スタチンとナイアシンの併用（Abstract＃188）

SEACOASTトライアルの結果、シンバスタチンと徐放性ナイアシンの併用はシンバスタチン単独よりも脂質プロファイルを有意に効果的に改善することが示唆された

SEACOAST trial suggests simvastatin plus extended-release niacin is significantly more effective than simvastatin alone for improving lipid profiles

SEACOASTトライアルの結果、シンバスタチンと徐放性ナイアシンの併用はシンバスタチン単独よりも脂質プロファイルを有意に効果的に改善することが示唆された、とAmerican Heart Association学会で発表された。この24週間のトライアルでは、シンバスタチン20mgまたは40mgと徐放性ナイアシンの併用、または対照群のシンバスタチン80mgと短時間作用型ナイアシンを併用する群に無作為に割り付けた。低用量併用療法群の患者はシンバスタチン20mg単独群と比較し、non-HDLコレステロールが有意に低下しまたHDLコレステロールおよび中性脂肪レベルが有意に改善した。40mgシンバスタチンを含む高用量併用療法群の患者はシンバスタチン80mg単独と同程度にnon-HDLコレステロールが低下し、HDLコレステロールおよび中性脂肪は80mgシンバスタチン単独よりも有意により改善した。

Full Text

The phase III SEACOAST trial suggests that a fixed-dose combination of simvastatin and extended-release niacin is significantly more effective than simvastatin alone for improving lipid profiles, according to a presentation at the annual meeting of the American Heart Association.

The combination product included the manufacturer's proprietary extended-release niacin, NiaspanR.
The 24-week enrolled more than 600 patients with elevated non-HDL (type II hyperlipidemia or mixed dyslipidemia) to compare simvastatin alone to a combination of extended-release niacin combined with simvastatin. The study was designed to evaluate the safety and efficacy of the combination following simvastatin monotherapy.

Patients randomized to the low-dose group received Niaspan 2000 mg/simvastatin 20 mg, Niaspan 1000 mg/simvastatin 20 mg, or simvastatin 20 mg. Patients in the high-dose group received Niaspan 2000 mg/simvastatin 40 mg, Niaspan 1000 mg/simvastatin 40 mg or simvastatin 80 mg. Those in the simvastatin control groups received a 50 mg dose of immediate-release niacin to maintain blinding.

Patients in the low-dose group receiving combination treatment achieved 14-percent (1000 mg/20 mg) and 23-percent (2000 mg/20 mg) reductions in non-high-density cholesterol compared with a 7-percent reduction with 20 mg simvastatin therapy alone.

Additionally, combination treatment resulted in significant improvements in high-density cholesterol of 18 percent (1000 mg/20 mg) and 25 percent (2000 mg/20 mg) compared with 7 percent with 20 mg simvastatin alone. Similarly, significant reductions in triglycerides of 27 percent (1000 mg/20 mg) and 38 percent (2000 mg/20 mg) were seen in those treated with combination therapy compared with a 15-percent reduction with simvastatin monotherapy.

In the high-dose group, patients treated with combination therapy showed similar (non-inferior) improvements in non-high-density cholesterol of 11 percent (1000 mg/40 mg) and 17 percent (2000 mg/40 mg) compared with a 10-percent improvement with 80 mg simvastatin therapy alone. Additionally, the high-dose combination group demonstrated significant improvements in high-density cholesterol of 15 percent (1000 mg/40 mg) and 22 percent (2000 mg/40 mg) compared with a 1-percent decrease for 80 mg simvastatin monotherapy. Triglyceride levels among the high-dose combinations groups dropped 23 percent and 32 percent, respectively, in contrast to a 0.3 percent increase in those randomized to 80 mg simvastatin monotherapy.

Treatment with the four different doses of niacin combined with simvastatin for 24 weeks was well tolerated. There was no evidence for increased risk of hepatotoxicity or myopathy with the combination.

Patients in the study treated with the low-dose combination containing 20 mg simvastatin had significantly better reductions in non-high-density lipoprotein cholesterol compared with 20 mg simvastatin therapy alone, as well as significant improvements in high-density cholesterol and triglyceride levels.

Patients who received the high-dose combination with 40 mg simvastatin experienced reductions in non-high-density cholesterol comparable with 80 mg simvastatin alone, as well as significantly better improvements in high-density cholesterol and triglycerides than achieved with 80 mg simvastatin alone.

Flushing was the most commonly reported side effect associated with niacin. It was generally mild and could be lessened by taking aspirin 30 minutes prior to taking the medication at bedtime. Six percent of patients on the combination discontinued therapy due to flushing compared with a 0.8 percent discontinuation rate with simvastatin alone.

"Patients know that it's important to manage the "bad" cholesterol, but it's essential to control HDL and triglyceride levels as well," said Christie Ballantyne, MD, Baylor College of Medicine and Methodist DeBakey Heart Center, Houston, Texas, and lead investigator on the study. "With the SEACOAST study, SIMCOR provided comparable LDL lowering to simvastatin with significant benefit in raising good cholesterol and lowering triglycerides. This type of combination approach could be an important tool in treating patients with complex lipid disorders."