

Gastric peroral endoscopic myotomy for the treatment of refractory gastroparesis: a multicenter international experience

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ABSTRACT

Background Gastroparesis is a difficult-to-treat motility disorder with a poor response to medical therapy. Gastric peroral endoscopic pyloromyotomy (G-POEM) has been offered as a novel therapy in the treatment of refractory gastroparesis. We present a multicenter case series of our experience with G-POEM.

Methods This is an international multicenter case series of patients who underwent G-POEM for the treatment of gastroparesis. The severity of gastroparesis was assessed by delayed gastric emptying scintigraphy (GES) and an elevated gastroparesis cardinal symptoms index (GCSI). Patients then underwent G-POEM using the submucosal tunneling technique. The primary endpoint was improvement in the GCSI score and improvement in gastric emptying on repeat scintigraphy. Secondary endpoints were technical success, complication rate, procedure duration, and length of hospital stay post-procedure.

Results G-POEM was technically successful in all 33 patients. Symptomatic improvement was seen in 28/33 patients (85%), with a decrease in symptom score by GCSI from 3.3 to 0.8 at follow-up ($P < 0.001$). The mean procedure duration was 77.6 minutes (37–255 minutes). Mean GES improved significantly from 222.4 minutes to 143.16 minutes ($P < 0.001$). Complications were minimal and included bleeding ($n = 1$) and an ulcer ($n = 1$) treated conservatively. The mean length of hospital stay post-procedure was 5.4 days (1–14 days). The mean follow-up duration was 11.5 months (2–31 months).

Conclusion G-POEM is a technically feasible, safe, and successful procedure for the treatment of refractory gastroparesis. A further multicenter comparative study should be performed to compare this technique to laparoscopic pyloromyotomy.

Introduction

Gastroparesis is a chronic, poorly understood, debilitating disorder of the stomach, which is characterized by delayed gastric emptying without evidence of mechanical obstruction. Symptoms include nausea, vomiting, early satiety, and/or epigastric

pain and can significantly affect a patient's quality of life. There has been a reported increase of 150% in prevalence in recent years [1–3]. The most common causes of gastroparesis include diabetes, medication, viral infection, postsurgical, and idiopathic [4, 5].

Current treatments are limited but include dietary modification and pharmacotherapy agents such as antiemetics and prokinetics. At present, metoclopramide is the only US Food and Drug Administration (FDA)-approved medication for the management of gastroparesis, but it has a black box warning for tardive dyskinesia with long-term use [6, 7]. In addition to the above treatments, surgical interventions for the management of refractory gastroparesis have also been described [8]. A gastric electrical stimulation device has been studied, but this is only FDA approved for humanitarian use and most research studies testing this device have had a small sample size [9]. Finally, laparoscopic pyloroplasty, as reported by Hibbard et al. [8], showed an 83% improvement in symptoms 1 month following the procedure.

Several endoscopic treatments for gastroparesis have been studied. Endoscopic injection of botulinum toxin is thought to decrease pyloric tone, thereby improving gastric emptying [10]. Initially, botulinum toxin injection showed promising results; however, two recent randomized controlled trials did not show any benefit when compared with placebo (saline injection) [3, 11, 12]. Clarke et al. reported the use of transpyloric stenting for the management of these patients [3, 13]. Case series have described a 75% clinical response in patients who underwent transpyloric stenting; however, this was associated with high rate of stent migration, limiting its clinical utility [14].

The first gastric peroral endoscopic pyloromyotomy (G-POEM) was performed in 2013 without any adverse events and offered significant improvement in the patient's symptoms after 12 weeks of follow-up [9]. Recently, a multicenter study showed a clinical response in 26/30 patients (86%) during a median follow-up of 5.5 months, with the occurrence of only two adverse events [1]. This was confirmed by a recent study from Gonzalez et al. [15], in which the mid-term efficacy of G-POEM reached 70% at 6 months.

In this study, we present an international multicenter case series of our experience with G-POEM in the treatment of refractory gastroparesis

Methods

Patient population

Refractory gastroparesis was defined as gastroparesis not responding to a combination of dietary changes, correction of electrolyte abnormalities, prokinetic medications, or antiemetic therapy for at least 6 months. Inclusion criteria encompassed symptomatic refractory gastroparesis with an abnormal gastric emptying study. Exclusion criteria included previous gastric surgery, inability to tolerate endoscopy, severe coagulopathy, and active gastritis or ulcer.

This was an international multicenter case series of patients who underwent G-POEM for the treatment of refractory gastroparesis over a 3-year period. Data were captured prospectively in a dedicated database at each institution and analyzed retrospectively.

Severity of gastroparesis was assessed by delayed gastric emptying scintigraphy (GES) and elevated gastroparesis cardinal symptoms index (GCSI). The GCSI is based on three sub-

scales: post-prandial fullness/early satiety (4 items); nausea/vomiting (3 items), and bloating (2 items), with each item being scored from 0–5 [16]. Pre-procedure gastric emptying studies were obtained 2–4 weeks prior to the intervention and were performed as previously published [17, 18].

Patients underwent gastric pyloromyotomy using a submucosal tunneling technique similar to that used for peroral endoscopic myotomy (POEM). The primary endpoint was clinical success assessed by improvement in GCSI score and gastric emptying on repeat scintigraphy. Secondary endpoints were the technical success of the procedure, complication rate, procedure duration, and length of hospital stay post-procedure.

G-POEM technique

All procedures were performed with the patient under general anesthesia in a supine position by operators who had performed at least 50 esophageal POEMs prior to performing this procedure. The esophagus and the stomach were cleared with water lavage and gentamicin wash. An ERBE generator (Ere, Tübingen, Germany) and a T- or I-type HybridKnife was used to perform mucosal incision. Carbon dioxide was used for insufflation in all patients. A Coagrasper (FD-411QR; Olympus) was used to achieve hemostasis of any large vessels.

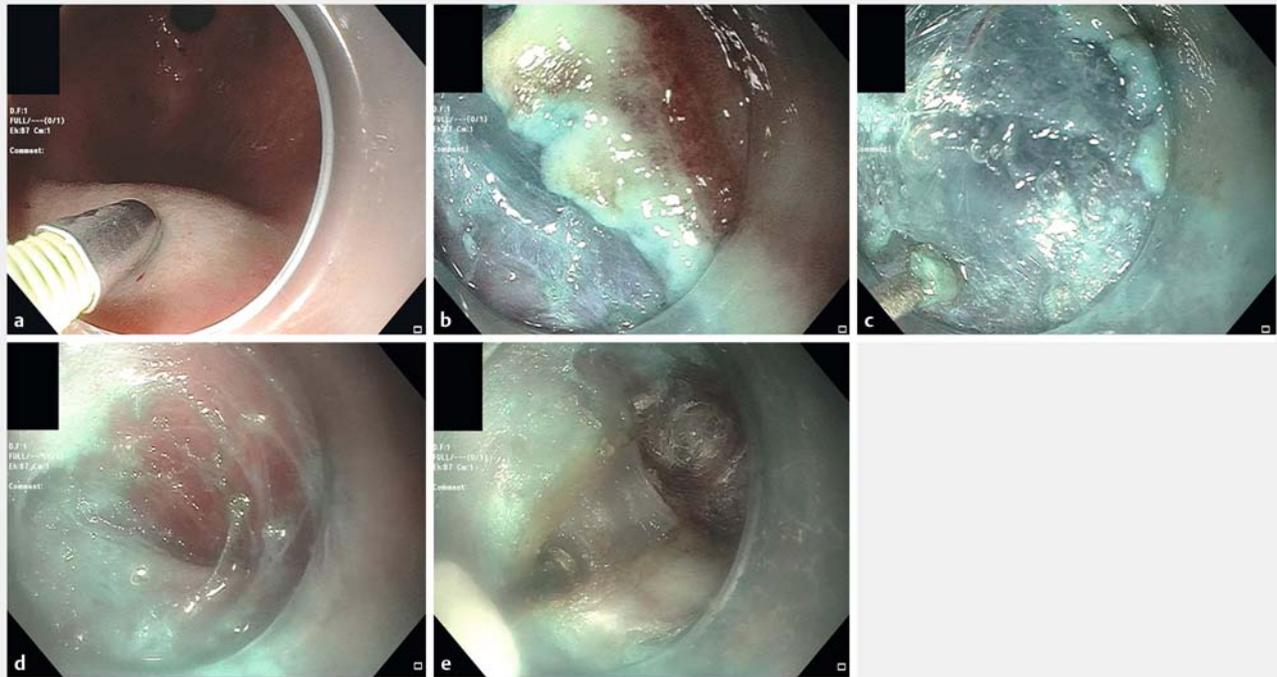
The mucosal entry site was created at the 5- or 6-o'clock position, approximately 5–6 cm proximally to the pylorus along the greater curvature of the stomach (the lesser curvature in two patients). A submucosal bleb was created with a premixed methylene blue/normal saline solution (5 mL/500 mL) (► Fig. 1a). A 2-cm mucosal incision was then performed (► Fig. 1b). A submucosal tunnel was created by dissection of submucosal fibers using spray coagulation up to the pyloric ring (► Fig. 1c). Selective myotomy of the pyloric circular muscle was performed with the HybridKnife or the IT2 knife (► Fig. 1d,e) and the myotomy was extended for 3 cm proximally into the antrum. After myotomy, the tunnel was lavaged with gentamicin and the mucosal entry site was closed with hemostatic clips or sutures (► Video 1).

Postoperative care

Patients were admitted post-procedurally for observation for at least 1 day in all cases. A post-procedure upper gastrointestinal series was obtained to ensure there was no extraluminal leakage prior to the initiation of a clear liquid diet for 2–3 days post-procedure. Patients were then moved onto a soft diet if they tolerated the trial of clear liquid. They were then instructed to continue to observe a low residue diet for gastroparesis. Post-procedure gastric emptying studies were obtained 4–6 weeks post intervention.

Statistical analysis

All statistical analyses were performed using SPSS 15.0 statistics software (SPSS Inc, Chicago, Illinois, USA). Continuous variables were expressed as the mean \pm standard deviation (SD) and categorical data were displayed as number (n) and percentage (%). Two-sided *P* values < 0.05 were considered significant. Repeated-measures *t* test analyses were conducted for symptomatic and score variables from baseline to resolution follow-up period.



► **Fig. 1** Endoscopic views showing: **a** the submucosal bleb created by needle injection of the lifting solution (methylene blue and saline) 5 cm proximally to the pylorus; **b** a horizontal incision of 1–2 cm made at the 5- or 6-o'clock position to allow mucosal entry into the submucosal space; **c** submucosal tunneling performed with dissection of the submucosal fibers until the pyloric ring is seen; **d** the pyloric ring is seen at the end of the submucosal tunnel; **e** full-thickness myotomy is performed starting at the pylorus and proceeding proximally.

Results

G-POEM was performed in 33 patients, 10 cases from America and 23 from France. The majority of patients (22 [66.7%]) were women. The mean age of the patients was 52 (range 21–85).



► **Video 1** Step-by-step video demonstrating the technique for gastric peroral endoscopic pyloromyotomy (G-POEM).
Online content viewable at:
<https://doi.org/10.1055/a-0596-7199>

The most common etiologies of gastroparesis were idiopathic ($n=12$) and post-surgical ($n=12$), followed by diabetes ($n=7$) and scleroderma ($n=2$). Five patients were on prokinetic medications at the time of G-POEM, four underwent prior endoscopic treatment with botulinum toxin injection, and two had undergone gastric stimulator placement. ► **Table 1** summarizes the patient demographics.

The most common complaints in the preoperative symptomatic assessment by GCSI were early satiety, gastric fullness, and nausea. The mean preoperative GES time was 222.4 minutes, with gastric retention of solid food of 45% at 4 hours.

G-POEM was technically successful in all 33 patients. The mean procedure duration was 77.6 minutes (range 37–255 minutes) (► **Table 2**). The mean length of the pyloric myotomy was 3.34 cm (2–6 cm). The most common mucosal entry site was at the posterior lateral aspect of the antrum, only two patients underwent an anterior approach for tunnel entry. In 30 patients, the tunnel was closed with clips only, in two patients with clips and suturing, and in one patient with suturing only.

Complications were minimal and included bleeding ($n=1$) and ulcer ($n=1$). The bleeding was encountered during the creation of the tunnel and was treated with a Coagrasper. The ulcer was thought to be a mucosal defect, which was treated with clip placement. The mean length of hospital stay post-procedure was 5.4 days (1–14 days). No patient to date has undergone repeat endoscopic therapy post-GPOEM.

► Table 1 Pre-procedure baseline characteristics of the 33 patients who underwent gastric peroral endoscopic pyloromyotomy.

Mean age, years	52
Sex, male, n (%)	11 (33)
Etiology of gastroparesis, n (%)	
▪ Diabetes	7 (21.2)
▪ Post-surgical	12 (36.4)
▪ Idiopathic	12 (36.4)
▪ Scleroderma	2 (6.1%)
Prior treatment, n (%)	11 (33%)
▪ Medication	5
▪ Botulinum injection	4
▪ Gastric stimulator	2

► Table 2 Details of the 33 gastric peroral endoscopic pyloromyotomy procedures carried out.

Technical success, n (%)	33 (100%)
Tunnel entry site, n (%)	
▪ Anterior	2 (6%)
▪ Posterior	31 (94)
Tunnel length, mean (range), cm	3.34 (2–6)
Procedure time, mean (range), minutes	77.6 (37–255)
Closure type, n (%)	
▪ Clips	32 (97)
▪ Suture	3 (9.1)
Complications, n (%)	2 (6%)
▪ Bleeding	1
▪ Ulcer	1

Primary outcomes

Symptomatic improvement was seen in 28/33 patients (85%), as defined by a decrease in symptom score by GCSI from a preoperative mean score of 3.3 to a postoperative mean score of 0.8 at follow-up ($P < 0.001$) (► **Table 3**). The mean follow-up duration was 11.5 months (2–31 months). The postoperative scores in each individual symptom index within the GCSI all decreased significantly: the mean score for gastric fullness decreased from 4.2 to 1.3 ($P < 0.001$); for early satiety from 4 to 1.2 ($P < 0.001$); for nausea from 3.66 to 1.3 ($P < 0.001$); and for vomiting from 2.5 to 0.3 ($P < 0.001$).

Secondary outcomes

The mean GES improved significantly from 222.4 minutes to 143.16 minutes ($P < 0.001$). Specifically, a significant decrease in gastric retention volume was seen at durations of both 2 hours and 4 hours on the GES (75.8% vs. 58.2% at 2 hours; $P = 0.01$; and 45% vs. 29.6% at 4 hours; $P = 0.04$) (► **Table 3**).

Discussion

This is the largest multicenter series of gastric pyloromyotomy for the treatment of gastroparesis to date. G-POEM was successfully performed in all patients with only two adverse events

seen, both of which were managed conservatively. The results showed an excellent response rate, with 85% of patients having both symptomatic improvement and a decrease in delayed gastric emptying by GES. This adds to the accumulating evidence supporting G-POEM as a technically feasible, safe, and efficacious treatment option for patients with gastroparesis who respond to pyloric-directed therapy to improve gastric emptying.

Currently, the most common surgical treatment for patients with refractory gastroparesis failing medical therapy is pyloroplasty. This was first described by Heinike and Mikuliez-Radecki in 1887 [19]. This technique further evolved into laparoscopic pyloroplasty, which is less invasive, with faster recovery; the technique has been evaluated in multiple different studies with a recent retrospective study that included 28 patients showing 83% improvement in symptoms following laparoscopic pyloroplasty at 1-month follow-up [8].

Different pathophysiologic mechanisms, such as impaired gastric contractile ability, vagal injury/neuropathy, pyloric dysfunction, and gastric arrhythmia, have been proposed to be the underlying cause of symptoms in patients with gastroparesis [20]. The rationale for interventions on the pylorus is based on the pyloric dysfunction (or pylorospasm) theory. Initially, multiple small studies showed intrapyloric injection of botulinum toxin improved both gastric emptying and patients' symptoms.

► Table 3 Comparison of the primary outcomes before and after the gastric peroral endoscopic pyloromyotomy procedure.

	Preoperative	Postoperative	P value
Mean GCSI score	3.3	0.8	<0.001
Mean GES time, minutes	222.4	143.2	<0.001
Mean gastric retention at 2 hours, %	75.8	58.3	0.01
Mean gastric retention at 4 hours, %	45.0	29.6	0.04

GCSI, gastroparesis cardinal symptoms index; GES, gastric emptying scintigraphy.

► **Table 4** Previous studies of gastric peroral endoscopic pyloromyotomy reported in the literature.

Study	Total number of patients	Clinical success rates	Follow-up, months	Adverse event rate
Shlomovitz et al. [24]	7	85% (symptom improvement); 80% (normalization of GES)	6.5	14%
Khashab et al. [1]	30	86% (symptom improvement); 47% (normalization of GES)	5.5	6.7%
Dacha et al. [25]	16	81% (decrease in GCSI); 75% (normalization of GES)	12	0%
Gonzalez et al. [3]	12	85% (decrease in GCSI); 75% (normalization of GES)	3	0%
Xue et al. [26]	14	61% (decrease in GCSI); 83% (decrease in GES)	2	0%

GES, gastric emptying scintigraphy; GCSI, gastroparesis cardinal symptoms index.

A retrospective study of 179 patients by Coleski et al. [21] demonstrated decreased symptoms of gastroparesis 1–4 months after intrapyloric injection in 51.4% of patients, with an increase in clinical response to 73.4% of patients after a second injection. However, two recent randomized controlled trials did not show any benefits compared with placebo [3, 11, 12]. Based on these studies, the American College of Gastroenterology's clinical guideline did not recommend intrapyloric injection of botulinum toxin for patients with gastroparesis [22].

In 2013, Clarke et al. described the use of transpyloric stenting for the management of those patients who are refractory to medications [13]. Furthermore, Khashab et al. [14] demonstrated 75% clinical response in 30 patients with refractory gastroparesis who underwent transpyloric stenting with adequate follow-up. In their study, greater clinical success was seen in patients with symptoms of nausea and vomiting rather than in those with a predominant symptom of pain. However, one of the most common disadvantages of transpyloric stenting is the associated high rate of stent migration. This has been demonstrated in several different studies, even after the use of sutures or clips for stent anchoring.

Another treatment that has been suggested with good clinical response is surgical pyloroplasty for gastroparesis, which is more invasive. With continuous development of endoscopic devices and rapid advances in endoscopic technology, endoscopists have become more interested in treating various gastrointestinal disorders with endoluminal approaches. After successfully performing endoscopic pyloromyotomy in a porcine model, Khashab et al. performed the first endoscopic pyloromyotomy in 2013, without any adverse events and with significant improvement in patient's symptoms after 12 weeks of follow-up [6, 23]. The procedure is similar to esophageal POEM in terms of its techniques and principles, therefore it has been named G-POEM.

Since it was first reported, multiple studies have evaluated the safety of this procedure. (► **Table 4**; [24–26]) Recently, a multicenter study evaluated the efficacy and safety of G-POEM. In this retrospective study, the authors were able to show a clinical response in 26/30 patients (86%) during a medi-

an follow-up period of 5.5 months, with the occurrence of only two adverse events [1, 6]. GES post-procedure was obtained in only 17/30 patients, with improvement seen in 14 of them.

In the current study, we present the largest multicenter case series of G-POEM to date. In our cohort of 33 patients who underwent G-POEM, symptomatic improvement was seen in 28/33 patients (85%), with a decrease in symptom score by GCSI from 3.3 to 0.8 at follow-up. The GES was obtained in all patients before and after the procedure, with a significant decrease in mean GES time from 222 minutes to 143 minutes. The mean postoperative gastric retention was 29% at 4 hours compared with 45% preoperatively, with mean follow-up time of 11.2 months, which represents the longest follow-up reported to date. There were few adverse events noted, which were all managed conservatively, and the mean hospital length of stay was 5.4 days.

Interestingly, only four operators from only three different centers with great experience in performing esophageal POEM were included. This contrasts with a previously published series that included many centers and operators with different skill levels [1], which obviously makes the data very difficult to generalize.

Taken together, the available data suggest that pyloric-directed endoscopic myotomy may be a promising, safe, and feasible treatment option for refractory gastroparesis. Compared with botulinum toxin injection, it has better clinical outcome for efficacy; compared with pyloric stenting, it has the advantage of longer durability, and no concern of stent migration or revision being required because of occlusion.

There are several limitations to our study. Firstly, we recognize the retrospective nature of our series, with its inherent biases. Secondly, despite being the largest reported series to date, G-POEM is a procedure that is still in its early clinical phase of practice and there is not the large volume of data on long-term safety and efficacy that there is for esophageal POEM.

Based on these results, G-POEM is a technically feasible, safe, and successful procedure for the treatment of refractory gastroparesis. Increased training of advanced endoscopy techniques is necessary for more widespread use of G-POEM. Fur-

ther large-scale, multicenter prospective studies should be performed to validate our early findings. A comparison of G-POEM with laparoscopic pyloromyotomy is a further area of investigation to evaluate the outcome of an endoscopic versus a surgical approach for pyloric myotomy in the treatment of gastroparesis.

Competing interests

Michel Kahaleh has received grant support from Boston Scientific, Fujinon, EMcison, Xlumena Inc., W.L. Gore, MaunaKea, Apollo Endosurgery, Cook Endoscopy, ASPIRE Bariatrics, GI Dynamics, NinePoint Medical, Merit Medical, Olympus, and MI Tech. He is a consultant for Boston Scientific, Xlumena Inc., Concordia Laboratories Inc, ABBvie, and MaunaKea Tech. Amy Tyberg is a consultant for EndoGastric Solutions. None of the other authors have conflicts of interest to report.

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