Radioactive Seed Localization of Nonpalpable Breast Lesions

Description

Radioactive seed localization is used to locate nonpalpable breast lesions, which have become more common with increasing use of breast cancer screening in asymptomatic women. This technique is used to target breast-conserving surgery (BCS) or excisional biopsies, or to identify the location of the original cancer after neoadjuvant chemotherapy. A radiologist places a titanium “seed” containing radioactive iodine-125 ($^{125}\text{I}$) with an 18-gauge needle using ultrasound, mammography, or stereotactic guidance. The surgeon then locates the seed and the breast tissue that needs to be removed, using a gamma probe. Alternative methods to localize nonpalpable breast lesions include wire localization, the traditional approach, or radioguided occult lesion localization.

Background

More nonpalpable lesions are currently detected (about 25% to 35% of breast cancers at diagnosis) due to the increased use of breast screening in asymptomatic women. These nonpalpable lesions require a localization technique to perform excisional biopsies or breast-conserving surgery (ie, lumpectomy).

Radioactive seed localization on nonpalpable breast lesions uses radio-opaque titanium seed(s) containing radioactive $^{125}\text{I}$. These seeds are inserted by a radiologist using ultrasound or stereotactic guidance to identify the location of a nonpalpable breast lesion. They may be placed several days or weeks before surgery. The surgeon then uses a gamma probe to locate the radioactive seed and remove it with surrounding tissue. One study mentioned that the radiation dose associated with the $^{125}\text{I}$ seeds (0.29 mCi) was less than for a mammogram or chest radiograph. The range of radioactive dose in one group of studies ranged from 3.7 to 10.7 MBq (one megabecquerel [MBq] = 0.027 mCi). (1, 2) Seeds were 4.5 x 0.8 mm, which has been described as similar to a grain of rice. The half-life of $^{125}\text{I}$ is 60 days and $^{125}\text{I}$ is a 27-keV source of gamma radiation. (3) It can be detected on a different signal than the 140-keV technetium-99 ($^{99}\text{Tc}$) that may be used for sentinel lymph node biopsy. Once the radioactive seed is removed, its presence in the tumor specimen is confirmed using the gamma probe. Lack of radioactivity in the tumor cavity is also assessed to ensure that the radioactive seed has not been left in the breast. A disadvantage of radioactive seed localization is that special procedures must be followed to safely handle and track the radioactive seed before placement and after excision. In 1 public hospital (ie, in clinical practice), a seed was lost after excision, and procedures were changed to prevent recurrence.
Radioactive seed localization may also be used to guide excision after neoadjuvant chemotherapy, which is performed primarily in women with locally advanced cancer in an effort to shrink the tumor. A proportion of these women (25% to 32%) are then able to have BCS rather than mastectomy. The challenge is that if there is a complete clinical and radiological response, it may be difficult to localize the original tumor bed. Pathologic confirmation of response is needed since there is residual microscopic cancer in about half of these patients. Radioactive seed localization can mark the tumor location before beginning neoadjuvant chemotherapy.

The traditional localization method for nonpalpable breast lesions is image-guided wire localization. This approach has limitations including the following: the wire can bend or be displaced (since the wire protrudes from the breast); there may be scheduling issues, because the wire should be placed on the same day as the surgery; and the radiologist may follow a different route to place the wire than the surgeon does to excise the lesion, which may make it more difficult to locate all of the lesion and may worsen cosmetic outcomes. The percentage of cases with positive margins following wire localization is 14% to 47%.

An alternative developed in the late 1990s is radioguided occult lesion localization (ROLL). First, a twist marker is placed in the breast to mark the tumor. Before surgery, a liquid radioactive radiotracer (Tc-99) is injected next to the twist marker using image guidance. Again, the surgeon uses a gamma probe to locate the radiotracer and guide the incision. The main disadvantage of this approach is that the radiotracer has a short half-life of about 6 hours. It also does not provide a point source of radiation as radioactive seed localization does. An advantage is that Tc-99 also may be used for sentinel lymph node biopsy, so the same radiotracer is used for both purposes. Alternatively, a radioactive seed and Tc-99 for sentinel lymph node biopsy can also be used concurrently.

A final alternative is intraoperative ultrasound-guided resection, although it is discussed less frequently in this literature. It can only be used when the lesion is detectable using ultrasound. No studies comparing this approach with radioactive seed localization were found.

Radioguided seed localization was first tested in a randomized trial in 2001. Based on the number of publications and systematic reviews, there appears to be increased interest in this technique since approximately 2010.

**Regulatory Status**

The BrachySciences Radioactive Seed Localization Needle with AnchorSeed™ (Biocompatibles, Inc., Oxford, CT) received 510(k) marketing approval on October 18, 2011 (K111979). This device is indicated for the localization of suspicious tissues (non-palpable lesions) for excision with the use of radioactive seeds.

On December 19, 2012, the Best® Localization Needle with I-125 Seed received 510(k) marketing clearance (K122704). This device is indicated for breast localization under the direct supervision of a qualified physician. It consists of an iodine-125 seed and an 18-gauge 5-cm to 20-cm needle.
These devices are not always used for radioactive seed localization. Radioactive seeds approved for another indication (ie, off-label) may also be implanted with an 18-gauge needle. These seeds were initially approved for permanent implantation (ie, brachytherapy) in selected localized tumors such as prostate cancer. These seeds use I-125 beads (activity from 0.1 to 1.0 mCi) encapsulated in a titanium tube. An example is International Isotopes Inc. I3RAD I-125 Seed, which received 510(k) marketing clearance September 21, 1999 (K992963). FDA Product code: KXK

Related Policies

None

Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Radioactive seed localization of nonpalpable breast lesions may be medically necessary. It is expected to result in outcomes that are equivalent to alternatives such as wire localization or radioguided localization.

Rationale

Two randomized controlled trials (RCTs) compared radioactive seed localization to wire localization among patients scheduled for breast-conserving surgery or excisional biopsy. (1, 4) Gray et al (2001) randomized 97 U.S. women with nonpalpable breast lesions to radioactive seed localization (n=51) or wire localization (n=47). (1) The method of randomization was not reported. Fifty-six patients underwent excisional biopsies for suspicious lesions that were judged inappropriate for percutaneous biopsy techniques, and 41 patients with a confirmed diagnosis of breast cancer by core needle biopsy had BCS (47% of radioactive seed localization patients and 37% of wire localization patients). On imaging, 42 patients had calcification and 55 had a density. Both wire localization and radioactive seed localization were performed using ultrasound or mammography guidance. Surgery was performed up to 5 days later. Radiologists and patients rated the difficulty of the procedure following localization on a Likert scale from 1 (easiest) to 10 (most difficult), while the surgeons completed the same task after excision. Margins were considered to be positive if imprint cytology of the margins demonstrated malignant cells or if final histology demonstrated malignant cells <1 mm from any margin; only malignant tumors were included.

Fifty-two patients had invasive carcinoma; 9 had ductal carcinoma in situ; and 36 had benign lesions. There was no statistically significant difference in the number of patients with radioactive seed localization versus wire localization within each category. Outcomes for both localization techniques were the same for migration of the localization device (ie, seed or wire); ability to locate the lesion during surgery; time for radiographic localization and for surgical excision; subjective ease of procedure for radiologists, patients, or surgeons; and volume of tissue removed. Specimen radiographs were used with wire localization but not with radioactive seed localization. There were
fewer positive margins with radioactive seed localization than with wire localization (26% vs. 57%, p=0.02).

The second RCT published in 2011 was conducted at 3 Canadian sites and had a sample size of 205. (4) Participants had nonpalpable early stage breast cancer and were undergoing BCS. Randomization to radioactive seed localization or wire localization was centralized, concealed, and stratified (by surgeon for 7 surgeons). The 2 groups were similar except that multifocal disease was more common in the radioactive seed localization patients. Mean age was 60.9 years for the radioactive seed localization arm and 59.9 years for the wire localization arm. Exclusion criteria included male patients, pregnancy or lactation, multicentric or locally advanced disease, lobular carcinoma in situ (LCIS) only, and contraindications for BCS. Localization was performed using mammography or ultrasound on the day of surgery. Tumor location was confirmed using 2-view mammography. An intention-to-treat analysis was performed, and the power calculation was reported: A sample size of 333 patients could detect a 15% difference in positive margins across arms with 80% power and a 5% significance level.

In the radioactive seed localization arm, 18 patients had wire localization: 6 because the seed was not available at surgery; 3 because the seed would not deploy; and 2 because the seed was displaced. For 7 patients, no explanation was provided. In 3 cases, wire was added to seed localization to bracket larger lesions. One seed migrated, and 2 wires did. One wire fell out during surgery.

All index lesions were removed. There were no between-group differences except the following: mean operative time was shorter for radioactive seed localization (19.4 min vs 22.2 min, respectively; p<0.001); surgeons found excision after radioactive seed localization easier (p=0.008), and patients found radioactive seed localization less painful (p=0.038). However, there was no statistically significant difference in patients’ anxiety level. There were no between-group differences in proportion of positive margins (10.5% for radioactive seed localization vs. 11.8% for wire localization) or reoperation rates. Results for positive margins were similar when the analysis was rerun based on the treatment patients received (per protocol analysis). Also, the percentage of positive margins was higher for ductal carcinoma in situ (DCIS) than for invasive cancer (20.4% vs. 9.2%; p=0.020). A related study analyzed factors associated with positive margins, including localization under stereotactic guidance, in situ disease, large tumor size, and multifocal disease. (5)

A retrospective analysis from the Netherlands compared radio-guided occult lesion localization (ROLL) using technetium-99 (Tc-99) with radioactive seed localization using ultrasound guidance for seed placement. (6) Mammography was used to confirm correct placement of the twist marker or seed. Patients then had neoadjuvant chemotherapy and BCS with wide local incision. Before surgery, patients underwent contrast-enhanced magnetic resonance imaging (MRI); those without enhancement in the original tumor area were considered complete radiologic responders and had more limited excision to confirm complete pathologic response. (Carcinoma in situ was not counted.). With ROLL, after injection of the radiotracer, scintigraphy with a dual-head gamma camera was performed to verify correct placement of the tracer. Radiologists and surgeons reported the time for each procedure and the level of difficulty on a Likert scale from 1 (no difficulty) to 5 (very difficult); patients reported pain and anxiety on a Likert scale from 0 (no pain) to 6 (severe pain).
After neoadjuvant chemotherapy, 24 patients had palpable lesions or a different localization method was performed. ROLL (n=83) or radioactive seed localization (n=71) was performed in 154 patients. No complications occurred during the localization procedure. For patients undergoing the ROLL technique, 51% had complete radiologic response, and 30% had complete pathologic response. For patients with radioactive seed localization, 51% had complete radiologic response, and 38% had complete pathologic response. Weight of the excised specimen was similar between groups. Thirteen patients in each group had positive pathologic margins. Six patients in each group underwent further surgery, either additional local excision (1 ROLL patient and 3 radioactive seed localization patients) or mastectomy (5 ROLL patients and 3 radioactive seed localization patients). Other patients who had positive margins underwent adjuvant radiotherapy with a boost to the original tumor bed. There were no major postoperative complications in either group, with a median follow-up of 51 months (range, 5-67). After a mean follow-up of 22 months (range, 4-45 months), 6 (7%) of 83 ROLL patients had disease recurrence (including 1 DCIS local recurrence) and died due to metastatic disease. Eight (11%) of 71 patients undergoing radioactive seed localization developed metastatic disease and died within 24 months of follow-up; no isolated local recurrences occurred.

The 3 studies described are summarized in Table 1.

Table 1. Summary of 3 Radioactive Seed Localization Studies

<table>
<thead>
<tr>
<th>Measure</th>
<th>Gray 2001 (1)</th>
<th>Lovrics 2011 (4)</th>
<th>Donker 2013 (6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comparison</td>
<td>RSL vs. WL (randomized)</td>
<td>RSL vs. WL (RCT)</td>
<td>RSL vs. ROLL (nonrandomized)</td>
</tr>
<tr>
<td>Patient population</td>
<td>Undergoing excisional biopsy or BCS</td>
<td>Undergoing BCS</td>
<td>Undergoing BCS after neoadjuvant chemotherapy with complete or partial response</td>
</tr>
<tr>
<td>Sample size</td>
<td>97*</td>
<td>205**</td>
<td>154</td>
</tr>
<tr>
<td>Mean/median age (yrs.)</td>
<td>NR</td>
<td>RSL: 60.9; WL: 59.9</td>
<td>RSL: 49; ROLL: 50</td>
</tr>
<tr>
<td>Migration of localization device</td>
<td>No substantial migration for RSL or WL</td>
<td>RSL: 1 seed WL: 2 wires and 1 wire fell out</td>
<td>NR</td>
</tr>
<tr>
<td>Removal of suspicious lesion</td>
<td>100% for both</td>
<td>100% for both</td>
<td>100% for both</td>
</tr>
<tr>
<td>Volume of extracted tissue</td>
<td>NS (RSL, 55.7 ml; WL, 73.5 ml)</td>
<td>NS(RSL, 191.1 cc; WL,183.8 cc)</td>
<td>NS (RSL, 48 g; ROLL, 53 g)</td>
</tr>
<tr>
<td>Time for localization (min)</td>
<td>NS</td>
<td>NS</td>
<td>NR</td>
</tr>
<tr>
<td>Time for surgery (min)</td>
<td>NS</td>
<td>RSL, 19.4; WL, 22.2; p&lt;0.001</td>
<td>NR</td>
</tr>
<tr>
<td>Retrieval of titanium seed (RSL)</td>
<td>100% (without specimen radiograph)</td>
<td>NR but mean time = 2.3 min (SD=3.8 min); (with specimen radiograph)</td>
<td>100% (with specimen radiograph)</td>
</tr>
</tbody>
</table>
Eighteen patients in the RSL arm received wire localization because the seed was not available (n=6) or the seed could not be placed (80% of these 12 occurred among radiologists with limited experience early in the trial). In another 3 patients, a wire was placed with the seed to bracket larger lesions.

Patient withdrew, management changed (to mastectomy or no surgery), surgery performed in hospital without approval from REB (not defined but presumably Research Ethics Board in Canada).

** Eighteen patients in the RSL arm received wire localization because the seed was not available (n=6) or the seed could not be placed (80% of these 12 occurred among radiologists with limited experience early in the trial). In another 3 patients, a wire was placed with the seed to bracket larger lesions.

Additional comparative articles include one by Hughes et al (2008), who compared radioactive seed localization in 383 patients to wire localization performed previously in 99 patients with nonpalpable lesions undergoing breast procedures. (2, 7) Patients were from 3 sites of the same institution. Seed migration more than 2 cm occurred in one patient, possibly due to a hematoma that developed after localization, and re-excision was performed during the initial surgery. Positive margins occurred in 27% of radioactive seed localization patients and in 46% of wire localization patients (p<0.001). Re-excision was undertaken in 8% of radioactive seed localization patients and in 25% of wire localization patients to achieve negative margins (p<0.001). Patients were asked to score the pain of the localization procedure and convenience of localization and surgery on a 10-point visual analog scale. Median pain scores were similar between groups (2.2 and 2.3; p=0.9). There were no major adverse effects, but 6 radioactive seed localization patients (2%) and 1 wire localization patient (1%) had wound infections.

Groups from 2 cancer centers in the U.S. reported on their experience with radioactive seed localization. Diego et al (2014) compared outcomes for 128 women who underwent radioactive seed localization and 196 women who underwent wire localization before excisional breast biopsy for nonpalpable high-risk lesions during 2 consecutive years at the University of Pittsburgh Medical Center. (8) Outcomes for excisional biopsies performed after radioactive seed localization during 1 year
(postlearning curve) were collected prospectively and compared with retrospective outcomes for excisional biopsies performed after wire localization by the same surgeons (n=4) during the previous year. In both groups, mean patient age was 54 years, and the most common high-risk lesions were atypical hyperplasia (58%) and papilloma (23%). Forty-one percent of radioactive seeds and all wires (100%) were implanted/placed the day of surgery; 44%, 2%, and 13% of radioactive seeds were implanted 1, 2, and 3 days before surgery, respectively. Mean specimen volume was less in the radioactive seed localization group compared with the wire localization group (mean [SD], 26 [22] cm vs 37 [33] cm; ANOVA, p=0.001). There was no statistical between-group difference in mean operating room time (27 minutes in both groups; analysis of variance [ANOVA], p=0.9), despite greater trainee presence in the radioactive seed localization group; proportion of patients with additional tissue removed after specimen radiograph (3% in both groups; chi-square, p=0.4); proportion of target lesions retrieved (99% in the radioactive seed localization group vs 98% in the wire localization group; chi-square, p=0.5); or the proportion of patients upstaged to carcinoma (5% in the radioactive seed localization group vs 6% in the wire localization group; chi-square, p=0.5). All implanted radioactive seeds were retrieved at surgery.

In a similar study, researchers from Memorial Sloan-Kettering Cancer Center compared outcomes for 431 women who underwent radioactive seed localization and 256 women who underwent wire localization before lumpectomy for invasive or intraductal cancers during 2 consecutive 6-month periods. (9) Outcomes for the radioactive seed localization group were collected prospectively during the first 6 months of use, and for the wire localization group, retrospectively during the previous 6 months. Surgeons (n=10) and radiologists did not change between study time periods. Median patient age was approximately 60 years in both groups (Wilcoxon test, p=0.31), and 77% of patients in both groups had invasive cancer. The proportion of patients with features known to impact the probability of positive margins, such as tumor size, presence of an extensive intraductal component, or pure DCIS, was similar between groups. Ninety percent of radioactive seeds were implanted the day before surgery, and all wires (100%) were placed the morning of surgery. There was no statistical between-group difference in the incidence of positive margins (tumor on ink) or close margins (≤1 mm from ink) (total 25% in both groups; chi-square, p=0.38); reoperations to improve margins (≈ 23% in both groups; chi-square, p=0.83); specimen volume (median [range], 21 cm³ [0.2-311] in the radioactive seed localization group vs 19 cm³ [0.9-198] in the wire localization group; Wilcoxon test, p=0.074); or operative time for lumpectomy alone (Wilcoxon test, p=0.18) or lumpectomy with axillary lymph node dissection (Wilcoxon test, p=0.86). Operative time for lumpectomy plus sentinel lymph node biopsy was longer in the radioactive seed localization group compared with the wire localization group (median [range], 55 minutes [29-140] vs 48 minutes [12-110]; Wilcoxon test, p<0.001), which was attributed to use of a more complex probe capable of detecting both I-125 and T-99.

Rao et al (2010) reported on their experience in using radioactive seed localization in a public hospital, in a retrospective matched-pair analysis of patients undergoing wire localization during the same period. (10) One seed was lost after excision (ie, it was not in the excised specimen) and was assumed discarded in the surgical drapes or suctioned into the suction canister and discarded. Procedures were changed after this event to prevent recurrence. The study reported on 50 successful seed localizations in cancer patients and the matched controls. All seeds were recovered, and there was no seed migration. The re-excision rate was 42% for radioactive seed localization and 54% for wire localization.
This difference was not statistically significant (p=0.46), which the authors attributed to small sample size.

In addition to these comparative studies, several single-arm studies report on radioactive seed localization. (11-15) Gobardhan et al (2013) examined the use of radioactive seed localization in 85 patients undergoing neoadjuvant chemotherapy and BCS for invasive cancer. (11) Another 4 patients independently requested mastectomy, and 8 were scheduled for mastectomy based on tumor characteristics; they are not included in the analysis. Thirty-two of 85 patients had multifocal tumors; 23 patients had more than 1 seed placed. Seeds were in place for a median of 4 months (range, 0-8). All patients received radiotherapy after BCS, and some received hormonal therapy or trastuzumab, as appropriate. After chemotherapy, 26 patients achieved clinically CR, and 51 PR. No residual tumor, ie, pathologically CR, occurred in 19 patients (36%), and resection was microscopically complete in 78 patients (92%). Four patients had focally involved margins and had a higher radiation boost to the tumor bed; 3 patients had extensively involved margins and had mastectomies. No re-excisions were performed, nor were there any wound healing problems. At a mean follow-up of 11 months, there were no local recurrences.

McGhann et al (2011) reported on a retrospective review of 1,000 consecutive radioactive seed localizations in 978 patients following percutaneous biopsy at a single U.S. institution. (12) Some of these cases were reported by Hughes et al (2008). (2) Breast surgery was performed by 3 surgeons. Based on final pathology, 55% of the lesions were invasive cancer; 22%, DCIS; 11%, atypical hyperplasia; and 13%, benign pathologic lesions. In 46% of cases, intraoperative re-excision was performed based on surgeon or pathologist opinion. Fifteen percent of cancer cases underwent a second procedure for re-excision when the final margins were <2mm. At mean follow-up of 33 months (range, 0.03-90.6), 9 patients experienced a local recurrence; there were no regional or distant recurrences. Of 1148 seeds deployed, there was seed displacement during successful lesion excision for 30; vasovagal response on seed deployment for 4; failure to deploy seed properly on first attempt for 3; and for 1 each, wrong incision or seed migration preoperatively. All radioactive seeds were retrieved.

Van Riet et al (2010) reported on radioactive seed localization among 325 consecutive women with nonpalpable, biopsy-confirmed breast cancer. (14) Women with DCIS on core biopsy were excluded. Seed localization failed in 3 women and was redone successfully on the second attempt. The seed was dislodged during surgery in 6 patients, 4 of whom underwent re-excision after specimen radiology. Complete resection was accomplished in 310 procedures, while 15 had positive margins.

A 2011 study of seed migration after radioactive seed localization found that in 45 patients with radioactive seeds in situ for 59.5 days on average (range, 3-136 days), mean standard deviation (SD) seed migration was 0.9 mm (SD=1.0 mm). (16) Cox et al assessed whether specimen radiographs are required during breast surgery or biopsy after radioactive seed localization. (17) These radiographs are routinely used during surgery after wire localization to ensure that the suspected lesion has been excised. The aim of the study was to demonstrate that specimen radiographs are not needed with radioactive seed localization when the seed is within 1 cm of the lesion, the surgeon removed the seed without dislodging it from the tissue, and the pathologist can grossly identify the lesion and retrieve the
seed. In an analysis of 124 women (142 lesions), specimen radiographs were performed on 32 lesions. This occurred more often with microcalcifications than with masses and in women undergoing excisional biopsy than in those having BCS.

Authors overlap in 6 of the studies previously discussed. (1, 2, 7, 12, 17, 18)

A meta-analysis of radioactive seed localization versus wire localization included both of the randomized studies previously discussed (although for unstated reasons, the authors categorized Gray et al (2001) (1) as a cohort study with a control group) and 3 other cohort studies with control groups. (19) The authors noted that the quality of the studies was limited, with only 1 RCT, and cohort studies with retrospective wire localization control groups. (1, 2, 4, 7, 10) Two outcomes had moderate but statistically insignificant heterogeneity at the 0.05 level. Fixed effect models were used in all cases. The results are as follows: Positive margins for wide local incision are significantly less likely for radioactive seed localization versus wire localization (odds ratio [OR], 0.51; 95% confidence interval [CI], 0.36 to 0.72; p<0.001) for 5 trials. Reoperations were less likely for radioactive seed localization (OR, 0.47; 95% CI, 0.33-0.69; p<0.001) for the 4 trials included. Shorter surgery is significantly more likely using radioactive seed localization versus wire localization (mean difference, –1.32 min; 95% CI, –2.32 to –0.32; p=0.01) for the 2 trials included. Based on 2 trials, there was no statistically significant difference in the volume of breast tissue excised during surgery (mean difference, 1.46 cm³; 95% CI, –22.35 to 25.26; p=0.90). Results of this meta-analysis should be interpreted with caution given the quality of the included studies. Barentsz et al (2013) conducted a systematic review of 6 studies, all previously discussed. (20)

Section Summary: The highest quality study on the use of radioactive seed localization versus another localization technique is the randomized controlled trial by Lovrics et al. (4) The study was unblinded, given the obvious nature of the different techniques. Results showed no statistically significant differences between the 2 techniques, except for a slightly shorter time to perform radioactive seed localization, less difficult excisions reported by surgeons, and reduced pain (but not anxiety) reported by patients. A smaller randomized study by Gray et al 2001 reported significantly fewer positive margins, but other metrics in Table 1 did not differ statistically between modalities or were not reported. (1) More favorable results for radioactive seed localization (ie, fewer positive margins or re-excisions) were reported inconsistently in other studies and may have been impacted by tumor characteristics. Therefore, the comparative performance of radioactive seed localization versus wire localization or radioguided occult lesion localization can be assessed reliably only in randomized trials. The limited evidence does not demonstrate a difference in performance between radioactive seed localization and either wire localization or, with more limited evidence, radioguided occult lesion localization.

Ongoing Clinical Trials

Online site ClinicalTrials.gov currently lists 1 active, open-label trial of radioactive seed localization (NCT01901991). Patients at a single center in Denmark who have a nonpalpable breast lesion (carcinoma in situ or invasive carcinoma) will be randomized 1:1 to wire-guided localization (with ultrasound or mammography guidance) or radioactive seed localization (with ultrasound guidance). Lesion localization will be confirmed by mammography in both treatment arms. Outcomes include
reoperation rates, amount of excised tissue, and breast surgery duration. Estimated enrollment is 410 patients, and expected completion date is April 2017.

Practice Guidelines and Position Statements

A search of the National Guideline Clearinghouse (www.guidelines.gov) and National Comprehensive Cancer Network (www.nccn.org) yielded no policies on the use of radioactive seed localization in the breast.

American College of Radiology

In 2013, ACR issued a practice guideline for imaging management of DCIS and invasive breast carcinoma. (21) Both wire localization (using mammographic, sonographic, or magnetic resonance imaging [MRI] guidance) and radioactive seed localization (using mammographic or sonographic guidance) as techniques for preoperative image-guided localization of nonpalpable breast lesions.

U.S. Preventive Services Task Force Recommendations

Use of radioactive seed localization is not a preventive service.

Summary

Radioactive seed localization is an alternative technique to wire localization or radioguided occult lesion localization among women with nonpalpable breast lesions. It may be used before excisional biopsy or breast-conserving surgery, with or without neoadjuvant chemotherapy. Clinical outcomes of these 3 localization techniques are likely to be equivalent. Therefore, radioactive seed localization of nonpalpable breast lesions may be considered medically necessary.

Medicare National Coverage

There is no national coverage determination (NCD).

References


Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2013</td>
<td>New Policy</td>
<td>Policy updated with literature review; references 3, 8-9 added; reference 21 updated. No change to policy statement.</td>
</tr>
<tr>
<td>March 2015</td>
<td>Update Policy</td>
<td></td>
</tr>
</tbody>
</table>

Keywords

Radioactive localization, breast

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 20, 2015 and is effective April 15, 2015.

Signature on file

Deborah M. Smith, MD, MPH