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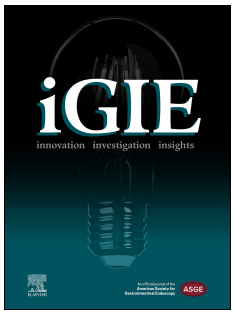

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“Through-Stent-Enterography”: first experience with a novel technique intended to improve safety in endosonographic-guided gastroenterostomy (with video).

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Abstract

Background and Aims

Endosonographic-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 (LAMS) 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” between July 2020 and March 2022 were retrospectively collected and analyzed. Primary endpoint was to assess the technical success. Secondary endpoints were to assess adverse events, rate of reinterventions and clinical success.

Results

Technical success was achieved in all cases (n=39). In two cases a second puncture was required to place the stent successfully. In one case, misdeployment could be avoided after a negative enterogram. In the other case, misdeployment occurred despite a positive enterogram a 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, which can potentially reduce the risk of misdepolyment of the stent.

Key Words

Endosonograpic-guided gastroenterostomy; Hot-Axios stent; lumen apposing metal stent; through-stent-enterography; gastric outlet obstruction; therapeutic endoscopic ultrasound

Background and aims

Gastric outlet obstruction (GOO) is a common complication of several gastrointestinal 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 (SGE) and endoscopic enteral stenting (ES) 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 while enteral stenting has high reintervention rates due to tumor overgrowth and stent migration [4-8].

In the past years clinical evidence has shown that EUS-guided gastroenterostomies (EUS-GE) can combine the advantages of SGE and ES 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 outcome [15]. Stent-misdeployment (SM) with either the proximal or the distal flange in the peritoneum remains the main challenge due 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 those 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^{TM}, Boston Scientific, Massachusetts, USA) by introducing the "through-stent-enterography" (TSE): This simple technique is performed by injecting contrast medium through the guidewire-channel of the stent, respectively its 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 between July 2020 and March 2022 were included. Patients were identified through our endoscopic database and the technique was confirmed by revising the fluoroscopic images and endoscopic reports. Using our electronic database, patient data and clinical records were collected (table 1). STROBE guidelines were used for reporting.

The primary endpoint 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 endpoints were to assess the number of avoided stent-misdeployments based on TSE and the number of stent-misdeployments despite TSE. Additionally, we assessed the rate of adverse events and need for reinterventions as well as the clinical success which was defined by the patients' tolerability for oral food intake.

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 AXIOS^{TM} stent from Boston Scientific with a diameter of either 15mm or 20mm. The puncture was performed by applying pure cut current using an electrosurgical generator (settings: pure cut mode, 100 Watts, ICC 200, autocut mode, effect 5; VIO 300D ERBE Electrosurgery, Tübingen, Germany). A 22-gauge peripheral venous catheter (blue Vasofix® safety, B. Braun Melsungen AG, Melsungen, Germany) was used to perform TSE by injecting contrast medium through the stent.

TSE-assisted EUS-GE technique description

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

In order to create a gastrojejunal anastomosis, first a gastroscope is used to place a 7 Fr 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, 10-20mcg of butylbromide are administered intravenously prior to the puncture. The small bowel lumen is then filled with saline and methylene blue via the nasobiliary catheter. Using the echoendoscope, the targeted small bowel loop is identified 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 the identification of the small bowel using fluoroscopy. However, the amount used should be kept to a minimum to

have optimum conditions for the “through-stent-enterography”. Once an eligible loop nearby 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 2cm inside the small bowel lumen. To confirm the correct position of the stent before deploying the distal flange, “through-stent-enterography” is performed. Therefore, a 22-gauge peripheral venous catheter is used to inject about 10mcl of contrast medium through the guidewire-channel of the LAMS application system which takes approximately 15-30 seconds (figure 1, video). If the distal flange has been placed correctly, a well-defined enterogram is achieved and the stent can be deployed safely (figure 1, video). If the enterogram is not successfully achieved with TSE (figure 2), the LAMS is withdrawn into the echoendoscope to avoid stent-misdeployment 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 dilation of the central part of the LAMS was not performed in any patient. In this study we used the classification system for stent-misdeployments that had been introduced recently by Khashab et. al. as shown in table 2 [16].

Ethics

The study was approved by the local ethics committee on 26th of April 2022 under the symbol 2022-175-S-KK. Due to 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 shown in table 1. In 27 cases (69.2%) the gastroenterostomy was performed because of malignant GOO, whereby pancreatic cancer (43.6%) and pancreatic or duodenal metastases of other cancers (25.6%) were 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.

Outcome 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 “through-stent-enterogram” was achieved 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 (0-128) prior to the examination did not compromise the visibility of the “through-stent-enterogram” significantly in any of the cases. Neither did the contrast medium added to the saline which was administered via the nasobiliary tube prior to the puncture as described in the methods section. However, its use was and should be kept to a minimum.

In one case of a patient (patient 20/39) with metastatic kidney cancer, TSE showed ill-defined leakage of contrast medium with the absence of a “through-stent-enterogram”, indicating that the distal tip of the stent was not inside the small bowel lumen (figure 2). Consequently, the stent was retracted into the echoendoscope, a second puncture

was performed and the stent was deployed correctly after a successful TSE. The initial puncture site in the gastric wall was not clipped. The following upper gastrointestinal series did not show any signs of gastric leakage. During the post-procedural monitoring of the patient no adverse events have been observed and there was no need for reintervention.

In another patient (patient 32/39) 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 stent-misdeployment. To prevent leakage after the puncture, the stent was removed, the puncture site in the stomach was closed via OTSC and a fully covered, self-expanding metal stent (SEMS) was then deployed into the small intestine. Upon revising the video footage of the EUS, it became clear that the stent was not deep enough inside the bowel lumen (<2cm) so that it dislocated during the deployment. No post-interventional adverse events have been 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 3 clinically unsuccessful cases the patients had ongoing symptoms of nausea and vomiting despite of technically functioning gastroenterostomies. All 3 patients had highly progressive and metastatic tumors with peritoneal carcinosis. No adverse events associated to the TSE method have been observed. In one case respiratory insufficiency with need for endotracheal intubation occurred during sedation, most likely caused by preexisting fluid overload.

Discussion

Endosonographic-guided gastroenterostomy 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 when compared to enteral stenting, it can also offer symptom relief for patients that are too debilitated for a surgical gastroenterostomy [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]. Stent-misdeployment 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 Khashab et al. classified stent misdeployment into 4 types as shown in table 2 [16]. By far the most common types were the types 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 the 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 like in the retrograde rendez-vous method, making them time consuming and hard to master [12, 13]. Others require special equipment like 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 as it eliminates the need for initial needle puncture or tract dilation [13, 18, 25, 26]. However, the major perceived fear with this method is the risk of stent deployment into the peritoneum or colon as 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 prior to stent insertion is clever and can help to minimize the risk for misdeployment [18]. Yet, 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.

Furthermore, during the puncture with the LAMS with its electrocautery tip, the loss of sonographic visibility for a short moment is often inevitable due to the electrical current (figure 3, video) [27]. Due to the high mobility of the small bowel, chances they evade the stent during the puncture are not negligible [13, 27]. In the authors’ opinion it can be a major challenge at times to regain orientation after the puncture as the peritoneal cavity or the colon may resemble a jejunal loop in EUS. The relatively high incidence of type I and type II stent-misdeployments and also the existence of type IV misdeployments indicate, that the endosonographic image alone however 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 “through-stent-enterography” prolonged the standard direct puncture technique by about 30-60 seconds. We did neither observe that the small bowel loop was pushed away from the echoendoscope due to the injection of contrast medium (video) 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 in order to identify the most suitable jejunal loop for puncture did not limit the use of TSE in any of our cases.

Compared to previous studies [5, 11, 12, 21, 22] our technical success rate with 100% was high. Part of the explanation is certainly that all of our EUS-GEs have been

performed with the most advanced technology which is the electrocautery LAMS, whereas in most of the studies mentioned before the gastroenterostomies were at least partly created with stents without electrocautery tip. Yet, also with high end technology, stent-misdeployments are a subject of concern.

In our study a stent-misdeployment could be avoided in a case where TSE was able to show the incorrect stent position inside the peritoneal cavity while it was not clearly visible in EUS (figure 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 as the stent was not deployed yet and thus the puncture channel was not dilated. No post-interventional adverse events have been observed. While one avoided type I misdeployment is certainly not yet enough to state an improvement of safety profile of the TSE assisted technique overall compared to the sole direct puncture technique, it shows its potential nonetheless. 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 abortion of the procedure out of uncertainty.

In one 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 misdeployment as the small bowel was punctured. In this case the TSE technique was beneficial to differentiate between type I and type II misdeployment by confirming the enterotomy and thus it changed the management decision.

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

There are several limitations to the study which are mainly due to the retrospective methodology and the small patient collective of 39 patients. To avoid selection bias, consecutive patients were included in the study. Furthermore, important endpoints such as the clinical success and post-procedural adverse events were based on medical records and lack scoring systems like the gastric outlet obstruction scoring system (GOOSS) to objectify the results. Additionally, the single-center design of the study in a specialized tertiary hospital with only two different and very experienced examiners may have contributed to the high technical success rate and it limits the generalizability of our data.

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 misdeployments especially in cases where endosonography alone does not suffice to confirm the correct or incorrect stent position. Therefore, 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.

Disclosures

There are no conflicts of interest to disclose.

Tables

Patients	**39**	
Sex	Female Male	17 (43.6%) 22 (56.4%)
Mean age	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 (post-inflammatory/ post-operative/ post-radiotherapeutic)	3 (7.7%)
	Afferent loop syndrome	2 (5.1%)
Symptoms	Nausea Vomiting Abdominal pain	33 (84.6%) 28 (71.8%) 16 (41%)

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

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

Table 2: Classification of stent misdeployments into types I-IV [16]

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

Table 3: post-interventional outcome including, puncturing attempts, technical and clinical success, stent misdeployment types, avoided stent misdeployments due to TSE, adverse events and reinterventions. The only adverse event was a respiratory insufficiency caused by preexisting fluid overload.

Figure Legends

Figure 1: "Through-stent-enterography" (TSE): Left: Injecting contrast medium through the LAMS using a common 22-gauge venous catheter. Right: Live enterogram (white star) under fluoroscopy indicating the distal flange of the stent is positioned correctly in the small bowel lumen.

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.

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

Table Legends

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Table 3: post-interventional outcome including puncturing attempts, technical and clinical success, stent misdeployment types, avoided stent misdeployments due to TSE, adverse events and reinterventions. The only adverse event was a respiratory insufficiency caused by preexisting fluid overload.

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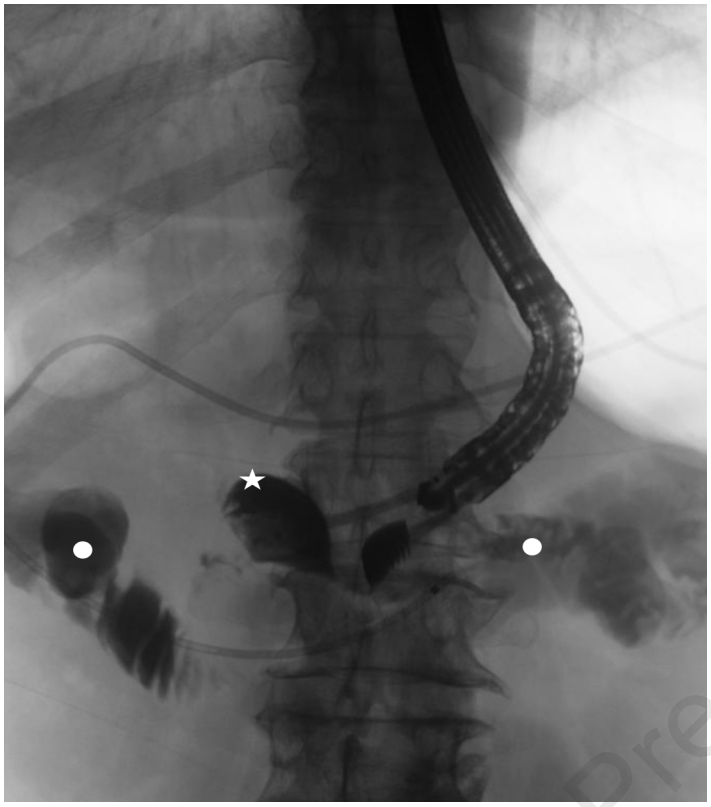

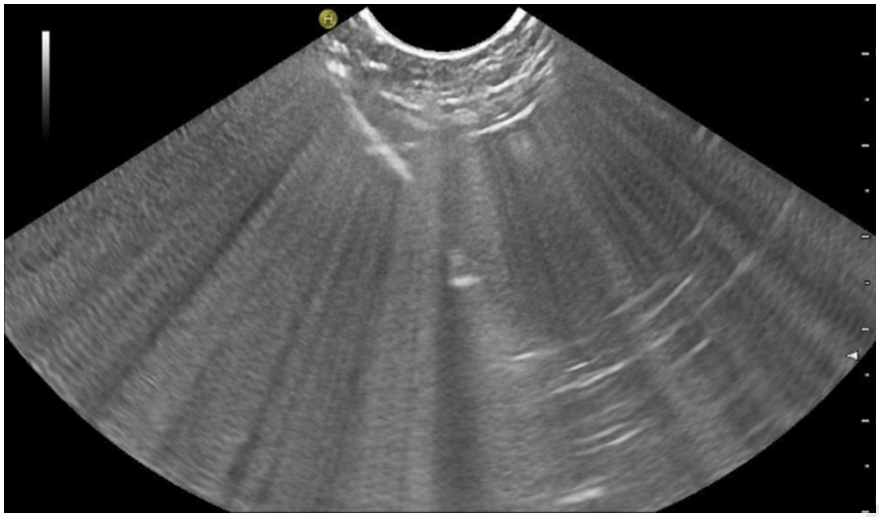

Abbreviations

ES	*enteral stenting*
EUS-GE	*endosonographic-guided gastroenterostomy*
GE	*gastroenterostomy*
GOO	*gastric outlet obstruction*
GOOSS	*gastric outlet obstruction scoring system*
LAMS	*lumen apposing metal stent*
OTSC	*over-the-scope-clip*
SEMS	*self-expanding metal stent*
SGE	*surgical gastroenterostomy*
SM	*stent-misdeployment*
TSE	*through-stent-enterography*