Impact of analysis of frozen-section margin on reoperation rates in women undergoing lumpectomy for breast cancer: Evaluation of the National Surgical Quality Improvement Program data

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Background. *Reoperation for positive margins after lumpectomy for breast cancer is common. Intraoperative analysis of frozen-section (FS) margins permits immediate re-excision, avoiding reoperation. The aim of this study was to compare reoperation rates between an institution using routine FS analysis of all margins and the National Surgical Quality Improvement Program (NSQIP) data.*
Methods. *We designed a retrospective cohort analysis comparing the NSQIP data from a FS single institution with the national NSQIP data from 2006 to 2010. Women undergoing lumpectomy for cancer were identified (N = 24,217), and reoperation rates were compared by the use of χ^2 analyses and multivariable logistic regression. During this time period, NSQIP did not differentiate between reoperations for complications or oncologic reasons. Reoperation rates for mastectomy patients (N = 21,734) and lumpectomy patients without cancer (N = 2,777) over the same time period were analyzed as controls, because reoperations after these procedures likely would be for reasons other than positive margins.*
Results. *The 30-day reoperation rate after lumpectomy for cancer was greater nationally than at the FS institution (13.2% vs 3.6%, P < .001). Multivariable analysis showed that patients in the national NSQIP data set were over four times as likely to undergo reoperation as those at the FS institution's (odds ratio 4.19). The reoperation rates were similar between the two, both for patients undergoing mastectomy (4.7% vs 4.5%, P = .84) and those undergoing lumpectomy for benign diagnosis (2.9% vs 5.9%, P = .39).*
Conclusion. *Intraoperative FS margin analysis decreases the number of reoperations for patients undergoing breast conservation for breast cancer. This technique has important implications for patient satisfaction and cost of care. (Surgery 2014;156:190-7.)*

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Women diagnosed with breast cancer who elect to undergo breast-conservation surgery are known to be at risk for requiring a second operation to re-excise positive margins. The goal of breast-conservation surgery is to achieve an acceptable cosmetic result with negative margins; however, negative margins cannot always be reliably assessed intraoperatively, and therefore in cases with positive or close margins on final pathology, margin re-excision at a second independent operation is required. Re-excision rates in the literature vary widely but are generally in the range of 15–40%.[1-5]

At our institution, intraoperative frozen-section (FS) assessment of the surgical margins of neoplastic breast specimens is performed routinely.[6-9] This FS analysis allows for immediate

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re-excision of positive or close margins during the initial operation, thus decreasing the risk of a close or positive margin on final pathology. This method results in a lesser rate of delayed positive margins of approximately 3% and minimizes rates of reoperation for margin control.[9]

In this study, we evaluated the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) data regarding 30-day reoperation rate in patients undergoing breast-conservation surgery for breast cancer and compared the findings from our institution with the national rates. Because NSQIP did not collect data regarding the indication for the reoperation until 2011, all take-backs were coded as a complication and considered together, regardless of the indication which includes hematoma, infection, and other operations for operative complications, as well as re-excision for margin control. As control groups, we also compared lumpectomy for benign breast conditions and mastectomy.

Our hypothesis was that reoperation after lumpectomy for breast cancer would be lesser at Mayo Clinic Rochester (MCR) than in the National NSQIP data because of the routine use of FS pathology and intraoperative evaluation of all surgical margins at MCR, which guides intraoperative re-excision, but that this process would have no effect on reoperation rates after mastectomy or lumpectomy for benign disease.

METHODS

This study was approved by the Institutional Review Board of MCR. Women undergoing breast procedures were identified from 2006−2011 NSQIP data. Our institution started participating in NSQIP in 2006. Using *International Classification of Disease*, 9th Revision diagnosis and Common Procedural Terminology procedure codes, women were categorized as (1) undergoing lumpectomy for breast cancer; (2) undergoing lumpectomy for other, noncancer, indications; and (3) women who underwent mastectomy for breast cancer. All procedures were limited to women undergoing breast operations without immediate reconstruction (Table I).

International Classification of Disease, 9th Revision, diagnosis codes used were those beginning with 174 for breast cancer and 233 and 233.0 for DCIS. The Common Procedural Terminology codes used over the period of our study were: for lumpectomy for cancer (19301, 19302, 19160, 19162), lumpectomy for noncancer indication (19301, 19302, 19160, 19162), and for mastectomy (19303, 19304, 19307, 19180, 19182, 19240); cases combined with a reconstruction code were excluded from all groups (Table I).

NSQIP is the leading nationally validated, risk-adjusted, outcomes-based program to measure the quality of surgical care.[10] To minimize bias in favor of smaller outpatient procedures, a maximum of three lumpectomy procedures are captured per 8-day cycle. The database meets >95% interrater variability standards and capture rate at MCR is >95% at 30 days.

The primary outcome of interest was 30-day reoperation rate, with a focus on rates from 2006 to 2010. For this period before 2011, NSQIP reported a return to the operating room (OR) for any reason, variable "RETURNOR": "Returns to the operating room within 30 days include all major operative procedures that required the patient to be taken to the surgical operating room for intervention of any kind. 'Major surgical procedures' are defined as those cases in any and all surgical subspecialties that meet Program criteria for inclusion."

A separate analysis was performed for the year 2011 because of a change in the variables. In 2011 NSQIP introduced a new variable, "REOPERATION," focusing on unplanned return to the OR: "Yes" is entered if the patient had an unplanned return to the OR for an operative procedure related to either the index or concurrent procedure performed. This return must be within the 30-day postoperative period. The return to the OR may occur at any hospital or surgical facility (ie, your hospital or at an outside hospital). Note: This definition is not meant to capture patients who go back to the OR within 30 days for a follow-up procedure based on the pathology results from the index or concurrent procedure. Examples: "Exclude breast biopsies which return for re-excisions; insertion of port-a-cath for chemotherapy."[11]

We compared procedures in the NSQIP data performed at MCR (Saint Mary's Hospital and Rochester Methodist Hospital) with those performed at other NSQIP hospitals. Patients at MCR were identified using internal identifiers. Before 2011, NSQIP did not include reason for reoperation within 30 days; however, we were able to assess reason for return to the OR in the MCR cohort, using electronic medical record review for the NSQIP cases.

We compared patient factors and reoperation rates after lumpectomy for cancer across institution (MCR versus other NSQIP hospitals) using χ^2