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EPIDEMIOLOGY

Radiofrequency identification tag localization is comparable to wire localization for non-palpable breast lesions

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Abstract

Purpose Radiofrequency identification (RFID) tag localization (TL) is a technique of localizing non-palpable breast lesions that can be performed prior to surgery. We sought to evaluate whether TL is comparable to wire localization (WL) in regard to specimen size, operative time, and re-excision rate.

Methods A retrospective cohort analysis was performed on TL and WL excisional biopsies and lumpectomies performed by 5 surgeons at 2 institutions. Cases were stratified by surgery type and surgical indication. Associations between localization technique and specimen volume, operative time, and re-excision rate were assessed by univariate and multivariate analyses.

Results A total of 503 procedures were included, 147 TL (29.2%) and 356 WL (70.8%). Nineteen (12.9%) RFID tags were placed before surgery, ranging 1–22 days. All intended targets were removed. TL and WL excisional biopsy and lumpectomy specimen volumes were similar ($p = 0.560$ and 0.494). TL and WL excisional biopsy and lumpectomy + SLNB operative times were similar ($p = 0.152$ and 0.158), but TL lumpectomies without SLNB took longer than WL (57 min vs 49 min; $p = 0.027$). Re-excision rates were similar by surgical procedure ($p = 0.615$), surgical indication (DCIS $p = 0.145$; invasive carcinoma $p = 0.759$), and confirmed by multivariable analysis (OR 0.754, 95% CI 0.392–1.450; $p = 0.397$).

Conclusions TL has similar surgical outcomes to WL with added benefit that TL can occur prior to the day of surgery. TL is an acceptable alternative to WL and should be considered for non-palpable breast lesions.

Keywords Tag localization · Wireless localization · Non-palpable breast lesions

Introduction

Several studies have shown that breast-conserving therapy (BCT) is as effective as mastectomy in the treatment of breast cancer [1, 2], and since then, BCT has become widely adopted with the majority of women choosing lumpectomy over mastectomy [3]. Due to improvements in imaging technology and more frequent breast cancer screening, one-third of breast cancers are not palpable at diagnosis [4]. Wire localization (WL) has been used extensively to mark non-palpable lesions for excision. While effective, WL has its limitations, namely wire dislodgement, pain, placement vasovagal episodes, and the need to couple radiology and surgery schedules [5, 6].

Alternative localization methods have been developed to address the limitations of WL, including radioactive seeds, radar reflectors, magnetic seeds, and radiofrequency identification (RFID) tags [5]. Radioactive seed localization (RSL) is the oldest wireless method, and numerous studies have shown comparable outcomes to WL [7–10]. The downside of RSL is that it requires strict radioactive handling regulations, which is not an issue with other non-wire localization methods. RFID tag localization (TL) is a newer wireless method that uses a 9-mm RFID tag implanted in the breast to transmit a radiowave signal, which can be detected within 6 cm at the skin using a handheld loop probe and within 4 cm in the tissue using a surgical pencil probe [11]. The

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LOCalizer™ RFID tag has been approved for long-term placement over 30 days prior to surgery.

Although feasibility studies exploring its use and effectiveness have been performed [12, 13], data that evaluate the accuracy of TL is lacking. To our knowledge, this is the first study comparing TL to WL. We sought to evaluate whether TL is comparable to WL in regard to specimen size, operative time, and re-excision rate.

Methods

A retrospective cohort analysis was performed on consecutive WL and TL breast surgeries to compare specimen size, operative time, and re-excision rate. All surgeries were performed by 5 breast surgeons at 2 Massachusetts General Hospital locations. All localization procedures were performed by breast imaging radiologists under ultrasound or stereotactic guidance (Fig. 1). The study protocol was reviewed and approved by the Institutional Review Board.

All TL procedures were identified from July 2018 through October 2018, representing our initial 3-month experience with TL. All WL procedures were identified from initiation of the electronic medical record (EMR) (April 2016) until adoption of an alternative localization method (December 2016). Localized excisional biopsies and lumpectomies with or without sentinel lymph node biopsy (SLNB) were eligible for inclusion. Lesions requiring more than one marker for bracketing were included, but bilateral and multicentric lesions resulting in more than one lumpectomy specimen were excluded. Procedures involving TL lymph node excision were also excluded.

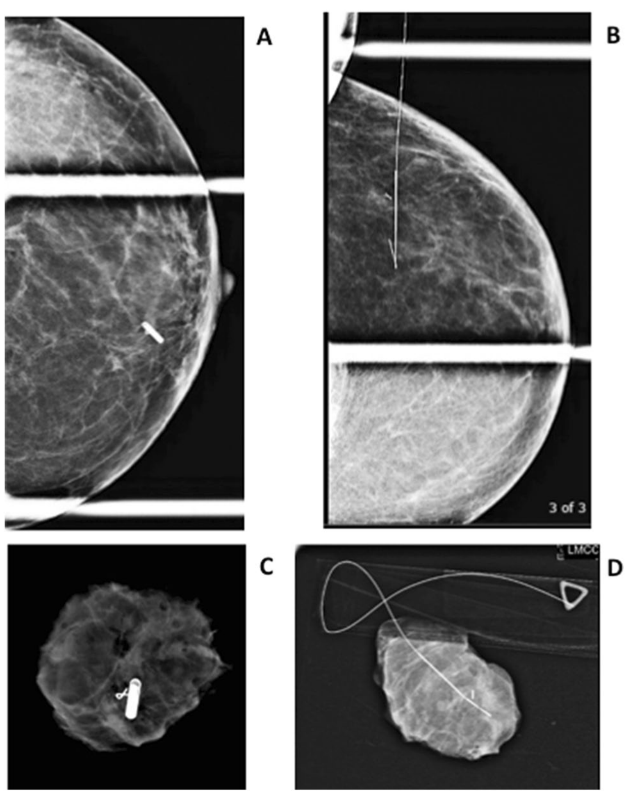

Fig. 1 Two invasive ductal carcinomas excised following TL and WL. **a** and **b** Craniocaudal mammogram views following localization, demonstrating tag and wire in position. **c** and **d** Specimen X-ray following TL and WL lumpectomies demonstrating clip and tag or wire in specimen

The main variable of interest was localization method (TL vs. WL). All variables, including age, number of wires or tags, type of surgery, surgical indication, final pathology, and lesion size were obtained by chart abstraction. Surgical indication was determined by preoperative biopsy pathology (or surgeon note if biopsy was not performed) and categorized as atypia, ductal carcinoma in situ (DCIS), invasive carcinoma, or other, which included fibroepithelial lesions (FEL), papillomas, radial scars, and imaging abnormalities requiring surgical biopsy. Final pathology was based on surgical pathology report and categorized as atypia, DCIS, invasive carcinoma, or other, which included FEL, papillomas, and benign or normal breast tissue without residual atypia or malignancy. Lesion size was defined as the largest dimension in centimeters from the pathology report. Size was only available for tumors, DCIS, and FEL and was missing for 140 WL procedures (39.3%) and 48 TL procedures (32.6%).

The main outcomes of interest were median specimen volume (cm^3), operative time (min), and re-excision rate. Specimen volume was calculated using the ellipsoid formula (4/3 × Π × ½ width × ½ length × ½ height) from dimensions obtained in the pathology report [9, 14, 15]. Shaved margins were not included in specimen volume. Decision to obtain shaved margins should not have been influenced by localization method, and surgeons were consistent across localization methods. Operative time was defined as the number of minutes from surgical incision to end of surgery as documented in the EMR by the circulating nurse. Re-excision was defined as a return to the operating room for re-excision or completion mastectomy.

Univariate statistics were used to examine the cohorts and compare outcomes in terms of localization method. Differences in outcomes were examined by surgical procedure and surgical indication. Associations between localization technique and specimen volume, operative time, and re-excision rate were assessed by Wilcoxon rank-sums, independent *t*-tests, and χ^2 tests, respectively. A logistic regression model adjusting for surgery type, indication, final pathology, lesion size, and surgeon was used to estimate the odds ratio (OR) and 95% confidence interval (CI) for the association between marker and re-excision rate. Statistical significance was determined using a 2-sided alpha-level of 0.05. All analyses were completed using SAS, version 9.4 (SAS Institute).

Results

A total of 503 procedures were included; 147 (29.2%) were TL and 356 (70.8%) were WL. All intended targets were removed with both TL and WL. All wires were placed on the day of surgery. Nineteen (12.9%) RFID tags were placed before the day of surgery, ranging from 1 to 22 days.

Patient and procedural factors stratified by localization method are summarized in Table 1. Mean patient age was approximately 60 years in both cohorts. Most lesions required localization with only one marker, although more WL lesions were bracketed than TL lesions (10.7% vs. 4.8%; $p=0.035$). The most common procedure performed was lumpectomy with SLNB (40.2%), followed by excisional biopsy (35.2%) and lumpectomy alone (24.6%). The most common surgical indication was invasive carcinoma (48.3%), followed by other (18.7%), DCIS (16.5%), and atypia (16.5%). The most common final pathology was invasive carcinoma (47.3%), followed by other (18.3%), DCIS (17.7%), and atypia (16.7%). Mean lesion size was 1.2 cm overall with TL lesions slightly smaller than WL lesions by 3 mm (1.0 cm vs. 1.3 cm; $p=0.016$).

Outcomes stratified by surgical procedure and surgical indication are summarized in Tables 2 and 3, respectively. Median volumes were similar for TL and WL excisional biopsy specimens (8.2 vs. 8.0 cm^3; $p=0.560$) and lumpectomy specimens (19.3 vs. 16.5 cm^3; $p=0.494$). Median specimen volumes were also similar for TL and WL procedures performed for atypia (9.4 vs. 9.0 cm^3; $p=0.695$) and other diagnoses (6.4 vs. 6.9 cm^3; $p=0.244$). TL specimens were significantly larger when performed for DCIS (24.4 vs. 15.7 cm^3; $p=0.026$) and smaller when performed for invasive carcinoma (15.0 vs. 20.2 cm^3; $p=0.026$).

Table 1 Patient and procedural characteristics

	Tag localization $N=147$	Wire localization $N=356$
Age (mean, SD)	59.5 (14.0)	60.3 (12.8)
Number of markers		
One	140 (95.2%)	318 (89.3%)
Two or more	7 (4.8%)	38 (10.7%)
Surgery		
Excisional biopsy	53 (36.1%)	124 (34.8%)
Lumpectomy	34 (23.1%)	90 (25.3%)
Lumpectomy + SLNB[a]	60 (40.8%)	142 (39.9%)
Surgical indication		
Atypia	23 (15.7%)	60 (16.8%)
Other[b]	30 (20.4%)	64 (18.0%)
DCIS[c]	24 (16.3%)	59 (16.6%)
Invasive carcinoma	70 (47.6%)	173 (48.6%)
Final pathology		
Atypia	19 (12.9%)	65 (18.3%)
Other[b]	33 (22.5%)	59 (16.5%)
DCIS[c]	20 (13.6%)	69 (19.4%)
Invasive carcinoma	75 (51.0%)	163 (45.8%)
Lesion size (cm)[d] (mean, SD)	1.0 (0.8)	1.3 (0.9)

[a]Sentinel lymph node biopsy

[b]Fibroepithelial lesion, papilloma, imaging abnormality

[c]Ductal carcinoma in situ

[d]For measurable tumors, DCIS, fibroepithelial lesions

Table 2 Outcome by surgical procedure

	Tag localization	Wire localization	*p* value
Median specimen volume (cm^3) (IQR)			
Excisional biopsy	8.2 (12.3)	8.0 (14.5)	0.560
Lumpectomy ± SLNB[a]	19.3 (21.8)	16.5 (16.8)	0.494
Mean operative time (min) (SD)			
Excisional biopsy	34 (11)	36 (12)	0.152
Lumpectomy	57 (29)	65 (29)	0.023
Without SLNB[a]	57 (19)	49 (16)	0.027
With SLNB[a]	73 (24)	68 (25)	0.158
Re-excision rate			
Lumpectomy ± SLNB[a]	18 (19.1%)	39 (16.8%)	0.615

[a]Sentinel lymph node biopsy

Table 3 Outcome by surgical indication

	Tag localization	Wire localization	*p* value
Median specimen volume (cm^3) (IQR)			
Atypia	9.42 (10.16)	8.97 (14.96)	0.695
Other[a]	6.42 (11.80)	6.88 (16.6)	0.244
DCIS[b]	24.36 (29.72)	15.71 (21.71)	0.026
Invasive	15.01 (14.01)	20.22 (21.16)	0.026
Mean operative time (min) (SD)			
Atypia	35 (12)	32 (10)	0.224
Other[a]	37 (12)	36 (10)	0.474
DCIS[b]	64 (26)	50 (17)	0.020
Invasive	68 (23)	64 (25)	0.222
Re-excision rate			
Atypia	0	0	N/A
Other[a]	5 (16.7%)	2 (3.2%)	0.012
DCIS[b]	7 (29.2%)	9 (15.2%)	0.145
Invasive	11 (15.7%)	30 (17.3%)	0.759

[a]Fibroepithelial lesion, papilloma, imaging abnormality

[b]Ductal carcinoma in situ

Mean operative time was similar for excisional biopsy (34 vs. 36 min; $p=0.152$) and lumpectomy with SLNB (73 vs. 68 min; $p=0.158$). There was no difference in the number of lymph nodes removed between TL (2.0 ± 1.3) and WL SLNB procedures (1.0 ± 1.7) ($p=0.906$). TL lumpectomies without SLNB took longer than WL lumpectomies (57 vs. 49 min; $p=0.027$), as did TL procedures for DCIS (64 vs. 50 min; $p=0.020$). Mean operative time was similar for procedures for invasive carcinoma ($p=0.222$), atypia ($p=0.224$), and other indication ($p=0.474$).

Re-excision rates were similar for TL and WL lumpectomies (19.1% vs. 16.8%; $p=0.615$). When stratified by surgical indication, re-excision rates for invasive carcinoma were similar (15.7% vs. 17.3%; $p=0.759$). However, re-excision rates were higher for TL lumpectomies for DCIS (29.2% vs. 15.2%; $p=0.145$), but this was not statistically significant. Of the 7 TL-DCIS lesions that required re-excision, 4 were localized with 1 tag and 3 with 2 tags. Out of all 7 TL-DCIS lesions that were bracketed, 3 required re-excision (42.9%). Comparatively, of the 14 WL-DCIS lesions that were bracketed, only 1 required re-excision (7.1%). The re-excision rate for TL-DCIS was similar to WL when one tag/wire was used (23.5% TL vs. 17.8% WL) but higher for bracketed TL lesions (42.9% vs. 7.1%). Re-excision rates were also higher for TL procedures performed for other indication (16.7% vs. 3.2%; $p=0.012$), but this reflects a higher upgrade rate of benign or unknown lesions to malignancy and not a limitation of the localization method. When adjusted for clinically relevant characteristics, localization method was not associated with re-excision (TL vs. WL OR 0.754, 95% CI 0.392–1.450; $p=0.397$).

Discussion

Based on our study, we believe that TL is as effective as WL for non-palpable breast lesions. We found no significant difference between the two localization methods in terms of overall specimen volume, operative times, and re-excision rates, although there was some variability based on lesion type.

Overall, TL and WL lumpectomy specimen volumes were similar, but when stratified by indication, TL specimens were larger in DCIS and smaller in invasive carcinoma. It is unclear if this difference is related to the localization method or due to differences in lesion size. Mammography reports did not consistently report dimensions of calcifications in those with DCIS. Pathologic lesion size was also missing for approximately one-third of all specimens. While we did not capture data regarding receipt of neoadjuvant chemotherapy or endocrine therapy, it is possible that those with missing lesion sizes had undergone neoadjuvant therapy with a complete pathologic response. Plus, some cases of DCIS may have been unmeasurable due to multifocality or discontinuous patterns of growth. Overall, we feel that the volume differences between TL and WL DCIS and invasive carcinoma specimens were more likely due to inherent differences in lesion size rather than localization method.

We also observed that TL lumpectomies and TL procedures for DCIS took longer than WL. This difference ranged from 8 to 14 min. A difference in operative time was not observed across other surgeries or other indications. There is a learning curve especially with bracketing RFID tags. Each tag has a unique ID number, but if two tags are placed closer than 1.8 cm, the unique ID will not appear on the tag reader due to interference, making it difficult for the surgeon to accurately locate the tag(s). For short distance brackets or very superficial lesions, WL may still be preferred over TL. While these data represent our initial 3-month experience with TL, we anticipate this discrepancy in operative time to improve with experience and improved patient selection.

Although there was no statistical difference between re-excision rates and localization method in univariate or multivariate analyses, re-excisions following lumpectomies for DCIS were nearly twice as common in the TL cohort compared to WL. Further investigation is warranted to determine whether this trend continues with increasing surgeon and radiologist experience with TL and if a significant difference is detected with a larger sample size. Our data showed similar re-excision rates for DCIS when one tag/wire was used but a higher re-excision rate for bracketed TL-DCIS lesions, suggesting a possible limitation of TL. In addition, the tag's diameter requires placement with a 14-gauge needle, much larger than the needle used for wire placement. This large bore needle creates a tract through the breast tissue, and if a margin's integrity is disrupted by this tract, this could cause ink placed on its outer surface to inadvertently settle into this tract and lead to a false-positive margin. Further study is warranted to test this hypothesis. In all, larger specimen volumes, longer operative times, and a trend toward more re-excisions suggest opportunity for improvement in TL for DCIS, and while TL and WL methods are comparable overall, further study is needed to determine if these outcomes in TL for DCIS persist over time with increasing experience.

There are potential advantages of TL over WL. First, RFID tags have been approved for long-term placement over 30 days prior to surgery. This decouples the radiology and surgery procedures, which can lead to improved patient flow, operating room efficiency, and patient convenience as previously shown [9]. In this study, 12.9% of tags were placed before the day of surgery. The remaining 87.1% that underwent same-day TL were likely not local and did so to minimize trips to the hospital.

An additional advantage of TL over WL is its potential for lymph node localization. As more patients undergo neoadjuvant chemotherapy, those with biopsy-proven nodal disease may be downstaged and able to avoid axillary lymph node dissection [16]. It has been shown that localizing previously clipped nodes for removal is an important component in minimizing the false-negative rate of SLNB following neoadjuvant chemotherapy [17, 18]. Targeted excision of a clipped axillary lymph node with TL may play an important role in SLNB for this patient population.

To our knowledge, this is the first study to compare TL to WL. We believe that by including all eligible consecutive TL procedures for both benign and malignant non-palpable breast lesions, the data are representative of a high-volume breast center. The study does have its limitations. Because it is retrospective, we cannot account for all biases, including the inherent variability of surgical outcomes across surgeons. In addition, during this initial experience of TL, some non-palpable lesions still underwent WL as opposed to TL. While this was due in part to developing comfort of the practitioner, there are instances when WL may still be desired [19].

Conclusion

TL and WL specimen volumes and re-excision rates were similar across surgeries for non-palpable breast lesions. TL lumpectomies for DCIS took longer than comparable WL procedures, a difference that we anticipate will decrease with experience. Given the comparable outcomes and added benefit of placement flexibility, TL should be considered for non-palpable breast lesions.

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Compliance with ethical standards

Conflict of interest Dr. McGugin declares that she has no conflict of interest. Dr. Spivey declares that she has no conflict of interest. Dr. Coopey declares that she has no conflict of interest. Dr. Smith declares that she has no conflict of interest. Ms. Kelly declares that she has no conflict of interest. Dr. Gadd declares that she has no conflict of interest. Dr. Hughes has received a speaker honorarium from Hologic. Dr. Dontchos has provided consultant work for GE Healthcare. Dr. Specht declares that she has no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

Research involved in human or animal rights This article does not contain any studies with animals performed by any of the authors.

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