



Efficacy of new niacin/simvastatin combination product

Data presented at the Scientific Sessions of the American Heart Association Annual Meeting, showed that combination extended release (ER) niacin/simvastatin was effective and well-tolerated. According to Christie Ballantyne, Baylor College of Medicine and Methodist DeBakey Heart Center, Houston, Texas, this approach could be an important tool in treating patients with complex lipid disorders.

This was a double-blind, randomised 24-week study in more than 600 patients with elevated non-HDL cholesterol (type II hyperlipidaemia or mixed dyslipidaemia). After a run-in on simvastatin monotherapy, patients were assigned to either a low-dose (20 mg) or high-dose simvastatin group. In the low-dose group, patients were randomised to daily treatment with ER niacin/simvastatin (2000/20 mg or 1000/20 mg) or simvastatin 20 mg. In the high-dose group, patients were randomised to daily treatment with ER niacin/simvastatin (2000/40 mg or 1000/40 mg) or simvastatin 80 mg. Patients in the simvastatin monotherapy groups also received 50 mg immediate-release niacin to maintain blinding.

Patients in the low-dose group on combination treatment achieved dose-related improvement in all lipid parameters (Table 1).

Table 1. Lipid changes from baseline (%) in low-dose simvastatin group

Treatment	Non-HDL-C	LDL-C	TG	HDL-C
Niacin/S (1000/20 mg)	-14	-13	-27	+18
Niacin/S (2000/20 mg)	-23	-14	-38	+25
S (20 mg)	-7	-7	15	+7

In the high-dose simvastatin group, both combination doses (with 40 mg simvastatin) were comparable to simvastatin 80 mg monotherapy with respect to reduction in non-HDL-C and showed dose-related improvements in HDL cholesterol and triglycerides (Table 2).

Table 2. Lipid changes from baseline (%) in high-dose simvastatin group

Treatment	Non-HDL-C	LDL-C	TG	HDL-C
Niacin/S (1000/40 mg)	-11	-9	-23	+15
Niacin/S (2000/40 mg)	-17	-12	-32	+22
S (80 mg)	-10	-13	+0.3	-1

Treatment with the four different doses of ER niacin/simvastatin was well tolerated.

Flushing occurred in 59% of patients on ER niacin/simvastatin and 47% of patients on simvastatin monotherapy; 6% and 0.8% of these patients discontinued due to flushing. There was no evidence for increased risk of hepatotoxicity or myopathy with the combination therapy.

Reference

1. Ballantyne C, Davidson M, McKenney J et al. The safety and efficacy of a combination of extended-release niacin and simvastatin in patients with dyslipidemia (SEACOAST): A dose-ranging study. *Circulation* 2007;116:II_127. Abstract 188.