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Original Research Article

Adverse drug reaction profile of anticancer agents in a tertiary care centre of rural Maharashtra: a cross-sectional study

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ABSTRACT

Background: The present study was undertaken to analyse the clinical spectrum, pattern of ADR reported, most common suspected drugs, timing of reporting of suspected ADR, outcome, severity and causality assessment of adverse drug reactions among oncology patients reported at our ADR monitoring Centre.
Methods: The descriptive cross-sectional study was carried out for two months in the oncology department of a tertiary care rural hospital. ADR reporting form Version 2.4 was used for recording information of all patients of any gender and age who were suspected cases of adverse drug reactions receiving chemotherapy.
Results: Total 83 ADRs were reported within the duration of two months. The number of males and females were 21 and 62, respectively with mean age 56.9±11.6 years for males and 59.6±8.8 years for females. The age group most commonly reported with suspected ADR was 61-70 years (28.9%). Of the 83 ADR reported, the most common suspected drug was Paclitaxel (47, 56.6%). The most common indications for the use of these anticancer drugs was reported to be CA breast (43, 51.8%). Most of the ADRs (38, 45.8%) were reported immediately. On applying Naranjo's Causality Assessment Scale, 61 and 22 ADRs fell in the category of Probable and Possible, respectively.
Conclusions: The occurrence of ADR among patients on chemotherapy is high. The reported ADR were common and predictable. Hence diligent monitoring in ADR may help manage and prevent morbidity associated with anti-cancer drugs.

Key words: Adverse drug reactions, Pattern, Oncology, Causality assessment

INTRODUCTION

The World Health Organization (WHO) defines ADR as "a response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function"[1]. Adverse drug reactions (ADRs) are the one of the leading causes of repeated hospitalization and adversely affects the quality of life.[2] It has been observed that drug induced conditions lead to 5% of all hospital admissions and 10-20% of hospitalized patient develops ADRs.[3] Due to the soaring prevalence and at times potentially serious repercussion of drug therapy, ADRs may have a dramatic impact in clinical practice and on the health of society.[4] According to the Indian Council of Medical Research (ICMR), the estimated number of

new cancer cases in India was 1.39 million in 2020.[5] The burden is not limited to specific types of cancer but encompasses a wide range of malignancies, including breast, lung, oral, cervical, and colorectal cancers. According to the Maharashtra Cancer Registry, an estimated 150,000 new cancer cases were reported in the state in 2020.[6] The most common types of cancer in Maharashtra include oral, breast, cervical, lung, and gastrointestinal cancers. The prevalence of ADRs among oncology patients ranges from 9.2% to 15.4%.[7-11] Johnson et al. demonstrated that timely reporting of ADRs led to appropriate treatment adjustments, resulting in improved patient outcomes and reduced treatment-related toxicities.[12] Dr. Vitthalrao Vikhe Patil Pravara Rural Hospital (VVPPRH), Loni is one of the ADR Monitoring Centre (AMC) for monitoring and reporting ADRs through pharmacovigilance programme of India (PvPI) since 2017. In view of large number of cancer patients that the Hospital caters, it was desirable to know the pattern of ADRs reported in oncology patients. The present study was undertaken to analyse the clinical spectrum, pattern of ADR reported, most common suspected drugs for the suspected ADR reported, timing of reporting of suspected ADR, outcome, severity, causality and preventability of adverse drug reactions among oncology patients reported at our ADR monitoring Centre.

METHODS

The present study was an observational, cross-sectional study, conducted in February and March 2023, in the patients receiving cancer chemotherapy at oncology department of Dr. VVPPRH, Loni. All the suspected ADRs reported to the ADR Monitoring Centre (ADR monitoring form Version 2.4.) during February and March 2023 from the oncology patients, irrespective of their age and gender, were included in the study. There were no exclusion criteria. All the ADRs reported during the above study period were included in the sample (Universal sample). The sample size of the study was 167. The ADRs reported were recorded and evaluated for the total number of ADR reported, age, gender, frequency, pattern of ADR, the drugs suspected, the indications of the suspected drugs, time to report the ADR, severity of ADR and causality assessment of the ADR. The causality assessment was done by the departmental causality assessment committee. The causal relationship between the suspected drug and ADR observed was determined by using the WHO causality assessment scale. The causality is categorized into 6 types, i.e., Certain, Probable, Possible, Unlikely, Conditional/Unclassified and Unassessible/Unclassifiable. The Naranjo's algorithm has 10 questions with options of "Yes", "No" and "Do not know" as answers. The questions are objective in nature. The score is summed to categorize the causality into Definite, Probable, Possible and Unlikely. The severity of Adverse drug reactions was assessed by using the modified Hartwig and Siegel scale. The ADRs are classified into Mild, Moderate and Severe, based on various factors like requirement for change in drug treatment, effect on the duration of stay in hospital and disability caused by the ADR. Serious ADR was defined as any ADR which was fatal, life-threatening, permanently/significantly disabling, required initial hospitalization, or prolonged hospitalization, caused a congenital anomaly, required intervention to prevent permanent impairment or damage.[13] The variables of the study were recorded in a pretested google form and extracted as excel sheet. Descriptive statistical analysis was performed with the SPSS software package version 26.

RESULTS

A hundred and sixty-seven ADRs were reported within two months of February and March at our AMC. Out of these ADRs, Eighty-three ADRs were reported from the patients receiving cancer chemotherapy. A hundred and fifty-one patients admitted in the oncology ward, thus the ADR in oncology which amounts to 54.9%. The number of males and females were 21 and 62, respectively. As shown in (Figure 1), the age group most commonly reported with suspected ADR was 61-70 years (28.9%).

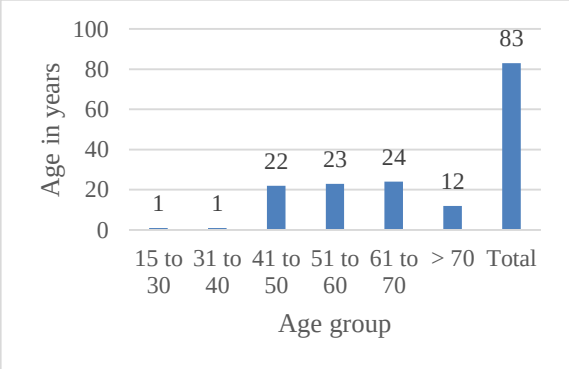

Figure 1: Distribution of patients with respect to age group.

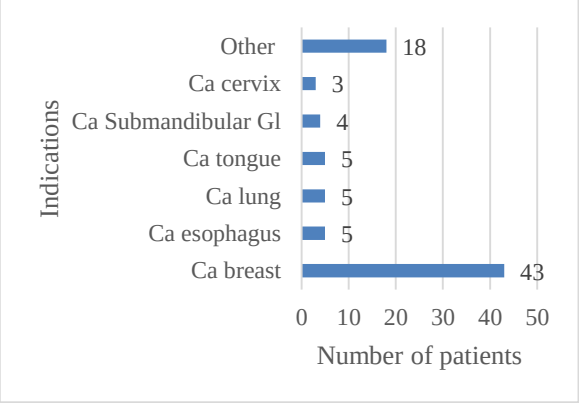

Figure 2: Indications for use of drugs.

There was no statistical difference (p=0.3374, unpaired t test) between average age of males (56.9±11.6 years) and females (59.6±8.8 years). (Figure 2) depicts Indications for use of drugs. Ca breast (43, 51.8%) was the most common indication for use of drugs suspected in ADR. The most

common system affected was Gastrointestinal (51.8%) followed by dermatological (30.12%) and musculoskeletal (10.84%) (Figure 3).

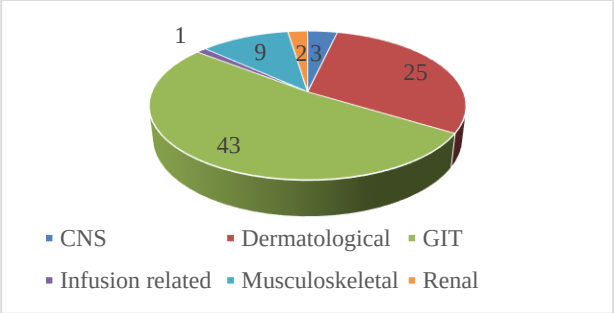

Figure 3: Distribution of ADR with respect to classification of ADR.

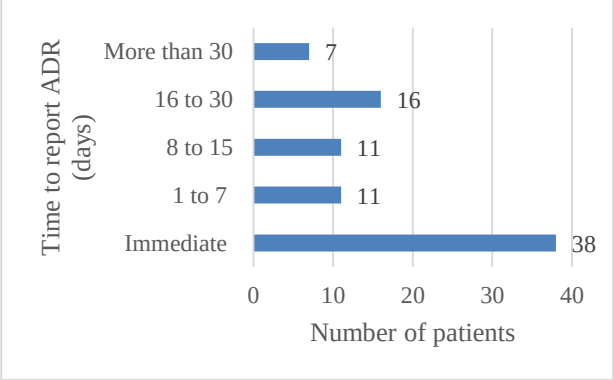

Figure 4: Distribution of patients with respect to time to report ADR.

As shown in (Table 1), the most common drug suspected was Paclitaxel (47, 56.6%) followed by Cisplatin (16, 19.3%) and Adriamycin (9, 10.8%). (Figure 4) represents time to report ADR calculated by subtracting date of administration of drug and date of reporting ADR. Most of the ADRs (38, 45.8%) were reported immediately. On applying Naranjo's Adverse Drug Reaction Probability Scale, 61 and 22 ADRs fell in the category of Probable and Possible, respectively (Table 2). On application of modified Hartwig and Siegel scale, majority of the ADR reported were mild (81.1%). Serious ADR was reported in one patient receiving Cisplatin+Paclitaxel. The ADR reported was Difficulty in breathing, fever and chills. The patient recovered from the episode. As shown in (Table 3), apart from one patient receiving Cisplatin+Paclitaxel (who had Difficulty in swallowing taste change, abdominal pain and decreased appetite), all patient either recovered (N=3) or were recovering (N=79).

DISCUSSION

The practice of cancer medicine has changed dramatically nowadays with treatment available for many previously fatal malignancies. Adjuvant chemotherapy has proven to extend life and prevent disease recurrence. Despite these therapeutic successes, many of the antineoplastic drugs possess narrow therapeutic index and a greater potential for causing adverse effects such as nausea/vomiting, neutropenia/anaemia/pancytopenia, alopecia, constipation/diarrhoea, and fatigue/tiredness.[14] The present study focuses on the pattern of ADR in the patients suffering from various cancers and undergoing chemotherapy at our hospital. Out of 167 ADRs reported during the duration of the study, 83 ADRs (49.7%) were reported from the oncology patients. Previous studies conducted in India reported ADRs in 9.2% to 15.4% of patients, which is very low as compared to the present study. [7-14] This finding of our study is similar to that of Lavan et al.[15] Patients with cancer have high levels of multi morbidity and poly pharmacy, which require vigilance for related adverse outcomes. ADRs of 54.9% of patients admitted in the Oncology department were reported. In the study by Chopra et al ADRs were reported in 58.6% of patients, which is similar to the present study.[16] The demographic profile of the present study shows that females were more commonly reported with ADRs than males (74.6%). There are many studies which show that ADRs are more commonly reported with females than males.[16-19] Contrary to the above findings, there are studies who have found males to have more ADRs than females.[20,21] In the present study, the incidence of breast carcinoma was found to be highest among all the other cancers. The most common age group reporting the ADRs was between 61-70 years old (Figure 1) similar to that reported by other studies.[20,21] The International Conference on Harmonization considers older people a 'special population', as they differ from younger adults in terms of comorbidity, polypharmacy, pharmacokinetics and greater vulnerability to adverse drug reactions.[22] Some studies have reported ADRs to be most common in the age group of 41-60 years.[17,18] The overall incidence of ADRs are reported more in the elderly vulnerable population.[23] The possible explanation could be that the metabolizing capacity of the liver and the renal excretory functions are generally compromised in old age leading to building up of drug levels in the body thereby raising the possibility of ADRs. The highest incidence of ADRs was seen in patients receiving chemotherapy for breast carcinoma which is consistent with other studies[16-18] The most common malignancy reported in our setting was Breast carcinoma, so the incidence of ADR reported was greater in females as compared to males similar to Sharma et al and Poddar et al followed by others like CA cervix, CA tongue, CA lung, etc.[16,17] A study by Gunaseelan et al reported that patients with leukemia(s) encountered more ADRs followed by lung cancer and breast cancer.[23-26] A similar study by Mrugank and Hareesha, 2013 observed that gastrointestinal and breast cancers were more commonly associated with ADRs.[27] The differences can be probably due to the racial variations and the geographical distribution of the populations. Among the organ system involvement, the most common ADRs were seen with the gastrointestinal system followed by skin (Figure 3), consistent with other studies.[16,20]

Table 1: Distribution of ADRs with respect to drugs and their indications.

Name of drug	ADRs	Indication	Average ADRs/ drug
Adriamycin (9)	Discoloured nails (5), Oral ulcer (3), Limb pain (2), Nausea (2), Diarrhoea, Dysphagia and Tremors=15	Ca breast	1.67
Carbocystiene (5)	Joint pain 2, Limb pain 2, Diarrhoea, Dizziness, Dysphagia, Headache, Nausea=9	Ca breast (2), Ca Ovary, Ca tongue, Cervical Lymphadenopathy	1.8
Cisplatin (16)	Nausea (7), Vomiting (6), Fever (4), Dysphagia (3), Chills (2), Joint pain (2), Oral ulcer (2), Swollen limbs (2), Abdominal pain, Loss of Appetite, Constipation, Discoloured nails, Dry mouth, Dyspnea, Dysuria, Hair fall, Limb pain, Weakness=38	Ca breast (2), Ca tongue (5), Ca buccal mucosa, Ca cervix (2), Ca larynx (2), Ca urinary bladder, cancer, NA (2)	2.4
Paclitaxel (47)	Hair fall (32), Dysphagia (22), Joint pain (22), Discoloured nails (20), Loss of appetite (18), Limb pain (12), Abdominal pain (8),Vomiting (8), Dizziness (6), Itching (6), Diarrhoea (4), Difficulty in walking (4), Dysguesia (4), Frequent micturition (4), Heartburn (4), Nausea (4), Rash (4), Tiredness (4),Weakness (4), Blue tongue (2), Brown tongue (2), Discoloured skin (2), Melanochia (2), Melanuria (2),Swollen jaws (2),Tingling (2)=204	Ca breast (28), Ca oesophagus (4), Ca Submandibular Gland (4), Ca lung (2), Ca endometrium (2), Ca GBS (2), Ca Bladder, Ca breast, Ca buccal mucosa, Ca cervix, Ca Ovary	4.34
Gemcitabine	Acidity, Loss of appetite, Vomiting	Ca breast	3
Methotrexate	Limb pain, Vomiting	Ca breast	2
Oxaliplatin	Hot flushes	Ca oesophagus	1
Pemetrexed	Rash (2), Black stool=3	Ca lung (3)	1

Among the chemotherapeutic drugs, most common drug suspected to be causing ADR was found to be paclitaxel, Cisplatin and Adriamycin (Table 1). These findings are similar to other studies.[16,23,24]

Table 2: Classification of ADR's with respective to Naranjo's ADR probability scale.

Medication	Possible	Probable
Adriamycin	0	3
Adriamycin + Cyclophosphamide	2	4
Carbocystiene	1	3
Cisplatin	3	7
Cisplatin + Gemcitabine	0	2
Cisplatin + Paclitaxel	2	5
Methotrexate + Cyclophosphamide	1	0
Oxaliplatin	0	1
Paclitaxel	4	26
Paclitaxel + Carbocystiene	8	8
Pemetrexed	1	2
Grand Total	**22**	**61**

Taxanes are commonly indicated in tumours of head and neck, lung, peritoneal and gynaecological tumours. The most common ADRs seen with taxane was loss of hair, discolouration of nails, loss of appetite, dysphagia, joint pains etc (Table 1). Taxanes act by stalling the cellular processes that are needed for cells to divide. This action causes cancer cells to stop dividing and slows the growth of cancer or kills the cells. Adding taxane to chemotherapy improves the survival and prevents the cancer from coming back as compared to chemotherapy with no taxane.[28] Administered intravenously to humans, cisplatin is used as first-line chemotherapy treatment for patients diagnosed with various types of malignancies, such as leukaemia, lymphomas, breast, testicular, ovarian, head and neck, and cervical cancers, and sarcomas.[29] Cisplatin use caused ADRs like nausea, vomiting, dysphagia, weakness, discolouration of nails, dry mouth, joint pain, etc (Table 1). The cytotoxic mechanism of cisplatin is initiated by its interaction with DNA to form adducts; leading to apoptosis or programmed cell death.[30] They are often selected due to their strong anti-tumor activity despite its severe adverse effects.[31] Adriamycin (Doxorubicin) may be used to treat soft tissue and bone sarcomas and cancers of breast, ovary, bladder and thyroid. It is also used to treat acute lymphoblastic leukaemia, acute myeloblastic leukaemia, Hodgkin lymphoma, and small cell lung cancer.[32] Common ADRs seen with Adriamycin were discoloured nails, oral ulcers, pain in limbs, nausea, tremors, etc. (Table 1) Doxorubicin inhibits the enzyme topoisomerase II, causing DNA damage and induction of apoptosis.[32] Present study also highlights the importance

of timing of reporting of ADR. Majority of the ADRs were reported immediately to the AMC (Figure 4).

Table 3: Distribution of patients with respect to recovery status.

Medication	Not recovered	Recovered	Recovering
Adriamycin	-	-	3
Adriamycin + Cyclophosphamide	-	-	6
Carbocystiene	-	-	4
Cisplatin	-	-	10
Cisplatin + Gemcitabine	-	-	2
Cisplatin + Paclitaxel	1	2	4
Methotrexate + Cyclophosphamide	-	-	1
Oxaliplatin	-	-	1
Paclitaxel	-	1	29
Paclitaxel + Carbocystiene	-	-	16
Pemetrexed	-	-	3
Total	1	3	79

Early detection and active monitoring of the ADR provides the benefit of initiating risk management plan if needed, helps in measuring the ADR incidence, helps in preventing predictable adverse effects, creates awareness among the health care team, patients, pharmacists and nurses about the adverse drug effects. This is an important parameter which needs to be evaluated by a larger study sample.

The scrutiny of causal association using the Naranjo Scale of Causality assessment showed that 73.4% ADR fell in the category of 'Probable' and 26.5 % were 'Possible' (Table 2). These finding are similar to studies by Chopra et al and Ramasubbu et al.[16,34] With the use of this same scale, two other studies reported 100% and 61% of probable scores for causality.[35,36]

These findings suggest that one should be watchful of the common ADRs of the drugs prescribed, which fall under the category of probable and possible. On application of Hartwig and Siegel Assessment Scale, majority of the ADR reported were mild (81.1%). In the study by Chopra et al, 86.97% the ADRs reported in this study were mild.[16] Studies conducted by Ramasubbu et al and Kishore et al showed that 80.2% of the ADR to be of moderate severity.[34,37] Majority of the patients (95%) were reported to be recovering from the ADRs (Table 3). ADRs observed in the study like nausea, weakness, joint pains can be prevented by proper dietary counselling before the initiation of chemotherapy.[34]

Limitations

The study sample consists of ADRs reported during two months only. The trend of ADRs could not be known due to short study period. As the ADRs reported were limited to one AMC only, the finding of the study cannot be extrapolated to larger population.

CONCLUSION

The occurrence of ADR among patients on chemotherapy is high. Majority of the ADRs were reported immediately. The reported ADR were common and predictable. Hence diligent monitoring in ADR may help manage and prevent morbidity associated with anti-cancer drugs.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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