

Research Article



A Comparative Study of Effectiveness of Two Intensive Statin Regimen in the Treatment of Coronary Artery Disease in a Tertiary Care Hospital

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ABSTRACT

The study's goal is to compare and evaluate Rosuvastatin and Atorvastatin's efficacy and the numerous variables that affect the progression of coronary artery disease. Statin prescription recommendations for people with coronary artery disease (CAD) and their safety and effectiveness in people with high cholesterol levels are included. For the 100 patients who received statins for coronary artery disease, we calculated the results using SPSS Software, which includes the Mean technique, standard deviation method, t-test, and chi-square test. The percentage of men in group I was 87 per cent, while the percentage in group II was 80%. Groups I and II, on the other hand, had female populations of 13 and 20%, respectively. The baseline comparison of lipid profiles showed a significant difference between the two groups. The baseline values of total cholesterol were compared, and a significant difference was found statistically in patients treated with Rosuvastatin at a p-value <0.0001. Likewise, baseline values of HDL-CH were compared, and a significant difference was found statistically in patients treated with Rosuvastatin at P value <0.0001 in group I and 0.0003 in group II. The baseline values of LDL-CH were compared, and a significant difference was found statistically in patients treated with Rosuvastatin at P value 0.0271 in group I and 0.0101 in group II. The baseline values of Triglycerides were compared, and a significant difference was found statistically in patients treated with Rosuvastatin at P value 0.0104 in group I and 0.0184 in group II. Results illustrate that Rosuvastatin is safer and more effective in lowering LDL-CH levels than Atorvastatin. Management and lowering serum cholesterol levels is the main objective in attempting to prevent or treat atherosclerotic cardiovascular events. We considered Percentage changes in lipid parameters and rates of LDL-CH goal attainment in patients with coronary artery diseases. Rosuvastatin was found to be more effective than Atorvastatin at a confidence interval of 95%. Hence P-value <0.05 is considered significant.

Keywords: Coronary artery disease, Cardiac Rehabilitation, Revascularization, Hyperlipidemia.

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INTRODUCTION

Aim

The study's goal is to compare and evaluate Rosuvastatin and Atorvastatin's efficacy, as well as the numerous variables that affect the progression of coronary artery disease. Statin prescription recommendations for people with coronary artery disease (CAD), as well as their safety and effectiveness in people with high cholesterol levels, are included.

Coronary artery disease

The most common cardiovascular disease in the world is coronary artery disease (CAD). Developed and underdeveloped trying to compare have found this illness to be the primary cause of mortality. Heart disease can be caused by a variety of reasons, including lifestyle, environmental exposure, and heredity. Diabetes, hypertension, smoking, hyperlipidemia, obesity,

homocystinuria, and psychological stress are all potential causes of coronary artery disease (CAD).

Atherosclerosis is the most common cause of coronary artery disease (CAD), weakening or blockage of coronary arteries. If you have a myocardial infarction, your blood supply to your heart's muscles is suddenly cut off, and as a result, your heart begins to deteriorate rapidly. The most common cause of this life-threatening incident is a blood clot blocking a coronary artery, which is known as coronary artery disease or cad in the case of the coronary artery.

A blood clot is a mixture of activated platelets and fibrin strands that help maintain the clot while activated platelets assemble to close the rupture site. One of the most essential components of this chain reaction is factor Xa and prothrombin. Factor Xa cleaves prothrombin into thrombin when it comes into contact with it. One molecule of element Xa can catalyze the activation of a thousand molecules of thrombin, which split fibrinogen into fibrin and combine into strands. Thrombin stimulates platelet activation via attaching to the platelet's PAR receptors, which in turn increases platelet aggregation. In addition to occurring in the blood flow, this activation also occurs primarily on the plaque surface. A specific treatment target for preventing arterial clot formation is thrombin because of its effects on platelets and fibrin. For individuals with cad, reducing thrombin production is a promising strategy



that is now being investigated to avoid stroke, myocardial infarction, or cardiovascular death.

Symptoms

Some symptoms may only arise when the heart is working hard, like it would be during strenuous exercise. As the coronary arteries narrow, less blood reaches the heart, causing symptoms to intensify or return more frequently.

Cardiovascular illness can cause a variety of symptoms and signs:

Chest pain (angina)

Fatigue

Heart Attack

Breathlessness

Dizziness/light-headedness

Risk factors

Some of the identified risk factors of CAD in the world are:

- High blood pressure is a common health problem.
- Improved economic conditions and rapid acculturation.
- A increase in the use of tobacco.
- Blood lipids are too high.
- Physical inactivity, slowness, and weight gain.
- Diabetic complications and a lack of nutrition

Management of Coronary Artery Disease

Lifestyle and pharmacological management

CAD treatment is aimed at reducing symptoms and improving prognosis. Patients with coronary artery disease (CAD) can benefit from lifestyle changes, risk factor reductions, and pharmacological treatment options based on current scientific evidence, as well as patient education. Recommendations for a lifestyle include quitting smoking, eating healthfully, exercising regularly, managing weight and lipids, and controlling blood pressure and blood sugar. A 36% decrease in mortality after MI is linked to quitting smoking.

A healthy diet lowers the risk of CVD with a goal BMI of less than 25 kg/m², as shown in the table below.

Cardiovascular disease (CVD) mortality and morbidity can be reduced by regular exercise in persons with established CAD.

Three times a week, patients with angina pectoris or chronic stable heart failure should engage in 30 minutes of moderate-to-vigorous exercise.

Both symptom relief and the prevention of cardiovascular events are the primary goals of pharmacological therapy for people with stable coronary artery disease (CAD).

Revascularization

Patients with SCAD with acceptable coronary architecture can now be handled with PCI, thanks to the new procedures, equipment, stents, and adjuvant therapies. A patient's prognosis and symptoms, as well as the severity of their obstructive coronary artery stenosis and the extent of their ischaemia, should all be considered when deciding whether or not to undertake revascularization surgical procedure

Cardiac Rehabilitation

The treatment of coronary artery disease (CAD) requires a multidisciplinary approach that includes a reduction in risk as well as cardiac rehabilitation. Cardiovascular rehabilitation should be offered to patients with coronary artery disease, including those with recurrent angina. Reducing mortality, cardiovascular disease (CVD), and hospitalization are all reduced with cardiac rehabilitation exercises. As a result, the research shows that health-related quality of life can be improved (QoL). Cardiac rehabilitation in a cardiac Centre, which is not inferior, can be used in the selected subgroup. Cardiovascular rehabilitation participation is relatively low, particularly among women, the elderly and those with lower socioeconomic status, and systematic referral might assist.

Angioplasties and other non-surgical procedures may also be necessary, such as stent implantation, CABG, or off-pump arteria bypass operations.

Statins

Definition

Statins inhibit 3-hydroxy-methylglutaryl coenzyme A (HMG-CoA) reductase, which is responsible for the reduction in the serum low-density lipoprotein (LDL)-cholesterol level. Since the introduction of statin in 1987, many clinical studies have reported that statin therapy reduces major cardiovascular events by reducing the LDL-cholesterol level, which led to a revolution in the management of cardiovascular disease². Statins are drugs used to lower cholesterol. Your body needs some cholesterol to work properly. But if you have too much in your blood, it can stick to the walls of your arteries and narrow or even block them.

If diet and exercise don't reduce your cholesterol levels, you may need to take cholesterol medicine. Often, this medicine is a statin. Statins interfere with the production of cholesterol in your liver. They lower LDL (bad) cholesterol levels and raise HDL (good) cholesterol levels. This can slow the formation of plaques in your arteries.

Statins are relatively safe for most people, but they are not recommended for pregnant patients or those with active or chronic liver disease. They can also cause serious muscle problems. Some statins also interact adversely with other drugs. You may have fewer side effects with one statin drug than another³.



Mechanism of Action

Statins work by competitively blocking the active site of the first and key rate-limiting enzyme in the mevalonate pathway, HMG-CoA reductase. Inhibition of this site prevents substrate access, thereby blocking the conversion of HMG-CoA to mevalonic acid⁴.

Types of Statin drugs

1. Atorvastatin.
2. Fluvastatin.
3. Lovastatin (Mevacor® or Altoprev™).
4. Pitavastatin (Livalo® or Zypitamag®).
5. Pravastatin.
6. Rosuvastatin (Crestor® or Ezallor Sprinkle®).
7. Simvastatin (Flolipid® or Zocor®).

Sometimes, statins are put along with another med: Simvastatin and Atorvastatin with ezetimibe.

Drug Information

Atorvastatin

At a daily dosage of 80mg, it has the highest LDL-CH reducing efficacy and can be stiffer. Triglycerides are reduced more effectively at this dosage if they were elevated at the start of treatment. In contrast to the other statins, atorvastatin has a plasma $\frac{1}{2}$ of 18-24 hours, which is significantly longer than that of other statins.

Dose: 10 – 40 mg/day (max 80mg/day)

ATORVA, AZTOR, ATORLIP 5, 10, 20 mg tablets.

Rosuvastatin

This is a strong newer statin with a plasma half-life of 18-24 hours that is rarely prescribed. Severe hypercholesterolemia results in greater LDL-Cholesterol decrease, in part because of the longer plasma persistence of the drug. Rosuvastatin raises HDL-CH by 15% to 20% higher than other statins in patients with increased Triglyceride levels.

Dose: Start with an amount of 5 mg OD; increase up to 20mg/day if needed (40mg/day)

ROSUVAS, ROSYN 5, 10, and 20 mg tablets.

Differences between statins

For patients with nephropathy, statins vary in their ability to lower total and triglycerides, LDL cholesterol, and HDL cholesterol, as well as their risk of drug interactions and reported safety.

Cholesterol levels are reduced by a certain percent with Simvastatin and Atorvastatin. Both Atorvastatin and Fluvastatin are recommended for renal patients. Fluvastatin and Atorvastatin are the most cost-effective statins.

There is an increased risk of adverse effects from Atorvastatin, lovastatin, and simvastatin with grapefruit juice. Fruit crushes should be avoided by those on statins⁵.

Uses of Statins

- In terms of lowering LDL cholesterol, statins are the most easy option (this is usually stated as "bad" cholesterol).
- Reduce the risk of heart attack, stroke, or angina. Improve cardiovascular health in persons with type 2 diabetes or arteria coronaria by lowering their risk of subsequent cardiovascular disease.
- When it available to treat primary hyperlipidaemias with elevated LDL cholesterol, statins are the first-choice medicine.
- Since each statin has a well-documented dose-response relationship, the initial dose of the chosen statin should raise the LDL-Ch level to the goal. Adjustment should be made every three to four weeks based on cholesterol readings.
- Rosuvastatin has recently been shown to reduce the risk of venous thromboembolism.
- In diabetics, they are the first-choice medication for the treatment of dyslipidaemia. As long as there are no bad side effects, statin medication is continued.

Adverse effects of statins

A great proportion of people who take statin medicines tolerate them, but for a small number of people, they are unbearable.

Fewer side effects with the statins are:

- Nausea
- Hair loss
- Skin prickling, numbness, or tingling.
- Liver inflammation
- Stomach discomfort might be caused by inflammation of the pancreas.
- Skin problems like rashes or acne
- Sexual dysfunctions
- Indigestion, diarrhoea, and other symptoms of a dysfunctional digestive system.
- Muscle pain, tenderness, weakness(myalgia)
- Low blood platelet count.

Statins also carry warnings that memory loss, mental confusion, neuropathy, high blood sugar, and type 2 diabetes are possible side effects. It's important to remember that statins may also interact with other medications you take.



MATERIALS AND METHODS**METHODOLOGY****Site of study**

Aster Prime Hospital, Ameerpet, Hyderabad, Telangana, India, is where the study is actually occurring.

Ethics Approval

The study was carried out with the approval of the institutional ethical committee with an ethics approval number APH/IEC/2021/23.

Study design

Rosuvastatin and Atorvastatin were studied and compared in a prospective comparative trial for the treatment of coronary artery diseases.

Study duration

In the Cardiology Department, a six-month trial is taking place.

Sample size

A total of 100 individuals with hyperlipidemia and cardiovascular disease participated in this study.

Study procedure

We collected the following data:

- Patient's Demographic details like age, gender,
- The most common grievances are: Past Medical History, Current Illness History, and Medications Taken Prior
- The patient's diagnosis, co-morbid disorders, and investigations are carried out to arrive at a final diagnosis and care plan.
- Medications currently to be used (prescribed meds, frequency and length of use, brand/generic)
- A record of the patient's medical history, treatment plans, and lab test.

Sources of data

Information gathered from a patient data collecting form, medication history form, treatment plan, and lab results.

Selection criteria**a) Inclusion Criteria:**

- The evaluation of patients of both sexes for the presence of coronary artery disease
- Patients of both genders receive statin therapy.
- The trial was accessible to people with a family history of coronary artery disease.

b) Exclusion Criteria:

- Pediatrics
- Females who are lactating and pregnant were excluded from the study.

Method of study

Comparative study at the cardiology department of Aster Prime Hospital, Hyderabad, was conducted for six months. There were to be at least 100 cases of coronary artery disease as well as co-morbidities. To gather demographic information about patients, a suitable data collecting form was created. Statin therapy (a medicine prescribed, brand/generic, dose/route/frequency/duration) and laboratory monitoring measures were also part of the data set we collected on age, gender, and diagnosis. Version 20 of the statistical analysis program SPSS was used in the study.

RESULTS

Sample Size = Group I (Rosuvastatin)- 15; Group II (Atorvastatin) – 15

- Test Performed: T-test, Chi-square test
- Software used: SPSS version 20
- Confidence interval is 95%, hence P-value <0.05 is considered significant

Table 1: Comparison of Lipid Profile at Baseline

Parameter	Group I	Group II	P value
Total cholesterol	163.4±9.15	163.1±10.17	0.9794
LDL	100.5±9.59	95.93±7.52	0.7108
HDL	33.64±2.25	38.43±2.41	0.1594
Triglycerides	196±35.17	173.6±32.08	0.6425

Differences between the two groups were found to be statistically significant.

Table 2: Comparison of Total Cholesterol before and after treatment

Group	Review	Minimum	Maximum	Mean ± SEM	P value
I	BT	92	220	163.4 ± 9.15	<0.0001
	AT	90	150	121 ± 4.85	
II	BT	95	233	163.1 ± 10.17	<0.0001
	AT	90	180	124.7 ± 5.98	

Between the two groups, statistically, there was a substantial difference.



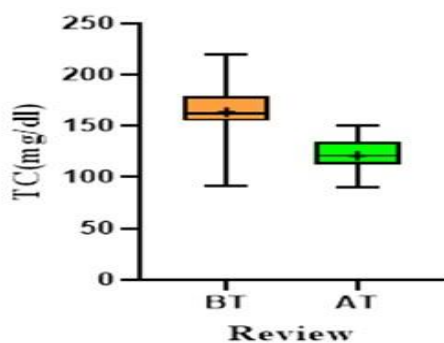


Figure 1: Comparison of Total Cholesterol in Group I

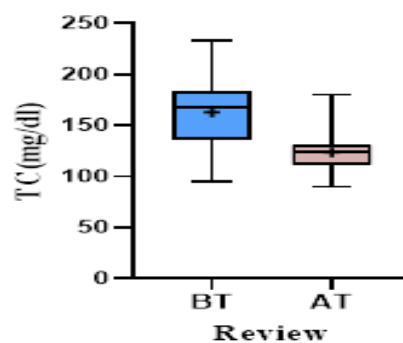


Figure 2: Comparison of Total Cholesterol in Group II

Table 3: Comparison of LDL before and after treatment:

Group	Review	Minimum	Maximum	Mean ± SEM	P value
I	BT	42	168	100.5 ± 9.59	0.0271
	AT	40	130	90.79 ± 6.51	
II	BT	45	141	95.93 ± 7.52	0.0101
	AT	50	130	89.64 ± 5.84	

Statistically, the LDL levels between the two groups before and after treatment differed significantly.

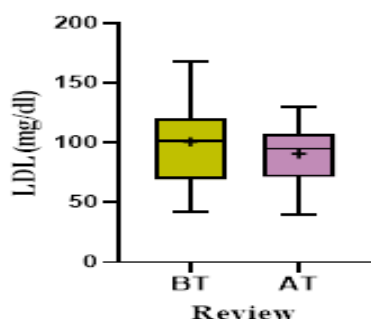


Figure 3: Comparison of LDL in Group I

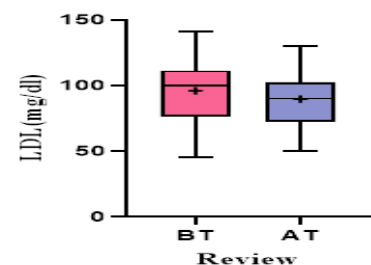


Figure 4: Comparison of LDL in Group II

DISCUSSION

Among all causes of death, cardiovascular disease is the main factor, with nearly 235 per 100,000 death rates. In most patients, cardiovascular diseases are especially endorsed with atherosclerosis. Atherosclerotic cardiovascular disease (ASCVD) is thought to be influenced markedly by coronary artery disease. To treat hypercholesterolemia-induced cardiovascular illnesses, such as ASCVD, statins should be used to reduce cholesterol levels significantly.

Aster Prime Hospital in Hyderabad was the site of this study. There are no exclusions from the trial for individuals between the ages of 20 and 80 with coronary artery disease on statin drug treatment. Information about the patients' personal and medical histories as well as the diagnoses and treatments they received was gleaned from medical records and entered into standardized data collecting forms.

- With SPSS version 20, 100 individuals are included in the study, all of them had coronary artery disease.
- The percentage of men in group I was 87 percent, while the percentage in group II was 80 percent. Groups I and II, on the other hand, had female populations of 13 and 20 percent, respectively. A P-value of less than 0.05 is judged non-significant due to the 0.6242 percent confidence interval.
- Male patients in our research had mean ages of 53.07± 2.27 while female patients had mean ages of 59.14± 3.35. (As the confidence interval is 0.1462, the p-value is deemed significant.)
- A statistically insignificant difference in the ages of the two groups was discovered.
- Statin prescription guidelines have been evaluated, and the differences between the guidelines and the practical approach to adjusting lipid-lowering medications in light of evidence and guidelines' recommendations have been shown.
- Rosuvastatin was prescribed to 60 patients, whereas Atorvastatin was administered to 40 patients, according to the patient's treatment chart.
- And that's what an independent t-test was looking for when it came to the P-value for statin efficacy on



lipid cholesterol levels like total cholesterol, triglycerides, low density lipoproteins (LDL), and high-density lipoproteins (HDL).

- Statistically, the two groups had no significant difference in baseline lipid profiles.
- According to statistics, the cholesterol levels in the two groups before and after therapy were significantly different.
- The level of HDL-Ch was also increased after treatment with Rosuvastatin with a p-value <0.0001 in group I and 0.0003 in group II.
- Statistically, the LDL levels between the two groups before and after treatment differed significantly with a p-value 0.0271 in group I and 0.0101 in group II.
- The triglyceride levels of the two groups were significantly different before and after treatment with rosuvastatin, with p values of 0.0104 in group I and 0.0184 in group II, respectively.

CONCLUSION

There were 100 patients in this study from Aster Prime Hospital Hyderabad who were evaluated for their risk of coronary artery disease progression, practise, safety and efficacy of statin treatment. There were variables related to the onset of coronary artery disease, and Rosuvastatin and Atorvastatin were compared in terms of their effectiveness in lowering this risk.

The typical age of the patients was 34 to 80 years old. Male hyperlipidemic patients accounted for 87% of those in groups I and II, whereas females represented for 13% of those in groups I and 20% of all those in group II.

Rosuvastatin was shown to be more effective than Atorvastatin in lowering LDL-Ch levels in our research participants when compared to Atorvastatin.

In addition, rosuvastatin boosted HDL-CH and significantly decreased total cholesterol and triglycerides compared to atorvastatin.

A number of clinical recommendations have been produced to achieve the most effective use of statins in daily clinical practice.

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