SentimagIC: A non-inferiority trial comparing superparamagnetic iron oxide with Tc99 and blue dye in the detection of axillary sentinel nodes in patients with early stage breast cancer

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Methods

Sentinel lymph node biopsy (SLNB) using radiosotope with or without blue dye is a highly accurate method for staging the axilla in clinically node-negative breast cancer patients.

However both techniques have drawbacks:

- Short half-life, availability, and handling issues for radiosotope
- Risk of allergic reactions to blue dye.

There is a need for new agents for lymph node mapping.

The Sentimag system, an investigational device in the US, already trialled in Europe,2,3 uses a non-radioactive magnetic tracer and a handheld magnetic probe to identify sentinel nodes.

The Sentimag Intraoperative Comparison (SentimagIC) study compared magnetic lymph node detection with the standard combination of radiosotope and blue dye for breast SLNB.

Results

Analysis of the primary endpoint showed a per node detection rate for SiennaXP of 94.3% and Control 93.5%. The difference in detection rates (SiennaXP – Control) = 0.8% (95% binomial CI lower bound = -2.1%), resulting in a P-value of 0.0065 for non-inferiority.

SiennaXP is therefore non-inferior to Control for lymph node detection within pre-specified non-inferiority margin of 5% with 85% power.

Results summary

Detection rate per subject, % (95% CI) 99.3% (95.3, 99.8)
Detection rate per node\* 93.5% (91.5, 94.6)
Concordance per subject 94.3% (91.8, 95.7)
Detection rate per node-positive subject 95.5% (94.0, 96.5)
Mean nodes per subject (SD) 2.4 (0.19)

Reference:


Conclusions

SiennaXP, a magnetically-detected tracer is non-inferior to the standard dual technique of radiosotope and blue dye for axillary sentinel lymph node detection in early stage breast cancer. This provides a potential alternative tracer for SLNB that avoids the drawbacks of radiosotope and blue dye.

Acknowledgements: The authors would like to thank all those who have contributed to the SentimagIC study. The study was funded by Endomagnetics Inc, Austin TX.

Sentinel lymph node biopsy with the Sentimag magnetic probe (left)

Subject characteristics, n = 147

<table>
<thead>
<tr>
<th>Age, Median, years</th>
<th>Tumor type, n (%)</th>
<th>Weight, Median, lbs</th>
<th>BMI, Median kg/m²</th>
</tr>
</thead>
<tbody>
<tr>
<td>62 (Range 35 - 85)</td>
<td>Invasive</td>
<td>160 (105 - 302)</td>
<td>29 (18 - 52)</td>
</tr>
<tr>
<td>0.02</td>
<td>Non-invasive / DCIS</td>
<td>117/147 (79.6)</td>
<td>18/147 (12.3)</td>
</tr>
<tr>
<td>12/147 (8.2)</td>
<td>Other</td>
<td></td>
<td></td>
</tr>
<tr>
<td>113/126 (89.7)</td>
<td>Positive</td>
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SLNB procedure N = 147

Sentimag probe

Excised lymph node

Tc99 + Blue Dye

SiennaXP

Results

Follow-up visit N = 147

Concordance per subject 94.3% (91.8, 95.7)
Detection rate per node-positive subject 95.5% (94.0, 96.5)
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Sentinel lymph node biopsy with the Sentimag magnetic probe (left)

Subject disposition

Consented N = 147

Withdrawn prior to SLNB N = 13

SLNB procedure N = 147

Follow-up visit N = 147

Sentimag magnetic tracer

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