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Initial experience and outcomes of per oral pyloromyotomy for the treatment of refractory gastroparesis

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Abstract

Background Gastroparesis can be a debilitating disease process for which durable treatment options are lacking. While dietary changes and pharmacotherapy have some efficacy, symptoms frequently recur and some patients progress to needing supplemental enteral feeding access. Per oral pyloromyotomy (POP) has been shown to be a durable minimally invasive treatment option for refractory gastroparesis with a low side effect profile, and therefore has been performed at this institution for the past 6 years.

Methods This was a retrospective case series of all patients who underwent a POP at a single institution over a 6-year period (2018–2023). Patient demographics, preoperative symptomatology and subsequent workup, postoperative complications, and symptom recurrence were collected and analyzed.

Results There were 56 patients included in the study. There was a 1.8:1 female:male ratio. The average patient age was 56 years old (range 23–85). The average duration of symptoms was 1–3 years. Thirty-eight percent of patients had undergone previous endoscopic therapy for gastroparesis (pyloric botox injection or pyloric dilation) and 16% of patients underwent multiple endoscopic therapies. Twenty-nine percent of patients were on a medication for gastroparesis. Past surgery was the most common gastroparesis etiology for POP (50% of patients). Diabetes (23%) and idiopathic (19%) were the other most common gastroparesis etiologies for POP. Nausea was the most common symptom at first follow-up (30%) but these patients continued to improve with 14% of patients continuing to endorse nausea at 6 months. Twenty-seven percent of patients developed symptom recurrence. Forty percent of patients with symptom recurrence underwent a repeat endoscopic or surgical therapy.

Conclusions In this present study, POP leads to durable results in approximately 75% of patients with minimal complications. Furthermore, the majority of patients who do develop symptom recurrence do not require additional gastroparesis interventions.

Keywords Per oral pyloromyotomy · Gastric per oral endoscopic myotomy · Gastroparesis · Endoscopy

Gastroparesis, a debilitating gastrointestinal disorder, is characterized by delayed emptying of the stomach without any mechanical obstruction [1]. This condition profoundly affects the quality of life of affected individuals, leading to symptoms such as nausea, vomiting, bloating, early satiety, and abdominal discomfort [2].

Gastroparesis can arise from various causes, including diabetes mellitus, post-surgical complications, neurological disorders, and idiopathic factors [3]. Diabetes mellitus, particularly type 1, is a prominent etiological factor, attributed to autonomic neuropathy affecting gastric motility. Surgical procedures such as vagotomy, esophagectomy, gastric bypass surgery, and fundoplication can disrupt vagus nerve thus altering the normal functions of the stomach, leading to gastroparesis. Additionally, neurological conditions like

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Parkinson's disease or multiple sclerosis may impair the neural regulation of gastric motility. Despite extensive research, a considerable portion of gastroparesis cases remain idiopathic, underscoring the need for further investigation into its underlying mechanisms [4].

The pathophysiology of gastroparesis involves dysfunction in the mechanisms regulating gastric motility. In gastroparesis, the normal rhythmic contractions of the stomach are impaired, leading to delayed emptying of food from the stomach. Dysfunction of an intact vagus nerve, which controls gastric motility, plays a central role particularly in diabetic gastroparesis [5].

Managing gastroparesis involves a multifaceted approach aimed at alleviating symptoms, improving gastric emptying, and addressing underlying causes. Lifestyle modifications, such as dietary changes (e.g., small, frequent meals low in fat and fiber), avoiding carbonated beverages, and chewing food thoroughly, can help manage symptoms [6]. Medications may be prescribed to stimulate gastric motility (prokinetic agents), control nausea and vomiting, or manage pain and discomfort. However, the efficacy of these medications varies among individuals, and long-term use may be limited by side effects [7].

In cases refractory to conservative measures, more invasive interventions may be considered. Enteral nutrition via feeding tubes can provide adequate nutrition, while bypassing the stomach [8]. Surgical options, such as gastric electrical stimulation or pyloroplasty, aim to improve gastric emptying and symptom control by stimulating the stomach utilizing electrical current or transecting the pyloric muscle improving gastric emptying [9, 10].

While a laparoscopic pyloroplasty can be performed safely and with good clinical results, this is still associated with complications, some of which can be severe [11]. Therefore, after the development of the per oral endoscopic myotomy for the treatment of achalasia, the same principle was developed and used to divide the pylorus endoscopically instead of the lower esophageal sphincter [12]. This study describes the per oral pyloromyotomy (POP) and its outcomes at a tertiary care referral center for the treatment of refractory gastroparesis, while also serving as a review of the benefits of per oral pyloromyotomy.

Materials and methods

Procedures

All patients with suspected gastroparesis based on their symptomatic presentation and/or past surgical history underwent a gastric emptying study in the nuclear medicine department [13]. After a confirmed diagnosis radiographically, the patients were taken to the operating room for a per oral pyloromyotomy.

A diagnostic EGD was first performed to rule out any mechanical obstructions. A soft cap was applied to the end of the endoscope and using a sclerotherapy injection needle, a submucosal wheel was made just above the pylorus on the lesser curve of the stomach with a solution of methylene blue, epinephrine, and dextrose. A transverse mucosotomy was then made and the submucosal plane entered with the endoscope. The pyloric muscle was then identified by its shiny white circular appearance and using a triangle tip knife, the muscle was divided—ensuring that all muscle fibers were divided resulting in muscle separation. The mucosotomy was then closed with multiple endoscopic through the scope clips. All procedures were performed outpatient and the patient was continued on a liquid diet for 1 week postoperatively. No routine postoperative imaging was obtained. All patients had a postoperative visit 2 weeks after surgery and as needed afterward.

Database

A retrospective database was created which included all patients who underwent a POP by a single surgeon at a tertiary care facility over 6 years (2018–2023). Patient demographics, operative details, and outcomes were collected from the electronic medical record. Outcomes included symptom improvement, symptom recurrence, and need for additional gastroparesis procedures after a POP.

This study was approved by the University Hospitals Institutional Review Board (STUDY20230771).

Results

During the study period, 56 patients were enrolled, comprising 36 females and 20 males resulting in a female-to-male ratio of 1.8:1. The average age of the patients was 56 years (ranging from 23 to 85).

Nausea was the predominant preoperative symptom, with 77% of patients reporting, followed by emesis, experienced by 69% of patients. On average, symptoms persisted for 1–3 years (ranging from less than 6 months to over 10 years). Thirty-eight percent had undergone a prior endoscopic therapy for gastroparesis, including pyloric botox injection or pyloric dilation, and 16% had received multiple endoscopic treatments. Additionally, 29% were taking medication for gastroparesis.

Previous surgery, particularly esophagectomy and fundoplication, constituted the primary etiology for gastroparesis in 50% of patients, with diabetes (23%) and idiopathic factors (19%) also being significant contributors. Of the 28 patients with post-surgical gastroparesis, 8 had previously

underwent a paraesophageal hernia repair, 10 had undergone a fundoplication, 9 had undergone an esophagectomy, and 1 patient had undergone a distal pancreatectomy with splenectomy.

A single perioperative complication (NSTEMI) occurred from which the patient recovered well.

Nausea remained the most common symptom during initial follow-up (30%), though only 14% continued to experience it 6 months postoperatively. Symptom recurrence was observed in 27% of patients, with an average symptom recurrence interval of 11 months (ranging from 6 months to 3 years). Forty percent of patients with recurring symptoms (11% of the total study population) underwent further endoscopic or surgical interventions.

When both symptom recurrence and need for an additional endoscopic or surgical intervention was analyzed between etiology groups, a higher proportion of patients with post-surgical (35%) or diabetic (42%) etiologies developed recurrent gastroparesis symptoms compared with idiopathic etiology (5%). ($p = 0.04$) However, there was no difference in the need for either endoscopic or surgical intervention. ($p = 0.27$).

Discussion

Gastroparesis is a debilitating condition characterized by delayed gastric emptying without mechanical obstruction. It significantly affects the quality of life of patients, leading to symptoms such as nausea, vomiting, bloating, and abdominal pain [14]. Traditional treatment options include dietary modifications, medications, and invasive procedures like pyloroplasty. However, in recent years, per oral pyloromyotomy (POP) has emerged as a promising minimally invasive intervention for managing gastroparesis [15].

Per oral pyloromyotomy involves accessing the pylorus endoscopically, thereby eliminating the need for external incisions. This minimally invasive approach reduces surgical trauma, postoperative pain, and hospitalization duration compared to conventional surgical procedures. Patients undergoing POP typically experience shorter recovery times and can resume normal activities sooner, improving their overall quality of life [16].

Clinical studies have demonstrated significant improvement in symptoms following per oral pyloromyotomy in patients with refractory gastroparesis [17]. By enhancing gastric emptying and reducing pyloric resistance, POP alleviates symptoms such as nausea, vomiting, early satiety, and bloating. Moreover, the sustained relief provided by POP translates into long-term benefits, minimizing the need for recurrent interventions and medical therapies as shown with these current data. The superior symptom control achieved with per oral pyloromyotomy compared with medications and lifestyle modifications enhances patient satisfaction. This current study showed a 73% durable response rate to POP with only 11% of patients requiring either further endoscopic or surgical interventions (see Fig. 1). Idiopathic gastroparesis may respond better to POP and further studies are needed to better understand the differences in pathophysiology between the various etiologies of gastroparesis.

While this study did not evaluate cost specifically, per oral pyloromyotomy also offers potential cost savings compared to traditional surgical approaches for gastroparesis management, a disease with quite high healthcare utilization costs [18]. The shorter hospital stays, reduced postoperative complications, and decreased reliance on long-term medications contribute to lower healthcare expenditures. Additionally, the outpatient nature of POP allows for efficient resource utilization and outpatient scheduling, further optimizing healthcare delivery.

There have been other published manuscripts evaluating the long-term efficacy of per oral pyloromyotomy that have shown similar long-term efficacy rates. One of the first larger case series by Rodriguez et al. showed good clinical response to POP in 47 patients with minimal complications [19]. Mondragón et al. showed a 77.5% clinical success rate at 48 months [20]. In their study, diabetic gastroparesis had the best response to POP followed by idiopathic. This is in contrast to the current study in which idiopathic gastroparesis showed the lowest rate of gastroparesis recurrence. This may be explained by the different patient populations

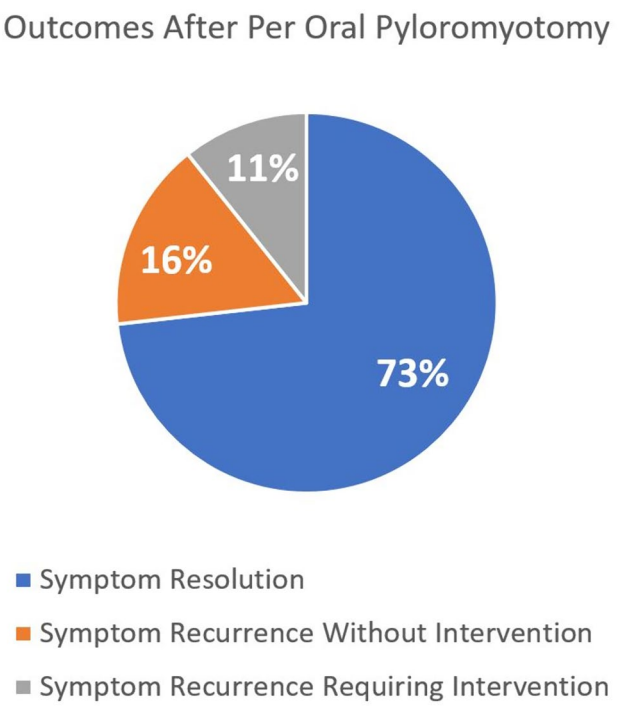

Fig. 1 Outcomes after per oral pyloromyotomy

between the two studies. Finally, Labonde et al. described a 62.5% clinical response rate in 42 patients at 36 months, again similar to this current study [21].

Strengths of this study include its patient number, reliable follow-up (albeit short follow-up), and a complete dataset including past gastroparesis interventions and etiologies. Limitations of this study include its retrospective nature, a 1-year follow-up, which is short given POPs decreasing efficacy with time, and the lack of quantitative symptom scoring.

per oral pyloromyotomy represents a significant advancement in the management of gastroparesis, offering several advantages over conventional treatment modalities. Its minimally invasive approach and efficacy in symptom relief make it a valuable therapeutic option for patients with refractory gastroparesis. Furthermore, the potential for reduced healthcare costs and improved patient outcomes underscores the importance of integrating per oral pyloromyotomy into the clinical management of gastroparesis. As research and technology continue to evolve, per oral pyloromyotomy holds promise for further optimizing the treatment landscape and improving the lives of individuals living with gastroparesis.

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Declarations

Disclosures Jeffrey Marks reports consultant fees from Boston Scientific and Steris Endoscopy. He has also served on the ACS Board of Governors and SAGES Governing Board. Joshua Lyons reports consultant fees from Steris Endoscopy. Hamza Nasir Chatha, MD; Christina Boutros, DO; Saher-Zahra Khan, MD; Jamie Benson, MD; Guy Katz, MD; Patrick Wieland, MD have no conflicts of interest or financial ties to disclose.

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