



Original Article

A Prospective Study on Response to Neo-Adjuvant Chemotherapy on Locally Advanced Breast Carcinoma in A Tertiary Care Centre of North-East India

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ABSTRACT

Patients with locally advanced breast cancer (LABC) include patients with large primary tumors (>5 cm), tumors involving the chest wall or skin, ulceration or satellite skin nodules, inflammatory carcinoma, bulky or fixed axillary nodes, and clinically apparent internal mammary or supraclavicular nodal involvement (stages IIB and III). The introduction of neoadjuvant chemotherapy (NACT) in LABC offered us advantages like initiation of early systemic therapy, down-staging of tumors, which makes inoperable tumors operable and renders tumors suitable for breast conserving surgery (BCS) and improve survival outcome.

AIM: This prospective, hospital based observational study conducted at a tertiary care centre in Assam aims to evaluate the outcome of Neo-adjuvant chemotherapy in our patients with locally advanced breast carcinoma, focusing on Tumour and Nodal Response and role in Surgical management.

Materials and Methods: Our study was a Prospective Observational study, including 30 LABC patients at GMCH Surgery department, who were treated with NACT, followed by surgery and radiotherapy for a duration of one year from March 2024 to March 2025. All statistical analyses were performed using appropriate statistical software. Continuous variables were summarized using mean \pm standard deviation (SD). Categorical variables were expressed as frequencies and percentages. Chi-square test (χ^2) and Fisher-Exact test was used to assess associations between categorical variables such as clinical response and breast-conserving surgery eligibility.

Conclusion: NACT achieved a high overall response rate, facilitating tumor downstaging, improving operability, and enabling breast-conserving surgery eligibility in a substantial proportion of patients. While receptor status did not show a statistically significant association with treatment response, triple-negative and HER2-positive subtypes exhibited high chemosensitivity.

Keywords: Locally Advanced Breast Cancer (LABC), Neo-adjuvant Chemotherapy (NACT).

INTRODUCTION

The concept of using chemotherapy before surgery to shrink tumours and reduce tumour burden, had its origins in the early 1980s, with a key reference to Frei. The earliest clinical study was reported by the Milan Cancer Institute in 1981.

Another landmark study in this field was the National Surgical Adjuvant Breast and Bowel Project (NSABP) B-18 trial in 1997. It proved conclusively that NACT reduces tumour size, allows for more breast conserving surgeries, and provides a way to monitor tumour response to treatment. Since then, NACT has become a standard treatment modality for Locally Advanced Breast Cancer (LABC).

METHODOLOGY

Study Design: It is a Prospective Observational study, including 30 LABC patients at GMCH Surgery department, who were treated with NACT, followed by surgery and radiotherapy for a duration of one year

Study Setting

The study was conducted in the Department of General Surgery at Gauhati Medical College and Hospital, Guwahati, a tertiary care center with facilities for onco-surgery, radiological investigations, and histopathological examination

Study Duration

The study was carried out over a period of one year, from **from March 2024 to March 2025**, ensuring adequate patient enrollment and completion of data collection

Participants – Inclusion and Exclusion Criteria

Patients aged 10 years and above, with biopsy and radiologically proven Locally Advanced Breast Cancer(LABC) were included. Exclusion criteria were age below 10 and patients refusing consent for NACT and patients with contraindications for chemotherapy

Study Sampling

A consecutive sampling method was used. All eligible patients who presented during the study period and met the inclusion criteria were enrolled without randomization

Study Sample Size

A total of 30 patients were included in the study. This number was based on the expected case load and ensured sufficient statistical power for comparison

Study Groups

There were no separate intervention groups. Each patient was assessed for response to NACT using standardized diagnostic modalities

Study Parameters

Parameters included demographic data, clinical signs and symptoms, laboratory results, radiological findings and histopathology results.

Study Procedure

After clinical evaluation and investigations, NACT was administered and response to therapy was evaluated for each patient, followed by appropriate surgical procedures.

Study Data Collection

Data were recorded in a structured proforma including history, examination findings, lab investigations(including HPE) and results of radiological investigations along with surgical notes.

- A thorough history and clinical examination was done.
- The pathologic diagnosis and hormonal receptor status was confirmed by core needle biopsy before treatment.
- Complete Metastatic workup with contrast enhanced CT THORAX+ABDOMEN and Bone scan.
- Patient with biopsy proven LABC with ECOG PERFORMANCE STATUS 0-2 who gave consent were included and patient with contraindication to chemotherapy were excluded.
- After evaluation, 8 cycles of NACT were administered at 2 or 3 weekly intervals as per hormonal receptor status
- Clinical response (CR) was assessed by clinical examination and radiological evaluation as per RECIST 1.1 criteria
- After surgical resection, pathological responses was evaluated.
- Radiotherapy was given to all patients in STATE CANCER INSTITUTE, GMCH. Tamoxifen or Letrozole was given to hormone receptor positive patients for 10 years according to the menopausal status.

Data Analysis

Data were analyzed using SPSS and EXCEL. Continuous variables were summarized using mean \pm standard deviation (SD).

Categorical variables were expressed as frequencies and percentages.

Chi-square test (χ^2) and Fisher-Exact test was used to assess associations between categorical variables such as clinical response and breast-conserving surgery eligibility.

A p-value < 0.05 was considered statistically significant

Ethical Considerations

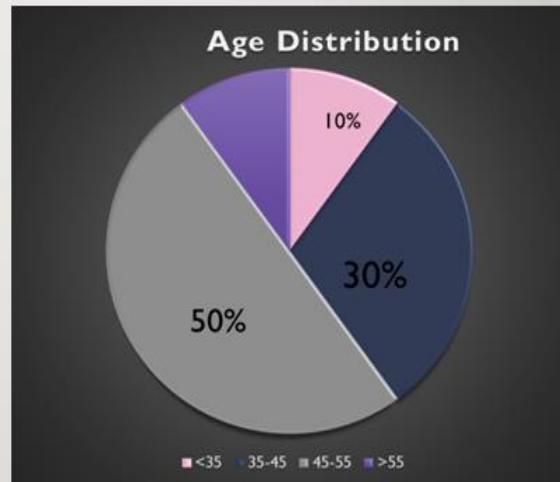
Ethical approval was obtained from the Institutional Ethics Committee. Written informed consent was taken from all patients. Confidentiality was maintained throughout the study.

RESULTS AND ANALYSIS

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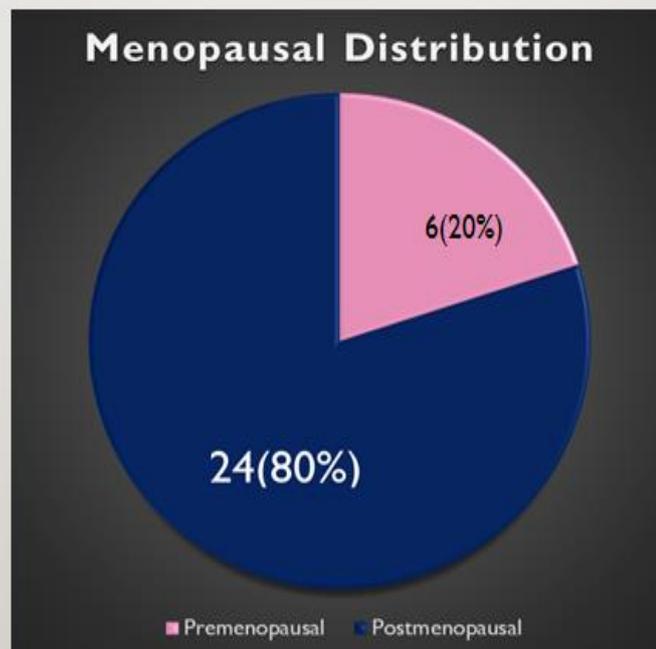
Age distribution:

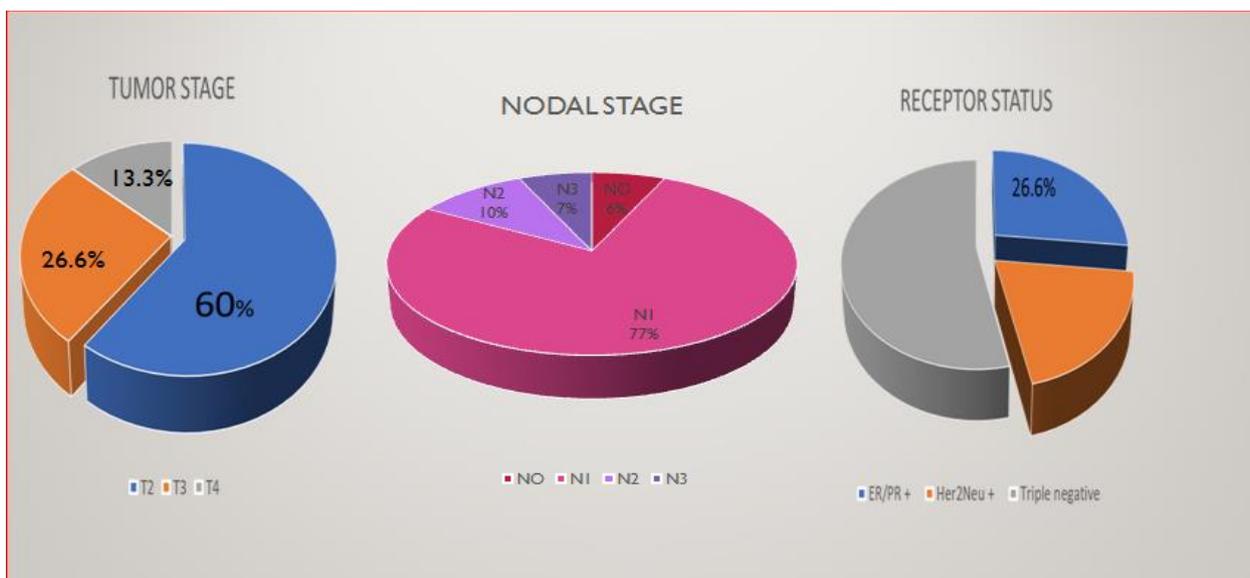
| Age | Number of patients |
|-------------|--------------------|
| < 35 years | 3 |
| 35-45 years | 9 |
| 45-55 years | 14 |
| > 55 years | 4 |



- Median age falls in the 45-55 years range, with maximum patients (50%) in this age group.
- Mean age is 45-50 years.

Relation of menopausal status with occurrence of LABC:



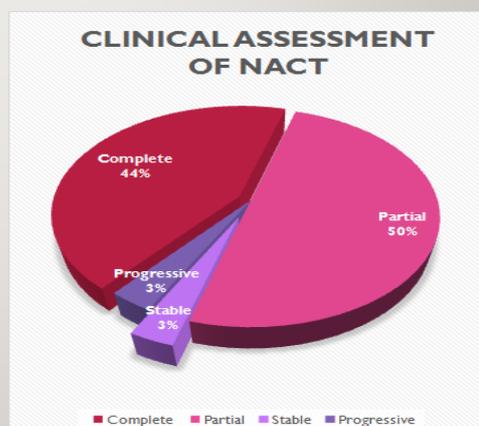


Tumor staging and Receptor status:

| T Stage | No. of Patients |
|------------------------|-----------------|
| T2 | 18 |
| T3 | 8 |
| T4 | 4 |
| N Stage | |
| N0 | 2 |
| N1 | 23 |
| N2 | 3 |
| N3 | 2 |
| Receptor status | |
| ER, PR positive | 8 |
| Her2Neu Positive | 6 |
| Triple negative | 21 |

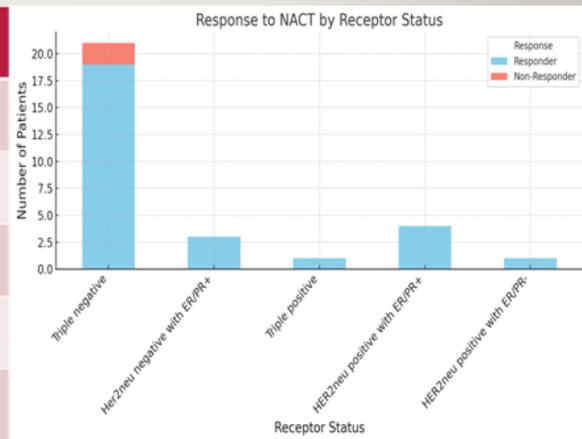
Response of NACT:

| Clinical assessment | Number of patients | Percentage |
|---|--------------------|------------|
| Complete response | 13 | 43.3% |
| Partial response | 15 | 50% |
| Stable disease | 1 | 3.3% |
| Progressive disease | 1 | 3.3% |
| Post operative pathological assessment | | |
| Complete response | 10 | 33.3% |
| Partial response | 18 | 60% |



Response of NACT and Receptor status:

| Receptor status | COMPLETE RESPONSE | PARTIAL RESPONSE | STABLE | PROGRESSIVE |
|--------------------------------------|-------------------|------------------|--------|-------------|
| Triple negative | 9 | 10 | 1 | 1 |
| Her2neu NEGATIVE with EITHER ER/PR + | 1 | 2 | | |
| TRIPLE POSITIVE | 0 | 1 | | |
| HER2NEU POSITIVE WITH EITHER ER/PR + | 2 | 2 | | |
| HER2NEU POSITIVE WITH BOTH ER/PR - | 1 | 0 | | |



The p-value is 0.922 (not statistically significant)

Surgery: Breast conserving surgery was possible in 23 cases (76.7%) out of which only 2 patient opted for BCS, whereas 28 patients (64.9%) underwent modified radical mastectomy with axillary dissection. Most of the patients (78%) underwent axillary dissection up to level II. At a median follow-up period of 12 months 1 patient developed locoregional recurrence.

DISCUSSION

- The median age of presentation in our study was 46 years, which aligns with the studies by Raina et al. and Min et al. that reported it to be 47 and 49 years, respectively^(1,2).
- The lower proportion of premenopausal women (20%) observed in our study may be influenced by regional factors such as limited breast cancer screening, later presentation, and differing health-seeking behaviors, as previously reported by Yadav et al. and Chen et al.^(3,4).
- A notable finding in our study was the predominance of T2 stage tumors (60%), differing from historical data by Agarwal et al., where T3/T4 tumors were more common in LABC⁽⁵⁾.
- In our study, 76.6% patients presented with nodal status, N1, 10% with N2, and 6.6% with N3 disease, which aligns with the experience reported by Boughey et al⁽⁶⁾.
- We observed a high overall response rate of 93.3%, with 43.3% achieving a complete clinical response (CR) and 50% a partial response (PR). These findings are in accordance with existing literature by Kaufman M et al. and Von Minckwitz G et al. who reported response rates of 70% and 90% respectively.^(7,8)
- Furthermore, the low stable disease (6.6%) and absence of progressive disease in our study are consistent with previous studies by Cortazar et al. and Boughey et al., where stable or progressive disease occurred in less than 10% of patients^(6,9).
- Our study demonstrates high clinical response rates to NACT, with 100% by HER2-positive and 90.4% by triple-negative breast cancer (TNBC). These findings are consistent with Gianni et al., who reported high response rates in HER2-positive tumors, and Liedtke et al., who demonstrated higher chemosensitivity in TNBC^(10,11). The lack of statistical significance in our study is likely due to small sample size, as larger studies like that by von Minckwitz et al. have confirmed molecular subtype as a strong predictor of NACT response⁽⁸⁾.
- The principal limitations of this study include the small sample size, particularly for subgroup comparisons by receptor status.
- The median follow-up of 12 months restricts conclusions on long-term disease-free or overall survival.

CONCLUSION

NACT achieved a high overall response rate, facilitating tumor downstaging, improving operability, and enabling breast-conserving surgery eligibility in a substantial proportion of patients. While receptor status did not show a statistically significant association with treatment response, triple-negative and HER2-positive subtypes exhibited high chemosensitivity.

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