

New, long-acting insulin therapy demonstrates Cardiovascular Safety

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Singapore - During a symposium, titled "Cardiovascular Safety of Insulin Degludec vs. Insulin Glargine in Patients with Type 2 Diabetes at High Risk of Cardiovascular Events (DEVOTE) Trial Results," at the American Diabetes Association's 77th Scientific Sessions at the San Diego Convention Center, investigators presented that a new, ultra-long acting insulin product, insulin degludec, has comparable cardiovascular safety to insulin glargine U100 and is also associated with significant reductions in severe hypoglycemia.

The Phase 3, multi-center, international, randomized, double-blind DEVOTE study was designed to evaluate the relative cardiovascular safety of insulin degludec (IDeg)¹ compared to insulin glargine (IGlar) U100 when added to a standard of care regimen for people with type 2 diabetes. IDeg is a new generation, once-daily, injectable basal insulin that provides duration of action of at least 42 hours. IGlar is the most commonly prescribed insulin product for people with type 2 diabetes, and its cardiovascular safety was established through the ORIGIN trial published in 2012.

The DEVOTE trial evaluated 7,637 people with type 2 diabetes who were at high risk of major adverse cardiovascular events (MACE), for a period of approximately two years.

Severe hypoglycemia is defined as an episode of low blood glucose which is profound enough that the patient requires assistance from another person in order to recover. It is the most serious acute complication of insulin treatment and can be lead to seizures, coma or even death. IDeg resulted in 27 percent fewer patients experiencing an episode of severe hypoglycemia and a 40 percent overall reduction of total episodes of severe hypoglycemia. Patients in the IDeg-treated group also experienced a 53 percent reduction in the rate of nocturnal severe hypoglycemia.

All severe hypoglycemic events of the study participants during the trial period were evaluated and confirmed by a group of external experts, and the differences were all statistically significant.

"The findings of the DEVOTE study are in line with previous clinical trials comparing insulin degludec to insulin glargine U100,

so we are pleased to be able to provide conclusive evidence regarding the safety of insulin degludec for patients with type 2 diabetes who are at high risk of cardiovascular complications," said study investigator Dr. Steven Marso, MD, chief medical officer for HCA Midwest Health cardiovascular services.