NEW METHODS

Novel intragastric trocar placed by PEG technique permits endolumenal use of rigid instruments to simplify complex endoscopic procedures

Andrew C. Storm, MD, Hiroyuki Aihara, MD, Christopher C. Thompson, MD, MHES

Boston, Massachusetts, USA

Background and Aims: The lack of triangulation has restricted the growth of flexible endoscopic surgical techniques. In addition, endoscope channel size limits the type of tools that can be used. A novel percutaneous intragastric trocar (PIT) has been developed to address these issues. The aim of this study was to evaluate the procedural characteristics of PIT placement and removal, as well as its therapeutic applications.

Methods: We placed 10 PIT devices in 8 Yorkshire pigs. We performed therapeutic procedures in 5 animals, including 3 endoscopic submucosal dissections (ESD), 2 gastroesophageal junction stapling procedures, and 2 full-thickness resections (FTR). Access site closure was standardized and performed in each animal, and leak testing was then completed. Immediately after this, necropsy was performed to determine whether acute adverse events had occurred. The primary endpoint was technical success, with secondary endpoints of successful access site closure and therapeutic procedure time.

Results: Ten devices in 8 pigs were placed successfully (100%) into the stomach without adverse events. ESD was completed in 3 cases with a mean time of 13.5 minutes. Stapling at the gastroesophageal junction and FTR were each completed in 2 cases. Full-thickness suture closure was determined to be complete and successful on leak test in all 10 closure attempts. Necropsy revealed no acute adverse events in all cases.

Conclusions: The PIT device, deployed using the standard procedural steps of percutaneous endoscopic gastrostomy tube placement, is safe and effective for use in the porcine model. PIT allows use of rigid instruments not previously available to the flexible endoscopist, including laparoscopic staplers, and potentially shortens procedure times for complex endoscopic techniques by allowing adjustable tissue traction.

Limitations of transoral endoscopic therapy include lack of triangulation for tissue exposure, dissection, and instrumentation, as well as the relatively small channel size endoscopes. Percutaneous endoscopic gastrostomy (PEG) placement is well understood, mastered, and performed by many practicing gastroenterologists. A novel percutaneous intragastric trocar (PIT) has been designed to assist the endoscopist with the aforementioned issues and is placed like a PEG. The device is intended to serve as a trocar for introducing rigid laparoscopic instruments by the endoscopist to aid therapeutic maneuvers. The PIT (Endo-TAGSS LLC, Leawood, Kan) is currently in pre-U.S. Food and Drug Administration animal studies.

Abbreviations: ESD, endoscopic submucosal dissection; FTR, full-thickness resection; GEJ, gastroesophageal junction; PEG, percutaneous endoscopic gastrostomy; PIT, percutaneous intragastric trocar.

DISCLOSURES: *Endo-TAGSS provided the prototype PIT devices free of charge (10 devices) used in this study. ERBE loaned the use of an electrocautery generator for this study. The authors received no financial incentive, including no consulting fees, relating to this study or the devices used in this study, and none of the authors hold any financial stake in ENDO-TAGSS. C.C. Thompson has acted as a consultant for Boston Scientific and has been a consultant and received research support from Apollo Endosurgery and Olympus. H. Aihara has been a consultant for Olympus. A. C. Storm disclosed no financial relationships relevant to this publication.*

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Current affiliations: Department of Medicine, Division of Gastroenterology, Hepatology and Endoscopy, Brigham and Women's Hospital, Boston, Massachusetts, USA.

Reprint requests: Christopher C. Thompson, MD, MHES, Department of Medicine, Division of Gastroenterology, Hepatology and Endoscopy, Brigham and Women's Hospital, 75 Francis St, Boston, MA 02115.

The aim of our study was to use a living porcine model to (1) determine the feasibility and safety of PIT placement and access site closure, (2) study efficacy of rigid tools made available by PIT, and (3) evaluate whether PIT can simplify technically challenging endoscopic procedures.

MATERIALS AND METHODS

This preclinical study focused on determining the procedural technique and therapeutic possibilities of the PIT device.

Percutaneous intragastric trocar

The PIT consists of a trocar with a 6- or 13-mm inner diameter (with 10- or 16-mm outer diameter) with a removable tapered introducer headpiece (Fig. 1). The PIT is placed via the principles of a pull-PEG. The device is stabilized externally with an adjustable locking disc (Fig. 1B). The tapered headpiece is replaced with a self-sealing instrument introducer cap to guide passage of rigid instruments. An internal bumper stabilizes the platform and provides traction to appose the stomach to the anterior abdominal wall.

Animal studies

Eight Yorkshire pigs (35-45 kg) were studied following American Physiological Society guidelines.[1] The animals were sedated using intramuscular tilazole 6 mg/kg, and xylazine 4 mg/kg. The animals were mechanically ventilated under 2% isofluorine. Several procedures, outlined below, were performed, and 1 to 2 PITs were placed in each pig and removed at the end of the procedure to evaluate the closure method. All animals were killed for necropsy after the procedures to ascertain occurrence of any acute adverse events.

PIT placement and procedural characteristics

A standard gastroscope (GIF-H180, Olympus, Tokyo, Japan) was used for PIT placement and to perform the procedures. The PIT was placed following the principles of pull-PEG placement; angiocatheter needle access, wire exchange, and external wire traction. The following therapeutic procedures were performed (Fig. 2):

1. ESD. A simulated 3- to 4-cm lesion was outlined at the greater curvature of the stomach with cautery. A single PIT was placed through the anterior gastric wall of the mid-body of the stomach in an ideal location to assist ESD. The lesion was lifted using saline solution, circumferentially incised, and a 5-mm forceps (EndoGrasp; Tyco Healthcare Group, Norwalk, Conn) was introduced through the PIT for countertraction. ESD was performed by an expert (H.A.) using endoscopic tools (Hybrid knife, ERBE, Marietta, Ga; SB knife, Sumitomo, Tokyo, Japan) and an electrocautery generator (VIO300D; ERBE). Procedure time measured from the initial saline solution lift to complete resection was recorded.
2. Full-thickness resection. Full-thickness resection (FTR) was accomplished with 2 PIT devices (1 each with inner diameter of 6 mm and 13 mm) placed 5 cm apart within the lower gastric body for triangulation. Five-millimeter forceps were used to pull the full-thickness fundic gastric wall through the jaws of the stapler (EndoGIA; Tyco Healthcare Group) placed through the 13-mm PIT. The procedure was visualized endoscopically and the FTR specimen was transorally retrieved for inspection.
3. Gastroesophageal junction stapling. To prove the concept of stapling at the gastroesophageal junction (GEJ), using the 2 PIT devices previously used for FTR, full-thickness stapling and cutting at the GEJ was performed to simulate a GEJ myotomy using the stapler and 5-mm forceps.
4. Access site closure and necropsy. Access site closure after device removal was accomplished with 2 full-thickness crossing sutures in the following fashion: two 14-gauge angiocatheters achieved percutaneous access to the stomach on opposing sides of the PIT using guidance channels in the external locking disc (Fig. 3). A 2-0 silk tie was passed through one catheter and mini-biopsy forceps (Cook. Bloomington, Ind) through the opposite catheter. Using biopsy forceps through the gastroscope, we passed the suture to the mini-biopsy forceps and then externalized it. Catheters were removed over the silk, leaving a full-thickness suture across the access site. This was repeated perpendicularly to create crossing sutures, which were tied externally. A leak test was performed by submersion of the sutured tract followed by maximal gastric insufflation. Necropsy was then performed in all cases.

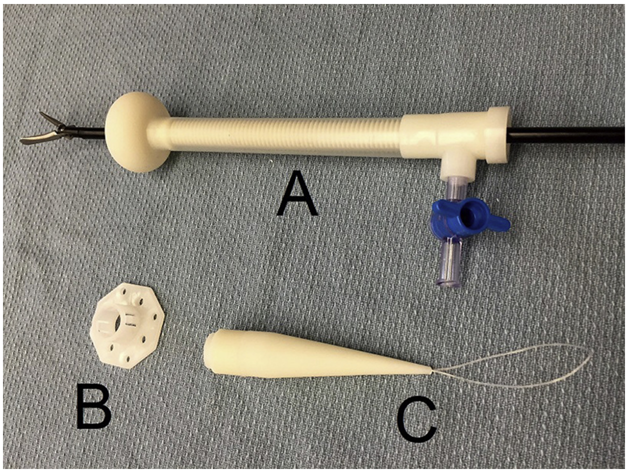

Figure 1. The PIT device. **A**, Trocar fitted with a self-sealing cap and laparoscopic forceps placed through the device. **B**, External bolster to secure the device and guide angiocatheter-directed suture placement. **C**, Removable headpiece with monofilament loop.

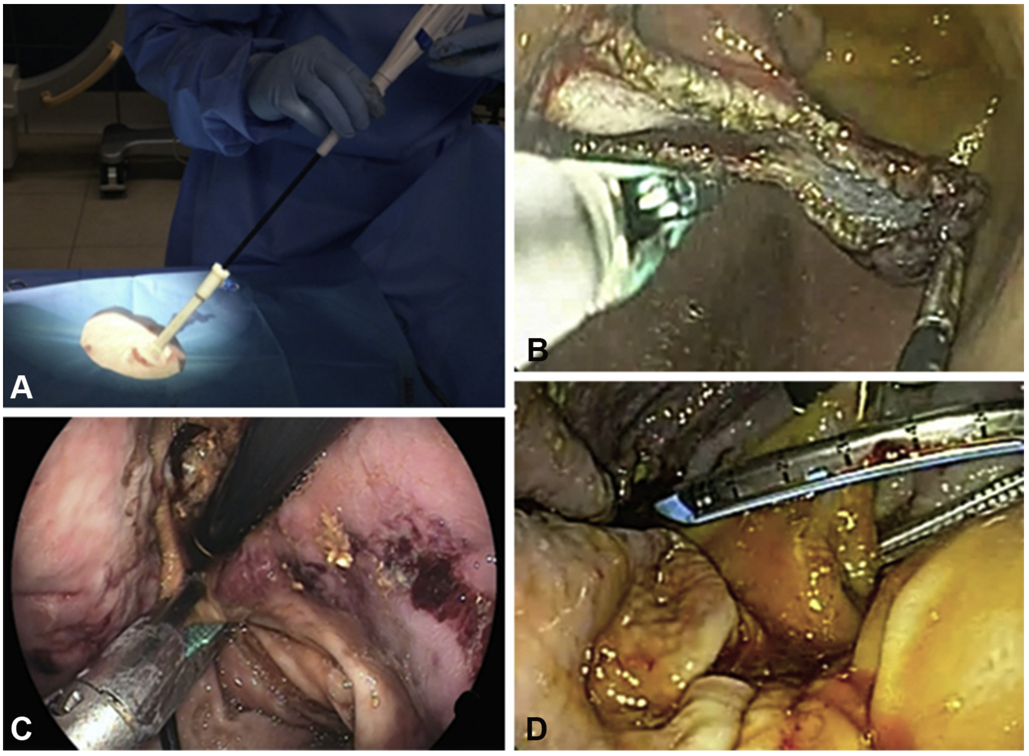

Figure 2. PIT device in vivo (pig study). **A**, Device in place from external view, with laparoscopic grasper in use. **B**, Laparoscopic graspers (right) provide tissue traction for ESD. **C**, Laparoscopic stapling at the gastroesophageal junction (gastroscope seen in retroflexion). **D**, Full-thickness resection accomplished with dual PIT placement, graspers used to provide traction on tissue, which is seen pulled up through laparoscopic stapler jaws for stapling and cutting.

RESULTS

Ten PIT devices were placed successfully in 8 pigs without premature removal. Seven therapeutic procedures were performed in 5 pigs: 3 ESD, 2 FTR, 2 GEJ stapling, and cutting procedures (Table 1). The first 3 pigs in the study underwent PIT placement, rigid instrument insertion testing, PIT removal, tract closure, and leak testing. ESDs were completed in less than 15 minutes (mean, 13.5 minutes) without perforation or bleeding, assisted by a laparoscopic grasper for tissue retraction.

In 2 pigs, dual PIT placement was performed to demonstrate triangulation, and FTR was successfully performed, assisted by a stapler placed via PIT. An FTR specimen measuring approximately 5 cm in the greatest diameter was obtained from the gastric fundus in 2 cases without bleeding. In addition, GEJ stapling was performed successfully in these same animals.

There were no premature deaths or intraprocedural adverse events. Closure of the PIT tract was successful in all cases, confirmed by the leak test and necropsy. There was no perforation, intraprocedural hemodynamic instability, or bleeding.

DISCUSSION

The PIT device was placed successfully in 8 pigs without adverse events. The device permitted fast and safe ESD, FTR, and intragastric stapling. Closure of the access site was successful in all cases.

Of immediate use to the endoscopist, the PIT system significantly reduces the time and workload of traditional ESD.[2] Although countertraction techniques in ESD exist, none include the adjustable traction force and direction afforded by the PIT technique.[3-5]

Limitations include the large defect created by the 13-mm PIT model. Although the access site was closed successfully in all cases, development of smaller staplers will permit similar applications through a smaller PIT model. Another limitation is that PIT placement for assistance in resection of anterior wall lesions would be difficult. Finally, because this was a non-survival study, delayed events including wound infection, bleeding, and healing issues including scar formation were not assessed.

The concept of percutaneous intragastric surgery is not new.[6,7] In percutaneous intragastric surgery, trocars are surgically placed into the stomach in a sterile operating suite.[8] Another device, a multichannel laparoscopic port

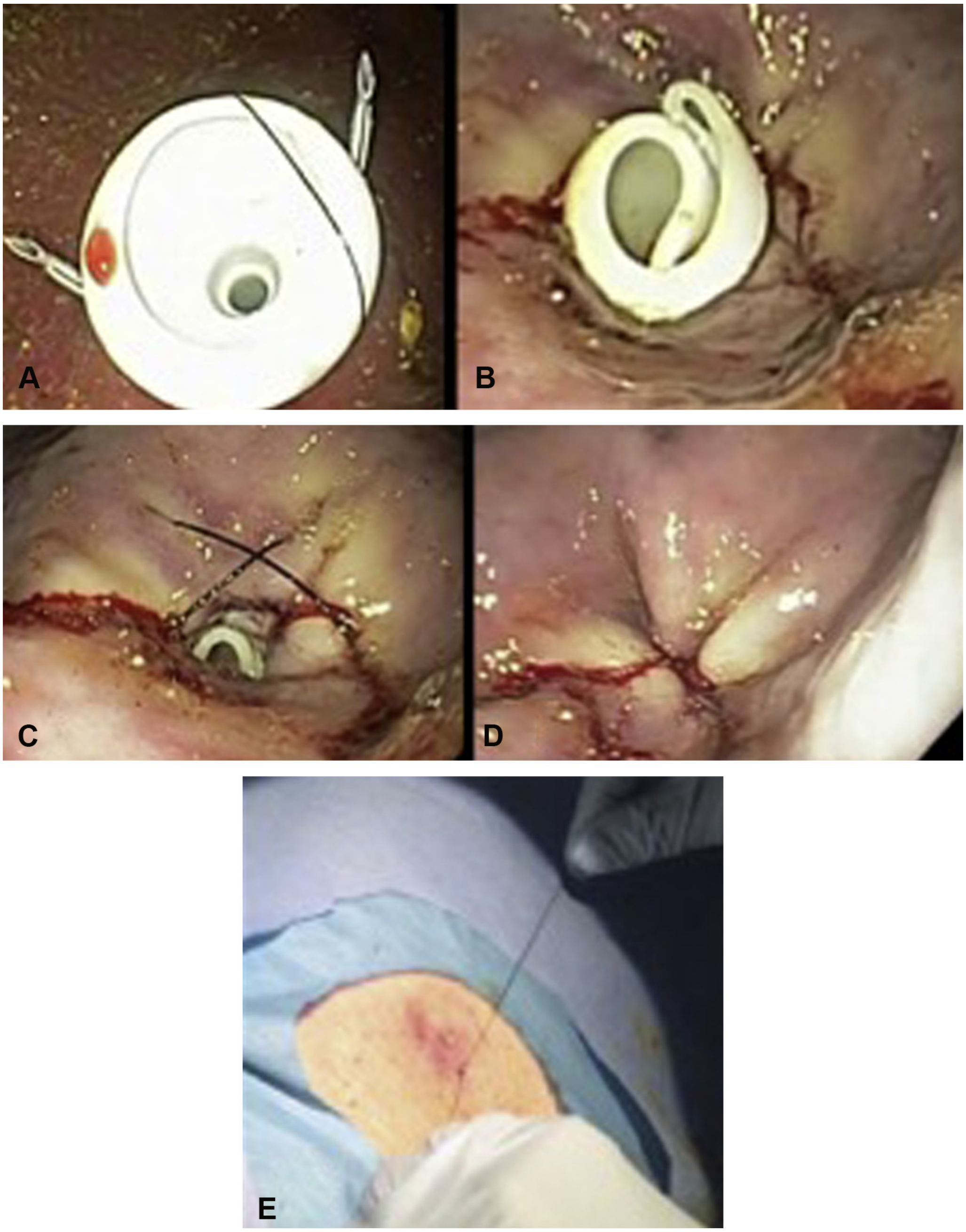

Figure 3. Percutaneous intragastric trocar access site closure technique. **A**, Angiocatheters placed to exchange full-thickness sutures. **B**, External traction applied to percutaneous intragastric trocar, collapsing internal bumper. **C**, Bumper externalized showing crossing sutures. **D**, Sutures pulled tight. **E**, Sutures secured with knots externally.

(X-Gate; Sumitomo, Bakelite Co., Tokyo, Japan), is placed with a larger 25-mm incision. This also requires a sterile operating room and is much larger (outer diameter 70 mm) than the PIT.[9]

Increasingly invasive techniques including ESD and peroral endoscopic myotomy are performed in the endoscopy suite; limitations include procedural complexity and the learning curve.[2,10] Technologies that simplify these techniques may increase adoption of such procedures. In a pig model, PIT helps to dramatically simplify the technically challenging procedure of ESD, and allows for new devices, such as staplers, not currently in the endoscopist's toolbox. It is possible that PIT will allow endoscopists to perform more challenging procedures in routine practice.

The PIT system, placed using the safe and familiar technique of PEG, allows for triangulation and novel intra-lumenal techniques in a dual endoscopic/laparoscopic operating field governed by the endoscopist. PIT holds the promise of simplifying and adding efficiency

TABLE 1. Overview of device placement characteristics and interventions by case

Pig	Number of PIT devices placed	PIT size(s) used (mm)	Time to place PIT(s) (min)	Intervention	Time of therapeutic procedure(s) (min)	Acute adverse event
1	1	6	12	None	n/a	None
2	1	6	10	None	n/a	None
3	1	6	8	None	n/a	None
4	1	6	7	ESD: 3 × 3 cm resection	14.5	None
5	2	13 and 6	16	Gastric FTR and GEJ stapling	45	None
6	2	13 and 6	17	Gastric FTR and GEJ stapling	35	None
7	1	6	5	ESD: 4 × 4 cm resection	12	None
8	1	6	9	ESD: 3 × 3 cm resection	14	None

PIT, Percutaneous intragastric trocar; *n/a*, not applicable; *ESD*, endoscopic submucosal dissection; *FTR*, full-thickness resection; *GEJ*, gastroesophageal junction.

to technically demanding endoscopic procedures and warrants further investigation.

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