高用量EPAによる心血管疾患予防 (LBS.01 Abstract 19515)

REDUCE-IT：高用量の高純度EPAを含むオメガ3脂肪酸製剤は心血管イベントのリスクを軽減する

REDUCE-IT: High dose of pure EPA in omega-3 drug cuts risk of cardiovascular events

EPAとして知られ高純度かつ安定した形のオメガ３脂肪酸は、スタチンを内服しても依然として心血管疾患リスクが高い患者における心血管疾患、心筋梗塞、および脳卒中による死亡リスクを軽減した、とAmerican Heart Association Scientific Sessions 2018で発表され、同時に*New England Journal of Medicine*に掲載された。REDUCE-ITトライアルの結果、イコサペント酸エチルが重大な心血管イベントを25%減少させ、うち20%は心血管疾患死の減少、31%はMIの減少であり、28%は脳卒中の減少であった。

Full Text

Results released from a major clinical trial may have direct implications for patients who remain at increased cardiovascular risk despite taking statin therapy. The trial, led by investigators at Brigham and Women's Hospital, has found that a drug developed by Amarin Corporation plc, icosapent ethyl – a pure and stable form of the omega-3 acid known as EPA – reduced the risk of death due to cardiovascular causes, myocardial infarction (MI), and stroke in this population.

The main results of the Reduction of Cardiovascular Events with Icosapent Ethyl-Intervention Trial (REDUCE-IT) were presented by Deepak L. Bhatt, MD, MPH, executive director of Interventional Cardiovascular Programs at the Brigham and professor of medicine at Harvard Medical School, at the American Heart Association Scientific Sessions 2018 and published simultaneously in the *New England Journal of Medicine*.

"We are reporting a remarkable degree of risk reduction," said Bhatt. "We've found that icosapent ethyl reduced the risk of important cardiovascular events by 25 percent, including a 20 percent reduction in death due to cardiovascular causes, a 31 percent reduction in MI, and a 28 percent reduction in stroke. The REDUCE-IT trial sets a new standard of care for patients who have elevated triglycerides and are at increased cardiovascular risk despite statin therapy. This may be the biggest development in cardiovascular prevention since statins."

Icosapent ethyl is a prescription medication approved to reduce triglyceride levels in patients with very high triglycerides. Studies have suggested that icosapent ethyl may have additional attributes such as anti-inflammatory and cell membrane-stabilizing properties that may also contribute to reducing cardiovascular risk.

REDUCE-IT included more than 8,000 patients with well-controlled LDL-cholesterol who were taking statins to prevent a first or subsequent cardiovascular event. Approximately 70 percent of patients in the study had established atherosclerosis and the rest had diabetes plus at least one other cardiovascular risk factor. Patients had triglyceride levels that ranged from borderline high (135 mg/dL) to near very high (499 mg/dL). Patients were randomized to receive either 2 grams icosapent ethyl twice daily or a placebo and were followed for an average of approximately five years.

Hospitalization for chest pain, MI, procedures for coronary artery disease such as stenting, stroke, and cardiovascular death occurred in 17.2 percent of patients taking icosapent ethyl versus 22 percent of patients taking the placebo – an absolute risk reduction of 4.8 percent. The team also reported a significant 26 percent reduction in the trial's key secondary endpoint, which included cardiovascular death, nonfatal heart attack, or nonfatal stroke (11.2 percent for the icosapent ethyl group vs. 14.8 percent for the placebo group).

The researchers note that cardiovascular benefits appeared similar irrespective of patients' baseline levels of triglycerides or levels achieved after one year, suggesting that the cardiovascular risk reduction was not solely tied to achieving a more normal triglyceride level.

"The exact mechanisms responsible for the impressive benefits seen in the REDUCE-IT trial are not currently known," said Bhatt. "The significant effects on very different endpoints, such as cardiac arrest and stroke, suggest that this drug may have multiple biological mechanisms of action that have not been shown for any other therapy and cannot be generalized to other omega-3 products."

REDUCE-IT was sponsored by Amarin. Brigham and Women's Hospital receives research funding from Amarin for the work Bhatt did as the trial chair and as the international principal investigator.

Cardiology特集

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