SHORT-TERM AND LONG-TERM EFFECTS OF PITAVASTATIN AND SIMVASTATIN ON FASTING PLASMA GLUCOSE IN PATIENTS WITH PRIMARY HYPERLIPIDEMIA OR MIXED DYSLIPIDEMIA AND ≥2 RISK FACTORS FOR CORONARY HEART DISEASE

ACC Moderated Poster Contributions
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Background: Recent meta-analyses showed deterioration of glucose metabolism following administration of statins. Limited information is available on the glycemic effect of a recently approved statin, pitavastatin (PTA). In Phase 3 non-inferiority trials, LDL-C reductions with PTA 2 mg and 4 mg were comparable to simvastatin (SMV) 20 mg and 40 mg, respectively. This post-hoc analysis examined the short- and long-term effects of PTA 4 mg (maximum dose) compared with SMV 40 mg (recently approved maximum dose) on changes in fasting plasma glucose (FPG) in patients with primary hyperlipidemia (PH) or mixed dyslipidemia (MD) and ≥2 risk factors for coronary heart disease (CHD).

Methods: FPG data were prospectively collected as part of a 12-week, Phase 3 study comparing PTA 4 mg (n=228) with SMV 40 mg (n=111) in patients with PH or MD and ≥2 risk factors for CHD (NK-104-304) and as part of the 44-week extension study (NK-104-309) in patients who elected to continue therapy beyond 12 weeks [PTA 4 mg (N=116) and SMV 40 mg (N=49)]. Changes in FPG levels from baseline to end of the 12-week trial and through completion of the extension period (56 weeks total) were assessed using t-tests and between treatments using a general linear model, adjusting for country, age, gender, body mass index, and use of ACE inhibitor, diuretic, or ß-blocker at randomization.

Results: No significant changes in FPG when compared with baseline were observed with PTA at 12 weeks (mean change -0.03 mg/dL, p=0.963) or at 56 weeks (2.2 mg/dL, p=0.060). FPG was unchanged with SMV at 12 weeks (-1.40 mg/dL, p=0.209), but was significantly increased (7.5 mg/dL, p=0.0001) at 56 weeks. After excluding patients with type 2 diabetes mellitus, consistent results were observed for PTA at 12 weeks (-0.35, p=0.564) and at 56 weeks (n=110, 2.3, p=0.054) as well as for SMV (n=103, -1.2, p=0.286 at 12 weeks and n=46, 7.1, p<0.0001 at 56 weeks).

Conclusions: Both short- (12-week) and long-term (56-week) therapy with PTA 4 mg did not significantly change FPG, while long-term treatment with SMV 40 mg significantly increased FPG in patients with PH or MD and ≥2 risk factors for CHD. Further studies are needed to confirm these findings and their relevance to clinical outcomes.