

ORIGINAL ARTICLE – BREAST ONCOLOGY

Radioactive Seed Localization Compared to Wire Localization in Breast-Conserving Surgery: Initial 6-Month Experience

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ABSTRACT

Background. Wire localization (WL) of nonpalpable breast cancers on the day of surgery is uncomfortable for patients and impacts operating room efficiency. Radioactive seed localization (RSL) before the day of surgery avoids these disadvantages. In this study we compare outcomes of our initial 6-month experience with RSL to those with WL in the preceding 6 months.

Methods. Lumpectomies for invasive or intraductal cancers localized with a single ¹²⁵I seed (January–June 2012) were compared with those using 1 wire (July–December 2011). Surgeons and radiologists did not change. Positive and close margins were defined as tumor on ink and tumor ≤ 1 mm from ink, respectively. Demographic and clinical characteristics and outcomes were compared between RSL and WL patients.

Results. There were 431 RSL and 256 WL lumpectomies performed. Clinicopathologic characteristics did not differ between groups. Most seeds (90 %) were placed before the day of surgery. Positive margins were present in 7.7 % of RSL versus 5.5 % of WL patients, and 16.9 % of RSL versus 19.9 % of WL had close margins ($p = 0.38$). The median operative time was longer for lumpectomy and sentinel lymph node biopsy (SLNB) in the RSL group (55 vs. 48 min, $p < 0.0001$). There was no significant difference in the volume of tissue excised between groups.

Conclusions. In the first 6 months of RSL, operative scheduling was simplified, while rates of positive and close margins were similar to those seen after many years of experience with WL. Operative time was slightly longer for RSL lumpectomy and SLNB; we anticipate this will decrease with experience.

The widespread uptake of breast cancer screening, combined with improvements in imaging technology, has resulted in the frequent diagnosis of small nonpalpable breast cancers. Wire localization (WL) of nonpalpable cancers on the day of surgery is the most common localizing technique used when breast conservation is pursued, yet this procedure has several limitations. It is uncomfortable for patients, carries a risk of wire displacement or fracture during patient transportation from the radiology department to the operating table, and can result in delays or scheduling conflicts in radiology that impact operating room (OR) efficiency.^{1,2}

Techniques have been developed to replace wire localization. Ultrasound-guided lumpectomy directed at the hematoma (HUG) or a breast marker avoids preoperative localization, but requires surgeon training and a clearly visible hematoma or marker.^{3,4} Radio-guided occult lesion localization (ROLL) involves injecting ^{99m}Tc into the lesion the day before, or morning of, surgery.⁵ This can be combined with a technetium injection for sentinel lymph node (SLN) identification (SNOLL).^{5,6} Radioactive seed localization (RSL) positions a 4.5-mm ¹²⁵I seed in the breast tissue to be excised. Seeds have a half-life of 60 days, theoretically allowing insertion months prior to surgery if required (e.g., before neoadjuvant chemotherapy).^{7,8} The

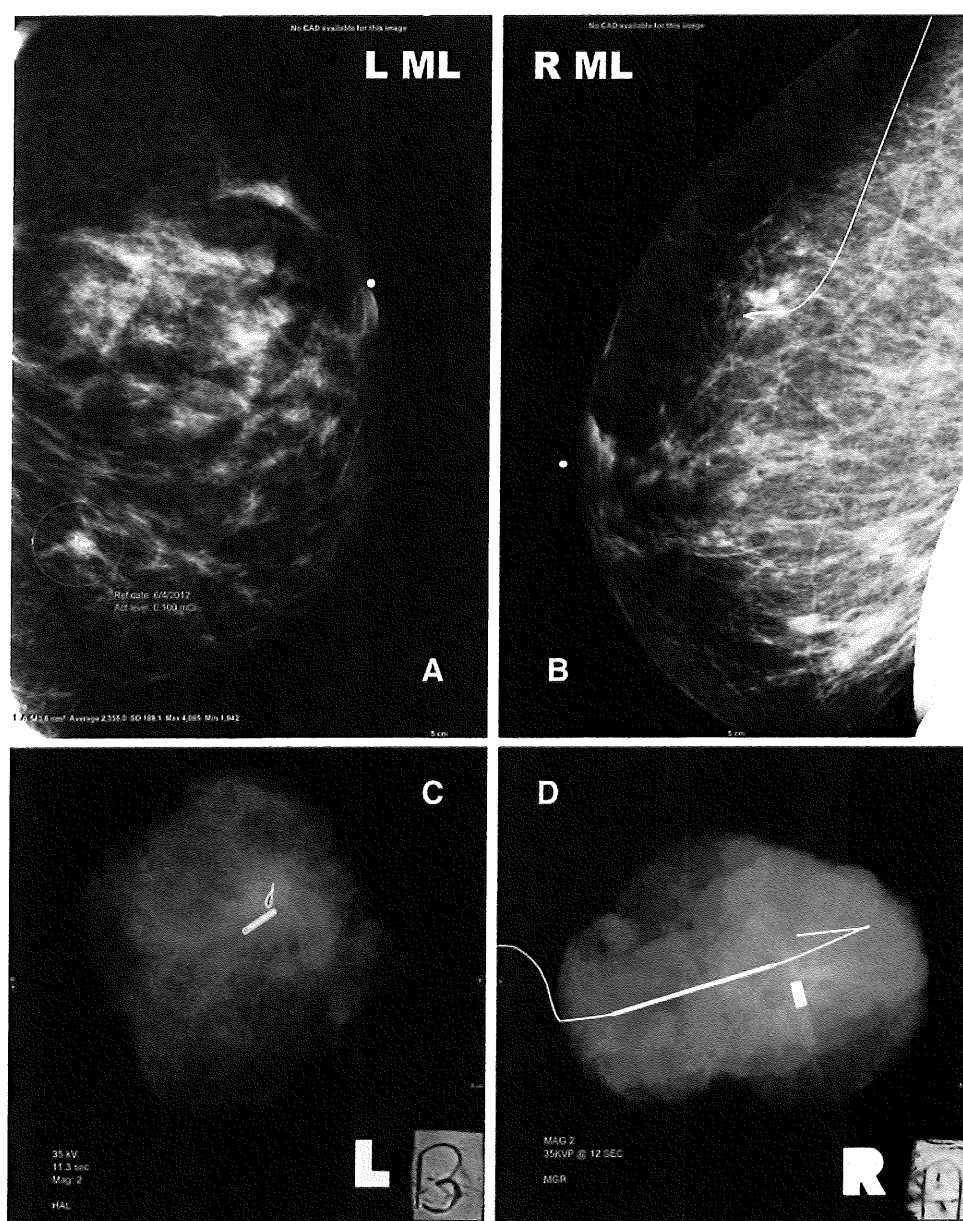
feasibility of RSL has been reported in institutional series.^{9,10} A small multicenter randomized control trial of WL versus RSL demonstrated no difference in the rates of positive or close margins ($p = 0.61$), but surgery was shorter following seed localization (mean, 19.4 vs. 22.2 min, $p < 0.001$).¹

In January 2012, the standard method of localizing nonpalpable breast lesions at Memorial Sloan-Kettering Cancer Center (MSKCC) changed from WL to RSL. The aim of this study was to compare our initial 6-month experience with RSL to our established practice of WL. The primary outcomes were the rates of positive and close margins, and the resulting rate of reoperation to improve margins between the 2 groups. Secondary outcomes were the lumpectomy volume and operative time.

PATIENTS AND METHODS

Following institutional review board approval, data were obtained from a prospectively maintained, registered database and patient electronic medical records. Patients with nonpalpable invasive breast cancer or ductal carcinoma in situ (DCIS) were eligible for inclusion if they were treated with breast-conserving surgery (BCS) at MSKCC and had localization performed with a single radioactive seed (January–June 2012) or a single wire (July–December 2011) (Fig. 1). Patients were excluded if they had more than 1 seed or wire inserted to localize a lesion, received neoadjuvant chemotherapy, had previous ipsilateral breast cancer, had multicentric cancer, or had stage IV breast cancer.

FIG. 1 Two 12-mm invasive ductal carcinomas excised following RSL or WL. **a** and **b** Mediolateral mammogram views performed following localization, demonstrating the radioactive seed and wire in position. **c** and **d** Specimen X-ray performed following the RSL and WL lumpectomies. *RSL* radioactive seed localization, *WL* wire localization



The surgeons and radiologists at our institution did not change between study time periods. Surgery was performed by 10 specialized breast surgeons. In December 2011, to facilitate the transition from WL to RSL, 2–4 initial cases of RSL were performed by each surgeon with a wire in place. The Node Seeker system and Gamma Probe (IntraMedical Imaging LLC, Los Angeles, CA), which detects both ^{99}Tc and ^{125}I , was used to perform the lumpectomy and SLN biopsy in RSL operations. During both study periods, lumpectomies were performed using the cavity shave approach, in which the index cancer was excised with a narrow margin of grossly normal breast tissue, and separate “shaved” margins were taken from the surgical cavity, oriented, and inked for evaluation.¹¹

The tumor size, histologic type, grade, occurrence of lymphovascular invasion (LVI), and the presence of DCIS or an extensive intraductal component (EIC) were acquired from the pathology report. Estrogen receptor (ER), progesterone receptor (PR), and HER2/neu status were also obtained. Microinvasion was defined as a focus of invasive carcinoma measuring <1 mm in size. An EIC was defined as the presence of intraductal carcinoma that was greater than 25 % of the invasive tumor mass and that was also present outside of the invasive tumor. The size of DCIS was approximated from the radiological size on preoperative imaging. Positive and close margins were defined as tumor on ink, and tumor ≤ 1 mm from ink, respectively.

The volume or weight of the lumpectomy specimen is not measured as part of routine pathology evaluation; however, the dimensions of the excised specimen are recorded. Hence, the volume of the initial excision was estimated using the formula for the volume of an ellipsoid: $\frac{4}{3} \times \pi \times \frac{1}{2} \text{ length} \times \frac{1}{2} \text{ width} \times \frac{1}{2} \text{ height}$. The operative time was obtained from the electronic operative record that detailed the start and finish times; cases where bilateral or additional procedures were performed were excluded from the operative time analysis.

Demographics, clinical factors, and outcomes were compared between the RSL and WL groups using χ^2 tests for categorical variables and Wilcoxon tests for continuous variables. A 2-tailed statistical analysis was performed using SAS version 9.1 (SAS Institute, Cary, NC), and p values less than 0.05 were considered statistically significant.

RESULTS

A total of 687 patients were included in the study; 431 had RSL from January to June 2012, and 256 had WL from July to December 2011. A considerable number of patients who had surgery from July to December 2011 were excluded because multiple wires were used for localization,

TABLE 1 Patient population examined in the RSL and WL groups

	January–June 2012	July–December 2011
Number of cancers localized	467	379
Excluded		
Transition: seed + wire	NA	34
Multiple wires/seeds	10	78
Previous ipsilateral cancer	13	3
Neoadjuvant therapy	13	4
Wire for re-excision	NA	4
Number included in study	431 (seed group)	256 (wire group)

RSL radioactive seed localization, WL wire localization, NA not applicable

or because during the transition period, both a seed and a wire were used for localization (Table 1). Localization prior to the day of surgery was performed for 90 % of the RSL group (median, 1 day preoperatively; range, 0–47 days); all wires were inserted on the morning of surgery.

There were no significant differences in the baseline characteristics of the patients in the 2 groups (Table 2). The median age at surgery did not differ and was approximately 60 years in both groups. Three-quarters of patients had surgery for an invasive carcinoma, and >80 % of invasive carcinomas were infiltrating ductal carcinomas. The median tumor size was 11 mm in each group. Approximately half of the invasive cancers were high grade, LVI was present in 20 %, and DCIS was present in >75 % of cases. For patients with DCIS \pm microinvasion, the median radiological size of DCIS was 10 mm in each group, and the nuclear grade was low or intermediate in nearly 70 % of cases.

The outcomes of the RSL and WL operations are shown in Table 3. The rate of positive margins (7.7 vs. 5.5 %) and close margins (16.9 vs. 19.9 %) were not different between the RSL and WL groups ($p = 0.38$). Reoperation to improve the margin of excision was performed in 23.0 % of patients in the RSL group and in 22.3 % of patients in the WL group ($p = 0.83$). Similarly, there was no significant difference in the initial lumpectomy volume between the RSL group and the WL group (median, 21.2 cm³; range, 0.2–311.0 cm³ vs. median, 19.0 cm³; range, 0.9–197.9 cm³; $p = 0.074$). Of note, this calculated volume did not include the separate cavity-shaved margins that were excised after removal of the seed or wire and should not have been influenced by the localization method used.

The operative time could be assessed accurately for 403 RSL operations and for 247 WL operations. For lumpectomy alone ($n = 142$), there was no difference in the

TABLE 2 Clinical and pathologic characteristics of the patients in RSL and WL groups

Characteristic	Seed group (<i>n</i> = 431)		Wire group (<i>n</i> = 256)		<i>p</i> value
	No.	%	No.	%	
Age; years, median (range)	59.7 (26.8–92.3)		60.8 (30.6–86.1)		0.31
Tumor type					0.28
Infiltrating ductal	261	60.6	169	66.0	
Infiltrating lobular (ILC)	43	10.0	18	7.0	
Infiltrating other	24	5.6	11	4.3	
DCIS + microinvasion	11	2.6	11	4.3	
DCIS	92	21.3	47	18.4	
<i>Infiltrating carcinoma</i>	(<i>n</i> = 328)	76.1	(<i>n</i> = 198)	77.3	
Tumor size; mm, median (range)	11.0 (1.0–41.0)		11.0 (1.5–30.0)		0.44
T1	300	91.5	176	88.9	0.33
T2	28	8.5	22	11.1	
Tumor grade					0.57
Not assessed/ILC	36	11.0	19	9.6	
I	50	15.2	29	14.6	
II	88	26.8	47	23.7	
III	154	47.0	103	52.0	
LVI present	69	21.0	37	18.7	0.52
DCIS					0.32
No DCIS	75	22.9	35	17.7	
DCIS present	232	70.7	147	74.2	
EIC	21	6.4	16	8.1	
Receptor subtype					0.90
ER/PR+, HER2–	287 (323) ^a	88.9	173 (197) ^a	87.8	
ER/PR+, HER2+	12 (323) ^a	3.7	8 (197) ^a	4.1	
ER/PR–, HER2+	5 (323) ^a	1.5	2 (197) ^a	1.0	
Triple negative	19 (323) ^a	5.9	14 (197) ^a	7.1	
LN metastases					0.45
Not assessed	6	1.8	2	1.0	
0	262	79.9	166	83.8	
1 or 2	52	15.9	24	12.1	
≥3	8	2.4	6	3.0	
DCIS (± microinvasion)	(<i>n</i> = 103)	23.9	(<i>n</i> = 58)	22.7	
Radiological size; mm: median (range)	10.0 (2.3–55.0)		10.0 (1.2–50.0)		0.61
Nuclear grade					0.51
Low	24	23.3	10	17.2	
Intermediate	46	44.7	31	53.4	
High	33	32.0	17	29.3	

RSL radioactive seed localization, WL wire localization, *T* tumor, *ILC* infiltrating lobular carcinoma, *LVI* lymphovascular invasion, *DCIS* ductal carcinoma in situ, *EIC* extensive intraductal component, *ER*+ estrogen receptor positive, *PR*+ progesterone receptor positive, *HER2*+, *HER2/neu* amplified, *LN* lymph node

^a Some patients were missing receptor status variables. Denominators reflect number of patients with data available

operative time between the RSL and WL groups (median, 31 min; range, 16–72 min vs. median, 33 min; range, 21–66 min; *p* = 0.18). The same was true for lumpectomy and axillary lymph node dissection (ALND) (*n* = 11), (median, 80 min; range, 62–105 min vs. median, 68 min; range, 50–150 min; *p* = 0.86). For lumpectomy and SLNB (*n* = 497), operative time was significantly longer for the RSL group than the WL group (median, 55 min; range, 29–140 min vs. median, 48 min; range, 12–110 min; *p* < 0.0001).

DISCUSSION

The ability to accurately localize nonpalpable lesions with a “wire” revolutionized breast cancer surgery after its first description in 1965.¹² The procedure, however, requires patients to first report to the radiology department for localization and await transportation to the OR with a wire protruding from the breast, which is often uncomfortable and carries a small risk of dislodgement or fracturing. The need for same-day localization also

TABLE 3 Outcomes of patients in the RSL and WL groups

Outcome	Seed group (<i>n</i> = 431)		Wire group (<i>n</i> = 256)		<i>p</i> value
	No.	%	No.	%	
Margin status					
Clear	325	75.4	191	74.6	0.38
Tumor on ink	33	7.7	14	5.5	
Close (≤ 1 mm from ink)	73	16.9	51	19.9	
Reoperation to improve margins	99	23.0	57	22.3	0.83
	No.	Median (range)	No.	Median (range)	
Initial lumpectomy volume (cm ³)	429	21.2 (0.2–311.0)	256	19.0 (0.9–197.9)	0.074
Operative time (min)					
All procedures	403	50 (16–140)	247	45 (12–150)	
Lumpectomy alone	96	31 (16–72)	46	33 (21–66)	0.18
Lumpectomy + SLNB	301	55 (29–140)	196	48 (12–110)	<0.0001
Lumpectomy + ALND	6	80 (62–105)	5	68 (50–150)	0.86

RSL radioactive seed localization, WL wire localization, SLNB sentinel lymph node biopsy, ALND axillary lymph node dissection

typically precludes placing such an operation as the first case on the OR schedule, and additional delays related to difficult wire placements or syncope during wire localization often interfere with OR efficiency, particularly at institutions with a high daily volume of localization procedures.

Following the introduction of RSL at our institution, 90 % of localizations were performed prior to the day of surgery, simplifying OR scheduling and minimizing patient inconvenience on the morning of surgery. In addition, as it is our practice to perform the radioisotope injection (⁹⁹technetium) for SLNB on the day prior to surgery, seed placement was scheduled on the same day as the isotope injection to minimize patient travel whenever possible. Same-day RSL was reserved for patients who were unable to travel to the hospital prior to surgery. The 10 participating surgeons felt that RSL simplified operative scheduling and patient flow in the operating room. Although not directly measured in our study, others have reported that the pain of the localization is similar between RSL and WL; yet patients reported that RSL was more convenient.^{13,14} In a small Canadian randomized controlled trial, using a Likert scale, patients rated RSL less painful than WL; however, a similar level of anxiety was experienced by both patient groups.¹

The primary outcome of this study was to compare our rates of complete excision of nonpalpable breast cancers localized with RSL versus WL. Characteristics known to influence the likelihood of positive margins, including tumor size, presence of an EIC, or pure DCIS, did not differ significantly between groups. No significant differences in completeness of excision related to localization technique

were observed, in spite of the fact that surgeons had many years of experience with WL and were in the initial 6 months of using RSL. Negative margins, defined as tumor not touching ink, were obtained at initial excision in 92.3 % of RSL cases and 94.5 % of WL cases. Close margins were present in 16.9 and 19.9 %, respectively. In their multicenter randomized controlled trial, Lovrics et al.¹ compared the outcome of 152 patients allocated to RSL and 153 patients allocated to WL for breast cancer. An intention-to-treat analysis was performed; however, 21 patients (14 %) randomized to the RSL group had WL performed, 3 of whom had both RSL and WL. In contrast to the eligibility criteria for our study, more than 1 seed or wire was used to perform localization in 9.9 and 13.7 % of cases, respectively. The rate of positive and close margins in this study also did not differ significantly by localization method. In the Netherlands, a retrospective comparison of RSL in 71 patients and ROLL in 83 patients following neoadjuvant chemotherapy has recently been performed. Positive pathological margins were found in 13 % of both the RSL and ROLL groups, and the rate of reoperation was similar, at 8 and 7 %, respectively.¹⁵

We also found no significant difference in lumpectomy specimen volume based on localization technique, similar to the Canadian randomized trial of RSL versus WL in which both the specimen volume and weight did not differ by localization technique.¹

The median operative time for patients in the RSL group was 5 min longer than for those in the WL group. However, operative times for lumpectomy alone or lumpectomy with ALND did not differ between groups. The median time to perform lumpectomy with SLNB was 7 min longer

in RSL patients than in WL patients (median, 55 min vs. median, 48 min, $p < 0.0001$), suggesting that this difference was related to the logistics of the probe used for both RSL and sentinel node detection. Prior to seed localization, the C-Trak system (Care Wise Medical, Morgan Hill, CA), with a simple on/off switch, was used for SLNB. The Node Seeker system, which detects both ^{125}I and $^{99\text{m}}\text{Tc}$ (IntraMedical Imaging LLC, Los Angeles, CA), has a complex operating system that requires a longer startup time, and the settings must be changed between the lumpectomy and SLNB procedures. In contrast to our experience, Lovrics et al.¹ found that the mean operative time was shorter for RSL than WL (19.4 vs. 22.2 min, $p < 0.001$). However, it is unclear how these operative times were obtained; following initial lumpectomy, the specimen radiograph was used to direct cavity re-excision in 47 % of operations, and almost all (98 %) patients had a SLNB or ALND performed.

Radiation safety issues related to the process of RSL in our institution are overseen by the Radiation Safety Service, Department of Medical Physics, and these have recently been described.^{16,17} The RSL program licensing required routine and emergency training of all persons involved in handling of seeds. An inventory log (database) tracked the receipt, storage, radiological implantation, surgical excision, explantation in pathology, and decay in storage of all seeds.¹⁷ The median seed radioactivity at the time of implantation was 83 μCi , and the median dose rate from patients with a single seed was 9.5 $\mu\text{Sv/h}$ at contact and 0.5 $\mu\text{Sv/h}$ at 1 m. The low dose of radioactivity associated with RSL has been previously shown: With a mean excision of 4 cm of breast tissue, the maximum dose to residual breast tissue approximates that of a 2-view mammogram.¹⁸ In general, seed placement occurred within 1 week of surgery. In 2 patients, surgery was performed 30 and 47 days after placement because of acute medical conditions necessitating postponement of surgery. Both seeds were retrieved without incident. Adverse events related to RSL were not encountered during this study, but have occurred in our institution. Technical difficulties during radiological seed placement required additional wire localization in 1 case, 1 seed used to localize an axillary lymph node could not safely be retrieved and was left in situ, and 1 seed was dropped and temporarily lost during pathological explanation.^{16,17} During surgical excision, care must be taken when using suctioning or surgical sponges close to the specimen to avoid unintentionally displacing the seed.

In summary, during the first 6 months of RSL in our institution, 90 % of localizations were performed prior to the day of surgery, the rates of positive and close margins did not differ from those seen following many years of experience with WL, and specimen volume was not significantly increased. A minimal increase in operating time was seen in

RSL patients undergoing both lumpectomy and SLNB, which we anticipate will decrease as surgeons and nursing staff become familiar with the new equipment. The 10 participating surgeons felt that RSL simplified operative scheduling and patient flow in the operating room.

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CONFLICT OF INTEREST None.

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