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Review Article

A STUDY ON DRUG UTILISATION REVIEW OF CARDIOVASCULAR DISEASES

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ABSTRACT

The prevalence of cardiovascular diseases is significantly increasing nowadays. Drug utilization evaluation of cardiovascular diseases helps to promote rational prescribing pattern in disease management which improves the patient quality of life. To understand the prescribing pattern of drugs used in cardiovascular diseases, promote patient awareness about the diseases, identify irrational prescription pattern and find the association of co-morbid conditions with the cardiovascular diseases. Total 100 patients suffering with various cardiovascular diseases were included in prospective observational randomized study within a time period of 6 months. The tools used throughout the study were patient information sheets and questionnaire. Patient medication history interview was carried out. The prescribing patterns of different cardiovascular drugs were noted. Statistical analysis including chi-square test to find the association of co-morbid conditions was performed with SPSS for windows, version 22.0. For the descriptive statistics percentage distribution was determined. From this study, the average prevalence of cardiovascular diseases was found to be more in males than in females. Among different comorbid conditions the dyslipidemia was comparatively high. Commonly prescribed drugs include anti-platelet and anti-hyperlipidemic medications. This study helps to understand rational drug use among the cardiovascular patients, to find out the association of co-morbid conditions and proper management of diseases. In order to obtain optimal drug therapy evidence based prescriptions must be encouraged besides lifestyle modifications.

Keywords:- Prospective study, Cardiac disease, Drug therapy.

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INTRODUCTION

Drug Utilization research was defined by WHO in 1977 as the marketing, distribution, prescription, and use of drugs in a society, with special emphasis on the resulting medical, social and economic consequences [1]. The principal aim of drug utilization research is to facilitate rational use of drugs in populations. Cardiovascular diseases mainly affect the heart and circulatory system. It is the common cause of premature morbidity and mortality. According to world health organization, cardiovascular diseases are the number one cause of death globally. In India cardiovascular diseases progression is very high and leading cause of mortality in people of age group 25 to 69 year [2]. Ischemic heart disease is the major cause of mortality in India. It is projected that ischemic heart disease will result in two and one half million Indian deaths up to 2020. Males are affected more than females .An estimated 17.5 million people died from cardiovascular disease in 2005, representing 30% of all global deaths. Of these deaths, an estimated 7.6 million were due to coronary heart disease and 5.7 million were due to stroke. Over 80% of cardiovascular disease deaths take place in low and middle-income countries. By 2020, almost 20 million people will die from cardiovascular disease, mainly from heart disease and stroke [3,4]. Cardiovascular disease includes coronary

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artery disease, angina, myocardial infarction, stroke, hypertensive heart disease, cardiomyopathy, endocarditis, congestive heart failure, deep vein thrombosis. Population based study shows that atherosclerosis is the major precursor of cardiovascular disease. The treatment options are antiplatelet drugs, anticoagulants, anti-anginal drugs, beta-blockers, angiotensin converting enzyme inhibitors, angiotensin receptor II blockers, calcium channel blocker, diuretics. Guidelines based on evidence from randomised controlled trial recommended that aspirin, beta blocker, angiotensin converting enzyme inhibitors, statins used in all cardiovascular disease patients and percutaneous coronary intervention or coronary bypass surgery as secondary prevention [5].

Drug utilization studies are needed to identify the trends as well as to set the priorities, not only in the interest of the regulatory control, but also as a basis of the planning program of education and information. The risk of cardiovascular diseases is being frequently monitored. Hence, it is need to do drug utilization study on cardiovascular disorders. Incidence of cardiovascular diseases, Acute Coronary Syndrome is rapidly increasing in India and causes high mortality. Drug utilization studies, which evaluate, and analyze the medical, social, and economic outcomes of the drug therapy are more meaningful, and observe the prescribing attitude of physicians with the aim to provide drug rationally [6]. Aim for carry drug utilization study is check the Pattern of different drug use (aspirin, clopidogrel, beta-blockers, angiotensin statins, converting enzyme inhibitors/Angiotensin Receptor Blockers) dose. regimenand compliance. The study of drug utilization is a component evaluates prescribing practices & recommends necessary modifications to achieve rational drug use. An attempt to delineate essential drug information requirements relevant to cardiovascular diseases for the benefit of physicians is one of the objectives of the study. Morbidity and mortality of cardiovascular diseases is controlled by good managing post cardiovascular diseases period. [7]. The American College of Cardiology Federation/American Heart Association guidelines 2011 recommended have pharmacotherapy with antithrombotics, Angiotensin converting enzyme inhibitors, Angiotensin Receptor Blockers and beta-blockers based on results of multiple controlled trials to improve survival benefits in Acute Coronary Syndrome. In spite of availability of standard guidelines, a wide variation exists in patterns of pharmacotherapy [8-10]. An observational study which evaluated treatment practices for acute myocardial infarction across hospitals in South India observed appropriate use of thrombolytics, beta-blockers and Angiotensin converting enzyme inhibitors among 83%, 78% and 99.3% of patients respectively. Only 40% of acute coronary syndrome patients received combined betablockers, statins and ACE-inhibitors in an Estonian study. Very few studies have evaluated factors that predict the

utilization of pharmacotherapy in patients with cardiovascular diseases. Use of angiotensin converting enzyme inhibitors [Adjusted Odds Ratio (aOR) 1/4 1.496 (1.055e 2.121)], whereas the diagnosis of unstable angina [aOR 1/4 9.803 (1.312e71.42)] and ST-elevation MI (STEMI) [aOR 1/4 8.064 (1.052e 62.5)] predicted use of statins [10-12]. Assessment of drug utilization patterns and potential determinants of utilization are highly essential to establish the optimal utilization of evidence-based therapies. This prospective observational study of drug utilization evaluation of cardiovascular disease evaluates risk factors, drugs prescribed by prescriber to modify therapy, irrational drug use, major adverse effects, common drug interactions and association between co-morbid conditions. This study attempts to analyze the prescription pattern of drugs used in CVDs to ensure rational therapy used to reduce morbidity and mortality.

METHODOLOGY

Study approval

The study was approved by institutional human ethics committee with ref: IHEC/SJCP/A.43/2015-2016.The study was carried out in a 450 bedded tertiary care teaching hospital.

Study design

A prospective observational study.100 cases selected from the inpatient department of tertiary care teaching hospital. Clinical data was collected from patient's medical records, lab reports, prescriptions and documented in case sheets for the purpose of study.

Inclusion criteria

All patients admitted in cardiology and general medicine department with cardiovascular disorder were included.

Exclusion criteria

Pediatric, pregnant and lactating women. Data was collected from the patients and medical reports with the help of a self-generated data entry form.

Statistical analysis

Different computer software's were used to analyse the data. The statistical tools used include SPSS, chi square test, p value and student t- test.

RESULTS

Total 100 in-patients were recruited in the study according to the inclusion criteria.

Gender of respondents (N=100)

Among 100 patients, 63 were males and 37 were females. The majority of the respondents were males as depicted in Table-1.

Table 1. Percentage distribution of population according their gender

Gender	No. of Patients	Percentage
Male	63	63%
Female	37	37%

Age of respondents (N=100):

Table 2. Percentage distribution of patients with respect to age

Age	No. of Patients	Percentage
0-20	0	-
21-40	3	3%
41-60	41	41%
61-80	44	44%
Above 80	12	12%

Risk factors (N=183)

Table 3. Percentage distribution of sample according to risk factors

Risk factors	No.of patients	Percentage
Family history	38	20.7%
Obesity	14	7.65%
High fatty foods	13	7.10%
High salty foods	23	12.56%
Stress	24	13.11%
Lack of physical activity	11	6.01%
Smoking	13	7.10%
Alcoholism	38	20.76%
Other diseases	9	4.91%
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Co-morbid conditions(N=117)

Table 4. Distribution of sample according to co-morbid conditions

Disease	No. of patients	Percentage
Diabetes mellitus	40	34%
Dyslipidaemia	44	37.6%
Thyroid disease	12	10.25%
Respiratory diseases	6	5.12%
Renal diseases	8	6.83%
Liver diseases	2	1.7%
Others	5	4.27%

Table 5. Chi square Test for testing the association between Diabetes and Dyslipidaemia

Frequency Statistics								
N	Gender	Dyslipidaemia	Diabe tes mellit us	Thyroid disease	Respiratory disease	Renal disease	Hepatic disease	Others
Valid	100	100	100	100	100	100	100	100
Missing	0	0	0	0	0	0	0	0
	Gender							
		Frequency		Percent	Valid Percent		Cumulative I	Percent
	.00	37		37.0	37.0		37.0	
Valid	1.00	63		63.0	63.0		100.0	
	Total	100		100.0	100.0			
	Dyslipidaemia							

		F	requen	су	Percent		Valid P	ercent	Cı	umulative Pero	cent
	.00		55		55.0		55.	.0		55.0	
Valid	1.00		45		45.0		45.	.0		100.0	
	Total		100		100.0		100	0.0			
				Di	abetes Mel	litus					
		F	requen	су	Percent		Valid P	ercent	Cı	umulative Pero	cent
	.00		60		60.0	_	60.	.0		60.0	
Valid	1.00		40		40.0		40.	.0		100.0	
	Total		100		100.0		100	0.0			
				T	hyroid Dise	ease					
		F	requen	су	Percent		Valid P	ercent	Cı	umulative Pero	cent
 	.00		89		89.0		89.	.0		89.0	
Valid	1.00		11		11.0		11.	.0		100.0	
	Total		100		100.0		100	0.0			
				Res	piratory Di	isease			~		
		F	requen	су	Percent	_	Valid P	ercent	Cı	imulative Pero	cent
L	.00		94		94.0	_	94.	.0		94.0	
Valid	1.00		6		6.0		6.0	0		100.0	
	Total		100		100.0		100	0.0			
					Renal Disea	ise			~		
		F	requen	су	Percent		Valid P	ercent	Cı	imulative Pero	cent
	.00		92		92.0	_	92.	.0		92.0	
Valid	1.00	1.00 8			8.0	_	8.0	8.0		100.0	
	Total		100		100.0		100	0.0			
				H	lepatic Dise	ase				1.1. 5	
		F	requen	су	Percent	_	Valid P	ercent	C1	imulative Pero	cent
L	.00		98 98		98.0		98.	.0		98.0	
Valid	1.00		2		2.0		2.0)		100.0	
	Total		100		100.0		100	0.0			
				(<u>Differ Disea</u>	ses	17 11 1 5			1.1. D	
	00	F	requen	cy	Percent		Valid P	ercent	Ci	imulative Pero	cent
X7.1.1	.00	<u>90</u> <u>95</u>			95.0		5.0			95.0	
valid	1.00 Tetel				5.0		5.0			100.0	
	Total		100		100.0		100	0.0			
				Case P	rocessing S	umm	ary				
		Val	: 1			Cases	s 			Tatal	
		v al	10	Dagaant	N	WIISS	ning Domo	ant	N	Total	Damaant
Diabatas *		IN		Percent	IN		Perc	em	N	1	Percent
Diabetes		100		100.0%	0		0.0	%	10	0	100.0%
a					_						
		Di	abetes	* Dyslipida	emia Cross	tabul	ation				
				· -	D	yslipio	laemia		T	1	
					0		1		10	tal	
		0		Count	55		5		60)	
D' L		0	% wi	thin Diabete	es 91.79	%	8.3	%	100.	0%	
Diabetes				Count	0		40)	40)	
		1	% wi	thin Diabete	es 0.0%	ó	100.	0%	100.	0%	
	T . (. 1			Count	55		45	5	10	0	
	Total		% wi	thin Diabete	es 55.09	%	45.0)%	100.	0%	
				Chi-Squ	are Tests						
		Value	-	Df	Asyn	np. Si	g	Ex	act Sig. (2-	Exact Sig.	
		value		וע	(2-s	ided)			sided)	(1-sided)	
Pearson Chi	-Square	81.481 ^a		1).	000					

Continuity Correction ^b	77.820	1	.000			
Likelihood Ratio	103.207	1	.000			
Fisher's Exact Test				.000	.000	
Linear-by-Linear Association	80.667	1	.000			
N of Valid Cases	100					
a. 0 cells (0.0%) have expected	count less th	an 5. The minimum expo	ected count is 18.00.		
b. Computed only for a 2x2 table						

Table 6. Chi square Test for testing the association between Diabetes and Dyslipidaemia

	Dyslipidaemia				
Diabetes		0	Yes		p Value
	n	%	n	%	
No (60)	55	91.7	5	8.3	<0.001
Yes (40)	0	0.0	40	100.0	<0.001

Study is carried out in 100 patients. Among 100 patients 40 patients had diabetics, out of it all patience developed Dyslipidaemia. And there are 60 patients without diabetics and among this, only 5 patients (8.3%) developed Dyslipidaemia. So there exists significant association between Diabetes and Dyslipidaemia. (Since p value< 0.05(significance value) Types of CVD (N=148)

Table 7. Percentage distribution of patients according to types of CVD

Types of CVD	No. of Patients	Percentage
Hypertension	69	46.62%
Angina	10	6.75%
MI	46	31.08%
Arrhythmia	2	1.35%
CVA	12	8.10%
Heart failure	9	6.08%

Prescribing trends of physician (N=583):

Table 8. Percentage distribution of CVD drugs prescribed

Prescribing Trend of Physician	No. of Patients	Percentage
Antianginal	28	4.8%
Diuretics	62	10.6%
ACE Inhibitors	30	5.14%
Calcium Channel	36	6.1%
ARB	81	13.8%
Beta Blocker	29	4.9%
Vasorelaxant	10	1.7%
Cardiac Stimulant	8	1.3%
Antiplatelet	95	16.2%
Anticoagulant	48	8.2%
Statins	83	14.2%
Antibiotics	33	5.6%
Antacids	40	6.8%

Prescribing pattern of anti-platelets: (N=108) Table 9. Percentage distribution of antiplatelet drugs

No. of Patients	Percentage
18	16.60%
32	29.60%
58	53.70%
	No. of Patients 18 32 58

Prescribing pattern of anti-hypertensives: (N=117)

Table 10. Percentage distribution of anti-hypertensives

Drugs	No. of Patients	Percentage
Atenolol	24	20.5%
Metoprolol	8	6.83%
Telmisartan	42	35.89%
Losartan	12	10.25%
Ramipril	3	2.56%
Carvedilol	5	4.27%
Amlodipine	17	14.52%
Diltiazem	6	5.12%

Prescribing pattern of anti-anginal drugs: (N=15)

Table 11. Percentage distribution of anti-anginals

0
5%
1%
.6

Prescribing pattern of diuretics: (N=95)

Table 12. Percentage distribution of diuretics

Drugs	No.of Patients	Percentage
Furosemide	52	54.7%
Torsemide	14	14.7%
Hydrocholrthiazide	11	11.5%
Spironolactone	18	18.9%

Prescribing pattern of anti-hyperlipideamics: (N=66)

Table 13. Percentage distribution of anti-hyperlipidemics

Drugs	No.of Patients	Percentage
Atorvastatin	56	84.8%
Rosuvastatin	8	12.1%
Atorvastatin+Rosuvastatin	2	3.03%

Prescribing pattern of anticoagulants (N=32)

Table 14. Percentage distribution of anticoagulants

Drugs	No.of Patients	Percentage
Heparin	24	75%
Enoxaparin sodium	8	25%

Prescribing pattern of antibiotics (N=45)

Table 15. Percentage distribution of antibiotics

Drugs	No.of Patients	Percentage
Cephalosporins	28	62.2%
Aminoglycosides	4	8.88%
Penicillins	13	28.88%

Prescribing pattern of anti-hyperglycemics (N=19)

Table 16. Percentage distribution of bronchodilators

Drugs	No.of Patients	Percentage
Insulin	16	40%
Glimepiride	18	45%
Metformin	6	15%

Prescribing pattern of miscellaneous drugs (N=265)

Drugs	No.of Patients	Percentage
Pantoprazole	88	33.2%
Lactulose	24	9.05%
Diphenhydramine	17	6.41%
NSAIDS	98	36.98%
Alprazolam	30	11.32%
Thyroxine sodium	8	3.01%
theophylline	6	2.7%

Table 17. Percentage distribution of miscellaneous drugs.

Medication adherence (N=50)

Table 18. Medication adherence

Level of adherence	No.of patients
Complete refusal	2
Partial refusal or only accepts minimum dose	4
Accepts only because compulsory or very reluctant	4
Occasional reluctance	2
Passive acceptance	2
Moderate participation	16
Active participation	70

Drug interactions (N=75)

Table 19. Percentage distribution of drug interactions

Drug Interactions	No. of patients	Percentage
Pantoprazole+Clopidogrel	29	38.6%
Metoprolol+Aspirin	15	20%
Warfarin+Clopidogrel	2	2.66%
Ceftriaxone+Heparin	18	24%
Losartan+Metoprolol	2	2.66%
Aspirin+Heparin	6	8%
Diltiazem+Aspirin	3	4%

Adverse drug reactions

Table 20. Percentage distribution of adverse drug reactions

ADR	No. of Patients	Percentage
Aspirin- Gastritis	6	6%
β Blocker- Fatigue	8	8%
Statins- Myalgia	2	2%

Medication error

Table 21. Percentage distribution of medication errors.

Туре	No.of Patients	Percentage
Drug interaction (major)	11	28.2%
Drug duplication	9	23.7%
ADR (major)	6	15.3%
Wrong time	7	17.9%
Compliance error	3	7.6%
Omission error	3	7.6%

DISCUSSION

The study entitled "Drug utilization review of cardiovascular disease" was a prospective observational study which includes a total of 100 in-patients. Gender: A

total number of 100 patients were enrolled in the study of which 63% were male patients and 37% were female patients. The male to female ratio among the patients was 2:1. The incidence of CVD was more common in males

when compared to females. Age: The study reveals that majority (44%) of patients having CVD were under the age group of 61-80. 41% of patients falls under age group of 41-60 and 3% of patients belong to age group of 21-40. 12% of patient with age above 80 were observed. From the data analyzed the risk of CVD is higher in age group 40-60. Risk factors: Among the major risk factors other diseases was 44% and alcoholism accounts for 38 highest percentage.Family history, obesity, stress and high salty foods also accounts for a major portion in the cardiovascular patients [13]. From the present study it can be concluded that there is a strong genetic predisposition in development of cardiovascular diseases. Co-morbid conditions: Various co-morbid conditions like diabetes mellitus(34%), hypothyroidism, dyslipidaemia(37.6%) were seen among patients and many of these were found to be risk factors of coronary artery disease. Dyslipidaemia and diabetes were the two most common co-morbid conditions found in most of the patients which increase the risk of coronary artery disease [14]. Among 100 patients 40 patients had diabetics ,out of it all patients developed Dyslipidaemia and there are 60 patients without diabetics and among this, only 5 patients (8.3%) developed Dyslipidaemia. So there exists significant association between Diabetes and Dyslipidaemia. From the present study it was concluded that DM is the most prevalent comorbid condition in patients reporting single co-morbidity and DM+Dyslipidaemia are the mostly prevalent comorbidities in patients reporting multiple comorbidities. Types of CVD:Among different cardiovascular disease hypertension(46.62) was found to be more prevalent. Followed by myocardial infarction(31.08%). Around 69 patients have elevated BP. Hypertension and other cardiovascular diseases are seen concomitantly in some patients. Drugs prescribed: The anti-platelet drugs aspirin and clopidogrel were used to reduce the cardiovascular mortality and non- fatal myocardial infarction in coronary artery disease. Among 100 prescriptions analyzed antiplatelet drugs were prescribed in 95 patients. Details of anti-platelet drugs prescribed are shown in. Out of these 95 patients, a fixed dose combination of aspirin and clopidogrel was found to be used in 58 patients. Aspirin alone was used in very few patients 32 and in 18 patients clopidogrel alone was used. All these drugs were prescribed in oral dosage form. Anticoagulant drugs prescribed include heparin and low molecular weight heparins and enoxaparin sodium. Anti-coagulants were prescribed in the form of injections given either by IV or SC route of administration.

Out of 100 patients, 40 patients had diabetes mellitus. Most of the patients were prescribed with human actrapid insulin during hospital stay of treatment. The doses of insulin were given based on the blood glucose levels. Very few patients were prescribed with oral hypoglycaemic agents.

The results of this study on drug prescribing pattern can provide a framework for continuous prescription audit in a hospital in-patient setting. This will help prescribers improve patient management by rationalizing prescribing practices. The under use of diuretics in monotherapy is the most important drawback of the present prescribing pattern as they are available at lower cost. Drug interaction: The major drug interaction encountered during this study was between pantoprazole and clopidogrel that reduces the effect of clopidogrel (38.6%). The other drug interactions mainly caused increased risk of bleeding. ADR:Metoprolol induced fatigue(8%) was the commonly seen ADR in this department followed by aspirin induced gastritis(6%).Myalgia caused by atorvastatin were also seen. Medication error: Drug interactions were found to be the common medication error and were reported. Others include duplication error, ADR, omission error and compliance error.

CONCLUSION

The study on drug utilization review in cardiovascular disease indicates the drugs prescribed were found to be rational. In order to obtain optimal drug therapy evidence based prescriptions must be encouraged besides the modifications in lifestyle and preventing risk factors. It also helps to find out the association of co-morbid conditions, major drug interactions, common adverse effects and common medication errors.

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CONFLICT OF INTEREST

None.

STATEMENT OF HUMAN AND ANIMAL RIGHTS

All procedures performed in human participants were in accordance with theethical standards of the institutional research committee and with the 1964Helsinki declaration and its later amendments or comparable ethicalstandards. This article does not contain any studies with animals performedby any of the authors.

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