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To Assess The Incidence And Types of ADRs Experienced By Hospitalised Patients Currently Undergoing Cancer Treatments and/or Supportive Treatment Therapies In Regional Cancer Centre of A Tertiary Care Teaching Hospital In West Rajasthan.

Amritpal Singh[1], R.P.Acharya[2], Rajvinder Kaur[3]

[1]M.D.Pharmacology (3rd year), [2]Sr. Prof. And head. Department of Pharmacology, S.P.M.C. Bikaner

[3] District Hospital Ganganagar

Correspondence Author: Dr. Amritpal Singh, M. D. Pharmacology, Department of Pharmacology, S.P.M.C. Bikaner.

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Abstract

Background: Adverse drug reactions (ADRs) are a worldwide problem associated with the use of drugs for curbing the ailments.

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: most common organ system affected by ADR were gastrointestinal system 135 (32.45%) followed by haematological 87 (20.91%), Central Nervous system 52 (12.50 %) and Dermatology 51 (12.25%).

Conclusion: The high incidence of chemotherapy-related ADRs among cancer patients is of concern. Setting up an effective ADR monitoring and reporting system (onco-pharmacovigilance) and creating awareness among health care professionals regarding the importance of ADR reporting may help prevent the problem.

Key words: ADRs, Cancer, Chemotherapy.

Introduction

Adverse drug reactions (ADRs) are a worldwide problem associated with the use of drugs for curbing the ailments. According to World Health Organisation (WHO), ADR can be defined as 'A response to a drug, which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function[1]. During the last decade it has been demonstrated by a number of studies that drug induced morbidity and mortality is one of the major problem for public health. With the large number of drugs being marketed it is becoming pertinent to monitor ADRs amongst the patients being treated with one or other drug. ADRs often impose a huge financial burden on healthcare system of a country. Some countries spend up to 20% of their hospital budget dealing with drug complications[2,3]. Worldwide, efforts are on-going to identify the ADRs, monitor the drug's use and improve prescribing habits of practitioners to ultimately make use of medicines more rational[4]. The incidence of ADRs varies with studies, which show incidences ranging from as low as 0.15% to as high as 30%[5-7]. Elderly and hospitalized patients are reported to be more susceptible to ADRs than the adult population (16.6% vs. 4.1%)[6]. Recent epidemiological studies estimated that ADRs are fourth to sixth leading cause of death[8]. Impact 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. The prevalence of ADRs of anticancer drugs in Indian context is 10-12%[9].

Material and methods

Study design: A prospective observational study.

Study period: The study was carried out between November 2015 to April 2016. (6 months)

Study place: Medical Oncology & Radiation Oncology Department in P.B.M. hospital and associated group of n hospital, Bikaner.

Study population:

The study population involved patients who were on chemotherapy in the Medical Oncology & Radiation Oncology Department in P.B.M. hospital and associated group of hospital, Bikaner

Inclusion Criteria:

1. Patient age between 18 to 65 years from both genders.
2. Patient receiving cancer chemotherapy.
3. New patients from first cycle of chemotherapy and afterwards.
4. Hospitalized patient**.**
5. Willingness to give written informed consent & available for **follow** up if any.

Exclusion Criteria:

1. Patients with drug reaction due to deliberate or unintentional over dosage.
2. ADR due to alternate systems like Ayurveda, Homeopathy, Unani.
3. Drug reaction occurring due to prescribing and dispensing error.
4. Mentally retarded or unconscious patients. Patients who were already on other Antipsychotic agents and drug abuse.
5. Reactions due to blood and blood products.
6. Non cooperative patients.
7. Patients with age < 18 year and > 65 year.
8. Patients who are critically ill.
9. Patients who has received radiotherapy or prior chemotherapy.
10. Pregnant and lactating females.
11. Drop outs will be excluded.

Assessment Tool:

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.

Study Methodology:

After obtaining approval and clearance from institutional ethics committee, Data of ADRs was collected from the patients admitted in the Medical Oncology & Radiation Oncology Department in P.B.M. hospital and associated group of hospital, Bikaner. Patient was included in the study after getting their written informed consent. The present study was a prospective study. Enrolment of patient was done from November 2015 to April 2016. Initially a new patient was selected for the study whose treatment plan includes chemotherapy. For each patient a detailed history taking was noted on day 0 which includes drug history, personal history, family history, present and past medical history, and history of allergy details of chemotherapy, presenting complaint were documented and any untoward event was labeled as adverse drug reaction.

Baseline laboratory investigations such as hemoglobin (Hb), total counts, differential counts, renal function test, serum electrolytes and liver function test were carried out in each patient. Then telephonically/personally(as per convenience of the patient) the follow up was done for any Adverse drug reactions if experienced by the patient was recorded on day 3, day 8, day 21. The patient was followed for 4-6 cycle of chemotherapy which varies

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according to treatment plan. Then patient was followed up for 30 days after the last cycle of chemotherapy. Data collected was entered in a specially designed Proforma (Case Recording Form) for study.

The study involves various aspects of ADR like types, grades, drugs causing them, onset and duration and outcome.

Follow-up

Follow up was done telephonically/personally(as per convenience of the patient)for the Adverse drug reactions if experienced by the patient was recorded .The patient was followed for up to 4 cycle of chemotherapy which vary according to treatment plan. Then patient was followed up for 30 days after the last cycle of chemotherapy.

Data analysis:

Data thus collected were entered into excel and were then analyzed with help of SPSS software through tables, diagrams and appropriate statistical test wherever required.

Results:

Table 1: Organ System Affected

Organ system	Male		Female		Total	
	No.	%	No.	%	No.	%
Gastrointestinal	53	32.31%	82	32.53%	135	**32.45%**
Haematological	34	20.73%	53	21.03%	87	**20.91%**
Central Nervous System	17	10.36%	35	13.89%	52	**12.5%**
Dermatological	20	12.19%	31	12.30%	51	**12.25%**
Musculoskeletal	10	6.09%	19	7.53%	29	**6.97%**
Cardiovascular	12	7.31%	10	3.96%	22	**5.28%**
Renal	4	2.43%	1	.39%	5	**1.20%**
Hepatic	1	.61%	-	-	1	**.24%**
Others	13	7.92%	18	7.14%	31	**7.45%**
Total	**164**	**100**	**252**	**100**	**416**	**100**

In our study ADRs detected in patients affected different organ systems according to the class of drug. Table 1 shows the organ system affected due to ADRs with gender distribution. The most common organ system affected by ADR were gastrointestinal system 135 (32.45%) followed by haematological 87 (20.91%), Central Nervous system 52 (12.50 %) and Dermatology 51 (12.25%).

Table 2: TYPE OF REACTION (Rawlin and Thomson)

Type	No .of ADR	Percentage (%)
Type A	**307**	**73.80%**
Type B	**109**	**26.20%**
Total	**416**	**100**

Table 2 show the classification of the ADRs encountered into Type A and Type B ADRs based on Thompson's and Rawlins classification. It was observed in study that, most of the reported ADR were of Type A 307(73.80%).

Table 3:-Naranjo Scale of ADRs

CAUSALITY	Male		Female		Total	
	No.	%	No.	%	No.	%
Definite	0	0	0	0	0	0
Probable	108	65.85%	169	67.06%	277	66.59
Possible	56	34.14%	83	32.93%	139	33.41%
Doubtful	0	0	0	0	0	0
Total	164	100	252	100	416	100

Table 3 show details of Probability assessment of ADR based on Naranjo's probability assessment scale. The result showed that majority of the ADR occurred in the study were probable 277 (66.59%) followed by possible

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139 (33.71%). No ADR comes in definite or doubtful ADR category.

Table 4:- Modified Hartwig Scale of ADRs

Severity	Male		Female		Total	
	No.	%	No.	%	No.	%
Mild	112	68.29%	174	69.04%	303	72.83%
Moderate	51	31.09%	75	29.76%	109	26.20%
Severe	1	.6%	3	1.19%	4	.96%
Total	164	100	252	100	416	100

Severity of the ADRs was determined by applying the Hartwig's Severity Assessment Scale. The results of assessment of the severity as shown in Table 4 revealed that 303 ADRs (72.83%) were mild in severity followed by 109 moderate (26.20%) and only about 1% ADRs were severe according to the scale.

Discussion

Most common organ system affect in present study was Gastrointestinal 32.45% followed by Haematology (20.91%) and C.N.S. (12.50%). This finding is similar to study conducted by Yash N.Goyal et al and Deepti Chopra et al. In contrary study done by Gunaseelan et al and Sunil Bellare et al showed that blood and lymphoid system was more commonly affected.

Surprisingly, the incidence of GI symptoms like nausea & vomiting were not that much common. This may be due to increased & regular use of pre-medications like proton pump inhibitors and anti-emetics like ondansetron prior to chemotherapy. Advances in the development of supportive care in oncology, for example, 5HT3 antagonists for the control of chemotherapy-induced nausea, have led to reductions in drug-related toxicity.

Most of the ADRs in present study were Mild (72.83%), 26.20% were moderate and only .96% were Severe in category. Only 4 patients required hospitalisation because of ADR. This shows that ADRs are due to cancer chemotherapy are rarely life threatening with appropriate pre-medications and early detection. Finding of present study was in accordance with study done by Deepti Chopra et al with slight difference in percentage . But studies done by Gunaseelan et al shows that mild ADRs were 17.9% where as moderate ADRs were 74.1%

Conclusion

The high incidence of chemotherapy-related ADRs among cancer patients is of concern. Setting up an effective ADR monitoring and reporting system (onco-pharmacovigilance) and creating awareness among health care professionals regarding the importance of ADR reporting may help prevent the problem.

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