

## OUTCOMES OF TRIPLE NEGATIVE BREAST CANCER IN EARLY BREAST CANCER WITH NEO ADJUVANT CHEMOTHERAPY

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### Abstract:

**Objectives:** To determine the outcomes of triple negative breast cancer in early breast cancer with neo adjuvant chemotherapy.

**Materials and Methods:** After approval from the review board, patients were enrolled following written informed consent for voluntary participation. Data were collected from all participants, including detailed physical examination findings and medical history. Demographic variables were noted. Patients received protocol-based treatment with either an immunotherapy-based regimen or standard neoadjuvant

anthracycline-based chemotherapy every three weeks for three cycles, along with standard supportive medications. Following treatment completion, surgery was performed and specimens were sent for histopathological evaluation. Data were recorded in a questionnaire and analyzed with SPSS 26.

**Results:** The majority of patients were between 31 and 40 years old, with a mean age of  $42.69 \pm 9.71$  years and a mean BMI of  $22.48 \pm 4.12$  kg/m<sup>2</sup>. Illiteracy, housewife position, urban living, right-sided sickness, and middling socioeconomic level were more prevalent. While there was no discernible correlation between treatment response and age, breast laterality, or BMI, nearly half obtained complete remission.

**Conclusion:** It was concluded that neoadjuvant chemotherapy plays a crucial role in the treatment of early triple-negative breast cancer, and that the best indicator of enhanced survival is pathological full response. To improve therapy response and optimize treatment techniques, more research is advised.

**Key words:** Triple negative breast cancer, neo adjuvant chemotherapy, complete response.

## INTRODUCTION:

Among the leading causes of mortalities worldwide are attributed to cancer. Breast cancer constitutes the most common type of cancer in women, which is also the most often detected disease in the world.(1) About fifteen to twenty percent of the instances of breast cancer are triple-negative (TNBC). This type breast cancer is distinguished by the absence of receptors for estrogen, progesterone and epidermal growth factor. TNBC is difficult to treat because it is hostile and there are few effective treatment options that are comparable to endocrine therapy in receptor positive tumours.(2) In its initial stages, the disease is often symptomless and localized. As a result, the main factors influencing the way patients experience and act, frequently with a major influence, are sensitivities and symptoms associated with therapy.(3) Crucially, toxicities from chemotherapy that doctors may consider clinically treatable can cause people a great deal more discomfort and disrupt their everyday lives. This may result in rapid treatment cessation or lack of compliance to therapy, which would lower effectiveness outcomes.(4)

Comparing patient's receptor positive and negative tumours are the source of a large portion of the current data gathered by researchers attempting to comprehend the distinctive characteristics of HER2-low status. These evaluations look at differences in genomes, outcome of therapy, and survival. General survival and response following neoadjuvant treatment are two outcomes that researchers have shown to differ significantly receptor positive and negative disease.(5) In order to anticipate the response of tumors in advance and provide appropriate adjunctive therapies, neoadjuvant cancer therapy (ChT) has become universally recognized as the primary treatment for early-stage TNBC.(6) It has been demonstrated that the pathological total response of TNBC following neoadjuvant ChT may foresee prolonged therapeutic advantages and act as a bridge to increased longevity. A full response percentage of 45% was obtained with the traditional neoadjuvant ChT regimen, which included anthracycline, cyclophosphamide, and taxane. One another study found a 41% overall pCR rate and a substantial correlation between pCR achievement and ECR (OR = 15.1,  $p < 0.001$ ). The time to death (HR =

0.28,  $p < 0.001$ ) and relapse (HR = 0.26,  $p < 0.001$ ) were longer for early responders with pCR.(7)

This study has been planned because there is scarcity of data with respect to outcomes of triple negative breast cancer with neo adjuvant chemotherapy in the context of local settings leading to research gap. Moreover, definitive knowledge on the best neoadjuvant treatment choice for TNBC remains lacking, and additionally there are uncertainties over the proportion of therapeutic advantages and hazards related combined cancer therapy. The study's findings will help clinicians treat and counsel patients with TNBC more effectively.

**Objective:** To determine the outcomes of triple negative breast cancer in early breast cancer with neo adjuvant chemotherapy.

#### **. MATERIALS AND METHODS:**

**Study Design:** Descriptive study.

**Study setting:** Department of Oncology, KTH, Peshawar.

**Duration of the study:** Duration of the study was 3 mont

hs

(from \_\_\_\_\_).

**Sampling Technique:** Non-probability Consecutive sampling technique was used for the recruitment of patients.

**Sample size:** Sample size of 129 patients was calculated by using WHO sample size calculator taking anticipated frequency of complete response with neoadjuvant chemotherapy in early breast cancer as 41.0% (7), 8.5% margin of error and 95% confidence level.

#### **Inclusion Criteria:**

- Patient of 18 to 80 years of age.
- Patients diagnosed with triple negative early breast cancer as per operational definitions.

#### **Exclusion Criteria:**

- Patients with synchronous breast cancer.
- Patients with a history of surgical or chemoradiotherapy to the same breast.
- Patients with poor left ventricular function
- Concomitant malignancy

**Methods:** Patients who met the selection criteria were recruited from the hospital's indoor department after

obtaining approval from the research regulatory committee. All enrolled participants were informed about the objectives, potential risks, and benefits of the

study, and written informed consent was obtained prior to enrollment. Demographic and baseline characteristics were recorded, including age (years), body mass index (BMI; weight in kilograms/height in meters<sup>2</sup>), breast laterality (left/right), residence, education level, occupation, and socioeconomic status. Baseline imaging, including ultrasound, mammography, and computed tomography (CT), was performed. Patients received treatment according to the study protocol, either with an immunotherapy-based regimen or with standard neoadjuvant anthracycline-based chemotherapy administered every three weeks for three cycles. Standard supportive medications, including dexamethasone, ranitidine, and 5-HT<sub>3</sub> receptor inhibitors, were administered. Following completion of therapy, surgery was performed, and tissue samples were sent for histopathological examination to document treatment outcomes, which were recorded in accordance with predefined operational definitions. All study data were documented by the researcher using a specially designed proforma.

**STATISTICAL ANALYSIS:** Data analysis was carried out using SPSS version 26. Continuous variables, such as age and BMI, were expressed as mean±standard deviation or median (interquartile range) after assessment of data normality using the Shapiro–Wilk test. Categorical variables, including breast laterality, tumor stage, residence, education, profession, socioeconomic status, and outcomes, were presented as frequencies and percentages. Outcomes were stratified according to age, breast laterality, tumor stage, and BMI. Post-stratification analysis was performed using the chi-square test or Fisher’s exact test as appropriate, with a significance level set at 5%.

**RESULTS:** The mean age of the participants was 42.69±9.71 years, while the mean body mass index (BMI) was 22.48 ± 4.12 kg/m<sup>2</sup>. Most patients belonged to the 31–40-year age group (45.0%), followed by those aged 41–50 years (27.9%), whereas smaller proportions were observed in the 18–30 years and >60 years age groups (7.0% each). Right-sided breast involvement was slightly more common than left-sided disease (52.7% vs. 47.3%). A majority of participants resided in urban areas (55.0%), with the remaining 45.0% from rural regions. Regarding educational

status, nearly half of the patients were illiterate (45.7%), followed by those with primary (30.2%) and secondary education (20.9%), while only a small proportion had higher education (3.1%). Most participants were housewives (71.3%), whereas 28.7% were employed. In terms of socioeconomic status, more than half of the patients belonged to the middle socioeconomic class (51.9%), followed by the low (31.0%) and high (17.1%) socioeconomic groups (Table 1). Regarding treatment outcomes, nearly half of the patients achieved a complete response (49.6%), while 37.2% demonstrated a partial response. Stable disease was observed in 13.2% of the participants (Table 2). Stratification of treatment response according to different variables showed no statistically significant associations. Across age groups, complete response was most frequently observed in patients aged 31–40 years (50.0%), while partial response was more common in the 31–40 and 41–50 year age groups (35.4% each), and stable disease was predominantly seen in patients aged 31–40 years (52.9%); however, the difference was not significant ( $p = 0.29$ ). With respect to breast laterality, complete response was observed in

48.4% of right-sided and 51.6% of left-sided tumors, while partial response and stable disease were slightly more frequent in right-sided disease, though this association was not statistically significant ( $p = 0.61$ ). Similarly, no significant association was found between BMI categories and treatment response ( $p = 0.12$ ), although complete response was most common among patients with normal BMI (42.2%), partial response was highest in the normal-weight group (62.5%), and stable disease was more frequently observed among overweight patients (35.3%) (Table 3).

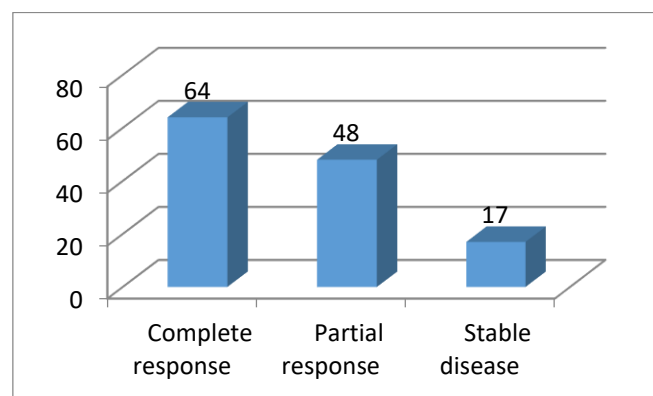
**Table 1:** Baseline Demographic and Clinico-pathological Characteristics of the Study Participants ( $n=129$ )

Variables	
Age (Years)	42.69±9.71
BMI	22.48±4.12
Age Groups	
18-30 years	9(7.0%)
31-40 years	58(45.0%)
41-50 years	36(27.9%)
51-60 years	17(13.2%)

>60 years	9(7.0%)
<b>laterality of breast</b>	
Right	68(52.7%)
Left	61(47.3%)
<b>Tumor stage</b>	
<b>Residence</b>	
Urban	71(55.0%)
Rural	58(45.0%)
<b>Education</b>	
Illiterate	59(45.7%)
Primary	39(30.2%)
Secondary	27(20.9%)
Higher Education	4(3.1%)
<b>Profession</b>	
House wife	92(71.3%)
Employed	37(28.7%)
<b>Socioeconomic Status</b>	
Low	40(31.0%)
Middle	67(51.9%)
High	22(17.1%)

**Table 2:** Frequency of participant on the basis of response(n=129)

<b>Outcomes</b>	
Complete response	64(49.6%)
Partial response	48(37.2%)
Stable disease	17(13.2%)



**Fig 1:** Frequency of participant on the basis of response

**Table 3:** Stratification of Response on the basis of different Variables (n=129)

	<b>Response</b>			p-Value
	Complete response	Partial response	Stable disease	
<b>Age Groups</b>				
18-30 years	5(7.8%)	3(6.3%)	1(5.9%)	0.29
31-40 years	32(50.0%)	17(35.4%)	9(52.9%)	
41-50 years	13(20.3%)	17(35.4%)	6(35.3%)	
50-60 years	7(10.9%)	9(18.8%)	1(5.9%)	
>60 years	7(10.9%)	2(4.2%)	0(0.0%)	
<b>laterality of breast</b>				
Right	31(48.4%)	27(56.3%)	10(58.8%)	0.61
Left	33(51.6%)	21(43.8%)	7(41.2%)	
<b>BMI</b>				
Underweight	19(29.7%)	5(10.4%)	2(11.8%)	0.12
Normal weight	27(42.2%)	30(62.5%)	8(47.1%)	
Overweight	14(21.9%)	12(25.0%)	6(35.3%)	
Obese	4(6.3%)	1(2.1%)	1(5.9%)	

**Discussion:** An established and very successful standard treatment for patients with early-stage triple-negative breast cancer (TNBC) is neoadjuvant chemotherapy (NACT), which aims to downstage the main tumor and affected lymph nodes.(8) Achieving a pathological complete response (pCR) is a key

objective of neoadjuvant therapy in breast cancer, as it has a direct and significant impact on survival outcomes. The main objective of the present descriptive study was to determine the outcomes of triple negative breast cancer in early breast cancer with neo adjuvant chemotherapy. The finding of the study

shows that nearly half of the patients achieved a complete response (49.6%), while 37.2% demonstrated a partial response. Stable disease was observed in 13.2% of the participants. It has been repeatedly shown that achieving pathological complete response (pCR) is a powerful and accurate indicator of better overall and disease-free survival outcomes for patients with breast cancer. The prognostic value of pCR as a surrogate endpoint in the management of breast cancer has been highlighted by numerous clinical studies and meta-analyses that have confirmed that patients who achieve pCR after neoadjuvant therapy have noticeably better long-term prognoses than those with residual disease.(9, 10) A pathological complete response (pCR) after NACT is highly correlated with markedly better long-term outcomes, such as increased OS and disease-free survival, underscoring the crucial prognostic and therapeutic significance of pCR in this patient population. According to a study conducted by Muhammad Rashid Hanif et al.(11) stated that 34.7%)achieved pathological complete response.

Acco

rding

to international literature, patients with triple-negative breast cancer (TNBC) receiving chemotherapy

regimens based on anthracycline–taxane have pathological complete response (pCR) rates that range from 22% to 45%.(12, 13) Patients with triple-negative breast cancer (TNBC) had greater pathological complete response (pCR) rates than patients with other breast cancer subtypes, according to a prospective study by Liedtke et al.(12) published in 2008 and carried out at the M.D. Anderson Cancer Center. Similarly, patients with triple-negative breast cancer (TNBC) who experienced pathological complete response (pCR) following neoadjuvant chemotherapy (NACT) had a considerably higher 10-year relapse-free survival (86% vs. 23%) than those who had residual disease, according to Symmans et al.(14) Furthermore, a retrospective research by Fisher et al. comparing adjuvant chemotherapy and neoadjuvant chemotherapy in TNBC found that patients who achieved pCR after NACT had an overall survival (OS) of 92.3%, while those with residual cancer had an OS of 67.2%.(15) The study's results confirm that pCR is a useful surrogate endpoint for TNBC management

in terms of prognosis. Tumor biology and chemosensitivity appear to be more important than baseline demographics, as patients who achieved pCR

showed higher response rates regardless of age, BMI, and tumor laterality. While this study did not show any significant differences in response stratified by age, BMI, or laterality, the trend toward more complete responses in patients with normal BMI is consistent with findings from other studies, highlighting the significance of metabolic and nutritional status in treatment response.

**Conclusion:** It was concluded that the finding of the present study confirm the main role of neoadjuvant chemotherapy in the treatment of early triple-negative breast cancer. Achieving a pathological complete response remains the most important predictor of improved survival, while further studies were recommended to attain better treatment response.

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