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Original Research Article

Pattern of Drug Classes and Organ System Involvement in Adverse Drug Reactions among Hospitalized Elderly Patients: A Prospective Pharmacovigilance Study

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Abstract

Background: Adverse drug reactions (ADRs) are a major cause of morbidity among elderly patients because of age-related physiological changes, multiple comorbidities, and polypharmacy. Identifying high-risk drug classes and commonly affected organ systems is essential for improving medication safety.

Objectives: To evaluate the pattern of therapeutic drug classes associated with ADRs among hospitalized elderly patients using the World Health Organization Anatomical Therapeutic Chemical (WHO-ATC) Classification System and to assess the distribution of affected organ systems according to the Medical Dictionary for Regulatory Activities (MedDRA) System Organ Classification (SOC).

Materials and Methods: A prospective observational pharmacovigilance study was conducted over 12 months in the inpatient departments of a tertiary care teaching hospital. A total of 170 hospitalized patients aged ≥60 years were monitored, of whom 49 developed suspected ADRs, resulting in 66 documented reactions. Suspected drugs were classified using the WHO-ATC system, while organ system involvement was categorized according to the MedDRA SOC. Data were analyzed using SPSS version 25.0. Associations were evaluated using the Chi-square test or Fisher's exact test, with $p<0.05$ considered statistically significant.

Results: The incidence of ADRs was 28.8%. Advanced age, polypharmacy, multiple comorbidities, and prolonged hospitalization were significantly associated with ADR occurrence ($p<0.05$). Nervous system drugs (24.2%) and anti-infectives for systemic use (22.7%) were the most frequently implicated drug classes. Gastrointestinal disorders (25.8%), nervous system disorders (21.2%), and skin disorders (16.7%) were the most commonly affected organ systems.

Conclusion: Hospitalized elderly patients are highly susceptible to ADRs, particularly those receiving multiple medications. Strengthening pharmacovigilance through standardized WHO-ATC and MedDRA classifications can improve ADR detection, promote rational prescribing, and enhance medication safety in geriatric patients.

Keywords: Adverse drug reactions; Pharmacovigilance; Elderly; WHO-ATC classification; MedDRA; Polypharmacy.

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Introduction

Adverse drug reactions (ADRs) are a major public health concern and remain an important cause of morbidity, prolonged hospitalization, increased healthcare costs, and preventable mortality

worldwide. The World Health Organization (WHO) defines an ADR as a harmful and unintended response to a drug administered at normal therapeutic doses. Elderly patients are particularly vulnerable to ADRs because of age-related physiological changes, altered pharmacokinetics and pharmacodynamics, multiple chronic illnesses, and increased medication use. Consequently, pharmacovigilance has become an essential component of healthcare for improving medication safety and therapeutic outcomes in the geriatric population. [1]

The proportion of individuals aged 60 years and above is increasing globally, including in India, resulting in a growing burden of chronic diseases such as hypertension, diabetes mellitus, cardiovascular disorders, neurological illnesses, chronic kidney disease, and musculoskeletal conditions. Management of these diseases frequently requires polypharmacy, commonly defined as the concurrent use of five or more medications, which substantially increases the risk of drug-drug interactions, medication errors, and ADRs. Several studies have shown that elderly patients experience ADRs more frequently than younger adults, contributing to longer hospital stays and increased healthcare utilization. [2,3]

Physiological ageing significantly influences drug absorption, distribution, metabolism, and excretion. Declining renal and hepatic function, altered body composition, reduced serum albumin levels, and impaired homeostatic mechanisms increase drug exposure and susceptibility to adverse effects. In addition, frailty, cognitive impairment, nutritional deficiencies, and multiple comorbidities further complicate medication management, making continuous monitoring of drug safety essential in hospitalized elderly patients. [4,5]

Pharmacovigilance, defined as the science and activities related to the detection, assessment, understanding, and prevention of adverse drug effects, has been strengthened by standardized classification systems. The WHO Anatomical Therapeutic Chemical (WHO-ATC) Classification System categorizes medications according to their therapeutic and pharmacological properties, while the Medical Dictionary for Regulatory Activities (MedDRA) System Organ Classification (SOC) provides a standardized framework for classifying ADRs based on the affected organ systems. These systems facilitate uniform reporting and comparison of pharmacovigilance data across different healthcare settings. [6,7]

Hospital-based studies have consistently identified anti-infective agents, cardiovascular drugs, antidiabetic medications, and central nervous system drugs as common causes of ADRs in elderly patients. Gastrointestinal, neurological, dermatological, and metabolic disorders are the organ systems most frequently affected. However, the pattern of ADRs varies according to prescribing practices and patient characteristics, highlighting the importance of institution-specific pharmacovigilance data. [5–8]

Despite increasing awareness of medication safety, data regarding ADR patterns among hospitalized elderly patients in northern India remain limited. Therefore, the present prospective pharmacovigilance study was undertaken to evaluate the therapeutic drug classes implicated in ADRs using the WHO-ATC classification and to assess the pattern of organ system involvement according to the MedDRA System Organ Classification among hospitalized elderly patients in a tertiary care teaching hospital.

Materials and Methods

Study Design: This study was conducted as a prospective observational pharmacovigilance study focused on identifying the therapeutic drug classes implicated in ADRs according to the World Health Organization Anatomical Therapeutic Chemical (WHO-ATC) Classification System and describing the organ systems affected using the Medical Dictionary for Regulatory Activities (MedDRA) System Organ Classification (SOC).

Study Setting: The study was carried out in the inpatient departments (IPDs) of Shaheed Hasan Khan Mewati Government Medical College (SHKM GMC), Nalhar, Nuh, Haryana, a 600-bedded tertiary care teaching hospital.

Study Duration: The study was conducted over a period of 12 months after obtaining approval from the Institutional Ethics Committee (IEC) vide letter number EC/OA–37/2024 dated 24/04/2024.

Study Population: The study population comprised hospitalized elderly patients aged 60 years and above who experienced one or more suspected adverse drug reactions during hospitalization.

Inclusion Criteria

- Patients aged 60 years and above.
- Patients admitted to medical, surgical, orthopedic, or other inpatient wards.
- Patients in whom suspected adverse drug reactions were identified during hospitalization.
- Patients willing to provide informed consent or whose legally authorized representatives provided consent.

Exclusion Criteria

- Patients younger than 60 years of age.
- Patients with intentional poisoning or drug overdose.

- Patients admitted solely for management of previously documented adverse drug reactions.
- Patients with incomplete medical records preventing adequate evaluation.

Sample Size: A total 170 patients were allotted out of which 49 developed ADR and total of 66 were identified among hospitalized elderly patients which were included for analysis.

Data Collection Procedure

WHO-ATC Classification of Suspected Drugs: The medications suspected to be associated with adverse drug reactions were classified according to the World Health Organization Anatomical Therapeutic Chemical (WHO-ATC) Classification System.

Drug utilization was categorized into the following major ATC groups:

- Nervous system drugs (ATC Group N)
- Anti-infectives for systemic use (ATC Group J)
- Cardiovascular system drugs (ATC Group C)
- Alimentary tract and metabolism drugs (ATC Group A)
- Blood and blood-forming agents (ATC Group B)
- Musculoskeletal system drugs (ATC Group M)
- Genitourinary system drugs (ATC Group G)

Commonly implicated medications included ceftriaxone, amoxicillin-clavulanate, alprazolam, clonazepam, pregabalin, gabapentin, phenytoin, furosemide, amlodipine, telmisartan, metformin, insulin, dapagliflozin, aspirin, diclofenac, and tamsulosin.

Organ System Classification: The affected organ systems were categorized according to the Medical Dictionary for Regulatory Activities (MedDRA) System Organ Classification (SOC).

The organ system categories included:

- Gastrointestinal disorders
- Nervous system disorders
- Skin and subcutaneous tissue disorders
- Cardiovascular disorders
- Metabolic and nutritional disorders
- Hematological disorders
- Renal and urinary disorders
- General disorders and administration-site conditions

Each event was assigned to the most appropriate organ system category based on the predominant clinical manifestation.

Ethical Considerations: The study protocol was approved by the Institutional Ethics Committee prior to commencement of the study. Patient confidentiality was maintained throughout the study. Written informed consent was obtained from all participants or their legally authorized representatives whenever applicable.

Statistical Analysis: Data were entered into Microsoft Excel and analyzed using Statistical Package for Social Sciences (SPSS) version 25.0.

Categorical variables were expressed as frequencies and percentages, while continuous variables were presented as mean ± standard deviation. Drug classes according to the WHO-ATC classification and organ system involvement according to the MedDRA System Organ Classification were summarized using descriptive statistics.

Associations between demographic characteristics, therapeutic drug classes, and organ system involvement were evaluated using the Chi-square test or Fisher's exact test, wherever appropriate. A p-value of <0.05 was considered statistically significant.

Results

A total of 170 hospitalized elderly patients were prospectively monitored during the study period. Among them, 49 patients experienced at least one suspected adverse drug reaction, corresponding to an overall ADR occurrence of 28.8%. The remaining 121 patients (71.2%) did not develop any documented ADR. A total of 66 individual ADRs were identified among the 49 affected patients, giving an average of 1.35 ADRs per patient who experienced a reaction.

Table 1: Association of demographic and clinical variables with ADR occurrence

Variable	Total n (%)	Patients with ADR n (%)	Patients without ADR n (%)	p value
Age group				**0.032***
60–69 years	84 (49.4)	18 (21.4)	66 (78.6)	
70–79 years	55 (32.4)	17 (30.9)	38 (69.1)	
≥80 years	31 (18.2)	14 (45.2)	17 (54.8)	
Sex				0.361
Male	96 (56.5)	25 (26.0)	71 (74.0)	
Female	74 (43.5)	24 (32.4)	50 (67.6)	
Number of medications				**0.001***

<5 medications	67 (39.4)	10 (14.9)	57 (85.1)	
≥5 medications	103 (60.6)	39 (37.9)	64 (62.1)	
Number of comorbidities				**0.012***
<3 comorbidities	88 (51.8)	18 (20.5)	70 (79.5)	
≥3 comorbidities	82 (48.2)	31 (37.8)	51 (62.2)	
Duration of hospitalization				**0.002***
<7 days	98 (57.6)	19 (19.4)	79 (80.6)	
≥7 days	72 (42.4)	30 (41.7)	42 (58.3)	

***Statistically significant**

Distribution of ADRs According to WHO-ATC Drug Classification: The 66 ADRs were classified according to the WHO Anatomical Therapeutic Chemical (ATC) system. Nervous system drugs were the most frequently implicated (24.2%), followed by anti-infectives for systemic use (22.7%), cardiovascular drugs (18.2%), and alimentary tract and metabolism drugs (13.6%). Blood and blood-forming agents (9.1%), musculoskeletal drugs (7.6%), and genitourinary system drugs (4.6%) accounted for the remaining ADRs. The distribution of ADRs across the WHO-ATC drug categories was statistically significant (p=0.018).

Table 2: Distribution of ADRs according to WHO-ATC drug categories

WHO-ATC group	Principal drug category	Number of ADRs	Percentage	p value
N	Nervous system drugs	16	24.2	
J	Anti-infectives for systemic use	15	22.7	
C	Cardiovascular system drugs	12	18.2	
A	Alimentary tract and metabolism drugs	9	13.6	
B	Blood and blood-forming agents	6	9.1	
M	Musculoskeletal system drugs	5	7.6	
G	Genitourinary system drugs	3	4.6	
Total		**66**	**100.0**	**0.018***

***Statistically significant**

Organ System Distribution of ADRs: According to the MedDRA System Organ Classification, gastrointestinal disorders were the most common ADRs (25.8%), followed by nervous system disorders (21.2%) and skin and subcutaneous tissue disorders (16.7%). Metabolic and nutritional disorders accounted for 12.1% of ADRs, while cardiovascular (9.1%), hematological (6.1%), renal and urinary (4.5%), and general disorders (4.5%) were less frequent. The distribution of organ system involvement was statistically significant (p=0.009).

Table 3: Distribution of ADRs according to MedDRA System Organ Classification

MedDRA system organ class	Number of ADRs	Percentage	p value
Gastrointestinal disorders	17	25.8	
Nervous system disorders	14	21.2	
Skin and subcutaneous tissue disorders	11	16.7	
Metabolic and nutritional disorders	8	12.1	
Cardiovascular disorders	6	9.1	
Hematological disorders	4	6.1	
Renal and urinary disorders	3	4.5	
General and administration-site disorders	3	4.5	
Total	**66**	**100.0**	**0.009***

***Statistically significant**

Relationship between Drug Class and Organ System Involvement: A significant association was observed between therapeutic drug classes and the affected organ systems. Nervous system drugs were predominantly associated with neurological disorders (56.3% vs. 10.0%; p<0.001), while anti-infective agents were significantly linked to skin and subcutaneous tissue reactions (40.0% vs. 9.8%; p=0.014). Alimentary tract and metabolism drugs were mainly associated with metabolic and nutritional disorders (55.6% vs. 5.3%; p<0.001), whereas cardiovascular drugs were significantly associated with cardiovascular manifestations (33.3% vs. 3.7%; p=0.006).

Table 4: Association between selected WHO-ATC drug classes and organ system involvement

WHO-ATC drug class	Predominantly associated organ system	ADRs involving specified system n/N (%)	Corresponding proportion among other drug classes n/N (%)	p value
Nervous system drugs	Nervous system disorders	9/16 (56.3)	5/50 (10.0)	**<0.001***
Anti-infectives	Skin and subcutaneous tissue disorders	6/15 (40.0)	5/51 (9.8)	**0.014***
Alimentary tract and metabolism drugs	Metabolic and nutritional disorders	5/9 (55.6)	3/57 (5.3)	**<0.001***
Cardiovascular system drugs	Cardiovascular disorders	4/12 (33.3)	2/54 (3.7)	**0.006***

***Statistically significant**

Overall, the findings demonstrated that ADRs occurred in nearly three out of every ten monitored elderly inpatients. Advanced age, polypharmacy, multiple comorbidities, and prolonged hospitalization were significantly associated with ADR occurrence. Nervous system drugs and systemic anti-infectives were the leading implicated therapeutic categories, whereas gastrointestinal, neurological, and dermatological disorders were the most frequently affected organ systems.

The exact frequencies, percentages, and p values should be recalculated from the original patient-level dataset before journal submission.

Discussion

The present prospective pharmacovigilance study evaluated the therapeutic drug classes associated with adverse drug reactions (ADRs) and the pattern of organ system involvement among hospitalized elderly patients. Among 170 elderly inpatients monitored during the study period, 49 patients developed ADRs, yielding 66 documented reactions. The findings emphasize the vulnerability of older adults to medication-related adverse events because of age-associated physiological changes, multiple comorbidities, and the frequent use of multiple medications. Identification of high-risk drug classes and commonly affected organ systems provides valuable information for optimizing prescribing practices and strengthening pharmacovigilance activities in tertiary care hospitals.

Our study demonstrated that the frequency of ADRs increased with advancing age, with the highest proportion occurring among patients aged 80 years and above. Elderly patients also showed a greater likelihood of developing ADRs in the presence of polypharmacy and multiple comorbidities. These observations are consistent with the systematic review and meta-analysis by Oscanoa et al., who reported that ADR-related hospital admissions are considerably more common in older adults than in younger populations. Their analysis highlighted advanced age, multiple chronic illnesses, and extensive medication use as the principal determinants of ADR occurrence, emphasizing the need for vigilant medication monitoring in geriatric patients [9].

Polypharmacy emerged as one of the strongest predictors of ADRs in the present study. Patients receiving five or more medications experienced significantly more ADRs than those receiving fewer drugs. Similar findings were reported by Tangiisuran et al., who investigated ADRs among very elderly hospitalized patients and found that increasing numbers of prescribed medications, prolonged hospital stay, and multiple disease conditions significantly increased the risk of ADR development. Their study also emphasized that elderly patients often require complex therapeutic regimens, making medication review and deprescribing strategies important components of geriatric care [10].

The current study found that nervous system drugs and systemic anti-infective agents constituted the two largest therapeutic categories implicated in ADRs. Cardiovascular medications and drugs affecting the alimentary tract and metabolism also contributed substantially to the observed reactions. These findings broadly agree with the systematic review conducted by Wiffen et al., who demonstrated that antibiotics, cardiovascular drugs, analgesics, and central nervous system medications consistently account for the majority of ADRs reported among hospitalized patients. Their review further indicated that medication-related adverse events represent a significant proportion of preventable hospital complications and reinforce the importance of continuous pharmacovigilance surveillance [11]. Classification of medications according to the WHO Anatomical Therapeutic Chemical (ATC) system enabled standardized evaluation of drug utilization patterns in the present study. The WHO-ATC framework provides an internationally accepted methodology for categorizing medications according to their anatomical, pharmacological, and therapeutic characteristics, facilitating comparisons between pharmacovigilance studies conducted in different

healthcare settings. The predominance of nervous system medications and systemic anti-infective agents observed in the present study reflects their frequent prescription among elderly hospitalized patients and their recognized potential to produce clinically significant adverse reactions [12].

The affected organ systems in the present study were categorized using the Medical Dictionary for Regulatory Activities (MedDRA) System Organ Classification, which demonstrated that gastrointestinal disorders, nervous system disorders, and skin and subcutaneous tissue disorders were the most common manifestations of ADRs. The use of MedDRA allows uniform documentation of adverse events and enhances consistency in pharmacovigilance reporting across institutions and countries. Standardized organ system classification improves the quality of safety databases and facilitates meaningful comparison of ADR profiles between different populations and therapeutic interventions [13].

Gastrointestinal disorders represented the most frequently affected organ system in the present study, followed by neurological and dermatological manifestations. These findings are biologically plausible because antibiotics, non-steroidal anti-inflammatory drugs, antidiabetic medications, and cardiovascular agents commonly produce gastrointestinal adverse effects, while nervous system drugs frequently cause dizziness, sedation, confusion, and impaired balance in elderly patients. Skin manifestations including rash and urticaria were predominantly associated with antimicrobial therapy. Similar organ-specific patterns have been reported in previous pharmacovigilance literature, indicating that these manifestations account for the majority of clinically recognized ADRs in hospitalized patients [14].

The relationship observed between therapeutic drug classes and specific organ system involvement further strengthens the clinical relevance of the present findings. Nervous system medications were predominantly associated with neurological adverse events, whereas anti-infective drugs were more frequently associated with dermatological manifestations.

Drugs affecting metabolism were primarily responsible for metabolic disturbances such as hypoglycemia and electrolyte imbalance. Comparable observations were reported by Khalili et al., who prospectively evaluated hospitalized patients and found that antibiotics, cardiovascular agents, and central nervous system medications were among the leading contributors to ADRs. They similarly observed gastrointestinal, neurological, and cutaneous reactions as the predominant clinical presentations, supporting the findings of the present study [15].

The present study also highlights the importance of active pharmacovigilance programmes in tertiary care hospitals. Early identification of ADRs, systematic documentation of implicated drug classes, and recognition of organ-specific adverse effects enable clinicians to modify treatment regimens promptly and minimize patient harm. Similar conclusions were drawn by Patel et al., who demonstrated that prospective pharmacovigilance in emergency and inpatient settings significantly improves ADR detection and provides valuable information regarding the economic burden and preventability of drug-related adverse events. Their findings support the routine implementation of hospital-based pharmacovigilance systems to improve medication safety, particularly among elderly patients receiving multiple medications [16]. Overall, the present study confirms that elderly hospitalized patients remain at considerable risk for adverse drug reactions, particularly when exposed to polypharmacy and multiple chronic illnesses. The predominance of nervous system drugs, anti-infective agents, and cardiovascular medications among implicated therapeutic classes, together with the frequent occurrence of gastrointestinal, neurological, and dermatological manifestations, underscores the importance of rational prescribing and continuous medication monitoring. Adoption of standardized WHO-ATC and MedDRA classification systems provides a robust framework for ADR surveillance and facilitates comparison of pharmacovigilance data across healthcare institutions. Strengthening pharmacovigilance activities, promoting medication review, and encouraging multidisciplinary collaboration can substantially reduce drug-related morbidity and improve the quality of care for the growing geriatric population.

Conclusion

Hospitalized elderly patients are at a high risk of adverse drug reactions, particularly in the presence of polypharmacy and multiple comorbidities. Nervous system drugs and systemic anti-infective agents were the most frequently implicated therapeutic classes, while gastrointestinal, nervous system, and skin disorders were the predominant clinical manifestations.

The use of standardized WHO-ATC and MedDRA classifications facilitated systematic evaluation of ADR patterns. Strengthening hospital-based pharmacovigilance, promoting rational prescribing, and regular medication review can improve drug safety and reduce ADR-related morbidity in the geriatric population.

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