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Single-Dye Sentinel Lymph Node Mapping for Targeted Axillary Dissection in Breast Cancer Patients After Neoadjuvant Chemotherapy: A Prospective Study

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BACKGROUND

- Accurate axillary staging in node-positive breast cancer after neoadjuvant chemotherapy (NAC) is a clinical challenge, especially when radioisotopes for dual-tracer mapping are unavailable.
- Targeted Axillary Dissection (TAD), which involves removing the clipped node (MLN) along with sentinel lymph nodes (SLNs), aims to improve accuracy.
- To prospectively evaluate the performance of single-agent methylene blue dye for SLN biopsy combined with clip-guided TAD in patients post-NAC.

METHODS

This was a prospective study conducted between July 2022 and February 2024 involving 29 women with initial cN1–2 breast cancer after ethical approval.

Study Protocol:

1. Pre-NAC: The biopsy-proven positive axillary lymph node was marked with a clip.
2. NAC: Patients received standard neoadjuvant chemotherapy.
3. Intraoperative Procedure:
   - 2–4 mL of methylene blue was injected peritumorally.
   - Blue-stained SLNs were identified and resected.
   - The clipped MLN was selectively excised.
4. Endpoints: The primary endpoints were the SLN identification rate (IR), concordance between MLN and SLNs, and the false-negative rate (FNR).

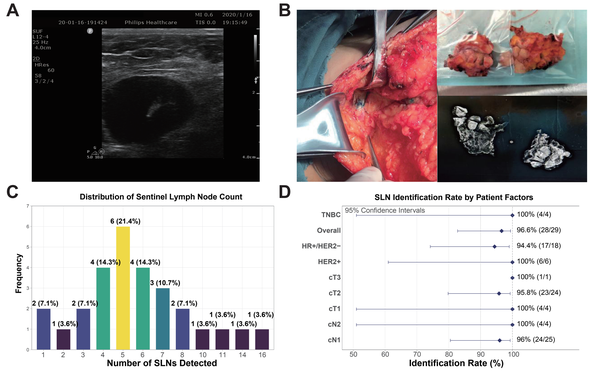


Figure 1. Single-dye sentinel lymph node biopsy with targeted axillary dissection demonstrated high identification rates across patient subgroups after neoadjuvant chemotherapy. (A) Representative ultrasound image of clip-marked positive axillary lymph node prior to neoadjuvant chemotherapy. **(B)** Surgical procedure and specimens: intraoperative identification of the blue-stained sentinel lymph node (left), resected sentinel lymph nodes (top right), and specimen radiography confirming clip retrieval (bottom right). **(C)** Distribution of sentinel lymph node (SLN) counts among successfully mapped cases (n=28), with a mean of 6.0 SLNs (95% CI: 4.74-7.26) per patient; the most common number of SLNs were detected was 5 (21.4% of cases). **(D)** Forest plot showing high SLN identification rates across different patient subgroups with 95% confidence intervals; the overall identification rate was 96.55% (28/29). *Abbreviations: SLN, sentinel lymph node; TNBC, triple-negative breast cancer; HR, hormone receptor; HER2, human epidermal growth factor receptor 2; cT, clinical tumor stage; cN, clinical nodal stage.*

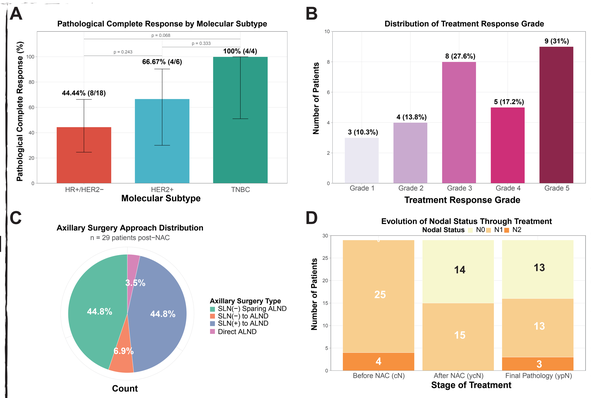


Figure 2. Treatment response profiles and subsequent surgical approaches varied significantly by molecular subtype after neoadjuvant chemotherapy in node-positive breast cancer patients. (A) Pathological complete response (pCR) rates differed by molecular subtype (n=28): TNBC showed highest response (95% CI: 51.01-100%), followed by HER2+ (66.67%, 95% CI: 30.00-90.32%) and HR+/HER2- (44.44%, 95% CI: 24.56-66.28%); a marginally significant difference was observed between HR+/HER2- and TNBC (p=0.068). **(B)** Distribution of treatment response grades in the Miller-Payne system (n=29): most patients achieved grades 3-5 responses (76%). **(C)** Axillary surgery approach distribution (n=29): 44.8% of patients avoided axillary lymph node dissection (ALND). **(D)** Evolution of nodal status through treatment phases, showing a progressive decrease in nodal burden. *Abbreviations: TNBC, triple-negative breast cancer; HR, hormone receptor; HER2, human epidermal growth factor receptor 2; NAC, neoadjuvant chemotherapy; SLN, sentinel lymph node.*

RESULTS

Primary Outcomes

The single-dye TAD technique demonstrated excellent performance:

- SLN Identification Rate (IR): 96.6% (28/29 patients)
- MLN-SLN Concordance: 100% (28/28 cases where MLN was retrieved)
- Marked Node as SLN: The clipped node was also a blue-stained SLN in 96.6% of cases (28/29)
- False Negative Rate (FNR): 9.1% (1 of 11 patients with residual disease)
- Adverse Events: No dye-related adverse events were observed.

Treatment Response and Surgical Impact

- Residual nodal disease was present in 37.9% (11/29) of patients after NAC.
- Nodal pathological complete response (pCR) was highest in TNBC (90%), followed by HER2+ (66.7%) and HR+/HER2- (44.4%) tumors.
- Crucially, 44.8% of patients successfully and safely avoided a full axillary lymph node dissection (ALND).

Our single-dye TAD technique outperformed historical single-dye methods and was comparable to dual-tracer techniques, with a substantially lower FNR.

Table 1. Baseline Patient Characteristics (N=29)

Characteristic	Value (Mean / N)	(95% CI / %)
Age (years)	51.38	(47.50 - 55.26)
Tumor Size (cm)	3.02	(2.66 - 3.37)
Ki67 Expression (%)	31.34	(20.73 - 41.96)
Clinical T Stage		
T1	4	(13.8%)
T2	24	(82.8%)
T3	1	(3.4%)
Clinical N Stage		
N1	25	(86.2%)
N2	4	(13.8%)
Molecular Subtype		
Luminal	18	(62.1%)
HER2+	6	(20.7%)
TNBC	5	(17.2%)
Pathological Type		
IDC	22	(75.9%)
DCIS	4	(13.8%)
IMPC	3	(10.3%)

Data are presented as mean (95% Confidence Interval) or N (%).
Abbreviations: CI, Confidence Interval; HR+, Hormone Receptor Positive; HER2-, Human Epidermal Growth Factor Receptor 2 -Negative; HER2+, Human Epidermal Growth Factor Receptor 2 -Positive; TNBC, Triple-Negative Breast Cancer; IDC, Invasive Ductal Carcinoma; DCIS, Ductal Carcinoma In Situ; IMPC, Invasive Micropapillary Carcinoma; NAC, Neoadjuvant Chemotherapy.

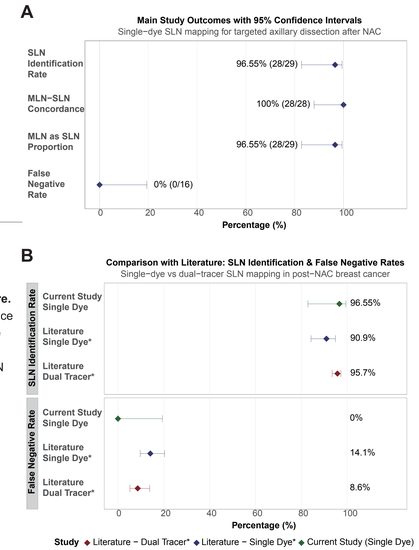


Figure 3. Single-dye sentinel lymph node mapping with targeted axillary dissection demonstrated superior outcomes compared to conventional techniques reported in the literature. (A) Forest plot displaying main study outcomes with 95% confidence intervals (n=29): high sentinel lymph node (SLN) identification rate (96.55%, 28/29), perfect MLN-SLN concordance (95% CI: 87.94-100%), consistent identification of MLN identification as SLN (96.55%, 28/29), and minimal false negative rate (95% CI: 0-19.36%). **(B)** Comparative analysis of current study findings versus published literature: the single-dye technique in this study achieved a higher SLN identification rate than previous single-dye reports (96.55% vs 90.9%) and was comparable to dual-tracer methods (95.7%);the false negative rate was substantially lower than both single-dye (14.1%) and dual-tracer (8.6%) literature values. *Abbreviations: SLN, sentinel lymph node; MLN, marked lymph node; NAC, neoadjuvant chemotherapy.*

CONCLUSIONS

- **The combination of single-blue-dye SLNB and clip-guided TAD is a highly effective procedure, achieving a high SLN identification rate of 96.6%.**
- **This technique yields an FNR of 9.1%, which is below the clinically accepted 10% benchmark, and demonstrates excellent MLN-SLN concordance.**
- **This minimally invasive approach allowed nearly 45% of patients to avoid ALND.**
- **Single-dye TAD is a pragmatic and reliable alternative to routine ALND or dual-tracer methods, particularly in resource-limited settings where radioisotopes are not available.**

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