



Reflector-guided breast tumor localization versus wire localization for lumpectomies: A comparison of surgical outcomes[☆]



Sejal N. Patel^a, Victoria L. Mango^b, Priya Jadeja^a, Lauren Friedlander^a, Elise Desperito^a, Ralph Wynn^a, Sheldon Feldman^c, Richard Ha^{a,*}

^a Columbia University Medical Center, Herbert Irving Pavilion, 161 Fort Washington Ave., 10th Floor, New York, NY 10032, United States

^b Memorial Sloan Kettering Cancer Center, 300 East 66th Street, New York, NY 10065, United States

^c Montefiore M-E Center for Cancer Care, 1521 Jarrett Place, Bronx, NY 10461-2606, United States

ARTICLE INFO

Article history:

Received 9 May 2017

Received in revised form 25 July 2017

Accepted 28 July 2017

Available online xxxx

Keywords:

Breast cancer

Tumor localization

ABSTRACT

Purpose: To compare surgical outcomes of SAVI SCOUT reflector localization (SSL) versus wire localization (WL) for breast tumors.

Methods: Retrospective review of 42 SSL cases and 42 WL cases. WL patients were consecutively matched for clinical-pathologic features. Final surgical outcome measures were tumor specimen volume, margin status, and re-excision rates.

Results: No significant differences were present in median specimen volumes (SSL-15.2 cm³ vs. WL-16.3 cm³), positive margin rate (SSL-9.5% vs. WL-7.1%), close margin rate (SSL-7.1% vs. WL-11.9%) or re-excision rate (SSL-7.1% vs. WL-9.5%).

Conclusion: SSL is an acceptable alternative to WL with no significant differences in surgical outcomes.

© 2017 Elsevier Inc. All rights reserved.

1. Introduction

Non-palpable breast cancers comprise approximately 25–35% of all breast cancers [1]. The standard method of preoperative localization of nonpalpable breast lesions is wire localization (WL). WL is performed the day of surgery and uses imaging guidance to percutaneously place a thin, hooked wire into the lesion [1,2]. Reported disadvantages of WL include an external component which could be potentially pulled, wire transection, kinking, patient discomfort, and negative impact on operating room (OR) efficiency due to coupling of radiology and OR scheduling [3–5].

The SAVI SCOUT Surgical Guidance System (Cianna Medical, Aliso Viejo, CA) is a novel technique that has recently been introduced for localization of nonpalpable breast lesions. This device is Food and Drug Administration (FDA) approved for placement up to 30 days prior to surgery. SAVI SCOUT localization (SSL) circumvents many of the disadvantages of WL because there is no external component, the device may be placed prior to the day of surgery, and there is a potential

for improved efficiency and workflow the day of surgery [6,7]. The benefits mirror many of those that radioactive seed localization (RSL) offers, however SSL is non-radioactive and therefore avoids patient and institutional radiation safety concerns.

SSL has been studied in early feasibility studies, including a study of 15 patients as well as a multi-institutional study with 154 patients showing 100% successful fiducial reflector placement and excision [7, 8]. Also most recently in a single institution study that performed 123 SSL in 100 patients, for benign, high risk, and malignant lesions [9]. These studies show that SSL is a reliable method of localization. To our knowledge, there have been no studies published directly comparing SSL to traditional WL. The purpose of this study is to compare surgical outcomes of SSL versus WL in biopsy proven breast tumors, to determine if SSL can be an alternative to WL.

2. Materials and methods

2.1. Patient and lesion characteristics

An IRB approved, HIPAA compliant retrospective study was conducted of lumpectomy cases performed by a single-surgeon to eliminate intra-operator variability. Patients included underwent placement of a single SSL or single WL of tumors measuring 2 cm or less on pre-operative imaging. Lesions > 2 cm were excluded due to treatment variability including utilization of neoadjuvant chemotherapy which can alter the tumor size for targeting and final specimen volume, which was one of

[☆] We have no disclosures. This was an IRB approved study. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

* Corresponding author.

E-mail addresses: snp9006@nyp.org (S.N. Patel), mangov@mskcc.org (V.L. Mango), phj2115@cumc.columbia.edu (P. Jadeja), lf2386@cumc.columbia.edu (L. Friedlander), ed2202@cumc.columbia.edu (E. Desperito), rtw2120@cumc.columbia.edu (R. Wynn), sfeldman@montefiore.org (S. Feldman), rh2616@cumc.columbia.edu (R. Ha).

the surgical outcome measures. Patients with bracketed lesions with SSLs or WLs, multicentric disease, and patients treated with neoadjuvant chemotherapy were also excluded.

Among 97 patients that underwent SSL with subsequent surgery by the same surgeon from 7/2015 to 1/2017, 42 patients met the criteria for the study. The comparison WL group was matched for age, size of the tumor and single wire localization. Forty-two consecutive patients that met the criteria were selected from WL cases performed by the same surgeon the previous year, from 1/2015 to 6/2015, prior to the adaptation of the SAVI SCOUT Surgical Guidance System. Final surgical pathology was recorded, including, tumor size, ER/PR/HER2/Ki67 status, histologic type, margin status, and re-excision rates. Positive and close margins were defined as tumor on ink and tumor ≤ 1 mm from ink, respectively, for invasive and in-situ pathology.

2.2. Lumpectomy and tumor volumes

Lumpectomy volumes are not routinely recorded in pathologic evaluation in our institution, however specimen dimensions are reported. The following formula of an ellipsoid was utilized to calculate lumpectomy and total specimen volumes: $\frac{4}{3} \times \pi \times \frac{1}{2} \text{length} \times \frac{1}{2} \text{width} \times \frac{1}{2} \text{depth}$ [3].

2.3. SAVI SCOUT surgical guidance system

The SAVI SCOUT Surgical Guidance System (Cianna Medical, Aliso Viejo, CA) consists of a unidirectional 12 mm fiducial reflector preloaded into a 16-gauge introducer needle, and a console and handpiece system which localizes the reflector and confirms functionality. The reflector is FDA cleared for placement for up to 30 days prior to surgery. It contains an infrared light receptor, transistor switch, and two nitinol antennae. The handpiece generates an audible signal when over the reflector, which is used for confirmation of placement and intraoperative orientation.

The fiducial reflectors were percutaneously placed into the breast by one of four fellowship trained breast radiologists. The introducer needle containing the reflector is placed via mammographic or sonographic guidance, and deployed adjacent to/within the targeted lesion or adjacent to the clip (Fig. 1a–c). Post-procedure mammograms were obtained in craniocaudal (CC) and medial-lateral oblique (MLO) views to confirm satisfactory placement of the reflector to the targeted lesion or clip (Fig. 1d,e). Post-lumpectomy specimen radiographs were obtained to document excision of the reflector and targeted lesion or clip (Fig. 1f).

2.4. Wire localizations

Kopans wire localization system utilizing the standard technique for placement was used in all WL cases [2]. A stainless steel 0.03 cm diameter wire with 22,600 kg/cm² tensile strength was used. The lesion was localized using either sonographic or mammographic guidance. If mammographic guidance was utilized, wire position was confirmed in both the CC and MLO views. Once satisfactory position is obtained with either imaging modality, the needle hub is held in place while the wire is introduced into the tissue through the needle, allowing the hook to deploy. 4–6 cm of the wire protrudes from the skin following the procedure.

2.5. Statistical methods

SSL and WL patient groups were compared based on demographics, clinical factors, and surgical outcomes using chi-square and Student *t*-tests. Statistical analysis was performed using SPSS, version 24 (IBM SPSS Statistics for Windows, Version 24.0, Armonk, NY). *p*-Values were calculated and *p*-value < 0.5 defined as significant.

3. Results

A total of 84 patients that underwent lumpectomy by a single surgeon were evaluated with 42 patients having SSL and 42 patients having WL. There was no significant difference in mean age or clinical-pathologic features between the SSL and WL groups ($p > 0.05$) (Table 1): mean age (SD) was 62.5 years (SD 11.3 years) in the SSL group and 64.7 years (SD 11.1 years) in the WL group; pathology confirmed invasive disease in 83.3% (35/42) of the SSL group and 78.6% (33/42) of the WL group; mean tumor size was 0.86 cm (SD 0.43 cm) in the SSL group and 0.81 cm (SD 0.38 cm) in the WL group. In the SSL group, ER or PR +, HER2 + and ER –/PR –/HER2 – rates were 92.9%, 7.1% and 0%, respectively, with mean Ki67 of 11.9% (SD 10.6%); In the WL group, ER or PR +, HER2 + and ER –/PR –/HER2 – rates were 95.2, 2.4% and 2.4%, respectively, with mean Ki67 of 12.1% (SD 9.3%).

Both SAVI SCOUT reflector and wire placements used sonographic or mammographic guidance. 100% (42/42) of SSL was performed prior to the day of the surgery (range 1–10 days, mean 2.8 days and median 2 days) and all were successfully excised. All patients with WL underwent wire placement the day of surgery and all were successfully excised. The mean distance between the target and SAVI SCOUT reflector on post localization mammogram was 0.4 cm (range 0–1.9 cm). Ultrasound guidance for SSL was used in 38% (16/42) of cases and mammogram guidance was used in 62% (26/42) cases. The mean distance between the target and the re-enforcement segment of the wire on post localization mammogram was 0.3 cm (range 0–1.3 cm). Ultrasound guidance for WL was used in 40.5% (17/42) of cases and mammogram guidance was used in 59.5% (25/42).

Post-lumpectomy median specimen volumes were 15.2 cm³ (range, 1.8–55 cm³) for the SSL group and 16.3 cm³ (range, 3.6–58.9 cm³) for the WL group. Positive margin, close margin and re-excision rates for the SSL groups were 9.5% (4/42), 7.1% (3/42), and 7.1% (3/42), respectively. The WL group was not significantly different ($p > 0.05$) with regard to positive margin, close margin and re-excision rates of 7.1% (3/42), 11.9% (5/42) and 9.5% (4/42), respectively. In the SSL group, all close margins occurred in patients with IDC and were not re-excised; of the patients with positive margins, one was not re-excised due to proximity to the fascia. In the WL group, 3 of the 5 patients with close margins demonstrated IDC and were not re-excised; of the patients with positive margins, one was not re-excised due to the proximity to the anterior (skin) margin. No complications occurred with placement or removal of the reflectors or wires. There were no postoperative complications.

4. Discussion

In this study, we evaluated surgical outcomes of patients undergoing SSL and WL lumpectomies. No statistically significant differences were present in the surgical outcome including median specimen volume, margin positivity rate, close margin rate and re-excision rate. Characteristics known to increase the likelihood of margin positivity, including tumor size and pure DCIS were comparable between both groups.

As mentioned, the positive margin, close margin and re-excision rates for our SSL groups were 9.5% (4/42), 7.1% (3/42), and 7.1% (3/42). Our results are similar to two prior studies that reported the same surgical outcomes with SSL. Cox et al. reported that malignant lesions had positive margin, close margin and re-excision rates of 14.9% (15/101), 14.9% (15/101), and 16.8% (17/101) [8]. Mango et al. reported of malignant lesions, positive margin, close margin and re-excision rates were 14.9% (15/101), 14.9% (15/101), and 16.8% (17/101) [9].

The technology most similar to SAVI SCOUT reflectors is radioactive seed localization (RSL), given the similar percutaneous placement using ultrasound or mammographic guidance without an external component. Murphy et al. compared the surgical outcomes of 431 RSL and 256 WL patients, and reported no difference in positive margin rate of

Download English Version:

<https://daneshyari.com/en/article/8821564>

Download Persian Version:

<https://daneshyari.com/article/8821564>

[Daneshyari.com](https://daneshyari.com)