

Incidence of Cardiovascular Events With Degludec Similar to Glargine

Safety study demonstrates noninferiority in patients with type 2 diabetes at high risk for cardiovascular events

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June 26, 2017 – The ultra-long-acting basal insulin degludec had a similar incidence of major cardiovascular events compared with insulin glargine in diabetic patients at elevated risk for cardiovascular events, according to the results of a new safety study.

Steven Marso, MD, with the Research Medical Center, in Kansas City, Missouri, and colleagues reported their findings on June 12 in the online publication of the *New England Journal of Medicine*.

Insulin degludec is a newer basal insulin with a long duration of action relative to insulin glargine (42 hours vs. 24 hours). Previous open-label trials have shown lower rates of hypoglycemia and more consistent glucose-lowering effects for degludec versus glargine. In light of the 2008 FDA guidance requiring the need to establish cardiovascular safety of new antihyperglycemic therapies, the DEVOTE study was conducted.

The DEVOTE study was a double-blind, event-driven cardiovascular outcomes trial in patients with type 2 diabetes at high risk for cardiovascular events. A total of 7,637 patients received either degludec or glargine administered once daily between dinner and bedtime, in addition to standard care. The primary endpoint was the occurrence of major cardiovascular event (death from cardiovascular causes, nonfatal myocardial infarction, or nonfatal stroke). Severe hypoglycemia was a defined secondary outcome.

A major cardiovascular event occurred in 8.5% of degludec patients versus 9.3% of glargine patients ($P < 0.001$ for noninferiority). Severe hypoglycemia occurred in 4.9% of patients receiving degludec versus 6.6% of glargine patients ($P < 0.001$ for superiority).

The rate of adverse events did not differ between the two therapies (44.7 vs. 50.1 events per 100 patient-years for degludec vs glargine).

The authors concluded, “In the context of this complex landscape of cardiovascular outcomes trials, we found that degludec was not associated with a greater risk of cardiovascular outcomes than was glargine at the same level of glycemic control.”

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Marso SP, McGuire DK, Zinman B, et al. Efficacy and Safety of Degludec versus Glargine in Type 2 Diabetes [published online June 12 2017]. *N Engl J Med*. 2017. doi: 10.1056/NEJMoa1615692.