

## Comparative Effect of Atorvastatin and Rosuvastatin in cardiovascular Diseased patients

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### Abstract

**Aim:** The purpose of the study is to compare the effectiveness of Atorvastatin and Rosuvastatin in cardiovascular disease patients.

#### Objectives:

- Comparison of Atorvastatin and Rosuvastatin in cardiovascular patients.
- Assessing and managing the cardiovascular disease.
- Monitoring the adverse effects, drug interactions, food interactions in cardiovascular disease patients.
- Assessing the complications and consequences reported by the patients.
- Counselling the cardiovascular patients about their disease and management.
- Compare the efficacy of equivalent doses of Rosuvastatin and Atorvastatin in lowering LDL -C levels.
- Compare the cost effectiveness of Rosuvastatin and Atorvastatin therapy.

**Methodology:** A prospective observational study was carried out at Departments of in and outpatients at Sai Srinivasa Hospital and Fathima Institute of Medical Sciences, for a period of 6 months (September 2018 to February 2019). All the patients who are diagnosed with cardiac problems were included in this study. Patients between ages of 30 - 70 yrs were considered. Patients with Pregnant, lactating, childrens, Diabetes Mellitus, Thyroid & Other than cardiovascular disease patients were excluded in the study.

**Results:** During the study 80 cases were recorded from SEP 2018 to FEB 2019 Among 80 patients, the incidence of CVD with hyperlipidemia was more at the age of 51-60 years in males. In the Atorvastatin group a decrease of 5.5% in LDL.C levels from that of base line mean LDL-C level was seen. In the Rosuvastatin group a decrease of 14.55% in LDL.C levels from that of base line mean LDL-C levels was seen, the difference in reduction being 9.0%.

In the Atorvastatin group there was 1.71% increase of HDL-C levels from that of mean base line HDL-C levels was seen. In the Rosuvastatin group the increase of HDL-C levels was only 0.4% from that of mean base line HDL-C levels. The difference in increase was more in Atorvastatin group, the difference being 1.31%.

There was significant decrease in LDL -C level ( $P < 0.001$ ) in Rosuvastatin group. So, this study shows that Rosuvastatin 10 mg/day is more effective than Atorvastatin 10 mg/day in lowering LDL-C levels in patients with Hypercholesterolemia.

**Conclusion:** Dyslipidemia is the most common co-morbid condition associated with cardiovascular disease.

The study was able to describe the comparative effect of Atorvastatin verses Rosuvastatin. Atorvastatin and Rosuvastatin have potent lipid lowering effect, but the spectrum of adverse effects is different in both the drugs. Hence Rosuvastatin is better to lower the LDL cholesterol than Atorvastatin. Atorvastatin is better to increase HDL cholesterol than Rosuvastatin, but both the drugs have their own limitations. So, by comparing the effect of both drugs, Rosuvastatin was recommended for patients having Hepato-toxicity disorders. Atorvastatin was recommended for patients who had complaints of myopathy.

This study shows that Rosuvastatin is more cost effective compared to Atorvastatin.

**Keywords:** Hyperlipidemia; CVD; Lipid Profile

## Introduction

### Cardiovascular diseases

#### Deinition

Cardiovascular diseases (CVDs) are a group of disorders of the heart and blood vessels [1]. It usually associated with a build-up of fatty deposits inside the arteries (atherosclerosis) and increased risk of blood clots.

#### Epidimology

According to world health organization statistics, cardiovascular disease (CVD) is the most common cause of mortality worldwide [2]. The morbidity and mortality in both developed and developing countries account for around 17 million deaths worldwide and 1.5 million deaths in India [3].

Low- density lipoprotein cholesterol (LDL-C) is one of the most studied risk factors for cardiovascular diseases [5].

#### Types of cardiovascular diseases

- Coronary heart disease,
- Ischemic heart disease,
- Myocardial infarction,
- Arrhythmia,
- Cardiomyopathy,
- Angina pectoris.
- Heart disease might be treated with medication or surgery.
- Quitting smoking and exercising regularly can help prevent heart disease.

There are many types of heart disease that affect different parts of the organ and occur in different ways.

#### Arrhythmia

Arrhythmia is defined as loss of cardiac rhythm, especially irregularity of heartbeat [4]. The normal cardiac cycle gives rise to normal sinus rhythm, which has rate of between 60 and 100 bpm [6]

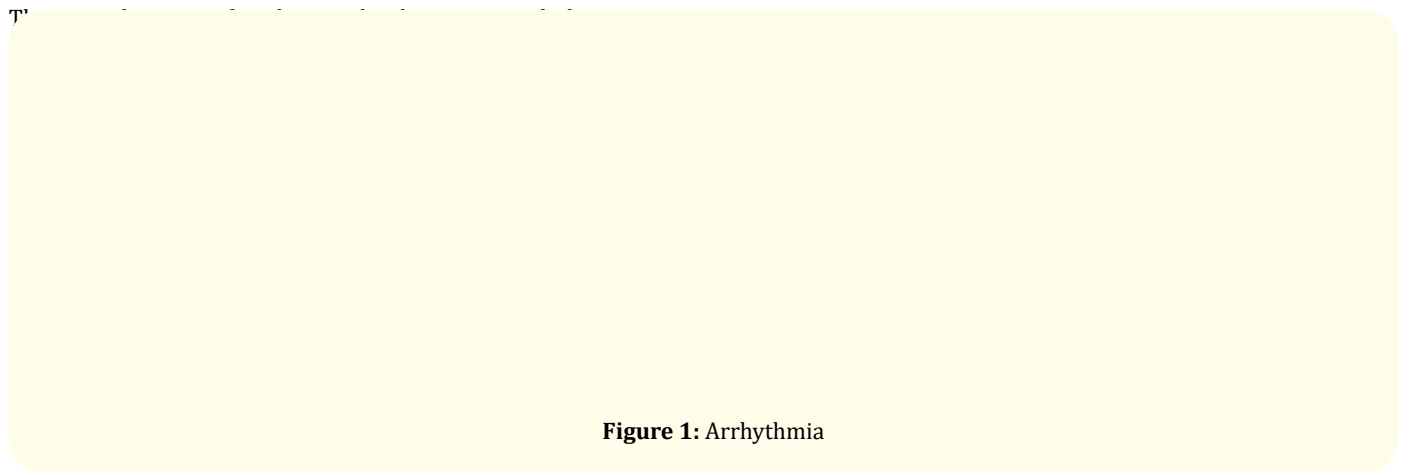


Figure 1: Arrhythmia

#### Arrhythmia include

##### Trachycardia

Rapid heartbeat, Greater than 120 beats/min [7].

This is normal sinus rhythm above 120 bpm when the individual at rest. This accompanies exercise and anxiety, but it is an indicator of some disorders.

Eg: fever, hyperthyroidism, some cardiac conditions [6].

##### Bradycardia

Slow heart rate, below 50 beats/min [8].

This is normal sinus rhythm below 50 bpm. This may occur during sleep and is common in athletes. It is an abnormality when it follows Myocardial Infarction (or) accompanies raised intracranial pressure [6].

### Coronary artery disease

CAD is defined as acute or chronic form of cardiac disability arising from imbalance between the myocardial supply and demand for oxygenated blood [9].

### Cardiomyopathy

Cardiomyopathy means disease of the heart muscle. In cardiomyopathy, the heart muscle becomes enlarged or abnormally thick or rigid.

### Myocardial infarction

It is defined as localized destruction of myocardial cells caused by interruption of the blood supply [17].

### Heart failure

It is a clinical syndrome caused by inability of the heart to pump sufficient blood to meet the metabolic needs of the body [21].

The left or right side of the heart might be affected. Rarely, both sides are effected.

### Pulmonary stenosis

It refers to a dynamic or fixed anatomic obstruction to flow from the right ventricle to the pulmonary arterial vasculature. Older children will generally have no symptoms.

### Angina pectoris [36]

Angina pectoris is a chest pain (or) discomfort that occurs when the heart muscle that does not get enough blood [36].

### Hyperlipidemia

Hyperlipidemia is defined as elevations of fasting total cholesterol concentration which may or may not be associated with elevated Triglyceride. lipids are not soluble in plasma but are instead transported in particles known as lipoproteins [24].

### Research methodology

#### Study design

A prospective observational study.

#### Study duration

06 months (September 2018 to February 2019).

#### Study site

The study entitled “Comparative effect of atorvastatin and rosuvastatin in cardiovascular diseased patients” was carried out in

a 500 bedded tertiary care teaching hospital located at Kadapa. The hospital is unique and well known for its services to people who came from various parts of the district. The Institutions Excels In Diverse Specialities Like General Medicine, General Surgery, Obstetrics, Gynecology, Pediatrics, And Neonatology, Orthopedics, Care And Supportive Center. The hospital has well staffed pharmacy.

### Department selected for the study in the hospital

The department selected for the study was departments of General medicine and Cardiology. The reason for selection of these departments was the comparison of Atorvastatin and rosuvastatin for reducing the lipid profile. A good co-operation from medical team added up to the reason for selecting the department for conducting the study.

### Data entry form

A separate data entry form for incorporating inpatient details were designed and the format contains provision to enter the details such as name, age, sex, height, weight, IP. No, date of admission, date of discharge, vital signs, reason for admission, past medical history, past medication history.

### Data analysis

The obtained data will be thoroughly to evaluate the comparative effect of atorvastatin and Rosuvastatin in cardiovascular disease patients to lowering the Lipid- cholesterol levels.

### Statistical analysis

Paired T test is based on the differences between the values of each pair, that is one subtracted from the other. In the formula for a paired t-test, this difference is notated as d. Formula of the paired t test is the ratio of the sum of the differences of each pair to the square root of n times the sum of the differences squared minus the sum of the squared differences, all over n - 1.

The formula for a paired t-test.

$$t = \frac{\sum D}{\sqrt{\frac{N \sum D^2 - (\sum D)^2}{N-1}}}$$

where,  $\sum d \sum d$  = Sum of the differences.

- Test was performed to calculate p value for the purpose of comparison of result by using software namely “Graph pad prism software (version 08)”.

**Results**

Both regimens were well tolerated but Rosuvastatin was more effective than atorvastatin in controlling lipid profile.

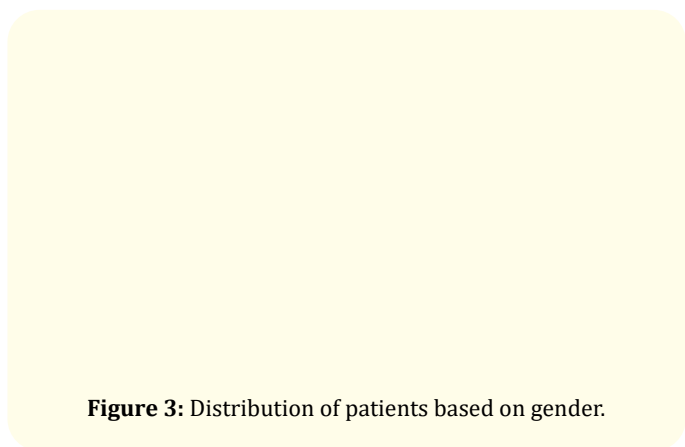
Among 80 patients, the incidence of CHD with hyperlipidemia was more in males as shown in table 2

**Demographic data based on age**

Parameters	Atorvastatin	Rosuvastatin
Age (%)		
30 - 40	0	0
41 - 50	13	18
51 - 60	17	20
61 - 70	10	02
Total	40	40

**Table 1:** Demographic data based on age.

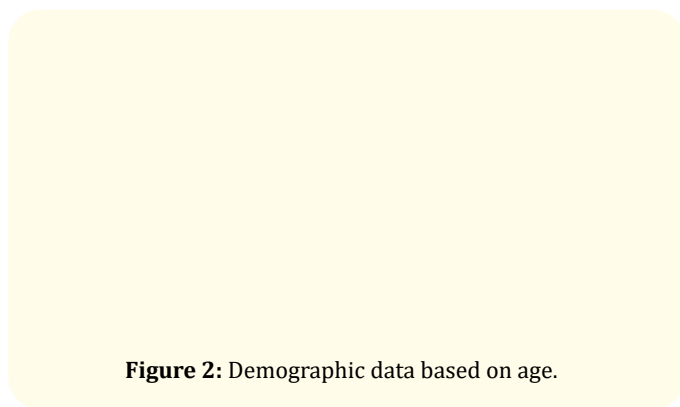
Among 80 patients, the incidence of CVD with hyperlipidemia was more at the age of 51-60 years as shown in table 1.



**Figure 3:** Distribution of patients based on gender.

Parameters	Atorvastatin (%)	Rosuvastatin (%)
Obesity	52	53.5
Hypertension	45	46.5
Smoking	28	30

**Table 3:** Percentage of patients with associated risk factors.

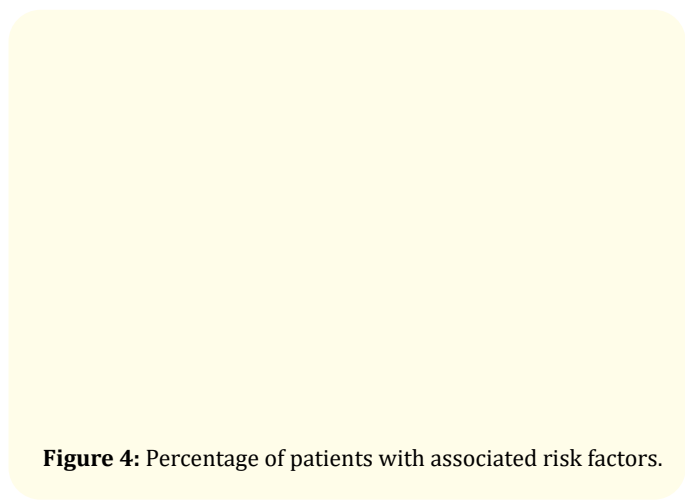


**Figure 2:** Demographic data based on age.

**Distribution of patients based on gender**

Parameters	Atorvastatin	Rosuvastatin
Sex (%)	80	87.5
Male		
Female	20	12.5
TOTAL	100	100

**Table 2:** Distribution of patients based on gender.



**Figure 4:** Percentage of patients with associated risk factors.

Among 80 patients, In Atorvastatin 52% of patients are associated with Obesity, 45% were Hypertension and 28% were smoking. In Rosuvastatin 53.5% were Obesity, 46.5% were Hypertension and 30% were smoking.

	Base line (mg/dl)	Atorvastatin (mg/dl)	% (mg/dl)	Base line (mg/dl)	Rosuvastatin (mg/dl)	% (mg/dl)
LDL-C	130.975	123.775	5.49723	131.2	112.1	14.5579
HDL-C	38.625	39.3	1.7176	40.3	40.3	0.4324

**Table 4:** Mean lipid levels in each group at the end of six months.

**Figure 5**

In the Atorvastatin group a decrease of 5.5% in LDL-C levels from that of base line mean LDL-C level was seen. In the Rosuvastatin group a decrease of 14.55% in LDL-C levels from that of base line mean LDL-C levels was seen, the difference in reduction being 9.0%.

In the Aorvastatin group there was 1.71% increase of HDL-C levels from that of mean base line HDL-C levels was seen. In the Rosuvastatin group the increase of HDL-C levels was only 0.4% from that of mean base line HDL-C levels. The difference in increase was more in Atorvastatin group, the difference being 1.31%.

There was significant decrease in LDL -C level ( $P < 0.001$ ) in Rosuvastatin group. So, this study shows that Rosuvastatin 10 mg/day is more effective than Atorvastatin 10 mg/day in lowering LDL-C levels in patients with Hypercholesterolemia.

In the above table 5 it shows that Rosuvastatin shows the more adverse effect of myalgia than that of Atorvastatin in various cardiovascular diseases. In Atorvastatin it shows that Hepatic disorder is most adverse effect compared with Rosuvastatin.

Adverse effects	Rosuvastatin			Atorvastatin		
	CAD	MI	CM	CAD	MI	CM
Myalgia	High	High	High	Low	Low	Low
Diarrhoea	High	Low	Low	Low	High	High
Nausea	Low	Low	Low	High	High	High
Hepatic disorder	Low	Low	Low	High	High	High

**Table 5:** Adverse effects of rosuvastatin v/s atorvastatin.

**Discussion**

Our findings show that rosuvastatin was consistently more effective than atorvastatin across their respective dose ranges in reducing LDL cholesterol and improving other lipid measures in patients.

The lipid lowering effects of equivalent doses of Atorvastatin 10 mg/day and Rosuvastatin 10 mg/day were compared in the present study. It was observed that Atorvastatin reduced LDL-C levels by 5.5% ( $P < 0.01$ ).

In the present study, the results represent the % of difference from that of LDL-C levels with the base line levels of the study group itself. The baseline mean lipid levels are LDL-C  $< 131$ mg/dl and HDL-C  $> 40$  mg/dl.

Atorvastatin 10 mg/day was found to be decrease LDL-C levels by 5.5%. HDL-C levels were found to be increased by 1.71% in the present study.

Rosuvastatin 10 mg/day was found to be decrease LDL-C levels by 14.55%. HDL-C levels were found to be increased by only 0.43% in the present study.

Rosuvastatin doses of  $\geq 10$  mg produce and substantial decreases in LDL cholesterol (i.o.  $\geq 35\%$ ).

Rosuvastatin reduced LDL cholesterol more than atorvastatin did at milligram equivalent doses of 10 and 20mg. Although statistical comparisons were not performed, greater proportions of patients were observed to reach currently recommended LDL cholesterol goals with rosuvastatin than with atorvastatin.

LDL cholesterol reduction and goal attainment with the 10mg dose of rosuvastatin were similar to those with 20mg dose of atorvastatin, but the HDL cholesterol levels increased significantly more with the 10mg dose of rosuvastatin than with the 20mg of atorvastatin.

These atorvastatin underscore the importance in clinical practice of ensuring that patients use statin therapy consistently to attain the full therapeutic benefits.

This multi-center trial, which is the largest trial of its kind to date comparing the lipid modifying of statins, showed the greater efficacy of rosuvastatin in reducing LDL cholesterol, compared with atorvastatin. The significantly greater LDL cholesterol reduction achieved with.

Rosuvastatin 10 to 80mg, compared with atorvastatin 10 to 80mg, which was an average difference of 8.2% across the dose range slopes.

Also the greater LDL cholesterol reduction achieved across dose ranges with rosuvastatin than with simvastatin and flavastatin confirmed the relative differences in the LDL cholesterol reducing efficacy of these statins, Which has been previously. As rosuvastatin dose increased to 40mg, HDL cholestrol changes from base line were increased.

### Conclusion

Dyslipidemia is the most common co- morbid condition associated with cardiovascular disease.

The study was able to describe the comparative effect of Atorvastatin verses Rosuvastatin. Atorvastatin and Rosuvastatin have potent lipid lowering effect, but the spectrum of adverse effects is different in both the drugs. Hence Rosuvastatin is better to lower the LDL cholesterol than Atorvastatin. Atorvastain is better to increase HDL cholesterol than Rosuvastain, but both the drugs have their own limitations. So, by comparing the effect of both drugs, Rosuvastatin was recommended for patients having Hepato-toxicity disorders. Atorvastatin was recomended for patients who had complaints of myopathy.

This study shows that Rosuvastatin is more cost effective compared to Atorvastatin.

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