

Efficacy of Rosuvastatin in Management of Dyslipidemia in Patients with Type-2 Diabetes Mellitus

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Abstract:

Background:- Dyslipidemia in patients with type 2 DM is very common in Indian scenario and it is a very worrisome condition. Its control reduces the mortality and morbidity in type 2 DM patients.

Aim:- To establish the efficacy of Rosuvastatin in management of dyslipidemia in type 2 DM patients.

Settings and Design:- Tertiary care hospital, Interventional study.

Conclusion:- Rosuvastatin is well tolerated and effective drug in the management of dyslipidemia in type 2 diabetic patients. The effective dose is 10mg daily as a single dose at any time of day.

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I. Introduction

Diabetes Mellitus refers to a group of common metabolic disorder that share the phenotype of Hyperglycemia, caused by absolute or relative insulin deficiency[1]. It is a syndrome with disordered metabolism and inappropriate hyperglycemia due to either a deficiency of insulin secretion or to a combination of insulin resistance and inadequate secretion to compensate[2]. Diabetes Mellitus is the most common endocrine disorder. In India Type-2 Diabetes Mellitus is the commonest and constitutes almost 95% of all adult Indian Diabetics. In this group, Dyslipidemia is very common and presently leading cause of death in association with cardiovascular disease. Diabetes and Dyslipidemia are independent risk factor of macrovascular disease, when they occur together risk is significantly increased[3].

The most common pattern of dyslipidemia in Type-2 diabetic patient is elevated triglyceride level and decreased HDL cholesterol level. The concentration of LDL cholesterol in Type 2 diabetic patient is usually not significantly different from non-diabetic individuals. The commonest lipid abnormality in Indian type 2 diabetic patient is increased triglyceride level, decrease HDL cholesterol is second commonest abnormality[4]. As per recent recommendation by National Cholesterol Education Programme – Adult treatment Panel[6], aggressive lowering of plasma lipid and lower treatment goal for serum lipid in type 2 diabetic patient is set up. Diet therapy alone is relatively ineffective in reducing total and LDL cholesterol and average serum cholesterol reduced by only 5%. Good control of glycemia with insulin therapy markedly reduces hypertriglyceridemia in type 2 diabetics but it has modest effect on HDL and LDL cholesterol level. Rosuvastatin is a synthetic statin that represents an advance in the pharmacologic and clinical properties of statins. Relative to other statins, Rosuvastatin possesses a greater number of binding interactions with HMG-CoA reductase and has a high affinity for the active site of the enzyme[5]. This is the latest and most potent statin with a plasma $t_{1/2}$ of 18-24 hours. The advantages of Rosuvastatin over other statins include – highest potency, once daily dosing, can be given at anytime of the day, greater LDL cholesterol reduction and HDL cholesterol elevation and reversal of atheromatous plaques. There are few data regarding the role of Rosuvastatin in management of Dyslipidemia in Indian Diabetics.

Therefore, this study was done to evaluate the efficacy and tolerability of Rosuvastatin in Dyslipidemia of Indian type2 diabetics.

II. Materials & Methods

The study was carried out with type 2 diabetic patients with dyslipidemia (criteria for selection mentioned below) attending the diabetic clinic and outpatient department of Patna Medical College & Hospital, Patna.

Inclusion criteria-

- History of DM for more than 5 years
- Presence of dyslipidemia(total cholesterol >200mg/dl, LDL-C >130mg/dl, triglyceride >170mg/dl).

- Dyslipidemic patients with good glycemic control
- Patient aged between 30 to 70 years

Exclusion criteria-

- patient with clinically significant or uncontrolled renal, hepatic and pulmonary disease or any other severe concurrent illness, acute infections and major surgeries were excluded.
- Patients with poorly controlled DM, psychiatric disturbance and alcohol intake >300ml/day were excluded from study.
- Females with child bearing potential were not considered for this study.

30 patients with type2 DM fullfilling the above criteria were chosen for study. We conducted an INTERVENTIONAL STUDY after proper clearance from institutional ethical committee. Only those patients who were on diet therapy and had uncontrolled dyslipidemia were considered for the study. Placebo therapy was given to all patients for the period of 2 weeks. Rosuvastatin was given in a dose of 10 mg per day as a single dose with evening meal to all patients for a period of 6 weeks.

Three readings of the lipid profile were considered:

1. The initial value with which the patient was selected for the trial was called the initial value.
2. Patients were given placebo therapy, the lipid profile was repeated after 2 weeks was called baseline evaluation.
3. The patients were given Rosuvastatin for a period of 6 wks. and lipid profile was repeated called final evaluation.

Comparison was carried out between baseline and final evaluation in all patients.

. Student paired T test was used for statistical analysis.

The criteria for good glycemic control : a.)HbA₁C<9.0%

b.)FPG <110mg/dl

c.)PPPG<140mg/dl.

Blood glucose control was maintained throughout the study period. For sample collection EDTA as the anticoagulant was used. Samples were collected in sitting position with minimal venous occlusion after 12 hrs. of fasting. Plasma was preferred and it was allowed for rapid cooling.

III. Results

This study was undertaken to evaluate the efficacy and tolerability of Rosuvastatin in the management of dyslipidemia in 30 subjects of type 2 DM. Patients of age group 30-70 were recruited in this study. Treatment was initiated with 10 mg of Rosuvastatin. Blood glucose, glycosylated hemoglobin and lipid profile estimation were done before and 6 weeks after commencement of Rosuvastatin therapy. The mean duration of diabetes was 8.83 years in study population. Out of 30 patients, 7 were smokers, 4 having hypertension and 3 patients had history of IHD. Among study population 7 were on insulin therapy and 23 were on oral hypoglycemic drugs. Mean HbA₁C was 6.85% at base line and 6.74% after final evaluation. This showed that glycemic control was normal throughout the study period.

Table-I

Age and Sex distribution of type 2 diabetic patient			
Age group	Male	Female	Total
30-40	1	1	2
41-50	4	2	6
51-60	8	5	13
61-70	5	4	9
Total	18	12	30

Figure-1.Histogram showing age and sex distribution of type2 diabetic patient

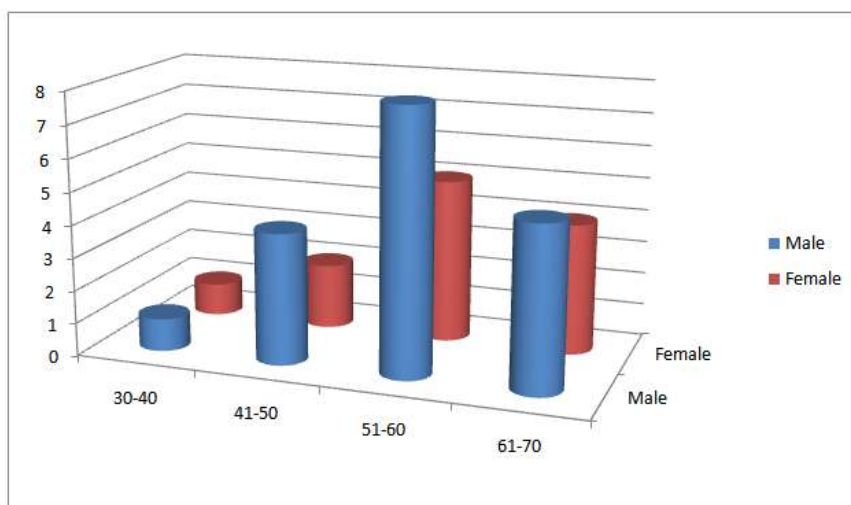
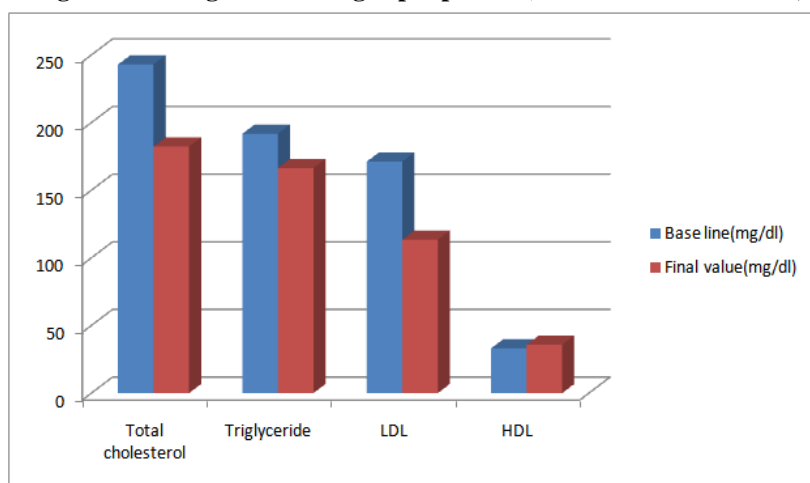


Table-II

Mean value of Lipid profile pre and post treatment			
	Mean base line(mg/dl)	Mean final value(mg/dl)	%change(average)
Total cholesterol	242.95	182.29	24.96%
Triglyceride	191.75	166.41	13.21%
LDL	171.16	113.41	33.74%
HDL	33.12	35.84	8.18%

Figure- 2.Histogram showing Lipid profile (Pre and Post treatment)



IV. Discussion

The present study was done to determine the efficacy and tolerability of Rosuvastatin in the management of dyslipidemia in Indian type 2 diabetics. The 6 wks. Rosuvastatin treatment (10mg/day) had significantly reduced the LDL cholesterol, total cholesterol, triglyceride level and increased HDL cholesterol like other workers. Serum total cholesterol was reduced by 24.96%, serum triglyceride level was decreased by 13.21%, HDL was increased by 8.18% and LDL was decreased by 33.74%.

No serious side effects were noted. There was no significant deterioration of RFT or LFT or significant increase in TSH or CPK levels. The different studies done shows similar results-

Michael B Clearfield et. al. observed reduction of total cholesterol by 28.2%, LDL by 44.6% , TG by 18.2% and elevation of HDL by 6.4% [7].

Anton H. Stalenhoef et. al. observed reduction of total cholesterol by 26.4%, LDL by 42.7%, TG by 19.1% and elevation of HDL by 9.5% [8].

Hyo-Soo KIM et. al. observed reduction of total cholesterol by 28.6%, LDL by 46.5%, TG by 18.1% and elevation of HDL by 6.2% [9].

V. Conclusion

We conclude that Rosuvastatin is well tolerated and effective drug in the management of dyslipidemia in type 2 diabetic patients. The effective dose is 10mg daily as a single dose at any time of day.

It is better than other statins in many ways and has little side effects. It effectively reduces total cholesterol, LDL, Triglycerides and also increases HDL. Rosuvastatin safely and beneficially alters the entire spectrum of lipoproteins in Indian patients. Results of previous randomised trials have shown that interventions able to lower LDL cholesterol concentrations can significantly reduce the incidence of coronary heart disease and the major vascular events in a wide range of individuals. Rosuvastatin should be started early in type 2 Diabetes patients to reduce dyslipidaemia and decrease complications which occurs due to dyslipidemia.

Conflict of interest- None

Funding-None

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