Medication does not reduce risk of recurrent CV events among patients with diabetes

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Use of the drug aleglitazar, which has shown the ability to lower glucose levels and have favorable effects on cholesterol, did not reduce the risk of cardiovascular death, heart attack or stroke among patients with type 2 diabetes and recent heart attack or unstable angina, according to a *JAMA* study released online to coincide with presentation at the 2014 American College of Cardiology Scientific Sessions.

Cardiovascular disease remains the dominant cause of death among patients with type 2 diabetes. No drug therapy specifically directed against diabetes nor strategy for tight glucose control has been shown to unequivocally reduce the rate of cardiovascular complications in this population, according to background information in the article. In phase 2 trials, aleglitazar significantly reduced glycated hemoglobin levels (measure of blood glucose over an extended period of time), triglycerides, and low-density lipoprotein cholesterol and increased high-density lipoprotein cholesterol (HDL-C).

A. Michael Lincoff, M.D., of the Cleveland Clinic, and colleagues conducted a phase 3 trial in which 7,226 patients hospitalized for heart attack or unstable angina with type 2 diabetes were randomly assigned to receive aleglitazar or placebo daily. The AleCardio trial was conducted in 720 hospitals in 26 countries throughout North America, Latin America, Europe, and Asia-Pacific regions.

The trial was terminated early (July 2013) after an average follow-up of 104 weeks, due to lack of efficacy and a higher rate of adverse events in

the aleglitazar group.

The researchers found that although aleglitazar reduced glycated hemoglobin and improved serum HDL-C and triglyceride levels, the drug did not decrease the time to cardiovascular death, nonfatal heart attack, or nonfatal stroke (primary end points). These events occurred in 344 patients (9.5 percent) in the aleglitazar group and 360 patients (10.0 percent) in the placebo group.

Aleglitazar use was associated with increased risk of kidney abnormalities, bone fractures, gastrointestinal bleeding, and hypoglycemia (low blood sugars).

"These findings do not support the use of aleglitazar in this setting with a goal of reducing cardiovascular risk," the authors conclude.

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