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SCIENTIFIC SESSION ABSTRACTS

OFFICIAL PROCEEDINGS

VOLUME X

Presentation Awards and Eligibility

Abstracts submitted are eligible for awards. The George Peters Award recognizes the best presentation by a breast fellow and is awarded $1,000. The Scientific Presentation Award recognizes an outstanding presentation by a resident or fellow and is awarded $500. All presenters are eligible for the Scientific Impact Award. The recipient of the award is selected by the audience.

The George Peters 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.

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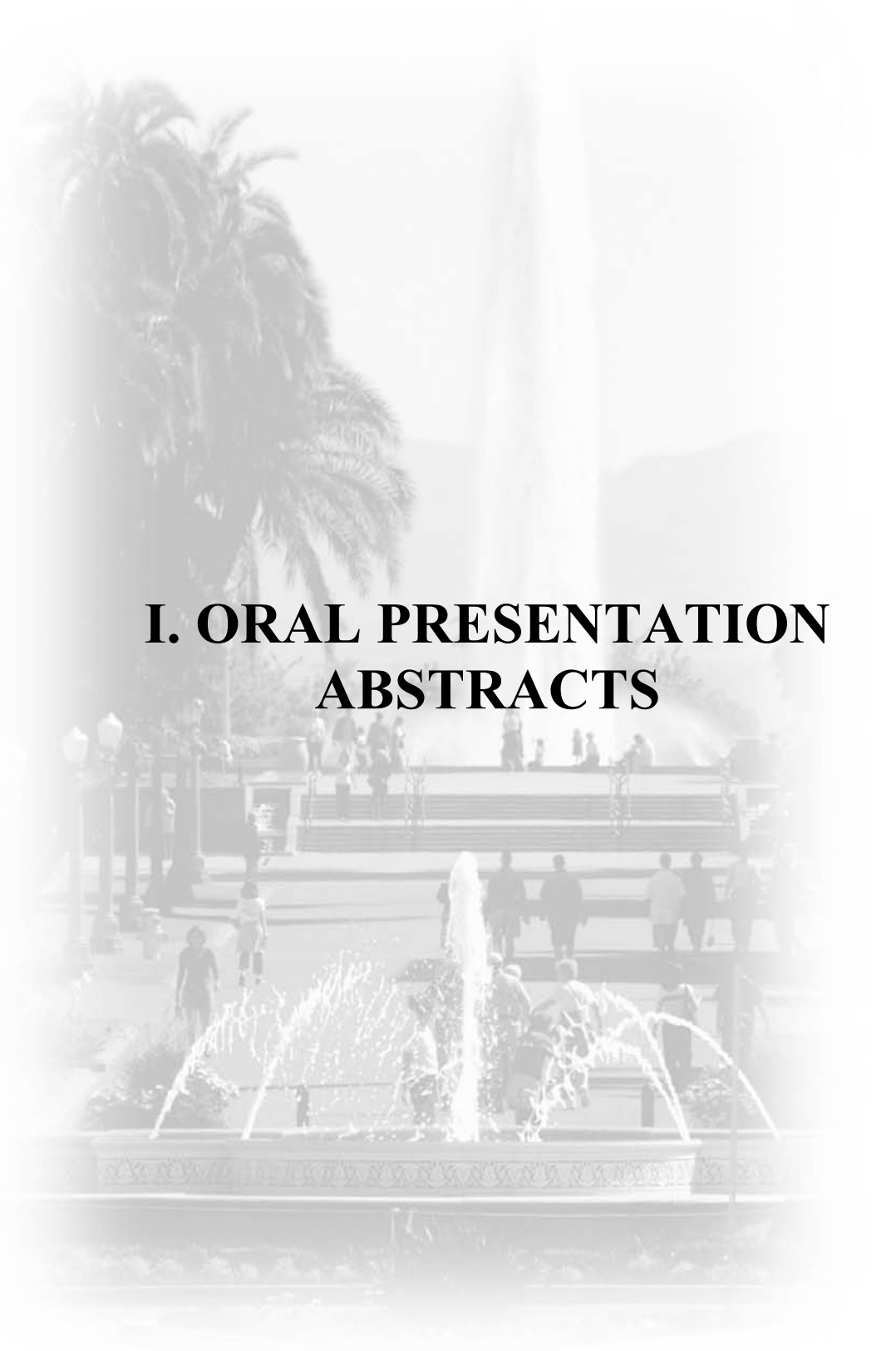

I. ORAL PRESENTATION ABSTRACTS

Note: Underscore indicates presenting author.

HER-2/neu Pulsed DC1 Vaccination in Patients With DCIS Induces Evidence of Changes in Cardiac Function

Susan Bahl, Ursula Koldovsky, Shuwen Xu, Harvey Nisenbaum, Kevin Fox, Paul Zhang, Louis Araujo, Joseph Carver, Brian J Czerniecki

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Objectives: Trastuzumab (Herceptin), a humanized monoclonal antibody against the extracellular domain of the human epidermal growth factor receptor 2 (HER2), has become the cornerstone of treatment for breast cancers that overexpress HER2, but has been associated with cardiac toxicity. We undertook a study using a HER-2-targeted dendritic cell (DC) vaccine to determine whether a cellular vaccine could be used to eliminate HER-2–overexpressing cells in patients who harbor high-risk DCIS lesions and whether the vaccine was associated with cardiac toxicity.

Method: Patients with histologically confirmed DCIS with HER-2/neu overexpression (>2+ intensity in at least 10% of cells) were recruited to this institutional review board–approved clinical trial. Subjects were screened by magnetic resonance imaging (MRI) before enrollment to eliminate individuals with obvious areas of invasive disease. Only patients requiring further surgical therapy for DCIS were eligible for neoadjuvant administration of 4 weekly vaccines consisting of IL-12 secreting DC (DC1) pulsed with MHC class I and class II peptides derived from HER-2. Thirty patients were recruited; 2 patients were screen failures and 1 withdrew secondary to inadequate cell yields, resulting in a total of 27 subjects. All patients underwent cardiac evaluation with multigated acquisition (MUGA) scan or echocardiography prior to and within 2 weeks of the final vaccine. ELISPOT and in vitro sensitization assays were used to determine CD4 and CD8 T-cell sensitization. Serum was tested with HER-2pos and HER-2neg breast cancer cell lines to determine presence of complement-fixing antibodies.

Results: All 27 subjects completed the scheduled vaccines that were well tolerated with the exception of fatigue, fevers, and chills. Immune response demonstrated approximately 90% rate of CD4 and CD8 T-cell sensitization to vaccination as assessed by in vitro immune monitoring tests. Half of all patients demonstrated a significant decrease in HER-2/neu expression following vaccination. Three of 27 patients demonstrated an asymptomatic decline of systolic function of less than 20% in their MUGA scans (Grade 1 or 2). One of these patients underwent repeat MUGA 30 days post completion of trial with a return of MUGA to baseline. All 3 patients had evidence of pre-existing complement-fixing antibodies to HER-2/neu. One of these patients had evidence of anti-IgG coating the DCIS ducts post vaccine, supporting antibody induction from vaccines. All 3 of these patients had evidence of response to vaccination.

Conclusions: The use of vaccines in the setting of high-grade DCIS may provide an opportunity to influence the natural history of this disease. Loss of HER-2/neu expression and apparent tumor regression for DCIS suggests a potential for HER-2/neu pulsed-DC1 vaccines to be useful as an adjunct to breast-conserving surgical strategies. This is the first report to demonstrate that vaccination against HER-2/neu in breast cancer patients can induce mild reversible cardiac toxicity. The cardiac toxicity appears to be associated with immune and clinical response. Despite existing antibodies, induction of a cellular immune response may augment the cardiac toxicity associated with anti-HER-2/neu therapy. Patients receiving targeted anti-Her-2/neu vaccines should be monitored for cardiac toxicity, regardless of an absence of symptoms.

Axillary Reverse Mapping to Identify and Protect Lymphatics Draining the Arm During Axillary Lymphadenectomy

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Objectives: Our initial results utilizing the axillary reverse mapping (ARM) procedure to identify lymphatics draining the arm during sentinel lymph node biopsy (SLNB) with or without axillary lymph node dissection (ALND) may explain why lymphedema still occurs during SLNB and, to a greater extent, during ALND. The objective of this study is to provide an update on our initial results with this new technique.

Method: This institutional review board–approved study from May 2006 to September 2008 involved patients undergoing SLNB ± ALND. Technetium sulfur colloid was injected in the subareolar plexus for SLNB. After SLN localization was assured, 2-5 ml of dermal blue dye were injected in the upper inner arm for localization of lymphatics draining the arm (ARM). The SLNB ± ALND was then performed through an incision in the axilla. Data was collected on identification rates of hot versus blue nodes; variations in ARM lymphatic drainage that may impact SLNB; crossover between the hot and the blue lymphatics and, when crossover was present, the incidence of metastases to arm lymphatics; and final pathological nodal diagnosis.

Results: Median age was 60.3 ± 11.3 years. Results are shown in the table below:

	Hot SLN ID Rate	**Hot SLN Positive for Malignancy**	**Blue ARM Lymphatics Identified Near or in SLN Field**	**Crossover Rate (Hot and Blue Nodes Removed)**	**Blue ARM Node Juxtaposed to SLN**	**Blue ARM Nodes ± Hot That Were Positive for Malignancy**
SLNB (n = 220) and/or ALND (n = 37)	214/220 (97.2%)	40/214 (18.7%)	87/214 (40.6%)	6/214 (2.8%)	12/214 (5.6%)	0/15

Lymphatics draining the arm were near or in the SLN field 40.6% of the cases, placing the patient at risk for disruption if not identified and preserved during an SLNB and/or ALND. Crossover of the blue ARM lymphatics with the hot SLN was seen in only 6 (2.8%) of the patients. In this initial series, another 12 (5.6%) of blue ARM lymphatics were juxtaposed to the hot SLNB but able to be preserved. Fifteen blue lymph nodes draining the arm were excised and were negative even in positive axillae.

Conclusions: Analysis of ARM results show that a significant number of patients are vulnerable to arm lymphatic disruption (37.8%) during axillary lymphadenectomy. It may explain the cause lymphedema seen after ALND and even SLNB. ARM demonstrated that arm lymphatics cross over with the SLN drainage of the breast only in a minority of cases (2.8%), that is the ARM node is rarely the sentinel node. When crossover was identified, none of these lymph nodes contained metastases. Maturation of ongoing studies will elucidate whether identifying and preserving the ARM blue nodes may translate into a lower incidence of postoperative lymphedema.

The Impact of MRI on Surgical Treatment of Invasive Breast Cancer

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Objectives: Controversy surrounds use of magnetic resonance imaging (MRI) in treatment of invasive breast cancer (IBC). Few have investigated the impact of MRI on surgical treatment. This study examines the relationship between MRI and surgical treatment.

Method: Retrospective review of prospectively collected database. IBC patients treated at a single institution with surgical resection and sentinel lymph node biopsy from January 2003-June 2008. Patients underwent MRI per surgeon's discretion. Continuous variables were compared among surgical groups or years using ANOVA F tests. Categorical variables were compared using chi-square tests. Multivariate analysis included generalized logit models and logistic regression models of surgical type and MRI use, respectively.

Results: Eight hundred fourteen patients were treated, with 562 (69%) undergoing breast conservation therapy (BCT), 151 (18.6%) mastectomy alone (M), and 101 (12.4%) M with reconstruction (M+R). Mean age was 66 in BCT, 65.7 in M, and 50.1 in M+R patients ($p < 0.001$). Mean tumor size was 1.4 cm in BCT, 2.9 cm in M, and 2.1 cm in M+R patients ($p < 0.001$). No significant difference in type of surgery performed was noted by year, but a significant increase in MRI use is noted from 2003-2008 (Table). In multivariate analysis, type of surgery performed was significantly associated with tumor size, multifocality, age, and MRI use, but not with tumor markers, nodal status, BMI, or genetic testing. Factors associated with MRI performance were multifocality, age, tumor size, tumor histology, BMI, and genetic testing, but not tumor markers, nodal status, or family history.

	2003	**2004**	**2005**	**2006**	**2007**	**2008**	***P* value**
BCT	67%	72%	71%	71%	64%	71%	0.175
M	17%	18%	18%	17%	29%	14%	
M+R	17%	11%	12%	12%	8%	15%	
MRI	19%	22%	29%	28%	41%	45%	<0.001
Genetic testing	5%	11%	9%	15%	17%	16%	0.004

Conclusions: Over 5 years, the use of MRI in patients with IBC increased without observable impact on surgical treatment. The factors associated with surgical decision were similar to those associated with MRI performance. We feel that patients undergoing MRI are more likely to undergo mastectomies, and that MRI helped elucidate appropriate surgical therapy.

Does Breast-Specific Gamma Imaging Alter Patient Management?

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Objectives: Although mammography remains the gold standard in breast cancer detection, breast-specific gamma imaging (BSGI) involves functional imaging of the breast tissue and can be used as an adjunct to mammography in high-risk patients. The objectives of this study are to (1) determine the number of patients with known breast cancer who had additional lesions detected on BSGI, and (2) examine how often screening BSGI alters the management of patients at high risk for breast cancer.

Method: We performed a retrospective review of 230 patients who underwent BSGI at our institution from January 2006 to December 2007. Patients underwent BSGI with intravenous injection of 30 mCi of technetium-99 ([99m]Tc)-sestamibi and were imaged in craniocaudal and mediolateral oblique projections. Study images were classified as positive (focal increased radiotracer uptake) or negative (no uptake or scattered heterogeneous physiologic uptake). All positive exams then underwent directed ultrasound. The BSGI results were compared with biopsy results when applicable.

Results: During the study period, BSGI exams were performed on 230 patients. Among those who underwent BSGI for a newly diagnosed cancer (n = 23), 3 had additional areas of abnormality. Two patients (8.7%) were diagnosed with a second mammographically occult malignancy, and 1 patient opted for a prophylactic mastectomy. Among those who underwent BSGI for other reasons (n = 207), 49 (24%) required further evaluation. Overall, there were 8 cancers detected (3.9%). Of these, 5 were invasive carcinoma, the smallest of which was 0.4 cm, and 3 were ductal carcinoma in situ (DCIS). The remaining pathology results included 2 papillomas, 1 ADH, 1 LCIS, and 37 benign biopsies.

Conclusions: In the 230 patients who underwent BSGI, management was changed in 23% of patients. Additional areas of cancer were detected in 4.8% of patients. BSGI has an important role in the clinical management of patients at high risk for breast cancer as well as those with known disease. Larger clinical trials are needed to assess the sensitivity and specificity of this interesting modality.

Factors Associated With Improved Outcome After Surgery in Metastatic Breast Cancer Patients

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Objectives: Traditionally, removal of the primary tumor in the setting of metastatic breast cancer (MBC) has not been associated with improved survival. However, recent studies suggest that improvement in survival can be achieved with surgical therapy in MBC. We seek to evaluate the factors that influence outcome of our patients with MBC who underwent mastectomy versus breast conservation (BCT).

Method: In a retrospective review of our prospective database, we identified 566 patients who presented with initial diagnosis of MBC between 1990 and 2007. Information collected included demographics, tumor characteristics, sites of metastases, type of operation, adjuvant therapy, overall survival (OS), and disease status at last follow-up.

Results: Of the 566 patients presenting with MBC, 156 (28%) underwent surgical removal of the primary tumor. Surgery was associated with an improved OS, with patients undergoing surgery of the primary tumor having a 33% OS versus those who did not have surgery with a 20% OS ($p = 0.0004$). A nonsignificant trend toward survival in the patients who underwent node dissection was seen (46% of those having node dissection survived versus only 17% of those with no node exam [$p = .26$]). Fifty-four patients (35%) had BCT, 94 (60%) had mastectomy and 8 (5%) had surgery of the primary tumor site that was not defined. Median follow-up time was 37 months (range, 1-98 months). Of those undergoing local therapy, mastectomy was associated with a 37% OS vs. breast conservation with a 20% OS ($p = 0.04$). Only 3 patients (3%) had positive margins after mastectomy, while 14 (26%) had positive margins after lumpectomy ($p \leq 0.001$). There were no statistically significant differences in the site of metastasis (e.g., bone vs. visceral vs. brain) or the receptor status of the original tumor in the mastectomy vs. BCT groups. There was also no statistically significant difference in rates of radiation therapy, taxane, or hormonal therapy in one group versus the other. Of note, only 61% of patients who underwent lumpectomy had subsequent radiation therapy. In addition, 34% of mastectomy patients had neoadjuvant chemotherapy vs. 15% of the BCT patients ($p = 0.02$).

Conclusions: Our study confirms that removal of the intact primary tumor for breast cancer patients with metastatic disease at presentation is associated with improved OS. In addition, it appears that within this patient subset, mastectomy is associated with a significantly improved OS. It is also possible that nodal dissection has some effect on OS, although we could not verify this with our sample size. Prospective clinical trials with correlative science are necessary to delineate the exact role of surgery in improving OS in patients presenting with MBC.

Surgical Management of the Axilla: Do Intramammary Nodes Matter?

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Objectives: In breast cancer, the significance of intramammary nodes, found either during surgery as sentinel lymph nodes (SLN) or incidentally on final pathologic examination, is uncertain. The purpose of this study is to find evidence for the appropriate surgical management of the axilla in the setting of intramammary nodes.

Method: Retrospective review of an institutional SLN database was performed for consecutive patients staged between September 1996 and December 2004. Intramammary lymph node identification was recorded and compared to the status of the axilla.

Results: Among 7140 patients, intramammary lymph nodes were identified in 152 (2%). These were identified at surgery as SLN in 15 patients (10%) and on pathologic examination in the remaining 137 (90%). Of the 15 intramammary SLN, only 2 were seen on preoperative lymphoscintigraphy. Two of 15 were found by isotope only, 0 of 15 by blue dye only, and 10 of 15 by dye plus isotope.

Axillary Status	**Intramammary Node-Negative**		**Intramammary Node-Positive**	
	Intramammary Nodes Identified As SLN at Surgery (n = 15)			
	# Patients	**ALND+ (%)**	**# Patients**	**ALND+ (%)**
Axillary SLN-	9	0/1 (0%)	3	0/1 (0%)
Axillary SLN+	2	0/2 (0%)	1	1/1 (100%)
	Intramammary Nodes Identified on Pathologic Examination (n = 137)			
	# Patients	**ALND+ (%)**	**# Patients**	**ALND+ (%)**
Axillary SLN-	68	1/4 (25%)	12	2/7 (29%)
Axillary SLN+	39	13/34 (38%)	18	5/17 (29%)

Completion ALND was done in 3 (27%) of 11 patients with negative intramammary SLN (2 of whom also had positive axillary SLN) and the completion ALND was negative in all 3. Completion ALND was done in 2 (50%) of 4 patients with positive intramammary SLN, 1 of whom had positive axillary SLN and the completion ALND was positive in that patient.

Conclusions: Intramammary lymph nodes in breast cancer patients are rare and are far more likely to be found by the pathologist than by the surgeon. When intramammary SLN are identified, the decision to perform a completion ALND should be based on the status of the axillary, not the intramammary, SLN.

Diagnosis of Breast Cancer in Women Age 40 and Younger: Delays in Diagnosis Are Common Due to Underutilization of Genetic Testing and Breast Imaging

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Objectives: Early detection of breast cancer in women age 40 and younger is challenging. We have previously reported that despite recent improvements in genetic testing and awareness of breast cancer risk, only modest gains have been made in achieving early detection in women ≤40. We wished to explore the current and potential impact of digital mammography, MRI, and genetic testing in this population.

Method: Clinic records identified 628 women diagnosed with breast cancer at age ≤40 between January 1996 and August 2008. Means of initial diagnosis, subsequent imaging studies, whether any relative had breast cancer, use of genetic testing, and tumor characteristics were recorded. Patients diagnosed after January 2004 (n = 295) had digital mammography (DM), while patients diagnosed earlier (n = 333) had film screen mammography.

Results: Median patient age was 37 (range, 21-40). Fifty percent (n = 314) of patients had a positive family history of breast and/or ovarian cancer. Genetic testing was performed in 40% of study patients, most only after diagnosis, and was positive for a BRCA gene mutation in 25% (61/247) of those tested, representing 10% of all patients diagnosed under age 40 in this population.

Initial means of tumor detection was self-exam in 71%, screening mammogram in 24%, MRI <1%, and clinical exam/other in 4%. When results were sorted into pre–digital mammography vs. digital mammography years, there was no difference in percent of tumors initially found by screening mammography (20 vs. 29%, respectively; p = NS), mean tumor size (1.9 vs. 2.0 cm, p = NS), or percent of patients with only DCIS (19 vs. 23%, p = NS).

Ninety-five percent of patients had a mammogram at or after diagnosis with 86% (511/595) abnormal and only 14% (81/595) normal. In 81% of the patients, this was their first mammogram. Among 264 patients who had an MRI at or after diagnosis, 85% confirmed the known tumor, 10% showed additional foci of cancer, and only 5% were normal. Among 255 patients who had both an MRI and mammogram at diagnosis, only 1.6% of cancers (n = 4) were not visualized.

Conclusions: Although fewer than 2% of breast cancers in women ≤ 40 were not detectable by mammography and/or MRI, 71% of tumors were first detected by patient self-exam, with half of tumors >2 cm in size. Most patients had never had a screening mammogram prior to diagnosis. Genetic testing was uncommon prior to diagnosis although 50% of patients ≤ 40 had a positive family history of breast cancer. These results underscore the importance of identifying young women who are at high risk, performing appropriate genetic testing and delivering appropriate mammographic and MRI screening.

Predictors of Complete Pathologic Response After Neoadjuvant Systemic Therapy for Breast Cancer

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Objectives: The use of neoadjuvant chemotherapy and endocrine therapy has steadily increased, enabling breast conservation in many patients. In a subgroup of cases, no residual tumor is identified at the time of resection. The purpose of this study was to determine clinicopathologic factors associated with complete pathologic response after neoadjuvant chemotherapy and endocrine therapy.

Method: Clinical, demographic, and pathologic data from all breast cancer patients treated at our institution are prospectively recorded in a database. We reviewed this database and identified 603 breast cancer patients who were treated with neoadjuvant chemotherapy or endocrine therapy between 2000 and 2007. All patients underwent surgical resection of their breast cancer following systemic treatment. Complete pathologic response (pCR) was defined by the absence of any residual invasive malignancy on final specimen analysis. Data were compared using chi-square and Fisher exact test. For more than 2 group comparisons and analyzing multiple dependent variables, MANOVA was used.

Results: Of 603 patients receiving neoadjuvant therapy for breast cancer, 85 (14%) had a pCR at the time of resection. A pCR was observed in 81 (15%) of 541 patients undergoing neoadjuvant chemotherapy, but in only 3 (5%) of 62 patients undergoing neoadjuvant endocrine therapy ($p < 0.05$). On univariate analysis, 4 factors were found to be significantly associated with pCR: higher tumor grade ($p = 0.015$), lack of estrogen and progesterone receptor (ER/PR) expression ($p < 0.0001$), HER-2/neu amplification ($p = 0.025$), and negative lymph node status ($p < 0.0001$). On multivariate analysis, only ER/PR negativity, HER-2/neu nonamplification, and negative lymph node status were found to significantly correlate with pCR.

Conclusions: Overall, patients with "triple negative" (ER/PR negative and Her-2/neu nonamplified) breast cancer phenotypes are more likely to experience a pCR to neoadjuvant therapy compared to patients with ER/PR positive and Her-2/neu amplified tumors. A complete response to neoadjuvant therapy in the regional axillary lymph nodes (N0) is also associated with a pCR in the breast. While a pCR is more frequently observed following neoadjuvant chemotherapy, it is rare following neoadjuvant endocrine therapy.

Prognostic Indicators of Ipsilateral Breast Tumor Recurrence Following Breast-Conserving Therapy

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Objectives: Current clinical guidelines suggest the method of detection (clinical vs. radiographic) of ipsilateral breast tumor recurrence (IBTR) following breast-conserving therapy (BCT) does not influence survival. As a result, controversy exists regarding the optimal surveillance of such patients. Herein, we attempt to determine the prognostic significance of method of detection of IBTR on distant metastases (DM)-free survival.

Method: With IRB approval, a retrospective single-institution chart review of all newly diagnosed breast cancer patients treated between 1981 and 2007 was conducted to identify women treated with breast-conserving surgery. Of these, all patients who received adjuvant radiation therapy (RT) and subsequently developed IBTR were identified. Charts were reviewed for demographics, clinical presentation, method of detection, stage, type of therapy, histopathology, and margin status for both the primary and recurrent tumors. All patients presenting with DM following BCT or a suspected new primary with different histology following BCT were excluded.

Results: A total of 1733 patients were treated with breast-conserving surgery. Of these, 199 (11%) developed IBTR. One hundred fifty-seven of 199 patients received adjuvant RT following breast-conserving surgery and subsequently developed IBTR. Median follow-up for this cohort from the time of recurrence was 27 months (range, 1 to 231). Of all IBTRs, 86% occurred within the initial tumor bed. Sixty-five percent of IBTRs were detected radiographically, whereas 35% were detected clinically. The main outcome was time to DM. Median time from IBTR to DM was 151 months. Five-year DM-free survival following IBTR was 69.5%. Univariate analysis revealed the type of IBTR management, younger age, lymph node positivity at initial diagnosis, higher initial T stage, shorter time to IBTR, histology of recurrence (invasive > mixed invasive and DCIS > DCIS), and method of detection (clinical > radiographic) of IBTR were significant predictors of lower DM-free survival. On multivariate Cox regression analysis, clinically detected IBTRs remained a significant predictor of lower DM-free survival. Median DM-free survival for clinically and radiographically detected IBTRs was 54 months and >231 months (median was not reached), respectively. Adjusted relative risk for clinically detected IBTRs was 2.2.

Conclusions: Contrary to previous reports, clinical detection of local recurrence remains a significant risk factor for time to development of distant metastases. In contrast, radiographic detection of such recurrences confers a higher DM-free survival. These results support the necessity for regular and timely radiographic evaluations following IBTR in patients previously treated with BCT.

Rapid Noninvasive Imaging of the Biochemical Composition in Breast Tumor Margins

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Objectives: Annually, more than 165,000 women undergo breast-conserving surgery (BCS) for a breast malignancy and more than 30% require a re-excision surgery due to incomplete removal of the cancer. The long-term objective of this research is to develop an optically based technology to reduce the frequency of breast re-excisions. The goal of this study is to identify those tissue composition factors that define the differences between benign and malignant breast tissue.

Method: With IRB approval, a prospective study of optical spectral imaging of BCS margins is being performed. Breast specimens from consented patients are evaluated, post mammography, within a Plexiglas box designed to expose the margin face to the probes. The specimens have up to 3 margins evaluated, imaging requires 30 seconds for an area that is 3 x 2 cm, and the optical sensing depth is 2 mm. The optical spectral images are transformed into tissue composition maps with parameters of total hemoglobin concentration, beta-carotene concentration, and scattering. The ratio maps are computed for beta-carotene and scattering and total hemoglobin and scattering. The predicted outcome of a positive or negative margin is then compared to the actual pathology. Wilcoxon tests are used to detect significant differences between optically measured margins.

Results: Forty-eight patients have consented to margin analysis with the device. Fifty-five margins have undergone assessment and comparison to the final pathology. Mean invasive tumor size is 1.78 cm with a node positivity rate of 28%. Within 34 margins with pathologically confirmed positive margins, 13 were positive for disease and 21 had disease close (<2 mm) to the margin. Summary measures derived from the 2 ratio metric margin maps showed statistically significant differences between positive and negative margins ($p = .002$ and $p = .005$). The ratio map of beta-carotene/scattering showed the most significant difference reflecting a decrease in adipose content and an increase in cell density within malignant margins ($p = .002$).

Conclusions: We present a novel optical imaging device that provides a rapid, nondestructive assay of the biochemical composition of breast tumor margins. These compositional features demonstrate statistically significant differences between margins and can assist the surgeon in extent of tissue excision.

II. DISCUSSION POSTER ABSTRACTS

Validation of a Clinical Prediction Rule for Nonsentinel Node Metastasis

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Objectives: A significant proportion of patients with a positive sentinel lymph node (SLN) may have no further non-SLN metastases. A simple clinical prediction rule using preoperative and intraoperative factors has been developed to predict non-SLN metastases in these patients. The purpose of this study was to validate this clinical prediction rule in an independent population.

Method: Two prospective clinical investigative studies of a novel intraoperative RT-PCR assay for SLN metastases were performed in 12 sites across the United States. Of the 728 patients enrolled in those studies, 205 (28.2%) were found to be SLN positive by hematoxylin-eosin staining. Of these patients, 123 had further non-SLN removed at the time of the original surgery. Tumor size was not reported in 7 patients; the remaining 116 patients formed the cohort of interest for this study.

Results: The median patient age was 58 (range, 27-86) with a median tumor size of 2.2 cm (range, 0.2-22.0). The median number of SLN removed was 2 (range, 1-11), with a median of 1 SLN positive (range, 1-5). The median number of non-SLNs removed was 12 (range, 1-38), with 42 patients (36.2%) having non-SLN metastases. The previously published clinical prediction rule assigns 1 point if more than 1 SLN had metastatic disease, 1 point if more than 50% of all SLNs harbored metastases, and up to 4 points based on tumor size (1 point for T1a, 2 points for T1b or T1c, 3 points for T2, and 4 points for T3 tumors). In this cohort, the number of points correlated with non-SLN metastases with 0 (0%) of 2 patients with 1 point, 6 (19.4%) of 31 patients with 2 points, 9 (28.1%) of 32 patients with 3 points, 10 (37.0%) of 27 patients with 4 points, 10 (62.5%) of 16 patients with 5 points, and 7 (87.5%) of 8 patients with 6 points having non-SLN metastases, $p = 0.001$. Furthermore, the number of positive non-SLNs was also correlated with the number of points in this clinical prediction rule ($p = 0.001$). The area under the receiver-operator curve (AUC) was 71.8% (95% CI, 61.9%-81.7%). This compares favorably to the original publication in which the clinical prediction rule was developed [AUC, 68.0%; 95% CI, 64.9%-71.1%].

Conclusions: These data validate the previously published clinical prediction rule that provides a simple intraoperative tool to predict non-SLN metastases.

An 11-Year Experience With Invasive Lobular Carcinoma and Intraoperative Touch Prep Cytology With Sentinel Lymph Nodes

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Objectives: Lobular cancers comprise 8-14% of all breast cancers. We have established that one of the more sensitive techniques of intraoperative sentinel node evaluation is touch prep cytology. In this study we report our 11-year experience using intraoperative touch prep cytology (IOTPC) on lymph nodes (LNs) with patients having invasive lobular carcinoma.

Method: An IRB-approved retrospective study of our sentinel node data base was performed on patients with breast cancer. A total of 300 patients from 1997 through 2008 were diagnosed with invasive lobular breast carcinoma. Of these, 199 patients (66%) had a mixed lobular and ductal pattern and were excluded from this study. One hundred one patients (34%) did not show a mixed lobular and ductal pattern; these were included in this study. The SLN was identified via dual mapping. Our pathologists identified the LNs and bivalved them if they measured <6 mm along the long axis. Larger LNs were sectioned at 3-mm intervals. IOTPC was performed for the initial consult. Final diagnoses were confirmed with hematoxylin and eosin (H&E).

Results: A total of 242 SLNs were submitted for pathologic evaluation. Of these, 218 (90%) underwent IOTPC. Two hundred forty-two LNs (100%) were evaluated by H&E for final pathologic diagnosis. Seventeen LNs (8%) had a discrepancy between IOTPC and final H&E diagnosis. There was 1 false-positive result where IOTPC was positive and H&E was rendered negative. The remaining 16 LNs (7%) were false negatives. The sensitivity for IOTPC was 70%, and specificity was 99%. We had a total of 6 LNs diagnosed as isolated tumor cells (ITCs). Of these, 3 were in the false-negative group of LNs. An additional 4 LNs were diagnosed as micrometastases and these were also in the false-negative group. Of the 17 LNs with discrepancy between IOTPC and H&E, the primary tumor of 2 patients showed lymphovascular invasion, and 1 of those was diagnosed as an ITC.

Conclusions: The intraoperative evaluation of LNs using touch prep cytology is an excellent tool for our patients with breast cancer. Invasive lobular carcinoma presents a more difficult challenge due to the size of the tumor cells. In our study, we found that although our sensitivity is less than our previous results, IOTCP is still as reliable a tool to use in the diagnosis of LNs.

Disease-Specific Survival of Male Breast Cancer Patients

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Objectives: Breast cancer is the second most common cause of cancer mortality in women, however it remains less than 1% of all cancer deaths in men and represents 0.6% of all breast cancer diagnoses. The infrequent incidence has prevented investigators from prospectively studying the disease, especially issues of management and treatment response. Generally, most assume the disease to be equivalent between genders, but there are several specific aspects that place this assumption under suspicion. Historically, stage-stratified overall survival is similar between genders, but there is evidence that male breast cancer may have an improved disease-specific survival (DSS). This determination was the subject of our investigation.

Method: Consecutive men diagnosed with male breast cancer from 1982 to 2007 were enrolled into our IRB-approved prospective database. The investigational setting was an academic medical center. Patient data was used to match women of similar stage, age, histology, and date of diagnosis. Demographic and survival data were generated and comparative analysis was performed.

Results: Seventy consecutive men with a median age of 68 years had a median follow-up of 8.2 years. The overall survival Kaplan-Meier curves demonstrated no significant difference between the male and matched female patients (P = 0.916, log-rank test) with median survivals of 14.08 years and 15.17 years, respectively. The DSS was significantly different (P = 0.021, log rank test) with 5-year DSS of 85% and 72.2% and 10-year DSS of 80.5% and 64.2% for men and women, respectively.

Conclusions: Historically, male and female breast cancer has similar overall survival rates. Our analysis shows that although the overall survivals in both genders are similar, men with breast cancer are more likely to succumb from alternate causes of death than are women. The improved disease-specific prognosis for men has implications of an alternate biology.

The Role of a "Second Look" at Mammograpy and Biopsy of Benign/ Probably Benign Microcalcifications After an Abnormal Stereotactic Biopsy

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Objectives: Stereotactic biopsy of the breast is the procedure of choice for obtaining an accurate histological diagnosis of suspicious microcalcifications. Some patients present with multiple clusters of microcalcifications that are not clearly benign or malignant with a report recommending biopsy of one of the clusters (BI-RADS 4A). In patients with a pathology result of cancer or other abnormality necessitating excision, the mammogram is reviewed to determine the need for biopsy of additional groups of benign/probably microcalcifications prior to planning definitive surgery.

The purpose of this study was to examine the pathology results of vacuum biopsy of microcalcifications, initially reported as benign or probably benign, in patients with abnormal pathology results on a vacuum biopsy of suspicious microcalcifications

Method: A retrospective study of all patients undergoing stereotactic-guided vacuum biopsy of suspicious microcalcifications was completed. Patients who had further biopsy of benign or probably benign microcalcifications because of an abnormal pathology result on first biopsy were reviewed. Demographic, imaging, and pathology data, as well as change in surgical management, were recorded. Institutional review board approval was obtained for this study.

Results: Between January 2006 and July 2008, 721 patients had a stereotactic-guided vacuum biopsy in our institution. Eighty (11%) had cancer; 119 (17%) had other abnormal pathology. Of these, 24 patients had 27 additional biopsies of benign or probably benign microcalcifications. Abnormal pathology results were found in half (52%) of these additional biopsies (Table 1) and in those with ductal carcinoma in situ (DCIS), this rate was 75%. Two patients had their diagnosis upgraded and all 12 patients with abnormal results had a change in their surgical plan.

Table 1. Results of Biopsy of Benign/Probably Benign Microcalcifications After Abnormal Stereotactic Biopsy

Pathology of 1st Biopsy, N Patients (%)	Abnormal Pathology on 2nd Biopsy, N Biopsies (%)	Change in Surgery, N Patients	Upgrade
DCIS-7 (29)	6/8 (75) 3-carcinoma 2 atypical hyperplasia 1-radial scar	5	1-microinvasive
Atypical hyperplasia-16 (67)	8/19 (42) 1-carcinoma 6-atypical hyperplasia 1-papilloma	7	1-DCIS
Radial scar-1 (4)	0		
24 patients	14/27 (52)	12	2

Conclusions: Stereotactic breast biopsy has revolutionized the management of suspicious mammograms. Patients occasionally present with multiple clusters of microcalcifications with a recommendation to biopsy the most suspicious cluster. Although multiplicity in itself may be considered a benign characteristic, we found that in patients with abnormal findings on stereotactic biopsy of microcalcifications of low suspicion (BI-RADS 4A), benign and probably benign microcalcifications are associated with a high rate of abnormal pathology. All patients with an abnormal second biopsy had a change in their surgical plan. The clinical significance of many of these findings remains to be elucidated. However, these results suggest that benign or probably benign microcalcifications in a patient with a recent abnormal pathology result of microcalcifications are frequently not benign and support the practice of a "second look" at the mammogram and further biopsy of other clusters of microcalcifications.

Breast Self-Examination: Defining a Cohort Still in Need

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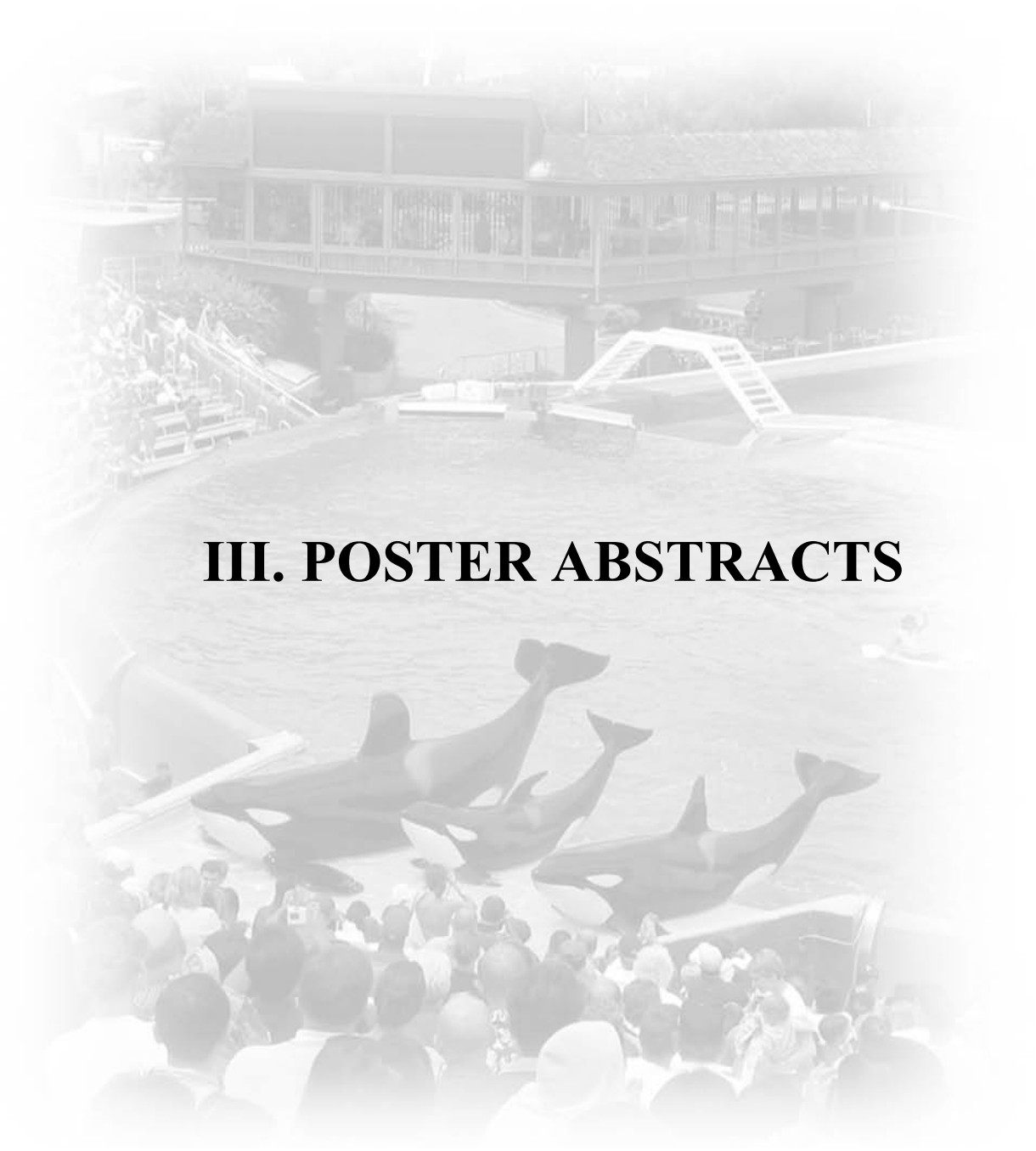
Objectives: Breast self-examination (BSE) is the only noninvasive procedure that can be regularly performed between interval breast imaging and clinical breast examination (CBE). However, BSE has been removed from national screening recommendations for breast cancer. The value of BSE to detect early breast cancer is controversial, especially with the routine utilization of mammography and introduction of breast magnetic resonance imaging (MRI). We hypothesized that BSE could aid in detection of new breast cancers in a cohort of high-risk women undergoing surveillance consisting of yearly screening breast MRI, mammography, and biannual CBE.

Method: With institutional review board approval, we conducted a prospective single-institution study of the ability of BSE to detect new breast cancers in 147 high-risk women undergoing yearly surveillance from July 1, 2004 to October 1, 2007. Participants had either (1) 5-year Gail-risk calculation $\geq$1.7%, (2) prior biopsy with atypical hyperplasia, lobular or ductal carcinoma in situ (LCIS/DCIS), or contralateral invasive breast cancer, (3) BRCA1/2 mutation, or (4) mantel radiation. Yearly screening CBE/BSE teaching and mammography were performed simultaneously followed by breast MRI. Women underwent additional CBE/BSE teaching at 6 months. Women reporting a mass on BSE underwent noninterval CBE followed by ultrasound.

Results: Fourteen breast cancers were detected in 12 women. BSE detected 6 of 14 breast cancers versus 6 of 14 detected by MRI and 2 of 14 by mammography. Of 24 masses detected by BSE, 6 of 24 were malignant. The sensitivity, specificity, and predictive value of BSE to detect breast cancer in our high-risk population was 58.3%, 87.4%, and 29.2%, respectively. Twenty-three women underwent diagnostic evaluation for an abnormal MRI (BI-RADS score $\geq$4). The sensitivity, specificity, and predictive value of a BI-RADS score of $\geq$4 to detect breast cancer was 66.7%, 88.9%, and 34.8%, respectively. The time interval between last MRI and the finding of cancer on BSE was 6-12 months.

Conclusions. Within this single-institution study, we have shown that BSE can detect new breast cancers in women undergoing intensive breast cancer screening. Our results provide evidence that BSE should not be abandoned as an adjunct for breast cancer education, as well as a surveillance tool for high-risk women.



III. POSTER ABSTRACTS

Axillary Staging Prior to or After Neoadjuvant Systemic Therapy? A Single Institutional Experience

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Objectives: The optimal timing for axillary staging in patients undergoing neoadjuvant systemic therapy for breast cancer remains controversial. Many have questioned the accuracy of sentinel lymph node biopsy (SLNB) following systemic treatment. Others report that patients may avoid axillary lymph node dissection (ALND) if the SLNB is negative following systemic treatment. The purpose of the current study was to investigate our institutional strategies for axillary staging in breast cancer patients undergoing neoadjuvant systemic therapy.

Method: Clinical, demographic, and pathologic data from all breast cancer patients treated at our institution are prospectively recorded. We reviewed this database and identified 596 patients who were treated with neoadjuvant chemotherapy or endocrine therapy between 2000 and 2007. Patients were divided into 3 groups based on the method of axillary staging used, including (1) pre-therapy fine needle aspiration biopsy (FNAB), (2) pre-therapy SLNB, or (3) post-therapy ALND. Data were compared using chi-square and Fisher exact test.

Results: Of 596 patients undergoing neoadjuvant systemic therapy, 115 underwent FNAB prior to therapy (Group 1). Group 2 included 142 patients who underwent SLNB prior to therapy—90 were negative and 52 were positive. Of the 52 with a positive SLN, 42 underwent ALND following therapy. Final pathology revealed that 50% had additional positive nodes. Group 3 included 339 patients who underwent ALND following neoadjuvant therapy without any pre-therapy assessment. Final pathology revealed that 202 (60%) had positive nodes and 137 (40%) had negative nodes. There was no significant difference between the groups with respect to patient age, race, clinical T/N stage, estrogen and progesterone receptor and Her-2neu status, or type of neoadjuvant therapy.

Conclusions: The lack of standardized recommendations for axillary staging in the setting of neoadjuvant systemic therapy leads to variable approaches within and between institutions. The use of ALND without any pre-therapy axillary assessment leads to overtreatment for a significant number of patients. Randomized clinical trials are needed to determine the feasibility and accuracy of SLNB following neoadjuvant systemic therapy. Until such data is available, pre-therapy axillary staging may reduce the number of unnecessary lymph node dissections.

Residual Nodal Disease in Biopsy-Proven N1/N2 Breast Cancer Patients Following Neoadjuvant Systemic Therapy

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Objectives: The feasibility and accuracy of sentinel lymph node biopsy (SLNB) following neoadjuvant systemic therapy has been widely debated. Further, the rate of persistent nodal disease following neoadjuvant chemotherapy and endocrine therapy has not been well established. The purpose of this study was to determine the rate of complete pathologic response in axillary lymph nodes following neoadjuvant therapy and the clinicopathologic factors associated with a complete response.

Method: Clinical, demographic, and pathologic data from all breast cancer patients treated at our institution are prospectively recorded in a database. We reviewed this database between 2000 and 2007 and identified 90 patients who were node-positive prior to neoadjuvant therapy based on image-guided fine needle aspiration biopsy; all 90 patients underwent axillary lymph node dissection (ALND) following neoadjuvant therapy. Data were compared using chi-square and Fisher exact test. For more than 2 group comparisons and analyzing multiple dependent variables, MANOVA was used.

Results: Of 90 breast cancer patients who were node-positive prior to neoadjuvant therapy, 71 (79%) had positive nodal disease on final ALND pathology and 19 (21%) had a complete nodal pathologic response. There was no difference between the 2 groups with respect to clinical N stage prior to neoadjuvant therapy (complete response group: 68% N0 and 32% N1 vs. partial/no response group: 79% N0 and 21% N1). The only factor predictive of a complete nodal response was the type of neoadjuvant therapy used; all 19 patients with a complete response received neoadjuvant chemotherapy and none received neoadjuvant endocrine therapy ($p < 0.05$). Age, race, tumor grade, clinical T and N stage, estrogen/progesterone receptor and Her-2neu status were not predictive of a complete nodal response.

Conclusions: Patient factors and tumor biology do not predict the minority of patients who experience a complete nodal response following neoadjuvant systemic therapy. The likelihood of a complete nodal response in patients undergoing neoadjuvant endocrine therapy is negligent; ALND, rather than SLNB, following treatment is indicated in this subgroup. Further studies are necessary to determine the accuracy of lymphatic mapping and SLNB in patients undergoing neoadjuvant chemotherapy.

The Predictive Value of Incidental PET/CT Findings Suspicious for Breast Cancer in Women With Nonbreast Malignancies

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Objectives: Positron emission tomography/computed tomography (PET/CT) is a vital component utilized in the evaluation and staging of patients with a malignant neoplasm. Through the use of this diagnostic modality, findings concerning for a second primary malignancy are occasionally encountered. The purpose of our study was to determine the ability of PET/CT to predict breast cancer in women being evaluated for nonbreast malignancies.

Method: A retrospective query of a prospectively acquired Nuclear Medicine database was performed to evaluate patients undergoing a PET/CT from January 2005 through July 2008. Patients with a nonbreast malignancy and findings concerning for a second primary breast cancer were identified. Clinical chart reviews were performed by experienced clinicians. All PET/CTs were read by a certified nuclear medicine radiologist.

Results: A total of 1500 PET/CTs were performed on 902 women for staging and follow-up of nonbreast malignancies. Of these, 5 women (0.55%) had findings concerning for a second primary malignancy of the breast. The median age of these women was 46 (range, 37-74). Further work-up revealed breast cancer in 4 of these women (80%), and 1 was found to have both fibrocystic changes and apocrine metaplasia (20%). Of the women diagnosed with breast cancer, all had T1 disease. Three of the 4 breast cancers identified were stage I; the other was stage IIA. The median intensity of the PET/CT for the malignant lesions was 2.3 SUV (range, 1.5-4.2). The benign disease registered 1.9 SUV. The positive predictive value of breast lesions exhibiting increased FDG uptake on PET/CT was 80%. All breast cancers identified were at a lower stage than the primary malignancy.

Conclusions: In the staging and surveillance of nonbreast malignancy, PET/CT occasionally identifies breast lesions with characteristics concerning for a second primary malignancy. Although uncommon, the high positive predictive value and the apparent difficulty of distinguishing between benign and malignant lesions with PET/CT indicate that a tissue diagnosis should be sought for all suspicious lesions.

Magnetic Resonance Imaging Application for Operative Planning in Patients With High-Grade DCIS

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Objectives: The value of magnetic resonance imaging **(**MRI) in preoperative staging for invasive breast cancer is well established especially for mammographically occult, contralateral disease and lobular histology. Less is known about the value of preoperative MRI and DCIS. Since high-grade DCIS seems to be biologically similar to invasive breast cancer, we sought to examine the value of MRI for preoperative planning in high-grade DCIS.

Method: Completed case records from our health system tumor registry for 2007 for patients receiving a biopsy-proven diagnosis of DCIS were examined for all patients with high-grade DCIS. Patients with invasive cancer were excluded. Thirty-two (n = 32) patients with high-grade DCIS received an MRI, and are the subjects of this descriptive review for radiology, pathology, and operative findings.

Results: Patients with high-grade DCIS and preoperative MRI ages at diagnosis ranged from 38 to 79, with a median age of 51. Calcifications were the presenting symptom for 22 patients (69%), while 4 (13%) presented with a palpable mass or asymmetry, 4 (12%) with a combination of abnormal calcifications and a mass, and 2 (6%) with nipple discharge. Thirty-one received MRI after an initial stereotactic, core, or open biopsy and 1 patient received an MR after a prior lumpectomy for a positive margin. At the initial excision, margins were positive or close (10 mm or less) in 75% (24/32) of patients, and 6 (19%) of 32 underwent another operation for re-excision of positive or close surgical margins (10 mm or less). MRI showed additional DCIS beyond the primary site in 21 (66%) patients, and MRI findings motivated 10 additional biopsies before definitive surgery. When MRI showed additional disease, the finding of additional high-grade DCIS influenced the surgical management for 13% (4/32) of patients. If the MRI was negative for additional DCIS, final histopathology was also negative for DCIS in all except 1 case.

Conclusions: In cases when there was MRI concordance to histopathological findings, MRI predicted the extent of disease found at surgery. Surgical planning for 82% (26/32) of this patient population was helped by a preoperative MRI. This descriptive review of a small sample size suggests that for patients with high-grade DCIS, MRI is helpful in preoperative planning to evaluate the extent of disease. An ongoing prospective study is underway to better help answer this question.

Tumor Characteristics and Patient Outcomes Are Similar Between Invasive Lobular and Mixed Invasive Ductal/Lobular Breast Cancers But Differ From Pure Invasive Ductal Breast Cancers

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Objectives: Although ductal histology represents the most common type of breast cancer in women, invasive breast cancers are a heterogeneous group. We investigated the patient and tumor characteristics associated with the less common invasive lobular (ILC) and mixed invasive ductal/lobular ("mixed") breast cancers to determine differences in patient and tumor characteristics and overall clinical outcomes compared to invasive ductal cancers (IDC).

Method: We retrospectively queried our institutional oncology data services' database and identified 4336 consecutive patients with stage I-IV invasive breast cancer treated at our institution between 1996 and 2006. Patient and tumor characteristics and vital status were recorded for each histologic subtype (IDC, ILC, and "mixed"). Patients with stage 0 disease and other histologic subtypes (tubular, mucinous, papillary) were excluded. Data were compared using chi-square and Fisher exact test. For more than 2 group comparisons and analyzing multiple dependent variables, MANOVA was used. Survival between the study groups was analyzed using Kaplan-Meier curves and the p values were calculated using log-rank test.

Results: Of 4336 patients treated at our institution during the study period, 3595 (82.9%) had IDC, 480 (11.1%) had ILC, and 261 (6.0%) had "mixed" cancers. There was no difference between histologic subtype and patient age (IDC, 56.4 years; ILC, 59.7 years; "mixed," 57.8 years). However, patients with IDC were more likely to be African-American (25%), compared to patients with ILC (17.5%) or "mixed" (15.2%) cancers ($p < 0.0001$). Patients with ILC and "mixed" tumors were more likely to be grade I/II, estrogen receptor positive, progesterone receptor positive, and Her2neu nonamplified compared to patients with IDC ($p < 0.0001$ for each). However, patients with ILC and "mixed" tumors were more likely to have larger tumors (T2 or T3) and stage III cancers compared to patients with IDC ($p < 0.0001$ for each). Patients with "mixed" cancers had a higher rate of nodal positivity (N1/N2) compared to patients with IDC or ILC ($p < 0.0001$). There was no difference between the groups with respect to rate of distant metastasis, laterality, or rates of mastectomy. Patients with IDC had the poorest 5-year (80%) and 10-year survival (61%), compared to patients with ILC (5-year, 87%; 10-year, 68%) and "mixed" (5-year, 84%; 10-year, 69%) cancers ($p = 0.029$).

Conclusions: "Mixed" invasive breast cancers possess clinical and tumor characteristics that are more similar to lobular histology rather than ductal histology. Patients with ILC and "mixed" cancers are diagnosed with larger tumors and with more advanced disease. Despite this finding, the biologic phenotype of ILC and "mixed" cancers are favorable and this translates to better survival compared to patients with pure IDC.

Prediction of Axillary Status From Sentinel Lymph Node Testing With an Intraoperative RT-PCR Test—Multicenter Analysis of 786 Patients

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Objectives: A molecular assay (GeneSearch™ BLN Assay, Veridex, LLC) intraoperatively detects metastases ≥0.2 mm in the sentinel lymph nodes (SLNs) to enable a decision for complete axillary lymph node dissections (ALND) in the same surgery for SLN-positive patients. Previous reports indicate the assay has high sensitivity and specificity versus permanent section histology on the same SLNs. More important is whether the assay provides high predictive value for the status of the entire axilla. This is the first multicenter report of the assay's ability to predict non-SLN status during clinical use.

Method: Four sites in the United States and 1 site in Belgium participated in this analysis. SLNs are cut into approximately 2-mm sections. Alternating sections are processed fresh in the assay. The assay detects mRNA expression of mammaglobin and cytokeratin19 and results are reported as positive or negative. The assay results are used to make intraoperative decisions for same surgery ALND. Some sites perform intraoperative frozen sections on the remaining alternating sections and all sites perform postoperative permanent section H&E. Typically, ALND is performed when any test (assay, frozen section, or permanent section histology) is positive. At some sites, ALND is also performed on patients with negative SLNs when the primary tumor is found to be larger than predicted by imaging. Non-SLNs from ALND are assessed per the sites' standard procedures with permanent section histology. For the purposes of this analysis, nodes are considered histologically positive when metastases are greater than 0.2 mm. Submicrometastases or isolated tumor cells are considered "negative."

Results: The assay has been used for intraoperative decision-making on 786 patients to date. Typical assay turnaround time to result is approximately 30 to 40 minutes. SLN positivity rates for the assay and permanent section histology are 21% and 18%, respectively. The table at right shows the positive and negative predictive values for ALN status for the assay alone, for permanent section histology alone, and for combined results. Results within clinical sites were similar to the combined data.

SLN Results		Non-SLN Status		
	N (patients)	# of ALNDs	# Non-SLN Pos	Predictive Performance
Histology				**Histology**
Neg	644	122	10	NPV: 92%
Pos	142	138	50	PPV: 36%
Macro	69	68	25	PPV: 37%
Micro	46	42	14	PPV: 33%
Assay				**Assay**
Neg	619	98	2	NPV: 98%
Pos	167	162	58	PPV: 36%
Combined				**Combined**
Both Neg	604	86	1	NPV: 99%
Both Pos	127	126	49	PPV: 39%
Assay+/H&E macro	65	64	25	PPV: 39%
Assay+/H&E micro	39	39	14	PPV: 36%
Assay only pos	40	36	9	PPV: 25%
Histology only pos	15	12	1	PPV: 8%

The assay's PPV for predicting non-SLN positivity is the same as that of permanent section histology (36%), while the assay's NPV is marginally higher (98% vs 92% for permanent section H&E, $p = 0.070$). In this evaluation, non-SLN positivity rates were very similar for patients with macrometastases (37%) or micrometastases (33%) on SLNs by H&E.

Conclusions: This RT-PCR assay on SLNs has high predictive performance for axillary status. The data to date indicate that the intraoperative assay result is as accurate as permanent section histology on SLNs for predicting non-SLN status. Further, non-SLN positivity is 25% (9 of 36) when SLNs are assay-positive but histology-negative. The intraoperative assay dramatically reduces the need for second surgery ALND (1.9% [15/786] of patients were assay-negative and histology-positive) and provides a particularly high NPV to assure the pathologist, surgeon, and patient that occult metastases are unlikely.

Intraoperative Molecular Pathology of Sentinel Axillary Lymph Nodes in Breast Carcinoma Patients

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Objectives: As at most institutions in the United States, intraoperative analysis of sentinel lymph node(s) (SLN) of breast cancer patients is performed by evaluating H&E-stained frozen sections. Confirmation by permanent section H&E is then performed postoperatively. The nonuniform distribution of metastases in SLNs results in the presence of metastases in some but not all samples examined by pathology. To reduce this effect, we are evaluating the performance of the first FDA-approved reverse transcriptase polymerase chain reaction (RT-PCR) assay, the GeneSearch™ Breast Lymph Node (BLN) Assay, which allows assessment of 50% of the node tissue to identify metastases greater than 0.2 mm in SLNs in addition to permanent section H&E.

Method: Currently 45 consecutive breast cancer patients have been assessed under the prospective study at our institution. All SLNs from each patient are cut into an even number of approximately 1-mm slabs, as is the current practice at our site. Alternating 1-mm slabs are tested by permanent section H&E with 2 sections taken from each face of the slab. IHC is then done on H&E negative cases. The remaining slabs are homogenized and the RNA is extracted with Assay sample preparation reagents and run with BLN Assay PCR reagents on the Cepheid SmartCycler® system. The assay uses RT-PCR to determine the positive/negative status of the SLN using 2 gene markers mammaglobin and cytokeratin 19. All BLN Assay results are considered for test validation purposes and are not used for patient management at our institution.

Results: Interim results of our work show of the 45 patients enrolled, 33 (73%) were negative and 8 (18%) were positive by both the BLN Assay and permanent section. Two patients (4%) were positive by the BLN Assay and negative by histology. Two were negative (4%) by the BLN Assay and positive only by extra histology sections required in this study. The routine histology did not detect any metastases in these 2 patients. The sensitivity of the assay compared to permanent section was 80% (8/10); specificity, 94% (33/35); and overall agreement, 91% (41/45).

Conclusions: At this stage of our study, assay performance, based on sensitivity and specificity, compares well to that found in the large multicenter U.S. registration study (87.6% and 94.2%, respectively). This assay can be used as an adjunct to traditional pathologic examination and could replace the use of H&E-stained frozen sections. We believe the GeneSearch™ BLN Assay can help detect metastases in SLNs that are missed by traditional histology because of the nonuniform distribution of the metastases.

Seroma After Breast Surgery: Identifying the High-Risk Patient

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Objectives: Seromas are common after breast and axillary surgery. A desirable approach to investigating novel prevention strategies would be to target patients at risk. The aim of this study was to perform multivariate analysis of risk factors for seroma development.

Method: A retrospective review of medical records was performed for 324 patients who underwent 561 breast and axillary procedures at a single institution from October 2004 to June 2006. Variables collected included patient demographic and clinical characteristics, as well as current medications, prior cancer treatments, and operative details. Univariate and multivariate analysis was performed using Cox proportional hazards regression.

Results: Three hundred twenty-four patients underwent 561 breast and axillary procedures, with 47 seromas that required intervention (47/561 = 8.4% of surgical sites). Seroma occurrence varied significantly by procedure type (p = 0.004): sentinel node (SN) biopsy, 3 (2.1%) of 142; lumpectomy, 10 (6.0%) of 167; axillary dissection, 2 (5.7%) of 35; mastectomy, 7 (14.3%) of 49; mastectomy + SN, 23 (16.2%) of 142; modified radical mastectomy, 2 (7.7%) of 26. Seroma was also more common in current smokers, 13 (21.3%) of 61, compared to prior smokers, 11 (8.5%) of 130, p = 0.03, and nonsmokers, 23 (6.2%) of 370, p = 0.0003. In patients with daily steroid use, seroma was significantly more common, 3 (42.9%) of 7, than among those without steroid use, 32 (7.5%) of 424, p = 0.01. Type of surgical procedure, current smoking, and daily steroid use remained significantly associated with increased risk of seroma in multivariate analysis. Notable factors of interest that did not show significant impact on seroma occurrence were BMI, prior radiation, chemotherapy within 90 days prior to surgery, diabetes, age, or number of lymph nodes removed.

Conclusions: Seroma occurs more frequently in smokers and patients using daily steroids, and in those undergoing mastectomy. Smokers and patients on steroids undergoing planned mastectomy are a higher risk population for seroma and may be candidates to target for preventive approaches.

Use Perioperative Gabapentin (Neurontin) in Reducing Postoperative Narcotic Usage in Patients Undergoing Mastectomy and Axillary Nodal Dissection

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Objectives: Although surgical options for the treatment of breast cancer have moved from the inpatient to outpatient setting, mastectomies and axillary nodal dissections can still result in significant postoperative pain, necessitating hospitalization and/or prolonged narcotic usage. Gabapentin has been reported to decrease acute and chronic pain in a variety of surgical procedures, but has not been used extensively in breast surgery. We sought to evaluate the impact of perioperative gabapentin on narcotic usage after either mastectomy and/or axillary nodal dissection.

Method: A retrospective chart review was performed for patients who underwent a mastectomy and/or axillary nodal dissection from January 2005 to September 2008. All surgeries were performed at a single institution by 2 fellowship-trained breast surgeons. Surgeon, type of surgery performed, operative time, initial pain score, average pain score, use of perioperative gabapentin, and amount of postoperative IV and/or PO narcotic were collected and analyzed using *t* test assuming equal variances.

Results: Four hundred twenty-six patients underwent 467 procedures, of which perioperative gabapentin was given in 226 cases (48.4%). Gabapentin was given either preoperatively or was initiated immediately postoperatively. Surgeon A performed 231 (49.5%), while surgeon B performed 236 (50.5%). There was no statistical difference between either groups in initial or average pain scores, but patients who received gabapentin used significantly less IV narcotics postoperatively (8.7 mg vs. 12.6 mg morphine, *p = 0.03). While PO narcotic usage during hospitalization was less in the gabapentin group (6.99 vs. 7.14 tabs), it was not significant.

	Initial Pain Score	Average Pain Score	# Times Score Taken	Length of Stay	Morphine (mg) IV*	Vicodin (tabs) PO
+ Gaba	3.1	3.4	14.5	1.23	8.7	6.99
No Gaba	3.2	3.5	15.6	1.38	12.6	7.14

Conclusions: Perioperative gabapentin reduced the usage of postoperative narcotics in patients undergoing mastectomies and/or axillary dissection. It has been demonstrated in the literature to reduce hot flashes, chronic pain, and even phantom pain in this patient population. Breast surgeons should give consideration to incorporating a perioperative gabapentin regimen for their patients undergoing mastectomies and/or axillary nodal dissection.

Breast-Specific Gamma Imaging: Integration Into Surgical Practice

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Objectives: Breast-specific gamma imaging (BSGI) utilizes a high-resolution, small field-of-view gamma camera, optimized to perform metabolic analyses of breast parenchyma. The technology has been in existence for over a decade, however, recent improvements in camera technology has allowed for the identification of even subcentimeter malignancies. Currently there are only 33 testing centers in the United States performing BSGI. This abstract describes our initial 1-year experience with the technology with particular emphasis on impact upon surgical management.

Method: Forty-seven patients underwent BSGI at our institution from June 2007 to June 2008. These patients also underwent conventional imaging that included ultrasonography and mammography. A subset of patients also underwent MRI as deemed necessary by the physicians involved. BSGI results were correlated with the final surgical management and final pathologic diagnosis.

Results: Fifteen of the 20 patients who had a positive BSGI scan underwent biopsy. Thirteen of these patients had breast cancer on pathology. To date, 12 of these 13 patients have undergone final surgical resections. Two of the 20 patients with positive BSGI went straight to surgery without biopsy, and both were proven to be cancer on final pathology. BSGI alone detected multifocal lesions in 2 of the 14 surgically managed patients, and preoperative planning was affected by these findings. Final pathology confirmed the presence of these multifocal lesions. Both patients had been considered for breast conservation therapy prior to BSGI.

Conclusions: BSGI appears to have a high sensitivity and specificity for breast carcinoma, and may be particularly useful in identifying patients with multifocal disease. The test is far less expensive than MRI and is much more acceptable to patients. There is potential for BSGI in guiding preoperative planning for breast carcinoma especially in patients whose other imaging studies are equivocal. Further study is required to establish the clinical utility and indications for BSGI.

Comparison of Home-Brew HER2 Testing With HercepTest and FISH: A Cautionary Tale

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Objectives: For patients with breast cancer, overexpression of HER2 is associated with an aggressive clinical course and determines the clinical efficacy from treatment with trastuzumab, a therapeutic monoclonal antibody. Immunohistochemistry (IHC) is the usual first step for determining HER2 status and a variety of commercially available antibodies, both monoclonal and polyclonal, have been used for this process. Our pathology lab recently switched from using a polyclonal antibody IHC methodology in a "home-brew" assay (HB-IHC) to using the HercepTest™, an FDA-approved kit [Dako] (HT-IHC). This study was done to compare the accuracy of HB-IHC and HT-IHC using FISH [PathVysion™, Abbott] as the gold standard in accordance with new ASCO/CAP guidelines.

Method: Using a tissue microarray containing tumoral and normal tissues from 50 patients with invasive breast cancer, HB-IHC, HT-IHC, and FISH were each used to determine HER2 status. Assays were performed according to manufacturers' guidelines. The results of the different tests were read independently and the reader was blinded to the results of the other tests. IHC 0-1+ was considered negative; 2+, indeterminate; and 3+, positive. All indeterminate IHC require further testing with FISH. All positive cases would be candidates for Herceptin therapy.

Results: By HB-IHC, HER2 was negative in 41 cases, 2+ in 5, and 3+ in 4. By HT-IHC, HER2 was negative in 44 cases, 2+ in 2, and 3+ in 4. HB-IHC and HT-IHC were concordant in 43 (86%) cases—the assays were both negative in 40 cases, both 2+ in 1 case, and both 3+ in 2 cases. Of the 7 discordant cases, 1 case was negative by HB-IHC and 2+ by HT-IHC, 2 were 2+ by HB-IHC and negative by HT-IHC, 2 cases were 2+ by HB-IHC and 3+ by HT-IHC, and 2 were 3+ by HB-IHC and negative by HT-IHC. HT-IHC was 100% concordant with FISH insofar as all negative cases by IHC were negative by FISH, and all positive cases by IHC were positive by FISH. In contrast, 50% of positive cases by HB-IHC were negative by FISH.

Conclusions: Our home-brew HER2 assay was not as accurate as the FDA-approved HercepTest, would lead to an increased number of cases reflexed to FISH (80% of HB-IHC 2+ were clearly negative or positive by HT-IHC and FISH), and overtreatment with trastuzumab (2 of 4 cases 3+ by HB-IHC were negative by HercepTest and FISH). Since important treatment decisions are based upon the HER2 assay, accuracy is essential. We strongly recommend using a standardized approach, including FDA-approved testing kits, rather than home-brew assays for the evaluation of HER2 status.

Comparison of Calcified and Noncalcified DCIS

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Objectives: Although pure DCIS is almost always diagnosed because of mammographic calcifications, noncalcified DCIS is frequently seen in association with noncalcified invasive cancers. The purpose of this study is to review the entire spectrum of DCIS and compare characteristics of DCIS with and without calcifications.

Method: A retrospective query of a prospectively created Breast Surgery database was performed to identify cases of DCIS with and without an invasive tumor diagnosed between the years 2003 and 2007. Characteristics of DCIS associated with mammographic calcifications were compared to those without calcifications.

Results: Of a total of 698 cases of DCIS (66% were associated with an invasive component), 383 (54.5%) were associated with calcifications on mammogram, and 315 (45.1%) did not have any detectable calcifications. The presence of calcifications was strongly associated with comedo histology (78% vs. 50% for noncomedo, $P < .001$), micropapillary histology (66% vs. 54% for nonmicropapillary, $P < .05$), grade of DCIS (49% grade 3 for calcified vs. 36% grade 3 for noncalcified, $P < .005$), and necrosis (64% vs. 38% without necrosis, $P < .001$). Comedo carcinoma was more likely than noncomedo carcinoma to be high grade, ER- and PR-negative, and to have necrosis. Although comedo type was most strongly associated with calcifications, this represented only 18% of total cases and 26% of DCIS with calcifications. For noncomedo DCIS, grade of the DCIS was no longer significantly associated with calcifications, and ER and PR positivity was strongly associated with calcifications (69% calcified for ER positive, vs. 43% for ER negative, $P < .005$). Multiple logistic regression showed the following variables to be significant: comedo histology, papillary histology, ER positivity, and necrosis.

Conclusions: A significant percent of DCIS is not calcified. Multiple biologic factors are associated with calcifications in DCIS. It is likely that many normal women harbor noncalcified DCIS that cannot be detected by current modalities.

The Relationship of Mammographic Density and Age: Implications for Screening

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Objectives: Breast density has been increasingly recognized as an independent risk factor for the development of breast cancer. Women with dense breasts have a 4- to 6-fold increased risk of developing breast cancer compared to women with less dense breasts. In addition, breast density may compromise the sensitivity of screening mammography. However, breast density has generally been associated with younger women. The proportion of postmenopausal and elderly women with dense breasts is unknown. The purpose of this study is to determine the relationship between age and breast density, with particular emphasis on postmenopausal women.

Method: The NYU institutional Radiology database was queried for 500 consecutive patients who presented for yearly screening mammography. All mammograms were done using digital technology and CAD. Radiographic breast density was defined according to the BI-RADS classification: (1) almost entirely fatty, (2) scattered fibroglandular tissue, (3) heterogeneously dense, (4) extremely dense. Descriptive analyses were used to evaluate the association between age and breast density.

Results: The median age of our cohort was 56 years (range, 25-93). There were 22 women (4%) under the age of 40, 137 (27%) between 40 and 49 years, 148 (30%) between 50 and 59 years, 119 (24%) between 60 and 69 years, 45 (9%) between 70 and 79 years, and 29 (6%) over the age of 80. Seventy-four percent of patients 40-49 years of age had dense breasts (BI-RADS categories 3 & 4). This decreased to 54% of women in their 50s. However, 42% of women in their 60s and 31% of women in their 70s had heterogeneously or extremely dense breasts.

Conclusions: Overall, the proportion of women with dense breasts decreases with increasing age. However, a meaningful fraction of women over 50 will still be characterized as having heterogeneously or extremely dense breasts. At this time, when the risk of breast cancer is increasing, the sensitivity of mammography is limited for these patients. Particularly for women at increased risk for breast cancer, additional screening methods should be considered. Breast density, not age, should be utilized in evaluating the potential benefit of screening ultrasound and/or MRI for pre- and postmenopausal women.

Use of Tumescent Mastectomy Technique As a Risk Factor for Native Breast Skin Flap Necrosis Following Immediate Breast Reconstruction

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Objectives: Native breast skin flap necrosis is a complication which can result from ischemic injury following mastectomy and can compromise immediate breast reconstruction. The tumescent mastectomy technique has been advocated by some as a method of allowing sharp dissection with minimal blood loss. This study was performed to determine whether tumescent mastectomy technique increases the risk of skin flap necrosis in an immediate breast reconstruction setting.

Method: The authors performed a retrospective analysis of consecutive immediate breast reconstructions performed over a 6-year period. A total of 380 mastectomies with reconstruction were divided into 2 cohorts for comparison: tumescent mastectomy vs. nontumescent mastectomy, both followed by immediate reconstruction. Incidence of minor and major skin flap necrosis was compared between the 2 cohorts as the primary outcome. Logistic regression analysis was performed to identify risk factors for native breast skin flap necrosis.

Results: A total of 275 patients underwent 170 unilateral and 105 bilateral mastectomies with immediate reconstruction, totaling 380 reconstructions. One hundred mastectomies were performed using the tumescent technique and 280 were performed without using the tumescent technique. Logistic regression analysis showed that the use of tumescent mastectomy, prior history of radiation therapy, patient age, and BMI were statistically significant risk factors for developing postoperative major native skin flap necrosis. Patients who underwent tumescent technique during mastectomy experienced a nearly 4-fold higher rate of major necrosis compared to those who did not undergo tumescent technique (OR, 3.64; $p < 0.001$). Prior history of radiation increased the odds of major necrosis approximately 3-fold (OR, 3.10; $p = 0.014$). For each 10-year increase in patient age, the odds of major necrosis increased by 1.57 times ($p = 0.010$). For each 1-unit increase in BMI, the odds of major necrosis increased by 1.10 times ($p = 0.006$).

Conclusions: Use of the tumescent mastectomy technique appears associated with a substantial increase in the risk of postoperative major skin flap necrosis in an immediate breast reconstruction setting.

Incidental Breast Lesions Identified by 18F-Fluorodeoxyglucose Positron Emission Tomography

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Objectives: The aim of our study was to evaluate our institutional experience with breast incidentalomas in a large series of positron emission tomography (PET) scans performed for patients without a known history of breast cancer and to determine the clinical significance of these lesions.

Method: Between March 2000 through June 2007, 45,000 18F-Fluorodeoxyglucose positron emission tomography (FDG-PET) scans were performed in patients with a primary malignancy other than breast cancer. Indications for PET scan included staging or restaging of disease, monitoring response to treatment, or identification of an unknown primary. One hundred sixty-three cases were identified with focal breast findings unrelated to the primary diagnosis, and thus deemed a breast incidentaloma. Retrospective review of PET scans and clinical history were performed for these patients to obtain results.

Results: In 103 (63%) of 163 cases, breast findings were associated with normal physiologic variation, lactation, implants, or benign calcifications. Chart review was conducted for the remaining 60 patients (37%). In 20 (33%) of 60, no additional evaluation of the breast findings was performed due to advanced stage of the primary malignancy. In the remaining 40 patients (66%) who underwent follow-up imaging, 22 (55%) of 40 demonstrated resolution or decrease in breast findings and no further evaluation was performed. In the other 18 patients (45%), additional breast imaging (mammogram, sonogram, MRI) or follow-up PET scan demonstrated significant findings and, of these, 12 of 18 underwent biopsy. Seven (58%) of 12 who underwent biopsy and 7 (39%) of 18 with persistent imaging findings were positive for malignancy including 6 cases of invasive ductal carcinoma and 1 lymphoma.

Conclusions: PET scanning is increasingly used for evaluation in patients with malignancy, and breast incidentalomas are occasionally identified. In our experience, for the highly selected group of patients found to have persistent breast imaging findings after identification on PET scan, 39% were malignant. The further evaluation of these lesions should be based on overall clinical status, and in patients with advanced disease, where results would not change the overall management, biopsy may not be warranted.

The Role of Radiation Therapy in Adenoid Cystic Carcinoma of the Breast

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Objectives: Adenoid cystic carcinoma is an uncommon form of breast cancer for which the role of adjuvant radiation therapy after resection of the primary tumor continues to be unclear. We hypothesized that postoperative radiation therapy would provide a significant benefit after surgical resection.

Method: The Surveillance, Epidemiology, and End Results database was queried for all patients undergoing an operation for primary breast adenoid cystic carcinoma between 1988 and 2005. Exclusions were made for those lacking information on surgical procedure and radiation therapy. Patients were divided based on the receipt of radiation therapy. Information on patient demographics (age, gender, and race), tumor characteristics (grade, tumor size, nodal status, presence of metastases, and hormone receptor status), treatment received (type of surgery and radiation therapy utilization), and outcomes were collected. Univariate survival comparisons were made utilizing the Kaplan-Meier method. Log-rank testing was used to determine statistical significance. Multivariate survival analysis was performed via a hierarchical Cox proportionate hazards regression whereby overall and cause-specific survival statistics were calculated.

Results: Three hundred seventy-six patients met entry criteria. Demographics were similar between groups in terms of age, gender, and race. Virtually all fully staged patients were stage I (147 patients) or II (103 patients). Few presented with stage III (6 patients) or stage IV (4 patients) disease. One hundred sixteen patients had incomplete staging information (primarily missing nodal status due to a lack of any attempt at either sentinel lymph node biopsy or axillary dissection). On univariate analysis, there was a significant difference in overall survival based on receipt of radiation therapy with an absolute survival benefit of 9% at 5 years and 21% at 10 years ($p = 0.005$), which persisted even when stratifying by stage. In the multivariate analysis, radiation therapy continued to be a significant factor with a hazard ratio of 0.44 (95% confidence interval = 0.22-0.88), even after accounting for demographic data, stage, and type of surgery. Cause-specific survival yielded similar results with a univariate 10-year absolute survival benefit of 7% ($p = 0.12$) and a hazard ratio of 0.1 (95% CI, 0.01-0.88) in the multivariate model.

Conclusions: Adenoid cystic carcinoma of the breast generally presents at an early stage, with few patients dying of their disease. However, after local surgical therapy, adjuvant radiation therapy appears to provide a benefit in both cause-specific and overall survival even after accounting for other factors. Further investigation into the radiosensitivity of these tumors may be warranted.

Intraoperative Sentinel Lymph Node Evaluation in Breast Cancer Patients: A Comparison of Routine Versus Selective Frozen Section

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Objectives: Axillary nodal status is one of the most important prognostic factors in breast cancer. Sentinel lymph node biopsy (SLNB) has become the preferred method for evaluating axillary nodes, however, the optimal method of intraoperative pathologic evaluation of sentinel nodes has not been determined. At our institution we have used 2 methods. Previously we performed routine frozen section (RFS) on all sentinel nodes (SN). We now perform selective frozen section (SFS) on nodes determined by the pathologist to be grossly suspicious. FS has the drawbacks of suboptimal histology when compared to permanent section, increased cost to the patient, and the possibility of missing micrometastases with the tissue lost using this technique. However, SFS might miss a metastatic node if the pathologist does not believe the node is grossly suspicious at the time of operative consultation. A false-negative FS might require axillary node dissection (AND) as a second operation if the final pathology shows nodal metastasis.

Method: We compared RFS and SFS for 202 breast cancer patients who underwent SLNB with a total of 439 SNs harvested. From 1998 to 2001 RFS was performed on 297 SNs harvested from 139 breast cancer patients. From 2004 to 2005, SFS was done in 64 patients with a total of 142 SNs. Data, including number of SLs, method of intraoperative evaluation, and the presence/absence of nodal metastasis, were analyzed.

Results: In the RFS group, 32 of the 297 SNs had metastases. Twenty-one of these nodes were found positive on FS, 2 were not evaluated by FS, and 9 were negative on FS but then found to be positive on permanent section, giving a false-negative intraoperative evalution rate (IER) for the RFS group of 9/30 (30%). In the SFS group, 21 of 142 SNs were positive for metastatic breast cancer. Eight nodes were positive on FS and 3 nodes were negative on FS but then positive on permanent section. Therefore, the false-negative IER for the SFS group is 3/10 (30%).

Conclusions: When we switched from RFS to SFS, our hope was that we would save operative time and expense. The charge for gross exam is $107 per node, whereas the charge for gross exam and FS is $216 per node, thus saving $109 per node with SFS. We were also concerned about finding more positive nodes on final pathologic exam that were not found during intraoperative evaluation, potentially leading to AND as a second procedure. However, our institutional experience shows that SFS is as accurate as RFS in the intraoperative evaluation of SNs in breast cancer patients with an equal risk of false-negative intraoperative evaluation in both groups.

Delayed Primary Breast Reconstruction With Tissue Expanders in the Irradiated Breast

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Objectives: Women who present with advanced cancers or multiple positive lymph nodes are more likely to require postmastectomy radiation. Delayed breast reconstruction is traditionally used when postmastectomy radiation is anticipated, but this leads to a reduction in the skin envelope and increases the need for large skin paddles. The final aesthetic results are less pleasing due to skin color mismatches and a quilted appearance. Immediate breast reconstruction is more desirable for women undergoing mastectomy. This study examines the use of tissue expanders as a bridge to delayed primary breast reconstruction in patients who require irradiation.

Method: A retrospective chart review was performed of all patients from January 1999 to August 2008 who required irradiation and underwent tissue expander placement for immediate reconstruction after modified radical mastectomy. This identified 45 patients who were treated with the following protocol: (1) immediate tissue expander placement at time of mastectomy, (2) tissue expansion during chemotherapy, (3) irradiation with tissue expander fully expanded, and final breast reconstruction with either (4) autogenous tissue and/or permanent implant after irradiation or (5) latissmus flap with tissue expander and subsequent implant exchange after tissue expansion.

Results: Forty-four patients had completed their final reconstruction, and 1 patient is awaiting the final phase of reconstruction. Forty patients had infiltrating ductal carcinoma, and 5 patients had infiltrating lobular carcinoma. Complications during the first phase of reconstruction included 11 tissue expander contractures, 2 tissue expander infections, 1 leakage of the tissue expander, 1 tissue expander extrusion, and 1 hematoma. For the final reconstruction, 25 patients underwent latissmus flap with tissue expander and subsequent implant exchange. Other reconstructions include delayed transverse rectus abdominis myocutaneous (TRAM) flap (5 patients), free TRAM (6 patients), and permanent implants (8 patients). During the final reconstruction phase, complications include 8 implant contractures, 5 seromas, 3 abdominal hernias requiring repair, 1 radiation-induced fat necrosis, and 1 implant infection. Preliminary results show patients have satisfactory aesthetic outcomes.

Conclusions: The use of tissue expanders as a bridge during delayed primary breast reconstruction is a safe, reliable option with minimal complications. This method results in satisfactory aesthetic outcomes and should be considered as a reconstructive option for patients requiring postoperative radiotherapy.

Surveillance of Mastectomy Patients Reconstructed With Implants: MRI Recommendations

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Objectives: Surveillance of mastectomy patients reconstructed with implants has been limited to physical exam alone. Unencumbered by data, many insurance companies reimburse and the American College of Radiology recommend screening with MRI for early recurrence in the reconstructed breast cancer patients. We sought to determine the value of MRI in evaluating postmastectomy patients reconstructed with implants for recurrence.

Method: The study consisted of a retrospective review of charts from September 2006 to September 2008 in patients that had undergone breast cancer surgery and reconstruction with implants. The MRIs and MRI reports were reviewed for abnormal findings, number of generated biopsies, and pathological results.

Results: A total of 48 patients with 78 breast reconstructions had breast MRI as part of their follow-up over a 2-year period. Average age was 52 ± 10 years. Average size of the tumor was 1.6 cm ± 1.5 cm. Surgery consisted of bilateral (24) or unilateral-skin sparing mastectomies (8), bilateral simple mastectomies (5), unilateral simple or modified radical mastectomy (12). A single patient with bilateral total skin-sparing mastectomy and reconstruction presented with a linear area of enhancement in the contralateral reconstructed breast. The abnormal area was biopsied under ultrasound guidance and found to be benign. Thus we had 1 false-positive finding in 78 (1.3%) examined breasts. All other MRIs generated, including those with contralateral intact breast (20), were without abnormality and no patient in this series presented with recurrence.

Conclusions: This represents the first data on MRI in the breast cancer patient with implant reconstruction. MRI done for screening after breast cancer surgery and reconstruction was basically noncontributory to the physical exam of these patients. MRI is an expensive screening tool that has not been shown to add more information than physical exam and ultrasound. On the other hand, the false-positive rate is extremely low. We recommend continued screening with physical exam and follow-up of abnormal exams with ultrasound and biopsy. MRI may still be of use in patients with an indeterminate exam, for visualization of the extent of disease of a known recurrence, or screening of the contralateral intact breast.

Wound Complications From Surgery in Pregnancy-Associated Breast Cancer

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Objectives: Little data exists regarding complications that occur in pregnant and peripartum women undergoing breast surgery. There are concerns that the anatomic and physiologic changes of the peripartum breast may affect the outcomes for breast conservation therapy. We present the complications of breast conservation surgeries and mastectomies performed for pregnancy-associated breast cancer.

Method: From April 1989 through April 2008, 68 breast cancer patients underwent surgical management of their pregnancy-associated breast cancer (PABC), defined as surgery during pregnancy or within 1 year postpartum, as part of an ongoing institutional review board–approved prospective protocol designed to evaluate the safety of administering chemotherapy during the second and third trimesters of pregnancy. Women who had surgery were examined for the rate of postoperative wound complications, milk fistula, cellulitis, abscess, or hematoma.

Results: Sixty-eight patients underwent surgical management of pregnancy-associated breast cancer. Thirty-six patients had surgery while pregnant, and 32 had surgery within 1 year postpartum. Seventeen pregnant patients had excisional biopsies for diagnosis, with no complications or milk fistulae noted. Forty-nine patients underwent total mastectomy. Nineteen were treated with segmental mastectomy, 4 of whom had sentinel lymph node biopsy and 15 of whom had axillary lymph node dissection.

There were 4 cases of cellulitis in total mastectomy patients, all treated in the outpatient setting. There was 1 axillary abscess treated with percutaneous drainage and antibiotics in a patient undergoing mastectomy who had previously had segmental mastectomy and axillary lymph node dissection. One hematoma was noted in a patient undergoing segmental mastectomy. This was managed conservatively. There were no documented milk fistulae in any of the patients.

Conclusions: In our case series, we had minimal postoperative complications and no milk fistulae for those patients undergoing surgery for PABC. When compared to those who had mastectomy for PABC, women who underwent breast-conserving therapy do not appear to have increased frequency of complications.

Lipomodeling of the Breast—Early Results of 29 Patients

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Objectives: Lipomodeling is the autologous transfer of adipose tissue to correct congenital and postsurgical deformities of the breast. Complications are minimal, and the main disadvantage is fat resorption leading to volume loss and necessitating repeat procedures. Recent improvements in the technique have increased the range of application in congenital deformities, and following benign and malignant breast surgery. This study aimed to evaluate the cosmetic results, patient satisfaction and complications of the technique at our institution.

Method: Patients presenting at the breast clinic and who were deemed suitable for lipomodeling were included in the study. Data were prospectively collected from clinic and operating theaters. A mixture of lignocaine, normal saline, and adrenaline was injected into donor sites in the abdomen and thighs, and 3-mm cannulae were used to manually aspirate fat. This was centrifuged for 5 minutes at 3000 rpm, and the purified fat was injected into the breast using a blunt 3-mm injection cannula. Patients were followed in a specialist breast clinic. A postal satisfaction survey was carried out.

Results: Between November 2007 and July 2008, 28 females and 1 male patient, mean age of 49 years (31-61), underwent 33 lipomodeling procedures.

Table 1. Characteristics of Patients Undergoing Lipomodeling (n = 29)

Previous surgery	28/29 (96.6%)
Mean time since surgery	39.8 months (5-180)
Breast-conserving surgery (BCS)	4/28
Mastectomy & reconstruction	21/28
Mastectomy alone (male)	1/28
Excision of benign lesion	1/28
Aesthetic breast augmentation	1/28
Congenital tuberous deformity	1/29 (3.4%)
Previous radiotherapy (RT)	15 (51.7%)
Mean time since RT	55.2 months (11-125)

Volume deficit was observed to be the main deformity in all patients. A visible depression was noticed in 10 (34.5%) of 29 patients, flap atrophy in 5 (17.2%) of 29 patients, skin or scar tethering in 8 (27.6%) of 29 patients, and visible implant rippling in 3 (10.3%) of 29 patients. Lipomodeling was required in the upper pole in 48.3%, medial aspect in 24.1%, and overlying the surgical scar in 24.1% of the patients.

62.1% of the patients underwent a simultaneous ipsilateral or contralateral procedure. The mean volume of harvested fat was 207.03 (85-510), and the mean injected per breast was 114.12 (45-206). Lipofilling was stopped because of satisfactory results (15 patients), tissue tension (5 patients), or insufficient fat (2 patients). Mean operative time was 71.9 min (45-100). At 3 months follow-up, 20 patients were seen, with 75% of them achieving good volume retention. Ten patients were booked for further lipomodeling. There were no early complications and fat necrosis was observed clinically in 6 patients and confirmed radiologically in 4 patients. 76.5% of patients (13/17) reported marked improvement in the breast shape and 64.7% (11/17) reported marked improvement in general appearance.

Conclusions: Early results have shown satisfactory cosmetic outcome and patient satisfaction. Lipomodeling constitutes an autologous choice of reconstruction which is widely applicable in breast surgery. However, longer follow-up is required to assess the durability and long-term outcomes, especially following BCS.

Promoters and Barriers to Mammography Screening in Multiethnic Inner City Patients

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Objectives: From 1999 to 2003, the reported mammography screening rate in the United States reached 70% among women aged 40 and above. However, since 2000 mammography rates have declined significantly and disparities remain among different ethnicities. The goal of this study was to understand which factors promote and deter annual screening among women 40 and above who received care at multiethnic inner city community health centers (CHCs). It was hypothesized that women who had screening mammograms have more positive health behaviors/attitudes, fewer transportation problems, fewer time constraints, more sophisticated healthcare literacy on breast cancer screening, and an overall better clinical experience.

Methods: Women at 4 different inner city CHCs were asked to fill out a 32-question self-administered survey. Questions focused on 6 topics: behaviors and attitudes toward mammography screening, transportation issues, time constraints, healthcare literacy on breast cancer screening, overall quality of the clinic experience (scheduling, access, waiting times), and perceived quality of the patient-provider interaction. The women were divided into 2 groups: Group A—Women who had a mammogram performed in the last 2 years and Group B—Women who had never had a mammogram performed or for whom it had been more than 2 years since their last mammogram. The 2 groups were compared in the 6 specific topics using the Epi Info statistical analysis program.

Results: One hundred forty-four (84%) of 172 women who were approached agreed to fill out the survey. Thirty-three percent considered themselves Hispanic/Latina, 40.2% White, 8.7% Black, 3.6% Asian, and 14.5% identified as "Other." Of the women surveyed 80% self-reported as Group A and 20% as Group B. Group A women were more likely to have had someone (provider, relative, friend) recommend they get a mammogram (85.1% vs 70%), significantly more likely to have a primary care provider (PCP) (96% vs 71%; $P<.05$), and significantly more likely to have a female PCP (79% vs 53%; $P<.05$). Group B women reported they were "too busy" (54% vs 13%; $P<.05$) and would be more likely to obtain a mammogram if they had access to a walk-in clinic (94% vs 48%; $P < .05$). Overall, 73% of women thought a mammogram prevented breast cancer; 82.4% thought a mammogram was the best screening tool for breast cancer; and 40% feared the mammogram might show a breast cancer. Compared to all other ethnic groups, women who identified themselves as Hispanic/Latina, were significantly more likely to find a mammogram uncomfortable and more likely to express fear that a mammogram might show breast cancer.

Conclusions: Factors positively associated with adherence to mammography screening in a multiethnic inner city patient population were (1) recommendation for mammography from anyone, (2) having a PCP, and (3) having a female PCP. Lack of adherence to mammography screening is related to a combination of patient and healthcare delivery factors including patient healthcare literacy, provider characteristics, and ease of access/scheduling flexibility. Mammography screening continues to be a challenging public health problem.

Concordance of Invasive Breast Cancer Pathologic Size and MRI

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Objectives: Controversy surrounds the proper use of magnetic resonance imaging (MRI) in the diagnosis and treatment of invasive breast cancer (IBC). Few have investigated the accuracy of MRI estimation of IBC size compared with final pathology. This study aims to analyze the concordance between MRI and IBC size.

Method: Retrospective review of a prospectively collected database of patients treated at a single institution for IBC with surgical resection and sentinel lymph node (SLN) biopsy from January 2003-June 2008. Patients underwent MRI under the discretion of the treating surgeon. Continuous variables were compared among groups (underestimation, >1.0 cm; underestimation, 0.5-1.0 cm; concordance, <0.5 cm, overestimation, 0.5-1.0 cm; and overestimation, >1.0 cm) using ANOVA F tests and categorical variables were compared using chi-square tests.

Results: Two hundred seventy-three patients underwent breast MRI over 5 years with 190 IBCs measured on both MRI and final pathology. One hundred patients (53%) had concordance of MRI and IBC size within 0.5 cm. MRI overestimated the size of 62 tumors (33%): 15 (8%) by 0.5-1 cm and 47 (25%) by >1 cm. MRI underestimated 28 tumors (15%): 13 (7%) by 0.5-1 cm and 15 (8%) by >1 cm. Receiving neoadjuvant chemotherapy ($p = 0.001$), tumor size ($p < 0.0001$), and lymph node status ($p = 0.01$) were associated with discordance of MRI and pathologic measurements, with larger tumors and positive nodes associated with underestimation by MRI and smaller tumors and negative nodes associated with overestimation of size by MRI. Patients with tumors 2-5 cm had an equal distribution of under and over estimation. Patient age ($p = 0.49$), multifocal disease ($p = 0.24$), and tumor type ($p = 0.42$) were not associated with MRI-pathologic concordance. Among patients with tumor size overestimated by MRI, 65% had satellite lesions, DCIS, and/or lymphovascular invasion in tissue surrounding the main tumor, 9% had atypical ductal hyperplasia, 13% had proliferative breast tissue, and 13% had benign findings or no pathologic comment.

Conclusions: Breast MRI is concordant with pathologic tumor size within 0.5 cm among 53% of patients. The majority of patients with tumor size overestimated by MRI have significant findings in the main tumor mass requiring excision. Neoadjuvant chemotherapy and particularly small or large tumor size are associated with MRI-pathologic discordance. These findings are important to keep in mind when making surgical decisions.

Palpable Breast Cancers and Age: A Need for Change

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Objectives: It has long been stated that young women diagnosed with breast cancer fare worse than their more mature counterparts who have benefited from formal breast cancer screening. However, many women are still diagnosed when their cancer is palpable, regardless of age. We sought to analyze what differences exist in palpable breast cancers between women ≥40 and those ≤39.

Method: A prospective database of 1685 women with palpable, non–screen-detected, invasive breast cancers was reviewed. Patients and tumor characteristics were compared based on age group at diagnosis.

Results: Younger women were found to have higher grade tumors with more lymphovascular invasion (LVI) and more ER/PR-negative and HER2/neu-positive cancers than women ≥40. Despite the fact that tumor size and nodal positivity was similar, women ≤39 had lower breast cancer–specific and distant disease-free survival rates than women over 39.

	Age ≤ 39	**Age ≥ 40**	***P* value**
Number of patients	344	1341	
Invasive ductal	326 (95%)	1173 (87%)	
Invasive lobular	18 (5%)	168 (13%)	
Average age	35	59	
Average tumor size (mm)	28.9	28.6	0.86
Average nuclear grade	2.52	2.30	<0.0001
Average BRS score	6.83	6.26	<0.0001
% ER positive	55	76	<0.0001
% PR positive	51	65	0.0001
% HER2/neu positive	39	21	0.0003
% Triple negative	18	12	0.11
% LVI	34	29	<0.0001
% Node positive	45	43	0.30
12-yr BCSS	68.9	77.5	0.001
12-yr DDFS	59.9	73.0	<0.0001

Conclusions: Screening has improved survival from breast cancer. Yet too many women are still diagnosed with palpable cancers. Women who are younger than the current screening guidelines are more likely to recur and die from their breast cancer but have no means for early detection unless identified as high risk due to a positive family history. Improvements need to be made in breast cancer screening strategies as more young women are being diagnosed with, and thus dying from, breast cancer.

Infiltrating Lobular Carcinoma of the Breast: Superior Prognosis When Compared to Infiltrating Ductal Carcinoma

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Objectives: Breast cancer is commonly divided into invasive ductal and lobular varieties. We were interested in the presentation, prognostic, and outcome differences between these 2 common breast cancer types.

Method: A prospective breast cancer database containing 3122 infiltrating breast carcinomas (median follow-up, 7 years) was reviewed. Numerous factors, including distant disease-free survival (DDFS), breast cancer–specific survival (BCSS), and local recurrence–free survival (LRFS), were determined for both types of cancer.

Results:

	Ductal	**Lobular**	***P* value**
Number of patients	2761 (88%)	361 (12%)	
Avg age	54	56	0.001
Avg tumor size	24 mm	31 mm	< 0.0001
% Nonpalpable	26%	25%	NS
% ER positive	72%	87%	< 0.0001
% PR positive	63%	75%	< 0.0001
Avg nuclear grade	2.35	1.85	< 0.0001
% LVI Pos	25%	20%	0.04
% Positive nodes	35%	32%	NS
% Overexpress HER2/neu	26%	7%	< 0.0001
10-year DDFS	77%	80%	0.07
10-year BCSS	81%	86%	0.08
10-year LRFS	88%	91%	NS

Conclusions: Lobular carcinomas represented 12% of our invasive cases. Aside from the fact that they were greater in size at diagnosis, all other prognostic factors were more favorable for lobular carcinomas. This resulted in a better DDFS and BCSS in spite of their larger size.

Minimizing Barriers to Rehabilitation Therapy for Breast Cancer Patients in an Inner City Public Hospital: A Success Story of Collaboration

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Objectives: In 2007, our breast program received grant funding to increase patients' awareness of signs and symptoms of lymphedema, quality of life among breast cancer (BC) patients with lymphedema, and physician/nurse awareness of lymphedema. Approximately 89% of the women diagnosed with BC in our program are African American, and about 80% are indigent, uninsured, or Medicaid recipients. Rehabilitation staff training, program logistics, and patient outcomes were developed in collaboration with a local community-based nonprofit BC rehabilitation organization. Our objective is to reach underserved women and improve survivorship issues among BC patients who do not have access to high-quality medical care.

Method: Through grant support, an occupational therapist certified in lymphedema was funded to spend 40% of time dedicated to BC patients. Patients for referral were seen in the surgical oncology breast clinics by the therapist and educational sessions were conducted for patient groups during clinic time as well. To monitor patients with lymphedema, circumferential measurements were taken from the palm to the axilla every 4 cm for both the affected and nonaffected arms. Patients with a discrepancy in arm measurement were treated for lymphedema. A subgroup received 60-90 minutes of complete decongestive therapy (CDT) for 4 weeks. Measurements were calculated to show a percentage of decreased volume over time. Lymphedema education was presented to nurses, medical students, residents, and physicians to raise awareness for referrals.

Results: From April 1, 2007, to March 31, 2008, 595 patients were served in the program. More than 250 patients were seen in the breast clinic by the therapist for lymphedema evaluation and/or educated on the warning signs of lymphedema. The total number of referrals to rehabilitation increased by 71% from 62 in 2006 to 106 in 2007. Newly referred patients who did not show up for appointments decreased from 48% to 28%. Seventy-three patients were evaluated in the rehabilitation department and for the subgroup of patients receiving CDT (n = 9), on average, the decrease in lymph volume was 42%. More than 100 staff members received education on identifying and referring patients with lymphedema to the program.

Conclusions: Incorporating certified lymphedema therapists in our surgical clinics increased referral volume for an underserved group of women. Improvement in quality of life was achieved by decreasing lymph volume for CDT-treated patients. The collaboration with the local community-based nonprofit BC rehabilitation organization and continued grant funding has allowed us to expand the program to focus on other rehabilitation issues such as pain control, range of motion, and function. Additionally, we have implemented a preoperative assessment model according to Gergich N et al (1). This new model may further affect the "do not show rate" for newly referred patients. More detailed patient outcomes are being collected that include measurements of lymph volume, patient-specific functional scale scores, pain level, and quality of life with the FACT-B tool. The impact of this program has had an enormous positive effect for our patients.

1. Gergich N et al: Preoperative assessment enables the early diagnosis and successful treatment of lymphedema. Cancer 2008;112:2809–19.

Specialists Provide More Consistent and Comprehensive ASCO-Recommended Surveillance of Breast Cancer Survivors Than Primary Care Physicians

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Objectives: To document the physician specialty and medical follow-up care provided over time to breast cancer (BrCa) patients after definitive surgery at an academic center.

Method: Patients in this IRB-approved study were a cohort of women with stage I-III BrCa enrolled from 1996-2006 at 1 site as part of a multicenter trial. Exclusions were due to incomplete medical records, metastases or death within 6 months post surgery, noncompliance, or loss to follow-up. Complete follow-up data was collected for 270 patients, with a mean follow-up of 6.1 years after definitive surgery. Charts were reviewed based on American Society of Clinical Oncology (ASCO) guidelines for recommended surveillance frequency and care after BrCa treatment, including physical exam of the breast and axilla and mammography. Statistical significance was determined by chi-square analysis.

Results: Most patients (87%; n = 236) were followed by specialists (breast surgeon or medical oncologist), with 13% (n = 34) followed by primary care physicians (PCP). Patients at greater risk for recurrence tended to receive specialist care; they differed from patients followed by PCP with respect to disease stage ($p = 0.007$), tumor size ($p = 0.018$), nodal status ($p = 0.018$), and vascular or lymphatic invasion (($p = 0.02$; $p = 0.004$). Guidelines were followed with decreasing frequency over time and differed by provider. Specialists more consistently followed patients at ASCO-recommended intervals ($p \leq 0.025$). Clinical surveillance provided at each visit also differed significantly with physician specialty; women seen by PCP were less likely to have documented clinical exams of the breast ($p < 0.04$), physical exams of the axilla ($p < 0.005$), or annual mammograms ($p < 0.02$).

Conclusions: Most patients who received breast cancer surgery at an academic center continued to be followed by specialists. Specialists more consistently followed ASCO guidelines for surveillance frequency and care. Therefore, it may not be advisable to routinely transfer care of breast cancer patients from specialists to PCP for surveillance follow-up. These findings highlight the need for educational intervention to better disseminate current surveillance guidelines so they will be incorporated into the standard medical practice of all providers.

A Preliminary Comparison of Targeted Risk Assessment to the Gail Model: Is There a Better Way to Assess the High-Risk Patient?

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Objectives: The Gail model has been the standard for evaluating elevated breast cancer risk and has been validated in major prevention trials. A more individualized approach using targeted assessment and genomics may be helpful in determining who is truly at high risk. This study compares the Gail score with 2 newer methods of detecting risk: OncoVue®, a genomic assay using fragments of buccal DNA and RNA, and Sentinel Breastscan™, which uses artificial intelligence to interpret risk based on blood flow patterns.

Method: Forty-four patients were enrolled in our high-risk program from July 2007 through July 2008. Gail score was calculated, and all patients also underwent OncoVue® (OV) testing and Sentinel Breastscan™ (SS). Results were retrospectively reviewed. A 5-year Gail score of ≥1.7% was considered high risk. The 5-year OV score was considered elevated according to average-risk comparisons. SS neural network scores were high (elevated) or low according to flow characteristics.

Results: Mean patient age was 48 years (range, 38-58). Patients were grouped as under 45 (11 patients, 25.0%), 45-54 (30 patients, 68.2%), and over 54 years (3 patients, 6.8%). All patients had an elevated 5-year Gail. The 5-year Gail correlated with the 5-year OV in 23 patients (52.3%). The remaining 21 (47.7%) had high 5-year Gail and normal 5-year OV scores. The 5-year Gail correlated with the SS in 33 patients (75.0%). The remaining 11 (25.0 %) had high 5-year Gail and low SS scores. The 5-year OV correlated with the SS in 26 patients (59.1%). Nineteen (43.2%) had high scores and 7 (15.9%) had low scores on both tests. Eighteen patients (40.9%) had no correlation, with 4 (9.1%) having high 5-year OV and low SS scores, and 14 (31.8%) having normal 5-year OV and high SS scores. All 3 tests (5-year Gail, 5-year OV, SS) were elevated in 19 patients (43.2%), whereas 25 (56.8%) did not have complete correlation. In 21 of these patients, the Gail and OV scores did not correlate, and the SS correlated with the Gail in 66.7% and with the OV in 33.3%. The remaining 4 patients' Gail and OV scores did correlate (both elevated), but their SS was low.

Conclusions: OncoVue® and Sentinel BreastScan™ correlated with the Gail model in 52.3% and 75.0% of patients, respectively. Therefore, these newer modalities may identify a cohort of patients traditionally identified as high risk who are actually not at high risk, 47.7% by OV and 25.0% by SS. The 19 patients with all 3 tests elevated may be at highest risk, while those with only 1 elevated may be at lesser risk. Genomics and angiogenic patterns may more accurately predict risk than historical factors and may be more cost-effective tools to identify patients who need to be followed in high-risk programs. Continued follow-up for future breast cancer occurrence may indicate that one or a combination of these techniques is valuable in more accurately determining risk.

The Use of Primary Breast Tumor Response As a Surrogate to Predict Nodal Status in Triple-Negative Breast Cancer Patients Who Undergo Neoadjuvant Chemotherapy

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Objectives. Triple-negative (TN) breast cancer is characterized by lack of expression of estrogen receptor (ER) and progesterone receptor (PgR), and the absence of HER2 protein overexpression. These cancers preferentially affect young and African-American women. They tend to be more aggressive clinically with a high histological grade. Many of these patients will receive neoadjuvant chemotherapy (NAC) in order to downstage the tumor size and hopefully obtain increased survival if they can achieve a complete pathological response in their primary tumor. This study will investigate the relationship between the pathological response of the primary tumor with the nodal status of the patient after neoadjuvant chemotherapy

Method: A total of 28 TN patients underwent NAC with 2-4 cycles of doxorubicin and cyclophosphamide, followed sequentially by a taxane plus or minus carboplatin, with or without bevacizumab. All patients underwent either a mastectomy or partial mastectomy for the primary tumor depending on residual tumor size and patients' preference. All patients underwent sentinel node biopsy unless there was palpable axillary adenopathy in which case no sentinel node biopsy was performed. All patients with palpable axillary adenopathy and positive sentinel nodes had a completion axillary node dissection. The postsurgical breast tissue sample and axillary samples was serially sectioned and examined for residual disease.

Results: Fifteen patients (54%) had a complete pathological response of the primary tumor. Seven (25%) of the patients were nonresponders and 6 (21%) were partial responders based on RECIST criteria.

Residual Disease	**Lymph**	**Node**	
Breast	Present	Absent	*Total*
Present	9	4	13
Absent	0	15	15
Total	9	19	28

The sensitivity and specificity was 100% and 79%, respectively. The accuracy was 86%. The negative predictive value was 100% and the positive predictive value was 69%.

Conclusions: Based on the results seen in this study, the response in the primary tumor can be used as a surrogate marker to predict the presence or absence of disease in the axilla of TN breast cancer patients who undergo neoadjuvant third-generation chemotherapy. The clinical application of these findings would be to use a noninvasive method, such as dynamic contrast magnetic resonance imaging, to measure the absence or presence of the residual disease in the primary breast prior to surgery and maybe save the patient a negative lymph node dissection.

Breast Cancer Mortality After Local Invasive Recurrence in Patients With Ductal Carcinoma In Situ of the Breast

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Background: Local recurrence after treatment for ductal carcinoma in situ (DCIS) is not only demoralizing, but if invasive, it is a threat to life. Although local recurrence (both invasive and noninvasive) is the most commonly reported study endpoint, invasive recurrence, distant recurrence, and breast cancer mortality are the endpoints of greatest importance.

Method: A prospective breast cancer database was reviewed. The incidence and actuarial rate of local recurrence, distant recurrence, and death in patients with DCIS was determined by treatment and other prognostic factors.

Results: Among 1401 patients treated for DCIS, there have been 89 noninvasive and 73 invasive local recurrences (12-yr actuarial recurrence rate = 19%); 10 patients with invasive recurrences have developed distant metastatic disease, 8 of whom have died of breast cancer. Seventy additional patients have died of other causes without local or distant recurrence. The median follow-up of patients with invasive local recurrence was 10.7 years. Fifty-eight percent of recurrences were stage 1, 18% were stage 2A, 14% were 2B, and 10% were stage 3 or 4. Local recurrences were the most difficult to diagnose within the group of patients treated with excision and radiation therapy, in whom radiation fibrosis developed. These recurrences were larger, more likely to be palpable, and had a longer median time to recurrence when compared with patients treated by excision only.

Conclusions: The rates of invasive and noninvasive recurrences are similar. Overall, a breast cancer mortality after treatment for DCIS, regardless of which treatment is chosen, is unlikely, approximately 1%. Most patients with local invasive recurrence and all patients with noninvasive recurrences can be salvaged.

Intraoperative Fluoroscopy for Radiographic Marker Localization During Surgical Breast Excision

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Objectives: Core needle biopsy is currently the standard of care for evaluation of abnormal breast imaging findings. Surgical excision is recommended for certain pathologic findings such as risk lesions or malignancy, or when there is discordance between imaging and pathology results. A radiographic marker (RM) sometimes placed at the time of biopsy may be used to guide mammographic wire localization, though some lesions seen sonographically may be localized with intraoperative ultrasound (IOUS) with or without preoperative wire placement. In the majority of cases, this RM is identified in the initial specimen signifying excision of the area of concern. If it is not found, it may be problematic identifying the breast tissue containing the marker to ensure complete excision of the biopsy site. Fluoroscopy can identify the RM, leading to a more targeted and successful excision of breast tissue. We recently began using intraoperative fluoroscopy (IF) in our institution to aid in intraoperative marker localization.

Method: We reviewed all patients who underwent surgical breast biopsy with IF from January to October 2008. Preoperatively, all patients had undergone core needle biopsy and RM placement with pathology findings requiring surgical excision. Localization was performed on the day of operation with either preoperative mammographic wire localization or IOUS. We used IF for patients whose marker was not initially visualized on intraoperative radiograph of the breast tissue specimen. When it appeared that accurate excision of the tissue with the marker might be difficult, IF was used prior to incision to mark the skin overlying the marker and sometimes the trajectory of the wire, if present. Specimens were evaluated by IF, therefore confirming accurate excision and also eliminating the need for specimen radiograph in some cases.

Results: Thirty-four patients underwent surgical breast biopsy with intraoperative fluoroscopic guidance. Six had their lesions identified by ultrasound guidance and 28 had wire localization. Four patients underwent excision for atypical lobular hyperplasia, 4 for flat epithelial atypia, 3 for intraductal papilloma, 3 for atypical ductal hyperplasia, 6 for ductal carcinoma in situ, 5 for invasive cancer, 1 for radial scar, 1 for a fibroepithelial lesion, and 7 for a combination of the abovementioned lesions. Fluoroscopy was successful in localizing the radiographic marker, and therefore biopsy site, in all cases.

Conclusions: Intraoperative fluoroscopy can be used successfully during excisional breast biopsy for radiographic marker localization under several circumstances, including difficult cases where the marker is located deep in the breast tissue and for incomplete initial excisions. This resource can be utilized with minimal extra cost, and may lead to shorter operative times and removal of less breast tissue when repeat excision is required.

MRI Fails to Predict Axillary Disease After Biopsy in Breast Cancer Patients

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Objectives: To determine the significance of lymphadenopathy seen on MRI following biopsy in women with invasive breast cancer.

Method: Between 2004 and 2006, 140 women with known or suspected breast cancer were prospectively enrolled in a study to determine the clinical importance of gadolinium-enhanced MRI after breast biopsy. MRI was followed by sentinel node biopsy (61) or axillary dissection (45) in 106 of 132 patients with invasive breast cancer. Forty-one (39%) of 106 underwent a follow-up MRI after completion of breast cancer treatment.

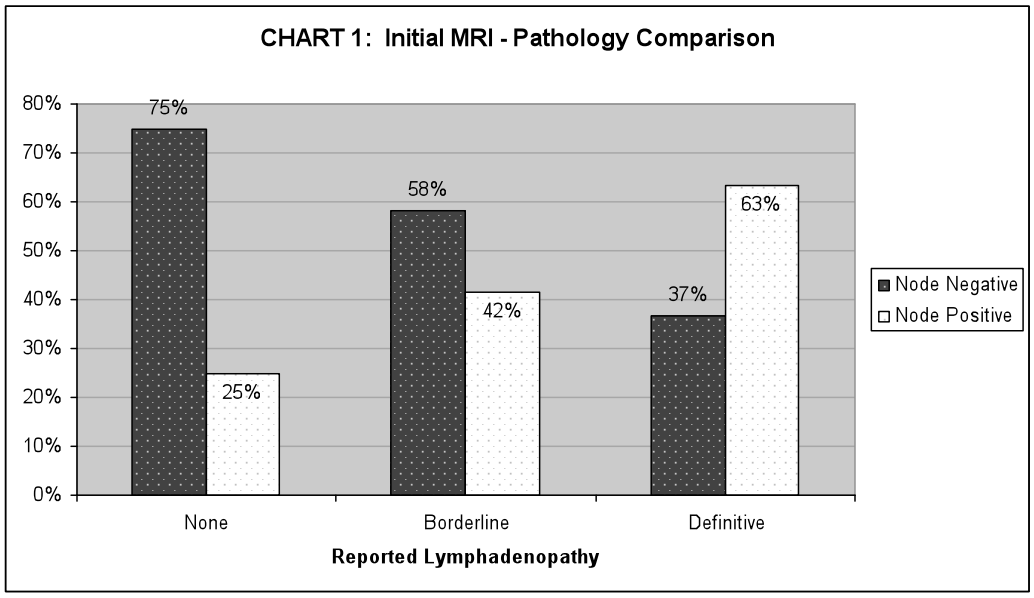
Lymphadenopathy identified on MRI was classified as "definitive" or "borderline." "Definitive" required the description of a lymph node with a short axis greater than 1 cm, loss of the fatty hilum, or a spiculated border, or a statement that there were "enlarged" or "abnormal" axillary lymph nodes. Any report with qualifiers (mildly, slightly, borderline) or contradictions (e.g., enlarged but with preservation of the fatty hilum) was classified as borderline. The true positive rate was based on final pathology results: defined as an axillary metastasis greater than 2 mm in size.

Results: Lymphadenopathy was noted in 54 (51%) of 106 newly diagnosed breast cancer patients.

Table 1. Reported Lymphadenopathy

	Initial MRI	Follow-up MRI
None	52 (49%)	38 (93%)
Borderline	24 (23%)	3 (7%)
Definitive	30 (28%)	0 (0%)
Total	106 (100%)	41 (100%)

If both borderline and definitive were considered positive, MRI had a sensitivity of 29/42 (69%), a specificity of 39/64 (61%), and a positive predictive value of 29/54 (54%). Considering only definitive as positive, the sensitivity was 19/42 (45%), specificity 53/64 (83%), and positive predictive value 19/30 (63%). There was a statistically significant correlation between MRI and pathology, as seen in Chart 1 (p value = .003). Nevertheless, the false-positive rate was 37% in the definitive and 58% in the borderline groups.



With the exception of 14/106 patients who had clinical signs of axillary disease (palpable, FNA positive or PET-CT positive), sentinel node biopsy (mean, 3.8 nodes) was routinely utilized. Forty-five (43%) of 106 ultimately had an axillary dissection (mean, 14.3 nodes), including 22 (73%) of 30 in the definitive, 13 (54%) of 24 in the borderline, and 10 (19%) of 52 in the "no lymphadenopathy" group.

Forty-one patients had follow-up MRIs an average 591 days (range, 28-1175) after axillary surgery. Approximately half (21/41) were done after sentinel node biopsy; the remainder (20/41) followed an axillary dissection. Thirty-eight (93%) of 41 follow-up MRIs were normal, 3 (7%) showed borderline abnormalities, and none had definitive lymphadenopathy.

Conclusions: Lymphadenopathy is commonly identified in MRIs performed after biopsy in newly diagnosed breast cancer patients. Even in the most worrisome (definitive) group, however, 37% of patients had no pathologic evidence of axillary metastases. Therefore, MRI should not influence the approach to axillary staging, apart from rare circumstances where lymph nodes are described with multiple abnormal features. MRI findings should rarely preclude a sentinel lymph node biopsy.

Optimizing the Benefits of MRI and PET-CT in the Initial Work-up of Breast Cancer Patients

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Objectives: To study the impact of gadolinium-enhanced MRI and 18F FDG PET-CT on the surgical treatment of women with breast cancer.

Method: One hundred forty women awaiting surgery for known or suspected breast cancer were prospectively enrolled between 2004 and 2006. Only those with invasive breast cancer who completed PET-CT and MRI imaging prior to surgery (n = 113) were included in this analysis. All subjects were followed for a minimum of 2 years.

Imaging studies were interpreted by subspecialty radiologists. Three breast surgeons independently reviewed each report to determine whether it changed the surgical management (e.g., led to biopsy of additional lesions, altered a planned lumpectomy, or identified metastatic disease). Based on the final pathology and clinical follow-up, each change in clinical management was categorized as correct or incorrect.

Patients who had needle biopsies (FNA or core biopsy) were compared to those who had surgical procedures (excisional biopsies or lumpectomies) to assess the impact of procedures done prior to imaging. Statistical analysis employed a series of binomial or chi-square tests.

Results: MRI altered surgical management twice as often as PET-CT (67/113 [59%] vs. 34/113 [30%]) ($p < .001$).

Changes in Clinical Management	MRI	PET-CT
Biopsy of an unsuspected ipsilateral lesion	69%	27%
Biopsy of an unsuspected contralateral lesion	16%	15%
Altered a planned lumpectomy*	34%	9%
Changed from lumpectomy to mastectomy	28%	24%
Biopsy of a nonbreast lesion	2%	18%
Axillary dissection instead of sentinel node biopsy	5%	38%
Chemotherapy as exclusive treatment	5%	18%

* A larger resection, different shape or extent, including satellite lesions, etc.

When imaging followed needle biopsy, MRI correctly changed management in 48 (86%) of 56 and PET-CT in 24 (87%) of 28 patients. In contrast, imaging that followed surgery led to many unhelpful interventions (MRI, 7/11 [64%]; PET-CT, 4/6 [67%]). False-positive results were 10 times more likely when MRI (OR = 10.5, 95% CI = 2.49, 44.25) or PET-CT (OR = 12.0, 95% CI = 1.62, 88.71) followed surgery.

Effect of Imaging on Surgical Management	MRI		PET-CT	
	Largest Procedure Done Prior to Imaging			
	FNA or Core	Exc or Lump	FNA or Core	Exc or Lump
Change	56 (59%)	11 (61%)	28 (30%)	6 (33%)
Correct	*48 (51%)*	*4 (22%)*	*24 (25%)*	*2 (11%)*
Incorrect	*8 (8%)*	*7 (39%)*	*4 (4%)*	*4 (22%)*
No Change	39 (41%)	7 (39%)	67 (71%)	12 (67%)
Total	95 (100%)	18 (100%)	95 (100%)	18 (100%)

When PET-CT preceded MRI, PET-CT findings were addressed in 14 (22%) of 65 MRI reports. No PET-CT addressed MRI findings.

Conclusions: Preoperative MRI affects surgical decision making in approximately 59% of postbiopsy breast cancer patients; PET-CT affects 30%. Unsuspected breast disease is best defined by MRI. PET-CT excels at identifying axillary disease and distant metastases. Surgical management is more likely to be "correct" when imaging follows FNA or core biopsy (MRI, 86%; PET-CT, 87%), compared to imaging after surgery (MRI, 36%; PET-CT, 33%). Ordering PET-CT prior to MRI may also affect accuracy. Ultimately, surgeons should make every effort to establish a tissue diagnosis using FNA or core biopsy.

Surgeon Quality Measures From the NQMBC™ (National Quality Measures for Breast Centers)

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Objectives: Quality of surgical care has become a primary interest of patients, clinicians and payers. Although there is much interest in assessing surgical quality of care, little has been documented of the outpatient surgical care of the breast cancer patient. The National Consortium of Breast Centers (NCBC) has created a unique method to examine the quality of breast care provided by breast centers across the country.

Method: The NCBC Quality Initiative Committee formulated an initial series of 36 measurements of breast center quality in 2005, called the National Quality Measures for Breast Centers (NQMBC™). Both published literature and expert opinion were used to develop these measures. In order to integrate submitted answers and to provide comparison reports, an interactive website was created. Consecutive patient data collected over a month concerning each measurement question is submitted to the website. New data may be submitted twice yearly. Breast centers can compare themselves with other centers who answered the questions. Comparison results are available for a specific point in time or serially over years. If desired, aggregate results, including all submitted answers, can be filtered to see only centers of similar size and demographics. No monetary charges are required to participate in this program. To confirm accuracy of submitted data, random audits are required. Results on several surgical measurements are reported here to demonstrate the power of this system.

Results: NQMBC™ data has been received from more than 200 centers via the Internet. A few initial questions pertinent to surgeons are discussed here, although many other surgical questions have yet to be tabulated. Results are expressed as the mean average, including 25th and 75th percentiles for each metric. More than 19,000 patient encounters helped answer 7 surgical questions. Results of questions, including 25th and 75th percentiles, with number of patient encounters contributing to data are: needle/core biopsy as the method of cancer diagnosis occurred in 90% (78%, 98%, n = 5,500); time between needle biopsy and initial cancer surgery was 14 days (11, 19.5, n = 5,400); time between surgical biopsy and pathology result was 2 days (1.7, 3.0, n = 1,700); percent closest surgical margin identified and measured in mm was 100% (96.5%, 100%, n = 2,000). These and other surgical questions are reviewed to provide some insight as to the value of such measurements to be used to distinguish quality surgeons.

Conclusions: Using a real-time, Web-based quality program, breast centers may input data and obtain immediate comparisons with other centers. Surgical data provides benchmarks that may be used to recognize high-quality surgical care they provide or to identify areas which need improvement. Results of some initial surgical measures from more than 19,000 patient encounters demonstrate the power of Web-based data evaluation.

Conversion to Outpatient Mastectomy as a Preferred Option

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Objectives: Since the concern of "drive through" mastectomies of the 1990s, outpatient surgical and anesthetic techniques have improved while hospital acquired infections have risen. Outpatient mastectomy may be a preferred option of care if it maintains patient comfort, avoids complications, and lowers costs. We present a consecutive series of patients treated with routine outpatient mastectomy compared with a similar group of inpatient mastectomy patients.

Method: A protocol for outpatient mastectomy was developed in 2007 that included patient/family education, recovery room training, and visiting nurse coordination. Our consecutive series contained 54 mastectomy patients, half inpatients (overnight) and half outpatients (no overnight). We defined outpatient mastectomy as patients treated with unilateral or bilateral, total or modified mastectomy without immediate reconstruction, whose postoperative facility time was less than 5 hours without an overnight stay and then discharged home. Patients requiring longer observation or those who wanted inpatient care would be admitted to the hospital. Comparison data included tumor characteristics, peri- and post-operative data as well as patient satisfaction survey results.

Results: All but 4 patients had unilateral mastectomy, with bilateral mastectomy occurring in 1 patient in the outpatient group and 3 in the inpatient group. Each group had similar primary tumor characteristics, with both groups tending toward large tumors with positive nodes. Ages ranged from 33-94 years; outpatient average age, 62. Sentinel node biopsy occurred in one third of each group with axillary dissections as appropriate in each group. Patients spent an average of 3.4 hours in the facility after outpatient mastectomy while average stay in the hospital was 2.1 days. Visiting nurses made home visits to outpatients an average of 5.9 times (range, 2-10) and no outpatient required hospitalization or reoperation. None of the outpatients had infections, hematomas, returns to surgery. Drains remained an equal number of days in both groups. Written patient satisfaction surveys revealed 100% good-to-excellent satisfaction with care in both outpatient and inpatient groups. Estimated cost benefits clearly favor outpatient mastectomy.

Conclusions: Improved outpatient techniques in the face of increasing hospital-acquired infections make outpatient mastectomy feasible and desirable. Implementing a focused protocol, including visiting nurse education and communication and preoperative patient and family education, yields excellent patient satisfaction. Our results from a consecutive series of outpatient mastectomy patients demonstrate the old stigma associated with outpatient mastectomy is unjustifiable. Outpatient mastectomy is a preferred option of care for most patients requiring total or modified mastectomy without immediate reconstruction.

American Society of Breast Surgeons MammoSite® RTS Registry Trial: Ductal Carcinoma In Situ Subset Analysis—4-Year Data in 194 Treated Lesions

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Objectives: A subset analysis of the American Society of Breast Surgeons (ASBS) registry trial of patients with ductal carcinoma in situ (DCIS) was performed to compare results to patients receiving accelerated partial breast irradiation (APBI) for invasive tumors and results in patients with DCIS receiving whole-breast irradiation.

Method: One hundred ninety-four cases of DCIS were identified from a total of 1449 cancers treated on the ASBS registry trial. Details of the trial are previously published. Analysis of the entire group of cases was performed in regard to toxicity and local control.

Results: One hundred ninety-four breasts in 192 patients were treated on the trial with a histologic diagnosis of DCIS. Median age was 62.1 years (range, 40-88) with 40.1 and 10.9% younger than 60 and 50 years, respectively. Nuclear grade distribution was 35.6, 31.4, 17, and 16% high grade, intermediate grade, low grade, and unknown, respectively. Necrosis was known to be present in 42.3% of cases. Comedo/solid architecture was known to be present in 68% of cases. Median tumor size was 8.0 mm (range, 0.1- 45; 15.5% unknown). Median margin was 2 mm. Two cases had positive margins and 56 cases had less than 1-mm margins. Ninety-nine patients (51%) received hormonal therapy. The median follow-up was 40.6 months (range, 0–67.6). Two isolated ipsilateral breast failures occurred. The isolated ipsilateral breast failure rate was rate was 1% (crude) and 1.53% 4-year actuarial. One additional patient had a breast and axillary failure. The total in breast 4-year actuarial failure rate was 2.09%. One of the patients had an elsewhere failure (0.69% 4-year actuarial rate). Two of the failures were true recurrences (1.41% 4-year actuarial). Two additional patients had contralateral failures (1.5% 4-year actuarial rate). Additional details of the cases with in breast failures will be presented. Infection occurred in 16 patients for an 8.2% rate. All infections were in the first 12 months after treatment. Seroma formation was reported in 23.2%, with 8.8% and 7.7% symptomatic and requiring intervention, respectively. Seroma formation was statistically higher in open versus closed cases for all seromas (28.7% open cases and 18.7% of closed cases). The relationship between seroma and infection will be discussed. Fat necrosis was reported in 1 patient (0.5%). Cosmetic outcome was good to excellent in 91.4% of patients with evaluation at 36 months.

Conclusions: The ASBS registry trial includes the largest published collection of DCIS treated with APBI. Four-year follow-up shows result similar to those with invasive cancer treated with APBI, as well as DCIS treated with whole-breast irradiation.

Local and Paravertebral Block Versus General Anesthesia for Elective Outpatient Breast Cancer Surgery

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Objectives: Most contemporary breast cancer surgical procedures are performed with general anesthesia (GA). A recent publication documented that GA was used for 98% of breast cancer operations in 3823 patients treated in university and VA hospitals. We hypothesized that (1) most breast cancer surgery can be performed with local and regional anesthetic (LRA) techniques, (2) LRA is safe, and (3) LRA is superior to GA with regard to postoperative nausea and vomiting (PONV), postoperative pain, need for unplanned hospital admission, postanesthesia care unit (PACU) time, and PACU charges.

Method: We performed an IRB-approved interim review of 6 months of prospectively collected data gathered by June 2008 for 70 consecutive breast cancer operative cases performed at a single institution. We excluded male patients and patients undergoing myocutaneous flap reconstruction. Local anesthesia was provided by 0.25% bupivicaine with epinephrine and the maximum allowable dose was 2.5 mg/kg. Regional anesthesia was provided by a paravertebral block at 6 levels with a long-acting local anesthetic. LRA was accompanied by intravenous sedation. A 10-point visual analogue pain scoring system was utilized for pain scores. Pain score change was defined as pain at 1 week minus pain at discharge. We then compared the combined LRA group to the GA group. The chi-square test compared group proportions. If expected cell count criterion failed, the Fisher exact test was used. The Wilcoxon rank-sum test compared continuous variables. A p value less than 0.05 was considered significant.

Results: The difference of the average PACU time between groups resulted in an estimated difference in charges of $850 per patient.

	LRA		GA		p Value	Test
Patients	52 (74%)		18 (26%)			
	Median	**Range**	**Median**	**Range**		
Age	68.5	(42, 91)	53.5	(31, 89)	.044	Wilcoxon
BMI	28.3	(19, 51)	25.9	(15.9, 33.4)	.034	
ASA score	2	(1,4)	2	(1,3)	.036	
Charlson comorbidity score*	21	(0,90)	65	(0,90)	.009	
Discharge pain score	1	(0,5)	2.5	(0,5)	.027	
1 week pain score	0	(0,5)	1.5	(0,7)	.011	
PACU time (min)	140	(50,460)	233	(117,410)	< .001	
	(N)	**(%)**	**(N)**	**(%)**		
Mastectomy patients (all types)	11	(21%)	12	(67%)	.001	chi-square
Complications (excluding PONV)	3	(6%)	5	(28%)	.023	Fisher
PONV	5	(9.6%)	9	(50%)	< .001	
Unplanned overnight admission	0	(0%)	3	(17%)	.015	
Conversion from LRA to GA	0	(0%)				
	LRA		**GA**			
Pain score change (mean ± std dev)	-.69 ± 1.5		0 ± 2.7		.005, >.999	Paired t

*Estimate of 10-year survival based on patient comorbidities.

Conclusions: A high percentage of patients (74%), including elderly patients with significant comorbidities, may undergo breast cancer operations safely with LRA. LRA techniques provide excellent intraoperative and postoperative pain control for patients undergoing lumpectomy, full axillary lymphadenectomy, mastectomy and expander/implant reconstruction. LRA was associated with decreases in complications, pain, PONV, unplanned overnight admissions, PACU time, and charges compared to GA. Confidence in the safety of LRA may increase the number of patients undergoing breast cancer surgery who are elderly or have comorbidities.

An Analysis of the Immunophenotype and Gene Expression Profiles of Mesenchymal Stem Cells Derived From the Stroma of Benign and Malignant Breast Tissue

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Objectives: Mesenchymal stem cells (MSCs) are multipotent adult stem cells found in many tissues in the human body, including the bone marrow and adipose tissue. These cells can also be isolated from the stroma of benign and malignant breast tissue. The aim of this study is to isolate and perform a comparison of the immunophenotype and gene expression profiles of MSCs in the stroma of both benign and malignant breast tissue, and to determine if these differences may contribute to our understanding of the interaction of stromal MSCs with cancer cells in the tissue-specific microenvironment, and to cancer progression and metastases.

Method: MSCs in culture, between passages 1 to 6, derived from 4 patient samples of benign and malignant breast tissue each, were used for all experiments. Phenotypic characterization was performed by flow cytometry with a panel of fluorescent-labeled specific antibodies. The gene expression profiles were compared using Human Ref 8 V3 arrays (Illumina Inc., CA). The data was analyzed using Genespring (Agilent Inc., Singapore) and analysis of signaling pathways was conducted using the Ingenuity Pathways Analysis (Ingenuity Inc., CA).

Results: Flow cytometric analyses revealed that the immunophenotype of MSCs from breast stroma in both benign and malignant groups were positive for HLA class I, CD 29, CD44, CD73, CD90, CD105, and CD166, and negative for the hematopoietic lineage markers CD14, CD34, and CD45. Additionally, significant percentages of HLA-DR positive MSCs were found in samples belonging to the malignant group. An analysis of gene expression profiles showed that, on average, 1000 genes were differentially expressed in MSCs in the malignant group, compared to the benign group. Of these, 190 genes were differentially expressed across all MSC samples from the malignant group. The differentially expressed genes were grouped by cell function and diseases using the Ingenuity Pathways Analysis. It was found that genes involved in cellular movement, cell-to-cell signaling and interaction, cardiovascular system development, lipid metabolism, cancer, respiratory disease, cardiovascular disease, renal disease, and inflammatory disease were upregulated in MSCs from the malignant group. Genes involved in LPS-mediated inhibition of RXR function, FXR/RXR activation, PXR/RXR activation, and LXR/RXR activation were also significantly overexpressed in MSCs from the malignant group.

Conclusions: From this data, we conclude that the phenotype of breast stromal MSCs is similar to that originally described for MSCs (Caplan, 1991) but negative for hematopoietic lineage markers. Additionally, MSCs derived from malignant breast tissue were found to significantly express HLA-DR, which warrants further investigation. Distinct gene expression profiles were also found for MSCs from malignant breast tissues, compared to benign samples. Bioinformatics analysis of gene function and signaling pathways involved predicts that MSCs from malignant breast samples may have a significant effect on the cancer microenvironment through the activation of genes involved in various cellular functions and via lipid activated nuclear receptors like the LXR and RXR receptors. Further work in this area may contribute to our understanding of the role of breast stromal MSCs in regulating invasion and metastasis of breast cancer cells.

Use of Sentinel Node Biopsy in DCIS: When Do You Find a Positive Node?

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Objectives: Performing sentinel node biopsy (SLNB) on patients undergoing surgery for ductal carcinoma in situ (DCIS) remains controversial with regards to the risk-benefit ratio of SLNB, especially if the diagnosis of DCIS is made on a core needle biopsy (CNB). Our objective was to assess the features associated with SLN-positive disease in patients diagnosed with DCIS on core biopsy in hopes of improving the preoperative selection process.

Method: A prospectively gathered database of surgically treated breast cancer patients was reviewed for patients with a sole diagnosis of DCIS on CNB from 1997 to 2008. Four thousand five hundred fifty-three patients were initially identified through database search. Patients were eliminated if they had incomplete records, diagnosis made on excisional biopsy, no SLNB performed, invasive carcinoma, or microinvasion on CNB. Four hundred seven patients had SLNB after confirmation of pure DCIS on CNB. Patient's age, race, personal and family history of breast cancer, tumor characteristics (radiologic and pathologic), type of surgery, SLNB results, and follow-up data, including treatment and recurrence, were recorded.

Results: Four hundred seven patients with DCIS on CNB underwent further surgical therapy involving SLNB. Of the original 407 patients, 291 (71%) had a final diagnosis of DCIS alone. The remaining 118 patients (29%) had invasive disease (median size of 1.4 cm.). Median age was 56 (range, 25-90). Median follow-up time was 39 months (range, 1-136). Two hundred thirty-six patients (58%) underwent lumpectomy, 171 (42%) had mastectomy. Median number of sentinel nodes examined was 2 (range, 0-6). A total of 31 (7.6%) of 407 patients with initial diagnosis of DCIS on core biopsy had a positive SLNB at the time of surgery. Eleven (3.8%) of 291 patients with a final diagnosis of DCIS had positive SLN versus 20 (16.9%) of 118 patients upstaged to invasive carcinoma postoperatively ($p = 0.0001$). Three of the positive SLN were micrometastasis; 2 demonstrated isolated tumor cells. Of the 31 patients with a positive SLN, 27 (87%) exhibited comedonecrosis versus only 178 (53%) with negative SLNB ($p = 0.0016$). Of the 27 with comedonecrosis, 9 (33%) exhibited DCIS only on final pathology, while 18 (67%) showed invasive carcinoma. There were no significant differences with regards to age, race, tumor grade, or receptor status (ER/PR) relative to SLN status. Local recurrence was seen in 10% of patients, regardless of SLN status.

Conclusions: Our study confirms that the rate of finding a positive SLN at surgery for suspected DCIS is less than 10%. If only DCIS is found on final pathology, the positive SLNB rate is even lower. In our series, the only preoperative factor predictive of SLN positivity is the presence of comedonecrosis. However, lymph node status is not predictive of local recurrence. This study supports the conclusion of others that SLNB may not change the outcome in DCIS-only patients, but those with comedonecrosis may benefit from the prognostic information gained from SLNB.

Bacteriologic Features of Surgical Site Infections Following Breast Surgery

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Objectives: Antibiotic prophylaxis to prevent surgical site infections (SSI) following breast surgery is of critical importance given the increased incidence of resistant organisms. This is especially important in patients undergoing nonautologous reconstruction for whom SSI may lead to loss of tissue expander or implants. We sought to investigate breast SSI to determine the most common bacterial isolates in our hospital and the patterns of antibiotic resistance, and whether our standard perioperative antibiotic is appropriate for the common flora seen in our population.

Method: Our microbiology laboratory database was reviewed to identify positive culture results from breast tissue, swab, or aspirated fluid between June 1997 and August 2008. This yielded 88 patients with positive breast culture results. Thirty-five of these were from lactational or nonlactational abscesses and were excluded. The electronic medical record was then reviewed for age, type of operation, and pathologic diagnosis.

Results: Among the 53 women who had breast surgery, 41.5% (22/53) underwent mastectomy, and 33.9% (18/53) underwent lumpectomy. Thirty-two percent underwent sentinel lymph node biopsy or node dissection in addition to their primary procedure. Mean age was 51 years (range, 27-81). Malignancy was present in 74% (39/53) of patients, with invasive ductal carcinoma being most prevalent. A total of 63 bacterial isolates were identified in these 53 patients, with 15% of patients having a polymicrobial culture result. Of the isolates, 51% (32/63) were gram-positive organisms and 49% (31/63) were gram-negatives.

Table 1. Prevalence of Bacterial Isolates in Breast SSI

Gram Positives	Prevalence	Gram Negatives	Prevalence
Staphylococcus aureus	24 (38%)	*Pseudomonas aeruginosa*	8 (12.7%)
Coagulase-negative *Staphylococcus*	4 (6.3%)	*Proteus mirabilis*	6 (9.5%)
Enterococcus species	3 (4.8%)	*Escherichia coli*	6 (9.5%)
Corynebacterium striatum	1 (1.6%)	*Enterobacter cloacae*	3 (4.8%)
		Other	8 (12.7%)

Among the gram-positive isolates, there was 1 case of MRSA and 2 cases of *Staphylococcus epidermidis* resistant to both nafcillin and trimethoprim/sulfa. There were 8 gram-negative isolates resistant to cefazolin, representing 13% (8/63) of all isolates, and 1 isolate resistant to trimethoprim/sulfa. All those tested were sensitive to piperacillin/tazobactam, levofloxacin, and ceftriaxone. Gram-negative infections were equally prevalent in patients regardless of malignant versus benign pathology.

Conclusions: Gram-negative infections were commonly associated with breast SSI, and were seen in nearly half of the infections in this cohort. Additionally few MRSA-related infections were encountered. These findings are significant, given that 13% of all isolates were resistant to cefazolin, our current perioperative antibiotic of choice. Consequently, our data support modification of the empiric choice of perioperative antibiotics in order to cover both gram-positive and gram-negative bacteria, although coverage of MRSA is not essential.

Single-Stage Breast Reconstruction With Inferior Deepithelialized Dermal Flaps and Saline Implants—An Innovative Solution to the Problem of Breast Reconstruction in the Patient With Macromastia

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Objectives: Breast surgeons are frequently faced with the dilemma of performing mastectomies and offering reconstructive options to patients with macromastia and obesity. This patient population presents with a multitude of problems that increase surgical complication rates and compromise cosmetic outcomes.

We are presenting a series of single-stage saline implant reconstructions using an inferior deepithelialized dermal flap harvested from redundant lower pole skin to achieve optimal implant coverage and breast projection.

Method: Over a period of 3 years, 70 mastectomies were performed using a Wise Pattern skin incision, an inferior dermal flap combined with medial and lateral acellular dermal matrix patches and a saline implant for single-stage reconstruction. This technique takes advantage of surplus lower-pole breast skin and uses the de-epithelialised surplus skin as an autologous tissue lining for the lower implant pocket making elevation of rectus fascia or serratus muscle unnecessary. Excellent breast projection and implant coverage is achieved in a single stage without the need for tissue expansion. All patients presented with various degrees of macromastia and ptosis, and most patients who did not undergo bilateral mastectomies underwent immediate or delayed contralateral symmetrising reduction mammoplasty. We compared postoperative complication rates and number of surgical procedures to traditional reconstructive procedures.

Results: Seventy mastectomy reconstructions were performed during this period. Of these implant reconstructions, 4 patients (3%) developed postoperative infections requiring IV antibiotic treatment with 3 (2%) patients requiring removal of the implant. Two patients (1%) developed partial mastectomy flap necrosis requiring prolonged wound care. Seven patients (10%) experienced minor delayed wound healing with no flap loss.

Conclusions: Skin-reducing mastectomy with inferior deepithelialized flaps and immediate implant reconstruction produces excellent cosmetic results with low complication rates, fewer operative procedures, and high patient satisfaction in this growing subgroup of breast cancer patients.

Macromastia, which traditionally is considered one of the most difficult problems in reconstructive breast surgery, can now be considered a unique opportunity to offer immediate single-stage breast reconstruction with excellent cosmetic results.

A Comparative Analysis of Core Needle Biopsy and Final Excision for Breast Cancer: Histology and Marker Expression

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Objectives: Recently, there has been increased reliance on preoperative core needle biopsy (CNB) not only for establishing a diagnosis, but for selecting treatment for breast cancer patients. Tumor characteristics and marker expression may be used to choose neoadjuvant therapy and have been proposed as predictive markers for the presence of sentinel lymph node metastases. This has shifted our own practice away from reliance on fine needle aspirates. However, little is known about the accuracy of CNB in predicting these features of breast cancer. Therefore we undertook this study to evaluate CNB as a predictor of breast cancer histology and marker expression.

Method: From our breast cancer registry, we identified 209 cases with a preoperative CNB. Biopsies were performed under clinical, ultrasound, and stereotactic guidance. Demographic and clinical data were abstracted. Individual pathology and procedure reports were reviewed to confirm data accuracy and validity. Statistical analysis was performed with an SAS software package.

Results: CNB demonstrated cancer in 195 (93%) of 209 cases, while 5 (2%) showed atypia and 9 (4%) were benign. Among neoplastic cases, exact tumor histology concordance was 86%. DCIS on CNB was upgraded to invasive cancer in 10 (23%) of 43 cases; 2 cases with microinvasion on CNB were downgraded to DCIS after excision. Concordance between CNB and final excision for marker expression, with kappa values, is shown below:

Parameter	Concordance	κ
Grade (1,2,3)	63%	0.439727
Mitotic rate (grouped <5, 5-9, ≥10/10hpf)	61%	0.381277
ER (+/-)	88%	0.708716
PR (+/-)	78%	0.542497
Ki67 (favorable = < 15%, borderline = 15-30%, unfavorable = >30%)	59%	0.360158
HER-2/neu (0, 1+, 2+, 3+)	56%	0.391972
HER-2/neu (negative = 0/1+, positive = 2+/3+)	81%	0.590822
p53 (negative = <5%, positive = ≥5%)	77%	0.498967

Conclusions: In our series, CNB accurately diagnosed cancer in 93% of cases and the type of malignancy in 86%. Concordance for all but ER expression had kappa values <0.7. Reliance on CNB grade and marker expression for critical decision-making may be inadvisable. Further study is warranted to determine how best to use grade and marker expression data from CNB in the treatment of breast cancer patients.

The Effect of Simultaneous Margin Excision in Breast Conservation Upon Margin Status

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Objectives: Negative margins are critical in breast conservation therapy (BCT) to decrease the risk of local recurrence. Some surgeons remove a single lumpectomy specimen, while others remove a central segment of tissue and additional segments. This study was performed to evaluate the effect of each method on margin status and whether this is simply a function of the volume of tissue removed.

Method: A retrospective chart review of all patients undergoing BCT for core biopsy proven invasive breast cancer between January 2006 and August 2008 was conducted to evaluate the 2 techniques. Presentation and pathologic characteristics, surgical technique (the number of simultaneous segments), volume of all specimens, and final margin status were recorded.

Results: Among 262 cancers in 260 women, 216 (82%), 17 (6.5%), and 29 (11%) had ductal, medullary, and lobular carcinomas, respectively. There were 34 segmental mastectomies (13.0%) with positive margins. A single segment was removed in 71 patients (27.1%) while 191 patients underwent excision of $\geq$1 segment (range, 1-6). Average tumor and total specimen size were 1.7 cm and 158.7 cm^3, respectively. While 117 (44.7%) were palpable, 153 (58.6%) underwent needle localization. Specimen volume did not increase as the number of segments taken increased (p = 0.31), and average total specimen volumes were smallest when 0 additional segments were excised (142.7 cm^3) but largest with the removal of only 4 additional segments (186.9 cm^3). Positive margins were present in 15 resections (21.1%) with only 1 segment removed, while 19 (9.9%) were positive when $\geq$1 segment was excised. The risk of a positive margin declined with smaller tumor size (p = 0.017), but was not assisted by palpability (p = 0.85), needle localization (p = 0.46), or a greater volume excised (p = 0.98). Despite a lack of correlation between the number of segments and the volume removed, the risk of positive margins decreased significantly as the number of segments removed increased (p = 0.026). In a multiple logistic model of margin status, the number of segments, tumor size, use of needle localization, volume resected, and palpability, only smaller tumor size (p = 0.0021), and a higher number of segments removed (p = 0.016) lowered the risk of margin positivity.

Conclusions: While palpability and needle localization did not assist in BCT margin status, excision of a greater number of segments during BCT lowered the likelihood of positive margins. Because increasing the number of segments resected didn't correlate with volumes and greater volume removal didn't lower the risk of positive margins, the benefit of additional segmental excision may be due to avoidance of pathologic artifact via examination of additional segments.

Management and Outcomes of Patients With Margins Positive for DCIS After Mastectomy for Early-Stage Breast Cancer

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Objectives: Mastectomy is the treatment of choice for DCIS when it is multicentric or associated with a large mass, or after multiple excisions with positive margins. There is not, however, a consensus about management of DCIS at or close to the margins after mastectomy. We aimed to study current management methods and the subsequent outcomes specific to positive margins after mastectomy.

Method: A retrospective review of pathology reports of 734 mastectomies performed between 1997 and 2007 for DCIS alone and for early-stage (T1N0M0) invasive breast cancer associated with DCIS was undertaken. The reports were analyzed for margin involvement, which was defined as DCIS ≤2 mm from the margin. Exclusion criteria were tumor >2 cm, positive nodes, or margins involved with invasive cancer. The management of close/positive margins was assessed, as was local and systemic recurrence.

Results: One hundred specimens had pure DCIS and the remainder had invasive cancer and associated DCIS. Ten specimens with pure DCIS and 8 with coexisting invasive cancer had close or positive margins. Margins were positive for DCIS in 5 (2 pure DCIS) specimens and were within 2 mm in 13 specimens. All 5 patients with DCIS at the margin were treated with postmastectomy radiation therapy (PMRT). Six of 18 received tamoxifen; only 2 of whom had pure DCIS and would not likely have been offered the therapy if not for the margins. Five patients received chemotherapy for invasive breast cancer. One patient with stage 1 disease and positive margins for DCIS had a distant recurrence, but no local recurrence. She received post-op chemotherapy, PMRT, and tamoxifen. There were no reported local recurrences and no re-excisions for positive margins in this cohort.

Conclusions: Positive margins for DCIS after mastectomy are successfully treated with postmastectomy radiation. Close margins (< 2 mm) can be closely observed. There was no difference in outcome between those followed by observation alone vs. those who had either postmastectomy radiation, tamoxifen, or both.

MRI As Compared to Mammogram in the Evaluation of Size, Number of Lesions, and Nodal Status of Breast Cancer

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Objectives: Magnetic resonance imaging (MRI) is thought to be more sensitive and specific in detecting breast carcinoma (BrCa) than mammogram. Our study compares the lesion size, lymph node status, and additional ipsilateral or contralateral lesions between MRI and mammogram.

Method: A retrospective study was performed on 252 patients with BrCa undergoing MRI and mammogram, with number and size of lesions compared to pathology.

Results: In the total of 252 patients, tumor size was reported in 242 lesions by MRI, 170 lesions by mammogram, and 150 lesions by both. In 242 MRI-detected lesions, 9% had the same size, 63% were overestimated by a mean of 0.52 cm, and 28% were underestimated by a mean of 0.66 cm. For the mammogram-detected lesions (n = 170): 10% had the same size, 38% were overestimated by a mean of 0.88 cm, and 52% were underestimated by a mean of 0.70 cm. In the 150 lesions detected by both MRI and mammogram, MRI overestimated lesion size in significantly more patients than mammogram ($p < 0.0003$), and mammogram underestimated lesions size in significantly more patients than MRI ($p < 0.0006$). MRI tended to overestimate tumor size in tumors less than 2 cm more so than tumors greater than 2 cm. Mammogram tended to overestimate tumor size in tumors <1 cm, but tended to underestimate tumor size in tumors >1 cm. MRI detected 56 additional lesions in 51 patients (15%), resulting in a change in management in 18% of the patients with additional ipsilateral lesions and 38% of patients with additional contralateral lesions. MRI also detected suspicious lymphadenopathy in 19% of patients.

Conclusions: MRI effectively evaluates the lesion size with a tendency toward overestimation, especially in tumors 2 cm or less. MRI can detect additional lesions in ipsilateral and contralateral breasts, leading to a change in management. The identification of suspicious lymphadenopathy further supports the clinical utility of MRI in the evaluation of BrCa.

The Impact of Age on the Surgical Management of Breast Cancer

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Objectives: Survival of patients undergoing mastectomy and breast conservation surgery (BCS) for women with breast cancer is equivalent, but treatment options are affected by many factors. Our goal was to identify factors influencing a women's choice between mastectomy and BCS and, specifically, the influence of age on this choice.

Method: Five thousand two hundred thirty-five patients undergoing either mastectomy or BCS for invasive and ductal carcinoma in situ (DCIS) were identified in a retrospective review of a prospectively accrued breast cancer database between the years of 1994 and 2007. Logistic regression analysis was used to estimate the association (OR = odds ratio) between surgical procedure and patients' clinicopathologic characteristics.

Results: Of the 5235 patients, 4072 (78%) patients had invasive breast carcinoma and 1163 (22%) had DCIS. BCS was performed in 62% of patients with invasive carcinoma and 67% of patients with DCIS. A significant difference in BCS rates was observed across age groups in patients with invasive carcinoma and DCIS. On logistic regression analysis, older age, absence of reconstruction, earlier stage, smaller tumor size, and absence of lymphovascular invasion were significant independent predictors of BCS among patients with invasive carcinoma. Similarly, older age, absence of reconstruction, and smaller tumor size were significantly associated with BCS among patients with DCIS. Race was not a significant predictor of BCS in both groups. Using age <40 years as the reference group, a significant preference toward BCS was observed among patients with invasive carcinoma in age groups 40-49 (OR = 1.6; 95% CI, 1.2-2.1), 50-59 (OR = 1.5; 95% CI, 1.1-1.9), and 60-69 (OR = 1.4; 95% CI, 1.1-1.8). No significant difference was found in age group ≥70 (OR 1.1; 95% CI, 0.8-1.5). In contrast, a significant preference toward BCS was observed across all DCIS age groups: 40-49 (OR = 1.7; 95% CI, 1.0-2.9), 50-59 (OR = 2.0; 95% CI, 1.2-3.3), 60-69 (OR = 1.8; 95% CI, 1.1-3.1), and ≥70 (OR = 1.9; 95% CI, 1.1-3.3), when compared to the <40- year population.

Conclusions: Age is clearly associated in the decision-making process in breast cancer treatment. Older women with invasive carcinoma and DCIS were more likely to select BCS over mastectomy. Future research is needed to elucidate psychosocial factors that influence surgical treatment in relation to age.

What Do Breast Surgeons Do?

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Objectives: It is clear that breast surgery differs greatly from other areas of general surgery. The purpose of this study is to critically examine the role of the breast surgeon to help facilitate institutional planning and resource allocation.

Method: We reviewed all new patient visits to our university-based breast center surgery practice for the calendar years 2006 and 2007, and assessed reason for referral, diagnostic and treatment procedures performed, patient outcome, and recommended and actual patient follow-up.

Results: Of 10,381 total breast surgery patient visits during this time period, 2334 (22%) represented new patient visits and are described in the following table:

Reason for Referral	Frequency	Needle bx by Surgeon	Needle bx by Radiology	Surgery Performed	Cancer Diagnosed
Recent Dx cancer	252/2334 (11%)	4% (11/252)	17% (43/252)	73% (186/252)	100% (252/252)
ADH etc on core	90/2334 (4%)	0%	8% (7/90)	81% (72/90)	17% (15/90)
Abn mammogram	828/2334 (35%)	6% (50/828)	37% (304/828)	36% (294/828)	16% (131/828)
Mass felt by patient	673/2334 (29%)	14% (93/673)	13% (90/673)	25% (168/673)	10% (67/673)
Mass felt by MD	95/2334 (4%)	17% (16/95)	14% (13/95)	16% (15/95)	12% (11/95)
Breast pain	156/2334 (7%)	3% (4/156)	5% (7/156)	9% (14/156)	2% (3/156)
Nipple discharge	75/2334 (3%)	4% (3/75)	7% (5/75)	39% (29/75)	8% (6/75)
High-risk screening	105/2334 (5%)	0%	9% (9/105)	3% 3/105)	0%
Second opinion	60/2334 (3%)	2% (1/60)	3% (2/60)	14% (8/60)	48% (29/60)

Of the 89% of patients without a referral diagnosis of cancer, 8% had a needle biopsy by the surgeon, 21% had needle biopsy by radiology, and 29% underwent surgery. Thirteen percent of these patients were diagnosed with cancer. During the initial workup, more than 90% had a mammogram or ultrasound and 12% had an MRI. After completion of initial work-up and/or therapy, 6-month or 1-year follow-up was recommended for 59% of the patients. During this follow-up period, 26 new cancers were identified.

Conclusions: The specialty of breast surgery is unique in its nonoperative volume and extensive duration of follow-up. Strategies need to be designed to make this process more time-efficient for the surgeon.

Sentinel Lymph Node Performance Metrics and Re-excision Lumpectomy Rates Determined the Success Rate of a Patient-Centered, One-Step Approach to Breast Cancer Surgery

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Objectives: Patient-centered care is 1 of 6 goals recommended by the Institute of Medicine in "Crossing the Quality Chasm: Building a Better Healthcare System in the 21st Century." Patient-centered performance measures include the success rate of 1-step surgery and patient self-assessment of postoperative pain and cosmesis. The aim of this study was to identify and audit patient-centered quality indicators to create a breast center report card that could be provided to patients, third-party payors, and other care providers for comparison. We hypothesize that the processes of care and the performance that result in successful 1-step surgery, adequate pain control, and good cosmesis are measurable and therefore could be used for economic and quality comparisons between institutions.

Method: An IRB-approved retrospective review of consecutive patients undergoing sentinel lymph node biopsy (SLNB) for breast cancer at a single institution from April 1998 to December 2006 was conducted. Males and neoadjuvant chemotherapy patients were excluded. Sentinel lymph node (SLN) performance metrics and re-excision lumpectomy rates were determined. Immediate intraoperative assessment of SLN's was performed by frozen section analysis of multiple sections stained with H&E. The identification of a positive SLN resulted in immediate axillary lymphadenectomy. A postal survey was also mailed to patients in 2006-2007 to query patients about postoperative cosmetic satisfaction and pain control.

Results:

Components of 1-Step Surgery (1998-2006 unless otherwise indicated by *)

Percentage eligible patients offered SLNB*	348/374 (93%)
SLN identification rate	682/697 (98%)
Immediate intraoperative assessment of SLN performed	609/682 (89%)
Sensitivity of intraoperative identification of positive SLN	86/131 (66%)
Re-excision lumpectomy rate for SLNB patients*	40/232 (17%)
% Patients (lumpectomy or mastectomy) with single-step surgery*	320/367 (87%)
% Patients (lumpectomy) with single-step surgery*	189/232 (81%)

*Years 2004-2006

Patient Self-Assessment of Cosmesis and Pain Control

2006-2007 cosmesis (5-point scale)	
Excellent to very good	103/134 (77%)
2007 pain control (3-point scale)	
Intraop "definitely good"	69/72 (96%)
First week "definitely good"	60/72 (83%)

Conclusions: The components of care that contribute to a patient-centered assessment of breast cancer surgery are measurable. Intraoperative identification of positive SLNs, immediate completion lymphadenectomy for node-positive patients, and low re-excision lumpectomy rates allow most patients to undergo 1-step surgery. Cosmetic results and analgesic efficacy are additional patient-centered quality indicators. Both can be measured by survey. Institutional comparisons of these metrics have the potential to indentify performance outliers. The study of outliers may help design quality initiatives to improve patient-centered care. Transparency of metrics could potentially be utilized by patients, payors, and policy makers for patient steerage. Further study of patient-centered quality indictators (conducted by care providers and their professional societies) are necessary for refinement of definitions, consensus development, and risk adjustment to aid policy makers.

Sentinel Lymph Node Biopsy After Neoadjuvant Chemotherapy in Breast Cancer: A Tertiary Care Experience

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Objectives: We reviewed sentinel lymph node (SLN) biopsies after neoadjuvant chemotherapy for breast cancer in a tertiary care setting. Our objectives included the assessment of the rate of successful identification of SLNs and analysis of SLN biopsy results and tumor characteristics. These results were compared with biopsy results of patients who did not undergo neoadjuvant chemotherapy.

Method: This was a retrospective study of prospectively collected data. SLN biopsies performed after neoadjuvant chemotherapy for breast cancer between January 1, 2006, and August 31, 2008, were evaluated for the rate of SLN identification, the number of SLNs removed, the percentage of positive SLN biopsies, and the number of positive SLNs. Recurrence and follow-up information was collected for this neoadjuvant (NEO) group. Information from a previously collected dataset of non-neoadjuvant (NON) patients with invasive breast cancer who successfully underwent SLN biopsies from June 1, 2007, to May 31, 2008, was compared with the NEO group for demographics, tumor characteristics, and SLN biopsy results. Statistical comparisons were made using the Student *t*, Wilcoxon's rank sum, chi-square, or Fisher exact tests.

Results: Two hundred thirty-one breasts (224 patients) were evaluated (NEO = 52; NON = 179). There were no significant differences in the number of SLNs removed (mean NEO = 3.3; NON = 3.1; $p = 0.545$), the percentage of positive axillae (NEO = 23.8%; NON = 21.2%; $p = 0.776$), or the number of positive SLNs (mean NEO = 1.3; NON = 1.5; $p = 0.627$) between the 2 groups. The patients in the NEO group were younger ($p < 0.0001$), had higher grade tumors ($p < 0.0001$), were more likely to have a mastectomy ($p = 0.046$), and were more likely to have ER-negative ($p = 0.007$) and Her2Neu-positive ($p = 0.0002$) tumors. In the NEO group, the mean clinical tumor size was 4.5 cm before chemotherapy; the postchemotherapy pathologic size was 1.4 cm. An SLN was identified in 100% of the NEO breasts. There were no local recurrences with a mean follow-up of 1 year (range, 0.02-2.4 years).

Conclusions: NEO patients presented with clinically large tumors and were more likely to have ER-negative and Her2Neu-positive tumors than NON patients. In 100% of NEO patients, an SLN was successfully identified, and the number of SLNs removed was commensurate with the NON patients. No local recurrences were noted in the NEO group. After neoadjuvant chemotherapy, the node-positive rate was the same as in the NON group, implying chemotherapy effect.

Does MRI Accurately Predict Residual Disease in Breast Cancer Patients?

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Objectives: The accuracy of magnetic resonance imaging (MRI) in diagnosing residual disease in patients treated with excisional biopsy or breast conservative therapy for breast cancer is unclear. Areas of enhancement around the lumpectomy cavity may represent benign postsurgical changes or residual disease. Our goal was to determine whether MRI is a useful tool in predicting residual disease in patients needing further surgical intervention.

Method: A review of an institutional breast sentinel lymph node database between 2003 and 2008 identified patients who had contrast-enhanced MRI prior to undergoing re-excision or mastectomy after excisional biopsy/breast conservative therapy due to either positive or close (<2 mm) margins or suspicion of recurrence. Histopathologic correlation with image findings was performed.

Results: Forty-three women underwent MRI after excisional biopsy or breast conservative therapy but prior to re-excision or mastectomy. Of 28 patients in whom MRI suggested residual disease, 19 (68%) were found to have residual carcinoma pathologically. Conversely, of 15 MRIs that indicated no evidence of residual disease, 6 patients (40%) were found to have residual disease pathologically. The overall sensitivity and positive predictive value (PPV) of MRI detecting residual disease was 76% (95% CI, 58%-93%) and 68% (95% CI, 49%-82%), respectively. When MRI was conducted within 28 days of the original surgery, it was 83% (95% CI, 52%-98%) sensitive in detecting residual disease with a PPV of 71% (95% CI, 42%-92%). When MRI was done after 28 days, the sensitivity was 69% (95% CI, 42%-87%) and PPV was 64% (95% CI, 39%-84%). Of the 19 patients with MRIs accurately detecting residual disease, 5 had invasive cancer only, 10 had in situ carcinoma only, and 4 had both invasive and in situ disease (either ductal or lobular type). Of the 6 patients with residual disease not appreciated on MRI, 2 had invasive cancer and 4 had in situ carcinoma (again, either ductal or lobular type). In the 9 patients whose MRI indicated residual disease but none was found on pathology, 1 had atypia, 3 had fat necrosis, 3 had giant cell inflammatory reaction, and 2 had normal breast tissue at the excision site.

Conclusions: MRI is able to detect residual disease among the majority of patients undergoing re-excision or mastectomy for breast cancer. Based on this small sample, the time period between original surgery and MRI does not appear to affect the positive predictive value to a significant extent. There remains a substantial rate of false-positive MRIs among these patients, which are largely due to inflammatory processes that resemble residual disease.

The Rate of Identification of Isolated Tumor Cells Reflects Disparities in the Delivery of Breast Cancer Care

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Objectives: Disparities in the quality of health care delivered among different socioeconomic strata (SES), ethnic groups, and health care systems are well documented. The identification of isolated tumor cells (ITCs) in axillary lymph nodes of patients with breast cancer requires diagnosis of early-stage disease, appropriate implementation of sentinel lymph node (SLN) dissection, and pathologic analysis of the SLN with serial sectioning and immunohistochemical staining. We sought to determine factors that are associated with the identification of ITCs.

Method: We performed a retrospective cohort review of N0(i+) breast cancer patients diagnosed between 2004 and 2006 in the California Cancer Registry. The proportions of patients in SES quintiles (1 = lowest to 5 = highest), race/ethnicity groups, and hospital volume tertiles (low = 1-241 cases/yr, medium = 242-491 cases/yr, high = ≥492 cases/yr) were compared between the ITC and the overall breast cancer populations using odds ratios (OR) with 95% confidence intervals (CI).

Results: Three hundred sixty-nine patients had ITCs. With increasing SES, the proportion of patients with ITCs increased: 7.1% of patients with ITCs were SES1; 15.7%, SES2; 20.3% SES3; 23.9%, SES4; and 33.1%, SES5. 69.4% of patients with ITCs were non-Hispanic white; 12.8%, Asian; 11.9%, Hispanic; and 5.2%, non-Hispanic black. Hispanic women were significantly less likely to have ITCs when compared to the overall proportion of Hispanic women with breast cancer (OR = 0.70; 95% CI, 0.49-0.95). 46.9% of ITCs were identified in high-volume hospitals (OR = 1.80; 95% CI, 1.47-2.21), though high-volume hospitals represented only one third of all surgical cases. SLN dissections were performed less frequently in patients in the lowest (vs. highest) SES quintile (OR = 0.37; 95%CI, 0.35-.040), non-white (vs. white) patients (Hispanic OR = 0.60; 95% CI, 0.57-0.63; Asian OR = 0.78; 95% CI, 0.74-0.83; non-Hispanic black OR = 0.66; 95% CI, 0.61-0.72), and low- and medium- (vs. high) volume hospitals (OR = 0.41; 95% CI, 0.39-0.43 and OR = 0.68; 95% CI, 0.65-0.72, respectively).

Conclusions: ITCs are identified less frequently in Hispanic women, in women of lower SES, and in lower volume hospitals. These findings may reflect lower rates of early-stage diagnoses and underutilization of standard surgical and pathologic techniques, and suggest that these populations receive disparate qualities of breast cancer care.

Complications Associated With Postoperative Antibiotic Prophylaxis After Breast Surgery

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Objectives: Evidence-based data support the administration of a single-dose of preoperative prophylactic antibiotics for breast surgery. There is little to no data concerning the complications of continued antimicrobial prophylaxis in the postoperative period in these patients.

Method: Retrospective review of patient charts from breast/axillary operations was performed between July 2004 and June 2006 collecting data regarding demographics, timing of prophylactic antibiotics (ABX), treatment of surgical site infection (SSI), and complications of ABX therapy. ABX complications were analyzed by patient treatment group: preoperative prophylaxis alone, postoperative prophylaxis, and therapeutic intent for concern of SSI. Fisher exact test was used to compare ABX complication rates with level of significance set at 0.05.

Results: Three hundred ninety-eight patients underwent breast and/or axillary operations during the study period, including 44 patients with immediate reconstruction. Three hundred sixty-nine patients (93%) received ABX; 358 (90%) of all patients were given a single preoperative dose, 90 (23%) received postoperative prophylactic oral ABX, and 82 (21%) were prescribed ABX for therapeutic intent. Of the 90 patients receiving postoperative prophylactic ABX, 43 had immediate reconstruction. Among all 369 patients receiving ABX, 15 (4%) had an ABX-related complication (Table 1). These complications were attributed to postoperative prophylaxis in 5 and to the therapeutic regimen in 10; none were attributed to the single preop dose. The rate of ABX-related complication was significantly higher among those who received ABX for postoperative prophylaxis (6%, 5/90) compared to those receiving only a single preoperative dose (0%, 0/179), p = <0.001.

Table 1. Complications by Antibiotic Therapy Group

Prophylaxis Antibiotic Group	Rash	Diarrhea	Nausea/Vomiting	Hypersensitivity Reaction	Total
Preoperative	0	0	0	0	0
Postoperative	2	2	2*	0	6*
Therapeutic intent	3*	4	3	1	11*
Total	5*	6	5*	1	17*

*One patient in each of the postoperative prophylaxis and the therapeutic intent group had 2 complications.

Conclusions: Antibiotic-related complications are uncommon after a single preoperative prophylactic dose but occur more frequently with longer courses of antibiotics used as postoperative prophylaxis. Considering the potential harm of postoperative ABX after breast surgery, the administration of postoperative prophylaxis should be reexamined.

Disparities in BRCA Testing: Insurance Coverage Is Not a Barrier

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Objectives: Strategies to reduce the risk of developing breast and ovarian cancer in carriers of deleterious BRCA 1 and 2 mutations are readily available. However, many people who are at high risk of having these genetic mutations are reluctant to obtain the test. We sought to identify factors associated with choice of testing, and specifically to determine if insurance coverage impacts decision making.

Method: We performed a retrospective cohort review of high-risk patients referred to a multidisciplinary breast health center for BRCA testing between January 2001 and March 2008. Demographic variables were compared between those who completed genetic testing and those who did not by chi-square and logistic regression analyses.

Results: Two hundred thirteen patients were referred for BRCA testing. The mean age was 49.2 years (range, 16-84). Five patients were male. 63.4% were white; 15%, Hispanic; 6.6%, black; and 4.7%, Asian. Insurance coverage for testing was available in 91.1% of patients, of whom 49.2% had private, 26.7% had HMO, and 24.1% had government-sponsored insurance. One hundred eleven patients (52.1%) underwent testing. On multivariate analysis, patients were significantly more likely to complete testing if they had a personal history of breast cancer (62.0% of patients) ($p < 0.0001$), had at least some college education (59.2%) ($p = 0.017$), and were of lower socioeconomic status (29.6%) ($p = 0.015$). There were no statistically significant differences in tested vs. untested groups by age, race, language, marital status, parity, family history, or insurance status. Of patients whose insurance plans offered coverage for genetic testing, 51.4% underwent testing and 48.6% did not (p = NS). Of those who had no insurance coverage for testing, 41.2% underwent testing and 58.9% did not (p = NS).

Conclusions: Our data show that half of those at risk for carrying a BRCA mutation do not undergo testing. Insurance coverage for genetic testing does not influence the decision to test. Developing counseling instruments that explain the benefits of testing to unaffected high-risk individuals or targeted to those with a high school level education may be a strategy to improve testing rates.

Success of Neoadjuvant Chemotherapy in Downsizing Breast Cancer for Breast Conservation Therapy at a Regional Hospital

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Objectives: Studies have shown that neoadjuvant chemotherapy (NC) can increase the rate of breast conservation (BC) for patients with large tumor-to-breast ratios and for patients with Stage 2 and Stage 3 disease. Although there is no survival benefit of mastectomy compared to BC, the rates of BC therapy, especially in the Southeastern United States, remain low. The purpose of this study is to determine the success of NC in downsizing breast cancer for attaining BC at a Southeastern regional medical center.

Method: A retrospective chart review was conducted on all women with breast cancer who had chemotherapy prior to surgery between January 1, 2003, and June 30, 2007. Women with stage 4 disease, multicentric disease, or contraindications to radiotherapy were excluded from analysis. Patients were evaluated for pre- and post-chemotherapy size and stage, tumor histology, and rates of BC.

Results: Sixty-five tumors (63 patients) were included in the study. The mean patient age was 50 years. Infiltrating ductal carcinoma was the predominant tumor type occurring in 92% of cases. The mean pre-chemotherapy tumor size was 3.9 cm (range, 1.6-10). The mean post-chemotherapy tumor size was 1.5 cm (0-8.0). Sixty-nine percent (45/65) of the tumors experienced size reduction ($p < .001$). Seventy percent (46/65) of the tumors also experienced a clinical stage reduction ($p < .001$). Twenty-seven percent (18/65) of the tumors had complete pathologic response. Sixty-nine percent (45/65) of patients in this series received BC therapy. Post-chemotherapy tumor size was the only factor that had significant correlation to BC therapy ($p = 0.032$). Triple-negative status, menopause status, tumor type, nodal disease, ER, PR, and Her2Neu status were not significant in predicting rate of BC.

Conclusions: The success of NC in downsizing breast cancer to achieve BC at our institution is comparable to results published from other institutions. The overall rate of BC therapy at our institution and that reported by other Southeastern medical centers remains low, compared to other regions of the country. These regional differences, however, do not appear to be attributable to a difference in the response to NC.

Does Everyone With Invasive Breast Cancer Need a Sentinel Lymph Node Biopsy?

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Objectives: Lymph node status is the most important prognostic indicator of breast cancer outcome. The current standard of care is to perform a sentinel lymph node (SLN) biopsy on patients diagnosed with clinically node-negative invasive breast cancer. However, the morbidity of SLN biopsy is not negligible: postoperative pain, decreased range of motion, paresthesia, lymphedema, and rarely anaphylaxis associated with isosulfan blue or other dyes. Therefore, it becomes valuable to identify a subset of patients for whom SLN biopsy may not be necessary. Accurately predicting which tumors have the least likelihood of lymph node metastasis can potentially spare patients for whom SLN biopsy would have minimal benefit. We analyzed patient demographics and tumor characteristics to identify the potential subset of invasive breast cancer patients for whom SLN biopsy may reasonably be avoided.

Method: In order to evaluate which patients have the highest probability of SLN metastasis, we performed a retrospective review of patients from our IRB-approved multicenter study initiated in 1996, enrolling a total 1424 patients. Patients having DCIS without microinvasion, missing variables, and male gender were excluded. Included in the analysis were 1225 patients, 73% of whom had negative sentinel nodes by AJCC (6^{th} edition) staging. The factors analyzed for predictability of positive lymph nodes included age, tumor size, tumor location, lymphvascular invasion (LVI), multicentricity, multifocality, nuclear grade, ER/PR positivity, and tumor differentiation. Univariate models identified characteristics most predictive of positive sentinel lymph nodes. All variables were then evaluated using multivariate logistic regression analysis.

Results: In univariate analysis, age, tumor size, tumor location, LVI, multicentricity, and multifocality, were significantly associated with SLN metastasis ($p < .05$). Multivariate logistic regression model revealed age, size, LVI, multicentricity/multifocality and tumor differentiation as predictive of positive SLN status whereas tumor location in the upper inner quadrant was predictive of negative SLN metastasis ($p < .05$). Utilizing the multivariate model, we identified a subset of patients with a ≤10% probability of positive sentinel lymph nodes. Women ≥65 years old with final pathological tumor size ≤1.5 cm who did not display LVI, poor differentiation and multicentricity/multifocality were in this favorable subset. This patient subgroup represented 15% of the database population.

Conclusions: In our analysis, tumor size, age, LVI, tumor location, tumor differentiation, and muticentricity/multifocality prove to be important variables in determining a patient's risk of SLN metastasis. Using our multivariate model, we found a subset of patients with a ≤10% chance of positive SLNs. Careful use of this data may further allow surgeons to tailor the decision to perform a SLN biopsy on breast cancer patients.

Accelerated Partial Breast Irradiation via SAVI: 1-Year Follow-up

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Objectives: Accelerated partial breast irradiation (APBI) offers women a more compact course of treatment with 10 fractions given over 5 days as opposed to an approximately 6-week-long course of daily therapy for whole-breast irradiation (WBI). Over the past several years, several devices have entered the market for APBI brachytherapy. One of these devices is Cianna Medical's SAVI, Strut Adjusted Volume Implant. It combines the surgical implant simplicity of a balloon brachytherapy device with the dose flexibility of interstitial brachytherapy. The purpose of this study is to illustrate the effectiveness in treatment with our follow-up results.

Method: The SAVI device was placed in a total of 63 patients treated at UC San Diego (35 patients) and 21st Century Oncology (28 patients). The device contains a central strut that can be loaded with the high-dose rate (HDR) radiation source, as well as several peripheral struts (6-10). The peripheral struts offer the advantage of dose modulation according to patient anatomy, thus maximizing tumor bed coverage while sparing normal tissues (skin and lung). The patients were planned and treated using the SAVI device. Data was retrospectively analyzed for infection rate, seromas, cosmesis, and local recurrence.

Results: In the 63 patients treated with SAVI, the overall cosmesis was rated as excellent with outstanding tumor bed coverage, while keeping skin dose less than 100% of the prescribed dose in all patients treated. This included 25 patients with skin bridges less than 7 mm. There were 2 infections (3%), 0 seromas (0%), and 0 local recurrences (0%) with a median follow-up of 12 months (range, 1-19 months).

Conclusions: The design of the SAVI device eliminates skin distance and breast size limitations, as well as conformance issues. The treatment outcomes have been outstanding with excellent cosmesis, including 0 seromas and 0 recurrences. There were 2 infections reported (3%) with only 1 requiring cessation of treatment.

Body Mass Index Is Not a Risk Factor for Lymphedema in Older Breast Cancer Women

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Objectives: Since body weight is a modifiable factor, the aim of this study was to determine the relative contribution of patient body mass index (BMI) to the development of lymphedema (LE) in a large, contemporary, unselected population of older breast cancer patients.

Method: Telephone surveys were conducted among women (65-89 years) from 3 states (CA, FL, IL) who had initial breast cancer surgery in 2003. The presence of LE, BMI (at time of surgery and at approximately 4 years postoperatively), treatment and pathology information were obtained from survey response, Medicare claims, and state tumor registries.

Results: Of the 2154 patients treated by 966 surgeons, 333 (15.5%) had self-reported LE at a median of 48 months postoperatively. On univariate analysis, recent BMI (27.9 vs. 26.5; $p < 0.001$) and BMI at time of surgery (27.7 vs. 26.8; $p = 0.005$) were associated with LE but a change in BMI since surgery (0.0 vs. -0.3; $p = 0.234$) was not. Race, tumor grade, and receipt of radiation or hormonal therapy were not associated with LE. At the time of surgery, women who were of a healthy weight (BMI < 25.0), overweight (BMI, 25-29.9), or obese (BMI $\geq$ 30) had a 13.5%, 16.2%, and 19.7% risk of developing LE, respectively. The mean number of lymph nodes removed increased with each higher BMI category (5.7, 6.1, and 7.0, respectively; $p = 0.016$). On multivariate analysis, when controlling for all other variables, the only independent predictor of LE was the removal of more than 5 lymph nodes ($p < 0.0001$).

Conclusions: Four years postoperatively, 15.5% of a contemporary, population-based cohort of elderly breast cancer survivors have self-reported LE. A relationship between higher BMI and risk for LE exists on univariate analysis; however, this association appears to be accounted for by the greater number of lymph nodes removed among women with higher BMI. We showed no relationship between weight change and the development of LE over this limited 4-year time interval.

NOTES