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Original Research Article

Adverse drug reactions monitoring among breast cancer patients in a tertiary care teaching hospital

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ABSTRACT

Background: Breast cancer is responsible for 13% of deaths among women globally. The present study aimed to assess adverse drug reactions (ADRs) in breast cancer patients receiving treatment in a tertiary care teaching hospital.
Methods: This retrospective and descriptive study was conducted in the oncology department at sree mookambika institute of medical sciences, Kulasekharam, covering six months from May 2022 to November 2022. The study includes patients of any age diagnosed with breast cancer, treated with chemotherapy, and who developed at least one ADR during or after treatment. Patients who developed ADRs due to fresh blood or blood product infusion and had a history of drug abuse or accidental poisoning were excluded from the study.
Results: Three hundred fifty-eight breast cancer patients were evaluated, of which 142 developed ADRs. The study revealed that breast cancer was most prevalent among women aged 41-50. Seven (4.92%) had a history of tobacco smoking, 129 (90.85%) patients were married, and only 13 (9.15%) were unmarried. The most commonly prescribed chemotherapeutic drug for breast cancer patients was docetaxel (19.01%), Cyclophosphamide (15.49%) and nab. paclitaxel (12.67%). The study found that the most frequent ADR observed among the patients was febrile neutropenia (18.30%), followed by nausea and vomiting 14.79%). Causality assessment reported that 61.27% (87) of the ADRs were probable, and 29.58% (42) were possible.
Conclusions: Spontaneous adverse drug reporting and structured management are essential for monitoring the safe use of drugs. The findings suggest the need for effective pharmacovigilance programs and improved patient care in administering chemotherapeutic agents.

Keywords: ADR, Pharmacovigilance, Breast cancer, Anticancer drugs

INTRODUCTION

The world health organization defines ADR as any harmful and unexpected response to medication at doses typically used in medical treatment, diagnosis, or prevention. Breast cancer is among the most prevalent forms of cancer worldwide. Due to advancements in screening and treatment options, including surgery, radiation, and medication, the survival rate for patients with breast cancer has significantly improved.[1] Chemotherapy is an effective approach in treating numerous tumours, as it can reduce the size of malignant cells before surgery and reduce the risk of breast cancer recurrence following surgery. In advanced breast cancer cases, chemotherapy may be the sole treatment option. However, adverse reactions to medication are common during chemotherapy, affecting 70-80% of patients who undergo the treatment. These reactions can significantly impact a patient's quality of life.[2] ADRs such as alopecia, nausea, vomiting, neutropenia, bone marrow depression, hypersensitivity, hand-foot syndrome, and diarrhoea have been reported during medication treatment. These

reactions are a significant and widespread clinical issue that causes human suffering, extended hospital stays, and increased healthcare costs.[3]

Pharmacovigilance is the scientific discipline that identifies, assesses, and prevents harmful medication reactions. Medication toxicity can be a significant obstacle to providing effective treatment to patients across all levels of healthcare. Identifying ADRs has become increasingly critical as the market for new medications expands. In India, the Pharmacovigilance Program was established in 2010 to monitor drug safety and create an ADR database specific to the Indian population.[4]

Implementing a hospital-based monitoring and reporting program for adverse drug effects can aid in identifying potential ADRs and evaluating the associated risks of using anticancer medications.[5,6] Such programs can also aid in preventing future occurrences of ADRs. Unfortunately, many ADRs go unreported due to a lack of awareness among healthcare professionals and the prescriber's fear of litigation. Therefore, it is crucial to identify and recognize chemotherapy-induced ADRs in breast cancer patients, as doing so can improve the quality of life for patients and reduce associated healthcare costs.

The current study assessed the type and causality of ADRs using the WHO Causality Assessment Scale and evaluated the pattern of ADRs.

METHODS

A retrospective, descriptive case record study was conducted among breast cancer patients under chemotherapy in the oncology department at Sree Mookambika institute of medical sciences, Kulasekharam, for six months, from May 2022 to November 2022. This study was conducted after obtaining approval from the Institutional Ethics committee and informed consent.

Patients of any age diagnosed with breast cancer treated with chemotherapy developed at least one ADR during or after the treatment period were included.

Patients who developed ADR due to fresh blood or blood product infusion, a history of drug abuse, history of accidental poisoning were excluded.

Three hundred fifty-eight breast cancer patients who received chemotherapy were enrolled in this study. Out of which 142 cases developed ADR. Since this institution is an ADR monitoring centre, the clinical and demographic data regarding patient details and occurrence and nature of ADRs, suspected drug, type of ADRs, duration of hospital stay and outcome were directly collected from their medical case records and the data analysis was done.

Data entered into MS excel and calculated. Demographic data were presented in frequency and percentages.

RESULTS

Most patients fall within the age range of 41-50 years, with 63 patients (44.37%) and the least affected age group was found to be 31-40 years (13.38%). All 142(100%) patients were female, and 7 (4.92%) were tobacco-smoking. The 129 (90.85%) patients were married (Table 1).

Table 1: Demographic details of the breast cancer patients, (n=142).

Variables		N	Percentage (%)
Age group (Years)	31-40	19	13.38
	41-50	63	44.37
	51-60	34	23.94
	>60	26	18.30
Gender	Male	0	0%
	Female	142	100
Tobacco use	Yes	7	4.92
Marital status	Unmarried	13	9.15
	Married	129	90.85

Table 2: Suspected anticancer drugs causing ADRs, (n=142).

Suspected anticancer drugs causing ADRs	N	Percentage (%)
Adriamycin	19	13.38
Cyclophosphamide	22	15.49
Docetaxel	27	19.01
Paclitaxel	9	6.33
Gemcitabine	19	13.38
Trastuzumab	17	11.97
Nab. paclitaxel	18	12.67
Capecitabine	11	7.74

The most commonly used drug causing ADR was docetaxel, used in treating 27 patients (19.01%), followed by cyclophosphamide (15.49%), gemcitabine (13.38%) and adriamycin (13.38%). The least commonly used drug was paclitaxel (6.33%) (Table 2).

Table 3: Distribution of pattern of ADRs among patients, (n=142).

Pattern of ADRs	N	Percentage (%)
Infection	18	12.67
Nausea /vomiting	25	17.6
Alopecia	10	7.04
Febrile neutropenia	26	18.3
Allergic reaction	19	13.38
Hand foot syndrome	1	0.7
Bone marrow suppression	13	9.15
Fatigue	14	9.86
Diarrhoea	16	11.27

The most commonly reported ADR was febrile neutropenia and nausea/vomiting (18.30%) and (17.60%), respectively, followed by an allergic reaction (13.38%) and infection (12.67%). In contrast, hand foot syndrome was reported as the least common ADR (Table 3).

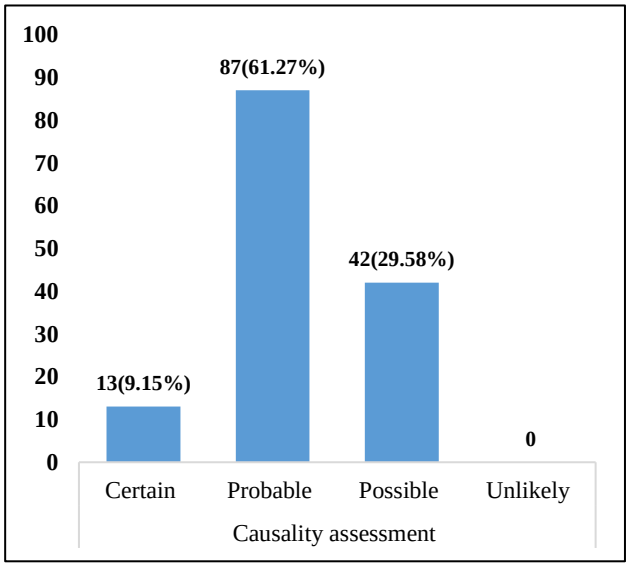

Figure 1: Distribution of causality assessment.

Most reported ADRs were assessed to be probable at 61.27%, followed by possible 29.58% (Figure 1).

DISCUSSION

This study aimed to monitor ADRs among breast cancer patients in a tertiary care hospital and assess causality using the WHO causality assessment scale. The study found that the majority of patients (44.37%) were treated in the age group of 41-50 years, which is consistent with previous research conducted by Chopra et al.[7] Balkhi et al conducted a study on neoadjuvant therapy and found that docetaxel was frequently used in this setting.[8] Hormonal therapy commonly involved letrozole, while targeted therapy often included trastuzumab. In our study, 27 patients (19.01%) received docetaxel, which is the most frequently used drug, followed by cyclophosphamide (15.49%), gemcitabine (13.38%) and adriamycin (13.38%). These findings contradict the Chopra study, where cisplatin was the most commonly prescribed drug.[7] Our study found that most breast cancer patients (90.85%) were married, while only a small percentage (9.15%) were unmarried. This is in contrast to the meta-analysis of 49 publications, which found that unmarried and lifelong single women had a higher risk of breast cancer compared to married women.[9]

The study revealed that febrile neutropenia (18.30%) was the most frequently reported ADR, followed by nausea and vomiting (17.6%). These results differ from Nath et al studies, which identified mucositis and respiratory disorders as the most prevalent ADRs.[10] Belachew et al findings indicated that the most common ADRs were nausea and vomiting (18.9%), infections (16.7%) and neutropenia (14.7%).[11] Additionally, Sharma et al reported that the most frequent ADRs were infections (22.4%), nausea/vomiting (21.6%), and febrile neutropenia (13%).[12] In this study, the WHO causality assessment scale revealed that 61.27% of ADRs were classified as probable, and 29.58% were classified as possible. This differs from the study conducted by Wahlang et al which found that 80% of ADRs were classified as possible.[13]

Overall, this study provides important information about the prevalence of ADRs and the causality of these reactions among breast cancer patients. The differences in findings between this study and previous research suggest that ADR variability may depend on factors such as drug therapy and patient population. These findings underscore the importance of monitoring and managing ADRs in breast cancer patients and highlight the need for further research to understand these reactions' impact on patient outcomes.

CONCLUSION

These findings highlight the need for effective pharmacovigilance programs to identify and manage ADRs in breast cancer patients, particularly while administering chemotherapeutic agents. It is important to monitor and address these ADRs to enhance patient safety and improve the quality of care for breast cancer patients in India.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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