



# It Is Not an Obituary of Sentinel Lymph Node Biopsy or Surgery to Axilla, It's a De-Escalation of Surgery to Axilla in Early Breast Cancer: A Traditional Review

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## ABSTRACT

In breast cancer (BC), surgical treatment of the axilla has undergone a paradigm shift from axillary lymph node dissection (ALND), through sentinel lymph node biopsy (SLNB), and ultimately to omission of axillary surgery. In BC, following neoadjuvant systemic therapy (NAST), there has also been a de-escalation from ALND to SLNB and targeted axillary dissection, with false-negative rates reduced to an acceptable level of less than 10%. Trials are ongoing to omit ALND when SLNB is positive in post-NAST BC cases. Additionally, ongoing trials are evaluating the omission of axillary surgery in post-NAST ycN0 patients. Based on an extensive literature search, this review highlights the sequential de-escalation of axillary surgery in patients with early breast cancer (EBC), irrespective of whether surgery was performed upfront or after NAST, with the same oncological outcomes on follow-up. cTis, 1–3 cN0 and cTis, 1–2 cN0-1 EBC patients have been included. Trials and studies involving cT0-4 and cN1-2 BC patients, and trials including both EBC and locally advanced BC patients, have been excluded to keep the study population uniform, consisting only of EBC cases. Examples of trials discussed in this review include NSABP-B04, NSABP-B 32, ACOSOG Z 11, IBCSG 23-01, AMAROS, SENOMAC, SOUND, INT 09/98, ALLIANCE A011202, AXSANA, EUBREAST-01, among others. In conclusion, de-escalation of surgical intervention to the axilla in EBC patients planned for upfront surgery or NAST requires an individualized approach based on the patient's condition and favorable tumor subtype. To date, a positive SLNB after NAST mandates ALND. Trials to nullify the same, with non-inferior oncological outcomes, are underway. There is a shift towards avoiding axillary surgery altogether in favourable BC cases.

**Keywords:** De-escalation of surgery to axilla; early breast cancer; post neoadjuvant systemic therapy; trials; upfront surgery

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## Key Points

- Axillary surgery in early breast cancer (EBC) has shifted from axillary lymph node dissection (ALND) to the less morbid sentinel lymph node biopsy (SLNB), and initiatives are underway to address the axilla non-surgically.
- 1–2 SLNB if positive, does not mandate ALND in EBC.
- If EBC presents with a favorable subtype, SLNB may be omitted in selected patients.
- Before neoadjuvant systemic therapy (NAST), axillary ultrasound with fine needle aspiration/core needle biopsy and marking of suspicious lymph nodes should be considered. False negative rate of SLNB post NAST can be decreased to <10% with removal of  $\geq 3$  SLNs, dual-agent mapping, adopting targeted axillary dissection.
- Till date, if SLNB is positive post NAST, guidelines advice ALND.

## Introduction

Axillary surgery for breast cancer has evolved substantially from the 1970s to the 2000s (1). The evolution has been from axillary lymph node dissection (ALND) in all cases of breast cancer, to sentinel lymph node biopsy (SLNB) in treatment-naïve early breast cancer (EBC), to SLNB in post-neoadjuvant systemic therapy (NAST) EBC, and possibly no surgery at all in treatment-naïve or post-neoadjuvant chemotherapy (NACT) EBC (1-4).

In this article, we discuss the evolution of axillary intervention in EBC and future research directions.

## Methods

An extensive literature search was conducted in PubMed on the evolution of axillary surgery in EBC. Following this, a Boolean search was also conducted using the terms “EBC” AND “no surgery to axilla”. Twenty-six studies on the management of the axilla in EBC

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were thoroughly reviewed. These included trials, reviews, and original articles. Five of them were original articles, two were review articles, and the remainder were randomized controlled trials (RCTs) and ongoing trials with results pending. Only studies including patients with cTis, 1–3, cN0 EBC and cTis, 1–2, cN0–1 EBC, irrespective of upfront surgery or post-NAST surgery, were included. No age limit was applied. Among the studies identified after an extensive literature search, one trial (ACOSOG 1071) was excluded because it included patients with cT0–4 and cN1–2 stages. Another study that included cT1–4, cN1–3 BC patients and analysed axillary intervention in patients post NAST (ICARO study) was also excluded. SN-FNAC and GANEA 2 were also excluded.

## Discussion

### EBC Patients for Upfront Surgery

The study carried out by Magnoni et al. (1) briefly described the historical evolution of axillary surgery in breast cancer, including nearly all trials from the 1970s to the 2000s.

NSABP-B04 reported the 25-year findings of an RCT initiated in 1971 on 1079 clinically node-negative and 586 clinically node-positive patients. The node-negative patients underwent either radical mastectomy or total mastectomy without axillary dissection, the latter accompanied by postoperative irradiation [radiotherapy (RT)]. They underwent total mastectomy with ALND only if they became node-positive. The node-positive patients underwent radical mastectomy or total mastectomy without axillary dissection but with postoperative irradiation. It was found that node-negative patients had optimal outcomes even without radical mastectomy when locoregional treatment was sufficient (i.e., only mastectomy and axillary RT). Similar was the finding in node-positive patients on obtaining cumulative-incidence estimates of outcome. Adequate locoregional treatment, instead of radical mastectomy, resulted in comparable overall survival (OS) and disease-free survival (DFS) (5). Based on their inference and extrapolation of this view, axillary surgery can also be de-escalated if locoregional treatment is sufficient.

The 1990s saw the de-escalation of ALND in favor of SLNB, driven by the increased risk of lymphedema (9–15%), seroma (15–20%), shoulder dysfunction (8–10%), and pain, numbness, and paraesthesia (30–35%) following ALND (6–8). The shift was towards a less-morbid procedure with similar outcomes.

NSABP-B 32 (1999–2004) was an RCT initiated with the same objective; its primary endpoint was OS (9). This is the largest RCT on BC performed to date. A total of 5,611 patients who were cN0 and underwent lumpectomy or mastectomy and SLNB were enrolled. Stratification was based on age ( $\leq 49$  y,  $\geq 50$  y), clinical tumor size ( $\leq 2.0$  cm, 2.1–4.0 cm,  $\geq 4.1$  cm), and planned surgery (lumpectomy, mastectomy). One group underwent SLNB and ALND, while the other underwent SLNB followed by ALND only if the SLNB was positive. Among the 5,611 BC patients, 3,989 were SLNB-negative and were analysed. Of these, follow-up information for 3,986 SLNB-negative patients was analysed at a median of

96.5 months (70.1–126.7 months). The OS was comparable between the two groups. The group that underwent SLNB and ALND had an OS of 97%, whereas the group that underwent SLNB only had an OS of 95%, a difference of only 2%. DFS and a forest plot summarizing the hazard ratios and 95% confidence intervals for all sites of first treatment failure showed similar results between the two groups (10).

Once it was shown that outcomes were similar in cN0 patients who underwent SLNB only and were SLNB-negative and in those who underwent ALND, the search for further de-escalation began. What if SLNB alone could suffice even if it were positive in one or two lymph nodes (LNs), or if the SLNs had micrometastases?

The ACOSOG Z0011 and the IBCSG 23-01 were trials designed to demonstrate that SLNB alone is sufficient even in patients with positive SLNB (9).

ACOSOG Z 11 (May 1999 to December 2004) (11) included BC patients who were cT1–2 and cN0, who underwent breast conservation surgery (BCS) with SLNB and had 1–2 positive nodes. A total of 891 patients were randomised to SLNB alone ( $n = 446$ ) or SLNB with ALND ( $n = 445$ ). In the primary analysis, 436 patients in the SLNB-only group and 420 patients in the SLNB with ALND group were included. The median total number of nodes containing metastases in both groups was 1. All patients underwent whole-breast radiation; any third-field radiation was prohibited. However,  $\leq 50$ -year-old patients numbered only 160 compared to 266 patients who were  $> 50$  years of age; most patients in the study were hormone receptor positive (i.e., a favourable biological subtype); the prespecified sample size of 1,900 participants could not be achieved due to low accrual and a low event rate; and tangential breast radiation also partly irradiated the axilla. The primary outcome was OS, and the secondary outcome was DFS. The 10-year OS was 86.3% in the SLNB-only group and 83.6% in the SLNB followed by ALND group. 10y-DFS rates were 80.2% and 78.2%, respectively.

Around the same time, the IBCSG 23-01 trial (12) was conducted from 2001 to 2010. This was an RCT. In addition to patients undergoing BCS, as in the ACOSOG Z 11 trial, 9% of patients in this trial underwent mastectomy. Nine hundred and thirty-four patients with cT1–2, cN0 disease who underwent BCS or mastectomy and had SLNs with micrometastasis (SLNs were entirely sectioned at 50–200  $\mu$ m intervals, and each section was examined by hematoxylin and eosin staining) were randomised to ALND and no-ALND groups. A total of 464 patients in the ALND group and 467 patients in the no-ALND group were finally analysed. The primary outcome was DFS. DFS was 87.8% in the no-ALND group and 84.4% in the ALND group.

Therefore, ACOSOG Z11 and IBCSG 23-01 demonstrated that if the SLNB burden is low, ALND can be omitted in selected patients with non-inferior oncological outcomes.

Almost simultaneously with ACOSOG Z11 and IBCSG 23-01, the AMAROS trial was conducted from Feb 19, 2001, to April 29, 2010 (9).

In the AMAROS trial (13), a randomized, multicentre, open-label, phase 3 non-inferiority trial, 1,425 of 4,823 patients with cT1–2, cN0 disease were SLNB-positive. Of these 1,425 patients, 744 were randomised to undergo ALND and 681 to undergo axillary RT. Local treatment of the breast included BCS plus whole-breast radiotherapy (WBRT), mastectomy with or without RT, and systemic therapy. Median follow-up was 6.1 years, and the primary endpoint was 5-year axillary recurrence-free survival (RFS). The 5-year axillary RFS was 0.43% after ALND versus 1.19% after axillary RT, whereas lymphedema was more frequent in the ipsilateral arm during follow-up at 1, 3, and 5 years in the ALND group.

OTOASOR Trial: After positive SLNB was a study similar to AMAROS, with tumor size  $\leq 3$  cm and 8-year follow-up data. OS in the ALND and SLNB +RT groups was comparable, at 77.9% and 84.8%, respectively (14).

Therefore, surgical intervention in the axilla for cN0 patients who have a positive SLNB could be limited to SLNB rather than proceeding to ALND, provided adequate regional and systemic treatment was given. These trials encouraged a further increase in the SLNB threshold. To date, SLNB has been considered sufficient even when positive in low-burden disease, such as 1–2 SLN-positive cases, SLNB-positive only for micro-metastasis, and EBC patients with a favorable biological subtype (10–13).

The SENOMAC trial, a prospective, randomized, non-inferiority phase 3 trial, aimed to omit ALND in cT1–3, cN0 BC patients with 1–2 positive SLNB nodes and with SLNB positive for extranodal extension (ENE). Thus, this trial was one step higher than ACOZOG Z11, IBCSG 23-01, and AMAROS. It included male patients, patients who had undergone mastectomy, and SLNB-positive patients with ENE. The primary endpoint was OS. A total of 2766 patients were enrolled from January 2015 and December 2021, across five countries, and 1335 underwent SLNB only and 1205 underwent completion ALND. Median follow-up was 46.8 months. The estimated 5-year OS was 92.9% in the SLNB-only group and 92.0% in the completion ALND group (15). However, SENOMAC had its limitations. The mean age was 61 years, and the majority of BC patients were older than 65 years. Young patients were not adequately included. T3 tumors comprised only 5.5% of the study subjects, and the mean tumor size was 2.44 cm. Only 22% were grade 3 per the Nottingham histologic grade, and 87.3% of patients were estrogen receptor (ER)-positive and human epidermal growth factor receptor 2 (HER2)-negative. Only 68.8% required RT (BCS and T3), but 95% of the study subjects received RT, indicating RT overuse. This study focused more on lymphedema than on other side effects (16).

From the above trials, it was evident that SLNB was used only for axillary staging and did not provide any therapeutic benefit.

James et al. (2) carried out a review that claimed that omitting SLNB in select cases and introducing a non-invasive predictive model was a viable option according to currently available literature. They have mentioned several trials, such as SOUND, BOOG 213-08, INSEMA, and the Choose Wisely recommendations from CALGB trials, which indicate that SLNB is unnecessary for cN0 EBC patients. This review also reported that SLNB can be identified in 95% of cases with cN0 axilla, with a false-negative rate (FNR) of 6–10% and an overall accuracy of 96%. Furthermore, the axillary recurrence rate after negative SLNB is  $<1\%$ .

Among the above-mentioned trials, the SOUND trial was a prospective non-inferiority phase 3 RCT conducted between February 6, 2012 and June 30, 2017, in Italy, Switzerland, Spain, and Chile that compared SLNB versus observation after axillary ultrasound in 1463 women with tumor size  $\leq 2$  cm and cN0 on examination and ultrasonography who were planned for BCS. The primary endpoint of the study was distant disease-free survival (DDFS) at 5 years, analysed on an intention-to-treat basis. Secondary endpoints included cumulative axillary recurrence, DFS, OS, and treatment recommendations. 708 patients were in the ALNB group and 697 in the observation group. Patients were followed for a median of 5.7 years. The DDFS was 97.7% in the SLNB group and 98% in the observation group. The

5y-DFS was 93.9% in the no-intervention group and 94.7% in the SLNB group. Thus, this trial provided evidence that the cumulative incidence of lymph-node recurrences was 0.4% at 5 years in the no-intervention group. Despite the comparable results of SLNB versus no intervention, as reported in SOUND, this trial had several drawbacks. The Majority of the patients had favourable biology (ER positive, HER2 Neu negative); 87.8% of patients were postmenopausal, and the tumors studied were T1 (4).

Further evidence from Ontario Health (Cancer Care Ontario) and ASCO suggests that SLNB is not required for patients aged  $\geq 70$  years with T1cN0 invasive breast cancer that is HR(+) and HER2-negative (17).

There is robust evidence from previous studies supporting SOUND findings. Recently, Agresti et al. (18) performed a 20-year follow-up analysis of patients recruited under INT 09/98 RCT and reported similar findings. Five hundred seventeen patients with T1N0 breast cancer, aged 18–65 years, were randomized in INT 09/98 to quadrantectomy with ALND or to quadrantectomy alone. The primary endpoint was OS, which was 93.3% and 91.5%, respectively. The current study followed these patients for 20 years and found no significant difference between the two arms. Axillary relapse with distant metastases was similar in both arms, suggesting that the adverse outcome is attributable to the aggressive biology of the tumor, which is independent of axillary intervention (18). Another RCT conducted between 1993 and 2002 compared axillary clearance versus no axillary clearance in women  $\geq 60$  years old (median: 74y) with cN0, T1–T3, of whom 80% were ER positive. Two hundred thirty-four patients underwent additional ALND, and 239 patients underwent breast surgery only. All patients received tamoxifen. The median follow-up was 6.6 years. The OS and DFS were similar: 75% vs 73% and 67% vs 66%, respectively (19). The National Comprehensive Cancer Network (NCCN) (4.2022) states that axillary staging may be considered optional for patients with favourable tumors—for whom selection of adjuvant systemic therapy and/or RT is unlikely to be affected by axillary staging—and for elderly individuals and those with serious comorbid conditions.

Therefore, in EBC patients planned to undergo upfront surgery, de-escalation of axillary surgery has resulted in omission of axillary surgical intervention. If patient selection is appropriate, de-escalation of surgical intervention can even involve omission of axillary surgery.

If that is the case with EBC, the question arises: what is the ideal treatment of the axilla in ductal carcinoma *in situ* (DCIS) and in patients with T0N1 tumors?

Patients with high-grade DCIS undergoing mastectomy should undergo SLNB because there is a 15% chance of upstaging to microinvasion or invasive carcinoma. Some suggest SLNB in DCIS patients undergoing BCS who have a palpable lump, anticipating upstaging on final histopathology. For others, an individualised approach should be adopted (20).

For T0 N1 tumors, which account for 0.8% of breast cancers, a core needle biopsy of the axillary LN to determine the tumor subtype and an MRI to locate the breast lesion are important. MRI can detect breast tumors in 85% of cases. Once the tumor subtype is known, one should proceed with the conventional treatment regimen. If the tumor is not located in the breast on imaging, only ALND leads to loco-regional recurrence (LRR). Therefore, intervention to the breast is also important, whether with mastectomy or WBRT, as both have the same LRR and OS (20, 21).

**EBC Patients for NAST Followed by Surgery**

With more emphasis on the tumor subtype, there are indications of giving NAST in EBC patients also.

The St Gallen Consensus (2017) established that, in patients with a clinically negative axilla who receive NAST, SLNB is appropriate and favored its being carried out after NAST (22). The German S3 guidelines state that SLNB is adequate after NAST for patients with clinically and sonographically node-negative (cN0/iN0) pre-treatment status (23).

Now that cN0 patients were subjected only to SLNB after NAST/NACT, the initiative to de-escalate axillary surgery for patients who down-staged from cN+ to ycN0 began. A study by El-Tamer and Kovacs (24) provided the criteria for SLNB after NACT, which included N1 disease pre NACT; clinically deemed node-negative status after NACT; presence of a team well-versed in SLNB; availability of dual mapping techniques for SLNB; resection of all SLNs (or  $\geq 3$  SLNs); pathologic confirmation of complete response in axillary LNs; and evidence of treatment effect in the SLNs as the optimal conditions. On the other hand, a registry-based study on residual axillary metastases in node-positive breast cancer patients after NACT reported that no consensus exists on the optimal axillary staging method after NACT for patients who were clinically node-positive at diagnosis. This study analysed 383 cases (3).

Some ongoing trials include ALLIANCE A011202 (NCT01901094), in which SLNB-positive patients were randomized to ALND followed by nodal irradiation (undissected axilla, SCF, IMN—internal mammary node) or to no ALND and RT to the axilla, SCF, and IMN. Results will provide more refined insight into axillary management post-NAST/NACT.

Further analysis of SENTINA, which included patients who converted from N+ to N0 status showed that use of a dual tracer reduced the FNR to 8.6% and that using three SLNs reduced it to 7.3% (25). Therefore, the technique of SLNB and the number of SLNs removed post NACT governed the FNR, supporting the criteria suggested by El-Tamer and Kovacs (24). Even though ACOSOG Z1071, SN-FNAC, and GANEA 2 were excluded because they did not include only EBC patients, the findings were similar.

An acceptable FNR for SLNB after NAST is <10%, which led to the development of newer techniques. Targeted axillary dissection (TAD), using a clip or iodine seed to localize the pre-NACT positive LN, was implemented. This reduced the FNR to an acceptable 1.4%. Also, in 23% of patients, the clipped LN was not the SLN (26). A broad description of TAD is the removal of the targeted LN (pre-NACT) along with SLNs. Thus, techniques such as TAD or marking of the axillary LN with radioactive iodine (MARI) were superior to SLNB in patients with positive N who underwent NAST, achieving an excellent five-year axillary recurrence-free interval of 97% (27). In TAD, the FNR was only 2%, while in MARI it was 7%. Radioactive iodine seed localization in the axilla with the sentinel-node procedure also demonstrated a low FNR of 3.5% (28).

An abstract from the San Antonio Breast Cancer Consortium 2023 concluded that in patients with post-NACT SLNB showing only isolated tumor cells (ITC), ALND can be omitted (26). However, this study included cT1-4, cN0-3 tumors, which is an exclusion criterion

for this review. But if higher stage of tumors can have omission of ALND after SLNB with ITC post NAST/ NACT, the findings can even be applied in EBC patients.

To date, India does not have her own guidelines for the management of initial cN+ patients who have undergone NAST/NACT. European Society for Medical Oncology and NCCN recommend SLNB with additional recommendations (dual tracer/clipping/marking/minimum 3 nodes); the American Society of Breast Surgeons recommends SLNB and, if SLNB is not identified, ALND; and the German AGO guidelines suggest TAD and, if TAD is not identified, ALND as equivalent. Guidelines from Italy, Denmark, Hungary, and Russia advocate SLNB/TAD, while Swedish and Austrian guidelines still suggest ALND.

A prospective, non-interventional cohort study in 3,000 patients across 20 countries, named the AXSANA study, has been initiated to fill the knowledge gap regarding the precise treatment of the axilla for patients with cN+ who became ycN0 after systemic therapy.

Just as no axillary surgical intervention has been shown to be optimal in EBC patients undergoing upfront surgery, studies have demonstrated similar findings in patients post NAST. A pooled analysis was carried out of cN0 breast cancer patients who were HER2-positive or had triple-negative breast cancer (TNBC) and who underwent NAST. The analysis showed that the overall ypN+ rate was 2.16%. Hence, they suggested that when the risk of nodal disease is sufficiently low, axillary surgery can be safely omitted in selected patients (29).

Extrapolating these findings, investigators have initiated EUBREAST-01, a prospective non-randomized, single-arm surgical multicentre trial in patients  $\geq 18$  years of age with cN0, cT1-T3 tumors who have TNBC, are HER2 Neu (+), are planned for BCS, and have achieved pathological complete response in the breast lump after systemic therapy. The study lasted 2 years and recruited 267 patients. The endpoint is axillary RFS (30). Similar to this, another European trial, ASICS, also has results pending.

Thus, even in patients who were cN+ pre-NACT/NAST and became ycN0 post-systemic therapy, studies suggest limiting axillary surgery to SLNB/TAD. However, guidelines for management of the axilla post-NAST are still awaited in treatment-naïve, non-metastatic breast cancer patients.

**Conclusion**

As we are de-escalating axillary surgery for EBC planned for upfront surgery and for EBC post-NAST, patient selection using an individualised approach is key. ALND is not mandated for treatment-naïve EBC patients with 1–2 positive nodes on SLNB. Before NACT, axillary ultrasound with tissue diagnosis and marking of suspicious LNs should be considered. FNR of SLNB can be reduced to <10% with the removal of  $\geq 3$  SLNs, dual-agent mapping, and adoption of TAD. To date, if SLNB is positive after systemic therapy, the long-established ALND remains the surgical treatment of choice. Results of EUBREAST-01, ASICS AND AXSANA are awaited and could herald another revolutionary change in axillary surgery for BC patients.



## Footnotes

## Authorship Contributions

Concept: R.M., P.R., B.K.S.; Design: R.M., P.R., B.K.S.; Data Collection or Processing: R.M., P.R., B.K.S.; Analysis or Interpretation: R.M., P.R., B.K.S.; Writing: R.M., P.R.

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