International Journal of Basic & Clinical Pharmacology
Sreeja R et al. Int J Basic Clin Pharmacol. 2026 Jan;15(1):106-111
http://www.ijbcp.com
pISSN 2319-2003 | eISSN 2279-0780

DOI: https://dx.doi.org/10.18203/2319-2003.ijbcp20254160

Original Research Article

Adverse drug reactions: a prospective observational study at a tertiary care hospital

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Received: 11 November 2025
Accepted: 08 December 2025

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ABSTRACT

Background: Reporting and assessing adverse drug reactions is essential for regulators to monitor, research and maintain patient safety. The main purpose of this study was to report, assess the adverse drug reactions and its incidence at a tertiary care hospital.
Methods: This was a prospective observational study conducted in a tertiary care hospital in Bengaluru. A total of 184 suspected adverse drug reactions were recognized and documented during the study period of six months. After data collection, each suspected adverse drug reactions were assessed.
Results: The suspected adverse drug reactions were reported and evaluated from 178 patients. Among them, 60.11% were adults and 35.39% were elderly patients. The majority of patients were females (55.98%) followed by males (44.02%). A higher number of adverse drug reactions was reported from the general medicine department (48.37%). The majority of the route of administration of suspected drugs was through the oral route (54.31%). Most of the Adverse drug reactions outcome were recovered/resolved (57.60%). The severity of the majority of ADRs was moderate (77.17%). According to causality assessment, most of the ADRs were probable (75%) and were classified as type A (54.34%) reactions. The incidence rate of ADRs during the study period was 0.93%.
Conclusions: The study results indicate a significant decrease in the occurrence of adverse drug reactions compared to previous year. This reduction highlights the need for enhanced monitoring, improved drug safety measures and more effective ADR reporting. This investigation draws attention to ADR reporting practices and highlights the need for a more organized approach to ADR detection and management in hospitals.

Keywords: Adverse drug reaction, Incidence, Pharmacovigilance programme of India, Patient safety, Spontaneous reporting

INTRODUCTION

Adverse drug reactions (ADRs) are harmful and unintended responses to medications that occur at doses normally used in humans. They are a major contributor to morbidity and mortality and add substantially to the overall healthcare burden and medical costs.[1] WHO defines an ADR as "any response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function".[2] This excludes overdose (accidental or intentional). In the healthcare sector, ADRs continue to be a concern. The impact of ADRs includes lowering the quality of life, an increase in the number of hospitalizations, an increased economic burden on health management and an increased rate of mortality.

ADRs account for around 20% of medical expenses in some countries and are among the top 10 primary causes of death.[3] Monitoring and detecting ADRs in hospitals is important for improving healthcare quality and drug safety. Assessing the incidence rate of ADRs is essential

for comprehending their clinical impact and for developing suitable preventive strategies. Hence, reporting of ADRs is essential for the regulators to monitor, research and maintain patient safety. Early detection and prevention of ADRs are crucial, as they can lead not only to morbidity and mortality but also to increased healthcare costs associated with their management. In India, ADR monitoring and reporting continue to be in its infancy.[4] India is a developing country with a large drug-consuming population. Insecurity, hectic schedules, lack of training and lack of awareness about the Pharmacovigilance Programme of India (PvPI) were common reasons for underreporting.[5]

The fundamental concern with spontaneous reporting structures is underreporting, which may amount to as much as 98%.[7] Constant monitoring will improve patient safety. Systematic monitoring by physicians and other healthcare professionals can reduce the safety issues that an ADR may cause.[6] The primary objective of this study was to identify, assess and report ADRs in a tertiary care hospital. The secondary objectives included determining the distribution pattern of ADRs with respect to various parameters, uploading the reported ADRs to the PvPI and determining the incidence rate of adverse drug reactions in the tertiary care hospital.

METHODS

This was a prospective observational study conducted at Bangalore Baptist Hospital over 6 months. The study population included inpatients and outpatients suspected of having an ADR. This study used an active method of identifying ADRs collected from all the departments of a tertiary care hospital. The procedure included daily rounds of PharmD students to different departments of the hospital and collection of information on adverse drug reactions. All the inpatients admitted in the hospital for the treatment of a particular condition were included in the study, including patients admitted due to adverse drug reactions, patients in the emergency experiencing ADRs, ADRs in pregnancy and lactating women and ADRs experienced by outpatients.

Patients admitted for accidental or intentional poisoning or overdose, patients admitted due to drug abuse, test dose reactions and ADRs occurring due to drug administration errors were excluded. The data of this study were collected from multiple sources, including the patient's profile form, treatment charts, laboratory data, physician notes, nurse notes, discharge summary, outpatient chart, intra–hospital referral form, patient interviews and records retrieved from the medical records department. These sources provided the necessary information for conducting the study. Inpatients of all age groups who developed adverse drug reactions were included in the study. Adverse events caused by administration errors, non-compliance, test doses or overdoses were excluded from the study. Causality assessment of the reported ADRs was carried out by using the WHO causality assessment scale. The drug reactions were classified as certain, probable, possible or unlikely. The severity of reactions was assessed using the Modified Hartwig and Siegel scale as mild, moderate and severe. The type of ADR was characterized using the Wills and Brown classification as Type A, B, C, etc. After the data were collected and the assessment was completed, spontaneous reporting of ADR was performed on Vigiflow.

The collected data were used to assess the distribution patterns of ADRs according to various parameters, such as age and sex. The collected information was assessed using various supportive resources, such as pharmacology textbooks and databases such as Medscape and Lexicomp. The ADRs were collected and filled according to the "Suspected ADR Reporting Form (Indian Pharmacopoeia Commission)" version 1.4.

After the assessment of ADRs, reporting was done to the Indian Pharmacopeia Commission through Vigiflow. Incidence was calculated with the rate of new cases or events over a specified period for the population at risk for the event. The incidence is commonly the newly identified cases of an ADR. The incidence rate of ADRs being reported during the study was included. Then this data was analysed every month to see the incidence rate of ADRs happening at the hospital by using the number of new instances of the event of ADR during a specific period of time and dividing that by the total number of patients admitted to the hospital at risk during the study period.

Study duration

The study period was from January 2024 to June 2024.

Study type and site

This was a prospective, observational study conducted at a Tertiary care hospital.

Study population

The study population includes inpatients and outpatients suspected to have an ADR.

Inclusion criteria

All the inpatients admitted in the hospital for the treatment of particular condition. Patients admitted due to adverse drug reaction. Patients in Emergency experiencing ADR. ADRs in pregnancy and lactating women ADRs experienced by outpatients

Exclusion criteria

Patients admitted for accidental or intentional poisoning or overdose. Patients admitted due to drug abuse. Test dose reactions. ADRs occurring due to drug administration errors

Statistical analysis

Data was analysed using descriptive statistics and expressed in straightforward percentages.

RESULTS

Overall, 184 ADRs and 197 suspected drugs causing adverse drug reactions were identified among 178 patients and documented during the six-month study period. A total of 107 patients (60.11%) belonged to the adult age group (18–64 years), followed by 63 elderly patients (35.39%) (Table 1).

Among them, in terms of patient demographics, 103 (55.98%) were female and 81 (44.02%) were male (Figure 1). The distribution of suspected drugs according to the route of administration showed oral route in 54.31% of cases, intravenous route in 32.49%, subcutaneous route in 6.60%, topical route in 3.05%, nasal route in 2.03% and inhalation route in 1.52% (Figure 2).

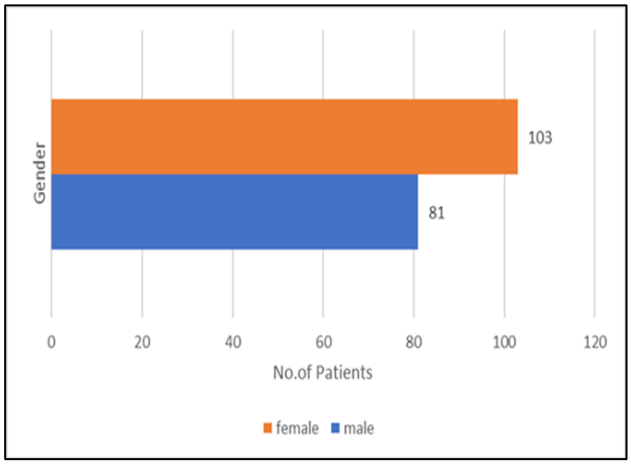

Figure 1: The gender-wise distribution of ADRs in patients.

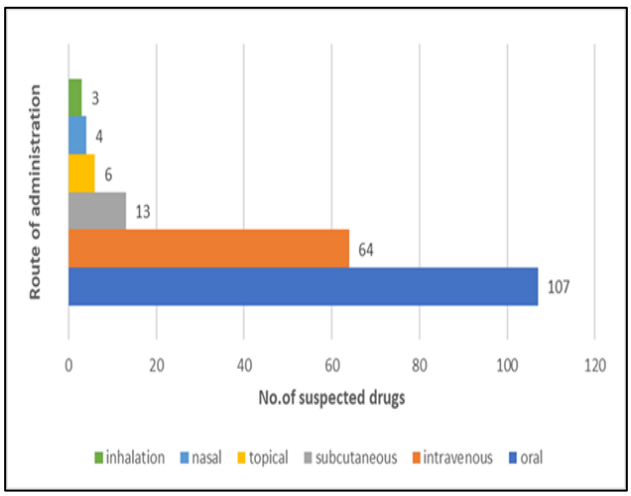

Figure 2: The distribution of suspected drug according to the route of administration.

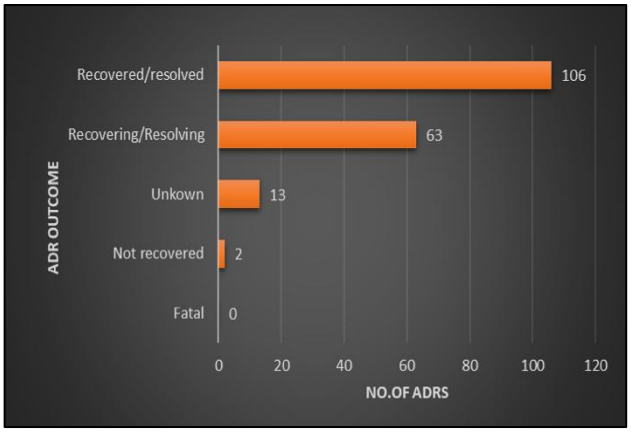

Figure 3: The Distribution of ADRs according to the outcome.

The department-wise distribution of ADRs indicated that general medicine reported 89 ADRs (48.37%), followed by critical care with 20 (10.87%), cardiology 16 (8.69%), oncology 16 (8.69%), dermatology 9 (4.89%), haematology 6 (3.26%), nephrology 6 (3.26%), rheumatology 2 (1.09%), emergency department 5 (2.71%), paediatrics, OBG and radiology with 3 ADRs each (1.63%), orthopaedics and neurology with 2 ADRs each (1.09%) and surgery, physical health and rehabilitation with 1 ADR (0.56%) (Table 2).

Adverse drug reaction

The distribution of ADRs according to the seriousness of the reaction. The majority of suspected drugs were found to have caused/prolonged hospitalization (64.67%), followed by other medically important conditions (14.67%), life-threatening reactions (8.15%) and disabling (1.63%) (Table 3). The distribution of ADRs according to the outcomes: most of the ADRs were recovered/resolved (57.60%), followed by recovering/resolving (34.23%), outcome unknown (7.06%) and not recovered/not resolved (1.08%). (Figure 3)

Assessment of adverse drug reactions

The causality assessment of ADRs was conducted using the WHO causality scale. The majority of ADRs (75%, n=138) were classified as probable and possible, followed by certain (20.10%, n=37), unlikely (4.34%, n=8) and one case as unlikely (0.54%, n=1). In terms of severity, most ADRs were moderate (n=142, 77.17%), followed by mild (n=25, 13.58%) and severe (n=17, 9.23%). According to the Wills and Brown classification, the majority of ADRs were type A (54.34%), followed by type B (42.93%), type C (2.71%) and type D (0.54%) (Table 4).

Incidence rate

A total of 19,597 patients were admitted during the study period. A total of 103 (55.98%) of ADRs were observed in females and 81 (44.02%) of ADRs were seen in males. The

incidence rates of ADRs were higher in adults 60.11%. The incidence rate of ADRs was found to be 0.93%, calculated based on 184 reported ADRs among 19,597 patients admitted during the study period. This indicates that approximately 9 to 10 out of every 1,000 patients experienced an adverse drug reaction.

Table 1: The age group-wise distribution of patients.

Age category	Age group (in years)	Male		Female		Total	% Total
		N	%	N	%		
Infant		2	1.12	2	1.12	4	2.25
Child	0-1	1	0.56	1	0.56	2	1.12
Adolescent	1-12	2	1.12	0	0	2	1.12
Adult	13-17	39	21.9	68	38.20	107	60.11
Elderly	18-64	39	21.9	24	13.48	63	35.39
Total	≥65	83	46.6	95	53.7	178	100

Table 2: The department-wise distribution of ADRs.

Department	No. of ADRs
General medicine	89 (48.37%)
Critical care	20 (10.87%)
Cardiology	16 (8.69%)
Surgery	1 (0.54%)
Oncology	16 (8.69%)
Paediatrics	3 (1.63%)
Nephrology	6 (3.26%)
Emergency department	5 (2.71%)
Orthopaedics	2 (1.09%)
OBG	3 (1.63%)
Gastroenterology	0 (0%)
ENT	0 (0%)
Haematology	6 (3.26%)
Dermatology	9 (4.89%)
Neurology	2 (1.09%)
Physical health and rehabilitation	1 (0.54%)
Radiology	3 (1.63%)
Rheumatology	2 (1.09%)
Total	184

Table 3: The distribution of ADRs according to the seriousness of the reaction.

Seriousness of the reaction	No. of male	No. of female	No. of ADRs
Yes	77 (41.84%)	87 (47.28%)	164 (88.7%)
Caused prolonged hospitalization	54 (35.32%)	65 (35.32%)	119 (64.67%)
Other medically important condition	12 (6.52%)	15 (8.15%)	27 (14.67%)
Life threatening	5 (2.71%)	10 (5.43%)	15 (8.15%)
Disabling/incapacitating	0 (0%)	3 (1.63%)	3 (1.63%)
Results in death	0 (0%)	0 (0%)	0 (0%)
Congenital anomaly	0 (0%)	0 (0%)	0 (0%)
No	8 (4.34%)	12 (6.52%)	20 (8.86%)
Total			184

Table 4: The distribution of ADRs according to causality, severity and type.

Parameters	No. of ADRs (%) n=184
Causality	
Possible	37 (20.10)
Probable	138 (75)

Continued.

Parameters	No. of ADRs (%) n=184
Certain	8 (4.34)
Unlikely	1 (0.54)
Severity	
Mild	25 (13.58)
1	9
2	16
Moderate	142 (77.17)
3	53
4a	75
4b	14
Severe	17 (9.23)
5	15
6	0
7a	2
Type of ADR	
A	100 (54.34)
B	79 (42.93)
C	5 (2.71)
D	1 (0.54)

DISCUSSION

A total of 184 ADRs were identified and reported during the six-months study period. In this study, the occurrence of ADR was more in females (55.98%) when compared to males (44.02%). This difference can be due to more female patients getting admitted and monitored.

And some studies have reported that female subjects are at higher risk of ADRs compared with men.[8] Also, the collection of ADRs from female wards was done more extensively than from male wards by the students. Paediatric and geriatric patients are more vulnerable to experiencing ADR often.

However, in this study adult patients belonging to the group of 18-64 years were reported to experience a maximum number (60.11%) of ADRs. These patients were likely to visit the hospital more often during the study period. In this hospital, the department-wise distribution of ADRs from general medicine was the most common where 89 ADRs (48.37%) were reported which was consistent with the study from Telangana.[9]

But in contrast to other studies, 10, where most of the ADRs were reported from the dermatology department. This is because of the lack of separate wards for these specialties; specialists' visits will be done in general or other wards where a patient is admitted.

Drug

In this study, 197 suspected drugs were reported and a majority 54.31% were oral route of administration. This is because the majority of drugs are administered by oral route. This is in correspondence with study.[10]

Reaction

In this study, the distribution of ADRs according to the outcomes most of the reactions were Recovered / Resolved at 57.60%, while the students did follow-ups until the patients recovered. outcome unknown (7.06%), was due to patients being discharged or moved to another ward or department. 88.76% of the reactions were serious and among them, 8.43% were life-threatening reactions. Study findings from India reported that life-threatening ADRs were 8.15% which is similar to our study findings.[10]

Assessment

In this study type A reactions accounted for 54.34% of ADRs followed by type B reactions at 42.93%. This was consistent with the study conducted in South India.[9] Type A reactions occur as the result of known pharmacological properties of the drug. Assessment of ADRs according to the WHO causality scale. Most ADRs 75% were probable followed by 20.10% of possible reactions. These findings were consistent with a study done in a tertiary care hospital conducted in Kerala for one year, where 71.42% were classified as probable and 18.3% were possible.[9] Severity assessment findings were 77.17% with moderate severity followed by Mild 13.58%. Which was not consistent with some studies.[9] The majority percentage of ADRs were Mild (53.7%) followed by moderate (35.4%) and severe (10.9%). This is because of the under-reporting of ADRs.

Incidence rate

In this study, the incidence of ADRs in the hospital was found to be 0.93%. This indicates that out of every 1,000 patients admitted, approximately 9 had an incidence of ADR. This is not consistent with some studies.[11,12] This

might be because of the lower number of admissions in a month and Under reporting of adverse drug reactions.

The study period was limited. There was underreporting of ADRs by healthcare professionals and patients. Some ADRs may take years to develop (delayed onset), making them difficult to identify within the scope of the study. Some of the data, such as expiry date and batch number, were missing due to limited access to proclaim the data. Patients on multiple medications increased the difficulty in attributing ADRs to a specific drug. Incomplete or poorly integrated electronic health records impacted the ability to track and analyze ADR data efficiently. Difficulty in obtaining follow-up information on ADR outcomes may have limited the completeness of data collection.

CONCLUSION

In conclusion, this investigation has provided a thorough need for the identification, evaluation and reporting of ADRs in healthcare settings. Emphasizing the key role of health care professionals particularly nurses, doctors and clinical pharmacists in the aspect of the medical safety of patients through quick reaction procedures and ADR linkages. The investigation draws attention to ADR reporting practices and highlights the need for a more organized approach to ADR detection and management in hospitals. Through the improvement of the communication systems and the promotion of cooperation between the health care providers, we can secure the best patient safety monitoring and enhance the treatment of patients.

Last but not least, this research stresses the significance of the establishment of a culture of autonomous data collection in medical facilities. The doctors and clinical pharmacists are as important in the cycle of ADR reporting. The technical skills and the availability of medical records from the patient's side are what make them equally necessary. The cooperation between these specialists can facilitate the ADR reporting to become more structured, hence quicker and more believable. The research restricts the designing of stringent ADR reporting protocols and a regular training schedule for all medical personnel to develop a proactive approach to pharmacovigilance.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Sreeja R, Ramaiah B, Prabhudev BR, Bangi P. Adverse drug reactions: A prospective observational study at a tertiary care hospital. Int J Basic Clin Pharmacol 2026;15:106-11.