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Original Research Article

Assessment of triggering tools and risk factors of adverse drug reactions at a tertiary care hospital

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ABSTRACT

Background: Adverse drug reactions are a significant cause of morbidity, mortality, and healthcare burden, making their identification, reporting, and prevention critical. This study aimed to assess the incidence, risk factors, causality, severity, and preventability of adverse drug reactions in a tertiary care hospital using standardized pharmacovigilance tools.
Methods: A prospective observational study was conducted among inpatients across multiple departments. Data were analyzed using the World Health Organization-Uppsala Monitoring Centre causality scale, Hartwig's severity scale, and the Thornton and Schumock preventability scale. Clinical grading was performed using the common terminology criteria for adverse events version 5.0 to determine associations between risk factors and adverse outcomes.
Results: A total of 258 adverse drug reactions were identified from 313 suspected drugs. Adults comprised 57.7% of cases and elderly patients 37.2%, with females accounting for 51.9%. Antibiotics were the leading cause at 25.5%. Analysis showed that 88.3% of reactions were serious, with 62.01% requiring hospitalization or extended stay. Clinical recovery was observed in 86% of patients. Causality assessment classified 77.5% of reactions as probable. Approximately 55.03% of events were probably and definitely preventable, primarily linked to errors in dosing or administration. Polypharmacy and multiple comorbidities were identified as the primary risk factors for serious outcomes.
Conclusions: Adverse drug reactions are frequent among adults and the elderly, with antimicrobials most commonly implicated. The high proportion of serious events emphasizes the need for rational prescribing, continuous monitoring, and active pharmacovigilance to enhance patient safety.

Keywords: Adverse drug reactions, Causality assessment, Pharmacovigilance, Triggering tools

INTRODUCTION

Adverse drug reactions (ADRs) represent a significant challenge in healthcare, contributing to increased morbidity, mortality, and healthcare costs. ADRs are defined as noxious and unintended responses to medications occurring at normal therapeutic doses used for the prevention, diagnosis, or treatment of diseases. Evaluating the preventability of ADRs is a crucial aspect of pharmacovigilance because it helps determine whether an ADR could have been avoided through appropriate prescribing, monitoring, or patient management strategies.[1]

Assessment of ADRs requires causality evaluation to determine the relationship between drug exposure and

clinical outcomes. Various methods, including global introspection and standardized scales, are commonly used in clinical practice.[2] Recently, trigger tools have been adopted to detect adverse drug events by identifying indicators such as abnormal laboratory values, use of antidotes, or sudden drug discontinuation.[3] Studies also show that antibiotics are frequently implicated in ADRs in tertiary care settings, highlighting the need for focused pharmacist monitoring and intervention.[4]

Adverse drug reactions are a major cause of hospital admissions and prolonged stays, highlighting the importance of early detection and effective monitoring. Medication safety has largely depended on spontaneous reporting by healthcare professionals, which, although vital for post-marketing surveillance, is limited by underreporting and inconsistency, necessitating more proactive approaches. Hospital-based studies show that while spontaneous reporting is useful in identifying ADRs in tertiary care settings, particularly with antibiotics, but inconsistencies emphasize the need for improved awareness and structured pharmacovigilance systems.[4,10]

The occurrence of ADRs is influenced by several patient-related and treatment-related factors. Age is an important determinant, with elderly patients being more vulnerable due to polypharmacy, multiple comorbidities, and altered drug metabolism.[5] Beyond traditional demographics, recent global health crises such as the COVID-19 pandemic have highlighted the need to assess ADR risk factors in acutely ill patients on experimental or multi-drug therapies, with trigger tools providing important pharmacovigilance insights often missed by traditional methods.[6] Data from pharmacovigilance systems have helped identify additional risk factors for ADRs, including drug interactions and underlying medical conditions.[7]

Standardized systems such as the common terminology criteria for adverse events (CTCAE) have enhanced consistency in toxicity assessment and ADR reporting, enabling accurate documentation and timely clinical interventions.[8] However, gaps persist in the systematic identification and prevention of ADRs in routine practice, highlighting the need for comprehensive evaluation of ADR patterns, risk factors, and preventability to shift from reactive to proactive management in tertiary care settings.[1] To strengthen ADR detection and global signal monitoring, this study employs VigiFlow, an electronic system developed by the Uppsala Monitoring Centre (UMC), for standardized collection and processing of Individual Case Safety Reports (ICSRs) in line with international pharmacovigilance standards.[9]

The present study evaluated ADRs in a tertiary care setting using structured pharmacovigilance methods, including trigger tools and CTCAE classification, and assesses associated risk factors. It also analyzed demographic and clinical characteristics, along with causality (WHO scale), severity, and preventability of ADRs. All identified ADRs were reported to the Pharmacovigilance Programme of India (PvPI) via the VigiFlow system.

METHODS

A prospective observational study was conducted from January to July 2025 at Bangalore Baptist Hospital to identify, assess, and report ADRs as part of routine pharmacovigilance activities. ADR data were actively collected during ward rounds, review of outpatient records, and discussions with healthcare professionals. Information was obtained from case sheets, medication charts, laboratory reports, physician and nursing notes, discharge summaries, referral documents, and interviews with patients or caregivers.

The study included inpatients and outpatients from all departments, except oncology and dermatology, who were suspected to have ADRs. This also included patients presenting to the emergency department, those admitted due to ADRs, and pregnant or lactating women with ADRs. Patients with non-drug-related conditions, incomplete records, test dose reactions, intentional poisoning or overdose, chemotherapy-related ADRs, dermatology referrals, and those who did not give consent were excluded.

Demographic details and relevant clinical information such as diagnosis, medication history, onset and outcome of the reaction, and laboratory findings were documented along with details of the suspected drug including dose, route, indication, and management of the reaction.

All suspected ADRs were recorded using the suspected adverse drug reaction reporting form issued by the Indian Pharmacopoeia Commission. Causality was evaluated using the WHO-Uppsala Monitoring Centre scale, while severity and preventability were assessed using the modified Hartwig and Siegel scale and the modified Schumock and Thornton scale, respectively. ADRs were also categorized based on the affected organ system and seriousness using the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0. Validated ADRs were reported to the Pharmacovigilance Programme of India through the VigiFlow system. The collected data were analyzed descriptively to determine the distribution and pattern of ADRs according to demographic factors, drug classes, organ systems, severity, preventability, and risk factors, with results expressed as frequencies and percentages.

Statistical analysis

Data were analysed using descriptive statistics and expressed as percentages. Associations between demographic and clinical characteristics and ADRs were evaluated using the Chi-square test or Fisher's exact test. A p value of <0.05 was considered as statistically significant. A p value of <0.05 was considered as statistically significant.

RESULTS

A total of 258 adverse drug reactions were documented during the study period, involving 313 suspected drugs that resulted in 319 individual reactions, indicating that multiple drugs and reactions were implicated in several cases. Demographic analysis revealed that adults aged 18-64 years accounted for the highest proportion of ADRs (57.75%), followed by the elderly population, while pediatric and adolescent age groups contributed minimally as shown in Table 1. Females (51.9%) experienced slightly more ADRs than males.

An analysis of the therapeutic classification of the 313 drugs studied revealed that antibiotics were the most frequently implicated class, accounting for 25.05% of the total. This was followed by cardiovascular agents, anti-tubercular drugs, NSAIDs, antidiabetics, and analgesics. The remaining medications were grouped into a miscellaneous others category, which collectively represented 26.19% as illustrated in Figure 1. Department-wise distribution of 258 ADRs, with the highest proportion reported from general medicine (60.08%), followed by cardiology (8.53%) and surgical departments (6.20%). Moderate contributions were seen from OBG, geriatric medicine, nephrology and pediatrics as shown in Table 2.

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

Age groups	Age range (years)	No. of ADRs (N)			Percentage
		Male	Female	Total	
Infant	0-1	0	1	1	0.39
Child	1-12	8	2	10	3.88
Adolescent	13-17	1	1	2	0.78
Adult	18-64	69	80	149	57.75
Elderly	≥65	46	50	96	37.21
Total		124	134	258	

Table 2: Department-wise distribution of ADRs.

Departments	No. of ADRs (N)	Percentage
General medicine	155	60.08
Cardiology	22	8.53
Surgical	16	6.20
OBG	13	5.04
Geriatric medicine	12	4.65
Nephrology	7	2.71
Paediatrics	7	2.71
physical medicine and rehabilitation	5	1.94
neureology	4	1.55
plastic surgery	4	1.55
urology	4	1.55
emergency medicine	2	0.78
ent	2	0.78
Orthopedics	2	0.78
Endocrinology	1	0.39
Hematology	1	0.39
RMU	1	0.39
Total	258	

Among the 258 reported ADRs, 228 (88.3%) were classified as serious, most commonly resulting in or prolonging hospitalization, followed by other medically important conditions and life-threatening reactions, with no cases of death or congenital anomalies as depicted in Table 3. Analysis of patient outcomes revealed that the vast majority achieved recovery or resolution (86.05%). As illustrated in Figure 2, the remaining cases were classified as recovering (8.14%), unknown (2.33%), not recovered (1.94%), or fatal (1.55%).

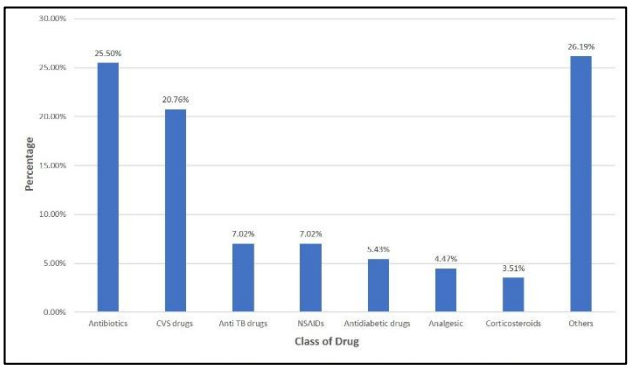

Figure 1: Therapeutic classification of drugs implicated.

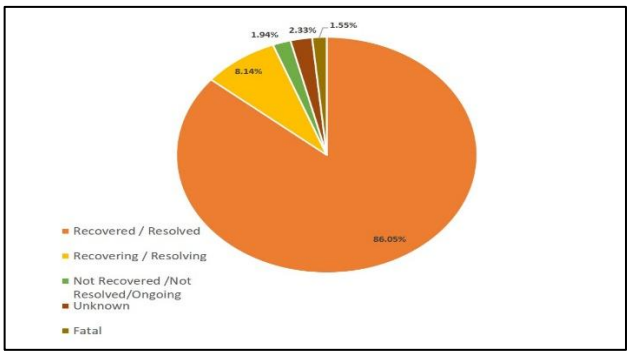

Figure 2: Distribution of ADRs based on outcome.

Table 3: Distribution of ADRs based on seriousness of the reaction.

Seriousness of the reaction	No. of ADRs, (%)
Yes	228 (88.3)
Caused/prolonged hospitalization	160
Other medically important condition	53
Disabling/incapacitating	1
Life threatening	14
Results in death	0
Congenital anomaly/birth defect	0
No	30 (11.6)
Total	258

Causality assessment using the WHO-UMC scale revealed that the majority of ADRs were categorized as probable (77.5%), followed by certain (12%) and possible associations. Regarding clinical impact, the Hartwig severity assessment scale indicated that most reactions were mild (63.18%) or moderate (31.78%), with very few classified as severe. Furthermore, preventability analysis via the Schumock and Thornton scale showed that 45% of ADRs were not preventable, while 33% were preventable and a small proportion were probably preventable, as shown in Table 4.

Risk factor analysis showed no significant association between gender and ADR severity (p=0.67), and none of the individual drug classes demonstrated significant differences between non-serious and serious ADRs (all p>0.05), although antibiotics were most frequently implicated (65 minor, 9 serious). The number of suspected drugs was highly significant (p=0.00072), with polypharmacy (>2 drugs) increasing the risk of serious ADRs. While major diagnoses were not significantly associated (p=0.075) and comorbidities (p=0.061) showed near-significant trends, whereas maternity status had no association (p=0.7577) as presented in Table 5.

Table 4: Distribution of ADRs according to causality, severity, preventability assessment.

Parameters	No. of ADRs, (%)
Causality (WHO causality assessment scale)	
Certain	31 (12.01)
Probable	200 (77.5)
Possible	27 (10.4)
Unlikely	0
Unclassified	0
Unclassifiable	0
Total	258
Severity (Hartwig severity assessment scale)	
Mild	163 (63.17)
Level-1	11
Level-2	152
Moderate	82 (31.78)
Level-3	76
Level-4	6
Severe	13 (5.03)
Level-5	12
Level-6	1
Level-7	0
Total	258
Preventability (Schumock and Thornton scale)	
Not preventable	116 (44.96)
Definitely preventable	85 (32.94)
Probably preventable	57 (22.09)
Total	258

Table 5: Risk factor assessment and clinical determinants of ADR severity based on CTCAE grading.

Characteristics	ADRs belong to grade 1, 2 from CTCAE (n=218) non-serious ADRs	ADRs belong to ≥ grade 3 from CTCAE (n=40) Serious ADRs	P value
Gender			
Male	106	18	0.67*
Female	112	22	
Age			
Infant (0-1 year)	1	0	
Child (1-12 years)	10	0	
Adolescent (13-17 years)	2	0	
Adult (18-64 years)	126	23	
Elderly (>65 years)	79	17	
Suspected drugs			
Antibiotics	65	09	0.343*
NSAIDs	22	07	0.283
Anti tubercular Drugs	05	03	0.125
Anti coagulants	22	04	1.000
Anti diabetic drugs	13	02	1.000

Continued.

Characteristics	ADRs belong to grade 1, 2 from CTCAE (n=218) non-serious ADRs	ADRs belong to ≥ grade 3 from CTCAE (n=40) Serious ADRs	P value
Antihypertensives	10	00	0.375
Corticosteroids	08	03	0.395
Diuretics	14	01	0.478
Others	62	14	0.680*
Number of suspected drugs			0.00072*
≤2	214	35	
>2	4	5	
Major diagnosis			
Cardiovascular diseases	24	03	0.778
Respiratory diseases	39	07	1.000*
Infection	22	04	1.000
Endocrinologic diseases	17	01	0.323
Gastrointestinal disease	27	02	0.274
Others	89	23	0.075*
Risk factors			
Comorbidities (accompanied diseases) (n=258)			0.0610*
0	43	1	
1	33	4	
2	31	8	
3	48	12	
>4	63	15	
Maternity status (n=134)			0.7577*
Pregnant	7	1	
Non pregnant	105	21	

*By Chi Square test.

Table 6: Number of ADRs based on organ system according to the CTCAE v5.0.

Organ system according to the CTCAE v5.0	No. of ADRs	Percentage
Skin and subcutaneous tissue disorders	100	31.34
Metabolism and nutrition disorders	40	12.53
Gastrointestinal disorders	34	10.66
General disorders and administration site conditions	31	9.72
Nervous system disorders	16	5.02
Vascular disorders	16	5.02
Respiratory, thoracic and mediastinal disorders	16	5.02
Blood and lymphatic system disorders	13	4.08
Renal and urinary disorders	10	3.13
Cardiac disorders	9	2.82
Immune system disorders	8	2.51
Hepatobiliary disorders	5	1.57
Investigations	5	1.57
Endocrine disorders	4	1.25
Infections and infestations	4	1.25
Musculoskeletal and connective tissue disorders	3	0.94
Reproductive system and breast disorders	2	0.63
Eye disorders	1	0.31
Injury, poisoning and procedural complications	1	0.31
Psychiatric disorders	1	0.31
Total reactions	319	

Using the CTCAE v5.0 scale, 319 ADRs were identified across various organ systems. The majority of ADRs affected the skin and subcutaneous tissue (31.34%), predominantly presenting as rash and pruritus. Metabolism and nutrition disorders (12.53%) were mainly attributed to hypo-/hyperglycemia and electrolyte imbalances, while gastrointestinal disorders commonly included diarrhoea, vomiting, and gastritis. General disorders, along with nervous, respiratory, and vascular system disorders, were also observed. Fewer cases involved the blood and lymphatic, renal, and cardiac systems as summarized in Table 6.

DISCUSSION

Adverse drug reactions remain a significant cause of patient morbidity and prolonged hospital stays in tertiary care environments. While spontaneous reporting is a standard monitoring method, its effectiveness is often limited by high rates of under-reporting and data inconsistencies. The present study evaluated ADRs and associated risk factors in a tertiary care hospital using pharmacovigilance tools, identifying a total of 258 ADRs involving 313 suspected drugs, indicating that ADRs remain a significant clinical concern among hospitalized patients. The findings are consistent with previous pharmacovigilance studies, which have reported that ADRs contribute notably to patient morbidity and increased healthcare burden.[10] The occurrence of multiple ADRs associated with several drugs in this study further emphasizes the complexity of drug therapy in clinical practice.

Demographic analysis in this study revealed that adults (57.75%) and the elderly were the most frequently affected groups, with a marginal predominance in female patients (51.9%) over males (48.1%). These findings align with existing literature, which consistently identifies adult and geriatric populations as having the highest ADR burden.[12] The observed gender disparity is widely attributed to distinct physiological profiles and pharmacokinetic variations between males and females, which can influence drug metabolism and sensitivity.[12,13] Additionally, earlier research has consistently shown that elderly patients are more susceptible to ADRs (92.5%), largely due to polypharmacy, comorbidities, and age-related changes in drug metabolism, while adults represent a major proportion due to higher healthcare utilization.[14]

In this study, Antibiotics were the most frequently implicated drug class with 25.50%, followed by cardiovascular drugs and anti-tubercular drugs. This finding is consistent with pharmacovigilance data from tertiary care hospitals, which demonstrate that antimicrobials account for a substantial proportion (53.7%) of reported ADRs.[10] Furthermore, the results of this study are consistent with earlier research highlighting a significant contribution of antibiotics to hospital-based ADRs, which may be attributed to their extensive clinical utilization and higher risk of hypersensitivity reactions.[4]

In this study, the general medicine department reported the highest incidence of ADRs (60.08%), followed by cardiology (8.53%) and surgical units (6.20%). These findings are consistent with those of Jiang et al, where general medicine that includes gastroenterology, endocrinology, and respiratory medicine accounted for the majority of ADR reports, followed by cardiology. The higher incidence of general medicine in both studies may be attributed to the management of patients with multiple comorbidities requiring several medications, thereby increasing the risk of adverse drug reactions due to polypharmacy.[19]

Causality assessment using the WHO-UMC scale showed that most ADRs were categorized as probable (77.5%), followed by certain (12.01%) reactions. Similar findings have been reported in earlier studies, where ADRs were predominantly classified as probable (54.86%) due to a clear temporal relationship between drug exposure and the adverse event without definite rechallenge evidence.[21] Preventability assessment revealed that the majority of ADRs were non-preventable (44.96%), while a smaller proportion were definitely preventable, with even fewer classified as probably preventable. This high incidence of non-preventable cases aligns with the findings of Iftikhar et al., 2018 who reported that 41.6% of reactions were unavoidable.[22] A similar trend was observed by Keche et al, where a significantly higher proportion (73.61%) of ADRs were classified as non-preventable. Additionally, polypharmacy and drug-drug interactions were identified as significant contributors to ADR occurrence in hospitalized patients.[21] Severity analysis indicated that most reactions were mild (63.17%) to moderate (31.78%), with only a small proportion being severe (5.03%), which is consistent with previous studies reporting mild (33.3%) and moderate (37.0%) ADRs as the most common outcomes among hospitalized patients.[11]

The findings of the present study show partial agreement with Won et al. 2022, who analyzed risk factors for serious ADRs in elderly hospitalized patients and identified polypharmacy (≥8 drugs), altered liver function, and use of high-risk drugs such as antibiotics as significant predictors, while gender showed no significant association. Similarly, in the present study, most demographic and clinical variables including gender, comorbidities, and major diagnoses were not significantly associated with serious ADRs. However, polypharmacy was the only factor that showed a strong and statistically significant association ($p=0.00072$). In contrast to Won et al., individual drug classes and other clinical variables did not demonstrate significant associations in this study. These differences may be due to variations in study population, smaller sample size of serious ADRs, differing definitions of polypharmacy, and lack of laboratory data in the present study.[5]

In the present study, ADRs classified using CTCAE criteria were most commonly related to skin (31.34%), metabolic disorders (12.53%), and gastrointestinal

(10.66%) associated with drugs such as antibiotics and cardiovascular medications. Similar findings were reported by Pandya et al, where trigger tools identified ADRs mainly involving gastrointestinal (21%), cardiac (19.3%), and skin-related events (17.1%) in hospitalized patients. Although the distribution varies slightly due to differences in patient populations and clinical settings, both studies highlight the usefulness of trigger tools in improving ADR detection and systematic classification.[3]

A primary limitation of this study was the lack of continuous patient follow-up, which may have limited the detection of delayed adverse reactions or long-term clinical outcomes. Additionally, the findings are based on data from a single tertiary care hospital, which may restrict the generalizability of the results to other healthcare settings with varying prescribing patterns and patient populations. Important factors such as genetic predisposition, nutritional status, and socioeconomic conditions that could influence ADR susceptibility were not assessed. Furthermore, the completeness of the data was affected by potential under reporting from healthcare professionals, and certain details, including expiry dates and batch numbers, were unavailable due to limited access.

CONCLUSION

The present study evaluated 258 adverse drug reactions in a tertiary care hospital and identified a high incidence of serious events (88.3%), particularly among adults and the elderly. The results identify antimicrobials as the most common causative agents, while polypharmacy serves as the primary significant predictor for serious ADR outcomes. Although most cases were categorized as probable and resulted in clinical recovery, the identification of a substantial proportion of preventable events highlights critical gaps in current medication management. While most reactions were mild to moderate in severity, the frequent involvement of systemic metabolic and skin-related disorders underscores the complexity of treating patients with multiple comorbidities. Overall, this study emphasizes that active pharmacovigilance, structured reporting through systems like VigiFlow, and rational prescribing are essential to mitigating the healthcare burden of ADRs and enhancing patient safety in hospital settings.

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