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Prospective study on the efficacy of endoscopic through-the-scope tack and suture system for gastric peroral endoscopic myotomy mucosal incision site closure

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ABSTRACT

Background and study aims Mucosal closure after gastric per-oral endoscopic myotomy (G-POEM) can be difficult due to the thick gastric mucosa. We evaluated the use of a novel through-the-scope (TTS) suture system for G-POEM mucosotomy closure.

Patients and methods This was a single-center prospective study on consecutive patients who underwent G-POEM with TTS suture closure between February 2022 and August 2022. Technical success was defined as complete mucosotomy closure with TTS suture alone. On subgroup analysis, we compared performance on TTS suturing between the advanced endoscopist and the advanced endoscopy fellow (AEF) under supervision.

Results Thirty-six consecutive patients (median age 60 years, interquartile range [IQR] 48.5–67], 72 % women) underwent G-POEM with TTS suture of the mucosotomy. Median mucosal incision length was 2 cm (IQR: 2–2.5). Mean mucosal closure and total procedure time were 17.5 ± 10.8 and 48.4 ± 16.8 minutes, respectively. Technical success was achieved in 24 patients (66.7 %) and 100 % of the cases were adequately closed with a combination of TTS suture and clips. When compared to the advanced endoscopist, the AEF required > 1 TTS suture system for complete closure significantly more frequently (66.7 % vs. 8.3 %, $P = 0.009$) and more time for mucosal closure (20.4 ± 12.1 vs. 11.9 ± 4.9 minutes, $P = 0.03$).

Conclusions TTS suturing is effective and safe for G-POEM mucosal incision closure. With experience, technical success is high, and most closures may be achieved using a single TTS suture system alone, which has important cost and time implications. Additional comparative trials with other closure devices are need1ed.

Introduction

Gastric peroral endoscopic myotomy (G-POEM) is a promising pylorus directed therapy for gastroparesis syndrome, a chronic debilitation condition characterized by delayed gastric emptying in the absence of mechanical obstruction [1, 2]. As opposed to esophageal POEM, mucosal incision closure during G-POEM can be technically more challenging due to several factors, including the notoriously thicker gastric mucosa and often looped position of the endoscope in the distal stomach [3]. Although the clinical impact of mucosal closure during G-POEM

has not been fully elucidated, it is standard practice to close the incision as to avoid any potential morbidity.

A novel TTS suturing system (X-Tack Endoscopic HeliX Tacking System, Apollo Endosurgery, Austin, Texas, United States) has been recently introduced as a potential strategy for challenging gastrointestinal defect closure [4,5]. In this study, we aimed to evaluate the use of the TTS suturing system for mucosal incision closure during G-POEM.

Patients and methods

Study design

This was a single-center prospective study of consecutive patients who underwent G-POEM for medically refractory gastroparesis between February and August 2022. Medically refractory gastroparesis was defined as patients with persistent symptoms despite the use of dietary adjustment and medications (i.e. metoclopramide) in the context of delayed gastric emptying (>10 % retention at 4 hours on gastric emptying scintigraphy) [1].

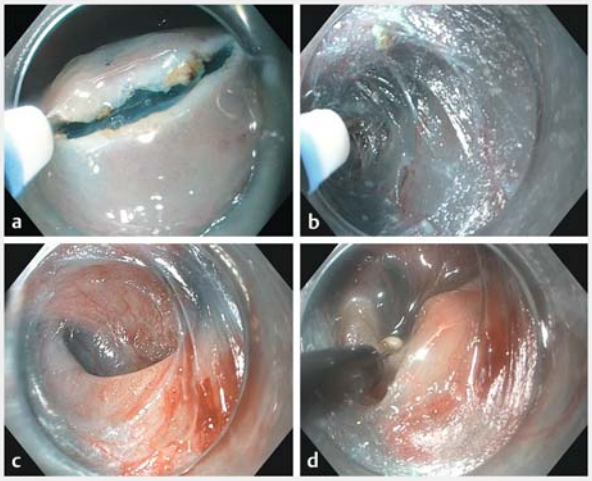
The TTS suturing system was used as the first-line closure approach for all patients during the study period. All procedures were performed by a single advanced endoscopist (D.Y.) or an advanced endoscopy fellow (AEF) (H.M.K) under his direct supervision. Both D.Y. and H.M.K had undergone training on the TTS suture system by the manufacturer. The advanced endoscopist had prior experience with over-the-scope (OTS) and had performed>15 TTS suture clinical cases prior to this study. The AEF had limited prior exposure to both OTS (<5 clinical cases) and TTS suture system (no clinical cases). The study was approved by the institutional review board for human research at AdventHealth, Orlando, Florida, United States (IRB#1798543).

G-POEM procedure

The G-POEM procedure was performed as previously described [6,7]. In brief, all patients were under general anesthesia. A submucosal injection of 6 % hetastarch admixed with methylene blue was performed approximately 5 cm proximal from the pylorus on the greater curvature. Following submucosal lift, a transverse mucosal incision of 1.5 to 2.5 cm was made with a high-pressure needle-free electrosurgical knife (Hybrid I-type knife, ERBE, Marietta, Georgia, United States). Submucosal dissection was then performed with the electrosurgical knife and repeated dyed saline injections until the pyloric ring is identified. Pyloromyotomy was then completed using an insulated tip knife (IT-2 knife, Olympus America, Center Valley, Pennsylvania, United States) (▶ **Fig. 1**).

Mucosal incision closure with the TTS suturing system

Mucosal closure was performed using a gastroscope-length TTS suturing system (▶ **Fig. 2**). A single TTS suture system is composed of four helical coil tacks 5 mm in length that are prestrung together onto a 3–0 polypropylene suture. The first helical tack, which is already preloaded onto the delivery catheter, is inserted through the scope and advanced into the tissue



▶ **Fig. 1** Gastric per-oral endoscopic myotomy (G-POEM). **a** Transverse mucosal incision with needle-type knife. **b** Submucosal tunneling. **c** Endoscopic view of the pyloric ring. **d** Endoscopic pyloromyotomy with insulated tip electrosurgical knife.

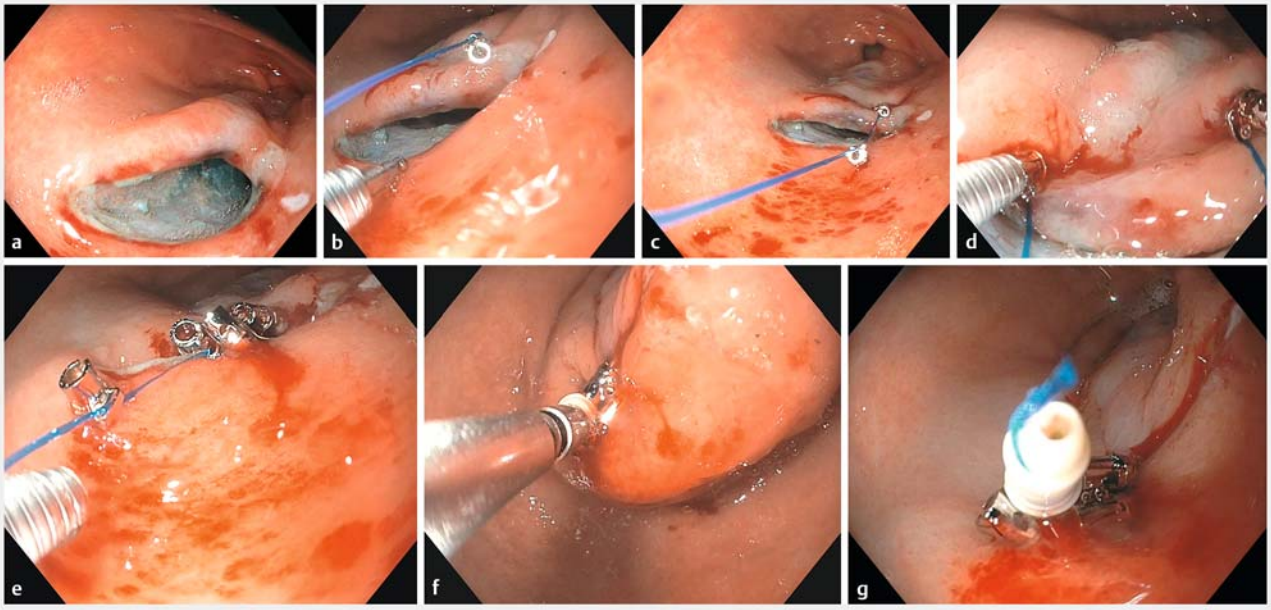
using the driver handle and further secured by clockwise rotation of the handle prior to its release. The first tack is placed approximately 3 to 5 mm superolateral to the transverse mucosal incision. Additional tacks are sequentially loaded and deployed via the delivery catheter in a "Z" pattern, with each tack less than 10 mm from the previously placed tack and the final tack 3 to 5 mm inferolateral to the mucosal incision (▶ **Fig. 2**). Once all tacks are secured, the delivery catheter and protective liner are removed, and the suture cinch loaded. Tension is then applied to the suture and the cinch is deployed at the site of the final tack. Additional TTS suture systems and/or TTS clips were used at the discretion of the endoscopist.

Post-procedure care

All patients were observed in the postoperative recovery area in the endoscopy unit following G-POEM. As per protocol, patients were admitted for routine observation and kept nil per os (NPO) until computed tomography of the abdomen/pelvis with intravenous and oral contrast showed no evidence contrast extravasation to suggest a leak. Following this, patients were transitioned to a liquid diet for 2 to 3 days, soft mechanical diet for 2 to 3 days, and then advance as tolerated. Patients completed a 5-day course of antibiotics and remained on a proton-pump inhibitor once daily for 30 days.

Data collection and measured outcomes

The primary outcome was technical success with the TTS suture system, defined as complete closure of the mucosal incision with the TTS suture system without the need for adjunct closure devices. Secondary outcomes included: (1) number of TTS suture systems utilized for closure; (2) mucosal closure time (from mounting of the TTS suture system device onto the endoscope to completion of mucosal closure); (3) procedure time (from submucosal injection to completion of mucosal inci-



▶ **Fig. 2** Through-the-scope (TTS) suture closure of G-POEM mucosotomy. **a** Transverse mucosal incision defect on the greater curvature. **b** The first tack is placed 5 mm superolateral to the defect. **c** The second tack is placed medial to the first one on the opposite margin. **d** The third tack is then placed superior to the defect, continuing with a running "Z" pattern. **e** The last tack is placed 5 mm inferolateral to the mucosal defect. **f** Tension is applied by pulling the suture and advancing the cinch prior to deployment. **g** Complete defect closure.

sion closure); and (4) adverse events as previously defined [8]. The length of the mucosal incision was estimated using the width of the 12.4-mm distal attachment cap (D-201-11804, Olympus America, Center Valley, Pennsylvania, United States) as reference. G-POEM technical success was defined as successful completion of the procedure as intended.

Statistical analysis

Descriptive statistics for each baseline variable was obtained and expressed as mean, standard deviation (SD), median and interquartile ranges (IQR). Fisher's exact test or Student's *t* test were used for comparison of categorical and continuous variables, respectively. Nominal *P* values are reported and $P < 0.05$ was considered significant. Statistical analyses were performed using SPSS version 28.0 (IBM Corp. Armonk, New York, New York, United States).

Results

A total of 36 patients (median age 60 years, interquartile range [IQR] 48.5–67, 72 % women) underwent G-POEM for the treatment of medically refractory gastroparesis during the study period. G-POEM was performed exclusively by the advanced endoscopist in 13 cases and by the AEF under supervision in the remainder 23 procedures. G-POEM was successfully completed in 100 % of the cases. Procedural characteristics are summarized in ▶ **Table 1**.

Technical success with TTS suture, defined as mucosal incision closure with TTS alone, was achieved in 24 of 36 patients (66.7 %), using one system (n = 20), two systems (n = 3), or three systems (n = 1). TTS clips were utilized in addition to the TTS suture system for complete closure in the remainder 12 (33.3 %) cases. In nine of these cases, an additional one (n = 6) or two (n = 3) TTS clips were placed to close any residual visible gaps following TTS suturing. In three cases, either three (n = 1) or four (n = 2) TTS clips were used for mucosal closure following suture breakage during cinching. The mean procedure and closure times were 48.4 (SD 16.8) and 17.5 (10.8) minutes, respectively.

On subgroup analysis, technical success of mucosal closure with TTS suture alone was achieved by the advanced endoscopist in 92.3 % (12/13) compared to 52.2 % (12/23) by the AEF ($P = 0.03$). Among these cases, the AEF required more than one TTS system for complete closure more frequently than the attending endoscopist (66.7 % vs 8.3 %, $P = 0.009$). The mean closure time was significantly shorter by the advanced endoscopist vs. the AEF (11.9 [SD 4.9] vs 20.4 [SD 12.1], $P = 0.03$) (▶ **Fig. 3**). There was no significant difference in the mean number of additional TTS clips used for complete closure between the advanced endoscopist (mean 1.3 ± 0.6) and the AEF (mean 2.1 ± 1.3) ($P = 0.3$).

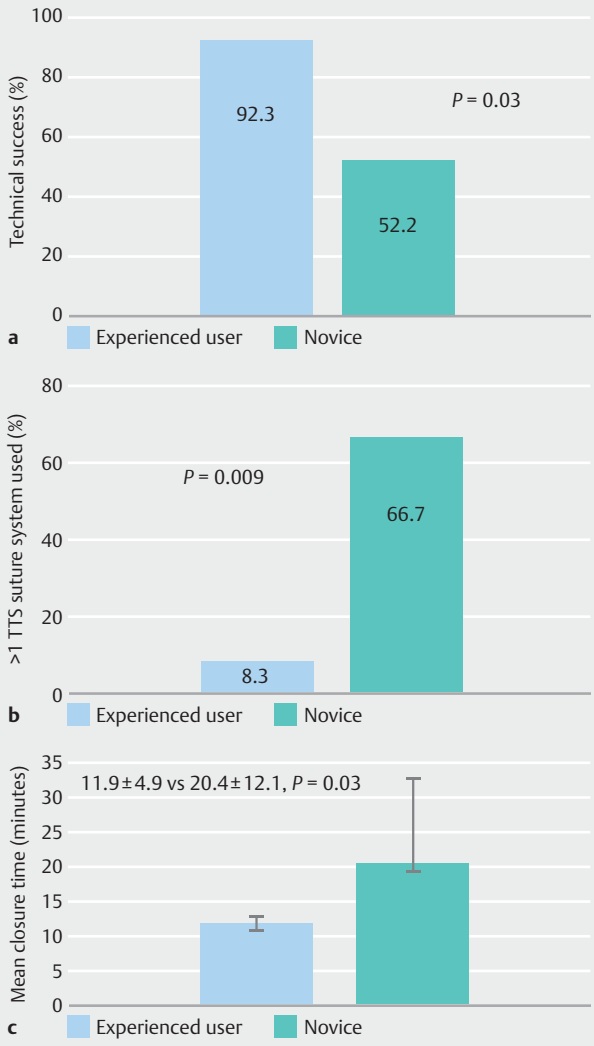
Thirty of 36 patients were admitted post-procedure. Of them, 18 reported abdominal pain (n = 7), nausea (n = 2), or both (n = 9) on postoperative Day 1. All of these patients were adequately managed with medications (analgesics and antiemetics) without requiring additional tests or interventions. Computed tomography of the abdomen/pelvis with intravenous and oral contrast showed no contrast extravasation for all cases. The mean hospital length of stay was 1.7 (SD 1.1) days.

▶ **Table 1** Baseline and procedure characteristics.

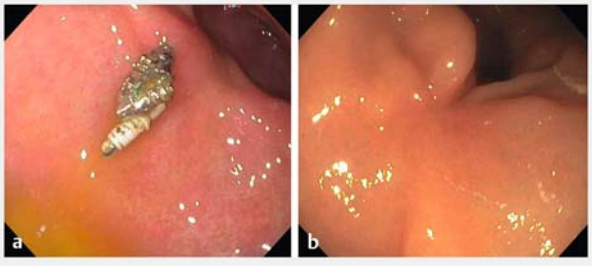
Characteristics	
Age, median (IQR), years	60 (48.5–67)
Female, n (%)	26 (72)
Etiology of gastroparesis, n (%)	
▪ Diabetes mellitus	11 (30.6)
▪ Idiopathic	17 (47.2)
▪ Postsurgical	8 (22.2)
G-POEM, n (%)	
▪ Performed by AEF under supervision of advanced endoscopist	23 (63.9)
▪ Performed by advanced endoscopist	13 (36.1)
Procedure parameters	
▪ Mucosal incision length, median (IQR), cm	2 (2–2.5)
▪ Submucosal tunnel length, median (IQR), cm	5 (5–5)
▪ Pyloromyotomy length, median (IQR), cm	2 (2–2)
Procedure times	
▪ Mucosal incision, mean (SD), minutes	3.6 (1.9)
▪ Submucosal tunnel, mean (SD), minutes	19 (9.6)
▪ Pyloromyotomy, mean (SD), minutes	7.7 (3.9)
▪ Mucosal incision closure, mean (SD), minutes	17.5 (10.8)
▪ Total procedure time, mean (SD), minutes	48.4 (16.8)
Technical success, n (%)	24 (66.7)
▪ With 1 system	20
▪ With 2 systems	3
▪ With 3 systems	1
Mucosal closure with TTS suture system and TTS clips, n (%)	12 (33.3)
▪ With 1 additional clip	6
▪ With 2 additional clips	3
▪ With 3 additional clips	1
▪ With 4 additional clips	2

IQR, interquartile range; G-POEM, gastric peroral endoscopic myotomy; AEF, advanced endoscopy fellow; SD, standard deviation; TTS, through-the-scope.

Twenty-five of 36 patients (69.4%) underwent follow-up endoscopy at a median of 3 months (IQR: 3–4) for post-GPOEM assessment of the pylorus using endoscopic functional luminal impedance planimetry (EndoFLIP EF-322 N, Medtronic, Inc., Shoreview, Minnesota, United States). The TTS suture and tacks were noted to be intact in 16 (64%) of these patients whereas only a scar was seen in the remaining group (▶ **Fig. 4**).



▶ **Fig. 3** Performance comparison between experienced vs novice TTS suture users. **a** Technical success rate. **b** Proportion of cases requiring >1 TTS suture system for complete closure. **c** Mean closure time.



▶ **Fig. 4** Endoscopic view of the mucosal incision site. **a** TTS suture tacks in place. **b** Clean scar at 3-month follow-up.

Discussion

G-POEM is a promising pylorus-directed therapy for medically refractory gastroparesis [1, 2]. Secure closure of the mucosotomy after G-POEM is indispensable in restoring luminal integrity and avoiding major morbidity. However, mucosal incision closure during G-POEM can be technically challenging. The gastric mucosa is thicker than in other parts of the gastrointestinal tract, which increases the difficulty of securely grasping and approximating the incision margins. The closure method for the mucosal incision is often dependent on the orientation of the mucosotomy [3]. TTS clips are generally preferred for a longitudinal mucosotomy, given the familiarity of TTS clips and the easier perpendicular clip alignment to the longitudinal incision orientation [7]. Conversely, a transverse mucosotomy is less amenable to safe closure with TTS clips and is usually apposed with OTS suturing [9]. However, this modality requires additional steps in scope removal and exchange to mount the device [10]. A single center prospective study of 40 patients compared the efficacy of TTS clips (n = 20) and OTS suturing (n = 20) after G-POEM [11]. Successful closure was achieved in 100 % with suturing and 90 % with TTS clips ($P = 0.49$). While this difference was not statistically significant presumably due to the small sample size, the two patients with failed TTS clip closure did require rescue methods for tissue approximation.

TTS suturing is a novel and simple suture application that does not require scope withdrawal or exchange prior to its use. The efficacy and safety of the TTS for challenging gastrointestinal defect closure and stent fixation was recently reported in a retrospective multicenter study [4]. This is the first prospective study evaluating the efficacy of TTS suturing for mucosal closure after G-POEM. Secure mucosal closure with TTS suturing alone was achieved in 67 % and adequate endoscopic closure in 100 % of the cases.

Although the TTS suture system is less complex than its OTS suturing counterpart, there are some practical considerations that should be noted when using this closure device. For one, as it has been previously highlighted in other studies [12], care must be taken when providing tension on the suture as this is prone to breakage if excessive force is applied. Indeed, suture breakage during cinching was noted in 3 out of our 36 (8.3 %) cases. As opposed to OTS suturing in which slight "bending" of the suture cinch catheter during tightening is often an indicator of adequate tension, we recommend releasing suture tension by 1 mm or so prior to cinch deployment as to prevent breakage.

Equally as important to tension application during cinching, appropriate helical tack positioning is crucial for both secure closure and to minimize the use of additional TTS suture systems or adjunct closure devices. In our study, additional TTS suture systems were needed in four cases, three of which were due to placing the helical tacks very close to each other resulting in a considerable residual gap needing additional closure. In one case, suture breakage occurred after the first system leading to the use of two additional tack systems for complete closure. Overall, our study demonstrated that the advanced endoscopist was significantly more likely to achieve adequate closure using only one TTS suture system as compared to the AEF, presumably due to an increased familiarity on how to strategically place the helical tacks sequentially to achieve complete closure. Importantly, the endoscopist should be aware that gaps larger than 2 to 3 cm may require more than one tack system. We recommend against placing the tacks > 5 mm lateral to the incision margins or > 10 mm apart from each other since increasing the space between the tacks can lead to the creation of multiple tissue gaps that can be challenging to close. In addition to tack location, every effort should be placed in aligning and driving the tack perpendicular to the thick gastric mucosa as to reduce the risk of slippage. We recommend at least two clockwise rotations of the driver handle after advancing the helical tack into the tissue as to ensure adequate fixation and to prevent dislodgement after releasing the tack.

Our study should be interpreted in the setting of its strengths and limitations. This is the first study on TTS suture closure for GPOEM in which the data were collected prospectively and specific endpoints defined a priori. Second, we performed a subgroup analysis to evaluate the performance of TTS suturing between endoscopists with different experience levels with the device. In all, when compared to the AEF, technical success with TTS suture alone was higher in the hands of the advanced endoscopist (92 % vs 52 %, $P = 0.003$) and associated with shorter closure time (mean difference of –8.5 minutes). While these results are not necessarily unexpected, it does further emphasize some of the technical hurdles when using this device for the first time. We believe that the inclusion of all our consecutive cases performed by both the advanced endoscopist and the AEF under supervision increases the generalizability of our findings regarding the uptake of this device for G-POEM cases across centers. We also acknowledge the limitations. The overall sample size was relatively small. In the absence of a comparative arm, we were unable to perform direct comparisons with other closure modalities with regards to procedure difficulty, closure time and costs. Furthermore, the relatively small number of cases precluded more detailed comparative analysis (i. e. learning curve) among the operators and this should be a point of emphasis in subsequent studies. We also acknowledge that the performance of the TTS suture was only evaluated for transverse mucosal incisions and thereby it remains unclear whether these results can be generalized to cases in which a longitudinal mucosal incision is performed during GPOEM.

Conclusions

In conclusion, our study suggests that TTS suturing is an effective and safe modality for G-POEM mucosotomy closure. Importantly, we demonstrate that with experience, technical success is high and most closures may be achieved using a single TTS suture system alone, which has important cost and time implications. Additional prospective comparative trials and cost-effective analyses are needed to establish the role of TTS suturing in our armamentarium for G-POEM mucosotomy closure.

Competing interests

D Yang is a consultant for Olympus, Fujifilm, Apollo Endosurgery, Medtronic, and Microtech.
MA Arain is a consultant for Boston Scientific, Olympus, Cook Medical and Medtronic.
MK Hasan is a consultant for Boston Scientific and Olympus. All other authors have nothing to disclose.

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