



Laparoscopic pyloroplasty versus endoscopic per-oral pyloromyotomy for the treatment of gastroparesis

Joshua P. Landreneau¹ · Andrew T. Strong^{1,2} · Kevin El-Hayek^{1,2} · Chao Tu³ · James Villamere¹ · Jeffrey L. Ponsky^{1,2} · Matthew D. Kroh^{1,2,4} · John H. Rodriguez^{1,2}

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Abstract

Background Gastroparesis is a debilitating functional disorder of the stomach characterized by delayed gastric emptying absent an obstructive etiology. Surgical or endoscopic disruption of the pylorus has been utilized to treat this disease, but there is little evidence comparing laparoscopic pyloroplasty (LP) with endoscopic per-oral pyloromyotomy (POP). Herein we describe our experience at our institution using a propensity-matched cohort study to compare outcomes between these procedures.

Methods All patients who underwent LP for the treatment of gastroparesis from October 2014 through September 2017 at our institution were retrospectively reviewed. Propensity scoring was used to match these patients 1:1 to patients undergoing POP during this time period based on gender, age, and etiology of gastroparesis. Symptom scores using the Gastroparesis Cardinal Symptom Index (GCSI), scintigraphic gastric emptying studies (GES), and perioperative outcomes were compared between matched cohorts. Thirty patients underwent LP for gastroparesis during the study period which were matched 1:1 with patients undergoing POP. The etiology of gastroparesis was 63.3% idiopathic ($n=19$), 20.0% post-surgical ($n=6$), and 16.7% diabetic ($n=5$) in both cohorts.

Results Patients who underwent LP had a longer average length of stay (4.6 vs. 1.4 days, $p=0.003$), operative time (99.3 vs. 33.9 min, $p<0.001$), and estimated blood loss (12.9 vs. 0.4 mL, $p<0.001$). There were more complications in the LP cohort (16.7 vs. 3.3%, $p=0.086$), which included surgical site infection (6.7 vs. 0%, $p=0.153$), pneumonia (6.7 vs. 0.0%, $p=0.153$), and unplanned ICU admission (10.0 vs. 0.0%, $p=0.078$). LP and POP both resulted in similar, significant improvements in both in GCSI scores and objective gastric emptying.

Conclusions Per-oral endoscopic pyloromyotomy (POP) is safe and effective for the treatment of medical refractory gastroparesis. POP has less perioperative morbidity compared to LP with *comparative functional outcomes*.

Keywords Gastroparesis · Pyloroplasty · Pyloromyotomy · Laparoscopic · Endoscopy

Gastroparesis is a debilitating functional disorder that marked by delayed gastric emptying in the absence of

mechanical obstruction [1]. This condition can arise from a number of underlying etiologies, classically classified as idiopathic, diabetic, and post-surgical, and is characterized by a failure of the stomach to effectively propel a food bolus into the small intestine. This delay in gastric emptying leads to a common array of symptoms including nausea, vomiting, bloating, and early satiety. The incidence of gastroparesis is increasing, with estimated annual hospital admissions attributed to gastroparesis increasing more than 313% from 1997 to 2013 with a corresponding dramatic increase in healthcare resource utilization [2]. Gastroparesis is estimated to affect more than 5 million adults in the United States; and with the significant rise in the incidence of diabetes, particularly

✉ Joshua P. Landreneau
landrej@ccf.org

¹ Department of General Surgery, Cleveland Clinic, Cleveland, OH, USA
² Cleveland Clinic Lerner College of Medicine, Case Western Reserve University, Cleveland, OH, USA
³ Cleveland Clinic Department of Quantitative Health Sciences, Lerner Research Institute, Cleveland Clinic Foundation, Cleveland, OH, USA
⁴ Digestive Disease Institute, Cleveland Clinic Abu Dhabi, Abu Dhabi, United Arab Emirates

among younger patients, gastroparesis is likely to pose an even greater clinical concern in the future [3, 4].

While diet modifications in combination with antiemetic and/or pro-kinetic medications are first-line therapies for gastroparesis, these tend to lose their efficacy over time or be associated with prohibitive side effects. Those who fail to achieve durable response or are unable to tolerate medical therapies may be labeled medically refractory. For patients with medically refractory gastroparesis, surgical interventions may be an option. These include implantation of gastric stimulators, roux-en-y gastric bypass, or subtotal gastrectomy [5]. Currently, the surgical intervention with the best level of evidence is gastric electrical stimulation [6].

Gastroparesis results from disruptions in the normal neuromuscular structures and alterations of the coordinator myoelectric function of the stomach. The disruptions in particular sub-processes are dependent on the disease etiology. There is evidence that the pylorus plays a role in the manifestation of gastroparesis in at least some subtypes of this disease. For instance, pyloric contractions have been observed to be higher in amplitude and longer in duration in diabetic patients with gastroparesis compared to healthy controls based on pyloric manometry [7]. Such findings have led surgeons and endoscopists to apply a number of therapies aimed at disrupting the sphincter function of the pylorus. These therapies aim to maintain pyloric patency, reducing its barrier function to gastric emptying. These include intrapyloric injection of botulinum toxin, transpyloric endoluminal stenting, pneumatic dilation, and surgical disruption of the pylorus [8–11].

In recent years, advances in endoluminal surgical techniques have led to a novel endoscopic therapy for medically refractory gastroparesis: per-oral pyloromyotomy (POP). In this procedure, a submucosal tunnel is developed to approach and then divide the circular muscular fibers of the pylorus, analogous to the methods utilized in per-oral endoscopic myotomy (POEM) to divide the lower esophageal sphincter for the treatment of achalasia.

POP accomplishes the same goal of surgically dividing the pylorus, similar to laparoscopic pyloroplasty (LP) without the invasiveness of a laparoscopic or open surgical procedure. As such, we hypothesized that patients undergoing POP would have similar outcomes as those following LP with less perioperative morbidity. Herein, we now compare our institution's experience with POP and LP through a propensity-matched cohort analysis.

Methods

After approval by the Institutional Review Board, patients undergoing pyloroplasty between October 2014 and September 2017 were retrospectively identified based on billing

codes from the electronic medical record. All patients were included with the exception of patients undergoing concurrent pyloroplasty as part of another primary operation (such as esophageal reconstruction with a gastric conduit), and age less than 18 years old. POP patients were identified from a prospectively maintained database containing all patients undergoing this procedure at our institution.

Patient demographics, perioperative information, 30-day outcomes, and 90-day outcomes were collected for all patients. Demographics included gender, age, Body Mass Index (BMI), comorbidities, etiology of gastroparesis, and previous interventions related to gastroparesis. Other preoperative information collected included symptom scoring with GCSI and 4-h solid-phase GES. Perioperative details included intraoperative complications, estimated blood loss (EBL), operative time, and length of stay (LOS). 30-day outcomes included procedure-related complications, repeat operations, and unplanned readmissions. 90-day outcomes included BMI and post-procedure GCSI and GES results. For patients who failed to follow-up at 90 days, patients were contacted by telephone to assess GCSI scores.

Patient selection

Patients with suspected gastroparesis are evaluated by a multidisciplinary clinic at our institution including psychiatry, gastroenterology, nutrition specialists, and surgery. Gastroparesis-related symptoms are quantitated using the Gastroparesis Cardinal Symptom Index (GCSI), a widely validated questionnaire which scores in three domains: post-prandial fullness/early satiety; nausea/vomiting, and bloating. An overall score is an average of the three domains [12, 13]. Objective measurements of gastric emptying are assessed using either a wireless motility capsule or 4-h solid-phase gastric emptying scintigraphy (GES), which is considered the gold standard for assessing gastric motility [14]. This study consists of administering a low-fat, egg-white meal containing technetium-99m sulfur colloid labeled egg albumin. Gastric retention of the egg meal is measured at baseline and at 1, 2, and 4 h after consumption and the results are reported as a retained percentage. Greater than 37–90% retention at 1 h, greater than 30–60% at 2 h, and greater than 0–10% at 4 h are considered delayed gastric emptying.

Procedural techniques

Laparoscopic pyloroplasty

Patients are in a supine position under general anesthesia. A total of four laparoscopic ports are placed in a gentle “U” shape, with all being above the umbilicus. The right medial port is typically 10 mm to accommodate needles for intracorporeal suturing. Once the pylorus is identified, two

stay sutures are placed cephalad and caudad. A longitudinal incision is performed completely through the pylorus, with extension to the duodenum and gastric antrum. This is then closed transversely in a classical Heineke–Mikulicz fashion [15]. Hemostasis is assured, and a standard gastroscope is introduced to endoscopically evaluate the pylorus for patency and leak. This procedure is depicted in Fig. 1.

POP

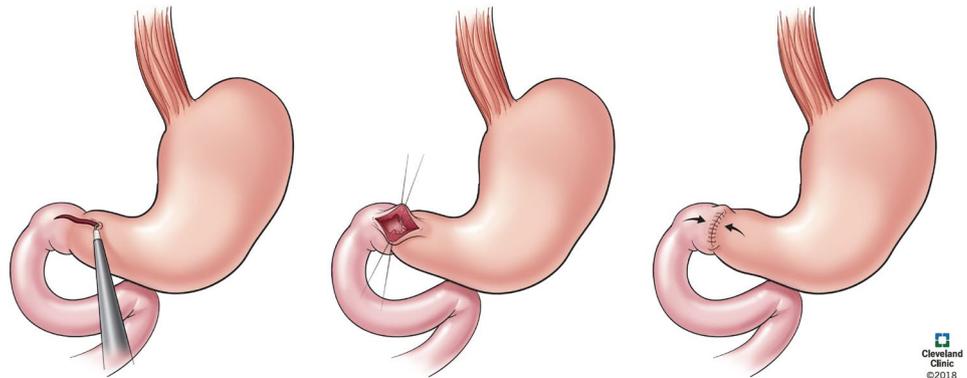
The POP technique has been extensively detailed previously [16]. Briefly, patients are placed supine and general anesthesia is administered with orotracheal intubation. A standard gastroscope with an affixed beveled, silicone-based cap is used. Following diagnostic upper endoscopy, a submucosal bleb is raised along the lesser curve of the stomach using 5–7 mL of injection solution. A 1.5-cm mucosotomy is made using an endoscopic knife with cut energy. A tunnel is developed in the submucosal plane, dividing the loose areolar

tissue until the pylorus is identified. The pylorus is then completely divided. After assurance of hemostasis, the gastroscope is withdrawn from the tunnel and the mucosotomy is closed using multiple endoscopic clips. This procedure is depicted in Figs. 2 and 3.

Propensity matching

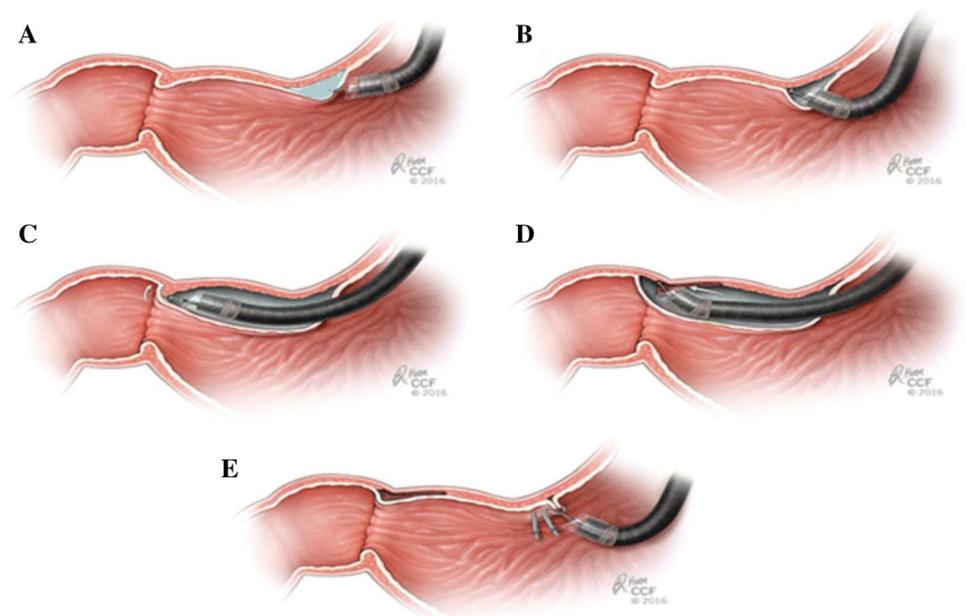
Propensity scores were used to match LP patients to POP patients in order to balance the distributions of age at intervention, gender, and gastroparesis etiology between these groups. The propensity scores were estimated using a logistic regression model involving these predictors, resulting in a score on the scale of the linear predictor. Using these scores, matching of POP patients to similar pyloroplasty patients proceeded using functionality in the matching package of R [17]. Balance was assessed using absolute standardized mean differences, which are the absolute value of the difference in means between groups, expressed as a percentage of

Fig. 1 Heineke–Mikulicz Pyloroplasty. With a laparoscopic approach, a longitudinal incision is performed completely through the pylorus, with extension to the duodenum and gastric antrum. This incision is then closed transversely in a classical Heineke–Mikulicz fashion to increase the diameter at pylorus and maintain greater patency



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Fig. 2 Steps of Per-Oral Pyloromyotomy (POP): A submucosal bleb is made with injection of methylene blue along the greater curvature proximal to the pylorus. A mucosotomy is made over the bleb followed by development of a submucosal plane which is extended to the pylorus. The pylorus is divided and the mucosotomy is closed with endoscopic clips



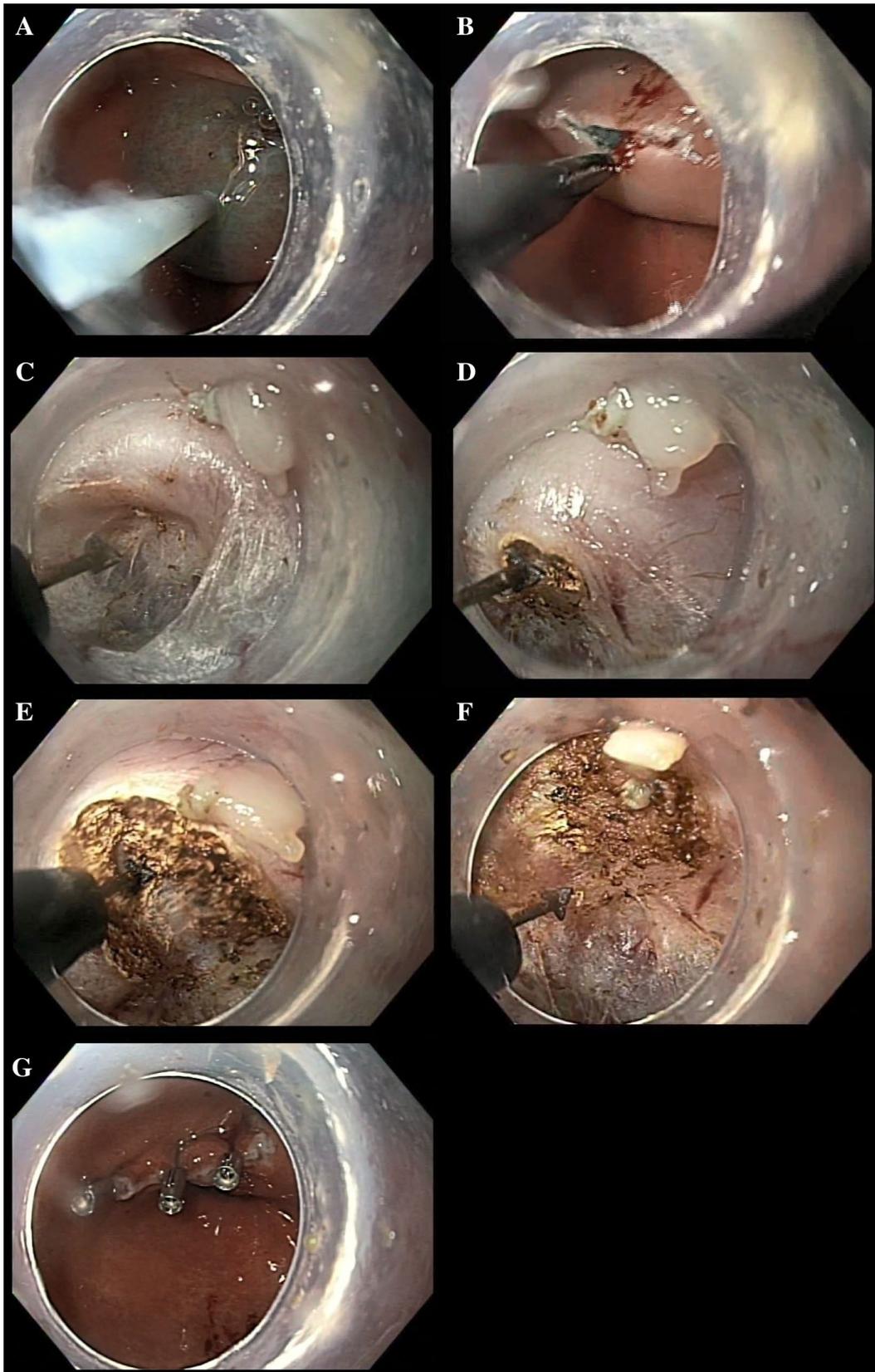


Fig. 3 Per-oral pyloromyotomy (POP), procedural steps. **A** Raising of a submucosal bleb by submucosal injection of 0.1% methylene blue; **B** transverse mucosotomy along the lesser curvature of the stomach proximal to the pylorus; **C** development of a tunnel in the submucosal plane to expose the pyloric ring; **D** division of the pyloric muscle fibers beginning at the duodenal bulb; **E** continuation of the pyloromyotomy; **F** completion of the pyloromyotomy with extension onto the lesser curvature of the stomach; **G** closure of the mucosotomy using endoscopic clips

the standard deviation within treated patients. One common recommendation is that reasonably matched groups are indicated by all important variables having standardized mean differences $\leq 10\%$. All analyses were done in R version 3.3.1 (2016-06-21).

Calculations and statistics

Summary statistics for patient demographics and operative variables are expressed as mean \pm 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.

Results

A total of 30 patients underwent laparoscopic pyloroplasty at our institution from October 2014 through September 2017. These patients were matched with 30 patients undergoing POP during the study period with no differences in age, gender, or etiology of gastroparesis between the two cohorts following propensity matching. The etiology of gastroparesis was 63.3% idiopathic ($n = 19$), 16.7% from diabetes ($n = 5$), and 20% post-surgical ($n = 6$) in both cohorts. There were no differences in documented comorbid conditions between the POP and pyloroplasty groups including diabetes mellitus, chronic obstructive pulmonary disease (COPD), hypertension, and end-stage renal disease on dialysis. A similar number of patients had previous interventions for gastroparesis (63.3% in POP, 40.0% in pyloroplasty, $p = 0.07$) with the exception of more patients with prior intrapyloric botulinum toxin injection in patients undergoing POP compared to pyloroplasty (50.0 vs. 3.3%, respectively, $p < 0.001$). These data are summarized in Table 1.

Procedural time was significantly less in the POP cohort (33.9 vs. 99.3 min, $p < 0.001$), as was estimated procedural blood loss (0.4 vs. 12.9 mL, $p < 0.001$) and length of hospital stay (1.4 vs. 4.6 days, $p = 0.003$). Follow-up information at

30 days post procedure was available in 28 patients undergoing POP (93.3%) and 22 patients following laparoscopic pyloroplasty (73.3%). There were more complications within 30 days of surgery in patients undergoing laparoscopic pyloroplasty than those undergoing POP, although this did not reach statistical significance (16.7 vs. 3.3%, respectively, $p = 0.086$). These included two patients with superficial surgical site infection (6.7%), three patients with unplanned intensive care unit (ICU) admission (10.0%), and two patients with post-operative pneumonia (6.7%). There were no surgical site leaks in either cohort. One patient in each cohort (3.3%) had a reoperation within 30 days following their procedure which included a negative diagnostic laparoscopy in a POP patient for abdominal pain and a laparoscopic tube jejunostomy in a LP patient for nutritional support. There was one mortality within 30 days in the POP cohort due to a cardiac event found to be unrelated to the procedure and no mortalities in the cohort undergoing LP. These perioperative details are summarized in Table 2.

A total of 25 patients completed 90-day follow-up after undergoing POP (83.3%) with 21 patients following laparoscopic pyloroplasty (70.0%). The mean percent retention at four hours based on scintigraphic gastric emptying decreased significantly following either intervention (32.9–10.7% in POP, $p = 0.042$; 35.9–2.5 with LP, $p = 0.029$), although there was no difference when comparing the two procedures. GES were available in seven patients (23.3%) post LP and eleven patients (36.7%) after POP, with normal gastric emptying at 4 h in 100 and 72.7%, respectively. There was no observed difference in achieving normal 4-h emptying retention between the two cohorts ($p = 0.141$). Most patients had improved GES after undergoing either POP or laparoscopic pyloroplasty (85.7 vs. 83.3%, respectively) with no difference in this outcome between the two procedures ($p = 0.907$).

There was no difference in pre-procedure overall GCSI score or any of the subdomain scores between the two cohorts. Patients undergoing either POP or pyloroplasty had significant improvement in each subdomain of the GCSI as well as overall GCSI scores post-procedure (POP: 4.0–2.4, $p < 0.001$; pyloroplasty: 4.0–2.3, $p = 0.001$). There were no differences pre- or post-procedure between the two cohorts in total GCSI score or any of the subdomains. These gastroparesis-related outcomes are summarized in Table 3.

Discussion

Gastroparesis is a debilitating disease in which prior therapies do not adequately address clinical need and whose prevalence is likely to continue to increase in the future. Diet modifications, lifestyle adjustments, and prokinetic and/or antiemetic medications remain the first-line

Table 1 Demographics of the cohort

Variable	POP (<i>n</i> = 30)	Pyloroplasty (<i>n</i> = 30)	<i>p</i> value
Mean age (\pm SD, years)	44.1 \pm 13.5	45.4 \pm 14.5	0.95
Female gender (<i>N</i> , %)	23 (76.7%)	23 (76.7%)	> 0.99
Mean BMI (\pm SD, kg/m ²)	24.9 \pm 7.1	26.1 \pm 6.7	0.90
Comorbidities (<i>N</i> , %)			
Hypertension	8 (26.7%)	15 (50.0%)	0.07
COPD	3 (10.0%)	0 (0.0%)	0.08
Diabetes mellitus	6 (20.0%)	6 (20.0%)	> 0.99
Etiology of gastroparesis (<i>N</i> , %)			> 0.99
Idiopathic	19 (63.3%)	19 (63.3%)	–
Diabetes	5 (16.7%)	5 (16.7%)	–
Post-surgical	6 (20.0%)	6 (20.0%)	–
Patients with previous interventions for GP	19 (63.3%)	12 (40.0%)	0.07
Enteral access	12 (40.0%)	8 (26.7%)	0.28
Gastric electrical stimulator (<i>N</i> , %)	7 (23.3%)	6 (20.0%)	0.76
Intrapyloric botulinum toxin injection (<i>N</i> , %)	15 (50.0%)	1 (3.3%)	< 0.001

POP per-oral pyloromyotomy, SD standard deviation, BMI body mass index, COPD chronic obstructive pulmonary disease, ESRD end-stage renal disease on dialysis

Table 2 Perioperative details

Variable	POP (<i>n</i> = 30)	Pyloroplasty (<i>n</i> = 30)	<i>p</i> value
Mean operative time (\pm SD, min)	33.9 \pm 18.8	99.3 \pm 41.8	< 0.001
Mean estimated blood loss (\pm SD, mL)	0.4 \pm 1.3	12.9 \pm 10.7	< 0.001
Mean length of stay (\pm SD, days)	1.4 \pm 1.0	4.6 \pm 5.6	0.003
Complications within 30 days (<i>N</i> , %)	1 (3.3%)	5 (16.7%)	0.086
Surgical site infection (<i>N</i> , %)	0 (0.0%)	2 (6.7%)	0.153
Unplanned ICU admission (<i>N</i> , %)	0 (0.0%)	3 (10.0%)	0.078
Reoperation (<i>N</i> , %)	1 (3.3%)	1 (3.3%)	> 0.99
Pneumonia (<i>N</i> , %)	0 (0.0%)	2 (6.7%)	0.153
Readmission within 30 days (<i>N</i> , %)	2 (6.7%)	5 (16.7%)	0.232

POP per-oral pyloromyotomy, SD standard deviation, ICU intensive care unit

therapies; however, medical management often does not achieve durable efficacy. Several surgical options exist for patients with medically refractory disease, although there is no consensus as to which procedure is best for managing this challenging population. In general, we prefer an approach that delays resection or bypass as these are not always well-tolerated procedures.

Gastric electrical stimulation has become a popular first-line treatment for medically refractory gastroparesis although with inconsistently demonstrated efficacy [18]. However, up to 20% of patients experience significant long-term complications following this procedure, including infection, migration, and erosion of the stimulator device and/or leads, gastric perforation, and chronic pain [19]. More invasive and morbid approaches include subtotal or total gastrectomy and roux-en-y gastric bypass [5]. In recent years, there has been increasing evidence

that surgical disruption of the pylorus is a safe and effective therapy for medically refractory gastroparesis [20].

In the largest published case series to date regarding laparoscopic pyloroplasty for the treatment of gastroparesis, Shada et al. described 177 patients over a 5-year period. In patients with follow-up GES, 89% showed objective improvement in emptying; there was significant improvement in eight out of nine predefined gastroparesis symptom domains [21]. The pyloroplasty cohort in this current study demonstrated similar results, showing significant improvement in both GES and GCSI scores.

With recent advances in endoluminal surgical techniques, division of the pylorus can be reliably accomplished endoscopically with POP as opposed to a laparoscopic or open approach. This technique was first demonstrated in a porcine model in 2012 by Kawai et al. followed by the first published case series humans by Khashab et al. in 2013, referred to

Table 3 Comparison of gastroparesis-related outcomes pre- and post-procedure

	POP	<i>p</i> value [€]	Pyloroplasty	<i>p</i> value [€]	<i>p</i> value [£]
BMI (kg/m²)					
Pre	24.9 ± 7.1	Ref	26.1 ± 6.7	Ref	0.90
Post	24.9 ± 6.6	> 0.99	27.2 ± 8.1	0.92	0.83
GCSI					
Nausea/vomiting subscore					
Pre	3.7 ± 1.0	Ref	4.0 ± 1.0	Ref	0.380
Post	2.0 ± 1.5	< 0.001	1.6 ± 1.5	< 0.001	0.448
Early satiety/fullness subscore					
Pre	4.2 ± 0.9	Ref	3.9 ± 1.5	Ref	0.434
Post	3.0 ± 1.6	0.001	2.7 ± 1.7	0.014	0.601
Bloating subscore					
Pre	3.9 ± 1.6	Ref	4.3 ± 1.5	Ref	0.455
Post	2.2 ± 1.8	0.002	2.7 ± 1.9	0.028	0.438
Total GCSI					
Pre	4.0 ± 0.8	Ref	4.0 ± 1.1	Ref	> 0.99
Post	2.4 ± 1.5	< 0.001	2.3 ± 1.5	0.001	0.849
Gastric emptying					
Pre: 4-h % retention	32.9 ± 5.4%	Ref	35.9 ± 5.5%	Ref	0.102
Post: 4-h % retention	10.7 ± 4.4%	0.042	2.5 ± 0.8%	0.029	0.163
Improved gastric emptying	6 (85.7%)	–	5 (83.3%)	–	0.907
Normal 4 h gastric emptying	8 (72.7%)	–	7 (100.0%)	–	0.141

Data are displayed as mean ± standard deviation and count (column %)

POP per-oral pyloromyotomy, BMI Body Mass Index, GCSI Gastroparesis Cardinal Symptom Index

[€]*p* value is for comparison to baseline values within group; this is a paired *t* test exploring the difference in means based on complete case analysis

[£]*p* value is for comparison between POP and LP groups

as gastric per-oral endoscopic myotomy (G-POEM) in their study [22, 23]. In the largest published case series to date which was completed at our institution, 47 patients undergoing POP were found to have significant improvement in both symptoms and GES with minimal procedure-related complications [24]. In several smaller case series, there have been similar demonstrations of short-term efficacy following POP [25, 26].

Our results demonstrate improvements in both symptom scores and objective gastric emptying following either POP or LP, giving further evidence that pyloric disruption is a viable therapy. Both cohorts showed significant improvement in GES and GCSI scores, with no differences in these outcomes measures between either interventions. Predictably, POP appears superior to LP in several metrics of perioperative morbidity including operative time, estimated blood loss, and length of hospital stay. Both cohorts required one reoperation within 30 days of their procedure, which included a negative diagnostic laparoscopy following POP for abdominal pain and the laparoscopic placement of a jejunostomy feeding tube shortly after pyloroplasty. Overall complications were also fewer in the POP cohort, although this study may be underpowered to assess that outcome. The

complication profiles are different between the two procedures, as there are no external incisions with POP that are at risk for surgical site infection. This also leads to far less post-procedure pain and faster recovery when comparing POP to LP, which is reflected in shorter observed length of hospital stay. There was a single mortality in the POP group due to a cardiac event several weeks following intervention, this was found to be unrelated to the procedure with post-mortem investigation revealing no surgical site pathology. Our institution has now performed over 200 POP procedures with this being the only death in our case series, and it was included by chance in this current study following propensity matching. Overall, given the equivocal functional outcomes with fewer perioperative morbidity, this study demonstrates that POP should be considered as effective as pyloroplasty for the surgical management of gastroparesis with a trend towards a safer profile.

Importantly, management with either POP or LP does not preclude future intervention with the other technique for patients who do not achieve long-term improvement. Due to our lesser curve approach with POP, the pyloric incision is 90 degrees offset when comparing to pyloroplasty. At our institution, several patients have now

undergone POP after failing pyloroplasty and vice versa. In addition, gastric electric stimulator placement remains a viable option after either procedure, which has had previously demonstrated efficacy in patients who have failed pyloroplasty [27]. For those that fail all organ-preserving interventions, neither POP nor pyloroplasty are a barrier to future gastrectomy or bypass. Thus, POP or pyloroplasty can be considered first-line, organ-sparing interventions that preserve all future surgical options in the event of treatment failure. In this regard, POP may have additional benefit when compared to pyloroplasty, as there is no violation of the peritoneal space and presumed less risk of scarring and adhesions which may complicate future interventions.

There are several important limitations to the present study, including its retrospective design. This study was conducted a single, tertiary-referral center that has now accumulated the largest known case series in the world for conducting POP, so its ability to be reproduced at others centers is not known. While 30 patients in each arm of the study were sufficiently powered to demonstrate significant differences in certain procedural details and functional outcomes of gastroparesis, it was underpowered to definitively demonstrate differences in other perioperative outcomes. Finally, in some patients GCSI scores were not prospectively recorded, and while a majority of patients had follow-up information at 90 days, many of these patients did not complete GES following their procedure.

Conclusion

Both laparoscopic pyloroplasty and POP are safe and can produce short-term subjective and objective improvement in medically refractory gastroparesis. POP is associated with less perioperative morbidity than laparoscopic pyloroplasty and should be considered a first-line surgical therapy for patients who fail medical management. Additional studies are required to determine the long-term efficacy of POP and compare its outcomes with other surgical interventions.

Compliance with ethical standards

Disclosures Matthew D. Kroh has no conflict of interest relevant to this publication. Outside of the scope of this work, he serves as a consultant for Levita Magnetics and Medtronic. He has received research funding from Cook. John H. Rodriguez has no conflict of interest relevant to this publication. Outside of the scope of this publication, he has received research funding from Pacira Pharmaceuticals and Intuitive Surgical. Joshua Landreneau, Andrew Strong, Kevin El-Hayek, Chao Tu, James Villamere, and Jeffrey Ponsky have no conflict of interest or financial ties to disclose.

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