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Original Research Article

Adverse drug reaction prevalence pattern among drugs and its correlation with causality assessment in ADR monitoring centre in Kerala over 6 months

Sunil Nettath*

Department of Pharmacology, GMC, Palakkad, Kerala 678013, India

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***Correspondence to:**
Dr. Sunil Nettath,
Email: docsunil2005@gmail.com

ABSTRACT

Background: Prevalence of adverse drug reactions had been studied extensively in the past to find out the drug pattern distribution of ADR. In this study, authors tried to find out the prevalence pattern and its correlation with the WHO causality assessment over the 6 months.
Methods: This study was done in Govt Medical College Palakkad Kerala as an observational study. Without revealing the identity of the patients as is done in ADR reporting in pharmacovigilance program, a retrospective data collection was done by collecting different types of ADR reported in this hospital for the previous six months. Only data of inpatients was collected and tabulated for different group of drugs. Then using the WHO scale of causality assessment, the ADR individually was classified to probable, possible, or certain and tabulated.
Results: In this study, the prevalence pattern of drugs causing ADR was evaluated over six months in a tertiary care centre. Out of the 45 cases reported, major ADR were for antibiotics (55.5%) and anticancer agents (18.2%) and the least reported ADR were for vaccines and supplements (2.2%). In causality assessment WHO scale only one case was certain (2.2%). Here the majority Causality assessment was found to be probable (44.45%) and possible (51.2%).
Conclusions: From this study it is concluded that the antibiotics has the major ADR pattern. It's also known that the probable and possible causalities are more common when ADR are reported.

Keywords: ADR-Adverse drug reactions, Causality assessment, Pharmacovigilance

INTRODUCTION

The World Health Organization (WHO) defined drug as "any substance or product that is used or intended to be used to modify or explore the physiological system, or pathological state in the benefit of the recipient".[1] Adverse drug reaction can be defined as "an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product".[2]

The incidence of ADR varies from as low as 0.15% to as high as 30% in various studies.[3,4]

More than half of these ADRs are not recognized by the physicians on admission and ADRs may be responsible for death of 15 of 1000 patients admitted.[5]These figures represents a serious concern related to drug safety even in countries having a reasonable ADR monitoring system.[5,6]

In a study from South India, it was observed that 3.7% of the total hospitalized patients were suffering from ADR,

among which 1.3% were fatal. 0.7% of the hospital admissions were due to ADRs.[7]

A study by Arulmani et al, revealed that among the collected ADR reports in the hospital, 3.4% were confirmed ADR related cases which need to be hospitalised and 3.7% ADRs even developed in the patients during the time of hospital admission.[8] Thus authors have decided to do a study in this tertiary care centre in Palakkad, Kerala to find out the drug pattern prevalence of ADR and its causality assessment.

Objective of the study was to prevalence pattern of types of drugs causing ADR over six months and correlation of ADR with causality assessment using WHO scale.

METHODS

This study was done in govt medical college Palakkad Kerala as a retrospective observational study. After getting ethical committee approval and consent from the pharmacovigilance committee of ADR monitoring centre GMC Palakkad, without revealing the identity of the patients, a retrospective data collection was done by collecting different types of ADR reported in this hospital for the previous six months (May 2018-October 2018). Those included were only inpatients from the hospital for whom ADR was reported for the pharmacovigilance program of India.

The patients of all age and sex were included. The excluded were those reported from out patients and those from other hospitals. These included ADR data was collected and tabulated for different group of drugs. Then using the WHO scale causality assessment was done and then classified to probable, possible, or certain. The results were analysed using percentage prevalence out of the ADR reported during these months. The percentage occurrence of WHO probability scale was also analysed.

RESULTS

In this study, the prevalence pattern of drugs causing ADR was evaluated over six months in a tertiary care centre. The results were tabulated in the excel sheet and percentage for each ADR drug class was calculated.

Of the 45 reported cases, 30 patients were male and rest 15 were females (Figure 1).

Out of the 45 cases reported, major ADR were for antibiotics (55.5%). The antibiotics which were causing ADR were, antituberculous drugs, cefixime, ceftriaxone, ampicillin, amoxicillin, amoxicillin with clavulunic acid etc. Among the antibiotics the most common adverse drug reaction was rash caused by antituberculous drugs. The second commonest was anticancer agents (18.2%). The anticancer agents which caused adverse drug reactions were carboplatin, paclitaxol, and methotrexate. The ADR were minor and probable in anticancer agents. This result shows that the majority reported ADR were for chemotherapy agents. The analgesics with ADR were 6.6% and the psychiatric drugs were 4.4%. This shows that the next common ADR were the NSAID and the psychiatric drugs. The offending drugs were Diclofenac and lithium respectively for NSAIDs and Psychiatric drugs. These adverse effects were also causality assessed as probable.

Table 1: Type of drugs with ADR and percentage of patients.

Type of drugs with ADR	No of patients	Percentage
Antibiotics	25	55.5%
Anticancer agents	10	18.2%
Psychiatric drugs	2	4.4%
Analgesics	3	6.6%
Supplements	1	2.2%
Vaccines	1	2.2%
Antihypertensives	1	2.2%
Others	2	4.4%
Total	45	

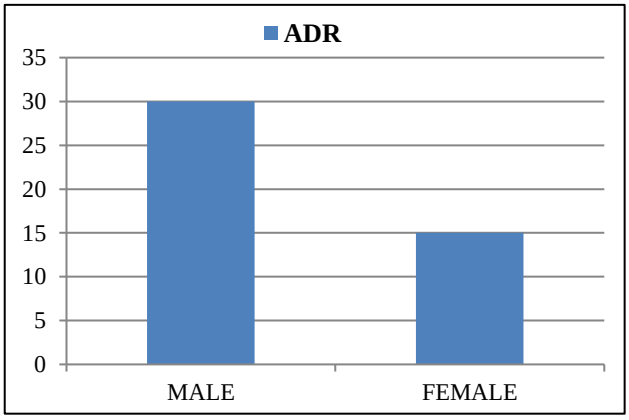

Figure 1: Male and female distribution of ADR.

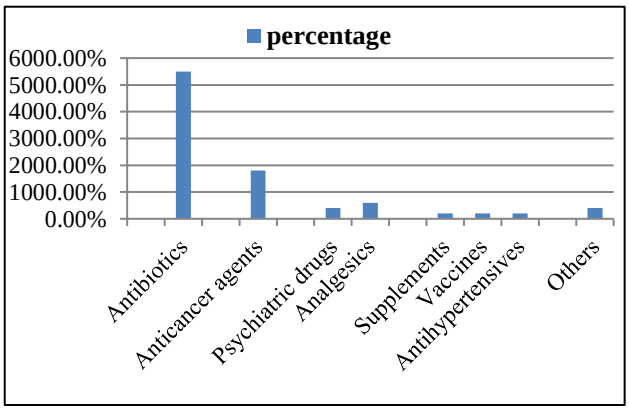

Figure 2: Prevalence pattern of drugs causing ADR.

The least reported ADR were for vaccines, supplements and antihypertensives (each 2.2%) (Table 1 and Figure 2) which means the safest among all were the vitamins,

supplements and antihypertensives. The offending vaccine was antirabies vaccine with rash. The antihypertensive was enalapril causing cough which was possible by causality.

In causality assessment WHO probability scale, only one case was certain (2.2%), which means definite association of ADR with the drug. Here the majority Causality assessment was found to be probable (44.45%) and possible (51.2%) (Figure 3) which also has a strong correlation for ADR with the drug. There was only 2.2% unlikely which means a weak correlation with ADR.

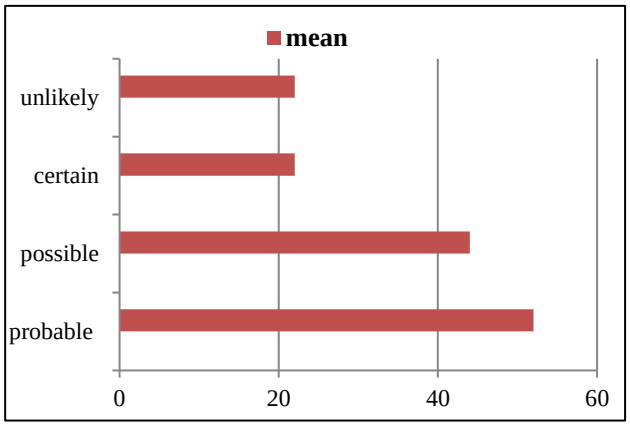

Figure 3: Causality assessment (WHO scale) percentage scale.

DISCUSSION

Pharmacovigilance is the program conducted worldwide to report various adverse reactions occurring due to drugs that are already being marketed. In this study, the prevalence pattern of drugs causing ADR was evaluated over six months in a tertiary care centre. Out of the 45 cases reported, major ADR were for antibiotics (55.5%) and anticancer agents (18.2%) and the least reported ADR were for vaccines and supplements (2.2%). In causality assessment WHO scale only one case was certain (2.2%). Here the majority Causality assessment was found to be probable (44.45%) and possible (51.2%).

In other study done by Anjan Athikari et al, the prevalence drug pattern was more for antibiotics (63.07%) which is close to this study.[9] A study in Brazil also indicated 40.7% of the ADRs were due to anti-infective agents.[10] Analogous results were also reported at regional pharmacovigilance centre in Portugal.[11] Both these reports suggested antibiotics were the most common drug involved in adverse reaction. A study performed with Nigerian children by Priyadarshini et al, also reported antibiotics responsible for 67% of the ADRs.[12]

In this study too, authors got similar results of greater percentage ADR prevalence of antibiotics (55.5%).

In another study done by Dinesh K. Badyal et al, the causality assessment was 83.5% probable by WHO scale, compared to our study were 51.2%possible and 44.5% probable causality assessment.[13] Here the result is not similar to the previous study, but the possible score slightly outweighs the probable score (51.2% vs 44.5%).

There are some contrary reports compared to our study like a study showing the most commonly identified ADRs were Gastrointestinal 47.40%, followed by Neurotoxicity 24.67%, cutaneous reactions 20.12%, Hepatic 4.54% and Kidney 3.24%. 74.67% of the ADRs were probable and 20.77% were possible type and only 4.54% were definite. 74.67% ADRs were found to be type A, and 25.32% type B.[14] This particular study was done with a large number of ADR reports collected over a span of a year. But this study reported ADR were small. It was retrospective and done with only 6 months data and also authors excluded data of out patients and patients from other hospitals.

Limitation of the study is that only six months observation and data was taken. Number of ADR reported were only few. Also, strength of the study is that the data collected was fool proof from the vigiflow software of WHO and pharmacovigilance. The causality assessment was done using WHO scale which is universally accepted.

CONCLUSION

From this study, it is concluded that the antibiotics has the major ADR pattern. Its also known that the probable and possible causalities are more common when ADR are reported.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee of GMC, Palakkad, Kerala, India

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