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SCIENTIFIC SESSION ABSTRACTS

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

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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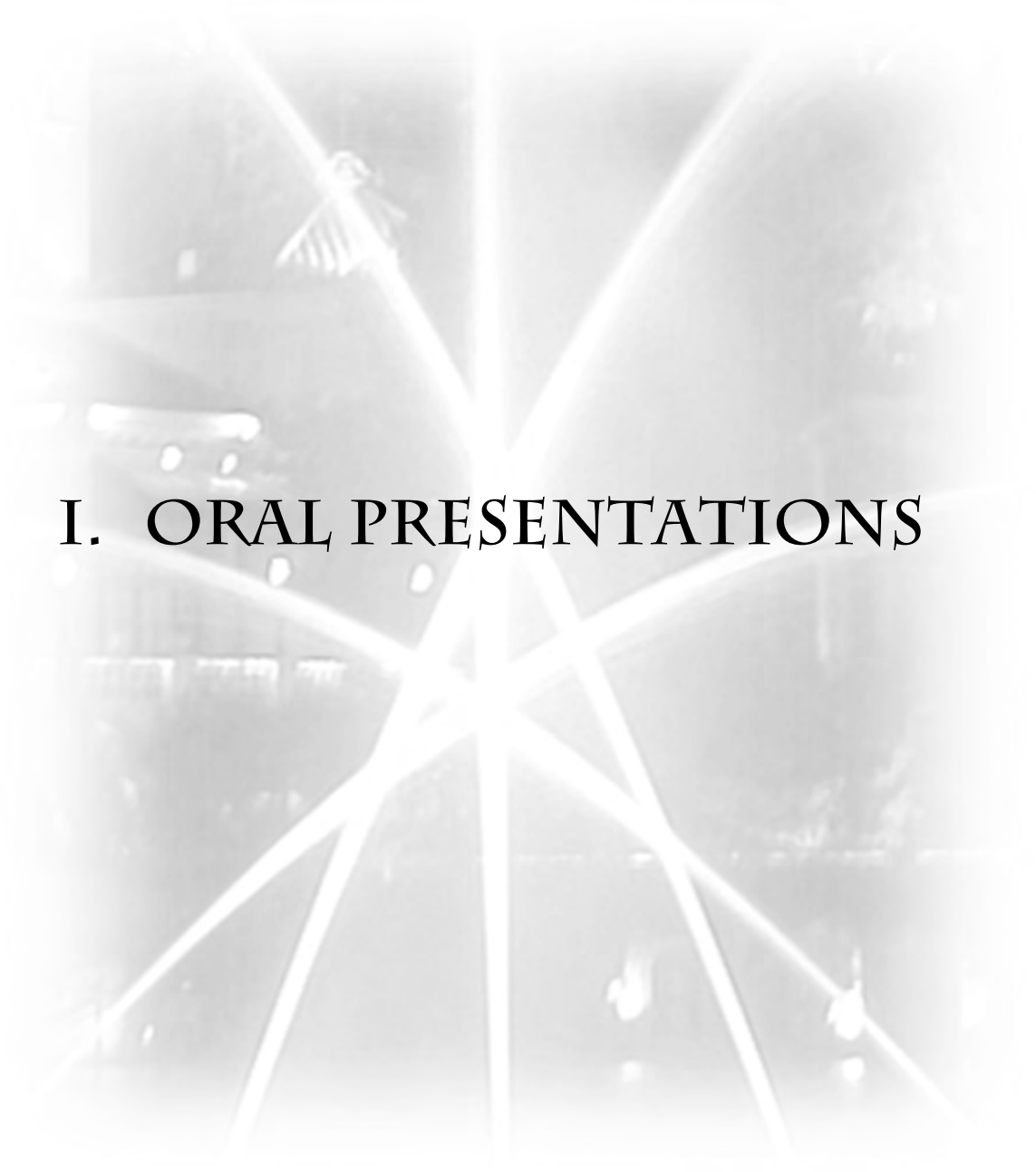

I. ORAL PRESENTATIONS

Note: Underscore indicates presenting author.

10-Year Experience With Hematoma-Directed, Ultrasound-Guided Breast Lumpectomy

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Objective: Pain, patient inconvenience, vasovagal symptoms, scheduling problems, wire malposition, and a positive margin rate of 40 to 75% are associated with needle-localized biopsy (NLBB). Despite these problems, this is still the primary means of identifying nonpalpable lesions in the breast. We hypothesized that the hematoma-directed, ultrasound-guided (HUG) procedure for intraoperative localization of nonpalpable lesion would allow for lumpectomy without the downfalls of needle localization and decrease the high positive-margin rate with NLBB.

Methods: This is a retrospective study from January 2000 to October 2009. Electronic chart review identified lumpectomy procedures performed in clinic or in the operating room. These patients underwent preoperative biopsy diagnosis by ultrasound (US) or stereotactic means. When excision was necessary, either needle localization or HUG was then planned. A 7.5-MHz linear array transducer was used intraoperatively for the HUG procedures and a block of tissue surrounding the hematoma was removed.

Results: Localization procedures were performed in 460 patients: 126 (27%) via needle localization and 334 (73%) via HUG. The previous core biopsy site in 100% of patients was successfully excised using HUG: 151 (45%) of 334 were benign and 183 of 334 (55%) were malignant; margins were positive in 42 (23%) of these 183. NLBB was successful in 100% of patients, 80 (63%) of 126 were benign and 46 (37%) of 126 were malignant; margins were positive in 21 (46%) of these 46. Margin positivity was significantly higher for NLBB than HUG ($P = 0.04$, Fisher exact).

Conclusions: This 10-year experience, representing the largest to date, suggests that HUG is more accurate in localizing nonpalpable lesions than NLBB. Compared to the additional painful procedure of NLBB, HUG is also more time- and cost-efficient. Preoperative needle core biopsy is not only the minimally invasive diagnostic procedure of choice, but also becomes the localization procedure when excisional biopsy is necessary.

The Impact of Breast Density on the Presenting Features of Malignancy

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Objective: Mammographically dense breast stroma has been associated with an increased risk of breast cancer. Limited visibility on mammography has also led to speculation that tumors arising in dense breasts may be more advanced at diagnosis and carry a worse prognosis. This study was undertaken to examine the relationship between breast density and presenting features of breast cancer.

Methods: Data were obtained from a prospectively maintained, single-institution database of 628 invasive breast cancers in patients treated from October 2005 to June 2007. Mammographic density was scored by the Breast Imaging Reporting and Data System (BI-RADS) classification at initial presentation (1 = mostly fatty, 2 = scattered fibroglandular, 3 = heterogeneously dense, 4 = very dense). Patients were classified as having either fatty breasts (BI-RADS 1 + 2) or dense breasts (BI-RADS 3 + 4) for analysis. Chi-square and multivariate logistic regression were used to identify associations between breast density and clinicopathologic variables.

Results: Breast density was classified as BI-RADS 3 in the majority (61%) of patients. A BI-RADS score of 1, 2, and 4 were assigned to 5%, 23%, and 11% of patients, respectively. Patients with dense breasts (3 + 4) were significantly younger than those with fatty breasts (1 + 2), median age, 53 versus 62 years, respectively ($P < 0.0001$), and were more likely to have mammographically occult tumors (13% vs 1%, $P < 0.0001$). Patients with dense breasts were also more likely to present only with suspicious calcifications or architectural distortion compared to those with fatty breasts ($P < 0.0001$). Controlling for patient age, there were no differences in tumor size, grade, lymphovascular invasion, multifocality, nodal positivity, or molecular subtype defined by immunohistochemistry for ER, PR, and Her-2 between patients with dense and fatty breasts. Tumors in dense breasts were more likely to have an extensive intraductal component (19% vs 9%, $P = 0.02$), but there was no difference in type of surgery (breast conservation vs mastectomy) between groups. When patients with BI-RADS 4 density were compared to all others, there was a trend toward more lobular and nonductal histologies in patients with dense breasts ($P = 0.06$). These patients were also more likely to have mastectomy (OR, 0.57; $P = 0.03$), however this difference did not persist after controlling for age.

Conclusions: Breast cancers arising in patients with BI-RADS 3 and 4 breast density share the same clinical and molecular profiles as those arising in patients with fatty breasts. Despite limitations in mammographic visibility, increased breast density is not associated with diagnosis at a more advanced stage or with aggressive clinical features. The trend toward lobular and special phenotypes in those with very dense breasts further supports that breast density does not predict for worse outcomes and should not be considered a contraindication to breast-conserving therapy.

5-Year Outcome in Patients Classified in the "Unsuitable" Category Using the American Society of Therapeutic Radiology and Oncology (ASTRO) Consensus Panel Guidelines for the Application of Accelerated Partial Breast Irradiation: An Analysis of Patients Treated on the American Society of Breast Surgeons MammoSite® Registry Trial

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Objective: We applied the American Society of Therapeutic Radiology and Oncology (ASTRO) Consensus Panel (CP) guidelines for the application of accelerated partial breast irradiation (APBI) to patients treated with this technique on the American Society of Breast Surgeons MammoSite® registry trial to determine potential differences in outcome of patients classified in the "unsuitable" category.

Methods: Of 1449 cases treated with APBI on the registry trial, 176 fit the criteria for the unsuitable CP category: a total of 130 cases were <50 years of age, 13 had positive margins, 38 had positive lymph nodes, 6 had tumors >3 cm in size, and 11 had an EIC >3 cm. Rates of ipsilateral breast tumor recurrence (IBTR) and regional nodal failure (RNF) were assessed. Median follow-up was 49.2 months.

Results: The 5-year actuarial rate of IBTR for "unsuitable" cases was 5.28% and the RNF rate was 0.63%. By comparison, the 5-year actuarial IBTR rates for various subsets of patients were as follows: all 1449 cases (3.82%, *P* = 0.2328); all 1449 cases, excluding unsuitable cases [n = 1273] (3.62%, *P* = 0.1652); invasive-only cases [n = 1255] (3.88%, *P* = 0.2432); and invasive-only cases, excluding unsuitable invasive cases [n = 1105] (3.91%, *P* = 0.2362). On univariate analysis for variables potentially associated with IBTR in all 1255 cases with invasive cancer (including age, tumor size, nodal status, overall stage, margin status, ER status, presence of an EIC, and ASTRO unsuitable category designation), only negative ER (-) status was associated with the 5-yr rate of IBTR (*P* = 0.0011). No other variable (including unsuitable designation by the ASTRO CP guidelines) was associated with a higher rate of IBTR.

Conclusions: The ASTRO CP guideline designation of "unsuitable" did not differentiate a subset of patients with a significantly worse rate of IBTR when treated with the MammoSite® breast brachytherapy catheter to deliver APBI.

Complication Rates of Radiation on Tissue Expander and Autologous Tissue Breast Reconstruction

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Objective: To evaluate risk factors for complications of tissue expander and autologous tissue breast reconstructions and determine if radiation increases complication rates.

Methods: We performed a retrospective review of patients who underwent mastectomy plus autologous tissue or expander/implant reconstruction at the Cleveland Clinic. Univariate and multivariate analysis were performed to evaluate for risk factors for complications. A complication was considered major if it required reoperation.

Results: A total of 942 patients were included in the study. In the tissue expander/implant population, there was a total complication rate of 31.8% and overall major complication rate of 24.4%. Radiation increased the major complication rate from 21.2% to 45.4%, but tissue expander reconstruction still successful in 70.1% of patients. In the autologous reconstruction group, there was a total complication rate of 31.5% and a major complication rate of 19.7%. There was no statistically significant difference between the radiated and nonradiated autologous tissue reconstructions with major complication rates of 17.9% and 20.5%, respectively.

Conclusions: Total complication rates were similar between tissue expander and autologous reconstructions. Increased major complication rates in patients with tissue expander reconstructions occurred in those with radiation, but was still successful in the majority of patients. Radiation had no influence on autologous tissue reconstruction and should not exclude autologous reconstruction from a complication standpoint.

Molecular Detection of Micrometastatic Breast Cancer in Histopathology-Negative Axillary Lymph Nodes Fails to Predict Breast Cancer Recurrence: A Final Analysis of a Prospective Multi-institutional Cohort Study

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Objective: The presence of axillary lymph node (ALN) metastases remains one of the most significant predictors of prognosis in women with breast cancer. Frequently it plays a critical role for determining whether adjuvant systemic chemo or hormonal therapy is recommended. Unfortunately 20 to 30% of node-negative patients will develop distant metastases within 10 years. Recognizing those women who are diagnosed as lymph node–negative at the time of primary surgery but who may relapse later is very important. One approach proposed to estimate the risk for relapse of disease is to detect occult nodal metastases at the time of diagnosis. The presence of this micrometastatic disease may help explain the relatively worse prognosis seen in a proportion of node-negative patients. To address the clinical relevance of molecular detection of occult breast cancer in sentinel lymph nodes (SLN) and nonsentinel axillary lymph nodes (ALN), we initiated the Minimally Invasive Molecular Staging of Breast Cancer (MIMS) trial, a multi-institutional prospective cohort study. This trial represents the first prospective cohort study in which a multimarker, real-time RT-PCR analysis was applied to the detection of breast cancer micrometastases in ALN.

Methods: Sentinel and/or nonsentinel ALN from 501 breast cancer subjects with T1-T3 primary tumors were analyzed by standard histopathology and multimarker, real-time RT-PCR analysis. For this study, 7 breast cancer–associated genes (*mam mamB, PIP, CK19, muc1, PDEF,* and *CEA*) known to be overexpressed in metastatic breast cancer compared with control lymph nodes were used. Following their initial operation, patients were followed at their respective institutions per routine practices. Follow-up data were collected up to 5 years after the initial operation.

Results: Of the original number of breast cancer subjects enrolled, 352 completed the 5-year follow-up. For these patients, the 5-year relapse-free survival rate was 95.4% (95%CI, 92.4%-97.2%). Fifteen recurrences were noted, 4 of which were local, 8 were distant, and 3 were both local and distant. Forty-eight percent of the 352 followed patients (n = 168) demonstrated evidence of molecular over expression. No signal gene or combination of study genes was predictive of recurrence. We did not find any association between the numbers of markers overexpressed with real-time RT-PCR in recurrence versus nonrecurrence. The low incidence of recurrences and possibly marker selection/sensitivity could be contributing factors to this negative predictive outcome.

Conclusions: While there is an abundance of literature regarding potential molecular markers for the detection of metastatic breast cancer, there is very little data in the literature regarding the clinical relevance of pathology-negative/molecular-positive ALNs as determined by RT-PCR. This is an interesting topic and has several implications, including better treatment options for women with micrometastatic disease as well as improved sensitivity and specificity of SLN biopsy. Despite interim data and those from smaller series that suggest a prognostic correlation between the presence of molecularly detected micrometastatic disease in ALN of breast cancer patients and traditional predictors of prognosis, the genes in this study panel failed to be predictive of clinical relapse.

Disparities in Reconstruction Rates After Mastectomy

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Objective: Few studies have examined the factors influencing whether breast cancer patients undergo reconstruction, either immediate or delayed, after mastectomy. This study was undertaken to determine the variables associated with the use of reconstruction in 4 counties in Southern California: Los Angeles, Orange, San Bernardino, and Riverside.

Methods: Postmastectomy reconstruction rates were determined from the California Office of Statewide Health Planning and Development database over a 5-year period from 2003 to 2007. International Classification of Disease-9 codes were used to identify patients undergoing reconstruction after mastectomy. Differences in reconstruction rates were examined by calendar year, age, race/ethnicity, insurance status, and hospital characteristics.

Results: The total number of patients undergoing mastectomy with or without reconstruction was 2936 in 2003, increasing to 3151 in 2007. The proportion of patients undergoing any type of reconstruction (immediate or delayed) rose from 21.4% in 2003 to 29.3% in 2007. Women under the age of 40 had the highest proportion of immediate reconstruction rates compared to other age groups. Compared with Caucasians, African Americans were half as likely to undergo immediate reconstruction (OR = 0.49; 95% CI, 0.38-0.62). Patients with private insurance were more likely to undergo immediate reconstruction than patients with Medi-Cal (OR = 7.12; 95% CI, 6.04-8.39; $P < 0.0001$). Teaching hospitals were nearly twice as likely to perform immediate reconstruction compared to nonteaching hospitals. Patients undergoing procedures at NCI-designated comprehensive cancer centers (NCI-CCC) are more likely to undergo flap reconstruction than implant (OR = 2.76; 95% CI, 2.15, 3.56) versus patients undergoing procedures at other hospitals. Teaching hospitals are less likely to perform flap versus implant reconstruction (OR = 0.79; 95% CI = 0.63, 1.00). Delayed reconstruction was offered at a small number of hospitals; the number increased from 22 to 35 hospitals over the 5-year period.

Conclusions: A minority of patients undergo reconstruction, although the rate is increasing. Insurance status, race/ethnicity, and type of hospital appear to be significant factors limiting the use of reconstruction.

Disparities in the Use of Sentinel Lymph Node Dissection in Early-Stage Breast Cancer

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Objective: Sentinel lymph node dissection (SLND) is considered standard of care for patients with early-stage breast cancer. Utilization of SLND has been proposed as a quality measure for breast cancer care. We sought to identify factors associated with utilization of SLND in early-stage breast cancer.

Methods: Patients with stage I/IIA/IIB invasive breast carcinoma from 2004-2007 with records in the California Cancer Registry were evaluated. The proportions of patients undergoing SLND were compared with regard to demographic characteristics by uni- and multi-variable analyses.

Results: Of 55,207 patients identified, 36,459 (66.0%) underwent SLND. The majority were female (99.4%); the average age was 60.8 years (range, 19-105). More patients presented with stage I disease (56.6%), than stage IIA (30.3%) or IIB (13.1%). Partial mastectomy was performed in 64.3% of patients and 58.8% were treated in non-ACOS-approved hospitals. Most patients were non-Hispanic white (66.8%), followed by Hispanic (15.2%), Asian/Pacific Islander (11.4%), and non-Hispanic black (5.7%). The proportions of patients in SES quintiles increased from 10.2% in the lowest quintile to 28.8% in the highest. Multivariable analysis showed the odds ratios for undergoing SLND as follows:

Category		Odds Ratio	95% Confidence Interval	*P* Value
Age	<40	1.41	1.29-1.55	<0.001
	40-64	1.53	1.47-1.59	<0.001
	≥65	1		
Stage	I	1		
	IIA	0.75	0.72-0.78	<0.001
	IIB	0.53	0.50-0.56	<0.001
Year of diagnosis	2004	1		
	2005	1.35	1.28-1.42	<0.001
	2006	1.56	1.48-1.65	<0.001
	2007	1.59	1.51-1.68	<0.001
Surgery type	Total mastectomy	0.51	0.49-0.53	<0.001
	Partial mastectomy	1		
ACOS status	Approved	1		
	Not approved	0.88	0.85-0.92	<0.001
SES	SES 1 (lowest)	1		
	SES 2	1.23	1.15-1.32	<0.001
	SES 3	1.43	1.34-1.54	<0.001
	SES 4	1.74	1.62-1.86	<0.001
	SES 5 (highest)	2.01	1.87-2.15	<0.001
Race/ethnicity	Hispanic	0.78	0.74-0.83	<0.001
	Asian/Pacific Islander	0.81	0.77-0.86	<0.001
	Non-Hispanic black	0.84	0.78-0.91	<0.001
	Non-Hispanic white	1		

Conclusions: SLND use has increased over time; however, only two thirds of eligible patients undergo this recommended procedure. Using SLND as a quality measure demonstrates significant disparities that have implications not only for patient and provider education, but also for health care policy and reform.

Incidence and Management of Local-Regional Recurrence Following Immediate Breast Reconstruction in Patients With 0 and 1 to 3 Positive Lymph Nodes Treated Without Postmastectomy Radiation Therapy

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Objective: Immediate breast reconstruction after mastectomy is preferable for patients (pts) who have a low risk of local-regional recurrence **(**LRR). There has been widespread use of postmastectomy radiation therapy **(**PMRT) in patients with 1 to 3 positive lymph nodes (LN), ased on older trials demonstrating LRR rates in the 20 to 25% range. The use of PMRT following reconstruction is associated with poor aesthetic outcome and a high complication rate. Therefore, many patients are currently delaying reconstruction because of the potential need for PMRT. This study was performed to determine current LRR rates and outcomes following immediate breast reconstruction in pts with 0 to 3 positive LNs who did not receive PMRT.

Methods: Clinical and pathologic factors from 498 pts identified from the prospectively maintained Breast Cancer Database were analyzed. Pts who had T1 or T2 tumors and 0 to 3 positive LNs treated with primary mastectomy with SLN biopsy or axillary dissection and immediate breast reconstruction from 1997 to 2002 were studied. *No pts in this cohort received neoadjuvant therapy or PMRT.* Fisher's exact test and Kaplan-Meier analysis were used.

Results: Median age was 49 yrs, 85% had T1 and 15% had T2 tumors, 24% had 1 to 3 positive (pos) LNs, and 76% of pts received adjuvant chemotherapy or hormonal therapy. Autogenous reconstruction was performed in 70% of pts, whereas 30% had tissue expander placement. There were 81 pts with 1 pos LN, 28 pts with 2 pos LNs, and 9 pts with 3 pos LNs in this cohort. At a median follow-up of 90 mos, LRR occurred in only 16 pts. The 10-year LRR rate in 380 pts with 0 pos LNs was 3.89% and 4.26% in the 118 pts with 1-3 pos LNs. Among pts with pos LNs, the median size of the largest LN metastases (mets) was 4 mm (range, 0.25-30 mm), with 34% of pts having LN mets ≤ 2 mm. Pts who were younger than 40 and had ER-negative tumors had significantly higher rates of LRR ($P < 0.02$). Median time to LRR was 39 mos. LRR was detected as a palpable mass in 50% of pts. The location of the LRR was the skin of the reconstructed breast (44%), parasternal/internal mammary node region (25%), supraclavicular region (25%), and in the pectoralis major muscle (6%). Multimodality therapy was utilized for all pts with LRR (94% systemic, 69% surgery, 81% RT). Surgery was performed in the 11 pts who did not have or develop distant mets. At last follow-up, 44% of pts with an LRR (n = 7) had died of disease.

Conclusions: LRR rates are extremely low following primary mastectomy and immediate breast reconstruction in pts with T1 and T2 breast cancer with 0 to 3 positive LNs. The extremely low rates of present-day LRR are likely due to improvements in imaging, patient selection for immediate reconstruction, pathologic assessment that identifies minimal disease, and systemic adjuvant therapies. Stage II breast cancer pts reflect a heterogeneous group. Therefore, routine use of PMRT in all pts with 1 to 3 positive LNs should be discouraged based on present-day LRR rates.

Long-Term Follow-up Study of a Multicenter Sentinel Node Trial: Molecular Detection of Sentinel Node Metastases Predicts Distant Recurrence

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Objective: Sentinel lymph node biopsy enables a more comprehensive and sensitive evaluation of lymph nodes for metastatic disease. In 1996, we initiated a prospective multicenter Sentinel Node Trial to test the hypothesis that RT-PCR analysis of sentinel lymph nodes (SLN) would improve the detection of metastases and their prognostic value. We have previously reported interim analysis of the first cohort of 275 consecutively enrolled patients; PCR detection of SLN metastases significantly correlated with distant recurrence (dR) and improved staging by SLN pathology alone. Here we report mammaglobin PCR results for the entire molecular study group with current follow-up (mean, 7 years after surgery.)

Methods: More than 1400 breast cancer patients, excluding stage IV or those with palpable nodes, were enrolled from 1996 to 2006 at 16 IRB-approved sites, with the first 900 chronologically enrolled designated for PCR analysis. SLN (average, 2 per patient) were serially sectioned (2 mm) and examined by H&E staining ± immunohistochemistry at multiple levels. Alternate sections were flash-frozen for RNA extraction. RNA was assayed by Taqman qRT-PCR for mammaglobin and beta-actin. Patients were excluded with poor-quality RNA, if all SLN were unavailable or if lost to follow-up. Results from 788 patients are reported.

Results: The mammaglobin marker was highly specific (99% based on 130 cervical nodes from noncancer patients) with a sensitivity of 81% (based on pathology-positive SLN). Mammaglobin expression in SLN correlated with other established prognostic factors and was detected in the majority of recurrent patients (63/107). Detection of SLN metastases by PCR alone strongly correlated with dR in all patients ($P < 0.0001$ by log-rank analysis). Seventy-five percent (595/788) of study patients were negative for SLN macrometastases (>2 mm) by pathology. Of these patients, 17% (n = 99) had at least 1 SLN that was PCR+ and had a significantly lower recurrence-free survival (dRFS) compared to those node-negative patients who were also PCR-negative (81.3% vs 90.8%; $P = 0.016$). The combination of pathologic and molecular analysis provided the strongest correlation with distant metastases and improved the prognostic value of SLN staging. The presence of histology-identified nodal micrometastases (≤2 mm) was also associated with a shorter dRFS ($P = 0.02$, compared to node-negative patients). PCR detected metastases in SLN of 77/560 patients lacking any metastases >0.2 mm by pathology; 10 of the pN0 (mol+) patients have recurred (82.9% pN0 [mol+] dRFS vs 90.8% pN0 dRFS; $P = 0.12$).

Conclusions: This is the first long-term outcome study to evaluate the clinical significance of PCR-detected SLN metastases. Mammaglobin remains an exceptional PCR marker for SLN metastases. Molecular detection improves the prognostic value of SLN staging by pathology alone. This large study confirms our interim analysis of the first cohort and highlights the value of SLN biopsy for increased identification of axillary metastases. It also validates the evolution of AJCC staging guidelines to further define the extent of regional metastases and to include molecular analysis. Molecular analysis may be able to better quantitate smaller volumes of disease in SLN and establish clinically appropriate thresholds to distinguish those truly node-negative patients who do not require node dissection or adjuvant therapy from those who may benefit.

Triple-Negative Breast Cancers: Unique Clinical Presentations and Outcomes

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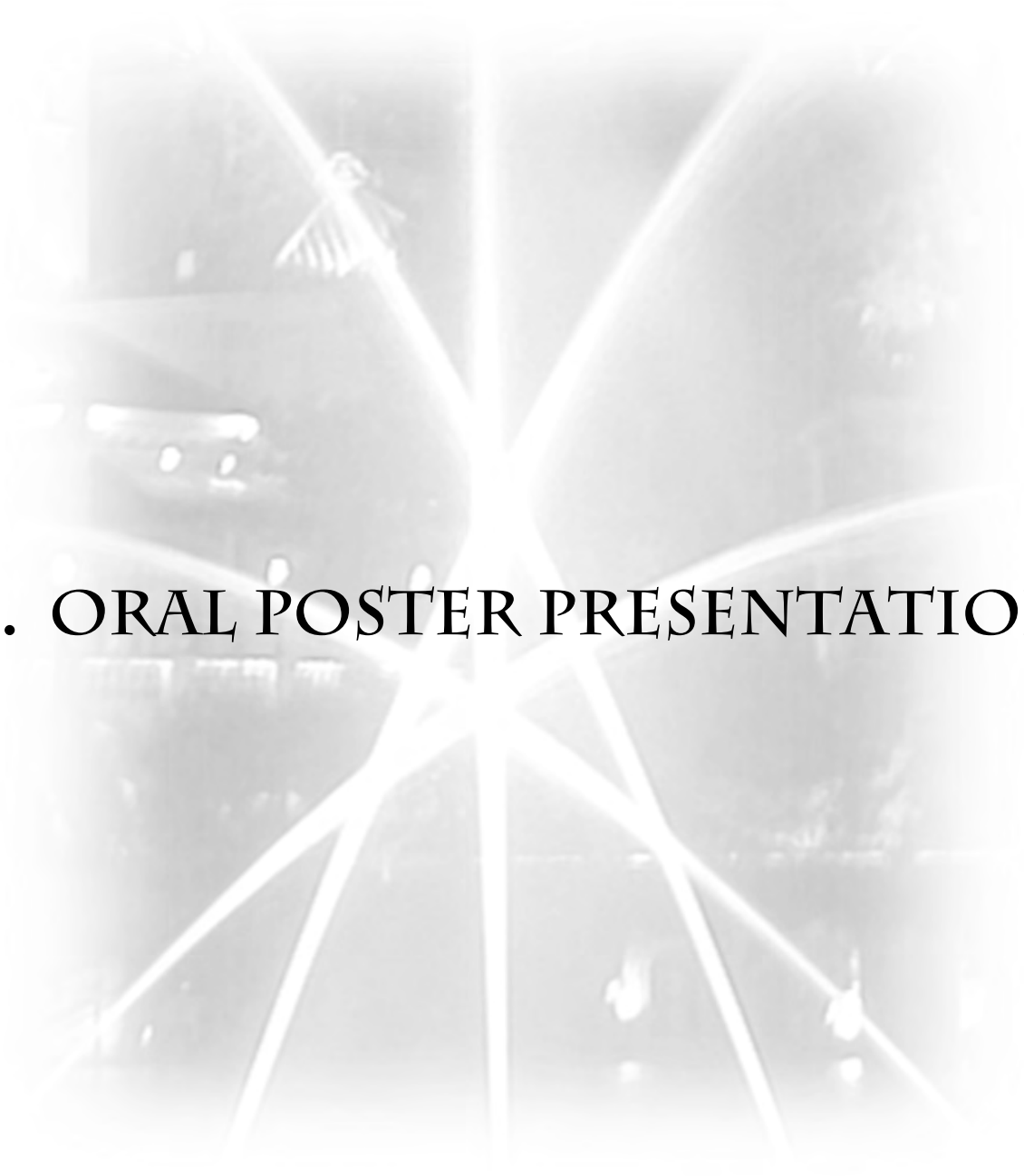
Objective: The status of tumor markers [estrogen receptor (ER), progesterone receptor (PR), and HER2 expression] provides predictive and prognostic information for patients with invasive breast cancer. We explored the clinical presentation and surgical outcomes of patients based upon these tumor markers, focusing specifically on triple-negative (ER-/PR-/HER2-) breast cancers.

Methods: A retrospective review was performed of a prospectively collected database of patients treated for invasive breast cancer with surgical resection and sentinel lymph node biopsy at a single institution from 2000-2008. Three tumor marker groups were compared: triple-negative (TN) [ER-/PR-/HER2-]; HER2+ [ERx/PRx/HER2+]; and ER+ [ER+/PRx/HER2-]. Continuous variables were compared across groups using ANOVA F tests and categorical variables were compared using chi-square tests. Overall survival was assessed using Kaplan-Meier curves.

Results: Over 8 years, 1062 patients with known tumor marker status were treated: 124 TN (12%), 210 HER2+ (20%), and 728 ER+ (68%). Patients with TN cancers were younger, averaging 59.6 years in age, compared to 62.0 in HER2+ and 64.5 in ER+ (P = 0.0001). Body mass index and a strong family history of breast cancer were statistically similar across groups. However, genetic testing was conducted more frequently in TN patients (17%) than in HER2+ and ER+ (10% for both groups, P = 0.06). Of those tested, deleterious BRCA mutations were identified most often among TN patients (24% TN, 10% HER2+, 4% ER+, P = 0.019). The mean TN tumor size was 2.1 cm, versus 2.0 cm for HER2+ and 1.8 cm for ER+ (P = 0.036). Besides being larger, TN tumors were more commonly diagnosed by self or clinical breast exam, as opposed to screening mammography (55% TN, 43% HER2+, 42% ER+, P = 0.025). Multifocal disease occurred less frequently in TN patients (14% TN, 24% HER2+, 20% ER+, P = 0.14). Angiolymphatic invasion was less common with TN cancers (18%) compared to HER2+ (24%), but both had higher rates than that seen with ER+ (15%, P = 0.006). The incidence of lymph node metastases was lowest in TN patients (21% TN, 36% HER2+, 32% ER+, P = 0.012). Mastectomy with or without reconstruction was performed more commonly for TN and HER2+ cancers (41% and 42%, respectively), compared to ER+ (31%, P = 0.016). Patients with TN tumors were most likely to receive adjuvant chemotherapy (68% TN, 43% HER2+, 26% ER+, P < 0.0001). Local and/or regional recurrence developed most frequently with TN tumors (5.7% TN, 2.9% HER2+, 1% ER+, P = 0.001). Though the difference was not statistically significant, 5-year overall survival was worst for patients with TN cancers: 85% for TN (95% CI, 74-98%), 94% for HER2+ (95% CI, 89-99%), and 91% for ER+ (95% CI, 88-95%).

Conclusions: Patients with TN breast cancers present differently from others; they are younger and more commonly possess palpable tumors. These patients are more likely to undergo genetic testing and have BRCA mutations identified. Although TN tumors are larger, they are less frequently associated with lymph node metastases and multifocality. Patients with TN cancers have higher rates of local-regional recurrence and lower overall survival. Knowledge of these unique factors is important for clinicians and investigators as we devise individualized treatments and seek new therapeutic options.



II. ORAL POSTER PRESENTATIONS

Surgeon-Read Screening Mammography: An Analysis of 10,020 Examinations

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Objective: To establish whether dedicated breast surgeons can deliver a reading performance of screening mammography similar to specialized breast radiologists. We present a first analysis of surgeon-read screening mammography at a dedicated breast health center.

Methods: All mammography performed at a dedicated, surgeon-run breast health center between January 2003 and June 2009 was entered into a prospective database. Data recorded were age of the patient, indication for mammography, hormonal replacement therapy and its duration, prior breast surgery, the outcome of the mammography, abnormality characteristics and location, and final histopathology. Cases of confirmed cancer were entered into a separate database with detailed histopathology and therapy recording. Conventional guidelines for screening mammography indications were adhered to: women had to be 40 years of age or older, asymptomatic, and without a personal history of breast cancer. Mammography was performed exclusively by certified mammography technicians on state-of-the-art film screen and from July 2006 on full-field digital equipment. Mammograms were double-read by 2 experienced breast surgeons. Outcomes were classified in a simplified system based on BI-RADS: BI-RADS 3 and 4 lesions were summarized as indeterminate; these lesions underwent further imaging (special views or ultrasound) or proceeded directly to tissue acquisition or underwent short-term (6 month) follow-up imaging. BI-RADS 5 lesions proceeded directly to tissue acquisition by ultrasound-guided fine-needle aspiration, ultrasound-guided core biopsy, or stereotactic core or stereotactic hookwire biopsy.

Results: Of 13,622 mammograms, 10,020 were performed for screening. In 40- to 49-year-old women, 4177 screening mammograms were performed; of these, 7.8% were performed in women on hormonal replacement therapy; in 24%, prior breast surgery had been performed. The recall rate was 4.3%; a biopsy rate of 1.7% and a cancer diagnosis rate of 4.1 per 1000 examinations. The malignancy rate of biopsy was 23%. In women 50 years and older, 5843 mammograms were performed; of these, 50.0% in women on HRT, in 31% prior breast surgery had been performed. The recall rate was 5.0%, the biopsy rate 2.3%, the cancer diagnosis rate 11.5 per 1000 examinations, and the malignancy rate of biopsy 49%. Of the cancers detected, 36% were in situ, and of invasive cancers 85% were node-negative. The average size of invasive cancer was 11.9 mm.

Conclusions: These figures established by a dedicated, surgeon-led team fall well within the range expected in organized national screening programs run by specialized breast radiologists in Europe and Australia. By having far fewer recalls, a lower biopsy rate with a higher malignancy rate of biopsy and a high cancer detection rate, these figures exceed those expected of highly skilled radiologists in the United States and provide a first benchmark for surgeon-read screening mammography.

Use of Preoperative MRI for Invasive Lobular Cancer—Good, Better, but Maybe Not the Best?

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Objective: Invasive lobular carcinoma (ILC) of the breast is difficult to diagnose both clinically and radiographically. Magnetic resonance imaging (MRI) is being increasingly used in the evaluation of newly diagnosed breast cancers and it is hoped that MRI can improve ILC detection and estimation of extent of disease. The goal of this study was to assess the sensitivity of MRI in detecting ILC and to correlate tumor size on MRI with size on final pathology.

Methods: We performed a retrospective review of a prospective breast cancer database from which we identified all patients diagnosed with ILC at our institution between 1998 and 2008. The study group included patients who underwent mammography, ultrasound, and MRI as part of their preoperative work-up. Tumor size on pathology was compared with size on clinical breast examination (CBE), mammography, ultrasound, and MRI. Concordance was defined as size on imaging or CBE within ±0.5 cm of size on final pathology. The degree of overestimation and underestimation was also measured. Correlation between pathologic size and size on imaging or CBE was measured using Pearson correlation analysis for each modality.

Results: A total of 199 patients presented with ILC over the time period. Seventy patients (35%) with 72 cancers had all radiographic modalities utilized for their cancer evaluation preoperatively. Mean age was 63 years with a mean tumor size of 2.46 cm (SEM, 0.25) on final pathology. Twenty-two percent of patients received preoperative MRI in 2001, compared with 47% in 2008. The mean tumor size (cm) on CBE, mammography, ultrasound, and MRI was 3.63 (SEM, 0.37), 3.02 (SEM, 0.45), 2.14 (SEM, 0.26), and 2.68 (SEM, 0.26), respectively. The sensitivity for detection of ILC on CBE, mammography, ultrasound, and MRI was 53%, 66%, 90%, and 98%, respectively. MRI-based tumor size was concordant with pathologic size in 33 tumors (55%). MRI overestimated size by more than 0.5 cm in 18 tumors (30%) and underestimated size in 8 tumors (13%). In contrast, overestimation was found in 9% of tumors by mammography versus 10% by ultrasound versus 9% by CBE; underestimation was found in 16% of tumors by mammography versus 31% by ultrasound versus 11% by CBE. Correlation of measured tumor size with size on final pathology was better for MRI (R = 0.75) than for mammography (R = 0.65), CBE (R = 0.63), and ultrasound (R = 0.45, all P < 0.01). A total of 80 patients underwent MRI as part of their preoperative workup. MRI detected a contralateral cancer in 5 patients (6%), of which 4 were ILC.

Conclusions: The preoperative use of MRI doubled during our study period. For ILC, MRI has better concordance rate, sensitivity of detection, and correlation with tumor size on pathology than CBE, mammography, or ultrasound. MRI also detects contralateral disease previously unobserved. Nevertheless, a significant proportion of cases are overestimated on MRI, and correlation remains only at 0.75. The use of MRI for ILC is supported by our data but the need for further improvement and refinement of imaging remains.

Sentinel Lymph Node Biopsy After Primary Systemic Therapy

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Objective: Sentinel lymph node biopsy (SLNB) without axillary lymph node dissection (ALND) in SLN-negative patients is a standard of care for most breast cancer patients. SLNB for axillary staging after primary systemic therapy (PST) is still contraindicated due to possibly reduced accuracy, while data are lacking. Purpose of this study was to evaluate the accuracy of SLNB after PST.

Methods: One hundred eighty-five breast cancer patients were treated with PST—160 patients received preoperative chemotherapy and 25 patients received preoperative endocrine therapy. One hundred forty-three of 160 patients with preoperative chemotherapy and 22 of 25 patients with preoperative endocrine therapy were eligible for evaluation. The combination of blue dye and radioactive tracer was used for identification of SLNs. All patients received SLNB and axillary lymph node dissection.

Results: Pathologic complete response rates and breast-conserving therapy rates were 15% and 71.9% in the preoperative chemotherapy group and 0% and 72% in the preoperative endocrine therapy group, respectively. Identification rate, sensitivity, overall accuracy, and false-negative rate were 81.1% (116/143), 91.7% (55/60), 95.7% (111/116), and 8.3% (5/60) in the preoperative chemotherapy group and 77.3% (17/22), 90.0% (9/10), 94.1% (16/17), and 10.0% (1/10) in the preoperative endocrine therapy group, respectively.

Conclusions: SLNB after primary systemic therapy is accurate and the results are comparable to those of primary SLNB. SLNB after PST could spare ALND in up to 40% of patients with primary positive axillary lymph nodes.

Is Breast Conservation Safe for Metaplastic Breast Cancer?

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Objective: Metaplastic carcinoma is an epithelial malignancy of the breast with sarcomatous differentiation that accounts for less than 1% of all mammary tumors. Prior studies have suggested that metaplastic carcinoma is associated with an increased frequency of local recurrence. Consequently, total mastectomy is often recommended as the primary surgical treatment. We compared the outcome of metaplastic carcinoma treated by breast-conserving surgery (BCS) versus total mastectomy (TM).

Methods: All patients undergoing definitive surgical procedures for primary metaplastic carcinoma of the breast at our institution between 1990 and 2009 were identified using tumor registry, surgical, and pathology databases (N = 82). Thirty-two patients had undergone BCS. TM patients were selected to match BCS patients for age, pathological tumor size, and lymph node status. Matching was managed to ensure the best possible balance between groups for the matching covariates. The final analysis included 32 BCS patients and 26 matched TM patients. Local recurrence–free, distant recurrence–free, and overall survival were calculated using the method of Kaplan-Meier and compared using the Mantel-Cox log-rank test.

Results: BCS and TM groups were well matched for age (52.5 vs 52.7, P = 0.95), pathologic tumor size (2.6 cm vs 2.3 cm, P = 0.33), adjuvant chemotherapy (76% vs 67%, P = 0.56), and nodal disease (30% vs 34%, P = 1). Twenty-seven percent of TM patients received chest wall radiation. With a median follow-up of 81 months (range, 6-234), there was a trend for improved overall survival with TM (HR 0.56; 95% CI, 0.22-1.5; P = 0.26), no difference in distant disease–free survival with TM (HR 0.67; 95% CI, 0.19-2.3; P = 0.67) and improved local recurrence–free survival with TM (HR 0.22; 95% CI, 0.06-0.91; P = 0.037). The 5-year local recurrence–free survival was 96% for TM as compared to 74% for BCS.

Conclusions: Total mastectomy is associated with a reduced local recurrence rate in metaplastic breast cancer but no clear improvement in distant disease–free or overall survival.

Role of Completion Axillary Lymph Node Dissection for Sentinel Node-Positive Breast Cancer Patients

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Objective: The role of completion axillary lymph node dissection (ALND) after identification of nodal metastases by sentinel lymph node biopsy (SLNB) remains debated. The purpose of this study was to examine differences in recurrence and survival rates for patients undergoing SLNB alone versus SLNB with completion ALND.

Methods: Patients with breast cancer who underwent SLNB and who had nodal metastases were identified from the Surveillance, Epidemiology and End Results (SEER) database (1998 to 2004). Patients with follow-up time less than 24 months were excluded. Clincopathologic and outcomes data were examined for patients who underwent SLNB alone versus SLNB with completion ALND.

Results: Twenty-seven thousand six hundred ninety-four patients with positive nodes were identified; 4,639 (16.8%) underwent SLNB alone, and 23,055 (83.3%) underwent SLNB with completion ALND. Patients were significantly more likely to undergo SLNB alone if they were older (median age, 59 years old), had positive estrogen receptor status or low grade tumor, or were treated with breast-conserving surgery. From 1998 to 2004, the proportion of patients who underwent SLNB alone for microscopic metastases increased 21% (1998) to 37.8% (2004) ($P < .001$). In patients with microscopic nodal metastases (n = 6956), there were no significant differences in regional recurrence or overall survival for patients who underwent SLNB alone versus completion ALND. In patients with macroscopic nodal metastases (n = 20,738), there was a significant lower risk of developing regional recurrence for completion ALND (hazard ratio, 0.23; $P = 0.037$); there were no significant differences in overall survival for patients who underwent SLNB alone versus completion ALND.

Conclusions: There is an increasing trend toward performing an SLNB alone when there was microscopic nodal disease. Compared with SLNB alone, completion ALND results in lower risk of developing regional recurrence for breast cancer patients with macroscopic nodal disease; however, at a median follow-up of 50 months it does not appear to improve survival outcomes for breast cancer patients with macroscopic or microscopic nodal disease.

III. POSTER PRESENTATIONS

Infectious Complications After MammoSite Partial Breast Irradiation

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Objectives: Partial breast irradiation (PBI) with MammoSite brachytherapy has emerged as an abbreviated postlumpectomy radiotherapy option for selected patients with breast cancer. The objective of this study was to determine the frequency of infectious complications in patients undergoing PBI utilizing MammoSite brachytherapy catheters placed postoperatively using the closed technique.

Methods: At the beginning of our MammoSite experience, 1 patient had a catheter placed intraoperatively. The cavity evaluation device (CED) was used in 2 additional patients. These 3 patients were excluded from this study. Since 2005 at our institution, 52 MammoSite catheters were placed in 51 patients postoperatively under ultrasound guidance, using the closed technique. One patient had metachronous bilateral breast cancers 2 years apart, both treated with MammoSite PBI. MammoSite catheters were placed under local anesthesia. We used a full sterile prep and drape, sterile gowns and gloves, and surgical masks. At the end of the procedure, Bacitracin ointment was liberally applied to the catheter exit site, followed by a bulky gauze dressing. All patients received prophylactic antibiotics throughout their treatment. Pretreatment CT was performed 1 to 3 days after catheter placement. All patients were treated twice daily for 5 days for a total dose of 34 Gy. Patient characteristics are shown in Table 1. All patients had negative axillary nodes.

Table 1

N = 52	
Patient age (mean)	67 (48-93)
Laterality	
Right	29 (57%)
Left	21 (41%)
Bilateral	1 (2%)
Tumor type	
Invasive cancer	18 (35%)
DCIS	34 (65%)
Catheter type	
Small spherical	46 (88%)
Elliptical	1 (2%)
Large spherical	5 (10%)

Results: MammoSite catheters were placed an average of 20 days postop (12-36). Two MammoSite balloons ruptured during treatment and were easily replaced (1 large spherical and 1 elliptical balloon). One patient had significant balloon asymmetry on CT, which also required catheter exchange. All patients who had catheters placed completed the full course of treatment. The median follow-up time was 23 months for all patients, and 26 months for patients treated before 2009 (N = 44). Two patients (3.8%) developed infectious complications. Both of these patients developed lumpectomy site abscess requiring open drainage, 3 months and 12 months posttreatment. A third patient with lower outer quadrant lumpectomy developed an abscess at the armpit sentinel node site which appeared unrelated to the MammoSite procedure. There were no ipsilateral breast tumor recurrences.

Conclusions: MammoSite PBI can be performed with a low complication rate. All patients who had catheters placed completed the full course of treatment. Infectious complications are rare with the postoperative closed technique. We believe that rigid attention to sterility during the procedure is very important. Early results are promising with regard to acceptably low cancer recurrence rates, but long-term results are unknown. Eligible patients should be encouraged to participate in the NSABP B-39/RTOG 0413 study, which randomizes patients to either PBI or conventional whole-breast radiotherapy. However, many low-risk patients are no longer eligible to participate in that trial. These low-risk patients should still be offered PBI after a careful informed consent discussion.

Correlation of Preoperative Breast MRI and Final Pathology in Prophylactic Mastectomy Specimens

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Objective: In the era of increasing prophylactic mastectomy rates, the importance of pre-operative breast MRI is somewhat controversial. Some question the role of MRI in decision-making regarding the need for sentinel lymph node biopsy in patients undergoing prophylactic mastectomies. We examined the MRI findings of a population of patients undergoing prophylactic mastectomies with and without sentinel lymph node biopsy, and compared the results to the final pathology of these specimens.

Methods: One hundred twenty-two patients who underwent 146 prophylactic mastectomies were retrospectively reviewed from a prospectively enrolled IRB-approved registry of patients at Georgetown University Hospital who underwent mastectomy for breast cancer risk reduction from January 2008 to September 2009. Patient demographics, breast cancer history, and genetic testing were recorded. MRI findings for all patients who underwent a bilateral breast MRI prior to prophylactic mastectomy were compared to the final histology in the prophylactic mastectomy and nodal specimens.

Results: The mean age of patients undergoing prophylactic mastectomy was 46 years (range, 28-78 years). Of these patients, 82.7% were Caucasian and 58.1% had a family history of breast cancer. Ninety-two patients (75%) had a current diagnosis of breast cancer and 12 patients (9.8%) had a breast cancer recurrence. Forty-five patients (36.9%) underwent pre-operative genetic testing, of which 21 patients (17.2%) proved to be carriers of a *BRCA*-1/2 mutation. Bilateral breast MRI was obtained preoperatively in a total of 108 patients (88.5%) who had 132 prophylactic mastectomies (90.4%). MRI detected additional suspicious lesions that were previously undetected by conventional breast imaging in 18 breasts (13.6%). Final pathology was significant for 8 (6.1%) malignancies (6 noninvasive and 2 invasive cancers), 2 atypical lesions, 2 benign proliferative pathologies, and 6 nonproliferative findings. Seventeen (10.6%) patients who had a normal MRI were found to have abnormalities on final pathology. Of these, 14 were atypia and 3 (2.3%) were DCIS. No invasive cancers were missed. Sentinel lymph node biopsy on the prophylactic side was performed in 36 breasts (27.3%), of which all were negative. Sentinel lymph node biopsy was performed in 6 breasts that had abnormal MRI findings, and all were negative. Final pathology correlated to MRI findings in 119 breasts (90.2%). The sensitivity of MRI was 72.7% and the specificity was 91.7%.

Conclusions: In patients undergoing prophylactic mastectomy, bilateral breast MRI may be a valuable preoperative tool as an indicator of final pathology. A negative breast MRI may eliminate the use of sentinel lymph node biopsy and its associated morbidity in the prophylactic mastectomy setting.

Impact of Preoperative Breast MRI on Timing of Surgery and Type of Intervention in Newly Diagnosed Breast Cancer Patients

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Objective: As the possibility of omitting otherwise occult lesions which would eventually amount to local recurrence, current guidelines are including breast magnetic resonance imaging (BMRI) as a useful staging tool in the preoperative diagnosis for breast cancer. Nevertheless, the impact of BMRI on waiting periods and surgical treatment is still unclear. The purpose of this paper is to determine if preoperative BMRI delays surgical treatment for newly diagnosed breast cancer and how new lesions found with this imaging modality alter the final surgical approach.

Methods: From April 2007 to April 2009, 188 newly diagnosed breast cancer patients underwent surgery as their initial treatment at the Marvelle Koffler Breast Centre in Toronto, Ontario, Canada. In this retrospective study, patients were divided into 2 study arms. In the time gap arm, those who had BMRI taken after the initial pathological diagnosis and before surgery (n = 71) were compared to a non-MRI group (n = 76). In order to evaluate if change occurred, patients who chose more aggressive treatment and whose BMRI were available before surgery was proposed were excluded: MRI group (n = 50) versus non-MRI group (n = 74). We examined the effect on time delay from date of proposed treatment and conversion from conservative to more radical surgery and/or unilateral to bilateral procedures.

Results: Mean age of this study was 59.7 years (BMRI group: 54.6 years vs non-BMRI group: 64.4 years, $P < 0.001$). Overall waiting period between histologic diagnosis and treatment was 34.2 days (BMRI 36.0 days vs non-BMRI 32.3 days, $P = 0.15$); delay between date surgical management was proposed and date of surgery for BMRI group was 24.2 days versus non-BMRI group was 22.5 days, $P = 0.38$. Additional work-up resulted in 7 otherwise occult breast lesions that required change. Fourteen percent of patients who underwent BMRI had change in surgical management, distributed as follows: 5 unilateral lumpectomies changed to unilateral mastectomy, 1 case of unilateral mastectomy was converted to bilateral mastectomy, and 1 case of unilateral lumpectomy was changed to bilateral lumpectomy. The mastectomy rate was greater in those with BMRI (MRI group: 26% vs non-BMRI: 10.8%, $P = 0.02$)

Conclusions: Preoperative BMRI did not delay surgical treatment, though it did correlate with a higher rate of radical treatment.

Allo-Bra: A New 1-Stage Breast Reconstruction Option Following Skin/Nipple-Sparing Mastectomy

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Objective: There are multiple reconstructive options following mastectomy. The novel Allo-Bra procedure involves use of an allograft (acellular dermal matrix) to form an implant pouch superficial to the pectoralis major muscle for a single-stage reconstruction. This is a new technique with limited data; therefore a review of all patients undergoing Allo-Bra reconstruction was performed.

Methods: A retrospective analysis of prospectively collected data on 14 patients undergoing immediate, 1-stage, implant-based Allo-Bra breast reconstruction. The technique uses a piece of hydrated acellular dermis draped over a steel cage, dermal side up, to fixate the shape. The Allo-Bra is secured by anchoring the acellular dermis to the anterior chest muscle fascia. A silicone implant is placed within the pouch to complete the reconstruction. Data review included demographics, pathology, and surgical outcomes.

Results: Fourteen patients (27 breasts) underwent skin-sparing (n = 5, 36%) or nipple-sparing mastectomy (n = 9, 64%), followed by immediate single-stage implant reconstruction using the Allo-bra. Surgery was performed for prophylaxis in 2 patients, 6 had ductal carcinoma in situ, and 6 had invasive breast cancer. Mean age was 47 years. Mean BMI was 24. No patients used tobacco at the time of their operation, however 2 patients had a significant past smoking history. Mean tumor size was 1.2 cm for DCIS and 2.1 cm for invasive breast cancer (5 infiltrating ductal and 1 mixed ductal/lobular carcinoma). Ten patients underwent sentinel lymph node biopsy; 2 (20%) had metastases and went on to have complete axillary dissection. Mean total operative time for bilateral mastectomies with reconstruction was 4.5 hours. Unilateral mastectomy with reconstruction operative time was 2.75 hours. Jackson-Pratt drains remained in place for a mean of 8 days. Hospital stay was 1 night for 11 patients (80%) and 2 nights for 3 patients (20%). There was no nipple loss among the patients who underwent Allo-Bra reconstruction. Postoperative complications included 1 patient with a hematoma requiring surgical evacuation and 1 patient who developed bilateral implant infection requiring explantation after antibiotic failure. Median follow-up was 4 months. Cosmesis, as assessed by the plastic surgeon, was good to excellent in 11 patients, including 2 who had undergone whole-breast radiation with follow-up at 5 and 12 months postoperatively. One patient had bilateral inframammary fold flattening at 2 months. One had grade 2-3 bilateral capsular contracture. Two patients developed seromas—1 in the patient with bilateral implant infection and 1 requiring simple aspiration. Ten patients (70%) no longer required narcotic pain medication by the time of first follow-up (within 7 days).

Conclusions: The Allo-Bra breast reconstruction is an option that can be performed in 1 stage at the time of mastectomy without disrupting the pectoralis muscle. In our early experience, the Allo-Bra provides good cosmesis with low rates of capsular contracture, minimal discomfort, and short postoperative hospital stay. It also appears that this type of reconstruction may remain durable following whole-breast radiation, however longer follow-up is needed.

Reverse Axillary Mapping During Sentinel Node Biopsy for Breast Cancer: Experience in Private Practice

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Objective: The onset of sentinel node biopsy for breast cancer has reduced the risk of lymphedema in breast cancer patients, but there nevertheless remains a small risk of lymphedema. Reverse axillary mapping to identify and avoid injury to upper extremity lymphatics has the potential to reduce even more the risk of lymphedema. This study evaluates the feasibility of reverse axillary mapping in a community breast cancer surgery practice**.**

Methods: This study included 47 women with new breast cancer diagnosis. At the time of surgery, confirmation of a radioactive sentinel node in the axilla was made. Two cc of lymphazurin was then injected into the ipsilateral upper inner arm intradermally and subcutaneously, and the injection site was massaged. Blue lymphatics and lymph nodes were preserved when observed in the area of the SLN.

Results: Of the 47 patients, 38 patients had breast conservation, and 9 had mastectomies. Two patients had axillary node dissections following a positive sentinel lymph node. Only 1 patient (2%) had a blue lymph node which was also radioactive and therefore also a sentinel lymph node, and was removed for testing. In the remainder of the cases, blue dye was observed in the tissue adjacent to the sentinel lymph node(s), but was easily avoided and blue lymph nodes and lymphatics were not injured. At 8 months follow-up, no lymphedema has been observed.

Conclusions: Arm lymphatics and lymph nodes are almost always separate from breast sentinel lymph nodes. Reverse axillary mapping is feasible to perform in community breast surgery practice, and has the potential to reduce even more the risk of lymphedema after sentinel node biopsy.

Targeted Intraoperative Radiotherapy Trial for Breast Cancer: Review After First 10 Years of Clinical Application

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Objective: Most early local recurrences occur in the primary tumor bed, despite the fact that multicentric foci are found in over 60% of cases outside the index quadrant. Thus partial breast irradiation after breast-conserving surgery may be an alternative to whole-breast external beam radiotherapy (EBRT) for selected patients and is now recommended by many consensus guidelines. The work represents the first long-term randomized safety and efficacy data of intra-operative radiotherapy (IORT) as an alternative to EBRT after breast-conserving surgery for early breast cancer.

Methods: In July 1998, we pioneered the use of targeted intraoperative radiotherapy (TARGIT) with "INTRABEAM" that delivers therapeutic irradiation (~20 Gy at surface and ~5 Gy at 1cm) delivered with a spherical applicator, inserted in the tumor bed at the time of surgery. We have established the safety and tolerability of the technique in phase II studies. In March 2000 we launched an international trial comparing TARGIT versus EBRT as a noninferiority study with the primary outcome as local recurrence (LR). The recruitment goal of 2232 (powered to test noninferiority, HR <1.25) is expected to be complete by April 2010, by which time the maximum follow-up will be 114 months.

Results: An updated analysis of the first 300 patients in a phase II study where IORT was used as the boost has demonstrated an actuarial 5-year local recurrence–free survival of 1.5% in a group of unselected patients. Furthermore, over the past 7 years, 77 patients deemed unfit for EBRT have been treated in this way, with median age of 66 years and a median follow-up of 37 months. To date there have been 2 local recurrences, which gives an estimated annual local recurrence rate of 0.78%. Our combined experience so far suggests that the technique is safe, well tolerated, and virtually free of short-term toxicity.

Conclusions: If TARGIT is eventually shown to be noninferior to EBRT, then we could offer most women with small operable tumors complete local therapy in 1 session avoiding 3-6 weeks of postoperative therapy. This may be preferable to many women, including those seeking breast-conserving surgery in the developing world and for women living in remote areas of the Western world.

Breast Conservation in Women With Multifocal-Multicentric Breast Cancer: Is It Feasible?

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Objective: The incidence of preoperatively identified multifocal and multicentric breast cancer is rising with improved sensitivity and increasing utilization of imaging modalities, including breast MRI. Based on retrospective, historic data, breast conservation in women with multiple tumors has been discouraged due to high rates of local regional recurrence. These studies, however, do not extrapolate to current day practice as they do not incorporate the use of modern endocrine therapies and currently accepted margin analysis. This study is designed to evaluate the oncologic safety of breast conservation in women with multiple breast primaries.

Methods: After receiving Institutional Review Board approval, we retrospectively reviewed the charts of 21 women who underwent breast conservation surgery for 2 or more synchronous, ipsilateral cancers separated by 2 or more centimeters in our institution between 1998 and 2008. We extracted data including tumor size, receptor status, adjuvant therapies administered, and local-regional and systemic recurrence.

Results: Twenty-one women underwent breast conservation surgery in the time period evaluated. Median follow up was 2.9 years. Total time at risk for the cohort was 64.1 person years. One patient (4.8%) experienced a local recurrence. Both tumors in this patient were invasive ductal carcinoma, ER/PR negative and HER2 positive. Time to LRR was 2.5 years. One patient (4.8%) developed metastatic disease and succumbed to breast cancer during the study period. Both invasive lesions in this patient were ER/PR and HER2 negative. Median time to distant recurrence was 2.9 years.

Conclusions: While small in numbers, our data support the use of breast conservation in women with multifocal/multicentric breast cancer with local regional recurrence and overall survival rates equivalent to those seen in women with a single focus of cancer. Additional prospective trials are warranted to better assess the oncologic safety of breast conservation in this population and to identify possible subsets of women at higher risk for local recurrence.

Comparative Study Between Histological and Molecular Methods for Sentinel Node in Breast Cancer

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Objectives: 1.To compare the diagnostic accuracy of a molecular method (OSNA) against an exhaustive histological method for the detection of sentinel node (SN) metastases in breast cancer. 2. To evaluate the diagnostic percentages of macrometastases, micrometastases, and ITC with both methods.

Methods: On 1 branch, 473 SN were entirely processed making serial 2-mm-thick sections. Then pairs of 4-µm microtome sections every 150 µm were stained with H&E and AE1/AE3 cytokeratin, respectively. On the other, 168 cases were studied following the molecular OSNA procedure based in the detection of mRNA of the Cytokeratin19 by RT-Lamp amplification in homogenized material of tissue of entire lymph node.

Results: Three hundred sixty-two benignant cases (75.7%) were found in the histological group and 154 (81.4%) in the OSNA group, without significant statistical differences between them (chi-square = 0.968; *P* = 0.3253). Within the metastatic histological group, 75 cases (64.6%) were macrometastases, 28 cases (24.1%) micrometastases, and 13 cases (11.2%) isolated tumor cells (ITC). In the OSNA metastatic group, 10 cases (28.5%) were macrometastases, 16 cases (45.7%) were micrometastases, and 9 cases (25.7%) were ITC. The statistical differences between each group were significant (chi-square = 26.38; *P* = 0.0001).

Conclusions:

1. The results of both methods in the discrimination between benign and malignant cases show no statistical significant differences, therefore, OSNA method is as good as histological one to discriminate between benign and malignant cases.

2. Within the metastatic group, OSNA method shows a favorable statistical significant difference, compared to the histological method in detecting small-volume metastases (micrometastases and ITC).

3. Besides, the OSNA method shows a statistical tendency to better define between micrometastases and ITC when compared to the histological method.

4. A major problem with the histological method can be the discrimination between micrometastases and macrometastases.

Institutional Trends in the Performance of Nipple-Sparing Mastectomies

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Objectives: Recently, the concept of nipple-sparing mastectomy (NSM) has been gathering increased recognition as an alternative to more traditional approaches. Its acceptance was limited at first, due to questions concerning its oncologic safety. However, mounting evidence supporting the practice of NSM for both prophylactic and oncologic purposes is leading to its more widespread use and broadened indications. We aim to analyze our institutional experience and trends with respect to the use of NSM.

Methods: A retrospective review of our institutional database (from January 2000 to September 2009) was performed to identify patients who underwent NSM. This group was evaluated for outcome, including short-term complications and long-term recurrence. These patients were further subdivided into 2-year intervals to analyze the institutional trends in the performance of NSM.

Results: Between 2000 and 2009, we identified 83 patients who underwent 144 nipple-sparing mastectomies. The indications for surgery were: 97 (67%) prophylactic risk-reduction, 20 (14%) ductal carcinoma in situ (DCIS), 25 (17%) invasive cancer, and 2 (1%) phyllodes tumor. Three patients (2%) were found to have cancer at the nipple margin, warranting further excision. Fifty-eight (40%) had some degree of skin desquamation or necrosis, but only 7 (5%) required operative debridement. Four (2.8%) were treated for infection. Of the 97 prophylactic NSMs, 5 specimens (5%) were found to harbor occult cancer (4 DCIS and 1 invasive lobular cancer). None of the 83 patients have had a breast cancer recurrence attributable to the 144 NSMs. When grouped by 2-year intervals (2001-02, 2003-04, 2005-06, 2007-08), the institutional trend has been toward a steady increase in the number of NSMs (n = 5, 22, 34, 45), as well as an increase in the proportion of cases performed for cancer (0%, 23%, 32%, 47%). In the latter 3 subgroups, in which there were cases performed for invasive carcinoma, there was a slight increase in the average size of the tumor (1.1 cm, 1.5 cm, 1.7 cm). Already, the first 9 months of 2009 show a continuance of these trends, with 36 NSMs performed on 20 patients, 10 (50%) with current cancer diagnoses.

Conclusions: The trends at our institution illustrate the growing acceptance of NSM. The procedure is being used with increased frequency, both prophylactically and in patients with invasive and in situ breast cancers. Due to its minimal rates of complication or long-term risk, both patients and surgeons are increasingly selecting NSM as an alternative to skin-sparing mastectomy or breast-conserving surgery. While NSM is not standard, our experience supports the selective use of NSM in both prophylactic and malignant settings.

Reduction in Second Surgeries for Axillary Lymph Node Dissection in Breast Cancer Patients Using an Intraoperative RT-PCR Assay

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Objectives: Intraoperative detection of metastases in sentinel lymph nodes (SLNs) of breast cancer patients is typically performed using frozen section (FS) or touch preparation (TP). This allows immediate full axillary lymph node dissection (ALND), rather than a second surgery ALND, which is based on postoperative permanent section H&E (PS) evaluation only. However, both FS and TP have limited sensitivity, resulting in continuing second surgeries. An FDA- approved molecular assay (GeneSearch™ BLN Assay, Veridex, LLC) can intraoperatively detect SLN metastases ≥0.2 mm with a higher sensitivity than traditional intraoperative techniques, which may reduce second surgeries. This is a comparison of the second-surgery ALND rates at our institution before and after the use of the BLN assay.

Methods: ALND data at our institution was retrospectively gathered from January 2005 to January 2009. All patients with invasive breast cancer undergoing SLN biopsy received FS and PS. After July 31, 2007, the BLN assay was added. TP was not performed. Prior to use of BLN, SLNs were bisected and FS done on each half. Once BLN was added, SLNs were cut along the short axis into ~2mm sections. Alternating sections were homogenized for RT-PCR; all remaining sections were tested by FS and PS. If any intraoperative test is positive, ALND is done immediately. SLNs are only histology-positive if metastases are ≥ 0.2 mm.

Results: January 2005 to July 31, 2007 there were 649 partial mastectomy (PM) and complete mastectomy (CM) patients with SLN biopsy; 156 (24%) had an ALND. FS missed 52 patients later identified with PS, resulting in a 33% (52/156) rate of second surgery. August 2007 to January 2009 there were 386 PM/CM patients with SLN biopsy; 87 (24%) had an ALND. BLN assay and FS combined missed 5 patients, resulting in a 6% (5/87) rate of second surgery. This reduction rate is significant ($P < 0.0001$). The number of PM/CM patients with SLN biopsies is similar for 2005, 2006 and 2008, averaging 278. The 2007 volume is lower as a result of a leave of absence by the head surgeon. Average ALND rates are similar (24% prior to BLN assay and 23% after). Overall performance as compared to PS on 386 patients since July 2007 shows an increase in sensitivity and comparable specificity of the BLN Assay (sensitivity: 92%, specificity: 92%), compared to FS (sensitivity: 68%, specificity: 99%).

Conclusions There was a substantially decreased need for second-surgery ALNDs after July 31, 2007, while the overall proportion of patients needing ALND did not increase (24% vs 23%). This indicated that BLN assay was not too sensitive, so it did not cause additional ALNDs to be done, but rather caused ALNDs to done at the right time. Some of this reduction may be caused by improved histologic sampling for FS. However, the 24% sensitivity increase of BLN versus FS compared to PS accounts for most of the reduction in second surgeries. This reduction of second surgeries at our institution has reduced stress on patients and medical staff and has reduced hospital costs.

Bursitis As a Significant Cause of Breast Pain: Underrecognized and Undertreated

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Objectives: Pain is one of the most commonly reported breast complaints. Referred pain from inflammation of the shoulder bursa is often overlooked as a cause of breast pain. The objective of this study is to evaluate the role of shoulder bursitis as a cause of breast/chest pain.

Methods: An IRB-approved retrospective review from July 2005 to September 2009 identified 461 patients presenting with breast/chest pain. Cases identified with a trigger point in the medial aspect of the ipsilateral scapula were treated with a bursitis injection at the point of maximum tenderness. The bursitis injection contains a mixture of local anesthetic and corticosteroid. Presenting complaint, clinical response, and associated factors were recorded and treated with descriptive statistics.

Results: Average age of the study group was 53.4 ± 12.7 years, and average BMI was 30.4 ± 7.4. One hundred three patients were diagnosed with shoulder bursitis as the cause of breast pain and received the bursitis injection. Most cases (81/103 or 78.6%) presented with the breast/chest as the site of most significant discomfort, where 8.7% (9/103) had the most severe pain at the shoulder, 3.9% (4/103) at the axilla, and 3.9% (4/103) at the medial scapular border. Of the treated patients, 83.5% (86/103) had complete relief of the pain, 12.6% (13/103) had improvement of symptoms with some degree of residual pain, and only 3.9%(4/103) did not respond at all to the treatment. The most commonly associated factor to the diagnosis of bursitis was the history of a previous mastectomy, present in 27.2% (28/103) of the cases.

Conclusions: Shoulder bursitis represents a significant cause of breast/chest pain (22.3% or 103/461) and can be successfully treated with a local injection at site of maximum tenderness in the medial scapular border.

Pseudoangiomatous Stromal Hyperplasia of the Breast: A Series of 8 Patients

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Objectives: Pseudoangiomatous stromal hyperplasia (PASH) is a benign mesenchymal proliferative lesion of the breast that must be differentiated from low-grade angiosarcoma. In 2005 there had been only 109 cases reported since its initial description in 1986. Its clinicopathological spectrum ranges from focal, incidental microscopic findings to clinically and mammographically evident breast masses. Through this study we hope to add to the small number of cases reported in the literature and better define the pathological, clinical, and therapeutic approaches to PASH.

Methods: We retrospectively reviewed the data from 1999 to 2009 of women who were diagnosed with PASH by either surgical excision or radiographic biopsy. This is a single institution study in which 8 cases were identified.

Results: All 8 women (100%) presented with breast masses either on imaging or clinically. Six (75%) of the 8 women were diagnosed on surgical excision of the breast mass, 2 (25%) diagnosed with core needle biopsy though 1 was diagnosed after both techniques. The tumors ranged in size from 0.3 cm to 7.0 cm. All women were premenopausal or perimenopausal at diagnosis. The patients' ages ranged from 30 to 54 years old. Pathology from each case reviewed was significant for findings of PASH as well as another benign entity, most commonly stromal fibrosis and benign proliferative disease; 1 case was in association with atypical ductal hyperplasia. All patients were treated with local excision.

Conclusions: PASH is a rare but benign breast lesion presenting mostly in premenopausal women. These 8 cases is one of the larger series to be reported and the presentation of masses in them all is quite rare. This study suggests that this is primarily a diagnosis of premenopause and perimenopause. Management is conservative surgery or careful observation.

Molecular Breast Imaging for Assessing Response to Neoadjuvant Chemotherapy

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Objectives: Accurate assessment of response to neoadjuvant chemotherapy (NAC) is important for determining surgical management. Molecular breast imaging (MBI) provides functional imaging using dedicated gamma cameras to image radiotracer uptake in the breast. The objective of this prospective clinical trial was to investigate the ability of MBI to assess response to NAC.

Methods: Women with breast cancer scheduled for NAC were eligible for the study. MBI was performed prior to initiation of NAC and again after completion of therapy, but prior to surgery. Patients received 30 mCi Tc-99m sestamibi and MBI was performed using a dedicated dual-head CZT-based gamma camera system. Post-NAC pathology findings were used as the gold standard for assessing disease extent and response to therapy and correlated with MBI findings.

Results: A total of 11 patients (12 breasts) enrolled to date have completed imaging and surgery. Average pre-NAC lesion size was 7 cm (range, 4-12 cm). In the pre-NAC MBI, 1 patient had a contralateral cancer found on MBI and MRI. MBI was concordant with pathology in 8 cases (67%). Of the 4 discordant cases, 2 showed no uptake on MBI and pathology found residual disease of 1 mm in 1 case and 6 mm in the other, 1 case MBI showed low-intensity uptake and pathology revealed a pathological complete response (pCR), and 1 case MBI showed 7-cm uptake and pathology revealed fibrosis over 7 cm but residual invasive disease was over 3 separate areas, the greatest measuring 1.2 cm. Four cases underwent both MBI and MRI. Two cases with a pCR showed no uptake on MBI, but residual enhancement on MRI in the area of fibrosis. One case as described above was negative on MBI and MRI with 1-mm residual disease on pathology. One case had concordant MBI, MRI, and pathology findings regarding extent of residual disease.

Conclusions: In this pilot study, MBI was shown to offer accurate assessment of post-NAC disease extent and response to therapy. Evaluation of complete response was more accurate with MBI than MRI.

Delays in Time to Treatment and Survival Impact for Breast Cancer Patients

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Objectives: Delays between diagnosis and treatment may decrease breast cancer survival and, often, these delays may correlate with racial and socioeconomic factors. The purpose of this study is to evaluate delays in initial treatment for patients diagnosed with breast cancer and determine their impact on overall patient survival.

Methods: A retrospective review of all patients undergoing breast cancer treatment between August 2005 and December 2008 in the comprehensive, multidisciplinary breast oncology program of a tertiary referral center was undertaken. Treatment location, either in an indigent, county hospital (CH) clinic or in a university hospital (UH) clinic, was used as a surrogate for socioeconomic status. Patients diagnosed outside the system, where records of treatment initiation were unclear, or those who were lost to follow-up were excluded from the final analysis. Interval to treatment, calculated from date of diagnosis to first resection, chemotherapy, or radiation treatment, as well as overall survival, was compared between the 2 groups. Independent samples *t* test and Kaplan-Meier analysis were used to compare the 2 groups where appropriate.

Results: Of 1845 patients treated for breast cancer during the study period, 1337 patients were included in the study population. Six hundred thirty-four patients were treated in the CH group and 703 were treated in the UH group. Interval to treatment was longer in the CH group compared to the UH group (33.2 ± 1.2 vs 53.4 ± 2.0 days; mean ± SEM, $P < 0.0001$). However, Kaplan-Meier analysis revealed no difference in overall survival between the 2 groups.

Conclusions: The interval from diagnosis to treatment of breast cancer within the same comprehensive breast cancer center was longer in the CH group when compared to matched counterparts in the UH group. Despite this difference, there was no effect on overall survival. Further study is warranted to identify the factors, both systemic and socioeconomic, that contribute to this difference in time from diagnosis to treatment.

No Value for Axillary Intervention in Patients With Ductal Carcinoma In Situ

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Objectives: During the 1980s, axillary node dissection was done routinely for ductal carcinoma in situ (DCIS). During the 1990s, axillary node dissection was performed much less frequently. By 2000, sentinel lymph node biopsy (SNB) had become popular for invasive breast cancer and was being increasingly used for DCIS. This study was designed to evaluate the value of sentinel node biopsy and/or axillary dissection for patients with pure DCIS.

Methods: From 1980 to September 2009, 690 patients with pure DCIS had 1 or more axillary nodes removed during the course of their treatment. All 690 patients had their nodes processed by hemotoxylin and eosin (H&E) staining. Two hundred ninety-eight of these patients underwent sentinel lymph node biopsy and had their nodes processed by immunohistochemistry (IHC), as well as H&E. If invasive or microinvasive cancer was found at final pathology, no matter how small the focus, the patient was not included in this series. Data was collected within a prospective database.

Results: Five (0.72%) of 690 patients had positive axillary nodes by H&E staining; 3 were macrometastases (≥2 mm) and 2 were isolated tumor cells (ITCs <0.2 mm). The 3 patients with macrometastases were upstaged and treated with chemotherapy. Eleven (3.7%) of 298 patients who had sentinel node dissections had positive nodes by IHC. All were ITCs (4-200 tumor cells). All sentinel nodes were negative by H&E and no patient was upstaged or treated with chemotherapy. None of the 16 patients with positive nodes by any method had a regional or distant recurrence and none died of breast cancer after an average of 103 months of follow-up. The table below compares node-positive by any method and node-negative patients:

	Node-Negative	Node-Positive
N	674	16
Axillary recurrences	2 (0.3%)	0
Metastatic breast cancer	7 (1%)	0
Death from breast cancer	5 (0.7%)	0

Conclusions: Nodal positivity by H&E in patients with pure DCIS is unusual (0.72%). Nodal positivity by IHC is more common (3.7%). Axillary intervention added little to patient care in this series. Among 690 patients, treatment was changed for only 3 (0.4%) who had H&E macrometastases and received chemotherapy. These data do not support upstaging patients with ITCs to stage II nor do they support sentinel lymph node biopsy or axillary node dissection for any patient with DCIS. Sentinel node biopsy can always be done at a later date for the small percentage of patients proven to have invasive breast cancer after excision, except for those undergoing mastectomy. The elimination of SNB for the 40,000 women a year with DCIS who are conservatively treated could save the U.S. health care system an estimated $80 million a year.

Axillary Sentinel Lymphadenectomy for 877 Cases of Invasive Breast Cancer: Challenge to Routine Completion Axillary Lymph Node Dissection

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Objectives: AJCC staging criteria adopted in 2002 classify axillary sentinel lymph nodes (SLN) for breast cancer as node-negative (N0), isolated tumor cells (N0(i+)), micrometastatic (N1mi), or macrometastatic (N1) positive. Guidelines recommend completion axillary node dissection (ALND) when positive SLNs are identified, although controversy exists regarding its routine use for individuals with N0(i+) or N1mi disease. We examined our experience in patients undergoing SLN dissection for invasive breast cancer to identify proportions of disease in each category and to determine subsequent axillary surgical management when a positive SLN was found.

Methods: Institutional Review Board approval was obtained for a retrospective review of the records of all patients who underwent an SLN procedure for invasive breast cancer between 1/1/2003 and 1/31/2009. SLN specimens were either performed or reviewed internally and classified per current AJCC criteria. All internal procedures were performed by 1 of 7 breast surgeons or surgical oncologists. Pathology records were queried to determine SLN pathology, identify whether subsequent ALND was performed, and determine nodal status of ALND specimens. Percentages were calculated and Fisher's exact test was used for statistical analysis.

Results: A total of 877 patients with invasive breast cancer who underwent a SLN procedure for initial axillary staging were identified. There were 640 patients with N0 (73%), 26 with N0(i+) (3%), 49 with N1mi (6%), and 162 with N1 (18%) SLNs identified. Of the 26 N0(i+) patients, 2 (8%) underwent subsequent ALND and all additional axillary nodes were negative. Among the 49 N1mi SLN patients, 28 (57%) had a completion ALND, where 4 (14%) were found to have additional positive axillary nodes. The remaining 24 N1mi patients (86%) had no additional nodal disease identified. For the 162 patients with N1 SLN disease, 152 (94%) had a subsequent completion ALND, where 66 (43%) had additional positive nodes identified. The remaining 86 N1-positive patients (57%) were node-negative at ALND. There were 24 N0(i+) (92%), 21 N1mi (43%), and 10 N1 (6%) patients who did not undergo completion ALND, with none of these individuals experiencing an axillary recurrence to date. Patients with N1 SLN disease were significantly more likely to both undergo completion ALND (P = 0.0001) and to have additional non-SLN node disease identified (P = 0.0018) than their N1mi and N0(i+) counterparts.

Conclusions: The majority of patients undergoing an axillary SLN dissection at our cancer center were node-negative. When sentinel node involvement was identified, it was more likely to be N1 than either N1mi or N0(i+) disease. Patients with N1-positive SLNs were more likely to undergo a completion ALND, suggesting stronger adherence to the ASCO guidelines for N1 than for N1mi or N0(i+) SLN status. In our experience, failure to identify additional nodal disease, as well as no axillary recurrences when completion dissection did not occur, argues against routine utilization of ALND in N0(i+) individuals. Furthermore, given the low probability of finding additional axillary disease in micrometastatic-positive patients, we believe it is reasonable to consider completion ALND for N1mi SLN disease on an individualized basis.

Metastases in Sentinel Lymph Nodes Are Most Commonly Found in the Most Radioactive Part of the Lymph Node

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Objectives: The axillary nodal status is the single most important prognostic factor in breast cancer. It has a pivotal role in planning the adjuvant treatment, and underdiagnosis may adversely affect prognosis. It has been shown that the node with the highest radioactivity count in a patient is usually the one most likely to be involved by metastases if present. The detection of small metastases in sentinel nodes at frozen section examination may be difficult. Failure to do so may result in the need for a second operation for completion axillary dissection, or the information may be lost altogether. In order to improve intraoperative detection of small metastases and to improve the efficiency of their detection by frozen section as well as subsequent paraffin section, we assessed the relationship between the levels of radioactivity counts in different parts of a sentinel node with the probability of the presence of small metastases in those parts of the node.

Methods: Sentinel lymph nodes were sliced by hand into a number of slices that varied with the size of the node (2 to 3 slices in most cases). The radioactivity of each slice was measured by a scintimeter well and recorded, and the slices with the highest radioactive counts were examined by frozen section. Clinical suspicion of metastases, size of the metastasis, the radioactivity count of the slices harboring metastases in relation to other slices of the same node, and presence of tumor in additional slices were also noted.

Results: One hundred thirty-three patients were included. The average number of radioactive nodes per patient was 3.6 (range, 1-6). Thirty (23%) of the 133 patients had positive sentinel nodes. In 8 of the 30, metastases were detected by palpation and visual examination of the node and confirmed by microscopy. In 22 patients, metastases were detected only by microscopic examination, of whom 10 patients had micrometastses and 1 had isolated tumor cells. Of these 11 patients, the radioactivity was higher than the range of the scintimeter and radioactivity between slices could not be differentiated. In 9 of the remaining 10, the most radioactive slice was involved by a micrometastasis and in 5 this was the only slice with metastasis, no tumor being found in the other slices. Frozen section detected the micrometastases in 3 (30%) and the rest were found on subsequent paraffin section, with metastases present in the hottest slice in 27 (93%) of the 29 patients, excluding the node whose hottest slice could not be differentiated.

Conclusions: If there is a metastasis in a sentinel node, it is most likely to reside in the slice with the highest radioactivity count. In our hands this technique did not significantly improve the rate of detection of micrometastasis by frozen section, but further study in larger numbers of patients is warranted.

Use of Screening Mammography in Octogenarians

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Objectives: There are limited data regarding the utility of screening mammography in octogenarians. Given current fiscal constraints, we sought to determine factors associated with routine screening in this population.

Methods: The National Health Interview Survey (NHIS) is a population-based annual survey conducted by the Centers for Disease Control that is designed to be representative of the civilian, noninstitutionalized U.S. population. The 2005 survey, which included a supplement regarding cancer screening practices, was queried to determine factors that correlated with the use of mammography in the octogenarian population. Statistical analyses were performed using SUDAAN software.

Results: Of the 1110 women over the age of 80 surveyed, 580 (52.5%) reported having had a mammogram within the preceding 2 years. The majority of these women had this done as part of a routine screening exam (92.3%) as opposed to due to a specific problem. More octogenarians who had a mammogram within the past 2 years claimed that a physician had recommended a mammogram within the past year (79.3% vs 10.1%, $P < 0.001$). Octogenarians who had a recent mammogram were more likely to have a family history of breast cancer (15.3% vs 7.9%, $P = 0.005$), were more likely to have a personal history of breast cancer (13.9% vs 6.2%, $P = 0.005$), were more likely to be currently taking hormone replacement therapy (HRT; 75.1% vs 24.9%, $P = 0.020$), were more likely to rate themselves as being in “excellent” health (11.4% vs 8.4%, $P = 0.008$), were more likely to have at least a high school education (74.6% vs 58.6%, $P < 0.001$), were less likely to have a family income of less than $20,000 per year (29.6% vs 34.0%, $P = 0.016$), and were less likely to live in the Northeast (18.6% vs 27.6%) and more likely to live in the South (39.1% vs 32.3%), $P = 0.045$. Patients who perceived themselves as being at increased risk for developing cancer were somewhat more likely to have a recent mammogram (13.8% vs 8.7%, $P = 0.053$). On multivariate analysis, use of HRT (OR, 6.56; 95% CI, 2.00–21.53; $P = 0.001$), region of residence (South vs Northeast OR, 1.75; 95% CI, 1.10-2.79; $P = 0.030$), and education level (OR = 1.85; 95% CI = 1.25-2.74, $P = 0.002$) remained significant predictors of mammography use in the octogenarian population. Family history ($P = 0.083$), personal history of breast cancer ($P = 0.199$), perceived cancer risk ($P = 0.252$), and health status ($P = 0.094$) were no longer significant in the model.

Conclusions: Many octogenarians continue to have screening mammograms on a regular basis, largely based on physician recommendation which varies based on region. While some risk factors (such as HRT use) are associated with mammography in this population, others (such as family and personal history of breast cancer) are not correlated with its use. The cost-effectiveness of such strategies remains to be defined.

10-Year Experience Evaluating Safety and Efficacy of Extended Partial Mastectomy and Immediate Reduction Mammoplasty Reconstruction in Large-Breasted Patients

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Objectives: While tumor size greater than 5 cm is an established indication for undergoing a mastectomy, this dictum may not apply to large-breasted patients. An oncoplastic approach combining a partial mastectomy, even with large tumors, with simultaneous reduction mammoplasty would provide a sound oncologic procedure along with the benefit of immediate breast reconstruction. Prior European studies have demonstrated excellent results, and here we present our consecutive 10-year experience using this approach.

Methods: All patients undergoing partial mastectomy and reduction mammoplasty performed our institution from 2000 to 2009 were included. Medical records were reviewed for demographics, breast cancer data, oncologic and reconstructive operations, postoperative recurrences, complications, and need for additional operations.

Results: Seventy-nine simultaneous partial mastectomy and reduction mammoplasty operations were performed in 74 patients. Average size of tumors based on pathology was 2.9 cm for DCIS (0.05 cm-17.0 cm), 2.4 cm for IDC (0.2 cm-8.9 cm), 3.5 cm for lobular carcinoma (1.6 cm-8.0 cm), and 5.7 cm for Phylloides tumors (3.7 cm-7.6 cm). Fourteen breasts had stage 0 disease, 14 breasts were stage I, 30 breasts were stage II, 17 breasts were stage III, 2 patients had stage IV disease, and 2 patients had Phylloides tumors. Average follow-up was 36.3 months (1-101 months). Sixty-eight patients (91.9%) were able to achieve successful breast conservation while 6 patients (8.1%) progressed to completion mastectomy, 1 of whom was for recurrence. However, 14 patients (17.5%) required a re-excision, 1 of whom for local recurrence, and 2 patients (2.5%) required multiple re-excisions to achieve clear margins. Twelve patients (16.2%) developed postoperative complications, including fat necrosis (n = 2), hematoma requiring operative evacuation (n = 1), cellulitis requiring admission for intravenous antibiotics (n = 2), seroma (n = 3), and wound healing complications (n = 4), 1 of which necessitated operative debridement and closure.

Conclusions: A partial mastectomy-reduction mammoplasty/mastopexy technique is a viable option for breast conservation, even for larger tumors, combining a safe oncologic procedure with excellent cosmesis. While longer follow-up is necessary, a joint effort between breast surgeons and plastic reconstructive surgeons has a high probability of success with low recurrence rates.

Breast Cancer in Asian Women: Disparities in Presentation and Treatment

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Objectives: Screening mammograms have been credited for the reduction in breast cancer mortality over the past few years in the U.S. NCCN guidelines recommend annual screening mammogram, yearly clinical breast exam (CBE) and monthly self-breast exams (SBE) for early detection of breast cancer. However, there are disparities in the rate of screening mammograms between ethnic groups.[1] In the U.S., there is evidence of increasing rates of breast cancer among Asian women.[2] We examined whether Asian breast cancer patients presented with palpable masses more often than screening mammogram compared to the Caucasian population, and whether this translated to a later stage at presentation or difference in surgical outcome.

Methods: An IRB-approved, retrospective chart review of a breast cancer database was performed from 11/2003-09/2009. Patient and tumor factors were examined: patient's age at diagnosis, mode of presentation consisting of mammogram, CBE or SBE, and tumor stage. Surgical treatment, consisting of partial mastectomy (PM) and total mastectomy (TM), and reconstruction rates for patients who underwent TM were compared between the Asian and Caucasian population.

Results: There were a total of 2576 patients in the database with 1333 Caucasian and 96 Asian patients. The mean age of breast cancer diagnosis in the Asian population was 51.5 and in the Caucasian population 55.7 (P = 0.0002). The Asian population presented with a higher rate of palpable breast cancer: 51 (53%), compared to the Caucasian population, 499 (37%) (P = 0.002). There was no statistically significant difference between the stage at presentation, surgical treatment, or reconstruction rates among the Asian population compared to Caucasians (Table 1).

Table 1. Summary of presentation and treatment of Asian and Caucasian breast cancer

	Palpable	**Early Stage**	**Late Stage**	**Partial Mastectomy**	**Total Mastectomy**	**Reconstruction**
Asian	51 (53%)	90 (94%)	6 (6%)	70 (73%)	26 (27%)	13 (50%)
Caucasian	499 (37%)	1195 (92%)	108 (8%)	950 (73%)	350 (27%)	234 (67%)
P value	0.002	0.50	0.50	0.97	0.97	0.41

Conclusions: In our study Asian patients presented with breast cancer at a statistically significant younger age and with a higher rate of palpable lesions compared to their Caucasian counterparts. However, this did not affect the stage at the time of diagnosis, the rate of total mastectomy or immediate reconstruction. Further studies are necessary to evaluate the effect of this disparity on survival and investigate the potential socioeconomic factors that may contribute to this difference in presentation of breast cancer in Asian patients.

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The Association Between Lobular Involution and Histology in Older Women With Nonpalpable Lesions

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Objectives: The involution of glandular tissue in the breast occurs over a woman's lifetime and is most pronounced after menopause. This process involves the regression of both the lobular acini and stroma, with replacement by fatty tissue. In some women, this process is incomplete and the glandular tissue persists. Recent studies have found an inverse association between degree of lobular involution identified in benign breast biopsies and subsequent risk of developing breast cancer. This study was designed to investigate the relationship between lobular involution and histology in a population of mature women undergoing open biopsy for nonpalpable breast lesions.

Methods: The study cohort consisted of women aged ≥60 years who had a needle-localized breast biopsy at NYU Langone Medical Center in 2008. Variables of interest included age, degree of involution, and final histology. The number of acini per lobule was assessed by a single pathologist. Degree of involution was classified by the criteria used by Hartmann et al: none (0%), partial (1-74%), and complete (>75%). Histology was categorized as benign (nonproliferative lesions, proliferative lesions without atypia, lesions with atypia) and malignant (intraductal and invasive cancers). Descriptive and chi-square analyses were performed to evaluate the relationship between involution and histology.

Results: There were 199 women who underwent 208 biopsies. Nine women had bilateral lesions. The median age in our cohort was 67 years. There were 12 (6%) nonproliferative lesions, 30 (14%) proliferative lesions, and 37 (18%) atypical lesions. In our cohort, 46 (22%) biopsies showed ductal carcinoma in situ and 83 identified (40%) invasive carcinoma. In summary, 79 lesions (38%) were benign and 129 (62%) were malignant. When assessed for degree of involution, 17 women (8%) had none, 59 (30%) were partially involuted, and 123 women (62%) had complete involution. As expected, the majority of women in our cohort exhibited complete involution. However, 38% of our patients over 60 were found to have significant persistence of glandular breast tissue. In our cohort of women over 60 years of age undergoing image-guided surgical breast biopsies, there was no association between age and degree of lobular involution, as defined by Hartmann et al. In addition, the degree of lobular involution did not correlate with biopsy pathology. In fact, the majority of the identified malignancies (38%) occurred in women with complete involution.

Conclusions: Hartmann and colleagues identified lack of lobular involution as a risk factor for breast cancer by looking at long-term outcomes after benign breast biopsies in women of all ages. As we focused on a cohort of postmenopausal women, our data are insufficient to address the relationship between lobular involution and subsequent risk of breast cancer. However, the complete lack of association between degree of lobular involution and malignant histology in our study of postmenopausal women may suggest a role for stromal factors in the development of breast cancer in that population. Further investigation is warranted to focus on the subset of postmenopausal women with incomplete lobular involution and better understand how that histologic finding impacts on their risk of breast cancer.

Minimally Invasive Stereotactic Excisional Biopsies of High-Risk Breast Lesions: An Attractive Alternative

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Objectives: Excisional biopsies are recommended for all high-risk breast lesions. In the present report, the authors review their experience with SiteSelect, a commercially available device used for minimally invasive stereotactic excisional biopsies of the breast.

Methods: Thirty-five patients, who underwent stereotactic core biopsy, were shown to have high-risk breast lesions on pathology. Diagnoses included atypical hyperplasia (n = 24), complex sclerosing lesions (5), columnar cell changes with atypia (4), papillary lesions (1), and hemangiomas (1). Subsequently, they underwent minimally invasive stereotactic excisional biopsies. A 15-mm-diameter SiteSelect device was used in 29 patients, a 10-mm device in 1, and a 22-mm device in 5. Data on lesion capture, specimen orientation, final pathology, complications, patient satisfaction, and cosmetic outcomes were obtained.

Results: In all cases, specimen mammography demonstrated adequate capture of the lesion and biopsy site. Final pathology demonstrated benign tissues in 21 patients, atypia in 10, and complex sclerosing lesions in 3. One patient was found to have ductal carcinoma in situ with a maximum diameter of 3 mm and a minimum margin of 2 mm; no further intervention was recommended. At 17 months, 1 patient developed cancer in the contralateral breast; at a median of 24 months, all other patients demonstrated no further evidence of disease. Hematoma was the most common complication (n = 3, 9%). Five patients rated the procedure as less uncomfortable than the original core biopsy, 28 as no more uncomfortable, and 2 as slightly more uncomfortable. All patients expressed that they would undergo the procedure again. All patients were satisfied with the cosmetic results.

Conclusions: Minimally invasive stereotactic excisional biopsy is an effective and safe means of diagnosing and treating high-risk breast lesions. It allows for adequate pathologic evaluation, is well tolerated, and provides for excellent patient satisfaction and cosmesis. Moreover, in the event that a small cancer is found, the procedure in and of itself may be oncologically adequate.

Papillary Lesions: Pathologic Scoring Can Predict Malignancy and Guide Management

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Objectives: The appropriate management of papillary lesions (PL) diagnosed on core biopsy is controversial. On one hand, the potential for upstaging to cancer argues for routine excision of all PL. On the other hand, the low incidence of cancer on excision argues for a more selective approach. As such, there are no clear guidelines in determining who should and who should not undergo excision. To better understand the risk of malignancy in PL and the indications for their excision, we reviewed the clinical history, pathology, and outcomes of patients with PL demonstrated on core-needle biopsy.

Methods: Pathology records were reviewed to identify all cases in which PL were identified on core-needle biopsy between March 2006 and May 2009. Following core-needle biopsy, all patients either underwent excision or demonstrated no changes on mammogram for a minimum of 6 months. Only patients whose original core biopsy slides were available for review were included. Data on presentation, risk factors, mammographic findings, pathology, and outcome were collected. Pathology slides were screened by 4 breast pathologists and a score from 1 to 3 was assigned for each of the following characteristics: degree of sclerosis, architectural complexity, and cytologic atypia. A score of 1 denoted mild abnormality, a score of 3 denoted severe abnormality. These scores were summed to create a total score.

Results: Twenty-five patients were included. All were female; the median age was 61 (28-85). Three (12%) had a prior history of benign PL. Two (8%) had a family history of breast cancer. Mean absolute 5-year and lifetime Breast Cancer Risk Scores (BCR) were 1.5% and 7.6%, respectively; relative BCR were 1.4 (range, 0.3-9.0) and 1.5 (range, 0.5-7.4). Eighteen patients (72%) presented with a mammographic lesion, 4 (16%) with discharge, 3 (12%) with a palpable mass. Fourteen patients (56%) underwent excisional biopsy, 2 of whom (14%) were diagnosed with a malignant lesion. Eleven (44%) were observed; none were found to have cancer. Relative 5-year and lifetime BCR were higher in the cancer versus no-cancer group ($P < 0.05$). Moreover, pathologic scoring differed between the groups. Of 25 cases, only 2 had malignant findings on excision; both received a total score of 9.

Conclusions: Over 50% of PL were excised and, of these, only 14% were found to be malignant. A scoring system for PL—one based on degree of sclerosis, architectural complexity, and cytologic atypia—can differentiate those lesions that are likely to be malignant from those lesions that are likely not to be malignant. This may allow for more accurate selection of patients for excision. However, larger studies are needed to validate these findings and to determine appropriate cutoffs for management decisions.

103 Breast Reconstructions With Simultaneous Balancing Procedures on the Contralateral Breast

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Objectives: In patients undergoing unilateral breast reconstruction, contralateral breast balancing procedures, such as breast reduction or mastopexy, may be needed for symmetry in up to 67% of cases.[1] Although it is possible to do balancing procedures at the time of reconstruction, most plastic surgeons choose to delay performing the balancing procedure. This delay often requires patients to wait months for their adjuvant therapy to be completed before undergoing another surgery to attain symmetry. In order to avoid these drawbacks, we began to perform simultaneous balancing procedures at the time of breast reconstruction. In this study, we review the safety and efficacy of this combined approach and discuss the indications for its use.

Methods: One hundred three consecutive combined breast reconstructions and contralateral balancing procedures performed between 1999 and 2006 were reviewed. Data obtained included patient age, body mass index, type of reconstruction and balancing procedure, specimen weight, transfusion rate, complications, and revisions for symmetry. Statistical analysis was performed using unpaired *t* tests to compare BMI, specimen weight, and need for nonautologous transfusion.

Results: The average patient age was 48 years (range, 28-68). Reconstruction included TRAM flaps (55 pedicled, 23 free), DIEP flaps (18), latissimus flaps (2), and tissue expanders (1). All but 2 reconstructions were immediate. Balancing procedures included reduction mammaplasty (54), followed by mastopexy (48) and augmentation (1). Transfusion rate was 7.8%, an acceptably low rate for breast reconstruction. There was no relation between patient BMI or specimen weight and transfusion requirement. There were no surgical complications requiring return to the O.R. and only 1 medical complication, a deep venous thrombsis. The overall revision rate for symmetry was 6.8%. Seven patients underwent revisions for symmetry on the reconstructed breast, 2 of whom also had contralateral breast revisions during the same procedure.

Conclusions: Many patients appreciate having immediate reconstruction at the time of mastectomy because it avoids an additional surgery and an interval of asymmetry. Similarly, patients appreciate having their balancing procedure done at the time of reconstruction in order to avoid these same drawbacks. Concerns over increased complications, increased bleeding, difficulty attaining symmetry, and possibly decreased reimbursement lead many plastic surgeons to delay procedures on the contralateral breast until the reconstruction has healed and the patient has finished adjuvant therapies. Our experience shows mastectomy, reconstruction, and a balancing procedure may be accomplished in a single surgery, safely and effectively. Candidates for combined surgery are those who have an aesthetically unsuitable contralateral breast as a model for reconstruction and those for whom abdominal flap reconstruction is planned, but who do not have sufficient flap volume to match the nondiseased breast. Simultaneous balancing is less appropriate in expander reconstructions and when adjuvant radiotherapy is anticipated, as the final reconstructed breast shape and volume may be difficult to anticipate. In conclusion, simultaneous balancing and reconstruction can be associated with low rates of complications, transfusion, and revisions and should be considered for appropriately selected patients.

1. Losken A, Carlson G, Bostwick J, et al. Trends in unilateral breast reconstruction and management of the contralateral breast. *Plast Recon Surg*. 2002;110:89-97.

Preoperative MRI After Diagnosis of Breast Cancer: Biopsy Confirmation Is Imperative Prior to Surgery

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Objectives: Magnetic resonance imaging (MRI) is an increasingly used imaging modality for evaluation of breast cancer with high sensitivity but lower specificity. In this study we investigate the rate of MRI leading to additional imaging, biopsies, and specificity of MRI findings.

Methods: A retrospective review was performed of patients diagnosed with breast cancer who underwent preoperative MRI imaging 2001-2008. Patients were divided into 2 groups: (1) index cancer visualized on mammogram and no additional mammographic abnormalities, and (2) index cancer visualized on mammogram with additional mammographic abnormalities. Patients were excluded if their breast cancer was mammographically occult.

Results: Three hundred (22%) of 1340 patients underwent preoperative MRI imaging. Of these, additional imaging because of MRI findings was recommended in 159 patients (53%) and 95 patients (32%) had 174 additional biopsies, including 17 patients with biopsies of bilateral breasts. Overall 47 patients, 4 with bilateral positive biopsies, (50%) had 64 (37%) positive biopsies as a result of MRI findings. Fifty percent of ipsilateral biopsies and 23% of contralateral biopsies were positive. Eighteen patients (19%) had mammographic correlates for MRI findings outside of the index lesion leading to 28 biopsies. Of these, 80% of ipsilateral biopsies were positive and 38% of contralateral biopsies were positive. Ninety-three second-look ultrasounds (USs) were performed to investigate MRI findings, including 12 for bilateral findings after normal mammograms and 4 for normal contralateral mammograms with abnormal ipsilateral mammograms. Eighty-two patients (88%) had a second-look US to identify suspicious findings, leading to 132 US-guided biopsies. Thirty-six patients had 61 ipsilateral biopsies with 43% being positive, and 46 patients had 71 contralateral biopsies of which 18% were positive. Twelve patients underwent 14 MRI-guided biopsies, including 1 patient who required MRI-guided biopsy after US biopsy. Of these, 33% of ipsilateral and 60% of contralateral biopsies were positive. The rates of positive biopsies resulting from MRI findings changed over time: 2001, 60%; 2002, 15%; 2003, 25%; 2004, 19%; 2005, 39%; 2006, 45%; 2007, 57 %; 2008, 45%.

Conclusions: While breast MRI yields additional findings in already diagnosed breast cancer that may lead to alterations in surgical management, there are also a substantial number of false-positive findings that lead to increased imaging and biopsy. MRI findings with correlates on mammography are much more likely to be malignant, and ipsilateral findings are more likely to represent malignancy than contralateral findings. Physicians must counsel patients referred for MRI about the significant risk of additional imaging and additional biopsies that may prove to be due to benign findings and plan treatment based on histologic assessment rather than imaging findings.

Photodynamic Detection of Human MDA-231 Breast Cancer Cells In Vitro Using Aminolevulinic Acid-Aided Fluorescence Spectroscopy

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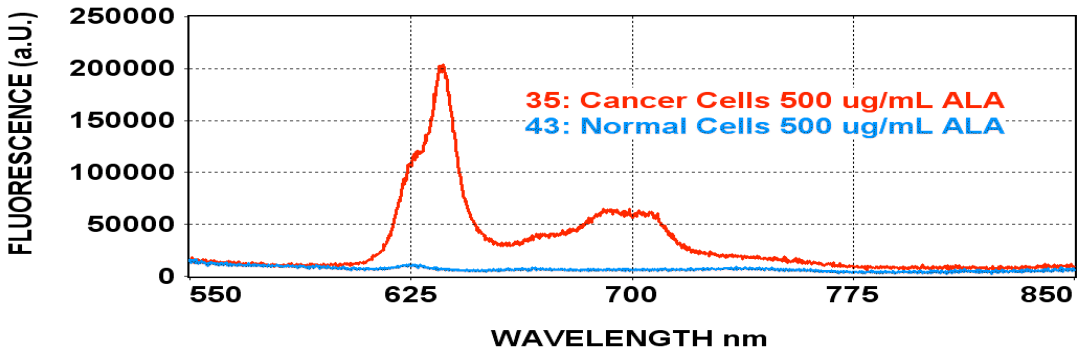
Objectives: Photodynamic techniques have been shown to be effective in detecting tumors in multiple tissue types. This method is based on the preferential incorporation of a fluorescent dye within neoplastic cells. We hypothesized that the preferential uptake of aminolevulinic acid (ALA) by tumor cells can be detected and quantified with fluorescence spectroscopy. This may potentially lead to improved intraoperative margin assessment in breast-conserving surgery.

Methods: Detroit 525 fibroblast cells were selected as nonmalignant control cells. MDA-231 breast cancer cells were chosen as a malignant cell line. Cells were allowed to grow to >80% confluence. The cells were then treated with varying concentrations of ALA and incubated for 18 hours. Detroit 525 and MDA-231 cells were then evaluated for protoporphyrin IX (PpIX) production using fluorescence spectroscopy. To activate ALA-induced PpIX fluorescence, the cells were illuminated using broadband light filtered with a 405-nm optical bandpass filter.

Results: Fluorescence emissions from ALA-treated cancer cells were substantially higher than the emissions from ALA-treated normal cells. We observed 2 fluorescent absorbance peaks in the cancer cell line, centered at 635 nm and 700 nm (Figure 1). We also observed a dose dependent increase in the fluorescent absorbance intensities with increasing concentrations of ALA. The untreated cells exhibited no fluorescence while cells treated with ALA exhibited dose-dependent fluorescence. We acquired 3 fluorescence spectra at 6-minute intervals for MDA-231 treated with 500 µg/ml of ALA to demonstrate the reproducibility of our measurements. We observed a region of the spectrum centered at 625 nm, which progressively decreased with time. We then collected spectral data at time t and t + 4 hours and observed the peak fluorescence decreased by 10.7% in 4 hours.

Figure 1



Conclusions: The preferential uptake of ALA by MDA-231 versus normal cells was demonstrated using fluorescence spectroscopy. This data provides proof of concept for a novel intraoperative margin assessment tool to potentially reduce the number of reoperations due to positive margins not identified intraoperatively. Additional studies using cell lines and patient tissues are required to validate these findings.

Nipple-Sparing, Skin-Sparing Mastectomy: An 11-Year Retrospective Study

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Objectives: This study is to provide statistically significant data to support the need for nipple-sparing, skin-sparing mastectomy (NSM). So long as a patient can be treated adequately for breast cancer, the most conservative approach would be desirable. Lumpectomies are widely acceptable. We feel that adding the nipple-sparing portion to a skin-sparing mastectomy is not only acceptable but beneficial psychologically and cosmetically to the patient.

Methods: Beginning in 1998, NSMs were performed as indications permitted. One hundred forty-nine patients underwent 228 NSMs. These patients were chosen clinically from a group of patients who either had breast cancer requiring a mastectomy, strong family history, or were gene-positive. All patients were required to see an oncologist, a radiation specialist, and a plastic surgeon. Patients were informed that this procedure was investigational and not the standard of care. Patients entered this study at varying intervals.

Results: Of the 228 NSMs, 77 were bilateral and 74 were unilateral. Ninety-two were done because of invasive cancer and 41 had in situ cancer. Six patients were gene-positive, 7 had a strong family history, and 1 patient had repeated lumpectomies for a phylloides tumor. One patient had a nipple recurrence, requiring the nipple to be removed and subsequently is cancer-free post 5 years. Eight patients had recurrences to other areas of the breast requiring lumpectomies and all are cancer-free. None of the gene-positive or family history patients developed cancer.

Conclusions: From this relatively small but lengthy study, we feel that NSMs have a place in the surgical treatment of breast cancer. The procedure itself leaves very little additional breast tissue when compared to skin-sparing mastectomies. We feel there is a distinct advantage psychologically and cosmetically.

Synchronous Breast and Lung Cancers: Report of Hospital Cases and Review of SEER Tumor Registry

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Objectives: Breast and lung cancers are the 2 most frequent cancers detected in women, yet synchronous cancer is a rare finding. We decided to look at women diagnosed with both breast and lung cancers within 5 years of each other and see if there are common characteristics between these patients.

Methods: Hospital tumor registry from 2002-2009 and SEER tumor registry from 2000-2006 were retrospectively reviewed. Patients included in the study were women who were diagnosed with both primary breast cancer and primary lung cancer within 5 years of each other. Clinical and pathological features of each tumor were analyzed.

Results: In the SEER registry, the frequency of lung cancer in breast cancer patients from 2000-2006 was 0.95% (3354/351,739). Among them, 534 were diagnosed with lung cancer within 5 years after their breast cancer diagnosis. Four hundred fifty-four of 534 (85%) were white. One hundred nine patients (20%) had the primary lung cancer simultaneous or during the same year as the breast cancer. After a median follow-up of 37 months (2-83 months), the overall survival rate was low at 43%. Our hospital data recorded 0.82% (27/3284) of breast cancer patients from 2002-2008 were also diagnosed with lung cancer. Nine were diagnosed with both lung and breast cancers within 5 years of each other. All 9 patients were postmenopausal, had at least a 20-pack-year smoking history, and were diagnosed with breast cancer first. In 5 of those 9 patients, lung cancer was detected as a result of preoperative staging or postoperative follow-up. Of the 9 patients diagnosed with synchronous breast and lung cancer between 2002 and 2009, 6 are still living.

Conclusions: The data indicates that synchronous breast and lung cancers are associated with a high mortality rate. Although routine screening is not recommended for early detection of lung cancer, further studies may help identified breast cancer patients who may benefit from screening for lung cancer.

Depression, Anxiety, and Quality of Life Following a Breast Biopsy: Effects of Diagnostic Outcome and Previous Biopsy History

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Objectives: The possibility of breast cancer is faced by every woman who undergoes a breast biopsy. Recent research supports the hypothesis that stress and mood disturbance may be common consequences, even if the biopsy results are benign. In this study of women who have had a breast biopsy within the previous 4 months, we explore the impact of biopsy on emotional well-being and quality of life (QoL) in the setting of: (1) previous history of breast biopsy, and (2) histopathologic outcome. We hypothesized that women with multiple biopsies whose outcome was positive for malignancy would experience the highest level of stress and mood disturbance.

Methods:

Population—Participants were recruited from a larger study addressing QoL, spiritual and emotional well-being, cognitive performance, and immunologic resilience following breast cancer diagnosis. The design matched patients with breast cancer and benign controls on age, education, race, and menopausal status.

Instruments—Histopathology report, HOPE QoL Scale, State Anxiety (STAI) Subscale, and Patient Health Questionnaire (PHQ-9) for depression.

Outcomes—Depression, anxiety, and QoL subscale scores (physical well-being, psychological well-being, treatment distress, fear, social concerns, and spiritual well-being).

Statistics—Two-factor analysis of variance was used to assess the effect of histopathologic outcome and a history of past biopsies. Age, education, and income were partialed out in the analysis.

Results:

1. Of 65 patients with breast cancer and 53 benign controls, a main effect for histopathological outcome was found, such that women with malignancy had poorer social QoL ($P < 0.0001$), but better spiritual QoL ($P = 0.01$), than controls.

2. Of 118 participants, 79 experienced their first, while 39 had 1-14 prior breast biopsies. A main effect was found for previous breast biopsy history, with this group showing less treatment distress ($P = 0.03$) and better psychological well-being (trend, $P = 0.06$) compared to those undergoing their first biopsy.

3. The primary hypothesis was not supported, as no interactions for measures of state anxiety or depression were noted for either a previous biopsy history nor histopathologic outcome. However, as expected, those with malignancy had poorer overall psychological QoL than controls ($P = 0.03$).

Conclusions:

1. Both biopsy outcome and prior history of breast biopsy can significantly impact the QoL response to a current biopsy.

2. Those with malignancy report poorer social well being, but appear to have a higher level of spiritual well-being than controls.

3. Women undergoing their first biopsy experience more distress related to treatment and poorer psychological QoL than those with a previous biopsy history.

4. As expected, women with a malignancy report more overall psychological distress than those with a benign outcome.

Overall, QoL measures appear to be particularly useful in evaluating the impact of life stress from breast biopsy, regardless of outcome.

Incidence of Occult Carcinoma and Premalignant Changes in Mammaplasty Specimens

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Objectives: To determine the incidence and type of premalignant or malignant changes in mammaplasty specimens. To determine the incidence of these changes according to age distribution.

Methods: Retrospective database review of patients who underwent a reduction mammaplasty between 1999 and 2009 was performed from pathology records at a single institution.

Results: Seven hundred patients were identified from the database. Six hundred forty-four (92%) had bilateral reduction mammaplasty performed for cosmesis, and 56 patients (8%) had unilateral reductions performed to match a reconstructed breast after mastectomy. Of the 644 patients who had bilateral reductions, 25 (4%) had significant pathologic findings. Twenty patients (3%) had premalignant changes (atypical ductal hyperplasia, atypical lobular hyperplasia, LCIS), and 5 patients (0.8%) had occult cancer (3 had DCIS and 2 had IDC). The likelihood of finding premalignant changes or cancer increased with advancing patient age (0.8 percent for patients <40 years old and 10 percent for patients >60 years old).

Table 1. Bilateral Reduction Mammaplasty

Age	N	Atypical Ductal Hyperplasia	Atypical Lobular Hyperplasia	LCIS	DCIS	Infiltrating Ductal Carcinoma
<40	361	2 (0.55%)	0	1 (0.28%)	0	0
40-49	152	2 (1.31%)	3 (1.97%)	2 (1.31%)	2 (1.31%)	1 (0.66%)
50-59	101	3 (2.97%)	3 (2.97%)	1 (0.99%)	1 (0.99%)	1 (0.99%)
>60	30	0	2 (6.67%)	1 (3.33%)	0	0

Of the 56 patients who underwent unilateral mammaplasty, 12 patients (21%) had significant pathologic findings. Ten patients (18%) had premalignant changes. Two patients (3.5%) had DCIS. The incidence of finding premalignant changes or cancer in this population also increased with advancing patient age (0 for patients <40 years old to 25% for patients >60 years old).

Table 2. Unilateral Mammaplasty After Contralateral Carcinoma

Age	N	Atypical Ductal Hyperplasia	Atypical Lobular Hyperplasia	LCIS	DCIS	Infiltrating Ductal Carcinoma
<40	11	0	0	0	0	0
40-49	13	2 (15.4%)	0	1 (7.69%)	0	0
50-59	20	3 (15.0%)	0	1 (5.00%)	2 (10.0%)	0
>60	12	1 (8.33%)	2 (16.7%)	0	0	0

Conclusions: The likelihood of finding unsuspected premalignant changes is low (4.3%), and the incidence of cancer in reduction mammaplasty specimens is even lower (1.0%). However, the incidence of both premalignant changes and carcinoma increase with advancing age. When a unilateral mammaplasty is performed to match a breast reconstructed after cancer surgery, the likelihood of identifying premalignant changes or cancer increases more than fourfold. Therefore, one should consider additional radiologic imaging in the preoperative workup of patients with a history of carcinoma prior to undergoing unilateral mammaplasty.

Breast Cancer in Elderly Women (>80 years): Variation in Standard of Care?

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Objectives: As the population ages, increasing numbers of elderly women with breast cancer are expected. Whether women at advanced ages receive similar treatments as their younger counterparts is unclear. The current study aim was to determine treatment and outcomes for women ≥80 years with breast cancer.

Methods: We reviewed our surgical database and identified 134 patients ≥80 years old treated for breast cancer between 1998 and 2009. Data collected included mode of presentation, patient comorbidities, tumor characteristics, treatment, and outcomes. Descriptive statistics were utilized for data summary.

Results: Of 134 women ≥80 years old, 146 breast cancers were diagnosed. Only 66 (45%) of the cancers were detected by screening mammography. Comorbidities (pulmonary, cardiac, renal, hematologic, neurologic, and/or diabetes) existed in 44% of patients. Surgical therapy included partial mastectomy in 50% and mastectomy in 50%. Although 10 women (7%) with an invasive breast cancer had no form of axillary staging, 26 women (18%) had an axillary lymph node dissection without sentinel lymph node biopsy, despite clinically and pathologically node-negative disease. The pathologic stage included 16 (11%) stage 0, 78 (53%) stage I, 25 (17%) stage II, 9 (6%) stage III, 1 (1%) stage IV, and 17 (12%) unstaged. Of 73 patients undergoing partial mastectomy, only 47% received adjuvant radiation. Of 146 cancers, 121 (83%) were estrogen receptor positive; 94% of eligible patients received endocrine therapy (37% tamoxifen; 57% aromatase inhibitor). Fourteen (10%) patients received adjuvant chemotherapy, including 5 of 14 (36%) with “triple negative” disease. Eleven (8%) cancers were Her2neu amplified; only 1 patient received adjuvant trastuzumab. At follow-up, 91 patients (68%) were alive without evidence of disease. Only 6 (4%) died of breast cancer.

Conclusions: Although women ≥80 years are more likely to be diagnosed with breast cancer when symptomatic, the majority have early-stage disease with favorable tumor biology. High rates of mastectomy and unnecessary axillary dissection represent potential surgical over-treatment. While most women eligible for anti-estrogen therapy received it, adjuvant radiation, chemotherapy, and/or trastuzumab were underutilized. Despite these variations, older women with breast cancer are unlikely to suffer breast cancer–related mortality.

Micrometastatic Disease As a Predictor for Additional Breast Cancer Axillary Metastatic Burden

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Objectives: Sentinel lymph node biopsy (SLNB) has become the standard for axillary staging in patients with clinically node-negative breast cancer. The clinical significance and management of micrometastatic (0.2-2 mm) sentinel lymph node (SLN) disease remains unclear. Our study aims were to determine the rate of non-SLN metastasis, the rate of axillary recurrence, and to compare actual non-SLN metastasis rates with those predicted by the MSKCC nomogram.

Methods: We reviewed our prospectively maintained surgical database and identified 1409 stage I-III breast cancer patients who underwent SLNB; 121 (9%) were identified with micrometastases (0.2- to 2-mm tumor deposits) and included in the analysis. Patients were divided according to whether they underwent completion axillary lymph node dissection (ALND) (Group 1) or had no further axillary surgery (Group 2). The rates of non-SLN metastases in Group 1 patients were compared to that predicted by the MSKCC nomogram. Axillary recurrence rates were identified in Group 2 patients. Data were compared using chi-square and Fisher's exact test.

Results: Of 121 patients with micrometastatic SLN disease, 55 (45%) underwent completion ALND (Group 1) and 66 (55%) had no further axillary surgery (Group 2). The rate of non-SLN metastases in Group 1 patients was 9 (16%) of 55, which is significantly less than that predicted by the MSKCC nomogram (mean, 29%; P <0.05). Eight patients had macrometastatic disease (>2 mm) in their residual positive non-SLNs, while 1 patient had only micrometastatic disease. Patient age, race, tumor histology, tumor size, tumor grade, and ER/PR/Her2neu status did not differ significantly between Group 1 patients with positive non-SLNs and those with negative non-SLNs. At follow-up, no patient in Group 1 experienced an axillary recurrence, while only 1 (1.6%) patient in Group 2 experienced an axillary recurrence.

Conclusions: The actual rate of positive non-SLNs for breast cancer patients with SLN micrometastases who underwent completion ALND was significantly less than that predicted by the MSKCC nomogram. Although 16% of breast cancer patients who underwent completion ALND for SLN micrometastases had positive non-SLNs, the rate of axillary recurrence is negligible regardless of the extent of axillary staging.

Are We Overtreating Papillomas Diagnosed on Core Needle Biopsy?

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Objectives: Breast papillomas are commonly diagnosed on core needle biopsy. Most studies support surgical excision for papillomas with atypia because as many as one half will be upgraded to DCIS or invasive carcinoma on final pathology. The literature is less clear on the management of papillomas without atypia on core biopsy. Our goal was to determine factors associated with pathology upgrade on excision.

Methods: Our pathology database was searched to find all breast papillomas diagnosed by core needle biopsy over the past 10 years. A total of 277 charts were retrospectively reviewed and lesions associated with atypia or malignancy on core biopsy were excluded. Two groups were identified: papillomas that were surgically excised (Group 1) and those that were not (Group 2). These charts were reviewed for the subsequent diagnosis of cancer or high-risk lesions. Chi-square test, Jonckheere-Terpstra test, and Fisher's exact test were used to analyze the data.

Results: One hundred ninety-four papillomas in 187 patients were identified. Eighty-four of these lesions underwent surgical excision (43%). Caucasian women were more likely to have their lesions excised (P = 0.035). Palpable lesions were more frequently excised (P = 0.020). Twelve percent of excised lesions were upgraded to in situ or invasive cancer. All invasive cancers were T1. One patient had micrometastases in a sentinel node; the rest were node-negative. Increasing age was a predictor of pathology upgrading (P = .035). Clinical presentation, location within the breast, and prior and concurrent breast cancer were not associated with a higher rate of pathology upgrade. Follow-up was available for 63 of the women in Group 2. No ipsilateral cancers developed in this group with a median follow-up of 43 months.

Conclusions: Twenty-four percent of patients diagnosed with papillomas on image-guided biopsies have upgraded lesions on excision, and half of these are upgraded to in situ or invasive malignancy. Older women are more likely to be diagnosed with cancer in our study. All of the cancers diagnosed were stage 0 or I. For women in whom excision was not performed, those papillomas did not become clinically significant.

Clinical Utility of Breast-Specific Gamma Imaging in Patients Receiving Neoadjuvant Chemotherapy: An Institutional Review

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Objectives: BSGI is a novel, physiologic approach to breast cancer diagnosis and detection based on angiogenesis and metabolic activity. Other technologies, such as MRI, have been shown to evaluate patient response to neoadjuvant chemotherapy. This study evaluates the utility of BSGI in gauging tumor response to neoadjuvant chemotherapy.

Methods: A chart review was conducted of all patients who were treated with neoadjuvant chemotherapy and who had BSGI before and after chemotherapy at The George Washington University Breast Care Center. Measurements of abnormal uptake were directly measured on BSGI in 3 dimensions and the longest axis was used. Pre-chemotherapy ultrasound and mammographic measurements were compared to pre-chemotherapy BSGI measurements. Pathologic size at surgical excision was compared to post-chemotherapy BSGI measurements. Measurements were considered to be consistent when within 5 mm.

Results: Eleven patients who had BSGI prior to and following neoadjuvant chemotherapy were included in this study. BSGI accurately reflected tumor size within 5 mm when compared to postoperative pathology specimens in all 11 patients. BSGI measurements were within 5 mm in 6 of the 10 patients with pre-chemotherapy ultrasound measurements, and within 1 cm in 9 of 10 of these patients. Eight (72%) of 11 patients had a good to excellent response demonstrated by significant decreases in the size of their lesion on BSGI which was corroborated on final surgical pathology. The 3 patients (18%) who demonstrated a poor response had persistent uptake in the area of their tumor as well as extensive uptake in the axillary lymph nodes on both pre- and post-chemotherapy BSGIs. There were 3 patients (27%) with no uptake on BSGI studies that had either microscopic disease or residual tumor <5 mm. Conversely, there were 2 patients (18%) with small areas of very faint uptake who had negative histopathology.

Conclusions: BSGI is accurate in establishing tumor size within 5 mm after neoadjuvant chemotherapy in patients with breast cancer. BSGI is less reliable in detecting residual microscopic disease in these patients. Although additional studies are needed, BSGI should also be considered to determine patient response to neoadjuvant chemotherapy.

Mastectomy and Contralateral Prophylactic Mastectomy Rates in Breast Cancer Patients Treated at The George Washington University Breast Care Center

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Objectives: Breast conservation surgery (BCS) followed by radiation is as effective as mastectomy for long-term survival and is considered standard of care for early-stage breast cancer. Although breast conservation rates are consistently higher, an increasing number of patients are opting for cancer-side mastectomies (CM) and often contralateral prophylactic mastectomies (CPM). Our study investigates whether there are increasing trends in our patient population toward CM and CPM and identifies common factors associated with those electing to have more extensive surgery.

Methods: A retrospective analysis was performed on 811 breast cancer surgeries between January 2001 and June 2009 at The George Washington University Breast Care Center. Patients who elected to have BCS were compared to those who were eligible for BCS but chose CM. We also compared CM patients who had CPM to those who had CM only. Variables considered were age, race, presentation, pathology, family history, previous history of contralateral breast cancer, number of children, and use of neoadjuvant therapy. Two-sample *t* tests were employed to test the equality of means for continuous variables and chi-square tests of independence were applied to categorical variables. In cases with counts less than 5 in any category, Fisher's exact tests were used.

Results: A history of contralateral breast cancer was the only statistically significant factor associated with patients electing to have CM (Table 1), while age, family history, and decision to proceed with reconstruction were statistically significant factors associated with CPM (Table 2). There were several additional factors that approached statistical significance also summarized below.

Table 1

Characteristic	BCS	Elected to Have CM Over BCS	*P* Value
Patients	487	35	< 0.0001
History of contralateral breast cancer	7%	33%	< 0.001
Family history of breast cancer	38%	52%	0.1
Presented with palpable mass	42%	34%	0.13
Invasive cancer	77%	89%	0.16
DCIS	23%	11%	0.16

Table 2

Characteristic	CM and CPM	CM Only	*P* value
Patients	69	255	< 0.001
Age	47	55	< 0.001
Family history of breast cancer	63%	41%	< 0.001
Immediate reconstruction	63%	45%	< 0.001
African American	36%	49%	0.13
Caucasian	61%	45%	0.13

Conclusions: In this study, patients who opted for CM over BCS were more likely to have a diagnosis of invasive cancer, a family history of breast cancer, and a history of contralateral breast cancer than those who had BCS. Patients who elected to have CPM were more likely to be Caucasian, younger, presented with a palpable mass, have a family history of breast cancer, and were more likely to undergo immediate reconstruction.

Utilization of Radiofrequency Identification Tags for Localization of Nonpalpable Breast Lesions

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Objectives: Intraoperative localization of nonpalpable breast lesions is standardly performed using a percutaneous hookwire. However, problems with migration of these wires and the need to place them in the radiology suite immediately prior to operative excision can be problematic. Radiofrequency identification (RFID) technology offers potential advantages over wire-localization by eliminating the extracutaneous component and allowing placement of the device days or weeks preoperatively. The aim of this study was to compare RFID-guided excision with standard needle localized excision in turkey and cadaver breasts in order to determine the feasibility of RFID technology in this capacity.

Methods: Three surgical residents each performed excisions guided by RFID and then again by hookwires, all in turkey breasts. Accuracy of localization, time to complete lumpectomy, and ability to achieve a margin were assessed for both methods. Separately, 2 surgeons were each asked to perform 6 RFID-guided and 6 hookwire-guided lumpectomies in cadaver breasts to determine the same endpoints.

Results: All 3 residents were able to successfully localize and resect marked tissue on the first attempt using both the RFID system and hookwire localization techniques. For the surface localization activity, horizontal offset proved better with the use of hookwires. The total time required to perform excision and the overall volume of tissue removed were comparable between the 2 methods. Subjective evaluations indicated that the RFID system was easy to use, accurate, and viable as an alternative to the hookwire. In the cadaver specimens, surface localization with the reader was within 1-cm accuracy (0.83 ± 0.1 cm). Time to excise was slightly better for the hookwires but comparable (4.57 minutes ± 1.92 minutes with RFID and 4.23 minutes ± 0.85 minutes with hookwire). Margins measured by RFID were accurate to 0.29 cm ± 0.20 cm. Three of 12 wires were exposed at the hook portion, and 1 wire completely dislodged during dissection. None of the 12 RFID tags were exposed or dislodged.

Conclusions: Use of RFID technology in the localization of nonpalpable breast lesions proved in this study to be at least comparable to the current standard and would offer a number of potential advantages over the hookwire system. Benefits of this technology are that it can: (1) be inserted completely within the breast parenchyma; (2) be placed days or weeks prior to the operation; (3) resist migration, breakage, or complete dislodgement during dissection; (4) decrease or eliminate the need for intraoperative imaging of the specimen to confirm excision; (5) avoid large learning curves by using familiar concepts and technology; (6) be easily visible on ultrasound; (7) be uniquely identified and distinguished from other markers; and (8) indicate to the surgeon how much tissue is surrounding the marker, thus indicating a margin. The surgeons who participated in the study rated the RFID system highly in terms of its potential clinical benefits and ease of use. Clinical studies in human subjects are now needed to prove efficacy.

Intraoperative Ultrasound Can Decrease Re-Excision Lumpectomy Rate in Patients With Palpable Breast Cancers

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Objectives: It is well known that physical examination does not accurately delineate the extent of breast cancer. If physicians could accurately determine the extent of breast cancer by palpation, re-excision lumpectomy should be a rare event. By contrast, at least 1 re-excision for close or involved margins is necessary in 15-69% of patients undergoing a breast-conserving operation. The current study was performed to evaluate the potential benefit of intraoperative ultrasound in the performance of breast-conserving operations for palpable breast cancers in carefully matched patients.

Methods: A retrospective chart review was performed of patients with a palpable cancer who underwent a breast-conserving operation with intraoperative ultrasound from 2004 to 2008. Twenty-two patients underwent lumpectomy with intraoperative ultrasound. Each of these patients was matched with 2 patients who underwent a breast-conserving operation without intraoperative ultrasound over the same time period. Patients were matched according to clinical tumor size, clinical stage, body mass index, and age at diagnosis.

Results: Twenty-two consecutive patients who underwent lumpectomy with intraoperative ultrasound were matched with 44 patients who underwent lumpectomy without intraoperative ultrasound. The demographic characteristics were similar with respect to age, ethnicity, insurance status, height, weight, and body mass index. Patients were matched by clinical tumor size and clinical stage and therefore both groups were nearly identical. The cancers in both groups were predominantly infiltrating ductal carcinoma. Tumor characteristics were also similar with respect to lymphvascular invasion, extensive intraductal component, and Her2-neu status. Patients who underwent lumpectomy with intraoperative ultrasound were significantly less likely to have a positive (transected) or close margin (41% vs 9%, $P = 0.01$). As a result, patients who underwent lumpectomy with intraoperative ultrasound were significantly less likely to require a re-excision procedure (34% vs 9%, $P = 0.04$). In the intraoperative ultrasound group, none of the patients had more than 1 involved margin. In the lumpectomy-alone group, 6 patients had involvement of more than 1 margin. The lumpectomy volumes in the lumpectomy with intraoperative ultrasound group were smaller than the volumes in the lumpectomy-alone group, however, this difference was not statistically significant.

Conclusions: Intraoperative ultrasound can decrease the rate of positive margins and re-excision lumpectomy in patients with palpable breast cancers.

Quality-of-Life Scores Between Patients Undergoing Accelerated Partial Breast Irradiation and External Beam Radiation Following Breast Conservation Surgery

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Objectives: Current studies are investigating the efficacy of accelerated partial breast irradiation (APBI) as an alternative method of delivering adjuvant radiation therapy to the breast following breast-conserving surgery. This technique may offer advantages over traditional external beam radiation (EBR) therapy given the short duration in course of therapy and potential advantage of sparing the remainder of the breast from undergoing radiation treatment changes and effects. Our study aims to determine if these characteristics of therapy contribute to quality-of-life differences, as measured objectively.

Methods; Participating patients who underwent adjuvant radiation therapy with either APBI or EBR at a single radiation center completed FACT-G questionnaires with a breast-specific subscale to evaluate their quality of life prior to radiation therapy (baseline) and immediately following completion of radiation therapy (6 wk) and at 3 months after treatment.

Results: Seventy-four patients completed the surveys. APBI (n = 28) patients tended to be older (average age, 65) than the EBR (n = 46), whose average age was 56. Within the EBR group, there was not significant improvement in their Fact-B score over time. However, within the APBI group, patients had a significantly higher score when compared to their baseline. This is a similar finding to our prior study of 45 women.

	Baseline FACT-G	6 week FACT-G	3 mth FACT-G	Baseline Subscale	6 week Subscale	3 mth Subscale
APBI	98.00	83.25	91.00	30.00	30.00	30.00
EBR	90.94	90.96	91.77	25.98	26.73	27.29

Conclusions: There is no significant difference in quality-of-life scores between patients undergoing APBI or EBR either before or after therapy. Although the therapy is not expected to improve their quality of life, it is apparent APBI patients were more satisfied 3 months after treatment than when compared to baseline. This study illustrates that the use of APBI did not produce unsatisfactory quality-of-life effects evident in the short-term period, further supporting the use of this modality as a potential alternative to traditional EBR.

Risk Factors Associated With Breast Lymphedema Following Breast Surgery

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Objectives: Lymphedema is a well-recognized complication involving the ipsilateral upper extremity following breast/axillary surgery but can also occur in the breast after surgery. We therefore prospectively evaluated clinical and surgical factors associated with the development of postoperative breast lymphedema (BLE).

Methods: In this single-institution, prospective clinical study, patients undergoing unilateral breast-preserving surgical procedures were evaluated preoperatively and at regular intervals for 1 year following breast surgery. Each patient was monitored for the development of BLE at each follow-up visit based on a graded physical examination that focused on clinical signs of edema and erythema. A patient was classified as having BLE if: (1) a clinical impression of BLE was present at 2 or more visits beyond 1 month after surgery, or (2) a clinical impression of BLE was present at 1 visit greater than 1 month after surgery with either moderate or severe edema or erythema. Data on patient risk factors and surgical factors were collected. Two sample *t* tests and chi-square tests were used to assess the association of these factors with the development of BLE. Logistic regression was then used for multivariate analysis.

Results: A total of 128 women were analyzed in this study. The surgical procedures were: breast biopsy (n = 29), wide local excision (WLE) (n = 19), WLE + sentinel node biopsy (SLNB) (n = 68), and WLE + axillary dissection (n = 12). Thirty patients (23.4%, 95% CI 16.4% to 31.7%) developed BLE. Median length of follow-up was 11 months, with 57% having a follow-up visit at 12 months. Median time to onset of BLE was 66 days (range, 7-344 days). The strongest factor associated with development of BLE was undergoing any axillary surgery, with BLE occurring in 30/80 (38%) of patients with an axillary procedure vs no BLE seen in any of the 48 patients who did not undergo any axillary surgery ($P < 0.0001$). The frequency of BLE did not differ significantly ($P = 0.33$) between those who had SLNB (40%) and those undergoing ALND (25%); similarly the number of lymph nodes removed was not significantly different between those with and without BLE ($P = 0.82$). Larger volume of breast tissue resected and longer length of breast incision were both associated with increased risk of BLE ($P < 0.01$ for each). In contrast, orientation and location of the breast incision were not associated with BLE. Body mass index (BMI) was higher in women with BLE (31.6, SD 6.4) compared to those without BLE (28.4, SD 6.1, $P = 0.02$). Both axillary surgery ($P < 0.0001$) and BMI ($P = 0.01$) remained significantly associated with the development of BLE in multivariate analysis.

Conclusions: The primary risk factor for breast lymphedema is axillary surgery and appears to be unrelated to the number of lymph nodes removed. These findings are consistent with a physiologic mechanism of surgical disruption of the primary lymphatic drainage of the breast.

A Single Institution Shows No Difference in Recurrence Rates Between Accelerated Partial Breast Irradiation With MammoSite Balloon and Whole-Breast Irradiation

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Objectives: The purpose of this study was to compare the local recurrence rates for 198 early-stage breast cancers treated with breast-conserving surgery (BCS), followed by accelerated partial breast irradiation (APBI) using MammoSite or whole-breast irradiation (WBI). The secondary objective was to identify factors associated with local recurrence.

Methods: Between 2004 and 2007, 116 patients at a single institution enrolled into an IRB-approved registry and received BCS followed by APBI. Inclusion criteria were unifocal DCIS or invasive ductal or lobular carcinoma, tumor ≤2 cm, ER/PR +/-, negative margins, and negative nodes. The APBI cohort was matched to 82 patients from the same time period that met the criteria for APBI but received WBI. Physician and patient preference determined the mode of radiation. APBI included 3400 cGy in 10 fractions, twice daily. All patients completed radiation, endocrine, and chemotherapy as indicated. Minimum follow-up was 2 years; mean follow-up, 41 months. Groups were similar in menopausal status, histological type, and grade. WBI had younger patients (mean age = 62 yr vs 66 yr, $P = 0.0366$) and larger tumors (mean = 1.10 cm vs 0.95 cm, $P = 0.0283$). Fisher's exact test was used for rate comparisons; log-rank test and Cox proportional hazards model were used for survival analysis.

Results: Five APBI patients (4.31%) and 3 WBI (3.66%) patients developed local recurrence in the breast ($P = 1.000$). Two APBI patients recurred at the original tumor site and 3 recurred elsewhere in the breast. All 3 WBI recurrences were at the original tumor site. There was 1 axillary and 1 distal recurrence in the APBI group. One WBI patient died of her disease. There was no difference in the time to recurrence (mean = 40 months APBI vs 58 months WBI, $P = 0.6431$). One patient in each group developed cancer in the contralateral breast. Tumor size >1 cm had a hazard ratio of 15.731 over tumor size ≤1 cm for recurrence independent of treatment group ($P = 0.0107$).

Conclusions: There was no significant difference in local recurrence rates with APBI and WBI. Tumor size >1 cm was an independent risk factor for local recurrence.

Redefining Lumpectomy Using the Sick Lobe Hypothesis and Ductal Anatomy

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Objectives: The "sick lobe" hypothesis states that breast cancers evolve from entire lobes or portions of lobes of the breast where initiation events have occurred early in development and these cancers develop synchronously or asynchronously throughout that lobe or sublobe segment rather than by migration of malignant cells up and down the ducts. The implication is that some cancers are isolated events in a small geographic region and others are truly multi-focal but still isolated to single lobar-ductal units.

Methods: This is a single-surgeon retrospective review of early-stage breast cancer lumpectomy patients treated from 1/2000 to 2/2005. Ductal endoscopy was used where possible to define ductal anatomy and map proliferative changes within the sick lobe if multifocal. Lumpectomy was fashioned on the basis of assumptions of the sick lobe hypothesis where this additional ductoscopic information made it possible.

Results: Breast conservation surgery for stage 0-2 breast cancer with an attempt to perform endoscopy in association with therapeutic lumpectomy was performed in 554 patients. Endoscopy was successful in identifying the duct connecting to the tumor in 465 cases. Endoscopy was unsuccessful in 16% of cases and these underwent traditional lumpectomy. With an average follow-up of >5 years for the entire group, annual hazard rate for local failure in traditional lumpectomy without ductal mapping was 0.97%/yr and for lumpectomy with ductal mapping and excision of entire sick lobe was 0.18%/yr. In ductal mapping cases, 42% of patients were found to have extensive disease within their "sick lobe."

Conclusions: Targeting breast cancer lumpectomy using ductal mapping with the philosophy of excision of regional abnormal proliferative activity seems associated with lower local failure rates in this nonrandomized series. Randomized clinical trials which address lumpectomy as would be defined by the new "sick lobe" hypothesis are needed.

Method of Detection of New Breast Cancers in Women Aged 40-49: A Review of the Data From the Cambridge Breast Center

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Objectives: Debate persists as to the value of mammography in younger women and when to begin screening mammography. The American Cancer Society advises women to begin screening at age 40. Mammography is known to be less sensitive in women with dense breast tissue, which is commonly seen in young women. In addition, there is a lower incidence of breast cancer in women under 50. For these reasons, primary care physicians may not advise women to begin screening until their 50s. This retrospective review identifies the number of women aged 40-49 with new breast cancers detected on screening versus diagnostic mammography.

Methods: Patients with new breast cancer diagnosed between September 2005 and December 2008 were identified from the Cambridge Breast Center database. Patients were excluded if they had a history of breast cancer prior to September 2005, were transferring care from another institution, had LCIS, were male breast cancer patients, or did not have ductal or lobular carcinoma (eg, breast lymphoma). A subset of women aged 40-49 were reviewed. Within each subset, the method of detection (ie, screening vs diagnostic mammography), stage of disease at diagnosis, and breast conservation rates were studied.

Results: The number of cancers in women aged 40-49 found on screening and diagnostic mammography was 18/39 (46%) versus 21/39 (54%). In the diagnostic group, 2 patients had stage 0, 7 patients had stage 1, 9 patients had stage 2, and 3 patients had stage 3 disease. Two patients in the diagnostic group developed metastatic disease during the study period. More patients underwent mastectomy in the diagnostic group than in the screening group (57% vs 27%). In the screening group, 5 patients had stage 0, 8 patients had stage 1, and 5 patients had stage 2 disease. There were no patients with stage 3 or 4 disease. More patients in the screening group were amenable to breast conservation (73% vs 43%).

Conclusions: Approximately 18% of women with breast cancer in our population were aged 40-49. Of these women, 46% of cancers were found by screening mammography. Of the 54% of cancers found by diagnostic studies, more than half of these women had never had a mammogram. More cancers detected by diagnostic studies were of later stage and required mastectomy. There were no stage 3 or 4 disease in the screening group and 2 women in the diagnostic group developed metastatic disease in the study period. Based on our experience, we strongly advocate screening mammography beginning at age 40 in our population.

Invasive Potential of DCIS: Human Ductal Carcinoma In Situ Contains Malignant Progenitor Cells

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Objectives: It has been hypothesized that a majority, if not all, of invasive breast cancer progresses from a ductal carcinoma in situ (DCIS) precursor stage. To test this hypothesis, this study (A) tested whether xenotransplanted DCIS living structures will grow as neoplasms and invade in vivo in NOD SCID mice, and (B) established and characterized the existence of human DCIS derived progenitor cell lines that can be propagated in vivo and in vitro.

Methods: This study directly and functionally studied the molecular origin of the invasive phenotype using fresh living human DCIS tissue and employing a novel organ culture and microdissection technology This study utilized leftover pure DCIS or DCIS admixed with invasive breast cancer tissue, not required for diagnosis, obtained at the time of standard-of-care work-up for a suspicious breast lesion.

Results: Multiple independent xenograft transplants of human intermediate/high-grade DCIS lesions (n = 18), with no histological evidence of invasive carcinoma, generated 16 xenograft tumors within 1 month in NOD SCID mice. In vitro cultivation successfully propagated DCIS derived cells with anchorage independent growth and spheroid formation, in serum free medium supplemented with EGF, insulin, and estrogen. We then isolated, characterized (profile of 48 signal pathway proteins, epithelial antigens and stem cell markers), and propagated (without the requirement for extrinsic immortalization) the invasive DCIS epithelial cells possessing progenitor cell characteristics.

Conclusions: This demonstrated that individual fresh human DCIS neoplastic cells already possess the full capacity for functional tissue invasion in mouse xenograft models. It further characterises the nature of invasive progenitor cells within DCIS. These findings support an exciting new hypothesis: Invasive capacity arises early but is being held in check in the breast ductal niche microenvironment. The functional insights and our novel model system for studying the functional biologic invasive phenotype in individual human breast premalignant lesions will offer a new approach for developing and testing individualized chemoprevention and intervention strategies for DCIS.

The Use of Breast MRI Surveillance in Women at High Risk for Breast Cancer: A Single Institutional Experience

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Objectives: Studies have validated the role of breast magnetic resonance imaging (MRI) screening for high-risk patients. The reported specificity, need for additional imaging, and biopsy rates vary. The current study aims were to determine the indications for MRI use, false-positive rates, and correlation with routine breast imaging at our institution.

Methods: We reviewed 275 breast MRIs performed on 200 high-risk patients between 2005 and 2008. Data included number of patients requiring second-look imaging, number and result of additional biopsies, and correlation of MRI findings with routine imaging. Gail scores were calculated based on the patient's personal and family history.

Results: During the study period, 200 high-risk patients underwent 275 breast MRIs. The average age of the study population was 45 (range, 18-76). Gail scores were calculated for 108 patients; the average Gail score was 25%. An additional 21 patients had known BRCA1 or BRCA2 mutations, 10 patients previously received radiation therapy for Hodgkin's lymphoma, and Gail scores were unable to be calculated for 61 patients. Of the 275 MRIs, 49 (18%) had suspicious findings requiring second-look ultrasound. Twenty-one of the 49 (8% of total) undergoing second-look ultrasound required biopsy. Of the 21 patients undergoing biopsy, 4 (2%) had a malignancy (2 invasive, 2 in situ). Two of the 4 cancers were also visible on routine breast imaging performed concurrently with the MRI. One cancer was detected in a BRCA carrier, 1 was in a patient who had previous radiation, and 2 were in patients undergoing breast MRI for a >20% estimated lifetime risk. The false-positive rate for breast MRI screening in our cohort of high-risk patients was 17%.

Conclusions: Despite appropriate patient selection according to risk assessment tools, the rate of cancer detection in high-risk patients undergoing breast MRI at our institution is only 2%. The need for additional imaging and biopsy remains high. Although breast MRI may provide benefits when compared to routine mammographic screening for some high-risk women, further analysis is necessary to determine if this strategy is cost-effective.

MammaPrint Feasibility in a Large Academic Medical Center: Initial Experience

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Objectives: Mammaprint (MP), the 70-gene prognosis-signature tool, has been validated in many European studies. Prospective multicenter trails are ongoing to validate its applicability in the U.S. The purpose of our study was to evaluate the ease of implementing such a prognostic tool in a large tertiary care center. We also wanted to evaluate, within our diverse patient population, the risk and receptor assessment by MammaPrint and compare it with established methods.

Methods: The patient population was from the Breast Center at Columbia University. Our prospective study accrued 56 breast cancer patients, with a tumor size of 1 cm or greater. We used this size to allow for adequate tissue for our pathology lab. A sample of the fresh breast tumor was taken from the OR to the pathology lab and then sent via courier in dry ice to Agendia Labs BV. The RNA was harvested and analyzed for 70-gene MP profile and estrogen (ER), progesterone (PR), and Her-2-neu oncogene (HER2) receptors, called TargetPrint (TP). The tumors were independently evaluated by the pathology department at Columbia University for usual histology and for ER, PR, and HER-2 status by using immuno-histochemical stains and FISH. A database was established to analyze results.

Results Over 1 year, 56 MammaPrint results from 56 patients were obtained. We were able to capture 40% (56/139) of patients who were eligible for MP analysis. Forty-three (76%) of these had adequate RNA integrity for analysis and the rest (23%) had inadequate RNA or quantity not sufficient (QNS). The surgical specimens included 19 mastectomies, 34 lumpectomies, and 2 core biopsies. The ethnic distribution was 37 (67%) whites and 18 (33%) nonwhites, which included 9 (16%) Hispanics, 6 (11%) blacks, and 3 (5%) Asians. Thirty-three (60%) patients were found to be high risk, 7 (13%) low risk, and 15 (27%) QNS. Three patients did not undergo TargetPrint analysis. We also saw a rise in capture over the last 6 months of accrual (43 vs 13). Nine discordant results were found in 8 patients when comparing receptor status (2 ER, 6 PR, and 1 HER2), without a definable pattern. By discordant, we mean the receptor results are positive while our lab assessment by IHC/FISH were negative (or vice versa).

Conclusions: MammaPrint was successfully implemented in a large tertiary medical center. The 8 patients with discordant receptor results (18%), as well as risk status reports, may potentially result in significant change in clinical management. The ability to implement the test in a diverse patient population makes this a potentially important tool for patient care.

Pure Tubular Carcinoma of the Breast

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Objectives: Tubular carcinoma (TC) of the breast is recognized as a variant of infiltrating ductal carcinoma with low potential for spread to axillary lymph nodes (ALN), metastasis, and recurrence after extirpation. Several reports have examined the frequency of lymph node metastasis in patients with TC and postulated that axillary staging could potentially be omitted in this population. The aim of our study was to determine the frequency of axillary lymph node metastasis in patients with pure TC.

Methods: With IRB approval we retrospectively identified patients diagnosed with TC from 1987-2009 in our institution's cancer registry. All identified cases were reviewed by 2 breast pathologists. Pure TC was defined as having >90% tubule formation, low nuclear grade, and rare-to-no mitoses. Medical records were reviewed for clinicopathologic data, including tumor size, number of positive and negative sentinel lymph nodes (SLNs) and ALNs, treatment, and recurrence.

Results: One hundred four cases (102 women) of pure TC were identified. Median age was 61 years (43-86). Median tumor size was 0.8 cm (range, 0.1-1.8). The tumors were estrogen receptor positive and progesterone receptor positive in 96% (50/52) and 92% (48/52) of tested cases, respectively. Her2 testing was negative in all 5 cases tested. Axillary nodes were staged as follows: SLN surgery (55), SLN and ALND (17), ALND (19), and none (13). Five patients received adjuvant chemotherapy and are alive without evidence of disease. With median follow-up of 5.2 years (range, 0.1-16.5), 1 patient has recurred locally and 11 patients have died of causes unrelated to breast cancer. In the 91 cases with axillary staging, the median tumor size was 0.8 cm (range, 0.1-1.8), of which 83 cases (91%) were node-negative and 8 cases (9%) were node-positive. Cases with positive nodes had tumor sizes of 0.5, 0.9, 0.9, 1.0, 1.1, 1.2, 1.3, and 1.5, respectively. Six cases had 1 positive node, 1 had 2 positive nodes, and 1 had 3 positive nodes. Mean tumor size was greater in the node-positive cases (1.05 cm; median, 1.1; range, 0.5-1.5) compared with 0.85 cm (median, 0.8; range, 0.1-1.8) for the node-negative cases (P = 0.101, Wilcoxon rank sum test) although this did not reach statistical significance. Seven of the 45 cases that were >0.8 cm (i.e., the median tumor size for this cohort) had at least 1 positive LN compared with only 1 of the 46 cases that were ≤0.8 cm (16% vs 2%, P = 0.030, Fisher's exact test). There were no significant differences between the node-positive and node-negative cases in terms of patient age, ER positivity, PR positivity, or multifocality of disease (see table).

	Node-positive (n = 8)	**Node-negative (n = 83)**	***P* value**
Age (median)	56	57	0.68
Tumor size (cm, median)	1.05	0.80	0.10
ER positive	100%	96%	1.00
PR positive	100%	91%	1.00
Multifocal	0%	8%	1.00

Conclusions: Axillary metastases are uncommon in pure tubular carcinoma and nodal positivity is rare with tumors 0.8 cm or less in size. Most are hormone receptor positive and have a low local recurrence rate.

Molecular Subtype Profile Reveals Therapy Predictive Power

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Objectives: Classification of breast cancers into molecular subtypes may be important for accurate selection of therapy for patients. Here we report the respective chemotherapy responsiveness of the molecular subtype profile defined Luminal, Her2, and Basal type. Also, we report on conversion of this robust gene expression profile to a high-throughput, extensively validated clinical diagnostic tool.

Methods: An 80-gene subtype profile was developed based on a series of 200 samples with concordant ER, PR and Her2 receptor IHC and single gene readout status. Previously we reported the excellent validation of the profile classification using 784 samples. Here we report a second in silico validation consisting of 133 samples (Hess et al, JCO, 2006) which tested the profile as a predictor of pathological Complete Response (pCR) in these patients treated with T/FAC neoadjuvant chemotherapy. Currently, experiments are carried out on custom-made diagnostic microarrays to determine the test reproducibility, accuracy, and precision.

Results: In the 133 publicly available samples, the profile classified 62% (82) as Luminal-type, 18% (24) as Her2-type, and 20% (27) as Basal-type. These results were consistent with percentages found in the training and validation cohorts (n = 1079; 295 training and 784 validation samples); 66% (712) Luminal-type, 18% (194) as Her2-type, and 16% (173) Basal-type. Chemotherapy response was measured by pCR at the time of surgery. In the Luminal-type subgroup, 9% (7) of patients showed pCR; in the Her2-type subgroup, 50% (12) of patients had a pCR; and in the Basal-type subgroup, 56% (15) of patients had a pCR. To make the test available clinically, the profile was translated into a diagnostic test using the Agilent 8-pack format that supports high throughput, high quality, and robustness.

Conclusions: The developed multi-gene profile can classify breast cancer tumors into Luminal-, Her2-, and Basal-type subgroups. Within the subgroups, a significant difference in chemotherapy response, as measured by pCR, is observed. Implementation of this knowledge may improve the clinical management of breast cancer patients, by enabling the physician to decide who is most likely to benefit from chemotherapy or endocrine therapy prior to surgery. The 8-pack custom microarray is suitable for use in a high-throughput clinical diagnostic environment.

Upper Extremity Lymphedema Rates Following Sentinel Lymph Node Biopsy for Breast Cancer

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Objectives: Lymphedema (LE) is a common and often debilitating complication following axillary lymph node dissection (ALND) for breast cancer. The rates of LE following ALND have been well documented in the literature, as ALND was previously the standard of care for patients with invasive breast cancer. The less invasive sentinel lymph node biopsy (SLNB) procedure has become the standard of care, sparing patients from a complete ALND if the sentinel lymph nodes are negative. Initial evidence has pointed to a significant decrease in rates of LE following SLNB for breast cancer surgery; however data is limited as various definitions of LE have been utilized in individual studies. The current study followed a cohort of breast cancer patients from 2004 to 2009 that have undergone SLNB to determine rates of LE as defined by the American College of Surgeons Oncology Group (ACSOG) Z0010 related to SLNB.

Methods: Patients undergoing SLNB were enrolled in an IRB-approved, single-phase prospective study that included measurements of the right and left upper extremities at the upper and forearm locations preoperatively and then at 6-, 12-, and 24-month intervals postoperatively. Measurements were recorded and stored in a secure database according to unique patient identification numbers. LE was defined as an increase in arm diameter greater than 2 cm as compared to the contralateral or control arm as per ACSOG Z0010.

Results: A total of 8 (7.7%) of the enrolled 103 patients experienced LE. However, 6 of those 8 patients required ALND due to positive SLNs. As a result, 2 (2%) of the 97 patients who underwent SLNB developed LE. Both of those patients had a total of 2 lymph nodes removed and had breast conservation with postoperative radiation therapy to the breast. There were 6 (26%) of 23 patients who developed LE following ALND. Those patients had a range of 10 to 40 nodes removed at time of surgery.

Conclusions: Reported LE rates following SLNB in patients with breast cancer are in the range of 7-10%, as compared to ALND rates of 20-30%. Our results demonstrate an LE rate of 2% in women undergoing SLNB, compared to 26% in patients who required ALND. Potential reasons for the lower rate of LE for patients undergoing SLNB at this institution may include the education of all patients before and after surgery about LE prevention, and closer monitoring of all patients regardless of the procedure they had. Future studies evaluating patients for changes in arm circumferences less than 2 cm are necessary.

Sonographic Tomography of the Breast and Axilla for the Preoperative Staging of Breast Cancer Prior to Definitive Surgery

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Objectives: Sonographic tomography is a new ultrasound-based imaging technique that allows for the diagnostic evaluation of the entire breast and axilla. This study was performed to assess the accuracy of sonographic tomography as compared to MRI in the determination of the exact extent of disease prior to definitive surgery for breast cancer.

Methods: Forty-one women who presented with either clinical or radiologic abnormalities were diagnosed with breast cancer following a diagnostic work-up with sonographic tomography and core-needle biopsy between August 2007 and June 2008 in an outpatient clinic. All these women, subsequent to their diagnosis, underwent bilateral contrast-enhanced MRI prior to surgery to determine if there were areas of tumor extension, multifocality, axillary adenopathy, or contralateral disease that would affect their planned surgery. Following definitive surgery, both imaging techniques were then compared retrospectively for accuracy with surgical pathology findings.

Results: Sonographic tomography accurately staged breast cancer preoperatively in 68% of cases, while MRI did so in 54% of cases. The resulting improvement in overall accuracy is 14% (2-28%).

Conclusions: Sonographic tomography appears noninferior to contrast-enhanced breast MRI in the determination of the extent of disease prior to definitive breast cancer surgery. Further, prospective study is needed to further evaluate this new imaging technique for preoperative staging prior to definitive surgery.

Preoperative Staging With Magnetic Resonance Imaging and Confirmatory Biopsy Improves Surgical Outcomes in Women With Breast Cancer Without Increasing Rates of Mastectomy

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Objectives: The use of MRI for the staging of breast cancer prior to definitive surgery is controversial. MRI is known to detect additional foci of disease that can change surgical plans, but false-negative findings can lead to unnecessary mastectomy. The use of needle biopsy to evaluate findings on MRI that could alter surgical planning has been recommended, but never studied. This study is a retrospective review to evaluate the effect of MRI preoperative staging with biopsy confirmation of suspicious findings on rates of reoperative surgery, conversion to mastectomy after attempted conservation, and successful breast conservation.

Methods: One hundred eighty-four women were diagnosed with breast cancer by needle biopsy in an outpatient clinic between January 2004 and June 2008. Of these, 79 underwent bilateral, contrast-enhanced breast MRI before definitive surgery and 105 did not. Suspicious findings on MRI, other imaging studies, or clinical exam that could alter planned surgery underwent repeat needle biopsy at the discretion of the surgeon. A retrospective chart review was performed to compare the 2 groups with respect to rates of reoperative surgery, conversion to mastectomy after a failed attempt at conservation, successful breast conservation, and confirmatory biopsies.

Results: Sensitivity and specificity of MRI for preoperative staging is 0.81 and 0.84, respectively. There was no significant difference between the groups in age, menopausal status, stage, or receptor status. Fewer women who undergo preoperative staging required repeat surgery (12% vs 27%, $P = 0.004$) or required a mastectomy after a failed attempt at conservative therapy (9% vs 24%, $P = 0.05$). There is no difference in the proportion of women who successfully completed conservative therapy and those treated radically (52% vs 53%), but there is a significant increase in women who undergo repeat needle biopsy to confirm suspicious findings after initial diagnosis in the MRI group (25% vs 11%, $P = 0.04$).

Conclusions: Preoperative staging with MRI and confirmatory biopsy can improve surgical outcomes by decreasing the number of women returned to the operating room for repeat operative procedures or conversion to mastectomy after an initial attempt at conservation. Mastectomy rates are not increased; suggesting that women who undergo mastectomy following staging would undergo mastectomy following failed conservative therapy if they were not staged. Prospective study is needed to further evaluate this hypothesis. The cost of this improvement is a 14% increase in women who require confirmatory biopsy.

Reliability of Preoperative Percutaneous Biopsy of Sonographically Suspicious Axillary Lymph Nodes in Invasive Breast Cancer

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Objectives: Our objective in this project was to determine the accuracy of percutaneous biopsy of suspicious axillary lymph nodes.

Methods: Ultrasound of the breast is part of the routine diagnostic work-up of breast cancer patients. Axillary ultrasound with percutaneous biopsy of suspicious lymph nodes can provide useful information both to guide surgical management, as well as consideration of neoadjuvant therapy. We performed a retrospective review of all axillary ultrasound-guided percutaneous biopsies performed at our institution between 2003 and 2007. Suspicious-appearing lymph nodes underwent either fine needle aspiration (FNA) biopsy or core needle biopsy of the lymph node. Cytology of FNA was reported as positive for malignancy, reactive change, or negative for malignancy.

Results: Two hundred ten patients underwent axillary ultrasound with percutaneous biopsy of a single axillary node, 175 with FNA and 35 with core biopsy. One hundred forty-six patients (70%) had a positive FNA or core biopsy of an axillary node, obviating the need for sentinel lymph node biopsy. In the group of 64 patients with negative or reactive findings, 17 patients (27%) had positive nodes at the time of axillary surgery and the remaining 47 (73%) had negative axillary nodes at surgery. Further dividing these 64 patients into 2 groups (negative vs reactive findings), patients with a negative biopsy had similar rates of positive nodes at axillary surgery (7/30 = 23%) compared to those with reactive findings on axillary biopsy (10/34 = 29%). With regard to biopsy technique, 92% (32/35) of nodes sampled with core biopsy were positive vs 65% (114/175) of nodes biopsied with FNA, likely reflecting some selection bias for use of core biopsy technique in nodes with a higher tumor burden. None of the patients undergoing percutaneous biopsy had a complication due to the procedure. There were 24 patients in our study with biopsy-proven axillary metastases who underwent neoadjuvant chemotherapy. At axillary dissection, 11 had negative lymph nodes, 12 had positive nodes, and 1 patient refused axillary surgery. Excluding these neoadjuvant patients, the sensitivity of axillary ultrasound/biopsy was 88% (122/139), specificity was 100% (47/47), and positive predictive value was 100% (122/122).

Conclusions: Percutaneous biopsy of suspicious axillary lymph nodes provides information that aids in treatment planning. When percutaneous biopsy is positive, it is highly reliable and sentinel node biopsy is not necessary. Negative and reactive results with axillary lymph node biopsy resulted in similar rates of positive axillary nodes at surgery. The techniques are safe and have a low complication rate.

Too Many Mastectomies? Patients' Perceptions on Breast Surgery

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Objectives: The number of patients choosing mastectomy is increasing. We assessed patients' perceptions on their decision-making process.

Methods: A chart review and survey was conducted for female patients who underwent mastectomy surgery by 1 surgeon between June 1, 2008, and October 31, 2009.

Results: Fifty female patients underwent 73 mastectomies. Twenty-six mastectomies were for traditional indications, including large cancer size relative to breast size, multicentricity, locally advanced disease, or recurrent breast cancer following prior lumpectomy and radiotherapy. Five were performed for failed attempts at breast-conserving surgery. Sixteen mastectomies were chosen over lumpectomy. One was selected for a large phyllodes tumor. One was for an unknown breast primary with axillary involvement and contralateral locally advanced breast cancer. Twenty-four mastectomies were prophylactic. Forty-three patients completed a survey pertaining to their reasoning behind mastectomy surgery. Twenty-two respondents selected mastectomy for piece of mind in helping ensure removal of their cancer with a decreased risk for recurrence. Seven cited size of disease, multicentricity, or locally advanced breast cancer as their main consideration in having a mastectomy. Three associated mastectomy with survival. Three felt their doctors' recommendations caused them to choose mastectomy. Two preferred mastectomy due to family history. Two wanted to try to avoid radiation. Two chose mastectomy due to failed breast conservation. One opted for mastectomy because of bilateral breast cancer. One felt interpretation of her breast imaging was too difficult as a greater extent of disease was found on final pathologic assessment compared with what was anticipated based on preoperative imaging.

Conclusions: Patients were uniformly happy with their decision to pursue mastectomy. When asked if they would have done anything differently, most patients would not have changed a thing. However, 2 patients wished they had chosen mastectomy over initial lumpectomy. One would have opted for no reconstruction, while 1 would have delayed reconstruction. One would have preferred prophylactic mastectomy in addition to the mastectomy for her cancer. Interestingly, 2 of the 22 patients who underwent prophylactic mastectomy would not have chosen prophylactic surgery if they had to choose again.

Obese Patients Present With More Advanced Cancers: The Impact of Obesity on Breast Cancer

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Objectives: Obesity has been linked to many adverse health consequences, including breast cancer. The effect of obesity on clinical presentation, tumor characteristics, and ultimate outcome in breast cancer still needs to be defined. Our goal was to obtain a better understanding of the impact of obesity on breast cancer so as to aid healthcare providers in screening, counseling, and planning therapeutic interventions.

Methods: Retrospective review of a prospectively collected database of patients treated at a single institution for invasive breast cancer from 2000 to 2008 was carried out. We compared 2 groups: women classified as non-obese (BMI < 30) and women who were classified as obese (BMI ≥ 30). Continuous variables were compared between the 2 groups using ANOVA F tests and categorical variables were compared using chi-square tests. Survival data was analyzed using Kaplan-Meier analysis.

Results: Of 1352 total patients, 1026 (76%) were classified as non-obese and 327 (24%) were obese. Although there was no difference in mean age between the groups, fewer obese breast cancer patients presented at young ages: 2% of obese patients <40 years old; 8%, 40-50; and 90%, >50 years (vs 4%, 14%, and 82% for nonobese patients, $P = 0.0019$). Obese patients were more likely to present with disease on imaging rather than by clinical exam (67% vs 56%, $P = 0.0006$). This difference was almost entirely due to a lower rate of obese patients presenting with masses on self–breast exam (28% vs 38% for non-obese patients) as the rate of cancer presenting by the detection of a mass by clinical breast exam was 5% for obese patients and 6% for non-obese patients were similar ($P = 0.0066$). Seventy-one percent of obese patients had tumors <2 cm versus 79% of non-obese patients, even though tumors in obese patients were less likely to be palpable ($P = 0.0045$). Obese patients were significantly more likely to have lymph node metastases (31% vs 25%, $P = 0.026$). Rates of breast conservation therapy were 69% for obese patients and 70% for non-obese patients (P = NS), but obese patients underwent immediate reconstruction when they were treated with mastectomy only 29% of the time versus 47% of non-obese patients ($P = 0.0058$). No differences between groups were seen with regard to adjuvant therapy, recurrence, family history, or tumor markers (ER, PR, Her2). On multivariate analysis, obese patients trended toward a worse overall survival with a hazard ratio of 1.53 (95% CI, 0.97-2.53).

Conclusions: Obese patients are more likely to present with nonpalpable tumors that are larger and have a higher rate of lymph node metastases compared to non-obese patients. Obesity does not appear to impact expression of tumor markers. Obesity did not result in differences in treatment except for a lower rate of immediate reconstruction among obese patients. Even though there was no difference in adjuvant therapy, obese patients had a worse survival, perhaps due to lead-time bias. Consequently, timely radiologic screening is critical in this group of patients.

Areolar- and Nipple Areolar–Sparing Mastectomy for Breast Cancer Treatment and Prevention—Report of an Initial Experience in the Community Hospital Setting

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Objectives: The use of areolar-sparing (AS) or nipple areolar–sparing (NAS) mastectomy for the treatment or prevention of breast cancer has been the subject of increasing dialogue in the surgical literature over the past decade. The majority of reports on this subject have come from academic institutions. We report the initial experience of a large community hospital with AS and NAS mastectomies for both breast cancer treatment and prevention.

Methods: A retrospective chart review was performed of patients undergoing either AS or NAS mastectomies from November 2004 through September 2009. Data collected included patient gender, age, family history, cancer type and stage, operative surgical details, complications, adjuvant therapies, and follow-up.

Results: Forty-three patients underwent 60 AS and NAS mastectomies. Forty-two patients were female and 1 was male. The average age was 48.7 years (range, 28 to 76 years). Forty mastectomies were for breast cancer treatment and 20 were prophylactic mastectomies. The types of cancers treated were: invasive ductal (19), invasive lobular (5), DCIS (15), and malignant phyllodes (1). Forty-seven mastectomies (78.3%) were performed using inframammary incisions. Biopsy and coring of the nipple was performed in all NAS mastectomies. All patients underwent immediate reconstruction with either tissue expanders or permanent implants. There was a 5.0% incidence of full-thickness skin, areolar, or nipple tissue loss. Other complications included post-op bleeding (1), infection (2), or early removal of tissue expanders (3). The average follow-up of the series was 14.5 months (range, 1 to 59 months). One patient developed Paget's disease of the areola 34 months after an AS mastectomy (recurrence rate = 2.5%). No other instances of local recurrence have occurred.

Conclusions: AS and NAS mastectomies can be safely performed in the community hospital setting with low complication rates and good short-term results. These procedures are starting to be viewed in our community as possible alternatives to skin-sparing mastectomies in properly selected cases of breast cancer and for prophylactic mastectomies.

Mammographic Arterial Calcifications and 10-Year Risk for Coronary Artery Disease

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Objectives: To prospectively evaluate the value of mammographic arterial calcifications (MAC) identifying women at risk for coronary artery disease (CAD), based on Framingham risk score (FRS) testing. Several studies have indicated MAC identified on screening mammography may identify women at risk of CAD, diabetes, stroke, and peripheral vascular disease. FRS testing has been shown to reliably indicate a women's risk of developing CAD over the next 10 years. This study investigates the utility of mammography to identify women with no prior history of CAD or diabetes at increased risk of developing CAD bases on their FRS. The simultaneous use of screening mammography to screen for breast cancer and identifying women at risk for CAD could be very cost-effective tool for improving women's health since CAD is the leading cause of death in women over 50.

Methods: All women undergoing screening mammography at our institution over a 2-year period were asked to fill out a health questionnaire regarding their history of CAD and diabetes. All mammograms were evaluated for MAC by our breast health center's dedicated radiologists. Women with a self-reported history of CAD and/or diabetes were excluded from our study group. Women with no history of CAD or diabetes were contacted by our investigators and their blood pressure, serum cholesterol, and glucose, along with smoking history, were recorded. This data was used to calculate an FRS, which represents a validated tool to determine a 10- year risk for CAD. FRS, along with age and presence or absence of MAC, was recorded. Differences in FRS frequencies, according to presence or absence of MAC, were analyzed using chi-square test. Value of $P < 0.05$ was considered statistically significant**.**

Results: A total of 4361 women were screened by mammography in our institution. Of these, 3626 women had no personal history of CAD and/or diabetes. Three hundred eighty (10.48%) women were found to have MAC. A total of 75 women underwent FRS testing, of which 56 (75%) had MAC and 19 (25%) had absent MAC. Average age in both groups was 60 (43-69). The FRS in both populations (with and without MAC) ranged from less than 1% to 14%. Average FRS for both groups was not significantly different—it was 3.6% in the group without MAC, as opposed to 3.9% for the group with MAC. Women were subdivided according to FRS into 3 groups: minimal risk (FRS < 1%), low risk (FRS, 1-4%), and moderate risk (FRS > 5%). Difference in frequencies between subgroups was evaluated by chi-square test. Those women with MAC had a significantly higher FRS than women without MAC (P <0.0012).

Conclusions: Women with MAC had a significantly higher Framingham risk score > 1% as opposed to women without MAC. Similarly those women without MAC had a very low 10-year risk of developing CAD. This study continues to accrue patients. This study supports prior studies indicating vascular calcifications identified on screening mammography can identify a group of women at increased risk for developing CAD.

Framingham Risk Score	MAC (present)	MAC (absent)	MAC (present)	MAC (absent)	*P* value
0% to .99%	2	4	4%	21%	0.0012
1% to 4%	38	10	68%	53%	
5% to 14%	16	5	28%	26%	

A Single Intratumoral Injection of Tc 99 Sulfur Colloid for Tumor Localization and Sentinel Lymph Node Biopsy in Breast Cancer

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Objectives: Primary surgical principles in breast cancer involve removal of the tumor and axillary staging. The most common operation used to fulfill these principles is lumpectomy and sentinel lymph node biopsy. These 2 procedures are performed at the same setting but require different localization techniques. We describe our experience with a single procedure that is used to localize both the primary breast cancer and sentinel lymph nodes.

Methods: Patients included had ultrasound-detectable lesions that underwent lumpectomy and sentinel lymph node biopsy. On the afternoon before surgery, 3.1 mc of Tc sulfur colloid was injected directly into the tumor. After 5 minutes of massage, lymphoscintigraphy was performed. If no sentinel node was identified, the patient returned to nuclear medicine for repeat imaging the next morning. If lymphoscintigraphy was still negative, a subareolar injection of 1.5 mc of Tc sulfur colloid was performed. In the operating room, the Neoprobe was used to guide the excision of the primary tumor and the sentinel lymph node.

Results: Forty-one patients were treated with this localization protocol. Mean tumor size was 15.3 mm. Mean number of sentinel nodes removed was 4.1. Seventy-seven percent were postmenopausal. Negative initial surgical margins were achieved in 32 patients (78%). Lymphoscintigraphy was positive in 36 patients (88%) after the intratumoral injection. Two patients with negative lymphoscintigraphy were found to have radioactivity in the axilla by preoperative Neoprobe examination and 3 patients required an additional subareolar injection of Tc sulfur colloid (all 3 had upper outer quadrant tumors). In the beginning of the study, 7 patients also had wire localization performed until the surgeons gained confidence in the technique. For the 7 patients who had a wire placed, the average delay in operating room starting time was 39 minutes. For the 34 patients who did not have a localizing wire placed, the average delay in operating room starting time was 11 minutes. In addition, two-thirds of cases in which intratumoral injection alone was performed had operative delays of less than 5 minutes.

Conclusions: A single intratumoral injection of 3.1 mc Tc sulfur colloid is an effective localization technique for performing lumpectomy and sentinel node biopsy.

Survival Benefit of Surgery in Stage IV Breast Cancer Patients?

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Objectives: There is no standardized surgical treatment for patients who present with stage IV breast cancer. Traditionally surgery has been palliative, with primary treatment being systemic therapy with cytotoxic and/or hormonal agents. Several retrospective studies have cited an improved overall survival (OS) with extirpation of the primary tumor. We sought to determine if surgery in stage IV breast cancer patients confers a survival advantage.

Methods: We identified 319 female patients diagnosed with de novo stage IV breast cancer between 1985 and 2004. Data was collected from a prospectively maintained database and included age, tumor characteristics, type (chemotherapy and hormonal) and year of systemic treatment, surgical margin status, and number and location of metastatic sites. Kaplan-Meier curves were generated and the log-rank test compared differences in overall survival.

Results: One hundred ninety patients (60%) underwent resection of the primary tumor. Patients undergoing surgery for their primary tumor had a median survival of 35 months versus 25 months for those who did not (P = 0.024). Margin status did not impact survival. The median OS for patients with estrogen receptor (ER) positive tumors was 43 versus 23 months for those with ER negative tumors (P = 0.009). Patients with metastases at 1 site versus multiple sites had a median survival of 35 versus 23 months (P = 0.002). Inflammatory breast cancer patients had a median survival of 19 versus 35 months for those without (P = .0031). In multivariate analysis, including surgical treatment, histology type (invasive vs inflammatory), age group ($\leq$50 vs >50), ER status, systemic therapy, and number of metastatic sites (single vs multiple), significant factors associated with improved OS were noninflammatory histology type (P = 0.0011), ER positive status (P = 0.0195), and single metastatic site (P = 0.0141).

Conclusions: The improved overall survival seen in stage IV breast cancer patients undergoing surgical resection is primarily attributed to favorable tumor and clinical characteristics, not to surgical intervention. A randomized clinical trial is needed to ensure that the survival benefit seen in patients undergoing surgery is not due to selection bias.

The Preoperative Role of Breast-Specific Gamma Imaging for Breast Cancer Patients: A Comparison With Conventional Imaging Modalities

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Objectives: We wanted to assess the clinical efficacy of breast-specific gamma imaging (BSGI) as compared with that of conventional imaging modalities (mammography, ultrasonography, and MRI) as a presurgical examination for patients with breast cancer.

Methods: From April to May 2009, a retrospective review was performed for the prospectively collected 144 patients who were diagnosed with breast cancer. All the patients received a conventional imaging examination and BSGI before definitive surgery. The patients underwent BSGI with intravenous injection of 30 mCi of 99mTc-sestamibi through the contralateral antecubital vein. After 10 minutes, the craniocaudal (CC) and mediolateral oblique (MLO) images were obtained. All the imaging findings were correlated with the final pathologic examination.

Results: The mean age of the patients was 49.7 ± 9.4 years (range, 27-77). In 144 patients, 167 malignant lesions were identified by pathologic examination (invasive cancer, 97 [67%]; ductal carcinoma in situ, 14 [10%]; and invasive cancer with carcinoma in situ, 33 [23%]). The conventional imaging modalities found 167 malignant lesions and BSGI found 156 malignant lesions. The rate of correspondence was 93.4% between the conventional imaging modalities and BSGI for malignant lesions. For BSGI, there were 8 false-positive findings and 11 false-negative findings. BSGI found no occult cancers that were missed by conventional imaging modality. For making the diagnosis of axillary lymph node metastasis, the sensitivity, specificity, and accuracy were 33%, 92%, and 69% for BSGI and 56%, 78%, and 69% for USG, respectively.

Conclusions: BSGI may have the potentiality to make a correct diagnosis in breast cancer patients. However, in this study, it seems that BSGI is not superior to conventional imaging modalities. BSGI is not a standard method to evaluate breast cancer lesions before surgery.

Nine-Month Follow-Up Results of a Trial Utilizing Xoft Axxent Electronic Brachytherapy To Deliver Intraoperative Radiation Therapy for the Early-Stage Breast Cancer Treatment

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Objectives: Accelerated partial breast irradiation (APBI) is emerging as a valid alternative to whole-breast radiation therapy (WBRT) in breast-conserving therapy (BCT) for early-stage breast cancer. Xoft Axxent Electronic Brachytherapy (XB) is a form of portable, balloon-based APBI that utilizes an electronic source for kilovoltage irradiation delivery and has minimal shielding requirements. As such, XB becomes a logical and convenient modality for delivery of intraoperative radiation therapy (IORT). We report initial results and clinical outcomes of a trial that utilizes XB to deliver IORT for patients with early-stage breast cancer.

Methods: Eleven patients were enrolled on an IRB-approved protocol. Inclusion criteria included patients >45 years of age, unifocal tumors with infiltrating ductal or DCIS histology, tumors ≤3 cm, and uninvolved lymph nodes. Intraoperative ultrasound was used to verify a minimum 1 cm of balloon-to-skin distance, as well as to evaluate the conformance of the balloon to the surrounding breast tissue. A pliable lead shield was placed over the pectoralis fascia prior to delivery of radiation. Pre-loaded radiation plans for balloon inflation sizes of 40 cc to 70 cc were used to deliver radiation prescription dose of 20 Gy to the balloon surface.

Results: The mean time for radiation delivery was 22 minutes and the total mean procedure time was 1 hour 39 minutes. The mean balloon-to-skin distance by ultrasound was 1.4 cm. All margins of excision were negative on final pathology. At a mean follow-up of 9 months, overall cosmesis was rated as excellent in 6 of 11 patients and good in the remaining 5. Three patients reported mild postoperative breast pain, 3 patients developed mild erythema of the skin, 1 patient developed grade 2 fibrosis, and 1 patient developed grade 1 fibrosis. To date, no infection, fat necrosis, desquamation, rib fracture, or cancer recurrence had been observed.

Conclusions: IORT utilizing XB is emerging as a feasible, well-tolerated, and patient-friendly alternative to APBI. Further research and longer follow-up data on XB and other IORT methods is needed to establish clinical efficacy and safety on this treatment.

Diagnostic Excision Is Warranted for Pleomorphic Lobular Carcinoma In Situ

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Objectives: Pleomorphic lobular carcinoma in situ (PLCIS) is a rare variant of LCIS that histologically mimics DCIS, but for which the optimal management remains unknown. When found on core needle sampling, excisional biopsy is recommended for definitive diagnosis. However, there is no consensus as to whether PLCIS should be managed as a preinvasive neoplasm with excision to negative margins or whether close follow-up and/or chemoprevention may be offered. We examined the management of patients diagnosed with isolated PLCIS on biopsy to clarify its clinical significance.

Methods: An IRB-approved retrospective chart review of all patients diagnosed with isolated PLCIS on core (n = 7) or excisional (n = 7) biopsy from 1992-2009 was performed. PLCIS with concomitant DCIS or invasive cancer on initial biopsy, or cases identified in patients with a prior personal history of breast cancer, were excluded.

Results: There were 14 patients diagnosed with isolated PLCIS on initial biopsy. All 7 patients initially diagnosed on percutaneous core needle biopsy with PLCIS underwent subsequent surgical excision, and 4 individuals upstaged to DCIS and/or invasive cancer. The 7 patients initially diagnosed on excisional biopsy all had PLCIS close to (≤2 mm) or involving surgical margins, and 5 underwent re-excision, revealing DCIS or invasive cancer in 4.

Method of Initial PLCIS Diagnosis	No Additional Surgery	PLCIS Alone	PLCIS+ Dcis	PLCIS+ Invasive Cancer
Core needle biopsy (n = 7)	0	3	2	2
Surgical excisional biopsy (n = 7)	2	1	2	2
Total (n = 14)	2	4	4	4

There were 7 patients with close or positive PLCIS margins among the 12 who had a subsequent surgical excision. Two of these 7 patients underwent immediate mastectomies and both had PLCIS positive mastectomy margins. Four of the 7 underwent multiple attempts at re-excision to attain PLCIS negative margins, failing in 2 patients who later had mastectomies due to PLCIS+DCIS positive margins and anxiety in the case of the second. One patient did not undergo additional surgery. Of the initial 14 patients, 6 ultimately underwent mastectomies, 4 bilateral. Ultimately, there were 5 patients with persistently close or positive PLCIS margins. Three were placed on adjuvant tamoxifen or aromatase inhibitor, although none received radiotherapy specifically for PLCIS. There have been no cancer recurrences to date (mean follow-up, 43.2 months).

Conclusions: This is the largest series describing the management and outcomes when isolated PLCIS is found on initial biopsy. Patients with pleomorphic LCIS identified on a diagnostic biopsy are at very high risk of harboring DCIS or invasive cancer at subsequent therapeutic excision. Excisional biopsy should be performed following a core needle biopsy diagnosis of PLCIS, with generous sampling at the time of excisional biopsy warranted to rule out concomitant DCIS or invasive carcinoma. The presence of PLCIS at margins is common in both lumpectomy and mastectomy specimens, and rates of breast conservation appear low when PLCIS negative margins are pursued. Although limited by small study size, PLCIS positive margins do not appear to incur a higher risk of developing cancer.

Abstract Withdrawn

The Diagnostic Reliability of Nipple Discharge Cytology

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Objectives: The most common etiologies of pathologic nipple discharge are papilloma and fibrocystic changes. The incidence of occult malignancy in women who present with nipple discharge in the absence of image abnormalities is <3%. Nipple fluid cytology is a simple and potentially reliable method of diagnosing a pathologic etiology. In this study, we set out to determine the negative predictive value of nipple discharge at our institution.

Methods: Cases were identified via a database from the Department of Pathology. A retrospective chart review was performed on female patients, ages 26 to 80, who underwent cytologic evaluation of nipple discharge from 1998 to 2007. Patients who presented with pathologic discharge, without palpable findings on clinical exam, and subsequently had surgical excision were selected. These patients were then separated into those with breast imaging abnormalities (mammogram, ultrasound, galactogram, and MRI) and those without imaging abnormalities. Nipple discharge is routinely submitted as a dry smear or placed in a methanol-based preservative. Cytologic diagnoses are categorized as negative, atypical, or suspicious for papillary neoplasm, and definitive papillary neoplasm. Operative procedures were duct excision/ breast biopsy with or without ductoscopy. Final surgical pathology was separated into papilloma, cancer or atypia with or without papilloma, or benign (fibrocystic changes and duct ectasia).

Results: Eighty-eight patients were selected. The majority of the patients presenting with pathologic discharge were 40 to 49 years of age regardless of breast imaging findings. Final surgical pathology showed papilloma in 46 patients, of which 14 had negative cytology; fibrocystic changes/benign findings in 28 patients, of which 9 had negative cytology; and 14 patients with cancer or atypia, of which 3 had negative cytology. The patients were then separated based on their imaging findings. Suspicious findings on breast imaging included calcifications, masses, dilated ducts with filling defects, and focal retroareolar MRI enhancements. Negative imaging was seen in 9 of 26 patients with negative cytology, 34 of 57 patients with suspicious or atypical cytology, and 4 of 5 patients with definitive papilloma cytology. The negative predictive value of nipple discharge cytology increases when there are no abnormalities seen on breast imaging, 79.6% compared to 62%. The positive predictive value of nipple cytology increases with suspicious findings on breast imaging, 76% compared to 65%.

Conclusions: Together with breast imaging, nipple cytology is a useful adjunct in the work-up of women with pathologic nipple discharge.

Does Blue Dye Contribute to the Success of Sentinel Node Mapping for Breast Cancer?

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Objectives: Although initial sentinel lymph node (SLN) mapping studies suggested that dual mapping with blue dye and radioisotope decreased false-negative rates, concerns about allergic reactions have caused many surgeons to abandon routine use of the blue dye. We sought to evaluate the utilization of blue dye in addition to isotope and its relative contribution to SLN identification rates and potential false-negative rates at a high-volume institution.

Methods: Using a prospectively maintained database, 3402 clinically node-negative breast cancer patients who underwent SLN dissection between 2002 and 2006 were identified. Trends in utilization of the 2 techniques and results of SLN mapping were assessed through retrospective review. Statistical analysis was performed with Student *t* test and chi-square analysis.

Results: Two thousand forty-nine patients underwent mapping with dual technique—1353 with radioisotope only. Blue dye use decreased gradually over time (69.8% in 2002 to 48.3% in 2006, $P < 0.0001$). Blue dye was used significantly more frequently in patients with higher BMI, African American race, higher T stage, and in those undergoing breast-conserving surgery. Patients who received blue dye were significantly more likely to have undergone preoperative lymphoscintigraphy (LSG). Of those who underwent LSG, patients receiving blue dye were more likely to have had no drainage identified. Additionally, patients receiving blue dye had lower pre-excision axillary counts, and were more likely to not have SLNs localized transcutaneously at the time of surgery. Patients with dual mapping had fewer SLNs removed (mean, 2.7 vs 2.9; $P = 0.03$). There was no difference in SLN identification rates between patients who had dual technique versus isotope alone (both 98.4%). In patients who had dual mapping, blue and hot nodes were more likely to be involved than nodes that were only hot or only blue (51.8% vs 23.8% vs 36.9%, $P <0.0001$). Four (0.8%) of 496 patients who had dual mapping and a positive SLN, had a blue but not hot node as the only involved SLN. None of the 4 had significant counts detected in the axilla intraoperatively. Nine (0.4%) of 2049 patients who had dual mapping had allergic reactions attributed to blue dye.

Conclusions: Blue dye use has decreased with increasing institutional experience with SLN mapping and varies with respect to patient and tumor characteristics as well as the type of surgery. Nodes that are both blue and hot are most likely to be involved, thus blue dye may assist in identifying the first echelon nodes. However, in patients with adequate isotope uptake in the axilla, blue dye is unlikely to improve the identification rate or the false-negative rate. Thus, in experienced hands, the use of blue dye can be individualized, weighing the relative benefit of blue dye against its cost and potential risks.

Image-Guided Breast Biopsy: The Experience of a Breast Surgeon in a Rural Community

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Objectives: Image-guided breast biopsy, either stereotactic core or ultrasound-guided core needle biopsy, have become the diagnostic modality of choice for both occult and palpable breast abnormalities. The objective of this study is to analyze safety, competency, accuracy and clinicopathologic correlation of stereotactic and ultrasound-guided core biopsies performed by a surgeon in a rural community and compare it to national data.

Methods: We retrospectively reviewed medical records of all patients undergoing any image-guided breast biopsy (stereotactic core, ultrasound-guided core needle biopsy, or fine needle aspiration biopsy) from 1/1/2000 to 12/31/2007. Data analyzed included indication for the biopsy, BI-RADS class of the lesion biopsied, review of postbiopsy mammogram, pathology on biopsy specimen and correlation with pre-biopsy findings, indication for subsequent surgery, surgical procedure, pathology on the surgical specimen, results of follow-up mammography after biopsy (up to at least 1 yr), and any complications from the biopsy.

Results: A total of 586 patients underwent 640 image-guided biopsies, which included 408 stereotactic vacuum-assisted/core needle biopsies (SCNB), 200 ultrasound-guided vacuum-assisted/core needle biopsies (US-CNB), and 32 ultrasound-guided fine needle aspiration biopsies (US-FNA). Of the 408 SCNBs, 380 were successful (success rate of 93.1%); all the US-CNB and US-FNA were successful. Of the 586 patients, 401 had benign pathology, 131 had invasive malignancy, 39 had in situ disease (DCIS & LCIS), 10 had invasive malignancy of special type and 5 had other pathology. Of the 586 patients, 207 underwent subsequent surgery; of these 130 underwent lumpectomy, 48 underwent excisional biopsy and 29 underwent mastectomy. Lack of clinicopathologic correlation was suspected in 12 patients; of these patients, 7 were felt to have inadequate sampling of the area of interest requiring excisional biopsy (final pathology was benign in all 7 patients), 3 had initial pathology suspicious for malignancy requiring excisional biopsy (final pathology was benign in all 3 patients). One had initial pathology that was benign but the ultrasound image remained suspicious. This patient underwent an excisional biopsy with final pathology being benign. The last patient had an initial SCNB which was benign, but on follow-up 2 years later the lesion grew, requiring an excisional biopsy with final pathology positive for an intracystic papillary carcinoma. Of the 586 patients, 365 (62.3%) returned to clinic at 6 months and 311 (53.1%) returned to clinic at 1 year with follow-up imaging. Of the 311 patients available for follow-up more than 1 year, only 1 patient developed malignancy after an initial benign SCNB yielding a negative predictive value of 99.68% (310/311). Of the 586 patients, 11 (1.65%) had complications, of these 7 had hematomas (6 SCNB and 1 US-CNB) which were managed nonoperatively, 2 (both SCNB) had hemorrhage requiring a trip to the operating room (0.34%), and 2 (both US-CNB) had infection at biopsy site requiring antibiotics (0.34%).

Conclusions: The results of our study compare favorably with results of similar studies done by nonsurgeons. Image-guided breast biopsies can be performed reliably, safely, and competently by surgeons.

Re-Excision Rate for Breast Cancer Surgery: A 2-Tier Quality Indicator

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Objectives: Summarizing quality care into a single indicator is difficult when multiple influencing factors coincide. In many cases, exclusions and qualifiers can be used to refine the indicator. But some empirically sound indicators cannot be refined by exclusions alone. A second tier of measures must be examined to accurately interpret this type of indicator. Re-excision rate for breast cancer surgery is one such 2-tier quality indicator. We report results from the National Quality Measures for Breast Centers (NQMBC) regarding re-excision rate for breast cancer surgery with this 2-tier concept in mind.

Methods: A quality indicator of the NQMBC includes the re-excision rate for initial breast cancer surgery. After acceptance into the NQMBC program, centers submit their response to this quality measure twice yearly. Each center can compare themselves with all other centers who have answered this question or with centers similar to their own. A minimum of 30 patients must be reviewed to submit a 6-month result. All centers who submitted data as of September 2009 are reviewed.

Results: There were 29 breast centers submitting 91 individual results to the re-excision indicator representing at least 2,730 patients considered in determining results. Average re-excision rate for initial cancer surgery was 22.5% (range, 0-90; StdD, 17.28%; $90^{th}/10^{th}$ percentile, 4.1% to 41%). Re-excision rate cannot be interpreted by itself without considering a second tier of quality measures. These include measures for cosmetic results, mastectomy rate, quality of pathologic margin evaluation, frequency of DCIS, patient choice, and other measures. A second tier of quality measures useful to interpret re-excision rate are included here. These include breast conservation rate (average, 72.4%), cosmetic results (4.8 out of 5), adequacy of pathologic margin evaluation (94.8% adequate), and patient choice (4.7 out of 5). Only after consideration of all these issues, can proper interpretation of the re-excision rate indicator occur.

Conclusions: Re-excision rate for initial breast cancer surgery as a quality indicator is measurable but must be interpreted properly. Re-excision rate is reported by 29 breast centers representing more than 2730 patients. Proper interpretation of outlier results requires a second tier of measures, such as mastectomy rate and cosmetic results. Care should be taken to avoid application of quality indicators without second-tier measures necessary to interpret outliers.

Timeliness of Breast Care: A 2-Tier Quality Indicator

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Objectives: Summarizing quality care into a single indicator is difficult when multiple influencing factors coincide. In many cases, exclusions and qualifiers can be used to refine the indicator. But some empirically sound indicators cannot be refined by exclusions alone. A second tier of measures must be examined to accurately interpret this type of indicator. Timeliness of breast care is one such 2-tier quality indicator. We report results from the National Quality Measures for Breast Centers (NQMBC) regarding timeliness of breast care with this 2-tier concept in mind.

Methods: Two quality indicators of the NQMBC include (a) time between diagnostic mammogram and needle/core biopsy and (b) time from needle/core biopsy to initial breast cancer surgery (both submitted in business days). After acceptance into the NQMBC program, centers submit their response to these 2 quality measures twice yearly. Each center can compare themselves with other centers who have answered these questions or with centers similar to their own. A minimum of 30 patients must be reviewed to submit each data point.

Results: There were 84 breast centers submitting 270 answers to each question, representing at least 8,100 patients considered in determining results. Average time to needle biopsy from diagnostic mammogram was 7.6 days (range, 0-33; StdD, 5.29; $90^{th}/10^{th}$ percentile, 2.0 to14.1 days). Average time from needle biopsy to initial cancer surgery was 16.2 days (range, 1.0 to 40.5; StdD, 6.66; $90^{th}/10^{th}$ percentile, 8.3 to 25.0 days). Outliers may either be performing poorly or have valid reasons for their results. A second tier of quality measures is necessary to interpret individual results (eg, specialist availability, use of MRI or genetic testing, communication issues, second opinions, payer issues, patient refusal, etc). Only after consideration of these issues can proper interpretation of this quality indicator occur.

Conclusions: Timeliness of breast care as a quality indicator is measurable but must be interpreted properly. Time between (a) diagnostic mammogram and needle biopsy and (b) from needle biopsy to initial cancer surgery is reported by 84 breast centers. Proper interpretation of outlier results require a second tier of measures to direct quality improvement to those centers that need it and to accept a valid result from others that may appear as outliers.

Long-Term Follow-up of Breast Cancer Patients Treated With Intraoperative Radiotherapy Using the Intrabeam Device

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Objectives: In an effort to decrease the time requirements for postoperative radiation therapy in women undergoing breast conservation for early breast cancer, we evaluated the use of intraoperative radiation, using the Intrabeam device, given during wide excision and followed by whole-breast radiation without a targeted boost. Our aim was to observe the long-term local recurrence rates and disease-free survival of our cohort and record adverse reactions to the therapy.

Methods: Between April 2000 and April 2003, we enrolled patients with Tis, T1, and T2 clinically node-negative breast cancers who were undergoing breast conservation into an IRB-approved observational study of intraoperative radiotherapy, using the Intrabeam radiation system, combined with postoperative whole-breast radiation. The intraoperative radiation supplanted the use of postoperative boost during whole-breast radiation. Patients were scheduled for follow-up every 3 months for the first year and every 6 months thereafter. Breast cancer status and adverse reactions, as classified by RTOG/EORTC grading system, were recorded.

Results: We enrolled 59 patients with 60 breast cancers and a median age of 59 (ages, 38-87); 35.6% had stage 2 disease. Our median follow-up time was 84 months during which time we had 3 (5.1%) systemic recurrences (2 at 12 months and 1 at 21 months) and 5 (8.3%) breast recurrences (at 32, 43, 69, 70, and 88 months). Two of the breast recurrences occurred in different area of the breast from the original tumor and greater than 5 years after the primary excision. The disease-free survival was 86.4%. Five patients had positive margins requiring re-excision after IORT, including 1 mastectomy. None of these patients developed a recurrence. We noted grade 1 adverse reactions in 8 patients, grade 2 in 8 patients, and 1 patient with a grade 3 reaction. Post-op radiation was omitted in 4 patients and none of these patients recurred.

Conclusions: We have determined that IORT combined with post-op whole-breast radiation can be a safe and effective adjuvant treatment for breast cancer treated by breast conservation. Our recurrence and disease-free survival rates compare favorably to most of the prospective randomized trials of breast conservation with radiotherapy. It has the benefit of decreasing the time required for postoperative whole-breast irradiation from approximately 6½ weeks to 5 weeks. IORT improves on the accuracy of the boost treatment, provided in a more timely fashion. We anxiously await the results of the TARGIT international trial to see if IORT with Intrabeam may be all the adjuvant radiotherapy required in selected patient populations.

Analyzing the Risk of Recurrence After Mastectomy for DCIS: A New Use for the USC/Van Nuys Prognostic Index

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Objectives: Patients with DCIS treated with mastectomy seldom recur locally or with metastatic disease. When patients with DCIS recur with invasive cancer, they are upstaged and their lives are threatened. We questioned whether histopathologic data could be used to predict these infrequent events so that preventive measures could be considered.

Methods: We reviewed a prospective database consisting of 1456 patients with pure DCIS. All patients were scored from 4 to 12, prior to mastectomy, using the USC Van Nuys Prognostic Index (VNPI), an algorithm based on DCIS size, nuclear grade, necrosis, margin width, and patient age. Probabilities of recurrence and death were calculated using the Kaplan-Meier method.

Results: Four hundred eighty-eight patients with pure DCIS were treated with mastectomy and are the subject of this abstract. None received any form of postmastectomy treatment, including radiation therapy or tamoxifen. Average follow-up was 83 months. Eleven patients developed recurrences: 2 metastatic without local recurrence, 1 metastatic with a preceding local invasive recurrence, and 8 local recurrences without metastatic disease. All 11 patients who recurred scored 10 to 12 using the USC/VNPI. No patient scoring 4 to 9 recurred. Nine of 11 recurrences were invasive; 2 were DCIS. All 11 patients who recurred had multifocal disease and comedo-type necrosis; 8/11 had multicentric disease. The probability of local recurrence following mastectomy for all patients was 3% at 12 years. In the table, mastectomy patients scoring 4 to 9 are compared with those scoring 10 to 12.

USC/VNPI score	4 to 9	10 to 12	*P* value
N	246	242	
Ave age	55	47	< 0.001
Ave size	27 mm	61 mm	< 0.001
Ave nuclear grade	2.02	2.73	< 0.001
# Local recurrence only	0	8	0.004
# Local recurrence then metastatic	0	1	NS
# Metastatic only	0	2	NS
# Inv recur	0	9	0.002
Probability any recurrence @ 12 years	0%	9.6%	0.0004
Probability local recurrence @ 12 years	0%	7.8%	0.002
Probability distant recurrence @ 12 years	0%	2.5%	NS
Probability breast cancer death @ 12 years	0%	1.9%	NS

Conclusions: There were no recurrences among mastectomy patients who scored 4 to 9 using the USC/VNPI. Patients scoring 10 to 12 were significantly more likely to develop recurrence after mastectomy. At risk were young patients with large high-grade tumors, multifocal or multicentric tumors, and close or involved mastectomy margins. For every 100 patients with USC/VNPI scores of 10 to 12, 10 patients will recur by 12 years and 2-3 will develop metastatic disease. Patients with scores of 9 or less are at little risk for recurrence. These data should be considered when counseling a patient who is considering postmastectomy radiation therapy or tamoxifen and when considering follow-up with MRI.

Predictive Value of BI-RADS Classification for Young Patients

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Objectives: The Breast Imaging Reporting and Data System (BI-RADS) is the standard grading tool for malignancy potential. BI-RADS 4 or 5 and occasionally 3 will lead to a biopsy. The aim of this study was to assess the positive predictive value of mammography and/or ultrasonography (US) in women aged 50 years or younger based on the recommendations for biopsies and the final pathology results.

Methods: We performed a retrospective analysis of all mammography and US reports issued from September 2005 to January 2007 at a large county hospital resulting in biopsies in women 18 to 50 years. Data collected included demographics, imaging modality, breast density, nature of the findings, BI-RADS grade, and final pathology.

Results: Four hundred seventy-five biopsies in 395 patients were reviewed. A total of 43 biopsies (9%) were malignant, 31 (6.5%) were invasive carcinomas, and 12 (2.5%) were noninvasive. The positive predictive value of BI-RADS 3 (n = 11) was 9.1%, BI-RADS 4 (n = 440) 5.9% and BI-RADS 5 (n = 24) 66.7%. Of the 168 biopsies recommended by both mammography and US, 15 (8.9%) were malignant. When US was the only tool (n = 205), only 7 (3.4%) were malignant; whereas when mammography was the only tool (n = 99), 20 (20.2%) were malignant. Two (15.4%) of 13 fat-replaced breasts with suspicious findings resulted in malignancy, compared to only 13 (6%) of 215 moderate/heterogeneously dense breasts and 6 (14.6%) of 41 severely dense breasts resulting in malignancy. In terms of lesions, 26% of suspicious calcifications were malignant versus 6.8% of masses/nodules and only 3.6% of suspicious cysts. Additionally, 4.3% of lesions reported as <1 cm were malignant, compared to 3.6% for lesions between 1 and 2 cm and 11.8% for lesions above 2 cm. None of the 40 biopsies performed on women age 18-29 were malignant, versus 9 of 115 (7.8%) for age 30-39 and 34 of 320 (10.6%) for age 40-50.

Conclusions: The positive predictive value of the current screening modalities diminishes markedly in women under the age of 50 and drops even more below the age of 40. Calcifications or masses larger than 2 cm especially in fat-replaced breasts should be biopsied, but the current BI-RADS criteria might have to be revised for other findings and younger patients.

Better Cosmetic Outcome After Intraoperative Radiotherapy Compared With External Beam Radiotherapy for Early Breast Cancer: Objective Assessment of Patients From a Randomized Controlled Trial

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Objectives: The international randomized TARGIT Trial started accrual in 2000 to determine if there is equivalence between the novel technique of IORT (intraoperative radiotherapy with Intrabeam® [Carl Zeiss, Germany]) and conventional external beam radiotherapy (EBRT) in women with early, low-risk breast cancer suitable for breast conservation as primary treatment. The main outcome measure is risk of local relapse within the treated breast. We report here the 1-year data from a subprotocol assessing cosmesis in a subset of 118 women over 50 participating in the TARGIT Trial from 1 center (Perth, Australia).

Methods: Frontal digital photographs from 118 patients (60 IORT, 58 EBRT) taken at baseline and 1 year after completion of breast-conserving surgery were assessed blinded to randomized treatment using specialist software (BCCT.core 2.0, INESC Porto, Portugal) which produces a composite score (Excellent, Good, Fair, Poor) based on symmetry, color, and scar. Statistical advice on logistic regression using Stata (StataCorp, USA) was given by the Biostatistics Group, The Joint UCL, UCLH, & Royal Free Biomedical Research Unit.

Results: Median age at randomization was 61 (IQR, 56-67) years; photographs were taken before and after surgery (median, 11 months; IQR 11-12); all patients were free from recurrence. The composite scores were combined into Excellent/Good and Fair/Poor (see Table 1). Seventy-seven percent (46/60) of patients randomized to IORT had Excellent/Good cosmetic outcome at 1 year, compared with 60% (35/58) randomized to EBRT. The odds of Excellent/Good outcome at 1 year, adjusted for the baseline composite score, was significantly higher in the IORT group compared to EBRT, adjusted odds ratio = 2.38 (95% CI, 1.04-5.43), $P = 0.039$.

Conclusions: These results indicate that the cosmetic effects of targeted radiotherapy using Intrabeam® are significantly improved compared to those obtained with conventional EBRT, 1 year after surgery.

Table 1. Cosmetic Outcome by Randomized Treatment at Baseline and 1 Year (n = 118)

Randomized Tx →	EBRT		IORT	
After 1 year → Baseline ↓	Excellent or Good	Fair or Poor	Excellent or Good	Fair or Poor
Excellent or Good	32	20	42	9
Fair or Poor	3	3	4	5

Preliminary Results With Accelerated Partial Breast Irradiation in High-Risk Breast Cancer Patients

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Objective: To analyze prognostic factors, acute toxicity, and cosmetic results in adequately staged breast cancer patients who were treated with accelerated partial breast irradiation (APBI).

Methods: Axillary staging was required for invasive carcinomas. Between February 2003 and June 2009, 204 women with early-stage breast carcinomas were treated with postlumpectomy APBI using multicatheter, MammoSite, or Contura brachytherapy to 34 Gy in 10 fractions bid. Six patient characteristics were examined for prognostic significance: (1) pN stage, (2) estrogen receptor (ER) status, (3) histological subtype, (4) margin status, (5) age, and (6) tumor size. Median follow-up was 22 months.

Results: There were 3 failures in the ipsilateral breast (all were elsewhere failures), 1 relapse in the axilla, and 7 relapses at any site. Table 1 shows that the presence of 1-3 positive axillary node(s) had a significant adverse effect on ipsilateral breast tumor control (P = 0.045) and locoregional control (P = 0.001). The presence of an ER (-) tumor had a significant adverse effect on relapse-free survival (Table 1, P = 0.04). There was no significant difference in acute toxicity by treatment technique (Table 2, P = 0.09). At 24 months post-irradiation, 2% of patients have poor, 3% have fair, 23% have good, and 72% have excellent cosmetic results.

Table 1. Log-Rank Test *P* Values for Patient Characteristics

Patient Characteristic	Ipsilateral Breast Tumor Control	Locoregional Control	Relapse-Free Survival
1-3 Positive axillary node(s)	**0.045**	**0.001**	0.055
ER (-) tumor	0.48	0.09	0.04
Ductal carcinoma In situ or invasive lobular carcinoma	0.38	0.31	0.89
Close margins (<2 mm)	0.52	0.63	0.91
Age <50 years	0.64	0.88	0.41
Tumor size = 21-30 mm	0.71	0.76	0.54

Table 2. Acute Toxicity by Brachytherapy Technique

Acute Toxicity	Multicatheter Brachytherapy (n = 34)	MammoSite Brachytherapy (n = 111)	Contura Brachytherapy (n = 59)
Infection	6% (2)	4% (4)	0% (0)
Breast pain	3% (1)	7% (8)	3% (2)
Breast fibrosis	0% (0)	1% (1)	0% (0)
Seroma	0% (0)	11% (12)	12% (11)
Infection and seroma	0% (0)	0% (0)	2% (1)
Rib pain	0% (0)	1% (1)	0% (0)
Fat necrosis	0% (0)	0% (0)	2% (1)
Total	9% (3)	24% (26)	19% (15)

Conclusions: Patients with 1-3 positive axillary node(s) were at increased risk for failure elsewhere in the ipsilateral breast or axilla and patients with ER (-) tumors were at increased risk for relapse at any site. However, it is unclear whether the pN1a and ER (-) patients would have fared any better if they had received whole-breast irradiation rather than APBI. Acute toxicity did not defer significantly based upon APBI technique, and cosmetic results were typically good to excellent. We believe that patients with 1-3 positive axillary node(s) or ER (-) tumors should be treated on clinical trials, such as NSABP B-39/RTOG 0413, to better define the role of APBI.

Initial Experience of a Breast Cancer Risk Assessment Program in a Community Hospital

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Objectives: It is well accepted that early detection results in improved outcomes in women with breast cancer. It is also known that each woman has a different level of risk, based on her personal, reproductive, and family history. Various models have been developed for use in the clinical setting to help predict a woman's risk of hereditary cancer. Many institutions have developed surveillance programs to follow women at elevated risk in hopes of early detection of cancers, but referral into these programs rely on assessment of the woman's risk by the primary care physicians. The purpose of this study is to report our experience of using a computerized risk assessment at the time of annual screening mammogram and its transition into a clinical surveillance program.

Methods: All women receiving annual screening mammogram at our institutional breast imaging center are offered a 3-minute questionnaire (Hughes riskApps™, Boston, MA). This computerized software utilizes the patient's responses regarding personal, reproductive, and family history to estimate her risk of developing breast cancer. Those women with higher than average risk (>15% lifetime risk by Gail model, >10% risk by BRCAPRO or Myriad models, or presence of atypia on previous biopsy) are offered entry into an intensive surveillance program coordinated by a women's health nurse practitioner. Depending on the woman's individual level of risk, she may be a candidate for more intensive imaging and clinical examination or referral for genetic risk assessment, chemoprevention, and prophylactic surgery. Care is coordinated with the patient's primary care practitioner, OB-GYN, and supervising breast surgeon.

Results: During the study period October 1, 2008, to September 30, 2009, 18,267 women were offered the questionnaire at the time of screening mammogram. In total, 6,216 completed the questionnaire; median age of the cohort was 51 years (range, 21-89). Based on their responses, 712 women were found to be high risk (8.7% of women screened). Of those deemed high risk, 131 women accepted entry into the surveillance program and underwent consultation by a nurse practitioner. Fifty-nine patients met criteria for annual MRI screening. Core biopsy was prompted due to imaging findings on 15 patients, leading to additional diagnosis of atypical hyperplasia in 3 women. After review of their family pedigrees, 70 women were referred for genetic testing; 2 were found to be BRCA carriers. In addition, 5 patients were referred for consultation regarding prophylactic mastectomy, and 12 opted for formal discussion of chemoprevention.

Conclusions: This study documents the success of implementing an institution-wide program to screen for individuals at elevated risk of breast cancer. Those women who are deemed high risk (8.7% of the cohort) are offered entry into a clinical surveillance program. Additional prospective studies are in progress to determine whether entry into high-risk programs will result in improved outcomes for women deemed high risk.

Is the Use of Preoperative MRI Predictive of Mastectomy? 5-Year Experience at a Single Academic Institution

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Objectives: Several recent studies have described increasing rates of unilateral and bilateral mastectomy. The use of breast MRI has also risen rapidly, leading to speculation that the high false-positive rate and need for multiple biopsies associated with MRI may contribute to more mastectomies. The objective of this study was to determine whether newly diagnosed patients who underwent preoperative MRI were more likely to undergo mastectomy compared to those who did not have a preoperative MRI.

Methods: A retrospective review was performed of all newly diagnosed breast cancer patients at our academic breast center from 2004 to 2009.

Results: The percent of newly diagnosed breast cancer patients having MRI prior to surgery increased from 6% in 2004 to 70% in 2008. Among 513 patients who underwent diagnostic MRI, 288 were abnormal, 201 had 1 or more biopsies, and 60 had additional sites of cancer diagnosed. Patients with a malignant biopsy, or those with an abnormal MRI who did not undergo biopsy, had an increased mastectomy rate ($P < .001$). However, patients with a normal MRI or a benign biopsy actually had a decreased mastectomy rate ($P < .005$). Although there was a trend toward more bilateral mastectomies, the overall mastectomy rate did not change over this time period.

	n	Lumpectomy	Ipsilateral Mastectomy	Bilateral Mastectomy	Total Mastectomy
No MRI	819	62%	26%	12%	38%
MRI					
Normal	225	67%	19%	14%	33%
Abnormal					
Ipsilateral	143	55%	34%	12%	46%
Contralateral	61	56%	18%	26%	44%
Both	84	48%	25%	27%	52%
MRI biopsy					
None	107	42%	36%	22%	58%
Benign	141	71%	21%	8%	29%
Malignant					
Ipsilateral	41	34%	39%	27%	66%
Contralateral	15	33%	0	67%	67%
Both	4	0	0	100%	100%

Conclusions: Although there is a strong relationship between the result of an MRI and the choice of surgery, the overall effect is not always to increase the mastectomy rate. At our institution some patients who were initially considering mastectomy chose lumpectomy after an MRI.

To Screen or Not to Screen: American Cancer Society Guideline for MRI Screening in Patients Who Are Diagnosed With LCIS

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Objectives: The American Cancer Society (ACS) guidelines recommend breast MRI screening for women with ≥20% lifetime risk of breast cancer by models that are predominantly hereditary (Tyrer-Cuzick [TC], BRCAPRO, or Claus). Furthermore, the ACS states that there is insufficient evidence to recommend for or against MRI screening in women with LCIS. As Tyrer-Cuzick is the only one of these models that includes LCIS as a risk factor, it was of interest to determine whether MRI screening would be recommended for women with LCIS based on the Tyrer-Cuzick model.

Methods: With IRB approval, we identified 48 women diagnosed at our hospital with LCIS between 2000 and 2007 for whom family history and other risk factors were available. We then ran TC on these women to determine their lifetime risk of breast cancer and their risk of harboring a BRCA1 or BRCA2 mutation.

Results: All 48 women with LCIS had ≥20% lifetime risk of breast cancer by TC, while only 3/48 women had ≥10% of harboring a BRCA mutation. While the TC model results would suggest MRI screening, this was almost exclusively due to the LCIS, with only 3 of 48 being considered to be at elevated hereditary risk.

Conclusions: While the ACS guidelines state that there is not enough evidence to recommend for or against breast MRI screening for LCIS, all women with LCIS in our series met the criteria of ≥20% lifetime risk of breast cancer, making them all eligible for MRI screening. The high lifetime risk was not due to hereditary risk in 45 of 48 patients. A clarification of the ACS guidelines may be in order.

Cavity Shave Margins Reduce Reoperation Rates in Primary Breast Cancer

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Objectives: Breast-conserving therapy (BCT) has become an accepted method of treating early breast cancer. One particular challenge of BCT for the surgeon is ensuring complete tumor removal at the time of initial surgery. Previous studies have reported 30-50% rates of reoperation to ensure complete tumor removal with adequate surrounding margins. One method utilized to improve rates of complete tumor removal at time of initial operation is routine excision of additional cavity shave margins (CSM) after removal of the primary partial mastectomy specimen. We hypothesized that routine re-excision of margins at time of initial surgery reduces the need for additional surgery.

Methods: A single-institution retrospective review was performed. All women, 18 years or older, with new diagnosis of invasive or in situ breast cancer who underwent partial mastectomy between 1/1/2004 and 10/1/2009 were included. Five hundred thirty-three charts were reviewed. Of those, 57 patients had undergone neoadjuvant chemotherapy and were excluded. Of the remaining 476 patients, 69 underwent CSM at the time of initial operation. These 69 patients were matched with patients that had undergone partial mastectomy without CSM in terms of tumor size, presence of extensive intraductal component, and primary histology (invasive ductal carcinoma, invasive lobular carcinoma, or pure DCIS).

Results: The 2 groups were well matched for age, nuclear grade, associated lymphovascular invasion (LVI), receptor status, and multifocality. Of the 138 patients making up the study population, 31.9% (44/138) required return to OR for re-excision of margins. Rate of return to OR was 21.7% (15/69) in the CSM group and 42.0% (29/69) in the match group *(P* = 0.011). Multivariate analysis that included CSM, directed re-excision, patient age, tumor size, tumor histology, extent of DCIS, race, nuclear grade, LVI, estrogen receptor status, and multifocality found that factors significantly associated with the need for additional operation included CSM (odds ratio, 9.2; 95% CI, 2.8-30.5; *P* = 0.0003), extent of DCIS (odds ratio, 7.0; 95% CI, 1.8-27.0; *P* = 0.005), and directed re-excision (odds ratio, 6.4; 95% CI, 1.7-25.1, *P* = 0.007).

Conclusions: These data indicate that CSM at time of initial partial mastectomy decreases the rate of re-excision by as much as 9-fold. CSM is a simple surgical technique that requires no additional specialty equipment or specific training, and should be considered at the time of initial operation to reduce the need for subsequent reoperation.

Breast Seroma After Intraoperative Radiotherapy With Low-kv X-rays

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Objectives: Intraoperative radiotherapy **(**IORT) for breast cancer using 50-KV x-rays (Intrabeam™) is of increasing interest over the last few years. This modality differs from conventional fractionated radiotherapy in irradiating the tumor bed with a single protracted dose of irradiation. Therefore IORT of the tumor bed after breast-conserving surgery (BCS) might possibly be associated with higher rates of wound seroma.

Methods: One hundred fifty-six patients with breast cancer transferred to our department betweeen 2005 and 2007 were analyzed regarding the occurence of breast seroma. Seventy-four patients had undergone IORT during BCS (IORT group), 82 had BCS without IORT (EBRT group). All patients had a CT scan for treatment planning 3-6 weeks after BCS. Seroma was verified by clinical examination and/or CT scan. Clinical and treatment-related factors were analyzed including patient age, body mass index (BMI), breast volume, index quadrant, and interval between surgery and radiotherapy.

Results: Median patient age was 63.8 years for the IORT group and 62.6 for the EBRT group. BMI < 24.9, 25-29.9, and >30 was almost equally distributed in both groups. Both groups had 20% patients with a BMI over 30. Breast volume on average was 1193 cc and 1073 cc, respectively. Clinical palpable seroma in the IORT group were evident in 17 patients (22%), 3 of them (14%) had to be treated by puncture, whereas 20 patients (24%) of the EBRT group had palpable seroma and 10 of them (12%) had to be treated. Only detected via CT scan without clinical relevance were 45 seroma (58%) and 23 (27%), respectively. Neither clinical nor radiological seroma had 15 (20%) and 41 (49%), respectively. A subanalysis of the data regarding the 3 BMI groups showed no significant correlation between BMI and seroma.

Conclusions: IORT of the tumor bed doesn´t seem to increase the rate of clinical relevant seroma compared to a normal control group, but the fluid seen in CT scans (without any clinical relevance) are up to twice as much as in non-IORT patients, especially in obese patients. Other factors have yet to be statistically analyzed.

Breast Cancer Surveillance in High-Risk Young Women: Is It Feasible?

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Objectives: The objective of this study was to examine the characteristics of young women enrolled in our Special Surveillance Breast Program (SSBP) for women at high risk for developing breast cancer.

Methods: We performed a retrospective review of our SSBP prospective database. Inclusion criteria for this study included age between 25 and 40, enrollment between 1992 and March 2008, and completion of at least 1 follow-up visit. Patient characteristics, imaging, biopsies, pathology, and surgical interventions were examined.

Results: The mean age at enrollment was 33 years in the 387 women who met our study criteria. The majority of participants were highly educated and predominantly white. Ashkenazi Jewish ancestry was reported in 28% and the majority (92.7%) had a strong family history and/or known or probable BRCA mutation. At entry into SSBP, 56% had undergone mammography and 6% had ever had an MRI. After enrollment, mammography was performed in 92% of participants and MRI in 61%. A small number of participants, 57 women (14.7%), did not have any MRI performed until greater than 5 years post enrollment. We found a greater number of participants underwent biopsy after enrollment (23% vs 35%). However, the majority were benign and the rate of LCIS and/or atypia remained constant (10% before and 13% after enrollment). There were no breast cancers diagnosed during our study period. Risk-reducing bilateral mastectomy was an uncommon intervention with only 14 participants (3.6%) undergoing the procedure. Despite their high level of education, voluntary enrolment, and high-risk status, only 77% returned for a third visit and 56.6% for a fourth. The mean duration of enrollment was less than 5 years (56.6 months) and only 48% were still enrolled at the end of the study period.

Conclusions: Understanding the characteristics of women who enroll in and adhere to recommendations of a screening program is crucial to optimizing prevention and early diagnosis in those at high risk for developing breast cancer. Despite targeting the highest risk patients, the attrition rate from our surveillance program is high. Further study into factors that may affect young women's adherence to screening protocols is warranted.

Comparison of Lymphedema in Patients With Axillary Lymph Node Dissections (ALND) to Those With Sentinel Lymph Node Biopsy Followed by Immediate and Delayed ALND

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Objectives: Several studies have shown that breast cancer patients who undergo a sentinel lymph node biopsy (SLNB) alone have decreased lymphedema rates than patients undergoing a full axillary lymph node dissection (ALND). This the main benefit of SLNB over an ALND. However, about 15% of patients who intend to have an SLNB alone and have negative nodes on intraoperative pathologic examination are found to have positive nodes on final microscopic hematoxylin eosin examination. We hypothesize that patients who have delayed ALND following SLNB will have higher rates of lymphedema.

Method: The NSABP B-32 study had 207 patients enrolled at our hospital with follow-up data on 199 patients. The study randomized patients with clinically negative axilla to SLNB followed by ALND (group A, N = 98) and SLNB with intraoperative touch prep and ALND if positive (group B, N = 101). All patients underwent preoperative volumetric arm measurements however, only the patients who were node-negative in both groups had routine postoperative arm measurements for lymphedema for 2 years We contacted node-positive patients for postoperative arm measurements in the study. In group A, 24 node-positive patients had SLNB followed by immediate ALND (subgroup A1, N = 24); in group B, 15 patients had SLNB followed by immediate ALND for postivity on touch prep (subgroup B1, N = 15), and 14 patients had delayed ALND following the SLNB because of positive result on subsequent hematoxyline eosin staining (subgroup B2a, N = 14)

Results: In group A (N = 98) patients assigned to SLNB and ALND, the lymphedema rate for node-negative ALND (5/74) was 6.8%, node-positive immediate ALND (4/39). (Combination of subgroup-A1 {3/24} and subgroup-B1 {1/15}) was 10.3%. In the 72 patients in group B who got only the SLNB, there was 0% lymphedema (0/72); and in the subgroup B2a with delayed ALND there was 14.3% lymphedema (2/14). In comparison of the immediate and delayed ALND for node-positive patients, our study was not statistically significant, P = 0.65 (10.3% v/s 14.3%). Comparison of node-negative ALND (5/74 = 6.8%) to all node-positive immediate and delayed ALND (6/53 = 11.3%) also was not statistically significant P = 0.52. In comparison of lymphedema for node-negative ALND to SLNB alone, it approached significance, P = 0.058 (6.8% v/s 0 %).

Conclusions. There was no difference in the lymphedema rate between the immediate and delayed ALND, however, comparison is difficult given the limited sample size of only 14 patients in the delayed ALND group. Hence we urge the other centers of NSABP-32 to validate this data by contacting the node-positive patients for a volumetric arm measurement. The lymphedema rates for SLNB alone was 0%, and approached statistical significance when compared to node-negative ALND.

Acceptance of Chemoprevention by Women at High Risk for Breast Cancer

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Objectives: Identification of women at high risk for breast cancer involves assessment of personal and family history. This information can be combined in various computer models, such as the Gail model, to give patients an estimate of their 5-year and lifetime risk of developing this disease. If a patient is determined to be at high risk for breast cancer, various risk-reducing strategies are discussed, including the use of chemoprevention. The purpose of this study was to determine the acceptance of chemoprevention among high-risk women at a single institution.

Methods: Women were seen in a specialized high-risk breast clinic at the University of California, Irvine from September 2007 to September 2009. All patients underwent extensive counseling regarding breast cancer risk, which included utilizing the Gail risk model. Patients with a personal history of atypical ductal hyperplasia (ADH), atypical lobular hyperplasia (ALH), or lobular carcinoma in situ (LCIS) or a Gail risk score of 1.66% or greater were considered to be at high risk for developing breast cancer. Tamoxifen or raloxifene was discussed as a chemopreventive agent for those patients without contraindications including endometrial cancer, history of blood clots or pulmonary embolism, or current hormone replacement therapy use.

Results: One-hundred thirty-one patients were evaluated and received a Gail risk score. Seventy-three patients were felt to be candidates for chemoprevention. Only 7 patients elected to proceed with chemoprevention and all 7 of these patients elected to be prescribed Evista. Two of these patients were already on Evista for osteoporosis as prescribed by their primary physician. No patient consented to be placed on tamoxifen.

Conclusions: Chemoprevention is commonly offered to women at high risk for developing breast cancer. However, our small sample of patients was reluctant to be prescribed tamoxifen or raloxifene despite research indicating the efficacy of these medications in reducing breast cancer risk. Further studies are indicated to determine the reasons that patients decline this chemopreventive strategy.

Magnetic Resonance Imaging (MRI)-Guided Breast Biopsy: Experience at a Community Comprehensive Breast Center With MRI-Guided Breast Biopsy Capability

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Objectives: Magnetic resonance imaging (MRI) of the breast is a highly sensitive imaging modality used in diagnosing breast cancer. BI-RADS category 4 or 5 lesions detected on MRI that are not visible on ultrasound or mammogram require biopsy with MRI direction. The objective of our study was to evaluate MRI-guided, vacuum-assisted needle biopsy at a comprehensive breast center staffed by radiologists subspecializing in breast imaging.

Methods: An institutional review board (IRB)-approved retrospective chart review of MRI-guided breast biopsies at our comprehensive breast center between June 2005 and June 2009 was performed. Abnormalities detected on MRI for which biopsy was recommended subsequently underwent targeted ultrasound. In cases where the abnormality could be located on ultrasound, ultrasound-guided biopsy was performed. Abnormalities visible only on MRI were scheduled for MRI-guided biopsy with a 9-gauge, vacuum-assisted biopsy device. Follow-up MRI was performed on all patients 6 months after biopsy.

Results: Two hundred twenty-nine MRI-guided breast biopsies of BI-RADS category 4 or 5 lesions not visible on targeted ultrasound were scheduled in 198 patients. Of those 229, 168 (73%) had their initial MRI performed at our facility and 61 (27%) were performed at outside facilities. Fifty-five (90%) of 61 cases were performed at facilities lacking MRI-guided biopsy capability. In 31/229 (14%) cases, lesions were not visualized on second MRI. Nineteen (61%) of 31 of those had their initial MRI performed at an outside facility resulting in a cancellation rate of 31% (19/61). The remaining 12/31(39%) had their initial MRI at our comprehensive breast center, yielding a cancellation rate of 7% (12/168). One hundred ninety-eight (86%) of 229 biopsies were performed. Fifty-six (28%) of 198 demonstrated either malignancy or high-risk lesions. Thirty-three (59%) of 56 demonstrated malignancy. Invasive malignancy was found in 24/33 (73%) and ductal carcinoma in situ (DCIS) in 9/33 (27%). Twenty-three (41%) of 56 were high-risk lesions. Of those high-risk lesions, 11/23 (48%) were atypical ductal hyperplasia, 3/23 (13%) atypical lobular hyperplasia, 5/23 (22%) lobular carcinoma in situ, and 4/23(17%) papilloma.

Conclusions: MRI-visualized BI-RADS category 4 or 5 lesions not seen with other imaging modalities require MRI-guided biopsy for diagnosis. A significant percentage of such lesions, 28% in our study, are malignant or high risk. Patients who have MRIs performed at facilities lacking biopsy capability are more likely to have subsequent unnecessary MRIs and to be scheduled for unneeded biopsies. Breast MRIs should ideally be performed by individuals with special training in breast imaging and biopsy at a facility with MRI-guided breast biopsy capability.

Prospective Comparison of the OSNA Breast Cancer System to Imprint Cytology for the Intraoperative Analysis of Sentinel Lymph Nodes From Cancer of the Breast

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Objectives: Sentinel lymph node (SLN) mapping for cancer of the breast has become a standard of care. Intraoperative analysis of SLN is important for clinical decision making. However, the optimal method of intraoperative analysis of SLN for cancer of the breast is unclear. Intraoperative imprint cytology has been shown to be a useful, however molecular techniques are quite promising for such analyses. In this trial, we prospectively compared imprint cytology with an intraoperative molecular technique, the OSNA (one-step nucleic acid amplification) Breast Cancer System.

Methods: A prospective multicenter trial of intraoperative evaluation of SLN from breast cancer patients using isothermal amplification (RT-LAMP) for cytokeratin 19 (OSNA Breast Cancer System) has been completed, This trial accrued 496 patients from whom 1044 SLNs were harvested, sectioned with a novel 5-blade, 1-mm cutter, and alternative slices were submitted for analysis by either OSNA molecular analysis or detailed pathology, respectively. At individual sites' preference, imprint cytology was also determined for most of the 6 slices in 272 patients. Results of the 2 systems were analyzed and compared to final pathologic reports.

Results: A total of 532 SLN were evaluated (1.96 SLN/patient) with both imprint cytology and OSNA molecular analysis. Time to completion for the OSNA assay averaged 45 minutes for up to 3 SLN. Overall, 15.2% of SLN were positive, making 21.3% of patients positive on final pathology. Overall agreement to final pathology was 93.4% for OSNA and 93.8% for imprint cytology. However, the sensitivity for OSNA was significantly higher than imprint cytology: 80.3% versus 63.0%, P = 0.023, and macrometastases were found in 88.1% versus 76.2% of patients. In comparison with histopathology, IC missed macrometastases in 15 SLNs while the same was true for OSNA in only 4 SLNs.

Conclusions: When compared to final histopathology, OSNA had a similar rate of agreement with imprint cytology but was significantly more sensitive than imprint cytology. This, as well as the objective nature of the assay, its automation, and ease of use, suggests that the OSNA Breast Cancer System may be of significant value for centers interested in intraoperative analysis, particularly those without ready access to cytopathologic expertise.

Spontaneous Malignant Transformation In Vitro of Adipose-Derived Mesenchymal Stromal Cells From Patients With Benign and Malignant Breast Lesions

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Objectives: To report on the occurrence of the spontaneous malignant transformation in vitro of adipose-derived mesenchymal stromal cells (Ad-MSCs) from patients with benign and malignant breast lesions.

Methods: From early 2008, adipose tissue from the breast stroma of 150 patients with both benign as well as malignant disease were individually collagenase-digested and the resulting cell pellets were seeded into cell culture flasks. Cells were cultured in media and trypsinised when subconfluent. Of the 150 patient samples, it was observed that cultures from 8 patients (4 from malignant and 4 from benign patient samples) were seen to have developed a distinct population of epithelial-like (EL) cells in addition to the Ad-MSCs. Surface phenotype of these cells were determined by flow cytometry and compared to the surface phenotype of normal Ad-MSCs from the same patients. Tumorigenic property of these cells was also determined by soft agar assay and telomerase expression.

Results: During serial passaging, it was noticed that a distinct population of cells with EL morphology began to appear in some of the cultures (between passage 3 to 12). The EL cells were usually observed in colonies interspersed among the fibroblast-like Ad-MSCs. These cells were much smaller than Ad-MSCs and had a distinct syncytial-like morphology under electron microscopy. EL cells had decreased levels of expression of CD44, CD29, and HLA Class I when compared to the normal Ad-MSCs. EL cells were able to form colonies in the soft agar. They proliferated extensively and can be maintained in continuous culture for long periods of time, in keeping with the detection of high levels of telomerase expression.

Conclusions: We have identified an immortal cell population which arose in our routine cultures of stroma-derived Ad-MSCs, which we have termed “EL cells.” EL cells are distinctly different from Ad-MSCs in morphology, immunophenotype, and growth properties. Further studies, including the tumor xenograft assay and global gene expression analysis comparing both the EL cells and the Ad-MSCs, are underway.

Breast-Specific Gamma Imaging Used As An Adjunct to Mammography

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Objectives: To evaluate molecular breast imaging as an excellent supplemental modality for detecting cancer in dense breast tissue, evaluation of abnormal mammogram or ultrasound exams, and investigating patients with concerning clinical breast exams.

Methods: Retrospective review of breast-specific gamma imaging (BSGI) studies performed as part of clinical work-up in patients undergoing BSGI due to abnormal imaging, physical exam, significant family or personal breast cancer history, or dense breast.

Results: A positive BSGI was recorded in 264 of the 664 patients studied with 180 confirmed cancers. Overall, the sensitivity was 85% with a specificity of 81%. The positive predictive value (PPV) was 68% and the negative predictive value (NPV) was 92%. Using the Breast Imaging Reporting and Data System (BI-RADS) if patients had BI-RADS 1-3 score, 23 of 76 positive studies were true positives. In BI-RADS 4-6 category, there were 154 of 180 true-positive exams confirmed by pathology. The PPV for BI-RADS 1-3 was 30% compares favorably with expected BI-RADS prediction of <2% malignancy rate for this category. In the BI-RADS 4-6 group, the PPV increased significantly to 86%.

Conclusions: BSGI is a useful adjunct in the imaging work-up of breast patients and has a high sensitivity and specificity. It is best used to further evaluate equivocal mammographic or ultrasound findings, as the positive predictive value is highest in this setting. However, in high-risk patients with BI-RADS 1-3, it will improve cancer detection significantly.

Neoadjuvant Chemotherapy Followed by Oncoplastic Breast-Conserving Techniques Is a Safe and Successful Alternative to Mastectomy

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Objectives: Neoadjuvant chemotherapy can downstage tumors and safely enable breast conservation for women who would otherwise be obligated to total mastectomy. However, some tumors, even after postchemotherapy shrinkage, have residual tumor foci spanning the original tumor bed. For women with either large tumors or multifocal disease, yet sufficiently large breast volume, wide excision combined with reduction mammoplasty, or oncoplastic techniques, enables breast conservation as an alternative to mastectomy. The aim of this study is to compare the outcome after oncoplastic breast-conserving techniques between patients undergoing neoadjuvant chemotherapy for tumor downstaging versus patients without neoadjuvant treatment. Endpoints evaluated included the ability to successfully achieve breast conservation, the rate of re-excision for positive margins if conservation was achieved, local and distant recurrence, and rate of completion mastectomy.

Methods: We retrospectively reviewed the medical records of 74 patients with a total of 79 breast cancers, consecutively treated with reduction mammoplasty and contralateral reduction for symmetry, between 1999 and 2009. In 10 years, this constituted approximately 2% of total case volume performed at our tertiary care university cancer center. Two patients with stage 4 disease at presentation were excluded from this analysis.

Results: Of 77 tumors, 43% (n = 33) received neoadjuvant chemotherapy for stage 2 (58%, n = 19) and stage 3 (42%, n = 14) disease. Cases without neoadjuvant treatment presented with stage 0 (32%, n = 14), stage 1 (27%, n = 12), stage 2 (32%, n = 14), stage 3 (5%, n = 2), and phylloides (5%, n = 2). Nearly all neoadjuvant cases (96%, n = 31) achieved breast conservation, with only 2 cases (6%) resulting in completion mastectomy. Similarly, the majority of non-neoadjuvant cases (93%, n = 41) underwent successful breast-conserving therapy, with only 4 cases (9%) requiring completion mastectomy. Re-excision for positive margins was performed in 6/33 (18%) and 10/44 (23%), in the neoadjuvant and non-neoadjuvant groups. Two non-neoadjuvant patients required multiple re-excisions to achieve clear margins. By the median follow-up of 31 months (range, 1-125 months), rates of recurrence in the neoadjuvant and non-neoadjuvant groups were comparable: local recurrence was observed in 1/31 (3.2%) and 1/41 (2.4%) patients, respectively. One patient chose re-excision, and the other opted for mastectomy. Distant recurrence occurred in 2 neoadjuvant patients (6%) at 1 and 2 years post-surgery. Fifty-seven of 77 (74%) received postoperative radiation. Overall, rates of postoperative complications in neoadjuvant and non-neoadjuvant groups were similar (12% vs 16%).

Conclusions: Although patients undergoing neoadjuvant chemotherapy presented with more advanced clinical stage compared to the non-neoadjuvant subset, outcomes in both were equally successful in regards to the ability to achieve breast conservation, low rates of re-excision at the time of initial surgery, and low rates of local recurrence. Follow-up spanned a 10-year period, however median follow-up of 31 months requires continued prospective analysis to establish long-term outcomes. The use of neoadjuvant chemotherapy in combination with oncoplastic reduction and concomitant reduction mammoplasty with reduction of the contralateral breast safely extends the option of breast-conserving treatment, providing a valuable option emotionally and physically, especially in the neoadjuvant setting, when post-mastectomy radiation therapy would likely be recommended.

Systematic Review of Radio-Guided Surgery for Nonpalpable Breast Cancer

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Objectives: Approximately one-third of breast cancer is image-detected and requires a localization procedure to guide surgical excision. Positive margin and re-operation rates are high for these procedures. Radio-guided localization techniques (RGL) (radio-guided occult lesion localization [ROLL] and radioguided seed localization [RSL] have developed over the last 10 years as an alternative to standard wire-guided localization (WGL) for the excision of nonpalpable breast lesions. In RGL, preoperative insertion of a radioactive seed or radiotracer into the primary tumor is performed and surgical resection is guided by an intraoperative gamma probe.

Methods: We performed a comprehensive literature review to identify clinical studies using either ROLL or RSL. Studies were included if they included invasive or in situ breast carcinoma and reported pathologically assessed margin status or volume of tissue excised as primary outcomes. Two reviewers assessed the eligibility and quality of the studies, independently and in a standardized fashion. Relevant demographic data, tumor characteristics and surgical outcomes data were abstracted and a quantitative data analysis was performed using Comprehensive Meta Analysis Version 2.2.048 software. Log odds ratios and their appropriate variability estimates were reported.

Results: Five databases (PubMed, Embase, Cochrane, CINAHL, and Cancerlit) were searched in order and yielded 73 references on ROLL and RSL. The Horizon estimate is 76 with a 95% confidence interval (CI) of 73 to 83. This suggests that the search obtained 96% of the references, and that 3 were missed by the search. Forty-seven of these were clinical studies using ROLL (n = 42) or RSL (n = 5). We excluded 25 studies (duplicate data, ongoing studies, margin outcome not reported). Ten studies compared RGL to WGL, while 12 studies were single cohorts using RGL. In the end, 8 studies met eligibility criteria and were included in the quantitative analyses, which were performed in 3 different ways. The 2 randomized controlled trials (RCT; n= 78) were first combined; the combined odds ratio (OR) was 0.246 with a combined 95% CI, 0.091 to 0.668 (P = 0.006). Six cohort studies (n = 1063) were then combined the same way, generating an OR of 0.363 and 95% CI, 0.267 to 0.494 (P < 0.001). The 2 RCTs and 6 cohort studies were then combined (n = 1141), giving a combined OR of 0.351 and 95% CI, 0.261 to 0.471 (P < 0.001).

Conclusions: The results of this systematic analysis of RGL versus WGL demonstrate that RGL technique produces lower positive margins rates compared to standard WGL. While this review is limited by the small size and number of RCTs, the odds ratios suggest that RGL may be a superior technique to guide surgical resection of nonpalpable breast cancers. These results should be confirmed by larger RCTs.

The Epidemiology, Clinicopathological and Prognostic Characteristics of Triple-Negative Breast Cancer Compared With Non–Triple-Negative Breast Cancer

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Objectives: Triple-negative breast cancers (TNC) are increasingly reported to be associated with higher grade cancers and worse prognosis. They are also associated with BRCA mutation. Ethnic variations in tumor characteristics and clinical presentation of breast cancer are also increasingly being emphasized. This study aims to look at the tumor characteristics and factors which may influence the presentation and prognosis of TNC in a cohort of Chinese women.

Methods: A retrospective review was performed in a prospectively collected database of breast cancer patients treated in a tertiary hospital between 1995 and 2006. Clinicopathological, epidemiological variables and clinical outcomes were evaluated.

Results: A total of 558 women with breast cancer were included in this cohort, of which 96 (17%) had TNC and 462 (83%) had non-TNC. The median follow-up duration was 5 years. There was no significant difference in age of presentation in both groups (mean age, 54.6 vs 53.7 years old). TNC were 2.5 times more likely to be associated with higher tumor grade (P = 0.0043), and were 1.9 times more likely to have lymphovascular invasion (P = 0.0057). TNC were more likely to present with N3 nodal status (19.4% vs 9.3%, P = 0.03), although overall staging showed no difference. There was no statistically difference in 3-year and 5-year disease-free survival and overall survival between the 2 groups, however, the disease-specific mortality was 1.9 times higher in TNC versus non-TNC (29.2% vs 17.8%, P = 0.015). TNC was 4.7 times more likely to have local relapse (P = 0.0012). Obesity (P = 0.04), earlier menarche (P = 0.05), and higher parity (P = 0.006) were all associated with TNC. 23.7% of TNC patients who undertook BRCA testing were found to be mutation carriers.

Conclusions: There were similarities and differences in associated sociodemographic factors compared to the West. Chinese women presented at a similar age in both groups, whereas TNC presented at a statistically younger age in the West (53 vs 57.7). Survival was similar in TNC and non-TNC in Chinese, while in the West prognosis was worse in TNC. There was also a lower rate of BRCA mutation in TNC. Larger-scale study on different ethnicities will increase our understanding in TNC to achieve more personalized management.

Cumulative Imaging Radiation Exposure Following Breast Conservation Therapy

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Objectives: Low-dose ionizing radiation from medical imaging may induce cellular damage and increase the risk of cancer. While health care workers are restricted to a maximum annual dose of 50 mSv, the exposure to patients from medical imaging is not monitored. After breast conservation therapy (BCT), patients are subjected to annual screening mammography and additional systemic surveillance imaging. Suspicious lesions found on mammography may require additional radiation exposure in the form of diagnostic mammography, stereotactic biopsies, and needle localizations. The cumulative radiation exposure and total effective dose absorbed by tissues from these studies over time is unknown. Our objectives were to determine the cumulative radiation exposure of breast cancer survivors after completion of BCT, and to compare exposure levels in 2 historical cohorts.

Methods: Retrospective cohort study of 71 patients who received BCT in 1997 (n = 45) or 2002 (n = 26). Cumulative radiation exposure during follow-up from diagnostic imaging attributable to breast cancer was recorded, including all surveillance and diagnostic breast imaging, and systemic surveillance imaging. The follow-up period commenced with the completion of radiotherapy and ended with the date of either last NED follow-up, diagnosis with stage IV disease, or date of subsequent mastectomy.

Results: The mean age was 57 years. One patient (1%) had stage 0 breast cancer; 51%, stage I; and 49%, stage II. Median follow-up was 101 months. In the first 5 years after BCT, the average patient from 1997 (vs 2002) underwent 5.2 (5.3) mammograms, 1.6 (0.5) chest x-rays, 0.3 (0.04) other x-rays, 0.9 (1.2) CT scans, 0.7 (0.4) bone scans, and 0.1 (0.04) PET/CT scans. Two patients from 1997 had sentinel lymph node biopsy for a second breast cancer. One patient from each cohort had a needle localization, and 3 patients from 1997 had stereotactic biopsies. Over the first 5 years following adjuvant radiotherapy, patients in the 1997 cohort received a mean annual dose of 3.1 mSv while patients in the 2002 cohort received 2.9 mSv (P = 0.43). For all 71 patients over the mean follow-up of 101 months, mean cumulative effective dose per patient from diagnostic imaging was 25.0 mSv, or 3.5 mSv annually. CT accounted for 46% of cumulative dose versus 25% for mammography. A nonbreast malignancy developed in 11% (n = 8), none of which are considered to be associated with radiation exposure.

Conclusions: In the first 5 years after BCT, the average breast cancer survivor receives 3.0 mSv of annual radiation exposure due to screening and diagnostic imaging, in addition to the mean environmental radiation exposure of 2 to 3 mSv per year. Modern practice patterns have not altered radiation exposure. Additional radiation exposure necessitated by workup of suspicious lesions detected within the remaining breast tissue was not a common event. Overall radiation exposure in breast cancer survivors is low, and need not dissuade patients from BCT. However, it seems prudent to consider the risks of radiation exposure when ordering potentially low-yield screening studies in asymptomatic patients.

Surgical Trends in BRCA1/2 Mutation Carriers With Breast Cancer: A Single-Institution Experience

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Objectives: Women who are carriers of BRCA 1 and BRCA 2 (BRCA 1/2) genetic mutations are at a higher risk than the general population of developing breast cancer in their lifetime. At our institution they are followed in our Cancer Risk Evaluation Program (CREP). We hypothesized that the use of genetic testing since 1996 has led to significant changes in the surgical decision making of these patients.

Methods: Our study cohort included 163 BRCA 1/2 mutation carriers who were diagnosed with breast cancer between 1963 and 2009 and have been followed and treated in our institution's CREP. We evaluated the types of surgery that they had: lumpectomy, unilateral mastectomy, bilateral mastectomy (including contralateral prophylactic mastectomy), and reconstruction according to the year of their breast cancer diagnosis.

Results: Seventy-six (53%) of 144 of our BRCA 1/2 mutation carriers underwent bilateral mastectomies. The rate of immediate bilateral mastectomy rose from 0% to 31% after the period of 1990-1994 as the rate of unilateral mastectomy fell from 75% to 5%. As bilateral mastectomies increased, so did the women who opted for immediate reconstruction after their surgery. The percentage of women opting for breast-conserving surgery did not significantly change from 56% to 64%. Genetic testing results also affected the surgery choice of 41 (51%) of 81 women, converting them from their original breast-conserving surgery choice to bilateral mastectomy.

Conclusions: Bilateral mastectomy use has increased in breast cancer patients with BRCA 1 and BRCA 2 mutations, with a significant increase in use after 1996. This corresponds to the time when BRCA 1/2 testing was commercially available. Over the same period, there has been a total increase in bilateral breast reconstruction, especially with free flaps. This will have implications for upfront versus delayed contralateral and bilateral prophylactic mastectomies in the future.

Transforming Cancer Surgery: Assessing Efficacy of a Guided Imagery Meditation Audio CD in Newly Diagnosed Breast Cancer Patients

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Objectives: The prevalence of depression and anxiety among newly diagnosed breast cancer patients has been reported to be as high as 46%. Psychological reactions to a diagnosis of breast cancer and supportive measures have been linked to treatment response and survival. As many as 87% of women diagnosed with breast cancer utilize complimentary/alternative therapies. We initiated a pilot study of the use of a guided imagery audio CD for newly diagnosed breast cancer patients awaiting surgery.

Methods: Women aged 18-85 undergoing a lumpectomy or mastectomy with or without reconstruction for biopsy-proven DCIS or invasive carcinoma were offered participation. Pre-operatively they completed a questionnaire covering demographic factors, and rated their attitudes and expectations regarding surgery, meditation, and mind/body relationship on a 1-5 Likert scale. They then received the "Transforming Cancer Surgery" CD to take home, and were encouraged to listen to it daily until surgery. At least a week after surgery, participants completed a follow-up questionnaire about attitudes immediately before surgery and at present. We categorized participants by number of times they reported listening to the CD, using chi-square tests to assess statistical significance.

Results: Of 34 women who completed the study thus far (target N = 50), 16 reported listening 1-4 times, 12 reported listening 5-25 times, and 6 reported not listening to the CD. Demographic characteristics were not associated with listening. At baseline, 4 participants (11.8%) reported feeling more than moderately depressed, 16 (47.1%) reported feeling anxious. Patients who subsequently listened to the CD scored lower, at baseline, than nonlisteners on feeling emotionally prepared for surgery (P = 0.01). Frequent listeners reported statistically significant improvement from baseline to follow-up on 3/12 measures; less frequent listeners and nonlisteners showed no improvement. On follow-up, 4 participants still reported more than moderate depression, and 10 reported more than moderate anxiety.

Conclusions: Most participants, especially those who felt emotionally unprepared for surgery, were willing to listen to the guided imagery CD. We cannot claim, but we cannot rule out, the possibility that the CD caused attitudes to improve among frequent listeners. Our pilot study continues, but our findings argue for further research on the effects of the guided imagery/audio CD among patients awaiting surgery for breast cancer.

A Comprehensive Assessment of Tumescent Injection and Sharp Dissection for Skin-Sparing Mastectomy

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Objectives: Tumescent infiltration to define the subcutaneous plane for flap elevation is a well-defined plastic surgical technique throughout the body. Within the field of breast surgery, tumescent injection and sharp dissection has been described for conventional mastectomy. Proposed advantages of this practice include reduced operative time, uniform flap thickness, potential limiting of thermal injury to the skin flaps, and access to deep tissue dissection through a smaller incision. Recently, it has been suggested that this approach may result in an increased incidence of skin flap necrosis, particularly in patients with prior radiation, increased age, history of smoking, elevated body mass index, and other co-morbidities. We reviewed our series of consecutive skin-sparing mastectomy (SSM) with tumescent injection and sharp dissection, with/without immediate reconstruction, to assess patient outcomes.

Methods: We reviewed our mastectomy database from January 2007 to September 2009 for patients undergoing SSM for a diagnosis of breast cancer: invasive ductal carcinoma (IDC), infiltrating lobular carcinoma (ILC), and ductal carcinoma in situ (DCIS). Twenty-eight SSM were performed on 25 patients. Each mastectomy was completed utilizing tumescent injection and sharp dissection. All patients were offered the opportunity for immediate reconstruction. Outcomes were assessed during postoperative hospital stay and at routine 2-week follow-up examination.

Results: Fourteen patients had a primary diagnosis of DCIS (1 bilateral, B/L), 9 patients with IDC, and 2 ILC (1 with contralateral DCIS). One patient had a contralateral prophylactic SSM for BRCA gene mutation. Invasive carcinoma tumor size ranged from 1-4.3 cm. Patient median age was 50 yrs (range, 30-74). Co-morbidities included diabetes mellitus (5), coronary artery disease (1), and smoking (2). One patient had a prior B/L mastopexy. Additionally, 2 received prior chemotherapy and ipsilateral conventional whole-breast radiotherapy: one, 10 years prior for a primary breast cancer and the other, as part of primary breast-conserving therapy. In 20 cases, a SLNBx utilizing both technetium and lymphazurin blue dye was performed at the time of the SSM. Twenty-one patients opted for immediate breast reconstruction (9 TRAM flaps and 14 tissue expanders, TE). Initial saline placed in the TE averaged 162 cc (10 cc-360). One patient presented post-op week 2 with mastitis that resolved with oral antibiotics. No skin flap necrosis, dehiscence, seroma, bleeding, or wound infections occurred. There have been no recurrences to date.

Conclusions: When performed properly, tumescent injection and sharp dissection for SSM is safe and effective in an increasing variety of patient populations. This technique efficiently results in optimal oncologic and aesthetic outcome for patients having to undergo mastectomy.

An Analysis of Fine Needle Aspiration Versus Core Needle Biopsy in Clinically Palpable Breast Lesions: A Report on the Predictive Values and a Cost Comparison

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Objectives: Fine needle aspiration (FNA) is a well-established tool in biopsy of breast masses. However, there has been a shift toward the use of core needle biopsy (CNB) with image guidance secondary to providers citing decreased accuracies and high inadequacy rates in FNA specimens. We hypothesize that FNA has comparable predictive values to CNB and is more cost-effective, making it a more attractive modality for use in the initial biopsy of palpable breast lesions.

Methods: A retrospective chart review was conducted on 162 patients who underwent either FNA or CNB of a palpable breast lesion and had histological confirmation with surgical biopsy in the calendar year of 2005 at our institution. The cohorts involved 68 in the FNA group and 94 in the CNB group. The predictive values were calculated. A basic cost analysis to perform an FNA without imaging versus CNB with imaging was performed

Results: There were no false-positives or false-negatives in either CNB or FNA groups. There were 37 patients with a benign FNA cytology and negative pathology for malignancy. There were 13 patients with malignant FNA cytology and positive pathology. There were 4 patients with suspicious FNA cytology, 3 of whom were positive. There were 14 patients with inadequate FNA cytology, 7 of whom were benign, 2 of whom were malignant, 1 of whom had a follow-up FNA that was benign, and 4 of whom had at least 1-year radiographic evidence of stability. When taking the suspicious and inadequate specimens into account, FNA was diagnostic 74% of the time. The sensitivity was 89%, specificity was 98%, positive predictive value was 94%, negative predictive value was 96%, and accuracy was 96%. There were 41 patients with benign CNB and negative pathology. There were 50 patients with malignant CNB and positive pathology. There were no inadequate specimens in the CNB group; however, there were 3 suspicious CNB specimens all of which were positive for malignancy. The CNB was diagnostic 97% of the time with sensitivity, specificity, positive and negative predictive values, and accuracy of 100%. The differences in the predictive values did not reach statistical significance. The cost to perform an FNA without imaging was $166.34, compared to CNB with imaging which was $477.92.

Conclusions: This analysis demonstrated that there were no false-positive or false-negative specimens in either FNA or CNB groups. It also demonstrated comparable predictive values between the 2 modalities. In addition, FNA was more cost-effective. FNA is still a viable option for biopsy of palpable breast lesions.

Expanding the Role of Breast Conservation Surgery to Large and Retroareolar Tumors by Different Oncoplastic Techniques

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Objectives: Oncoplastic breast surgery comprises 2 main techniques: replacement and displacement methods. This study evaluates and compares 2 procedures of synchronous reconstruction with breast conservation surgery (BCS) commonly used at our institution, namely, the autologous latissimus dorsi (LD) flap and the inferolateral dermoglandular flap of Grisotti.

Methods: The study included 52 patients with histologically proven breast cancer who were treated by BCS and immediate reconstruction. Among them, 29 had volume replacement with the LD flap while the remaining 23 underwent advancement of an inferolaterally based dermoglandular flap. Patients' age ranged from 31 to 62 years (mean, 48.4 ± 10.2 years). In the first group, tumors' size ranged from 28 to 69 mm (mean, 48 ± 13.4), while in the second group, it ranged from 4 to 33 mm (mean, 16.9 ± 8.6 mm). In the first group, tumor location involved the central quadrant in 45%, the upper quadrants in 41% and the lower quadrants in 14% of cases; while in the second group it was strictly retroareolar in 73.9% but extended beyond the areolar edge for a maximum of 1.5 cm in 26.1%.

Results: In the first group, the median size of the lumpectomy specimen was 219 cm^3. The safety margins obtained ranged between 0.9 and 2.8 cm. The mean combined operating time was 238 minutes. The mean blood loss was 320 ml and no patient required blood transfusion. The median hospital stay was 5 days. No serious sepsis or flap viability problems were encountered. Cosmetic results were satisfactory in 69% of patients. Only 17% showed some asymmetry in size, 7% some discrepancy in skin color and 7% a mild difference in nipple-areola complex (NAC) level. In the second group, the free safety margin ranged from 9 to 13 mm (mean, 10.2 ± 0.9 mm). The procedure lasted a mean time of 195 ± 12.7 minutes and blood loss was estimated at a mean of 225 ± 64.8 ml. Hospital stay ranged from 2 to 10 days (median, 4 days). Postoperatively, superficial flap sloughing occurred in 2/23 patients and localized full thickness sloughing in 1/23 patients. Cosmetic results were found excellent in 26.1%, good in 34.8%, satisfactory in 30.4%, poor in 8.7%, and very poor in none. Both procedures did not delay the start of adjuvant treatment nor did they hamper clinical and mammographic follow-up.

Conclusions: Mastectomy can be avoided in a large number of women with small breast/tumor ratio or with retroareolar tumors thanks to various oncoplastic techniques. The LD and the Grisotti flaps are 2 examples. These procedures will preserve women's self-esteem without compromising the adequacy of resection, with minimal morbidity, very satisfactory cosmetic results, no need for prosthesis, and no interference with postoperative clinical or radiological follow-up.

Breast Care: Can a Rural Program Produce Equivalent Results?

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Objectives: Several studies have shown a relationship between breast cancer survival and hospital and surgeon volume. Smaller hospital and surgical volumes, lack of surgeon specialization, and rural settings are associated with worse outcomes. Patient access, surgeon skills and knowledge, and inconsistency of referral for postoperative adjuvant care were seen as potential causative factors for this discrepancy. Our hospital is a 180-bed acute care inpatient teaching facility that serves 8 rural counties, 5000 square miles. Three surgeons care for 100 new breast cancer patients each year. We investigated programatic changes and compared our outcomes to national benchmarks.

Methods: A breast care committee was organized as a multidisciplinary committee to oversee breast care. A mid-level breast care coordinator position was created to improve patient navigation through the system beginning with an abnormal mammogram or exam. We improved access to screening by adding remote mammography sites, a mobile mammography unit, same-day appointments, and by providing low-cost and free examinations. Data were obtained from our institution's mammography registry, breast care coordinator, and tumor registry. The tumor registry is maintained by certified tumor registrars and is approved by the American College of Surgeons Commission on Cancer. Our data were compared to published data.

Results: While the major goal was to provide equivalent survival, we also looked at other measures of quality. Screening mammography has increased with improved access; 60% are performed at satellite locations. Time from abnormal mammogram to definitive surgery has been decreased by more than 50%. All patients were presented at Breast Tumor Board and the institution met or surpassed all standards set by the NCDB e-QuIP for adjuvant therapy.

Stage	0	I	II	III	IV
Institution	94%	92%	83%	40%	25%
NCDB	94.9%	90.6%	81.7%	55.9%	18.2%

Conclusions: We have shown that by organizing a multidisciplinary approach to breast care, quality care can be received in a smaller, rural setting. The care needs to be coordinated from screening to long-term follow-up. Special attention should be given to insuring appropriate postoperative adjuvant treatment. Comprehensive breast cancer care provided in a rural setting can be equivalent to that of larger volume urban hospitals.

Are Percutaneous Biopsy Rates a Reasonable Quality Measure in Breast Cancer Management?

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Objectives: Percutaneous needle biopsy rather than open surgical biopsy is the recommended procedure for diagnosis of breast pathology. Use of percutaneous needle biopsy has been proposed as a quality measure of breast cancer care. We evaluated rates and reasons for failure of patients undergoing percutaneous needle biopsy as the initial diagnostic procedure for evaluation of breast pathology.

Methods: We performed a retrospective cohort review of patients undergoing image-guided percutaneous and open surgical excisional breast biopsies from January 2006 through July 2009 at a multidisciplinary breast health center. For patients who underwent open surgical biopsy, factors associated with failure to undergo a percutaneous approach were analyzed.

Results: During the study period, 1196 breast biopsies were performed; 87 (7.3%) were open surgical biopsies and 1109 (92.7%) were percutaneous needle biopsies. The average patient age was 54 years (range, 14-94). The majority of patients had a BI-RADS score of 4 on imaging (68.8%). Imaging used for percutaneous guidance or needle localization was ultrasound in 58.9%, mammogram in 40.0%, and MRI in 0.9%. Patients were more likely to undergo open surgical excisional biopsy if mammogram imaging was used ($P < 0.001$), the lesion was in the central or lower inner quadrant of the breast ($P = 0.002$), the image had a BI-RADS score of 1 or 6 ($P < 0.001$), or the targeted lesion was calcifications ($P < 0.001$). There were no differences in rates of percutaneous biopsy by age, size of lesion, or breast density. Reasons for failure of percutaneous biopsy were technical (calcifications not visualized, breast too thin, patient could not lie prone, proximity to implant, etc) in 86.2% of cases. No reason was documented in 10.3% and 3.4% of patients refused a percutaneous approach.

Conclusions: The majority of patients in this series underwent percutaneous biopsy as an initial diagnostic approach to the clinical management of breast diseases. Most percutaneous failures are due to technical reasons and subsequent open biopsies are only rarely undertaken for other reasons. Percutaneous biopsy rates are a reasonable quality measure in breast cancer care. Documentation of failure to meet this benchmark should be stringently monitored.

Resection Margins in Ultrasound-Guided Breast-Conserving Surgery

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Objectives: Inadequate resection margin rates range from 4% to 41% following breast-conserving surgery. Inadequate margins on pathologic examination is an important predictor of increased incidence of ipsilateral breast cancer recurrence. Patients with close or involved margins have repeated operations until an acceptable margin is achieved. Two small series have shown that intraoperative ultrasound will result in positive margins in 4% (palpable lesions) and 11% (nonpalpable lesions). We quantified size of margins attained following intraoperative-ultrasound-guided breast conserving surgery and assessed the relationship of the size of these margins to several variables: tumor size, multifocality, palpability, ductal versus lobular histology, and the presence of an intraductal component.

Methods: From June 2008 until October 2009, patients with known breast cancer undergoing breast-conserving surgery, and in whom the operating surgeon visualized the tumor by ultrasound, were included. Patients were excluded if ultrasound margins were not recorded, if margin re-excision was directed by participation in a clinical trial rather than ultrasound findings, or if the patient had neoadjuvant chemotherapy. For nonpalpable cancers, a localizing wire was inserted under ultrasound guidance preoperatively. An ultrasound probe covered by a sterile sleeve was used to guide resection after incision. After excision, saggital and transverse tumor margins were measured by ultrasound. Additional resections were performed if margins were close, at the discretion of the surgeon. Ultrasound measurements were prospectively recorded and compared with pathologic margins.

Results: Thirty-eight patients were included. Mean age was 61.7 (±12.2; range, 30-89). There were 33 (79%) invasive ductal carcinomas, 4 (11%) invasive lobular, 1 (3%) mixed ductal and lobular, and 3 (8%) other histologies. Sixteen (42%) of the patients had additional DCIS associated with their cancers. Twenty-one patients (55%) had palpable tumors and tumor size was 1.7 cm (±0.7; range, 0.7-3.0) clinically and 2.0 cm (±1.0; range, 0.7-4.8) as measured by the pathologist. Nine patients (24%) had multifocal tumors. Of these, only 4 patients were diagnosed with multifocal disease before surgery. There was good correlation between margins recorded by ultrasound and those measured by the pathologist (R^2 0.533505, $P < 0.0001$). Fourteen patients had margins re-excised at the time of surgery, 12 (86%) in the direction of the closest pathological margin. Three patients (8%) had re-operation for close or involved margins, all of them in tissue that had been excised additionally as indicated by ultrasound. Two of the 3 patients had multifocal disease that had not been detected preoperatively. There was no residual cancer detected on pathological examination of the re-operation specimen in any of the patients. No patient had to have mastectomy because of involved margins. Underestimation of margins by ultrasound versus pathology margins was only affected by multifocality ($P = 0.004$). Tumor size, palpability, histology, and the presence of intraductal carcinoma did not cause significant underestimation of margins by ultrasound.

Conclusions: Intraoperative ultrasound may be an effective tool to maintain a low level of re-operation after breast-conserving surgery. The only factor that affects the accuracy of ultrasound appears to be the presence of multifocal tumors that were not detected preoperatively.

The Distribution of Recurrence Scores and Other Parameters in Onco*type* DX® Submissions by Surgeons Compared to Medical Oncologists

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Objectives: The recurrence score (RS) generated by the Onco*type* DX Breast Cancer Assay quantifies the likelihood of distant recurrence and potential chemotherapy benefit in early stage, ER+ breast cancer patients. The objective of this study was to examine whether there are differences in the RS distribution and other parameters when the Onco*type* DX assay is ordered by surgeons versus medical oncologists.

Methods: Forty-four thousand seventy-nine tumor specimens from early-stage, ER+ breast cancer patients were analyzed in the Genomic Health laboratory from October 2008 until September 2009. Standardized quantitative RT-PCR analysis for the 21 genes was performed; reference normalized gene expression measurements ranged from 2 to 15, each 1-unit reflects a ~2-fold change in RNA. Parameters such as patient age, HER2-status, nodal status, histopathology, type of specimen submitted, and time from surgery to RS report generation were recorded. We compared the observed distribution of RS results and parameters described above for submissions initiated by surgeons versus medical oncologists.

Results: There were 34,317 samples submitted by medical oncologists and 9762 by surgeons over a period of 12 months. The average patient age was 58 years old for tests ordered by both groups. Most submissions were HER2-negative, however, surgeons sent a statistically significant higher percentage of HER2-positive samples (2.4%) compared to medical oncologists (1.8%). The standard histopathology was similar for both groups, with 85% ductal and 7% lobular cancers. Approximately 12% of samples were submitted as core needle biopsies by both groups. The distribution of RS results was identical for surgeons and medical oncologists, with 55% low risk, 32% intermediate, and 12% high risk. There was a statistically significant difference in the number of node-positive assays ordered, with medical oncologists submitting 4.6% of samples compared to 3.7% for surgeons. The time from surgery to RS report generation was notably different between groups. On average, patients received their RS results 35 days from surgery (median, 26 days) when surgeons ordered the Onco*type* DX assay, compared to 51 days (median, 40 days) when medical oncologists ordered.

Conclusions: The distribution of RS results and most clinicopathological parameters is consistent between surgeons and medical oncologists. However, surgeons ordered the Onco*type* DX assay more frequently for HER2-positive patients, whereas medical oncologists ordered more often for node-positive patients. The time from surgery to RS report generation was significantly shorter when surgeons ordered the test. Given the anxiety that patients experience following surgery and prior to making an adjuvant treatment decision, there could be value in surgeons ordering the Onco*type* DX assay as it is expected to reduce the time required for patients to receive results. Moreover, having RS results at the time of first consult with the medical oncologist can lead to a smoother and more meaningful conversation with the patient.

Should We Excise All Breast Core Biopsy–Proven Papillary Lesions?

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Objectives: In current surgical and radiologic literature, there still remains a lack of consensus on management of core biopsy–proven papillary lesion. The primary objective of our study is to identify histologic features which determine our clinical decision in identifying which patients warrant immediate surgical excision versus a subset of patients who can undergo close surveillance.

Methods: We will perform a retrospective chart review of patients diagnosed with papillary lesion by core biopsy, treated at the Breast Health Center of Women and Infants' Hospital between January 1999 and August 2009. The patients included will have had core biopsy–proven papillary lesions, including intraductal papillomas, papillomatosis, sclerosing papillomas, and intraductal papillomas with atypical ductal hyperplasia. The patients excluded will have history of ductal carcinoma in situ, lobular carcinoma in situ, or invasive carcinoma, either diagnosed concomitantly with the papillary lesion or diagnosed previously.

Results: The results reflect the patients reviewed from December 2004 until December 2007. We have reviewed 57 patients and the average age of the population is 50.8 years, with a range between 27 and 80 years. The reason for core biopsy was image-detected calcifications in 31.6% (n = 18), mass in 61.4% (n = 35), calcifications with mass in 5.3% (n = 3), and MRI enhancement in 1 patient. The core biopsy approach was stereotactic guidance in 35.1%, ultrasound guidance in 63.1%, and MRI guidance in 1 patient. Of the total 57 patients, 38 patients underwent surgical excision, 17 underwent close-surveillance with clinical breast exam and/or radiologic monitoring, and postbiopsy management was unknown in 2 patients. We reported 89.5% (n = 34) patients to have benign findings with concordance between core biopsy and surgical excision pathology. We had 4 patients with malignant findings, of which 7.4% (n = 2) patients had focally bordering ductal carcinoma in situ, 1 had ductal carcinoma in situ, and 1 had invasive ductal carcinoma. Of the group that underwent close surveillance (n = 17), 13 patients (76.5%) had follow-up with radiographic imaging and/or clinical exam and there was no evidence of second-breast event in this group. The duration of follow-up ranged from 8 to 48 months. We had 3 patients lost to follow-up, and 1 patient in the surveillance group underwent surgery within 8 months secondary to nipple discharge and her pathology showed ductal carcinoma in situ with microinvasion. Atypical ductal hyperplasia was identified in 16 patients, and all underwent surgery except 1 patient whose management is unknown. In the ADH group, 11 patients who underwent surgical excision had benign findings and 4 patients had malignant findings as previously described.

Conclusions: In conclusion, there is a trend toward histopathologic concordance between core biopsy and surgical excision pathology. We identified atypical ductal hyperplasia to be present in the core biopsy findings of patients who on final surgical excision pathology had diagnosis of ductal carcinoma in situ or invasive carcinoma. As we increase our sample size, we will prove that in the absence of atypical ductal hyperplasia, close surveillance of papillary lesion can be a reasonable alternative to surgical excision.

Breath Analysis by Mass Spectrometry: A New Tool for Breast Cancer Detection?

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Objectives: Investigate the utility of the analysis of breath volatile organic compounds (VOCs) as an effective and affordable modality for breast cancer (BC) detection and monitoring. We collected breath samples with a simple portable device to determine whether BC patients have breath VOC distinct from those in healthy volunteers.

Methods: A prospective IRB-approved pilot study enrolled 20 healthy volunteers ≥40 years of age, BC-free within 5 years, and a negative mammogram within 1 year of breath collection and 20 newly diagnosed stage II-IV BC patients. After fasting for 2 hours, the study subjects deeply exhaled into a Markes Bio VOC Breath Sampler equipped with a Radiello diffusive sampler 5 times at 5-minute intervals trapping alveolar breath VOCs. Potential interferents were identified through a questionnaire completed during the collection session. The exhaled breath samples were analyzed by thermal desorption/gas chromatography/mass spectrometry. Three hundred eighty-three VOCs were identified in the breath of both populations.

Results: In conformance with other researchers, our results indicate that individual compound identification is not appropriate for determining the presence or absence of disease, but aggregate low-dimensional summaries and compound quantities result in specific patterns that can confirm disease. Laplacian eigenmaps were used to construct informative combinations of individual VOCs with high discriminatory power. A definite clustering of the presence of BC from cancer-free points was found. We achieved an overall sensitivity of 72%, and a specificity of 64% resulting in a correct classification rate of approximately 77% for differentiating breast cancer cases from no cancer.

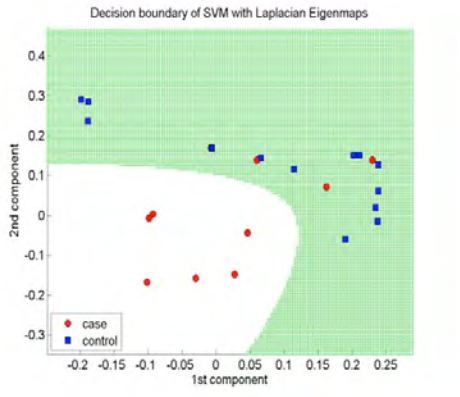

Figure 1. Classification of a new point from a validation set is performed using decision boundaries (green-white). Red points represent cancer patients and blue points represent control subjects.

Conclusions: Our data show promising evidence that BC patients can be differentiated from healthy volunteers through distinct breath VOCs. We continue to accrue to this pilot study with the intent of developing portable collection and sensing devices for women without access to standard screening, interval screening for patients at high risk for BC, and disease monitoring for BC patients after completion of treatment.

The Role of Preoperative Magnetic Resonance Imaging: Is There an Impact on the Surgical Treatment of Breast Cancer Patients?

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Objectives: The routine use of magnetic resonance imaging (MRI) for the diagnosis and treatment of breast cancer remains controversial. Prior studies have shown an increased length of time from diagnosis to treatment and an increased rate of mastectomy in patients who received preoperative MRI. The purpose of this study is to examine the relationship between MRI and the surgical treatment of breast cancer.

Methods: Two hundred five patients diagnosed with invasive breast cancer or ductal carcinoma in situ (DCIS) between 2008 and 2009 were retrospectively reviewed at a single institution. Data was collected and analyzed for differences between patients who received MRI and those who did not. We evaluated length of time from diagnosis to treatment, mastectomy rate, percentage of breast conservation, and number of biopsy procedures performed.

Results: A total of 205 patients were analyzed, of which 126 (61.5%) underwent breast conservation and 79 (38.5%) underwent mastectomy. Of these patients, 64.4% had the pathologic diagnosis of invasive ductal carcinoma (IDC), 7.3% invasive lobular carcinoma (ILC), 6.8% mixed invasive ductal and lobular carcinoma, and 21.5% DCIS. Preoperative MRI was performed in 67.8% of patients. There was no significant difference in time from diagnosis to treatment or association with the type of surgical treatment. The percentage of patients who had mastectomy was equal in the MRI and non-MRI group, 38.8% and 37.9%, respectively. MRI was, however, associated with an increased number of breast biopsies per patient ($P = 0.001$).

Conclusions: At this institution, preoperative MRI led to an increased number of breast biopsies per patient without an observable difference in time to surgery or type of surgical treatment. These findings may be related to the growing experience of our radiologists and surgeons with breast MRI. While the number of MRIs performed continues to increase, the usefulness of preoperative MRI has yet to be established. Further studies are necessary to evaluate if MRI has a true impact on clinical outcome or overall survival.

Nipple Aspirate Fluid As a Tool for Comprehensive Risk Assessment in a Breast Specialty Practice

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Objectives: To characterize breast cancer risk factors in asymptomatic women and determine how nipple aspirate fluid (NAF) atypia findings might affect clinical care in a dedicated breast practice.

Methods: Previous studies have shown that atypia in NAF is a marker of increased risk (2-5X) for breast cancer. Over the last 15 months, local primary care physicians performed 1800 tests with a new device (HALO® Breast Exam), which automates the collection of NAF. These tests are typically performed during well-woman visits on asymptomatic patients. Subsequently, 21 patients with atypia (1.2% of patients) found in NAF were referred to our breast practice comprised of a dedicated breast surgeon and breast radiologist. None of these patients had previously been referred for risk evaluation and counseling prior to the HALO exam. All patients underwent standard clinical evaluation, including comprehensive risk assessment with analysis of family history, breast density, etc. The breast radiologist performed all indicated imaging procedures and interpretations. MRI was performed if diagnostic mammography and/or ultrasound did not provide sufficient information for clinical decision making. All patients are followed after initial risk assessment, counselling, and imaging studies.

Results: Age range was 37-53 with a mean age of 45. All but 1 patient had heterogeneously dense to extremely dense breasts (using BI-RADS classifications), conferring additional risk in those women over age 45 (11 or 55%). Seven (33%) of 21 patients had a family history, but only 1 patient had strong family history (first-degree relative). All but 2 patients (19) were eligible for annual screening mammography, but only 5/21 (24%) had had a screening mammogram within the last 12 months. Seven (33%) patients had imaging findings considered “suspicious” (BI-RADS) requiring minimally invasive biopsy for tissue sampling with follow-up excisional biopsy if clinically indicated. Five of 7 had findings of interest including papilloma. Two of the patients with papilloma had associated atypia, including ADH and ALH; the patient with confirmed ADH on excisional biopsy was offered tamoxifen. At 6-month and 12-month follow-up (n = 9 who have had follow-up to date), 7 of the women had signs of proliferative breast activity, including increased nodularity, irregular masses, and palpable findings.

Conclusions: Patients who had not previously been offered risk evaluation, assessment, and reduction options are now being closely followed in our practice with 6-month clinical visits, staggered imaging studies—mammography and MRI—and referrals for chemoprevention and genetic counseling, if indicated. Consideration of atypical NAF results helped us triage patients for better utilization of clinical and imaging resources. The HALO test may assist community primary care physicians identify patients who need risk evaluation and close clinical follow-up. Long-term follow-up, including annual HALO exams and analysis of patient demographics, clinical and imaging results, may help us better understand breast physiology and may result in the early detection and treatment of breast cancer, particularly in patients we can identify as higher risk individuals.

Preoperative Genetic Risk Assessment Among Women Undergoing Bilateral Prophylactic Mastectomy for Cancer Risk-Reduction

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Objectives: Preoperative genetic risk assessment is an important decision-making tool for women who are considering cancer risk-reducing surgery. Our objective was to determine the prevalence of BRCA testing among women undergoing bilateral prophylactic mastectomy (BPM), and to review the characteristics of women who choose BPM within a single metropolitan health care system.

Methods: We retrospectively reviewed records of women who underwent BPM within a single health care system that includes 6 metropolitan hospitals. Our study included women with biopsy-proven lobular carcinoma in situ (LCIS) and atypical hyperplasia (AH), excluding those with a preoperative diagnosis of invasive carcinoma of the breast or ductal carcinoma in situ (DCIS). We collected information on patient demographics, breast cancer risk factors, BRCA testing, reconstruction, and associated cancer-reducing surgeries. We compared patient characteristics of women undergoing preoperative BRCA testing to those not tested.

Results: From January 2002 to July 2009, a total of 55 BPMs were performed. Documented indications for BPM were family history of breast cancer (n = 33, 60.0%) or preoperative breast biopsy demonstrating LCIS (n = 10, 18.1%) or AH (n = 4, 7.3%). Three women had multiple risk factors, while 8 women (14.6%) had none of these risk factors documented. Only 20 women (36.4%) had BRCA testing prior to BPM; 18 women had BRCA mutations (32.7% of all women who underwent BPM). Compared to women not tested, BRCA-tested women were younger (38.4 years vs 47.5 years, $P = 0.001$) with a stronger family history of cancer (100% vs 45.7%, $P < 0.001$). More BRCA-tested women (n = 7, 35%) had previous or simultaneous cancer risk-reducing surgery (hysterectomy/oopherectomy) at the time of BPM than nontested women (n = 5, 14.2%, $P = 0.04$). BRCA-tested women also underwent reconstruction more frequently (90.0% vs 57.1%, $P = 0.01$).

Conclusions: In this study from a metropolitan health care system, we found that most women who undergo BPM do not receive preoperative genetic testing. Further studies are needed to fully understand the decision-making process that leads to irreversible risk-reducing surgery in the absence of precise genetic risk assessment.

A Prospective Controlled Trial of the PEAK PlasmaBlade® in the Evaluation of Breast Cancer Surgical Specimens With Touch Prep

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Objectives: Approximately 20-50% of malignant breast lump excisions result in positive margin status, requiring additional excisional procedures. The traditional method of margin evaluation relies upon histological examination of paraffin-embedded tissue; however, traditional electrosurgical (ES) devices impart thermal injury to within 1-2 mm of the margin, destroying nuclear grading information and degrading fine tissue architecture. Imprint cytology (IC) has been used to evaluate surgical specimens intraoperatively for residual malignancy, however this technique requires an experienced cytopathologist for interpretation and sample quality is limited by extensive electrosurgical artifact. We present the results of a prospective trial using automated IC analysis in conjunction with the PEAK PlasmaBlade (PB) during breast cancer excision to assess the relative thermal injury to breast tissue and ability to retrieve undamaged cells for IC analysis. The PB uses pulsed radiofrequency energy with a highly insulated electrode tip to create a precision edge for cutting with minimal thermal injury.

Methods: Female subjects with an established diagnosis of palpable invasive ductal carcinoma underwent excision and 6 standard margin faces were examined via IC and compared to calibrated scalpel (SC) margins. Calibrated margins were collected by cutting into the tumor with PB and ES. Permanent section (H&E) and immunofluorescent IC slide images were captured using digital slide scanning technology. Evaluation of thermal injury depth at the margin was conducted blindly against the true and calibrated margins. Analysis of the distribution of intact surface epithelial cells from IC was conducted using a proprietary diagnostic software algorithm.

Results: We studied 9 patients. The mean thermal injury depth of calibrated positive margins for ES was 410.59 μm (max, 1802.28) and 125.83 μm (max, 512.73) for PB; at the true-negative margin, these values were 296.59 μm (max, 948.88) and 221.60 μm (708.97), respectively. The automated analysis demonstrated that IC of the calibrated margins cut with PB could be analyzed using automated microscopy as the fluorescent staining pattern and the shapes and sizes of the harvested nuclei were sufficiently similar to cells harvested by a cold scalpel. High- resolution fluorescence analysis of the cells harvested by IC demonstrated minimal thermal injury compared to ES and H&E analysis showed the cells could be graded for identification of single cancer cells.

Conclusions: The thermal injury depth varied with the margin tissue type. In the calibrated positive margin model, a significant 69% reduction with PB compared to ES was observed ($P < 0.002$); this difference was not present on the true-negative margins. This discrepancy may be attributed to the negative margin tissue largely being adipose tissue which, upon contact with ES, liquefies and becomes a strong insulator against further thermal injury. For large infiltrates of cancer within the margin, the presence of low thermal injury provides enhanced margin analysis ability. For IC, it was observed that epithelial cells may be harvested by imprint cytology from the PlasmaBlade margin. These cells stained positive for cytokeratin and Hoechst consistent with a modest thermal injury and were sufficiently undamaged for cell grading in H&E staining.

Microwave Thermography (Oncoscan) As an Adjunct to Standard Breast Imaging

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Objectives: Many women undergo unnecessary breast biopsies based on a suspicious clinical finding. We wanted to establish the utility of microwave thermography as an adjunct to standard breast imaging in women scheduled for definitive biopsy.

Methods: One hundred eleven patients were scheduled for breast biopsy based on an abnormal physical exam, mammogram, and/or ultrasound. Each patient was preoperatively screened with Oncoscan—a noninvasive test of thermal activity in the breast that measures microwave emissions of breast tissue by passive microwave radiometry. Twenty temperature recordings were obtained from each of 10 locations in the target breast and in the corresponding locations in the contralateral breast. An additional 5 temperature recordings were then obtained in the area of the suspicious finding. A detection algorithm was used to incorporate increments of temperature readings into a total score. A significant score then designated a patient as having increased thermal activity (Oncoscan positive).

Results: Thirty-seven patients had breast cancer: IDC, 15; ILC, 3; DCIS, 16; LCIS, 3. The remaining 74 patients had benign disease, although 11 had either atypical ductal hyperplasia (ADH) or atypical lobular hyperplasia (ALH). The Oncoscan detected increased thermal activity in 42 patients, while 69 patients were considered Oncoscan-negative (Table 1).

Table 1.

	Oncoscan +	**Oncoscan -**
Benign	15	48
ADH/ALH	9	2
LCIS	1	2
DCIS	7	9
ILC	0	3
IDC	10	5

Of the 37 patients with breast cancer, 18 were Oncoscan-positive. Of the 69 patients with benign disease, the Oncoscan was negative in 50 (Table 2).

Table 2.

	Cancer	**Cancer + ADH/ALH**
Sensitivity	18/37 (49%)	27/48 (56%)
Specificity	50/74 (68%)	48/63 (76%)
PPV	18/42 (43%)	27/42 (64%)
NPV	50/67 (75%)	48/69 (70%)

Conclusions: The positive predictive value (PPV) for Oncoscan detection of breast cancer was 43%, comparing favorably with both mammogram and ultrasound. If one includes the common precursors of breast cancer—LCIS, ALH, and ADH—the PPV was 64%. This appears to be a promising technology as an adjunct to our current imaging modalities for breast cancer.

Angiosarcoma Following Breast Conservation Therapy: Our Experience, a Presentation of Cases and Review of Literature

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Objectives: Angiosarcoma of the breast is a relatively rare and aggressive malignancy of endovascular origin. It is being reported with increasing frequency as more emphasis is placed on breast conservation therapy with adjuvant radiation. We look at our experience with post-radiation angiosarcoma of the breast over a 24-year period, and present 2 cases.

Methods: A retrospective chart review of all patients treated with breast conservation surgery and postsurgical breast radiation from 1985 to present was conducted. Eight cases of angiosarcoma were identified. Histological features of the tumors were studied. Clinical and follow-up information were obtained. Two are presented in a case review looking at median interval to diagnosis, diagnosis methods, and treatment.

Results: Of the 4579 cases of adjuvant radiation therapy, 8 cases of angiosarcoma was identified (0.17%). Median interval to diagnosis was 58 months. Mean age at diagnosis was 52. Treatment was in the form of wide excision with reconstruction.

Conclusions: Although rare, postradiation angiosarcoma of the breast is a potentially devastating complication of breast conservation treatment. Compared with other iatrogenic angiosarcomas of the breast, it has a much shorter latency period. It is difficult to diagnose clinically and pathologically, and requires a high index of suspicion on the part of the clinician and the pathologist. Early diagnosis has a key role in improving morbidity and mortality.

A Randomized Controlled Trial of the PEAK PlasmaBlade in Open Breast Biopsy Compared to Scalpel and Traditional Electrosurgery

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Objectives: Traditional electrosurgery is associated with significant thermal injury to surrounding tissue during cutting and coagulation. While such thermal necrosis has been previously shown to negatively affect wound healing and postoperative course, few studies have investigated the impact of cautery artifact on pathological analysis. We present the results of a prospective, randomized, controlled study examining the effect of the PEAK PlasmaBlade on the pathological analysis of biopsy-proven breast malignancies (ductal and invasive carcinomas) compared to scalpel and traditional electrosurgery. The PlasmaBlade is a new tissue dissection instrument that uses pulsed radiofrequency energy with a highly insulated electrode tip to create a precision edge for cutting with minimal thermal injury and simultaneous hemostasis.

Methods: Thirty female subjects were randomized to either the standard of care (SOC)—scalpel (SC: #10 blade) and traditional electrosurgery (ES: Coag, 30W)—or the PlasmaBlade (PB: Cut 4 on skin; Coag 6 subcutaneous) for open lumpectomy of their suspected breast malignancy. Intraoperative data (operative time, estimated blood loss) were collected for the 2 treatment arms. Blinded histological data were recorded for tumor type, grade, size, thermal injury depth, char amount, epithelial margin damage, and effect of margin quality on diagnosis. A composite score was used to characterize the overall histological quality of the sample from these variables. Postoperatively, skin scar width for both treatment arms was recorded for comparison.

Results: Operative time, estimated blood loss, and excised sample size for the PB and SOC arms were equivalent (64 ± 4 min vs 63 ± 8 min, $P = 0.87$; 21.4 ± 7.4 mL vs 20.8 ± 2.4 mL, $P = 0.85$; 2.6 ± 1.2 cm vs 1.2 ± 0.3 cm, $P = 0.85$). Histological analysis demonstrated that use of the PB reduced thermal injury depth to the excised specimen by 65% compared to ES (132.22 ± 22.68 μm vs 380.00 ± 25.07μm, $P < 0.001$). Subjectively, scores obtained for char amount, epithelial margin damage, and effect on diagnosis revealed that use of the PB improved these values by 27%, 39%, and 20%, respectively (1.2 ± 0.2 vs 1.6 ± 0.2, $P < 0.01$; 1.3 ± 0.2 vs 2.2 ± 0.2, $P = 0.02$; 1.5 ± 0.5 vs 1.8 ± 0.4, $P = 0.04$). Overall, samples excised with the PB received a 29% higher histological quality score than ES samples (4.0 ± 0.6 vs 5.6 ± 0.4; $P < 0.01$). Postoperatively, skin scar width and quality were equivalent for SC and PB incisions at 6 weeks following surgery ($P = 0.98$).

Conclusions: Despite a small study size, the PlasmaBlade offers significant advantages over the standard of care in thermal injury depth, char amount, epithelial margin damage, and effect on diagnostic quality during pathological analysis of lumpectomy specimens. PlasmaBlade samples also demonstrated significantly improved histological quality scores than the standard of care group with equivalent operative time and estimated blood loss. On skin, PlasmaBlade scars demonstrated equivalent scarring to the traditional scalpel.

Reexcision Rates and Its Relationship to the Breast Lesion Excision System As the Initial Core Biopsy Device

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Objectives: The objective was to examine the reexcision rates when a diagnostic core is done using the Breast Lesion Excision System (BLES). To identify the size of tumors, the percentage of the tumor excised at initial core biopsy, the type of tumor, the incidence of complete excision at initial core biopsy, the margins associated with complete excision, and the significance of LVI seen at biopsy.

Methods: The study was a prospective cohort analysis of patients with early breast cancer identified on mammography. Patients presented with biopsy-proven cancer using the BLES. Exclusion criteria included patients who underwent initial mastectomy, was found to have multicentric or multifocal disease requiring mastectomy. All BLES specimens were inked and sent to pathology. A positive margin was considered to be microscopically confirmed disease at the margin. Relevant data was then abstracted from pathological, radiological, and operative reports. Tumors were classified as intraductal, lobular, ductal carcinoma in situ, mucinous, and tubular. The size of tumor initially excised at biopsy and residual tumor in the specimen post BCT were measured. The percentage of tumor removed at initial biopsy was calculated, as well as the incidence of complete excision of the cancer on original BLES biopsy. Of those patients who had complete excision, margin status was identified on the initial biopsy as well as size of the tumor. Lymphovascular Invasion was examined from the initial biopsy and correlated to the sentinel node. Reexcision rate was then calculated for all patients who underwent breast conservation therapy.

Results: One hundred forty-nine BLES stereotactic cases were reviewed. Thirty-seven cases (24.8%) were identified that had a biopsy of cancer. Pathology revealed 12 cases of DCIS, 18 IDC, 4 ILC, 2 tubular, and 1 mucinous. Seven patients who were found to have an extensive tumor, multifocality and underwent mastectomy as their surgical treatment were excluded from the study. Of the 30 patients who underwent needle localization, 14 (47%) showed no residual cancer on final pathology. Margin assessment from the Intact device showed positive margins in 8 patients (57%) and margins between 1 to 3 mm for the remainder. Of those cancers totally excised on initial biopsy, size ranged from 17 mm to 4 mm. On those 16 patients (53%) who had residual disease at the time of BCT, the size ranged from 9 mm to 7.5 cm. The percentage of tumor removed on initial biopsy by the BLES was 76%. Lymphovascular invasion was examined in 19 patients. Of 17 patients identified as negative, 16 had negative sentinel nodes (94%) and 1 positive for micrometastasis (6%). The re-excision rate for all patients undergoing needle localization following the BLES procedure was 6.6%.

Conclusions: The BLES has a low reexcision rate of 6%, lower than the national average of 30%. This may be due to total excision or removal of a substantial portion of the cancer at time of biopsy. All factors should be taken into account when trying to identify factors that can reduce reexcision rates, including the initial biopsy device.

Implementation and Evolution of a High-Risk Screening Program for Hereditary Breast and Ovarian Cancer Syndrome in a Community Hospital Setting

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Objectives: To implement hereditary breast and ovarian cancer (HBOC) syndrome in a breast center. Follow the testing patterns regarding age, risk factors, patient presentation, and surgical management over time. Evaluate the changes that occur.

Methods: A prospective study to evaluate data on all patients who met criteria for testing of HBOC syndrome. The study evaluated ages, whether affected or unaffected, and reason for presentation. The most common risk factors were identified, as well as number of individuals tested preoperatively. The data were analyzed both yearly and jointly. Surgical procedures were reviewed regarding the BRCA-negative patients and the management for those who were BRCA-positive.

Results: The average age for testing was 50. The ages ranged from 23 to 80. While affected individuals were the majority at 56.5% over the previous 3 years, in 2009 affected individuals were tested 48% of the time, showing a gradual change over time. The risk factors most commonly identified were breast cancers <50 in 52% of all patients followed by multiple breast cancers and ovarian cancer at 19% and 18%, respectively. Other risk factors were around 2-3%. All patients who were diagnosed with breast cancer were tested preoperatively so true risk regarding breast and ovarian cancers could be discussed, as well as the surgical and medical management options. Of those individuals who were tested, the reason for consultation was categorized. Breast cancer was identified 31% of the time. This was closely followed by the category “Benign Conditions” at 29%. Increased risk was at 25%, while suspicious mammogram/ultrasound was 15%. If we look at the yearly statistics, we see dramatic changes in ratio of initial presentation. In 2007 diagnosis of breast cancer was at 50% of all testing, suspicious mammogram/ultrasound was 24%, benign conditions was 22%, and increased risk was 4%. In 2009 breast cancer was down to 20%, suspicious mammogram/ultrasound down to 15.5%, “Benign Conditions” at 24%, and increased risk up to 40% Surgical management was divided into BRCA-positive and BRCA-negative patients. In high-risk individuals who were BRCA-negative, 61% had breast conservation therapy, 8% underwent mastectomy, 6% bilateral mastectomy, 13% mastectomy plus reconstruction, and 12% with bilateral mastectomy plus reconstruction. In the BRCA-positive patients, all patients who underwent surgery (33%) had bilateral mastectomy and reconstruction. They were in the ages of 40-49 and 50-59. All other individuals opted for medical screening. These individuals were in the age groups of 20-29, 30-39, 60-69, 70-79, and 80-89.

Conclusions: The indications for HBOC syndrome are well known. Once an individual or center becomes more familiar with the process, more unaffected individuals are identified and high-risk screening is performed on all patients being seen in the practice. By identifying the true risk of an individual, appropriate decisions can be made regarding surgery. In the high risk, BRCA-negative population, breast conservation therapy is the majority of surgical procedures. BRCA-positive patients opted for bilateral mastectomy with reconstruction for surgical management.

Does Pre- and Post-Neoadjuvant Breast Imaging Influence Treatment Decisions in Patients Undergoing Neoadjuvant Chemotherapy for Invasive Breast Cancer?

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Objectives: Evaluate the role of breast and axillary imaging modalities for surgical decision making in postneoadjuvant chemotherapy patients.

Methods: A retrospective chart review of 55 patients who underwent neoadjuvant chemotherapy between 2005-2008 was conducted.

Results: The mean age of the patients was 51.8 years. Forty-six (84%) had invasive ductal carcinomas. The average pre-neoadjuvant tumor size was 4.1 cm. Thirty-three (60%) patients underwent lumpectomy. Fifty-one (93%) patients had a response to neoadjuvant chemotherapy with 15 (29%) having a complete pathologic response. For 27 patients with a pre- and post-chemotherapy MRI, the average change in tumor size was 2.0 cm (49%). For lumpectomy patients, the average decrease in tumor size was 1.7 cm (49%) by MRI and 3.0 cm (86%) by final pathology. For mastectomy patients, there was a 3.1-cm (61%) decrease by MRI and 3.6-cm (71%) decrease at final pathology. Twenty-five (45%) patients had abnormal axillary lymph nodes diagnosed by axillary ultrasound (AUS) before chemotherapy. Twenty-three (92%) of these were biopsy-proven metastases. Twenty-one underwent post-neoadjuvant axillary imaging, by MRI, AUS, or positron emission scan. Four of 5 patients with MRI were found to have persistent lymphadenopathy: 2 with negative sentinel lymph node biopsy (SNB) and 2 with negative axillary lymph node dissections (ALND). One patient with a negative MRI had a positive ALND. In 7 patients with only a post-neoadjuvant AUS, 1 was positive but had a negative SNB. In the remaining 6 patients, 5 had positive SNB. In 8 patients with MRI and AUS after neoadjuvant chemotherapy, 3 had positive imaging: 1 had a positive SNB, 1 had a negative SNB, and 1 had a negative ALND. In 5 patients with both negative AUS and MRI post-neoadjuvant chemotherapy, 3 had negative SNBs, 1 had a negative ALND, and 1 had a positive SNB. Of the 25 patients with pre-neoadjuvant abnormal nodes, 16 underwent SNB after chemotherapy. Eight (50%) had positive SNB. Seven (88%) of these underwent completion ALND and 5 (71%) of these had additional positive non-SN. Thirty patients had negative or unknown nodal status preoperatively: 9 by clinical examination, 12 by axillary ultrasound, 7 by axillary ultrasound-guided biopsy, 1 by both MRI and axillary ultrasound, and 1 by MRI alone. At the time of surgery, 27 underwent SNB and 3 had ALND. Five (19%) had positive SNs. Four underwent completion ALND and 2 of these had additional positive non-SNs.

Conclusions: MRI was a good tool to monitor tumor response to neoadjuvant chemotherapy, but did not correlate with final pathology. MRI was not an accurate predictor of post-neoadjuvant tumor size and underestimated the true tumor response. Surgical decision making should not be based only on post-treatment MRI. AUS and MRI may be useful components of pre- and post-neoadjuvant chemotherapy axillary evaluation. Post-neoadjuvant AUS and/or MRI may help guide surgeons evaluating a partial response to neoadjuvant chemotherapy. However, post-neoadjuvant imaging did not correlate with surgical lymph node pathology and should not be used in lieu of appropriate lymph node staging.

Inadequate Margins of Excision When Undergoing Mastectomy for Breast Cancer: Which Patients Are at Risk?

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Objectives: Clear margins of excision are a key to the local control of breast cancer. Less is known about margin management among patients undergoing mastectomy than for those undergoing lumpectomy. We analyzed the margin status and risk factors for positive margins among patients who underwent skin-sparing mastectomies (SSM) and traditional total mastectomies (TM).

Methods: Patients undergoing mastectomies from 2003 to 2009 were included. Margins of excision were considered positive if invasive carcinoma or ductal carcinoma in situ was at an inked margin and were considered close if such disease was within 2 mm of an inked margin.

Results: Four hundred twenty-six patients were identified. The mean age was 60 years and 90% were white. Mean tumor size was 2.6 cm and 44% had multifocal disease. One hundred seventy-seven patients (42%) underwent SSM with reconstruction and 249 (58%) TM. In the first mastectomy specimen, 19 patients (4%) had positive margins and an additional 53 patients (12%) had close margins of excision. Of these patients, 54 (75% of those with close margins, 13% of all patients) underwent re-excision of margins intraoperatively while 17 (25% of those with close margins, 4% of all patients) returned to the operating room for re-excision after final pathologic assessment. Eight patients (2%) with close final margins did not undergo re-operation and the majority of these (7) had a close posterior margin. The rate of positive or close margins on the initial specimen was 29% for SSM versus 12% for TM ($P < 0.01$) and the rate of re-operation for margins was 7% for SSM versus 2% for TM ($P < 0.01$). Patients with close or positive margins were younger (56 vs 60 years, $P = 0.01$), had larger tumors (3.1 vs 2.4 cm, $P = 0.03$), had more palpable cancers (63% vs 40%, $P = 0.01$), and a higher incidence of multifocal disease (58% vs 41%, $P = 0.04$). Logistic regression analysis revealed that the independent risk factors for initial close or positive margins included SSM (odds ratio, 2.59; 95% CI, 1.38-4.84), multifocal disease (OR, 2.08; 95% CI, 1.11-3.90), and upper-inner quadrant location (OR, 2.90; 95% CI, 1.45-5.79). Reoperation for close or positive margins was significantly associated only with SSM (OR, 4.3; 95% CI, 1.12-16.53). Twenty-three percent of patients underwent radiation therapy, including 12% of SSM and 33% of TM patients. The mean follow-up time was 28 months and the local recurrence rate was 0.9%. The rates of local recurrence and overall survival were 3% and 96%, respectively, for those with initially close or positive margins and 1% and 91%, respectively, for those with initially negative margins (P = NS for both). Local recurrence rates were not different for those undergoing SSM (1.1%) versus TM (0.8%, P = NS). No patient with close margins who did not undergo re-excision experienced a local recurrence.

Conclusions: Mastectomy patients are at risk for positive or close margins of excision. Patients undergoing SSM, with multifocal disease, or upper-inner quadrant disease are at significantly higher risk. These patients warrant more vigilant intraoperative attention to margin status to assure negative margins at the end of the first operation.

Comparative Analysis of Sentinel Lymph Node Mapping in Breast Cancer by 1% Lymphazurin Versus 1% Methylene Blue

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Objectives: Lymphazurin (L) has been widely used for sentinel lymph node mapping (SLNM) in breast cancer (BrCa) with or without radiosulfur colloid. Due to the recent unavailability and occasional adverse anaphylactic reactions of L, Methylene Blue (M) is being used for SLNM. A prospective comparison was made between L and M for patients (pts) with early stage BrCa undergoing SLNM to identify the differences between the 2 dyes.

Methods: Only pts with early stages (T1, T2) breast cancer with clinically negative nodes were included. SLNM was performed by injection of 3-5 ml of L or M in the subaereolar, intraparenchymal, and intradermal areas. If touch preparations of SLNs were negative for metastasis, no further node dissection was performed. Data was obtained regarding age, stage of the disease, sentinel lymph node status, accuracy, sensitivity, and adverse reactions for both groups.

Results: Three hundred eleven consecutive pts were studied between 2005 and 2009. L was used in 167 pts (53%) and M in 146 pts (47%); average age was 61 for both groups. SLNM was successful in 100% of pts in both groups with similar numbers of SLNs per pt (2.5 in the L group vs 2.42 in the M group, $P = 0.7$), nodal positivity (26% in the L group vs 19.2% in the M group, $P = 0.17$) and additional lymph nodes harvested. There was only 1 skip metastasis found in the M group. The most significant adverse reaction in the L group was generalized blue hives (2.5%) and drop in pulse oximetry (18.2%). The pulse oximetry drop was not clinically significant, however, in any pt. Skin necrosis was the most common side effect in the M group (3.4%). There was no axillary recurrence in either group. Cost per vial of L was $210 vs $7 for M.

Conclusions: L and M are equally effective for successful SLNM in early BrCa pts. Absence of anaphylaxis, lack of drop in pulse oximetry, and lower cost make M more desirable for SLNM than L.

The Prognostic Role of Quality of Life Assessment in Breast Cancer

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Objectives: While the use of quality of life (QoL) assessments has been increasing in the clinical oncology community, few studies have examined the prognostic significance of QoL in breast cancer. We investigated the association between QoL at presentation and survival in breast cancer patients.

Methods: We examined 1511 breast cancer patients treated at 2 single-system cancer centers between Jan 2001 and Dec 2008. QoL was evaluated in the study patients prior to initiation of treatment using the validated survey instrument EORTC-QLQ-C30. The QLQ-C30 incorporates a global scale, 5 functional scales, and 9 symptom scales. Scores range from 0 to 100 with higher scores in the global and functional scales and lower scores in the symptom scales indicating better QoL. Patient survival was defined as the time interval between the date of first patient visit and the date of death from any cause/date of last contact. Univariate and multivariate Cox regression analyses were performed to evaluate the prognostic significance of QoL after controlling for the effects of age, tumor stage, and prior treatment history.

Results: Mean age at presentation was 52.5 years. There were 590 analytic and 921 non-analytic patients. Patient stage of disease at diagnosis was I, 335; II, 591; III, 290; IV, 159; and 136 indeterminate. Median overall survival was 32.8 months (95% CI, 27.6-38.0). Mean global QoL score was 62.0 and 61.8 for locoregional (stages I-III) and metastatic (stage IV) disease, respectively; $P = 0.93$. Mean global QoL score was 67.2 and 58.1 for analytic and nonanalytic disease, respectively; $P < 0.001$. On univariate analysis, QoL function and symptom scales that were predictive of survival were physical ($P < 0.001$), role ($P < 0.001$), cognitive ($P = 0.003$), social ($P < 0.001$), fatigue ($P < 0.001$), nausea/vomiting ($P <0.001$), pain ($P < 0.001$), dyspnea ($P < 0.001$), loss of appetite ($P < 0.001$), and constipation ($P <0.001$). However, when evaluated by multivariate Cox regression analyses, only role function (degree of impairment of work and/or leisure/hobby related activities) was found to be significantly associated with survival; this was independent of other QoL function and symptom scales, age, stage, and treatment history ($P = 0.02$) such that patients with higher (better) role function scores at baseline had better survival. Higher stage of disease and prior treatment history were also found to be statistically significant predictors of worse survival in the multivariate analysis ($P < 0.001$ for both).

Conclusions: This study suggests that baseline QoL provides useful prognostic information in breast cancer. While further studies should focus on more extensive evaluation of the prognostic significance of QoL in breast cancer, these findings have important implications for patient stratification in clinical trials and may aid decision-making in clinical practice.

Quantifying Breast Cancer Risk From Atypia and Hyperplasia via Nipple Aspiration: A Synthesis of Evidence

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Objectives: Advances in technology make collection and analysis of nipple aspirate fluid (NAF) simpler and easier (Proctor et al 2005). Previous studies found increased risk of breast cancer (BC) associated with different cytologies. We address the incremental risk of BC associated with nipple aspirate fluid (NAF) cytology beyond that of the Gail score (GS), 5-year BC risk (Gail et al, 1989).

Methods: We carry out a synthetic analysis data from 4 prospective studies reported elsewhere (Tice et al, 2005, Wrensch et al, 2001) and totaling 6935 women between the ages of 18 and 83 (mean, 43.7) at time of enrollment. NAF extraction was attempted and cytology determined for each participant. The GS was calculated for each woman. Because the women were recruited mostly from breast clinics, the overall 5-year BC rate was higher than predicted by GS. We therefore recalibrated individual GS by regressing observed 5-year rates on GS quintiles. We stratified by NAF cytology to estimate whether cytology could account for risk beyond GS and to quantify any incremental risk. Observed 5-year cancer risks within category of NAF cytology were calculated as number of events divided by total exposure in 5-year units. These were adjusted by the overall mean GS, giving relative risk beyond GS.

Results:

Cytology	Cases Within 5 yrs/N	Expected Incidence (Weighted Mean of Adjusted GS)	Relative Risk* (95% Credible Interval)
Atypia	5/110 (4.55%)	1.00%	3.99 (1.30, 9.59)
Hyperplasia	20/945 (2.12%)	0.87%	2.12 (1.25, 3.59)
Other	54/5880 (0.92%)	1.01%	0.79 (0.56, 1.17)

*Relative to unknown cytology.

The BC risk associated with a finding of atypia was higher than for other cytologies, but this increased risk was limited to the initial 5 years. Atypia increased 5-year BC risk by 3.99 times that calculated from GS. The predictive value of a negative test, neither atypia nor hyperplasia, was 99.1%. In absolute terms, and assuming a relative risk of 3.99 associated with atypia, a U.S. woman with atypia at age 48 would have a 5-year BC risk of 4%, up from a pre-test 5-year incidence of about 1%. However, only about 1% of 48-year-old women have atypia. The risk associated with all cytologies other than atypia increased over time, consistent with the increased risk of BC with age.

Conclusions: Testing NAF provides evidence of risk of breast cancer diagnosis within next 5 years even after accounting for GS. Consistent with other studies (Sauter et al, 1997, Fabian & Kimler, 2000), a finding of hyperplasia or atypia increases risk while other findings slightly decrease risk. We found no evidence that cytology provides information about breast cancer risk beyond 5 years.

Increase in Contralateral Prophylactic Mastectomy—Echoes of a Bygone Era?

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Objectives: Surgical therapy for invasive breast cancer includes breast conservation therapy (BCT) or mastectomy (M) with or without reconstruction (±R). Recent studies demonstrate an increase in the incidence of contralateral prophylactic mastectomy (CPM). The goal of this study was to determine factors associated with CPM.

Methods: A breast cancer database was prospectively collected from 2000 through 2008 and retrospectively reviewed. Treatment groups analyzed included breast conservation therapy (BCT), unilateral mastectomy (M), and bilateral mastectomy. Patients with bilateral cancers were excluded from analysis. Continuous variables were compared using ANOVA F tests and categorical variables were compared using chi-square tests. Multivariate analysis was performed using logistic regression and a generalized logit model.

Results: A total of 1393 patients underwent surgery for invasive breast cancer: 69% BCT, 21% M, and 10% bilateral mastectomy. Of women treated with bilateral mastectomy, 70% chose CPM while the other 30% had bilateral cancer. Over the 9 years of this study, the rate of CPM increased significantly from 0% to 20% ($P < 0.001$), Table 1. Although there was a significant increase in overall mastectomy rate, no change in the incidence of unilateral mastectomy ±R was seen. Younger patient age was associated with CPM (mean 55 years vs 65 years BCT vs 63 years M, $P < 0.001$). This was especially true for patients <40 (44% underwent CPM). Other factors associated with CPM included significant family history ($P = 0.04$), genetic testing ($P < 0.001$), and a positive BRCA gene mutation ($P = 0.002$). Tumor characteristics included positive axillary lymph nodes ($P < 0.001$) and triple-negative disease (ER-/PR-/HER2 normal, $P < 0.001$). Patients undergoing M had a diagnosis of infiltrating lobular carcinoma more frequently (20%) than those undergoing CPM (12%) or BCT (12%) ($P = 0.003$). Interestingly, immediate breast reconstruction was more common among women who underwent CPM (61%) than unilateral M (33%) ($P < 0.001$). Finally, preoperative magnetic resonance imaging (MRI) of the breast was also associated with CPM ($P < 0.001$). On multivariate regression comparing BCT to CPM, only age (OR = 0.93; 95% CI, 0.91-0.95), tumor size (OR = 1.55; 95% CI, 1.27-1.88), multifocal disease (OR = 3.84; 95% CI, 2.20-6.72), and MRI performed (OR = 3.46; 95% CI, 2.11-5.68) were statistically significant. Comparing M to CPM, only age (OR = 0.96; 95% CI 0.94-0.98) and genetic testing (OR = 2.88; 95% CI, 1.47-5.64) were statistically significant.

Table 1. Trends in Surgical Therapy

Type of Surgery	2000	2001	2002	2003	2004	2005	2006	2007	2008
BCT	94%	74%	75%	67%	69%	67%	69%	63%	62%
M ± R	6%	24%	23%	27%	26%	26%	19%	23%	18%
CPM ± R	0%	2%	3%	6%	6%	7%	12%	14%	20%

Conclusions: The rate of mastectomy for newly diagnosed breast cancer patients is increasing because patients are choosing CPM, while the rate of unilateral mastectomy remains steady. This is particularly true for patients of younger age and strong family history. The availability of immediate breast reconstruction likely also plays a role. How stage and multifocal disease impact decision-making needs further exploration.

Review of Third and Fourth Re-excision for Narrow or Positive Margins of Invasive and Intraductal Carcinoma (DCIS)

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Objectives: The trend in breast surgery has shifted toward breast conservation. There are no studies in the literature looking at the third and fourth re-excision. We reviewed our third and fourth breast re-excision cases, with an analysis of various factors used in making this decision.

Methods: A retrospective analysis was done of 3246 patients who underwent either a lumpectomy or a needle localization biopsy between January 2003 and December 2007. We identified 585/3246 (18%) patients who underwent re-excision surgery for positive or close margins of invasive carcinoma or DCIS. On reviewing these cases, we found that 75/585 (13%) and 17/585 (3%) patients underwent third and fourth re-excisions, respectively. These cases formed our current study group.

Results: The mean patient age was 57 years (range, 33-87). Family history was positive in 23 (31%). Pathological diagnosis by trucut biopsy was available in 43 patients (57%) before the first excision. The first excision was guided by needle localization in 38 patients (51%), while lumpectomy was done in 37 patients (49%). The pathological diagnosis after excision revealed 42 (56%) cases with both invasive carcinoma and DCIS, 26 (35%) with DCIS and 7 (9%) with invasive carcinoma. Of the 68 patients with DCIS, 31 (46%) had comedonecrosis. Invasive cancer size ranged from 1 to 48 mm (mean, 18 mm). Majority of the invasive carcinoma were poorly differentiated (45%) as compared to moderately (27%) and well differentiated (28%). Third re-excision was done 31 days (range, 8-123) after the second re-excision. Re-excision of margins was done in 45 cases (60%), while 30 patients (40%) underwent mastectomy. The indication of third re-excision was a presence of positive and/or close (≤1 mm) margins for invasive carcinoma or DCIS in 72/75 patients, while 3/75 patients underwent re-excision for 2-mm margins. Margins were involved in 8 cases with invasive carcinoma, and in 25 cases with DCIS. Upon re-excision, histopathology revealed that 28/75 (37%) patients had no residual tumor. Residual tumor mandated a fourth re-excision in 17 cases, which was done 45 days (range, 14-87) after the third surgery. Re-excision of margins was done in 6 patients, while 11 patients underwent mastectomy. DCIS in margins accounted for most (16/17 cases) of the fourth re-excisions. Histopathology after re-excision revealed no residual tumor in 7/17 (41%) patients. Further analysis revealed 51 (68%) tumors that were positive for ER and PR, and HER2 positive in 26 (35%). Axillary lymph nodes were positive in 14 (19%) patients. Involved or close margins with DCIS was the most common indication for re-excision, accounting for 61/75 (82%) of third and 16/17 (94%) of fourth re-excisions.

Conclusions: Majority of the re-excisions in our patients were done for margins less than 1 mm. Lower rates of re-excision were noted in well-differentiated invasive carcinomas. A close or involved DCIS margin was more likely to lead to a third and even a fourth re-excision, pointing toward the multifocal nature of this premalignant condition. Absence of residual tumors in 40% patients of third and fourth re-excision calls for a review of margin guidelines for breast re-excision.

What Affects Hong Kong Chinese Women in Choosing the Type of Surgery for Breast Cancer?

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Objectives: Despite comparable survivals following early-stage breast cancer for women treated with breast-conserving surgery (BCS) and mastectomy, women of Chinese origin have been found to have a higher rate of mastectomies instead of BCS. In a previous local review of BCS, we found the rate of BCS is low (21.9%) as compared to that of Western countries. This study was conducted to examine the psychosocial factors on treatment decision-making processes in Hong Kong Chinese women.

Methods: Patients with early-stage breast cancer who completed surgical treatment at a university hospital from August 2008 to July 2009 were included in the study. A questionnaire with 5 dimensions of social concern was developed; these dimensions included self-image and sexuality, survival and cure concerns, concerns on subsequent treatments, role of family or friends, and role of surgeons or specialist breast nurses.

Results: One hundred sixty-five patients with early breast cancer were recruited into the study. Eighty-two (56.2%) patients had mastectomy, 41 (28.1%) had breast conservation, and 23 (15.8%) had mastectomy followed by reconstruction. Patients choosing mastectomy were found to be older ($P = 0.003$) and married ($P = 0.003$). They are less concerned about self-image and sexuality and role of family or friends. Overall, survival and cure concerns, as well as role of surgeons or specialist breast nurses, were significantly more important than the other dimensions in treatment decision-making processes ($P < 0.000$).

Conclusions: Rate of breast conservation is low among Chinese women. Surgeons and specialist breast nurses' recommendation and provision of survival and outcome information may help encourage more suitable Chinese patients to choose breast conservation.

Preoperative Breast Biopsy Performed by Nonradiologists Delays Time to Definitive Surgery in Breast Cancer

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Objectives: Breast cancer patients should have definitive surgery with the minimum number of procedures and admissions. Our aim was to identify factors that influence timely surgical management and the number of surgical procedures for women with breast cancer in a population-based analysis.

Methods: All women newly diagnosed with invasive breast cancer from April 1, 2003, to March 31, 2004, were identified from the Ontario Cancer Registry. Multivariate analysis was undertaken to evaluate the association of age, income quintile, region, community size, and effect of diagnostic biopsy on number of admissions for surgical procedures and time to definitive surgical management.

Results: A total of 7121 women were diagnosed with breast cancer, of which 6555 (92%) underwent surgical treatment. Definitive surgical management was achieved in a single admission in 4693 (72%) of patients, 1862 (28%) required 2 or more separate admissions. Women aged ≥70 years at diagnosis were more likely to have definitive surgery during a single admission (OR, 2.17; 95% CI, 1.63-2.88). Number of admissions and mean number of days to definitive surgery varied moderately according to patient place of residence but there was no association between socioeconomic status or community size. Preoperative breast biopsy (FNA or core) was performed in 5358 (82%) of the women. This was performed by a radiologist in 3454 (64%) and nonradiologist, usually a surgeon, in the remaining 1904 (36%). Patients having an image-guided biopsy by a radiologist were significantly more likely to have definitive surgery in a single admission when compared to those biopsied by a nonradiologist (79% vs 66%; OR, 1.72; 95% CI, 1.50–1.97). Greater number of admissions was directly associated with longer waits for definitive surgery; mean time for 1, 2, and 3+ admissions was 35.2, 41.4, and 87.8 days, respectively.

Conclusions: Factors associated with number of admissions to definitive surgery included age ≥70 years, patient residence, and whether a radiologist performed the biopsy. We recommend that preoperative breast biopsy is image-guided and performed by a radiologist as this facilitates timely surgical management.

Disparities in Breast Cancer Surgery Persist Particularly Among the Elderly

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Objectives: Variation in the treatment of breast cancer has previously been demonstrated in North America. The purpose of this study was to re-examine practice patterns on a population level to determine if disparities and gaps in care persist.

Methods: All patients diagnosed with breast cancer from April 1, 2003, to March 31, 2004, were identified from the Ontario Cancer Registry. Administrative data linkages with physician billing codes and Canadian Institute of Health Research datasets were used to determine patient demographics, health provider details, and treatments performed on patients within 1 year of diagnosis.

Results: A total of 7121 women were diagnosed with breast cancer during the study period. Of these, 6555 (92%) underwent surgical treatment; 1829 (27.9%) of these patients were aged ≥70 years. Preoperative imaged-guided breast biopsy (FNA or core biopsy) was performed in 82% of cases but were less frequent in patients aged >70 years (76.5%). Overall 4021 (60%) of patients underwent breast-conserving surgery. Mastectomy was more frequent in patients ≥70 years old (42.5%), compared to those 50–59 years old (33.2%). Of patients ≥70 years old, 27.3% did not undergo any form of axillary staging procedure. Breast reconstruction was performed in 17.1% of mastectomy patients. Breast reconstruction decreased with increasing age group; 39.4% of 20- to 30-year-old and 8.6% of 60- to 69-year-old patients had reconstruction. For patients undergoing breast-conserving surgery, 87.4% had a postoperative radiation oncology consultation and 82.7% (3327) actually received radiation treatment. Approximately 90% of all patients in the 20- to 69-year age groups had postoperative radiation oncology consultation and treatment, however, these figures dropped to 73.5% and 63.3%, respectively, for patients aged ≥70 years.

Conclusions: Disparities in the management of breast cancer persist and these particularly affect the elderly, who are being undertreated.

Assessment of Clinical Breast Examination Training in a Colombian Medical School: Is There Room for Improvement?

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Objectives: As mammograms proved to be a highly sensitive in detecting nonpalpable abnormalities, the use of clinical breast exam (CBE) has steadily declined despite the fact physicians are able to detect a significant number of cancers by examination. The American Cancer Society even includes it along with breast self-examination and mammograms as the current recommendation for early detection of breast carcinoma. Oftentimes, physicians possess modest skills and confidence in CBE, possibly as a result of deficient training during medical school. The purpose of this study is to evaluate current knowledge of CBE in medical students taught by traditional means through sporadic patient contact and examine the effectiveness of introducing standardized simulation and multimedia-based instruction as a tool to improve knowledge and skill performance in CBE.

Methods: Medical students in clinical clerkship years (n = 341) were initially surveyed using a 20-question exam on the technique and justification of CBE, as well as the level of exposure during training. We then randomly selected a group of traditionally trained students (n = 52) and compared them with a group (n = 68) that underwent a 1-hour didactic lecture, instruction video, and silicone-model workshop by 2 attending breast surgeons. Both groups took the same theoretical test and an objective structured clinical examination (OSCE). Overall student changes were analyzed. All hypothesis tests were two-tailed (significance level <0.05).

Results: Of the 341 students, 254 (88.2%) reported they knew how to perform a proper CBE, though 75.2% failed to describe basic steps. There was a general lack of knowledge of when CBE is indicated, but an adequate understanding of the theoretical background which supports its use. Sixty percent of surveyed students considered that the training they received was “insufficient” and 70% considered it a “very necessary” skill. Medical students prior to graduation obtained statistically significant, higher scores in all aspects of the survey when compared to the other groups. When the traditionally and structured trained groups were compared, there was a statistically significant improvement in the average number of correct steps (1.9 vs 4.3, $P < 0.00001$) and justifications (1.2 vs 4.3, $P < 0.00001$) described. OSCE scores for student who underwent didactic training proposed in this study fulfilled all the basic steps in CBE and were significantly higher that traditionally trained students (100% vs 69%, $P < 0.00001$).

Conclusions: The use of formal, standardized and multimedia-based training may prove to be an important asset when teaching medical students how to perform CBE. Still, actual experience with patients is needed to refine this skill and physician-patient interaction.

Nipple-Sparing Mastectomy: Indications, Preoperative Planning, and Intraoperative Techniques

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Objectives: Breast conservation has been the recommended treatment for early-stage breast cancer, but may not be feasible for some women. Mastectomy may be necessary for large ratio of tumor volume to breast size, multicentric disease, diffuse calcifications, and contraindication to radiotherapy or personal choice. Mastectomy may also be considered for individuals with inherited BRCA 1 or 2 mutations and for prophylaxis in the individual with a biopsy-proven contralateral breast cancer. Recent reports suggest that there has been a shift in patient choice from breast conservation to mastectomy. There has also been a significant shift in favor of sparing the skin envelope and nipple areolar complex (NAC) when mastectomy is performed for better cosmesis. The aim of this study is to examine the indications, preoperative planning, intraoperative techniques, and oncologic safety of nipple-sparing mastectomy (NSM).

Methods: Retrospective analysis of 36 patients who underwent NSM over the last 3 years at an academic multidisciplinary breast center. NSM were done for treatment of breast cancer, risk reduction in BRCA 1 or 2 gene mutations, and/or for contralateral prophylaxis. Exclusion criteria included clinical suspicion of NAC involvement, inflammatory carcinoma, and preoperative chemotherapy. This study examines the demographics, indications, preoperative evaluation, surgical technique, reconstructive options, cancer involvement of NAC, and recurrence.

Results: Data were available for 60 NSM performed on 36 patients (17 had BRCA 1 or 2 mutations), with median age of 49 (25-69), and median follow-up of 9.25 months (0.5-34.75). Indications for mastectomy were: 26 for risk reduction in BRCA 1 or 2 mutation carriers, 14 for treatment of invasive cancers, 8 for treatment of DCIS, and 12 for contralateral prophylaxis. Preoperative evaluation of cancer patients included mammography and MRI, showing an overall mean size (20.8 and 17.5 mm, respectively) and distance to NAC (66.3 and 53.1 mm, respectively). NSM was performed through a variety of incisions: 11 inframammary, 12 radial, 5 tennis-racket, 6 modified Wise reduction mammaplasty pattern, and 2 periareolar. Patients also had an assortment of reconstructive techniques: 23 expander placement, 7 immediate reconstruction with implants, 2 DIEP, 2 TRAM, 1 combined flap and expander, and 1 Alloderm with fat injection. No NAC involvement was detected at intraoperative frozen section. One nipple showed pagetoid spread of LIN on permanent and it was resected at a second operation. Axillary staging was performed on 25 patients with invasive cancer and/or DCIS, 2 had positive sentinel lymph node biopsy and underwent axillary lymph node dissection. There has been no evidence of locoregional recurrence thus far.

Conclusions: The coupling of clinical assessment with modern imaging techniques allows for selection of patients who can be considered for NSM with a low incidence to pathologic involvement of the NAC. Preoperative planning that involves both the plastic surgeon and the breast surgeon led to combining a wide variety of incisions with many reconstructive options for optimal aesthetic outcomes. Short-term follow-up also suggests concurrence with larger published series that NSM is an oncologically safe approach.

Will Preoperative MRI Lower Re-Excision Rates in Women Undergoing Breast-Conserving Operations for Breast Cancer?

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Objectives: Approximately 140,000 women undergo breast-conserving surgery each year in the U.S. for breast cancer. However, 20-40% of patients (approximately 60,000) undergo re-excision to obtain clear margins. Tumor size, young age, DCIS, and microcalcifications have been previously shown to be associated with increased re-excision rates. We hypothesized that MRI, because of better delineation of tumor size, would decrease re-excision rates in women undergoing breast conservation.

Methods: A retrospective chart review of patients treated for breast cancer at a large community hospital breast center between January 2005 and December 2007. During that period, 364 women were treated with breast conserving operations: 183 (50%) had preoperative MRI (pMRI) and 181 did not (noMRI). Re-excision was performed on 90/364 (26%) patients. Outcome data included surgeon, age, stage of cancer, histopathology, margin, and re-excision (ReX).

Results: pMRI and noMRI patients were similar in stage (Tis, $P = 0.547$; T1, $P = 0.456$; T2, $P = 0.234$; T3, $P = 0.166$), histopathology (ductal, $P = 0.143$; lobular, $P = 0.741$) and DCIS ($P = 0.463$), but pMRI were younger ($p < 0.001$). Fifty-nine (32%) pMRI patients had reX compared to 33 (18%) noMRI patients (unadjusted OR = 2.13; $P = 0.002$). In addition to having greater likelihood of pMRI, reX pts were more likely to be younger ($P = 0.030$), have greater stage ($P = 0.008$) and operated on by surgeon C ($P = 0.006$). In adjusted analysis using step-wise selection criteria, only pMRI (OR = 1.70; $P = 0.046$), stage ($P = 0.019$), and surgeon ($P = 0.047$) remained predictive of reX.

Conclusions: Contrary to expectations, the use of preoperative breast MRI was associated with an increased re-excision rate. This increased association has never been previously shown. As younger women are at higher risk for reX and are more likely to have an MRI ordered, age is likely a confounder, though it was not statistically significant in adjusted analysis. While this association must be corroborated, how and if the results of preoperative breast MRI are used in planning surgical excision should be further studied.

Differences in Disease Presentation, Management Techniques, Treatment Outcome, and Toxicities in African American Women With Early-Stage Breast Cancer Treated With Breast-Conserving Therapy

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Objectives: Data on patients treated with breast-conserving therapy (BCT) for early-stage breast cancer were examined to detect differences in disease presentation, management techniques, and long-term treatment outcomes, and toxicities based upon ethnicity.

Methods: Six hundred ninety-nine cases of breast cancer (African American women [AA], n = 39; Caucasian [C] women, n = 660) treated with BCT were analyzed on race, clinical and pathologic characteristics at presentation, management techniques, treatment-related toxicities, recurrence, and survival. Median follow-up was 12.2 years.

Results: At diagnosis, AA women were younger (49% vs 29% < 50 years old, $P = 0.002$), had larger tumors (mean, 17.0 mm vs 13.9 mm, $P = 0.032$), more ER (-) tumors (56% vs 18%, $P < 0.001$), and higher nuclear grade tumors (grade III, 52% vs 29%, $P = 0.006$). Compared to C women, AA patients more frequently received adjuvant chemotherapy (59% vs 19%, $P < 0.001$) and nodal irradiation (26% vs 13%, $P = 0.033$). No other significant treatment differences were observed. After treatment, AA women experienced more breast pain ($P = 0.001$), arm edema ($P = 0.046$), and less excellent versus good cosmetic results ($P = 0.008$), but there were no statistically significant differences in local recurrence ($P = 0.232$), distant metastasis ($P = 0.263$), overall survival ($P = 0.131$), or cause-specific survival ($P = .092$) based upon race.

Conclusions: These results suggest that AA women present with larger and more aggressive breast tumors and, as a result, more frequently received adjuvant chemotherapy and nodal irradiation. Small differences in treatment-related toxicities and cosmesis were observed, but no differences in efficacy were identified.

Characterization of DCIS and Prediction of Recurrence Using Molecular Markers

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Objectives: Gene expression profiling can now identify distinct molecular subtypes. It is increasingly being used for prognosis and treatment decision-making in patients with invasive breast cancer. Our goal was to determine whether clinical and pathologic features varied by molecular subtype in patients with pure ductal carcinoma in situ (DCIS).

Methods: DCIS subtypes were classified by immunohistochemical (IHC) surrogates as luminal A (ER+ and/or PR+, HER2-), luminal B (ER+ and/or PR+, HER2+), HER2 (ER- and PR -, HER2+), and basal ((ER- and PR -, HER2-). HER2 positive patients had to be 3+ by IHC or amplified (ratio > 2.0) by FISH. Kaplan-Meier analyses were used to determine probabilities of local recurrence by individual subtypes and by groups. All data were obtained from a prospectively collected database.

Results: One hundred sixty-six patients with pure DCIS had data sufficient to allow them to be divided into 4 molecular subgroups. Luminal A patients had the best prognostic features. HER2 patients had the worst prognostic features and were treated with the highest percentage of mastectomies. Median follow-up was 92 months.

	Luminal A	Luminal B	Basal	HER2
N	76	43	11	36
Average age	53	52	54	49
Average size	31 mm	38 mm	44 mm	58 mm
Av nuclear grade	2.21	2.58	2.58	2.81
Av USC/VNPI	7.96	8.77	8.83	10.25
Av margin width (BCT only)	6.0 mm	5.5 mm	3.3 mm	2.9 mm
Mastectomy	36%	35%	36%	67%

Numerous groupings and comparisons were analyzed. All patients were grouped into luminal A versus non-luminal A. For patients undergoing excision alone, the 8-yr recurrence probability for luminal A patients treated by excision alone was 28%; for non-luminal A, it was 83% ($P = 0.003$). All patients treated with postoperative radiation therapy or mastectomy for luminal A versus non-luminal A showed no significant differences in recurrences.

Conclusions: Molecular subtyping for patients with DCIS is promising. HER2 testing should be considered for DCIS patients, especially those undergoing excision alone. The patients in this series who had HER2 analyses tended to score toward the higher end (worse prognosis) of the USC/VNPI (University of Southern California/Van Nuys Prognostic Index). Postexcisional radiation therapy should be considered for non-luminal A subtypes.

Breast Exam Proficiency: Training Third-Year Medical Students

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Objectives: The teaching of proper patient breast examination to medical students is an often overlooked portion of their curriculum. It is assumed that they have been trained in how to perform a proper breast history taking and physical examination prior to reaching their third year. The objective of this study was to evaluate the students' breast exam skills and improve their proficiency.

Methods: Each group of third-year medical students (n = 50) rotating on the surgery service at the University of Arizona from December 2008 through September 2009 participated in a breast exam using standardized patients at the start and completion of the surgery rotation. Individually the students were asked without any preparation to perform a pre-test focused breast history and physical examination on a standardized patient while being observed and evaluated by one of the surgical faculty. Following the pre-test, the students were given verbal feedback to improve future performance. Following the post-test, the outcome from both exams was compared to determine improvement.

Results: We used repeated-measures *t* tests to compare student performance on the pre- and post-tests. Our analysis showed statistically significant improvements with $P = 0.01$ in both the history and physical exam components. Using Cohen's d, we found the intervention to have "medium" effect size with the physical exam having a slightly greater effect size than the history component.

Conclusions: Both history-taking and physical examination scores improved with the post–breast exam. Students were more confident with their skills following these exercises. Providing formalized training was found to be beneficial in terms of thoroughness of technique and comprehensiveness in the exam. The results of this study provide the foundation to incorporate breast exam training into the third-year medical student curriculum.

Excellent 10-Year Outcome Following Multicatheter Interstitial Brachytherapy in Unsuitable Patients As Categorized by the ASTRO Consensus Panel

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Objectives: We report 10-year local control and overall survival outcomes in patients with early-stage breast cancer who fit criteria for the "unsuitable" category (eg, high risk) as defined by the current American Society of Therapeutic Radiology and Oncology (ASTRO) Consensus Panel (CP) guidelines, following breast-conserving therapy with accelerated partial breast irradiation (APBI) employing multicatheter interstitial brachytherapy (MIB).

Methods: One hundred ninety-nine patients treated with APBI MIB were retrospectively stratified into the 3 ASTRO CP groups (suitable [S] (n = 95) (48%), cautionary [C] (n = 63) (32%), and unsuitable [U] (n = 41) (21%). Patients were classified as U if they had any one of the following high risk factors: age < 50, BRCA1/2 mutation present, stage T3 or T4, tumor size > 3 cm, positive margins, multicentricity, extensive intraductal component (EIC) > 3 cm, pure DCIS histology > 3 cm, positive lymph nodes (LN), or use of neoadjuvant chemotherapy. Patients were grouped into this category based upon the following findings: 19 (46%) < 50 years of age and 23 (56%) with (+) LNs. An analysis was completed of these patients to assess rates of ipsilateral breast tumor recurrence (IBTR), regional nodal failure (RNF), distant metastases (DM), disease-free survival (DFS), cause-specific survival (CSS), and overall survival (OS). The median follow-up was 10.6 years (1.0-14.6).

Results: The median age of the U cohort was 50 years (40-78). Nineteen patients (46%) were age <50, 1 (2%) had a close margin, 3 (7%) had an EIC (≤ 3 cm), 23 (56%) had (+) LNs, and 15 (37%) received adjuvant chemotherapy. The 10-year actuarial rates for IBTR, RNF, DM, DFS, CSS, and OS were 2.5%, 5.9%, 11.2%, 88.9%, 92.2%, and 82.1, respectively. On univariate analysis (age [categorical & continuous variable], margin status [positive vs close or negative], presence or absence of an EIC, LN [+] vs [-], and use of systemic chemotherapy), no variable was associated with IBTR. Only EIC was a significant prognostic factor for DM, DFS, CSS (all P = 0.003) and OS (P = 0.018). Age, margin status, LN, and adjuvant chemotherapy use were not associated with any endpoint.

Conclusions: Ten-year results using APBI in patients listed in the unsuitable group of the ASTRO CP categories experienced excellent rates of local tumor control. These data suggest that additional factors (as yet undefined) may be needed to help differentiate which patients are not acceptable candidates for this treatment approach.

Survival Benefit for Tamoxifen in Estrogen Receptor Negative and Progesterone Receptor Positive Low-Grade Breast Cancer

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Objectives: Estrogen and progesterone receptor (ER/PR) status is widely accepted and routinely checked as a valuable predictor of response to endocrine therapy. The benefit of adjuvant tamoxifen therapy in patients with ER-positive (ER+) tumors is confirmed, but it is still controversial in patients with ER-/PR+ tumors.

Methods: In this study, we evaluated and identified the indication of hormone therapy for breast cancer patients. Women with breast cancer who were diagnosed between 2002 and 2006 were identified from the cancer registry databases of Changhua Christian Hospital. The patients were divided into 4 groups according to their ER/PR phenotypes, and survival was assessed after long-term follow-up.

Results: The 5-year overall survival was 85% and was better in younger women (age <50 y/o). Patients with double-positive tumors had a better 5-year survival rate (94%), and patients with double-negative tumors had the worst outcome (74% survival rate). For patients with ER-/PR+ tumors, tamoxifen was given as adjuvant hormonal therapy in 97 out of 128 cases. We further stratified the patients with ER-/PR+ tumors into 2 strata by histological grade: low grade (I and II) and high grade (III). In the low-grade group, hormonal therapy increased the survival benefit, but not the high grade group. Patients with ER+/PR+ tumors had better clinical outcomes; patients with ER-/PR- tumors experienced the worst outcome whereas single-positive cases were in between.

Conclusions: High-grade tumor with ER-/PR+, adjuvant tamoxifen therapy may have no survival benefit whereas for those patients with low-grade ER-/PR+ tumors, adjuvant tamoxifen therapy is highly suggestive.

Variation in the Surgical Management of Patients With Atypical Breast Cancer Histologies: Biology Dictates Technique?

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Objectives: In eligible candidates, breast conservation therapy (BCT) has become standard for treatment of the primary tumor in breast cancer. Similarly, nodal staging in patients with no clinical lymphadenopathy is now routinely performed by sentinel lymph node biopsy (SLNB), and axillary dissection (ALND) reserved for those with a positive SLND. Although trends and variations in the use of BCT, SLNB, and ALND for ductal adenocarcinoma have been well studied, little is known about atypical breast cancer histologies.

Methods: The Surveillance, Epidemiology and End Results (SEER) database was used to identify 17,962 patients diagnosed with mucinous, tubular, medullary and papillary carcinoma of the breast from 1998 to 2006. Only patients with T1 or T2 tumors (<5 cm in size) were included and coded information for the use of BCT, SLNB, and ALND extracted for each patient. Stage IV patients were excluded.

Results (Table): Overall 69% of patients underwent BCT and 45% SLNB. For the entire cohort, the use of SLNB increased dramatically from 12% in 1998 to 63% in 2006, whereas BCT rate remained relatively stable at 67% in 1998 to 69% in 2006. Use of BCT varied depending on histology, ranging from 58% for papillary to 78% for tubular carcinoma. Similar variation was seen in the use of SLNB; from 34% for papillary to 52% for tubular carcinoma. In 24% of patients with papillary, 17% of tubular, and 18% of mucinous carcinoma no axillary staging was done. Of patients who underwent SLNB, rates of nodal positivity were highest for medullary (18%) and lowest for tubular (6.8%); but in patients undergoing ALND only, the highest rate of nodal positivity was seen in medullary carcinoma (33.6%). The majority (78%) of patients who were node-positive on SLNB went on to have a completion ALND overall. Patients with T1 tumors and either tubular or mucinous histologies undergoing SLND had a low rate of nodal positivity; 6.4% and 6.0%, respectively.

	Tubular n = 5629	**Medullary n = 2237**	**Mucinous n = 8651**	**Papillary n = 1445**	***P* value**
Mean age in years ± SEM	61.4 ± 0.2	52.8 ± 0.3	67.4 ± 0.2	67.2 ± 0.4	< 0.001
BCT	77.7%	68.6%	64.5%	58.3%	<0.001
SLNB	51.5%	40.1%	43.1%	33.7%	<0.001
ALND only	31.2%	54.9%	39.4%	42.5%	<0.001
No axillary staging	17.3%	5.0%	17.5%	23.8%	<0.001
Positive on ALND	8.8%	33.6%	10.4%	18.5%	<0.001
Positive on SLNB	6.8%	18.4%	8.2%	14.5%	<0.001
ALND for positive SLNB	75%	86%	69.6%	80%	0.001
Overall rate of nodal positivity	6.3%	26.2%	7.7%	13%	<0.001

Conclusions: There is wide variation in the use of BCT, SLNB and ALND in patients with atypical breast cancer histologies, which may partly be due to perceived differences in biological aggressiveness. In patients with T1 mucinous or tubular breast cancer, the routine use of SLNB may be questioned due to the low rate of nodal positivity. Furthermore, the discrepancy in nodal positivity in patients with medullary carcinoma undergoing SLNB or ALND for axillary staging is worrisome and needs further study.

Health-Related Quality of Life After Intraoperative Radiotherapy (IORT) for Breast Cancer Using Lw-kV X-rays

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Objectives: Intraoperative radiotherapy (IORT) is currently being evaluated as a novel approach during breast-conserving surgery (BCS). IORT can be used either as a tumor bed boost followed by external beam radiotherapy (EBRT) or as single treatment in prospective studies (eg, TARGIT). In a matched cross-sectional study, we assessed long-term quality of life (QoL) in patients with early breast cancer treated with BCS and/or IORT and/or EBRT.

Methods: QoL was compared in 23 patients treated with IORT, 23 patients treated with IORT + EBRT, and 23 patients treated with EBRT. Patients were matched on age and time interval since BCS, and had similar demographic and clinical characteristics. IORT was given with 50-kV x-rays (INTRABEAM TM system, Carl Zeiss Surgical, Oberkochen/Germany) delivering 20 Gy at the applicator surface. EBRT (46-50 Gy in 2-Gy fractions in the IORT + EBRT group, and 56 Gy in 2-Gy fractions in the EBRT group) was initiated after completion of wound healing and/or chemotherapy. The mailed questionnaires included the EORTC QLQ-C30 (cancer- specific QoL; range, 0-100), EORTC QLQ-BR23 (breast-cancer-specific QoL; range, 0-100), FACT-F (fatigue), HADS (anxiety and depression), Rosenberg scale (global self-esteem), and body image scale (range, 0-30). With 18 to 70 months of follow-up, all patients were disease free.

Results: There were only few differences between the 3 groups. In general, IORT + EBRT was not significantly different from EBRT. There was a nonsignificant trend toward more pain (42.8 ± 32.9 vs 27.5 ± 34.7) and reduced QoL (57.6 ± 20.7 vs 70.3 ± 23.9). IORT alone had a comparable QoL (70.3 ± 23) and less breast symptoms (8.6 ± 12.3 vs 19.2 ± 23.8) and body image concerns (1.7 ± 3.3 vs 2.3 ± 3.7) compared to EBRT (P = n.s.). IORT alone induced significantly less breast symptoms (8.6 ± 5.3 vs 26.1 ± 27.6, P = 0.01) and pain (23.9 ± 24.5 ± 42.8 ± 32.9, P = 0.04), compared to IORT + EBRT.

Conclusions: Patients with breast cancer after BCS + IORT +/- EBRT present with comparable QoL like patients receiving EBRT without a boost.

Intraoperative Radiotherapy (IORT) As a Boost During Breast-Conserving Surgery (BCS) Using Low-kv X-rays: The First 5 Years of Experience With a Novel Approach

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Objectives: IORT during BCS has been recently introduced using different devices. We report the first 5 years of a single-center experience after introduction of a novel approach to deliver IORT as a tumor bed boost during BCS for breast cancer.

Methods: One hundred fifty-five breast cancers in 154 women (median age, 63 years; range, 30-83 years, T1/T2 = 100/55, N0/N+ = 108/47) were treated between 02/2002 and 12/2007 at the University Medical Center Mannheim, in whom IORT as tumor bed boost was applied using 50-kV X rays (20 Gy, INTRABEAM, Carl Zeiss Oberkochen), followed by 46-50 Gy external-beam whole-breast radiotherapy (EBRT). Chemotherapy, if indicated, was given before EBRT. The median interval between BCS+IORT and EBRT was 40 days. Median follow-up was 34 mon (max, 80 mon; 1 pt lost to f/u). Overall survival (OS) and local relapse–free survival (LRFS) were calculated at 5 years using the Kaplan-Meier method. Seventy-nine patients were evaluated at 3 years f/u for late toxicity using the LENT SOMA system.

Results: Ten patients died, 2 suffered from in-breast relapse and 8 developed distant metastases (5 yr OS = 87.0%, 5 yr LRFS = 98.5%). Grade III fibroses of the tumor bed were detected in 5% of the patients after 3 years. Skin toxicity was mild (teleangiectases and hyperpigmentations in about 6% each).

Conclusions: IORT as a tumor bed boost using low-kV X-rays followed by EBRT yields low recurrence and toxicity rates.

Predictors of Breast Cancer Development in Women Diagnosed With Atypia Ductal Hyperplasia and Atypia Lobular Hyperplasia

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Objectives: Atypia diagnoses of atypia ductal hyperplasia (ADH) and atypia lobular hyperplasia (ALH) are common benign breast disease conditions. While atypia is a known risk factor for developing breast cancer, there is need for greater understanding of the affects other risk factors have in conjunction with an atypia diagnosis in order to create individualized risk- reduction strategies. This cohort analysis was conducted to investigate the association of atypia diagnosis with clinically significant confounders to breast cancer among women at high risk for breast cancer.

Methods: The Women at Risk Registry provided the study population. The development of breast cancer is the outcome of interest. Exposure variables of interest includes family history of breast cancer, body mass index (BMI), history of birth control pill use, alcohol use, smoking, age of delivery, Gail scores, and diagnosis of ADH and ALH. Odds ratios, stratified by atypia status, were calculated for each risk factor of interest. *P* values were calculated to determine statistical significance.

Results: The study population included 1598 high-risk women, including 921 (57.6%) with a history of biopsy-proven atypia. The remaining 677 (42.4%) women did not have atypia but met one of the other high-risk eligibility criteria. Within the total study population, 50 (3.1%) developed breast cancer. Of the 50 with breast cancer, 29 (58%) had a history of atypia. Alcohol use was found to be significantly associated with the development of breast cancer (P = 0.0201) and showed an increased interaction among women with atypia (OR = 2.13; 95% CI, 0.95-4.81), compared to women without atypia (OR = 1.71). Atypia was also found to be a confounder of the association between breast cancer development and having a first-degree relative with breast cancer. The odds of breast cancer when there is a history of first-degree relatives is greater among women with atypia (OR = 1.48; 95% CI, 0.64-3.35), compared to women without atypia (OR = 0.98; 95% CI, 0.41-2.63). The other risk factors of interest did not show a statistically significant association with breast cancer when stratified by atypia status.

Conclusions: The findings indicate that the presence of atypia interacts with the use of alcohol and confounds the association between presence of a first-degree relative with breast cancer and the development of breast cancer. While this study further supports the established literature, these findings also support the need to address modifiable risk factors in high-risk patients, leading to more individualized protocols for risk reduction.

With Mastectomies on the Rise, Are Bilateral Mastectomies on the Rise?

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Objectives: The recent publication of a 13-year trend analysis of the selection of mastectomy versus breast conservation therapy in 5865 patients demonstrated the significant rise in mastectomy rate. In that analysis, patient preference and fear of genetic or recurrence risk, as well as "intangible" factors, appeared to be shifting decisions toward mastectomy and away from breast conservation. If these observations are accurate, then the trend toward bilateral mastectomy should likewise be prevalent as the shift toward mastectomy for these causes would likely drive patients toward prophylactic removal of the contralateral normal breast. This report attempts to validate these factors that influence patient decisions to choose such definitive surgical therapies.

Methods: Five thousand eight hundred sixty-five patients undergoing either mastectomy or BCT for invasive and in situ breast cancer were identified in retrospective review of a prospectively accrued breast cancer database between the years of 1994 and 2007. Univariate and multivariate logistic regression analysis were used to estimate the odds ratio (OR) of the association between mastectomy and patients' clinicopathologic characteristics.

Results: Of the 5865 patients, 3736 underwent BCT, while 2129 underwent mastectomy. The overall surgical volume decreased over the 13-year study period. Mastectomy rates during the periods of 1994-1998, 1999-2003, and 2004-2007 were 33%, 33%, and 44%, respectively ($P < 0.01$). Plastic reconstruction rates during the same time periods were 16%, 5%, and 7%, respectively ($P < 0.01$). On logistic regression analysis, gender, age < 40 years, plastic reconstruction, increase tumor size, and lymphovascular invasion were significant independent predictors of mastectomy. Using the period of 1994-1998 as the reference group, mastectomy rate rose strongly from 1999-2003 (OR, 1.2) and from 2004-2007 (OR, 1.8). Further analysis demonstrated over the same time periods that bilateral (prophylactic) mastectomy rose concomitantly at a rate greater than mastectomy alone, 123% and 11%, respectively ($P < 0.002$).

Conclusions: The perception of an increasing treatment choice toward mastectomy has been confirmed at this institution. Possible reasons for this change may be a younger population with higher lifetime risk, fear of recurrence, higher stage disease, more biologically aggressive or diffuse tumors. Patient preference, fear of genetic or recurrence risk, and "intangible" factors appear to be shifting decisions toward mastectomy and are further confirmed by the fact that this significant rise in mastectomy was associated with even an accelerating trend toward bilateral mastectomy.

The Impact of Needle Core Size and Number on Upgrade Rates of DCIS Diagnosed by Core Biopsy

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Objectives: Ductal carcinoma in situ (DCIS) diagnosed by core needle biopsy has been associated with upgrade rates to invasive breast cancer (IBC) of 8-30% on subsequent surgical excision. We sought to determine the impact of needle core size and number on the upgrade rate of DCIS found on core biopsy.

Methods: We reviewed image-guided percutaneous needle core biopsies that yielded a diagnosis of DCIS and final pathology results on subsequent surgical excision at our institution between 2005 and 2009. The proportion of cases upgraded to IBC on final pathology were evaluated by patient age, biopsy year, BI-RADS score, breast location, type of imaging finding, needle gauge, and number of cores taken.

Results: The average patient age was 59.3 years (range, 35-83). The majority of patients (84.9%) had a BI-RADS score of 4. One-half of lesions were located in the upper outer quadrant. The target lesions were calcifications (78.2%) or mass lesions (21.8%). The needle core size was larger than 11 gauge in 25.5% of cases, and 11 gauge or smaller in 74.6% of cases. The average number of core samples taken was 5.9 (range, 4-10). A total of 55 cases of DCIS diagnosed on needle core biopsy in which final pathology was available were identified. Fourteen (25.5%) were upgraded to IBC on surgical excision. Upgrade to IBC on final surgical pathology was associated with an imaged mass lesion (P = 0.03) and taking more than 6 core samples (P = 0.03). No significant differences in upgrade rates were found based on age, biopsy year, BI-RADS score, location, needle gauge, or when fewer than 6 core samples were taken.

Conclusions: These results demonstrate that upgrade of DCIS to IBC is not unusual, but is not affected by core size. The association of 6 or more cores with a higher upgrade rate may reflect a bias toward more aggressive sampling of clinically suspicious lesions. When counseling patients regarding the potential upgrade to IBC when DCIS is found on core biopsy, imaging/clinical characteristics rather than core size may be more important.

Endoscopic Sentinel Node Biopsy Is Less Invasive and Facilitated by SPECT-Fused 3D-CT Lymphography

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Objectives: The endoscopic surgery for the breast diseases has been proven safe and aesthetic and named as video-assisted breast surgery (VABS). We also applied it for the sentinel node (SN) biopsy. It needs only 1-cm-long skin incision and a narrow tunnel to SN. However, it sometimes has difficulty in detecting the dye-stained node. The radioisotope (RI) method is useful, but RI may not be uptaken by true SN. We firstly succeeded to fuse the single photon emission computed tomography (SPECT) with 3D-CT mammary lymphography (LG). It can show the detailed position of all SN with or without RI uptake.

Methods: 3D-CT LG was performed to mark SN on the skin. Above the tumor and near the areola, 2 ml of Iopamidol 300 was injected subcutaneously. Images of CT scan were taken at 1 and 3 min after injection to produce a 3D image of lymph ducts and nodes. For the lymphoscintigraphy, 99mTc phytate 74mBq was injected, and SPECT was taken after 2 hours. We fused it with 3D-CT LG. SN biopsy was performed by dye and RI method The skin incision was made 1 cm long in the axilla on the marked position. The endoscopic view was made through the optical trocar Visiport and showed stained lymph ducts and SNs, which can be navigated by RI detector probe.

Results: We have performed VABS on 260 patients, SN biopsy by dye-staining method on 50 patients, with 3D-CT LG on 160 patients, and SPECT fused 3D-CT LG on 20 patients. All RI-positive SNs coincided with 3D-CT LG-detected SNs. We could detect their position in the axillary lymphatic mapping by RI detector probe during surgery. The average sampled number of SN was 2.3. The dye-negative SN and RI-negative SN could be removed endoscopically. The SN metastases were 45 (28%). The other non-SN of axillary nodes could be observed. There was no false-negative study. The wound scars were inconspicuous and aesthetic.

Conclusions: The endoscopic SN biopsy is aesthetic and less invasive, which is facilitated by SPECT-fused 3D-CT LG.

Axillary Lymph Nodes Retrieval Is Not Affected After Neoadjuvant Chemotherapy for Locally Advanced Breast Cancer

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Objectives: Lymph nodes are the most important prognostic factor for breast cancer. Many reports confirmed that the number of positive lymph nodes is proportional to the total number of axillary nodes dissected. Neoadjuvant chemotherapy is becoming a standard therapeutic option for advanced stages of breast cancers. Some studies reported fewer lymph nodes retrieval following neoadjuvant chemotherapy, which became main line of treatment for locally advanced breast cancer.

Methods: Forty-seven consecutive patients with locally advanced breast cancer (stage IIB or higher) who received neoadjuvant chemotherapy and underwent modified radical mastectomy (group A) were evaluated and compared to 448 patients with breast cancer (stage II) who underwent modified radical mastectomy then received adjuvant therapy (group B) during 2007.

Results: For patients who received neoadjuvant chemotherapy, the total number of axillary lymph nodes retrieved was 16.48 ± 5.63 vs 16.8 ± 5.09 for patients who underwent surgery first. The number of positive lymph nodes for the neoadjuvant group was 3.86 ± 5.7 versus 5.84 ± 5.82 for the second group. The correlation between the number of positive lymph nodes to total number of lymph nodes for patients receiving neoadjuvant Cth was $r = 0.373$, and for the other group the correlation was $r = 0.338$. There was no significant difference between total number of lymph nodes retrieved from both groups.

Conclusions: This study shows that there is no difference between axillary lymph nodes dissected from patients receiving neoadjuvant chemotherapy, compared to patients undergoing surgery first followed by adjuvant treatment. We believe that this depends mainly on surgical technique for complete axillary dissection of all 3 levels and adequate pathological examination.

Breast Reconstruction With Pedicled TRAM Flap: Long-Term Oncological and Cosmetic Results From a Developing Country

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Objectives: Pedicled TRAM flap is one of the most common methods of autologous breast reconstruction. Despite advances in free-flap breast reconstruction, pedicled TRAM flap remains an excellent option for unilateral breast reconstruction. This is a retrospective study of 54 patients who underwent breast reconstruction with pedicled TRAM flap from 2003 to 2008. Oncological and cosmetic results were reviewed.

Methods: Fifty-four patients underwent breast reconstruction with pedicled TRAM flap from October 2003 to December 2008. Mean follow-up was 21 months (range, 6-61 months) Forty-two patients underwent immediate breast reconstruction (IBR). Eight patients had delayed breast reconstruction (DBR) with monopedicled TRAM flap. Four patients had TRAM flap for chest wall reconstruction after extensive surgery for either recurrent disease or osteoradionecrotic ulcers.

Results:

Oncological results: No single case of local recurrence. In the IBR group, 1 patient developed contralateral axillary lymph bode metastasis, 2 patients developed bone metastasis, and 1 patient developed lung metastasis. In the DBR group, 1 patient developed contralateral breast cancer 2 years after reconstruction (5 years after original mastectomy) and 1 patient developed lung metastasis 16 months after reconstruction.

Early complications: One patient had D.V.T (1.8%)

Flap-related complications: Complete flap loss, 1 patient; partial flap loss, 4 patients (7.4%); 3 patients had wound infection (5.5%); and 1 patient had hematoma.

Donor site complications: Seroma, umbilical necrosis.

Delayed complications: No hernia was seen. One patient had only abdominal bulge.

Cosmetic results: They were evaluated by surgeon and patients. Patients who underwent TRAM flap reconstruction for chest wall coverage were excluded from this evalauation. Excellent results in 12 patients, very good in 19 patients, good in 17 patients, poor in 2 patients.

Conclusions: Pedicled TRAM flap remains a gold standard in breast reconstruction. It enables the surgeon to create a normal ptotic and soft breast after mastectomy. It is a cheaper alternative and available technique in low-income countries, compared to breast implants (more expensive, not all forms are present, need to more surgical interventions to exchange). Long-term cosmetic results are much better than use of implants. Cost-effectiveness of TRAM flap breast reconstruction in low-income countries favors its use over breast implants.