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A retrospective study of outcome of neoadjuvant chemotherapy in patients with locally advanced breast carcinoma at tertiary care hospital in South Gujarat

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Abstract

Background: Locally advanced breast carcinoma (LABC) constitutes a significant proportion of breast cancer cases in developing countries. Neoadjuvant chemotherapy (NACT) plays a crucial role in tumor downstaging and improving surgical outcomes. This study aimed to evaluate the response and outcomes of NACT in patients with LABC at a tertiary care hospital in South Gujarat. ***Material and Methods***: A retrospective observational study was conducted on 50 patients with LABC between October 2024 and November 2025. Patients were selected based on predefined inclusion and exclusion criteria. All patients underwent clinical, radiological, and pathological evaluation followed by NACT using standard chemotherapy regimens. Response to treatment and adverse effects were recorded, and all patients subsequently underwent surgery. ***Results***: The majority of patients were aged 35–54 years (58%) and postmenopausal (58%). Most patients had T3 tumors (54%) with nodal involvement predominantly at N1 stage (54%), and Stage IIIA disease (54%). Luminal A subtype was most common (36%), followed by Luminal B (24%), while HER2-enriched and triple-negative subtypes each accounted for 20%. Following NACT, partial response was observed in 80% of patients, complete response in 14%, and disease progression in 6%. The most frequent adverse effect was nausea and vomiting (86%), followed by alopecia (40%) and loss of appetite (38%). ***Conclusion***: NACT is an effective modality in the management of LABC, with a high rate of tumor response and acceptable toxicity, facilitating improved surgical outcomes.

Keywords: Locally advanced breast carcinoma, neoadjuvant chemotherapy, treatment response, receptor status, adverse effects.

INTRODUCTION

Breast carcinoma remains the most frequently diagnosed malignancy among women worldwide and represents a major public health concern, particularly in developing countries where patients often present at advanced stages [1]. In India, a substantial proportion of breast cancer cases are diagnosed as locally advanced breast carcinoma (LABC), accounting for approximately 30–50% of all presentations, which significantly impacts treatment outcomes and survival [2].
LABC is characterized by large primary tumors, involvement of skin or chest wall, and/or extensive regional lymph node metastasis, typically corresponding to Stage IIB–IIIC disease according to the American Joint Committee on Cancer (AJCC) classification [3]. These tumors are often not amenable to upfront surgical resection due to their extent and require multimodality management.

Neoadjuvant chemotherapy (NACT) has emerged as a cornerstone in the management of LABC. It is administered prior to definitive surgery with the primary objectives of tumor downstaging, improving operability, and increasing the likelihood of breast-conserving procedures [4]. Several studies have demonstrated that NACT offers survival outcomes comparable to adjuvant chemotherapy while providing the added advantage of assessing tumor responsiveness in vivo [5]. Furthermore, response to NACT, particularly achieving pathological complete response (pCR), has been associated with improved long-term outcomes and survival, especially in aggressive molecular subtypes such as HER2-positive and triple-negative breast cancers [6]. However, variability in response rates and treatment-related toxicities remains a challenge, necessitating further evaluation in different clinical settings.

Given the high burden of LABC and the evolving role of NACT, this study was undertaken to assess the treatment response, clinicopathological characteristics, and adverse effects associated with NACT in patients with LABC at a tertiary care center in South Gujarat.

MATERIALS AND METHODS

This retrospective observational study was conducted at a tertiary care hospital in South Gujarat after obtaining approval from the Institutional Ethics Committee. A total of 50 patients diagnosed with LABC were included. Cases were selected from admitted (indoor) patients based on predefined inclusion and exclusion criteria.

Inclusion Criteria: Patients of any age presenting with breast carcinoma fulfilling criteria for locally advanced disease were included. These comprised individuals with:

- Large primary tumor measuring >5 cm (T3)
- Chest wall involvement (T4a)
- Skin involvement including ulceration, peau d'orange, or satellite nodules (T4b)
- Inflammatory carcinoma (T4d)
- Fixed axillary lymph nodes (N2a)
- Clinically evident internal mammary lymph nodes (N2b)
- Periclavicular lymph node involvement (N3)

These clinical features corresponded to Stage IIB, Stage IIIA, and Stage IIIB according to the American Joint Committee on Cancer (AJCC) staging system.

Exclusion Criteria

- Patients with early-stage breast carcinoma (T0, T1, T2 with N0; and tumors <2 cm with N1 corresponding to Stage I and IIA)
- Patients clinically diagnosed as LABC but found to have distant metastases on further evaluation
- Patients presenting with local recurrence or subsequent development of distant metastases at initial evaluation.

Data Collection and Diagnostic Workup: After obtaining informed written consent from patients and their relatives, all enrolled patients underwent detailed clinical evaluation. Radiological investigations included mammography and/or ultrasonography. Histopathological confirmation was obtained using core needle biopsy or fine needle aspiration cytology, as per clinical discretion.

Diagnosis was established using the triple assessment approach, incorporating clinical examination, imaging, and pathological evaluation. Additional investigations such as two-dimensional echocardiography and bone scan were performed whenever feasible to assess cardiac status and exclude distant metastasis prior to initiation of chemotherapy.

Treatment Protocol: All patients received NACT. The chemotherapy regimen was selected based on clinical judgment and patient factors. The commonly used regimens included:

- **FAC regimen:**

5-fluorouracil (600 mg/m², intravenous, day 1),
Adriamycin (50 mg/m², intravenous, day 1),
Cyclophosphamide (600 mg/m², intravenous, day 1)

- **AC followed by T regimen:**

Adriamycin (60 mg/m², intravenous, day 1),
Cyclophosphamide (600 mg/m², intravenous, day 1),
followed by Paclitaxel (175 mg/m², intravenous, day 1)

- **CMF regimen:**

Cyclophosphamide (600 mg/m², intravenous, day 1),
Methotrexate (40 mg/m², intravenous, day 1),
5-fluorouracil (600 mg/m², intravenous, day 1)

Chemotherapy was provided free of cost through the hospital cancer care center. Patients received a minimum of 3–4 cycles of NACT, and response was assessed clinically by the treating oncosurgeon.

Outcome Assessment: Response to chemotherapy and treatment-related adverse effects were documented during the treatment period using structured study proformas. Following completion of NACT, patients underwent modified radical mastectomy. The study outcomes were analyzed based on the collected clinical, pathological, and treatment response data.

RESULTS

A total of 50 patients diagnosed with LABC were included in the study. The majority of patients belonged to the age group of 35–54 years (58%), followed by those aged >55 years (30%), while only 12% were between 25–34 years, indicating a predominance of middle-aged and older patients in the study population (Table 1).

With respect to body surface area (BSA), most patients were distributed in the range of 1.51–1.60 m² (32%), followed by 1.31–1.40 m² (30%). Patients with BSA between 1.41–1.50 m² constituted 20%, while 18% had BSA >1.60 m² (Table 2).

Assessment of gonadal status revealed that 58% of patients were postmenopausal, whereas 42% were premenopausal, suggesting a higher burden of disease among postmenopausal women (Table 3).

Tumor staging showed that 54% of patients presented with T3 disease, while 46% had T4 tumors. None of the patients were categorized as N0, whereas nodal involvement was most commonly N1 (54%), followed by N2 (30%) and N3 (16%). Based on overall staging, 54% of patients were classified as Stage IIIA, 30% as Stage IIIB, and 16% as Stage IIIC, indicating that the majority of cases were in advanced stages at presentation (Table 4).

Regarding receptor status, Luminal A subtype was the most prevalent (36%), followed by Luminal B (24%). HER2-enriched and triple-negative subtypes each accounted for 20% of cases, demonstrating a heterogeneous distribution of molecular subtypes within the study population (Table 5).

Evaluation of response to NACT showed that a partial response was achieved in the majority of patients (80%), while complete response was observed in 14% of cases. Progressive disease was noted in 6% of patients, indicating an overall favorable response to chemotherapy in most patients (Table 6).

The most commonly observed adverse effect of chemotherapy was nausea and vomiting (86%), followed by alopecia (40%) and loss of appetite (38%). Other side effects included mucositis (18%), neutropenia (14%), and headache (14%), reflecting the expected toxicity profile associated with chemotherapy regimens (Table 7).

Table 1: Age Distribution of Patients with LABC (n = 50)

Age	No.	%
25-34	6	12
35-54	29	58
>55	15	30

Table 2: Distribution of Patients According to Body Surface Area (BSA) (n = 50)

BSA	No.	%
1.31-1.40	15	30
1.41-1.50	10	20
1.51-160	16	32
>1.60	9	18

Table 3: Distribution of Patients Based on Gonadal Status (Premenopausal vs Postmenopausal) (n = 50)

	No.	%
Premenopausal	21	42
Postmenopausal	29	58

Table 4: TNM Classification and Clinical Staging of Patients with LABC (n = 50)

Tumour Staging	No.	%
T3	27	54
T4	23	46
Nodal Staging	**No.**	**%**
N0	0	0
N1	27	54
N2	15	30
N3	08	16

Stage	No.	%
IIIA	27	54
IIIB	15	30
IIIC	08	16

Table 5: Distribution of Patients According to Hormone Receptor and HER2 Status (n = 50)

Receptor status	No.	%
Luminal A (ER+ve PR +ve Her2 –ve)	18	36
Luminal B (ER+,PR+,HER2+)	12	24
Her2+ Enriched (ER-ve PR -ve Her2 +ve)	10	20
Triple negative	10	20

Table 6: Response to NACT in Study Population (n = 50)

Response to chemotherapy	Number	%
Complete Response	7	14
Partial Response	40	80
Progressive disease	3	6

Table 7: Adverse Effects Observed Following Chemotherapy (n = 50)

	Number	%
Nausea/Vomiting	43	86
Headache	07	14
Alopecia	20	40
Loss of Appetite	19	38
Neutropenia	07	14
Mucositis	09	18

DISCUSSION

The present study evaluated the clinical profile, response to NACT, and treatment-related toxicities in patients with LABC. The findings demonstrate that the majority of patients achieved a favorable response to NACT, with 80% showing partial response and 14% achieving complete response. These results are comparable with previous studies reporting overall response rates ranging from 70% to 90% in LABC patients treated with NACT [7].

In the current study, most patients presented in the 35–54-year age group and at advanced clinical stages, reflecting the trend seen in developing countries where delayed presentation is common. Similar observations have been reported in Indian studies, where a large proportion of patients present with advanced disease requiring multimodal management [8]. Tumor staging in this study showed a predominance of T3 and node-positive disease, consistent with the typical presentation of LABC. Nodal involvement, particularly N1 and N2 disease, has been shown to significantly influence prognosis and treatment outcomes [9]. The high proportion of Stage IIIA cases in this study aligns with previous reports indicating that this stage constitutes the bulk of LABC presentations.

Regarding molecular subtypes, Luminal A was the most common subtype observed, followed by Luminal B, HER2-enriched, and triple-negative tumors. Literature suggests that response to NACT varies significantly with molecular subtype, with HER2-positive and triple-negative cancers demonstrating higher rates of pathological complete response, whereas luminal tumors tend to show relatively lower responsiveness [10].

The response rates observed in this study are in concordance with existing evidence indicating that NACT is effective in downstaging tumors and improving operability. Importantly, pathological response has been identified as a key prognostic factor, with better survival outcomes associated with higher response rates [11]. Large pooled analyses have demonstrated that achieving a complete response is strongly correlated with improved disease-free and overall survival [12].

Adverse effects observed in the present study, including nausea, vomiting, alopecia, and neutropenia, were consistent with the known toxicity profile of commonly used chemotherapy regimens. Similar toxicity patterns have been widely reported, with gastrointestinal symptoms and hematological toxicities being the most frequent complications of anthracycline- and taxane-based regimens [13]. Despite these side effects, treatment was generally well tolerated, and completion of planned chemotherapy cycles was feasible in most patients.

The study findings further support the established role of NACT as an effective therapeutic strategy in LABC, providing tumor downstaging without compromising survival outcomes. Evidence from randomized trials indicates that neoadjuvant and adjuvant chemotherapy yield comparable survival outcomes, reinforcing the utility of preoperative systemic therapy in appropriate patients [14].

CONCLUSION

NACT in patients with LABC demonstrated a favorable therapeutic response, with the majority of patients achieving partial or complete tumor regression, thereby facilitating surgical management. The study population predominantly comprised middle-aged and postmenopausal women presenting at advanced stages, underscoring the need for earlier detection. The toxicity profile observed was consistent with standard chemotherapy regimens and was generally manageable. Overall, NACT remains an effective and practical approach in downstaging tumors and improving operability in locally advanced breast carcinoma, particularly in resource-limited tertiary care settings.

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