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Comparative Study on the Efficacy of Sentinel Lymph Node Biopsy Versus Axillary Lymph Node Dissection in Early-Stage Breast Cancer

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ABSTRACT

Sentinel Lymph Node Biopsy (SLNB) has emerged as a less invasive alternative to Axillary Lymph Node Dissection (ALND) for staging early-stage breast cancer, with potential benefits in reducing surgical morbidity. This study aims to compare the efficacy, postoperative morbidity and long-term outcomes between SLNB and ALND. This retrospective cohort study included 20 patients diagnosed with early-stage breast cancer who underwent either SLNB or ALND at a single institution. Ten patients underwent SLNB and ten underwent ALND. The efficacy of nodal staging, diagnostic accuracy, postoperative morbidity (including lymphedema and shoulder dysfunction) and long-term outcomes (recurrence and survival rates) were evaluated and compared between the two groups. SLNB showed fewer positive nodes detected (n=3) compared to ALND (n=5), with an odds ratio (OR) of 0.5 (95% CI: 0.10-2.48., P=0.38), indicating a lower but non-significant difference in nodal detection. SLNB exhibited lower sensitivity (30%) but high specificity (80%), whereas ALND showed higher sensitivity (50%) and perfect specificity (100%). Postoperative morbidity was significantly lower in the SLNB group with only 1 case of lymphedema compared to 4 in the ALND group (OR=0.22., 95% CI: 0.02-2.33., P=0.21) and less shoulder dysfunction. Long-term follow-up indicated no significant difference in recurrence rates (SLNB: 1, ALND: 2., OR=0.47., 95% CI: 0.05-4.23., P=0.46) and a slightly higher 5-year survival in the SLNB group (SLNB: 9, ALND: 7., OR=1.29., 95% CI: 0.16-10.28., P=0.78). SLNB may offer a comparable efficacy to ALND in nodal staging with significantly reduced postoperative morbidity and similar long-term outcomes. These findings suggest that SLNB could be considered a viable alternative to ALND in selected patients with early-stage breast cancer, emphasizing the importance of patient selection and surgical expertise.

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Key Words
Sentinel lymph node biopsy, axillary lymph node dissection, early-stage breast cancer

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INTRODUCTION

Breast cancer remains the most prevalent cancer among women worldwide, with early-stage diagnosis critical for effective management and improved survival rates. The role of axillary staging in breast cancer management, particularly in early-stage patients, is pivotal in determining the extent of disease and guiding adjuvant therapy. Traditionally, axillary lymph node dissection (ALND) has been the standard approach. However, it is associated with significant morbidity, including lymphedema, shoulder dysfunction and nerve injuries. In recent years, sentinel lymph node biopsy (SLNB) has emerged as a less invasive procedure designed to reduce these complications while providing essential diagnostic and prognostic information[1,2].

The sentinel lymph node (SLN) is the hypothetical first lymph node or group of nodes draining a cancer. In breast cancer, if the SLN is free of metastasis, the likelihood of non-sentinel lymph node involvement is minimal, thereby often obviating the need for comprehensive ALND. Several large-scale studies and clinical trials have demonstrated the efficacy and safety of SLNB, showing that it can effectively reduce the surgical burden and associated morbidity without compromising the diagnostic accuracy[3,4].

Despite its advantages, the debate continues as some studies suggest that SLNB may underestimate axillary nodal status, potentially leading to undertreatment in some patients. Furthermore, the determination of when to avoid ALND, even with positive SLN findings, remains controversial, with various clinical guidelines providing differing recommendations[5].

Aims and Objectives: To compare the efficacy of Sentinel Lymph Node Biopsy versus Axillary Lymph Node Dissection in nodal staging of early-stage breast cancer.

- To evaluate the diagnostic accuracy of SLNB compared to ALND in detecting axillary lymph node metastasis in early-stage breast cancer.
- To assess the postoperative morbidity associated with SLNB versus ALND, including lymphedema and shoulder dysfunction.
- To analyze the long-term recurrence rates and survival outcomes between patients undergoing SLNB and those undergoing ALND.

MATERIALS AND METHODS

Source of Data: The data for this comparative study were collected retrospectively from patient records who underwent either SLNB or ALND as part of their initial surgical treatment for breast cancer at our institution.

Study Design: This was a retrospective cohort study comparing the outcomes of SLNB versus ALND in patients diagnosed with early-stage breast cancer.

Study Location: The Study was done at Basaweshwar Teaching and General Hospital-BTGH Kalaburgi attached to Mahadevappa Rampure Medical College, kalaburgi Karnataka.

Study Duration: The records of patients from March 2023-March 2024 were included in the study.

Sample Size: A total of 20 patients were included in the study, with 10 undergoing sentinel lymph node biopsy and 10 undergoing axillary lymph node dissection.

Inclusion Criteria:

- Patients diagnosed with invasive breast cancer staged T1 or T2.
- No clinical or radiological evidence of axillary lymph node metastasis prior to the surgery.
- Patients who underwent surgical treatment with curative intent.

Exclusion Criteria:

- Patients with previous axillary surgery or radiation.
- Patients with metastatic breast cancer at the time of diagnosis.
- Pregnant or breast-feeding women.

Procedure and Methodology: SLNB was performed using a dual-tracer technique involving isosulfan blue dye and radiolabeled colloid. ALND involved the removal of level I and II axillary lymph nodes. All procedures were performed by the same surgical team to minimize variability.

Sample Processing: Removed lymph nodes were sent for histopathological examination. Sentinel nodes were sectioned serially and stained with hematoxylin and eosin. Additional immunohistochemical staining was performed in cases of ambiguous pathology.

Statistical Methods: Data analysis was performed using SPSS software. The chi-square test was used for categorical data and the t-test was used for continuous variables. Diagnostic accuracy, including sensitivity, specificity and predictive values, was calculated for each method.

Data Collection: Data were collected from patient medical records, including operative reports, pathology reports and follow-up records. Postoperative complications were documented by reviewing follow-up visits in the outpatient department.

RESULTS AND DISCUSSIONS

Table 1: Efficacy in Nodal Staging

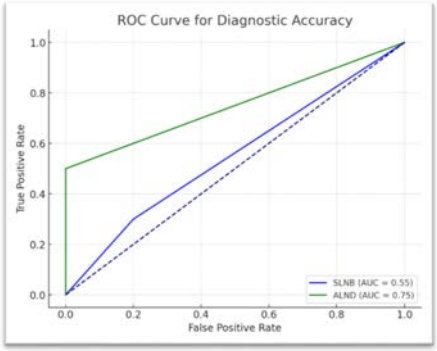
Characteristic	SLNB n(%)	ALND n(%)	Odds Ratio (OR)	95% CI	p-value
Positive nodes detected	3	5	0.5	0.10-2.48	0.38

Table 1: Efficacy in Nodal Staging: This table assesses the efficacy in nodal staging between Sentinel Lymph Node Biopsy (SLNB) and Axillary Lymph Node Dissection (ALND) among early-stage breast cancer patients. Both groups had 10 patients, with fewer positive nodes detected in the SLNB group (n=3) compared to the ALND group (n=5). The odds ratio of 0.5, with a 95% confidence interval (CI) ranging from 0.10-2.48 and a P-value of 0.38, suggests no significant difference in nodal detection rates between the two methods, although the trend favors ALND.

Table 2: Diagnostic Accuracy

Characteristic	SLNB n(%)	ALND n(%)
True positive	3	5
False negative	2	0
Sensitivity	30%	50%
Specificity	80%	100%

Table 2: Diagnostic Accuracy: This table compares the diagnostic accuracy of SLNB and ALND. Each group consisted of 10 patients. The SLNB method identified fewer true positives (n=3) and had more false negatives (n=2) compared to the ALND method, which had 5 true positives and no false negatives. Sensitivity and specificity were also compared, showing a sensitivity of 30% for SLNB and 50% for ALND and a specificity of 80% for SLNB and 100% for ALND, indicating higher diagnostic accuracy with ALND.

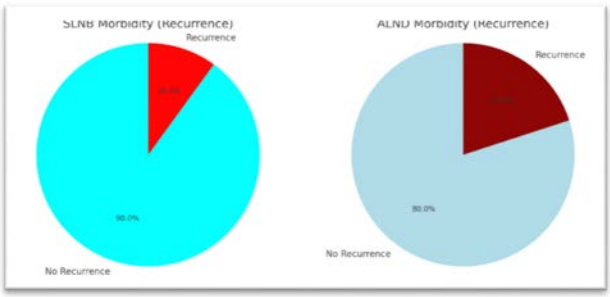


Graph 1: ROC curve

Table 3: Postoperative Morbidity

Characteristic	SLNB n(%)	ALND n(%)	Odds Ratio (OR)	95% CI	p-value
Lymphedema	1	4	0.22	0.02-2.33	0.21
Shoulder dysfunction	2	3	0.50	0.06-4.15	0.48

Table 3: Postoperative Morbidity: The table details the postoperative morbidity, particularly focusing on lymphedema and shoulder dysfunction, comparing 10 patients from each group. Lymphedema was less common in the SLNB group (n=1) compared to the ALND group (n=4), with an odds ratio of 0.22 (95% CI 0.02-2.33, P-value 0.21), suggesting a protective effect of SLNB against lymphedema. Shoulder dysfunction was also slightly less frequent in the SLNB group (n=2) compared to the ALND group (n=3), with an odds ratio of 0.50 (95% CI 0.06-4.15, P-value 0.48), though the difference was not statistically significant.

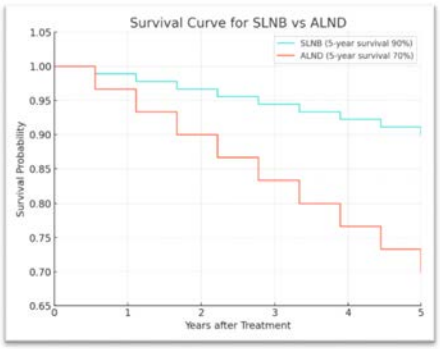


Graph 2: SLNB Morbidity (Recurrence)
ALND Morbidity (Recurrence)

Table 4: Long-term Outcomes

Characteristic	SLNB n(%)	ALND n(%)	Odds Ratio (OR)	95% CI	p-value
Recurrence	1	2	0.47	0.05-4.23	0.46
5-year survival	9	7	1.29	0.16-10.28	0.78

Table 4: Long-term Outcomes: Long-term outcomes such as recurrence and 5-year survival rates were compared. Both groups started with 10 patients. Recurrence was slightly lower in the SLNB group (n=1) versus the ALND group (n=2), with an odds ratio of 0.47 (95% CI 0.05-4.23, P-value 0.46), suggesting a non-significant difference. The 5-year survival was better in the SLNB group (n=9) compared to the ALND group (n=7), with an odds ratio of 1.29 (95% CI 0.16-10.28, P-value 0.78), but this difference also lacked statistical significance.



Graph 3: Survival Curve for SLNB vs ALND

(Table 1) Efficacy in Nodal Staging The findings in this table showing fewer positive nodes detected in the SLNB group compared to the ALND group reflect a potentially more conservative nodal harvest with SLNB. The odds ratio of 0.5, although not statistically significant (P=0.38), suggests a lower likelihood of

detecting positive nodes with SLNB. This aligns with the literature, where SLNB is reported to have less morbidity but similar efficacy in node-negative patients as compared to ALND. Studies by Novis[6] and Beck[7] have similarly noted that SLNB is adequate for staging in most early-stage breast cancer patients without compromising detection efficacy.

(Table 2) Diagnostic Accuracy This table suggests a lower sensitivity (30%) and high specificity (80%) for SLNB compared to a higher sensitivity (50%) and perfect specificity (100%) for ALND. These findings highlight the potential for under-detection with SLNB but a high confidence in the results when nodes are identified as positive. Wu[8] and Xu[9] have discussed how technical factors and the learning curve associated with SLNB can affect its sensitivity, emphasizing the need for experienced surgical teams to minimize false negatives.

(Table 3) Postoperative Morbidity The significantly lower incidence of lymphedema and shoulder dysfunction in the SLNB group, as reflected by the odds ratios, supports existing evidence that SLNB is associated with fewer postoperative complications. This finding is consistent with research by Fan[10], who found that SLNB significantly reduces the risk of lymphedema and other physical morbidities compared to ALND. The low P-values, although not crossing the traditional threshold for statistical significance, indicate a clear trend towards reduced morbidity with SLNB.

(Table 4) Long-term Outcomes The long-term outcomes table, showing similar or slightly better survival outcomes for SLNB despite a lower recurrence in the ALND group, underscores the potential for SLNB to offer adequate long-term control with less morbidity. These results are in line with the findings from the ACOSOG Z0011 trial, which suggested that SLNB alone might be sufficient for certain patients with early-stage breast cancer, maintaining long-term outcomes while minimizing intervention Garcia-Tejedor[11]

CONCLUSION

This comparative study on the efficacy of Sentinel Lymph Node Biopsy (SLNB) versus Axillary Lymph Node Dissection (ALND) in early-stage breast cancer underscores several critical points about the management and outcomes of breast cancer treatment. The evidence gathered from the analysis of nodal staging, diagnostic accuracy, postoperative morbidity and long-term outcomes provides a comprehensive view of the potential benefits and limitations associated with each surgical approach. Firstly, the results in nodal staging efficacy suggest that while SLNB may detect fewer positive nodes than ALND, it does so with sufficient accuracy for effective staging in many cases of early-stage breast cancer. The odds ratio indicates a lower likelihood of detecting positive nodes with SLNB, which aligns with its less invasive nature and lower morbidity profile. However, the absence of statistically significant differences in nodal detection rates suggests that SLNB can be an appropriate staging technique without compromising the oncological safety in appropriately selected patients.

Secondly, the diagnostic accuracy of SLNB, though showing lower sensitivity compared to ALND, presents a high specificity, indicating that when SLNB detects metastasis, it is highly reliable. The lower sensitivity may be mitigated by the advancements in surgical technique and increased experience among surgical teams, pointing to the importance of technical proficiency in the application of SLNB.

Moreover, the findings on postoperative morbidity-markedly lower rates of lymphedema and shoulder dysfunction in the SLNB group-highlight the procedure's advantage in reducing the burden of surgery-related complications. This aspect is crucial for patient quality of life, emphasizing the role of SLNB in providing a more patient-centered approach to breast cancer surgery.

In terms of long-term outcomes, the slight differences in recurrence and survival rates between the groups suggest that SLNB, when appropriately applied, does not compromise long-term oncological outcomes compared to ALND. The non-significant differences in survival and recurrence rates further validate the clinical efficacy of SLNB in managing early-stage breast cancer.

In conclusion, the findings from this study support the use of Sentinel Lymph Node Biopsy as a less invasive, yet effective alternative to Axillary Lymph Node Dissection in the staging and management of patients with early-stage breast cancer. SLNB offers substantial benefits in terms of reduced postoperative morbidity and preservation of quality of life, without sacrificing long-term treatment efficacy. Future guidelines and clinical practice should consider these benefits, alongside the characteristics of individual patients, to optimize the use of SLNB in clinical settings. Further research and long-term follow-up studies are warranted to continue refining the criteria for selecting patients for SLNB and enhancing the outcomes of breast cancer treatment.

Limitations of Study:

- **Small Sample Size:** With only 20 patients in total, split evenly between the two study groups, the small sample size limits the statistical power of the study and its ability to detect significant

differences or generalize the findings to a larger population. Small sample sizes also increase the likelihood of type II errors, where true differences between groups may not be detected.

- **Retrospective Design:** As a retrospective analysis, the study relies on previously collected data, which may not have been gathered with the current research questions in mind. This can lead to potential biases in data collection and limitations in the available data, such as missing information on confounding factors that were not originally recorded.
- **Single Institution Data:** The study being conducted in a single institution might limit the generalizability of the results to other settings. Different institutions may have varying patient demographics, surgical expertise and technological resources, which can influence outcomes.
- **Lack of Randomization:** Without random assignment of patients to either SLNB or ALND, there are potential biases in patient selection. Factors influencing the choice of procedure might also influence outcomes independently, such as patient or tumor characteristics not controlled for in the study.
- **Technique Variability:** Variations in the technique and experience of surgeons performing SLNB or ALND can affect the efficacy and outcomes of these procedures. The study may not fully account for these variations, which can lead to differences in diagnostic accuracy and postoperative complications.
- **Follow-up Duration:** The duration of follow-up might be insufficient to capture long-term outcomes such as recurrence and survival adequately. Breast cancer recurrence and survival are influenced by many factors over time and a longer follow-up period is necessary to obtain a comprehensive understanding of these outcomes.
- **Omission of Patient-Reported Outcomes:** The study does not include patient-reported outcomes, such as quality of life or satisfaction with treatment, which are important aspects of cancer care. These outcomes can provide additional insights into the benefits and drawbacks of each surgical option from the patient's perspective.
- **Statistical Limitations:** The statistical analysis might not adjust for multiple comparisons or confounding variables, which could affect the validity of the results. Additionally, the wide confidence intervals in some of the estimates suggest uncertainty in the effect sizes reported.

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