"Through-stent enterography": first experience with a novel technique intended to improve safety in endosonography-guided gastroenterostomy

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Background and Aims: Endosonography-guided gastroenterostomy (EUS-GE) is a novel technique to manage symptoms of gastric outlet obstruction. Major challenges are the high mobility of intestinal loops and the transient loss of endosonographic visibility during the puncture. This can lead to stent misdeployment, which can be associated with potentially fatal adverse events. By injecting contrast medium through the guidewire channel of the lumen-apposing metal stent application system under fluoroscopic guidance, a positive enterogram can confirm the position of the stent inside the intestinal lumen before its deployment. The aim of this study was to describe this novel technique and to assess its feasibility.

Methods: The data of 39 consecutive patients undergoing EUS-GE with "through-stent-enterography" from July 2020 to March 2022 were retrospectively collected and analyzed. The primary end point was technical success. Secondary end points were adverse events, reinterventions, and clinical success.

Results: Technical success was achieved in all cases (n = 39). In 2 cases, a second puncture was required to place the stent successfully. In 1 case, misdeployment could be avoided after a negative enterogram. In the other case, misdeployment occurred despite a positive enterogram and reintervention was needed. Clinical success was achieved in 92.3% (n = 36). No major adverse events or mortalities were encountered.

Conclusions: "Through-stent enterography" after the puncture to confirm the correct position of the stent in the small bowel is a novel and simple technique that can potentially reduce the risk of misdeployment of the stent. (iGIE 2024;3:247-53.)

Gastric outlet obstruction (GOO) is a common adverse effect of several GI and pancreaticobiliary malignancies and can also be caused by different benign diseases, such as chronic pancreatitis. Symptoms can vary widely, including dysphagia, reflux, nausea, vomiting, early satiety, weight loss, and dehydration, which can lead to severe impairment and a decreased quality of life.[1–3] Surgical gastroenterostomy (GE) and endoscopic enteral stenting are the traditional treatment options for patients with GOO. They both provide high success rates and effective symptom relief, yet they each have several drawbacks that limit their use. Surgery is invasive and carries a higher risk of perioperative adverse events, and enteral stenting has high reintervention rates owing to tumor overgrowth and stent migration.[4–8]

In recent years, clinical evidence has shown that endosonography-guided gastroenterostomy (EUS-GE) can combine the advantages of surgical GE and enteral stenting while potentially overcoming their drawbacks.[5,9–13] The most advanced technique is the EUS-guided direct puncture using a lumen-apposing metal stent (LAMS) with an electrocautery tip.[14] Despite promising results, its widespread clinical adoption is limited by the technical difficulty and associated adverse events with potentially fatal outcomes.[15] Stent misdeployment (SM) with either the proximal or the distal flange in the peritoneum remains the main challenge owing to the high mobility of the small intestine and the distortion of sonographic visibility during the puncture with the electrocautery stent.[5,12,13,16] Several methods have been described to overcome this problem, but most of the techniques demand extra devices or are complicated to master.[17–20]

To improve the safety of EUS-GE without increasing the complexity of the procedure, we have modified the direct puncture technique with an electrocautery LAMS (Hot Axios; Boston Scientific, Boston, Mass, USA) by introducing "through-stent enterography" (TSE). This simple technique is performed by injecting contrast medium through

the guidewire channel of the stent application system, after the small intestine has been punctured. Thereby, the correct position of the stent can be confirmed under fluoroscopic guidance before its deployment. The aim of this case series was to report the first experience with the TSE-assisted EUS-GE technique and to evaluate its feasibility.

METHODS

Study design and population

This was a single-center retrospective study, conducted at a tertiary referral center (Klinikum Rechts der Isar der Technischen Universität München) to report the first experience with the TSE-assisted EUS-GE technique and to assess its feasibility. All consecutive subjects with symptomatic GOO from July 2020 to March 2022 were included. Patients were identified through our endoscopic database, and the technique was confirmed by reviewing the fluoroscopic images and endoscopic reports. Patient data and clinical records were collected from our electronic database (Table 1). STROBE guidelines were used for reporting.

The primary end point was to assess the technical success of the TSE-assisted EUS-GE, which was defined as successful stent deployment in a patient. This was confirmed by a barium follow-through before and after the procedure. Secondary end points were to assess the number of avoided SMs based on TSE and the number of SMs despite TSE. In addition, we assessed the rate of adverse events and need for reinterventions, as well as clinical success, which was defined by the patient's tolerability for oral food intake.

TABLE 1. Characteristics and clinical data of the 39 consecutive patients who underwent TSE-assisted EUS-GE

Patients	39
Sex	
Female	17 (43.6)
Male	22 (56.4)
Age, y	62.4 ± 2.5 (23-90)
Indication for EUS-GE	
Malignant obstruction	
Pancreatic cancer	17 (43.6)
Metastases	7 (17.9)
Papillary carcinoma	1 (2.6)
Cholangiocellular carcinoma	1 (2.6)
Lymphoma	1 (2.6)
Benign causes	
Gastroparesis	4 (10.3)
Peptic pyloric stenosis	3 (7.7)
Other duodenal stenosis (postinflammatory/postoperative/postradiotherapeutic)	3 (7.7)
Afferent loop syndrome	2 (5.1)
Symptoms	
Nausea	33 (84.6)
Vomiting	28 (71.8)
Abdominal pain	16 (41)

Values are n, n (%), or mean ± SD (range).
EUS-GE, Endosonography-guided gastroenterostomy; *TSE*, through-stent enterography.

Equipment

For all interventions, a gastroscope (GIF-HQ190; Olympus Medical Systems Europe, Hamburg, Germany) and a Pentax linear echoendoscope (EG-3870UTK; Pentax, Tokyo, Japan) were used. All gastroenterostomies were established using the direct puncture technique with the Hot AXIOSTM stent from Boston Scientific with a diameter of either 15 mm or 20 mm. The puncture was performed by applying pure cut current with the use of an electrosurgical generator (settings: pure cut mode, 100 W, ICC 200, autocut mode, effect 5; VIO 300D; ERBE Electrosurgery, Tübingen, Germany). A 22-gauge peripheral venous catheter (blue Vasofix safety; B. Braun Melsungen, Melsungen, Germany) was used to perform TSE by injecting contrast medium through the stent.

TSE-assisted EUS-GE technique

All procedures were performed with the patient in prone position under sedation with intravenous propofol and midazolam. All patients had received antibiotic prophylaxis before the procedure.

To create a gastrojejunal anastomosis, first a gastroscope is used to place a 7F nasobiliary catheter into the small bowel distal to the obstruction under fluoroscopic guidance. The gastroscope is then exchanged with the echoendoscope. To keep small-bowel motility to a minimum, 10 to 20 mg butylbromide is administered intravenously before the puncture. The small-bowel lumen is then filled with saline solution and methylene blue via the nasobiliary catheter. The echoendoscope is used to identify the targeted small-bowel loop by locating the intraluminal nasobiliary tube and by observing the fluid turbulence during the injection of water and methylene blue. Additional injection of contrast medium via the nasobiliary tube helps to facilitate identification of the small bowel with the use of fluoroscopy. However, the amount used should be kept to a minimum to have optimum conditions for TSE. Once an eligible loop near the gastric wall is identified, a transgastric direct puncture with the LAMS is performed while applying heat via the electrocautery tip. The LAMS should be inserted for at least 2 cm inside the small-bowel lumen. To confirm the correct position of the stent before deploying the distal flange, TSE is performed. A 22-gauge peripheral venous catheter is used to inject about 10 mL contrast medium through the guidewire channel of the LAMS application system, which takes approximately 15 to 30 seconds (Fig. 1; Video 1, available online

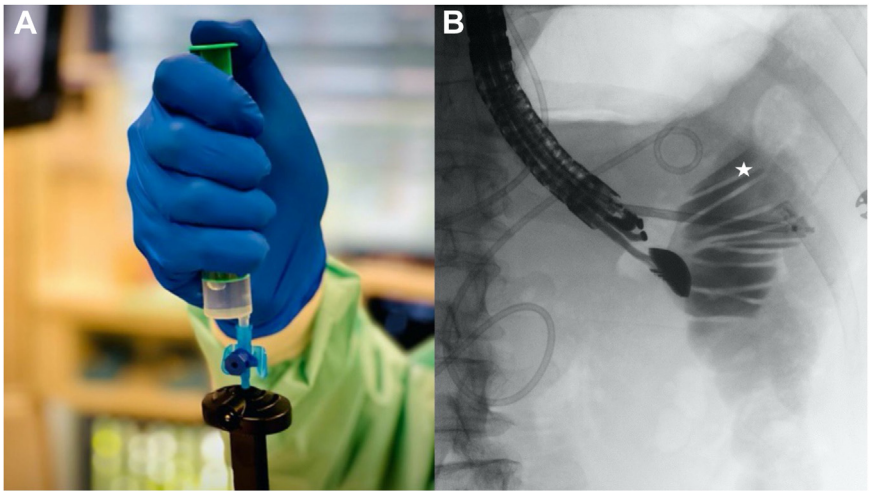

Figure 1. "Through-stent enterography." **A,** Injecting contrast medium through the lumen-apposing metal stent with the use of a common 22-gauge venous catheter. **B,** Live enterogram (*white star*) under fluoroscopy indicating that the distal flange of the stent is positioned correctly in the small-bowel lumen.

at www.igiejournal.org). If the distal flange has been placed correctly, a well defined enterogram is achieved and the stent can be deployed safely (Fig. 1; Video 1). If the enterogram is not successfully achieved with the use of TSE (Fig. 2), the LAMS is withdrawn into the echoendoscope to avoid SM and a new puncture is attempted. After complete deployment of the LAMS, the backflow of methylene blue from the small intestine into the gastric lumen and the ability to observe the small-bowel mucosa through the LAMS confirm the success of the procedure. Intraprocedural dilatation of the central part of the LAMS was not performed in any patient. In this study we used the classification system for SMs that had been introduced recently by Ghandour et al,[16] as presented in Table 2.

Ethics

The study was approved by the local ethics committee on April 26, 2022, under the symbol 2022-175-S-KK. Because of the retrospective design of the study, written consent was waived.

RESULTS

Subjects

A total of 39 consecutive patients were included in this study with symptoms of GOO of different etiologies, as presented in Table 1. In 27 cases (69.2%), the gastroenterostomy was performed because of malignant GOO, with pancreatic cancer (43.6%) and pancreatic or duodenal metastases of other cancers (25.6%) being the most common indications. In 12 cases (30.8%), a gastro-enteric anastomosis was established out of benign indications. Nausea (84.6%), vomiting (71.8%), and abdominal pain (41.0%) have been the most frequent symptoms of gastric outlet obstruction. In all 39 procedures, the TSE technique was applied without adverse events.

Outcomes and troubleshooting

Technical success was achieved in all cases (n = 39). A total of 41 punctures were required to successfully establish a GE in all 39 patients. In 37 cases, a TSE was obtained immediately after the first puncture and the stent was deployed correctly without adverse events. Two cases required a second puncture. Remnants of contrast agent that had been applied to the patients for the upper gastric series a median interval of 4 days (range, 0-128 days) before the examination did not compromise the visibility of the TSE significantly in any of the cases. Neither did the contrast medium added to the saline solution that was administered via the nasobiliary tube before the puncture. However, its use was and should be kept to a minimum.

In 1 case, a patient with metastatic kidney cancer, TSE showed ill defined leakage of contrast medium with the absence of a TSE, indicating that the distal tip of the stent was not inside the small-bowel lumen (Fig. 2). Consequently, the stent was retracted into the echoendoscope, a second puncture was performed, and the stent was deployed correctly after successful TSE. The initial puncture site in the gastric wall was not clipped. The subsequent upper GI series did not show any signs of gastric leakage. During the postprocedural monitoring of the patient, no adverse events were observed and there was no need for reintervention.

In another patient, with locally progressed pancreatic cancer and consecutive GOO, TSE was successful after the puncture of the small intestine. However, during the deployment of the stent, the distal flange dislocated from the small bowel into the peritoneum with the result of a type II SM. To prevent leakage after the puncture, the stent was removed, the puncture site in the stomach was closed

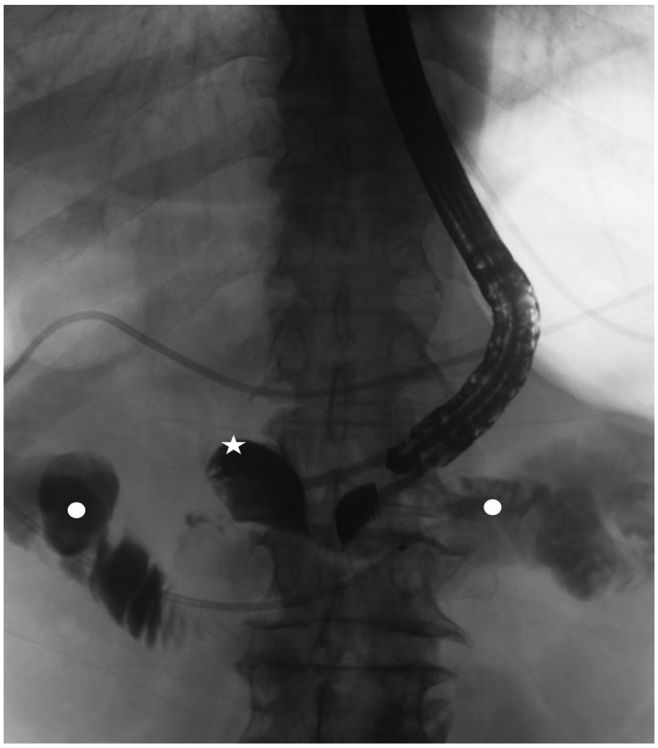

Figure 2. Absence of a through-stent enterogram after puncture. Ill-defined leakage of contrast medium (*white star*) indicates an incorrect position of the distal flange of the stent after the puncture. The stent was therefore retracted and deployed correctly in a second puncture. The contrast medium in the actual small bowel lumen (*white dots*) is a remnant after injection via the nasobiliary tube at the beginning of the examination.

TABLE 2. Classification of stent misdeployments into types I-IV[16]

Type I	Distal flange deployed in the peritoneum without enterotomy and proximal in the stomach
Type II	Distal flange deployed in the peritoneum with enterotomy and proximal in the stomach
Type III	Distal flange deployed in the small bowel and proximal in the peritoneum
Type IV	Distal flange deployed in the colon and proximal in the stomach

via over-the-scope clip, and a fully covered self-expandable metal stent (SEMS) was then deployed into the small intestine. Review of the EUS video footage showed that the stent was not deep enough inside the bowel lumen (<2 cm), so that it dislocated during the deployment. No postinterventional adverse events were observed in this case. One week later, the SEMS was removed and the EUS-GE was created with technical success using the TSE technique.

Clinical success was achieved in 92.3% (n = 36). In the 3 clinically unsuccessful cases, the patients had ongoing symptoms of nausea and vomiting despite technically functioning GEs. All 3 patients had highly progressive and metastatic tumors with peritoneal carcinosis. No adverse events associated with the TSE method were observed. In 1 case, respiratory insufficiency with need for endotracheal intubation occurred during sedation, most likely caused by preexisting fluid overload.

DISCUSSION

EUS-GE is a novel technique to treat gastric outlet obstruction of benign or malignant etiology. While it provides higher clinical success rates and significantly lower rates of reintervention compared with enteral stenting, it can also offer symptom relief for patients who are too debilitated for a surgical GE.[5,9–12,21] In expert hands, the technique has been proven to be safe and effective in many previous studies, stating technical success rates between 86.9% and 95.3% and clinical success rates from 85.5% to 93.4%.[22,23] Despite its impressive clinical results, its use is still limited to highly specialized centers. A limitation to a wider spread clinical adoption is certainly the technical difficulty and the associated risk of potentially severe adverse events.[15] SM is above all the most common cause for severe adverse events and was reported to occur in up to 10% of all interventions.[6,11,12,16]

In a recent retrospective study, Ghandour et al[16] classified stent misdeployment into 4 types, as presented in Table 2. By far the most common types were I (63.1%) and II (30.4%), with the proximal flange placed correctly in the stomach and the distal flange deployed in the peritoneum, either without (type I) or with (type II) enterotomy. This indicates that the correct deployment especially of the distal flange is key to technical success in EUS-GE.

To achieve this, a variety of different techniques have been developed.[19,20] Although most of them are indeed very sophisticated, they often require multiple steps and sometimes even multiple changes of endoscopes, as in the retrograde rendezvous method, making them time consuming and hard to master.[12,13] Others require special equipment, such as double-balloon catheters, that are not universally available.[20,24] The direct puncture technique with an electrocautery LAMS is the most advanced and time-efficient technique because it eliminates the need for initial needle puncture or tract dilatation.[13,18,25,26] However, the major perceived fear with this method is the risk of stent deployment into the peritoneum or colon, because their differentiation from the small bowel can be difficult at times. The method of using a methylene blue infusion into the small bowel and a "finder" needle to aspirate the blue tinge fluid before stent insertion is clever and can help to minimize the risk for misdeployment,[18] but after having confirmed the correct position of the echoendoscope with the finder needle method, the needle has to be exchanged with the stent, which increases the chances of losing the initial position.

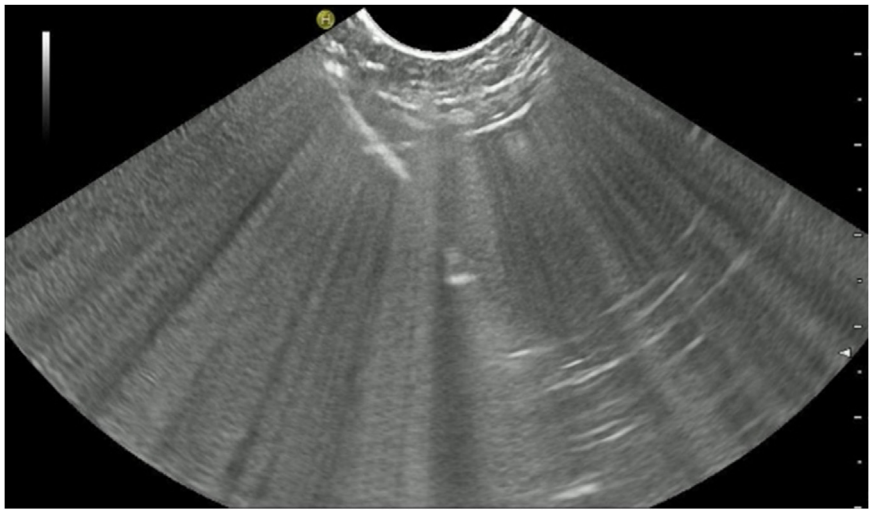

Figure 3. Impaired endosonographic vision during direct puncture using an electrocautery tip stent.

Furthermore, during the puncture with the LAMS with its electrocautery tip, loss of sonographic visibility for a short time is often inevitable owing to the electrical current (Fig. 3; Video 1).[27] Because of the high mobility of the small bowel loops, chances that they evade the stent during the puncture are not negligible.[13,27] In our opinion, it can be a major challenge at times to regain orientation after the puncture, because the peritoneal cavity or the colon may resemble a jejunal loop in EUS. The relatively high incidence of type I and type II SMs, as well as the existence of type IV SMs, indicates that the endosonographic image alone might not be sufficient to ensure the correct positioning of the stent before the distal flange is deployed.

By injecting contrast medium through the wire channel of the stent application system under fluoroscopic guidance, the current position of the tip of the stent can be visualized at the very moment before it is deployed. The TSE prolonged the standard direct puncture technique by about 30 to 60 seconds. We did not observe that the small-bowel loop was pushed away from the echoendoscope because of the injection of contrast medium (Video 1), nor did we lose access to the punctured loop during the very short time of injection in any of our patients. The contrast medium injected via the nasobiliary tube to identify the most suitable jejunal loop for puncture did not limit the use of TSE in any of our cases.

Compared with previous studies,[5,11,12,21,22] our technical success rate (100%) was high. Part of the explanation is certainly that all of our EUS-GEs were performed with the most advanced technology, that is, the electrocautery LAMS, whereas in most of previous studies the GEs were at least partly created with stents without electrocautery tips. Yet also with high-end technology, SMs are a subject of concern.

In our study, an SM could be avoided in a case where TSE was able to show the incorrect stent position inside the peritoneal cavity when it was not clearly visible in EUS (Fig. 2). The stent was therefore retracted and deployed successfully inside the small-bowel lumen after a second puncture. The initial puncturing site in the gastric wall was not clipped, because the stent was not deployed yet and therefore the puncture channel was not dilated. No postinterventional adverse events were observed. Although 1 avoided type I SM is certainly not yet enough to state an improvement of safety profile of the TSE-assisted technique overall compared with the sole direct puncture technique, it nonetheless shows its potential. Furthermore, by applying the TSE technique to visualize the current position of the stent, the deployment of the LAMS can be performed with high confidence, thus potentially avoiding unwarranted aborting of the procedure out of uncertainty.

In 1 case, despite positive TSE, the LAMS was misdeployed with the distal flange of the stent in the peritoneum and the proximal inside the gastric lumen, resulting in a type II SM because the small bowel was punctured. In this case, the TSE technique was beneficial to differentiate between type I and type II SM by confirming the enterotomy and thus it changed the management decision.

The 2 examiners involved in the cases reported in this study were already highly experienced in various different techniques of EUS-GE, including the direct puncture, before the TSE-assisted direct puncture was introduced in our department.

There are several limitations to the study, mainly owing to the retrospective methodology and the small patient cohort of 39 patients. To avoid selection bias, consecutive patients were included in the study. Furthermore, important end points, such as clinical success and postprocedural adverse events, were based on medical records and lack scoring systems, such as the GOO scoring system, to

TABLE 3. Postinterventional outcomes, including puncturing attempts, technical and clinical success, stent misdeployment (SM) types, avoided SMs owing to TSE, adverse events, and reinterventions

Patients	39
Punctures	41
Technical success	39 (100)
Clinical success	36 (92.3)
SMs	
Type I	0
Type II	1 (2.4%)
Type III	0
Type IV	0
SMs avoided owing to TSE	
Type I	1 (2.4)
Type II	
Type III	
Type IV	
Adverse events	
Respiratory insufficiency*	1
Reinterventions	1 (2.4)

Values are n or n (%).
TSE, Through-stent enterography.
*The only adverse event was respiratory insufficiency caused by preexisting fluid overload.

objectify the results. In addition, the single-center design of the study in a specialized tertiary hospital with only 2, and very experienced, examiners may have contributed to the high technical success rate and limits the generalizability of our data (Table 3).

In conclusion, our study findings showed promising results, suggesting that using fluoroscopy and injection of contrast medium via the undeployed stent in combination with endosonography can help to avoid SMs, especially in cases where endosonography alone does not suffice to confirm the correct or incorrect stent position. Thus, potential adverse events and unnecessary costs could be prevented. The technique can be performed without any relevant additional costs or additional risk to the patient. Whether this modified technique truly makes the EUS-guided gastroenterostomy safer remains to be confirmed in bigger, randomized trials.

IRB AND PATIENT CONSENT DECLARATION

The study was approved by the local ethics committee on April 26, 2022, under the symbol 2022-175-S-KK. Because of the retrospective design of the study, written consent was waived.

DISCLOSURE

All authors disclosed no financial relationships.

Abbreviations: EUS-GE, endosonography-guided gastroenterostomy; GE, gastroenterostomy; GOO, gastric outlet obstruction; LAMS, lumen-apposing metal stent; SM, stent misdeployment; TSE, through-stent enterography.

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