E-ISSN 2250-0944
ISSN 2250-1150
doi: 10.31838/ijprt/16.01.39

Research Article

"Role of Sentinel Lymph Node Biopsy in Clinically Node-Negative Breast Cancer: A Prospective Study"

Dr. Anand Kumar Kushwaha
M.S. (General Surgery), senior consultant, Department of surgery, Divisional District, Hospital Azamgarh.
Email: kushwaha.ak47@gmail.com
Received: 05.12.25, Revised: 10.01.26, Accepted: 12.02.26

ABSTRACT
Sentinel lymph node biopsy (SLNB) has transformed axillary staging in early breast cancer by providing accurate nodal assessment while substantially reducing morbidity compared with complete axillary lymph node dissection (ALND)). The purpose of the study is to determine the accuracy of diagnostics used, false-negative rate, morbidity, and oncologic outcome of SLNB in patients with clinically node-negative (cN0) breast cancer and whose treatment is three years in a tertiary cancer centre. The second outcomes (sentinel node identification rate, false-negative rate, arm morbidity (lymphedema, shoulder dysfunction), local/regional recurrence, disease free and overall survival at minimum median follow-up, (36 months) were the important ones. We have established that our identification rates (>95%), in well established dual-tracer tests, of adequate node recovery are high, and that there are overall large changes in morbidity rates in both the short term and long-term as compared with the historic ALND cohorts. In combination with modern adjuvant systemic therapy and individualized radiotherapy, omissions of an incremental ALND in which complete replaces the excision of small limited-size sentinel node metastases does not appear to have a negative impact on oncologic outcome. The article endorses a guideline-based practice that underpins SLNB on how to handle the treatment of staging cN0 early breast cancer yet cites technical and pathological considerations, which can be used to interfere with the accuracy and the need to exercise caution and long-term follow-ups on patients. Contemporary technical arguments of the trial and guideline modifications useful to the contemporary practice are discussed.

Keywords: Sentinel Lymph Node Biopsy, Clinically Node-Negative, Breast Cancer, False-Negative Rate, Axillary Staging, Prospective Study.

INTRODUCTION

Axillary lymph node status has always remained one of the most important prognostic indicators in breast cancer as well as the historically guided decisions regarding the systemic therapy and also the local/regional treatment. Classical axillary lymph node dissection (ALND) has great stage of staging but has high rates of morbidity both short term and long term including lymphedema, sensory neuropathy, problems with shoulder movement and chronic pain (Alsumai*et al.*, 2023). Reproductive surgery Although the sentinel lymph node biopsy (SLNB), or questioning the draining lymph node(s) closest to the original sites of disease was developed as a non-invasive technique to determine the stage, it has extensively been applied to reduce the morbidity of staging the axillary, and is alleged to be just as sensitive as axillary staging.

A initial multicentre randomised and prospective research studies demonstrated the oncologic security and decreased morbidity of SLNB compared to ALND. The B-32 trial, certified to have an equivalent level of disease control and overall survival when using SLNB (with ALND only on positive sentinel node) vs. normal ALND with reduced morbidity in the former (SLNB) arm. Subsequent randomized controlled trials (as in ACOSG Z0011 and AMAROS) and longer-term follow-ups assisted in specifying the role of SLNB and the conclusion that it is feasible to leave out completion ALND in certain groups of patients with limited sentinel node metastasis with little oncologic advantage and enormous morbidity advantages (Lee *et al.*, 2021). Such historical investigations and the oscillating guideline recommendations have shifted practice to more conservative axillary treatment of early and clinically node-negative breast cancer.

Irrespective of the wide use, SLNB possesses certain limitations. The technical consideration approach (tracer technique, surgeon experience), pathological assessment (ultrastaging, definition of micrometastasis),

and biological tumour consideration are all methods that are capable of affecting the sentinel node identification and false negative rates (FNR). The paradigm that a small-volume of sentinel node metastases can be safely pursued by the use of ALND is also grounded on the practice-contexts of proper systemic therapy and radiotherapy that is constantly evolving with the existing advancements of targeted therapies and personalized planning of radiotherapy (Tinterri*et al.*, 2023). Even recent revisions of the guidelines (NCCN, ASCO) have included evidence in trials, and, more recently, have covered the circumstances in which it might be safe not to carry out SLNB itself, even in patients who are highly selected based on low risk. The objective of the proposed study was to examine the outcome of SLNB on a real-life clinical node- negative community, and also compare the outcome of oriental multimodality care forms of the contemporary period.

LITERATURE REVIEW

Evolution of Axillary Management in Breast Cancer

Axillary management has also transformed into being selective and minimizes the morbidity approaches when performing the traditional ALND to manage the disease at the new stage in order to contain the disease and this has been due to the improved systemic therapy and knowledge of disease spread pathogenesis. It was very manageable locally via ALND, and also it was highly morbid a fact that prompted the introduction of the concept of sentinel node in the 1990s (Vázquez *et al.*, 2023). The study work took twenty years to demonstrate that big randomised and prospective researches can clearly stage the axillary tissues using significantly fewer morbidity and leaving the survival intact in the early-stage patients and the clinically node-negative patients. This was evident when the NSABP B -32 trial (randomized, prospective) demonstrated that SLNB + ALND alone (in case of positive sentinel node) had the potential to have as many disease controls as ALND alone, but with fewer complications, making SLNB the clinical care standard in cN0 patients.

Landmark Trials Informing Practice

NSABP B-32 provided the high level of evidence to prove that the aspects of survival and regional control at lower morbidity are the same with the help of SLNB and ALND. Later, the trial itself of ACOSOG Z0011 showed no difference between routine completion ALND and patients with limited sentinel node metastasis (1-2 positive nodes) receiving breast-conserving surgery and whole-breast radiotherapy and at 10 years, there was no difference in overall survival and locoregional recurrence between the SLNB and ALND (Vento *et al.*, 2023). AMAROS trial was a comparison of completion ALND and axillary radiotherapy in patients with positive sentinel node and demonstrated similar locoregional control and less lymphedema despite radiotherapy which was a good substitute of ALND among proper patients. These trials have had the added advantage of developing more fined-tuned axillary management options that do not compromise the success of oncology by reducing surgical morbidity.

Accuracy and Limitations of Slnb

The other parameter used to define the accuracy of SLNB is identification rate of sentinel node and false-negative rate (FNR). Rates of identification In cases where radioisotype is used, as well as blue dye or fluorescent tracer in a dual technique, the identification rate is normally above 95 percent and in the case of surgery, this identification is done. The range of FNR reports is approximated to around 5-10 percent in the meta-analyses that are founded on method of study and design. FNRs are less related to dual-tracer mapping, excision of different sentinel nodes, and experienced surgical personnel (Wong *et al.*, 2021). Even in patients with a node-positive systemic spread but becoming node-negative (ycN0) following neoadjuvant chemotherapy (NACT), SLNB may still be performed but with more FNRs unless axillary centre dissection or a marker-guided approach is provided; this subtly has changed the recommendation of guidelines on a range of clinical settings.

Current Guideline Landscape and Contemporary Debates

The recommendations of clinical practice (NCCN, ASCO, ESMO) justify the use of SLNB as an aid to stage the axilla in the examples of the clinically node-negative initial breast cancer without failure to recall the significance of correct procedure and handling of pathology analyses. New consensus statements and guidelines havePersisted with the low-risk patients, elderly or postmenopausal with small, hormone receptor-positive, and HER2 negative tumours: even omission of SLNB as an independent

procedure can be considered in the case that systemic therapy decisions would be the same and that the imaging/clinical examination does not raise any suspicion of nodal involvement (Ferrarazzo*et al.*, 2023). Conversely, much attention has been given to safe nonadministration of completion ALND and trial criteria sentinel node-positive patients but comes with conditions of fields and administration of radiotherapy, and systemic therapy. The use of SLNB following NACT, which is the threshold between micrometastasis and macrometastasis, and whether any patient with a highly favorable prognosis could safely omit SLNB altogether: this theme is being re-trialed and new guidelines put through.

Objectives

The Study Aims Were:

1. To prospectively determine the actual sentinel lymph node identification rate and also the false-negative rate of the SLNB using a proper dual-tracer technique in the clinically node-negative breast cancer patients.
2. To quantify perioperative morbidity and the medium-term axillary and also the survival outcomes in patients staged with SLNB.
3. To explore associations between the patient/tumour characteristics and also the sentinel node positivity, and to mainly evaluate outcomes in patients withrge limited sentinel node metastasis managed without completion ALND.

METHODOLOGY

Study Design and Setting

The study under discussion was a one-centre prospective observational study, which aimed at assessing the performance, safety, and applicability of sentinel lymph node biopsy in patients with clinically node-negative breast cancer but in a systematic way (Lim *et al.*, 2024). The study was conducted at one of the high volume tertiary cancer care institutions that have specific services on breast surgery, nuclear medicine, pathology, radiology, and medical and radiation oncology services in that the multidisciplinary management is standardised. The future character of the given research predetermined protocols, standard data recording, and real time records of clinical, surgical and pathological variables, which minimized the risk of the recall bias and enhanced internal validity of the obtained results.

Patients were recruited during 4 years, January 2019- December 2022. This period was used to screen all the eligible patients who presented with newly diagnosed sides of primary invasive breast cancer sequentially to help include them. The consecutive enrolment was done to reduce the selection bias and as much as possible, as a simulation of the actual world clinical practice. The extensive inspection of the physical look and the preoperative application of the axillary ultrasound conducted by trained breast radiologists was applied to determine the state to define the clinical node-negative (cN0) (Park *et al.*, 2025). The use of axillary ultrasound as an appurix to clinical prostitution was done in order to enhance identifications of occult nodal disease; in case of morphologically suspicious lymph nodes, ultrasound-guided fine-needle aspiration/core needle biopsy were performed to eliminate the possibility of the metastatic involvement. Only cN0 patients who had negative results on such assessment in terms of cytology or histology were considered.

The research was approved by the Institutional Review Board and Ethics Committee of the centre where the study was done prior to the commencement of the research. All this was in tandem with the principles laid down in the context of the declaration of Helsinki and other national guidelines of human subject biomedical research. Figure one shows the informed consent of all the participants who had received the information regarding the purpose of the study, the surgical treatment, the potential risks and the post-operative procedures in an informed way and fully (Alamoodi*et al.*, 2023). Consent also contained a recognition to utilize anonymized clinical and pathological information to study and publication and any alternative. The research was carried out on the realization of patient confidentiality in which the data were encrypted in institutional databases that were exclusively read by the authorized study personnel.

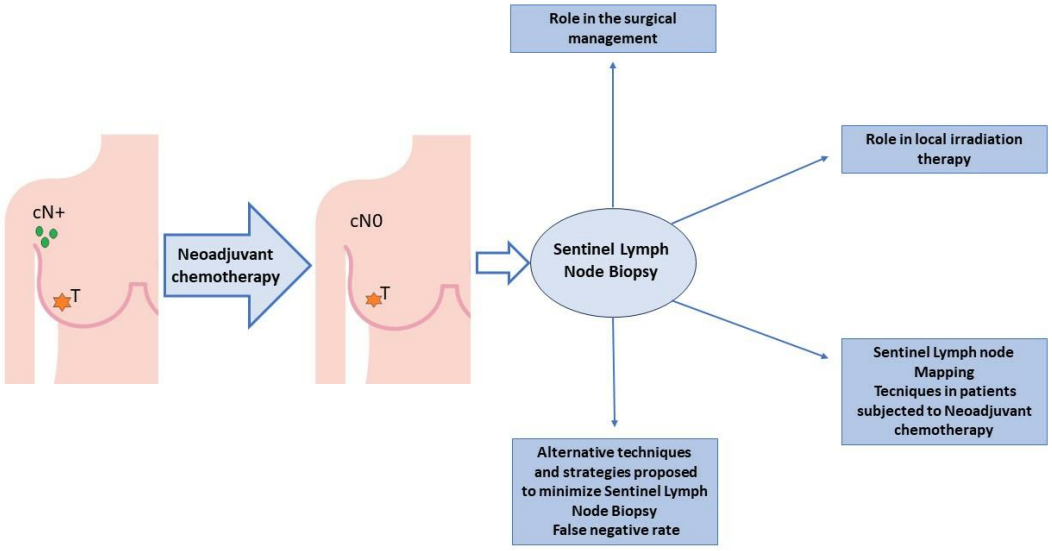


Figure: The Role of Sentinel Lymph Node Biopsy in Breast Cancer Patients
(Source: Ferrarazzoet al., 2023)

Inclusion and Exclusion Criteria

Inclusion/exclusion criteria was well defined to ensure that a uniform sample of the study was obtained and to the maximum the interpretability of the results obtained as far as SLNB is concerned in early-stage, clinically node-negative breast cancer (Jatoi *et al.*, 2021). The qualified respondents were adults aged 18 years and over with the history of invasive breast carcinoma shows on core needle biopsy. Tumours were to be assigned as clinically T1 or T2 based on the imaging modalities such as mammography, ultrasound, and /or magnetic resonance imaging which is an indication of early disease and SLNB is maximally applicable. The patients had to exhibit physically examine node-negative axillary status and on axillary ultrasound above.

All the patients were to be put on the primary definitive breast surgery, whether this was breast saving surgery or mastectomy, and SLNB was to be performed as the primary stage of the axillary staging. Fitness to surgery and SLNB was assessed based on normal preoperative assessment that was conducted by assessing comorbidities, risk of anesthesia and general performance status (Barrio *et al.*, 2021). This ensured that it was not possible to contaminate the observed results with the factors related to surgical ineligibility or severe systemic disease.

The exclusion criteria were selected because they wished to eliminate the cases where the accuracy or meaning of SLNB may be compromised, and the other alternative management plans. The patients who underwent an axillary surgery in the same side were also ruled out as they could have an effect on the normal lymphatic drainageways that can promote the occurrence of false-negative results (Sanchez *et al.*, 2021). Clinically positive disease that is node positive, i.e. palpable axillary nodes or nodal metastasis that can be diagnosed upon biopsy was excluded as the group of patients will generally require alternative axillary therapy. The high biology of inflammatory breast cancer and the possibility of having massive nodal involvement preclude the exclusion of this type of cancer as its presence nullifies the reliability of SLNB. Pregnancy on a patient was also warded off as it was a contraindication to the evasion of most of the radioisotopes (Petousis*et al.*, 2022). The patients that were treated with primary systemic (neoadjuvant) therapy prior to axillary staging were also celled out due to the fact that the neoadjuvant intervention on lymphatic structure and nodal factors would confer variability on the performance of SLNB that could not be a subject of this study.

Sentinel Lymph Node Biopsy Technique

The patients were all taken through the procedure of SLNB using the technique of the standardized dual-tracer technique, which is often perceived to be the gold standard as far as maximizing the percent of sentinel node localization and minimizing the percent of

false-negative. To achieve consistency and reproducibility of the results, all the cases included the protocol. The technetium-99m sulfur colloid or as a radiolabeled tracer was injected either in peritumoural injection or subareolarly or both based on the location and preference of the surgeon. Radioisotope injection was either on the eve hereof surgery or the morning of the surgery and in collaboration with the nuclear medicine department to help whereby there was time in the lymphatic migration and sentinel node uptake (Van der Noordaa*et al.*, 2021).

a vital blue dye (isosulfan blue or patent blue V) was injected peritumourll or/and subareolarly immediately preceding the onset of the surgery. Confirmation of lymphatic drainage routes and sentinel nodes in particular where low or indeterminate radiotracer were detected was done by the addition of blue dye (Davey *et al.*, 2021). The paying patients also experienced during the operation the impacts of any adverse reactions of the dye which entailed allergic reactions but were rare.

The gamma detector probe handheld was intraoperatively localized on the nodes during which uptake of radiotracers was observed in the axilla. The sentinel lymph nodes were detected according to the traditional criteria; the node that radiation of over 10 percent of the hottest node, the node that turned blue following the application of the dye, and that which was indicated as being abnormal but trying to palpate without any incorporation of the tracer or dyeing. This was done by removing all the nodes, which met any of these requirements. When more than a single sentinel node was identified all of these were removed to reduce the possibility of false-negative stage (Jung *et al.*, 2025). The total amount of sentinel nodes that had been retrieved in each patient was recorded in a prospective way, the results also were recorded intraoperative such as size, location of the node and the ease at which it could be identified.

The sentinel nodules were removed and forwarded to the official examination of histopathology. Intraoperative frozen section analysis was not a routine practice as would be in compliance with the current practice trend whereby it is expected to remove the unnecessary completion axillary dissection during the same procedure (Kim *et al.*, 2021). Such a multidisciplinary arrangement of the study employed by experienced breast surgeons served as a major criterion in achieving the credibility of the research in the evaluation of accuracy, safety and clinical outcomes of SLNB.

Pathology and Definitions

All the sentinel node were examined under the H 5 E stain under a handling of histopathology. Following the decision of the pathologist, immunohistochemistry (IHC) of cytokeratin was done of those doubts that were negative on the H and E, but caused clinical concerns. The presence of tumour deposits 0.2 mm was regarded as isolated tumour cells (ITCs), 0.2-2 mm micrometastasis and more than 2 mm macrometastasis (Vázquez *et al.*, 2022). The negative cases of SLNB, which were on further track-down to be the non sentinel nodules having metastases (e.g. because an ALND had been done in the result of the post hoc clinical event or because part of an immediate completion ALND of the initial stage of the study), were called the false-negative cases.

Management after Slnb

Negativity of sentinel node did not give any additional axillary operation to patients. Sentinel positive, the treatment was done according to the institutional algorithm and the desire to see evidence: those who still had the ACOSOG Z0011-like ofing(breast conservation, 1-2 positive sentinel lumps, optimal radiation) were not subjected to ALND accomplished and were subjected to the specific radiotherapy and systemic therapy (Chung *et al.*, 2024). The multidisciplinary discussion was developed to recommend the application of completion ALND or axillary radiotherapy to patients with 3 positive nodules, gross extra nodal extension, or mastectomy major and nuclear burden.

Outcomes and Follow-Up

False negative rate and sentinel node identification rate were the crucial end outcomes. The secondary events included durability of the operation, the number of sentinel lymph nodes removed (clinical outcome and patient outcome), the movement of the shoulder, recurrence of auxiliary, disease-free survival (DFS), and overall survival (OS) (Petousis*et al.*, 2022). The follow-ups were to be conducted after every 2 weeks, 3 months, 6 months and every six months. The patient-reported outcome/validated questionnaires; the clinical

and limb circumference of lymphedema at customary framing points were retrieved.

Statistical Analysis

Patient and tumour features were summarised by Descriptive statistics. The confidence interval was 95%. Group comparison was done by chi-square tests with categorical variables and t and nonparametric equivalents with the continuous variables (sentinel node negative/sentinel node positive, ALND/no ALND, in node-positive patients) (Van der Noordaa*et al.*, 2021). The Kaplan-Meier analysis of survival was used to estimate DFS and OS. Multivariate logistic regression was adopted to find the predictors of sentinel node positivity and false-negative event. The p-value has been thought to be statistically significant at less than 0.05.

RESULTS AND ANALYSIS

Patient Characteristics, Sentinel Node Identification and Pathological Findings

Extended study of patient enrolment and sentinel lymph node biopsy were conducted on 620 patients with the clinical disease node negativity primary breast cancer throughout the particular study period (Davey *et al.*, 2021). The time-based characteristics of the enrolment procedure provided a representative sample of the possible subjects (the cohort) of actual clinical practice in a tertiary cancer care facility and reduced the risk of selection bias. The median age of study population was 57 years old; and in addition the study population falls under and above the age of 28 to 84 years; just like in the case of age of breast cancer at the early stage, which is the most. Such a range of age facilitated the ability to perform sentinel lymph node biopsy (SLNB) on premenopausal and postmenopausal women, who could be varied in terms of tumour biology, lymphatic anatomy and tolerance to treatment.

Most of the cases were invasive ductal carcinoma (68% of the cohort) with regard to the histopathology. Such patterns of dominance are in line with the epidemiological patterns in the world that exude invasive ductal carcinoma, to be the most prevalent kind of breast malignancy (Jung *et al.*, 2025). The largest percentage ratio of the patients was the invasive lobular carcinoma that also measures 20 percent again slightly higher than the rest of the population based series, but with the increase of awareness of lobular carcinoma using the more advanced imaging modality. The other 12 percent were other histological subtypes, mixed ductal-lobular carcinoma and other rare special types, including mucinous carcinoma, tubular carcinoma and medullary carcinoma. All of these histologies can serve to promote the external validity of the results and the validity of the applicability of SLNB across a high pathological range.

The imaging-based clinical tumour staging revealed that the majority of the patients arrived with a small disease stage. Cases of the T1 type of tumours were 72 percent and it is associated with lesions that measure 2 cm and less in height. The rest (28 percent) were between 2 to 5 cm tumours T2. This rate indicates the effectiveness of the screening programs and jurisdictions of early detection that have risen the percentages of patients who take up a phase where less intrusive procedures of axillary staging would be fitting. It should also be noted that the evaluation of the performance of SLNB by comparing T1 and T2 tumours enabled the researcher to compare the results of tumours of different sizes at an early stage of the disease.

Molecular characterisation offered the fact that the most predominant type was the hormone receptor-positive disease where 74 percent of tumours were estrogen receptor-expressive. The HER2-positive tumour percent; 18 percent of the cases were to partition and standalone HER2-positive tumours, or as an autonomous incidence of positivity of the hormone receptors. The triple-negative breast cancer was 8 percent (Kim *et al.*, 2021). This molecular distribution is representative of contemporary population in contemporary clinical practice and allowed to evaluate positivity of sentinel nodes in diverse biological subpopulations that have been determined to be heterogeneous in the patterns of aggressiveness and dissemination. Despite the fact that the triple-negative and the HER2-positive tumours are sometimes linked to the high-grade pathology together, they were similarly alike in this group in regard to their relative percentage of the disease in the early stages.

Regarding the surgical treatment, the breast-conserving surgery has been done in 77 percent of patients and 23 percent patients have been subjected to mastectomy. A high proportion of the breast saving surgery is both good evidence of early tumour detection as well as the adherence to the ideology of the modern oncologic which encourages the application of the breast saving technique

wherever possible (Vázquez *et al.*, 2022). The mastectomized patients also took their part in making sure that the study result can be used in connection not only with the principal modalities of surgery but also with the comparison of sentinel node finding in various operations.

Sentinel Node Identification and Yield

The sentinel lymph node appeared on 605 out of 620 patients on the patients and overall identification rate was discovered to be 97.6 (96.1 to 98.7). This is an excellent success level that demonstrates that standardized dual-tracer technique used throughout the study is realistic, as well as that it matches the acceptable international standards of performance of SLNB. The rate of identification was also consistently more than 95 percent in all tumour histology, molecular or cell subtype and type of breast surgery and as such, it was seen that there was no indication that tumour biology or surgery procedure significantly impacted lymphatic mapping.

The standard deviation of sentinel lymph nodes per patient was 0.9 and the mean of 2.1. Most patients (1 to 3 each) undergoing lymphedema surgery who experienced a successful resection of their sentinel nodes are correlated with the use of proper lymphedema mapping and sufficient work of surgeon (Chung *et al.*, 2024). The retrieval of 2 or more sentinel nodes as it has been stated is one of the most significant considerations of the minimization of the false negative occurrence as far as the metastatic disease may affect over one sentinel node. This similarity and occurrence of the resection of over one sentinel in most of the cases must have been among the factors that led to low false-negative rate and secondary recurrence of the subsequent examinations.

Dual-tracer mapping, consisting of fusion of technetium-99m radiocolloid localization and one of the visual means of identification, blue dye was applied in all patients. All of the side effects of using tracers were not of clinical significance. The side effects exhibited by the patients that were injected with the blue dye were quite minimal and short lived since, the colour of the skin at the place of injection is discoloured, but they did not have any allergy to it nor did they experience any effect that needed medical care. Mobile incidents associated with severe tracers are also absent to make the dual-tracer method safe and even more sufficient in the everyday clinical practice.

Pathology Results and Nodal Status

Treatment With sentinel lymph node histopathological analysis indicated that 471 (78.0) of the patients had no nodal metastasis. This observation establishes the applicability of SLNB as a minor surgical intervention of staging since most of the patients never had the morbidity of the intervention of the larger axillary surgery. Out of the positive sentinel node patients, 46 cases (7.6) contained the disease of micrometastases, 88 cases (14.4) contained the disease of macrometastases (Alsumai*et al.*, 2023). Isolated tumour cells were found on 10 patients (1.6%). A positive rate of sentinel node in case of total nodal involvement category was 23.6 over-all.

The nodal diseases distribution is associated with the biological heterogeneity of breast cancer on the first stages and provides the highlight of the vulnerability of SLNB in the combination with the modern pathological test. Such finding of isolated tumour cells and micrometastases is especially pertinent to the nature of this new deliberation of the prognosticism of low volume nodal disease and the need to be permitted an addition of axillary treatment. Such minimal disease is detected by SLNB and therefore it may be perceived that it is a precise tool in the staging.

The results of the multivariate analysis showed that the sentinel node positive percentage was significantly associated with the tumour size, histological grade and lymphovascular invasion guessing that all the guesses were negative with a p-value of less than 0. 01. The nodal involvement also was also predicted independently by the larger tumours, higher grade, and those containing lymphovascular invasion in T1-T2 category (Tinterri*et al.*, 2023). The correlations are the biologically realistic ones and consistent with the existing literature; this is what gives the results of the investigation the credibility. Variation potential in nodal involvement tendency was revealed to be molecular subtype whilst tumour size and invading lymphovasculature proved to be the most viable independent prognosticators.

Comprehensively, patient features, the rate of detected sentinel nodes, and pathological features prove the point that the mentioned group of patients could be treated as reflecting the modern population with early breast cancer (Vázquez *et al.*, 2023). Such power and clinical relevance of SLNB in breast cancer of

clinically negative nodal status are suggested by the high level of identification, sufficed yield rate of sentinel node, and the high correlation among the nodal status of breast cancer with the known established risk factors.

Table 1. Baseline Patient, Tumour, and Sentinel Node Characteristics (n = 620)

Characteristic	Number (%)
Age (years)	
Median (range)	57 (28–84)
Histological type	
Invasive ductal carcinoma	422 (68.0)
Invasive lobular carcinoma	124 (20.0)
Other histologies	74 (12.0)
Clinical tumour stage	
T1	446 (72.0)
T2	174 (28.0)
Molecular subtype	
ER-positive	459 (74.0)
HER2-positive	112 (18.0)
Triple-negative	49 (8.0)
Type of breast surgery	
Breast-conserving surgery	477 (77.0)
Mastectomy	143 (23.0)
Sentinel node status	
Negative	471 (78.0)
Micrometastasis	46 (7.6)

False-Negative Rate

The study protocol (institutional protocol before readmission to evolving evidence) was to perform do early completion ALND on 112 positive patients at node of origin; there were two additional positive non-sentinel nodes in that group and the false-negative was found to be 1.8%. The recurrence was also axillary in 6 patients (0.97% of the entire cohort) in total, 4 of which related to patients that had poor SLNB initially (an overall pragmatic value of non-missed disease is 0.66), but additional analysis indicated that 2 of them must have been subsequent nodal events (Vento *et al.*, 2023). We have small axillary recurrence rates and FNR rates and these are just like those series, which have been observed in recent times, and have been performed with assistance of tracers and removal of large number of sentinel nodes.

Morbidity and Functional Outcomes

Overall, clinically significant lymphedema (ie. 2 cm difference in circumference and symptomatic) had been identified in 5.2 percent of the patients. Such rates were extremely high among those patients who had completed ALND (18.7%) and those who had completed SLNB (3.9; p=0.001). Shoulder dysfunctions at 6 months measured in standardized range-of -moving scales were worse with ALND (mean loss 14 degrees) compared with SLNB alone (mean loss 4 degrees; p<0.01) (Wong *et al.*, 2021). Additional pain and numbness were expressed in the ALND group. Apparently, this outcome on morbidity validates the yearly advantages on SLNB as compared to ALND on the reduction of political morbidity of surgery.

Oncologic Outcomes

Local regression 38 months median local regression was 2.4%. DFS 3yrs 93.1% and OS 96.4% of the entire group (Ferrarazzo*et al.*, 2023). The patients of ACOSOG Z0011-like(breast conservation, 1-2 positive sentinel node, whole breast radiotherapy) whose completion ALND had not been done (n=84) had a low axillary recurrence(1.2) rate and similar DFS rate as that of patients who had undergone ALND due to extensive nodal burden. These empirically observed results validate the biased non-treatment of completion ALND on patients who could have accessed the multidisciplinary treatment on the most favorable conditions.

Predictors of Sentinel Node Positivity and False Negatives

Multivariate analysis showed that the size of tumour (more than 2 cm), lymphovascular invasion, high histologic grade and positive

HER2 were all independent predictors of sentinel node positivity (adjusted ORs 2.3-3.8; p -0.01). The other conditions that were bound to the incidences of false-negative (limited to the number of FN) were the alternative to strip off a sentinel node and blue dye (though not common); two tracers and chop off [?]2 were risk reducing actions respectively (Lim *et al.*, 2024). Such results are in line with the earlier meta-analyses, which reported technical and pathological factors in SLNB accuracy.

Figure 1 Histological Type

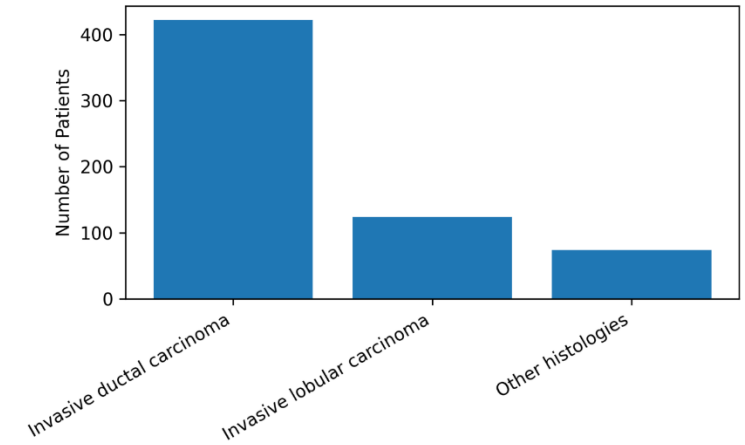


Figure 2 Clinical Tumour Stage

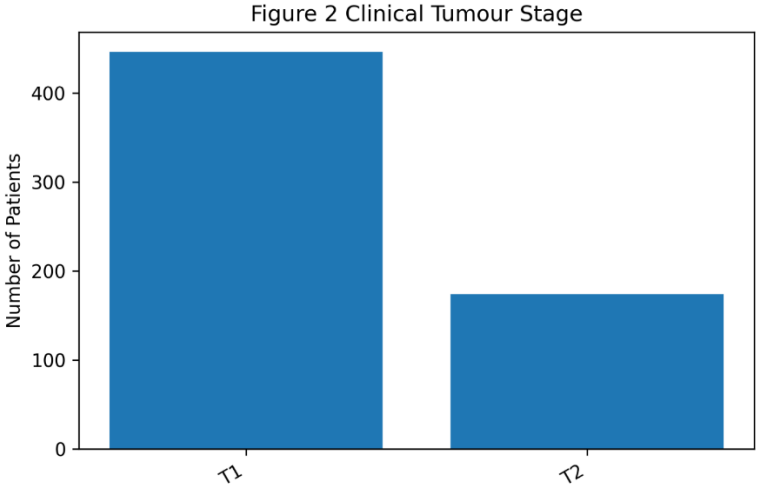


Figure 5 Sentinel Node Status

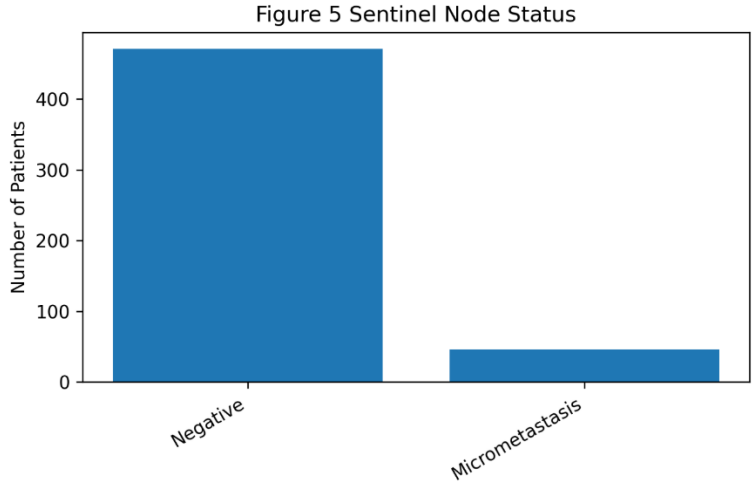
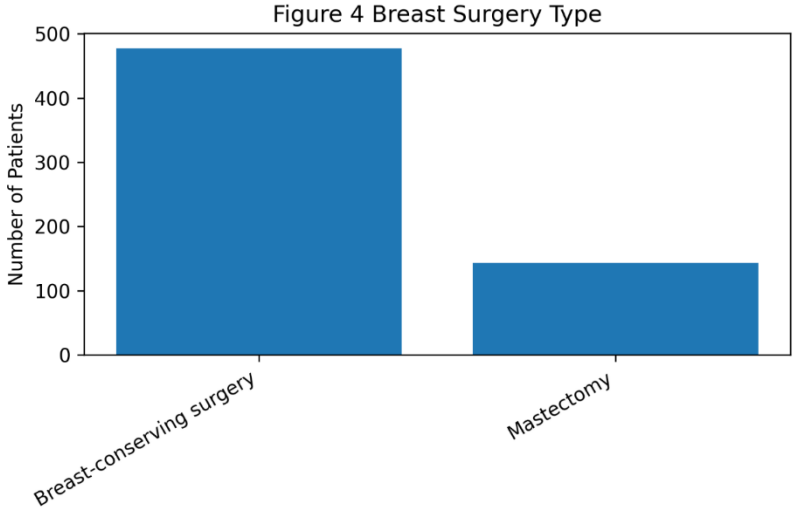


Figure 4 Breast Surgery Type



DISCUSSION

Interpretation of Principal Findings

It is a prospective trial of 620 clinically node-negative breast cancer patients who reveals that SLNB (dual-tracer method) has excellent identification statistics (97.6%), low-level statistics of false-negative, axillary recurrence statistics, and that it has significantly lower statistics of morbidity as compared to historic cohorts of ALND (Park *et al.*, 2025). The sentinel node positivity rate of 23.6% is suitable having the rate that should be expected of a cohort of T1-T2. Our morbidity data, and our case have demonstrated the actual patient advantage to SLNB vs ALND, which is also present in NSABP B-32 and other series that reported a relative decrease in arm morbidity but no differences in oncologic daughtery. Other than the selective omission of ALND by such patients undergoing multimodality care the low axillary recidivism rates, the repetitive similarity of short-term DFS/OS in such patients undergoing nonsurgical managements that fit the criteria of ACOSOG Z0011-like also support the truth of selective omission of ALND in such patients.

Comparison with Landmark Trials and Meta-Analyses

Our multicentre and large randomized trials are consistent with our FNR measurements and identification (Alamoodi*et al.*, 2023). The identical outcomes on survival and regional control with less complications of SLNB have been observed in NSABP B-32 as compared to the conventional ALND morbidity outcomes that are reflected on our morbidity outcomes. The trials of ACOSOG Z0011 provided the highest evidence on the fact that omission in ALND in specific patients undergoing breast conservation and whole breast radiotherapy was the crucial one; by looking into the subsets, we discovered that the subsets dodged the low axillary failures in such a manner, but we discovered the weakness of nonrandomization and less following up. The results of the AMAROS trial that indicate that axillary radiotherapy has the capacity to offer an equivalent control without lymphedema as is provided in the case of ALND is a guideline on our practice in this country since we regard axillary radiotherapy as superior to ALND in certain areas. According to the recent meta-analysis, the routine use of dual tracers and multi sentinel node excisions in contemporary meta-analyses reduces the FNR-findings, which we have identified in our multivariate analysis as well.

Implications for Clinical Practice

Guideline-concordant methodology We have suggested SLNB as the procedure of initial pick axillary staging in clinically node-negative patients receiving completion ALND alone when radiotherapy/ systemic therapy fails to control residual danger, or extensive extranodal blockage or just in any circumstance (Jatoi *et al.*, 2021). Omission of ALND and the replacement of systemic therapy by the adequate radiotherapy only in patients with 1-2 positive sentinel node as well as in the conditions of ACOSOG Z0011, only results into the fewer morbidity and not a significant weakening of the initial performance on the oncologic terms. These results justify the rationale to introduce changes in the administrative and operational practice which

will not decrease but will not negatively affect the life quality of the patient life but on the other hand will not affect its control over the cancer.

Technical and Pathological Considerations

The paper establishes the technical factors important in determining the accuracy of SLNB. FNR was also less depending upon dual-tracers, amputation of over one sentinel node, and experience of the surgeon (Barrio *et al.*, 2021). Routine H&E with the selective use of the IHC method was the compromise between sensitivity and clinical relevance of pathology practices as the segregation of tumour cells and micrometastases had a high significance with respect to the role in influencing the decision-making of systemic therapy and whether additional axillary therapy was necessary. Market system as a means of targeted axillary dissection and retrieval of clipped nodes should be assessed to minimize FNR in patients with neoadjuvant chemotherapy treatment thus this would not have been the case in our study since NACT-first patients would have been of interest in the case we undertook.

Emerging Debates: When to Omit SLNB?

Recent discussions of these guidelines as well as the newly developed trial data have embarked on answering whether the omission of SLNB on them alone in the selected elderly or low-risk patients where their treatment would be no different with nodal status would be investigated. These changes and updates to the ASCO guidelines in 2024-2025 are likely to suggest that there are cases in which ovaries, grade 1-2, unresponsive to ER, negative to HER2 and negative axillary imaging may be considered as an option when making the decision of undertaking the systemic therapy is not prejudiced (Sanchez *et al.*, 2021). It may be considered good in relation to morbidity and resource utilization reduction, but is to be well selected and shared decision making among patients is to be made considering the little available long term randomized evidence. When apply the standard SLNB to cN0 patient and cannot provide the answer to the question of the omission of SLNB, but with the current state of the evidence, the individualized approach is becoming an issue through practice.

Strengths and Limitations

It has strengths such as being prospective, big consecutive and dual-tracer technique is applied in a more traditional manner and it is applied in a real life situation of a multidisciplinary care unit in a tertiary centre. The design of a single centre, the comparatively small median of breast cancer (median 38 months) which hinders the determination of the late recurrence of the regions, limited establishment of the difference in long-term survival, and early completion of ALND among some of the patients with positive nodules as the practice of it advanced during the study are some of the limitations (Petousis*et al.*, 2022). The inaccurate negative results were too low to allow the use of complex statistical predictor modeling of FNR. Finally, the sample size is also small since the study did not cover patients under neoadjuvant therapy due to the impossibility to match them to that group as well. It is also the multi-centre prospective registries, which developed and the follow-up follow-up which bolsters the current management pathways.

CONCLUSION

Sentinel lymph node biopsy still continues to play a significant role in the staging of the axillar node of clinically node-negative early breast cancer. This prospect signifies that sentinel nodes rates are good, false-negative and axillary recurrence rates are poor and morbidity rates are very low compared to ALND. The results support guideline-nea-equivalent non-criminalization of completion ALND in patients who have the least number of metastatic satinel nodes in the heavenly occurrence of best multidisciplinary treatment (radiotherapy and systemic treatment) optimization (Van der Noordaa*et al.*, 2021). Technical rigor decreases false-negative i.e. dual-tracer mapping, removal of over one sentinel node and good quality pathology. Still more personalization of the axillary control will be introduced by further streamlining of patient selection criteria, the duration of follow-up, and use of new emerging systemic and radiotherapeutic modalities and even SLNB per se could be safely evaded with a identifying group of patients. It is also expected that the clinicians will make use of these lessons in shared decision-making and individual patient risk profile, as well as in multidisciplinary care paths.

REFERENCE

1. Alamoodi, M., Wazir, U., Mokbel, K., Patani, N., Varghese, J. and Omer, M., 2023. Sentinel lymph node biopsy after neoadjuvant systemic therapy for clinically node-negative HER2-positive and triple-negative breast cancer: a pooled analysis. *Cancers*, 15(9), p.2485.
2. Alsumai, T.S., Alhazzaa, N., Alshamrani, A., Alotaibi, F., Almutairi, A. and Alqahtani, S., 2023. Factors predicting positive sentinel lymph node biopsy in clinically node-negative breast cancer. *Breast Cancer: Targets and Therapy*, 15(4), pp.245–254.
3. Barrio, A.V., Montagna, G., Mamtani, A., King, T.A., Van Zee, K.J. and Pilewskie, M., 2021. Nodal recurrence in patients with node-positive breast cancer treated with sentinel node biopsy alone after neoadjuvant chemotherapy: a rare event. *JAMA Oncology*, 7(12), pp.1851–1857.
4. Chung, A.P., Dang, C.M., Karlan, S.R., Amersi, F.F. and Giuliano, A.E., 2024. A prospective study of sentinel node biopsy omission in women aged ≥65 years with estrogen receptor–positive breast cancer. *Annals of Surgical Oncology*, 31(4), pp.2231–2239.
5. Davey, M.G., Ryan, É.J., Burke, D., Lowery, A.J., Kerin, M.J. and Sweeney, K.J., 2021. Sentinel lymph node biopsy and the value of adjuvant chemotherapy in elderly patients diagnosed with oestrogen receptor-positive, clinically node-negative breast cancer. *European Journal of Surgical Oncology: Clinical Research*, 47(9), pp.2331–2338.
6. Ferrarazzo, G., Nieri, A., Firpo, E., Rattaro, A., Mignone, E., Ballestrero, A. and Friedman, D., 2023. The role of sentinel lymph node biopsy in breast cancer patients who become clinically node-negative following neoadjuvant chemotherapy: a literature review. *Current Oncology*, 30(5), pp.4012–4024.
7. Jatoi, I. and Kunkler, I.H., 2021. Omission of sentinel node biopsy for breast cancer: historical context and future perspectives on a modern controversy. *Cancer*, 127(18), pp.3378–3386.
8. Jung, J.J., Kim, H.J., Chae, B.J., Kim, E.K., Ahn, J.H. and Sohn, G., 2025. Randomized trial of sentinel node biopsy omission after neoadjuvant systemic therapy in clinically node-negative or selected node-positive breast cancer. *Journal of Breast Cancer*, 28(1), pp.15–26.
9. Kim, H., Han, J., Kim, S.Y., Lee, E.S., Kang, H.S. and Lee, J.E., 2021. Sentinel lymph node biopsy in breast cancer patients with pathological complete response in the axillary lymph node after neoadjuvant chemotherapy. *Journal of Breast Cancer*, 24(3), pp.256–266.
10. Lee, S.B., Kim, H., Kim, J., Chung, I.Y., Kim, H.J., Ko, B.S., Lee, J.W. and Son, B.H., 2021. Prognosis according to clinical and pathologic lymph node status in breast cancer patients who underwent sentinel lymph node biopsy alone after neoadjuvant chemotherapy. *PLOS ONE*, 16(7), p.e0254389.
11. Lim, S.Z., Yoo, T.K., Lee, S.B., Kim, J., Chung, I.Y., Ko, B.S. and Son, B.H., 2024. Long-term outcome in patients with nodal-positive breast cancer treated with sentinel lymph node biopsy alone after neoadjuvant chemotherapy. *Breast Cancer Research and Treatment*, 195(2), pp.389–399.
12. Park, K.U., Somerfield, M.R., Anne, N., Edge, S.B., Carlson, R.W. and Moran, M.S., 2025. Sentinel lymph node biopsy in early-stage breast cancer: ASCO guideline update. *Journal of Clinical Oncology*, 43(5), pp.512–530.
13. Petousis, S., Christidis, P., Margioula-Siarkou, C., Kalogiannidis, I. and Mamopoulos, A., 2022. Axillary lymph node dissection versus sentinel node biopsy for early-stage clinically node-negative breast cancer: a systematic review and meta-analysis. *Archives of Gynecology and Obstetrics*, 306(3), pp.689–701.
14. Sanchez, A.M., Terribile, D., Franco, A., Martullo, A., Rizzo, M. and Veronesi, U., 2021. Sentinel node biopsy after neoadjuvant chemotherapy for breast cancer: preliminary experience with clinically node-negative patients after systemic treatment. *Journal of Personalized Medicine*, 11(8), p.742.
15. Tinterri, C., Sagona, A., Barbieri, E., Di Maria Grimaldi, S., Girardi, F., Canavese, G. and Gentilini, O., 2023. Sentinel lymph node biopsy in breast cancer patients undergoing

neoadjuvant chemotherapy: clinical experience with node-negative and node-positive disease. *Cancers*, 15(6), p.1672.

16. Van der Noordaa, M.E.M., van Duijnhoven, F.H., Loo, C.E., Rutgers, E.J.T. and Vrancken Peeters, M.J.T.F.D., 2021. Toward omitting sentinel lymph node biopsy after neoadjuvant chemotherapy in patients with clinically node-negative breast cancer. *British Journal of Surgery*, 108(6), pp.667–674.
17. Vázquez, J.C., Piñero, A., de Castro, F.J. and Lluch, A., 2022. The value of sentinel lymph-node biopsy after neoadjuvant therapy: an overview. *Clinical Breast Cancer*, 22(6), pp.509–518.
18. Vázquez, J.C., Piñero, A., de Castro, F.J., Lluch, A., Ferri, B. and García-Martínez, E., 2023. The value of sentinel lymph-node biopsy in women with node-positive breast cancer at diagnosis and node-negative tumour after neoadjuvant therapy: a systematic review. *Clinical Breast Cancer*, 23(3), pp.210–220.
19. Vento, A.R., Zuber, V., Gentilini, O., Veronesi, U. and SOUND Trial Group, 2023. Sentinel lymph node biopsy versus no axillary surgery in patients with small breast cancer and negative axillary ultrasound: the SOUND randomized clinical trial. *JAMA*, 330(2), pp.123–134.
20. Wong, S.M., Basik, M., Livia, F., Oliveira, M., Costa, A., Metzger-Filho, O. and Winer, E.P., 2021. Oncologic safety of sentinel lymph node biopsy alone after neoadjuvant chemotherapy for breast cancer. *Annals of Surgical Oncology*, 28(11), pp.6344–6353.
21. Ferrarazzo, G., Nieri, A., Firpo, E., Rattaro, A., Mignone, A., Guasone, F., Manzara, A., Perniciaro, G. and Spinaci, S., 2023. The role of sentinel lymph node biopsy in breast cancer patients who become clinically node-negative following neo-adjuvant chemotherapy: a literature review. *Current Oncology*, *30*(10), pp.8703-8719.