ACC.15
TCT@ACC-i2 | innovation in intervention

A1633
JACC March 17, 2015
Volume 65, Issue 10S

Stable Ischemic Heart Disease

EZETIMIBE DOES NOT INCREASE FASTING GLUCOSE LEVELS MORE THAN STATINS ALONE IN NON-DIABETIC, HYPERCHOLESTEROLEMIC PATIENTS

Poster Contributions
Poster Hall B1
Sunday, March 15, 2015, 9:45 a.m.-10:30 a.m.

Session Title: Lipids and Lipid Lowering in Stable Ischemic Heart Disease
Abstract Category: 27. Stable Ischemic Heart Disease: Therapy
Presentation Number: 1194-364

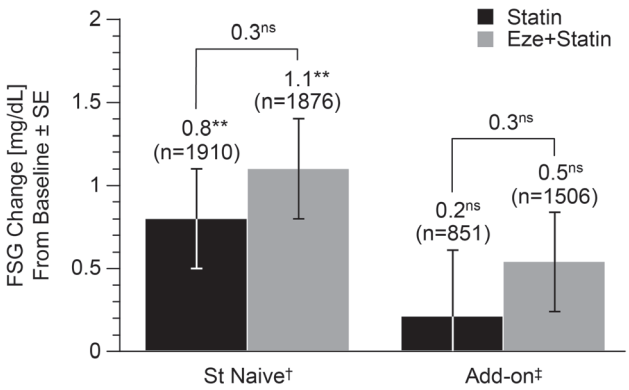
Authors: *Peter P. Toth, Alberico Catapano, Michel Farnier, JoAnne Foody, Joanne Tomassini, Erin Jensen, Adam Polis, Thomas Musliner, Andrew Tershakovec, Merck & Co., Inc., Whitehouse Station, NJ, USA, CGH Medical Center, Sterling, IL, USA*

Background: Statin (St) therapy can be associated with a slightly increased risk of diabetes mellitus (DM) and insulin resistance in nonDM patients. In prior studies, ezetimibe (Eze)+St did not increase fasting serum glucose (FSG) more than St alone in St naïve, nonDM, hypercholesterolemic (HC) patients for up to 96 wks. This analysis assessed the effects of Eze on FSG changes when given to nonDM, HC patients on stable St therapy.

Methods: Data was pooled from 2 randomized, double blind, add on‡ (Eze added to stable St [n=1506] vs placebo [n=851] studies) for 8 wks in nonDM patients at baseline (BL). Mean FSG changes from BL were estimated for each treatment group (LDA model¶) and between treatment differences calculated. Numbers of patients with FSG ≥126 mg/dl and effect of BL cofactors were also assessed.

Results: No significant FSG increases from BL were observed with St and Eze+St in add on studies; the between treatment group difference was also not significant (p>0.05; Figure). The lack of an Eze effect on FSG is consistent with prior findings in St naïve subjects comparing Eze+St vs St. FSG changes were not related to age, and BL BMI, HDL-C and TG, nor to changes from baseline in LDL-C, BMI, HDL-C, TG and ApoB. Proportions of patients with FSG ≥126 mg/dl during the trial were low, similar for St and Eze+St, and highest in those with BL FSG ≥100-≤126 mg/dL.

Conclusion: In HC patients on stable St therapy, addition of Eze did not increase FSG levels more than St therapy, consistent with Eze+St therapy effects in St naïve patients.



†1st line: 7 studies in St-naïve/drug wash-out HC patients treated with Eze 10 mg + St vs St (10 to 80 mg of simvastatin and atorvastatin, 10 to 40 mg lovastatin and pravastatin) during 12 weeks; ‡2nd line Add-on: 2 studies in HC patients on St therapy (10 to 80 mg of atorvastatin, simvastatin, pravastatin, fluvastatin and lovastatin, 0.2 to 0.8 mg cerivastatin) ≥6 weeks prior to study entry, randomized to Eze 10 mg vs placebo; ns=not statistically significant at the 0.05 alpha level; **p<0.01. Change from baseline assessed using longitudinal data analysis (LDA) model with terms for treatment and trial¶.