Long-Term Outcome of Gastric Per-Oral Endoscopic Pyloromyotomy in Treatment of Gastroparesis

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BACKGROUND & AIMS: Gastric per oral endoscopic pyloromyotomy (GPOEM) is a promising treatment for gastroparesis. There are few data on the long-term outcomes of this procedure. We investigated long-term outcomes of GPOEM treatment of patients with refractory gastroparesis.

METHODS: We conducted a retrospective case-series study of all patients who underwent GPOEM for refractory gastroparesis at a single center (n = 97), from June 2015 through March 2019; 90 patients had more than 3 months follow-up data and were included in our final analysis. We collected data on gastroparesis cardinal symptom index (GCSI) scores (measurements of postprandial fullness or early satiety, nausea and vomiting, and bloating) and SF-36 questionnaire scores (measures quality of life). The primary outcome was clinical response to GPOEM, defined as a decrease of at least 1 point in the average total GCSI score with more than a 25% decrease in at least 2 subscales of cardinal symptoms. Recurrence was defined as a return to baseline GCSI or GCSI scores of 3 or more for at least 2 months after an initial complete response. The secondary outcome was the factors that predict GPOEM failure (no response or gastroparesis recurrence within 6 months).

RESULTS: At initial follow-up (3 to 6 months after GPOEM), 73 patients (81.1%) had a clinical response and significant increases in SF-36 questionnaire scores (indicating increased quality of life) whereas 17 patients (18.9%) had no response. Six months after GPOEM, 7.1% had recurrence. At 12 months, 8.3% of patients remaining in the study had recurrence. At 24 months, 4.8% of patients remaining in the study had a recurrence. At 36 months, 14.3% of patients remaining in the study had recurrence. For patients who experienced an initial clinical response, the rate of loss of that response per year was 12.9%. In the univariate and multivariate regression analysis, a longer duration of gastroparesis reduced the odds of response to GPOEM (odds ratio [OR], 0.092; 95% CI, 1.04–1.3; P = .001). On multivariate logistic regression, patients with high BMIs had increased odds of GPOEM failure (OR, 1.097; 95% CI, 1.022–1.176; P = .010) and patients receiving psychiatric medications had a higher risk of GPOEM failure (OR, 1.33; 95% CI, 0.110–1.008; P = .052).

CONCLUSIONS: In retrospective analysis of 90 patients who underwent GPOEM for refractory gastroparesis, 81.1% had a clinical response at initial follow-up of their procedure. 1 year after GPOEM, 69.1% of all patients had a clinical response and 85.2% of initial responders maintained a clinical response. Patients maintained a clinical response and improved quality of life for as long as 3 years after the procedure. High BMI and long duration gastroparesis were associated with failure of GPOEM.

Keywords: Therapy; Diabetes; Gastric Emptying; Psychologic.

Abbreviations used in this paper: BMI, body mass index; GCSI, Gastroparesis Cardinal Symptom Index; GE, gastric emptying; GES, gastric electrical stimulators; GP, gastroparesis; GPOEM, gastric per-oral endoscopic pyloromyotomy; ICC, interstitial cells of Cajal; J-tube, jejunostomy tube; SF-36, Short Form-36.

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Gastroparesis (GP) is a chronic, debilitating motility disorder characterized by nausea, vomiting, early satiety, and postprandial fullness.[1,2] In 2007, the age-adjusted prevalence of GP per 100,000 persons was approximately 4-fold higher in women than men: 37.8 and 9.6, respectively.[3] Furthermore, incidence of GP hospitalization seems to be rising, reported as high as a 300% increase from 1997 to 2013, with an estimated annual health care cost of $568 million.[4] GP can have a significant adverse impact on the overall quality of life of the affected patient.[5] No definitive cure for GP currently exists with most available treatment options focusing on symptom control with diet modification and prokinetic medications. Unfortunately, prokinetic medication use is often limited by possible dangerous side effects including arrhythmia, tardive dyskinesia, and tachyphylaxis.

Gastric electrical stimulators (GES) are an interventional therapeutic option, particularly for nausea-predominant GP in patients with diabetes; however, efficacy of such devices has proven underwhelming.[6] It is estimated that 20% of patients receive no benefit from such devices, with open-label studies reporting 1-year clinical response rates between 45% and 74%.[7–13] Durability of clinical response further limits broad adoption of this technology with 1 study reporting only 25% of patients who found clinical benefit maintaining response at 3 years and only 26% and 44% of patients reporting reductions in nausea and vomiting, respectively, at 10 years. In addition to the need for laparoscopic implantation of the device and removal before magnetic resonance imaging, device-related complications are reported in 15% of patients. These include bowel obstruction, perforation, lead migration, and wound complications. Complications are associated with a removal rate of 6.3%–12.8%.[8–10,12,14]

Another therapeutic intervention is pyloric disruptive therapy. Laparoscopic pyloromyotomy has been shown to improve symptom scores by 83%–86% and improves or normalizes gastric emptying (GE) in nearly 60%–90% of GP patients.[15] Widespread use of this surgical approach is limited by postoperative adverse events including leaks, suture line bleeding, and wound infections.[15] Alternatively, gastric per-oral endoscopic myotomy (GPOEM) is an endoscopic pyloric disruptive therapy for GP wherein a submucosal tunnel is created to approach and then myotomize the pyloric muscle. GPOEM was debuted in 2013 following the adoption of per-oral endoscopic myotomy for treatment of achalasia.[8] Since that time, several studies have reported an average of 83.9% (62%–90%) short-term (6 months to 1 year) clinical success on GPOEM in GP patients.[16–26] Benefits of GPOEM over laparoscopic pyloroplasty include shorter operative time, less intraprocedural blood loss, and a shorter length of stay.[27]

Despite the initial promising short-term results, proof of longer-term outcome is fundamental for wider adoption of GPOEM for treatment of GP. Thus, our study aims to evaluate the long-term outcomes of GPOEM in treatment of patients with refractory GP and identify factors that predict failure of GPOEM.

What You Need to Know

Background

Gastric per oral endoscopic pyloromyotomy (GPOEM) is a promising treatment for gastroparesis, yet there are few data on the long-term outcomes of this procedure.

Findings

In retrospective analysis of 90 patients who underwent GPOEM for refractory gastroparesis, 80% had an initial clinical response and more than 90% maintained that response 1 year after the procedure. Patients maintained a clinical response and improved quality of life for as long as 3 years after the procedure.

Implications for patient care

GPOEM minimize health care utilization and improve the long term quality of life of patient with refractory gastroparesis. High body mass index and long duration gastroparesis are associated with failure of GPOEM—these factors should be considered when selecting treatment for patients with gastroparesis.

Materials and Methods

After approval by the institutional review board at Emory University, we conducted a retrospective case series of all patients who underwent GPOEM for refractory GP between June 2015 and March 2019. The procedures were performed by an endoscopist experienced with the procedure and typically assisted by an advanced endoscopy fellow. The Gastroparesis Cardinal Symptom Index (GCSI) score was calculated by averaging the mean score of 3 subscales: (1) postprandial fullness/early satiety, (2) nausea/vomiting, and (3) bloating.[28] Eight aspects of quality of life, including physical functioning, role limitation caused by physical health, bodily pain, general health, vitality, social functioning, role limitation caused by emotional problems, and mental health were assessed using the Short Form-36 (SF-36) questionnaire. The scores were calculated using a revised International Resource Center for Health Care Assessment scoring system and reported as a median of each category. An average score of all 8 domains was used to assess the overall quality of life similar to our previous publication.[29,30]

Definitions

Refractory gastroparesis. GP with poor response to greater than 6 months of dietary modifications and trial

of maximally tolerated doses of prokinetic medications after ruling out mechanical obstruction.

Radiologic criteria. Radiologic criteria for the diagnosis of GP was retention percentage of more than 10% at 4 hours during a GE study using a standard low-fat, low-calorie meal.

Clinical response. Decrease of at least 1 point in the average total GCSI score with more than a 25% decrease in at least 2 subscales of cardinal symptoms.

Nonresponders. Patients who underwent GPOEM and did not experience a decrease of GCSI score by 1 point.

Recurrence. Defined as recurrence of GP symptoms and return to the baseline GCSI or GCSI ≥3 lasting at least 2 months after initial complete response.

Clinical failure. No clinical response (as defined previously) at initial follow-up or patients with recurrence of symptoms within 6 months.

Body mass index. Body mass index (BMI) was classified according to the World Health Organization definition: underweight, BMI <18.5 kg/m^2; normal weight, BMI 18.5–25 kg/m^2; obese, BMI 30–40 kg/m^2; and morbidly obese, BMI ≥40 kg/m^2.

Technical Detail

The procedure has been described in detail in our prior published studies.[15,16] After identification of the pyloric ring, a selective single or double circular myotomy was performed. Double myotomy was defined as a second selective myotomy was performed at the 4- or 5-o'clock position with at least 1 cm maintained between the 2 pyloromyotomies. All patients were given prophylactic antibiotics during the procedure. Patients were kept NPO the remainder of the day of the procedure and discharged the following morning after tolerating a liquid diet unless there was suspicion of procedural complication (eg, abdominal pain, bleeding).

GE studies were obtained 4–8 weeks post-intervention. Impact of GPOEM on nutrition was measured by transition from feeding tube–predominant diet to oral intake predominant and reduction or discontinuation of antiemetic medications during the study period. Hospitalization rate and emergency room visitation rate was reported 6 months before and 6 months after GPOEM.

Statistical Analysis

Comparative analyses, total average GCSI, and subscale scores pre- and post-GPOEM were performed using repeated measures, analysis of variance, and post hoc paired Student *t* test with Bonferroni correction. The univariate analysis was made using the chi-square test and multivariate analysis using linear logistic regression. Kaplan-Meier graph with estimates with error bars was used to calculate recurrence. A stepwise logistic regression was used to evaluate the factors that predict clinical failure. A *P* value of less than 0.05 was considered statistically significant. Data were analyzed using SPSS version 22.0 statistical software (IBM Corporation, Armonk, NY).

Results

Clinical Outcomes

Ninety-seven patients (18 males and 79 females) underwent GPOEM from June 2015 to March 2019. Ninety (17 males and 73 females) patients had more than 3 months follow-up and were included in the final analysis with a technical success (complete pyloromyotomy) rate of 100% (Table 1). The mean age was 47 ± 14 years, and the mean duration of symptoms was 5.3 ± 4.4 years. Average GCSI before GPOEM was 3.8 ± 0.6. Average total procedure time (from esophageal intubation to removal of the endoscope from the mouth) was 50 ± 13 minutes.

Seventy-four patients underwent a GES before and after the GPOEM: 47 (63%) patients had normalized GES after the procedure, 25 (34%) patients had improvement of the GE, and 2 (3%) patients had worsening of the GE. Overall, there was a significant improvement in gastric retention at 4 hours from an average baseline of 50.6% ± 27.3% to 20.1% ± 23.5% at 2 month post-procedure (t = -6.4; $P < .01$) (Figure 1).

Out of the 90 patients, 73 (81%) exhibited a clinical response and 17 (19%) patients did not exhibit a clinical response at initial follow-up between 3 and 6 months

Table 1. Perioperative Baseline Characteristics

	GPOEM (n = 90)
Female, n (%)	73 (81)
Age, *y*	42.4 ± 12.6
Age >60	15
BMI pre-GPOEM, *kg/m^2*	27.65 ± 7.4
Etiology, n (%)	
Diabetes	38 (42)
Idiopathic	42 (47)
Others	10 (11)
Duration of disease, *y*	5.3 ± 4.4
Pharmacotherapy, n (%)	
Erythromycin	55 (61)
Metoclopramide	86 (96)
Domperidone	43 (48)
Other antiemetics	51 (57)
Nutritional support, n *(%)*	
PPN and TPN	6 (7)
J-tube	11 (12)
Previous therapy, n (%)	3 (13)
Botulinum injection	6 (7)
Gastric electrical stimulation	14 (16)
GCSI pre-GPOEM	3.8 ± 0.6

BMI, body mass index; GCSI, Gastroparesis Cardinal Symptom Index; GPOEM, gastric per-oral endoscopic pyloromyotomy; J-tube, jejunostomy tube; PPN, peripheral parenteral nutrition; TPN, total parenteral nutrition.

following GPOEM (Table 2). Seven patients were unable to be tracked during the follow-up period (4 died and 3 were otherwise unreachable).

At 6 months, 5 (7.1%) patients had recurrence of symptoms and 65 patients (92.9%) maintained clinical response. At 12 months, 4 (8.3%) patients had recurrence of symptoms and 44 (91.7%) patients maintained clinical response. At 24 months, 1 (4.8%) patient had a recurrence and 20 (95.2%) patients maintained clinical response. At 36 months, 1 patient (14%) had recurrence and 6 (86%) patients maintained clinical response (Table 2). One year after receiving GPOEM, 69.1% of all patients had a clinical response and 85.2% of initial responders maintained a clinical response. For patients who experienced an initial clinical response, from 6 to 36 months of follow-up the rate of loss of that response was 12.9% per year.

Health Care Use Following Gastric Per-Oral Endoscopic Pyloromyotomy

In patients with clinical success following GPOEM, GP hospitalizations decreased from 8.2 $\pm$ 12 in the 6 months before GPOEM to 0.7 $\pm$ 1.5 in the 6 months after GPOEM ($t = 3.6$). Additionally, monthly emergency room visits decreased from average 2.0 $\pm$ 2.9 pre-GPOEM to 0.3 $\pm$ 0.7 post-GPOEM ($t = 3.4$; $P = .02$). There was no statistically significant change in the rate of health care use in nonresponders following GPOEM.

Quality of Life

Throughout the follow-up period of the responders (mean, 16 months), there was a significant improvement in quality of life on SF-36 survey following GPOEM ($P < .001$). A total of 73%, 65%, 51%, and 45% had improvement in quality of life during 6 months (n = 48), 12 months (n = 32), 24 months (n = 21), and 36 months (n = 16) following GPOEM. There was a statistically significant correlation between the clinical response and improvement in SF-36 score ($P = .001$). Subgroup analysis showed a significant improvement in physical functioning, role limitation caused by physical health, general health, vitality, social functioning, role limitation caused by emotional problems, and mental health.

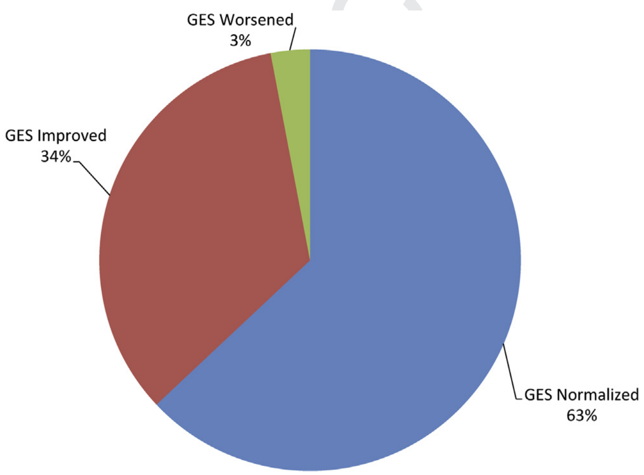

Figure 1. Gastric emptying results following gastric per-oral endoscopic pyloromyotomy.

Nutrition and Antiemetic Medications

Before GPOEM, 12 patients relied on jejunostomy tubes (J-tubes) for feeding and 5 patients relied on total parenteral nutrition. Of the 12 J-tube-dependent patients, 9 managed to tolerate oral intake and forego J-tube nutritional dependence following their procedure. Of the total parenteral nutrition–dependent patients, 3 were able to discontinue therapy.

Before GPOEM 55 (61%) patients were on erythromycin, 86 (96%) patients were on metoclopramide, 43 (48%) patients were on domperidone, and 51 (57%) patients were on other antiemetics. Six months following GPOEM 59 (66%) patients discontinued the schedule antiemetics.

Factors Predicting Failure of Gastric Per-Oral Endoscopic Pyloromyotomy

We evaluated the impact of age, gender, resistance to endoscope passage, gastric pacemaker placement, smoking, history of abdominal pain, history of opioids use, history of chronic narcotic use, history of psychiatric disorder, etiology of GP, BMI, and initial GCSI score (including subcategories).

In univariate and multivariate regression analysis, a longer duration of GP reduced the odds of response to GPOEM (odds ratio, 1.4; 95% confidence interval, 1.07–1.8; $P = .002$). In univariate analysis, higher BMI, history of psychiatric medication use, and history of pain medication use all increased odds of GPOEM failure. In multivariate logistic regression, patients with high BMIs had increased odds of GPOEM failure (odds ratio, 1.097; 95% confidence interval, 1.022–1.176; $P = .010$) and patients receiving psychiatric medications had a higher risk of GPOEM failure (odds ratio, 1.33; 95% confidence interval, 0.110–1.008; $P = .052$) (Table 3).

Complications

Most of the patients (80%) were discharged within 24-hour observation. The length of hospital stay was 2.2 $\pm$ 2.0 days. Four patients had adverse events following the procedure (2 mild and 2 moderate adverse event). One incident of tension capnoperitoneum and another of bleeding from the ulcer at the mucostomy site occurred during the timeframe evaluated in this study. The patient with tension capnoperitoneum was managed by needle decompression and had a good clinical outcome. The patient with a bleeding ulcer was managed by

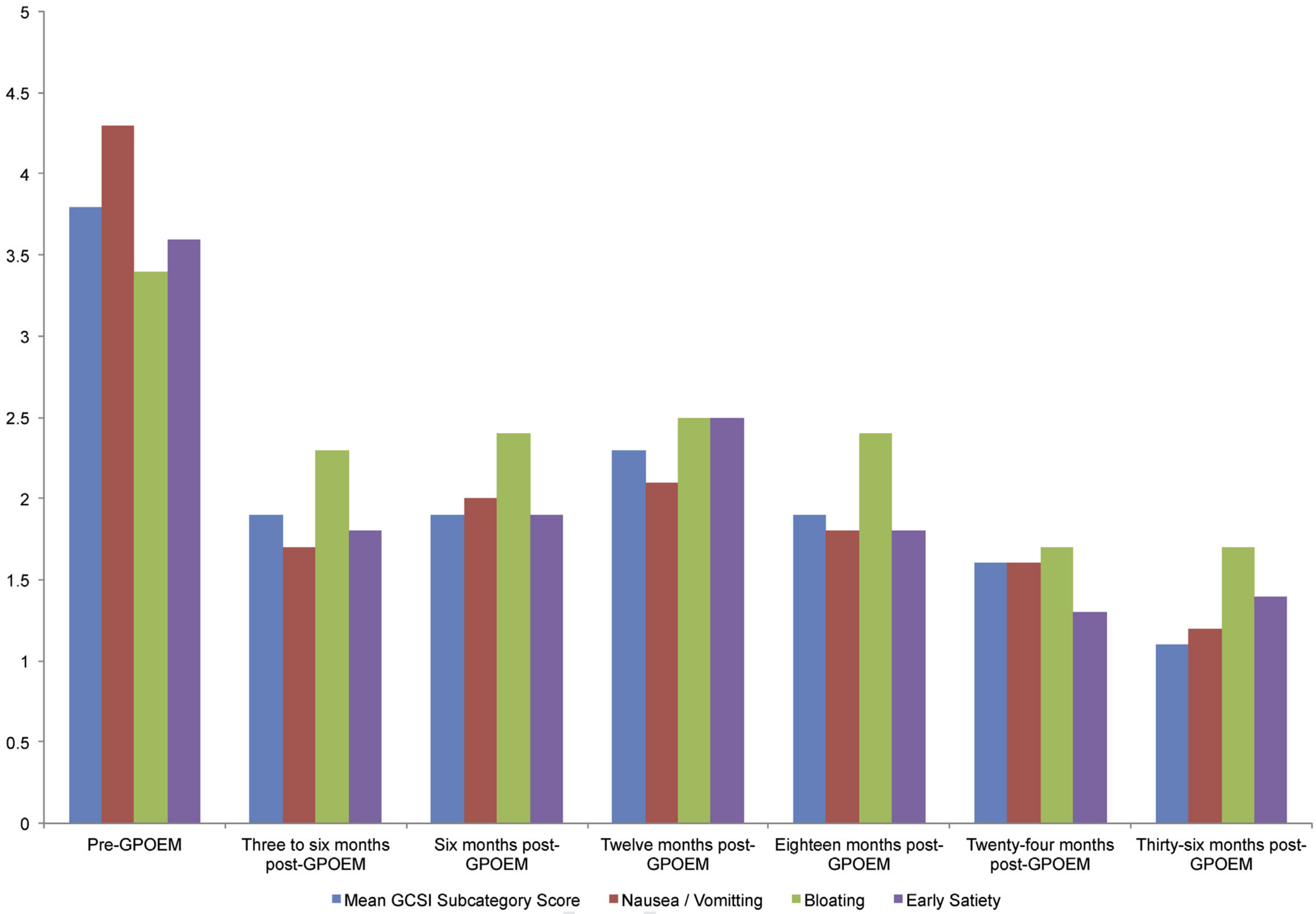

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Figure 2. Total gastroparesis cardinal symptom score during the study period.

endoscopic treatment and oral proton pump inhibitors and likewise did well. A single patient had abdominal pain after the procedure. There was a negative computed tomography scan of the abdomen for pneumoperitoneum or leak. The patient was managed with pain control, brief hospitalizations, and ultimately was discharged home without further issues. One patient had an exacerbation of preexisting chronic obstructive pulmonary disease that was believed to anesthesia-related. No patients required surgical intervention following their procedure, nor was any procedure-related mortality witnessed.

Discussion

Despite the initial promising results, GPOEM is still considered an experimental procedure. Several factors have as of yet precluded a wider adoption of GPOEM in treatment of GP. First, there is a steep learning curve associated with performing this procedure because of a difficult scope position in the short tunnel compared with per-oral endoscopic myotomy. Second, the current body of evidence suggests that up to one-third of patients may not exhibit clinical response to treatment.[19,20] Third, there exists a paucity of data on the long-term outcomes of GPOEM.

Our results demonstrate that following GPOEM, 81% of patients had a significant clinical response at time of first follow-up 3–6 months post-procedurally. Moreover, 1 year after their GPOEM, 85.2% of initial responders maintained their clinical response (69.1% of patients overall). Furthermore, clinical response to GPOEM was found to be durable with only 12.9% of initial responders losing that response per year up to 36 months post-procedurally. Although only 7 patients were able to be followed at 3 years or greater post-GPOEM, 6 maintained clinical response, suggestive of promising durability of the procedural benefit. To our knowledge, this is the longest comprehensive follow-up study on the outcome of GPOEM.

The first 30 patients in our cohort were previously published in a study comparing the clinical success and increase in quality of life with a control group of patients who did not receive GPOEM.[30] The initial 40 patients were published in a study comparing diabetic with nondiabetic GP.[19]

This study has a different objective than our previous 2 publications. First, this study centers on calculating long-term clinical and quality-of-life outcomes following GPOEM. Second, we seek to calculate the risk of recurrence during the follow-up period. Finally, via multivariate analysis we seek to identify factors predictive of GPOEM failure.

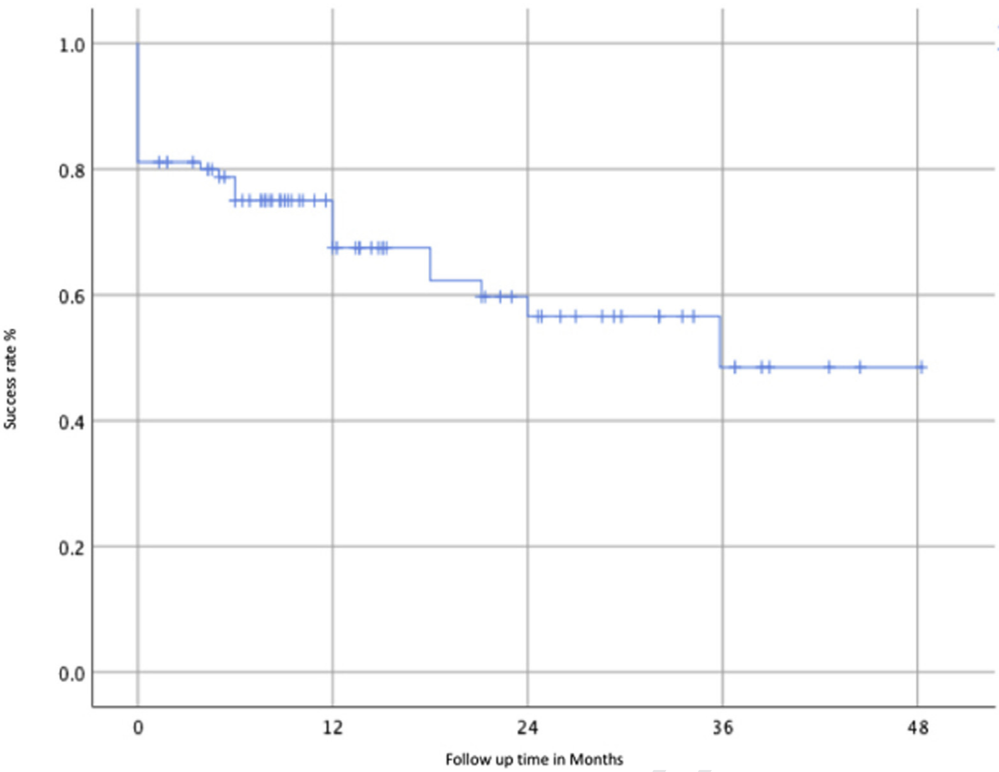

Figure 3. Kaplan-Meier curves for the 3-year success rate of GPOEM.

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There exists a limited understanding of GP pathophysiology. In healthy patients, GE is mediated by a complex system including the interstitial cells of Cajal (ICC) and enteric neurons that regulate fundic accommodation, antral contraction, and pyloric relaxation.[31] It is theorized that 1 of the underlying causes of GP is an initial immune insult leading to universal fibrosis and physiological changes in the gastrointestinal tract.[32] Histologic studies show defects in the morphology of enteric neurons, smooth muscle cells, and ICC, as well as increased concentrations of inflammatory cells in gastric tissue.[33] Other studies have reported damage to intrinsic neurons, loss of ICC, and loss of heme oxygenase-1.[21]

This dysregulated inflammatory response reported in prior studies on GP may contribute to the recurrence of symptoms that a minority of the patients in our cohort experienced. Namely, fibrosis of the pyloric myotomy site could result in contraction and stricture of the pyloric ring and subsequent recurrence of symptoms. The combination of lack of separation of the pyloric muscle following myotomy (unlike the separation in esophageal muscle following per-oral endoscopic myotomy) in addition to the underlying increase in inflammatory response and fibrosis in GP patients may explain recurrence during the first years following GPOEM. Two patients with initial positive response followed by a recurrence of symptoms within the first year following GPOEM underwent upper endoscopy revealing of increased resistance of scope passage through the pylorus. Repeat GPOEM showed fibrosis at the myotomy site, likely resulting in stricture of the pyloric ring. Repeat myotomy in these patients resulted in regaining clinical response.

Another explanation of recurrence of symptoms or nonresponse to GPOEM is the multifactorial nature of GP and worsening of other phases of gastric digestion. It is hypothesized that GPOEM eliminates pylorospasm and improves antropyloroduodenal coordination; however, there is no impact on other pathophysiologic features of GP including fundic hypocontractility, antral hypomotility, gastric arrhythmia, and autonomic neuropathy.[34] As such, the benefit of adding GES to patients with unfavorable outcomes to GPOEM is an important area of future study. Finally, GPOEM does not preclude the immune reactions that result in damage to the enteric neurons and loss of ICC. Thus, the continuous loss of ICC cells can lead to terminal GP that is refractory to pylorus-targeted therapy.[35,36]

In our study, 2 patients who were nonresponders underwent Roux-en-Y gastric bypass and laparoscopic gastrectomy with subsequent improvement in their GP symptoms. Given the relatively safe profile of GPOEM and high technical success rate, it may be used to triage patients with suspected terminal refractory GP for more definite surgical resection once identified as nonresponders to GPOEM.

The impact of GP on quality of life may be underestimated. Many patients had an extremely limited quality of life that impacted their professional, interpersonal, and social life. Our long-term results demonstrated the significant and sustainable impact of GPOEM on the improvement in quality of life. Consistent with previous studies on the topic, our results suggest decreased health care use and improved quality of life following GPOEM.[30,37]

Table 2. Long-Term Outcome of GPOEM

		Initial follow-up (>3 mo and <6 mo post-GPOEM)	6-mo follow-up (%)	12-mo follow-up (%)	18-mo follow-up (%)	24-mo follow-up (%)	36-mo follow-up (%)
Patients eligible for survey		90	73	48	35	21	7
Patients who achieved initial clinical response		73 (81.1)					
Patients who failed to achieve initial clinical response		17 (18.9)					
Lost to follow-up		0 (0)	3 (4.1)	0 (0)	4 (11.4)	0 (0)	0 (0)
Surveyed patients who lost initial clinical response			5 (7.1)	4 (8.3)	3 (9.7)	1 (4.8)	1 (14)
Surveyed patients who maintained clinical response			65 (92.9)	44 (91.7)	28 (90.3)	20 (95.2)	6 (86)
Mean GCSI subcategory score[a]		1.9 ± 1.0 (P < .001)	1.9 ± 1.0 (P = .01)	2.3 ± 1.3 (P = .12)	1.9 ± 1.2 (P = .03)	1.6 ± 1.2 (P = .35)	1.1 ± 1.2 (P = .37)
GCSI subcategory score[a]	Nausea/vomiting	1.7 ± 1.4 (P < .001)	2.0 ± 1.6 (P = .006)	2.1 ± 1.6 (P = .04)	1.8 ± 1.5 (P = .05)	1.6 ± 1.5 (P = .9)	1.2 ± 1.2 (P = .34)
	Bloating	2.3 ± 1.4 (P < .001)	2.4 ± 1.6 (P = .001)	2.5 ± 1.7 (P = .007)	2.4 ± 1.6 (P = .35)	1.7 ± 1.5 (P = .21)	1.7 ± 1.8 (P = .36)
	Early satiety	1.8 ± 1.1 (P < .001)	1.9 ± 1.4 (P = .01)	2.5 ± 1.6 (P = .68)	1.8 ± 1.5 (P = .21)	1.3 ± 1.5 (P = .75)	1.4 ± 1.1 (P = .64)

GCSI, Gastroparesis Cardinal Symptom Index; GPOEM, gastric per-oral endoscopic pyloromyotomy.
[a]GCSI scores before GPOEM: mean GCSI 3.8 ± 0.6, nausea/vomiting 4.3 ± 1.1, bloating 3.4 ± 1.5, early satiety 3.6 ± 1.

Additionally, among those previously dependent on J-tube or total parenteral nutrition, most of our affected cohort was able to decrease reliance on these alternative methods of nutrition. At 3-year follow-up, almost half of the patients with maintained clinical response had a significant reduction in health care use. Given the estimated health care cost of GP patients in the United States of $568 million annually, extrapolation of this finding suggests a significant opportunity for health care savings. Identification of patients who are most likely to benefit from GPOEM, including the validation of endoluminal functional lumen imaging probes, is a critical area for future research. This, along with continued refinement of the pyloromyotomy technique to avoid fibrosis and symptom recurrence, is key for the widespread adoption of GPOEM.

To identify the factors that predict clinical failure of GPOEM, we elected to analyze patients with initial nonresponse in addition to 6-months recurrence. As the placebo effect has been demonstrated in prior GPOEM studies, this interval was selected as to account for its potential impact in the short-term on GCSI scoring following the procedure. Frequency of emergency room visitation and hospitalization provided further objective measures of symptomatology following GPOEM. Our results suggest an association between high BMI and failure of GPOEM. Likewise, long-duration GP was also associated with poor outcomes of GPOEM. These results correlate with our prior finding.[16]

Strengths of our study include a large sample size relative to the novelty of this procedure, the long-term follow-up of clinical response, and the identification of factors predictive of clinical failure. Nevertheless, our

Table 3. Factors Predicting Failure of GPOEM

	Univariate					Multivariate			
		95% CI					95% CI		
Variables	OR	Lower	Upper	P value	P value	OR	Lower	Upper	P value
Body mass index	1.070	1.000	1.130	.04	.010	1.097	1.022	1.176	.010
Duration of GP	1.143	1.023	1.278	.019	.002	1.4	1.07	1.8	.002
Psych medications	1.434	0.165	1.144	.091	.052	1.33	0.110	1.008	1.33
Pain medication	3.9	1.2	12.6	.02	.469	0.703	0.271	1.825	.703

CI, confidence interval; GP, gastroparesis; GPOEM, gastric per-oral endoscopic pyloromyotomy; OR, odds ratio.

study has several limitations. First, it is a retrospective study from a single center, which inherently limits generalizability. Second, because of the longitudinal nature of data collection, there exists an unequal number of patients at each time. Third, we did experience loss of follow-up on some patients, which is at least in part attributable to the referral nature of our tertiary care institution. We overcame this limitation by conducting surveys via telephone for patients unable to be seen in clinic for follow-up to evaluate the GCSI, SF-36 score, and report emergency room visits and admissions. Finally, patient-reported GCSI outcomes are inherently subject to recall bias; however, we relied on other objective measures including improvement of GE and health care use following GPOEM to validate our results.

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Conflicts of interest
The authors disclose no conflicts. Q3