A PROSPECTIVE STUDY OF EFFECT OF PITAVASTATIN VERSUS ATORVASTATIN IN PATIENT WITH DYSLIPIDAEMIA

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ABSTRACT

BACKGROUND

Over 16 million people die each year from non-communicable disease (NCDS) between the ages of 30 and 70, of which 82% are in developing country. Out of all non-communicable diseases, cardiovascular disease is one of the important cause of death.

METHOD

Present study is designed to evaluate the efficacy of pitavastatin in hyperlipidaemia of coastal Andhra Pradesh. In this study, all patients with dyslipidaemia are enrolled; regarding diabetes mellitus patients under study, all the patients are taking same type of anti-diabetic drug. In the beginning of the study, HDL, LDL, total cholesterol and triglyceride was measured, around 40 patients were enrolled and were randomized and divided into two groups.

RESULT

Percentage change in mean of HDL in group A and B was 12.62 and 16.41. Percentage change in mean of LDL in group A and B was 17.58 and 18.47. Percentage change in mean of total cholesterol in group A and B was 19.78 and 17.96. Percentage change in mean of TG in group A and B was 21.68 and 18.12.

CONCLUSION

Regarding comparative efficacy of individual drugs except HDL concentration both are almost equally effective in reduction of total cholesterol, LDL and triglyceride. For increase in HDL, pitavastatin is more effective than atorvastatin.

KEYWORDS

Pitavastatin, Atorvastatin, Dyslipidaemia.

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INTRODUCTION: Over 16 million people die each year from non-communicable disease (NCDS) between the ages of 30 and 70, of which 82% are in developing country.[1] Out of all non-communicable diseases, cardiovascular disease is one of the important cause of death.

Out of all modifiable risk factors for atherosclerosis, hyperlipidaemia and more specifically hypercholesterolaemia is a major risk factor, even in the absence of other factors, hypercholesterolemia is sufficient to stimulate lesion development.[2] National Lipid Association of America has given clinical recommendation for dyslipidaemia which has been followed for this study.[3] Atorvastatin is an established statin for the treatment of hyperlipidaemia and is available in various doses like 10 mg, 20 mg and 40 mg. Pitavastatin is new drug for treatment of hyperlipidaemia available as oral tablets in doses like 1 mg, 2 mg and 4 mg. Present study is designed to evaluate the efficacy of pitavastatin in hyperlipidaemia of coastal Andhra Pradesh.

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MATERIAL AND METHODS: This is a prospective, randomized, open-labelled study carried out in the Department of General Medicine, Rangaraya Medical College, Kakinada. The patient enrolled for this study were from the OPD of General Medicine. Before start of the study, permission was taken from institutional ethics committee. Written consent was obtained from each patient on predesigned consent form. This study was carried out in between April 2014 to Jan 2016. Patient was enrolled on the basis of exclusion and inclusion criteria.

Inclusion Criteria	Exclusion Criteria
HDL for male < 40 mg/dL	-Hepatic and renal diseases
Female <48 mg/dL	-H/O Hypersensitivity
LDL >160 mg/dL	-pregnancy

In this study, all patient with dyslipidaemia are enrolled; regarding diabetes mellitus patients under study, all the patients are taking same type of anti-diabetic drug. In the beginning of the study, HDL, LDL, total cholesterol and triglyceride was measured, around 40 patients were enrolled and were randomized and divided into two groups. Group A were given atorvastatin 10 mg and group B were given pitavastatin 1 mg. Patients were advised to take these drug in the evening at 8 p.m. In the start of the study, all basal

parameters were measured and in the end of the study, all parameters were repeated. Data was interpreted as percentage change in mean of each parameter. HDL was estimated by ZAK modified method, LDL by W.D Friedewald, R. I. Lavya and D.C. Fredericton and triglyceride was estimated by Debnath modification of Neri and Frienge.

RESULTS: All the parameters of both the group were calculated in the start of study. In group A taking atorvastatin 10 mg, the mean HDL was 41.2 mg/dL in the start of the study, after 12 weeks it increased to 46.4 mg/dL, percentage change in the mean HDL value was 12.62%. LDL concentration in the start of study was 134.2 mg/dL which was reduced to 110.6 mg/dL, so percentage change in the mean was 17.58%. The total cholesterol in the start of study was 200.2 mg/dL which was reduced to 160.6, percentage change in mean was 19.78%. Similarly, triglyceride concentration was reduced from 140.8 mg/dL to 110.4 mg/dL. Percentage change in mean was 21.68.

In group B patients who were taking 1 mg pitavastatin, mean HDL concentration was increased from 40.6 to 47.2 (mg/dL). Percentage change in mean was 16.41%. The mean LDL concentration was 136.4 mg/dL in the start of the study which was reduced to 111.2 mg/dL, percentage change in LDL was 18.47%.

	Atorvastatin (20) M;F=16:4		**Pitavastatin (20) M;F=17:3**	
	Before treatment (Mean)	**After treatment (Mean)**	**Before treatment (Mean)**	**After treatment (Mean)**
HDL (mg/dL)	41.2	46.4	40.6	47.2
LDL (mg/dL)	134.2	110.6	136.4	111.2
Total chol. (mg/dL)	200.2	160.6	198.2	162.6
Triglyceride (mg/dL)	140.8	110.4	130.2	106.6

Table 1: Change in parameter after 12 week of treatment

	Atorvastatin	**Pitavastatin**
HDL(mg/dL)	12.62%	16.41%
LDL(mg/dL)	17.58%	18.47%
total chol. (mg/dL)	19.78%	17.96%
Triglyceride(mg/dL)	21.68%	18.12%

Table 2: Percentage change in mean after 12 week of treatment

Mean total cholesterol was 198.2 mg/dL in the start of the study which was reduced to 162.6 mg/dL, percentage change in mean was 17.96 mg/dL. Similarly, the reduction in mean triglyceride concentration was from 130.2 mg/dL to 106.6 mg/dL, percentage change was 18.12%.

DISCUSSION: Atorvastatin is an established drug for the treatment of dyslipidaemia and pitavastatin is a new drug which is also in use now a days. Both the drugs have same mechanism of action. In present study, we have studied the effect of both drugs on dyslipidaemia. In our study, we have found that both the drugs have increased the HDL concentration; in group A % increase in mean was lower than the group B, that is 12.62% and 16.41% respectively, which is similar to the study of Punita et al.[4] LDL concentration was decreased more in group B that is 18.47% than group A that is 17.58% but this difference is not much which is similar to the study of Kazumasa et al.[5] Total cholesterol concentration was reduced higher in group A than group B. That is 19.70% and 17.96% which similar to the study of Dragons Budinski et al.[6] Triglyceride concentration was decreased more in Group A than Group B which is similar to the study of J. Gumprecht et al, but in not as per Nakarin et al.[7,8] This difference may be due to patients recruited in our study and regional variation. Overall, there is no much difference in other parameters but there is difference in the increase in concentration of HDL which was higher in group B than group A.

CONCLUSION: From our study, we can conclude that both the drugs are effective in the treatment of dyslipidaemia. Regarding comparative efficacy of individual drugs except HDL concentration, both are almost equally effective in reduction of total cholesterol, LDL and triglyceride, for increase in HDL. Pitavastatin is more effective than atorvastatin. But a long term study by dividing patient into various groups on the basis of aetiology of the dyslipidaemia is required.

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