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Original Article

Impact of Neoadjuvant Chemotherapy on Tumor and Nodal Response in Breast Cancer-An Observational Study

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ABSTRACT

Introduction: Breast cancer is common in India, with variable responses to Neoadjuvant Chemotherapy (NACT), which is essential for tumor downstaging, breast conservation, and prognostic assessment. This study evaluated the effectiveness of NACT in reducing lymph node positivity in breast cancer patients. **Materials and Methods:** An ambispective observational study was conducted over six months at a tertiary care oncology center, including 70 adult female breast cancer patients who received NACT followed by surgery. Clinical, demographic, tumor, and treatment data were collected from medical records. Tumor staging followed AJCC TNM criteria, and treatment response was assessed clinically and pathologically. Statistical analysis evaluated associations with pathological complete response, with $p < 0.05$ considered significant. **Results:** Among 70 breast cancer patients, 65.7% were aged over 50 years and approximately 80% were postmenopausal, with most presenting at stage II (52.8%) or stage III (40.0%). Overall response to neoadjuvant chemotherapy was observed in 68.6% of patients, including a pathological Complete Response rate (pCR) of 28.6%. Higher pCR rates were noted in HR–/HER2+ and triple-negative subtypes. Tumor size ≤2 cm ($p < 0.001$) and clinical nodal stage ($p = 0.03$) were significant predictors of response, while grade III toxicities were low and comparable across regimens. **Conclusion:** This study demonstrates that NACT demonstrated pCR rates comparable to international data, especially in HER2-positive and triple-negative breast cancer. Treatment response was primarily influenced by tumor biology and size rather than demographic factors, and limited breast conservation highlights the importance of early detection and supportive care.

Keywords: Breast cancer, Neoadjuvant chemotherapy, Pathological complete response, TNBC, HER2, AJCC.

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INTRODUCTION

Breast Cancer (BC) is the most commonly diagnosed malignancy among women worldwide and accounts for nearly 13% of cancer-related deaths, approximately 7.6 million annually. Globally, BC incidence ranges from 12 to 31 per 100,000 women and continues to rise due to urbanization, unhealthy lifestyles, poor awareness, and limited screening (Dodiya *et al.*, 2015). In India, delayed diagnosis is common, resulting in a high burden of Locally Advanced Breast Cancer (LABC), which constitutes 30-60% of cases compared with 10-20% in Western countries (Choudhary *et al.*, 2021). The assessment relies on accurate diagnostic evaluation, staging, and prognostic stratification, with key emphasis on Hormone Receptors (HR), i.e. Estrogen Receptor (ER), Progesterone Receptor (PR) and Human Epidermal Growth Factor Receptor-2 (HER2) status, which determine tumor behaviour. The Nottingham Prognostic Index is used to assess tumor severity, while staging is based on the American Joint Committee on Cancer (AJCC) TNM classification (Yadav *et al.*, 2025; Simos *et al.*, 2015). These parameters collectively aid in predicting disease progression and clinical outcomes. Breast cancer has a multifactorial aetiology, influenced by hormonal, genetic, and lifestyle factors such as early menarche, late menopause, family history, alcohol intake, and obesity (Yadav *et al.*, 2025; Simos *et al.*, 2015; Iyengar *et al.*, 2015; Munsell *et al.*, 2014; Key *et al.*, 2001). These factors affect not only the risk of developing breast cancer but may also influence response to chemotherapy, with varying complete response rates reported across different patient and tumor profiles (Naaman *et al.*, 2022; Chavez-MacGregor *et al.*, 2016; Liedtke *et al.*, 2008).

The main treatment approaches used in breast cancer including surgery, radiotherapy, hormonal therapy, immunotherapy, precision medicine, and chemotherapy, with therapeutic decisions guided by patient- and tumor-related factors (Yadav *et al.*, 2025). Chemotherapy may be delivered in the neoadjuvant, adjuvant, or palliative setting based on disease

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stage and treatment goals. Neoadjuvant Chemotherapy (NACT), introduced in the 1980s, has become an integral part of breast cancer care and is increasingly used even in early-stage disease. Common NACT regimens include anthracycline-based combinations, taxane-based regimens, anthracycline-taxane combinations, and HER2-targeted regimens for HER2-positive disease. Administered prior to surgery, NACT enables tumor downstaging, improves operability, enhances the feasibility of breast-conserving surgery, and allows evaluation of treatment response. Evidence from clinical trials indicates that NACT offers overall and disease-free survival outcomes comparable to adjuvant chemotherapy, while significantly increasing rates of breast conservation (Guarneri *et al*., 2006; Wolmark *et al*., 2001; Woeste *et al*., 2021).

Achieving pathological Complete Response (pCR) after NACT has emerged as a key surrogate indicator of favourable prognosis in breast cancer, particularly among biologically aggressive subtypes. Recent advances in systemic therapy have substantially improved pathological complete response rates in HER2-positive and Triple-Negative Breast Cancer (TNBC), while hormone receptor-positive/HER2-negative tumors continue to demonstrate comparatively lower response rates (Petruolo *et al*., 2021). Despite these treatment advances, about 20-30% of eligible patients still choose modified radical mastectomy, mainly due to genetic risk factors, concerns about cosmetic outcomes, and fear of cancer recurrence (Christian *et al*., 2020). While NACT offers markedly oncologic benefits, it is frequently associated with adverse drug reactions that may impact quality of life, perioperative outcomes, and treatment adherence. Effective supportive care and careful timing of surgery ideally within 3 to 8 weeks following NACT are essential to optimize outcomes and minimize complications (Cullinane *et al*., 2021; American Society of Breast Surgeons, 2023; Chopra *et al*., 2016; Tu *et al*., 2024; Tajani *et al*., 2024).

In India, many breast cancer patients present with locally advanced disease due to delayed diagnosis and uneven access to healthcare. Although NACT is commonly used, real-world data on its effectiveness, safety, and treatment-related adverse events are limited. The impact of patient and tumor factors such as body mass index, tumor grade, TNM stage, and molecular subtype on treatment response and surgical outcomes is also not well understood in the Indian setting. Therefore, generating real-world observational data is essential to improve treatment decisions and patient care.

The present study aims to assess the real-world effectiveness and safety of NACT in patients with locally advanced breast cancer, with emphasis on lymph node downstaging, tumor response and pathological outcomes, subtype-specific responses, and the impact of treatment-related adverse drug reactions on therapeutic outcomes.

MATERIALS AND METHODS

An ambispective observational study was conducted at the Oncology Department at a tertiary care centre, over a period of six months. The study included 70 female patients aged ≥18 years with histologically confirmed breast cancer who received NACT followed by surgery. Patients who underwent radiotherapy or adjuvant chemotherapy, presented with recurrent or metastatic disease, or were pregnant or lactating were excluded.

The ambispective design involved both retrospective and prospective data were collected from medical records and patient follow-up case sheet during the study period, without introducing any additional investigations, interventions or modifications to existing treatment regimens. Clinical and demographic details, including age, menopausal status, clinical stage, tumor grade, Body Mass Index (BMI), and receptor status, were collected from medical records using a structured data collection form. BMI was categorized according to World Health Organization criteria. Tumor characteristics including ER, PR, HER2, and Ki-67 status were obtained from Immunohistochemistry (IHC) reports. Bilateral mammography findings were recorded from patient case sheets.

Tumor staging before and after NACT was assessed using the TNM classification based on AJCC guidelines and was considered as clinical assessment criteria for tumor response. The type of NACT received, such as sequential anthracycline and taxanebased regimens in HER2negative tumors, and docetaxel, carboplatin, and Trastuzumab (TCH) regimens in HER2positive tumors were obtained from the clinical case records and medical records department. Treatment response was assessed clinically after each chemotherapy cycle and confirmed using post-NACT biopsy reports, with pCR recorded. The study was conducted according to the ethical guidelines established by the Declaration of Helsinki and other guidelines like Good Clinical Practice Guidelines.

Statistical Analysis

Sample size estimation considered statistical power and evidence from previous studies; using Cochran's formula, 70 patients were deemed adequate. Associations between baseline variables and pCR were analysed using Chi-square or Fisher's exact test, followed by univariate logistic regression. A p-value <0.05 was considered statistically significant.

RESULTS

A total of 70 patients with breast cancer were enrolled in the study. The majority were aged >50 years (46, 65.7%), demonstrating a predominance of older individuals. Most participants were postmenopausal, accounting for approximately 80% of the study population and a considerable proportion were overweight or obese. Tumors were more commonly located in the left breast.

Table 1: Characteristics of the study participants (N=70).

Patient characteristics	Number of patients N (%)
Age (years)	
≤50	24(34.2)
>50	46(65.7)
Menopausal status	
Premenopausal	14(20.0)
Postmenopausal	56(80.0)
BMI	
Under/Normal	24(34.2)
Overweight	28(40.0)
Obese	18(25.7)
KI-67%	
<20%	12(17.1)
≥20%	58(82.8)
Laterality of tumor	
Right	28(40.0)
Left	42(60.0)
Tumor size area	
≤2	30(42.8)
2-5	14(20.0)
>5	26(37.1)
Clinical Nodal Stage	
N0	14(20.0)
N1	41(58.5)
N2	13(18.5)
N3	02(2.8)
TNM Staging (AJCC)	
I	02(2.8)
II	37(52.8)
III	28(40.0)
IV	03(4.2)
Receptor status	
HR+ and HER2 -	27(38.5)
HR+ and HER2+	13(18.5)
HR- and HER2+	16(22.8)
TNBC	14(20.0)
LV involvement	
Present	48(68.5)
Absent	22(31.4)
NACT regimens	
Anthracycline+ Taxane	42(60.0)
TCH	28(40.0)
Surgery	
MRM	61(87.1)
BCS	09(12.8)

BMI: Body mass index, TNM: Tumor, Lymph node and Metastasis, AJCC: American joint committee on cancer, HR: Hormone receptor, HER2: Human epidermal growth factor receptor 2, TNBC: Triple-negative breast cancer, LV: Lymphovascular Involvement, NACT: Neoadjuvant chemotherapy, TCH: Docetaxel, carboplatin, and trastuzumab, AC-T: Anthracycline+ Taxane, MRM: Modified radical mastectomy, BCS: Breast conservative surgery.

In terms of size, 42.8% of patients had tumors ≤2 cm, while 37.1% presented with tumors >5 cm. Nodal involvement was frequent, with N1 disease being the most common (58.5%). The majority were classified as Stage II (52.8%) or Stage III (40.0%) at diagnosis. The predominant molecular subtype was hormone receptor-positive and HER2-negative (38.5%). Lymphovascular invasion was frequently observed (68.5%). Most patients received anthracycline plus taxane-based neoadjuvant chemotherapy (60%), and modified radical mastectomy was the most common surgery performed (87.1%) as shown in Table 1.

In the current study, out of the 70 patients the largest group, comprising 42.85% (30 patients), exhibited a partial response characterized by nodal downstaging. Complete response, defined as total regression of nodal disease to ypN0, was achieved by 28.57% (20 patients). Meanwhile, 17.14% (12 patients) showed no response with no notable improvement in nodal status, and 11.42% (8 patients) experienced disease progression as shown in Table 2, demonstrated by worsening nodal involvement after treatments.

In the present study, among 70 breast cancer patients receiving NACT, an overall response (pCR + cPR) was observed in 48 patients. The highest pCR rates were noted in HR-/$HER2^{+}$ and TNBC subtypes. TCH-based regimens demonstrated better responses in HER2-positive tumors, whereas AC-T based regimens showed favourable responses in TNBC. $HR^{+}/HER2^{-}$ tumors exhibited comparatively lower pCR rates but a higher proportion of partial responses as illustrated in Table 3.

To assess the association between clinicopathological and treatment variables and response outcomes to NACT, the Chi-square test was applied to the data presented in Table 4, and corresponding p-values were calculated. Chi-square values were compared with the degrees of freedom using the Chi-square distribution table (right-tailed probabilities). A significance level of 0.05 was considered as demonstrated in Table 4. On analysis, tumor size showed a statistically significant association with

response outcome ($p < 0.01$), and a significant association was also observed with clinical nodal stage ($p = 0.03$). No significant association was found between treatment response and other variables, including age, menopausal status, BMI, tumor laterality, TNM stage, receptor status, lymphovascular invasion, NACT regimen, and type of surgery ($p > 0.05$).

Univariate analysis revealed that tumor size ≤2 cm was a strong predictor of achieving pCR, with a statistically significant association ($p < 0.001$). Patients with larger tumors (>2 cm) had no observed pCR, highlighting the prognostic importance of tumor burden. Other factors, including younger age, premenopausal status, HER2 positivity, and high Ki-67 index (≥20%), showed higher pCR rates but did not reach statistical significance. BMI (Overweight vs Obese) had no predictive value in this study as shown in Table 5.

The toxicities associated with the respective chemotherapy regimens are summarized in Table 6. Grade-III hematological toxicity was comparable between the two groups, with an incidence of 4.1% in the ACT arm and 3.8% in the TCH arm. Among non-hematological toxicities, gastrointestinal toxicity was the most frequently observed, occurring in 30.6% of patients receiving ACT and 45.3% of those treated with TCH. Musculoskeletal toxicities were also common in both arms, reported in 34.7% of ACT patients and 35.8% of TCH patients. Neurological toxicities were observed exclusively in the ACT arm (10.2%), while dermatological toxicities were more frequent in the TCH arm (15.1%) compared to the ACT arm (6.1%). Respiratory toxicities were noted only among patients receiving ACT (14.3%). No significant difference was observed in the incidence of hematological toxicities between the two treatment groups.

DISCUSSION

Breast cancer is one of the most common malignancies among women globally, with a rising incidence in low- and middle-income countries such as India. NACT plays a crucial role in the management of locally advanced breast cancer by enabling tumor downstaging, increasing the feasibility of breast-conserving surgery, and allowing assessment of treatment response. In the present study, most patients (65.7%) were older than 50 years, indicating an older age profile compared with several Indian studies reporting a median age of 46-48 years (Choudhary *et al.*, 2021; Agarwal *et al.*, 2018; Narendra *et al.*, 2014; Lokesh *et al.*, 2023; Raina *et al.*, 2011). This pattern is closer to Western data, where the median age at diagnosis is approximately 54.5 years (Fisher *et al.*, 1998), possibly reflecting regional differences in disease presentation and healthcare-seeking behaviour. Consistent with earlier reports (Guarneri *et al.*, 2006), age was not an independent predictor of pCR. Additionally, over 80% of patients were postmenopausal, a higher proportion than reported in other Indian studies (Narendra *et al.*, 2014; Raina *et al.*, 2011), suggesting inter-centre variability. Although menopausal status may be associated with tumor subtype distribution, evidence indicates that tumor biology, stage, and grade are stronger determinants of response to NACT than age or menopausal status (Choudhary *et al.*, 2021; Guarneri *et al.*, 2006).

Obesity was common in our study, with 65.7% of patients classified as Overweight or Obese (BMI ≥25). The association between BMI

Table 2: Treatment response to NACT based on pre- and post-nodal staging.

Treatment Response	Pre-Nodal Stage (cN)	Post-Nodal Stage (ypN)	Number of Cases N (%)
Complete Response	cN1	ypN0	16
	cN2	ypN0	4
		Subtotal	20 (28.57%)
Partial Response (Downstage)	cN0	ypN0/1	8
	cN1	ypN0/1/2	18
	cN2	ypN1/2/3	4
		Subtotal	30 (42.85%)
No Response (No Change)	cN0	ypN0	2
	cN1	ypN0/1	7
	cN2	ypN2	3
		Subtotal	12 (17.14%)
Progressive Disease	cN1	ypN1/2	4
	cN2	ypN2/3	2
	cN3	ypN3	2
		Subtotal	8 (11.42%)

cN: Clinical nodal stage; ypN: Post-Neoadjuvant stage.

Table 3: pCR and Overall Response by Receptor Status and Regimens.

Receptor Status	Regimens	pCR (N)	cPR (N)	Overall (pCR + cPR) (N)
HR+ & HER2−	AC-T (N=23)	5	11	16
	TCH (N=4)	0	2	2
Subtotal		5	13	18
HR+ & HER2+	AC-T (N=4)	0	3	3
	TCH (N=9)	3	5	8
Subtotal		3	8	11
HR− & HER2+	AC-T (N=3)	1	0	0
	TCH (N=13)	6	3	9
Subtotal		7	3	9
TNBC	AC-T (N=12)	5	5	10
	TCH (N=2)	0	0	0
Subtotal		5	5	10
Grand Total		20	28	48

HR: Hormone receptor, HER2: Human epidermal growth factor receptor 2, TNBC: Triple-negative breast cancer, TCH: Docetaxel, carboplatin and trastuzumab, AC-T: Anthracycline and taxane-based regimen, pCR: Pathological complete response, cPR: Clinical partial response.

and response to NACT remains inconsistent. While an Indian study reported lower pCR rates among obese women (Lokesh *et al.*, 2023), BMI was not significantly associated with pCR in our analysis, possibly due to the limited sample size. Factors such as body surface area-based dose capping and the predominance of aggressive, high Ki-67 tumors may have influenced outcomes. Given the increasing prevalence of obesity in urban India and its association with poorer long-term outcomes (Lokesh *et al.*, 2023; Kroenke *et al.*, 2006), addressing metabolic health remains an important component of breast cancer management.

Hormone receptor-positive/HER2-negative disease was the most common subtype (38.6%), followed by HER2-positive (22.9%) and triple-negative breast cancer (20%), consistent with previous Indian studies that report higher proportions of biologically aggressive subtypes compared with Western cohorts (Dodiya *et al.*, 2015; Choudhary *et al.*, 2021; Noronha *et al.*, 2020). As triple-negative and HER2-positive tumors are more chemosensitivity, this distribution likely contributed to the overall pCR rate of 28.6% observed in our study despite advanced-stage disease. Consistent with national and global evidence, higher pCR rates were seen in triple-negative and HER2-positive tumors, while hormone receptor-positive/HER2-negative tumors showed the lowest response (Choudhary *et al.*, 2021; Guarneri *et al.*, 2006; Narendra *et al.*, 2014; Noronha *et al.*, 2020). HER2-positive patients achieved superior pCR, particularly with TCH-based regimens, supporting existing literature (Guarneri *et al.*, 2006; Cullinane *et al.*, 2021). Overall, these findings emphasize that tumor biology is a stronger determinant of response to NACT than host-related factors such as BMI or menopausal status (Lokesh *et al.*, 2023; Noronha *et al.*, 2020; Kroenke *et al.*, 2006).

A notable observation was the high proliferative index, with more than 80% of tumors exhibiting a Ki-67 value ≥20%. While high Ki-67 is generally associated with poorer long-term prognosis, it is also linked to increased chemosensitivity and may have contributed to the favorable short-term responses observed. Prior studies have similarly reported higher pCR rates in high-grade, ER-negative, and HER2-positive tumors (Guarneri *et al.*, 2006; Narendra *et al.*, 2014). In addition to the pCR rate, 42.9% of patients achieved a partial response, placing our results within the mid-to-upper range of Indian studies and comparable to international trials reporting pCR rates of 13-26% (Guarneri *et al.*, 2006; Wolmark *et al.*, 2001).

Several clinicopathological and treatment-related factors influence the likelihood of achieving pCR. Smaller tumors

Table 4: Neoadjuvant chemotherapy outcomes using various response measures.

Clinicopathological features and treatment details	Response outcomes N=70				*p* value
	pCR N=20(%)	cPR N=30(%)	cPD N=8(%)	cNR N=12(%)	
Age (years)					
≤50	9(12.8)	10(14.2)	1(1.4)	4(5.7)	0.44
>50	11(15.7)	20(28.5)	7(1.00)	8(11.4)	
Menopausal status					
Premenopausal	5(7.1)	7(10.0)	0(0.0)	2(2.8)	0.46
Postmenopausal	15(21.4)	23(32.8)	8(11.4)	10(14.2)	
BMI					
Under/Normal	8(11.4)	8(11.4)	2(2.8)	6(8.5)	0.75
Overweight	14(20.0)	8(11.4)	3(4.2)	3(4.2)	
Obese	8(11.4)	4(5.7)	3(4.2)	3(4.2)	
Laterality of tumor					
Right	8(11.4)	13(18.5)	0(0.0)	7(10.0)	0.07
Left	12(17.1)	17(24.2)	8(11.4)	5(7.1)	
Tumor size area					
≤2	20(28.5)	9(12.8)	0(0.0)	1(1.4)	<0.01
2-5	0(0.0)	11(15.7)	1(1.4)	2(2.8)	
>5	0(0.0)	10(14.2)	7(10.0)	9(12.8)	
Clinical Nodal Stage					
N0	4(5.7)	8(11.4)	0(0.0)	2(2.8)	0.03
N1	12(17.1)	18(25.7)	4(5.7)	7(10.0)	
N2	4(5.7)	4(5.7)	2(2.8)	3(4.2)	
N3	0(0.0)	0(0.0)	2(2.8)	0(0.0)	
TNM Staging (AJCC)					
I	1(1.4)	1(1.4)	0(0.0)	0(0.0)	0.78
II	11(15.7)	18(25.7)	3(4.2)	5(7.1)	
III	7(10.0)	11(15.7)	4(5.7)	6(8.5)	
IV	1(1.4)	0(0.0)	1(1.4)	1(1.4)	
Receptor status					
HR^+ and $HER2^-$	5(7.1)	13(18.5)	4(5.7)	5(7.1)	0.53
HR^+ and $HER2^+$	3(4.2)	8(11.4)	1(1.4)	1(1.4)	
HR^- and $HER2^+$	7(10.0)	3(4.2)	2(2.8)	4(5.7)	
TNBC	5(7.1)	6(8.5)	1(1.4)	2(2.8)	
LV involvement					
Present	13(18.5)	19(27.1)	7(10.0)	9(12.8)	0.56
Absent	7(10.0)	11(15.7)	1(1.4)	3(4.2)	
NACT regimens					
Anthracycline+ Taxane	11(15.7)	19(27.1)	4(5.7)	8(11.4)	0.82
TCH	9(12.8)	11(15.7)	4(5.7)	4(5.7)	
Surgery					
MRM	16(14.2)	26(22.8)	8(11.4)	11(7.1)	0.51
BCS	4(5.7)	4(5.7)	0(0.0)	1(1.4)	

pCR: Pathological complete response, cPR: Clinical partial response, cNR: Clinical no response, cPD: Clinical progressive disease, AJCC: American joint committee on cancer, HR: Hormone receptor, HER2: Human epidermal growth factor receptor 2, TNBC: Triple-negative breast cancer, TCH: Docetaxel, carboplatin, and trastuzumab, AC-T: Anthracycline+Taxane based regimens.

Table 5: Factors predicting pCR.

Factors predicting pCR	pCR (N)	P-value
Age (years)		
≤50(n=24)	9	0.17
>50 (n=46)	11	
Menopausal status		
Pre (n=14)	5	0.52
Post (n=56)	15	
Receptor Status		
HER2-positive (HER2+) (n=29)	10	0.35
HER2-negative (HER2-) (n=41)	10	
Tumor size area		
≤2cm (n=30)	20	<0.001
>2cm (n=40)	0	
Ki67%		
< 20% (n=12)	2	0.12
≥ 20% (n=58)	23	
BMI		
Overweight (n=28)	14	0.71
Obese (n=18)	8	

and lower nodal burden are consistently associated with better responses (Wolmark *et al.*, 2001; Narendra *et al.*, 2014). In this study, patients with lower clinical nodal involvement (N0-N1) demonstrated higher pCR and partial response rates than those with N2-N3 disease, consistent with international observations (Guarneri *et al.*, 2006; Noronha *et al.*, 2020). TNM stage itself was not significantly associated with response ($p = 0.77$), suggesting that individual tumor and nodal characteristics may be more predictive than overall stage (Wolmark *et al.*, 2001; Woeste *et al.*, 2021; Fisher *et al.*, 1998). Hormone receptor-negative status and completion of planned chemotherapy were also associated with improved outcomes (Choudhary *et al.*, 2021; Narendra *et al.*, 2014). Clinical pharmacists play a supportive role by optimizing dosing, monitoring toxicities, and improving adherence, thereby indirectly contributing to better responses.

After completion of NACT, most patients (87.1%) underwent modified radical mastectomy, while only 12.9% underwent Breast-Conserving Surgery (BCS). This contrasts with Western practice, where NACT is commonly used to facilitate BCS (Woeste *et al.*, 2021; Petruolo *et al.*, 2021; Agarwal *et al.*, 2018). In India, low BCS rates largely reflect advanced stage at presentation, extensive nodal disease, skin or chest wall involvement, patient preference, fear of recurrence, and limited access to radiotherapy (Choudhary *et al.*, 2021; Raina *et al.*, 2011; Noronha *et al.*, 2020). Treatment-related toxicity was generally manageable. Grade III

Table 6: Safety details.

System/Organ toxicity	ACT arm N = 49	TCH arm N =53
Gastrointestinal	15	24
Hematological	2	2
Musculoskeletal	17	19
Neurological	5	-
Dermatological	3	8
Respiratory	7	-

hematological toxicity was uncommon and comparable between ACT and TCH regimens (4.1% vs. 3.8%), consistent with previous reports (Dodiya *et al.*, 2015; Raina *et al.*, 2011). Gastrointestinal toxicity was the most frequent non-hematological adverse effect and occurred more often with TCH, as reported earlier with taxane- and platinum-based regimens (Lokesh *et al.*, 2023; Raina *et al.*, 2011). Musculoskeletal toxicities were similar across regimens, neurological toxicity was observed only with ACT, while dermatological toxicity was more frequent with TCH, supporting known regimen-specific toxicity profiles (Dodiya *et al.*, 2015; Lokesh *et al.*, 2023; Raina *et al.*, 2011).

Limitation of the Study

Every study has its own limitations, and this observational study is no different. Our study has a few limitations as it was an ambispective analysis and may have suffered from selection bias. As it was conducted at a single center, the findings may have limited generalizability. The relatively short study duration of 6 months and the small sample size of 70 patients may have restricted the depth of analysis. The retrospective component relied on medical records with potential missing data and day-care-based treatment limited post-discharge follow-up and toxicity. Additionally, unwillingness among some patients to disclose past medical history and occasional language barriers limited effective communication and may have affected the completeness of data collection

CONCLUSION

This study evaluated NACT in 70 Indian women with breast cancer and observed an encouraging pCR rate of 28.6% despite advanced-stage presentation. The highest responses occurred in HER2-positive and triple-negative tumors, confirming that tumor biology and chemosensitivity are the main predictors of response, while demographic factors had minimal impact. Although effective tumor downstaging was achieved, breast-conserving surgery remained uncommon due to late presentation, limited radiotherapy access, and patient and physician preferences. Treatment-related toxicities were generally manageable, enabling most patients to complete planned therapy. Overall, the study demonstrates that with evidence-based protocols and multidisciplinary care, neoadjuvant outcomes in Indian breast

cancer patients can be comparable to international standards, highlighting the importance of early detection and improved access to comprehensive care.

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ABBREVIATIONS

BC: Breast Cancer; **NPI:** Nottingham Prognostic Index; **AJCC:** American Joint Committee on Cancer **TNM:** Tumor, Lymph node and Metastasis; **HER2:** Human Epidermal Growth Factor Receptor 2; **ER:** Estrogen Receptor; **PR:** Progesterone Receptor; **HR:** Hormonal Receptor; **TNBC:** Triple Negative Breast Cancer; **NACT:** Neoadjuvant Chemotherapy; **pCR:** Pathological Complete Response; **cPR:** Clinical Partial Response; **cNR:** Clinical No Response; **cPD:** Clinical Progressive Disease; **TCH:** Docetaxel, carboplatin, and trastuzumab, **AC-T:** Anthracycline+ Taxane based Regimen.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ETHICAL CONSIDERATIONS

This study did not require ethical approval because it was an observational study that did not involve any intervention, treatment or administration of medication, although the study was conducted according to the ethical guidelines established by the Declaration of Helsinki and other guidelines like Good Clinical Practice Guidelines. The research was conducted by observing and analysing existing data, without modifying any treatment plans or affecting the participants' care in any way.

SUMMARY

This ambispective observational study evaluated the effectiveness of neoadjuvant chemotherapy in Indian breast cancer patients. The findings should be interpreted considering the single-centre design, modest sample size, and limited follow-up, which may affect generalizability and long-term outcome assessment. Variations in chemotherapy regimens and routine clinical practices could also influence response outcomes. Nevertheless, the study provides valuable real-world evidence from an Indian tertiary care setting and highlights the need for larger, multicenter studies to further validate these observations and guide optimized neoadjuvant treatment strategies.

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