

Effect of Statins on Cad in Diabetic and Non-Diabetic Patients

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I. INTRODUCTION:

Coronary Artery Disease:

It is the disease of arteries that supply blood to the heart. CAD is the most common form of heart disease affecting nearly 80% of the Indian population every year. It occurs as a result of obstructed blood flow in the arteries. This obstruction in the blood flow is mainly caused by deposition of cholesterol on the arterial walls or due to plaque formation; this obstruction due to cholesterol is called as atherosclerosis. Atherosclerosis is preventable. Over the years a person diagnosed with CAD can further develop ischemia, angina (chest pain), myocardial infarction (heart attack) and further progress into heart failure.

Diagnosis of CAD: To diagnose CAD the following tests need to be performed- Electrocardiogram, echocardiogram, stress test/treadmill test/exercise stress test, angiogram, cardiac CT scan. The blood tests include: Lipid profile test, C-reactive protein tests. The efficacy of statins can be figured out using the lipid profile test.

Treatment of CAD: Management of CAD can be done by four methods (i) Surgical procedures; (ii) Catheter management; (iii) Non-invasive procedures and (iv) Medical management.

- 1. Surgical procedures:** These include Coronary Artery Bypass Surgery, Arterial Coronary Artery Bypass Graft (CABG) and Off-Pump Bypass Surgery.
- 2. Catheter management:** These include Cardiac Catheterization and Coronary Interventional Procedures and Angioplasty.
- 3. Non-invasive procedure:** Enhanced External Counterpulsation.
- 4. Medical management:** These help prevent progression of disease and recurrent cardiovascular events. It included three most important class of medication (i) Lipid

lowering agents (ii) Anti-hypertensive drugs and (iii) Anti-platelet agents.

Since this study is done in medically managed patients medical management of CAD is explained below with intensive information on statin therapy.

- 1. Lipid lowering agents:** There are several different types of medications that are designed to treat high cholesterol levels. **Statins** are one of the most well-known categories of cholesterol drugs that can lower your cholesterol.

A. Statin Therapy: In prevention of cardiovascular disease, statins are the first-line treatment. Statins work by reducing the amount of cholesterol produced by the liver thus lowering the risk of heart attacks and strokes, which is one reason why they are so widely prescribed. Statins that are available in India include: Atorvastatin, Rosuvastatin, Simvastatin, Pravastatin, Fluvastatin, Lovastatin Pitavastatin

Statins are not advisable for every patient with high cholesterol, especially for those patients with liver problems. Although the side effects of statins are low, it can include muscle pain, higher blood glucose levels and memory issues. All statins are designated as '**Category X**' by the US-FDA which means the use of statins is contraindicated during pregnancy. Most commonly used statins in the hospitals is atorvastatin and rosuvastatin. These 2 statins are explained in detail below.

Effect of statins on CAD patients:

Statins are known to effectively reduce cardiovascular events and mortality in patients with CAD. Besides the primary effect of lowering the LDL-C levels it has also shown pleiotropic effects like improved endothelial function, reduced inflammation, reduced thrombus formation and plaque stabilization.

Effect of statins in diabetic patients:

In diabetic patients with cardiovascular disorder statins are to be prescribed based on the patients' atherosclerotic risk factors rather than only considering LDL levels. The ACC/AHA guidelines for the prevention of cardiovascular disease-2013 do not provide any information on what should be the goal LDL levels which is also followed by the 2017 ADA guidelines. High dose statin therapy is to be given for all diabetic patients who have a history of CAD. Moderate dose statin therapy is to be given to patients < 40 years and > 70 years who have CAD risk factors like LDL > 100mg/dL, smoking, high blood pressure, family history of premature atherosclerosis.

According to a study titled "Efficacy of lipid lowering drug treatment for diabetic and non-diabetic patients: meta-analysis of randomized controlled trials" carried out by Joao Costa et.al he concluded that lipid lowering agents especially statins have significantly reduced cardiovascular risk in diabetic and non-diabetic patients but, the benefit was seen more in diabetic patients for both primary and secondary prevention.

Effect of statins in non-diabetic patients:

Many studies on statins claim that, statins do possess a diabetogenic effect and each type of statin may show different effect on glucose metabolism. A study conducted in Korea concluded that intensive and adherent use of statins is significantly associated with increase in fasting glucose of non-diabetic individuals. The use of atorvastatin, rosuvastatin and simvastatin had a significant impact on the increased fasting glucose level compared to pravastatin, lovastatin and fluvastatin.

Another study that was conducted in the Department of Pharmacology of Mahatma Gandhi Medical College and Research Centre, Puducherry, India, titled "Dose and time-dependant effect of statins on glycemic status and their association with new onset diabetes mellitus" carried out by Padmavathi S et.al. concluded that out of the 22 subjects that were undertaken in study 17 subjects had developed hyperglycemic symptoms after starting their treatment with statins. They also concluded that there was 27% increased risk of developing new onset of diabetes in patients who are on statin therapy. Elevated levels of RBS, FBG and HbA1c were also noted.

AIMS AND OBJECTIVES

Aims: To prove that statins is an effective lipid-lowering drug both in diabetic and non-diabetic

patients despite its controversial use in non-diabetic patients

Objectives : To enhance cautious use of statins in non-diabetic patients.

Methodology:

STUDY SITE: The study was conducted in the Department of Cardiology in Aster Prime Hospital, Ameerpet, Hyderabad, Telangana, India.

STUDY DESIGN A Prospective Observational study was carried out to study "The Effect of Statins on CAD in Diabetic and Non- Diabetic patients."

STUDY DURATION: The study is carried out for a duration of six months i.e., from December 2020 - May 2021.

SAMPLE SIZE: The present study was carried out on 107 patients who have been given statin therapy for CAD.

STUDY PROCEDURE: The following data was collected:

- Patient's baseline characteristics like age, gender, weight, etc.
- Patient's diagnosis was noted from the patient's case file.
- Type of statin prescribed to the patient

SOURCES OF DATA:

- Patient data collection form

SELECTION CRITERIA Inclusion criteria:

- Patients of both the genders of age 18 – 90 years having CAD.
- Patients who are Diabetic and Non-Diabetic having CAD.
- Patients having Hypertension.
- Patients receiving statin therapy.

STUDY GROUP The study was carried out in the following two groups of patients one diabetic and the other non-diabetic. Group 1: 62 Diabetic patients given Statin therapy. **And** Group 2: 46 Non - Diabetic patients given Stain therapy.

METHOD OF STUDY: This is a prospective observational study carried out for a period of 6 months in the cardiology department. A total of 107 patients who have CAD and have been given statin therapy were taken into consideration.

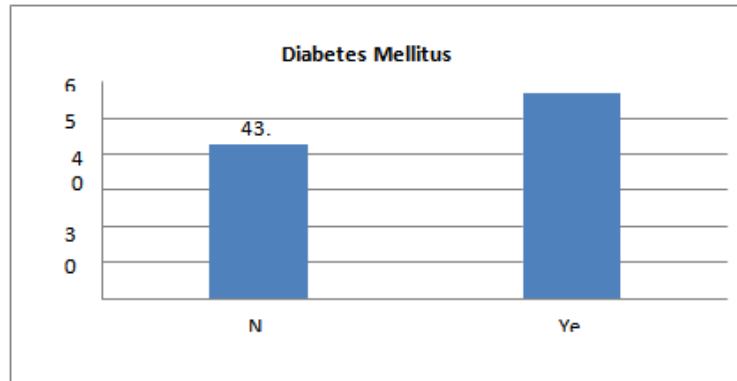
The patients are divided into two groups of DIABETIC (Group 1) and NON – DIABETIC (Group 2).

The patients were administered with desired doses of statins such as atorvastatin, rosuvastatin, atorvastatin + aspirin, clopidogrel + atorvastatin+ aspirin and subsequent data was analyzed is

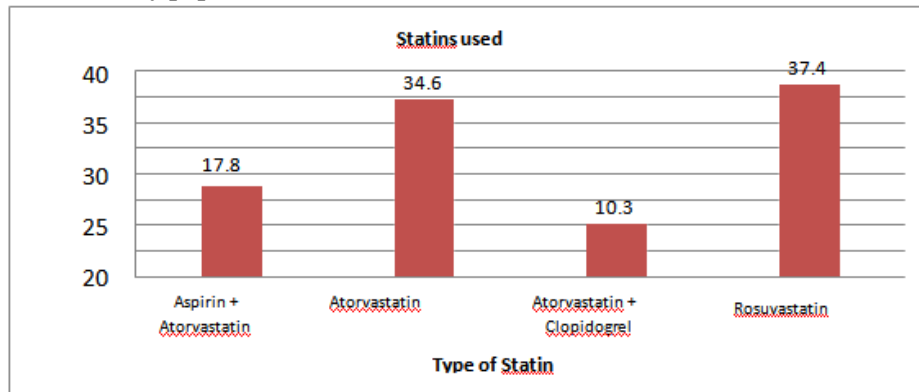
collected in the data collection form. Duration of treatment, adverse effects, primary hemodynamic parameters, effect on cholesterol levels were monitored and recorded.

II. RESULTS

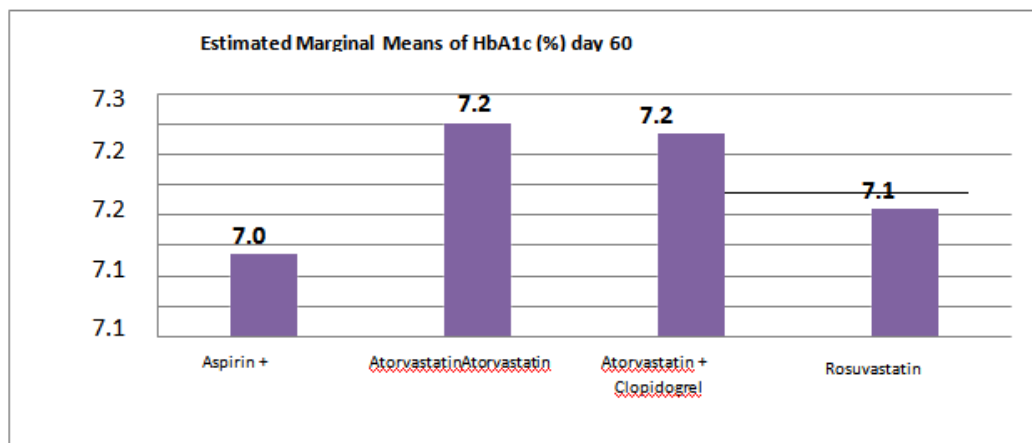
1. patients(N=61) are Number of diabetic and non-diabetic patients:



2. Statin used in the study population:



2. HBA1c levels due to Statins.



III. DISCUSSION

- A study was conducted at the Aster Prime Hospital in Hyderabad in the Department of Cardiology. A total of 107 patients of both genders under the age group of 18-90 years who were admitted for CAD .
- The patients were divided into two groups i.e..
 - Group- 1: Diabetic patients in which 29.39% females and 33.64% males were present.
 - Group- 2: Non - Diabetic in which 14.01% females and 28.97% males were present.

1. From this study we can see that there was a significant increase in the HbA1C levels in the non-diabetic patients on statin therapy. The mean value had increased from 6.2 to 6.6 in non-diabetic patients P- value= 0.048. This increase in the HbA1C levels is graphically shown

2. Atorvastatin, rosuvastatin and the combination drugs of atorvastatin increases the diabetic risk in non-DM patients

- From the above mentioned our aim that statins can increase the blood sugar levels and induce type 2 Diabetes mellitus in non – diabetic patients is proved and the objective of cautious use of statins is important for non-diabetic patients along the objective of monitoring the glucose levels in non-diabetic patients is met.

IV. CONCLUSION

This prospective observational study concludes that the use of statins like atorvastatin, rosuvastatin and the combination drug of atorvastatin which is atorvastatin along with aspirin; and atorvastatin along with clopidogrel increases the risk of development of type-2 diabetes mellitus in non-diabetic patients diagnosed with CAD who are on statin therapy. An increase in the RBS levels and HbA1c levels were seen non-diabetic patients indicating that statins can induce T2DM in non-diabetic patients. This increase in RBS and HbA1c levels were independent of the statin prescribed for the treatment which indicates rosuvastatin, atorvastatin and the combination drugs of atorvastatin can induce T2DM in non-diabetic patients. This suggests that cautious use of statins should be done in non-diabetic patients. Furthermore, the ability of these drugs to lower the lipid levels in both diabetic and non-diabetic patients is similar. A decrease in LDL/HDL ratio and LDL levels is seen in diabetic and non-diabetic patients. An increase in HDL values is also seen in both diabetic and non-diabetic patients irrespective of the statin used. The efficacy of statins in the treatment of cardiovascular disorders and their

benefit is undeniable which is clearly established and widely accepted. Thus, by this study it is concluded that the use of statins for the treatment of CAD in non-diabetic patients needs to be cautious as it can induce T2DM in them for which regular monitoring of glucose levels in the body needs to be checked and the therapeutic efficacy of statins to effectively lower the lipid levels in both diabetic and non-diabetic patients is independent of its controversial use in non-diabetic patients.