



## Was Reexcision Less Frequent for Patients with Lobular Breast Cancer After Publication of the SSO-ASTRO Margin Guidelines?

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### ABSTRACT

**Background.** The Society of Surgical Oncology and American Society for Radiation Oncology consensus guidelines defined a negative margin for breast-conserving surgery (BCS) as no ink on tumor, and implementation has reduced rates of additional surgery for patients with invasive ductal cancer (IDC). The outcomes for invasive lobular cancer (ILC) patients are uncertain.

**Methods.** This study identified patients who had stage 1 or 2 ILC treated with BCS from January 2010 to February 2018. The guidelines were adopted 1 January 2014. Clinicopathologic characteristics, margin status, and reexcisions were compared before and after adoption of the guidelines and with those of IDC patients treated from May 2013 to February 2015.

**Results.** Among 745 early-stage ILC patients undergoing BCT, 312 (42%) were treated before the guidelines and 433 (58%) after the guidelines. Most clinicopathologic characteristics were similar between the two groups, with differences in lobular carcinoma in situ, lymphovascular invasion, and node-positivity rates. The overall rates of additional surgery declined significantly after the guidelines (31.4 to 23.1%;  $p = 0.01$ ), but the difference did not

reach significance for reexcisions (19.9 to 15.2%;  $p = 0.12$ ) or conversions to mastectomy (11.5 to 7.9%;  $p = 0.099$ ) individually. Between eras, no difference in incidence or number of tumor on ink or  $\leq 2$  mm margins was observed (all  $p = 0.2$ ). Larger tumors, younger age, and pre-guideline era were independently associated with additional surgery. Only younger age was predictive of mastectomy. Among 431 pre-guideline and 601 post-guideline IDC patients, reexcisions declined from 21.3 to 14.8% ( $p = 0.008$ ), and conversion to mastectomy was rare (0.6%). The magnitude of reduction in any additional surgery (interaction,  $p = 0.92$ ) and reexcisions (interaction,  $p = 0.56$ ) was similar between ILC and IDC.

**Conclusions.** Despite differences in growth pattern and conspicuity, guideline adoption significantly reduced additional surgery among ILC patients, with a magnitude of benefit similar to that among IDC patients.

Invasive lobular carcinoma (ILC) comprises 10–15% of all breast cancers<sup>1</sup> and is biologically distinct from the more common invasive ductal carcinoma (IDC). Classic ILC displays a characteristic single-file formation of discohesive cells infiltrating the breast stroma, with loss of membranous E-cadherin.<sup>1</sup> This inherently infiltrative growth pattern poses diagnostic challenges because ILC may have a poorer clinical and radiographic definition.<sup>2,3</sup> As a result, historically, the feasibility of breast-conserving surgery (BCS) for ILC was questioned.<sup>2,4</sup> Histology was not examined in early randomized trials demonstrating similar locoregional control and survival with breast-conserving therapy (BCT) compared to mastectomy for early-stage invasive cancer.<sup>5,6</sup> However, similar long-term results have since been reported for populations of pure

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ILC patients, dependent upon achievement of negative margins<sup>3,7</sup> Contemporary rates of locoregional recurrence after BCT for ILC are less than 6% when negative margins are obtained.<sup>8</sup>

The 2014 Society of Surgical Oncology (SSO) and American Society for Radiation Oncology (ASTRO) consensus guidelines defined a “negative” margin as no ink on tumor, based upon a meta-analysis of 33 studies with 28,162 patients that demonstrated no improvement in ipsilateral breast tumor recurrence with a wider margin, including a subset analysis supporting applicability to ILC.<sup>9</sup> Single-center studies and population-based samples have demonstrated a decrease in additional surgery after initial lumpectomy with dissemination of the consensus guideline.<sup>10–13</sup> However, ILC patients comprised less than 20% of the study populations,<sup>10,12,13</sup> and outcomes for ILC patients remain unclear. We sought to examine the impact of the margin consensus guidelines on rates of reexcision and conversion to mastectomy after initial BCS for ILC, and to identify factors predictive of additional surgery.

## METHODS

After Institutional Review Board approval, we identified consecutive women with clinical stage 1 or 2 pure ILC treated with BCS from 1 January 2010 to 1 February 2018 with planned subsequent whole-breast radiotherapy (WBRT). Patients who received neoadjuvant chemotherapy, those with bilateral cancers, and those with a personal history of prior breast cancer were excluded from the study.

During the study period, all the surgeons at our institution routinely used seed localization for non-palpable lesions and a cavity-shave margin technique with separate submission of individual margins. This approach involves resection of the index lesion, followed by retrieval of separately shaved margins from the surgical cavity, with a metal clip or suture designating the final margin surface. The primary specimen was not assessed for margin status. Margins were defined as positive when ILC was present at an inked surface of the cavity-shave specimen. Lobular carcinoma in situ (LCIS) on ink was not considered a positive margin. When tumor was present in the separately submitted margin or margins, a measurement was provided in millimeters to the inked surface.

Our breast disease management team uniformly adopted the SSO-ASTRO consensus recommendations 1 January 2014. The patients were grouped into two study periods: “pre-guideline,” defined as those treated before 1 January 2014, and “post-guideline,” defined as those treated after 1 January 2014.

Clinicopathologic characteristics, margin status, and rates of reexcision and conversion to mastectomy among ILC patients were examined before and after guideline adoption. Rates of additional surgery then were compared with those for patients with clinical stage 1 or 2 pure IDC similarly treated with BCS and WBRT from May 2013 to February 2015. This subset of pure IDC patients was derived from a previously published cohort of patients with early-stage invasive breast cancer, among whom early uptake of the consensus guidelines was examined.<sup>10</sup>

The pre- and post-guideline eras were compared using the Wilcoxon rank-sum test for continuous variables and Fisher’s exact test for categorical variables. Uni- and multivariable analyses of factors associated with additional surgery were performed using binary logistic regression. The factors included in the univariable analyses were determined a priori, and adjustment factors included in the multivariable Cox regression analysis were based on univariable results. Tests for interaction were performed to assess whether changes in additional surgery were due to guideline era differences between IDC and ILC patients. A *p* value lower than 0.05 was considered statistically significant. All statistical analyses were conducted using R software version 3.5.0 (R Core Development Team, Vienna, Austria).

## RESULTS

From 1 January 2010 to 1 February 2018, 745 women with early-stage ILC underwent BCT, with 312 (42%) treated pre-guideline and 433 (58%) treated post-guideline. The characteristics of the population are summarized in Table 1. The median age was 62 years, and the majority of the cancers were pT1 (74.2%), were estrogen receptor (ER) positive (97.9%), had classical morphology (80%), and were node negative (79.6%). Whereas higher rates of associated LCIS (95.5% vs. 89.6%; *p* = 0.004), lymphovascular invasion (16.0% vs. 6.9%; *p* < 0.001), and node positivity (19.9% vs. 10.9%; *p* = 0.002) were observed in the pre-guideline versus post-guideline eras, all other clinicopathologic features were similar between the treatment periods.

The pre- and post-guideline eras did not differ in the closest margin (*p* = 0.21) or the number of margins 2 mm or smaller (*p* = 0.22; Table 2). The overall rate of reoperation after initial BCS was 26.6%. The rates for additional surgery showed an absolute decrease of 8% after guideline adoption, from 31.4% pre-guideline to 23.1% post-guideline (*p* = 0.01). This trend was observed for both reexcision lumpectomies (19.9 to 15.2%) and conversion to mastectomy (11.5 to 7.9%), although the difference between

**TABLE 1** Clinicopathologic characteristics of all invasive lobular cancer (ILC) patients stratified by pre- or post-guideline era of treatment

Characteristic	All ( <i>n</i> = 745) <i>n</i> (%)	Pre-guideline ( <i>n</i> = 312) <i>n</i> (%)	Post-guideline ( <i>n</i> = 433) <i>n</i> (%)	<i>p</i> Value
Median age: years (IQR)	62 (53–70)	61 (52–69)	63 (53–70)	0.35
Breast density				0.10
Fatty	43 (5.8)	19 (6.1)	24 (5.5)	
Scattered fibroglandular	233 (31.3)	83 (26.6)	150 (34.6)	
Heterogenous	392 (52.6)	172 (55.1)	220 (50.8)	
Extremely dense	77 (10.3)	38 (12.2)	39 (9.0)	
MMG/US size: cm (IQR) <sup>a,d</sup>	1.1 (0.8–1.7)	1.2 (0.8–1.6)	1.1 (0.8–1.7)	0.46
MRI performed	382 (51.3)	151 (48.4)	231 (53.3)	0.20
MRI size: cm (IQR) <sup>d</sup>	1.6 (1.1–2.4)	1.5 (1.1–2.3)	1.7 (1.1–2.5)	0.25
Pathologic tumor size: cm (IQR) <sup>d</sup>	1.4 (0.9–2.1)	1.4 (0.9–2.0)	1.3 (0.9–2.1)	0.99
Associated LCIS	686 (92.1)	298 (95.5)	388 (89.6)	0.004
Associated DCIS	117 (15.7)	54 (17.3)	63 (14.5)	0.31
Receptor subtype				0.64
ER+/HER2–	713 (95.7)	296 (94.9)	417 (96.3)	
ER+/HER2+	17 (2.3)	7 (2.2)	10 (2.3)	
ER–/HER2+	4 (0.5)	3 (1.0)	1 (0.2)	
ER–/HER2–	7 (0.9)	3 (1.0)	4 (0.9)	
Unknown	4 (0.5)	3 (1.0)	1 (0.2)	
Type				0.42
Classic	596 (80.0)	248 (79.5)	348 (80.4)	
Pleomorphic	133 (17.9)	60 (19.2)	73 (16.9)	
Alveolar	14 (1.9)	4 (1.3)	10 (2.3)	
Unknown	2 (0.3)	0 (0)	2 (0.3)	
LVI <sup>b</sup>	80 (10.7)	50 (16.0)	30 (6.9)	< 0.001
Pathologic T classification				0.45
T1	553 (74.2)	236 (75.6)	317 (73.2)	
T2	183 (24.6)	74 (23.7)	109 (25.2)	
T3	9 (1.2)	2 (0.6)	7 (1.6)	
Pathologic N classification				0.002
N0 or N0(i+)	593 (79.6)	236 (75.6)	357 (82.4)	
N1	109 (14.6)	62 (19.9)	47 (10.9)	
NX <sup>c</sup>	43 (5.8)	14 (4.5)	29 (6.7)	
Pathologic stage				0.43
1	485 (65.1)	195 (62.5)	290 (67.0)	
2A	210 (28.2)	94 (30.1)	116 (26.8)	
2B	50 (6.7)	23 (7.4)	27 (6.2)	

IQR interquartile range, MMG mammogram, US ultrasound, MRI magnetic resonance imaging, LCIS lobular carcinoma in situ, DCIS ductal carcinoma in situ, ER estrogen receptor, HER2 human epidermal growth factor receptor 2, LVI lymphovascular invasion

<sup>a</sup>Size not stated or occult in 91 cases

<sup>b</sup>Unknown in 14 cases

<sup>c</sup>No axillary surgery performed for 43 patients due to age

<sup>d</sup>Values for these rows are medians

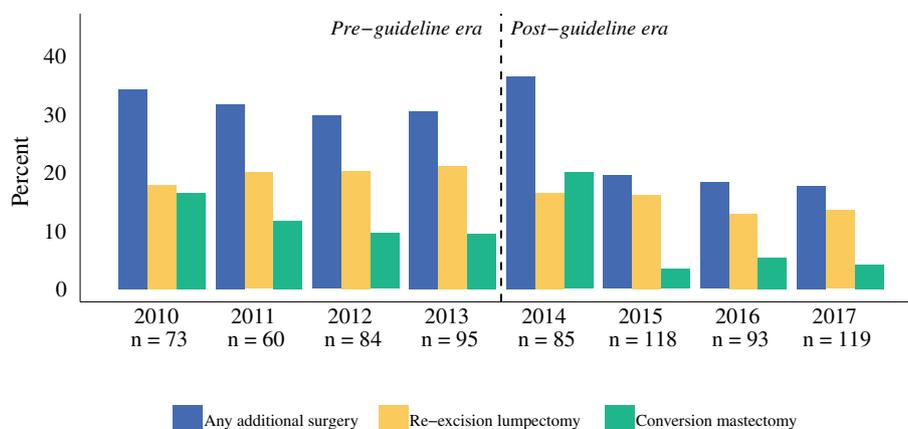
guideline eras did not reach statistical significance for these individual procedure types (Fig. 1). Margin status and rates of additional surgery are summarized in Table 2.

Among the patients who underwent conversion to mastectomy (*n* = 70), 17 (24.3%) had no residual carcinoma, 7 (10.0%) had ductal carcinoma in situ (DCIS)

**TABLE 2** Margin status and additional surgery after initial lumpectomy

	All (n = 745) n (%)	Pre-guideline (n = 312) n (%)	Post-guideline (n = 433) n (%)	p Value
Closest margin				0.21
Tumor on ink (mm)	121 (16.2)	50 (16.0)	71 (16.4)	
≤ 1	137 (18.4)	67 (21.5)	70 (16.2)	
1.1–2	47 (6.3)	22 (7.1)	25 (5.8)	
> 2	440 (59.1)	173 (55.4)	267 (61.7)	
If ≤ 2 mm margin(s), no. of margins involved				0.22
1	176 (57.7)	74 (53.2)	102 (61.4)	
2	80 (26.2)	43 (30.9)	37 (22.3)	
≥ 3	49 (16.1)	22 (15.8)	27 (16.3)	
Any additional surgery	198 (26.6)	98 (31.4)	100 (23.1)	0.01
Reexcision lumpectomy	128 (17.2)	62 (19.9)	66 (15.2)	0.12
Conversion to mastectomy	70 (9.4)	36 (11.5)	34 (7.9)	0.10

**FIG. 1** Annual rates of any additional surgery, reexcision lumpectomy, and conversion to mastectomy



alone, and 46 (65.7%) had residual invasive carcinoma. The median size of residual carcinoma was 0.6 cm (interquartile range [IQR], 0.3–1.1).

In the univariable analysis, increased odds of additional surgery were associated with larger tumor size (odds ratio [OR] 1.46; 95% confidence interval [CI] 1.25–1.69;  $p < 0.001$ ) and pre-guideline era (OR 1.52; 95% CI 1.1–2.12;  $p = 0.01$ ), whereas decreased odds of additional surgery were associated with older age (OR 0.96; 95% CI 0.95–0.98;  $p < 0.001$ ). No statistically significant associations were observed for breast density or tumor morphology.

In the multivariable analysis, increased odds of additional surgery remained significantly associated with larger tumor size (OR 1.55; 95% CI 1.33–1.81;  $p < 0.001$ ) and pre-guideline era (OR 1.61; 95% CI 1.15–2.27;  $p = 0.006$ ), whereas reduced odds of additional surgery remained significantly associated with older age (OR 0.96; 95% CI 0.94–0.97;  $p < 0.001$ ). Reduced odds of conversion to

mastectomy were significantly associated only with older age (OR 0.96; 95% CI 0.93–0.99;  $p = 0.005$ ) in the univariable analysis.

For comparison, 1032 patients with pure IDC were identified from the previously studied cohort.<sup>10</sup> Of these patients, 431 (42%) were treated pre-guideline, and 601 (58%) were treated post-guideline. The overall rate of additional surgery after initial BCS was 17.5%. A 7% absolute decline occurred after guideline adoption, with additional surgery decreasing from 21.3 to 14.8% ( $p = 0.008$ ).

In a model designed to assess interactions between histology and guideline era, the magnitude of reduction in any additional surgery (interaction,  $p = 0.92$ ) and reexcision lumpectomy (interaction,  $p = 0.56$ ) was similar between ILC and IDC. Conversion to mastectomy among IDC patients was rare (performed for only six patients [0.6%] overall), limiting further analyses of this effect.

## DISCUSSION

In this contemporary population of early-stage ILC patients treated with upfront BCS, we demonstrated a significant decline in rates of additional surgery, from 31.4 to 23.1%, after adoption of the SSO-ASTRO consensus guidelines endorsing a margin of “no ink on tumor.” The extent of margin involvement did not differ between eras, and the magnitude of reduction in reoperation was similar to that seen in IDC patients.

Reported rates of additional surgery after initial BCS for invasive cancer in the pre-guideline era ranged from 20 to 75%.<sup>14–16</sup> In a large population-based sample of patients with stage 0–2 cancer treated between 2000 and 2010, lobular histology was shown to be an independent predictor of additional surgery.<sup>17</sup> Since dissemination of the consensus guidelines in 2014, more recent studies show a subsequent decline in reoperations but include few patients with ILC.<sup>10,12,13</sup> The overall rate of additional surgery in our study was 26.6%, which decreased from 31.4% in the pre-guideline era to 23.1% in the post-guideline era. Rosenberger et al.<sup>10</sup> reported a similar reduction in reexcisions, from 21.4 to 15.1%, after guideline adoption among 1205 patients with stage 1 or 2 invasive breast cancer treated from January 2013 to October 2014, 127 (11%) of whom had ILC. Chung et al.<sup>12</sup> also saw reexcisions decrease from 19 to 13% ( $p = 0.03$ ) among 846 patients undergoing BCS, including 169 cases (20%) of lobular or mixed ductal/lobular histology. Bhutiani et al.<sup>13</sup> similarly demonstrated a decline in reexcision lumpectomy, from 37 to 9% ( $p < 0.001$ ), after guideline adoption among 237 patients undergoing BCS, 26 (11%) of whom had ILC. To our knowledge, the current study is the largest study showing a decline in additional surgery after primary BCS in a contemporary population of patients with pure ILC, demonstrating a reduction similar in magnitude to that observed for IDC.

With the success of BCT contingent on achievement of negative margins, it is noteworthy that higher rates of margin positivity have been observed in ILC than in IDC, ranging from 12.3% to as high as 63% in early studies.<sup>4,18,19</sup> In the current study, the rate of margin positivity among the ILC patients was 16.2% and did not differ between the pre- and post-guideline eras.

The cavity-shave margin technique, uniformly used at our institution, has been suggested to decrease rates of margin positivity in ILC. In a randomized trial of 235 patients with stage 0–3 cancer undergoing BCS, use of the cavity-shave margin technique resulted in significantly lower rates of positive margins (19% vs. 34%;  $p = 0.01$ ) and reexcisions (10% vs. 21%;  $p = 0.02$ ), but only 9% of the patients in this study had lobular histology.<sup>20</sup> In a subsequent study of 365 patients with stage 1–3 pure ILC, Mukhtar et al.<sup>21</sup> found

lower rates of positive margins with the use of cavity-shaved margins (OR 0.39; 95% CI 0.2–0.7;  $p = 0.002$ ) after adjusting for size and multifocality.

In our study, cavity-shaved margins were routinely used, and both the rate and number of positive margins and margins smaller than 2 mm were similar before and after guideline adoption. Given our consistent technique and no difference in disease burden between the pre- and post-guideline eras, the use of this method likely did not account for the observed decline in reexcisions, but may have contributed to our comparatively lower rates of margin positivity than in other series.

Despite higher reported rates of margin positivity in ILC, multiple studies have shown no difference in local control or survival outcomes compared with IDC when negative margins are ultimately obtained.<sup>4,18,19</sup> Importantly, many of these studies also predate modern improvements in preoperative imaging, localization, and surgical techniques as well as routine use of systemic endocrine therapy, which is of particular benefit for patients with overwhelmingly ER positive ILC.<sup>1</sup>

In addition to the pre-guideline era of treatment, younger age and larger tumor size were predictive of additional surgery among ILC patients in this study, consistent with previously reported results in populations composed mainly of patients with IDC. In a National Cancer Database study of 316,114 patients who had early-stage cancers treated with BCS from 2010 to 2014, the rate of additional surgery was 38.5% among the youngest patients (age, 18–29 years) compared with 16.5% among those older than 80 years ( $p < 0.001$ ).<sup>17</sup> Increasing tumor size also showed a linear association with repeat surgery ( $p < 0.001$ ).<sup>17</sup> Similarly, in a population-based sample of 89,448 women treated with primary BCS from 2003 to 2013 in New York State, reoperation was higher among women younger than 50 years of age than among women 65 years of age or older (37.7% vs. 26.3%;  $p < 0.001$ ).<sup>22</sup> Although most of the patients in these studies had ductal histology, our findings suggest similar trends among early-stage ILC patients, which are not altered by application of the margin guideline.

Conversion to mastectomy among the ILC patients in our study declined from 11.5 to 7.9% after guideline adoption, which did not reach significance, and remained markedly higher than the rates of conversion to mastectomy among the IDC patients, which was performed in less than 1% of cases. This is consistent with previous studies, with rates of mastectomy after initial BCS ranging from 4.9 to 37% in ILC versus < 1 to 22% in IDC.<sup>2,3,10,23–25</sup>

Unreliable clinical and imaging assessment, and the cohesive and multifocal nature of ILC have been suggested as the rationale for higher rates of conversion to mastectomy. However, among the patients who did undergo

completion mastectomy in the current study, 24% had a benign mastectomy specimen, and the median size of the remaining tumor was only 0.6 cm among those with residual disease. This raises the possibility that those with a minimal residual disease burden may have achieved negative margins with reexcision lumpectomy and may have potentially avoided mastectomy. Younger age was the only factor predictive of both additional surgery and conversion to mastectomy, consistent with previous reports,<sup>22</sup> and this may reflect the interplay of clinical factors and patient choice.

The limitations of this study included its retrospective nature and inability to examine physician- and patient-level decision making. However, its strengths included a large consecutive population of women who had early-stage pure ILC treated with consistent and contemporary surgical and pathologic techniques. The uniform guideline adoption among a large group of surgeons enabled demonstration of a substantial impact of the consensus guidelines on patients with the less-common lobular histology.

## CONCLUSIONS

In our large population of early-stage ILC patients treated with primary BCS, we demonstrated a significant decline in additional surgery with uniform adoption of the 2014 SSO-ASTRO consensus margin guidelines. The extent of this reduction was similar to that seen among patients with IDC, with younger age and larger tumor size predictive of reoperation. Although rates of conversion to mastectomy also have decreased, this reduction was not statistically significant, and rates remain higher among patients with lobular histology. In the contemporary era of superior radiologic, pathologic, and surgical techniques, we anticipate continued progress in tailoring therapies and avoiding overtreatment for this innately unique subset of breast cancer.

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