

Assessment of Drug Related Problems and Prescription Auditing in Patients Undergoing Chemotherapy for Breast Cancer in a Private Cancer Hospital: An Observational Study

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ABSTRACT

Background: Chemotherapy stands as a cornerstone in the management of breast cancer, offering substantial benefits in terms of disease control and survival outcomes. However, the complexity of chemotherapy regimens coupled with the potential for Drug-Related Problems (DRPs) underscores the importance of meticulous prescription auditing and proactive intervention to optimize treatment efficacy and safety. **Aim and Objectives:** Prescription auditing for patients receiving chemotherapy for breast cancer, determining the risk factors linked to breast cancer, and finding drug-related issues with chemotherapy treatments for patients with breast cancer. **Materials and Methods:** This is prospective observational research that lasted six months. Breast cancer patients who were above 18 years of age and were on chemotherapy along with supportive care medications were enrolled. **Results:** The study included 100 participants in total. The majority were in the age group of 40-60 years ($n=72$, 72%). Age is one of the most common risk factors in our study. Prescription auditing revealed that in ($n=33$, 33%) prescriptions, necessary pre-laboratory tests were not performed, and in ($n=2$, 2%) of patients, demographic details and dose calculation were missing during a few cycles of chemotherapy. Most commonly reported ADRs were chemotherapy-induced alopecia ($n=60$, 37%) and chemotherapy-induced anaemia ($n=26$, 16%). 61% ADRs were probable and 20% ADRs were certain according to the WHO-UMC causality assessment. **Conclusion:** This study underscores the importance of prescription auditing and careful monitoring of drug-related problems in breast cancer patients undergoing chemotherapy. Interventions based on these audits significantly enhance treatment safety and efficacy, potentially improving patient outcomes.

Keywords: Alopecia, Anaemia, Breast cancer, Causality assessment, Chemotherapy.

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INTRODUCTION

Cancer is a leading cause of death in both economically developed and developing nations. Unfortunately, the burden is likely to increase globally as the population develops and ages, particularly in less developed countries, which account for about 82% of the world's population. Breast Cancer (BC) has been found to increase with the adoption of lifestyle behaviours such as poor dietary habits, sedentary lifestyle, smoking, and reproductive characteristics such as having a low number of births and first births at an older age, which have further increased the cancer burden in less economically developed countries.¹ A World

Health Organization (WHO) research study states that breast cancer is one of the most prevalent diseases in women worldwide, impacting 2.1 million people annually and being the primary cause of cancer-related deaths in women. In India, BC has now surpassed the most often occurring cervical cancer and become a main cause of cancer death.² In 2012, over 70,218 women died from BC in India, which was the largest number of BC-related deaths worldwide that year. Furthermore, the five-year survival rate of women suffering from breast cancer in India is only 60% compared to the United States, where it is reported to be 89%.³ The prime cause of high BC-related morbidity in India is due to the unavailability of appropriate medical care.⁴ As a result, it is critical to identify current anti-neoplastic and supportive care utilization trends. Prescription auditing is an important strategy for preventing medication misuse and promoting reasonable drug use. Analyzing the various prescribing indicators can reveal information about the performance of health care



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practitioners in terms of appropriate drug use. The quality of a prescription indicates a physician's expertise and approach to logical prescribing.⁵ However, rigorous evaluations indicate that prescribing errors are prevalent, affecting anything from 4.2 to 8.2% of prescriptions. These prescribing errors can also have negative consequences. Almost four out of every 1000 prescriptions include flaws that could have serious consequences. Errors can occur at any stage of prescribing, including the choice of medicine, dose, mode of administration, and incorrect frequency or duration of treatment. Inaccurate writing, poor readability of handwriting, or insufficient writing of a prescription can all lead to misinterpretation, resulting in errors in dispensing and administration. Prescription indicators play an important part in the delivery of healthcare services around the globe.⁶ Appropriate medication use can help significantly reduce morbidity and mortality rates. Chemotherapy medicines have a limited therapeutic index. They target both cancer cells and the rapidly proliferating normal cells of the skin, hair, gut, and bone marrow. Frequent use of chemotherapy causes nausea, vomiting, alopecia, and neutropenia. Chemotherapy-Induced Neutropenia (CIN) is the most common hematological toxicity.⁷ Breast cancer is a multifactorial disease, and various factors such as aging, premature puberty, late menopause, first pregnancy after the age of 30, infertility, no breastfeeding, genetic factors, chest radiography, birth control pills, socioeconomic status, smoking and alcohol consumption, inadequate physical activity, unhealthy diet, overweight and obesity, dense breast tissue, and a history of other cancers (especially ovarian and endometrial cancers) play a role in the occurrence of BC.⁸ BC is 100 times more prevalent in women than in men. BC has increased in most emerging countries during the last few decades as a result of lifestyle changes. It has also been linked to an increase in deaths in underdeveloped communities. BC grows slowly and can be recognized and treated in its early stages. Early detection of BC prevents disease progression, increases patient survival, and reduces mortality.⁹

MATERIALS AND METHODS

This is a Prospective observational study conducted over a period of 6 months at the study setting Halamma Kerudi Cancer Hospital, Bagalkot. The Institutional human ethical committee had approved the study (Ref. No: HSK COP /IEC/23/2) and written informed consent was taken from patients before including into study according to eligibility criteria.

Inclusion criteria: Female Patients aged ≥ 18 years and on chemotherapy for Breast cancer.

Exclusion criteria: This study excluded Patients who are not willing to participate in study and age less than 18 years excluded from study.

Sample size calculation: Taking into account the prevalence of ADR, At $p=28.7\%$,¹⁰ 95% confidence interval and 10%

error, Sample size 'n': $[(DEFF \cdot Np) / (1-p)] / [(d^2 / Z_{21-\alpha/2}^2 \cdot (N-1) + p \cdot (1-p)] = 100$.

Study Procedure

The data were collected from the hospital inpatients in a pre-designed case record form. The information in each medication chart included the name, age, gender, family history, social habits, diet, height, weight, body surface area, address, clinical data such as diagnosis, past medication history, co-morbidities, and allergy status, and therapeutic data such as name of the drug, dose, frequency, route, and duration of administration, concurrent medication(s), laboratory tests, and results. Prescription auditing is done by using the WHO prescribing indicator and prescription auditing form, identifying drug-related problems by using drug information resources, and assessing risk factors by using a risk assessment form.

Statistical analysis

Data analysis was done by using statistical methods like Odds ratio and Chi-Square test to analyse the association of ADRs between different chemotherapy regimen.

RESULTS

During the hospital stay, 100 breast cancer patients were screened. BC was found more common ($n=72$, 72%) among the age group 40-60 (Table 1). In our study, 100 patients were assessed for risk factors. Out of 100 patients ($n=82$, 82%), patients belong to the age group 40-80 (Table 2). Six different classes of anti-cancer drugs were prescribed: anthracyclines ($n=74$, 32%) were mostly prescribed, followed by alkylating agents ($n=71$, 31%) (Table 3). A total of 163 ADRs were reported in the 6-month study period. The patients on two drug regimens were placed in category one; category two includes patients who were on three drug regimens, and category three includes patients who were on four drug regimens. Among all the ADRs, alopecia ($p=0.03994$) and anemia ($p=0.0016$) were more common in all three categories, and it was statistically significant (Table 4). The odds ratio for the development of different ADRs from different chemotherapy drugs was assessed in 100 patients (Table 5). Upon WHO-UMC causality assessment, the majority of reports were rated as Probable ($n=99$, 61%), followed by Certain ($n=33$, 20%) and Possible ($n=31$, 19%). By the Hartwig Severity Scale, mild and moderate reactions accounted for ($n=75$, 46%) and ($n=88$, 54%), respectively. Among 100 patients, 2 possible drug-drug interactions were found with the combinations Doxorubicin+ Dexamethasone ($n=68$, 68%) and Doxorubicin+Cyclophosphamide ($n=68$, 68%). The prescribing indicator shows that the percentage of drugs prescribed from the WHO-EDL was 100% (Table 6). This study employed prescription auditing guidelines provided by the Indian Health Mission, aiming to evaluate the quality and appropriateness of prescriptions in our target healthcare settings. Five criteria, such as P1 (patient details, patient parameters, BSA), P2 (prescription

orders), P3 (protocol and scheduling), P4 (prescribed medicine, dose calculation), and P5 (patient organ function and lab test), were considered for prescription auditing. After auditing, in 2 prescriptions, patient parameters like BSA and age were missing, and dose calculation based on patient parameters was missing; in 33 patients, relevant patient organ function tests were missing.

DISCUSSION

Age and gender are the two factors most closely linked to the incidence of breast cancer. As people age, the prevalence of breast cancer rises.¹¹ 82% of the patients in our study are between the ages of 40 and 80. The purpose of this study was to ascertain how common risk factors were and how women over the age of 18 perceived their risk of BC. According to the frequency of risk factors in the women under investigation, the most prevalent risk factor for BC was age (82%). Following old age, family history and obesity were the most common risk factors for BC in the current study. In the studies by Rohparvarzadeh in Isfahan and Badrian *et al.*¹² in Dehaghan, a body mass index

of 30 or more was identified as one of the primary risk factors for BC. In the study by Osei *et al.*, 14.3% of individuals had a family history of BC.¹³ Drug utilization studies provide insight into prescribing practices and characterize early signs of irrational drug use.¹⁴ The prescribing indicator shows that the average number of prescriptions prescribed from the WHO list of medicines was 100%, in contrast to Sandeep Kumar *et al.*,¹⁵ who found values around 56.25%, because prescription patterns vary from clinician to clinician, patient to patient, and disease condition in that location. As a result, this could account for the percentage discrepancy between the two studies. All cytotoxic medications were prescribed in injection form with a 100% value, which matches Sandeep Kumar *et al.*'s percentage. The majority of patients ($n=68$, 68%) were initiated on a cytotoxic medication combination of doxorubicin and Cyclophosphamide (AC), and taxanes were added subsequently, taxanes boosted the efficacy of chemotherapy.¹⁶ In this study, ($n=71$, 71%) of the patients were treated with alkylating drugs, with ($n=64$, 64%) percent being on a taxane-based regimen with AC. This study discovered

Table 1: Distribution of study subjects according to Age.

Age in years	No. of patients (%)
20-40	18 (18)
40-60	72 (72)
60-80	10 (10)

Table 2: Assessment of risk factors in breast cancer patients.

Risk category	Percentage (%)
Age (40-80 years)	82
Family history	10
Early menarche and late menopause.	2
Late Birth of 1 st child / Nulliparity.	3
Obesity	8
ERT or OC	0

Table 3: Functional classification of cytotoxic drugs.

Functional classification	Cytotoxic drugs	% of Prescriptions
Platinum compounds	Carboplatin	21
	Cisplatin	2
Taxanes	Paclitaxel	51
	Docetaxel	13
Antimetabolites	Gemcitabine	2
Anthracyclines	Doxorubicin	68
	Epirubicin	6
Alkylating agent	Cyclophosphamide	71
Monoclonal antibodies	Trastuzumab	6

Table 4: Assessment of ADR using Chi-Square test.

Sl. No.	ADRs	Cat 1 (n=48)	Cat 2 (n=40)	Cat 3 (n=12)	Total (n=100)	p-value (chi-square test)
1	Nausea and vomiting	11 (22.9)	8 (20)	2 (16.6)	21 (21)	0.8754
2	Alopecia	35 (72.9)	19 (47.5)	6 (50)	60 (60)	0.03994
3	Anaemia	12 (25)	6 (15)	8 (66.6)	26 (26)	0.0016
4	Constipation	3 (6.2)	4 (10)	3 (25)	10 (10)	0.1534
5	Thrombocytopenia	1 (2)	1(2.5)	1 (8.3)	3 (3)	0.5102
6	Leukocytopenia	0	3 (7.5)	1 (8.3)	4 (4)	0.1449
7	Neuropathy	3 (6.25)	10 (25)	2 (16.6)	15 (15)	0.1385
8	Oedema	3 (6.25)	3 (7.5)	0	6 (6)	0.6279
9	Diarrhoea	4 (8.3)	3 (7.5)	1 (8.3)	8 (8)	0.9887
10	Others	5 (10.4)	3 (7.5)	2 (16.6)	10 (10)	0.6442

p-value less than 0.05 is considered as statistically significant Cat 1- Two drug regimens, Cat 2- Three drug regimens, Cat 3- Four drug regimens.

Table 5: Assessment of ADR using Odd's ratio.

Drug use (No. of Prescription)	Anaemia (OR)	Alopecia (OR)	Neuropathy (OR)
Carboplatin (23)	8 (1.74)	2 (0.031)	4 (1.26)
Paclitaxel (40)	2 (0.82)	10 (0.06)	11 (5.31)
Doxorubicin (68)	8 (0.10)	48 (4)	-
Cyclophosphamide (68)	8 (0.10)	48 (4)	-

Table 6: WHO Prescribing indicators.

Prescribing indicators (n=100)	
Average number of cytotoxic drugs prescribed per prescription.	2.51
Average number of drugs prescribed per prescription.	7.41
Percentage of drugs prescribed from WHO-EDL.	100%
Average number of cytotoxic injections prescribed per prescription.	100

that the most regularly utilized classes of medications were anthracyclines and alkylating agents, which were responsible for ADRs. When this study was analyzed, alkylating drugs were found to cause ADR in (n=72.72%) of the patients, followed by anthracyclines in (n=68.68%). This study demonstrates that ADRs affected the skin, hematology, and gastrointestinal tract, which is the most common. Chemotherapy destroys both cancer cells and rapidly dividing normal bone marrow cells, resulting in myelosuppression that affects WBCs, platelets, and RBCs.¹⁷ Anemia caused by chemotherapy is one of the most serious hematological adverse reactions.¹⁸ In this study, anemia was more common in category 3 patients than the other two groups (p=0.001). The Chi-Square test is a reliable statistical approach for analysing categorical data that determines whether there is

a significant relationship between two categorical variables; it allowed us to determine if the frequency of anemia varied significantly between patient groups based on the number and type of chemotherapy medications used. The low p-value (0.001) indicates that the occurrence of anemia in group 3 patients is most likely linked to the treatment regimen rather than random variation. Alopecia was more significant in category 1 patients, affecting (n=35, 72.9%) of patients, with a statistically significant p-value of 0.04.¹⁹ Patients who had AC+T therapy (category 2) experienced peripheral neuropathy (n=10.25%). Some Adverse Drug Reactions (ADRs) should be highlighted specifically. Two cases of severe hiccups caused by cyclophosphamide were treated in a hospital. The odds ratio findings provide important insights into the ADR risk profiles linked with various chemotherapeutic

medications.²⁰ The increased risk of anemia with carboplatin, neuropathy with paclitaxel, and baldness with doxorubicin and cyclophosphamide emphasize the significance of customized patient treatment. Understanding these risks allows healthcare practitioners to take proactive steps to reduce ADRs, such as dose modifications, symptom monitoring, and supportive care measures.²¹ Furthermore, these findings may influence future research aimed at improving chemotherapy regimens to balance efficacy and tolerability. The ADRs were treated with various drugs. Dexamethasone may affect Doxorubicin metabolism and clearance, changing its therapeutic efficacy and raising the risk of side effects such as cardiotoxicity.²² Similarly, the combination of Doxorubicin and Cyclophosphamide, which is identified in 68% of patients, is widely utilized in chemotherapy protocols but carries major hazards. Both medicines have overlapping toxicities, such as myelosuppression and cardiotoxicity, which can be increased when administered simultaneously. This combination demands close monitoring of blood counts and cardiac function, as well as proactive actions to manage and reduce the negative effects. In this study, injectable ondansetron was the most regularly used drug to treat ADRs, followed by blood transfusion, dexamethasone, and ranitidine. The majority of patients were given antiemetics as preventative medication, including dexamethasone.²³ Nonetheless, the use of premedication has not completely prevented harmful drug reactions. This shows that current ADR prevention and management measures need to be improved. Improved prevention methods and early detection of medication toxicity have the potential to help lessen the severity of adverse drug reactions. Important organ function tests and lab data were missing in 33 patients. Clinical pharmacists and physicians are responsible for ensuring adequate laboratory testing.

CONCLUSION

In conclusion, this study has delved into the critical realm of drug-related problems and prescription auditing in the context of patients undergoing chemotherapy for breast cancer. The exploration of drug-related problems, encompassing issues like drug interactions and adverse reactions, has underscored the need for a comprehensive approach to pharmaceutical care. The vulnerability of breast cancer patients undergoing chemotherapy necessitates heightened vigilance and personalized interventions to mitigate potential risks and enhance treatment efficacy.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

DRP: Drug-related problems; **ADR:** Adverse drug reaction; **BC:** Breast cancer; **UMC:** Uppsala monitoring center; **EDL:** Essential drug list; **CIN:** Chemotherapy induced neutropenia.

ETHICAL APPROVAL AND CONSENT TO PARTICIPATE

The Institutional human ethical committee approved the study (Ref. No: HSK COP /IEC/23/2), Patient consent has obtained before the study.

SUMMARY

This study highlights age as the primary risk factor for breast cancer (BC), with family history and obesity also playing significant roles. The majority of patients received chemotherapy regimens combining doxorubicin, cyclophosphamide, and taxanes, with common adverse drug reactions (ADRs) including anemia, alopecia, and peripheral neuropathy. Alkylating agents and anthracyclines were found to cause the most ADRs. Despite premedication, ADRs were not fully prevented, indicating a need for improved prevention and monitoring strategies. Close monitoring of patients and better detection of drug toxicity were emphasized to mitigate the impact of chemotherapy side effects.

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