



Further experience with gastric stimulation to treat drug refractory gastroparesis

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Abstract

Background: Gastric electrical stimulation (GES) has been introduced for patients with gastroparesis refractory to pharmacological therapy.

Methods: From April 1998 until November 2001, 55 patients underwent GES implantation at Kansas University Medical Center. All patients had prolonged gastric retention of a solid meal by scintigraphy at baseline. The etiologies were diabetes mellitus in 39, related to previous surgery in 9, and idiopathic in 7. Symptoms were graded using a 5-point scale and quality of life was assessed with the SF-36 questionnaire. Body mass index and nutritional parameters were monitored. Hemoglobin A1C was measured in the diabetic patients.

Results: Total symptom scores and the physical and mental composite scores of quality of life improved significantly. On average, gastric emptying did not change. Body mass index and body weight increased significantly. And days spent in hospital admissions were significantly decreased. At 1 year, diabetic patients experienced reduced hemoglobin A1C. Four devices were removed. One patient died of a pulmonary embolus postoperatively.

Conclusions: In a large series of patients with gastroparesis, GES significantly improved symptoms and quality of life. © 2003 Excerpta Medica, Inc. All rights reserved.

Keywords: Gastroparesis; Gastric electrical stimulation; Gastric motility; Quality of life; Gastric emptying

Gastroparesis is a debilitating condition characterized by failure of the gastric emptying capacity of the stomach and associated with nausea, vomiting, epigastric pain, premature satiety, abdominal fullness, bloating, epigastric pain, and weight loss [1,2]. The condition can progress to the point that functional persons are reduced to an existence tied to a hospital or emergency room for intravenous hydration and medications. Patients are often unable to work, attend school, or socialize, and have no good long-term solutions [3]. Prokinetic agents that increase the motility of the stomach are variable in their ability to provide relief, may have degrees of tachyphylaxis, and have many side effects, lim-

iting their usefulness [4]. Surgical options, namely gastric resections, have not been uniformly helpful and have an accompanying mortality and morbidity [5,6]. The majority of patients who develop gastroparesis have long-standing diabetes; others develop the condition after surgical procedures, possibly related to vagal nerve damage or gastric resection; and some have no clear etiology and are labeled idiopathic. The latter subgroup is suspected to have sustained viral damage of gastric neural function, assumedly associated with gastroenteritis. Except for those patients who developed gastroparesis after a viral illness, the majority of patients do not spontaneously improve [7].

We have reported our initial experience with the gastric pacemaker and noted that the pacemaker did not entrain gastric slow waves or cause the stomach to contract [8]. Additionally, in the first 25 patients implanted, gastric emp-

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tying did not consistently improve [8]. Thus we now feel the device should be called a gastric electrical stimulator, an appropriate term for the low energy current involved.

Despite the modest effect on gastric emptying, the overwhelming majority of patients improved in terms of the frequency and severity of both nausea and vomiting. The initial report did not address other aspects of their outcome, such as, gastrointestinal total symptom score, quality of life measures, and nutritional aspects.

In this report, we examined 55 patients who have had the device in place for at least a year. The devices continued to be effective and improved not only the total symptom score, but also the patients' quality of life, nutrition, and the degree of control of glucose in the diabetic patients.

Material and methods

From April 1998 to November 2001, 55 patients underwent placement of a totally implantable gastric electrical stimulator (GES; Medtronic, Minneapolis, Minnesota) by an open surgical technique. The investigation was approved by the Human Subjects Committee of the University of Kansas Medical Center.

Surgical technique

The surgical procedure was performed through an upper midline incision. All previous tube gastrostomies or gastrojejunostomies were taken down. Two permanent electrodes were placed on the greater curvature of the antrum of the stomach, at 9.5 and 10.5 cm proximal to the pylorus in the following manner. The electrodes are now made with the conducting end attached to a piece of monofilament, nonabsorbable suture, which is in turn connected to a needle. The needle was first pushed tangentially through the muscular wall of the stomach, taking care not to enter the lumen. We have used both external ultrasonography and endoscopic ultrasonography to check the position of the needle [9]. The most straightforward technique is intraoperative gastroscopy to visually check that the needle is not seen from the lumen. We now use this technique exclusively to check electrode placement.

Each electrode was next positioned in the muscularis propria layer by pulling the needle, the monofilament suture, and finally the electrode into the stomach wall. The electrodes were secured to the serosa of the stomach using 5-0 silk sutures and a plastic disk. The other end of each electrode was connected to the GES and the GES was positioned in a subcutaneous pocket on top of the abdominal wall fascia to the right of the umbilicus. A 3-0 prolene stitch was used to secure the device to the fascia. The load impedance of the circuit was checked both before and after the GES was placed in the pocket. The pocket was generously irrigated with an antibiotic containing solution and the pa-

tient was given intravenous antibiotics both prior to surgery and for 2 days postoperatively.

The GES system (Enterra) system consists of the implantable neurostimulator (Medtronic model 7425G), two intramuscular leads (Medtronic model 4301), and an external programmer (Medtronic model 7432). The initial parameters were programmed to standardized parameters (frequency = 14 Hz, intensity = 5 milliamp, pulse width = 330 microsecond, cycle ON = 0.1 second, and cycle OFF = 5.0 second). The stimulator could be activated in the operating room but was usually activated 48 hours postoperatively.

After placement of the GES in the pocket, the pocket was closed by sewing the subcutaneous tissue to the fascia. Afterwards, a feeding jejunostomy was created in the proximal small bowel if the patient was already using a combined gastrojejunal tube (which was always removed) was requiring total parenteral nutrition for nutritional repletion (which was always stopped), was markedly malnourished, or was unable to reliably take oral medications.

An abdominal flat plate was taken in the immediate postoperative period to document the position of the wires and the GES and to be a reference for comparison should issues arise about the functioning of the device.

Body mass index was derived from the patients' height and weight. Gastric emptying was determined from the percent remaining of a radiolabeled standardized solid meal at 4 hours, with <10% being considered normal [2]. The hemoglobin (Hb) A1 glycosylated value was measured in a fasting blood sample.

Symptom assessments, gastric emptying, quality of life, weight, and level of Hb1AC in diabetic patients were measured at baseline and at 6 months and 12 months postoperatively. Symptom assessments came from a self-administered questionnaire at follow-up appointment. The gastrointestinal total symptom score was calculated as the sum of the 5-point categorical scales (0 for absent up to 5 for extremely frequent or extremely severe) of both frequency and severity of seven symptoms: vomiting, nausea, early satiety, bloating, postprandial fullness, epigastric pain, and epigastric burning. Quality of life was assessed using the SF-36 questionnaire. Two summary scores derived from SF-36 are reported: Physical Composite Score (PCS) and Mental Composite Score (MCS) [10]. The PCS and MCS are norm-based scales. Mean PCS and MCS scores for the general US population is 50.

Data are presented as means \pm SEM. The paired Student's *t* test was used to determine significant differences between means (Microsoft Excel; Microsoft, Redmond, Washington). Significant differences were noted if *P* less than 0.05.

Results

The first patient received a gastric electrical stimulator at the University of Kansas in April 1998 and the last in this series in November 2001. All the patients evaluated in this

Table 1
Summary of subjective and objective parameters

	Baseline	6 months	12 months
Gastric emptying	45% \pm 3.7 (52)	33% \pm 4.0 (46)*	38% \pm 5.3 (36)
Total symptom score			
Severity	20 \pm 0.68 (54)	10 \pm 1.1 (46)*	9.1 \pm 1.2 (41)*
Frequency	21 \pm 0.66 (54)	11 \pm 1.1 (46)*	10 \pm 1.2 (41)*
Quality of life			
Physical composite score	24 \pm 1.1 (54)	32 \pm 1.5 (47)*	33 \pm 1.7 (41)*
Mental composite score	37 \pm 1.6 (54)	48 \pm 2.0 (47)*	48 \pm 1.6 (41)*
Body weight (kg)	64.5 \pm 2.1 (55)	65.1 \pm 2.0 (45)	65.4 \pm 1.9 (44)*
Body mass index	22.9 \pm 0.7 (55)	22.3 \pm 0.7 (45)	23.3 \pm 0.6 (44)*
Hemoglobin A1C	9.8% \pm 0.49 (29)	9.0% \pm 0.56 (23)	8.5% \pm 0.45 (24)*

* Refers to statistical significance ($P < 0.05$) of the 6-months or 12-month data compared with the respective baseline measurement.

report are at least 1 year postimplantation. The mean patient age was 40.5 years (range 21 to 66) and 76% were women. The average duration of their disease was 9.9 years. Thirty-nine (71%) patients were diabetic (mean duration 18.4 years), 9 (16%) were postsurgical, and 7 (13%) had idiopathic gastroparesis. The postsurgical cases included 4 patients who had Nissen funduplications, 4 patients who had cholecystectomies, and 1 patient who had a vagotomy and pyloroplasty. Two of the postsurgical patients underwent a standard sham meal challenge to measure serum pancreatic polypeptide levels in order to assess vagal integrity. The patient who had the vagotomy and pyloroplasty had no vagal function but 1 patient with the Nissen fundoplication did have an intact vagus. Both patients responded to the device.

Six patients, all diabetic, have died since their operation. One patient died in the immediate postoperative period of a pulmonary embolus, which we believe was related to very limited activity prior to surgery. The 5 other patients died more than a month postoperatively. One patient refused dialysis and died 3 months postoperatively. Two died at 9 months, 1 of a myocardial infarction and another of aspiration pneumonia. One patient committed suicide at 14 months, and the other death occurred at 19 months from complications of diabetes.

The GES has been removed in 4 patients, all diabetic, at 3, 10, 12, and 16 months. The first 2 were removed solely because of a postoperative infection. In the third case, the GES was placed without being sutured to the fascia and, during physical activity, the device was pushed up against the rib cage and then out against the skin, causing inflammation. The skin became bruised and secondarily infected. The infection did not respond to antibiotics, and the device was removed. The final patient developed a small bowel volvulus about the wires. In this patient, the GES was originally placed in the right lower quadrant of his abdominal wall. Owing to pain and discomfort from the device in this location, the device had already been moved once. When he presented with the volvulus, he was treated with a small bowel resection and removal of the GES; he has since recovered.

In 3 patients, the device was moved or replaced. Two

patients, both diabetic patients, had the device placed in the right lower quadrant to prevent migration and interaction with the rib cage and both patients had problems. One patient had to have the device repositioned. By having the device so far away from the stomach, the electrodes lost electrical contact with the stomach and the patient required replacement of both the device and the electrodes into the usual position to the right of the umbilicus. The other patient had the device repositioned at 9 months and is the patient mentioned above, who later suffered an internal volvulus around the wires at 15 months. The third patient, postsurgical, was involved in a motor vehicle accident in which her sternum and three ribs were fractured. Her symptoms reappeared 7 days after the accident and the load impedance was found to be increased. On reexploration, one of the leads had become detached. The device and the electrodes were replaced and her symptoms improved very soon after surgery.

The results for these 55 patients are summarized in Table 1. Similar to our first report [6], gastric emptying was significantly improved at the first measurement, but the numerical difference was small. This improvement was not sustained at 12 months. However, a third of these patients did achieve normal gastric emptying (<10% remaining at 4 hours). Of that third, 58% were diabetic patients, 25% idiopathic, and 17% postsurgical.

Gastrointestinal total symptom scores for both severity and frequency were significantly improved at 6 months ($P < 0.05$). Despite the lack of overall continued improvement of gastric emptying, total system scores remained significantly reduced at 12 months. Quality of life parameters also improved with the mental composite score approaching normal, rising from 37 to 48. The majority of the improvement happened within the first 6 months. There was no change from 6 months to 1 year. The physical composite score also improved significantly but not as dramatically. The patients demonstrated a marked decrease in need for hospitalization. For the year prior to placement of the GES, the average for days spent hospitalized was 57 ± 9 (range 0 to 252); the next year, this average fell to 17 ± 3 days

(range 0 to 69; $P < 0.05$). This reduction alone could explain much of their improvement in quality of life.

In terms of nutritional parameters, the patients' average body weight increased by almost a kilogram and the body mass index by 0.4 units. In concert with this increase in body weight, the majority of patients had their jejunal feeding tubes removed by 1 year and no one was receiving total parenteral nutrition. Of the 25 patients who had a jejunal feeding tube (1 had a gastrojejunostomy) after placement of the GES, only 8 (32%) required this feeding approach at 12 months. In the diabetic patients, there was a reduction in the HbA1C levels, which achieved significance by 12 months.

Comments

The patients in this series were initially part of the WAVESS study ($n = 9$), a prospective, double-blind, randomized trial initiated by Medtronic to assess the effectiveness and safety of the device [11] or part of the CUESS study, a prospective trial for compassionate use of the device ($n = 32$). In March 2000, the Food and Drug Administration approved the therapy as a humanitarian device exemption (HDE) and this therapy was called Enterra. The other patients ($n = 14$) were implanted with this device under HDE protocol. The same inclusion and exclusion criteria were used in all of these patients and careful follow-up continues. The overwhelming response of these patients remains positive to this therapy.

All operations were performed through an open approach. Although the operation can be performed laparoscopically, a number of factors may support an open approach: (1) the exact placement of the electrodes in relation to the pylorus is felt by the surgeon to be critical and difficult to do laparoscopically; (2) the length of the skin incision is determined by the size of the device; (3) many patients need to have their previous gastrostomy tubes taken down, the stomach closed, and jejunal feeding tubes placed if their nutritional status is precarious preoperatively; and (4) many patients have undergone previous abdominal operations, including gastric surgery. Antibiotics are given preoperatively and postoperatively for 2 days and antibiotic containing solution is used intraoperatively in an effort to prevent infection in the pocket. Since implementing this prophylactic regimen, there have been no more infectious complications.

In this report, the GES improved total symptom scores for both severity and frequency in patients for up to 1 year. Excluding the patients who died, those whose device was removed, and those lost to follow-up, 67% of the patients had a more than 50% decrease in total symptom score and are unequivocally termed a treatment success. Only 3 patients had an increase in their symptom score. The remainder still felt improved and benefited by the device although experiencing less than a 50% decrease in total symptom score. These results should be compared and contrasted to

total or completion gastrectomy, the other surgical treatments for severe gastroparesis. These operations improve 43% to 80% of patients but require a major surgical procedure and loss of the stomach [6,12,13]. This new treatment has changed our approach to GP. Presently, approximately half of the patients referred to our center for gastroparesis go on to receive GES therapy.

As in our previous report, the improvement in symptoms was not tied to improvement in gastric emptying nor to any particular etiology of GP. Although gastric emptying was significantly improved at 6 months; the mean value of the remaining meal was still three times normal. At 1 year, the average residual at 4 hours was the same as at baseline, despite the fact that the total symptom score remained significantly reduced. However, of the seven symptoms scored, nausea and vomiting were reduced more than postprandial fullness, bloating, and early satiety. That these later symptoms were still present is consistent with the observed slow gastric emptying. The lack of correlation between gastric emptying and symptoms has been noted before. In diabetic patients, treated with motility agents, the improvement in symptoms was not associated with an improved gastric emptying time [14]. Hence GES therapy is a powerful anti-nausea and antiemetic therapy despite not predictably improving gastric emptying.

It should be noted that a third of the patients did achieve normal emptying at 4 hours after 12 months of therapy and deserve discussion. This group did not come exclusively from one etiologic subgroup. Compared with the whole group, these patients were younger and had a shorter duration of GP. Possibly, in the diabetic patients, improving glucose control and reducing Hb1AC may led to improved gastric emptying over time. One of the patients has continued to do well after his pacemaker was removed at 12 months owing to erosion and infection. Additionally, virus-induced gastroparesis can and does spontaneously resolve over time [15].

As would be expected, improvement in total gastrointestinal symptom score was associated with improvement in physical and mental quality of life measures. The physical composite score improved at 6 months, rising from about 24% to 33%. This improvement may be limited by the substantial comorbidities these patients experience from their underlying disease, commonly diabetes. The majority of the diabetic patients develop gastroparesis after they have had diabetes for some years and many also suffer from nephropathy, neuropathy, retinopathy, and other diabetic complications. Some of these patients were diagnosed with depression and anxiety and a third had hypothyroidism. The mental composite score, however, normalized. This suggests that the GES does not correct all the physical issues, particularly in the setting of a chronic disease process such as diabetes, but it clearly makes life more tolerable for the majority of patients. These functional improvements need to be viewed from the perspective that these patients are young (average age 40.5 years) women (76%) and men in the

prime years of their life and can be returned to families and employment activities.

In terms of nutrition, the patients eat better and gain weight. Both mean body weight and body mass index were higher at 1 year; although the absolute amount of improvement was not great, about 1 kg in 12 months. Since these patients were quite ill at the time of surgery and steadily losing weight, they were often receiving nutritional support preoperatively, both enteral and parenteral. After GES implantation, these same patients were no longer requiring parenteral nutritional support, had often stopped using their feeding jejunostomy tubes, and were maintaining or gaining weight—an impressive turn around. Patients who do not return for follow-ups are not counted. These patients were doing so well, they did not feel the need to return.

For the diabetic patients, the improvement in symptoms clearly allowed for better eating habits and improvement in glucose control. Diabetic patients are known to have worse metabolic control when they suffer with gastroparesis. Yet, improvement in gastric emptying with cisapride has not been shown to result in improved glycemic control [14] exactly opposite to what was found in our patients. With GES, the prevention of vomiting means more stable glucose control by preventing the fluctuations of glucose with predictable oral caloric intake. Over time, sustained improved glucose control and reduced HbA1C could reduce other diabetic complications; additionally, reduction in vomiting makes the patients better candidates for pancreas transplantation, since immunosuppressants can be taken orally and predictably absorbed without vomiting.

The mechanism of action of the GES remains to be elucidated. The early experience in patients who had both a GES and recording electrodes did not demonstrate entrainment of the stomach electrical activity by the GES [16]. Additionally, only a third of the patients normalized gastric emptying; certainly less than the two thirds whose symptoms improved. Thus GES does not usually improve the gastric motility to achieve a reduction of the patients' gastrointestinal total symptom score. Other areas that could be affected by GES include gastric fundic relaxation [17], the autonomic nervous system [18], release of gastrointestinal hormones, including ghrelin [19], and activation of central nervous system control mechanisms for nausea and vomiting.

In conclusion, the gastric electrical stimulator improves symptoms, quality of life measures, glycemic control, hospital admissions, and stabilizes nutritional parameters in patients with all forms of gastroparesis. The mechanism by which the stimulator achieves these beneficial effects and the duration of its effect require further study (several of our early patients have had the device for 5 years and are continuing to do well). This report of the extensive experience at a single center emphasizes the important role and impact of this new method in treating and changing the lives of these gastroparesis patients, previously unresponsive to standard care.

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Discussion

K. Murayama (Chicago, IL): The authors report their personal series of 55 patients who have had a totally implantable gastric electrical stimulator (GES) placed to treat gastroparesis over a 43-month period. In the current work, they present a follow-up study to the work previously presented at this meeting and published in 2001. The initial report described the first 25 patients and they have added 30 patients for the current manuscript. Unfortunately, there was no stated hypothesis in the manuscript.

The mechanism of action for this device in the treatment of gastroparesis is still unknown. While many patients have symptomatic improvement, it apparently does not cause stomach contraction and only modestly improves gastric emptying, although this benefit is not sustained at 12 months. The most remarkable improvement was in the days of hospitalization after placement of the GES. In the year prior to placement, the mean number of days hospitalized was 57 and in the year after placement the mean was 17 days.

Although the days of hospitalization clearly decreased in your study after placement of the unit, the mean body weight increased only 0.9 kg and the BMI increased by only 0.4. Apparently, from your analysis, these values are statistically significant although I would recommend rechecking that analysis and regardless, is this really a clinically significant weight gain after one year? I suppose if you consider that without the device their weight would continue to drop off, then maybe this is a significant weight gain. To play devil's advocate, since the subjective parameters you measured showed significant improvement in spite of minimal weight gain, is there any possibility that some of the benefit, or even a large portion of the benefit, is really a placebo effect. I believe in your initial study there were patients who crossed over between two groups with the stimulator either on or off and did your findings there completely eliminate the placebo effect as an explanation for the benefit? As you know, several other surgeons performed this procedure laparoscopically, and I appreciate your explanation in the manuscript addressing why you choose to perform this placement via an open approach. However, while a skin incision does need to be made to place the unit, I think a laparoscopic approach does eliminate a defect in the fascia that could result in either hernia formation or fascial dehiscence and evisceration. Have you had any of these complications, since by definition all of these patients are malnourished when they come to you, I would think they have a higher incidence of these complications. Is this really gastroparesis since they have significant symptomatic

improvement, yet no improvement in their gastric emptying. Have you turned off the unit in any of your patients and what results have you seen? You have 1-year follow-up in your study here, but it is clear that you probably have longer follow-up and are the benefits sustained beyond 1 year?

Jameson Forster: I agree with you that the weight gain is very minimal statistically, and it is problematic. There are a couple of problems with the data. Initially when we were looking at these patients, we had enough money that they came back. However, some have not come back. We are missing 15 patients at the end on the 12-month anniversary and the question would be if some of those have done a lot better and are not returning because things are going well for them; that's one explanation. I don't have another clear explanation. I think that placebo effect is a very real possibility and the initial study was stopped because Medtronic felt that there was no benefit being shown. Doctor McCallum has reanalyzed the data and I believe it's being published shortly. They have identified that there is an improvement in these patients. I would just suggest that when it comes out in print, you look at it and see whether or not it makes sense to you. There is a prospective randomized trial that Medtronic is starting now. We are up to about 110 patients and we have 4 or 5 patients already in that trial. In this trial, the patients are not randomized until 3 months after surgery when there are no perioperative issues and then they will be randomized to being off or on and then have a crossover.

The other question is have we ever turned it off; there have only been a couple of patients who have had it removed and so far they seem to be doing quite well, so it's sort of interesting whether you get things started, whatever that means, and that they continue to have momentum to finish up, I don't know, but the 1 patient who had it removed at 12 months was a diabetic with a lot of troubles. Once it was put in, he started doing a lot more exercise and golfing, and at that time I was not suturing the pacemaker to the fascia, and it rode up onto his right rib subcostal area and came out the skin eventually with an infection; I removed it, and he continued to do well, so I don't know whether there is something that we are resetting with this. We have not seen hernias, it is sort of a strange issues, because I believe that these are malnourished individuals. They do vomit, you do have increased abdominal forces, so you would expect it. The only hernia we have had has been one where I inadvertently (not a patient in this group) put the J-tube through a previously placed mesh patch by error and it caused an infection. I removed it and she had a hernia afterwards.

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