Format: Abstract

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Post-marketing study of clinical experience of atorvastatin 80 mg vs 40 mg in Indian patients with acute coronary syndrome- a randomized, multi-centre study (CURE-ACS).

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Abstract

OBJECTIVE: To generate comparative clinical data in Indian patients with acute coronary syndrome (ACS) in terms of safety and efficacy of atorvastatin 80 mg vis-à-vis atorvastatin 40 mg

MATERIALS AND METHODS: A total of 236 patients with diagnosed ACS (with TIMI Risk score > or = 3) within preceding 10 days were randomized to receive either atorvastatin 80 mg or atorvastatin 40 mg once daily for 12 weeks. Out of 236 patients, data for 173 was analyzed who had both baseline and post-baseline lipid assessment. The primary end point of the trial was percentage change in LDL-C at the end of treatment from baseline. Other end points were change in high sensitivity C reactive protein, incidence of increase in liver enzymes > or = 3 times upper limit of normal and incidence of myotoxicity (with or without elevation of creatinine phosphokinase) at the end of treatment.

RESULTS: A dose-dependent response was observed with greater reduction of LDL -C in atorvastatin 80 mg (27.5% vs 19.04%) than that of atorvastatin 40 mg group. Both the treatment groups had a significant reduction ($p < 0.001$) in LDL-C at the end of 6 and 12 weeks in comparison to baseline. hs-CRP was also significantly reduced ($p < 0.001$) in both the treatment groups i.e. atorvastatin 80 mg (76.15%) and atorvastatin 40 mg (84.4%) from baseline at the end of 12 weeks. Both doses of atorvastatin were well tolerated. No patient had elevation of (> or = 3 times of upper limit of normal) liver enzymes or creatinine phosphokinase. One patient on atorvastatin 80 mg complained of myalgia. There were no dose-related differences in incidence of adverse events between two treatment groups.

CONCLUSION: The CURE-ACS trial indicated that atorvastatin 80 mg was more effective than atorvastatin 40 mg in terms of reduction in LDL cholesterol and was as safe and well tolerated as 40 mg dose in Indian patients with ACS.

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