EFFECTIVENESS OF ROSUVASTATIN OVER ATORVASTATIN IN MANAGING DYSLIPIDAEMIA IN UNCOMPLICATED TYPE 2 DIABETES MELLITUS - AN INSTITUTIONAL BASED STUDY

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ABSTRACT

BACKGROUND

Diabetes mellitus is a metabolic disorder due to absolute or relative deficiency of insulin or insulin resistance which is characterized by hyperglycaemia. To evaluate the efficacy of Rosuvastatin and Atorvastatin in correcting dyslipidaemia in type 2 diabetic patients.

MATERIAL AND METHODS

A retrospective data analysis was performed where uncomplicated type 2 diabetes mellitus patients with dyslipidaemia but with good glycaemic control, who received either Rosuvastatin 10 mgs or Atorvastatin in 20 mgs. The various lipid parameters were recorded at the start of statin treatment and after 12 weeks of treatment. Results were compared, and statistical analysis was done.

RESULTS

Both drugs reduced the levels of Total cholesterol, Serum triglyceride & LDL-cholesterol levels and raised the serum level of HDL-cholesterol. The mean changes for Rosuvastatin & Atorvastatin were 74.89 ± 10.04, 50.20 ± 14.09, 74.45 ± 10.12 & 43.75 ± 5.69, 31.88 ± 2.17, 46.36 ± 6.22 respectively for the bad cholesterols and the mean rise in the serum level of good cholesterol was 9.6 ± 0.10 & 8.94 ± 0.98. The observations were statistically significant.

CONCLUSION

Rosuvastatin was found to be a better drug for managing dyslipidaemia in type 2 diabetics.

KEYWORDS

Statins, rosuvastatin, atorvastatin, type 2 diabetes mellitus, dyslipidaemia.

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BACKGROUND

Diabetes mellitus is a metabolic disorder due to absolute or relative deficiency of insulin or insulin resistance which is characterized by hyperglycemia.[1] Altered lipid metabolism is a common association.[1] Diabetes mellitus (DM) is a coronary heart disease (CHD) risk equivalent and a major cause of morbidity and mortality worldwide.[2] Prevalence of diabetes mellitus in India is high and India is going to be the diabetic capital of the world. Long-term complications are due to development of micro- & macro-vascular complications and involve almost all vital organs such as heart, eyes, kidney, blood vessels, and nervous system.[3]

Diabetes and diabetic dyslipidaemia are closely associated, and literatures suggest approximately 80% of diabetic deaths are attributed to the later that is responsible for the cardiovascular.[4] Higher concentration of LDL-Cholesterol have been documented in diabetics and is responsible for higher CHD thus lowering LDLc level is the target of treatment in diabetic dyslipidaemia. The statins (3-hydroxy-3-methylglutaryl Co-enzyme A (HMGCoA) reductase inhibitors) are established drug of choice in the management of dyslipidaemia in diabetes to reduce cardiovascular risk both in primary and secondary prevention.[5,6] Aggressive management of diabetic dyslipidaemia is the mandate of most of the guidelines and these guidelines suggest to achieve the lipid goals by use of drugs if necessary in. [7]

The dose of the different statins varies to achieve the same target and these lower the LDLc levels from 20 to 60%. Among the statins Rosuvastatin is the newest and most potent one and hence preferred in patients requiring aggressive lowering of lipids.[8,9] Studies have demonstrated that intensive lowering of LDLc with high dose atorvastatin does not reduce the primary outcome of major coronary events.[10] Studies have suggested a better milligram dose dependant efficacy of Rosuvastatin than Atorvastatin in cases of hypercholestrolemia.[11]

Aims and Objectives

To evaluate the efficacy of Rosuvastatin and Atorvastatin in correcting dyslipidaemia in type 2 diabetic patients. The present study was conducted to evaluate the efficacy of

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Rosuvastatin in patients with type-2 diabetes mellitus with dyslipidaemia in Indian population.

MATERIALS AND METHODS

The retrospective data analysis was conducted on patients of type 2 diabetes mellitus with dyslipidaemia. Inclusion criteria were (1) Type 2 DM on fixed dose oral antidiabetic agent (glimepiride + metformin) with good glycemic control i.e. HbA1c value <8% and are dyslipidemic i.e. LDLc level >129 mgs / dL and (2) receiving either Rosuvastatin 10 mg daily or Atorvastatin 10 mg daily for a period of 12 weeks. Exclusion criteria are (a) Insulin dependent Diabetics, (b) Diabetics with complications, (c) Diabetics with abnormal – physical examination findings / laboratory parameters, ECG or any other investigation findings and (d) history of any associated acute illness. A total of 60 patients who met the inclusion criteria were included in the study group of which 30 patients received Rosuvastatin 10mg a day and 30 patients received Atorvastatin 20mg a day. The HbA1c levels and fasting Total cholesterol, Triglyceride, LDLc & HDLc levels were collected in each case at the start of the treatment at the end of the study period. And evidences suggestive of an adverse drug effects if found were also recorded.

RESULTS

The change in the various lipid parameters after 12 weeks of treatment with both the statins is depicted in the Table 1. It is clearly evident from the findings that both the drugs have reduced the serum levels of the parameters like Total cholesterol, Serum Triglyceride & LDL-cholesterol and raised the level of HDL-cholesterol.

Parameters		Rosuvastatin 10 mg	Atorvastatin 20 mg
T. Cholesterol	Before	278.09 ± 62.2	264.52 ± 57.46
	After	203.21 ± 52.15	220.77 ± 51.77
Triglyceride	Before	216.73 ± 48.58	224.76 ± 45.91
	After	166.53 ± 34.50	192.88 ± 48.08
HDLc	Before	35.69 ± 5.39	37.02 ± 4.71
	After	45.29 ± 5.84	45.96 ± 3.73
LDLc	Before	199.05 ± 59.36	182.55 ± 54.07
	After	124.61 ± 49.25	136.23 ± 47.85

Table 1. Change in Lipid Parameters in Type 2 Diabetics After 12 Weeks Treatment, Values in Mean ± SD

On statistical evaluation of the findings it was observed that, the reduction of the serum level of the parameters like Total cholesterol, Serum Triglyceride & LDL-cholesterol after the treatment period by both the drugs was statistically significant and the rise in the serum level of HDL-cholesterol was also statistically significant. However, the efficacy of Rosuvastatin in regulating dyslipidaemia was superior to that of Atorvastatin as evident from the mean change in the corresponding values before and after the treatment period. The statistical findings obtained is depicted in Table 2.

Lipid Profile parameter	Rosuvastatin Mean ± SD	Atorvastatin Mean ± SD	Two tailed p value, df=48
Cholesterol	74.89 ± 10.04	43.75 ± 5.69	P<0.0001
TG	50.20 ± 14.09	31.88 ± 2.17	P<0.0001
HDL	9.6 ± 0.10	8.94 ± 0.98	P=0.0016
LDL	74.45 ± 10.12	46.36 ± 6.22	P<0.0001

Table 2. Mean Change in Lipid Profile Parameters in Rosuvastatin and Atorvastatin Treated Groups

No record of any significant adverse drug reaction in any of the patients were found.

DISCUSSION

The increasing incidence of Type 2 diabetes is alarming and poses a major public health problem. Literatures suggest that there is an early occurrence of the disease in India by a week when to the west.[8] Dyslipidaemia is a common co-morbidity and it has been attributed for the increased incidences of cardiovascular complications. Lipid lowering drugs especially the statins have been proved to be beneficial in reducing the cardiovascular complications in both diabetics and non-diabetcs.[12]

In the present study all 60 individuals are type 2 diabetic mellitus patients who were on oral anti-diabetic agent with good glycemic control (HbA1c values were below 8%) and were dyslipidemic i.e. LDL-cholesterol levels were above 129 mgs / dL. On evaluation of the values of all the four lipid parameters i.e. Total cholesterol, Serum triglyceride, LDL-cholesterol & HDL-cholesterol, the present study observed a statistically significant reduction in the values of first three parameters known as the "bad cholesterols" and raised the serum levels of the last one known as the "good cholesterol". The mean change in LDL-cholesterol level in the Rosuvastatin group was 74.45 ± 10.12 gms / dL and the same for Atorvastatin group was 46.36 ± 6.22 mgs / dL. This observation was statistically significant (P = <0.001) This observation was in accordance with the findings of Bullano et al.[13] However the observation was discordant with the study of Costa J et al 2006, who observed a statistical non-significant difference between the two groups.[12]

When change in HDL-cholesterol levels are observed, Rosuvastatin raised the mean value by 9.6 ± 0.10 mgs / dL and the same for Atorvastatin was 8.94 ± 0.98 mgs / dL. This observation was statistically significant (P = 0.016). The observation was concordance with that of Stalenhoef AF et al 2005.[14]

On rest two parameters both the drugs caused statistically significant reduction in the serum levels however Rosuvastatin was found to be more efficacious as is evident from the fact that the mean change is approximately one and half times more by it.

CONCLUSION

The present study concluded that both the drugs under study were effective in the management of dyslipidaemia in type 2 diabetics but Rosuvastatin was found to be

significantly more effective than Atorvastatin in the same dose. No adverse drug effect was noted in both the cases.

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