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Original Article

Identification of Drug Related Problems by Clinical Pharmacist in Prescriptions with Polypharmacy: A Prospective Interventional Study

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ABSTRACT

Objectives: Drug Related Problems (DRPs) and prescriptions with polypharmacy may lead to increased health care cost, morbidity, mortality and decreased quality of life. The objective of the study was to assess the pattern of DRPs associated with polypharmacy. **Methods:** It is a hospital based prospective interventional study carried out for 6 months in the Department of General Medicine. The DRPs were identified by researchers during ward rounds by reviewing the patient case reports. Problems identified and recognized was documented and discussed with the concerned health care team. **Results:** During the study period, 150 patient case sheets were reviewed to identify 213 DRPs. The most common DRP was found to be Adverse Drug Reactions (ADRs) (45%) followed by needs additional drug therapy (26.8%), untreated indication (13.6%) and Drug-Drug Interactions (DDIs) (11.7%). Binary logistic regression was performed to identify the predictors of DRPs. It was observed that number of comorbidities (Adjusted odds ratio (AOR) = 3.68 ($p < 0.001$)), geriatric population and polypharmacy were the major predictor. **Conclusion:** The study highlights the importance of drug therapy review to minimize DRPs, ADRs, polypharmacy, framing of new deprescribing guidelines and algorithms for drugs which are utilized inappropriately, deprescribing of redundant drugs during routine clinical practice and appointment of clinical pharmacist in hospitals to achieve better therapeutic outcomes and improved patient care.

Key words: Adverse drug reactions, Clinical Pharmacist, Deprescribing, Drug related problems, Polypharmacy, Predictors.

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INTRODUCTION

The French Society of Clinical Pharmacy, describes DRP as a circumstance or an event concerning to the drug therapy that potentially or actually interferes with desired health outcomes.[1] Medication therapy is an imperative treatment methodology, besides a dominant part of diseased population utilize different medicines simultaneously leading to polypharmacy and hyperpolypharmacy. In current clinical practice, prescribers regularly utilize more number of medications to treat each comorbid conditions in patients; and this circumstance convolutes, when patients visit physicians of various specialities, which may prompt the occurrence of potential DRPs. Polypharmacy is commonly specified when the drugs have been prescribed by multiple physicians, or when a person is taking too many medicines and might not been coordinated well.[2] Daily consumption of five or more medications is termed as polypharmacy.[3] Some research studies has categorized polypharmacy as consumption of more than four drugs and two drugs as major and minor respectively.[4] Polypharmacy may make the patient a derisory disciple to the endorsed solution.[5] According to Hepler and Strand Classification, the DRPs are grouped into 8 classifications as drug use without indications, improper drug selection, drug interaction, adverse drug reaction, over dosage, needs additional drug therapy, sub therapeutic dosage, improper drug selection and untreated indications.[6] DRPs such as ADRs, interactions, and potentially inappropriate drug use are common and cause up to 30% of hospitalizations among old individuals. Much more in danger are individuals with dementia or cognitive impairment, where 41% of hospital admission have been judged as caused or partially caused by DRPs.[7] Since, DRPs are a vital issue and a significant number of them are preventable, the specific hazard factors that encourage the event of DRPs are of extensive intrigue. These include female gender, polypharmacy, administration of medications with a narrow therapeutic range or renal disease, age more than 65 years and the utilization of oral anticoagulants and diuretics.[8]

In a systemic review, Krähenbühl Melcher *et al.* found that around 8% of hospitalized patients encounter an ADR and 5–10% of all drug prescriptions or drug applications are mistaken.[9] In general medicine, around 15% of hospitalized patients and 12– 17% of patients after discharge experience ADRs.[10-11] In a study conducted by Nascimento, 91.7% of DRPs was reported.[12] However, limited data is available on the prevalence of DRPs in India which provides a scope for clinical pharmacist intervention in overall patient care and in minimizing drug related problems.[13-14]

The role of clinical pharmacist is to identify and endorse utilization of safe and effective medications to resolve these DRPs, by analysing the medicine regimen to be cost-effective, safe, and optimum/ appropriate.[3] The rational utilization of medications could be upgraded by possessing detailed knowledge and information about DRPs with relation to the patients, doctors and pharmacists.[15] Identification of DRPs and awareness on drugs which have high risk of DRPs are essential components of treatment which may lessen DRPs, morbidity, mortality and improve personal satisfaction of patients.[16] Frequency of incidence of DRPs are

generous and clinical pharmacist interventions may help in diminution of DRPs in developing countries such as India.[14] The current study aimed to provide information to quantify the burden of DRPs among patients with polypharmacy and contribute to the design and implementation of risk management plans.

MATERIALS AND METHODS

Study sample

A prospective interventional study was conducted among the inpatients and outpatients of the Department of General Medicine of a tertiary care hospital for a duration of 6 months from November 2016 to April 2017. Permission was obtained from Human Ethics Committee of the hospital to carry out the study. The inclusion criteria was patients aged 18 years and above and including all routes of administration such as topical, inhaled, intravenous, oral and over the counter drugs etc. Patients admitted to intensive care units or other units were excluded from the study. From the literature review, Tigabu *et al.*, has observed that the prevalence of DRPs in their study was found to be 73.5%.[17] Expecting similar results in our present study with 95% confidence interval (CI) and with 10% relative precision, the sample size was found to be 150 subjects. 150 patients satisfied the aforementioned criteria and enrolled for the study.

Data collected

DRPs identified were recorded and discussed with the concerned health care team. DRPs were categorized by utilizing Hepler and Strands classification of DRPs 1990 (Hepler and Strand, 1990). Out of 210 patients, 150 of them satisfied the criteria. Patient information was collected from medical record and through interviews. The information obtained was analysed to identify DRPs (Figure1).

Statistical analysis

The statistical analysis were performed using SPSS 20.0 statistical package. The binary logistic regression was used to see the association between independent variable (DRPs) and dependent variable (age, gender, comorbidities, number of drugs received). Odds ratio (OR) with 95 % confidence interval was also computed for each variable for the corresponding P value. The value of P <0.05 was considered as statistically significant.

RESULTS

Hundred and fifty patients were followed and reviewed during the six months study period in the Department of General Medicine. A total of 150 patients were screened for DRPs out of which 75 (50%) patients were males and 75 (50%) patients were females. Most of the patients (42%) were in the age group >60 years followed by 41-60 years (36%). Among the study population, 42 (28%) were diagnosed with 1 comorbidity followed by 38 (25.3%) with 2 comorbidities and most of the patients received more than 10 drugs 73 (48.7%). The details of patient demographics are shown in Table 1. In this study population, 70 (28.11%) had hypertension and 65 (26.10%) had Type 2 diabetes mellitus (T2DM) as their comorbid conditions which is described in Table 2.

Drug Related Problems

The most common DRP in patients was ADRs in 96 (45%) patients trailed by needs additional drug therapy in 57 (26.8%) patients, untreated indication in 29 (13.6%) patients and drug-drug interaction in 25 (11.7%) patients. Figure 2 presents the type of DRPs. Chi-square test was used to analyse the degree of association between age group, gender, comorbidities and the number of drugs patient received with DRP. A significant statistical association was found in variables such as comorbidities (p<0.01), age (p<0.01) and number of drugs received (p<0.01) with DRPs. Among the number of drugs, patients receiving more than 10 drugs were found to have significantly more number of DRPs. There was no association seen between gender and DRPs (p=0.7438). Correlation between the demographic features and DRPs are shown in Table 3.

The drug class that was most involved in causing DRP was found to be antihypertensive agents (41%). Based on the results, there is a high risk for patient who are receiving anti-hypertensives in our study to develop DRPs with Odds Ratio (OR): 1.574 (95% CI: 1.340-1.849) followed by patient who are receiving anticonvulsant OR: 1.556 (95% CI: 1.053-2.299). Table 4 describes the most common classes of drugs that have high risk of developing DRPs.

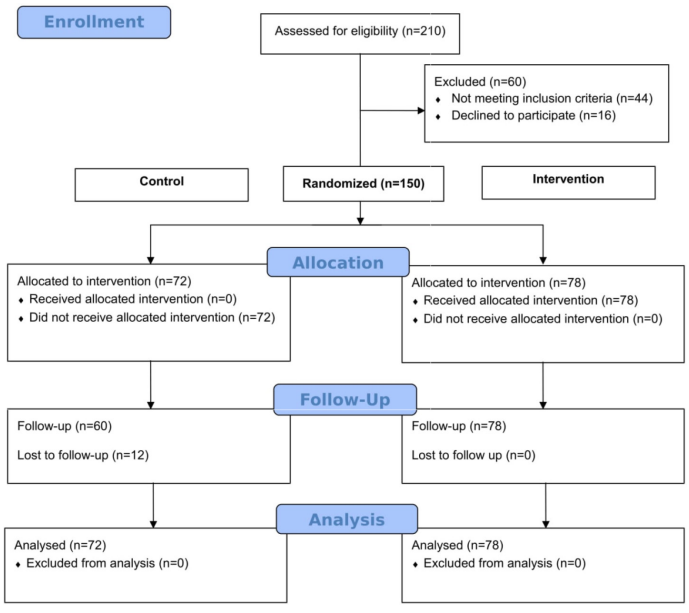

Figure 1: Flow chart for selection of study population.

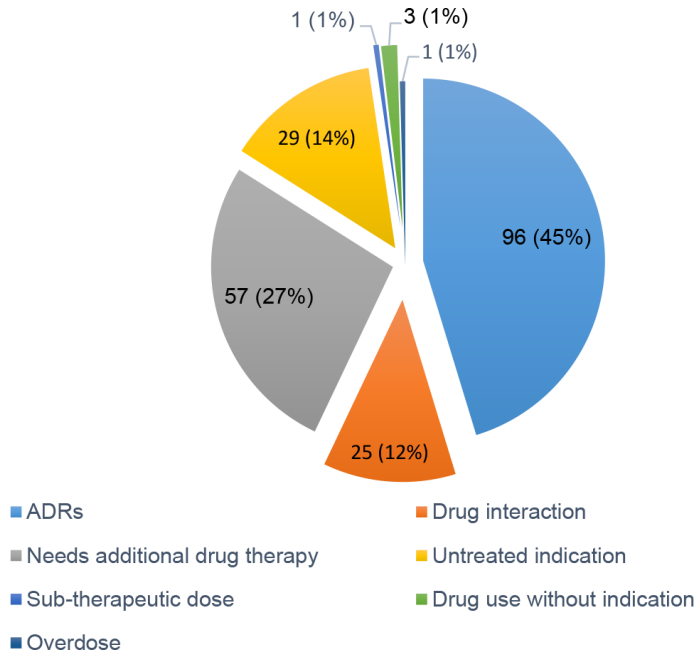

Figure 2: Types of DRPs.

Pharmacist Intervention

The most frequent pharmacist intervention provided was cessation and addition of drug which accounts for 67 (31.4%) interventions. Addition of drug was done in 62 (29.1%) interventions and cessation of drug was done in 29 (13.6%) interventions. Various suggestions provided by intervening pharmacist are summarized in Figure 3. Out of the 213 DRPs, the significance level 'minor' was found to be high 140 (65.7%) followed by significance level 'moderate' 71 (33.3%) and 'major' 2 (1%). The significance level of DRPs is shown in the Figure 4. Suggestion by intervening pharmacist was accepted and therapy changed in 144 (67.6%) DRPs, suggestion accepted but therapy not changed in 64 (30%) DRPs and neither suggestion accepted nor therapy changed in 5 (2.4%) conditions. The result of clinical pharmacist recommendation is shown in the Figure 5.

Predictors associated with drug related problem

The univariable analysis showed three predictors that were significantly associated with DRP occurrence (Table 5). Independent factors which predicted the occurrence of DRPs in the study population were gender, age, average number of drugs/day, route of administration, number of comorbidities and polypharmacy were analysed to determine whether they could predict the occurrence of DRPs or not. The result of the binary logistic regression showed that association was observed between age above 60 years (OR: 2.594, 95% CI 1.254-5.366, $p<0.01$), presence of more than 2 comorbidities (OR: 2.708, 95% CI 1.309-5.608, $p<0.01$) and polypharmacy (OR: 2.338, 95% CI 1.009-5.419, $p<0.05$) with the occurrence of DRPs.

DISCUSSION

In our study, we evaluated the DRPs in patient with polypharmacy in a tertiary care hospital. 213 DRPs were identified from 78 patients. Out of 78 patients, majority of DRPs occurred in males (51.3%) as compared to females which is in consistent with the earlier study conducted by Ramanath *et al.*[3] The increase might be due to amplified medication use

Table 1: Demographic details and characteristics of study population.

Detail	Characteristics	Number (%)
Gender	Male	75 (50)
	Female	75 (50)
Age	18-40 years	33 (22)
	41-60 years	54 (36)
	>60 years	63 (42)
Comorbidities	None	32 (21.3)
	1	42 (28)
	2	38 (25.3)
	3	22 (14.7)
	>4	16 (10.7)
Number of drugs prescribed	2-5	14 (9.3)
	6-10	63 (42)
	>10	73 (48.7)

Table 2: Comorbid conditions of study population.

Comorbid condition	Number of patients	Percentage
Hypertension	70	28.11
T2DM	65	26.10
Heart disease	26	10.44
AKI	15	6.02
Hypothyroidism	13	5.22
Stroke	10	4.01
Seizure	8	3.21
Anemia	8	3.21
Bronchial Asthma	9	3.61
COPD	4	1.60
Others	21	8.43

T2DM- Type 2 Diabetes Mellitus, AKI- Acute kidney injury, COPD- Chronic Obstructive Pulmonary Disease

Table 3: Correlation between age group, gender, comorbidities, number of drugs received with DRP.

Variables	No. of patients without DRPs		No. of patient with DRPs		Total no. of patients (%)	Chi square value with Significance
	Observed Value	Expected Value (χ^2)	Observed Value	Expected Value (χ^2)		
Age group						
18-40	24	15.84 (4.20)	9	17.6 (3.88)	33 (22)	χ^2 = 18.846,
41-60	30	25.92 (0.64)	24	28.08 (0.59)	54 (36)	P= 0.0001
>60	18	30.24 (4.95)	45	32.76 (4.57)	63 (42)	
Gender						
Male	35	36 (0.03)	40	39 (0.03)	75 (50)	χ^2 = 0.107,
Female	37	36 (0.03)	38	39 (0.03)	75 (50)	P= 0.7438
Comorbidities						
None	26	15.36 (7.37)	6	16.64 (6.80)	32 (21.3)	
1	22	20.16 (0.17)	20	21.84 (0.16)	42 (28)	χ^2 =24.624,
2	15	18.24 (0.58)	23	19.76 (0.53)	38 (25.3)	P= 0.0001
3	5	10.56 (2.93)	17	11.44 (2.7)	22 (14.7)	
>4	4	7.68 (1.76)	12	8.32 (1.63)	16 (10.7)	
Drugs received						
2-5	13	6.72 (5.87)	1	7.28 (5.42)	14 (9.3)	χ^2 =23.525,
6-10	37	30.24 (1.51)	26	32.76 (1.39)	63 (42)	P= 0.0000
>10	22	35.04 (4.85)	51	37.96 (4.48)	73 (48.7)	

DRPs- Drug related problems

Table 4: Classes of drug and their risk in the development of DRPs.

Class of the drug	No. of patient receiving the drug	No. of DRPs occurred in the patients	Percentage (%)	Risk ratio	P value
Antimicrobials	105	13	16.7	1.141	0.008
Antidiabetic	73	10	12.8	1.159	0.001
Bronchodilator	41	8	10.3	1.242	0.000
Anti-platelets	51	4	5.1	1.063	0.038
Antihypertensive	85	32	41.0	1.574	0.000
Anticonvulsant	14	5	6.4	1.556	0.000
Corticosteriods	29	5	6.4	1.208	0.000
Thyroid hormone	13	1	1.3	1.083	0.087*

*Not significant, DRPs- Drug related problems

Table 5: Binary logistic regression result of predictors associated with drug related problem.

Factor	Odds Ratio	95% CI		P Value
		Lower limit	Upper Limit	
Gender				
Female	1.112	0.547	2.261	0.769
Male	Reference			
Age				
<60 years	2.594	1.254	5.366	0.010**
>60 years	Reference			
Comorbidities				
<2	2.708	1.309	5.602	0.007**
>2	Reference			
Polypharmacy				
2-5 drugs	2.338	1.009	5.419	0.048**
>5 drugs	Reference			
Route of Administration	0.990	0.409	2.396	0.982
Oral	Reference			
IV				

CI- Confidence Interval, R.O.A-Route of administration, I.V- Intravenous, **Significant at 0.05

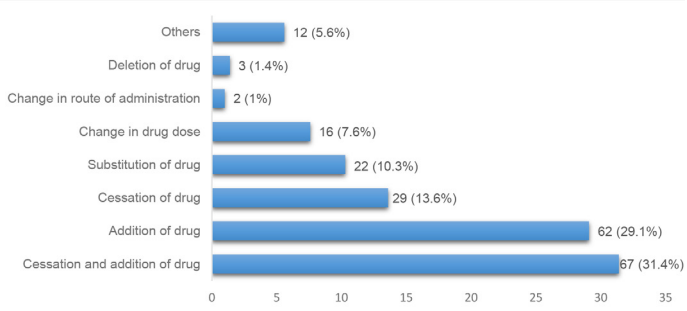

Figure 3: Suggestions provided by intervening pharmacist.
**Major: Problems requiring intervention, expected to prevent or address very serious drug related problems, with a minimum estimated effect on reducing hospital stay by not less than 24 hrs.*
** Moderate: Problems requiring adjustments, which are expected to enhance effectiveness of drug therapy producing minor reductions in patient morbidity or treatment costs.*
**Minor: Problems requiring small adjustments and optimization to therapy, which are not expected to significantly alter hospital stay, resource utilization or clinical outcome.*

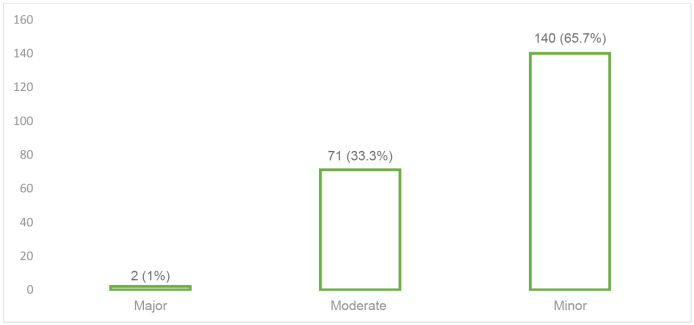

Figure 4: Level of significance of drug related problem.

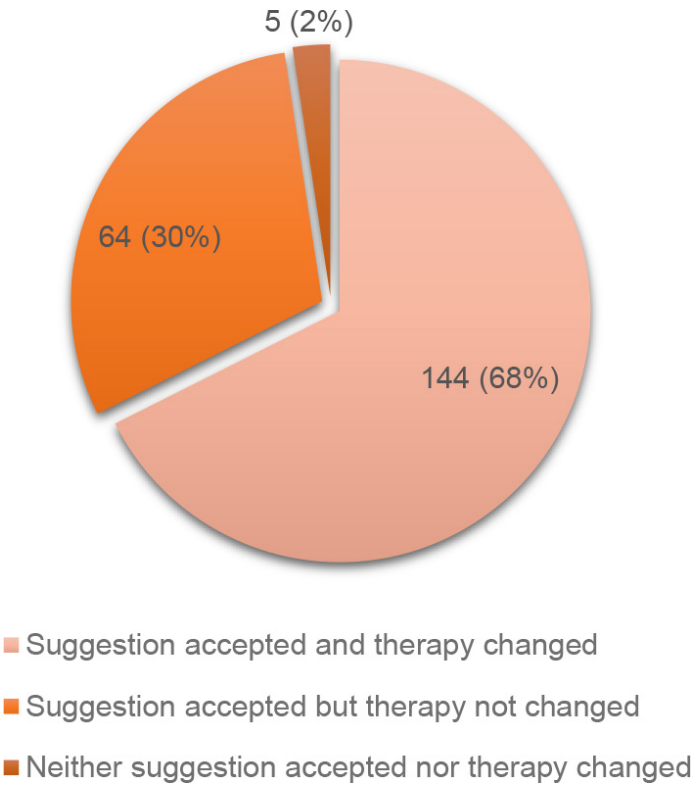

Figure 5: Results of clinical pharmacist recommendations.

because of their multiple comorbid conditions and due to various risk factors like smoking, alcoholism and sedentary life style etc. The incidence of DRPs was high in patients aged above 60 years (57.7%) as compared to the age group between 18-60 years (42.3%). These results might be due to multiple drug regimens owing to their multiple co-morbidity and age related changes in pharmacokinetics and pharmacodynamics in elderly patients. This also indicates that special attention should be given to older age group by regular review of drug therapy, which might help potentially to decrease DRPs. This finding is in accordance with the study conducted in Southern India.[13] In the present study, occurrence of DRPs was found to be high in patients with more than 1 comorbidities. It reveals that patient who has comorbidities have increased risk of developing DRPs. Patients receiving more than 10 drugs were found to have more DRPs (65.4%). It has been observed that the number of drugs at admission and the number of clinical/pharmacological risk factors were both independent risk factors for the occurrence of DRPs which was similar to the results obtained in the study conducted by Ahmad *et al*.[18] In our study, the most prevalent disease conditions were hypertension and diabetes. Outcomes of study led by Patel V *et al*., conducted in India makes a comparable determination that the statistical prevalence of cardiovascular disease and diabetes is the highest.[19]

With respect to the profile of DRPs, ADRs was the predominant domain which conformed to the study done in an Indonesian hospital.[20] Inappropriate combination of drugs with other drugs contributed to the predominant cause of ADRs. 31(50.8%) females were found to be affected with ADR more when compared to male. This was comparable to the findings obtained from the study conducted by Vijayakumar *et al*., where 53.4% female patients experienced higher incidences of ADRs.[21] This may be due to pharmacokinetic, pharmacodynamic and hormonal changes in women. Majority of ADRs occurred in geriatric patients which is in line with the study documented by Shareef *et al*.,[22] The elderly population has higher prevalence of chronic diseases and usage of multiple drugs which predisposes them to develop ADRs.

Needs additional drug therapy constitute 26.8% of total DRPs. The most common condition that needs additional drug therapy was found to be hyponatremia (28%) followed by pedal edema (15.8%), diarrhoea (7%), hepatotoxicity (5.3%) and hyperkalemia (5.3%).This may be due to the fact that patients are administered several drugs for their disease condition which in turn leads to different adverse events thereby requiring additional drug therapy.[17] Untreated condition accounts, generally because of failure of physician to focus on minor patient disease conditions like presence of anemia while treating other major conditions. Untreated indication was followed by drug-drug interaction (12%). The severity assessment of drug-drug interaction was done and classified as major, moderate and minor. Most of the DDIs were of major severity (64%) followed by moderate interactions (36%). Most frequent DDIs was seen between aspirin and diuretics (48%) which cause nephrotoxicity. So patient should be monitored with renal function. Our study is contradictory to the study done by Kaliamurthy *et al*. where moderate DDIs (65.9%) constituted more.[23] DDIs results from the use of at least two or more medications that conceivably changes its efficacy and lead to adverse event. Measuring these hazard factors, DIs may hence influence the seriousness of illness. Identification of these factors is important to improve prescribing patterns.

Dechallenge/ or addition of drug (31.4%) were the suggestions most frequently provided by the clinical pharmacist. Drug discontinuation and drug change in the study were due to ADRs and significant drug interaction. Addition of drug was suggested in cases like untreated indication. Other recommendation made in our study included substitution of drug, change in drug dose, change in route of administration, deletion of drug and others. Change in drug dose has been suggested in the case of sub therapeutic doses, overdose, ADRs and DDIs. Of the total 213 DRPs, the level of significance 'minor' was found to be high in 140 (65.7%) followed by the level of significance 'moderate' in 71 (33.3%) and 'major' in 2 (1%). These study findings were parallel with the study done by Adepu *et al*., which reported that 49% of DRPs as 'minor' significance.[5] The minor significance level was the level of problems requiring small adjustments and optimization to therapy, which are not expected to significantly alter hospital stay, resource utilization or clinical outcome.

The acceptance rate of pharmacist intervention was found to be high (67.6%). This finding is in par with the study conducted by Shareef *et al*. which showed a higher acceptance rate of clinical pharmacist interventions by the physicians (96.21%).[22] In 30% of DRPs, interventions was accepted but the therapy was not changed which may be due to lack of proper information which is needed to strengthen the interventions provided or the intervention provided were thought to be irrelevant which suggest that a clinical pharmacist can contribute to better patient care if involved in health care team.

In the attempt of identify predictors of DRPs, our results supports that the patient having comorbidities (OR: 2.708, $p>0.01$), geriatric population (OR: 2.594, $p>0.01$) and polypharmacy (OR: 2.338, $p>0.05$) are the important risk factors for DRPs. From our analysis, we did not observe any statistically significant correlation between route of administration and gender. These results were similar with the study published by Abdela *et al*.[24] in which patients with polypharmacy (2.748; 1.544–4.889) were also associated with increased risk of DRP. Definitely, the use of more number of medications are necessary to control the medical conditions. Therefore, it is necessary to monitor before prescribing a medication whether DRPs is caused due to current medication. This indicates that a clinical pharmacist can contribute to better patient care if involved in the health care team.

The real barrier of the study was that the paediatric population were excluded, given the reality that even this population is prone to develop DRPs. The less sample size estimate in our study doesn't take into consideration to recognize the relation between gender and risk of developing DRPs.

CONCLUSION

The present study concluded that the circumstance of DRPs in hospitalized patients receiving polypharmacy in India is equivalent to that in different nations. One essential interpretation of this would be the fact that DRPs have been examined and revealed for a long period of time, lessons and encounters from these studies have not precisely been converted into powerful management of these issues. Our investigation demonstrated that the pervasiveness of DRPs in the department of General Medicine is high. Special preference ought to be given to the patients who are at a higher risk of developing DRPs. The association between increasing number of medications used with DRPs is solid. Survey of the patient medication treatment by a clinical pharmacist can emphatically impact the results and quality of care. The present investigation features the way that clinical pharmacist can assume a critical part in the healthcare management by rationalizing and optimizing the drug therapy for accomplishing better personal satisfaction.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

ABBREVIATIONS

DRPs: Drug related problems; **T2DM:** Type 2 diabetes mellitus; **ADRs:** Adverse drug reactions; **DDIs:** Drug-Drug interactions; **OR:** odds ratio; **AOR:** Adjusted odds ratio; **CI:** Confidence Interval.

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