RESEARCH PAPER

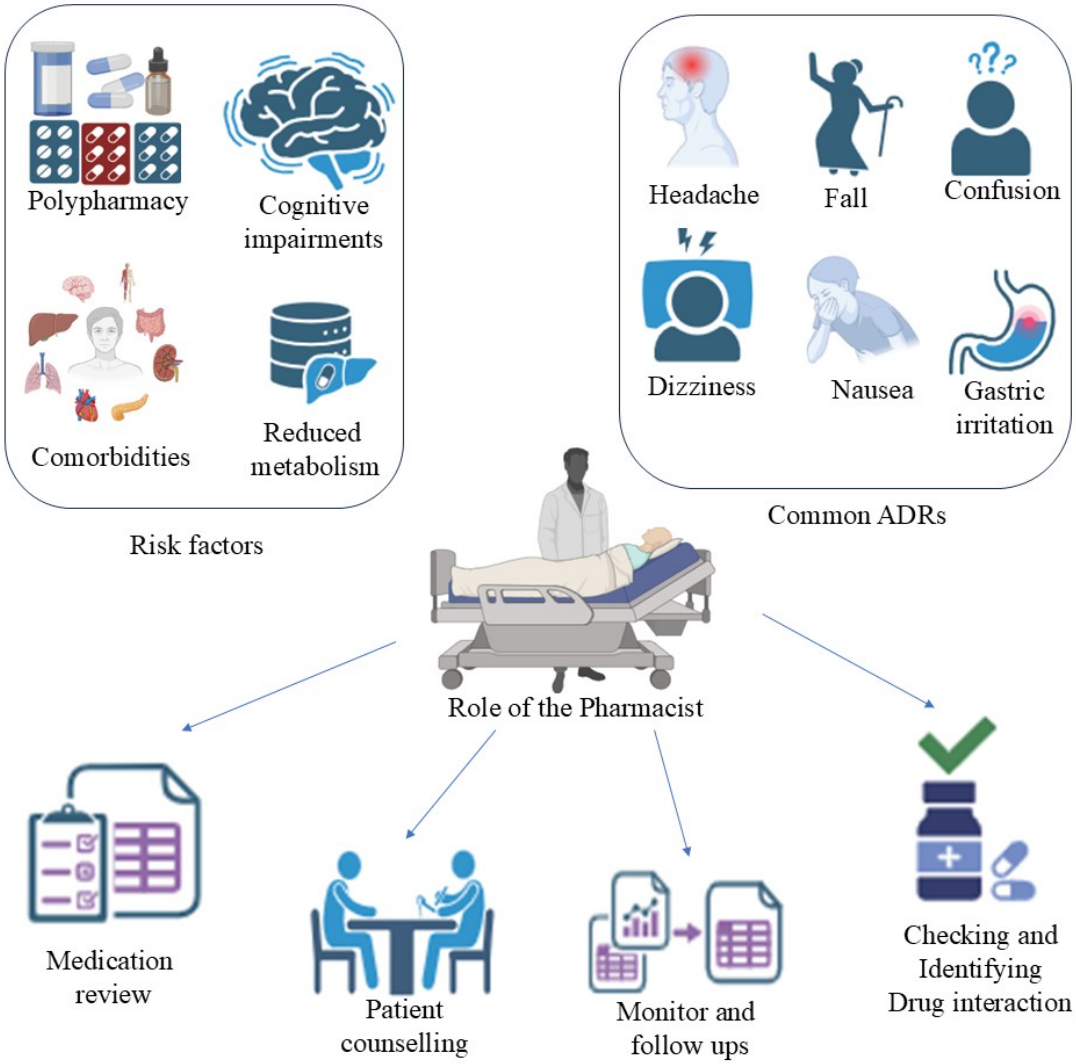
A Prospective Study Of Adverse Drug Reaction Severity And Pharmacist Intervention Outcomes In Hospitalized Elderly Patients

Soumya M K[1], R. Margret Chandira [2*]

[1] Research Scholar,Vinayaka Mission's Research Foundation, VMCOP, Salem, Tamil Nadu, India,636008
[2*]Professor and HOD, Department of Pharmaceutics,Vinayaka Mission's College of Pharmacy(VMCOP), Salem, Tamil Nadu, India,636008

***Corresponding Author;** M.Pharm,PhD
*Professor and HOD, Department of Pharmaceutics, VMCOP, Salem, Tamil Nadu, India,636008.

GRAPHICAL ABSTRACT



ABSTRACT

Background:
Drug-related problems have a significant influence on clinical outcomes and can cause unexpected healthcare burden. The adverse drug reactions (ADRs) increase the incidents that have a negative influence on drug-related complications. Pharmacists play a critical role in mitigating such risks associated with ADRs.

Objectives: To analyse the patterns of ADRs and their severity among elderly inpatients and to evaluate the outcome of pharmacist intervention using the CLEO tool.

Methods: A prospective interventional study was conducted among 365 inpatients aged 60 years and above. Patients admitted to clinical oncology, palliative care, organ transplantation and intensive care units were excluded. The ADRs were reported, and causality and severity were assessed using the Naranjo algorithm and the WHO-UMC criteria. The

*Author for Correspondence:R. Margret Chandira

data were documented using Microsoft Excel 2007 and statistically analysed. Pharmacist-led interventions were provided and evaluated using the CLEO Tool.
Results: Among 365 elderly inpatients, the incidence of ADRs was 31%. The clinical manifestations of most reactions were haematological abnormalities (21%). In causality assessment, the majority of reactions (50.4%) showed a possible association with the suspected medication (p = 004) and were of moderate severity (45.1%). CLEO scoring of Pharmacist-led interventions reflected 62% clinical impact (p=0.01), 47% economic outcomes (p=0.04), and 34% organizational improvements.
Conclusion: There was a higher incidence of ADRs among elderly patients, showing a significant association with the suspected drug. Also, the severity of most of these ADRs was moderate. Based on these observations, it was concluded that interventions offered by pharmacists resulted in better detection and handling of ADRs among elderly inpatients.

Keywords: Adverse Drug Reactions, Elderly patients, Causality, Severity, CLEO tool
How to cite this article: Soumya MK, Chandira RM. A Prospective Study of Adverse Drug Reaction Severity and Pharmacist Intervention Outcomes in Hospitalized Elderly Patients. Int J Drug Deliv Technol. 2026;16(13s): 779-790.
DOI: 10.25258/ijddt.16.13s.84.

INTRODUCTION

Adverse Drug Reactions (ADR) refer to the unintended effects of drugs manifesting at conventional doses when used in humans for the treatment or prevention of disease [1]. The presence of ADRs when treatment is ongoing is not desirable and can influence the treatment outcomes. Based on their potential severity, the ADRs can influence the hospital stay of the individual; this directly affects the treatment costs and the quality of life [2]. Though the ADRs cannot be avoided when treatment takes place, it is imperative to continue monitoring the situation to avoid complications arising from taking the medications [3].

The possibility of getting adverse reactions from the medications is high among the elderly when compared to the young and healthy individual [4]. The elderly are more likely to suffer from multiple conditions, leading to multiple prescriptions. Polypharmacy is a major cause of drug-related problems among elderly patients. The common drug-related issue caused by polypharmacy is drug interactions [5]. Drug interactions can significantly affect therapeutic efficacy and may cause adverse events, thereby impairing quality of life [6].

As per the literature evidence, the overall ADRs incidence reported among geriatric patients were 12.94% [7]. In India, ADRs incidence among the geriatric group ranges from 5.9 to 6.7% [8]. The incidence of ADRs among the elderly population in Asia was 12.15%, whereas in Australia and Europe it was 22.94% and 12.34%, respectively. In the United States, on average, 18.76% of the elderly patients suffer from ADRs during the course of the treatment [7]. The overall ADRs incidence reported among geriatric patients were 17.53%, among outpatients 19.54%, and hospitalisation due to ADRs 6.92% [7,9]. The incidence of ADRs is higher in the elderly population compared to other age groups [10]. Various scales are used in clinical settings to assess the causality of ADRs, including the WHO-UMC scale and Naranjo's algorithm [11,12].

The elderly population needs specialised care services to monitor treatment, improve medication adherence, and reduce medication- and disease-related complications to enhance quality of life. Frequent monitoring and continuous follow-up are required among elderly patients to identify and resolve ADRs and prevent medication-related complications.[13] The study objective was to analyse the pattern of adverse drug reactions, and their severity among elderly inpatients of a tertiary care hospital (TCH) and also to provide pharmacist interventions to identify, resolve and/ or prevent ADRs. This study employed the CLEO (Clinical, Economic, and Organisational) tool, a comprehensively validated and widely acknowledged instrument suitable for evaluating pharmacist interventions.[14]. By capturing clinical relevance, cost implications, and organisational benefits, the CLEO tool (Annexure 1) enables a holistic evaluation of pharmaceutical care services.

MATERIALS AND METHODS

Study design and study area

A prospective interventional study was conducted at a TCH in the northern district of Kerala for 6 months (July 2024 to January 2025).

Sampling method

Patient enrolment was conducted using convenience sampling.

Study Criteria

i) Inclusion and exclusion criteria

The study included geriatric inpatients aged 60 years and older of both genders with acute illness who were willing to participate. Patients admitted to clinical oncology, palliative care, organ transplant recipients and patients in intensive care units were excluded from the study.

Sample size

Considering the proportion of ADR occurrence (P) as 0.5, a marginal error (d) of 5%, and a Z value of 1.96, the sample size was calculated as 329 elderly patients. Anticipating a 10% non-response rate, the sample size was adjusted to 365 elderly patients. The sample size was calculated using the formula:

$$n = (Z\alpha/2)^2 P(1-P)/d^2$$

Study Procedure

The study was conducted on the inpatient departments of a TCH, and the subjects were selected by visiting the hospital after consent was taken, on the basis of the inclusion and exclusion criteria. The information required for the study was collected by personal interviews, case records, prescription charts, and laboratory reports. The parameters to be collected for the study include demographic, medical, medication, drug, ADRs, and relevant laboratory information.

The ADRs that occurred during the treatment were collected and submitted to the concerned authorities. The assessment of the causality of the ADRs was done by using the WHO-UMC scale [11], and the Naranjo causality assessment scale [12].

The severity and the preventability of the ADR were assessed by the Modified Hartwig and Siegel Scale [15], and the Modified Schumock and Thornton's Criteria [16], respectively. The collected data were documented in Microsoft Excel 2007 and analyzed with the Statistical Package for Social Sciences (SPSS) software Version 26.

Ethical Considerations

Permissions were obtained from the Institutional Ethics Committee before initiating the study, Reference No.: 001/2022/CCOPS/IEC. The participants were enrolled only after obtaining written consent.

Statistical Data Analysis

Descriptive statistics were computed for all variables, with categorical data such as frequencies and proportions as well as continuous data include means plus standard deviations or medians. Associations between categorical variables were assessed using the Chi-Square test of independence. A p-value of less than 0.05 was considered statistically significant.

RESULTS

Among 365 elderly patients, ADRs were identified in 113. The causality assessment of the ADRs was carried out using the WHO-UMC scale and the Naranjo causality assessment scale. The severity and preventability of the ADRs were assessed using the Modified Hartwig and Siegel Scale and the Modified Schumock and Thornton's criteria, respectively.

Demographic characteristics of the study population with ADRs

Among 113 ADRs reported, the majority of reactions occurred among patients aged 60-70 years (61.1%), followed by those aged 71-80 years (32.7%) and those aged over 81 years (6.2%). The incidence of ADRs was higher in males than in females. **(Table 1)**

TABLE 1: BASELINE CHARACTERISTICS OF THE STUDY POPULATION

Variables	**Frequency (%) n = 113**
Age group	
60 – 70 years	69 (61.1)
71 – 80 years	37 (32.7)
Above 80 years	07 (6.2)
Gender	
Male	71 (62.8)
Female	42 (37.2)

Disease condition of the study population with ADRs

The most common disease conditions presented by the study population with ADRs were hypertension (28 patients), followed by diabetes mellitus (23 patients) and stroke (14 patients). The other disease conditions presented by the study population are listed in **Table 2**.

TABLE 2: COMMON DIAGNOSTIC CONDITIONS

Diagnosis	**Frequency (%)**
Hypertension	28 (24.9)
Diabetes Mellitus	23 (20.0)
Stroke	14 (11.4)
Congestive Heart Failure	10 (8.6)
Ischemic Stroke	7 (5.7)
Myocardial Infarction	7 (5.7)
Rheumatoid Arthritis	7 (5.7)
Urinary Tract Infection	7 (5.7)
Psychiatric illness	5 (4.5)

Pulmonary Tuberculosis	5 (4.5)

ADRs occurred in the study population

In a total of 365 elderly patients, ADRs occurred in 113 patients during the therapy. The ADRs presented by the study population include haematological abnormalities (21%), skin reactions (17.5%), gastrointestinal manifestations (16.66%), renal problems (11.4%), electrolyte imbalances (10.6%), Cardiovascular (6.1%), general systemic (7.8%), respiratory (4.4%), and neuronal problems (3.5%).

The incidence of Cardiovascular (6.1%), general systemic (7.8%), respiratory (4.4%), and neuronal (3.5%) **(Figure 1)**. ADRs were comparatively less common in the cohort. However, it had a significant clinical implication due to its potential severity and its impact on therapy outcomes.

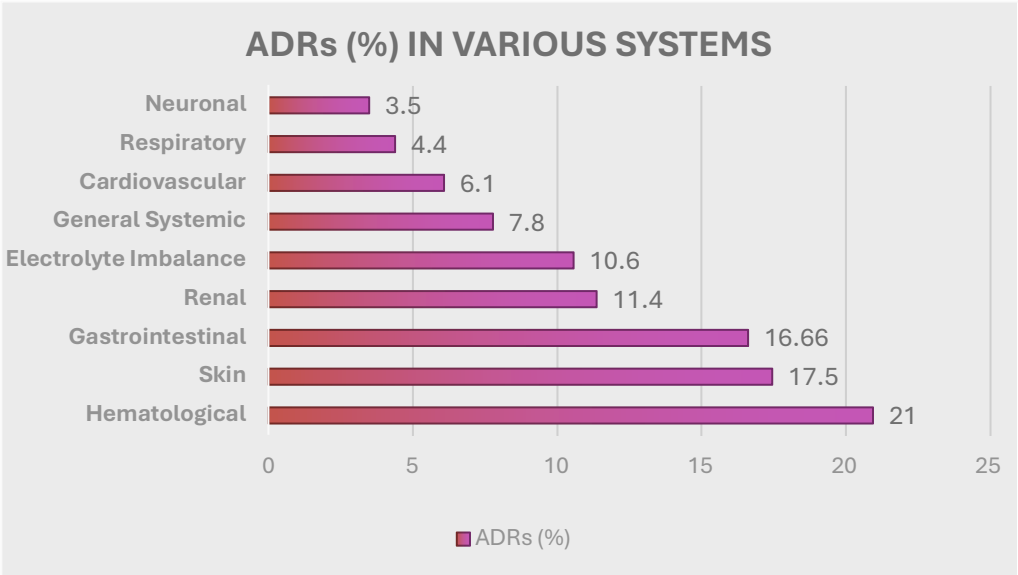


FIG. 1: COMMON ADRS IDENTIFIED IN THE STUDY POPULATION

Anatomical Therapeutic Chemical Classification (ATC) of the ADRs

As per the ATC classification, the majority of the ADRs were associated with the cardiovascular system (23 ADRs), followed by the Alimentary Tract/Metabolism (21 ADRs) and anti-infectives for systemic use. The most common pharmacological agents involved in ADRs were blood glucose-lowering agents (n = 9), followed by beta-lactam antibacterials (n = 4), psychostimulants (n = 4), nootropics agents (n = 4), antipsychotics (n = 4) and angiotensin II receptor blockers (n = 4). The data is presented in **Table 3**.

TABLE 3: ANATOMICAL THERAPEUTIC CHEMICAL CLASSIFICATION (ATC) OF THE ADRS

ATC Classification	**Frequency (%)**
C - Cardiovascular System	23 (20.4)
A - Alimentary Tract/Metabolism	21 (18.6)
J - Anti-infective Systemic	20 (17.7)
N - Nervous System	16 (14.2)
B - Blood/Blood Forming Organs	14 (12.4)
ATC Subclassification	
Blood glucose lowering drugs	9 (8.0%)
Beta-lactam antibacterials	4 (3.6%)
Psychostimulants and nootropics	4 (3.6%)
Antipsychotics	4 (3.6%)
Angiotensin II receptor blockers (ARBs)	4 (3.6%)
Non-steroidal anti-inflammatory and antirheumatic agents	3 (2.7%)
Quinolone antibacterials	3 (2.7%)
Combinations of oral blood glucose lowering drugs	3 (2.7%)
Antithrombotic agents	3 (2.7%)
Vitamin K antagonists	2 (1.8%)
Beta blocking agents, selective	2 (1.8%)

Calcium channel blockers	2 (1.8%)
Aldosterone antagonists	2 (1.8%)
High-ceiling diuretics	2 (1.8%)
Aminoglycoside antibacterials	2 (1.8%)
Glucocorticoids	2 (1.8%)
Direct factor Xa inhibitors	2 (1.8%)
Opioids analgesic	2 (1.8%)
Other Subclasses (Count, n = 1)	46 (41.1%)
Total	**113 (100%)**

Causality Assessment

The Naranjo Causality assessment of ADRs showed that, most ADRs had a possible (57 ADRs) association with the suspected medication followed by probable (35 ADRs), definite (14 ADRs) and unlikely (7 ADRs) Fig. 2. While in WHO- UMC Scale, it was observed that 64 ADRs in possible, 31 in probable, 11 in certain and 7 in doubtful category **(Table 4)**.

TABLE 4: CAUSALITY ASSESSMENT OF ADR

Naranjo Scale	**Frequency (%)**
Definite	14 (12.4)
Possible	57 (50.4)
Probable	35 (31)
Unlikely	7 (6.2)

WHO- UMC Scale	
Certain	11 (9.7)
Doubtful	7 (6.2)
Possible	64 (56.6)
Probable	31 (27.4)

Causality Assessment by WHO–UMC Scale Across ATC Drug Classes

The statistically significant **p value (p = 0.045)** suggests the strong relationship between the ATC category and causality classifications. The cardiovascular system medications exhibited the highest adverse drug reactions (n = 23), with a significant number identified as probable (n = 9) and certain (n = 3), indicating a relatively stronger causal link. The drugs of alimentary tract and metabolism accounted for 21 ADRs, mainly categorized as possible (n = 12), but there were also a notable number of certain and probable cases. Antiinfectives intended for systemic use led to 20 ADRs, primarily classified as possible (n = 13), reflecting the use of these drugs and the complex nature of reactions seen in hospitalized patients. **(Table 5)**

TABLE 5: CAUSALITY ASSESSMENT OF ADRS ACROSS ATC DRUG CLASSES

	CAUSALITY ASSESSMENT BY WHO- UMC SCALE					
ATC CLASSIFICATION OF DRUG	**Certain**	**Doubtful**	**Possible**	**Probable**	**Total**	**P VALUE**
A- Alimentary Tract and Metabolism	4	1	12	4	21	**0.045**
B- Blood and Blood Forming Organs	0	0	11	3	14	
C -Cardiovascular System	3	0	11	9	23	
H -Systemic Hormonal Preparations, Excl. Sex Hormones and Insulins	2	1	2	0	5	

J- Antiinfectives for Systemic Use	0	3	13	4	20	
L-Antineoplastic and Immunomodulating Agents	0	0	2	4	6	
M -Musculo-Skeletal System	2	0	4	0	6	
N -Nervous System	0	2	9	5	16	
R- Respiratory System	0	0	0	1	1	
V-various	0	0	0	1	1	
Total	11	7	64	31	113	

Severity Assessment

The severity assessment of the ADRs showed that majority of the ADRs were moderate (51 ADRs) followed by mild (47 ADRs) and severe (15 ADRs) **(Table 6).**

TABLE 6 : SEVERITY ASSESSMENT OF ADRS

Severity scale	**Frequency (%)**
Level 1 (mild)	47 (41.6)
Level 2 (moderate)	51 (45.1)
Level-3 (severe)	15 (13.3)

Predictability and Preventability Assessment

Most of ADRs observed in the study were not predictable (83 ADRs) followed by predictable (30 ADRs). While assessing the preventability of ADRs, it was observed that 13 ADRs were definitely preventable. 80 were non preventable, 19 were probably preventable and 1 was preventable **(Table 7)**

TABLE 7: PREDICTABILITY AND PREVENTABILITY ASSESSMENT OF ADRS

Predictability	**Frequency (%)**
Not Predictable	83 (73.5)
Predictable	30 (26.5)
Preventability	
Definitely Preventable	13 (11.5)
Non preventable	80 (70.8)
Probably preventable	19 (16.8)
Preventable	1 (0.9)

Severity and Outcome of ADRs

The severity associated with the ADRs and patient outcomes (recovered, recovering and unknown) were significant (p = 0.001) (**Table 8 & Fig. 2).** Most of the ADRs resulted in complete recovery (n=98), with 14 cases recovering and one with unknown outcome. Proportions in the severe cases of ADR indicating prolonged clinical impact and complexity of management. This pattern underscores the greater morbidity and longer recovery period associated with severe ADRs.

TABLE 8. SEVERITY VS OUTCOME OF ADR (p=0.001)

	OUTCOME OF ADRS				
SEVERITY SCALE	**Recovered**	**Recovering**	**Unknown**	**Total**	**P VALUE**
Level 1 (mild)	46	1	0	47	**0.001**
Level 2 (moderate)	43	8	0	51	

Level-3 (severe)	9	5	1	15	
Total	**98**	**14**	**1**	**113**	

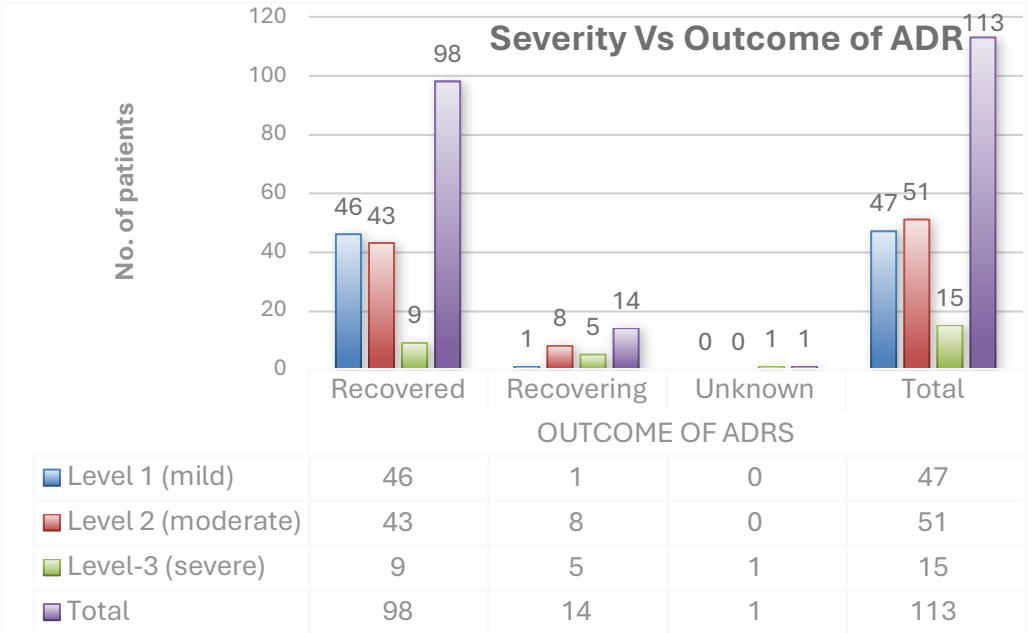


FIG. 2. SEVERITY VS OUTCOME OF ADR (P=0.001)

Pharmacist Intervention & Outcomes

While considering the seriousness of the reaction most of the ADRs required intervention (55.7%) such as drug withdrawal (69.1%), dose reduction (21.2%) or drug substitution (8.8%), followed by no severe reaction (22.1%), prolonged hospitalisation (18.6%) and required additional care (15%). **(Table 9)**

TABLE 9: SERIOUSNESS OF REACTION AND INTERVENTION PROVIDED

Variable	Category	Frequency (%)
Seriousness of the Reaction	Required intervention	63 (55.7)
	No Serious Reaction	12 (10.6)
	Prolonged Hospitalization	21 (18.6)
	Required Additional Care	17 (15)
Intervention provided	Drug Withdrawal	78 (69.1)
	Dose Reduction	24 (21.2)
	Drug substitution	10 (8.8)

Pharmacist recommendations, including identification, resolution, and optimisation of pharmacotherapy, were provided for identified adverse drug reactions. Of these, 85% of interventions were accepted by physicians, reflecting high clinical relevance. **(Table 10)**

TABLE 10: OUTCOME OF INTERVENTIONS

Intervention Outcome	Result (%)	Interpretation
Acceptance of intervention by physician	85%	High level of interdisciplinary collaboration and clinical relevance
Rejected interventions	15%	Due to clinical judgment, patient-specific factors, or alternative management

Intervention impact Assessment with CLEO Tool

The CLEO tool (Clinical, Economic, and Organizational outcomes) provides a structured and validated framework to assess the impact of pharmacist interventions. The clinical implications of the interventions were found in 43% of interventions (p = 0.01). Economic and Organisational outcomes were 33% and 24%, respectively, indicating a substantial and meaningful contribution to improved patient outcomes. **(Fig.3)**

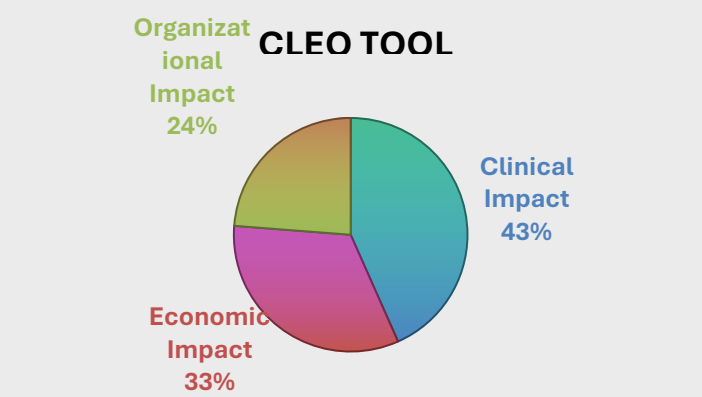


FIG. 3. CLEO TOOL- INTERVENTION IMPACT

DISCUSSION

The current study was done to evaluate the incidence of ADRs, their causality, and their severity among elderly patients. In elderly patients, most participants were between 60 to 70 years old, and most patients were male.

The incidence of ADR in the study was found among 113 patients (30.95%) of the elderly population. The higher incidence of ADR in the study population can be attributed due to the factor of polypharmacy and changes occurring in the physical and biochemical parameters of the elderly. The result can be compared with the study performed by Dagnew et al. and Yadesa et al. [17, 18].

The prevalence of metabolic disorders, such as hypertension, diabetes mellitus, and its complications, was common among the study population. This could be attributed to the effects of age, including reduced muscle mass, abdominal fat, and inflammation. The results obtained from this study support Suastika K et al., who states that the elderly group had a 1.4 times greater risk for developing metabolic syndrome than the young age groups [19, 20]

The majority of ADRs identified were haematological problems, followed by skin rashes. This may be due to variations in medication pharmacokinetics in older patients. The findings were comparable to those of the study by Woo SD et al., in which dermatological reactions were common, followed by gastrointestinal issues. [21,22]

In this study, drugs acting on the cardiovascular system (20.4%), alimentary tract and metabolism, and systemic anti-infectives accounted for 18.6% and 17.7%, respectively, of all ADRs detected in elderly patients. This trend is reflective of the higher disease burden due to hypertension, diabetes, and infections in elderly subjects that requires chronic drug therapy. These findings have been supported by Giardina et al. (2018), who identified that in hospitalized geriatric patients, the majority of ADRs were attributed to drugs with cardiovascular and antidiabetic pharmacological effects. At the subclass level, blood glucose-lowering drugs, antihypertensives, and anti-infectives predominated [23]. Their frequent appearance can be attributed to polypharmacy, various age-related alterations in pharmacokinetics and pharmacodynamics, and their narrow therapeutic ranges. Lavan and Gallagher (2016) commented that reduced hepatic metabolism, impaired renal function, and age-related alteration in protein binding increase drug-toxicity risk in elderly individuals [4].

The outcome of the causality analysis indicated that the majority of the ADRs were possible, followed by probable, and the reactions were of moderate severity. The p-value (p = 0.045) indicated a very important relationship between the drug class code (ATC) and the causality analysis.

The assessment of causality established that the ADRs were possible, followed by probable, while the severity of the reactions was moderate. There were significant relationships between the assessment of causality, severity, and the occurrence of the ADRs. The patients mostly recovered from the ADRs. The results of the research can be compared with the research findings by Jiang et al. [24].

Patients with mild ADRs experienced the greatest recovery, whereas patients with severe ADRs experienced a low rate of recovery, suggesting a significant association between the severity of ADRs and recovery. The ADRs experienced by the participants appeared to greatly influence the recovery of the participants as well as their quality of life [25]. The evaluation of potential as well as existing ADRs to a certain extent affected the clinical, economic, as well as organizational efficiency, which was determined by the CLEO Tool.

This study made it possible to determine the main categories of medications implicated in ADRs. The

causality and severity assessment, as well as the pharmacist interventions to lower the risks posed by ADRs among elderly were done [26]. This is considered an important strength of the study. The main weaknesses the study were the single-center approach and the small sample size. The multi-center, interventional, and large sample size can be accomplished in this field of study to determine the influence of specialized care on the treatment outcome and quality-of-life among the elderly population.

SUMMARY AND CONCLUSION

This research was carried out to examine the incidence, causality, and severity of adverse drug reactions amongst elderly patients, since this group of people is highly prone to drug-related problems owing to physiological changes associated with advancing age, as well as the fact that many of them tend to be on multiple medications. A vast majority of participants were aged between 60-70 years, with more males than females. These demographic findings are consistent with trends observed in similar geriatric studies and reflect the growing burden of chronic diseases in this age group.

The prevalence of ADRs reported in this study is noted to be 30.95%, thereby making it clear that almost all the elderly have been exposed to at least one ADR. This is attributed to several factors such as polypharmacy, pharmacokinetics and pharmacodynamics, and age-related changes in the functioning of the organs. There are studies by Dagnew et al. and Yadesa et al. that have reported similar results as this study, thereby making it clear that this particular issue has been well noted by several scientists. This study therefore has significant importance as it lays down the need to monitor all medications among the elderly.

Conditions like metabolic disorders, hypertension, diabetes mellitus, and complications arising from them had a high prevalence in the study population. These results can be attributed to physiological changes due to advancing age, like changes in body physiology due to loss of muscle mass and abdominal obesity due to chronic inflammation. Results are in concordance with earlier studies that pointed towards a greater risk of metabolic syndrome in elderly patients compared to younger patients. The presence of these chronic conditions often necessitates long-term pharmacotherapy, further increasing the risk of ADRs.

Regarding the pattern of adverse reactions, haematological disorders were the most frequently observed, followed by dermatological reactions such as skin rashes. These reactions may be linked to altered drug metabolism and clearance in older adults. Although some variation exists compared with other studies, which report dermatological and gastrointestinal reactions as more common, the overall findings reinforce the idea that elderly patients experience a wide spectrum of ADRs affecting multiple organ systems.

An analysis of drug classes associated with ADRs revealed that medications acting on the cardiovascular system were the most commonly implicated, followed by drugs affecting the metabolism and alimentary tract, and systemic anti-infectives. At the subclass level, antihypertensives, hypoglycaemic agents, and anti-infective drugs were frequently involved. This pattern reflects the high prevalence of cardiovascular diseases, diabetes, and infections in the elderly, as well as the prolonged and often complex treatment regimens required for these conditions. Age-related reductions in hepatic and renal function, along with narrow therapeutic indices of certain drugs, further contribute to high risk of adverse effects.

Causality assessment using the WHO-UMC scale indicated that most ADRs were classified as possible, followed by probable, while the majority were of moderate severity. A statistically significant association was observed between the anatomical therapeutic chemical (ATC) drug class and causality, suggesting that certain drug groups are more likely to be linked with ADRs in elderly patients. Additionally, a significant relationship between causality and severity was observed, indicating that reactions with stronger causal associations tended to have greater clinical impact.

In terms of outcomes, most patients recovered from their adverse reactions, particularly those who experienced mild ADRs. However, patients with severe ADRs demonstrated poorer recovery, emphasising that increasing severity is associated with less favourable outcomes. These findings suggest that ADRs not only influence therapeutic success but also substantially affect the quality of life of elderly patients. The application of pharmacist-led interventions and the use of the CLEO tool for evaluating clinical, economic, and organisational outcomes contributed to the effective identification and mitigation of ADRs, leading to improved patient care.

In conclusion, this study highlights the considerable burden of adverse drug reactions among elderly patients and identifies key drug classes and clinical factors associated with their occurrence. The systematic assessment of ADR causality and severity, along with the implementation of pharmacist interventions, represents a major strength of the study. Despite its limitations, including a relatively small sample size and a single-centre design the findings provide valuable insights into medication safety in the geriatric population. Future multicentre studies with larger sample sizes and interventional designs are recommended to further evaluate the impact of specialised pharmaceutical care on therapeutic outcomes and quality of life in elderly patients

Ethical Considerations

Permissions were obtained from the Institutional Ethics Committee before initiating the study, Reference No.: 001/2022/CCOPS/IEC.

Acknowledgements

Acknowledgements to the hospital administration, study participants, and all who cooperated during the study are greatly appreciated.

Conflicts of Interests
The authors have no conflicts of interest to declare

Funding
No financial support was provided for this research.

Abbreviations
ADR- *Adverse Drug Reaction,* **CLEO-** *Clinical, Economic, and Organisational* Impact Tool, **WHO-UMC-** World Health Organization – Uppsala Monitoring Centre, **ATC-** *Anatomical Therapeutic Chemical* classification system

Author Contribution
Idea and manuscript editing: Dr. R. Margret Chandira
Research design and manuscript preparation: Soumya M K

REFERENCES

1. Coleman JJ, Pontefract SK. Adverse drug reactions. Clin Med (Lond). 2016 Oct;16(5):481-485. doi: 10.7861/clinmedicine.16-5-481.https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6297296/
2. Zhao H, Ni P, Zhao Q, Liang X, Ai D, Erhardt S, Wang J, Li Y, Wang J. Identifying the serious clinical outcomes of adverse reactions to drugs by a multi-task deep learning framework. Communications Biology. 2023 Aug 24;6(1):870. doi: 10.1038/s42003-023-05243-w. https://www.nature.com/articles/s42003-023-05243-w
3. Coleman JJ, Ferner RE, Evans SJ. Monitoring for adverse drug reactions. British journal of clinical pharmacology. 2006 Apr;61(4):371-8. doi: 10.1111/j.13652125.2006.02596.x.https://bpspubs.onlinelibra ry.wiley.co m/doi/10.1 111/j.1365-2125.2006.02596.x
4. Lavan AH, Gallagher P. Predicting risk of adverse drug reactions in older adults. Therapeutic advances in drug safety. 2016 Feb;7(1):11-22. doi: 10.1177/2042098615615472.https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4726675/
5. Krustev T, Milushewa P, Tachkov K. Impact of polypharmacy, drug-related problems, and potentially inappropriate medications in geriatric patients and its implications for Bulgaria: narrative review and meta-analysis. Frontiers in public health. 2022 Mar 3;10:743138. doi: 10.3389/fpubh.2022.743138. https://www.frontiersin.org/articles/10.3389/fpubh.2022.743138/full
6. Gurel N, Üresin Y, Şen S, ŞEN S. Drug-Drug Interactions and Their Association With Quality of Life in Patients With Hypertension. Cureus. 2024 Mar 20;16(3).doi: 10.7759/cureus.56526. https://www.cureus.com/articles/165573-drug-drug-interactions-and -their-association-with-quality-of-life-in-patients-with-hypertension
7. Hadia R, Joshi D, Bhil D, Maheshwari R. Incidence of adverse drug reactions among elderly patients: A systematic review and meta-analysis. Journal of the Scientific Society. 2022 May 1;49(2):91-102. doi: 10.4103/jss.jss_50_22.https://jssjournal.com/article.asp?issn=09745009;year=2022;volume=49;issue=2;spage=91;epage=102;type=0
8. Brahma DK, Wahlang JB, Marak MD, Sangma MC. Adverse drug reactions in the elderly. Journal of pharmacology and pharmacotherapeutics. 2013 Jun;4(2):91-4. doi: 10.4103/0976-500X.110872. https://www.ncbi.nlm .nih.gov/pmc/articles/PMC3689234
9. Wawruch M, Zikavska M, Wsolova L, Kuzelova M, Kahayova K, Strateny K, Kristova V. Adverse drug reactions related to hospital admission in Slovak elderly patients. Archives of gerontology and geriatrics. 2009 Mar 1;48(2):186-90. doi: 10.1016/j.archger.2008.01.004.https://doi.org/10.1016/j.archger.2008.01.004
10. Davies EA, O'mahony MS. Adverse drug reactions in special populations–the elderly. British journal of clinical pharmacology. 2015 Oct;80(4):796-807. doi: 10.1111/bcp.12596. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4594734/
11. World Health Organization (WHO)-Uppsala Monitoring Centre. The use of the WHO-UMC system for standardized case causality assessment. Available from: http://www.who-umc.org/Graphics/24734.pdf.
12. Naranjo CA, Busto U, Sellers EM, Sandor P, Ruiz I, Roberts EA, Janecek E, Domecq C, Greenblatt DJ. A method for estimating the probability of adverse drug reactions. Clinical Pharmacology & Therapeutics. 1981 Aug;30(2):239-45. doi: 10.1038/clpt.1981.154.https://ascpt.onlinelibrary.wiley.com/doi/10.1038/clpt.1981.154
13. Shinu C, Dilip C. Impact of pharmaceutical care programme on health outcome of geriatric patients. Clinical Epidemiology and Global Health. 2020 Sep 1;8(3):894-8. doi: 10.1016/j.cegh.2020.02.019. https://www.sciencedirect.com/science/article/pii/S2213398420300544
14. Vo HT, Charpiat B, Chanoine S, et al. CLEO: a multidimensional tool to assess clinical, economic and organisational impacts of pharmacists' interventions. Eur J Hosp Pharm 2021;28:193–200. 10.1136/ejhpharm-2020-002642https://ejhp.bmj.com/content/28/4/193
15. Hartwig SC, Siegel J, Schneider PJ. Preventability and severity assessment in reporting adverse drug reactions. Am J Hosp Pharm. 1992;49(9):2229–32. https://www.ajhp.org/content/49/9/2229
16. Schumock GT, Thornton JP. Focusing on the preventability of adverse drug reactions. Hosp Pharm. 1992;27(6):538.

https://journals.sagepub.com/doi/10.1177/00185787 9202700611

17. Dagnew SB, Moges TA, Ayele TM, Wondm SA, Yazie TS, Dagnew FN. Adverse drug reactions and its associated factors among geriatric hospitalized patients at selected comprehensive specialized hospitals of the Amhara Region, Ethiopia: a multicenter prospective cohort study. BMC geriatrics. 2024 Nov 16;24(1):955. doi: 10.1186/s12877-024-05515-y.https://bmcgeriatr.biomedcentral.com/articles/10.1186/s12877-024-05515-y
18. Yadesa TM, Kitutu FE, Tamukong R, Alele PE. Prevalence, incidence, and characteristics of adverse drug reactions among older adults hospitalized at Mbarara regional referral hospital, Uganda: a prospective cohort study. Clinical Interventions in Aging. 2021 Sep 22:1705-21. doi: 10.2147/CIA.S332251.https://www.dovepress.com/prevalence-incidence-and-characteristics-of-adverse-drug-reactions-among-peer-reviewed-fulltext-article-CIA
19. Suastika K, Dwipayana P, Saraswati IM, Kuswardhani T, Astika N, Putrawan IB, Matsumoto K, Kajiwara N, Taniguchi H. Relationship between age and metabolic disorders in the population of Bali. Journal of Clinical Gerontology and Geriatrics. 2011 Jun 1;2(2):47-52. doi: 10.1016/j.jcgg.2011.03.001. https://www.sciencedirect.com/science/article/pii/S2210833511000158
20. Saad MA, Cardoso GP, Martins Wde A, Velarde LG, Cruz Filho RA. Prevalence of metabolic syndrome in elderly and agreement among four diagnostic criteria. Arq Bras Cardiol. 2014 Mar;102(3):263-9. doi: 10.5935/abc.20140013. Epub 2014 Feb 10. PMID: 24676226; PMCID: PMC3987322. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3987322/
21. Won SH, Suh SY, Yim E, Ahn HY. Risk Factors Related to Serious Adverse Drug Reactions Reported through Electronic Submission during Hospitalization in Elderly Patients. Korean J Fam Med. 2022 Mar;43(2):125-131. doi: 10.4082/kjfm.21.0086. Epub 2022 Mar 17. PMID: 35320898; PMCID: PMC8943238. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8943238/
22. Woo SD, Yoon J, Doo GE, Park Y, Lee Y, Lee SH, Lee YH, Ye YM. Common causes and characteristics of adverse drug reactions in older adults: a retrospective study. BMC Pharmacology and Toxicology. 2020 Dec 10;21(1):87. doi: 10.1186/s40360-020-004649. https://bmcpharmacoltoxicol.biomedcentral.com/articles/10.1186/s40360-020-00464-9
23. Giardina C, Cutroneo PM, Mocciaro E, et al. Adverse drug reactions in hospitalized patients: Results of the FORWARD study. Front Pharmacol. 2018;9:350.https://www.frontiersin.org/articles/10.3389/fphar.2018.00350/full
24. Jiang H, Lin Y, Ren W, Fang Z, Liu Y, Tan X, Lv X, Zhang N. Adverse drug reactions and correlations with drug–drug interactions: A retrospective study of reports from 2011 to 2020. Frontiers in pharmacology. 2022 Aug 22;13:923939. doi:10.3389/fphar.2022.923939. https://www.frontiersin.org/articles/10.3389/fphar.2022.923939/full
25. Pei-Ju Liao, Chien-Tai Mao, Tun-Liang Chen, Shin-Tarng Deng, Kuang-Hung Hsu BMJ Open 2019;9:e026771. doi:10.1136/bmjopen-2018-026771, Factors associated with adverse drug reaction occurrence and prognosis, and their economic impacts in older inpatients in Taiwan: a nested case– control study.https://bmjopen.bmj.com/content/9/3/e026771
26. Yaacob NLC, Loganathan M, et al. The Impact of Pharmacist Medication Reviews on Geriatric Patients: A Scoping Review. Korean Journal of Family Medicine. 2024 https://www.kjfm.org/journal/view.php?doi=10.4082/ kjfm.23.0108

ANNEXURE 1

CLEO TOOL DIMENSIONS FOR ASSESSING PHARMACIST INTERVETION

Dimensions	Score	Description
Clinical Impact (C)	**–1**	Negative clinical impact (potential patient harm)
	0	No expected clinical impact
	1	Minor clinical impact (limited clinical benefit, no change in prognosis)
	2	Moderate clinical impact (improvement in patient care or pr evention of harm)
	3	Major clinical impact (significant improvement in patient ou tcomes or prevention of serious adverse events)
	4	Avoidance of a fatal outcome
Economic Impact (E)	**–1**	Negative economic impact (increase in direct healthcare cost s)
	0	No economic impact
	1	Positive economic impact (reduction in direct costs, cost sav ings)
Organisational Impact (O)	**–1**	Negative organisational impact (increased workload, process disruption)
	0	No organisational impact
	1	Positive organisational impact (improved workflow, time sa ving, enhanced safety or coordination)