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Variability in the Quality of Pathology Reporting of Margin Status Following Breast Cancer Surgery

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Abstract

Background—Accurately determining margin status is important for breast cancer treatment. The College of American Pathologists (CAP) developed guidelines to standardize reporting of margin status. The aim of this study was to determine statewide concordance with CAP breast cancer reporting guidelines for margin status.

Methods—The Vermont Breast Cancer Surveillance System (VBCSS) tracks mammography-related services provided to all women treated for breast cancer at hospitals in Vermont. These data include accompanying pathology reports, which were analyzed for descriptions of margin status. The CAP protocols have both requirements and recommendations for margin status reporting. Reports were “minimally compliant” if they adhered to the requirements stated in the CAP protocols or “maximally compliant” if they included the recommended protocols in addition to those required.

Results—There were 2,016 reports that met the inclusion criteria. A total of 71.1% were minimally compliant and 37.3% were maximally compliant with the CAP guideline standards. There was a statistically significant rise in compliant reports with minimally compliant reports increasing from 55.7% in 1998 to 79.3% in 2006, and maximally compliant reports rising from 4.7% in 1998 to 53.7% in 2006 (Chi square trend test, $p < 0.001$) for both cohorts.

Conclusions—Reporting of margin status in breast conserving surgery varies widely. There is a significant rise in guideline compliance with margin status reporting from 1998 to 2006; however, overall compliance remains suboptimal. This study provides evidence to support the need for quality improvement measures in the implementation of CAP guidelines for reporting margin status following breast conserving surgery.

INTRODUCTION

For most patients with early stage breast cancer, breast conserving therapy has become a standard surgical approach to treatment. Although studies demonstrate that survival rates following breast conserving surgery are equivalent to those obtained after mastectomy [1], breast conservation may be associated with an increased risk of local recurrence [2].

Surgical margin status following breast-conserving surgery is considered to be one of the strongest predictors for local recurrence [1–4], as well as an important factor affecting the outcome of breast cancer treatment [5]. In general, patients with tumors in which negative margins are able to be achieved are considered to be excellent candidates for breast

conservation, especially when also treated with adjuvant radiation therapy [6]. Positive margins determined by microscopic evaluation significantly increase the risk of local recurrence and would therefore be an indication for re-excision [3, 4, 6, 7]. A 2000 study conducted by the Joint Center for Radiation Therapy determined that patients with extensively positive margins had a local recurrence rate of 27%, whereas patients with focally positive margins had a local recurrence rate of 14% [4]. The role of close margins (<1–2 mm) in local recurrence is less clear, and the therapeutic indications are still debated [3]. At the University of Pennsylvania, patients with “close” margins (defined as ≤ 2 mm) who were treated with breast conserving therapy had eight-year local recurrence rates of 17%, and those with negative margins (defined as >2 mm) had local recurrence rates of 9% [7]. Appropriate assessment and reporting of margin status as a component of the pathological evaluation can be a key factor impacting the overall quality of breast conserving surgery and subsequent care.

The College of American Pathologists (CAP) developed guidelines to standardize reporting of surgical margin status. The CAP guidelines were not required for pathological evaluation of breast cancer specimens until January 1, 2004 when the Commission on Cancer of the American College of Surgeons mandated the use of the checklist elements of the protocols as part of its Cancer Program Standards for Approved Cancer Programs for hospitals seeking Commission on Cancer certification. Prior to 2004, these guidelines were only recommended for use. According to protocols representing years 1998 to 2006, pathologists are requested to document margin status, including orientation and distance between the carcinoma and specific margins, with all identifiable margins evaluated for involvement of carcinoma, both grossly and microscopically [8]. Ideally, orientation of the specimen should be performed by the surgeon with sutures, clips, inks, or a diagram and recorded in the pathology report. Orientation of the specimen is important because, in the event that an inadequate margin is identified on pathological examination, this information guides surgical re-excision to the specific margin(s) involved rather than necessitating re-excision of the entire biopsy cavity. This process helps to minimize the amount of tissue excised and improves cosmetic results [9]. With appropriate orientation and specimen integrity, the pathologist is to report the distance to the closest negative margin in order to meet minimal compliance standards. Although not required, CAP protocols recommend reporting margin status from all six orientations (i.e., superior, inferior, medial, lateral, anterior, posterior) [3].

While attempts have been made to standardize reporting of surgical specimens for malignancies through the CAP guidelines, breast cancer pathology reporting continues to vary widely. A 2002 study which evaluated the extent to which these guidelines have been implemented in practice demonstrated that key elements in the evaluation of margin status which affect breast cancer treatment are often omitted. These key elements included gross description and size, orientation and involvement of surgical margins, and description of histologic features. In this study, surgical margins were inked in 77% of the cases, and margins were oriented in only 25% of the cases. Additionally, the distance to the closest margin was reported in only 69% of the cases [10]. Similar results were also obtained in a 2006 study which found surgical margins inked in 58% of the cases, margin status reported in only 76% of the final pathology reports, and surgeon orientation of the specimens performed in 65% of the cases [11]. These studies demonstrate that there is considerable variability in pathology reporting of margin status which may in part be due to issues with adherence to the CAP protocols.

Using a subset of the Vermont Breast Cancer Surveillance System (VBCSS) dataset which includes women who have undergone breast conserving therapy, the aim of this study was to determine state-wide concordance with CAP breast cancer reporting guidelines for margin status among pathology reports completed between 1998 and 2006. The purpose of this

study was to evaluate the quality of pathology reporting of lumpectomy specimens with respect to orientation of the specimen and completeness of margin status reporting. Specifically, we sought to determine the number of reports that met minimal and maximal CAP guideline compliance standards, to examine how reporting varied over time, and to recommend means to improve the quality and performance of margin status reporting by identifying best practices and standards-of-care essential for continuous quality improvement.

METHODS

The VBCSS collects pathology data for all women who had breast cancer surgery in Vermont. These data come from both small and large volume hospitals throughout Vermont. Reports for patients with breast cancer were identified from the VBCSS database between 1998 and 2006. Pathology reports for patients who were diagnosed with invasive ductal carcinoma, invasive lobular carcinoma, ductal carcinoma in situ (DCIS), or mixed invasive (lobular and ductal)-DCIS and subsequently underwent breast conserving surgery were reviewed and analyzed for descriptions of specimen orientation and margin status.

A total of 4,482 reports were available in the VBCSS database. Independent chart audits were performed by a single data abstractor over a three month period. Charts were reviewed in alphabetical order, starting with scanned reports from 2006 to 2003 and then continuing with paper reports from earlier years. Among the paper reports, those pertaining to patients in the Medicare cohort of another study were assessed first.

Margin status in the pathology reports was analyzed across three variables: 1) final margin status as positive or negative, 2) distance to closest negative margin, and 3) specimen orientation. CAP reporting guidelines from 1998 and updated as recently as 2005 for invasive breast carcinomas and 2009 for DCIS were used as standards to assess the degree of compliance of margin status reporting. CAP guidelines from the years 1998 to 2009 do not differ from one another in terms of what is required specifically in the evaluation and reporting of margin status for both invasive breast cancers and DCIS [3, 8, 12].

The following six-point scale was used for each of the six margins in each pathology report: 1) positive margin, 2) negative margin, 3) negative margin with a measurement of distance documented, 4) not applicable, 5) unable to assess due to a specific reason documented in the report, and 6) not reported. The distance to the closest negative margin was measured as a scalar value when the margin was not specified. Specimen orientation was measured on the following five-point scale: 1) yes, 2) no, 3) not reported, 4) unable to assess, and 5) not applicable.

The CAP protocols have both requirements and recommendations with respect to margin status reporting. Each report was determined to be either “minimally compliant” if it adhered to the requirements stated in the CAP protocols or “maximally compliant” if it included the recommended protocols in addition to those required. To be considered “minimally compliant,” either 1) all six margins were documented as unable to be assessed, 2) margins were reported to be uninvolved (negative) with carcinoma and included a measurement of distance from the closest negative margin, or 3) at least one margin was reported to be positive for carcinoma. To be considered “maximally compliant,” pathology reports needed to document each of the six margins as either positive or negative with a measurement of distance to each negative margin.

Following the review, some reports were excluded from the analysis. These included: reports that were slide reviews, reports with diagnoses of synchronous primaries, miscoded

reports which were actually needle biopsies with no accompanying excision pathology, and reports with no residual tumor found on excision following a positive biopsy (Figure 1).

Compliance measures were stratified by year, and differences in reporting of margin status over time were assessed using the Chi-Square trend test. Statistical analyses were performed using SAS 9.2 (SAS Institute, Cary, NC).

RESULTS

Fifty-four percent of the 4,482 pathology reports identified from the VBCSS dataset were reviewed for this study (n=2,417). From this sample of 2,417 reports, 401 were excluded, leaving 2,016 reports (45%) that were included in the analyses of margin status. Among the population of all reports, the median patient age at the time of diagnosis was 58.9 years, and among reports that were included in the analysis, the median patient age was 67.3 years (Table 1).

Complete orientation of the specimen with respect to all six margins was documented in 57.7% of the reports, and in 28.5% of the reports, no orientations were provided. Reports with no orientations included those in which it was specifically stated by the pathologist that the surgeon failed to orient the specimen (3.8%). The reporting of specimen orientation for all six margins rose from 44.8% in 1998 to 69.3% in 2006. There was also a decline in the number of reports where no specimen orientation was documented from 41.0% to 22.0% over this eight year period (Figure 2).

Overall, 71.1% of the reports were minimally compliant and 37.3% were maximally compliant for margin status reporting over the eight year period. There was a significant rise in minimally compliant reports from 55.7% in 1998 to 79.3% in 2006 (Chi-Square trend test, $p<0.001$). Maximal compliance also rose significantly from 4.7% in 1998 to 53.7% in 2006 (Chi-Square trend test, $p<0.001$) (Figure 3). Of the 2,016 reports, 583 (28.9%) were not compliant, meaning that margins were not reported as being unassessable, no positive margins were reported, and no distance to a negative margin was reported. In five reports (0.25%), all six margins were lacking any documented assessment.

DISCUSSION

Providing quality care for patients undergoing surgery for breast cancer relies on the consistent, complete, and accurate pathology reporting of margin status. According to CAP guidelines, the lumpectomy specimen should be oriented by the surgeon for margin evaluation, and the pathologist should assess margins according to orientation and document the distance to the closest margin [8]. This information is clinically important as it may influence decision-making for re-excision as well as utilization of radiation therapy. In the present study, only 71.1% of the reports analyzed met minimally required CAP compliance standards and only 37.3% met “maximal,” or recommended, compliance standards. It is important to note that several reports reviewed in the present study described margins as being “free” without further specification as to how close the cancer was approaching the surgical margins. A similar finding was demonstrated in a 2001 study by the European Organization for Research and Treatment of Cancer (EORTC) which found margins reported as “free,” without further description, in 49% of the cases [13]. Despite suboptimal compliance with margin distance reporting, the results from the present study show that there has been a significant improvement over the eight year period of this study. Minimal compliance with the CAP guidelines for reporting margin distance increased from 55.7% in 1998 to 79.3% in 2006. Maximally compliant reports rose from 4.7% in 1998 to 53.7% in 2006. The positive trend in compliance reporting is encouraging and may reflect the

mandatory use of the CAP guidelines for the evaluation of lumpectomy specimens beginning in 2004 [3] or better dissemination of the guidelines through the CAP Cancer Committee task force efforts. However, with two years of mandatory guideline use in place, compliance with margin status reporting is still suboptimal, and efforts to better understand the barriers to reporting margin status would serve to improve the quality of breast cancer care.

Although only 57.7% of the reports provided evidence of complete specimen orientation, reporting these is the shared responsibility of the surgeon who must perform the orientation and the pathologist who must recognize and document the specimen orientation. The specimens reported by pathologists as not being orientated by the surgeon was only 3.8%, which suggests that there may have been other factors resulting in the observed lack of documented specimen orientation. Alternatively, a greater number of specimens received by the pathologists may not have been oriented by the surgeon and simply not specifically documented as such in the pathology report. Improving the lines of communication between pathologists and surgeons may serve to positively impact this trend.

Without a clear consensus on what distance is considered to be an adequate margin, there may be less emphasis placed on pathologists to provide this information accurately in the pathology reports. Currently, there is no widely accepted definition of an adequate negative margin for patients undergoing breast conserving surgery. A study conducted in 2009 at the University of Michigan investigated what surgeons consider to be an adequate margin, and demonstrated a wide variation ranging from “no tumor found on the ink” to a margin greater than 1cm, regardless of whether the diagnosis was invasive cancer or DCIS [5]. The lack of reporting specific distances could also be reinforced by surgeons who may not take margin distance into account as part of their surgical decision-making process. Developing a standard margin definition based on the clinical data and emphasizing its importance in the clinical care process might have the potential to improve compliance in reporting margin distance.

Methods involved in the microscopic margin evaluation process may also impact compliance rates. For example, inking the surface of the biopsy specimen is the most commonly used method of margin evaluation and can be complicated by over-inking or by defects in the surface of the specimen, causing the ink to penetrate deeper into the tissue. Additionally, the surfaces of some specimens can be irregular and very large, rendering margin assessment by means of inking highly subject to sampling error [9]. Poor compliance in these cases may be the result of technical issues in specimen processing that impair accurate margin assessment and may not be reflected in the final report to explain why margin distance was not measured. It is therefore important for pathologists to include this information in the report if margin evaluation cannot be properly performed due to these technical difficulties.

There are several limitations to our study. Due to resource limitations, only 54% of the available reports were reviewed during the three-month study period. In order to completely and accurately represent margin reporting in this VBCSS dataset, the remaining reports would need to be reviewed. Additionally, the sample selection method was not random, and as a consequence, external validity may have been affected. The sample included 78% of the reports from 2006, and 65% of the reports from 2005 but only 38% of the reports from earlier years. The observed compliance rates in this study may be falsely elevated due to under-representation of reports from 1998 to 2004, which had lower overall compliance. We also introduced an age bias by reviewing reports on Medicare patients before others. This bias is reflected in the differences in median ages between the population of reports and the sampled reports over the time period. Furthermore, only one individual data abstractor

analyzed the pathology reports for margin compliance, and this could have introduced reviewer bias. We cannot speak to any other biases which may have been introduced inadvertently. Future study will address these limitations to better represent the sample.

In summary, our study identified variation in pathology reporting of specimen orientation and margin status which may impact the quality of breast cancer treatment in Vermont. To date, there is little data that measures the extent and clinical impact of variation in pathology reporting of margin status; however, it is clear that reporting margin status in breast cancer varies widely at these hospitals under investigation. Vital information that affects surgical decision-making and adjuvant treatment is often missing or incomplete. There is a positive trend that shows a significant rise in guideline compliance with margin status reports from 1998 to 2006; however, overall compliance remains suboptimal. A better understanding of the potential barriers to compliance with CAP guidelines would greatly benefit the quality of pathology reporting and subsequent patient care. This study provides evidence supporting the need for quality improvement measures in the implementation of CAP guidelines for reporting margin status following breast conservative surgery and for improved communication between surgeons and pathologists.

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SYNOPSIS

Surgical margin status is vital to breast cancer treatment. This study demonstrates that the quality of reporting margin status for breast cancer varies widely and emphasizes the need for quality improvement measures in the implementation of guidelines for accurate reporting.

Figure 1.
Exclusion criteria flow chart

Figure 2.
Number of orientations for each of the six margins reported by year.

Figure 3.
Minimal and maximal compliance with margin status reporting by year.

Table 1

Total number of reports, included reports, and median patient age for the total and included reports stratified by year.

Year	Total Number of Reports	Median Age of Total Reports	Included Reports	Median Age of Included Reports
1998	459	60.9	212 (46%)	69.5
1999	578	59.5	225 (38%)	69.6
2000	520	59.3	213 (41%)	69.3
2001	537	58.7	196 (36%)	68.3
2002	493	59.3	178 (36%)	70.4
2003	492	58.3	156 (31%)	70.5
2004	471	58.6	165 (35%)	72.3
2005	437	58.5	284 (65%)	61.3
2006	495	58.6	387 (58%)	59.6
Total	4,482	58.9	2,016 (45%)	67.3