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Per oral endoscopic pyloromyotomy for refractory gastroparesis: initial results from a single institution

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Abstract
Introduction Gastroparesis is a debilitating disease characterized by delayed gastric emptying in the absence of mechanical obstruction. A new intramural technique, per oral endoscopic pyloromyotomy (POP), has been proposed as an alternative to surgical pyloroplasty for the management of medical refractory gastroparesis. Herein, we detail the short-term results of POP at our institution.
Methods POP was first performed at our institution in January 2016. All patients undergoing POP for management of gastroparesis from January 2016 through January 2017 were prospectively followed. All patients underwent a 4-h, non-extrapolated gastric emptying scintigraphy study and were asked to rate their symptoms using the Gastroparesis Cardinal Symptom Index (GCSI) at their pre-procedure visit and at 3 months post-procedure.
Results A total of 47 patients underwent POP during the defined study period. Twenty-seven (57.4%) patients had idiopathic gastroparesis, 12 (25.6%) had diabetic gastroparesis, and eight (17.0%) had post-surgical gastroparesis. Forty-one (87.2%) patients had at least one previous intervention (i.e., enteral feeding tube, gastric pacer, botox injection) for their gastroparesis symptoms. All patients had evidence of gastroparesis on pre-procedure gastric emptying studies. The average length of hospital stay was 1 day. One patient died within 30-days of their index procedure which was unrelated to the procedure itself. The average pre-procedure percentage of retained food at 4 h was 37% compared to an average post-procedure percentage of 20% ($p < 0.03$). The average pre-procedure GCSI score was 4.6 compared to an average post-procedure GCSI of 3.3 ($p < 0.001$).
Conclusions POP is a safe and feasible endoscopic intervention for medical refractory gastroparesis. Additional follow-up is required to determine the long-term success of this approach in alleviating gastroparesis symptoms.

Keywords Endoscopy · Gastroparesis · Pyloromyotomy

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Gastroparesis is a chronic and debilitating disease characterized by a delay in gastric emptying in the absence of mechanical obstruction [1]. In the United States, gastroparesis is reported to occur in approximately five million people [2–4]. Despite the prevalence of this disease, the treatment of gastroparesis remains challenging due to the spectrum of associated symptoms and underlying etiologies that contribute to its pathophysiology. One such factor that is thought to contribute to this disease is pyloric dysfunction [5, 6].

Patients with pyloric dysfunction are thought to benefit most from pyloric-targeted therapies for management of their gastroparesis. Historically, pyloric-targeted therapies have included surgical pyloroplasty, botulinum toxin injection of the pylorus, and endoscopic transpyloric stenting [7–10]. While these interventions have all been shown to provide gastroparesis symptom relief, these therapies are not without disadvantages. Specifically, pyloroplasty is invasive and requires a surgical operation, botulinum toxin has questionable long-term efficacy, and transpyloric stents almost always migrate distally into the small bowel if left in place for long term [6].

Recently, endoscopy has emerged as a safe and effective approach to the management of achalasia through per oral endoscopic myotomy (POEM) [5, 6]. Along with a general acceptance of the POEM procedure, has come the adoption of submucosal tunneling techniques to target the pylorus. First described in humans in 2013 by Kashab et al., per oral endoscopic pyloroplasty (POP) is a minimally invasive, endoscopic approach to the management of medical refractory gastroparesis. While the use of the POP procedure has been described in small case reports, the safety and feasibility of this procedure remain relatively unknown. The purpose of this study is to detail our institution's experience with POP and to assess the safety and feasibility of this technique for the management of medical refractory gastroparesis.

Materials and methods

Patient selection

Patients who are suspected of having gastroparesis are evaluated in a multidisciplinary clinic at our institution. This multidisciplinary clinic includes a psychiatrist, a dietitian, a gastroenterologist, and four minimally invasive surgeons. The initial evaluation for patients with gastroparesis includes both a subjective and objective assessment of their symptoms. The subjective component of their gastroparesis is evaluated through the use of the Gastroparesis Cardinal Symptom Index (GCSI). The GCSI is a validated questionnaire comprising nine questions divided into three symptom sub-scales: nausea and vomiting ($n = 3$), post-prandial fullness and early satiety ($n = 4$), and bloating ($n = 2$) [11–13]. Patients are asked to rate the severity of their symptoms on a six point scale, with a score of zero corresponding to the absence of symptoms and a score of five corresponding to the most severe symptoms [11–13].

The objective component of gastroparesis is evaluated through gastric emptying scintigraphy (GES). At our institution, patients are asked to ingest a radiolabeled solid meal after which their gastric retention is assessed at 1, 2, and 4 h post-ingestion. This is measured as the percentage of radiotracer retained in the stomach. At our institution, abnormal gastric emptying is defined as greater than 37–90% retention at 1 h, greater than 30–60% at 2 h, and greater than 0–10% at 4 h. Patients referred to our institution may come with outside imaging, such as a wireless motility capsule study, which is an acceptable alternative to GES when patients cannot tolerate ingestion of the liquid required for the GES study.

Patients who have both subjective and objective signs consistent with impaired gastric emptying are first treated with medical therapy directed at symptom alleviation. Medical therapy often includes a combination of pro-motility agents, anti-nausea medications, and medications to decrease gas and bloating symptoms. Patients are trialed on these medications for a minimum of 6 months. Should patients have ongoing symptoms despite medical therapy, they are then referred to one of the minimally invasive surgeons for surgical evaluation.

The surgical evaluation of patients with gastroparesis at our institution is outlined in Fig. 1. In patients where there is a concern for malnutrition based on evaluation by a registered dietitian, enteral access, either in the form of a laparoscopic jejunostomy tube or venting gastric tube with feeding jejunostomy tube, is often the first recommendation for surgical intervention at our institution. In patients who prefer simultaneous enteral access and a gastric emptying procedure, they are offered a laparoscopic pyloroplasty and are therefore outside the scope of this paper. In a majority of patients who do not have malnutrition, endoscopic gastroduodenoscopy (EGD) is the first intervention performed to rule out distal obstruction and to evaluate for response to injection of the pylorus with botulinum toxin. Botulinum toxin works by binding to presynaptic cholinergic receptors, reducing pyloric motor activity and leading to improved gastric emptying [7]. While controversy exists surrounding the use of botulinum toxin for long-term treatment of gastroparesis, we simply perform botulinum toxin injection of the pylorus to determine if a patient responds to pyloric-targeted therapy. If a patient returns to clinic following botulinum toxin pyloric injection and reports symptomatic improvement, they are offered surgical management in the form of either laparoscopic pyloroplasty or POP.

We began performing POP in January 2016. All consecutive patients undergoing POP from January 2016 through January 2017 were prospectively followed. Patient demographic information, procedure details, and 30- and 90-day outcomes were collected. Patient demographic information included age, gender, body mass index (BMI), comorbidities, etiology of gastroparesis, pre-procedure medications used for gastroparesis symptom alleviation,

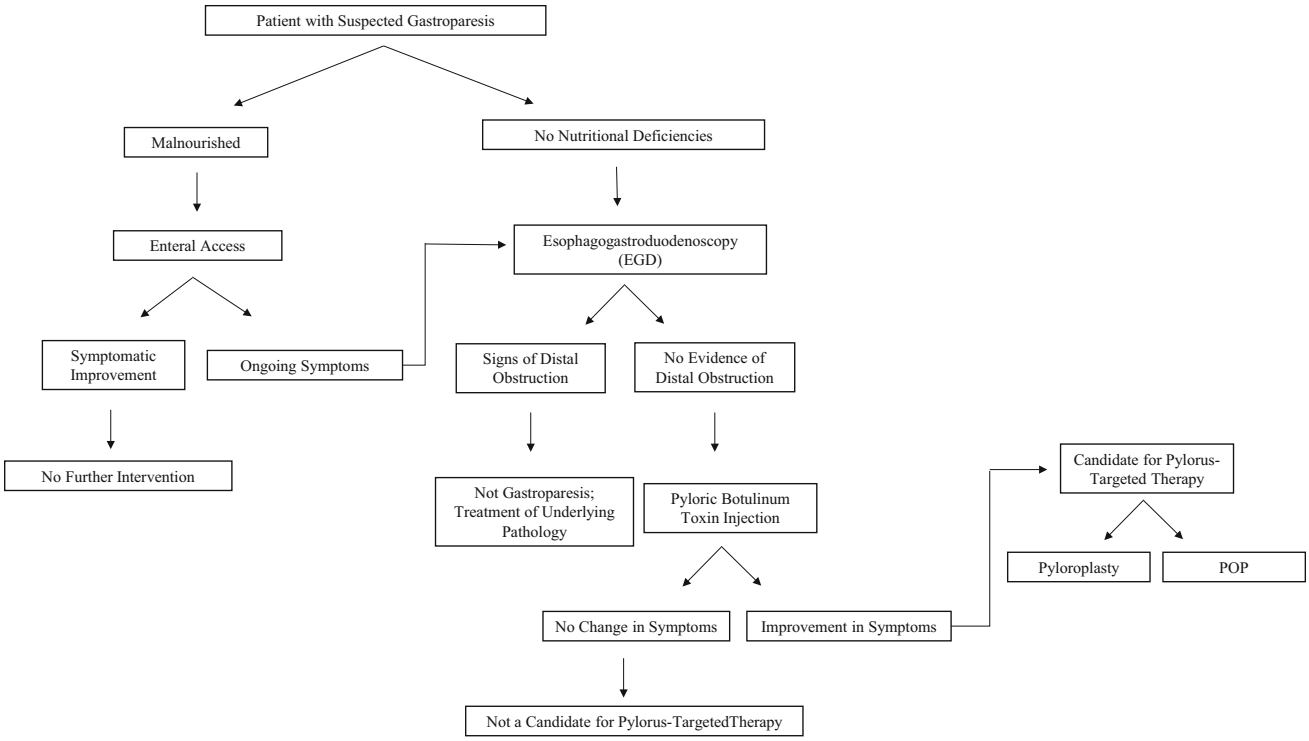

Fig. 1 Surgical evaluation algorithm to determine candidacy for per oral endoscopic pyloromyotomy

pre-procedure GES results, and pre-procedure GCSI results. Procedure details included intraoperative complications, including gastric or duodenal perforation or hemorrhage, operative time, and length of hospital stay. Thirty-day outcomes included organ space infection, defined as a delayed gastric or duodenal perforation or intra-abdominal abscess diagnosed by clinical examination or computed tomography (CT) imaging, gastric or duodenal ulcer, unplanned readmission to the hospital, unplanned return to the operating room, and mortality. Ninety-day outcomes included BMI, post-procedure changes to gastroparesis medications, and post-procedure GES and GCSI results.

POP procedure

All procedures were performed in the operating room under general anesthesia. Patients were placed supine on the operating room table. Following induction of general anesthesia, patients received pre-procedure antibiotics based on Surgical Care Improvement Project (SCIP) protocol. A standard length, high-definition, forward-facing endoscope is used. Carbon dioxide insufflation is begun after which a full diagnostic EGD is performed to ensure that there are no abnormalities observed in the antrum, pylorus, or duodenum. The stomach is lavaged and retained food particles are evacuated after which the POP procedure is begun.

The steps of the POP procedure are outlined in Figs. 2 and 3. The POP procedure is begun by injecting methylene blue into the submucosa of the stomach approximately 5 cm proximal to the pylorus along the lesser curvature. While previous case series have described the performance of the POP procedure along the greater curvature of the stomach, we prefer to perform our dissection along the lesser curvature of the stomach as the orientation of the endoscope is the same as during a POEM procedure [6, 14, 15]. A transverse mucosotomy is made at the proximal aspect of the methylene blue injection using a triangular tip knife (KD-640L, Olympus, Tokyo) that is approximately 2 cm in length. The endoscope is then advanced through the submucosal tunnel, just past the pyloric channel, using spray coagulation for any vessels encountered during the dissection and repeat methylene blue injection at sites where the submucosal dissection plane is difficult to define. Next, the myotomy is performed, which begins approximately 2 cm proximal to the pylorus and ends at the most distal aspect of the pyloric ring. During the myotomy, care must be taken to appropriately identify the transition from the pylorus to the duodenum as the duodenal mucosa is thin and perpendicular to the plane in this area which increases the potential for duodenal perforation. The submucosal tract is inspected to ensure that it is hemostatic after which it is closed with endoscopic clips.

Post-procedure, patients are kept *nil per os* overnight. On post-procedure day number one, patients undergo a routine upper gastrointestinal fluoroscopy study to ensure that there is no obstruction or signs of perforation. Patients are then advanced to a clear liquid diet. At our institution,

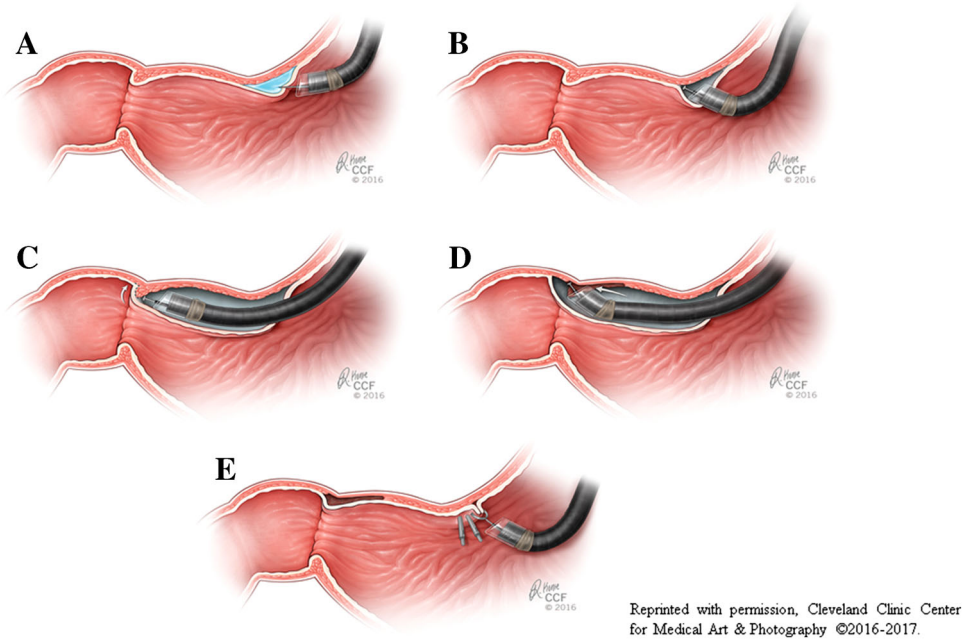

Fig. 2 Per oral endoscopic pyloromyotomy procedure, sagittal view. **A** Injection of methylene blue for creation of the submucosal tunnel. **B** Development of the submucosal tunnel. **C** Extension of the submucosal tunnel to the first part of the duodenum. **D** Pyloromyotomy, beginning approximately two centimeters proximal to the pylorus and ending in the first part of the duodenum. **E** Closure of the myotomy with endoscopic clips

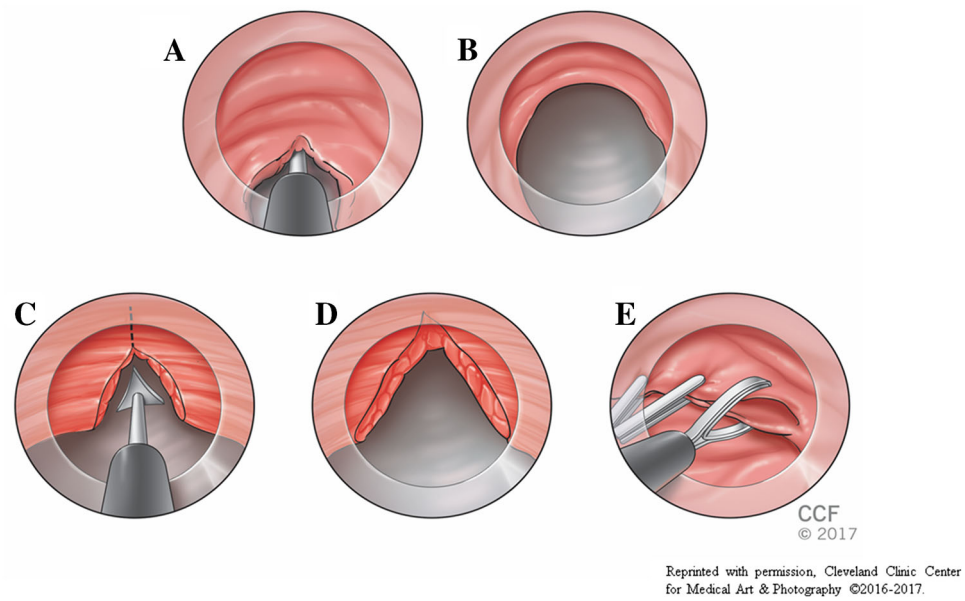

Fig. 3 Per oral endoscopic pyloromyotomy procedure, in-scope view. **A** Development of the submucosal tunnel. **B** In-scope view of the developed submucosal tunnel. **C** Pyloromyotomy, beginning approximately two centimeters proximal to the pylorus and ending in the first part of the duodenum. **D** In-scope view of the pylorus following muscular division. **E** Closure of the myotomy with endoscopic clips

patients are routinely discharged to home on post-procedure day number one with instructions to maintain a liquid consistency diet for 2 weeks. Patients are prescribed sucralfate and proton pump inhibitor twice daily for 4 weeks to prevent ulceration at the site of mucosotomy.

Outcomes of interest

The purpose of this study is to detail the safety and efficacy of POP for the management of medical refractory gastroparesis. The safety of POP was defined as the ability to successfully complete the endoscopic pyloromyotomy without gastric or duodenal perforation, massive intraluminal hemorrhage, or death related to the procedure. The feasibility of POP was defined as the ability of the procedure to produce gastroparesis symptom relief as measured by an improvement in post-procedure GCSI scores, a decrease in the total number of gastroparesis medications used, and evidence of improved gastric motility on post-procedure GES studies obtained at 90-days post-procedure.

Statistical analysis

Summary statistics for patient demographics and operative variables are expressed as mean ± standard deviation for continuous variables and count and column percent for categorical variables. Tests of significance comparing pre- and post-procedure outcomes of interest were performed using two sample *t* tests for continuous variables and Chi square or Fisher's exact test for categorical variables. All statistical analysis was performed using SAS 9.4 Software (SAS Institute, Cary, NC, USA) and $p < 0.05$ was considered statistically significant. This study was approved by our Institutional Review Board.

Results

A total of 47 patients underwent POP procedure at our institution from January 2016 through January 2017. Thirty-seven (78.7%) of the patients were female, the average age at the time of procedural intervention was 43.7 years, and the average BMI of the cohort was 27.2 kg/m [2] (Table 1). The most common cause of gastroparesis was idiopathic ($n = 27$, 57.4%). Forty-one patients had at least one intervention for their gastroparesis prior to POP; 21 (44.7%) had an enteral feeding tube, 16 (34.0%) had a gastric electrical stimulator, and 28 (59.6%) had previous pyloric botulinum toxin injection. The average length of hospital stay post-procedure was 1 day (range 0–4 days).

Table 1 Patient demographics and operative details

Variable	Outcome
Age, years (mean, SD)	43.7 ± 14.8
Female gender (*N*, %)	37 (78.7%)
BMI, kg/m^2 (mean, SD)	27.2 ± 9.6
HTN (*N*, %)	14 (30.4%)
COPD (*N*, %)	2 (4.3%)
Diabetes mellitus (*N*, %)	13 (27.7%)
ESRD requiring dialysis (*N*, %)	1 (2.1%)
Etiology of gastroparesis (*N*, %)	
Idiopathic	27 (57.4%)
Diabetes mellitus	12 (25.6%)
Post-surgical	8 (17.0%)
Previous interventions (*N*, %)	
Enteral access	21 (44.7%)
Gastric electrical stimulator	16 (34.0%)
Botulinum toxin injection	28 (59.6%)
Operative time, min (mean, SD)	41.2 ± 28.5
Length of hospital stay, days (mean, SD)	1.09 ± 0.6

N number, *SD* standard deviation, *BMI* body mass index, *ASA* American Society of Anesthesiologist, *HTN* hypertension, *COPD* chronic obstructive pulmonary disease, *ESRD* end-stage renal disease, *GCSI* Gastroparesis Cardinal Symptom Index

A total of 42 (89.4%) patients had 30-day follow-up available. No patient experienced a gastric or duodenal perforation, intraluminal hemorrhage, or procedural-related death. One patient did, however, die within 30-days of surgery which was related to their underlying cardiac disease as proven on autopsy. Furthermore, no patient experienced an organ space infection, gastric or duodenal ulcer, unplanned readmission to the hospital, or unplanned return to the operating room.

A total of 31 (66.0%) patients completed 3 month follow-up (Table 2). There was a statistically significant improvement in each component of the GCSI score as well as the average GCSI score. Furthermore, there was a significant decrease in the number of anti-emetic medications used by these patients post-procedure. A total of 16 (34.0%) patients underwent post-procedure gastric emptying evaluation. There was a statistically significant decrease in the percentage of 4-h gastric retention ($p = 0.03$). One (3.8%) patient diagnosed with idiopathic gastroparesis has since gone on to undergo a laparoscopic total gastrectomy 9 months post-procedure for ongoing gastroparesis symptoms post-POP.

Discussion

Management of patients with gastroparesis remains clinically challenging. The development of a multidisciplinary approach including a gastroenterology motility specialist, dietitian, psychologist, pain management specialist, and a general surgeon has dramatically improved both patient and caregiver experiences at our institution. It has been our experience that this multidisciplinary approach has facilitated proper evaluation, nutritional optimization, chronic pain rehabilitation, and patient education regarding the diagnosis and management of gastroparesis. These key aspects of our multidisciplinary approach have led to improvement in the process of identifying patients with medical refractory gastroparesis and thus appropriate selection of surgical candidates.

While there are many surgical options for the treatment of gastroparesis, these interventions do not always reliably produce durable symptomatic relief [16]. Gastric electrical stimulation has become a popular surgical modality for management of medical refractory gastroparesis [17]. Nevertheless, long-term device-related complications requiring revision are not uncommon and long-term results have been somewhat variable across different institutions [18]. Over the past few years, there has been a paradigm shift towards gastric emptying procedures. Case series have demonstrated objective improvement in gastric emptying

Table 2 Comparison of gastroparesis symptoms, pre- and post-procedure

Measure of gastroparesis	Pre-procedure $N = 47$	3-Month follow-up $N = 31$	p value
BMI, kg/m^2 (mean, SD)	27.2 ± 9.6	24.7 ± 7.7	0.25
Average GCSI score (mean, SD)			
Nausea/vomiting score	4.4 ± 1.3	2.9 ± 1.6	<0.001
Post-prandial fullness score	4.8 ± 1.0	3.8 ± 1.7	0.002
Bloating score	4.7 ± 1.3	3.1 ± 1.7	<0.001
Total score	4.6 ± 0.9	3.3 ± 1.4	<0.001
Number of gastroparesis			
Medications (*N*, %)			
Promotility			0.59
0	38 (80.9%)	40 (85.1%)	
1	7 (14.9%)	4 (8.5%)	
2	2 (4.2%)	3 (6.4%)	
Anti-emetic			<0.001
0	10 (21.2%)	28 (59.6%)	
1	20 (42.6%)	6 (12.8%)	
2	14 (29.8%)	12 (25.5%)	
3	3 (6.4%)	1 (2.1%)	
Antacid			0.7
0	32 (68.2%)	32 (68.1%)	
1	10 (21.3%)	12 (25.5%)	
2	5 (10.6%)	3 (6.4%)	
Anti-gas/bloat medications			0.27
0	41 (87.2%)	45 (95.7%)	
1	6 (12.8%)	2 (4.3%)	

Measure of gastroparesis	Pre-procedure $N = 47$	3-Month follow-up $N = 16$	p value
GES, 4 h retention percentage (mean, SD)	37.2 ± 25.1	20.4 ± 26.1	0.03

N number, *BMI* body mass index, *SD* standard deviation, *GES* gastric emptying scintigraphy

times following laparoscopic pyloroplasty in patients with medical refractory gastroparesis [19, 20]. Results from published studies on laparoscopic pyloroplasty procedure have been easily reproduced at our institution.

With the evolution of transmural endoscopic surgery and lessons learned from the per oral endoscopic myotomy (i.e., POEM) procedure for achalasia, per oral pyloromyotomy became a natural evolution at our institution. For patients with medical refractory gastroparesis, POP has been proposed as a viable alternative to current surgical interventions and is currently our-first line treatment option for patients evaluated at our institution. While this is the largest case series to date, we acknowledge that our results must be interpreted with caution as nearly one-third of patients have not yet returned for short-term follow-up. Nevertheless, for the patients available for follow-up, we found that POP is safe, feasible, and effective over the short term for relief of gastroparesis symptoms. This improvement in gastroparesis symptoms was observed in both subjective terms as reflected by an improvement in all three components of the GCSI and the average GCSI score as well as in objective terms as reflected by an improvement in 4-h gastric retention and decreased overall use of anti-emetic medications.

The feasibility and improvement in patient symptoms seen in our study is consistent with previous case series detailing pylorus-targeted therapy for gastroparesis. For example, Khashab et al. [10] in 2015 detailed the clinical response of 21 patients to transpyloric stent placement. In another study by Khashab et al. [5], they found that 26 of 30 patients had short-term symptomatic improvement following POP. Additional small case studies including 16, 12, and seven patients, respectively, have also detailed the efficacy of the POP procedure over the short term [14, 15, 17].

In addition to the feasibility of POP, our study highlights the safety of this procedure. Specifically, this procedure was not associated with any gastric or duodenal perforations or intraluminal hemorrhage. We found that performing this procedure along the lesser curvature was technically easier and more straightforward than previously described greater curvature techniques and continues to be our preferred approach [14, 15, 21]. We also found that dissection beyond the pylorus and into the duodenal bulb is unnecessary for symptom alleviation and increases the risk of mucosal perforation as the duodenal mucosa in quite thin in this area tends to lie perpendicular to the direction of the submucosal tunnel. Furthermore, the use of methylene blue along the submucosal place facilitates clear visualization of the muscle, mucosa, and areolar tissue, and the triangle tip knife is a wonderful dissecting tool which provides for excellent hemostasis throughout the dissection.

Previous studies have hypothesized that the underlying cause of gastroparesis may help direct clinical treatment [14]. Nevertheless, only one patient in our study went on to require additional intervention for their gastroparesis symptoms following their POP procedure. Therefore, we are unable to definitively conclude from our study that patients with one particular cause of gastroparesis may benefit more from the POP procedure over another cause of gastroparesis. However, we did note that the nausea/vomiting and the bloating components of the GCSI had the most significant improvement at 3 months post-operatively. Furthermore, the only statistically significant change in gastroparesis medications occurred in the average number of anti-emetic medications taken post-procedure. It should be noted, however, that it was not uncommon for patients to go through an initial period of worsening symptoms. We hypothesize that this is likely due to edema at the pylorus and the use of medications that impair gastric emptying throughout the short hospital course, such as narcotic medication. This period of worsening symptoms was most common at the time of the initial postoperative visit with improvement in symptoms at 3 months post-procedure as demonstrated in our results.

Despite our results, our study does have limitations which are worth discussing. First and foremost, this is a single-institution study in a tertiary referral system. While we were able to demonstrate the safety and feasibility of the POP procedure over the short term, the reproducibility of our results in community and academic-affiliated settings remains to be determined. Second, not all patients who were eligible for 30-day or 3-month follow-up returned to clinic for post-procedure evaluation, creating the potential for over- or under-reporting of improvement in gastroparesis symptoms. This may have been in part due to geographic and economic limitations inherent to the fact that this is a tertiary referral system as many patients traveled from out of state to have the procedure done. Nevertheless, we have begun phone follow-up and have provided all patients with the documentation needed to obtain a post-procedure GES study which we hope will improve our long-term follow-up results. Finally, our study is limited to short-term follow-up only without comparison to other currently available pylorus-directed therapies. Therefore, additional studies are needed to determine the long-term durability and superiority of the POP procedure for relief of gastroparesis symptoms.

Conclusion

To date, this is the largest case series to detail short-term outcomes following POP for medical refractory gastroparesis. We found that patients have both objective and subjective improvement in gastroparesis symptoms over the short term and that POP is both a safe and feasible treatment option for medical refractory gastroparesis over the short term. Additional studies are needed to determine the long-term durability of the POP procedure for relief of gastroparesis symptoms.

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Compliance with ethical standards

Disclosures John H. Rodriguez has no conflict of interest relevant to this publication and is a consultant for Gore and has received research funding from Intuitive Surgical. Matthew D. Kroh has no conflict of interest relevant to this publication and is a consultant for the Levita™ Magnetic Surgical System and has received research funding from Cook Biotech, Medtronic and Pacira Pharmaceuticals. Ivy N. Haskins has no conflict of interest relevant to this publication but has received a Resident Research Grant from the Americas Hernia Society. Andrew T. Strong, Ryan L. Plescia, Matthew T. Allemang, Robert S. Butler, Michael S. Cline, Kevin El-Hayek, and Jeffrey L. Ponksy have no conflict of interest or financial ties to disclose.

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