エボロクマブはPAD患者における心血管イベントリスクを低下させる(2017 AHA, Session

FOURIER：PCSK9阻害薬は末梢動脈疾患患者の予後を改善する

FOURIER: PCSK9 inhibitor improves outcomes for patients with peripheral artery disease

末梢動脈疾患（PAD）患者に対し、スタチン療法にPCSK9阻害薬エボロクマブを併用することで将来の心血管イベントリスクを軽減することが示された、とのFOURIER 試験のサブ解析の結果が2017 American Heart Association Scientific Sessions で発表され、*Circulation* に掲載された。PAD患者はMIまたは脳卒中リスクが高いため、心血管イベントの絶対リスク減少率が大であった（PAD患者3.1%、非PAD患者1.6%）。エボロクマブは、PAD患者の主要有害下肢イベントリスクを、プラセボに比べ約半分に低下させた。PADを有しMIまたは脳卒中リスクを有さない患者において、エボロクマブは2.5年間の心血管または有害下肢イベントリスクを6% 低下させた。

Full Text

Patients with peripheral artery disease (PAD) are at high risk of myocardial infarction (MI), stroke and cardiovascular death. In addition, PAD patients can suffer major adverse limb events, such as acute limb ischemia that can lead to limb loss. Managing PAD is challenging for patients and physicians alike - despite best available treatment including high-intensity statins, risk of cardiovascular and limb events remains high. With few clinical trials focused on patients with PAD, physicians must often extrapolate from studies in broader populations with atherosclerosis about the best treatment approach for these patients. Unfortunately, few of these studies have characterized limb risk and fewer have demonstrated benefits of preventive therapies in reducing this risk.

A new sub-analysis of the FOURIER clinical trial, however, now offers information on the safety and effectiveness of giving the PCSK9 inhibitor evolocumab on top of statin therapy to this high-risk population. At the 2017 American Heart Association Scientific Sessions, Marc Bonaca, MD, MPH, investigator at the TIMI Study Group and director of the Aortic Disease Center at Brigham and Women's Hospital, presented results from the sub-analysis, which are published simultaneously in *Circulation*.

"Whenever trials like FOURIER demonstrate benefit of a therapy in a broad population, we then want to understand the efficacy and safety in subpopulations to help clinicians understand which patients are going to derive the greatest absolute benefit. We've found that several sub-groups of patients respond well to evolocumab, but it's especially encouraging to see these results for patients with PAD since this is a population at heightened cardiovascular risk and there are few therapies that modify limb risk," said Bonaca. "We see that adding evolocumab can make a big difference for these patients."

The team analyzed data from more than 3,600 trial participants, half of whom had no history of an MI or stroke. Evolocumab reduced risk of a future cardiovascular event for patients with or without PAD. Because patients with PAD are at especially high risk of a MI or stroke, these patients had a higher absolute risk reduction (3.5% PAD, 1.6% no PAD) of a cardiovascular event. In addition, evolocumab reduced their risk of a major adverse limb event by about half, compared to PAD patients who received the placebo. Among patients with PAD and no history of an MI or stroke, evolocumab reduced risk of a cardiovascular or adverse limb event by 6 percent over 2.5 years. Researchers report that the number needed to treat (NNT) is as low as 16 for this patient population. The team found no offsetting safety concerns.

Bonaca presented PAD findings as part of a Clinical Trials Update at the Scientific Sessions.

Evolocumab is a member of a new class of cholesterol lowering drugs known as PCSK9 inhibitors that have emerged as an effective treatment for drastically lowering LDL cholesterol beyond what is possible with statin therapy alone. Previous research demonstrated that evolocumab effectively reduces LDL cholesterol by approximately 60 percent. The FOURIER trial (Further Cardiovascular OUtcomes Research with PCSK9 Inhibition in subjects with Elevated Risk) was designed to determine whether evolocumab, when added to statin therapy, would reduce adverse cardiovascular events.

FOURIER was designed in a collaboration between the Executive Committee and the trial sponsor, Amgen, which manufactures evolocumab and provided a research grant to the TIMI Study Group at BWH. The TIMI Study Group conducted all data analyses presented in the paper. Sabatine and the TIMI Study Group receive research grants from various pharmaceutical companies that produce other lipid-lowering therapies and Sabatine reports receiving honoraria from Amgen and various pharmaceutical companies that produce other lipid-lowering therapies.

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