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Original Research Article

An insight into the adverse drug reactions considering causality, severity, preventability and adherence among patients receiving anticancer drugs at a North Indian rural tertiary care centre

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ABSTRACT

Background: The cytotoxic nature of anticancer drugs and their limited therapeutic index make adverse drug reactions (ADRs) a significant challenge in therapeutics in oncology. These adverse drug reactions have a major effect on quality of life, therapeutic results and patient adherence. An estimated 1,392,179 cancer cases were reported in India in 2020, representing an incidence rate of 98.7 incidences per 100,000 people. With a prevalence of 10-12%, ADRs are more common among hospitalised and elderly patients. It is essential to comprehend the causality, severity and preventability of ADRs in order to optimise cancer treatment and enhance patient safety.
Methods: An observational study was conducted at a tertiary care centre in western Uttar Pradesh. Chemotherapy patients were observed for adverse drug reactions. The Modified Hartwig and Siegel scale was used to assess the severity, the WHO-UMC scale was used to determine causality and the Schumock and Thornton criteria were used to determine preventability. Treatment adherence was also examined using Modified Morisky scale.
Results: The most frequent ADRs were gastrointestinal and haematological. The majority of ADRs were categorised as moderately severe, mostly non-preventable and probable in the causation evaluation. In several instances, treatment adherence was impacted.
Conclusions: ADRs from anticancer drugs continue to be a major clinical problem. Risks can be mitigated and patient safety can be enhanced with timely intervention and regular monitoring.

Keywords: Adverse drug reactions, Anticancer drugs, Causality assessment, Oncology, Preventability, Pharmacovigilance, Severity grading

INTRODUCTION

Adverse drug reactions (ADRs) are a significant concern in oncology, where anticancer drugs, due to their narrow therapeutic indices and complex pharmacodynamics, often result in a high incidence of ADRs. These reactions can range from mild to life-threatening, impacting patient adherence to treatment regimens and overall outcomes. Most anti neoplastic drugs have a narrow therapeutic index and are liable to cause several ADR's. These adverse drug effects lead to poor compliance by patients. In India, the projected number of cancer patients are 1,392,179 and the incidence of cancer is about 98.7 per 100,000 population in the year 2020.[1] Multimodal approaches like chemotherapy, radiotherapy, immunotherapy, hormonal therapy, surgery, biological agents, cryosurgery are available for the treatment of cancer.[2] Assessing the causality, severity and preventability of ADRs is crucial in managing cancer therapy, as it helps in identifying risk factors, optimizing drug use and improving patient safety.

Antineoplastic agents having narrow therapeutic index are more cytotoxic and can damage the normally dividing cells along with the cancerous cells. Patients taking anticancer drugs are more prone to develop ADRs because of multidrug treatments.[3] The prevalence of ADRs of anticancer drugs, in Indian context, is 10-12%.[4] Elderly and hospitalised patients (16.6%) are more susceptible to develop ADRs than the adult population (4.1%).[5]

Moreover, adherence to anticancer treatment is often compromised due to the fear of ADRs, leading to suboptimal therapeutic outcomes. Understanding the patterns and predictors of ADRs and their influence on adherence can inform strategies to mitigate risks and enhance treatment efficacy. In a tertiary care setting, where complex cases are managed, this study aims to systematically evaluate the ADRs associated with anticancer drugs, focusing on their causality, severity, preventability and the impact on patient adherence.

Indian hospitals struggle to monitor side effects of cancer medications, hindering effective treatment. Limited research on drug safety in India prompted our study, analyzing adverse drug reactions in cancer patients undergoing chemotherapy at a tertiary care hospital in western UP.

To determine the nature and severity of ADRs in cancer patients on anticancer drug from the Department of Radiotherapy and Oncology of a tertiary care teaching hospital.

Objectives

Determine the likelihood of ADR caused by anti-cancer drugs. Evaluate the severity of adverse drug reactions. Assess the preventability of adverse drug reactions. Ascertain patient adherence to therapy influenced by ADRs caused by chemotherapeutic agents.

METHODS

Study design and setting

This descriptive study was conducted at the Uttar Pradesh University of Medical Sciences (UPUMS), Saifai, Etawah, a tertiary care center known for its comprehensive oncology services. The study focused on patients who developed adverse drug reactions (ADRs) due to anticancer drugs between March 2023 and October 2023.

Sampling technique

A conventional sampling technique was employed to select participants. This method was chosen to ensure the inclusion of patients who experienced ADRs during their course of anticancer therapy. The study included patients across different cancer types and treatment regimens to capture a diverse range of ADRs.

Sample size

As a conventional sampling technique was employed, a total of 83 patients were analysed. This sample size reflects the context of a rural tertiary care center, where awareness regarding adverse drug reactions and their significance remains limited, primarily due to factors such as illiteracy and other sociodemographic variables

Study tools

WHO-UMC causality assessment scale

This scale was used to evaluate the causality of the ADRs. It categorizes ADRs into different levels (certain, probable, possible, unlikely, etc.) based on the relationship between the drug and the observed reaction.

Modified Hartwig and Siegel scale

This tool assessed the severity of the ADRs. The scale classifies reactions into mild, moderate or severe, considering factors such as the need for treatment modification, hospitalization or permanent disability.

Schumock-Thorton Scale

This scale was used to assess the preventability of the ADRs. It helps determine whether the ADR could have been avoided with appropriate measures during treatment.

Modified Morisky scale

To evaluate patient adherence to anticancer drug regimens, the Modified Morisky Scale was utilized. This tool measures adherence based on patient responses to specific questions related to their medication-taking behavior.

Data collection and analysis

Data were collected through patient interviews and documentation of observed ADRs during treatment. Each ADR was assessed for causality, severity and preventability using the respective scales. Patient adherence to prescribed anticancer drugs was also evaluated.

The collected data were systematically entered and analysed using SPSS 29. Descriptive statistics, including frequencies and percentages, were calculated to present the distribution and characteristics of ADRs, as well as adherence patterns. The results were then assessed, to determine the nature, severity, adherence and preventability of Adverse Drug Reactions in patients taking chemotherapeutic agents.

Ethical considerations

The study was conducted following ethical guidelines, with approval obtained from the Institutional Ethics

Committee of UPUMS. Informed consent was secured from all participants, ensuring confidentiality and the right to withdraw from the study at any time.

RESULTS

A total of 334 ADRs were reported from 83 patients. Total 62.6% females developed ADRs and age group of 51-60 years (31.10%) were affected the most. Bronchogenic carcinoma (20.9%) was found to be the most common cancer. Most common ADRs observed was emesis (52%) followed by alopecia (38%).

Figure 2 illustrates the distribution of ADRs based on the WHO-UMC causality assessment scale. The majority of ADRs were classified as "Probable" (45%), followed by "Possible" (32.75%) and "Certain" (11%). Smaller proportions were categorized as "Unlikely" (6.25%), "Conditional" (3%) and "Unclassifiable" (2%).

Figure 3 displays the distribution of patient adherence based on the Modified Morisky Scale. It shows that 69% of the patients have good knowledge about their medication regimen, while 31% are high in motivation to adhere to their treatment.

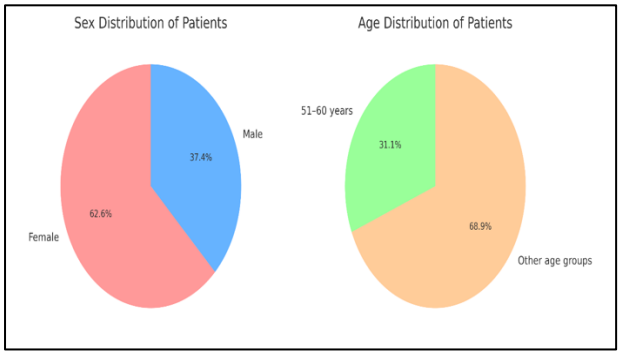

Figure 1: Sex and age distribution of the Patients.

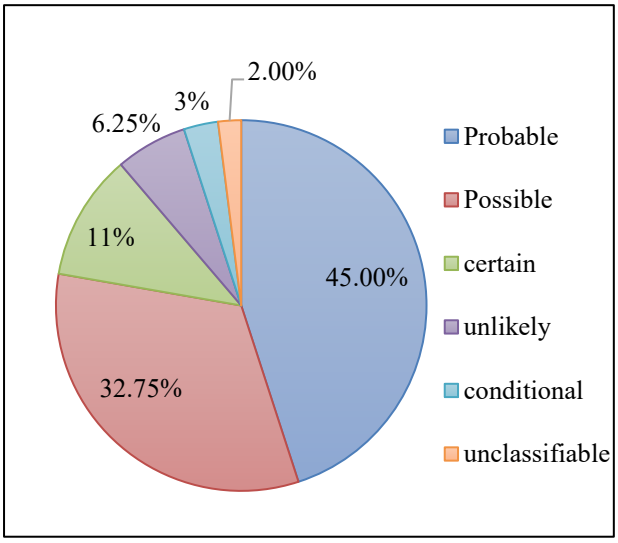

Figure 2: WHO-UMC causality.

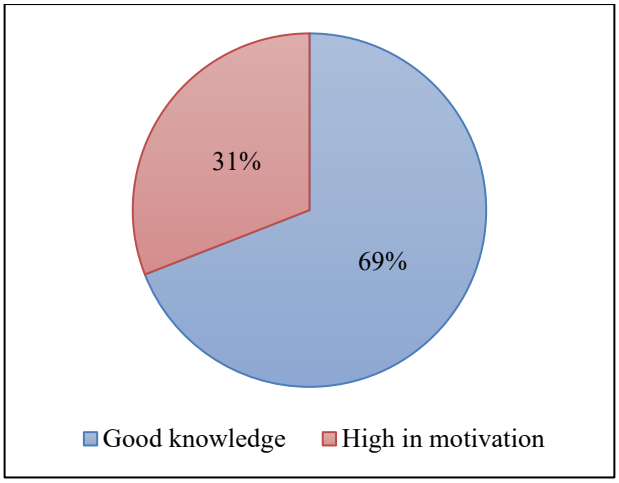

Figure 3: Modified Morisky Scale.

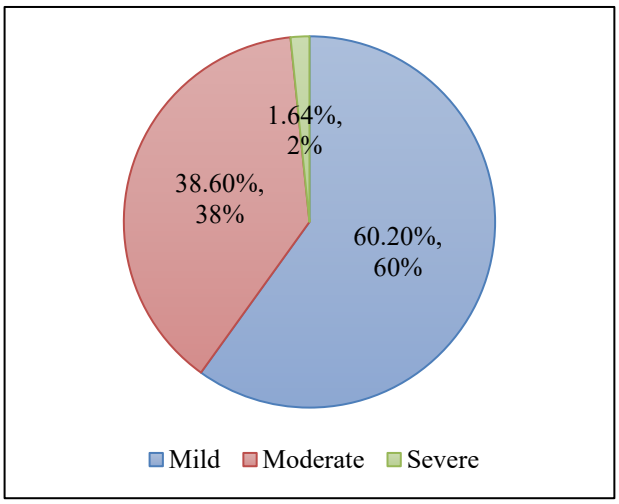

Figure 4: Modified Hartwig and Siegel scale.

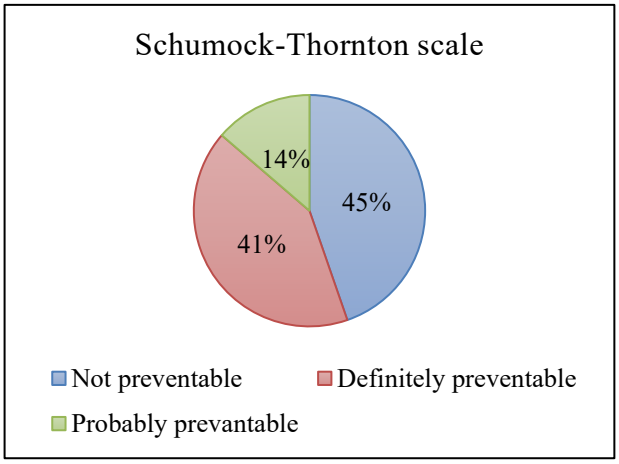

Figure 5: Schumock-Thornton scale.

Figure 4 shows the severity distribution of ADRs based on the Modified Hartwig and Siegel scale. The majority of ADRs were classified as "Mild" (60.2%), followed by

"Moderate" (38.6%). A small percentage of ADRs were categorized as "Severe" (1.64%).

Figure 5 illustrates the distribution of preventable and non-preventable events according to the Schumock-Thornton scale with three categories: "Not preventable" (45%), "Definitely preventable" (41%) and "Probably preventable" (14%).

The table 1 shows the adverse drug reactions (ADRs) experienced by patients receiving anticancer drugs. Alopecia was the most common ADR (17.32%), followed by anorexia (14.66%) and anemia (14.24%). Leucopenia and nausea/vomiting each affected 10.73% of patients. Less common ADRs included oral candidiasis (4.38%), neuropathy (4.27%) and bicytopenia (4.27%). Rare ADRs, such as anaphylaxis, rashes and headache, occurred in about 1% or less of patients. These findings highlight the most frequent and significant ADRs in cancer therapy.

Table 2 lists the anticancer drugs used in the study, along with their corresponding usage percentages. Carboplatin was the most commonly used drug (20.21%), followed by Cisplatin (14.71%) and Paclitaxel (10.32%). Other frequently used drugs included Docetaxel (8.93%) and Oxaliplatin (7.34%). Less commonly used drugs such as Gemcitabine (5.95%), Cyclophosphamide (4.77%) and 5-Fluorouracil (3.71%) were also noted. Drugs like Vincristine, Doxorubicin and Etoposide were used in smaller percentages, each under 3%. The "Others" category accounted for 1% of the drugs used. This distribution emphasizes the predominance of platinum-based chemotherapies (Carboplatin and Cisplatin) and taxanes (Paclitaxel and Docetaxel) in cancer treatment regimens.

Table 1: Adverse drug reactions (ADRs) experienced by patients receiving anticancer drugs.

Adverse drug reactions	N (%)
Alopecia	17.32
Anorexia	14.66
Anaemia	14.24)
Leucopenia	10.73
Nausea and vomiting	10.73
Oral candidiasis	4.38
Neuropathy	4.27
Bicytopenia	4.27
Itching	4.16
Diarrhoea	2.4
Pain abdomen	1.64
Thrombocytopenia	1.42
Anaphylaxis	1.09
Rashes	1.09
Headache	0.98
Myalgia	0.98
Hand and foot syndrome	0.87
Dizziness	0.87
Insomnia	0.66
Constipation	0.66
Hepatotoxicity	0.55
Facial flushing	0.55
Mucositis	0.55
Fever	0.55
Pancytopenia	0.44
Gastritis	0.44
Others	1.31

Table 2: Anticancer drugs used in the study, along with their corresponding usage percentages.

Drugs used number (%)	(%)
Carboplatin	20.21
Cisplatin	14.71
Paclitaxel	10.32
Docetaxel	8.93

Continued.

Drugs used number (%)	(%)
Oxaliplatin	7.34
Gemcitabine	5.95
Cyclophosphamide	4.77
5-Fluorouracil	3.71
Vincristine	2.78
Doxorubicin	2.58
Etoposide	2.58
Capecitabine	2.38
Pemetrexed	2
Erlotinib	1.56
Leucovorin	1.59
Rituximab	1.59
Methotrexate	1.39
Others	1

DISCUSSION

This study investigated the nature and severity of adverse drug reactions (ADRs) experienced by cancer patients receiving anticancer drugs at a tertiary care teaching hospital. Key findings highlighted a significant proportion of patients (62.57%) experiencing at least one ADR during treatment. Emesis (vomiting) was the most prevalent ADR, followed by alopecia. The majority of ADRs were classified as "probable" or "possible" by the WHO-UMC causality assessment scale. Most were categorized as "mild," but a small percentage were "severe". Similar finding was demonstrated by Mishra et al.[6] While 69% of patients demonstrated good knowledge about their medications, only 31% showed high motivation for adherence, suggesting potential barriers to treatment compliance. Carboplatin and Cisplatin were the most frequently used anticancer drugs.

The high incidence of ADRs underscores the potential complications associated with cancer therapy. Emesis and alopecia are well-established ADRs, particularly with drugs like cisplatin and carboplatin. The dominance of "probable" and "possible" causality necessitates further investigation to confirm specific drug-related reactions. While most ADRs were mild, the presence of severe cases emphasizes the critical need for close patient monitoring and management strategies to minimize adverse effects. The moderate level of adherence could be attributed to various factors, including the side effects themselves, treatment regimen complexity or psychological distress. Genderwise, female (62.5%) female experienced most ADRs, in the age spectrum of 51-60 years this is in sync with the study conducted by Mukeram et al who demonstrated similar findings.[7] Advanced age could have been one of the reasons for the same.

The study identified a higher prevalence of ADRs in the 41-60-year age group, aligning with Pushpalatha and Durga et al.[8] This vulnerability could be due to altered drug metabolism, comorbidities and polypharmacy, which are more common in older individuals. Similarly, breast, lung and colorectal cancers exhibited the highest ADR rates, reflecting global cancer statistics by Chopra et al.[9] This association underscores the need for tailored pharmacovigilance strategies for different age groups and cancer types.

The findings revealed a predominance of gastrointestinal disorders, followed by hematological abnormalities and dermatological reactions, aligning with Wahlang et al, Akbarali et al and Reilly et al.[10-12] Notably, 31.74% of ADRs were classified as severe, emphasizing the importance of proactive management, as highlighted by Romalt et al.[13] Strategies like antiemetic prophylaxis and scalp cooling can improve patient comfort and adherence.

The majority of ADRs (72.46%) were categorized as "probable," reflecting the complexity of establishing causality in cancer patients with multiple medications and co-existing illnesses. This aligns with the challenges discussed in previous research. Furthermore, 76.35% of ADRs were classified as predictable similar to Anik et al.[14] This suggests opportunities for proactive risk mitigation through comprehensive patient education and close monitoring.

This study was conducted at a single center with a limited sample size. Additionally, the retrospective design relies on medical record data, which might not capture all ADRs experienced by patients.

CONCLUSION

The study highlights the importance of comprehensive patient education regarding potential ADRs associated with anticancer drugs. Implementing preventive measures, such as antiemetic prophylaxis for nausea and vomiting and scalp cooling for alopecia, could improve patient tolerance and adherence to treatment. Prospective studies with larger sample sizes could provide more robust data on the prevalence and causality of ADRs. Research could

explore the impact of ADRs on patient quality of life and identify strategies to improve symptom management. Investigating factors influencing patient adherence to anticancer medications could inform interventions to enhance treatment completion.

This study provides valuable insights into the nature and severity of ADRs experienced by cancer patients undergoing anticancer therapy. By acknowledging these challenges and implementing strategies to mitigate them, healthcare professionals can optimize treatment outcomes and patient well-being.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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