

Gastric Electrical Stimulation with the TANTALUS[®] System in Obese Type 2 Diabetes Patients: Effect on Weight and Glycemic Control

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Abstract

Background:

The TANTALUS[®] System is an investigational device that consists of an implantable pulse generator connected to gastric electrodes. The system is designed to automatically detect when eating starts and only then deliver sessions of gastric electrical stimulation (GES) with electrical pulses that are synchronized to the intrinsic antral slow waves. We report the effect of this type of GES on weight loss and glucose control in overweight/obese subjects with type 2 diabetes mellitus (T2DM). This study was conducted under a Food and Drug Administration/Institutional Review Board-approved investigational device exemption.

Method:

Fourteen obese T2DM subjects on oral antidiabetes medication were enrolled and implanted laparoscopically with the TANTALUS System (body mass index 39 ± 1 kg/m², hemoglobin A1c [HbA1c] $8.5 \pm 0.2\%$). Gastric electrical stimulation was initiated four weeks after implantation. Weight, HbA1c, fasting blood glucose, blood pressure, and lipid levels were assessed during the study period.

Results:

Eleven subjects reached the 6-month treatment period endpoint. Gastric electrical stimulation was well tolerated by all subjects. In those patients completing 6 months of therapy, HbA1c was reduced significantly from $8.5 \pm 0.7\%$ to $7.6 \pm 1\%$, $p < .01$. Weight was also significantly reduced from 107.7 ± 21.1 to 102.4 ± 20.5 kg, $p < .01$. The improvement in glucose control did not correlate with weight loss ($R^2 = 0.05$, $p = .44$). A significant improvement was noted in blood pressure, triglycerides, and cholesterol (low-density lipoprotein only).

Conclusions:

Short-term therapy with the TANTALUS System improves glucose control, induces weight loss, and improves blood pressure and lipids in obese T2DM subjects on oral antidiabetes therapy.

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Abbreviations: (ACCORD) Action to Control Cardiovascular Risk in Diabetes, (CVD) cardiovascular disease, (GCM) gastric contractility modulation, (GES) gastric electrical stimulation, (HbA1c) hemoglobin A1c, (HDL) high density lipoprotein, (LDL) low density lipoprotein, (NHANES) National Health and Nutrition Examination Survey, (SW) slow waves, (T2DM) type 2 Diabetes mellitus, (UKPDS) United Kingdom Prospective Diabetes Study

Keywords: diabetes, electrical stimulation, gastric contractility modulation, glucose control, hemoglobin A1c, obesity

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