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Cost Analysis of a Surgical Consensus Guideline in Breast-Conserving Surgery

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Abstract

Background—The SSO/ASTRO consensus statement was the first professional guideline in breast oncology to declare “no ink on tumor” as a negative margin in patients with stages I/II breast cancer undergoing breast conservation therapy (BCT). We sought to analyze the financial impact of this guideline at our institution using a historic cohort.

Study Design—We identified women undergoing re-excision following breast-conserving surgery for invasive breast cancer from 2010–2013 using a prospectively-maintained institutional database. Clinical and billing data were extracted from the medical record and from administrative resources using CPT codes. Descriptive statistics were used in data analysis.

Results—Of 254 women in the study population, 238 (93.7%) had stage I/II disease and 182 (71.7%) had invasive disease with DCIS. A subcohort of 83 patients (32.7%) who underwent BCT for Stage I/II disease without neoadjuvant chemotherapy had negative margins after the index procedure per the SSO/ASTRO guideline. The majority had invasive ductal carcinoma (70, 84.3%) and had invasive disease (45, 54.2%) and/or DCIS (49, 59.0%) within 1 mm of the specimen margin. Seventy-nine patients underwent one re-excision, and 4 patients underwent two re-excisions, accounting for 81 hours of operative time. Considering facility fees and primary surgeon billing alone, the overall estimated cost reduction would have been \$195,919, or \$2,360 per affected patient, under the guideline recommendations.

Conclusions—Implementation of the SSO/ASTRO consensus guideline holds great potential to optimize resource utilization. Application of the guideline to a retrospective cohort at our institution would have decreased the overall re-excision rate by 5.6% and reduced costs by nearly \$200,000. Further analysis of patient outcomes and margin assessment methods is needed to define the long-term impact on surgical practice.

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Keywords

Breast cancer; Margin status; Breast conserving surgery; Breast conservation therapy

Introduction

As one of the standard of care options in early stage breast cancer, breast conservation therapy (BCT) has proven comparable to mastectomy in rates of disease-free and overall survival.¹ Despite this equivalence in outcome, positive surgical margins following BCT have been associated with a significantly increased risk of local recurrence.^{2–6} Margin status has become a critical factor in the management of patients undergoing BCT, and the controversy surrounding the importance of negative margins and the absence of definitive guidelines have led to a wide variability in surgeon practice regarding the threshold for re-excision. In 2002, the landmark National Surgical Adjuvant Breast and Bowel Project (NSABP) B-06 trial prompted the widespread acceptance of BCT and considered no tumor cells at the inked specimen margin to be a negative margin, but this definition failed to translate universally into practice until recently.¹

Numerous studies have debated the significance of close margins and the most appropriate threshold for re-excision based on patient and tumor characteristics. Prior to early 2014, up to 60% of patients underwent re-excision for management of margins, and adequacy of pathologic margin status remained surgeon-specific and highly ambiguous, ranging from no tumor at the inked margin to margin widths > 5 mm.^{6–11} In May 2014, the Society of Surgical Oncology (SSO) and American Society of Radiation Oncology (ASTRO) published a consensus statement recommending that the definition set forth in NSABP B-06 become the global standard for an adequate margin in breast-conserving surgery (BCS) in women with stage I/II disease undergoing adjuvant whole breast radiation therapy.¹² Drawing upon a meta-analysis of 33 studies, a multidisciplinary consensus panel determined that no significant differences in local recurrence were present regardless of factors such as patient age, tumor biology, or presence of an extensive intraductal component in the setting of “no ink on tumor”.¹²

The consensus guideline aims to standardize the surgical component of BCT in women with early stage breast cancer and to positively influence a diverse array of patient outcomes and system processes. We sought to analyze the potential impact of the consensus guideline on surgical practice at our institution and to extrapolate its financial impact and potential cost savings utilizing a historic cohort.

Methods

Study Population

Approval from the institutional review board at Washington University in St. Louis was obtained prior to the commencement of this study, and written informed consent of patients was not required. From a prospectively-maintained institutional database, all patients undergoing breast re-excision procedures following index breast-conserving surgery

between January 2010 and December 2013 were identified. All female patients age 18 years or older with invasive breast carcinoma with or without ductal carcinoma *in situ* (DCIS), diagnosed by pre-operative image-guided needle core biopsy or by excisional biopsy, were selected for inclusion in the analysis. Patients with pure DCIS and those undergoing the primary surgical procedure for their breast cancer diagnosis at another hospital or surgical center were excluded. A retrospective cohort study was conducted, and clinical, demographic, and pathologic data were recorded upon review of the electronic medical record. During the time period of the study, five breast oncologic surgeons were practicing at our institution.

Data Analysis

Patient characteristics including age, race, ethnicity, weight, and medical therapies were extracted from the clinical record. The original operative notes and pathology reports were utilized to obtain information on the index and re-excision surgical procedures, tumor histology, and surgical margins. Tissue specimen margins were intraoperatively marked in two dimensions with a short stitch placed superiorly and a long stitch placed laterally. A dedicated team of breast pathologists was the sole resource for specimen processing, and tumor dimensions were assessed on both gross and microscopic evaluation. Tissue specimens were inked on all margins, serially sectioned at 3 to 5 mm intervals, and stained by hematoxylin and eosin per standard protocol. The pathologic examination included documentation of the tumor-margin distance, and margin positivity was defined as the presence of invasive disease or DCIS at the inked margin. Close margins were divided into categories defined by distance between the tumor and any inked margin (anterior, posterior, medial, lateral, superior, and inferior).

Cost data from our institution were retrieved from facility and administrative databases based on CPT codes and work relative value units (RVUs). Information for individual patient encounters was collected for facility costs and primary surgeon billing alone. Facility data included any equipment, staff, medication, and operating room costs as well as any costs associated with inpatient admission, if applicable. Primary surgeon costs were calculated based upon institutional billing data, utilizing CPT codes and the associated average clinical cost per physician work RVU.

Study data were managed using REDCap electronic data capture tools hosted at Washington University in St. Louis.¹³ Descriptive statistics were used to assess frequency distributions, and analyses were performed using a statistical package, SAS 9.4 (SAS Institutes, Cary, NC).

Results

From January 2010 to December 2013, 1506 patients underwent breast-conserving surgery at our institution, 384 (25.5%) of whom required subsequent re-excision for close or positive margins. Of this re-excision population, 254 (66.1%) had invasive disease and formed our study cohort, while the remaining 130 (33.9%) had pure DCIS without any invasive component and were therefore excluded. Average age was 60.3 ± 12.3 years, and nearly three-quarters of the patients were Caucasian (185, 72.8%). The majority of the patients

were being treated for early-stage disease (Stage I: 157, 61.8%; Stage II: 81, 31.9%). Clinical demographics are summarized in Table 1.

Regarding margin status at index procedure, 105 patients (41.3%) had margins positive for invasive disease (58, 22.8%), DCIS (37, 14.6%), or both (10, 3.9%). The most commonly involved margins were the anterior (36, 34.6%) and the inferior (30, 28.8%). The mean number of positive margins was 1.5 ± 0.8 , and the majority of patients with positive margins only had 1 margin (42, 61.8%) or 2 margins (19, 27.9%) involved. Excluding patients with focally or extensively positive margins, 119 patients (46.9%) had close margins (≤ 2 mm), again with the anterior (48, 29.8%) and the inferior (38, 23.6%) most frequently identified as at risk (Table 2).

On re-excision, only one patient underwent completion mastectomy, while the remaining 253 patients (99.6%) underwent cavity re-excision or repeat partial mastectomy. The average time from the index procedure to re-excision was 26.6 ± 17.9 days (range 9–180 days). Shown in Table 3, 171 patients (67.3%) had negative re-excision histology on pathological exam, 47 (18.5%) had residual DCIS, and 27 (10.6%) had residual invasive disease. Of the 171 patients with negative re-excision histology, 45 (26.3%) initially had positive margins for invasive disease while 25 (14.6%) initially had positive margins for DCIS. Thirty-three women (13.0%) underwent a repeat re-excision procedure for persistent close or positive margins, with 13 (5.1%) undergoing cavity re-excision and 20 (7.9%) undergoing simple mastectomy.

To evaluate the impact of the consensus guideline on our historic cohort, we identified the subset of patients with stage I/II disease who had close but not positive margins, who received adjuvant whole breast irradiation, and who had not been treated with neoadjuvant chemotherapy (Figure 1). Eighty-three patients (32.7%) met the criteria, and these patients underwent a total of 87 procedures which would not have taken place under the guideline, utilizing approximately 81 hours of operative time. The majority of these patients had a primary histology of invasive ductal carcinoma (70, 84.3%) and had margins which were ≤ 1 mm from the tumor (invasive disease: 45, 54.2%; DCIS: 49, 59.0%). On re-excision, 62 (74.7%) had negative histology; however, 2 (2.4%) had residual invasive ductal carcinoma, 15 (18.1%) had residual DCIS, and 4 (4.8%) had lobular carcinoma in situ (Table 4).

Assessing costs at our institution, we accounted for facility and primary surgeon costs alone, which did not consider the additional physician fees from anesthesiology, radiology, pathology, and other services. All costs were adjusted for inflation to 2016 U.S. dollars utilizing the medical care component of the Consumer Price Index.¹⁴ From this data, mean facility cost for a re-excision procedure was \$1,323 (range \$742 – \$3,483), and mean surgeon cost was \$1,037 (range \$523 – \$2,575). For the 83 patients who would not have undergone re-excision per the guideline, the sum total of facility and primary surgeon costs for the re-excision procedures was \$195,919, which translates to approximately \$2,360 per patient or \$2,252 per re-excision procedure. Index and re-excision encounter cost distributions are presented in Table 5.

Discussion

Over the last several decades, surgical management of early stage breast cancer has become increasingly noninvasive, and BCT epitomizes the critical importance of multidisciplinary cancer care. The optimization of each component – surgery, radiation oncology, medical oncology – directly contributes to the success of BCS as a minimally invasive surgical approach. However, the challenge of defining adequate margin status has plagued surgeons since the advent of BCT as one of the options in the standard of care.

The SSO/ASTRO consensus statement was the first professional guideline supporting “no ink on tumor” as the definition for an adequate margin in early invasive breast cancer treated with BCT.¹² This holds substantial implications for the field of breast oncology, since the guideline does not require modification for specific populations of patients previously found to be at higher risk for local recurrence, including those with unfavorable biologic subtypes or age younger than 40.¹² Importantly, the guideline for invasive disease encompasses patients with or without concurrent DCIS, which differs substantially from the guideline for patients undergoing BCS for pure DCIS, which recommends a margin of at least 2 mm.¹⁵ In our study, we investigated the potential impact of the consensus guideline for invasive disease on surgical practice at our institution and the estimated cost reduction from its implementation.

In review of the 4 years prior to the release of the consensus guideline, our institutional average re-excision rate was 25.5%, which is comparable to other reported values.^{10,16–20} Our study demonstrates that application of the consensus guideline for invasive disease would have decreased this rate to 19.9%. In our population of patients with invasive disease undergoing re-excision, 41% had positive margins following the index procedure, though the majority of the patients only had one margin involved. On average, patients in our sample underwent re-excision after 26.6 ± 17.9 days, and for the 33 patients requiring a second re-excision procedure, the mean time from their index procedure was nearly 6 weeks (41.2 ± 41.3 days). This may also be an underestimate of the time factor involved in re-excision, given that our sample is drawn from a large comprehensive cancer center where over 600 new cases of breast cancer are diagnosed each year. Patients treated at a non-cancer center have previously been shown to experience much more variable times to treatment, which may negatively affect overall outcomes.^{21,22}

Consistent with other studies, the anterior margin was most frequently involved in our patients, generally related to abutment of the lumpectomy specimen to the skin and the lack of additional breast tissue amenable to resection.²³ This trend was observed by McIntosh et al. in an analysis of 200 patients undergoing BCT for T1-2 tumors who had close or positive margins, did not undergo re-excision prior to radiation therapy, yet had low 5- and 10-year local recurrence rates at 3% and 5%, respectively. In 34 of 37 patients (92%) with a close or positive anterior margin, surgeons documented tumor superficiality as the predominant rationale for moving ahead with radiation therapy instead of attempting re-excision first.²⁴ As more women are treated based on the guideline, the influence of multidisciplinary management in determining long-term outcomes in the setting of close margins will become especially prominent.

In our overall study population, re-excision histology was negative in 171 patients (67%), yet residual disease was found in the remaining 33%, with invasive cancer in 27 patients and DCIS in 47. Of the patients with negative re-excision histology, 62 (36.2%) had previously had a positive margin following their index procedure. Under the consensus guideline, 83 patients of the 254 with invasive cancer (32.7%) would have been spared re-excision, and these women would have proceeded directly to adjuvant therapy. Though a similar majority (62, 74.7%) of these patients had negative re-excision histology, 2 were noted to have residual invasive cancer, 15 had DCIS, and 4 had LCIS on re-excision. This again emphasizes the importance of radiation in the management of patients with close margins, since this residual disease would not have been found following primary surgery. Despite the guideline's definite short-term benefit in reducing re-excision rates, it is critical to consider the associated importance of appropriate adjuvant radiation and systemic therapy on long-term outcomes in women undergoing BCS.

As a complementary approach to reducing re-excision rates during BCS, intraoperative margin assessment has come under increasing scrutiny with the implementation of the guideline. Ranging from imprint cytology to macroscopic margin assessment, several methods of intraoperative evaluation have been shown to be successful in decreasing the need for second surgeries.^{25–28} One method which has gained recent interest involves cavity shave margins, particularly when used in routine fashion, which has been shown to decrease re-excision rates by over 50%.²⁹ In our study, five surgeons with differing techniques were practicing at our institution during the time period from which the current patient sample was drawn. Though all of the surgeons performed directed shave margins in select cases, no consistent method of intraoperative assessment was utilized. Within the context of the guideline, the standardization of cavity shave margins represents a possible solution in reducing the amount of residual disease while avoiding additional operations and further minimizing the cost of treatment. However, the effect of cavity shave margins on total excision volume, patient-reported aesthetic and quality of life outcomes, and cost/resource utilization necessitates additional review.

Though our study is limited by data from a single institution, it is clear that the consensus guideline will result in substantial cost savings for both patient and provider in the treatment of early stage breast cancer with BCT. Over the course of 4 years, we found that nearly \$200,000 would have been saved if the consensus guideline had been in place, which is equivalent to an average of \$2,360 per patient who would not have undergone re-excision. Furthermore, since our data only includes facility fees and primary surgeon billing for the surgical encounters, this is a highly conservative underestimate of the total cost of treatment from the practice of re-excision for close margins. A recent decision analysis by Baliski et al. of BCS in British Columbia demonstrated that avoidance of re-excisions based on the SSO/ASTRO consensus guideline may have the potential to save over \$1 million annually in their population, accounting for surgical and radiation costs for 1800 BCS procedures per year.²⁰ Another decision analysis by Abe et al. considered a hypothetical cohort of 140,000 BCT patients in the United States per year with a 20.6% baseline probability of close margins and undergoing one re-excision procedure. Surgical costs estimated using Medicare reimbursement rates would decrease more than \$20 million dollars if no re-excisions were performed for close or negative margins.³⁰ Beyond resource utilization and physician effort,

it is also important to consider the opportunity cost, missed work days for patients and caregivers, and the non-negligible distress caused by the need to return for surgery and the delay to adjuvant therapy. In our study, 81 hours of operating room time were committed to re-excisions which would not have occurred under the consensus guideline, and this represents potential consequences on a wider scale to other patients who may have received their surgical procedures during this time.

Future research will be vital in demonstrating the long-term impact of the SSO/ASTRO consensus statement on surgical practice in breast oncology. With the added clarity of margin adequacy that the guideline provides, an intensified focus on intraoperative margin assessment and multidisciplinary coordination will guide optimization of patient care.

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Figure 1.
Consensus Guideline Cohort Data Attrition Diagram

Table 1

Clinical Demographics and Tumor Characteristics (n = 254)

Variable	Mean $\pm$ SD	n	%
Age, y	60.3 $\pm$ 12.3		
< 50		55	21.7
50		199	78.3
Race			
White		185	72.8
Black/African American		66	26.0
Asian		3	1.2
BMI	29.3 $\pm$ 7.4		
< 25		69	27.2
25 – 29		82	32.3
30 – 34		56	22.1
35		47	18.5
Surgical site			
Right breast		130	51.2
Left breast		124	48.8
Tumor size, cm	1.7 $\pm$ 1.3		
Pathologic T			
T1		186	73.2
T2		58	22.8
T3		10	3.9
Stage			
I		157	61.8
II		81	31.9
III		15	5.9
IV		1	0.4
Receptor status			
ER+		220	86.6
PR+		195	76.8
Her2+		31	12.2
ER+/PR+/Her2+		19	7.5
ER+/PR+/Her2–		171	67.3
ER+/PR–/Her2+		5	2.0
ER+/PR–/Her2–		23	9.1
ER–/PR+/Her2–		3	1.2
ER–/PR–/Her2+		7	2.8
ER–/PR–/Her2–		24	9.4
Histology			

Variable	Mean $\pm$ SD	n	%
Invasive ductal carcinoma		199	78.4
Invasive lobular carcinoma		29	11.4
Mixed carcinoma		5	2.0
Other carcinoma		15	5.9
Both invasive disease and DCIS		182	71.7
Adjunct procedures			
Sentinel lymph node biopsy		202	79.5
Axillary lymph node dissection		18	7.1
Localization technique		235	92.5
Neoadjuvant chemotherapy		33	13.0
Radiation			
Whole breast		180	70.9
Partial breast		30	41.1
Unknown		44	17.3

DCIS, ductal carcinoma in situ.

Table 2

Index Procedure Characteristics

Variable	Mean $\pm$ SD	n	%
Margin status (n = 254)			
Positive		105	41.3
Invasive disease at margin		58	22.8
DCIS at margin		37	14.6
Both invasive disease and DCIS at margin		10	3.9
1 mm		134	52.8
> 1 mm – 2 mm		9	3.5
Margin characteristics for invasive disease			
Positive margin number (n patients = 68)	1.5 $\pm$ 0.8		
1		42	61.8
2		19	27.9
3		5	7.4
4		1	1.5
5		1	1.5
Positive margin location (n margins = 104)			
Anterior		36	34.6
Posterior		15	14.4
Medial		6	5.8
Lateral		5	4.8
Superior		12	11.5
Inferior		30	28.8
Close margin location, $\leq$ 2 mm (n margins = 161)			
Anterior		48	29.8
Posterior		23	14.3
Medial		10	6.2
Lateral		9	5.6
Superior		33	20.5
Inferior		38	23.6

DCIS, ductal carcinoma in situ.

Table 3

Re-Excision Histology Characteristics

Re-excision histology (n = 254)	n	%
Negative	171	67.3
Invasive ductal carcinoma	18	7.1
Invasive lobular carcinoma	8	3.2
Mixed carcinoma	1	0.4
DCIS	47	18.5
Atypical ductal hyperplasia	1	0.4
LCIS	5	2.0
Atypical lobular hyperplasia	3	1.2

DCIS, ductal carcinoma in situ; LCIS, lobular carcinoma in situ.

Table 4

Consensus Guideline Cohort Characteristics (n = 83)

Variable	n	%
Index histology		
Invasive ductal carcinoma	70	84.3
Invasive lobular carcinoma	7	8.4
Mixed carcinoma	1	1.2
Other carcinoma	5	6.0
Invasive disease + DCIS	62	74.7
Index procedure margin status, mm		
Invasive disease ≤ 1	45	54.2
Invasive disease > 1–2	9	10.8
Invasive disease > 2–5	18	21.7
DCIS ≤ 1	49	59.0
DCIS > 1–2	1	1.2
Re-excision histology		
Negative	62	74.7
Invasive ductal carcinoma	2	2.4
DCIS	15	18.1
LCIS	4	4.8

DCIS, ductal carcinoma in situ; LCIS, lobular carcinoma in situ.

Table 5

Cost Analysis for Consensus Guideline Cohort (n = 83)

Variable	Mean $\pm$ SD	Median	Range	Total
Index encounter cost *				
Facility	1,872.60 $\pm$ 426.40	1,826.30	1,122.60 – 3,480.60	155,422.60
Primary surgeon	1,500.10 $\pm$ 335.00	1,685.10	588.20 – 1,685.10	124,506.20
Re-excision encounter cost *				
Facility	1,323.40 $\pm$ 621.90	977.80	742.30 – 3,483.00	109,846.10
Primary surgeon	1,037.00 $\pm$ 455.90	890.10	523.60 – 2,575.20	86,072.80

* All costs in 2016 US dollars.