Device Lowers Weight, Glucose in Type 2 Diabetes

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AMSTERDAM — A novel gastric electrical stimulation device can potentially improve glucose levels and induce weight loss in obese patients with type 2 diabetes on oral antihyperglycemic therapy, Dr. Christoph Rosak said in a poster presentation at the annual meeting of the European Association for the Study of Diabetes.

The implantable device, called the Tantalus system, is manufactured by MetaCure Ltd. It has met marketing requirements in Europe (CE marking) and is indicated for the treatment of both type 2 diabetes and obesity (defined as a body mass index of 30-50 kg/m^2). It is currently in phase III trials in the United States.

The Tantalus system comprises a pulse generator and bipolar leads that are implanted laparoscopically in the antrum and fundus of the stomach. When food intake occurs, the system delivers nonexcitatory electrical stimulation to the gastric wall, thereby increasing the amplitude of the contractions and allowing the vagal nerve to send a signal to the brain, triggering earlier satiety. Previous data suggested that the device could safely produce clinically significant weight loss and reduce blood pressure in morbidly obese individuals at 1 year (Obes. Surg. 2006;16:627-34).

In the current phase II open-label study, 24 obese patients with type 2 diabetes were implanted with the Tantalus. Subjects included 9 men and 15 women, with a mean BMI of 41.7. In all, 7 patients used insulin; the other 17 took oral antihyperglycemic medication. The 16 patients on oral diabetes drugs who completed a 1-year follow-up showed a significant mean weight loss of 5.5 kg and reductions in waist circumference, Dr. Rosak, of Krankenhaus Sachsenhausen, Frankfurt, Germany, said during the poster presentation.

A subset of eight patients who were initially not well controlled (hemoglobin A_{1c} greater than 7%) on stable oral medications had a significant decrease in mean HbA_{1c} from 8.34% to 7.44%, and a drop in fasting plasma glucose from 206 mg/dL to 158 mg/dL. Available data on self glucose monitoring showed a significant decrease in 2-hour postprandial levels from 176 mg/dL to 141 mg/dL. The other eight patients on oral agents either changed their medication regime during treatment or had been well controlled initially, Dr. Rosak said.

Patients on insulin don't respond as well to the device [because] exogenous insulin may interfere with the vagal signal.

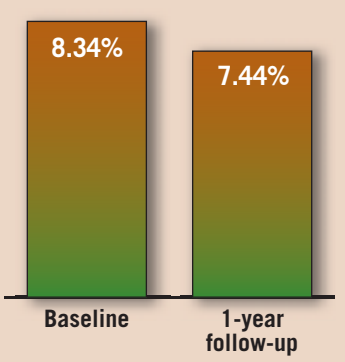
DR. ROSAK

In contrast, the four insulin-treated subjects who completed the 1-year study showed no significant changes in HbA_{1c} or weight. It's not clear why insulin-treated patients don't respond as well to the Tantalus, but one theory is that exogenous insulin may interfere with the vagal signal, he said.

Dr. Harold Lebovitz, professor of medicine at the State University of New York Downstate Medical Center, Brooklyn, and a consultant to MetaCure, said the Tantalus could "improve glycemic control with an associated weight loss in type 2 diabetic patients inadequately controlled on combinations of oral agents."

It may also work in insulin-treated patients, he said, noting that some of the insulin-treated patients in the study were adjusting their premeal bolus doses, which would have masked the device's effect. "The meaningful data were the results in the patients on oral agents since their medication doses were kept constant" he said. ■

Mean HbA_{1c} Levels in Eight Gastric Stimulation Patients



Note: Based on patients initially not well controlled on stable oral medications.
Source: Dr. Rosak