



Original article

Surgical margin reporting in breast conserving surgery: Does compliance with guidelines affect re-excision and mastectomy rates?



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ABSTRACT

Purpose: Margin status is important in guiding decisions to re-excise following breast-conserving surgery (BCS) for breast cancer. The College of American Pathologists (CAP) developed guidelines to standardize pathology reporting; however, compliance with margin documentation guidelines has been shown to vary. The aim of this retrospective study was to determine whether compliance with CAP guidelines affects re-excision and mastectomy rates.

Methods: We identified 1423 patients diagnosed with breast cancer between 1998 and 2006 who underwent BCS with negative margins. CAP compliance was categorized as maximal, minimal, or non-compliant. Statistical analyses were performed comparing the frequency of re-excision and mastectomy after initial BCS according to CAP margin reporting guideline compliance. Data were adjusted for provider facility by including a clustering variable within the regression model.

Results: Patients with non-compliant margin reporting were 1.7 times more likely to undergo re-excision and/or mastectomy than those with maximally compliant reporting. Level of compliance was most strongly associated with the frequency of mastectomy; non-compliant margin reporting was associated with a 2.5-fold increase in mastectomy rates compared to maximally compliant reporting. The results did not substantially change when the analyses accounted for clustering at the provider facility level.

Conclusions: Our findings suggest that compliance with CAP guidelines in pathology reporting may be associated with variation in re-excision and mastectomy rates following BCS.

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Introduction

Breast conserving surgery (BCS) is widely considered to be the standard operative approach for treating most patients with early stage breast cancers. It is also one of the most commonly performed cancer procedures in the United States. Approximately 60%–75% of breast cancer cases are initially treated with BCS [1]. Among these cases, rates of re-excision vary widely across surgeons and institutions (from 0 to 70% in some reports) even after adjusting for clinical factors [1–6]. The goal of BCS is to achieve adequate surgical margins during the initial surgical resection while optimizing the aesthetic appearance of the breast. Additional surgery with re-excision may not only compromise cosmesis, but also can

increase morbidity and costs [7,8] for patients while delaying initiation of appropriate adjuvant treatment.

Surgical margin status is considered one of the strongest predictors for local recurrence and an important factor guiding the decision to re-excise [9–14]. It is standard practice to re-excise additional breast tissue for positive margins to reduce the risk of local recurrence [2–5]. The therapeutic decisions for positive margins are relatively straightforward; however, only recently has there been published consensus over what constitutes an adequate negative margin [15,16]. Historically, the criteria for an adequate negative margin had relatively arbitrary thresholds ranging from “no tumor at inked margin” to 10 mm or more [12,17]. Although absence of tumor at the inked margin is the current recommendation from national clinical consensus guidelines [15,16], there has been considerable variation in practice patterns among surgeons regarding the decision to re-excise or perform a mastectomy based on margin distance [2,18,19].

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While aspects of surgical decision-making are shown to be affected by subjective interpretations of negative margin distance, these decisions may also be affected by variations in the adequacy of pathologic margin status reporting practices. According to protocols established by the College of American Pathologists (CAP), pathologists are required to document the distance to the closest negative margin with further recommendation to include margin distance at all six specimen orientations. Our previous work demonstrated that there is variability in compliance with these guidelines for reporting surgical margin status, with more than a quarter of reports not meeting the minimal CAP requirements for margin reporting and only about a third of reports containing all recommended elements of CAP guideline protocols [20].

To date, there are no studies investigating the relationship between the level of compliance with margin reporting CAP guidelines for negative margins and the surgeon's decision to re-excite or perform a mastectomy. The objective of this study was to retrospectively review pathology reports documenting negative margins from initial BCS specimens and determine whether compliance with reporting guidelines established by the CAP affects re-excision and mastectomy rates immediately following initial surgery.

Methods

Data

We used existing data from the Vermont Breast Cancer Surveillance System (VBCSS), which collects demographic, radiology and pathology data for all women receiving breast imaging services in the state of Vermont since 1994 [21]. The VBCSS is part of both the National Cancer Institute's Breast Cancer Surveillance Consortium (<http://breastscreening.cancer.gov/>) and the recently formed Population-based Research Optimizing Screening through Personalized Regimens (PROSPR) program (<http://appliedresearch.cancer.gov/prospr/>). This study was approved by the Institutional Review Board at the University of Vermont.

Study population

We included women in the VBCSS diagnosed with breast cancer during 1998–2006 whose initial breast cancer surgery was BCS. A total of 2242 potentially eligible cases were identified. We excluded all reports with one or more positive margins (defined as tumor present at the inked margin) on the initial BCS specimen (N = 433), since it is standard practice to re-excite if positive margins are found [2–5,7,8,15]. Thus, only cases that had negative margins on the initial pathology report were included in the analysis. Eligible breast cancer cases included diagnoses of invasive breast cancer, ductal carcinoma in situ (DCIS), and mixed invasive/DCIS breast cancer. BCS procedures included any of the following: lumpectomy, excisional biopsy, or partial mastectomy as initial treatment. Cases were excluded if the corresponding pathology report for their initial diagnosis met any of the following criteria: reports from slide reviews (N = 49), reports with diagnoses of synchronous primaries (N = 20), and reports with no residual tumor found on excision following a positive biopsy (N = 317). This yielded a final sample size of 1423 cases available for analysis. Re-excision and/or mastectomy were considered only for patients who had these procedures immediately following the initial BCS and not for patients who had further surgery for a recurrence. These cases were treated by 63 different surgeons practicing at 18 facilities in Vermont, with pathology reports provided by 53 different pathologists.

Data collection

Data on patient demographics, including age and ethnicity, are routinely gathered by the VBCSS via questionnaires at patient visits to all mammography clinics in Vermont. Copies of all breast specimen pathology reports interpreted in the state of Vermont are routinely provided to the VBCSS. A variety of quality control procedures are employed during the collection of this pathology data, including validation checks during data entry and active follow-up with facilities regarding patients with imaging recommendations for biopsy for whom we have not received a pathology report. Pathology data from the VBCSS has previously been used in a number of publications regarding breast cancer screening performance and breast cancer risk [22–24]. For this project, a single data abstractor (SP) reviewed pathology reports corresponding to the initial breast conserving surgery for each patient to abstract data on tumor characteristics, surgical margins, and compliance with CAP margin reporting guidelines. For each of the six possible margins, we recorded whether negativity/positivity and margin distance were reported. Margins were categorized as positive if there was tumor present at the inked margin described in the pathology report and excluded from the analysis.

Using the same approach as in our previous study [20], we categorized reports based on compliance with CAP guidelines. Reports termed “minimally compliant” were those that only reported the distance to the closest negative margin, as *required* by CAP protocols. Reports that were termed “maximally compliant” were those that documented each of the six margins (anterior, posterior, lateral, medial, superior, and inferior) as either positive or negative with a measurement of distance to each negative margin, which is *recommended* by CAP protocols. “Noncompliant” reports were those that did not fulfill minimally compliant criteria (i.e., reports that did not document the distance to the closest negative margin).

Additional collected data included cancer type, tumor grade, and tumor size from pathology reports at the time of initial breast conserving treatment.

Statistical analysis

We compared the frequency of re-excision and mastectomy based on the level of compliance with CAP margin reporting guidelines. The Cochran-Armitage trend test was used to test for crude trends across the compliance categories. Multivariable logistic regression was used to examine the association between CAP guideline compliance and frequency of re-excision and mastectomy while adjusting for potentially confounding factors identified a priori, including age, calendar year, type of cancer (invasive, DCIS, mixed), tumor grade, and tumor size. We adjusted for provider facility by including a facility identifier as a clustering variable within the regression model to account for potential within-facility correlation. Sensitivity analyses explored the impact of accounting for clustering at the surgeon level rather than the facility level. Significance was defined by two-sided $P \leq 0.05$. Confidence intervals were reported at the 95% level. Analyses were performed using SAS 9.2 (SAS Institute, Cary, NC).

Results

The mean patient age was 67.0 years and 97% of the study population with known ethnicity were non-Hispanic white (Table 1). Most tumors (44.7%) were mixed invasive carcinoma with DCIS, grade 2 tumors, and measured less than 10 mm (Table 2). Cases which did not undergo re-excision or mastectomy after their initial breast conserving surgery were more likely to be 75 years or older, to have been diagnosed later in the study period, have

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