MedicalXpress

Intensive cholesterol-lowering treatment: No significantly better outcomes

August 29 2016

Survival and other cardiovascular outcomes were not significantly reduced with intensive treatment using a second-line cholesterol-lowering medication on top of a standard statin, compared to statin treatment alone in patients with acute coronary syndrome (ACS) and dyslipidemia, investigators reported here.

However, findings from a sub-analysis of the HIJ-PROPER (Heart Institute of Japan-PRoper level of lipid lOwering with Pitavastatin and Ezetimibe in acute coRonary syndrome) trial offer some intriguing clues that might help identify patients who could benefit from the more intensive cholesterol-lowering regimen.

"Although the results from our study were negative, they also suggest a potentially interesting direction for future research," noted presenter Nobuhisa Hagiwara, MD, PhD, from Tokyo Women's Medical University, who presented the study a Hot Line session at ESC Congress 2016.

"Based on these findings we should next assess whether evaluating cholesterol absorption markers might be a potentially new way to personalize cholesterol treatment strategies in a real-world clinical setting."

The study included 1,734 patients with ACS and dyslipidemia from 19 hospitals in Japan.

All patients had undergone coronary angiography and were then randomized to receive an intensive cholesterol-lowering combination of statin (pitavastatin) plus ezetimibe (with a target low-density lipoprotein cholesterol (LDL-C) level of of ? 70 mg/dL), or pitavastatin alone (with an LDL-C target of 90 to 100 mg/dL).

The primary endpoint of the study was a composite of all-cause death, non-fatal myocardial infarction, non-fatal stroke, unstable angina, or revascularization with either percutaneous coronary intervention (PCI) or coronary-artery bypass grafting (CABG).

After a follow-up of at least 3 years, the more intensive treatment was not associated with significantly better rates of the primary endpoint (hazard ratio [HR] 0.89, 95% confidence interval [CI] 0.76-1.04, P=0.152), or any of the individual components of it.

However, a subgroup of patients with higher baseline levels of the cholesterol absorption marker sitosterol (median value more than 2.2 μg/mL) did derive significant benefit from the intensive regimen, reported Prof Hagiwara.

In this subgroup, the primary endpoint occurred significantly less often in the intensively-treated compared to the statin monotherapy arm (HR 0.71, 95% CI 0.56-0.91. P-value for interaction=0.010) - a finding that was not seen among those with baseline sitosterol levels below this value (HR 1.11, 95% CI 0.88-1.39).

"Statins inhibit cholesterol synthesis but do not affect cholesterol absorption," explained Professor Hagiwara. "In this pre-specified sub-analysis we showed that individuals with high levels of cholesterol absorption responded favourably to the more intensive treatment. Obviously more research is needed, but this suggests that measurement of cholesterol absorption may help to identify which patients might

benefit from treatment with combination statin plus ezetimibe therapy."

Although statin therapy is highly effective in reducing LDL-C to a certain point, further decreases are difficult to achieve, he added. As a result, less than 30% of high-risk patients treated with statin monotherapy currently reach their optimal LDL-C goal in a real-world setting.

"We now think that inhibiting cholesterol absorption may be instrumental in reducing cardiovascular events in ACS patients with high cholesterol absorption. This subanalysis from the HIJ-PROPER trial suggests that combined inhibition of both cholesterol synthesis and cholesterol absorption may help us reduce cardiovascular events in these patients."

Provided by European Society of Cardiology

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