

COMPARATIVE EFFICACY OF ROSUVASTATIN AND ATORVASTATIN IN PATIENTS WITH CORONARY ARTERY DISEASEAkhilendran R.¹, Hima Mahesh¹, Fahida Farook¹, Swathi M.¹, Pradeep P.², Veena Vijayan G.^{1*}¹Sreekrishna Collegae of Pharmacy and Research Centre, Parassala, Thiruvananthapuram.²Cosmopolitan hospitals Pvt. Ltd, Pattom, Thiruvananthapuram.**Corresponding Author: Veena Vijayan G.**

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ABSTRACT

The objective of study was to compare the lipid lowering efficacy of Atorvastatin and Rosuvastatin in Coronary Artery Disease patients. In this study we analyzed data of 130 patients of IP and OP department of tertiary care hospital in south Kerala over a period of 6 months. Patients above 18yrs of age presenting with coronary artery disease and dyslipidemia were included in this study. The lipid profile values were noted and rechecked at an interval of 6 weeks to compare the efficacy of Atorvastatin and Rosuvastatin. Atorvastatin 20mg was comparable to Rosuvastatin 10mg. According to the doseresponse analysis, mean differences between the LDL, Triglyceride and Total cholesterol dose responses of Rosuvastatin 10 to 40mg versus Atorvastatin 10 to 40mg were significant. HDL C increasing effect of Rosuvastatin at doses of 10, 20, 40mg were found to be comparatively higher than Atorvastatin at similar doses after 6 weeks of treatment. Across dose ranges HDL C increasing effect was found to be rising with dose with both statins. The best LDL C, Triglyceride and Total Cholesterol reductions with Rosuvastatin were obtained at dose of 40mg. The study concluded with the findings that Rosuvastatin was found to be more efficacious in lowering LDL level compared to Atorvastatin.

KEYWORDS: Comparative study, Atorvastatin, Rosuvastatin, Dyslipidemia.**INTRODUCTION**

CAD is defined as acute or chronic form of cardiac disability arising from imbalance between the myocardial supply and demand for oxygenated blood. Narrowing of obstruction of the coronary arterial system is the most common cause of myocardial anoxia.^[1]

Cardiovascular disease is the main health problem in developed countries. Prevention is presented as the most effective and efficient primary care intervention,^[2] whereas cardiac rehabilitation programs are considered the most effective of secondary prevention interventions; however, these are underuse^[3] Statins are currently the most effective drugs for lowering low-density lipoprotein cholesterol (LDL-C) and represent the first choice for treating hypercholesterolemia.^[4]

Statins are very well known to reduce cardiovascular events and mortality in patients with coronary artery disease or at high risk of cardiovascular disease.^[5] Mainly the patients were prescribed with Atorvastatin for reducing the elevated cholesterol level and limited data are available regarding the comparative efficacy of Atorvastatin, therefore it is rational to assess the efficacy of Atorvastatin compare to Rosuvastatin. The main objective of the study was To compare the lipid lowering efficacy and cost effectiveness of Rosuvastatin and

Atorvastatin. The study was carried out for a period of 6 months. The study was conducted at the cardiology department of a 550 bedded multispecialty hospital Sample size was 130 patients. The lipid profile values were noted down and rechecked results at an interval of 6 weeks. The study also provides information regarding comparative efficacy of statins and Rosuvastatin was found to be more efficacious in lowering LDL level compared to Atorvastatin. At recommended starting doses, Rosuvastatin (10 mg) was more efficacious than Atorvastatin (20mg) in terms of LDL-C lowering, LDL-C goal achievement, and improving the atherogenic lipid profile. Rosuvastatin was found to be more cost effective than Atorvastatin. This study shows that Rosuvastatin is more cost effective compared to Atorvastatin. For future research the study should be done in a large sample and for long duration of period as a multicentre study.

METHODOLOGY**Study design**

- Prospective-observational study.

Study setting

- The study was conducted at the cardiology department of 550 bedded multispecialty hospital, Cosmopolitan hospitals (pvt ltd.), Thiruvananthapuram.

Study duration

- The study was conducted for a period of 6 months from October 2014 to March 2015.

Sample size

$$N = \frac{Z\alpha^2 PQ}{D^2}$$

Zα = 1.96

P = Anticipated percentage of CAD patients admitted or visited in cardiology department.

Q = 100- P

D = Precision factor, it is 20% of P Here, P value was found to be 93.23.

Q = 6.77

D = 18.65

$$N = \frac{1.96^2 * 1.196 * 93.23 * 6.77}{18.65^2 * 18.65}$$

N = 130

Enrollment

Inclusion criteria

- Patients above 18yrs of age presenting with coronary artery disease and dyslipidemia.
- Patients require to have Total cholesterol >200mg/dl, LDL> 130mg/dl, HDL< 40 and Triglyceride> 150mg/dl.
- Patients willing to participate in the study.

Exclusion criteria

- Patients aged below 18 years.
- Pregnant women.
- History of sensitivity to statins.

- Presence of serious or unstable medical or psychological conditions.
- Renal impairment (CrCl<30ml/min).
- Acute liver disease (AST or ALT> 100IU/L) or unexplained persistent elevations of serum transaminases.
- Patients not willing to participate in study.

STUDY PROCEDURE

A prospective observational study was carried out at cardiovascular department of a tertiary care hospital. A written informed consent was taken in prescribed format from patients with CAD attended cardiology department. Patients who met the inclusion criteria were enrolled in the study. All information relevant to study was collected from case records and direct interview of the patients with the help of physician. The demographic characters, comorbid conditions, cardiology investigation results, drug dose frequency etc. were documented in the proforma. The lipid profile values were noted and rechecked at an interval of 6 weeks to compare the efficacy of Atorvastatin and Rosuvastatin. For data entry we had used the software Microsoft excel and for the analysis SPSS (statistical package for social science) version 17.0. Student T test was the statistical tests used.

RESULTS AND DISCUSSION

In this study, we analysed the data of 130 patients visited/admitted in the cardiology department of a tertiary care hospital in south Kerala over a period of 6 months. This study had provided a picture on comparative efficacy of Rosuvastatin versus Atorvastatin.

Efficacy of Atorvastatin and Rosuvastatin on lipid lowering

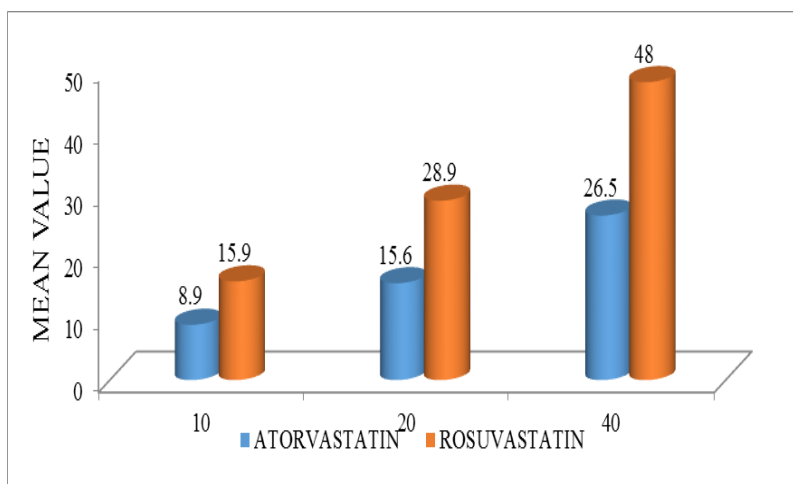


Fig.1 Comparison of lowering of LDL between group based on dose (N=130)

Table.1 Comparison of lowering of LDL between group based on dose(N=130)

Dose	Atorvastatin			Rosuvastatin			t	P
	Mean	SD	N	Mean	SD	N		
10	8.9	3.2	21	15.9	3.7	18	6.45**	0.000
20	15.6	6.3	26	28.9	5.3	31	8.62**	0.000
40	26.5	6.5	19	48.0	6.9	15	9.33**	0.000

**:- Significant at 0.01 levels

Atorvastatin 20mg was comparable to Rosuvastatin 10mg. According to the dose-response analysis, mean differences between the LDL cholesterol doseresponses of Rosuvastatin 10 to 40mg versus Atorvastatin 10 to 40mg were significant (Table:1). In the pairwise, dose-to-dose comparisons with Atorvastatin, Rosuvastatin 10mg reduced LDL cholesterol significantly more than

Atorvastatin 10mg, Rosuvastatin 20mg reduced LDL cholesterol significantly more than Atorvastatin 20, and Rosuvastatin 40mg reduced LDL cholesterol significantly more than Atorvastatin 40mg. The best LDL-C reductions with Rosuvastatin were obtained at dose of 40mg. The results were in concordance with STELLAR trial.^[6]

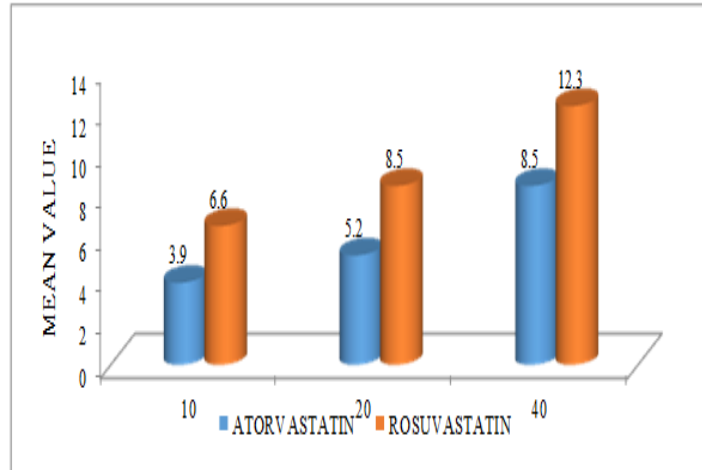


Fig.2 Comparison of increasing of HDL between group based on dose (N=130)

Table: 2 Comparison of increasing of HDL between group based on dose (N=130)

Dose	Atorvastatin			Rosuvastatin			t	P
	Mean	SD	N	Mean	SD	N		
10	3.9	2.2	21	6.6	2.5	18	3.55**	0.001
20	5.2	2.1	26	8.5	2.3	31	5.66**	0.000
40	8.5	3.0	19	12.3	2.6	15	3.86**	0.001

**:- Significant at 0.01 level

HDL increasing effect of Rosuvastatin at doses of 10, 20,40mg were found to be comparatively higher than Atorvastatin at similar doses after 6 weeks of treatment (Fig: 22). Across dose ranges HDL C increasing effect was found to be rising with dose with both statins. Rosuvastatin at dose of 10mg, 20mgand 40mg doses was

found to have raised HDL levels significantly more than Atorvastatin 10mg, 20mg, 40mg doses respectively. Result was found to be in concordance with STELLAR trial by Peter H Jones et al.^[6], the trial has shown HDL C rising effect of Rosuvastatin over dose ranges.

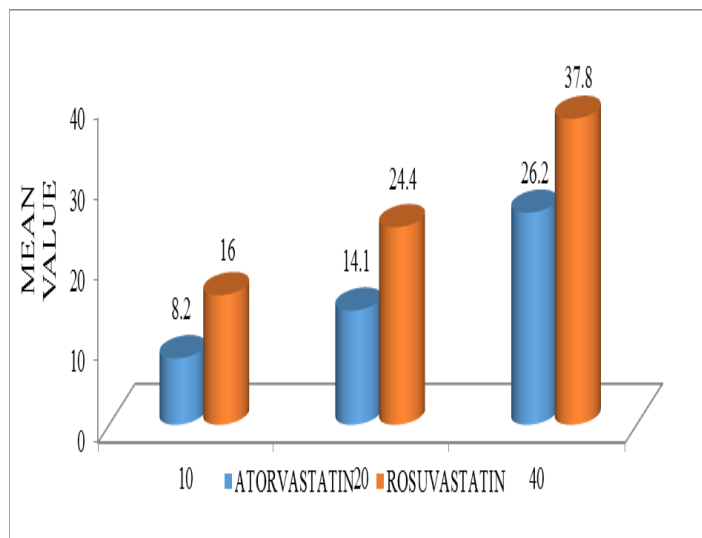


Fig: 3 Comparison of lowering of TG between group based on dose(N=130)

Table.3 Comparison of lowering of TG between group based on dose (N=130)

Dose	Atorvastatin			Rosuvastatin			t	P
	Mean	SD	N	Mean	SD	N		
10	8.2	3.9	21	16.0	3.6	18	6.47**	0.000
20	14.1	5.5	26	24.4	5.0	31	7.32**	0.000
40	26.2	7.6	19	37.8	12.1	15	3.43**	0.002

**:- Significant at 0.01 level

Atorvastatin 20mg was comparable to Rosuvastatin 10mg.^[6] According to the dose-response analysis, mean differences between the triglyceride dose responses of Rosuvastatin 10 to 40mg versus Atorvastatin 10 to 40mg were significant (Table:3). In the pairwise, dose-to-dose comparisons with Atorvastatin, Rosuvastatin 10mg reduced LDL cholesterol significantly more than

Atorvastatin 10mg, Rosuvastatin 20mg reduced LDL cholesterol significantly more than Atorvastatin 20mg and Rosuvastatin 40mg reduced LDL cholesterol significantly more than Atorvastatin 40mg. The best triglyceride reductions with Rosuvastatin were obtained at dose of 40mg.

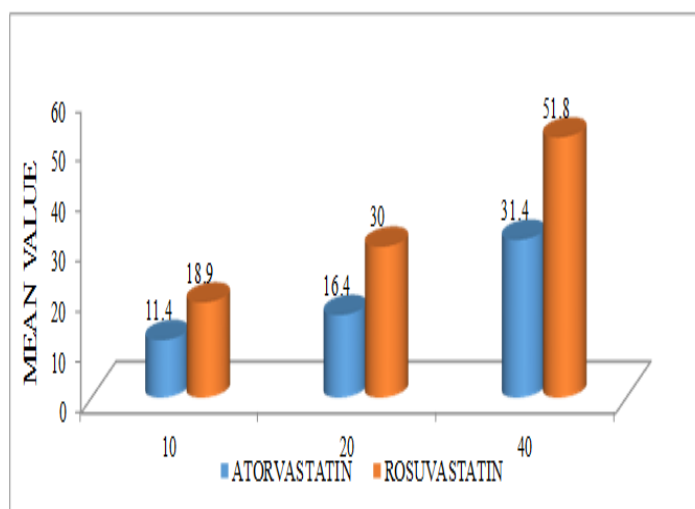


Fig.4 Comparison of lowering of TC between group based on dose (N=130)

Table: 4 Comparison of lowering of TC between group based on dose(N=130)

Dose	Atorvastatin			Rosuvastatin			t	P
	Mean	SD	N	Mean	SD	N		
10	11.4	4.4	21	18.9	4.3	18	5.38**	0.000
20	16.4	3.8	26	30.0	5.5	31	10.68**	0.000
40	31.4	7.3	19	51.8	12.0	15	6.14**	0.000

**:- Significant at 0.01 levels

Atorvastatin 20mg was comparable to Rosuvastatin 10mg.^[6] According to the dose-response analysis, mean differences between the total cholesterol dose responses of Rosuvastatin 10 to 40mg versus Atorvastatin 10 to 40 mg were significant. In the pairwise, dose-to-dose comparisons with Atorvastatin, Rosuvastatin 10mg reduced total cholesterol significantly more than Atorvastatin 10mg, Rosuvastatin 20mg reduced total cholesterol significantly more than Atorvastatin 20, and Rosuvastatin 40mg reduced LDL cholesterol significantly more than Atorvastatin 40mg. The best total cholesterol reductions with Rosuvastatin were obtained at dose of 40mg. The result of present study was in concordance to study Sameer maruthiadsuleet al.^[7] The result of present study was similar to the study done by Jong seon park et al.^[8]

CONCLUSION

Dyslipidemia is the most common co morbid condition associated with CAD.

The study was able to describe the comparative efficacy of Atorvastatin verses Rosuvastatin. This study shows that Rosuvastatin is more cost effective compared to Atorvastatin. For future research the study should be done in a large sample and for long duration of period as a multicentre study.

Comparative study of statins

The study also provides information regarding comparative efficacy of statins and Rosuvastatin was found to be more efficacious in lowering LDL level compared to Atorvastatin.

At recommended starting doses, Rosuvastatin (10 mg) was more efficacious than Atorvastatin (20mg) in terms of LDL-C lowering, LDL-C goal achievement and improving the atherogenic lipid profile.

Rosuvastatin was found to be more cost effective than Atorvastatin.

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REFERANCE

1. Dipro J T, Talbert R L, Yees G C, Matzke GR, Wella B G, Posey L M. Pharmacotherapy, A Pathophysiologic approach. 6th ed. MCGRAW-HILL: Medical Publishing Division, 219-250.
2. Harisson's Principle of internal medicine 18th edition Dan L Longo, Anthony S, Fauci, Dennis L Kasper 18th edition. Shargelleon, Mutnickalanetal. Comprehensive pharmacy review, 7th edition (India) Pvt. Ltd, 2003; 723-795
3. Walker R, Whittlesea C, Clinical pharmacy and Therapeutics., 5th ed. Churchill Livingstone publication, 312-333
4. Herfindal E, Gourley D, Hart L. Clinical pharmacy and therapeutics. Baltimore: Williams & Wilkins, 1992; 829-853
5. Jones. H.P. Davidson, H.M, Stein, A.E, Bays, E.H, Mc Kenney, M.J, Miller. Eetal. Comparison of the efficacy and safety of Rosuvastatin versus Atorvastatin, Simvastatin, and Pravastatin across doses (STELLAR TRIAL) Am J Cardiol, 152-160.
6. A.M Sameer, B S Mirsa, Gade PR et al., Int J Diabetes dev ctries, Apr to June, 2009; 29(2): 74-79
7. S. Jong, Park et al. Korean Journal Of Internal Medicine, Atorvastatin on lipid lowering and glycemic control in patients with with metabolic syndrome and hypercholesterolemia, 2010; 25.