# Axillary dissection versus no axillary dissection

in patients with breast cancer and sentinel-node metastases

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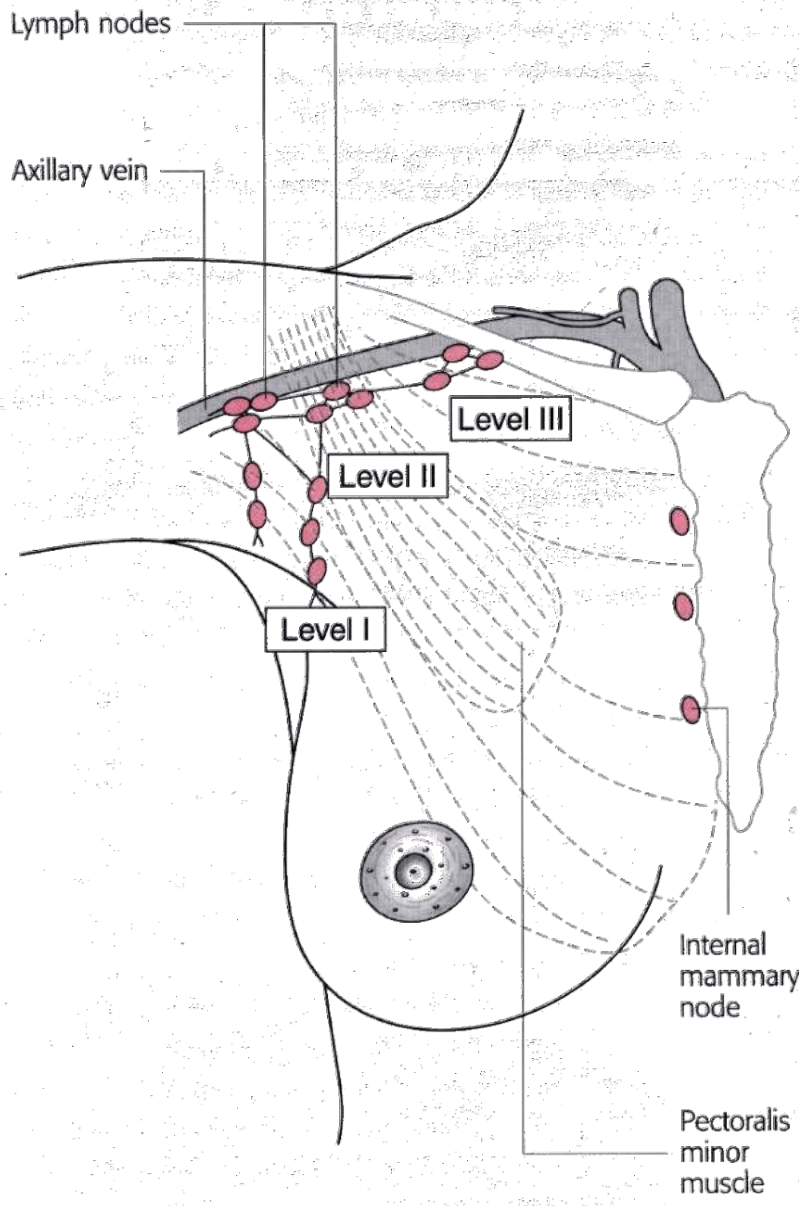
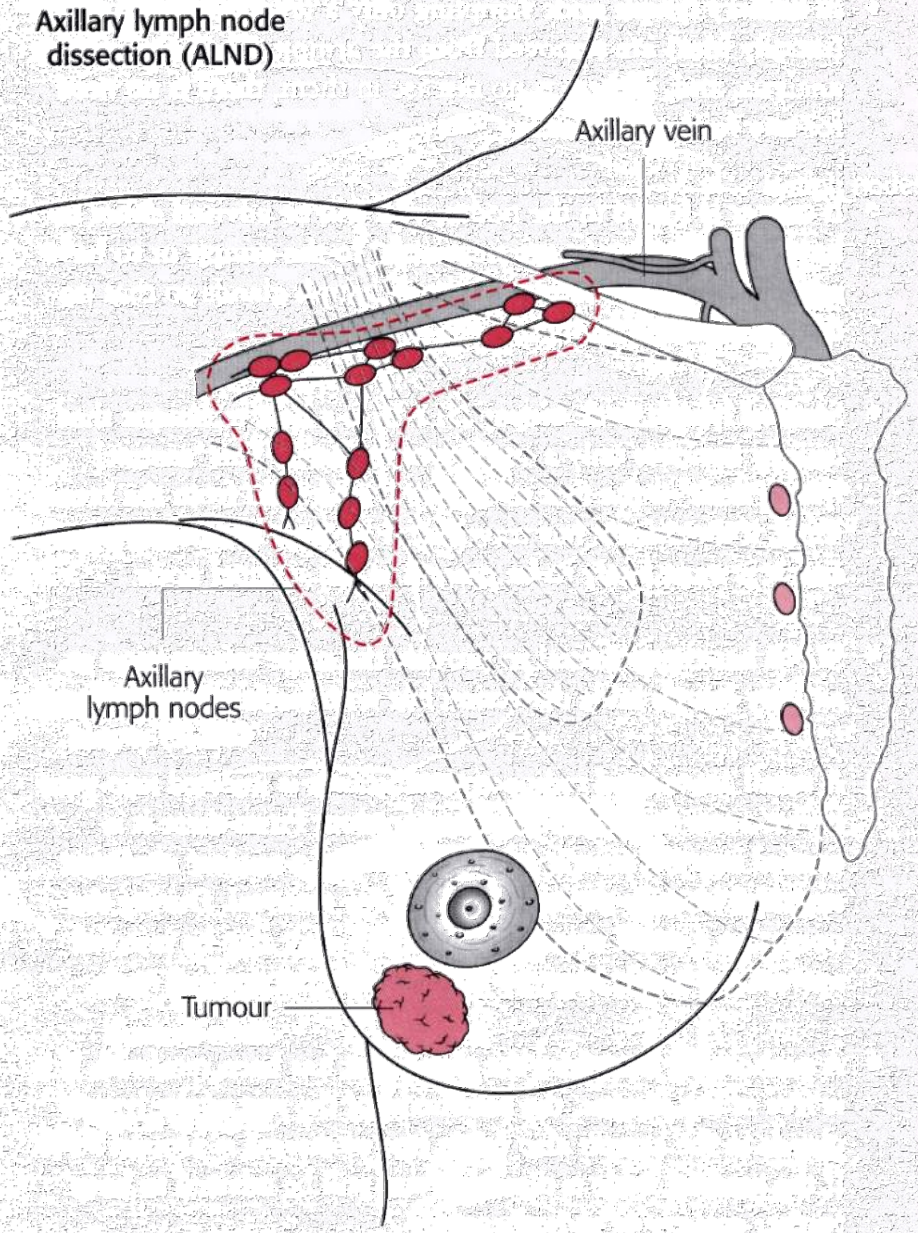
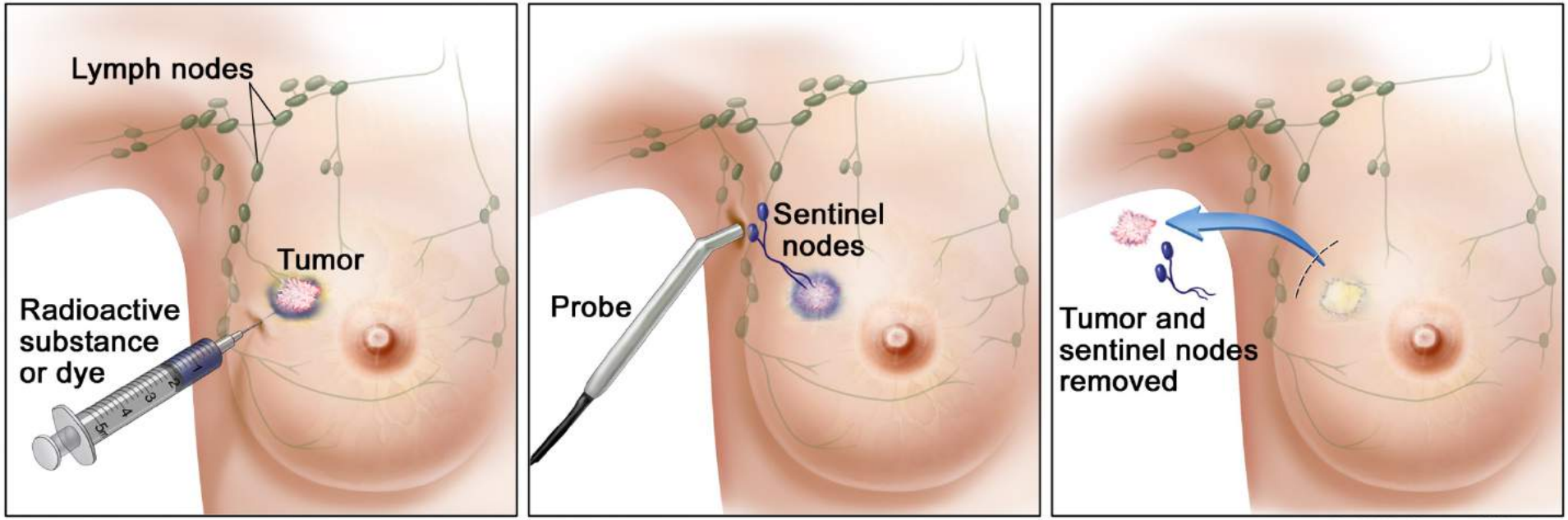
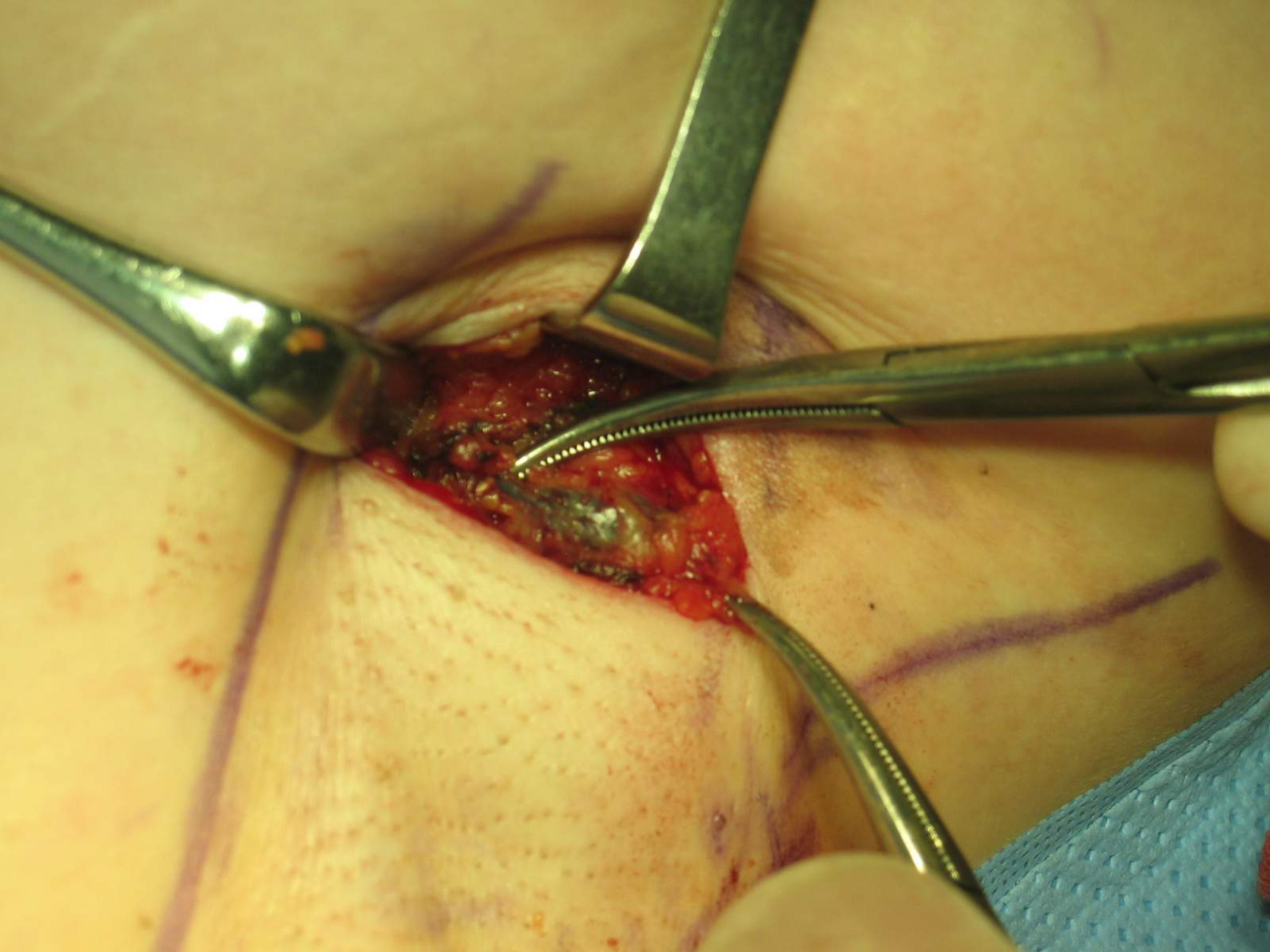

Lymph nodes
Axillary vein
Level III
Level II
Level I
Internal mammary node
Pectoralis minor muscle


Axillary lymph node dissection (ALND)
Axillary vein
Axillary lymph nodes
Tumour

## Sentinel Lymph Node Biopsy





# Sentinel node biopsy (SLNB) first series and first generation trials

- First series
  Krag DN et al.:Surg Oncol 1993: 2:335-339
  Giuliano AE et al.: Ann Surg 1994: 220:391-398
  Albertini JJ et al.: JAMA 1996: 276:1818-182

- 69 series and 5 randomized trials:
  - SLNB succesfull rate 96%
  - Average false negative rate 7%

- Regional relaps rate in SLN neg, FU 8 let: 0.4% (Weaver DL et al. NEJM, 2011; Rutgers EJ et al. JCO, 2008)

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EJSO 40 (2014) 1203–1208

www.ejso.com

# Long-term follow-up of 5262 breast cancer patients with negative sentinel node and no axillary dissection confirms low rate of axillary disease

V. Galimberti [a,*], A. Manika [a], P. Maisonneuve [b], G. Corso [a], L. Salazar Moltrasio [a], M. Intra [a], O. Gentilini [a], P. Veronesi [a,c], G. Pagani [a], E. Rossi [a], L. Bottiglieri [d], G. Viale [c,d], N. Rotmensz [b], C. De Cicco [e], C.M. Grana [e], C. Sangalli [a], A. Luini [a]

*Conclusion*: Long-term follow-up of our large series confirms that axillary metastasis is infrequent when AD is omitted in SN-negative breast cancer patients, and has low impact on overall survival.

Axillary relaps rate : 1,7 % (median FU 7 years)

# Undissected Lymph Nodes and Nodal Recurrence

| Study (Year) ALND vs None | Positive Nodes in ALND | Nodal Recurrence in No ALND |
|---|---|---|
| NSABP B-04 (1977) | 40% | 15% |
| Martelli (2005) | 23% | 1.8% |
| IBCSG (2006) | 28% | 3.0% |
| ACOSOG Z0011 (2010) | 27% | 0.9% |

***No significant differences in overall survival.***

***All nodal metastases do not progress or metastasize.***



Fisher B. *Cancer* 39:2827-2839, 1977; Martelli G. *Ann Surg* 2005; 242(1): 1–6; Rudenstam CM, et al. *J Clin Oncol.* 2006;24:337-344; Giuliano AE. *Ann Surg* 2010; 252(3):426-32.

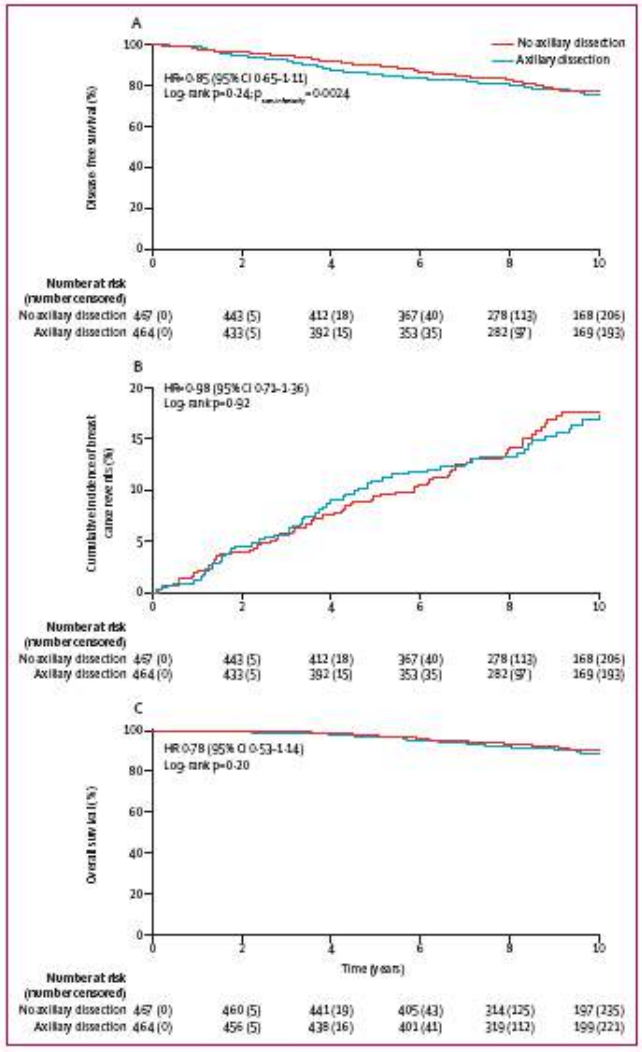
# Open questions when the sentinel lymph node is metastatic

- Omitting ALND in metastatic SLN?
- SLNB after neoadjuvant CT?
- Omitting axillary staging (no SLNB!)?

www.thelancet.com/oncology Vol 19 October 2018

# Axillary dissection versus no axillary dissection in patients with breast cancer and sentinel-node micrometastases (IBCSG 23-01): 10-year follow-up of a randomised, controlled, phase 3 trial

*Viviana Galimberti, Bernard F Cole, Giuseppe Viale, Paolo Veronesi, Elisa Vicini, Mattia Intra, Giovanni Mazzarol, Samuele Massarut, Janez Zgajnar, Mario Taffurelli, David Littlejohn, Michael Knauer, Carlo Tondini, Angelo Di Leo, Marco Colleoni, Meredith M Regan, Alan S Coates, Richard D Gelber, Aron Goldhirsch, for the International Breast Cancer Study Group Trial 23-01**




| | No axillary dissection (n=467) | Axillary dissection (n=464) |
|---|---|---|
| Disease-free survival events* | 101 (22%) | 117 (25%) |
| Breast cancer events | 74 (16%) | 75 (16%) |
| Local recurrences | 14 (3%) | 13 (3%) |
| Regional events | 9 (2%) | 3 (1%) |
| Ipsilateral axillary failures | 8 (2%) | 2 (<1%) |
| Distant | 41 (9%) | 47 (10%) |
| Contralateral breast | 10 (2%) | 12 (3%) |
| Non-breast cancer events | 27 (6%) | 42 (9%) |
| Second (non-breast) primary | 17 (4%) | 23 (5%) |
| Death without previous cancer event | 6 (1%) | 2 (<1%) |
| Death with unknown cancer status | 4 (<1%) | 17 (4%) |
| Deaths | 45 (10%) | 58 (13%) |

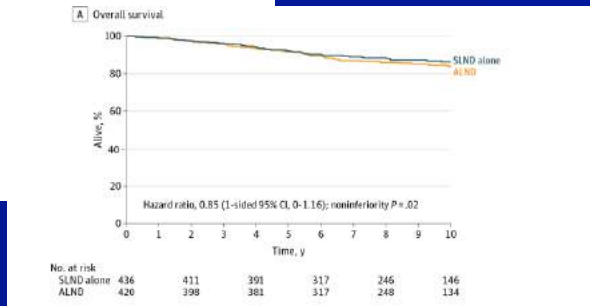
Data are n (%) in the intention-to-treat population after a median follow-up of 9·7 years (IQR 7·8–12·7). *Includes breast-cancer events and non-breast cancer events.

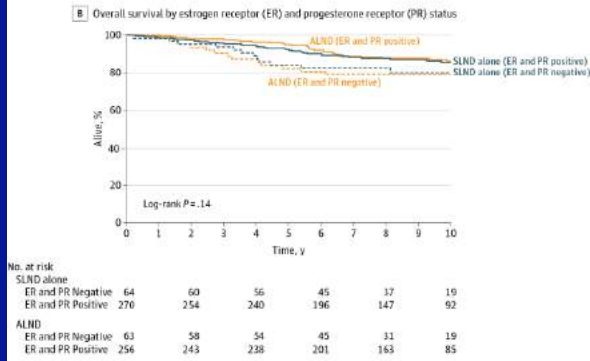
*Table 1:* Disease-free survival events and number of deaths

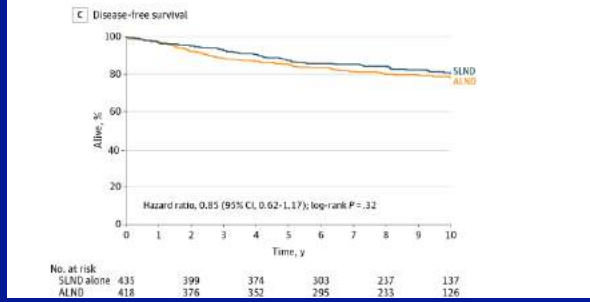
Number and Cumulative Incidence of Locoregional Recurrences (%) at Specific Time Points

| | ALND | | | | SLND only | | | |
|---|---|---|---|---|---|---|---|---|
| Time | # at risk | LRR events | Local events | Regional events | # at risk | LRR events | Local events | Regional events |
| 1 year | 375 | 1 (0.3%) | 1 (0.3%) | 0 (0.0%) | 394 | 2 (0.5%) | 1 (0.2%) | 1 (0.2%) |
| 2 year | 342 | 9 (2.4%) | 8 (2.1%) | 1 (0.3%) | 365 | 3 (0.7%) | 1 (0.2%) | 2 (0.5%) |
| 5 year | 286 | 15 (4.0%) | 13 (3.5%) | 2 (0.5%) | 279 | 12 (3.3%) | 8 (2.2%) | 4 (1.1%) |
| 10 year | 130 | 21 (6.2%) | 19 (5.6%) | 2 (0.5%) | 139 | 17 (5.3%) | 12 (3.8%) | 5 (1.5%) |

Giuliano A et al: Ann Surg. 2016 Sep; 264(3): 413–420.




# The ACOSOG Z0011 Trial

- Breast conserving surgery
- T1-2, clinically N0, <=2 positive SLN, no extranodal extension

Giuliano A et al: JAMA. 2017 Sep 12;318(10):918-926

Published in final edited form as:
*Lancet Oncol*. 2014 November ; 15(12): 1303–1310. doi:10.1016/S1470-2045(14)70460-7.

# Radiotherapy or surgery of the axilla after a positive sentinel node in breast cancer (EORTC 10981-22023 AMAROS):a randomised, multicentre, open-label, phase 3 non-inferiority trial

**Mila Donker**, **Geertjan van Tienhoven**, **Marieke E Straver**, **Philip Meijnen**, **Cornelis J H van de Velde**, **Robert E Mansel**, **Luigi Cataliotti**, **A Helen Westenberg**, **Jean H G Klinkenbijl**, **Lorenzo Orzalesi**, **Willem H Bouma**, **Huub C J van der Mijle**, **Grard A P Nieuwenhuijzen**, **Sanne C Veltkamp**, **Leen Slaets**, **Nicole J Duez**, **Peter W de Graaf**, **Thijs van Dalen**, **Andreas Marinelli**, **Herman Rijna**, **Marko Snoj**, **Nigel J Bundred**, **Jos W S Merkus**, **Yazid Belkacemi**, **Patrick Petignat**, **Dominic A X Schinagl**, **Corneel Coens**, **Carlo G M Messina**, **Jan Bogaerts**, and **Emiel J T Rutgers**

radiotherapy group. 5-year axillary recurrence was 0·43% (95% CI 0·00–0·92) in the axillary lymph node dissection group and 1·19% (0·31–2·08) in the axillary radiotherapy group. The one-sided 95% CI for the underpowered non-inferiority test on the HR was 0·00–5·27, with a non-inferiority margin of 2. In the group of 3131 patients with a negative sentinel node, 25 axillary recurrences occurred during the entire follow-up period (axillary recurrence rate 0·72%, 95% CI 0·39–1·04).



is non-inferior to axillary lymph node dissection. The AMAROS trial cannot answer the remaining question of which subset of clinically node-negative, sentinel-node-positive patients still require axillary treatments. In our opinion, if further axillary treatment is needed in clinically node-negative, sentinel-node-positive patients, axillary radiotherapy could be chosen instead of axillary lymph node dissection because it provides comparable axillary control and less morbidity.

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EJSO 43 (2017) 672–679

www.ejso.com

# Eight-year follow up result of the OTOASOR trial: The Optimal Treatment Of the Axilla – Surgery Or Radiotherapy after positive sentinel lymph node biopsy in early-stage breast cancer: A randomized, single centre, phase III, non-inferiority trial

Á. Sávolt [a,*], G. Péley [b,†], C. Polgár [c], N. Udvarhelyi [d], G. Rubovszky [d], E. Kovács [e], B. Győrffy [f], M. Kásler [a], Z. Mátrai [a]

*Conclusions*: The long term follow-up results of this prospective-randomized trial suggest that RNI without cALND does not increase the risk of axillary failure in selected patients with early-stage invasive breast cancer (cT ≤ 3 cm, cN0) and pN1(sn). Axillary radiotherapy should be an alternative treatment for selected patients with sentinel lymph node metastases.



Axillary relaps rate :

ALND 2% vs RT 1,7%

# ALND can be omitted in :

- Breast conserving surgery
  - ITC
  - micrometastases
  - Macrometastases in <= 2 SLN, no extracapsular extension, followed by RT of the breast
- Mastectomy
  - ITC, micrometastases

Regional RT an option !

# Ongoing trials studying no ALND in macrometastatic SLN after mastectomy

**Table 1** Ongoing clinical trials in axillary surgery [95]

| | Country/name | Population | Randomization | Endpoint | Size | Start | End | TAXIS overlap |
|---|---|---|---|---|---|---|---|---|
| 1 | Italy: SOUND IEO S637/311 NCT02167490 | cT1cN0 US negative | SLN vs. observation | DDFS | 1560 | Jan 2012 | Jan 2017 | No |
| 2 | Germany: INSEMA NCT02466737 | cT1–2 cN0 US negative | 1. SLN vs. observation 2. 1–2 SLN+ → ALND vs. no ALND | DFS | 7095 | Sept 2015 | Sept 2024 | No |
| 3 | France: SERC/IPC 2012–001 DNCT01717131 | cT1–2 cN0 | ALND vs. no ALND | DFS | 3000 | July 2012 | July 2025 | Minimal |
| 4 | China: Z0011-China NCT01796444 | cT1–2 cN0 1–2SLN+ | ALND vs. no ALND | DFS | Not shown | Jan 2013 | June 2026 | No |
| 5 | Sweden: SENOMAC NCT02240472 | cT1–2 cN0 cT1–2 iN1 1–2 SLN+ | ALND vs. no ALND | BCSS | 3500 | Jan 2015 | Dec 2029 | Minimal |
| 6 | United Kingdom: POSNOC NCT02401685 | cT1–2 1–2 SLN+ | ALND or axillary radiotherapy vs. no axillary treatment | Axillary recurrence | 1900 | Jan 2014 | Mar 2023 | No |
| 7 | Netherlands: BOOG 2013–07 NCT02112682 | cT1–2 cN0 1–3 SLN+ mastectomy | ALND or axillary radiotherapy vs. no axillary treatment | RRR | 878 | June 2014 | June 2027 | No |
| 8 | USA: Alliance A011202 NCT01901094 | cT1-3cN1 (S)LN+ after NACT | ALND+ extended regional nodal irradiation vs. axillary radiotherapy + extended regional nodal irradiation | IBC-RFI | 2918 | Feb 2014 | Jan 2024 | Partial |

*ALND* axillary lymph node dissection, *BCSS*, *DFS* disease-free survival, *IBC*, *NACT*, *RFI*, *RRR*, *SLN* sentinel lymph node, *US* ultrasound

# SERC

| | | | | | | |
|---|---|---|---|---|---|---|
| France: SERC/IPC 2012–001 DNCT01717131 | cT1–2 cN0 | ALND vs. no ALND | DFS | 3000 | July 2012 | July 2025 |

Compared to previous randomized trials, patients with one or more positive SN, multicentric tumours, <=T2 N0, ITC or micro-metastases or macro-metastases with or without capsular effraction were allowed to participate. Neoadjuvant chemotherapy (NAC) with SLNB before chemotherapy, mastectomy or conservative breast surgery was permitted.

undergo ALND. Axillary ultra-sonography was a systematic recommended pre-operative exam but was not recorded in the trial.

| | | | | |
|---|---|---|---|---|
| Involved SN | <=2 | 925 (98.51) | 424 (98.60) | 501 (98.43) |
| | > 2 | 14 (1.49) | 6 (1.40) | 8 (1.57) |
| | ITC | 57 (6.31) | 22 (5.30) | 35 (7.17) |
| SN status | Micro | 298 (33.00) | 137 (33.01) | 161 (32.99) |
| | Macro | 548 (60.69) | 256 (61.69) | 292 (59.84) |

Houvenaeghel *et al. BMC Cancer* (2018) 18:1153
https://doi.org/10.1186/s12885-018-5053-7

# SENOMAC

| | | | | | | |
|---|---|---|---|---|---|---|
| Sweden: SENOMAC<br>NCT02240472 | cT1–2 cN0<br>cT1–2 iN1<br>1–2 SLN+ | ALND vs. no ALND | BCSS | 3500 | Jan 2015 | Dec 2029 |

**Table 1** Inclusion and exclusion criteria according to the SENOMAC study protocol

| | |
|---|---|
| Inclusion criteria | Primary invasive breast cancer T1-T3[a] |
| | Preoperative ultrasound of the axilla performed |
| | Macrometastasis in not more than two lymph nodes at sentinel node biopsy |
| | Written informed consent |
| | Age 18 years or older |
| Exclusion criteria | Palpable regional lymph node metastasis prior to surgery |

de Boniface *et al. BMC Cancer* (2017) 17:379

# POSNOC

| | | | | | | |
|---|---|---|---|---|---|---|
| United Kingdom: POSNOC NCT02401685 | cT1–2 1–2 SLN+ | ALND or axillary radiotherapy vs. no axillary treatment | Axillary recurrence | 1900 | Jan 2014 | Mar 2023 |

**POSNOC: key differences from Z11**

Axillary ultrasound is mandatory

Mastectomy patients are eligible
Prospective pathology reporting

Only patients with macrometastases are eligible
Patients with extranodal invasion are eligible
Radiotherapy quality assurance programme

Axillary treatment in the standard group may be axillary lymph node dissection or axillary radiotherapy

*A. Goyal, D. Dodwell / Clinical Oncology 27 (2015) 692–695*

# BOOG 2013-07

| | | | | | | |
|---|---|---|---|---|---|---|
| Netherlands: BOOG 2013–07 NCT02112682 | cT1–2 cN0 1–3 SLN+ mastectomy | ALND or axillary radiotherapy vs. no axillary treatment | RRR | 878 | June 2014 | June 2027 |

SLNs, are eligible for inclusion. Clinically N0 is defined as no signs of axillary lymph node metastases at physical examination and preoperative axillary ultrasound (or negative cyto-/histopathology). Primary systemic therapy and

van Roozendaal *et al. BMC Cancer* (2015) 15:610

# N+ prior to neo CT

- Standard today
  - Dual tracer, at least 3 SLN removed

**Factors Impacting the SLNB False-Negative Rate in the SENTINA, ACOSOG Z1071, and SN FNAC Studies**

| Study | Number SLNs removed | | | P value | Tracer used | | P value |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | ≥3 | | Single tracer | Dual tracer | |
| SENTINA | 24% | 19% | 7% | 0.008 | 16% | 9% | 0.15 |
| ACOSOG Z1071 | - | 21% | 9% | .007 | 20% | 11% | .05 |
| SN FNAC study* | 18% | 5%** | | | 16% | 5% | |

*False negative rates reported here consider immunohistochemially detected isolated tumor cells node positive

**False negative rate 5% with ≥2 SLNs removed

Abbreviations: SLNB, sentinel lymph node biopsy; SENTINA, Sentinel Neoadjuvant; ACOSOG, American College of Surgeons Oncology Group; SN FNAC, Sentinel Node Biopsy Following Neoadjuvant Chemotherapy; SLNs, sentinel lymph nodes

# N+ prior to neo CT

- ALND
  - Allways in macrometastases
  - No consensus in ITC or micrometastases

ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

*Annals of Oncology* 28: 1700–1712, 2017
doi:10.1093/annonc/mdx308
Published online 21 June 2017

SPECIAL ARTICLE

# De-escalating and escalating treatments for early-stage breast cancer: the St. Gallen International Expert Consensus Conference on the Primary Therapy of Early Breast Cancer 2017

G. Curigliano[1*,†], H. J. Burstein[2†], E. P. Winer[2], M. Gnant[3], P. Dubsky[3,4], S. Loibl[5], M. Colleoni[1], M. M. Regan[6], M. Piccart-Gebhart[7], H.-J. Senn[8] & B. Thürlimann[9], on behalf of the Panel Members of the St. Gallen International Expert Consensus on the Primary Therapy of Early Breast Cancer 2017

| Local therapy | Theme | De-escalation | Escalation |
|---|---|---|---|
| Primary surgery: invasive breast cancer | Margins | Re-excision and mastectomies can be avoided with margins no larger than no tumor on ink | Re-excision for larger margins discouraged including cases with aggressive biology |
| | Multifocal and multicentric disease | Breast conservation if margins clear and RT anticipated | Mastectomy in other cases |
| Surgery for DCIS | Margins | 2 mm margins sufficient to avoid second surgery | Re-excision for larger margins discouraged |
| Surgery after neoadjuvant chemotherapy in case of downstaging in breast and axilla | Surgery of the breast | Resection of residual disease and not original tumor area | Resection of the original tumor area in cases of refractory disease |
| | Margins | No tumor on ink in concentric shrinkage/unifocal residual disease | Consider re-excision (2 mm margins) in multifocal residual disease/'scattered' remission |
| | Sentinel lymph node biopsy in cN (−) at diagnosis | Appropriate in most cases | Axillary dissection if sentinel lymph node metastasis detected |
| | Sentinel lymph node biopsy in cN (+) at diagnosis | Appropriate only if three or more lymph nodes detected as sentinels | Axillary dissection in most cases outside of clinical trials |

EJSO 42 (2016) 361–368

# Sentinel node biopsy after neoadjuvant treatment in breast cancer: Five-year follow-up of patients with clinically node-negative or node-positive disease before treatment

V. Galimberti [a,*], S.K. Ribeiro Fontana [a], P. Maisonneuve [b], F. Steccanella [a], A.R. Vento [a], M. Intra [a], P. Naninato [a], P. Caldarella [a], M. Iorfida [c], M. Colleoni [c], G. Viale [d,e], C.M. Grana [f], N. Rotmensz [b], A. Luini [a]

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[d] Department of Pathology, European Institute of Oncology, Via Ripamonti 435, 20141 Milan, Italy
[e] University of Milan, School of Medicine, Milan, Italy
[f] Division of Nuclear Medicine, European Institute of Oncology, Via Ripamonti 435, 20141 Milan, Italy

Accepted 20 November 2015
Available online 25 December 2015

Table 3
Post-surgery characteristics of 396 women with cT1-4 N0-1/2 breast cancer, according to cN status prior to neoadjuvant treatment.

| | cN0 | | cN1/cN2 | |
|---|---|---|---|---|
| | N | % | N | % |
| **All** | 249 | 100 | 147 | 100 |
| **pT** | | | | |
| ypT0 | 26 | 10.4 | 26 | 17.7 |
| ypTx | 5 | 2.0 | 12 | 8.2 |
| ypT1 | 94 | 37.8 | 58 | 39.5 |
| ypT2 | 100 | 40.2 | 41 | 27.9 |
| ypT3 | 23 | 9.2 | 10 | 6.8 |
| ypT4 | 1 | 0.4 | – | – |
| **Positive nodes** | | | | |
| None | 157 | 63.1 | 70 | 47.6 |
| 1–3 | 67 | 26.9 | 45 | 30.6 |
| 4–9 | 17 | 6.8 | 27 | 18.4 |
| 10+ | 8 | 3.2 | 5 | 3.4 |

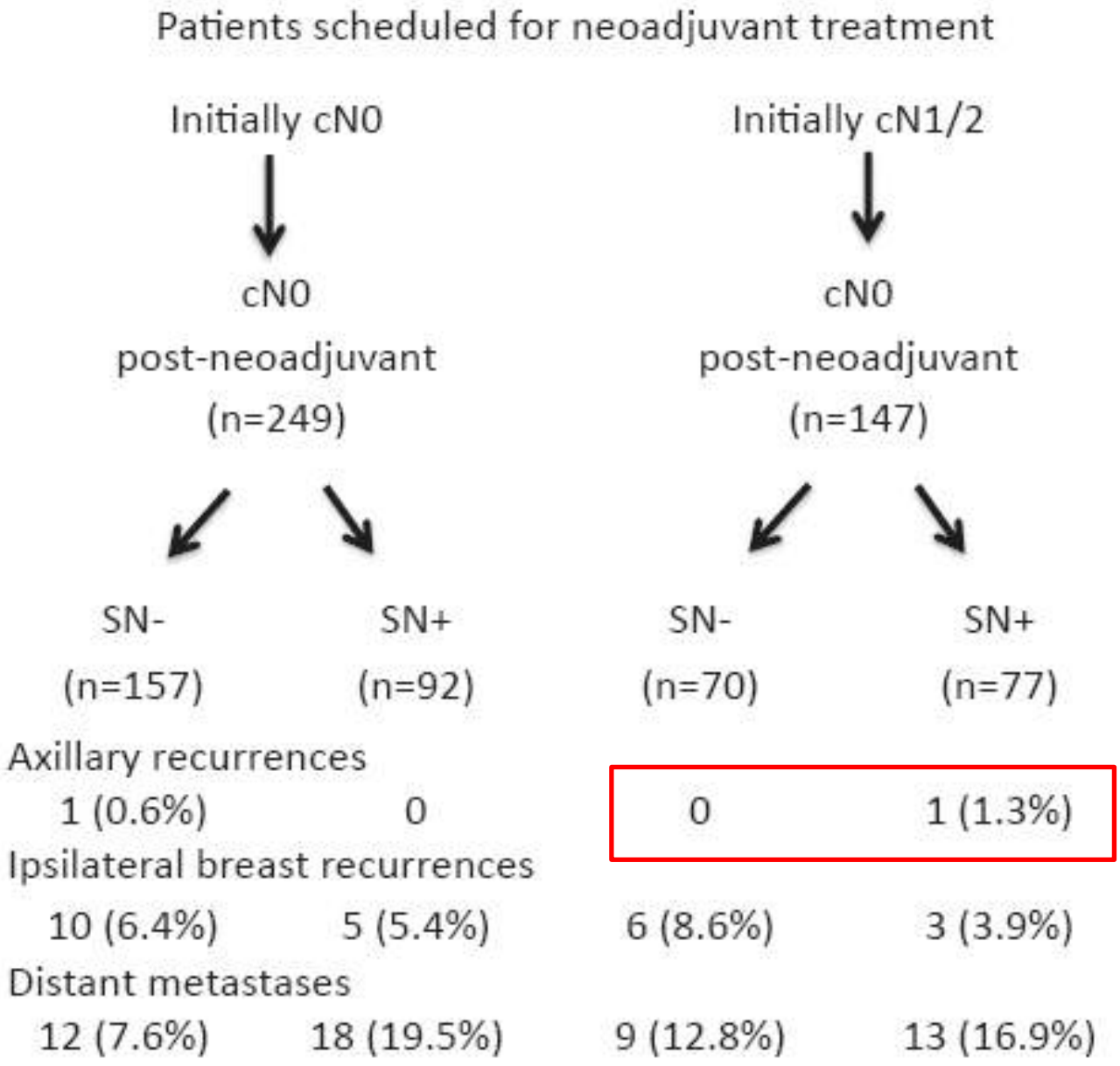


Figure 1. Study flow chart.

# Removal of marked positive lymph node + SLN (after neo CT)
# FNR below 10%


- Boughey JC, Suman VJ, Mittendorf EA, et al. Sentinel lymph node surgery after neoadjuvant chemotherapy in patients with node-positive breast cancer: the ACOSOG Z1071 (Alliance) clinical trial. JAMA 2013;310(14):1455–61.

- Donker M, Straver ME, Wesseling J, et al. Marking axillary lymph nodes with radioactive iodine seeds for axillary staging after neoadjuvant systemic treatment in breast cancer patients: the MARI procedure. Ann Surg. 2015;261(2):378–82.

- Caudle AS, Yang WT, Krishnamurthy S, et al. Improved axillary evaluation following neoadjuvant therapy for patients with nodepositive breast cancer using selective evaluation of clipped nodes: implementation of targeted axillary dissection. J Clin Oncol. 2016;34(10):1072–8.

- Christian Siso, MD1, Juan de Torres, MD2, Antonio Esgueva-Colmenarejo, MD1,3, Martin Espinosa-Bravo, MD1,3, Neus Rus, MD2, Octavi Cordoba, MD1,3, Roberto Rodriguez, MD1,3, Vicente Peg, MD3,4,5, and Isabel T. Rubio, MD, PhD1,3. Intraoperative Ultrasound-Guided Excision of Axillary Clip in Patients with Node-Positive Breast Cancer Treated with Neoadjuvant Therapy (ILINA Trial), Ann Surg Oncol https://doi.org/10.1245/s10434-017-6270-z

# Comparison of Axillary Lymph Node Dissection With Axillary Radiation for Patients With Node-Positive Breast Cancer Treated With Chemotherapy

https://clinicaltrials.gov/ct2/show/study/NCT01901094

| | | | | | | |
|---|---|---|---|---|---|---|
| USA: Alliance A011202 NCT01901094 | cT1-3cN1 (S)LN+ after NACT | ALND+ extended regional nodal irradiation vs. axillary radiotherapy + extended regional nodal irradiation | IBC-RFI | 2918 | Feb 2014 | Jan 2024 |

1. Breast surgery (lumpectomy or mastectomy) and sentinel lymph node surgery must be completed within 56 days of the completion of neoadjuvant chemotherapy.
2. A minimum of 1 sentinel node and a maximum of 6 total nodes (sentinel + non-sentinel) are identified and excised by the surgeon. Patients who do not have an identifiable sentinel lymph node will not proceed to Registration/Randomization.
3. At least one lymph node (sentinel or non-sentinel) with a metastasis greater than 0.2 mm in greatest dimension identified on intra-operative pathologic assessment. Note: Isolated tumor cells (metastases less than or equal to 0.2 mm) will be treated as node negative disease (N0i+). Axillary lymph node dissection [ALND] is not to be performed prior to Registration/Randomization.

Arm 1: ALND + nodal radiation therapy

Surgery: For patients randomized to axillary lymph node dissection (ALND), it is recommended that a complete level I and II dissection with resection of minimum of a total of 8 lymph nodes (SLN and ALND together) be done. Level III dissection is not required, but may be performed at the discretion of the surgeon. If fewer than 8 lymph nodes (SLN and ALND together) are resected, then the patient will discontinue protocol treatment.

Radiation Therapy: Radiation is delivered to the breast/chest wall, undissected axilla, supraclavicular nodes and internal mammary nodes in the first 3 intercostal spaces. Treatment will be given 5 days a week over 5-6 weeks.

Arm 2: Axillary radiation and nodal radiation therapy

Radiation Therapy: Radiation is delivered to the breast/chest wall, full axilla including Levels I, II, III, supraclavicular nodes and internal mammary nodes in the first 3 intercostal spaces. Treatment will be given 5 days a week over 5-6 weeks.

# TAXIS

**Objective**

The main objective of the trial is to test the hypothesis that treatment with TAS and axillary radiotherapy (RT) is non-inferior to axillary lymph node dissection (ALND) in terms of DFS of breast cancer patients with positive nodes at first presentation in the era of effective systemic therapy and extended regional nodal irradiation.

Henke *et al. Trials* (2018) 19:667
https://doi.org/10.1186/s13063-018-3021-9

Trials

STUDY PROTOCOL Open Access

## Tailored axillary surgery with or without axillary lymph node dissection followed by radiotherapy in patients with clinically node-positive breast cancer (TAXIS): study protocol for a multicenter, randomized phase-III trial

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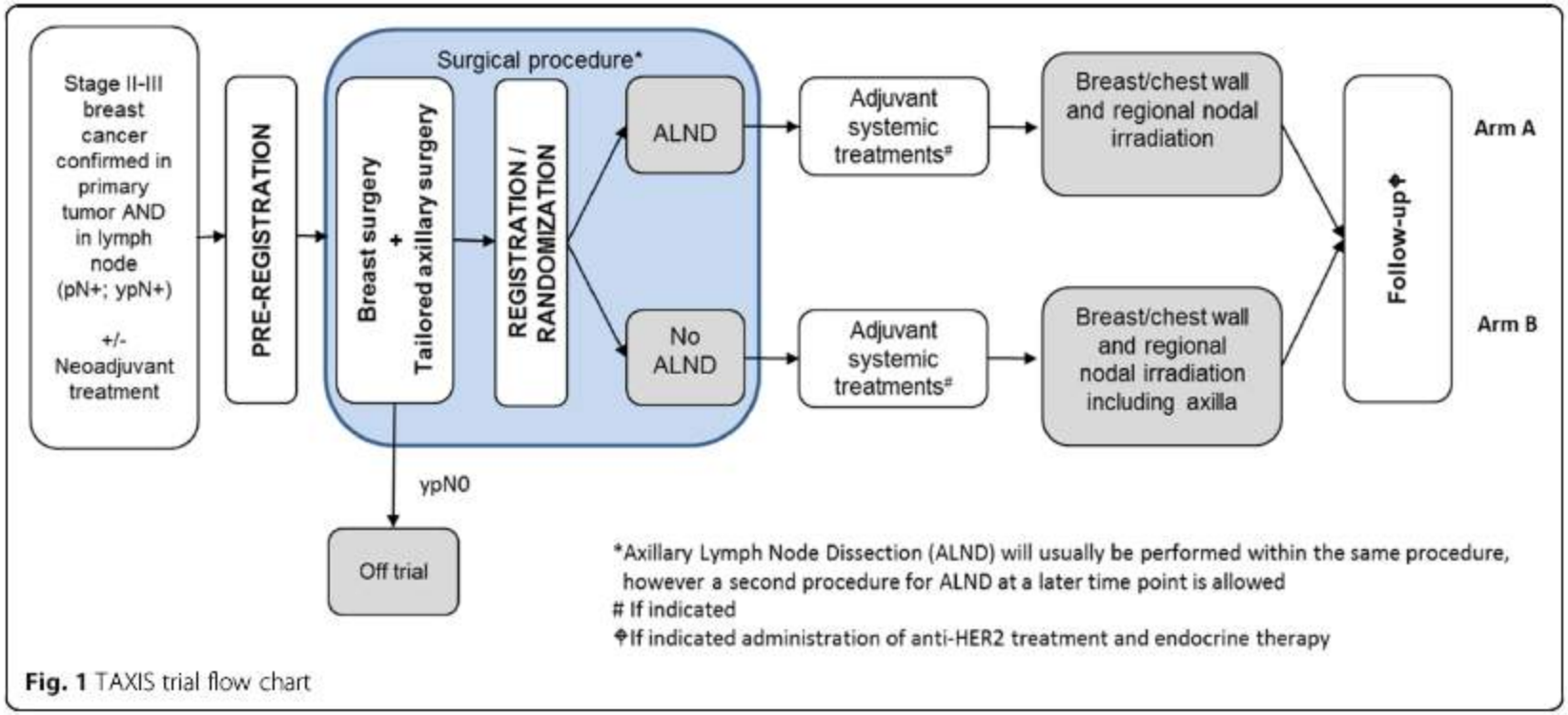



**Fig. 1** TAXIS trial flow chart

- TAS OBLIGATORY
  (tailored axillary surgery)
  - SLN + all palpable lymph nodes removed

- TAD (institutional choice)
  (targeted axillary dissection)

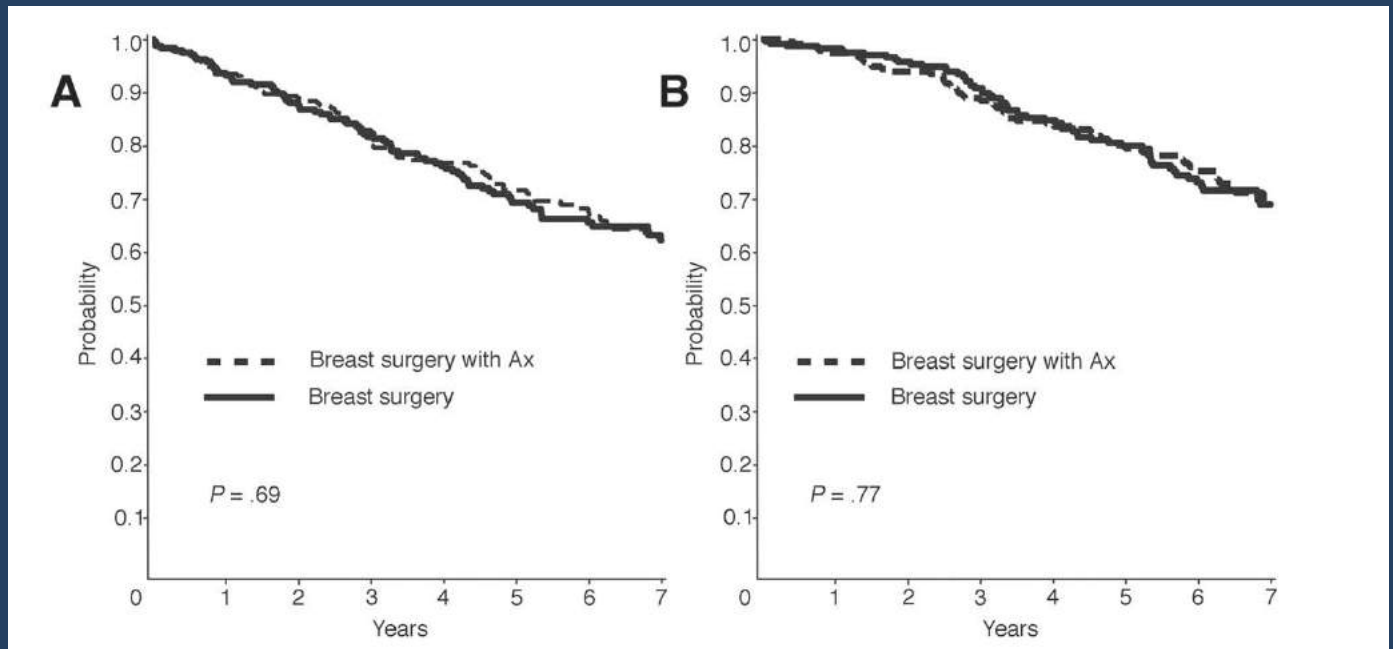
# TAXIS

- Enrolling since July 2018
- 1500 patients planned by 2023
- Follow up until 2043

# No surgical axillary staging

- Randomized Trial Comparing Axillary Clearance Versus No Axillary Clearance in Older Patients With Breast Cancer: First Results of International Breast Cancer Study Group Trial 10-93, JCO, 2005

Women older than 60,
Clinically No,
Hormonal therapy




| Treatment | Total Patients | Total Events | 6-Year DFS% ± SE | HR (Sx + Ax/Sx) | 95% CI |
|---|---|---|---|---|---|
| Sx + Ax | 234 | 92 | 67 ± 3 | 1.06 | 0.79 to 1.42 |
| Sx | 239 | 89 | 66 ± 3 | | |

| Treatment | Total Patients | Total Events | 6-Year OS% ± SE | HR (Sx + Ax/Sx) | 95% CI |
|---|---|---|---|---|---|
| Sx + Ax | 234 | 72 | 75 ± 3 | 1.05 | 0.76 to 1.46 |
| Sx | 239 | 71 | 73 ± 3 | | |

Viewpoints and debate

The Breast 21 (2012) 678–681

# Abandoning sentinel lymph node biopsy in early breast cancer? A new trial in progress at the European Institute of Oncology of Milan (SOUND: **S**entinel node vs **O**bservation after axillary **U**ltraSou**ND**)

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- 1464 patients randomized
- Accrual completed (June 2017)
- Results to be published

## Trial SOUND

**S**entinel node vs **O**bservation after axillary **U**ltra-sou**ND**

- Patients with breast cancer ≤2.0 cm
- Any age
- Candidates to Breast Conserving Surgery
- Negative preoperative axillary assessment

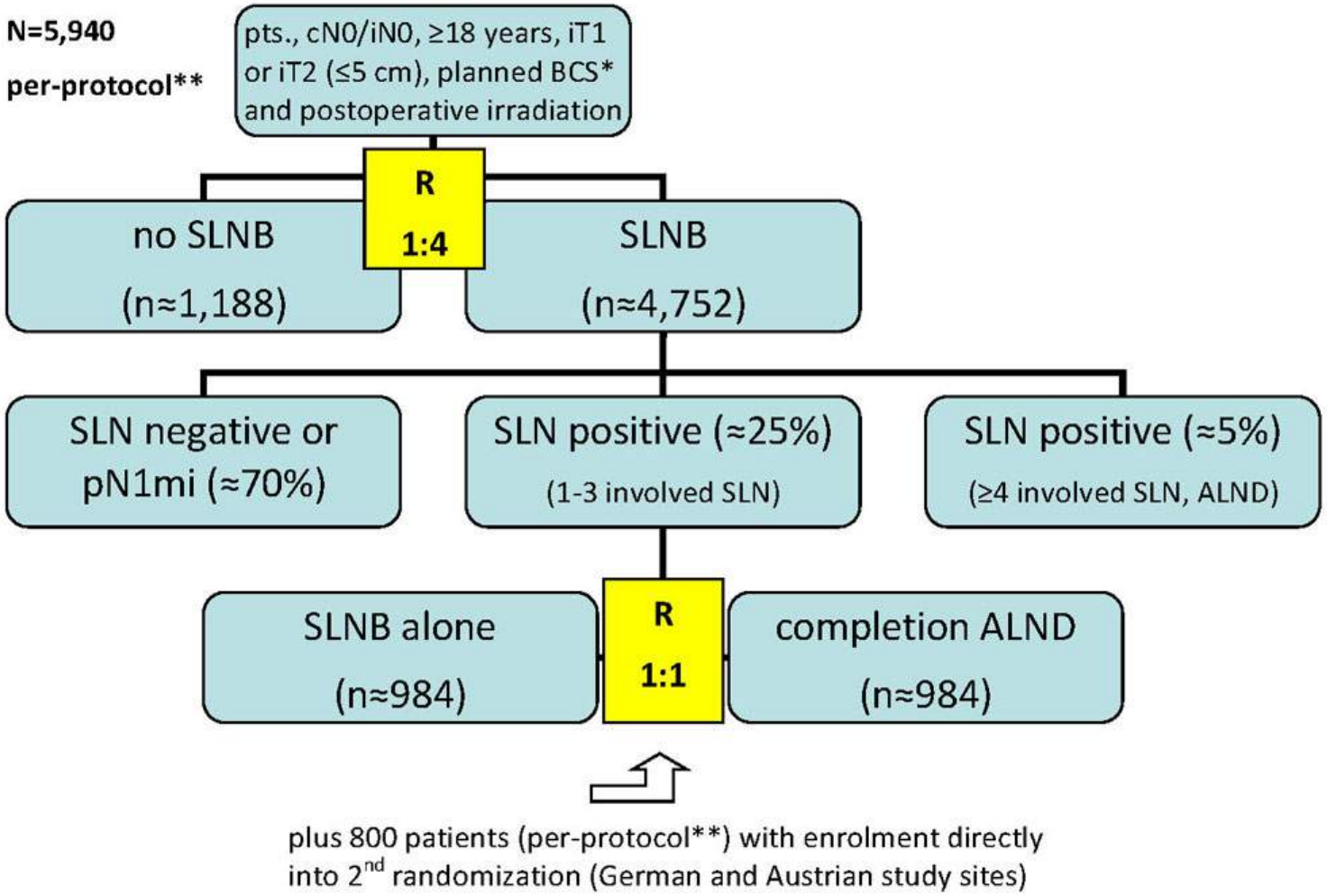
(negative ultra-sound of the axilla or negative FNAC of a single doubtful axillary lymph node)

**Randomization**

SNB policy  No axillary surgery

# ABCSG 43 / INSEMA

| | | | | | | |
|---|---|---|---|---|---|---|
| Germany: INSEMA<br>NCT02466737 | cT1–2 cN0<br>US negative | 1. SLN vs. observation<br>2. 1–2 SLN+ → ALND vs. no ALND | DFS | 7095 | Sept 2015 | Sept 2024 |



# BOOG 2013–08

- cN0 T 1-2
- Axillary ultrasound performed
- SLNB : non SLNB
- Also after neoCT
- N= 1644

Roozendaal *et al. BMC Cancer* (2017) 17:459
DOI 10.1186/s12885-017-3443-x

# Conclusions

- Further de-escalation of indication for completion of ALND
- First results will be available in next decade
- There will still be subgroup of patients to be studied
  - i.e. No imaging staging of axilla…..