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Original Research Article

Adverse drug reactions in hospitalized patients in a tertiary care teaching hospital: analysis of the reported cases

Althab Begum M., Satyajit Mohapatra*, R. Jamuna Rani

Department of Pharmacology, SRM Medical College Hospital and Research Center, SRM University, Chennai, Tamil Nadu, India, 603203

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***Correspondence to:**
Dr. Satyajit Mohapatra,
Email: satyajitmp@gmail.com

ABSTRACT

Background: Adverse Drug Reactions (ADR's) contributes to the burden of drug-related morbidity and mortality. ADRs are seen frequently in hospitals due to a variety of factors like complexity of diseases, drug interactions, polypharmacy, and possible negligence. The purpose of the study was to identify and assess ADR in various departments of a tertiary care teaching hospital.
Methods: A prospective spontaneous reporting was carried out in a tertiary care teaching hospital during a period of four months from November 2016 to February 2017. All suspected spontaneous ADRs were assessed and the information was collected and analyzed by the pharmacologists for causality assessment using the Naranjo's causality assessment scale.
Results: A total of 30 ADRs were reported with female preponderance (70%). Majority of ADRs were from General Medicine and Oncology departments. The most affected organ systems were skin (80%) followed by the gastrointestinal system (13.3%). The most frequent drugs causing ADRs were antibiotics (56.3%) in which type B reactions were more compared to type A and followed by anticancer drugs (10%). The severity assessment showed that most of them were mild reactions (76.6%). Causality assessment revealed that 90% of the reactions were probable, 10% were possible and no reactions were unlikely.
Conclusions: The study accomplished that ADRs are widespread and a few of them raised the healthcare expenditure due to increased hospital stay. The reporting of the ADRs to regional Pharmacovigilance centers should be encouraged to ensure drug safety.

Keywords: Adverse drug reactions, Drug safety, Pharmacovigilance

INTRODUCTION

As per the World Health Organization's (WHO) definition, the ADR is "response to a drug, which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function.[1] ADR is a global problem and a major concern in patient safety and clinical practice and patients are treated with multiple drugs where ADRs are inevitable. The potential consequences of ADR are it affects patient's quality of life, it imposes significant economic burden to the patients and make them to lose confidence in their treating patients. If we believe that the first principle in treating patients is 'primum non nocere' i.e., 'above all do no harm' we should be aware of the possibility of ADRs.

The aim of this study is to establish a causal relation between the drug and adverse events. The causality assessment system proposed by the World Health Organization Collaborating Centre for International Drug Monitoring, the Uppsala Monitoring Centre (WHO–UMC), and the Naranjo Probability Scale are the generally accepted and most extensively used methods for causality assessment in clinical practice.[2] Early recognition, evaluation and monitoring of ADR are essential to improve public health. In the United States, it has been

reported that ADRs due to over the counter and prescription drugs from 1966 to 1996 affected 6.7% of patients with 3.2% death.[3] While similar figures are not available for India, it is logical to assume that the figures would be much higher considering high levels of unmonitored and indiscriminate drug use widespread in the country.[4] ADR monitoring and reporting activity is in its early years in this country. India is a developing country with a large drug utilizing population. It is the fourth largest producer of pharmaceuticals in the world with over 6000 licensed drug manufacturers and around 60,000 branded formulations. It is also emerging as a clinical trial focus exposing greater population to new drugs.

It is critical to identify ADRs at the earliest and to prevent them if possible, to ensure the welfare of the patient at a reasonable expenditure. Pharmacovigilance plays an important role in judicial use of medicines.[5] It is estimated that only 5% of ADRs are reported.[6,7] For effective patient care, there is an urgent need to develop better preventive strategies and reporting of ADR by every health care provider to be made mandatory.

The Central Drugs Standard Control Organisation (CDSCO), New Delhi, under the guidance of Ministry of Health and Family Welfare, Government of India has initiated a countrywide pharmacovigilance programme (PvPI), with the All India Institute of Medical Sciences (AIIMS), New Delhi as the National Coordinating Centre for monitoring ADRs in the nation. Our hospital is one of the centres for monitoring and reporting ADRs through this programme.

PvPI increased the ADRs monitoring centers from 90 to 150 including the private hospitals, which led to increasing in ADR reporting. India became the first country in reporting the Individual Case Safety Reports of more than one lakh to Vigiflow, Uppsala Monitoring Centre. It has to be made mandatory for all health-care providers such as physicians, dentists, nurses, pharmacists to report ADRs as part of their professional responsibility, even if they are doubtful about the specific relationship with the given medication. One of the most important ways to prevent adverse drug events is to share information since all medication errors are preventable.

METHODS

After Institutional Ethical Committee approval, hospitalization due to adverse drug reactions from various departments in this tertiary care hospital was analyzed. A prospective study was conducted from November 2016 to February 2017, for a period of four months. ADR details were obtained after getting oral informed consent from the concerned patients. The data for the study were taken from case sheets, investigation reports, personal interviews with clinicians, and personal interviews with patient or patient's attendant, past history of medications and reports of Medical and surgical interventions. The causality assessment of the reported ADRs was done using the Naranjo causality assessment scale into definite, probable, or possible.[8] After calculating the total score, based on the score they were grouped as certain if score >9, probable if score is between 5-8 and possible if score is between 1-4. The modified Hartwig and Siegel scale defines the severity of ADR as mild, moderate or severe according to factors like necessities for change in treatment, length of hospital stay, and the disability produced by the ADR.[9]

RESULTS

Descriptive analysis of the ADR data collected is done by Microsoft Excel software and expressed as percentage comparison. The number of hospital admissions due to Adverse Drug Reaction was 30. Of these 09 (30%) were male and 21 (70%) were female. The more number of ADR's were reported 36-59 years 14 (46.6%) patients, and least were in elderly age group comprised of 4 patients (13.2%) (Table1). According to the Naranjo's causality assessment scale, 6.66% of the ADRs were certain, 86.6% probable and 6.66% were possible as shown in Figure 1.

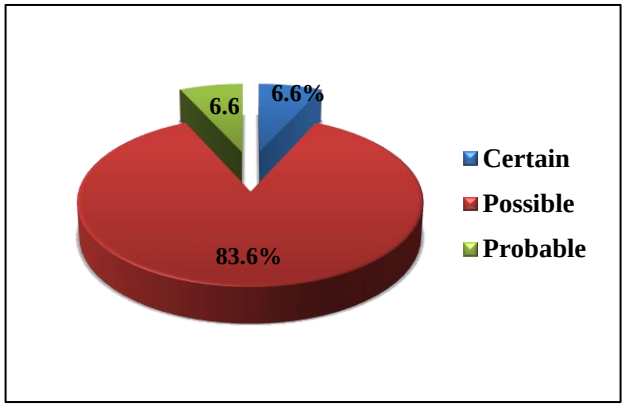

Figure 1: Causality assessment of the total ADRs reported using Naranjo's scale.

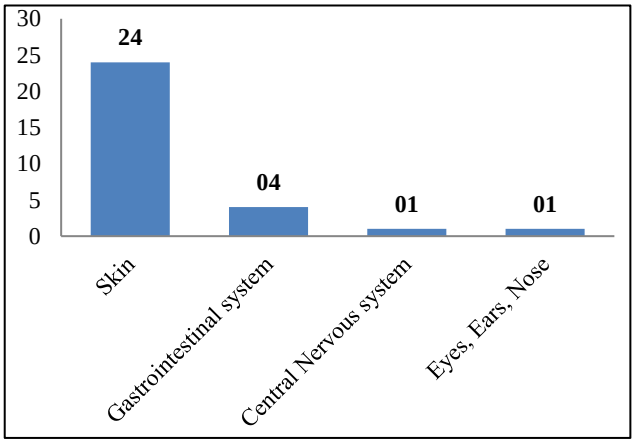

Figure 2: Different organ system affected due to ADRs and the total number of ADRs involved the corresponding organ system.

Out of 30 ADR's the major preponderance of drugs were Antimicrobial agents, 16 (53.3%) and anti cancer drugs

(20%). Among them, Ciprofloxacin was the highest with 04 (13.3%), followed by Ceftriaxone 03 (10%) as shown in Table 2.

Table 1: Age and gender distribution in reported ADR's.

Age distribution	Male	Female
<35 years	5(16.6%)	7(23.3%)
36-59 years	2(6.6%)	12(40%)
60 years	2(6.6%)	2(6.6%)
Total	9(30%)	21(70%)

Table 2: Drugs and the routes of administration involved in reported ADRs.

Drugs	Route	No. of ADRs
Ciprofloxacin	IV	04(13.3%)
Ceftriaxone	IV	03(10%)
Sulfonamide	P/o	02(6.6%)
Oxaliplatin	IV	02(6.6%)
Fluconazole	P/o	02(6.6%)
Ranitidine	IV	02(6.6%)
Renerve Plus	P/o	02(6.6%)
Amoxicillin	IV	01(3.3%)
Cefixime	IV	01(3.3%)
Paclitaxel	IV	01(3.3%)
Cefotaxime	IV	01(3.3%)
Sulfasalazine	P/o	01(3.3%)
Paracetamol	IV	01(3.3%)
Cefaperazone and Sulbactam	IV	01(3.3%)
Ringer Lactate	IV	01(3.3%)
Vancomycin	IV	01(3.3%)
Timolol Eye Drops	E/d	01(3.3%)
Cisplatin	IV	01(3.3%)
Benzocaine	E/A	01(3.3%)
Sulfadoxime	P/o	01(3.3%)
Total		N=30

IV: Intravenous, P/o- per oral, E/d- Eye drops, E/A- -External Application

Table 3: ADRs reported from various departments.

Department wise ADR reported	No. of ADR's (%)
Medicine	23.3
Oncology	20
Surgery	13.3
Obstetrics and Gynaecology	10
Dermatology	10
Nephrology	10
Orthopaedics	6.6
Ophthalmology	3.3
Cardiothoracic	3.3

The most number of ADR's were reported in the department of General Medicine (23.3%), Oncology (20%) and General Surgery (13.3%) as mentioned in Table 3. Itching was the most common ADR reported in 09 patients (30%) followed by swelling 06 (20%) and rashes 06 (20%) (Table 4). The most commonly affected system was found to be the skin 24 (80%), followed by Gastrointestinal system 4 (13.3%) as in Figure 2.

Table 4: Different types of Adverse drug reactions.

Reactions	Drugs prescribed	No. of ADRs (percentage)
Itching	Cefotaxime, ceftriaxone, Oxaliplatin, ciprofloxacin, fluconazole, Cefperazone and sulbactam	09(30%)
Swelling	Amoxicillin, sufonamide, oxaliplatin, sulfasalazine, renerve plus	06(20%)
Rashes	Ceftriaxone, sulfadoxime, ceftriaxone, cefixime, ringer lactate, paracetamol	06(20%)
Vomiting	Paclitaxel, fluconazole, renerve plus, cisplatin	04(13.3%)
Redness	Ranitidine	01(3.3%)
Blister	Beczocaine	01(3.3%)
Redness of eye	Timolol eye drops	01(3.3%)
Burning sensation	Vancomycin	01(3.3%)
Syncope	Ranitidine	01(3.3%)

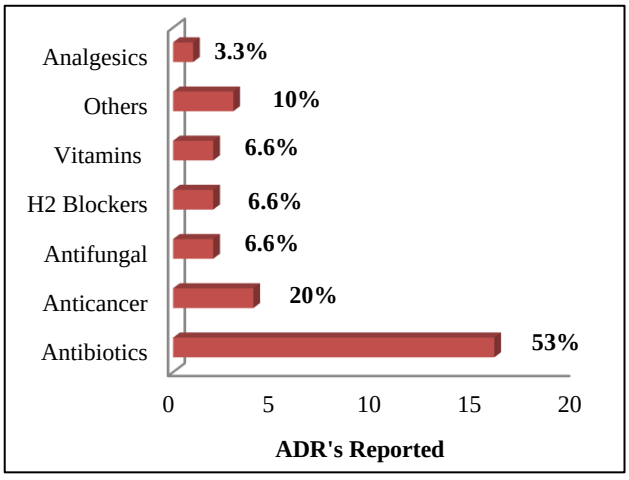

Figure 3: Different group of drugs and the total number of reactions reported for each group in percentage.

DISCUSSION

The data are limited for the spontaneous adverse drug reaction (ADR) reporting system in India and its

comparison in terms of causative drugs, seriousness of the reactions, and the different organ system involved in the ADRs. Spontaneous ADR reporting by health professionals and individuals is practiced in many countries, but in India there is lack of spontaneous reporting. The Pharmacovigilance program of India has taken an initiative in reporting of ADRs from various ADR monitoring center routinely.

ADR Monitoring Committee that is charged with the responsibility of reviewing all suspected cases of ADRs and forwarding the list of confirmed cases to the National coordinating Centre (NCC). We have analysed the ADRs reported from the ADR monitoring center of the medical college.

Majority of ADRs (86.6%) were seen in adult age group which was comparable with the previous study by Sharma et al. where it was 50.4%.[10] The most frequent ADRs were due to the antibiotics which could be associated with increased frequency of prescription of antibiotics. The number of ADRs were high in General Medicine and General Surgery departments due to amplified use of antibiotics in these departments for the treatment and prophylaxis of various diseases and also since the patients admitted were with multiple co morbidities requiring polypharmacy.

Classification of reported ADR's revealed Type B predominance. This result is in line with the study by Suthar and Desai but on the contrary, studies conducted by Oshikoya et al, and Stavreva et al, showed a preponderance of Type A reactions.[11-13]

On analysing the fate of the suspected drugs, it was found that the drug was withdrawn in most of the cases and the dose was reduced in some while no change was made in others considering the risk benefit ratio in particular patients. Majority of the patients recovered completely from the ADR since most of the reactions were mild according to the modified Hartwig and Siegel scale. However, the study carried out by Shamna et al, reported that moderate reactions were more followed by mild and severe ones. The causality assessment of the reported ADRs according to the Naranjo scale revealed that no reactions were unlikely and most of them were probable with a lesser number of possible and definite ADRs. This data is in correlation with the study of Jimmy Jose et al.[14]

CONCLUSION

This study creates awareness to the healthcare professionals and patients on the significance of scrutinizing and reporting the adverse drug reactions. In order to ensure the safety of the drugs the healthcare system should promote the spontaneous reporting and documenting of Adverse Drug Reactions.

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

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