Original research article

Pattern of adverse drug reactions reported: A hospital based cross-sectional study

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Abstract

Aim: The aim of the present study to determine the patterns of adverse drug reactions reported in the tertiary care hospital.

Methods: This observational, retrospective study was done in the Department of Pharmacology, Darbhanga medical college, Bihar, India. A total of 200 ADRs were reported during the study period. Each ADR was analyzed for demographic data, relationship to drugs as per causality assessment, and frequency of ADRs.

Results: A total of 200 ADRs were reported from both outpatients and inpatients of various departments. Most of the ADRs were found in females (55%) and patients of the age group 20 to 50 years (85%). Most of the ADRs were reported from the ART center (39%), dermatology (20%), oncology (11%), pediatrics (9%), and medicine (8%). The number of ADRs was distributed according to the department where they were reported. Overall, 40% of the ADRs are due to the anti-retroviral therapy, 29% due to the antibiotics, and 14% due to the nonsteroidal anti-inflammatory drugs (NSAIDs). Causality assessment was done by using the WHO-UMC scale, in which most of the ADRs were reported as probable (50%) followed by possible (48%). Severity assessment was done by a modified Hartwig and Siegel scale, in which most of them are mild (74%).The most commonly occurred ADRs were rash (40%), followed by nausea and vomiting (25%).

Conclusion: The maximum number of ADRs were reported with ART drugs. So, it is advisable to have close monitoring of the ART to prevent ADRs in these patients. Serious ADRs such as SJS and TEN are most familiar with analgesics and sulpha antibiotics.

Keywords: ADRs, analgesics, antibiotics

Introduction

One of the main unavoidable risk factor in the use of drug therapy is the adverse reactions to the drugs. [1] It is therefore one of the major concerns in medicine. It has been described by the World Health Organization as a “noxious, unintended and undesired effect of a drug, which occur at doses used in humans for prophylaxis, diagnosis or cure of a disease”. [2] ADRs are common, at times can be life threatening and in general leads to increased expenses. This is the reason that the clinicians are requested to be aware of the reactions that can be caused by the drugs before prescribing them.[3] ADRs are common in the hospital setup. They have been classified into two types, one that is the cause of hospitalization and the other which occurs after hospitalization. It is estimated that 5% of the hospitalizations and one in 10-20% of the

hospitalized patients are due to drug reactions.[4] In 1994, it was suggested by Lazarou J et al, that 10000 deaths in US had occurred due to ADRs, although this was considered to be biased and inflated data.[5,6] Consequently a few studies were conducted wherein the data accumulated was small, and thus the documentation of the ADRs was minimal. In India, ADRs are said to occur in 1.8% to 25.1% of the population, with 8% of them leading to hospitalization. About 50% of the commonly used drugs result in adverse reactions, which was not detected prior to approval.[7,8] Pharmacovigilance relates to the activities concerning the detection, assessment, understanding and prevention of these adverse drug reactions. [2] Although the field of science is developing by leaps and bounds, there is a lot of underreporting of the ADRs that takes place, thus giving a wrong picture. It is important for the clinicians to be aware of the toxicity of the prescribing drugs and be vigilant of the reactions that can occur. Proper information is useful to identify and minimize, if possible, the preventable ADRs, thus ensuring a safe and effective use of the drug. [4] Therefore reporting of the adverse reaction, may it be through health care professionals or the patients themselves is of utmost importance to give an accurate estimate of the severity of the drug and also if the ADRs are casual, preventable or severe.

Material and Methods

This observational, retrospective study was done in the Department of Pharmacology, Darbhanga medical college, Bihar, India, after taking the approval of the protocol review committee and institutional ethics committee. The data required for this study were obtained from the ADR Monitoring Centre. A total of 200 ADRs were reported during the study period. Each ADR was analyzed for demographic data, relationship to drugs as per causality assessment, and frequency of ADRs.

Statistical analysis

Microsoft Excel 2019 and SPPS Version 22 were used for data analysis. The causality was done by using the WHO-UMC system, and the severity assessment was done by using the modified Hartwig and Siegel scale. The ADRs were represented as department and pharmacological class wise frequency. The types of reactions due to ADRs and serious ADRs were also analyzed.

Results

A total of 200 ADRs were reported from both outpatients and inpatients of various departments. Most of the ADRs were found in females (55%) and patients of the age group 20 to 50 years (85%) [Table 1]. Most of the ADRs were reported from the ART center (39%), dermatology (20%), oncology (11%), pediatrics (9%), and medicine (8%). The number of ADRs was distributed according to the department where they were reported (table 2). Overall, 40% of the ADRs are due to the anti-retroviral therapy, 29% due to the antibiotics, and 14% due to the nonsteroidal anti-inflammatory drugs (NSAIDs) (table 3). Causality assessment was done by using the WHO-UMC scale,9 in which most of the ADRs were reported as probable (50%) followed by possible (48%) [Table 4]. Severity assessment was done by a modified Hartwig and Siegel scale, in which most of them are mild (74%) [Table 4]. The most commonly occurred ADRs were rash (40%), followed by nausea and vomiting (25%) [Table 5]. Some of the severe ADRs reported were Stevens-Johnson syndrome/ toxic epidermal necrolysis, acute kidney injury, acute psychosis, and febrile neutropenia. Drugs that caused severe ADRs are Zidovudine (ART), Sulfadiazine, sulfamethoxazole (sulphonamide-antibiotics), and Diclofenac sodium (NSAIDs).

Table 1: Distribution of ADRs according to age and genderamong the study population

	No. of ADRs (n = 200)
Age in years	
Below 20	20 (10%)
20-50	170 (85%)
Above 50	10 (5%)
Gender	
Male	90 (45%)
Female	110 (55%)

Table 2: ADRs distribution reported in various departments (*n* = 200)

Parameter	Number of patients	Percentage
ART Centre	78	39
Dermatology	40	20
Oncology	22	11
Paediatrics	18	9
Medicine	16	8
Psychiatry	12	6
Pulmonology	10	5
Gynaecology	2	1
Surgery	2	1

Table 3: ADRs distribution based on pharmacological class (*n* = 200)

Drugs	**Number**	**Percentage**
ART Drugs	80	40
Antibiotics	58	29
NSAIDs	28	14
CNS drugs	16	8
Anti tuberculosis drug	10	5
Anti cancer drug	4	2
Oral hypoglycemics	2	1
Anti hypertensive drugs	2	1

Table 4: Distribution of ADRs based on causality and severityassessment (n = 200)

Causality Assessment by WHO-UMC Scale	**Number (percentage)**
Certain	2 (1%)
Probable	100 (50%)
Possible	96 (48%)
Unlikely	2 (1%)
Severity assessment by modified Hartwig and siegle scale	
Mild	148 (74%)
Moderate	46 (23%)
Severe	6 (3%)

Table 5: Distribution of ADRs based on types of reactions andseverity

Type of reactions dueto ADR	**Number (percentage)**
Rush	80(40)
Nausea and vomiting	50(25%)
Headache	24(12%)
Dizziness	12 (6%)
Diarrhea	8 (4%)
Abdominal pain	4 (2%)
Constipation	4(2%)
Insomnia	2 (1%)
Severe ADRsreported	14
Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis	9(64.29)
Acute Kidney Injury	2 (14.29%)
Acute Psychosis	2 (14.29%)
Febrile Neutropenia	1 (7.14%)

Discussion

India is said to be the second highest market for the sale of prescription drugs in the world, yet only about 2% of the adverse drug reactions are reported. The main cause for this low figure is the underreporting of the ADRs. Thus, it is imperative that more of the ADRs are reported so that the correct picture is attained and we get the real picture of the scenario. This study was conducted to ascertain the number of ADRs in our institute.

The ADRs are one of the most common causes for low adherence to treatment, and evaluation of ADRs may help clinicians to optimize the drug regimens. The demographic details of our study showed female gender predominance over males regarding ADRs, which was similar to the results of other studies conducted by Kumar[10] and Sutradhar et al.[11] Several other studies have found that ADRs are more common in males than in females. So, the influence of gender is purely incidental only and has no influence on the number of ADRs reported.

The most frequently implicated group of medicines in the ADRs were ART drugs, which is similar to a study by Behera et al.[12] The second and third most ADRs are due to the anti-microbial drugs and NSAIDs, which were similar to a study by Sutradhar et al.[11] The organ system most affected by ADRs in this study was the skin (rash, 40%), which was similar to many studies. Causality assessment showed that most of the ADRs were probable (50%); similar results were found in the study by Kumar[10] and Raja et al.[13]

Overall, 48% of the ADRs were reported under “possible” in causality assessment, and multiple drugs that were prescribed at the same time are the reason behind it. The most common and severe forms are SJS/TEN, and they are reported to the WHO-UMC through VIGIFLOW.14 Most of the ADRs were mild and probably required minimum medical intervention for management. This is similar to another study by Arulmani et al.[15] There are various probable reasons identified for underreporting the ADRs, such as lack of knowledge of physicians, time constraint, non accessibility of ADR (CDSCO) reporting forms, lack of incentives, etc. In our interaction with clinicians, similar reasons for underreporting were found.

Conclusion

In our study, most of the ADRs were reported with ART drugs. So, it is advisable to have close monitoring of the ART to prevent ADRs in these patients. Serious ADRs such as SJS and TEN are most familiar with analgesics and sulfa antibiotics. Physicians should advise the patients to abstain from the usage of nonprescription drugs. The study of ADRs in a particular institute using demographic patterns will contribute to patient safety by sensitizing the clinicians in that particular institute.

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