Intraoperative Ultrasound Localization of Hydrogel-Based Breast Biopsy Markers as an Alternative to Wire Localization for Non-Palpable Breast Malignancies

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Background

• Suspicious lesions undergo image-guided biopsy

• Clips placed to facilitate future localization

Hydrogel-based Biopsy Markers

• Traditional clips
  – Ultrasound: Poor visualization
  – Mammography: Good visualization

• Hydrogel-based markers
  – Ultrasound: Good visualization
  – Mammography: Good visualization

Wire-Localization

• Wire localization
  – Additional procedure
    • Increased patient discomfort
    • Increased cost
    • Can delay surgical start time

  – Technical limitations
    • Wire entry site remote from lesion
    • Challenge planning incision placement
    • Difficulty estimating location of wire tip
    • Poorly placed wire

Clinical Question

• Is use of a hydrogel-based marker alone reliable for intraoperative localization?

• No Financial Disclosures
Methods

• Inclusion Criteria
  – Breast-conserving surgery
  – Non-palpable malignancy
  – Ultrasound-visualized
  – 1/1/2011 – 7/1/2013
  – Hydrogel-based marker

Methods

• Study Protocol
  – Preoperative clinic ultrasound by surgeon
    • Ultrasound-guided intraoperative localization
    • Preoperative wire-localization
  – Specimens include skin and fascia
  – Confirmatory intraoperative specimen radiograph

Methods

• Primary Endpoints
  – Marker visualization
  – Marker retrieval
  – Lesion retrieval
  – Margin status
  – Re-excision rate

Results

• 89 patients met inclusion criteria
  – 67 (75%) Intraoperative Ultrasound Alone
  – 22 (25%) Preoperative Wire-localization
  – Reasons cited for additional localization procedure
    – 7 (32%) Not visualized
    – 4 (18%) Migration of clip
    – 11 (50%) Further clarification

Results

<table>
<thead>
<tr>
<th>Preoperative Factors</th>
<th>Intraoperative US (n = 67)</th>
<th>Wire-localization (n = 22)</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>62</td>
<td>58</td>
<td>0.3</td>
</tr>
<tr>
<td>BMI</td>
<td>28</td>
<td>29</td>
<td>0.4</td>
</tr>
<tr>
<td>Invasive Malignancy</td>
<td>97%</td>
<td>98%</td>
<td>0.7</td>
</tr>
<tr>
<td>DOS</td>
<td>7%</td>
<td>6%</td>
<td>0.7</td>
</tr>
<tr>
<td>Imaging Size (Average)</td>
<td>11cm</td>
<td>12cm</td>
<td>0.8</td>
</tr>
<tr>
<td>Imaging Size (Range)</td>
<td>4 - 48mm</td>
<td>0.24mm</td>
<td></td>
</tr>
<tr>
<td>Neoadjuvant Chemotherapy</td>
<td>1%</td>
<td>1%</td>
<td>0.03</td>
</tr>
<tr>
<td>Time to Surgery</td>
<td>33.4 days*</td>
<td>50 days</td>
<td>0.05</td>
</tr>
</tbody>
</table>

Results

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<tr>
<td>Operative Time</td>
<td>94 min</td>
<td>130 min</td>
</tr>
<tr>
<td>Specimen Size</td>
<td>73 cm</td>
<td>86 cm</td>
</tr>
<tr>
<td>Marker Retrieval</td>
<td>12/12 (100%)</td>
<td>21/21 (100%)</td>
</tr>
<tr>
<td>Lesion Retrieval</td>
<td>12/12 (100%)</td>
<td>22/22 (100%)</td>
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<tbody>
<tr>
<td>Tumor Size</td>
<td>17 cm</td>
<td>14 cm</td>
<td>0.5</td>
</tr>
<tr>
<td>Positive Margins</td>
<td>2 (9%)</td>
<td>0 (0%)</td>
<td>0.4</td>
</tr>
<tr>
<td>Re-excision Rate</td>
<td>2 (9%)</td>
<td>2 (9%)</td>
<td>0.4</td>
</tr>
</tbody>
</table>

Conclusions

• Intraoperative ultrasound localization of hydrogel-based breast biopsy markers for nonpalpable sonographic malignancy is:
  – Accurate
  – Efficient
  – Can improve the patient care experience

Results

• Cost-effective Analysis
  Routine use of Hydrogel-based Biopsy Marker for Ultrasound-guided Core Needle Biopsy
  – Save MediCare $113 per patient