

CLINICAL AND PROGNOSTIC SIGNIFICANCE OF PATHOLOGICAL COMPLETE RESPONSE FOLLOWING CONTEMPORARY NEOADJUVANT THERAPY IN TRIPLE NEGATIVE BREAST CANCER: A PROSPECTIVE OBSERVATIONAL STUDYAmith M. N.^{1*}, Viola Vinita Dsa¹, Umesh M.², Charan C. S.², Abhilash G. H.³, Hanumanthachar Joshi K.⁴^{1,2}Department of Pharmacy Practice, Sarada Vilas College of Pharmacy, Mysuru.³Consultant Medical and Hemato Oncologist, Bharath Hospitals and Institute of Oncology, Mysuru.⁴Department of Pharmacognosy, Sarada Vilas College of Pharmacy, Mysuru.***Corresponding Author: Amith M. N.**

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ABSTRACT

Background Information: Pathological complete response (pCR) serves as a key prognostic indicator in breast cancer, particularly in triple-negative breast cancer (TNBC). Achievement of pCR following neoadjuvant chemotherapy (NACT) correlates with improved long-term outcomes, including enhanced overall survival (OS) and disease-free survival (DFS). **Objectives:** To evaluate the prognostic significance of pathological complete response (pCR) defined as the absence of residual invasive breast cancer in the breast and axilla following neoadjuvant chemotherapy (NACT) and surgical resection in triple-negative breast cancer (TNBC) patients. **Methods:** This prospective observational study, titled "Clinical and Prognostic Significance of Pathological Complete Response Following Contemporary Neoadjuvant Therapy in Triple- Negative Breast Cancer" was conducted over 6 months in the Medical Oncology Department at Bharath Hospitals and Institute of Oncology, Mysuru. Following written informed consent, eligible TNBC patients undergoing neoadjuvant chemotherapy (NACT) were interviewed to collect clinical and pathological data, including immunohistochemistry reports, tumor grading, AJCC/TNM staging, BI-RADS category, and histopathology, for assessing pathological complete response (pCR); all data were systematically recorded and analyzed descriptively. **Results:** This study enrolled 61 patients diagnosed with triple-negative breast cancer (TNBC). Neoadjuvant chemotherapy regimens included AC + paclitaxel (60.65%), paclitaxel alone (8.19%), and AC alone (31.14%). Pathological complete response (pCR) was achieved in 34.42% of TNBC patients. **Conclusion:** Achieving pathological complete response (pCR) following contemporary neoadjuvant therapy was observed in 34.42% of triple-negative breast cancer (TNBC) patients and correlates with improved long-term outcomes, including enhanced overall survival (OS) and event-free survival (EFS). These findings affirm pCR as a valuable early surrogate endpoint for treatment efficacy and a robust prognostic marker in TNBC.

KEYWORDS: Triple Negative Breast Cancer, Post NACT, pCR, Prognostic Significance.**1. INTRODUCTION**

Breast cancer is a heterogeneous group of malignancies arising from the breast, characterized by uncontrolled proliferation of cancerous cells that divide more rapidly than normal cells and evade immune surveillance and/or apoptotic signals. These tumor cells can disseminate from the primary site to distant organs through the bloodstream or lymphatic system, leading to metastatic

disease.^[1] Breast tumors that are immunohistochemically characterized by the absence of estrogen receptor (ER), progesterone receptor (PR), and HER2 overexpression (and, by definition, lack of HER2 gene amplification on fluorescence in situ hybridization) are classified as triple-negative breast cancer (TNBC) and account for approximately 15% to 20% of all breast carcinomas. Compared with hormone receptor-positive or HER2-

positive disease, TNBC follows a more aggressive clinical course, with earlier age of onset, greater metastatic potential, and poorer clinical outcomes, as reflected by higher relapse rates and lower survival.^[2] Epidemiological studies using cDNA microarrays and immunohistochemical markers have classified breast cancers into five distinct molecular subtypes: Luminal A (ER-positive and/or PR-positive, HER2-negative), Luminal B (ER-positive and/or PR-positive, HER2-positive), HER2-overexpressing (ER-negative, PR-negative, HER2-positive), Basal-like (ER-negative, PR-negative, HER2-negative, with expression of cytokeratin 5/6 and/or epidermal growth factor receptor), and Normal breast-like tumors. Approximately 75% of triple-negative breast cancers express basal markers, leading to the frequent (and often inaccurate) use of “triple-negative” as a surrogate for the basal-like subtype. Triple-negative tumors account for about 10–20% of invasive breast cancers and are associated with a poorer prognosis compared with luminal tumors.^[3] Risk factors for TNBC include breast cancer diagnosis at young age, menarche at young age, high parity, lack of breast feeding, high body mass index and African American ethnicity. The majority of BRCA1 tumours are TNBC.^[4]

Triple-negative breast cancer (TNBC) is a heterogeneous disease that can be further subclassified into six molecular subtypes based on gene expression profiles: immunomodulatory (IM), luminal androgen receptor (LAR), basal-like 1 (BL1), basal-like 2 (BL2), mesenchymal (M), and mesenchymal stem-like (MSL). The BL1 and BL2 subtypes share high expression of genes involved in cell division and cell cycle progression. However, BL1 is additionally characterized by elevated expression of DNA damage response-related genes, including those associated with DNA repair and DNA replication, whereas BL2 shows higher expression of growth factor signaling pathways. The immunomodulatory (IM) subtype exhibits strong expression of genes linked to immune cell processes, including natural killer cell pathways, TH1/TH2 signaling, cytokine signaling, B-cell receptor (BCR) signaling, and antigen processing. The mesenchymal and mesenchymal stem-like subtypes are enriched for genes involved in extracellular receptor interaction, cell motility, and cell differentiation pathways. However, MSL differs notably from the mesenchymal subtype by showing low expression of claudin genes, underscoring the molecular diversity within TNBC.^[5]

Triple-negative breast cancer (TNBC) can be diagnosed using a combination of imaging and immunohistochemistry (IHC). Imaging modalities include mammography, breast ultrasound, and magnetic resonance imaging (MRI). IHC is routinely performed for breast carcinoma subtyping through staining of tumor cells for key biomarkers, including estrogen receptor

(ER), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER2). To enhance the accuracy and consistency of IHC testing for ER, PR, and HER2, the American Society of Clinical Oncology (ASCO) and the College of American Pathologists (CAP) have published comprehensive guidelines, which are periodically updated to improve reliability, reproducibility, and reduce false-positive and false-negative results. According to these recommendations, ER and PR are considered positive if at least 1% of tumor cells show immunoreactivity. HER2-positive cases identified by IHC should be confirmed by fluorescence in situ hybridization (FISH) to minimize diagnostic errors that could affect treatment selection and efficacy.^[5]

Triple-negative breast cancer (TNBC) carries the worst prognosis among the major molecular subtypes of breast cancer. Limited understanding of its underlying biology and the lack of effective targeted therapies mean that cytotoxic chemotherapy remains the mainstay of systemic treatment. Although TNBC is associated with higher mortality compared with luminal-type breast cancers (ER-positive and/or PR-positive, HER2-negative), neoadjuvant chemotherapy (NACT) is more likely to result in a pathological complete response (pCR) in patients with TNBC than in those with luminal tumors. Pathological complete response is an important clinical endpoint, as patients who achieve pCR after surgery have improved survival outcomes, and this survival benefit is particularly pronounced in the more aggressive subtypes, including TNBC and HER2-positive breast cancers.^[6] Anthracyclines (e.g., Doxorubicin/Adriamycin) and Taxanes (e.g., paclitaxel) are commonly used in the treatment of triple-negative breast cancer. Chemotherapy regimens include the AC regimen (doxorubicin plus cyclophosphamide), which inhibits DNA and RNA synthesis and is typically administered in 21-day cycles. Paclitaxel, a microtubule-stabilizing mitotic inhibitor, may be used as part of a sequential neoadjuvant or adjuvant treatment strategy.^[7]

Pathological complete response (pCR) is defined as the absence of all invasive and in situ carcinoma in the breast and in the sampled regional lymph nodes after neoadjuvant therapy, corresponding to ypT0 ypN0 in the American Joint Committee on Cancer (AJCC) staging system. Achieving pCR is considered a strong surrogate predictor of improved long-term survival. Because of this, the U.S. Food and Drug Administration (FDA) recommends using pCR as a primary endpoint in neoadjuvant therapy trials. Patients with more aggressive subtypes—including triple-negative, HER2-positive, hormone receptor-negative, and high-grade hormone receptor-positive/HER2-negative tumors—tend to derive the greatest survival benefit when pCR is attained.^[8]

The core objective of this study is to evaluate the

prognostic relevance of pathological complete response (pCR) in breast cancer by assessing the absence of all invasive tumor in the breast and axillary lymph nodes after completion of neoadjuvant chemotherapy and surgical resection in patients with triple-negative breast cancer.

2. MATERIALS AND METHODOLOGY

2.1 Study Site

This prospective observational study was conducted at Bharath Hospitals & Institute of Oncology, located on Outer Ring Road, Hebbal, Mysuru. The center operates as a comprehensive cancer care facility under the aegis of Sada Sharada Tumor & Research Institute, Mysuru, Karnataka, India. The hospital has an approximate bed capacity of 100 and offers specialized services in medical oncology, radiation oncology, surgical oncology, and paediatric oncology.

2.2 Study Design

The study was designed as a prospective observational study.

2.3 Study Period

Data collection and patient follow-up were carried out over a six-month period from March 2024 to August 2024.

2.4 Department selected for study

The research was conducted in the Department of Medical Oncology, which houses a fully operational outpatient department (OPD). This day-care OPD features 30 beds and typically manages 75–100 patients daily.

2.5 Ethical approval for the study

The study protocol received approval from the Institutional Ethics Committee of Bharath Hospitals & Institute of Oncology, Mysuru. Written informed consent was obtained from all participants prior to enrolment.

2.6 Study Criteria

2.6.1 Inclusion criteria

- Female patients aged 20–70 years.
- Histologically confirmed triple-negative breast cancer (TNBC).
- Receiving neoadjuvant chemotherapy (NACT) followed by surgical resection.
- Eligible for evaluation of pathological complete response (pCR).

2.6.2 Exclusion criteria

- Patients' non-adherent to neoadjuvant chemotherapy (NACT) or follow-up.
- Patients lacking immunohistochemistry (IHC) reports or confirmatory histopathology.

2.7 Study population – sample size

One proportion formula is used for calculating the sample size. It is as follows:

$N = Z^2PQ/d^2$, where

N is the required sample size.

Z is 1.96 for a 95% confidence interval.

P is prevalence (10%).

Q is 1-P.

d2 is the maximum allowable error (5%)

A sample size (study population) of 61 was incorporated for the study.

2.8 Sources of data collection

- **Outpatient Department (OPD) Records:** Patient demographics, clinical symptoms, diagnosis, and treatment plans collected directly during OPD consultations.
- **Hospital Medical Records:** Detailed histories, laboratory results, imaging studies, treatment outcomes, and prior interventions extracted from inpatient and follow-up files.

2.9 Study Procedures

Informed Consent: Institutional ethics committee-approved informed consent forms (ICFs) in English and Kannada were obtained from eligible patients after explaining the study in their preferred regional language (signature or thumb impression).

Data Collection Form: A standardized form captured demographics (e.g., age, gender, weight, address), clinical data (e.g., TNBC diagnosis, TNM staging, BI-RADS category, grading, IHC, FISH, cytology, mammography), and treatment details (e.g., NACT regimens, pre/post-operative therapies, concurrent medications).

Patient Enrollment: Patients meeting inclusion criteria were enrolled during OPD visits post- ICF.

Data Collection: Patients were interviewed in regional languages; data were sourced from OPD/hospital records, with IHC reports, grading, staging, and BI-RADS documented accordingly.

Statistical Analysis: Data were analyzed using SPSS version 20. Descriptive statistics (percentages, means, tables, graphs) and inferential tests (chi-square, t-tests) were applied.

pCR Assessment and Interpretation: Pathological complete response (pCR) was defined per ASCO/CAP guidelines as "no residual carcinoma" (ypT0N0) on histopathology, corroborated by IHC, grading, pathological staging, and BI-RADS.

2.10 Methodology

The methodology of pCR assessment in these subtypes involves clinical, pathological, and treatment criteria.

Triple-Negative Breast Cancer

Triple-negative breast cancer (TNBC) is an aggressive subtype of invasive breast cancer characterized by the absence of estrogen receptor (ER), progesterone receptor

(PR), and human epidermal growth factor receptor 2 (HER2) overexpression and/or gene amplification. In patients with TNBC, neoadjuvant therapy is administered prior to surgery to reduce tumor size, facilitate breast-conserving surgery, and allow early assessment of treatment response.

Neoadjuvant Chemotherapy Regimens Used in our study population, the following neoadjuvant chemotherapy regimens were used:

AC regimen

AC is a commonly used anthracycline-based regimen in breast cancer, where:

A = Adriamycin (doxorubicin) 60 mg/m² IV on Day 1
C = Cyclophosphamide 600 mg/m² IV on Day 1

Each cycle was repeated every 21 days for a total of 4 cycles.

Anthracycline-based regimen

Adriamycin (doxorubicin) 60 mg/m² IV on Day 1, repeated every 21 days.

Taxane-based regimen (weekly paclitaxel)

Paclitaxel 175 mg/m² IV administered as 3-hour infusion every 3 weeks.

Pathological complete response (pCR) is defined as the absence of residual invasive and in situ carcinoma on hematoxylin and eosin evaluation of the entire resected breast specimen and all sampled regional lymph nodes following completion of neoadjuvant systemic therapy, corresponding to ypT0 ypN0 in the current American Joint Committee on Cancer (AJCC) staging system. After receiving neoadjuvant chemotherapy (NACT),

patients in our study showed favorable pCR rates, which are associated with improved overall survival (OS) and disease-free survival (DFS). Post-mastectomy (post-MRM) histopathology reports were reviewed to determine pCR status in patients diagnosed with triple-negative breast cancer.

3. RESULTS

A total of 61 patients from the Medical Oncology Department who met the eligibility criteria were included in the analysis.

3.1 Triple Negative Breast Cancer

Age group of study population in Triple Negative Breast Cancer.

Table 1: Age Group Distribution of the Study Population in Triple-Negative Breast Cancer.

Age (in years)	No. of Patients	Percentage
Pre-Menopausal (30-45)	29	47.54
Menopause (46-55)	19	31.14
Post-Menopausal (56-85)	13	21.31

3.1.1 Age

The mean age of the patients was 50 years. The majority of patients belonged to the 30–45 years age group (n = 29; 47.54%), followed by the 46–55 years age group (n = 19; 31.14%) and the 56–85 years age group (n = 13; 21.31%) among those diagnosed with triple-negative breast cancer. The age-group distribution of the study population is presented in Figure 1.

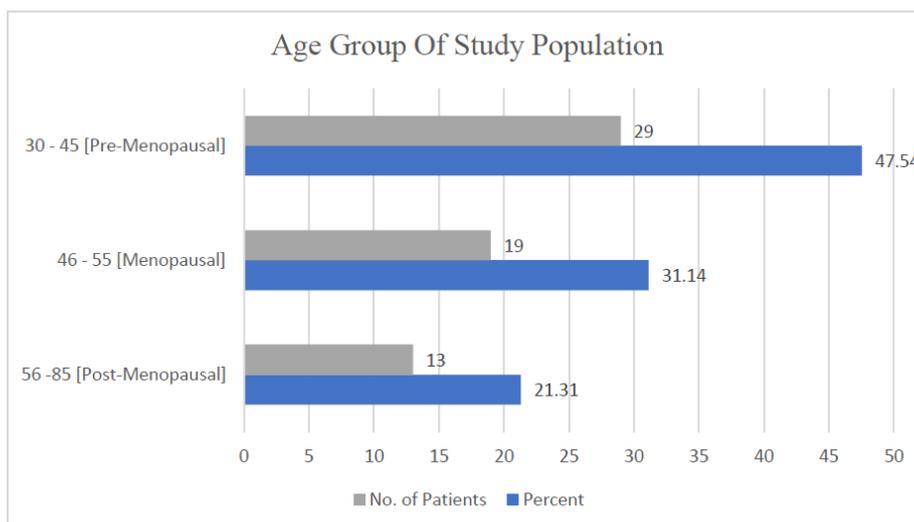


Figure 1: Age-group distribution of the study population in triple-negative breast cancer.

3.1.2 Diagnosis

Table 2: Diagnostic characteristics of patients with triple-negative breast cancer.

Diagnosis	No. of Patients	Percentage
Carcinoma Left Breast	33	54.09
Carcinoma Right Breast	28	45.90

On analysis of the diagnosis in the study population, all 61 patients were diagnosed with triple-negative breast cancer. Tumors were located in the left breast in 33

patients (54.09%) and in the right breast in 28 patients (45.90%). The distribution of tumor laterality in triple-negative breast cancer patients is presented in Figure 2.

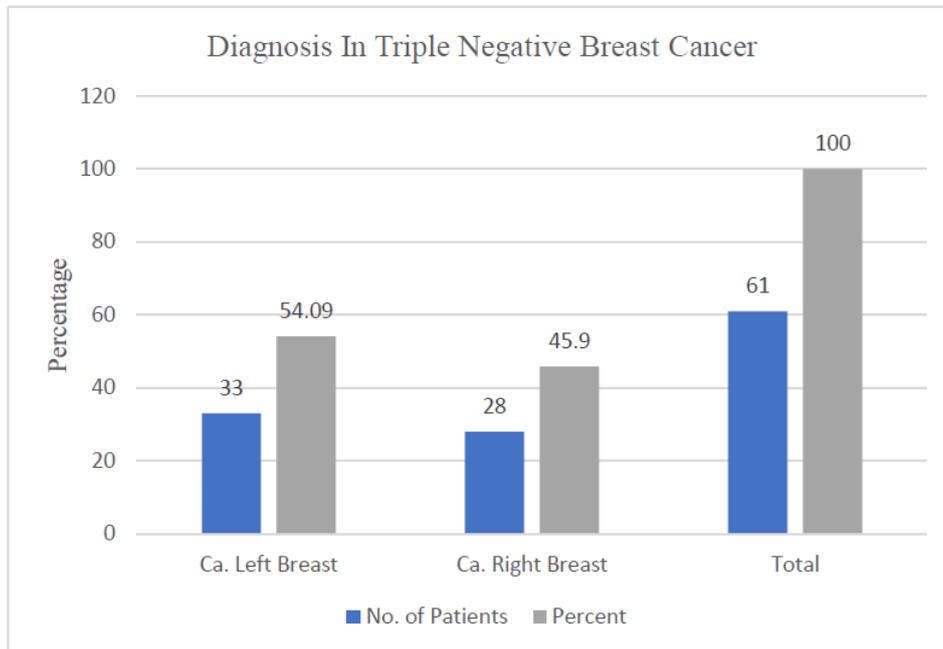


Figure 2: Diagnosis in Triple Negative Breast Cancer.

3.1.3 Histopathology

Table 3: Histopathological characteristics in triple-negative breast cancer.

Histopathology	No. of Patients	Percentage
Invasive Ductal Carcinoma	54	91.80
Infiltrating Ductal Carcinoma	6	9.83

On analysis of the histopathology in the study population, all 61 patients were diagnosed with triple-negative breast cancer. Invasive ductal carcinoma was observed in 54 patients (91.80%), and infiltrating ductal carcinoma was observed in 6 patients (9.83%).

3.1.4 Molecular subtypes – IHC

Table 4: Molecular subtypes in triple-negative breast cancer.

Molecular subtypes	No. of Patients	Percentage
ER: -ve, PgR: -ve, HER2: -ve	61	100.0

On analysis of molecular subtypes by immunohistochemistry in triple-negative breast cancer, all 61 patients (100%) were found to be negative for estrogen receptor (ER), progesterone receptor (PgR), and HER2 receptors (ER-negative, PgR-negative, HER2-negative).

3.1.5 Ki 67 – Proliferation Index

Table 5: Ki-67 proliferation index in triple-negative breast cancer.

Ki 67	No. of Patients	Percentage
<15%	23	37.70
>15%	38	62.29

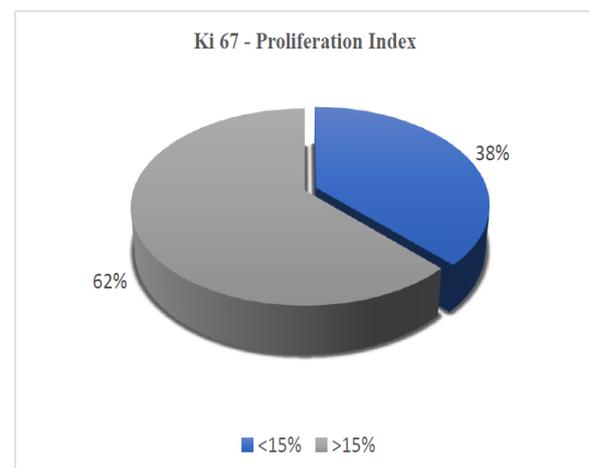


Figure 3: Ki-67 proliferation index in triple-negative breast cancer.

3.1.6 Pathological Staging

The distribution of patients according to pathological tumor (T) and node (N) stage after treatment is summarized in the table below.

- **ypT0N0** (no residual tumor and no lymph node involvement) was the most frequent stage, observed

- in 21 patients (34.42%).
- **pT1** (n = 16 patients; 26.22%) comprised small tumors (T1) with variable lymph node status (N0, N1, N1a, N3a), indicating early-stage disease with limited nodal involvement.
 - **pT2** (n = 17 patients; 27.86%) included moderately larger tumors (T2) with lymph node stages ranging from N0 to N3a, reflecting more extensive local disease that remains potentially treatable.
 - **pT3** (n = 5 patients; 8.19%) represented larger tumors with significant lymph node involvement (N1, N1a, N3a), indicating advanced local tumor burden and substantial regional spread.
 - **pT4** (n = 2 patients; 3.27%) was the least frequent stage, showing the lowest proportion as tumor stage increased.

Further details of pathological staging are presented in Figure 4

Table 6: Pathological staging in triple-negative breast cancer.

Pathological Staging	No. of Patients	Percentage
ypT0N0	21	34.42
pT1 [N0, N1, N1a, N3a]	16	26.22
pT2[N0, N1, N1a, N2, N2a, N3, N3a]	17	27.86
pT3[N1, N1a, N3a]	5	8.19
pT4 [N0, N1, N1a, N2]	2	3.27

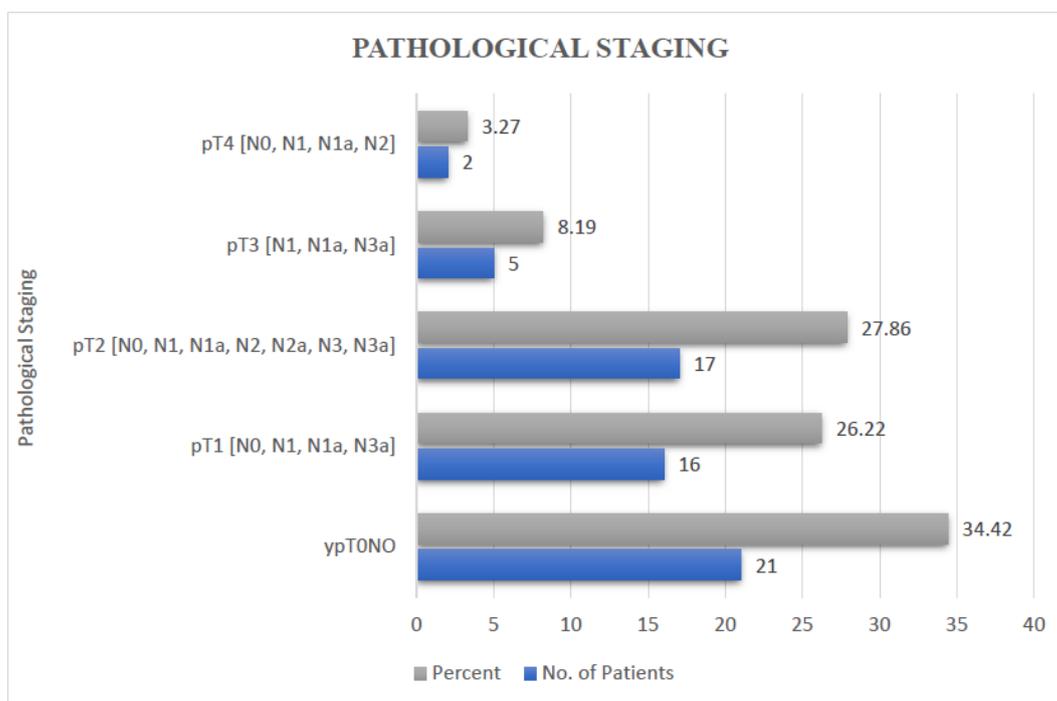


Figure 4: Pathological staging in triple-negative breast cancer.

3.1.7 Surgery

Table 7: Surgery in triple-negative breast cancer.

Surgery	No. of Patients	Percentage
Mastectomy + Axillary Dissection	25	40.98
Breast Conservative Surgery + Axillary dissection	36	59.01

A total of 61 patients underwent one of two surgical procedures: mastectomy with axillary lymph node dissection (n = 25; 40.98%) and breast-conserving

surgery with axillary lymph node dissection (n = 36; 59.01%). The details are presented in Figure 5.

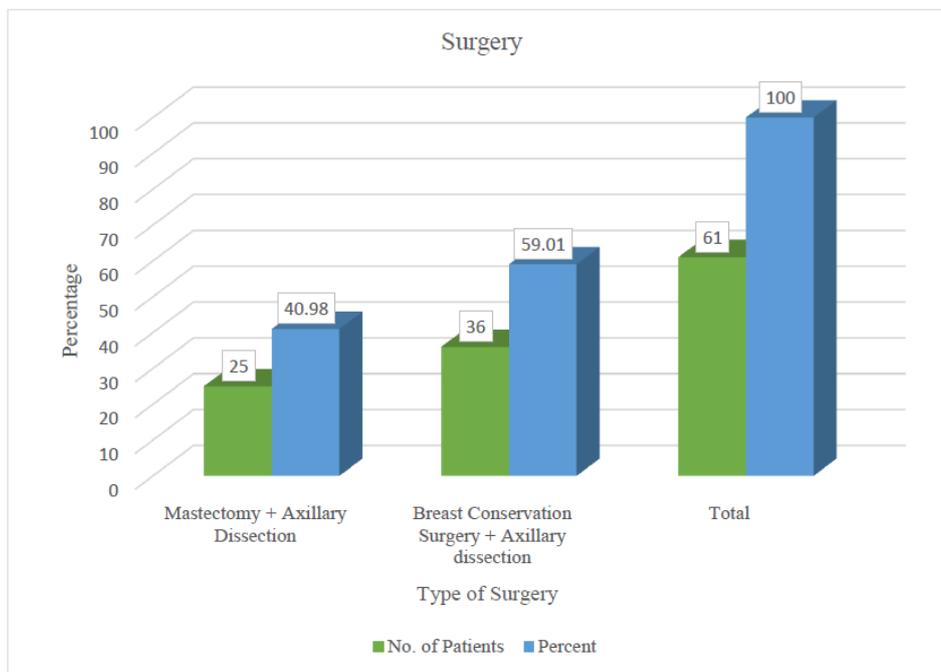


Figure 5: Surgery in triple-negative breast cancer.

3.1.8 Treatment given in triple negative breast cancer
Table 8: Treatment given in triple-negative breast cancer.

Treatment	No. of Patients	Percentage
AC + PACLITAXEL	37	60.65
AC	19	31.14
PACLITAXEL	5	8.19

On analysis of treatment in triple-negative breast cancer patients, the majority received neoadjuvant chemotherapy regimens, with AC + paclitaxel administered in 37 patients (60.65%), paclitaxel alone in 5 patients (8.19%), and the AC regimen in 19 patients (31.14%). The distribution of neoadjuvant chemotherapy regimens is shown in Figure 6.

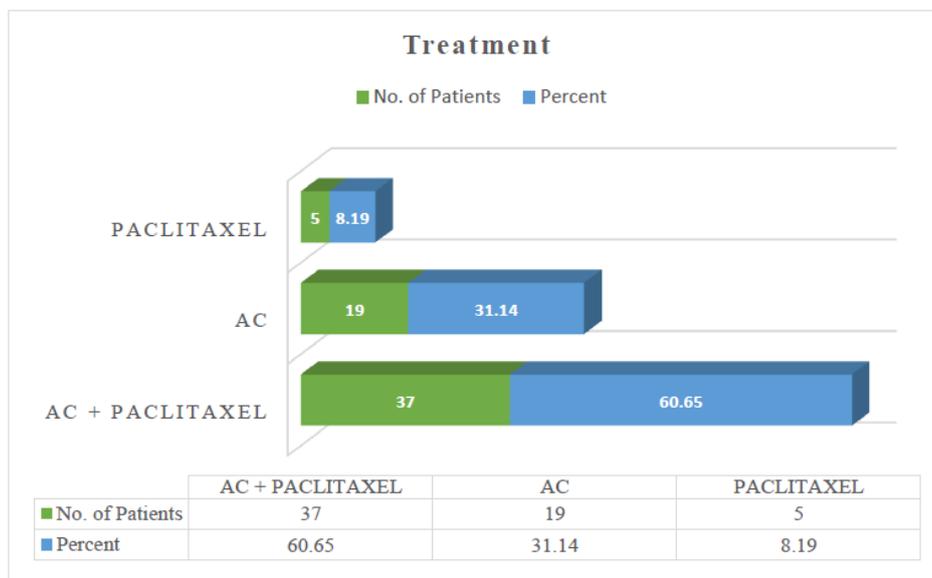


Figure 6: Treatment given in triple-negative breast cancer.

4. DISCUSSION

The present prospective observational study evaluated pathological complete response (pCR) and associated clinicopathological characteristics in 61 patients with triple-negative breast cancer.

4.1 Pathological Complete Response (pCR)

In the present study, the pathological complete response (pCR) rate was 34.42%, which is comparable with previously reported pCR rates of approximately 30–40% following Anthracycline-Taxanes-based neoadjuvant

chemotherapy in triple-negative breast cancer. The NSABP B-27 trial demonstrated improved pathological response with sequential Taxanes administration, and the CALGB 40603 trial reported pCR rates ranging from 34% to 41%, depending on the treatment regimen. Furthermore, a pooled analysis published in *The Lancet Oncology* confirmed that achievement of pCR is strongly associated with improved survival outcomes in aggressive breast cancer subtypes, including TNBC.

4.2 Age Distribution

The majority of patients in this study were in the younger age group (30–45 years), which is consistent with previous literature indicating that triple-negative breast cancer is more common in younger and premenopausal women. Dent *et al.*, in a study published in *Cancer*, similarly reported a higher prevalence of TNBC in younger age groups.

4.3 Histopathology

Invasive ductal carcinoma was the predominant histological subtype in our study, accounting for over 90% of cases, which aligns with global breast cancer data and international treatment guidelines such as those from the National Comprehensive Cancer Network (NCCN), which report invasive ductal carcinoma as the most common subtype across molecular categories.

The high Ki-67 proliferation index observed in our study further supports the biologically aggressive nature of triple-negative breast cancer and may partially explain the favorable pathological complete response (pCR) rates.

4.4 Pathological Response and Prognostic Implications

The attainment of ypT0N0 status in 21 patients (34.42%) reflects effective tumor eradication following neoadjuvant chemotherapy. Multiple studies have demonstrated that pathological complete response (pCR) is a strong prognostic marker in triple-negative breast cancer. A pooled analysis by Cortazar *et al.* showed that patients achieving pCR had significantly improved event-free survival and overall survival in TNBC.

4.5 Treatment pattern

The majority of patients received sequential anthracycline- and taxane-based chemotherapy, reflecting the current standard of care as recommended by the European Society for Medical Oncology (ESMO) guidelines for early-stage triple-negative breast cancer.

5. CONCLUSION

The prospective observational study demonstrated a pathological complete response (pCR) rate of 34.42% in 61 patients diagnosed with triple-negative breast cancer after receiving contemporary neoadjuvant chemotherapy. The findings support the clinical effectiveness of neoadjuvant chemotherapy in achieving meaningful

tumor downstaging and improving survival outcomes. Pathological complete response also represents an important surrogate marker for favorable prognosis in triple-negative breast cancer.

6. Limitations

This study has several limitations. The main drawback is the relatively small sample size of 61 patients. Although achievement of pathological complete response (pCR) is generally associated with improved outcomes, not all patients who attain pCR experience long-term survival, and there remains a risk of recurrence or relapse. Additionally, limited biomarkers were available to predict which patients would achieve pCR after neoadjuvant chemotherapy (NACT), which restricts the ability to fully assess the prognostic impact and individualize treatment strategies.

Future Directions

Future multicenter studies with larger sample sizes and extended follow-up are required to further evaluate survival outcomes and validate the present findings. Further research exploring biomarker-guided therapy and the incorporation of novel agents, such as immunotherapy, may help improve pathological complete response (pCR) rates in triple-negative breast cancer.

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Competing Interests

Authors have declared that no competing interests exist.

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