Outcomes of Endoscopic Ultrasound-guided Gastroenterostomy Using Lumen-apposing Metal Stent in the Treatment of Malignant and Benign Gastric Outlet Obstruction: A Case Series

Kannikar Laohavichitra, M.D., Jerasak Wannaprasert, M.D., Thawee Ratanachu-ek, M.D.

Department of Surgery, Rajavithi Hospital, College of Medicine, Rangsit University, Bangkok, Thailand.

ABSTRACT

Objective: To study the outcomes of endoscopic ultrasound-guided gastroenterostomy (EUS-GE) using lumen-apposing metal stent (LAMS) in patients with benign and malignant gastric outlet obstruction (GOO).

Materials and Methods: This single-center study retrospectively reviewed the medical records of benign and malignant GOO patients who underwent EUS-GE between May 2019 and September 2023. We evaluated the technical success, adverse events related to the techniques used, clinical success, and recurrence and reintervention rates.

Results: A total of twelve patients who underwent three different EUS-GE techniques were included in this study. The first method was the direct over-the-guidewire technique, the second was the wireless-freehand method, and the third was modified endoscopic ultrasound-guided double-balloon occluded gastroenterostomy bypass (M-EPASS). All 3 techniques used preloaded oroenteral catheters in combination. Technical success was achieved in 83.3% (10/12) of patients, and there were 16.6% (2/12) failures due to misdeployment. One (8.3%) severe adverse event occurred resulting in peritonitis during the direct over-the-guidewire method. The second failure, which ensued after use of the wireless-freehand technique, achieved successful stent deployment at the second attempt without any complications. Clinical success was 100% (11/11), and mean follow up was 6.2 months. There was one (9.1 %) incidence of recurrence at 12-month follow up.

Conclusion: EUS-GE is effective in the management of GOO, and the wireless-freehand and M-EPASS techniques in combination with oroenteral catheters should be the technique of choice in term of safety and efficacy.

Keywords: EUS-guided gastroenterostomy; lumen-apposing metal stent; gastric outlet obstruction; benign; malignant
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INTRODUCTION

Endoscopic ultrasound-guided gastroenterostomy (EUS-GE) using lumen-apposing metal stent (LAMS) has been used as an alternative treatment for malignant gastric outlet obstruction (GOO). It has been shown by many studies to achieve good clinical outcomes and to result in fewer complications compared to surgical gastrojejunostomy; furthermore, it requires less reintervention compared to endoscopic enteral stenting. Recent publications have investigated the use of this procedure for the treatment of benign GOO and reported similar outcomes. However, the technical success and adverse events reported in many studies still vary, probably because of the use of various unstandardized techniques, the different equipment utilized for the procedure in each center, and the small number of patients in most of the studies. With regard

Corresponding author: Kannikar Laohavichitra
E-mail: niphangnga@yahoo.com
Received 10 January 2024 Revised 7 February 2024 Accepted 15 February 2024
ORCID ID:http://orcid.org/0000-0002-7546-1691
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to benign GOO, data is still limited with respect to long-term placement of the stent and attendant complications, the need for a stent, and the proper timing of its removal. Our study retrospectively reviewed the use of EUS-GE in malignant and benign GOO using electrocautery-enhanced LAMS in order to investigate its outcomes in terms of technical success, adverse events following each technique, clinical success, and recurrence and reintervention rates at long-term follow up.

MATERIALS AND METHODS

This research was approved by the Institutional Review Board (code:66164). The medical records were retrospectively reviewed of individuals who underwent EUS-GE between May 2019 and September 2023, and 12 patients were included in the study. The nature of the GOO was confirmed by the results of esophagogastroduodenoscopy (EGD) and/or abdominal CT scan, with GOO score of 0-1 (Table 1).[1] The inclusion criteria for malignant obstruction were unresectable diseases and benign GOO unfit for surgery. The exclusion criteria were massive ascites.

All patients underwent general anesthesia or deep sedation with propofol, and antibiotic prophylaxis was administered preoperatively. The procedures were performed using a 15x10 mm. or 20x10 mm in diameter LAMS with electrocautery-enhanced delivery system called Hot AXIOSTM Stent (Boston Scientific Corp., Marlborough, MA, United States) which facilitated trans-gastric puncture and stent deployment in a single step.

The technical steps of EUS-GE.

Gastroscopy with gastric irrigation was performed prior to starting EUS-GE with the aim of eliminating gastric content. Preloaded devices included nasobiliary tube; balloon catheter for stone extraction or nasojejunal tube feeding over the 0.025 or 0.035-inch guidewire beyond the tumor; and an oroenteral tube with an endoscopy irrigation pump to continuously infuse the mixed solution of normal saline combined with contrast medium and a small amount of blue dye, such as indigo carmine or methylene blue, during the EUS-GE procedure in order to facilitate the visualization of enteral segment by EUS. One of three EUS-GE techniques was then employed.

Direct EUS-GE over-the-guidewire technique: After continuously infusing the mixed solution into the targeted enteral loop via an oroenteral catheter, as described previously, the target intestinal loop was identified under EUS and fluoroscopy. After this, a transgastric puncture of the loop was performed using a 19 G needle, followed by fluid aspiration using blue dye to confirm that the correct intestinal loop was aspirated, and then a 0.025inch guidewire was placed into the small bowel. The needle was exchanged for the LAMS with an electrocautery-enhanced delivery system which was then advanced from the stomach through the target intestinal loop while applying cautery using the ERBE (ERBE Elektromedizin GmbH; Tübingen, Germany) with electrocautery setting (Effect 5; 100 W Autocut) over the guidewire. The distal flange was deployed under EUS vision and pulled back until it was close to the wall of the targeted enteral loop, and the proximal flange was positioned intra-channel of the echoendoscope before being pushed away from the scope under endoscopic vision.

Wireless-freehand insertion technique: After the target enteral loop was identified using the technique described earlier, the LAMS with electrocautery-enhanced delivery system was advanced and then deployed in the same maneuver without placement of any guidewire.

Modified endoscopic ultrasound-guided double-balloon occluded gastroenterostomy bypass (M-EPASS): After placing a balloon for stone extraction via an oroenteral catheter, an additional stent graft balloon catheter such as ReliantTM stent graft balloon catheter (Medtronic) or the Coda® balloon catheter (Cook Incorporated, Bloomington, IN) was advanced over a 0.025 or 0.035-inch guidewire and positioned at the ligament of Treitz for temporary occlusion of the duodeno-jejunal segment to prevent rapid draining of the infused fluid from affecting the prolonged visualization of the target enteral loop in order to facilitate the EUS-GE procedure (Fig 1 & 2). The LAMS with electrocautery-enhanced delivery system was then deployed using the wireless-freehand technique.

After the LAMS was deployed, the correct position of the stent was confirmed by passing the mixed solution through the stent into the gastric lumen. All patients were allowed a fluid diet the day after the procedure if

TABLE 1. The gastric outlet obstruction scoring system

Level of oral intake	Score
No oral intake	0
Liquids only	1
Soft solids	2
Low-residue or full diet	3

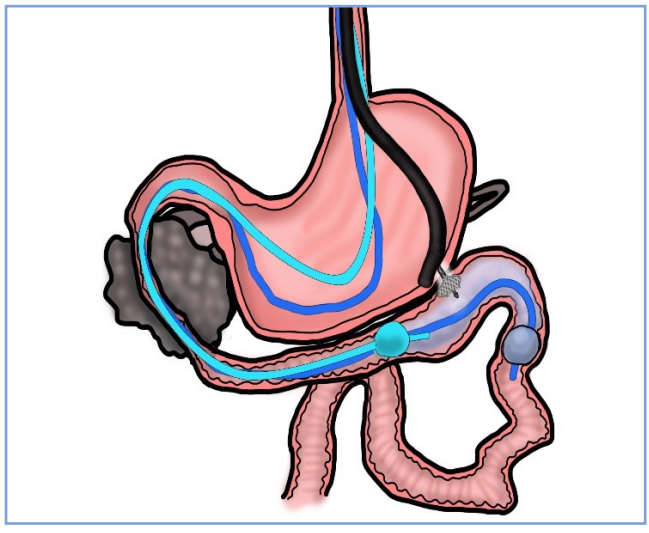

Fig 1. Double balloon catheter technique

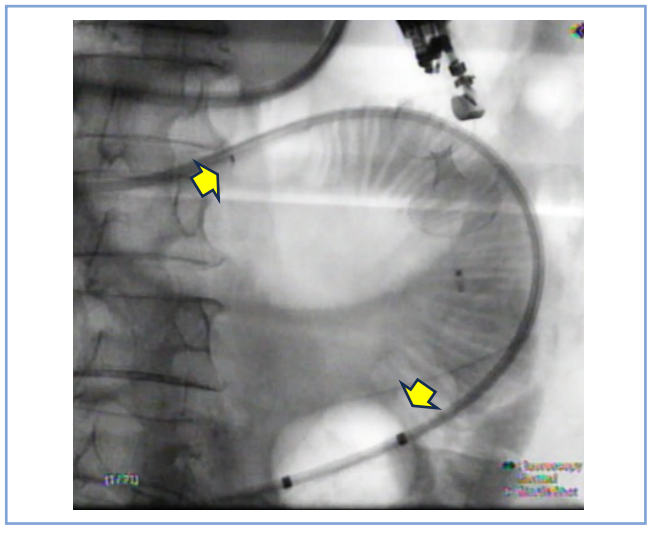

Fig 2. Double balloon catheter technique: the balloon extraction catheter and stent graft balloon catheter (arrows)

Medical illustrator: Tanyaporn Chantarojanasiri, M.D.

no signs of perioperative complications were observed, and they progressed to a full diet on the following day.

Technical success was defined as the correct positioning of the stent deployment. Adverse events were recorded as perforation, bleeding, peritonitis, and cardiopulmonary adverse events from sedation. Clinical success was defined as improvement in GOO score from 0-1 to 2-3. Recurrence was defined as a decrease in the GOO score to 0-1 after earlier improvement.

RESULTS

A total of 12 consecutive patients underwent EUS-GE. Their mean age was 57.8 years (range 30-82 years), and 10 of them were female. Nine had malignant etiologies, 2 had benign conditions, and one had an uncertain diagnosis. The majority of the obstructions were located at the 1st-3rd parts of the duodenum with two cases of pyloric obstruction. Preoperative GOO scores were 0-1, and the duration of the presence of obstruction varied from 0.5-6 months (Table 2).

All patients successfully demonstrated enteral segment after preloading of an oroenteral catheter and continuous infusion of the mixed solution. Ten patients had technical success (Table 3). The first technical failure occurred as a result of misdeployment of the first flange into the peritoneal cavity, after which the patient developed peritonitis immediately, probably due to improper preoperative stomach preparation resulting in severe contamination of the abdominal cavity. She underwent laparotomy in order to decontaminate the infected material and then had surgical gastrojejunostomy. She had a good recovery and was discharged about a week later. The second technical failure (patient No.9) had stent misdeployment at the first attempt under the wireless-free hand technique, but a stent was successfully deployed at the second attempt using the same technique in the same session after endoscopic closure of the gastric defect had been performed with a clip, and no peritonitis developed. In summary, the technical success of the wireless-freehand technique was 75% (3/4), while the M-EPASS approach achieved 100% (6/6), and the overall technical success was 83.3% (10/12). Unfortunately, one success was achieved with an unknown technique because no data were recorded, while the direct over-the-guidewire technique achieved no technical success 0% (0/1).

All eleven patients who successfully received EUS-GE attended final follow up at a mean of 6.2 months (range 0.75-22 months), and they all achieved clinical success and had improved their GOO score to 2-3. The longest stent patency was recorded at 20 months with a 10x20 mm diameter stent. Only one patient (patient number 2) developed recurrent obstructive symptoms from tissue ingrowth, with decreased GOO score down to 0 at the 12-month follow up after also receiving a 10x20 mm diameter stent. After failing to respond to endoscopic balloon dilation, he received an additional LAMS size 10x20 mm (stent in stent) with the use of a therapeutic gastroscope after the tissue ingrowth was burned using forced argon plasma coagulation of 60 watts. The stent patency was observed endoscopically and intraoperative contrast medium from the gastric site was found to have passed through the stent into the jejunum (Fig 3). The patient had good response with GOO score 3 at the last 5-month follow up. The patient with SMA syndrome (patient number 11) had endoscopic stent removal after 5-month follow up and regained weight. Contrast study showed improvement in the duodenal obstruction, and there were no adverse events during stent removal.

TABLE 2. Patient characteristics

Patient	Age	Gender	Co-morbidities	Etiology of GOO	Location of obstruction	Duration of obstruction (months)	Pre-operative GOO score
1	72	Female	CHF	Peptic stricture	Pylorus	2	1
2	30	Male	None	Hilar cholangiocarcinoma	1st-2nd part duodenum	5	0
3	56	Female	None	Carcinoma of the uncinate process of the pancreas	2nd part duodenum	1	0
4	71	Female	DM, HT, DLP	Distal cholangiocarcinoma	1st-2nd part duodenum	0.5	0
5	47	Female	None	Breast cancer with pancreatic metastasis	1st-2nd part duodenum	2	0
6	51	Female	None	Right-sided colon cancer	Pylorus to 2nd part duodenum	0.5	0
7	59	Female	None	Gallbladder cancer	1st-2nd part duodenum	3	0
8	62	Male	None	Carcinoma of the head of pancreas	2nd-3rd part duodenum	3	1
9	71	Female	None	Carcinoma of the head of pancreas	2nd part duodenum	2	0
10	58	Female	None	Carcinoma of the uncinate process of the pancreas	1st-2nd part duodenum	3	1
11	35	Female	DM, neurogenic bladder, acute kidney injury, urinary tract infection	SMA syndrome	2nd -3rd part duodenum	6	1
12	82	Female	HT, CKD, DLP, Compression fracture T11	Duodenal obstruction unidentified cause	2nd part duodenum	1	0

Abbreviations: GOO: gastric outlet obstruction, CHF: congestive heart failure, DM: diabetes mellitus, HT: hypertension, DLP: dyslipidemia, CKD: chronic kidney disease

TABLE 3. Patient and procedural characteristic

Patient	Techniques	Stent size (mm)	Technical success	Adverse events	LOS (day)	Post-op. GOO score	Clinical success	Recurr.	F/U (Mo.)
1	Direct over-the-guidewire	10x15	No	misdeployment & Peritonitis	10	-	-	-	-
2	Wireless-freehand	10x20	Yes	No	8	3	Yes	Yes	22
3	Wireless-freehand	10x20	Yes	No	19	3	Yes	No	20
4	M-EPASS	10x15	Yes	No	12	3	Yes	No	7
5	M-EPASS	10x20	Yes	No	8	2	Yes	No	5
6	Missing data	10x20	Yes	No	18	3	Yes	No	1
7	Wireless-freehand	10x20	Yes	No	13	3	Yes	No	4
8	M-EPASS	10x20	Yes	No	29	3	Yes	No	1
9	Wireless-freehand	10x20	No	misdeployment	11	3	Yes	No	4
10	M-EPASS	10x20	Yes	No	12	3	Yes	No	0.75
11	M-EPASS	10x20	Yes	No	72	2	Yes	No	5
12	M-EPASS	10x20	Yes	No	9	3	Yes	No	2

Abbreviations: LOS: length of hospital stay, Post-op: postoperative, GOO: Gastric outlet obstruction, Recurr: recurrent, F/U: follow up, M-EPASS: Modified endoscopic ultrasound-guided double-balloon occluded gastroenterostomy bypass

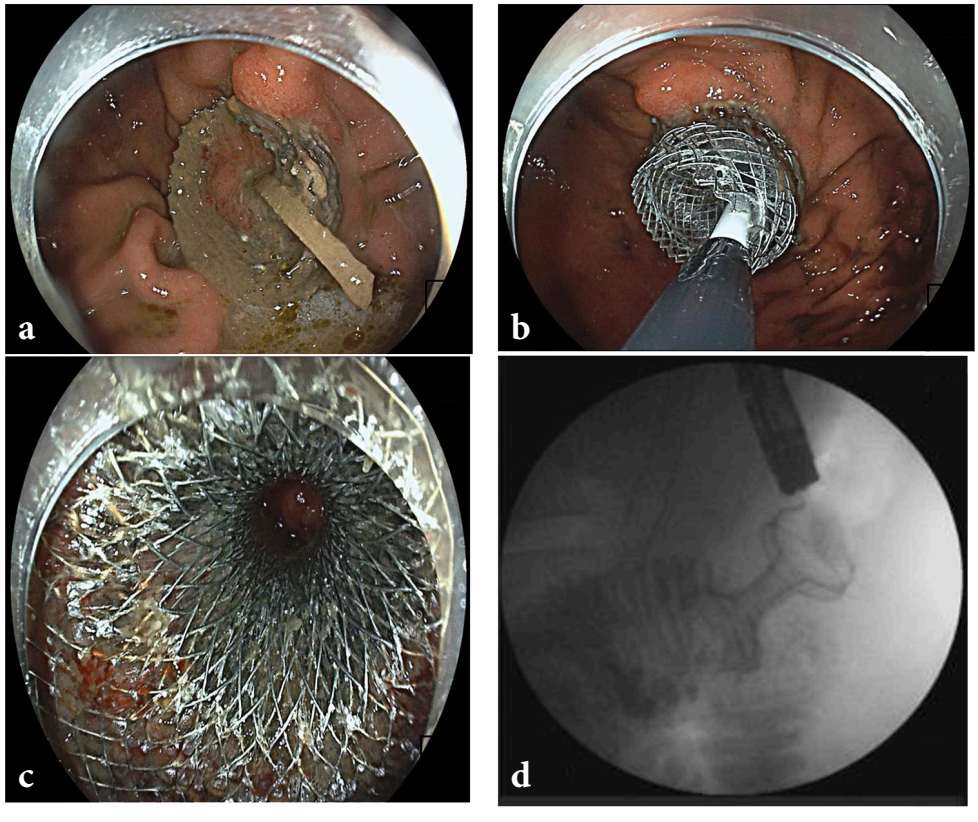

Fig 3. a. Previous stent occlusion, b. Deploying the second stent (stent in stent technique) using a therapeutic gastroscope, c. Endoscopic image showing patency of the stent after deploying the second stent, d. Contrast study showing good patency of the stent.

DISCUSSION

Surgical gastrojejunostomy, both open and laparoscopic, was a modality of treatment for malignant GOO which had long-term patency but entailed high morbidities because of patients being unfit for surgery. Endoscopic duodenal stenting replaced it as a minimally invasive treatment which yielded benefits in terms of rapid relief of obstructive symptoms and shorter hospital stay, but this modality resulted in high rates of recurrent obstruction due to tumor ingrowth with the need for reintervention, and it was therefore proposed for the treatment of choice only in cases with a life expectancy of shorter than 3 months.[2] EUS-GE has recently become the preferred alternative treatment with many multicenter studies, reviews, systematic reviews and meta-analyses demonstrating that it was minimally invasive, had rapid efficacy and longer patency than endoscopic duodenal stenting, and had similar patency but fewer adverse events compared to surgery.[2-5]

Earlier designs of the deployment system of LAMS had no cautery tip, so that the EUS-GE procedure involved multiple steps, such as transmural puncture, placement of a guidewire, and needle tract dilation using a balloon or cautery dilator catheter followed by LAMS with over-the-guidewire deployment. The complexity of the procedure affected technical success as well as adverse events, with earlier publications reporting technical success ranging from 90-92 %[6,7]; however, some patients required salvage procedures, such as bridging, using fully-covered self-expandable metal stents (FCSEMS) or utilizing LAMS via the natural orifice transluminal endoscopic surgery (NOTES) technique, to correct the misplaced stents. One study also reported major adverse events (11.5%) from peritonitis, bleeding and abdominal pain resulting in the need for laparotomy.[7]

Recently, an electrocautery-enhanced LAMS has been developed and is widely used for EUS-GE in order to allow multi-step stent placement in a single device which decreases operative time and appears to increase technical success and minimize adverse events. On W. et al[8] reported EUS-GE using cautery-enhanced LAMS in a multi-center study. Various techniques were used and demonstrated a technical success rate of 92% with just 8% of moderate adverse events resulting from mis-deployment. With this in mind, our center favored the use of the electrocautery-enhanced LAMS to simplify the technical steps, and we achieved similar overall technical success of 83.3% (range 75-100% for each technique) with just one (8.3%) severe adverse event.

One major concern in performing EUS-GE regards the need for improvement of the method used for stent deployment in order to improve technical success and minimize complications. The technique has been developed through various clinical trials and can be classified into 2 types: the direct over-the-guidewire technique and the wireless-freehand insertion method.[9-11]

The direct over-the-guidewire method, with or without pre-procedural saline infusion into the small bowel loop, requires a trans-gastric puncture using a 19-gauge needle to enable preloading of a guidewire into the targeted loop and a one-step exchange to the electrocautery-enhanced LAMS system before the stent is deployed. Physicians in some clinical trials have preferred using a balloon-assisted (targeted) method involving preloading a 15-20 mm. stone-retrieval balloon or balloon dilation catheter over the guidewire into the targeted enteral loop before making a trans-gastric puncture of the inflated balloon to help confirm that the correct enteral loop has been punctured before continuing with the next step of deploying the LAMS. Chen YI et al.[12] reported that these two techniques seem to be comparable in terms of technical success and safety[12] The disadvantage of the over-the-guidewire technique is that it requires more exchanges and carries a risk of mis-deployment as a result of rapid fluid migration from the target loop[10], which can push the stent during the procedure.[11]

The wireless-freehand insertion technique requires some devices to assist with fluid administration into the target intestinal loop to achieve good visualization under EUS. Placing an oroenteral catheter used to be the most popular technique, as it was easy to find suitable catheters. Insertion of a specially designed double-balloon enteric tube (Tokyo Medical University type; Create Medic Co., Ltd, Yokohama, Japan), called an endoscopic ultrasonography-guided double balloon-occluded gastrojejunostomy bypass (EPASS), across the obstruction point was another option. The additional procedure prior to insertion of the LAMS system involved inflating the two balloons with contrast medium and infusing fluid into the small bowel segment between the two balloons to facilitate stent placement. However, these specially designed catheters are not commercially available worldwide. Lately, many studies' authors have advocated the use of the wireless-freehand insertion technique, as they believe it to be superior to the direct over-the-guidewire method in terms of safety and efficacy because of its high technical success of 98-100% and its low incidence of adverse events (2.8-7%) without severe complications[13-15]; on the other hand, others have claimed that the EPASS procedure potentially enhances technical success and safety.[16,17] Basha J, et al.[18] reported that EUS-GE with the EPASS technique was also feasible

in patients presenting with ascites, stating technical success of 91.6%, clinical success of 83.3 and 0% adverse events, and these results were not significantly different from those achieved in patient without ascites.

Mario A, et al.[19] developed a technique to mimic EPASS by using two vascular balloons, which they called a modified approach to EUS-guided double-balloon-occluded gastroenterostomy (M-EPASS), to facilitate EUS-GE. The technical success rate was 91%, clinical success was 80%, and there was just one adverse event due to stent migration. The M-EPASS technique seems to be comparable with EPASS, but the latter has the advantage of using commercially available accessories.

Over 20 single-arm studies have been published about EUS-GE in malignant GOO, with technical success varying between 80-100%, clinical success 73-95% and serious adverse events numbering approximately 3-6%.[20] The results achieved in our center seem comparable with overall technical success. The M-EPASS technique and the wireless freehand combined with oroenteral catheter were 83.3%, 100% and 75% respectively. One incidence (8.3%) of a severe adverse event from the direct over-the-guidewire technique persuaded us to change our technique of preference to the wireless-freehand method, and we are now becoming more comfortable with the M-EPASS technique. The high incidence of mis-deployment of 16.7% (2/12) is probably related to the learning curve associated with becoming familiar with the procedure, as proficiency is normally achieved after completion of 7-25 procedures.[20]

With regard to clinical success associations with stent size and patency, recent studies have recommended that a large luminal diameter with the 20-mm LAMS is technically feasible and more likely to achieve tolerance of a soft solid or complete diet.[15,20-21] This recommendation is in keeping with the findings of our study, in which the majority of stents used for EUS-GE were 20-mm, and the patients still had GOO score of 2-3 in the mean follow up period of 6.2 months (range 0.75-22 months), with longest patency of about 20 months and one stent occlusion from tissue ingrowth at 12-month follow up. Only two patients received 15-mm stent: one of these had technical failure due to mis-deployment, while the other still had good GOO score at 7-month follow up.

Some retrospective studies have reported the use of EUS-GE specifically for benign conditions, such as peptic stricture, anastomotic stricture, duodenal hematoma, acute/chronic pancreatitis, pancreatic pseudocyst/walled-off pancreatic necrosis, superior mesenteric artery syndrome, and caustic stricture[22,23] They demonstrated that it was a promising modality for benign GOO, especially for cases which were unlikely to respond to dilation therapy or in cases when this technique was not possible. Physicians were able to avoid surgery for GOO in 83.3% of cases.[23] The technical and clinical success rates were similar to those of patients with malignant conditions. The most commonly reported adverse events occurred mostly in mild conditions such as abdominal discomfort and stent mis-deployment, but there were also some severe adverse events. Chen YI et al.[22] reported gastric leak after elective stent removal which needed surgical intervention, and James TW et al.[23] reported bleeding from a gastric ulcer at the anastomotic site 2 days after the procedure. There was also a case of small bowel obstruction resulting from LAMS migration 1 year after deployment which required laparotomy for removal of the stent, while in another patient, the gastrojejunostomy stent was found to have transversed from the stomach through the colon and into the jejunum but without contrast leakage. Recurrence of GOO while the stent was in place was mostly caused by food impaction, and this was successfully managed by endoscopic removal, but there were some cases which needed surgical intervention.[22,23] James TW et al.[23] recommended that the stent stay in place for a mean time of 8.5 months and should be removed after improvement in GOO to avoid complications from the stent; however, some recurrent GOO still occurred after stent removal. Our study showed one good response after EUS-GE in a benign condition (SMA syndrome), with the patient having the stent removed at 5-month follow up. Generally in case of malignant, LAMS will be reintervention when re-obstructive symptoms occur. In case of benign condition apart from re-obstruction, Elective exchange should be considered to avoid troublesome of tissue ingrowth and overgrowth. Six month interval is preferable by expert endosonographers.[24]

CONCLUSION

EUS-GE is effective in the management of GOO, and the wireless freehand method combined with the M-EPASS technique or oroenteral catheter should be the technique of choice in term of safety and efficacy. However, a larger prospective study is needed to further evaluate this technique in treating both benign and malignant GOO.

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