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ENDOLUMINAL SURGERY

Hybrid endoluminal stapled pyloroplasty: an alternative treatment option for gastric outlet obstruction syndrome

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Abstract

Background Gastroparesis is a rapidly increasing problem with sometimes devastating consequences. While surgical treatments, particularly laparoscopic pyloroplasty, have recently gained popularity, they require general anesthesia, advanced skills, and can lead to leaks. Peroral pyloromyotomy is a less invasive alternative; however, this technique is technically demanding and not widely available. We describe a hybrid laparo-endoscopic collaborative approach using a novel gastric access device to allow endoluminal stapled pyloroplasty as an alternative treatment option for gastric outlet obstruction.

Methods Under general anesthesia, six pigs (mean weight 33 kg) underwent endoscopic placement of intragastric ports using a technique similar to percutaneous endoscopic gastrostomy. A 5 mm laparoscope was used for visualization. A functional lumen imagine probe was used to measure the cross-sectional area (CSA) and diameter of the pylorus before, after, and at 1 week after intervention. Pyloroplasty was performed using a 5 mm articulating laparoscopic stapler. Gastrotomies were closed by endoscopic clips, endoscopic suture, or combination. After 6–8 days, a second evaluation was performed. At the end of the protocol, all animals were euthanized.

Results Six pyloroplasties were performed. In all cases, this technique was effective in achieving significant pyloric dilatation. The median pre-pyloroplasty pyloric diameter (D) and cross-sectional area (CSA) were 8 mm (4.9–11.6 mm) and 58.6 mm^2 (19–107 mm^2), respectively. After the procedure, these values increased to 13.41 mm (9.8–17.6 mm) and 147.7 mm^2 (76–244 mm^2), respectively ($p = 0.0152$). No important intraoperative events were observed. Postoperatively, all animals did well, with adequate oral intake and no relevant complications. At follow-up endoscopy, all incisions were healed and the pylorus widely patent.

Conclusions Hybrid endoluminal stapled pyloroplasty is a feasible, safe, and effective alternative method for the treatment of gastric outlet obstruction syndrome.

Keywords Gastric emptying · Gastroparesis · Endoscopy · Pyloroplasty · Hybrid surgery · Laparo-endoscopic collaborative surgery

Functional and motility disorders of the stomach are among the most common conditions encountered in gastrointestinal clinical practice [1]. Patients with these disorders can present with upper gastrointestinal symptoms such as postprandial fullness, early satiety, epigastric pain, upper abdominal bloating, belching, nausea, and vomiting. Since routine diagnostic work-up usually fails to identify the origin

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of symptoms, diagnosis is often made late and after many expensive studies [2].

The treatment of these disorders is also controversial. Pharmacological therapies are limited and generally show modest and delayed effects, when the physical condition and nutritional status of patients are already compromised [3]. The lack of medical alternatives that can offer an effective and early resolution to this condition has motivated the search for other therapeutic options that can overcome the current limitations.

Historically, surgical treatment has been considered the last resource and is reserved for patients with chronic and severe conditions [4]. However, the role of surgery in the treatment of this pathology has been re-evaluated and the focus of much research recently [5–7]. Even then, in most cases, remain difficult to weigh the potential benefits against the risks involved in performing surgery in this type of patient.

Peroral pyloromyotomy (POP) has emerged as a less invasive alternative that could eliminate the need for general anesthesia and allow faster oral intake [8]. Nevertheless, there are some important technical contrains that make this procedure highly skill-dependent [9].

Therefore, for functional and motor disorders of the stomach (i.e., gastroparesis), surgery could put the patient at increased risk but endoscopic procedures may not be completely feasible due to their technical limitations. For this reason, here, we propose a hybrid laparo-endoscopic collaborative approach using a novel gastric access device to allow standard laparoscopic tools to be used for pyloroplasty as an alternative treatment option for this condition.

Materials and methods

Animals

The present preclinical prospective survival study (No. 38.2015.01.069) was approved by our local ethics committee on animal experimentation. All animals used in the laboratory were managed according to French laws for animal use and care and according to the directives of the European Community Council (2010/63/EU).

Six female pigs (*Sus scrofa domesticus*, ssp. large white, mean weight 33 kg) were included in the study. Animals were allowed to eat and drink water up to 1 h prior to surgery. Cefalexin (300 mg) was administered as prophylaxis during induction. Ketamine (7 mL) and Azaperone (3 mL) were administered intramuscularly 1 h before the procedure as premedication. Induction of anesthesia was achieved using intravenous propofol combined with pancuronium (2 mL) and then maintained with 2% isoflurane after endotracheal intubation.

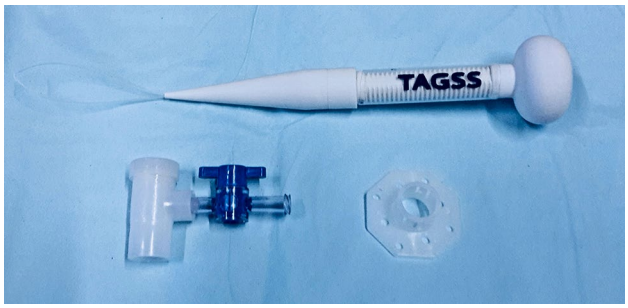

Fig. 1 Trans-abdominal gastric surgical system (TAGSS®) (Endo-TAGSS LLC, Leakwood KS, USA)

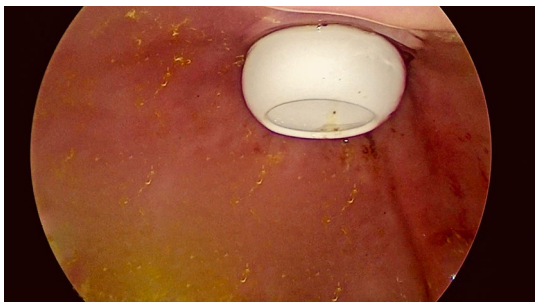

Fig. 2 Placement of the TAGSS® ports inside the gastric cavity

After the procedure, the animals were housed in individual cages and oral intake was started 2 h later. The clinical status was checked twice a day by an animal care technician.

Procedures

Upper endoscopy and TAGSS® port placement

Animals were placed in a supine position under general anesthesia and mechanical ventilation. An upper endoscopy was performed using a high-definition forward-view gastroscope (Olympus Medical Systems, Tokyo, Japan). The stomach was washed as needed and carefully surveyed. Under endoscopic control, 2 or 3, 5 mm intragastric ports (Endo-TAGSS, Leakwood KS, USA) were inserted using a similar technique to a percutaneous endoscopic gastrostomy, as described in a previous report [10] (Fig. 1). After port placement, a laparoscopic insufflator and laparoscopic instruments were used to assist with the rest of the procedure (Fig. 2).

EndoFLIP® protocol

At the end of the TAGSS® placement, a functional lumen imagine probe (EndoFLIP®, Crospon, Inc., Galway, Ireland) was placed across the pylorus through one of the ports

(Fig. 3). The air insufflated during endoscopy was removed and the intrabag pressure was zeroed within the stomach; therefore, subsequent pressure measurements were relative to the baseline gastric pressure. Diameter and cross-sectional area (CSA) measurements were made with the bag filled to 30 mL. EndoFLIP® measurements were monitored in real-time to ensure proper bag placement by using direct visualization through both the endoscope and laparoscope. If the bag had migrated, it was repositioned and the measurement was repeated. These values were compared with the values obtained by repeating the EndoFLIP® protocol after pyloroplasty (Fig. 4).

Endoluminal pyloroplasty

Under laparoscopic frontal vision, a traction suture was applied at the middle of the posterior pyloric ring of the gastric conduit. Through one of the TAGSS® ports, a 5 mm cartridge-based, minimally invasive stapling system (Dextera® MicroCutter 5/80 Stapler, Dextera Surgical Inc. Redwood City, CA, USA) was introduced to linearly section the inner posterolateral portion of the pylorus (Fig. 5). Any

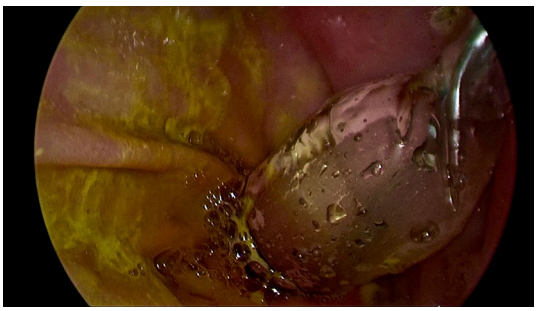

Fig. 3 Endolumenal functional lumen imaging probe probe (EndoFLIP®, Crospon, Inc., Galway, Ireland) placed inside the pylorus

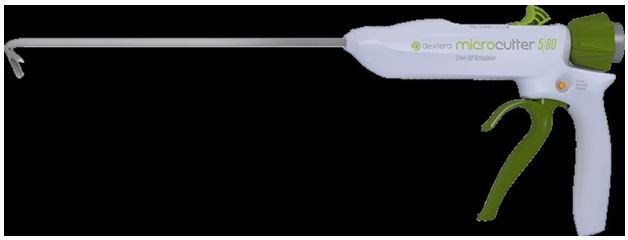

Fig. 5 Dextera® MicroCutter 5/80 Stapler (Dextera Surgical Inc. Redwood City, CA, USA)

significant bleeding at the stapling line was controlled by 3–0 lactomer glycolide/lactide copolymer sutures (Polysorb™, Covidien, Mansfield, MA, USA) tied intracorporally. After verifying hemostatic closure of the stapling line, a new measurement of intraluminal dimension was made to determinate its change following the procedure (Fig. 6).

Gastric wall closure

After the pyloroplasty was completed, three different methods were used to close the access site intragastrically: (1) endoscopic clips: over-the-scope clips (OTSC® Ovesco Endoscopy GmbH, Tuebingen, Germany) or Padlock Clip™ (Aponos Medical, Kingston, NH, United States). (2) endoscopic suturing system (OverStitch™—Apollo Endosurgery, Austin, Texas), and (3) intragastric suture with laparoscopic instruments. Each was evaluated with respect to their feasibility, complexity, quality of healing, and performance time. Abdominal wall sites were closed in layers and the procedure time was recorded.

Between POD 6–8, pigs underwent gastroscopy, EndoFLIP® tests, and explorative laparotomy to assess the diameter and CSA of the pylorus, quality of pylorus healing, quality of gastric wall cicatrization, adhesions and/or

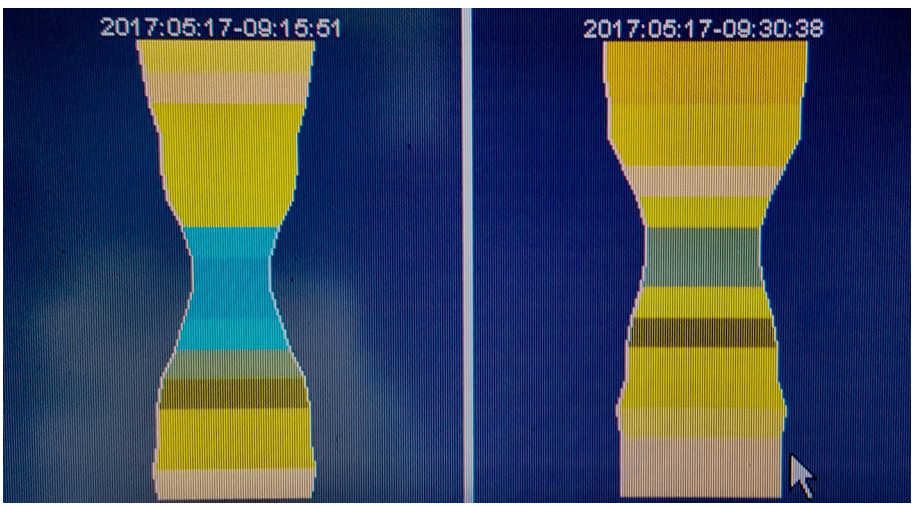

Fig. 4 Comparison between EndoFLIP® image before and after hybrid endoluminal stapled pyloroplasty

Fig. 6 Hybrid endoluminal stapled pyloroplasty

Fig. 7 Comparison of closing time between exclusive OTS clips and laparoscopic or endoscopic intraluminal suture +/− OTS clips

intra-abdominal collections, and quality of healing of the abdominal wall. At the end of the experimental protocol, animals were euthanized by intravenous injection of a lethal dose of potassium chloride.

Results

Six endoluminal linear stapled pyloroplasties were performed. In half of the cases, the procedure was carried out with a 3-port TAGSS® approach and in the other half of the cases it was carried out with a 2-port TAGSS approach. The mean operative time was 112 min. The median duration of endoscopy and placement of intragastric portals was 21 min (range 13–44 min), 54 min for EndoFLIP® evaluation and stapling (range 33–78 min), and 40.7 min for gastric access site closing time (range 16–69 min).

The insertion of the TAGSS® ports was feasible and occurred without complications in all cases, except in one case where decoupling of one of the ports was observed. This decoupling required its endoscopic removal, resulting in prolongation of the operative time. After pyloroplasty, one of the cases presented active bleeding in the stapling line that was solved with an endosgastric transfixation suture, without other eventualities.

The median pyloric diameter before pyloroplasty was 8 mm (range 4.9–11.6 mm) and the median postpyloroplasty diameter was 13.41 mm (range 9.8–17.6 mm) ($p = 0.0152$). The prepyloroplasty pyloric CSA was 58.6 mm^2 (19–107 mm^2) and its postpyloroplasty value was 147.7 mm^2 (76–244 mm^2) ($p = 0.0152$).

Gastric access site closure was performed exclusively by OTSC® clips in two cases, combining endoscopic suture + OTSC® in three cases, and intragastric suture with laparoscopic instruments in one case. Adequate closure quality was observed with all alternatives. The time taken to close was the parameter with the most variation (21–61 min). OTSC® closure was invariably the fastest (Fig. 7).

All animals had satisfactory postoperative evaluations, with adequate oral intake and no relevant complications. After 1 week, they were reoperated to verify the healing quality of the gastric wall and pyloroplasty. Likewise, the functional EndoFLIP® values were compared with those obtained previously after the procedure.

Adequate healing of the gastric and duodenal mucosa was observed endoscopically in all cases. The mean pyloric diameter was 13.2 mm and the mean CSA was 141.3 mm^2, indicating that the values obtained after pyloroplasty were maintained during the late postoperative period (Figs. 8, 9).

During laparotomy evaluation, adequate closure of the serosa was observed in all animals. No findings in the abdominal cavity were seen in four animals. In one, in adhesions of the gastric wall to the abdominal wall were observed, with no evidence of perforation, and in another, an inflammatory plastron was observed around the pylorus

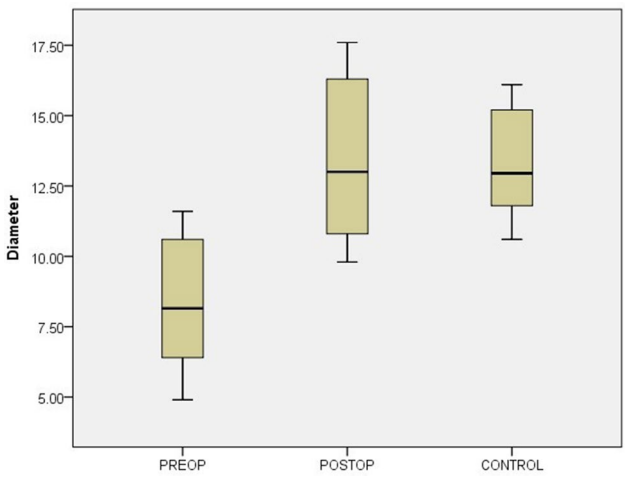

Fig. 8 Pyloric diameter (mm) before and after hybrid endoluminal stapled pyloroplasty

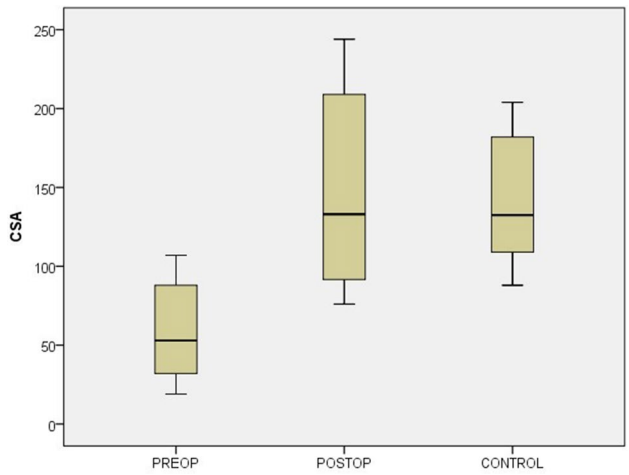

Fig. 9 Cross-sectional area (mm^2) before and after hybrid endoluminal stapled pyloroplasty

with a subserous collection on the pyloric wall but with no evidence of perforation.

Healing of the abdominal wall was adequate, with two localized subcutaneous abscesses without clinical repercussion.

Discussion

We describe here an alternative method for performing pyloroplasty through a hybrid laparoscopic–endoscopic approach. We found that the combined endoscopic–laparoscopic approach of the gastric cavity had three major strengths: it enabled intraluminal pyloroplasty to be carried out, it facilitated the use of laparoscopic instruments with which the surgeon is used to working, and it allowed the utilization of instruments that cannot be used during exclusively endoscopic procedures (i.e., minimally invasive stapling systems), thereby enabling fast and safe pyloric sectioning.

Surgical disruption of the pylorus as treatment for functional gastric outlet obstruction is a concept derived from the treatment of infants with pyloric stenosis [11]. However, so far, both exclusively laparoscopic and exclusively endoscopic approaches have had several limitations for the treatment of patients with gastroparesis.

Pyloroplasty is considered superior to other surgical alternatives (e.g., total or subtotal gastrectomy and gastrojejunostomy) because it is more physiological and maintains gastroduodenal continuity [12]. Gastrectomy has not shown favorable results in patients with an intact gastroparetic stomach and, therefore, it is mostly recommended only for patients presenting with gastroparesis after gastric surgery [13]. Laparoscopic pyloroplasty produces early improvement of symptoms by as much as 90–100%, improves gastric emptying by 85–96%, and normalizes radiological and scintigraphic studies in 54–77% of all patients evaluated [14, 15]. Based on these results, some authors have proposed that pyloroplasty should be the primary treatment of gastroparesis [9]. However, in patients with severe deterioration of the general condition or with co-morbidities, laparoscopic pyloroplasty is rather invasive, and carries a high risk of complications [16].

On the other hand, POP has also shown good efficacy in patients fitting this profile. In several very small series with limited follow-up, improvement or disappearance of symptoms has been reported in 92% of patients [17]. However, there are some important limitations to consider in this setting: it is difficult to control the stability of the endoscope in the distal stomach, there are no precise anatomical landmarks between the muscular layers of antrum and pylorus, and the duodenum has very thin and fragile muscular and mucosal layers [18]. Because of these, POP is considered to be technically demanding, and is often not widely available.

In this context, a hybrid approach combining laparoscopic and endoscopic strategies may represent an acceptable therapeutic alternative. Such an operation could be a surgical procedure whose invasive steps are treated with endoscopic techniques or an endoscopic procedure whose technical problems are overcome or reduced by one or more surgical steps [19].

Recent advances in surgical instrumentation and endoscopic technology have allowed operators to accomplish difficult tasks more accurately. The development of new operative tools and the invention of new operative techniques offer many more options for the treatment of difficult pathologies. Intraluminal treatment options allow endoscopists to perform interventions that were previously only possible through surgery. At the same time, with the evolution of laparoscopic instruments, surgeons can now offer minimally invasive procedures that favor a more functional outcome and faster patient recovery compared to more aggressive procedures [20]. Currently, both techniques—endoscopy and laparoscopy—can be considered complementary and could be used in combination during specific procedures.

Our findings show that the boundaries between endoscopy and surgery are becoming increasingly blurred. In certain circumstances, this merging favors the combination of resources and tools to perform faster, less invasive, and more accurate procedures.

During our research, we presented as a limitation the lack of a standardized method of gastrostomy closure. Although the methods used were satisfactory, the small sample size and the short observation period do not allow for long-term conclusions. It is, therefore, advisable to conduct a prospective evaluation with a more extensive sampling.

Conclusions

Hybrid pyloroplasty is a feasible alternative for the treatment of gastric outlet obstruction syndrome. This approach retains the advantages of endoscopic and laparoscopic instruments while being a less invasive procedure than laparoscopic pyloroplasty. The procedure may be performed in a reasonable time and learned by surgeons and endoscopists with a short learning curve.

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Compliance with ethical standards

Disclosures Drs. Cristians Gonzalez, Jung-Myun Kwak, Federico Davrieux, Ryohei Watanabe, Jacques Marescaux and Lee Swanstrom, have no conflicts of interest or financial ties to disclose.

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