Radioactive Seed Localization vs. Wire Guided Localization of Nonpalpable Invasive and In Situ Breast Cancer: A Danish Multicenter Randomized Controlled Trial


Rigshospitalet & Herlev Hospital, University of Copenhagen, Denmark
Preoperative lesion localization

Radioactive seed localization (RSL)  Wire guided localization (WGL)
Aim

To compare RSL and WGL in a randomized controlled trial

• Danish setting
• Multicenter trial
• Margin status after breast conserving surgery
Patients

Nonpalpable lesions

Invasive breast cancer (IBC) or ductal carcinoma in situ (DCIS)

Visible on ultrasound

Eligible for breast conserving surgery
Methods

Radiology – Patients’ pain perception

Surgery – Duration of surgical procedure & Weight of excised specimen

Pathology – Margin status
Trial profile

RSL  WGL

444  409/413  35

206  195  192
Allocation  Intention-to-treat  Per-protocol

207  195  186
Results

• Inclusion period was Jan 1, 2014 to Feb 4, 2016

• Baseline characteristics were alike

• Significantly more patients with DCIS in the WGL group (p=0.006)
## Margin status

<table>
<thead>
<tr>
<th></th>
<th>RSL n (%)</th>
<th>WGL n (%)</th>
<th>P-value</th>
<th>OR (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intention-to-treat</strong></td>
<td></td>
<td></td>
<td>0.65</td>
<td>1.15 (0.63-2.10)</td>
</tr>
<tr>
<td>Negative</td>
<td>172 (88.2%)</td>
<td>169 (86.7%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>23 (11.8%)</td>
<td>26 (13.3%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Per-protocol</strong></td>
<td></td>
<td></td>
<td>0.62</td>
<td>1.17 (0.64-2.14)</td>
</tr>
<tr>
<td>Negative</td>
<td>164 (88.2%)</td>
<td>166 (86.5%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>22 (11.8%)</td>
<td>26 (13.5%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>IBC</strong></td>
<td></td>
<td></td>
<td>0.997</td>
<td>1.0 (0.53-1.89)</td>
</tr>
<tr>
<td>Negative</td>
<td>172 (88.7%)</td>
<td>164 (88.6%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>22 (11.3%)</td>
<td>21 (11.4%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Secondary outcomes

<table>
<thead>
<tr>
<th></th>
<th>RSL</th>
<th>WGL</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight total (g)</td>
<td>29 (18.5-43.0)</td>
<td>26 (18.0-40.0)</td>
<td>0.54</td>
</tr>
<tr>
<td>Duration (min)</td>
<td>10 (7-12)</td>
<td>10 (7-15)</td>
<td>0.12</td>
</tr>
<tr>
<td>Pain Perception</td>
<td></td>
<td></td>
<td>0.28</td>
</tr>
<tr>
<td>No</td>
<td>13 (7.9%)</td>
<td>4 (2.9%)</td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>88 (53.3%)</td>
<td>76 (55.1%)</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>48 (29.1%)</td>
<td>41 (29.7%)</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>16 (9.7%)</td>
<td>17 (12.3%)</td>
<td></td>
</tr>
</tbody>
</table>
Results

- Complication rate \( (p=0.89) \)
- Sentinel node identification rate \( (p=1.0) \)
Conclusion

No significant difference in:

- **Margin status**
- Duration of the surgical procedure
- Weight of the excised specimen
- Patients’ pain perception
Perspectives

- RSL offers a major logistic advantage

- Two previous randomized trials with similar results on margin status

- Can we implement RSL as standard procedure?
Acknowledgement

The trial was funded by:

/DANSK KRAEFTFORSKNINGS FOND / The Danish Cancer Research Foundation

/Kræftens Bekæmpelse / The Danish Cancer Society