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### Evaluation and assessment of rosuvastatin 40mg treatment in high risk dyslipidemic patients (EARTH Study)

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**Introduction:** Rosuvastatin is commonly used in the treatment of dyslipidemia, however, studies with rosuvastatin 40 mg in Indian patients with high cardiovascular risk are lacking.

**Objective:** To assess the safety and efficacy of rosuvastatin 40mg in dyslipidemic patients with high cardiovascular risk. **Material and methods:** In an open label, non-comparative, multicentric, post marketing observational study, 574 Indian patients were enrolled. Treatment was started with rosuvastatin 40 mg once daily for one month. After one month, patients achieving target goal of LDL-C < 70 mg/dl were shifted to rosuvastatin 20 mg once daily for next two months and those not achieving were continued on 40mg. At third month, patients achieving LDL-C < 70 mg/dl continued 20 mg and those not achieving the target goal were continued on 40mg for next three months. Lipid profile was repeated after six month. The primary evaluation parameter was percentage of patients achieving target serum LDL-C goal < 70 mg/dl at the end of one, three and six month. The secondary evaluation parameters included percentage reduction in serum LDL-C, serum. total cholesterol, serum triglyceride and percentage increase in S. HDL-C level at the end of one, three and six month, and effect on serum creatinine at six months. Global assessment for efficacy and tolerability was recorded by the doctor and patient at the end of six months. All adverse events were also recorded.

**Results:** Compared to baseline, there was significant increase in number of patients achieving serum LDL <70 mg/dl at one, three and six months. Similarly, significant reduction in serum LDL, total cholesterol and triglyceride level and increase in HDL was seen at one, three and six months. There was no significant effect on serum creatinine level. Most of the patients reported efficacy as either excellent or good as evaluated by both doctors and patients. Close to 95% of the patients reported tolerability as "good" as per global evaluation of tolerability by patients as well as doctors. Rosuvastatin was generally well tolerated. The incidence of adverse event was 9.9% with headache, myalgia, constipation and vomiting being the commonly reported adverse events. All the adverse events were of mild to moderate intensity and all of them resolved during the treatment. None of the patient required termination of treatment because of adverse event.

**Conclusion:** Rosuvastatin is effective and well tolerated medicine for the treatment of dyslipidemic patients with high cardiovascular risk.

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