No increased cardiovascular risk detected for new diabetes medication

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An international, multidisciplinary team including investigators from Brigham and Women's Hospital (BWH) has found that lixisenatide, a member of a class of glucose-lowering drugs frequently prescribed in Europe to patients with diabetes, did not increase risk of cardiovascular events including heart failure. These results - the first to be reported on the cardiovascular safety of a glucagon-like peptide 1 (GLP-1) receptor agonist - were presented today at the American Diabetes Association's 75th Scientific Sessions.

"There are a large number of patients around the world who take this class of agents to help manage their glucose -based on our results patients and their healthcare providers should be reassured of the cardiovascular safety of lixisenatide even if they are at high risk for heart-related problems," said Marc Pfeffer, MD, PhD, a member of the Cardiovascular Medicine Division at BWH, professor at Harvard Medical School and principal investigator for the ELIXA (Evaluation of LIXisenatide in Acute Coronary Syndrome) trial.

Patients with type 2 diabetes are at high risk for developing cardiovascular disease and some glucose-lowering drugs have been associated with an additional increase risk of adverse cardiovascular effects. These observations prompted the US Food and Drug Administration and the European Medicines Agency to establish guidelines for clinical trials to ensure that new therapies do not put type 2 diabetes patients at increased cardiovascular risk.

In the ELIXA study, researchers enrolled more than 6,000 type 2 diabetes patients from 49 countries who had recently recovered from a heart attack or other acute coronary event to evaluate the effects of lixisenatide on a population at high risk of a cardiovascular event. The large, double-blind, placebo-controlled study measured multiple outcomes, including cardiovascular death, heart attack, stroke, hospitalization for chest pain and heart failure.

Overall, the research team found that the drug had a neutral effect on risk of cardiovascular problems - that is, it neither increased nor decreased risk, all within the limits of the FDA's safety guidelines. In addition, lixisenatide provided a modest benefit in terms of weight gain, and no increase in cancers or pancreatitis.

"ELIXA provides data showing that this treatment can be used in a safe manner without worsening cardiovascular prognosis of patients with type 2 diabetes, even among the highest risk population - those with a pre-existing history of heart failure," said Eldrin Lewis, MD MPH, a physician in the Cardiovascular Medicine Division at BWH and an associate professor at Harvard Medical School.

For researchers at the Brigham and their collaborators, the results of the study are just the beginning: the data collected from 6,000 patients all over the world will be used for future analysis to better understand the prognosis for patients with diabetes.

"We now have an expansive data set from patients with type 2 diabetes from around the globe, and we look forward to collaborating with our international ELIXA co-investigators to further explore data about cardiovascular outcomes in this patient population," said Brian Claggett, PhD, of BWH's Cardiovascular Medicine Division.

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