


REVIEW

Evaluating the impact of radiofrequency spectroscopy on reducing reoperations after breast conserving surgery: A meta-analysis

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Abstract

Background: The benefits of breast conserving surgery for breast cancer patients are well established. To achieve adequate margins of excision, intraoperative management of breast margins is a critical factor through reducing reoperation for inadequate positive margin excision and associated morbidity and cost. Radiofrequency spectroscopy is a technology that could significantly reduce positive margins when used intraoperatively as an adjunct to other margin management methods.

Methods: A meta-analysis was completed with 10 publications comparing use of radiofrequency spectroscopy technology (MarginProbe) with standard margin assessment procedures. Three randomized controlled studies and seven retrospective studies comparing MarginProbe to historical controls were included. The primary endpoint was reduction of re-excision rates. Statistical significance level was set at the two-sided 5% level corresponding to two-sided 95% confidence intervals (CIs) of the pooled relative risk estimates.

Results: A total of 2335 patients from 10 publications were included in this meta-analysis. The overall relative reduction in re-excision rate was 0.49 (95% CI: 0.38–0.64, $p < 0.001$). Statistical methods were used to examine publication bias.

Conclusion: Despite the limited randomized controlled trials available comparing radiofrequency spectroscopy to standard operation procedures, the data from the 10 studies demonstrate a statistically significant reduction in re-excision rate of 49% for MarginProbe usage, currently the only technology indicated for intraoperative identification of breast cancer tissue at the lumpectomy specimen margin.

KEYWORDS

breast cancer, breast conserving surgery, MarginProbe, meta-analysis, re-excision

INTRODUCTION

Breast conservation therapy, including lumpectomy and sentinel lymph node biopsy followed by radiation therapy, is the best treatment plan for women with early-stage breast cancer. The goal of lumpectomy is to completely excise the tumor with negative margins while maintaining acceptable cosmesis.¹ Positive surgical margins result in a two-fold increased rate of local recurrence, a risk not mitigated by adjuvant therapy.² In an effort to facilitate clearance of surgical margins, surgeons have utilized a wide variety of intraoperative techniques with variable levels of

success, such as specimen imaging, full cavity shave margins, pathological gross assessment, frozen section, and touch preparation.³ Despite these efforts, surgical re-excisions, as a result of positive margins, are still termed “the other breast cancer epidemic” with contemporary studies reporting rates exceeding 20% in patients with invasive ductal carcinoma (IDC), and often greater in invasive lobular carcinoma (ILC) and ductal carcinoma in situ (DCIS).^{4,5} In 2014, the SSO-ASTRO Margin Guideline was developed defining a positive margin for invasive cancer as “no tumor on ink.”⁶ Although guideline adoption has resulted in a decrease of re-excision rate, multiple studies

continue to report re-excision rates between 14% and 22% for invasive cancer.⁷⁻⁹ More than this, a 2018 review of Medicare beneficiaries reported a 17.2% re-excision rate among 5337 surgeons in the post-guideline era, including a re-excision rate more than 30% among 17.5% of surgeons. This study also found that overall re-excision rates after breast conserving surgery (BCS) vary widely among surgeons from 0% to 91.7%.¹⁰ All these findings emphasize the need for technologies that improve margin evaluation and clearance at the time of initial BCS.

With the goal of enhancing the surgeon's ability to achieve histologically clear margins at the initial operation, the MarginProbe device was developed as an adjunct device to provide real-time intraoperative assessment of the excised breast specimen margins using radiofrequency spectroscopy technology.¹¹ While use of radiofrequency spectroscopy technology does not omit postoperative pathological assessment of the excised breast specimen, its use allows the surgeon to identify and immediately excise positive margins in the operating room, thereby reducing the need for reoperation due to positive surgical margins.^{12,13} Until now, MarginProbe is the only FDA approved device for intraoperative margin assessment at the time of BCS.

Multiple studies have evaluated the impact of MarginProbe device on achieving negative surgical margins when combined with standard of care (SOC) procedures.^{12,14} These studies demonstrated a 20%–80% relative reduction in the rate of margin re-excision when compared to BCS performed without MarginProbe. However, despite the demonstrated ability of radiofrequency spectroscopy technology to decrease the rate of margin re-excision, variance in the inclusion criteria, trial design, surgeons experience, and magnitude of benefit across various studies have held back rapid adoption of MarginProbe. To obtain a more precise estimate of the ability of the MarginProbe device reducing the need for margin re-excision, we performed a systematic literature review and meta-analysis of the randomized and “real-world” studies of radiofrequency spectroscopy technology with the MarginProbe.

METHODS

Search strategy and selection criteria

We searched the PubMed MEDLINE database on December 31, 2022 using the search terms “Margin Probe,” “intraoperative margin assessment,” “radiofrequency spectroscopy,” and “breast cancer surgery.” Selection criteria included English language, peer-reviewed publications, margin assessment using the MarginProbe and margin re-excision rates must be reported. Repeated studies and studies without re-excision rates or comparison groups were excluded. The PRISMA guideline was followed to report the including/excluding studies.¹⁵

Data extraction

Two investigators reviewed and selected the papers independently (JW and LZ). If these two investigators had any disagreement, a third investigator (ZP) would review the publication again and make the final decision. Data extracted included the following items: First author's names, publication journal, year of publication, study design, number of patients, re-excision rates of control group, re-excision rate of MarginProbe group, and relative reduction rate. All the extracted data were also cross-checked by JW and LZ.

Statistical analysis

Data were analyzed with the Metafor package in R Foundation for Statistical Computing, (Vienna, Austria) software version 4.2.1.¹⁶ Statistical significance level was set at the two-sided 5% level corresponding to two-sided 95% confidence intervals of the pooled relative risk estimates.

Potential publication bias was examined using funnel plots and by Egger's test.^{17,18} The funnel plot shows the effect size of the different studies on the *x*-axis and an estimate of the sample size on the *y*-axis. Small studies should have higher variability in estimates of relative risk compared with larger studies, and divergence from this pattern may indicate the presence of publication bias. Egger's test could test the asymmetry of the funnel plot. Sensitivity analyses were performed by excluding each single study from analyses, one at a time, and repeating the whole meta-analysis. This shows how each individual study affects the overall estimate of the rest of the studies.¹⁹

RESULTS

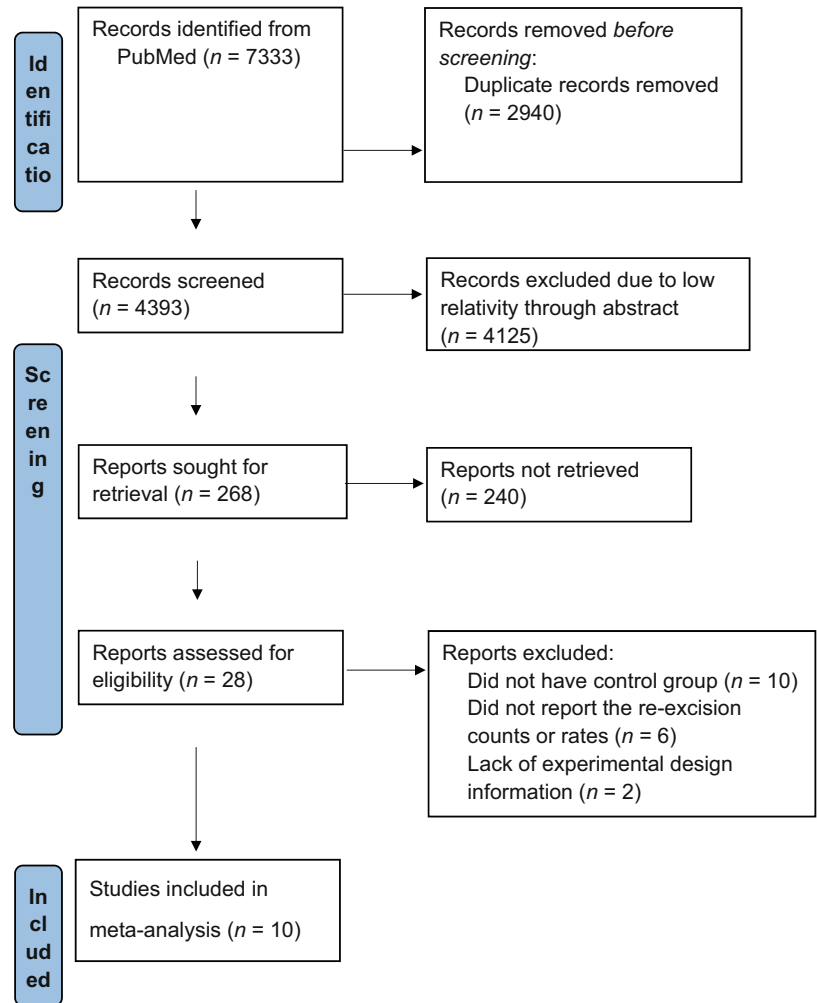
Characteristics of included studies

Searching PubMed using the search terms yielded a total of 7333 items: MarginProbe (25 items), intraoperative margin assessment (2363 items), radiofrequency spectroscopy (1806 items), and breast cancer surgery (3139). There was a total of 2940 duplicate publications across search terms, leaving 4393 items. Limiting articles to MarginProbe related, 28 items remained. A further 18 articles were excluded from the current analysis because they did not have a control group or were lacking experimental design or data information (Figure 1). Finally, 10 studies were included in the final meta-analysis (Table 1).

Meta-analysis of the primary endpoints

Ten studies were included in the meta-analysis for analyzing the impact of the MarginProbe device on achievement of

FIGURE 1 Publication selection flow chart following the PRISMA guideline.



negative surgical margins. Of those, three studies are randomized controlled trials (RCTs) and seven are treatment with MarginProbe versus historical studies. Based on the meta-analysis results, the overall relative reduction in re-excision rate was 0.49 (95% CI: 0.38–0.64, $p < 0.001$) (Figure 2).

A sensitivity analysis was performed to confirm the robustness of our findings and to confirm that the outcome of our meta-analysis could not be attributed to the disproportionate weight of any single study. We recalculated the pooled risk estimates for the remainder of the studies by omitting one study at a time, which resulted in little change of the observed risk estimates from 0.43 (95% CI: 0.34–0.55) to 0.52 (95% CI: 0.39–0.69), all statistically significant less than 1. This confirms the findings and indicates that the effect of re-excision is not substantially modified by any one study.

Publication bias was assessed using the Egger test, which suggested there is no publication bias ($p = 0.0774$) in current meta-analysis. Visual inspection of contour-enhanced funnel plots (Figure 3) also did not identify substantial asymmetry except for one study²⁰ which fell outside of the funnel.

DISCUSSION

Ten studies (three RCT and seven historical cohort studies) were examined through a meta-analysis, which demonstrated the benefits of the MarginProbe for reducing the burden of margin re-excision following BCS.

The MAST and Pivotal trials randomized patients to SOC alone versus SOC plus MarginProbe.^{20,21} The MAST trial SOC protocol permitted intraoperative gross and microscopic examination of the primary specimen, while the Pivotal trial did not. Furthermore, the Pivotal trial was limited to patients with nonpalpable disease, whereas participants in the MAST trial had nearly equal distribution of palpable and nonpalpable disease. Geha et al. also reported RCT (SOC alone vs. SOC plus MarginProbe) results in their own institution, but with much smaller sample size.²² Blohmer et al. Kupstas et al. and Sebastian et al. compared re-excision rates with MarginProbe use to historical controls in patients with IDC, ILC, and DCIS, whereas Thill et al. restricted its single arm analysis to patients with DCIS alone.^{23–26} Coble et al. was unique in its comparison of MarginProbe use to full cavity shave²⁷ and Cen et al. focused the comparison (with MarginProbe vs. without MarginProbe)

TABLE 1 Characteristics of all 10 eligible studies included in meta-analysis.

Publication	Study type	Total N	Control group			MarginProbe group			Relative reduction rate, %
			Event	Negative	Re-excision rate, %	Event	Negative	Re-excision rate, %	
Allweis et al. ²¹	RCT	293	19	131	12.7	8	135	5.6	55.8
Schnabel et al. ²⁰	RCT	596	77	221	25.8	59	239	19.8	23.4
Thill et al. ²⁶	Treatment vs. historical data	109	26	41	38.8	7	35	16.7	57.1
Sebastian et al. ²⁵	Treatment vs. historical data	351	48	138	25.8	16	149	9.7	62.4
Blohmer et al. ²³	Treatment vs. historical data	322	51	121	29.7	22	128	14.7	50.5
Coble & Reid, ²⁷	Treatment vs. historical data	336	30	169	15.1	9	128	6.6	56.4
Kupstas et al. ²⁴	Treatment vs. historical data	240	18	102	15.0	7	113	5.8	61.1
Geha et al. ²²	RCT	46	8	15	34.8	1	22	4.3	87.5
LeeVan et al. ²⁹	Treatment vs. historical data	-	-	-	8.6	4	56	6.7	22.5
Cen et al. ²⁸	Treatment versus historical data	42	8	18	30.8	1	15	6.3	79.7

Abbreviation: RCT, randomized controlled trial.

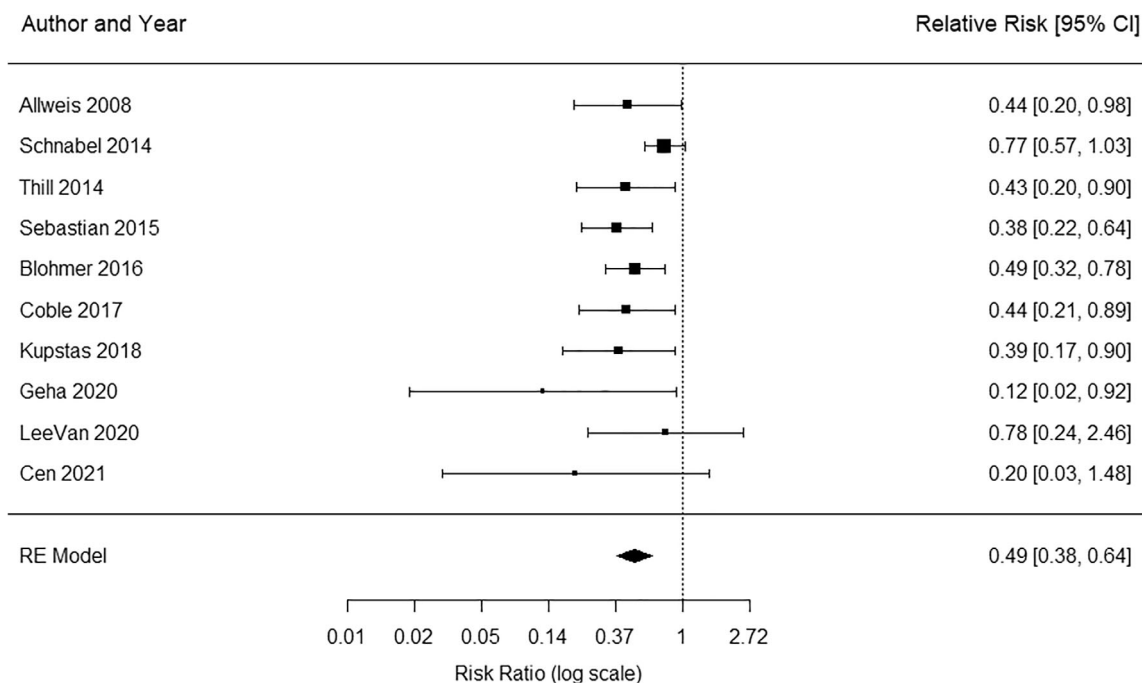


FIGURE 2 Forest plot results of all 10 studies used in meta-analysis. Each black square represents the relative risk of having re-excision, as calculated for each study and listed in the column “Relative Risk” on the right. The horizontal lines to the left and right of each square represent the lower and upper confidence limits, and the actual values are listed on the right. The pooled risk ratio is represented in the bottom row with black diamond. The left and right points of the diamond indicate the confidence limits.

on patients without complete response following neoadjuvant chemotherapy who underwent BCS.²⁸ LeeVan et al. compared MarginProbe surgery results to the prior year BCS results using just standard operating procedures.²⁹ All these studies also differ in participating surgeons, from as few as 1–5 surgeons in eight studies to between 35 and 53 surgeons in the two large RCTs, reflecting the potential for “real world” technical variability across surgeons and

study sites. However, despite these differences, the sensitivity analysis confirms the robustness of the pooled data and demonstrates that intraoperative use of the MarginProbe achieves significant reductions in the rate of margin re-excision than by other techniques for intraoperative margin assessment.

As is common with meta-analyses, it is important to note that in these results there may be confounding factors

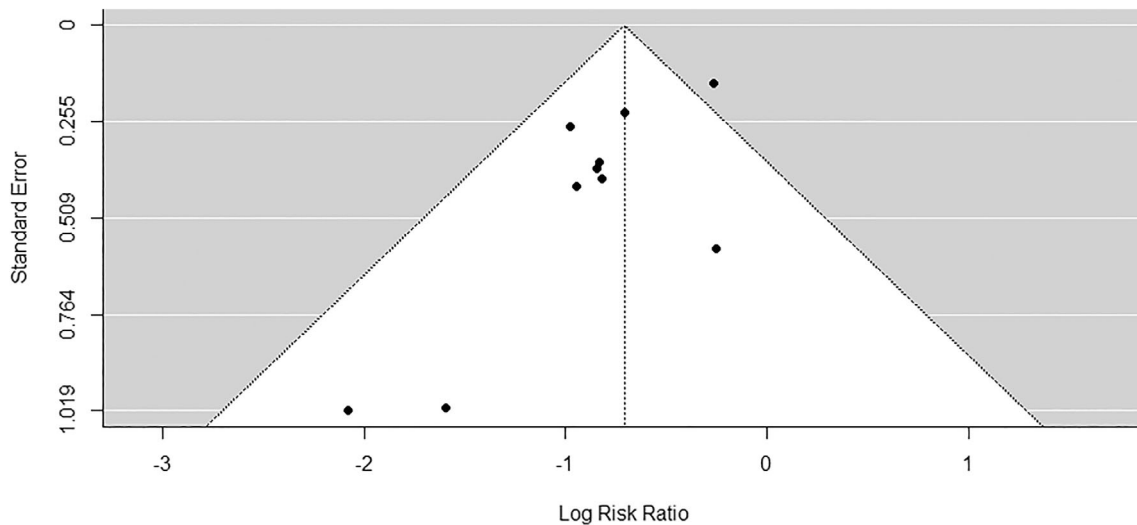


FIGURE 3 Funnel plot results of all 10 studies used in meta-analysis. Each dot represents a study. The y-axis is the standard error of the effect estimate. Larger studies with higher power are placed towards the top. Lower powered studies are placed towards the bottom. The x-axis shows the risk ratio for the study. The plot should ideally resemble a pyramid funnel, with scatter due to sampling variation. The shape is expected because the studies have a wide range of standard errors.

that were not included in current analysis. Within the current meta-analysis, the largest study, Schnabel et al.²⁰ showed some publication bias based on the Egger test, with a p -value slightly over 0.05 ($p = 0.0774$). However, the sensitivity analysis demonstrated that the inclusion or exclusion of this study did not affect the results of the whole meta-analysis. Additionally, there were several MarginProbe studies that could not be included in the analysis, due to the significant differences in risk factors, selection criteria and data availability. Despite these potential shortcomings, the results demonstrate the benefit of radiofrequency spectroscopy use in reducing the burden of margin re-excision by 50%.

The need for re-excision of surgical margins is driven by the inherent limitations of technology to efficiently assess the actual microscopic extent of malignancy intraoperatively. Although microscopic margin assessment practices, such as frozen section and touch preparation, can detect microscopic disease at the surgical margin, the technical limitations of these methods (e.g., issues with freezing fatty breast tissue, inability to evaluate the entire specimen margin surface, etc.) are resource intensive, costly, and not practical to perform in the span of most lumpectomy procedures. While not eliminating the need for microscopic margin analysis, radiofrequency spectroscopy overcomes several of these challenges by providing a portable, handheld device that can examine the entire face of the surgical specimen using a 7 mm sensor that provides immediate feedback from each measurement. The obvious advantage to the surgeon utilizing MarginProbe is that actionable information provided by the device can permit selective intraoperative excision of device-detected positive margins, thereby reducing the need for reoperation.

Maintaining local control while maximizing cosmetic outcome is the essential of BCS. While wide excisions and

full cavity shaving have demonstrated improvement in reducing reoperation rates, the increased volume of tissue resected to achieve negative margins can have implications on long-term cosmetic outcomes.⁴ Use of radiofrequency spectroscopy has raised a similar concern in that the potential of false positive readings may lead to unnecessary excision of surgical margins, risking an impact to breast cosmesis.^{14,30} When assessing the impact of additional shaves taken with use of radiofrequency spectroscopy, multiple studies report little to no increase in total volume of tissue removed and no effect on cosmesis.^{20,21}

In addition to increasing the risk of developing breast cancer, high breast density poses a challenge to efforts to obtain clear lumpectomy margins.³¹ Researchers at Memorial Sloan Kettering found that on multivariate analysis, high breast density was significantly associated with increased odds of re-excision (OR 1.37, 95% CI: 1.00–1.86).³² Although radiofrequency spectroscopy may be used to reduce re-excision rates in all breast density types, false positive radiofrequency spectroscopy readings are more commonly observed in high density breast tissue due to similarities in the dielectric properties of fibrous and malignant tissue. Nonetheless, analysis of patients in the Pivotal trial stratified by breast density found that as a patient's density category increased, so too did the rate of histologically positive margins, underscoring the need for improved intraoperative margin assessment tools above and beyond traditionally utilized intraoperative techniques.³³ A separate study by Police et al. found that despite a higher risk of false positive device readings in dense breast tissue, MarginProbe provided the highest clinical benefit to those patients with higher breast density categories—the very population where the risk of true positive margins is greatest.³⁴ The review by Gray et al. suggested that due limited specificity, routine

MarginProbe evaluation should not be recommended as long as the rates of positive margins are not exceedingly high (>40%).³⁵

Although we included all published studies as of December 2022 in the meta-analysis, the main limitation of this study is the minority of RCTs and the heterogeneity and small to moderate size of some studies. While individually these studies represent use across varied institutional/hospital settings, surgeons, surgical volumes, tumor types, and margin assessment protocols, this meta-analysis demonstrates that MarginProbe does achieve a statistically significant reduction in the burden of reoperation for margin re-excision in women undergoing breast conserving surgery for breast cancer.

In conclusion, in an emerging era of value-based health, the need to ensure negative margins and reduce the rate of reoperation will become increasingly important. Although national consensus guidelines have standardized the definition of a positive margin with the goal of reducing the rate of arbitrary re-excisions, re-excision rates of 14%–22% continue to be reported, which emphasizes the need for technological innovations that could improve the detection of microscopic disease at the surgical margin. The present meta-analysis demonstrates the ability of radiofrequency spectroscopy with MarginProbe, as an adjunct to SOC, to reduce the relative risk of margin re-excision in women undergoing lumpectomy, potentially increasing the rate of breast conservation, improving breast cosmesis, reducing the morbidity of reoperation, and reducing related healthcare costs.

AUTHOR CONTRIBUTIONS

Jingzhen Wang searched databases, performed the statistical analysis and wrote the first draft of the manuscript. Lixia Zhang searched databases and extracted the data. Zezheng Pan designed the study and revised the article critically. All authors contributed to the article and approved the submitted version.

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CONFLICT OF INTEREST STATEMENT

The authors declare that there is no conflict of interest.

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