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PREVALENCE AND PREDICTORS OF DRUG-RELATED PROBLEMS AMONG MEDICAL WARD PATIENTS IN A SECONDARY CARE REFERRAL HOSPITAL: A PROSPECTIVE HOSPITAL-BASED INTERVENTIONAL STUDY

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ABSTRACT: Drug-Related Problem (DRP) affects the hospital stay, healthcare budget, quality of life, morbidity, and mortality. The study aims to assess the prevalence and predictors of DRPs in hospitalized patients and provide intervention. A prospective interventional study was conducted in the in-patient medical department of the NGO hospital. A total of 310 subjects were enrolled and screened for the presence of DRP. The identified DRPs were categorized according to the Hepler and Strands. Depending on DRP, the clinical pharmacist provided an intervention at the patient and physician level and recorded the acceptance. The data was analyzed using SPSS™. Binary logistic regression was employed to associate risk factors with DRPs. The prevalence of DRPs in the medical department was 80.0%, with a 0.93 DRP/patient average. Drug interactions(DI) (28.4%) and adverse drug reactions (ADR) (21.8%) are the most common DRPs. Anti-microbials (78.0%) and Anticonvulsants (81.2%)showed a greater risk of developing DRPs. Variables like advanced age, the habit of alcohol and smoking, hospital stay, and polypharmacy were significantly associated with DRPs. A total of 179 interventions were recommended, and the acceptance rate was 83.7%. Dosage (23.6%), time adjustment (17.9%), and counseling (15.6%) are the most common pharmacist interventions. Patient counseling is a widely accepted and implemented intervention. The prevalence of DRPs in in-patients of the medical ward was 80.0%. DI and ADR are the most common DRPs found in our study. Developing a drug policy focused on factors associated with DRPs may reduce the burden of DRPs and improve patient outcomes.

INTRODUCTION: A drug-related problem (DRP) is an event or circumstance that occurs during the treatment of a disease that actually or potentially interferes with the achievement of optimal health outcomes [1].

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Drugs are considered a double-edged sword, where appropriate drug use can cure the ailments; if not, they can cause harm to the patient in the form of drug-related problems [2].

In hospitalized patients, drug-related problems may ensue during prescribing, dispensing, administration of drugs, and treatment follow-up [3]. DRPs are classified into eight categories according to Hepler and Strand. They include; untreated indication, improper drug selection, subtherapeutic dosage, overdosage, adverse drug reaction, failure

to receive drugs, drug interactions, and drug use without an indication [4]. Patients admitted to medical wards are at greater risk of developing DRPs due to several factors: acute illnesses, advanced age, comorbidities, younger patients with severe disease, polypharmacy, renal impairment, and frequent change in the drug therapy [5]. Previous studies suggest that most hospitalized patients will experience at least one DRP during their hospital stay. For example, studies from Southwest Ethiopia, Northern Sweden, Spain, Jordan, and Norway reported that the prevalence of DRPs among hospitalized patients was 73.5%, 66.0%, 45.1%, 41.8%, 98.3% and 81.0%, respectively 3, [6–9]. The DRPs significantly impact hospital stay, healthcare budget, quality of life, morbidity, and mortality [10]. Therefore, early detection and prevention can minimize the negative impact of DRPs on health and economic outcomes. The Indian evidence shows that most DRP studies focused on specific illnesses/drugs/populations or ambulatory patients [11–13]. Also, few studies addressed the predictors of DRP and the medical team's acceptance of recommended clinical pharmacist interventions [14]. There was no study performed to assess the DRPs in Indian rural hospital settings. The study aims to assess the prevalence and predictors of drug-related problems in medical wards of a rural secondary care referral hospital.

MATERIALS AND METHODS: A prospective hospital-based interventional study was conducted in the in-patient medical department of a 330 bedded NGO charity hospital - Rural Development Trust Hospital, situated in a small village of Bathalapalli, in the socio-economically backward district of Anantapur, Andhra Pradesh, India.

Study Criteria: All patients aged 18 years or more and admitted to the in-patient medical wards between December 2018 and August 2019 (9 Months) are eligible for the study. Patients admitted to the Intensive Care Unit (ICU) who refused to give consent, readmitted during the study period, and were discharged before collecting data were excluded from the trial.

Ethical Considerations: The study was conducted after getting ethical clearance from the Institutional Review Board (Reg. No: RIPER-IRB-PP-2018-043). After explaining the study protocol and objectives in an understandable language, oral and written informed consent was obtained from all enrolled subjects. Patients' names and other identifiers were not mentioned in the data collection tool to ensure confidentiality.

Sample size and Sampling Technique: To estimate the number of subjects that need to be included in the study, a single proportional population formula was used with a prevalence of DRPs of 28.0% from else report, 95% confidence interval, 5% of margin of error, design effect 1%, and 80% power, which was calculated as 284. The eligible subjects were chosen for the study using a convenient sampling technique.

Study Procedure: A total of 310 subjects who met the study criteria were enrolled by taking oral and written informed consent. A pre-designed and structured data collection form was used to collect the selective information from the data resources (patient case sheets, medication charts, lab reports, and patient/caregiver interviews). The data collection form mainly contains patient demographics, clinical features, social habits, past medical and medication history, laboratory details, current diagnosis, current medication therapy, and progressive daily report. The current medication therapy details include all drugs' names, route of administration, dose, frequency, duration, indication, and date of drugs started and stopped. The past medical and medication history includes allergies (food and medicine), comorbidities, and previously received drugs. The study investigator evaluated the appropriateness of drug therapy using various resources like primary (standard literature), secondary (Micromedex), and tertiary (*e.g.*, BNF, AHFS, and Martindale), which are available in the Pharmacy Practice department. The identified DRPs were recorded and categorized according to Hepler and Strands classification of DRPs 1990as an untreated indication, improper drug selection, subtherapeutic dosage, overdosage, adverse drug reaction, failure to receive drugs, drug interactions, and drug use without an indication. Depending on the type of DRP, the clinical pharmacist applies the specific intervention to patients/healthcare providers to achieve a better therapeutic outcome. The healthcare providers' acceptance level of clinical pharmacist intervention was categorized as;

1. Intervention accepted therapy changed, 2. Intervention accepted therapy not changed, 3. Neither intervention accepted nor therapy changed and 3. No intervention

Data Analysis: The data wasanalyzed using SPSS™ 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 clinical pharmacist interventions in the study population. A binary logistic regression analysis test was employed to test for significant association between the age, gender, comorbidities, length of the hospital stay, polypharmacy, and route of the administration towards getting DRPs. The findings are considered as a statistically significant association if $P < 0.05$.

RESULTS: A total of 310 subjects were enrolled in the study. The findings of our research revealed that the majority of the patients are between the ages of 18 and 40 years (129; 41.6%), males (188; 60.6%), normal weight (238; 76.8%), rural residents (252; 81.3%), no allergy (304; 98.1%), no habit of smoking and alcohol consumption (125; 40.3%), not suffering from any co-morbid condition (177; 57.1%), stayed in hospital less than or equal to four days (214; 69.0%), taking drugs less than five (194; 62.6%) and the hospital is at least once in the past 12 months (174; 56.1%).

The distribution of the socio-demographic and clinical characteristics of the study subjects is shown in **Table 1.**

TABLE 1: SOCIO-DEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF THE STUDY POPULATION (N=310)

Variable	Frequency (%)
Age in years (Mean ± SD)	
18-40	129 (41.6)
41-60	97 (31.3)
>60	84 (27.1)
Gender	
Male	188 (60.6)
Female	122 (39.3)
BMI (Mean ± SD)	
<18	29 (9.3)
18-25	238 (76.8)
≥25	43 (13.9)
Location	
Urban	58 (18.7)
Rural	252 (81.3)
Allergies	
No	304 (98.1)
Yes	6 (1.9)
Social habits	
None	125 (40.3)
Smoking	35 (11.3)
Alcohol consumption	52 (16.8)
Both	98 (31.6)
Comorbidities	
None	177 (57.1)
One	80 (25.8)
Two	38 (12.2)
More than or equal to three	15 (4.8)
Hospital stays (Days)	4.68±2.34
≤4 days	214 (69.0)
>4 days	96 (30.9)
Average no. of drugs/day	6.43±3.56
<5	194 (62.6)
≥5	116 (37.4)
Last 12 months, hospital admissions	
Yes	174 (56.1)
No	136 (43.8)

SD=Standard Deviation

TABLE 2: TYPE OF DRUG-RELATED PROBLEMS IDENTIFIED AMONG PATIENTS ADMITTED IN THE MEDICAL WARD

Drug-related problem	Frequency	Percentage of total DRP (N=289)	Percentage of total Patients (N=248)
Untreated indication	19	6.6	7.6
Improper drug selection	26	8.9	10.5
Subtherapeutic dosage	28	9.7	11.3
Over dosage	37	12.8	14.9
Adverse drug reaction	63	21.8	25.4
Failure to receive drugs	16	5.5	6.4
Drug interactions	82	28.4	33.1
A drug used without an indication	18	6.2	7.2

Among 310 study subjects, 248 (80.0%) had drug-related problems (DRPs). 289 DRPs were identified in the study, with an average of 0.93 DRPs/Patient. Drug interactions (28.4%) and adverse drug reactions (21.8%) are the most commonly identified DRPs in the study. The distribution of the DRPs according to the percentage of total DRPs and patients were represented in **Table 2.**

TABLE 3: DISTRIBUTION OF THE DRUG-RELATED PROBLEMS ACCORDING TO THE DRUG CATEGORY

Drug/drug class	No.	UI	IDS	STD	OD	ADR	FRD	DI	DWI	Total (%)
Antimicrobials	123	05	10	12	17	21	04	24	3	96 (78.0)
Vitamins and Minerals	32	01	-	-	-	-	-	03	8	12 (37.5)
Corticosteroids	35	-	-	-	05	04	02	03	1	15 (42.8)
NSAIDs	68	02	-	-	03	10	-	05	2	22 (32.3)
Antacids	38	-	05	-	-	-	-	04	2	11 (28.9)
Oral hypoglycemic agents	39	01	-	01	01	02	01	04	-	10 (25.6)
Beta-blockers	42	02	03	03	-	02	03	02	-	15 (35.7)
Diuretics	36	02	-	-	05	02	-	04	-	13 (36.1)
CCBs	28	-	02	-	03	02	-	02	-	09 (32.1)
Laxatives	12	-	01	-	02	-	-	-	1	04 (33.3)
ACE Inhibitors	29	06	02	06	-	02	-	02	-	18 (62.1)
Bronchodilators	30	-	04	03	-	03	-	02	-	12 (40.0)
Statins	15	-	-	-	-	02	01	03	-	06 (40.0)
Anti Muscarinic	28	-	-	-	01	04	-	05	-	10 (35.7)
Thyroid hormone	23	-	-	02	-	01	05	06	-	14 (60.9)
Anticoagulants	12	-	-	01	-	01	-	01	-	03 (25.0)
Anticonvulsants	16	-	-	-	-	05	-	08	-	13 (81.2)
Narcotic analgesics	09	-	1	-	-	02	-	02	1	06 (66.6)

UI=Untreated Indication; IDS=Improper Drug Selection; STD=Sub-therapeutic dose; OD=Over Dose; ADR=Adverse Drug Reaction; FRD=Failure to receive drug; DI=Drug Interaction; DWI=Drug without indication.

The distribution of the drug-related problems according to drug category wise was represented in **Table 3**. Anti-microbials (78.0%), Anticonvulsants (81.2%), Narcotic analgesics (66.6%), ACE Inhibitors (62.1%), and Thyroid hormones (60.9%) show a greater risk of developing DRPs.

TABLE 4: ASSOCIATION OF PATIENT CHARACTERISTICS FOR THE DEVELOPMENT OF DRPs (N=310)

Variable	Frequency (%)	Presence of DRPs (%)	Odds ratio (95% CI)	*P-value*
Age in years (Mean ± SD)				
18-40	129 (41.6)	74 (57.4)	Ref	Ref
41-60	97 (31.3)	93 (95.9)	17.1 (6.34-57.7)	<0.001
>60	84 (27.1)	81(96.4)	19.8 (6.683.2)	<0.001
Gender				
Male	188 (60.6)	144 (76.6)	Ref	Ref
Female	122 (39.3)	104 (85.2)	1.76 (0.97-3.28)	0.063
BMI (Mean ± SD)				
<18	29 (9.3)	23 (79.3)	Ref	Ref
18-25	238 (76.8)	190 (79.8)	1.03 (0.36-2.60)	0.947
≥25	43 (13.9)	35 (81.4)	1.14 (0.34-3.80)	0.827

Location				
Urban	58 (18.7)	46 (79.3)	Ref	Ref
Rural	252 (81.3)	202 (80.1)	1.05 (0.50-2.11)	0.884
Allergies				
No	304 (98.1)	243 (79.9)	Ref	Ref
Yes	6 (1.9)	5 (83.3)	1.25 (0.17-30.33)	0.837
Social habits				
None	125 (40.3)	93 (74.4)	Ref	Ref
Smoking	35 (11.3)	25 (71.4)	0.86 (0.37-2.06)	0.725
Alcohol consumption	52 (16.8)	40 (76.9)	1.14 (0.54-2.52)	0.724
Both	98 (31.6)	90 (91.8)	3.85 (1.73-9.35)	<0.001
Comorbidities				
None	177 (57.1)	133 (75.1)	Ref	Ref
One	80 (25.8)	67 (83.7)	1.70 (0.87-3.48)	0.125
Two	38 (12.2)	35 (92.1)	3.84 (1.23-16.44)	0.022
More than or equal to three	15 (4.8)	13 (86.7)	2.14 (0.52-14.49)	0.316
Hospital stays (Days)	4.68±2.34			
≤4 days	214 (69.0)	160 (74.8)	Ref	Ref
>4 days	96 (30.9)	88 (91.7)	3.69 (1.74-8.66)	<0.001
Average no. of drugs/day	6.43±3.56			
<5	194 (62.6)	146 (75.2)	Ref	Ref
≥5	116 (37.4)	102 (87.9)	2.39 (1.27-4.69)	0.007
Last 12 months, hospital admissions				
Yes	174 (56.1)	140 (80.4)	Ref	Ref
No	136 (43.8)	108 (79.4)	0.94 (0.53-1.65)	0.819

SD=Standard Deviation

Table 4 shows the association of socio-demographic and clinical profiles toward the development of DRPs in patients admitted to the medical ward. Variables like age of more than 40 years, the habit of alcohol consumption and smoking, hospital stay more than four days, and taking drugs more than or equal to five were significantly associated with the development of DRPs with a P value less than 0.05.

TABLE 5: CLINICAL PHARMACIST INTERVENTIONS AND THEIR ACCEPTANCE LEVELS

Category of intervention	No. (%)	Accepted intervention and implemented	Accepted intervention but therapy not implemented	Neither intervention accepted nor implemented
Dosage adjustment	42 (23.5)	28 (66.7)	4 (9.5)	10 (23.8)
Drug change	21 (11.7)	12 (57.1)	8 (38.1)	1 (4.8)
New Drug added	17 (9.5)	8 (47.0)	6 (35.3)	3 (17.6)
Drug stopped	15 (8.4)	6 (40.0)	4 (26.7)	5 (33.3)
Patient counselling	28 (15.6)	28 (100.0)	0 (0.0)	0 (0.0)
Monitoring of lab parameters	24 (13.4)	16 (66.7)	3 (12.5)	5 (20.8)
Time adjustment in drug therapy	32 (17.9)	22 (68.7)	5 (15.6)	5 (15.6)

A total of 179 pharmaceutical interventions were recommended to resolve drug therapy problems. The acceptance rate of the clinical pharmacist recommended intervention was 83.7%.

In our study, dosage (42; 23.6%) and time interval adjustment (32; 17.9) and patient counselling (28; 15.6%) are the most commonly recommended pharmacist interventions to resolve DRPs. Pharmacist-mediated patient counselling is a widely accepted and implemented intervention to DRPs lying at the patient level.

The distribution of clinical pharmacist interventions and their acceptance levels were represented in **Table 5.**

DISCUSSION: Assessment of the DRP prevalence and identification of risk factors associated with DRPs in in-patient hospital settings is essential for developing interventions at the individual patient level. The study findings revealed that the prevalence of DRPs in the medical department was 80.0%, with an average of 0.93 DRP/patient. The magnitude of DRPs in this study is high compared

to the other studies conducted in Gondar (66.0%), Dessie referral hospital (75.5%), Tikur Anbesa hospital (70.4%), Jimma University hospital (73.5%), and Indian hospital (41.8%) [12, 15–18]. However, this study shows less rate of DRPs compared to the study conducted in Kenya (93.8%), Norway (81.0%), and Jordan (98.3%) [8, 19, 20]. The primary reason for the wide variation in the prevalence of DRPs across countries might be due to changes in their clinical practice, a different classification system for DRPs, and varied healthcare settings. The study recommends providing evidence-based interventions to reduce the burden of DRPs. Also, the study endorses the researchers' use a single classification system in the assessment of DRPs. This helps in the comparison of intra and inter-country variation of the DRP magnitude.

In this study, drug interactions (28.4%) and adverse drug reactions (21.8%) are the most commonly identified DRPs. A study conducted in Adama Hospital Medical College, Ethiopia, and Navie Hospital, Northern Sweden, showed that ADR and drug interaction are the predominant DRPs identified, respectively, nearly similar to the current study [18, 21]. However, the study conducted in Ethiopia shows an unnecessary drug therapy is the major DRP10. The least common drug therapy problem observed in this study is failure to receive drugs, similar to the study conducted in Southwest Ethiopia [10]. The low rate of medication non-adherence observed in this study is due to the administration of drugs by the nurses in in-patient hospital settings.

In this study, Anti-microbials (78.0%), Anticonvulsants (81.2%), and Narcotic analgesics (66.6%) drug classes were associated with a high rate of DRPs. Studies conducted in Northeast (28.0%) and Southwest Ethiopia (25.0%) also show that antimicrobials are the primary drugs in developing DRPs [10, 16]. In contrast, a study conducted in Gondar revealed proton pump inhibitors are associated with a high rate of DRPs. The wide variability in the drug class involved in developing DRP is due to different practice guidelines and patient and physician preferences across the countries. A total of 179 pharmaceutical interventions were recommended to resolve drug therapy problems. The acceptance rate of the clinical pharmacist recommended intervention was 83.7%. The acceptance rate of pharmacist intervention is not clearly assessed in previous studies on DRPs in clinical practice [22–24]. Few studies show that the percentage of pharmacist-led interventions' acceptance is very inconsistent. In two studies, the acceptance rate of clinical pharmacist interventions was lower (56% and 69%) than in the current study [25, 26]. Whereas, in two studies, the acceptance rate was more than 80% which is similar to the findings of the present study [7, 27]. In the current study, pharmacist-led patient counselling is the highly agreed intervention in resolving drug therapy problems to achieve a definite outcome. The wide acceptance of recommended interventions in this study is majorly due to the running of clinical pharmacy services in the hospital for 10 years; clinicians trust pharmacist-provided information, clinically relevant recommendations by the pharmacist, and delivery of evidence-based and unbiased information using an authentic software.

Variables like age of more than 40 years, the habit of alcohol consumption and smoking, hospital stay more than four days, and taking drugs more than or equal to five were significantly associated with the development of DRPs with a P value less than 0.05. In the aging process, the patient will suffer from comorbidities, take multiple medications, and hepatic and renal function failure are the few reasons for the development of DRPs. The positive impact of age on the development of DRPs was also observed in various studies conducted in India, Southwest Ethiopia, and Northern Sweden [7, 14, 18].

However, a study conducted in Jordan showed that advanced age is not a predictor of the existence of DRPs [8]. This might be due to variation in the type of medical care offered to the specific age of the population. The polypharmacy in this study is also one of the major contributing factors to drug interactions. These results were similar to the study conducted by Abdela *et al.*, in which polypharmacy showed a positive association with developing DRPs [28]. These findings suggest that control on the number of prescribed medications to treat medical conditions will reduce the risk of the development of DRPs. Prolonged hospital stay is associated with an increased risk of DRPs due to an increased

number of drugs to treat hospital-acquired infections.

Strengths and Limitations: The study provides evidence on predictors of DRPs and clinical pharmacist interventions provided to combat DRPs in rural hospital settings of South India. As the study is a cross-sectional study, it identifies associations, not an exact causal relationship, between risk factors and the development of DRP. The study was conducted in a rural secondary care referral hospital.

So, the findings of this study may not be generalized toward primary and tertiary care hospitals. The outcome of clinical pharmacist interventions was not evaluated as this study was not collected data on a regular practice basis. In the future, randomized comparative studies are required to address the impact of clinical pharmacist interventions on economic, clinical, and humanistic outcomes (ECHO)

CONCLUSION: The study concludes that the prevalence of DRPs in medical ward patients was 80.0%. 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 DRPs may reduce the burden of DRPs and improves patient outcomes. In our study, dosage adjustment and patient counselling are the most commonly recommended pharmacist interventions to resolve DRPs. Pharmacist-mediated patient counselling is a widely accepted and implemented intervention to reduce DRPs lying at the patient level. Clinical pharmacist needs to work with the healthcare team in the rationalization of the prescription and to improve the clinical outcomes.

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