



A tale of two operations: re-excision as a quality measure

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Breast cancer represents one of the leading cancer diagnoses in women. Given the epidemiologic salience of the disease, a large body of research has been dedicated towards optimizing care and improving outcomes. One of the preeminent studies in breast cancer occurred with the NSABP B-06 trial establishing equivalence between breast-conserving surgery (BCS) followed by radiotherapy and mastectomy (1). Since this landmark finding, BCS accounts for approximately 65% of all operations for breast cancer (2). An unavoidable consequence of BCS is that a subset of women will ultimately have positive margins and require reoperation. Reports in the literature on re-excision rates after BCS have been found to range from 20% to 30% in large database studies (3,4). Re-excision rates vary dramatically in single-institution reports and several patient, tumor, treatment and facility factors have been associated with reoperation after BCS (3,5,6).

Optimizing re-excision rates after BCS is critical on both the patient level and the systems level. Reoperation after BCS results in additional time away from work and added mental and physical stress to patients. Furthermore, it results in delays in adjuvant therapy. On a systems level, reoperations result in increased medical costs and global improvement in rates would translate to significant savings to the healthcare system. In a study by Yu *et al.*, a reduction in re-excision rate of 5.6% in a single-institution cohort reduced costs by approximately \$200,000 (7). Despite variable rates of re-excision in the literature and the impact to both patients and institutions, there is no well-established benchmark for re-excision rates. Given the documented variability, reoperation rate has been posed as a potential

quality metric for institutions (8).

In the study by Landercasper *et al.*, the authors leveraged the National Cancer Database (NCDB) to identify characteristics associated with reoperations with the overarching aim of finding potential targets for initiatives to reduce overall rates of re-excision and to discuss the integrity of re-excision for risk-profiling. The overall reoperation rate found in the study was 16.1%, consistent with published rates. Several factors in adjusted analysis were noted to be associated with reoperation, including patient factors such as younger age, tumor factors such as lobular histology, larger tumor size, positive nodal status and treatment factors such as neoadjuvant chemotherapy use (9). Similar findings have been noted in the literature in both single-institution and large database studies (3,5).

The disparate re-excision rates found in the literature in single-institution studies suggest that there is variability between facilities. Perhaps the most striking finding from the results of Landercasper and colleagues is the significant inter-facility variation in reoperation rate. The authors noted that the association with facility ID and reoperation rates remained despite adjusting for patient, tumor and treatment characteristics as well as facility volume and case mix (9). In a multi-institution analysis of 4 institutions and 3 large health plans, McCahill *et al.* also found similar and significant surgeon and institutional variation in re-excision rates (3). As Landercasper *et al.* acknowledge, the use of an administrative database limits a thorough analysis of between- and within-institution factors that could be driving this variability. This includes but is not limited to assessment of technical factors, margin assessment and

judgment at the surgeon level, and method of localization at the institution level.

Given the relatively low complication profile and predominantly outpatient or short-stay practice associated with surgery for breast cancer, traditional metrics of quality are not applicable. The disparate rates in re-excision at the single-institution and national database level raise the question of whether underlying differences in care could be driving the variability and suggest that re-excision may be a plausible marker for quality assessment. Landercasper and colleagues stratified facilities into tiers of reoperation performance. After partial risk adjustment on the 5 highest factors associated with reoperation, 11% of facilities shifted performance quartiles compared with the unadjusted model. After adjusting for all 18 factors associated with reoperation, 21% of facilities shifted quartiles compared to the partial risk adjustment model. Overall, 25% of facilities shifted quartiles of performance in the fully adjusted model compared to the unadjusted model (9). These findings suggest that using unadjusted reoperation rates as a quality metric has high potential for bias. Furthermore, adjusted reoperation rates are highly sensitive to the parameters considered and should be used with caution.

The recent release of the Society of Surgical Oncology and American Society for Radiation Oncology (SSO-ASTRO) consensus guidelines in 2014 regarding surgical management of invasive breast cancer established that no tumor touching the inked margin of the surgical specimen represents a negative margin and completion of surgical therapy (10). Since the consensus statement, data indicate that re-excision rates have improved (4). The 2004–2015 time-period of the study by Landercasper *et al.* includes data from before and after the SSO-ASTRO consensus statement published in 2014. The authors performed a time-trend analysis to evaluate the impact of the SSO-ASTRO guidelines on reoperation rates. The authors found that reoperation rates from 2014–2015 were less than the expected value derived from modeling based on pre-guideline data. This finding translated to a statistically significant decline in rates after the introduction of the consensus statement. In a multi-institution study by McCahill and colleagues investigating variability in re-excision after BCS prior to the publication of SSO-ASTRO consensus statement, the authors' findings highlighted the impact of a lack of clear guidelines on re-excision rates. In this study, nearly half of patients with close margins underwent re-excision and significant surgeon-level variance in decisions regarding re-excision for negative margins was noted (3). Taken in concert, these findings

suggest that the introduction of clear guidelines for margin status may address much of the variability in re-excision patterns and alter the lense with which we must view these findings given that the majority of data points occurred prior to the introduction of the SSO-ASTRO consensus statement. Evaluation of inter-facility variability after the SSO-ASTRO consensus guidelines is an important consideration for further study.

While the inter-facility variability is high, there is also consistent redemonstrations of patient and tumor factors associated with re-excision, such as young age, positive margins and lobular histology (3,5,6,9). Several interventions and novel technologies have been associated with reduced re-excision rates. Interventions such as cavity shave margins have demonstrated success in decreasing reoperation rate, though shave margins often lead to higher tissue volume excision and can potentially result in impairment to cosmetic outcomes (11,12). Alternate interventions such as intraoperative frozen section have also been associated with lower re-excision rates (13). Application of this technique is resource heavy for institutions and prolongs operative time. Consideration of developing a risk prediction model to identify patients at high risk for re-excision and to introduce targeted application of existing technologies may hold promise as an approach to reducing reoperation.

Though subject to the acknowledged limitations of large-scale database analysis, the study by Landercasper and colleagues is the first to quantify effect size of contributors to re-excision and evaluate adjusted risk-profiling of institutions. The authors' findings demonstrate the need to establish a benchmark for re-excision rates and further investigate surgeon and institutional variation, particularly after the institution of SSO-ASTRO consensus guidelines. Reoperation rates are a potentially ripe area of quality improvement in the field of breast cancer surgery. Re-excisions are inevitable, but we can no longer accept wide variation in those rates as simply chance occurrence. Surgeons must lead the charge in defining this quality metric—or it will be defined for us by entities less engaged and knowledgeable of the nuances we face with every breast conservation attempt.

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Footnote

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to declare.

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