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Comparison of efficacy of rosuvastatin as a cholesterol synthesis inhibitor with atorvastatin in subjects with hypercholesterolemia

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6 stage

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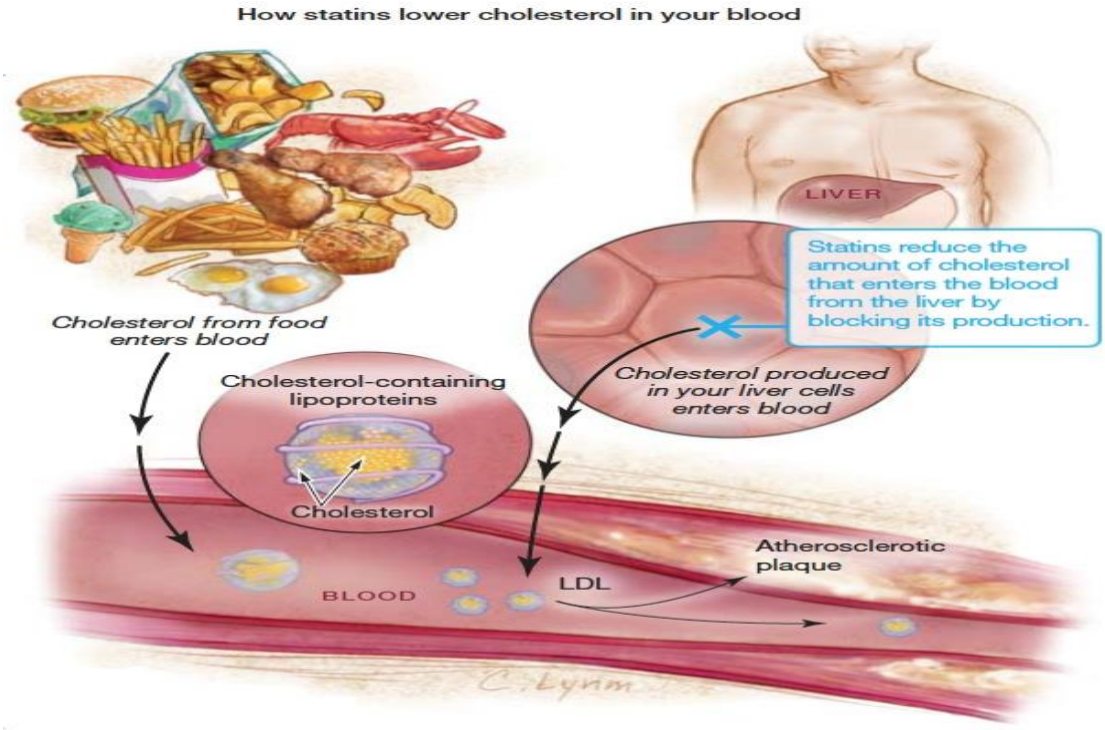
2021 - 2020

Abstract

The aim of the present study was to compare the lipid lowering effect of atorvastatin and rosuvastatin in patients (n=52) with hyperlipidemia. Patients were assigned to atorvastatin 10 mg or rosuvastatin 5 mg daily for 8 weeks. The blood was collected at baseline and after intervention to measure the serum lipid profile. The level of serum total cholesterol in both atorvastatin and rosuvastatin groups was significantly reduced after intervention ($p<0.00001$ and $p<0.00001$ respectively) but no statistically significant difference ($p=0.503$) was observed between the two statin-treated groups. The reduction of serum triglyceride level was also significant ($p=0.046$ in atorvastatin group and $p=0.0006$ in rosuvastatin group). No significant difference was observed between the two groups ($p=0.312$). The serum LDL-C level was reduced significantly in both atorvastatin group ($p<0.00001$) and rosuvastatin group ($p<0.00001$). Again no statistically significant difference ($p=0.749$) was observed between the two groups. No significant change was observed in the serum HDL level. Intergroup difference was not significant ($p=0.721$). The present study indicates that both atorvastatin and rosuvastatin improve the lipid profile but no significant change was observed between the two groups.

Introduction

Hyperlipidemia is an abnormal elevation of serum lipid levels in the blood which culminate in the development of atherosclerosis.1 Atherosclerosis is a chronic disease of arterial wall and may give rise to myocardial infarction, ischemic stroke and peripheral vascular disease as its after math.2 Globally, one-third of ischemic heart disease is attributable to high cholesterol level, which is estimated to cause 2.6 million death and 29.7 million disabilities.3 Hydroxymethyl glutaryl coenzyme-A (HMG Co-A) reductase inhibitor drugs (statins) are quite effective in treating dyslipidemia and therefore, are widely used for prevention and treatment of cardiovascular diseases.4 By reducing the synthesis of mevalonate, the immediate product of HMG-CoA, statins inhibit the synthesis of cholesterol.5 Several drugs are included within the statin group, among them atorvas-tatin and now-a-days rosuvastatin is widely used. The present study was planned to compare the lipid lowering efficacy of the newer emerging and promising statin rosuvastatin with the existing commonly used statin atorvastatin in patients with dyslipidemia so as to guide the present treatment strategies.



Materials and Methods

An 8-week, randomized, open trial was conducted by recruiting the patients from the outpatient Department of Cardiology. Eligible patients were randomized to receive once daily dose of 10 mg atorvastatin or 5 mg rosuvastatin for 8 weeks. The study population comprised 52 hyperlipidemic patients, both male and female,6 aged 20-75 years.7-9 Eligibility criteria for randomized treatment included the fasting LDL-C level >160 mg/dL and fasting triglyceride level <400 mg/dL.10 Patients were treated by other lipid lowering drugs,11 history of smoking, alcohol intake12 and hypersensitivity on any member of the statin group of drugs,11 taking anti inflammatory medications,12 anti-oxidant vitamins (vitamin A, C, E),13 anticoagulant or antiplatelet drugs,14 impaired liver and renal function,11,15 having serious infections or terminal illness,12 pregnant women and nursing mother Were not enrolled.11 Baseline measurements included the levels of serum total cholesterol, triglyceride, low-density lipoprotein cholesterol (LDL-C) and high-density lipoprotein cholesterol (HDL-C) with follow-up measurements after 8 weeks. With all aseptic precaution, 5 mL of blood was collected by venipuncture from the antecubital vein and kept it in 1 x 5 mL K3EDTA (anticoagulant) containing test tube. The plasma was separated by centrifugation (3,500 rpm for 10 min) and stored at labeled Eppendorf tube by micropipette, then stored at -20°C in a refrigerator until analysis. Drugs were advised to take at night before meal. Regularity of drug intake was ensured over telephone and from the patient's compliance sheet. Patients were asked to report any adverse effect of the medication given during the period of study. Patients was strictly advised to take fat restricted diet. Statistical analysis Data were processed and recorded in the Microsoft Excel Worksheet. The quantitative variables were expressed as mean ± SD. Differences in mean values between groups were assessed by using the two tailed paired and unpaired student's t-test. The level of significance was set at 'p' value less than 0.05.

Discussion

Data from the VOYAGER meta-analysis suggested that each rosuvastatin dose is equivalent to dose 3-3.5 time higher for atorvastatin regarding reduction of LDL-C.16 This would indicates that 5 mg rosu-vastatin equivalent to 15-20 mg of atorvastatin. The present study has observed the beneficial effects of atorvastatin and rosuvastatin on serum lipid profile. Both of them significantly reduced the serum total cholesterol, triglyceride and LDL-C levels significantly after drug treatment, which was according to previous research findings.11, 17, 18 A 12-week study shows with both rosuvastatin (5 mg) and rosuvastatin (10 mg) significantly reduced the total cholesterol and LDL-C compared with atorvastatin (10 mg)-treated patients.19 Another study of 8-week treatment with rosuvastatin (10 mg) significantly decreased the triglyceride and LDL-C to a better extent as compared to that of atorvastatin (10 mg).6 This would suggests that 5 mg dose of rosuvastatin may be inadequate for the significant improvement of lipid profile compared to 10 mg atorvastatin. In present study, no significant elevations were noticed regarding HDLC levels. Inspite, small reduction of HDL-C level was observed in both the groups. This bears resemblance with one previous study using atorvastatin and rosuvastatin, which shows mild reduction of serum HDL-C level after 4 weeks of treatment.11 A similar study has demonstrated the decreased HDL-C level in the initial 6 weeks followed by increased level of HDL-C after 16 weeks of intervention.20 Although no clear explanation is available at the moment regarding this decrease in HDL-C level of the present study, it could be expected that perhaps a longer time period than 8 weeks would have been required to effectively demonstrate the effects of the statins upon serum HDL-C level. In this trial, both atorvastatin and rosuvastatin were quite effective in reducing serum LDL-C level in hyperlipidemic patients. When the serum lipid lowering effects were assessed by percentage, rosuvastatin demonstrated a higher percentage of ameliorating changes compared to those of atorvastatin. Both drugs exhibited a similar safety profile. Therefore, rosuvastatin constitutes a better therapeutic option compared to atorvastatin for reducing the serum LDL-C level in patients with hyperlipidemia.

Conclusion

Both atorvastatin and rosuvastatin have effectively improved the lipid profile in hyperlipidemic patients. No significant change is observed between the two groups, although considering percentage changes of effects produce by the rosuvastatin appears better.

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