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Pattern, Causality and Severity Assessment of Antibiotic-Induced Adverse Drug Reactions in a Tertiary Care Teaching Hospital: A Prospective Observational Study

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ABSTRACT

Background: Adverse drug reactions (ADRs) remain a significant cause of morbidity and hospital burden worldwide. Antibiotics are among the most frequently prescribed medications in hospital settings and are commonly associated with ADRs. Monitoring antibiotic-induced ADRs through pharmacovigilance programs is essential to improve patient safety and optimize therapeutic outcomes.

Objective: To evaluate the pattern, causality, severity, and preventability of antibiotic-induced adverse drug reactions in hospitalized patients at a tertiary care teaching hospital.

Methods: A prospective observational study was conducted among 100 hospitalized patients who developed ADRs following antibiotic therapy. Data were collected using a structured ADR reporting form. Demographic characteristics, weight distribution, organ systems affected, types of antibiotics, ADR severity, causality

assessment, preventability, and management strategies were analysed. Causality was assessed using the Naranjo algorithm, severity using Hartwig severity scale, and preventability using the Modified Schumock and Thornton scale. Data were analysed using descriptive statistics.

Results: Among 100 ADR cases, females accounted for 72% and males 28%. The majority of patients weighed 51–60 kg (34%), followed by 41–50 kg (26%). Gastrointestinal reactions were the most frequently observed ADRs (22%), followed by dermatological (19%) and CNS reactions (18%). According to Rawlins and Thompson classification, Type B reactions were predominant (55%), followed by Type A reactions (35%). Severity assessment revealed 44% severe ADRs, 44% moderate, 8% mild, and 4% significant reactions. Causality analysis using the Naranjo scale indicated that 89% of ADRs were probable, 6% possible, 4% doubtful, and 1% highly probable. Preventability assessment demonstrated that 30% ADRs were preventable, 60% probably preventable, and 10% not preventable. Bactericidal antibiotics accounted for 76% of ADRs, whereas bacteriostatic drugs contributed 24%. Management strategies included drug withdrawal combined with symptomatic treatment (40%) as the most common intervention.

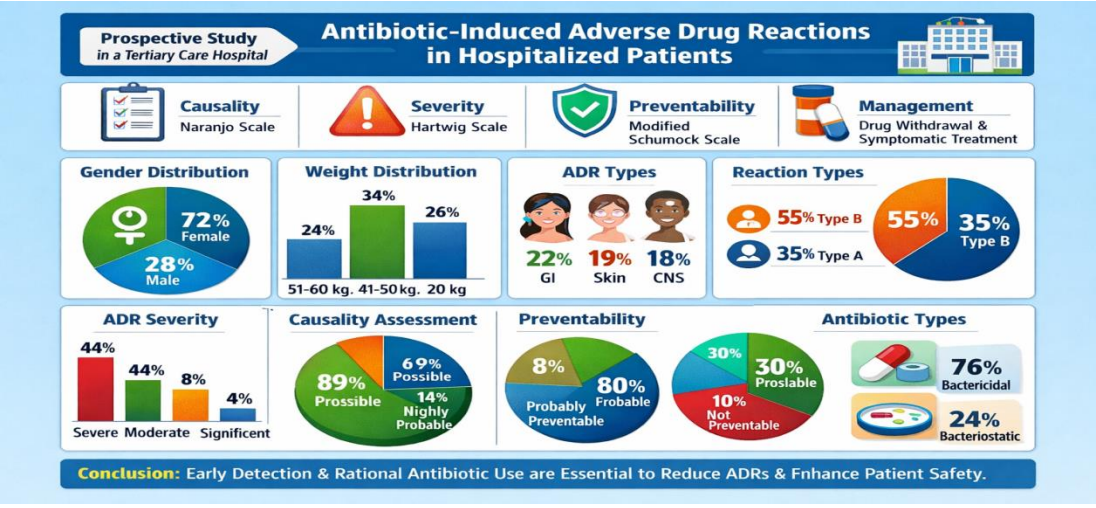
Conclusion: Antibiotic-associated ADRs remain a significant concern in hospitalized patients, with gastrointestinal and dermatological manifestations being most common. Early detection, systematic pharmacovigilance, and rational antibiotic use are essential to reduce the burden of ADRs and enhance patient safety.

Keywords: Adverse drug reactions, Antibiotics, Pharmacovigilance, Causality assessment, Severity analysis.

Abbreviations

ADR – Adverse Drug Reaction
GIT – Gastrointestinal Tract
CNS – Central Nervous System
IEC – Institutional Ethics Committee

Graphical abstract



INTRODUCTION

Medications remain one of the most frequently utilized interventions in modern clinical practice for the prevention, diagnosis, and treatment of diseases. Despite their undeniable therapeutic benefits, drugs may also produce undesirable and sometimes harmful effects. These unintended effects are collectively known as adverse drug reactions (ADRs). According to the World Health Organization (WHO), an ADR is defined as "a response to a medicinal product which is noxious and unintended and occurs at doses normally used in humans for prophylaxis, diagnosis, therapy of disease, or for the modification of physiological functions.[1] The monitoring of ADRs has become an integral component of healthcare systems worldwide because such reactions significantly influence patient safety, treatment outcomes, and healthcare costs.

Globally, ADRs represent a major public health concern. Several epidemiological investigations have reported that ADRs contribute substantially to hospital admissions, prolonged hospitalization, increased healthcare expenditure, and in severe cases, mortality. [2] In developed countries, ADRs are estimated to be among the leading causes of morbidity and mortality in hospitalized patients. A landmark meta-analysis reported that ADRs account for approximately 6–7% of all hospital admissions and are responsible for a significant proportion of inpatient complications. [3] These findings highlight the need for effective pharmacovigilance systems to identify, evaluate, and prevent drug-related adverse events.

Among the various therapeutic classes of medications, antibiotics are widely recognized as one of the most commonly prescribed groups of drugs in both community and hospital settings. Antibiotics play a crucial role in combating infectious diseases and have contributed immensely to the reduction of morbidity and mortality associated with bacterial infections. However, their widespread use, and sometimes inappropriate or irrational prescribing, has increased the likelihood of antibiotic-related adverse drug reactions. [4] Antibiotics are known to cause a wide spectrum of ADRs affecting multiple organ systems, including the gastrointestinal tract, skin, central nervous system, liver, kidneys, and haematological system.

The gastrointestinal system is particularly vulnerable to antibiotic-induced disturbances because antimicrobial agents can disrupt the normal intestinal microflora. This disruption may result in symptoms such as nausea, vomiting, abdominal discomfort, diarrhoea, and antibiotic-associated colitis. [5] Dermatological reactions are another common manifestation of antibiotic-induced ADRs and may range from mild skin rashes to severe hypersensitivity reactions such as Stevens–Johnson syndrome or toxic epidermal necrolysis. [6] Similarly, certain classes of antibiotics are known to cause neurotoxicity, nephrotoxicity, hepatotoxicity, or haematological abnormalities, depending on their pharmacological characteristics.

Another factor contributing to the occurrence of ADRs is the increasing complexity of pharmacotherapy in hospitalized patients. Many patients receive multiple medications simultaneously, a phenomenon known as polypharmacy. Polypharmacy increases the risk of drug–drug interactions and enhances the likelihood of adverse reactions. [7] Furthermore, patient-specific factors such as age, gender, genetic variations, nutritional status, and underlying comorbidities can influence drug metabolism and susceptibility to ADRs. Elderly patients in particular are at greater risk because of age-related physiological changes affecting pharmacokinetics and pharmacodynamics.

Recognizing the importance of monitoring drug safety, pharmacovigilance has emerged as a key discipline within clinical pharmacology and public health. Pharmacovigilance is defined as the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. [8] The primary objective of pharmacovigilance programs is to improve patient safety by identifying previously unrecognized adverse reactions and evaluating the risk–benefit balance of medications.

In India, the Pharmacovigilance Programme of India (PvPI) was established by the Ministry of Health and Family Welfare to strengthen ADR monitoring across the country. The program operates through a network of ADR monitoring centres that collect and analyse data on suspected adverse reactions. [9] Despite these efforts, underreporting of ADRs continues to remain a major challenge in the healthcare system. Lack of awareness among healthcare professionals, inadequate reporting infrastructure, and limited training in pharmacovigilance practices are among the factors responsible for underreporting.

Systematic evaluation of ADRs in hospital settings can provide valuable information about the safety profile of commonly used medications. Observational studies focusing on ADR patterns help clinicians identify high-risk drugs, susceptible patient groups, and preventable risk factors. Such studies also contribute to the development of safer prescribing practices and improved therapeutic guidelines.

In this context, the present prospective observational study was undertaken to evaluate antibiotic-induced ADRs among hospitalized patients in a tertiary care teaching hospital. The study aimed to analyse the pattern of ADRs, identify the organ systems most frequently affected, assess causality using the Naranjo algorithm, evaluate the severity of reactions using the Hartwig severity scale, and determine the preventability of ADRs using the Modified Schumock and Thornton criteria. The findings of this study are expected to provide valuable insights into antibiotic safety and contribute to the strengthening of pharmacovigilance practices in hospital settings.

MATERIALS AND METHODS

Study Design: A prospective observational study was conducted to evaluate antibiotic-induced ADRs.

Study Setting: The study was conducted in the Department of General Medicine of a tertiary care teaching hospital.

Study Duration: The study was carried out over a period of six months.

Study Population: A total of **100 hospitalized patients** who developed adverse drug reactions following antibiotic therapy were included.

Inclusion Criteria

- Patients aged above 18 years
- Patients who developed ADRs after receiving antibiotics
- Patients who provided informed consent

Exclusion Criteria

- Intentional poisoning

- Incomplete patient data
- Patients unwilling to participate

Data Collection

Data were collected using a structured ADR reporting form including:

- Demographic details
- Weight distribution
- Type of antibiotic
- ADR characteristics
- Management strategies
- Clinical outcomes

Assessment Tools

Causality Assessment: Causality of ADRs was evaluated using the Naranjo algorithm.

Severity Assessment: Severity of ADRs was assessed using the Hartwig severity scale.

Preventability Assessment: Preventability of ADRs was determined using the Modified Schumock and Thornton scale.

Statistical Analysis: Data were analysed using descriptive statistics including frequencies and percentages.

RESULTS

Table 1: Demographic Characteristics of Study Population (n = 100)

The demographic characteristics of the study population are presented in Table 1. Among the 100 patients who experienced adverse drug reactions, females constituted the majority with 72% of cases, while males accounted for 28%. Regarding weight distribution, most patients were in the 51–60 kg category (34%), followed by the 41–50 kg group (26%), with smaller proportions observed in higher weight categories.

Variable	Category	Number of Patients	Percentage (%)
Gender	Male	28	28%
	Female	72	72%
Weight Distribution (kg)	41–50	26	26%

	51–60	34	34%
	61–70	15	15%
	71–80	11	11%
	81–90	9	9%
	90–100	5	5%

Table 2: Distribution of Antibiotic-Induced Adverse Drug Reactions by Organ System and Rawlins–Thompson Classification (n = 100)

Table 2 presents the distribution of adverse drug reactions according to organ systems involved and the Rawlins and Thompson classification. Gastrointestinal reactions were the most frequently reported ADRs (22%), followed by dermatological (19%) and central nervous system reactions (18%). Based on Rawlins and Thompson classification, Type B reactions were predominant (55%), followed by Type A reactions (35%), indicating that a majority of ADRs were unpredictable in nature.

Parameter	Category	Number of Cases	Percentage (%)
Organ System Involved	**Gastrointestinal (GIT)**	22	22
	Dermatology	19	19
	Central Nervous System (CNS)	18	18
	Haematology	16	16
	Renal	7	7
	Allergic reactions	7	7
	Others	6	6
	Hepatic	3	3
	Cardiovascular	2	2
Rawlins and Thompson Classification	**Type A**	35	35

	Type B	55	55
	Type C	7	7
	Type E	3	3

Table 3: Severity and Causality Assessment of Antibiotic-Induced Adverse Drug Reactions (n = 100)

Table 3 illustrates the severity and causality assessment of the reported adverse drug reactions. Severe and moderate reactions were equally common, each accounting for 44% of the total ADRs, while mild and significant reactions constituted smaller proportions. Based on the Naranjo causality scale, the majority of ADRs were categorized as probable (89%), followed by possible (6%), doubtful (4%), and highly probable (1%).

Parameter	**Category**	**Number of Cases**	**Percentage (%)**
Severity Assessment	**Severe**	44	44
	Moderate	44	44
	Significant	4	4
	Mild	8	8
Causality Assessment (Naranjo Scale)	**Highly Probable**	1	1
	Probable	89	89
	Possible	6	6
	Doubtful	4	4

Table 4: Preventability, Antibiotic Action, and Predictability of Antibiotic-Induced Adverse Drug Reactions (n = 100)

Table 4 presents the assessment of preventability, type of antibiotic action, and predictability of adverse drug reactions observed during the study. A majority of ADRs were categorized as probably preventable (60%), while 30% were preventable and 10% were not preventable according to the modified Schumock and Thornton criteria. Most reactions were associated with bactericidal antibiotics (76%), whereas bacteriostatic agents

accounted for 24% of cases. Additionally, a higher proportion of ADRs were found to be unpredictable (74%) compared to predictable reactions (26%), indicating the complex nature of antibiotic-induced adverse events.

Parameter	Category	Number of Cases	Percentage (%)
Preventability Assessment	**Preventable**	30	30
	Probably Preventable	60	60
	Not Preventable	10	10
Antibiotic Action	**Bactericidal**	76	76
	Bacteriostatic	24	24
Predictability of ADRs	**Predictable**	26	26
	Unpredictable	74	74

Table 5: Management Strategies Adopted for Antibiotic-Induced Adverse Drug Reactions (n = 100)

Table 4 summarizes the management approaches adopted for the reported adverse drug reactions. The most common intervention was drug withdrawal combined with symptomatic treatment, accounting for 40% of cases, followed by drug withdrawal alone in 20% of patients. Other strategies included specific treatment, symptomatic management, dose alteration, or combination approaches, while only 1% of cases required no change in therapy. These findings highlight that discontinuation of the suspected antibiotic along with supportive care was the most frequently employed strategy for managing ADRs.

Intervention	Number of Cases	Percentage (%)
Drug withdrawal + symptomatic treatment	40	40
Drug withdrawal	20	20

Specific treatment	10	10
Symptomatic treatment	10	10
Drug withdrawal + specific treatment	10	10
Dose alteration	5	5
Dose alteration + symptomatic treatment	4	4
No change in therapy	1	1

DISCUSSION

The present prospective observational study was conducted to analyse antibiotic-associated adverse drug reactions in hospitalized patients at a tertiary care teaching hospital. ADR monitoring is an essential component of pharmacovigilance because it enables early detection of drug-related problems and facilitates the development of strategies to improve medication safety.

In the present study, female patients constituted a greater proportion of ADR cases compared with male patients. Similar gender-based differences have been reported in previous pharmacovigilance studies, where women were observed to experience ADRs more frequently than men. Several factors may explain this difference, including variations in pharmacokinetic parameters such as body fat composition, hormonal influences, and differences in drug metabolism. [10] Additionally, women may receive certain medications more frequently than men, which could also contribute to increased reporting of ADRs.

Weight distribution analysis showed that the highest number of ADR cases occurred in patients weighing between 51 and 60 kg. Body weight can significantly influence the pharmacokinetics of drugs because it affects drug distribution, metabolism, and elimination. Inappropriate dosing that does not account for patient weight may increase the likelihood of adverse drug reactions, particularly with antibiotics that have narrow therapeutic indices.

Evaluation of organ systems affected by ADRs revealed that gastrointestinal reactions were the most common adverse effects observed in the study population. Gastrointestinal disturbances such as abdominal pain,

diarrhoea, and nausea are well-recognized adverse effects associated with several classes of antibiotics. The disruption of normal gut microbiota caused by antimicrobial agents is considered the primary mechanism responsible for these reactions. [11] Similar findings have been reported in several hospital-based pharmacovigilance studies, which identified gastrointestinal manifestations as the most frequently reported ADRs associated with antibiotic therapy.

Dermatological reactions were the second most common ADRs observed in the study. Antibiotic-induced skin reactions may occur due to immunological hypersensitivity mechanisms or non-immunological pharmacological effects. Skin manifestations may vary from mild maculopapular rashes to severe life-threatening conditions such as Stevens–Johnson syndrome. Early recognition of dermatological ADRs is essential because prompt withdrawal of the offending drug can prevent progression to more severe reactions. [12]

Central nervous system involvement was also observed in a considerable proportion of patients. Certain antibiotics, particularly those capable of crossing the blood-brain barrier, may produce neurological adverse effects including dizziness, seizures, confusion, and insomnia. These reactions are often dose-dependent and may occur more frequently in patients with renal impairment or altered drug clearance.

The Rawlins and Thompson classification of ADRs demonstrated that Type B reactions were more common than Type A reactions in the present study. Type B reactions are unpredictable and are not directly related to the pharmacological action of the drug. They often occur due to immunological mechanisms or genetic susceptibility. In contrast, Type A reactions are usually dose-dependent and predictable based on the known pharmacological properties of the drug. [13]

Severity assessment revealed that a significant proportion of ADRs were categorized as moderate to severe. Moderate reactions typically require therapeutic intervention or modification of drug therapy, whereas severe reactions may result in prolonged hospitalization or life-threatening complications. The presence of severe ADRs in the study population highlights the clinical importance of careful monitoring of antibiotic therapy in hospitalized patients.

Causality assessment using the Naranjo algorithm indicated that the majority of ADRs were classified as probable. The Naranjo scale is widely used in pharmacovigilance studies because it provides a systematic method for determining the likelihood that a drug caused a particular adverse event. [14] A high proportion of probable reactions suggests a strong association between antibiotic therapy and the observed adverse events.

Preventability analysis showed that a considerable proportion of ADRs were classified as preventable or probably preventable. Preventable ADRs often occur due to inappropriate drug selection, incorrect dosing, drug interactions, or inadequate monitoring of patients. These findings emphasize the importance of rational prescribing practices and regular monitoring of patients receiving antibiotic therapy.

Management of ADRs in the present study primarily involved withdrawal of the suspected drug along with symptomatic treatment. In some cases, specific treatment or dose modification was required. Prompt identification and appropriate management of ADRs are essential to prevent complications and improve patient outcomes.

The results of this study underscore the need for strengthening pharmacovigilance practices in hospital settings. Encouraging healthcare professionals to report suspected ADRs can significantly enhance the detection of drug safety signals and contribute to safer prescribing practices.

CONCLUSION

The present study highlights the pattern, causality, severity, and management of antibiotic-induced adverse drug reactions in a tertiary care teaching hospital. A higher incidence of ADRs was observed among female patients, and most cases were reported in patients within the 51–60 kg weight group. Gastrointestinal, dermatological, and central nervous system reactions were the most frequently affected organ systems, indicating that antibiotics commonly influence multiple physiological systems.

Based on the Rawlins and Thompson classification, Type B reactions were the most predominant, suggesting that a large proportion of ADRs were unpredictable in nature. Severity assessment revealed that severe and moderate reactions were equally common, each accounting for a considerable proportion of cases. Causality assessment using the Naranjo scale indicated that most ADRs were categorized as probable, confirming a strong association between the suspected antibiotic and the observed reactions.

The majority of adverse reactions were associated with bactericidal antibiotics, and a large proportion of ADRs were classified as probably preventable. Management of ADRs primarily involved withdrawal of the suspected drug along with symptomatic treatment, highlighting the importance of prompt identification and appropriate intervention.

Overall, the findings emphasize the need for continuous pharmacovigilance, early detection, and rational use of antibiotics to minimize the occurrence of adverse drug reactions. Implementation of structured ADR monitoring systems, awareness among healthcare professionals, and patient education can significantly contribute to improving drug safety and optimizing therapeutic outcomes in clinical practice.

Study Limitations: This study has certain limitations that should be considered while interpreting the results. The study was conducted in a single tertiary care teaching hospital with a relatively limited sample size of 100 patients, which may restrict the generalizability of the findings to other healthcare settings. Additionally, only spontaneously reported adverse drug reactions were included in the analysis; therefore, some mild or unreported reactions might have been missed. Furthermore, detailed follow-up of patients was limited, which could affect the long-term assessment of ADR outcomes.

Strengths of the Study: Despite the limitations, the study provides valuable insights into the pattern, severity, causality, and preventability of antibiotic-induced adverse drug reactions in a tertiary care hospital. The use of standardized assessment tools such as the Naranjo causality scale and Modified Schumock and Thornton preventability scale enhances the reliability of the findings. The study also highlights practical management strategies used for ADRs in routine clinical practice.

Future Recommendations

Recommendations: Strengthening pharmacovigilance programs in hospitals is essential for early detection and reporting of antibiotic-related adverse drug reactions. Regular training programs for healthcare professionals regarding ADR reporting and rational antibiotic use may help reduce preventable reactions. Further multicentre studies with larger sample sizes are recommended to better understand the epidemiology and risk factors associated with antibiotic-induced ADRs.

REFERENCES

1. World Health Organization. The importance of pharmacovigilance. Geneva: WHO; 2002.
2. Pirmohamed M, et al. Adverse drug reactions as cause of hospital admission. BMJ. 2004; 329:15-19.
3. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients. JAMA. 1998; 279:1200-1205.
4. Edwards IR, Aronson JK. Adverse drug reactions: definitions, diagnosis and management. Lancet. 2000; 356:1255-1259.
5. Bartlett JG. Antibiotic-associated diarrhea. N Engl J Med. 2002; 346:334-339.
6. Roujeau JC, Stern RS. Severe adverse cutaneous reactions to drugs. N Engl J Med. 1994; 331:1272-1285.
7. Maher RL, Hanlon J, Hajjar ER. Clinical consequences of polypharmacy in elderly. Expert Opin Drug Saf. 2014; 13:57-65.
8. WHO. Safety monitoring of medicinal products. Geneva: WHO; 2002.
9. Central Drugs Standard Control Organization. Pharmacovigilance Programme of India. New Delhi; 2010.
10. Rademaker M. Do women have more adverse drug reactions? Am J Clin Dermatol. 2001; 2:349-351.
11. McFarland LV. Antibiotic-associated diarrhea. Am J Gastroenterol. 2008; 103:185-193.
12. Mockenhaupt M. Severe cutaneous adverse reactions to drugs. Chem Immunol Allergy. 2012; 97:135-144.
13. Rawlins MD, Thompson JW. Pathogenesis of adverse drug reactions. In: Davies DM, editor. Textbook of adverse drug reactions. Oxford University Press; 1977.
14. Naranjo CA, et al. A method for estimating probability of adverse drug reactions. Clin Pharmacol Ther. 1981; 30:239-245.ss