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## CASE REPORT

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## Gastric Electrical Stimulation for Treatment of Drug Refractory Gastroparesis

Reza A. Hejazi, M.D.  
Irene Sarosiek, M.D.  
Brian R. Davis, M.D.  
Richard W. McCallum, M.D.

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### Introduction

Gastroparesis is a disorder characterized by a spectrum of recognized symptoms with evidence for gastric retention in the absence of mechanical obstruction. The range of symptoms includes nausea, vomiting, early satiety, and postprandial fullness. Abdominal discomfort and pain are also noted by some patients. It can be complicated by weight loss, malnutrition, dehydration, and electrolyte abnormalities in moderate to severe cases.

Published data have not identified the true prevalence of gastroparesis, but up to 7% of the United States population has been suggested to have some symptoms of gastroparesis. It affects women more than men with a female-to-male ratio of 4:1, and the mean age of onset is 34 years. The most common systemic disease associated with gastroparesis is diabetes mellitus. It is estimated that up to 5 million diabetic patients (combining type 1 and type 2) have gastroparesis in the United States alone based on a population estimate of 23 million diabetics. Idiopathic gastroparesis has a similar population incidence. The subgroup of postsurgical patients undergoing an abdominal or thoracic surgery (e.g., Nissen fundoplication) and accidental vagal nerve injury constitute the next common cause of gastroparesis with an estimated number of about 1 million patients affected (1–4).

We present here a case of severe and drug refractory gastroparesis who ultimately benefited from gastric electrical stimulation (GES) to control of symptoms of nausea/vomiting, bloating and abdominal pain.

### CASE PRESENTATION

A 33-year-old woman was referred for evaluation of refractory nausea and vomiting of 8 months duration. She had a 20-year history of type I diabetes mellitus complicated by retinopathy and peripheral neuropathy. Her glycemic control was suboptimal and occasionally blood sugars were in the 20-mmol/L (360 mg/dL) range and the recent hemoglobin A1c level was 9.6%. Her symptoms were occurring postprandially about 30–40 minutes after a meal and were characterized by nausea, epigastric fullness, bloating, and pain. Vomiting was less frequent (2–3 days/wk); however, when it did occur, it was usually 2 to 4 hours after eating and on several occasions she had identified food in the vomitus that she consumed the previous day. Her severe nausea and vomiting have led to 12 emergency department visits and 4 hospitalizations in the past year. She was not able to work and take care of her family because of those symptoms. She spends most of her day lying in bed or sitting in a chair. She also lost 9 kg in this time frame. She weighs about 50 kg and was 158 cm tall

(body mass index: 20 kg/m<sup>2</sup>). Her abdominal examination revealed epigastric fullness and tenderness. No focal neurologic deficits were elicited. Initial investigations including complete blood count, comprehensive metabolic panel, thyroid function tests (thyroid stimulating hormone, 2 mIU/L; free T4, 6 mg/dL), and random cortisol levels (18 mcg/dL) were normal. Further testing that included *Helicobacter pylori* and celiac sprue serology were negative; an abdominal ultrasound, small-bowel series, and upper gastrointestinal endoscopy did not show any abnormalities. Later, a 90-minute scintigraphic test to measure gastric emptying was performed with a radiolabeled egg meal and was consistent with the diagnosis of gastroparesis (t1/2, 180 min; normal, <100 min). Management recommendations for diabetic gastroparesis by her gastroenterology consultant included dietary modification (small frequent meals and a low-roughage diet), starting metoclopramide orally at 10 mg 4 times/day and promethazine at 25 mg orally every 4 hours as needed. Recommendations also were made to control her blood sugars aggressively. Although she noticed some improvement in symptoms initially with these therapeutic measures, the response seemed to wane over the next few months. Because the patient had a less-than-desired clinical response to the earlier-described measures and she was failing to thrive, her gastroenterologist had referred her to our tertiary care medical center for further evaluation. The patient wants relief from nausea, which she regards as the most disabling symptom, and seeks an opinion regarding gastric electric stimulation versus other potential therapeutic agents for gastroparesis. The patient presented to us had a 4-hour gastric emptying study that showed 33% retention of the meal at the end of 4 hours (normal, <10% retention) in our center. She was started on domperidone 10 mg 4 times a day instead of metoclopramide and the dose was titrated up to 30 mg 4 times a day. Transdermal scopolamine patch 1.5 mg every 3 days and nortriptyline 20 mg at bedtime also were prescribed. The patient did well for about 4 months with improvement in symptoms and reduced need for hospitalization. However, after about 6 months her symptoms started worsening again and weight loss persisted. At that time the option of surgically implanting the Enterra device, including the risks and benefits of the procedure, were discussed with the patient and she wished to proceed. The GES was implanted successfully and a back-up jejunostomy tube also was placed during surgery. She had a favorable outcome with the procedure and reported a greater than 75% improvement in symptoms at the 6-month follow-up visit although her gastric emptying study still showed 30% retention of the meal at the end of 4 hours. During that visit, the J tube was removed and her blood sugar control

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was better (HbA1c of 7.5%). The symptom response was sustained even after 1 year, and she was able to stop all antiemetics, scopolamine patch, and nortriptyline. However, we recommended that domperidone be continued at 20 mg 4 times a day as a background prokinetic in view of the continued delay in gastric emptying.

**DISCUSSION**

GES is an approach for refractory gastroparesis that has been approved and initiated for the past 10 years. The US Food and Drug Administration approved a high-frequency, low-energy GES (Enterra Therapy System, Medtronic, Minneapolis, Minnesota) in March 2000 under a Humanitarian Device Exemption for symptomatic relief in patients with diabetic and idiopathic gastroparesis. (5) The clinically available GES- Enterra (Figures 1A & B and 2) consists of a pair of electrodes sutured to the muscular layer of the greater curvature of the stomach, 8.5 cm and 9.5 cm proximal to the pylorus, and connected to a pulse generator, called the *neurostimulator*, which is implanted in a subcutaneous pocket in the abdominal wall, usually in the right upper quadrant. The pulse generator can be activated and programmed externally and the usual battery life expectancy is 8 to 10 years depending on the energy parameters programmed. The system can be implanted by laparotomy or laparoscopy; the former approach gives a greater control for lead implantation in the right location in the stomach and the opportunity for back-up jejunostomy tube placement and to obtain gastric wall biopsies. Laparoscopy has been associated with some reports of lead damage and insulation trauma that could result in shock waves and reports of pain. Follow-up data for periods up to 10 years after device implantation report a sustained improvement in symptoms over many years. An early improvement in symptoms can be appreciated in the first 3 to 6 months after placement of the device and generally predicts a long-term control of symptoms over many years. GES also improves quality of life, reduces requirement for health care use, improves glycemic control in diabetic patients, reduces dependence on enteral or parenteral nutrition, and also improves nutritional status. In addition, it also is possible that patients with diabetic gastroparesis can become candidates for renal and pancreas transplant if needed because control of gastroparetic symptoms ensures more reliable bioavailability of immunosuppressants. Apart from diabetic and idiopathic gastroparesis, GES has been evaluated in patients with postvagotomy gastroparesis and seems to be as efficacious. (6, 7) In summary, GES is the major advance in this field in the past 10 years, offering new hope to this patient population. This option is now available at Texas Tech University Health Sciences Center and we have successfully implanted 3 patients since January 2010.



**Figure 1:** A & B: Enterra system with programmer (A) and pulse generator (B)



**Figure 2:** Laparotomy for implanting Enterra system

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Reza A. Hejazi, M.D., Post Doctoral Research Associate, Department of Internal Medicine, Texas Tech University HSC - Paul L. Foster SOM, El Paso, Texas.

Irene Sarosiek, M.D., Associate Professor, Department of Internal Medicine, Texas Tech University HSC - Paul L. Foster SOM, El Paso, Texas.

Brian R. Davis, M.D. is Clinical Assistant Professor for the Department of Surgery at Texas Tech University Health Sciences Center at El Paso, Texas.

Richard W. McCallum, M.D., FACP, FRACP (Aust), FACC, Founding Chair, Department of Internal Medicine, Texas Tech University HSC - Paul L. Foster SOM, El Paso, Texas.