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Research Article

PROSPECTIVE OBSERVATIONAL STUDY IN CARDIAC UNIT WITH IMPACT OF CLINICAL PHARMACIST IN TERTIARY CARE HOSPITAL

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ABSTRACT

Objective: The present study is aim to assess the impact of clinical pharmacist in cardiac unit. **Methodology**: It was a prospective observational study conducted in cardiac inpatient setting of tertiary care hospital. The newly admitted case was randomly selected on daily basis and reviewed for the potential DDIs and followed up for the assessment of observed drug interaction effect. The data collected in predesigned data collection form for 200 patient of age 65 year and over. The study was conducted for 6 month duration.

Result: Out of 200 prescription the mean age of the study population was 71.47 ±6.96 years. The male – female ratio of the study population of 200 cardiac patients, 63.6% were male. Out of 200 prescriptions analyzed, it was found that 265 drug interactions were present. This study showed a median number of 1.33 DDIs in each cardiac patient. The study reveals pharmacokinetic type interaction (56.2 %) and pharmacodynamic interactions (40%), the majority of which was moderate severity (55.4%). Major severity 39.6%.Decreased efficacy in 56 (23.93%) cases followed by bleeding (21.36%).Out of the 265 interventions proposed, the most frequent suggestion was on monitoring for adverse effect (43%) followed by dose adjustment (18%). 26% of interventions were accepted and therapy was changed. The incidence rate of adverse drug reaction was found to be 13.2%.

Conclusion: It was concluded that geriatric patient with CVDs are at the higher risk of getting drug-drug interaction related adverse effect and ADR. Which can be avoided by a prior pharmacist intervention.

INTRODUCTION

Cardiovascular diseases (CVDs) claim the most number of deaths worldwide. According to a WHO report (2012), CVDs cause about 31% of all deaths annually (approximately 17.5 million deaths). Coronary heart disease contributes to about 7.4 million deaths whereas strokes contribute to another 6.7 million deaths. It is estimated that by 2030 approximately 23.6 million people will die from CVDs, making it the single leading cause of death (WHO, 2016).

Although pharmacotherapy in cardiovascular diseases can improve the well-being of patients, its benefits may be weighed against drug-related problems (DRPs). It is defined as any event or circumstance involving pharmacotherapy that interferes with the patient achieving an optimum outcome of medical care. According to Hartshorn *et al*. (2006) Drug – Drug Interaction (DDI) is said to occur when the effect of one drug is altered when it is used in conjunction with another drug (Hartshorn *et al*, 2006). It can occur either pharmacokinetically or pharmacodynamically. Pharmacokinetic interaction occurs when one of the concurrently administered drugs has the potential to alter the pattern of absorption, distribution, metabolism and excretion of the other drug. In a pharmacodynamic interaction, concurrently administered drugs may modify the effect of either of the drugs. (Byrne, 2003) It has been found that DDI cause a number of severe adverse drug reactions (ADR) warranting emergency admissions and prolonged hospitalizations. It is estimated that DDI contribute to about 6 to 30% of all ADRs. Furthermore, ADR due to DDI accounts for about 2.8% of all hospital admissions every year (Pirmohamaed M *et al*, 2004). Pharmacotherapy for cardiovascular diseases has evolved with the introduction of new drugs as a result of continuous research. The complex regimen increases the risk of drug interaction to a great extent5. The role of drug-drug interaction during therapy can be considered a bivalent outcome which can be either beneficial or profoundly unintended and distressful. The identification of such unintended interaction is the primary goal of this research. The incidence of actual occurrence of drug interactions has

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been reported to be much lower, ranging from 0 to 1.3%6. Some studies have shown that up to 11% of all patients are affected by symptoms attributable to DDIs and that DDIs are responsible for up to 2.8% of hospital admissions Kurfees JF *et al* (1987). The enormous variations in such data can lead to unambiguous conclusions. Therefore, a systematic investigation is necessary to be considered especially in geriatric patients.

Type of drugs most likely to be involved in clinically important drug interactions

1. Drugs with narrow safety margin e.g. digoxin, amiodarone.
2. Drugs affecting closely regulated body functions, e.g. antihypertensive, anticoagulants.
3. High plasma protein bound drugs like NSAID's, oral anticoagulants.
4. Drugs metabolized by saturation kinetics e.g. phenytoin, theophylline.

Drug interaction involves the Precipitant drug and the Objective drug. The precipitant drug is that which alters the action/pharmacokinetics of the other drug. The objective drug is the drug which undergoes a change in its action or pharmacokinetics.

In simple definition, An ADR is any unwanted effect of a drug over and above its expected therapeutics occurring during clinical use. The WHO defines an ADR as ''any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease, or for the modification of physiologic function.'' Thus this definition excludes (either accidental or intentional), drug abuse, and treatment failures and drug administration errors and overdose Kurfees JF *et al* (1987).

MATERIALS AND METHODS

Location and duration of study

The study was conducted in thecardiac unit of geriatric patient of south Indian tertiary care hospital, which is a 300 bedded hospital. Study was conducted for a period of 6 months from October to March 2015.

Study design

It was a prospective observational study conducted in the cardiac inpatient setting.

Sample size

200 prescription was evaluated during the 6 month interval period.

Study criteria

Inclusion Criteria

- All elderly cardiac patients admitted in cardiac ward.
- Patients who were taking at least two drugs and had a hospital stay of at least 48 hours

Material used: Case Record, Treatment Chart, Lab Master, Physician Notes, Patient Medication Rack, Nurses Comment, Site (Micromedex)

Method of data collection

The newly admitted case was randomly selected on daily basis and reviewed for the potential DDIs and followed up for the assessment of observed drug interaction effect.

Study procedure

The patient demographics and all medically relevant information was noted in a predefined data collection form. Alternatively, these case charts were reviewed for potential drug interactions, drugs involved in interactions (dose, route, frequency, therapy duration, indication), laboratory investigations, followed up for assessing observed adverse drug interaction and pharmacist's intervention. The changes and the daily notes in the case sheets were followed until the patient was discharged or shifted to other wards. The Micromedex, Medscape and references books were used as tools to review the prescription and case charts. The clinical pharmacist's intervention was done by suggesting physician about the drug related problems.

Adverse drug interactions occurred due to drug-drug interaction was recorded in an ADR Reporting Form. For each adverse drug reaction, the following information was recorded: type of adverse event, seriousness, onset and resolution, severity, casualty, action taken, and event outcome, and was analyzed using the following methods: causality assessment by WHO and Naranjo scales, severity by Hartwig scale. Drug-drug interaction check was performed using Micromedex-2. According to this tool, drug interactions were categorized as minor, moderate or major which indicates the possible risks of occurrence of the potential drug interactions which can occur in patients, but not the actual severity of drug interactions. The data obtained was used to categorize interactions based on the mechanism as pharmacokinetic or pharmacodynamics. The pharmacokinetic drug interactions were further categorized into interactions based on absorption, distribution, metabolism and elimination. The severities of the interactions were assessed and categorized as major (can cause permanent damage or life risk), moderate (can cause harm and treatment are required) or minor (can cause small or no clinical effect, with no treatment required).The data were stored confidentially and subjected to further analysis using the appropriate software.

Statistical analysis

The data was subjected to descriptive analysis using Microsoft excel version 2013. Results were expressed in percentages and mean‑standard deviation (SD).

RESULT AND DISCUSSION

DDI is always a matter of concern and may impact in the effective management of patient's illness. It may pose a significant health hazard to patients when the risk-benefit ratio of combining interacting drugs is not accurately estimated. (Sharma S *et al*, 2014) Consequently, Drug- drug interactions can be considered responsible for anything from minor morbidities to fatal consequences (Aparasu R *et al*, 2007)

For the purpose of this study, the focus has been maintained on cardiac patients among the elderly. An aging population worldwide indicates larger numbers of geriatric patients among

whom heart disease is the leading cause of death. Variations in cardiovascular physiology with normal aging and prevalent co-morbidities cause differences in the outcomes of common cardiac problems as well as the response to their treatments. Patient-centered goals of treatment such as maintenance of independence and symptom reduction may be preferred over increased longevity. New less intensive treatments are likely to improve results in elderly patients who previously have been considered at prohibitive risk for traditional procedures.

There are however, limited clinical trials involving geriatric patients and recommendations from studies involving younger patients often lack evidence-based support for subjects over 75 years of age.

Patients Demographics

The present study looks to examine the pattern of pDDIs from data collected from 200 patients admitted to the cardiac unit of the geriatric ward from October 2014 to March 2015. This data was analyzed for assessment of potential drug-drug interactions. The mean age of the study population was 71.47 ±6.96 years (Table.1) comparatively higher than the study conducted in Nepal by Sharma S *et al*. (2014), but similar to the study by Bacic *et al* (2010). Where the mean age was reported as 73years.

In considering the male – female ratio of the study population of 200 cardiac patients, 63.6% were male, bearing in mind that men are more prone to heart disease than women in this particular age group. (Jousilahti *et al*, 1999) Similarly, a study conducted in Bangladesh also reported a higher dominance of men (72%) among cardiac patients.

In general, elderly patients are at higher risk for DDIs as they are likely to have multiple diseases and poly-pharmacy that usually result in an increased duration of disease condition and altered physiology. In this study, the majority of the patients had a hospital stay of between five to ten days. The median hospital stay was 7 days (Table no.1).

Table 1 The demographic details of geriatric patients involved in the study

Parameter	Gender				Total	
	Male		Female			
	n	%	n	%	n	%
Patient age (Years)						
65-70	63	31.5	62	31	125	62.5
71-75	12	6	8	4	20	10
76-80	18	9	14	7	32	16
81-85	5	2.5	4	2	9	4.5
86-90	9	4.5	5	2.5	14	7
Sub total	**107**	**63.5**	**93**	**46.5**	**200**	**100**
Duration of hospital stay (Days)						
<5	35	17.5	38	19	63	31.5
5-10	43	21.5	31	15.5	82	41
>10	29	14.5	24	6	55	27.5
Number of drugs per prescription						
3-5	27	13.5	18	9	45	22.5
6-10	45	22.5	50	25	95	47.5
>10	35	17.5	25	12.5	60	30
Main diagnosis						
Hypertension	41	20.5	32	16	73	36.5
MI	21	10.5	9	4.5	30	15
CHF	27	13.5	18	9	45	22.5
Atrial fibrillation	4	2	5	2.5	9	4.5
ACS	7	3.5	4	2	11	5.5
CVA	10	5	4	2	14	7
Others/Miscellaneous	11	5.5	7	3.5	18	9

In another study conducted in Pakistan, median hospital stay was reported as 6 days. (Murtaza *et al*, 2015)

Prescribing pattern

An important index of a prescription audit is the average number of drugs per prescription. To minimize the risk of drug interactions and to keep hospital costs low, it is better to keep the number of drugs per prescription as low as possible. The mean number of drugs (8.97) (Table no.1) received by patients in the current study was higher compared to a report from a study in 2012 by Bacic-Vrca *et al* in 2012 which recorded a mean of 7.34 drugs. This may be accorded to the physician's tendency to poly-pharmacy and also multi-diagnosed prescriptions written for some patients. Out of 200 prescriptions analyzed, it was found that 265 drug interactions were present. Interestingly, current literature reports an incidence rate of 30.67 % in a study by Patel *et al* in 2011 from a South Indian Hospital, 91.6 % from a study by Murtaza *et al* in 2015 in Pakistan and 14.66 % from a study by Mateti *et al* in 2011 at Manipal University.

From among the 265 drug interactions, 60 types of drug interaction combinations were identified. However, another study from a South Indian teaching hospital identified 388 pDDIs in 249 patients involving 51 different drugs with a total of 74 different drug combinations. It is to be noted that Cardiac patients have previously been found to have a higher chance of having drug interactions as compared to any other group of patients. (Cruciol-Sousza JM *et al*, 2006, Carter BL *et al*, 2004).

Many of the commonly used cardiovascular drugs interact with one another and are often used together to treat cardiac conditions following a risk-benefit assessment. It is imperative that many clinicians balance the benefits of pDDIs against the risks when prescribing patients with multidrug regimens. An example of this risk-benefit assessment would be combined anticoagulant - anti-platelet therapy where an increase in the risk of hemorrhage with the combined therapy needs to be considered against the risks of thromboembolism without it. Benefits of multidrug regimens are unlikely to always outweigh their risks; therefore, decisions regarding usage of interacting drugs must always be tailored to suit each patient. This study showed a median number of 1.33 DDIs in each cardiac patient (Table no.2). A study held earlier at ATH by Ismail *et al* in 2012 reported the similar median number of pDDIs in cardiac patients (Ismail M *et al*., 2012).

Analysis of the drug interaction mechanism identified here reveals pharmacokinetic type interaction (56.2 %) to be found in higher numbers as compared to pharmacodynamic type interactions (40%) (Fig no.1). The findings obtained here are similar to those reported by Vonbach *et al*. (2008) and Aparasu *et al*. (2007) who reported 76% of pharmacokinetic interactions and 22% of pharmacodynamic interactions, respectively. However, another study by Patel *et al* in 2011 reported contrast results of higher pharmacodynamic interactions (64.69%) (Patel VK *et al*, 2011). Out of the total pDDIs identified, the majority constituted of an interacting combination of moderate severity (55.4%). Major severity interacting combination identified was 39.6% (Table no.2). This finding is similar to most of the DDI studies conducted worldwide. The studies in MTH, India and Palestine showed similar results. The pDDIs

identified, 53.6% were not specified and 33.2% were delayed onset in nature. This suggests that even if there was an interaction occurring during the concomitant administration, it may not become evident immediately. If these combination of drugs were to be continued on an outpatient basis, this could potentially lead to decreased efficacy leading to therapeutic failures or potential for delayed adverse events. Therefore, the duration of concomitant drug use should also be taken into account when prescribing relevant interacting drugs.

The most common interacting pair identified was aspirin/clopidogrel, clopidogrel/atorvastatin, atorvastatin/amiodarone and atorvastatin/azithromycin (Table no.3). The values obtained here are similar to a study in India where Patel *et al* reported aspirin (44.85%) followed by atorvastatin (7.22%). Similarly, Smithburger PL *et al*. 2010 reported the involvement of blood coagulation modifier in a maximum number of pDDIs. This might be due to frequent use of this drug class among the cardiac patients in the present study. Decreased efficacy was the commonest clinical consequences in 56 (23.93%) cases followed by bleeding (21.36%). A study conducted in the cardiology department of Kasturba Medical College reported bleeding (86.63%) as the commonest clinical consequences (Mateti UV *et al*, 2011). Prolonged hospital stay is another factor associated with the occurrence of pDDIs as reported in this study. According to the results obtained from a study conducted in Brazil by Riechelmann *et al* in 2005 in hospitalized patients; it was found that patients with prolonged hospital stay had a significant association with pDDIs (Riechelmann RP *et al*, 2005). Patients taking multiple drugs in this study were also at higher risk of pDDIs. A study held at Switzerland by Egger *et al* in 2007, in a cardiac ward, similarly found that incidence of pDDIs increased with increase in a number of drugs prescribed (Egger SS *et al*, 2007). The findings suggest that pDDIs are associated with elder patients, increased number of drugs and patients with longer duration of hospital stay.

Table 2 Classification of pDDI based on their onset and severity

Onset of pDDI	Number of pDDI	% of pDDI
Rapid	35	13.2
Delayed	88	33.2
Not specified	142	53.6
Total	265	100
Severity of pDDI	Number of pDDI	% of pDDI
Major	105	39.6
Moderate	147	55.4
Minor	13	5

Adverse drug-drug Interaction

The incidence rate of adverse drug interactions was found to be 13.2%. This rate is lower than the study conducted in Iran by Gholami *et al* in 2008. Another study by Patel *et al* in 2011 reported 17.53% of observed drug interaction which is higher than this study. The most common drug interaction pair resulting in adverse drug reaction was aspirin/clopidogrel (5). Bleeding was the most important interaction in (10) cases followed by hypoglycemia (5) and QT-interval prolongation (4) (Table no 4). The most common objective drug is aspirin and the precipitant drug is clopidogrel. Similarly, Bleeding was the most common clinical effect of observed drug interaction in South Indian study by Patel *et al* in 2011.

Pharmacists Intervention

Out of the 265 interventions proposed, the most frequent suggestion was on monitoring for adverse effect (43%) followed by dose adjustment (18%) (Fig no.2) and 26% of interventions were accepted and therapy was changed (Fig no.3). A study conducted in Coimbatore reported 251 interventions, which is less than this study. Of the 251 intervention, most common were related to drug interaction followed by making changes. This higher result might be due to a larger sample size than this current study (Abraham RR 2012).

A study conducted in Brazil by Reis *et al* in 2013 reported 76.32% acceptability of the interventions by Clinical pharmacists, which is higher compared to this study (Reis *et al*, 2013).

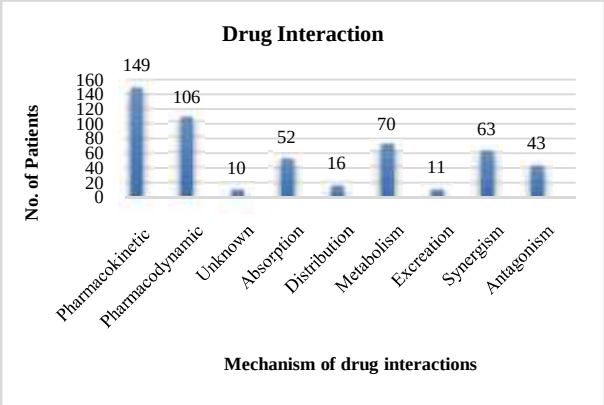

Fig 1 Schematic distribution of the drug interactions based on the mechanism of causing drug interaction.

Table 3 Top 10 common pDDI (n=265)

pDDI pair	Possible Effect	Male		Female		Total	
		N	%	N	%	N	%
Aspirin/Clopidogrel	bleeding	17	6.4	3	1.13	20	7.5
Clopidogrel/atorvastatin	Decreased efficacy	11	4.15	7	2.6	18	6.79
Atorvastatin/amiodarone	rhabdomyolysis	7	2.64	0	0	7	2.64
Aspirin/Acenocoumarol	bleeding	4	1.5	3	1.13	7	2.64
Atorvastatin/Azithromycin	rhabdomyolysis	5	1.88	1	0.37	6	2.26
Atorvastatin/Clarithromycin	rhabdomyolysis	3	1.13	3	1.13	6	2.26
Acenocoumarol/Clopidogrel	bleeding	3	1.13	2	0.75	5	1.88
Carvedilol/aspirin	Decreased efficacy	3	1.13	2	0.75	5	1.88
Insulin/aspirin	hypoglycaemia	3	1.13	2	0.75	5	1.88
Ramipril/Spironolactone	hyperkalaemia	3	1.13	2	0.75	5	1.88
Sub Total		59	22.26	25	9.43	84	31.69

It is important to note that, in our study, recommendations to physicians by attending pharmacists regarding pharmacotherapy monitoring were recorded only as educational actions, therefore without any measure of acceptability. This aspect may have led to a decrease in the acceptability rate of the study.

CONCLUSION

Thus it was concluded that geriatric patient with CVDs are at the higher risk of getting drug-drug interaction related adverse effect and ADR. Which can be avoided by a prior intervention.

Table 4 Observed adverse drug reaction in cardiac inpatients due to drug-drug interaction (Total DI, n =265)

Object Drug	Precipitant Drug	No. of ADR n=35(%)	Adverse outcome	Mechanism of reaction
Aspirin	Clopidogrel	5(14.2)	Bleeding	Synergism
Amiodarone	Nebivolol	3(8.57)	Bradycardia	Metabolism
Aspirin	Heparin	3(8.57)	Bleeding	synergism
Enalapril	Spironolactone	3(8.57)	Hyperkalemia	synergism
Amiodarone	Atorvastatin	2(5.71)	Muscle pain	metabolism
Aspirin	Acenocoumarol	2(5.71)	Bleeding	synergism
Clopidogrel	Acenocoumarol	2(5.71)	Bleeding	synergism
Clopidogrel	Atorvastatin	2(5.71)	Thrombocytopenia	metabolism
Domperidone	Cilnidipine	2(5.71)	QT prolong	metabolism
Furosemide	Hydrocortisone	2(5.71)	Hypokalemia	synergism
Insulin	Aspirin	2(5.71)	Hypoglycemia	unknown
Metformin	Ramipril	2(5.71)	Hypoglycemia	unknown
Aspirin	Ramipril	1(2.85)	Hypertension	Antagonism
Domperidone	Atorvastatin	1(2.85)	QT prolong	metabolism
Insulin	nebivolol	1(2.85)	Hypoglycemia	synergism
Spironolactone	Aspirin	1(2.85)	Hyperkalemia	synergism
Venlafaxine	Ivabradine	1(2.85)	QT prolong	synergism

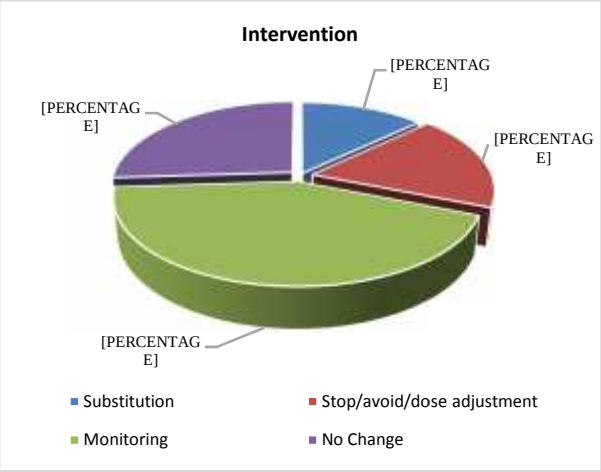

Fig 2 Distribution of type of therapeutic interventions involved in managing occurred drug interactions.

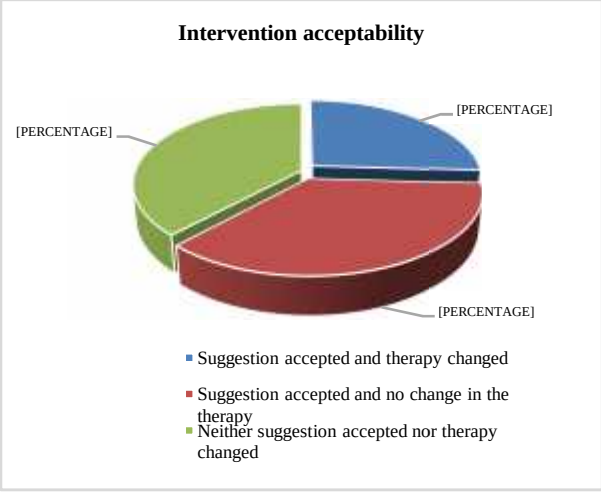

Fig 3 Distribution of acceptability ratio of the therapeutic interventions due to drug-drug interactions.

A through prescription audit by a pharmacist can improve the outcome of the treatment by and most of the major adverse effect and ADR can be avoided.

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