



## **Prescribing Pattern and Medication Related Problems in Hospitalized Diabetic Patients: A Hospital-Based Study**

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### **Authors' contributions**

The conception, design, interpretation, compilation of results and execution of the study work was carried out in collaboration among all authors. The corresponding author drafted the manuscript and incorporated the suggestions from other authors. All authors read and approved the final manuscript.

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### **ABSTRACT**

**Aim:** To assess the drug-related problems (DRPs) and World Health Organization (WHO) core prescribing indicators among hospitalized diabetic patients.

**Methodology:** A prospective, observational study was made among the diabetic inpatients of the General Medicine Department of a tertiary care hospital located in Tirupati, Andhra Pradesh, India. A suitable data collection form was used to collect the data pertaining to demographics, clinical variables, DRPs, and WHO prescribing indicators. Descriptive statistics like frequency, mean, and percentage were used to represent the demographics, distribution of DRPs, and prescribing indicators in the study. Inferential statistics like Chi-square test was employed to test the significant association between the demographics and occurrence of DRPs.

**Results:** A total of 199 diabetic patients were enrolled in this study. The mean age of the study participants was 55.8±11.3. The study shows the prevalence of DRPs in diabetic in-patients was

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48.7%. The most commonly identified DRPs are drug interactions (53; 45.3%), adverse drug reactions (24; 20.5%), and untreated indication (21; 17.9%). Patient characteristics like, advanced age ( $\geq 60$  years), presence of co-morbid condition, comprising more than 5 drugs in prescription, and stay in the hospital for more than four days are significantly associated with the development of DRPs. Findings of WHO indicators show the average number of drugs, percentage of drugs prescribed by the generic name, percentage of encounters with an antibiotic, injection, and from essential drug list have deviated from standards of WHO.

**Conclusion:** The prevalence of DRPs in diabetic in-patients was 48.7%. Drug interactions and adverse drug reactions are the most common DRPs found in our study. Developing the drug policy guidelines focused on factors associated with DRP and WHO prescribing indicators may reduce the burden of DRPs and improves patient outcomes.

*Keywords: Diabetes; prescribing pattern; drug use indicators; drug-related problems.*

## 1. INTRODUCTION

Diabetes Mellitus (DM) is a chronic disorder of multiple etiologies characterized by prolonged hyperglycemia with disturbance in the metabolism of carbohydrates, proteins, and lipids, due to defect in insulin action, insulin secretion, or both [1]. Globally, it was estimated that 415 million adults are suffering from diabetes [2]. According to the estimates of the International Diabetes Federation (IDF), there are 72.9 million people are suffering from diabetes in 2017, this value is projected to rise to 134.3 million by the year 2045 [3]. In India, the prevalence of diabetes was increasing in rural areas parallel with urban areas [4]. Diabetes is accompanied by various co-morbidities will increase the risk of micro and macrovascular complications [5]. The existence of co-morbidities and diabetic complications will change the drug therapy requirements to achieve targeted blood glucose levels. The diabetic patients are highly vulnerable to develop drug-related problems. This was majorly due to multiple medications, polypharmacy, aging, poor medication adherence, co-morbidities, and lifelong requirement of pharmacological and non-pharmacological therapies. Drug-related problems will potentially interfere with the desired outcomes of drug therapy and increase hospitalization rates, economic burden, and mortality [6]. Evidence shows that drug therapy in diabetes can cause at least one drug-related problem per patient [7,8]. However, most of the drug-related problems are preventable [9]. Early detection of drug-related problems and their determinants in diabetic patients will provide a platform to implement appropriate interventions to reduce the burden and to improve the clinical outcomes. About one-third of the global population lacks access to essential medicines. Polypharmacy and failure to prescribe drugs in

accordance with standard clinical guidelines are some of the irrational practices. Irrational use of drugs in diabetic patients can result in increased morbidity, mortality, waste of resources, and adverse drug reactions [2,3]. The World Health Organization (WHO)-International Network for the Rational Use of Drugs (INRUD) developed a set of core drug use indicators that are useful for studying patterns of drug prescribing in health-care facilities and to measure the rational use of drugs [4,5]. There was a scarcity of evidence about the prescribing pattern and drug-related problems occurrence in diabetic patients in Indian settings. The study was aimed to assess the prescribing pattern, prevalence, and predictors of drug-related problems in hospitalized diabetic patients.

## 2. METHODOLOGY

### 2.1 Study Area

In-patient wards of the medical department of a tertiary care hospital located in Tirupati, Andhra Pradesh, India. The hospital was equipped with 1000 beds and serves all people residing around Tirupati.

### 2.2 Study Population

199 diabetic in-patients were selected based on the inclusion and exclusion criteria.

### 2.3 Study Design

A hospital based prospective observational study.

### 2.4 Study Criteria

#### 2.4.1 Inclusion criteria

Diabetic patients aged 18 years or above, irrespective of gender, suffering with or without

co-morbid conditions, and taking treatment on in-patient basis.

#### 2.4.2 Exclusion criteria

Patients admitted in intensive care unit (ICU), severely ill, or taking treatment on out-patient or ambulatory basis. Not willing to give consent to participate in the study.

#### 2.5 Sampling Technique

The required sample size was determined by using Epi-info 7 statistical software, given by the center for disease control (CDC), USA. The sample size was estimated as 196 by considering 15% of DRPs reported in previous studies conducted in India, design effect 1%, cluster 1%, power 80%, a margin of error 6%, and confidence level 95%. A random sampling technique was used to select the diabetic patients who satisfy the study criteria during in-patient medical ward visits. A random number table generator was used to select the subjects for our study. This process was repeated until we get a sufficient sample size during the study period.

#### 2.6 Study Duration

November 2017 to June 2018.

#### 2.7 Study Procedure

A total of 199 diabetic patients were enrolled in the study by proper informed consent procedure. A pre-designed, suitable data collection form was used to collect data about patient demographics, clinical characteristics, WHO core drug use indicators, and DRPs from the medical records, treatment charts, nursing notes, physician notes, and direct patient interview. The study data variables are; participants' age, gender, weight, educational status, residential area, social habits, co-morbidities, diabetic complications, prescribed drugs, number of medications, and hospital stay. The collected data were subjected to assess WHO prescribing indicators like, the average number of drugs per prescription, percentage of drugs prescribed by generic name, percentage of encounters with an injection prescribed, percentage of encounters with an antibiotic prescribed, and percentage of drugs prescribed from the essential drug list (EDL). The documented DRPs were categorized by utilizing Hepler and Strands classification of DRPs 1990 (Hepler and Strand, 1990).

#### 2.8 Data Analysis

The data was analyzed by using Social Sciences version 23.0 (SPSS™, Chicago, IL, USA). Descriptive statistics like mean, standard deviation, number, and proportion were used to represent the demographics, clinical characteristics, distribution of DRPs, and prescribing indicators of the study population. Chi-square (Fisher-exact) test was employed to test for a significant association between the age, gender, location, comorbidities, length of hospital stay, and the number of drugs towards getting DRPs. The findings are considered as statistically significant association if  $P < 0.05$ .

#### 3. RESULTS

A total of 199 diabetic patients were enrolled in this study. The mean age of the study participants was  $55.8 \pm 11.3$ . The majority of the patients were belonging to an age group of more than 60 years (116; 58.3%), males (107; 53.8%), illiterate (171; 85.9%), rural residency (180; 90.4%), no habits (128; 64.3%), at least one co-morbidity (97; 48.7%), and stayed in the hospital more than four days (133; 66.8%) as represented in Table 1.

Among 199 diabetic patients, drug-related problems (117) were observed in 97 patients. The study shows that the prevalence of DRPs in diabetic in-patients was 48.7%. The most commonly identified DRPs are drug interactions (53; 45.3%), adverse drug reactions (24; 20.5%), and untreated indication (21; 17.9%). The complete profile of DRPs was represented in Table 2.

Patient characteristics like, advanced age ( $\geq 60$  years), presence of the co-morbid condition, comprising more than 5 drugs in prescription, and stay in hospital more than four days are significantly associated with the development of DRPs in patients admitted in in-patient medical wards. All findings of associations were represented in Table 3.

The findings of the WHO prescribing indicators revealed that the average number of drugs per encounter was 6.9, percentage of drugs prescribed by generic name was 63.8%, percentage of encounters prescribed by antibiotics was 87.9%, percentage of encounters prescribed with injection was 95%, and percentage of drugs prescribed from the EDL was 85.3%. All five prescribing indicators were not as per the WHO standards as represented in Table 4.

**Table 1. Demographics and clinical characteristics of the study population (n=199)**

<b>Variable</b>	<b>Frequency (%)</b>
Age in years (Mean $\pm$ SD)	55.8 $\pm$ 11.3
< 60 years	116 (58.3)
$\geq$ 60 years	83 (41.7)
Gender	
Male	107 (53.8)
Female	92 (46.2)
Literacy	
Illiterate	171 (85.9)
Literate	28 (14.1)
Location	
Urban	19 (9.5)
Rural	180 (90.4)
Social habits	
Alcohol	17 (8.5)
Smoking	10 (5.0)
Smoking + Alcohol	33 (16.6)
Tobacco chewing	5 (2.5)
Betelnut chewing	6 (3.0)
None	128 (64.3)
Co-morbidities	
One	97 (48.7)
Two	33 (16.6)
Three	4 (2.0)
None	65 (32.7)
Hospital stays (Days)	
$\leq$ 4 days	66 (33.2)
> 4 days	133 (66.8)

*SD=Standard deviation*

**Table 2. Distribution of drug related problems (n=117)**

<b>Category of DRP</b>	<b>Frequency (%)</b>	<b>DRP observed</b>	<b>Frequency</b>
Drug use without indication	1 (0.8)	Nutritional supplements	1
Untreated Indication	21 (17.9)	Anemia	2
		Hypercholesterolemia	2
		Fever	7
		Cough	2
		Edema	1
		Vomiting	4
		Anorexia	1
		Breathlessness	1
		Chest discomfort	1
Improper drug selection	5 (4.3)	Mefloquine	1
		Ofloxacin + Ornidazole	1
		Tramadol	1
		Propranolol	1
		Prednisolone	1
Sub-therapeutic dosage	3 (2.6)	Piperacillin + Tazobactam	1
		Atorvastatin	1
		Metoprolol	1
Over dosage	4 (3.4)	Metformin	1
		Insulin	2
		Furosemide	1
Failure to receive drugs	6 (5.1)	Insulin	6
Drug interaction	53 (45.3)	Insulin with aspirin induces hypoglycemia	4
		Insulin with carvedilol induces hypoglycemia	2
		Insulin with atenolol induces hypoglycemia	7
		Insulin with ciprofloxacin induces hypoglycemia	2
		Insulin with enalapril induces hypoglycemia	2
		Insulin with norfloxacin induces hypoglycemia	3

Category of DRP	Frequency (%)	DRP observed	Frequency
		Insulin with octreotide induces hyperglycemia	2
		Glimepiride with propranolol may increases the risk of hypoglycemia	2
		Glimepiride with fenofibrate may increases the risk of hypoglycemia	4
		Clopidogrel with enoxaparin increases the risk of bleeding	1
		Metformin with metoprolol may induce the hypoglycemia	3
		Metformin with ranitidine may induce the hypoglycemia	1
		Metformin with aspirin may induce the hypoglycemia	2
		Metformin with enalapril may induce the hypoglycemia	1
		Rabeprazole with frusemide may induce hypomagnesaemia	1
		Pantoprazole with warfarin increases the risk of bleeding	1
		Acarbose with aspirin will increases the risk of hypoglycemia	1
		Fluconazole with glimepiride increases the risk of hypoglycemia	2
		Captopril with losartan may increases the risk of hyperkalemia	2
		Glimepiride with isoniazid increases the risk of hypo or hyperglycemia	1
		Levofloxacin with metformin increases the risk of hypo or hyperglycemia	3
		Digoxin with metformin increases the risk of arrhythmias	1
		Atenolol with glipizide increases the risk of hypoglycemia	1
		Atorvastatin with clopidogrel increases the risk of bleeding	2
		Nifedipine with pioglitazone increases the risk of hypoglycemia	2
Adverse Drug Reactions	24 (20.5)	Glimepiride induced dizziness	1
		Glibenclamide induced hypoglycemia	1
		Plain Insulin induced giddiness	2
		Plain Insulin induced fatigue	1
		Insulin induced headache	1
		Insulin induced hypoglycemia	1
		Metformin induced loose stools	2
		Pantoprazole induced constipation	1

Category of DRP	Frequency (%)	DRP observed	Frequency
		Plain Insulin induced hypokalemia	1
		Ceftriaxone induced diarrhea	7
		Zidovudine + Lamivudine + Nevirapine induced anemia	2
		Antitubercular therapy induced gastritis	2
		Aspirin induced gastritis	1
		Amlodipine induced pedal edema	1

*DRP=Drug related problem*

Table 3. Correlation between patient characteristics and drug related problems

Variable	Total (n=199)	Presence of DRPs	Chi-square	P value
Age (Years)			16.3	<0.001
≥ 60	83 (41.7)	55 (54.2)		
<60	116 (58.3)	42 (44.8)		
Gender			2.5	0.089
Male	107 (53.7)	46 (42.9)		
Female	92 (46.2)	51 (55.4)		
Location			1.2	0.230
Rural	180 (90.4)	85 (47.2)		
Urban	19 (9.5)	12 (63.1)		
Co-morbidities			62.7	<0.001
Yes	134 (67.3)	92 (68.6)		
No	65 (32.7)	5 (7.7)		
No. of drugs			57.7	<0.001
> 5	145 (72.9)	95 (65.5)		
≤ 5	54 (27.1)	2 (3.7)		
Hospital stays			14.6	<0.001
≤ 4 days	66 (33.2)	19 (28.8)		
> 4 days	133 (66.8)	78 (58.6)		

*DRP=Drug related problem*

**Table 4. Distribution of WHO Core prescribing indicators among diabetic patients**

Indicator	Average/Percentage	WHO standard derived or ideal (%)
Average number of drugs per encounter	6.9	1.6-1.8
Percentage of drugs prescribed by generic name	63.8%	100
Percentage of encounters prescribed with an antibiotic	87.9%	20.0-26.8
Percentage of encounters prescribed with an injection	95%	13.4-24.1
Percentage of drugs prescribed from EDL/Formulary	85.3%	100

*EDL=Essential drug list; World Health Organization*

#### 4. DISCUSSION

The World Health Organization (WHO) core drug use indicators of prescribing practices estimate the performance of health-care professionals in a key area related to the appropriate use of drugs. Hence, this study was aimed to analyze the prescribing indicators among diabetic patients which will help to promote rational use of drugs and achieve definite outcomes. In our study, the average number of drugs per encounter was 6.9, which was far more when compared with the standard WHO recommended value of 1.6-1.8. Polypharmacy leads to many consequences such as side effects, drug-drug interactions, medication non-adherence, unnecessary drug expenses, and risk of antibiotic resistance [10]. Our study results revealed that there was a high percentage of prescribing of antibiotics, and injections among diabetic patients in reference with WHO standards. There was a need to develop guidelines to reduce the use of antibiotics and injections among diabetic patients. This will reduce the antimicrobial resistance and injection site reaction/adverse events. The WHO suggests all medical practitioners prescribe drugs in generic name and from essential medicine list. But our study findings are not as per the norms of WHO standards. All physicians are encouraged to prescribe drugs in generic name and from EDL. This will reduce the risk of dispensing errors and the cost of the prescription. The present study shows that diabetes was high among males (53.8%) compared to females (46.2%). Similar findings are also observed in previous studies conducted on diabetes [1,11]. The mean age of the diabetic patients was found to be  $55.8 \pm 11.3$ , and the majority are suffering from at least one co-morbidity. These findings were supported by the previous studies conducted in diabetic patients [1,7,12]. The pharmacist plays an important role in the identification, evaluation, and management of DRPs in the healthcare system. In the present study, a total of 117 DRPs

were identified in 199 in-patients of the medical ward, which is 0.6 DRP per patient. The prevalence of DRPs in diabetic in-patients was 48.7%. The findings of our study show a lower rate of DRP compared to the studies conducted in Wolaita Soddo, Eastern Ethiopia, and Southern Ethiopia. [12,13]. These studies showed that 83.1% of diabetic patients experience at least on DRP with a mean number of  $1.8 \pm 0.751$ . A Danish study showed an average of 4.1 DRP per patient [14]. The wide discrepancy among these studies is due to a change in the method of data collection and analysis of DRPs. Previous studies used PCNE classification of DRP, whereas our study used Hepler and Strand method. Even, socio and demographic characteristics and co-morbidities of the participants of different studies also affected the rate of DRP. The study findings revealed that drug interaction (53; 45.3%) was the most commonly identified drug-related problem in diabetic patients. These results are parallel with the findings of the study conducted in Southern Ethiopia [15]. The reason might be due to diabetic patients having a high rate of cardiovascular, neurological, ophthalmic, renal, and thyroid complications than non-diabetic patients. These complications can direct the physician to prescribe multiple medications, which in turn increases the rate of drug interactions [16]. Adverse Drug Reaction (ADR) is the second (20.5%) most common DRP identified in our study. Continuous and timely assessment of ADRs is very important to provide appropriate interventions in diabetic patients. These findings are nearly similar to the study conducted in Addis Ababa, and Ethiopia [15,17]. Other DRPs include untreated indication (17.9%), failure to receive drugs (5.1%), improper drug selection (4.3%), overdose (3.4%), underdose (2.6%), and drug use without indication (0.8%). The majority of the studies revealed that medication non-adherence is the most common DRP among diabetic patients [11,18]. The low rate of medication non-



adherence problem resulted in our study, it was due to the study performed in in-patient settings of the hospital. The study findings revealed that age more than 60 years, presence of comorbidity, prescribed more than five drugs, and stayed in hospital more than four days were significantly associated with the development of DRPs among diabetic patients admitted in in-patient medical ward. All these variables increase the risk of polypharmacy and cause the development of potential drug interactions, ADRs, and medication non-adherence. The DRP secondary to polypharmacy will lead increase in the cost of medications and hospitalization [19]. Similar findings are also observed in the study conducted in Malaysia [11].

## 5. CONCLUSION

The study concludes that the prevalence of DRPs in diabetic in-patients was 48.7%. Drug interactions and adverse drug reactions are the most common DRPs found in our study. Developing the drug policy guidelines focused on factors associated with DRP and WHO prescribing indicators may reduce the burden of DRPs and improves patient outcomes. The clinical pharmacist needs to work with the diabetic team in the rationalization of the prescription and to improve the clinical outcomes.

## 6. STRENGTHS AND LIMITATIONS

Our study provides an evidence on the pattern of DRPs and prescribing patterns in diabetic patients admitted to a hospital. This evidence useful to develop a diabetic drug policy to control the DRPs in diabetic patients. As the study was conducted in in-patient, the findings may not be applied to patient taking treatment on OP or ambulatory basis.

## CONSENT

As per the international standard or university standard, patients' written consent has been collected and preserved by the authors.

## ETHICAL APPROVAL

This research work was approved by the institutional ethics committee (SPSP/2017-2018/PHD01) of the institute and was conducted for a period of 8 months.

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## COMPETING INTERESTS

Authors have declared that no competing interests exist.

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