Alternatives to Pre-operative Wire Localization: Recent Advances

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Disclosures

• None
Outline

• Traditional wire localization
• Radioactive seed localization
• SAVI SCOUT guided localization
• Future directions
Pre-Lecture Questions

Following Radioactive Seed Localization with I-125, the radiation dose to remaining breast tissue post surgery is equivalent to:

A. Chest CT  
B. Chest x-ray  
C. 2-view mammogram  
D. Stereotactic (mammo guided) biopsy
Pre-Lecture Questions

SAVI SCOUT reflector is FDA approved for placement how many days pre-op?

A. 0 (must be done day of surgery)
B. 5
C. 7
D. 30
Outline

- Traditional wire localization
- Radioactive seed localization
- SAVI SCOUT guided localization
- Future directions
Wire Localization

- Placed pre-operatively to guide surgical resection of abnormal breast tissue (non-palpable lesions)

- Used for benign and malignant lesions since 1970s

- Placed with mammo or US guidance, occasionally MR

- Most common method
  - Widely accepted
  - Least expensive
Wire Localization

- External component
  - Must be stabilized
- Thick portion surgeon can palpate in surgery
- Hook stabilizes position
Wire Localization
Can place multiple wires in the same breast
Wire Localization
Can place multiple wires in the same breast
Wire Localization: Limitations

- External component
  - Can be pulled/displaced-> post procedure MG, pt transfer

- Patient discomfort

- Wires break/ transected
Wire Localization: Limitations

– Must be done day of surgery

• Coordinate rad and surg schedules -> Delays

• Must be done at the hospital

• Patients NPO and anxious
  – 7% vasovagal reaction

Wire Localization: Limitations

• Radiologists and surgeon ideal procedure approach may be different (i.e. wire skin entry site not always ideal for surgery)

• Difficult to reposition once deployed

• WL positive margins: 12-60%

Wire Localization: Complications
Wire Localization: Complications
Wire Localization: Retained wire fragment
Outline

• Traditional wire localization
• Radioactive seed localization
• SAVI SCOUT guided localization
• Future directions
Radioactive Seed Localization (RSL)

- Iodine-125 (I-125) labeled titanium seed
  - Similar to prostate brachytherapy
  - Half life ~59 days
  - Seed activity: 0.100 to 0.125 mCi

- Surgery guided by gamma probe
Radioactive Seed Localization (RSL)

• Removal verified by
  – Counts in specimen
  – Specimen x-ray
  – Absence of counts in breast

• Different photopeak than Tc-99m
  – 27 keV vs 140 keV
  – Done in conjunction with sentinel node mapping
Radioactive Seed Localization (RSL)

- Visible on mammography and US
- No MRI localizations
  - Lack MRI compatible probe/Geiger counter
Seed Placement

- 18-guage needle
- Seed pre-loaded
  - Shielded until seed placement
- Tip occluded with bone wax
  - Occasionally seed sticks
- Stopper prevents premature deployment
RSL Advantages

• Patient comfort

• No external component

• Performed prior to day of surgery (up to 5d)
  – Flexibility/efficiency with scheduling

• Outpatient facility

RSL Disadvantages

- Radiation to normal tissue
- Must control activity per seed
- Limit time seed implanted
- Logistics
  - Seed storage, tracking, disposal
RSL Tracking: Multi-department effort

NUCLEAR MEDICINE

BREAST IMAGING

OPERATING ROOM

PATHOLOGY

DISPOSAL  RADIATION SAFETY

**Must account for radioactive source at all times, seed only ~5mm**
RSL: How much radiation?

- Radiation dose decreases with increasing distance from seed
- Tissue receiving greatest dose is removed in surgery
- Remaining tissue dose is similar to 2 view mammogram

Ultrasound guided RSL

- Find lesion
- Place tip of needle at or in the lesion
- Deploy seed
Radioactive Seed Localization (RSL)

Courtesy of Dr. Sandra Brennan
Localization of Calcifications

Courtesy of Dr. Sandra Brennan
RSL Published Data

• Sung, et al (MSKCC)
  – Comparable procedure time, margin status to wire loc
  – Lesion retrieval: 100% (356/356 lesions)
  – Mean seed to target distance was 1 mm (range 0–20 mm)
  – Adverse events:
    • 1 seed not retrieved (axilla)
    • 1 case targeted clip not excised but lesion removed
    • median seed migration distance <1 mm (range 0–15 mm) ->
      standard vs textured seeds

Sung et al. EJR 2013: 82 (9) 1453–1457.
RSL vs WL: Outcomes

- Surgical outcomes as measured by frequency of positive margins

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<th>RSL + margins</th>
<th>WL + margins</th>
<th>p-value</th>
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Sharek, et al. AJR 2015;204:872:877
RSL vs WL: Outcomes

- Sharek, et al. no significant difference in:
  - closest surgical margin
    - RSL and WL mean 0.45cm
  - Re-excision rates
    - 21.1% RSL and 26.3% WL
  - Ratio of tumor volume to initial surgical specimen volume

Sharek, et al. AJR 2015;204:872:877
RSL vs WL: Radiology Workflow Improvements

- 34% increase scheduled biopsy slot utilization
- 4.1 day average decrease in biopsy wait time after RSL institution
RSL: Summary

• Benefits
  – Fully implanted (no displacement)
  – Can be done a day or more before surgery with improved OR and radiology efficiency
  – Margin outcomes similar or better than with WL

• Limitations
  – Radiation safety regulations
  – Radiation exposure to patients (low)
  – Can’t reposition once deployed
Outline

• Traditional wire localization
• Radioactive seed localization
• **SAVI SCOUT** guided localization
• Future directions
SAVI SCOUT*

- Electromagnetic wave reflective device (reflector)
  - FDA approved (Dec 2014)
  - *Up to 7 days preop*
  - Non-radioactive
  - 1.2 cm length

- Two antennae, infrared (IR) light receptor and transistor switch

- Now surge resistant, helps protect from malfunction if contacts electrocautery

* ® Cianna Medical Group, Aliso Viejo, CA
SAVI SCOUT Reflector

• Percutaneously inserted adjacent to/within breast targets under MG or US guidance

• Local anesthesia

• Needle 5, 7.5 and 10cm lengths

• Delivery device not MR compatible
  • Reflector MR safe up to 3T (image artifact ~5 mm)
SAVI SCOUT Detection

- Post placement confirmation
  - Mammogram and percutaneous detection

Percutaneous Detection:
- Pulsatile IR light from handpiece
- Activates reflector transistor switch creating electrical connection between the antenna
- EM waves emitted by handpiece are reflected back
- Audible feedback -> cadence increases with proximity of handpiece and reflector
SAVI SCOUT Surgical Excision

- Target/reflector removal verification:
  - Handpiece specimen interrogation
  - Specimen radiography
  - Pathologic analysis
SAVI SCOUT Pilot Study

- Cox et al, University of South Florida

- 50 patients (10 excisional biopsy, 40 lumpectomy)
  - 100% reflector placement, localization, excision
  - Placed 1-6 days before surgery
  - Avg 2.8 mm between reflector and target (0-15mm)

SAVI SCOUT Pilot Study

- 50 patients
  - 41 cancer final pathology (avg 1.3 cm, 0.1-2.7 cm)
  - No adverse events
  - 38/41 (93%) clear margins
  - 9/41 (22%) close margins (within 1 mm)
  - 3/41 (7%) recommended for re-excision

Cox et al. Ann Surg Oncol pub online 3 Feb 2016
SAVI SCOUT Pilot Study

• 2 reflectors not detected on post-placement verification step
  – 4.5 and 6 cm from the skin

• 6 reflectors day of surgery not detected until after skin incision
  – learning curve with handpiece (more directional than gamma probe)
  – manufacturer incorporated console display screen to ensure optimal handpiece technique for skin surface detection

• No wires placed-> used MG to estimate skin incision after which handpiece guided dissection and removal

Cox et al. Ann Surg Oncol pub online 3 Feb 2016
SAVI SCOUT Pilot Study: Physician Satisfaction

• 2 surgeons rated ease of localization at removal 9.2 and 9.4 (<5 worse than WL, 5 = WL, >5 better than WL)
  – Similar to RSL

• Radiologists rated placement ease and patient comfort at 4.1 and 4.5
  – Using 13 cm reflector delivery system designed for pilot and ultrasound guidance, very difficult for mammo
  – Since redesigned 5, 7.5, 10 cm lengths and lighter

Cox et al. Ann Surg Oncol pub online 3 Feb 2016
CUMC Feasibility Study

• 15/15 (100%) reflectors successfully placed
  – 0.2 cm mean target-reflector distance on post-procedure mammo

• 15/15 (100%) targets/reflectors excised

• Final pathology
  – 5 malignancies (0.5-1.2 cm; 1 IDC, 1 ILC, 2 DCIS, 1 papillary ca); neg margins
  – 5 high risk lesions (2 ALH, 3 papillomas)
  – 5 benign concordant results

Mango, V, Ha R, Gomberawalla A, Wynn R, Feldman S. Accepted for publication AJR March 2016
CUMC Feasibility Study

- 14/15 (93%) target-reflector distance within 0.3 cm (specimen XR compared with post placement mammo)

- 1/15 (7%) specimen demonstrated a 2.7 cm increased target-reflector distance – reflector in a large post-biopsy hematoma

Mango, V, Ha R, Gomberawalla A, Wynn R, Feldman S. Accepted for publication AJR March 2016
CUMC Feasibility Study

• Average reflector depth
  – Post-procedure mammogram 2.4 cm (1.2-3.7 cm)
  – Ultrasound 1.0 cm (0.5-2.5 cm)

• No procedural or related post-operative complications identified

• No patients required re-excision

Mango, V, Ha R, Gomberawalla A, Wynn R, Feldman S. Accepted for publication AJR March 2016
- Placed 2 reflectors in 7 patients and 3 in 1 patient with successful excision of target/reflectors
- As close as 2.6 cm apart
Reflector Displacement

- Reflector placed inferomedial to target, wire placed to assist with localization
- Intra-operative ultrasound may also assist
SAVI SCOUT Benefits

– Patient satisfaction
– OR scheduling flexibility
– Independent radiologist and surgeon procedure approach
– Point source for continuous reorientation in the OR
– No radioactive safety precautions

***Testing ongoing for potential placement >7 days (will need FDA approval)
SAVI SCOUT Limitations

- Need for more data -> prospective multi institution trial ongoing
- Cost
- Lesion depth
- Nickel allergy
- ?bracketing
- Patient may not return within 7 day window
- Can’t reposition once deployed
SAVI SCOUT Summary

• Accurate method to localize and excise non-palpable breast lesions

• Comparable margin positivity and re-excision rates

• Overcomes many limitations associated with wire and I-125 seed localization
Conclusion

• No perfect way to localize breast lesions

• Understanding benefits and limitations of WL vs RSL vs SS will help us make informed individualized decisions for our patients

• Further research and development are necessary for continuous improvement of these techniques
Thank you!

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