



EVALUATION OF ADVERSE DRUG REACTION (ADR) OF CANCER CHEMOTHERAPY IN A TERTIARY CARE HOSPITAL, KOLKATA

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ABSTRACT

Objective: Cancer is a disease which is spreading globally at an alarming rate. A number of medications are being used to treat this disease. Another large number of medications are accounted for different medical complexities in these patients. Undesirable effects of medications are a natural phenomenon and should be recognized, analyzed. Measures should be taken with specifically with best use of drugs to reduce human suffering. Present study will investigate adverse drug reactions in cancer patients attending a tertiary care hospital in Kolkata. **Methods:** This is an observational study conducted at R.G. Kar Medical College & Hospital for a period of one month. Data was collected from the Oncology department of the college and evaluated on the basis of age, sex, diagnosis, drugs responsible for the adverse effects, symptoms of the adverse effect and evaluation of causality assessment. **Results:** In this study, 20 patients were identified out of the patients attending oncology out of which 40% were male and 60% female. Most of the patients (35%) were in the age group of 50 to 59 years. Most common cancers diagnosed in the present study population were lung cancer (25%) in male, and breast carcinoma (20%) in female. It was found that carboplatin was most commonly prescribed drug (15%). **Conclusion:** Anticancer drugs have a narrow therapeutic index. However, early detection of harmful drug effect helps to modify the doses or the regimen. The duration of the study was only for a month, a major limitation.

KEYWORDS: Adverse Drug Reaction, Observational Study, Anticancer drugs.

INTRODUCTION

Drugs are very important for human survival. They are used for diagnosis, treatment, prevention of diseases. However along with beneficial effects, they can develop some noxious or adverse effects in the body. Such effects are known as adverse drug reactions (ADR). According to World Health Organisation (WHO), an adverse drug reaction is defined as a response to a medicinal product 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 restoration, correction or modification of physiological function.^[1] Drug reactions are most commonly seen during the use of anti-cancer drugs. Cancer is a disease in which there is uncontrolled proliferation of the cells and spread of these abnormal cells within the body. The anti-cancer drugs either kill these cancer cells or modify their growth.^[2]

Chemotherapy is a part of a multimodal approach in the treatment of malignancy.^[3] Chemotherapy regimens are immensely complex. The selectivity of majority of the drug is limited and they are one of the most toxic drugs used in therapy.^[2] Epidemiological research from

Australia showed that 11% of ADRs in Australian Hospitals were associated with anti-neoplastic drugs and immunosuppressive drugs with antineoplastic drugs being the most common agents responsible for medication-related-hospitalizations.^[5]

Study from South India also documented antineoplastic agents as the most common class of drugs causing the ADRs.^[6] Besides their impact on human life, ADRs significantly affects health costs as well. ADRs thus cause a huge burden on the society because of the increased incidents of the morbidity and mortality. It may so happen that a drug which was found to be safe in the clinical trial may produce serious ADRs. This may be due to the fact that clinical trials generally have limited sample size, though there are other limitations of clinical trial also. Therefore, ADR monitoring and reporting is an essential need for the betterment of the well being of the patient.

Thus, the present study aims to determine the prevalence of ADR caused by various chemotherapeutic agents in

patients suffering from malignant diseases in a Tertiary Care Hospital, Kolkata.

MATERIAL AND METHODS

MATERIALS

1. Patients admitted in the Department of Oncology were included in the study.
2. Pre designed case record form
3. Prescriptions available from the patients.

METHOD

This is a cross-sectional, observational study and was carried out at R. G. Kar Medical College & Hospital, Kolkata, West Bengal, India. Willing patients of both the genders between the age group of 18 to 80 years attending Department of Oncology, R.G. Kar Medical College & Hospital were requested to join this study. Only those patients signed the Inform Consent Form, were included in the study. Data was collected was done using a structured predesigned case record form which included patient characteristics such as age, gender, diagnosis, and prescription characteristics such as name of the drug, strength and dosage form, number of units dispensed. The study was conducted in the month of June 2016.

The study was conducted after permission from institutional ethics committee of R.G. Kar Medical College & Hospital.

RESULT AND OBSERVATIONS

Present study screened ADRs in patients with different malignancies admitted for anticancer chemotherapy in the in-patient Department of Radiotherapy (Oncology), R.G. Kar Medical College & Hospital, Kolkata. In the period of one month, 20 patients agreed to participate in the present study. Out of those 20 patients, 12 patients were female (60%) and 8 were male (40%). (Figure 1).

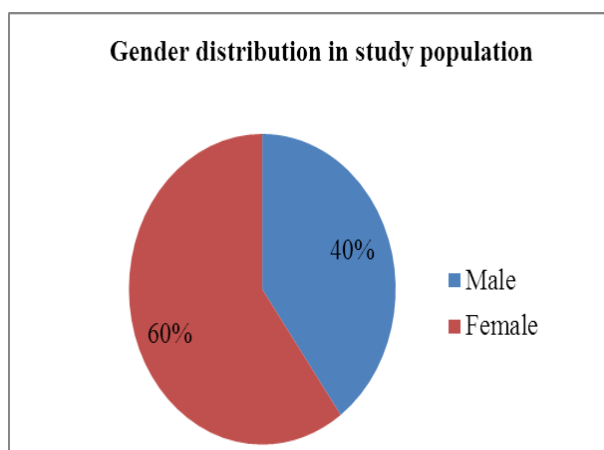


Figure 1: Distribution of gender profile in the study population (n=20)

In the present study, most of the patients (35%) in the study were found to be in the age group of 50-59 years. Five patients (25%) were in the age group of 40-49 years. 4 patients (20%) in the age group of 30-39 years,

two patients (10%) 20-29 years and one patient (5%) each were in the age group of 60-69 and 70-79 years. (Figure 2).

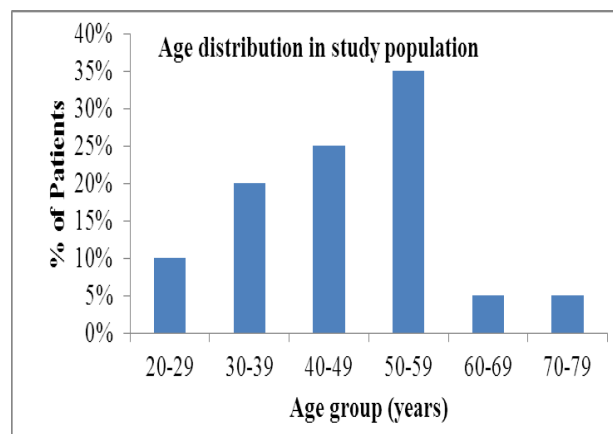


Figure 2: Distribution of Age of the patients (n=20)

Most common malignancy diagnosed in the study population was lung cancer (25%). In the female patients, breast cancer was most predominant (20%). Stomach cancer accounted for the 15% of the study population. Sinder cell carcinoma thigh, colon cancer, cervical cancer, metastasis of the neck node and Hodgkin's lymphoma represented 5% each in the study population. (Figure 3).

Figure 3: Distribution of malignancies in the study population (n=20)

It was found that Carboplatin was given to most of the patients (15%), followed by Docetaxel (13%), Doxorubicin and Cisplatin (9% each). (Figure 4) Etoposide, Paclitaxel, Capcitamine, Oxaliplatin were each prescribed to 7% of the study group and Gemcitabine and Vinblastine were given to 4% of the study population each. Epirubicine, Decarbazine, Bleomycine, Vincristine, 5-Fluorouracil and Ifosfamide were given to 2% of the population each.

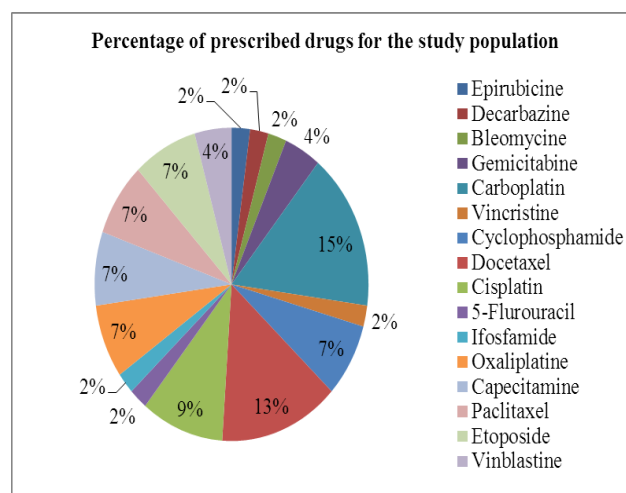


Figure 4: Distribution of drugs prescribed for the study population (n=20)

Figure 5 showed the pattern of Adverse Drug Reaction in patients. A total no of 38 ADRs were documented. Most common ADRs were neuropathic limb pain (23%) and hyperpigmentation of the skin and nails (18%) followed by xerostomia (7%) and black stool (7%). Other ADRs, which were noted, are allergy (5%), scaling (5%), cloudy vision (5%), lower abdominal pain (2%), anorexia (2%),

metallic taste (2%), swelling of limbs (2%), burning sensation (2%), chest pain (2%), orthostatic hypotension (2%), body ache (2%), anemia (2%), insomnia (2%), water discharge (2%) and increase in serum creatinine level (2%).

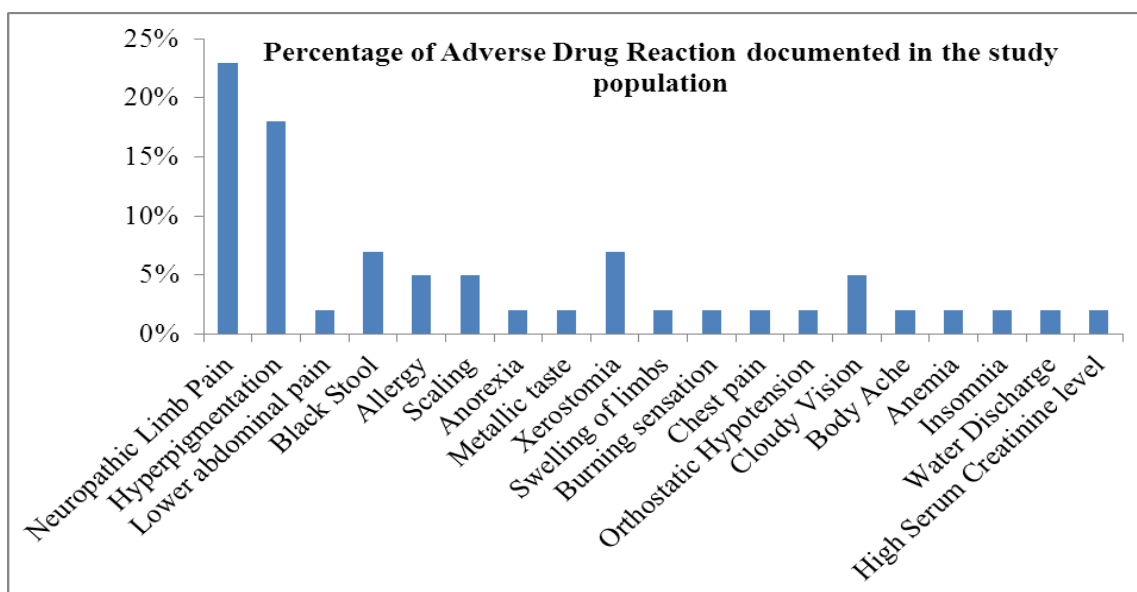


Figure 5: Distribution of ADR documented in the study population (n=38).

DISCUSSION

Various studies have been conducted around the globe to know about the ill effects of various drugs. Present study searched various adverse effects of different chemotherapeutic agents.

Gender based profile showed that the present study comprised more of female patients (60%). Study from South Korea showed that 66% of the patients were female when they analyzed patterns of ADRs in different age groups.^[6]

Prevalence of ADR was found to be higher (35%) in patients in the age group of 50-59 year old patients. A similar study from South India showed ADRs due to cancer chemotherapy were most (26.2%) in the age group of 51-60 years.^[7] Although a study from Ethiopia showed that the maximum no of ADRs were in the age group of 41-50 years (38.9%) followed by 51-60 years (13.8 %).^[8] This may be due low metabolizing capacity and poor renal function in elderly patients. The therapy of these patients consisted of multiple different antineoplastic drugs, all of which can cause potential ill effects. These adverse effects may occur early during therapy or late after completion of therapy. Although many of the effects are short lived and reversible others can be permanent and can cause long term physical and psychological problems in the patients.^[9]

Platinum compounds such as carboplatin and cisplatin showed maximum number of ADRs (The result is

similar to the study done in Ethiopia in which platinum compounds accounted for 31.4% of the ADRs in cancer patients.^[8] Wahlang *et al.*, from Meghalaya also reported that most of the ADRs are caused by platinum compounds.^[10]

Alopecia, nausea, vomiting, constipation and anorexia are common to all patients which is similar to the data documented by Wahlang *et al.*^[10] and Chatterjee *et al.*^[11] Apart from these, the most prevalent ADRs were neuropathic limb pain and hyperpigmentation of skin and nails affecting 3% and 18% of the patients respectively. A study from Dehdarun, India also documented 7.98% of the ADRs were hyperpigmentation of skin and neuropathy accounted for 29.7%.^[12] Small sample size and short study period are major limitation of the study.

CONCLUSION

Prevalence of ADRs was found more in women, in patients with Carboplatin and Cisplatin regimen. Early detection of ADRs may help to modify the doses or regimen to maximize the therapy. Future prospective studies will help in identifying patients at risk with development of ADRs and reform the therapy.

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