



RESEARCH ARTICLE

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

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Abstract

Background: Adverse drug reactions are an important cause of mor-bidity, prolonged hospital stay, increased healthcare expenditure, and treatment non-compliance. Pharmacovigilance plays a vital role in identifying, assessing, monitoring, and preventing adverse drug reactions. Systematic reporting and evaluation of adverse drug reactions are essential for improving medication safety in clinical practice. **Materials and Methods:** A prospective observational study was conducted in the Department of Pharmacology. A total of 180 adverse drug reaction reports received from various clinical departments were analyzed. Patient demographic details, suspected drug, clinical manifestation, route of administration, seriousness, outcome, and management were recorded. Causality assessment was performed using the WHO-UMC causality assessment scale and Naranjo algorithm. Severity was assessed using the modified Hartwig and Siegel severity assessment scale. Preventability was evaluated using modified Schumock and Thornton criteria. Data were analyzed using descriptive statistics. **Aim:** To evaluate the pattern, causality, severity, preventability, and commonly implicated drug groups among adverse drug reactions reported in a tertiary care teaching hospital. **Results:** Among 180 adverse drug reaction reports, females constituted 98 (54.4%) cases and males constituted 82 (45.6%) cases. The most commonly affected age group was 31–60 years. Antimicrobials were the most commonly implicated drug group, followed by non-steroidal anti-inflammatory drugs, antiepileptics, antihypertensives, and antidiabetic drugs. Cutaneous reactions were the most common clinical presentation, followed by gastrointestinal and central nervous system reactions. Most reactions were categorized as probable or possible by causality assessment. The majority were mild to moderate in severity. Most reactions were not preventable, while a small proportion was probably preventable. **Conclusion:** Adverse drug reactions are commonly encountered in hospital practice, with antimicrobials and non-steroidal anti-inflammatory drugs being frequently implicated. Cutaneous and gastrointestinal reactions were the commonest presentations. Regular adverse drug reaction monitoring, active pharmacovigilance, rational prescribing, and sensitization of healthcare workers are essential for improving patient safety.

Keywords: Adverse Drug Reaction, Causality Assessment, Drug Safety, Pharmacology, Pharmacovigilance, Severity Assessment.

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1 | INTRODUCTION

Adverse drug reactions are undesirable and unintended responses to medicines occurring at doses normally used for prophylaxis, diagnosis, or treatment of disease. They are an important cause of patient morbidity and are increasingly recognized as a major public health concern. Adverse drug reactions may lead to treatment interruption, additional medication use, hospital admission, prolonged hospitalization, disability, and rarely death. (1)

The safety of medicines cannot be completely established before marketing because pre-marketing clinical trials are conducted in relatively small, selected populations under controlled conditions. Rare, delayed, chronic, or population-specific adverse effects may become evident only after a drug is used widely in routine clinical practice. Therefore, post-marketing surveillance and pharmacovigilance are essential components of drug safety monitoring. (2)

Pharmacovigilance refers to the science and activities related to detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. It aims to improve patient safety, promote rational use of medicines, identify signals, and provide evidence for regulatory action where necessary. Spontaneous reporting of adverse drug reactions by healthcare professionals remains an important method of pharmacovigilance. (3)

Adverse drug reactions may affect any organ system. Cutaneous manifestations such as rash, urticaria, pruritus, fixed drug eruption, angioedema, and Stevens-Johnson syndrome are commonly reported. Gastrointestinal symptoms such as nausea, vomiting, abdominal pain, diarrhea, and gastritis are also frequent. Other reactions may involve the central nervous system, cardiovascular system, respiratory system, liver, kidneys, and hematological system. (4)

Several factors influence the occurrence of adverse drug reactions. These include age, gender, genetic factors, polypharmacy, comorbidities, renal or hepatic impairment, drug interactions, self-medication, inappropriate prescribing, dose errors, previous allergy, and prolonged treatment. Elderly patients and

hospitalized patients are particularly vulnerable because they often receive multiple drugs and have altered pharmacokinetics. (5)

Assessment of adverse drug reactions requires structured evaluation. Causality assessment helps determine the likelihood that a suspected drug caused the reaction. Commonly used methods include WHO-UMC causality categories and the Naranjo algorithm. Severity assessment helps classify reactions as mild, moderate, or severe, while preventability assessment identifies whether the reaction could have been avoided by appropriate measures. (6)

In India, pharmacovigilance has gained importance through structured adverse drug reaction monitoring centers and national reporting programs. However, underreporting remains a major limitation. Many healthcare professionals may fail to report adverse drug reactions due to lack of awareness, uncertainty regarding causality, lack of time, fear of blame, or assumption that only serious reactions need reporting.

Hospital-based adverse drug reaction monitoring provides useful information on local drug safety patterns. It helps identify commonly implicated drug groups, clinical presentations, seriousness, preventability, and outcomes. The present study was conducted to evaluate the pattern, causality, severity, preventability, and implicated drug groups among adverse drug reactions reported in a tertiary care teaching hospital.

2 | MATERIALS AND METHODS

This prospective observational study was conducted in the Department of Pharmacology. A total of 180 adverse drug reaction reports received from various clinical departments were analyzed.

All suspected adverse drug reactions reported from outpatient and inpatient departments during the

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study period were included. Reports with incomplete essential information, medication errors without clinical reaction, accidental poisoning, drug abuse cases, and reactions due to alternative or unknown medicines without adequate details were excluded.

Adverse drug reaction reports were collected using a structured reporting format. Information recorded included patient age, gender, clinical department, suspected drug, dose, route of administration, indication, duration of therapy, description of reaction, time relationship between drug intake and reaction onset, dechallenge, rechallenge where applicable, concomitant medications, treatment given, seriousness, and final outcome.

The suspected drugs were categorized into drug groups such as antimicrobials, non-steroidal anti-inflammatory drugs, antiepileptics, antihypertensives, antidiabetic drugs, gastrointestinal drugs, and others. Clinical manifestations were categorized according to the organ system involved.

Causality assessment was performed using the WHO-UMC causality assessment scale and Naranjo adverse drug reaction probability scale. Reactions were classified as certain, probable, possible, unlikely, conditional, or unassessable according to WHO-UMC criteria. Naranjo assessment categorized reactions as definite, probable, possible, or doubtful.

Severity assessment was performed using the modified Hartwig and Siegel severity assessment scale. Adverse drug reactions were classified as mild, moderate, or severe depending on the clinical impact, need for treatment, prolongation of hospital stay, and presence of permanent harm or life-threatening features.

Preventability assessment was done using modified Schumock and Thornton criteria. Reactions were categorized as definitely preventable, probably preventable, or not preventable based on factors such as inappropriate drug use, known allergy, dose error, drug interaction, monitoring failure, and availability of safer alternatives.

Outcome was recorded as recovered, recovering, continuing, unknown, or fatal. Seriousness was as-

sessed based on whether the adverse drug reaction resulted in hospitalization, prolonged hospital stay, disability, life-threatening event, congenital anomaly, or death.

Data were analyzed using descriptive statistics. Categorical variables were expressed as frequencies and percentages. Results were presented in tabular form. Institutional ethical committee approval was obtained before commencement of the study. Patient confidentiality was maintained throughout the study.

3 | RESULTS

3.1 | Total of 180 adverse drug reaction reports were analyzed during the study period

Female patients constituted 98 (54.4%) cases, while males constituted 82 (45.6%) cases. The most commonly affected age group was 31–60 years, accounting for 88 (48.9%) reports. Elderly patients above 60 years constituted 32 (17.8%) cases. This indicates that adverse drug reactions were observed across all age groups but were more frequently reported among adults.

Antimicrobials were the most commonly implicated drug group, involved in 62 (34.4%) reactions, followed by non-steroidal anti-inflammatory drugs in 34 (18.9%) cases. Antiepileptics, antihypertensives, and antidiabetic drugs were also important contributors. This pattern reflects high use of antimicrobials and analgesics in hospital practice.

Cutaneous reactions were the most common clinical presentation, observed in 74 (41.1%) cases. Gastrointestinal reactions were reported in 42 (23.3%) cases, followed by central nervous system reactions in 24 (13.3%) cases. Cutaneous manifestations included rash, itching, urticaria, and fixed drug eruption. Gastrointestinal reactions included nausea, vomiting, diarrhea, and gastritis.

Most reactions were categorized as possible or probable. Possible reactions accounted for 86 (47.8%) cases, while probable reactions accounted for 82 (45.6%) cases. Certain causality was assigned in only 4 (2.2%) cases, mainly because rechallenge was rarely performed due to ethical and safety concerns.

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TABLE 1: Demographic Characteristics of Patients with ADRs

Variable	Frequency (%)
Male	82 (45.6)
Female	98 (54.4)
Age ≤18 years	18 (10.0)
Age 19–30 years	42 (23.3)
Age 31–60 years	88 (48.9)
Age >60 years	32 (17.8)

TABLE 2: Commonly Implicated Drug Groups

Drug Group	Frequency (%)
Antimicrobials	62 (34.4)
NSAIDs	34 (18.9)
Antiepileptics	22 (12.2)
Antihypertensives	18 (10.0)
Antidiabetic drugs	16 (8.9)
Gastrointestinal drugs	10 (5.6)
Others	18 (10.0)

TABLE 3: Clinical Pattern of ADRs

System Involved	Frequency (%)
Cutaneous reactions	74 (41.1)
Gastrointestinal reactions	42 (23.3)
Central nervous system reactions	24 (13.3)
Cardiovascular reactions	14 (7.8)
Metabolic/endocrine reactions	12 (6.7)
Respiratory reactions	6 (3.3)
Others	8 (4.4)

TABLE 4: Causality Assessment Using WHO-UMC Scale

Causality Category	Frequency (%)
Certain	4 (2.2)
Probable/Likely	82 (45.6)
Possible	86 (47.8)
Unlikely	6 (3.3)
Conditional/Unclassified	2 (1.1)

TABLE 5: Severity Assessment Using Modified Hartwig and Siegel Scale

Severity	Frequency (%)
Mild	96 (53.3)
Moderate	72 (40.0)
Severe	12 (6.7)

Most adverse drug reactions were mild, accounting for 96 (53.3%) cases. Moderate reactions were observed in 72 (40.0%) cases, while severe reactions were reported in 12 (6.7%) cases. Severe reactions required urgent intervention, hospitalization, or intensive monitoring.

Most adverse drug reactions were not preventable, accounting for 136 (75.6%) cases. Probably preventable reactions were observed in 36 (20.0%) cases. Definitely preventable reactions were relatively uncommon and included cases related to known allergy, inappropriate dose, or avoidable drug interaction.

Most patients recovered completely after withdrawal of suspected drug, dose adjustment, or symptomatic treatment. Recovery was documented in 118 (65.6%) cases, while 42 (23.3%) patients were recovering at the time of reporting. No fatal reaction was reported during the study period.

4 | DISCUSSION

The present prospective observational study evaluated the pattern, causality, severity, preventability, and outcome of adverse drug reactions reported in a tertiary care teaching hospital. A total of 180 adverse drug reaction reports were analyzed. Female predominance was observed, and the most commonly affected age group was 31–60 years. Antimicrobials were the most frequently implicated drugs, followed by non-steroidal anti-inflammatory drugs. Cutaneous reactions were the most common presentation.

Lazarou et al. reported that adverse drug reactions are an important cause of morbidity and mortality among hospitalized patients. (7) The present study also supports the clinical significance of adverse drug reaction monitoring, as many reported reactions required drug withdrawal, symptomatic management, or treatment modification.

Pirmohamed et al. showed that adverse drug reactions are an important cause of hospital admission and healthcare burden. (8) In the present study, although fatal reactions were not observed, moderate and severe reactions together accounted for 46.7%

of cases, indicating that adverse drug reactions can significantly affect clinical care.

Edwards and Aronson emphasized that adverse drug reactions should be clearly identified and classified to improve drug safety. (9) In the present study, structured documentation helped categorize reactions according to suspected drug, clinical pattern, causality, severity, preventability, and outcome.

Olivier et al. reported that spontaneous reporting systems are useful for pharmacovigilance but are affected by underreporting and variable reporting quality. (10) In the present study, spontaneous and stimulated reporting from clinical departments formed the basis of data collection, emphasizing the need for sensitization of healthcare workers.

Gurwitz et al. reported that preventable adverse drug events are common among older adults, especially due to polypharmacy and comorbidities. (11) In the present study, 17.8% of reactions occurred in patients above 60 years. Elderly patients require careful prescribing, dose adjustment, and monitoring.

Sriram et al. reported that antimicrobials and non-steroidal anti-inflammatory drugs are frequently implicated in adverse drug reactions in hospital settings. (12) The present study showed a similar pattern, with antimicrobials causing 34.4% and NSAIDs causing 18.9% of adverse drug reactions.

Arulmani et al. observed that cutaneous manifestations are among the commonest adverse drug reactions reported in hospital-based studies. (13) In the present study, cutaneous reactions accounted for 41.1% of cases and included rash, itching, urticaria, and fixed drug eruption.

Ramesh et al. reported that dermatological and gastrointestinal reactions are commonly reported adverse drug reactions in hospital practice. (14) In the present study, gastrointestinal reactions were the second most common group, accounting for 23.3% cases. These included nausea, vomiting, diarrhea, and gastritis.

Shamna et al. emphasized that causality and severity assessment are important components of adverse drug reaction monitoring. (15) In the present study, WHO-UMC and Naranjo scales were used for causality assessment, while modified Hartwig and

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TABLE 6: Preventability Assessment

Preventability Category	Frequency (%)
Definitely preventable	8 (4.4)
Probably preventable	36 (20.0)
Not preventable	136 (75.6)

TABLE 7: Outcome of ADRs

Outcome	Frequency (%)
Recovered	118 (65.6)
Recovering	42 (23.3)
Continuing	12 (6.7)
Unknown	8 (4.4)
Fatal	0 (0.0)

Siegel scale was used for severity assessment. Most reactions were possible or probable.

Most reactions in the present study were mild or moderate. Mild reactions usually required symptomatic treatment or observation, while moderate reactions required drug withdrawal, dose adjustment, or additional therapy. Severe reactions were less common but clinically important.

Certain causality was assigned in only 2.2% cases. This is expected because rechallenge is rarely performed in routine practice due to ethical concerns and risk to the patient. Most hospital-based adverse drug reactions are therefore categorized as probable or possible.

Preventability assessment showed that 24.4% reactions were definitely or probably preventable. Preventable reactions may be reduced by avoiding known allergens, checking previous drug history, adjusting doses in renal or hepatic impairment, monitoring high-risk drugs, and avoiding irrational polypharmacy.

Antimicrobials were the most frequently implicated drug group. This may be due to their widespread use in outpatient and inpatient departments. Rational antibiotic use, culture-guided therapy where appropriate, and avoidance of unnecessary antimicrobial prescribing can reduce adverse reactions and antimicrobial resistance.

NSAIDs were the second most commonly implicated group. These drugs are frequently used for pain and fever, sometimes without prescription. Gas-

tritis, rash, urticaria, and hypersensitivity reactions were common. Proper counseling regarding dose, duration, contraindications, and avoidance of self-medication is important.

Antiepileptics contributed to 12.2% reactions. These drugs are known to cause cutaneous reactions, sedation, dizziness, and rarely severe hypersensitivity reactions. Patients receiving antiepileptics should be counseled regarding early reporting of rash or systemic symptoms.

The absence of fatal reactions in the present study is reassuring. However, it should not reduce the importance of active pharmacovigilance because serious reactions may be rare but preventable with timely recognition and intervention.

The present study has certain limitations. It was conducted at a single tertiary care hospital. Underreporting cannot be completely excluded. Laboratory confirmation of all reactions was not possible. Long-term follow-up was limited. Future studies with active surveillance and electronic reporting may provide stronger data.

5 | CONCLUSION

Adverse drug reactions are commonly encountered in hospital practice and require systematic monitoring. In the present study, antimicrobials and non-steroidal anti-inflammatory drugs were the most frequently implicated drug groups. Cutaneous reactions

were the commonest clinical presentation, followed by gastrointestinal and central nervous system reactions. Most reactions were classified as possible or probable, and the majority were mild to moderate in severity. A proportion of reactions was preventable, highlighting the importance of rational prescribing, medication history review, patient counseling, and pharmacovigilance training. Active adverse drug reaction monitoring and reporting should be encouraged among healthcare professionals to improve patient safety and promote rational use of medicines.

REFERENCES

1. International drug monitoring: the role of national centres. World Health Organ Tech Rep Ser. 1972;498:1–25.
2. ; 2002.
3. Edwards IR, Aronson JK. Adverse drug reactions: definitions, diagnosis, and management. *Lancet*. 2000;356(9237):1255–1259.
4. Rawlins MD, Thompson JW. Mechanisms of adverse drug reactions. In: DM D, editor. *Textbook of Adverse Drug Reactions*. Oxford University Press; 1991. .
5. Davies EC, Green CF, Taylor S, Williamson PR, Mottram DR, Pirmohamed M. Adverse drug reactions in hospital in-patients. *PLoS One*. 2009;4(2):4439–4439.
6. Naranjo CA, Busto U, Sellers EM, Sandor P, Ruiz I, Roberts EA. A method for estimating the probability of adverse drug reactions. *Clin Pharmacol Ther*. 1981;30(2):239–245.
7. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients. *JAMA*. 1998;279(15):1200–1205.
8. Pirmohamed M, James S, Meakin S, Green C, Scott AK, Walley TJ. Adverse drug reactions as cause of admission to hospital. *BMJ*. 2004;329(7456):15–19.
9. Edwards IR, Aronson JK. Adverse drug reactions: definitions, diagnosis, and management. *Lancet*. 2000;356(9237):1255–1259.
10. Olivier P, Montastruc JL. The nature of the scientific evidence leading to drug withdrawals for pharmacovigilance reasons in France. *Pharmacoepidemiol Drug Saf*. 2006;15(11):808–812.
11. Gurwitz JH, Field TS, Harrold LR, Rothschild J, Debellis K, Seger AC. Incidence and preventability of adverse drug events among older persons. *JAMA*. 2003;289(9):1107–1116.
12. Sriram S, Ghasemi A, Ramasamy R, Devi M, Balasubramanian R, Ravi TK. Prevalence of adverse drug reactions at a private tertiary care hospital in south India. *J Res Med Sci*. 2011;16(1):16–25.
13. Arulmani R, Rajendran SD, Suresh B. Adverse drug reaction monitoring in a secondary care hospital in South India. *Br J Clin Pharmacol*. 2008;65(2):210–216.
14. Ramesh M, Pandit J, Parthasarathi G. Adverse drug reactions in a south Indian hospital: their severity and cost involved. *Pharmacoepidemiol Drug Saf*. 2003;12(8):687–692.
15. Shamna M, Dilip C, Ajmal M, Mohan PL, Shinu C, Jafer CP. A prospective study on adverse drug reactions of antibiotics in a tertiary care hospital. *Saudi Pharm J*. 2014;22(4):303–308.

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