Portuguese Journal of Gastroenterology

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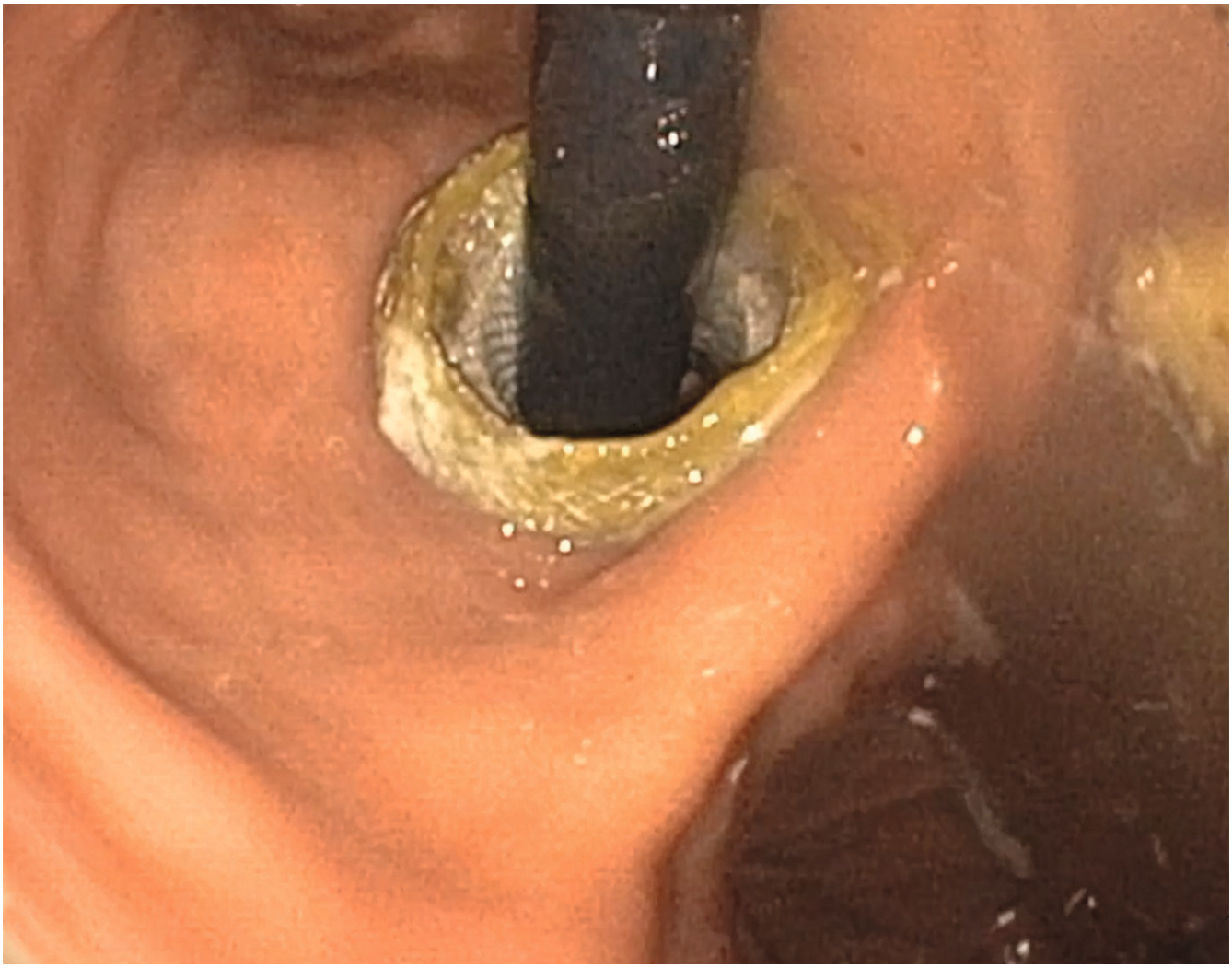

Highlights in this issue:

Review article: Therapeutic Endoscopic Ultrasound: Current Indications and Future Perspectives

Review article: Best Practices in Esophageal, Gastroduodenal and Colorectal Stenting

Review article: Esophageal Stenting – How I do It

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Aims and Scope

The *GE Portuguese Journal of Gastroenterology* (formerly *Jornal Português de Gastrenterologia*), founded in 1994, is the official publication of Sociedade Portuguesa de Gastrenterologia (Portuguese Society of Gastroenterology), Sociedade Portuguesa de Endoscopia Digestiva (Portuguese Society of Digestive Endoscopy) and Associação Portuguesa para o Estudo do Fígado (Portuguese Association for the Study of the Liver).
The journal publishes clinical and basic research articles on Gastroenterology, Digestive Endoscopy, Hepatology and related topics. Review articles, clinical case studies, images, letters to the editor and other articles such as recommendations or papers on gastroenterology clinical practice are also considered. Only articles written in English are accepted.

Price per printed issue: Free of charge
ERC-No.: 117866
Editor address: Rua Abranches Ferrão, nº 10–14º, PT–1600-001 Lisbon (Portugal)

ISSN Online Edition: 2387–1954

Journal Homepage: www.karger.com/pjg
Bibliographic Indices: This journal is regularly listed in bibliographic services, including PMC, PubMed, Web of Science, SciELO Citation Index, Google Scholar, DOAJ, Scopus, and WorldCat.

Publication Data: *GE Port J Gastroenterol* is published 6 times a year. Volume 30 with 6 issues appears in 2023.

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GE – Portuguese Journal of Gastroenterology

Vol. 30, Suppl. 1, 2023

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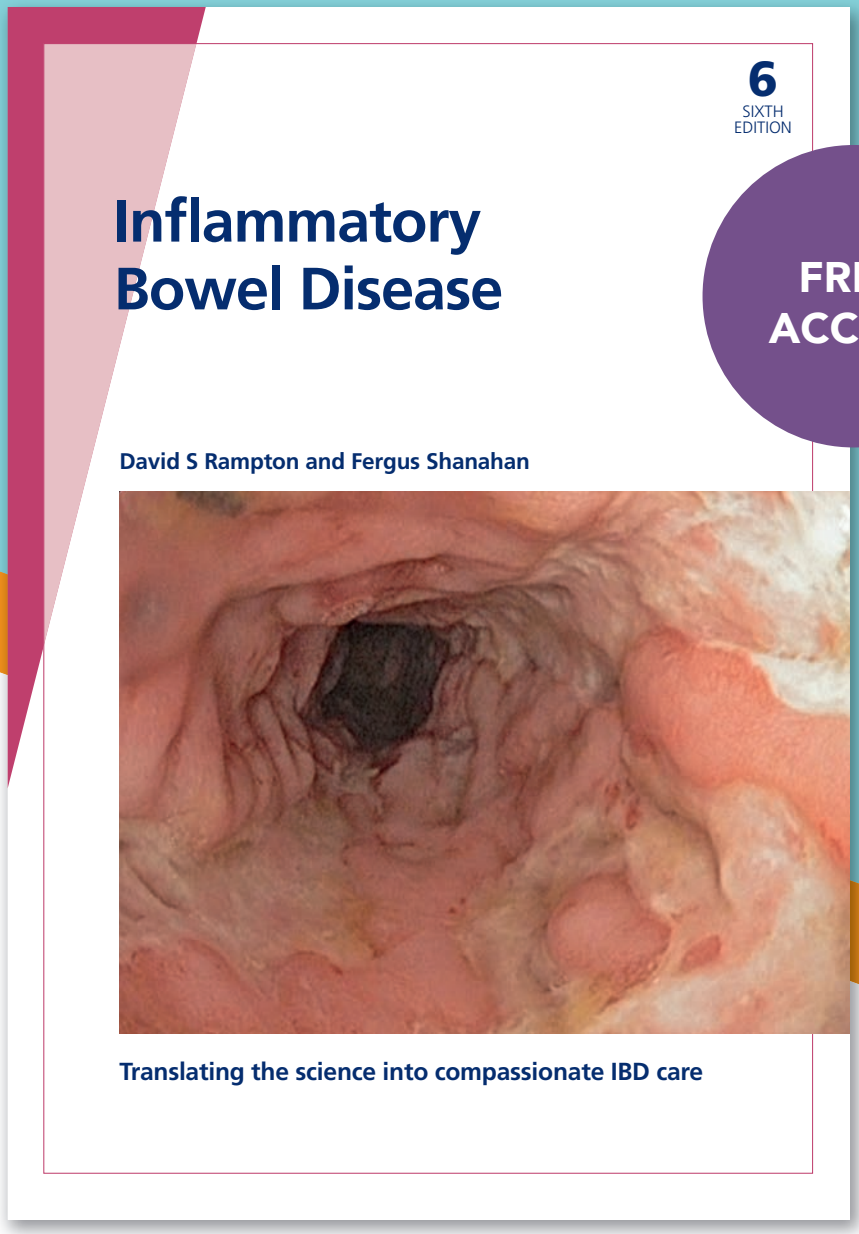

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Editorial

GE Port J Gastroenterol 2023;30:1–3
DOI: 10.1159/000531271

Received: May 18, 2023
Accepted: May 24, 2023
Published online: July 21, 2023

Luminal and Extraluminal Applications of Endoscopic Stenting: A Bright Future for Gastroenterology

Joel Ferreira-Silva[a, b] Diogo Libânio[c, d] Eduardo Rodrigues-Pinto[a, b]

[a]Gastroenterology Department, Centro Hospitalar São João, Porto, Portugal; [b]Faculty of Medicine of the University of Porto, Porto, Portugal; [c]Gastroenterology Department, Portuguese Institute of Oncology, Porto, Portugal; [d]MEDCIDS – Department of Community Medicine, Health Information and Decision, Faculty of Medicine, University of Porto, Porto, Portugal

Keywords
Endoscopy · Endoscopic ultrasound · Endoscopic stenting · Lumen-apposing metal stent

Aplicações luminais e extraluminais de próteses endoscópicas: um futuro brilhante para a gastroenterologia

Palavras Chave
Endoscopia · Ultrassonografia transendoscópica · Prótese endoscópica · Prótese metálica de aposição de lúmen

In recent years, considerable strides have been made in therapeutic endoscopy and specifically in stent technology to overcome strictures and fistulas. As such, several types of devices with advanced designs and materials are continuously being developed, and this evolution has helped expand the applications of therapeutic endoscopy to new horizons. The best example of this is the use of lumen-apposing metal stents (LAMS) in therapeutic endoscopic ultrasound (EUS), allowing for the endoscopic treatment of pancreaticobiliary and luminal disease previously reserved for surgical or percutaneous treatment. Thinking outside the box and using new devices to seal fistulas that cannot be managed with conventional endoscopic devices is also sometimes needed. While exciting, this continuing evolution and the growing number of therapeutic endoscopy applications may present a challenge for gastroenterologists to keep updated with the state of the art.

This special issue of *GE – Portuguese Journal of Gastroenterology* is dedicated to therapeutic endoscopy including 8 articles that provide further evidence of the safety, feasibility, and favorable outcomes of different applications of stents and similar devices in endoscopic therapeutic procedures, in particular the application of stents in therapeutic ultrasound endoscopy, luminal stenting, and treatment of leaks, perforations, and fistulas. The review articles also include several technical tips and tricks from experts that can clearly be helpful to the majority of endoscopists.

Canakis and Baron [1] performed a review article focused on current indications and innovations in therapeutic EUS. The therapeutic role of EUS has evolved to become a complementary technique to endoscopic retrograde cholangiopancreatography (ERCP) to provide adequate drainage in patients with pancreatic and biliary

karger@karger.com
www.karger.com/pjg

Correspondence to:
Eduardo Rodrigues-Pinto, edu.gil.pinto@gmail.com

disorders. EUS allows visualization of the intra and extrahepatic biliary tree and pancreatic duct, as well as extraluminal structures, serving as a platform for various successful drainage strategies described in this article. Technical description, efficacy, and safety of different techniques for drainage of pancreaticobiliary obstruction, pancreatic cyst ablation, gastric varices management, and gallbladder drainage can be found in this study. This review goes in line with previous studies, as well as the GRUPUGE guideline on EUS-guided biliary drainage [2–4].

Tarrio et al. [5] performed a single-center retrospective study evaluating the efficacy and safety of EUS-guided choledochoduodenostomy in 20 patients with distal malignant biliary obstructions after failed ERCP. LAMS were the stent most often used (n = 15; 75.0%). Technical and clinical success rates were 100% and 89.5% (n = 17/19) at 7th day and 93.3% (n = 14/15) at 30th day, in line with previous studies [6]. These results are encouraging, especially in patients after ERCP failure, where other alternatives, like percutaneous drainage, are nowadays considered suboptimal. The reported rate of early complications is also similar to previous studies [7].

Two review articles regarding luminal stenting are also included in this supplemental issue – one by Medas et al. [3] focused on the description of current practice in luminal stenting for malignant and benign indications throughout the gastrointestinal tract, and other by Silva et al. [8] focused on the technique and personal experience of esophageal stenting. Technical description, safety, and efficacy of esophageal, gastroduodenal, and colonic stenting are described in the first article, while the "How I do" article regarding esophageal stenting [8] addresses the characteristics of some of the currently available stents, offering an elaborated description of insertion delivery systems, techniques of placement, as well as some tips and tricks regarding placement and management of adverse events. This can be extremely helpful to understand and avoid the occurrence of adverse events and comes in line with recent technical reviews [9].

In summary, self-expandable metallic stents are an excellent option for the treatment of patients with unresectable esophageal cancer, malignant tracheoesophageal fistulas, recurrent benign esophageal strictures, esophageal transmural defects, malignant gastric outlet obstruction (GOO), and malignant colonic obstruction. However, gastroduodenal stenting now competes with EUS-guided gastrojejunostomy for the title of first-line therapy for GOO. In this regard, Antunes et al. [10] described a case series of three EUS-guided gastroenterostomies for the palliation of malignant GOO, using the wireless endoscopic simplified technique, with technical and clinical success in all patients. A detailed description of this technique is provided.

Sometimes endoscopists need to innovate and think outside the box to overcome complex and particular situations. For instance, Brito et al. [11] presented a case series describing the application of Niti-S esophageal mega-stent in 2 patients with anastomotic leaks after oncologic surgery. Both cases achieved leak resolution after 2 weeks without adverse events. Self-expandable metallic stent placement for luminal defects is a safe, well-established therapeutic technique; however, limitations include stent migration and incomplete sealing. Bariatric stents might have a role in addressing these limitations.

Kumaira Fonseca et al. [12] presented a case study that evaluated the use of a cardiac septal defect occluder (CSDO) in the treatment of a patient with a chronic gastrocutaneous fistula after bariatric revisional surgery. In this case, fistula closure was achieved after placement of a second CSDO between the discs of a former dislodged CSDO. CSDO might be an emerging technique for closure chronic, mature gastrointestinal fistulas. The study presents the first *off-label* use of the Occlutech® occluder for the treatment of a chronic fistula after bariatric revisional surgery.

Chálim Rebelo et al. [13] presented an EUS-directed transgastric ERCP in a patient with Roux-en-Y gastric bypass and choledocholithiasis, providing a detailed description of the technical steps of this innovative technique. In this case, placement of a 10 × 15 mm LAMS allowed endoscopic access to the native papilla 3 weeks later, with LAMS being transposed with the duodenoscope without need for further dilation. When transposition of the stent with the duodenoscope proves difficult, other techniques can be pursued [14].

In sum, the role of endoscopic stenting in the management of patients with gastrointestinal diseases has expanded greatly in recent years, with increasing use of endoluminal and transluminal stents. We are particularly excited about the growing establishment of EUS-guided therapies. These studies provide evidence that this therapeutic approach will be standard practice in the near future, as an alternative for biliary and pancreatic drainage and for the creation of several types of enteric anastomosis, with excellent safety and clinical success. However, standardization of the different techniques and limited number of therapeutic EUS experts are limitations that need to be overcome.

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GE – Portuguese Journal of Gastroenterology

Review Article

GE Port J Gastroenterol 2023;30(suppl 1):4–18
DOI: 10.1159/000529089

Received: October 21, 2022
Accepted: December 26, 2022
Published online: February 20, 2023

Therapeutic Endoscopic Ultrasound: Current Indications and Future Perspectives

Andrew Canakis[a] Todd H. Baron[b]

[a]Division of Gastroenterology and Hepatology, University of Maryland School of Medicine, Baltimore, MD, USA;
[b]Division of Gastroenterology and Hepatology, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA

Keywords
Endoscopic ultrasound · Biliary drainage · Hepaticogastrostomy · Choledochoduodenostomy · Pancreatic ductal drainage · Necrotic fluid collections · Pancreatic cyst ablation · Lumen apposing metal stents

Abstract
The transcendence of endoscopic ultrasound (EUS) from diagnostic to therapeutic tool has revolutionized management options in the field of gastroenterology. Through EUS-guided methods, pancreaticobiliary obstruction can now be utilized as an alternative to surgical and percutaneous approaches. This modality also allows for gallbladder drainage in patients who are not ideal operative candidates. By utilizing its unique imaging capabilities, EUS also allows for drainage access points in cases of gastric outlet obstruction as well as windows to ablate pancreatic cystic lesions. As technical progress continues to evolve, interventional gastroenterology continues to push the envelope of minimally invasive therapeutic procedures in a multidisciplinary setting. In this comprehensive review, we set out to describe current indications and innovations through EUS.

Ecoendoscopia Terapêutica: Indicações Atuais e Perspetivas Futuras

Palavras Chave
Ecoendoscopia · Ultrassonografia · Drenagem biliar · Hepatico-gastrostomia · Ablação de cistos pancreáticos · Próteses de aposição de lúmen

Resumo
A transformação da ecoendoscopia (EUS) de um método de diagnóstico a ferramenta terapêutica revolucionou a abordagem na gastroenterologia. As terapêuticas guiadas por EUS, nomeadamente as obstruções pancreatobiliares, constituem agora alternativas às abordagens cirúrgicas e percutâneas. Esta modalidade terapêutica permite também a drenagem da vesícula biliar em doentes que não são candidatos cirúrgicos. Além disso, ao utilizar as suas capacidades únicas de imagem, a EUS permite a drenagem em casos de obstrução da saída gástrica, bem como realizar a ablação de lesões císticas pancreáticas. O crescente progresso da gastrenterologia permite o desenvolvimento de procedimentos terapêuticos minimamente invasivos num ambiente multidisciplinar. Nesta revisão, propusemos-nos a descrever as atuais indicações e inovações através da EUS.

Karger@karger.com
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Correspondence to:
Todd H. Baron, todd_baron@med.unc.edu

Introduction

The introduction and widespread implementation of endoscopic ultrasound (EUS) as a minimally invasive therapeutic modality has garnered significant attention in recent years. EUS has significantly revolutionized the field of interventional gastroenterology. The European Society of Gastrointestinal Endoscopy (ESGE) advises that these therapeutic EUS procedures be performed by experienced endoscopists at centers with adequate multidisciplinary support [1, 2]. In this state-of-the-art review, we will highlight the current indications for therapeutic EUS, including drainage of hepatobiliary and pancreatic obstruction, ablation of pancreatic cysts, management of gastric varices (GVs), and gallbladder drainage.

Methods

We conducted a literature search across three databases (PubMed, Embase, and the Cochrane Library) up to November 2022. The research topics were prepared by the senior author (T.H.B.) and the literature search was performed by the first author (A.C.). Topics included drainage of hepatobiliary/pancreatic obstruction, pancreatic cyst ablation, GVs management, and gallbladder drainage. All study types were included (randomized controlled trials, retrospective, prospective, meta-analyses, case series, and case reports).

EUS Therapy for Biliary Obstruction

In instances of benign and malignant biliary obstruction, endoscopic retrograde cholangiopancreatography (ERCP) with transpapillary stenting remains the first-line management option [3–6]. In expert hands, ERCP has a success rate of up to 95% with an adverse event (AE) rate <10% [7, 8]. Difficult, failed, or impractical cannulation can be attributed to surgically altered anatomy (SAA), prior duodenal stenting, tumor obstruction, or periampullary diverticulum/tumor [3, 6]. Furthermore, difficult cannulations are also associated with higher rates of AEs, especially post-ERCP pancreatitis (approximately 5.3–6.6% of all cases) [9, 10]. In the setting of unsuccessful ERCP, current guidelines recommend reattempting the procedure at least two to 4 days later in order to optimize success by improving biliary visualization (decreased edema), patient sedation, and availability of specialized guidewire equipment [3].

Historically, percutaneous transhepatic biliary drainage (PTBD) has been utilized as salvage therapy in the event of ERCP failure. PTBD is associated with a high success rate (95%); however, AEs are not uncommon (up to 30%), and the presence of an external catheter has also been associated with a reduced quality of life [6, 11]. It is in this setting where EUS-guided biliary drainage (EUS-BD) evolved as an alternative minimally invasive approach. The first reported case of EUS-guided bilioduodenal anastomosis was performed in 2001 [12]; since then, there have been a multitude of studies describing various techniques to accomplish EUS-BD. Compared to PTBD, EUS-BD is associated with fewer AEs and unscheduled reintervention rates with similar rates of success [13–15].

As such, EUS-BD has emerged as a reliable alternative when ERCP is not feasible [5]. Currently, performance of EUS-BD is limited to high volume centers driven by local expertise. The endoscopic learning curve is linked to procedural volume whereby technical success, procedure time and decreased AEs dramatically improve with operator experience [16–19]. It has been suggested that 33 and 100 cases are needed to achieve technical proficiency and mastery, respectively [18, 19]. The authors of this review article recently published a large single-center study (all procedures conducted by Dr. Baron) of EUS-guided transhepatic biliary drainage where total AEs (18.6%) significantly decreased over the 7 year time period in a cohort of over 200 patients [20]. That being said, EUS-BD is still a challenging procedure, largely limited to tertiary centers where there are rare instances of ERCP failure. One study found that ERCP failure in native papilla occurred in 0.6% (3/524 cases), in which all 3 patients were successfully managed by EUS-BD [21]. Yet there is growing evidence that EUS-BD can be considered as a first-line approach.

EUS-BD Techniques

Before delving into comparative studies, it is first important to describe the methods of biliary decompression, which can be achieved through rendezvous (RV), antegrade or transluminal approaches [22]. EUS-RV is limited to cases where the papilla can be reached and used as salvage therapy when conventional ERCP fails, whereby guidewire is accessed through the papilla in an antegrade fashion [22]. This approach is associated with a success and a major AE rate of 80% and 11%, respectively [22]. In RV, the puncture site (via transgastric into left intrahepatic duct or transduodenal into the extrahepatic duct) enables guidewire placement across the stricture/papilla without fistula tract formation [2]. Antegrade stent placement involves transhepatic puncture, passage of a guidewire across the obstruction, and passage of a

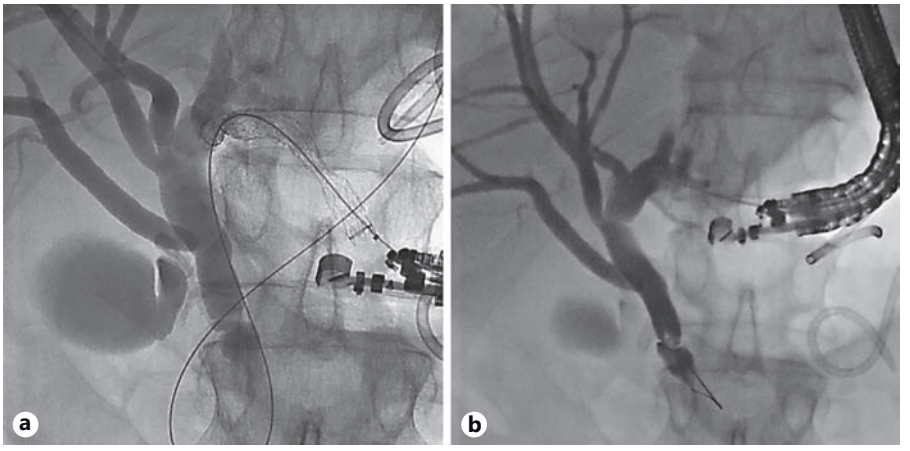

Fig. 1. EUS-guided hepaticogastrostomy in a patient with necrotizing pancreatitis and biliary obstruction due to extrinsic compression, failed ERCP due to duodenal obstruction. **a** Initial puncture through gastric wall and cholangiogram showing distal bile duct obstruction. **b** After placement of transgastric fully covered self-expandable metal biliary stent into left hepatic duct.

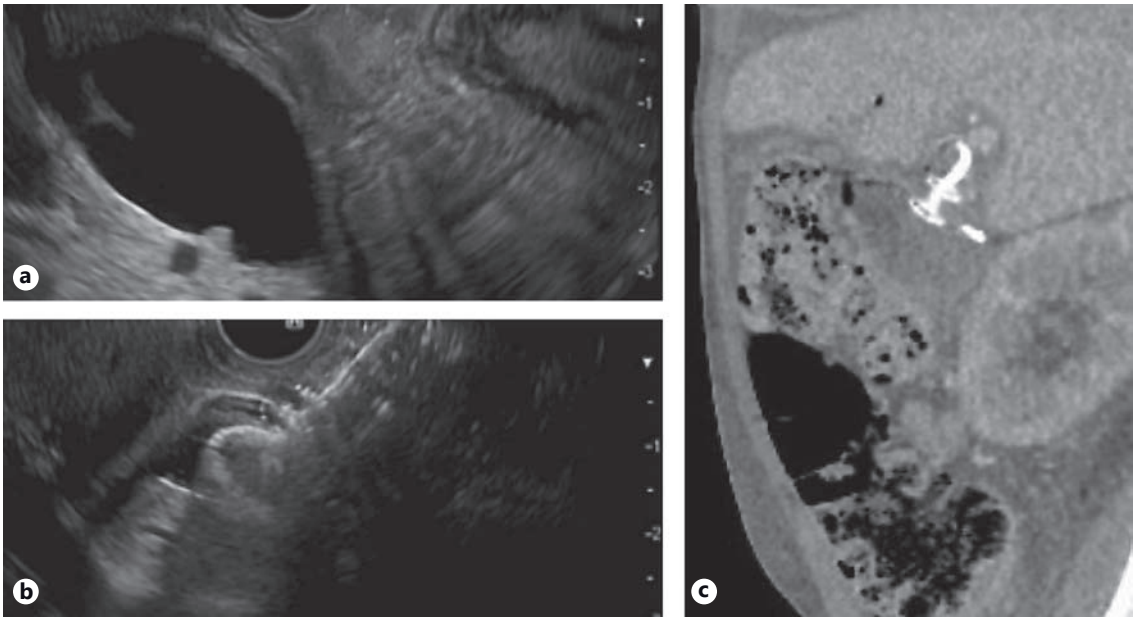

Fig. 2. EUS-guided choledochoduodenostomy in a patient with malignant biliary and duodenal obstruction. **a** Echoimage of markedly dilated CBD prior to placement of luminal apposing metal stent. **b** Echoimage immediately after deployment of 8 mm diameter luminal apposing metal stent into distal CBD. **c** Follow-up CT for continued care. Sagittal image shows luminal apposing stent with plastic stent within at site of choledochoduodenostomy.

stent antegrade across the obstruction such that the entire stent is within the biliary tree. If technical failure occurs, antegrade stenting can be converted to transmural or PTBD [2]. In general, direct transmural drainage is preferred using a hepaticogastrostomy (HGS) or choledochoduodenostomy (CDS) approach. Antegrade stenting, performed by placing an internal stent transhepatically, has fallen out of favor as it can be cumbersome with only a 77% technical success rate [22].

HGS typically involves creating an anastomosis between the lesser curvature of the stomach and a dilated left intrahepatic duct using a partially or fully covered self-expanding metal stent (SEMS) (Fig. 1) [23]. Meanwhile, CDS involves tract formation between the duodenal bulb and common bile duct with placement of a SEMS or lumen apposing metal stent (LAMS) (Fig. 2) [24]. Of note, luminal access points for transhepatic biliary drainage can also include the esophagus and jejunum [20].

Table 1. Comparison of HGS versus CDS

	CDS	HGS
Technical considerations	Long endoscope position in duodenal bulb	Dilated intrahepatic duct of approximately 4 mm is required
Clinical benefits	Smaller diameter (6 or 8 mm) cautery-enhanced LAMs make procedure technically easier	Does not interfere with surgical resection Multiple luminal access points
Limitations	Difficulty managing stent misdeployment Might interfere with pancreaticoduodenectomy (Whipple) May be more stent occlusion due to food, particularly in GOO	Technically more challenging Lack of dedicated stents in most countries

Transhepatic and transduodenal drainage methods have been extensively compared [25–36] with similar rates of technical and clinical successes based on three recent meta-analysis [37–39]. A recent international multicenter study of 182 patients (HGS 95 vs. CDS 87) found that technical success was 92% in both groups, while clinical success was slightly higher in the CDS cohort (100 vs. 86%) [36]. The authors found that CDS was associated longer term stent patency at the expense of slightly higher AEs [36]. Another multicenter randomized trial comparing HGS ($n = 24$) to CDS ($n = 23$) reported a technical success rate of 100% and 95.7%, respectively [35]. They found no differences in stent patency or AEs. Based on their results, the authors felt that switching between either procedure can be considered when technical challenges arise.

At the moment, there is no standardized algorithm between the two techniques. EUS-guided transhepatic drainage is the first-line method for patients with surgically altered anatomy or hilar obstruction (Table 1). Our recent single-center retrospective study of 215 patients primarily utilized a transgastric approach in 188 cases, where we reported a technical and clinical success rate of 85.3% and 87.25, respectively [20]. Advantages to transhepatic drainage are that in the event of complete stent misdeployment, the peritoneal space involving HGS may be easier to manage in the event of emergency surgery [20]. Additionally, the HGS location may allow for easier surgical resection of the duodenum (during Whipple operation for pancreas head cancer) in operative candidates. We do recognize that this is a technically difficult procedure and use in the community is likely impracticable.

There is evidence supporting the use of EUS-BD as the primary method for biliary decompression in instances of malignant biliary obstruction [22]. Three randomized controlled trials comparing EUS-BD to ERCP found no major differences in technical or clinical success rates [40–42]. That being said, a meta-analysis of these studies found that EUS-BD was linked to a lower rate of stent dysfunction, which leads to less interruption in oncological treatment plans [43]. Similarly, a recent meta-analysis of 5 studies involving 361 patients, found that ERCP was associated with higher rates of reintervention (22.6 vs. 15.2%) and tumor overgrowth (odds ratio 5.3) [44]. While there was no difference in overall survival, one study showed that quality of life was higher in the EUS group [41]. At the moment, larger comparative studies are needed to determine if avoiding transpapillary stenting can influence oncologic treatment outcomes.

EUS Drainage of Pancreatic Ductal Obstruction

EUS-guided pancreatic duct drainage (EUS-PDD) is a technically complex procedure associated with a high rate of AEs [2]. It is indicated when ERCP fails (3–10% of cases) or is not possible in cases of SAA [1]. While surgery is superior for long-term symptomatic relief of chronic pancreatitis [45], not all patients are ideal operative candidates and some may prefer a minimally invasive alternative. Main pancreatic duct (MPD) obstruction can result from chronic pancreatitis, pancreatojejunostomy anastomotic strictures, congenital anomalies, or disconnected pancreatic duct syndrome; these etiologies can result in significant patient discomfort and/or bouts of acute recurrent pancreatitis due to underlying ductal and interstitial hypertension [46]. At this juncture, EUS-PDD can be utilized to provide decompressive therapy.

The two approaches include RV-assisted endoscopic retrograde pancreatography (RV-ERP) or EUS-antegrade. In terms of safety and efficacy, RV-ERP is favored, while an antegrade approach is typically employed when RV-ERP is technically unsuccessful or not possible [1, 2, 47]. A 19-gauge needle is preferred to create a transgastric to MPD access point – the MPD diameter should be ≥4 mm [2]. In cases of SAA, a transenteric route can also be

used [46]. Assuming there is an endoscopically accessible native papilla (or anastomosis), a guidewire can be passed in an anterograde fashion in order to perform a ERP. Compared to a transmural approach, the RV-ERP method preserves anatomy and may provide better physiological drainage of the ductal stricture [1, 48]. Furthermore, avoiding the need for thermal energy or tract dilation to create a fistula may reduce the risk of bleeding, pancreatic leakage, and gastric leakage into the retroperitoneal space [1]. Yet, when direct drainage is required, cautery and non-cautery transmural stent placement can be accomplished via an EUS-antegrade fashion.

While there are limited head-to-head studies, RV-ERP is universally considered the first method used followed by EUS-antegrade. A large retrospective study demonstrated improved technical success with ERP-RV (95.6%) versus transgastric pancreaticogastrostomy (77.8%) with an added benefit of a lower rate of AEs [49]. As salvage therapy, antegrade drainage has demonstrated pooled technical and clinical success rates of 89% and 87%, respectively [46]. The critical step of creating a pancreaticogastrostomy is dependent upon successful stent placement through the tract. There are no standardized techniques, though we prefer to use a 19G needle, a 0.025" diameter × 450 cm long biliary guidewire, avoidance of cautery whenever possible, and least possible dilation of the tract to achieve the desired stent placement. In terms of stent placement, plastic stents are preferential due to ease of placement, which may reduce AEs in the event of stent dislodgement [50]. In one study fully covered SEMS were placed in 25 technically successful cases; no stent migration occurred and mean stent patency was 127 days [51]. There has been a case report using LAMS and a double-pigtail plastic stent [52], though more data are needed to determine patient selection. A recent study utilized a technique to reduce the risk of leakage and stent migration by dilating the pancreaticogastrostomy tract to 4 Fr using an angioplasty balloon and placing a 3-Fr stent with the pigtail in the pancreatic duct and the straight end extending at least 3 cm into the gastric lumen [53]. The authors reported an 88% technical and 62.5% clinical success rate with no instances of stent-related AEs [53].

While the optimal stent type is being investigated, the need for antegrade stent exchange following pancreaticogastrostomy is still debated among centers. Since drainage is occurring through the gastric wall without an intervening stricture, the need for repeat stent exchange of the MPD can be determined based on clinical/radiographic features or as a standard caliber upsizing procedure after the index endoscopy. An early retrospective study of 36 patients undergoing EUS-guided pancreatogastrostomy and pancreatobulbostomy found that 55% of patients experienced stent obstruction or migration over a median 14.5-month follow-up period requiring 29 repeat endoscopies [54]. Based on their findings, the authors recommended a proactive stance for stent exchange/upsizing using the existing transmural fistula. However, another group found that only 15% (4/26) of their patients experienced stent dislocation over a median follow-up of 9.5 months [55]. The authors supported watchful waiting in the absence of symptoms and radiologic confirmation of stent placement. A recent technical review recommended an elective stent exchange in order to widen the fistula as means to facilitate additional endoscopic therapy through the tract [46]. In light of these different approaches, we believe that the existing tract can be used ≥4 weeks after the initial procedure when the tract has matured [56].

The technical difficulties related to antegrade approach limit its use to expert centers. One study suggested that the learning curve for efficiency (i.e., reduction in procedure time), and proficiency were seen following the 27th and 40th cases when performed by a single operator [57]. However, these results are not generalizable given the expertise of that highly experienced endoscopist. With the current available studies, the AE rates of EUS-PDD range from 12 to 15% [46, 58]. The majority of these consist of abdominal pain, bleeding, infection, pancreatitis, and perforation and are recognized immediately or early post-procedurally [2]. While some studies have reported higher AEs than cited above, the heterogeneity of patients, and use of varying equipment and techniques make it difficult to compare and analyze these findings [46]. Moving forward, we believe that pancreatic ductal drainage may evolve to the use of small-diameter CMSEMS (6 mm) that will reduce the risk of leakage and bleeding.

EUS-Guided Gastroenterostomy for Gastric Outlet Obstruction

Malignant gastric outlet obstruction (GOO) is a mechanical obstruction that can extend from the pylorus or proximal duodenum to the third duodenum. Symptoms range from early satiety to intractable nausea, vomiting, and abdominal pain which result in nutritional deficiencies and poor quality of life [59]. As a result, these patients may also experience significant delays in administration of chemotherapy. Traditionally, bypassing this obstruction was achieved with a surgical gastrojejunostomy (S-GJ) or placement of an enteral self-expandable

Table 2. Comparing early versus late drainage of pancreatic fluid collections

First author, year	Study design	Total number of subjects (early vs. late drainage)	Mortality, early versus late drainage, %	Necrosectomy, early versus late drainage, %	Number endoscopic interventions needed for infected necrosis	Total complication rates, %	Length of stay, days
Boxhoorn, 2021 [79]	Multicenter, randomized trial	104 (55 ED vs. 49 LD)	13 versus 10	51 versus 22	4.4 versus 2.6*	76 versus 82	59 versus 51
Rana, 2021 [78]	Single-center, retrospective	170 (34 ED vs. 136 LD)	5.7 versus 0	50 versus 7.4	6 versus 3.1	20 versus 1.5**	N/A
Oblizajek, 2020 [82]	Single-center, retrospective	38 (19 ED vs. 19 LD)	0 versus 0	58 versus 79	4 versus 3	21 versus 32	26 versus 6
Trikudanathan, 2018 [80]	Single-center, retrospective	193 (76 ED vs. 117 LD)	13.2 versus 4.3	6.9 versus 0.9	1 versus 1	20.6 versus 18.24***	37 versus 26
Chantarojanasiri, 2018 [81]	Single-center, retrospective	35 (12 ED vs. 23 LD)	8 versus 4	50 versus 69.5	1 versus 9	25 versus 21.7	27.5 versus 31

ED, early drainage; LD, late drainage. * Included surgical, endoscopic, and radiologic interventions. ** Only post-procedure bleeding reported. ***No difference in total AEs, including stent dysfunction, bleeding, fistulae, and new onset diabetes. There were 7 cases of perforation in LD and none with ED.

metal stent (SEMS). However, both methods are somewhat limiting. While a S-GJ can provide longer palliation than SEMS, its use is offset by the high morbidity and mortality associated with surgery in already frail patients with a poor performance status [60]. Meanwhile, enteral stenting (with SEMS) can produce comparable clinical results, yet these benefits are short-lived due to due to recurrent obstruction that occurs in 50% of patients within 6 months [59, 61]. The goal for managing GOO is to relieve the obstruction and allow patients to resume peroral intake.

In this context, the application of EUS-guided gastroenterostomy (GE) is a safe and effective, minimally invasive alternative with comparable outcomes and fewer re-interventions compared to enteral stenting [62] and S-GJ [63], when performed by expert endoscopists. This is especially beneficial for patients with end-stage malignancy who are not surgical candidates. A handful of studies have explored outcomes in both benign and malignant GOO with technical and clinical success rates ranging from 87 to 100% and 84 to 92%, respectively [30, 63–66]. The ability to provide durable symptomatic relief may also be enhanced by the use of larger LAMS (20 mm) which may decrease the risk of re-obstruction and allow patients to tolerate a more regular diet [67].

When performing EUS-GE, there are various technical approaches that have been well documented in the literature, including antegrade traditional/downstream method, antegrade RV method, retrograde enterogastrostomy, EUS balloon-occluded GE bypass, direct method, and wireless/water-filling technique [68, 69]. A recent retrospective study analyzed the water-filling technique in 107 patients across three European centers with a technical success, clinical success, and AE rate of 94%, 91%, and 10%, respectively [70]. At our center, we place a nasobiliary tube at or just beyond the ligament of Treitz to distend the duodenum using a standard irrigation system as used for luminal endoscopy. After injection of glucagon to paralyze the bowel, we place a 20 mm LAMS with enhanced electrocautery tip using a "freehand" technique. At the moment, there is no method that has proven superior and comparative studies are needed to determine which approach may limit AEs.

As EUS-GE becomes more widely used, we expect this technique to become a more widely used as a therapeutic method that may potentially replace surgery as a first-line option. Indeed, in our practice, we have largely abandoned enteral SEMS in favor of EUS-GE, except in patients with a life-expectancy inferior to 3 months and those with large volume ascites.

EUS-Guided Drainage of Necrotizing Pancreatic Fluid Collections

Therapeutic EUS has also found a role in ESGE guidelines for managing complications of acute necrotizing pancreatitis by facilitating transmural drainage necrotic pancreatic fluid collections [71]. Acute pancreatitis is common cause of hospitalization, with annual costs exceeding USD 2 billion, where up to 20% of patient develop severe (necrotizing) pancreatitis [72]. Necrotizing pancreatitis, a feared sequel, is associated with a significant morbidity and mortality – especially when infection is present [73]. Infected and symptomatic fluid collections require multidisciplinary treatment [74]. Drainage and debridement are recommended once the collection encapsulates and matures, which typically takes >4 weeks [75]. With advancements in EUS, there has been a paradigm shift in endoscopically managing these collections, instead of traditional surgical necrosectomy [76]. Percutaneous drainage alone is often avoided whenever possible due to the risk of pancreatocutaneous fistula formation. The last author of this review pioneered early work in this setting, over the past few years EUS drainage of pancreatic fluid collections has evolved to the use of LAMS, with the large diameters (15 and 20 mm) for management of WON. Patients with lower percentages of necrotic debris by volume, those with collections less than 10 cm in size and lack of paracolic extension can often avoid the need for additional interventions such as direct endoscopic necrosectomy [77].

Studies have sought to compare early versus late drainage of infected, necrotic pancreatic collections when clinically indicated (Table 2) [78–82]. Overall these studies reported somewhat similar rates of AEs, though the early drainage groups appeared to require more reinterventions [78–82]. A recent meta-analysis of 6 studies with 630 patients reported no significant differences in technical success, clinical success, mortality, or overall AEs in early ($n = 182$) versus standard ($n = 448$) drainage groups [83]. The implementation of LAMS has seemingly revolutionized management by simplifying the technical aspects to potentially limit AEs. Also, the significantly larger stent diameters (15 or 20 mm) can improve drainage and decrease the number of endoscopic sessions needed [84]. A recent study comparing EUS-guided drainage with plastic stents ($n = 138$) and LAMS ($n = 28$) found no differences in mortality, complications, or resolution rates but did note LAMS were associated with a shorter time to resolution [78]. Yet, another comparative study between LAMS ($n = 78$) and traditional cystoenterostomy ($n = 78$) reported a faster resolution time favoring LAMS (86.9 vs. 133.6 days) [85]. The introduction of a larger, 20 mm LAMS, can further reduce the need for endoscopic necrosectomy [86].

EUS-Guided Ablation of Pancreatic Neoplasms

EUS-guided ablation of pancreatic cystic neoplasms has evolved as a reliable minimally invasive option – especially in patients who are poor surgical candidates. With the advent of improved cross-sectional imaging, incidental findings of pancreatic cysts are rising with no overall change in mortality [87]. Pancreatic cystic neoplasms represent a broad spectrum of clinicopathological lesions with varying degrees of malignant potential. Stratifying these lesions based on their malignant potential and presence of symptoms dictates management options i.e. surveillance versus resection [88]. In patients who require treatment, surgical resection is often associated with a high morbidity and mortality; furthermore, some patients may not be ideal operative candidates or decline surgery. It is in this setting where EUS-guided ablation techniques have emerged as an alternative treatment option [89]. Cyst ablation can be performed by injecting ablative agents (ethanol or paclitaxel) or through radiofrequency ablation (RFA). Ablation is indicated for a presumed mucinous cystadenoma or intraductal papillary mucinous neoplasms (IPMNs) that are unilocular or oligolocular, as well as cyst >3 cm or enlarging cyst with a diameter >2 cm [90]. Typically cyst measuring 2–6 cm with fewer than 6 locules respond best to ablation [90, 91]. The cyst is accessed through a transgastric or transduodenal approach where a 22 gauge or 19-gauge fine needle aspiration is used to evacuate the cyst cavity before lavage with the ablative agent takes place [89].

EUS-ablation with ethanol was first used in 2005 as a means to destroy epithelial lining through cell membrane lysis, vascular occlusion and protein denaturation with complete and partial resolution rates ranging from 9% to 78% and 14–40%, respectively [92–95]. This wide range of result was likely influenced by varying study designs, heterogeneity of cyst treated and differing concentrations of ethanol used (80–100%). In addition to varied results, the AEs associated with ethanol ablation, i.e., abdominal pain and acute pancreatitis occur not uncommonly ranging from 3.3% to 33.2% [88].

The addition of paclitaxel, a chemotherapeutic agent, has been found to improve complete cyst resolution up to 79% (Table 3) [90]. Paclitaxel was initially used following ethanol lavage in 2008 [93], whereby its hydrophobic and viscus properties were thought to reduce the chances of leaking and providing a longer duration of ablation in the

Table 3. Summary of EUS-guided ethanol and paclitaxel ablation studies

Author, year	Study design	Total subjects (types of cysts, %)	Mean diameter, mm	Ablative agent used	Median follow-up, months	Complete resolution	AEs (*n*)
Oh, 2008 [93]	Prospective, single center, pilot	14 (MCN 14%, SCA 2%, lymphangioma 21%, unknown 43%)	22.5	Ethanol 88–99% + paclitaxel	9	79%	Pancreatitis (1), abdominal pain (1), hyperamylasemia (6)
Oh, 2009	Prospective, single center	10 (MCN 30%, SCA 40%, unknown 30%)	29.5	Ethanol 99% + paclitaxel	8.5	60%	Pancreatitis (1)
Oh, 2011	Prospective, single center	52 (MCN 17%, SCA 29%, PC 4%, unknown 50%)	31.8	Ethanol 99% + paclitaxel	21.7	62%	Pancreatitis (1), splenic vein obliteration (1)
DeWitt, 2014 [92]	Prospective, single center	22 (IPMN 55% MCN 27% SCA 18%)	25	Ethanol 99% + paclitaxel	27	50%	Abdominal pain (4), pancreatitis (3), peritonitis (1), gastric wall cyst (1)
Moyer, 2016 [98]	Prospective, single center, RCT, pilot	10 (IPMN 30%, MCN 70%)	30	Ethanol 80% (5) or saline (5) followed by paclitaxel + gemcitabine	6 and 12	Ethanol arm: 6 months 50%; 12 months 75%, ethanol-free arm: 6 months 67%; 12 months 67%	Ethanol arm: pancreatitis (1), ethanol-free arm: none
Moyer, 2017	Prospective, RCT	39 (IPMN 69%, MCN 23%, indeterminate 8%)	25	Ethanol 80% (18) or saline (21) followed by paclitaxel + gemcitabine	12	Ethanol: 61%, ethanol free: 67%	Ethanol: abdominal pain (4), ethanol free: none
Kim, 2017	Prospective, single center	36 (BD-IPMN 39% MCN 44% SCA 14% PC 3%)	25.8	Ethanol 100% (8) or ethanol 100% + paclitaxel (28)	22.3	56%	Pancreatitis (4), abdominal pain (4), intracystic hemorrhage (1)
Choi, 2017	Prospective, single center	164 (IPMN 6.7%, MCN 43%, SCA 9.7%, PC 1.8%, indeterminate 38.4%)	32	Ethanol + paclitaxel	72	72%	Pancreatitis (6), PCs (2), abscess (2), intracystic hemorrhage (1), pericystic spillage (1), pancreatic duct stricture (1), splenic vein obstruction (1), portal vein thrombosis (1)

RCT, randomized control trial; SCA, serous cystadenomas; MCNs, mucinous cystic neoplasms; IPMNs, intraductal papillary mucinous neoplasms; BD, branch duct; PC, pseudocyst.

cyst itself through microtubule inhibition [89]. The synergistic effects of ethanol and paclitaxel were promising, and one study found that post-ablation neoplastic DNA mutations were disrupted and eliminated in 72% of cases [92]. Compared to ethanol ablation alone, post-ablation AEs (15 vs. 21.7%) and complete resolution rates (63.6 vs. 32.8%) are significantly improved using paclitaxel-based regimens [96]. There was a concern that post-procedural acute pancreatitis (3.3–9.8%) was associated with ethanol extravasation into the pancreatic parenchyma [88]. In an effort to determine the safety and efficacy of alcohol-free ablation, a prospective double-blind randomized trial (known as the CHARM trial) compared an admixture of paclitaxel and gemcitabine with or without 80% ethanol in a cohort of 39 patients with mucinous-type cysts [97]. The investigators found that there was no major difference in complete resolution rates (61% with and 67% without ethanol) with an added benefit of no AEs experienced in the alcohol-free cohort. In order to validate these findings on larger scale, the CHARM II trial is currently underway with an expected study completion date in April 2023 [98].

Alternatively, RFA can be performed through electromagnetic energy and high-frequency alternating currents via mono- or bipolar probe, using an echogenic 19-gauge needle tip, that can induce cell death by causing coagulative necrosis, hyperthermic injury, and a delayed immune response to the cyst in question [88, 89]. When this energy is transmitted to the targeted lesion, echogenic bubbles can be visualized on EUS. Only a handful of studies have explored RFA as means to treat pancreatic cysts and pancreatic neuroendocrine tumors (pNETS) with promising results [99–101]. A recent meta-analysis found that location of a pNET in the pancreatic head/neck was a positive predictor of clinical success [102]. The meta regression reported a pooled clinical success and AE rate of 85.2% and 14.1%, respectively [102]. A prospective multicenter study including 16 IPMNs, 14 pNETs, and 1 mucinous cyst adenoma reported a very low AE rate (only two events occurring in the first 2 patients treated), which was virtually eliminated when prophylactic measures (i.e., antibiotics, rectal diclofenac and cyst aspiration before RFA) were taken [99]. Of note, in regards to pNETs, the best results appear to be for treatment of insulinomas and non-functional pNETs ≤2 cm.

Still in its infancy, EUS-guided ablation may prove useful in selected patients with high risk or symptomatic pancreatic cysts, further studies will be needed to determine if there is a cost saving and/or mortality reducing component. In patients who are not surgical candidates, it is possible that EUS-guided ablation could alter surveillance recommendations moving forward, though comparative studies are needed. In current guidelines, EUS-guided cyst ablation should not be performed outside a dedicated investigation protocol.

EUS-Guided Coil Embolization

While esophageal varices are more common, GVs are associated with severe bleeding, higher mortality rates, and rebleeding episodes [103]. The therapeutic endoscopic armamentarium for GV is somewhat limited, though in recent years EUS methods have found a role in managing these serious bleeds. Injecting cyanoacrylate glue has traditionally been used to resolve acute bleeding and provide secondary prophylaxis. Yet, bleeding is influenced by the size and wall tension of the varix, and endoscopic injection of glue does not always allow for full visualization, which can increase the risks of rebleeding. Furthermore, this technique is technically challenging and associated with severe AEs, including systemic embolization [104]. Other disadvantages include inadvertent unroofing of the varix, deep ulcerations at the injection site, and damage to the endoscope itself [105].

In this context, EUS-guided injection provides unique luminal views that can fully characterize the varix and confirm obliteration on doppler ultrasound while reducing the risks of glue embolization (Fig. 3) [106]. Utilizing this approach, EUS-guided coil embolization has been investigated as an additional hemostatic method that promotes clot formation [104]. In a large study of 152 patients, combination therapy with cyanoacrylate glue and coils was technically successful in 99% of cases with only three episodes of post-treatment bleeding [107]. The coils serve as a scaffold with synthetic fiber that contains and minimizes the amount of glue needed [108]. Compared to glue injection alone, combination therapy requires fewer endoscopic sessions while limiting AEs [109]. A recent randomized trial compared combination (cyanoacrylate plus coil) therapy (n = 30) to coil monotherapy (n = 30) and found that combination therapy led to significantly higher rates of obliteration (86.7 vs. 13.3%) with lower rates of rebleeding or reintervention needed [110].

In an effort to further describe the benefits of combination therapy, a recent meta-analysis of 11 studies with 536 patients, confirmed that combination therapy resulted in higher rates of technical and clinical success compared to cyanoacrylate alone [111]. In terms of AEs, combination therapy and coil monotherapy demonstrated comparable results (10 vs. 3%), while cyanoacrylate injec-

tion was associated with a 21% adverse even rate [111]. Interestingly, recent studies have postulated the replacement of glue with an absorbable gelatin sponge (AGS), which is typically used as a hemostatic agent in interventional radiology and surgical procedures [105, 112, 113]. The AGS is a purified water-insoluble plug that can absorb 45 times its volume in blood [105, 112, 113]. An added benefit is that it is not associated with post-treatment ulceration and cannot damage the endoscope. In a matched cohort study, the use of coil embolization plus AGS was superior to glue injection alone in terms of lower rebleeding rates, transfusion requirements and rates with up to 9 months of follow-up [112]. The authors added that in their cohort they used more coils (~8 per case) compared to 1–3 coils used in a prior study [114]. Their thought process was that using a significantly larger coil volume could aggressively obliterate feeder vessels at multiple vascular points [112]. While this technique is promising, AGS is not FDA approved and is therefore limited in use.

Another alternative is the use of thrombin injection, which can achieve hemostasis by converting fibrinogen to fibrin thereby promoting clot production and platelet aggregation [115]. One study by Frost and Hebbar [115] demonstrated the feasibility and efficacy of this approach using an EUS-guided injection technique. The authors treated 5 patients for primary prophylaxis and three with active bleeding using EUS-thrombin – and found that only 1 patient with active bleeding failed to achieve hemostasis [115]. There were no AEs. Another randomized control trial (RCT) by Lo et al. [116] compared endoscopic thrombin ($n = 33$) to cyanoacrylate ($n = 35$) and found that both groups had similar rates of hemostasis, but the thrombin cohort experienced lower rates of AEs (12 vs. 51%) with no instances of gastric ulceration. Other added benefits of thrombin are the excellent safety profile (minimal risk of embolism or ulceration compared to glue injection) and ease of use. Additional EUS-guided studies are needed to determine its role in variceal hemorrhage.

The rapid adaptation of EUS-guided coil embolization is emerging as a promising treatment option for GV. The ability to decrease complications while maintain effective hemostasis should reduce the costs associated with GV bleeding, though further studies will be needed.

EUS-Guided Gallbladder Drainage for Acute Cholecystitis

EUS-guided gallbladder drainage (EUS-GBD) has also emerged as novel and clinical useful management option in patients with symptomatic cholelithiasis and/or acute cholecystitis who are not optimal surgical candidates. In instances of acute cholecystitis, early laparoscopic cholecystectomy remains the gold standard [117]. However, patients with advanced age, poor performance status, significant comorbidities, or prior abdominal surgery causing adhesions may be unfit for surgery due to high rates of morbidity and mortality [118]. A delay in surgery can increase the risk of gallstone-related complications by 14% at 6 weeks, 19% at 12 weeks, and 29% at 1 year [119]. Thus, providing alternative routes of decompression via a percutaneous or endoscopic approach have been investigated. Traditionally, a percutaneous cholecystostomy has been performed, though tube maintenance, dysfunction and patient discomfort are often challenging for patients [118]. A percutaneous approach may worsen a patient's quality of life, while also increasing costs associated with long-term care issues related to readmissions and reinterventions, with AEs ranging from 4% to 51% [120].

Since its first description in 2007 by Baron and Topazian, EUS-GBD has rapidly evolved with improved clinical outcomes following the introduction of LAMS [121]. Over time, the use of plastic stents, SEMS, and then LAMS has led to ongoing technical and clinical success with a dramatic reduction in AEs (18.2% plastic stent, 12.3% SEMS, 9.9% LAMS) [122]. When compared to percutaneous drainage, EUS-GBD serves an opportunity to treat poor surgical candidates through a minimally invasive approach that lowers rates of reintervention and unplanned readmissions [120, 123–126]. Two recent comparative meta-analyses found no difference in technical or clinical success; however, they demonstrated that EUS-GBD was associated with lower AEs, shorter hospital stays, and fewer reinterventions which lead to decreased readmissions [120, 124]. Similar findings were seen in a randomized control trial of 80 patients undergoing EUS or percutaneous gallbladder drainage in high risk surgical candidates [123]. It has also been associated with significantly lower post-procedural pain [126].

When compared to the gold standard (laparoscopic cholecystectomy), a propensity score analysis found that EUS-GBD was comparable (technical success 100 vs. 100%, clinical success 93.3 vs. 100%, 30 day AEs 13.3 vs. 10%) – suggesting this method can be considered as a reliable alternative in patients who are not ideal operative candidates [127]. It has also been studied in 15 patients with cirrhosis (average MELD 15 ± 7) with a technical success rate of 93.3% and two AEs (1 mild, 1 severe) [128].

With increasing use of EUS-GBD with LAMS, higher risk patients are being treated. It is important to comment that with a permanent fistula created with LAMS a bridge to laparoscopic cholecystectomy may not be possible [118]. Though successful surgery has been documented in patients stented with plastic stents [129]. Future studies may yet demonstrate the feasibility of safe laparoscopic resection after LAMS placement, perhaps after resolution of inflammatory changes, endoscopic removal of LAMS, and fistula closure.

Conclusion

Over the past 20-years therapeutic, EUS has catapulted itself as reliable therapeutic tool that has expanded the field of interventional gastroenterology. Translating theoretical implications into practical methods has allowed EUS-guided therapies to change practice management worldwide. We believe it is inevitable that EUS-guided transmural biliary drainage will be accepted as an alternative to ERCP for the relief of malignant biliary obstruction. Similarly, EUS-guided GE will also become the accepted treatment for relief of malignant GOO over S-GJ and endoscopic luminal stent placement. Yet, at the present time, a lack of standardized training and limited expertise will confine these techniques to high volume centers where multidisciplinary ancillary support is required.

Statement of Ethics

This is an invited review article, as such ethics approval does not apply.

Conflict of Interest Statement

Dr. Todd H. Baron is a consultant and speaker for Boston Scientific, W.L. Gore, Cook Endoscopy, and Olympus America. Dr. Andrew Canakis declares no relevant funding for this work. All authors disclosed no financial relationships.

Funding Sources

None.

Author Contributions

Andrew Canakis: performed research, collected, and wrote the paper. Todd H. Baron: designed the study and revised the paper. All authors approved the final version of the manuscript.

Data Availability Statement

All data generated or analyzed during this study are included in this article. Further inquiries can be directed to the corresponding author.

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GE – Portuguese Journal of Gastroenterology

Review Article

GE Port J Gastroenterol 2023;30(suppl 1):19–34
DOI: 10.1159/000527202

Received: April 1, 2022
Accepted: August 22, 2022
Published online: November 7, 2022

Best Practices in Esophageal, Gastroduodenal, and Colonic Stenting

Renato Medas[a, b] Joel Ferreira-Silva[a, b] Mohit Girotra[c] Monique Barakat[d]
James H. Tabibian[e, f] Eduardo Rodrigues-Pinto[a, b]

[a]Gastroenterology Department, Centro Hospitalar São João, Porto, Portugal; [b]Faculty of Medicine of the University of Porto, Porto, Portugal; [c]Digestive Health Institute, Swedish Medical Center, Seattle, WA, USA; [d]Division of Gastroenterology, Stanford University, Stanford, CA, USA; [e]Division of Gastroenterology, Department of Medicine, Olive View-UCLA Medical Center, Sylmar, CA, USA; [f]UCLA Vatche and Tamar Manoukian Division of Digestive Diseases, David Geffen School of Medicine at UCLA, Los Angeles, CA, USA

Keywords
Endoscopic stenting · Esophageal obstruction · Gastric outlet obstruction · Colonic obstruction

Abstract
Endoscopic stenting is an area of endoscopy that has witnessed noteworthy advancements over the last decade, resulting in evolving clinical practices among gastroenterologists around the world. Indications for endoscopic stenting have progressively expanded, becoming a frequent part of the management algorithm for various benign and malignant conditions of the gastrointestinal tract, from esophagus to rectum. In addition to expanded indications, continuous technological enhancements and development of novel endoscopic stents have resulted in an increased success of these approaches and, in some cases, allowed new applications. This review aimed to summarize best practices in esophageal, gastroduodenal, and colonic stenting.

Melhores Práticas Em Próteses Endoscópicas Esofágicas, Gastroduodenais e Colorretais

Palavras Chave
Próteses endoscópicas · Estenose esofágica · Obstrução de saída gástrica · Estenose cólica

Resumo
A colocação de próteses endoscópicas é uma técnica que tem testemunhado avanços notáveis na última década, resultando na evolução da prática clínica diária dos gastroenterologistas em todo o mundo. As indicações para a colocação de próteses endoscópicas têm expandido progressivamente, tornando-se uma opção cada vez mais frequente no algoritmo de abordagem das mais variadas condições benignas e malignas do trato gastrointestinal (desde o esófago ao reto). Além da expansão nas indicações, o aprimoramento tecnológico contínuo e o desenvolvimento de novas próteses endoscópicos resultaram num maior sucesso dessas abordagens e, em alguns casos, permitiram novas aplicações. Esta revisão tem como objetivo resumir as melhores práticas em colocação de próteses endoscópicas esofágicas, gastroduodenais e colorretais.

Karger@karger.com
www.karger.com/pjg

Correspondence to:
Eduardo Rodrigues-Pinto, edu.gil.pinto@gmail.com

Introduction

Over the last few years, therapeutic endoscopy has evolved into the preferred approach, or at least a valid alternative, for management of several gastrointestinal (GI) conditions, wherein surgery was considered the standard therapy for decades [1]. Endoscopic stenting is one such aspect of therapeutic endoscopy that has witnessed noteworthy advancements. Traditionally, the main indications for endoscopic stenting were limited to the palliation of malignant disorders, such as obstructive esophageal cancer, malignant gastric outlet obstruction (GOO), and malignant colonic obstruction [2]. More recently, indications for endoscopic stenting have gradually expanded to include a variety of nonmalignant/non-obstructive disorders, such as external compression of the GI tract, GI transmural defects (e.g., perforations, fistulae, and leaks), and selected cases of refractory benign strictures [3]. Moreover, advances in biotechnology and clinical expertise have helped mitigate stent-related adverse events (AEs) [4]. In this review, we aim to summarize the evidence and experience supporting the best practices in luminal endoscopic stenting, with a specific focus on esophageal, gastroduodenal, and colonic stenting (Table 1).

Esophageal Stenting

Malignant Esophageal Cancer

Palliation of Malignant Dysphagia

The main goal of esophageal stenting is palliation of malignant dysphagia in patients with esophageal cancer to improve nutritional intake. Although stenting provides a rapid relief of dysphagia symptoms, it is preferable in patients with an expected short survival (<3 months) (Fig. 1) [5]. A meta-analysis by Wang et al. included three randomized clinical trials (RCTs) and showed similar outcomes between fully covered self-expandable metal stent (FC-SEMS) and partially covered SEMS (PC-SEMS), without differences in stent migration, obstruction, or bleeding [6]. Pooled data from available studies showed a major AE rate of 18% with PC-SEMS and 21% with FC-SEMS (most frequently reflux, severe pain, bleeding, and ingrowth/overgrowth) [7]. Different stent designs have been developed in order to prolong stent patency and reduce AEs; however, this is hard to accomplish as stents do not affect natural history of the disease. Regarding anti-reflux stents, for example, a 2019 meta-analysis [8] and a subsequent RCT [9] failed to prove their superiority regarding improvement of reflux, dysphagia score, or related AEs (stent migration, bleeding, and obstruction).

One major drawback of stent use in patients with longer survival is the increased risk of stent dysfunction and AE occurrence. Even though SEMSs are associated with earlier symptom relief, for patients with longer expected survival (≥3 months), brachytherapy seems to provide better quality of life, long-term dysphagia relief, and fewer AEs, when compared to SEMS placement [10, 11]. However, despite being associated with better long-term results, brachytherapy is underused in clinical practice [12, 13]. Overall severe AEs from brachytherapy alone may occur in up to 23% of cases, mostly including brachytherapy-related stenosis (12%) and fistula formation (8%) [14]. The effect of combined brachytherapy and stenting on AE rates is not completely clear; however, it seems to provide better dysphagia relief in patients with survival longer than 3 months and higher overall survival, compared to SEMS alone [15]. Patients may also be palliated with external beam radiotherapy (EBRT) alone [16, 17]. A recent propensity score-matched analysis that compared EBRT alone with brachytherapy alone suggested that EBRT may offer a faster and safer dysphagia relief compared to brachytherapy, with similar long-term outcomes [18]. A recent RCT that compared EBRT alone with a combination of EBRT and chemotherapy found that EBRT alone had similar dysphagia relief and survival as the combination therapy, but fewer AEs [19].

Some retrospective cohorts evaluated patients submitted to SEMS placement, with ≥6-month survival, and concluded that SEMS may be a valid alternative, especially in centers where brachytherapy is not widely available. Despite the increased risk of AEs over time, most of them can be managed endoscopically [20–22].

Irradiation stents have been developed to combine advantages of both SEMS and radiotherapy. A 2017 [23] and a 2021 [24] meta-analysis comparing irradiation SEMS (loaded with ^{125}I beads) versus traditional SEMS showed prolonged patient survival and stent patency with irradiation stents, with no differences in AE rates. Biodegradable stent (BDS) role in the palliation of malignant dysphagia is not adequately defined and should not yet be considered a valid alternative to SEMS [25].

Recommendation: Patients with life expectancy of less than 3 months or suffering from severe dysphagia should be considered for SEMS placement. FC- or PC-SEMS may be considered. Brachytherapy should be considered when available in patients with expected longer survival.

Table 1. Summary of best evidence for each indication regarding different types of stents

Section	Subsection	Author, year	Indication/study design	Participants	Technical and clinical success	Outcomes
Esophageal stenting	Palliative esophageal cancer	Wang, et al., 2020 [6]	Systematic review and meta-analysis including 3 RCTs, 1 prospective and 1 retrospective cohort studies	542 patients 229 (42.3%) FC-SEMS versus 313 (57.7%) PC-SEMS	No differences in technical success (OR 1.22 [0.30–5.03])	No differences in migration rate (OR 0.63 [0.37–1.08]), stent obstruction due to tumor overgrowth (OR 0.81 [0.47–1.39]), bleeding (OR 0.57 [0.21–1.58]), and chest pain (OR 1.06 [0.44–2.57])
		Pandit, et al., 2019 [8]	Systematic review and meta-analysis including 8 RCTs	395 patients 192 (48.6%) anti-reflux stent versus 203 (51.4%) standard stent	–	No differences in dysphagia (SMD –0.33 [–0.71, 0.05]), GERD score (SMD –0.17 [–0.78, 0.45]), stent migration (OR 1.37 [0.66–2.83]), bleeding (OR 1.43 [0.40–5.13]), or stent occlusion (OR 1.66 [0.60–4.60])
		Dua, et al., 2019 [9]	RCT	60 patients 30 (50.0%) anti-reflux stent versus 30 (50.0%) standard stent	Technical success 100% in both groups	No differences in dysphagia improvement and GERD score. Similar rates of stent migration (44 vs. 38%, $p = 0.29$)
	Refractory benign esophageal stricture	Fuccio, et al., 2016 [46]	Systematic review and meta-analysis including 10 prospective and 8 retrospective cohort studies	444 patients 227 (51.1%) FC-SEMS versus 140 (31.5%) SEPS versus 77 (17.4%) BDS	Overall clinical success 40.5% No differences in clinical success (SEMS 40.1%, SEPS 46.2%, BDS 32.9%)	No differences in migration rate (SEMS 31.5%, SEPS 33.3%, BDS 15.3%) and overall AE rate (SEMS 21.9%, SEPS 19.4%, BDS 21.9%)
		Law et al., 2018 [52]	Systematic review and meta-analysis including 7 retrospective case-control studies and 7 case series	212 patients All patients underwent stent fixation (90.6% FC-SEMS)	Technical success 96.7% Clinical success 100%	Stent migration rate 15.9% Suture-related AEs 3.7%
		Park et al., 2022 [53]	Retrospective cohort study	433 procedures 239 (55.0%) without fixation versus 140 (32.0%) with suturing versus 54 (12.0%) with OTSC	Clinical success 43.0%	OTSC had lower migration rate (35% OTSC vs. 57% suturing vs. 62% without fixation, $p = 0.0013$) and higher median time to migration (6-week OTSC vs. 5-week suturing vs. 3-week without fixation, $p = 0.0023$)
	Leaks, perforations, and fistulas	Dasari et al., 2014 [66]	Systematic review of 27 case series	340 patients 117 (34.4%) SEMS 148 (43.5%) SEPS 70 (20.6%) both SEPS/SEMS used 5 (1.5%) BDS	Technical success (SEMS 96.5 vs. SEPS 89.9%, $p = 0.025$). Similar clinical success (86.2 vs. 86.2%)	SEMS (vs. SEPS) had lower risk of migration (11.0% vs. 27.0%, $p = 0.09$) and endoscopic reintervention (5.0% vs. 22.0%, $p = 0.09$). No differences in stent perforation or bleeding
		Kamarajah et al., 2020 [67]	Systematic review including 3 prospective and 63 retrospective cohort studies	995 patients 810 (81.4%) SEMS 185 (18.6%) SEPS	Higher technical success with SEMS (95 vs. 91%, $p = 0.032$). No difference in clinical success (83 vs. 82%, $p = 0.605$)	SEPS had higher migration rates (24 vs. 16%, $p = 0.001$) and need of repositioning (11 vs. 3%, $p < 0.001$). No differences in overall perforation rate (2 vs. 1%, $p = 0.126$), bleeding (1 vs. 1%, $p = 0.710$)
		van Boeckel et al., 2011 [68]	Systematic review of 25 nonrandomized clinical studies	267 patients 159 (59.6%) SEPS versus 34 (12.7%) FC-SEMS versus 74 (27.7%) PC-SEMS	No differences in clinical success (SEPS 84%, FC-SEMS 85%, PC-SEMS 86%, $p = 0.97$)	Stent migration was more frequent in SEPS group (31% SEPS, 26% FC-SEMS, 12% PC-SEMS, $p < 0.001$). No difference in tissue in- and overgrowth (3% SEPS, 7% FC-SEMS, 12% PC-SEMS, $p = 0.68$)
	Variceal bleeding	Marot et al., 2015 [89]	Systematic review and meta-analysis including 1 RCT and 12 case series	146 patients (100%) placed FC-SEMS	Technical success 95.0%	Pooled estimated rate for failure to control bleeding (0.18 [0.11–0.29]), rebleeding after stent removal (0.16 [0.04–0.48]), migration rate (0.28 [0.17–0.43])
Gastroduodenal stenting	Malignant GOO	Minata et al., 2016 [103]	Systematic review and meta-analysis including 5 RCTs	443 patients 221 (49.9%) C-SEMS versus 222 (50.1%) U-SEMS	No differences in technical (RD 0.00 [–0.04 to 0.04]) and clinical success (RD 0.02 [–0.03 to 0.07])	U-SEMS had lower risk of migration (RD 0.09 [0.04–0.14]) and higher risk of obstruction (RD –0.21 [–0.27, –0,15]) No differences in bleeding (RD –0.01 [–0.03 to 0.02]), perforation (RD 0.01 [–0.01 to 0.03]), fracture (RD 0.01 [–0.02 to 0.04]), or reintervention (RD –0.03 [–0.11 to 0.06])

Table 1 (continued)

Section	Subsection	Author, year	Indication/study design	Participants	Technical and clinical success	Outcomes
Colonic stenting	Malignant obstruction	Mashar et al., 2019 [121]	Systematic review and meta-analysis including 1 RCT, 7 prospective and 2 retrospective cohort studies	753 patients 301 (40.0%) C-SEMS versus 452 (60.0%) U-SEMS	No differences in technical (RR 1.02, $p = 0.21$) and clinical success (RR 1.03, $p = 0.32$)	U-SEMS associated with lower risk of overall complications (RR 0.57 [0.44–0.74]), tumor overgrowth (RR 0.29 [0.09–0.93]), and stent migration (RR 0.29 [0.17–0.48]) and longer patency (SMD 18.47 [10.46–26.48]), but higher risk of tumor ingrowth (RR 4.53 [1.92–10.69])
		Yang et al., 2013 [122]	Systematic review and meta-analysis including 1 RCT, 2 prospective cohort studies	176 patients 85 (48.3%) C-SEMS versus 91 (51.7%) U-SEMS	No differences in technical (RR 0.98 [0.93–1.03]) and clinical success (RR 1.00 [0.96–1.05])	C-SEMS associated with lower risk of tumor ingrowth (RR 0.21 [0.06–0.70]), but higher risk of overgrowth (RR 2.68 [0.54–13.3]) and stent migration (RR 11.70 [2.94–48.27])
		Zhang et al., 2012 [123]	Systematic review and meta-analysis including 1 RCT and 3 prospective and 2 retrospective cohort studies	464 patients 246 (53.0%) U-SEMS versus 218 (47.0%) C-SEMS	No differences in technical (RR 1.01 [0.98–1.04]) and clinical success (RR 1.03 [0.98–1.09])	U-SEMS associated with higher risk of tumor ingrowth (RR 5.59 [2.23–16.10]), prolonged stent patency (SMD 15.34 [4.31–26.37]), and lower late migration rate (RR 0.25 [0.08–0.80]). No differences in tumor overgrowth (RR 0.33 [0.09–1.22]), early migration (RR 0.73 [0.27–2.00]), perforation (RR 0.50 [0.08–3.11]), and overall complications (RR 0.79 [0.58–1.09])

BDS, biodegradable stent; SEMS, self-expandable metal stent; FC, fully covered; PC, partially covered; C, covered; U, uncovered; SEPS, self-expandable plastic stents; OR, odds ratio; RD, risk difference; RR, relative risk; SMD, standardized mean difference.

Bridge-To-Surgery Patients

In the curative setting, as bridge to surgery, SEMS placement is not recommended by most recent guidelines, since it may be associated with worse oncologic outcomes, a lower rate of R0 resection, increased 3-year follow-up recurrence, lower overall survival, and a higher rate of major AEs [26, 27]. Although some recent studies reported no differences in R0 resection rate and overall survival, SEMS placement may increase postoperative morbidity and mean operative time making surgery more challenging [28–30]. Nevertheless, esophageal stents are helpful to ameliorate nutritional status during or before neoadjuvant therapy and/or surgery [31]. Only two studies addressed the potential advantages of esophageal stents compared to standard feeding techniques, with SEMS being associated with lower rates of chemoradiotherapy interruption, greater improvement of albumin, lower body weight loss, and major operative complications, when compared to feeding tube or oral nutrition [32], while SEPSs were considered at least as safe and effective as surgical jejunostomy (no differences in weight loss and albumin) [33]. Available studies lack information about stent dwell time till surgery [29, 31, 34, 35]. However, a study reported no differences between SEMS and non-SEMS groups in median time from diagnosis-to-surgery (132 vs. 140 days, $p = 1.0$) [30].

Recommendation: Currently, SEMSs are not recommended in the curative setting, as bridge to surgery.

Esophago-Respiratory Fistulas

When a fistula develops between the esophagus and trachea or bronchi, the underlying malignancy is invariably incurable, regardless of the primary site. This condition is associated with a poor survival, so palliative management is preferred in most cases [36]. Esophageal stents may be used for treatment of malignant tracheo- and bronchoesophageal fistulas, due to their safety and effectiveness profile, with lower morbidity and mortality compared to surgery [37]. The reported clinical success of SEMS ranges from 67 to 100%, and reintervention is needed in up to 39% of the cases, mainly due to stent migration, persistent fistula, and aspiration [38].

Combined placement of stents in both the esophagus and the tracheobronchial tree is another management strategy for esophago-respiratory fistulas (ERF), being indicated if esophageal stenting could compromise the respiratory tract via extrinsic compression (more likely in mid-/proximal ERF); if there is a pre-existing tracheal stenosis; and in cases of large fistulas (>20 mm) [39–41]. However, patients who require dual esophageal and airway stenting are at risk

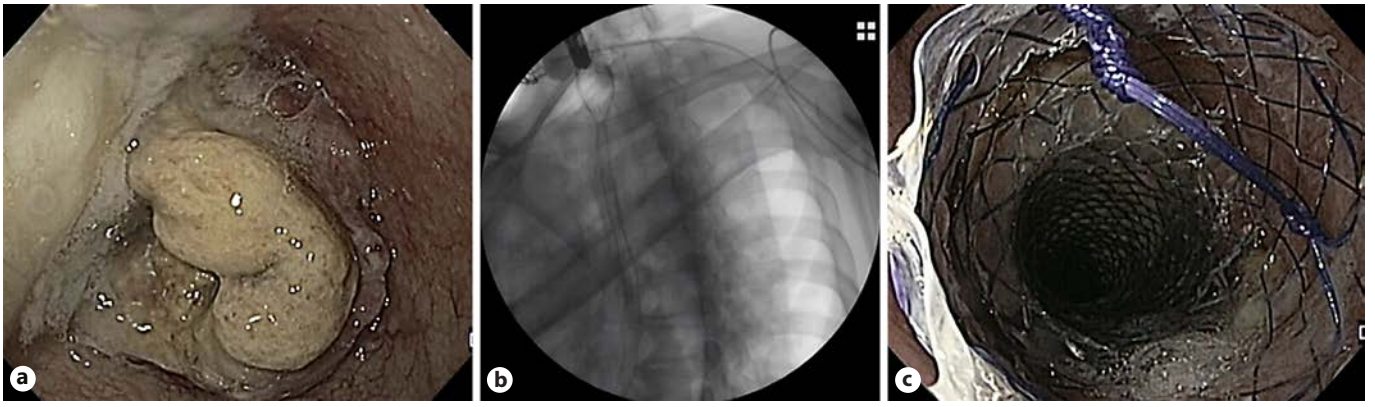

Fig. 1. Patient with dysphagia secondary to an esophageal squamous cell carcinoma located in the mid esophagus. **a** Endoscopic image showing proximal view of the lesion. **b**, **c** Fluoroscopic and endoscopic images after placement of a partially covered 150 × 20 mm self-expandable metal stent.

for fistula worsening due to pressure necrosis on both sides of the fistula from the two opposing stents [42]. Bronchoesophageal fistulas are reported in 5–10% of patients with esophageal cancer; in most of these cases, placement of a single stent, either a tracheobronchial or an esophageal stent, is enough to seal the fistula [43].

If double stenting is performed, airway stenting should be placed first to reduce the risk of airway compromise and the risk of esophageal stent migration [44]. Mean survival does not seem to be impacted by single or double stenting [45].

Recommendation: FC-SEMS or PC-SEMS can be considered for the treatment of ERF, as long as the fistula is covered by the stent membrane. Double stenting should be considered if risk of respiratory tract compromise secondary to the esophageal SEMS, if pre-existing tracheal stenosis and if large fistulas (>20 mm).

Benign Disorders

Refractory Benign Esophageal Strictures

Esophageal stents have been studied as an option for refractory benign esophageal strictures (RBES). They should only be considered after therapeutic failure of other endoscopic alternatives, like dilation or incisional therapy. A 2015 meta-analysis from Fuccio et al. [46] (n = 444) reported a clinical success of 40.5% and an overall AE rate of 20.6%, with stent migration being the most common AE (28.6%). To prevent stent migration, a variety of techniques and devices have been used with FC-SEMS, such as through-the-scope clips [47], over-the-scope clips (OTSC) [48], and endoscopic suturing [49]. Different retrospective single-center and multicenter studies [49–51] and a meta-analysis [52] support the supposition that endoscopic stent fixation in benign esophageal stenting prevents stent migration. Only one study compared different stent fixation techniques, with OTSC significantly decreasing stent migration rates as compared to no fixation or endoscopic suturing, while also increasing clinical success rate [53]. Two studies found that previous stent migration was a risk factor for similar future events; therefore, stent fixation should be considered in patients with high risk for stent dislocation and/or previous stent migration.

A stent dwell time of 6–12 weeks is recommended, to allow stricture remodeling and at the same time prevent stent embedment [26]. FC-SEMSs are preferable over PC-SEMS for RBES treatment, since PC-SEMSs are associated with stent embedment, leading to an increased risk of AEs during stent removal [54]. Despite different available methods for embedded PC-SEMS removal (stent-in-stent [SIS], argon plasma coagulation, overtube technique, inversion technique), comparative studies for these different techniques are lacking. Overtube and inversion techniques employ shear forces on a distinct area to facilitate stent extraction; however, these techniques may be more invasive and potentially lead to perforation. Argon plasma coagulation technique, by using heat for removal, is less complicated but could potentially fail in severe cases. SIS technique (placement of FC-SEMS overlapping the embedded PC-SEMS, followed by removal of both after 10–14 days) is more expensive and time-consuming, but it is the best-studied procedure and is usually recommended because of the lowest expected complication rate [55].

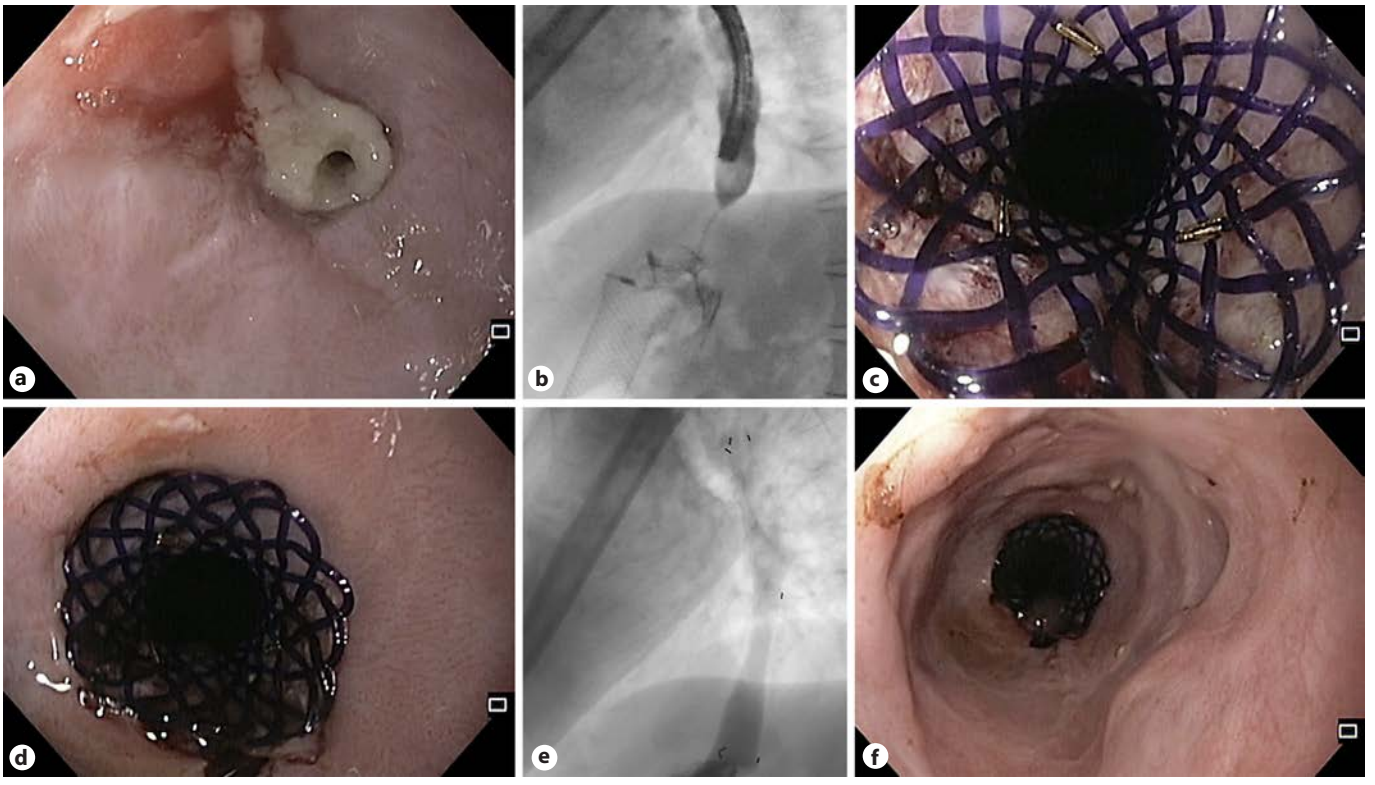

Fig. 2. Patient with a refractory benign esophageal stricture due to caustic ingestion, submitted to multiple endoscopic treatments (Savary and balloon dilatation, fully covered self-expandable metal stent placement). **a** Endoscopic image of esophageal stricture. **b** Fluoroscopic image revealing a 2-cm-long stricture after contrast instillation. **c–f** Endoscopic and fluoroscopic images after placement of a 25/20/25 × 100-mm biodegradable noncovered stent.

A meta-analysis of 18 studies did not show significant differences in clinical success, stent migration, and complication rates between BDS, SEMS, or SEPS [46]. However, patients with BDS (Fig. 2) may require fewer endoscopic reinterventions [56–58]. Despite this, updated European Society of Gastrointestinal Endoscopy (ESGE) guidelines do not recommend BDS over other stents [26]. Lumen-apposing metal stents (LAMSs) also have been evaluated for RBES, but available data are limited to small case series [59–62]. They may be considered in patients with short RBES up to 10 mm (Fig. 3). In patients with persistent dysphagia despite stent placement, surgery should be considered. Self-dilatation with boogies may be an option for poor surgical candidates [63].

Recommendation: Temporary placement of self-expandable stents may be considered for RBES. No recommendation can be made regarding a specific type of expandable stent. When SEMSs are used, FC-SEMS should be preferred. Stent fixation techniques can be used to mitigate migration risk.

Leaks, Perforations, and Fistulas

Recent advances in endoscopy have prompted a paradigm shift in the management of esophageal leaks, perforations, and fistulas, from surgery to minimally invasive endoscopic approaches [64]. Even though these terms are often used interchangeably, in strict terms, they are completely different [65]. Therefore, their treatment should be individualized.

Based on three systematic reviews on the use of PC-SEMS, FC-SEMS, and SEPS in anastomotic leaks and perforations, the clinical success rate of esophageal stent placement is 81–87%, with no difference among the stent types [66–68]. Only two studies [69, 70] evaluated fistulas individually, with clinical success ranging from 45.5 to 90.1%; however, SEMSs were used almost always in combination with other endoscopic/pulmonary techniques; clinical success decreased with orifice size increase [69]. Huh et al. [71] and Suzuki et al. [72] reported higher clinical success for perforations compared to leaks (100% vs. 60–80%), with anastomotic leak group needing a longer

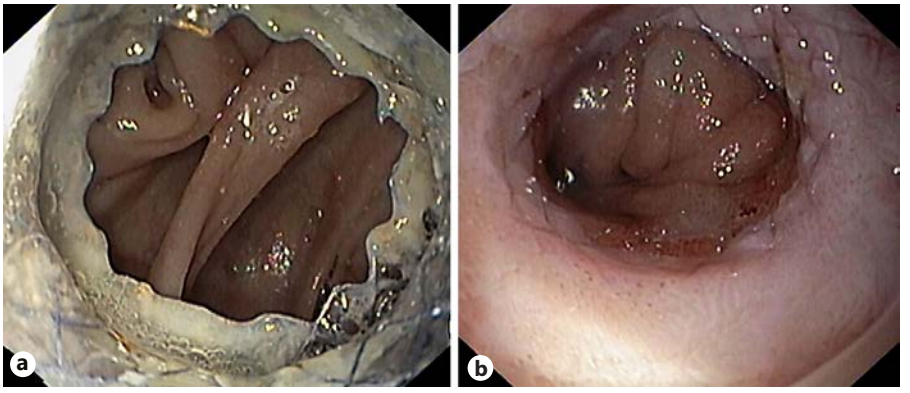

Fig. 3. Patient with a refractory esophagojejunal anastomotic stricture who underwent placement of a lumen-apposing metal stent (LAMS) across the stricture. **a** Endoscopic image of the LAMS placed across the stricture. **b** Esophago-jejunal anastomotic stricture remodeling after LAMS removal.

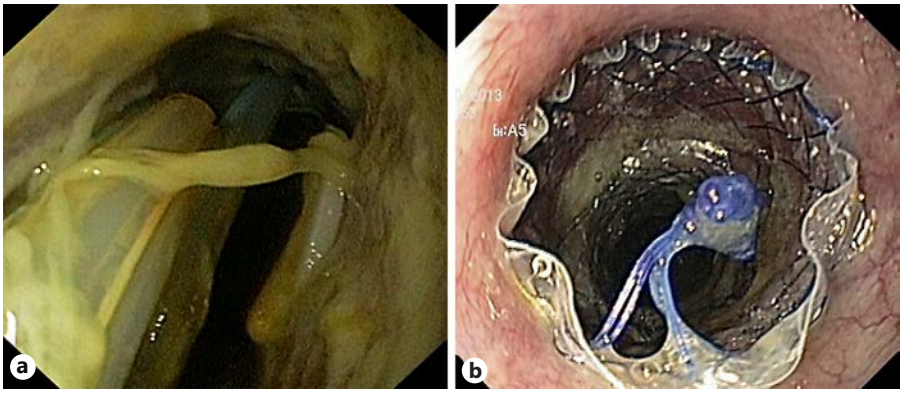

Fig. 4. Patient with an anastomotic leak after total gastrectomy. **a** Endoscopic image showing an anastomotic leak occupying more than 50% of the luminal circumference. **b** Immediately after placement of a fully covered self-expandable metal stent.

stent dwell time (≥4 weeks) compared with the perforation group (75% vs. 27.3%, $p = 0.022$). Overall AEs ranged from 3.8 to 50% [70, 71, 73, 74], with stent migration (8.5–42%) [67, 74–78] and strictures or stent-induced ulcers (3–48%) [73, 79] being the commonest. Even though stent-related AEs are typically managed endoscopically, severe AEs (14.7%) [80] can occur, requiring nonendoscopic advanced management.

The selection of the right stent design also remains a challenge (Fig. 4). Even though clinical success rates are comparable, SEMSs perform better than SEPS in leaks and perforations, with higher technical success (95% vs. 91%, $p = 0.032$), reduced risk of migration (16% vs. 24%, $p = 0.001$), and need for stent repositioning (3% vs. 11%, $p < 0.001$), as well as lower risk of perforation when considering anastomotic leaks only (0% vs. 2%, $p = 0.013$) [67]. Migration rates are higher with FC-SEMS versus PC-SEMS (odds ratio [OR] 2.44, 95% CI 1.13–5.31; $p = 0.024$) [77]; however, suturing FC-SEMS may render migration rates similar to PC-SEMS (adjusted OR 0.56, 95% CI 0.15–2.00; $p = 0.37$), without the difficulties in removal of PC-SEMS and a lower risk of AEs (21% vs. 46%, $p = 0.37$) [51]. Shim technique (silk thread attached to proximal end of the stent and to the patient ear via the nares) [81] as well as stents with wider diameters [77, 82] may also result in lower migration rates. Data regarding the role of BDS in management of esophageal transmural defects are limited. Only two studies, comprising 13 and 4 patients, are available: despite a clinical success of 77.8–100%, mucosal reaction (2/4 patients) is a drawback, causing dysphagia and requiring endoscopic dilation [83, 84].

Predictive factors for stent failure/mortality include persistence of fistula orifice after 6 months of endoscopic treatment (OR 44, 95% CI 3.38–573.4; $p = 0.004$) [69], larger fistula size [69], if stent was used after failure of revisional therapy compared with stent used as initial treatment (55% vs. 100%, $p = 0.013$) [73], continuous leakage after stent placement [85], decreased physical performance preoperatively [85], and concomitant esophagotracheal fistula [85]. Van Halsema et al. [86] developed a prediction rule for successful stent placement in the context of benign upper GI leakage, consisting of etiology, location, size of the leak, and C-reactive protein level at diagnosis. Iatrogenic/spontaneous perforation (vs. leaks or fistulas), proximal defect location (<25 cm from the

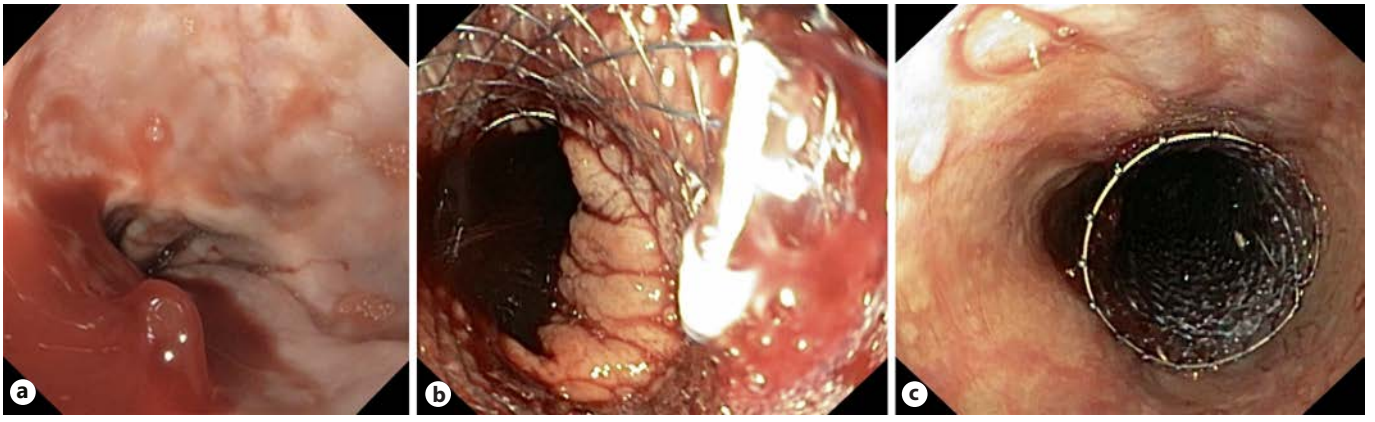

Fig. 5. Patient with cirrhosis Child-Pugh C and severe esophageal variceal bleeding. **a** Endoscopic image showing active bleeding from an esophageal varix. **b**, **c** Endoscopic image after placement of a dedicated fully covered self-expandable metal stent (SX-Ella Danis stent) with bleeding control.

incisive), lower C-reactive protein levels, and smaller defect sizes (<1 cm) were considered predictors of better outcomes; after validation in a different patient cohort, the rule was found to significantly discriminate between failure (NPV 86%) and success (PPV 87%) of stent placement in patients with a predicted low (≤50%) or high (≥70%) clinical success, respectively.

ESGE-updated guidelines recommend removing the stent 6–8 weeks after placement [26], even though there is a tendency to remove or replace stents at shorter interval times, to reduce stent-related AEs. SEMSs have been compared to endoscopic vacuum therapy for the treatment of post-surgical leaks in two systematic reviews and meta-analyses [87, 88], with endoscopic vacuum therapy being associated with higher leak closure, more endoscopic device changes, shorter duration of treatment, and lower rates of mortality and/or major complications. Given the high complexity and particularities of transmural defects, in most cases a multimodality approach is adopted, but endoscopic stenting remains one of the most frequently used options in these patients [77].

Recommendation: Temporary SEMS placement can be considered for leaks, perforations, and fistulae. Considering the complexity of these transmural defects, a multimodality approach is often preferred.

Acute Variceal Bleeding

In the setting of refractory acute variceal bleeding, several systematic reviews and meta-analyses [89–91] support use of SEMS in successful control of severe or refractory acute variceal bleeding, without significant device-related AEs (Fig. 5). This strategy is often used as a bridge to transjugular intrahepatic portosystemic shunt or liver transplantation in a significant proportion of patients [89], and 6-week survival is mostly related to the severity of the underlying liver disease. Dedicated FC-SEMSs (SX-Ella Danis) for esophageal variceal bleeding are available; when used, retrieval should be performed using a specifically designed system [92, 93]. There is only one RCT comparing FC-SEMS (SX-Ella Danis stent) with balloon tamponade [94], with successful therapy more frequent in the stent group (66% vs. 20%), with a significantly higher rate for control of bleeding (85% vs. 47%), lower transfusion requirements, and a lower incidence of serious AEs (15% vs. 47%), mainly due to differences in aspiration pneumonia (0 vs. 5) and esophageal tear (1 patient in the balloon tamponade group); no significant difference in 6-week survival was observed (54% vs. 40%). In most published studies, FC-SEMSs were left in place for up to 2 weeks [95–98], although extended dwell time up to 30 days has been reported. *Recommendation*: FC-SEMS placement may be considered for the treatment of severe or refractory esophageal variceal bleeding, as a bridge to transjugular intrahepatic portosystemic shunt or liver transplantation.

Gastroduodenal Stenting

GOO typically involves the distal stomach and/or the proximal small bowel (although it may also affect the distal small bowel) and may be secondary to mechanical/obstructive or motility causes. Mechanical obstructions can be benign or malignant [99]. The traditional ap-

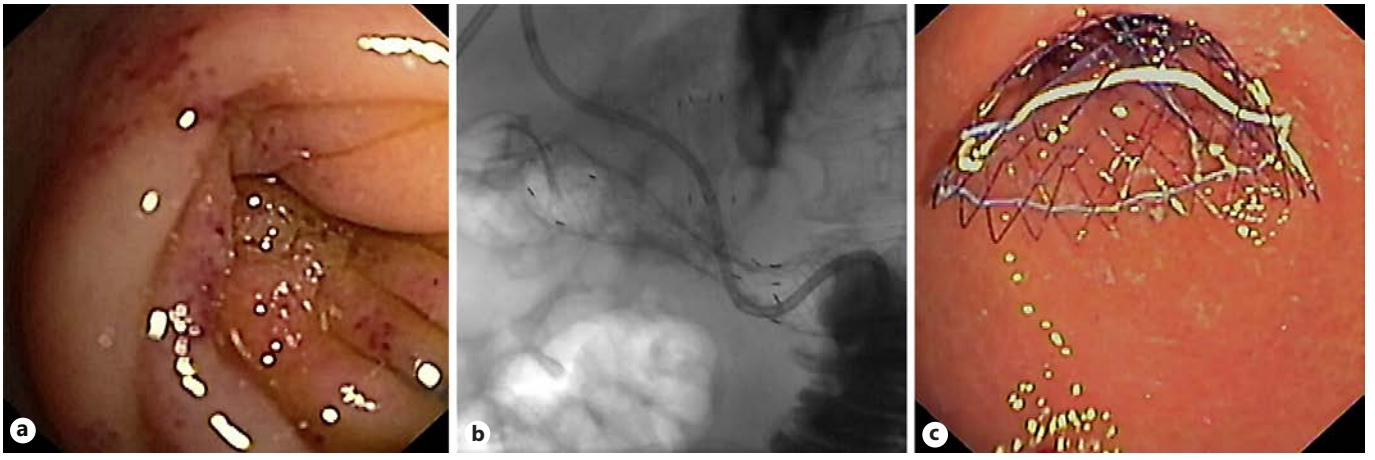

Fig. 6. a Patient with pancreatic cancer and previous biliary self-expandable metal stent with gastric outlet obstruction due to tumor invasion in the second portion of the duodenum. **b**, **c** Fluoroscopic and endoscopic images after placement of an uncovered 140 × 20 mm self-expandable metal stent.

proach for management of malignant GOO involves surgical gastrojejunostomy, via either open or laparoscopic access, although less invasive alternatives including endoscopic placement of luminal SEMS (Fig. 6) and, more recently, endoscopic ultrasound (EUS)-guided gastroenterostomies have become increasingly popular. On the contrary, benign GOO is generally managed with endoscopic balloon dilation (EBD), reserving more invasive techniques for EBD refractory cases [100].

A recent meta-analysis favored surgical gastrojejunostomy over SEMS due to longer overall survival and fewer needs for reintervention. Although postoperative mortality and AEs were similar between the two groups, the SEMS group had shorter hospital stay and shorter time to resume oral intake [101]. Technical and clinical success was 83.3–100% and 75–100%, respectively [101]. Therefore, patients with short life expectancy (<6 months), especially those who are high surgical risk, may be better candidates for luminal SEMS [102]. Regarding the stent type for GOO, a 2016 meta-analysis noted no significant difference in technical or clinical success, AEs, and reintervention for covered SEMS (C-SEMS) and uncovered SEMS (U-SEMS), but as expected, migration rate was higher, while obstruction rate was lower with C-SEMS [103].

In patients with combined malignant duodenal and biliary obstruction, "double stenting" should be the standard of care practice, due to its lower invasiveness and shorter recovery time [104]. Regarding approach for biliary stenting, endoscopic retrograde cholangiopancreatography stenting might be associated with a lower AE rate compared to EUS-guided biliary drainage and should be considered the preferred approach, when feasible [105].

Only a few case series have been published regarding SEMS as salvage therapy for benign GOO who failed initial EBD attempt. Despite symptomatic improvement in almost 80% of the patients, SEMS placement is limited by stent migration rates up to 47% [106, 107], with no robust evidence to recommend SEMS over surgery in these patients [102].

Recommendation: In patients with life expectancy below 6 months, especially if at high surgical risk, luminal SEMS can be considered. Otherwise, gastro-enteric anastomosis should be considered, either surgical or endoscopic. Combined malignant duodenal and biliary obstruction should be approached with "double stenting."

Colonic Stenting

Malignant Colonic Obstruction

Colonic stenting is a valid alternative to emergency surgery in patients with malignant colonic obstruction, either as bridge to surgery or palliative intention. Prophylactic stenting, in the absence of symptomatic obstruction, should not be performed. Most of the literature concerns left-sided obstructing colon cancer (Fig. 7), excluding (distal) rectal cancers; however, SEMS may also be successfully placed in malignant obstruction of the prox-

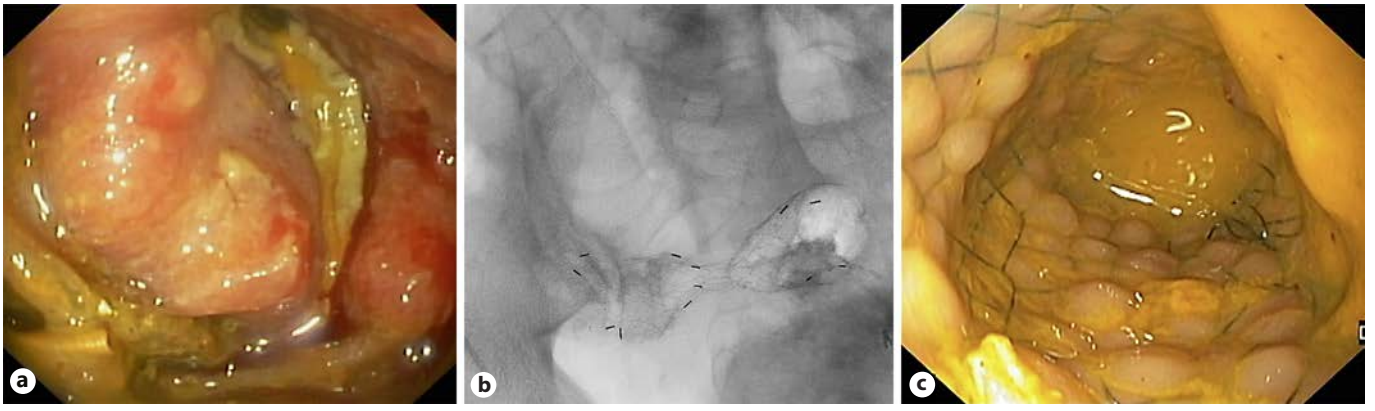

Fig. 7. Patient with malignant colonic obstruction due to colorectal cancer. **a**, **b** Fluoroscopic and endoscopic images after placement of an uncovered 80 × 20 mm self-expandable metal stent.

imal/right colon [108]. As a bridge to surgery, colonic stenting is associated with fewer overall AEs, similar 30-day mortality rate, and a higher proportion of primary anastomoses, compared to emergency surgery. Even though pre-surgical colon stenting (as bridge therapy) may be associated with a higher overall tumor recurrence, this did not translate into a significant difference in terms of disease-free survival or overall survival on 3- and 5-year follow-up [109, 110]. The worse oncologic outcomes seem to be explained by stent-related perforations, with overall survival being better in studies with lower perforation rates. The ideal time interval for surgery after colonic stenting should be balanced between stent-related AEs (reduced by a short interval) and surgical outcomes (improved by a longer interval). ESGE-updated guideline suggests a 2-week interval between stent placement and surgery [111]. In patients who are not good candidates for colonic stenting (locally advanced disease requiring neoadjuvant therapy or longer stenosis) or who fail stent placement, a decompressing stoma may be an alternative as a bridge to surgery, allowing a higher chance of successful primary anastomosis [112].

In a palliative setting, most meta-analyses have demonstrated SEMS to be associated with lower short-term mortality, hospital stay, early AEs, stoma rates, and time to initiation of chemotherapy, compared to emergency surgery. Conversely, late AEs were more frequent in the SEMS group [113–117]. Chemotherapy does not seem to be a risk factor for colonic stent-related complications in general; however, in patients already receiving bevacizumab, stent placement is not advised due to high risk of perforation [111].

Extra-colonic malignancy complicated with colonic obstruction may benefit from palliative colonic stenting and is associated with fewer AEs compared to decompressive surgery. Unfortunately, technical and clinical success rates are lower compared to primary colonic cancer [118–120].

In terms of type of colonic stents, 3 meta-analyses have compared U-SEMS and C-SEMS, noting similar technical and clinical success, but U-SEMSs were associated with fewer overall AEs, including less tumor overgrowth, lower migration rates, longer patency, and fewer re-insertions, although at the cost of higher risk of tumor ingrowth [121–123]. The main complications included perforation, stent failure, stent migration, and stent re-obstruction [124]. Migration should be treated with stent replacement or SIS technique in the palliative setting, and early surgery in the bridge-to-surgery patients [125].

Recommendation: SEMS can be considered for malignant colonic obstruction treatment as bridge to surgery (advantages and disadvantages of its placement must be discussed with the patient) or in palliative setting. Despite lower success rate, SEMS can also be used for extra-colonic malignant obstruction treatment.

Benign Colonic Obstruction

In recent years, the use of SEMS has been extended to treatment of benign GI strictures secondary to diverticulitis, radiation colitis, inflammatory bowel disease, and endometriosis, as well to management of post-anastomotic colonic leaks, strictures, and fistulas [126]. However, majority of data available in this regard are derived from retrospective studies.

Table 2. Summary of main indications for esophageal, gastroduodenal, and colonic stenting and recommended types of stents for each indication

Indication	Recommended stent
Esophageal stenting	
Malignant esophageal cancer	Palliative intention
	Mid-esophageal strictures: FC or PC-SEMS
	Distal esophageal strictures: PC-SEMS
	Bridge to surgery
	Not recommended
ERF	FC or PC-SEMS (fistula needs to be covered by stent membrane)
RBES	FC-SEMS, LAMS, or BDS
Leaks, perforations, and fistulas	FC or PC-SEMS
Refractory acute variceal bleeding	FC-SEMS or dedicated stents (SX-ELLA Danis stent)
Gastroduodenal stenting	
Malignant GOO	Expected survival <6 months
	U-SEMS
	Expected survival >6 months
	EUS-guided gastro-enteric anastomosis (LAMS)
Benign GOO	Not recommended (consider EUS-guided gastro-enteric anastomosis)
Colonic stenting	
Malignant colonic obstruction	U-SEMS
Malignant extra-colonic obstruction	U-SEMS
Benign colonic obstruction	Not recommended

BDS, biodegradable stent; EUS, endoscopic ultrasound; FC, fully covered; LAMS, lumen-apposing metal stent; PC, partially covered.

Several studies have reported outcomes of colonic stenting for diverticulitis-associated strictures, as a bridge to surgery or for palliation (in poor surgical candidates). A systematic review ($n = 66$) concluded that the AE rate was not acceptable to warrant its use (11/66 perforations) [127]. Regarding fibrostenosic Crohn's disease (CD) refractory to medical treatment, SEMS use is only described in small case series [128]. The largest case series, with a stent dwell time of 4 weeks, showed treatment efficacy of 64.7%, with one AE (proximal stent migration). Distal stent migration (52%) was not considered an AE but rather an incident [129]. A systematic review evaluated SEMS placement for the management of colorectal surgical complications including anastomotic strictures, leaks, or fistulas. A high early success rate (73.3%) was observed; however, anastomotic strictures were more challenging to treat, as around 50% of the patients had persistent stenosis and 26% required EBD after stent placement [130]. Complications were reported in 41.5% patients, mainly SEMS migration, explained by the inherent characteristics of C-SEMS [131]. Colonic stent placement in bowel obstruction due to endometriosis, colonic fistulas, radiation-induced stenosis, or ischemic colitis is also reported in literature, but only as case reports or short case series [126, 127].

The largest case series of BDS in colon and ileocolic anastomotic strictures report a technical success of 90–100% but only a modest stricture resolution of 45–83%. Unlike in esophageal strictures, mucosal hyperplastic reaction after BDS placement has not been reported in intestinal strictures [132, 133]. Use of BDS for CD strictures can theoretically overcome the shortcomings of SEMS (stent migration and need for stent removal); however, absence of biodegradable through-the-scope colonic stents makes deployment proximal to the sigmoid technically challenging. Data are very limited in this context. A case series of 11 BDS for treatment of CD strictures of the terminal ileum or colon (deployed through overtube, assisted by a stiff guidewire, and fluoroscopy guidance) revealed high technical success (90.9%), but early stent migration occurred in 3 patients [134].

Henceforth, limited available data do not support endorsement of SEMS placement in the context of benign colonic conditions and should only be considered in case-by-case basis after multidisciplinary discussion. *Recommendation*: SEMS placement in benign colonic strictures should not be routinely performed.

Conclusion

Endoscopic stenting practices and techniques are continuously evolving, requiring clinicians to be aware of updated evidence in this field (Table 2). For patients with unresectable esophageal cancer, SEMS placement is recommended as a palliative measure if expected survival is less than or equal to 3 months. If available, brachytherapy should be considered as an adjunct for patients with expected survival above 3 months. SEMS placement is also recommended for patients with malignant tracheoesophageal fistulas as well as patients with RBES and transmural defects. Gastroduodenal stenting should be considered in patients with malignant GOO, especially those who have a short life expectancy (below 6 months). Colonic SEMS is the preferred treatment for palliation of malignant colonic obstruction and can be considered as bridge to surgery in selected patients. In all cases, individualized considerations and the multidisciplinary context should be made when developing management recommendations and plans.

Statement of Ethics

The authors state that this article did not require ethics approval, since it is a review article and does not involve animal or human studies.

Conflict of Interest Statement

None of the authors acted as reviewer or editor of this article. None of the authors disclosed personal conflicts of interest or financial relationships relevant to this publication.

Funding Sources

The authors have no funding sources to declare.

Author Contributions

Conception and design: Eduardo Rodrigues-Pinto. Literature review: Renato Medas and Joel Ferreira-Silva. Drafting of the article: Renato Medas. Critical revision of the article for important intellectual content: Mohit Girotra, Monique Barakat, James H. Tabibian, and Eduardo Rodrigues-Pinto. Final approval of the article: Eduardo Rodrigues-Pinto.

Data Availability Statement

Our study did not have any original data.

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GE – Portuguese Journal of Gastroenterology

Review Article

GE Port J Gastroenterol 2023;30:35–44
DOI: 10.1159/000530704

Received: September 18, 2022
Accepted: January 25, 2023
Published online: June 12, 2023

Esophageal Stenting: How I Do It

Rui Silva

Gastroenterology Department, Portuguese Oncology Institute of Porto, Porto, Portugal

Keywords
Esophageal neoplasms · Self-expandable metal stents · Endoscopy · Adverse events

Abstract
Endoscopic esophageal stent placement is an effective palliative treatment for malignant strictures and has also been successfully used for benign indications, including esophageal refractory strictures and iatrogenic leaks and perforations. Despite several decades of evolution and the wide variety of esophageal stents available to choose from, an ideal stent that is both effective and without adverse events such as stent migration, tissue ingrowth, or pressure necrosis has yet to be developed. This paper is an overview of how this evolution happened, and it also addresses the characteristics of some of the currently available stents, like their material and construction, delivery device, radial and axial force pattern, covering and size which may help to understand and avoid the occurrence of adverse events. The insertion delivery systems and techniques of placement of an esophageal self-expandable metal stent are reviewed, as well as some tips and tricks regarding placement and management of adverse events.

Próteses esofágicas: uma abordagem pessoal

Palavras Chave
Neoplasias do esófago · Próteses metálicas auto-expansíveis · Endoscopia · Eventos adversos

Resumo
A colocação endoscópica de próteses esofágicas metálicas auto-expansíveis é um tratamento paliativo eficaz da estenose maligna, tendo também sido usada com sucesso em indicações benignas, como no caso de estenoses refratárias do esófago ou de perfurações e deiscências iatrogénicas. Apesar de várias décadas de evolução e não obstante existir uma grande variedade de escolha de próteses esofágicas, ainda está por desenvolver a prótese ideal que apresente simultaneamente uma eficácia elevada e uma incidência reduzida de complicações como migração, crescimento tecidular ou necrose por pressão. Este artigo fornece uma visão global de como esta evolução ocorreu e aborda as características de algumas das próteses atualmente existentes no mercado, como o seu material e tipo de construção, padrão de força axial e radial, cobertura e dimensões, que poderão ajudar a compreender e a evitar a ocorrência desses eventos adversos. São analisados os sistemas de libertação e técnicas de introdução das próteses metálicas auto-expansíveis, com alguns truques e dicas relativas à colocação das próteses e abordagem de eventos adversos.

This article was solicited as an invited review by the editorial board with the aim to reflect my personal experience on esophageal stenting in an oncology center setting. The article has therefore been written accordingly, with expert-based opinions supported or prompted

karger@karger.com
www.karger.com/pjg

Correspondence to:
Rui Manuel Almeida da Silva, rsgastro@sapo.pt

by clinical data, but with the purpose to stir debate using available relevant evidence.

History of Esophageal Stents

The current acceptable origin of the word stent is that it derives from the name of a dentist, Charles Thomas Stent (1807–1885) who was an English dentist notable for his advances in the field of denture making. He developed a formula made of gutta-percha, a plastic substance made from a Malaysian tree called percha tree used for filling a tooth after a root canal procedure. The etymological origin of "stent" as a term in surgery started with Johannes F. Esser in 1917, which used Stent's dental compound as a mold for bridging skin grafts [1]. The term "stent" became popular among surgeons for such applications and was then later used to define any surgical mold for bridging tissues until a healing process has taken place, as in 1954, when Remine and Grindlay described the use of a polyethylene tube as "to act as a stent for the anastomosis" in experimental biliary surgery [2]. In gastroenterology, Molnar and Stockum in 1974 were the first to use the term stent to describe a percutaneous transhepatic catheter used to relieve an obstructive jaundice [3] and, in 1980, Nib Soehendra and Reynders-Frederix described the endoscopic placement of a biliary stent for the palliation of a malignant biliary obstruction [4]. Since then, this latter procedure has become the preferred method to relieve jaundice and improve quality of life for patients with advanced malignant biliary obstruction.

Gastrointestinal (GI) stents have been originally used to treat obstructing cancer in the GI tract. From early modern medicine in the 19th century until nowadays, GI tract cancer or luminal palliation has always been a huge challenge for surgeons and physicians. In esophageal cancer, for example, there were multiple nonsurgical attempts to relieve dysphagia. In 1845, James Leroy d'Etoilles, a French surgeon, was the first to treat malignant dysphagia with a tube made out of ivory, without success [5]. A few years later in 1885, Charters James Symonds performed the first successful esophageal stenting procedure by using an esophageal semirigid tube with a proximal funnel attached to a silk suture which was brought out of the mouth and attached to the patient's ear, providing adequate nutrition and palliation, while also improving quality of life [6]. Subsequently, considerable advances have been made and further technical developments included the use of a stent introducer over a guide wire technique, the direct endoscopic insertion, and the use of several materials like latex or silicone to increase softness of the stents without the need for external fixation, such as the Celestin® and the Wilson-Cook® tubes [7, 8]. However, these esophageal stents, originally designed as rigid or semirigid, cylinder-like prostheses, while being the best palliation measure at that time, avoiding surgery, had poor efficacy and high adverse event rates, such as migration, obstruction, and perforation of the GI tract [9].

Self-Expandable Metal Stents

The concept of placing a self-expandable metal stent (SEMS), inserted through a small diameter delivery system which conform to the GI tract angulations, has been borrowed from the cardiovascular setting. In fact, the first SEMS to be inserted in the esophagus were two 20 mm endovascular Wallstents® in patients with inoperable esophageal cancer [10]. The use of SEMS has allowed additional anatomical areas to be bypassed, decreased the risks associated with placement of relatively large diameter plastic tubes, and has expanded our ability to palliate and effectively treat a wide variety of GI disorders. According to several randomized controlled trials, the use of SEMS was associated with significantly reduced stent-related adverse events when compared to plastic prosthesis, with better palliation of dysphagia, shorter hospital days, and longer survival [11, 12]. To this extent, their development and application has been nothing short of revolutionary, quickly replacing plastic prosthesis as the method of choice in the treatment of malignant dysphagia and, to a lesser extent, refractory benign esophageal strictures and GI tract fistulas, leaks, and perforations.

Actual SEMS differ considerably in their properties as defined by the material used, their shape, the mesh stent pattern, and the type and design of the cover that surrounds the stent mesh (Table 1). These different characteristics and designs may ultimately influence stent choice and clinical outcome since, despite several decades of evolution, there is no ideal stent type to date that fits all cases. That would be one with a reliable and simple stent deployment system, good visibility on fluoroscopy, radial force high enough to allow a good expansion but without causing pain or pressure necrosis, high flexibility and conformability around angulations and flexures of the GI tract, resistance to obstruction and migration but with the ability to be easily removed if necessary. Nevertheless, the specific implications of the different stent characteristics

Table 1. Overview of selected esophageal stents and relevant characteristics for clinical practice

Manufacturer Stent name	Type	Material	Cover	Length (cm)	Stent diameter (mm)	Introducer size (mm)
Boston Scientific						
Ultraflex®	NC	Nitinol	None	7/10/15	18/23	5.3
	PC		Polyurethane	10/12/15[a]	18/23; 23/28	
Wallflex®	PC	Nitinol	Polyurethane	10/12/15	18/23; 23/28	6.2
	FC				18/25/23; 23/28	
Polyflex®	FC	Polyester	Silicone	9/12/15	16/20; 18/23; 21/25	12/13/14
Agile® TTS	PC	Nitinol	Silicone	6/10/12/15	14/19; 18/23	3.5
	FC					
Cook Medical						
Evolution®	PC	Nitinol	Silicone	8/10/12.5/15	20/25	8
	FC			8/10/12	18/23; 20/25	
M.I. Tech						
Hanarostent®	NC	Nitinol	None	9/12/16	22/28	4
	PC		Silicone	6–17	18/24:22/28	6
	FC			6–18	18/24; 22/28	6–8
Hanarostent® TTS	PC	Nitinol	Silicone	6/8/10/12/15	18/26; 20/26	3.5
	FC					
Taewoong Medical						
Niti-S®	PC	Nitinol	Silicone	6/8/10/12/15	16/24; 18/26; 20/28	5.3; 6.7
	FC					
Niti-S® TTS	PC	Nitinol	Silicone	6/8/10/12/14/15	18/26; 20/26	3.5
	FC					
ELLA-CS						
SX Ella BD®	BD	Polydioxane	None	6/8/10/13.5	18/23; 20/25; 23/28; 25/31	6; 9.3

[a]Length only available in small diameter stents.

on clinical outcome are not completely understood due to the lack of high-level evidence from head-to-head comparisons in randomized clinical trials.

Stent Materials and Construction

The materials used in stent design are of utmost importance to the successful function and lifetime of the device. This structural material must be biocompatible, have sufficient elasticity so as to be compressed for loading into the tubular delivery system, and able to exert sufficient radial force upon expansion to re-establish patency of the esophageal lumen [13]. Currently, self-expandable stents may be manufactured from two materials, polymer or metal.

The two polymer stents commercially available until recently were the Polyflex® (Boston Scientific) and the SX Ella BD® (ELLA-CS). Polyflex® was developed in 2003 and was a SEPS – self-expandable plastic stent, made of woven plastic polyester strands and fully covered with a silicone membrane. In malignant setting, SEPS became an alternative to SEMS with comparable efficacy in palliation of advanced esophageal carcinoma [14, 15]. Furthermore, due to its full coverage and less granulation tissue reaction, it was easily removed endoscopically and it was the only FDA approved stent for benign indications. Other indications for their use were the removal of uncovered or partially covered SEMS thorough a stent-in-stent technique and the increase of the radial force that helps to achieve full expansion of previously deployed SEMS [16]. However, SEPS did not come pre-loaded and the delivery system was significantly larger and rigid, requiring pre-insertion dilation up to 15 mm. SEPS also had a high radial expansion force, causing chest pain, and was more prone to migration as they were fully covered [17, 18]. Due to this high risk of adverse events, the production of the Polyflex® has been terminated.

The SX Ella BD® is a self-expandable biodegradable stent developed in 2007 which is composed of polydioxanone, a surgical suture material. The advantage of a biodegradable stent is that they do not have to be removed after they are implanted, being particularly useful in benign conditions. The stent maintains its integrity and radial force for 6–8 weeks after placement and disintegration occurs by 11–12 weeks, accelerated by the gastric acid [19]. Although biodegradable stents may provide a valuable alternative to SEPS and SEMS, they still present some complications of migration and tissue regrowth and have multiple external factors affecting its mechanical integrity and degradation rate. They also need manual loading and assembly of the delivery system immediately prior to insertion, with the disadvantage of requiring larger delivery systems compared to similar metal stents [20]. Therefore, further improvements are necessary so that they may have a consistent clinical result in terms of luminal patency, as well as be considered an effective, patient-friendly alternative [21].

The most recent and commonly used SEMS are made of nitinol, a memory-shape alloy with super-elastic characteristics made of nickel and titanium that, once deformed, may return to the pre-deformed state after heating to the body temperature, thus exerting self-expansive forces until they reach their maximum fixed diameter [22]. In addition to shape memory, nitinol also has super-elastic properties, allowing structure deformations without breaking. The nitinol is wire woven into a tubular structure that, compared to the first stainless steel models like the Wallstent® (Boston Scientific) and Gianturco-Z® stent (Cook Medical), resulted in a more flexible stent that could be constrained into a reduced caliber delivery system and advanced over a guide wire [13].

The Ultraflex® esophageal stent from Boston Scientific was the first commercially produced stent to be made of nitinol. The small and flexible delivery system allowed easy deployment. However, it was completely uncovered and encountered the same complications of tumor ingrowth as other uncovered SEMSs. To overcome that problem, a partially covered Ultraflex® stent was developed. In 1997, this partially covered Ultraflex® stent was the first esophageal SEMS inserted in our institution, in a young woman with a recurrent gastric cancer at the esophagojejunal anastomosis, and it is still currently being used by many gastroenterologists, me included. More recently, in 2008, the Gianturco-Z® stent (Cook Medical) was replaced by the nitinol-made Evolution® Controlled Release Esophageal Stent System, a new improved and unique delivery system alternative to the traditional push-pull deployment system, enabling accurate placement of the stent. While Ultraflex® only has its rectosigmoid counterpart (the over-the-wire Ultraflex Precision®), the Evolution® system has a family of stents to treat not only esophageal but also gastroduodenal, biliary, and colonic strictures. Similarly, Boston Scientific also has the Wallflex® family of nitinol-made stents encompassing the GI tract, with a "soft" version for gastroduodenal and colonic locations.

However, the elastic properties of the SEMS are provided not only by nitinol itself but also from a combination of the material with the construction of the stent. There are laser cut stents, with very high radial force and lower foreshortening, usually less than 10%, thus allowing for more accurate deployment [23]. However, these stents are very rigid, with a high axial force [24]. The axial force is considered to be the force that a stent exerts to straighten when it bends along the longitudinal axis. If the axial force is too high, the stent will exert strong forces to straighten its shape. As a result, they will have less flexibility, not conform well to anatomic flexures and hold an increased risk of causing excessive pressure and trauma to the esophageal wall [25]. This laser cut stents differ from the woven wire-braided or knitted configuration. In the braided stents, the nitinol wires cross over each other but do not interlock. They have a high radial force and, although being more flexible, that configuration retains a relativity high axial force specially when coated, due to the restriction of the movement of the wires by the silicone dipping, heightening the risk of kinking on flexion [26]. In addition, braided stents shorten significantly upon expansion, thus being less predictable when deployed. In the knitted design stents, the wires hook around each other like a wire fence within the stent structure that allows the stent wires to displace not only laterally but also in a longitudinal fashion, resulting in a stent with low axial force and high flexibility [24, 27]. Knitted stents conform well to anatomical flexures, such as the gastroesophageal junction, and have the ability to absorb compressive forces and adapt to esophageal peristalsis, being more likely to stay in place and avoid migration [13]. Although knitted stents tend to have a lower radial force than braided ones, they retain the ability to expand into the original diameter and configuration [24].

Stent Covers

The original esophageal SEMS were mostly uncovered, which allowed for good embedding into the tumor and surrounding esophageal tissue, ensuring good anchorage

and reducing the risk of migration. However, uncoated stents are prone to tissue hyperplasia and tumor ingrowth through the stents interstices, eventually leading to new stricture or obstruction [28].

To overcome these adverse events, a variety of polymers like polyethylene, polyurethane, and silicone have been used for stent coating. While polyurethane and external silicone are prone to mechanical damage and early degradation in an acidic environment, expanded polytetrafluoroethylene is less elastic but when applied as an external membrane provides a more durable barrier against tumor ingrowth [13].

Fully covered stents avoid stent embedding and prevent tissue ingrowth, also preventing the extravasation of secretions and ingested oral content when a GI leak is present [29]. They are endoscopically retrievable and increasingly being used not only for palliation of malignant dysphagia but also off-label in the setting of benign esophageal diseases like strictures, perforations, and leaks since they can be placed for extended periods of time without embedment. Nevertheless, they should be kept in place no more than 12 weeks since tissue hyperplasia may still occur at the stent margins due to friction during peristalsis [30]. However, those advantages came with the trade-off of an increased risk of migration, which may lead to recurrent dysphagia or, in case of leaks and leaks, incomplete sealing of the defect [29, 31]. Furthermore, in the latter context, fully covered stents adhere less well to the esophageal wall, allowing the passage of luminal content in the space between the stent and the esophageal wall.

A compromise is presented by partially covered stents, designed to improve stent patency, where several millimeters of the stent ends are left bare to achieve mucosal fixation, minimizing migration, while most of the middle is covered, providing a partial barrier against ingrowth [32]. Additionally, embedded flanges of partially coated SEMS provide optimal sealing of leaks and fistula to divert luminal contents, reducing leakage between the stent and the esophageal wall [33]. This is particularly relevant in critically ill patients with anastomotic leaks after upper GI surgery where the insertion of a partially covered SEMS may play a crucial role as a quick, safe, and effective treatment. Although they are generally retrievable up to 1 or 2 weeks after placement, the longer dwell times needed in these cases (up to 8 weeks) often require either the obliteration of the tissue ingrowth in the uncovered portions near the edges of the stent with argon plasma coagulation or the insertion of a second high radial force fully covered stent (a Polyflex® was used in the original description) inside the first one. After a period of 10–14 days, the inner stent is extracted, and an attempt at removing the original stent can be made. Under fluoroscopy, a therapeutic scope and two foreign body grasping forceps (a rat tooth for the lasso loop and an alligator jaw for the metallic mesh) are used to invert inward the upper flange of the stent (and if necessary also the lower one) until it dislodges from the esophageal wall, using afterward the purse string lasso loop to remove it. This technique, known as "stent in stent," should only be attempted by experienced operators, ideally using a combination of endoscopy and fluoroscopy to assess stent mobilization and to reduce the risk of perforation [34].

Stent Size

The size of the stent is another variable to be considered and that can influence outcomes. Larger diameter stents are usually desirable as they aim to establish maximal luminal diameter, reducing and delaying the risk of re-obstruction by luminal ingrowth, while providing optimal sealing of leaks and fistula to divert luminal contents [35, 36]. They are also recommended in settings associated with an increased risk of migration such as extrinsic compressions, location at the gastroesophageal junction or esophagojejunal anastomosis, or when there is no stricture, like in fistula and leaks. The trade-off is a higher incidence of chest pain, usually during the first 24–48 h but sometimes persisting beyond the early post-procedural period, mainly in tumors previously submitted to radiotherapy [37]. Furthermore, the use of large stents should be avoided in the smaller proximal esophageal lumen or when there is any tracheal compression by the tumor [38]. If there is tumor extension into the airway occluding more than one-third of the tracheal lumen, a tracheal stent must be inserted first. Rare cases of anastomotic leak enlargement have also been described with the use of high radial force large diameter stents [39].

The length of the stent should be enough to allow the 1.5–2 cm flanges to surpass the tumor. An exception to this rule is stent placement in the most proximal esophagus, where the stent flange should not be positioned too far proximally into or across the upper esophageal sphincter. However, as long as a flexible small diameter, low radial force stent is used, it may be left immediately below the cricopharyngeus, there will be no risk of aspiration or patient intolerance. Likewise, stents crossing the gastroesophageal junction should be at least 12 cm long, so they may anchor in the esophagus, and no more than 1.5 to

Fig. 1. Illustration of the delivery system of the Ultraflex® esophageal stent. Arrows indicate how to release the stent by pulling out the string. Note the green suture at the proximal end for stent repositioning.

2 cm of stent should be left below the tumor and free in the stomach, in order to avoid distal migration and the impaction of the stent on the opposite gastric wall [40, 41]. In patients with high risk of stent migration, the use of a novel over-the-scope clip device (stentfix OTSC®) manufactured by Ovesco Endoscopy significantly reduced stent migration rate compared with that without stent fixation, with no or few adverse events related with clip application or removal [42].

Insertion Technique

Precise placement of SEMS in the esophagus is relatively straightforward and generally easier than stent placement in other locations. Adequate patient sedation is mandatory for these procedures as coughing and patient movement during stent insertion can result in misdeployment. The first step is to perform an upper endoscopy to define the proximal and distal margins of the malignant stricture or lesion. However, the stricture is oftentimes very tight or difficult to allow the passage of a standard gastroscope. In those cases, several endoscopic maneuvers like luminal suction, rotation of the endoscopic insertion tube, locking the angulation control knobs, and stiffening of the endoscopic tip with a forceps or metallic guide wire should be attempted. If, despite all efforts, the gastroscope cannot pass through the stricture, there are several options: contrast may be injected under fluoroscopy to delineate the lesion, a pediatric upper endoscope may be used, or the stricture may be dilated.

Although aggressive dilation should be avoided since it may increase the risk of perforation, dilation up to a maximum diameter of 11 mm with a bougie is quite safe. That will permit a standard endoscope to pass beyond the tumor with the advantage of allowing the full evaluation not only of the stricture characteristics and length but also of the rest of the upper GI tract. Moreover, it will also allow the use of an endoscopic clip to mark the margins of the lesion for fluoroscopic visualization since most clipping fixing devices are not compatible with the working channel of the pediatric upper endoscopes. Precise marking is of utmost importance mainly when there is a small margin of error like in the proximal cervical esophagus, where the stent should be positioned immediately below the cricopharyngeus, when there is the need to seal a leak or fistula or even in the cardia, where no more than 1.5 to 2 cm of stent should be left free in the stomach, as previously mentioned. Additionally, in some delivery systems like the Ultraflex®, the stent is tied down to the outside of the delivery catheter by a silk thread, which makes the system bulky and externally rough, resulting in the highest need for predilation. After passing the gastroscope through the stricture, the margins of the area to be stented should be marked with two endoclips, namely in the middle esophagus or in case of large leaks where we want to center the stent, or with only one endoclip in lesions of the cardia or near the upper esophageal sphincter, where there is a one-sided narrower margin of error. A metallic stainless steel guide wire (Savary-Gilliard®, Cook Medical) is then left in place with the tip in the second part of the duodenum or

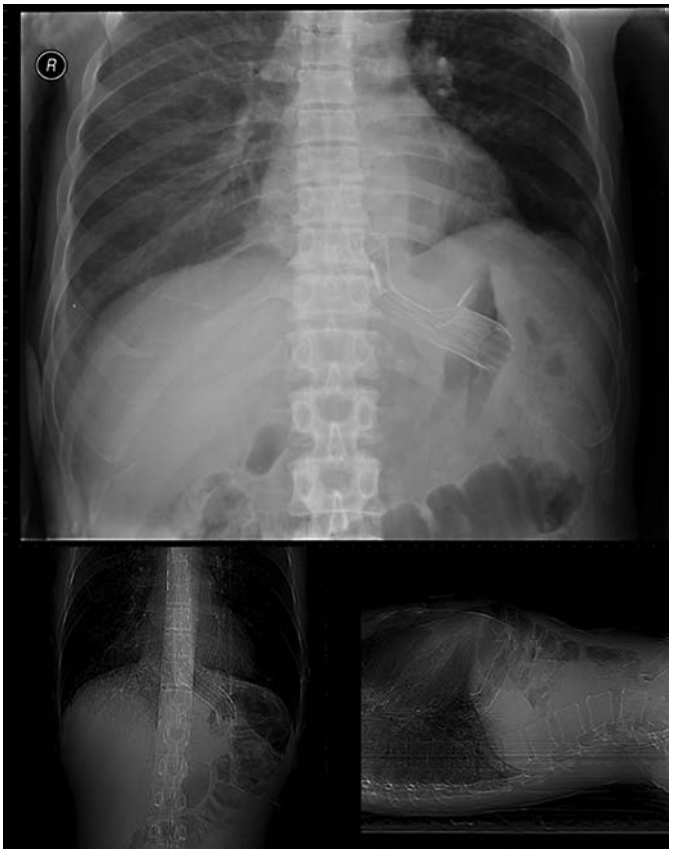

Fig. 2. Radiologic and CT scout appearance of the Ultraflex® stent placement across the gastroesophageal junction. Higher flexibility allows better conformability in anatomically challenging areas like GI angulations, reducing the risk of pressure necrosis and migration.

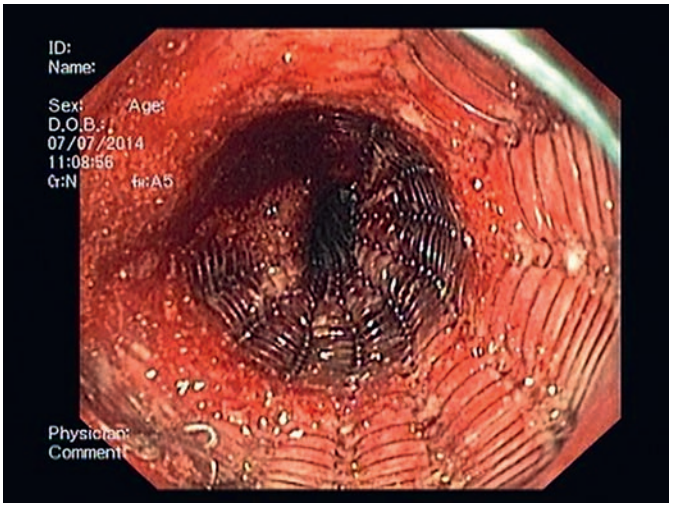

Fig. 3. Endoscopic view of the partially covered Ultraflex® esophageal stent immediately after deployment.

looping in the antrum, and the endoscope is removed. The use of a stiff guide wire allows for a greater support and stability, especially when placing a floppy stent delivery system distally in the esophagus or gastroesophageal junction. If a metallic guide wire is not available, another option is to use an extra stiff 0.035″ guide wire like the Lunderquist® (Cook Medical). In very narrow and complex strictures difficult to negotiate, you may use a guide wire with a hydrophilic tip like the Jagwire® Stiff Shaft (Boston Scientific) eventually with the help of a three lumen, dual port cannula Tandem® XL (Boston Scientific) for simultaneous contrast injection.

Stent Selection

There are a wide variety of stent designs that are commercially available in current practice, each with its purported advantages and limitations. Since there is no ideal stent type to date that fits all cases, achieving expertise with different models will aid physicians in selecting the optimal SEMS for a given condition. In my personal experience, stent flexibility is the most important feature in stent selection that should be taken into consideration as I believe that the incidence of complications like migration and pressure necrosis can be reduced with increased flexibility.

Worldwide, Ultraflex® is one of the most commonly used stents for treatment of malignant dysphagia. This stent, made of knitted nitinol, has a central cover of polyurethane and has uncovered ends at the proximal and distal 15 mm stent ends. It is available in two diameters (18-mm body/23-mm proximal flare and 23-mm body/28-mm proximal flare) and in both proximal and distal release delivery systems. It is mounted with a long thread that holds the compressed stent. The end of the thread is pulled through the catheter lumen to the opposite end of the catheter and tied to a plastic ring. The stent is released by pulling the thread (Fig. 1). After expansion, it foreshortens up to 30–40%, which makes precise stent placement difficult [9]. Moreover, although there are four radiopaque markers in the delivery system (the inner two markers indicating the final position of the covered part of the deployed stent and the outer two, the position of the uncovered portion), these markers are not very reliable and some experience is needed for accurate positioning. The main advantage of the Ultraflex® is its axial force being the lowest among the currently available stents, which makes it soft and flexible [25]. That better conformability to the esophageal wall and angulations allows for a reduced migration rate, less pressure necrosis, and a better sealing of GI leaks [43]. The latter, along with the benefit of having the distance from the upper margin of the stent to the

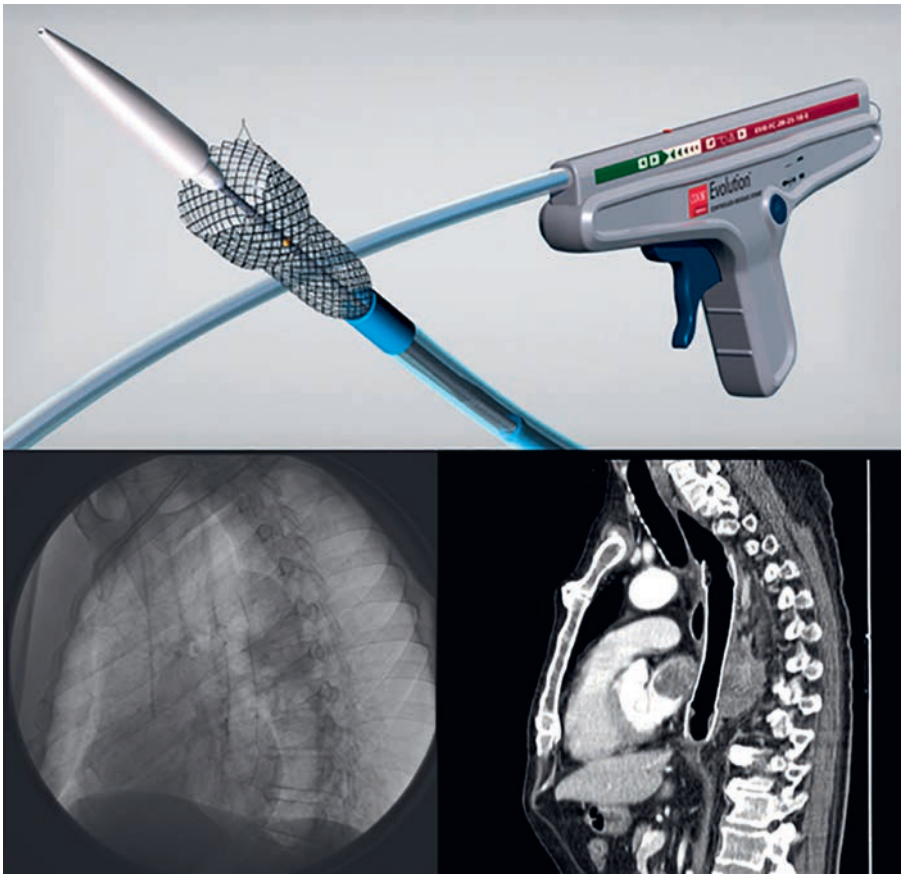

Fig. 4. Evolution® Controlled Release Esophageal Stent System. Radiologic and CT view after deployment in a case of extrinsic esophageal compression caused by an obstructive pulmonary cancer.

Table 2. Overview of clinical success and adverse events with esophageal SEMS placement for malignant and benign indications

	Malignant indication	Esophageal leakage	Benign stricture
Clinical success (%)	80–95 [49]	81–87 [50–52]	24–41 [53, 54]
Major complications (%)			
Major bleeding	8.0	0.6–1.3	1.8–3
Aspiration pneumonia	5.0	0.7	0.7–1.3
Perforation	2.0	0.7–1	0.9–1.3
Recurrent dysphagia (%)	31.0	20	28-29
Tissue overgrowth	14.0	2.7	0–2.2
Stent migration	11.0	12–16.5	24.5–28
Food obstruction	7.0	1.1	0–2.2
Retrosternal pain (%)	30.0	0.5	4.3–5.0

incisors depicted on the introducer system, allows for its placement in patients with anastomotic leaks in intensive care units without the need for fluoroscopic guidance [44]. The proximal release small diameter Ultraflex® is also the ideal stent to be inserted in high strictures close to the upper esophageal sphincter, since it allows a more precise control of the stent position during expansion, while the distal release large diameter one is most suitable for placement across the gastro-esophageal junction [13] (Fig. 2, 3).

The Evolution® (Cook Medical) is a braided mesh stent that is made from a single woven, nitinol wire. These stents have an internal and external silicone coating in order to prevent ingrowth and recurrent dysphagia. The internal stent cover also precludes adherence of fibrous food to the stent

mesh. Two different versions are available: a partially covered with 20 mm uncovered distal and proximal flares and a fully covered version. The stent is available in lengths varying from 8 to 15 cm and a body diameter of 20 mm with flanges of 25 mm and is placed with a pistol-grip delivery system which allows controlled release and recapturing, if needed. The braided construction and the silicone encasement of the stent mesh allows for a higher expansion force than the Ultraflex®, making it ideal for placement in strictures with a large tumor bulk or surrounding fibrosis in the mid-esophagus [26, 45] (Fig. 4). In addition, the fully covered version of the stent also has a repositioning lasso loop in both ends, making it easily retrievable. This fully covered stent is most suitable for placement as the inner stent in the "stent-in-stent" technique, as explained above, or when there is recurrent malignant dysphagia due to tumor progression and overgrowth at the proximal or distal stent ends. In the latter, a second fully covered stent is placed through the first stent, adequately covering the site of tumor overgrowth. Endoscopic clipping may be used to fix this stent to the mesh of the previous one, avoiding the risk of stent migration. With this technique, we take the advantage of the full coverage to resist tissue ingrowth and reduce episodes of recurrent dysphagia without the disadvantage of a higher risk of stent migration.

Table 2 shows an overview of clinical success and adverse events with esophageal SEMS placement for malignant and benign indications. Although there is a relatively high risk of adverse events, most of these are minor and can be prevented or managed endoscopically, like stent migration and tissue in- or overgrowth. The minor adverse event rates are comparable between malignant and benign indications. Observed major complications included esophageal perforation, hemorrhage, and pneumonia due to aspiration. Innovations requiring further evaluation and validations studies include radioactive stents, with improved dysphagia grades and median survival in patients treated with I-125 loaded stents [46], and drug eluting stents with bi- or multilayer configuration for localized delivery of various drugs like paclitaxel or 5-fluorouracil, these still with no clinical data in humans [47, 48].

Although the initial stent selection has a significant impact on the clinical outcome in patients with inoperable malignancy, there are no data to date demonstrating significant differences in outcomes or complications among SEMS types. Most evidence is of low grade, based on case series or small comparative studies. Therefore, the choice of specific SEMS has been based on availability and endoscopist's preference and experience. Better understanding of the factors affecting stent performance and a more individualized approach to each patient should be adopted in order to choose between the multiple stenting options.

Conflict of Interest Statement

Rui Silva is a consultant for Cook Medical and Boston Scientific Corporation.

Funding Sources

There were no funding sources.

Author Contributions

Rui Silva confirms sole responsibility for the following: study conception and design, data collection, analysis and interpretation of results, and manuscript preparation.

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GE – Portuguese Journal of Gastroenterology

Clinical Case Study

GE Port J Gastroenterol 2023;30(suppl 1):45–51
DOI: 10.1159/000524420

Received: December 21, 2021
Accepted: February 8, 2022
Published online: April 28, 2022

Niti-S Esophageal Mega-Stent: An Emerging Endoscopic Tool with Different Applications in the Management of Surgical Anastomotic Leaks

Mariana Brito[a, b] Gonçalo Nunes[a, b] Carlos Luz[c] Gabriel Oliveira[c]
Pedro Pinto Marques[a] Jorge Fonseca[a, b]

[a]Department of Gastroenterology, Hospital Garcia de Orta, Almada, Portugal; [b]PaMNEC – Grupo de Patologia Médica, Nutrição e Exercício Clínico, CiiEM, Centro de investigação interdisciplinar Egas Moniz, Monte da Caparica, Portugal; [c]Department of Surgery, Hospital Garcia de Orta, Almada, Portugal

Keywords
Anastomotic leak · Esophageal Mega-Stent · Esophageal stent · Endoscopy

Abstract
Introduction: Anastomotic leak (AL) is a dangerous complication in the early postoperative period after total gastrectomy or esophagectomy being associated with high mortality. Self-expandable metal stents (SEMS) play a significant role in AL management. Only one case report described the use of Mega-Stent in AL setting. The authors report a two-case series with different applications of a Niti-S esophageal Mega-Stent in AL management. ***Case Report:*** Case 1 is a 67-year-old male who underwent an esophagectomy due to a squamous cell carcinoma of the distal esophagus. The early postoperative period was complicated with AL and gastropleural fistula. Initially, an OTSC was deployed in the dehiscence but failed to resolve AL. The esophageal Mega-Stent was further placed in-between the esophagus and the bulbus. Post-stenting contrast studies confirmed no further AL.Case 2 is an 86-year-old woman who underwent total gastrectomy with roux-en-y esophagojejunostomy due to a gastric adenocarcinoma, complicated with AL. A partially covered metal stent (PCMS) was placed to cover the anastomosis. Computed tomography confirmed leakage persistence and a second PCMS was deployed, resolving the AL. Several weeks later, both PCMSs presented ingrowth from granulation tissue. An esophageal Mega-Stent was placed (stent-in-stent technique) and 2 weeks later, all stents were removed, with no AL recurrence. ***Discussion/Conclusion:*** SEMS placement for AL is a safe, well-established therapeutic technique. Limitations include stent migration and incomplete cover of large AL. Mega-Stent can be an emerging tool for endoscopic AL management.

Mega-Stent esofágico Niti-S: uma ferramenta endoscópica emergente com diferentes aplicações na abordagem das deiscências anastomóticas

Palavras Chave
Deiscência anastomótica · Mega-Stent esofágico · Prótese esofágica · Endoscopia

Karger@karger.com
www.karger.com/pjg

Correspondence to:
Mariana Brito, marianasbrito076@gmail.com

Resumo

Introdução: A deiscência anastomótica (DA) é uma complicação grave no pós-operatório precoce da esofagectomia e gastrectomia total, pela sua elevada mortalidade. As próteses metálicas autoexpansíveis (PMAE) desempenham um papel fundamental no tratamento das DA. Na literatura, há apenas um caso descrito sobre a utilização de um *Mega-Stent* no contexto de DA, que não complicação bariátrica. Os autores reportam uma série de dois casos com diferente aplicação do *Mega-Stent* esofágico no tratamento de DA. ***Descrição do caso:*** Caso 1: Homem de 67 anos, submetido a esofagectomia por carcinoma epidermóide do esófago distal. O período pós-operatório precoce foi complicado de DA com fístula gastro-pleural. Inicialmente foi colocado um *clip* OTSC no orifício da deiscência com insucesso técnico e clínico, sendo posteriormente utilizado o *Mega-Stent,* posicionado desde o esófago até ao bulbo duodenal. Estudos contrastados posteriores confirmaram resolução da DA. Caso 2: Mulher de 86 anos, submetida a gastrectomia total com reconstrução em Y-Roux e esofagojejunostomia por adenocarcinoma gástrico, complicada de DA. Neste contexto foi colocada uma PMAE parcialmente coberta (PMAE-PC) sobre a área da anastomose. A tomografia computorizada subsequente demonstrou persistência de extravasamento. Foi colocada uma segunda PMAE-PC, com posterior resolução da DA. Semanas depois, ambas as PMAE-PC apresentavam tecido de granulação nos topos, tendo sido colocado o *Mega-Stent* (técnica *stent-in-stent*) e decorridas duas semanas, todas as próteses foram facilmente extraídas, confirmando-se sucesso no tratamento da DA. ***Discussão/conclusão:*** A utilização de PMAE nas DA constitui uma técnica terapêutica segura e bem estabelecida, contudo passível de apresentar limitações tais como a migração ou incapacidade de cobrir totalmente DA de maiores dimensões. O *Mega-Stent* esofágico pode constituir uma ferramenta útil na terapêutica endoscópica destes doentes.

Introduction

Anastomotic leaks (AL) are one of the most worrisome complications in the early postoperative period, either after a total gastrectomy or an esophagectomy [1, 2].

The AL incidence after esophagectomy ranges from 5 to 40% [3–5]; for AL post gastrectomy, several groups have reported rates of 5–7% [6, 7].

AL results in high mortality, often requiring repetitive therapeutic interventions and is associated with prolonged hospitalization [7, 8]. Early diagnosis and timely treatment are of utmost importance to avoid serious AL-related complications. However, early recognition of AL can be difficult due to the different clinical scenarios, often indistinguishable from symptoms caused by physiological postoperative inflammatory response or infection [9].

AL treatment options include conservative approach, endoscopic interventions, or surgery. The nonsurgical approach should be the initial strategy, reserving surgical reintervention for conservative measures' failure. Depending on the size and location of AL, a variety of endoscopic procedures can be selected, namely: endoscopic clips (mainly over-the-scope clips – OTSC), self-expandable metal stents (SEMS), endoscopic vacuum therapy and fibrin glue [10–12]. SEMS play a significant role in the management of these patients. There have been several reports of AL endoscopic treatment with SEMS placement [13, 14]. Only one case report described the use of an esophageal Mega-Stent in a patient with postesophagectomy gastropleural fistula [15]. Herein, the authors describe two examples of the utility of Mega-Stent in AL management.

Case Report

Case 1

A 67-year-old male was referred to the Surgery Outpatient Clinic with a 4-month history of dysphagia and weight loss. The patient was a former smoker. Other relevant past medical history included squamous cell carcinoma (SCC) of the head, surgically resected in the previous year, and colorectal cancer diagnosed 10 years before, that underwent right hemicolectomy. The upper GI endoscopy revealed a SCC of the distal esophagus. Clinical staging was cuT3N3aM0, according to computed tomography (CT), endoscopic ultrasonography (EUS) and fluorodeoxyglucose positron-emission tomography (FDG-PET) findings. The patient underwent neoadjuvant chemoradiotherapy and control CT showed clinical response. Afterwards, an Ivor-Lewis esophagectomy was performed without immediate complications. Two days after the procedure, the thoracic drain poured biliary fluid. Endoscopy with fluoroscopic control was performed, confirming the suspicion of AL of the gastric staple line of the esophagogastric anastomosis (EGA). An OTSC was placed in the dehiscence orifice. The patient started total parenteral nutrition (TPN). Three days later, fever was noted and thoracic CT revealed extraluminal oral contrast from the gastric conduit to the right pleura, confirming the presence of a gastropleural fistula (Fig. 1). Repeated endoscopy identified the OTSC previously placed in situ (Fig. 2a). Immediately below the EGA, in the posterior wall of the gastric conduit, a small orifice was seen, and a fluoroscopic image confirmed extraluminal contrast

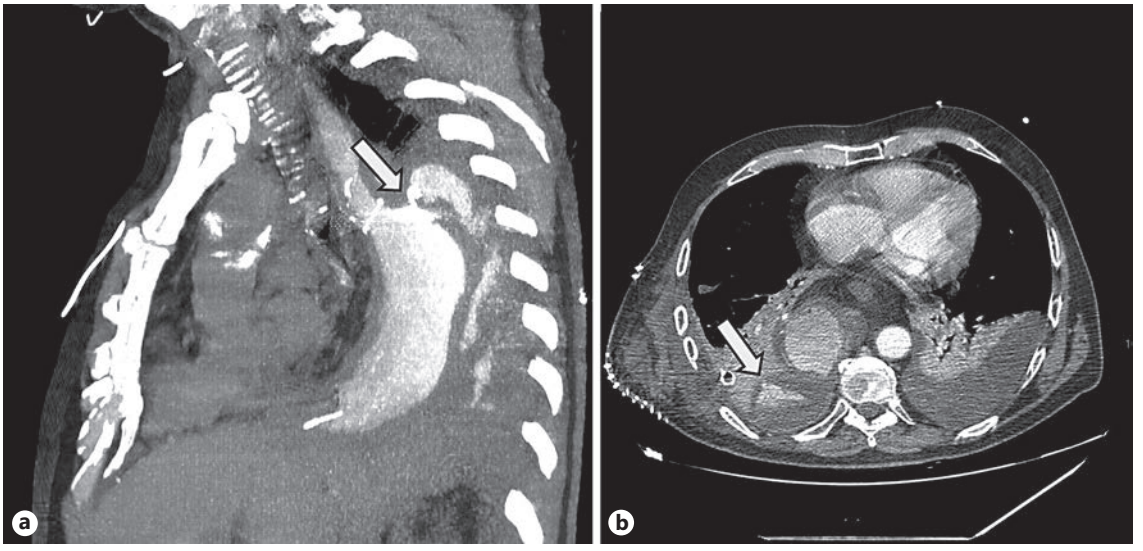

Fig. 1. Computed tomography. **a** Dehiscence of the gastric staple line of the esophagogastric anastomosis (arrow). **b** Gastropleural fistula with oral contrast in the pleural cavity (arrow).

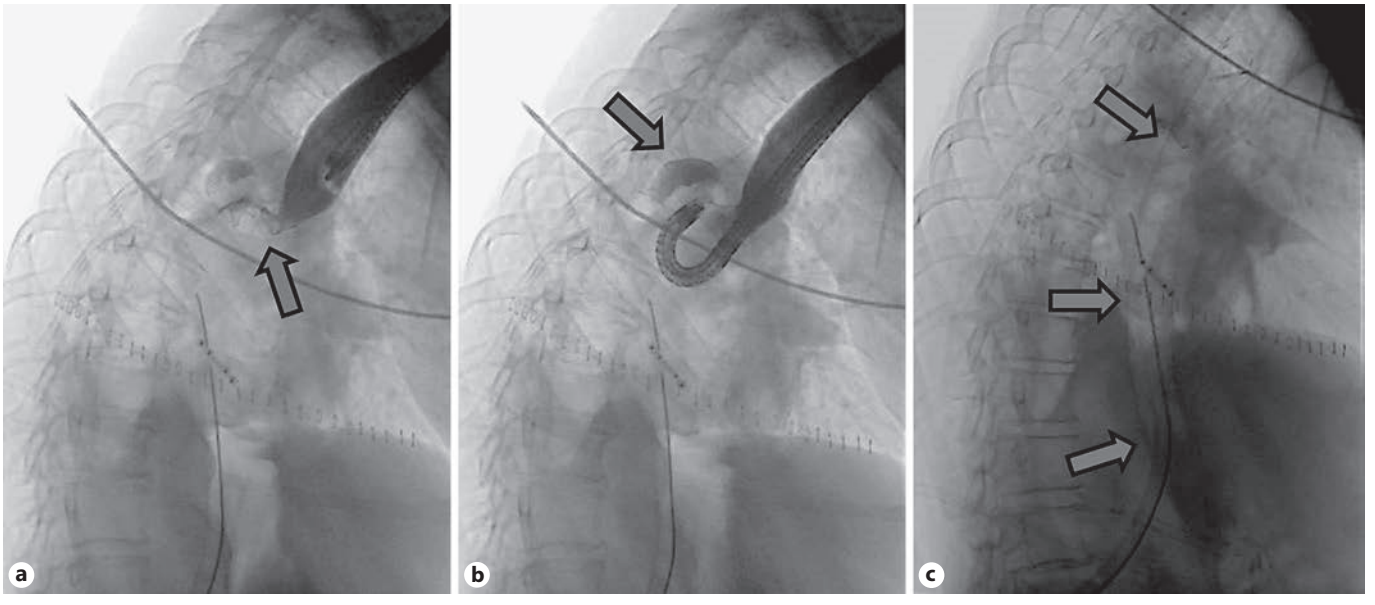

Fig. 2. Fluoroscopic image. **a** OTSC clip (arrow) placed in the first esophagogastroduodenoscopy. **b** Extraluminal contrast leakage (arrow) from the gastric conduit. **c** Niti-S™ MEGA™ Esophageal Stent (Mega-Stent), placed between the esophagus and the bulbus (arrows).

leakage (Fig. 2b). The previous OTSC clip was removed with a grasp and soft coagulation with Argon Plasma was applied at the orifice margins. Another OTSC was placed over the dehiscence orifice, and no further extraluminal contrast was observed at fluoroscopic evaluation. Given the friability of the tissue surrounding the OTSC and the failed first attempt with this method, we complemented therapy with a fully covered metal stent (FCMS). A Niti-S™ MEGA™ Esophageal Stent (Mega-Stent) from Taewoong Medical measuring 28 × 230 mm (Fig. 3) was chosen to ensure gastric conduit exclusion and facilitate healing. The proximal end of the stent was anchored in the esophagus and the distal end in the proximal bulbus (Fig. 2c). Three through-the-scope (TTS) clips were also used at the proximal end of the Mega-Stent to avoid migration. The patient improved and subsequent radiologic con-

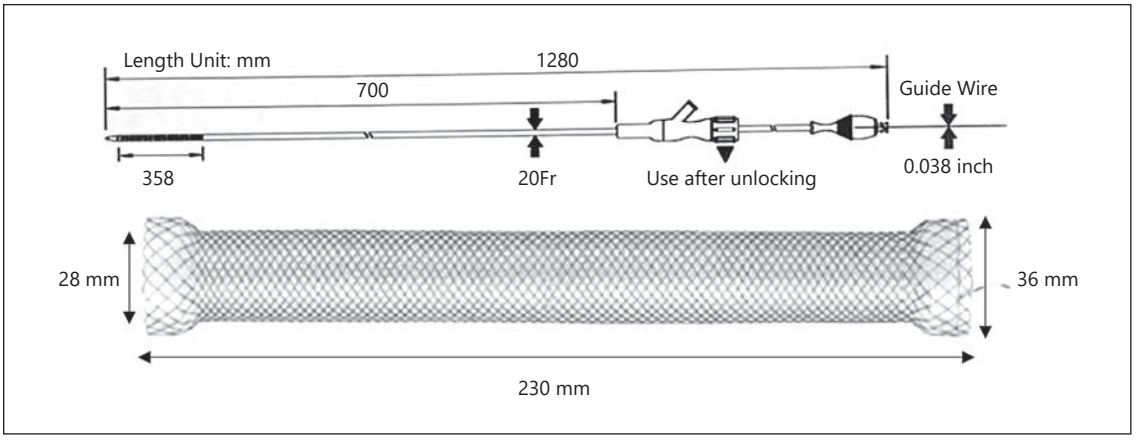

Fig. 3. Characteristics of Niti-S™ MEGA™ esophageal stent (adapted from Taewoong Medical).

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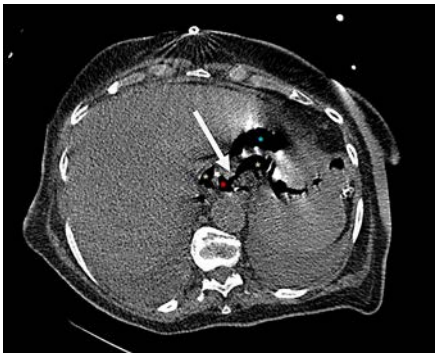

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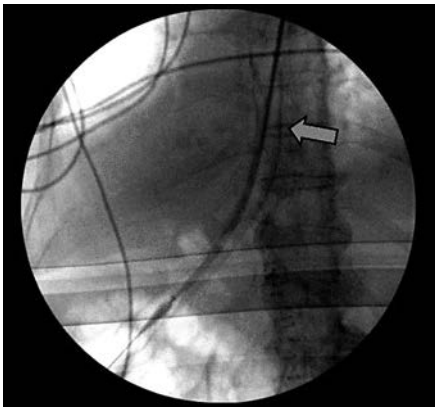

Fig. 4. Computed tomography showing anastomotic dehiscence (arrow). Red asterisk: esophagojejunal anastomosis. Blue asterisk: jejunum. Green asterisk: extraluminal air.

Fig. 5. Fluoroscopic image of partially covered metal stent placed in the esophagus, covering dehiscence.

trol showed progressively AL resolution. Several infectious complications significantly increased hospital in-stay length. TPN was maintained during most of the hospital admission. Enteral nutrition was started on the 36th day after Mega-Stent placement and parenteral support was discontinued after 40 days. Before patient discharge, repeated CT confirmed absence of AL and ambulatory endoscopy was scheduled for 6 weeks later to remove the stent which was easily performed with a grasp. Scar tissue was observed in the previous AL location, and no extraluminal contrast was observed at fluoroscopic evaluation, thus confirming successful of endoscopic treatment.

Case 2

An 86-year-old woman was referred to the Surgery Outpatient Clinic with a 1-month history of low solid food dysphagia. Relevant medical history included left nephrectomy due to tuberculosis and iodine contrast allergy. Endoscopy revealed ulcerated gastric neoplasia, involving the anterior wall of the distal corpus and proximal antrum. Biopsies were consistent with well-differentiated gastric adenocarcinoma. CT and FDG-PET showed local lymph node involvement but no distant metastasis. Staging laparoscopy did not reveal peritoneal metastasis. Given the patient's good performance status (ECOG-0/Karnofsky-90), total gastrectomy with Roux-en-Y esophagojejunostomy was performed without immediate complications after a thorough informed consent had been obtained. A feeding jejunostomy was also left for immediate nutritional support. On the third postoperative day, the patient presented fever, thoracalgia and dyspnea. Thoracic CT confirmed AL (Fig. 4). Endoscopy did not identify a clear dehiscence orifice. However, at fluoroscopic evaluation, extraluminal contrast was seen at the esophagojejunal anastomosis (EJA) site. A 23 × 125 mm PCMS was placed to cover the EJA (Fig. 5). The patient started TPN. Ten days after surgery, biliary drainage was noted in the thoracic drain. CT demonstrated oral contrast leakage at the proximal end of the PCMS. EGD with fluoroscopic control confirmed minimal extraluminal contrast at the proximal third of the stent. A new 23 × 125 mm PCMS was placed to cover the leakage area, the proximal end located 5 cm above the previous stent, secured with 3 TTS clips. After this intervention, the patient presented clinical improvement. Repeated CT confirmed absence of leakage. She was weaned off TPN, being discharged after 47 days due to several infectious complications. Endoscopic removal of both stents was scheduled for 10 weeks after discharge. Due to granulation tissue on both ends of the PCMS, the endoscopy team decided to place a

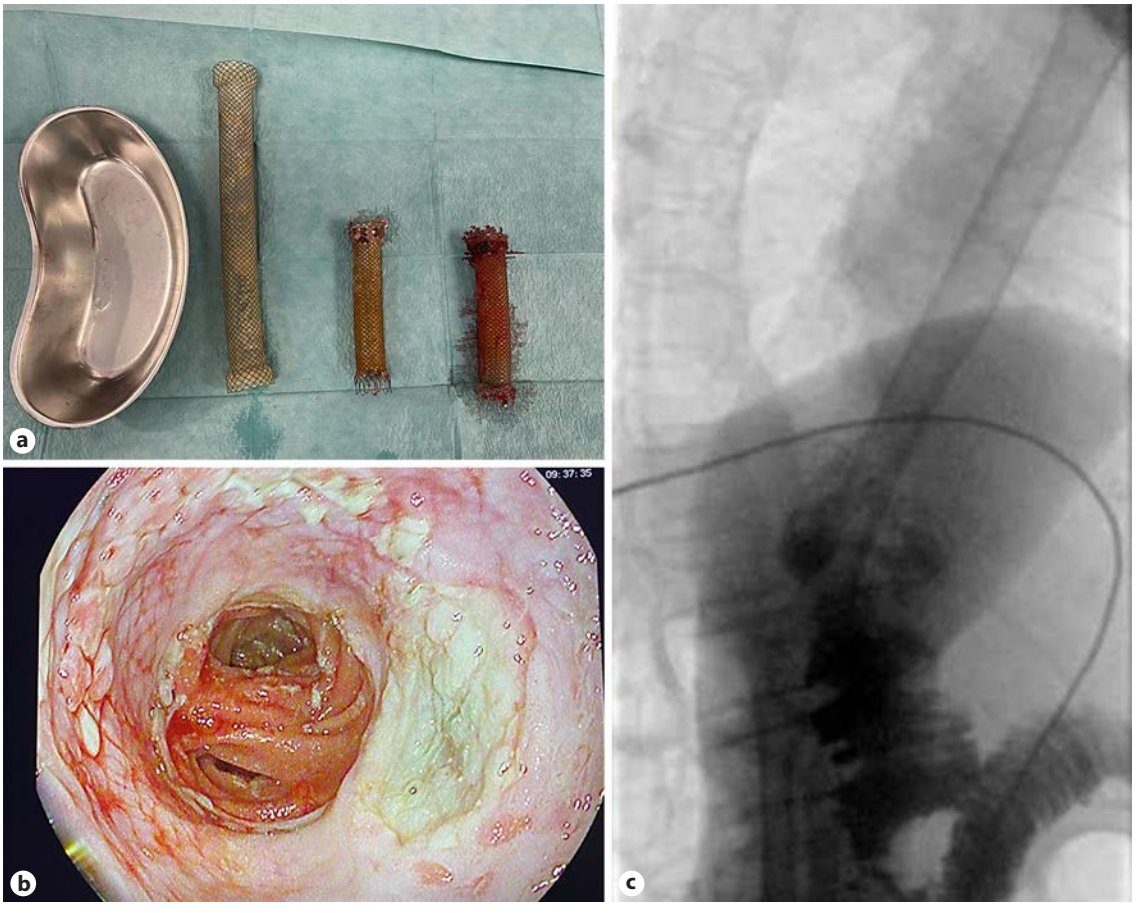

Fig. 6. a Three stents removed endoscopically after using the Mega-Stent for stent-in-stent technique. **b** Endoscopic image of anastomosis with no evidence of dehiscence. **c** Fluoroscopic image revealing no extraluminal leakage.

Mega-Stent to cover both uncovered tops (stent-in-stent technique). Two weeks later, the three stents could be easily removed using a grasp without complications (Fig. 6a). The anastomosis presented no dehiscence (Fig. 6b) and, at fluoroscopic evaluation, no leakage was seen (Fig. 6c).

Discussion

AL after oncologic surgery is a very serious and challenging problem. Gastrectomy plus lymphadenectomy followed by EJA is the standard treatment for gastric cancer. Despite advances in surgical techniques and perioperative management, EJA leak remains a serious and potentially fatal complication of total gastrectomy [16]. Overall, the mortality rate associated with EJA leak is approximately 30% [7]. Esophagectomy, on the other hand, is a technically challenging procedure, prone to high incidence of complications. AL after cancer resection remains one of the most feared complications, associated with high mortality [17].

Isolated AL can sometimes be successfully managed with conservative treatment, including antibiotics, nil by mouth, nasojejunal tube or parenteral feeding. Several endoscopic approaches including SEMS, endoscopic vacuum therapy and clips have been reported to be useful in treating AL and can result in healing with minimal morbidity [11–14]. Revisional surgery presents a challenge and carries a risk of further complications. However, surgical intervention is sometimes required for refractory AL cases after failed conservative or endoscopic approach. No evidence supporting a specific treatment option for AL has been defined for lacking high-quality studies [18, 19].

Vacuum therapy has shown good results in the literature, but in both our cases, only small dehiscence orifices were observed, without a cavity contacting with esophageal lumen, thus making it an inadequate scenario to apply vacuum therapy. Also, we have little experience with this treatment, as opposed to OTSC and luminal stents. The endoscopic SEMS placement for cases of AL or fistula presents a safe and well-established therapeutic technique, with low overall procedure-related mortality. However, stent migration and failure to completely cover large AL are the main pitfalls of the procedure [20]. The use of multiple or larger stents can be a way of overcoming such limitations. Several reports described the use of a Mega-Stent for managing leaks after laparoscopic sleeve gastrectomy [21–23]. In fact, the Mega-Stent was developed for management of leaks after sleeve gastrectomy, but the EGA leak presents a similar behavior, thus Mega-Stent is a valid option in this situation. Only one case report described clinical success using a Mega-Stent in a case of postesophagectomy gastropleural fistula [15].

In our first case, the patient underwent an esophagectomy and presented AL in the proximal part of the gastric conduit. The choice of the Mega-Stent arose after a first failed attempt of AL treatment using an OTSC. Considering the abrupt diameter transition between the esophagus and the stomach, a standard sized SEMS would not properly seal the AL. Also, since conventional stents would present a significant migration risk, an esophageal Mega-Stent was selected to ensure gastric conduit exclusion and facilitate healing while minimizing dislodgment, as it could be placed and anchored between the esophagus and the bulbus. Nevertheless, we chose to place 3 TTS clips in the proximal end of the Mega-Stent to guarantee stent fixation. OTSC and endoscopic suturing are recommended to prevent stent migration. Unfortunately, we had no more OTSC with adequate size for this purpose available at that moment in our unit. Furthermore, the placement of an OTSC would be a more expensive strategy just for preventing stent migration. As endoscopic suturing was not available in our center, we considered the placement of TTS clips to be the best choice in this case. The AL was successfully treated.

Regarding the second patient, with an EJA leak after a total gastrectomy, a first PCMS was placed in attempt to treat the AL. The choice of a PCMS was to prevent stent migration. However, one stent could not resolve the AL, so we placed a second PCMS, successfully treating the AL. Stent removal was scheduled 10 weeks thereafter, but due to granulation tissue on both PCMS, we opted to perform a stent-in-stent technique using an esophageal Mega-Stent. The use of a single standard size FCMS would not have enough length to cover both uncovered portions of the previously placed stents. The alternative would be to place two FCMS, either in the same endoscopic procedure or in different endoscopic times and removing them sequentially in two stent-in-stent approaches. In this case, the Mega-Stent proved very useful in this case since we removed all three stents 14 days later without complications. This case illustrates an alternative application of the Mega-Stent in AL management.

The authors believe that the Mega-Stent can be an emerging tool for endoscopic management of surgical AL since it is safe, easy to place, able to treat large AL and reduces the risk of stent migration. It can also be used in stent in-growth cases, avoiding the need for multiple FCMS, thus simplifying the procedure.

Statement of Ethics

Written informed consent was obtained from both patients for publication of this case report.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Funding Sources

The authors have no funding sources regarding the present manuscript.

Author Contributions

Mariana Brito wrote the manuscript. Gonçalo Nunes performed the endoscopic procedures. Mariana Brito, Gonçalo Nunes, Carlos Luz, Gabriel Oliveira and Pedro Pinto Marques were enrolled in patients' management. Gonçalo Nunes, Gabriel Oliveira and Jorge Fonseca reviewed the manuscript. Gonçalo Nunes and Jorge Fonseca supervised the study.

Data Availability Statement

All data generated or analyzed during this study are included in this article. Further enquiries can be directed to the corresponding author.

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GE – Portuguese Journal of Gastroenterology

Clinical Case Study

GE Port J Gastroenterol 2023;30(suppl 1):52–56
DOI: 10.1159/000526507

Received: January 21, 2022
Accepted: March 28, 2022
Published online: September 12, 2022

Endoscopic Management of a Chronic Gastrocutaneous Fistula after Bariatric Revisional Surgery Using a Novel Cardiac Septal Occluder

Mariana Kumaira Fonseca[a] Nelson Heitor Vieira Coelho[b]
João Luiz Langer Manica[c] Rafael Ramos Ramblo[d] Ingrid Elisa Spier[e]
Artur Pacheco Seabra[a]

[a]General Surgery Department, Hospital Moinhos de Vento, Porto Alegre, Brazil; [b]Gastroenterology and Endoscopy Department, Hospital Moinhos de Vento, Porto Alegre, Brazil; [c]Interventional Cardiology in Congenital Heart Disease Department, Hospital Moinhos de Vento, Porto Alegre, Brazil; [d]Radiology and Diagnostic Imaging Department, Hospital Moinhos de Vento, Porto Alegre, Brazil; [e]Critical Care and Internal Medicine Departments, Hospital Moinhos de Vento, Porto Alegre, Brazil

Keywords
Bariatric surgery · Gastric fistula · Endoscopy · Gastrointestinal · Septal occluder device

Resumo

Introduction: Endoscopic techniques are now considered the first-line approach for the management of bariatric surgery-related fistulas. The off-label use of cardiac septal defect occluders (CSDO) is an emerging technique that has demonstrated favorable outcomes for the closure of extravascular defects, including gastrointestinal (GI) disruptions. Previous case reports have reported similar results with the CSDO Amplatzer™ for the management of GI disruptions following bariatric surgery. However, the use of similar alternative devices for this purpose has not yet been described.
Case Presentation: This case report presents the first reported use of the Occlutech® CSDO for the treatment of a chronic gastrocutaneous fistula after bariatric revisional surgery. Despite apparent initial success – no extravasation of contrast material through the device in the contrast study after the CSDO placement – fistula closure failed due to partial dislodgement of the device. The placement of a second device between the discs of the former one ultimately sealed the fistulous orifice. ***Discussion:*** In chronic GI fistulas, the mature tract is often not liable to the application of standard endoscopic methods, leading to failed closure attempts. A new application of Occlutech® CSDO can obviate the clinical burden of a high-risk laparotomy in these cases. Appropriate endoscopic equipment as well as the involvement of a multidisciplinary team are prime conditions to ensure successful patient outcomes.

Karger@karger.com
www.karger.com/pjg

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Correspondence to:
Mariana Kumaira Fonseca, marianakumaira@gmail.com

Tratamento endoscópico de fístula gastrocutânea crônica após cirurgia bariátrica revisional com novo dispositivo de oclusão septal cardíaco

Palavras Chave
Cirurgia bariátrica · Fístula gástrica · Endoscopia · Gastrointestinal · Dispositivo para oclusão septal

Resumo

Introdução: As técnicas endoscópicas são atualmente consideradas abordagens de primeira linha no manejo das fístulas associadas a cirurgia bariátrica. O uso *off-label* de dispositivos de oclusão do septo cardíaco (CSDO) é uma técnica nova que tem demonstrado resultados favoráveis no encerramento de defeitos extra-vasculares, incluindo fístulas gastrointestinais. Relatos de caso prévios reportaram resultados semelhantes com o CSDO Amplatzer™ para o tratamento de fístulas gastrointestinais pós cirurgia bariátrica. No entanto, o uso de dispositivos alternativos semelhantes para esse fim ainda não foi descrito. ***Relato de Caso:*** Este relato de caso apresenta o primeiro uso reportado do CSDO Occlutech® para tratamento de fístula gastrocutânea crônica após cirurgia bariátrica revisional. Apesar do aparente sucesso inicial – nenhum extravasamento de contraste através do dispositivo na fluoroscopia após a colocação do CSDO, houve recorrência da drenagem fistulosa devido ao deslocamento parcial do dispositivo. A colocação de um segundo dispositivo entre os discos do primeiro acabou por encerrar o orifício fistuloso. ***Discussão:*** Nas fístulas gastrointestinais crônicas, o trajeto epitelizado muitas vezes não é passível de aplicação dos métodos endoscópicos tradicionais, levando a múltiplas tentativas fracassadas de encerramento. A nova aplicação de Occlutech® CSDO pode evitar o risco de uma laparotomia de alto risco nesses casos. Equipamentos endoscópicos adequados, bem como o envolvimento de equipe multidisciplinar são condições primordiais para garantir o sucesso do tratamento.

Introduction

Gastrointestinal (GI) fistulas are one of the most feared adverse events after abdominal surgery and constitute the second-leading cause of death among patients undergoing bariatric procedures, with a mortality rate of up to 14.7% [1]. They mostly occur in the gastrojejunal anastomosis or along the gastric vertical staple line [2], with an estimated incidence of 0.7–5% [3]. Despite recent advances in treatment modalities, it remains a therapeutic challenge and often requires clinical intensive care, multiple radiological, endoscopic, and surgical procedures, and interdisciplinary involvement [3, 4].

Endoscopic techniques are now considered the first-line approach for the management of bariatric surgery-related fistulas, as they spare many patients who would otherwise undergo revisional surgery at an increased risk of adverse events [3]. A variety of different procedures and devices has been proposed with variable success rates, including clips, mesh plugs, self-expandable metal stents, tissue sealants, suturing platforms, internal drainage, vacuum therapy, brushes, and argon plasma coagulation [3, 5–7].

The use of cardiac septal defect occluders (CSDO) is an emerging technique that has demonstrated favorable outcomes for the closure of extravascular defects, such as bronchopleural, tracheoesophageal, enteroatmospheric, and rectovaginal fistulas [5]. Other studies have reported similar results with the CSDO Amplatzer™ for the management of GI disruptions following bariatric surgery [8]. However, the use of alternative devices for this purpose has not yet been described. The current report presents the first off-label use of the Occlutech® occluders for the treatment of a chronic fistula after bariatric revisional surgery.

Case Report

A 52-year-old male with a body mass index of 23.6 kg/m^2 and no comorbidities was referred to our institution for surgical consultation due to a chronic post-bariatric gastrocutaneous fistula. His bariatric history started in 2002, after he underwent an open modified Scopinaro procedure at an initial weight of 216 kg (BMI 57.4 kg/m^2). Despite midterm satisfactory results (44% total weight loss), the patient presented with weight reganance and an incisional hernia. Bariatric revisional surgery and hernia repair were performed in 2017 at a weight of 170 kg (BMI 45.1). He soon developed a gastric pouch leak with multiple intra-abdominal collections and sepsis, which required a long period of conservative management with open abdomen and negative wound pressure therapy, parenteral nutrition, and intravenous antibiotics.

Over the course of several months, he developed an epithelized gastrocutaneous fistula with controlled but persistent drainage out of the proximal edge of his planned ventral hernia (Fig. 1a). An upper endoscopy identified a fistulous orifice at the proximal edge of the vertical staple line, just below the esophagogastric junction, measuring approximately 8 mm (Fig. 1b), with extraluminal extravasation that led to a recurrent left subphrenic abscess (Fig. 1c).

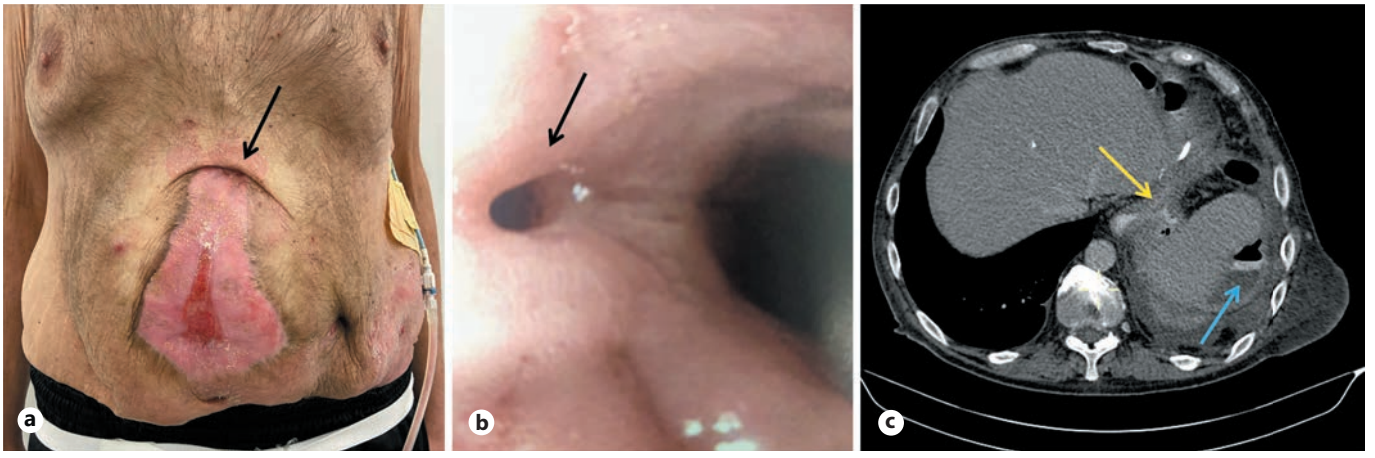

Fig. 1. a Clinical photograph (arrow: cutaneous orifice of fistula; pigtail drain in left subphrenic abscess). **b** Endoscopic image of the fistula opening (arrow) below gastroesophageal junction. **c** CT scan: extravasation of oral contrast media (yellow arrow); left subphrenic abscess (blue arrow).

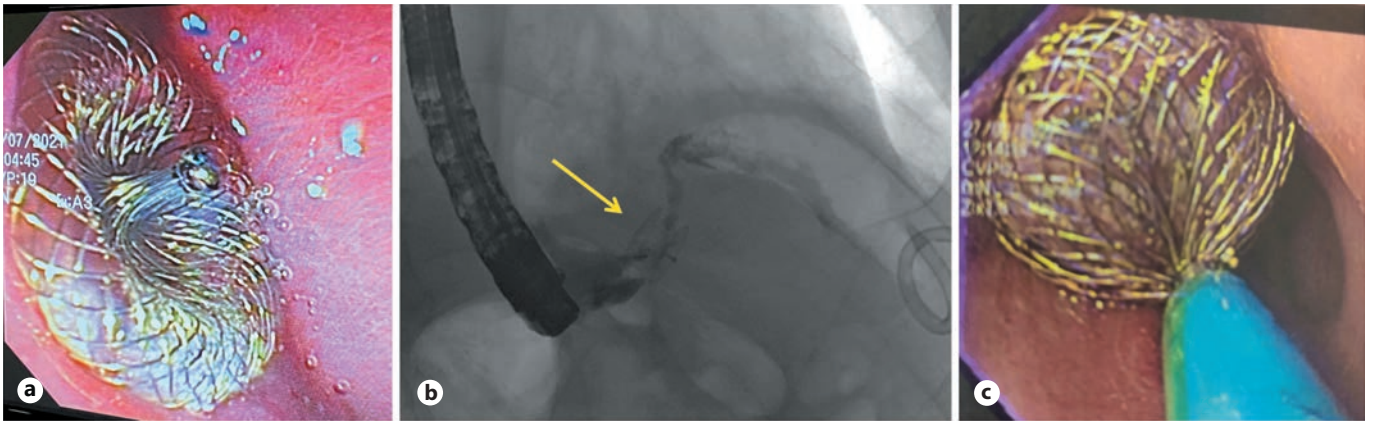

Fig. 2. a Endoscopic visualization of the first device in place – Occlutech® mVSD occluder. **b** Fluoroscopic image after partial dislodgement of the device; fistula cannulation demonstrating extraluminal extravasation of contrast material through the occluder. **c** Endoscopic visualization of the second device in place – Occlutech® Figulla Flex II occluder.

Endoscopic treatment was considered the preferred choice for this case, given the poor nutritional status and hostile abdomen. For years, he had undergone multiple attempts at fistula closure using argon plasma coagulation, internal and external drainages, clipping, fibrin sealants, e-vac therapy, and stenting.

Discouraged with multiple failed repair attempts, he was referred for further evaluation in our center. After a multidisciplinary team discussion, a decision was made to proceed with an innovative endoscopic technique. The placement of a CSDO across the fistula orifice was planned with the agreement and written consent of the patient.

An Occlutech® muscular VSD occluder (Occlutech International AB, Helsingborg, Sweden) was selected due to the long funnel-shaped aspect of the defect, similar to a ventricular septal defect. This device consists of a braided nitinol disc designed to adapt to the shape of the defect and effectively achieve immediate closure. The patch material also serves as a matrix for subsequent tissue ingrowth and granulation that may contribute to fistula closure [9].

The procedure was performed in the catheterization laboratory under intravenous sedation and topic anesthesia. The fistula was cannulated from the esophagus by a biliary stent deployment system under direct endoscopic guidance and the extraluminal leakage was documented by contrast injection. An Amplatz™ extra stiff guidewire (Cook Medical, Bloomington, IN, USA) was inserted through the fistula orifice and its adequate position was confirmed by fluoroscopy. The delivery system was introduced over the guidewire and the CSDO was deployed under endoscopic and

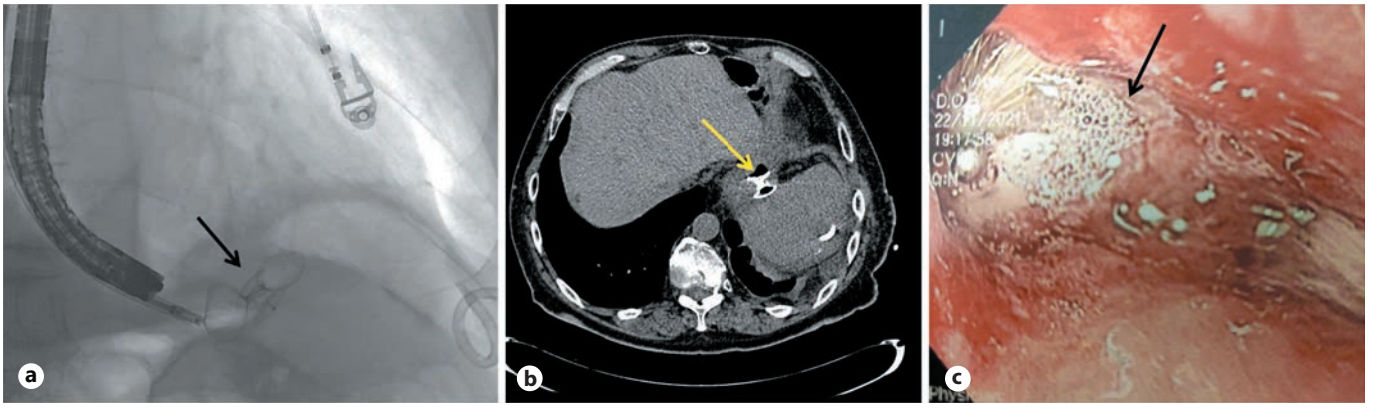

Fig. 3. a Fluoroscopic image showing the first device positioned between the two (luminal and extraluminal) discs of the second one. **b** CT scan with both devices in place, with no extravasation of oral-administered contrast media. **c** Endoscopic visualization of both devices engrafted.

fluoroscopic guidance with no immediate adverse events (Fig. 2a). A contrast study after the CSDO placement demonstrated no extravasation of contrast material through the device.

After the procedure, restricted oral intake was required for 24 h. The patient was placed on a liquid diet for 10 days and was advanced to a regular diet on day 12, despite the 10–15cc remaining daily drainage through the pigtail drain positioned at his left subphrenic abscess. Nearly 6 weeks later, the pigtail was accidentally displaced, and the patient progressively developed systemic signs of sepsis. Computed tomography and fluoroscopy documented recurrence of the abscess and partial dislodgment of the 8-mm mVSD CSDO (Fig. 2b). The device probably tore the friable tissue around the fistulous orifice and got stuck in the tunnel-shaped tract, and it was not possible to see or snare the device by endoscopic view. Given the apparent (though limited) success of the device, a second attempt with an oversized disc (Occlutech® Figulla Flex II UNI 24-mm) was made (Fig. 2c), ultimately sealing the fistulous orifice with the former device positioned between the two discs of the new one (Fig. 3a).

At the 6-month clinical and imaging follow-up, upper endoscopy and contrast-enhanced CT scan showed the device already engrafted and a significant reduction of the chronic abscess, with no signs of fistula recurrence (Fig. 3b, c). The pigtail was maintained in the subphrenic space to monitor any sign of fistula recurrence and occasionally drained debris from the chronic abscess. It was finally removed after the follow-up imaging, and no drainage was observed from its insertion orifice or the previous cutaneous fistulous tract.

Discussion/Conclusion

The concept of the use of CSDO for the treatment of GI fistulas is not novel, albeit formally it is considered an off-label indication. Its use in the setting of post-bariatric fistula treatment is still very limited to a small number of case reports [5, 10–12]. To the best of the authors' knowledge, no reports on the use of the Occlutech® devices for this purpose are available comparable to former studies with the Amplatzer™ Occluders.

Early results suggest this technique is particularly useful for poor surgical candidates with chronic GI fistulas that have had failure of closure attempted with standard endoscopic methods [8]. In these cases, the persistent inflammation, fibrosis, and epithelialization of the tract is often not liable to the application of clips, sutures, sealants, and conventional ablative techniques, leading to failed closure attempts in up to 20% of cases [12].

In the presented case, multiple attempts using endoscopic techniques have ultimately failed due to a mature fistula tract and a chronic adjacent abscess. Nevertheless, a new application method of the Occlutech® endoscopic device has obviated the clinical burden of a high-risk laparotomy, providing a more suitable alternative to surgical repair.

This case also enlightens the importance of perseverating on minimally invasive modalities to manage these challenging cases. It is also of note that appropriate endoscopic equipment, as well as the involvement of a multidisciplinary team comprising of advanced endoscopists, surgeons, interventional radiologists, and interventional cardiologists, are prime conditions to ensure successful patient outcomes.

In conclusion, this report has successfully demonstrated the technical feasibility, safety, and efficacy of the Occlutech® occluders for the endoscopic treatment of a chronic gastrocutaneous fistula. Given that the long-term efficacy of the off-label use of CSDO for GI fistula closure is unknown, further trials are expected to assess and compare different devices and other treatment modalities.

Statement of Ethics

Informed consent was obtained from the patient for writing up this article and including images.

Conflict of Interest Statement

Dr. Nelson Coelho is a consultant for Boston Scientific and Dr. João Luiz Manica is a proctor for Tecmedic. The other authors have no financial conflicts of interest to disclose.

Funding Sources

No funding to declare.

Author Contributions

Conceptualization: Artur Seabra, Nelson Coelho, João Manica, and Ingrid Spier. Data collection: Mariana Kumaira Fonseca and Rafael Ramblo. Literature review: Mariana Kumaira Fonseca. Original draft preparation: Mariana Kumaira Fonseca and João Manica. Review and editing: Artur Seabra, Nelson Coelho, and Ingrid Spier.

Data Availability Statement

The complete data of this study are not publicly available due to the patient's privacy but are available from NHVC upon reasonable request.

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GE – Portuguese Journal of Gastroenterology

Endoscopic Snapshot

GE Port J Gastroenterol 2023;30(suppl 1):57–60
DOI: 10.1159/000526127

Received: February 15, 2022
Accepted: May 3, 2022
Published online: August 29, 2022

The Cutting-EDGE: Biliary Intervention in Altered Anatomy

Carolina Chálim Rebelo Nuno Nunes Diogo Bernardo Moura
Francisca Corte-Real José Renato Pereira Maria Antónia Duarte

Gastroenterology Department, Hospital do Divino Espírito Santo de Ponta Delgada, Ponta Delgada, Portugal

Keywords
EUS-directed transgastric ERCP · Lumen apposing metal stent · EUS-guided biliary drainage · Roux-en-Y gastric bypass · Altered anatomy

The cutting-EDGE: intervenção biliar em anatomia alterada

Palavras Chave
CPRE transgástrica guiada por ecoendoscopia · Prótese de aposição luminal · Drenagem biliar guiada por ecoendoscopia · Bypass em Y-de-Roux · Anatomia alterada

Endoscopic access to the native papilla in patients with Roux-en-Y gastric bypass (RYGB) can be challenging when managing pancreaticobiliary disease. The endoscopic ultrasound (EUS)-directed transgastric endoscopic retrograde cholangiopancreatography (EDGE), a technique first described in 2013 by Kedia et al. [1], consists in the creation of a temporary fistula between the gastric pouch, or the proximal jejunum, and the excluded stomach, by placing a lumen-apposing metal stent (LAMS) under EUS guidance.

We present a case of a 59-year-old woman, with a previous personal history of RYGB (grade III obesity). She developed an acute calculous cholecystitis and was submitted to laparoscopic cholecystectomy. A magnetic resonance cholangiopancreatography, performed 1-month after surgery, showed residual choledocholithiasis. After a multidisciplinary discussion, EDGE was proposed.

The procedure was performed in two stages, both under deep sedation, orotracheal intubation, and fluoroscopic control (video). In the first phase, a linear echoendoscope (GF-UCT180; Olympus Medical Systems, Japan) was advanced to the gastric pouch to localize the excluded stomach. When the closest point between the gastric pouch and the excluded stomach was located, a transmural puncture was performed, using a 19-G aspiration needle (Expect™; Boston Scientific®, Marlborough, MA, USA). Then the needle stylet was withdrawn, and 300 mL water-soluble contrast medium was injected into the excluded stomach, using EUS and fluoroscopic control. A 10 × 15-mm LAMS (HotAxios™; Boston Scientific®) was used to create an access to the excluded stomach: the distal flange was deployed under fluoroscopic and EUS guidance, and the proximal flange was deployed under endoscopic visualization into the remnant gastric pouch (Fig. 1). Three weeks later, after gastro-gastric fistula maturation, the second stage was performed: a standard duodenoscope (TJF-Q190V; Olympus Medical Systems, Japan) was advanced through the LAMS into the excluded stomach and then passed in an antegrade manner to the major

Karger@karger.com
www.karger.com/pjg

Correspondence to:
Carolina Chálim Rebelo, carolinachalimrebelo@gmail.com

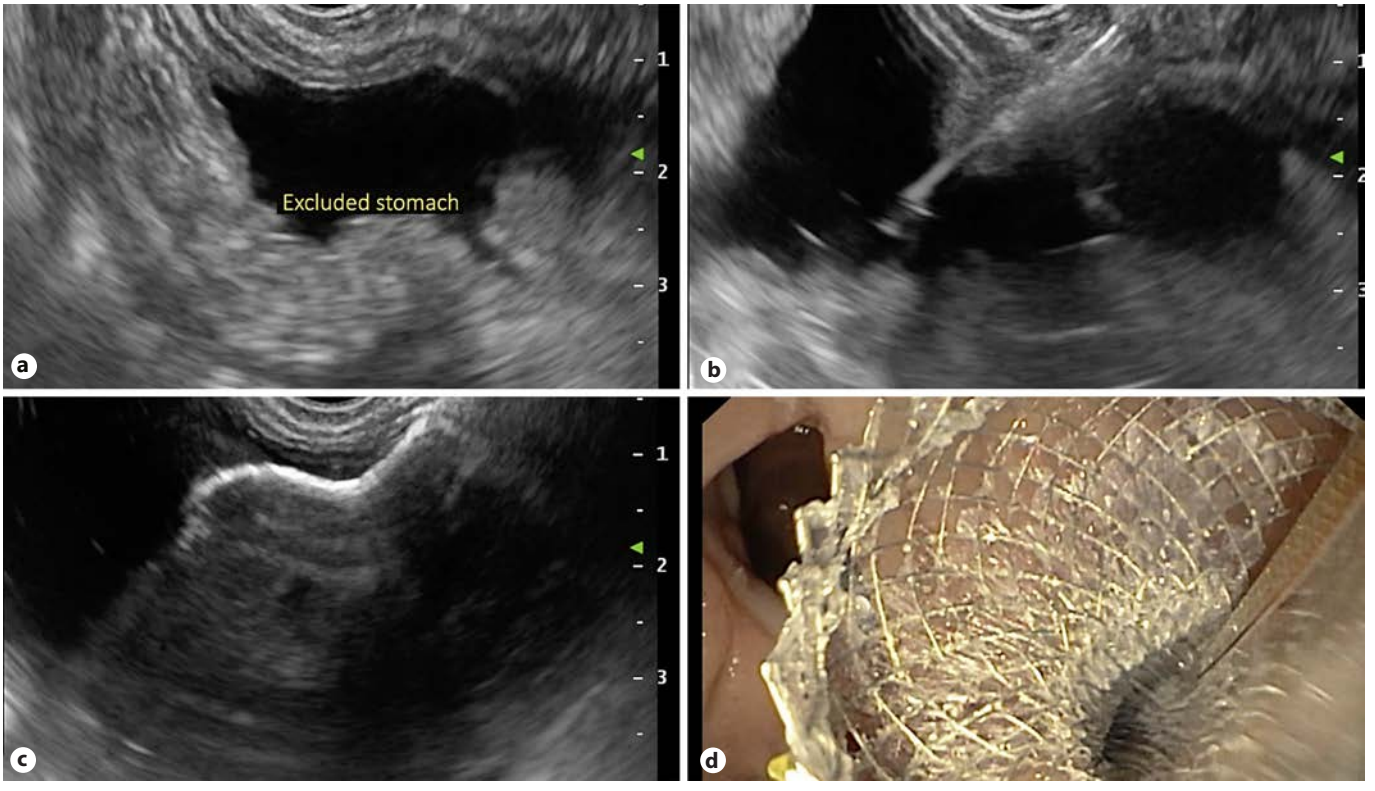

Fig. 1. First phase of procedure. **a** Echoendoscopic localization of the excluded stomach. **b** Transmural puncture with water-soluble contrast injection into the excluded stomach. **c**, **d** Deployment of the LAMS to create a gastro-gastric fistula.

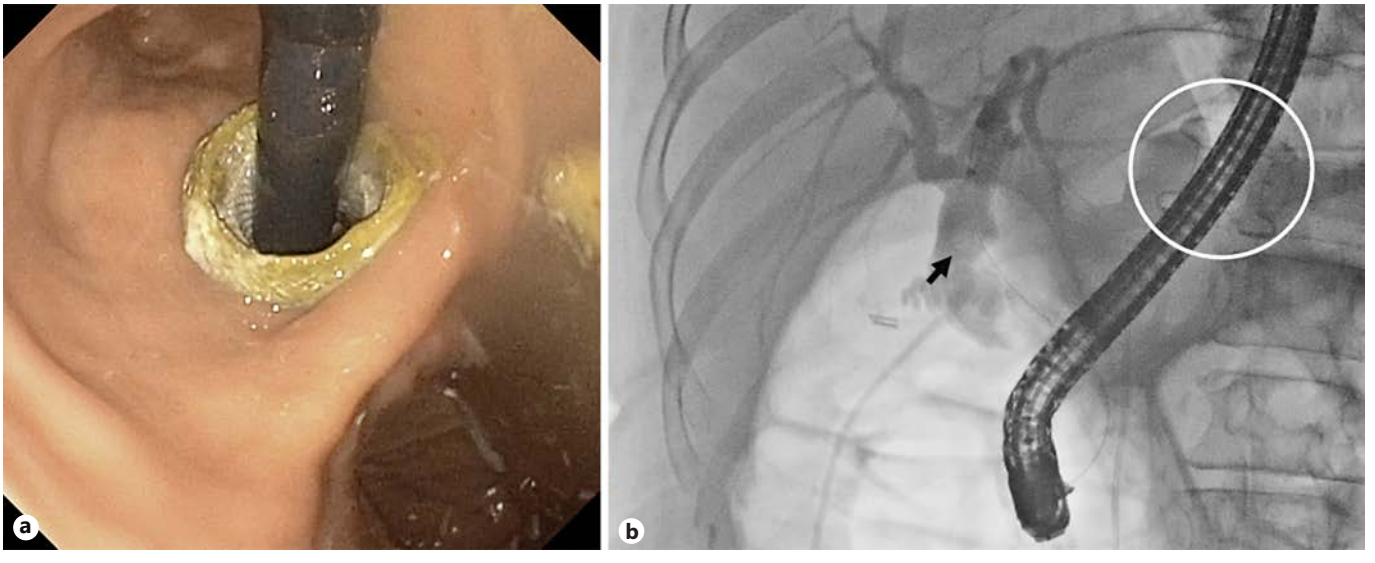

Fig. 2. Second phase of procedure, 3 weeks later: ERCP was performed through the LAMS (white circle), with bile duct stone removal (black arrow). **a** Endoscopic view. **b** Fluoroscopic control.

GE Port J Gastroenterol 2023;30(suppl 1):57–60
DOI: 10.1159/000526127

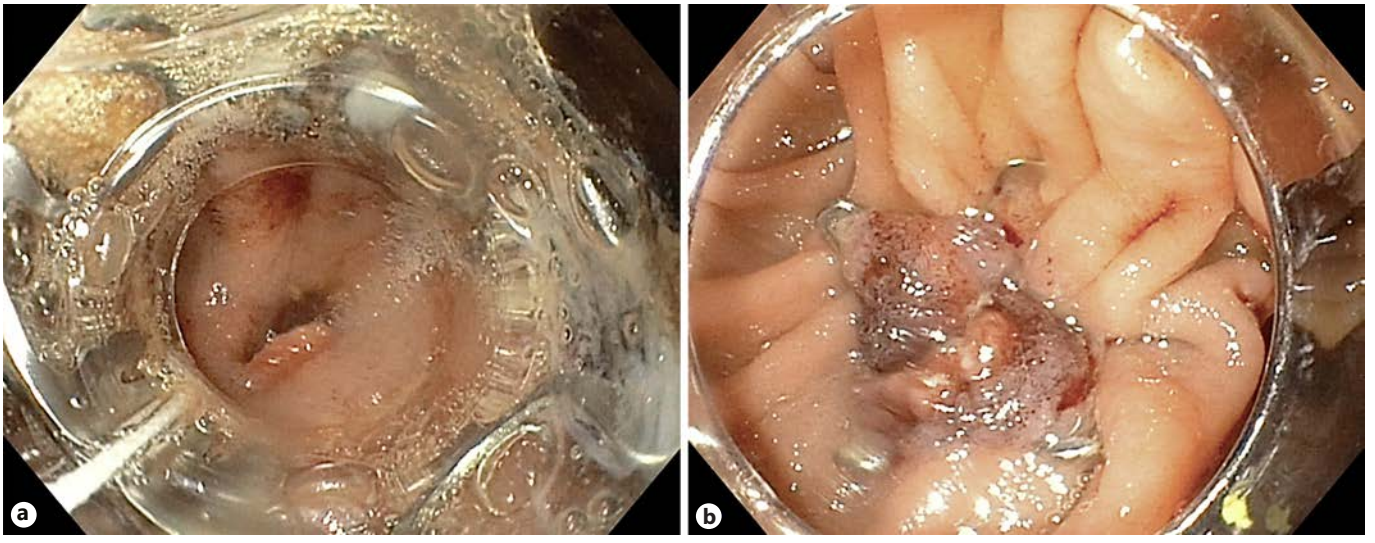

Fig. 3. a, **b** Four weeks later, the LAMS was removed, and the fistula was closed with OTSC®.

papilla (Fig. 2). Due to a mature fistula and a fully expanded stent, there was an easy duodenoscope passage through the LAMS, obviating the need for balloon dilatation. A conventional ERCP was performed, with bile duct stone removal. After the ERCP was completed, the duodenoscope was removed carefully, to prevent stent migration. The patient showed no immediate or late complications. Four weeks later, the LAMS was removed, and the fistula was closed with an over-the-scope clip (OTSC®, Ovesco Endoscopy, California, USA) (Fig. 3).

EDGE is a new technique with high technical (95.5–100%) and clinical success (95.9–98%) rates, compared to the ones of laparoscopy-assisted ERCP (LA-ERCP) (95.3% and 92.9%, respectively) and superior to enteroscopy-assisted ERCP (71.4% and 58.7%, respectively) [2–4]. EDGEs' adverse events (AE) occur in 15.7–27.8% of cases. Most AE are minor, related to stent migration or misdeployment [2, 4, 5]. They are comparable to AE of laparoscopy-assisted ERCP (17.4%), but higher than those of enteroscopy-assisted ERCP (8.4%) [3, 4]. EDGE is a minimally invasive procedure that can be performed in a single session, if necessary. The 20-mm LAMS may be associated with reduced stent migration rates and higher single-session ERCP, but further studies are needed [2, 5]. We describe the EDGE technique step-by-step, a procedure with high clinical and technical success rates and with an acceptable safety profile, as it is an option when ERCP is mandatory in patients with RYGB.

Statement of Ethics

The patient provided her written informed consent to publish this case and images.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Funding Sources

None.

Author Contributions

C.C.R. was responsible for writing the clinical case, review of the literature, editing the video and the script of the manuscript. N.N. performed the procedure, gave important scientific input, and reviewed the manuscript. D.B.M. gave the title. D.B.M. and F.C.-R. contributed with review of the literature. J.R.P. and M.A.D. guaranteed the accuracy of the content and did the final review before submitting.

Data Availability Statement

All data generated or analyzed during this study are included in this article. Further inquiries can be directed to the corresponding author.

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GE – Portuguese Journal of Gastroenterology

Endoscopic Snapshot

GE Port J Gastroenterol 2023;30(suppl 1):61–64
DOI: 10.1159/000527015

Received: March 30, 2022
Accepted: June 1, 2022
Published online: October 20, 2022

EUS-Guided Gastroenterostomy for the Management of Malignant Gastric Outlet Obstruction: A Single-Center Initial Experience

Pedro Bernardes Antunes Tiago Leal Raquel Gonçalves Bruno Gonçalves

Gastroenterology Department, Hospital de Braga, Braga, Portugal

Keywords
Gastric outlet obstruction · Gastroenterostomy · Lumen-apposing metal stent · Therapeutic endoscopic ultrasound

Gastroenterostomia guiada por ecoendoscopia para o tratamento de obstrução gástrica maligna: experiência inicial num centro

Palavras Chave
Ecoendoscopia terapêutica · Gastroenterostomia · Obstrução saída gástrica · Prótese de aposição luminal

Gastric outlet obstruction (GOO) is a potential complication of gastric and pancreatic cancer, with additional morbidity and mortality [1]. Symptom relief is the main goal of interventional treatment, allowing resumption of oral diet, avoiding malnutrition and loss of quality of life. Endoscopic ultrasound-guided gastroenterostomy (EUS-GE) has emerged as an alternative to enteral stenting or surgery in this setting [2]. We present this single-center case series where EUS-GE was performed with technical and clinical success.

First, we describe the case of a 79-year-old male diagnosed with a metastatic poorly cohesive gastric carcinoma of the antrum, who refused chemotherapy. He developed food intolerance due to GOO, and a transpyloric uncovered self-expandable metal stent (SEMS; 22 mm × 9 cm; Evolution® Duodenal; Cook Medical, Bloomington, IN, USA) was initially placed with clinical improvement. After one month, symptoms recurred, and tumoral ingrowth of the SEMS was endoscopically confirmed. After a multidisciplinary team meeting, it was decided to propose the patient for EUS-GE. During the procedure, under general anesthesia with orotracheal intubation, 900 cc of saline solution with methylene blue was instilled, manually with syringe, to promote jejunal dilation, using a catheter (6 Fr × 200 cm, GLO-TIP II, Cook Medical, Bloomington, IN, USA), introduced through the stricture over a guidewire (0.035 in × 450 cm, Jagwire™; Boston Scientific, Marlborough, MA, USA). Under ultrasonographic guidance (Pentax EG38-J10UT linear echoendoscope; Pentax medical, Tokyo, Japan, with Hitachi-Aloka HI VISION Noblus processor), the bowel loop was accessed with a "wireless endoscopic simplified technique" (WEST), placing a Hot AXIOS™ lumen-apposing stent (LAMS; 15 mm × 10 mm; Boston Scientific, Marlborough, MA, USA) through the lesser curvature of the stomach. The enteral communication was therefore cre-

Karger@karger.com
www.karger.com/pjg

Correspondence to:
Pedro Bernardes Antunes, pedrobba@gmail.com

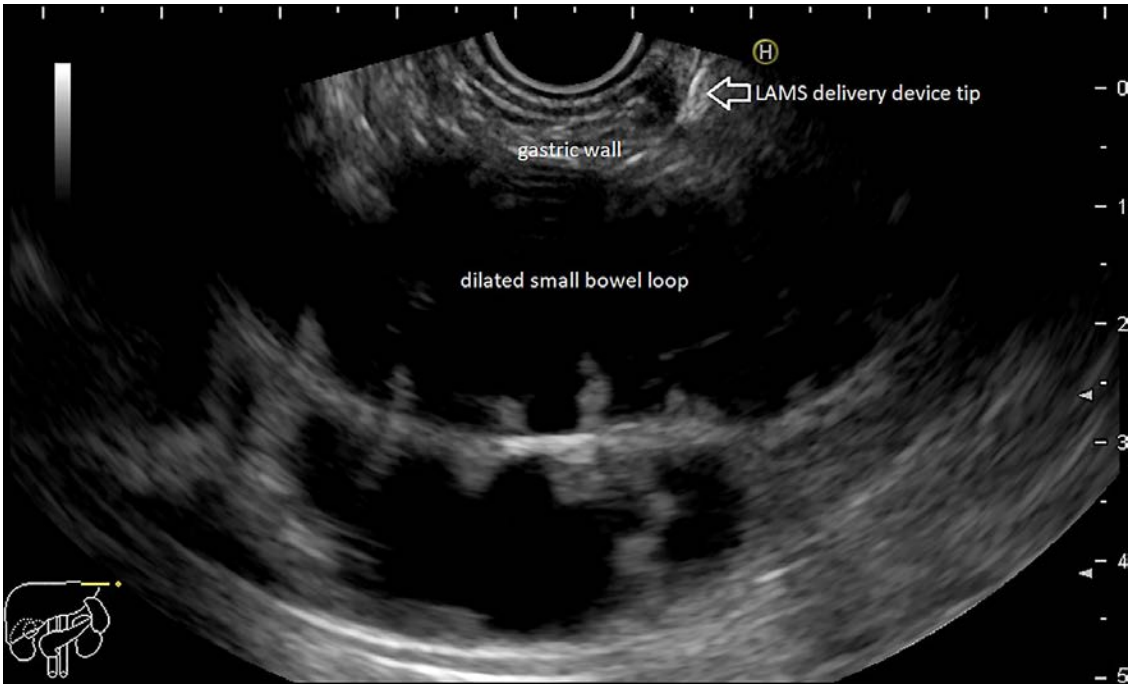

Fig. 1. Jejunal loop identified by EUS and preparation for direct puncture with the LAMS delivery system device – "freehand" technique.

ated and then dilated with a through-the-scope balloon (Hercules® 3 Stage Wireguided; Cook Medical, Bloomington, IN, USA) up to 15 mm. Patient restarted oral food intake within 12 hours and remained food-tolerant until he deceased, 3 months after procedure.

Second, we present the case of a 75-year-old woman with a pancreatic ductal adenocarcinoma of the uncinate process, locally advanced with mesenteric vessels' involvement, proposed only for palliative radiotherapy. She first presented with obstructive jaundice and underwent an endoscopic retrograde cholangiopancreatography with successful placement of biliary SEMS (6 cm × 10 mm, WallFlex™ Biliary RX Uncovered; Boston Scientific, Marlborough, MA, USA). Six weeks later, she developed GOO symptoms, and endoscopically, stricturing tumoral infiltration of the distal second portion of the duodenum was observed. After multidisciplinary team discussion, the patient was proposed for EUS-GE, which was performed with placement of a 20 mm × 10-mm LAMS through the posterior gastric wall using WEST. Balloon dilation was not performed because of mild self-limited bleeding. Liquid diet was resumed the day after and was successfully progressed with no limitations. The patient died 4 months after the procedure due to disease progression, with no GOO recurrence.

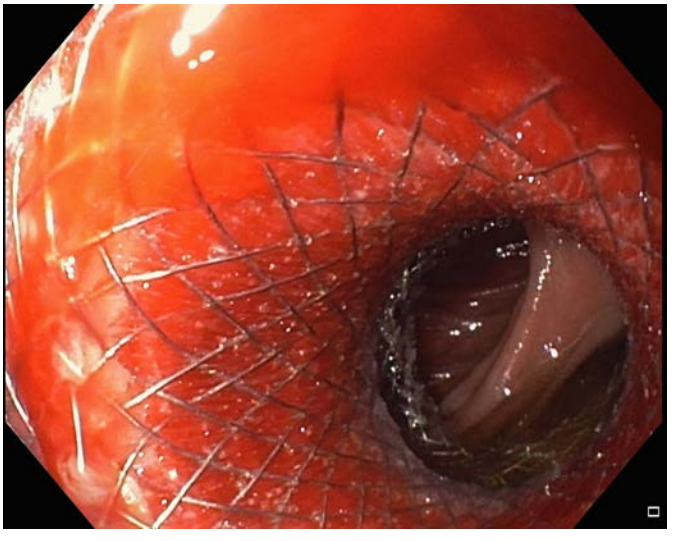

Fig. 2. Gastroenterostomy endoscopic appearance after LAMS lumen balloon dilation.

The last case describes a 58-year-old male with gastric adenocarcinoma of the antrum proposed for palliative chemotherapy and immunotherapy. One month after diagnosis, he developed nausea and early satiety complaints

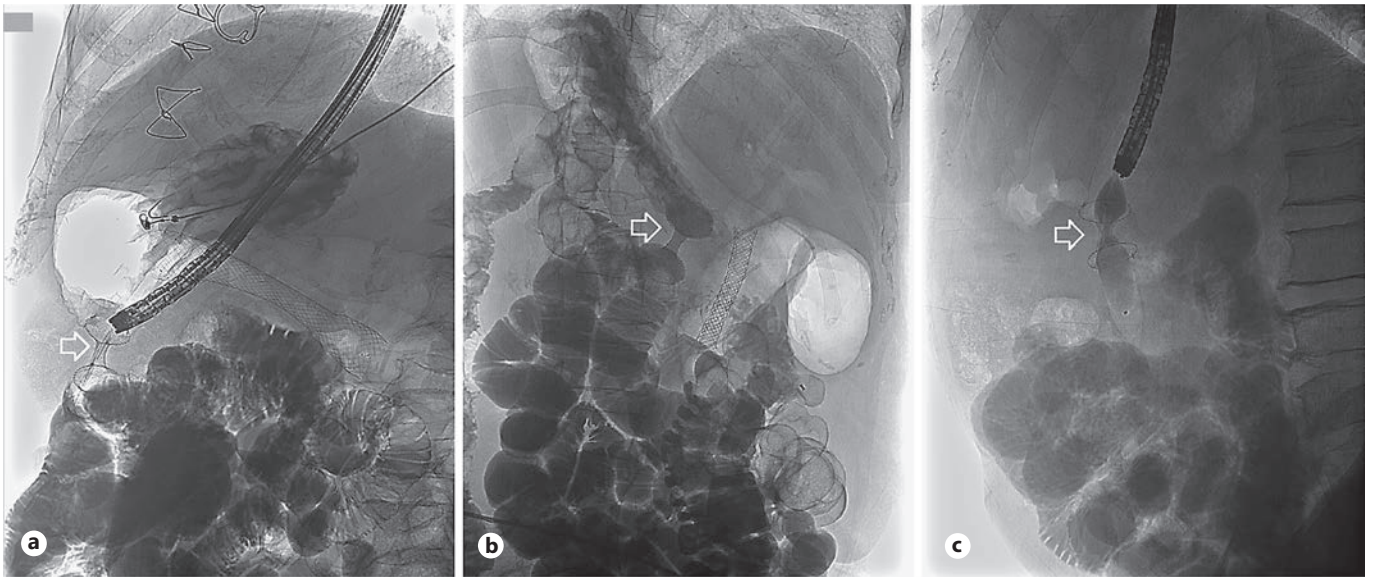

Fig. 3. Fluoroscopic confirmation of LAMS correct placement (arrows) in patient 1 (**a**), 2 (**b**), and 3 (**c**).

and, taking into account his good performance status, was proposed for EUS-GE. A 15 mm × 10-mm LAMS was placed through the posterior gastric wall, also using WEST, followed by stent balloon dilation. Eight months after the procedure, the patient is under transtuzumab with good clinical response and no GOO symptoms.

EUS-GE is reported to be an effective therapeutic alternative for GOO with rates of technical and clinical success around 90% [3, 4]. In this series, we used the WEST approach, allowed by the cautery-enabled LAMS single-step insertion that is believed to reduce stent misplacement chances (Fig. 1–3). Although there are now available balloon catheters that could help occluding a jejunal loop for puncture [4], successful bowel loop dilation was easily achieved by infusion through a regular catheter in all cases. EUS-GE allies the best and avoids the worst of both previous approaches, surgery and stenting, allowing minimal invasiveness, short time to oral refeeding, short hospital stay, and long-term patency, with low complication rates [5].

Statement of Ethics

This research was conducted ethically in accordance with the World Medical Association Declaration of Helsinki. Ethical approval was not required for this study in accordance with national guidelines. Informed consent was obtained from the participants for publication of this case series and any accompanying images.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Funding Sources

None.

Author Contributions

Pedro Bernardes Antunes was responsible for the design of the study, collecting the data, and drafting of the manuscript. Tiago Leal and Raquel Gonçalves were responsible for critical revision of the work for important intellectual content. Bruno Gonçalves was responsible for the design of the study, interpretation of the data, critical revision of the work for important intellectual content, and the main endoscopist performing all the procedures. All the authors approved the final version to be published and agreed to be accountable for all aspects of the work.

Data Availability Statement

All data generated or analyzed during this study are included in this article. Further inquiries can be directed to the corresponding author.

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GE – Portuguese Journal of Gastroenterology

Research Article

GE Port J Gastroenterol 2023;30(suppl 1):65–73
DOI: 10.1159/000528808

Received: July 30, 2022
Accepted: November 7, 2022
Published online: March 13, 2023

EUS-Guided Choledochoduodenostomy after Failed Endoscopic Retrograde Cholangiopancreatography in Distal Malignant Biliary Obstruction

Isabel Tarrio[a] Marta Moreira[a] Tarcísio Araújo[a] Luís Lopes[a, b, c]

[a]Gastroenterology Department, Hospital de Santa Luzia, ULS do Alto Minho, Viana do Castelo, Portugal; [b]Life and Health Sciences Research Institute (ICVS), School of Medicine, University of Minho, Braga, Portugal; [c]ICVS/3B's - PT Government Associate Laboratory, Braga/Guimarães, Portugal

Keywords

Obstructive jaundice · EUS-guided biliary drainage · Choledochoduodenostomy · Lumen-apposing metal stent · Endoscopic ultrasonography

Abstract

Introduction: Malignant biliary obstruction drainage is essential, since jaundice is associated with morbidity and mortality. Endoscopic retrograde cholangiopancreatography (ERCP) is the recommended procedure for biliary drainage, with percutaneous biliary drainage being the classic alternative in cases of unsuccessful ERCP. Recently, endoscopic ultrasound-guided biliary drainage has been emerged as a new option, with EUS-guided choledochoduodenostomy (EUS-CDS) being considered an effective and safe method in the drainage of distal obstructions of the common bile duct. ***Aim:*** The aim of the study was to evaluate the efficacy and safety of EUS-CDS performed in patients with distal malignant biliary obstructions, after failed ERCP. ***Methods:*** Single-center retrospective cohort study between July 2017 and June 2022 including all consecutive patients submitted to EUS-CDS in our center. The primary outcomes were "technical success" and "clinical success," defined as "resolution of jaundice or improvement in total serum bilirubin level above 50% at 7th day and above 75% at 30th day after the procedure." Secondary outcomes were procedure-related adverse events, endoscopic reintervention, and survival time. ***Results:*** EUS-CDS was performed in 20 patients (65.0% male; median age 76 years). The most frequent etiology for the biliary obstruction was pancreatic adenocarcinoma (n = 17; 85.0%), and most patients presented at advanced stages of cancer (12/60% in stages III or IV). ERCP failure was mainly due to the presence of obstruction in the duodenal lumen (n = 11; 55.0%). Fully covered metallic stents were used in all patients, mostly HotAxios™ (n = 15; 75.0%). The technical success rate was 100%, and the clinical success rate was 89.5% (n = 17/19) at 7th day and 93.3% (n = 14/15) at 30th day. Four patients (20.0%) developed cholangitis within the first 30 days after the procedure; there were no late complications, and no patient died as a complication of the procedure. In 2 patients (10.0%), endoscopic reintervention was necessary due to stent migration, incidentally detected. Median survival was 93 days (minimum 5–maximum 751). ***Conclusion:*** EUS-CDS was effective in biliary decompression of malignant obstructions of the common bile duct, with high clinical success and a favorable safety profile.

Karger@karger.com
www.karger.com/pjg

Karger
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Correspondence to:
Isabel Tarrio, isatarrio@gmail.com

Coledocoduodenostomia guiada por ecoendoscopia após falência da CPRE na drenagem de obstruções biliares malignas distais

Palavras Chave
Icterícia obstrutiva · Drenagem biliar guiada por ecoendoscopia · Coledocoduodenostomia · Prótese metálica

Resumo
Introdução: A drenagem das obstruções biliares malignas é essencial, uma vez que a icterícia está associada a morbimortalidade. A colangiopancreatografia retrógrada endoscópica (CPRE) é o procedimento recomendado para a drenagem biliar, sendo a drenagem biliar percutânea (DBP) a alternativa clássica, se verificado insucesso. Recentemente, a drenagem da via biliar guiada por ecoendoscopia tem-se apresentado como uma nova opção, sendo a coledocoduodenostomia guiada por ecoendoscopia (CGE) considerado um método eficaz e seguro na drenagem de obstruções da via biliar distal. ***Objetivo:*** Avaliar o sucesso técnico e clínico e a segurança da CGE em doentes com obstrução da via biliar distal, após falência da CPRE. ***Métodos:*** Estudo de coorte retrospetivo, entre Julho/2017 e Junho/2022, de todos os doentes submetidos a CGE no nosso centro. Determinaram-se como *outcomes* primários o "sucesso técnico" e o "sucesso clínico" ("melhoria ≥50% na bilirrubinemia ao 7.º e ≥ 75% ao 30.º dias após o procedimento"). Os outcomes secundários incluíram a frequência de eventos adversos, necessidade de reintervenção e taxa de sobrevida. Foram utilizadas curvas de Kaplan-Meier para descrever a sobrevida. ***Resultados:*** A CGE foi realizada em 20 doentes (65.0% do sexo masculino; idade mediana 76 anos). A etiologia mais frequente para a obstrução foi o adenocarcinoma pancreático (*n* = 17; 85.0%) e a maioria dos doentes apresentava-se em estadios avançados da neoplasia (12/60% em estadios III ou IV). A falência da CPRE deveu-se à presença de obstrução no lúmen duodenal em 55.0% dos doentes (*n* = 11). Em todos os doentes foram utilizadas próteses metálicas totalmente cobertas, maioritariamente HotAxios™ (*n* = 15; 75.0%). A taxa de sucesso técnico foi de 100% e de sucesso clínico foi de 89.5% ao 7.º dia (*n* = 17/19) e 93.3% ao 30.º dia (*n* = 14/15). Quatro doentes (20.0%) desenvolveram colangite nos primeiros 30 dias após o procedimento; não se verificaram complicações tardias e nenhum doente faleceu como complicação do procedimento. Em 2 doentes (10.0%) foi necessária reintervenção por migração da prótese, detetada incidentalmente. A sobrevida mediana foi de 93 dias (mínimo 5 - máximo 751). ***Conclusões:*** A CGE foi efetiva na descompressão biliar de obstruções malignas da via biliar distal, com elevado sucesso clínico e um perfil de segurança favorável.

Introduction

Malignant biliary distal obstructions usually present at late stages, precluding a curative therapeutic approach in most patients. The management of obstructive jaundice is of paramount importance, since it is associated with disabling symptoms, such as pruritus, and increased risk of cholangitis, hepatic disfunction, and liver failure. Undrained biliary obstruction is also associated with higher mortality, as shown by the series of Stark and Hines (2015), in which about 38% of patients with no palliative treatment died after complications of biliary obstruction [1, 2].

Historically, surgical biliodigestive anastomosis was the first method for biliary drainage in irresectable diseases, but it was associated with high rates of post-procedure mortality (rounding 15–30%) and up to 65% of morbidity [3]. Currently, endoscopic retrograde cholangiopancreatography (ERCP) is the primary modality for biliary drainage, but it fails in up to 35% of cases. In patients in whom standard ERCP is not possible, percutaneous biliary drainage (PTBD) is a very effective procedure and represents an alternative to failed ERCP. However, it is associated with a rate of adverse events (AEs) ranging up to 33% of patients and also with increased morbidity and a negative impact in patient's quality of life [4, 5].

Endoscopic ultrasound-guided biliary drainage, described for the first time by Giovannini and colleagues in 2001, has increasingly become an alternative method of biliary decompression, with high rates of technical and clinical efficacy, and fewer AEs than PTBD. Among the endoscopic ultrasonography-guided techniques, recent evidence has suggested that both EUS-guided choledochoduodenostomy (EUS-CDS) and hepaticogastrostomy present high technical and clinical success rates, but EUS-CDS seems to be associated with short procedure times and less early AEs, possibly being a preferable method in the drainage of distal obstructions of the common bile duct (CBD) [6–9]. We aimed to evaluate the efficacy and safety of EUS-CDS performed in patients with distal malignant biliary obstructions, after failed ERCP.

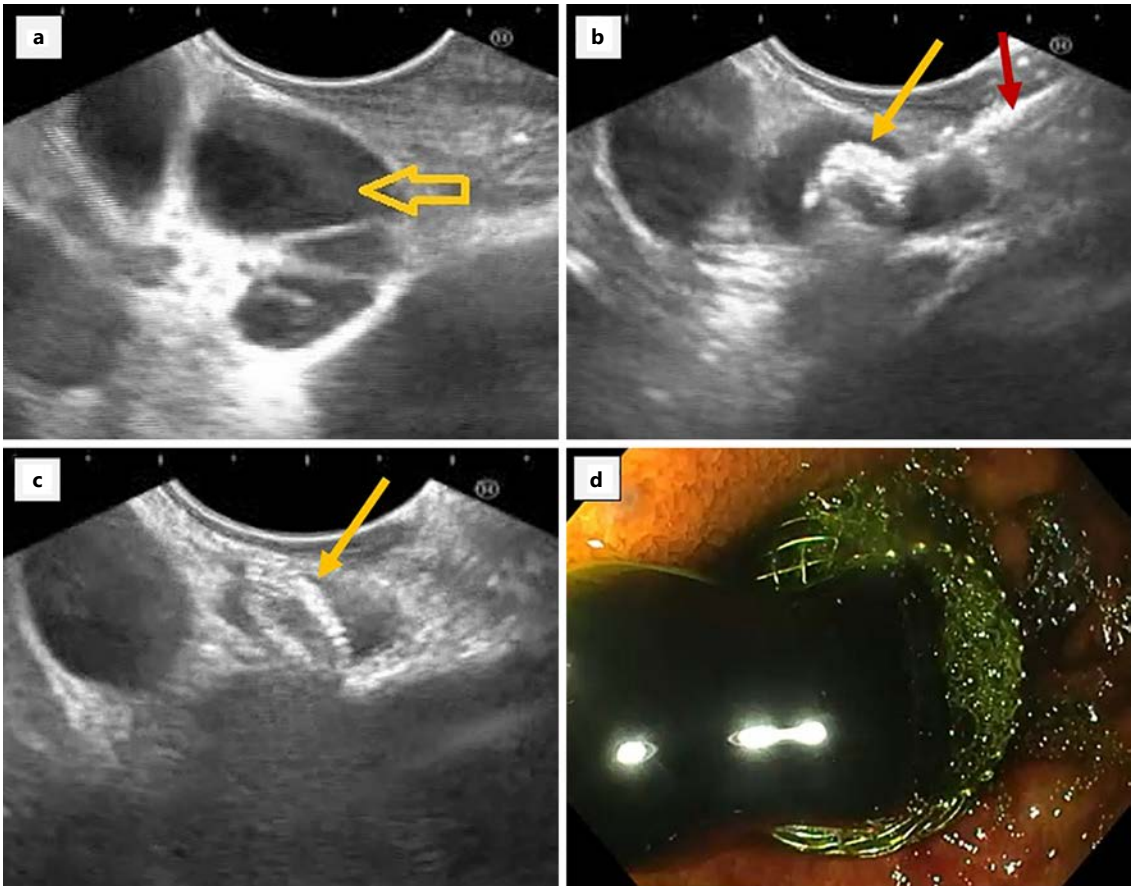

Fig. 1. Technique of endoscopic ultrasound-guided choledochoduodenostomy (EUS-CDS). **a** Ecoendoscopy showing a dilated common bile duct (yellow arrow). **b** HotAxios™ distal flange placement in common bile duct lumen (yellow arrow) by an electrocautery-assisted device system (red arrow). **c** HotAxios™ biliary stent opened and placed in common bile duct. **d** HotAxios™ showing bile flow (duodenal perspective).

Materials and Methods

Study Design and Patient Selection

We performed a single-center retrospective cohort study between July 2017 and June 2022 in a tertiary referral center for interventional endoscopy. We included all consecutive patients with malignant distal biliary obstruction (with malignancy confirmed/suspected by histology or radiologic studies) who failed ERCP-guided biliary drainage. We excluded patients under 18 years old, with malignant infiltration of the duodenal bulb and with CBD diameter inferior to 10 mm.

Procedure and Materials

All procedures were performed by an experienced endoscopist (LL) in ERCP (>300/year for the last 15 years) and EUS (>250 linear EUS/year for the last 10 years), with patients in left lateral position and under sedation with propofol, administered by an anesthesiologist. All EUS-CDS was performed with Pentax EG3870UTK (Pentax, Tokyo, Japan) or Olympus GF-UCT180 (Olympus, Tokyo, Japan) linear echoendoscopes.

Between 2017 and 2018, EUS biliary drainages were performed under fluoroscopy guidance, using fully covered biliary stents or lumen-apposing metal stents (LAMSs), according to the preference of the endoscopist and stent availability at the time of the procedure. The echoendoscope was advanced into the duodenal bulb, where the dilated CBD was identified. The CBD was punctured from the duodenal bulb using a 19-G needle (Expect, Boston Scientific), and a cholangiogram was performed. Subsequently, a 0.035-inch guidewire (Jagwire™, Boston Scientific) was introduced into the bile duct and the tract dilated with a 6-Fr cystotome (Cysto-Gastro-Set; EndoFlex, GmbH; endoCUT 40 W/effect 1). The stent was deployed using a fluoroscopy and endoscopy guidance. Since 2019, EUS-CDS was performed using a new electrocautery-enhanced LAMS (HotAxios™ ; Boston Scientific, Marlborough, MA, USA), under real-time ultrasound guidance using pure-cut electrocautery (100 W) to reach the CBD. The LAMS type (8 × 8 mm or 8 × 6 mm) was selected according to the endoscopist, and the proximal flange was released using an intra-channel technique. Figure 1 presents the technique of EUS-CDS.

Table 1. Patient's demographics and characteristics

Age, years, median ± SD (range)	76±18 (57–96)
Gender, *n* (%)	
Male	13 (65.0)
Female	7 (35.0)
Etiology of biliary obstruction, *n* (%)	
Pancreatic adenocarcinoma	17 (85.0)
Ampullary adenocarcinoma	2 (10.0)
Duodenal adenocarcinoma	1 (5.0)
Tumor staging (TNM staging system), *n* (%)	
Stage IV	9 (45.0)
Stage III	3 (15.0)
Stage IIB	2 (10.0)
Stage IIA	2 (10.0)
NE	3 (15.0)
NA	1 (5.0)
Reason for ERCP failure, *n* (%)	
Duodenal obstruction	11 (55.0)
Neoplastic infiltration of the papilla	7 (35.0)
Cannulation failure	2 (10.0)

Values are presented as median ± SD (interquartile range) for age and as absolute frequencies (%) for the other variables. NE, non-evaluated; NA, non-appliable.

Outcome Measures

The primary outcomes were "technical success," defined as "correct deployment of the stent between the CBD and the duodenum, with visualization of bile flow" and "clinical success," defined as "resolution of jaundice or improvement in total serum bilirubin level above 50% at 7th day and above 75% at 30th day after the procedure." Secondary outcomes were (i) procedure-related AEs, (ii) endoscopic reintervention, and (iii) survival time. AEs were defined as "early" if occurred within 30 days after the procedure or as "late" if after 30 days; we used the American Society for Gastrointestinal Endoscopy lexicon to classify AE severity as mild, moderate, severe, or fatal [10].

Statistical Analysis

Continuous variables were described using the median and interquartile range; categorical variables were described as proportions and frequency counts. Overall median survival time was calculated from the time of the procedure until the patient's death, and the Kaplan-Meier method was used for the survival analysis. Statistical Package of the Social Sciences® software (IBM SPSS Statistics for Windows, version 28.0.1.1) was used for data analysis.

Ethics

The Local Ethics Committee approved this retrospective study. Informed consent was obtained from all patients prior to the procedure, as standard medical practice.

Table 2. Characteristics of lumen-apposing metal stents

Characteristics of stents	*N* (%)
Stent	
HotAxios™	15 (75.0)
Wallstent™	3 (15.0)
HANAROSTENT™	1 (5.0)
Evolution™	1 (5.0)
Stent diameter	
6 × 8 mm (HotAxios™)	12 (60.0)
10 × 60 mm (Wallstent™ and Evolution™)	4 (20.0)
8 × 8 mm (HotAxios™)	3 (15.0)
20 × 14 mm (HANAROSTENT™)	1 (5.0)

Values are presented as absolute frequencies (%).

Results

Patient's Demographics and Clinical Characteristics

EUS-CDS was attempted in 20 patients (65.0% male), aged from 57 to 96 years old (median age 76 years) with malignant distal biliary obstruction, after failed ERCP. The most frequent etiology of the obstruction was pancreatic adenocarcinoma (*n* = 17; 85.0%), and most patients presented at late stages of cancer (60% in stages III or IV). In the majority of patients, failure of ERCP was secondary to a duodenal obstruction that precludes the passage of the duodenoscope into the second portion of the duodenum (*n* = 11; 55.0%). The patients' demographics and clinical characteristics are summarized in Table 1.

Procedure-Related Outcomes

In 12 patients (60.0%), the EUS-CDS was performed in the same endoscopic session, immediately after ERCP failure. The remaining 8 patients (40.0%) were admitted from other hospitals, in which there were no available technical resources and/or experienced endoscopists in EUS-guided biliary drainage.

The obstruction resulted on a CBD median dilation of 14.5 mm (±5.5), ranging from 10 to 22 mm. HotAxios™ was the chosen LAMS in all the 15 patients (75.0%) submitted to the procedure after the year 2019. The characteristics of stents are detailed in Table 2.

The stent was correctly placed in all patients (20/20), resulting in a technical success of 100%. Clinical success was achieved in 17 of 19 (89.5%) patients at the 7th day (1 patient died within the first week due to nosocomial pneumonia). At the 30th day, the clinical success was

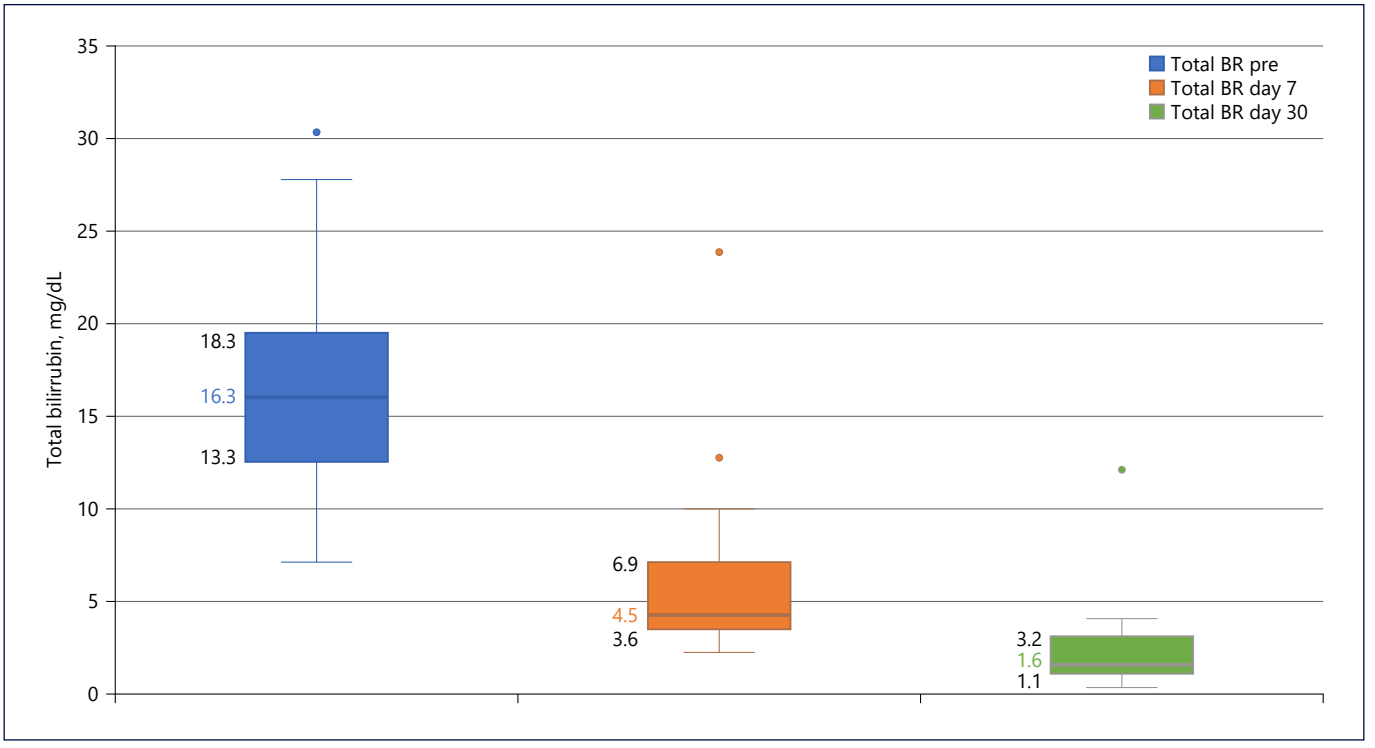

Fig. 2. Trend of decreasing total bilirubin level at 7th and 30th days after EUS-guided choledochoduodenostomy.

93.3% (14/15); during this time, 4 patients have died: 2 patients in the sequence of nosocomial pneumonia and 1 patient, in whom palliative Roux-en-Y gastrojejunostomy and hepaticojejunostomy were performed, died after fecaloid peritonitis in the context of surgical anastomosis dehiscence, and the fourth patient died due to general condition deterioration (evolution of primary disease). Total serum bilirubin variation is shown in Figure 2.

Adverse Events

Four patients (20.0%) presented with cholangitis within the first 30 days after the procedure, in one case evolving into septic shock. All cases were medically managed with antibiotics and neither resulted in death. Other major complications, such as hemorrhage, perforation, peritonitis, or pancreatitis, were not observed.

Endoscopic Reintervention

In 2 patients (10.0%), a second endoscopic procedure was necessary, due to asymptomatic stent migration. In 1 case, the stent migration (Evolution™) to the gastric antrum was observed in an upper endoscopy performed for upper gastrointestinal bleeding, 9 months after the EUS-CDS. In the other case, an abdominal computed tomography performed 11 days after the procedure revealed HANAROSTENT™ migration into the proximal jejunum. Both cases occurred before the introduction of HotAxios™ LAMS and were successfully managed endoscopically. Table 3 demonstrates the outcomes after the EUS-CDS procedure.

Follow-Up

The patients were followed for a median time of 93 days (±175), ranging from 5 to 751 days. In this time, 16 patients (80.0%) died because of disease-related complications.

Four patients (20%) were submitted to surgery: in 3 (15%), a cephalic duodenopancreatectomy was performed, with curative intent; in the remainder, a Roux-en-Y gastrojejunostomy and hepaticojejunostomy were performed due to irresectability of the cancer, observed during the surgery. Three (15%) patients received chemotherapy. Kaplan-Meier curve showing patient survival estimate after EUS-CDS is shown in Figure 3.

Table 3. Outcomes after EUS-guided choledochoduodenostomy

Post EUS-guided choledochoduodenostomy assessment	
Technical success, *n* (%)	20/20 (100)
Clinical success, *n* (%)	
7th day after EUS-CDS*	17/19 (89.5)
HotAxios™	12/14 (85.7)
WallFlex™	3/3 (100)
Evolution™	1/1 (100)
HANAROSTENT™	1/1 (100)
30th day after EUS-CDS*	14/15 (93.3)
HotAxios™	11/12 (91.2)
WallFlex™	1/1 (100)
Evolution™	1/1 (100)
HANAROSTENT™	1/1 (100)
Adverse events	4/20 (20.0%)
Early (<30 days), *n* (%)	
Cholangitis	4/20 (20.0)
HotAxios™	4/15 (26.7)
WallFlex™	0/3 (0.0)
Evolution™	0/1 (0.0)
HANAROSTENT™	0/1 (0.0)
Late (>30 days), *n* (%)	0
Reintervention, *n* (%)	2/20 (10.0)
Stent migration	2/20 (10.0)
HotAxios™	0/15 (0.0)
WallFlex™	0/3 (0.0)
Evolution™	1/1 (100)
HANAROSTENT™	1/1 (100)
Surgery, *n* (%)	4/20 (20.0)
Cephalic duodenopancreatectomy, *n* (%)	3/20 (15.0)
Roux-en-Y gastrojejunostomy and hepaticojejunostomy, *n* (%)	1/20 (5.0)
Chemotherapy, *n* (%)	3/20 (15.0)
Radiotherapy	0

* Excluding patients lost to follow-up due to early death.

Conclusion

Our study represents the largest cohort of patients submitted to EUS-CDS in a Portuguese center and revealed that it is an effective technique for biliary drainage in patients with malignant distal biliary obstruction who failed ERCP, with a favorable safety profile when performed in an experienced center for advanced biliopancreatic endoscopy. To our knowledge, this is the first retrospective study to report the experience of EUS-CDS in a Portuguese population with malignant distal biliary obstruction.

Currently, ERCP is the first-line strategy in the drainage of malignant biliary obstructions but even when performed by experts, it is not successful in up to 35% of patients, due to stomach or duodenal obstruction, surgical-altered anatomy or to anatomic changes of the papilla that prevent its cannulation. In our cohort, all patients submitted to EUS-CDS presented with duodenal obstruction, malignant infiltration of the papillary area, or an intradiverticular papilla that precluded successful ERCP. Although some recent studies suggest the repositioning of EUS-CDS as the initial choice for biliary drainage, in our department we use ERCP, reserving EUS-CDS for failed cases, as recommended by major endoscopy societies and reported from a large number of tertiary centers [4, 9].

EUS-CDS has emerged as an alternative to PTBD in cases of impossibility or failure of biliary drainage by ERCP. Since its introduction, important technical upgrades were observed, particularly with the emergence of the LAMS, the development of smaller stents – 6 and 8 mm – suitable for biliary drainage and, more recently, the addition of the electrocautery tip that allows direct fistulotomy within the bile duct, avoiding guidewire manipulation and biliary tract dilation [11].

Our results demonstrate that EUS-CDS was successfully achieved in all the patients, even though our patient's median CBD size (14.5 mm) could be a risk factor for technical failure, as mentioned by Garcia-Sumalla et al. [12] who described that a CBD diameter above 15 mm was associated with higher technical success rates. Other studies also verified high rates of feasibility of EUS-CDS: for example, in the systematic review performed by Peng et al. [13] the pooled rate of technical success was 95.1% (CI = 90.6–97.5%; I2 = 255), while in another systematic review that only included studies published between 2015 and 2020, technical success rates ranged from 88.0 to 100%. Our high technical success may be in part explained by the utilization of the latest technical innovations in EUS-guided biliary drainage, as the electrocautery-enhanced delivery system allows a single-stage access and stent introduction, minimizing the procedure complexity. Besides, fully covered metal stents were used in all patients and these have demonstrated not only higher efficacy and safety but also an increased durability and patency rate, when compared to plastic and partially covered metal stents. Since 2019, HotAxios™ was used in all patients submitted to EUS-CDS in our center; the rationale for this choice is the easiness of its insertion due to the cautery on the tip, as well as the presence of bilateral flanges that allow a better lumen-to-lumen apposition, with a reduced probability of stent displacement and biliary leakage [12–16].

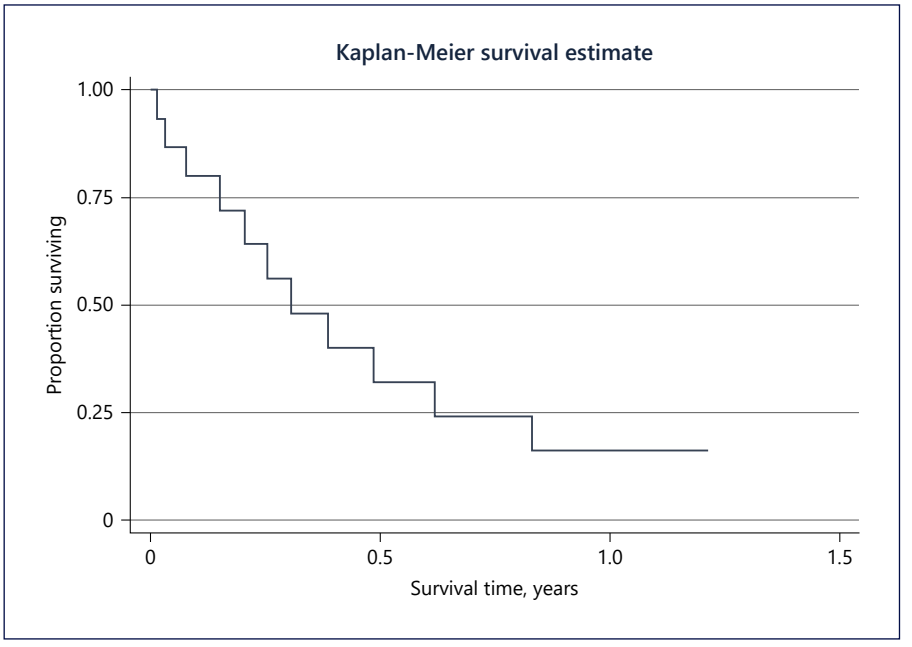

Fig. 3. Kaplan-Meier curves showing patient survival estimate after EUS-CDS.

For the analysis of clinical success, we excluded patients lost to follow-up due to early death, as none of the patients had died as a result of the procedure, but due to infectious or post-surgical complications or general status deterioration, so that the clinical success of the endoscopic technique cannot be affected by these losses. In fact, in 4 of the 5 patients who died before 30 days of follow-up, a greater than 50% decrease in baseline bilirubinemia was observed at some point. Our high clinical success – 89.5% at 7th day and 93.3% at 30th day after the procedure – is similar to previous studies: a recent systematic review found a pooled clinical success rate of 93.3% (CI = 90.6–97.5%), and clinical success rates tend to be even higher in more recent systematic reviews, as the one performed by Ogura and Itoi, that reviewed EUS-CDS performances between 2015 and 2020 and found an overall clinical success rate of 97.0%, correlating this improvement with the new technical developments, like the ones we used in our patients [13, 15, 16].

The AE rate in our study was 20.0%, which is in line with previous published evidence on EUS-BD, that reported AE in 17–23% of patients. Over the years, it has been verified a changing trend in the EUS-guided biliary drainage AE rate: in their study, Ogura and Itoi subcategorized the analysis of EUS-CDS performance in 2 time periods and found that until 2015, the overall AE was about 16%, whereas since 2015–2020, there has been a slight improvement to about 12% of AE, possibly assignable to the experience and progression on the learning curve and, mostly, to the use of LAMS. In the same review, it was also verified a changing trend on the predominant complications: until 2015, the two most frequent AEs associated with EUS-CDS were perforation and bile leakage, but after 2015, cholecystitis and cholangitis predominate. The decreased utilization of plastic stents seems to justify these findings since they require previous dilation of the fistulous path, which is associated with higher bile leakage. On the other hand, self-expandable LAMSs seal the gap between the neofistula and the stent, preventing bile leakage and, therefore, biliary peritonitis. Another recent systematic review supports this, having found that self-expandable LAMSs were associated with significantly lower AE compared to plastic stents (17.52% vs. 31.03%; $p = 0.013$). Our study seems to accompany this trend, since cholangitis was the only major AE registered. Besides, all stent dysfunctions occurred before the beginning of HotAxios™ utilization in our center, whose design confers more stable CBD-duodenum anchorage. It is still unclear whether the insertion of a double-pigtail plastic stent through the LAMS improves the stent patency – the ongoing BAMPI trial will determine whether this technical variant offers a clinical benefit in EUS-CDS for the management of distal malignant biliary obstruction [15–19].

Although cholangitis was the only complication of EUS-CDS verified in our cohort, other relevant AEs are

described in the literature. Of note, the most common intraprocedural complication of EUS-CDS using LAMS is stent maldeployment (particularly when the diameter of CDB inferior to 15 mm), and it can be managed by preloading a guidewire in the delivery system to guide the bile duct access after removing the misdeployed stent. In a long-term perspective, stent occlusion is the most frequent AE, with a median time of occurrence of 5–12 months [9, 20].

Although usually presented as a palliative procedure, 3 of our patients were submitted to surgery with curative intent and the presence of the stent (HotAxios™ in all cases) did not prevent the performance of surgery. For years, the most used alternative to ERCP was PTBD. In their systematic review, Khashab et al. [21] found that compared to EUS-CDS, PTBD presents with similar technical success but slightly less clinical success. However, they verified that PTBD was associated with higher complications and need of reintervention, ultimately making EUS-CDS more cost-effective. Another recent systematic review concluded that when available, EUS-CDS may be preferable to PTBD due to a better safety profile, clinical and technical success. Based on current evidence, the European Society of Gastrointestinal Endoscopy strongly recommends that, when locally available, EUS-guided biliary drainage is preferred over PTBD, after failed ERCP, in malignant distal biliary obstruction [9, 21, 22].

As previously mentioned, several recent studies had concluded that EUS-CDS may be equivalent to ERCP as a primary method for the drainage of distal malignant biliary obstructions, showing comparable technical and clinical success rates. However, EUS-CDS has revealed both a reduced procedural time and a better safety profile, in particular in regard to the risk of postprocedural pancreatitis, that is null in EUS-CDS, since it is performed away from the major papilla [23].

Our study has some limitations, including the retrospective design and the absence of a control group (for example, of patients in whom PTBD was performed). Although the number of patients is not large, the sample size is not much inferior to most single-center studies from tertiary centers; to our knowledge, the single-center study with highest number of patients is the one of Matsumoto et al. [20] that included 151 participants; however, the patients were enrolled throughout a 14-year period, in a mean of 10 procedures per year, which reveals the relatively low number of EUS-CDS performed. With this in mind, there is the need of collecting data from a large number of centers in order to achieve meaningful insights as a randomized controlled trial with enough power faces huge challenges to be implemented.

Concluding, in our study EUS-CDS was an effective technique for biliary decompression in patients who failed ERCP. Further work is needed, including randomized and cost-effectiveness studies, comparing EUS-CDS with ERCP, to establish EUS-CDS as a primary drainage technique.

Statement of Ethics

This study protocol was reviewed and approved by *CES – Comissão de Ética para a Saúde ULSAM*, approval number 52/2022. Written informed consent was obtained from participants. The research was conducted ethically in accordance with the Declaration of Helsinki (2014) [24].

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Funding Sources

No funding was received for this study.

Author Contributions

Luís Lopes and Tarcísio Araújo: study conception and design. Isabel Tarrio and Marta Moreira: data collection, analysis, and interpretation of the results. Isabel Tarrio: preparation of this paper. All the authors reviewed the results and approved the final version to be published.

Data Availability Statement

All data generated or analyzed during this study are included in this article. Further inquiries can be directed to the corresponding author.

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GE – Portuguese Journal of Gastroenterology

Erratum

GE Port J Gastroenterol 2023;30(suppl 1):74
DOI: 10.1159/000531228
Published online: June 6, 2023

In the article by Canakis and Baron entitled "Therapeutic Endoscopic Ultrasound: Current Indications and Future Perspectives" [GE Port J Gastroenterol. 2023, DOI: 10.1159/000529089], Figure 3 was missing from the original publication. Figure 3 is shown here.

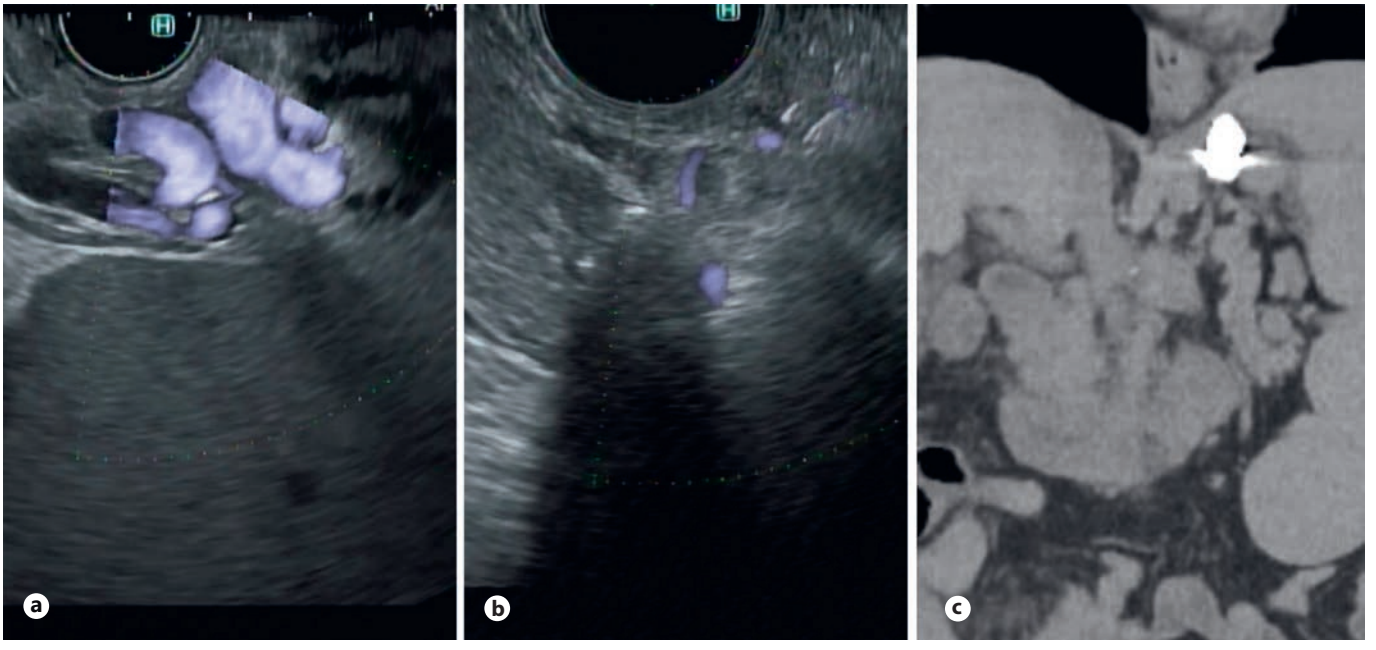

Fig. 3. EUS-guided variceal embolization. **a** Gastric varices as seen by linear echoendoscope. **b** Echo image after placement of coils and glue into gastric varix via a 19G needle. Lack of flow as seen by Doppler. **c** Follow-up coronal CT scan obtained for routine management showing coils in place within the gastric varices.

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