ORIGINAL RESEARCH PAPER
Volume - 12 | Issue - 05 | May - 2023 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

"PHARMACOVIGILANCE IN RADIOTHERAPY DEPARTMENT DUE TO CANCER CHEMOTHERAPY IN A TERTIARY CARE TEACHING HOSPITAL, JAMNAGAR"

Pharmacology

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ABSTRACT

Background & objectives: An adverse drug reaction (ADR) is defined by World Health Organization (WHO) as 'Any response to a drug which is noxious, unintended and occurs at doses used in man for prophylaxis, diagnosis or therapy'. ADRs associated with cancer chemotherapy warrant analysis on their severity and preventability. The objective of this study is to analyse the pattern of ADRs to chemotherapeutic agents in cancer patients. **Methods:** A total of 147 cancer patients in oncology ward of a tertiary care hospital, Jamnagar were monitored for suspected ADRs during the course of chemotherapy from 8th January 2022 to 7th July 2022. Clinical events were recorded and analysed with regard to the demographics and drug details of the patients. **Results:** A total of 92 ADRs were recorded from 147 cases. The ADRs commonly encountered included anemia , vomiting, thrombocytopenia, mucositis, leukopenia, alopecia, hearing loss, hypernatremia, and myalgia. Cisplatin, paclitaxel, carboplatin and docetaxel were used for the treatment of commonly found cancers in this region. Naranjo's causality assessment showed 48.92% possible (score 1-4) and 51.08% probable (score 5–8). Severity of adverse reactions showed 68.48% mild, 25% moderate and 6.52% severe. A total of 11.96% of ADRs were preventable reactions. **Conclusions:** This study emphasises the need of active monitoring as a crucial tool for the early detection, evaluation and prompt management of adverse drug reactions in cancer chemotherapy patients. The observed ADRs were preventable although ADRs such as anemia, hypernatremia and alopecia were not preventable.

KEYWORDS

Adverse drug reactions, Cancer, Chemotherapy, Naranjo causality assessment, Tertiary care hospital.

INTRODUCTION

The development and use of drugs in various types of diseases has brought wonders to the human race but it has also set new threats in the form of adverse drug reactions (ADRs). According to WHO an Adverse drug reaction (ADR) is defined as "a response to a drug which is noxious & unintended, which occurs at doses normally used in human for prophylaxis, diagnosis or therapy of disease or for modification of physiological function".[1] Worldwide, ADRs accounted for 10% of hospital admissions [2] and 6% of hospitalized patients suffer from ADRs.[3] With the introduction of pharmacovigilance in recent times, more ADRs are reported and documented in various parts of the world.

Effect of ADRs on patients includes the lowering of quality of life, increase in number of hospitalizations, increased economic burden on health management and increased rate of mortality.[4]

Many of the adverse effects of anticancer agents are an extension of their therapeutic action disturbing all fast-dividing cells and anticancer agents have become one of the major causes of complications of cancer treatment that affect the patient's survival, treatment outcomes and morbidity and mortality rates. ADRs are so common in oncology that they came around to being accepted as a foreseeable component of the cancer therapy.[5]

Pharmacovigilance activities aimed to monitor the safe use of medicines are particularly important in oncology due to the inherent toxicity of anticancer agents.[6] Knowledge of the toxicity profile of the main drugs used in cancer treatment is important strategically for prevention, detection and early management of suspected adverse drug reactions (ADRs) related to cancer chemotherapy. Spontaneous reporting of ADRs contributes substantially to signal detection in drug safety surveillance, especially for rare and acute reactions; hence, the objective of this evaluation.[7]

METHODS

Study Design

The study was a hospital-based prospective observational study conducted from 8th January 2022 to 7th July 2022 in patients who received chemotherapy in the oncology ward of a tertiary care hospital after taking approval from the Institute Ethics Committee (approval no.:16/01/2022). A total of 147 patients gave written informed consent to participate in the study. Consent forms were in a predesigned format approved by the Institute. All 147 patients were interviewed and monitored during the course of chemotherapy for any possible ADR.

Data Collection

Appropriate proforma forms developed in accordance with the ADR reporting form of the Central Drugs Standard Control Organization (CDSCO), Government of India, were used for collecting data regarding the patients' demographic profile, the details of drugs received during chemotherapy session and also any pre-existing medical condition which may lead to any ADR.

Data Analysis

The pattern of ADRs obtained was analysed. The suspected drugs were identified and their causal associations were analysed by using the Naranjo scale. The severity and preventability of ADRs were analysed by using the Hartwig Siegel's severity assessment scale and the Schumock and Thornton scale, respectively.

RESULTS

Patient's Demographic Pattern

A total of 147 patients who were receiving cancer chemotherapy participated in our study, among which 82 (55.78%) were male and 65 (44.22%) were female. Out of 147 patients only 92 patients were developed adverse drug reaction (ADR) in our study, among which 57 (61.96%) were male and 35 (38.04%) were female.

Analysis Of ADRs With Suspected Drugs

In our study, ADRs were found in 92 patients out of the 147 participants and a total of 92 ADRs were recorded and analysed. The ADRs were seen more in male participants which accounted for 61.96% (n = 57) than in female participants which accounted for 38.04% (n = 35). Among the ADRs encountered, the most common was anaemia (30.43%), which was followed by vomiting (18.48%), thrombocytopenia (16.33%), mucositis (15.21%), leukopenia

(6.52%), alopecia (5.43%), hearing loss (3.26%), hypernatremia (2.17%) & myalgia (2.17%). (Table 1).

Table 1: Most Common ADRs Due To Anti-cancer Drugs

Sr No.	ADR	No. Of ADR	Percentage (%)
1	Anemia	28	30.43
2	Vomiting	17	18.48
3	Thrombocytopenia	15	16.33
4	Mucositis	14	15.21
5	Leukopenia	6	6.52
6	Alopecia	5	5.43
7	Hearing loss	3	3.26
8	Hypernatremia	2	2.17
9	Myalgia	2	2.17

Analysis Of Types Of Cancer And Chemotherapeutic Agents

The commonly used drugs for chemotherapy in patients were the cisplatin, carboplatin, paclitaxel and docetaxel for the treatment of cancers of oral cavity, supraglottic, lung, glottis, larynx and breast. Most common anti-cancer drugs causing ADRs in this study are cisplatin, paclitaxel, carboplatin and docetaxel. (Table 2)

Table 2: Most Common Anti-cancer Drugs Causing ADRs

Sr No.	Drug	No. Of ADRs	Percentage (%)
1	Cisplatin	39	42.39
2	Paclitaxel	27	29.35
3	Carboplatin	19	20.65
4	Docetaxel	7	7.61

Causality And Severity Assessment

The ADRs were analysed for causality assessment with the Naranjo scale which showed 51.08% probable (score 5–8) and 48.92% possible (score 1-4) association with the suspected drugs.

The assessment of the severity of adverse reactions by using the Hartwig scale showed that 68.48% were mild, 25% were moderate and 6.52% were severe.

Preventability was assessed by using the Modified Schumock and Thornton scale which showed that 11.96% of reactions seen in our study were mostly preventable, while 88.04% were not preventable.

DISCUSSION

After the ADRs were collected and analysed, we observed that in our study the population belonging to the mean age group of 46 years were more prone to the development of ADRs during cancer chemotherapy which can be compared with one study Poddar et al.[8] that was conducted in Bangladesh. The incidence of ADRs was greater in male participants (61.96%) as compared with female participants (38.04%) which can be explained from the higher incidence of lung & oral cancer seen in our setting as also reported from western and eastern parts of India showed in Goyale et al. [9] & Prasad et al. [10] However, studies from other parts of India and Bangladesh showed a higher incidence of ADRs in cases affecting female patients like in Sharma et al.[11]& Poddar et al.[8]

Cisplatin, carboplatin, paclitaxel and docetaxel containing regimens were commonly used and were found to be associated with most of the ADRs in our setting which is comparable with other study reports like Sharma et al.[11]

In our study, the most common organ system affected was blood which was followed by gastrointestinal tract. This finding was related to the results of the study named Mallik et al.[12] While in Chopra et al.[13] found that gastrointestinal tract is the most frequently involved organ system which was followed by blood system.

The most common ADR due to anticancer drug in our setting was anemia followed by vomiting. This is similar to the study conducted by Gunaseelan et al.[14] in which anemia was the most common ADR. According to a study by Sharma et al.[11] most commonly occurring ADRs were infections (22.4%), nausea/ vomiting (21.6%), febrile neutropenia (13%) and anaemia (7.2%). The reason for these variations could be the non-reporting of mild ADRs like nausea and vomiting.

A total of 18.48% cases of vomiting is reported in our setting which is significantly lower as compared with 31.5% that was reported in other study like Kirthi et al.[15] The lower incidence of this adverse reaction in our patients is attributed to the prompt premedication with antiemetic drugs such as granisetron as well as to the judicious administration of ranitidine, pantoprazole and dexamethasone.

In our study, a total of 5.43% patients suffered from alopecia, a figure which is less as compared with 51% and 58% that were reported in previous studies like Surendiran et al.[16]and Poddar et al[8].

On analysing the causality assessment of the ADRs by the Naranjo score, we found that 51.08% of cases showed probable and 48.92% showed possible association whereas Khandelwal et al.[17] reported 100% and Goyal et al.[9] reported 61% of probable scores using the same scale.

Analyses of the severity of these adverse reactions using Hartwig's severity scale revealed that majority of the ADRs (68.48%) were mild followed by moderate (25%) and severe (6%), a finding which was comparable with the above two studies conducted in western and southern India.

Assessment of the preventability by the Schumock and Thornton scale showed that only 11.96% of the ADRs could have probably been prevented in patients who had symptoms of vomiting, myalgia , and mucositis where appropriate premedication was given and proper dietary counsel was ensured before the start of chemotherapy.

CONCLUSION

The analysis of ADRs associated with the cancer chemotherapy in a hospital setup gives an insight regarding the causality, severity and preventability of the identified ADRs. It may also create awareness among the treating physicians that can prevent further occurrence of similar ADRs in the same patient. Pharmacovigilance is of utmost importance to ensure safe and effective medications, more so in palliative health care services. Proper evaluation of ADRs helps in preventing their recurrence in subsequent chemotherapeutic cycles. Our study highlighted the common ADRs of anticancer drugs as well as their causality, severity and preventability. The intensive surveillance from our end has led to early detection of some common but important ADRs and to some extent contributed towards achieving the goal of pharmacovigilance in this part of the country**.**

Acknowledgements

The authors are immensely grateful to the Institutional Ethical Committee for approval of the study. We wish to thank the patients and staff of the Oncology department of Guru Gobind Government Hospital, Jamnagar, for their cooperation in this study. We are also grateful to our Dr. Nandini Desai (Dean of Shri M.P.Shah Government Medical College and hospital, Jamnagar), Dr. H.R.Trivedi (Head of Department, Pharmacology) and Dr. Shilpa Jadav (Assistant professor, Department of Pharmacology) for their kind cooperation, guidance and support for successful completion of the study.

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