Immediate-Release Niacin (NIALOR®) Suppresses Postprandial Lipemia to a Much Greater Extent Than Extended-Release Niacin (NIASPAN®): A Head-to-Head, Double-blind, Crossover Trial

Introduction. In cardiovascular outcome trials, diurnally-dosed immediate-release (IR) niacin prevented Coronary Heart Disease events and all-cause mortality, whereas nocturnally-dosed extended-release (ER) niacin failed to do so.

Hypothesis. NIASPAN® (ER niacin) does not suppress postprandial lipemia as effectively as NIALOR ® (IR niacin).

Methods. In a random-order, double-blind crossover study, we conducted oral fat tolerance tests (OFTTs) on dyslipidemic patients following placebo, ER niacin (NIASPAN®), and IR niacin (NIALOR®). Fasted subjects took study drug 1h before an OFTT of heavy cream (50gm/m2 fat), and blood was sampled multiple times over 12h. ER niacin (NIASPAN®) was given as a single 2g dose, whereas 2g IR niacin (NIALOR®) was dosed as 500mg q2h x 4 to emulate ER niacin exposure. We assessed postprandial triglycerides (ppTGs, mg/dL) by area under the curve (AUC 0-12h, mg/dL*h) and incremental AUC (incAUC). Healthy controls underwent an OFTT on placebo.

Results. We enrolled 23 dyslipidemic patients and 22 healthy controls. In dyslipidemic subjects on placebo, fasting TGs rose +134 mg/dL post-fat: AUC 2035, incAUC +786. IR niacin (NIALOR®) significantly suppressed ppTGs, rising only +78 mg/dL: AUC 1554 (p=0.001 vs placebo), incAUC +380 (p=0.001 vs placebo). Importantly, ER niacin (NIASPAN®) had no significant effect on ppTGs compared with placebo, with TGs rising +123 mg/dL over baseline: AUC 1864 (p=0.20 vs placebo), incAUC +652 (p=0.31 vs placebo). IR niacin (NIALOR®) lowered ppTGs to a significantly greater extent compared to ER niacin (p=0.001). Healthy controls on placebo had an AUC of 1563 (p=0.95 vs IR niacin in dyslipidemics) and incAUC +369 (p=0.92 vs IR niacin in dyslipidemics). IR niacin (NIALOR®), but not ER niacin (NIASPAN®), normalized the postprandial lipid response in dyslipidemic subjects.

Conclusions. Acutely-dosed IR niacin (NIALOR®) robustly suppressed postprandial lipemia in dyslipidemic subjects compared to placebo-treated healthy controls. In marked contrast, the same dose of ER niacin (NIASPAN®) failed to significantly suppress postprandial lipemia. This suggests ER niacin is inferior to IR niacin in reducing atherogenic postprandial lipoproteins, which importantly contribute to atherogenesis and coronary disease. This finding may help explain why IR niacin was effective in reducing Coronary Heart Disease events in outcome trials whereas ER niacin was not.