



To Study the Pattern of Adverse Drug Reaction Due to Cancer Chemotherapy in Regional Cancer Centre of a Tertiary Care Teaching Hospital in West Rajasthan

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Abstract

Background: Cancer, a term that elicits a shock in the nerve endings of every individual touches every country in the world.

Material and Method: It was a prospective observational study. The study was carried out between November 2015 to April 2016 conducted in medical Oncology & Radiation Oncology Department in P.B.M. hospital and associated group of hospital, Bikaner.

Result: female 43(252) were more affected by ADR as compared to male patients 34 (164). anaemia (14.42%) was the most common ADR followed by Vomiting (10.34%) and Nausea (9.13%).

Conclusion: Chemotherapeutic drugs have a narrow therapeutic index and the dosage needed to achieve a therapeutic response usually proves toxic to the body's rapidly proliferating cells.

Keywords: ADRs, Cancer, Chemotherapy.

Introduction

Cancer, a term that elicits a shock in the nerve endings of every individual touches every country in the world.¹ Cancer incidences and death rates are rapidly increasing world widely as well as in India.²

According to Global Cancer Network (GLOBOCAN) 2012 report, an estimated 14.1 million new cancer cases and 8.2 million cancer-related deaths occurred in 2012. Prevalence estimates for 2012 show that there were 32.6 million people alive who had cancer diagnosed in the previous five years. The prevalence of cancer

is expected to increase, it has been estimated that by the year 2030, there will be 22.2 million new cancer cases and over 13.1 million cancer deaths will occur annually in the world.⁴

Cancer chemotherapy first introduced in the 1960s, before that surgery and radiation therapy was the only means of cancer treatment.¹⁴ Chemotherapeutic drugs have a narrow therapeutic index and the dosage needed to achieve a therapeutic response usually proves toxic to the body's rapidly proliferating cells.¹⁶ Adverse drug reactions (ADRs) are any noxious, unintended and undesired effects of a drug which

occur at doses normally used in man for prophylaxis, diagnosis or treatment of disease, or for the modification of physiological function.¹⁷

The state wise distribution of different cancer patients in India shows that Rajasthan is among the most effected states of India due to various cancer.²⁰ Acharya Tulsi Regional Cancer Treatment & Research Centre situated in P.B.M. hospital, Bikaner. Most of the cancer patients from catchment area come to Bikaner for treatment of various types of cancers. Considering the impact of ADRs on morbidity and mortality rates and the immense potentiality of cancer chemotherapeutic agents to produce a wide range of ADRs, studies to evaluate the incidence and nature of ADRs in this population was needed. It may also create awareness among the treating physicians. The previous studies of ADEs in cancer chemotherapy shows different aspect of ADRs, but studies in this regards in this region was lacking despite the fact that it covers such a large population from four to five states including Punjab , Hariyana ,UP and Bihar also. With this background the present study was designed.

Material and Method

It was a prospective observational study. The study was carried out between November 2015 to April 2016 conducted in medical Oncology & Radiation Oncology Department in P.B.M. hospital and associated group of hospital, Bikaner. The study population involved patients who were on chemotherapy.

Inclusion Criteria

New Patients between 18 to 65 years of age from both genders who were receiving cancer chemotherapy from first cycle of chemotherapy and after wards.

Results

Table 1: Patients Demographic: Gender

Gender	No. of patient	No. of ADR	Percentage (%)
Male	30	164	39.42%
Female	40	252	60.57%
Total	70	416	100%

Exclusion Criteria

Patients with drug reaction due to deliberate or unintentional over dosage, ADR due to alternate systems like Ayurveda, Homeopathy, Unani and drug reaction occurring due to prescribing and dispensing error were excluded from study. Patients who have received radiotherapy or prior chemotherapy and Pregnant and lactating females were also excluded.

Data of ADRs with detailed history were collected from the patients admitted in the Medical Oncology & Radiation Oncology Department. Monitoring for adverse effects was done based on daily questioning of symptoms during their admission period in hospital. To record ADRs pre designed pre structured proforma containing questions regarding clinical history, demographic data, drug history, personal history, family history, present and past medical history, and history of allergy details of chemotherapy, presenting complaint, baseline laboratory investigations such as hemoglobin (Hb), total counts, differential counts, renal function test, serum electrolytes and liver function test was used. Causality was assessed by both WHO Causality Assessment Scale and Naranjo's Algorithm. Preventability was assessed by Modified Schumock and Thornton scale. The severity of ADRs was assessed by modified Hartwig and Siegel scale.

No invasive investigation was undertaken or suggested to the treating physician as a part of the study. The drug effects which were described by the patients and effects which were diagnosed and reported were documented.

The data collected on the ADR from the study site was analyzed into various parameters viz. type of ADR, probability, severity, preventability and detection of drugs implicated in the ADRs encountered. The results revealed that female 43(252) were more affected by ADR as compared to male patients 34 (164).

The findings indicate that the majority of patients, who encountered ADRs during the study period

were in the age group of 51-60 years (32.86%) followed by 41-50 years (27.43%) and 60 years and above (22.85%). Incidence of ADRs was more in illiterate group (44.28%). After analysing data we found that anaemia (14.42%) was the most common ADR followed by Vomiting (10.34%) and Nausea (9.13%).

Table 2: Spectrum Of ADRs

ADRs	Male		Female		Total	
	No.	%	No.	%	No.	%
Anemia	24	14.63	36	14.28	60	14.42
Neutropenia	7	4.2	14	5.56	21	5.04
Nausea	16	9.75	22	8.73	38	9.13
Vomiting	19	11.58	24	9.53	43	10.34
Abdominal pain	7	4.26	15	5.95	22	5.28
Alopecia	11	6.7	17	6.74	28	6.73
Rash	7	4.26	12	4.76	19	4.56
Headache	11	6.7	24	9.53	35	8.41

Table 2 shows presenting complaints and adverse drug reaction causes by different drug regimen during cancer chemotherapy found in this study. After analysing data we found that anaemia (14.42%) was the most common ADR followed by Vomiting (10.34%) and Nausea (9.13%).

Discussion

Chemotherapy has proven to extend life and prevent disease recurrence. Despite these therapeutic successes, many of the antineoplastic drugs has narrow therapeutic index and a high potential for causing adverse effects such as nausea/vomiting, neutropenia/ anemia/ pancytopenia, alopecia, constipation/ diarrhea, and fatigue/tiredness.

In gender distribution, majority of the study subjects were females (60.57%) indicating higher incidence of ADR in females which is in consistence with earlier studies like Gunaseelan et al (60.7%), Ajitha Sharma et al (55.9%) and Deepti Chopra et al (73.6%) . On the contrary, there are studies like Yash N.Goyal et al (54.29%), Sunil Bellare et al (55.3%) and Anju Prasad et al (53%) where males were found to

have more number of ADRs as compared to females.

Age of the subjects ranged from 18 years to 65 year and the mean age was 51.6 year with standard error of mean is 10.75. Majority of the study subjects were in the age group of 51-60 year (32.86%) which is in accordance with previous study done by Yash N.Goyal et al, Ajitha Sharma et al and Anju Prasad et al. In present study the incidence of ADRs among elderly and older adults was significantly higher than other age groups. This may be due to the low metabolizing capacity and reduced excretory functions leading to accumulation of drugs in the body and thus increasing the risk of ADRs.²¹ As a result extra precautions should be taken while using chemotherapy in the elderly population.

Commonest ADRs found in present study were Anaemia (14.42%) vomiting (10.34%) and nausea (9.13%). Few other studies like Deepti Chopra et al, Yash N.Goyal et al and Anju Prasad et al reported nausea and vomiting as the most common ADR. Studies carried out by Ajitha Sharma et al reported Infection (22.4 %) as the most common ADR, while study conducted by

Sunil Bellare et al reported Alopecia (27.76%) to be commonest ADR. Cancer chemotherapy damages rapidly dividing cells of bone marrow resulting in myelosuppression thus affecting white blood cells, platelets and red blood cells. This myelosuppression leads to anemia and lowering of immunity. Nausea and vomiting are prominent with most cytotoxic agents and is caused mainly due to direct stimulation of chemoreceptor trigger zone.

Conclusion

Chemotherapeutic drugs have a narrow therapeutic index and the dosage needed to achieve a therapeutic response usually proves toxic to the body's rapidly proliferating cells. However, early detection of drug toxicity helps to modify the doses or the drug regimen to minimize toxic effects.

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