Outcomes of lumen apposing metal stent placement in patients with surgically altered anatomy: Multicenter international experience

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Key words
Endoscopy Lower GI Tract, Stenting, Endoscopy Small Bowel, Endoscopic ultrasonography

received 26.6.2024
accepted after revision 6.9.2024
accepted manuscript online 9.9.2024

Bibliography
Endosc Int Open 2024; 12: E1143–E1149
DOI 10.1055/a-2411-1814
ISSN 2364-3722
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ABSTRACT

Background and study aims Although outcomes of lumen-apposing metal stents (LAMS) placement in native anatomy have been reported, data on LAMS placement in surgically altered anatomy (SAA) are sparse. We aimed to assess outcomes of LAMS placement in patients with SAA for different indications.

Patients and methods This was an international, multicenter, retrospective, observational study at 25 tertiary care centers through November 2023. Consecutive patients with SAA who underwent LAMS placement were included. The primary outcome was technical success defined as correct placement of LAMS. Secondary outcomes were clinical success and safety.

Results Two hundred and seventy patients (125 males; average age 61 ± 15 years) underwent LAMS placement with SAA. Procedures included EUS-directed transgastric ERCP (EDGE) and EUS-directed transenteric ERCP (EDEE) (n = 82), EUS-guided entero-enterostomy (n = 81), EUS-guided biliary drainage (n = 57), EUS-guided drainage of peripancreatic fluid collections (n = 48), and EUS-guided pancreaticogastrostomy (n = 2). Most cases utilized AXIOS stents (n = 255) compared with SPAXUS stents (n = 15). Overall, technical success was 98%, clinical success was 97%, and the adverse event (AE) rate was 12%. Using AGREE classification, five events were rated as Grade II, 21 events as Grade IIIa, and six events as IIIb. No difference in AEs were noted among stent types ($P = 0.52$).

Conclusions This study shows that placement of LAMS is associated with high technical and clinical success rates in patients with SAA. However, the rate of AEs is noteworthy, and thus, these procedures should be performed by expert endoscopists at tertiary centers.

Introduction

The lumen apposing metal stent (LAMS) is a cutting-edge endoscopic device utilized for both benign and malignant conditions [1, 2]. Its unique "barbell" shape features flanged ends that provide a remarkably low risk of migration. While initially designed for draining pancreatic fluid collections (PFC) due to its larger inner lumen diameter compared with plastic stents or traditional self-expanding metal stents, it also enables endoscopes to access collections and conduct direct necrosectomy.

Numerous endoscopic ultrasound (EUS)-guided techniques have been described in recent years [2]. Notably, the deployment of LAMS through EUS guidance has enabled the treatment of a wider range of gastrointestinal conditions, including gastric outlet obstruction (GOO), drainage of fluid collections in the pancreas and other intraabdominal and pelvic areas, gallbladder drainage, and treatment of distal malignant biliary obstruction, among others [2, 3].

Recently, there has been a surge in use of LAMS to manage patients with surgically altered anatomy (SAA). These patients would have otherwise needed surgical or percutaneous interventions. The wide lumen design of LAMS allows easy access to the distant parts of the gastrointestinal tract that would have previously been difficult to reach [3]. As a result, minimally invasive interventions have gained immense popularity, with a growing body of literature [4, 5].

However, data are limited on outcomes following LAMS placement in SAA. To bridge this critical knowledge gap, we aimed to analyze a large cohort of patients who underwent LAMS placement in SAA for various indications.

Patients and methods

Study design and population

Our study analyzed data from 25 international tertiary care centers, with 12 located in Italy, five in the United States, two in Belgium, and one each from Norway, Switzerland, Ecuador, Costa Rica, Saudi Arabia, and India. Consecutive patients with SAA underwent EUS-guided placement of LAMS through November 2023 for various indications, including malignant biliary obstruction, cholecystitis, drainage of peri-PFC, EUS-guided creation of enteric anastomoses, and EUS-directed transgastric endoscopic retrograde cholangiopancreatography (EDGE). Demographic information, procedure-related details, and follow-up data were collected from electronic charts and telephone contacts. The study was approved by the institutional review board of Humanitas Mater Domini as well as individual contributing centers.

Study outcomes, definitions, and statistical analysis

We considered technical success as the primary outcome, which meant successful placement of LAMS. We also measured clinical success by monitoring improvements in clinical parameters such as bilirubin level, white blood cell count, and ability to tolerate an oral diet. We categorized adverse events (AEs) as either early, occurring within 48 hours, or late, occurring after 48 hours. These events included bleeding, perforation, stent migration, mortality, and others. The AGREE classification was used to rate AEs [6]. Descriptive statistical analysis was performed using SPSS v27 (IBM, Armonk, New York, United States). A test of proportion (Z-test) was used to compare AE rates among stent types.

Technique

Experienced operators performed all procedures under general anesthesia or propofol sedation using therapeutic EUS. LAMS, which included both AXIOS (Boston Scientific) and SPAXUS (Taewoong Medical) stents, were utilized. The AXIOS stents were available in sizes ranging from 6 × 8 mm to 20 × 10 mm, while the SPAXUS stents were available in sizes ranging from 8 × 20 mm to 16 × 20 mm. Endoscopists used either LAMS with or without a cautery tip based on their preferences or institutional availability. Placement of LAMS with a guidewire or using free-hand puncture technique was also at the discretion of the endoscopist.

Results

A total of 270 patients were included, 125 of whom were male. The average age of the cohort was 61 ± 15 years (▶ **Table 1**). Overall, use of LAMS in SAA was associated with a high technical success rate (98%) as well as a high clinical success rate (97%). The AE rate was 12% (n = 32/270). Twenty-one cases utilized non-cautery enhanced LAMS while 249 utilized cautery enhanced LAMS. In addition, 15 cases utilized SPAXUS stents where one AE was noted compared with the remaining 255

▶ **Table 1** Procedures and outcomes of lumen apposing metal stents in surgical anatomy.

Procedure and outcomes	Values
EUS-guided transgastric ERCP (EDGE) and EUS-directed transenteric ERCP (EDEE)	82
EUS-guided entero-enterostomy	81
EUS-guided biliary drainage	57
EUS-guided drainage of peri-pancreatic fluid collections	48
EUS-guided pancreatogastrostomy	2
AXIOS	255
SPAXUS	15
Technical Success	98%
Clinical Success	97%
Overall adverse events	12%
AGREE Classification	
▪ Grade II	5
▪ Grade IIIa	21
▪ Grade IIIb	6

EUS, endoscopic ultrasound; ERCP, endoscopic retrograde cholangiopancreatography.

▶ **Table 2** Outcomes following EDGE and EDEE.

Procedure	n	Technical success	Clinical success	Adverse event
EDGE	79	97.5%	97.5%	Early bleeding (1) Early perforation (1) Late perforation (1) Abdominal distension/nausea (1)
EDEE	3	100%	100%	Stent misdeployment (1)

EDGE, endoscopic ultrasound-directed transgastric endoscopic retrograde cholangiopancreatography; EDEE, endoscopic ultrasound-directed transenteric endoscopic retrograde cholangiopancreatography.

▶ **Table 3** EUS-guided placement of LAMS for biliary drainage.

Procedure	n	Technical success	Clinical success	Adverse event
EUS-cholecystogastrostomy	24	87.5%	79.2%	Early bleeding (2) Early perforation (1)
EUS-choledochoduodenostomy	14	100%	93%	Impacted food (1)
EUS-colecystoduodenostomy	10	100%	100%	Stent occlusion from BD stone (1) Jaundice 2/2 BD stricture (1) Late bleeding (3) Early bleeding (1)
EUS-cholecystojejunostomy	6	83.3%	83.3%	Stent misdeployment (1)
EUS-hepaticogastrostomy	2	100%	100%	Late migration (1) Sub-hepatic collection (1)
EUS-choledochojejunostomy	1	100%	100%	None

EUS, endoscopic ultrasound; LAMS, lumen apposing stent.

cases which utilized AXIOS stents with 31 associated AEs. To this end, there was no statistical differences in AEs between SPAXUS and AXIOS ($P = 0.52$). Cases using SPAXUS stents had 100% technical and 100% clinical success rates while AXIOS was associated with 98% technical success and 97% clinical success rates.

Overall, AEs included early bleeding (2%), late bleeding (2%), perforation (2%), early migration (1%), late migration (1%), pulmonary embolism (< 1%), jaundice (< 1%), subhepatic fluid collection (< 1%), fever (< 1%), nausea & abdominal distention (< 1%), stent misdeployment (< 1%), and stent occlusion (< 1%). Two cases of late stent migration led to the formation of gastrocolonic fistulas.

EUS-directed transgastric ERCP and EUS-directed transenteric ERCP

Eighty-two patients with SAA underwent the EDGE procedure or EUS-directed transenteric ERCP (EDEE). Surgical anatomy included Roux-en-Y gastric bypass (80) and other (2). Indications included abdominal pain (4), abnormal computed tomography findings (1), afferent loop syndrome (1), bile leak (2), bleeding (1), common bile duct (CBD) stricture (3), cholangitis (21), choledocholithiasis (24), elevated liver enzymes (1), fine-need aspiration and radiofrequency ablation of an insulinoma at the head of the pancreas (1), unknown jaundice or obstruction (12), access pancreas (3), surgical stricture (1), unknown/other (6), and surgical exclusion (1). The stents used included 8 × 8 mm (HOT AXIOS; 1), 15 × 10 mm (Hot AXIOS; 9), and 20 × 10 mm (Hot AXIOS; 71). Overall, stent placement was associated with a high technical success rate and clinical success rate, as well as a low rate of AEs though two perforations were noted with one stent misdeployment (▶ **Table 2**).

EUS-guided entero-enterostomy

Eighty-one patients with SAA underwent creation of entero-enterostomy. Sixty-nine percent were indicated for malignancy whereas 31% were indicated for benign etiology. Surgical anatomy included proximal total gastrectomy (2), proximal subtotal gastrectomy (5), Billroth I (3), Billroth II (7), pylorus preserving Whipple (17), not pylorus preserving Whipple (18), Roux-en-Y gastric bypass (20), duodenal switch (1), distal gastrectomy (1), and others (7). Stents used for drainage included 16 × 20 mm (Cold SPAXUS; 2), 8 × 20 mm (Hot SPAXUS; 1), 10 × 20 mm (Hot SPAXUS; 1), 10 × 10 mm (Hot AXIOS; 1), 15 × 10 mm (Cold AXIOS; 28), 15 × 15 mm (Hot AXIOS; 3), and 20 × 10 mm (Hot AXIOS; 45). Overall, stent placement was associated with a high technical success rate and clinical success rate, as well as a low rate of AEs although two perforations were noted with one stent misdeployment (▶ **Table 3**). Two cases (within the malignant subgroup) were not technically successful due to difficulty with distending the distal small bowel.

▶ **Table 4** Outcomes following EUS-guided creation of entero-enterostomy.

Procedure	n	Technical success	Clinical success	Adverse event
EUS-gastroenterostomy	64	97%	97%	Late bleeding (1) Early stent migration (2) Late stent migration (2) Early perforation (1) Pulmonary embolism (1)
EUS-jejunojejunostomy	13	100%	100%	Early migration (1)
EUS-gastroduodenostomy	1	100%	100%	None
ESU-duodenojejunostomy	3	100%	100%	Late bleeding (1) Perigastric effusion (1)

▶ **Table 5** EUS-guided drainage of peri-pancreatic fluid collections.

Procedure	n	Technical success	Clinical success	Adverse event
EUS-cystgastrostomy without pigtail stents	25	100%	100%	Intraprocedural bleeding (1)
EUS-cystgastrostomy with pigtail stents	20	100%	100%	Delayed bleeding (1) Fever (1)
EUS-cystjejunostomy without pigtail stents	1	100%	100%	None
Other	2	100%	100%	None

EUS, endoscopic ultrasound.

Biliary drainage

Fifty-seven patients with SAA underwent EUS-guided biliary drainage (BD) for malignant (n = 35) and non-malignant etiologies (n = 22). Surgical anatomy included Billroth II (14), Billroth I (12), pylorus preserving Whipple (8), not pylorus preserving Whipple (4), Roux-en-Y bypass (3), sleeve gastrectomy (3), total gastrectomy (2), proximal subtotal gastrectomy (2), partial gastrectomy with Roux-en-Y bypass (2), hepaticojejunostomy (2), bilio-digestive anastomosis (1), duodenojejunostomy (1), gastrojejunostomy (1), McKeon esophagectomy with Roux-en-Y bypass (1), and esophagectomy with hemigastrectomy and gastric pull-up (1).

For cases of malignant biliary obstruction, 34% of patients (n = 12/35) failed prior ERCP and stayed on average of 11 days in the hospital (total) and 9 days after their procedure. In patients who underwent CBD drainage, the average diameter was 18 ± 4 mm. Only AXIOS stents were used, which included 20 × 10 mm (8), 15 × 15 mm (5), 15 × 10 mm (8), 10 × 10 (4), 8 × 8 mm (4), and 6 × 8 mm (3), unknown (3). For non-malignant BD, cases were performed for indications of cholecystitis (15), biliary stones (3), biliary strictures (3), and cholangitis (1). LAMS used included 10 × 20 mm (1; SPAXUS), 10 × 10 mm (15), 15 × 10 mm (4), and 20 × 10 mm (2). Patients were discharged on average 6.5 days after their procedure. Overall, stent placement was associated with a very high technical success rate and clinical success rate, as well as a low rate of AEs (▶ **Table 4**).

Drainage of peri-PFC

Forty-eight patients with SAA underwent drainage of peri-PFC. Surgical anatomy included proximal subtotal gastrectomy (1), Billroth I (4), Billroth II (2), sleeve gastrectomy (13), pylorus preserving Whipple (15), not pylorus preserving Whipple (8), Total pancreatectomy pylorus preserving (1), Roux-en-Y gastric bypass (2), and others (2). Patient symptoms included fever (16), nausea/vomiting (15), abdominal pain (13), fever + abdominal pain (2), asymptomatic (1), and poor oral intake with elevated CRP (1). The average fluid collection size was 82.5 ± 28.8 mm while the average fluid collection size at the time of stent removal was 19.2 ± 13.1 mm. Stents used for drainage included 10 × 20 mm (Cold SPAXUS; 5), 16 × 20 mm (Cold SPAXUS; 1), 16 × 20 mm (Hot SPAXUS; 4), 10 × 10 mm (Hot AXIOS; 14), 15 × 10 mm (Cold AXIOS; 9), 15 × 15 mm (Hot AXIOS; 10), and 20 × 10 mm (Hot AXIOS; 5). Overall, stent placement was associated with a high technical success rate and clinical success rate, as well as a low rate of AEs (▶ **Table 5**). Furthermore, 20 cases utilized double pigtail stents whereas 28 cases did not use double pigtail stents, with no difference in outcomes noted.

Pancreaticogastrostomy

Two cases of pancreaticogastrostomy were reported in patients with non-pylorus preserving Whipple that utilized 6 × 8 mm hot AXIOS stents. Both procedures had 100% technical success and 100% clinical success with no AEs.

Discussion

Our study represents the first extensive evaluation of LAMS placement in SAA. By conducting an international multicenter study involving 270 patients, we found that LAMS placement in SAA boasts impressive technical and clinical success rates. While AEs were notable, there were no endoscopy-related cases of mortality. Use of LAMS in SAA yielded a remarkable technical success rate of 98% and a clinical success rate of 97%. In total, 32 of 270 individuals experienced AEs, resulting in a 12% AE rate. These events encompassed early and late bleeding, perforation, migration, pulmonary embolism, jaundice, subhepatic fluid collection, fever, nausea and abdominal distention, stent misdeployment, and stent occlusion.

In our study, LAMS were used for biliary decompression in treatment of malignant biliary obstruction as well as treatment of non-malignant etiologies. To this end, EUS-BD is a viable alternative to ERCP, specifically by directly accessing the bile duct or the gallbladder [7]. A meta-analysis of 18 studies examining EUS-BD in SAA reported pooled technical success, clinical success, and AE rates of 97.8% (95% confidence interval [CI], 95.8–99.7%), 94.9% (95% CI, 91.8–98.1%), and 12.8% (95% CI, 7.4–18.1%), respectively [8]. Our results are in line with these outcomes. It is important to note that the European Society of Gastrointestinal Endoscopy recommends considering EUS-BD as a treatment option for malignant biliary obstruction after failed ERCP, provided local expertise is available [9].

Moreover, endoscopic gallbladder drainage is used in management of patients with cholecystitis who are deemed poor surgical candidates [10, 11]. Compared with the percutaneous approach, EUS-BD using LAMS has demonstrated similar technical and clinical success, but lower AE rates, shorter hospital stays, and reduced rates of unplanned readmissions and recurrent cholecystitis [12]. Despite limited data on LAMS placement for acute cholecystitis in SAA, our findings support the feasibility of this procedure in this specific patient population. Notably, our study showed 100% technical success and 100% clinical success, and minor AEs with no cases of perforation, misdeployment, or stent migration.

LAMS are used for managing symptomatic patients with peri-PFC. Our study reported outcomes of LAMS placement in SAA for the drainage of peri-PFC. To this end, we found that LAMS placement for this indication was associated with good technical and clinical success rates with minor AEs. No difference in outcomes was noted in cases utilizing double pigtail stents versus those not using double pigtail stents. A meta-analysis of eight studies (n = 460) showed that the clinical success rate (relative risk [RR] 1.00, 95% CI 0.87–1.14) and overall AE risk (RR 1.60, 95% CI 0.95–2.68) remained comparable between groups who used double pigtail stents versus those who did not use double pigtail stents [13].

In past decades, the EDGE or EDEE procedure has gained significant popularity, with Tyberg et al. suggesting 25 to 35 procedures were needed to become proficient [14, 15]. A retrospective multicenter study conducted by Runge et al. with 178 patients undergoing the EDGE procedure showed a technical success rate of 98% (175/178) with a mean procedure time of 92 minutes [16]. However, periprocedural AEs occurred in 15.7% of patients (mild 10.1%, moderate 3.4%, severe 2.2%), with laparoscopic management required for four severe cases [16]. A meta-analysis of 16 studies involving 470 patients showed a pooled technical success rate of 96% (95% CI 92% - 97.6%) where clinical success was achieved in 91% of cases (95% CI 85% - 95%) [17]. In addition, the study reported a 17% rate of AEs including failure of fistula closure (17%), stent migration (7%), bleeding (5%), post-EDGE weight gain (4%), perforation (4%), and post-ERCP pancreatitis (2%) [17]. Our study also found high technical and clinical success rates; however, two cases of perforation and one case of stent misdeployment were reported. Thus, this underscores a need for prudence and good endoscopic skills to minimize these risks.

This study also examined outcomes associated with creation of EUS-guided entero-enterostomies. Traditionally, this procedure was performed using a surgical approach. More recently, EUS-GE has been shown to be superior to enteral stenting in treating GOO. A recent randomized trial showed that EUS-guided gastroenterostomy led to reduced reintervention rates, better stent patency, and improved eating habits when compared with duodenal stenting [18]. Our study contributes to the growing body of literature showing that creation of entero-enterostomies is viable, even in patients with SAA [19, 20, 21]. Finally, two cases of pancreaticogastrostomy were reported with good outcomes. Although our study drew from a large international multicenter cohort, only two cases of LAMS placement for this indication were observed, thus illustrating that this procedure is rarely performed, even by expert endoscopists [22]. Larger studies evaluating endoscopic pancreaticogastrostomy are needed.

Our study has limitations. First, this was a retrospective study, which is subject to inherent bias, particularly selection bias. Second, we were unable to perform statistical comparisons due to the heterogeneity of the sample and the small sample sizes of specific procedures. Third, this study was underpowered to detect differences between stent types and should be interpreted with caution. Finally, long-term follow-up data are lacking. Despite these limitations, it remains the first and most extensive analysis of LAMS in patients with SAA across various indications. Moreover, our study draws on a vast sample size from multiple international centers. Given that prospective studies or randomized trials are not readily available specifically for patients with surgical anatomy, we are confident that our study offers valuable insights and guidance to endoscopists who frequently employ LAMS for these indications.

Conclusions

In conclusion, interventional EUS has greatly broadened our therapeutic capabilities in creating novel gastrointestinal conduits. With the emergence of additional data, particularly in patients with SAA, it is anticipated that these endoscopic methods will become more common practice. Our study shows that LAMS placement in patients with SAA is effective and associated with good clinical outcomes. However, these procedures are associated with notable AEs.

Conflict of Interest

Benedetto Mangiavillano has no conflict of interest regarding this paper but is consultant for Taewoong medical.

References

[1] Sharma P, McCarty TR, Chhoda A et al. Alternative uses of lumen apposing metal stents. World J Gastroenterol 2020; 26: 2715 doi:10.3748/wjg.v26.i21.2715

[2] Bhenswala P, Lakhana M, Gress FG et al. Novel uses of lumen-apposing metal stents: a review of the literature. J Clin Gastroenterol 2021; 55: 641–651 doi:10.1097/MCG.0000000000001566

[3] Ichkhanian Y, Jovani M. Use of lumen apposing metal stents in patients with altered gastrointestinal anatomy. Curr Opin Gastroenterol 2023; 39: 348–355 doi:10.1097/MOG.0000000000000965

[4] Chowdhury SD, Diez-Redondo P, Pérez-Miranda M. Approach to biliary access in patients with altered anatomy. Tech Gastrointest Endosc 2016; 18: 98–106

[5] Spadaccini M, Giacchetto CM, Fiacca M et al. Endoscopic biliary drainage in surgically altered anatomy. Diagnostics 2023; 13: 3623 doi:10.3390/diagnostics13243623

[6] Nass KJ, Zwager LW, van der Vlugt M et al. Novel classification for adverse events in GI endoscopy: the AGREE classification. Gastrointest Endosc 2022; 95: 1078–1085 doi:10.1016/j.gie.2021.11.038

[7] Sharaiha RZ, Khan MA, Kamal F et al. Efficacy and safety of EUS-guided biliary drainage in comparison with percutaneous biliary drainage when ERCP fails: a systematic review and meta-analysis. Gastrointest Endosc 2017; 85: 904–914

[8] Tanisaka Y, Mizuide M, Fujita A et al. Endoscopic ultrasound-guided biliary drainage in patients with surgically altered anatomy: A systematic review and Meta-analysis. Scand J Gastroenterol 2023; 58: 107–115

[9] van der Merwe SW, van Wanrooij RLJ, Bronswijk M et al. Therapeutic endoscopic ultrasound: European Society of Gastrointestinal Endoscopy (ESGE) Guideline. Endoscopy 2022; 54: 185–205 doi:10.1055/a-1717-1391

[10] Koutlas NJ, Pawa S, Russell G et al. Endoscopic ultrasound-guided gallbladder drainage: beyond cholecystitis. Diagnostics 2023; 13: 1933 doi:10.3390/diagnostics13111933

[11] Crino SF, Rimbaș M, Gabbrielli A et al. Endoscopic ultrasound guided gallbladder interventions: a review of the current literature. J Gastrointestin Liver Dis 2019; 28: 339–347 doi:10.15403/jgld-215

[12] Teoh AYB, Kitano M, Itoi T et al. Endosonography-guided gallbladder drainage versus percutaneous cholecystostomy in very high-risk surgical patients with acute cholecystitis: an international randomised multicentre controlled superiority trial (DRAC 1). Gut 2020; 69: 1085–1091

[13] Giri S, Harindranath S, Afzalpurkar S et al. Does a coaxial double pigtail stent reduce adverse events after lumen apposing metal stent placement for pancreatic fluid collections? A systematic review and meta-analysis Ther Advan Gastrointest Endosc 2023; 16: doi:10.5946/ce.2023.297

[14] Kedia P, Sharaiha RZ, Kumta NA et al. Internal EUS-directed transgastric ERCP (EDGE): game over. Gastroenterology 2014; 147: 566–568 doi:10.1053/j.gastro.2014.05.045

[15] Tyberg A, Kedia P, Tawadros A et al. EUS-directed transgastric endoscopic retrograde cholangiopancreatography (EDGE): the first learning curve. J Clin Gastroenterol 2020; 54: 569–572 doi:10.1097/MCG.0000000000001326

[16] Runge TM, Chiang AL, Kowalski TE et al. Endoscopic ultrasound-directed transgastric ERCP (EDGE): a retrospective multicenter study. Endoscopy 2021; 53: 611–618 doi:10.1055/a-1254-3942

[17] Deliwala SS, Mohan BP, Yarra P et al. Efficacy & safety of EUS-directed transgastric endoscopic retrograde cholangiopacreatography (EDGE) in Roux-en-Y gastric bypass anatomy: a systematic review & meta-analysis. Surg Endosc 2023; 37: 4144–4158

[18] Teoh AY, Lakhtakia S, Tarantino I et al. Endoscopic ultrasonography-guided gastroenterostomy versus uncovered duodenal metal stenting for unresectable malignant gastric outlet obstruction (DRA-GOO): A multicentre randomised controlled trial. Lancet Gastroenterol Hepatol 2024; 9: 124–132 doi:10.1016/S2468-1253(23)00242-X

[19] Amato A, Tarantino I, Facciorusso A et al. Real-life multicentre study of lumen-apposing metal stent for EUS-guided drainage of pancreatic fluid collections. Gut 2022; 71: 1050–1052 doi:10.1136/gutjnl-2022-326880

[20] Mangiavillano B, Moon JH, Crinò SF et al. Safety and efficacy of a novel electrocautery-enhanced lumen-apposing metal stent in interventional EUS procedures (with video). Gastrointest Endosc 2022; 95: 115–122

[21] Facciorusso A, Amato A, Crinò SF et al. Definition of a hospital volume threshold to optimize outcomes after drainage of pancreatic fluid collections with lumen-apposing metal stents: a nationwide cohort study. Gastrointest Endosc 2022; 95: 1158–1172

[22] Hayat U, Freeman ML, Trikudanathan G et al. Endoscopic ultrasound-guided pancreatic duct intervention and pancreaticogastrostomy using a novel cross-platform technique with small-caliber devices. Endosc Int Open 2020; 8: E196–E202