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Research Article

INCIDENCE AND MANAGEMENT OF CHEMOTHERAPY-INDUCED ADVERSE DRUG REACTIONS IN CANCER PATIENTS

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ABSTRACT

Objectives: The objective of the study is to evaluate the prevalence, pattern, severity, causality, and preventability of chemotherapy-induced adverse drug reactions (ADRs) in cancer patients at a north Indian rural tertiary care teaching hospital.

Methods: One hundred cancer patients undergoing chemotherapy were recruited for this 12-month prospective observational study. Purposive sampling was employed, and data were gathered through patient interviews, interactions with healthcare professionals, and spontaneous ADR reporting. The Schumock and Thornton scale, the Modified Hartwig and Siegel scale, and Naranjo's scale were used to evaluate the causation, severity, and preventability of ADRs.

Results: Among 100 patients, 58% were female and 48% were aged 41–60 years. A total of 271 ADRs were reported. Combination therapy accounted for 78% of ADRs, while 22% were linked to monotherapy. Gastrointestinal ADRs were the most frequent (38.75%), followed by skin-related and hematological reactions. Most ADRs were classified as mild (84.87%), possible in causality (67.15%), and not preventable (64.94%). Despite ADRs, 77% of patients continued chemotherapy.

Conclusion: Chemotherapy-induced ADRs are common and predominantly associated with combination regimens. Strengthening pharmacovigilance and implementing individualized treatment strategies may help to mitigate and address ADR burden, thereby improving patient outcomes.

Keywords: Chemotherapy, Adverse drug reactions, Pharmacovigilance, Cancer, Anticancer drugs.

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INTRODUCTION

Cancer remains one of the most formidable challenges in global healthcare, with its incidence and mortality rates continuing to rise [1]. According to the Global Cancer Observatory (GLOBOCAN) 2020 report by the International Agency for Research on Cancer, approximately 19.2 million new cancer cases and 9.9 million cancer-related deaths were recorded globally in 2020. In India, the scenario is equally alarming with an estimated 1.39 million new cancer cases and an incidence rate of about 98.7/100,000 population in the same year [2]. Despite significant advancements in the understanding and treatment of various malignancies, cancer continues to evoke fear and hardship among patients and their families, largely due to its association with severe side effects and the limitations of current therapeutic approaches.

The main treatment options for cancer are surgery, radiation therapy, and chemotherapy [3]. Although chemotherapy is a key component in cancer care, it often leads to various adverse drug reactions (ADRs) that can greatly affect patients' quality of life. The World Health Organization describes ADRs as harmful and unintended effects resulting from a drug taken at standard doses for prevention, diagnosis, or treatment. The narrow therapeutic index of many anticancer drugs often leads to toxicities that can be as debilitating as the disease itself. These toxicities arise due to the cytotoxic nature of chemotherapy, which, while targeting cancer cells, also damages healthy, rapidly dividing cells, leading to a range of adverse effects [4].

Given the widespread use of chemotherapy in cancer treatment, understanding and managing ADRs associated with anticancer drugs is of paramount importance. In India, the prevalence of ADRs related to anticancer drugs ranges between 10 and 12%, with a higher incidence observed among elderly and hospitalized patients. ADRs not only affect patient health and increase mortality rates but also place a considerable financial strain on healthcare systems. It is estimated that managing ADRs accounts for around 1.7% of a hospital's overall budget, underscoring the importance of effective pharmacovigilance and strategies for managing ADRs [5].

Despite the availability of newer, more targeted therapies, traditional chemotherapy agents continue to play a critical role in cancer treatment. However, these agents are associated with a higher risk of ADRs due to their nonspecific mechanism of action. While targeted therapies and biologics offer the promise of reduced toxicity, they are not without their own set of ADRs, including immunogenicity and infusion-related reactions. Furthermore, the underreporting of ADRs, particularly in low- and middle-income countries like India, exacerbates the challenge of accurately assessing and managing these reactions [6].

There is a clear gap in the literature concerning the comprehensive monitoring and evaluation of ADRs associated with anticancer drugs in the Indian context. Most studies have focused on specific drug classes or patient populations, leaving a significant gap in our understanding of the overall burden of ADRs in cancer patients undergoing chemotherapy. This study seeks to address this gap by systematically quantifying the prevalence, severity, and preventability of ADRs in a cohort of cancer patients treated at a tertiary care teaching hospital in North India.

The main goal of this study is to determine the prevalence of ADRs linked to anticancer medications in a tertiary care teaching hospital in North India. Specifically, the study aims to:

1. Evaluate the pattern of ADRs associated with different classes of anticancer drugs
2. Estimate the frequency and severity of these ADRs
3. Assess the causality of the observed ADRs using standardized pharmacovigilance tools
4. Determine the preventability of ADRs to identify potential areas for intervention and improvement in clinical practice.

METHODS

A prospective, observational, follow-up study was conducted in the Department of Radiation and Surgical Oncology at Uttar Pradesh University of Medical Sciences, Saifai, Etawah after getting approval from Institutional Ethics Committee (534/UPUMS/DSW/Ethical/2022–2023 dated December 22, 2022). The study spanned 12 months, from January 2023 to February 2024, and involved patients who were undergoing cancer chemotherapy.

Study population

It is purposive sampling method was used where at least 30 patients were needed for statistical robustness, i.e., for statistical precision in our study, we recruited 100 patients. Purposive sampling technique was used owing to the peculiarity of the study (as study was performed on rural population having developing areas following Chemotherapy). Over a period of 12 months, we monitored 100 patients and observed a total of 271 ADRs, adhering to the inclusion and exclusion criteria of our study. Informed consent was obtained from all participants before enrollment, ensuring that they were fully aware of the study's objectives and procedures. Confidentiality of the patient's identity was maintained.

Data collection

Data were gathered using the following methods:

- Spontaneous ADR reporting method was employed for data collection
- Interviews were conducted with patients or their caregivers
- Discussions were held with healthcare professionals
- Case sheets, treatment charts, and investigation reports were reviewed
- ADRs suspected by healthcare providers were reported using the form designed by the Central Drug Standard Control Organization (CDSCO). That is standard ADR reporting Forms.

Statistical analysis

Data so collected was tabulated in an Excel sheet under the guidance of statistician. The means and standard deviations of the measurements per group were used for statistical analysis (Statistical Package for the Social Sciences [SPSS] 25.00 for Windows; SPSS inc., Chicago, USA). Difference between two groups was determined using Chi-square test and the level of significance was set at $p<0.05$. For qualitative and quantitative data, descriptive and inferential statistics (mean, frequency, Chi-square test, and regression) are used wherever needed.

Data analysis

The study examined data from 100 cancer patients treated at UPUMS, Saifai, Etawah. Sources of data included spontaneous ADR reports, interviews with patients and caregivers, discussions with healthcare professionals, and reviews of case sheets and treatment charts. ADRs suspected by providers were reported using CDSCO forms. Participants were cancer patients over 18 years receiving anticancer drugs who consented to the study. Those excluded had concurrent treatments, liver or kidney impairments, used alternative medicine, had intellectual disabilities, or substance use disorders. Data collection focused on patient information, chemotherapy details, and occurrences of ADRs. The evaluation analyzed demographics, cancer types, medication categories, ADR distribution, and assessed causality using Naranjo's probability scale, severity using the Modified Hartwig and Siegel scale, and preventability with the Schumock and Thornton assessment scale.

RESULTS

In a hospital-based prospective observational study of 100 cancer patients, the majority were female (58%), while males accounted for 42%. The findings indicated that women were more susceptible to ADRs from anti-cancer therapies compared to men. Regarding age, most participants (48%) were between 41 and 60 years old, followed by 31% who were over 60, and 21% who were in the 18–40 age groups. The study revealed that 77% of patients received combination therapy, with 23% undergoing monotherapy, underscoring the widespread use of combination treatments in cancer care.

Most ADRs reported were non-hematological, comprising 80.44%, while hematological ADRs accounted for 19.56%, indicating that non-hematological reactions were notably more prevalent. Breast cancer was the most common type of cancer, affecting 20% of participants, followed by buccal mucosa cancer (15%) and gallbladder cancer (14%), with other cancer types affecting less than 10% of subjects (Table 1 and Fig. 1).

In our research, most patients were treated with alkylating agents (43%), followed by natural products (25%). Alkylating agents showed the highest rate of ADRs. The gastrointestinal system was mainly impacted by non-hematological ADRs, with nausea/vomiting (14.7%), anorexia (11.9%), and diarrhea (7.8%) being the most common. Skin-

Table 1: Cancer distribution among the study subjects

Site of malignancy	Number of study subjects	%
Breast	20	20
Buccal mucosa	15	15
Gallbladder	14	14
Tongue	07	07
Ano-rectal	07	07
Larynx	06	06
Cervix	05	05
Endometrium	05	05
Ovary	05	05
Palate	03	03
Soft tissue sarcoma	03	03
Colon	02	02
Penis	01	01
Esophagus	01	01
Ewing's sarcoma	01	01
Lung	01	01
NHL	01	01
Stomach	01	01
Testis	01	01
Urinary bladder	01	01
Total	100	100

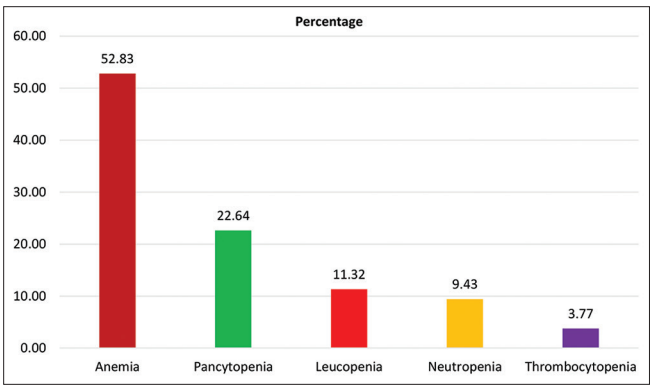

Fig. 1: Hematological adverse drug reactions among the study subjects, n=100

related ADRs, particularly alopecia (17.4%), were also notable. While central nervous system symptoms and musculoskeletal issues occurred less frequently, they were still noted (Fig. 2 and Table 2).

Using various assessment tools, 67.15% of ADRs were categorized as "possible," 30.99% as "probable," and the remainder as "doubtful" according to Naranjo's probability scale. Most ADRs were mild, with 84.87% rated as mild, 14.02% as moderate, and 1.10% as severe, based on the Modified Hartwig and Siegel scale. The Schumock and Thornton scale revealed that 64.94% of ADRs were not preventable, 20.29% were probably preventable, and 14.76% were definitely preventable. In addition, 77% of patients continued their chemotherapy despite experiencing ADRs (Fig. 3).

DISCUSSION

Neoplasia, or "new growth," involves the formation of neoplasms, specifically tumors. ADRs from anti-cancer medications can significantly hinder patient adherence and increase discomfort, necessitating effective monitoring and mitigation. A study at Uttar Pradesh University of Medical Sciences investigated ADRs over a year, revealing that 10–12% of cancer patients in India experience these reactions, yet reporting remains low due to limited awareness among healthcare professionals. In rural areas, challenges such as socio-cultural beliefs, lack of awareness about cancer symptoms, and misleading herbal remedy advertisements further complicate treatment, often leading to harmful interactions between chemotherapy and herbal products. As a result, many rural patients suffer from ADRs with inadequate support and reporting.

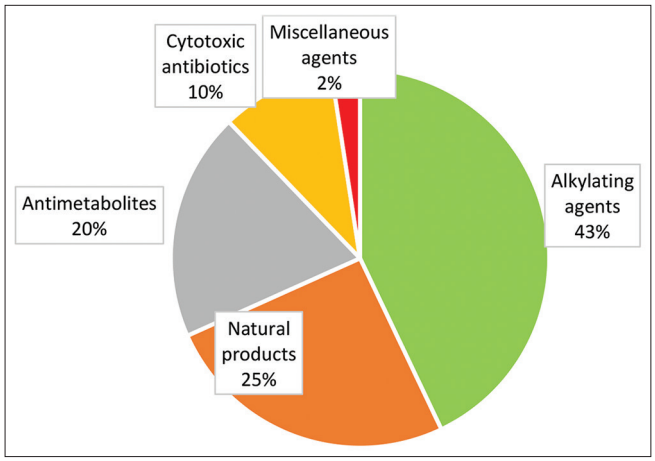

Fig. 2: Groups of anticancer drugs prescribed among study subjects, n=100

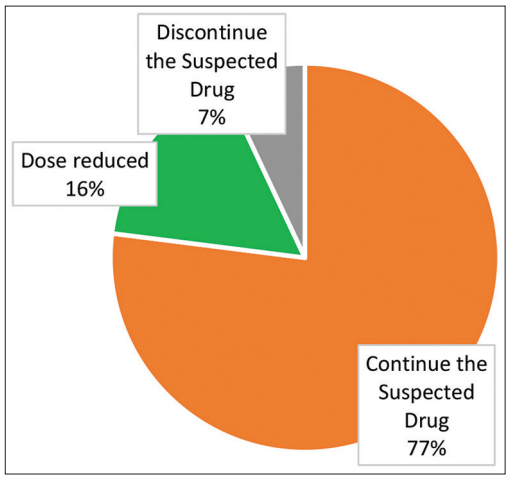

Fig. 3: Management of adverse drug reactions

The demographic analysis of the study population showed higher cancer prevalence among women, with 58% of participants being female and 42% male. This aligns with findings from other studies indicating that women often experience more ADRs to anticancer treatments. Factors such as hormonal changes, variations in drug metabolism, and differences in how adverse effects are reported contribute to this gender disparity. A significant part of this difference can be linked to the high incidence of breast cancer, which represented 20% of the cases. Breast cancer is among the most prevalent cancers worldwide, especially in women, consistent with our findings [7].

Regarding age, the majority of patients (48%) were aged 41–60 years, followed by 31% who were over 60, and 21% aged 18–40. This trend reflects the increased cancer risk associated with age, as older adults face more cumulative risk factors. These results are in line with earlier research, including a 2016 study by Danbatta *et al*., which reported a similar gender distribution, highlighting the higher prevalence of breast cancer among females. Such trends are often seen in areas with effective breast cancer screening programs, as evidenced by our study's finding of breast cancer accounting for 20% of cases. In addition, a 2019 study by Sharma *et al*., noted a comparable age distribution, confirming that 41–60 years was the most affected demographic, echoing our finding that 48% of patients fell within this range. The predominance of cancer in middle-aged individuals underscores the cumulative effects of lifestyle and environmental risk factors over time [8].

In terms of cancer distribution, breast cancer was the most common malignancy in this study (20%), followed by buccal mucosa (15%) and gallbladder cancer (14%). These results are consistent with a study by GLOBOCAN 2020, which found that breast cancer remains the most diagnosed cancer in women worldwide [9,10]. In addition, a study by Mohan *et al*., identified similar trends in oral cancers (buccal mucosa) in India, attributed to high tobacco use [11]. Gallbladder cancer prevalence aligns with studies from regions where chronic infections, like typhoid, and gallstone disease are common. The relatively lower incidence of other cancers, such as tongue, ano-rectal, and cervix, was also observed in other regional studies, such as Reddy *et al*., which noted that while these cancers are common, they are less prevalent compared to breast and buccal mucosa cancers in certain populations [12].

The occurrence of ADRs was a key aspect of the study, where 271 ADRs were reported, with 78% associated with combination therapy and 22% with monotherapy. This is consistent with findings from studies such as Verma *et al*., which also found a greater incidence of ADRs in

Table 2: System-wise distribution of ADRs

S. No	Organ system	No. of ADRs	Percentage
1	Gastrointestinal System	105	38.75
	GIT	Nausea/vomiting	32
		Anorexia	26
		Diarrhea	17
		Constipation	10
		Abdominal discomfort	07
		Mouth ulcer	05
		Taste alteration	04
		Heart burn	03
		Hiccups	01
2	Skin and appendages	54	19.93
3	Hematology	53	19.56
4	Central nervous system	19	7.01
5	Musculoskeletal system	15	5.53
6	General	06	2.21
7	Eye	05	1.84
8	Cardiovascular system	04	1.47
9	Respiratory system	04	1.47
10	Ear	02	0.74
11	Renal system	02	0.74
12	Others	02	0.74
Total		271	100

ADRs: Adverse drug reactions, GIT: Gastrointestinal tract

patients receiving combination therapies [13]. The combination of multiple drugs often results in increased toxicity, as different agents may have additive or synergistic side effects. This study also parallels findings by Mukherjee *et al*., who noted that chemotherapy regimens involving taxanes and platinum compounds are particularly associated with gastrointestinal and hematological ADRs [14].

Among monotherapy patients, cisplatin accounted for 61.7% of ADRs, followed by paclitaxel (13.3%), docetaxel (10%), and carboplatin (8.3%), consistent with existing research highlighting cisplatin's significant role due to its efficacy and cost-effectiveness in cancer treatment. In combination therapies, the highest ADR incidence was noted with the Paclitaxel+Cisplatin+5-Fluorouracil regimen (26.1%), followed by Paclitaxel+Carboplatin (19%) and Doxorubicin+Cyclophosphamide (11.4%). These findings align with previous studies, emphasizing that while combination therapies enhance efficacy and combat resistance, they also complicate ADR management due to the cumulative toxicity of the drugs involved [15,16].

Non-hematological ADRs were more prevalent (80.44%) than hematological ones (19.56%). The majority of non-hematological ADRs affected the gastrointestinal system, with nausea/vomiting (14.7%), anorexia (11.9%), and diarrhea (7.8%). Skin-related reactions, like alopecia (17.4%), were also notable. While central nervous system symptoms and musculoskeletal issues were less common, they were still noted. Regarding ADR determinants, females had a higher incidence of hematological ADRs, while males experienced more non-hematological ADRs. These findings are comparable to those reported by Singh *et al*., who also found gastrointestinal toxicities to be predominant in cancer patients undergoing chemotherapy [17]. Studies by Patel *et al*., further support the prevalence of skin toxicities, particularly alopecia and rashes, in patients treated with taxane-based regimens [18,19]. Hematological toxicities, including anemia, leukopenia, and thrombocytopenia, observed in 19.56% of patients, are consistent with the findings of a study by Kumar *et al*., where myelosuppression was a common side effect of chemotherapy [20].

Using the Naranjo probability scale, 67.15% of ADRs were classified as possible, while 30.99% were classified as probable. This illustrates the challenge of establishing a clear causal relationship between medications and ADRs in cancer patients, who often have multiple comorbidities and complex treatment plans. Notably, none of the ADRs were categorized as definite, highlighting the complexities of managing side effects in oncology. This distribution is in line with findings from other oncology studies, such as those by Malik *et al*., which found that the majority of ADRs in cancer treatment fall into the possible or probable categories due to the difficulty in attributing ADRs to a specific drug amidst complex treatment regimens.

The Modified Hartwig and Siegel severity scale indicated that most ADRs (84.87%) were mild, with 14.02% classified as moderate and only 1.10% as severe. These results consistently show that most chemotherapy-induced ADRs across various studies are mild to moderate, with severe reactions being quite uncommon. This pattern indicates that while severe ADRs are rare, most reactions are manageable and require monitoring rather than discontinuation of therapy [21].

In our study, the Schumock and Thornton preventability assessment scale showed that 64.94% of ADRs were classified as not preventable, 20.29% as probably preventable, and 14.76% as definitely preventable. This indicates that while many ADRs are deemed not preventable, a significant portion might be avoided with better management practices. This aligns closely with Patel and Patel, highlighting a significant number of ADRs that may not be preventable but also emphasizing the need for improved pharmacovigilance and management strategies [22].

In terms of ADR management, our findings showed that 77% of cases involved continuing the suspected drug despite ADRs, with dose reductions or discontinuations in fewer cases. Koliyakodu *et al*., reported similar practices, underscoring the complex decision-making process in managing ADRs and the need for individualized treatment approaches [23].

The study's limitations include its single-center design and a relatively small sample size, constrained by the study's duration. In addition, many participants were from rural areas and lacked awareness about how to report ADRs. The categorization of numerous ADRs as "Not Preventable" may reflect difficulties in monitoring elements such as laboratory tests and interactions between medications.

CONCLUSION

In a year-long study at UPUMS, Saifai, Etawah, 100 cancer patients were observed while receiving either single or combination drug therapies. The majority of participants were female (58%) and within the 41–60 age range (48%). The most frequently occurring cancers were breast cancer (20%) and buccal mucosa cancer (15%). The study indicated that combination therapies resulted in the highest incidence of ADRs, primarily non-hematological, with alopecia being the most prevalent. Cisplatin showed the greatest occurrence of ADRs. Most ADRs were considered possible and mild, with many labeled as non-preventable. Management of ADRs included continuing treatment, dose reduction, or discontinuation of drugs. Future studies should aim to minimize ADRs through personalized medicine, enhanced pharmacovigilance, and targeted strategies that balance treatment effectiveness with side effects. Continued monitoring and supportive care are crucial for effective ADR management.

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ETHICAL APPROVAL

The study was carried out following approval from the Institutional Ethics Committee (534/UPUMS/DSW/Ethical/2022–2023, dated December 22, 2022).

AUTHOR'S CONTRIBUTION

Amresh Kumar: Contributed to the conception or design of the work, collected the data, analyzed and interpreted the data, drafted the manuscript, and revised the manuscript critically for important intellectual content. Alok Dixit: Contributed to the conception or design of the work, supervision of study, analysis and interpretation of the data, review of manuscript, revising the manuscript critically for important intellectual content, and approving the final version to be submitted for publication. Chandra Veer Singh: Contributed in the supervision of study, drafting the manuscript, reviewing of manuscript, and revising the manuscript. Ajit Kr Mishra: Contributed to the supervision of the study, treatment of patients referred the patients for ADR monitoring, review of the manuscript, and revision of the manuscript critically for important intellectual content. Kailash Mittal: Contributed to the supervision of the study, treatment of patients, and referred the patients for ADR monitoring, review of the manuscript, and revision of the manuscript critically for important intellectual content. Pooja Singh: Collected the data, analyzed and interpreted the data, drafted the manuscript, and revised the manuscript.

ETHICAL DECLARATION

The research was conducted in line with the Declaration of Helsinki and obtained approval from the Institutional Ethics Committee (534/UPUMS/DSW/Ethical/2022–2023, dated December 22, 2022) of the tertiary care teaching hospital.

CONFLICT OF INTEREST

Authors declare that there is no conflict of interest.

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