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Medication Utilization in Incident Adverse Drug Reactions of Cancer Chemotherapy in a Tertiary Care Hospital

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Abstract: *The main objective of the study is to describe the occurrence rates and causality evidence of cancer medication–associated adverse drug reactions (ADRs) and to evaluate Medication Utilization in managing the occurred ADRs.The patient's data was collected using patient data collection forms in inpatient Radiotherapy department. The ADR assessment is done by using WHO causality assessment scale and Naranjo's causality assessment scale. In a total of 536 patients,78% (n=418) experienced adverse drug reactions. Patients with single adverse drug reaction are 43% (n=178) of 418, whereas 23% (n=96) experienced two adverse drug reactions and 9% (n=38)were found to be experiencing more than 2 adverse drug reactions. Alopecia 95% (n=397), Nausea and vomiting 82% (n=343), myelosuppression42.1% (n=176), Skin pigmentation15.3% (n=64), itching11.4% (n=48), Diarrhea11% (n=46), mucositis10.2% (n=43), Constipation6.22% (n=26), cardiotoxicity2% (n=8) are most commonly observed ADRs.Approximately 78% of patients taking chemotherapy experienced adverse drug reactions that are mostly managed by utilizing proper medications, which further elucidate the opportunity for clinical pharmacists to monitor and manage adverse drug reactions cautiously, thereby minimizing the after effects of chemotherapy and improving the patient's outcomes.*

Keywords: *Adverse drug reactions (ADRs), Medication Utilization, WHO causality assessment, Naranjo's causality assessment scale.*

I. Introduction

An adverse drug reaction (ADR) is defined by World Health Organization (WHO) as "Any response to a drug which is noxious, unintended and occurs at doses used in man for prophylaxis, diagnosis ortherapy[1]. Effective treatment of cancer remains one of the biggest challenges to modern medicine. Due to conventional therapies such as chemotherapy and radiation often falling short of their goals, and to patient dissatisfaction concerning adverse effects associated with these treatments, complementary and alternative medicines (CAM) are becoming increasingly popular. Sometimes the ADRs are so serious and severe that, cost needed to treat morbidity and mortality due to it, is more than the cost needed to treat the actual condition of interest. The acute effects of frequent administration of anti-neoplastic drugs includes nausea-vomiting, via a central mechanism and sometimes extremely severe[2]. Cancer chemotherapeutic drugs very often show ADRs. Nausea, vomiting, myelosuppression, mucositis etc. are very common ADRs due to cancer chemotherapy. Many of the adverse effects of anti-neoplastic are an extension of their therapeutic action, which is not selective for malignant cells but affects all rapidly dividing cells; anti-neoplastic therapy is made possible only by increased sensitivity or less effective recovery of malignant cells compared with normal cells[2].

So, the objective of the present study was to evaluate the pattern of ADRs occurring in cancer patients treated with chemotherapy in a tertiary care hospital of India.In this study, the developed data was used (1) to study drug exposure in medical inpatients, (2) to determine the frequency of medication-related events, (3) to estimate the contribution of ADRs to hospital admissions, (4) to characterize types of ADRs observed.

II. Materials And Methods

The study was conducted in a radiotherapy department of a tertiary care teaching hospital, India. The data was collected from the radiotherapy department. ADRs reported by patients were assessed using WHO causality assessment scale and Naranjo's causality assessment scale.Patients with any type of cancer and taking chemotherapy were included in the study. Patients with cancer and undergoing radiationwere excluded in the study. Data is entered into data collection forms. Drug name, duration of therapy and route of administration were recorded for all medications. Medication data during stay also include dosages, dates and times of drug administration.

III. Results

A total of 536 participants were included in the study and the study has been conducted for the duration of 6 months. Among the total, 78% (n=418) experienced adverse drug reactions. Patients with single adverse drug reaction are 43% (n=178) of 418, whereas 23% (n=96) experienced two adverse drug reactions and 9% (n=38) were found to be experiencing more than two adverse drug reactions. The noted adverse drug reactions and their incidence are given in Fig.1.

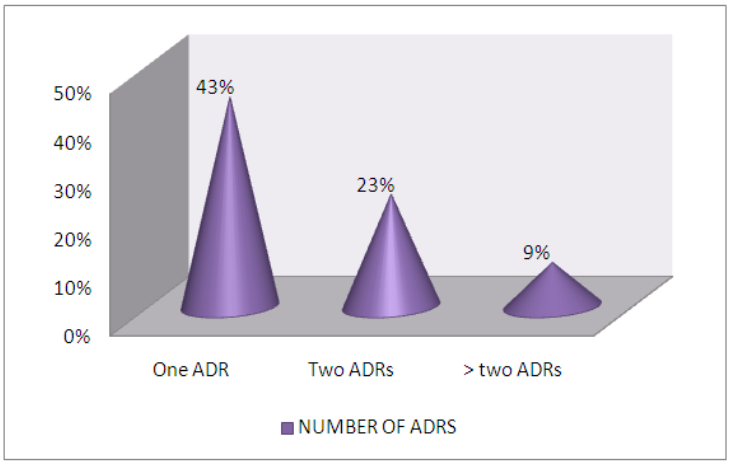

Fig.1 Incidence of adverse drug reactions

Alopecia is observed to be the most common adverse drug reaction which is observed in 95% of people who experiences ADRs followed by nausea and vomiting in 82% of people. Myelosuppression, skin pigmentation and itching are also observed considerably. Cardio toxicity is observed to be rare but serious. Observed ADR is given in Fig.2.

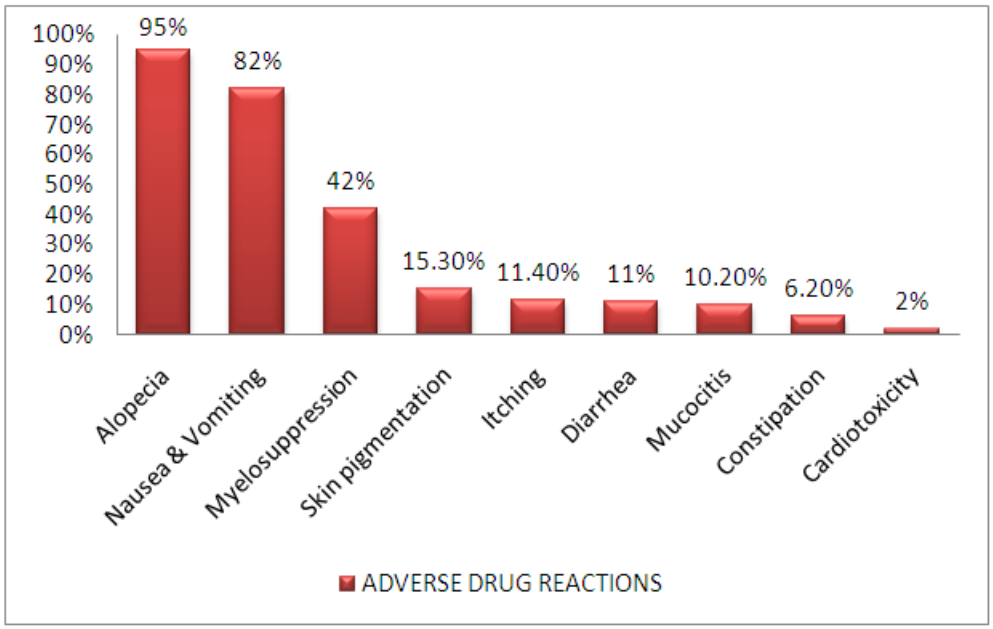

Fig.2 Adverse drug reactions observed

From the causality assessment scale it was proved that ADRS like alopecia is certain in 99.4% of patients; nausea and vomiting is certain in 97.03% of patients and probable in 2% of patients; myelosuppression is certain in 98% of patients and probable in 1.2% of patients; cardiotoxicity is certain in 87.5% of patients and probable in 12.5%, which shows that these ADRs are truly because of chemotherapy but the ADRs like itching, diarrhea and constipation may be because of adjuvant drugs or other reasons. The further details on remaining ADRs are furnished in Fig.3

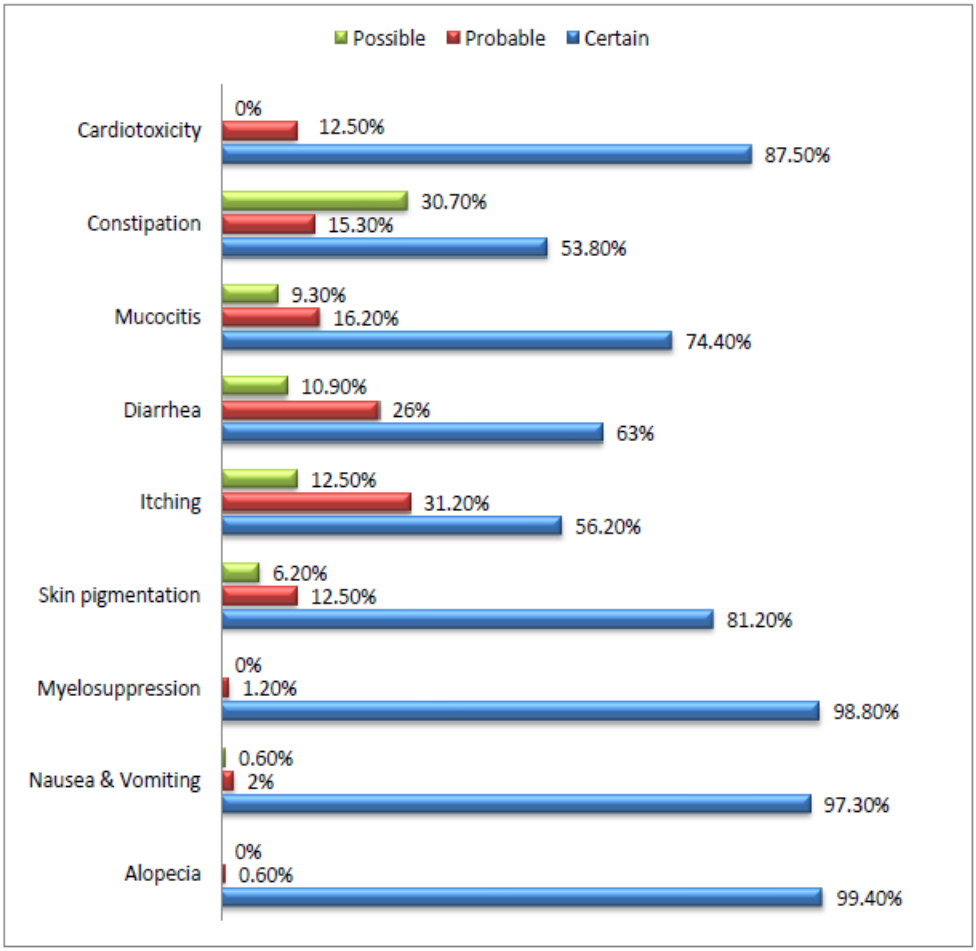

Fig.3 Causality assessment of ADRs

The most serious adverse drug reactions that lead to hospitalization are 6.2% that is 26 cases. Among these 10 (38.4%) are due to severe dehydration because of nausea and vomiting, 8 (30.7%) with Diarrhea, 4(15.5%) with severe mucositis, 2 (7.7%) with Neutropenia and 2 (7.7%) are with cardiotoxicity. The recovery rate is 62% i.e. 10 patients died of those adverse drug reactions. Detailed representation is shown in Fig.4.

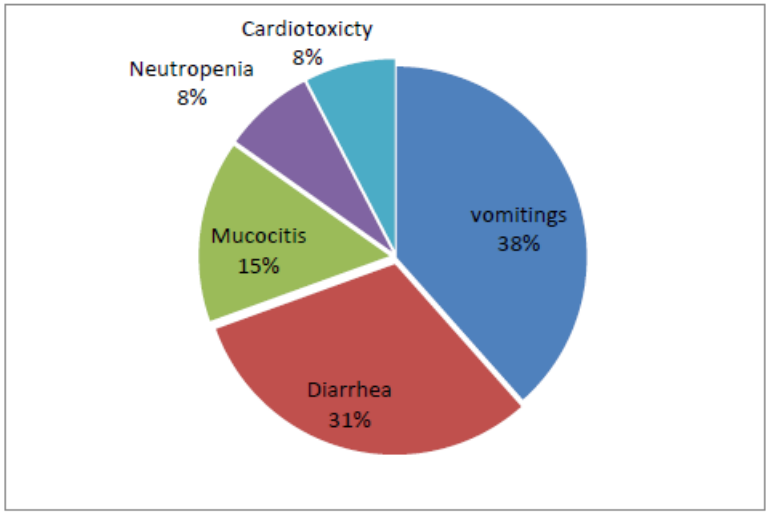

Fig.4 Hospitalized due to adverse drug reactions

The mortality rate is about 38% among the 26 patients and 62% of the patients recovered well after the treatment and this is depicted in Fig.5

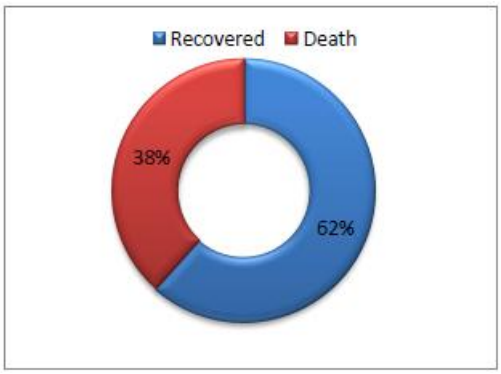

Fig.5 ADR treatment outcome

The drugs and their proportions for management of chemotherapy induced adverse drug reactions include Filgrastim(100%) for myelosppression, metachlopromide (87.0%) and Ondansetron (70%) for nausea and vomiting, different antibiotics like Piperacillin+Tazobactum (77.8%) and Ceftriaxone for neutropenia induced fever (73.3%), and Dulcolax (66.6%) for constipation. Further details are furnished in Fig.6.

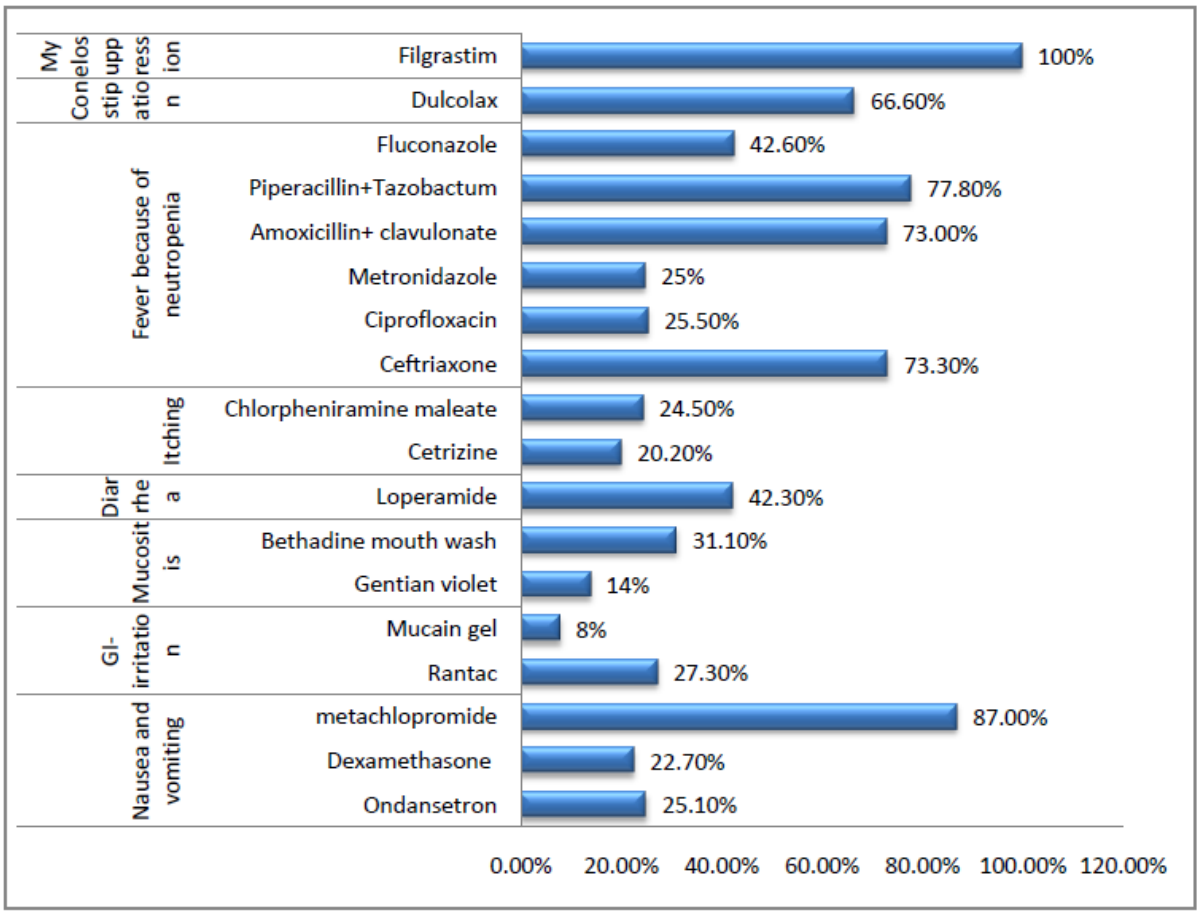

Fig.6: Drug utilization for the management of adverse drug reactions

IV. Discussion

Occurrence of more than one adverse drug reactions is very common in patients who receive chemotherapy. Among the total 78% (n=418) of the subjects experienced adverse drug reactions.Alopecia is observed to be the most common adverse drug reaction which is observed in 95% of people who experiences ADRs. Nausea and vomiting is also one of the most common ADR and observed in 82% of people. Surprisingly myelosuppression is only observed in 42% of people which is much lesser as compared to standard literature and the other commonly observed ADRs include skin pigmentation, mucositis, cardiotoxicity observed in 15.3%%, 10.2% and 2% respectively. Causality assessment was done for all the reported ADRs, no literature

was found on chemotherapeutic drugs for causality assessment. On doing this, it was found that most of ADRs like alopecia, nausea and vomiting, myelosupression, cardiotoxicity, were found to mostly probable and then certain.

Susan Gaye Poole, conducted a study on incidence of adverse drug reactions (ADRs) in oncology patients hospitalized, and found that Twenty-eight admissions (9.6%) were related to drug therapy. One hundred and thirty-four ADRs occurred in 86 inpatient episodes of care (31.6% of admissions). One hundred and four ADRs (60.8%) were associated with active therapy for malignancy or infection. Supportive therapy, including analgesics and antiemetics, were implicated in 67 (39.2%) adverse events[3]. In our study among all the observed adverse drug reactions, 6.2% (26) hospitalizations were due to serious ADRswhere 10(38.4%) are with severe dehydration because of nausea and vomiting, 8(30.7%) are with Diarrhea, 4 (15.5%) are with severe mucositis, 2(7.7%) with Neutropenia and 2(7.7%) with cardiotoxicity. The recovery rate is 62% and mortality rate is 38% (10) with serious adverse drug reactions.

The drug utilization for the management of the observed ADRs was observed and adjuvant drugs include filgrastim; antiemetics like metochlopromide, ondansetron; antibiotics like fluconazole, piperacillin+tazobactum, ceftriaxone, amoxicillin+clavulanic acid etc; dulcolax; antihistamines, anti-diarrhoeals.

V. Conclusion

Approximately 78% of patients taking chemotherapy experienced adverse drug reactions that are mostly managed by utilizing proper medications, which further elucidate the opportunity for clinical pharmacists to monitor and manage adverse drug reactions cautiously, thereby minimizing the after effects of chemotherapy and improving the patient's outcomes.

References

[1]. Megan L. Steele,1 Jan Axtner, et.al; Adverse Drug Reactions and Expected Effects to Therapy with Subcutaneous Mistletoe Extracts (Viscum album L.) in Cancer Patients; Evidence-Based Complementary and Alternative Medicine; Volume 2014

[2]. Karin Fattinger, MalgorzataRoos, et.al; Epidemiology of drug exposure and adverse drug reactions in two Swiss departments of internal medicine; Br J ClinPharmacol. Feb 2000; 49(2): 158–167.

[3]. Susan Gaye Poole, Michael Joseph Dooley; Establishing a baseline incidence of adverse drug reactions in hospitalised oncology patients; J OncolPharmPract June 2000 vol. 6 no. 2 55-59.

[4]. The use of the WHO-UMC system for standardized case causality assessment, The Uppsala monitoring Centre.

[5]. Lapeyre-MestreM , Gary J, Incidence and cost of adverse drug reactions in a French cancer institute; Eur J ClinPharmacol. 1997;53(1):19-22.

[6]. Karch FE, Lasagna L. Toward the operational identification of adverse drug reactions. ClinPharmacolTher.1977;21:247–254.

[7]. Atkin PA, Shenfield GM. Medication-related adverse reactions and the elderly: a literature review. Adverse DrugReactToxicol Rev. 1995;14:175–191.

[8]. Pirmohamed M, Breckenridge AM, Kitteringham NR, Park BK. Fortnightly review: adverse drug reactions. Br MedJ. 1998;316:1295–1298.

[9]. Smith CC, Bennett PM, Pearce HM, et al. Adverse drug reactions in a hospital general medical unit meritingnotification to the Committee on Safety of Medicines. Br J ClinPharmacol. 1996;42:423–429.

[10]. Lee A, Thomas SHL (2003) Adverse drug reactions. In: Clinical Pharmacy and Therapeutics Roger. (3rdedn), Churchill Livingstone, Spainp 33-34.

[11]. Sweetman SC (2002) Martindale: The Complete Drug Reference. (33rdedn), Pharmaceutical Press. London, UK

[12]. Beers MH, Berko R (1999) The Merk manual of Diagonosis and Therapy. (17thedn), Merck Publishing Group, USA.

[13]. Jason Lazarou, Msc. Brucel et.al, Incidence of Adverse drug reaction in hospitalized patients, A meta-analysis of prospective observational study, American medical association; April 15, 1998; No.15.

[14]. P. A. Routledge, M. S. O'Mahony et.al, Adverse drug reactions in elderly patients; British Journal of Clinical Pharmacology; 2003, 57:2 121–126.

[15]. A. Surendiran, N. Balamurugan et.al, Adverse drug reaction profile of cisplatin-based chemotherapy regimen in a tertiary care hospital in India: An evaluative studyl; Indian Journal of Pharmacology, Feb 2010; 42(1): 40–43.

[16]. Pierre Pouyanne, Francoise Haramburu et.al, Admissions to hospital caused by adverse drug reactions: cross sectional incidence study; British medical journal, January 2000.