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

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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 cm^3 vs. WL-16.3 cm^3), 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.

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

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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: $4/3 \times \pi \times$ ½length $\times$ ½width $\times$ ½depth [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-lumpectomey 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/cm^2 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 cm^3 (range, 1.8–55 cm^3) for the SSL group and 16.3 cm^3 (range, 3.6–58.9 cm^3) 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

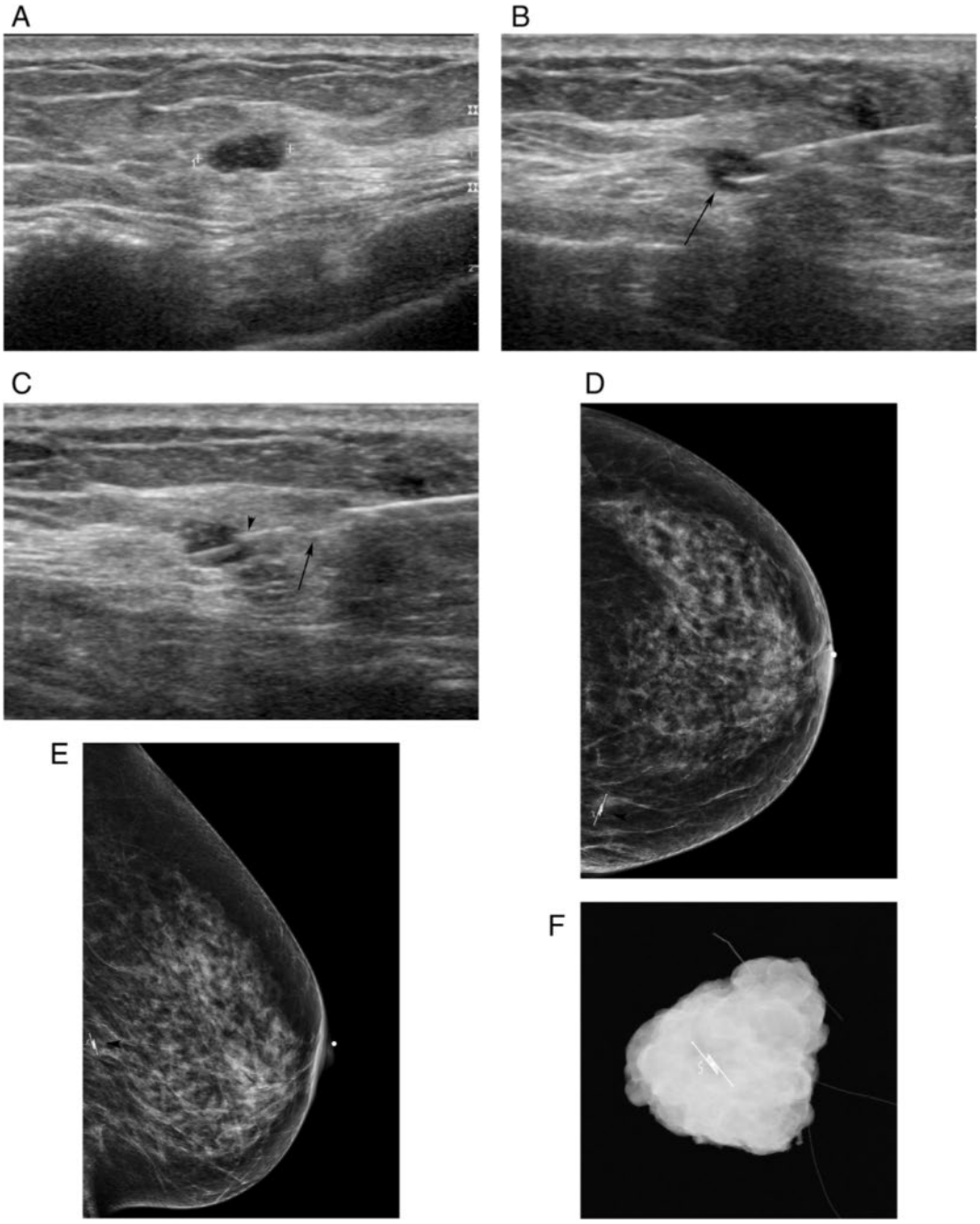

Fig. 1. a: 52-year-old female with recent diagnosis of invasive ductal carcinoma. Sonographic images demonstrate a 1.1 cm hypoechoic mass at the 3:00 axis, 10 cm from the nipple. b: Image demonstrates the SAVI SCOUT introducer needle with the beveled edge indicated by the arrow. The beveled edge is seen at the center of the mass. c: The bevel of the needle has been pulled back after deploying the SAVI SCOUT reflector, which is seen at the arrow head. d,e: Craniocaudal and medial-lateral oblique post-procedure mammograms in the same patient demonstrate an S shaped biopsy clip and SAVI SCOUT reflector associated with the mass in the medial right breast, indicated by the arrow head. f: Post-lumpectomy specimen in the same patient demonstrates the resected mass with S shaped biopsy clip and SAVI SCOUT reflector.

RSL 7.7% (33/431) vs. wire localization 5.5% (14/256) ($p = 0.38$), or median excision volumes [3]. These findings are comparable to existing surgical literature comparing RSL and WL, showing no significant difference in surgical outcomes [1]. Our similar results suggest that SSL may be a comparable alternative to RSL or WL.

One major benefit of SSL compared to RSL is the non-radioactive feature of the device, which is a great advantage for both patients and providers. Patients may feel more comfortable with having a non-radioactive device in the breast for up to 30 days. Additionally, there are potentially less hurdles in implementing this technology compared to RSL, which may require additional administrative oversight by the institution's Radiation Safety Officer.

Both SSL and RSL allow for greater flexibility in scheduling, potential of improved workflow and resource utilization as both may be placed in advance of the surgery date. I^{125} has a half-life of 60 days and SSL is FDA approved for placement 30 days in advance [3]. In a study comparing workflow of RSL vs. WL, Sharek et al. found prior to the institution RSL at their institution, on average they had 35% unfilled procedure slots [10]. After RSL was implemented, <1% of slots went unfilled due to interchangeable scheduling of RSL, biopsies, and other procedures. This represented a reported 34% improvement in efficiency and resource utilization.

SSL has a potential benefit of increased patient comfort compared to WL, most attributable to the fact that there is no external wire component. The Cox et al. study conducted patient and physician surveys

Table 1
Clinical-pathologic factors - SAVI SCOUT localization vs. wire localization.

	SAVI SCOUT Localization ($n = 42$)	Wire localization ($n = 42$)	p-Value
Clinical-pathologic factors			$p > 0.05$
Mean age (SD)	62.5 years (11.3)	64.7 years (11.1)	
Tumor characteristics, *n*, (%)			
ER or PR +	39 (92.9%)	40 (95.2%)	
HER2 +	3 (7.1%)	1 (2.4%)	
ER −/PR −/HER2 −	0 (0%)	1 (2.4%)	
ki67, mean (SD)	11.9 (10.6)	12.1 (9.3)	
Pathology, *n*, (%)			
DCIS	7 (16.7%)	9 (21.4%)	
IDC	29 (69%)	27 (64.3%)	
ILC	6 (14.3%)	6 (14.3%)	
Mean tumor size (SD)	0.86 cm (0.43)	0.81 cm (0.38)	
Median specimen volume (range)	15.2 cm^3 (1.8–55 cm^3)	16.3 cm^3 (3.6–58.9 cm^3)	

which showed of the patients who completed a post-procedure survey, 75/105 (71%) were very satisfied with SAVI SCOUT, and 97% of patients would recommend it to other patients [8]. Physician surveys rated patient comfort at 3.7/5 and overall patient experience at 4.1/5. This suggests that patients report the SSL experience to be comfortable. (Tables 2 and 3.)

Another benefit of RSL is improved patient wait time, work flow, and convenience [10–12]. Sharek et al. reported on average the patient wait time for a percutaneous biopsy prior to RSL implementation was 4.1 days (range 1.6–8.9 days), and after the RSL was introduced this decreased to 3.4 days [10]. This represents an improvement in patient wait time. Hughes et al. reported that RSL patients had a significantly higher convenience score of 8.5/10, compared to 7.4/10 for the WL group ($p = 0.02$) [11]. Dauer et al. reported improvement in work flow, with the median time from arrival time to preoperative set up to time in operating room was significantly reduced from median of 243 min (SD 78 min) in WL patients, compared to median of 103 min (SD 72 min) in RSL patients [12]. These improvements could be similarly observed with SSL patients, however future work flow and efficiency studies with SSL are required.

To the best of our knowledge, this is the first study directly comparing single SSL to single WL in the setting of early stage breast cancer. It is notable that the SSL does have a high up front and per device cost (negotiated per institution), however, this may be obviated in a bundled payment system. Loving et al. demonstrated that RSL reduced total health care costs per patient by an average of $115 compared to WL patients, within a bundled payment system [13]. As RSL programs require the support of the nuclear medicine department and radiation safety personnel, one can infer that the ultimate cost savings from SSL may be even more substantial. However, future studies are required to analyze the cost-effectiveness of SSL.

New to the market in the United States is Magseed (Endomagnetics, Inc., Austin, TX), which is a magnetic lesion marker also used in breast localization. To our knowledge there is no data currently published in the literature evaluating the feasibility or efficacy of Magseed, however it appears to employ a similar percutaneous localization method as SSL for breast lumpectomy. Given the limited data of this device, further information is needed to make a fair comparison to WL, SSL, and RSL.

Limitations of this study include a retrospective review of a small sample size from a single institution. Larger multi-institutional prospective randomized studies would be necessary to fully compare SSL to WL.

Table 2
Procedural parameters - SAVI SCOUT localization vs. wire localization.

	SAVI SCOUT localization ($n = 42$)	Wire localization ($n = 42$)
Localization modality		
Ultrasound guidance	16 (38%)	17 (42%)
Mammographic guidance	26 (62%)	25 (59.5%)
Timing with surgery		
Performed prior to day of surgery, *n*	42 (100%)	0 (0%)
Mean days prior to surgery (range)	2.8 days (1 − 10)	0 (0%)
Performed day of surgery, *n*	0 (0%)	42 (100%)

Table 3
Surgical outcomes - SAVI SCOUT localization vs. wire localization.

	SAVI SCOUT localization ($n = 42$)	Wire localization ($n = 42$)	p-Value
Surgical outcomes			$p > 0.05$
Mean distance to target (range)	0.4 cm (0–1.9 cm)	0.3 cm (0–1.3 cm)	
Positive margin *n*, (%)	4 (9.5%)	3 (7.1%)	
DCIS *n*, (%)	1 (2.4%)	2 (4.8%)	
Invasive *n*, (%)	3 (7.1%)	1 (2.4%)	
Close margin *n*, (%)	3 (7.1%)	5 (11.9%)	
DCIS *n*, (%)	0 (0%)	2 (4.8%)	
Invasive *n*, (%)	3 (7.1%)	3 (7.1%)	
Re-excision (%)	3 (7.1%)	4 (9.5%)	

5. Conclusion

There was no significant difference in surgical outcomes of breast lumpectomies following SSL compared to WL. In a clinical-pathologically matched group, median tumor volume, close margin rate, positive margin rate, and re-excision rates were all comparable. The SAVI SCOUT surgical guidance system is a reasonable alternative to wire localization with added advantage of scheduling efficiency and patient comfort.

References

[1] Lovrics PJ, Goldsmith CH, Hodgson N, McCready D, Gohla G, Boylan C, et al. A multicentered, randomized, controlled trial comparing radioguided seed localization to standard wire localization for nonpalpable, invasive and in situ breast carcinomas. Ann Surg Oncol 2011;18(12):3407–14.
[2] Kopans DB, DeLuca S. A modified needle-hookwire technique to simplify preoperative localization of occult breast lesions. Radiology 1980;134(3):781.
[3] Murphy JO, Moo TA, King TA, Van Zee KJ, Villegas KA, Stempel M, et al. Radioactive seed localization compared to wire localization in breast-conserving surgery: initial 6-month experience. Ann Surg Oncol 2013;20(13):4121–7.
[4] Chadwick DR, Shorthouse AJ. Wire-directed localization biopsy of the breast: an audit of results and analysis of factors influencing therapeutic value in the treatment of breast cancer. Eur J Surg Oncol 1997;23(2):128–33.
[5] Frank HA, Hall FM, Steer ML. Preoperative localization of nonpalpable breast lesions demonstrated by mammography. N Engl J Med 1976;295(5):259–60.
[6] Cox CE, Garcia-Henriquez N, Glancy MJ, Whitworth P, Cox JM, Themar-Geck M, et al. Pilot study of a new nonradioactive surgical guidance technology for locating nonpalpable breast lesions. Ann Surg Oncol 2016;23(6):1824–30.
[7] Mango V, Ha R, Gomberawalla A, Wynn R, Feldman S. Evaluation of the SAVI SCOUT surgical guidance system for localization and excision of nonpalpable breast lesions: a feasibility study. AJR Am J Roentgenol 2016:W1–4.
[8] Cox CE, Russell S, Prowler V, Carter E, Beard A, Mehindru A, et al. A prospective, single arm, multi-site, clinical evaluation of a nonradioactive surgical guidance technology for the location of nonpalpable breast lesions during excision. Ann Surg Oncol 2016;23(10):3168–74.
[9] Mango VL, Wynn RT, Feldman S, Friedlander L, Desperito E, Patel SN, et al. Beyond wires and seeds: reflector-guided breast lesion localization and excision. Radiology 2017;161661.
[10] Sharek D, Zuley ML, Zhang JY, Soran A, Ahrendt GM, Ganott MA. Radioactive seed localization versus wire localization for lumpectomies: a comparison of outcomes. AJR Am J Roentgenol 2015;204(4):872–7.
[11] Hughes JH, Mason MC, Gray RJ, McLaughlin SA, Degnim AC, Fulmer JT, et al. A multisite validation trial of radioactive seed localization as an alternative to wire localization. Breast J 2008;14(2):153–7.
[12] Dauer LT, Thornton C, Miodownik D, Boylan D, Holahan B, King V, et al. Radioactive seed localization with 125I for nonpalpable lesions prior to breast lumpectomy and/or excisional biopsy: methodology, safety, and experience of initial year. Health Phys 2013;105(4):356–65.
[13] Loving VA, Edwards DB, Roche KT, Steele JR, Sapareto SA, Byrum SC, et al. Monte Carlo simulation to analyze the cost-benefit of radioactive seed localization versus wire localization for breast-conserving surgery in fee-for-service health care systems compared with accountable care organizations. AJR Am J Roentgenol 2014;202(6):1383–8.