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COMPARISON OF THE EFFECTIVENESS OF ONDANSETRON IN BREAST CANCER PATIENTS AFTER CHEMOTHERAPY FAC (*Fluorouracil, Doxorubicin Cyclophosphamide*) AND TC (*Taxane Cyclophosphamide*)

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Abstract

Breast cancer is one of the leading causes of morbidity and mortality in women worldwide. Chemotherapy with the regimens of FAC (Fluorouracil, Doxorubicin, Cyclophosphamide) and TC (Taxane Cyclophosphamide) is often used in the treatment of breast cancer, but side effects such as Chemotherapy-Induced Nausea and Vomiting (CINV) can impact the patient's quality of life. Ondansetron, a 5-HT3 serotonin receptor antagonist, has been widely used as an antiemetic therapy. This study aims to compare the effectiveness of Ondansetron in overcoming CINV in breast cancer patients receiving FAC and TC regimen chemotherapy. The research design used Quasi-Experimental with Two Group Pretest-Posttest, involving 36 patients selected by purposive sampling at Ken Saras Hospital in December 2024 – January 2025. Data were collected using the Rhodes Index of Nausea, Vomiting, and Retching (RINVR) and analyzed by paired-sample t-test and independent-sample t-test. The results showed that Ondansetron effectively lowered the RINVR score significantly in both groups ($p = 0.00$). However, there was no significant difference in the effectiveness of Ondansetron between the FAC and TC regimens, either before ($p = 0.065$) or after ($p = 0.118$) chemotherapy. The conclusions of this study showed that Ondansetron had good effectiveness in reducing CINV in both groups of patients, although there was no significant difference between the regimens.

Keywords: Breast Cancer, Chemotherapy, Ondansetron, FAC Regimen, T Regimen.

INTRODUCTION

Breast cancer is the type of cancer with the highest incidence in the world and is the leading cause of cancer death in women. Based on the report *Global Burden of Cancer* (GLOBOCAN) 2020, there were 2.26 million new cases of breast cancer worldwide with a death rate of 685 thousand cases. In Indonesia, breast cancer also occupies the highest position with 65,858 new cases and 22,430 deaths (Sung et al., 2021). Breast cancer incidence rate in Indonesia reaches 40.3 per 100,000 women (Herawati et al., 2021). This high incidence and mortality rate suggests that breast cancer is a health problem that needs special attention.

Management of breast cancer depends on the stage of the disease, with primary therapies including surgery, radiotherapy, hormonal therapy, and chemotherapy (Apriantoro & Kartika, 2023). Chemotherapy is the main choice, especially in the advanced stages or as neoadjuvant therapy to improve tumor operability (Prayoga, 2019). One of the chemotherapy regimens that is often used in breast cancer patients is *Fluorouracil, Doxorubicin, and Cyclophosphamide* (FAC) and *Taxane (Docetaxel)* and *Cyclophosphamide* (TC) (Haryani, 2022; Sardjan, 2022). Although effective in suppressing the growth of cancer cells, chemotherapy often causes significant side effects, one of which is nausea and vomiting due to chemotherapy or *Chemotherapy-Induced Nausea and Vomiting* (CINV).

CINV can be classified into three types based on the time of its onset, namely acute (occurs in the first 24 hours after chemotherapy), delayed (occurs more than 24 hours after chemotherapy), and anticipatory (appears before chemotherapy as a psychological response to previous experiences). Acute or delayed nausea and vomiting are common side effects, with the highest risk appearing within 1-6 hours of chemotherapy. Patients receiving chemotherapy agents such as *Cyclophosphamide* are at higher risk of delayed emesis, which can last up to six days after chemotherapy (Vonny et al., 2023).

To treat CINV, various antiemetic drugs have been developed, one of which is ondansetron. Ondansetron works by inhibiting serotonin type 3 (5-HT3) receptors in the digestive tract and central nervous system, preventing the activation of nerve pathways that trigger nausea and vomiting (Huang et al., 2021; Padoli & DA, 2018). Several studies have shown that the use of ondansetron can significantly reduce the incidence of CINV, improve patients' quality of life, and improve adherence to cancer therapy (Vonny et al., 2023). However, although the effectiveness of ondansetron in treating CINV has been widely studied, there have been no studies that specifically compare the effectiveness of ondansetron in treating CINV in breast cancer patients receiving chemotherapy with FAC and TC regimens. To date, there are still limited studies that directly compare the effectiveness of ondansetron in the two regimens, so the effect of differences in the emetogenic characteristics of FAC and TC on the response of antiemetic therapy has not been adequately explained.

This study aims to compare the effectiveness of ondansetron in reducing nausea and vomiting in breast cancer patients undergoing chemotherapy with FAC and TC regimens. The results of this study are expected to provide more specific scientific information about the effectiveness of ondansetron in the two regimens, so that it can be a basis for consideration in the selection of more optimal CINV prevention and treatment strategies for breast cancer patients.

METHOD

Breast cancer is the type of cancer with the highest incidence in the world and is the leading cause of cancer death in women. Based on the report *Global Burden of Cancer* (GLOBOCAN) 2020, there were 2.26 million new cases of breast cancer worldwide with a death rate of 685 thousand cases. In Indonesia, breast cancer also occupies the highest position with 65,858 new cases and 22,430 deaths (Sung et al., 2021). Breast cancer incidence rate in Indonesia reaches 40.3 per 100,000 women (Herawati et al., 2021). This high incidence and mortality rate suggests that breast cancer is a health problem that needs special attention.

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RESULTS AND DISCUSSION

This study is a quantitative study with *a quasi-experimental two-group pretest-posttest design* conducted at Ken Saras Hospital from September 2024 to January 2025. Respondents consisted of 36 post-chemotherapy patients with FAC and TC regimens who experienced nausea and vomiting, selected through purposive sampling based on inclusion and exclusion criteria. Primary data were obtained from the RINVR questionnaire, while secondary data were taken from hospital medical records. Data analysis was conducted using IBM SPSS Statistics version 27, with *a paired-sample t-test* to compare RINVR scores before and after ondansetron administration in each group, as well as an *independent-sample t-test* to assess differences in score changes between the FAC and TC regimens.

Table 1. Distribution of Respondent Characteristics

Variable	FAC Group				TC Group			
	Red ± SD	Min-Max	n	%	Red ± SD	Min-Max	n	%
Age	59.33 ± 7,723	49-82	18		54.67 ± 7,340	40-64	18	
BMI (kg/m²)								
Underweight (< 18.5)			0	0%			0	0%
Normal (18.5 – 22.9)			8	44.4 %			6	33,3 %
Overweight (23.0 – 24.9)			10	55,6 %			10	55,6 %
Obesity I (25.0 – 29.9)			0	0%			2	11,1 %
Obesity II (> 30.0)			0	0%			0	0%
Marital Status								
Married			16	89,9 %			17	94,4 %
Unmarried			0	0%			0	0%
Widow			2	11,1 %			1	5,6%
Parity Status								
0			0	0%			0	0%
1-2			9	50%			10	55,6 %
> 2			9	50%			8	44,4 %
Family History of Breast Cancer								
Yes			8	44,4 %			9	50%
No			10	55,6 %			9	50%

Based on Table 1, the age of the respondents in the FAC group ranged from 49 to 82 years with an average of 59.33 years, while in the TC group it ranged from 40 to 64 years with an average of 54.67 years. The majority of respondents in both groups had overweight BMI (55.6%). Most of the respondents were married, namely 89.9% in the FAC group and 94.4% in the TC group. The distribution of parity status in the FAC group was balanced between respondents with 1–2 children and >2 children (50% each), while in the TC group the majority had 1–2 children (55.6%). A family history of breast cancer was more common in the TC group (50%) compared to the FAC group (44.4%).

Table 2. Distribution of respondents based on nausea and vomiting scores before and after ondansetron was given

Variable	FAC Group			TC Group		
	Red ± SD	Min-Max	n	Red ± SD	Min-Max	n

Nausea and vomiting score before being given ondansetron	18.78 ± 5.151	6-25	18	15.39 ± 5,489	4-25	18
Nausea and vomiting score after being given ondansetron	15.56 ± 6.555	0-25	18	12.11 ± 6,333	0-20	18

Based on Table 2, the average score of nausea and vomiting before ondansetron administration in the FAC group was 18.78 (range 6–25), while in the TC group it was 15.39 (range 4–25). After ondansetron, the average nausea and vomiting scores decreased to 15.56 (range 0–25) in the FAC group and 12.11 (range 0–20) in the TC group, indicating a decrease in the degree of nausea and vomiting in both groups.

Table 3. Differences in nausea and vomiting scores in the FAC and TC groups before and after being given ondansetron

Groups	Nausea and vomiting score before being given ondansetron	Nausea and vomiting score after being given ondansetron	*p*
	Red ± SD	Red ± SD	
FAC Group	18.78 ± 5,151#	15.56 ± 6,555#	0,00*
TC Group	15.39 ± 5,489#	12.11 ± 6,333#	0,00*

Description =
= Normal data distribution
* = Significant (α=95%)

Based on Table 3, analysis using the Paired Sample t-test with a significance level of 95% (α=0.05) showed that there was a significant difference between nausea and vomiting scores before and after ondansetron administration in both groups. In the FAC group, the decrease in nausea and vomiting scores was significant with p-value = 0.00 (p<0.05). The same thing happened in the TC group, where there was a significant decrease in score with p-value = 0.00 (p<0.05).

Table 4. Differences in nausea and vomiting scores between the FAC and TC groups before and after ondansetron administration.

	Groups		*p*
	FAC	TC	
Nausea and vomiting score before being given ondansetron	18.78 ± 6.555a	15.39 ± 5.489a	0,065
Nausea and vomiting score after being given ondansetron	15.56 ± 6.555a	12.11 ± 6.333a	0,118

Description =
= Normal data distribution
* = Significant (α=95%)

Based on Table 4, the results of the Independent t-test with a significance level of 95% (α = 0.05) showed that there was no significant difference in nausea and vomiting scores before ondansetron between the FAC and TC groups with a p-value = 0.065 (p>0.05). In addition, after ondansetron, the difference in nausea and vomiting scores between the two groups was also not significant with p-value = 0.118 (p>0.05).

DISCUSSION

The results of this study showed a significant decrease in nausea and vomiting scores after ondansetron in both study groups, namely patients who received chemotherapy with FAC and TC regimens. The FAC group experienced a decrease in the average score from 18.78 to 15.56, while the TC group showed a decrease from 15.39 to 12.11. Although patients with the TC regimen showed a greater decrease, the results of the differential test using the Independent t-test did not find a significant difference between the two groups in either the score before and after ondansetron administration.

These findings support the guidelines issued by the *American Society of Clinical Oncology (*ASCO*), Multinational Association of Supportive Care in Cancer (*MASCC*) / European Society for Medical Oncology (*ESMO*)*, and *National Comprehensive Cancer Network (*NCCN*)* that classifies the FAC regimen as chemotherapy with a high emetic risk and the TC regimen as chemotherapy with a moderate emetic risk (Foundation, 2022; Herrstedt et al., 2024; Hesketh et al., 2020). Based on tests *Paired sample t-test*, these results show that patients with

the TC regimen experienced a greater reduction in RINVR scores compared to the FAC group, which is consistent with the guideline that regimens with a lower emetic risk tend to provide better outcomes in the reduction of post-chemotherapy nausea and vomiting symptoms.

Several previous studies have also supported these findings. A study by Della et al. reported that oral administration of ondansetron 8 mg with dexamethasone prior to chemotherapy with moderate emetic risk could prevent acute nausea and vomiting in 75% of patients, with only 1% of patients experiencing severe nausea and vomiting (Ng & Della-Fiorentina, 2010). Another study conducted by Sun et al. also corroborated these findings by stating that ondansetron has good antiemetic effectiveness and a high safety profile in patients with malignant tumors undergoing chemotherapy with moderate to high emetic risk. This can be explained by the mechanism of action of ondansetron as an antagonist of the 5-HT3 receptor that directly inhibits the emetic pathway in the brain's vomiting center.(Sun et al., 2025)

However, the test results *Independent t-test* in this study it is contrary to the guidelines that the FAC regimen is more at risk of causing nausea and vomiting than the TC regimen. The absence of a significant difference in posttest scores between the two groups can be attributed to several factors. A study conducted by Ghosh et al. found that palonosetron is superior to ondansetron in controlling nausea and vomiting due to high and moderate emetogenic chemotherapy. In moderate emetogenic chemotherapy, palonosetron showed better control of post-chemotherapy nausea and vomiting than ondansetron, and in high-emetogenic chemotherapy, palonosetron was also more effective in controlling acute and delayed CINV although the results were not statistically significant (Ghosh & Dey, 2010). These findings suggest that the effectiveness of antiemetics may vary depending on the type of 5-HT3 receptor antagonist used.

In addition to pharmacological factors, the patient's individual condition also plays a role in the effectiveness of antiemetic therapy. A study conducted by Huang et al. revealed that pain and insomnia factors can worsen a patient's physical condition, decrease immunity, and reduce the ability to deal with chemotherapy side effects, including nausea and vomiting. In addition, a history of previous nausea and vomiting is also a significant risk factor for the occurrence of acute INV. Patients with previous experiences of nausea and vomiting on chemotherapy are more prone to experiencing similar symptoms due to the mechanism *conditioned response*.(Huang et al., 2021) Psychosocial factors can also play a role in the severity of nausea and vomiting experienced by patients. Research conducted by Devita Fajrina et al. shows that emotional support and patient self-acceptance contribute to reducing chemotherapy side effects, including nausea and vomiting. Patients who receive good family support as well as motivation from the surrounding environment tend to have a more positive mindset, which can ultimately help in reducing the intensity of CINV.(Padoli & DA, 2018)

The study has limitations because nausea and vomiting scores are obtained based on *self-reported* data from patients, which can be influenced by individual subjectivity as well as psychological factors such as anxiety and tolerance to symptoms. In addition, this study did not strictly control for other disruptive variables that could potentially affect outcomes. Therefore, further research with a more rigorous design, such as cohort studies or randomized clinical trials, is needed to confirm these findings and explore other factors that contribute to patients' responses to antiemetic therapy. Further analysis of factors such as age, nutritional status, previous history of chemotherapy, as well as psychosocial support is also expected to provide new insights in the management of chemotherapy side effects in breast cancer patients

CONCLUSION

This study showed that the rate of nausea and vomiting before ondansetron administration was higher in the group of patients undergoing chemotherapy with the FAC regimen compared to the TC regimen. After ondansetron administration, there was a significant decrease in both groups, with a greater decrease in the TC group. Analysis using the Paired Sample t-test showed that the difference in nausea and vomiting scores before and after ondansetron was significant in both groups with p-value = 0.00 ($p < 0.05$). However, the results of the Independent t-test showed that there was no significant difference between the FAC and TC groups either before or after ondansetron administration, with p-values of 0.065 ($p > 0.05$) and 0.118 ($p > 0.05$, respectively.

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