

## ORIGINAL ARTICLE



OPEN ACCESS

Received: 07-05-2025

Accepted: 07-08-2025

Published: 31-03-2026

**Citation:** Suchitra R, Snigdha M, Rajesh KS. Drug Utilization and Adverse Drug Reactions in the Elderly: A Cross-sectional Analysis in a Tertiary Care Geriatric Unit. 2026; 16(1):15-20.  
<https://doi.org/10.58739/jcbs/v16i1.25.217>

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Funding: None

Competing Interests: None

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Published By Sri Devaraj Urs Academy of Higher Education, Kolar, Karnataka

ISSN

Print: 2231-4180

Electronic: 2319-2453



# Drug Utilization and Adverse Drug Reactions in the Elderly: A Cross-sectional Analysis in a Tertiary Care Geriatric Unit

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## Abstract

**Introduction:** Elderly patients are at a higher risk of polypharmacy and adverse drug reactions (ADRs) due to multiple comorbidities and age-related pharmacokinetic changes. This study aims to evaluate prescribing trends and ADRs among elderly patients in a tertiary care geriatric unit. **Materials and Methods:** An observational cross-sectional study was conducted on 250 elderly patients. A total of 1824 drugs were prescribed. Prescribing patterns were evaluated using WHO/INRUD indicators, and ADRs were assessed using the WHO causality assessment criteria. **Results:** Cardiovascular diseases were the most prevalent (24%), followed by endocrine disorders (18.8%). The most commonly prescribed drugs included pantoprazole, aspirin, atorvastatin, telmisartan, and metformin-glimepiride. As per WHO core prescribing indicators, the average number of drugs per prescription was 7.4, with 71.9% prescribed from the essential drug list and 54% by generic names. Injectable drugs were used in 22% of encounters, and the average number of antibiotics per encounter was 2.33. Causality assessment of ADRs classified aspirin, ofloxacin, azithromycin, rifampicin, metronidazole, amoxicillin-clavulanic acid, ceftriaxone, and ciprofloxacin as 'Probable'. Iron sucrose-induced hypersensitivity reactions and orange-colored urine due to rifampicin were classified as 'Certain'. ADRs caused by diclofenac, heparin sodium, valsartan-sacubitril, rifampicin, ethambutol, and nicorandil were classified as 'Possible'. **Conclusion:** This study highlights the prevalence of polypharmacy and ADRs in elderly patients. The findings underscore the need for rational prescribing practices and enhanced pharmacovigilance to improve drug safety and efficacy in geriatric care.

**Keywords:** Adverse drug reaction, Drug utilization studies, Geriatric

## 1 Introduction

The aging population presents significant challenges for healthcare due to altered pharmacokinetics and pharmacodynamics in the elderly. Age-related changes, such as decreased renal and hepatic clearance, altered protein binding, and changes in body composition, impact drug absorption, distribution, metabolism, and excretion. These changes increase the risk of both sub-therapeutic and toxic drug levels<sup>1</sup>. Additionally, pharmacodynamic alterations,

including altered receptor sensitivity, further complicate treatment<sup>2</sup>.

Elderly patients often have multiple co-morbidities such as hypertension, diabetes, and heart failure, leading to polypharmacy, which increases the risk of adverse drug reactions (ADRs), drug-drug interactions, and non-adherence<sup>3</sup>. The complexity of managing these patients requires careful balancing of therapeutic benefits against

potential harm, as the elderly are particularly vulnerable to ADRs due to physiological changes<sup>4</sup>.

Given these challenges, selecting the right medication at the right dose and duration while minimizing polypharmacy and avoiding potentially inappropriate medications is crucial. However, studies show that inappropriate prescribing is common in the elderly, often leading to preventable ADRs and poor outcomes<sup>5</sup>.

This study aims to evaluate the prescribing patterns of drugs and adverse drug reactions in elderly patients admitted to the Geriatric department of a tertiary care hospital. By identifying areas for improvement and potential inappropriate medicine use, the research seeks to form strategies for optimizing drug therapy, reducing ADR risk, and improving health outcomes.

**Aim:** To evaluate the prescribing pattern of drugs and adverse drug reactions in elderly patients admitted in Geriatric department of Tertiary care hospital.

**Objectives:** To assess the prescribing patterns of various drugs in elderly patients admitted in tertiary care hospital using WHO INRUD indicators<sup>6</sup>. To identify and analyse adverse drug reactions in elderly using WHO UMC Causality assessment scale<sup>7</sup>.

## 2 Materials & Methods

### • Study site and study period

The study was conducted from May 01 to July 31, 2023, in the Geriatric wards of a tertiary care hospital.

### • Regulatory Approval

Necessary approval by The Scientific Review Committee and The Institutional Ethical Committee of Human Research was received before proceeding for the study.

### • Study Design & Data Collection

This was an observational cross-sectional study, carried out in the geriatric wards of a tertiary care hospital. Prescription details were recorded in data collection form. Among the parameters captured for this study included sociodemographic data, clinical data (clinical presentation, diagnosis) and medicines prescribed (dose, route, duration, frequency, combination treatment).

### • Population, Inclusion, and Exclusion criteria

The study population consisted of patients, aged 65 years and older, of both genders, who were admitted to the geriatric wards of the Hospital. These patients needed to have a hospital stay of more than 24 hours. Patients were excluded from the

study if they were not willing to participate in the study or were admitted to outpatient department, intensive care units or emergency wards.

### • Sample size determination

The sample size was determined by using the formula  $n = z^2(p)(1-p)$ . The study conducted on the prescribing of drugs in the geriatric wards of a tertiary care hospital involved a sample size of 250 patients.

### • Data Analysis:

Data were analysed for the following indicators:

- Demographic characteristics: Age and sex wise distribution
- Prevalence of diseases among study population
- Comorbid conditions associated in the study population
- Different classes of drugs prescribed to patients for various clinical conditions.
- Assessment of prescribing pattern as per WHO-INRUD drug use indicators:
- Average number of drugs per prescription.
- Percentage of drugs prescribed with the generic name.
- Percentage of the drugs prescribed from the WHO List of Essential Medicines, 2023.
- Percentage of encounters with an injectable.
- Average number of antibiotics per encounter,
- Adverse drug reactions using WHO UMC causality assessment scale.

### • Descriptive Statistics

Means, medians, and percentages for continuous and categorical variables were calculated. The data was presented using tables, charts, and graphs.

## 3 Results

Out of the total study population, 150 patients (60%) were male, and 100 patients (40%) were female. The majority of the patients, 90.8%, fell within the age group of 65 to 75 years, making it the most prevalent age group observed in [Table .1].

The study population exhibited a diverse range of health conditions, with cardiovascular diseases being the most prevalent, affecting 24% of the participants. Endocrine disorders, including diabetes mellitus, were the second most common, present in 18.8% of the study population. Additionally, 16% of the patients were diagnosed with infectious diseases. The rest of the cases belonged to other organ systems as mentioned in Table. 2.

**Table 1: Demographic characteristics: Age and sex wise distribution**

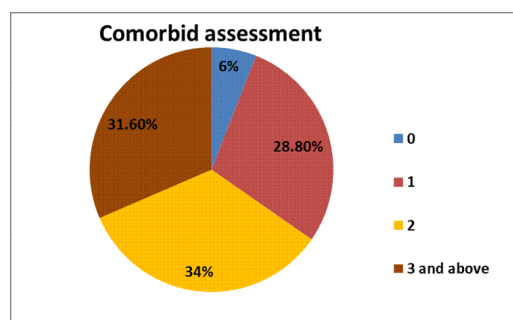
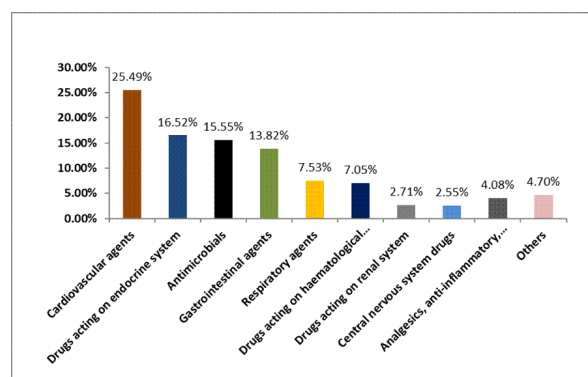
Variables	Number of patients
<b>Age (years)</b>	
65-75 years	227
76-85 years	19
86 years and above	4
Total	250
<b>Gender</b>	
Male	150
Female	100
Total	250

**Table 2: Prevalence of diseases among study population**

Target organ system	Number of patients (N)	Frequency (%)
Cardiovascular system	60	24
Endocrine system	47	18.8
Infectious diseases	40	16
Gastrointestinal system	33	13.2
Respiratory system	25	10
Neurological system	20	8
Haematopoietic system	18	7.2
Renal system	7	2.8
<b>Total</b>	<b>250</b>	

The frequency of the number of associated comorbid conditions is given in Fig. 1. Percentage of patients with no comorbidities were 6%, Majority of patients (34%) suffered from two comorbid conditions followed by 31.6% of patients with three or more comorbid conditions. Diabetes, hypertension and kidney disease were the most common comorbidities in the study population ([ Fig. 1]).

A total of 1824 drugs were prescribed to the study population. A significant portion of the medications prescribed to the elderly population were cardiovascular agents (25.49 %), followed by drugs acting on the endocrine system (16.52 %). The remainder of the drugs acting on other organ systems is shown in Fig. 2.

**Fig. 1: Number of associated comorbid conditions in the study population****Fig. 2: Distribution of drugs according to therapeutic classification**

Out of total number of 1824 drugs prescribed, the most commonly prescribed drug for geriatric patients was pantoprazole (7.73 %). Patients prescribed aspirin, atorvastatin and ceftriaxone were 4.60 %, 3.61 %, and 2.41 % respectively. The metformin-glimepiride combination at 2.02 % reflects the management of diabetes, a common endocrine disorder in this age group. Other commonly prescribed drugs are shown in Table. 3.

WHO drug use prescribing indicators revealed several important findings. The average number of drugs per prescription was 7.4. The percentage of drugs prescribed by their generic names was 54.04 %. 71.98% of the drugs were prescribed from the WHO List of Essential Medicines, 2023. The study also found that injectables were used in 22% of patient encounters. On average, 2.33 antibiotics were prescribed per prescription (Table. 4).

Hypersensitivity reactions were the most frequently observed adverse drug reactions. Several drugs were implicated in causing dermatological lesions, including aspirin, ofloxacin, azithromycin, metronidazole, amoxicillin-clavulanic acid, ceftriaxone, and ciprofloxacin (Table. 5).

**Table 3: Ten most commonly prescribed drugs for geriatric patients**

Sr. no	Medications prescribed	Route	Percentage %
1	Pantoprazole	Parenteral /Oral	7.73
2	Aspirin	Oral	4.60
3	Atorvastatin	Oral	3.61
4	Telmisartan	Oral	2.41
5	Metformin hydrochloride + Glimepiride	Oral	2.02
6	Calcium + Vitamin D3	Oral	1.53
7	Amoxycillin + clavulanate + Potassium	Parenteral	1.42
8	Ceftriaxone	Parenteral	1.31
9	Lactulose	Oral	1.31
10	Paracetamol	Oral / Parenteral	1.20
<b>Total number of drugs prescribed</b>		<b>1824</b>	

**Table 4: WHO core drug use prescribing indicators**

Sr. No.	Prescribing Indicators	Average WHO (n or %)	Standard value
1.	Average number of drugs per prescription	7.4	(1.6 – 1.8)
2.	Percentage of drugs prescribed from essential drugs list (WHO-EML)	71.98%	100%
3.	Percentage of drugs prescribed with generic names	54.04%	100%
4.	Percentage of encounters with an injectable	22%	< 20%
5.	Average number of antibiotics per encounter	2.33	(1.6 – 1.8)

WHO-EML: World Health Organization Essential Medicines List.

These reactions were classified as ‘Probable’ according to the WHO-UMC causality assessment framework due to the observed temporal relationship between drug administration and the reaction, coupled with a positive ‘Dechallenge’ response. Diclofenac was linked to acute kidney injury while haematemesis was observed to be associated with heparin sodium. Hyperkalaemia was associated with valsartan-sacubitril combination and nicorandil. Although optic neuritis caused by ethambutol is well documented, it could be as a result of underlying disease in elderly patients or concomitant medications. These reactions were classified as ‘Possible’ based on the WHO-UMC criteria. Rifampicin caused discoloration of urine to orange in elderly patients, and the reaction was classified as ‘Certain’, as this is a

**Table 5: WHO-UMC Causality Assessment of adverse drug reactions associated with drugs prescribed in elderly**

Sr no	Suspected medication	Adverse drug reaction	Causality assessment
1	Aspirin	Itching and rash	Probable
2	Diclofenac	Acute kidney injury	Possible
3	Iron sucrose	Shivering, thrombophlebitis, breathlessness	Certain
4	Ofloxacin	Itching and rash	Probable
5	Heparin sodium	Hematemesis	Possible
6	Sacubitril + valsartan	Hyperkalaemia	Possible
7	Azithromycin	Itching and rash	Probable
8	Rifampicin	Drug eruptions	Possible
9	Metronidazole	Multiple dark raised skin lesions	Probable
10	Ethambutol hydrochloride	Optic neurosis	Possible
11	Rifampicin	Orange coloured urine	Certain
12	Amoxycillin + potassium clavulanate	Skin rash	Probable
13	Ceftriaxone	Rash, itching, swelling of lips	Probable
14	Ciprofloxacin	Itching and rash	Probable
15	Nicorandil	Hyperkalaemia	Possible

well-documented and characteristic effect of the drug and also ‘Dechallenge’ test was positive. Adverse drug reaction linked to iron sucrose was considered ‘Certain’ because of clear and consistent evidence, including resolution upon withdrawal.

## 4 Discussion

In the study population, the prevalence of diseases revealed that 24% of patients suffered from cardiovascular diseases followed by 19% from endocrine disorders particularly diabetes and 16% from infectious diseases. The high prevalence of cardiovascular diseases among geriatric patients aligns with the well-documented risk factors such as hypertension, hyperlipidemia, and age-related degenerative changes. Endocrine diseases, particularly diabetes mellitus, were also prominent, further reflecting the common metabolic issues faced by the elderly. Comparing these findings with a similar study by Smith *et al.* (2020), where cardiovascular diseases accounted for 27% and endocrine disorders for 21%, shows a consistent trend in the burden of chronic diseases in older adults<sup>8</sup>. Conversely, a conflicting study by Kumar *et al.* (2019) reported lower rates of cardiovascular diseases (18%) and a higher prevalence of endocrine disorders (25%) among a different geriatric population, potentially reflecting differences in lifestyle, healthcare access, and regional disease patterns<sup>9</sup>.

In the study, the most commonly prescribed drugs for geriatric patients were pantoprazole (7%), aspirin (4%), atorvastatin (3%), telmisartan (2.41%) and metformin-glimepiride combination (2%). The high use of pantoprazole reflects the

need for managing gastrointestinal issues, which are common in the elderly. Aspirin, atorvastatin and telmisartan usage highlights the focus on cardiovascular health, while drugs for diabetes, such as the metformin-glimepiride combination, address the high burden of metabolic disorders in this population. These findings align with a study by Gupta *et al.* (2021), which also reported pantoprazole (6.5%) and cardiovascular agents like aspirin (4.3%) and atorvastatin (3.2%) as commonly prescribed medications in geriatric patients<sup>10</sup>.

The study on drug utilization patterns in geriatric patients revealed that the average number of drugs per prescription was 7.4, indicating a high level of polypharmacy, commonly seen in older populations due to multiple comorbidities. The percentage of drugs prescribed by their generic name was 54%, reflecting moderate adherence to cost-effective prescribing practices. A substantial 71.8% of the drugs were from the Essential Drug List (EDL), suggesting good compliance with standardized guidelines. Injectables were used in 22% of patient encounters, indicating a preference for parenteral therapy in certain clinical situations.

When compared with a study by Patel *et al.* (2020), the results showed similar trends, with an average of 7.2 drugs per prescription and 56% of drugs prescribed by their generic name. Additionally, the use of injectables was reported in 25% of encounters, a slightly higher rate compared to this study's 22%<sup>11</sup>.

The findings of this study highlight the prevalence and diversity of adverse drug reactions (ADRs) in geriatric patients, reinforcing the importance of careful medication management in this vulnerable population. Dermatological hypersensitivity reactions, particularly to commonly used antibiotics and analgesics such as amoxicillin-clavulanic acid, ciprofloxacin, and aspirin, necessitate vigilant monitoring due to their significant impact on patient quality of life<sup>12</sup>. Additionally, the identification of diclofenac as a contributor to acute kidney

injury and the association of haematemesis with heparin underscores the need for individualized therapeutic strategies<sup>13</sup>. Moreover, the documented link between hyperkalaemia and the valsartan-sacubitril combination presents a critical consideration for managing patients with heart failure<sup>14</sup>. The classification of optic neuritis related to ethambutol as 'possible' invokes the challenge of discerning medication-related effects from those caused by underlying pathologies, particularly in older adults who often present with polypharmacy<sup>15</sup>. Conversely, the 'certain' classification of rifampicin and iron sucrose-related reactions affirms their predictable nature and reinforces the value of withdrawal testing in confirming causality<sup>16, 17</sup>. Thus, these results underscore the necessity of integrating pharmacovigilance into geriatric care practices to mitigate the risk of ADRs and enhance patient safety.

## 5 Conclusion

This cross-sectional study on drug utilization and adverse drug reactions in elderly patients revealed a high prevalence of cardiovascular and endocrine diseases, with diabetes, hypertension, and kidney disease being the most common comorbidities. Cardiovascular and endocrine drugs were the most frequently prescribed, with a notable trend of polypharmacy. The high use of injectable formulations suggests a need for rapid therapeutic action and better bioavailability in this population. Adverse drug reactions were common, with hypersensitivity reactions being the most frequent. These findings emphasize the need for cautious prescribing and close monitoring to enhance medication safety in elderly patients. However, the study's cross-sectional design limits long-term assessment of drug safety and effectiveness. Additionally, reliance on clinical records for adverse drug reaction reporting may have led to underreporting. Future research with longitudinal follow-up and active monitoring is necessary for a more comprehensive understanding of drug utilization and safety in the elderly.

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