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Original Article

Incidence of Drug-Drug Interactions among Patients Admitted to the Department of General Medicine in a Tertiary Care Hospital

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ABSTRACT

Background: Drug-Drug Interactions (DDIs) contribute to increased rate of morbidity and mortality increasing the need for intense monitoring of patient safety which can be achieved by detecting and preventing morbidities associated with DDIs. **Objective and Methodology:** The present work was a prospective study carried out for a period of six months, to assess the incidence of DDIs in patients admitted to the Department of General Medicine at a tertiary care hospital. **Results:** Prescriptions of 411 patients were analysed, out of which 165 (40.15%) prescriptions were identified with potential DDIs whereas clinical manifestations of actual DDIs were observed and reported in 23 (5.6%). A total of 657 DDIs were observed of which 6 (0.9%), 240 (36.5%), 374 (56.9%) and 33 (5.6%) were of contraindicated, major, moderate and minor severity respectively. Based on the mechanism 310 (47.2%) of the identified DDIs were pharmacodynamic and 243 (36.9%) were pharmacokinetic interactions. There was a positive correlation between the number of DDIs and risk factors such as length of hospital stay, number of drugs prescribed and co-morbidities. **Conclusion:** This study concludes that awareness on the most prevalent DDIs can help the practitioners to prescribe drugs with a low risk for DDIs and prevent the concomitant use of dangerous drug combinations.

Key words: Drug-drug interactions, General medicine, Pharmacodynamic, Pharmacokinetic, Severity, Risk factors.

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INTRODUCTION

Drugs are intended to alleviate disease and improve the quality of life in patients. However, many drugs are reported to cause unwanted reactions ranging from mild rashes to severe adverse reactions with fatal outcomes. Due to the complexity of disease and its comorbidities, multi-drug therapy is the current practice which is found to be alarming as it may result in drug related problems.[1] Drug-drug interactions represent an important and widely under- recognized source of medication errors and is responsible for 23% of hospital admissions.[2] Rational drug utilization may facilitate global reduction in drug induced morbidity and mortality.[1] Prescriptions with polypharmacy need a thorough evaluation in order to avoid any chance of Drug Related Problems (DRPs) which might result in adverse drug reactions, therapeutic insufficiency and increase the healthcare expenses. The involvement of pharmacist in a health care system may prevent such DRPs.[3]

Administration of two or more drugs may lead to interactions resulting in alteration of therapeutic response or unwanted effects which are not observed with either of the drugs when consumed alone. DDIs may be severe enough to warrant hospital admissions for patients who got it manifested.[4-5] Ahmad *et al*, 2015 has reported 66% of DDIs in the Department of General Medicine at a tertiary care hospital in Karnataka.[6] Studies have confirmed polypharmacy as one of the major risk factor for the incidence of DDIs.[7] DDIs contribute 20-30% incidence of ADRs which may increase the chance of hospital admission or lengthen the hospital stay.[8] Bhagavathula *et al*, reported the occurrence of 40% DDIs in prescriptions with 5 drugs and 80% with 7 medications or more.[9]

Healthcare organizations must focus on patient safety monitoring for improvised health delivery. The scarcity of national studies on drug interactions and indiscriminate use of drugs, highlight the need for more studies that may contribute for planning and formulation of public health policies in this field.[10] Therefore, the current study was taken up to improvise the patient safety by monitoring, identifying and preventing DDIs.

MATERIALS AND METHODS

It is a prospective study conducted to identify the DDIs in patients admitted to the Department of General Medicine at a tertiary care hospital, Bangalore and this study was conducted between January and June 2016. This study was approved Institutional Ethics Committee (IEC) of M.S. Ramaiah Medical College, Bangalore.

Data collection

The data were retrieved from case sheets, medication charts, laboratory reports and by conducting medication history interviews. The patient profile form was developed which included patient's demographics, history of medications and allergy, diagnosis and clinical laboratory values. DDI form included the details of DDIs with its classifications based on severity, documentation and mechanism.

Data analysis

DDIs were analysed using Stockley's textbook of drug interactions, Micromedex online database system, Medscape drug interaction checker

and Drugs.com. Further, DDIs were classified based on the type and severity of interaction as contraindicated, major, moderate and minor along with mechanism of interactions.

Statistical analysis

Association between factors such as length of hospital stay, number of drugs per prescription, number of comorbidities and DDIs were analysed by chi-square test using SPSS V_{20}.

RESULTS

In this study, a total of 411patients were enrolled, out of which 243 (59.1%) were males and 168 (40.9%) were females (Figure 1). The prescriptions of the enrolled patients were analysed and the maximum number of drugs per prescription of the study population was 22 and minimum number was 2. Among 411 prescriptions, 39 (9.5%) prescriptions were below 4 medications and 372 (90.5%) were above or equal to 4 medications. The result shows that many prescriptions followed polypharmacy.

Among 411 prescriptions, 165 (40.1%) were observed with pDDIs and 23 (5.6%) showed actual DDIs respectively (Figure 2). A total of 657 DDIs were identified in 188 prescriptions. Out of 188 prescriptions with DDIs 123 (65.4%) prescriptions were in the range of 1-3 DDIs followed by 37 (19.7%) in the range of 4-6 and 28 (14.9%) above 6 DDIs (Table 1). 105(25.5%) DDIs were identified in male whereas 83(20.2%) were identified in female (Table 2). DDIs were found to be highest among patients aged above 50 years, 106 (25.7%) followed by patients aged between 25-50 years, 62 (15.1%). The difference in proportion of incidence of DDIs with different age groups was statistically significant ($p<0.05$) (Table 3). Majority of the study population had co-morbidities along with their primary diagnosis (Figure 3).

In this study, the identified DDIs were classified based on the severity, documentation and mechanism (Table 5, 6 and Figure 4). Among the 657 DDIs per prescription, 6 interactions (0.9%) came under the classification of contraindication, 240 (36.5%) fall under major severity, 374 (56.9%) were of moderate severity and 37 (5.6%) were of minor severity. 657 DDIs were analysed for their type or mechanism of interaction. Out of which, 310 were pharmacodynamic DDIs, 243 were pharmacokinetic DDIs. Out of 657 DDIs, 68 (10.4%) were excellent, 249 (37.9%) were good and 340 (51.8%) were fair based on documentation criteria. Mechanism of actual DDIs and most frequently identified pDDIs along with their manifested and anticipated effects are described in Table 7 and 8 respectively. Factors such as length of hospital stay, number of co-morbidities and number of drugs per prescription were analysed and a statistically significant association between occurrence of DDIs and their factors were noted (Table 4).

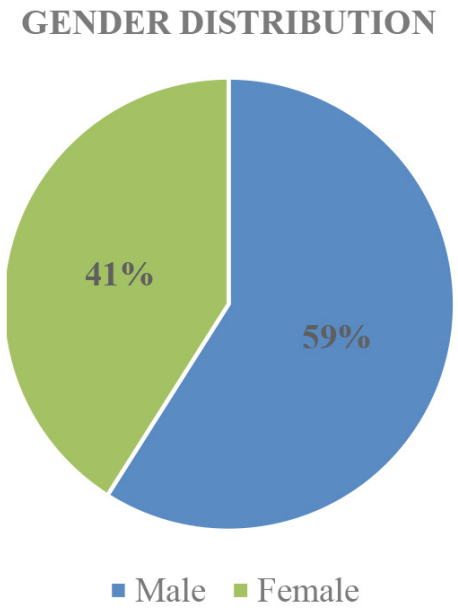

Figure 1: Gender distribution.

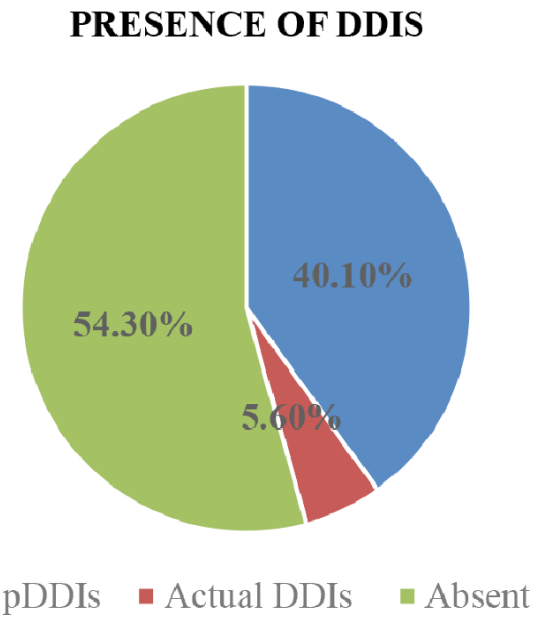

Figure 2: Presence of DDIs.

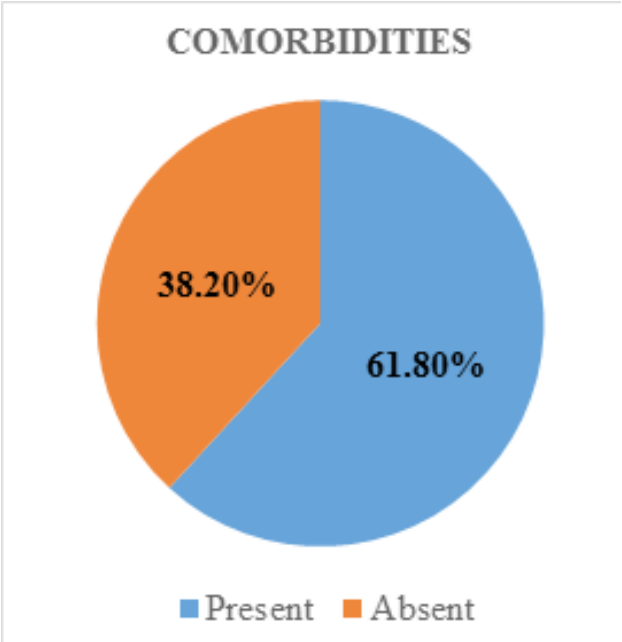

Figure 3: Presence of comorbidities.

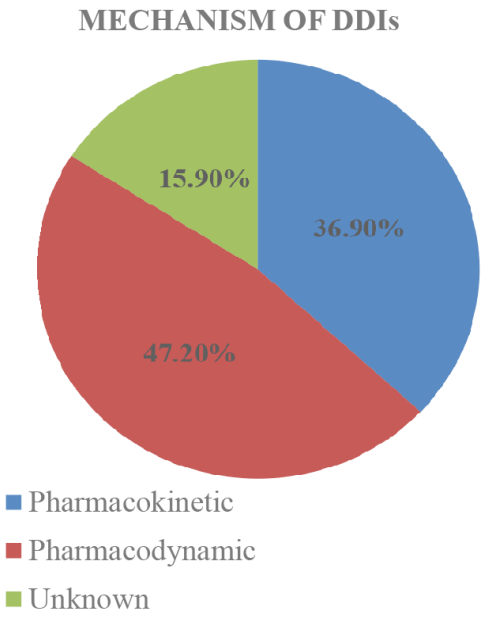

Figure 4: Mechanism of DDIs.

Table 1: Number of DDIs per prescription.

Number of DDIs	Number of patients	Percentage (%)
1-3	123	65.4%
4-6	37	19.7%
>6	28	14.9%
Total	188	100%

DISCUSSION

As the number of medications increase, the complexity of therapy also increases which could lead to DRP and further reduce the clinical outcome. Drug interactions are recognized as the most dangerous DRP.[11]

In this study, majority of the population were males which was similar to a study conducted by Ahmed *et al.* (2015).[6] and contrast to the study conducted by Mateti U *et al.*[12]

In this study, majority of patients fall under the age group of 25-50 years. The mean age was 45.7 ± 19 years. The maximum and minimum age of patients were 88 years and 15 years rspectively. Cruciol-Souza *et al.* (2006) has reported in their study that the average age of inpatients was 52.7 ± 18.9 years ranging from 12 to 98 years.[8] Our study is online with the studies conducted by Jimmy *et al.* (2012), Bhagavathula *et al.* (2014), Nag *et al* (2011).[9,13,14] In this study, there was no appreciable difference in proportion of DDIs among both the genders.

It was found that the maximum number of drugs per prescription was 22 and minimum was 2. Out of 411 prescriptions, 188 were found with

Table 2: Gender wise distribution of DDIs per prescription.

Range	Male		Female		Total
	Number of patients	Percentage	Number of patients	Percentage	
1-3	67	35.6%	56	29.8%	123
4-6	21	11.2%	16	8.5%	37
>6	17	9.1%	11	5.9%	28
Total	105	55.9%	83	44.1%	188

The chi square statistic is 0.3758. The p-value is 0.828694. The result is not significant at $p<0.05$.

Table 3: Age wise categorization of DDIs per prescription.

Age group (years)	1-3		4-6		>6		Total
	Number of patients	Percent	Number of patients	Percent	Number of patients	Percent	
<25	19	10.1%	1	0.5%	0	0%	20
25-50	48	25.5%	10	5.3%	3	1.6%	61
>50	56	29.8%	26	13.8%	25	13.3%	107
Total	123	65.4%	37	19.6%	28	14.9%	188

The chi square statistic is 23.01. The p-value is 0.000126. The result is significant ($p<0.05$).

Table 4: Predictors associated with the occurrence of DDI.

DDIs	Length of Hospital Stay in Days				Number of Co-morbidities					Number of drugs per prescription				
	1-3	4-6	>6	Total	0	1-3	4-6	>6	Total	2-4	5-7	8-10	>10	Total
0	134	83	6	223	93	11	20	13	137	30	42	12	2	86
1-3	13	15	16	44	34	16	22	18	90	7	41	26	5	79
4-6	11	22	24	57	29	13	26	28	96	1	68	42	20	131
>6	11	34	42	87	1	11	32	44	88	1	31	19	64	115
Total	169	154	88	411	157	51	100	103	411	39	182	99	91	411

Predictors	Chi- square statistic	P value
Length of hospital stay	126.75	<0.001
Number of medicines	116.69	<0.001
Concurrent illness	186.65	<0.001

Table 5: Severity of DDIs.

Severity	Number of DDIs		Percentage (%)
	pDDIs	Actual DDIs	
Contraindicated	6	0	0.9%
Major	219	21	36.5%
Moderate	366	8	56.9%
Minor	36	1	5.6%
Total	627	30	100%

Table 6: Documentation of DDIs.

Documentation	Number of DDIs		% of DDIs
	pDDIs	Actual DDIs	
Excellent	68	0	10.4%
Good	243	6	37.9%
Fair	326	24	51.8%
Total	627	30	100%

Table 7: Mechanism of identified actual DDIs and the effect produced.

Interactions	Frequency	Severity	Documentation	Mechanism	Effect produced
Quetiapine + Carbamazepine	2	Major	Fair	Pharmacokinetic	Increased drowsiness and reduced Quetiapine concentration
Pyrazinamide +Rifampin	1	Major	Good	Unknown (additive)	Hepatic injury (ALP increased)
Oxcarbazepine +Tolvaptan	1	Major	Fair	Pharmacokinetic	Reduced tolvaptan concentration and hyponatremia (123.5mEq)
Aspirin+ Calcium carbonate	2	Moderate	Fair	Pharmacokinetic	Decreased salicylate effect
Aspirin + Hydrocortisone	1	Minor	Good	Pharmacodynamic	Gastric ulceration
Aspirin +Clopidogrel	6	Major	Fair	Pharmacodynamic	GI bleeding
Cefotaxime + Warfarin	1	Major	Good	Unknown	Increased INR (3.5)
Metalazone + Torsemide	2	Major	Good	Pharmacodynamic	Hyponatremia (122, 120.9mEq/L)
Digoxin + Aspirin	1	Major	Good	Pharmacokinetic	Hyperkalemia (6.1mEq/L)
Heparin + Enoxaparin	3	Major	Fair	Pharmacodynamic	Bleeding manifestation
Furosemide + Metoprolol	2	Moderate	Fair	Pharmacodynamic	Hypotension (98/64, 86/60 mmHg)
Furosemide + Albuterol	2	Moderate	Fair	Pharmacodynamic	Hypokalemia (2.5, 2.7mEq/L)
Metformin + Insulin aspart	2	Moderate	Fair	Pharmacodynamic	Hypoglycaemia (GRBS- 65, 91 mg/dl)
Levofloxacin + Tramadol	1	Major	Fair	Pharmacodynamic	Seizures
Ondansetron + Levofloxacin	3	Major	Fair	Pharmacodynamic	Prolongation of QT interval

Table 8: Mechanism of most frequently identified pDDIs and their anticipated effects.

Interactions		Frequency	Anticipated effects
Contraindicated	Fluconazole+Ondansetron	4	Increased risk of QT prolongation
	Clarithromycin+Ivabradine	1	Increased ivabradine exposure and risk of QT prolongation
	Clarithromycin+Fluconazole	1	Increased Clarithromycin exposure and risk of cardiotoxicity
Major	Clopidogrel+Aspirin	37	Increased risk of bleeding
	Enoxaparin+Aspirin	19	Increased risk of bleeding
	Azithromycin+Ondansetron	15	Increased risk of QT prolongation
	Clopidogrel+Enoxaparin	14	Increased risk of bleeding
	Amlodipine+Clopidogrel	11	Decreased antiplatelet effect and increased risk of thrombotic effect
	Metronidazole+Ondansetron	10	Increased risk of QT interval prolongation and arrhythmia
Moderate	Atorvastatin+Clopidogrel	26	Decreased formation of clopidogrel active metabolite
	Furosemide+Aspirin	23	Decreased diuretic and antihypertensive efficacy
	Iron+Pantoprazole	22	Reduced iron bioavailability
	Aspirin+Insulin	15	Increase the risk of hypoglycemia
	Atorvastatin+Azithromycin	13	Increased risk of rhabdomyolysis
	Aspirin+Spironolactone	11	Decreased diuretic effectiveness hyperkalemia or nephrotoxicity
	Aspirin+Ramipril	10	Reduced ramipril effectiveness
Minor	Folic acid+Nitrofurantoin	5	Decreased folic acid serum level
	Aspirin+Ranitidine	4	Decreased salicylate blood levels and antiplatelet effect of aspirin
	Aspirin+Phenytoin	3	Decreased phenytoin concentrations

the DDIs. A total of 657 DDIs were found with an average of 3.49 DDIs per patients. Our work revealed that the overall prevalence of DDIs were 46% and the prevalence rate of DDIs were reported to be 49.7%, 56.2%, 63% and 78% were reported by Cruciol-Souza *et al.* (2006), Vonbach *et al.* (2008), Umretiya *et al.* (2015) and Bhagavathula *et al.* (2014) respectively.[8-9,15-16]

The study showed that the incidence rate of DDIs were more in males than females, this may be because maximum of the study population were males. These findings were similar to the studies carried out by Umretiya *et al.* (2015) and Nag *et al.* (2011).[13,16] whereas in contrast to the studies by Lubinga *et al.* (2011), Jimmy *et al.*(2012) and Moura *et al.* (2009) which reported high incidence rate of DDIs in females.[7,17,14]

Age distribution revealed the incidence rate of DDIs to be highest among patients aged above 50 years which could be attributed to the fact that the number of co morbidities are more in older patients which leads to polypharmacy in this population and it has further increased the chances of developing DDIs. The studies conducted by Bista *et al.* (2009), Merlo *et al.* (2001), Jimmy *et al.* (2012) showed that the incidence rate of DDIs was 36% in the age range of 46-60 years and 30.95% in the age above 60 years.[14,18,19] Whereas the study conducted by Ismail *et al.* (2011), Lubinga *et al.* (2011), Nag *et al.* (2011) reported incidence rate of DDIs more in the age range of 30-40 years.[7,13,20] Here, the ranges for the DDIs were categorized as: 1-3, 4-6 and >6. Among 188 prescriptions with DDIs, 1-3 DDIs were found in maximum prescriptions. There was no statistically significant difference between male and female with respect to incidence of DDIs.

In 411 prescriptions, 188 (45.7%) prescriptions had at least one interacting drug combination. Among the 657 DDIs, majority were classified as moderate which is comparable with the results of Ahmad *et al.* (2015) where the major, moderate and minor pDDIs were 44 (31.65%), 75 (53.95%) and 20 (14.38%) respectively.[6]

Most of the DDIs were fair in documentation which is similar to the work of Jimmy *et al.* (2012) who reported the documentation of DDIs to be fair 165 (50%), good 134 (40.61%) and excellent 31 (9.39%).[14]

657 DDIs were analyzed for their type or mechanism of interaction. Out of which, maximum were pharmacodynamic mechanism. Lubinga *et al.* (2011) revealed that the majority of DDIs were postulated to occur through pharmacodynamic mechanism followed by pharmacokinetic. In our study the most commonly interacting drug combination was found to be aspirin and clopidogrel 43 (6.5%), which was expected to increase the risk of bleeding manifestations.

As the length of hospital stay increased, the number of medicines also escalated, which further increased the chance of occurrence of DDIs. In our study there was a positive association between the length of hospital stay, number of comorbidities, number of drugs per prescription and the number of DDIs ($p< 0.001$). Similar associations were observed by Sharma *et al.* (2014) among cardiac patients in a teaching hospital in Nepal.[21]

Out of 188 prescriptions, 23 of them showed 30 clinical manifestations and upon reporting of those DDIs by Clinical pharmacist few drug combinations were withdrawn from the regimen and appropriate management was done. Among those manifestations, the serious reactions were QT prolongation and bradycardia due to Ondansetron and Levofloxacin combination in a 31 year old female patient admitted in MICU and manifestation of seizures due to Tramadol and Levofloxacin combination in a 19 year old female. In both the cases the interacting drug levofloxacin was withdrawn and substituted with suitable alternatives, which resulted in improvement of the above conditions.

CONCLUSION

Our study concludes that the incidence rate of DDIs is high at the study site. Majority of the patients received polypharmacy. The identified predictors responsible for DDIs were polypharmacy, age, duration of hospital stay and the number of comorbidities. Hence, it is important to develop a systemic approach to minimize the possible DDIs. Clinical relevance of certain DDIs might be because of their pharmacological actions. The clinical pharmacist is of prime importance to provide information for a better decision on therapy, improve quality of treatment and reduce risks in the patients.

This study tries to put forward the common DDIs which we came across in tertiary care hospitals and this may be a forewarning to health care team about reactions that may occur due to an interaction, as well as provide a support material for physicians to choose an alternate therapy, dose adjustments and patient monitoring. Most often the consequences of DDIs can be managed by withdrawal of potential drugs, specific symptomatic treatments, using alternative drug or dose adjustments. Awareness on the most prevalent DDIs can help the practitioners prescribe drugs with a low risk for DDIs and thereby prevent the concomitant use of dangerous medication combinations.

LIMITATION

Long-time follow up of the patients was not possible because of which delayed onset DDIs could not be assessed.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

ABBREVIATIONS

DDIs: Drug-Drug Interactions; **DRPs:** Drug related problems; **IEC:** Institutional Ethics Committee.

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