# Axillary Sentinel Lymph Node Biopsy After Neoadjuvant Chemotherapy in Clinically Node-Negative Early Breast Cancer: Feasibility and Safety in Triple-Negative and HER2-Positive Breast Cancer Subtypes

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## Background

Axillary sentinel lymph node biopsy (SLNB) is the standard procedure for axillary staging in patients with clinically node-negative (cN0) early breast cancer (BC). Neoadjuvant chemotherapy (NACT) achieves a pathologic complete response (pCR) in 30-50% of patients with biopsy-confirmed N1 disease. Targeted axillary dissection (TAD) has been shown to reduce false-negative rates in clinically node-positive (cN+) patients following NACT. While triple-negative breast cancer (TNBC) and HER2-positive BC exhibit high response rates to NACT (potentially leading to ypN0 status), the feasibility and safety of SLNB after NACT in cN0 patients with TNBC or HER2-positive BC remain insufficiently established by high-quality evidence[1-3] .

## Objective

This study aimed to evaluate the feasibility of SLNB following NACT in patients with clinically node-negative TNBC and HER2-positive early BC, and to assess the oncologic safety of omitting axillary lymph node dissection (ALND) in SLNB-negative patients via long-term follow-up.

## Methods

A prospective single-arm trial was conducted on 404 patients with primary early breast cancer (BC, cT1b-2N0M0, age ≤70 years) who were enrolled and received neoadjuvant chemotherapy (NACT) at Peking University Cancer Hospital from October 2017 to May 2023. Inclusion criteria were: histologically confirmed invasive carcinoma, indication for chemotherapy, and eligibility for SLNB before NACT (including cases with suspicious lymph nodes but negative results on fine-needle aspiration [FNA] or core needle biopsy [CNB]). Exclusion criteria included: history of prior malignancies, contraindications to chemotherapy, prior axillary surgery, or refusal of NACT, evaluation, or study participation. Tumor subtypes were categorized as HER2-negative/hormone receptor < 10% (n=147) and HER2-positive (n=242). NACT regimens were heterogeneous, including protocols such as TCbH(P) and ddEC-T±H(P). SLNB was performed using a technetium-99m-labeled tracer.

## Conclusion

SLNB following NACT in patients with clinically node-negative TNBC and HER2-positive early BC shows high success rates and low positivity rates. Omitting ALND in SLN-negative patients appears feasible, with a low risk of axillary recurrence, indicating potential oncologic safety. However, longer follow-up durations and larger-scale studies are required to validate the long-term outcomes of this approach.

## Results

**Table 1 :** The status of sentinel lymph nodes and the clinical pathological characteristics of patients

| | SLN detection | | | | | SLN status | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Fail (n = 17) | | Success (n = 372 ) | | p | Negtive (n = 363) | | Positive (n = 9 ) | | p |
| | n | % | n | % | | n | % | n | % | |
| Age | | | | | 0.024 | | | | | 0.952 |
| ＜50 | 3 | 17.6 | 169 | 44.2 | | 165 | 45.5 | 4 | 44.4 | |
| ≥50 | 14 | 82.4 | 203 | 55.8 | | 198 | 54.5 | 5 | 55.6 | |
| Menopausal status | | | | | 0.070 | | | | | 0.823 |
| No | 5 | 29.4 | 193 | 51.9 | | 188 | 51.8 | 5 | 55.6 | |
| Yes | 12 | 70.6 | 179 | 48.1 | | 175 | 48.2 | 4 | 44.4 | |
| Histology type | | | | | 0.801 | | | | | 0.680 |
| IDC | 16 | 94.1 | 344 | 92.5 | | 336 | 92.6 | 8 | 88.9 | |
| Others | 1 | 5.9 | 28 | 7.5 | | 27 | 7.4 | 1 | 11.1 | |
| Grade | | | | | 0.281 | | | | | 0.211 |
| 1or2 | 6 | 35.3 | 198 | 53.2 | | 191 | 52.6 | 7 | 77.8 | |
| 3 | 10 | 58.8 | 147 | 40.4 | | 146 | 40.2 | 1 | 11.1 | |
| Unknown | 1 | 5.9 | 27 | 7.2 | | 26 | 7.2 | 1 | 11.1 | |
| US T category | | | | | 0.809 | | | | | 0.171 |
| 1 | 3 | 17.6 | 88 | 23.7 | | 88 | 24.2 | 0 | 0.0 | |
| 2 | 13 | 726.5 | 269 | 72.3 | | 260 | 71.6 | 9 | 100.0 | |
| 3 | 1 | 5.9 | 15 | 4.0 | | 15 | 4.1 | 0 | 0.0 | |
| US T response | | | | | 0.220 | | | | | 0.000 |
| SD/PD | 3 | 17.6 | 118 | 31.7 | | 110 | 30.3 | 8 | 88.9 | |
| PR/CR | 14 | 82.4 | 254 | 68.3 | | 253 | 69.7 | 4 | 11.1 | |
| MRI T category | | | | | 0.585 | | | | | 0.967 |
| 1 | 4 | 23.5 | 135 | 36.3 | | 132 | 36.4 | 3 | 33.3 | |
| 2 | 10 | 58.8 | 193 | 51.9 | | 188 | 51.8 | 5 | 55.6 | |
| 3 | 1 | 5.9 | 8 | 2.2 | | 8 | 2.2 | 0 | 0.0 | |
| Unknown | 2 | 11.8 | 36 | 9.7 | | 35 | 9.6 | 1 | 11.1 | |
| MRI T response | | | | | 0.798 | | | | | 0.000 |
| SD/PD | 1 | 5.9 | 34 | 9.1 | | 29 | 8.0 | 5 | 55.6 | |
| PR | 8 | 47.1 | 182 | 48.9 | | 181 | 49.9 | 1 | 11.1 | |
| CR | 2 | 11.8 | 61 | 16.4 | | 61 | 16.8 | 0 | 0.0 | |
| Unknown | 6 | 35.3 | 95 | 25.5 | | 92 | 25.3 | 3 | 33.3 | |
| US LN | | | | | 0.676 | | | | | 0.597 |
| normal | 9 | 52.9 | 216 | 58.1 | | 210 | 57.9 | 6 | 66.7 | |
| abnormal | 8 | 47.1 | 156 | 41.9 | | 153 | 42.1 | 3 | 33.3 | |

**Table 1 :** Continued

| | SLN detection | | | | | SLN status | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Fail (n = 17) | | Success (n = 372 ) | | p | Negtive (n = 363) | | Positive (n = 9 ) | | p |
| | n | % | n | % | | n | % | n | % | |
| US LN after NACT | | | | | 0.624 | | | | | 0.183 |
| normal | 16 | 94.1 | 337 | 90.6 | | 330 | 90.9 | 7 | 77.8 | |
| abnormal | 1 | 5.9 | 35 | 9.4 | | 33 | 9.1 | 2 | 22.2 | |
| MRI LN | | | | | 0.284 | | | | | 0.074 |
| No | 4 | 23.5 | 158 | 42.5 | | 151 | 41.6 | 7 | 77.8 | |
| Yes | 11 | 64.7 | 174 | 46.8 | | 173 | 47.7 | 1 | 11.1 | |
| Unknown | 2 | 11.8 | 40 | 10.8 | | 39 | 10.7 | 1 | 11.1 | |
| MRI LN after NACT | | | | | 0.438 | | | | | 0.246 |
| No | 5 | 29.4 | 163 | 43.8 | | 158 | 43.5 | 5 | 55.6 | |
| Yes | 7 | 41.2 | 136 | 36.6 | | 135 | 37.2 | 1 | 11.1 | |
| Unknown | 5 | 29.4 | 73. | 19.6 | | 70 | 19.3 | 3 | 33.3 | |
| NACT cycles | | | | | 0.568 | | | | | 0.039 |
| 4 | 0 | 0.0 | 7 | 1.9 | | 6 | 1.7 | 1 | 11.1 | |
| ≥5 | 17 | 100.0 | 365 | 98.1 | | 357 | 98.3 | 8 | 88.9 | |
| NACT regimen | | | | | 0.172 | | | | | 0.313 |
| Without anthracycline | 0 | 0.0 | 37 | 9.9 | | 37 | 10.2 | 0 | 0.0 | |
| With anthracycline | 17 | 100.0 | 335 | 90.1 | | 326 | 89.8 | 9 | 100.0 | |
| Biological subtype | | | | | 0.768 | | | | | 0.787 |
| HER2−/HR＜10% | 7 | 41.2 | 140 | 37.6 | | 137 | 37.7 | 3 | 33.3 | |
| HER2+ | 10 | 58.8 | 232 | 62.4 | | 226 | 62.3 | 6 | 66.7 | |
| Ki-67 | | | | | 0.353 | | | | | 0.014 |
| ＜15% | 0 | 0.0 | 18 | 4.8 | | 16 | 4.4 | 2 | 22.2 | |
| ≥15% | 17 | 100.0 | 3654 | 95.2 | | 347 | 95.6 | 7 | 77.8 | |
| Breast surgery | | | | | 0.697 | | | | | 0.369 |
| BCS | 9 | 52.9 | 179 | 48.1 | | 176 | 48.5 | 3 | 33.3 | |
| Mastectomy | 8 | 57.1 | 193 | 51.9 | | 187 | 51.5 | 6 | 66.7 | |
| Breast tumor pCR | | | | | 0.060 | | | | | 0.001 |
| No | 4 | 23.5 | 174 | 46.8 | | 165 | 45.5 | 9 | 100.0 | |
| Yes | 13 | 76.5 | 198 | 53.2 | | 198 | 54.5 | 0 | 0.0 | |

US T category: The T - stage evaluated by ultrasound.
US Tumor response: Ultrasound evaluation of breast tumor response.
MRI T category: The T - stage evaluated by magnetic resonance imaging (MRI).
MRI Tumor response: MRI evaluation of breast tumor response.
US LN: Initial axillary lymph node status on ultrasound (Initial axillary lymph node status on ultrasound (abnormal lymph nodes are defined as target-ring shaped lymph nodes with cortex ≥3mm, or hypoechoic lymph nodes).
US LN after NACT: The morphology of lymph nodes on ultrasound after neoadjuvant chemotherapy.
MRI LN: Whether axillary lymph nodes were visible on MRI at initial presentation.

- **The success rate of SLNB was 95.63% (95% confidence interval [CI]: 93.60%-97.66%).**
- Among 372 successful SLNB cases (median number of lymph nodes retrieved: 2, range: 1-10), 9 patients had positive SLNs, with a SLN-positive rate of 2.42% (95% CI: 0.86%-3.98%).
- Univariate analysis showed that ultrasound (US) T response, magnetic resonance imaging (MRI) T response, number of NACT cycles, Ki-67 expression level, and breast tumor pCR were factors influencing lymph node status ($p < 0.5$) (Table 1). **Multivariate analysis identified US T response as an independent significant factor (p=0.041).**
- During a median follow-up of 43 months (range: 6-85 months), 1 patient developed ipsilateral axillary recurrence, with an ipsilateral axillary recurrence rate of 0.28% (95% CI: 0.05%-1.54%) among 363 SLN-negative patients who did not undergo ALND.

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