



 HYPERTENSION, LIPIDS AND PREVENTION

A DOUBLE BLIND, RANDOMIZED, MULTICENTER, PARALLEL GROUP, PLACEBO CONTROL TRIAL TO EVALUATE THE EFFECT OF STATIN THERAPY ON TRIGLYCERIDES LEVELS IN MEXICAN HYPERTRIGLYCERIDEMIC PATIENTS

ACC Poster Contributions

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Background: The ATPIII recommendations for patients with hypertriglyceridemia (HTG) are first to lower the low-density lipoprotein cholesterol (LDL-C) levels and then triglycerides (TG) in order to reduce cardiovascular (CV) risk. Some patients with HTG did not exhibit elevated LDL-C but represents a group with an increased CV risk. Statins have been shown convincingly to reduce cardiovascular morbidity and mortality in multiple large outcomes trials in various populations with substantial reductions in LDL-C and TG levels in non-diabetic and diabetic patients. The primary objective was to evaluate the efficacy of rosuvastatin in reducing TG levels in HTG Mexican patients from baseline to week 8.

Methods: This was a randomized, double blind, parallel group, placebo control, study. Patients entered a 5-week lead-in period, after which eligible patients (≥ 18 years, with TG ≥ 200 , ≤ 800 mg/dl, statin naive, and without statin contraindication), were randomized to receive treatment with either rosuvastatin 10 (Group 1 (G1)) or 20 mg/day (G2) or placebo (G3) once daily for 8 weeks to evaluate the effects on triglycerides levels in hypertriglyceridemic patients.

Results: 335 patients were randomized; we show preliminary result of 270 patients (G1:90; G2: 95 and G3: 85). 138 women, mean age of 53 ± 12 years old; median (Md) body mass index of 29.29 (interquartile range (IR) 26.63 - 32.35). DM2 patients were 36 (13.3%) and with hypertension 84 (31.1%). At baseline G1-3 Md laboratory values were: TG: 278, 268, 281 mg/dl (Kruskal Wallis (KW) $p=0.47$); LDL-C: 128, 129, 127 mg/dl ($p=0.77$); HDL-C 33, 34, 31 mg/dl ($p=0.15$); glucose: 97, 97, 95 mg/dl ($p=0.14$); CRP 3.1, 3.1, 3.1 mg/L ($p=0.94$). At eight weeks of treatment the Md percentage reduction of G 1-3 was: TG 26%, 33% and 8% (KW $p=0.0001$), (U Man Whitney (UM) G1-2 $p=0.08$, G1-3 $P=0.002$, G2-3 $P=0.0001$); LDL-C: 35%, 44% and -4% ($p=0.001$) (G1-2 $P=0.0001$, G1-3 $P=0.0001$, G2-3 $p=0.0001$). And the Md percentage increment of HDL cholesterol G1-3 was 12%, 7%, 0% ($p=0.03$) (G1-2 $p=0.14$, G1-3 $p=0.015$, G2-3 $p=0.14$). No serious adverse event was observed.

Conclusions: In this trial of HTG Mexican patients, rosuvastatin significantly reduce TG levels and improve the atherogenic lipid profile.