

Ezetimibe reduces cardiovascular events in diabetics with recent acute coronary syndrome

August 30 2015

Ezetimibe reduces cardiovascular events in patients with diabetes and a recent acute coronary syndrome, according to a subgroup analysis of the IMPROVE-IT trial presented at ESC Congress today by co-principal investigator Dr Robert Giugliano, physician in cardiovascular medicine at Brigham and Women's Hospital in Boston, US. Ezetimibe achieved greater reductions in LDL cholesterol than statins alone, resulting in lower risks of cardiovascular events in patients with diabetes. The benefits observed in diabetics were greater than in those without diabetes.

"Acute coronary syndromes, including myocardial infarction (heart attack) and [unstable angina](#) (threatened [heart attack](#)), are a leading cause of death and disability worldwide," said Dr Giugliano. "In addition to lifestyle changes, medications to lower blood cholesterol are helpful to prevent future cardiac and vascular events such as myocardial infarction and stroke. Statins are recommended for patients with and without diabetes, but the benefit of adding a non-statin has been less clear."

Improved Reduction of Outcomes: Vytorin Efficacy International Trial (IMPROVE-IT) is the largest and longest study with ezetimibe. The six year trial included 18 144 patients who had been hospitalised with an acute coronary syndrome within the previous ten days, were not being treated with ezetimibe or the highest dose of potent statins, and who had an LDL cholesterol between 1.3 and 3.2 mmol/L (50-125 mg/dL).

Patients were randomised to ezetimibe (10 mg) or placebo. All patients received 40 mg simvastatin, which was increased to 80 mg if LDL cholesterol on treatment was greater than 2.04 mmol/L (79 mg/dL).

Patients were followed for a median of six years for the primary composite of cardiovascular death, myocardial infarction (MI), hospitalisation for unstable angina, [coronary revascularization](#) ?30 days, and stroke. The main finding of the trial was that ezetimibe significantly reduced the chances of a future major cardiac or vascular event by 6.4% compared to placebo, with no increase in adverse safety events.²

The analysis presented today provides the outcomes in the 4 933 (27%) patients with diabetes, one of the prespecified subgroups. The investigators found that in diabetics, ezetimibe added to a statin lowered LDL cholesterol at 1 year by 1.1 mmol/L (43 mg/dL) compared with 0.6 mmol/L (23 mg/dL) with a statin alone. Diabetics receiving ezetimibe had a 14% relative risk reduction (5.5% absolute reduction; number needed to treat [NNT] = 18) over placebo for the primary composite endpoint (hazard ratio [HR] = 0.86; 95% confidence interval [CI] = 0.78-0.94) compared with a 2% relative reduction for non-diabetics (HR = 0.98; 95% CI = 0.91-1.04).

"The non-statin, cholesterol-lowering drug ezetimibe, when added to background therapy with a statin, was particularly effective in patients with diabetes who had been admitted to the hospital with an acute coronary syndrome," said Dr Giugliano. "Ezetimibe is an oral drug taken once daily that reduces LDL (or 'bad') cholesterol) by blocking cholesterol absorption in the gut. This is a different action than that of statins, which block cholesterol production in the liver and have been shown to be highly effective in preventing cardiac and vascular events in a wide variety of patients."

In diabetics, the greatest reductions in cardiovascular events were in

ischaemic stroke (39%), myocardial infarction (24%), and the composite of death due to cardiovascular causes, [myocardial infarction](#), or stroke (20%). In diabetics and non-diabetics, there were no differences between ezetimibe and placebo in safety outcomes including liver test abnormalities, muscle side effects, gall bladder related events and cancer.

Dr Giugliano concluded: "Our results are particularly good news for [patients](#) with diabetes who have coronary artery disease. We found that in diabetics with recent acute coronary syndrome, ezetimibe added to simvastatin reduced LDL cholesterol by (0.5 mmol/L) (20 mg/dL) more than simvastatin alone and achieved an average LDL [cholesterol](#) of 1.4 mmol/L (54 mg/dL). This greater reduction resulted in lower risks of future [cardiovascular events](#) relative to placebo."

More information: Dr Giugliano will present the abstract 'Benefit of Adding Ezetimibe to Statin Therapy on Cardiovascular Outcomes and Safety in Patients With vs Without Diabetes: the IMPROVE-IT Trial'

Provided by European Society of Cardiology

Citation: Ezetimibe reduces cardiovascular events in diabetics with recent acute coronary syndrome (2015, August 30) retrieved 6 May 2024 from <https://medicalxpress.com/news/2015-08-ezetimibe-cardiovascular-events-diabetics-acute.html>

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