

# Gastrointestinal System Adverse Drug Reactions in Geriatric Patients in Odisha

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## ABSTRACT

**Aim and objective:** Geriatrics is a specialty that deals with the care of the aged. The term “geriatric population” refers to those over 60 years. In India, the elderly make up 8.14% of the population. The pharmacokinetic and pharmacodynamic aspects of the delivered medications are affected by their complicated physiological and pathological profiles. Polypharmacy can lead to various drug–drug interactions and adverse drug reactions (ADRs) in elderly. Gastrointestinal (GI) system ADRs are mostly found in hospitalized elderly. Gastrointestinal ADRs include upper gastrointestinal bleeding (UGI) bleed, diarrhea, etc.; these are the frequent causes of seriousness and hospitalization in geriatric patients. These ADRs are difficult to manage. To prevent ADRs, we need to understand the risk of potential inappropriate prescribing. Deprescribing in appropriate time can prevent medication-related atrocities. Clinical pharmacological reconciliation and review would help us understand anticholinergic burden associated with polypharmacy. Gastrointestinal system ADRs in geriatric patients have been the subject of a small number of research in India, but none have been undertaken in Odisha. Therefore, the aim of this study is to evaluate the GI ADRs that geriatric patients in Odisha experience.

**Materials and methods:** This prospective, hospital-based observational study was carried out by the SCB Medical College and Hospital's Department of Pharmacology and Geriatric Medicine. From August 2016 to July 2018, all elderly patients (aged  $\geq 60$  years) with ADR diagnoses were included. The Suspected Adverse Drug Reaction Reporting Form of Indian Pharmacopoeia Commission Version 1.3 was filled out with the ADRs and their features. The prevalence and profile of GI system ADRs were observed. The WHO-UMC System rated their causation, the Hartwig's Severity Scale evaluated their severity, and the Schumock and Thornton Preventability Scale evaluated their preventability.

**Results:** In 2 years, 236 geriatric ADRs were documented, 11% of which involved the GI system. Out of the GI system ADRs, 85% ADRs were found to be in possible category, 92.3% were found to be of moderate in intensity, and 84.6% were found to be probably preventable. The most frequent GI system ADR identified was UGI bleeding caused by nonsteroidal anti-inflammatory drugs (NSAIDs) (61.5%).

**Conclusion:** Most of the ADRs were found to be of moderate intensity according to Hartwig's Severity Scale and probably preventable according to Schumock and Thornton Preventability scale. NSAID-induced UGI bleeding is the major type of GI system ADR found in this study.

**Keywords:** Adverse drug reaction, Antidiabetic agents, Central nervous system, Elderly, Gastrointestinal, Hospitalized, Upper gastrointestinal bleeding.

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## INTRODUCTION

- Adverse drug reactions are unwanted or adverse reactions that occur after administration of one or more drugs. Elderly prescriptions account for half of prescriptions.<sup>1</sup>
- Adverse drug reaction: A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function.<sup>2</sup>
- Adverse drug reactions risk is increasing day by day in elderly because their physiological and pathological changes can alter pharmacokinetics and pharmacodynamics of administered drugs.<sup>2</sup>
- According to data, ADR is one of the most common causes of death and morbidity in developed countries. According to recent USFDA data, ADR is now the 4–6th leading cause of death.<sup>3</sup> Due to the effect of age on drug disposition especially renal and hepatic clearance in elderly patients, same therapeutic dose may produce an exaggerated pharmacological response manifested in terms of ADRs. Early detection and prevention of ADRs play an important role to decrease the mortality and morbidity keeping in view the high cost and resources involved in the management of ADRs.

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- Various studies from abroad and India show that polypharmacy is prevalent and correlates with increased potential for ADR, inappropriate prescribing, and drug interactions.<sup>4–8</sup>

- The ADRs in elderly adults are four times more common than younger adults. One in six hospital admissions of elderly patients is due to ADRs.<sup>9-11</sup>
- Different literature survey reveals that out of all geriatric ADRs in India, 29–32% were GI system ADRs such as upper GI bleed, diarrhea, etc.<sup>12-15</sup>
- To prevent ADRs, we need to understand the risk of potential inappropriate prescribing. Deprescribing in appropriate time can prevent medication-related atrocities. Clinical pharmacological reconciliation and review would help us to understand anticholinergic burden associated with polypharmacy.<sup>16,17</sup>
- Adverse drug reactions are more in elderly and can lead to serious hospitalization. Very few studies conducted regarding this in abroad and India, and no such type of study in Odisha is found.
- Therefore, this study of ADRs in the GI in elderly patients is being conducted at our tertiary care hospital.

## AIMS AND OBJECTIVES

This study was carried out to study GI ADRs with the following objectives:

- Prevalence of GI system ADRs in geriatric patients
- Profile of GI system ADRs in elderly
- Causality of GI ADRs assessed by Naranjo ADR Probability and WHO-UMC scale
- Severity of GI ADRs evaluated by Hartwig's scale
- Preventability of GI ADRs evaluated by Schumock and Thornton scale in our tertiary care teaching hospital

## METHODOLOGY AND STUDY DESIGN

- Study type: A prospective, hospital-based observational study
- Study site: Department of Pharmacology (ADR monitoring center) in collaboration with Geriatric Medicine department of SCB Medical College and Hospital, Cuttack
- Study period: August 2016 to July 2018
- Informed consent was taken from all geriatric patients
- Ethical committee approval number is 583/26.02.18

### Inclusion Criteria

- Geriatric patients ( $\geq 60$  years) of both sexes presenting in the Department of Geriatric Medicine with all types of suspected ADRs were included in the study.
- The detailed information of the GI system ADRs was evaluated.

### Exclusion Criteria

- Patients who refused to give consent, those with substance abuse, and those with intentional or accidental intoxication were excluded from the study.

### Statistical Analysis

Correct data collection after all patient consent. Data disaggregated by age-groups (60–69, 70–79, and  $\geq 80$  years) and gender-wise, and evaluated statistically in Excel. Most data are expressed as percentages.

## RESULTS

Table 1 shows the number of ADRs that affected various body systems. The most commonly affected body system was skin system, i.e., 100 (42.3%) ADRs, followed by metabolic system, i.e., 68 (28.8%)

**Table 1:** ADRs in different body system

System involved	No. of ADR (n = 236)	% of ADR
Skin	100	42.3
Metabolic	68	28.8
GI	26	11
CNS	12	5
Respiratory	10	4.2
Blood	10	4.2
Musculoskeletal	6	2.5
Renal	4	1.6

**Table 2:** Demographic profile of GI system ADRs in geriatric patients

Gender	No. (%ADRs)
Male	21 (80.8%)
Female	5 (19.2%)

**Table 3:** Number and percentage of GI system ADRs in different age-groups

Age-groups	No. and % of ADRs
60–69 years	20 (76.9%)
70–79 years	4 (15.4%)
$\geq 80$ years	2 (7.7%)

**Table 4:** Type and percentage of GI system ADRs due to different drugs

Type of GI system ADRs	Number of ADRs with %	Drugs causing ADRs
NSAID-induced UGI bleed	16 (61.5%)	Aceclofenac and diclofenac
Antibiotic-induced diarrhea	8 (30.8%)	Amoxycyclav and penclav
Immunosuppressant-induced mouth ulcer	2 (7.7%)	Methotrexate

ADRs followed by GI system, i.e., 26(11%), central nervous system (CNS) system, i.e., 12 (5%), and respiratory system, i.e., 10 (4.2%).

The total ADRs in geriatric patients are 236, out of which GI system ADRs are 26. Table 2 depicts the demographic profile of GI system ADRs in geriatric patients. Maximum 80.8% GI system ADRs found in males followed by females (19.2%).

The total ADRs in geriatric patients are 236, out of which GI system ADRs are 26. Table 3 above shows number and percentage of GI system ADRs in different age-groups. Maximum 76.9% of GI system ADRs found in group (60–69 years). Least ADRs (7.7%) found in very old age-group ( $\geq 80$  years).

Table 4 depicts type and percentage of GI system ADRs due to different drugs. Maximum GI system ADRs are NSAID-induced UGI bleed (61.5%) found in our study due to diclofenac and aceclofenac followed by antibiotic-induced diarrhea (30.8%) due to amoxycyclav and penclav.

Table 5 depicts NSAID-induced UGI bleed (61.5%) most common GI system ADRs found in our study followed by antibiotic-induced diarrhea (30.8%) followed by immunosuppressant-induced mouth ulcer (7.7%).

**Table 5:** Percentage of different GI system ADRs

NSAID-induced UGI bleed	16 (61.5%)
Antibiotic-induced diarrhea	8 (30.8%)
Immunosuppressant-induced mouth ulcer	2 (7.7%)

**Table 6:** Causality assessment by various scales

Causality category	WHO-UMC scale Number of ADRs (%)	Naranjo ADR probability scale-Number of ADRs (%)
Certain/definite	0	0
Probable	4(15%)	4(15%)
Possible	22(85%)	22(85%)
Unlikely	0	0
Conditional/ unclassifiable	0	0
Total	26 (100%)	26 (100%)

**Table 7:** Severity assessed by Hartwig's scale

Severity	Level	Number of ADRs	Total (%)
Mild	1	0	0
	2	0	
Moderate	3	0	92.3%
	4	24	
Severe	5	2	7.7%
	6	0	
	7	0	

**Table 8:** Preventability assessment by Schumock and Thornton scale

Preventability of ADRs	
Definitely preventable	2 GI system ADRs
Probably preventable	22 GI system ADRs
Not preventable	2 GI system ADRs

Table 6 shows the percentage of ADRs attributed to various categories of both WHO-UMC and Naranjo scales. WHO-UMC scale shows that 22 (85%) ADRs in possible category, 4(15%) in probable category. Naranjo Probability scale shows that 22(85%) ADRs in possible category and 4 (15%) ADRs in probable category.

Table 7 above shows Hartwig's severity scale, according to this scale 24(92.3%) ADRs were found to be of moderate intensity and 2 (7.7%) ADRs were found to be of severe intensity.

The total GI system ADRs in geriatric patient are 26. Table 8 above depicts preventability of ADRs by Schumock and Thornton preventability scale. According to this scale, 22 (84.6 %) ADRs were observed to be in probably preventable, 2 (7.7 %) were observed to be in definitely preventable, and 2 (7.7%) were observed to be in not preventable category.

## DISCUSSION

- This study documented 26 (11%) gastrointestinal ADRs over the 2-year period, compared to 102 (31.88%) ADRs observed by Devi et al.<sup>9</sup> 29 (29.89%) of ADR was observed by Pauldurai et al.<sup>2</sup> (January 2013–January 2014) from ADR in older adults in a corresponding study.

- In this study, 77% GI system ADRs in age-group 60–69 years with 8% ADRs reports  $\geq 80$  years, which may be due to less patients above 80 years coming to the Department of Geriatric Medicine.
- Up to 80.8% ADR was observed from the gastrointestinal tract in men in our study. This largely corroborates the study of Devi et al.<sup>9</sup> 177 (55.31%).
- In this study, GI ADR (11%) ranked third among all elderly ADRs, in contrast to GI ADR (29.89%) reported by Pauldurai et al.<sup>2</sup> (31.88%), GI system ADRs observed by Devi et al.<sup>9</sup>
- In this study, NSAID-induced upper gastrointestinal bleeding (61.5%) was the largest type of ADR in the gastrointestinal system compared to upper gastrointestinal bleeding (41.3%) reported by Pauldurai et al.<sup>2</sup>

## CONCLUSION

- Most of the GI system ADRs found in this study were moderate in intensity and probably preventable.
- Mostly, GI system ADRs found in males in this study.
- The largest gastrointestinal ADRs in this study is NSAID-induced upper gastrointestinal bleeding.
- ADR monitoring should be done perfectly by ADR monitoring centers in worldwide to provide maximum health benefit to patients in the society and collaborative effort of physicians, clinical pharmacologists, pharmacologists, and other medical staffs needed for this.

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