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Clinicopathologic Characteristics, Pathological Response and Safety Profile of Triple-Negative Breast Cancer (TNBC) Patients: A Retrospective Study in Yogyakarta

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ABSTRACT

Background: Triple-negative breast cancer (TNBC) is a uniquely aggressive molecular subtype associated with poor prognosis, high proliferation rates, and significant genomic instability. **Objective:** This study aimed to determine the clinicopathologic characteristics, pathological response, and safety profile of TNBC patients in a local clinical setting. **Method:** A retrospective cohort study was conducted on 50 female patients at a private hospital in Yogyakarta (2019–2022). Chemotherapy regimens were categorized into platinum-based (carboplatin and taxane) and non-platinum-based (anthracycline-taxane, capecitabine, or methotrexate) groups. Pathological complete response (pCR) was defined as the total absence of residual invasive carcinoma in both the breast tissue and sampled regional lymph nodes (ypT0/Tis ypN0). Data were extracted from medical records and analyzed using bivariate statistical tests. **Results:** The mean age was 48.48 years (95% CI: 46.24–50.72), with 76% of patients aged 40-59. Most patients presented with cT2 tumor size (38%) and cN0 nodal status (58%). The mean Ki67 index was 24.96 (95% CI: 19.29–30.63), with 44% of patients exhibiting high proliferation (≥ 30%). The overall pCR rate was 20% (10/50). The platinum group achieved a higher numerical pCR rate (25%, 6/24) compared to the non-platinum group (15.4%, 4/26), though the difference was not statistically significant (OR = 1.833, 95% CI: 0.448–7.511, p = 0.490). A high Ki67 index (≥ 30%) was significantly associated with superior pCR achievement (OR = 7.428, 95% CI: 1.365–40.413, p = 0.014). Adverse drug reactions (ADRs) occurred in 66% (33/50) of patients, predominantly chemotherapy-induced nausea and vomiting (22%) and neurological disorders (20%). **Conclusion:** High Ki67 expression was associated with therapeutic response in this cohort. No statistically significant difference in pCR or total ADR incidence was observed between regimens in this sample. The study is limited by its single-center design and small sample size (n=50)

Keywords: Breast Cancer, TNBC, Clinicopathologic, Ki67, Chemotherapy

INTRODUCTION

Breast cancer remains the most frequently diagnosed malignancy globally and represents the leading cause of cancer-related mortality among women (Alkabban & Ferguson, 2023). In Indonesia, the disease accounts for approximately 18.6% of all cancer cases, with an incidence rate of 12 per 100,000 women (Kementerian Kesehatan Republik Indonesia, 2018; World Health Organization International Agency for Research on Cancer (IARC), 2021). A significant clinical challenge in the Indonesian landscape is that approximately 80% of new cases are identified at advanced or progressive stages, complicating therapeutic management and worsening patient outcomes (Kementerian Kesehatan Republik Indonesia, 2018). This malignancy is a heterogeneous disease classified into various molecular subtypes (Orrantia-Borunda et al., 2022), among which Triple-Negative Breast Cancer (TNBC) is of particular concern due to the absence of estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER2) expression (Kumar & Aggarwal, 2016).

TNBC is characterized by its aggressive biological behavior, high proliferation rates, and significant genomic instability (Kumar & Aggarwal, 2016). It typically affects younger women and is associated with a poor prognosis, exhibiting a high recurrence rate following surgical intervention. Unlike other subtypes, TNBC patients often experience shorter median survival time and a rapid relapse interval, typically between 19 to 40 months (Damaskos et al., 2019). Historically, the mortality rate within the first five years after diagnosis has been reported to be as high as 40%, emphasizing the lethal nature of this subtype (Damaskos et al., 2019). Despite advancements in targeted therapies, chemotherapy remains the cornerstone of TNBC management in the neoadjuvant and adjuvant settings (Gradishar et al., 2024). Current international guidelines recommend the use of platinum agents (carboplatin or cisplatin) in combination with taxanes to improve pathological complete response (pCR) rates (Gradishar et al., 2024; Poggio et al., 2018).

Recent studies have highlighted the predictive value of biomarkers such as the Ki67 proliferation index in assessing tumor aggressiveness and response to neoadjuvant chemotherapy (Wu et al., 2019; X. Zhu et al., 2020). While a high Ki67 index is often linked to worse long-term survival, it has paradoxically been associated with a higher likelihood of achieving pCR, as rapidly dividing cells are more sensitive to cytotoxic agents (X. Zhu et al., 2020). Attaining pCR, defined as the absence of residual invasive carcinoma, is recognized as a critical surrogate endpoint for improved overall and recurrence-free survival(Pennisi et al., 2016; Sahoo et al., 2022). Furthermore, the safety profile of chemotherapy is a critical consideration in clinical pharmacy, with adverse drug reactions (ADRs) like chemotherapy-induced nausea and vomiting (CINV), neurological disorders, and hematological toxicities frequently impacting patient compliance and quality of life (Lai et al., 2022; Oun et al., 2018).

Research on TNBC in Indonesia remains limited, with existing studies such as Hermansyah et al., (2021) focusing on general clinicopathologic trends without a detailed safety audit of specific regimens. In the Yogyakarta region, there is a particular gap in evidence regarding how local clinical practices and patient profiles influence therapeutic outcomes. This study addresses this gap by providing a preliminary evaluation of clinicopathologic markers and safety profiles at a local private hospital. The novelty of this research lies in its specific correlation of the Ki67 index with pCR achievement alongside a detailed audit of platinum versus non-platinum regimens from a clinical pharmacy perspective. Therefore, this study aims to determine the clinicopathologic characteristics, pathological response, and safety profile of TNBC patients in Yogyakarta to facilitate more personalized and effective local care plans.

MATERIALS AND METHOD

Design

This research utilized an observational analytic design with a retrospective cohort approach. This design was chosen to evaluate the clinicopathologic characteristics and therapeutic outcomes of patients based on historical medical data recorded over a specific period.

Population

The target population for this study consisted of all female patients diagnosed with Triple-Negative Breast Cancer (TNBC) at a private hospital in Yogyakarta, Indonesia. The accessible population included patients whose clinical records were initiated between January 2019 and January 2022.

Sample

The study population was selected using a total sampling approach based on historical medical records from January 2019 to January 2022. To ensure clinical homogeneity, patients were audited against the following strict inclusion criteria: (1) female patients aged 18–65 years; (2) histopathologically confirmed TNBC, characterized by the absence of estrogen receptor (ER), progesterone receptor (PR), and a HER2 score of 0 or 1+; (3) completion of the prescribed neoadjuvant chemotherapy cycles; and (4) possession of complete medical records regarding disease status and therapy. Patients who did not complete their prescribed regimen were excluded. A total of 50 subjects met the criteria, divided into a platinum-based group (n=24) receiving carboplatin in combination with taxanes (paclitaxel or docetaxel) and a non-platinum-based group (n=26) receiving

regimens such as anthracycline-taxane (AC-T/EC-T), capecitabine, or methotrexate-based combinations. Patients typically received 6 cycles of neoadjuvant chemotherapy, with surgical resection (MRM or BCT) performed following the final cycle.

Data Sources

The primary data sources were secondary clinical records extracted from the medical records division of the hospital. To ensure data integrity, any patient records with missing essential clinical endpoints, such as post-surgical pathology reports or documented chemotherapy regimens, were excluded from the final analysis

Data Collection Techniques/Instruments

Data were systematically collected using a specifically designed Data Collection Form (DCF) Clinical staging (cT and cN) followed the American Joint Committee on Cancer (AJCC) 8th Edition(H. Zhu & Doğan, 2021). The Ki67 proliferation index was categorized as high (≥30%) or low (<30%) based on the St. Gallen International Expert Consensus (Burstein et al., 2019; Goldhirsch et al., 2013).

The operational definition of pathological complete response (pCR) was strictly defined as the total absence of residual invasive carcinoma in both the breast tissue and sampled regional lymph nodes (ypT0/Tis ypN0) upon pathological evaluation following neoadjuvant therapy(LeVasseur et al., 2020; Sahoo et al., 2022). Safety assessments utilized the WHO standard for grading Chemotherapy-Induced Nausea and Vomiting (CINV) (Franklin et al., 1994), while other toxicities were graded using the National Cancer Institute's Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0 (US Department of Health and Human Services, 2017).

Data Analysis Procedures

Quantitative data was processed using professional statistical software. Univariate analysis identified the frequency and percentage distribution of categorical variables. Bivariate analysis using the Pearson Chi-square test (or Fisher's Exact test for cell frequencies) determined the relationship between chemotherapy regimens and clinical outcomes, specifically pCR achievement and the incidence of ADRs. Statistical significance was established at a p-value of <0.05

Ethics

This study was conducted in accordance with the ethical principles for medical research involving human subjects. Ethical approval was formally granted by the Health Research Ethics Committee of the participating private hospital in Yogyakarta (Protocol No. 67/KEPK-RSB/X/23).

RESULTS

Clinicopathologic Characteristics

Table 1. Clinicopathologic Characteristics of TNBC Patients (n=50)

Characteristic	Frequency (n)	Percentage (%)
Age Group		
18–39 years	6	12
40–59 years	38	76
≥60 years	6	12
Clinical Tumor Size (cT)		
cT1 (≤20 mm)	7	14
cT2	19	38
cT3	14	28
cT4	10	20
Clinical Nodal Status (cN)		
cN0	29	58
cN1	18	36
cN2	3	6
Ki67 Proliferation Index		
Low (<30%)	28	56
High (≥30%)	22	44

This study evaluated 50 female patients diagnosed with Triple-Negative Breast Cancer (TNBC). The mean age was 48.48 years (range 29–65), with the majority (76%) belonging to the 40–59 age group. As shown in Table 1, 38% of patients presented with cT2 tumor size and 58% were node-negative (cN0) at initial diagnosis.

Regarding surgical management, 52% (n=26) of the cohort underwent Modified Radical Mastectomy (MRM), while 36% (n=18) received Breast Conserving Therapy (BCT).

Pathological Complete Response and Predictor Variables

Overall, 10 of 50 patients (20.0%) achieved pathological complete response (pCR) after neoadjuvant chemotherapy (Table 2).

Table 2. Bivariate Analysis of pCR Achievement by Predictor Variables (n=50)

Predictor Variable	pCR (n=10)	Non-pCR (n=40)	Odds Ratio (95% CI)	p-value
Chemotherapy Regimen				
Platinum-based (n=24)	6 (25.0%)	18 (75.0%)	1.833 (0.448–7.511)	0.490
Non-Platinum (n=26)	4 (15.4%)	22 (84.6%)	1.0	-
Ki-67 Proliferation Index				
High (≥30%) (n=22)	8 (36.4%)	14 (63.6%)	7.428 (1.365–40.413)	**0.014**
Low (<30%) (n=28)	2 (7.1%)	26 (92.9%)	1.0	-

*Note: *Pearson's Chi-Square or Fisher's Exact Test where cell counts <5*

Safety Profile and Adverse Drug Reactions

Adverse drug reactions (ADRs) occurred in 33 of 50 patients (66.0%). The distribution of ADRs by regimen group is presented in Table 3.

Table 3. Distribution of Adverse Drug Reactions (ADR) by Regimen Group

Type of ADR	Platinum (n = 24)	Non-Platinum (n = 26)	Total (n = 50)
CINV	9 (37.5%)	2 (7.7%)	11 (22.0%)
Neurological	3 (12.5%)	7 (26.9%)	10 (20.0%)
Hematological	3 (12.5%)	2 (7.7%)	5 (10.0%)
Gastrointestinal	1 (4.2%)	3 (11.5%)	4 (8.0%)
Others	1 (4.2%)	2 (7.7%)	3 (6.0%)
Total with ADR	**17 (70.8%)**	**16 (61.5%)**	**33 (66.0%)**

DISCUSSION

Clinicopathologic Characteristics

The mean age at diagnosis was 48.48 years (95% CI: 46.24–50.72; range 29–65), with most patients (76%) belonging to the 40–59 age group. This finding aligns with a meta-analysis of Indian patients which reported a mean incidence age of 47.5 years, suggesting that TNBC in certain Asian populations may predominantly affect middle-aged women rather than younger cohorts (Kulkarni et al., 2020). Clinically, most patients presented with cT2 (38%) or cT3 (28%) tumors, reflecting the typically aggressive growth pattern of TNBC before detection. Furthermore, 58% of the population were node-negative (cN0) at initial diagnosis (Hermansyah et al., 2021).

The predominance of MRM in this cohort reflects the high proportion of cT2 and cT3 tumors in this Yogyakarta-based population, where radical surgery is often clinically preferred to ensure clear margins. These findings align with international standards suggesting that BCT remains a safe and viable option when combined with radiotherapy. The choice of procedure in this cohort was primarily guided by traditional clinicopathologic factors and patient preference rather than the molecular subtype alone (Di Leone et al., 2023; Freedman et al., 2009; Turashvili et al., 2018).

Pathological Response and Predictor Variables

Although the pCR rate was numerically higher in patients receiving platinum-based regimens, the absence of statistical significance should be interpreted cautiously because of the limited sample size. This pattern is consistent with global literature suggesting that adding a platinum agent to

taxane-anthracycline neoadjuvant chemotherapy may increase pCR by targeting DNA-repair vulnerabilities in TNBC (J. Li et al., 2022; Poggio et al., 2018).

The strong association between high Ki67 expression and pCR supports the "Triple-Negative Paradox," in which tumors with aggressive biological markers and high proliferative activity may be more sensitive to cytotoxic chemotherapy agents and therefore achieve superior pathological responses (Keam et al., 2011; Wu et al., 2019; X. Zhu et al., 2020).

Safety Profile and Adverse Drug Reactions

Chemotherapy-induced nausea and vomiting (CINV) was the most prevalent ADR (22%), particularly in the platinum group (37.5% vs 7.7%). This is expected as platinum agents like carboplatin have a high emetogenic potential by stimulating serotonin release in the gastrointestinal tract (Oun et al., 2018). Neurological disorders (20%) were more frequent in the non-platinum group (26.9%), likely related to the use of taxanes which can induce cumulative neurotoxicity by affecting peripheral nerve microtubules (Lai et al., 2022; Scripture et al., 2006).

Study Limitations

The findings of this study are limited by the small sample size (n=50), which results in limited statistical power and may fail to detect modest but clinically relevant differences between regimens. Furthermore, the single-center retrospective design may introduce selection bias, and the use of historical medical records carries a risk of ADR underreporting. Consequently, this small sample size and limited event rate mathematically precluded the use of multivariable logistic regression to safely adjust for potential confounders.

CONCLUSION

Triple-negative breast cancer patients in this Yogyakarta-based cohort are predominantly middle-aged and typically present with aggressive clinicopathologic traits, specifically cT2 tumor size and cN0 nodal status. This study indicates that a high Ki67 proliferation index was associated with the achievement of pathological complete response (pCR) in this cohort, suggesting its potential utility as a predictive marker for therapeutic sensitivity in local clinical settings. Furthermore, no statistically significant difference was observed in this sample regarding overall pCR rates or the total incidence of adverse drug reactions between platinum-based and non-platinum-based chemotherapy regimens. While both treatment strategies were found to be clinically manageable, the results must be interpreted with caution due to the study's single-center retrospective design and small sample size (n=50), which resulted in limited statistical power and the possibility of underreported adverse events. These preliminary findings highlight the necessity of integrated clinicopathologic profiling to facilitate more personalized and effective management plans for triple-negative breast cancer patients.

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