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RESEARCH ARTICLE

Pharmacoeconomics study of rosuvastatin single daily dose versus alternate day dosing in hyperlipidemia patients

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ABSTRACT

Background: In country like India, therapy with rosuvastatin recommended dose may cost between Rs. 400.00 and Rs. 800.00/month. The lower and middle income groups of Indian society are rapidly becoming major sufferers of cardiovascular disease, among all non-communicable diseases, the economic burden of rosuvastatin therapy may be substantial for this large section of population. **Aims and Objectives:** The aim of the study was to study the cost-effectiveness of rosuvastatin on alternate day versus daily dosing regimen in hyperlipidemia patients. **Materials and Methods:** The research was carried out at MNR Medical College and Hospital's department of pharmacology in association with general medicine. According to the inclusion criteria, 50 patients aged 30–60 years of both sexes were included in this prospective open label trial. The research lasted 6 weeks. All the participants were included in study after obtaining the informed consent and approval of the Institutional Ethics Committee was obtained before enrolment of participants. All patient data were obtained using a pre-designed proforma and put into an excel spreadsheet. **Results:** A total of 42 patients are included with 16 females (38%) and 26 men (62%). Cost of daily rosuvastatin for 6 weeks is Rs. 1087.80 (yearly daily dosing expenses 9453.50%) accounting for mean reduction of LDL-cholesterol (LDL-C) of 33.50% and for alternate day rosuvastatin for 6 weeks is 543.90% (yearly alternate day dosing expense 4713.80%) accounting for mean reduction of LDL-C of 31%. **Conclusion:** Treatment with alternate day dose of rosuvastatin is comparably cost-effective when compared to currently practicing daily dose rosuvastatin therapy.

KEY WORDS: Rosuvastatin; Lipid; Pharmacoeconomics; Socio Economic Status; Coronary Vascular Disease

INTRODUCTION

A chronic condition affects over half of all adults and around 8% of children (aged 5–17 years) globally. As a result of this, as well as an ageing population, the need for health-care resources is growing. Medications are a cost-effective treatment modality, but with estimates of 50% non-adherence to long-term therapy for chronic illnesses, deliberate and accidental drug non-adherence is a widespread and ongoing healthcare issue. Medication adherence is defined as "the extent to which patients' behavior fits agreed-on instructions from the prescriber," stressing the importance of patients' actions and emphasizing the changeable part of non-adherence.[1,2]

Rosuvastatin besides being among the most prescribed statins and has longer effect half-life of 20–30 h, due to active metabolites.[3] In India, the recommended dose of rosuvastatin

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may cost between Rs. 400.00 and Rs. 800.00/month. The lower and moderate income sectors of Indian society are progressively becoming major victims of cardiovascular disease (CVD), and the cost burden of rosuvastatin medication may be significant for this large segment of the population.[4] Because rosuvastatin has a longer half-life, this study indicates that by utilizing alternate day doses of rosuvastatin, a significant LDL-cholesterol (LDL-C) decrease can still be accomplished while lowering overall therapy costs. In India, the recommended dose of rosuvastatin may cost Rs. 25.90/- per day. The yearly expense to the patient for the alternate day regimen is Rs. 4713.80/-, whereas the yearly expenditure to the patient for the daily dosage regimen is Rs. 9453.50/-. The lower and middle income groups of Indian society are rapidly becoming major sufferers of CVD among all non-communicable diseases and the economic burden of rosuvastatin therapy may be substantial for this large section of population.[5]

Because rosuvastatin has a long half-life, it can be delivered in alternate day doses and still produce a significant LDL-C decrease while lowering overall therapy costs.[6-8] India being a developing country with growing number of non-communicable diseases including the CVDs and diabetes mellitus among the adults. In both the cases, dyslipidemia plays a key role in the disease morbidity and mortality. The daily regimen can be economic burden to many of the middle and lower class of socioeconomic system, who makes the backbone of the Indian economy and the social health welfare schemes. Hence, the present study aimed to study the cost-effectiveness of rosuvastatin on alternate day versus daily dosing regimen in hyperlipidemia patients.

MATERIALS AND METHODS

The research was carried out at MNR Medical College and Hospital's department of pharmacology in association with general medicine. According to the inclusion criteria, 50 patients aged 30–60 years of both sexes were included in this prospective open label trial. The research lasted 6 weeks. All the participants were included in study after obtaining the informed consent and approval of the Institutional Ethics Committee was obtained before enrolment of participants.

The trial, which lasted 6 weeks, was completed by 42 individuals. Eight participants were eliminated from the study. There were two patients with allergic dermatitis, two patients with gastrointestinal distress, two patients with sleeplessness, and two patients with myalgia. All of the patients are from the lower and moderate income brackets.

The investigation included all patients aged 30–60 years with LDL-C levels >130 mg/dl, total cholesterol levels >200 mg/dl, hypertension, CAD, and sedentary or poor physical activity. Patients with NIDDM, hypothyroidism,[9] smokers,[10,11] immuno-suppressants, steroids, azole antifungals, diuretics, non-adherence to lipid-lowering drugs, substantial hypertriglyceridemia (>400 mg/dl), pregnancy, breastfeeding mothers, and patients with liver dysfunction were excluded from the research. Rosuvastatin 10 mg with brand name Crestor of Astra Zenica Company was used in this study. Group A received 10 mg of Rosuvastatin daily for 6 weeks. Group B received 10 mg of Rosuvastatin on alternative day for 6 weeks. Fasting plasma lipid parameters and liver enzymes were measured for both the groups on 0 day, 4th and 6th week. Data between two groups were compared.

Before participating in the research, all individuals provided voluntarily informed consent in the approved way. Following baseline investigations, two groups were started on rosuvastatin 10 mg. Patients in Group A were given daily dosages of rosuvastatin (odd number of patients), whereas patients in Group B were given 10 mg rosuvastatin every other day (even no. patients) The trial includes patients with plasma LDL-C levels >130 mg/dl and total cholesterol levels >200 mg/dl. The lipid profile was rechecked at the conclusion of the 4th–6th weeks.

Statistical Analysis

All patient data were obtained using a pre-designed proforma and put into an excel spreadsheet. The demographic information was summarized using the mean, standard deviation, frequency, and percentage. To compare the summarized continuous data at different time intervals, the student paired *t*-test was performed. The study was carried out on Windows 10 using SPSS v23 and $P = 0.05$ was considered statistically significant.

RESULTS

Initially, 50 patients were included in the trial and eight of them were lost to follow-up (six males and two female). A total of 42 patients took part in the trial, including 16 females (38%) and 26 men (62%), all of whom were from lower and moderate socioeconomic backgrounds. Patients aged 31–40 years comprised 36% of the total, patients aged 41–50 years comprised 38%, and patients aged 51–60 years

Table 1: Baseline characteristics of the study participants

Characteristics	Group A (*n*=21)	Group B (*n*=21)
Age	30–60	30–60
Gender (male/female)	13/8	13/8
Total cholesterol (mg/dL)	258.57±40.21	238.91±22.84
LDL cholesterol (mg/dL)	182.35±33.29	164.32±17.67
HDL cholesterol (mg/dL)	40.17±6.49	40.95±7.01
Triglycerides (mg/dL)	214.17±69.00	224.00±77.54
VLDL (mg/dL)	42.82±14.74	41.36±14.31
TC/HDL	6.44±1.37	5.97±1.22
LDL/HDL	4.61±1.07	4.10±0.92

Table 2: Percentage reduction in the lipid profile parameters in both groups

Parameters	Group A				Group B			
	At 0–4 weeks	At 4–6 weeks	At 0–6 weeks	*P*-value	At 0–4 weeks	At 4–6 weeks	At 0–6 weeks	*P*-value
	Mean±SD (a)	Mean±SD (b)	Mean±SD (c)		Mean±SD (a)	Mean±SD (b)	Mean±SD (c)	
Total cholesterol (mg/dL)	–14.92	–10.67	–24	0.001* (a*b, b*c, a*c)	–12.29	–10.62	–21.61	0.001* (a*b, b*c, a*c)
LDL cholesterol (mg/dL)	–18.60	–18.26	–33.50	0.001* (a*b, b*c, a*c)	–17.67	–16.18	–31.0	0.001* (a*b, b*c, a*c)
HDL cholesterol (mg/dL)	13.09	6.01	19.89	0.001* (a*b, b*c, a*c)	10.89	5.60	17.09	0.001* (a*b, b*c, a*c)
Triglycerides (mg/dL)	–28.82	–11.06	–36.70	0.001* (a*b, b*c, a*c)	–32.36	–13.25	–41.33	0.001* (a*b, b*c, a*c)
VLDL (mg/dL)	–29.26	–10.86	–37.0	0.001* (a*b, b*c, a*c)	–27.58	–10.82	–35.42	0.001* (a*b, b*c, a*c)
TC/HDL	–22.98	–16.53	–35.71	0.001* (a*b, b*c, a*c)	–20.94	–15.89	–33.50	0.001* (a*b, b*c, a*c)
LDL/HDL	–28.42	–22.42	–44.46	0.001* (a*b, b*c, a*c)	–25.60	–17.70	–38.78	0.001* (a*b, b*c, a*c)

included 26%. Patients were divided into two groups: Group A (daily dose) and Group B (alternate day dosing) [Tables 1 and 2].

DISCUSSION

In the present study, 10 mg tablet rosuvastatin had a cost of Rs. 25.90/- per tablet. Therefore, the cost of daily rosuvastatin for 6 weeks is Rs. 1087.80 (yearly daily dosing expenses 9453.50/-) accounting for mean reduction of LDL-C of 33.50%. The cost of treatment with alternate day rosuvastatin for 6 weeks is 543.90/- (yearly alternate day dosing expense 4713.80/-) accounting for mean reduction of LDL-C of 31%.

In India, the recommended dose of rosuvastatin may cost between Rs. 400.00 and Rs. 800.00/month. The lower and medium income sectors of Indian society are fast becoming significant CVD patients, accounting for one-quarter of all non-communicable disease-related days lost, and the cost impact of rosuvastatin medication may be enormous for this big segment of the population. Because rosuvastatin has a long half-life, this study argues that by taking alternate day doses of rosuvastatin, a large LDL-C decrease, an increase in HDL levels, and a greater reduction in TG may still be obtained while lowering overall treatment costs. According to the aforementioned statistics, the cost of treatment with daily dosage rosuvastatin is Rs. 282/- per percentage reduction of LDL-C per year, compared to Rs. 152/- per percentage reduction of LDL-C per year with the other therapy. This amounts to savings of Rs. 130/- per percentage reduction of LDL-C per year with alternate day rosuvastatin therapy over the daily treatment regimen. According to Kanis *et al*. study, total adherence is associated with more quality-adjusted life years gained and higher treatment costs than partial adherence. Although adherence appears to be a substantial cost-effectiveness driver, the effect is dependent on a variety of other factors. The cost-effectiveness of partial adherence is greatly influenced.[12]

Strengths

This is one of the studies from India documenting the cost-effectiveness of the statins among the hyperlipidemia patients. There is paucity of such pharmacoeconomics study on such topic in the literature published. This study will help for further investigation of the treatment regimen impact on the pharmacoeconomics and adherence to the treatment schedule by the patients.

Limitation

The study has lot of strength, with some limitations which might include the small population size studied. The study can be extended to larger population of various economic status, education, and occupational status.

CONCLUSION

The results of the present study indicate that treatment with alternate day dose of rosuvastatin is comparably cost-effective when compared to currently practicing daily dose rosuvastatin therapy.

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