



Gastric Electrical Stimulation

COMPLEX DIGESTIVE DISEASE CENTER GASTROINTESTINAL MOTILITY SERVICES

At California Pacific Medical Center we are committed to bringing new and advanced diagnostic tools, medical treatments and surgical options to the physicians we serve and the patients they care for. Through this procedure profile, our physicians illustrate actual medical situations that provide you with a window into their practice of diagnosis, treatment and patient follow-up.

What is Gastric Electrical Stimulation (Enterra™ Therapy)?

Gastric electrical stimulation (GES) utilizes an electrical device, Enterra™ Therapy, called a gastric pacemaker, to provide mild electrical stimulation to the lower stomach nerves. Transmitted through a neurostimulator, these mild electrical pulses encourage the stomach to contract and help to relieve nausea and vomiting. Utilizing minimally invasive surgical techniques, the gastric pacemaker is placed subcutaneously below the rib cage in the abdomen. Two intramuscular lead wires with electrodes are implanted into the stomach muscle wall to deliver mild electrical pulses for symptom control. This therapy is reversible and can be turned off at any time by the motility specialist.



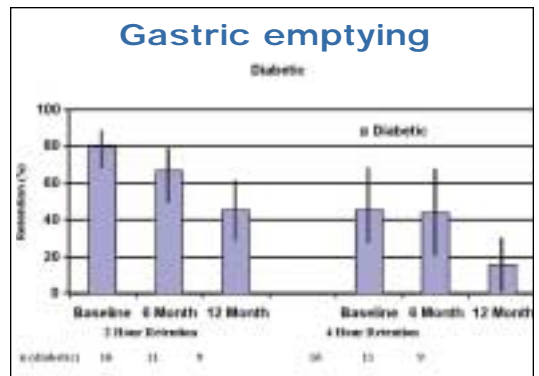
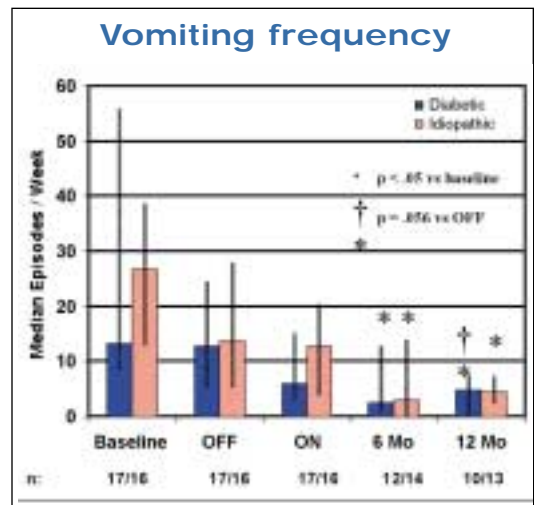
Enterra™ device

The Enterra™ Therapy system was designated as a Humanitarian Use Device by the FDA in the fall of 1999. Humanitarian Use Devices are medical devices specially designated by the FDA for use in treatment of rare medical conditions with an incidence of less than 4000 patients per year.

Why does a patient need GES?

Patients diagnosed with gastroparesis, a disorder in which food moves through the stomach more slowly than normal, who have not responded to or are intolerant of

conservative therapies are candidates for GES. Many of these patients have difficulty eating and experience severe, chronic vomiting and nausea. Some patients may even require tube feeding to ensure adequate nutrition. There are a number of causes for gastroparesis including diabetes mellitus, anorexia and bulimia, lupus, and brain disorders. However, nearly 60% of the cases have an unknown origin. GES is used only when medication is not effective in controlling symptoms that can be serious, including malnutrition and severe dehydration. In clinical studies, GES reduced vomiting frequency by up to 81% from baseline at 12 months follow-up.



For patient referrals: (888) 637-2762 www.cpmc.org

case studies

1. Diabetic Gastroparesis/ Sarcoidosis

Case Overview

A 31 year-old female was referred to the Complex Digestive Disease Center presenting with extensive nausea and vomiting which required seven hospitalizations in the last eight months. The patient has been treated unsuccessfully with Zofran, Reglan and erythromycin on prior admissions in an attempt to control her symptoms. The diagnostic gastrointestinal motility study showed absence of phase 3 contractions in the stomach. Esophagogastroduodenoscopy identified no obstructions of the stomach. The patient continued to experience vomiting, nausea with epigastric discomfort and irregular bowel movements.

Treatment

The patient was referred to our minimally invasive surgery program for laparoscopic gastric pacemaker insertion. She was given a general anesthesia and using an upper endoscopy to ensure accurate wire placement, the electrodes were placed within the stomach smooth muscle wall 10 cm from the pylorus. The pacemaker was set with a 14 pulses per second cycling mode.

Outcome

Ten days post laparoscopic gastric pacemaker insertion there was a marked decrease in nausea and vomiting. Within two months her gastrointestinal problems were stable with little vomiting or nausea. The patient returned for a gastric emptying study showing normal gastric emptying under the influence of the gastric pacemaker.

The gastric emptying improved from T-half emptying time of 400 minutes to normal of 60 minutes.



Laparoscopic image of electrodes attached to stomach wall.

2. Idiopathic Gastroparesis/ Gastric Reflux/ Hiatal Hernia

Case Overview

A 41-year-old woman was referred to the Complex Digestive Disease Center with a five-year history of severe uncontrollable vomiting. In addition, she had severe gastric reflux and had undergone a laparoscopic cholecystectomy, which did not improve her symptoms. Medication therapy of Zofran and Tigan controlled her vomiting to a certain extent. However, her condition was now affecting her ability to maintain employment.

Treatment

The patient underwent gastric and small intestinal motility studies and a gastric emptying study to confirm gastroparesis. It was decided that a laparoscopic Nissen fundoplication, pyloroplasty and lysis of adhesions be performed to reduce her severe reflux, prior to insertion of the

gastric pacemaker device. Two weeks after these procedures the patient returned to the hospital for GES insertion.

Outcome

Her surgery proceeded smoothly without complications and she was discharged home for follow-up with her local GI specialist. She has experienced a 60% improvement of symptoms.

The gastric emptying improved from T-half emptying time of 268 minutes to normal of 28 minutes.

3. Diabetes Mellitus/ Gastroparesis

Case Overview

A 34-year-old diabetic man was referred to the Complex Digestive Disease Center with a 7-year history of severe gastroparesis. He had been unable to tolerate or had been unresponsive to conventional medical therapy for this condition. He was recently seen in his local hospital emergency room due to his inability to maintain minimal nutritional intake where a nasogastric tube was placed to decompress the abdomen. He had been hospitalized 10 times in the last year and vomiting up to 6 times a day. He had lost approximately 100 pounds over the last four years. The patient had a T-half emptying time of 280 minutes with no isotope leaving the stomach for two hours.

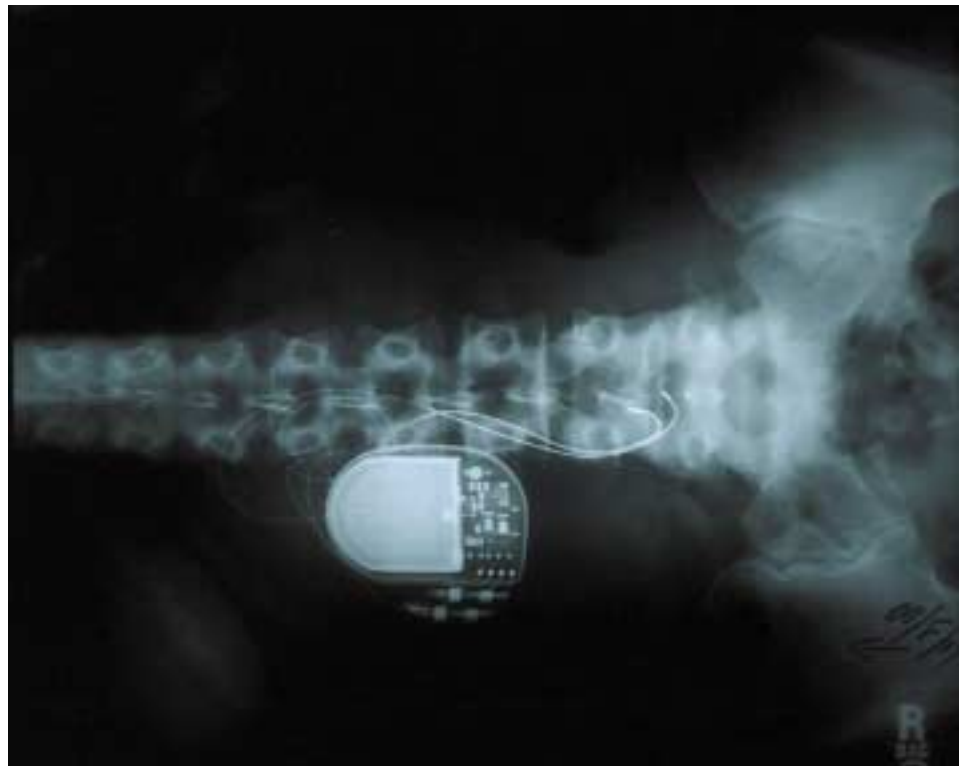
Treatment

The patient underwent abdominal ultrasound, gastric and small intestinal motility studies and a gastric emptying study to confirm gastroparesis. It was decided that he was an excellent candidate for insertion of the gastric pacemaker device.

Outcome

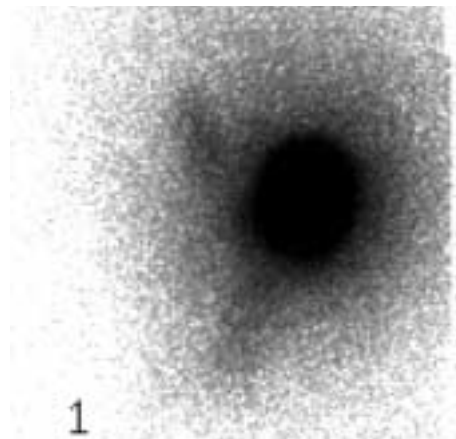
His surgery proceeded without complications and he was discharged home for follow-up with his local GI specialist.

The gastric emptying improved from T-half emptying time of 280 minutes to normal of 45 minutes.

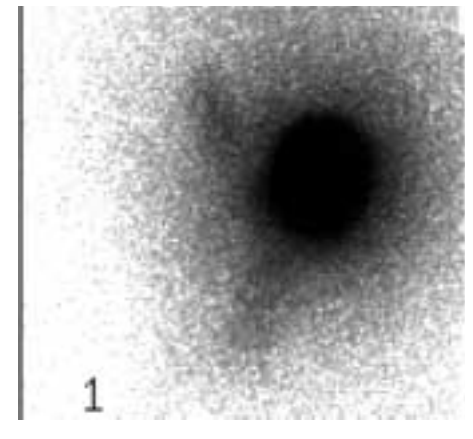


X-ray of implanted Enterra™ device

Gastric Emptying Study



Pre-stimulant.



Post-stimulant.

Gastric Electrical Stimulation

What are the risks?

- Undesirable change in stimulation, possibly related to cellular changes around the electrodes, shifts in electrode position, loose electrical connections, or lead fractures
- Risks associated with general anesthesia and laparoscopic surgical techniques including bleeding, infection, pain, and conversion to open
- Neurostimulator migration that may necessitate surgical revision
- Persistent pain at the neurostimulator site
- Seroma at the neurostimulator site
- Perforation of the stomach wall
- Migration of leads
- Allergenic or immune system response to the implanted materials
- Loss of therapeutic effect

How is the gastric electrical stimulator implanted?

The implantation of the gastric electrical stimulation device, which is approximately 2½" long, 2" wide and ½" thick, is done surgically under general anesthesia. Our minimally invasive surgeon implants two small electrodes into the stomach muscle wall. Lead connectors are run subcutaneously along the abdomen and connected to the neurostimulator. The neurostimulator is placed beneath the skin in the abdomen, positioned below the rib cage and above the belt line. The duration of surgery is usually one to three hours. Patients are required to stay overnight in the hospital for observation.

What can a patient expect?

The hospital stay is usually from 1 to 5 days. Most patients experience a gradual reduction in symptoms during the first 6 to 12 months, however this varies from patient to patient.

Depending on the amount of stimulation each patient requires, the batteries last from 5 to 10 years, at which point the neurostimulator is replaced. Patients rarely notice the mild stimulation to the stomach. Although the symptom reduction is gradual, greater than 80% of patients have reported a significant decrease in vomiting frequency.

Patient referral to the Gastrointestinal Motility Services

Patients need a referral from their primary care provider or physician specialist prior to scheduling their evaluation and surgery. Medical records, pertinent laboratory reports, and imaging reports need to be forwarded to California Pacific's Motility Services to determine referral indication appropriateness. Patients need to be seen in consultation prior to scheduling the Enterra™ Therapy procedure.

Insurance coverage

Many insurance policies cover Enterra™ Therapy. In order to avoid unexpected medical expenses, it is always best for your patients to contact their insurance company prior to treatment to confirm coverage for this service and obtain prior authorization.

For more information

Please contact the Center for Complex Digestive Disease Gastrointestinal Motility Services or Dr. William J. Snape, Jr.

William J. Snape, Jr., M.D.

Medical Director, Gastrointestinal Motility Services
2340 Clay Street, 2nd Floor
San Francisco, California 94115
(415) 600-1138
e-mail: snapew@sutterhealth.org

Gregg H. Jossart, M.D.

Director, Minimally Invasive Surgery Program
2100 Webster St. #518
San Francisco, California 94115
(415) 561-1310
e-mail: jossarg@sutterhealth.org

For Patient Referrals

(888) 637-2762

www.cpmc.org