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Original Research Article

Assessment and management of adverse drug reactions in general medicine department: a prospective observational study

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ABSTRACT

Background: Adverse drug reactions (ADRs) are unintended and harmful responses to medications given at normal therapeutic doses. They contribute significantly to morbidity and prolonged hospital stays, particularly in general medicine departments where polypharmacy and comorbidities are common. The study aimed to monitor, evaluate, and prevent ADRs among inpatients in the general medicine department using established pharmacovigilance tools to enhance treatment safety and effectiveness.
Methods: A prospective observational study was conducted over three months in the general medicine department of a tertiary care hospital. Inpatients aged ≥18 years receiving at least one medication and consenting to participate were included. ADRs were identified through active monitoring of clinical signs and records. Each ADR was evaluated for causality (using WHO-UMC and Naranjo's algorithm), severity (Hartwig and Siegel scale), and preventability (Schumock and Thornton scale).
Results: Among 170 patients, the highest incidence of ADRs was observed in the 41-60 years group (40.6%), with females affected more than males. Hypertension (HTN) and diabetes were common comorbidities. The most frequently suspected drugs included Inj. Monocef, Inj. Levipil, and Inj. Zofer. Antibiotics and gastrointestinal medications accounted for the majority of ADRs. The majority of ADRs were moderate, probable in causality, and potentially preventable. Management involved withdrawal or dose adjustment of the suspected drug, leading to high recovery rates.
Conclusions: This study emphasizes the importance of vigilant ADR monitoring in general medicine. Early detection, risk factor evaluation, and proper management significantly reduce ADR related complications. Strengthening pharmacovigilance practices can enhance patient safety and therapeutic outcomes in clinical settings.

Keywords: Adverse drug reactions, Pharmacovigilance, General medicine, Causality, Severity, Preventability, Polypharmacy

INTRODUCTION

Pharmacovigilance is the scientific discipline focused on detecting, evaluating, understanding, and preventing adverse effects associated with medicinal products. Although it has gained significant ground globally, especially in Western countries, its development in India remains relatively nascent. Initiated in 1998 with India's collaboration with the Uppsala monitoring centre, pharmacovigilance has become increasingly vital due to growing awareness among regulators, healthcare professionals, and the public regarding drug safety. With the globalization of drug markets and India's emergence as a hub for clinical trials, the need for robust post-marketing surveillance has intensified. The absence of long-term safety data for newly introduced drugs emphasizes the critical role of pharmacovigilance. Regulators now demand proactive safety monitoring, including risk management plans and real-time signal detection

throughout a drug's lifecycle. India's national pharmacovigilance programme plays a central role in ensuring drug safety beyond pre-marketing clinical trials, which often do not reflect real world conditions. Effective pharmacovigilance depends on collaboration between regulatory authorities and monitoring centers, ensuring prompt regulatory action, public safety, and informed clinical decision-making.[1,2]

ADEs, ADRs, and side effects are key terms within pharmacovigilance, with ADRs defined as harmful, unintended responses occurring at normal therapeutic doses. While all ADRs are ADEs, not all ADEs qualify as ADRs. Serious ADRs those causing hospitalization, disability, or death may arise from treatment, dose adjustments, drug interactions, or patient-specific factors like age, genetic profile, or comorbidities.[3,4]

ADRs are broadly classified into six types (A-F) and further analysed using the DOTS framework (Dose, timing and susceptibility). Type A reactions are dose-dependent and predictable, whereas type B reactions are idiosyncratic. Types C to F encompass chronic, delayed, withdrawal-related, and treatment failure-related reactions. Mechanisms underlying ADRs range from pharmacokinetic and pharmacodynamic factors to pharmaceutical causes.[5,6]

ADRs must be reported through standardized forms by healthcare professionals and patients alike. Reporting methods include spontaneous reporting, cohort studies, case-control studies, and vital statistics review. Management strategies involve discontinuation or dose adjustment of the offending drug, substitution with safer alternatives, and patient education. General medicine, the clinical discipline primarily involved in diagnosing and managing internal diseases, is integral to pharmacovigilance activities. Internists frequently encounter ADRs in routine practice and play a pivotal role in early detection.[7,8]

Aim and objectives

Aim

The study aimed to monitor, evaluate, and prevent ADRs among inpatients in the general medicine department using established pharmacovigilance tools to enhance treatment safety and effectiveness.

Objectives

Objectives were to determine the most common ADRs observed in the general medicine ward, to assess causality using the WHO-UMC scale and Naranjo's algorithm, to evaluate ADR severity through the modified Hartwig and Siegel scale, to assess preventability using the Schumock and Thornton criteria, to identify potential risk factors such as age, gender, comorbidities, and polypharmacy and to propose recommendations for improved ADR monitoring and prevention.

METHODS

A prospective observational study was conducted over three months in the general medicine department of Owaisi hospital and research centre, Hyderabad. Adult inpatients (≥18 years) receiving at least one general medication were enrolled after informed consent, excluding pregnant/lactating women, those on short-term therapy (<7 days), or with known hypersensitivities. (Study period: September 2024 to November 2024).

Data collection and assessment

Patients were screened daily, and demographic, clinical, and medication-related information was collected. Suspected ADRs were identified through clinical monitoring and healthcare staff reports. Each case was assessed for causality (WHO-UMC, Naranjo), severity (Hartwig and Siegel), and preventability (Schumock and Thornton).

Risk factor analysis and management

Risk factors such as age, sex, comorbid conditions, medication count, and hospital stay duration were analyzed. Confirmed ADRs were managed through dose adjustments, drug substitution, or withdrawal, with supportive care as needed.

Reporting and statistical analysis

All findings were documented using CDSCO forms, and severe cases were reported to the PvPI. Data were analyzed descriptively using Microsoft Excel, with outcomes including ADR incidence, severity distribution, implicated drug classes, risk factor correlations, and overall patient impact.

RESULTS

A total of 170 patients admitted to the general medicine department at Owaisi health and research center were included in this prospective observational study. The incidence, causality, severity, preventability, management, and outcomes of ADRs were evaluated using established pharmacovigilance scales and observational parameters. The results are presented below.

Demographic details of study participants

Age-wise distribution

Patients were grouped into five age categories. The 41-60 years age group exhibited the highest incidence of ADRs (n=69;40.6%), followed by 61-80 years (n=52;30.5%), suggesting a higher susceptibility among middle-aged and elderly patients (Table 1).

Gender-wise distribution

Among 170 patients, females were more affected (n=95;55.9%) than males (n=75;44.1%) (Table 1).

Department-wise distribution

ADRs were assessed across multiple departments within the general medicine unit. The general medicine department recorded the highest number of ADRs, with 38 cases, followed by the neurology department with 29 cases, and gastroenterology with 24 cases. The mean incidence rate of ADRs was highest in the neurology and general medicine departments (0.2632). Both departments also exhibited the highest standard deviation (0.4524), reflecting a wider variability. Pediatrics (Pead) reported 16 cases, while cardiology reported 19 cases. Other departments like pulmonology, nephrology, and RICU showed lower frequencies. Notably, departments like OP (Outpatient), general surgery, gynaecology, MICU, and Others reported no ADRs (Table 1).

Chief complaints on admission

The most common presenting complaints were fever (n=35), vomiting (n=30), shortness of breath (n=22), and chest pain (n=15) (Table 1).

Distribution of ADRs based on comorbidities (past history)

The analysis of comorbidities revealed that HTN was the most prevalent comorbid condition, with 66 patients, followed by diabetes mellitus (DM) with 26 patients, and no known comorbidities (NIL) in 21 patients. The mean number of patients per comorbidity was 14.5 (SD: 19.88), indicating high variation (Table 2).

Distribution based on present medical history

The most common category was nil history in 29 patients. Among medical conditions, HTN and DM were notable, found in 22 and 16 patients, respectively. Social factors such as alcoholism (13 patients) and smoking (8 patients) were also reported. The mean number of patients per category was 12 (SD: 9.71) (Table 2).

Family history of patients with ADRs

The majority had either no significant family history (67 patients) or a non-specific history (51 patients). Documented familial conditions included (DM: 9 patients) and (HTN: 8 patients) (Table 2).

Diagnosis-wise distribution of ADRs

Among patients who developed ADRs, the most common diagnoses were UTI (11 patients), CAD (10), Asthma (9), and HTN (8). The mean number of ADRs per diagnosis was 7 (SD: 2.49), indicating relatively uniform distribution.

Drugs in patient management

An assessment of 81 different drugs used in the management of hospitalized patients (not those causing ADRs) revealed that Inj. Pantoprazole was the most frequently administered (128 times), followed by Inj. Zofer (99), Inj. Monocef (51), Inj. PCM (24), and Inj. Piptaz (25). The mean frequency of drug usage was 12.73 (SD: 26.63), highlighting high variability in prescribing trends.

Suspected drugs responsible for ADRs

Out of 12 different drugs identified, Inj. Monocef was the most commonly suspected (11 cases), followed by Inj. Levipil (8 cases), Inj. Zofer (7), and Inj. Metrogyl (5). The mean number of ADRs per suspected drug was 4.5 (SD: 2.68).

Drug classes responsible for ADRs

Antibiotics and GI medications were the leading contributors to ADRs. Specific drugs causing ADRs included ceftriaxone (most commonly implicated), pantoprazole and furosemide.

Route of administration

The oral route was associated with the highest number of ADRs.

Length of hospital stay

Most ADRs occurred in patients hospitalized for 6-10 days (n=69;40.6%), followed by 11-15 days (n=46;27%).

ADR management

Most ADRs were managed by withdrawing the suspected drug or altering the dose.

Outcome of ADRs

The recovery rate was high, demonstrating effective early intervention in most cases.

Reintroduction of suspected drugs

Most suspected drugs were not reintroduced after ADRs (126 cases), while reintroduction occurred in 20 cases.

Causality assessment

WHO-UMC scale

The majority of ADRs were classified as probable.

Naranjo algorithm

The majority of ADRs (47%) fell under the probable category and validating findings from the WHO-UMC scale.

Severity of ADRs (modified Hartwig and Siegel scale)

Most ADRs were moderate, requiring therapeutic management but not life-threatening.

Preventability (Schumock and Thornton scale)

Nearly 55% of ADRs were considered potentially avoidable, indicating need for tighter therapeutic monitoring.

Risk factors identified

Risk factors included polypharmacy, elderly age, impaired renal/hepatic function, and pre-existing chronic conditions.

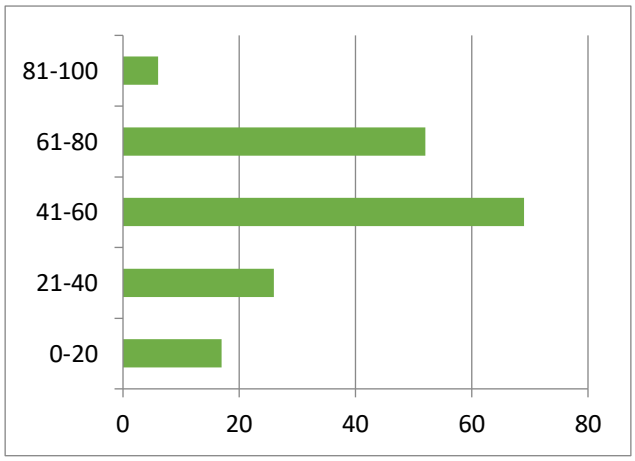

Figure 1: Age-wise distribution of patients with ADRs, (n=170).

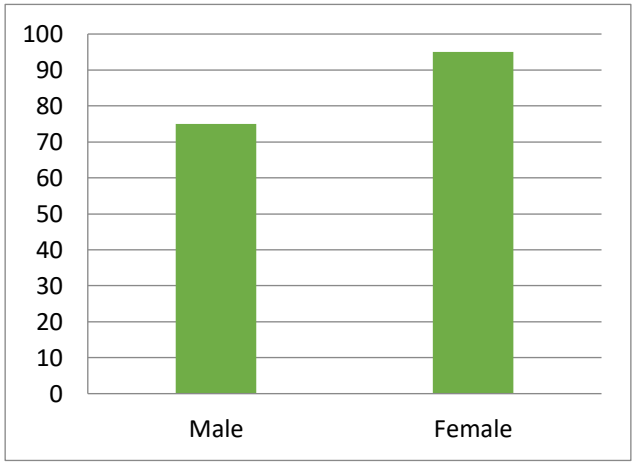

Figure 2: Gender-wise distribution of patients with ADRs, (n=170).

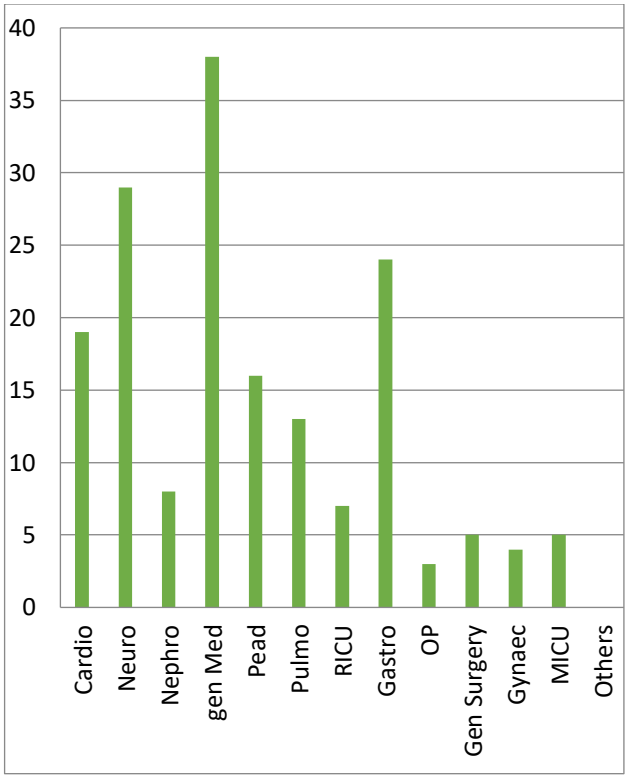

Figure 3: Distribution of ADRs across hospital departments.

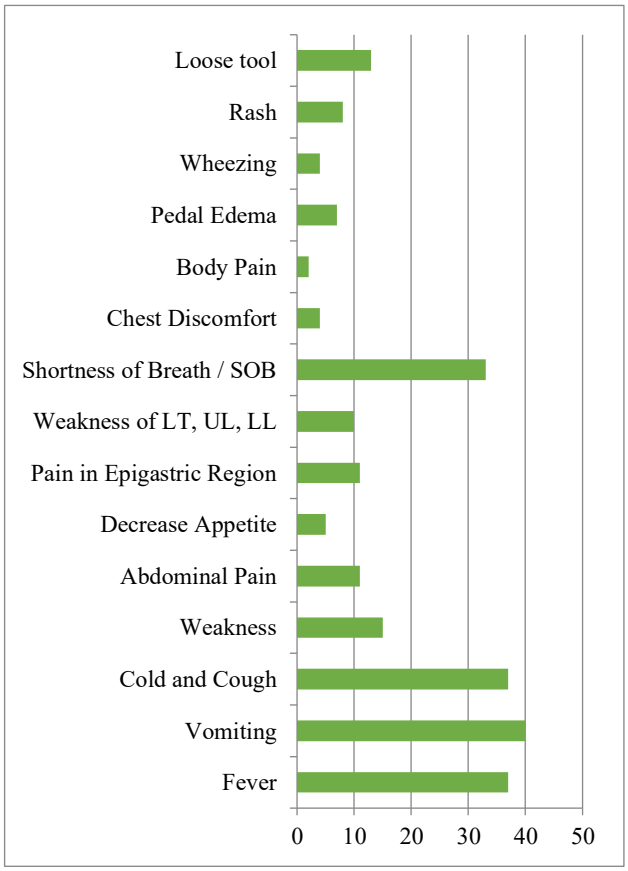

Figure 4: Distribution of chief complaints on admission among patients with ADRs.

Table 1: Demographic and clinical characteristics of study participants distribution of ADRs based on past medical history, present history, and family history, (n=170).

Categories	Sub-category	N	Mean	SD
Age (in years)	0-20	17	9.27	
	21-40	26	31.46	
	41-60	69	50.12	
	61-80	52	69.63	
	81-100	6	85.67	
Gender	Male	75	0.4647	
	Female	95	0.5353	
Departments	Cardio	19	0.107	0.308
	Neuro	29	0.2632	0.4524
	Nephro	8	0.1053	-
	General medicine	38	0.2632	0.4524
	Pediatrics (Pead)	16	0.1579	0.3746
	Pulmonology (Pulmo)	13	0.0833	-
	RICU	7	0.1053	-
	Gastroenterology (Gastro)	24	0.1647	-
	Outpatient (OP)	3	0	-
	Gen Surgery	5	0	-
	Gynaec	4	0	-
	MICU	5	0	-
	Others	0	0	-
Chief complaints	Fever	37	-	
	Vomiting	40	-	
	Cold and cough	37	-	
	Weakness	15	-	
	Abdominal pain	11	-	
	Decrease appetite	5	-	-
	Pain in epigastric region	11	-	
	Loose tool	-	-	
	Wheezing	-	-	
	Body pain	-	-	
	Shortness of breath / SOB	-	-	
Past history (Comorbidities)	HTN	66	14.5	19.88
	DM	26		
	Not known (NIL)	21		
	Asthma	10		
	CAD	4		
	Seizures	4		
	Hypothyroid	5		
	CKD	2		
	Gall bladder stone	3		
	Ulcer	4		
Present history	Not significant (Not sig)	21	12	9.71
	Nil	29		
	HTN	22		
	DM	16		
	Alcoholic	13		
	Smoker	8		
	Decrease appetite	4		
	Asthma	3		
	Weakness	2		
	SOB	2		
Family history (FHx.)	Nil	67	17.75	21.99
	Not significant (Not sig.)	51		
	DM	9		
	HTN	8		
	Smoker	3		
	Anemia	2		
	Gutka chewer	1		
	Alcoholic	1		

Table 3: ADRs management, outcome, assessment of causality, severity, and preventability.

ADRs management type	N	Seriousness type	N	Outcome type	N	Reintroduction type	N
ADRs							
Drug withdrawn	129	No	77	Recovered	121	Not reintroduced	126
Dose reduced	20	Hospitalisation	81	Recovering	49	Yes (Reintroduced)	20
Dose not changed	15	Other medically important	5			Effect unknown	23
Continue drug	4	Life threatening	5				
WHO-UMC causality	**N**	**Naranjo scale**	**N**	**Seighal scale (Severity)**	**N**	**Thornton scale (Preventability)**	**N**
Assessment of causality, severity, and preventability							
Probable	90	Definite	0	Level 1 (Minor)	19	Probably Preventable	8
Possible	50	Probable	140	Level 2 (Moderate)	94	Probably not preventable	4
Certain	20	Possible	30	Level 3 (Major)	37	Not preventable	100
Unlikely	8	Doubtful	0	Level 4 (Severe/ life-threatening)	9	Probable	40
				Level 4a (Life-threatening)	6	Possible	5

DISCUSSION

This prospective study investigated the incidence, severity, causality, preventability, and outcomes of ADRs among 170 patients admitted to the general medicine department at Owaisi health and research center.

The highest proportion of ADRs (22.3%) was observed in the general medicine unit, which aligns with previous studies by Sharm et al, Ramesh et al and Sriram et al. These findings likely reflect the complexity of patient cases and frequent use of high-risk medications in this department. The majority of ADRs occurred in patients aged 41 to 60 years (40.6%), followed by those between 61 and 80 years. This age pattern supports the observations of Gurwitz et al who pointed out that physiological changes related to aging and the presence of multiple comorbidities increase vulnerability to drug reactions. Furthermore, a higher incidence among female patients (55.9%) was noted, echoing Raut et al who suggested that hormonal and metabolic factors might contribute to this trend.[9,10]

Antimicrobials emerged as the most implicated drug class, with ceftriaxone leading among individual drugs, followed by gastrointestinal and cardiovascular medications. This distribution is consistent with findings by Primohamed et al who documented few ADRs associated with antibiotics and NSIDs. The risks linked to medications like pantoprazole and furosemide further highlight the importance of careful drug selection and monitoring.[11]

Assessment using the WHO-UMC system and the Naranjo algorithm showed that most ADRs were classified as "probable", which indicates a strong temporal relationship and clinical consistency, similar to results reported by Khan et al. Regarding patient outcomes, 71% achieved complete recovery, while 29% were still improving at discharge, and no fatalities were reported. These outcomes align with those described by Jose and Rao, who emphasized the value of early detection and intervention, contrasting with higher ADRs-related mortality rates reported by Lazarou et al in the U.S.[22]

Severity analysis, based on the modified Hartwig and Siegel scale, indicated that most ADRs were moderate and did not require prolonged hospitalization-findings that are in line with the work of Tandon et al. Approximately 55% of ADRs were considered preventable, underscoring the need for meticulous prescribing and ongoing monitoring. Similar observations were made by Tangiisuran et al highlighting the potential of clinical pharmacists and decision-support systems to reduce avoidable ADRs.[13]

The majority of reactions were linked to oral medications (58.8%), followed by parental routes, a pattern consistent with the findings of Classen et al who reported higher risks associated with injectable therapies. In most cases (74.1%), re-exposure to the offending drug was avoided, reflecting a cautious and patient-centered approach, as advocated by Biagi et al. Overall, these results highlight the crucial importance of strengthening pharmacovigilance efforts, providing continuous training for healthcare professionals, and involving clinical

pharmacists more actively in-patient care to minimize ADR risks and improve overall safety.[14]

CONCLUSION

ADRs represent a silent yet significant challenge in clinical practice, especially within general medicine departments where patients are typically treated with a multitude of medications for diverse and often chronic conditions. This prospective observational study revealed the frequency and nature of ADRs, as well as the profound implications they have on patient safety, hospital stay, and treatment outcomes.

The findings highlight those middle-aged and elderly patients, particularly those with comorbidities such as HTN and diabetes, are disproportionately affected by ADRs. Antibiotics, gastrointestinal agents, and anticonvulsants were among the most common culprits. These ADRs, while mostly moderate in severity, led to extended hospitalization and required clinical interventions such as drug withdrawal or dose modification. Fortunately, most patients showed favorable outcomes with timely management.

The reporting of ADRs is not merely a procedural obligation; it is a moral and clinical responsibility. Timely identification and management of ADRs through thorough clinical monitoring, appropriate use of causality and severity scales, and rational prescribing practices are key to mitigating their impact. Furthermore, continuous training for healthcare professionals, patient education, and institutional encouragement of ADR reporting systems are essential to reduce preventable harm.

In conclusion, this study not only underlines the prevalence of ADRs but also reinforces the pivotal role of vigilant pharmacovigilance. A well-informed and proactive approach to ADR monitoring can transform clinical care by safeguarding patients, improving therapeutic outcomes, and contributing to the development of a safer, more responsive healthcare system.

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