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

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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.

(footnotes appear on last page of article)

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.

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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.

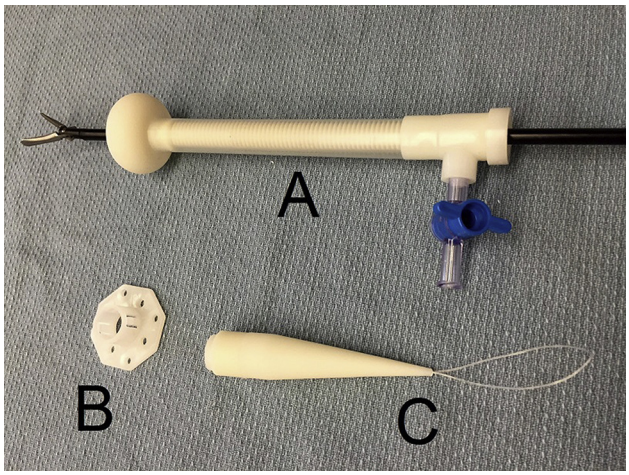

Figure 1. The PIT device. **A**, Trocar fitted with a self-sealing cap and laparoscopic forceps placed through the device. **B**, External bolster to secure the device and guide angiocatheter-directed suture placement. **C**, Removable headpiece with monofilament loop.

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,