A pilot study comparing Sentimag/Sienna XP versus standard modality for sentinel lymph node identification in patients with breast cancer

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Conflict of interest statement

• MedQuest has sponsored the Sienna XP and SentiMag system for use for this study

• The company had no involvement in the collection and interpretation of data, writing of the manuscript and the decision for publication.
Introduction

• Sienna XP is a new particulate magnetic tracer developed for SLNB.

• This pilot study compares Sienna XP with standard tracers for:
  – Technical feasibility
  – Accuracy
Background

• The particles, coated in a biocompatible molecule (carboxydetran), are clinically proven to be non-toxic.

• These particles are small enough to be taken up into the lymphatics within minutes and large enough to be filtered in the lymph nodes, accumulate and be detected by a magnetic probe.

• If allowed ample time before SLNB harvest, the node will appear brownish-black, suitable for visual localisation.
Methods

• Prospective, non-inferiority study
• July 2016 to February 2017
• Study population: women with cTis –T2 N0 M0 breast cancer
• 6 surgeons involved

• **Exclusion criteria:**
  • Intolerance to iron or dextran compounds, magnetic tracers, or superparamagnetic iron oxide;
  • Iron-overload disease;
  • Pacemakers or other implantable devices on the chest wall
Intra-operative proceedings (1)

Radioisotope technique:
- Subdermal injection of 99mTc radioisotope was performed at the department of nuclear medicine before admission to the operating room

Blue dye technique:
- Subareolar injection of 1.5 ml of Patent blue dye was injected followed by 5 minutes of breast massage.

Magnetic technique:
- Subareolar injection of 2 ml of Sienna XP and 5 minute massage
- Minimum of 20 minutes interval before SLNB
- Plastic retractors and forceps were used with the Sentimag probe
Intra operative proceedings (2)

- SLNs that were identified with either radioisotope, blue dye, or magnetic tracer were removed.

- Clinically suspicious LN identified during SLNB, not identified by either method were also removed.

- All SLNs were assessed intraoperatively by frozen section

- Postoperatively in formalin-fixed embedded sections using haematoxylin and eosin staining.
Results (1)

• Definition of a successful SLN procedure was the identification of at least one SLN

• Sentinel node identification rate

<table>
<thead>
<tr>
<th>Technique</th>
<th>Numbers</th>
<th>Percentage</th>
<th>Mean number of SLN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard - Blue dye (16)</td>
<td>19/20</td>
<td>95</td>
<td>2.0</td>
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<tr>
<td>Standard - Radioisotope (4)</td>
<td></td>
<td></td>
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<tr>
<td>Magnetic</td>
<td>20/20</td>
<td>100</td>
<td>2.8</td>
</tr>
</tbody>
</table>
Results (2)

- 56 SLNs in total
- 55 Sentimag

- Radioisotope & Sentimag (n=9)
- Sentimag only (n=16)
- Blue dye & Sentimag (n=30)
- Blue Dye only (n=1)
Results (3)

• 33 of 55 Sentimag detected SLN had brownish discolouration.

• Mean duration before SLNB
  – Brown nodes: 65.9 min
  – Hot (Sentimag signal) only nodes: 36 min.
Histopathology (1)

- 25% (5 of 20) of patients were found to have macrometastasis on frozen section
- A total of 9 nodes were identified by both arms

<table>
<thead>
<tr>
<th>Patient</th>
<th>N (Total)</th>
<th>Sentimag and blue</th>
<th>Sentimag only</th>
<th>Clinically suspicious</th>
</tr>
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<tbody>
<tr>
<td>15</td>
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</tr>
<tr>
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<td>1 (2)</td>
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<tr>
<td>4</td>
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<tr>
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<tr>
<td>2</td>
<td>1 (3)</td>
<td>1 *</td>
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</tbody>
</table>
Discussion (1)

• Patient 6: failed localisation by standard technique; magnetic technique identified 4 negative SLNs.

• Patient 2: 1 positive SLN detected initially by the blue dye technique; Sentimag signal was found to be present but weak.

• Patient 1: micrometastasis on paraffin section in 1 SLN identified by both standard and magnetic techniques.
• The magnetic tracer can be injected in the operation room and surgeons can proceed with incision after obtaining a clear transcutaneous signal with the magnetometer.

• With sufficient time from the injection to SLNB, the node may be identified by colour.

• Most of the surgeons reported the magnetic technique as easy to perform

• Some inconvenience with the use of plastic instruments and the need to repeatedly calibrate the magnetic probe
Discussion (3)

- Our results showed that the magnetic technique performs equivalently well in comparison to the standard techniques.

- High identification rate (not inferior to standard techniques)

- Detects more lymph nodes than standard techniques.
Discussion (4)

• Pilot study

• Provides encouraging preliminary results to support the use of the magnetic technique in SLNB.

• Dual technique in the same patient may bias detection rate

• However, SLNB with Sentimag followed with axillary clearance (histology) to assess accuracy of technique is not ethical
Conclusion

- Sienna XP performs as well as standard blue dye and radioisotope tracers in SLNB for breast cancer.

- Safe procedure and easy to perform.

- It has the potential to become a standard method of localisation of SLN.
Thank you
Questions?
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