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ORIGINAL ARTICLE – BREAST ONCOLOGY

Impact of the SSO-ASTRO Margin Guideline on Rates of Re-excision After Lumpectomy for Breast Cancer: A Meta-analysis

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ABSTRACT

Background. One in five patients undergoing initial lumpectomy for invasive breast cancer subsequently undergoes re-excision or mastectomy. A lack of clarity of when to re-excise based on lumpectomy margin width contributes to this high rate of reoperation. We sought to determine the impact of the Society of Surgical Oncology (SSO) and American Society of Radiation Oncologist (ASTRO) margin guideline on reoperation rates after lumpectomy. The guideline recommended omission of routine re-excision in specimens with "no ink on tumor".

Methods. A systematic literature review was performed. For eligible studies, a random-effects model was used for a meta-analysis of lumpectomy re-excision prevalence before and after publication of the SSO-ASTRO margin guideline. Study heterogeneity was measured by the Cochran's Q test.

Results. Five institutional, one population-based, and one national registry study met inclusion requirements. Sample size per study ranged from 237 to 26,102. There was significant interstudy heterogeneity (Q = 19.779; p = 0.003). Pooled re-excision prevalence was 22% (confidence interval [CI] 20–23) before and 14% (CI 12–15) after guideline publication. With the pre-guideline re-excision prevalence used as the reference value, the associated odds ratio for re-excision after the guideline was 0.65 (CI 0.54–0.78; $p < 0.0001$).

Conclusions. The findings of a 35% reduction in the odds of re-excision after the guideline publication and a reduction in re-excision prevalence from 22 to 14% supports the notion that the SSO-ASTRO margin guideline was impactful. These findings are congruent with the projected reductions in re-excision at the time of guideline publication.

Reoperations after initial lumpectomy for breast cancer are common enough that some surgeons have termed them "epidemic."[1] Rates often exceed 20%, and there is extreme variability in surgical re-excision rates among surgeons in the same practice settings.[2–8] Until 2014, there was no consensus regarding the definition of an adequate specimen margin for patients undergoing breast-conserving surgery (BCS) with planned whole-breast irradiation for early-stage invasive cancer [9,10] This lack of clarity regarding appropriate margin width contributed to high rates of re-excision. In 2013, Houssami and colleagues conducted a meta-analysis of more than 30 studies, which reported the relationship between final microscopic margin status, negative margin width and risk of local recurrence and found that margins more widely clear than "no ink on tumor" were not effective in decreasing local recurrence.[10] A Society of Surgical Oncology (SSO) and American Society for Radiation Oncology (ASTRO) multidisciplinary panel subsequently developed an evidence-based guideline endorsing "no ink on tumor" as a standard for patients with Stage I-II invasive cancer undergoing BCS with whole-breast irradiation.[9] This guideline was first presented in the fall of 2013 and was available online and in print in February and March of 2014, respectively.[9]

The projected impact of this guideline included a decrease in margin re-excision rates and patient and system-level cost savings.[11–21] Since the guideline publication date, multiple studies have evaluated both the projected and the actual efficacy of the guideline to reduce re-excision rates.[6,7,11–16,18–21] For example, using the American Society of Breast Surgeons (ASBrS) Mastery[SM] database,

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Schulman et al. demonstrated a 3.8% decrease in re-excision within a year of guideline publication.[7] This early downward trend in re-excision rates also was identified by Morrow et al. in a population-based study using patients identified from the Surveillance, Epidemiology, and End Results (SEER) database.[18] Institutional studies investigating pre- and post-guideline re-excision rates have also reported decreased use of re-excisions after BCS.[6,15,19–21]

In this study, we sought to determine the impact of the SSO-ASTRO margin guideline on re-excision prevalence. A secondary goal was to determine the impact of the guideline on the patient's final breast status (breast conservation or mastectomy). We hypothesized that fewer patients would undergo re-excision after the guideline.

METHODS

A systematic literature search and a quantitative analysis were conducted and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses [PRISMA]. This study was conducted as a meta-analysis; it did not involve recruitment or inclusion of new patients or patient data. Therefore, this study was deemed exempt from Institutional Review Board (IRB) review.

Identification of Studies

Two parallel search engines (PubMed and Ovid-MEDLINE®) were used to create a comprehensive list of relevant peer reviewed articles. The search was restricted to those papers published in 2014 and after with the search terms: "breast"; "guidelines"; "margins"; "reoperation"; "re-excision" and SSO ASTRO, with or without the Boolean term "AND." Only the articles published in English were assessed. All abstracts were screened independently by three coauthors. A total of 22 studies were identified on Ovid-MEDLINE® and 23 on PubMed.

Eligibility Criteria

The abstracts of each study were reviewed. Studies included in the meta-analysis contained pre- and post-guideline cohorts of patients with stage I-II invasive cancer who underwent BCS as the initial operation and reported actual re-excision prevalence. Studies were excluded if they reported an expected re-excision prevalence that was mathematically calculated but not measured in real time. Full texts of the studies meeting inclusion criteria were screened for any deviation from inclusion criteria. Seven articles were selected for the meta-analysis (Fig. 1).[6,7,15,18–21] Five were single-institutional studies, one was population-based, and one identified patients from a voluntary national registry (Table 1). All reported reoperation prevalence for each cohort except for the Surveillance, Epidemiology, and End Results Program (SEER) publication, which analyzed trends over time.[18] The principal investigator of this study provided the raw data, without patient or facility identifiers, for calculating the re-excision prevalence for each cohort. The surgical date was designated to be 1 month after the listed diagnosis date and a "washout" period was used to create pre- and post-guideline cohorts (operation before January 2014 vs. after June 2014).

Data Extraction, Outcomes, and Confounding Variables

The primary outcome of interest was pre- and post-margin guideline re-excision prevalence. Re-excision was defined either as repeat lumpectomy or mastectomy after initial lumpectomy. A secondary outcome was final breast status (conservation vs. mastectomy). During data extraction from eligible studies, geographic sites and sources of the data from each study were collected. For each study, we recorded whether a "washout" time-period was specified before the onset of post-guideline data collection and whether investigators collected information on potential confounding variables, such as patient, tumor, and treatment characteristics, before and after the guideline.

Data Analysis

The pooled prevalence of re-excision for the pre- and post-guideline cohorts was calculated using double-arcsine transformation as described by Barendregt et al..[22] Additionally, the odds ratio for re-excision was calculated for each study (Fig. 3). An unadjusted overall odds ratio for the meta-analysis was calculated using the method described by DerSimonian and Laird, which is a random-effects model.[23,24] Heterogeneity between studies was measured using the Cochran's Q test. A two-tailed p value < 0.05 was considered significant.

Investigation of bias and overlap between institutional studies and national databases as well as between the two national databases was undertaken with mapping of geographic location. Contribution by patient and zip code in all databases in the meta-analysis was confidential; overlap was presumed by location.

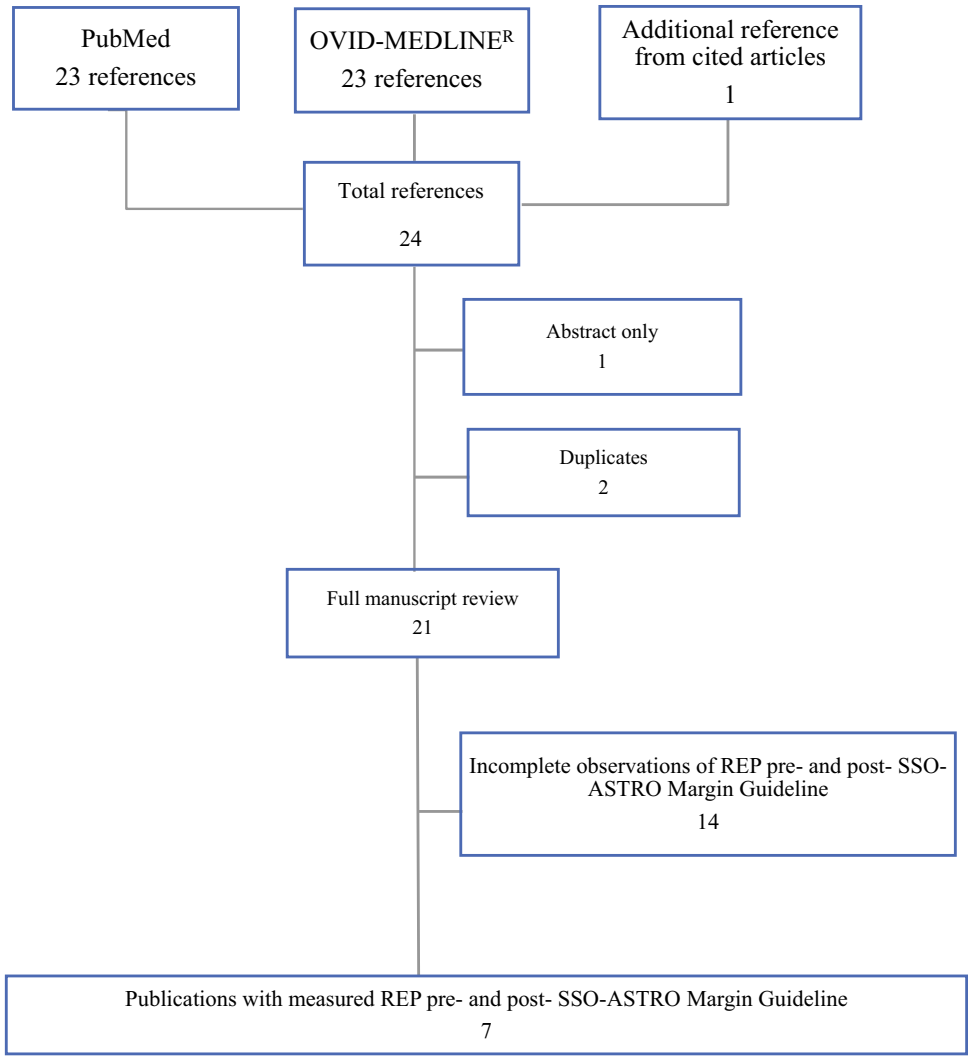

FIG. 1 Studies selected for full review and meta-analysis based on the preferred reporting items for systematic reviews and meta-analyses (PRISMA)

REP: Re-excision prevalence

RESULTS

Studies and Patients

Seven studies met inclusion criteria. Two utilized national databases. These were the voluntary ASBrS Mastery[SM] and the population-based SEER registry.[7,18] The remaining five were institutional studies.[6,15,19–21] All data were from the continental United States. The study-specific database sites, sample sizes, and re-excision prevalence are summarized in Table 1. The pooled pre- and post-guideline cohorts consisted of 16,282 patient data points in the pre-guideline cohort and 15,900 data points in the post-guideline cohort. Possible overlap between studies using geographic distribution can be visualized in Fig. 2. The ASBrS Mastery[SM] database was presumed to include a nationwide sample while the study utilizing the SEER database was restricted to Los Angeles county and the state of Georgia, decreasing the overlap between these publications. No institution-to-institution overlap was detected, but we acknowledge that the ASBrS database may include contributions from surgeons that practice at the five single institutions reported here or at the two SEER locations. By the Cochran's Q test, there was significant heterogeneity between studies ($Q = 19.779$; $p = 0.003$).

Outcomes

In comparing the post- to the pre-guideline time periods, five of seven studies demonstrated a significant reduction in re-excision prevalence (odds ratios varying from 0.17 to 0.73; Table 1; Fig. 3). Two had a nonsignificant reduction in re-excisions. No study showed an increase in re-excision prevalence after guideline publication.

By meta-analysis, re-excision prevalence declined from 22% (confidence interval [CI] 20–23) to 14% (CI 12–15)

TABLE 1 Re-excision prevalence (REP) pre- and post- SSO-ASTRO margin guideline publication

First author	Database type	Database name	Total sample size		REP pre-SSO (%)	REP post-SSO (%)	Absolute change REP (%)	Relative change REP (%)	*p* value
			Pre	Post					
Schulman[7]	National	ASBrS Mastery[SM]*	13,297	12,805	20.2	16.5	3.7	22.4	< 0.005
Rosenberger[6]	Institutional	Memorial Sloan Kettering Cancer Center	504	701	21.4	15.1	6.3	41.7	0.006
Gladden[21]	Institutional	University of Colorado School of Medicine	505	358	11.9	10.9	1	9.2	0.65
Morrow[18]	Population-based	SEER‡	851	1125	27.3	18.2	9.1	50.0	< 0.001
Bhutiani[15]	Institutional	University of Louisville	126	111	36.5	9	27.5	305.2	< 0.001
Chung[19]	Institutional	Cedars-Sinai Medical Center	597	248	19.3	12.9	6.4	49.3	0.03
Patten[20]	Institutional	Levine Cancer Institute, Carolinas Healthcare System	402	552	20.4	16.3	4.1	25.2	0.104

*The American Society of Breast Surgeons

‡Surveillance, epidemiology, and end results program

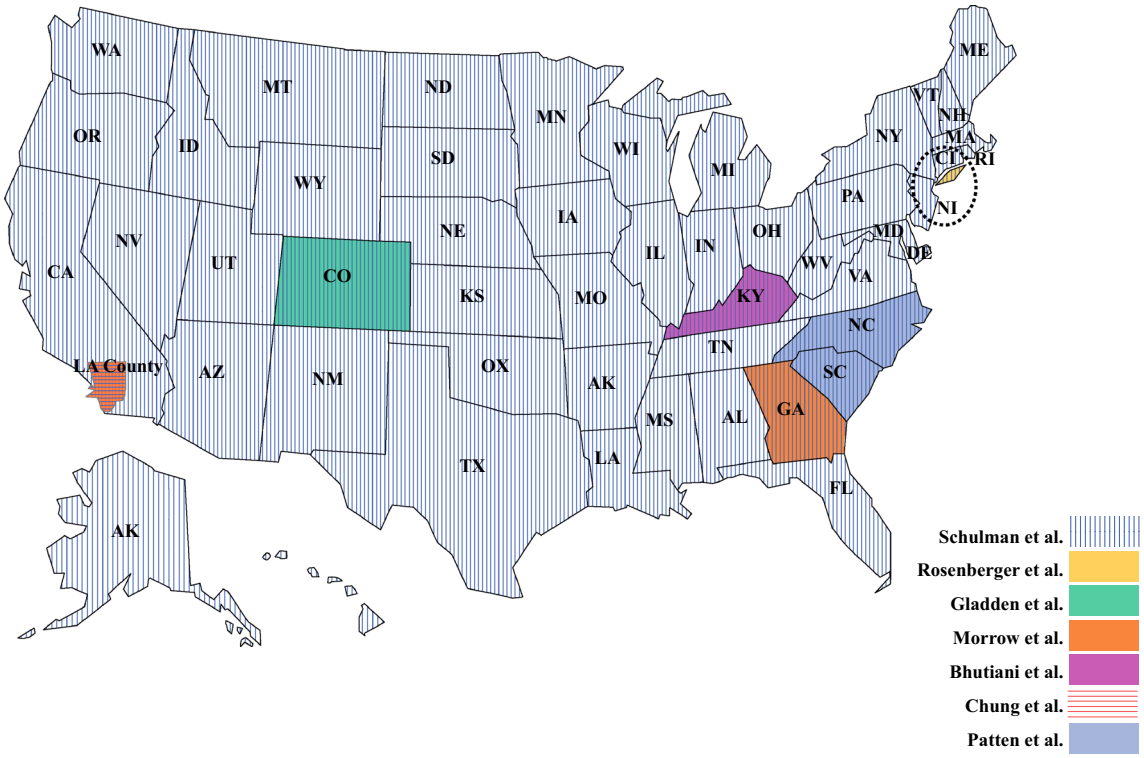

FIG. 2 Geographic distribution of sample population by study

following guideline publication. With the pre-guideline re-excision prevalence used as the reference value, the associated odds ratio for re-excision after the guideline was 0.65 (CI 0.54–0.78; $p < 0.0001$).

In the meta-analysis, three of seven studies reported the number of patients with conversion to mastectomy when re-excision was performed.[6,15,18] In two of these, the BCS rate increased after the publication date of the SSO-ASTRO margin guideline. In the SEER study and a single-institution study, the rate increased from 91.3 to 95.2% ($p = 0.001$) and 80.7% to 87.1% ($p = 0.03$), respectively.[15,18]

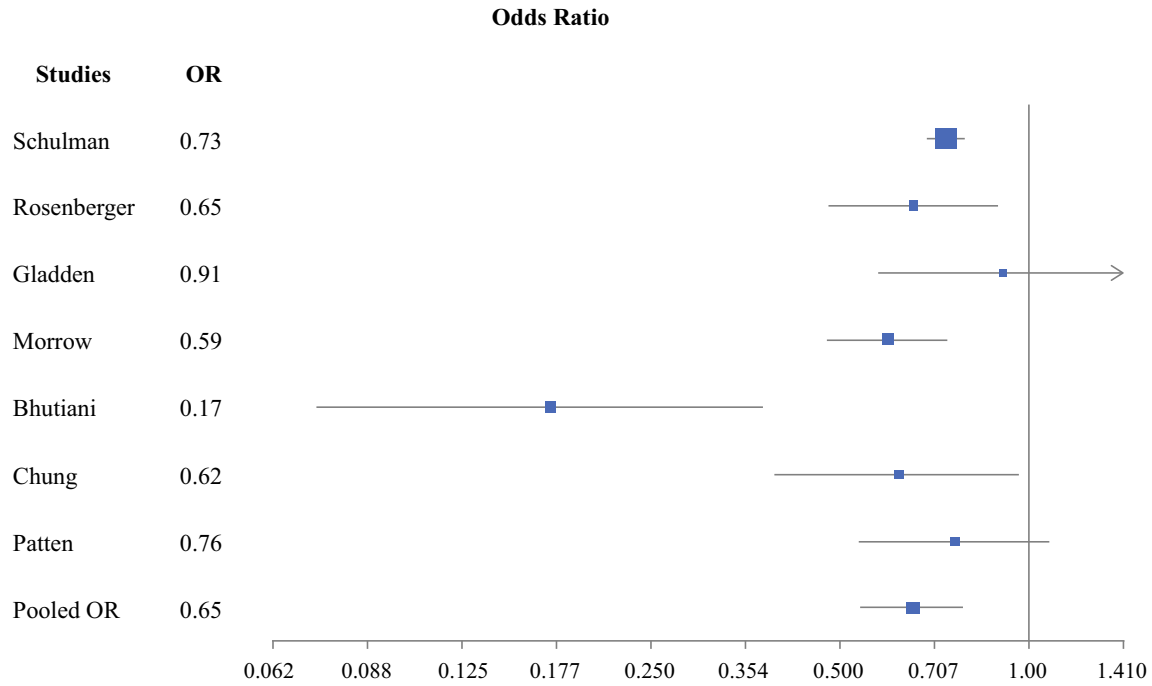

FIG. 3 Forest plot of odds ratio of re-excision and associated confidence interval. Reference level is prevalence pre-guideline publication. (Box size reflects study sample size)

Confounders

All seven studies in the meta-analysis compared some patient, tumor, and treatment characteristics before and after the guideline. The number of these independent adjustment variables by study ranged from 6 to 17.[6,7,15,18–21] In the most detailed analysis, Rosenberger et al. reported 17 factors and found no differences across time-periods.[6] The six other studies in the meta-analysis identified only a few differences across time periods. Among these, there was no consistent pattern of patient or pathologic factors known to be associated with increased re-excisions (such as very young age or greater tumor size) that differed between the pre- and post-guideline cohorts. Only a few studies compared utilization of specific techniques known to be associated with fewer re-excisions, such as cavity shaves, before and after the guideline. In Louisville, the use of cavity shaves increased from 24 to 59% ($p < 0.001$).[15] Others reported routine use of cavity shaves before and after the guideline.[6,19]

DISCUSSION

A primary purpose of guideline development is to accelerate the implementation of new evidence-based medicine into routine practice. Unfortunately, there is ample evidence of delay in the adoption of new evidence-based care.[25–27] It is therefore important to determine whether guidelines are being adopted. If delays are identified, then interventions, such as auditing, benchmarking, disseminating information, and various other performance incentives, ought to be considered.[28]

In our meta-analysis, those patients undergoing BCS after the publication of the SSO-ASTRO guideline had a 35% reduction in odds of reoperation. This finding supports the notion that the SSO-ASTRO guideline is being implemented and is impactful. By meta-analysis, re-excision prevalence decreased from 22 to 14%. Overall, our findings suggest that the margin guideline was incorporated into surgeon practice soon after its development. If the decrease in re-excision prevalence as reported here is indeed due to a decrease in re-excisions of close margins from guideline adherence, then the observed reduction in re-excision prevalence nearly matches the upper limit of the predicted reduction (30–40%) in patients undergoing re-excision for close, but ink-negative margins.[7,8]

The purpose of this study was to use a surrogate measure of SSO-ASTRO lumpectomy margin guideline compliance (re-excision prevalence) to assess whether providers of care were adopting the guideline. Direct measurement of guideline compliance, by reviewing reasons for re-excision stratified by margin status and width was not possible, because few publications reporting reoperation rates also capture the reasons for reoperation. To our knowledge, no national patient registry except the ASBrS Mastery[SM] records these "reasons".[7,8] However, by a survey of their

membership in 2015, DeSnyder et al. reported that 92% of 777 surgeons were familiar with the SSO-ASTRO guidelines, 95% re-excised for tumor on ink and very few (1.3%) re-excised for margins greater than ink-negative.[29] Because the ASBrS membership includes a broad spectrum of surgeons (academic affiliated, nonacademic affiliated, general, and breast-only) and the majority of survey respondents understood the guideline, re-excision prevalence ought to be a good surrogate for guideline compliance.

The re-excision prevalence of 14% by meta-analysis after the guideline does not yet achieve the ASBrS endorsed target goal of less than or equal to 10%.[30] Yet, this result demonstrates a significant improvement in re-excision prevalence compared with other studies.[2–5] We anticipate further reductions as guideline adoption increases.

Several investigators measured outcomes other than re-excision before and after guideline publication. In three studies, the final breast status after initial lumpectomy was reported.[6,15,18] Two of these three demonstrated increases in the final BCS rate after guideline dissemination. These findings support the concept that re-excisions impact the final breast status, increasing mastectomies in populations of patients initially choosing breast conservation. A single study provided a patient-reported outcome measure. This investigation utilized the validated BREAST-Q instrument and found that the "satisfaction with breast" median scores increased from 61 to 77 ($p = 0.03$).[15] Significant cost savings have also been estimated or quantified in multiple studies.[6,13–21]

The current study has limitations. There was no consistency in the type and number of independent variables used for adjustment of pre- and post-guideline re-excision prevalence in individual studies. On the other hand, when measured, most studies demonstrated few to no differences between patient and tumor characteristics across time periods, and there were no major changes in screening guidelines during the study period that could potentially increase the proportion of small cancers unlikely to require re-excision. Another limitation was the potential for the same patient encounter to have been reported more than once due to some geographic overlap of patient cohorts. Because all patients were de-identified, it is not possible to discern whether this occurred. Few studies in this meta-analysis provided all reasons for re-excision; thus, it is not possible to determine with certainty if guideline implementation was the primary driver of the observed reductions in re-excision. Competing reasons for reductions in re-excision seen after 2014 could include unmeasured confounders, such as increased use of those processes of care that are associated with fewer reoperations. In particular, there is high-level evidence and consensus that routine shaving of cavity margins lessens the need for re-excision.[30–32] However, in the two institutions reporting the use of cavity shaves before the guideline, a reduction in the use of re-excision was observed, suggesting that cavity shaves were not the sole explanation for the observed decrease in re-excision after guideline dissemination.[6,19] Furthermore, two studies reporting reasons for re-excision suggested that avoidance of re-excision for "close" margins would result in a decrease in re-excision rates similar to that observed in the present meta-analysis.[7,8] Lastly, there were various "washout" time intervals between the measurements of re-excision during the pre- and post-guideline time periods. As such, those reports with short time-intervals might underestimate but would not negate the finding of fewer re-excisions after guideline publication.

To our knowledge, this is the first meta-analysis to assess the impact of the development and publication of the SSO-ASTRO margin guideline on re-excision after lumpectomy. In addition to providing evidence of a significant reduction in re-excision prevalence, the studies comprising the meta-analysis also provided insight into the potential contribution of the margin guideline to improve final breast status by lessening conversion to mastectomy in patients initially wanting breast conservation. Other strengths include a total sample size exceeding 30,000 patient encounters, broad geographic representation, and academic and nonacademic (SEER and ASBrS)-affiliated surgeon diversity.

CONCLUSIONS

By meta-analysis, re-excision prevalence after initial lumpectomy for invasive breast cancer declined significantly from 22 to 14% after publication of the SSO-ASTRO margin guideline. This result suggests that the guideline has been effective and is influencing surgeon practice.

Moving forward, initiatives to decrease reoperation rates are still warranted, because a prevalence of 14% is still higher than those from other cancer sites.[33] Furthermore, an endorsed consensus conference target goal of 10% has not yet been achieved, and some surgeons contributing to SEER still indicate by survey that they recommend margins beyond "no tumor on ink".[18,30]

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CONFLICT OF INTEREST The authors declare that they have no conflict of interest.

DISCLOSURE Monica Morrow-Honoraria from Roche and Genomic Health

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