International Journal of Basic & Clinical Pharmacology
Gurung A et al. Int J Basic Clin Pharmacol. 2025 Mar;14(2):233-240
http://www.ijbcp.com
pISSN 2319-2003 | eISSN 2279-0780

DOI: https://dx.doi.org/10.18203/2319-2003.ijbcp20250483

Original Research Article

A prospective study on identification, assessment, and spontaneous reporting of adverse drug reactions at a tertiary care hospital

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Received: 24 December 2024
Revised: 18 January 2025
Accepted: 20 January 2025

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ABSTRACT

Background: Adverse drug reactions (ADRs) significantly contribute to global morbidity and mortality. Voluntary ADR reporting is crucial for the Pharmacovigilance Programme of India (PvPi), which identifies and quantifies medication risks. This study monitors ADRs from various departments of a tertiary care hospital, assessing them for causality, preventability, and severity before reporting to the Indian Pharmacopoeia Commission (IPC).
Methods: This prospective study was conducted over six months at a tertiary care hospital, which is an approved ADR Monitoring Centre (AMC). Data was collected by PharmD students, who assessed each ADR for causality, severity, and preventability using the World Health Organization (WHO) scale, Hartwig's severity scale, and Schumock and Thornton scales. Descriptive statistics were used for analysis.
Results: A total of 358 suspected ADRs were evaluated. Most reactions (87.98%) were classified as "moderate" in severity, with 45.53% considered not preventable. The majority of ADRs were categorized as probable (84.07%), with Class J drugs (Anti-infectives) being the most associated (29.89%). Most reports came from General Medicine (53.35%), and the primary affected organ systems were metabolic and nutritional (21%).
Conclusions: Most ADRs in this study were caused by antimicrobials, highlighting the need for careful prescribing and patient monitoring. Type A ADRs were often underreported, with healthcare professionals focusing primarily on Type B and H reactions. This study emphasizes the importance of voluntary ADR reporting and the vital role of clinical pharmacists in assessing and documenting these reactions.

Keywords: Adverse drug reaction, Pharmacovigilance, Causality assessment, Modified hartwig and seigel severity assessment scale

INTRODUCTION

Any undesirable effect of a drug that develops during its clinical use ahead of its anticipated therapeutics is known as an adverse drug reaction (ADR). The 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 physiologic function."[1] Therefore, drug abuse, treatment failure, accidental or intentional overdoses, and errors in drug administration are not included in this definition.[2] "Drugs are Double-Edged Weapons" even though drugs are the most common medical intervention used for relieving suffering, they can also be fatal.[3] As appropriately cited by Peter Mere Latham an English physician and educator – "Poisons and medicine are often times the same substance given with different intents".

According to recent epidemiological studies, ADRs are estimated to be the fourth to sixth leading cause of mortality.[4] ADRs can negatively affect patient health and healthcare costs by increasing mortality and morbidity in both hospitalized and outpatient patients.[3] "The impact of ADRs includes increased hospitalizations, higher mortality rates, reduced quality of life, and a greater financial burden on health management."[4] The reported incidence of adverse drug reactions in India ranges from 3.7% to 32.7%.[5]

Pharmacovigilance is a crucial aspect of drug therapy, but it is not widely implemented in Indian hospitals. Reports on ADR monitoring in India have been limited. This may be due to the country's ongoing evolution of ADR monitoring practices. The WHO defines pharmacovigilance as the science and activities concerned with the detection, assessment, understanding, management and prevention of adverse effects or any other medication/vaccine-related problems. Under the authority of the Ministry of Health & Family Welfare, the Indian government introduced the PvPI in July 2010 with the overarching goal of guaranteeing patient safety for more than one billion people in India.[6] Promoting the safest use of medications by supporting proper pharmacovigilance education and training initiatives nationwide is one of PvPI's main goals.[7]

Despite the significant concern that adverse drug reactions (ADRs) pose to the public, medical professionals, the pharmaceutical industry, and regulatory bodies, the practice of monitoring and reporting ADRs is still in its early stages in India. Awareness and effective systems for ADR monitoring are essential to ensure drug safety and public health, highlighting the need for further development in this area.[3] Despite accounting for around 10% of the world's medication consumption, India is a developing nation with a sizable drug-using population, yet just 2% of all medication adverse drug reactions are reported there. The primary cause of this is India's inadequate ADR reporting.[8] Despite their frequent occurrence, ADRs are frequently overlooked. ADRs as many medical practitioners are not aware that they must notify the PvPI or AMC of all ADRs.[9] Health professionals are essential in reporting adverse drug reactions (ADRs) globally because they assist in identifying significant and uncommon ADRs that were previously unidentified.

This study is therefore being carried out to raise awareness among healthcare practitioners regarding the early detection, prevention, and spontaneous reporting of adverse medication reactions, so that the morbidity, mortality, and medical expenses related to ADRs will sharply decline. Additionally, this research attempts to highlight the involvement and functions of pharmacists in India's national pharmacovigilance initiatives.

METHODS

This observational study collected ADRs from various departments of Bangalore Baptist Hospital over six months, from March 2023 to August 2023. It employed both active methods, where pharmacists actively searched for suspected ADRs, and passive methods, encouraging prescribers to report them.

Data collection began with demographic details such as age, sex, admission date, and treatment onset, followed by patient diagnosis, medical and medication history, reason for admission, and patient status at the time of ADR reporting. Laboratory data supporting the ADR's occurrence were also gathered. Additionally, information on how the ADR was managed, including any treatment modifications or discontinuations, was recorded.

The suspected drug data included administration date, strength, route, frequency, indication, discontinuation date, batch number, manufacturer, and expiry date. ADRs were then assessed for probability using the WHO scale, classified as certain, probable, possible, unlikely, or unclassified. Preventability was evaluated with the modified Schumock and Thornton scale, categorizing as definitely, probably, or not preventable.

Finally, severity was noted using the modified Hartwig and Siegel scale, grading reactions as mild, moderate, or severe based on treatment changes, hospital stay duration, and associated disability. ADR types were classified using the Wills and Brown classification.[10,11] Once the data was collected and the assessment was completed, spontaneous reporting of ADRs was carried out using the "Suspected ADR Reporting Form (Indian Pharmacopoeia Commission)" version 1.3 on Vigiflow. All individual case safety reports (ICSRs) were submitted to the IPC monthly.

Inclusion criteria

All inpatients admitted to the hospital for the treatment of a specific condition were included. This encompasses patients admitted specifically due to ADRs as well as those in the emergency department experiencing such reactions. Additionally, ADRs occurring in pregnant and lactating women, as well as outpatients triggered by both prescribed medications and over-the-counter drugs, were included.

Exclusion criteria

ADRs occurring due to alternative systems of medicines such as Ayurveda, Homeopathy, Unani, etc. as well as patients admitted for accidental or intentional poisoning or overdose were not recorded. All test dose reactions and ADRs occurring due to administration errors were also excluded.

Statistical analysis

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

RESULTS

During a six-month study on ADRs, it was found that 54.46% of these reactions occurred in adults aged 18 to 64 years, while 37.98% were reported in elderly patients aged 65 years and older.

Furthermore, the distribution of ADRs by gender showed that there were 183 incidents in male patients and 175 incidents in female patients, indicating a male predominance (Table 1).

Of the total 358 ADRs reported, 46.64% occurred in outpatients, while 53.35% occurred in inpatients. Most ADRs were reported from the general medicine department, accounting for 191 ADRs (53.35%). This was followed by the critical care department with 38 ADRs (10.61%) and the cardiology department with 24 ADRs (6.70%) (Table 2).

The oral route of administration was responsible for the majority of ADRs, constituting 64.67% of the cases. In 81.25% of the reported ADRs, the suspected drugs were withdrawn, while no changes in dosage were made for 8.15% of the cases.

According to the anatomical therapeutic chemical (ATC) classification, the anatomical class of medications most often associated with ADRs was the anti-infective system (J), which had 110 cases (29.89%). This category was followed by the alimentary tract and metabolism (A) with 70 cases (19.02%) and the cardiovascular system (C) with 59 cases (16.02%). Within the anti-infective category, the most common drugs causing ADRs were antibacterials (J01) with 71 cases (18.29%) and antimycobacterial agents (J04) with 31 cases (7.98%) (Table 3).

Table 1: Age and gender-wise distribution of ADRs.

Age group	Age range (in years)	No. of ADRs N (%)		
		Male	Female	Total
Infant	0-1	1	0	1 (0.279)
Child	1-12	8	7	15 (4.189)
Adolescent	13-17	6	5	11 (3.072)
Adult	18-64	100	95	195 (54.469)
Elderly	≥65	68	68	136 (37.988)
Total		183	175	358

Table 2: Department-wise distribution of ADRs.

Department	No. of ADR's N (%)
General medicine	191 (53.35)
Critical care	38 (10.61)
Cardiology	24 (6.70)
Surgery	22 (6.14)
Oncology	22 (6.14)
Paediatrics	17 (4.74)
Nephrology	11 (3.07)
Emergency department	6 (1.67)
Orthopedics	6 (1.67)
OBG	5 (1.39)
Gastroenterology	4 (1.11)
ENT	3 (0.83)
Hematology	3 (0.83)
Dermatology	2 (0.55)
Neurology	1 (0.27)
Physical health and rehablitation	1 (0.27)
Radiology	1 (0.27)
Rheumatology	1 (0.27)
Total	358

Table 3: Distribution of ADRs according to therapeutic classification of drugs.

Anatomical class (code) (number of ADRs, %)	Therapeutic class (code)	No. of ADRs
Alimentary tract and metabolism (A) (70, 19.021)	Drugs for acid related disorder (A02)	6
	Drugs for functional gastrointestinal disorders A03)	7
	Antiemetics and antinauseants (A04)	8
	Bile and liver therapy (A05)	1
	Drugs for constipation (A06)	5
	Drugs used in diabetes (A10)	40
	Vitamins (A11)	1
	Mineral supplements (A12)	1
	Other alimentary tract and metabolism products (a16)	1
Blood and blood-forming agents (B) (24, 6.52)	Antithrombotic agents (B01)	20
	Antihemorrhagics (B02)	1
	Antianemic preparations (B03)	3
Cardiovascular system (C) (59, 16.03)	Cardiac therapy (C01)	1
	Antihypertensives (C02)	1
	Diuretics (C03)	28
	Vasoprotectives (C05)	10
	Beta blocking agents (C07)	9
	Calcium channel blockers (C08)	7
	Agents acting on the renin-angiotensin system (C09)	9
	Lipid modifying agents (C10)	1
Dermatologicals (D) (6, 1.63)	Antifungals for dermatological use (D01)	1
	Antipsoriatics (D05)	1
	Corticosteroids, dermatological preparations (D07)	3
	Antiseptics and disinfectants	1
Genito-urinary system and sex hormones (G) (4, 1.086)	Other gynecologicals (G02)	1
	Sex hormones and modulators of the genital system (G03)	1
	Urologicals (G04)	2
Systemic hormonal preparations, excluding sex hormones and insulins (H) (16, 4.347)	Corticosteroids for systemic use (H02)	14
	Thyroid therapy (H03)	2
Anti-infective systemic use (J) (110, 29.89)	Antibacterial for systemic use (J01)	71
	Antimycotics for systemic use (J02)	3
	Antimycobacterials (J04)	31
	Antiviral for systemic use (J05)	3
	Immune sera and immunoglobulins (J06)	2
Antineoplastic and immunomodulating agents(L) (17, 4.61)	Antineoplastic agents (L01)	15
	Immunosuppressants (L04)	2
Musculoskeletal system (M) (22, 5.97)	Anti-inflammatory and antirheumatic products (M01)	19
	Muscle relaxants (M03)	1
	Drugs for treatment of bone diseases (M05)	2
Nervous system (N) (33, 8.96)	Analgesics (N02)	16
	Antiepileptics (N03)	7
	Anti-Parkinson drugs (N04)	4
	Psycholeptics (N05)	5
	Psychoanaleptics (N06)	1
Antiparasitic products, insecticides and repellents (P) (1, 0.27)	Antiprotozoals (P01)	1
Respiratory system (R) (3, 0.81)	Drugs for obstructive airway disease (R03)	2
	Cough and cold preparations (R05)	1

Continued.

Anatomical class (code) (number of ADRs, %)	Therapeutic class (code)	No. of ADRs
Sensory organs (S) (1, 0.27)	Opthalmologicals (S01)	1
Various (V) (2, 0.54)	All other therapeutic products (V03)	1
	Contrast media (V08)	1

A greater number of ADRs were resolved (n=164), with only one case leading to a fatal outcome. Twenty different organ systems were affected, with the most impacted being metabolism and nutritional disorders (21%), followed by gastrointestinal disorders (19%) and skin and subcutaneous tissue disorders (18%).

The most frequently identified ADRs were hypoglycaemia (n=25) and hyponatremia (n=20), followed by vomiting (n=18) and hypokalaemia (n=15). (Table 4) According to the WHO causality scale, most ADRs 84.07%, were classified as probable, followed by 11.17% as possible, 4.46% as certain, and only 0.27% as unlikely.

When assessing the severity of ADRs using the modified Hartwig and Siegel scale, it was found that most reactions were moderate in severity, accounting for 87.98% (with levels classified as follows: level 3=79, 4a=147, 4b=89). Mild reactions constituted 9.77% (with level 1=2 and level 2=33), while severe reactions made up 2.23% (with level 5=6, level 6=1, and level 7a=1; no level 7b reactions were reported).

Using the modified Schumock and Thornton preventability scale, it was determined that 45.53% of ADRs were not preventable, while only 9.77% were classified as preventable. Additionally, when classifying ADRs according to Wills and Browns' classification, it was observed that most reactions were of type A, accounting for 40.78% (n=146), followed by type B at 19.27% (n=69), with only 2 type E reactions observed, representing 0.55%. (Table 5).

Table 4: Organ system affected by ADRs.

Organ system affected by the ADR	N (%)
Metabolism and nutrition disorders	76 (21)
Hypoglycaemia	25
Hyperglycaemia	6
Hypokalaemia	15
Hyperkalaemia	10
Hyponatremia	20
Gastrointestinal disorders	67 (19)
Diarrhoea	8
Constipation	2
Vomiting	18
Skin and subcutaneous tissue disorders	64 (18)
Steven-Johnsons syndrome	3
Urticaria	2
DRESS syndrome	3
Blood and lymphatic system disorders	25 (7)
Neutropenia	3
Thrombocytopenia	9
Coagulopathy	2
Pancytopenia	4
General disorders and administration site conditions	19 (5)
Swelling	8
Pedal oedema	2
Nervous system disorders	18 (5)
Headache	2
Syncope	2
Seizure	1
Hepatobiliary disorders	13 (4)
Drug induced hepatitis	8
Respiratory, thoracic, and mediastinal disorders	12 (3)
Dyspnoea	3

Continued.

Organ system affected by the ADR	N (%)
Haemoptysis	2
Cardiac disorders	11 (3)
Hypotension	5
Bradycardia	5
Immune system disorders	9 (3)
Infections and infestations	8 (2)
Vascular disorders	8 (2)
Eye disorders	6 (2)
Renal and urinary disorders	6 (2)
Acute kidney injury	1
Musculoskeletal and connective tissue disorder	5 (1)
Endocrine disorders	3 (1)
Psychiatric disorders	3 (1)
Investigations	2 (1)
Injury, poisoning and procedural complications	2 (1)
Reproductive system and breast disorders	1 (1)
Total	358

Table 5: Distribution of ADRs according to causality, severity, preventability and type.

Parameters	No. of ADRS (%) n=358
Causality	
Possible	40 (11.17)
Probable	301 (84.07)
Certain	16 (4.46)
Unlikely	1 (0.27)
Severity	
Mild	35 (9.77)
1	2
2	33
Moderate	315 (87.98)
3	79
4a	147
4b	89
severe	8 (2.23)
5	6
6	1
7a	1
Preventability	
Not preventable	163 (45.53)
Preventable	35 (9.77)
Probably preventable	160 (44.69)
Type of ADR	
A	146 (40.78)
B	69 (19.27)
C	37 (10.33)
D	61 (17.03)
E	2 (0.55)
H	43 (12.01)

DISCUSSION

ADRs are a significant health concern, as they can lead to mortality and morbidity while also increasing healthcare costs. Therefore, it is crucial to identify and prevent ADRs by effectively monitoring patients in any healthcare setting.

The demographic details of this study showed male gender predominance over females, which was similar to that of other studies conducted at Madhya Pradesh, Kerela, Ahmedabad and Puducherry.[3,5,12,13] Paediatric and geriatric patients are vulnerable to experiencing ADRs more often. However, in this study adult patients belonging to age

group of 18–64 years were reported to experience maximum number (53.98%) of ADRs. It could be likely due to the reason that a greater number of patients from this population is attending the hospital and are getting admitted for treatment and, also because this is the largest group according to the age group wise distribution of patients. Other studies conducted by Arulmani et al and Lihite et al, have documented similar findings.[6,14]

In this hospital, most of the ADRs were reported from general medicine department 53.35% which was in agreement with studies from Kerela and Chennai.[3,9] But in contrary to these other studies conducted in Guwahati, Puducherry, Chennai and Ooty revealed that most of the ADRs were reported from dermatology department.[5,6,9] From 368 suspected drugs majority (81.25%) of the drugs were withdrawn for the management of ADR and most of the ADRs were associated with oral use (64.67%) of drugs which was consistence with earlier documented reports.[6,13,14] Most of the reactions had recovered/ resolved 45.81% while reporting which was consistent with studies reported in the literature.[3,6,9,14] 17.44% of the outcomes were unknown because of the poor follow-up by the students after the patient had been shifted to another ward or discharged.

According to the anatomic therapeutic classification of drugs, class J drugs (Anti-infective systemic use) caused majority of the ADRs (29.89%) (n=110), antibacterial for systemic use (J01) caused ADRs in 71 patients, antimycotics for systemic use (J02) (n=3), antimycobacterial (J04) (n=31), Antiviral for systemic use (J05) (n=3), the result was similar to most of the studies done in India.[5,6,12,14] The reason being that anti-infectives are the most commonly prescribed drugs for the treatment and prophylaxis of various infections, these findings also highlight the need of a well-established antibiotic stewardship programs at hospitals in India. The most affected organ system were Metabolism and nutrition disorders (21%) followed by gastrointestinal disorder (19%) and skin and subcutaneous disorders (18%). The results were partially comparable with the study reported from Sanjay Gandhi Memorial Hospital, Rewa, Madhya Pradesh which revealed that gastrointestinal disorder accounted for 10% of the ADRs.[12]

Metabolism and nutrition disorders was the most common organ system affected in this study, this is because the analysis of the parameters like blood glucose levels, serum electrolyte concentrations, etc could be easily assessed by the pharm D students, due to which most of the ADRs identified belongs to this system. Hypoglycaemia (n=25) and hyponatremia (n=20) were the most identified ADRs followed. Our study findings were not in agreement with studies based in Northeast India, and South Indian studies where the skin was the most affected organ this may be due to the underreporting of ADRs from the dermatology department in our hospital.[5,6,14]

Type A reactions accounted for 40.78% of ADRs and followed by a type B reaction of 19.27%. These findings were in agreement with other study reports from South India where type A reactions were commonly observed.[3,5] Causality assessment of ADRs as per WHO scale reveals the majority of the ADRs, belong to probable (84.07%) followed by possible (11.17%) and certain (4.46%). These findings are in correspondence to multiple studies carried out using WHO scale.[12,15]

Studies conducted by Arulmani et al, Shamna et al, James et al, where Naranjo scale is used for causality assessment also has similar findings to this study.[3,9,14] As per severity, 87.98% of ADRs were moderate followed by mild 9.77% and only 2.23% of ADRs were found to be severe. Study findings of severity assessment using the Hartwig and Siegel scale from Madhya Pradesh, Kerela and Gujarat also revealed that most of the ADRs were moderate in severity.[3,12,15,16] The preventability assessment using the modified Schumock and Thornton scale revealed that most of the ADRs (44.69%) were probably preventable (45.53%) of the ADRs were not preventable, while (9.77%) were definitely preventable. Which was less in comparison to the study conducted in Travancore Medical College, where most of the ADRs (81.7%) were not preventable.[11]

The main limitation of this study was the short study duration and the lack of knowledge about ADRs and PV among healthcare professionals. This lack of understanding contributed to the underreporting of ADRs, particularly in certain wards. Hence, it is crucial to establish a structured system for reporting ADRs in a hospital to ensure that no ADRs are overlooked.

CONCLUSION

ADR is a significant limitation to the success of therapeutics, not only does it increase the healthcare cost it also diminishes the trust that patients have towards healthcare providers. Underreporting of ADRs is a major problem in India, even though it is one of the major consumers of pharmaceuticals, its contribution towards the world database is greatly lacking. In conclusion, it was seen that adults and geriatric patients were most affected by ADRs with male predominance.

Most of the reactions were Type A reactions, and the organ system affected was the metabolism and nutrition disorder the inconsistency of our findings with other studies suggests that Type A reactions and ADRs without physical signs were mostly ignored and underreported as mostly Type B and H reactions and dermal reactions were reported. Antimicrobials were the major class of drug-causing ADRs which depicts the irrational use of these agents and along with this also calls attention to the establishment of antibiotic stewardship programs in hospitals. Hence, this study highlights the role of well-trained pharmacists in the prevention, early identification, reporting, and documenting of ADRs.

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: Gurung A, Ramaiah B. A prospective study on identification, assessment, and spontaneous reporting of adverse drug reactions at a tertiary care hospital. Int J Basic Clin Pharmacol 2025;14:233-40.