AMAROS trial and beyond
(Has axillary clearance become obsolete?)

Emiel Rutgers
For doctors and nurses

6th Aarhus Workshop in: Breast Surgery

May 17-18, 2017

No financial disclosures

Emiel Rutgers
Question for you

Lady, 45 yrs, self detected breast cancer left breast, 1.5 cm, ER 90%, PgR 90%, unifocal. Ultrasound axilla: normal nodes

• Who would advice breast conservation and SN procedure?
Next question

Lady, 45 yrs, self detected breast cancer left breast, 1.5 cm, ER 90%, PgR 90%, unifocal, Ultrasound axilla normal nodes

• Who would do intraoperative examination of SN?
Next question

Histology: 16 mm gr 2 IDC, complete margins, Ki67 15%, SN meta 3 mm, 2nd node -ve

• Who would advice ALND?
Next question

Histology: 16 mm gr 2 IDC, complete margins, Ki67 15%, SN meta 3 mm, 2nd node -ve

• Who would advice wait and see?
Next question

Histology: 16 mm gr 2 IDC, complete margins, Ki67 15%, SN meta 3 mm, 2nd node -ve

• Who would advice RT to the axilla?
Next question
Other pathology!

Histology: 22 mm gr 2 IDC, complete margins, Ki67 30%, SN meta 7 mm, 2nd node 1 mm meta.

• Who would advice W & S, RT to the axilla, ALND?
Lymph nodes & breast cancer
Why knowing the lymph nodes status?
The old paradigm

- Provide for prognostic information to guide adjuvant systemic and regional treatment: surgery, radiotherapy, chemo/hormonal Rx
  
  ➢ Improved regional control
  ➢ Improved survival
Lymph nodes & breast cancer
Why knowing the lymph node status?
Improving regional control?

Yes, no doubt, but…
• At what price? Is this what we want?
Occurrence axilla after –ve SN
remind +/- 7% false positive if back up ALND is done!

studies 34
patients 14959
Occurrences (‘relapses’) 67
Risk 0.3%!

After ALND
Risk axillary relapse 0.8 – 2.3

+ ve Sentinel lymph nodes & further nodal involvement.
The nomograms: a complete new science

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<td>120</td>
<td>140</td>
<td>160</td>
<td>180</td>
<td>200</td>
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<tr>
<td>Predicted Probability of + Non-SLN</td>
<td>0.02</td>
<td>0.05</td>
<td>0.1</td>
<td>0.2</td>
<td>0.3</td>
<td>0.4</td>
<td>0.5</td>
<td>0.6</td>
<td>0.7</td>
<td>0.8</td>
<td>0.92</td>
</tr>
</tbody>
</table>
+ve Sentinel lymph nodes & further nodal involvement.

• I am not interested in the risk of further nodal involvement at ALND, but in the clinical relapse rate
Clinically node negative disease & +ve SN
Level 1 evidence

- IBCSG 027: Galimberti 2013
- AMAROS: Donker et al 2014
- OTOSAOR: ECCO 2017/EJSO 2017
ACOSOG Z0011

After a median follow-up of 6.3 years:

**Survival:**

Conclusions: Despite the potential for residual axillary disease after SLND, SLND without ALND can offer excellent regional control and may be reasonable management for selected patients with early-stage breast cancer treated with breast-conserving therapy and adjuvant systemic therapy.

Giuliano, JAMA 2011 Feb 9; 305(6); Giuliano, Ann Surg 2010; 252: 426-433;
ACOSOG Z0011

After a median follow-up of 9.25 years:

FIGURE 2. Cumulative incidence of locoregional recurrence by treatment arm.
Radiotherapy or surgery of the axilla after a positive sentinel node in breast cancer patients: final analysis of the EORTC AMAROS trial

By the EORTC Breast Cancer Group and Radiation Oncology Group
In collaboration with the Dutch BOOG Group and ALMANAC Trialists’ Group

Donker, Lancet Oncol 2014 Nov;15(12)
Hypothesis (in 1999)

Axillary radiotherapy provides local control and survival comparable to ALND with fewer side effects in women with a positive axillary SN
Eligibility Criteria

**Inclusion**
- Invasive breast cancer 0.5-5 cm
- Clinically N0
- BCT or mastectomy
- Any age
- Informed consent

**Exclusion**
- Multicentric disease
- Neoadjuvant systemic treatment
- Previous axillary treatment
- Prior malignancy
Trial design

Stratification: institution
Adjuvant systemic therapy by choice
Objectives

**Primary**: To demonstrate non-inferiority in axillary recurrence rate

**Secondary**:
1. To compare overall survival (OS) and disease-free survival (DFS)
2. To compare lymphedema, shoulder function and Quality of Life (QoL)
Endpoints and statistical design

Primary: 5-years axillary recurrence free rate
Non inferiority hypothesis (design):
• assumption: ALND 98%; ART >96%
• one-sided log-rank; alpha = 0.05; power = 80%
• 52 events needed

Secondary:
• Efficacy: OS and DFS
• Safety: shoulder function, lymphedema, QoL
ART

- Timing:
  Start < 12 weeks after SNB

- Extent:
  level I + II + III + medial SC

- Dose & schedule:
  25 x 2 Gy or equivalent

- Quality control:
  dummy run

*Hurkmans et al, Radiother Oncol 2003*
ALND

• Timing:
  < 12 weeks after SNB

• Extent:
  Level I + II mandatory
  Level III optional

• Additional ART:
  ≥ 4 positive nodes
2001-2010: 4806 patients enrolled (4766 required)
All included patients
n = 4806

SNB negative
N = 3131 (65.1%)

SNB positive
N = 1425 (29.7%)

SNB not identified
N = 132 (2.7%)

SNB other
N = 118 (2.5%)

Excluded
N = 146

Intent-to-treat  (ITT)
sample

ALND
N = 744

ART
N = 681

Excluded
N = 146

10 not eligible
85 ITC only (before amendment)
51 Non-compliance

Per Protocol (PP)
sample

ALND
N = 598

ART
N = 535

Excluded
N = 146

8
67
71
# Baseline clinical

<table>
<thead>
<tr>
<th></th>
<th>ALND (744 pts)</th>
<th>ART (681 pts)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Median age (Q1-Q3)</strong></td>
<td>56 (48 - 64)</td>
<td>55 (48 - 63)</td>
</tr>
<tr>
<td><strong>Menopausal stage</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>pre-menopausal</td>
<td>38.1 %</td>
<td>42.5 %</td>
</tr>
<tr>
<td>post-menopausal</td>
<td>57.7 %</td>
<td>54.5 %</td>
</tr>
<tr>
<td><strong>Median tumor size (Q1-Q3)</strong></td>
<td>17 mm (13 - 22)</td>
<td>18 mm (13 - 23)</td>
</tr>
<tr>
<td><strong>Grade</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>24.1 %</td>
<td>22.6 %</td>
</tr>
<tr>
<td>2</td>
<td>47.8 %</td>
<td>45.7 %</td>
</tr>
<tr>
<td>3</td>
<td>25.8 %</td>
<td>29.4 %</td>
</tr>
<tr>
<td><strong>Pre-operative ultrasound axilla</strong></td>
<td>59.2 %</td>
<td>61.5 %</td>
</tr>
</tbody>
</table>
## Treatment compliance

<table>
<thead>
<tr>
<th></th>
<th>ALND (744 pts)</th>
<th>AxRT (681 pts)</th>
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</thead>
<tbody>
<tr>
<td>Randomized treatment</td>
<td>631 (84.8 %)</td>
<td>590 (86.6 %)</td>
</tr>
<tr>
<td>Both treatments</td>
<td>41 (5.5 %)</td>
<td>1 (0.1 %)</td>
</tr>
<tr>
<td>Cross-over</td>
<td>46 (6.2 %)</td>
<td>68 (10.0 %)</td>
</tr>
<tr>
<td>No axillary treatment</td>
<td>24 (3.2 %)</td>
<td>22 (3.2 %)</td>
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</table>
## Baseline treatment

<table>
<thead>
<tr>
<th></th>
<th>ALND (744 pts)</th>
<th>AxRT (681 pts)</th>
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</thead>
<tbody>
<tr>
<td><strong>Breast surgery</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BCS</td>
<td>81.9 %</td>
<td>81.8 %</td>
</tr>
<tr>
<td>Mastectomy</td>
<td>17.1 %</td>
<td>17.8 %</td>
</tr>
<tr>
<td><strong>Systemic treatment</strong></td>
<td></td>
<td></td>
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<tr>
<td>chemotherapy</td>
<td>60.9 %</td>
<td>61.3 %</td>
</tr>
<tr>
<td>hormonal therapy</td>
<td>78.6 %</td>
<td>77.1 %</td>
</tr>
<tr>
<td>immunotherapy</td>
<td>6.0 %</td>
<td>6.4 %</td>
</tr>
<tr>
<td>no systemic treatment</td>
<td>9.0 %</td>
<td>9.4 %</td>
</tr>
<tr>
<td>RT breast/chest wall</td>
<td>84.8 %</td>
<td>87.7 %</td>
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</table>
## SN results

<table>
<thead>
<tr>
<th></th>
<th>ALND (744 pts)</th>
<th>AxRT (681 pts)</th>
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<tbody>
<tr>
<td><strong>Median number of SN</strong></td>
<td>2 (1-3)</td>
<td>2 (1-3)</td>
</tr>
<tr>
<td>removed (Q1-Q3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Size of metastases in SN</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>macrometastases</td>
<td>59.4 %</td>
<td>61.5 %</td>
</tr>
<tr>
<td>micrometastases</td>
<td>28.9 %</td>
<td>28.6 %</td>
</tr>
<tr>
<td>ITC</td>
<td>11.7 %</td>
<td>9.8 %</td>
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</table>

*Straver et al, Ann Surg Oncol 2010*
## ALND results

<table>
<thead>
<tr>
<th></th>
<th>ALND (744 pts)</th>
</tr>
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<tbody>
<tr>
<td>Median number of all nodes removed (Q1-Q3)</td>
<td>15 (12-20)</td>
</tr>
<tr>
<td>Number of additional positive nodes (besides SN)</td>
<td></td>
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<tr>
<td>0</td>
<td>67.1 %</td>
</tr>
<tr>
<td>1-3</td>
<td>25.0 %</td>
</tr>
<tr>
<td>≥ 4</td>
<td>7.8 %</td>
</tr>
</tbody>
</table>
Axillary recurrence rate

5-years axillary recurrence rate:
ALND 0.43%  (4 / 744 events (0.54%))
AxRT 1.19%  (7 / 681 events (1.03%))
<< hypothesis (2%)
Consequence: planned comparison is underpowered
Disease-free survival

HR: 1.17; 95% CI: 0.93-1.51
P = 0.18
Overall survival

HR: 1.17; 95% CI: 0.85-1.62
P = 0.34

Breast cancer specific deaths:
ALND: 53 (7.1 %)
AxRT: 54 (7.9 %)
Results side effects

50-70% form compliance at all time points
Lymphedema of the arm

Measured: 1, 3 and 5 years after treatment

Items:
1. Clinical observation
2. Treatment for edema:
   - sleeve garment
   - lymph drainage therapy
   - compression therapy
Lymphedema: clinical observation and/or treatment

Years after randomization

<table>
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<tr>
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<th>ALND</th>
<th>AxRT</th>
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<tr>
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<td>40.0%</td>
<td>21.7%</td>
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<td>3</td>
<td>29.8%</td>
<td>16.7%</td>
</tr>
<tr>
<td>5</td>
<td>28.0%</td>
<td>13.6%</td>
</tr>
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</table>

P < 0.0001
Lymphoedema: clinical observation

years since randomisation

0 10 20 30 40 50 60

ALND
ART
ALND+ART
Pre-operative ultrasound of the axilla

3 groups:
1. no ultrasound performed
2. ultrasound performed: no suspected nodes
3. ultrasound performed: suspected nodes, but CP negative
Results: # positive (sentinel) nodes

<table>
<thead>
<tr>
<th>SNB result</th>
<th>Not done (N=1752)</th>
<th>Normal (N=2667)</th>
<th>Abnormal, no metastases (N=314)</th>
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<tbody>
<tr>
<td>SNB+</td>
<td>478 (27.3)</td>
<td>691 (25.9)</td>
<td>83 (26.4)</td>
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<tr>
<td>SNB- / ITC only</td>
<td>1204 (68.7)</td>
<td>1868 (70.0)</td>
<td>223 (71.0)</td>
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<table>
<thead>
<tr>
<th>Additional positive nodes in ALND specimen</th>
<th>No</th>
<th>Abnormal, no metastases</th>
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<tbody>
<tr>
<td>No</td>
<td>156 (63.9)</td>
<td>34 (72.3)</td>
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<tr>
<td>Yes</td>
<td>88 (36.1)</td>
<td>13 (27.7)</td>
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Results: axillary recurrence rate

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<td>229</td>
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**Results: disease-free survival**

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<th>Axilla ultrasound</th>
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<td>326</td>
<td>1752</td>
<td>1637</td>
<td>1409</td>
<td>791</td>
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<tr>
<td>334</td>
<td>2667</td>
<td>2433</td>
<td>1526</td>
<td>602</td>
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<tr>
<td>49</td>
<td>314</td>
<td>295</td>
<td>214</td>
<td>100</td>
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(years)
AMAROS: not bitter but sweet
Conclusion AMAROS trial

- Both ALND and ART provide excellent and comparable locoregional control in SN+ patients
- Significantly less lymphedema after ART
- ART can be considered standard or… is a validated treatment for patients with SN +ve
Acknowledgement

We are very grateful to all the patients who participated in this trial
Acknowledgement

Research fellows: Mila Donker, Marieke Straver, Philip Meijnen

Principal investigators: Cornelis van de Velde, Robert Mansel, Geertjan van Tienhoven

EORTC headquarters: Nicole Duez, Leen Slaets, Jan Bogaerts, Carlo Messina, Corneel Coens, the IDMC

EORTC Breast Cancer Group
EORTC Radiation Oncology Group
Dutch BOOG Group
ALMANAC Trialists’ Group
BCT in clinically node negative disease & SN

Conclusion

• Breast cancer patients with clinically node negative disease and one or two tumor-positive SLNs can be safely treated with breast conserving surgery and radiotherapy without performing ALND.

→ Therefore, intra-operative assessment of SLNs should not be performed in these patients.
When is ALND for the treatment of breast cancer indicated? ASCO guideline update

- Women without SLN metastases should not receive ALND
When is ALND for the treatment of breast cancer indicated? ASCO guideline update

- Women with 1-2 metastatic SLNs who are planning to undergo breast-conserving surgery with whole-breast radiotherapy should not undergo ALND (in most cases).
When is ALND for the treatment of breast cancer indicated? ASCO guideline update

- Women with SLN metastases who will undergo mastectomy should be offered ALND.
When is ALND for the treatment of breast cancer indicated? ASCO guideline update

• Women with SLN metastases who will undergo mastectomy should be offered ALND.

➔ CONTROVERSY!?
SN and mastectomy

- EBCTCG overview sees advantage for post mastectomy RT in patients with 1-3 positive lymph nodes: better locoregional control and breast cancer related survival
Lymph nodes in breast cancer
RT after mastectomy?

Effect of radiotherapy after mastectomy and axillary surgery on 10-year recurrence and 20-year breast cancer mortality: meta-analysis of individual patient data for 8135 women in 22 randomised trials

EBCTCG (Early Breast Cancer Trialists’ Collaborative Group) *

EBCTCG, Lancet 2014 Jun 21
Lymph nodes in breast cancer.

RT after mastectomy?

**Figure 2A-C.** Radiotherapy (RT) after mastectomy.

1314 pN1–3 women with Mast+AD

**A** Locoregional recurrence first

- Log-rank \( p < 0.00001 \)

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<th>Time (Years)</th>
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<th>RT</th>
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<td>1</td>
<td>16.5%</td>
<td>20.3%</td>
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<tr>
<td>5</td>
<td>3.8%</td>
<td>1.8%</td>
</tr>
</tbody>
</table>

**B** Any first recurrence

- 10-year gain 11.5\% (SE 2.9)
- RR 0.68 (95\% CI 0.57–0.82)
- Log-rank \( p = 0.00006 \)

<table>
<thead>
<tr>
<th>Time (Years)</th>
<th>No RT</th>
<th>RT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>35.0%</td>
<td>45.7%</td>
</tr>
<tr>
<td>5</td>
<td>24.8%</td>
<td>34.2%</td>
</tr>
</tbody>
</table>

**C** Breast cancer mortality

- 20-year gain 7.9\% (SE 3.1)
- RR 0.80 (95\% CI 0.67–0.95)
- Log-rank \( p = 0.01 \)

<table>
<thead>
<tr>
<th>Time (Years)</th>
<th>No RT</th>
<th>RT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>36.8%</td>
<td>47.0%</td>
</tr>
<tr>
<td>5</td>
<td>31.2%</td>
<td>37.9%</td>
</tr>
</tbody>
</table>

Lymph nodes in breast cancer.
RT after mastectomy?

**Figure 5:** Effect of radiotherapy (RT) after mastectomy and axillary dissection (Mast+AD) on 10-year risks of locoregional and overall recurrence and on 20-year risk of breast cancer mortality in 1133 women with one to three pathologically positive nodes (pN1–3) in trials in which systemic therapy was given to both randomised treatment groups.

Analyses of locoregional recurrence first ignore distant recurrences, see appendix pp 8–9 for details. See appendix p 22 for analyses of both locoregional and distant recurrences, and appendix p 21 for analyses of overall mortality. RR=rate ratio. Vertical lines indicate 1 SE above or below the 5, 10, 15, and 20 year percentages.
Mastectomy, immediate reconstruction and radiotherapy

- Associated with less good cosmesis and more complications/ repeat surgeries
- Is in itself possible
- Local control appears not to be affected
SN & ALND
The controversies: our NKI team position

Positive SN & mastectomy in cN0

➢ First do mastectomy (incl. reconstruction if desired) and SN: then full pathology and discuss in MDM what to do: wait & see, ALND (+/- PMRT!) or PMRT
Lymph nodes in breast cancer. Where are we now?

NO lymph node treatment:
  • SN –ve
  • SN itc
  • SN micrometa <2 mm if systemic adjuvant treatments is given
  • SN macrometa, limited involvement, favourable tumorcharacteristics, incl. adj syst Rx & Whole Breast Breast Irradiation (Z-011 criteria)
Lymph nodes in breast cancer. Where are we now?

Radiotherapy to the axilla (usually ‘high tangents’ will do):

• SN macrometa high risk (multiple, larger primary)
Lymph nodes in breast cancer. Where are we now?

Lymph node treatment (ALND):
• Residual macrometastases after upfront therapy
• Patients undergoing a mastectomy with SN involvement where there is no indication for post mastectomy RT (but according recent EBCTCG Lancet paper there is a survival benefit after RT in 1-3 +ve nodes)
The fate of ALND (NKI data)

ALND with Mastectomy

Years: 1977 to 2014

Graph showing the percentage of ALND with mastectomy from 1977 to 2014.
The fate of ALND NKI data

ALND and Breast Conservation

Niet gedaan
Gedaan

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%


Gedaan
Niet gedaan

0 50 100 150 200 250 300 350


Gedaan
Niet gedaan
PRIMARY TREATMENT OF EARLY BREAST CANCER
ST. GALLEN 2017

ESCALATING AND DE-ESCALATING TREATMENT IN EARLY BREAST CANCER ACROSS SUBTYPES AND TREATMENT MODALITIES

Consensus & Controversy
Surgery of the Axilla

13. In patients with macro-metastases in 1-2 sentinel nodes, completion of axillary dissection can safely be omitted following:
Mastectomy (no radiotherapy to lymph nodes planned)

(1) Yes

(2) No  86%

(3) Abstain

15th St. Gallen International Breast Cancer Conference 2017 Consensus
Surgery of the Axilla

14. In patients with macro-metastases in 1-2 sentinel nodes, completion of axillary dissection can safely be **omitted** following:

Mastectomy (radiotherapy to lymph nodes planned)

(1) Yes  84%

(2) No

(3) Abstain

15th St.Gallen International Breast Cancer Conference 2017 Consensus
Surgery of the Axilla

16. In patients with macro-metastases in 1-2 sentinel nodes, completion of axillary dissection can safely be *omitted* following:
Conservative resection with radiotherapy using high tangents

(1) Yes  77%

(2) No

(3) Abstain

15th St.Gallen International Breast Cancer Conference 2017 Consensus
Thank you!
For inviting me
Your attention
The EORTC AMAROS team
The NKI Breast Cancer Team
Questions?