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Cost-effectiveness of surgeon performed intraoperative specimen ink in breast conservation surgery



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ABSTRACT

Background: Re-excision rates after breast conservation surgery are reported to be 20%-40%. Inaccuracies with specimen orientation may affect margin assessment. This study examined whether the addition of surgeon performed intraoperative inking of the lumpectomy specimen after adoption of margin guidelines would be cost-effective.

Methods: A retrospective review of a prospective surgical database was performed from 2009 to 2017. Patients with initial lumpectomy and a preoperative diagnosis of invasive breast carcinoma or ductal carcinoma in situ (DCIS) were included. Re-excision rates and the surgical costs per 100 initial lumpectomies were compared across three periods: before margin guideline publication, after guideline adoption, and after the addition of intraoperative surgeon performed specimen inking.

Results: Four hundred initial lumpectomies were evaluated. Overall re-excision rate was 21% ($n = 84$). There was a nonsignificant reduction in re-excision rates after margin guidelines from 24% ($n = 36$) to 20% ($n = 23$) and to 19% ($n = 25$) after addition of intraoperative specimen ink. Re-excision rates were significantly lower for invasive cancer than for DCIS across three periods (20%, 15%, and 12% versus 37%, 33%, and 31%) (odds ratio 3.31, $P = 0.007$). The estimated cost of re-excision per 100 initial lumpectomies decreased after guidelines by 25% (\$128,270) for invasive breast cancer and by 11% (\$102,616) for DCIS. The addition of intraoperative specimen inking after margin guideline adoption resulted in further 17% cost savings (\$66,692) for invasive breast cancer and 5% (\$41,308) for DCIS.

Conclusions: Surgeon performed intraoperative inking of the lumpectomy specimen after adoption of margin guidelines is a cost-effective technique in breast conservation surgery.

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Introduction

Breast conservation therapy (BCT) involves margin-negative lumpectomy followed by breast radiation therapy. Failure to achieve negative margins is associated with a two-fold increase risk of breast tumor recurrence.^{1,2} Historically, positive margin rates have been estimated to be as high as 18%-40%, requiring many patients to undergo repeat surgery to obtain negative margins.³⁻⁵ The risk of local recurrence rises progressively with the number of re-excisions needed to obtain clear margins.⁶ Undoubtedly, this has a negative impact on patient satisfaction as well as undo delays in treatment and unnecessary utilization of health care resources. A Canadian study by Pataky et al. 2016 demonstrated that efforts to lower reoperation rate could result in significant resource savings.⁷ A few studies have addressed the increased health care burden of re-excision rates in breast cancer.⁸⁻¹⁰ Variability in specimen orientation and processing can influence margin assessment. The most accurate specimen orientation is carried out by the surgeon in the operating room with either sutures or a six colored ink kit. The cost-effectiveness of surgeon performed intraoperative inking of lumpectomy specimens has not yet been evaluated in the literature.

In January 2014, the Society of Surgical Oncology–American Society for Radiation Oncology (SSO-ASTRO) Margin Consensus Guidelines were published and immediately adopted at our institution. These guidelines described an adequate negative margin as 2 mm for most cases of ductal carcinoma in situ (DCIS) and no ink on the tumor for invasive breast cancer.^{11,12} Although patient and nontumor-related factors do contribute to the high re-excision rate, certain measures have been studied to reduce additional operations for positive or close margins. These include preoperative diagnostic mammography, intraoperative specimen imaging, and pathological assessment of the specimen.¹³ Although the cumulative effect of these interventions may improve re-excision rates overall, there continues to be a high positive margin rate despite these interventions. Intraoperative assessment of lumpectomy margins either with frozen section or imprint cytology has a 70% sensitivity and can be limited by pathologist expertise.¹⁴ Efforts using routine shaved excision of all margins^{15,16} or the use of intraoperative optical and radiofrequency devices that can detect tumor cells at the margin and have resulted in a reduction in re-excision lumpectomy.¹⁷⁻¹⁹ However, none of these methods are completely effective and often involve excision of additional tissue that may not have been necessary.

There remains controversy surrounding the appropriate pathological processing of specimens. Specimen handling such as compression during radiography can contribute to margin errors.²⁰ Furthermore, specimen orientation is imperfect and can be subject to interpretation. Traditionally, the lumpectomy specimen is oriented by the surgeon using sutures to mark two or more of the six sides, which later allows the pathologist to ink it with six different colors. The specimen may also be transported and processed in a manner that can lead to tissue fragmentation and fat retraction before inking. Discordance between the surgeon and the pathologist

interpretation of margin orientation could influence the accuracy of margin assessment, and a discordance rate of 31% has been reported.²¹

For these reasons, surgeon-performed intraoperative specimen inking has been posited. Ink-directed re-excision is preferable to whole-cavity excision, as it will minimize the volume of breast tissue removed, without compromising outcomes.²² There is no consensus on the most appropriate method of specimen orientation in regard to sutures versus inking, and their effect on reducing breast lumpectomy re-excision has not yet been well assessed in the literature.¹³ Furthermore, no studies about cost-effectiveness of this method have been published. A 2010 study by Singh et al. evaluated their own lumpectomy specimen inking practice and showed some promising results by reducing re-excision rates by 50%.²³ However, their study was published before SSO-ASTRO margin guidelines and defined a close margin as less than 3 mm to DCIS. The purpose of this present study is to examine whether surgeon performed intraoperative inking versus standard suture orientation of initial lumpectomy specimens could improve re-excision rates by providing a more accurate specimen orientation before tissue handling. We further analyzed whether this practice would be cost-effective as it would require the purchase of a single-use disposable ink kit.

Methods

A retrospective review of a prospective breast surgical database was performed from August 2009 to May 2017. Institutional review board approval was obtained in accordance with our institution's standards and included a full waiver of informed consent. Cases included patients who had initial lumpectomy and a preoperative diagnosis of invasive breast carcinoma or DCIS on percutaneous core needle biopsy. The study excluded patients who were diagnosed by excisional biopsy. Data before new margin guideline publications (January 2014) was compared with a period after adoption of margin guidelines. Our surgeons began intraoperative inking of all initial lumpectomy specimens prospectively after November 2015. Re-excision rates after initial lumpectomy was compared across three periods: before margin guideline publication (August 2009-January 2014), after guideline publications (January 2014-October 2015), and after the addition of intraoperative surgeon performed specimen ink (November 2015-May 2017). Inking was performed by the attending surgeon immediately after the initial lumpectomy using a single-use disposable sterile ink kit (Figs. 1 and 2). Two fellowship-trained breast surgeons at a single academic institution performed all the operations in this study.

A minimum margin of 2 mm for DCIS was standard practice at our institution throughout all periods, and this practice was not altered by the new DCIS margin guideline publication (August 2016).¹² Multiple re-excisions for the same patient were only counted once. All newly diagnosed breast malignancies were prospectively reviewed at the multidisciplinary tumor board before treatment and surgical planning. Lesions larger than 3 cm in area were bracketed with radioactive seed

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