

A Study on Chemotherapy Induced Toxicities among Hospitalized Patients in Oncology Ward

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ABSTRACT

Background: Chemotherapy is an effective cancer treatment but chemotherapy-induced toxicity remains a major concern, as it can significantly affect patients' quality of life, lead to treatment intolerance and in some cases necessitate the discontinuation of therapy. **Materials and Methods:** A prospective observational study analysis of chemotherapy-induced toxicities conducted. Research done at Omega Cancer Specialty Hospital, Hyderabad for six-months duration in In-patient department of oncology ward. Study initiated after approval from Institutional ethics committee and obtaining the informed consent form patients. Above 16 years, both genders and patients with co-morbidities were included. Out-patients, cases below 16 years, pregnant women, nursing mothers and terminally ill patients excluded from study. SPSS version 24 implemented for statistical analysis. Confidence interval 95% and *p* value <0.05 considered significant. Associations between socio-demographic and clinical variables and chemotherapy-induced toxicities were evaluated using chi-square tests. **Results:** Out of 221 cases total of 349 chemotherapy-induced toxicities were documented. Majorly observed toxicities were leukopenia (31%), anemia (26%), and thrombocytopenia (24%). Females (67%) were more susceptible to toxicities than males (33%). Furthermore, patients aged (50-59) years were found to be at a higher risk of developing toxicity. Toxicity incidence was notably higher of 17% in patients undergoing dual therapy with (Paclitaxel and carboplatin) combination and during the second cycle of treatment. **Conclusion:** Chemotherapy-induced toxicities often lead to treatment delays, which can have detrimental consequences. Early identification can play a crucial role in clinical management, allowing for timely modifications in drug regimens to minimize toxicity and improve patient outcomes.

Keywords: Adverse Drug Reactions, Chemotherapy-Induced Toxicity, Hematological Toxicity, Prescription Pattern, Leukopenia.

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INTRODUCTION

The term "cancer" refers to a group of diseases with various types that can develop anywhere in the body. Normal cell growth and division is disrupted and cells continue to multiply uncontrollably. At the same time, old cells cluster together to form a mass of tissue known as a "tumor" in which old cells don't die as they should (Harsh Mohan, 2010). Normal cells undergo controlled division, death programme and they remain intact in place whereas cancerous cell divide unmanageable, disregard apoptosis and continue to relocate. Alteration of one or more gene produce malignant cells and an array of them result in cancer. The American Cancer Society (ACS) indicates that 1 in 2 males and individuals Assigned Male at Birth (AMAB), as well as

1 in 3 females and individuals Assigned Female at Birth (AFAB), will develop cancer (American Cancer Society, 2022). Although cancer can affect anyone, it is influenced based on sex and ethnicity. The 2022 annual report on cancer stats that it affects more men and AMAB compared to female and are concerned to black men more frequently (Sathish *et al.*, 2025). Early signs are weight loss, chronic tiredness, fever at night etc and warning signs are persistent lumps or bumps, difficult breathing and swallowing. Cancer is most often caused due to acquired genetic mutation. Smoking, diet, environmental toxins, hormone therapy augment the incidence of cancer. Adopting lifestyle changes such as quitting smoking, exercising, following diet programs can reduce cancer potential (Katzung, 2018). The primary types of cancer are: carcinoma, sarcoma, lymphoma and leukaemia (Brunton *et al.*, 2017). The four phases of malignancy based on size and location are stage I,II,III,IV which are cancer confined to small area, cancer not yet spread, might have spread to adjacent area, further even spread to organ respectively (Brierley *et al.*,



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2016). The elements of cancer management play a crucial role in shaping the patient's treatment objectives and, in turn, aid in identifying the patient's prognostic factors that includes kind of cancer, treatment variable, and patient factors. Chemotherapy utilizes drugs to destroy cancer cells. These targeted anticancer medications stop cancerous cells from multiplying, reproducing, and generating new cells. Its goals are to eradicate cancer, its recurrence, to reduce tumor before surgery, to alleviate pain etc. In addition to chemotherapy, other drug therapies such as hormone treatment, immunotherapy, and targeted therapies are used to treat cancer (National Cancer Institute, 2007). Medications are often given in combination to prevent the development of drug resistance (Amjad *et al.*, 2023). Though healthcare professionals try to balance out treatment with minimum negative impact, adverse effects are a part of all cancer therapy. So chemotherapy-induced toxicities can be categorized according to their pathophysiological or anatomical characteristics. Alopecia, nausea and vomiting, myelosuppression, cardiac toxicity, haemorrhagic cystitis, mucositis, hot flashes, electrolyte imbalance, Deep Vein Thrombosis (DVT) are toxicities connected to anti-cancer drugs. Delaying chemotherapy in oncology can jeopardize an individual's health and hinder the road to recovery. Chemotherapy is a cornerstone in the treatment of many cancers, and any delay in treatment can negatively affect outcomes. The risk of death increases significantly with the length of time cancer treatment is delayed, rising from 6% to 13% for individuals whose treatment is postponed by just 30 days (Talens *et al.*, 2021). In some instance, chemotherapy is indicated as not just efficient but also rehabilitative. Optimizing anticancer therapy for better efficacy and minimal toxicity involves evaluating and comparing current practices with established standards. As a result, drug utilization studies can aid in prioritizing the efficient allocation of healthcare resources (Patil *et al.*, 2023). Hence this study aims to conduct the analysis of chemotherapy induced toxicity in cancer patients with the objectives to scrutinize patterns, frequency, causality and severity of chemotherapy induced toxicities along with examining the prescribing pattern in delayed chemotherapy.

MATERIALS AND METHODS

The research was a prospective observational study on chemotherapy induced toxicities. It was initiated after the approval from Institutional Ethical Committee of Omega Speciality Hospital, Hyderabad having ethical approval No. OH/ECBHR/Pharm.D/01/2022-01. The hospital provides chemotherapy, radiotherapy, brachytherapy and palliative care which was the study site. Study duration was 6 months from September 2022 to February 2023. The study standards were set up with an inclusion criteria of in-patients from the oncology ward, patients above 16 years of age, patients possessing co-morbidities. Patients of both genders were considered. Exclusion criteria included out-patients, patients below 16 years, pregnant women, nursing mothers and patients who were near to death. Demographics and clinical data

was collected from patient case sheets. Necessary details of the suspected chemotherapy toxicities were recorded. Study was monitored effectively for data updation on regular basis and tracked which equipped the study to show patient advancement to chemotherapy induced toxicities. Statistical package for social science (SPSS®statistics) program IBM SPSS Statistics 24 was used for data analysis for obtaining graphs and results. Confidence interval 95% and p value <0.05 was considered significant. Data analysis consisted of examining the frequency and severity of combined hematological toxicity, combined Gastro-Intestinal (GI) toxicity and specific toxicities which were described based on demographic traits and medical variables. Chi-square testing was used to compare differences between subgroups for categorical data. Chi square tests was utilized to assess the associations between socio-demographic and clinical variables and chemotherapy induced toxicities, including combined GI and hematological toxicity. After discussing the intent of the study, all patients gave their full informed consent. The study followed the Declaration of Helsinki.

RESULTS

A sample size of 221 cases collected out of which 349 chemotherapy induced toxicities identified. Table 1 illustrates patients with (50-59) years have the highest incidence of chemotherapy induced toxicities with severity as mild (9%), moderate (18%) and high (6%). However, the association between age and toxicity was not found statistically significant as $p=0.867$. The severity was classified based on Hartwig and Siegel (Adverse Drug Reactions) ADRs causality assessment scale. Out of 221 cases moderate severity was seen majorly in 52% followed by 30% mild cases. In accordance with the gender distribution, females seen to experience chemotherapy induced toxicities in increased amount comprising of mild (23%), moderate (33%) and high (12%) comparative to male counterparts of mild (7%), moderate (19%) and high (6%). However, the association between gender and toxicity was not statistically significant as $p=0.2057$ was observed. During diagnosis of cancer types it was observed that patients enduring any type of cancer have their incidence of chemotherapy induced toxicities with varying frequency. Patients with blood cancer, bone cancer, brain cancer, skin cancer, kidney cancer, liver cancer had the least frequency of induced toxicities whereas reproductive cancer (23%) and breast cancer (22%) had highest frequency of chemotherapy induced toxicities. With reference to the chemotherapy regimen (Table 2), patients were prescribed more with (Paclitaxel+carboplatin) as dual therapy in 17% cases, which was observed to exhibit highest number of cases with toxicity. This was followed by mono-therapy prescription with only Paclitaxel in majorly 7% cases. Patients who have taken the course of 2 cycle (C) were highly inclined to have chemotherapy induced toxicities followed by 1C and 4C. Patients with the course of 7C, 16C, 21C, and 26C were least susceptible to toxicities and 3C, 5C, 8C, 9C were moderately susceptible. From

Table 3, chemotherapy induced toxicities majorly observed with respect to combined haematological toxicities of anaemia (26%), leukopenia (34%), thrombocytopenia (24%) and leucocytosis (1%). Next commonly observed gastro-intestinal toxicities were 9% nausea and vomiting, 6% diarrhoea and 6% constipation cases. Duration of hospital stay report that there had been delay in chemotherapy initiation where, most of the 54% patients experienced a delay of 24 hr followed by 48 hr delay in 46% patients and the longest delay observed was 14 days in 2% patients. On examining the prescription pattern in delayed chemotherapy it was observed that drugs utilized commonly were 91% blood products followed by 76% granulocyte colony stimulating factor. The commonly prescribed drugs for supportive care were Packed cell volume 30%, Inj. Filgrastim 32% and Inj. Romiplostin 16% given for management of symptoms listed in Table 4.

DISCUSSION

Our study, had chemotherapy-induced toxicities in the age group of (50-59) years which was comparable to a study done by (Tamang *et al.*, 2012). This maybe because older individuals may experience more toxicities (ADRs) due to decreased metabolic and excretory functions, which lead to the accumulation of the drug in the body and result in more adverse reactions (Shrestha *et al.*, 2019). So older patients must be taken care of with great vigilance. In the research at hand, toxicities were more frequently observed in females which aligns with finding in a study done in India by (Surendiran *et al.*, 2010). This maybe due to the pharmacokinetic and pharmacodynamic characteristic difference of the medications involved (Khanal *et al.*, 2014). In the present research most prevalent type pf cancer were reproductive cancer and breast cancer whereas a study conducted by (Pai Sunil *et al.*, 2016) reported that oropharyngeal cancer and cervical cancer remained the most common individual cancer type. In this research patients receiving dual therapy and mono-therapy were more susceptible to develop toxicities which could be due to various treatment modalities employed that are influenced by several variables including cancer staging, treatment costs,

and patient-doctor-related factors. Hence, in this study ADRs specifically induced by chemotherapy were considered which for which a study done by (Sharma *et al.*, 2015) was taken as a reference. In current study, greater chemotherapy induced toxicities were observed in the patients who have taken the course of 2nd cycle and the risk factors attributing to the toxicity include poly-chemotherapy and aging. As per a study done by (Belachew *et al.*, 2016) it is said that age-related declines in bone marrow reserve increased the likelihood of chemotherapy-induced myelo-suppression. It was noticed that most of the toxicities occurred after change of one plan to other chemotherapy hence most of the toxicities were found in 2nd cycle. Chemotherapy induced toxicities observed in this study was related to bone marrow suppression leading to various blood disorders which has been associated with potentially fatal consequences, treatment delays, poorer outcomes, and an excessive utilization of supportive care resources as explained in a study done by (Elting *et al.*, 2001). A 24 hr chemotherapy initiation delay was seen in most patients which was considered due to social stigma, financial issues, comorbidities, care plan differences, missed orders, unrecorded order revisions, unsigned doctor orders and lab test procedures described in a study done by (Bunnell *et al.*, 2013). The causality assessment of ADRs in our study of moderate severity was high and was in contrary to a study done by (Surendiran *et al.*, 2010; Uchiyama *et al.*, 2021). In this current study for the management of chemotherapy induced toxicity a total number of 369 drugs were given to the patient. Blood products were commonly prescribed and for supportive care packed cell volume, Filgrastim and Romiplostin were given which is comparable to a study done by (Ganser *et al.*, 1996). One of the most frequent adverse effects of cancer chemotherapy was nausea and vomiting, the use of newer anti-emetics has been seen to greatly reduced its incidence (Jenns K, 1994; Mallik *et al.*, 2007). In our study, the antiemetic dosage was generally increased to manage side effects.

Table 1: Toxicity Severity Based on Age.

Age Interval (Years)	Mild		Moderate		High		p value
	N	%	N	%	N	%	
20-29	01	0.5	0	0	01	0.5	0.8672
30-39	07	03	05	02	03	01	
40-49	13	06	19	8.5	07	03	
50-59	20	09	41	18	13	06	
60-69	15	07	31	14	10	05	
70-79	09	04	19	09	05	02	
80-89	01	0.5	01	0.5	0	0	
Total	66 (30)		116 (52)		39 (18)		

Table 2: Chemotherapy Regimen (Monotherapy).

Drugs	n= no. of cases	Percentage %
Capecitabine	1	0.5
Carboplatin	2	1
Carfilzomib	1	0.5
Cetuximab	2	1
Cisplatin	21	10
Cytarabine	1	0.5
Docequalip	2	1
Docetaxel	1	0.5
Doxorubicin	1	0.5
Eribulin	8	4
Gemcitabine	11	5
Methotrexate	1	0.5
Nivolumab	1	0.5
Oxaplatin	1	0.5
Paclitaxel	16	7
Pembrolizumab	4	2
Pertuzumab	1	0.5
Rituximab	3	1
Temozolomide	1	0.5
Transtuzumab	2	1
Bevacizumab	1	0.5

Table 3: Chemotherapy Induced Toxicities.

Toxicity based on organ system	Toxicity	n=No. of Cases		Gender			
				Male		Female	
		N	%	N	%	N	%
Combined	Anaemia	58	26	17	8	41	19
Haematological	Leukopenia	75	34	25	11	50	23
	Thrombocytopenia	52	24	17	8	35	16
	Leucocytosis	02	1	0	0	02	1
Gastro-intestinal	Abdominal pain	03	1	01	1	02	1
	Ascites	03	1	0	0	02	1
	Constipation	14	6	01	1	13	6
	Anal fissures	01	1	0	0	01	1
	Diarrhoea	13	6	02	1	11	5
	Abdominal distension	01	1	0	0	01	1
	Nausea and vomiting	20	9	06	3	14	6
	Mucositis	03	1	01	1	02	1
	Somatitis	0	0	0	0	0	0
Renal	Increased serum creatinine	01	1	01	1	0	0
	Burning micturition	01	1	0	0	01	1
Neurological	Anxiety	0	0	0	0	0	0
	Chills	01	1	01	1	0	0

	Insomnia	0	0	0	0	0	0
	Seizures	01	1	0	0	01	1
	Stress	01	1	01	1	0	0
Respiratory	Cough	17	8	05	2	12	5
	Shortness of breath/ dyspnoea	07	3	04	2	03	1
	Nasal discharge	01	1	01	1	0	0
Cardiac	Palpitation	01	1	0	0	01	1
Skin	Itching	03	1	0	0	03	1
	Bed sores	02	1	0	0	02	1
Endocrine	High RBS count	10	5	03	1	07	3
Inflammatory and infections	Swelling	03	1	02	1	01	1
	Pus discharge	04	2	03	1	01	1
	Fever	19	9	06	3	13	6
Others	Pain	16	7	06	3	10	5
	Self	01	1	0	0	01	1
	Weakness	03	1	02	1	01	1
	Secretion	01	1	01	1	0	0

Table 4: Therapeutic class of drugs used in toxicity management.

Therapeutic drug class	Frequency %, n=369
Antipyretics	19 (5.1%)
Analgesics	17 (4.6%)
Antiemetics	23 (6.2%)
Antihistamines	22 (5.9%)
Anti-diarrheal	09 (2.4%)
Antimicrobial	11 (2.9%)
Antipsychotic	06 (1.6%)
Anti-diabetic	05 (1.3%)
Blood products	91 (24.6%)
Cortico-steroids	02 (0.5%)
Granulocyte colony stimulating factor	76 (20.5%)
Laxative	15 (4.0%)
Mouth gargle	03 (0.8%)
Multi-vitamin, Riboflavin and TNA-Peri	10 (2.7%)
Thrombopoietin receptor agonist	45 (12.1%)
Proton pump inhibitor	05 (1.3%)
Others	10 (2.7%)

CONCLUSION

The prescription regimens of various single and combined therapies were examined, with combined drug regimens often linked to chemotherapy-induced toxicity, leading to

delays or cancellations. Many cases with reproductive cancer followed by breast cancer had paclitaxel+carboplatin treatment endured haematological and gastrointestinal toxicities most often observed in older patients. Most toxicity causalities were moderate to mild, observed more in female than male patients.

Switching off chemotherapy regimen to one another paved the way to toxicities. This study highlights the importance of active patient monitoring to promptly detect and manage toxicities, ensuring patient safety, toxicities, duration of hospital stay, economic burden were constrained via early detection. Our study also calls for further investigation into the variables influencing chemotherapy-induced toxicities and the factors contributing to inter individual variability, as these insights could enable personalized treatment approaches and improve patient outcomes. Additionally, understanding the factors influencing these toxicities, including patient demographics, treatment regimens, and comorbidities, is essential for optimizing treatment protocols. Hence, it is suggestive that future research should focus on identifying personalized approaches to minimize toxicity, ensuring more effective and safer chemotherapy regimens for diverse patient groups.

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ABBREVIATIONS

ACS: American Cancer Society; **AMAB:** Assigned Male at Birth; **AFAB:** Assigned Female at Birth; **DVT:** Deep Vein Thrombosis; **SPSS:** Statistical package for social science.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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