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Original Research Article

An observational study of adverse drug reactions reported in a rural tertiary care hospital

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ABSTRACT

Background: Adverse drug reactions (ADRs) are noxious and unintended effects of a drug that occurs at doses normally used in humans. ADRs may also result in diminished quality of life, increased physician visits, hospitalizations, and even death. The objectives of this study are to analyze and assess the causality and severity of reported ADRs.
Methods: A cross sectional study of ADRs reported to Pharmacovigilance cell of MNR Medical College and Hospital Sangareddy in a year. The details of the various ADRs were statistically analyzed to find out pattern of ADRs. The WHO-UMC causality category and Hartwig-Seigel Scale were used to assess causality and severity of ADRs respectively.
Results: The study shows, out of 60 suspected ADRs, the majority of ADRs were adults (68.3%) and out of whom 56% were females. According to the WHO-UMC Causality categories, 43.3% of the ADRs were categorized under Probable/likely, followed by possible (35%). The Hartwig-Siegel severity assessment scale shows that the majority (90%) of suspected ADRs were of mild category.
Conclusions: The pattern of ADRs reported in our study is comparable to other studies. The commonest organ system affected was gastrointestinal tract, nervous and cutaneous system. Antimicrobial agents were causing maximum ADRs and medicine and allied departments have more number of ADRs. This study provides a valuable database for ADRs due to all commonly used drugs at hospitals and also helps in creating awareness regarding safe & judicious use of drugs to prevent ADRs.

Keywords: Adverse drug reactions, Causality, Severity

INTRODUCTION

As per World Health Organisation (WHO), adverse drug reactions (ADRs) are often referred to as "any noxious and unintended effects of a drug that occurs at doses normally used in human beings for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function.[1] The increased risk for ADRs is mainly due to numerous medications, multiple chronic medical problems, and frequent acute illnesses in patients makes detection more difficult. Most commonly, ADRs are predictable, dose-related and are caused by a medicine's pharmacological action. ADRs can also be uncommon or rare, unpredictable and occur at commonly used therapeutic doses.[2] ADRs can be induced by drug-drug interactions, misuse, medication errors, or be associated with risk factors such as genetic susceptibility, age, gender or pre-existing medical history.

ADRs are rated as fifth leading cause of death and accounts for approximately 5% of all hospital admissions.[3] Adverse drug reactions may also result in diminished quality of life, increased physician visits, hospitalizations, and even death. In addition, they result in increased health care costs.

It is a known fact that premarketing clinical trials detect ADRs which are rare, delayed and occurs on long-term exposure. In view of this, Pharmacovigilance plays a prominent role in establishing the safety profile of marketed drugs.[4]

Pharmacovigilance is defined by WHO as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems".[5]

The WHO-Uppsala Monitoring Centre (UMC) causality system is used to detect the association between reported ADR with the drug. Causality assessment can help regulatory authorities in evaluating signal detection and risk-benefit decisions about medicines.[6,7] Severity describes the extent to which the ADRs influence the everyday life of the patients.

The present study is an effort to find out the pattern, causality and severity of ADRs at a rural tertiary care hospital.

Objective

The objectives of this study are to analyze the ADRs reported and to assess the causality & severity of the reported ADRs.

METHODS

This is a cross sectional study of ADRs reported to the Pharmacovigilance cell at MNR Medical College and Hospital, Sangareddy, Telangana. The Institutional Ethics Committee approval was taken prior to the study. All the ADRs which were reported from January 2018 to December 2018 were studied.

The data such as age, gender, causal drug group, types of reactions observed from suspected ADR reporting forms was collected. The details of the various adverse drug reactions were identified and analyzed to find the pattern of adverse drug reactions. The WHO- UMC causality category and Hartwig-Seigel scale was used to assess causality and severity of ADRs respectively.[8,9] The data was analyzed by using statistical methods.

RESULTS

In this study there were 60 suspected ADRs reported to the ADR monitoring centre, from various specialties of the hospital.The majority of ADRs was observed in adults (68.3%), out of which 56% were females and least (15%) in case of Pediatric age-group (Table 1). The mean age of the patient was 42.4±17.9 years.

Most of the ADRs were reported from the Medicine and allied departments (71.7%) (Figure 1). Among ADRs, maximum number (45%) of cases was reported by the Department of Medicine followed by Orthopedic (15%) and Pediatric (10%) departments. Whereas least number of cases were reported by the ophthalmology and dermatology departments (1.6% each) (Table 2).

Table 1: Age and gender wise distribution of ADRs.

Age (in years)	Sex		
	Male (%)	Female (%)	Total (%)
0-18	06 (20)	03 (10.0)	09 (15.0)
19-59	18 (60)	23 (76.7)	41 (68.3)
≥60	06 (20)	04 (13.3)	10 (16.7)
Total	30	30	60

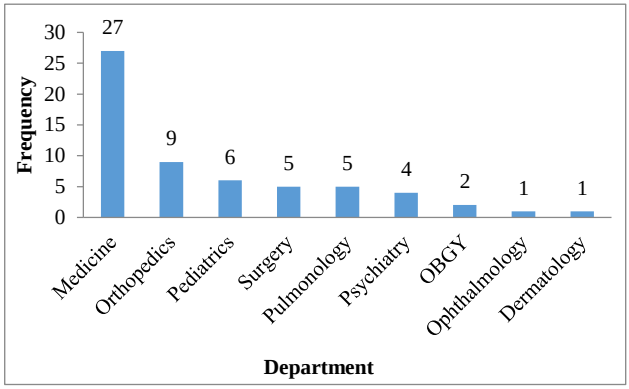

Figure 1: Speciality-wise distribution of ADRs.

Table 2: Department-wise distribution of ADRs.

Department	Number (%)
Medicine and allied	43 (71.7)
Surgery and allied	17 (29.3)
Total	60 (100)

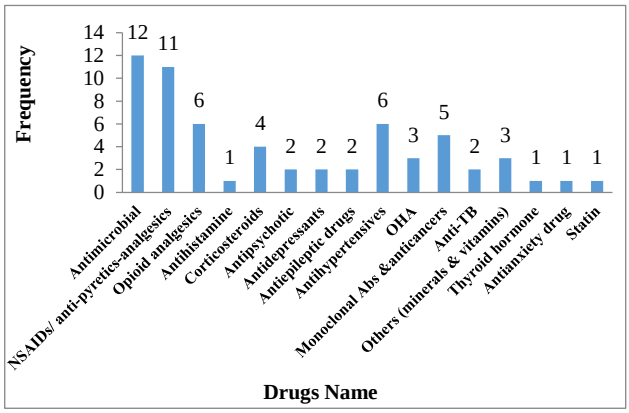

Figure 2: Distribution of drug class causing ADRs in patients.

The antimicrobial agents were more (23.3%) responsible for ADRs especially with beta lactam antibiotics like penicillins and cephalosporins, followed by non-steroidal anti-inflammatory drugs (NSAIDs) (18.3%), opioids and antihypertensive drugs (10% each) (Figure 2).

Table 3: System wise frequency distribution of adverse drug reactions.

System / organ class	Frequency	%
Gastrointestinal tract	20	30.3
Nervous system disorders	15	22.7
Skin and subcutaneous tissue disorders	15	22.7
General disorders and administrative site conditions	07	10.6
Respiratory, thoracic and mediastinal disorders	05	7.6
Genitourinary system	03	4.5
Hematopoietic system	01	1.5

The present study shows that the ADRs were more frequently seen in gastrointestinal system (30.3%) associated with vomiting as most common complaint and least in hematopoietic system (1.5%) associated with gum bleeding (Table 3).

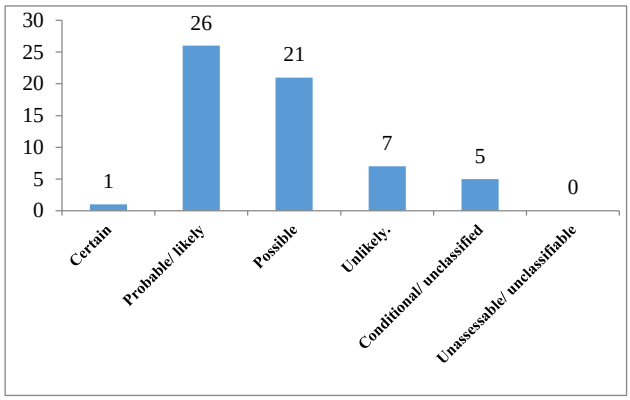

Figure 3: Distribution of ADRs as per WHO-UMC causality assessment scale.

According to the WHO-UMC Causality categories, 43.3% of the ADRs were categorized under probable/likely, followed by possible (35%) and few are unlikely (11.6%) (Figure 3).

Table 4: Distribution of ADRs as per Hartwig and Siegel severity scale.

Type of severity of ADRs	Number of cases	Percentage (%)
Mild	54	90
Moderate	06	10
Severe and lethal	00	-

The Hartwig-Siegel severity assessment scale shows that the majority (90%) of the suspected ADRs were of mild category i.e., level 1 and 2 of the scale (Table 4) which may need no change of drug or change of drug with no requirement of antidote to treat ADR, followed by level 3 i.e., moderately severe category, which needs change of drug for the clinical condition and an antidote or therapy to treat ADR, but there will be no increase in length of stay at hospital.

DISCUSSION

In present study, the evaluation of the reported adverse drug reactions shows no gender wise difference. The preponderance of gender distribution of ADRs differs in various studies. The study conducted by Begaud et al showed male preponderance while Shrivastava et al in their study in Nagpur showed more ADRs in female.[10,11]

Majority of the patients presented were aged between 18-60 years of age (68.3%), which was similar to other studies.[12,13]

In our study, most of the ADR's cases were registered from Medicine and allied departments, which was in accordance with the study conducted by Ponnusankar et al and Murphy et al.[13,14]

Maximum reported ADRs were related to use of antimicrobial class of drugs and these findings are in concordance with other studies followed by the use of NSAIDs recorded the more number of ADRs. Majority of patients with ADRs presented with symptoms associated with gastrointestinal tract, nervous system, and skin, subcutaneous tissue disorder which was similar to other study.[15,16]

Assessment of the ADRs using WHO-UMC causality assessment scale showed that 43.3% of cases were classified under probable followed by possible with 35%. These findings were in accordance with the other studies which documented highest reporting of ARDs under probable scale.[9]

Severity assessment by the modified Hartwing and Siegel scale showed that 90% ADRs were mild and 10% ADRs were moderate, nil were severe in our study. In similar study conducted by Rajesh Reddy et al documented 56.6% ADRs with moderate, 38.3% ADRs with mild and 5% ADRs were severe and lethal reactions.[17]

The limitation of our study was that, we did not consider other causality assessment scales in categorizing the adverse drug reaction. Other limitation was that the 'time of onset' and 'rechallenge' was not possible or performed and it needs a prospective study to know the above parameters and to assess outcome as well as preventability of the ADRs.

CONCLUSION

The pattern of adverse drug reactions reported in our study is comparable to other tertiary care hospital ADRs pattern. The commonest organ system affected was gastrointestinal tract followed by nervous system, skin and cutaneous system. Antimicrobial agents were causing maximum ADRs and the departments documented to

have more number of cases were medicine and allied departments. This study provides a valuable database for ADRs due to all commonly used drugs at tertiary care hospital. This would help to implement a pharmacovigilance resulting in a strict drug policies and adherence to the protocols. This would result in the better safety and patient care.

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

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