The Effect of MarginProbe in the Era of "No Ink on Tumor" Clear Margin Definition

James Pellicane, MD, FACS; Misti Wilson, MD, FACS; Kathryn Childers, RN, BSN, CBCN; Polly Stephens, MD, FACS
Bon Secours Virginia Breast Center- Bon Secours Cancer Institute, Richmond, VA

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Introduction

As of March 2014, the SSO/ASTRO guidelines of clear margins for invasive cancer have been "no ink on tumor". MarginProbe® is a device for intra-operative margin assessment, which is routinely used in our institution. This is a retrospective, observational chart review from sets of consecutive patients, before and after we started using the device. For both these sets, we have been using the no ink on tumor criterion. We looked at the impact of the updated guidelines and at the effect use of the device had on the rate of re-excision and volume of tissue removed.

Materials and Methods

MarginProbe is an intra-operative device for identifying, in real-time, cancerous tissue at the margins of excised lumpectomy specimens, enabling immediate reaction in the operating room. Lesion localization, specimen excision and orientation were performed according routine lumpectomy procedures. Following specimen excision, the device was used on all faces (margins) of the main specimen, but not on additional shavings. Additional shavings (**Figure 1**) were taken when the device indicated positive. Intraoperative imaging of the specimens was performed. Additional shavings were also taken based on clinical assessment. Historical re-excision rate was collected from a consecutive set of patients in the period before the device was put into use.

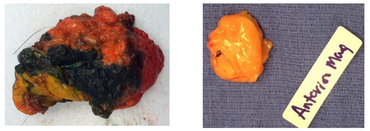

Figure 1 - Specimen and Shaving

Results

From November 2014 to August 2015, the device was used in 89 consecutive lumpectomy procedures. The comparison historical set consisted of 99 lumpectomy cases performed between April 2014 and November 2014. Subjects' pre-surgery baseline characteristics, as presented in **Table 1**, were similar between the two sets.

Table 1 - Subjects baseline characteristics

	MarginProbe set (N=89)	Historical set (N=99)
Age		
Mean (STD)	62.5 (12.6)	62.3 (11.0)
Tumor type		
Invasive Ductal	75%	58%
Invasive Lobular	5%	13%
DCIS	20%	29%
Receptor status		
ER+	67%	93%
PR+	58%	75%
HER2+	11%	17%

Table 2 presents tumor characteristics, based on final pathology. For both sets, in more than 55% of the cases there was DCIS present in the tumor. More than 70% of the tumors were smaller than 2 cm.

Table 2 - Tumor characteristics, based on final pathology

Tumor composition		
IDC	37%	19%
DCIS	20%	29%
IDC + DCIS	38%	40%
ILC	5%	13%
Tumor/lesion size		
Mean (STD) [cm]	1.5 (1)	1.5 (1.5)
<1cm	30%	37%
1 cm to 2 cm	41%	42%
>2 cm	29%	21%

	MarginProbe cases	Historical set	Absolute Reduction (% points)	Relative reduction	P-value
Lumpectomy procedures	89	99			
Re-excision procedures	3	16			
Re-excision rate	3.4%	16.2%	12.6%	79%	P<0.01

Table 3 – Comparison of re-excision procedures between the sets

From **Table 3,** the re-excision rate in the device set was 3.4% (3/89). In 5 additional cases, permanent pathology found cancer in shavings taken (based on positive device readings) even though the main specimen was clear. The re-excision procedure rate for the comparison historical set was 16.2% (16/99). The re-excision rate reduction was a statistically significant 79% (P<0.01).

	MarginProbe cases	Historical set
Shavings with no clinical benefit, per case; Mean (STD)	1.8 (1.4)	0.9 (1.6)
Main Specimen volume; Mean (STD)	78 (62) cc	87 (72) cc
Shaving volume; Mean (STD)	7.5 (6.9) cc	5.8 (5.2) cc
Total volume removed in the lumpectomy procedure; Mean (STD)	91 (63) cc	92 (72) cc

Table 4 – Comparison of additional margins taken and tissue volume removed between the sets

Table **4 shows** that use of device led to removal of, on average, 1.8 shavings with no clinical benefit, per case. In the historical set, 0.9 shavings with no clinical benefit were removed per case. The average volume of the main lumpectomy specimen was smaller in the device set, 78 cc, compared to 87 cc in the historical set. The average shaving volume was somewhat larger in the device set, 7.8 cc vs. 5.8 cc in the historical set. The total volume of tissue removed during the initial (lumpectomy) procedure was 91cc and 92 cc in the device and historical set, respectively.

Discussion

Even in the era of no ink on tumor margin assessment where some reports suggest re-excision rates are falling, utilization of MarginProbe significantly reduced re-excision rate in a group of 89 consecutive patients undergoing breast conservation surgery compared to historical controls of the previous 99 patients prior to device utilization. There was a modest increase in the number of cavity shavings taken, but overall, the volume of tissue excised remained the same. In 5 patients, there is a suggestion that the device may be more accurate in margin assessment as evidenced by positive shavings when the lumpectomy specimen was pathologically negative. Future utilization studies should focus on incidence of positive shavings, patient assessment of cosmetic outcomes and cost analysis.

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