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Research Article

A PROSPECTIVE OBSERVATIONAL STUDY ON USAGE AND EFFECT OF THROMBOLYTIC AGENT IN MI PATIENTS AT TERTIARY CARE HOSPITAL

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ABSTRACT

Thrombolytic drug have a very great history in saving many lives. They have a wide role in management of disease like ACS, MI, DVT, PE, STROKE etc. Though despite the fact they have proven to be so useful them still holds an upper hand in causality caused by them in history. Thus many studies has been performed to optimize the use of thrombolytic agents and so does new recombinant drug has been introduced since then. This study was performed to find out the various aspects of thrombolytic use and it did put a light on few of the possible factor associated with thrombolytic effects. This study was a Prescription audit which is one of the important component of clinical pharmacy, where clinical pharmacist plays important role in optimization of medication use, minimizing number of medication-related problems and improving medication therapy. The main objective of present study is to find out effect of thrombolytic agent on MI patient. This prospective observational study carried out for a period of 6 months in the Department of Pharmacy practice, Karnataka College of pharmacy, Bangalore Baptist Hospital, Bangalore. The study was conducted on 200 patient receiving thrombolytic Medication. The study showed that the maximum number of patient receiving Thrombolytic medication belongs to age group of 41 to 60 years, while comparing the prevalence of ADR E Alteplase, Streptokinase,Reteplase, Heparin and Enoxaparin respectively was identified which are associated with ADR, The highly prescribed drug was Alteplase , Reteplase and Streptokinase. Evaluation of prescription was performed as it was major factor in identification of drug related ADRs. They study also give an idea of incidence of morbidity and mortality due to thrombolytic treatment. A comparison is done between the treatment procedure and guideline for better understanding of link between the ADRs, Morbidity and mortality ratios.

INTRODUCTION

Coronary heart disease (CHD) is the major cause of death in most developed countries and in many developing countries. The clinical complications of CHD lead to substantial disability and are a main source of the rising cost of health care. While CHD incidence is decreasing in Western Europe, the United States, and Australia, it is steeply increasing in central and eastern Europe and, to some extent, in Asia and Africa.(Sytkowski PA *et al* 1990)The primary importance of improving health-related behavior in the population as a whole is emphasized. In the present document, the undervalued scope for preventive care at the individual clinical level is the major theme; it is based on the selection and management of persons whose level of risk cannot adequately be reduced by presently available population measures.

Age, sex, and personal and family history of cardiovascular disease are no modifiable risk factors for CHD. Hypercholesterolemia, hypertension, and cigarette smoking are the major modifiable risk factors. (Anderson KM *et al* 2004)The relationship between nutrition and CHD has now been well established and is mainly based on epidemiological findings in populations and nutritional intervention trials.
(Rimm EB *et al* 2003) Stroke is also an important issue in the population at risk for CHD. Patients with CHD often suffer from stroke and vice versa. Because stroke and CHD share several risk factors, strategies aimed at reducing CHD incidence might be expected to also decrease the incidence of cerebrovascular events. There is increasing evidence that both antihypertensive treatment and lipid-lowering therapy with statins, presumably through stabilization of atherosclerotic plaques with a consequent lower frequency of embolism, reduce the incidence of stroke. In Western countries, ischemic

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stroke is much more common than the hemorrhagic variety (≈80% versus 20%). Non-modifiable risk factors for ischemic stroke are age, sex, race, and inherited predisposition. Well-documented modifiable risk factors are hypertension (the single most important cause of stroke), diabetes, cardiac disease, cigarette smoking, overweight, elevated hematocrit, and increased levels of fibrinogen and tissue-type plasminogen activator inhibitor. (Hertog MGL*et al* 1993)

Hyperlipidemia is managed primarily by conservative measures (correction of overweight, a lipid-lowering diet, and removal of underlying causes); drug treatment is instituted only if conservative measures fail to achieve the lipid target value. The decision for lipid-lowering drug therapy should be based on trial data wherever possible. Five major, lipid-lowering trials with 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitors (statins) have been completed in recent years, and they form the basis of current recommendations. The results of these trials, the Scandinavian Simvastatin Survival Study (4S) the West of Scotland Coronary Prevention Study (WOSCOPS), the Cholesterol and Recurrent Events (CARE) study, the Air Force/Texas Coronary Atherosclerosis Prevention Study (AFCAPS/TexCAPS), and the Lovastatin in the Prevention of Ischemic Disease (LIPID) study, clearly show that lowering LDL cholesterol, the most atherogenic lipoprotein class, by statin drugs in addition to diet reduces the incidence of fatal and nonfatal myocardial infarction in both primary and secondary prevention.
Methodology:

Study Design

It was a prospective observational study conducted in patient at hospital in 200 patient with any age qroup.

Study Procedure

The study consisted of the following procedure

1. Selection of the topic.
2. Literature survey.
3. Approval from the institutional ethics committee and permission from the hospital was obtained before starting the study.
4. The data consisted of drug names, dispensing dates, prescribing wards.
5. Awareness about Drug-Drug interaction and spontaneous reporting to the concern authority.
6. Case analyzed based on criteria for usage pattern of statins in patient diagnosed with chronic heart disease and identify inappropriateness of medication.
7. The ages was classified as 4 class.
8. Drug-Drug interaction were detected using previously developed online interaction checker (Micromedex) database and Stockley's drug interaction book.
9. Communicated with patient or attainder related to history of patient.
10. Categorizing common drugs used in patient
11. Comparison of therapy with standard guideline.
12. Estimation of medication adherence.

RESULT

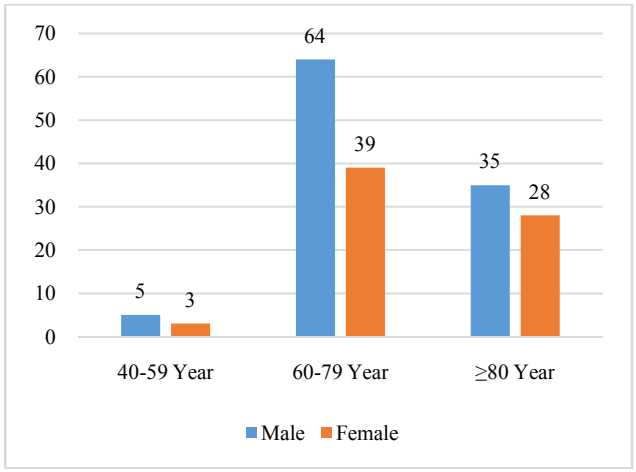

Figure 1 Age And Gender Distribution

Out of 200 patients, 132(66%) of patients recruited were male and 68(34%) were female patients

Table 1 Utilization Of Statins In Chronic Heart Disease

Drug	Gender				Total	
	Male		Female			
	N	%	N	%	N	%
Atorvastatin	81	68.6	37	31.4	118	59
Fluvastatin	2	67	1	33	3	1.5
Pravastatin	3	75	1	25	4	2
Rosuvastatin	26	55.3	21	44.7	47	23.5
Simvastatin	20	71.4	8	28.6	28	14
Total	132	60.5	68	39.5	200	100

Table 1 shows the utilization pattern of Statins, in the table as we can see Atorvastatin is highly prescribed drug which is about 118(59%) followed by Rosuvastatin 47(23.5%), Simvastatin 28(14%), Pravastatin 4(2%), and Fluvastatin 3(1.5%).

Table 2 adverse drug reaction

S.NO.	Suspected drugs	Effect of interaction	Incidence	Management
1	Clarithromycin + Atorvastatin	Weakness in leg muscle, and pain (Myopathy)	13	Drug cessation
2	Cyclosporine + Atorvastatin	Rhabdomyolysis	3	Drug cessation
3	Domperidone + Atorvastatin	QT interval prolongation	2	Drug cessation
4	Diltiazem + Simvastatin	Weakness in leg muscle, and pain (Myopathy)	1	Drug cessation
5	Ciprofloxacin + Simvastatin	Rhabdomyolysis	1	Drug cessation
		Total	20	

Table 2 shows resulting of ADR due to drug interaction and drugs involved were Atorvastatin, Simvastatin, Clarithromycin, Cyclosporine, Ciprofloxacin, Diltiazem, and Domperidone. Out of 200 case 20 were identified as having ADR i.e. 10% ADR.

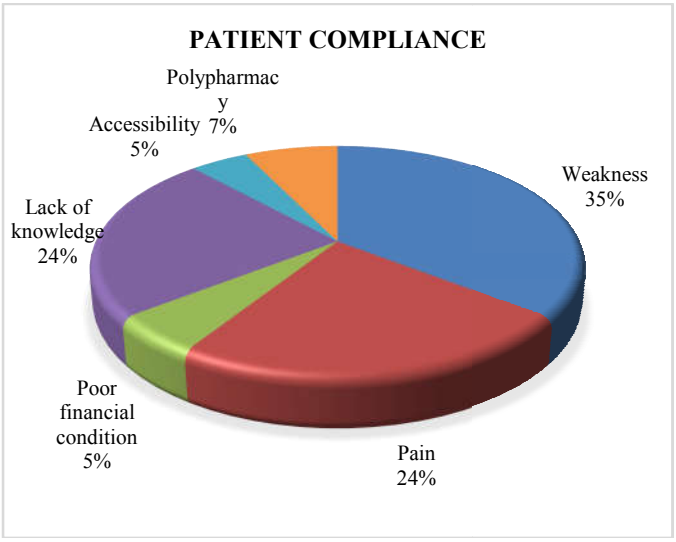

Figure 2 Occurance of Disease Condition During Tratmen

34(68%) was males and 16(32%) was females. In a similar study conducted by Jabansen M et.al it was show that shows that overall, 58.2% (95% CI, 54.6%-61.7%) of individuals with coronary artery disease and 52.0% (95% CI, 49.4%-54.6%) of individuals with diabetes aged older than 40 years were statin users .

Utilization pattern of Statins, in the table as we can see Atorvastatin is highly prescribed drug which is about 118(59%) followed by Rosuvastatin 47(23.5%), Simvastatin 28(14%), Pravastatin 4(2%), and Fluvastatin 3(1.5%). In survey counducted by Stephan R et,al in Vancouver, British Columbia, Toronto, Ontario, and Montreal, Quebec, Canada , a total of 15368 patients hospitalized with a diagnosis of CHF fulfilled the inclusion criteria for this study. In this final dataset, 6670 (43.4%) filled a prescription for atorvastatin, 4261 (27.7%) for simvastatin, 3209 (20.9%) for pravastatin, and 1228 (8.0%) for lovastatin. Statin agents differ in multiple characteristics, including liver and renal metabolism, half-life, and effect on other serum lipid components, bioavailability, and potency to reduce LDL-C. The study have shown that there was 20(10%) ADR caused due to drugs-drug interaction which was found to be happened in between Atorvastatin, Simvastatin interacting with Clarithromycin, Cyclosporine, Domperidone, Diltiazem, and Ciprofloxacin. The ADR caused by drug-drug interaction led to weakness in leg muscle, pain, Rhabdomyolysis, QT interval prolongation respectively.

Table 3 Comparison of therapy with standard guideline

S.No	AGE (Years)	LDL-C level in serum (mg/dl)	Goal of therapy	Standard guideline		Therapy used		No. of patient received therapy	
				ACC/AHA COR	ACC/AHA LOE	ACC/AHA COR	ACC/AHA LOE	Male	Female
1.	≤75	-	Clinical ASCVD	I	A	I	B	4	1
2.	>75	-	Clinical ASCVD	I	A	I	B	8	3
3.	Any age	≥190	Primary Prevention	I	B	IIa	B	2	2
4.	≥21	≥190	Primary Prevention	I	B	IIa	B	2	4
5.	40-75	70-189	Primary prevention – Diabetes	I	A	IIa	B	6	4
6.	40-75	70-189	Primary prevention-No Diabetes	I	B	I	A	3	2
7.	>75	<190	Primary prevention	IIb	C	IIa	B	7	3
			Total					32	19
								51	

Table 3 shows that during the treatment period total 51 out of which 32(62.7%) male and 19(37.3%) received therapy was not according to treatment guideline mention by ACC & AHA.

DISCUSSION

The study is much more focused on patient with Coronary artery disease, in the study we have compared the treatment with the standard guideline provided by AHA, ACC. In The study we have also evaluate the patient adherence to the statins, reasons behind non-adherence to the statin.

The present study was conducted in various department of tertiary care hospital and the sample size was 200: Out of 200 patients, 132(66%) of patients recruited were male and 68(34%) were female patients, 45(22.5%)of the patient were of the age group 40-59 years and out of this age group 31(69%) was males and 14(31%)was females, 105(52.5%) were of 60-79 years age group and in this age group 67(63.8%)was males and 38(36.2%) was females. 50(25%)were of ≥80 years age group and out of this age group

The result has shown that there was significant non-complains with statin therapy. The result shows the various reason to noncompliance to the treatment in which 39(35.45%) due to drug induced Weakness out of which 28(71.8%) male and 11(28.2%), 26(23.63%) due to Pain out of which 17(65.4%) male and 9(34.6%) Female, 6(5.45%) because of Poor financial condition out of which 5(83.33%) male and 1(16.7%) female, 26(23.63) due to lack of Knowledge regarding drug out of which 16(61.5%) were male and 10(38.5%) was female, 5(4.54%) because of Accessibility (rural population) 4(80%) was male and 1(20%) was female, and 8(7.3%) due to Polypharmacy out of which 6(75%) was male and 2(25%) was female. Out of 200 patient 110 was found to be non-compliant to the statin therapy because of various reasons mentioned in table no 8. In a similar study conducted by Ma J et.al shows that Statin use grew from 47% of all lipid lowering medications in 1992 to 87% in 2002, with atorvastatin being the leading medication in 2002. Statin use by patients with hyperlipidemia, as recorded by the number of patient visits, increased significantly from 9% of patient visits in 1992 to 49% in 2000

but then declined to 36% in 2002. Absolute increases in the rate of statin use were greatest for high-risk patients, from 4% of patient visits in 1992 to 19% in 2002. Use among moderate-risk patients increased from 2% of patient visits in 1992 to 14% in 1999 but showed no continued growth subsequently. In 2002, 1 y after the release of the Adult Treatment Panel III recommendations, treatment gaps in statin use were detected for more than 50% of outpatient visits by moderate- and high-risk patients with reported hyperlipidemia. Lower statin use was independently associated with younger patient age, female gender, African American race (versus non-Hispanic white), and non-cardiologist care. Adherence to cardiovascular medicines in rural population. The study was conducted in the department of medicine on patient diagnosed for HTN, CCF, & IHD over the period of 12 months. To assess the adherence the researcher used Morisky's Medication Adherence Scale. During comparison between the therapy used in current scenario and guideline it was noted that there was significant difference in table number 9 we can see that during the treatment period total 51 out of which 32(62.7%) male and 19(37.3%) received therapy was not according to treatment guideline mention by ACC & AHA. In a similar study done by Grundy SM et.al. Assessed the evidence base behind clinical guidance for primary prevention of cardiovascular disease with statins. The author has reviewed various literature in order to evaluate the need of statin use. The author has concluded that Statins are indicated for most patients with established ASCVD but their indications for primary prevention are much more nuanced. Most authorities agree that statin therapy is justified for individuals who are at high risk, or moderately high risk, of ASCVD. Risk status can be estimated by standard algorithms or based on the presence, or absence, of major risk factors. Unfortunately, standard algorithms are less robust in older people whose estimated risk is relatively high but whose actual risk may be low.

CONCLUSION

This study was conducted to evaluate the effectiveness of Stain in chronic heart disease patient at tertiary care hospital. It was concluded from the study that majority CHD cases was in male patient which may be because of male are more likely associated with habits of smoking and alcoholism. And the age group was highly affected was between 60 to 79 year old adults. Majority of patients admitted in hospital for the duration 7 to 8 days. The drug commonly prescribed for the treatment was Atorvastatin and Rosuvastatin. It was found that majority of prescription was without generic name and with inappropriate abbreviations. Study shows that Atorvastatin was interacting with clarithromycin, domperidone, digoxin and Rosuvastatin was interacting with Cyclosporine,those were major interactions. Most of the interaction was increasing effect of statin and causing myopathy, rhabdomyolysis and QT interval prolongation. In the study it was noted that adverse drug reactions involved were due to Atorvastatin and Simvastatin.More than half of the population had non-adherence with statin majorly due to reasons of statin induced weakness and pain apart from that other reason were of due to lack of knowledge regarding drug and Polypharmacy. It was concluded that more than 25% treatment prescribing was not according to guideline.

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