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COMPARING THE EFFICACY AND PHARMACOECONOMICS OF ATORVASTATIN AND ROSUVASTATIN

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ABSTRACT: The aim of the research work was to determine and compare the efficacy and pharmacoeconomics of Atorvastatin and Rosuvastatin. The cohort, observational, and prospective studies were conducted at KMC multispeciality hospital, Trichy. The hyperlipidemic patient was treated with Atorvastain (10 mg) and Rosuvastatin (5 mg) every day over a period of six months. Contemplating the inclusion and exclusion criteria, 104 patients were selected for the study. From the selected 104 patients, 52 patients were treated with Atorvastatin (Group-A) and Rosuvastatin (Group- B). The therapeutic effect of both drugs was compared. The level of Total cholesterol (TC), Triglyceride (TG), Low-density lipoprotein (LDL), and High-density lipoprotein (HDL) were estimated. Rosuvastatin-treated patient's reports showed a significant reduction in total cholesterol, triglyceride, and low-density lipid-protein, and increased the high-density lipoprotein during the therapy compared to Atorvastatin treated patient's group. The results revealed that Rosuvastatin is more effective than Atorvastatin and Rosuvastain is cost effective than Atorvastatin.

INTRODUCTION: Hyperlipidemia can be considered as one of the main factors that induce the risk of cardiovascular disease. Hyperlipidemia alters the lipid profile, increasing triglycerides, cholesterol, cholesterol esters, phospholipids, and plasma lipoproteins, including very low-density and low-density lipoprotein and reducing high-density lipoprotein levels [1].

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Atorvastatin is a highly effective 3-hydroxy-3-methylglutaryl–coenzyme. This reductase inhibitor suppresses hepatic cholesterol synthesis, thereby increasing hepatic low-density lipoprotein (LDL) receptors and altering the formation of very-low-density lipoprotein (VLDL) particles [2].

Rosuvastatin is a fully synthetic HMG-CoA reductase inhibitor. Rosuvastatin competitively inhibits the HMG-CoA reductase enzyme selectively and reversibly. This enzyme converts HMG-CoA to mevalonic acid in the cholesterol biosynthetic pathway, which is the rate-limiting step in cholesterol synthesis. Rosuvastatin, therefore, decreases hepatic sterol synthesis, which, in turn, leads to a decreased concentration of

hepatocellular cholesterol [3]. Clinical studies showed that statins could have a clinically relevant impact on the gut microbiome, providing a solid rationale for more and broader research of statins' impact on the gut microbiome [4]. Statins are drugs that could help individuals with type 2 diabetes reduce their risk of atherosclerotic cardiovascular complications [5]. Clinical trials were proved that Statin drugs were comparatively safer than other category drugs [6]. Rosuvastatin is directly involved in cholesterol biosynthesis and indirectly in the formation of other plasma lipids through cholesterol homeostasis. However, clinical investigations have shown that rosuvastatin medication causes considerable alterations in each fatty acid's levels [7]. The effectiveness of treatment depends on the correct drug selection and other influencing factors that alter the lipid profile, such as age, gender, social habits, diet and diseases such as hypertension and diabetes mellitus. Concerning all these factors, selecting the appropriate drug is a critical step in increasing therapeutic efficacy in patients [8]. Few studies evaluating the efficacy of both Atorvastatin and Rosuvastatin have been published in other countries [9-11]. So far, there has been no work reported in India comparing these drugs' efficacy and cost-effectiveness. Hence, the study's objective is to compare the efficacy of two statin drugs such as Atorvastatin and Rosuvastatin and assess the pharmacoeconomic study of two statin drugs.

MATERIAL AND METHODS: The Cohort, Observational and Prospective study was carried out at KMC Multispeciality hospital, Trichy, to collect the information about the patients.

The source of data was collected from outpatient department cards, laboratory data reports, treatment charts, and verbal communication with patients; the study was carried out on outpatients of OP ward who were currently following the treatment of hyperlipidemia in KMC hospital, Trichy.

Study Design: The study was conducted for a period of 6 months period by treating Atorvastatin (10mg) and Rosuvastatin (5mg) in the patients to assess the efficacy and pharmacoeconomics in the management of the management hyperlipidemia. The study was approved by the Institute of ethical committee KH/A/EST/CERT-39/16.

Patient Selection: The study population comprised of 104 patients, both male and female aged 18-80 years [12-17]. Patients had antilipidemic drugs with a co-morbid conditions such as Coronary artery disease, Myocardial infarction, Diabetes, and Hypertension were included, and Patients with pregnant or lactating women [18] and co-morbidity such as Acute emergency hypertensive patients, Renal transplant patients, Chronic renal failure, Malignancy condition and Liver diseased patients were excluded from the study. Patients were divided into Group A and Group B. Group A and Group B were treated Atorvastatin (10 mg) and Rosuvastatin (5 mg), respectively. The drugs were administered once daily after a night meal for 6 months. The patients were classified based on age, BMI, gender, social habits, and associated diseases such as hypertension, diabetes, and coronary heart disease, as listed below.

Categorization of Patients (n=104) According to Age: On categorization of patients according to age group, 14 (13%) patients were in the age group 31-40 years, 23 (22%) patients were in the age group 41-50 years, 37 (36%) patients were in the age group 51-60 years, 20 (19%) patients were in the age group 61-70 years, and 10(10%) patients were in the age of 50 years.

Categorization of Patients (n=104) According to BMI: 7 patients (7%) were under weight, 48 patients (43%) were in normal, 39 patients (34%) were in overweight and 10 (10%) patients were in obese.

Categorization of Patients (n=104) According to Gender-wise Comparison: Out of selected 104 patients, 46 (44%) patients were females and 58 (56%) patients were males.

Categorization of Patients (n=104) According to Social habits: Considering the social habits of the patients, 12 (12%) patients were smoker, 11 (10.5%) patients were alcoholic, 15 (14.3%) patients were smoker and alcoholic. Out of 104 patients 66 (63.2%) have no habits.

Categorization of Patients (n=104) According to Associated Disease: The included patients also had associated diseases like hypertension and diabetes mellitus.

38 (37.4%) patients had only hypertension, 32 (31.3%) patients had only diabetes mellitus, and 20 (19.34%) patients had both hypertension and diabetic mellitus.

Categorization of Patients (n=104) According to History of Corona Artery Diseases: 68 (30%) patients out of 104 patients had a previous history of coronary artery diseases. Lipid profiles such as Total cholesterol (TC), Triglyceride (TG), Low-density lipoprotein (LDL), and High-density lipoprotein (HDL) were estimated before and after the treatment to the all 104 patients.

RESULTS AND DISCUSSION: The present study aims to give information about the therapeutic effects of Atorvastatin and Rosuvastatin by comparing them with one another. The therapeutic effect of both drugs was evaluated by comparing the estimated values of TC (Total cholesterol), TG- (Triglyceride), LDL-C (Low-density lipoprotein), and HDL-C (High-density lipoprotein), which were obtained from the patient's blood sample. The initial reading (before treatment) was used as the baseline, and review values (after treatment) were taken by the end of the 6-month period. Before the commencement of the study, patients were categorized by different factors as mentioned in the previous section. Elderly patients were more prone to hyperlipidemia than younger ones. Male had more risk of acquiring hyperlipidemia compared to females. Among the female patients maximum of them were in the postmenopausal state. Comparing the gender-wise, it was found that the improvement in lipid profile was better in the case of female patients in both Atorvastatin and Rosuvastatin therapy compared to patients. Social habits like tobacco smoking, chewing, and alcohol use were some of the risk factors for hyperlipidemia. Patients with a non-vegetarian diet are prone to hyperlipidemia. In most hyperlipidemic patients, diseases like hypertension and diabetes mellitus were associated with hyperlipidemia. There was no significant alteration in heart rate after therapies in both groups. In Atorvastatin (group A) patients (n=52) the mean value change of heart rate at baseline was 74.86±2.940 after treatments for a period of 6 months, it becomes 74.05± 2.553. Rosuvastatin (group B) patients (n=52). The mean value change of heart rate at baseline was 75.69±2.420 after treatments for a period of 6 months; it becomes 74.58± minus 2.250. There was a significant decrease in systolic and diastolic blood pressure in both groups after the drug therapy. In Atorvastatin (group A) patients (n=52) the mean value change of blood pressure at baseline was 141.6±15.12, and after treatment for 6 months, it became 128.12 ± 5.870. In Rosuvastatin (group B) patients (n=52) the mean value change of blood pressure at baseline was 135.6±4.390, and after treatment for 6 months, it became 125.62±3.390. Atorvastatin and Rosuvastatin showed significant improvement in all lipid profiles. Group B (Rosuvastatin) treated patient's reports showed a significant reduction in total cholesterol, triglyceride, and low-density lipid-protein, during the therapy compared to Group A (Atorvastatin), while Group B (Rosuvastatin) treated patient's reports showed a significant increase in high-density lipid-protein, during the therapy compared to Group A (Atorvastatin). The results of the lipid profile data was depicted in **Table 1**. Cost details and cost-effective analysis of Atorvastatin and Rosuvastatin were mentioned in **Tables 2** & **3**. This result showed that Atorvastatin is costlier than Rosuvastatin when the cost is considered. But the efficacy in reducing the level of total cholesterol was more in Rosuvastatin.

TABLE 1: EFFECT OF ATORVASTATIN AND ROSUVASTATIN ON LIPID PROFILE

Lipid parameters	Atorvastatin			Rosuvastatin		
	Base	Review	Mean%	Base	Review	Mean%
T. CHO	216.6 ±3.073	183.7 ±1.224	-15.23	233.9 ±2.892	169.1± 2.003	-27.70
TG	170.5 ±4.098	119.7 ±2.886	-29.79	188.0 ±4.939	115.1 ±3.502	-38.77
LDL-C	145.6 ±1.459	97.48 ±1.307	-33.04	148.6 ±1.459	93.48±1.507	-37.09
HDL-C	39.63± 6.28	39.88 ±5.94	+0.63	38.4 ±4.57	39.98 ± 4.34	+3.4

P-value and base value calculated by one-way anova; P-value <0.001.

TABLE 2: COST DETAILS OF ATORVASTATIN AND ROSUVASTATIN

Drugs	No of tablets per day	Annual usage	Annual cost (Rs)	Monthly cost (Rs)	Cost per day
Atorvastatin	1	360	6966	580.50	19.35
Rosuvastatin	1	360	2682.75	230	7.35

TABLE 3: COST-EFFECTIVE ANALYSIS OF ATORVASTATIN AND ROSUVASTATIN

Drugs	Annual cost	Cholesterol reduction lower value	Cholesterol reduction upper value	Cost-effectiveness range (Rs/% Reduction cholesterol value)
Atorvastatin	6966	20	85	348.3-81.5
Rosuvastatin	2682	30	98	89.4-27.36

CONCLUSION: The present study results revealed that both Atorvastatin and Rosuvastatin showed significant improvements in all lipid profiles for hyperlipidemic patients. Patients with high TC, TG, LDL-C, VLDL-C and low HDL-C levels were effectively treated with Atovastatin and Rosuvastatin. In terms of efficacy, Rosuvastatin was more effective than Atorvastatin. Rosuvastatin was found to be a more cost-effective drug in hyperlipidemia than Atorvastatin.

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