

A Study of Adverse Drug Reactions in Cancer Patients Due to Chemotherapy in a Tertiary Care Hospital, Rims, Ranchi

Uma Shanker Prasad Keshri¹, Kavita Kumari², *Sumit Kumar Mahato³, Akhilesh Kumar⁴, Pholgu Protim⁵

¹(Associate professor, Department of Pharmacology and therapeutics, Rajendra Institute of Medical Sciences, Ranchi /Ranchi University, India)

²(Pharmacovigilance Associate, Department of Pharmacology and therapeutics, Rajendra Institute of Medical Sciences, Ranchi /Ranchi University, India)

^{3,4,5}(Junior Resident, Department of Pharmacology and therapeutics, Rajendra Institute of Medical Sciences, Ranchi /Ranchi University, India)

Corresponding author: *Sumit Kumar Mahato³

Abstract: Adverse drug reactions (ADRs) are adverse or unintended effects associated with medications and these are also associated with the use of anticancer drugs which have become a worldwide problem and monitoring these reaction are essential for safety of patient and prompt management is necessary for adherence to chemotherapy.

Material And Method: This is a retrospective study done in department of pharmacology in association with dept. of oncology Rims, Ranchi. Those patients who developed reaction during chemotherapy were included in this study taking either single or combination drug therapy. The causality assessment of the monitored ADRs were determined using WHO-UMC Causality Scale.

Result And Discussion: A total of 104 patient were included this study, of which 62 were female and 42 were male. Total of 236 ADR were incurred during chemotherapy. 53% were gastrointestinal ADR followed by haematological ADR 16%, C.N.S related ADR accounted for 12% followed by Skin 9%, Cardiovascular 3%, Renal 2% and others 5%. Causality assessment by WHO-UMC in our study was possible(86%), probable(13%), certain(1%), unlikely(0%), unclassified(0%), unassessable(0%).

Conclusion: Monitoring and management of ADR is essential for success of chemotherapy. As these ADR may steer the patient to make a judgment for stopping the medications and finally the occurrence of drug resistance and an amplified healthcare cost. If a proper educational system is implemented, so that most of the patients may report their ADR which may help to improve the patients adherence and therapeutic outcome.

Keywords: ADR, chemotherapy, noxious, WHO-UMC

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I. Introduction

Pharmacotherapy plays an important role in the maintenance of health. Every medication has a risk of adverse or unwanted effects, and evaluating the risk/benefit balance associated with use of a particular medication is a critical step in the decision to use pharmacotherapy. Adverse drug reactions (ADRs) are adverse or unintended effects associated with medications and have been defined by the World Health Organization (WHO) as “noxious and unintended responses to drugs occurring at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function”^[1]. Definition is independent of the mechanism of the adverse reaction which includes allergies, idiosyncrasies, pharmacological and toxicological mechanisms and interactions between different drugs.^[2] Studies based on medical records reviewed in the UK and other countries have reported that the prevalence of hospital admissions attributed to ADRs ranges from 2.3 to 21.2%, and that a substantial proportion of these ADRs are potentially preventable.^[3-6] Further 10 to 20% of all hospitalized patients experienced an ADR during their hospital admission.^[3,7,8] Lazarou et al reported an overall incidence of serious and fatal ADRs of 6.7% and 0.32% respectively, of hospitalized patients. The causality assessment of reported ADRs was done using WHO UMC Scale as Certain, Probable, Possible, Unlikely, Unclassified, Unassessable.^[9]

Adverse drug reactions may arise as a result of immunological or non-immunological mechanisms.^[10] According to Rawlins & Thompson classification, ADRs are defined as type A, type B, type C and type D.^[11] Type A reaction is an over enhancement of the normal pharmacology of the medication, is predictable and is related to dosage. Type B reaction is unrelated to normal pharmacology and is unpredictable. Type C reactions include those associated with prolonged therapy, e.g. analgesic nephropathy. Type D reactions consist of

delayed reactions, e.g. carcinogenesis and teratogenesis.^[12] A number of new chemotherapeutic agents have been used for the treatment of cancer. Chemotherapeutic drugs do have side effects. Side effects of chemotherapy are unwanted effects that happen as a direct result of taking a drug. It is easy to confuse drug side effects with symptoms of cancer. Different chemotherapeutic drugs have different short term and long term side effects and certainly not all chemotherapy drugs cause every side effect. In general, chemotherapy damages cells that are dividing, so the parts of the body where normal cells divide frequently are likely to be affected by chemotherapy. The mouth, intestine, skin, hair, bone marrow (the spongy material that fills the bones and produces new blood cells) are commonly affected by chemotherapy. Although most anti-cancer drugs have side effects, not every person gets them. A person may experience no side effects of chemotherapy, some side effects, or all of them. Whether or not a person will experience a particular side effect, when it will start and stop or how bad it will be, depends on many factors, like for how long a person has been taking the drug, his general health, the dose or amount of the drug, the way the drug is given and other drugs that have been given in combination.

The incidence of cancer is highest in developed countries, particularly in Northern America, Australia and New Zealand and in Northern and Western Europe. However, its impact in the developing world is growing at an alarming rate. More than 70% of all cancer deaths has been found to occur in low and middle income countries and these regions are projected to account for two thirds of all cases of cancer worldwide by 2050 (an increase of 15% since 1975). Present study aims to identify and characterize the pattern of ADRs related to commonly used chemotherapeutic drugs in Oncology department of Rajendra Institute of Medical Science, Rims, Ranchi

II. Material And Method

The present study is a retrospective study done in the department of pharmacology and therapeutics RIMS Ranchi in association with department of oncology RIMS Ranchi. All patients with confirmed cases of cancer of either sex who came for chemotherapy in oncology department for receiving single drug or combination drug chemotherapy were included in this study and those cases who were planned for surgery and radiotherapy and other reactions due to blood transfusion, drug abuse and intoxication were excluded from the study. ADRs were collected by filling the suspected ADR form for each patient who experienced ADR during or after treatment which is designed by Indian Pharmacopoeia Commission. This study was done for 06 month from October 2016 to March 2017

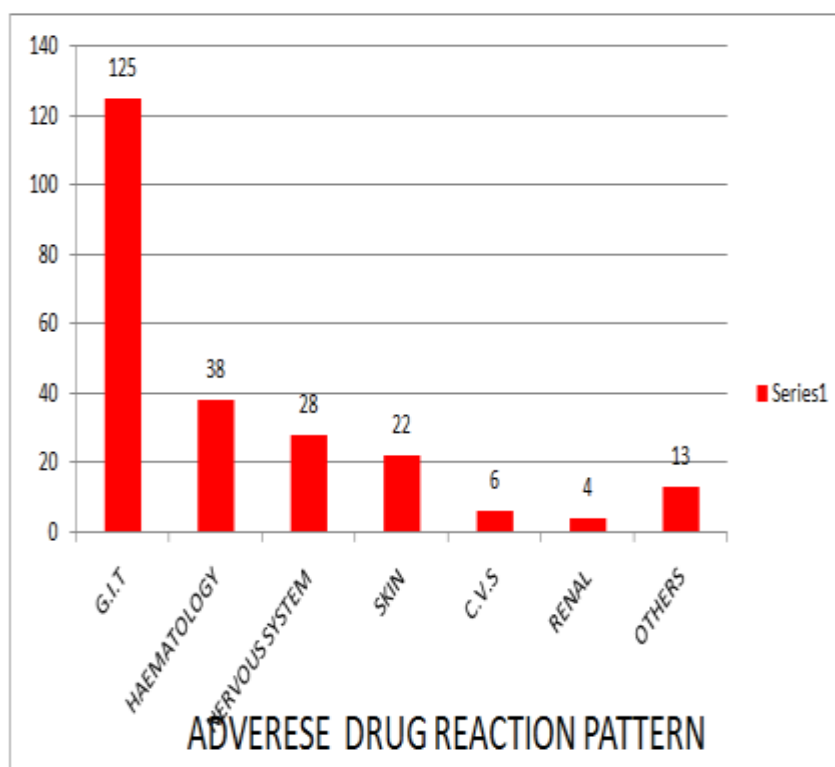


Figure 1: showing no. of adverse reaction occurred in each system

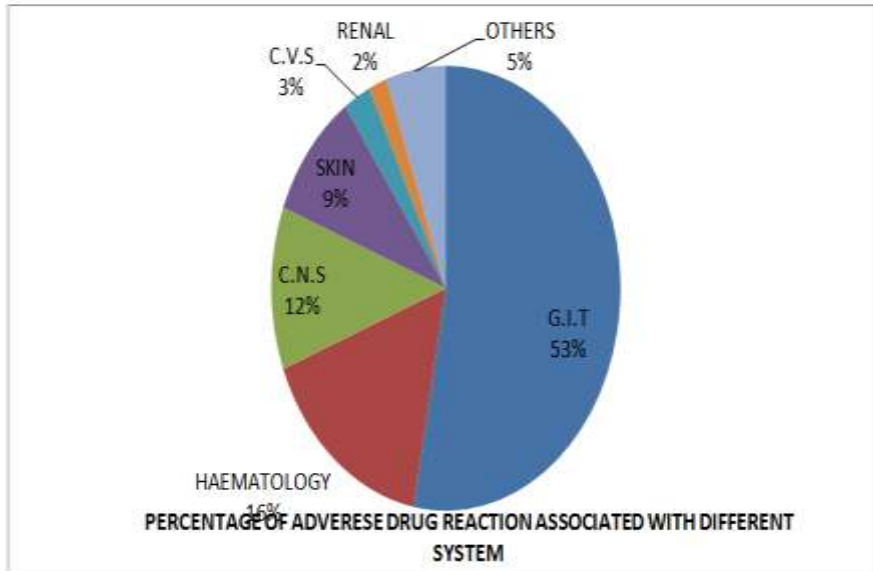


Figure 2: showing percentage distribution of ADR

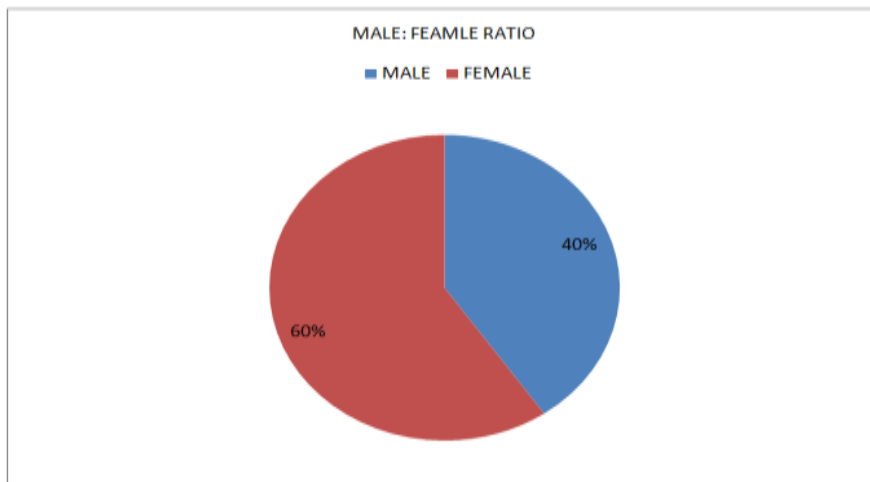


Figure 3: showing female:male ratio of Adverse drug reaction

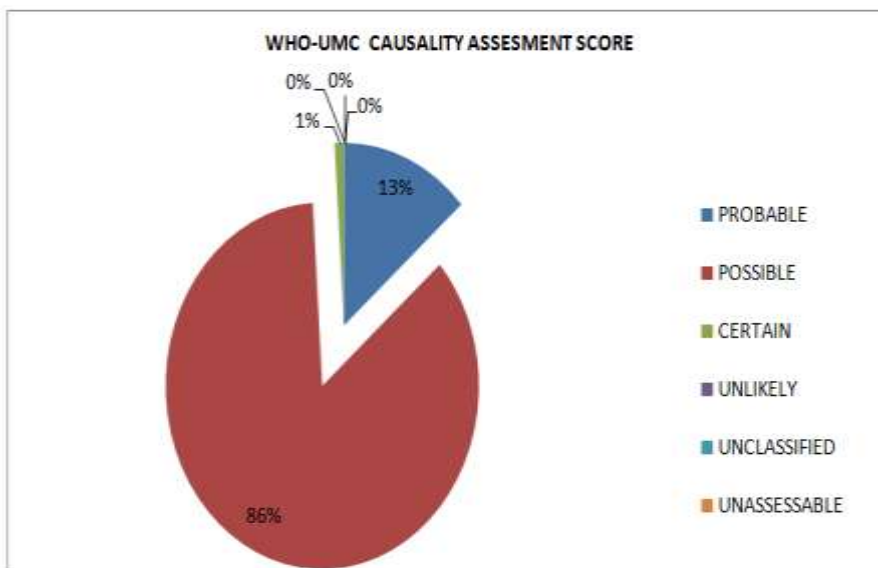


Figure 4: showing WHO UMC scale of causality

III. Result and discussion:

A total of 104 patient were included this study, of which 62 were female and 42 were male. Total of 236 ADR were incurred during chemotherapy. Adverse drug reactions induced by chemotherapy agents have become one of the major complications of cancer therapy that affect the patient's survival, treatment outcomes and morbidity and mortality rates.^[14]our study shows that incidence of ADR among female were 60% and remaining 40% were males,Poddar et al (2009)^[15] also reported similar results, this increased risk are not entirely clear but include gender-related differences in pharmacokinetic, immunological and hormonal factors as well as differences in the use of medications by women compared with men. Women generally have a lower lean body mass, a reduced hepatic clearance, have differences in activity of cytochrome P450 (CYP) enzymes (40% increase in CYP3A4, varied decrease in CYP2D6, CYP2C19 and CYP1A2), and metabolize drugs at different rates compared with men.^[16]Our study shows that out of 236 ADR experienced by the patient 53% were Gastrointestinal ADR followed by HaematologicalADR 16%,C.N.S related ADR accounted for 12% followed by Skin 9%, Cardiovascular 3%, Renal 2% and others 5%. Amongst g.i.t nausea and vomiting accounted for 53% of all g.i.t related ADR.The most common mechanism of chemotherapy induced nausea and vomiting is through activation of CTZ (Stewart, 1991), followed by constipation (16%), diarrhea and pain abdomen(11%) each and gastritis(10%). HaematologicalADR were second after git and anemia was reported to be 81% of all haematologicalADR followed by leucopenia (13%) followed by thrombocytopenia (6%). In this study nervous system finding which were include are tingling sensation in limbs (54%), headache(21%), insomnia, slurring of speech, dystonia, dizziness accounted for nervous system symptoms. Among skin ADR alopecia accounted for (77%) followed by itching, nail pigmentation and mouth ulcer. Other observed ADR were dysuria, fever with chills and increase in serum urea and creatinine. According to our study git side effect were most common followed by haematological which in contrast to other studies done by Mallik et al. who reported neutropenia as the commonest suspected ADR followed by emesis and alopecia.^[17] While, Poddar et al. reported elevated ESR, alopecia, vomiting and neutropenia as the common suspected ADRs.^[18]Surendiran et al. reported nausea, alopecia, anorexia and vomiting as the suspected common ADRs.^[19] Causality assessment by WHO-UMC in our study was possible(86%), probable(13%), certain(1%), unlikely(0%), unclassified(0%), unassessable(0%).

IV. Conclusion

Adverse drug reactions (ADRs) are a significant cause of morbidity and mortality and are a source of additional economic burden to the patients, their care-givers, and the healthcare systems that treat them. An early detection of these ADRs may help in minimizing the damage by either modifying the dose or changing the offending agent.To boost the quality of care provided in medicine, it is essential to implement a system that reduces the number of chemotherapy errors. Spontaneous reporting of ADRs is the cornerstone of pharmacovigilance and is essential for maintaining patient safety.

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