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RESEARCH ARTICLE

A profile of adverse drug reactions in a rural tertiary care hospital

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ABSTRACT

Background: Adverse drug reactions (ADRs) are a great concern in therapeutics. ADRs were ranked between the fourth and sixth leading causes of death in the USA. **Aims and Objectives:** The present study was conducted with the aim of identifying, analyzing the causality, pattern, and severity of ADRs occurring in our institution. **Materials and Methods:** A non-interventional observational study was conducted over 1 year from January to December 2015. The yellow forms dropped in the red ADR boxes are collected and analyzed for demographic data, causality, severity, drugs implicated, and organ system affected. The data were presented as numbers and percentages. **Results:** Antimicrobials are the most common drug class implicated in ADRs, and the dermatological system was the most common system affected by ADRs. All the reactions either belonged to the probable or possible category. Majority of reactions were non-serious. **Conclusion:** 175 ADRs were reported, which shows reporting was adequate. Awareness should be increased among health-care professionals regarding polypharmacy, which helps in reducing the ADR incidence.

KEY WORDS: Pharmacovigilance; Causality; Adverse Drug Reactions; Severity

INTRODUCTION

Adverse drug reactions (ADRs) are a great concern in therapeutics. An incidence of 5-35% is observed in all age groups among outpatients.[1] ADRs were ranked between the fourth and sixth leading causes of death in the USA.[2] Studies in India also have shown that ADRs accounted for 0.7% of total admissions and 1.8% of which resulted in death.[3]

As per World Health Organization (WHO), pharmacovigilance is defined as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse drugs reactions or any other drug-related problems."[4] Pharmacovigilance helps in measuring the burden of drug-induced morbidity and mortality.[5] The importance of pharmacovigilance can be understood by the fact that it has led to the withdrawal of some of the blockbuster drugs such as rofecoxib, rosiglitazone, and terfenadine.[6] There are several methods by which ADR monitoring can be done such as voluntary reporting, active surveillance by prescription-event monitoring and patient registries, epidemiological studies such as cohort and case-control studies.[7] However, voluntary reporting of ADR has been adopted by most countries because of its feasibility.[8]

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In India, the Central Drugs Standard Control Organization under the aegis of Ministry of Health and Family Welfare, in collaboration with Indian Pharmacopoeia Commission, Ghaziabad, has initiated nationwide Pharmacovigilance Program of India (PvPI). In India, PvPI has also adopted voluntary reporting of ADR and all peripheral ADR monitoring centers collect the ADR reports, assess and

forward to the national center through VigiFlow.[9] Our institute is also recognized as peripheral ADR monitoring center. The present study was conducted with the aim of identifying, analyzing the causality, pattern, and severity of ADRs occurring in our institution.

MATERIALS AND METHODS

A non-interventional observational study was conducted over 1 year from January 2015 to December 2015. Every year workshops are conducted by pharmacovigilance cell for all health-care professionals, i.e., clinicians, postgraduate students, interns, and nursing staff. They were informed about the importance of pharmacovigilance and trained for filling yellow forms. The yellow forms dropped in the red ADR boxes (installed in all wards, emergency units, and outpatient departments) were collected and checked for completeness, and the missing data were obtained either by personally visiting the patient or going through the case sheets in case of doubt or consulting the treating physicians if necessary. Prior ethics committee approval was obtained from the Institutional Ethics Committee. The causality assessment was done using the WHO scale[10] by a special committee with two experts from pharmacology and clinician. The severity of reactions was assessed using Hartwig and Siegel scale.[11] The data were analyzed and presented as numbers and percentages.

RESULTS

181 ADR forms were received by our pharmacovigilance center from various clinical departments. However, only 175 were analyzed and the rest were not included due to incompleteness of forms in terms of drug details or adverse reaction details.

Demographics

The patients were grouped into five age groups (0-15, 16-30, 31-45, 46-60, and above 60 years). Most of the patients were in the age group of 16-30 years (Figure 1). Most of them were female patients (60.6%).

Drugs Implicated in ADRs

The most common drug class implicated in ADRs is antimicrobials (57.1%) followed by nutritional supplements and non-steroidal anti-inflammatory drugs (Table 1). Under antimicrobials, most common drug class implicated was cephalosporins.

Organ System Involved in ADRs

The most common system affected by ADRs was dermatological system (42.9%) followed by the gastrointestinal tract and musculoskeletal system (Figure 2).

Table 1: Drug classes implicated in adverse drug reactions

Drug group	Number of ADRS
Antimicrobials	100
Nutritional supplements	16
NSAIDS	11
Antiepileptic	8
Opioids	6
Antiulcer	4
Antipsychotics	3
Local anesthetic	3
IV fluids	3
Antihypertensives	2
ASV	2
Antiseptics	2
Corticosteroids	2
Skeletal muscle relaxants	2
Other drugs	11

ADRS: Adverse drug reactions, NSAIDS: Non-steroidal anti-inflammatory drugs, IV: Intravenous, ASV: Antisnake venom

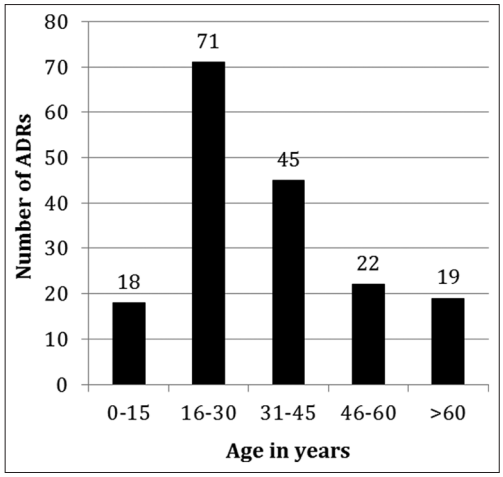

Figure 1: Age wise distribution of patients with adverse drug reactions

Severity of ADRs

Of 175 reactions, 157 (89.7%) were non-serious and 18 serious reactions (2 ADRs life-threatening, 16 required hospitalization or prolongation of hospitalization) (Figure 3).

Causality Assessment

WHO-UMC scale was used for causality assessment. 128 ADRs (73.1%) were assessed as probable, and 47 ADRs were assessed as possible. No reaction could be assessed as certain as rechallenge was not done in view of patient safety.

DISCUSSION

ADRs are recognized hazards of drug therapy. Early detection, evaluation, and treatment of ADR will reduce the morbidity

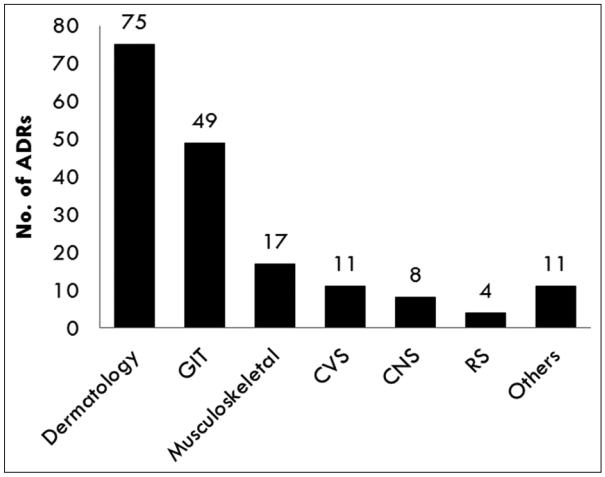

Figure 2: Organ systems affected by adverse drug reactions

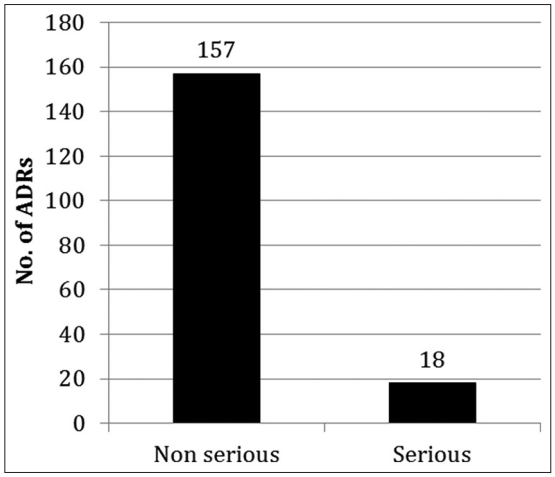

Figure 3: Severity wise distribution of adverse drug reactions

and mortality in the patients. Hence, pharmacovigilance becomes essential to increase the safety profile of the drugs.[12] Pharmacovigilance in India is still in infancy. Hence, there is a need to create awareness among patients and health-care professionals to report ADRs.[13]

In this study, 175 ADRs were reported in our institute over 1 year. The spontaneous voluntary reporting was adequate in our ADR monitoring center. Most of the ADRs were reported in females as compared to males which were similar to observation made by Swamy et al.[14] and Arulmani et al.[4] Most of the patients were of adult age group which is in accordance to previous studies conducted by Patidar et al.[15] and Lobo et al.[16] The reason could be most of the patients visiting outpatient and inpatients are adult age group.

Antimicrobials were the most common drug class implicated in causing ADRs which was consistent with previous studies.[14,15] Most common system affected by ADRs was dermatological system which was similar to previous studies conducted by Patidar et al.[15] and Dutta et al.[17] The reason for increased reporting of dermatological reactions could be due to the easy recognition of these reactions than reactions affecting other systems. Causality assessment was done using the WHO scale and was found that most of the reactions were of probable followed by possible category, none of the reactions were categorized as definite since rechallenge was not done. This may be due to the high incidence of polypharmacy, hence alternate causes cannot be excluded. Most of the reactions were non-serious, only 18 reactions were serious which were managed appropriately by health-care professionals hence no death were reported due to ADRs.

CONCLUSION

In the present study, most of the ADRs were reported due to antimicrobials, and the dermatological system was the most common system affected due to ADRs. The ADR reporting rate was adequate due to regular sensitization programs. Awareness should be increased among health-care professionals regarding polypharmacy which helps in reducing the ADR incidence. Pharmacovigilance is a continuous ongoing process which ensures the safety of the patients.

DRAWBACKS

Rechallenge was not done for ADRs because of ethical reasons which may affect the causality assessment. The treatment expenditure of ADRs was not assessed.

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