cases over 2 years: the year of the patient's index operation and the year prior. A Cox proportional hazards model with penalized cubic splines was used to examine the association between annual hospital volume and overall survival. Hospitals were categorized into high-volume and low-volume centers based on penalized cubic spline analysis. The log-rank test was used to examine survival difference between groups. Intergroup comparisons were made using X2 and analysis of variance.

Results: The final cohort included 59,043 patients. Based on penalized cubic spline analysis, a cutoff of \geq 270 cases/year was used to categorize patients as receiving their surgery at a high-volume center (9,110 patients) or a low-volume center (49,933 patients). High-volume centers were significantly associated with decreased risk of death (HR 0.814, CI 0.784-0.846, p<0.001). High-volume centers were associated with a slightly younger patient population (84.0 vs 84.1 years, p<0.001), proportionally more Black and Hispanic patient populations (8.2% vs 6.4% and 4.0% vs 2.5%, p<0.001, earlier-stage disease (Stage I: 56.6% vs 54.3%, p<0.001), performed more breast-conserving surgeries (68.6% vs 61.6%, p<0.001), and had a higher proportion of patients receiving adjuvant radiation (38.2% vs 36. 6%, p=0.004). There were no significant differences in ER, PR, or HER2 status, tumor size, tumor grade, or receipt of adjuvant chemotherapy or hormone therapy between high- and low-volume centers.

Conclusions: Among elderly breast cancer patients age 80 or above, there is a significant association between undergoing surgery at a high-volume center (defined as \geq 270 cases/year) and improved survival. Patients in this population who undergo surgery at high-volume centers are characterized by an earlier stage of disease and more commonly receive breast-conserving surgery, as well as subsequent adjuvant radiation.





Benign

581821 - Does previous history of cancer or atypia predict histologic upgrade for pure intraductal papillomas diagnosed via core biopsy? A study of 511 cases at a single institution

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Background/Objective: Management of pure intraductal papillomas (IDP) without atypia diagnosed on core needle biopsy (CNB) remains controversial given that reported rates of upgrade of IDP are highly variable in the literature, ranging from 5-20%. We sought to identify clinical and histologic factors that predict upgrade to atypia or malignancy in a large population.

Methods: A retrospective review was performed of all cases of pure IDP diagnosed on CNB and then surgically excised at a single institution from 2008-2018. Clinical, radiologic, and pathologic factors were compared in the no upgrade, upgrade to atypia, or upgrade to cancer groups. Univariate analysis was performed comparing no upgrade and upgrade to cancer or atypia.

Results: A total of 435 patients were identified, with a total of 511 IDP and a median age of 50 years (range 16-85). Of these patients, 55 (12.6%) were upgraded to atypia after surgical excision and 6 (1.4%) were upgraded to cancer [Table]. In the overall cohort, the presence of multiple papillomas in a single patient was a significant predictor of cancer or atypia (p=0.03), as well as older age (p<0.01) and a prior history of cancer, atypia, or IDP (p<0.01). No other clinical, radiologic, or histologic factors were found to be significant predictors of upgrade. Forty (9.2%) patients in the total cohort had prior history of cancer, and of these, 3 (8%) were found to have cancer after excision.

Conclusions: In patients with IDP and no atypia on CNB, the upgrade rate to malignancy was low, 1.4%, while 12.6% were upgraded to atypia. The clinical significance of identifying atypia in a papilloma is unknown, especially in a patient with a prior history of atypia. However, the majority of patients who were upgraded to either atypia or cancer had no prior history of high-risk or malignant breast disease, and are therefore considered true clinical upgrades. As such, excision for IDP should be considered.

| | Total C | ohort N=435 p | atients | | |
|---------------------------------------|--------------------------|---------------------------------|--|---------------------------------------|----------|
| Characteristic | | No Upgrade N= 374 (86.0%) | Upgrade to Atypia N= 55 (12.6%) | Upgrade to Cancer N=6 (1.4%) | p-value* |
| Age | Median (Range) | 49 (16-85) | 56 (26-81) | 61.5 (36-76) | < 0.01 |
| Number of IDP lesions per patients | Single Lesion N=380 | 332 (87.3%) | 44 (11.6%) | 4 (1.1%) | 0.03 |
| - 14 12 | Multiple Lesions N=55 | 42 (76.4%) | 11 (20.0%) | 2 (3.6%) | |
| Prior history | None | 308 (88.3%) | 38 (10.9%) | 3 (0.8%) | <0.01 |
| | Cancer | 27 (67.5%) | 10 (25.0%) | 3 (7.5%) | |
| | Atypia or HRL | 12 (75.0%) | 4 (25.0%) | 0 (0%) | |
| | Papillary Lesion | 27 (90.0%) | 3 (10.0%) | 0 (0%) | |

Table: Factors affecting upgrade of intraductal papilloma to atypical and cancerous lesions

(HRL = High risk lesion, IDP= Intraductal papilloma)

*comparison is made between no upgrade to any upgrade (atypia or cancer)

582177 - The Mother Infant Lactation Questionnaire (MILQ): A validated instrument to assess breastfeeding performance

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Background/Objective: Although there is an increasing focus on breastfeeding outcomes after breast surgery and promoting breastfeeding in general, there currently is no validated measure to assess lactation and breastfeeding performance.

Methods: The Mother Infant Lactation Questionnaire (MILQ) was developed by our group in conjunction with biostatistics, nursing, and lactation support staff to assess lactation and breastfeeding performance across multiple mother and infant domains. The MILQ was piloted in a sample of mothers between the ages of 18-45 years who were between 6 months - 5 years postpartum.

Results: A total of 15 subjects completed the MILQ (mean age: 31.8 years). All subjects produced milk within the first postpartum week, and 86.7% attempted to breastfeed. Two patients did not attempt breastfeeding due to preference or MRSA infection. Of mothers who breastfed, two-thirds used breastmilk to feed their children almost exclusively. Roughly one-third of breastfeeding mothers indicated having insufficient milk production, of which 50% of these patients underwent prior surgery for fibroadenoma or macromastia. Thirty-eight percent of breastfeeding mothers noted lack of employer support and space to breastfeed at work as a considerable barrier.

Conclusions: The MILQ has the potential to become a widely recognized tool for clinicians and researchers to quantify and compare breastfeeding and lactation performance. Our pilot data show that the majority of mothers in our sample attempt to breastfeed, with most exclusively using breast milk. All patients in our sample who underwent previous breast surgery were able to lactate and breastfeed, although with limited milk supply.

582217 - Assessing the clinical outcomes of a multidisciplinary benign breast conference <u>William Gunderson</u>, Collin Connor, Amanda Amin, Christa Balanoff, Jamie Wagner, Kelsey Larson *University of Kansas, Kansas City, KS*

Background/Objective: Guidelines for management of high-risk breast lesions with low potential for upgrade to malignancy on surgical excision are insufficient, and thus our institution developed a Multidisciplinary Benign Breast Conference (MBBC) with pathologic/radiographic concordance to review these cases and provide surgical vs. observational management recommendations. The goal of this project is to review the recommendations from MBBC and describe the clinical outcomes of those reviewed.

Methods: A single-institution retrospective review was performed of MBBC cases from January to December 2014. This date was selected to allow for 3-year follow-up to assess for development or identification of in situ or invasive breast cancer (BC). Patients with a prior or concurrent BC diagnosis were excluded. Clinicopathologic data were collected including patient demographics, pathology, conference recommendations, and clinical outcomes. Risk of BC was assessed for surgical versus observational recommendation groups.

Results: Two hundred fifty-four patients met inclusion criteria. Demographics and pathologic diagnosis are shown in the Table. MBBC recommendations included 74.4% (n=186) imaging follow-up; 23.2% (n=58) surgical consultation; and 2.4% (n=6) high-risk clinic referral. Surgical referral was associated with underlying pathologic diagnosis (p=0.003), but not with demographics or family history. Imaging follow-up recommendations included either 3-month imaging (n=8, 4.3%); 6-month imaging (n=95, 51.1%); or return annual screening (n=83; 44.6%). Subsequently, none of these patients required surgery, and no BC were diagnosed at the recommended imaging follow-up. Two patients (1.1%) were later diagnosed with BC 17 months (contralateral breast) and 27 months (ipsilateral breast, different quadrant) after MBBC. Of the 58 surgery referral patients, 79.3% (n=46) underwent excisional biopsy. Upgrade to BC occurred in 23.9% (n=11) on surgical pathology (DCIS n=9, IDC n=2). Of the remaining 35 surgical patients, 2 patients (4.3%) were subsequently diagnosed with BC 18 months and 24 months after MBBC, both in the contralateral breast. No patients referred to the high-risk clinic developed BC during follow-up.

Conclusions: MBBC appropriately allows for risk stratification and safe management recommendations for patients with high-risk benign breast lesions, with no BC missed in the interval imaging or high-risk clinic patients and appropriately high rate of BC diagnosed in the surgical patients. This multidisciplinary model can be adopted in programs looking for safe and effective ways to approach high-risk benign breast patients. As the program has progressed at the current institution, criteria for which patients do and do not require MBBC review have been developed. Future studies following outcomes over multiple years, assessing changes in MBBC review criteria, and overall cost analysis for this model are ongoing.

| Factor | Number of patients (%) | | |
|--------------------------------------|---|--|--|
| Age | 53 +/- 12 years | | |
| Gender | | | |
| Female | 250 (98.4%) | | |
| Male | 4 (1.6%) | | |
| Race | | | |
| Asian | 3 (1.2%) | | |
| African American | 31 (12.2%) | | |
| Caucasian | 208 (81.9%) | | |
| Unknown | 12 (4.7%) | | |
| Insurance | e stratu de la companya de la | | |
| Medicare | 80 (31.4%) | | |
| Medicaid | 5 (2.0%) | | |
| Private | 165 (65.0%) | | |
| Unknown | 4 (1.6%) | | |
| Family Hx BC | | | |
| Yes | 123 (52.7%) | | |
| No | 100 (39.4%) | | |
| Unknown | 31 (12.2%) | | |
| Abnormal Breast Imaging | | | |
| Mammogram | 191 (75.2%) | | |
| Ultrasound | 51 (20.1%) | | |
| MRI | 12 (4.7%) | | |
| Concordant | 245 (96.5%) | | |
| Discordant | 4 (4.7%) | | |
| Pathology | | | |
| Atypia (ADH/ALH) | 14 (5.5%) | | |
| Papilloma | 24 (9.4%) | | |
| LCIS | 3 (1.1%) | | |
| Radial Scar/Radial Sclerosing Lesion | 22 (8.6%) | | |
| Other | 187 (73.6%) | | |

Table:

576226 - Lactational phlegmon: A distinct clinical entity within the mastitis-abscess spectrum

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Background/Objective: The lactating breast is at risk for a number of conditions requiring surgical evaluation and intervention, yet there is a paucity of surgical literature to guide clinical decision-making. We aimed to characterize the presentation and treatment of lactational phlegmon, a previously undescribed complication of mastitis that may require surgical management.

Methods: We conducted a retrospective cohort analysis of women referred to a single breast surgeon for lactational mastitis between July 2016 and October 2018. Cases were categorized as uncomplicated mastitis, mastitis with phlegmon, or mastitis with abscess. Demographic variables and treatment details were extracted via chart review. Continuous variables were compared using ANOVA and categorical variables were compared using the Pearson Chi-square test. Analysis was performed using JMP v13.0 (Cary, NC).

Results: Among 52 women referred for lactational mastitis, 27 (51.9%) presented with uncomplicated mastitis, 15 with abscess (28.8%), and 10 with phlegmon (19.2%). Abscess was diagnosed clinically in 2 cases and with ultrasonographic confirmation in the remainder. Phlegmon was diagnosed by mass on physical exam with or without overlying erythema, as well as ultrasound demonstrating an ill-defined area of heterogeneous and hyperemic parenchyma, interdigitating fluid, and no discrete fluid collection. Patients in the 3 diagnostic groups were similar with respect to age (p=0.44), race/ethnicity (p=0.94), parity (p=0.45), and history of prior lactation (p=0.52). Overall, the mean age was 31.6 years (range 20-41). The majority of women were white (71.2%), and 19.2% were Hispanic. About half were primiparous (55.8%), and 30.8% had a history of lactation. There was a trend towards women with phlegmon being fewer weeks postpartum (mean 5.7, range 1-11 versus mean 14.2, range 2-52 for uncomplicated mastitis and mean 14.9, range 1-130 for abscess), but this was not statistically significant (p=0.47). Notably, patients with uncomplicated mastitis were prescribed a shorter duration of antibiotics (mean 9.7 days versus 14.2 days for abscess and 15.0 days for phlegmon, p<0.05) and had fewer encounters (mean 2.2 versus 4.1 for abscess and 4.6 for phlegmon, p<0.01). None of the uncomplicated mastitis patients required surgical intervention. In contrast, all patients with abscess were treated with a surgical procedure (5 aspiration, 10 catheter drainage). Aspiration was attempted in 7/10 phlegmon patients, with return of minimal non-purulent, serosanguinous fluid. Two phlegmons later coalesced into abscesses within 1 week of the initial consultation and were then effectively treated with a drainage procedure. Among the 8 phlegmons that did not coalesce into abscess, time to clinical resolution ranged from 8 days to greater than 3 months. Interval imaging was obtained in 2 patients due to persistent mass on follow-up exam, and both underwent core-needle biopsy for suspicious imaging findings, with pathology demonstrating acute and chronic mastitis.

Conclusions: Lactational phlegmon is a complication of milk stasis that warrants management distinct from that of uncomplicated mastitis or abscess. Aspiration does not appear to have an appreciable treatment effect, but an extended antibiotic course may reduce inflammatory and infectious symptomatology. We recommend follow-up examination and interval imaging to ensure complete resolution and to rule out occult mass as lead point for initial obstruction and inflammation. Breast surgeons are well-poised to manage lactational phlegmon as it may coalesce into an abscess requiring drainage and/or require biopsy in the setting of persistent mass.

582159 - Timing reduction mammaplasty in the adolescent patient

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Background/Objective: Reduction mammaplasty effectively reduces breast-related symptoms and restores quality of life in young women. However, operating on adolescents remains controversial due, in part, to fear of potential postoperative breast regrowth.

Methods: Symptomology, demographics, perioperative information, and postoperative outcomes were prospectively collected from patients undergoing bilateral reduction mammaplasty. Severity of macromastia was assessed using total breast tissue resection mass.

Results: A total of 564 subjects were included in analyses, with a mean age at surgery of 17.9 years. Although years since menarche was positively associated with macromastia severity, this association was no longer significant when examining healthy-weighted patients who were at least 2 years post menarche, and overweight/obese patients who were at least 7 years post menarche. Although postoperative breast regrowth occurred in 5% of our sample, there were significantly fewer instances of glandular breast regrowth in patients who underwent surgery after these biological time points.

Conclusions: Our findings suggest that maximum efficacy may be reached, and the risk for postoperative regrowth minimized, if reduction mammaplasty is performed at least 2 years post menarche in healthy-weighted patients and at least 7 years post menarche in overweight/obese patients. Of note, many third-party insurers still use strict age criteria (such as 18 years old) to authorize reduction mammaplasty. In light of our work, this age cut-off appears arbitrary.

581713 - Benign intraductal papilloma: Is surgical excision warranted?

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Background/Objective: In many countries, the current standard of care is to excise all papillomas of the breast despite recent studies demonstrating low rates of upgrade to malignancy on final excision. The objective of this study was to determine the rate of upgrade to malignancy in patients with papilloma without atypia.

Methods: A retrospective review of a prospectively maintained database of all cases of benign intraductal papilloma in a tertiary referral symptomatic breast unit was performed. Patients who had evidence of malignancy or atypia on core biopsy, along with those who had a history of breast cancer or genetic mutations predisposing to breast cancer were excluded. Age at presentation, presenting symptom, radiological findings. and final histopathological diagnosis were recorded.

Results: A total of 173 cases of benign papilloma diagnosed on core biopsy were identified, and 35 did not meet the inclusion criteria. The final cohort comprised 138 patients. The mean age at presentation was 51.1 (20-94). The most common presenting symptom was a lump (40.58%). Of the 114 patients who underwent excision, 1 had invasive ductal carcinoma, and 3 had DCIS, giving an upgrade rate of 3.51%. Upgrade to high-risk lesions (ALH, ADH, LCIS) was demonstrated in a further 14 patients (12.28%). One hundred (87.72%) patients were confirmed to have a benign papilloma only, and in 6 cases, no residual papilloma was found. Imaging on the day of planned surgery showed no residual corresponding

lesion in 2 patients. Of the patients who were managed conservatively, 1 went on to develop malignancy, and none developed a further high-risk lesion.

Conclusions: Patients with a diagnosis of benign papilloma with no atypia on core biopsy have a low risk of upgrade to malignancy on final pathology. This suggests that observation may be a safe alternative to surgical excision. However, further research is warranted to study the natural history of these lesions.

581845 - Benign papilloma excised at an NAPBC-accredited breast center: Analysis of local upgrade rates for use in patient counseling

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Background/Objective: Historically, intraductal papillomas diagnosed by needle biopsy have been excised due to the risk of upgrade to malignancy. In more recent series, the rate of upgrade of an intraductal papilloma without atypia (on core biopsy) to malignancy (on excision) is <10%. As a result, ASBrS and NCCN guidelines allow for observation without excision in select patients with a core biopsy showing papilloma without atypia. In order to inform the increasingly complex patient discussions around management of a papilloma without atypia diagnosed by core biopsy, it is important to examine our institutional upgrade rate from papilloma on needle core biopsy to atypia or malignancy on excisional biopsy.

Methods: This was a retrospective review of patients from a single institution between December 2010 through April 2018. Any patient with the diagnosis of intraductal papilloma by core biopsy who underwent excision were included in the study. Patients with atypia or papillomatosis in the core biopsy were excluded from the analysis. The clinical manifestations and radiographic characteristics were recorded for correlation with final diagnosis by excision.

Results: There were 87 patients with benign intraductal papilloma without atypia on core biopsy that underwent excisional biopsy. The mean age of diagnosis was 50 years. Thirty patients (34.5%) had symptomatic nipple discharge. Seventy-six patients (87.4%) had an associated mass on imaging. The average mass size was 0.8 cm. Twenty-four patients (27.6%) had associated calcifications. On excisional biopsy, 5/87 (5.7%) had atypia, and 3/87 (3.4%) had papillomatosis. No cases were upgraded to ductal carcinoma in situ or invasive breast cancer.

Conclusions: Management of benign papilloma diagnosed by core biopsy requires nuanced decisionmaking and should give consideration to patient risk aversion. It is important in patient counseling to discuss the risk of upgrade on surgical excision, both nationally and locally. Based on our study results, we can counsel patients with intraductal papilloma without atypia and concordant imaging that the risk of delayed cancer diagnosis at our institution is quite low. Patients who would consider increased surveillance or chemoprophylaxis in light of a diagnosis of atypia may benefit from excision of a papilloma. We recommend that other surgeons offering observation rather than excision of intraductal papilloma verify their own institutional rate of upgrade to atypia or malignancy.

Table: Upgrade rates of benign papilloma without atypia on excisional biopsy (n=87)

| | No atypia | Atypia | Papillomatosis | DCIS | Invasive breast cancer |
|--------------------|-------------|-----------|----------------|---------|------------------------|
| Patient number and | 70 (00 09/) | 5 (5 70/) | 2 (2 49/) | 0 (00/) | 0 (00() |
| percentages | 79 (90.8%) | 5 (5.7%) | 3 (3.4%) | 0 (0%) | 0 (0%) |

580505 - Cryotherapy for benign breast lesions: Preliminary results of a single-center experience

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Background/Objective: The aim of the study was to assess the effectiveness of using cryoablation under ultrasound guidance in office setting as treatment for biopsy-proven benign breast lesions.

Methods: This was a retrospective study of all ultrasound-guided cryoablation procedures performed for biopsy-proven benign breast conditions in a single center between September 2016 and March 2018. Data were collected on age, BMI, ethnicity, diagnosis, ablation protocol, and status of lesions at last follow-up. Commercially available Visica 2TM treatment system was used with standardized freeze-thaw-freeze cycle recommended for benign lesions. The procedures were done under real-time ultrasound monitoring of ice-ball formation.

Results: A total of 18 procedures were performed in 17 patients, of which 7 (41.2%) were Hispanic or Latino, and 10 (58.8%) were white. The mean (SD) age was 32.8 (12.2) years; mean (SD) BMI was 26 (4.6). Seventeen of 18 (94.44%) had fibroadenomas. The mean (SD) size of the lesion was 18.72 (8) mm; the mean (SD) reduction in size at 6 months was 46% (34%); further reduction in size at 12 months was documented for 3 patients with a mean (SD) reduction of 72.6% (24%) [p< 0.01, 95% CI (4.8-10.5)]. All patients received clinical exams and ultrasound at follow up. A total of 4 patients had a 100% resolution documented by ultrasound of lesion; 3 patients at 6 months and 1 patient at 12 months; these patients had pre-treatment lesion sizes less than 20mm.

Conclusions: Using office-based cryoablation for the treatment of benign breast lesions is safe and costeffective. Lesions less than 20mm have the highest rate of complete resolution at 6 months. Larger studies are warranted to identify the size cut-off and timing of complete resolution.

531044 - Upstage rates of atypical ductal hyperplasia and flat epithelial atypia in coreneedle biopsies in a community hospital with a large minority population

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Background/Objective: Many studies have sought to define the upgrade rate from atypical ductal hyperplasia (ADH) or flat epithelial atypia (FEA) to ductal carcinoma in situ (DCIS) or invasive carcinoma. Most of these have been performed in university hospitals, but community hospital data have not been validated. Additionally, ethnic or cultural diversity is rarely emphasized. We aim to examine the upgrade rates for ADH and FEA at a community-hospital with a large minority population.

Methods: IRB approval was obtained. A retrospective review of 2,120 total core-needle biopsies performed over 60 months at our community hospital was conducted. All data were analyzed and reviewed by a single researcher. Histopathology results displaying ADH and/or FEA in the initial core-needle biopsy were compared to follow-up open biopsy pathology.

Results: During the 60 months, 2,120 core-needle biopsies were performed. Of those, 1526 (71.9%) were benign, 170 (8%) were invasive carcinoma, 146 (6.9%) were DCIS, 177 (8.3%) were ADH, 52 (2.5%) were FEA, and 49 (2.3%) had other atypia. Excisional biopsy was performed for 109 of the pure ADH

cases, 20 of the FEA cases and 117 of the benign cases. Seven cases of ADH were upgraded to DCIS (6.4%), 1 to invasive carcinoma with DCIS (0.92%), and 1 to invasive carcinoma with other atypia (0.92%). One case of FEA was upgraded to invasive carcinoma with DCIS (5%). Five cases of benign pathology were upgraded to DCIS with other atypia (4.3%), and 1 was upgraded to invasive carcinoma (0.85%). This is an overall upstage rate of 6.5%, with 4.9% upgraded to DCIS, and 1.6% upgraded to invasive carcinoma. Of those patients with upgrade, 7 were English-speakers or had unknown primary language, 4 spoke Chinese, and there were 1 of each of the following languages: Polish, Bengali, Spanish, Korean, and Farsi/Persian.

Conclusions: Our study demonstrates upgrade rates of 8.4% for ADH and 5% for FEA, consistent with published studies. We additionally had an upgrade from benign pathology of 5%, which warrants further investigation. Despite the diversity of our patient population, as evidenced by the number of preferred languages spoken by our patients, we have upgrade rates similar to larger cohort studies.

575396 - Benign, atypical, and malignant breast adenomyoepithelioma: A single institution's experience

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Background/Objective: Breast adenomyoepithelioma (AME) tumors are infrequently encountered lesions of the breast that have been minimally reported on. AMEs are phenotypically variable myoepithelial cells along epithelial borders composed of a dual proliferation, which can be challenging to classify. The most common form of treatment has been documented as simple excision, although some malignant AME tumors have been treated with more invasive measures. This study investigates epidemiology and management practices of AME tumors in a large, academic medical center case review.

Methods: Female patients seen at our institution from 2008-2018 with a diagnosis of AME were retrospectively identified. Patients with a final pathologic diagnosis inconsistent with AME were excluded. Histopathologic, surgical, and follow-up data were collected. Epidemiology and management of benign, atypical, and malignant AMEs were extracted.

Results: We identified 16 patients with a final pathologic diagnosis of AME. The median age of the cohort was 47 years. Two patients had a known first-degree relative with breast cancer, and 9 patients initially presented with an abnormal mammogram, while 3 patients noticed a palpable mass prompting evaluation. While most (14/16) patients were surgically managed with excisional biopsy, 3 followed with formal lumpectomy with node sampling, and 2 had mastectomies performed. One patient had positive margins for benign AME, did not have further surgery, and was alive and well upon last follow-up. No true local recurrences were found; 1 patient had local recurrence suspected on mammogram, but biopsy was consistent with radial scar and sclerosing papilloma instead. Mean follow-up was 1322 months (range 0-4526).

Conclusions: We stratified AME based on 3 distinct histopathologic categories and presented characteristics and clinical outcomes of 1 of the largest single-institution series of breast AME, a rare diagnosis. This study met its aims: it not only reflects, but also greatly broadens, the minimal prior literature demonstrating surgical approach with excisional biopsy and low recurrence rates with follow-

up. Additionally, this study will serve as one of the largest to be considered for publication among those already published characterizing the rare breast AME, and it will be the first known study to classify AME characteristics based on histopathologic categories.

Complications

581677 - Short-term complications and their risk factors after breast surgery utilizing the NSQIP Database

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Background/Objective: We sought to identify the incidence of post-operative complications, and risk factors for complications, utilizing the NSQIP database.

Methods: The NSQIP database (2012-2016) was used to identify 105,973 patients who underwent breast surgery (lumpectomy, mastectomy, axillary dissection/sentinel lymph node biopsy, or reconstruction) based on CPT codes, which was then sorted by ICD-9 and ICD-10 codes for patients with invasive or in situ breast tumors. Patients were evaluated for risk factors including obesity, age (<40 years old), diabetes, smoking, wound class, and ASA class, and post-operative complications were evaluated. Univariate and multivariate logistic regression was used to identify predictors of any wound problem (superficial, deep-space infections, dehiscence).

Results: Wound complications were the most common post-operative complication encountered. Obesity (OR 2.42, 1.61-3.64) was the strongest predictor of post-operative wound complication followed by reconstruction (OR 1.84, 1.65-2.06), smoking (OR 1.79, 1.62-1.98), age less than 40 (OR 1.36, 1.17-1.58), and diabetes (OR 1.30, 1.18-1.45).

Conclusions: Short-term post-operative complications after breast surgery are low. Wound complications are the most common complications encountered. We have identified both modifiable and non-modifiable risk factors for the development of post-operative wound complications. Specifically, age less than 40, diabetes, obesity, smoking history, or reconstruction were predictive of post-operative wound complications. By identifying modifiable risk factors, practitioners can highlight the importance of blood sugar control, weight management, and smoking cessation to their patients. Efforts should be made to educate patients on these modifiable risk factors to reduce post-operative complications and their associated peri-operative health care costs. While we cannot comment on whether immediate, delayed, or the type of reconstruction contributed most to post-operative wound complications, we have identified the procedure itself as a risk factor. Previous studies have focused on the impact of the type of reconstruction on outcomes. A recent study by Olsen et al showed an increased risk of wound complications after immediate implant reconstruction compared to delayed. Future studies may look at outcomes following immediate versus delayed reconstruction as they relate to obesity, diabetes, and smoking history, which may help guide recommendations for the type of reconstruction best suited for each patient. Nonetheless, incidence of complications after breast cancer surgery is low. Practitioners should be aware of and educate patients regarding the modifiable and non-modifiable risk factors for developing complications post-operatively.

Table: Predictors of post-operative wound complications

| | Odds-ratio | 95% CI | Р |
|------------------------|------------|-----------|---------|
| White | 1.24 | 1.12-1.36 | P<0.001 |
| Age less than 40 years | 1.36 | 1.17-1.58 | P<0.001 |
| Obese | 2.42 | 1.61-3.64 | P<0.001 |
| Diabetes | 1.30 | 1.18-1.45 | P<0.001 |
| Smoking | 1.79 | 1.62-1.98 | P<0.001 |
| Wound class - 1 | 0.29 | 0.17-0.51 | P<0.001 |
| Reconstruction | 1.84 | 1.65-2.06 | P<0.001 |

CPM

576730 - Contralateral prophylactic mastectomies lead to increased surgical complications: A coarsened exact matching analysis of the National Surgical Quality Improvement Program (NSQIP) Database

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Background/Objective: Disagreement exists whether contralateral prophylactic mastectomies (CPM) significantly increase postoperative morbidity. Given this controversy, our aim was to compare the postoperative morbidity in patients undergoing bilateral mastectomy (i.e., CPM in addition to their unilateral therapeutic mastectomy) to those undergoing unilateral mastectomy for the treatment of unilateral breast cancer, using a large, multi-national surgical-outcomes database.

Methods: A retrospective cohort analysis was conducted using the American College of Surgeon's National Surgical Quality Improvement Program (NSQIP) 2007-2016 datasets, comparing postoperative morbidity between patients undergoing unilateral mastectomy versus bilateral mastectomy. Patients with a unilateral diagnosis of invasive or in-situ cancer undergoing mastectomy were identified. Those undergoing immediate reconstruction or possessing high-risk perioperative features were excluded. One-to-one coarsened exact matching (CEM) analysis was conducted to compare outcomes between the 2 groups (unilateral versus bilateral mastectomy). Data were pre-processed by CEM, balancing for the following variables: age, body mass index, diabetes, smoking history, dyspnea, functional status, chronic obstructive pulmonary disease, ascites, congestive heart failure, hypertension, renal failure, weight loss, American Society of Anaesthesiology class, current procedural terminology code, type of axillary surgery, and diagnosis. The primary outcome of interest was 30-day postoperative composite morbidity. Secondary outcomes included surgical site infections, postoperative bleeding, reoperations, readmissions, and length of hospital stay.

Results: A total of 8378 women were included, with 4189 in each of the 2 balanced comparison groups. Undergoing a CPM added, on average, 37 minutes of operative time. The median length of operation being 102 (Interquartile range minutes (IQR): 74-139) for the unilateral mastectomy group, and 139 minutes (IQR: 104-183.5) for the bilateral mastectomy group (p<0.001). The overall (composite) morbidity rates were 4.6% and 6.8% in the unilateral and bilateral mastectomy group versus 3.0% in the bilateral mastectomy group (p=0.001). Superficial site infection rate was 1.9% the unilateral mastectomy group versus 3.0% in the bilateral mastectomy group (p=0.001). Superficial site infection rate was 1.9% the unilateral mastectomy group versus 3.0% in the bilateral mastectomy group (p=0.002). Rates of bleeding requiring transfusion were also higher in the bilateral mastectomy group (4.3%) when compared to unilateral mastectomy patients (0.8%) (p<0.001). Between groups, there was no difference in respiratory, renal, cardiovascular, neurologic, urogenital or septic complications. Rates of unplanned readmissions (p=0.457) and reoperation (p=0.079) did not differ between the groups; however, reoperation and readmission data were only available between 2012 and 2016.

Conclusions: This large multi-center study demonstrates that the addition of contralateral prophylactic mastectomy results in higher surgical complication rates, especially rates of wound infection and bleeding.

581622 - Does bilateral mastectomy improve psychosocial outcomes and satisfaction among unilateral, non-hereditary breast cancer patients?

<u>Catherine Pesce</u>, Kristine Kuchta, Katharine Yao, Jennifer Jaffe, Mark Sisco NorthShore University Health System, Evanston, IL

Background/Objective: Many women with unilateral breast cancer elect bilateral mastectomy based on factors such as anxiety, fear of recurrence, pre-existing dissatisfaction with their breasts, and a desire for symmetry. This study sought to determine how BM impacts these outcomes.

Methods: This was a prospective cohort study of women with unilateral, non-hereditary breast cancer who underwent breast conservation (BCT), unilateral mastectomy (UM), or bilateral mastectomy (BM). All mastectomy patients underwent reconstruction. Women completed surveys that assessed anxiety (Hospital Anxiety and Depression Scale for Anxiety), fear of recurrence (Fear of Relapse/Recurrence Scale), and breast-specific psychosocial and satisfaction outcomes (BREAST–Q) before surgery and at 15 months post-op. A subset of BCT-eligible patients who elected BM was compared to a BCT control group matched for age, family history, and tumor stage. The Wilcoxon rank-sum test was used to compare outcomes between BCT, UM, and BM groups at each time point.

Results: A total of 158 women (98 BCT, 28 UM, and 32 BM) completed all surveys. The BCT group tended to be older and had earlier-stage tumors than the mastectomy groups. The UM group had greater anxiety scores before surgery than the BCT and BM groups (p=0.025); at 15 months, these scores had decreased in all groups, and differences were no longer significant (p=0.52). Post-operative fear of recurrence scores were also similar between all groups (p=0.68). Both mastectomy groups reported lower breast satisfaction than BCT patients before and after surgery (p=0.038 and 0.017, respectively) and BM patients trended toward lower satisfaction with their outcomes than UM patients (p=0.16). In the matched subset of BCT-eligible patients who underwent BM or BCT, there was no difference in anxiety or fear of recurrence at 15 months (p=0.39 and 0.80, respectively). However, postoperative psychosocial well-being was significantly lower in BM vs. BCT patients (p=0.006).

Conclusions: BM does not confer greater satisfaction or reduce anxiety and fear of cancer recurrence more than BCT or UM. However, BM may be associated with poorer psychosocial outcomes, especially among BCT-eligible women. Larger prospective studies are needed to confirm these findings.

| | Breast | Unilateral | Bilateral | p-value |
|---------------------------------------|--------------|-------------|-------------|---------|
| | Conservation | Mastectomy | Mastectomy | > |
| Ν | 98 | 28 | 32 | |
| HADS-A | | | | |
| Pre-Test | 7.3 ± 5.1 | 9.6 ± 4.4 | 7.5 ± 4.3 | 0.025 |
| 15 Month Post | 4.8 ± 4.2 | 5.5 ± 4.0 | 5.2 ± 4.1 | 0.519 |
| FRRS Total Score | | 8 | | 5 |
| 15 Month Post | 11.1 ± 3.9 | 11.7 ± 3.4 | 10.9 ± 4.0 | 0.675 |
| BREAST-Q Satisfaction with Breast | | | | |
| Pre-Test | 70.6 ± 22.5 | 65.9 ± 22.0 | 64.5 ± 18.7 | 0.038 |
| 15 Month Post | 74.6 ± 21.6 | 65.3 ± 17.4 | 64.3 ± 13.1 | 0.017 |
| BREAST-Q Psychosocial Well Being | | | | |
| Pre-Test | 78.1 ± 17.9 | 76.5 ± 15.9 | 68.9 ± 15.5 | 0.010 |
| 15 Month Post | 86.7 ± 18.0 | 81.6 ± 15.8 | 73.4 ± 19.2 | <.001 |
| BREAST-Q Satisfaction with Outcome | | | | |
| 15 Month Post | - | 71.1 ± 18.9 | 65.0 ± 11.4 | 0.159 |

Table: Pre-op and 15-month post-op survey results (mean ± standard deviation)

578969 - Striving to do no harm and yet respect patient autonomy: Plastic surgeons' perspectives of the consultation for breast reconstruction with women who have early-stage breast cancer

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Background/Objective: The rate of contralateral prophylactic mastectomy (CPM) has doubled over the previous decade in women considered low risk for developing a contralateral breast cancer. Previous evidence suggests that growing awareness, availability, and access to immediate reconstructive surgery may influence the decision to pursue this more aggressive treatment. Despite the strong association between CPM and breast reconstruction, little is known about the clinical encounter between patients and plastic surgeons. Therefore, a qualitative study was performed to understand how plastic surgeons describe their roles in the treatment decision-making process through their consultations with women who have non-high-risk early-stage breast cancer.

Methods: Purposive and snowball sampling strategies were used to recruit participants from academic and community hospitals across the province of Ontario, Canada. Plastic surgeons who perform reconstructive breast procedures participated in semi-structured one-on-one interviews that were audio recorded and transcribed verbatim. An inductive and interpretive thematic approach was initially used to analyze the data. The 4 principles depicted in Beauchamp and Childress's biomedical ethics framework – non-maleficence, autonomy, justice, and beneficence – were used as the conceptual lens to structure and interpret the findings.

Results: Eighteen Ontario plastic surgeons participated in the study and data saturation was reached. Ten of the 18 participants were female, and 56% (10/18) came from academic hospitals. Four themes were identified: (i) maintaining non-maleficence (i.e., do no harm by advising patients against CPM unless it is medically indicated), (ii) supporting patient autonomy (i.e., respecting patients' decisions to have CPM), (iii) delivering (un)equal healthcare (i.e., highlighting inequities that surround breast cancer management and reconstruction in Ontario), and (iv) providing care to enhance well-being (i.e., performing procedures consistent with patient's wishes to maximize quality of life). The ongoing push-pull between competing ethical principles was the overarching theme that resonated across the entire dataset; specifically, striving to balance parallel responsibilities to do no harm while also respecting patients' rights to make their own health care decisions (Table).

Conclusions: In this patient-centric decision-making climate, it is important for physicians to recognize that patients may value other outcomes, such as achieving greater peace of mind above other clinical factors, and are willing to incur additional risks in order to achieve this. A shared decision-making environment will help to reveal the rationale underlying each individual's treatment choice, which in turn, will allow physicians to appropriately weigh patient requests with the best available medical evidence when counselling women on surgical decision-making for breast cancer care.

Table:

| Themes | Representative Quotes from Ontario Plastic Surgeons |
|--|--|
| Over arching Theme Striving to Do No Harm and yet Respect Patient Autonomy | "I'm of the opinion that resecting a normal breast is not the way to treat the anxiety and I know it's easier said than done. It's hard to not share their anxiety and share their concerns but it's also more surgery to take off another breast and have another reconstruction" (ID 2) "I think we often struggle with the whole idea that we're taking off perfectly healthy tissue, we're adding another operation with another level of complexity and another potential risk for a patient and you can have a really awful outcome on the non-cancer side and so for all of that, I think we struggle" (ID 4) |
| Theme 1 Maintaining Non-Maleficence | "I say to them, there's no good reason to do this, there just isn'tyou're just like any woman who's never had breast cancerI try and counsel them out of it" (ID 18) |
| Theme 2 Supporting Patient Autonomy | "I know very few reconstructive surgeons who will ultimately say no to a prophylactic if the patient advocates for themselves, even in situations where there really isn't a good medical cancer reason to take off the opposite breastif they really want it, they're going to get it" (ID 4) |
| Theme 3 Delivering (un)Equal Healthcare | "The other obvious problem that's an issue is there's a lot of women in the province that aren't being offered reconstruction at the optimum time in the course of their treatment planning and that's just because of accessibility. I think in the more highly populated areas of southern Ontario it is offered, but once you get outside of southern Ontario, I'm not so sure" (ID 12) |
| Theme 4 Providing Care to Enhance Well-Being | "It's a quality of life surgery and I'm not saving anybody's life by reconstructing their breast, but I just want to make them really, really happy for the rest of their life. They will survive and are young, so I just really want them to get over this and live a happy life after" (ID 16) |

DCIS

582005 - Local recurrences after treatment for ductal carcinoma in situ: Comparing four different treatment modalities

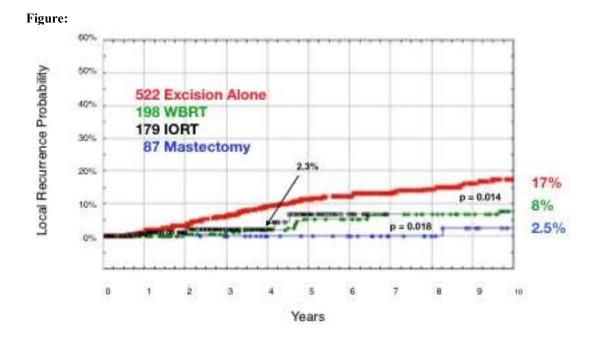
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Background/Objective: Mastectomy, excision with whole breast radiation therapy (WBRT), and excision alone are accepted methods of treatment for appropriately chosen patients with DCIS. The addition of WBRT to excision has been shown to reduce the risk of local recurrence by approximately 50%. Despite this, no trial has shown a difference in overall survival (OS) or breast cancer-specific survival (BCSS), regardless of treatment. DCIS patients at lower risk of local recurrence might benefit from excision plus intraoperative radiation therapy (IORT), which delivers radiation to the tumor bed during a single operative session. IORT reduces treatment time and limits damage to healthy tissue. In 2010, we began a prospective trial of IORT. This study reports the use of excision plus IORT as a fourth option for the treatment of DCIS.

Methods: A total of 986 patients with DCIS who met all institutional criteria for IORT as the only adjuvant radiation therapy were included in the study. IORT criteria included: tumor extent \leq 30mm, tumor margins \geq 2mm, no lymphovascular invasion, and negative lymph nodes when obtained. There were 179 DCIS patients who met these criteria and received excision plus IORT as their complete treatment and 807 additional DCIS patients who met all criteria but received standard treatment. All local events, regardless of the quadrant in which they occurred, were included in the Kaplan-Meier analysis. Treatment groups were then compared using the Log-Rank Test. X-ray IORT was delivered using the Xoft Accent System.

Results: There were 986 patients with DCIS who underwent the following treatments: mastectomy = 87 (9%), excision plus WBRT = 198 (20%), excision plus IORT = 179 (18%), excision alone = 522 (53%). The average follow-up for IORT was 36 months. For the 3 remaining treatment groups, it was 97 months. The probability of any ipsilateral breast recurrence for all 4 treatments is seen in the figure. As expected, the lowest probability of local recurrence (2.5%) was seen following mastectomy. The highest probability, 17.3%, was seen after excision alone, with excision plus WBRT in the middle (7.8%) (overall p=0.00008). The IORT curve is similar to the curve for WBRT (p=0.65). The probability of local recurrence for excision plus IORT is accurate to 4 years due to shorter follow-up and was 2.3%. If invasive recurrence is used as the endpoint, the 10-year probabilities of local invasive recurrence are as follows: mastectomy = 2.5%, excision plus WBRT = 5.5%, excision alone = 8.9% (overall p=0.06). The 4-year local invasive recurrence probability for IORT was 0.7%. OS and BCSS at 10 years were statistically the same for all 3 major treatment groups (93.9% and 99.3% respectively). OS and BCSS were 98.6% and 100%, respectively, at 4 years for the IORT group.

Conclusions: IORT is a promising new radiation modality that is less damaging to surrounding tissue, less expensive, and more convenient. It allows the full course of radiation therapy to be delivered in a single session. It may allow carefully selected patients with DCIS to forgo WBRT. As follow-up of the patients who received IORT increases, we would expect a local recurrence rate that is lower than excision alone but higher than excision plus WBRT. Patients receiving IORT should be appropriately counseled on the expected risk of recurrence and IORT should continue to be performed as part of a prospective registry or clinical trial until longer follow-up data are available.



581618 - Factors that may predict complete removal of DCIS on diagnostic core needle biopsy

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Background/Objective: The vast majority of ductal carcinoma in situ (DCIS) is diagnosed on core needle biopsy (CNB). This provides the starting point for patient treatment, and also tissue for biomarker analysis in window-of-opportunity design clinical trials. There is a subset of patients in whom their DCIS is completely removed on CNB, though there is limited literature on the determinants and the frequency of this. Our aim is to describe the incidence of complete removal of DCIS on CNB in our own institutional experience, and to evaluate if there are any demographic or clinical factors that are associated with this outcome.

Methods: Data for this study were collected through an institutional review of patients diagnosed with DCIS on CNB from 2007 to 2013 in a retrospective fashion after approval by our IRB. This yielded 620 patients. Demographic, clinical, imaging, and pathology data were collected. We investigated if whether complete removal of DCIS on CNB (Yes/No) is associated with patient factors in a univariate analysis. We used Fisher's Exact Tests for categorical variables, Wilcoxon rank-sum tests for continuous variables, and logistic regression for a multivariable model. Statistical analysis was performed using a significance level of 0.05 in SAS 9.4

Results: Of the 620 patients in the database, 82 (13.2%) had their DCIS completely removed on CNB. Of those 82 patients, 17 (20.7%) underwent mastectomy, while the remaining 65 were treated with wide excision (79.3%). On comparison of the 2 DCIS groups (Table), statistically significant associations were seen on univariate analysis with: size of calcifications on mammogram (p=0.02), pre-op ultrasound (US) performed (p<0.01), pre-op magnetic-resonance imaging (MRI) performed (p<0.01), type of image-guided biopsy (p=0.02), presence of necrosis (p<0.01), DCIS grade (p<0.01), lobular extension (p<0.01),

and positive hormone receptor (HR) status (p<0.01). Of the significant variables, the ones used in the multivariable logistic regression were size of calcifications and DCIS grade. The remaining variables were excluded due to low clinical significance and also to eliminate multi-collinearity. Only DCIS grade survived as significant in the multivariable logistic model, but we retained size of calcifications due to borderline significance in the logistic model and its clinical relevance. The final odds ratios demonstrated that DCIS grade was significantly associated with the outcome of no DCIS on final pathology (0.312, 95% confidence interval 0.21–0.46). The size of calcifications was not significant (0.83, 95% confidence interval 0.68–1.02). Of women with calcifications <1cm, 73% (139/191) had remaining DCIS on final surgical pathology.

Conclusions: Our results showed complete removal of DCIS on CNB in 13.2% of patients in our cohort; this is in a similar range as other studies (8%-14.8%). Prior literature identified both a lower DCIS grade and size of calcifications <1cm as predictive of complete disease removal on CNB. In our study, multivariate analysis identified that only a lower grade of DCIS significantly predicted absence of residual DCIS on final pathology. We would not recommend using size of calcifications as a predictor, as in our cohort 73% of patients with calcifications <1cm had residual disease. Additional studies are needed to find more specific criteria to identify patient eligibility criteria for participation in window-of-opportunity clinical trials.

| | DCIS on Final Pathology Report | | | | |
|--------------------------|--------------------------------|--|-----|--|-------------------|
| | | No | | Yes | |
| Patient Factors | N | Median (interquartile range) or N (%) | N | Median (interquartile range) or N (%) | <i>p</i> value |
| Size calcifications (cm) | 72 | 0.50 (0.40, 0.90) | 439 | 0.80 (0.30, 2.20) | 0.02 |
| Ultrasound performed | 82 | | 537 | | <0.01 |
| - No | | 50 (60.98) | | 266 (49.53) | |
| - Y es but no lesion | | 26 (31.71) | | 162 (30.17) | |
| - Y es but y es lesion | | 6 (7.32) | | 109 (20.30) | |
| MRI performed | 82 | | 531 | | < 0.01 |
| - N0 | | 26 (31.71) | | 188 (35.40) | |
| - Y es but no lesion | | 28 (34.15) | | 71 (13.37) | |
| - Y es but y es lesion | | 28 (34.15) | | 272 (51.22) | <u> </u> |
| Biopsy image type | 82 | | 532 | | 0.02 |
| - Stereotactic | | 78 (95.12) | | 454 (85.34) | |
| - MRI | | 1 (1.22) | | 8 (1.50) | |
| - Ultra sound | | 3 (3.66) | | 70 (13.16) | |
| Necrosis present | 82 | | 538 | | <0.01 |
| - No | | 50 (60.98) | | 174 (32.34) | |
| -Yes | 1 | 32 (39.02) | | 364 (67.66) | 1 |
| DCIS grade | 82 | | 536 | | <0.01 |
| -1 | | 29 (35.37) | | 55 (10.26) | |
| - 2 | | 35 (42.68) | | 214 (39.93) | 1 |
| - 3 | | 18 (21.95) | | 267 (49.81) | |
| Lobular extension | 82 | | 538 | | <0.01 |
| - No | | 66 (80.49) | | 337 (62.64) | |
| -Yes | | 16 (19.51) | | 201 (37.36) | |
| Hormone receptor | 75 | | 500 | | <0.01 |
| - Negative | | 4 (5.33) | | 91 18.20) | |
| - Positive | | 71 (94.67) | | 409 (81.80) | |

| Table: Parameters | associated with resid | lual DCIS on surgica | al pathology: | Univariate analysis |
|----------------------|-------------------------|----------------------|---------------|---------------------|
| I MOICE I MI MINUTUR | ubboelatea witth i colt | | | |

581911 - Is sentinel lymph node biopsy necessary in patients with ductal carcinoma undergoing mastectomy?

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Background/Objective: National clinical guidelines recommend performing a sentinel lymph node biopsy (SLNB) for patients with a diagnosis of ductal carcinoma in situ (DCIS) on core needle biopsy undergoing mastectomy, due to the possibility of finding invasive cancer on final pathology. When nodal staging is appropriate, it may not be feasible to perform a SLNB once the breast has been removed. Previous studies have demonstrated that approximately 20-30% of patients with DCIS will have upstage to have pathology specimens harboring invasive cancer at the time of surgery; however, many of those patients may not have nodal metastasis. SLNB is associated with a small but appreciable risk of morbidity, which calls into question the risk/benefit of the routine use of this procedure, given the potentially low rates of nodal metastasis when performed for DCIS. Our study aimed to use a large national cohort to define risk factors associated with a greater likelihood of nodal involvement, which may help inform a more selective approach to SLNB in patients with DCIS undergoing mastectomy.

Methods: The National Cancer Database was used to identify all patients with DCIS undergoing mastectomy and having SLNB between 2010 and 2015. We recorded the rate of upstaging to invasive carcinoma in the breast, as well as the pathological status of the sentinel node(s). Multivariable analysis was performed to identify clinical and pathological factors associated with sentinel node metastasis.

Results: Between 2010 and 2015, 6886 patients with DCIS underwent mastectomy with SLNB; 2358 patients (34%) were found to have invasive cancer on final pathology, and 175 (2.5%) had positive sentinel lymph node metastasis. Of note, 93% (163) of patients with positive sentinel node metastasis demonstrated upstaging to invasive carcinoma. Of the patients who were found to have invasive cancer, 163 (7%) had positive lymph nodes. Multivariable analysis demonstrated that high nuclear grade was associated with a greater likelihood of nodal disease when compared with low or intermediate grade (OR 1.54, 95% CI 1.10-2.17). Conversely, patients \geq 70 years and with \leq T1 tumors were less likely to have positive sentinel nodes (OR 0.55, 95% CI 0.29-0.99 and OR 0.06, 95% CI 0.03-0.12, respectively).

Conclusions: The routine use of SLNB in patients undergoing mastectomy has low utility, especially in patients \geq 70 and with \leq T1 tumors. Overall, very few patients with DCIS had sentinel nodal metastasis, even when upstaging to invasive carcinoma on final pathology. However, younger patients with high-grade DCIS undergoing mastectomy were observed to be at greater risk of harboring sentinel node metastasis. This data may help inform a risk-based approach to selecting which patients can be spared axillary staging during mastectomy for DCIS.

576124 - Physician comfort and knowledge level regarding observation of ductal carcinoma in situ at accredited breast centers

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Background/Objective: Ongoing clinical trials are examining the role of observation for ductal carcinoma in situ (DCIS). We explored reasons why physicians may not feel comfortable observing untreated DCIS and the association with physician knowledge about DCIS recurrence.

Methods: We report a cross-sectional survey of physicians practicing at breast centers accredited by the National Accreditation Program for Breast Centers (NAPBC). Participants were asked to complete a survey which illustrated various clinical scenarios to determine the physicians' comfort with observation and their knowledge of recurrence risks for DCIS.

Results: Three hundred seventy-nine out of 603 NAPBC centers (63%) participated, and 979 out of 1,761 (56%) physicians responded. Three hundred (32%) were medical oncologists, 316 (33.7%) were radiation oncologists, and 322 (34.3%) were surgeons. Four hundred seventy-eight (51%) were female; 226 (24.3%) saw <10 breast patients per week, and 325 (35%) had been in practice >20 years. Seven hundred forty-six (77.9%) stated it would be "somewhat to very difficult" to recruit patients to a randomized trial of observation of DCIS. When asked what the major reasons were to not participate in a DCIS observation trial, 540 (57.0%) responded "high risk of disease progression," 422 (44.3%) stated "risk of tumor upstaging," 401 (42.6%) indicated that "patient would likely not consent," 286 (30.1%) specified that it would be "going against standard of care," 81 (8.6%) admitted that they were "unsure how to explain active surveillance to patients," and 71 (7.5%) felt that their institution would not support observation. Physicians described themselves as "very" or "pretty" comfortable observing DCIS when it was: low grade (n=326, 35.25%), estrogen receptor-positive (ER), (n=215, 23.1%), or present in a 70year-old patient (n=217, 23.4%), versus high grade (n=15, 1.6%), spanning >3 cm (n=15, 1.6%), or present in a woman under 40 (n=16, 1.7%). On multivariate analysis, physician age and gender, years in practice, number of breast patients seen per week, and type were not independently associated with comfort level of observing low-grade DCIS. Overall, 549 (58.9%) believed that there was "weak to no evidence" to support nonsurgical management/observation of DCIS. Physician knowledge levels about recurrence risks after lumpectomy and mastectomy were high: 737 (78%) stated that the local recurrence risk at 10 years after lumpectomy without radiation was 10-30%, 817 (87.8%) stated that for lumpectomy with radiation it was 0-10% and 755 (81%) stated that local recurrence after mastectomy was <5%. When physicians were asked about the distant recurrence risk of DCIS without surgery, 80 (8.9%) answered that the risk was <1%, 279 (31%) stated 1-2%, 285 (31.7%) stated 3-4% and 256 (28.4%) felt that it was >5%. Physicians' knowledge estimating local recurrence risk was not associated with comfort level in observing DCIS nor associated with the perception of whether it would be difficult to recruit patients to an observational trial of DCIS.

Conclusions: Our findings suggest that while physicians have adequate knowledge levels of the natural history of DCIS, and report feeling comfortable with speaking with their patients, their discomfort in enrolling patients onto DCIS observation trials stems primarily from concerns regarding DCIS disease recurrence or progression. These findings may provide better understanding to overcome difficulty with patient accrual onto DCIS observation trials.

582075 - Tumor-infiltrating lymphocytes in a contemporary cohort of women with DCIS <u>Alison Price</u>, Farbod Darvishian, Ugur Ozerdem, Freya Schnabel, Jennifer Chun, Elianna Kaplowitz, Elizabeth Pirraglia, Andrea Troxel, Sylvia Adams, Daniel Roses *NYU Langone Health, New York, NY*

Background/Objective: Growing evidence suggests that tumor immune-microenvironment influences breast cancer carcinogenesis and prognosis. Density of tumor-infiltrating lymphocytes (TILs) within invasive breast cancer correlates with response to therapy, especially in triple-negative disease. The clinical relevance and outcomes of TILs within ductal carcinoma in situ (DCIS) is less understood.

Methods: Our institutional database was queried for pure DCIS from 2010-2018 (n=668). Local recurrences (n=13) were matched 1:4 to patients without recurrence. TILs were evaluated by the International TILs Working Group Guidelines. Percentage of TILs was assessed from the densest focus in 1 high-power field of stroma touching the basement membrane. Statistical methods included cluster analyses, logistic, and Cox regression models.

Results: Sixty-nine patients, including the 13 recurrences were evaluated. Fifty-four (78%) were treated by breast-conserving surgery (BCS). The median follow-up was 6.7 years. TILs were defined as sparse (<45%) and dense ($\geq45\%$). Dense TILs was associated with younger age (p=0.045), larger tumor size (p<0.001), high nuclear grade (p<0.001), comedo histology (p=0.016), necrosis (p=0.038), and recurrence (p=0.001). Nine patients with dense TILs had a mean time to recurrence of 74 months compared to 4 patients with sparse TILs who had a mean time to recurrence of 93 months (p=0.044) (Figure).

Conclusions: We found that dense TILs in DCIS was significantly associated with age, tumor size, grade, and histology. Most importantly, dense TILs are a significant predictor of recurrence in patients with DCIS, which underlies the prognostic importance of the immune microenvironment of early breast cancers.

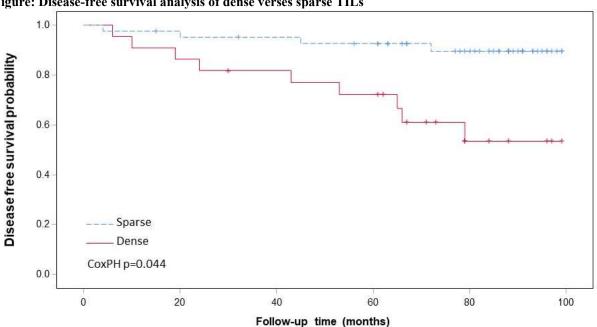


Figure: Disease-free survival analysis of dense verses sparse TILs

579850 - A Comparison of local recurrence risk estimates after breast-conserving surgery for DCIS: DCIS nomogram vs refined Oncotype DX Breast DCIS ScoreTM

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Background/Objective: Treatment options for DCIS are many, with local recurrence (LR) rates that vary widely. Although radiation (RT) after breast-conserving surgery (BCS) reduces LR by about 50%, it does not affect survival and has rare but potentially serious side effects. Here, we aim to compare 2 tools for estimating the risk of LR following BCS without RT: (1) the Memorial Sloan Kettering DCIS Nomogram, an online multivariable nomogram integrating 10 clinicopathologic and treatment factors (Nomogram), and (2) the Oncotype DX Breast DCIS Score™ (Genomic Health, Redwood City, CA), which is currently reported as a "refined" DCIS Score incorporating a genomic assay and 3 clinicopathologic factors (Refined DCIS Score).

Methods: We identified DCIS patients at lower risk for LR, using the standard clinical variables of age \geq 50 and DCIS size \leq 2.5cm, for whom the results of the genomic assay were available. The Nomogram (available online and free-of-charge at www.nomograms.org) incorporates age (as a continuum), family history, clinical vs radiologic presentation, nuclear grade, necrosis, margin status (>2mm vs \leq 2mm), number of excisions (as a surrogate for extent of disease), year of surgery, and use of adjuvant RT and endocrine therapy (ET). The Refined DCIS Score (commercially available, \$4620) adjusts for year of diagnosis and reports LR risk according to age (<50 or \geq 50), size (\leq 1cm, >1- \leq 2.5cm), and a 12-gene assay, and was designed to be independent of endocrine therapy use. LR risk estimates from the Refined DCIS Score were compared to those from the Nomogram. Refined DCIS Score LR risk estimates within 1-2% of the range of Nomogram estimates (Nomogram+/-ET) obtained by assuming use (Nomogram+ET) and non-use (Nomogram-ET) of ET were defined as concordant. We also compared the LR risk estimates of the Nomogram+/-ET with those of the Refined DCIS Score using a 10-year LR risk estimate of \geq 10% as the threshold for recommending RT. The estimates were deemed threshold-concordant if they were within 1-2% of each other, or if they were discordant but were on the same side of the 10% threshold (ie, both either <10% or \geq 10%).

Results: Fifty-nine patients were identified. The Refined DCIS Score and Nomogram+/–ET LR risk estimates were concordant in 54 of 59 (92%) women with DCIS. In the remaining 5 of 59 (8%), the Refined DCIS Score LR risk estimates were lower than the Nomogram+ET with an absolute difference of 3-8% and thus were discordant. For these 5, all of the Refined DCIS Score estimates of 10-year LR risk were <10% (range 5-8%), and all of the Nomogram+ET estimates were >10% (range 11-14%). These 5 patients with discordant and threshold-discordant LR risk estimates all had close margins ($\leq 2mm$).

Conclusions: Among 92% women age 50 and older with DCIS ≤ 2.5 cm in size, the LR risk estimates from the free-of-charge online Nomogram were concordant with those of a commercially available Refined DCIS Score costing >\$4600. Given that close margins are known to convey a significantly elevated LR risk, for the 8% with discordant risk estimates the Refined DCIS Score appears to underestimate the risk of LR and may lead to inappropriate omission of RT. Unless and until other data

show it to have a clinically significant advantage, the use of the costly Refined DCIS Score is not warranted in this population.

Disparities

578645 - Is metabolic syndrome associated with decreased survival in African American breast cancer patients?

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Background/Objective: African American (AA) patients living in Delaware have a decreased survival rate across all breast cancer types. The objective of this study was to assess if the presence of metabolic syndrome or specific medical comorbidities were associated with decreased survival in African American breast cancer patients in Delaware.

Methods: A retrospective database review from the Helen F Graham Cancer Center & Research Institute cancer registry was performed from 2006-2010. A total of 1672 breast cancer patients were identified, with 281 AA patients. All patient comorbidity data, including hypertension, diabetes, and obesity defined as BMI>30, were analyzed using Chi square analysis (p<.05) and log-rank-Mantel Cox for survival. Metabolic syndrome was defined as having hypertension, diabetes, and obesity.

Results: Breast cancer survival is twice as high in Caucasian patients as in AA patients (P.0001, HR 2.63, 95% CI 1.968-6.609). Patients with hypertension or diabetes had worse breast cancer-specific survival (p=.037). There was a higher incidence of hypertension, diabetes, and obesity in AA patients; however, there was no difference between races in breast cancer survival. Patients with metabolic syndrome have worse survival (p=.02, Log-rank-mantel cox), and although there was a higher incidence of metabolic syndrome in AA patients, there was no difference in breast cancer-specific survival between the races.

Conclusions: All patients with hypertension, diabetes, and/or metabolic syndrome have worse breast cancer-specific survival. Although AA patients were more likely to have metabolic syndrome, there was no difference in breast cancer-specific survival for patients with metabolic syndrome based on race. Continued investigation of modifiable risk factors for AA patients to improve breast cancer-specific survival is ongoing. Increased risk of developing breast cancer in patients with metabolic syndrome has been established in the literature. Our study now demonstrates worse breast cancer-specific survival further supporting the need to focus on management and prevention of obesity and associated comorbidities to improve breast cancer-specific survival.

557095 - Advanced stage at presentation in breast cancer patients in a rural, resourcelimited state

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Background/Objective: Breast cancer survival rates have increased in part due to screening and early detection initiatives. In our rural, resource-limited state, patients often lack access to screening mammography, with less than half of age-appropriate women receiving screening mammography. The purpose of this study was to determine whether breast cancer patients present to our surgery clinic at higher stages than those expected by national averages.

Methods: We performed a retrospective chart review of all breast cancer patients in the tumor registry from 2012 to 2016 for our hospital system, the largest provider of health care services for our state; approximately 500 new breast cancers are diagnosed and treated yearly.

Results: A total of 2438 new cancers were identified. Of those, 2388 had race, ethnicity, pathologic, and clinical staging available for assessment. Only 3% were non-white non-Hispanic, with American Indian as the third most common ethnicity followed by non-Hispanic Black, Asian, and Asian Indian. Thirty-three percent were Hispanic, with 64% identifying as white, non-Hispanic. Hispanic patients were more likely to present with early cancers (Stage 0 or 1, 66%) and 35% Stage 2, 3, or 4. White patients presented 63% Stage 0 and 1, 32% Stage 2, 3, or 4. The average non-invasive cancer rate in the US is 20%, but ours is much lower, likely due to less screening, at only 6% in American Indian patients, 15% in white non-Hispanic, 13% Hispanic, and 18% in Blacks. Six percent of patients in this cohort died between 2012 and 2016; of note, most of these patients were not diagnosed as Stage 4 at presentation (75%). Forty-eight percent of patients diagnosed with Stage 4 disease had died, with an additional 2% of patients with documented recurrence, either locoregional or distant. Twenty-eight percent were from a rural area (area with less than 50,000 inhabitants). Nine percent were lobular cancers, 15% HER2-amplified, and 9.5% triple-negative, of those with available receptors.

Conclusions: Breast cancer patients in our hospital system present at higher stage of disease than the national average, with less cases of in situ cancers due to decreased screening. We hope to promote increased screening and awareness initiatives throughout our poor, rural state to lower the stage at breast cancer presentation and improve outcome and survival for our patients.

581889 - Safety net hospital designation influences worse survival rates in breast cancer <u>Carissia Calvo</u>, Caitlin Hester, Rachel Wooldridge, James Huth, Natalia Partain, Andrea Colton, Marilyn Leitch, Adam Yopp, Deborah Farr *University of Texas Southwestern, Dallas, TX*

Background/Objective: Survival for invasive breast cancer remains poor among racial and ethnic minorities. Comparisons in patient outcomes across health care delivery systems can identify factors that contribute to persistent disparities in breast cancer survival. The aim of this study was to compare treatment utilization and outcome measures of breast cancer patients treated at safety net hospitals (SNH) and non-safety net hospitals (N-SNH).

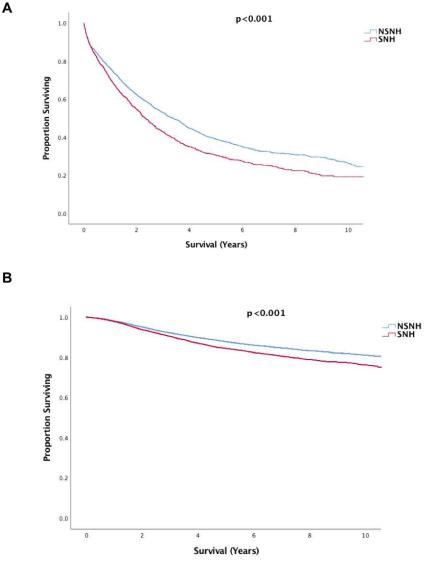
Methods: Women diagnosed with invasive breast cancer from 2001 to 2012 were identified in the Texas Cancer Registry (n=99,497). Demographics, tumor and hospital characteristics were compared between N-SNH (n=73,830) and SNH (n=25,667). Covariate-adjusted treatment use and disease-specific survival were compared.

Results: Compared with N-SNH, SNH disproportionally delivered care to uninsured (13.0% vs 1.8%, p<0.001) and racial/ethnic minority patients (Hispanic White: 38.7% vs 10.7%, Non-Hispanic Black: 14.4% vs 10.1%, p<0.001). Women at SNH were significantly more likely to have tumors \geq 4cm (16.1% vs 10.9%, p<0.001), triple-negative receptor status (8.3% vs. 6.5%, p<0.001), positive nodal disease (28.4% vs 24.3%, p<0.001), advanced regional stage (33.7% vs 29%, p<0.001), metastatic disease (5.9% vs 4.1%, p<0.001), and longer time to treatment (median 28 vs 24 days for regional stage, p<0.001; median 24 vs. 20 days for metastatic, p=0.004). SNH treated more locoregional disease with combination chemotherapy and surgery (localized: 17.0% vs 13.6%, p<0.001; regional: 38.6% vs 32.1%, p<0.001) and utilized chemotherapy or combined treatment modalities for metastatic breast cancer significantly more often compared to N-SNH (chemotherapy: 28.8% vs 26.7%, chemotherapy and surgery: 15.2% vs 13.0%,

chemoradiation: 6.1% vs 4.2%, p<0.001). Patients seen at SNH had worse 5-year, disease-specific survival compared to N-SNH in all patients (87.6% vs 91.4%, p<0.001), regional stage (Figure 1a) (84.5% vs 87.8% p<0.001), and metastatic stage (Figure 1b) (30.4% vs 38.9%, p<0.001). On multivariable regression analysis, differences in disease-specific survival remained significant after adjusting for demographics, insurance, and treatment (SNH vs N-SNH: HR 1.157; 95% CI, 1.12-1.20).

Conclusions: Racial/ethnic minority and uninsured women with more advanced disease and aggressive tumor subtypes were more often seen at SNH. These patients received more therapies, but they had a significantly longer time to treatment as well as associated worse disease-specific survival. Tumor biology and system-based factors may explain differences in outcomes.





Abbreviations: SNH, safety net hospital; NSNH, non-safety net hospital.

(A) Regional Stage Breast Cancer

(B) Metastatic Stage Breast Cancer

581029 - Disparities in the surgical treatment of breast cancer: A SEER population-based study

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Background/Objective: Breast cancer is among the top 3 most common malignancies. Surgical resection remains a pillar in the management of this disease. The literature suggests that racial and socioeconomic disparities exist in the incidence and survival of breast cancer. The aim of this study is to examine if disparities exist among breast cancer patients recommended for surgical treatment but are denied surgery due to reasons other than their cancer.

Methods: This was a retrospective analysis of patients diagnosed with non-metastatic breast cancer from 2004-2015 using the Surveillance, Epidemiology, and End Results (SEER) database. Univariate and multivariable analysis were performed to assess factors associated with having a contraindication to surgical resection. Kaplan-Meir survival curves were used to assess disparities in survival.

Results: There were 1139 (<1%) out of 411,001 patients who were recommended for surgery but had a surgical contraindication unrelated to their cancer. Being African American, having bilateral disease, and being widowed increased the odds of not having surgery of the primary site because of these contraindications with odds ratios of 1.6 [CI 1.2-2.2], 7.0 [CI 1.2-51.3], and 2.6 [CI 1.8-3.8] respectively. Patients denied surgery secondary to these risk factors had lower 5-year, disease-specific and overall survival rates: 96% vs. 70% (p=<0.001) and 88% vs. 19% (p=<0.001), respectively.

Conclusions: Racial, socioeconomic, and clinicopathologic disparities exist in the surgical treatment of breast cancer. Our next steps are to use the SEER-Medicare Linked Database to determine which co-morbidities are over-represented among patients denied surgery secondary to patient risk factors. With these data, subsequent interventions can be employed to optimize patients for surgery and improve survival rates for these vulnerable patients.

581523 - The influence of state-funded cancer care treatment program on clinical outcomes in breast cancer patients

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Background/Objective: The Delaware Cancer Treatment program (DCTP) provides free cancer care for patients without insurance until diagnosis, who earn up to 650% of Federal poverty level, have no comprehensive health insurance, and do not receive benefits from Medicare. Our aim was to determine whether the state-funded cancer care treatment program contributes to an improvement in mortality rate.

Methods: Patient demographics and breast cancer-specific survival of patients who were treated at the Helen F Graham Cancer Center & Research Institute at Christiana Care Health System (CCHS) from 2007-2017 were compared according to payer status, which included the state DCTP, Medicare, Medicaid, and private insurance. Tukey's multiple comparisons test, Chi squared and one-way Anova were used to determine the differences in age, ethnicity, and stage of presentation based on insurance status. Kaplan-Meyer and Log-rank analysis was used to determine differences in recurrence-free and breast cancer-specific survival among groups.

Results: Of the 7,179 breast cancer patients treated at CCHS during 2007-2017, 84 patients qualified for funding from the DCTP. Recurrence-free survival and overall survival were significantly lower for DCTP vs private and Medicaid, p<0.0001. There was no significant difference in survival or recurrence-free survival between uninsured and DCTP cases. Patients with DCTP funding were diagnosed at a significantly later stage than all other types of payers (p=0.047). Twenty-six percent of patients with DCTP were diagnosed at Stage IV. There were no significant differences in age between DCTP and private insurance, but Medicare patients were significantly older. There was a significant difference in race, with DCTP and uninsured patients being more often non-Hispanic African Americans or Hispanic than those with Medicare or private insurance. There were no racial differences between uninsured and DCTP patients.

Conclusions: Patients covered by the DCTP were more likely to be non-Hispanic African Americans and Hispanics. Disease-free and overall survival in these patients was worse than those with private insurance, Medicaid, or Medicare. This may be due to the fact that patients covered by DCTP had no insurance until time of diagnosis and were more likely to be Stage IV at presentation (26% Stage IV at presentation for DCTP patients compared to 5% Stage IV at presentation for the State of Delaware). These results indicate that although breast patients qualify for treatment coverage, there may be a failure to provide state-funded early screening programs that may help with earlier diagnosis

582078 - Institutional variations in the treatment of early-stage breast cancer <u>Apoorve Nayyar</u>¹, Paula Strassle¹, Kathleen Iles¹, Danielle Jameison¹, Kandace McGuire², Kristalyn Gallagher¹ ¹University of North Carolina at Chapel Hill, Chapel Hill, NC, ²Virginia Commonwealth University, Richmond, VA

Background/Objective: Multiple clinical trials have long established the clinical equipoise of breastconserving surgery (BCS) plus radiation therapy also referred to as breast-conserving therapy (BCT) to mastectomy for patients with early-stage breast cancer (BC). However, whether the primary treatment for BC varies across the institution type is currently unclear.

Methods: Women \geq 40 years old diagnosed with BC between 2004 and 2015, with clinical T1-T2 and N0-N1 stage, who underwent BCS or mastectomy in the National Cancer Database were included. Multivariable generalized logistic regression was used to assess differences in the utilization of mastectomy and BCS alone, compared to BCT, across institution type after adjusting for patient and cancer characteristics. Potential effect measure modification by age was assessed by including all interaction terms, and tested using likelihood ratio tests.

Results: Overall, 1,007,921 women were included: 48% underwent BCT, 15% underwent BCS alone, and 37% underwent mastectomy. The majority of patients received treatment at comprehensive community cancer centers (49%), followed by academic/research centers (30%), and integrated network cancer centers (11%). Compared to academic/research centers, patients receiving treatment at community centers were more likely to receive BCS alone (OR 1.06, 95% CI 1.04, 1.07) or mastectomy (1.05, 95% CI 1.04, 1.06). Similarly, patients receiving treatment at integrated network cancer centers were significantly more likely to receive BCS alone (OR 1.18, 95% CI 1.16, 1.21) compared to academic centers. Institutional differences were different across age, with older women more likely to undergo mastectomy at both community centers and integrated network cancer centers (Table). Younger women

treated at community centers and integrated network cancer centers were significantly more likely to receive BCS alone compared to their older counterparts (Table).

Conclusions: Significant variations exist in the treatment of breast cancer across institution type, with patients receiving treatment at non-academic centers less likely to receive recommended standard therapy after BCS. This study highlights the need for better understanding these differences and increasing access to radiation facilities to minimize variations in care that can impact patient outcomes.

| | Mastectomy | | BCS alone | | |
|-----------------|--|-------------------|----------------------------|------------------------------|--|
| | Comprehensive Integrated Community Network Cancer | | Comprehensive Community | Integrated Network Cancer | |
| | Cancer Center | Center | Cancer Center | Center | |
| | OR (95% CI) | OR (95% CI) | OR (95% CI) | OR (95% CI) | |
| 40-49 years old | 0.95 (0.93, 0.97) | 1.07 (1.03, 1.11) | 1.15 (1.09, 1.21) | 1.04 (0.96, 1.13) | |
| 50-59 years old | 0.99 (0.97, 1.01) | 1.05 (1.02, 1.08) | 1.21 (1.17, 1.26) | 1.37 (1.30, 1.44) | |
| 60-69 years old | 1.07 (1.04, 1.09) | 1.12 (1.08, 1.15) | 1.22 (1.18, 1.25) | 1.41 (1.35, 1.47) | |
| ≥70 years old | 1.21 (1.18, 1.23) | 1.21 (1.17, 1.25) | 0.95 (0.93, 0.97) | 1.06 (1.02, 1.09) | |

| Table: Adjusted odds of undergoing BCS alone and mastectomy, compared to BCT, across institution type, |
|--|
| stratified by age (reference – academic/research center) |

582201 - Breast tumors in obese women have worse prognostic features

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Background/Objective: Obesity is associated with inferior survival in breast cancer. We sought to explore relationships between patient weight and breast cancer presentation and outcomes across cancer subtypes.

Methods: We queried our 11,427-patient, single-institution, IRB-approved database for de novo cases of breast cancer diagnosed between January 1, 2009 and September 4, 2018. Body mass index at diagnosis (BMI, kg/m2) was categorized as per CDC guidelines: normal weight 18.5 - 24.9, overweight 25.0 - 29.9 and obese >=30. Underweight patients (<18.5) were dropped from further analysis. Age >55 was used as a proxy for menopausal status. Comparisons across categories were performed with Chi-squared analyses; non-parametric methodology was employed for continuous variables. Stata/MP 14.2 (StataCorp, College Station, TX) was used for all analyses.

Results: The study cohort included 5,241 ER+ or PR+, HER2-, 1,028 HER2+ and 1,020 ER-, PR-, HER2- (triple-negative, TNBC) patients with available BMI data. The distribution of BMI varied across subtypes (p=0.012), with higher rates of obesity (64.0%) among those diagnosed with TNBC (versus ~58% for other tumor types). Among the obese, ER+ or PR+, HER2- patients were significantly more likely to be post-menopausal (60.7% versus 44.3% for HER2+ and 47.8% for TNBC), p<0.001. Obese patients presented with larger tumors for ER+ or PR+, HER2- (median 2cm larger than normal weight) and TNBC (7cm larger than normal weight) p=0.0001, although this did not achieve statistical significance for HER2+ (p=0.073). Obese patients presented at higher pathologic stages for all cancer subtypes (p<0.05 for each), but particularly within TNBC. Nodal positivity was significantly more likely in the obese for all tumor types (63 – 69% of obese cases), p<0.009. Obese patients suffered recurrence in 71 – 76% of cases across all subtypes, p<0.001.

Conclusions: Obese patients present with larger breast cancers of higher pathologic stage and are more likely to have axillary disease and suffer recurrences in this single-institution series. Among patients with TNBC, rates of obesity were higher than in the other tumor subtypes. Intense investigation is needed to unravel the interplay of genetic, epigenetic, and environmental factors that may be contributing to these observations.

581633 - Bankruptcy among Indiana breast cancer patients: Who is at risk?

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Background/Objective: Indiana is consistently ranked among the top 10 states in the U.S. for personal bankruptcy. Studies have shown that cancer patients who file for bankruptcy have worse clinical outcomes than their financially solvent counterparts. Indiana's high bankruptcy ranking is significant as most bankruptcy filings are secondary to health care costs. The objective of this study is to identify the characteristics of breast cancer patients in Indiana susceptible to filing for bankruptcy and to understand the relationship between filing for bankruptcy and all-cause mortality.

Methods: The study comprised women ages 18-90 with a diagnosis of 0-IV breast cancer from January 1, 2008 through December 31, 2012 in the Indiana State Cancer Registry (ISCR). The ISCR cohort was linked to individuals filing for chapter 7 or 13 bankruptcy in the Northern and Southern Indiana bankruptcy courts within 4 years of a breast cancer diagnosis. Chapter 7 bankruptcy involves liquidation of assets to pay off debts and chapter 13 filers pay their debts with a payment plan over a defined time period. The Northern and Southern Bankruptcy courts represent bankruptcy filings for the entire state. Bivariate analysis comparing sociodemographic, clinical, and treatment variables between patients who filed for bankruptcy and those who did not was conducted. A logistic regression model was created to identify patients at increased risk of filing for bankruptcy after their diagnosis. A Cox regression model created on propensity score matching was used to determine the effect of filing for bankruptcy on 5-year all-cause mortality.

Results: The total study population was 32,993 with 674 (2.04%) filing for bankruptcy during the study period. Patients who filed for bankruptcy were younger (55 years [IQR 47-64] vs 61 years [IQR 51-71], p=0.00001), more likely to be uninsured (6.0% vs 2.8%, p=0.0001) and lived in an area with a high poverty level (43.5% vs 32.2%, p=0.0001). In addition, a higher percentage of the bankruptcy group lived an urban area (87.4% vs 82.5%, p=0.004) and were black (15.7% vs 8.6%, p=0.001). The groups differed on stage of presentation (p=0.015). There was no difference between the groups in the use of surgery (p=0.173), chemotherapy (p=0.731), or radiation therapy (p=0.164). In logistic regression analysis, age <40 years (OR 2.9, p=0.003), living in a high poverty area (OR 2.1, p=0.001), clinical Stage 3 disease (OR 1.9, p=0.035), and lack of insurance at diagnosis (OR 2.24, p=0.001) increased the odds of filing for bankruptcy after a breast cancer diagnosis. Conversely, having government insurance (Medicaid OR 0.30 p=0.006, Medicare 0.50 p=0.013) was protective against filing for bankruptcy compared to the privately insured. The propensity score matched cox regression analysis did not show a difference in 5-year survival between patients who filed for bankruptcy and their counterparts who did not file for bankruptcy (p=0.48).

Conclusions: Among Indiana breast cancer patients, younger age, residency in a high poverty area, no insurance at diagnosis, and regional disease at diagnosis increased the probability of filing for bankruptcy after a diagnosis of breast cancer. Contrary to other published studies, filing for bankruptcy did not

increase all-cause mortality in this cohort. Since government insurance at diagnosis was protective against filing for bankruptcy, future studies should focus on how state expansion of Medicaid can be leveraged to reduce health care cost-based bankruptcies in the state. In addition, programs should be developed to help treating providers identify at-risk patients and refer them to appropriate financial services.

581593 - Implications of race on presentation, treatment, and survival among nonmetastatic Indiana breast cancer patients

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Background/Objective: Indiana state cancer registry data indicates that breast cancer incidence is similar in black women compared to white women. However, black women have a 39% higher mortality rate. Explanations for this disparity may include socioeconomic factors, late cancer detection, and tumor biology. The objective of this study is to determine if there are differences in presentation, treatment, and 5-year all-cause mortality between insured black and white women undergoing treatment for breast cancer in Indiana.

Methods: Black and white women were identified in the Indiana state cancer registry (ISCR) and were eligible if ages 18-90, diagnosed with Stage I-III breast cancer, and covered by Medicaid, Medicare, or private insurance. Longitudinal data about treatment were drawn from the Indiana Network for Patient Care (INPC), a statewide database incorporating electronic medical records from more than 100 hospitals in Indiana. Patients who did not have treatment data in the INPC were excluded from the final cohort. All-cause mortality was identified from Social Security Administration data. Sociodemographic characteristics were assigned to patients based upon US Census data linked by patient ZIP Code. Bivariate analysis using log-rank tests and Kaplan Meier curves compared the groups. A multivariable cox proportional hazard model was used to evaluate the relationship between race and all-cause mortality after controlling for sociodemographic, comorbidities, stage and tumor characteristics, and treatment variables.

Results: A total of 7062 insured breast cancer patients were identified from 2008-2014. The sample included 416 black women (6%) and 6,646 white women (94%). Black women were younger (p=0.0001), lived in neighborhoods with a high poverty rate (p=0.001), had lower educational attainment (p=0.0018), and were more likely to have government insurance (Medicaid or Medicare) (p=0.001), compared to their white counterparts. Black women were more likely to present with clinical Stage II and III disease than white women (31% vs 27%, p=0.001), have estrogen receptor-negative disease (25.4% vs 16%, p= 0.0001), and have a high tumor grade (32% vs 24%, p=0.0001). There was no difference between the groups on the receipt of radiation therapy (p=0.671), use of hormone therapy (p=0.898), adjuvant chemotherapy (p=0.0860), and surgery type (mastectomy vs breast conservation) (p=0.399). A comparison of time from biopsy to surgery (p=0.9999) and time from surgery to radiation (p=0.9997) showed no statistically significant difference between the groups. Furthermore, there was no difference in 5-year, all-cause mortality between the racial groups on unadjusted Kaplan Meier analysis (p=0.9677). On multivariable analysis, race did not increase the risk of mortality (p=0.962).

Conclusions: Despite lower socioeconomic status and worse disease-related prognostic factors, black women in this study experienced similar treatment modalities, did not experience treatment delays, and had equivalent all-cause mortality to white women. These results indicate equivalent access to care and subsequent treatment may diminish disparities in mortality among black Indiana breast cancer patients.

Future studies should evaluate differences between the cohort in this study and patients who did not have treatment in INPC hospitals to better delineate variables contributing to statewide racial disparities.

581031 - Evaluation of age and stage at time of breast cancer diagnosis between racial groups in a safety net hospital: Are current screening recommendations missing the mark in underserved, racially diverse populations?

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Background/Objective: Earlier breast cancer screening of African American women has been proposed due to the finding of more aggressive cancer subtypes and higher mortality in that group. Furthermore, a small pilot study completed at our institution demonstrated that Hispanic women were diagnosed with breast cancer at significantly younger ages than Caucasian women. Given these observations, we sought to evaluate differences in the distribution of age and stage of breast cancer at the time of diagnosis between racial groups within a safety net hospital in a larger cohort in order to explore the greater question of whether underserved, racially diverse populations are underscreened.

Methods: All female patients with breast cancer diagnosed between 1996-2016 at our institution were included. Diagnoses determined to represent a breast cancer recurrence were excluded from this analysis. Patient demographics (age at diagnosis and ethnicity) as well as cancer characteristics (clinical stage at diagnosis and receptor status) were collected. Median age, clinical stage, and proportions of patients diagnosed younger than age 40 and diagnosed at Stage 0 or 1 were compared among racial groups. Rates of high-risk cancer subtypes (HER2-positive and triple-negative) were also compared between races.

Results: A total of 2,852 women were diagnosed with breast cancer from 1996-2016. Of these, 1,278 (44.8%) were Hispanic, 682 (23.9%) African American, 477 (16.7%) Caucasian, and 415 (14.6%) Asian. Hispanic women were diagnosed at a median age of 51 years (range 20-110), significantly younger than other race groups (p<0.001). Furthermore, the proportion of Hispanic women diagnosed younger than 40 years was significantly higher (15.6% versus 9.0% for Caucasians). In the analysis of clinical stage at diagnosis, African Americans were least likely to be diagnosed at stage 0 or 1 (31.6%) compared to Asians (41.3%), Hispanics (37.6%), and Caucasians (32.8%) (p=0.014). Hispanic women had higher rates of HER2-positive breast cancer at 31.7% compared to 24.3% of Caucasian women, whereas African Americans had higher rates of triple-negative cancers at 12.3% compared to 4.9% of Caucasian women.

Conclusions: In this single-institution study, Hispanic women were diagnosed at a significantly younger median age, with a higher proportion diagnosed younger than 40. With current guidelines recommending screening initiation at age 45 or 50 years, these findings suggest that Hispanic patients may benefit from earlier screening. African American women were diagnosed with fewer early-stage cancers and had more triple-negative disease, supporting the recommendations of earlier screening in this group. All race groups in this underserved population were diagnosed at median ages significantly lower than reported national median (age 62), suggesting socioeconomic factors may add to racial disparities. Further studies are needed to elucidate factors that might explain these differences in minority racial groups and in underserved populations so as to consider updates to the current 'one size fits all' approach to screening recommendations.

| Variables at time of | | Race/Ethnicity | | | | |
|--|-------------|----------------|-----------------------|------------|---------|--|
| diagnosis | Hispanic | Black | Caucasian | Asian | p-value | |
| Age | (n=1278) | (n=682) | (n=477) | (n=415) | | |
| Median age (range) | 51 (20-110) | 54 (18-88) | 54 (22-84) | 55 (25-84) | <0.001 | |
| Number of patients diagnosed before age 40 | 199 (15.6%) | 60 (8.8%) | 43 (9.0%) | 27 (6.5%) | <0.001 | |
| Clinical stage | (n=988) | (n=529) | (n=338) | (n=293) | <0.001 | |
| 0 | 119 (12.0%) | 49 (9.3%) | 30 (8.9%) | 31 (10.6%) | | |
| 1 | 252 (25.5%) | 118 (22.3%) | 81 (24.0%) | 90 (30.7%) | | |
| 2 | 327 (33.1%) | 169 (32.0%) | 107 (31.7%) | 79 (27.0%) | | |
| 3 | 189 (19.1%) | 92 (17.4%) | 52 (15.4%) | 51 (17.4%) | | |
| 4 | 101 (10.2%) | 101 (19.1%) | 68 (20.1%) | 42 (14.3%) | | |

Table: Patient age and cancer stage at time of diagnosis based on race

581921 - Characteristics of Hispanic breast cancer patients in an urban setting

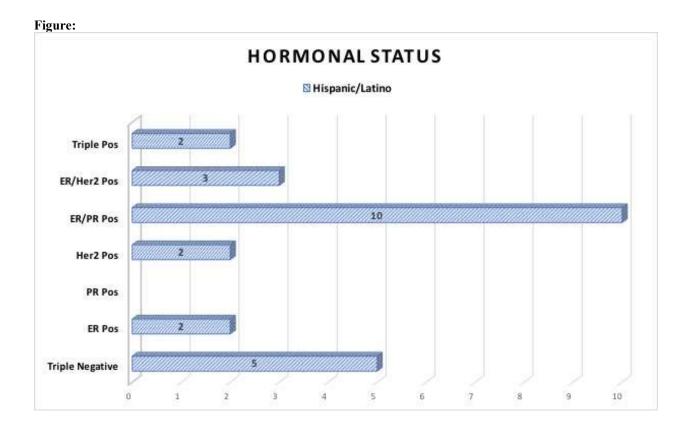
Adriana Suarez-Ligon¹, Lauren Cue², <u>Katherine Ottaviano</u>², Theresa Krawiec² ¹Rutgers CINJ at University Hospital, Newark, NJ, ²Rutgers New Jersey Medical School, Newark, NJ

Background/Objective: The US Census Bureau reports that in 2016, 18% of the US population identified as Hispanic or Latino. Hispanics are also the largest and youngest minority group in the United States. Cancer remains the leading cause of death in this population, with breast cancer as the number 1 newly diagnosed cancer among Hispanic women and also the leading cause of cancer death. The aim of our study was to look at the Hispanic subgroup of breast cancer patients and determine some of the particular characteristics of the group.

Methods: We did a single-institution retrospective chart review of all our Hispanic patients diagnosed with breast cancer who had office visits in an urban state hospital between September 2016 and 2017. We looked at the age of diagnosis, types of cancer, stage at diagnosis, hormonal status, and the genetics of the patients who were diagnosed in the study population.

Results: A total of 24 Hispanic women with breast cancer were identified. Ages ranged from 29 to 80. Women within the study population were more likely to have ER/PR-positive breast cancer 42% (n=10), similar to the general population, 21% (n=5) had triple-negative breast cancer as compared to the general population's 13%. Furthermore, 21% (n=5) of our patients presented at Stage III or IV, all of whom were under age 50. Most (83%, n=20) presented with invasive ductal or invasive lobular carcinoma, and 39% (n=9) had nodal involvement at the time of breast

Conclusions: The higher incidence of triple-negative breast cancer and later stages at presentation among our younger patients outlines the need for more resources to study the screening tools, types of breast cancer, and treatments among this underrepresented group. The higher mortality rates from breast cancer among Hispanic patients in the United States further emphasizes this point. Through screening and high-quality, timely treatment, as well as further research, we can work towards decreasing the mortality of a breast cancer diagnosis among our underrepresented groups.



581880 - Genetic variants among minority patients

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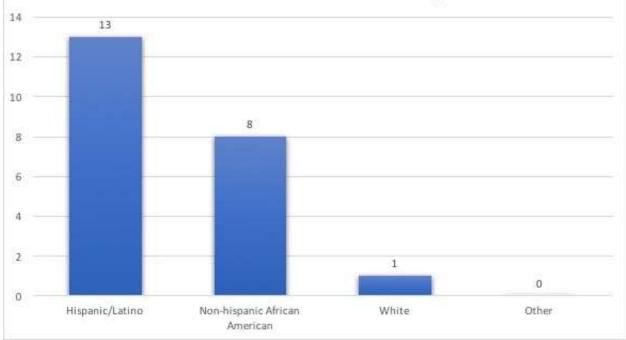
Background/Objective: It is thought that about 5-10% of breast cancers are caused by genetic mutations. The National Comprehensive Cancer Network (NCCN) has criteria that look at personal and family history of breast cancer and other cancers to determine a patients' eligibility for genetic testing. Despite these broad criteria, there is limited genetic testing done and, therefore, limited data available on Black and Hispanic women. What information we do have about pathogenic genetic mutations have mostly been extrapolated from individuals of European ancestry. As an example, Myriad myRisk Genetic mutations based on 3 studies looking solely at women of European descent. Given the genetic heterogeneity of the US population, we may not be able to extrapolate this information to predict cancer risk across the minority populations.

Methods: In this single-institution study, we looked at Black and Hispanic patients who met NCCN criteria for genetic testing for breast cancer. The patients were tested using the multi-gene panel sequencing performed by Myriad Genetic Laboratories over a 2-year period, between 2016 and 2018.

Results: In total, 62 patients underwent genetic testing. Of those patients, 23% (n=14) were Black and 58% (n=36) were Hispanic. Of the 62 patients, 8% (n=5) had known pathogenic mutations, 2 were white, while 3 were Hispanic. The genes of known pathogenic mutations were CHEK2, MUTYH, BRCA1, BRCA2, and TP53. Variants of uncertain significance were found in 35% (n=22), 8 were Black, and 13 were Hispanic. Variants of uncertain significance were found in many genes including BRCA2, TP53,

CHEK2, POLE, ATM, APC, and various others. Specifically, in those patients with a diagnosis of breast cancer (n=26) who met criteria for genetic testing, 38% (n=10) had variants of unknown significance.

Conclusions: Breast cancer risk based on genetic mutations is presumed to be uniform across the US population. However, it is not sufficient to use the known pathogenic mutations to determine breast cancer risk among all racial and ethnic groups. The high percentage of VUS in our patients already diagnosed with breast cancer and in our population in general lead us to believe that if more information is gathered on these variants of unknown significance, the clinical management could be tailored to populations who fall outside those of European descent potentially minimizing morbidity and mortality across underrepresented ethnic and racial groups.





581613 - Breast cancer in Chinese women: A comparative analysis

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Background/Objective: It has been hypothesized that Western lifestyle and dietary changes increased the risk of breast cancer in Chinese patients who migrated to US. However, in urbanized China, the incidence of breast cancer has surged twice as fast as the global rate in the past decade. Native Chinese patients have been reported to present at younger ages and have higher mortality rates compared to patients in Western countries. To determine if there were differences in clinical or pathological features between these 2 groups of patients, we compared Chinese patients with invasive breast cancer in a large breast cancer referral center in Beijing, China, with patients from our hospital in New York City during similar periods. Differences were investigated in this ethnicity within 2 major metropolitan areas with respect to age, stage distribution, hormonal receptors, and treatment modalities.

Methods: A single-center, retrospective chart review was performed on 204 Chinese American women treated for invasive ductal/lobular carcinoma at our hospital from 2006 to 2015 and similarly on 216 Native Chinese women in Beijing, China, from 2008 to 2017. Clinicopathologic characteristics and treatment modalities were compared using two-sample T-test, chi-square test, and Fisher's exact test.

Results: Native Chinese (NC) women presented at younger age than Chinese Americans (CA) (mean age 47.53 vs 54.58 yrs, p<0.0001). In regards to staging, NC patients presented with more early-stage cancer (Stage I/II) than CA (95.83% vs 90.20%, p=0.0228) and more hormone-receptor-positive tumors (92.13% vs 75%, p<0.0001). While more NC received mastectomy (72.22% vs 54.4%, p=0.0002), fewer NC received radiation (24.54% vs 59.31%, p<0.0001); however, more NC received chemotherapy (81.02% vs 63.24%, p<0.0001). Mean follow-up time of NC patients was 94.8 months with 2 overall mortalities vs 58.4 months in CA patients with 12 mortalities. Mean survival time for the deceased patients in NC and CA was 56.33 months vs 84 months, respectively.

Conclusions: Although native Chinese patients were diagnosed at younger age with invasive breast cancer compared to Chinese Americans, they presented at earlier stages and with more favorable hormonal receptor-positive tumors. Fewer breast conservation surgeries were performed in native Chinese patients. They were more likely undergo chemotherapy but not radiation. These results suggest that other locoregional factors such as potential access to screening and adjuvant treatments may be the cause for the discrepancies in this ethnic population.

| | Native | Chinese | Chinese | American | Р |
|--------------------------|--------|---------|---------|---------------------|---------|
| N | 216 | | 204 | | |
| Mean Age (Std Dev) | 47.53 | 9.05 | 54.58 | 11.87 | <0.0001 |
| Age Group | | | | | |
| <=50 | 139 | 64.35% | 88 | 40.14% | <0.0001 |
| >50 | 77 | 35.65% | 116 | 56.86% | |
| AJCC Stage Disease | | | | | |
| 1/11 | 207 | 95.83% | 184 | 90.20% | 0.0228 |
| III/IV | 9 | 4.17% | 20 | 9.80 <mark>%</mark> | |
| Hormonal Receptor Status | | | | | |
| HR + | 199 | 92.13% | 153 | 75% | <0.0001 |
| HR - | 17 | 7.87% | 51 | 25% | |
| Surgery | | | | | |
| Lumpectomy | 60 | 27.78% | 93 | 45.49% | 0.0002 |
| Mastectomy | 156 | 72.22% | 111 | 54.41% | |
| Chemotherapy | | | | | |
| Yes | 175 | 81.02% | 129 | 63.24% | <0.0001 |
| No | 41 | 18.98% | 75 | 36.76% | |
| Radiation Therapy | | | | | |
| Yes | 53 | 24.54% | 121 | 59.31% | <0.0001 |
| No | 163 | 75.46% | 83 | 40.69% | |

Table:

LRR

582114 - Impact of progesterone receptor status on rates of recurrence in estrogen receptor-positive breast cancer patients: A systematic review and meta-analysis

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Background/Objective: Assessment of estrogen (ER) and progesterone receptor (PR) status provides important prognostic information in breast cancer. However, the impact of single progesterone receptor negativity, is less well defined. The standardisation of immunohistochemical analysis of these receptors has reduced discrepancy in studies assessing the prognostic effect of progesterone receptor status. A systematic review and meta-analysis were undertaken to identify and assess studies that examined the impact of progesterone receptor negativity on outcomes in estrogen receptor-positive breast cancer.

Methods: The study was performed according to PRISMA guidelines. MEDLINE, PubMed, and the Cochrane Library were searched to identify studies comparing disease-free survival as the primary outcome and overall survival as the secondary outcome between progesterone receptor-positive (PR+) and -negative (PR-) status in ER-positive breast cancer (ER+). A meta-analysis of time-to-effect measures from each of the eligible studies was performed, specifically hazard ratios (HRs).

Results: Six studies involving 7724 patients in the ER+PR+ group and 1966 patients in the ER+PRgroup met the inclusion criteria. Treatment characteristics did not differ significantly between the 2 groups. Patients in the ER+PR- group had a higher risk of disease recurrence over the study time period than those who had ER+PR+ disease (DFS HR 1.54; 95% CI: 1.32 - 1.81; p<0.01). A similar result was observed for overall survival (OS HR 1.60; 95% CI: 1.19 - 2.14, p<0.01).

Conclusions: Progesterone receptor negativity is associated with a significant reduction in disease-free and overall survival in estrogen receptor-positive patients. This may have implications for treatment and surveillance strategies in this cohort of patients. Progesterone receptor remains an important prognostic marker and ER+PR- patients should be treated more aggressively as a result.

581227 - Outcomes of selective whole breast irradiation following lumpectomy with intraoperative radiation therapy for hormone receptor-positive breast cancer <u>Kristy Broman</u>, Weihong Sun, Jun-Min Zhou, Brooke Fridley, Roberto Diaz, Christine Laronga *Moffitt Cancer Center, Tampa, FL*

Background/Objective: For low-risk patients with breast cancer undergoing lumpectomy, the TARGIT-A randomized trial supported intraoperative radiation therapy (IORT) with selective addition of whole breast radiation (WBXRT) based on final clinicopathologic criteria. Many institutions use expanded TARGIT-A criteria in their recommendation for WBXRT after lumpectomy plus IORT. We evaluated local recurrence (LR) for hormone-receptor (HR) positive, early breast cancer women who had lumpectomy plus IORT, based on suitability for IORT alone versus those meeting TARGIT-A or expanded TARGIT criteria at Moffitt Cancer Center (TARGIT-MCC) for addition of WBXRT.

Methods: We performed a single-institution retrospective cohort study of women with hormone-receptor positive, clinically node-negative breast cancer who underwent lumpectomy plus IORT with selective

WBXRT intent from 2011-2015. Participants were categorized based on final clinicopathologic criteria as suitable for IORT alone or meeting criteria for additional WBXRT by either TARGIT-A (positive margin on initial lumpectomy specimen, final margin <1mm, final pathology invasive lobular carcinoma, extensive intraductal component) or TARGIT-MCC (final margin <2mm, additional factors of lymphovascular space invasion, positive sentinel lymph node, tumor >3cm, HR negative, multifocal or multicentric). LR was compared based on whether patients met criteria for WBXRT, had recommendation for WBRT, and on receipt of WBXRT using Fishers' exact tests.

Results: Among 195 cases in 193 patients, 57 (29.2%) met TARGIT-MCC criteria for additional WBXRT [of which 34 patients (17.4%) met TARGIT-A criteria]. WBXRT was recommended in 30 cases (27 of whom met TARGIT-MCC criteria, 3 for reasons outside established criteria); 21 (10.8%) patients received WBXRT. At median follow-up of 44.5 months, there were 13 LR (12 cases in patients who did not meet TARGIT-MCC criteria and did not receive WBXRT, 1 case in a patient who did not meet TARGIT-MCC criteria but was recommended WBXRT and declined). Receipt of WBXRT was not significantly associated with LR (0% (0/21) with WBXRT versus 7.5% (13/174) without WBXRT, p=0.368). In patients who met criteria for WBXRT but did not receive it, LR occurred in 10.8% (4/37) versus 0% (0/20) who met criteria and did receive it (p=0.286). The sole factor associated with decreased likelihood of LR was receipt of adjuvant endocrine therapy (3.9% with endocrine therapy versus 17.1% without, p=0.007).

Conclusions: In this cohort of women with HR-positive early breast cancer managed by lumpectomy with IORT and selective WBXRT using TARGIT-MCC criteria, LR was comparable in those who did and did not receive WBXRT, suggesting that selective WBXRT may have mitigated additional LR risk. Given that nearly all LR were in patients who were not recommended WBXRT, further work is needed to understand which additional factors predict LR to refine current selection criteria.

| | No Local Recurrence N=182 | Local Recurrence N=13 |
|---|------------------------------|--------------------------|
| Suitable for IORT alone (n = 138) | | |
| No recommendation for WXBRT | 127 | 8 |
| WBXRT recommended but not completed | 1 | 1 |
| WBXRT completed | 1 | 0 |
| Meet criteria for WBXRT (n = 57) | 53 | 4 |
| TARGIT-A | 32 | 2 |
| TARGIT-MCC | 21 | 2 |
| Met criteria and WBXRT recommended (n=27) | | |
| TARGIT-A | 17 | 0 |
| TARGIT-MCC | 10 | 0 |
| Met criteria and WBXRT received (n=20) | | |
| TARGIT-A | 13 | 0 |
| TARGIT-MCC | 7 | 0 |

Table: Outcomes of selective whole breast irradiation following lumpectomy with intraoperative radiation therapy for hormone receptor-positive breast cancer

582170 - Does managing vitamin D (VD) levels improve outcomes in breast cancer patients?

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Background/Objective: There is rather compelling epidemiologic data showing an association between low VD levels and both breast cancer risk and risk of recurrence. In 2008, we developed guidelines that called for checking 25-OH vitamin D levels at initial breast cancer presentation and correcting them to 40-60ng/ml, based on a meta-analysis showing that levels around 50ng/ml appeared to provide a 50% reduction in breast cancer risk. Previous work from our institution demonstrated an association between low VD levels and poor prognostic indicators in breast cancer, including younger age, non-Caucasian race, negative hormone receptor status, and high oncotype scores. There are no data available regarding the impact of correcting VD levels on breast cancer outcomes. To determine whether managing VD levels had an effect on recurrence after treatment of breast cancer, we updated our pre-existing dataset with information regarding outcomes.

Methods: The original dataset included 182 patients diagnosed with Stage 0-3 breast cancer in 2008-2009, who underwent surgery at our institution and had their clinicopathologic factors recorded. At this timepoint approximately half of the patients had VD levels checked and corrected if necessary. The association between VD management and clinicopathologic features was assessed using standard methods for contingency tables, and Student's T test for continuous variables, and the association of testing status with recurrence-free survival was assessed with Kaplan Meier curves (univariate) and Wilcoxan product limit estimates, controlled for age, stage, ER, PR, HER2, menopausal status, and family history (multivariate).

Results: There were 92 patients (50.5%) who had their VD levels managed as part of their breast cancer care (tested group), and 90 (49.5%) who did not (untested group). There were 4 bilateral cancers in each group. The median age at diagnosis in each group was 61 years. The median follow-up of each group was 107 months. There were 13 recurrences in the untested group and 5 in the tested group (p=0.04). Patients who had VD testing were significantly less likely to suffer recurrence or death than those who did not have their VD managed (p=0.01). This difference was attributable to the receptor-positive cancers. Outcomes among the triple-negative patients were no different between the 2 groups. Patients who had VD testing were more likely to have Stage 1 disease, whereas the untested group was more likely to have Stage 0, 2 or 3 disease (p=0.0013). Patients in the tested group were more likely to have ER-positive (p=0.018) and PR-positive (p =0.004) tumors, whereas those who did not have vitamin D checked were more likely to have luminal B or triple-negative phenotype tumors (p<0.0001). There were no significant differences in age, race, method of detection, family history, BRCA status, nodal involvement, Ki67, neoadjuvant therapy, Oncotype score, type of surgery, or length of follow-up between the groups. Fiveyear, recurrence-free survival (RFS) was 91% in the tested group and 80% in the untested group, but this difference did not reach significance in a multivariate model controlling for age, stage, ER, PR, HER2, or menopausal status (p=0.09).

Conclusions: There were more recurrences and worse recurrence-free survival (RFS) in the untested VD group, but the small number of events and the baseline differences between the groups make it difficult to attribute a role for management of VD in outcomes in this small dataset. The impact of vitamin D management is strongest in the ER/PR-positive population. A larger dataset with more events may clarify whether active VD management impacts the outcomes in breast cancer patients.

582052 - Long-term survival following sentinel lymph node biopsy in clinically nodenegative breast cancer patients treated with primary surgery or neoadjuvant chemotherapy

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Background/Objective: Sentinel lymph node biopsy (SLNB) has replaced axillary lymph node dissection (ALND) for axillary staging in patients with clinically node-negative (cN0) breast cancer. Local-regional recurrences are very rare and much less than what would have been expected based on false-negative rates associated with SLNB. Recurrence rates and associated risk factors may be different dependent on chemotherapy sequencing. Our aim was to compare long-term survival following sentinel lymph node biopsy in clinically node-negative breast cancer patients treated with primary surgery or neoadjuvant chemotherapy.

Methods: Patients with invasive breast cancer and a clinically negative axilla treated at the MD Anderson Cancer Center from 1993 to 2014 were included. All patients underwent SLNB without completion ALND. Subgroups were created for patients treated with surgery first and patients treated with neoadjuvant chemotherapy. Local-regional and distant recurrence rates were documented for each patient as well as recurrence-free and disease-specific survival. Survival was compared between the 2 groups. SLN status and other relevant clinical and pathologic factors were evaluated for their association with recurrence. Kaplan-Meier estimates of LRR-free survival and univariable and multivariable analysis of factors associated with LRR were performed.

Results: A total of 7294 patients were included: 6315 (86.6%) underwent surgery first, and 979 (13.4%) were treated with neoadjuvant chemotherapy. Median follow-up time for the entire cohort was 7.4 years (range, 2-20.3 years). In multivariable analysis, age younger than 50 years, progesterone receptor-negative disease, tumor size >2cm and estrogen receptor (ER)-negative disease/ER-positive disease not treated with endocrine therapy were associated with local-regional recurrence. In both groups, SLN status did not significantly affect local-regional recurrence rates. Overall, local-regional recurrence-free survival rates were not significantly different between the 2 groups. When adjusted for the number of adverse factors, local-regional recurrence-free survival remained similar for both groups (see Table).

Conclusions: Overall, local-regional recurrences following SLNB in clinically node-negative patients are rare. Local-regional recurrence-free survival was comparable between patients treated with surgery first and treated with neoadjuvant chemotherapy. Even after correcting for the number of adverse factors, local-regional recurrence-free survival remained similar between the 2 groups.

| | 5-year Loca | ll-regional recurrence fr | ecurrence free survival | | |
|------------------------|---------------|---------------------------|-------------------------|--|--|
| No. of adverse factors | Surgery first | NAC | P-value | | |
| 0 | 99.1 | 99.1 | 0.9 | | |
| 1 | 98.6 | 98.4 | 0.7 | | |
| 2 | 97.6 | 97.9 | 0.6 | | |
| 3 | 93.5 | 94.3 | 0.4 | | |
| 4 | 91.2 | 91.2 | 0.8 | | |

Table: Local-regional recurrence-free survival rates for clinically node-negative patients undergoing surgery first or receiving neoadjuvant chemotherapy based on the number of adverse factors of each patient

Lymphedema

582008 - The use of bioimpedance spectroscopy in the evaluation of simplified lymphatic microsurgical preventing healing approach (S-LYMPHA) for the prevention of lymphedema after axillary lymph node dissection

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Background/Objective: Lymphedema (LE) can occur in up to 30% of patients who undergo axillary lymph node dissection (ALND). Simplified Lymphatic Microsurgical Preventing Healing Approach (S-LYMPHA) is a lymphovenous anastomosis approach that has been shown to decrease the incidence of postoperative LE when measuring arm circumference. Bioelectrical impedance ratio (L-Dex) is a metric that measures changes in lymphatic flow and is reliable in the detection of LE. This study uses L-Dex ratio measurement as an objective assessment for LE in patients who underwent S-LYMPHA.

Methods: Patients with breast cancer undergoing ALND with and without S-LYMPHA between 2004 and 2018 with L-Dex measurements were selected from a prospectively maintained L-Dex database at a single institution. This database was initiated in June 2017, and patients were added upon the initial measurement of L-Dex. This included patients who were being managed for known clinical LE on a long-term basis. Electronic medical records were reviewed; L-Dex ratio and evidence of clinical lymphedema were assessed. Patients who underwent ALND with and without S-LYMPHA were compared. Statistical analysis was performed as follows: continuous data were tested for its distribution with Kolmogorov-Smirnov. Student T test was used for normally distributed variables, while Mann-Whitney was used for non-Gaussian variables. Categorical variable relationship was tested with Fisher's Exact Test. The alpha value for all analyses was 5%. All analyses were performed using SPSS 16.0 software.

Results: There were 86 patients who were identified and included in the study. Of these, 54 (62.8%) patients underwent ALND alone, and 32 (37.2%) underwent ALND with S-LYMPHA. LE occurred in 39 (70.9%) of the patients who underwent ALND alone and 2 (6.2%) of those who underwent ALND with S-LYMPHA (p<0.001). The median L-Dex was 7.45 (range -91 to 82) and 0.60 (range -8.4 to 9.2) for ALND alone and ALND with S-LYMPHA, respectively (p=0.01). Among patients with abnormal L-Dex ratios (greater than +10 or less than -10), there were 0 patients who had undergone ALND with S-LYMPHA and 29 (52.7%) patients who had undergone ALND alone (p<0.001). Twenty-nine of 39 (74.3%) ALND-only patients with LE had an abnormal L-Dex ratio.

Conclusions: L-Dex is accurate in the identification of clinical LE in patients who have undergone ALND with S-LYMPHA. It may be considered as an adjunct in the diagnosis of LE in this patient population.

| | ALND Alone 54 (62.8%) | ALND with SLYMPHA 32 (37.2%) | p-value |
|----------------|--------------------------|---------------------------------|---------|
| L-Dex * | 7.45 (-91 to 82) | 0.60 (-8.4 to 9.2) | 0.01 |
| Abnormal L-Dex | 29 (52,7%) | 0 (0%) | <0.001 |
| LE | 39 (70.9%) | 2 (6.2%) | <0.001 |

Table: Objective and clinical lymphedema incidence with and without simplified lymphatic microsurgical preventing healing approach

* Footnote: Data reported as median (range), L-Dex = Bioelectrical impedance ratio, Abnormal L-Dex = Bioelectrical impedance ratio measure above +10 or below -10, LE = lymphedema.

581562 – Long-term analysis of lymphedema diagnosed with bioimpedance in patients with early-stage breast cancer

Lisa Poole¹, Cynthia Chen², William Carter², Lina Sizer², Thomas Frazier² ¹Bryn Mawr Hospital, Havertown, PA, ²Bryn Mawr Hospital, Bryn Mawr, PA

Background/Objective: A previous IRB-approved study completed at our institution compared volume displacement (VD) and bioimpedance (L-Dex) measurements in a prospective cohort of Stage I and II breast cancer patients at risk for the development of lymphedema. That study covered 4 years, and historically, most lymphedema develops within a 3-year postoperative period. The aim of this study was to further evaluate retrospectively the patients who had not developed lymphedema to determine any late development and further evaluate L-Dex as a potential indicator of risk.

Methods: The original study conducted from 2010-2014 compared the utility of L-Dex measurement with the gold standard of volume displacement to evaluate the risk of lymphedema in patients with breast cancer. An IRB-approved retrospective study of the patients without clinical evidence of lymphedema at the conclusion of the initial study period was initiated to determine late occurrence of lymphedema and further evaluate bioimpedance as a predictor of risk. This included patients with normal and abnormal L-Dex measurements postoperatively compared to preoperatively. Patient charts were reviewed to determine if there was any documented evidence of lymphedema from 2014 to October 2018

Results: A total of 176 patients were identified without evidence of lymphedema at the conclusion of the initial study period. Of those 176 patients, 3 were excluded (death, inability to review chart). Thirteen patients were found to have lymphedema at conclusion of the initial study. Of those patients, 155 sentinel lymph node biopsies, and 31 axillary dissections were performed. Retrospective chart review was conducted on the 173 patients without evidence of lymphedema at the conclusion of the initial study period. A total of 85.5% (148) of patients had a normal L-Dex; 14.5% (25 patients) had an abnormal L-Dex. Although patients did not undergo continuous L-Dex monitoring, the chart documentation indicated changes in 4 patients sufficient to diagnose a delayed or late development of lymphedema. Two patients with normal L-Dex were found to have developed lymphedema, and 2 patients with abnormal L-Dex were found to have lymphedema. Three of 4 patients developing delayed lymphedema had completion axillary dissections (32, 53, and 13 lymph nodes removed). One patient had sentinel lymph node biopsy

only (5 lymph nodes removed). The patient who underwent sentinel lymph node biopsy did have an abnormal L-Dex. The overall rate of lymphedema was 9.1%. The rate of lymphedema following sentinel lymph node biopsy only was 1.29%. The long-term rate of lymphedema with a normal L-Dex was 1.35%, while an abnormal L-Dex had a rate of 8%.

Conclusions: The vast majority (76.5%) of patients who develop lymphedema will do so in the first 4 years postoperatively. This confirms that late development of lymphedema is less common and may be seen more often in patients with complete axillary dissection vs. sentinel node biopsy only. While the presence of an abnormal L-Dex did not appear helpful to determine "high risk" for lymphedema, a normal L-Dex did seem to correlate well with a "low risk" for lymphedema. We have found this helpful in reassuring patients regarding their risk and continue to use it in our survivorship plans.

Male Breast Cancer

582055 - How often is the nipple areolar complex involved in male breast cancer patients? Breaking the myth

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Background/Objective: Male breast cancer (MBC) is rare, accounting for <1% of all breast cancer cases, and incidence is increasing. According to the literature on MBC treatment, mastectomy is generally preferred to breast conservation surgery (BCS). Interestingly, data collected from the European Organization for Research and Treatment of Cancer (EORTC) show that 56% of MBC patients had Stage T1 cancer, but only 4% had undergone breast conservation surgery. The reasons suggested for this include the central location of many of the male breast tumors, possible nipple/skin involvement, and the paucity of breast tissue. Preoperative understanding regarding these factors can help in modifying the surgical options including preservation of nipple areola complex (NAC) in MBC undergoing mastectomy and performing BCS. The purpose of our study was to determine the proportion of cases with NAC involvement in MBC, and to see if there are imaging or clinical predictors of the feasibility of BCS and nipple-sparing mastectomy.

Methods: After institutional review board approval, we performed a retrospective review of all male patients with a diagnosis of breast cancer undergoing mastectomy from 2009-2017. Pathology (lesion size, histopathological type, receptor status) and presence or absence of NAC involvement was recorded. Mammographic distance to nipple (DTN) was measured, taken blinded to study design or other clinical pathologic characteristics by a fellowship trained, board-certified breast imager with 10 years of practice experience. Standard diagnostic metrics were computed.

Results: We identified 53 MBC patients with 54 mastectomy specimens, and a median age of 65 years (range 42-89). The median body mass index was 31 kg/m2. The majority of patients (87.03%) had invasive ductal carcinoma, Stage II (37.04%), ER-positive (96.3%), PR-positive (92.6%), HER2-negative (90.74%), and underwent simple mastectomy (74.07%), with a minority undergoing modified radical mastectomy (25.9%). Involvement of the NAC was present in 9 (16.7%) mastectomy specimens. The majority of patients (84.6%) had mammographic DTN <2cm, with only 7 (21.2%) patients showing NAC involvement in histopathologic evaluation. Of those patients (15.4%) with mammographic DTN >2cm, none had NAC involvement. Presentation with palpable mass was seen in 41 (75.9%) patients and nipple inversion in 7 (13.0%) patients. Of those patients with palpable mass on presentation, only 2 (4.9%) had NAC involvement; in men with nipple inversion, 6 (85.7%) had NAC involvement.

Conclusions: In this study, only a small proportion of MBC patients had NAC involvement despite mammographic NTD <2cm. We hope to perform a larger multi-institutional retrospective study as well as the use of prospective data registries, notably the EORTC International Male Breast Cancer Program, to add clarity to this important clinical question. We hope in the future to aid the surgeon in deciding on the feasibility of NAC preservation if mastectomy performed or provides BCS as an option in MBC patients.

582080 - Local therapy for male breast cancer: Stuck in the 20th century?

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Background/Objective: Male breast cancer (MBC) is infrequent compared to breast cancer (BC) in women. Due to the small numbers, most treatment for MBC is based on studies performed on women with BC. Interestingly, local treatment of MBC, including breast-conservation surgery and nipple-sparing mastectomy, is not utilized at the same rate used for women. We sought to further enrich data on current local therapies for MBC with the ultimate goal of determining barriers in surgical advancement.

Methods: After institutional review board approval, we queried the Indiana Cancer Registry (ICR) and the Indiana Network for Patient Care (INPC). We retrospectively reviewed data for all male breast cancer patients between the ages of 18-90 diagnosed from 2000-2017. Standard diagnostic metrics were computed. Bivariate analysis was done using Pearson's Chi-square and Fishers' exact tests and multivariable analysis using logistic regression. All hypotheses were tested at 0.05 level of significance.

Results: We identified 446 men diagnosed with BC, with a mean age at diagnosis of 66. Of this cohort, 339 (76%) underwent mastectomy, 51 (11.4%) underwent partial mastectomy (PM), and 56 (12.6%) did not have surgery. Most patients had Stage 2 disease (147, 33%) followed by Stage 1 (96, 21.5%) (Table). Patients undergoing PM were more likely to have Stage 1 disease compared to patients undergoing mastectomy (p<0.001). Of patients undergoing PM, only 35.3% underwent radiation therapy (p=0.023). There were no differences in the 2 groups regarding endocrine (p=0.06) and chemotherapy (p=0.12).

Conclusions: Our data confirm low rates of breast-conserving surgery in men with breast cancer and low use of adjuvant radiation therapy in these patients. With significant advances in the treatment of breast cancer for women, including use of neoadjuvant therapy for downstaging tumors and oncoplastic surgery including nipple-sparing mastectomy, the surgical treatment of MBC should be challenged in clinical practice. This may require better documentation of amount of gynecomastia, location of tumor from nipple, and discussing patient preference during cancer treatment discussion. Future research in this area should focus on the feasibility of procedures such as breast-conserving surgery and nipple-sparing mastectomy for MBC.

| Variable | Male Breast Cancer Patients (Range) |
|-----------------------------------|-------------------------------------|
| Age | |
| Median (IQR) | 67 (58-75) |
| Mean (SD) | 66.54 (12.13) |
| Race | |
| White | 394 (88.34) |
| Black | 43 (9.64) |
| Other | 3 (0.67) |
| Unknown | 6 (1.35) |
| Stage (Clinical) | |
| 0 | 22 (4.93) |
| 1 | 101 (22.65) |
| 2 | 112 (25.11) |
| 3 | 19 (4.26) |
| 4 | 29 (6.50) |
| Unstaged/not-applicable | 145 (32.51) |
| Missing | 18 (4.04) |
| Stage (Pathologic) | |
| 0 | 24 (5.38) |
| 1 | 96 (21.52) |
| 2 | 147 (32.96) |
| 3 | 46 (10.31) |
| 4 | 11 (2.47) |
| Unstaged/not-applicable | 113 (25.34) |
| Missing | 9 (2.02) |
| Grade | - () |
| 1 | 67 (15.02) |
| 2 | 201 (45.07) |
| 3 | 130 (29.15) |
| 4 | 2 (0.45) |
| B-cell | 1 (0.22) |
| Unknown/not stated/not applicable | 45 (10.09) |
| Surgery | |
| None | 56 (12.56) |
| Breast Conservation | 51 (11.43) |
| Mastectomy | 339 (76.01) |
| Number of Lymph nodes removed | |
| 0 | 92 (20.63) |
| 1-5 | 71 (15.92) |
| ≥6 | 91 (20.40) |
| Missing | 192 (43.05) |
| Radiation | |
| No | 348 (78.03) |
| Yes | 98 (21.97) |
| Hormone Therapy | |
| No | 262 (58.74) |
| Yes | 184 (41.26) |
| Chemotherapy | |
| No | 295 (66.14) |
| Yes | 151 (33.86) |

582433 - Demographic, clinical, and survival disparities in males with metastatic breast cancer

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Background/Objective: Male breast cancer (MBC) is relatively rare when compared to breast cancer in females and has been shown to be diagnosed at a later stage. Most of the treatment decisions for MBC are based on studies in females, though treatment for metastatic breast cancer is often less standardized. We sought specifically to assess the demographic, clinical, and survival differences between males and females with breast cancer metastatic at the time of diagnosis.

Methods: Using the National Cancer Database, we identified all patients who had clinically metastatic disease at the time of breast cancer diagnosis (cM1). We stratified patients based on sex as recorded in the medical record and compared demographics, clinical characteristics, and survival between the groups using both univariate and multivariate analyses.

Results: There was a total of 87,765 patients with cM1 breast cancer, 1224 (1.4%) of whom were male. Males had a higher rate of cM1 disease, (6.6 v. 4.6%), were older (64.3 v. 52.1 years), had more medical comorbidities at the time of presentation, and were more likely to be treated at a community cancer center than females (13.4 v. 11.0%, all p<0.001). Females had a higher proportion of triple-negative breast cancers (7.5 v. 4.6%), while males had a higher proportion of HR+/HER2- cancers (39.4 v. 31.1%) and tumors of higher grades (all p<0.001). Related to treatment, males were less likely to undergo treatment with chemotherapy (44.4 v. 51.6%, p<0.001), but more likely to undergo radiotherapy (36.4 v. 32.6%) and oncologic surgery on both primary (31.8 v. 27.5%, p<0.001) and other sites (6.9 v. 6.0%, p=0.04). Median overall survival was shorter for male patients (24.4 v. 27.2 months, p<0.001) with an unadjusted hazard ratio for death from any cause of 1.12 (95% C.I. 1.04-1.20, p<0.001). However, when adjusted for demographics and cancer characteristics, there was no difference in overall survival between male and female patients (HR 0.99, 95% C.I. 0.85-1.14, p=0.85).

Conclusions: We found differences in baseline demographics and cancer characteristics between male and female patients with cM1 breast cancer, which underscore the ongoing need for education and screening in male patients most at risk. These differences likely impacted both the treatment decisions made by the oncologic team and the ultimate survival of the patient. The lack of difference in adjusted survival supports the current practice of treating MBC based on data from studies performed in females.

Other

578320 - Decreasing adjuvant chemotherapy use in patients >50 years of age with earlystage breast cancer: A single-institution application of the TAILORx Study findings Shahrzad Abbassi Rahbar¹, Anna Shu², Amy Kirby²

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Background/Objective: The development of genomic profiling has changed the paradigm of early-stage breast cancer (ESBC) treatment with adjuvant chemotherapy. Oncotype DX (oDX) testing is indicated for patients with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative ESBC. The 21-gene oDX assay is used to generate a recurrence score (RS), which provides prognostic information that contributes to disease recurrence. Node-negative ESBCs are classified as having low (RS 0-10), intermediate (RS 11-25), or high (RS >26) risk of disease recurrence in 10 years. Recently published TAILORx study findings demonstrated noninferiority of adjuvant endocrine therapy compared to chemoendocrine treatment in patients aged 50 years or greater with node-negative ESBC and an intermediate-risk RS. Our objective was to identify the impact that implementing these recommendations would have on adjuvant chemotherapy use in our community hospital.

Methods: We conducted a retrospective, single-institution study of patients 50 years of age and older with ESBC. Patients diagnosed with ER-positive, HER2-negative, node-negative breast cancer between January 1, 2004 and December 31, 2017 and had oDX testing at our institution were included in the study. Rates of adjuvant chemotherapy use were calculated for each risk category and compared using Chi-square. Logistic regression analysis was performed to control for age. Differences in age between risk categories were assessed for using ANOVA, and the impact of age on adjuvant chemotherapy treatment was evaluated using student's t-test.

Results: A total of 266 patients were eligible for oDX testing, of which 187 (64.2%) had available results. Twenty-three patients were excluded due to node-positive disease, leaving 164 patients included in the analysis. Of these, 53 (32.3%) patients were categorized as low risk, 86 (52.4%) as intermediate risk, and 25 (15.2%) as high risk based on TAILORx RS cutoff values. In the intermediate group, 9 (10.4%) patients received adjuvant chemotherapy, and 21 (86%) patients received only endocrine therapy. A total of 30 patients with node-negative ESBC received adjuvant chemotherapy, of which 9 (30%) were in the intermediate-risk group, and 21 (70%) were in the high-risk group. No patients in the low-risk group received adjuvant chemotherapy, whereas 84% of patients in the high-risk group had chemoendocrine therapy. TAILORx risk classification (low, intermediate, high) was associated with rates of adjuvant chemotherapy use (p<0.0005), even when controlling for age. There was no difference in age between the risk classification groups (ANOVA, p=0.575). Patients that received chemotherapy were younger at 61.5±6.5 years of age compared to those that did not at 65.8±8.8 years of age (p<0.0005).

Conclusions: Previous studies have found that ~85% of patients with ESBC are adequately treated with adjuvant endocrine therapy alone, yet approximately 25% of these patients receive chemotherapy. As a result, many patients may be overtreated. The use of oDX is a valuable adjunct in the consideration of optimizing therapy, and clinical trials validating its use may increase its role in the decision-making process. Application of the TAILORx findings could decrease chemotherapy use by up to 30% in our patient population without impacting disease-free survival, recurrence, or overall survival. This would also decrease health care costs and treatment-associated adverse effects. However, treatment decisions are based on a variety of factors that may result in deviation from recommendations based on RS risk guidelines alone. This may ultimately mitigate the extent to which adjuvant chemotherapy would actually decrease based on findings from the TAILORx study.

581962 - New breast cancer AJCC staging eighth edition reflects cancer aggressiveness and immune response

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Background/Objective: The 8th edition of American Joint Committee on Cancer (AJCC) staging incorporated cancer biology by adding hormone receptor and HER2 status and pathological grade. We hypothesized that gene-expression profiles vary significantly among the stages in the 8th edition compared with the 7th edition.

Methods: Genomic and clinical data were obtained from the breast patient cohort of The Cancer Genome Atlas (TCGA) in Pan-Cancer Atlas publications. Pathologic grades were determined from the TIE database. Both the 7th and 8th edition AJCC staging were determined in the same patients. Genomic analyses were conducted using the bioinformatics algorithms we previously published.

Results: A total of 696 patients had information needed to be staged by both the 7th and 8th AJCC editions. The majority of patients who had different stages compared from 7th to 8th were "down-staged" to a lower stage by the 8th edition criteria. A total of 305 patients were "down-staged" by the 8th edition (256 from Stage II to I, 31 from III to I, and 18 from III to II). "Up-staging" in the 8th edition occurred in only 6 cases (all from II to III). The overall survival hazard ratio calculated using Cox regression between Stage I and II was greater in the 8th edition compared to the 7th edition (HR=1.50 and 1.22, respectively). Enrichment of cell proliferation-related gene sets such as E2F targets and G2M checkpoint, DNA repair as well as mTOR signaling gene sets, were observed in Stage II compared to I in both editions, whereas the enrichment of E2F targets and G2M checkpoint in Stage III compared to III were seen only with the 8th edition. When immune cell profiles were analyzed by TIMER algorithm, fractions of leukocytes and tumor-infiltrating lymphocytes were both significantly elevated in Stage II compared to Stage I only in the 8th edition. Activated natural killer and CD8 T cells, both of which are known as cytolytic immune cell subsets, were also higher in Stage II compared to I tumors only in the 8th (p=0.005 and <0.001, respectively) and not in the 7th edition (p=0.684 and <0.418, respectively) by Cibersort algorithm. On the other hand, suppressive immune cell subsets such as regulatory T cell were significantly higher in Stage III and IV tumors (p=0.035). CYT score and TCR diversity, which reflect immune activity, were significantly higher in Stage II compared to I tumors again only in the 8th (p=0.002 and 0.049, respectively). Concordantly, gene expressions of immune check point molecules such as PD1 and PD-L1 were also significantly higher in Stage II tumors only in the 8th (p<0.001 and 0.013, respectively) but not in the 7th edition (p=0.492 and 0.215, respectively). The mutation-related aspects such as Intra-Tumor Heterogeneity and Homologous Recombination Defects scores were significantly different among in the 8th edition (p=0.022 and <0.001, respectively) but not in the 7th edition stages (p=0.706 and 0.145, respectively). Finally, clustering of tumors by stage based on their expression of immune response genes was significantly improved when staged according to the 8th edition compared to the 7th edition.

Conclusions: Utilizing the gene expression profile and bioinformatics analyses, we found that the AJCC 8th edition staging system better discriminates breast cancer biology, such as cancer aggressiveness, intratumor heterogeneity, and immune response, than the 7th edition does.

581151 - Idiopathic granulomatous mastitis: A closer look at demographic characteristics and factors associated with recurrence in 474 patients

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Background/Objective: Idiopathic granulomatous mastitis (IGM) is an uncommon inflammatory disease of the breast with an obscure etiology. Although a rare entity in the US, the similarity of its presentation to breast cancer poses a diagnostic and therapeutic challenge. IGM recurrence rate has a wide reported range in the literature, from as low as 5% to as high as 50%. In this study, we aim to investigate the demographic and clinical characteristics as well as comparing them between patients with and without recurrence.

Methods: This is a retrospective review of a total of 474 patients diagnosed with IGM, comprising 2 large datasets of patients who visited breast clinics at Tehran and Mashhad university hospitals in Iran between 2001 and 2015 and 2005 and 2018 respectively. We reviewed patients' medical files to look for all noted characteristics and treatment modalities. We used Chi-square test to compare them between patients with and without recurrence. Univariate logistic regression analysis was applied to evaluate the association between each characteristic and recurrence. Finally, we used logistic regression test to adjust for possible confounders.

Results: All patients were females with the mean age of 33.9 years. Most patients had history of pregnancy and lactation (93.6% and 82.7% respectively). The most common clinical findings were pain and palpable mass (69.8% and 69.4% respectively). About half of the patients received medical treatment and corticosteroids were the most frequently administered medications. Among surgical approaches, abscess drainage was the most common intervention applied. There were 34.3% of patients who received both medical and surgical treatment, and about 15% of them did not receive any type of treatment at all. The total recurrence rate was 24.8%. Unadjusted analysis revealed that patients with skin lesions had significantly higher odds of recurrence (OR=1.83, 95%CI [1.12-3.00], p=0.01) which remained significant after adjusting for potential confounders.

Conclusions: IGM is an uncommon disease in the US that poses diagnostic and therapeutic challenges. The lack of malignant cells in the core biopsy and inflammatory changes with non-caseating granulomatous findings are hallmarks of IGM diagnosis. It can present at different levels of severity. To achieve the most favorable outcomes, we believe that management should focus on the level of the severity as well as avoiding disfiguring resections unless non-responsive to conservative treatment. Utilizing larger cohort of patients and longer follow-ups, as well as investigating other microbiological factors like the microbiome, could result in better understanding of the disease and help with its management.

Images: Clinical presentations of four patients with IGM



582059 - Overview of treatment regimen and survival in patients with angiosarcoma of the breast

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Background/Objective: While angiosarcoma of the breast is a rare entity, it carries a very poor prognosis. As many practicing breast surgeons will encounter only a handful of these lesions in their lifetime, a consensus on treatment has yet to be established. This study aimed to evaluate the impact of treatment type on survival for angiosarcoma of the breast.

Methods: The National Cancer Database (NCDB) was used to identify patients who were diagnosed with angiosarcoma of the breast between 2005 and 2015. For each patient, the treatment regimen could include up to 3 modalities - surgery, radiation, and systemic therapy. Surgery was further broken down into those patients receiving no surgery, breast conservation therapy (BCS), or mastectomy. For systemic therapy and radiation, while different treatment regimens were used, this was treated as an all-or-nothing event – the patient either received therapy or did not. Patients were grouped by the combination of treatments they received – BCS and systemic therapy; mastectomy + systemic therapy + radiation, etc. Survival was determined if the patient was noted to be dead or alive based on the last date of contact by the NCDB. Using this information, the percentage of patients surviving following each combination of treatment was calculated.

Results: There were 1098 patients diagnosed with breast angiosarcoma between 2005 and 2015. Of these patients, 1011 underwent surgery, 295 received systemic therapy, and 190 received radiation therapy. The most common treatment regimens were as follows: mastectomy only, mastectomy + systemic, BCS only, mastectomy + radiation, mastectomy + radiation + systemic therapy, with survival being 41%, 51%, 51%, 38%, and 48% respectively.

Conclusions: Regardless of treatment, patients with angiosarcoma of the breast have a poor prognosis. Most patients underwent surgical intervention as part of their treatment regimen, most commonly mastectomy. BCS and mastectomy + systemic therapy had slightly improved survival compared to other regimens. Further studies investigating the treatment modalities to delineate any impact on survival based on age, size of tumor, etc. may help shape further treatment recommendations.

581848 – Breast-enhanced recovery after surgery (BERAS) protocol decreases immediate postoperative narcotic utilization

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Background/Objective: National concern for opioid overuse and the increasing frequency of drug shortages have focused increasing attention on postoperative pain control. An enhanced recovery protocol for breast surgery patients was implemented at our institution in February 2017. Immediately following implementation, our group previously reported an increase in subjective patient satisfaction. With further patients now treated with this protocol, the aim of this study was to determine whether adherence to the pain control parameters of the BERAS protocol resulted in a difference in intraoperative and immediate postoperative opioid administration.

Methods: BERAS protocol implementation included parameters to address pain control, VTE prophylaxis, nausea, and early p.o. intake and mobilization. Specifically, pain control was addressed with administration of celecoxib 200mg and gabapentin 600mg in preoperative holding. PECSI and PECSII Blocks with ropivacaine were offered to all patients undergoing mastectomy or surgery extending into the axilla. Intraoperative administration of local anesthetic was at surgeon discretion, within allowable total dose. Preoperative or intraoperative acetaminophen was administered 1000mg. Retrospective analysis was performed on 100 consecutive patients from 3 surgeons prior to BERAS implementation and 100 consecutive patients after implementation. Patients undergoing partial mastectomy, partial mastectomy with axillary surgery (SLN biopsy or axillary dissection), mastectomy, and mastectomy with axillary surgery were included. Excluded populations included those undergoing excisional biopsy, reopening of lumpectomy for margin clearance, and immediate reconstruction. In addition, patients with chronic pain (defined as a chronic pain diagnosis in electronic health record or daily opioid use documented in electronic health record or state narcotic reporting system), were excluded. Postoperative PACU pain score (highest), intraoperative narcotic administration and postoperative immediate postoperative narcotic usage in morphine equivalents was compared. Demographic factors of age at surgery, BMI, median length of procedure, and major comorbidities were compared.

Results: Implementation of the BERAS protocol with focus on non-narcotic pain control significantly decreased narcotic usage in the immediate postoperative period (p<0.01). In addition, postoperative pain scores, as elicited by nursing, were significantly skewed toward improved early pain control in the post-BERAS group, with the majority of the patients in the BERAS group reporting pain at a level of zero as reported on a standard 0-10 pain scale (81%). Interestingly, intraoperative narcotic administration, as reported in morphine IV equivalents, did not reach statistical significance between the groups (p=0.13). Characteristics of patients included in the pre- and post-BERAS comparison groups did not differ in age at surgery, BMI, or major comorbidities.

Conclusions: Implementation of a BERAS protocol, including non-narcotic pain control in the perioperative and intraoperative period, decreases immediate narcotic usage and patient pain scores. The stable intraoperative usage rate is likely attributable to the emphasis in the protocol on nausea avoidance, one aspect of which is avoidance of nitrous oxide and minimization of inhaled anesthetic. Future directions include standardization of postoperative pain control following discharge with the eventual goal of a prospectively developed protocol with minimal inclusion of narcotics beyond the intraoperative period.

582144 - Compliance with anti-hormonal therapy after omission of radiation following breast-conserving surgery in favorable older patient subgroup

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Background/Objective: Anti-hormonal therapy is fundamental in the treatment of hormone-positive breast cancer. Several studies have suggested that omission of radiation in breast-conserving therapy is reasonable in older patient subgroups with favorable tumor characteristics, especially if the patients will receive anti-hormonal therapy. Commitment to anti-hormonal therapy is essential for these patients; however, compliance with the full regimen is not guaranteed. We aim to define anti-hormonal therapy and those who opted out of radiotherapy.

Methods: Our IRB-approved breast cancer registry database was used to identify women over 65 years old with a T1-T2, ER-positive primary breast cancer who had undergone breast-conserving surgery from 2010 to 2013 (allowing for 5 years of follow-up). Radiotherapy completion rates and duration of compliance to anti-hormonal therapy were defined. Compliance was defined as completing 60 months of anti-hormonal therapy as prescribed by the treating medical oncologist.

Results: We identified 188 patients age \geq 65 years who underwent breast-conserving surgery with negative margins for a T1-T2, ER-positive primary breast cancer between the years of 2010-2013. Of these, 93.6% underwent radiotherapy, and 6.4% opted out of radiotherapy. Of those that completed radiotherapy, only 56.3% competed 5 years of anti-hormonal therapy, and the remaining 43.8% were considered non-compliant. Of the patient subgroup who chose to omit radiotherapy, only 25% completed anti-hormonal therapy. The remaining 75% were non-compliant. Overall, most patients in this subgroup completed radiotherapy as part of breast-conserving therapy, but only 56% of these completed 5 years of anti-hormonal therapy. Of those that omitted radiotherapy, despite the known importance of anti-hormonal therapy compliance, only 25% completed the 5 years of anti-hormonal therapy.

Conclusions: These findings suggest that anti-hormonal therapy compliance is less than ideal across this population, regardless of the acceptance of radiotherapy (60 months of anti-hormonal therapy was completed by 56% for those who received radiotherapy and 25% for those who did not). This is important to consider when evaluating patients in this age group with favorable tumor biology who may be eligible to omit radiotherapy, as commitment to anti-hormonal therapy compliance is paramount. Further research is necessary to solidify these results and to define outcomes including local-regional recurrence rates, disease-free survival, and overall survival.

582156 - Managing necrotizing fasciitis of the breast: Is a radical approach always necessary?

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Background/Objective: Necrotizing fasciitis (NF) is a severe, fulminant infection characterized by widespread necrosis of the subcutaneous tissue and fascia with associated systemic toxicity. Predisposing conditions include diabetes, chronic alcoholism, advanced age, vascular disease, and immunosuppression. Breast involvement is rarely reported with the majority of cases due to trauma, biopsies, or surgery. Primary involvement of the breast is extremely rare and often misdiagnosed as an abscess, mastitis, or inflammatory breast cancer, leading to treatment delays. Although rarely reported, necrotizing fasciitis of the breast does occur in both genders, more frequently as a secondary extension of the arm, axilla, chest wall, or torso NF. Although it is a rapidly progressive and life-threatening disease, early recognition and surgical intervention can greatly reduce morbidity and mortality and allow for a less radical surgical approach because of subcutaneous tissue elasticity and the robust blood supply of the breast parenchyma. Regardless of the etiology, mastectomy has been the main treatment in the majority of published cases. The aim of this study was to review patients with either primary (PNF) or secondary (SNF) breast necrotizing fasciitis to identify factors leading to either a partial or total mastectomy. Our hypothesis was that a radical surgical approach to breast NF was not always indicated.

Methods: This was a retrospective chart review of breast NF cases seen at our institution between 2007-2018. Primary breast NF (PNF) was defined as the presenting disease process. Secondary breast NF (SNF) was defined as breast tissue involved, because of proximity to the necrotic tissue, muscle, and fascia spread from another source. Statistical analysis was utilized to assess patient demographic

characteristics such as age, length of stay, comorbidities, microbiology, surgical management, and survival rates.

Results: Eight cases were identified: 5 (63%) males and 3 (37%) females. Two (25%) patients had PNF; 6 (75%) patients had SNF. The median age was 43 years, with females older than males (51 vs 38 years). Diabetes, renal disease, and intravenous drug abuse (IVDA) were the most common comorbidities. The overall length of stay was a mean±sd of 46.5±20.3 days, 10.4±5.0 debriding operations, 3.2±1.5 reconstructive procedures, and debriding and grafting requirements of 2033±1222 cm2. Comparing the patients with primary and secondary breast NF, the median age for the PNF patients was 71.50 and 37.50 years for the SNF patients. The microbial cultured were 3 cases of Group A Streptococcus pyogenes (2 SNF, 1 PNF), 1 multi-resistant Staphylococcus aureus (PNF), 1 Pseudomonas (SNF), 1 Coagulase negative Staphylococcus (SNF), and 2 polymicrobial (SNF). Partial mastectomies were performed in 4 patients (3 males and 1 female, all with SNF), unilateral simple mastectomy was required for 1 patient (female with PNF), and 3 bilateral mastectomies were performed in 3 patients (1 male and 1 female with PNF; 1 male with SNF). Overall mortality was 37.5%. Two patients with PNF had 100% mortality; they were septic on arrival with multiple comorbidities and an advanced age. The 6 patients with SNF were younger and had a morbidity of 17% (1 patient).

Conclusions: In this study, a radical surgical approach was not indicated in cases where breast tissue was involved secondarily in both males and females. It was a necessity in cases of PNF. Our limited series shows that SNF can be safely managed with less radical approaches, while PNF requires more extensive debridement and is associated with higher mortality. Larger case studies are warranted to make further recommendations.

581465 - Implementation of an enhanced recovery after surgery (ERAS) protocol improves post-operative nausea and analgesia following total mastectomy

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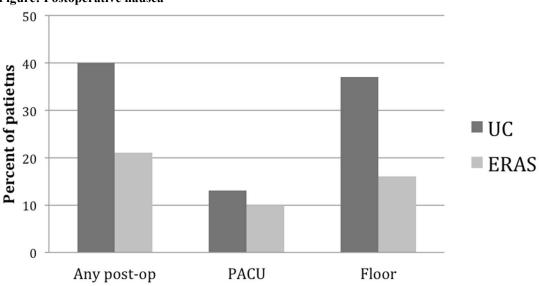
Background/Objective: Enhanced recovery after surgery (ERAS) protocols are patient care pathways that utilize a multimodal and interdisciplinary approach to perioperative care, designed to improve patient outcomes, including perioperative antiemetic and narcotic requirements. Because of high reported rates of postoperative nausea or vomiting (PONV) following total mastectomy, we implemented an ERAS protocol at our institution with the aim of reducing PONV, while simultaneously improving pain and decreasing opioid use. Our objective was to assess the efficacy of this newly implemented ERAS protocol in achieving this aim.

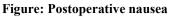
Methods: We implemented an ERAS protocol for all patients at a single institution undergoing total mastectomy, without reconstruction or with immediate tissue expander or direct implant reconstruction. The preoperative phase of the protocol includes patient counseling, prehabilitation, and optimization of comorbidities. In the holding area before surgery, patients receive acetaminophen, gabapentin, and perphenazine. Intraoperative measures include dexamethasone and ondansetron, with intraoperative Pecs block, and reduction in opioid use. Postoperative analgesia is multimodal, with acetaminophen, ketorolac, gabapentin, and as-needed opioids. We compared the outcomes of the patients from the first 2 months of ERAS implementation (ERAS group, n=72) with a retrospective usual-care cohort from the 3-month

period prior to ERAS implementation (UC group, n=83). Outcomes included incidence of PONV, measured with antiemetic use; patient-reported pain scores; post-operative opioid consumption, measured with oral morphine equivalents (OME); and length of stay.

Results: Demographic characteristics, including age, gender, race, and comorbidities, of the 2 groups were similar. Surgical characteristics, including laterality, axillary surgery, reconstruction use, and neoadjuvant therapy, were also similar. The incidence of PONV was lower in the ERAS group than the UC (21% vs. 40%, p = 0.011), see Figure. Patients in the ERAS group had lower total perioperative opioid consumption compared to the UC group (mean 44.1 OME vs. 104.3 OME, p<0.001). These differences in opioid consumption were seen more in the operating room and post-anesthesia care unit (PACU) settings; opioid consumption on the floor was similar between the 2 groups. Patient-reported pain scores were lower in the ERAS group than the UC group (mean highest pain score 6.4 vs. 7.4, p = 0.003). PACU length of stay and hospital length of stay were similar between the 2 groups.

Conclusions: Implementation of an ERAS protocol at our institution was successful in decreasing PONV in patients following total mastectomy with and without reconstruction. This was achieved with decreasing overall opioid consumption and without compromising patient pain.





580724 - Outcomes of oncoplastic breast surgery compared to breast-conserving surgery in breast cancer patients

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Background/Objective: Oncoplastic surgery (OPS) is a known alternative to standard breast-conserving surgery (BCS), but it may result in more tissue being removed. We sought to determine how the volume of tissue resected varied between OPS and BCS, and the impact this had on rates of complications, positive margins, and re-excisions.

Methods: A retrospective cohort study was conducted of patients who underwent either BCS or OPS for Stage 1-3 breast cancer and DCIS between August 1, 2016 and August 31, 2018. Clinicopathologic characteristics, volume of tissue resected, margin status, 30-day readmission for complications, and re-excision rates were evaluated. A positive margin was considered tumor at ink. Statistical analyses were performed using SPSS.

Results: In our cohort of 257 patients, 146 (57%) underwent OPS, and 111 (42%) BCT. Patient and tumor characteristics are shown in the Table. Mean age of the patients was 50 years. Patients who underwent OPS tended to have larger tumors (2.06cm vs. 1.74cm, p=0.019). Mean volume of tissue resected was also significantly larger in the OPS group (146.8cm3 vs.90.4cm3, p =0.001). After controlling for tumor size, OPS was not associated with a larger resection volume (p=0.056). Despite the larger mean resection volume, OPS was not associated with a higher rate of postoperative complications requiring readmission within 30 days (0 in both groups). None of the patients in the OPS group had positive margins, and therefore none required re-excision. This was significantly different from the BCT group in which 10 (8%) its patients had positive margins (p<0.001), and 5 (4.5%) underwent re-excision (p=0.127).

Conclusions: While OPS involves excision of larger volumes of breast tissue, it is associated with a significantly lower rate of positive margins and re-excision, without increasing complications resulting in readmission.

| Characteristic | Total | OPS | BCT | p-value |
|--------------------------------|-------------|--------------|-------------|---------|
| | (N=257) | (N=146) | (N=111) | |
| Age, median (range) in years | 50 | 49 (25-78) | 51 (20-86) | 0.513 |
| Histology,n | | | | |
| IDC | 235 | 135 | 100 | |
| ILC | 1 | 0 | 1 | |
| Metaplastic | 6 | 2 | 4 0. | |
| DCIS | 15 | 9 | 6 | |
| Tumor Size, median (range), cm | 0-4.9 (2.4) | 0-4.9 (2.06) | 0-4.5(1.74) | 0.019 |
| Neoadjuvant Chemotherapy n(%) | 50(19.4) | 24(16.4) | 26(23.4) | |

Table: Patient and tumor characteristics

582185 - Could cryoablation offer a non-surgical approach for treatment of low-risk, earlystage breast cancer?

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Background/Objective: Progress in breast cancer genomics provides a clearer understanding of tumor prognosis, allowing a more tailored approach to patient management. Patients identified with low-risk tumor biology potentially leads to less aggressive treatments. In fact, favorable ancillary features (e.g., low grade, +HR status) in early-stage breast cancer has led to altered management of elderly patients, eliminating the routine use of radiation and sentinel lymph node biopsy in appropriately selected patients. Therefore, the next step would be to identify a subset of patients with low-risk, early-stage breast cancer who could avoid surgical intervention of their breast tumor altogether. The ICE3 Trial is designed to

evaluate cryoablation as a non-surgical treatment of low-risk, early-stage breast cancer in women ≥ 60 years. Primary outcome is local ipsilateral breast tumor recurrence (IBTR), and secondary outcomes are disease-free survival, safety, and patient satisfaction.

Methods: The ICE3 trial is an IRB-approved, single-arm, multi-centered, non-randomized trial enrolling up to 200 patients. Inclusion criteria include women aged ≥ 60 years with low-risk (HR+, HER-2-), unifocal, small (≤ 1.5 cm) invasive ductal carcinoma and breast size allowing safe cryoablation. The office-based, single cryoablation treatment is performed with local anesthesia using the IceSense3TM Cryosurgical System (IceCure Medical, Ltd; Caesarea, Israel). The cryoprobe is inserted into the tumor center under ultrasound guidance. Each treatment consists of 2 freezes with an intervening thaw. The entire treatment takes 20-40 minutes depending on lesion size. Cryoablation is followed by appropriate adjuvant treatment at the physician's discretion. Patients are followed by breast imaging at 6 months and then annually up to 60 months post-procedure.

Results: To date, of 194 patients initially enrolled, 188 patients had a successful cryoablation procedure and are being followed; 41% with at least 2 years of follow-up, and 13% having been followed for a minimum of 3 years. The patient and tumor characteristics are detailed in Table 2. All patient tumors were infiltrating ductal carcinomas, Grade I or II, HR+ and HER-2 negative. Of the patients who underwent a sentinel lymph node (SLN) biopsy, only 1 patient was SLN positive. Variations from protocol enrollment criteria were identified post-ablation in 2 patients suspected of incomplete treatment due to inadequate cryoablation treatment time, 1 patient had an extensive intraductal component (EIC), 2 patients were Luminal B subtype, and 3 had tumor size >15mm on baseline imaging. To date, there have been 2 breast recurrences (1% IBTR), both with protocol violations (size >1.5cm and EIC). There are only minor device-related adverse events reported requiring no intervention.

Conclusions: The ICE3 trial, the largest controlled liquid nitrogen-based cryoablation trial without subsequent tumor excision, demonstrates a 1% IBTR to date with almost no complications. Further follow-up is required to demonstrate an acceptable, longer-term IBTR rate, although interim results are extremely positive. In the era of genomic profiling and individualized medicine, cryoablation may provide a tailored, office-based treatment for patients with early-stage, low-risk breast cancer.

| MONTHS | <6 | 6-11 | 12-23 | 24-35 | >36 |
|--------------|----|------|-------|-------|-----|
| PATIENTS No. | 38 | 32 | 41 | 53 | 24 |
| PATIENTS (%) | 20 | 17 | 22 | 28 | 13 |

| Table 1: 188 n | atients under follow | un: Table 2: Summar | v of clinical, imaging | , and pathological data |
|-----------------|----------------------|---------------------|------------------------|-------------------------|
| 1 abit 1, 100 p | anonto unuci ionom | up, 1 and 2. Summar | y or chinear, magnig | , and pathological data |

| Detions Changed and in | (|
|-----------------------------|---------------------------|
| Patients Characteristics | (n=188) |
| Mean Age (range) | 75 (61-93) |
| Tumor Characteristics | |
| Histology | |
| Infiltrating Ductal | 188(100%) |
| Other | 0 (0%) |
| Nottingham Histologic Grade | |
| Low - I (3-5) | 86 (46%) |
| Intermediate - II (6-7) | 102 (54%) |
| High – III (8-9) | 0 (0%) |
| Receptor Status | |
| ER positive (+) | 188 (100%) |
| PR positive (+) | 175 (91%) |
| Her 2 Negative (-) | 188 (0%) |
| Tumor size by ultrasound | |
| (Procedure Day) | |
| Mean (range), mm | Sagittal; 8.5 (2.5 -18) |
| | Transverse; 7.7 (2.8 -17) |

Data is expressed as n (%) unless otherwise specified.

ER estrogen receptor, PR progesterone receptor, HER2 human epidermal growth factor receptor 2

581261 - Intraoperative ketorolac use does not increase the risk of bleeding complications in breast surgery

<u>Thais Fortes</u>¹, Kristin Rojas¹, Peter Flom², Donna-Marie Manasseh¹, Charusheela Andaz¹, Patrick Borgen¹

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Background/Objective: The use of non-steroidal anti-inflammatory drugs (NSAIDs) such as ketorolac has been shown to be an effective adjunct to managing perioperative pain, specifically when part of a multimodal opioid-sparing enhanced recovery after surgery (ERAS) protocol. Furthermore, their ability to temper the systemic inflammation induced by surgery may improve oncologic outcomes. Transient systemic inflammation in surgery could facilitate angiogenesis of dormant micrometastases, proliferation of dormant single cells, and seeding of circulating cancer stem cells, potentially affecting the rate of early relapse. Although a meta-analysis of randomized controlled trials found that postoperative bleeding was not significantly increased with the use of ketorolac, perioperative NSAIDs often elicit strong negative opinions from breast surgeons. We sought to determine if administering intraoperative ketorolac would increase the incidence of bleeding complications in breast surgery.

Methods: A subset analysis of a previously described prospective cohort study including patients undergoing lumpectomy and mastectomy was performed. Patients were divided into 2 groups: those who received intraoperative ketorolac and those who did not. Bleeding complications were defined as severe bruising reported in the medical record or necessitating a call to the on-call physician, or hematoma formation. Bleeding complications were compared between the 2 groups using Fisher's exact test or t-test, and further analyzed with respect to surgical modality. Patients undergoing immediate reconstruction were excluded.

Results: Seven hundred fifty-eight breast surgeries were performed at a single institution in a 13-month period: 156 lumpectomies met inclusion criteria between July 2017 and February 2018; and of 153 mastectomies, 56 met inclusion criteria between September 2017 and August 2018. Two hundred thirteen patients were included in the total cohort: 101 received intravenous intraoperative ketorolac, and 112 did not. The 2 groups were similar in regards to sex, age, race, comorbidities, tobacco use, and proportion with malignant diagnoses. There were more axillary dissections in the group that did not receive ketorolac (n=16 v. n=5, p=0.03). When analyzed together, there was no difference in bleeding complications between the group that received intraoperative ketorolac and those who did not (3% v. 1.8%, p=0.67). There were 3 hematomas, 2 in mastectomy patients who did not receive ketorolac, and 1 in a mastectomy patient who did (1.0% v. 1.8%, p=1.00). All hematomas were managed conservatively, did not result in reoperation, and required blood transfusions. Other complications including seroma formation were not significantly different between the 2 groups, regardless of surgical modality.

Conclusions: In patients undergoing lumpectomy or mastectomy, the rate of bleeding complications including hematoma requiring intervention remained low whether intraoperative ketorolac was used or not. The use of intraoperative ketorolac is a useful adjunct for managing perioperative pain in breast surgery, may improve oncologic outcomes, and does not increase the risk of bleeding.

582157 - Implementing a safe and feasible ambulatory mastectomy program

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Background/Objective: With advances in breast reconstructive techniques, such as intraoperative local analgesia and pre-pectoral breast reconstruction, and the increasing move to bundled health care payment models, the dogma of a mandatory overnight stay for mastectomy deserves reevaluation. The aim of this study is to evaluate the outcomes of ambulatory mastectomy with the hypothesis that ambulatory mastectomy is safe and feasible.

Methods: Institution of an ambulatory mastectomy program in our medical center began in January 2018. A patient care protocol was developed by a team comprising breast and plastic surgery, anesthesiology, and nursing. Patient care guidelines included proper patient selection, setting patient expectations for ambulatory mastectomy at the preoperative consent visit, limiting operative time, intraoperative intravenous fluid and antiemetic recommendations, judicious use of narcotics, addition of intraoperative ketorolac (Toradol) and acetaminophen (Ofirmev), bupivacaine (Exparel) for reconstruction cases, 5-6 hour observation in PACU prior to discharge, arrangement for a post-operative day 1 outpatient visit with the breast or plastic surgeon, and a visiting nurse home visit post-operative day 1 for drain care. Patients with significant medical co-morbidities or expected lengthy procedural times were not eligible. We conducted a retrospective analysis of outcomes from a prospectively maintained database of all patients who underwent intended ambulatory mastectomy.

Results: Twenty-three patients were scheduled for ambulatory mastectomy in the 10-month study period. The majority of patients were discharged on POD 0 (83%); however, 4 patients were admitted for overnight observation (Table). The median age of patients who underwent ambulatory mastectomy was 50 (range 28-78), and the median body mass index was 26 (range 18-37). Eight (36%) patients had neoadjuvant chemotherapy. Nine (39%) patients underwent nipple-sparing mastectomy, and 4 (17%) patients had bilateral mastectomies. Regarding simultaneous axillary procedures, 20 (87%) patients had SLN mapping and biopsy, and 2 (9%) patients underwent axillary lymph node dissections. Nine (39%) patients had pre-pectoral tissue expander reconstruction, and 7 (30%) had retro-pectoral tissue expander reconstruction. There were no readmissions and all of the patients declined the POD 1 outpatient visit.

Conclusions: Ambulatory mastectomy is a safe and viable option for patients who require mastectomy with proper patient selection, institutional guidelines, and patient buy-in. Our patient cohort had no serious complications or need for readmission.

Table: Characteristics and outcomes of ambulatory mastectomies

| | N | % |
|--|----|----|
| Number of patients for planned AM | 23 | |
| | | |
| Neoadjuvant Chemotherapy | 8 | 36 |
| Bilateral Mastectomies | 4 | 17 |
| Sentinel Lymph Node Biopsy | 20 | 87 |
| Axillary Lymph Node Dissection | 2 | 9 |
| | | |
| Type of Breast Reconstruction | | |
| No Reconstruction | 5 | 22 |
| Retro-pectoral Tissue Expander | 7 | 30 |
| Pre-pectoral Tissue Expander | 9 | 39 |
| Pre-pectoral Implant | 1 | 4 |
| Latissimus Flap/Retro-pectoral Implant | 1 | 4 |
| Discharge on POD 0 | 19 | 83 |
| Admitted for overnight observation | 4 | 17 |
| Intraop Instability | 1 | 4 |
| Nausea | 1 | 4 |
| Severe Pain | 1 | 4 |
| Weather/Unsafe Discharge | 1 | 4 |
| Readmissions | 0 | 0 |
| Accepted POD 1 outpatient visit | 0 | 0 |

581186 - Generating awareness among Indian population through survivors: An innovative model for developing countries

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Background/Objective: To validate a new model for population awareness through breast cancer survivors.

Methods: Patients treated for breast cancer were included in the study group (Group A/n=431). An advocacy group called "Disha" (meaning "direction") was formed in collaboration with IPGMER Breast service. The survivors were trained in various performing arts, cancer awareness communication techniques, clinical breast examination, and psychological counselling of the patients undergoing treatment for breast cancer. The survivor-generated mass awareness program using play theatre mode and performing art was implemented. The control group (Group B/n=454) involved awareness generated through didactic lectures by health workers. Both the groups were made to present in the community, which were matched as regards age (Gr A 48 mean age/Gr B 51 years mean age), socioeconomic and educational status. The acceptance of the information by the community in various sub-populations were studied using questionnaires (pre- and post-awareness knowledge level assessment in both groups).

Results: Generation of awareness was more with Gr A both in the short term (44.3% versus 31%) and the long term (91% vs 46%). The significance was marginally more in higher socioeconomic and educated sub-populations, but had poor statistical significance (p=0.981).

Conclusions: The study puts forward the fact that "survivors" are the biggest ambassador for the society. Performing arts/play theatre is an excellent mode of reaching the minds of a population that tends to be in a denial mode about the disease. Not only does this have a major impact on the society, it also helps hugely in the physical and mental rehabilitation of the survivors. It can also create a meaningful social and economic rehabilitation scope for the survivors. This conforms to the WHO principles of early detection of breast cancer through population awareness and emphasizes woman's empowerment. The study could validate the significance of survivors in generating population awareness in India.

580096 - Evolving role of Oncotype DX® following TailoRx

<u>Anjuli Gupta</u>¹, Rachel Greenup², Hannah Williamson², Samantha Thomas², Shelley Hwang² ¹Duke University, Chapel Hill, NC, ²Duke University, Durham, NC

Background/Objective: Results from the TailoRx noninferiority trial demonstrated that women with early-stage, hormone receptor-positive (HR+) breast cancers and midrange Oncotype Dx scores may safely forego chemotherapy. Although these data have the potential to shift use of this assay from a three-tier to binary structure, the recurrence score (RS) cutpoints used in TailoRx did not entirely align with those commonly used in clinical practice. Thus, we sought to determine changes in patient stratification applying the RS ranges used in TailoRx, and to identify factors that are associated with high-risk scores using ranges in traditional clinical practice and outlined in the trial.

Methods: Using the National Cancer Database, we identified women 18-69 years old with clinically node-negative, HR+/HER2- unilateral invasive breast cancers with available recurrence score data from 2010 and 2015. Patients were classified by RS (low, intermediate, high) based on the traditional clinical ranges for Oncotype Dx (0-17, 18-30, 31-100) and compared to cutpoints used in TailoRx (0-10, 11-25, 26-100). Chi-square and t-tests were used to compare study groups on categorical and continuous variables, respectively. Unadjusted survival analyses were performed separately for each categorization of

recurrence risk (Traditional Oncotype and TailoRx ranges). An adjusted survival analysis was performed using a Cox proportional hazards model to assess the impact of Oncotype DX scores on overall survival (OS).

Results: Overall, 91,776 patients were identified, of which 59% (n=54,481) had Oncotype RS of 0-17, 33% (n=30091) 18-30, and 8% (n=7204) 31-100. Of these, 43% (n=39,579) had RS that changed with the application of TailoRx cutpoints. The number of patients with a low RS decreased (59% to 23%), while those with an intermediate or high RS increased (33% to 63%, and 8 to 33%, respectively) [Figure]. Histologically, 79% (n=72469) of patients had ductal cancers, but those with lobular carcinoma were more likely to have low RS (p<0.001). In both traditional clinical and TailoRx trial ranges, increasing tumor grade and T stage were associated with higher RS (p<0.001). Regardless of applied RS cutpoints, women with high RS were more likely to have PR-negative breast cancer than those in the low or intermediate risk groups (p<0.001). When using traditional RS ranges, women with intermediate (18-30) and high (>31-100) RS had lower adjusted OS (1.37 95% CI 1.20 - 1.57, p<0.001; 2.68, 95% CI 2.18 -3.30, p<0.001, respectively). However, application of revised TailoRx RS ranges resulted in similar adjusted OS for those with intermediate RS (11-25) and low RS (0-10) (1.14, CI 95% 0.98-1.32, p=0.07). Not surprisingly, women with traditional clinical high RS (26-100) had a worse adjusted OS (2.14, 95% CI 1.74-2.63, p<0.001) compared to those with a RS <25. Upgrading by application of TailoRx (n =39,579) RS ranges was associated with grade 3 (33% vs 8.1%), PR- (19.8% vs 3.9%), and T2 tumors (23% vs 17%) compared to those with a RS of 11-17.

Conclusions: Application of the TailoRx trial cutpoints resulted in redistribution of RS with reductions in low risk RS and increases in intermediate and high RS. Clinical predictors of high-risk scores persisted across traditional clinical and TailoRx ranges. As the oncology community incorporates these clinical trial data into practice, further investigation is needed to assess predictors of recurrence risk and to guide treatment decisions for women with intermediate RS.

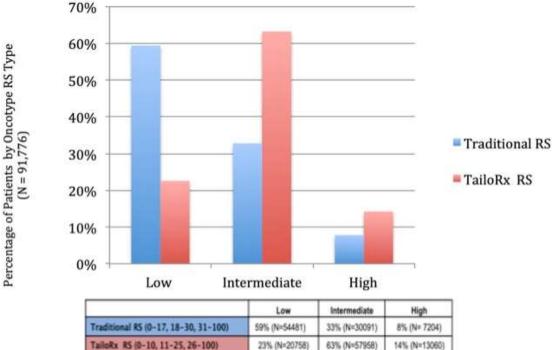


Figure: Redistribution of patients by recurrence score (RS) comparing traditional and TailoRx ranges

581564 - The standardization of outpatient procedure (STOP) narcotics: A prospective health systems intervention to reduce opioid use in ambulatory breast surgery Luke Hartford¹, Julie Ann Van Koughnett², Patrick Murphy², <u>Sarah Knowles</u>², Robin Wigen², Laura Allen², Daryl Gray², Muriel Brackstone², Ken Leslie², Allison Maciver²

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Background/Objective: There has been a 471% increase in the rate of opioid-related overdose deaths in women over the past 15 years. Many surgeons provide opioid prescriptions well in excess of what patients actually use, leading to potential diversion, prolonged use, and opioid dependence. We assessed a health systems intervention to adequately control pain, while reducing opioid prescriptions after ambulatory breast surgery.

Methods: A prospective non-inferiority study examined women aged 18-75 years, undergoing elective, ambulatory breast surgery procedures (lumpectomy or mastectomy, with and without sentinel lymph node biopsy or axillary node dissection). The primary outcome was average pain in the first 7 postoperative days. The Standardization of Outpatient Procedure (STOP) Narcotics was implemented and preintervention and post-intervention groups were compared. This multi-pronged, opioid-sparing strategy consisted of patient education, health care provider education, and intra- and post-operative non-opioid analgesia strategies. Patients completed brief pain inventories at their first postoperative clinic visit. Secondary outcomes included medication utilization (opioids, non-steroidal anti-inflammatories [NSAIDs], and acetaminophen), prescription renewals, and appropriate unused medication disposal.

Results: Average pain in the first 7 postoperative days was non-inferior in the post-intervention group, despite a significant decrease in median oral morphine equivalents prescribed (Table). This remained significant when comparing the extent of breast surgery and axillary procedures. Only 39/89 (44%) of patients filled their opioid prescription in the post-intervention group (p<0.001), and 8/89 (9%) patients reported needing an opioid for additional pain not controlled with acetaminophen and NSAIDs postoperatively. Prescription renewals and appropriate medication disposal rates did not significantly change.

Conclusions: A standardized pain care bundle was effective in minimizing and even eliminating opioid use after elective, ambulatory breast surgery while adequately controlling postoperative pain. The STOP Narcotics initiative minimizes unnecessary and unused opioid medication, with no significant increase in prescription renewals. This initiative provides a framework for future analgesia guidelines in ambulatory breast surgery.

| Primary and Secondary Outcomes | Pre-Intervention N = 85 | Post-Intervention N = 89 | p-value |
|--|----------------------------|-----------------------------|---------|
| Average pain in first 7 post-op days*, mean (SD) | 2.0 (1.8) | 2.1 (1.6) | 0.38 |
| Prescription given | | | |
| OME, median (25th, 75th) | 100 (68-135) | 50 (50-110) | < 0.001 |
| Number of pills, median (25th, 75th) | 25 (15-30) | 10 (10-22) | < 0.001 |
| Prescription renewals, n (%) | 3/64 (5) | 2/39 (5) | 1.0 |
| Appropriate medication disposal, n (%) | 6/64 (9) | 6/39 (15) | 0.09 |

| Tables | Dro intervention | and nost intor | vention comparison | |
|---------|------------------|------------------|--------------------|--|
| I apic. | | and post-milling | venuon comparison | |

* Eleven-point (0-10) numeric rating scale from modified brief pain inventory; OME = oral morphine equivalents; SD = standard deviation

581639 - Identifying practice patterns in the utilization of FDG PET/CT for staging breast cancer patients at a safety net hospital

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Background/Objective: Accurate staging is critical in determining treatment strategies in the management of breast cancer patients. FDG PET/CT has been preferentially used at our institution to evaluate for metastatic disease. FDG PET/CT has been listed as "optional" depending on certain criteria listed in the National Comprehensive Cancer Network (NCCN) Guidelines, and because of this, it has resulted in varying practice patterns of ordering this exam. The preliminary results of a Quality Oncology Practice Initiative (QOPI®) audit performed in our cancer center prompted concern for the over-ordering of FDG PET/CT for breast cancer patients. The goal of this study is to identify practice patterns and determine if our center is overutilizing FDG PET/CT based on the NCCN guidelines with the aim of modifying these practice patterns to reduce the ordering of unnecessary exams.

Methods: We retrospectively reviewed all breast cancer patients with FDG PET/CT ordered for initial treatment strategy between January 2017 to December 2017. The NCCN Guidelines Version 2.2017 was reviewed for the indication of FDG PET/CT in the workup ("optional" was considered an indication). A summary of indications includes the following: Clinical Stage IIIA (T3, N1, M0) - Preoperative systemic therapy; Stage IIA (T2, N0, M0), Stage IIB (T2, N1, M0 or T3, N0, M0), Stage IIIA (T3, N1, M0), Stage IIIA (T0-3, N2, M0), Stage IIIB (T4, N0-2, M0), Stage IIIC (Any T, N3, M0) - Recurrent or Stage IV disease; Clinical pathologic diagnosis of inflammatory breast cancer Stage T4d, N0-3, M0 - After lumpectomy or total mastectomy with surgical axillary staging resulting in greater than or equal to 4 positive axillary lymph nodes. Analysis was performed on characteristics of the entire population. A comparison was then performed between characteristics of those who did and did not meet NCCN indications. P-values were calculated by ANOVA for numerical covariates and Chi-square test or Fisher's exact test for categorical covariates, where appropriate.

Results: A total of 65 female breast cancer patients had an FDG PET/CT ordered for their initial treatment recommendation in 2017. Median age was 58 (range 31-87 years). The majority of patients were African American (81.5%) and had invasive ductal carcinoma (80.0%). Overall, 66.2% (n=43) of patients met NCCN indications while 33.8% (n=22) did not. FDG PET/CT scans that met criteria were more likely ordered for recurrent cancers and patients receiving preoperative chemotherapy (Table). When analyzing within the group that did not meet NCCN indications, 50% of the population had clinically node positive disease while 36.6% were clinically node negative (Table).

Conclusions: Approximately 1/3 of all FDG PET/CT scans ordered for initial staging and treatment guidance were ordered unnecessarily based on NCCN criteria. Practice patterns indicate that physicians were more apt to order a FDG PET/CT if the patient had a positive clinical nodal status, despite not in itself an indication to order the study. While our study is limited by a small sample size, it identifies a practice pattern possibly based on subjective rather than objective criteria. In an effort to apply a more uniform approach to the utilization of FDG PET/CT, our center has created a checklist of NCCN criteria to be reviewed during weekly multidisciplinary conference. We recommend that other institutions perform a similar evaluation and approach to minimize the ordering of unnecessary FDG PET/CT exams.

| ble: Met NCCN indications for PET | | | |
|-----------------------------------|------------|-----------|---------|
| | Yes (%) | No (%) | P-value |
| Recurrent Cancer | 11 (25.6) | 0 (0) | 0.011 |
| Not Recurrent Cancer | 32 (74.4) | 22 (100) | |
| | | | |
| Preoperative Systemic Therapy | 36 (83.7) | 8 (36.4) | <.001 |
| No Preoperative Systemic Therapy | 7 (16.3) | 14 (63.6) | |
| Clinically Node Positive | 24 (55.8) | 11 (50) | 0.510 |
| Clinically Node Negative | 17 (39.53) | 8 (36.6) | |
| Unknown | 2 (4.65) | 3 (13.64) | |
| | | | |

578105 – Five years of a successful peer mentor survivor program Dona Hobart¹, Marcia McMullin²

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Background/Objective: In August of 2013, a group of breast cancer survivors participated in a patient focus group exploring what services they would most benefit from. There was an overwhelming request for a program that would connect them with someone who had experienced breast cancer. Embrace Peer is a free, HIPAA-compliant, volunteer-run program connecting breast cancer survivors. This is a 5-year review of our data.

Methods: The program was formally started in the spring of 2014. We had no budget with which to create the program. We therefore initially utilized Google Docs, which is free and was approved by our legal as well as information technology department. Subsequently, we migrated to using OneDrive, as our hospital system had moved to Microsoft 365 for security purposes. The program was initially designed to simply provide a means of support to relieve stress, loneliness, and fear in our newly diagnosed breast cancer patients by providing them with a companion. Recruitment for both patients as well as mentors is coordinated through our breast health navigator and providers. Training for mentors is held biannually, and all previous mentors are invited to return. Training includes education on documentation, software, communication skills, as well other pertinent topics. Support for current mentors is now also provided. Additionally, we now also include a short interview with our breast health navigator in order to complete

the application process to become a mentor. This was added several years after the initiation of the program.

Results: Initially, we had 21 active mentors who completed 375 contacts (text, phone call, or in person). Currently, 52 have gone through mentor training. More than 100 patients have participated since the inception of the program. In all, 744 contacts have been documented in 5 years. (These data will be updated at the time of presentation. Additional training will occur in November 2018, and true 5-year numbers will be available after that.) There have been several unanticipated consequences of the program. The support that occurs mentor to mentor has been rated as very valuable by most participants. Additionally, a core group of mentors had been engaged in support of the overall survivor program. They have raised more than \$30,000 in support of this and other programs including a yearly overnight retreat for breast cancer survivors.

Conclusions: Embrace Peer is a foundational survivor program that fostered a community within our breast cancer survivors. Not only have the mentees benefited, but additionally, mentors express value in program participation. Such program strength from a biannual dinner meeting was an unanticipated but positive outcome. This low-cost program has enabled the continuation of other programs in support of breast cancer survivors. This is been accomplished through the sense of community and personal responsibility taken on by our mentors.

581670 - Understanding the biology of occult breast cancer: Examination of 31 cases finds aggressive behavior

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Background/Objective: Occult primary breast cancer is rare, and its biological behavior is not well known. The objective of this study was to evaluate clinical and pathological characteristics of occult breast cancer.

Methods: A prospective database of a large integrated health care system was reviewed to identify all patients diagnosed with occult breast cancer from 2008 through 2017. Occult breast cancer was defined as non-palpable, pathologically confirmed, primary breast cancer not detected on any of the imaging modalities, including ultrasound, mammography, and magnetic resonance (MR). Patient and tumor characteristics were evaluated. Histology slides were reviewed by a pathologist retrospectively.

Results: Of 31 patients with occult breast cancer, all were female, and mean age at diagnosis was 61 years old (range 44-83). All patients had mammography, 25 had ultrasound, and 17 had MR. Only 1 patient had extremely dense breast tissue on mammogram. Primary breast cancer site was not seen in any of the patients with any imaging modality. Clinical stage was IIA-IIIC in 71.0%, and 29.0% of patients presented with Stage IV disease. Twenty-three patients (74.2%) presented with lymph node metastases, 3 (9.7%) with bone metastases, 2 (6.5%) with metastasis to the orbit, 1 (3.2%) with liver metastases, 1 (3.2%) with lung metastases, and 1 (3.2%) with brain metastases. Nine patients (29.0%) had mastectomy, and 22 (71.0%) had lymph node dissection. Lumpectomy was performed in 2 (6.5%) patients, 1 for a mass identified intraoperatively, and the other based on imaging; however, both were negative for malignancy. Following lymphadenectomy, 15 (68.2%) had 1-3 positive nodes, 3 (13.6%) had 4-9 positive nodes, and 4 (18.2%) had 10 or more positive nodes. Mastectomy did not reveal a primary site in any of the 9 mastectomy patients. Of those who underwent non-surgical therapy, 12 (38.7%) had whole breast radiation, and 7 (22.6%) had axillary radiation. Twenty-eight patients (90.3%) underwent chemotherapy,

and 23 (74.2%) had hormone therapy. On pathological review, the majority of cases were invasive ductal carcinomas, and only 6 cases (19.4%) were invasive lobular carcinomas. The most common breast profile was ER+, PR+, HER2-, followed by ER+, PR+, HER2+, and triple-negative breast cancer. Nineteen cases (61.3%) were grade 3, 10 (32.3%) were grade 2, and 2 (6.5%) were grade 1 carcinomas.

Conclusions: Historically, occult breast cancer was considered to have low morbidity. In this study, we found that despite a favorable molecular receptor profile, approximately 60% patients had high-grade cancer, one-third of patients had N2-N3 disease, and one-third presented with distant metastatic disease, with metastasis to the bone, lung, liver, orbit, and the brain. Multicenter studies would further our understanding of occult breast cancer.

581779 - Single surgeon vs co-surgeon bilateral mastectomy: A comparison of operative times, postoperative nausea, narcotic usage, and length of stay

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Background/Objective: Longer operative times are associated with an increased risk of complications. In 2013, we introduced a co-surgeon technique for bilateral mastectomy to decrease operative times. Previous studies show that a co-surgeon technique for bilateral mastectomy decreases operative times without an increase in complications. Whether shorter operative times for bilateral mastectomy is associated with improved outcomes related to postoperative nausea, narcotic requirements, and length of stay (LOS) is unclear. We hypothesized that patients undergoing bilateral mastectomy with a co-surgeon technique have shorter operative times, less postoperative nausea, require fewer narcotic doses, and have a shorter LOS compared with a single surgeon technique.

Methods: A retrospective review of 410 patients undergoing bilateral mastectomy was performed from January 2010 through April 2016. Analyses were stratified by surgery with and without reconstruction. Total operative and mastectomy-only times were included. Number of postoperative anti-nausea and narcotic doses, and LOS were compared between single-surgeon vs co-surgeon groups. Statistical analyses included Wilcoxon tests, Poisson regression, and generalized linear models. Multivariate analysis included operative time, BMI, age, nodal surgery type, reconstruction type, and oncologic vs prophylactic surgery.

Results: Of 410 patients undergoing bilateral mastectomy, 311 (76%) had immediate reconstruction; 99 (24%) did not. Total operative time for single vs co-surgeon technique with reconstruction was 495 minutes vs 429 minutes (p=.005). Total operative time for single vs co-surgeon technique without reconstruction was 248 minutes vs 247 minutes (p=.86); however, univariate analysis showed that BMI was significantly higher in the co-surgeon group. For the reconstruction group, the average LOS for single vs co-surgeon technique was 2.7 days vs 2.1 days (p<.001). For the no reconstruction group, the average LOS for single vs co-surgeon technique was 1.8 days vs 1.1 days (p<.001). For the reconstruction group, the total number of narcotic doses for the surgeon vs co-surgeon technique was 10.6 vs 8.4 (p=.016). For the no reconstruction group, the total number of narcotic doses for the surgeon vs co-surgeon technique was 10.6 vs 8.4 (p=.016). For the no reconstruction group, the total number of narcotic doses for the surgeon vs co-surgeon technique was 10.6 vs 8.4 (p=.016). For the no reconstruction group, the total number of narcotic doses for the single vs co-surgeon technique was 7.0 vs 6.3 (p=.013). On multivariate analysis, this remained statistically significant for the reconstruction group with a co-surgeon technique. For the no reconstruction group, the total number of anti-nausea doses for the single vs co-surgeon technique was 2.0 vs 2.1 (p=.04). However, this did not remain significant in the multivariate analysis. In the reconstruction group, a co-surgeon technique was

associated with decreased operative times, shorter LOS, and fewer narcotic doses on multivariate analysis controlling for age, BMI, nodal surgery, type of reconstruction, and oncologic and prophylactic mastectomies.

Conclusions: For patients undergoing bilateral mastectomy with reconstruction, a co-surgeon technique was associated with decreased operative times, less narcotic use, and shorter LOS. We suggest considering a co-surgeon technique when performing a bilateral mastectomy, particularly with immediate reconstruction. An economic analysis to compare differences in costs and value for single surgeon vs co-surgeon technique may be warranted.

| | No Reconstruction (n=99) | | | Reconstructive Surgery (n=311) | | |
|---|--------------------------|----------------------|---------|--------------------------------|----------------------|---------|
| | 1 Surgeon (n=84) | 2 Surgeons (n=15) | P value | 1 Surgeon (n=244) | 2 Surgeons (n=67) | P value |
| Mastectomy Surgery Time* | 205.4 +/- 51.9 | 209.2 +/- 60.8 | 0.91 | 177.4 +/- 117.4 | 137.8 +/- 100.3 | <.001 |
| Total Surgery Time* | 248.0 +/- 55.4 | 246.9 +/- 62.6 | 0.86 | 495.0 +/- 190.5 | 428.7 +/- 160.8 | 0.005 |
| Length of Stay* | 1.8 +/- 0.9 | 1.1 +/- 0.3 | <.001 | 2.7 +/- 1.6 | 2.1 +/- 1.6 | <.001 |
| Age* | 53.8 +/- 12.0 | 54.3 +/- 12.7 | 0.89 | 47.2 +/- 8.8 | 46.0 +/- 10.1 | 0.35 |
| BMI** | 28.3 +/- 5.9 | 32.2 +/- 7.5 | 0.03 | 25.8 +/- 6.0 | 26.2 +/- 5.3 | 0.64 |
| Doses of Anti-Nausea Medication Post-Op – 12 hours*** | 1.3 +/- 1.3 | 0.9 +/- 1.4 | 0.29 | 1.0 +/- 1.3 | 0.9 +/- 1.2 | 0.64 |
| Doses of Anti-Nausea Medication Post-Op – Total*** | 1.8 +/- 1.9 | 1.1 +/- 1.6 | 0.21 | 2.0 +/- 2.3 | 2.1 +/- 3.1 | 0.04 |
| Doses of Narcotic Medication Post-Op – 12 hours*** | 3.1 +/- 2.3 | 4.3 +/- 1.8 | 0.03 | 3.4 +/- 2.4 | 3.1 +/- 2.1 | 0.22 |
| Doses of Narcotic Medication Post-Op – Total*** | 7.0 +/- 6.0 | 6.27 +/- 2.5 | 0.013 | 10.6 +/- 8.4 | 8.4 +/- 7.2 | 0.016 |

Table: Bilateral mastectomy: patients without reconstruction vs immediate reconstruction, descriptive and univariate analyses

* Wilcoxon Rank Test **Generalized linear model ***Poisson regression, controlled for Length of Stay for the Total Dose analysis.

580700 - Limiting narcotics for breast cancer patients: A prospective study

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Background/Objective: The opioid crisis is in part the result of poor pain control practices across the United States, yet great variation exists among providers regarding perioperative pain management for ambulatory procedures. A multimodal approach is effective in lowering the narcotic requirement postoperatively. In an academic practice of 4 breast surgeons, 1 surgeon elected to employ patient education and resident education to reduce opioid prescriptions for postoperative pain control.

Methods: A prospectively maintained database included all ambulatory patients of a single breast surgeon from August 2017 to July 2018. Patients underwent ambulatory breast surgical procedures under conscious sedation and were educated beforehand, prescribed a regimen of 0-15 narcotic tablets based on

extent of surgery, and given a standard dose of preemptive local anesthesia. In contrast, the standard practice of the group was continued for all other patients, which included education related to the surgery and a standard narcotic prescription. All residents involved were educated and instructed to employ the limited narcotic protocol for the index surgeon's patients. The patients were followed closely with telephone interviews and office visits to determine if their pain was well controlled or if they required an additional prescription.

Results: A total of 157 patients participated in this study. The mean age was 50.7 +/- 19.6 years. 61.1% underwent unilateral lumpectomy without sentinel lymph node biopsy. On postoperative day 1, of the 89 (57.4%) patients who responded, 77 patients (86.5%) reported minimal or no pain. The remainder of the patients were followed up in person within 1 week, and 100% reported their pain was well controlled. Patients were prescribed on average 5.7 narcotic tablets (Table). Thirty-nine (24.8%) patients received no narcotics. No patients called or presented to the emergency department for additional narcotic prescriptions.

Conclusions: Postoperative pain control can be optimized with a combination of preoperative patient education, resident instruction on the use of a pain control regimen, and limited narcotic prescriptions. The current study demonstrates that with this protocol, ambulatory breast surgery patients can be effectively managed with limited opioids, which may reduce over prescription of narcotic medications.

| Procedure Type | Number of Patients (%) | Average # tablets prescribed |
|--|------------------------|------------------------------|
| | | (mean +/- SD) |
| Unilateral lumpectomy | 96 (61.1) | 4.7 +/- 4.2 |
| Unilateral lumpectomy with sentinel | 46 (29.3) | 7.3 +/- 4.8 |
| lymph node biopsy | | |
| Bilateral lumpectomy | 4 (2.5) | 5 +/- 5.8 |
| Bilateral lumpectomy with sentinel lymph | 3 (1.9) | 13.3 +/- 2.9 |
| node biopsy | | |
| Other | 8 (5.1) | 6.9 +/- 2.6 |
| p value | | 0.005 |

Table: Procedure distribution and narcotics prescribed

581689 - A European Union approach to harmonizing and quality improvement of breast cancer care

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Background/Objective: In 2004, the European Parliament passed a resolution stating that any EU citizen diagnosed with breast cancer could obtain treatment at any other EU State. Thereafter, it became clear that the level of breast cancer care was quite uneven throughout the EU. A resolution was passed that a quality program be developed over 3 years that could be voluntarily engaged by the EU States. There existed European Guidelines for breast cancer screening and diagnosis, but there were none for breast cancer treatment services. This 3-year program will be completed in early 2019, which this report will cover.

Methods: The European Commission Initiative on Breast Cancer (ECIBC) requested expert and lay volunteers to participate in the 2 committees: the Guidelines Development Group (GDG) and the Quality Assurance Scheme Development Group (QASDG). The GDG would write an updated version of the existing screening and diagnosis guidelines, while the QASDG would develop a scheme including quality metrics for the remainder of the breast cancer journey after diagnosis. Meetings were held 3 times per

year at the Joint Research Centre (JRC) premesis in Ispra, Italy starting in 2015. Each committee had just over 30 people on them, including physicians, nurses, administrators, and other clinicians, lay representatives, and administrators of the JRC. Each committee developed research questions (PICO), which were sent to external sources for research and answers in a very structured manner. When quality measures were considered, a durable Delphi method of assessment was utilized to make final determinations as to value of any particular quality metric. Dr. Kaufman was the only American on the 32-member QASDG committee.

Results: The program is at its last 2 meetings, ending in February 2019. At this time, the draft of the breast cancer journey has been determined. Multiple quality potentials were identified and many have been accepted (see https://ecibc.jrc.ec.europa.eu/). Each quality indicator has been vetted via Delphi Rounds. The GDG has established several quality guidelines, which include age-appropriate screening advice as well as diagnostic guidelines. The full extent of their results will be forthcoming 3 months from this writing. The QASDG has a 3-pronged effort. They first collected data on requirements and care processes. Thereafter, in Delphi rounds, the requirements/indicators were either voted in or out. Thereafter, pilot testing of quality indicators will be performed. There were about 62 quality indicators agreed upon. The QASDG identified some indicators for surgical care. Breast centers should have at least 2 surgeons. All surgeons should care for at least 50 new breast cancer patients per year. The full complement of support services should be available at breast centers including breast care nurse (navigators) as well as psychosocial support (psycho-oncologist). Multiple members of the breast center are identified to be available on a regular basis. We hope to update this poster after the February completion of this 3-year program.

Conclusions: The European Committee has developed a mature program of screening and diagnostic guidelines as well as a structured quality assurance scheme with multiple quality indicators along the breast care journey. It is expected that multiple EU states will endorse and incorporate the ECIBC set of guidelines that will give harmony to the EU breast cancer treatment system.

580463 - Comparison of normal ultrasonographic findings of most commonly used textured breast implants in Korea

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Background/Objective: The number of breast augmentation using implants increases every year in Korea. The eight company implants were approved by Ministry of Food and Drug Safety (MFDS); Allergan, Bellagel, Eurosilicone, Mentor, Motiva, Sebbin, Silimed, Polytech (in alphabetical order). The purpose of this study is to understand and compare the normal ultrasonographic (US) findings of textured implants used in Korea.

Methods: We retrospectively reviewed US images from 3 different plastic surgery clinics. A total of 1532 women with intact implants without implant-related complication were included between 2016, September to 2018, September. The US study was done with Philips HD15 machine, Philips iU22 machine, and Samsung 70 machine with high-frequency linear probe.

Results: By US, Allergan shell had a total thickness of 1.4~1.6mm with 2 thin hyperechoic lines, each line about 0.5 to 0.6m. Bellagel microtexture shell had a total thickness of 0.9-1.1mm with 3 thin hyperechoic lines, each line about 0.2~0.3mm equally. Eurosilicone shell had a total thickness of 1.0~1.4mm with 2 thin hyperechoic lines in parallel, each line about 0.3~0.4mm. Mentor shell had a total

thickness of 1.0-1.2 mm with 2 thin hyperechoic lines, each line ranged 0.3 to 0.5mm. Motiva shell had a total thickness of 0.9-1.1 mm with 3 thin hyperechoic lines, each line about 0.2-0.3mm equally. Sebbin shell had a total thickness of 1.2-1.4 mm with 3 thin hyperechoic lines (2nd hyperecoic line slightly thicker than first & third line. Silimed shell had as a total thickness of 1.2-1.4 mm with outer line, which is 1 thin hyperechoic line range 0.2 to 0.3mm and inner line just below outer line, with a less hyperechoic line about $0.1 \sim 0.2$ mm. Polytech shell had a total thickness of 1.1~1.3 mm with 2 thin hyperechoic lines (0.4~0.6mm), which were nearly attached.

Conclusions: We compared the normal US findings of different implants that are most commonly used in Korea. By comparing the characteristics of the implant US finding at inserted state, each company's product was found with unique characteristics. Surgeons should be aware by knowing the normal shell seen from US is important to understand the implant-related complications. Further breast implant studies may benefit breast implant US findings

576195 - Outpatient surgery for breast cancer: Experience and outcome in 425 consecutive patients in a private breast clinic

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Background/Objective: Although advances in surgical and anesthetic techniques for breast cancer surgery have made it possible to treat breast cancer patients in outpatient settings, outpatient surgery for breast cancer is not yet common in Japan. The use of local anesthesia and intravenous sedation is a less immunosuppressive anesthetic technique and may contribute to a decrease in disease recurrence following surgical treatment in terms of the relationship between anesthetic technique and cancer recurrence. Here, we aimed to evaluate the feasibility, safety, efficacy, and surgical outcomes of outpatient surgery in breast cancer patients in a private breast clinic.

Methods: From May 2008 to September 2018, 425 consecutive patients with Stage 0–III breast cancer underwent breast-conserving surgery/axillar lymph node (ALN) management using local anesthesia and intravenous sedation or a combination with pethidine or an opioid receptor (OR) partial agonist. In principle, all patients received standard adjuvant chemotherapy and/or endocrine therapy, and postoperative radiotherapy after surgery. Retrospective evaluation of the patient outcome was performed.

Results: The clinical characteristics of the patients were as follows: Stage: 19 Stage 0 (4.4%), 231 Stage I (54.3%), 153 Stage II (36.0%), 22 Stage III (5.1%); tumor subtype: 302 luminal (L) type (71.0%), 45 L-HER2 (10.5%), 9 HER2 (2.1%), 16 triple-negative (TN) (3.7%); surgical procedure: partial resection (Bp)/sentinel lymph node biopsy (SNB) for 327 patients (76.9%), Bp/SNB/axillary lymph node dissection (Ax) for 28 patients (6.5%), Bp/Ax for 49 patients (11.5%), others for 21 patients (4.9%); frequently used anesthetic technique: lidocaine/propofol/midazolam and OR partial agonist or pethidine for 157 patients (36.9%), lidocaine/diazepam/midazolam and pethidine for 102 patients (24.0%), lidocaine/propofol and pethidine for 94 patients (22.1%). Sixty-five patients (15.2%) received neoadjuvant chemotherapy. All patients were able to go home after resting for 3-4 hours following surgery, and none of the patients revisited the clinic due to any complications. There were no deaths or severe intraoperative complications. In the postoperative period, 47 complications (11.0%) were observed: 11 wound infections, 3 cases of hematoma, and 33 axillary lymphoceles. The median follow-up period was 1,924 days (range: 28–3,775 days). Disease recurrence was observed in 21 patients (4.9%) during this time. The overall survival rate

was 96.3%, and the survival rates for each stage were 97.4% for Stage 0, 96.6% for Stage I, 95.9% for Stage II, and 85.7% for Stage III. The survival rates for tumor subtype were 97.0% for L type, 96.1% for L-HRE2, 80.0% for HER2, and 72.0% for TN breast cancer.

Conclusions: Outpatient surgery was well tolerated, feasible, and safe in patients with breast cancer receiving breast-conserving surgery/ALN management, and did not increase the risk of complications. Given that disease recurrence was lower than with general anesthesia, patients receiving local anesthesia/anesthetic sedation in an outpatient setting may benefit from reduced cancer recurrence and lower cancer-related mortality by avoiding general anesthesia/opioid-induced immunosuppression in the perioperative period.

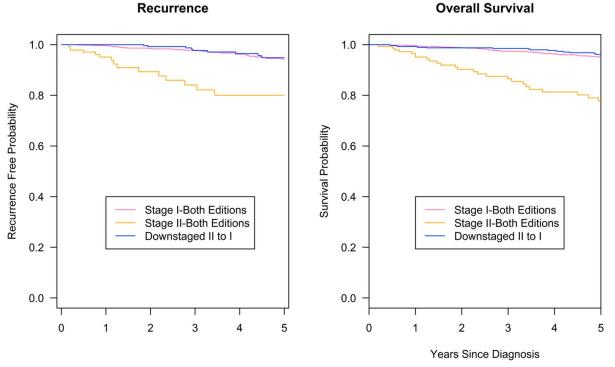
581811 - Re-classification with the AJCC 8th edition staging system improves outcome prediction for patients with anatomic Stage II disease and favorable tumor biology <u>Amanda Kupstas</u>, Tanya Hoskin, Judy Boughey *The Mayo Clinic, Rochester, MN*

Background/Objective: A clear staging system for breast cancer is imperative to inform prognosis and treatment. The AJCC 8th edition staging system for breast cancer has incorporated biologic factors known to have a predictive and prognostic value. This revised staging system results in stage reassignment for a significant portion of patients. The goal of this study was to analyze the 8th edition staging system and compare its performance relative to the 7th edition in a contemporary cohort of patients at our institution.

Methods: After IRB approval, we identified all patients with unilateral, non-metastatic breast cancer without prior history of breast cancer, and who did not undergo neoadjuvant systemic therapy from 2008-2017 using a prospectively maintained surgical database. Retrospective review of the electronic medical record was utilized to obtain information on patient, tumor, treatment, recurrence, and survival factors. Pathologic stage was calculated for individual patients both using AJCC 7th edition anatomic staging and AJCC 8th prognostic staging. The two staging systems were analyzed with respect to the endpoints of recurrence and overall survival using the Kaplan-Meier method and log-rank tests.

Results: Among 3554 patients undergoing primary surgery with all data necessary to calculate the 8th edition pathologic prognostic stage, the distribution of 7th edition anatomic staging was 867 (24%) Stage 0, 1774 (50%) Stage I, 748 (21%) Stage II, and 165 (5%) Stage III and of the 8th edition prognostic staging was 867 (24%) Stage 0, 2438 (69%) Stage I, 168 (5%) Stage II, and 81 (2%) Stage III. In the 8th edition staging system, only 12 (0.3%) of patients were reclassified to a higher numeric stage (Stage II to Stage III), but 681 (19%) were re-classified to a lower numeric stage. Most of these were accounted for by 7th edition anatomic Stage II patients, where 585/748 (78%) were reclassified as 8th edition prognostic Stage I (397 IA, 188 IB). Also, 96/165 (58%) 7th edition Stage III patients were re-classified to a lower stage in the 8th edition prognostic staging system (79 to IB, 6 to IIA, 11 to IIB). Among the 585 patients re-classified from 7th edition anatomic Stage II to 8th edition prognostic Stage I, most (92%) were HR+/HER2-, while 7% were HER2+ and <1% had TNBC; 267 (46%) were pN1. With respect to outcomes, patients reclassified from 7th edition Stage II to 8th edition prognostic Stage I were very similar to 7th edition Stage I patients with respect to recurrence (94.9% vs 94.2% recurrence free at 5 years, p=0.60) and overall survival (96.1% vs 95.1% at 5 years, p=0.14) and distinctly different from 7th edition Stage II patients who remained 8th edition prognostic Stage II in the new system (80% recurrence free and 78% surviving at 5 years, p<0.001 for both outcomes), see Figure. Recurrence and overall survival did not differ significantly between pN0 and pN+ in 7th edition anatomic Stage II patients reclassified to 8th edition prognostic Stage I (p=0.33 and p=0.93, respectively).

Conclusions: The new AJCC 8th edition prognostic staging reassigned a substantial number of patients relative to their 7th edition stage. The 8th edition prognostic staging system more accurately predicted outcomes in this cohort than the 7th edition. Further work is needed to evaluate the patients who were treated with neoadjuvant chemotherapy, which was not assessed in this study.



Figures: Outcomes in patients with Stage 1 and 2 breast cancer according to the AJCC 8th edition prognostic vs. 7th edition anatomic staging systems

581556 - Predictors of axillary node response in clinically node-positive patients undergoing neoadjuvant chemotherapy for breast cancer

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Background/Objective: Neoadjuvant therapy for locally advanced, node-positive breast cancer can result in conversion to node-negative disease and can potentially spare women the morbidity associated with axillary lymph node dissection. There is an increasing body of evidence describing factors associated with pathologic complete response (pCR). Based on studies to date, we hypothesize that (in order of importance) hormone receptor status, initial size of tumor, number of involved nodes at diagnosis, and tumor grade will be predictive of pCR.

Methods: Patients aged 18 and older, with clinical T1–4, N1-2, M0 breast cancer who received neoadjuvant chemotherapy followed by axillary lymph node dissection between 2004 and 2016 at the Misericordia Hospital, in Edmonton Alberta were identified from a prospectively maintained database. Using a combination of synoptic reporting, pathology reports, IMPAX and chart review, we collected patient demographics, nodal imaging pre- and post-neoadjuvant, initial tumor size as calculated based on MRI, US and/or mammography, final tumor size prior to surgery, final size on pathology, tumor type,

initial tumor grade, ER/PR/HER2 status, and type of adjuvant treatment. Our primary outcome of interest was axillary pathologic complete response following neoadjuvant chemotherapy, defined as no evidence of residual tumor in the axillary lymph nodes. Data were summarized using descriptive statistics. Associations between clinical/tumor characteristics and pCR were characterized using univariate analysis. Purposeful selection, using a combination of variables found to be statistically significant in the univariate analysis and factors with established clinical relevance, were used to create a multivariate regression model. Discrimination of the model was estimated using area under the curve of the receiver operator curve. A goodness of fit test was performed using the Hosmer-Lemeshow test. All statistical analyses were performed using STATA 15.

Results: A total of 517 patients underwent neoadjuvant chemotherapy and axillary lymph node dissection for node-positive breast cancer during the 12-year study period. Of these, 183 were excluded based on the presence of recurrent or metastatic disease, prior axillary lymph node surgery or missing information. Among the remaining 334 patients, pathologic complete response was achieved in 130 patients, in which approximately half demonstrated minimal (few scattered neoplastic cells) or no tumor burden remaining (invasive or in-situ).

Conclusions: In this large, single-centre, prospective cohort study, we demonstrate that more than a third of patients with node-positive breast cancer achieve pCR following neoadjuvant chemotherapy and in more than half of these patients, the residual tumor burden is either minimal or absent based on postoperative pathology. Subgroup analysis to establish predictive factors for axillary node response is ongoing. Our findings so far certainly challenge current practice guidelines that uniformly recommend axillary lymph node dissection for all women with node-positive breast cancer after neoadjuvant chemotherapy. An understanding of tumor and patient factors that predict pCR can spare women the morbidity associated with axillary lymph node dissection without compromising oncologic outcomes. Patients can also be specifically selected for neoadjuvant systemic treatment based on those factors found to best predict axillary response. Conversely, patients can be advised to undergo surgery first if their tumour does not exhibit these same predictive factors. Present studies, including this one, are limited by their observational study designs and short-term follow-up periods. A randomized control trial that takes into account consistently identified positive predictor factors in their patient selection and enables long term follow-up can (1) provide the robust evidence needed to put the findings of this study into clinical practice and (2) ensure recurrence rates and overall survival are not impacted by limiting the use of axillary lymph node dissection to high-risk patients only.

581883 - Application of a mind-body tool in a rural population to improve post-operative outcomes in women with breast cancer: A pilot study

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Background/Objective: Breast cancer is the most common cancer affecting women in the United States. While current breast cancer treatments are increasingly effective at improving survival, they can be associated with short- and long-term physiologic and psychologic effects that diminish quality of life, such as pain and insomnia. Mindfulness-based training programs are low-cost interventions that have been shown to improve quality of life and stress-related physiological effects. The aim of this study was to evaluate a well validated mind-body program – determining its feasibility, acceptability, and improvement in postoperative breast cancer patients in a rural setting.

Methods: Patients were recruited in the surgical clinic during routine post-op visits following either mastectomy or lumpectomy for breast cancer. Each participant completed a set of 3 surveys before and after the intervention: (PROMIS-29 (Physical Function, Anxiety, Depression, Fatigue, Sleep Disturbance, Ability to Participate in Social Roles and Activities, Pain Interference, Pain Intensity), PROMIS – Global QOL, and MAAS (Mindfulness Attention Awareness Scale). The intervention was an 8-week course: "The Stress Management and Resiliency Training (SMART) - Relaxation Response and Resiliency Program (3RP)," which has been well validated for the treatment of a wide variety of clinical problems. Feasibility, acceptability, quantitative survey data, and demographics were analyzed.

Results: Course acceptability was high with >80% completion rate. We identified barriers to recruitment with 23% of invited patients enrolling in the course, although >70% of patients approached (34/48) expressed interest. The chief limiting factor in enrollment was scheduling. Due to available staffing, the class was only offered on 1 day of the week, and the maximum number of participants was 15 due to course design. Despite the rural setting, distance to the hospital did not impact enrollment. Survey compliance was 100% for all instruments. There was a significant improvement in sleep (p=.046) and anxiety/depression (p=.048) after course completion, as well as trends in improvement in other aspects of QOL (see Table).

Conclusions: The intervention was found to be highly acceptable in our study population. Our main barrier in feasibility was course availability as we were only able to offer 1 course on 1 day of the week over an 8-week period. Even with our small sample size, the ability to show statistically significant improvement in certain QOL measures implies that the intervention is effective and beneficial in this population. This small pilot study identified barriers to feasibility, showed excellent acceptability, and demonstrated a preliminary benefit from the 3RP intervention in post-operative breast cancer patients. A larger inquiry with a randomized control trial is warranted.

| Survey | Category | Question Stem | P-value |
|------------------------|-------------------|--|---------|
| PROMIS v.1.1 – Global | Global 10 | How often have you been bothered by emotional problems such as feeling anxious, depressed, or irritable? | p=.0476 |
| Day to Day experiences | | I rush through activities without being really attentive to them. | p=.0776 |
| | | I drive places on 'automatic pilot' and then wonder why I went there. | p=.1485 |
| PROMIS-29 Profile v2.0 | Anxiety | In the past 7 days, I felt fearful. | p=.1611 |
| | | In the past 7 days, I found it hard to focus on anything other than my anxiety. | p=.1477 |
| | | In the past 7 days, my worries overwhelmed me. | p=.1565 |
| | Depression | In the past 7 days, I felt helpless. | p=.1668 |
| | Fatigue | During the past 7 days, I feel fatigued. | p=.1277 |
| | Sleep Disturbance | In the past 7 days, I had a problem with my sleep? | p=.046 |
| | | In the past 7 days, my sleep quality was. | p=.0725 |
| | | In the past 7 days, my sleep was refreshing. | p=.0974 |
| | Social | I have trouble doing all of my regular leisure activities with others. | p=.1635 |
| | Pain Interference | In the past 7 days, how much did pain interfere with work around the home? | p=.1508 |
| | | In the past 7 days, how much did pain interfere with your household chores? | p=.1112 |

Table:

581607 - Flat epithelial atypia identified on core needle biopsy does not require excision

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Background/Objective: The management of flat epithelial atypia (FEA) of the breast identified on core needle biopsy (CNB) has evolved and routine excision of FEA is being questioned. However, it is recognized that CNB may under sample an area of abnormality, and upstage rates to malignancy following excision of FEA on CNB have been reported in literature between 4-30%. Review of upstage to malignancy of pure FEA in our area demonstrated a low upstage to malignancy, and in 2012, a policy of selective excision of FEA was adopted. The purpose of this study was to evaluate the upstage rates of CNB diagnosed FEA from diagnostic centers across our region following this change, to identify factors predictive of malignancy, and to identify a group of patients at low risk of malignancy.

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 FEA identified on CNB between 2013 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, type of CNB, and associated histology, with upstage to cancer was evaluated.

Results: A total of 1986 patients having surgery for high-risk lesions were identified, with 187 having CNB diagnosis of FEA. Of these FEA cases, 89 were pure FEA, 71 were with concurrent atypical ductal hyperplasia (ADH), 6 with complex sclerosing lesion/radial scar, 9 with atypical lobular hyperplasia (ALH), 5 with lobular carcinoma in-situ (LCIS), 5 with papillary neoplasm (PN), and 2 with fibroadenoma. In total, 9 patients were upstaged to malignancy (4.8%), with 8 having concurrent ADH (2 invasive ductal carcinoma, 6 DCIS), and 1 with concurrent complex sclerosing lesion (1 DCIS). (Table). Compared to pure FEA, FEA with associated ADH or complex sclerosing lesion showed a significantly higher rate of upstaging (p=0.001, p=0.0001 respectively). The 8 patients with FEA and ADH that upstaged to cancer ranged in age from 42 to 66 years. Lesions ranged in size from 2-70mm. Two patients had only focal ADH on core biopsy. Further analysis of the pure FEA revealed that 68 patients presented with an image detected abnormality and the remainder with breast symptoms (mass 8, pain 4, not specified 9). The age of these patients ranged from 31 to 85 years old, with a mean age of 52 years. Observing the largest size of the lesion detected on either mammography, ultrasound, or MRI, the imaging size ranged from 2 to 45mm, with an average size of 13.2mm. Seventy-three percent of core biopsies were performed with stereotactic technique, while 12% were ultrasound-guided biopsies, and in 9%, the biopsy type was unknown.

Conclusions: The upstage rate to malignancy after excision of pure FEA at our center is 0%. Therefore, we now recommend that pure FEA with radiology and pathology concordance does not require surgical excision and can instead be followed with serial imaging. Additionally, patients with FEA in association with other high-risk lesions, should be managed as per indicated for the other high-risk lesion, due the variable associated upstage rates. We recommend excision of FEA with ADH.

| CNB Diagnosis | Number of cases | Number of upstages | Percentage of upstages (%) |
|---|-----------------|--------------------|-------------------------------|
| Pure FEA | 89 | 0 | 0 |
| FEA + ADH | 71 | 8 | 11.3 |
| FEA + complex sclerosing lesion/radial scar | 6 | 1 | 16.7 |
| FEA + ALH | 9 | 0 | 0 |
| FEA + LC IS | 5 | 0 | 0 |
| FEA + papillary neoplasm (no atypia) | 5 | 0 | 0 |
| FEA + fibroadenoma | 2 | 0 | 0 |
| Total | 187 | 9 | 4.8 |

Table: Breakdown of core needle biopsy diagnosed FEA

581956 - Regional anesthetic block PECS II: Applicability of an intraoperative technique in breast cancer surgery patients in Brazil

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Background/Objective: Pain is a frequent complaint in patients undergoing breast cancer surgery, which may increase the demand for analgesics and the length of hospital stay. Excessive demand for systemic analgesics increases serious adverse events, such as vomiting, ileus, thromboembolism, and myocardial infarction. In 2011, Blanco et al. described a technique of regional anesthetic blockade with good anesthetic control, through application of interfascial anesthetic guided by ultrasound in the pectoral muscles. Through the same technique (PECS II) performed intraoperatively, we sought to evaluate pain control in the immediate and late postoperative period. Here we bring the first results of applicability of the technique.

Methods: It will include 200 patients with diagnosis of breast cancer who will undergo breast surgery in a tertiary hospital in São Paulo, Brazil. During the surgical procedure, regional intraoperative anesthetic block with 0.375% ropivacaine will be performed using the PECS II technique: by direct visualization, injection of 10mL of the solution between the pectoralis major and pectoralis minor muscles; in the sequence, still under direct vision, injection of another 10mL of the solution between the minor pectoral and anterior serratus muscles. During hospitalization, patients will be approached regarding pain control, through a verbal numerical scale (0 to 10). At outpatient follow-up visits, patients will be evaluated after 6 months for evaluation of chronic pain.

Results: Preliminary results included 20 patients submitted to breast cancer surgery. The mean time of execution of the regional anesthetic block procedure was 5 minutes. The patients were submitted to conservative surgery or mastectomy. The mean pain reported in the immediate postoperative period was 4. There were no complications regarding the execution of the procedure so far.

Conclusions: The first results of the study show a great applicability of the PECS II technique in an intraoperative time - it is an easily replicable technique, which adds a little more time to the surgical

procedure. In the context of cancer patients, in whom the complaint of postoperative pain is frequent, the application of a regional anesthetic block technique may increase comfort and patient satisfaction. We recommend the routine use of the technique in breast cancer patient care services.



Image: PECS II application through direct view

581766 - The Impact of Oncotype DX in invasive lobular carcinoma of the breast: An institutional experience

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Background/Objective: The Oncotype DX is a 21-gene recurrence score assay (RS) that has guided the recommendations for adjuvant therapy in patients with early-stage, hormone receptor (HR)-positive, HER-2/neu-negative breast cancer. The prospective study validating the use of the Oncotype DX was in a population with largely invasive ductal breast cancers. We aimed to identify the distribution of RS for patient with early-stage pure invasive lobular carcinoma (ILC).

Methods: We performed a retrospective review of all patients with T1/T2 tumors, node-negative, HR positive, HER-2/neu-negative ILC at our institution between 2010 and 2015. Patients without RS available for review were excluded. Demographics, tumor characteristics, treatment rendered, RS, and local recurrence, and survival data were collected. Tumors were classified as either classic invasive lobular carcinoma or pleomorphic based on the Nottingham Grading System. Patients were categorized into risk groups based on traditional (pre-TAILORx) RS and TAILORx RS cutoff. Standard diagnostic metrics were computed.

Results: A total of 140 patients met inclusion criteria with a mean age of 60 years and median follow-up of 53 months and tumor size of 2.1cm. One hundred thirty-three (95.0%) tumors were classical ILC, 7 (5.0%) were pleomorphic ILC. Using the traditional RS, 89 (63.6%) were in the low-risk, 48 (34.3%) in the intermediate-risk, and 3 (2.1%) in the high-risk groups. All 3 patients in the high-risk group, 53 (37.9%) in the intermediate-risk, and 5 (5.6%) in the low-risk received adjuvant chemotherapy. Using the TailorX RS cutoff patients <50 years old, 23 (63.9%) were in the low-risk, 14 (38.8%) were in high-risk; for patients >50 years old, 23 (63.9%) were low-risk, while only 5 (4.8%) were high-risk. In patients >50, those with classical ILC were significantly less likely to have high-risk group >50 received chemotherapy and only 42.8% of patients <50 did. Overall 18.5% of patients in the cohort were recommended adjuvant chemotherapy. There were 3 (2.1%) local recurrences in the cohort, all 3 occurring in patients in a low-risk group, and none received chemotherapy. There were no (0%) disease-specific mortalities.

Conclusions: The Oncotype DX has been widely used for both early-stage invasive ductal and lobular carcinoma since its inception and validation, even though the validating study had a small percentage of patients with ILC. We have shown that in this population, there is a different distribution of RS than historical invasive ductal carcinoma, with less patients having high-risk RS. Oncotype DX testing may not provide additional information to guide adjuvant chemotherapy recommendations in specific subgroups of patients (i.e., patients over 50 with classical subtype). Further large prospective studies are necessary to validate the impact of Oncotype DX in ILC.

580460 - Axillary reverse mapping with indocyanine fluorescence imaging system in breast cancer patients with clinically negative nodes

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Background/Objective: We have developed the axillary reverse mapping (ARM) using an invisible near-infrared fluorescence imaging system (PDE; Hamamatsu Photonics, Hamamatsu, Japan). The fluorescence imaging system makes it possible to carry out sentinel lymph node (SLN) biopsy and ARM procedure in the same setting and same time. In this study, we evaluated whether it is oncologically safe to preserve ARM nodes during axillary lymph node dissection (ALND) in patients with positive SLN.

Methods: Five hundred seven patients with clinically negative nodes (cN0) underwent both SLN biopsy and ARM between May 2009 and November 2017. SLN mapping was performed by using subareolar injection of blue dye and peritumoral injection of radioisotope. The technique of ARM mapping was as follows. Before surgical prep, 0.1mL of indocyanine green (ICG) (Dianogreen; Dai-ichi Pharmaceutical, Tokyo, Japan) was injected subdermally into the inner side of the wrist and the injection site was massaged. The fluorescent ARM nodes and/or lymphatics were identified by using PDE. All blue-stained nodes and/or hot nodes were removed as SLNs. SLNs were serially sectioned at intervals of approximately 2mm and frozen sections were cut and histologically examined with hematoxylin and eosin (H&E) staining. If SLN was histologically involved, standard ALND was performed with removal of ARM nodes. Otherwise, identified ARM nodes were preserved unless they were the same as SLN. Postoperatively, ARM nodes were serially sectioned at intervals of approximately 2mm and histologically examined with H&E staining, while complete ALND specimens were bisected along the long axis, and 1 section from each node was subjected to H&E staining. SLNs and ARM nodes as well as non-ARM nodes containing macrometastases or micrometastases were considered positive.

Results: SLN was identified in 499 (98%) of 507 patients, and ARM nodes were identified in 159 patients in the SLN field. The crossover rate of SLN=ARM nodes was 28%. Among 95 patients with positive SLNs, SLN was the same as the ARM node in 27 patients (the concordance type), whereas it was not an ARM in the remaining 68 patients (the separate type). Among 70 patients who underwent ALND because of positive SLN, non-SLN=ARM node was not involved in 66 patients, while it was involved in 4 patients of the concordance type.

Conclusions: When ARM nodes were involved in patients with positive SLN, these were most often the SLN=ARM nodes. It may be concluded that ARM nodes that do not coincide with SLNs might be preserved during ALND in SLN-positive patients. Although the role of ARM procedure is limited in an era of Z-0011 trial, conservative ALND with ARM procedure may be indicated in patients with positive SLNs who do not meet with the Z-0011 criteria.

Table : Concordance and involvement of the ARM nodes and SLN

| | No. of patients | positive SLNs | No. of patients who underwent ALND because of positive SLNs | No. of patients with positive ARM nodes | No. of patients with positive non-SLN=non-ARM nodes |
|-------------------------------|-----------------|---------------|--|---|--|
| Separate type (SLN≠ARM) | 359 (72%) ' | 68 | 46 | 0 | 8 |
| Concordance type (SLN=ARM) | 140 (28%) | 27 | 24 | 20 (SLN=ARM nodes only were involved) 4 (Not only SLN=ARM nodes but also non-SLN=ARM nodes were involved) | 6 |
| Total | 499 | 95 | 70 * | 24 | 14 |

ALND: axillary lymph node dissection; ARM: axillary reverse mapping; SLN: sentinel lymph node

*: Included 340 patients whose the ARM node was not observed in the SLN field.

": Excluded 25 SLN-positive patients who omitted ALND.

582204 - Orthotopic implantation achieves better engraftment rate and faster growth than subcutaneous implantation in breast cancer patient-derived xenografts

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Background/Objective: Patient-derived xenograft (PDX) has come into the limelight as a murine model that better mimics human cancer; however, there has been no study that conducted a head-to-head comparison of orthotopic implantation of the tumor (Ortho) and ectopic implantation to subcutaneous space (Sq), or of the type of source tumor. We hypothesized that PDX models that are implanted Ortho generate more aggressive tumors than the ones implanted Sq, and conducted the head-to-head comparison of implantation site location (orthotopically in mammary fat pad (Ortho) vs. ectopically in subcutaneous space (Sq)). We also examined differences in generations (first, second, and third) and molecular subtypes (triple-negative breast cancer (TNBC) vs. ER(+) breast cancer).

Methods: We xenografted breast cancer tumors from 7 patients into NOD scid gamma (NSG) mice. Six tumors were ER(+)HER2(-), and 5 tumors were triple-negative (TN). As the control group, we used 2 PDX tumors purchased from University of Utah and conducted the same study.

Results: The overall engraftment rate in control tumors was significantly better in Ortho than Sq (93.7%) (n=45/48) vs. 59.1% (n=26/44), p<0.01) and the tumor growth curve demonstrated that Ortho tumors grew remarkably larger than Sq tumors. The overall engraftment rate in tumors from our institute was also significantly better in Ortho than Sq (70.1% (n=115/164) vs. 32.1% (n=45/140), p<0.01), and the tumor growth curve of representative examples demonstrated that Ortho tumors grew significantly larger than Sq tumors. In histopathological exams, Ortho tumors demonstrated more abundant mitotic figures compared with Sq tumors (19.2 vs 7.9, p<0.01). In Ki-67 immunostaining, Ortho tumors have more Ki-67 positive cells than Sq tumors (31.5 vs 21.8, p=0.015). Tumor engraftment in the first generation was low, but the rates in the second and third generations were significantly increased and also in each generation, engraftment rates of Ortho tumors were significantly higher than that of Sq tumors. The time it took for the first generation to grow was the longest of the 3 generations. The tumor growth curve of representative examples demonstrated that second-generation tumors grow remarkably faster and larger than first-generation tumors. ER(+) xenograft revealed significantly lower engraftment rate and slower tumor growth than TN xenograft. Even compared from the time of engraftment, the growth curve was remarkably slower. On the other hand, the engraftment rates of the second generation of ER(+) tumors were very similar to that of TN tumors. Ortho demonstrated better engraftment than Sq, even in this situation.

Conclusions: Orthotopic implantation showed better engraftment rate, increased tumor size, and more significant growth, regardless of the cancer subtypes.

575545 - Opioid use after breast-conserving surgery: Identifying risk factors for high opioid use

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Background/Objective: In 2017, the US Department of Health and Human Services declared the opioid epidemic a public health emergency. Responsible prescribing of opioids for postoperative pain control is critical to addressing this issue. We sought to identify both patient and surgical factors associated with increased opioid use after select breast surgical oncology procedures.

Methods: From November 2017 to March 2018, 316 patients undergoing segmental mastectomy, excisional biopsy, or central duct excision were surveyed 1 week post-operatively to determine their postoperative opioid use. Univariate and multivariable analyses were used to determine factors contributing to increased opioid use (highest quartile of use). All opioid prescriptions were converted to oral morphine equivalents (OME) for analysis.

Results: During the study period, 10 patients (3.2%) of the 316-patient cohort did not receive a narcotic prescription at discharge. The mean opioid prescription was 33.2 OME (median 15, range 0-280) with the distribution skewed to the right. There were 78 patients (24.7%) who reported they did not take any opioids in the week after discharge. Those in the highest quartile of use used more than 50 OMEs in the first postoperative week. Surgical factors such as bilateral oncoplastic surgery (60.8 OME vs 33.1 OME, p=0.0001), axillary lymph node dissection (61.5 vs 30.5, p=0.0003), and drain use (2 drains 71.1, 1 drain 40.4, no drains 26.2, p=0.0001) were associated with higher opioid use. Utilization of bupivacaine (29.5 vs 39.1, p=0.2), and liposomal bupivacaine (41.1 vs 32, p=0.2) were not associated with significantly lower opioid use. Younger patients (age <60 years) used significantly more opioids (39.6 vs 27.6, p=0.002). In a multivariate analysis, factors associated with the highest quartile of opioid use were smoking (odds ratio [OR] 4.6, p=0.02), preoperative opioid use within 30 days of surgery (OR 2.5, p=0.02), bilateral oncoplastic surgery (OR 2.5, p=0.02), high postoperative reported pain score (OR 1.7, p<0.0001), presence of at least 1 surgical drain (OR 1.6, p=0.02) and receiving a discharge prescription greater than 150 OMEs (OR 2.5, p<0.0001).

Conclusions: Smoking, preoperative opioid use, bilateral oncoplastic surgery, use of surgical drains, high reported postoperative pain score and receiving a higher OME discharge prescription are associated with higher opioid use after surgery. Given the wide variability of analgesic needs by patients, clinical criteria such as smoking status, pain requiring opioids in the preoperative setting, planned bilateral oncoplastic reconstruction, placement of surgical drains and patient reported postoperative pain scores should be used to help guide the appropriate tailoring of opioid prescriptions.

581635 - A systematic review of breast cancer risk in transgender patients after top surgery Mara Piltin¹, Monica Khattak², Kathryn Eckhert², Kahyun Yoon-Flannery³

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Background/Objective: There has been increasing interest in the transgender top surgery as 25 million individuals identify as transgender worldwide. Subcutaneous mastectomy has been the mainstay operation for top surgery in the female-to-male transgender population. Breast cancer cases in the transgender population have historically been reported, however long-term data have been scarce. We aim to assess the data on breast cancer in the transgender population after top surgery.

Methods: Using the PRISMA guidelines, a systematic review identified peer-reviewed articles in PubMed evaluating breast cancer risk in the transgender population after top surgery. The reported data included types of top surgery procedures, patient demographics, breast cancer characteristics, and breast cancer treatment method.

Results: The search yielded 131 articles; 10 articles met the inclusion criteria. A total of 17 breast cancer cases were observed from the included studies, with a mean age of 46 years. The most common tumor histology was invasive ductal carcinoma (50%). The majority of these patients had an estrogen receptor-positive disease (70.6%). None had any prior documented breast imaging modalities for breast cancer screening.

Conclusions: Perceived discrimination in the health care setting has been well documented in the transgender population, which has led to inadequate preventative health care. The risk of breast cancer remains in transgender patients transitioning from female-to-male after top surgery. Adequate screening including annual breast imaging and a clinical exam in conjunction with appropriate trans-health education may lead to better detection of breast cancer in this population. More robust studies are needed to contribute to population-based screening recommendations.

582001 – Same-day discharge for mastectomy - Is it safe? A population-based analysis <u>May Lynn Quan¹</u>, Alysha Crocker², David Olson³, Adam Elwi⁴, Angela Estey⁴, Lynn Headley², Shannon Parker⁴, Susan Anderes², Stafford Dean², Joseph Dort¹

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Background/Objective: Mastectomy for breast cancer has historically been an inpatient procedure in Alberta with an average length of stay (LOS) between 1-3 days. Given that same-day discharge (SDD) is medically safe and results in increased patient satisfaction, lower costs and inpatient bed days released, the Alberta Cancer Strategic Clinical Network (SCN) initiated a provincial breast health initiative supporting SDD for medically and socially fit patients. The initiative consisted of a comprehensive patient education package (paper and online) in addition to perioperative nursing, nurse navigator, and surgeon training/inservice, which was introduced across the province, starting in 2015. The objective of this study was to describe rates of SDD, overnight stay and 30-day complication rates for mastectomy during the implementation process, on a population level.

Methods: All patients undergoing mastectomy for breast cancer between April 2013 and September 2018 were identified using an administrative case definition from the acute or ambulatory care provincial data repository (respectively). The administrative case definition was developed using published literature,

Canadian Institute for Health Information (CIHI) reporting, and clinical expertise for patients with a least 1 breast cancer diagnosis code (ICD-10-CA) and at least 1 mastectomy procedure code (Canadian Classification of Health Interventions; CCI). Surgeries were deemed SDD if the patient was admitted, had surgery, and was discharged on the same calendar day (i.e., before midnight), otherwise they were reported as overnight stay (average calendar LOS 1.4 days). Emergency room (ER) visits and readmissions to hospital occurring within 30 days post-surgery were identified. Two-sample test of proportion were used to compare SDD and overnight stay 30-day outcomes.

Results: Overall, the proportion of SDD for mastectomy increased during the study period from 4% in 2013/14 to 40% in 2018/19, with marked increases occurring post-provincial SDD initiative in 2016/17. Prior to the initiative, one quarter of patients overnight had at least 1 ER visit, which was similar between groups post-initiative. There were no significant differences in ER visits or readmissions between those who had SDD compared to overnight stay.

Conclusions: Same-day discharge for mastectomy has increased over time, particularly after the initial introduction of the provincial SDD initiative. ER visits and non-elective readmissions did not differ between SDD and overnight stay, supporting the safety of SDD for mastectomy.

| 200 | Mastectomy | | ER Visits | | | admissions | |
|----------------|-----------------------|--------------------|-------------------|---------|-----------------------|-------------------|---------|
| Fiscal year | Same day discharge | Same day discharge | Overnight stay | p-value | Same day discharge | Overnight stay | p-value |
| 2013/14 | 4% (44/1142) | 7% (3) | 23% (253) | <0.05 | 5% (2) | 3% (35) | ns |
| 2014/15 | 6% (71/1137) | 14% (10) | 24% (256) | ns | 1% (1) | 4% (38) | ns |
| 2015/16 | 8% (93/1149) | 10% (9) | 24% (254) | <0.05 | 0% (0) | 4% (43) | <0.05 |
| 2016/17 | 21% (220/1050) | 25% (54) | 24% (200) | ns | 6% (13) | 3% (22) | ns |
| 2017/18 | 34% (346/1016) | 26% (83) | 24% (160) | ns | 2% (6) | 4% (26) | ns |
| 2018/19 | 40% (95/238) | 21% (20) | 22% (32) | ns | 3% (3) | 6% (8) | ns |

Table:

Note: * Apr-Jun 2018 included. ns: not significant at p-value 0.05.

581801 – Practice-changing potential of TAILORx: A retrospective review of NCDB from 2010-2015

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Background/Objective: Uncertainty regarding chemotherapy benefit among breast cancer patients with intermediate range Oncotype Dx recurrence scores (RS), 11-25, led to a large prospective randomized study known as the Trial Assigning IndividuaLized Options for treatment (TAILORx). Recent results from this trial demonstrated benefit for a subgroup of those \leq 50 years with RS between 16-25, and no benefit for all others with intermediate RS. We retrospectively evaluated receipt of chemotherapy in patients with intermediate range RS to determine potential for practice change based on TAILORx results.

Methods: Patients diagnosed with hormone-receptor positive, HER2-negative, N0 invasive breast cancer at 18-75 years of age and treated between 2010-2015 were identified in the NCDB. Per TAILORx criteria, patients with bilateral cancer and those not treated with adjuvant endocrine therapy were excluded. Patient groups were based on age at time of diagnosis and RS. Group A: \leq 50 years-RS 11-15; Group B: \leq 50 years-RS 16-25; Group C: >50 years- RS 11-25. We compared demographic, clinical, and pathologic factors to determine predictors of chemotherapy receipt in each group. Chi-square tests for univariable analysis and Poisson regression models for multivariable analysis were performed.

Results: A total of 37,087 eligible patients with intermediate RS were identified (Table). There were 6.3% of patients in Group A and 11.7% in Group C who received chemotherapy but may have avoided it based on TAILORx findings. By contrast, the majority of women in Group B, 64.7%, and thus 37.2% of all \leq 50 years did not receive chemotherapy where TAILORx has shown they may have benefited from this additional treatment. The receipt of chemotherapy in those with intermediate RS decreased across all groups as the years progressed. In Group A, high-grade tumors (PR 2.63, 95%CI: 1.66-4.15), T2 (PR 1.5, 95% CI 1.11-2.02), and those treated at community or comprehensive centers (PR 1.88, 95% CI: 1.14-3.10 and PR 1.57, 95% CI: 1.14-2.16) were more likely to receive chemotherapy. In Group B, moderategrade (PR 1.28, 95%CI: 1.15-1.43), high-grade (PR 1.88, 95% CI: 1.66-2.11) and T2 (PR 1.39, 95% CI 1.29-1.50) were more likely to receive chemotherapy, whereas those patients with government insurance (PR 0.86, 95% CI: 0.76-0.97) were significantly less likely to receive chemotherapy. In Group C, black patients (PR 1.17, 95% CI: 1.04-1.32), those with ER+PR- tumors (PR 1.63, 95% CI 1.48-1.79), moderate-grade (PR 1.48, 95%CI: 1.34-1.63), high-grade (PR 3.04, 95% CI: 2.72-3.39), or T2 (PR 1.54, 95% CI 1.44-1.66) were more likely to receive chemotherapy, whereas those patients with government insurance (PR 0.62, 95% CI: 0.58-0.67) or Charleson-Deyo scores ≥ 2 (PR 0.74, 95% CI: 0.57-0.95) were less likely.

Conclusions: The use of chemotherapy in patients with intermediate RS has progressively decreased over time across all age groups. Based on our data, the most potential impact of TAILORx findings on practice change is for the large group of patients \leq 50 with RS 16-25 who did not receive chemotherapy but may benefit. Factors related to omission of chemotherapy in this group should be further explored to optimize patient selection for chemotherapy in the future.

| | Total | Chemo | No Chemo |
|-----------------------------|--------|---------------|----------------|
| Group A ≤50yrs, RS 11-15 | 4,094 | 259 (6.3%) | 3,835 (93.7%) |
| Group B ≤50yrs, RS 16-25 | 5,523 | 1,950 (35.3%) | 3,573 (64.7%) |
| Group C >50yrs, RS 11-25 | 27,470 | 3,224 (11.7%) | 24,246 (88.3%) |

580350 - Performance and reporting variability in technical standards for breast cancer operations

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Background/Objective: The American College of Surgeons and the Alliance for Clinical Trials in Oncology have recently published 2 volumes of Operative Standards for Cancer Surgery, which outline technical aspects of oncologic operations for breast, lung, pancreas, colon, esophagus, melanoma, rectum, stomach, and thyroid considered essential for optimal performance. Standards addressing documentation of critical steps described in these manuals are currently being incorporated by the Commission on Cancer (CoC) in their revised standards for cancer center accreditation with implementation anticipated by 2020. The objective of this study was to assess the current status of documentation of essential steps according to Operative Standards in operative reports of breast cancer surgery.

Methods: Operative reports for cases of partial mastectomy (PM) and sentinel lymph node biopsy (SLNB) performed at a single CoC-accredited academic institution from January 2013 to May 2018 were analyzed. Reviewers assessed operative record compliance with the Operative Standards list of Oncologic Elements of Operative Record-Breast. The non-redundant Mastery of Breast Surgery (MBS) intraoperative quality measure (specimen orientation) was evaluated for comparison. Each reviewer was provided a training module with a sample operative record to simulate basic training of surveyors. The proportion of cases reporting critical elements and specimen orientation were compared by Pearson's Chi-squared analysis. Interrater reliability was assessed by Randolph's free-marginal multirater kappa.

Results: During the study period, 66 cases of PM with SLNB had complete operative reports available for review in electronic format. A total of 5 attending physicians performed operations, with 1 surgeon performing 50% of cases. Operative reports were completed by the attending surgeon in 63.6% of cases and resident in 36.5%. Ten reviewers (ranging in experience from third-year general surgery clerkship medical student to third post-graduate year general surgery resident) evaluated all 66 cases for 14 criteria (13 Oncologic Elements of PM and SLNB and one MBS measure). No operative records were identified where all critical elements were reported for PM with SLNB. The average time required to survey the operative report was 2 minutes (min) 41 seconds (sec). After the first 15 cases, the average survey time per case decreased from 3 min 55 sec to 2 min 19 sec (p<0.0001). Combined reporting performance and interrater reliability were variable across elements, and were highest for critical element #8 (use of SLNB) (30.6%, κ =0.43). MBS specimen orientation had both high proportion reported (87%) and interrater reliability for each element.

Conclusions: Adherence to essential elements of breast cancer operations listed in the Operative Standards manual was variably reported by surgeons performing PM and SLNB in the current study. Whether differential compliance is tied to discrepancies in surgeon documentation or reviewer abstraction, clarification of synoptic choices may help to improve reporting consistency. Rapidly evolving standards in technique or technology will require continuous appraisal of any mandated reporting elements for breast cancer surgery.

Table: Proportion reported, overall agreement, and interrater reliability for operative standards of cancer surgery oncologic elements – breast and mastery of breast surgery specimen orientation, n=660

| Oncologic Elements of Operative Record – Breast Partial Mastectomy | Average % Reported (Range) | % Overall Agreement (kappa, [95%Cl]) ¹ |
|--|----------------------------------|--|
| 0. What was the operative intent? (None mentioned, Primary excision, Re-excision, Prophylactic, Other) | 97.4 (77.3-100.0) ² | 87.5% (0.84 [0.79, 0.89]) |
| 1. What was the method of localization? (None mentioned, Needle, Radioactive seed, Ultrasound, Palpation, Other) | 86.8 (81.8-95.5)3 | 71.3% (0.67 [0.60, 0.75]) |
| 2. Was skin excised along with the partial mastectomy specimen? (None mentioned, Yes, No, Other) | 29.6 (3.0-75.8) ² | 62.4% (0.53 [0.47, 0.59]) |
| 3. What was the depth of resection of the partial mastectomy? (None mentioned,cm to fascia, Fascia resected) | 13.8 (3.0-30.3) ² | 81.1% (0.75 [0.68, 0.81]) |
| Were margins of the partial mastectomy checked with a pathologist? (None mentioned, Yes) | 25.0 (1.5-66.7) ² | 64.9% (0.53 [0.47, 0.59]) |
| 5. What was the margin status if it was checked? (None mentioned, Positive, Negative) | 7.4 (1.5-10.6) ² | 86.3% (0.82 [0.76, 0.87]) |
| 6. Was radiography used to identify the partial mastectomy specimen? (None mentioned, Yes, Other) | 73.8 (68.2-80.3) ³ | 84.0% (0.80 [0.75, 0.85]) |
| 7. Was a clip detected in the partial mastectomy specimen upon removal? (None mentioned, Yes, No) | 48.4 (19.7-84.9) ² | 61.9% (0.49 [0.43, 0.55] |
| Oncologic Elements of Operative Record - Breast: Sentinel Lymph Node Biopsy | | |
| 8. Was tracer used to perform the SLNB? (None mentioned, Yes, No) | 97.1 (90.9-100.0) ³ | 96.0% (0.95 [0.92, 0.98] |
| 9. What type of tracer was used to perform the SLNB? (None mentioned, Radioactive tracer, Blue dye, Dual tracer, Other) | 97.3 (90.9-100.0) ³ | 34.2% (0.23 [0.21, 0.26] |
| 10. What were the radioactive counts of the nodes? (None mentioned, ""#) | 15.0 (0-80.3) ² | 77.5% (0.76 [0.72, 0.81] |
| 11. What were the background counts of the nodes? (None mentioned, ""#) | 4.6 (0-15.2) ² | 92.5% (0.92 [0.88, 0.97]) |
| 12. Was an intraoperative assessment of the SLNB performed? (None mentioned, Mentioned that none was performed, Frozen section, Imprint cytology, Other) | 30.6 (3.0-75.8) ² | 54.3% (0.43 [0.36, 0.50] |
| Mastery of Breast Surgery | | |
| 1. Was the specimen oriented? (None mentioned, Yes, No) | 87.0 (74.2-95.5) ³ | 87.9% (0.84 [0.79, 0.89]) |

1 Randolph's free-marginal multirater kappa

² Pearson's Chi-squared for range p<0.01 ³ Pearson's Chi-squared for range p<NS

581861 - Intraoperative liposomal bupivacaine intercostal blocks vs paravertebral blocks for pain control in patients undergoing mastectomy with implant-based reconstruction Emily Siegel, Hai Tran, James Mirocha, Kapil Anand, Alice Chung, Elizabeth Kim, Edward Ray, Kendrick Slate, Armando Giuliano, Farin Amersi Cedars Sinai Medical Center, Los Angeles, CA

Background/Objective: Inadequate pain control frequently extends length of stay (LOS) for patients undergoing mastectomy with implant-based reconstruction (IBR). Studies have demonstrated improved pain control and early mobilization with the use of paravertebral blocks (PVB) in patients undergoing IBR. Liposomal bupivacaine (LB) has recently shown promise for pain control for these patients. This study evaluated outcomes for patients undergoing mastectomy with IBR with either the use of PVB or intraoperative LB intercostal blocks.

Methods: Review of a prospective database of patients undergoing mastectomy with IBR from August 2016 to January 2018 was performed. LB blocks were performed intraoperatively by 3 trained reconstructive surgeons while bupivacaine-based PVB was performed as a separate procedure by anesthesiologists. All opioids were converted to morphine milligram equivalents (MME). Clinical characteristics, opioid utilization, and LOS data were compared between PVB and LB patients.

Results: A total of 101 patients were identified, of whom 51 (50.5%) underwent PVB, and 50 (49.5%) underwent LB. Patients in both groups were similar in terms of age (47.6±11.2 years LB vs 47.3±9.6 years PVB, p=0.89), body mass index (22.8±3.4 LB vs 23.4±3.6 PVB, p=0.42), rates of bilateral mastectomy (70% LB vs 70.6% PVB, p=0.99) and rates of separate axillary incisions (54% LB vs 41.2% PVB, p=0.23). Operative time was higher for the PVB group (280.1±85.7 minutes LB vs 321.2±80.9 minutes PVB, p=0.02). Mean LOS was similar between groups (1.38±0.5 days LB vs 1.71±1.1 days,

p=0.06), as were readmission rates (6% LB vs 13.7% PVB, p=0.32). Postoperative pain scores rated 1-10 in the post-anesthesia care unit, on postoperative day (POD) 0 and POD 1 did not significantly differ between patients who received PVB and those who received LB (PACU: 4.1 ± 2.3 LB vs 3.2 ± 2.9 PVB, p=0.07; POD 0: 4.3 ± 2.3 LB vs 4.1 ± 2.0 PVB, p=0.99; POD 1: 5.0 ± 2.6 LB vs 5.7 ± 1.8 PVB, p=0.18). Patients receiving LB block had significantly more intravenous (IV) narcotic use during their entire hospitalization (24.5 (8-40) MME LB vs 4 (0-24) MME PVB, p=0.006), while oral opioid utilization was similar between groups (37.5 (30-67.5) MME LB vs 35 (20-52.5) MME PVB, p=0.27). In the first 24 hours, LB patients also had significantly higher IV opioid use (24 (8-38) MME LB vs 4 (0-24) MME PVB, p=0.003) suggesting a faster transition to PO narcotics in the PVB group. Percentage of patients utilizing anti-emetics was higher in the PVB group (52% LB vs 54.9% PVB, p=0.32).

Conclusions: Intraoperative intercostal LB blocks are associated with a small, non-significant decrease in LOS and do not decrease post-operative opioid consumption or pain scores in patients undergoing mastectomy with IBR. PVB should continue to be used as an adjunct for post-operative pain management in these patients.

582199 - Benefits of an interview match for breast fellowship positions

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Background/Objective: The number of candidates applying to breast surgical fellowship programs is outpacing available positions. As such, 'the match' process has become more competitive, and the significance of fellowship interviews more uncertain. Factors influencing the preferences of trainee applicants and programs are largely unknown. Aspiring fellows apply broadly to nearly all programs in order to maximize their choices. Fellowship programs too, especially those with a single position, are concerned about matching, and engage in interviewing many more candidates in order to safeguard themselves from not matching. Instituting an Interview Match would help decrease the number of interviews by allowing both parties to express some preferences and align both sides with more satisfactory pairing. We simulate various conditions to demonstrate the worth of an Interview Match using and not using tier-grouping.

Methods: To illustrate the benefit of an Interview Match, we simulated 20 programs, 10 East and 10 West, with 1 position each. The applicant pool has 34 candidates, 14 top-tier and 20 bottom-tier. We illustrate the different dynamics that arise between the status quo and using an interview match.

Results: Suppose 7 of the top-tier candidates prefer East, and the others prefer West; and similarly 10 of the bottom-tier candidates prefer East, and the others prefer West. Moreover, suppose these geographic preferences are not publicly known. Without an interview match, programs maximize their chances of matching by interviewing the 14 top-tier candidates as well as another 8 to 12 bottom-tier candidates, as there is a possibility that both top-tier candidates have a strong preference for other programs. Likewise, all candidates will want to interview at most programs and tell them that they are their top choice, in order to maximize their chances of matching. An interview match system, which elicits initial rankings from candidates, can use the fact that candidates have geographic preferences to suggest that candidates only interview at programs that are located in their preferred geographical location. This will reduce the number of interviews from 22 to 26 per program to 13 to 17 per programs, from 14 to 7 interviews for top-tier candidates and can reduce by 2 to 4 interviews for bottom-tier candidates.

Conclusions: In this thought experiment, the total number of interviews was at least 50% more than the number required, and both sides were interviewing with unlikely matches to maximize their chances of match. An interview match can use partial preferences to significantly reduce the number of interviews and increase the average quality of interviews.

578960 - Customized breast cancer risk assessment in an ambulatory clinic: A portal for identifying women at risk

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Background/Objective: Existing high-risk clinic models focus on patients with known risk factors, but may be missing many at-risk patients. Here we describe our experience implementing a universal risk assessment program in an ambulatory breast center.

Methods: Since May 2017, all patients presenting to our breast center have completed a customized intake survey addressing known breast cancer risk factors and lifestyle choices. Patient characteristics, family history (FH), breast cancer risk scores (Gail, Tyrer-Cuzick v7), and lifestyle factors were examined by reason for referral. Patients with a personal history of breast cancer, known high-risk lesions (atypical ductal/lobular hyperplasias and lobular carcinoma in situ), or genetic mutations were excluded from this analysis. Patients were considered at increased risk by model thresholds including: Gail 5-year risk >1.7% (35-59 years), Gail 5-year risk >5.5% (\geq 60 years), or Tyrer-Cuzick (T-C) v7 lifetime risk >20% at any age.

Results: From May 2017-April 2018, 1,624 patients completed the survey, and 874 (54%) patients formed our study cohort. Of these, 420 (48%) patients were referred for risk assessment (RA), and 454 (52%) were referred for non-specific breast complaints (NSBC). Patients referred for RA were younger (median age 47 vs 49years), less likely to be Hispanic/Latino (8% vs 16%), reported higher education levels, and stronger FH of breast cancer as compared to those referred for NSBC (all p<.05). Overall 389/874 (45%) patients were found to be at increased risk; 168/389 (43%) met criteria based on their Gail score, and 318/389 (82%) met criteria by their T-C lifetime risk score (Figure). Gail 5-year risks were similar between those referred for RA and those with NSBC; but RA patients more frequently met criteria by T-C score (p=.02). The only difference among those meeting high-risk criteria by reason for referral included higher rates of current smoking in NSBC patients (8% vs 1%, p<.01). All other demographics and lifestyle factors were similar among those identified to be at increased risk regardless of reason for referral. Of all patients at increased risk, a minority exceeded daily recommendations for alcohol consumption or were current smokers, whereas 149 (39%) were overweight (BMI >25) or obese (BMI >30), and only 159 (41%) met recommended exercise standards.

Conclusions: Standardized breast cancer risk assessment in an ambulatory breast clinic identified 45% of patients to be at increased risk; primarily encompassing lifetime risk between 20-40% by T-Cv7 risk score, with few differences between those referred for RA vs NSBC. The most prevalent modifiable risk factors included weight management and exercise habits. This clinical care model provides a unique opportunity to identify women at risk and address modifiable risk factors.

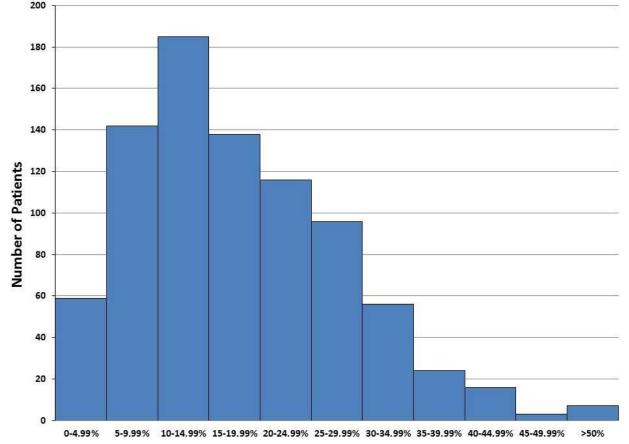


Figure: Distribution of Tyrer-Cuzick lifetime breast cancer risk scores among the study cohort

SLN

582163 - Management of positive sentinel lymph node biopsy following mastectomy

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Background/Objective: Axillary management of nodal disease can have a significant impact on locoregional control and survival. However, recent clinical trials suggest that a positive sentinel lymph node biopsy in select patients no longer mandates a completion axillary lymph node dissection (ALND), as a survival benefit has not been shown. In patients undergoing mastectomy found to have sentinel node metastasis, axillary radiotherapy may provide comparable regional control to ALND, with potentially less morbidity. Furthermore, the combination of ALND and axillary radiotherapy may also be considered. Data are lacking to guide clinical management decisions for patients with sentinel node metastasis who have undergone mastectomy. Our objective is to perform a comparative evaluation of the management of regional metastasis detected following SLNB in clinically node negative patients undergoing mastectomy, and to compare clinical outcome among the different modalities of axillary management.

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 from 2012-2015 who were clinically node-negative but found to have positive lymph node metastasis 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). Multivariable analysis and Cox proportional hazards ratio were performed.

Results: A total of 16,295 women with a positive SLNB at the time of mastectomy were identified. Of these, 5,722 (35%) proceeded to have an ALND, 1976 (12%) received PMRT, 5,424 (33%) underwent combination therapy, and 3173 (19%) had NFT. On multivariable analysis patients <40 were less likely to be associated with NFT when compared to patients \geq 70 (reference group 40-54) (OR 1.3 CI 1.1-1.6, OR 0.6 CI 0.5-0.7 respectively). Patients treated at high-volume facilities were less likely to be associated with NFT when compared to low- or medium-volume centers (OR 0.7 CI 0.6-0.8, OR 0.9 CI 0.8-1.0 respectively). Tumors with higher grade, and higher nodal involvement were also less likely to be associated with NFT (p<0.0001 for all the observations in the multivariable analysis). Cox proportion hazards ratio demonstrated a 48% decrease in mortality in patients treated with combined therapy when compared to NFT (HR 0.52 CI 0.40-0.68). No significant impact on mortality was observed with individual treatment with ALND or PMRT.

Conclusions: In patients undergoing mastectomy found to have sentinel node metastasis, combination therapy with both PMRT and ALND was seen to be associated with decreased mortality. Further characterization of patient and tumor features associated with this finding may help identify patients best suited for combined therapy.

580510 - Development of criteria for omission of surgical axillary staging in low-risk breast cancer patients

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Background/Objective: To determine criteria for omission of surgical axillary staging in patients with favorable histology implying a low-risk of metastatic disease

Methods: As an institution, we sought to determine if we could create an institutional practice guideline based on available nomograms to omit surgical axillary staging in a subgroup of patients in alignment with the SSO Choosing Wisely campaign. Charts were reviewed for patients meeting the following criteria over a 54-month period: Age 70+, Clinical Stage T1N0M0, ER+, and no LVI on biopsy, with plan for recommendation of adjuvant antihormonal. We calculated both the MSKCC and MDA Sentinel Lymph Node Metastasis nomograms on all patients in hopes of finding a common threshold such as 10% to help with this process. These calculations were then compared with actual outcomes.

Results: A total of 96 patients met the above criteria. Of these, 24 did not undergo surgical axillary staging due to various factors such as comorbidities, no change in management expected, or favorable histology. Of the remaining 72 patients, nomogram values ranged from 4-65 and 4-48 in the MSKCC and MDA nomograms respectively with average values of 26 and 17. Further breakdown on final pathology is shown in the Table. The 3 patients with N1mi disease did not require further axillary surgery according to national standard of care, and their treatment plan was not altered as a result. The initial pathology on the 2 patients with N2 disease was as follows: 1 was a 13mm Grade 1 IDC and the other an 8mm Grade 1 ILC. The patient with ILC did have pleomorphic lobular carcinoma on final surgical pathology. Both underwent completion axillary dissection and management was changed. Upon short follow-up, both are disease-free survivors.

Conclusions: MSKCC nomogram consistently overestimates risk of nodal involvement as compared to MDA nomogram. Neither nomogram accurately predicts nodal status. Only 2 patients of the 72 undergoing surgical axillary staging benefited from the procedure. Recommendations: Adopt SSO Choosing Wisely criteria to offer the option to avoid surgical axillary staging in women who meet the following criteria based on preoperative criteria: Age 70+, Clinical T1N0M0, ER+, No LVI on biopsy. Exceptions will be made at the provider's discretion who are borderline - for example, have T1 tumor approaching T2 status, etc.

| | N | MSKCC Nomogram Avg (range) | MDA Nomogram <u>Avg</u> (range) |
|--------------------------------|----------|-------------------------------|------------------------------------|
| TOTAL Number of Patients | 96 | 22 (4-65) | 14 (3-48) |
| No <u>SNBx</u> | 24 (25%) | 17 (5-48) | 10 (3-21) |
| SNBx Performed | 72 | | |
| pNo | 67 (93%) | 23 (4-65) | 15 (4-48) |
| pN1mi | 3 (4%) | 20 (16-28) | 13 (11-15) |
| pN2 | 2 (3%) | 34 (32-35) | 22 (17-26) |

Table: Pathologic nodal status vs. nomogram

580657 - Lack of clinical utility for sentinel lymph node biopsy in contralateral prophylactic mastectomies with in situ carcinoma or atypia

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Background/Objective: Routine use of sentinel lymph node biopsy (SLNB) during contralateral prophylactic mastectomy has been shown to have limited clinical value. However, its role in patients with high-risk lesions has not been evaluated, nor have the long-term axillary outcomes in high-risk cases in which SLNB has been omitted. The objective of the current study was to examine bilateral mastectomy patients with contralateral in situ carcinoma or atypia and determine the utility of SLNB.

Methods: A retrospective study included all bilateral mastectomy patients from March 1, 2005 to February 1, 2017. Patients were included if they had ipsilateral invasive carcinoma or ductal carcinoma in situ (DCIS) and contralateral in situ carcinoma or atypia. Patients with bilateral invasive cancer were excluded. Patients were divided into groups based on whether they underwent contralateral SLNB and if they had a known or occult contralateral lesion. Occult contralateral lesions were identified in the final pathology. Fisher's exact test was used to compare the groups. 2017 Medicare reimbursement rates were used to calculate the costs of contralateral SLNB.

Results: In this study, 73 patients were identified with contralateral high-risk lesions. Forty-two patients (57.5%) demonstrated LCIS. In 5 patients, occult invasive cancer was encountered (Table). Mean contralateral lesion size was 1.1 +/- 1.9cm in size. Thirty-six patients (49.3%) underwent contralateral SLNB. Patients with known high-risk lesions were more likely to undergo SLNB (80.6% vs. 19.4%, p<0.001). There were no positive sentinel lymph nodes in any patients who underwent contralateral SLNB. At a mean follow-up of 56 months, there were no local or axillary recurrences on the contralateral side. Eight patients had recurrences at the primary side or distant metastases. Omitting contralateral SLNB in this cohort would have resulted in cost savings of \$101,916.

Conclusions: Although considered a low-risk procedure, contralateral SLNB is costly and low yield. Based on the current study, SLNB is not indicated in patients undergoing contralateral prophylactic mastectomy for known in situ carcinoma or atypia.

| Table: Characteristics of contralateral lesions |
|---|
| Lesion |

| Lesion | Number of Patients (%) |
|------------------------|------------------------|
| LCIS | 42(57.5%) |
| DCIS | 23 (31.5%) |
| Occult invasive cancer | 5 (6.8%) |
| Atypia | 3 (5.6%) |

582153 - Slow uptake of surgeons using intraoperative radioisotope injection for sentinel lymph node biopsy

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Background/Objective: Radioisotope such as Technetium-99m (Tc-99m) optimizes identification rates of sentinel lymph node (SLN) biopsy. Injecting Tc-99m is usually done awake in nuclear medicine (NM). This is painful for the patient, and can cause anxiety and interdepartmental delays. Another method to avoid these problems is to inject Tc-99m after the patient is asleep in the operating room (OR). It has been demonstrated that there are no differences in SLN localization whether it is injected preoperatively or in the operating room. Though there are institutions that inject in the OR, it is unclear what the uptake in the breast surgical oncology (BSO) community is in performing their own intraoperative injections (IOI). As such, we are looking at the use and barriers that exist for performing IOI.

Methods: To assess the use of this technique in the United States, we sent a 5-question online survey to 59 attending breast surgeons and 60 current fellows in a BSO program associated with the 48 Society of Surgical Oncology accredited BSO Fellowship Programs. In addition, to demonstrate no difference in SLN localization, we used a retrospective chart review of a prospective database at a single institution between the years 2002-2014 to identify and calculate localization rates of 1,481 SLN biopsies using IOI of Tc-99m.

Results: Responses of the survey were collected via an online format for 6 weeks. The survey is listed in the Table. Of the 119 surgeons surveyed, 45 responded: 18/59 attendings (30.5%) and 27/60 fellows (45%). Thirty-eight percent of attendings and fellows say their institutions allow for IOI, 56% don't allow for it, and 6% report they are unsure. Of the 38% that allow it, advantages cited were patient comfort, avoids delays for the patient/surgeon, reimbursement, allows surgeon to control where the isotope is injected, and 1 surgeon reports using radioactive iodine seeds in the OR with similar advantages. Disadvantages of using IOI is noted that it can conflict with the NM department, competition for reimbursement, time it takes in the OR, state laws requiring NM involvement, and the lead that carries the Tc-99m is heavy. Of the 56% of surgeons who don't use IOI, barriers included those listed as disadvantages above as well as hospital policy, how they were trained, not knowing it was an option, there is no NM at their hospital, unsure about state requirements, needing a nuclear medicine license to inject and not actually knowing what the barriers are. Of the 45 respondents, 34 (76%) are unaware of RVUs and coding for IOI. Our single institution's localization rate using IOI of Tc-99m.

Conclusions: It has been shown that there are no differences in timing of rates and uptake in SLN localization when Tc-99m is injected in the OR after the patient is asleep. Though there are other institutions who utilize this technique, we have been unaware of the uptake in the BSO community in performing their own IOIs. Upon surveying surgeons nationwide, there are still barriers that exist in regards to the technique itself, perhaps developing a relationship with NM would assist with some of the perceived barriers that exist in preventing this approach.

Figure: intraoperative injection of radioisotope online survey

| Questions | Answer Choice |
|---|---|
| Does your institution allow for intraoperative injection of radioisotope prior to lymph node localization? | a.) Yes b.) No c.) Other (please specify) |
| If yes, your institution utilizes intraoperative injection of radioisotope, what are the advantages? Select all that apply. | a.) Patient comfort b.) Avoids delays for patient and surgeon c.) Reimbursement d.) No, we don't utilize intraoperative injection of radioisotope e.) Other (please specify) |
| 3.) If yes, your institution utilizes intraoperative injection of radioisotope, what are the disadvantages? Select all the apply | a.) Conflicts with nuclear medicine b.) Competition for reimbursement c.) No, we don't utilize intraoperative injection of radioisotope d.) Other (please specify) |
| 4.) If no, what are the barriers to your institution allowing the breast surgery team to inject radioisotope after the patient is asleep in the operating room? Select all the apply. | a.) Conflict with nuclear medicine department b.) Hospital policy c.) Time d.) How you were trained e.) Not knowing it was an option f.) Our institution utilizes intraoperative injection of radioisotope g.) Other (please specify) |
| 5.) Are you aware of RVUs and coding for intraoperative injection of radioisotope? | a.) Yes b.) No c.) Other (please specify) |

574696 - Lobular histology does not predict the need for axillary dissection among ACOSOG Z0011-eligible breast cancers

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Background/Objective: The ACOSOG Z0011 trial demonstrated that axillary dissection (ALND) may be safely omitted in women with ≤ 2 positive sentinel lymph nodes (SLNs) undergoing breast-conservation therapy (BCT). Patients with invasive lobular histology comprised a small minority of the studied population, and applicability to these innately discohesive cancers has been questioned.

Methods: From August 2010 to March 2017, patients having BCT for cT1-2N0 disease with positive SLNs were prospectively managed with ALND for >2 positive SLNs or gross extracapsular extension (ECE). Clinicopathologic characteristics, nodal burden, and locoregional recurrence were compared between patients with pure invasive ductal cancer (IDC) and pure invasive lobular or mixed ductal/lobular histology (ILC).

Results: Among 813 consecutive patients, 104 (13%) had ILC, and 709 (87%) had pure IDC. Compared to those with pure IDC, patients with ILC more often had multifocal tumors, lower nuclear grade, and less frequently had lymphovascular invasion (all p<0.001, Table). A median of 3 SLNs were excised in both groups (p=0.8). While ILC patients were more likely to have nodal macrometastases (82% ILC vs. 69% IDC, p=0.01) and >2mm ECE (31% ILC vs. 20% IDC, p=0.03), the proportion of patients with \geq 3 positive SLNs did not differ (14% ILC vs. 10% IDC, p=0.2). ALND was performed in 20 (19%) of ILC patients vs. 97 (14%) of IDC patients (p=0.18). At ALND, additional positive nodes were found in 80% of ILC vs. 57% of IDC patients (p=0.09), with a median of 2 vs. 1 (p=0.06) additional positive nodes in ILC and IDC, respectively. Both lobular histology (p=0.03) and increasing pathologic tumor size (p=0.03) were significantly associated with an increased number of additional positive nodes at ALND on multivariable analysis. Receipt of adjuvant radiation and systemic therapies was similar between groups. At median follow-up of 42 months, there have been no isolated axillary recurrences in either group.

Conclusions: Despite a higher rate of macrometastases in the sentinel nodes and association with more involved nodes at ALND, lobular histology was not predictive of the need for ALND. Axillary dissection is not indicated solely on the basis of lobular histology among patients otherwise meeting ACOSOG Z0011 eligibility criteria.

| Characteristic | ILC N = 104 | Pure IDC N = 709 | р |
|--------------------------------|-----------------|---------------------|---------|
| Age at surgery, years | 58 (34, 92) | 58 (30, 86) | 0.8 |
| Pathologic tumor size, cm | 1.75 (0.4, 5.2) | 1.70 (0.1, 5.7) | 0.3 |
| Palpable tumor | 40 (38%) | 299 (42%) | 0.5 |
| Abnormal nodes imaged | 23 (22%) | 181 (26%) | 0.5 |
| Preoperative nodal biopsy done | 4 (4%) | 45 (6%) | 0.4 |
| Receptor status | | | |
| ER+HER2- | 95 (91%) | 589 (83%) | |
| ER+ HER2+ | 5 (5%) | 58 (8%) | 0.3 |
| ER-HER2+ | 1 (1%) | 21 (3%) | |
| ER-HER2- | 3 (3%) | 41 (6%) | |
| Multifocal | 26 (25%) | 86 (12%) | < 0.001 |
| Lymphovascular invasion | 26 (25%) | 446 (63%) | < 0.001 |
| Nuclear grade* | | | |
| 1 | 19 (19%) | 18 (3%) | <0.001 |
| 2 | 63 (62%) | 390 (56%) | < 0.001 |
| 3 | 19 (19%) | 294 (42%) | |

Table: Clinicopathologic characteristics

ILC, invasive lobular cancer; IDC, invasive ductal cancer; ER, estrogen receptor

Values reported as median (interquartile range) or N (%)

*Nuclear grade unknown in N = 10 patients (7 pure IDC, 3 ILC)

581972 - Implementation of sentinel lymph node biopsy following neoadjuvant chemotherapy in clinically node-positive breast cancer

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Background/Objective: Multiple prospective clinical trials have recently evaluated the feasibility of sentinel lymph node biopsy (SLNB) in patients with clinically positive nodes undergoing neoadjuvant chemotherapy (NCT). The data have shown that a low false-negative rate can be attained in patients who become clinically node-negative after NCT provided that adequate nodal sampling is performed (i.e., at least 3 lymph nodes retrieved with the use of dual tracer). Although these clinical trial findings increase the number of patients potentially eligible for minimal approaches to axillary staging, the adoption of this approach into clinical practice may be limited, leaving patients unnecessarily exposed to the morbidity of an axillary node dissection. We aim to use the National Cancer Database (NCDB) to assess the implementation of recent clinical trial data regarding the feasibility of SLNB following NCT for clinically node positive patients, and determine factors associated with variation in clinical practice.

Methods: A retrospective analysis of the NCDB was performed. The study cohort consisted of women with Stage 1-3 invasive breast cancer diagnosed between 2012 and 2015. All patients underwent neoadjuvant chemotherapy (NCT) followed by axillary lymph node dissection (ALND). Pathological complete response (pCR) in the nodes was defined as absence of regional lymph node metastasis on final pathology according to the AJCC criteria. Descriptive statistics were performed to examine practice trends in different clinical settings.

Results: Of 1,857 women who underwent ALND after NCT, 407 (22%) had a pCR. In our cohort, a greater proportion of ALNDs were performed in non-academic institutions (1332, 71.7%). Age 40-54 years (811, 44%), low comorbidity score (1618, 87%), and lower socioeconomic level (1125, 60%) were all also associated with higher rates of ALND. Patients with hormone receptor-positive/HER2-negative tumors (1289, 69%), and tumors of low/intermediate grade (1017, 55%), were more likely to undergo ALND. All associations p<0.05.

Conclusions: Despite the promising results shown in prospective, randomized clinical trials, a large proportion of patients who exhibit complete nodal response to NCT still undergo ALND, and are therefore susceptible to the morbidity associated with this procedure. In our study, more than 20% of patients with clinically positive nodes treated with NCT were found to be pN0 at the time of ALND. Specific facility, patient, and tumor characteristics were associated with clinical practice variation in the use of SLNB following NCT. Although a portion of patients may have had clinical indications for ALND, our findings suggest that barriers may exist in the translation of clinical trial findings to routine practice. Efforts to address these potential barriers may result in better outcomes for patients treated for breast cancer.

580075 - Sentinel lymph node mapping in breast cancer after neoadjuvant chemotherapy: A single-institution experience

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Background/Objective: Neoadjuvant chemotherapy (NCT) is the standard of care for patients with locally advanced breast cancer (LABC). Its use in operable breast cancer is gaining wider acceptance. Sentinel lymph node mapping (SLNM) is currently the most accurate staging procedure for the axilla. The aim of our study is to assess the accuracy of sentinel lymph node biopsy after neoadjuvant chemotherapy both for operable and locally advanced breast cancer.

Methods: Between August 2004 and December 2017, we performed 132 SLNM after NCT. Patients received all chemotherapy cycles before surgery. The procedures were performed by a single surgeon, using dual technique (radioactive tracer and blue dye).

Results: All patients were diagnosed by core needle biopsy and had clip placement before NCT. Patients' age: 23-71 years. Histology of the primary breast cancer: infiltrating ductal carcinoma (IDC): 89; Infiltrating lobular carcinoma (ILC): 27; IDC and ILC: 7; others (papillary, colloid, tubular): 9. Molecular subtypes: luminal A & B: 40: HER2 overexpression: 36; triple-negative breast cancer (TNBC): 56. Patients were divided into 3 groups according to axillary status. Group 1: histologically positive axillary nodes by fine needle aspiration (FNA): 35; group 2: clinically palpable and/or radiologically suspicious nodes: 49; group 3: unknown axillary status and NCT given for the primary breast cancer: 48. No patient progressed on chemotherapy. Identification rate: 97%. SLN negative: 72 (no axillary dissection). SLN positive: 55 (all patients, except 1, had completion lymph node dissection); SLN not found: 5 (completion axillary dissection). Group 1: SLN negative: 14; SLN positive: 19; SLN not found: 2. Group 2: SLN negative: 30; SLN positive: 17; SLN not found: 2. Group 3: SLN negative: 28; SLN positive: 19; SLN not found: 1. SLN positive patients: 55 (axillary lymph node dissection: 54). No evidence of disease: 26. SLN not found: 5 (axillary dissection: 5; no evidence of disease: 3). Patients with SLN positive: macrometastasis: 42; micrometastasis: 12. In patients with SLN negative, 59 had no residual disease in the breast (luminal A + B: 4; HER-2 positive: 22; TNBC: 33). The number of SLNs removed: 16 patients: 1 SLN; 18 patients: 2; 85 patients: 3; 8 patients: 4; 5 patients: SLN not found. Follow-up: 5-177 month: no axillary recurrence as only site of disease.

Conclusions: Sentinel lymph node mapping is an accurate procedure after NCT. It provides an accurate staging and local control of the axilla, while preventing complications of axillary node dissection.

580621 - Nomogram incorporating axillary ultrasound characteristics can identify a subgroup of patients unlikely to benefit from sentinel lymph node biopsy

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Background/Objective: Axillary lymph node (ALN) status is an important factor for recommendation of adjuvant therapy in breast cancer (BC) patients. The Choosing Wisely campaign recommends against routine sentinel lymph node biopsy (SLNB) in patients >70 years old with BC who are at low risk of ALN metastasis. It would be useful to identify patients at low likelihood of ALN metastasis to inform decision-making regarding surgical management of the axilla. Qiu et al (Scientific Reports 2016; PMID

26875677) developed the Shantou nomogram to predict risk of ALN metastasis using preoperative prognostic factors and axillary ultrasound (axUS) characteristics. The Shantou nomogram was developed in a Chinese population with a high prevalence of nodal metastasis (51%). The purpose of this study is to validate the Shantou nomogram in a heterogeneous patient population with a lower prevalence of nodal metastasis.

Methods: This is a retrospective analysis of female BC patients at a single center between February 2011 to November 2013 with (1) invasive BC, (2) an axUS, and (3) had a SLNB or ALN dissection. Patients with locally advanced BC, neoadjuvant treatment, or bilateral BC were excluded. The clinical tumor size, ER status, grade, cortical thickness, and longest axis of the most suspicious ALN, and ALN hilum appearance (present/absent) on axUS are used in the Shantou nomogram to calculate the likelihood of ALN metastasis, referred to as the predicted risk. Predicted risk was correlated with actual pathology from surgical staging, using metastasis >0.2mm to define a positive node. The area under the ROC curve (AUC) was constructed to determine model fit, and the percent of cases with ALN metastasis as predicted by the Shantou nomogram in this cohort was examined using various predicted risk thresholds.

Results: A total of 357 patients met study criteria. The mean age was 61.9 years. Eighty percent of the patients were Caucasian, 14% were African American, and 6% declined to answer. The mean clinical tumor size was 1.9cm. Sixty-eight percent had invasive ductal carcinoma. Seventy-two percent were node-negative on SLNB. The median ALN cortical thickness and longest axis were 2mm and 16mm. Four percent of patients had absent ALN fatty hilum on axUS. The AUC for the Shantou nomogram in the study cohort was 0.70 (95% CI 0.64, 0.76). When using the predicted risk cut-off of <9.2%, the model identified 19.6% of the study cohort, in which only 8.7% of patients had nodal metastasis on pathology (Table).

Conclusions: The Shantou nomogram, although developed in a Chinese population, nevertheless showed fair predictive ability in a heterogeneous population. More impressively, the nomogram (incorporating both prognostic factors and axUS characteristics) is able to identify a sizeable subgroup of the study patients with a <10% risk of nodal metastasis. This is an improvement over axUS alone, as we have previously shown that cases with a negative axUS still have an 18% risk of nodal metastasis. While awaiting the results of clinical trials of SLNB omission for patients with a sonographically negative axilla, patients who wish to avoid over-treatment would benefit from individualized assessment of the risks and benefits of SLNB. For patients with a nomogram value of predicted risk <9%, it is unlikely that omission of SLNB would meaningfully affect survival. The nomogram results allow surgeons to quantify for patients the risk of systemic under-treatment if surgical staging of the axilla were omitted.

| Predicted risk (PR) threshold | Patient number & percentage (%) | Number of patients with ALN metastasis | Sensitivity (%), e.g. the likelihood of a true positive node having PR equal to or above the indicated threshold | Specificity (%), e.g. the likelihood of a true negative node having a PR below the indicated threshold | % with ALN metastasis |
|----------------------------------|---------------------------------|---|---|--|--------------------------|
| <4.6% | 22 (6.2%) | 0 | 100.0% | 8.6% | 0.0% |
| <5.3% | 31 (8.7%) | 1 | 99.0% | 11.7% | 3.2% |
| <9.2% | 69 (19.6%) | 6 | 94.0% | 24.5% | 8.7% |
| <10% | 73 (20.4%) | 8 | 92.0% | 25.3% | 11.0% |
| <20% | 152 (42.6%) | 30 | 70.0% | 47.5% | 19.7% |
| <30% | 224 (62.7%) | 48 | 52.0% | 68.5% | 21.4% |
| <40% | 268 (75.1%) | 57 | 43.0% | 82.1% | 21.3% |

SLN/NAC

581445 - Lymph node marking with 4% carbon suspension before neoadjuvant chemotherapy: A new option

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Background/Objective: Neoadjuvant chemotherapy (NAC) allows for more conservative breast cancer surgeries. However, the assessment of the axillary extension of the disease remains controversial due to the low identification and high false-negative rates of sentinel lymph nodes (SLNs) in this subgroup of patients. The use of markers for suspected axillary lymph nodes (ALNs) in ultrasonography (US) before NAC is an alternative to improve identification rate. Some methods have been used, either through the metal clip or use of I125 seed. Due to the obligation of a new marking guided by ultrasonography or mammography to identify the metallic clip, the difficulty of accessing I125 seed as well as a high cost associated with both methods, we propose the use of black carbon suspension as a low-cost method and easy identification during surgery. The objective is to determine the viability and the rate of identification of the lymph node marked with 4% carbon suspension and to compare it with the standard patented blue V sentinel lymph node technique.

Methods: A total of 122 women with axillary lymph node metastasis suspected on clinical evaluation were submitted to US-guided fine-needle aspiration biopsy of suspected ALNs and concomitant marking with carbon suspension. Patient were operated 3 to 6 weeks after the completion of neoadjuvant therapy. Blue dye injection was used intraoperatively to identify the sentinel lymph node (SLN). SLN and LNs marked with carbon suspension were biopsied and submitted to frozen sections. Based on these results, we classified the subjects according to their indication of axillary lymph node dissection (ALND) for each method. The intertest reliability for the indication of ALND between the methods was measured with the use of kappa statistics (k).

Results: LNs marked with carbon suspension and SLNs were identified in 98.4% (120/122) and 89.3% (109/122) of patients, respectively. In 62.3% (76/122) of patients, these LNs were the same. The overall agreement for ALND was 86.9% (106/122) between methods. While the sensitivity and specificity of carbon suspension to indicate ALND compared to SLN were 80% and 91% respectively, the adjusted agreement observed was k=.71 (p<.0001).

Conclusions: Carbon suspension has a high intraoperative identification rate of suspected LN before neoadjuvant chemotherapy, higher than the SLN identification rate with blue dye. However, these methods have a moderate agreement between the identified lymph nodes and the intraoperative indication of ALND. The use of the 4% carbon suspension as the lymph node marker in patients submitted to neoadjuvant chemotherapy is feasible and represents an alternative to the clip and the I125 seed.

 Table: Indication of ALND based on frozen sections of the SLN or the pre-NAC marked LN with 4% carbon suspension

| | | SLN | | |
|------------|---|-----|----|-----|
| | | + | - | |
| Carbon | + | 35 | 7 | 42 |
| Suspension | - | 9 | 71 | 80 |
| | | 44 | 78 | 122 |

582086 - Favorable local control in breast cancer patients following sentinel lymph node biopsy after neoadjuvant chemotherapy without axillary lymph node dissection

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Background/Objective: Axillary lymph node dissection (ALND) following sentinel lymph node biopsy (SLNB) with residual cancer in patients with locally advanced disease after neoadjuvant chemotherapy (NAC) is still the standard approach in many centers. Randomized trials are ongoing to address the question whether ALND could be safely omitted with a positive SLNB. In this study, we evaluated factors affecting local recurrence in patients with locally advanced breast cancer (LABC), who underwent SLNB without ALND after NAC.

Methods: Between 2003 to 2016, 223 patients with clinically node-positive LABC who received NAC and underwent SLNB without ALND were included in the study. All patients had whole breast and/or regional nodal irradiation. All recurrences of axilla, peripheric lymphatic, and breast were accepted as locoregional recurrence. Kaplan Meier survival and Cox regression analyses were used in statistical analyses.

Results: The median age was 46 (23-81). Of those, 167 (75%) were clinically T1-2, and 66 (25%) were clinically T3-4, whereas 180 were cN1 (81%), and 44 were cN2-3 (19%) before receiving NAC. Following NAC, patients underwent SLNB with blue dye alone (60%) or blue dye with radioisotope injection (40%). The median number of SLNs removed was 3(1-7). Of 223 patients, 147 patients (66%) were treated with breast-conserving therapy (BCT), whereas the remaining underwent mastectomy. Pathological analyses revealed that 40% had a pathologic complete response, and 67% had negative SLNs. The remaining 73 patients (33%) had positive SLNs (31 micrometastases, 12 isolated tumor cells and 30 macrometastases), and the majority had (90.4%) no extracapsular lymph node invasion. At a median follow-up time of 36 months (24-159), none of the patients developed an axillary recurrence. The

ipsilateral breast cancer recurrence rate was found to be 4.1% among patients with BCT, and 1 patient (0.45%) with micrometastatic SLNB was found to have a supraclavicular metastasis. Five-year locoregional recurrence (LRR)-free, disease-free survival (DFS), and disease-specific survival (DSS) rates were found as 93.1%, 76.4%, and 95%, respectively. No difference could be found in 5-year LRR-free survival, DFS, and DSS rates between patients with a negative or positive SLNB (LRR-rate: SLNB-negative, 93% vs SLNB-positive, 93.6%, p=0.47). However, pathologic complete responders were more likely to have a better 5-year DSS or DFS rate compared to non-responders (DSS-rate; HR=7.62, 95% CI, 0.9-65); and DFS-rate, HR=3.58, 95% CI, 1.41-9.1).

Conclusions: Our contemporary multidisciplinary management of LABC provides favorable outcome with excellent local control in selected patients with good responders to NAC. Our early findings suggest ALND could be safely avoided in patients with locally advanced breast cancer who underwent SLNB after receiving NAC with negative SLNs or low tumor burden such as micrometastasis/ITC or macrometasis without extracapsular extension as long as axillary radiation therapy is provided.

556984 - Axillary lymph node management in the era of neo-adjuvant chemotherapy, neoendocrine treatment, and targeted axillary dissection

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Background/Objective: Historically, most women diagnosed at time of presentation with node-positive breast cancer were managed surgically with axillary lymph node dissection (ALND). Recent studies have documented the safety and acceptable false-negative rates with sentinel lymph node biopsy (SLNB) and targeted axillary dissection (TAD) after neo-adjuvant chemotherapy (NAC) in node-positive patients who convert to node-negative. This study reviews practice paradigms for all receptor types of breast cancer and assesses how many patients were successfully downgraded from ALND to SLNB/TAD.

Methods: Retrospective chart review was performed for patients who underwent NAC or neo-endocrine therapy with presentation of node-positive disease from 9/2016 to 9/2018. Stage 4 patients were excluded. Data collected included demographics, treatment regimen, pathology results, and type of surgery performed.

Results: In total, 43 patients were included, and the majority presented with N1 disease. Average age was 63, ranging from 38 to 86. Nineteen percent had a complete pathologic response (pCR), and 7% converted to negative node status with persistent or partial response in the breast. The majority of patients with pCR were HER2 amplified (45%) or triple-negative (27%). Of all nodal responders, 91% received NAC, and 9% received neo-endocrine treatment. Fifty-five percent of hormone receptor-positive patients received NAC, 37% neo-endocrine therapy, and 8% both. Of these patients, node response was 19% for NAC and 8% for neo-endocrine treatment. All triple-positive patients received NAC. Targeted axillary dissection with sentinel lymph node biopsy was done in 65% of patients with no further axillary surgery; 36% of those having no residual nodal disease. Axillary lymph node dissection was completed in 35% of patients, with 40% of those having no additional positive nodes.

Conclusions: Targeted axillary dissection for neo-adjuvant and neo-endocrine patients has spared some women the morbidity of a complete ALND, either due to pCR or patient preference after discussion of risks and benefits. Going forward, our focus will be on further implementation of TAD/SLNB for those with pCR or nodal CR with continued monitoring of patient outcomes.

| RESPONSE | TOTAL | ER/PR- Her2 + | Triple Negative | Triple Positive | ER/PR+ Her 2 - | ER+ PR- Her2 - | ER + PR- HER2 + |
|-----------------|-------------|------------------|--------------------|--------------------|-------------------|-------------------|--------------------|
| pCR or Nodal CR | 11 (26%) | 3 (100%) | 3 (50%) | 2 (29%) | 2 (10%) | 1 (20%) | - |
| Partial | 25 (58%) | - | 2 (33%) | 5 (71%) | 15 (71%) | 3 (60%) | - |
| NONE | 7 (16%) | - | 1 (17%) | | 4 (19%) | 1 (20%) | 1 100% |
| TOTAL | 43 | 3 (7%) | 6 (14%) | 7 (16%) | 21 (49%) | 5 (12%) | 1 (2%) |

Table: Response rates by phenotype

581270 - National trends in the use of sentinel node biopsy after neoadjuvant chemotherapy in the United States

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Background/Objective: Neoadjuvant chemotherapy (NACT) is used to attempt to downstage patients with breast cancer who have large tumors and positive nodes. Surgical management of the axilla is becoming less extensive, even for patients having positive lymph nodes, although controversy exists over when to omit sentinel lymph node biopsy (SLNB) after NACT and proceed directly to axillary lymph node dissection (ALND). This study was performed to evaluate axillary surgery practice patterns in the United States for patients who have had NACT.

Methods: Using the National Cancer Database (NCDB), female patients over the age of 18 who underwent NACT for advanced, non-inflammatory breast cancer were identified. Axillary surgery was defined 2 ways. Consistent with the AJCC's (sn) staging designator definition, the first defined SLNB as those having 1-5 nodes removed, and ALND as those having ≥ 6 nodes. The second utilized the axillary surgery variables recorded after 2012, specifying SLNB, ALND alone, and SLNB converted to ALND. Patient and treatment characteristics were compared by surgical treatment, and predictive factors were explored using multivariable logistic regression analyses.

Results: Between 2006 and 2015, there were 235,235 patients fulfilling criteria, with a mean age of 54.7 \pm 11.3. Prior to NACT, 39.6% had Stage II, and 11.8% had Stage III disease. In total, 50.9% underwent breast-conserving surgery, and 32.7% underwent unilateral mastectomy. When using pathology variables, clinical node positivity was seen in 25.0%, and the mean number positive nodes on surgical pathology was 2.3 ± 7.4 overall. SLNB was performed in 49.0%, and 51.0% underwent ALND, with a 21.5% increase in SLNB from 2006 to 2015. The mean number of nodes removed was 2.6 ± 1.3 for SLNB and 16.1 ± 12.8 for ALND, and 74.4% of ALND had ≥ 10 nodes removed. Patients who underwent SLNB and ALND had 0.3 ± 1.5 and 4.4 ± 10.1 positive nodes, respectively. The use of SLNB in patients having NACT was predicted by patients with triple-negative disease, grade 3 and 4 tumors, private insurance, higher income and age, while primary ALND was seen more frequently in pre-NACT clinical N Stage ≥ 1 and clinical T Stage ≥ 2 , lobular histology, and hormone-positive/HER2-negative disease. Based on the surgical definition of SLNB and ALND, SLNB was done in 49.5%, primary ALND in 24.1%, and SLNB was converted to ALND in 26.4%. Between 2012 and 2015, there was a 2.9% decrease in SLNB procedures converted to ALND. Conversion from SLNB to ALND was predicted by pre-NACT clinical N Stage ≥ 1 and clinical T Stage ≥ 2 , lobular histology, and hormone-positive/HER2-negative disease.

Conclusions: The use of SLNB remains frequently used in patients having NACT, and its use has increased over time. The strongest predictor of SLNB use with NACT was clinical triple-negative disease, which may reflect the high response rate to NACT. A decrease in the rate of SLNB conversion to ALND may reflect improvements in response rates or better patient selection. Although the current literature has found false-negative identification rates to be higher when SLNB is used, it remains unclear whether the lack of recurrence data from SLNB has contributed to the lack of consensus. Further education and long-term outcomes data assessing such recurrence risks may assist in making practice more uniform nationally.

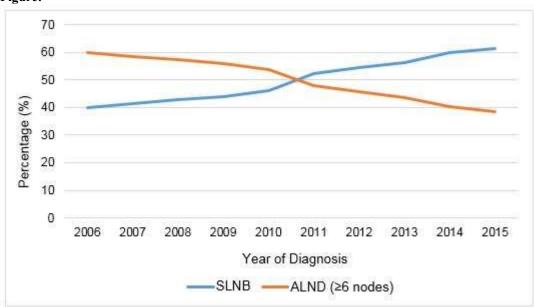


Figure:

581599 - Should sentinel lymph node dissection be offered after neoadjuvant therapy in breast cancer patients with N3 disease at diagnosis?

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Background/Objective: Utilization of sentinel lymph node dissection (SLND) in breast cancer patients with positive nodes after neoadjuvant chemotherapy has increased. We examine axillary response rates after neoadjuvant therapy in patients with clinical N3 disease at diagnosis to determine whether SLND should be considered.

Methods: Breast cancer patients who received neoadjuvant systemic therapy followed by surgery were selected from our institutional tumor registry (2009-2016). A total of 536 patients were identified. Patients with clinical N3 (American Joint Committee on Cancer 7th Edition) disease were included and patients with metastatic disease were excluded. Data were collected for patient demographics, tumor characteristics, systemic and surgical treatments, and pathology. Clinical and pathologic axillary response rates were assessed.

Results: Twenty-four patients with clinical N3 disease were identified. Median age at diagnosis was 49

years (range 33-68), all patients were female, and 56% were Hispanic (Table). Distribution of clinical stage at diagnosis was: T2N3 6 patients (25%), T3N3 9 patients (37.5%), T4a-cN3 5 patients (20.8%), and T4dN3 4 patients (16.7%). Approximated breast cancer subtype was hormone receptor (HR+) and human epidermal growth factor receptor-2 (HER2)-negative in 11 patients, HER2+ in 7 patients, and triple-negative in 6 patients. The majority of patients (95.8%) received multi-agent neoadjuvant therapy, and all patients with HER2+ tumors received anti-HER2 therapy (trastuzumab +/- pertuzumab). Modified radical mastectomy (MRM) was performed in 16 patients, with 5 having a pathologic complete response (PCR) in the axilla, 1 with HR+/HER2- disease, 2 with HER2+ disease, and 2 with triple-negative disease. Eight (33.3%) patients with a good or complete clinical response after systemic therapy underwent SLND. Completion axillary LND was necessary in 5 of these patients due to positive SLN. Overall, 16 out of 24 patients (67%) had residual positive nodes (median number 7, range 4-23).

Conclusions: The majority of breast cancer patients with clinical N3 disease at diagnosis did not have a PCR and significant residual nodal burden was identified in the axilla. We therefore do not recommend SLND alone in the majority of patients with clinical N3 disease after neoadjuvant therapy. Although repeat imaging and LN biopsy may be considered in order to identify the small subgroup of patients with PCR.

N (%)

| Tudent Characteristics | (/ 0 / |
|---|-----------|
| Age (median 49, range 33-68) | |
| <50 | 13 (54.1) |
| ≥50 | 11 (45.9) |
| Race/Ethnicity: | |
| Non-Hispanic White | 8 (33.3) |
| Non-Hispanic Black | 2 (8.3) |
| Hispanic | 14 (58.4) |
| Tumor Characteristics | |
| Clinical Stage | |
| T2N3a | 1 (4.2) |
| T2N3b | 3 (12.4) |
| T2N3c | 2 (8.3) |
| T3N3a | 1 (4.2) |
| T3N3b | 5 (20.8) |
| T3N3c | 4 (16.6) |
| T4a-cN3a | 2 (8.3) |
| T4a-cN3b | 2 (8.3) |
| T4a-cN3c | 0(0) |
| T4dN3a | 0(0) |
| T4dN3b | 0(0) |
| T4dN3c | 4 (16.7) |
| Approximated Breast Cancer Subtype | 4 (10.7) |
| HR* positive/HER-2# negative | 11 (35.8) |
| HER-2 positive | 7 (29.2) |
| Triple negative | 6 (25.0) |
| Pathologic Stage | 0(25.0) |
| TONO | 7 (29.3) |
| T1N0 | 1 (4.2) |
| T3N1 | 1 (4.2) |
| T1-2N2 | 6 (25.0) |
| T1-2/N2 T1-3N3 | 8 (33.3) |
| Treatment Characteristics | 0 (33.3) |
| Systemic Therapy Regimen | |
| Doxorubicin + Cyclophosphamide & Taxane | 12 (50.0) |
| Doxorubicin + Cyclophosphamide & Taxane Doxorubicin + Cyclophosphamide & Docetaxel + Cisplatin | 3 (12.4) |
| Docetaxel + Carboplatin + Trastuzumab | 4 (16.6) |
| Doxorubicin + Cyclophosphamide & Docetaxel + Trastuzumab + Pertuzumab | |
| Docetaxel + Carboplatin + Trastuzumab + Pertuzumab | 1 (4.2) |
| Paclitaxel + Trastuzumab | |
| | 1 (4.2) |
| Docetaxel + Cisplatin + Bevacizumab | 1 (4.2) |
| Docetaxel | 1 (4.2) |
| Surgical Management | 16/66 72 |
| Modified Radical Mastectomy | 16 (66.7) |
| Mastectomy + SLND [†] + cALND [†] | 5 (20.8) |
| Mastectomy + SLND | 2 (8.3) |
| Lumpectomy + SLND | 1 (4.2) |

Table: Patient, tumor and treatment characteristics for breast cancer patients with clinical N3 disease

*Hormone Receptor * Sentinel Lymph Node Biopsy

Patient Characteristics

⁺ Human Epidermal Growth Factor Receptor-2 ‡ Completion Axillary Lymph Node Dissection

582123 - Is sentinel lymph node biopsy possible after neoadjuvant chemotherapy in clinically-responsive inflammatory breast cancer patients?

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Background/Objective: With the placement of a marking clip in the affected node(s) prior to neoadjuvant chemotherapy, sentinel lymph node (SLN) biopsy is increasingly being utilized after neoadjuvant chemotherapy in breast cancer patients with clinically evident adenopathy, allowing a subset of patients to avoid axillary lymph node dissection (ALND). This evolving approach is still discouraged among patients presenting with inflammatory breast cancer (IBC). We sought to review the axillary complete pathologic response (AXcPR) rate following neoadjuvant chemotherapy among patients with IBC to determine whether this approach may be feasible.

Methods: We reviewed our IRB-approved, single-institution database for patients with IBC. Inclusion criteria for the study population were age ≥ 18 , clinico-pathologic diagnosis of IBC, and full documentation of completed standard tri-modal therapy for IBC. Patients with documented Stage IV disease at diagnosis were excluded. We collected data on demographics, preoperative axillary status, tumor characteristics including, histologic receptor and subtype, as well as treatment effect details.

Results: Among the 70 patients who fulfilled the criteria, 93% presented with clinically evident regional disease. There were 20 patients with hormone-receptor (HR)-positive/HER-2-negative disease. Of these patients, 19 (95%) had axillary disease following neoadjuvant chemotherapy. For 21 patients with the basal subtype, the AXcPR rate was 24%. For the 27 patients with HER-2-positive disease who had clinically evident regional disease, the AXcPR rate was 63%, with minimal difference between HR positive and HR negative. Among this population, the size or number of abnormal nodes on pre-chemotherapy imaging was not predictive of AXcPR. With a mean follow-up of 3.2 years, only 5 of 27 (18%) HER-2/neu-positive patients developed distant disease, compared with 37% for HR positive/HER-2-negative, and 57% for basal.

Conclusions: In this series of patients with IBC, pre-chemotherapy clip placement and postchemotherapy SLN biopsy may spare a considerable portion of HER-2 over-expressing patients from complete ALND. This approach would have modest impact for basal subtypes. Moreover, it would be the least impactful in patients with HR positive subtypes. Further research is needed to assure that this approach is feasible and accurate in IBC and better select out patients who are unlikely to have a complete pathologic response.

581509 - Sentinel lymph node removal after neoadjuvant chemotherapy: When to stop? <u>Brittany Murphy</u>, Malke Asaad, Courtney Day, Tanya Hoskin, James Jakub, Elizabeth Habermann, Judy Boughey *Mayo Clinic, Rochester, MN*

Background/Objective: For patients with invasive breast cancer undergoing primary surgery, it has been shown that if multiple sentinel lymph nodes (SLN) are identified by radionucleotide and/or blue dye, removal of 4 SLNs will accurately stage the axilla. Whether this same principle may be applied to patients undergoing chemotherapy in the neoadjuvant setting has not been determined. We sought to determine the number of SLNs needed to accurately stage the axilla in clinically node negative (cN0) patients who undergo neoadjuvant chemotherapy (NAC) for the treatment of invasive breast cancer.

Methods: We retrospectively identified all women age ≥ 18 years of age diagnosed with invasive breast cancer, cN0 at the time of diagnosis, received NAC, and underwent SLN surgery at our institution between September 2008 and September 2018. A prospectively maintained breast surgery database and review of the electronic medical record were used to obtain patient, tumor, and treatment variables. Univariate analysis was performed to compare factors associated with positive nodes and the order in which they were positive.

Results: We identified 454 patients who met our inclusion criteria (388 pN0, 66 pN+), with an average age of 51.5 years (range 21-84). Tumor biologies were: 174 (38.8%) HR+/HER2-, 100 (22.3%) HR+/HER2+, 40 (8.9%) HR-/HER2+, 134 (29.9%) HR-/HER2- (Table). The number of nodes removed was similar for both patients with pN0 and pN+ disease, with a median number of SLNs removed of 3.0 (IQR: 2.0, 4.0) for both groups and a range from 1-10 for pN0 patients and 1-8 for pN+ patients, p=0.87. Of the 66 (14.5%) patients who had a positive SLN, the first positive SLN was SLN #1 in 78.8%, #2 in 16.7% and #3 in 4.5% (Table). Of all patients with a positive node, that node was found by the third SLN removed.

Conclusions: Among cN0 patients treated with NAC for breast cancer, if a positive SLN is present, it is most commonly identified as the first sentinel node, and was identified by the third node in all cases in our series. This suggests that the number of SLNs removed in patients with cN0 disease at diagnosis who undergo NAC could be limited to the first 3 nodes.

| | pN0 (N=388) | pN+ (N=66) | Total (N=454) | p value |
|-----------------------------|----------------|---------------|------------------|---------------------|
| Age at Surgery | N 16 | | | 0.143 |
| (per patient) | | | | |
| N | 382 | 66 | 448 | |
| Mean (SD) | 51.9 (12.3) | 49.4 (9.8) | 51.5 (11.9) | |
| Median | 52.0 | 50.0 | 51.0 | |
| Q1, Q3 | 43.0, 61.0 | 43.0, 56.0 | 43.0, 60.0 | |
| Range | (21.0-84.0) | (28.0-73.0) | (21.0-84.0) | |
| Clinical T Category | | | | ⊲0.0001 |
| T1 | 82 (21.1%) | 7 (10.6%) | 89 (19.6%) | |
| T2 | 253 (65.2%) | 33 (50.0%) | 286 (63.0%) | |
| T3 | 49 (12.6%) | 24 (36.4%) | 73 (16.1%) | |
| T4 | 4 (1.0%) | 2 (3.0%) | 6 (1.3%) | |
| Tumor Biology | | | | 0.0001 ¹ |
| Missing | 6 | 0 | 6 | |
| HR+/HER2- | 133 (34.8%) | 41 (62.1%) | 174 (38.8%) | |
| HR+/HER2+ | 86 (22.5%) | 14 (21.2%) | 100 (22.3%) | |
| HR-/HER2+ | 39 (10.2%) | 1 (1.5%) | 40 (8.9%) | |
| HR-/HER2- | 124 (32.5%) | 10 (15.2%) | 134 (29.9%) | |
| Number of SLNs removed | | | | 0.873 |
| N | 377 | 66 | 443 | |
| Mean (SD) | 3.1 (1.5) | 3.1 (1.7) | 3.1 (1.5) | |
| Median | 3.0 | 3.0 | 3.0 | |
| Q1, Q3 | 2.0, 4.0 | 2.0, 4.0 | 2.0, 4.0 | |
| Range | (1.0-10.0) | (1.0-8.0) | (1.0-10.0) | |
| Number of SLNs positive | | | | |
| N | | 66 | 66 | |
| Mean (SD) | | 1.7 (0.9) | 1.7 (0.9) | |
| Median | | 1.0 | 1.0 | |
| Q1, Q3 | | 1.0, 2.0 | 1.0, 2.0 | |
| Range | | (1.0-5.0) | (1.0-5.0) | |
| First Positive SLN position | | | | |
| 1 | | | 52 (78.8%) | |
| 2 | | 11 (16.7%) | 11 (16.7%) | |
| 3 | | 3 (4.5%) | 3 (4.5%) | |

Stage IV

582162 - Primary tumor resection in de novo Stage IV breast cancer patients: Single academic center experience

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Background/Objective: Breast and axillary surgery in Stage IV breast cancer (BC) is outside current national standard of care guidelines but has been a topic of debate, particularly given recent prospective publications. Our goal was to assess the current practice and outcomes of primary site surgery in de novo Stage IV BC patients at an academic medical center.

Methods: Women 18 years or older at a single academic institution diagnosed with de novo Stage IV BC from 2011-2016 who underwent breast surgery were identified via tumor registry. A retrospective chart review was conducted for goal of surgery (treatment intent versus palliation), timing and type of operation along with follow-up outcomes. Data points were analyzed using descriptive variables. At follow-up, patients with stable disease versus those who had mortality were compared for differences.

Results: During the study years, 265 de novo Stage IV BC patients were treated at our institution, 10.2% (n=27) of which underwent breast and/or axillary surgery. Average age was 56 years, and follow-up was 40.9 months. The majority of patients were Caucasian (85.1%) and had Medicare (48.1%) or private (44.4%) insurance. Most did not have genetic testing (62.9%) or were negative (25.9%). The average tumor size was 6.2-3.7 cm. T stage distribution was T1 11.1%, T2 25.9%, T3 25.9%, and T4 37.0%. N stage distribution was N0 37.0%, N1 44.4%, N2 3.7%, N3 14.8%. Most patients had either 1 (37.0%) or 2 to 3 (44.4%) metastatic sites, with bone (81.5%) or liver (40.7%) most common. Systemic therapy was first line of treatment in most patients (66.6%), but one-third underwent breast/axillary surgery first. Mastectomy (n=23, 85.1%) was most common, and goal of surgery was most often treatment intent (n=23, 85.1%) rather than palliation (n=4, 14.8%). There was no 30-day mortality and low (n=1, 3.7%) 30-day morbidity for all patients. Mortality was 33.3% (n=9) during follow-up. There was no difference in demographics, tumor size, T and N stage, number of metastatic sites, initial cancer treatment, or type of surgery for patients who were stable versus those who had mortality. There was also no difference in goal of surgery for stable versus mortality patients (p=0.60).

Conclusions: Despite increasing discussion of surgery for de novo Stage IV BC patients, our data demonstrate few patients undergo operative intervention. This is an important illustration of the divide between data and scientific debate versus management in clinical practice, even at an academic center. Multidisciplinary development of patient care pathways based on current evidence may help identify may be suitable for surgery (and appropriately increase those appropriately offered surgery) versus those unlikely to achieve survival benefit.