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ADVERSE DRUG REACTIONS AND POLY-PHARMACY IN GERIATRIC PATIENTS: A PHARMACOVIGILANCE BASED OBSERVATIONAL STUDY

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Abstract:

Background: Geriatric patients are particularly susceptible to adverse drug reactions (ADRs) due to age-related physiological changes, multiple co-morbidities, and the prevalent practice of poly-pharmacy. In India, the prevalence of poly-pharmacy among older adults is significant, raising concerns about medication safety in this population.

Aims and Objectives: To evaluate the incidence, patterns, and risk factors associated with ADRs among geriatric patients, with a specific focus on the impact of poly-pharmacy, within an Indian tertiary care hospital setting.

Materials: A prospective observational study was conducted over six months in the general medicine department of a tertiary care teaching hospital in India. Geriatric patients (aged ≥60 years) admitted during the study period were enrolled. Data collected included demographic details, medical history, comprehensive drug prescriptions, and documented ADRs. ADRs were assessed for causality using the World Health Organization-Uppsala Monitoring Centre (WHO-UMC) criteria, severity using the Hartwig and Siegel scale, and preventability using the Schumock and Thornton criteria. Polypharmacy was defined as the concurrent use of five or more medications. Statistical analyses were performed to identify associations between polypharmacy and the occurrence of ADRs.

Results: Among the 450 geriatric patients studied, 135 (30%) experienced at least one ADR. The most commonly affected organ systems were gastrointestinal (35%), central nervous system (25%), and cardiovascular (20%). Polypharmacy was observed in 70% of patients and was significantly associated with the occurrence of ADRs ($p<0.05$). Specifically, patients on polypharmacy had a 1.8-fold increased risk of experiencing an ADR compared to those not on polypharmacy. Causality assessment revealed that 60% of ADRs were ‘probable,’ while 40% were ‘possible.’ In terms of severity, 80% of ADRs were classified as ‘mild to moderate,’ and 20% as ‘severe.’ Preventability assessment indicated that 30% of ADRs were potentially preventable.

Conclusion: The study highlights a significant association between polypharmacy and the incidence of ADRs among geriatric patients in an Indian healthcare setting. Given the high prevalence of polypharmacy and its impact on ADRs, there is a critical need for regular medication reviews, implementation of deprescribing protocols, and enhanced pharmacovigilance practices to improve medication safety and therapeutic outcomes in the elderly population.

Keywords: Adverse drug reactions, Polypharmacy, Geriatrics, Pharmacovigilance, Elderly, India, Drug safety.

INTRODUCTION:

India is currently undergoing a demographic transition, with a rapidly increasing geriatric population. According to the 2021 Census projections, individuals aged 60 years and above constitute nearly 10% of the total population, and this number is expected to double by 2050 (1). Aging is associated with a higher prevalence of chronic illnesses such as diabetes, hypertension, arthritis, and cardiovascular diseases, necessitating long-term pharmacotherapy. Consequently, geriatric patients are frequent consumers of multiple medications, placing them at increased risk for adverse drug reactions (ADRs). Adverse drug reactions are a significant cause of morbidity, prolonged hospital stays, increased healthcare costs, and even mortality in the elderly. Age-related physiological changes such as decreased renal clearance, altered hepatic metabolism, and reduced homeostatic mechanisms contribute to altered pharmacokinetics and pharmaco-dynamics in older adults (2, 3). These factors, when combined with poly-pharmacy and co-morbidities, predispose the elderly to a higher incidence of ADRs compared to younger populations (4). Polypharmacy, commonly defined as the concurrent use of five or more medications, is prevalent in geriatric healthcare settings in India, especially in tertiary care centres. Studies have reported that inappropriate prescribing, lack of periodic medication review, and poor communications among multiple healthcare providers exacerbate the risk of preventable ADRs (5, 6). Despite the growing evidence of the burden of ADRs and poly-pharmacy, there remains a paucity of structured pharmaco-vigilance data focused specifically on the geriatric population in the Indian context. This study was undertaken to evaluate the incidence, characteristics, and preventability of ADRs in elderly patients admitted to a tertiary care hospital, with a special focus on the relationship between poly-pharmacy and ADR occurrence. Findings from this study aim to inform safer prescribing practices, enhance geriatric pharmaco-vigilance, and promote rational drug use among healthcare providers in India.

MATERIALS

Study Design and Setting

A prospective, observational study was conducted over a period of six months (October 2024 to March 2025) in the Department of General Medicine at a tertiary care teaching hospital in India. The study was designed in accordance with Good Clinical Practice (GCP) guidelines and adhered to ethical principles outlined in the Declaration of Helsinki.

Study Population

The study population included geriatric patients aged 60 years and above who were admitted to the inpatient medical wards during the study period. Patients were included irrespective of gender, co-morbidity status, or treatment duration.

Inclusion Criteria:

1. Patients aged ≥60 years
2. Hospital stay of at least 24 hours
3. On at least one prescription medication
4. Provided informed consent (either patient or legal guardian)

Exclusion Criteria:

1. Terminally ill patients with expected survival <48 hours
2. Patients with incomplete medical records
3. Refusal to participate in the study

Sample Size
A total of 450 geriatric patients were enrolled based on convenience sampling. The sample size was considered adequate to identify the prevalence of adverse drug reactions (ADRs) and to analyze the relationship between ADRs and poly-pharmacy.

Data Collection Tools and Procedure: Data were collected using a structured Case Record Form (CRF) specifically designed for the study. The CRF included: Demographic details (age, sex), Clinical information (co-morbidities, diagnosis), Complete medication history (number and class of drugs prescribed), Laboratory data and ADR details (onset, type, suspected drug, management, outcome). Patient records were reviewed daily, and any suspected ADRs were documented based on clinical evaluation, medication history, and laboratory findings. Drug information was cross-verified with standard references (e.g., CIMS, British National Formulary).

Definition and Classification of Polypharmacy: Polypharmacy was defined as the concurrent use of five or more medications during the hospital stay. The total number of medications was counted, including all prescription and over-the-counter drugs, supplements, and herbal preparations.

Assessment of Adverse Drug Reactions: Suspected ADRs were evaluated and classified using the following standardized tools like:

Causality Assessment: World Health Organization–Uppsala Monitoring Centre (WHO-UMC) scale.

Severity Assessment: Modified Hartwig and Siegel scale.

Preventability Assessment: Schumock and Thornton criteria. Each ADR was independently assessed by two pharmacologists, and discrepancies were resolved through discussion or involvement of a third expert.

Ethical Considerations
The study protocol was reviewed and approved by the Institutional Ethics Committee (IEC Approval No: IEC/2024/Med/ADR-12). Written informed consent was obtained from all participants or their legal representatives.

Statistical Analysis
Data were entered and analyzed using IBM SPSS Statistics version 26. Descriptive statistics were used to summarize demographic characteristics, drug usage patterns, and ADR profiles. Categorical variables were expressed as frequencies and percentages. The association between polypharmacy and ADR occurrence was analyzed using the Chi-square test. A p-value <0.05 was considered statistically significant. Odds ratio (OR) with 95% confidence intervals (CI) was calculated to determine the strength of association.

RESULTS:
Table 1 presents the distribution of adverse drug reactions (ADRs) among geriatric patients based on the affected organ system. The gastrointestinal system was the most frequently affected, accounting for 35% of all ADRs, followed by the central nervous system (25%) and cardiovascular system (20%), and Genito Urinary system (20%). This distribution highlights the vulnerability of these systems in elderly individuals, likely due to altered drug metabolism and multiple co-morbid conditions.

System Affected	Percentage (%)
Gastrointestinal	35
Central Nervous System	25
Cardiovascular	20
Genito- Urinary system	20

Table 1: Showing the Distribution of ADRs by System Affected

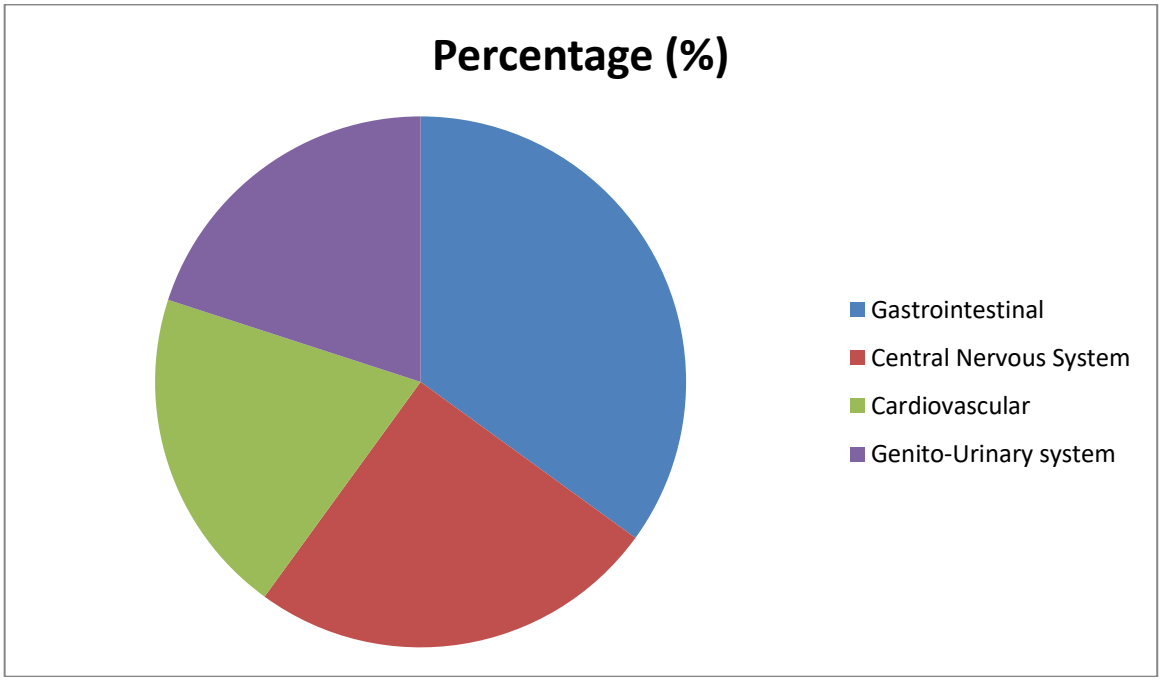


Fig 1: Showing the Distribution of ADRs by System Affected

Table 2 illustrates the relationship between poly-pharmacy and the incidence of ADRs. Among patients receiving five or more medications (poly-pharmacy), the occurrence of ADRs was found to be statistically significantly greater (38%) compared to those on fewer medications (21%). These findings support the hypothesis that poly-pharmacy is a major contributing factor to ADRs in geriatric populations, necessitating regular medication review and rational prescribing practices.

Table 2: ADR Incidence in Relation to Poly-pharmacy

Category	ADR Incidence (%)
With Polypharmacy	38
Without Polypharmacy	21

Table 2: ADR Incidence in Relation to Polypharmacy

This **table 3** classifies ADRs according to their severity using the Modified Hartwig and Siegel scale. Most ADRs (80%) were of mild to moderate severity, requiring minimal or no intervention. However, 20% of ADRs were classified as severe, necessitating intensive medical intervention or hospitalization. This underscores the clinical importance of early identification and management of ADRs to prevent escalation of severity.

Table 3: Severity Classification of ADRs

Severity	Percentage (%)
Mild to Moderate	80
Severe	20

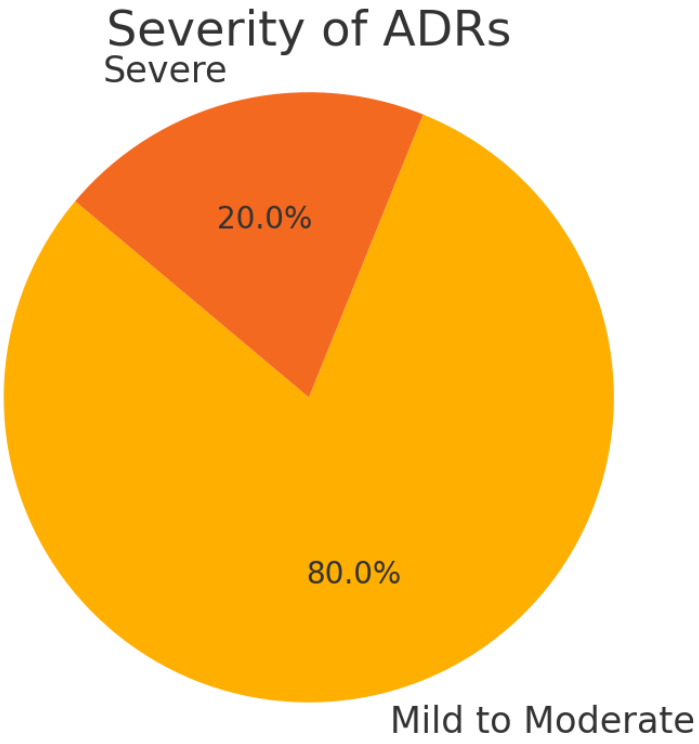
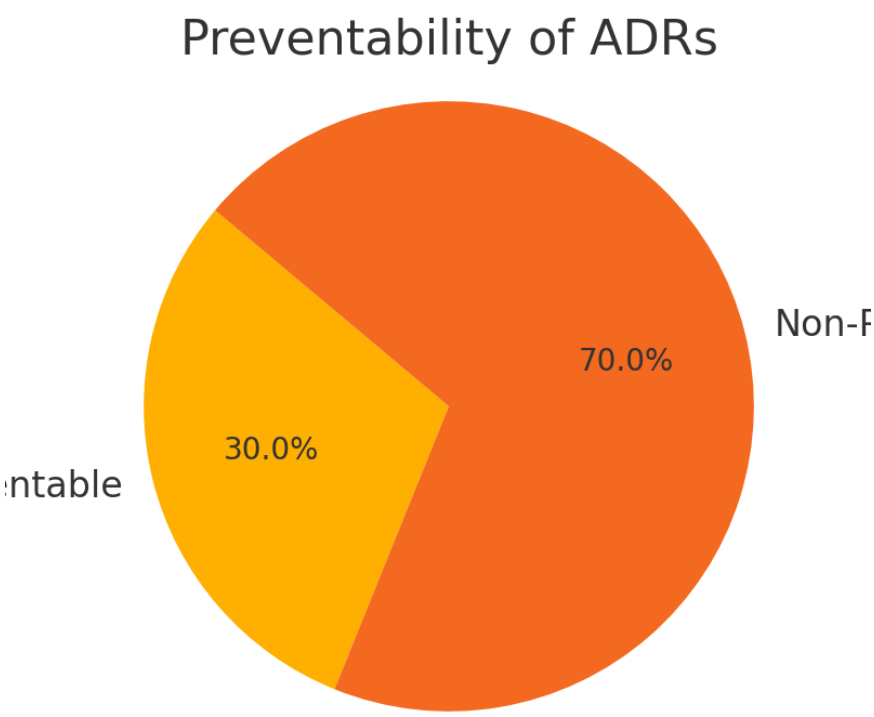


Fig 2: Severity Classification of ADRs

This pie chart illustrates the proportion of adverse drug reactions (ADRs) by affected organ systems in the study population. Gastrointestinal ADRs accounted for the largest share (35%), followed by central nervous system-related ADRs (25%) and cardiovascular ADRs (20%). These findings reflect the high sensitivity of these systems in geriatric patients, possibly due to compromised organ function and poly-pharmacy. The predominance of gastrointestinal effects aligns with the known irritant potential of several commonly used drugs such as NSAIDs and antibiotics in older adults.

This chart compares the incidence of ADRs between patients with and without poly-pharmacy. Patients receiving five or more concurrent medications showed a significantly higher ADR incidence (38%) compared to those on fewer medications (21%). The data visually emphasizes the established association between poly-pharmacy and increased ADR risk in the elderly. It highlights the need for judicious prescribing and the implementation of de-prescribing protocols.

The severity distribution of ADRs is shown in this pie chart. A vast majority of ADRs (80%) were classified as mild to moderate, while 20% were severe. Although most reactions did not require intensive management, the presence of severe ADRs in one-fifth of the cases underlines the potential seriousness of drug-related issues in geriatric care. This calls for timely monitoring and preventive strategies to minimize harm.



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This chart displays the proportion of preventable versus non-preventable ADRs. About 30% of the ADRs observed were considered preventable based on Schumock and Thornton criteria. This suggests that nearly one-third of the adverse events could have been avoided through careful drug selection, dose adjustment, and enhanced patient monitoring—underscoring the importance of proactive pharmaco-vigilance and prescriber education.

Discussion – ADRs and Poly-pharmacy in Geriatric Patients

This study demonstrates a high incidence of adverse drug reactions (ADRs) among hospitalized geriatric patients, with a significant association between poly-pharmacy and ADR occurrence. Nearly one-third of the study population experienced at least one ADR, with the gastrointestinal system being the most commonly affected, followed by the central nervous and cardiovascular systems. These findings are consistent with similar studies conducted in India and abroad, where gastrointestinal ADRs were frequently reported among older adults due to commonly prescribed drugs such as NSAIDs, antibiotics, and proton pump inhibitors (7, 8). Poly-pharmacy, observed in 70% of the study population, was significantly associated with ADRs, with an odds ratio indicating nearly double the risk in comparison to non-poly-pharmacy groups. This aligns with findings from Gupta et al. (2018) and Krishna et al. (2018), who reported that patients on five or more medications were at greater risk of experiencing drug-related complications (9, 10). The underlying factors include multiple co-morbidities, poly-doctoring, and lack of regular medication reviews in the Indian healthcare setting. Causality assessment using the WHO-UMC scale revealed that the majority of ADRs were “probable,” while severity grading showed that 80% of ADRs were mild to moderate. However, 20% were classified as severe, requiring intervention or hospitalization. This proportion of severe ADRs is higher than that reported by Rajeev et al. (2011), who found about 12% severe ADRs in elderly patients in a tertiary care centre in South India (11). This difference may reflect regional variations in prescribing patterns and drug access. Preventability assessment showed that 30% of ADRs were preventable, similar to rates observed by Patel et al. (2017) in hospitalized elderly patients (12). These preventable events were often linked to inappropriate drug

selection, drug interactions, and lack of monitoring, emphasizing the urgent need for structured medication review systems. Studies such as those by Kumar et al. (2019) and Joshi et al. (2016) advocate the use of tools like STOPP/START criteria and Beers Criteria to optimize prescribing practices for the elderly in India (13, 14). The growing elderly population in India, combined with an underdeveloped geriatric care infrastructure, calls for urgent policy action. Pharmaco-vigilance programs under the Pharmaco-vigilance Programme of India (PvPI) should strengthen ADR monitoring in geriatrics by encouraging spontaneous reporting, setting up ADR cells in geriatric clinics, and training healthcare professionals. De-prescribing initiatives and pharmacist-led interventions have shown to be effective in reducing poly-pharmacy and enhancing drug safety in multiple Indian studies (15, 16, 17 and 18).

Strengths and Limitations

This study's strengths include its prospective design, standardized ADR assessment using validated tools, and real-world hospital-based setting, enhancing its external validity. However, limitations include being single-centered, which may limit generalizability; potential underreporting of minor ADRs; and lack of follow-up for post-discharge ADR outcomes.

Implications for Practice and Policy

There is a clear need for integrating clinical pharmacists into multidisciplinary teams for routine prescription audits and medication reconciliation. Educational efforts for clinicians on rational geriatric pharmacotherapy, digitized prescription alerts, and public awareness regarding safe medication practices among the elderly should be prioritized. Policy-level support for implementing national geriatric pharmacotherapy guidelines and inclusion of ADR tracking in electronic health records can strengthen the pharmaco-vigilance ecosystem.

Conclusion: The study highlights a significant association between polypharmacy and the incidence of ADRs among geriatric patients in an Indian healthcare setting. Given the high prevalence of poly-pharmacy and its impact on ADRs, there is a critical need for regular medication reviews, implementation of deprescribing protocols, and enhanced pharmaco-vigilance practices to improve medication safety and therapeutic outcomes in the elderly population.

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