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Research Article

PATTERNS OF ADVERSE DRUG REACTIONS: A STUDY IN A TERTIARY CARE HOSPITAL

SHAKEEL AHMAD MIR*

Department of Clinical Pharmacology, Sher-i-Kashmir Institute of Medical Sciences, Srinagar, Jammu and Kashmir, India.
***Corresponding author: Shakeel Ahmad Mir; Email: drshakeelahmadmir@gmail.com**

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ABSTRACT

Objectives: The purpose of this study was to describe the pattern of adverse drug reactions (ADRs) in a tertiary care hospital, as ADRs are among the most common causes of morbidity and mortality.

Methods: This prospective study, which ran from January 2020 to December 2021, observed all patients admitted to the various departments of SKIMS Hospital Srinagar for the development of ADRs.

Results: ADRs were found to be slightly more prevalent in female patients (54.82%) and those aged 40–60 years (30.11%). Antibiotics (64.3%), anticancer drugs (9.4%), and gastrointestinal tract (GIT) medications (7.3%) were most commonly associated with ADRs. The commonly involved system organs were the skin (69.9%), the nervous system (24.1%), the GIT (19.5%), and the respiratory system (15.6%). 8.0% of ADRs were serious.

Conclusion: The prevalence of ADRs makes them a major concern. To ensure patient safety, active patient surveillance is critical to identifying and controlling ADRs.

Keywords: Adverse drug reaction, Pharmacovigilance, Drug safety.

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INTRODUCTION

Adverse drug reactions (ADRs) are a major health problem and a common cause of hospitalization, especially in the elderly [1]. Several studies have highlighted the public health importance of adverse drug effects. Most studies conducted in the late 1990s and early 2000s show that adverse events are the fourth- or sixth-leading cause of death. In addition to human health, side effects also have a significant impact on health-care costs [2]. Harmful adverse effects affect populations globally with significant mortality and morbidity [3]. All drugs can cause side effects, but not all patients experience the same level or type of side effects. Many factors play a role in the occurrence of side effects. These include age, sex, race, pregnancy, lactation, liver and kidney dysfunction, drug dosage, frequency, and many other factors [4]. 20.56% of the North Indian population was found to be poor drug metabolizers for some specific drug-metabolizing enzymes. In the Kashmiri ethnic population, CYP2C9*3 is the most common mutant allele [5]. In addition to genetic differences, differences in available drugs and medical practices can cause variations in ADR frequencies and patterns [2]. We tried to find the pattern of ADR in our tertiary care hospital.

METHODS

Study population

In this prospective study, conducted from January 2020 to December 2021, we monitored all the patients admitted to the different departments of SKIMS Hospital Srinagar. The causality assessment and severity of an ADR were done using relevant assessment tools.

Inclusion criteria

Inpatients with an admission period longer than 24 h, completely and correctly fill out ADR reports, authentic reports collected by hospital staff.

Exclusion criteria

Out patients, an admission period <24 hours, incomplete ADR reports, and reports from unknown or undocumented sources

Study tools

We used the latest version of the Suspected ADR Reporting form of the Indian Pharmacopoeia Commission.

Data analysis

The data were analyzed using Vassar Stats and manual calculators. Descriptive statistics were used to describe the results.

RESULTS

The total number of authentic ADRs reported was 518 (Table 1). 54.82% (n=284) of the hospitalized patients who suffered from ADRs were females, and 45.17% (n=234) were males (Table 2). 19.88% (n=103) were below 20 years, 27.60% (n=143) were 20–40 years, 30.11% (n=156) were 40–60 years, and 22.39% (n=116) were above 60 years (Table 3).

64.28% (n=333) ADRs were attributed to antibiotics, 9.45% (n=49) to anticancer drugs, 7.33% (n=38) to gastrointestinal tract (GIT) drugs, 2.50% (n=13) to CNS drugs, 0.96% (n=5) to CVS drugs, 8.10% (n=42) to hematological drugs, 5.40% (n=28) vitamins and minerals, and 1.93% (n=10) miscellaneous drugs (Table 4).

8.10% (n=42) were serious ADRs as per the WHO criteria, and 91.89% (n=476) were non-serious (Table 5).

69.88% (n=362) ADRs involved the skin, 24.13% (n=125) nervous system, 19.5% (n=101) GIT, 15.63% (n=81) respiratory system, 7.52% (n=39) CVS, 1.93% (n=10) ENT, 0.57% (n=3) genitourinary, 0.57% (n=3) eye, 0.19% (n=1) blood, and 18.72% (n=97) other system organs (Table 6).

DISCUSSION

The occurrence of ADRs and other drug-related problems varies by country and even between different regions within a country. There are numerous factors that predispose patients to ADRs, including drug-related and patient-related factors. With any drug at any given dose, the range of variability in patient response is 4-fold to 40-fold [6].

Table 1: Year-wise distribution of ADRs

Year	No of ADRs reported
2020	223
2021	295
Total	518

Table 2: Male-female ratio of ADRs

Gender	ADRs	
	No.	Percentage (age)
Male	234	45.17
Female	284	54.82

Table 3: Age-wise distribution of ADRs

Age	No of ADRs	Percentage (age)
Up to 20 Years	103	19.88
20–40 Years	143	27.60
40–60 Years	156	30.11
More than 60 Years	116	22.39

Table 4: Class of drugs involved in ADRs

Drug	No of ADRs	Percentage (age)
Antibiotics	333	64.28
Anticancer	49	9.45
GIT Drugs	38	7.33
CNS Drugs	13	2.50
CVS Drugs	05	0.96
Hematological Drugs	42	8.10
Vitamins & Minerals	28	5.40
Miscellaneous	10	1.93

Table 5: Serious and non-serious ADRs

Type of ADRs	No of ADR	Percentage (age)
Serious	42	8.10
Non-serious	476	91.89

Table 6: SOC/ATC-wise ADR distribution

SOC/ATC	No of ADRs	Percentage (age)
Skin and subcutaneous tissue	362	69.88
Nervous system	125	24.13
Gastrointestinal	101	19.5
Respiratory	81	15.63
Cardiovascular	39	7.52
Ear, nose, throat	10	1.93
Genito-Urinary	03	0.57
Eye	03	0.57
Blood	01	0.19
Others	97	18.72

(Due to multiple ADRs in one report, percentages do not sum up to 100)

Population differences in drug response, including susceptibility to ADRs, are affected by genetic variations [7]. It has been observed that 20.56% of the North Indian population is a poor drug-metabolizer for some specific drug-metabolizing enzymes [5]. In the ethnic Kashmiri population, CYP2C9*3 has been found to be the most frequent mutant allele [8].

The rate of ADRs was higher in females (54.82%) in this study, and a similar pattern was found in India at the national level. In this study, most of the patients (30.11%) who developed ADRs were in the age group of 40–60 years, while in national data, the highest numbers of ADRs were found in the age group of 18–44 years (38.5%). In our study, antibiotics were the drugs mostly responsible for ADRs (64.28%), followed by anticancer agents (9.45%), drugs used for hematological disorders (8.10%), and those acting on GIT (7.33%). At the national level, antibiotics were also the most commonly implicated drugs (30.4%), followed by anticancer drugs (26.3%) and GIT drugs (16.0%). In our study, 8.10% of ADRs were serious as per WHO criteria, as against to 28.10% at the national level [9]. In another study conducted in South India, the ADRs were most frequently reported in the adult age group (75%), with a slight female preponderance (60%). Antibiotics contributed to the maximum number of ADRs, followed by analgesics [10]. Another study from the same region found that most of the ADRs were in females (60%). The majority of ADRs were caused by NSAIDs (32.4%), followed by antimicrobials (20%). The most common organ system involved was the skin (38%). 18.6% of ADRs were serious.[11] In another study, the most commonly offending class of drug found was cardiovascular drugs (57.6%), and 1.6% of ADRs were serious in nature [12].

In another study on the incidence and patterns of ADRs among adult hospitalized patients in Ethopia, the commonly implicated drugs were antibiotics (26.2%), followed by cardiovascular (24.7%) and vitamins and minerals (13.8%) [13].

Another study found major ADRs for antibiotics (55.5%) and anticancer agents (18.2%), and the least reported ADRs were for vaccines and vitamin supplements (2.2%) [14].

The pattern of ADRs observed in our study may differ from other studies due to ethnic differences and patterns of drug use. Extensive data document the impact of ethnic variation on drug efficacy and safety [15].

The authors acknowledge that their results are not entirely consistent with those of other studies that looked at ADRs. It is challenging to estimate the true incidence of ADRs in the general population, with uncertainty about the number of patients exposed to a given drug, poor documentation, and underreporting.

CONCLUSION

Post-marketing surveillance can facilitate obtaining real-world data on the safety and efficacy of medicines as they are used in a heterogeneous population. A high number of ADRs caused by antimicrobials is an alarming situation, and judicious use of antimicrobials is an urgent need. This study provides current information on the demographic characteristics and drugs commonly involved in ADRs. The variations in ADR patterns across the globe reflect differences in prescribing patterns, ADR reporting methods, and individual drug responses.

ETHICAL APPROVAL

Yes.

AUTHORS` CONTRIBUTIONS

The author compiled the data, and after analyzing it, the article was structured.

CONFLICT OF INTEREST

None.

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