

# Lipid Lowering Effect in Hypertriglyceridaemia - Fenofibrate Vs Atorvastatin.

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## ABSTRACT

**Background:** Coronary artery disease (CAD), also known as ischemic heart disease (IHD), is a group of diseases that includes: stable angina, unstable angina, myocardial infarction, and sudden cardiac death. American Heart Association stressed upon control of high cholesterol and LDL to prevent acute coronary disease. The aim of the present study was to know whether fenofibrate or atorvastatin plays a better role in controlling hyperlipidaemia and thus to help in decreasing the burden of coronary artery disease on the society. **Methods:** This study is multicentric, prospective, comparative study conducted on 100 patients aged between 20-50 years, which were randomly selected. They were divided into two groups, A & B which received Fenofibrate and Atorvastatin respectively. Total cholesterol, Triglycerides, Low density lipids, High density lipids were estimated at the end 4, 8 and 12 weeks and compared with the baseline values. The values were expressed as mean  $\pm$  SD. Statistical analysis was done by using Student's paired t-test for quantitative and Chi-square test for qualitative parameters. The p value of  $<0.05$  was considered as statistically significant. **Result:** The fenofibrate plays a better role in controlling hyperlipidaemia as compared to atorvastatin. Total cholesterol and triglycerides were statistically better controlled by fenofibrate after 12 weeks of administration. High density lipoproteins level increased after administration of both the drugs but it was not statistically significant. Atorvastatin statistically played a better role in controlling low density lipoprotein than fenofibrate. **Conclusion:** Fenofibrate maybe recommended as lipid lowering agent in patients with hypertriglyceridaemia.

**Keywords:** Atorvastatin, Coronary artery disease, Fenofibrate, Hyperlipidaemia.

## INTRODUCTION

Coronary artery disease (CAD), also known as ischemic heart disease (IHD), is a group of diseases that includes: stable angina, unstable angina, myocardial infarction, and sudden cardiac death. A common symptom is chest pain or discomfort which may travel into the shoulder, arm, back, neck, or jaw. Occasionally it may feel like heartburn. Usually symptoms occur with exercise or emotional stress, last less than a few minutes, and get better with rest. Shortness of breath may also occur and sometimes no symptoms are present. The first sign is occasionally a heart attack. Other complications include heart failure or an irregular heartbeat.<sup>[1]</sup>

Risk factors include: high blood pressure, smoking, diabetes, lack of exercise, obesity, high blood cholesterol, poor diet, and excessive alcohol, among others. Other risks include depression. The underlying mechanism involves atherosclerosis of the arteries of the heart. A number of tests may help with diagnoses including: electrocardiogram, cardiac stress testing, coronary computed tomographic angiography, and coronary angiogram, among others.<sup>[2-5]</sup>

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Three decades back American Heart Association stressed upon control of high cholesterol and LDL to prevent acute coronary disease. It recommended dietary control and discontinuing the use of animal fat and use of statins in these patients.<sup>3</sup> 3-hydroxy-3-methylglutaryl-coenzyme A reductase inhibitors or statins were shown to reduce the level of LDL cholesterol in both the animal and human studies.<sup>3</sup> Result from statin trials have established that decrease in rate of coronary events was only 30% to 35%. This implies that a greater improvement could be achieved; though further interventional methods including therapy that modifies lipids other than LDL.<sup>[6,7]</sup>

Raised LDL and total cholesterol are common findings in western countries on contrary characteristic lipid abnormalities in Indian are following- 1) High triglyceride levels, 2) Low levels of HDL, 3) High level of small dense LDL, 4)

Atherogenic lipoprotein phenotype, 5) Moderately increased LDL levels.<sup>[8-10]</sup>

Every one mmol/L (88.5 mg/dL) increase in triglyceride increases risk of coronary disease by 32% in men and 76% in women.<sup>[11]</sup>

The aim of the present study was to know whether fenofibrate or atorvastatin plays a better role in controlling hyperlipidaemia and thus to help in decreasing the burden of coronary artery disease on the society.

## MATERIALS AND METHODS

This study is the multicentric, prospective, comparative study done in the department of Medicine for the period of one year. The aim of the study was to compare the effect of Fenofibrate and Atorvastatin in lowering the lipid level. This study was conducted on 100 patients aged between 20-50 years, which were randomly selected. The subjects were informed about the study and written consent was taken. They were divided into two groups, A & B which received Fenofibrate and Atorvastatin respectively.

### Inclusion criteria

- Age 20-50 years
- Triglyceride concentration of more than 200 mg/dL who have failed to achieve normal triglyceride levels laid down by NCEP ATP III guidelines after therapeutic lifestyle changes were included in this study.

### Exclusion criteria

- History of sensitivity to statins or fenofibrate.
- Secondary and familial hypercholesterolemia.
- Uncontrolled hypertension.
- Hypothyroidism.
- Serum creatinine above 2.5 mg/dL.
- LFT enzymes more than 3 times elevation
- Age <20 and >50 years.
- Pregnancy
- Not giving consent for participation in study.

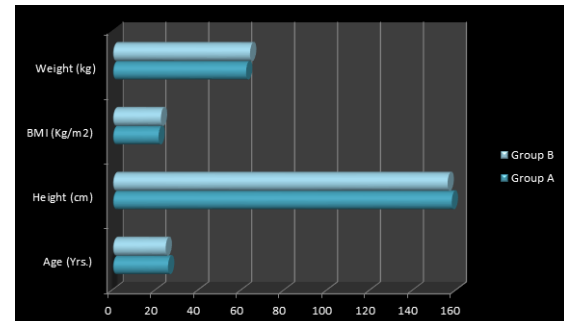
The Group A and B received Atorvastatin 10 mg and micronized fenofibrate 160 mg respectively. After taking drugs, lipid fractions (TC- Total cholesterol, TG- Triglycerides, LDL- Low density lipids, HDL- High density lipids) were re-estimated at the end 4, 8 and 12 weeks.

The values of the two groups were compared and expressed as mean  $\pm$  SD. Statistical analysis was done by using Student's paired t-test for quantitative and Chi-square test for qualitative parameters. The p value of <0.05 was considered as statistically significant.

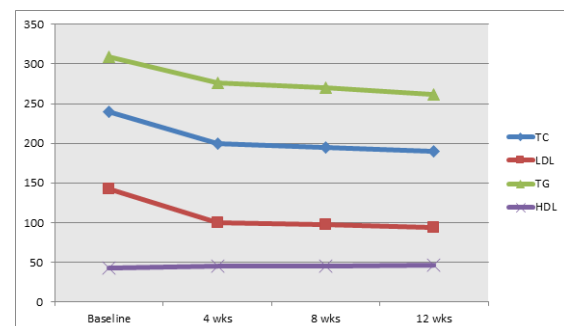
## RESULTS

This study was conducted on hundred patients in the age group of 20-50 years, which were divided into

two groups (50 each). The Group A and Group B received Fenofibrate and Atorvastatin in lowering the lipid level respectively. The demographic profile of these patients was compared. The difference in parameters of the patients (Age, weight, height, BMI) were found to be statistically insignificant ( $p > 0.05$ ) [Figure 1].

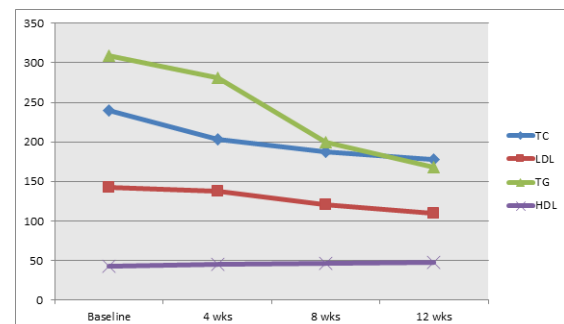


**Figure 1: Comparison of demographic characteristics in two groups.**



**Figure 2: Comparison of Mean Level of Lipid Profile in Study Group A between the Level Prior to Therapy and After 4, 8 and 12 Weeks of Therapy.**

[Figure 2] depicts the fall in level of all the parameters with time after the intake of drug Atorvastatin but the drastic fall was seen in the levels of LDL followed by TG and TC. Increase in the level of HDL was observed.



**Figure 3: Comparison of Mean Level of Lipid Profile in Study Group B between the Level Prior to Therapy and After 4, 8 and 12 Weeks of Therapy.**

[Figure 3] also depicts the fall in level of all the parameters with time after the intake of drug Fenofibrate but the drastic fall was seen in the levels of TG followed by LDL and TC. Increase in the level of HDL was observed.

**Table 1: Statistical Comparison of Lipid Profile in Group A and B after 12 Weeks of Therapy.**

Parameters	Group A		Group B		P value
	Mean	±S.D.	Mean	±S.D.	
TC	190	11.68	178	12.83	<0.05*
LDL	94	10.66	110	10.49	<0.05*
TG	262	15.91	168	13.99	<0.05*
HDL	46	16.90	48	21.79	>0.05

[Table 1] depicts that the fall in the levels of TC and TG was statistically significant in group B as compared to group A, whereas LDL level was statistically decreased in group A.

## DISCUSSION

The current study confirmed that administration of fenofibrate plays a better role in controlling hyperlipidaemia as compared to atorvastatin. Total cholesterol and triglycerides were statistically better controlled by fenofibrate after 12 weeks of administration. High density lipoproteins level increased after administration of both the drugs but it was not statistically significant. Atorvastatin statistically played a better role in controlling low density lipoprotein then fenofibrate.

In 2015 CAD affected 110 million people and resulted in 8.9 million deaths. It makes up 15.9% of all deaths making it the most common cause of death globally. The risk of death from CAD for a given age has decreased between 1980 and 2010, especially in developed countries. The number of cases of CAD for a given age has also decreased between 1990 and 2010. In the United States in 2010 about 20% of those over 65 had CAD, while it was present in 7% of those 45 to 64, and 1.3% of those 18 to 45. Rates are higher among men than women of a given age.<sup>[12,13]</sup>

Although, some investigators have shown some strong association of total cholesterol and LDL with coronary artery disease, other findings suggest that this disease arises at lower lipid concentrations in people from south Asia, then in those from other region.<sup>[14]</sup>

Lipid abnormalities such as high triglycerides and low HDL with normal LDL levels are common in people from south East Asian region. Hence, European/American recommendations of use of statins as first line agents may not entirely be applicable to all populations. The prevalence of coronary heart disease in India sharply rising from 4% in 1960 to 11% in 2001 between the age group of 30% to 70%.<sup>[15,16]</sup>

A comparison study between atorvastatin and micronized fenofibrate in the treatment of mixed hyperlipidaemia conducted by Bairaktari et al,<sup>[14]</sup> determines that atorvastatin was better in lowering levels of total and LDL cholesterol, whereas fenofibrate was more effective at lowering levels of triglycerides and raising the levels of HDL.

Studies piloted by Ellen RLB et al with fenofibrate had similar results. These studies prompted us to

compare the atorvastatin and fenofibrate in Indian patients with hypertriglyceridaemia.<sup>[15]</sup>

## CONCLUSION

The result of this study shows that fenofibrate plays a better role in controlling hyperlipidaemia as compared to atorvastatin. Total cholesterol and triglycerides were statistically better controlled by fenofibrate after 12 weeks of administration. High density lipoproteins level increased after administration of both the drugs but it was not statistically significant. Atorvastatin statistically played a better role in controlling low density lipoprotein then fenofibrate.

Thus, fenofibrate maybe recommended as lipid lowering agent in patients with hypertriglyceridaemia.

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