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An observational study of tolerability of rosuvastatin in patients with dyslipidemia

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Abstract
Dyslipidemia is an independent modifiable risk factor for cardiovascular disease (CVD) in addition to genetic influences coupled with diet, inactivity, smoking & co-morbidities.(4) Rosuvastatin is a new generation HMG-CoA reductase inhibitor, which has substantial lipid lowering capacity, exhibits some unique pharmacologic and pharmacokinetic properties. It has low extrahepatic tissue penetration, low potential for CYP3A4 interactions and substantial LDL-C lowering capacity and therefore has distinct advantages.(5,6) Cardiovascular disease (CVD) is a leading cause of death worldwide, and mortality due to CVD is higher in low- and middle-income countries.(1) In India, there has been an alarming increase in the prevalence of CVD over the past two decades so much so that it accounts for 24% of all deaths among adults aged 25-69 years. Indians have been found to develop CVD at a younger age than other populations.(2) The likely causes for the increase in the CVD rates include lifestyle changes associated with urbanization and the epidemiologic and nutritional transitions that accompany economic development. Dyslipidemia has been closely linked to the pathophysiology of CVD and is a key independent modifiable risk factor for CVD.(3) In India, there has been an alarming increase in the prevalence of CVD over the past two decades. Indians have been found to develop CVD at a younger age than other populations. The likely causes for the increase in the CVD rates include lifestyle changes and the epidemiologic and nutritional transitions that accompany economic development.

Keywords: HDL-C-high density lipoprotein cholesterol, LDL-C-low density lipoprotein cholesterol, VLDL-C-very low density lipoprotein cholesterol

Introduction
Dyslipidemia is an independent modifiable risk factor for cardiovascular disease (CVD) in addition to genetic influences coupled with diet, inactivity, smoking & co-morbidities. Rosuvastatin is a new generation HMG-CoA reductase inhibitor, which has substantial lipid lowering capacity, exhibits some unique pharmacologic and pharmacokinetic properties. It has low extrahepatic tissue penetration, low potential for CYP3A4 interactions and substantial LDL-C lowering capacity and therefore has distinct advantages. In India, there has been an alarming increase in the prevalence of CVD over the past two decades so much so that it accounts for 24% of all deaths among adults aged 25-69 years. Indians have been found to develop CVD at a younger age than other populations. The likely causes for the increase in the CVD rates include lifestyle changes associated with urbanization and the epidemiologic and nutritional transitions that accompany economic development. Dyslipidemia has been closely linked to the pathophysiology of CVD and is a key independent modifiable risk factor for CVD.

Materials & Methods
This was a single-centred, nonrandomized, observational study to assess the efficacy and safety of Rosuvastatin in 196 dyslipidemic patients in OPD&IPD for a period of 3 months (01/11/2017-31/01/2018). It was a single centred study conducted at Dr.B.R.Ambedkar Medical College and Hospital, Bangalore. Lipid profile of each subject was done before & at the end of 3 months, where rosuvastatin was given at a dose of 10/20mg per day. The inclusion criteria were all male and non-pregnant female dyslipidemic subjects; age range between 18-80 years.
The subjects with following criteria were excluded: Pregnant or lactating female subjects; TG>500 mg/dl and creatinine >20 mg/dl known hypersensitivity to Rosuvastatin; subjects who were suffering from hepatic or kidney dysfunction; subjects with hypothyroidism; history of drug or alcohol abuse and refusal to sign informed consent forms. Safety of Rosuvastatin in subjects with dyslipidemia was assessed by monitoring the frequency and type of adverse events (AEs) occurring in subjects. Informed consent was taken from all participating subjects. Physical and systemic examination data and lipid profile of each recruited subject was done before initiating therapy (baseline) and at the end of 3 months (post-treatment). Demographic characteristics and results of lipid profile tests are summarized with descriptive statistics, including mean and standard deviation (SD) for continuous variables, and frequency and percentages for categorical variables. Student t-test has been used to find the significance of the study parameters on continuous scale between two groups on metric parameters. (P value) $p \leq 0.05$ was taken to be statistically significant.

Conclusion
This study highlights the efficacy, safety and tolerability of Rosuvastatin therapy in patients with dyslipidemia. There were no significant drug-related adverse or serious events reported with Rosuvastatin. In our study, Rosuvastatin significantly lowered LDL-C, TC, TG levels and improved the HDL-C levels. Asians, particularly Indians, have a unique pattern of dyslipidemia; with lower high-density lipoprotein cholesterol (HDL-C), increased triglyceride (TG) levels and higher proportion of small dense low-density lipoprotein

cholesterol (LDL-C), with characteristic centripetal obesity. Prevention, detection and treatment and control of dyslipidemia should be of high priority incontrolling of CVD. The study findings establish that Rosuvastatin as a valuable choice for the first-line treatment to achieve lipid goals in the management of dyslipidemia in Indian patients and also to prevent the clinical sequelae of atherosclerotic cardiovascular disease (CVD). There was a significant reduction in the number of subjects who had high levels of LDL-C. In the present study, HDL-C increased by 20.98% in the study subjects. The TG reduction in our study subjects was 20%. Several clinical trials have unequivocally established the efficacy of statins in reducing the risk of CVD due to its antidyslipidemic effects.

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