

Authors and Disclosures

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Novel Ultra long-Acting Insulin as Effective as Insulin Glargine

June 29, 2010 (Orlando, Florida) — The combination of insulin degludec — a novel very-long-acting insulin — plus insulin aspart provided similar glycemic control to insulin glargine in insulin-naïve subjects with type 2 diabetes, according to a proof-of-concept study presented here at the American Diabetes Association (ADA) 70th Scientific Sessions.

Not only was the ultralong-acting insulin comparable to insulin glargine, it produced better postdinner glucose control and reduced glycosylated hemoglobin (HbA_{1c}) levels using a lower insulin dose, said Tim Heise, MD, from the Profil Institute for Metabolic Research in Neuss, Germany.

"These results warrant further study in larger phase 3 trials," he said.

Insulin degludec is a novel insulin analog that forms soluble multihexamer assemblies after subcutaneous injection, resulting in an ultralong duration of action. In this phase 2 proof-of-concept study, it was used in combination with insulin aspart.

"It is well known that there is a progressive decline in beta cell function in people with type 2 diabetes so that eventually they will require insulin. Nowadays, insulin is initiated in these patients very often using basal insulin," Dr. Heise said. "The decline in beta cell function doesn't stop there, but declines further; these patients need more than just basal insulin. In this formulation, which consists of 70% insulin degludec and 30% insulin aspart, we have something that covers postprandial and basal insulin needs."

The study randomized 59 patients to receive either metformin plus once-daily insulin degludec aspart and 60 patients to receive metformin plus insulin glargine for a period of 16 weeks.

All patients were insulin-naïve and were inadequately controlled with oral antidiabetes agents. Their mean age was 59 years, mean HbA_{1c} was 8.5%, and mean fasting blood glucose was 209 mg/dL. The patients took their insulin, which was titrated to a fasting plasma glucose target of 72 to 108 mg/dL, before dinner.

After 16 weeks, mean HbA_{1c} decreased from baseline in both groups, down 1.31% to 7.0% in the insulin degludec group and down 1.29% to 7.1% in the insulin glargine group. Both groups had similar rates of hypoglycemia (51% in the insulin degludec group and 50% in the insulin glargine group).

However, patients in the insulin degludec group required a significantly smaller dose than patients in the insulin glargine group. At the end of the trial, the mean daily insulin doses were lower for insulin degludec aspart than for insulin glargine (0.38 vs 0.45 units/kg).

"Adverse events were very few, and what few there were were mild," Dr. Heise told *Medscape Diabetes* after his talk. "There were no injection-site reactions reported in the study."

He added that the findings from this study will have to be confirmed in other studies.

"We need results of phase 3 studies, but based on phase 2 studies, patients requiring basal insulin replacement might benefit the most from degludec," agreed Bernard Zinman, MD, professor of medicine at the University of Toronto, in Ontario, who participated in the degludec study. "This includes patients with type 1 diabetes mellitus on [multiple daily injections] and type 2 patients requiring insulin therapy because of oral agent failure."

Asked whether this new agent will modify clinical practice, Dr. Zinman replied that "phase 3 studies are required to define this, but the phase 2 results are very promising."

Commenting on this study for *Medscape Diabetes*, Alan J. Garber, PhD, professor of medicine at Baylor College of Medicine in Houston, Texas, said that degludec has a unique ability to be mixed with other insulins.

"This allows the creation of a novel formulation that retains the smooth control of a long-acting basal with rapid-acting mealtime control from insulin aspart. This 2-component insulin retains the ultralow risk characteristics of degludec with simultaneous mealtime coverage," said Dr. Garber, who was not part of the study.

David Kendall, MD, chief scientific and medical officer of the ADA, added: "It is pleasing to see that many variations of insulins and insulin delivery devices are becoming available, because insulin is a very challenging treatment to deliver."

But he cautioned that the data are limited. "With this limited amount of data, it's almost impossible to say where it would fit, but suffice it to say that, at least to start, the longer-acting insulins, particularly those that can be combined with mealtime insulins, have proven very effective for a number of patients, both with type 1 and type 2 diabetes," Dr. Kendall told *Medscape Diabetes*.

The study was funded by Novo Nordisk. Dr. Heise reports financial relationships with Biocon, Boehringer Ingelheim, ConjuChem, Novo Nordisk A/S, AstraZeneca LP, BD Medical Diabetes Care, Bidel Inc., Eli Lilly and Company, GlaxoSmithKline, Hoffmann-La Roche, Karo Bio AB, MannKind Corporation, Merck Sharp & Dohme Limited, Novartis Pharmaceuticals, OptiScan Biomedical Corporation, Pfizer Inc., Sanofi-Aventis, Servier, and Sirtis. Dr. Zinman reports financial relationships with Amylin Pharmaceuticals, Inc., Boehringer Ingelheim, Eli Lilly and Company, GlaxoSmithKline, Merck & Co., Inc., and Novo Nordisk, Inc. Dr. Garber reports financial relationships with GlaxoSmithKline, Merck & Co., Novo Nordisk Inc., and Roche Pharmaceuticals. Dr. Kendall reports financial relationships with Amylin Pharmaceuticals, Inc., Bayer Vital Pharma, Daiichi-Sankyo, Eli Lilly and Company, Intarcia Therapeutics Inc., Merck & Co, Inc., Roche Pharmaceuticals, Takeda Pharmaceuticals North America Inc., UnitedHealthGroup/i3 Drug Safety, Abbott Diabetes Care, Dexcom, MannKind Corporation, Medtronic MiniMed, and Sanofi-Aventis.

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