Follow-Up after Gastric Electrical Stimulation for Gastroparesis

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BACKGROUND: Gastric electrical stimulation (GES) is used to treat medically refractory gastroparesis. However, there are few large series with outcomes beyond 12 months. This study reports surgical outcomes of GES for patients up to 8 years receiving treatment from a single institution.

STUDY DESIGN: A prospective database was reviewed from 2003 to 2013 for patients undergoing GES. Baseline patient characteristics were recorded, including age, sex, cause of gastroparesis, gastric emptying, and Hgb A1C. Outcomes variables included nutrition supplementation, additional operations, 30-day morbidity, and mortality. Pre- and postoperative pain and function scores are analyzed over time using generalized estimating equations. Patient outcomes in terms of reoperation rates and types of operations are also reviewed.

RESULTS: Seventy-nine patients underwent GES with a mean ± SD age of 43 ± 11 years and a BMI of 27 ± 8 kg/m^2. Symptom scores were available for 60 patients: 60 patients at baseline, 52 patients at 1 year, 14 patients during years 2 to 3, and 18 patients during years 4 to 8. Symptom scores decreased considerably in all categories. At 1-year follow-up, 44% and 31% of patients had at least a 25% reduction in symptom distress for functional and pain symptoms, respectively. Preoperatively, 9 patients required nutrition supplementation. After implantation, 34 (43%) patients underwent additional operations, with a mean of 2.15 operations per patient. Generator-related causes were the most common indication for reoperation, including battery exchanges and relocation. Other operations included 8 gastrectomies and 7 median arcuate ligament releases. Postoperatively, 4 patients required supplemental nutrition. There were no 30-day mortalities, but 11 patients died during the study period.

CONCLUSIONS: Gastric electrical stimulation was significantly associated with reductions in both functional and pain-related symptoms of gastroparesis. Patients who undergo GES have a high likelihood of additional surgery. (J Am Coll Surg 2015;220:57–63. © 2015 by the American College of Surgeons)

Gastroparesis is characterized by upper gastrointestinal (GI) symptoms of nausea, vomiting, and abdominal pain in the setting of delayed gastric emptying without mechanical obstruction. Most cases of gastroparesis are idiopathic, and diabetes accounts for the largest proportion of cases with a known cause. Other causes of gastroparesis include collagen vascular diseases, gastric surgery, Parkinson disease, hypothyroidism, malignancy, and end-stage renal disease.[1,2] Although the prevalence of gastroparesis is only 24.2 cases per 100,000 patients, delayed gastric emptying has a prevalence of up to 1,800 cases in 100,000 patients. This latter value suggests that the diagnosed cases represent only the tip of the gastroparesis "iceberg."[2,3]

Gastroparesis results in frequent hospitalizations and multiple radiographic, endoscopic, and laboratory studies.[4] Medical therapy consists of supportive care and prokinetic medications, which are of limited benefit because of poor efficacy and tolerability. Metoclopramide is the only prokinetic medication that has been approved by the FDA for gastroparesis. However, its use has declined sharply since the black box warning for tardive dyskinesia.[5] Erythromycin has been used off-label as a

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Abbreviations and Acronyms

GES = gastric electrical stimulation
GI = gastrointestinal
GET = gastric emptying test
MAL = medial arcuate ligament
TSS = Total Symptom Score

prokinetic, but its use is limited by tachyphylaxis, and domperidone is available on a restricted basis through a special FDA-administered program.[6] Surgical therapies are used to treat gastroparesis, including gastrostomy tubes, pyloroplasties, gastrojejunostomies, antrectomies, and total gastrectomies.[7,8] These procedures can provide relief for some patients, but all of these interventions are associated with potential morbidity and mortality. In addition, there is no guarantee that the breadth of GI symptoms will resolve.

Enterra Therapy (Medtronics, Inc.) is an implantable gastric electrical stimulator (GES) and was granted a humanitarian device exemption by the FDA for diabetic and idiopathic patients with medication-refractory gastroparesis. The device delivers high-frequency and low-energy electrical stimulation to the gastric wall.[6] Multiple studies have demonstrated significant short-term improvement in GI symptoms, health care costs, nutritional status, and quality of life in patients with gastroparesis after GES.[9-13] Data on long-term outcomes of GES are limited. The primary aim of this study is to analyze pre- and postoperative pain and function scores over time in patients after GES for refractory gastroparesis. The secondary aim of this study is to assess the reoperation rate and types of operations after GES.

METHODS

The study was approved by the IRB at the George Washington University Medical Center (#070308). From November 2003 to June 2013, patients with a diagnosis of gastroparesis were entered prospectively into the study. Patients were required to have a diagnosis of gastroparesis for at least 12 months and were refractory to nonoperative management. All patients were evaluated by a general surgeon and gastroenterologist with a detailed history and physical examination. After the initial evaluation, patients underwent CBC, electrolytes, upper endoscopy, CT, and a standard 2- and 4-hour gastric emptying test (GET) with a low-fat meal. After ingesting a technetium 99m sulfur-colloid meal of protein, carbohydrate, and fat, images of the stomach were taken for 4 hours. Retention times were measured and delayed gastric emptying was defined as >40% retention at 2 hours, >10% retention at 4 hours, or both. If the pretest blood glucose was >275 mg/dL or <75 mg/dL, the GET was not performed.

Patient demographics were recorded and a standard questionnaire was completed to assess preoperative GI symptoms from a pain and functional standpoint. This questionnaire is a standard Total Symptom Score (TSS) developed in 2004 by Lin and colleagues.[14] The TSS measures 9 parameters in terms of severity and frequency. Parameters are divided between 5 functional components and 4 pain symptoms. The functional components assess vomiting, nausea, early satiety, bloating, and postprandial fullness, and the pain components assess chest burning, epigastric burning, epigastric pain, and chest pain. The severity score was defined as 0 if absent, 1 if present and not inhibiting daily activities, 2 if mildly altering daily activities, 3 if significantly altering daily activities, and 4 if significantly prohibiting most daily activities. The frequency score was rated 0 if absent, 1 if rare, 2 if 2 to 3 times per week, 3 if 4 to 6 times per week, and 4 if more than 7 times per week. Patients complete the TSS forms at each visit and the data are self-reported without a physician present. The forms are distributed and collected by nursing personnel and physicians are blinded to the data.

After failing nonoperative therapy, gastroparetic patients underwent GES if their respective workup showed a prolonged GET with no evidence of mechanical obstruction. It should be noted that a GES can be placed even if the GET is normal, as long as the patient has a longstanding history of refractory nausea, vomiting, and weight loss. These individuals are listed as idiopathic gastroparetic patients, but their respective cohort is too small to attempt any meaningful analysis. From a technical standpoint, abdominal access is obtained at the umbilicus, followed by two 5-mm ports in the right flank and a 12-mm port in the left upper quadrant.[15] The first electrode is then placed 10 cm proximal to the pylorus. The electrode is inserted through a seromuscular tunnel approximately 1.5 cm in length to accommodate the active portion of the electrode. The electrode is secured with 3 sutures and a plastic disc to prevent dislodgement. A second electrode is placed 1 cm lateral and parallel to the first electrode along the greater curve of the stomach. The second electrode is secured in a similar fashion. Upper endoscopy is performed to ensure that the gastric mucosa has not been violated. The distal ends of the electrodes are extracted from the abdominal cavity through the 12-mm port. The abdomen is desufflated and a subcutaneous pocket is made for the generator. The distal ends of the electrodes are secured to the generator and the generator is sutured to the abdominal fascia. The generator is