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Research Article

A STUDY TO ASSESS, MONITOR, AND REPORTING OF ADVERSE DRUG REACTIONS IN A TERTIARY CARE TEACHING HOSPITAL: HIMS, HASSAN

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ABSTRACT

Objective: An adverse drug reaction (ADR) is an unwanted, undesirable effect of a medication that occurs during usual clinical use. ADR should be quickly identified and managed to limit their detrimental effects on the patient. This study was undertaken to characterize the pattern of ADRs reported through spontaneous reporting system at ADR reporting unit in a tertiary care teaching hospital.

Methods: A prospective, observational study was conducted over 3 years between September, 2017 and August, 2019. The ADRs reported were from patients admitted inpatient department of hospital. Evaluation of patient demographics, drug and ADR characteristics, and outcome of the ADRs. Causality and severity assessment was done by the World Health Organization system and Naranjos scale.

Results: 82 cases of ADRs were reported during the study period. More number of ADRs was from General Medicine and Pediatric departments, in which the most affected organ systems were the skin and the gastrointestinal tract. The antibiotic classes mostly accounted were cephalosporins. None of the ADR was fatal.

Conclusion: ADRs to antibiotics are common and will be resulted in increased health-care cost due to the need of some interventions and increased length of hospital stay. The health-care system should promote proper documentation and periodic reporting to regional pharmacovigilance centers to ensure drug safety.

Keywords: Adverse drug reaction, Adverse drug event, Pharmacovigilance.

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INTRODUCTION

Adverse drug reactions (ADRs) are one of the leading causes of (6.5–10.9%) and mortality (0.15–2.9%). Around 6% of hospital admissions are estimated to be due to ADRs and about 6–15% of hospitalized patients experience a serious ADR [1].

Adverse reaction can occur with any class of drugs. However the most troublesome classes of drugs were antibiotics followed antitumor agents; they are responsible for the recorded adverse effects in approximately 16% [2]. ADRs due to inappropriate medication use occur often in the real world of clinical practice but not in randomized control trails [3].

ADRs have a major impact on public health; reducing patients' quality of life and lead to financial burden on the health-care systems and family [4]. Moreover, it is a major limitation in providing health care. Hence, the need for an active surveillance system to remove the harmful drugs that have entered the market was well realized by the World Health Organization (WHO) [5]. Several reasons such as increase in workload, perception that reporting will not result in any improvement and lack of knowledge that an adverse event has occurred and fear of exposing oneself to litigation [6].

According to WHO, pharmacovigilance is a science and art to identification, understanding and assessment of risks associate with drugs. Moreover, they take steps to control the adverse effect of drugs. Pharmacovigilance starts from the pre-marketing of new drugs and even during the post-marketing of drugs [7,8].

The post marketing product is required to develop new information, which can focus on the benefits as well as risks of the product. Pharmacovigilance produces detailed information of marketed products to ensure their safe use [9]. Under-reporting has been the biggest challenge in voluntary reporting method/spontaneous ADRs reporting [10].

Patient safety by judicious use of medicines will prevent ADRs in modern medicine. Pharmacovigilance activity allows continuous Monitoring and identification of the drugs that cause ADRs and their supervision [11].

The present study was undertaken to characterize the ADRs reported in our hospital with regard to drugs, reaction, also to assess the organ system involved, class of drugs, and severity of the ADRs occurred.

METHODS

Study design

This hospital-based prospective and observational study was carried out in all departments of at Hassan institute of Medical Sciences (HIMS), Hassan for a period of 2 years (September 2017–August 2019).

Study population and data collection

- Study population: ADRs reported
- Study setting: HIMS teaching hospital
- Sample size: 104
- Method: Spontaneous ADR reports collected by Department of Pharmacology reported by doctors of all Departments, HIMS teaching hospital, Hassan
- Evaluation: Demographic data, drug class and system involved. Causality and severity assessment was done by World Health Organization- Uppasala Monitoring Centre (WHO–UMC) scale and Naranjo scale and Hartwig and Siegel scale, respectively.

In the Naranjo Algorithm, the drug reaction can be classified as definite, probable, or possible. The modified Hartwig and Siegel scale classifies severity of ADR as mild, moderate, or severe with various levels according to factors.

Ethical approval

The study was approved by the Institutional Ethical Committee of HIMS, Hassan.

Data analysis

The collected data were analyzed, and results were obtained, and conclusion was drawn.

Statistical analysis was performed with SPSS software, version17.0. $p<0.05$ was considered to be statistically significant.

RESULTS

In the current prospective observational reporting study, 104 cases of ADRs were reported spontaneously.

Age and gender distribution of patients observed in our study

Rate of ADRs is more common in middle age (75%) patients, and female (52.9%) were predominantly exposed than male due to several causes.

As per WHO UMC scale, probable were 66%, possible were 33%, and 1% certain.

Out of 104 ADRs, 57% of were mild and 42% were moderate, only 1% is sever. None of the ADRs was fatal.

A maximum number of ADRs were reported from the general medicine 47%, followed by pediatrics 14%, surgery 8%, dermatology and obstetrics and gynecology 7%, and least in ear, nose, throat and oncology 2% and 1%, respectively.

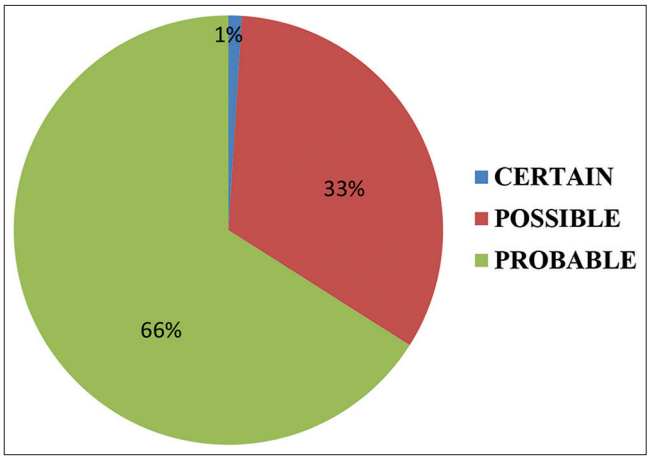

Fig. 1: Causality assessment using WHO-UMC scale

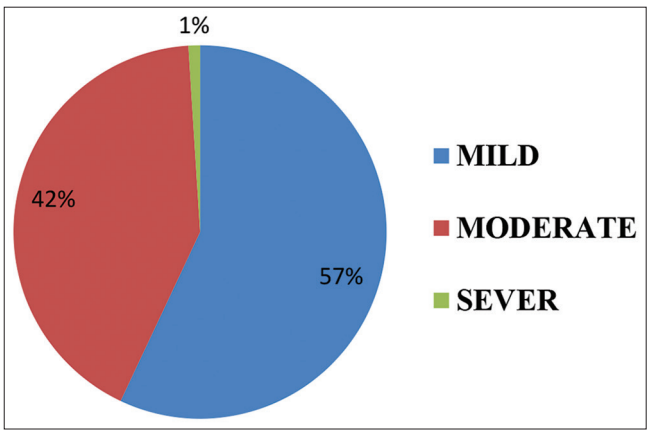

Fig. 2: Severity assessment using modified Hartwig and Siegel scale

The classes affected with ADRs are shown in above Fig. 4, which revealed that Antimicrobial drugs (57.7%) were the most accounted class followed by vaccine and sera 10%, non-steroidal anti-inflammatory drugs (NSAIDs) 6%, and corticosteroid and local anesthetics 5%.

From this study, it was found out that there were dermatological 60 (57.7%). % side effects were severe and more common, such as rashes, redness, and itching over the body. Followed by fever chills (27%), palpitation (12%), giddiness, vomiting, blurring of vision (8%), breathlessness, cough, nausea, and vomiting (5%). Complete fatigability weakness and alteration in blood glucose level were in seen in some patients.

DISCUSSION

Drugs are the most common medical interventions, primarily used to relieve sufferings. However, it has been recognized long ago that drug themselves can cause fatal. Sever ADRs were lead to mortality and morbidity and lead to loss in quality of life.

In our study, the pattern of ADRs reported in our hospital is comparable with other studies and demographic details of the present study showed female (52.9%) predominance over males (47.1%). A higher percentage of ADRs occurred in adult population (19–60 years) (75%) as similar to study conducted by Rehan *et al*. The highest percentage (66.2%) of ADRs was seen in adult patients. Female patients experienced more (57.5%) ADRs [11].

The majority of the ADRs were reported by General Medicine Department (45.2%) (Fig. 3) as compared to other study conducted by Shamna

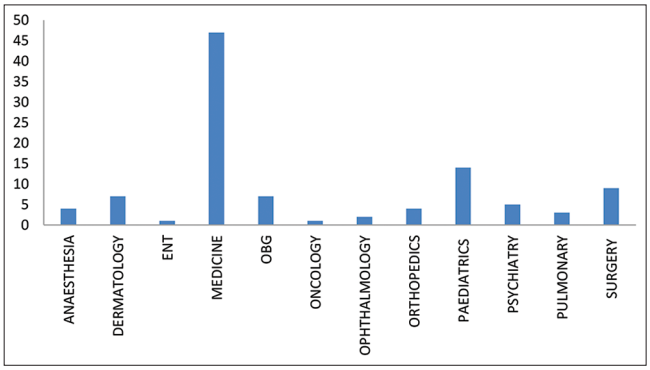

Fig. 3: Department wise distribution of ADRs

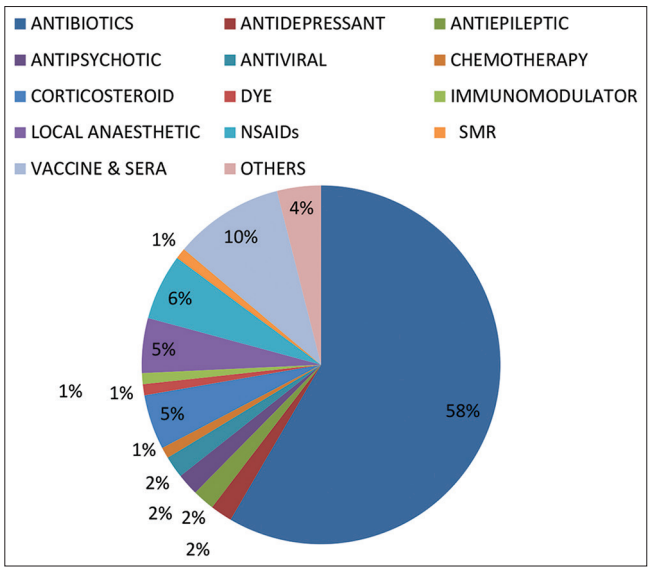

Fig. 4: Class of medicine versus ADRs

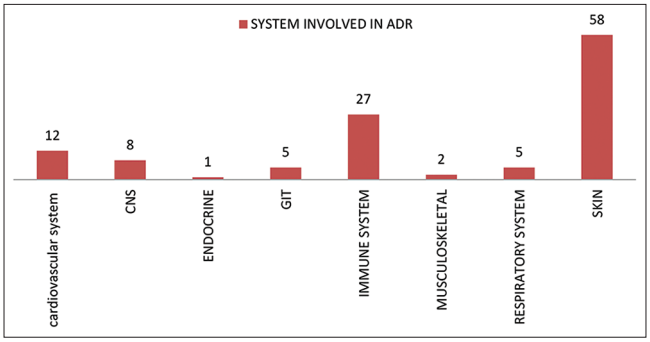

Fig. 5: Systems involved in ADR

Table 1: Demographic data

Demographic data	ADRs
Total number of ADRs reported	104
Gender-wise distribution	Male – 49 (47.1%) Female – 55 (52.9%)
Age-wise distribution	<18 years–16 (15.3%) 19–60 years – 78 (75%) >61 years–10 (9.7%)

ADRs: Adverse drug reactions

et al. ADRS in general medicine 12 (24.48%), followed by pediatrics 9 (18.36%) and dermatology 7 (14.28%) [12]. Most ADRs occurred due to (Fig. 4) antimicrobial drugs (56.7%) – Ceftriaxone, 2nd - vaccines and sera, followed by NSAIDs (Diclofenac) and Corticosteroids (Dexamethasone).

Shrivastava *et al.*, where they observed that an antimicrobial agent (AMA) was the drug class most commonly involved and NSAIDs were next to AMA [13].

In our study, the majority of the ADRs involved (Fig. 5) the skin (57.7%) as compared to the study conducted by Jose and Rao. Dermatological system (23.5%) was the most commonly affected organ system with skin rash (10.5%) as the most frequently reported reaction [14].

Giardina *et al.*, where they observed that the most frequent ADRs occurred during hospital stay were cutaneous (26.8%), general (13.4%), vascular (13.4%), and cardiac (11.5%) disorders and the drug classes mainly involved were antibacterials (38.2%) and antithrombotic agents (21.7%). ADRs were serious in 44.6% and probably preventable in 69.4% [15].

Most of the ADRs were probable (57.42%) and mild (42%) in our study. The relationship between the medication and the reaction was judged certain in eight, probable in 17, and possible in 74 cases in a study conducted by Mjörndal *et al.* [16].

CONCLUSION

ADRs have a harmful effect in patients. Depending on causality assessment, drugs from particular batch were discontinued for immediate safety of our patients. This study reveals that there is underreporting of ADRs by most departments in the hospital. All types of ADR should make mandatory to report it to the department of pharmacology. Hence, significant increase in reporting will improve patient care and drug optimization can be done.

ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee of HIMS, Hassan.

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CONFLICT OF INTEREST

None declared.

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