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ORIGINAL RESEARCH

A STUDY ON SAFETY AND EFFICACY OF ROSUVASTATIN IN NEWLY DIAGNOSED DYSLIPIDEMIC PATIENTS IN A TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT

Background: The aim of the study is to asses Efficacy and safety of Rosuvastatin in altering lipid profile of patients newly diagnosed with dyslipidemia.

Methods: This study was conducted in the outpatient department of Cardiology and General medicine in a tertiary care teaching hospital in Tamil Nadu, India. The study was done during period of January 2023 to November 2023.Patients diagnosed with Dyslipidemia were included in the study. Baseline characteristics like age, gender and variables like duration of illness and duration of therapy for other comorbidities were noted.The serum lipid profile values were also included from before the start of the study 0 weeks. The serum lipid profile was assessed periodically 4, 8, 12 weeks.

Results: Over 90 patients who were visiting cardiology and general medicine out patient department who are diagnosed with dyslipidemia were included in the study. The study showed LDL lowered by 40% in patients taking Rosuvastatin. LDL/HDL ratio by 40.43% in rosuvastatin.

Conclusion: By the above study we conclude that there is significant amount of lowering in serum LDL and VLDL levels after start of treatment with atorvastatin found in patient on metformin therapy.

Keywords: ?

INTRODUCTION

HMG CO-A Reductase inhibitors – Statins are one of the main drugs used in the treatment of dyslipidemia[1,2]. Statins have the ability to lower serum LDL cholesterol levels significantly. Statins are helpful in significantly lowering LDL levels a risk factor in coronary artery disease[3]. An decrease in LDL level by 1% decreases the risk of coronary artery related events by1 to 1.5%[4]. Statins are used as a primary and secondary prevention of dyslipidemia[5]. Rosuvastatin 10mg is prescribed once daily usually in the evening hours. The majority of cholesterol production occurs at night, between 12:00 and 6:00 am, and is regulated by the circadian rhythm[6]. As cholesterol synthesis is high during the evening hours HMG Co-A reductase enzyme inhibitors are always prescribed at night[7].

There are only a handful of studies analyzing the efficacy and safety of rosuvastatin in Kanyakumari district Tamil Nadu hence we considered it as worthwhile to do a study on efficacy and safety of rosuvastatin in newly diagnosed dyslipidemic patients.

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MATERIALS & METHOD

The Prospective observational study was carried out in a tertiary care private teaching hospital, Kanyakumari district, India.

Inclusion Criteria

- Patients aged above 18 years of age.
- Patients newly diagnosed with Dyslipidemia.
- Patient with coronary artery disease whose plasma lipid levels are fluctuating frequently.
- Patients with other comorbidity diabetes mellitus and hypertension and has a risk of developing coronary artery disease.

Exclusion Criteria

- Patients age less than 18 years and patients age more than 70 years
- Pregnant woman.
- Patients with infectious disaeses like Tuberculosis and HIV/hepatitis B.
- Patients with history of carcinoma, kidney disease.

Sample size of 90 was calculated. Sampling method was convenience sampling patients whoever fulfilled the inclusion and exclusion criteria were enrolled in the study.

Blood samples were collected for analyses of serum lipid levels, The level of LDL-Cholesterol, VLDL-Cholesterol, HDL Cholesterol, HDL/LDL Ratio was assessed initially at 0 weeks before the start of the treatment.

Patients were reviewed at 4 weeks, 8 weeks, 12 weeks and the serum LDL-C, Triglycerides, HDL-C, HDL/LDL ratio were recorded during the respective review period and history of any adverse effects were noted.

Statistical Analysis

- The data collected were analyzed using SPSS software version 23 by IBM corp. USA.
- ANOVA test was done to determine statistically significant differences in the means between the lipid profile.

Chi-Square test was used to analyze categorical data. A ‘P’ value of <0.5 is significant.

RESULTS

The results suggest that out of 90 patients enrolled in the study who are newly diagnosed with dyslipidemia.

Out of the 90 newly diagnosed dyslipidemic patients male patients were 47 (52.22%) and female patients were 43 (47.77%) [Table 1].

[Table 1]
Baseline Characteristics

1.Mean age of participants	
Age	50±3.5 years
2.Gender	
Male	47
Female	43
3.Blood pressure	
Mean Systolic Blood pressure	133.6±10.6
Mean Diastolic Blood pressure	90.3±8.3

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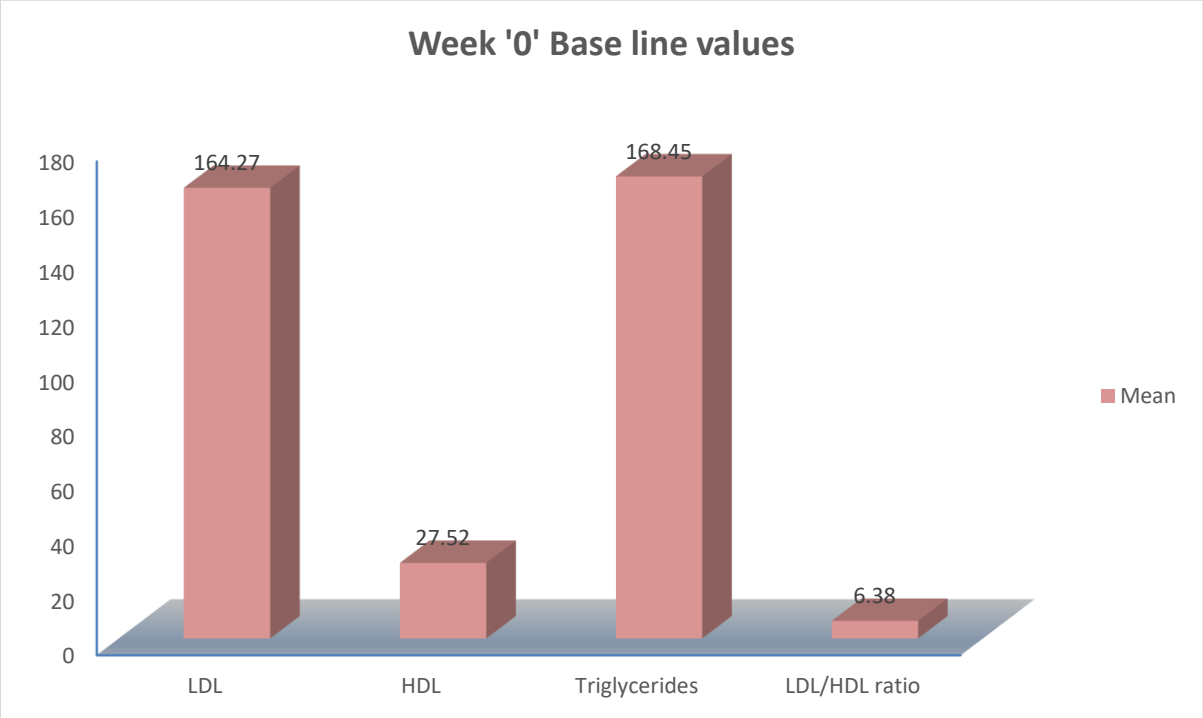
4.Known Case of Diabetes mellitus	
Yes	63
No	27
5.Known case of Hypertension	
Yes	53
No	37
6.Sedantary life style	
Yes	72
No	18

The mean blood pressure for systolic-133.6±10.6 and diastolic 90.3±8.3, out of 90 Patients 63 are known cases of diabetes mellitus, 53 patients were hypertensives, 72 patients had history of sedentary lifestyle.

The mean age of patients enrolled in the study was 50±3.5 years. The mean baseline value of LDL recorded at weeks '0' during diagnosis was 164.27 mg/dl. The mean HDL value was 27.52 mg/dl, The mean triglyceride value was 168 mg/dl. The mean LDL/HDL ratio was 6.38 [Table 2].

TABLE 2				
Week '0' Base line values				
	LDL	HDL	Triglycerides	LDL/HDL ratio
Mean	164.27	27.52	168.45	6.38
Minimum	135	14	132	3.13
Maximum	196	52	210	10.5



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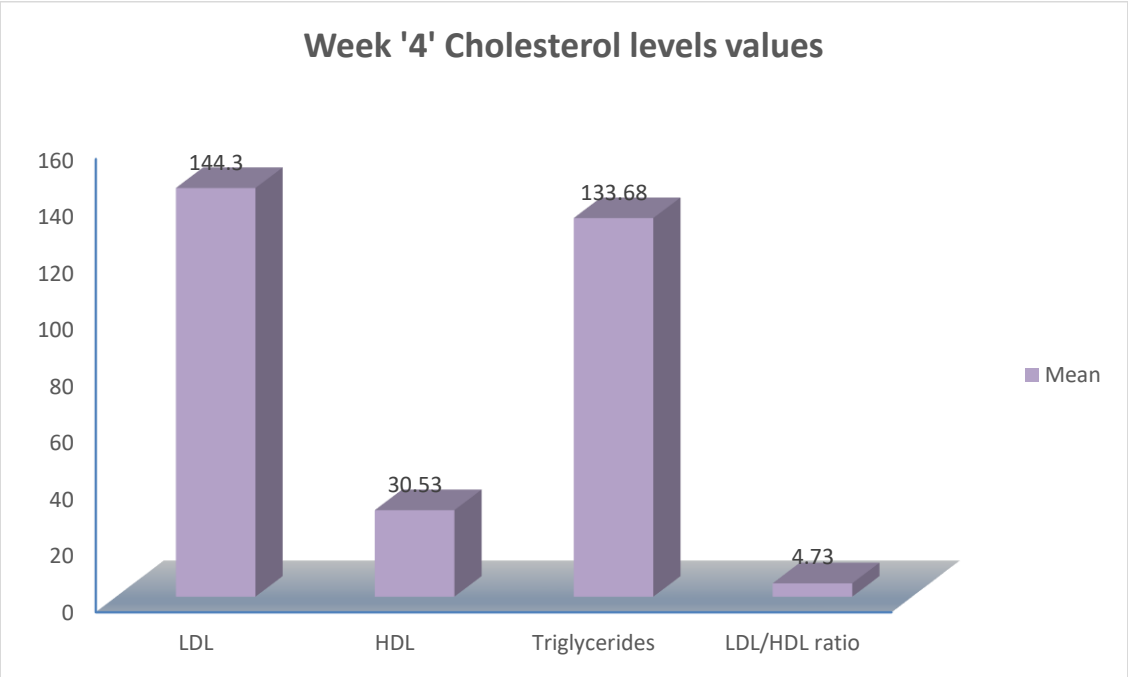
After the initiation of treatment with rosuvastatin 10 mg O.D The follow up blood investigation for LDL, HDL, Triglycerides, LDL/HDL ratio were done at 4 , 8, 12 weeks.
The value of LDL at week 4 was found to be 12.15% less than the baseline value and the value of HDL was found to elevated by 13.07% from the baseline value. The triglyceride levels reduced by 20.64% from the baseline value. The LDL/HDL ratio also reduced by 25.86% from the base line value[Table 3]

TABLE 3				
Week '4' Cholesterol levels values				
	LDL	HDL	Triglycerides	LDL/HDL ratio
Mean	144.3	30.53	133.68	4.73
Minimum	120	16	110	2.52
Maximum	176	54	185	8.5



At Week 8 on follow up the LDL value was reduced by 14.59% from the baseline value and the HDL levels increased by 21.8% from the baseline value, Triglycerides level reduced by 30.84% The LDL/HDL ratio reduced by 34.48% [Table 4].

TABLE 4				
Week '8' Cholesterol levels values				
	LDL	HDL	Triglycerides	LDL/HDL ratio
Mean	140.3	33.54	116.5	4.18
Minimum	106	18	104	3.1
Maximum	143	53	145	6.6

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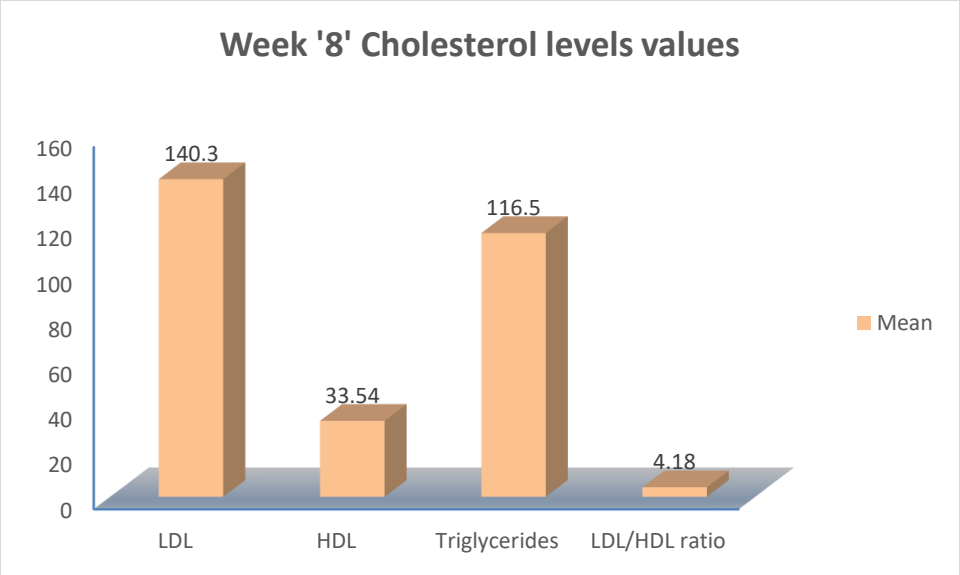
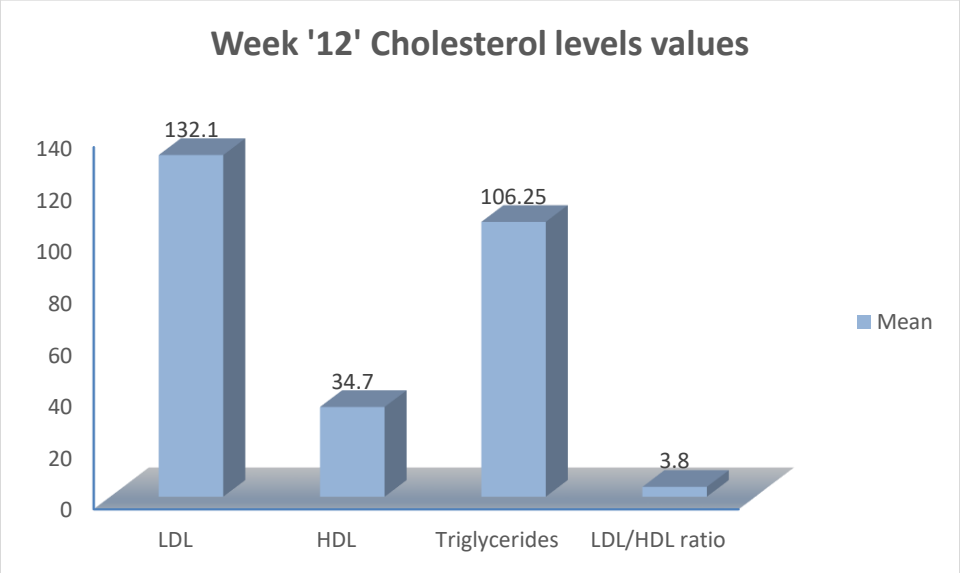


At Week 12 on follow up the LDL value was found to be reduced by 32.17% from the baseline values and serum HDL values are found to be elevated by 26.09%, Triglyceride values were found to be decreased by 62.2% and serum LDL/HDL ratio was found to be reduced by 40.43% [Table 5].

TABLE 5				
Week '12' Cholesterol levels values				
	LDL	HDL	Triglycerides	LDL/HDL ratio
Mean	132.1	34.7	106.25	3.8
Minimum	90	23	88	1.2
Maximum	133	58	126	4.3



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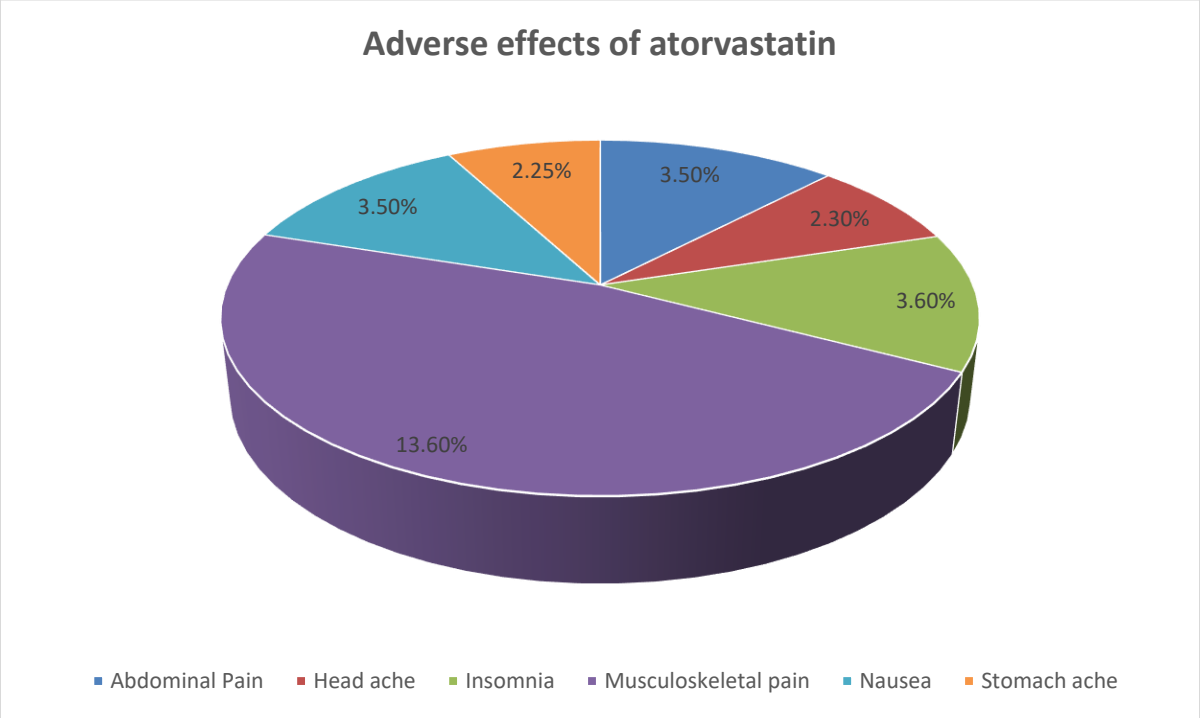
The difference in mean of the Serum LDL, HDL, Triglycerides, LDL/HDL ratio at 0, 4, 8, 12 weeks were found to be statistically significant (P<0.005)

Adverse effects

Based on the interviewing the patients for adverse effects were documented adverse effects were produced in 28.75% of the patients. The individual percentage of adverse effects were listed in the table [Table 6].

Adverse effects of atorvastatin	
Symptoms/Adverse effects	**Percentage of adverse effects**
Abdominal Pain	3.50%
Head ache	2.30%
Insomnia	3.60%
Musculoskeletal pain	13.60%
Nausea	3.50%
Stomach ache	2.25%



DISCUSSION

In our study the target LDL was achieved in 80% of the patients .This finding is similar to Schuster H et al [8] drugs other than rosuvastatin in the treatment of dyslipidemia. In our study, rosuvastatin reduced the level of triglycerides significantly by 36.92% from the baseline value from the first week and increase in HDL-C by 26.09% after 12 weeks of treatment. The level of LDL was reduced by 40% and the LDL/HDL ratio was 40.43%.In one study done by Olsson AG, Pears J, Mckellar J, Mizan J, Raza A., the reported mean percent change was -50.5%, -57.0%, and -62.6% for the 10-, 20-, and 40- mg dose groups from baseline to week 6 [12].

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The most common adverse effects in the study was found to be musculoskeletal pain which is contrary to a study done by Laffin et al [13] .By this study we conclude that rosuvastatin was found to be effective in achieving target control LDL levels within 12 weeks.

CONCLUSION

As per our study the low dose rosuvastatin prescribed by the physician in cases of newly diagnosed dyslipidemia found to lower the serum LDL, Triglyceride levels .The HDL-C levels were found to be elevated significantly and LDL:HDL ratio found to be lowered from the baseline value and are statistically significant.

Conflict Of Interest

There is no conflict of interest in this study.

Financial support and sponsor: Nil.

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