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A Retrospective Study of Adverse Drug Reaction Prevalence Pattern among Drugs and Its Correlation with Causality Assessment in ADR Monitoring Centre in AP

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Abstract:
Introduction: *All drugs have therapeutic effects and none are absolutely devoid of adverse effects and prescription of them should be judicious and with a satisfactory risk/benefit ratio. Pharmacovigilance has perceived several advancements throughout the world, over the past few decades. The WHO defines "Pharmacovigilance as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems, including herbal materials."*
Materials and Methods: *This study was done in Kurnool Medical College, Kurnool, AP as a retrospective observational study. After getting ethical committee approval and consent from the pharmacovigilance committee of ADR monitoring centre KMC Kurnool, 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.*
Results: *Out of the 313 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.*
Conclusion: *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.*
Key Words: *WHO, risk/benefit ratio, Pharmacovigilance*

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I. Introduction

All drugs have therapeutic effects and none are absolutely devoid of adverse effects and prescription of them should be judicious and with a satisfactory risk/benefit ratio. Pharmacovigilance has perceived several advancements throughout the world, over the past few decades.[1] The WHO defines "Pharmacovigilance as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems, including herbal materials."[2]

Common incidences of adverse drug reaction (ADR) in hospitals are recognized in the patients who are suffering from severe and complex disease process or are on multiple drugs, leading to drug interactions.[3] About 10%–20% ADRs reported are from hospitalized patients which leads to prolongation of a stay. ADR reporting has proven to be a useful tool for patients and health of every population, in reducing morbidity and mortality, but there is more scope for increasing the ADR reporting by the patient or his relative or by non-health-care professional (HCP).[4,5] Sensitization of Indian urban and rural population is the progressive concern of the Pharmacovigilance Programme of India (PvPI) and is the need of the hour. In Western countries, a variety of ADR reporting systems are functioning, but in India, it is mostly reported in the form of spontaneous reporting system, without mandatory legal binding. The main aim is to improve and keep vigilance on drugs to enhance patient safety and achieve better health benefits.[6,7]

Indian Pharmacopoeia Commission (IPC) has been functioning as the National Coordination Centre (NCC) for PvPI since April 15, 2011, to monitor the safety of drugs. ADR monitoring centers (AMCs) are functioning in (1) medical colleges and hospitals, (2) medical/central/autonomous institutes, (3) private hospitals, and (4) corporate hospitals. AMCs all over India (total 250; coordinated by NCC-PvPI) are the collecting body of the suspected ADR form, from the HCPs, non-HCPs, or patients directly or through Patient safety Pharmacovigilance Associate (PSPvA). PSPvA follows up the reports to get additional detailed information for scientific assessment. India has a vast ethnic population which suffers from a wide variety of diseases. The complete knowledge and data of ADRs of medicines including herbals, specific to the Indian population lacks, and we have to be dependent on data existing from Western countries. Hence, it is necessary to have a well-organized, voluntary, and broad-based ADR reporting system, to enhance our data and knowledge. At present, PvPI is a very efficient organization for reporting ADRs, but still, underreporting term has not gone from its dictionary. The underreporting of ADR is enormous and a daunting challenge for PvPI.[8]

II. Materials And Methods

This study was done in Kurnool Medical College, Kurnool, AP as a retrospective observational study. After getting ethical committee approval and consent from the pharmacovigilance committee of ADR Monitoring Centre, KMC, Kurnool, 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.

III. 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 313 reported cases, 164 patients were male and rest 139 were females (Figure 1).

Out of the 313 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	**135**	**43.13%**
Anticancer agents	**43**	**13.73%**
Psychiatric drugs	**36**	**11.50%**
Analgesics	**29**	**9.26%**
Supplements	**7**	**2.23%**
Vaccines	**5**	**1.59%**
Antihypertensives	**26**	**8.306%**
Others	**32**	**10.22%**
Total	**313**	**100**

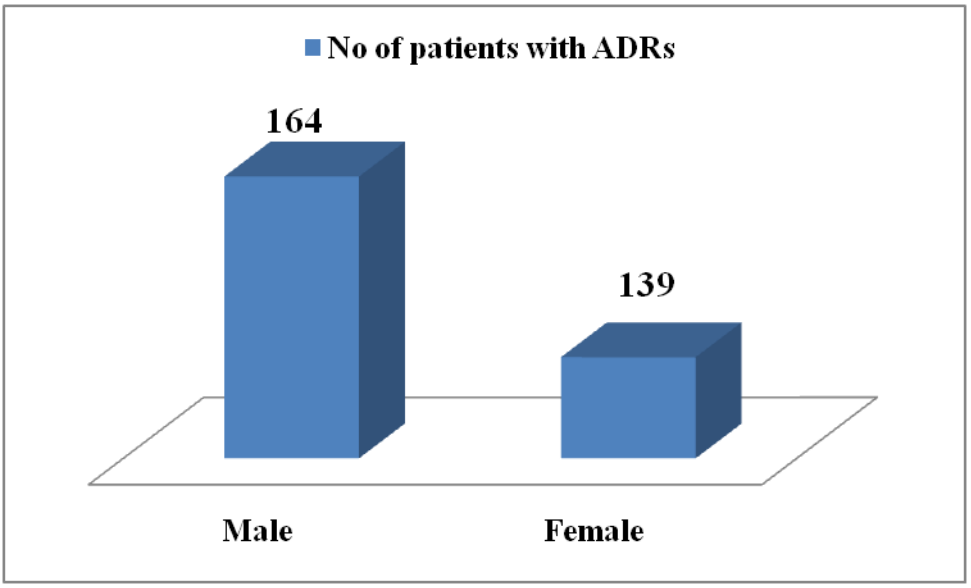

Figure 1: Male and female distribution of ADR

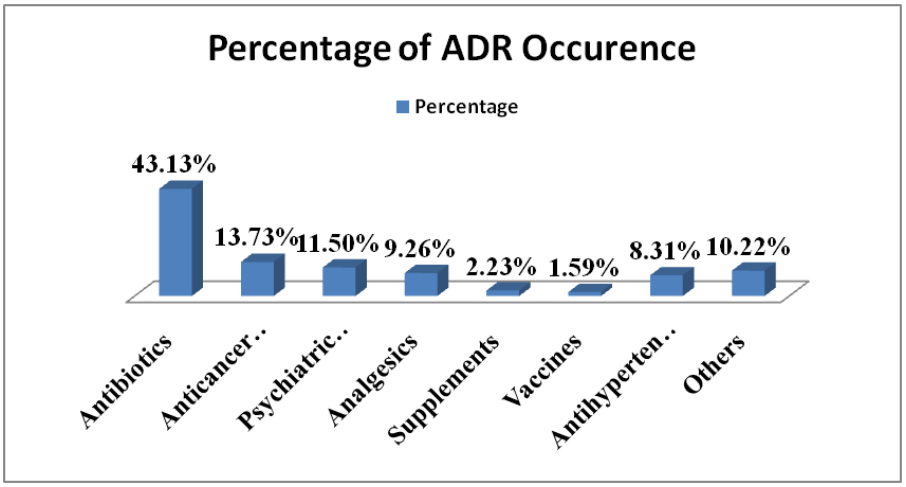

Figure 2: Prevalence pattern of drugs causing ADR

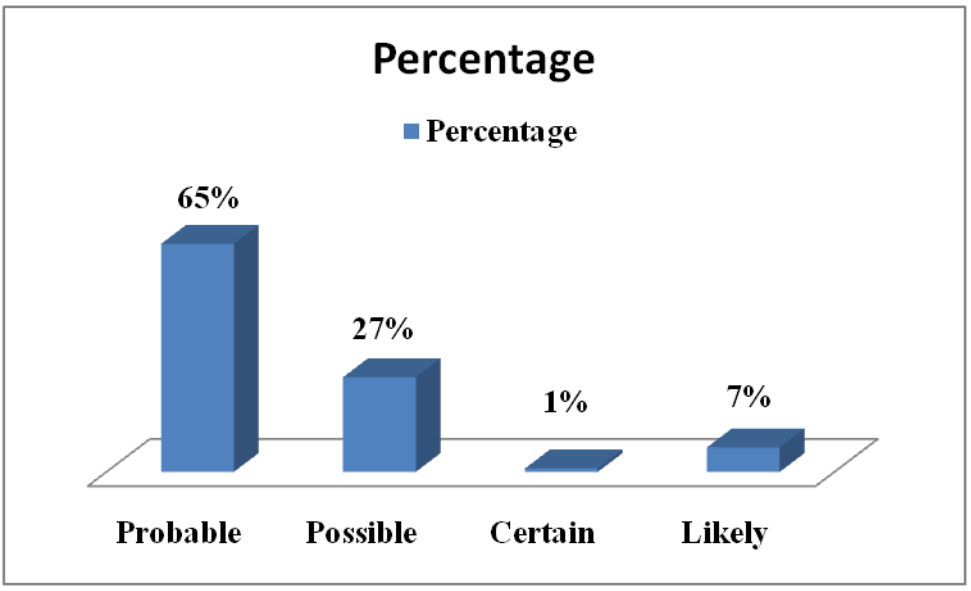

Figure 3: Causality assessment (WHO scale) percentage scale

IV. 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[9], the prevalence drug pattern was more for antibiotics (63.07%) which is close to this study. A study in Brazil also indicated 40.7% of the ADRs were due to anti-infective agents. Analogous results were also reported at regional pharmacovigilance centre in Portugal. 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.[10]

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%). [11]

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. 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.

V. Conclusion

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.

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