



Association of Polypharmacy and Drug–Drug Interactions with the Development of Adverse Drug Reactions in Multimorbid Hospitalized Patients

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ABSTRACT

Multimorbid hospitalized patients are at higher risk of developing drug-drug interactions and adverse drug reactions due to multiple medication administrations. The study aimed to associate polypharmacy and drug–drug interactions (DDI) with the development of adverse drug reactions (ADRs) among multimorbid hospitalized patients. A prospective, cross-sectional design was conducted in the general medicine department of Sri Venkateswara Ramnarayan Ruia Government General Hospital (SVRRGGH), Tirupati, Andhra Pradesh, India. Hospitalized patients who were over 18 years old, had at least two comorbidities, and were prescribed a minimum of two drugs were eligible for this study. An interview-based data collection tool was used to obtain demographics and clinical profiles for the study participants. The obtained data were used to identify DDIs and ADRs. A binary and multiple logistic regression analysis was used to associate polypharmacy and DDI with the development of ADRs. Polypharmacy was observed in all prescriptions of the participants, with an average medication count of 9.52. The prevalence of ADRs and actual and potential DDIs was 29.67, 10.54, and 89.83%, respectively. The majority of the DDIs were moderate (70.78%) on the severity scale, and ADRs were probable (60.00%) on the causality scale. Factors such as more than three comorbidities (AOR=19.83; 95% CI 1.06-371.28) and the presence of actual DDIs (AOR=1242.51; 95% CI 96.55-15990.23) were significantly associated with the development of ADRs among multimorbid hospitalized patients. Polypharmacy was most common among multimorbid hospitalized patients. Less than one-third of the participants have experienced ADRs, which were significantly associated with multi-morbidity and the presence of actual DDIs. Targeted pharmacist interventions based on the factors can reduce the burden of ADRs.

Keywords: Multi-morbidity, Polypharmacy, Drug-drug interaction, Adverse Drug Reaction, Hospitalized patients.

INTRODUCTION

Advances in public health and the wide accessibility of quality medical care and improved living conditions have led to increased life expectancy in almost all regions of the globe [1]. This process causes the accumulation of long-term conditions (LTC) and results in multi-morbidity. Co-existence of two or more chronic disorders is called multi-morbidity [2]. According to a report published by the Academy of Medical Sciences, multi-morbidity is considered a global health concern for both high- and low-middle-income countries [3]. Factors like population aging, lifestyle changes, and environmental exposure result in raising the burden of Non-communicable diseases (NCD) in low- and middle-income countries (LMIC) [3]. This results in an increased burden of NCD along with the infectious diseases in LMIC. These demographic and epidemiological changes result in more than one chronic disorder and increase the burden of multi-morbidity [3]. In India, the burden of multi-morbidity was increased due to changes in healthcare access, financial inequalities, and high rates of non-communicable diseases like diabetes and heart diseases [4]. Over time, the age of multi-morbidity was narrowed due to increased lifestyle disorders in young and middle-aged people [5].

Multi-morbidity leads to the use of multiple medications, which can result in polypharmacy [6]. Administration of an excessive number of medications (more than or equal to five) is called polypharmacy, which can cause irrational drug use [7]. Polypharmacy might be considered appropriate in multiple or complex medical conditions where the treatment is optimized according to the patient's needs as per the best available evidence, considering possible DDIs [8]. However, when polypharmacy recommendations are inappropriate, and the risks outweigh the benefits of a medication regimen, it can lead to poor medication adherence as well as the development of drug-drug interactions (DDIs) and adverse drug reactions (ADRs) [8]. The development of DDIs and ADRs was significantly influenced by patient-related factors (age, gender, and physiological alterations) and medication-related factors (duration of therapy, concomitant drugs administered, and dose) [9]. DDIs and ADRs were the major drug-induced consequences observed in multimorbid hospitalized patients, which can increase healthcare costs and negatively impact morbidity, mortality, and quality of life [10,11].

Many studies in India focused on the elderly population to estimate the prevalence and predictors of DDI and ADRs [12–16].

Additionally, several studies have been conducted on the adult population to provide evidence regarding DDIs and ADRs in both hospitalized patients and those in outpatient departments^[17-19]. To the best of our knowledge, the evidence regarding ADRs is scarce among multimorbid hospitalized patients who are at heightened risk of having polypharmacy prescriptions and the development of DDI and ADRs. The current study aimed to associate polypharmacy and drug–drug interactions with the development of adverse drug reactions among multimorbid hospitalized patients.

METHODOLOGY

Study Design and Settings

A prospective, cross-sectional, analytical design was used to associate DDIs and polypharmacy with the development of ADRs among multimorbid hospitalized patients. The study was conducted in the general medicine department of Sri Venkateswara Ramnarayan Ruia Government General Hospital (SVRRGGH), Tirupati, Andhra Pradesh, India. SVRRGGH is a 1500-bed tertiary care teaching hospital affiliated with Sri Venkateshwara Medical College (SVMC) and serving patients from the Tirupati and Chittoor districts and surrounding regions. The study was conducted for a period of six months from November 2024 to April 2025. The study was conducted as per STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines.

Ethical Considerations

The Institutional Ethics Committee approved the study proposal, data collection tool, and informed consent procedure at Sri Padmavathi School of Pharmacy (IEC-SPSP) with a registration number of SPSP/2024-2025/PHD19. The study was conducted in accordance with the ICH-GCP guidelines. After detailing the objectives, purpose, and scope of the research to the participants, oral and informed consent was obtained. Participants had the complete right to withdraw at any point in the study. The data obtained from the participants was concealed by allocating a code, and the identifiers were not revealed to anyone outside of the study. The confidentiality and anonymity of the participants were maintained during and after study completion.

Study Participants

Patients aged more than or equal to 18 years or older, irrespective of gender, admitted to the general medicine inpatient department, suffering from at least two comorbidities, and prescribed a minimum of two drugs were eligible to participate in this study. Patients who are not willing to participate were excluded from this study.

Sample Size Determination and Sampling Technique

The sample size for the current study was determined by using the Epi-Info Version 7.2.6.0 population survey stats calculator. By considering a prevalence (p) of 3.4% from an Indian study, a 95% confidence level, a 5% margin of error, and 80% power, the sample size was determined to be 50. After considering the 20% non-response rate, the final sample size was confirmed as 70^[18]. A convenient, non-probability sampling technique was used to capture the eligible study participants.

Data Collection Procedure

An interview-based data collection tool was prepared to obtain data from the study participants and medical record review. Four trained PharmD students were involved in obtaining data after getting informed consent from the eligible participants. Socio-demographic information such as age, gender, signs and symptoms, provisional and final diagnosis, comorbidities, laboratory investigations, and past and current medication details of the study participants was obtained prior to the analysis of DDI and ADRs.

After obtaining data from the study participants, the prescribed medications and medications used to manage comorbidities were processed in IBM Micromedex®, Drug Interaction Checking—electronic version (IBM Watson Health, Greenwood Village, Colorado, USA), to identify and grade the severity of potential and actual drug–drug interactions¹⁷. The severity of the DDI was graded as contraindicated, major, moderate, minor, and unknown based on the clinical significance of the effect.

The polypharmacy present among the prescriptions of the multimorbid hospitalized patients was determined by counting the number of drugs present in each prescription. More than or equal to five drugs present in the prescription were considered polypharmacy, and more than ten drugs were considered hyperpolypharmacy^[21].

Any negative reaction to drug therapy was classified as an adverse event for further investigation by the expert team, which aimed to confirm whether it was an adverse drug reaction. The expert team comprises a clinical pharmacologist, a clinical pharmacist, and a physician. The causal relationship between drug and adverse event was measured using the Naranjo scale for causality assessment and categorized into definite, probable, possible, and doubtful.

A total of 150 hospitalized patients were approached in the general medicine department. Among them, 136 met our study eligibility criteria. After removal of the patients who were unwilling and had improper medical records, 118 were subjected to data analysis. After data collection, demographics, polypharmacy, and DDI variables were associated with the development of ADRs in multimorbid hospitalized patients.

Data Analysis

The data obtained from the participants were entered in Microsoft Excel sheet and exported to IBM SPSS Statistics for Windows, version 22.0 (IBM Corp., Armonk, NY, USA) for analysis. Descriptive statistics such as frequency, percentage, mean, and SD were used to present the demographics, clinical, DDI, and ADRs profile of the study participants. We used a binary and multiple logistic regression analysis to associate independent variables (demographics and clinical variables) with the dependent variable (development of ADR). Variables with a *p*-value ≤ 0.2 in binary analysis were subjected to multiple logistic regression analysis to adjust for potential confounders linked with the dependent variable. A two-way *p*-value of ≤ 0.05 was considered a statistically significant value.

RESULTS

Among 118, about one-third (44; 37.29%) of the patients were aged more than sixty years, with a mean age of 54.42 ± 13.23 . The majority of the multimorbid hospitalized patients were males (86; 72.88%). More than half of the participants were suffering from two

Table 1: Socio-demographics and clinical characteristics of the study participants (n = 118)

Variable	Frequency (%)
Age in years (Mean \pm SD)	54.42 \pm 13.23
18–30	4 (3.39)
31–40	11 (9.32)
41–50	33 (27.97)
51–60	26 (22.03)
>60	44 (37.29)
Gender	
Male	86 (72.88)
Female	32 (27.12)
Number of comorbidities (Mean \pm SD)	2.50 \pm 0.66
2	74 (62.71)
3	35 (29.66)
4	9 (7.63)
Number of drugs (Mean \pm SD)	9.52 \pm 2.51
5-7	9 (7.60)
7-10	72 (61.02)
>10	37 (31.36)

Table 2: Characteristics of the ADRs and DDIs identified in multimorbid hospitalized patients (n = 118)

Variable	Frequency (%)
Presence of ADR	
Yes	35 (29.67)
No	83 (70.33)
Outcome of the ADR	
Recovered	20 (57.14)
Recovering	15 (42.86)
Causality	
Doubtful	0 (0.0)
Possible	14 (40.00)
Probable	21 (60.00)
Definite	0 (0.00)
Presence of actual DDI	
Yes	32 (10.54)
No	86 (89.46)
Presence of potential DDI	
Yes	106 (89.83)
No	12 (10.17)
Severity of DDI (n=332)	
Minor	9 (2.71)
Moderate	235 (70.78)
Major	88 (26.51)

comorbid conditions (74; 62.71%) and taking 7 to 10 medications (72; 61.02%) with a mean of 2.50 and 9.52, respectively. The distribution of the demographic and clinical profile of the study participants is presented in Table 1.

The prevalence of the ADRs among multimorbid hospitalized patients was found to be 29.67% (95% CI 21.53–37.90%). More than half of the patients recovered from the developed ADRs. The majority of the ADRs were graded as probable on the Naranjo causality assessment scale. The prevalence of actual and potential DDIs among participants was found to be 10.54 and 89.83%, respectively. A total of 332 drug–drug interactions (DDIs) were identified among 118 patients, resulting in an average of 2.81 DDIs per patient. Among 332 DDI (including potential and actual), 70.78% are reported to have a moderate severity level. The distribution of the ADR and DDI characteristics in multimorbid hospitalized patients is presented in Table 2.

Findings of the binary and multiple logistic regression analysis revealed factors like patients suffering from more than three comorbidities (AOR=19.83; 95% CI 1.06–371.28) and the presence of actual drug–drug interactions (AOR=1242.51; 95% CI 96.55–15990.23) in the prescription were significantly associated with the development of ADRs among multimorbid hospitalized patients. Table 3 presents binary and multiple logistic regression analyses of ADR predictors among multimorbid hospitalized patients.

DISCUSSION

Polypharmacy and DDIs are the major contributors to the development of ADRs among multimorbid hospitalized patients. The current study findings revealed that all multimorbid hospitalized patients were under polypharmacy prescriptions. This estimate was very high compared to other studies conducted on hospitalized patients in the different states of India, such as Kerala (60.0%), Karnataka (36.6%), Andhra Pradesh (38.5%), Assam (72.0%), Puducherry (53.0%), Tamil Nadu (40.0%), and Gujarat (50.9%) [22–28]. The high prevalence of polypharmacy in our study is likely due to the presence of multimorbid conditions among the participants. The complexity and count of the medicines administered were directly proportional to the number of comorbidities [29,30]. In our study, the prevalence of hyperpolypharmacy was found to be 31.35%. This estimate of 31.35% is lower than the prevalence rates found in other studies conducted in Kerala (35.7%), Andhra Pradesh (35.5%), and Gujarat (34.7%) [22,24,28]. The probable reason for the lower estimate of hyperpolypharmacy observed in our study might be due to the inclusion of the multimorbid hospitalized patients who are aged more than or equal to 18 years or older, compared with other studies that considered only elderly patients.

We found that the prevalence of actual DDIs was 10.54% in our study. Our study's prevalence of actual DDIs was lower than that of a Belgian study (21.95%) [31]. Whereas, compared to a study conducted in Romania (4.59%), it showed a lower prevalence of actual DDIs compared to our study [32]. The high prevalence observed in the Belgian study was attributed to the inclusion of patients admitted to the emergency department. In the emergency unit, drug therapies are targeted to save the lives of the patients; that increases the number of drugs and risk of actual DDIs. Additionally, variations observed

Table 3: Binary and multiple logistic regression analysis of predictors of ADRs among multimorbid hospitalized patients

Variable	Total (%)	ADR	COR (95% CI)	P value	AOR (95% CI)	p-value
Age (Years)						
< 60	72 (61.02)	24 (33.33)	Ref	Ref		
≥ 60	46 (38.98)	11 (23.91)	0.63 (0.27-1.45)	0.276		
Gender						
Male	86 (72.88)	28 (32.56)	Ref	Ref		
Female	32 (27.11)	7 (21.87)	0.58 (0.22-1.50)	0.262		
Comorbidity						
2-3	109 (92.37)	30 (27.52)	Ref	Ref	Ref	Ref
4-5	9 (7.63)	5 (55.55)	3.29 (0.83-13.09)	0.091	19.83 (1.06-371.28)	0.046
No. of drugs						
≤ 10	81 (68.64)	19 (23.46)	Ref	Ref	Ref	Ref
> 10	37 (31.35)	16 (43.24)	2.49 (1.08-5.70)	0.031	3.73 (0.48-28.86)	0.208
Actual DDI						
Yes	32	31 (96.87)	635.50 (68.34-5909.65)	<0.001	1242.51 (96.55-15990.23)	<0.001
No	86	4 (4.65)	Ref	Ref	Ref	Ref

across the studies were also connected with changes in study design, type of patients, age of the patients, and database or reference book used to identify DDIs. Actual DDIs are the interactions that exist in hospitalized patients and interfere with the outcomes of the drug therapy regimens. Pharmacists play a significant role in the identification and management of actual DDIs among hospitalized patients in order to improve clinical outcomes.

The prevalence of potential DDIs was found to be 89.83%. Parallel to our findings, a study conducted in Iran (86.2%) also revealed a nearly similar prevalence of potential DDIs [33]. However, a meta-analysis conducted considering middle- and high-income countries revealed a low pooled prevalence of potential DDIs (64.9%) compared to our study [34]. The high prevalence of potential DDIs in our study was mainly attributed to multi-morbidity. This finding enables the pharmacist to review the drug therapy and guide multimorbid hospitalized patients to prevent potential DDIs.

The prevalence of the ADRs among multimorbid hospitalized patients was found to be 29.67%. A systematic review revealed that the prevalence of ADRs ranges from 6 to 46% in high-income countries (HIC) and 10.7 to 64.0% in low- and middle-income countries (LMIC) [35]. The variations in study design, patient types, screening procedures used, and medications administered likely caused the inconsistent findings across the studies. In our study, comorbidities and actual DDIs were significantly associated with the development of ADRs among multi-morbidity patients. Studies conducted elsewhere also revealed similar predictors for the development of ADRs [35]. Multi-morbidity is linked to the use of complex medication regimens, which can heighten the risk of actual drug-drug interactions (DDIs) and lead to adverse drug reactions (ADRs). In our study, we observed the majority of ADRs among patients who had actual DDIs. These findings clearly demonstrate that pharmacists need to work on drug therapy in resolving DDIs to minimize the ADRs among multimorbid hospitalized patients.

CONCLUSION

Multimorbid hospitalized patients were under polypharmacy prescription with an average medication count of 9.52. Our study found that the prevalence of ADRs and actual and potential DDIs was 29.67, 10.54 and 89.83%, respectively. The majority of the DDIs were moderate on the severity scale, and ADRs were probable on the causality scale. Factors such as more than three comorbidities and the presence of actual DDIs were significantly associated with the development of ADRs among multimorbid hospitalized patients. Targeted pharmacist-mediated and tailored interventions based on the factors identified in our study can reduce the burden of ADRs among multimorbid hospitalized patients and improve the outcomes. Additionally, communication of these findings and raising awareness among healthcare professionals regarding the interplay between multi-morbidity, polypharmacy, DDI, and ADRs can create alerts while dealing with multimorbid hospitalized patients and reduce the burden of drug-induced consequences.

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