

Gastric Electrical Stimulation: A Novel Treatment for Gastroparesis

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ABSTRACT

Presented herein is a case report of a laparoscopic gastric electrical stimulator implantation for drug-refractory gastroparesis. Technical aspects of the procedure, as well as a review of the existing literature, are discussed. Gastric electrical stimulation offers a new alternative for the treatment of drug-refractory gastroparesis.

Key Words: Gastroparesis, Gastric electrical stimulation, Enterra.

INTRODUCTION

Gastroparesis is a debilitating condition characterized by delayed emptying of the stomach. Up to 36% of gastroparesis is of idiopathic origin, and 29% of diabetic origin.¹ The hallmark of gastroparesis is early satiety, which may progress to intractable nausea and vomiting. As a result of these chronic symptoms, patients may have difficulty meeting their nutritional and caloric needs. Dehydration, weight loss, electrolyte imbalances, along with a deteriorating quality of life may ensue. In conjunction with dietary modifications, medical treatment includes the use of prokinetic drugs. However, a majority of patients are intolerant to these medications.² Many patients require enteral and parenteral nutrition support. The development of a gastric electrical stimulation device has been associated with improvements in symptoms and an overall decreased cost of management of gastroparesis patients.³ Approved by the FDA in March 2000, electrical stimulation offers a promising therapy for gastroparesis refractory to medical treatment. A technique of laparoscopic stimulator implantation has yet to be described.

CASE REPORT

A 48-year-old Caucasian male with a history of hypertension and poorly controlled type II diabetes mellitus presented with 4 months of early satiety, epigastric pain, heartburn, nausea, and daily emesis. An upper gastrointestinal endoscopy did not reveal any anatomic abnormalities. Scintigraphy demonstrated greater than 50% gastric content retention after 2 hours (**Figure 1**). Neither dietary changes nor Metoclopramide administration provided symptomatic relief. A diagnosis of drug-refractory diabetic gastroparesis was made and a laparoscopic gastric electrical stimulator implantation was planned.

The procedure requires 4 ports (**Figure 2**). Ten-mm ports are placed in the left upper quadrant (lateral gastric retraction) and umbilicus (camera) and 5-mm ports (working ports) are placed in the left lower and right upper quadrants. The surgeon stands on the patient's right side. The pylorus is identified, and a ruler is used to identify a point 10 cm proximal to it along the greater curvature, which is in the region of the pacemaker area. Marks are made with electrocautery 1 cm apart on the gastric serosa.

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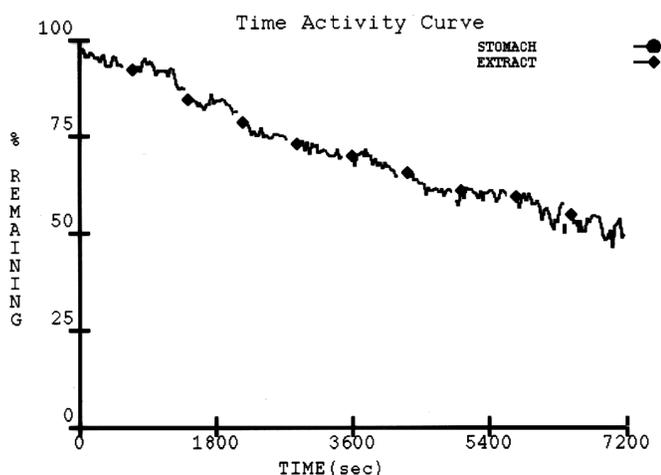


Figure 1. Gastric scintigraphy demonstrating a delayed pattern of emptying, with greater than 50% gastric retention at 2 hours.



Figure 2. Port placement for laparoscopic stimulator implantation.

The lead is prepared by tying 2 silk sutures to its anchor. After the lead is inserted through the left upper quadrant port, the Prolene suture, which comes attached to the electrode, is placed through the seromuscular layers of the stomach. An upper gastrointestinal endoscopy assures that the gastric mucosa has not been violated. The Prolene suture is used to pull the electrode into the gastric muscularis propria. The electrode is secured to the gastric wall by using the silk suture, which had been previously tied to the anchor with the intracorporeal knot tying technique. The above procedure is repeated for a second lead with its electrode placed 1cm from the first.

The leads are brought out through the left upper quadrant port. An external programming device is used to confirm

that the impedance between the 2 electrodes is between 200 and 800 Ohms. The electrodes are then further secured by placing a disc and 2 clips on the Prolene suture adjacent to the electrode (**Figure 3**).

An abdominal wall subcutaneous pocket is made for the stimulator 4 fingerbreadths below the left inferior costal margin. The leads are tunneled from the left upper quadrant port site to the subcutaneous pocket, where they are connected to the stimulator. Two sutures are used to secure the stimulator to the abdominal wall fascia. The pocket is closed in layers, and the stimulator parameters are set by using the external programming device. The voltage is calculated by multiplying the measured impedance by a current of 5 mA. The other parameters include a frequency of 14 Hz, a pulse width of 330 μ s and a cycling time of 0.1 seconds on and 5 seconds off.

One month following surgery, the patient no longer required Metoclopramide. Two months later, he was symptom free, on an unrestricted diet with significantly improved glycemic control, and hemoglobin A1C within the normal range. At 6 months following surgery, a gastric scintigraphy demonstrated a normal pattern of gastric emptying with 22% gastric content retention at 2 hours (**Figure 4**).

DISCUSSION

Patients with complaints of early satiety, abdominal pain, bloating, heartburn, nausea, and vomiting may be suspected of having gastroparesis.⁴ Persons with diabetes are especially susceptible to gastroparesis as long-standing hyperglycemia can lead to a vagal neuropathy.

Diabetics can become trapped in a downward spiral as their irregular food intake and absorption contributes to poor glycemic control, which in turn can exacerbate gas-

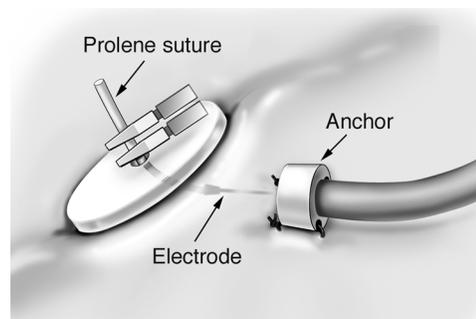


Figure 3. The electrode is secured by suturing the anchor to the stomach wall proximally, and placing a disc and 2 clips on the Prolene suture distally.

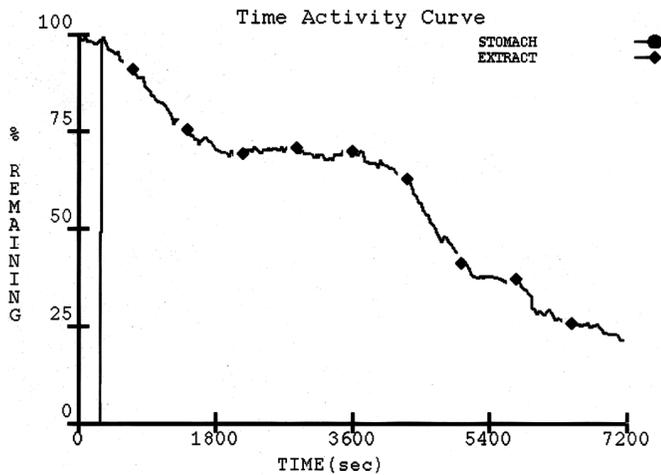


Figure 4. Gastric scintigraphy demonstrating a normal pattern of emptying with 22% gastric content retention at 2 hours.

troparesis. When predisposing conditions, such as diabetes or prior gastric surgery involving vagotomy, have not been identified, patients are classified as having idiopathic gastroparesis.

Contrast radiology or upper gastrointestinal endoscopy studies are essential to rule out such conditions as gastric outlet obstruction, but the most definitive test for a diagnosis of gastroparesis is gastric scintigraphy. Many consider the test positive if the time at which 50% of the technetium 99m-labeled test meal is eliminated from the stomach (T1/2) is greater than 120 minutes after ingestion. A T1/2 of 90 to 120 minutes is considered borderline for gastroparesis. Greater than 10% retention after 4 hours is also considered a positive test for delayed emptying.⁵ Lack of gastric scintigraphy standardization among different institutions makes interpretation of this test problematic. Just as no consensus exists as to what constitutes a positive test for delayed emptying, inconsistency exists regarding the content of the radiolabeled meal.

Once the diagnosis of gastroparesis has been established, a prokinetic therapy consisting of Cisapride, Domperidone, Erythromycin, or Metaclopramide may be offered. However only Erythromycin and Metaclopramide are commercially available in the United States, and up to 50% to 75% do not respond or tolerate them.² For drug-refractory gastroparesis, traditional surgical approaches have included decompressive gastrostomy and feeding jejunostomy tube placement.⁶ More invasive measures have consisted of pyloroplasty and antrectomy, and in some instances subtotal gastrectomy.

Many animal and human studies have been conducted in

an attempt to show the efficacy of electrical stimulation in the treatment of gastroparesis. Encouraging results have been reported with the use of a high-frequency, low-energy gastric electric stimulator, which is attached to 2 leads implanted into the gastric muscularis propria.⁷ The device was developed by Medtronic, Inc. (Minneapolis, MN, USA) and is marketed under the name Enterra Therapy.

Results from a randomized, double-blinded crossover multicenter trial of electrical stimulator implantation involving 33 drug-refractory gastroparesis patients from the US, Canada, and Europe demonstrated a decrease in weekly vomiting frequency by greater than half in 70% of the idiopathic and 77% of the diabetic patients.⁷ A 4% complication rate was observed including device infection and lead displacement.⁷ Further, 14 patients in a prospective study of gastric electrical stimulation had a feeding jejunostomy tube in place at the time of surgery. After 6 months, 11 of the 14 patients were sufficiently comfortable and stable with oral nutrition that their enteral access could be removed.⁸ The number of hospital days per year for patients with the gastric stimulator was cut by over 20 days. Patients with the gastric stimulator also have a decrease in utilization of outpatient health care resources.³

CONCLUSION

Gastroparesis can be an incapacitating condition for many patients. Although medical therapy should first be attempted, it often is not successful. Gastric electrical stimulation is a viable alternative. Laparoscopic implantation confers the recognized advantages of a minimally invasive approach.

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