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Adverse drug reaction monitoring of commonly prescribed antimicrobial agents in patients at Rama medical college, hospital and research centre, Kanpur

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ABSTRACT

Background: An adverse drug reaction (ADR) is defined as a harmful or unpleasant reaction due to the use of a drug and may cause different types of effects, such as side effects. The World Health Organization states that adverse drug effects are a response to harmful and unintended medicine and occur at doses normally used in men for the prevention, diagnosis, or therapy of disease or for modifying physiological function. **Aims and Objectives:** The objective of the study was ADR monitoring of commonly prescribed antimicrobial agents. **Materials and Methods:** The study was conducted at Rama Hospital and the Research Center Mandhana Kanpur. Data were collected from the patients attending the outpatient and inpatient departments (OPD and IPD) of the medicine departments during the study period at Rama Hospital Mandhana, Kanpur. The sample size was a total of 60 patients. The study duration was conducted for 1 year. Data were collected by analyzing OPDs and IPDs in the Department of Medicine. **Results:** There are different types of adverse drug effects; we observed only three types of adverse drug effects in this study. The most commonly observed ADR was type A (56.66%). Out of the total ADRs reported in antimicrobial agents, skin ADRs (42.02%) and gastrointestinal tract ADRs (57.97%) are higher. There are also three different types of severity conditions observed in patients prescribed antimicrobial drugs; among them, the most commonly observed severity conditions were mild (58.33%). **Conclusion:** These study findings suggest that antimicrobial drugs are generally safe for most patients but can cause mild ADRs. It is important to monitor patients for ADRs while taking antimicrobial drugs and to provide appropriate treatment if necessary. Pharmacovigilance programs can help to identify and monitor ADRs, which can lead to improved patient safety.

Key words: Pharmacovigilance; Anti-bacterial agents; Causality assessment

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INTRODUCTION

Adverse drug reaction (ADR) is defined as a harmful or unpleasant reaction due to the use of a drug and may cause different types of effects, such as side effects.[1] The World Health Organization (WHO) states that adverse drug effects are a response to harmful and unintended medicine and occur at doses normally used in men for the prevention, diagnosis, or therapy of disease or for modifying physiological function.[2] There are two types of adverse drug effects: dose-dependent (also called Type A, Augmented, Predictable), and dose-independent (Type B, Bizarre, Unpredictable, Idiosyncratic).[3] Factors that can cause ADRs are patients, drugs, diseases, and related social factors.[4]

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According to the WHO, pharmacovigilance (PV) is the pharmacological science relating to detecting, evaluating, understanding, and preventing adverse effects, particularly long-term and short-term side effects of medicines.[5] PV is important in clinical research, clinical trial safety, and post-marketing. In India,[6] PV started in 1986. ADRs monitoring was started in 12 regional centers covering a population of 50 million. India joined the WHO for adverse drug effects in 1997.[7] In 2005, WHO supported the World Bank and funded India's National PV Programme (NPPV).[8]

The use of PV is to support the safe and appropriate use of drugs. Promoting the detection of previously unknown ADRs and interactions and increases in the frequency of known ADRs, identifying risk factors for the development of ADRs, estimating quantitative aspects of benefit/risk analysis, and disseminating information to improve drug prescribing and regulation.

ADRs influence all age groups, yet geriatrics and pediatrics are the most commonly influenced ones. Geriatrics experience ADRs due to comorbid diseases, polypharmacy, and altered pharmacokinetic and pharmacodynamic changes, which enhance hospital admissions. Pediatrics, particularly neonates, experience ADRs due to immature organ development and instabilities in pharmacokinetics and pharmacodynamics. Administration of drugs acting on the central nervous system (CNS) during pregnancy may manifest teratogenic potential impacts on the fetus. Consumption of phenytoin increases the proportion of malformations such as orofacial clefts, cardiovascular deformities, and seizures. Medications such as carbamazepine, levetiracetam, and lorazepam can reach the fetus through breast milk and harm them. Hepatic and renal impairment with comorbidities, genetic polymorphisms, and medications with a narrow therapeutic index may demonstrate high occurrences of ADR.[9]

Globally, there is growing concern about the safe use of medications in hospital settings. It is well known that ADRs constitute a major problem in drug therapy and our society, both as a health care problem and as an economic burden. However, ADR monitoring and reporting activity is in its infancy in India.[10]

Disease prevalence, economic status, culture, and ethnicity contribute to ADR patterns.[11] The incidence of ADRs varies by study but ranges from 0.15% to 30%. In one study conducted at an Indian tertiary care hospital, antibiotics were responsible for 40.9% of ADRs.[12] An Australian tertiary center reported that antibiotics were related to 25% of ADRs.[13] Furthermore, previous studies have shown that 99.47% require additional medical intervention.[14]

Amoxicillin and Clavulanic Acid: Possible side effects include diarrhea, vomiting, nausea, thrush, and skin rash. They do not require much medical attention,[15] and some rare adverse drug effects, like cholestatic jaundice (also referred to as cholestatic hepatitis, a form of liver toxicity), have been associated with amoxicillin and Clavulanic acid. The reaction can happen up to several weeks after treatment has stopped and usually takes weeks to resolve. As with all aminopenicillins, amoxicillin has been associated with Stevens-Johnson syndrome and toxic epidermal necrolysis, although these reactions are rare.[16]

The magnitude of the problem of ADRs with antimicrobials in India is significant. A study published in the Indian Journal of Pharmacology in 2022 found that the incidence of ADRs to antimicrobials in India was 17.7%, with the most common ADRs being skin reactions, gastrointestinal reactions, and allergic reactions.[17]

In terms of ADR reporting on antimicrobials, India is still in its early stages. The NPPV of India was launched in 2010 to monitor the safety of drugs in India, but the reporting of ADRs is still voluntary, and under-reporting is a major problem.[17]

A study published in the Indian Journal of Medical Sciences in 2021 found that the reporting rate of ADRs to antimicrobials in India was only 0.07%, which is much lower than the estimated incidence of ADRs.[18] The current study was to identify the incidence and pattern of adverse drug effects (ADRs) of antimicrobial drugs. The secondary objectives were assessing ADRs' types, severity, and causality with antimicrobial drugs.

Aims and objectives

The current study was aimed to adverse drug reaction monitoring of commonly prescribed antimicrobial agents in patients at Rama medical college, hospital and research Centre, Kanpur. the Primary objective was to determine the incidence and pattern of adverse drug effects (ADRs) of antimicrobial drugs, and Secondary objectives was to assess the types, severity, and causality of ADRs associated with antimicrobial drugs.

MATERIALS AND METHODS

The study was conducted at Rama Hospital and the Research Center Mandhana Kanpur. Data were collected from the patients attending the outpatient and inpatient departments (OPD and IPD) of medicine departments

during the study period at Rama Hospital Mandhana, Kanpur. The sample size was a total of 60 patients. The study duration was conducted for 1 year. Data were collected by analyzing OPDs and IPDs in the Department of Medicine.

A spontaneous ADR reporting technique was used for data collection by reviewing case sheets or treatment charts and investigation reports, interviewing patients or attendants, and discussing with healthcare professionals.

ADRs were reported in the ADR reporting form provided by the Indian Pharmacopoeia Commission. Patients were asked in detail about ADRs. ADR monitoring was done systematically, adopting both spontaneous and intensive monitoring approaches.

Inclusion criteria

Patients of both genders attend IPD/OPD medicine departments and take treatment for various antimicrobials. Patients who were given written informed consent. Patients who are willing to give information about ADR and patients who have already been taking antimicrobial drugs for the last year are included in the study.

Exclusion criteria

Pregnant and lactating females. Patients who were unable to answer verbal questions were excluded from the study.

Data analysis

Types of ADRs

To better understand the impact of ADRs, it is pertinent to review various classifications of ADRs. According to Rawlins and Thompson's classification, ADRs are broadly classified as type A and type B. A Type A reaction is associated with the pharmacological actions of the drug and is predictable. In contrast, type B reactions are not associated with the pharmacological actions of the drug and are not predictable. It is also known as an idiosyncratic reaction. Type A reactions are more prevalent than type B. The original Rawlins and Thompson's classification of ADRs into type A (augmented) and type B (bizarre) has been expanded to six types, A to F.

Methods used to ensure adequate reporting

Patients who visited medicine OPD or were admitted to the hospital were observed for ADR by regular follow-up and laboratory findings like liver function tests, renal function tests, and blood pressure. Proper assessment of each ADR report and assessment of patients. A detailed discussion with the clinician and person who reported the ADR case.

Evaluation of data

ADRs are analyzed by the following procedure: patients' demographics, nature of the reaction, and characteristics of the drug involved.

Causality, severity, and preventability assessments of the ADRs were done. Types of ADRs: The ADRs are classified into different types, A to F.

Causality assessment

It is assessed by Naranjo's Probability Scale into definite, probable, possible, and doubtful, and with the WHO-UME system into certain, probable, possible, and unlikely.[19]

Preventability assessment

The preventability of the ADRs according to the modified Schumock-Thornton Criteria[20] was analyzed and categorized as definitely, preventable, probably, preventable, and not preventable.

Definitely preventable

Answering yes to one or more of the following implies that the ADR is preventable.

1. Was there a history of an allergy or a previous reaction to the drug?
2. Was the drug involved inappropriate for the patient's clinical conditions?
3. Was the dose, frequency, or route of administration appropriate for the patients, weight and disease status?

Probably preventable

Answering yes to one or more of the following implies that the ADR is probably preventable.

1. Was therapeutic drug monitoring required, or was the necessary laboratory test not done?
2. Was a documented drug interaction involved in the ADR?
3. Was poor compliance involved in the ADR?
4. Was a preventative measure not administered to the patients?
5. If a preventive measure was administered, was it inadequate or inappropriate? (Answer no if this question is not applicable.)

Not preventable

The ADR could not have been avoided by any reasonable means.

The severity of ADRs

According to the modified Hartwig severity scale, ADRs are classified into various levels.[21]

1. An ADR occurred, but there was no change in treatment with suspected

2. The ADR required that the suspected drug he held be discontinued or changed. No treatment or antidote is required
3. ADR with level 2 and/or an antidote or treatment required
4. Any level 3 ADR that increases the length of stay by at least 1 day was the reason for admission
5. Any level 4 ADR that required intensive medical care
6. The ADR caused permanent harm to the patients
7. 7a. The ADR was indirectly linked to the deaths of patients
   7b. The ADR was directly linked with the deaths of patients.

- Level 1, 2-Mild
- Level 3, 4-Moderate
- Level 5, 6, 7a, and 7b-Severe.

The seriousness of the ADRs

As per WHO criteria, a serious adverse reaction is any untoward medical occurrence that any dose results in.

1. Death
2. Life-threatening
3. Requires inpatient hospitalization and prolongation of existing hospitalization

The outcome of the ADRs

As per WHO criteria as fatal, continuing, recovering, recovered, unknown, or any other ADR reported.

Data management and statistical analysis

The data was collected and entered, and a master table was prepared using MS Excel software. Descriptive statistics have been used to present the data, i.e., percentages, proportions, etc.

Ethical clearance

The ethical committee clearance was taken before the study by the institution's ethical committee.

RESULTS AND DISCUSSION

The present study on adverse drug effects on antimicrobial drugs was conducted in the department of pharmacology in association with the department of medicine at Rama Medical College, Hospital and Research Centre, Kanpur.

The data were collected on 60 patients prescribed antimicrobial drugs over a period of 1 year. The number of patients prescribed antimicrobial drugs to males were 35 (58.33%) and females were 25 (41.66%). The highest proportion of patients prescribed antimicrobial drugs were in the 51-60 age group (38.33%), while the lowest proportion were in the 61-70 age group (6.66%) (Table 1).

For any bacterial infection, patients are prescribed mostly antimicrobial drugs. In the study, patients were prescribed different groups of antimicrobial drugs; the most commonly prescribed antimicrobial drugs in this study were Ceftriaxone (36.66%), followed by Ceftriaxone (33.33%), Levofloxacin (23.33%), Ciprofloxacin and Clindamycin (11.66%), Ampicillin (6.66%), and Amikacin1.(66%) (Table 2). In Stavreva et al.,[22] in his study, antibiotics were prescribed: amikacin (0.72%), ampicillin (2.06%), ceftriaxone (14.23%), and ciprofloxacin (2.89). A result revealed by Shamna et al.,[23] stated that ADR monitoring was done after prescribing an antibiotic, cephalosporin 17 (34.69%), followed by fluoroquinolones 15 (30.61%), penicillin's 7 (14.28%), others 3 (6.12%), polygene 2 (4.08%), aminoglycosides 2 (4.08%), Macrolide 1 (2.04%), oxazolidinone 1 (2.04%), and azoles 1 (2.04%).

Table 1: Age of patients prescribed antimicrobial drugs

S. No.	Age in years	No. of patients	Percentage
1	30–40	11	18.33
2	41–50	20	33.33
3	51–60	23	38.33
4	61–70	02	03.33
5	71–80	04	6.66
	Total	60	100

Table 2: Number of patients prescribed antimicrobial drugs

S. No.	Drugs	No of the patients were prescribed antimicrobial drugs	Percentage
1	Ceftriaxone	22	36.66
2	Ceftriaxone	20	33.33
3	Levofloxacin	14	23.33
4	Ciprofloxacin	07	11.66
5	Clindamycin	07	11.66
6	Ampicillin	04	6.66
7	Amikacin	01	1.66
	Total	60	100

Table 3: Type of ADRs reported in patients prescribed antimicrobial drugs

S. No.	Type of ADRs	No of the patients were prescribed antimicrobial drugs	Percentage
1	Type A	34	56.66
2	Type B	22	36.66
3	Type C	04	6.66
4	Type D	-	-
5	Type E	-	-
6	Type F	-	-
	Total	60	100

ADRs: Adverse drug reactions

There are different types of adverse drug effects; we observed only three types of adverse drug effects in this study. The most commonly observed ADRs were typed A (56.66%), followed by B (36.66%), and C (6.66%) (Table 3). Stavreva et al.,[22] observed that 63.64% are in type A and 31,82% are in type B. The study reported seriousness of 04 (6.66%) and non-seriousness of 56 (93.33%) in patients prescribed antimicrobial drugs. The study also coincides with the study of Shamna et al.,[23] ADRs, in which Type A 38 (77.55%) was the most common compared to Type B 11 (22.44%) reactions. According to Rawlin and Thompson, analysis of other reported ADRs revealed Type A was higher in his study. This result is in line with the study conducted by Oshikoya et al.,[24] and Stavreva et al.[22] But in another study by Suthar and Desai, all the reported reactions were Type B.

Table 4: The severity scale in patients prescribed antimicrobial drugs

S. No.	Type of severity	No of patients	Percentage
1	Mild	35	58.33
2	Moderate	22	36.66
3	Severity	03	05
	Total	60	100

Table 5: The causality assessment (Naranjo's scale) in patients prescribed antimicrobial drugs

S. No.	Causality assessment	No of patients	Percentage
1	Certain	0	0
2	Probable	12	20
3	Possible	45	75
4	Unlikely	03	5
Total		60	100

Table 6: The outcomes of ADRs in patients prescribed antimicrobial drugs

S. No.	Outcome	No of ADRs	Percentage
1	Fatal	-	-
2	Continuing	03	5
3	Recovering	06	10
4	Recovered	52	86.66
5	Unknown	-	-
Total		60	100

ADRs: Adverse drug reactions

Table 7: The Number of ADRs in patients prescribed antimicrobial drugs

ADR reported	No. ADR reported	Percentage
Skin	58	42.02
Rashes	36	26.08
Urticaria	07	5.07
Allergic reaction	05	3.62
Itching	03	2.17
Anaphylactic shock	07	5.07
Gastrointestinal tract	80	57.97
Diarrhea	14	10.14
Loss of appetite	04	2.89
Nausea	15	10.86
Vomiting	15	10.86
Metallic taste	15	10.86
Abdominal pain	17	12.31
Total	138	100

ADRs: Adverse drug reactions

There are also three different types of severity conditions observed in patients prescribed antimicrobial drugs; among them, the most commonly observed severity conditions were mild 58.33%, followed by moderate 36.66%, and severe 05% (Table 4). The study coincides with the study of Shamna et al.,[23] who reported that the severity of ADRs was monitored as moderate 31 (63.26%), followed by mild reactions 14 (28.57%).

This causality assessment scale (Naranjo's scale) as definable, probable, possible, and unlikely. However, in this study, most observed causality assessments (Naranjo's scale) were possible with 75%, followed by probable 20% (Table 5). Stavreva et al.,[22] in their study, estimated that 31.8% was possible and 68.2% was probable with Naranjo's scale index. Shamna et al.,[23] causality assessment was reported as per Naranjo's scale and showed that 71.42% were probable, 9 (18.36%) were possible, and 5 (10.20%) were definite. The outcomes of adverse drug reactions (ADRs) in patients prescribed antimicrobial drugs were as follows: 86.66% recovered, 10% were recovering, and 5% continued to experience ADRs (Table 5).

In this study, the most commonly reported ADR was related to Skin (42.02%), such as rash (26.08%), urticaria (5.07%), allergic reaction (3.62%), itching (2.17%), and anaphylactic shock (5.07%). Followed by the gastrointestinal tract at 57.97%, such as diarrhea at 10.14%, loss of appetite at 2.89%, nausea, vomiting and metallic taste at 10.86%, and abdominal pain at 12.31% (Table 7). The study coincides with the study of Shamna et al.,[23] who reported that organ effects were GIT at 38.77%, followed by the skin at 30.61%, others at 10.20%, CVS at 8.16%, hematology at 6.12%, CNS at 4.08%, and endocrine system at 2.04%.

Limitations of the study

The study was conducted at a single hospital, which may limit the generalizability of the findings to other hospitals or settings and the sample size of the study was 60.

CONCLUSION

This study investigated the adverse drug monitoring of different classes of antimicrobial drugs in patients at Rama

Medical College, Hospital and Research Centre. The most common ADRs were mild, possible, non-serious, and type A. The majority of patients recovered from their ADRs. Slightly more male patients than female patients were taking antimicrobial drugs. Skin and gastrointestinal tract ADRs were the most frequent types of ADRs reported for antimicrobial drugs. Most ADRs reported for antimicrobial drugs were possible according to the Naranjo scale.

These findings suggest that antimicrobial drugs are generally safe for most patients but can cause mild ADRs. It is important to monitor patients for ADRs while taking antimicrobial drugs and to provide appropriate treatment if necessary. PV programs can help to identify and monitor ADRs, which can lead to improved patient safety.

Healthcare professionals should be educated about the potential ADRs of antimicrobial drugs and how to monitor patients for these reactions. PV programs should be strengthened to improve the identification and monitoring of ADRs, especially for new and emerging antimicrobial drugs. More research is needed to better understand the long-term risks and benefits of antimicrobial drug use.

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Authors Contribution:
PB- Definition of intellectual content, literature survey, prepared first draft of manuscript, implementation of study protocol, data collection, data analysis, manuscript preparation and submission of article; **PV-** Concept, design, clinical protocol, manuscript preparation, editing, and manuscript revision; **BCV-** Design of study, statistical analysis and interpretation; **NN-** Review manuscript; **KJ-** Review manuscript; **SSA-** Literature survey and preparation of tables; **KPP-** Coordination and manuscript revision; **ADN-** Coordination and manuscript revision.

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