Course
Improving clinical skills in early breast cancer.
Ljubljana, 3-7 February 2003

The importance of Lymphnode Metastases

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Amsterdam
The importance of lymphnode metastasis

- Why
- Where
- How
Why?

• Prognostic information
• Regional tumor control
• Survival?
Where?

- Axilla
- Internal mammary chain
- Intra mammary
- Infra-supra clavicular
How?

• ALND
• 4-5 node sampling
• Triple biopsy (axilla, infraclavicular, IMC)
• Lymphatic mapping & SN procedure
SENTINEL NODE BIOPSY

= 

DIAGNOSTIC PROCEDURE
SENTINEL NODE BIOPSY

PURPOSE:

• SELECTIVE DETECTION OF LYMPH NODE METASTASES
SENTINEL NODE BIOPSY

GOVERNS TREATMENT DECISIONS

- SELECTIVE TREATMENT OF AXILLA (ALND and/or RADIOTHERAPY)
- ADJUVANT SYSTEMIC TREATMENT
- ADJUVANT RADIOTHERAPY OF INTERNAL MAMMARY CHAIN
SENTINEL NODE BIOPSY

History
Lymphatic Mapping and Sentinel Lymphadenectomy for Breast Cancer

Armando E. Giuliano, MD; Daniel M. Kirgan, MD; J. Michael Guenther, MD; Donald L. Morton, MD.

From the Joyce Eisenberg Keefer Breast Center, John Wayne Cancer Institute at Saint John’s Hospital and Health Center, Santa Monica, California

Lymphatic Mapping and Sentinel Lymphadenectomy for Breast Cancer

Armando E. Giuliano first 1994 experience

- Patent blue dye only
- 174 patients
- 114 successful (65.5%)
- 5/42 false negative (of +ve axilla)
Study design

- NKI/AvL anatomical study ’94-’95
- Patent blue dye into the tumor
- Modified radical mastectomy
30 patients

- drainage directly to the axilla
- not through subareolar plexus

30 patients

- 26 blue SN
- 4 failed
- 16 SN tumour negative (all nodes)
- 10 SN positive, 6 the only
History

• 1996 - 1998
  – NCI and University Hospital Groningen
  – 136 patients (NCI: 81 patients)
  – Confirmatory axillary lymph node dissection
  – Identification 93%
  – False-negative rate 5%

_Doting et al. Cancer 2000_
History

• Since January 1999
  – No axillary lymph node dissection in sentinel node negative patients
SENTINEL NODE BIOPSY AS DIAGNOSTIC PROCEDURE

1. NEEDS TO BE VALIDATED
2. NEEDS TO BE EQUAL OR BETTER THAN STANDARD PROCEDURE (= ALND)
3. NEEDS TO BE MASTERED AND QUALITY CONTROLLED
4. NEEDS TO BE STANDARDISED
5. NEEDS TO BE COST EFFECTIVE
SENTINEL NODE BIOPSY AS DIAGNOSTIC PROCEDURE

1. NEEDS TO BE VALIDATED

- THE NETHERLANDS CANCER INSTITUTE EXPERIENCE
Sentinel Node Biopsy In Breast Cancer
a review of 653 procedures

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R.A. Valdés Olmos, E.J.Th. Rutgers, B.B.R. Kroon

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The Netherlands Cancer Institute/Antoni van Leeuwenhoek hospital
Amsterdam, the Netherlands
Inclusion Criteria

- Proven T1-3 breast cancer
- Clinically N0 stage
  - Palpation
  - Ultrasound (since November 1999)
- Palpable and non-palpable
US axilla?

NKI/AvL experience

• 268 patients
• T1-2/N0 proven breast cancer
• Scheduled for SN procedure
US axilla?

NKI/AvL experience

• Learning curve radiologist
• If nodal cortex >2.5 mm: FNA
US axilla?

NKI/AvL experience

• FNA in 66 patients
• 37 tumour positive (56%)
• In all 118 patients had tumour +ve axilla
• 31% identified by US axilla & FNA
US axilla?

NKI/AvL experience

• Prevents in 14% of all N0 patients a SN procedure: they may have directly an ALND.
• 7 US axilla saves one SN procedure

Exclusion Criteria SN Procedure

- Previous treatment
  - excisional biopsy
  - radiotherapy
- Multicentric breast cancer
- Pregnancy
Patients

- January 1997 - March 2002
- 644 patients
- 9 bilateral
- 653 sentinel node procedures
- 136 non-palpable tumors
- 81 with confirmatory axillary dissection
Methods
Preoperative Lymphoscintigraphy

• Two-day protocol
• Intratumoral injection of $^{99m}$Tc-nanocolloid
• Volume: 0.2 ml; radioactive dose: 120 MBq
• Lateral images using hanging breast method
Methods
Preoperative lymphoscintigraphy
Methods

Surgery

• Intratumoral injection patent blue dye (1.0 ml)
• Gamma-ray detection probe
METHODS
Pathology

- Always frozen section: 75-80% identification of positive nodes
- Lymph node < 1 cm: 2 sections H&E, IHC (Cam 5.2)
- Lymph node > 1 cm: 3 or more sections H&E, IHC
Results
Surgery

• Identification 96% (629/653)
  – Axillary basin 97% (608/629)
  – Extra-axillary basins 26% (162/629)

• Average number of 2.0 SNs (0-7)

• Average number of 0.7 non-SNs (0-10)
Results

Pathology

• Mean tumour diameter 1.8 cm
• Axillary metastases: 36% (220/608)
  – 212 axillary sentinel node metastases
  – 8 false negative SN procedures (3.6%)
False negative procedures

- False negative rate: 3.6% (8/220)
  - 2 tumor-positive non-SNs in routine ALND
  - 3 palpable tumor-positive non-SNs
  - 2 tumor-positive non-SNs in lateral part of simple mastectomy specimen
  - 2 axillary recurrences after 10 & 22 months
False negative procedures
Presumptive causes

• Long interval between injection and surgery
• Tumor blocking
• Pathological sampling error
• Multifocal disease
Follow-up

Morbidity

- No lymphoedema
- 5-10% sensible nerve disturbance
- 1-3% shoulder function problem
Conclusions

- Overall visualization: 93%
- Overall identification: 97%
- False negative rate: 3.6%
SENTINEL NODE BIOPSY AS DIAGNOSTIC PROCEDURE

1. NEEDS TO BE VALIDATED

- THE NETHERLANDS CANCER INSTITUTE EXPERIENCE

- AND MANY, MANY OTHERS
SENTINEL NODE BIOPSY AS DIAGNOSTIC PROCEDURE

2. NEEDS TO BE EQUAL OR BETTER

- EUROPEAN INSTITUTE OF ONCOLOGY, MILAN
- MANY, MANY OTHER GROUPS
- NETHERLANDS CANCER INSTITUTE EXPERIENCE
SENTINEL NODE BIOPSY AS DIAGNOSTIC PROCEDURE

2. NEEDS TO BE EQUAL OR BETTER (and not worse)

- EUROPEAN INSTITUTE OF ONCOLOGY, MILAN STUDY.

Randomisation between ALND and SN procedure in 512 T1 N0 breast cancer patients:

- in both groups 35% lymph node metastasis.
- after 2 years no axillary recurrences.
WHY IS SENTINEL NODE BIOPSY BETTER THAN ALND?

- SELECTIVE (BETTER) HISTOLOGICAL EXAMINATION OF THE SENTINEL LYMPH NODE (S)

- SENTINEL NODE OUTSIDE AXILLA MAY RESULT IN BETTER STAGING: THE NKI/AVL EXPERIENCE
Methodology and Implications of Lymphatic Mapping and Sentinel Lymphadenectomy

Pieter J Tanis
Clinical relevance of sentinel nodes outside the axilla

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P. Tanis
SH Estourgie, OE Nieweg, RA Valdés Olmos, BBR Kroon

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The Netherlands Cancer Institute/Antoni van Leeuwenhoek Hospital
Amsterdam, the Netherlands
Introduction

Hypothesis:

Identification and investigation of sentinel nodes outside the axilla improves staging and will lead to better outcomes.

Lymph node status is the best prognostic factor.

Understaging by insufficient nodal sampling results in inferior survival rates by underutilization of adjuvant systemic treatments and insufficient locoregional control.

Extra-axillary sentinel nodes (EASNs) are defined as nodes outside level I and II of the axilla.
Methods
Preoperative lymphoscintigraphy
Results
Lymphoscintigraphy

- Visualization 92% (560/606)
- Axillary basin 95% (534/560)
- Extra-axillary basins 29% (164/560)
- Average number of 1.6 SNs (0-6)
- Average number of 1.6 non-SNs (0-13)
Results
Surgery

• Identification 96% (583/606)
• Axillary basin 97% (565/583)
• Extra-axillary basins 24% (142/583)
• Average number of 2.0 SNs (0-6)
• Average number of 0.7 non-SNs (0-10)
Internal Mammary Nodes
Incidence

30%

44%

18%

8%

Incidence 120/606 = 20%
Internal Mammary Nodes
Incidence

- 25%
- 9%
- 32%
- 16%
- 18%
Internal Mammary Nodes

Results

• Identification 86% (103/120)
• 144 SNs excised
  – radioactive 67%
  – blue and radioactive 33%
• 17/103 metastases (17%)
  – 5 axilla negative
Clavicular and Interval Nodes

Incidence

Supraclavicular 4%
Infraclavicular 13%
Interpectoral 12%
Lateral intramammary 54%
Medial intramammary 17%

Incidence 64/606 = 11%
Clavicular and Interval Nodes

Results

• Identification 83% (53/64)
• 65 SNs excised
  – blue 8%
  – radioactive 49%
  – blue and radioactive 43%
• 12/53 metastases (23%)
  – 5 axilla negative
## Clinical Consequences

<table>
<thead>
<tr>
<th>Patient</th>
<th>Tumor characteristics</th>
<th>Adjuvant therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>D (cm)</td>
<td>Grade</td>
</tr>
<tr>
<td>1</td>
<td>1.5</td>
<td>II</td>
</tr>
<tr>
<td>2</td>
<td>1.9</td>
<td>II</td>
</tr>
<tr>
<td>3</td>
<td>2.5</td>
<td>III</td>
</tr>
<tr>
<td>4</td>
<td>0.8</td>
<td>III</td>
</tr>
<tr>
<td>5</td>
<td>0.8</td>
<td>I</td>
</tr>
<tr>
<td>6</td>
<td>1.3</td>
<td>II</td>
</tr>
<tr>
<td>7</td>
<td>1.0</td>
<td>I</td>
</tr>
<tr>
<td>8</td>
<td>2.1</td>
<td>II</td>
</tr>
<tr>
<td>9</td>
<td>1.7</td>
<td>I</td>
</tr>
<tr>
<td>10</td>
<td>1.5</td>
<td>II</td>
</tr>
</tbody>
</table>
Conclusions

• The incidence of extra-axillary drainage is 31%.

• The identification rate of EASNs is 84%.

• Metastases in EASNs can be found in about 18% of patients.

• Upstaging was achieved in 10% of patients with an identified EASN.

• Management changed in 20%. 
Clinical relevance of SN outside axilla

Clinical Consequences of retrieval of extra axillary SN

- Few complications
- If tumor –ve or no drainage: no IMC irradiation
- If tumor +ve: IMC irradiation
- If the sole +positive SN (3-5%): adjuvant systemic treatment
WHY IS SN WORSE THAN ALND?

- POOR TECHNIQUE
- LOW SUCCESS RATE
- HIGH FALSE NEGATIVE RATE
HOW TO MINIMISE FALSE NEGATIVE RATE?

- LEARNING EXPERIENCE: > 20 CASES
- GOOD TEAM: SURGEON (high volume & experienced), NUCLEAR PHYSICIAN, PATHOLOGIST
- MORE THAN 90% IDENTIFICATION RATE
- < 5% FALSE NEGATIVE RATE
- PROSPECTIVE REGISTRATION AND CAREFUL CLINICAL FOLLOW-UP
1356 patients

54 patients failed mapping (4.0%)

1302 patients mapped successfully (96.0%)

12 ALND-positive (22.2%)

42 ALND-negative (77.8%)

929 SLN-negative (71.4%)

373 SLN-positive (28.6%)

120 ALND (Phase I) (12.9%)

809 observed (Phase II) (87.1%)

224 ALND-negative (60.1%)

149 ALND-positive (39.9%)

119 ALND-negative

1 ALND-positive

0 recurrences (mean follow-up of 20 months)
22 cases to reach and stay below the 10% failure rate

54 cases to reach the 5% failure rate
HOW TO MINIMISE FALSE NEGATIVE RATE?

INDICATION

- T1/2 N0 BREAST CANCER
- UNIFOCAL DISEASE
- PREOPERATIVE ULTRASOUND OF AXILLA TO EXCLUDE MACROMETASTASES
HOW TO MINIMISE FALSE NEGATIVE RATE?

TECHNIQUE

- USE TRIPLE TECHNIQUE: PREOPERATIVE LYMFOSCINTIGRAPHY, PATENT BLUE DYE, INTRAOPERATIVE PROBE
- REMOVE ALL SENTINEL NODES CAREFULLY
- CAREFUL HISTOLOGICAL WORK-UP
- IMMUNOHISTOCHEMISTRY REDUCES FALSE NEGATIVE RATE
HOW TO MINIMISE FALSE NEGATIVE RATE?

PATHOLOGY

IF THE SENTINEL NODE CONTAINS MICROMETASTASES: CHANCE OF MORE LYMPH NODE METASTASES IN THE AXILLA VARIES BETWEEN 8-24%!
Micrometastases?

- **Definition (UICC 2002):** < 2 mm (isolated tumor cells: < 0.2 mm!)
- If found in SN: treat axilla with ALND (8-24% chance of more +ve nodes), or radiotherapy (?).
- If sole finding in any node: **NO PROGNOSTIC SIGNIFICANCE!**
- ✗ Adjuvant systemic treatment according to primary tumor characteristics
<table>
<thead>
<tr>
<th>Investigator/year</th>
<th>Technical success rate</th>
<th></th>
<th></th>
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<tbody>
<tr>
<td></td>
<td>Radioisotope</td>
<td>Blue dye</td>
<td>Radioisotope + blue dye</td>
</tr>
<tr>
<td>Albertini/1996¹²</td>
<td>NS</td>
<td>45/62 (73)</td>
<td>57/62 (92)</td>
</tr>
<tr>
<td>Borgstein/1997¹³</td>
<td>33/33 (100)</td>
<td>33/33 (100)</td>
<td>33/33 (100)</td>
</tr>
<tr>
<td>O’Hea/1998²¹</td>
<td>52/59 (88)</td>
<td>44/59 (75)</td>
<td>55/59 (93)</td>
</tr>
<tr>
<td>Barnwell/1998²²</td>
<td>37/42 (88)</td>
<td>9/42 (21)</td>
<td>38/42 (90)</td>
</tr>
<tr>
<td>Van der Ent/1999⁴²</td>
<td>68/70 (97)</td>
<td>2/70 (3)</td>
<td>70/70 (100)</td>
</tr>
<tr>
<td>Hill/1999⁵⁷</td>
<td>393/492 (80)</td>
<td>419/492 (85)</td>
<td>458/492 (93)</td>
</tr>
<tr>
<td>Bass/1999⁵⁰</td>
<td>631/700 (90)</td>
<td>533/700 (76)</td>
<td>665/700 (95)</td>
</tr>
<tr>
<td>Cody/2001⁶⁰</td>
<td>844/966 (87)</td>
<td>785/966 (81)</td>
<td>922/966 (95)</td>
</tr>
</tbody>
</table>

Adapted from Liberman et al,² with permission. Numbers in parentheses are percentages.
NS, not stated.
<table>
<thead>
<tr>
<th>Method of SLN detection</th>
<th>No.</th>
<th>%</th>
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<tbody>
<tr>
<td>Blue dye</td>
<td>1105</td>
<td>81.5</td>
</tr>
<tr>
<td>Radiocolloid</td>
<td>1197</td>
<td>88.3</td>
</tr>
<tr>
<td>Blue dye and/or radiocolloid</td>
<td>1288</td>
<td>95.0</td>
</tr>
</tbody>
</table>

**Node characteristics (N = 2927)**

<table>
<thead>
<tr>
<th>Node characteristics</th>
<th>No.</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blue and hot</td>
<td>1848</td>
<td>63.1</td>
</tr>
<tr>
<td>Hot only</td>
<td>650</td>
<td>22.2</td>
</tr>
<tr>
<td>Blue only</td>
<td>364</td>
<td>12.4</td>
</tr>
<tr>
<td>All hot</td>
<td>2498</td>
<td>85.3</td>
</tr>
<tr>
<td>All blue</td>
<td>2212</td>
<td>75.6</td>
</tr>
</tbody>
</table>

Sentinel lymph nodes were identified in 1302 of 1356 patients (96%) and not found in 54 (4%). Data were incomplete in 12. One of 54 node-positive patients (2%) had a false-negative SLN.
IS SENTINEL NODE IN BREAST CANCER STANDARD OF CARE?

YES - IF CAREFULLY PERFORMED IN A EXPERIENCED TEAM WITH A SUCCESS RATE OF > 90% AND A FALSE NEGATIVE RATE OF < 5%

NO - IN EXPERIMENTAL SITUATIONS: AFTER CHEMOTHERAPY IN LARGE TUMOURS OR LOCALLY ADVANCED CANCER, WITHOUT PROPER TRAINING AND TECHNICAL POSSIBILITIES
The role of axillary clearance

IN:
• Axillary lymph node assessment (if SN cannot be performed)
• Early treatment in proven N+ve patients
  - US & FNA +ve, SN +ve

OR ONLY:
• Delayed treatment in clinically cN +ve patients
Elective axillary clearance in N+ve breast cancer is useful
Debate

Elective axillary clearance in N+ve breast cancer is useful.

To what price are we going to prevent uncontrollable regional disease, and does elective axillary clearance lead to a survival benefit?
Debate
Elective axillary clearance in N+ve breast cancer is useful

We do not need ALND for staging of lymphatic dissemination
(As sentinel node biopsy is available)
Debate
Elective axillary clearance in N+ve breast cancer is useful

• Our case: early treatment for node-positive disease by ALND will reduce uncontrollable regional disease substantially and may improve survival.
Debate

Elective axillary clearance in N+ve breast cancer is useful

About 30% of patients with axillary relapse will end with uncontrollable disease.

- Chua, Breast Journal 2002: 29%
- Recht, JCO 1991: 53%
- Mc Kinna, EJC 1999: 32%
Debate
Elective axillary clearance in N +ve breast cancer is useful

The chance of axillary recurrence in initially untreated clinical node negative breast cancer (T1C/T2) is about 15%.

- Greco: 18%
- Mc Kinna: 10%
- NASBP B-04: 18%
- And many others
Debate

Elective axillary clearance in N+ve breast cancer is useful

• If a “40% chance of a node positive axilla” will be left untreated initially, 10-20%(15%) of the patients will recur and 30% will have uncontrollable disease.
Debate
Elective axillary clearance in N+ve breast cancer is useful

• From every 100 patients with an initially untreated axilla (T1c/T2-cN0, or SN positive), 5 (30% from 15% from 100 patients) will end with uncontrollable disease, or 1 out of 20.
Debate

Elective axillary clearance in N +ve breast cancer is useful

- After axillary clearance in T1c/T2-cN0 breast cancer, about 40% will be node-positive and the chance of axillary recurrence is less than 1% (Bijker et al, Cancer 1999, Borger et al, JCO 1994), so the risk of uncontrollable disease is <1%. 
Debate
Elective axillary clearance in N+ve breast cancer is useful

- About 20% of all patients suffer from late morbidity from ALND (lymph-oedema, pain, and functional impairment).
Debate
Elective axillary clearance in N+ve breast cancer is useful

- So early treatment of T1c/T2-cN0, or SN positive axilllas will lead to late sequels in 20 out of 100 patients, balanced against 5 out of 100 uncontrollable regional disease if left initially untreated.
Debate
Elective axillary clearance in N+ve breast cancer is useful

This is worthwhile!
Debate
Elective axillary clearance in N+ve breast cancer is useful

Is radiotherapy of the axilla as effective?

• Hoebers et al, Cancer 2000.
• And many others.

➢ Axillary recurrence after 5-8 years of follow-up 1%, morbidity at maximum 5%.
Debate

Elective axillary clearance in N +ve breast cancer is useful

However:

- small series
- not randomised
- retrospective
- Promising results

Randomised trials needed to investigate the possibilities of reduction of morbidity of elective axillary treatment in T1c/T2-cN0, or SN positive patients (the EORTC SN AMAROS trial!).
Debate

Elective axillary clearance in N +ve breast cancer is useful

Survival benefit from elective axillary clearance?

• We do not need to go into the ‘Overgaard’ and ‘Ragaz’ studies.
• Elective ALND results in a 5.4% (CI 2.7-8.0%) survival benefit (meta analysis of 6 randomised trials, Orr, Ann Surg 1999).
<table>
<thead>
<tr>
<th>Trial</th>
<th>Number of patients</th>
<th>Follow-up (years)</th>
<th>Survival (%)</th>
<th>Difference (%)</th>
<th>Reduction (%)</th>
<th>p-value</th>
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<tbody>
<tr>
<td>Copenhagen</td>
<td>425</td>
<td>10</td>
<td>46</td>
<td>50</td>
<td>4</td>
<td>7.4</td>
</tr>
<tr>
<td>Guy's I</td>
<td>370</td>
<td>10</td>
<td>43.6</td>
<td>51.6</td>
<td>8</td>
<td>14.2</td>
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<tr>
<td>SES</td>
<td>498</td>
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<td>61</td>
<td>9.5</td>
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<td>B-04</td>
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<td>54</td>
<td>58</td>
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<td>8.7</td>
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<td>Guy's II</td>
<td>258</td>
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<td>57</td>
<td>73</td>
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<tr>
<td>Curie</td>
<td>658</td>
<td>5</td>
<td>92.6</td>
<td>96.6</td>
<td>4</td>
<td>45.9</td>
</tr>
</tbody>
</table>

NS, not significant.
Debate
Elective axillary clearance in N+ve breast cancer is useful

Conclusion

- Complete ALND is standard treatment in patients with T1c/T2-cN0 (and cN1!) or SN positive patients.
THANK YOU FOR YOUR ATTENTION ANY QUESTIONS?
Sentinel Node Biopsy and Excision of the Primary Tumor in Non-Palpable Breast Cancer
Introduction

- Small tumor size
- Low risk of axillary metastases
Methods
Preoperative Lymphoscintigraphy

• Day before surgery
• Intratumoral injection guided by ultrasound or stereotaxis
A 18G needle with a central venous catheter, loaded with a X-shaped hookwire.
Mammography after ultrasound localization of a tumor in the upper inner quadrant of the right breast.
Methods
Surgery

• Intratumoral patent blue dye (1.4 ml)
• Gamma-ray detection probe
Methods
Surgery on primary tumor

- Incision at the site of highest radioactivity
- Minimal margin of 1 cm around the lesion
Results
Sentinel node biopsy

• Visualization 92% (125/136)
  – Axillary basin 89% (111/125)
  – Extra-axillary basins 41% (51/125)

• Identification 96% (130/136)
  – Axillary basin 91% (118/130)
  – Extra-axillary basins 40% (51/130)
## Results

### Sentinel node biopsy

<table>
<thead>
<tr>
<th></th>
<th>Palpable</th>
<th>Non-palpable</th>
<th>p-value</th>
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</thead>
<tbody>
<tr>
<td>Visualization</td>
<td>93%</td>
<td>92%</td>
<td></td>
</tr>
<tr>
<td>Identification</td>
<td>97%</td>
<td>96%</td>
<td></td>
</tr>
<tr>
<td>Extra-axillary sentinel nodes</td>
<td>25%</td>
<td>39%</td>
<td>0.001</td>
</tr>
<tr>
<td>Axillary metastases</td>
<td>40%</td>
<td>15%</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
## Results

Excision of the primary tumor

<table>
<thead>
<tr>
<th></th>
<th>Palpable</th>
<th>Non-palpable</th>
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</thead>
<tbody>
<tr>
<td>Primary tumor</td>
<td>2.0-cm</td>
<td>1.3-cm</td>
</tr>
<tr>
<td>Clear margins</td>
<td>95.6%</td>
<td>93.4%</td>
</tr>
</tbody>
</table>
Conclusions

• Visualization and identification of the sentinel node is identical in palpable and non-palpable breast cancer

• Probe-guided excision of the non-palpable tumor is safe and facilitates the localization of the primary tumor