

NEJM Study Finds No Benefit to Statin Therapy in Adding Niacin



According to the results of a study published early online in the New England Journal of Medicine, the addition of niacin to statin therapy in patients with atherosclerotic cardiovascular disease and LDL cholesterol levels of <math><1.81\text{ mmol/L}</math> was not associated with any clinical benefits.

The authors note that elevated low-density lipoprotein cholesterol (LDL-C) levels are an established predictor of coronary heart disease (CHD) risk; there is however a residual risk seen despite achievement of target LDL-C levels. Epidemiological studies have suggested that low levels of high density lipoprotein cholesterol (HDL-C) are also an independent predictor of CHD risk, with a strong inverse relationship between levels and the rate of CHD events. Previous research has also suggested that HDL-C levels may have a prognostic value for patients receiving statin therapy that is independent of LDL cholesterol levels.

The purpose of the current study (AIM-HIGH) was to determine whether the addition of extended-release niacin to intensive statin therapy could reduce the risk of cardiovascular events in patients with established atherosclerotic cardiovascular disease and atherogenic dyslipidaemia (low levels of HDL-C, elevated triglyceride levels, and small, dense particles of LDL-C). A total of 3,414 such patients were randomised to treatment with niacin (1500-2000mg/day; $n=1,718$) or placebo ($n=1,696$) in combination with simvastatin (40-80mg/day) and ezetimibe if needed (10mg/day), to maintain target LDL-C levels (1.03-2.07 mmol/L).

The study was terminated after a mean follow-up of three years due to the lack of efficacy seen. The authors report that the primary endpoint of a first event out of a composite of death from coronary heart disease, nonfatal myocardial infarction, ischaemic stroke, hospitalisation for an acute coronary syndrome, or symptom-driven coronary or cerebral revascularisation, was seen in 16.4% of the niacin group and 16.2% of the placebo group (hazard ratio [HR] 1.02; 95% CI 0.87-1.21; $p=0.79$). This was despite a significant increase in median HDL-C, as well as improvements in triglyceride levels and LDL-C levels.

The authors acknowledge a number of limitations of their study, including the fact that the study may not have been long enough to detect any clinical treatment effect of niacin. They comment that further study is required to determine whether any benefits might be seen in higher-risk cardiac patients, or those whose LDL-C levels are not intensively controlled by statins.

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