Gastroenterology Research and Practice

Advances in Endoscopic Stenting 2021

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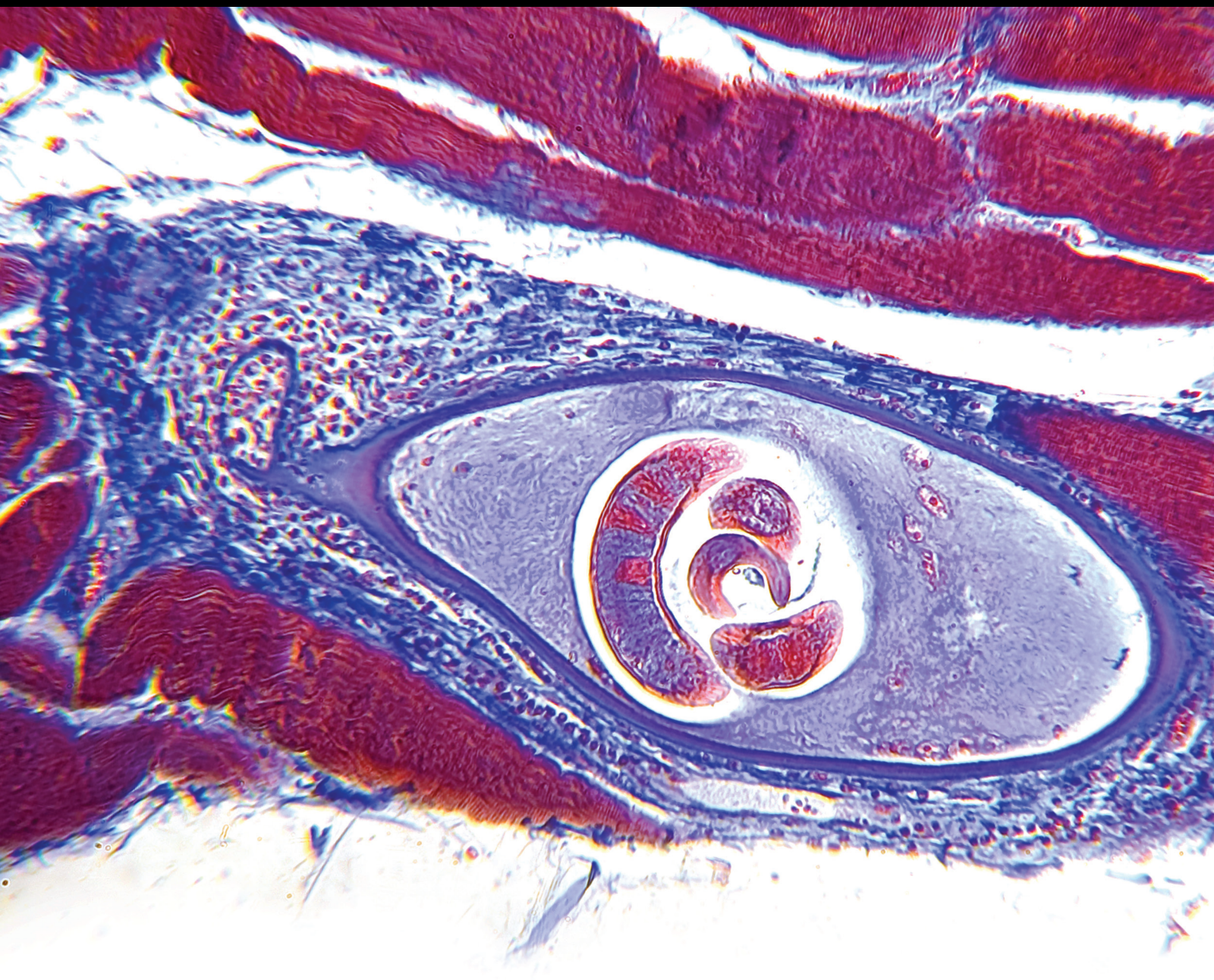

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Review Article

Futuristic Developments and Applications in Endoluminal Stenting

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Endoscopic stenting is a well-established option for the treatment of malignant obstruction, temporary management of benign strictures, and sealing transmural defects, as well as drainage of pancreatic fluid collections and biliary obstruction. In recent years, in addition to expansion in indications for endoscopic stenting, considerable strides have been made in stent technology, and several types of devices with advanced designs and materials are continuously being developed. In this review, we discuss the important developments in stent designs and novel indications for endoluminal and transluminal stenting. Our discussion specifically focuses on (i) biodegradable as well as (ii) irradiating and drug-eluting stents for esophageal, gastroduodenal, biliary, and colonic indications, (iii) endoscopic stenting in inflammatory bowel disease, and (iv) lumen-apposing metal stent.

1. Introduction

Endoscopic stents are hollow devices designed to prevent constriction or collapse of a tubular portion of gastrointestinal (GI) tract and currently used in management of variety of diseases of the esophagus, stomach, small bowel, colon, and bilio-pancreatic system. Common indications of endoscopic stents include reestablishment or maintenance of luminal patency in cases of malignant obstruction and temporary treatment of benign strictures, as well as sealing transmural defects and diverting luminal contents in leaks, fistulae, or perforations [1]. GI stents were originally designed as rigid, cylinder-like prostheses and, as a result, had poor efficacy and high adverse event rates [1]. However, stent design has been subject to continuous improvement.

In recent years, in addition to expansion in indications for endoscopic stenting, considerable strides have been made in stent technology, and several types of devices with advanced designs and materials are continuously being developed. In this review, we discuss the important developments in stent designs and novel indications for endoluminal and transluminal stenting. Our discussion specifically focuses on (i) biodegradable as well as (ii) irradiating and drug-eluting stents for esophageal, gastroduodenal, biliary, and colonic indications, (iii) endoscopic stenting in inflammatory bowel disease (IBD), and (iv) lumen-apposing metal stent (LAMS).

2. Biodegradable Stents

Self-expandable metal and plastic stents (SEMS and SEPS, respectively) are an effective treatment option in the

management of both benign and malignant strictures, as well as leaks and fistulae, throughout the GI tract [2, 3]. However, the use of these stents is associated with several common problems, such as stent migration, blockage, and tissue ingrowth, thus requiring repetitive endoscopic procedures. To overcome the shortcomings of SEMS and SEPS, biodegradable stents (BDS) with GI tract applications have been developed. BDS may be particularly useful in benign pathology, as well as clinical situations wherein the stent is needed temporarily, by obviating the need of a follow-up procedure typically required for stent removal. Moreover, BDS may also be associated with lower rates of stent migration and tissue ingrowth, thus offering additional advantages over SEMS. However, the radial force of BDS is weaker than that of SEMS and also requires manual mounting on a delivery system for deployment, making the process complicated compared to SEMS, which are available preassembled and ready-to-use [4]. Other disadvantages of BDS include significant stent shortening and radiolucency, except for added markers, thus making deployment challenging.

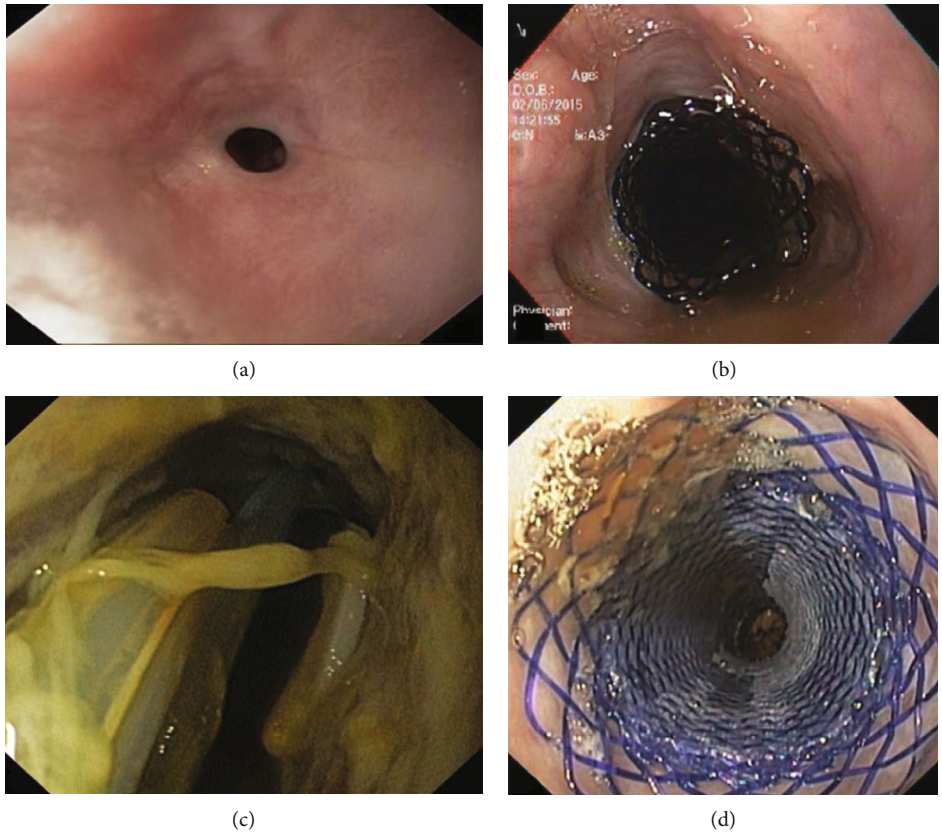
Different biomaterials with varied characteristics are used to manufacture BDS, most common being synthetic polymers: polylactide, polydioxanone (PDX), polycaprolactone, and poly-lactide-co-glycolide with self-expandable design [5]. Although no data exists comparing BDS stents manufactured from different biodegradable polymers, as a biodegradable material, PDX may have superior flexibility, degrade more slowly by hydrolysis, and retain its biomechanical properties longer than other polymers [6]. Usually, the radial force of BDS stent is maintained for 6 weeks following deployment, and the stent degrades in 6-24 weeks. Different BDS designs have been developed with applications in esophageal, small bowel, colonic, and pancreatobiliary tract pathology, as discussed below.

2.1. Biodegradable Stents in the Esophagus. BDS offer an emerging and promising treatment alternative in patients with benign esophageal strictures. Dilation is currently the standard of care in this context, allowing dysphagia improvement in the majority of patients [7]. However, repeated sessions are frequently required, and some strictures are refractory to dilations [7, 8]. In patients with refractory strictures, stent placement is an alternative treatment, wherein stricture remodelling due to indwelling stent results in improved luminal patency during the remission of the underlying inflammatory process [9]. Partially covered (PC) and fully covered (FC) SEMS have been traditionally used in such situations but present several limitations including stent migration, tissue ingrowth, and/or requirement for additional endoscopic procedures for stent removal [10]. The use of BDS has been suggested to overcome these limitations (Figures 1(a) and 1(b)), but compelling evidence for use of BDS over other stent types is still lacking [11–17]. The rationale behind BDS consists of a constant radial force applied for a specific amount of time (6–8 weeks), with concurrent progressive hydrolysis-mediated self-degradation (8–12 weeks), thus avoiding both the development of tissue overgrowth as well a need for repeat endoscopic procedure for stent removal.

Currently, PDX BDS, loaded manually prior to placement onto a 28Fr delivery system, not compatible with through-the-scope (TTS) placement technique, is the only commercially available BDS for esophageal use. Dhar et al. and Walter et al. compared BDS to endoscopic balloon dilatation (EBD) in two RCTs with 17 patients and 66 patients, respectively [16, 17]. The former study showed that stenting was associated with greater dysphagia scores, need of comedication and adverse events, thus not supporting use of BDS. On the contrary, the latter study showed that the BDS group ($n = 32$) underwent significantly less endoscopic dilations for recurrent stricture compared to the EBD group ($n = 34$) in initial 3 months, while this effect was lost by 6 months. This temporary benefit may reduce healthcare costs and improve the quality of life as a transient palliative intervention. However, in studies comparing different stent designs [15], all types of self-expandable stents appear to offer only modest (30-40%) rates of long-term dysphagia relief. Dysphagia recurrence, poststenting chest pain, and tissue hyperplasia were the most commonly reported adverse events [15]. In a meta-analysis of 18 studies (10 prospective, 8 retrospective studies; 444 patients), the efficacy and safety of expandable stenting (BDS, SEMS, or SEPS) for refractory benign esophageal stricture (RBES) were evaluated [13]. The pooled clinical success was 40.5%, migration rate was 28.6%, and overall complication rate was 20.6%. No statistically significant differences were noticed between the 3 groups in overall clinical success, stent migration, and complication rates. Considering these data, the updated European Society for Gastrointestinal Endoscopy (ESGE) guidelines do not recommend a specific type of stent (FCSEMS, SEPS, or BDS) since none have shown to be superior to any other for this indication [18]. The development of new esophageal BDS with different polymeric mixtures, currently available only for biliopancreatic diseases, could represent an attractive therapeutic option in the future, for the purpose of refractory benign esophageal stricture (RBES) management [19].

The role of BDS in the management of malignant esophageal strictures is not adequately defined, and in such scenarios, BDS is not yet considered a valid alternative to SEMS. Studies have evaluated outcomes of BDS in patients undergoing single dose brachytherapy [20], palliative radiotherapy [21], and neoadjuvant treatment or radical radiotherapy [22], but in each of these studies, despite adequate technical success and short-term dysphagia symptom improvement, unacceptably high rates of adverse events and complications (retrosternal pain, vomiting, epithelial hyperplasia, and stent-related death), stent dysfunction, and need for reintervention were reported [20–22]. To overcome these limitations, BDS using novel materials (elastic and biodegradable mixed polymer of Poly(ε-caprolactone) (PCL) and poly(tri-methylene carbonate) (PTMC) as the coated membrane on magnesium alloy stents) are being developed but have not yet been tested in humans [23, 24].

Regarding role of BDS in management of esophageal transmural defects (Figures 1(c) and 1(d)), the data is limited, with only two studies, comprising of 13 and 4 patients, wherein the clinical success ranged from 77.8 to 100%, but a



(a) (b) (c) (d)

Figure 1: (a, b) Endoscopic images of a patient with a refractory caustic esophageal stricture who underwent placement of a 25/20/25 × 100 mm biodegradable noncovered stent. (c, d) Endoscopic images of a patient with an esophageal-jejunal anastomotic leak who underwent placement of a 28/23/28 × 100 mm biodegradable fully covered stent, covering the leak.

drawback of mucosal reaction (2/4 patients) causing dysphagia requiring endoscopic dilation [25, 26].

2.2. Biodegradable Stents in the Small Bowel and Colon. Different studies have evaluated the safety and efficacy of BDS in the treatment of benign strictures in small bowel and colon, as well as for management of anastomotic colorectal strictures, stricturing Crohn's disease (CD), and postsurgical colonic fistulae [27–32]. The most common stent in this context is PDX BDS, initially developed for esophageal use, and as stated previously, it is not compatible with TTS deployment. Additionally the standard delivery system of PDX BDS with an active length of 75 cm precludes proximal colonic stent placement or in patients with considerable colonic angulation/tortuosity due to technical challenges [31].

The largest series of BDS stents in colon and ileocolic anastomotic strictures report a technical success of 90-100% but only a modest stricture resolution of 45-83% [28, 31], with early stent migration being the main reason for clinical failure. Unlike in esophageal strictures, mucosal hyperplastic reaction after BDS placement has not been reported in intestinal strictures. The use of BDS in CD strictures is discussed in greater detail in a different section of this article.

2.3. Biodegradable Stents in the Pancreatobiliary Tract. The use of BDS during endoscopic retrograde cholangiopancreatography (ERCP), until recently, was only reported in animal models [33–35]. In 2015, an insertion device enabling TTS deployment (diameter of 3.9 mm) compatible with PDX self-expandable BDS was developed. This technology was successfully tested first in a postoperative cystic duct biliary leak patient [36]. Subsequently, the same group of authors expanded the use of PDX BDS for benign biliary strictures, in addition to cystic duct leaks [37]. While all bile leaks ($n = 7$) healed successfully, the authors reported 83% clinical success in benign stricture ($n = 6$) treatment with median follow-up of 21 months (range 14-25). No early stent migrations or dysfunction were observed, and the stents degraded as expected in 3–6 months. However, mild acute cholangitis was reported in 3/13 (23%) patients within 90 days poststent deployment. Interestingly, similar high rates of mild acute cholangitis were reported with percutaneously placed PDX BDS as well [38]. Siiki et al. evaluated 32 patients prospectively, comparing plastic stents ($n = 24$) and BDS ($n = 8$) in the treatment of postcholecystectomy bile leak [39] and noted no statistical difference in the clinical success rate, rates of readmission, or 30-day adverse event rate (13% in both groups), although total drain output was lower in BDS patients (330 ml vs. 83 ml, $p = 0.002$). All patients with BDS were spared repeated endoscopy for stent removal.

Lindström et al. reported their experience of BDS in 7 patients with Roux-en-Y hepatojejunostomy anatomy, for

management of HJ strictures ($n = 3$) or intrahepatic strictures ($n = 4$) [40]. The authors noted stricture resolution in all cases, without any stent or cholangiography-related complication, and one stent migration in 90-day follow-up. More recently, a new helicoidal BDS with pancreatobiliary application has been described [19], with a nonexpandable design and the deployment mechanism similar to plastic stents, available in different sizes and variable rates of biodegradability, depending on the composition of the polymeric mixtures. Main indications of this new stent include prevention of post-ERCP cholangitis and postcholecystectomy bile duct stricture management, and the only adverse event reported was 1 post-ERCP pancreatitis, although premature stent migration occurred in 9.4% of the patients.

3. Irradiating and Drug Eluting Gastrointestinal Stents

SEMS have shown significant clinical success in the palliation of GI malignancies and are commonly used in the management of esophageal, gastric, duodenal, pancreaticobiliary, and colorectal obstructive neoplasia. However, these conventional stents can suffer from stent obstruction due to tumor and/or tissue ingrowth and/or overgrowth [41]. To overcome this limitation, there is growing interest in the development of irradiating and drug-eluting stents (DES), which can provide a sustained and localized release of drugs, which minimize tumor/tissue growth to optimize stent efficacy. As such, several stent designs that combine the mechanic characteristics of SEMS with different types of drugs have been developed, for clinical use in patients with esophageal and biliary malignancies [42].

Only a limited number of clinical trials have evaluated the role of irradiating and DES in patients with inoperable esophageal cancer-related dysphagia. In 2017, a meta-analysis (3 RCTs, 3 observational studies; 539 patients) by Chen et al. comparing traditional SEMS versus radioactive SEMS (loaded with iodine-125 seeds) or SEMS with brachytherapy [43] showed that SEMS with brachytherapy had a longer overall survival (2.7 months), as well as improved survival at 1, 3, and 6 months. Both stent types resulted in good immediate dysphagia relief, but radioactive stent performed better at 3 and 6 months of follow-up, without significant differences in complication rates. Moreover, a more recent meta-analysis in 2020 (6 RCTs; 403 patients) compared traditional SEMS with radioactive SEMS (loaded with iodine-125 seeds) [44] and showed no significant difference between the two stent types in either the dysphagia scores or stent restenosis, migration, severe chest pain, and other complications (hemorrhage, fistula formation). However, time to restenosis and overall survival were better in the radioactive stent group [45]. Several retrospective studies have also concurred that radioactive SEMS have a longer stent patency [45, 46] and better survival [45–47] with similar complication rates compared to traditional SEMS, albeit at a higher cost [48].

Following the huge clinical success of drug-eluting vascular/cardiac stents, there has been a significant curiosity in other applications of DES, including treatment of GI cancers [49]. While new DES utilizing various drugs (docetaxel, 5-fluorouracil, paclitaxel, or gemcitabine) combined with different types of stent construction technologies (such as 3D printing) and different varieties of polymer coatings are being developed [41, 48, 50–53], currently, there are no clinical data in humans for use of these DES for palliation of esophageal cancer.

The role of irradiating stents in the treatment of malignant biliary obstruction (MBO) has also been recently evaluated. Zhu et al. performed a randomized trial of 328 patients with unresectable MBO and found a longer patency time of irradiating stents (212 days) when compared to uncovered SEMS (104 days) [54]. Also, irradiating stents were significantly associated with decreased rates of stent restenosis and longer survival time (median 202 days vs. 140 days; $p = 0.020$), but no differences in technical success rate or rates of complications. DES have also been developed for MBO in an attempt to improve long-term stent patency of SEMS due to tumor ingrowth; however, there is a paucity of human data in this regard. Studies on paclitaxel eluting stents [55–57] consistently report no differences in survival or stent patency rates compared to covered metal stents, albeit with possibly higher rates of stent migration [57]. Similarly, a meta-analysis of five prospective studies evaluating efficacy of paclitaxel-eluting stents compared to SEMS [58] found no differences in pooled stent patency (OR 1.03, $p = 0.9$), overall survival (OR 1.16, $p = 0.6$), or adverse events. Another meta-analysis reported similar rates of survival and stent patency, but higher frequency of cholangitis-like symptoms in the DES group [59]. These suboptimal outcomes of DES may be due to the fact that dual chemotherapy (cisplatin and gemcitabine) may be more effective than paclitaxel alone [60]. Other DES using sorafenib and gemcitabine appear promising in vitro and in porcine models, though human studies are necessary to confirm their efficacy and safety [61, 62].

Finally, a few recent studies have evaluated the efficacy of polyglycolic acid sheet combined with covered SEMS for prevention of stricture formation after large esophageal endoscopic submucosal dissection (ESD) [63–65]. The rate of post-ESD esophageal stricture appears to be lower in patients treated with polyglycolic sheet SEMS when compared to patients treated with conventional SEMS or intralesional steroid injection, with similar safety profile, making it a promising alternative in this context.

4. Stents in Inflammatory Bowel Disease

Strictures are one of the most frequent complications of CD, occurring in up to a third of patients within 10 years of diagnosis, as a result of underlying disease, surgical anastomosis, or previous stricturoplasty [66]. Strictures in CD are more frequently localized in the small bowel rather than in the colon (64% vs. 5%, respectively). Bowel resection and stricturoplasty are effective for the treatment of primary or secondary (i.e., anastomotic) strictures; however, within 4 years after initial ileocolic resection, over 40% patients have recurrent obstructive symptoms [67], besides the risk of postoperative complications associated with the invasive

nature of surgical therapies. This high rate of recurrence suggests that conservative treatment should be preferred in order to avoid repeated surgery.

Currently, the endoscopic treatment of choice of CD strictures is EBD [68]. Several studies have proven safety and efficacy of EBD for primary or anastomotic strictures ≤4–5 cm in length, with success rates of 44-58% [69–71]; however, post EBD relapse requiring reintervention ranges from 46% to 62% [72, 73]. Therefore, patients with a poor immediate response or an absence of long-term efficacy could benefit from alternative endoscopic treatments or surgery. In these patients, endoscopic stents could represent a minimally invasive alternative.

Data regarding safety and efficacy of SEMS in the context of CD strictures is limited and inconclusive. Our literature review has identified 20 publications (mostly case reports/small series) with 71 patients [32, 74–86], wherein majority of patients with colonic or ileocolic anastomotic stricture previously treated with EBD were managed using FC-SEMS or PC-SEMS with a clinical success rate of 36-100%. Patients who achieved clinical success remained symptom free for up to 10-12 months of follow-up, with mean stenting duration being 28 weeks. Major adverse events included stent migration (especially with FC-SEMS and associated with stricture resolution), perforation in 2 patients (both with stent dwell time longer than 100 weeks), and technically difficult stent removal (especially with PC-SEMS). The largest of these series by Loras et al. in patients with ileocolonic anastomotic strictures treated with 20 mm diameter FC-SEMS, maintained for an average of 28 days showed treatment efficacy in 64.7% patients, with 1 adverse event (proximal stent migration) [87].

Das et al. evaluated the efficacy of seven-day stenting in 21 CD patients with terminal ileum or ileocolonic anastomosis stricture and noted symptom improvement in 81% patients, with only 5 reported adverse events (2 stent-related discomfort, 3 asymptomatic stent migrations) and no requirement for stricture-related surgery during follow-up (3-50 months) [88]. Hedenström and Stotzer compared 20 mm diameter SEMS ($n = 7$) and 18 mm balloon dilation ($n = 5$) in patients with symptomatic ileo-cecal stricture and noted significantly higher clinical success (defined as no need for repeated interventions) in the stent group (86%) compared to dilation alone (20%) [89]. However, the study was terminated preterm following the higher incidence of adverse events in the stent group (mainly pain and rectal bleeding in 53% of patients).

While BDS can theoretically avoid the shortcomings of SEMS, mainly stent migration and the need for stent removal, however, the absence of biodegradable TTS colonic stents makes deployment proximal to the sigmoid technically challenging. Data is very limited in this context [31, 85, 87, 90]. Rejchrt et al. reported a series of 11 patients with CD strictures of the terminal ileum or colon, in whom BDS stents were deployed through an overtube, assisted by a stiff guidewire and with fluoroscopy guidance, with high technical success (90.9%), but early stent migration (between 2 days and 8 weeks) in 3/11 patients [32].

5. Lumen-Apposing Metal Stents (LAMS)

The LAMS designed for transluminal drainage was first described in 2011 [88]. The unique design of LAMS combined with the properties of a FC stent allows direct apposition of two separate lumens with minimal risk of leakage of enteric contents [88]. Furthermore, the large stent diameter gives the additional advantage of allowing direct endoscope manipulation of the bridged lumen. Several LAMS designs are commercially available. Teoh et al. performed an ex vivo comparison of the lumen-apposing force (LAF) of 3 designs of available LAMS [91]. In this study, LAFs were significantly higher for stents A (Axios) and S (Spaxus) when compared with stent N (Nagi) ($p < 0.001$).

LAMS are now a well-established indication for drainage of pancreatic fluid collections, due to their safety and efficacy profile. Several meta-analyses have evaluated LAMS for the drainage of pancreatic collections [92, 93], with technical and clinical success of 98.9% and 90% for walled-off pancreatic necrosis and 97% and 98% for pancreatic pseudocysts [93], with an adverse event rate of 11%. LAMS have also been compared to plastic stents in this context [92], with better clinical success (pooled RR of 0.37) and better safety profile (pooled RR of 0.39).

5.1. Drainage of Abdominopelvic and Mediastinal Collections. Besides management of pancreatic fluid/necrosis collections, creation of a fistula for drainage of an infected cavity can theoretically be performed in any part of the accessible GI tract, as long as the collection is in close proximity with the GI wall. Percutaneous or surgical drainage of abdominal or mediastinal collections have been the standard of care till now; however, percutaneous approach is marred with shortcomings of an external drain, including dislodgement, blockage, leakage, and hence requiring additional procedures [94], while surgical drainage is usually reserved for patients with inaccessible collections or those who fail to improve with percutaneous drainage. EUS-guided drainage of abdominopelvic and mediastinal collections is evolving into a promising alternative; however, data regarding safety and efficacy is still limited.

EUS-guided drainage of mediastinal collections with LAMS (Figure 2) has been described in several case reports [95–98]. Transesophageal drainage was technically successful in all five patients reported in these series, without any major complications. Naso-esophageal tube was placed in 2 patients, and LAMS was left in place for 3-7 days, with esophageal fistula clip closure in all patients after LAMS removal [96–99]. EUS-guided drainage of abdominopelvic collections with LAMS is slightly better reported [99, 100]. The largest case series included 47 patients [100], where fluid collection secondary to pancreatic duct leak after pancreatic resections was the foremost cause, along with other postsurgical collections (liver transplantation, liver resection, cholecystectomy, colorectal resection, gynecologic surgery, and bariatric surgery). Drainage route was transgastric in the majority of patients, with transduodenal and transrectal access utilized in 5 and 8 patients, respectively. Overall technical and clinical success was 93.6% and 89.3%, respectively,

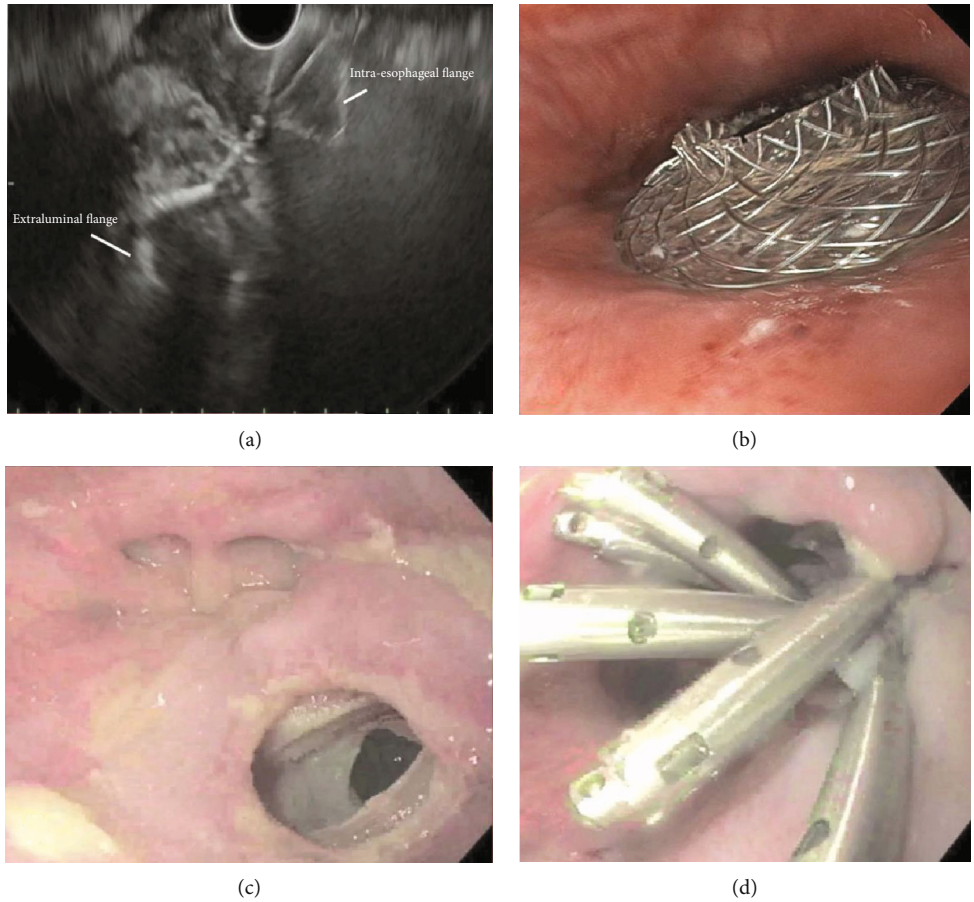


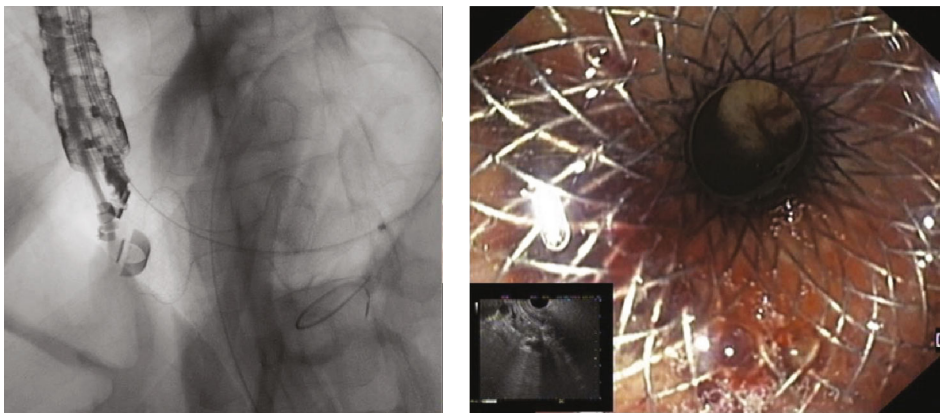
Figure 2: Patient with a mediastinal collection adjacent to the esophagus. (a) Endosonographic image showing deployment of a 10 mm diameter lumen apposing metal stent (LAMS). (b) Endoscopic image of the proximal flange placed in the esophagus. (c) Endoscopic image of the esophageal defect after LAMS removal. (d) Endoscopic image of the esophageal defect closed with endoclips.

with intraprocedural (stent migration) and postprocedural adverse events (1 migration, 1 perforation, 1 infection) in 4.25% and 6.4% of the patients, respectively [100, 101].

Finally, the role of EUS-guided plastic stent drainage of pelvic abscess has also been evaluated. A recent meta-analysis by Dhindsa et al. evaluated 8 studies with 135 patients with pelvic abscesses of different etiologies (mainly postsurgical and diverticulitis), with mean size 63.32 mm, and 83.7% being peri-rectal and remainder peri-colonic in location [101]. Drainage was performed with double-pigtail plastic stents and was reported technically successful in 100%. The calculated pooled rate of clinical success was 92% and 9.4%, adverse events with stent migration (5.5%) being the foremost.

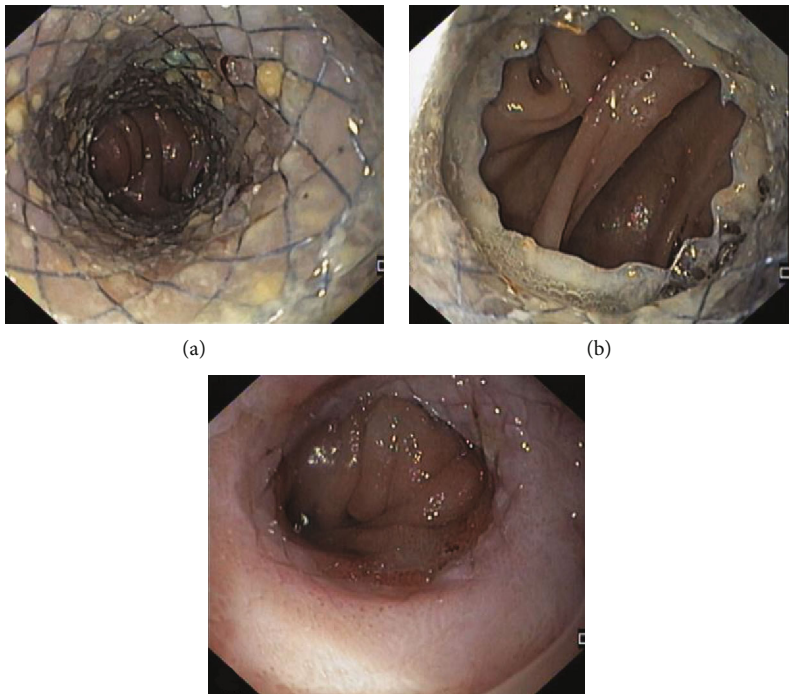
5.2. Gastro-Enteric and Entero-Enteric Anastomosis. EUS-guided gastro-enteric (GE) and entero-enteric (EE) anastomosis is an emerging technique in selected cases of gastric outlet obstruction (GOO), afferent loop syndrome (ALS), and patients who failed ERCP due to altered anatomy [102, 103]. The rationale of EUS-guided GE is similar to surgical gastro-jejunostomy (SGJ) and consists in identifying the target jejunal loop, followed by the creation of a gastro-jejunal or jejuno-jejunostomy under ultrasonographic and endoscopic visualization. Bi-flanged LAMS, particularly those with electrocautery-enhanced delivery systems, are the most used devices to create the GE anastomosis, and its availability increased the technical feasibility of the procedure [104]. This procedure is usually performed using a 15 mm diameter LAMS. EUS-GE is a technical complex procedure, especially on identifying a target jejunal loop and maintaining its relative position in close apposition to the stomach. Nowadays, there are three main techniques described to facilitate this limiting step during procedure: direct EUS-GE, device-assisted EUS-GE, and EUS-guided double balloon-occluded gastro-jejunostomy bypass (EPASS) [105].

A meta-analysis by Fan et al. evaluating the efficacy and safety of EUS-GE for GOO ($n = 285$) reported a pooled technical and clinical success of 92% and 90%, respectively [106]. These results were reproductible in a meta-analysis by McCarty et al. [107, 108]. Regarding safety, EUS-GE seems to have a relative low rate of AEs. Iqbal et al. [106] and McCarty et al. [108] reported a pooled incidence of AEs of 12% and 10.6%, respectively. Most reported AEs were stent misdeployment, peritonitis, bleeding, abdominal pain, and leakage. When compared to transluminal SEMS placement, EUS-GE have comparable technical and clinical effectiveness. Chandan et al. [109] reported a pooled rate for technical and clinical success of 95.2% and 93.3% in EUS-GE and



(a) (b)

Figure 3: Patient with a previous Roux-en-Y gastric bypass who presented with jaundice secondary to pancreatic cancer underwent endoscopic ultrasound directed transgastric ERCP (EDGE). (a) Fluoroscopic image showing a 20 mm diameter lumen apposing metal stent (LAMS) placed between the gastric pouch and the gastric remnant under EUS guidance. (b) Endoscopic image of the proximal flange of the LAMS in the gastric pouch.



(a) (b)

(c)

Figure 4: Patient with a refractory esophago-jejunal anastomotic stricture who underwent placement of lumen apposing metal stent (LAMS) across the stricture. (a, b) Endoscopic image of the LAMS placed across the stricture. (c) Esophago-jejunal anastomotic stricture remodelling after LAMS removal.

96.9% and 85.6% in SEMS. Pooled rate of reintervention was significantly lower with EUS-GE compared to SEMS (4% vs. 23.6%, $p = 0.001$); however, AEs were comparable between the two techniques. Khashab et al. [110] compared open SGJ and EUS–GE in patients with malignant GOO. Although technical success was lower with EUS-GE (86.7% vs. 100%, $p = 0.009$), there was no difference in clinical success (87% vs. 90%, $p = 0.18$). No significant statistically differences were found on recurrence and AE rates between the two groups. Kouanda et al. [111] did not found significant differences in technical or clinical success, symptom recurrence, reintervention, 30-day readmission, or 30-day mortality between EUS-GE and open SGJ. However, EUS-GE patients experienced shorter delays to resumption of oral intake and chemotherapy, had shorter lengths of stay, and reduced hospital costs. Perez-Miranda et al. [112] and

Bronswijk et al. [113] compared retrospectively EUS-GE and laparoscopic SGJ, reporting no differences in technical and clinical success between groups, but EUS-GE had significantly lower rate of AEs, reduced mean time to oral intake and shorter median hospital stays.

In patients who experienced surgeries involving the stomach or the duodenum, ampulla is less readily accessible, leading to a more challenging, in some cases, unsuccessful ERCP [114]. Most cases of altered anatomy involve Roux-en-Y gastric bypass (RYGB), but also Roux-en-Y hepaticojejunostomy, choledocojejunostomy and pancreaticoduodenectomy, or Billroth II procedures. To overcome difficult ERCP in surgical altered anatomy, endoscopic ultrasound–directed transgastric ERCP (EDGE) may be used [115]. EDGE is a procedure in which the gastric pouch is connected to the excluded stomach by placing a LAMS between them (Figure 3). Then, a "traditional" ERCP can be performed by passing an ERCP endoscope through the stent in direction to duodenum to reach de ampulla [116]. The ERCP can be performed either immediately or after a delay to avoid the risk of dislodging the stent. If the patient requires an urgent or emergent ERCP, the LAMS is balloon-dilated to allow the duodenoscope to pass through, although the risk of stent dislodgement remains. To minimize this risk, some authors suggest placement of an over-the-scope clip or endoscopic suturing to anchoring the stent in place [117, 118]. Dhindsa et al. [119] evaluated EDGE, LA-ERCP, and balloon enteroscopy-assisted ERCP (BEA-ERCP) outcomes in RYGB patients. Pooled rate of technical and clinical success of EDGE was comparable to LA-ERCP but was statistically superior to BEA-ERCP. AE rates were similar between EDGE and LA-ERCP. However, when compared to BEA-ERCP, EDGE had higher incidence of AEs. LAMS migration was the most common AE (13.3%), due to immature fistula or manipulation by duodenoscope [119]. A recent study reported a persistent fistula after LAMS removal as an uncommon event, but when present its closure is recommended. Weight regain due to persistent fistula may not be a concern since most studies point towards weight loss [120]. Additionally, EDGE is more cost-effective, compared to BAE-ERCP and LA-ERCP in RYGB patients [121]. EUS-directed transgastric intervention (EDGI) is described as a novel technique for other indication rather than ERCP, permitting successful interventions in the excluded stomach and duodenum of RYGB patients [122].

Afferent loop syndrome (ALS) is an uncommon complication after Billroth II gastro-jejunostomy but may also occur after Roux-en-Y reconstruction and pancreaticoduodenectomy (Whipple procedure). ALS is defined as a mechanical obstruction leading to distension of the afferent limb secondary to the accumulation of bile, pancreatic fluid, and proximal small bowel secretions, resulting in pancreaticobiliary symptoms, deranged hepatic panel, and elevated pancreatic enzymes [123, 124]. Usually, surgery is the mainstay treatment for ALS, although it depends on the obstruction cause and patient comorbidity. In malignant causes, especially in nonsurgical candidates, endoscopic intervention for palliation may play an important role [125]. Endoscopic access to afferent loop can be obtained by endoscope or enteroscope to perform EBD or placement of double-pigtail PS/SEMS into the stricture [126]. EUS-guided transgastric access to the afferent loop has been reported in malignant ALS, where afferent loop is not completely accessible due to long enteric segment, obstructing mass, tight angulation, long stricture, or recurrence after other endoscopic techniques [127, 128]. EUS-GE can be performed using a cautery or non-cautery-enhanced LAMS. After identifying the dilated loop *via* ultrasonography, a LAMS is deployed with the distal end in the afferent loop and the proximal end in the stomach or efferent loop. Some authors recommend the use of double pigtail stents through the deployed LAMS to prevent occlusion by food or tumor ingrowth [129]. A multicenter retrospective study evaluated 18 patients who underwent EUS-GE and EUS-EE to resolve ALS secondary to malignancy. Technical success was achieved in 100%, and clinical success included resolution of symptoms (88.9%) and expedited hospital discharge (11.1%). The most common procedure was a GJ (72.2%) [130]. When compared to luminal SEMS (historical cohort), EUS-GE group had higher rates of symptom resolution and less need for reinterventions [130].

5.3. Benign Gastrointestinal Strictures. LAMS have recently also been considered as a viable alternative to treat benign GI strictures. The unique design of LAMS with short length, saddle shape, and wide flanges makes them less prone to migration when compared to traditional SEMS. The data on this expanded indication is still evolving. In most descriptive studies, the stricture length was <10 mm, with migration rates being comparable to FC-SEMS fixed by suture. Tan et al. performed a meta-analysis of six studies with 144 patients [131], where in the most common stricture locations were gastro-jejunal anastomosis (33.3%), esophagogastric anastomosis (18.8%), gastro-duodenal anastomosis (17.4%), pylorus (13.2%), and colon (11.1%). The overall technical success rate was 98.3%, clinical success rate was 73.8% (Figure 4), and adverse events rate was 30.6%, with most common being stent migration (10.9%). Subgroup analysis showed higher rates of clinical success for colonic and pyloric strictures. No comparative studies of LAMS and SEMS and EBD have been reported so far.

6. Conclusion

The role of endoscopic stenting in the management of patients with gastrointestinal diseases has expanded greatly in recent years, both with increasing use of endoluminal and transluminal stents. BDS in the esophagus and colon show similar safety and efficacy to SEMS, with less need for reinterventions. Biliary BDS, especially helicoidal shaped, have shown favourable outcomes with minimal adverse events. DES, especially irradiating ones, might have a role in the palliative treatment of esophageal and biliary cancer by improving patients' survival. Stents also could prevent or delay the need for surgical resection and may be considered in Crohn's disease patients with colonic or ileocolonic anastomotic strictures, especially after EBD failure. Finally, LAMS have high rates of clinical success, with favourable

safety profile for management of mediastinal and postsurgical abdominopelvic collections, temporary treatment of GI benign obstructions, and may also be a valid alternative for GE creation in GOO, ALS, and biliary access in RYGB patients. GI stents continue to undergo design changes to address their limitations, and further technical refinements and studies to improve and demonstrate their efficacy are needed.

Conflicts of Interest

None of the authors disclosed personal conflicts of interest or financial relationships relevant to this publication.

Authors' Contributions

Eduardo Rodrigues-Pinto contributed to the conception and design. Joel Ferreira-Silva and Renato Medas contributed to the literature review. Joel Ferreira-Silva contributed to the drafting of the article. Mohit Girotra, Monique Barakat, James H. Tabibian, and Eduardo Rodrigues-Pinto contributed to the critical revision of the article for important intellectual content. Eduardo Rodrigues-Pinto contributed to the final approval of the article.

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Research Article

Stent Applications for Palliative Treatment in Advanced Stage Esophageal Cancers

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Background and Aim. Endoscopic stenting is a generally safe and effective palliative treatment for esophageal malignancies. In this study, we aimed to present endoscopic stent applications, adverse events, and relative advantages of covered versus uncovered stents in our center. *Methods*. We examined cases of endoscopic stenting for palliative treatment of advanced stage esophageal cancers between January 2014 and July 2019. Age, gender, location of mass, adverse events, survival time, and stent type were evaluated. Outcomes of fully covered and uncovered self-expanding stents were compared with regard to adverse events, including stent migration and occlusion. *Results*. The mean age of the patients was 66.4 ± 1, 52 were male, and 8 were female. Patients were followed up for a mean of 133 days. The most common complication due to stenting was migration. 13 patients developed adverse events. Migration was the most common adverse event, occurring in 8 (13%) patients. Although the migration rate of fully covered stents was higher than uncovered stents, there was no statistically significant difference ($p = 0.47$). Stent occlusion was observed in 4 patients. In three cases, it was due to the tumor; an uncovered stent was placed again in these cases. Food-related occlusion developed in one patient. There was no statistical difference in terms of overall adverse event rate when comparing fully covered stents to uncovered stents ($p = 0.68$). *Conclusion*. Endoscopic stenting is a viable palliative method with low morbidity and mortality in experienced centers. Though there are relative advantages with covered versus uncovered stents in individual cases, the overall adverse event rate is low and relatively similar.

1. Introduction

The number and breadth of endoscopic procedures performed continues to increase. Endoscopy is used universally in the diagnosis and treatment of many diseases. Endoscopic stenting has been increasingly used in the palliation of gastrointestinal malignancies [1]. Stenting provides a relatively easy and effective palliative treatment in patients with metastatic or advanced esophageal cancer.

Endoscopic stenting has been increasingly used in the palliation of gastrointestinal malignancies [1]. Stent insertion provides an easy and effective treatment exclusively in patients with metastatic or advanced esophageal cancer. Endoscopic stenting is a different method for the treatment of anastomosis leakage and esophageal fistula. Stent procedure in distal esophageal malignant stenosis is a simple and uncomplicated treatment method for the patient to relieve correct oral intake and dysphagia [2]. A similar accomplishment is partly achieved in proximal esophageal strictures [3]. Esophageal stent practiced in malignant stenosis can still be successfully practiced in benign stenosis [4]. There are numerous types of self-expandable stents (such as self-expandable biodegradable stents and self-expandable plastic stents). The use of SEMS has been on the increase. Uncovered (UC), semicovered, and fully covered (FC) stents are produced for use in different indications [5]. FC stents are used for anastomotic leakage and fistula. FC stents used for benign diseases can be removed if desired. UC stents are mostly preferred in malignant stenosis. Various complications related to the procedure concur with the use of endoscopic stents. Migration, fistula formation, bleeding, and occlusion are among the most common ones [4].

This study is aimed at discussing the results of self-expandable metal stent (SEMS) applications that we use for palliative treatment in patients with advanced esophageal cancer, in the light of the literature.

2. Methods

Study was made in the 1400-bed Necmettin Erbakan University Meram Medical Faculty Hospital in the Central Anatolian region of Turkey. Patients who underwent stenting for palliative treatment in our center due to advanced stage esophageal cancer between January 2014 and June 2019 were evaluated with case series analysis. The research was conducted according to the WMA Declaration of Helsinki-Ethical Principles for Medical Research Involving Human Subjects. The study was approved by the local ethics committee. 60 patients were included in our study. Patients with stent implantation due to benign esophageal stricture and postoperative leakage were excluded from the study. The type of stent was determined according to the indication and localization and size of the lesion. The stent length was determined upon endoscopy. The stent was used in stenoses that did not allow the passage of the scope. In occlusive lesions, the length of the stent was determined by imaging methods adjusting the length of the stent accordingly. We preferred uncovered (UC) stents for tumoral occlusion. Fully covered (FC) stents were preferred for the cases of fistula formation. In our clinic, stents with a length of 10-12 cm and a width of 20 french are used.

All endoscopic procedures were performed by 3 general surgeons in the general surgery clinic. All procedures were performed under anesthesia. The stents were inserted with guidewire under endoscopic control (Figure 1). In cases with in occlusive lesions where the endoscope was inapplicable, dilatation was performed first. 24 hours after the procedure, control radiographs were taken using X-ray. Oral intake was initiated following the X-ray control. Age, gender, location of mass, complications, survival time, and stent type of the patients were evaluated. Both stents (FC and UC) were compared for overall complication, occlusion, and migration development.

2.1. Statistical Analysis. The computer software used for biostatistical analysis was Statistical Package for the Social Sciences (SPSS 21 Inc., Chicago, IL, USA). Categorical variables were presented as frequency (percentage), and continuous variables were reported as mean ± standard deviation. Differences in patients' characteristics between FC and UC stents were examined by Pearson's chi-square test for categorical variables.

3. Results

Demographic data are given in Table 1. Sixty patients underwent stent insertion. The number of stents was 70. The mean age was 66.4 ± 16. Ten (16%) patients underwent multiple endoscopic stent placement. The stent was successfully inserted in all patients (Figure 1). Oral intake improved in all patients (completely in 75% and partly in 25%, respectively). The mean follow-up period was 133 ± 130 days. The mean length of hospital stay was 2.1 days [1–5].

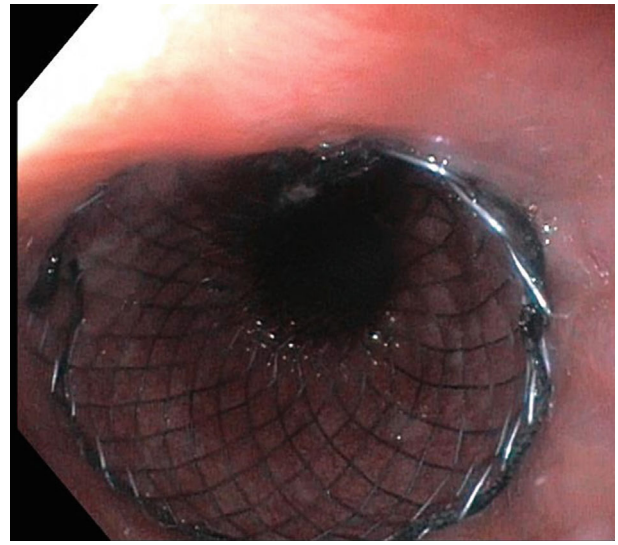

Figure 1: Stent placed in the esophagus.

13 patients developed complications. Migration was the most common complication after stenting. It occurred in 8 (13%) patients who underwent stent placement. In 3 (5%) of these patients, the stent was placed back to its previous position. It was applied especially in patients with migration occurring within a few days. In four (6%) patients, the stents were removed and changed with new ones. Only 1 patient developed a fatal complication. The patient died in the second postoperative month due to mediastinitis due to perforation. Stent migration occurred in 2 patients after chemotherapy (Figure 2). These patients were those who underwent FC stenting due to tracheoesophageal fistula. The old stent was removed, and a new one was placed.

Three patients (5%) developed hypotension during the procedure, and the procedure had to be interrupted. These patients had poor general status and apparent malnutrition. The procedure was successfully performed the next day.

One of the complications related to the stent is occlusion. It was seen in 4 patients. In three cases, occlusion due to a tumor was seen after 3 months. UC stent was placed again in these cases due to tumor growth. Food-related occlusion was observed in one patient and was removed endoscopically. Although the migration rate of FC stents was higher than UC stents, there was no statistically significant difference ($p = 0.47$). There was no statistical difference in terms of complications when FC stents and UC stents were compared ($p = 0.68$) (Table 2).

4. Discussion

In both malignant and benign UGI (upper gastrointestinal) tract occlusion, treatment with SEMS is considered to be a safer, less invasive, and effective method than oncological treatments and surgical. SEMS also reduces the rate of complications and length of hospital stay. In recent years, its use has increased as SEMS has a lower morbidity and

Table 1: Demographic characteristics of patients ($n = 60$).

	n (patient)	%	Mean ± SD
Sex			
Male	52	86	
Female	8	14	
Age (year)			66.4 ± 16
Survival (month)			4.4 ± 4.3
Stent			
Fully covered	10	16.7	
Uncovered	50	83.3	
Location of mass			
Proximal esophageal ca	18	30	
Cardioesophageal junction tumor	42	70	
Complication			
Migration	8	13	
Occlusion	4	6	
Perforation	1	2	

Figure 2: Covered stent migration.

Table 2: Compare of stent types.

	Fully covered stent ($n = 10$)	Uncovered stent ($n = 50$)	p value
Complication	4	9	0.68
Migration	3	5	0.47
Occlusion	1	3	0.52

mortality rate compared to conventional methods [5]. In this study, we shared our SEMS experiences in single center esophageal malignant occlusions. 30% of the cases were located in the proximal esophagus and 70% in the cardioesophageal junction.

While FC SEMS sees more migration, tumor growth is more common in cases with UC stent [6, 7]. We prefer FC stents more frequently due to their complete isolation, particularly in the fistulae, and easy removal. Migration occurred in 4 of 10 cases in which we applied a FC stent. The stents were placed back to their previous position. Stents that fell into the gastric cavity were removed and replaced with new ones. Rarely, stents were fixed with a hemostatic clip.

Most tracheoesophageal fistulas arise from locally advanced malignancy. In such cases, a covered metallic stent is applied for palliative treatment [8, 9]. Fully covered SEMS placement during the early term and minimally invasive drainage is an effective and safe treatment option [10]. In our series, Only 1 patient presented with fatal complications. In the second postoperative month, the patient died because of mediastinitis due to perforation. The occlusion was observed in 4 (6%) cases. They are advantageous as it is easier to remove them once the disease is treated. We mostly preferred FC stents in our cases with fistula formation. The handicap of using this type was a higher rate of migration. Although the migration rate of FC stents was higher than UC stents, there was no statistically significant difference ($p = 0.47$). Consequently, it resulted in a higher number of endoscopic interventions.

Oral intake is corrected in more than 95% of patients undergoing stent insertion due to occlusion [11, 12]. The accomplishment rate in fistula cases changes between 70% and 100% [13]. Stent migration, overgrowth, or ingrowth should be considered in patients presenting with dysphagia after oral intake was previously corrected. Dysphagia was corrected in all of our cases. Occlusion was observed due to tumor ingrowth in three patients. A second stent was inserted to solve these problems. One patient had a food-related occlusion, which was corrected by the endoscopic intervention. Other studies have demonstrated technical success rates (defined as successful insertion and adequate placement of the stent) of 83 to 100% and clinical success rates (defined as palliation of dysphagia) of 80 to 95% [14.] In our series, technical success was achieved in SEMS procedures (100%). Dysphagia improved in all our patients. However, 25% of the cases could not tolerate solid food and only tolerated liquid food. Before the stent was placed, all patients had liquid or solid food intolerance. Oral intake was provided after stent placement in all patients.

Although tumor internal growth rates of FC stents are reported to be lower than those of UC stents, migration rates are higher, particularly in the gastroesophageal junction, due to their limited adhesion ability. However, it is reported that short and thinner caliber stents can migrate more. In our series, the stent calibers were the same (20 mm). Stent migration is reported to occur in 10 to 25% of the coated stents and 2 to 5% of the UC stents [14]. The migration rate in our study was 30% in FC stents and 10% in UC stents, and our migration rate was 13% in all cases. Migration rate was higher compared to the literatüre. We think that this situation is caused by the termination of the procedure without waiting for the full opening of the stent during the procedure or the wrong stent selection. Neoadjuvant or palliative chemoradiotherapy is thought to increase the rate of stent migration [15]. Two of our patients had migration after chemoradiotherapy. When FC stents and UC stents were

compared, there was no statistically significant difference in terms of complications ($p = 0.49$).

Reocclusion usually occurs as a result of tumor overgrowth or food impaction, and its incidence is reported to be between 3 and 15% for covered and 10 and 42% for uncovered stents [16]. Stents covered with 5-fluorouracil or paclitaxel (drug-eluting stents) have been introduced to prevent tumor ingrowth in recent studies [17]. In this study, food-related occlusion was observed in 1 case and tumor ingrowth occlusion in 3 cases (6%).

Migration, occlusion, perforation, hemorrhage, and ulceration are the most widespread complications related to stents. Mortality rate stent application varies between 0.5% and 2% [18, 19]. Complications can be categorized under intraoperative or postoperative complications in the early and late periods. Timing of chemotherapy, stent length, and tumor stage is important parameters in the development of complications [20, 21]. Thirteen of our cases developed complications. Most of them were corrected with small interventions. Mortality was determined as 1%. However, our complication rate is higher compared to the literature. We attributed this situation to the long and strict follow-up period.

5. Conclusions

We found that there was no difference between stent types in terms of complication development among patients undergoing palliative endoscopic stenting of advanced esophageal cancers. Endoscopic stenting in this setting has low mortality and morbidity and is effectively in reducing dysphagia. The endoscopist must be experienced and prepared to address complications should they arise.

Data Availability

The data used to support the findings of this study are available from the corresponding author upon request.

Ethical Approval

Ethics committee approval was received for this study from the ethics committee of Necmettin Erbakan University Meram School of Medicine (IRB Number: 2021/3031).

Conflicts of Interest

Drs Mustafa Şentürk, Murat Çakır, Mehmet Aykut Yıldırım, and Ömer Kişi have no conflicts of interest or financial ties to disclose.

Authors' Contributions

Study planning was contributed by MŞ and MÇ. Data collection and analysis were contributed by MAY, MŞ and ÖK. Data interpretation was contributed by MŞ, MÇ, MAY, and ÖK. Drafting of the manuscript was contributed by MŞ and MÇ. Critical review of the manuscript was contributed by MŞ, MÇ, MAY, and ÖK. All authors approved the final version of the manuscript.

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Research Article

The Role of Lumen-Apposing Metal Stents in Transmural Endoscopic Drainage of Postinflammatory Pancreatic and Peripancreatic Fluid Collections

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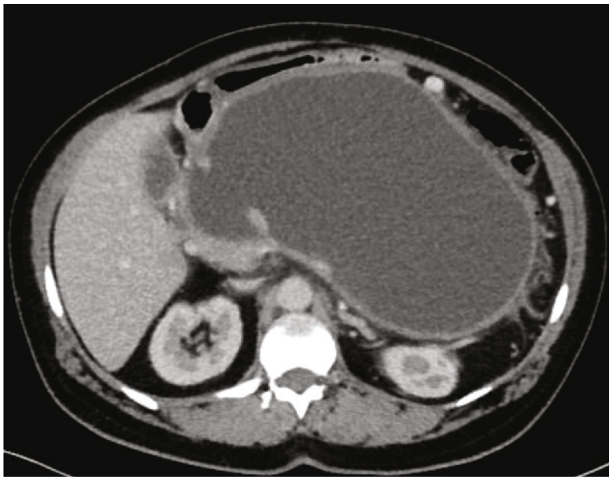
Rapid development of advanced gastrointestinal endoscopic techniques contributed to the appearance of new biomedical materials including polymers, which are used for the production of different types of endoprostheses. Endotherapy (ET) of postinflammatory pancreatic and peripancreatic fluid collections (PPFCs) with the use of lumen-apposing metal stent (LAMS) is an effective method of treatment. This paper describes the high efficacy of ET and its potential complications, which are mostly related to the design of the LAMS used. The high efficacy of LAMS in the transmural drainage of PPFCs is associated with lower safety of treatment. Complications of ET presented in the manuscript are mainly related to endoprosthesis' construction. This paper presents possible directions of development in the field of transmural LAMSs, which in the future may contribute to the invention of an innovative type of LAMS based on new biomedical technologies. Possibly, subsequent novel endoprosthesis projects, based on the above results, will be able to meet the current needs and requirements associated with endoscopic transmural drainage procedures in cases of postinflammatory PPFCs. The ultimate goal is to improve safety of minimally invasive techniques for treatment of the local consequences of pancreatitis.

1. Introduction

Acute pancreatitis (AP) of moderate and severe clinical course is associated with high risk of local complications and organ failure leading to increased mortality [1–4]. Pancreatic and peripancreatic fluid collections (PPFCs) that may appear in the late phase of pancreatitis in the form of pancreatic pseudocysts (Figures 1(a) and 1(b)) and walled-off pancreatic necrosis (WOPN) (Figure 2). These types of PPFCs are the most common local complications of acute and chronic pancreatitis [1–7]. For many years, the traditional treatment of postinflammatory PPFCs in the late phase of pancreatitis relied on surgical methods [7–10]. However, there has been recent dynamic development of minimally invasive techniques, including endoscopic transluminal methods [7–12]. While endoscopic treatment is an established method of managing these complications, some aspects of endotherapy are still a source of much controversy [7, 13, 14]. One of the most debated issues in interventional endoscopy of local complications in pancreatitis is the use of transmural self-expanding metallic stents (SEMSs).

Endoscopic transmural drainage consists in creating a fistula between the lumen of the PPFC and gastrointestinal tract to allow for outflow of the content from the PPFC into the gastrointestinal tract [7, 13, 15, 16]. During an endoscopic ultrasound- (EUS-) guided procedure of endoscopic transmural drainage of postinflammatory PPFCs, this can be visualized in the endosonographic image through the wall of the upper gastrointestinal tract [7, 16, 17]. Afterwards, a transmural puncture of the PPFC is performed under EUS



(a)

(b)

Figure 1: (a, b) A large pancreatic pseudocyst visualized by abdominal CECT in a female patient with acute pancreatitis.

guidance with the use of a needle and widened with a cystostome to a diameter of 10 Fr using coagulation. This forms a transmural cystostomy, which joins the gastrointestinal tract and the lumen of the PPFC [7, 17]. The next step of the endoscopic procedure is mechanical (with a dilator) or pneumatic (with a high-pressure balloon) dilation of the pancreaticocystogastrostomy or pancreaticocystoduodenostomy [7, 16, 17]. Once dilated, a transmural SEMS (Figure 3) or plastic stent(s) (Figure 4) is introduced through the cystostomy to facilitate passive transmural drainage of the collection contents into the gastrointestinal tract [7, 17]. Passive transmural drainage (Figures 3 and 4) is an effective method of endoscopic treatment of pancreatic pseudocysts, whose contents are entirely liquid [7, 15, 16]. In case of necrotic PPFCs that contain both liquefied necrotic material and tissue fragments, it is necessary to use active transmural drainage, which consists in inserting an additional nasal drain through the transmural cystostomy to enable flushing

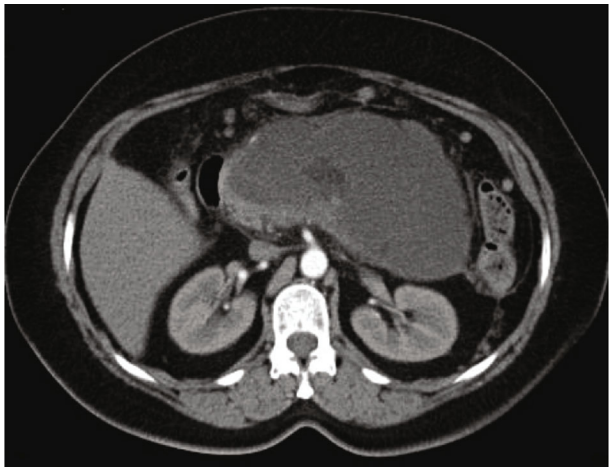


Figure 2: CECT of the abdomen in a patient with WOPN at week 8 of acute necrotizing pancreatitis.

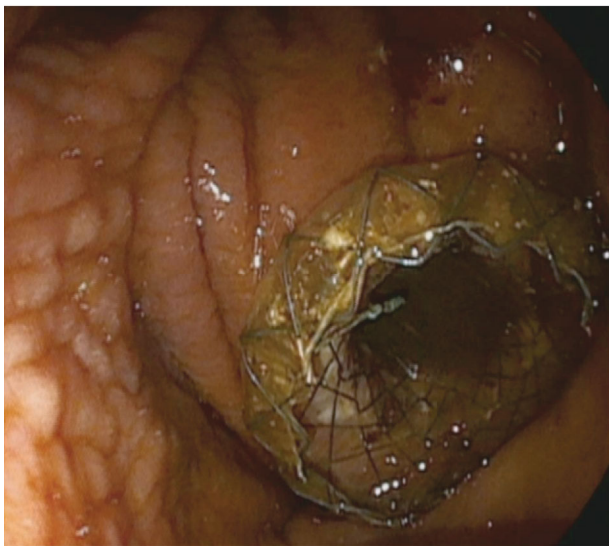


Figure 3: Passive transmural (transgastric) drainage of a postinflammatory pancreatic pseudocyst with a self-expanding stent.

of the collection cavity in the postoperative period (Figures 5(a) and 5(b)) [7, 17].

Development of advanced endoscopic techniques has led to rapid advancements in biomedical materials, including polymers for manufacturing endotherapeutic devices. Currently, there is a wide variety of transmural endoprostheses of different sizes, shapes, and designs for endoscopic treatment of postinflammatory PPFCs [7]. These endoprostheses are divided into two groups. The first group includes plastic stents, usually made of teflon or polyethylene [7, 17]. The second group includes SEMSs, often referred to as "lumen-apposing metal stents" (LAMSs) that are used in the treatment of postinflammatory pancreatic local complications [7]. For many years, the only type of endoprosthesis available for use in transmural drainage was plastic double-pigtail stents [17, 18]. However, LAMSs (Figures 6(a) and 6(b)) have been attracting increasing interest as a relatively

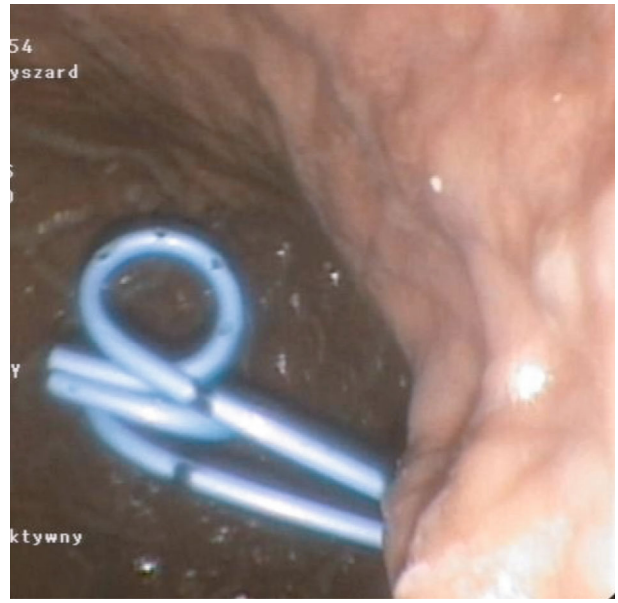


Figure 4: Passive transmural drainage of a pancreatic pseudocyst with two plastic double-pigtail stents.

new option in endoscopy [19–23]. LAMSs are a special type of SEMS used in a variety of gastrointestinal endoscopic procedures. They are made of nitinol wire and are fully covered with a silicone membrane [19–23].

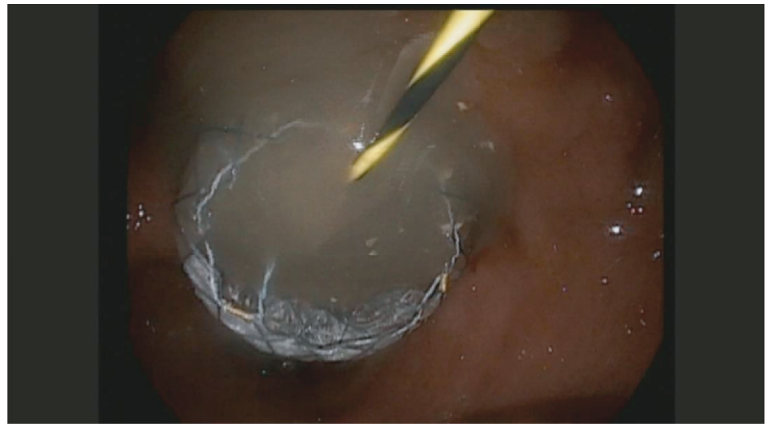
However, the role of LAMSs in transmural drainage remains unclear [7, 17–23]. This paper describes the outcomes of LAMS-based endoscopic treatment of postinflammatory PPFCs. Building on the authors' own experiences, this paper addresses the technical and structural features of transmural SEMSs and their usability in real-world clinical practice. The authors discuss the selection criteria for an appropriate type of endoprosthesis for transmural drainage of local complications of pancreatitis. Technical parameters of transmural endoprostheses are discussed in detail, with particular attention to endoscopic treatment complications associated with stent design. A number of novel methods have been presented for treating complications of endoscopic transmural drainage with the use of LAMSs. The main purpose of this study was to clarify the role of LAMSs in the transmural drainage of postinflammatory PPFCs.

In addition, the authors present an endoscopist's input regarding an ideal transmural endoprosthesis to improve the outcomes of endotherapy in postinflammatory PPFCs.

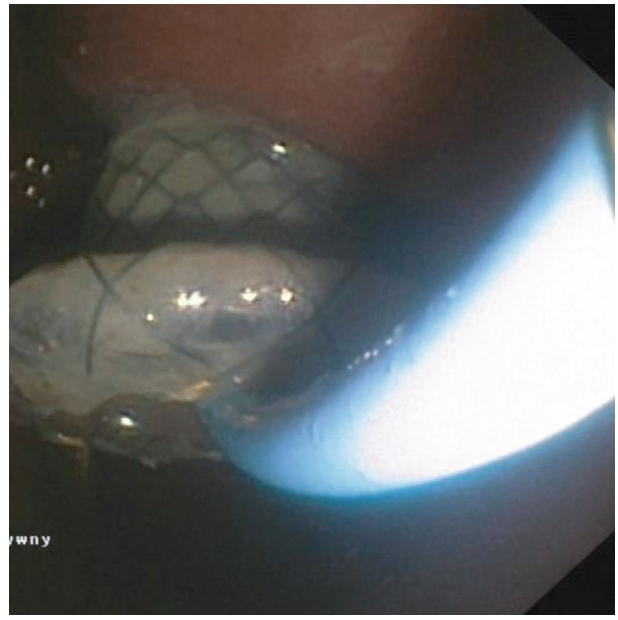
2. Materials and Methods

Prospective analysis of treatment outcomes in patients with postinflammatory PPFCs in late phase (>4 weeks) of pancreatitis, who received endoscopic treatment at the Department of General, Gastroenterological, and Oncological Surgery, Ludwik Rydygier Collegium Medicum, in Bydgoszcz, Nicolaus Copernicus University, in Toruń from 2018 to 2021.

The study was approved by the Ethics Committee at the Collegium Medicum of the Nicolaus Copernicus University



(a)



(b)

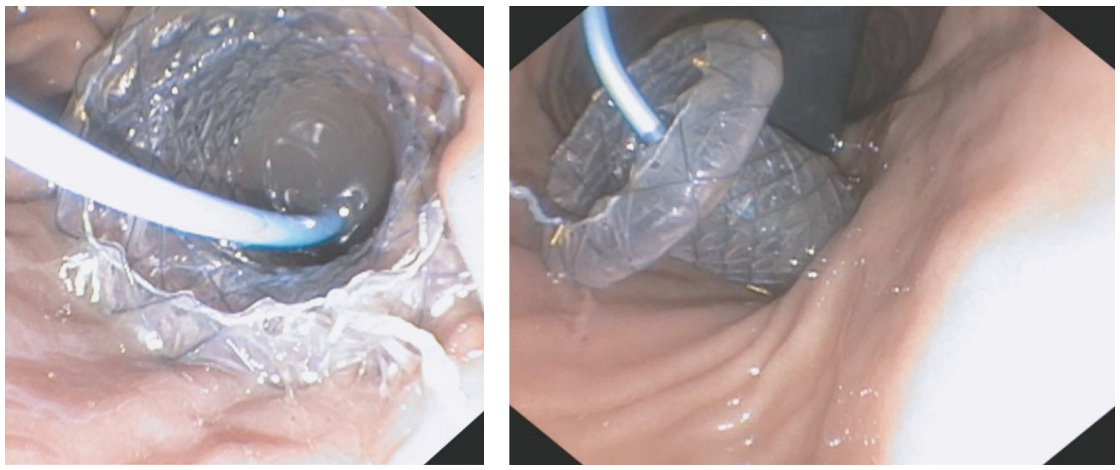
Figure 5: (a, b) Active transmural drainage of a WOPN. After the transmural fistula is created and a self-expanding stent (LAMS) is inserted transmurally through the fistula, (b) a nasal drain is introduced along (a) a guidewire into the necrotic area.

and was conducted in accordance with the Declaration of Helsinki. All patients provided informed consent for endoscopic procedures.

The diagnosis of pancreatitis, the criteria of clinical and morphological categorization, and all the definitions of local and systemic complications were based on the 2012 revised Atlanta classification [1–4]. The standards for conservative treatment for pancreatitis were based on international guidelines [24, 25]. Conservative treatment relied primarily on dietary treatment with intensive intravenous fluid therapy and analgesia. Moreover, additional treatment methods were used depending on concomitant organ impairment and the patient's overall clinical condition. Each individual case of pancreatitis (medical records and imaging results) was thoroughly discussed during interdisciplinary meetings of senior staff. Decisions were made regarding further management of the patient and the potential rationale for interventional treatment.

2.1. Study Inclusion Criteria. All patients with clinical symptoms of PPFCs due to acute or chronic pancreatitis were enrolled. The patients underwent endoscopic drainage procedures. Qualification for endoscopic treatment was based on the clinical picture and imaging results, primarily abdominal contrast-enhanced computed tomography (CECT). The start of endoscopic treatment was postponed until the collection became encysted at the latest. If it was necrotic, the necrotic material collected within the cavity became liquified and a WOPN was formed, which occurred four weeks from the onset of the disease and was determined on the basis of imaging examinations of the abdominal cavity.

2.2. Study Exclusion Criteria. Patients with PPFCs that were not a consequence of pancreatic inflammatory disease were excluded from the study. The study also excluded patients with postinflammatory PPFCs without clinical symptoms and those who had undergone surgery in the pancreatic



(a) (b)

Figure 6: (a, b) Active transmural drainage. Transmurally/transgastrically placed LAMS in a patient undergoing endoscopic drainage of a WOPN.

region. Patients who had undergone interventional treatment in the early phase (<4 weeks) of AP were also excluded.

2.3. Selection of the Type of Endoscopic Management [7, 26]. In patients with symptomatic PPFCs in the late phase of pancreatitis, transmural drainage using the single transluminal gateway technique (SGT) was performed if endoscopic ultrasound revealed that the distance between the wall of the collection and the gastrointestinal wall did not exceed 30 mm. In patients with sterile pancreatic pseudocysts, the method of choice was passive transmural drainage. In patients with infected pancreatic pseudocysts or WOPN (both sterile and infected), the method of intervention was active transmural drainage.

In the event that drainage with the single transluminal gateway technique (SGT) was ineffective and the fluid collection spreads beyond the lesser sac, multiple transluminal gateway technique (MTGT) was used. This technique has also been used in cases of multilocular postinflammatory PPFCs. If the necrotic areas were infected or transmural drainage was unsuccessful for WOPN patients, direct endoscopic necrosectomy was performed.

If endoscopic techniques with transmural access were ineffective, additional access to the collection cavity was created using percutaneous drainage (transperitoneal or retroperitoneal) or transpapillary drainage (through the major duodenal papilla). Endoscopic retrograde pancreatography (ERP) revealed communication between the main pancreatic duct (MPD) and the PPFC cavity.

2.4. Endoscopic Procedures. Endoscopic procedures were performed under general anesthesia with tracheal intubation. All patients provided informed consent for this procedure. All were performed by a single endoscopist, and the procedure entailed carbon dioxide insufflation and use of a linear echoendoscope (Pentax EG3870UTK, Pentax Medical, Tokyo, Japan), duodenoscope (Olympus TJF-Q180V, Olympus Corporation, Tokyo, Japan), and gastroscope (Olympus GIF-H185, Olympus Corporation). Before the procedure, all patients received prophylactic antibiotic treatment (ciprofloxacin or ceftriaxone). Samples of the material contained in the PPFC were collected for microbiological, cytological, and laboratory analyses.

2.5. Transmural Drainage with the Single Transluminal Gateway Technique (SGT) [7, 26]. Placement of the pancreaticogastric or pancreaticoduodenal anastomosis in the form of transmural cystostomy was performed under EUS guidance. The anastomosis between the gastrointestinal lumen and the collection cavity was created with a 10 Fr cystotome (Cystotome CST-10, Cook Endoscopy Inc., North Carolina, USA) and then dilated with a high-pressure balloon with a diameter of up to 15 mm (Cook Endoscopy or Boston Scientific). Through the stomy, a transmural metal endoprosthesis (LAMS) was inserted, measuring 16 mm in diameter and 20 mm, 30 mm, or 40 mm in length (Taewoong Medical or Olympus) (Figures 7 and 8). For active transmural drainage, a 7 Fr or 8.5 Fr nasal drain (Cook Endoscopy) and 7 Fr or 8 Fr double-pigtail stents (Cook Endoscopy) were inserted into the collection cavity through the LAMS. In the case of passive transmural drainage, only 7 Fr or 8.5 Fr double-pigtail stents (Cook Endoscopy) were used through LAMS.

2.6. Multiple Transluminal Gateway Technique (MTGT) [7, 26–29]. In patients with additional transmural stomy created between the collection and lumen of the gastrointestinal tract, the placement of the anastomosis was also decided under EUS guidance. The transmural cystostomy was created with a 10 Fr cystostome (Cystotome CST-10, Cook Endoscopy) and expanded with a high-pressure balloon with a diameter of up to 15 mm (Boston Scientific, Massachusetts, USA). Next, a metal endoprosthesis (LAMS) with a diameter of 16 mm and length of 30 mm or 40 mm (Taewoong Medical or Olympus) was inserted transmurally. Depending on the type of drainage, a 7 Fr or 8.5 Fr nasal (Wilson-Cook) and/or 7 Fr or 8 Fr double-pigtail stent (Wilson Cook) drain was inserted through the endoprosthesis and into the collection lumen.

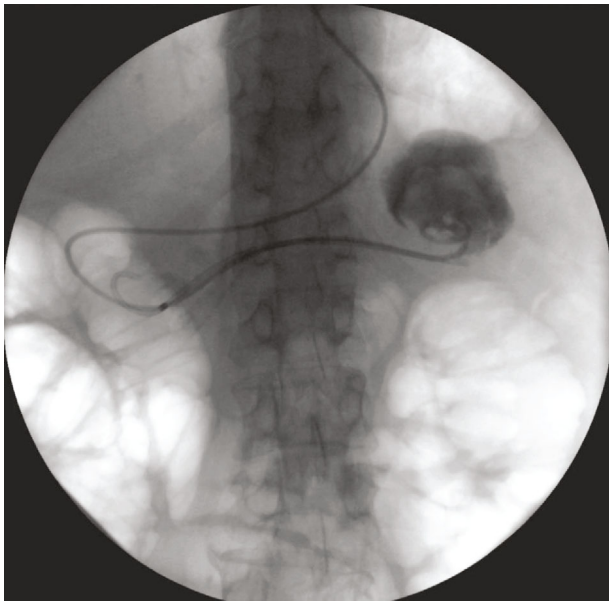


Figure 7: Active transpapillary drainage of a pseudocyst located in the pancreatic tail.

2.7. Direct Endoscopic Necrosectomy (DEN) [7, 26, 30–33]. Direct endoscopic necrosectomy procedures, which mechanically remove necrotic tissue, were performed in WOPN patients with no clinical improvement despite the drainage treatment or even if the necrotic collections became infected. The first stage of DEN involved removing the nasal drain. Through the transmural stomy with the LAMS inside, a gastroscope was introduced into the necrotic area. The necrotic collection cavity was subsequently flushed multiple times with saline solution, and the washings were removed by suction. A 15–20 mm extraction balloon (Cook Endoscopy) and Dormia basket (Cook Endoscopy or Olympus) were used to remove necrotic tissue under direct endoscopic image guidance. This procedure was repeated several times. Upon completion, the nasal drain and/or double pigtail plastic stents were reinserted transmurally.

2.8. Drainage System. When active transmural drainage was used, the PPFC was flushed with saline (60–200 mL) through the nasal drain every 2 hours during the first 48 hours of the postoperative period and every 4 to 6 hours on the following days. If the patient's clinical symptoms suggested PPFC infection, the antibiotic therapy was prolonged or the contents of the collection were cultured again with antibiotic susceptibility testing.

2.9. Treatment Efficacy Assessment. During active transmural drainage, the size of the fluid collection was measured every seven days via abdominal ultrasound. Abdominal CECT was used to confirm complete regression of the fluid collection or in cases where the patient's clinical condition deteriorated despite ongoing treatment. Active drainage was discontinued once clinical success could be established, while the patients were still on passive transmural drainage. After four weeks, an endoscopic procedure was performed during subsequent hospitalization and the passive transmural drainage was either continued (with transmural endoprostheses replaced) or discontinued (with the transmural endoprostheses removed). The decision to continue passive transmural drainage was made depending on the fluid collection size and the presence of any disruption in the MPD, as revealed during ERP. If the PPFC persisted in residual form (–30–40 mm) or recurred (>40 mm), passive endoscopic drainage was continued and the transmural endoprostheses were replaced for another four weeks. In cases of complete PPFC regression, an endoscopic procedure was performed to remove the transmural endoprostheses and passive endoscopic drainage was completed.

2.10. Definitions. Technical success was defined as successful placement under endoscopic and radiologic image guidance of the transmural stent with its distal and proximal ends located in the PPFC cavity and lumen of the gastrointestinal tract (stomach or duodenum), respectively. A procedure was confirmed to be technically successful if the contrast agent administered was flowing freely from the PPFC through the transmural stent without leaking out of the gastrointestinal tract or the stent.

Clinical success was defined as resolution of complaints associated with the presence of the PPFC and complete regression of the collection or its diameter decreasing to <40 mm in imaging tests.

Long-term success was defined as the absence of complaints and complete PPFC regression or its size decreasing to <40 mm during follow-up after the end of the endoscopic drainage.

Recurrence of fluid collection was understood as a collection size of >40 mm or reappearance of symptoms during follow-up.

Transmural stent dislocation was defined as the spontaneous migration of the transmural stent away from the anastomosis between the gastrointestinal lumen and PPFC cavity.

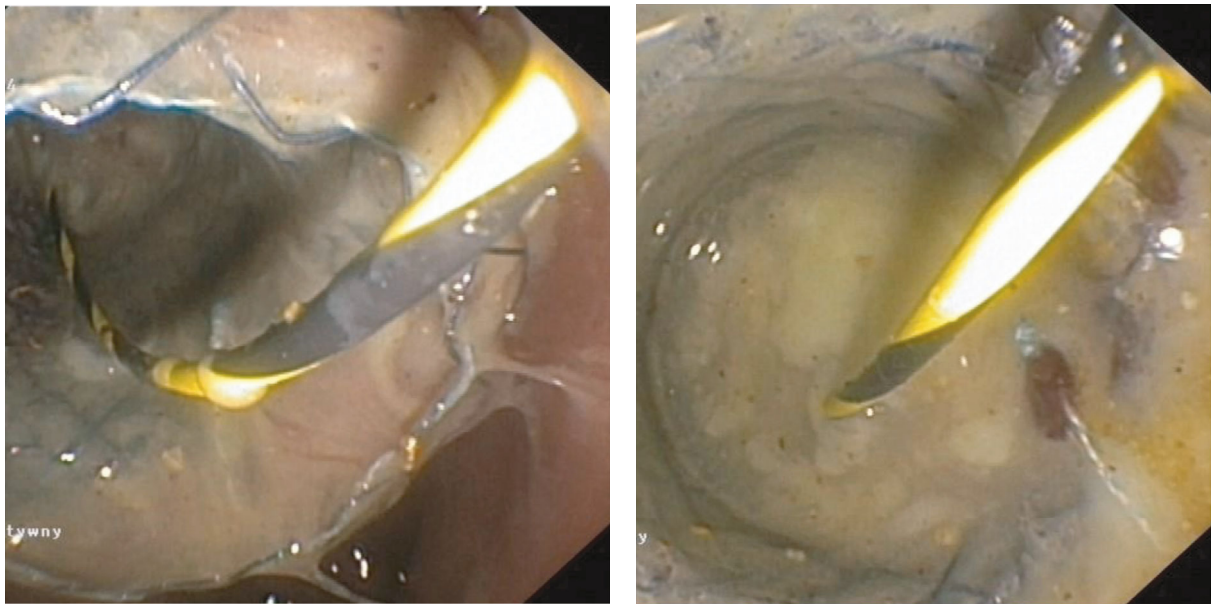
Early dislocation of the transmural stent was established if dislocation occurred within the first seven days following the procedure of endoscopic transmural drainage.

Late dislocation of the transmural stent was established if dislocation occurred more than seven days after the procedure.

Proximal stent dislocation was defined as migration of the transmural endoprosthesis from the anastomosis into PPFC lumen, where both flanges of the stent were inside the collection cavity and away from the gastrointestinal wall.

Distal stent dislocation was defined as migration of the transmural endoprosthesis from the anastomosis into the lumen of the gastrointestinal tract, where both flanges of the stent were inside the gastrointestinal lumen.

2.11. Statistical Analysis. All statistical calculations were conducted using the statistical software TIBCO Software Inc. (2017). Statistica software (data analysis software system), version 13, was also used (http://statistica.io). Quantitative variables are characterized using arithmetic means, standard deviation, median, and minimum and maximum values



(a) (b)

Figure 8: (a, b) Single transluminal gateway technique using LAMS for infected pancreatic pseudocyst treatment.

Table 1: Characteristics of the patients with PPFCs.

	All patients ($n = 257$)
Age, mean (range)	61.88 (20–83)
Sex, *n*, men (%)	205 (79.77%)
Etiology, *n*, (%)	
Alcoholic	166 (64.59%)
Nonalcoholic	91 (35.41%)
PPFC size (cm), mean (range)	14.96 (6.4–36.32)
Type of PPFCs	
Pancreatic pseudocyst	69 (26.85%)
Walled-off pancreatic necrosis	188 (73.15%)
Time from the pancreatitis to endotherapy (days), mean (range)	76 (29–411)

(range). Qualitative variables are presented as numbers and percentages.

3. Results

3.1. Patient Characteristics. The study enrolled 257 patients with symptomatic postinflammatory PPFCs who underwent an endoscopic transmural drainage procedure performed using LAMS; 188 patients (73.15%; 39 women and 149 men; mean age, 62.02 (21–83) years) were diagnosed with WOPN and 69 (26.85%; 13 women and 56 men; mean age, 60.93 (20–78) years) with pancreatic pseudocysts. The mean time from the onset of pancreatitis to the start of endotherapy (ET) was 76 (29–411) days. Chronic pancreatitis was diagnosed in 72 patients (28.02%). Detailed patient characteristics are presented in Table 1.

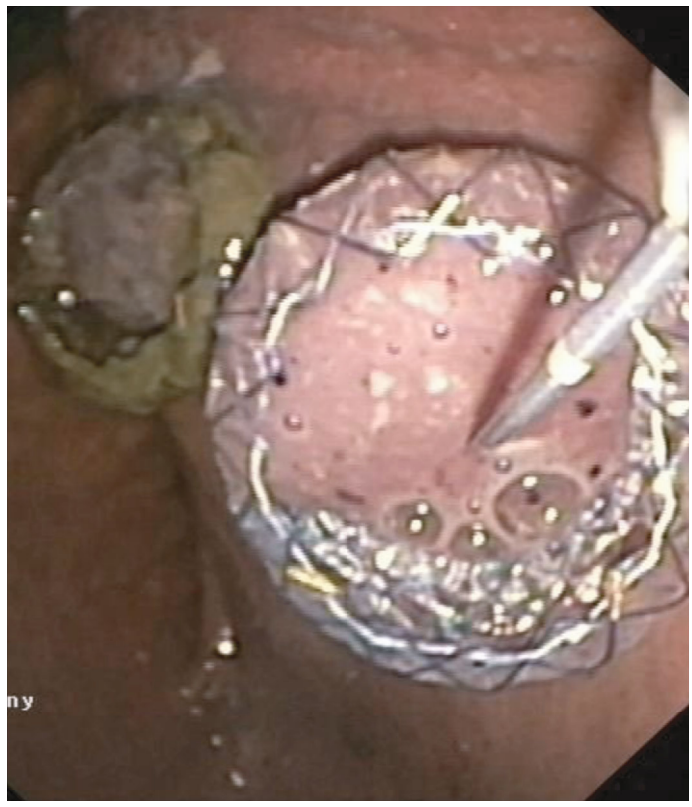
Table 2: Indications for endoscopic treatment of PPFCs.

Indication	Number of patients, *n* (%)
Infection	157 (61.09%)
Subileus/ileus	84 (32.68%)
Icterus	21 (8.17%)
Abdominal pain	121 (47.08%)
Weight loss	101 (39.3%)
Other	9 (3.5%)

An infection diagnosed on the basis of a positive culture of the PPFC contents was present in 115 patients with WOPN and in 42 patients with pancreatic pseudocysts. In both groups, the most common bacterial pathogens isolated from the fluid sample were *Escherichia coli*, *Klebsiella pneumoniae*, *Enterococcus faecalis*, and *Staphylococcus epidermidis*. The remaining indications for endoscopic treatment are shown in Table 2. A total of 112 patients (43.58%) presented with more than one indication for ET.

3.2. Endoscopic Treatment Technique. All 257 patients underwent endoscopic transmural drainage of postinflammatory PPFCs (transgastric in 223 patients and transduodenal in 34 patients). Twenty-seven patients with sterile pancreatic pseudocysts underwent passive transmural drainage initially. Active transmural drainage was performed in 230 patients (188 patients with WOPN and 42 patients with infected pancreatic pseudocysts). Additional active transpapillary drainage was performed in 11 patients (Figure 7) and an additional percutaneous drainage in 24 patients, and all 230 patients continued passive transmural drainage discontinuing active drainage.

Single transluminal gateway techniques (Figures 8(a) and 8(b)) were applied to 167 patients. Multiple transluminal



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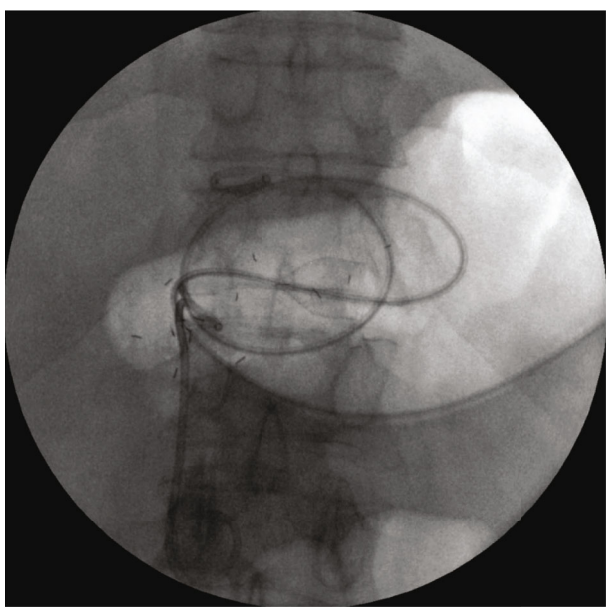

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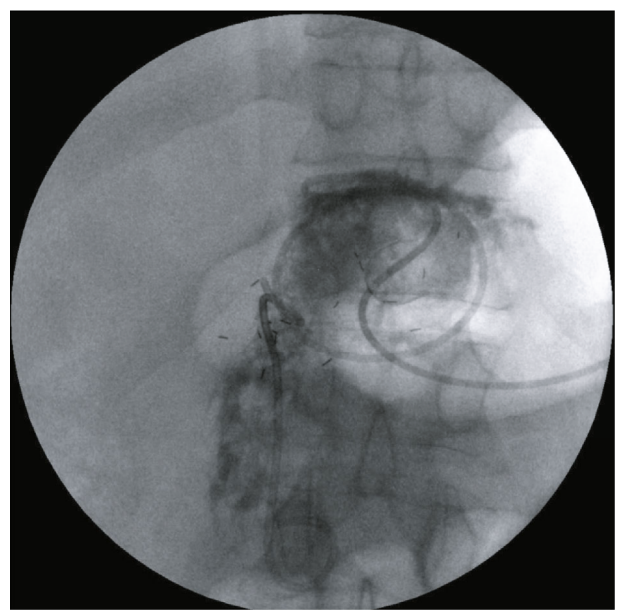


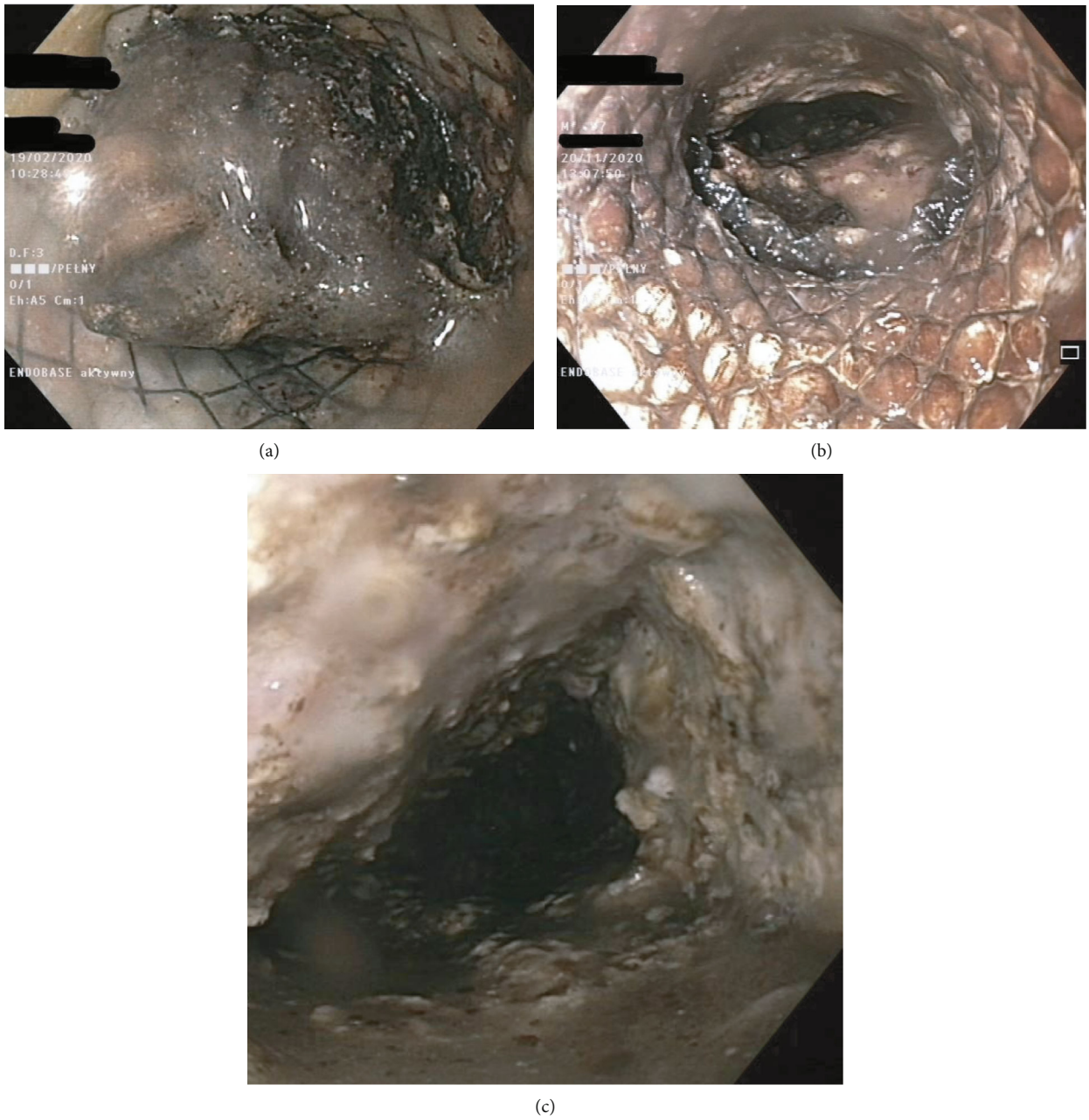
(c)

Figure 9: (a–c) MTGT using two LAMS in infected WOPN treatment.

gateway techniques (Figures 9(a)–9(c)) were used in 90 patients. DEN (Figures 10(a)–10(c)) was performed in 103 patients with WOPN.

3.3. Duration of Endotherapy. Active endoscopic drainage took an average of 13.34 (5–82) days. The average duration of passive transmural drainage was 84 (25–281) days. The mean number of endoscopic procedures was 8.61 (2–28). During the endoscopic treatment of the 257 patients with PPFCs, 942 LAMS were used.

3.4. Endoscopic Treatment Complications. Complications during endoscopic transmural drainage were observed in 34 patients (13.23%). Of these, a vast majority were stent-



(a) (b)

(c)

Figure 10: (a–c) DEN of an infected pancreatic necrosis. (a, b) Endoscopic image after insertion of a gastroscope into the lumen of the LAMS. (c) Image from the lumen of the infected WOPN after the gastroscope is delivered through the stent into the fluid collection.

related complications, constituting 32 of the complicated cases. Among the 34 patients who experienced endotherapy complications, 8 required surgical treatment. Detailed information on the complications is presented in Table 3.

3.5. Gastrointestinal Bleeding. The most common complication of endoscopic treatment was bleeding into the upper gastrointestinal tract, which was observed in 20 patients. For all cases, the cause was bleeding from the PPFC through transmural cystostomy into the gastrointestinal lumen (Figure 11).

Conservative treatment with blood transfusions and blood derivatives proved successful in 8 patients with gastrointestinal bleeding during ongoing transmural drainage. Endoscopic treatment with hemostatic powder (*Hemospray*, Cook Endoscopy) sprayed into the collection cavity was effective for managing bleeding in 5 patients. Another 5 patients required endovascular treatment with embolization of the perforated vessel (4 cases) or insertion of a stent graft to bypass the site of vascular rupture (1 case) (Figures 12(a)–12(c)). Among the patients who received endovascular treatment, 4 had bleeding from the splenic artery and 1 from the gastroduodenal artery. Due to the inefficacy of minimally invasive bleeding management techniques, 2 patients required surgical treatment. During laparotomy, the bleeding artery (the gastroduodenal artery in 1 case and the splenic artery in 1 case) was ligated using the stick tie technique.

Table 3: Complications of endoscopic treatment of patients with pancreatic fluid collections.

Complication	Number of patients	Treatment	Number of patients
Upper gastrointestinal bleeding	20	Conservative	8
		Endotherapy	5
		Endovascular treatment	5
		Surgical	2
Early dislocation of LAMS	7	Endotherapy	2
		Surgical	5
Perforation of PPFC	2	Percutaneous drainage	1
		Surgical	1
Late dislocation of LAMS	5	Endotherapy	5

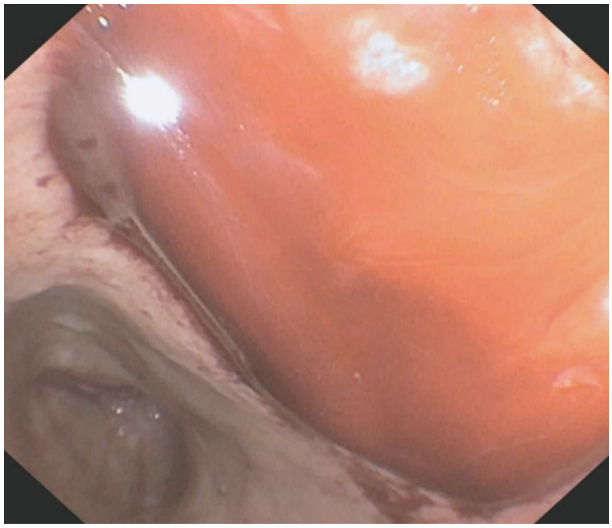


Figure 11: Endoscopic image (gastroscopy). Arterial bleeding from the collection cavity through the transmural LAMS into the gastric lumen.

3.6. Early Dislocation of the Transmural Stents. Of the 34 patients with complications, 7 developed a perforation of the gastrointestinal tract due to early dislocation of the transmural stent (Figures 13(a)–13(c)). Six patients developed proximal stent dislocation into the lumen of the PPFC (Figure 14). One patient developed distal dislocation of the transmural stent into the lumen of the gastrointestinal tract.

Endoscopic treatment to remove the dislodged stent and insert a new transmural endoprosthesis, accompanied by percutaneous decompression of the peritoneal cavity, proved to be an effective treatment method in 2 patients. The other 5 patients with early transmural stent dislocation required surgical treatment. All 5 patients had sutured gastrointestinal perforation, and the transmural stent was removed, while external (percutaneous) drainage was used to treat the pancreatic fluid collection. Among the 5 patients who underwent surgical treatment for early transmural stent dislocation, 3 required a laparotomy (Figures 15(a) and 15(b)) and 2 underwent the procedure successfully performed from laparoscopic access.

3.7. Pancreatic and Peripancreatic Fluid Collection Perforation. PPFC perforation with fluid leakage from the collection cavity into the retroperitoneal space was found in 2 patients. One of these patients required surgical treatment; laparotomy was performed with drainage and rinsing of the retroperitoneum. The other patient underwent successful percutaneous drainage of the retroperitoneal space without the need to resort to surgical treatment.

3.8. Late Dislocation of the Transmural Stents. Five of the 34 complicated cases developed late dislocation of the transmural stent. Two of these patients were diagnosed with distal dislocation of the stent into the gastrointestinal lumen. The remaining three patients had proximal dislocation of the transmural stent into the collection cavity. The average time from the procedure to the diagnosis of late dislocation was 17 (10–27) days. In all dislocation cases, an endoscopic procedure was performed wherein the dislodged stent was grasped with rat tooth forceps and pulled outside (Figures 16(a)–16(c)).

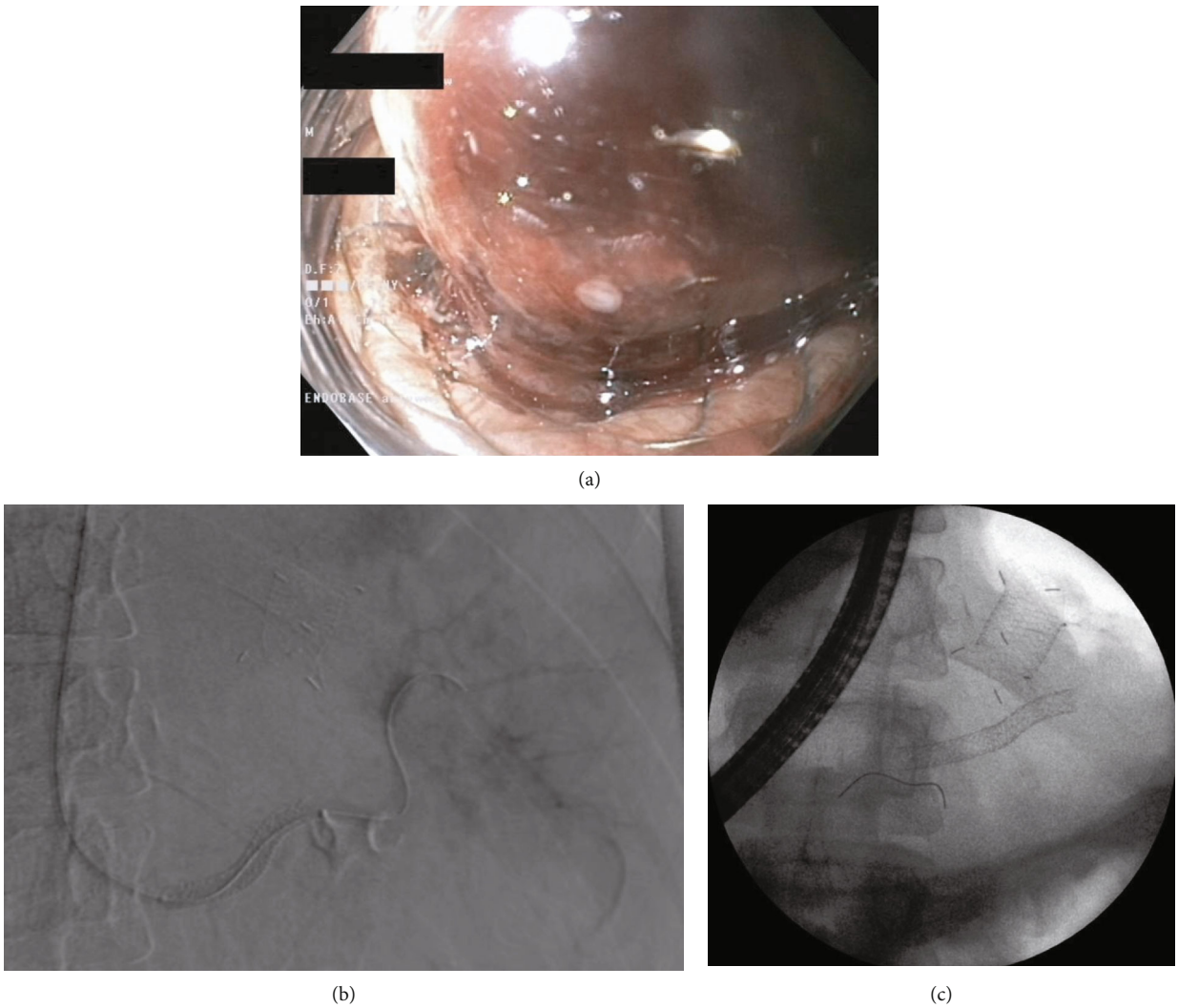
3.9. Efficacy of Endotherapy. Technical success of the transmural drainage procedure was achieved in 255 patients (99.22%). Clinical success was achieved in 242 patients (94.16%).

3.10. Mortality. Mortality during ET was observed in 8 patients (3.11%) and was not associated with ongoing endoscopic treatment. All fatal cases reported were caused by multiple organ failure during the course of severe acute necrotizing pancreatitis.

3.11. Long-Term Success. During the follow-up period, which lasted an average of 213 (32–1034) days, long-term success of PPFC ET was achieved in 221 patients (85.99%). PPFC recurrence was reported in 17 patients during follow-up. Of these, 15 patients underwent successful endoscopic treatment for recurrent fluid collection. In two patients, the recurrent PPFC necessitated surgical treatment.

4. Discussion

The choice of drainage technique in patients with postinflammatory PPFCs should rely primarily on experience of the treating medical center [7–13, 26–33]. This paper shows



(a)

(b)

(c)

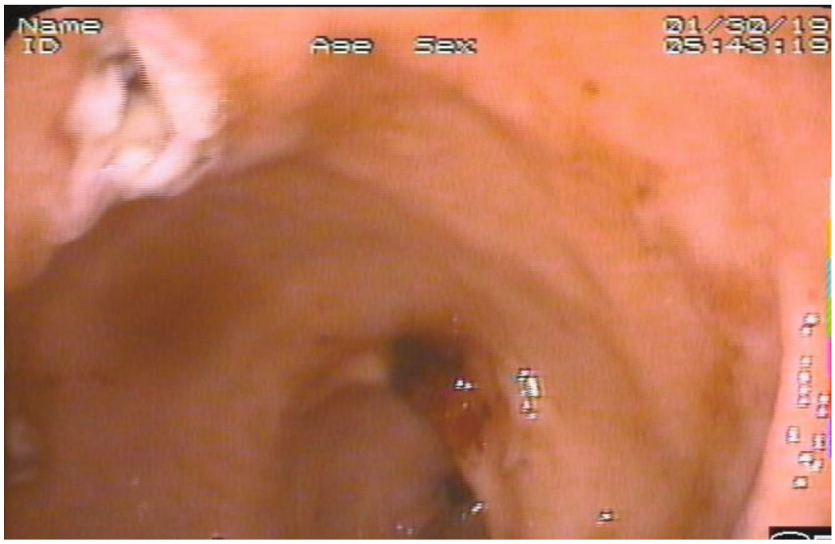
Figure 12: (a–c) Bleeding from the splenic artery during transmural drainage of a pancreatic necrosis. (a) The endoscopic image reveals a blood clot inside of the transmural stent. (b, c) The patient received endovascular treatment by inserting a stent graft to bypass the damaged vessel.

that ET can be an effective minimally invasive treatment for such patients. Despite the high efficacy of such treatments, its safety offers some significant space for improvement. As discussed above, most complications during endoscopic treatment of PPFCs are associated with the design of the transmural endoprosthesis. Therefore, it is reasonable to pursue further improvements in the quality of endoscopic equipment to minimize the incidence of complications. Meanwhile, efforts to advance the safety of endoscopic treatment with next-generation novel stent designs may contribute to greater efficacy of this treatment.

Traditionally, endoscopic transmural drainage of postinflammatory PPFCs has been performed using plastic (teflon or polyethylene) double-pigtail stents [7, 15–18]. The most commonly used procedure involves transmural insertion of several plastic stents to maintain the patency of the pancreaticogastric or pancreaticoduodenal cystostomy and to ensure undisturbed outflow of the fluid from the collection cavity into the gastrointestinal tract [15–18]. The wider the fistula, the more efficient is the transmural drainage [21, 22].

As a result of advancements in biomedical materials, SEMSs were introduced to the market [19–23, 34–41]. Currently, interventional treatment in gastroenterological endoscopy relies on SEMSs, which come in fully covered, partially covered, and uncovered versions [34, 35]. Uncovered SEMSs offer lower risk of migration, resulting from their higher potential for tissue overgrowth, but often lead to a shorter duration of patency, making it impossible to remove or replace the stent [34, 35]. Fully covered SEMSs are more prone to migration because they are covered with a special polymer coating that prevents tissue overgrowth and prolongs patency, while simultaneously facilitating removal or replacement [34, 35]. A sort of compromise is offered by partially covered SEMSs, which are usually nonremovable but less prone to migration or tissue overgrowth, which ensures longer duration of patency.

With this, only the fully covered type can find application in transmural drainage of postinflammatory PPFCs, where the SEMS must be removed upon treatment completion [7, 19–23]. A special polymer membrane that fully coats the



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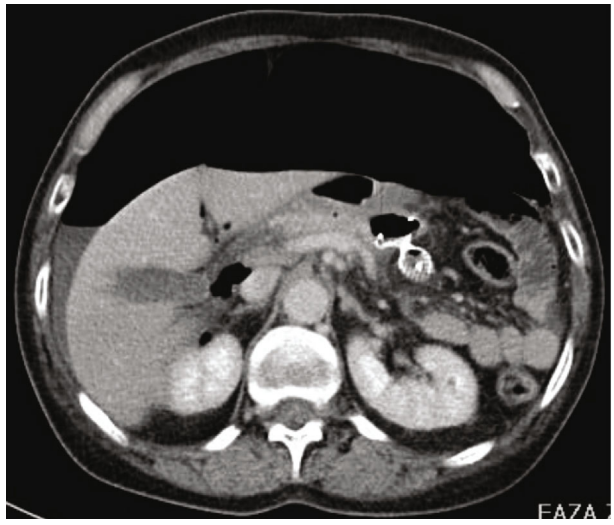


(c)

Figure 13: (a–c) Early proximal transmural stent migration. (a) The endoscopic image shows the transmural fistula without the stent. (b, c) Contrast-enhanced multiphase computed tomography image of the abdominal wall in a patient suffering from a perforation of the gastrointestinal tract due to early proximal dislocation of the transmural stent. (b, c) A large amount of air can be seen in the peritoneal cavity, as well as the dislodged transmural stent outside of the gastrointestinal lumen.

stent not only prevents tissue overgrowth but also ensures leak-proof quality of the connection, precluding any leakage of the collection fluid outside the gastrointestinal tract. SEMSs for transmural drainage are specially designed to ensure maintenance of the large width of the cystostomy [19–23]. Owing to the two-flange design of the transmural LAMS with the proximal flange oriented towards the gastrointestinal lumen and the distal flange into the collection cavity, the distance between the gastrointestinal wall and the wall of the PPFC at the site of the transmural fistula can be kept stable [19–23]. These benefits associated with the use of LAMS offer an advantage over plastic "double-pigtail" stents in terms of endoscopic treatment outcomes in the management of PPFCs [19–23]. The use of fully covered SEMS (LAMS) versus traditional plastic endoprostheses in transmural drainage improves treatment results in patients with postinflammatory PPFCs, most notably in the course of acute necrotizing pancreatitis [19–23]. Despite the good outcomes of transmural drainage with the use of LAMS, every type of stent has its own strengths and weaknesses and selection of the right endoprosthesis remains a challenge [7, 19–23]. This paper discusses complications observed during endotherapy of postinflammatory PPFCs, which were largely connected with the design of the transmural SEMS (LAMS) applied. Polymers and other biomedical materials are constantly evolving and next-generation endoprostheses may contribute to improvements in clinical outcomes. It appears that some of the challenges discussed in this publication might be resolved owing to new technologies being developed and implemented in the field of biomedical materials.

The two most common and most serious groups of complications associated with the endoscopic treatment of

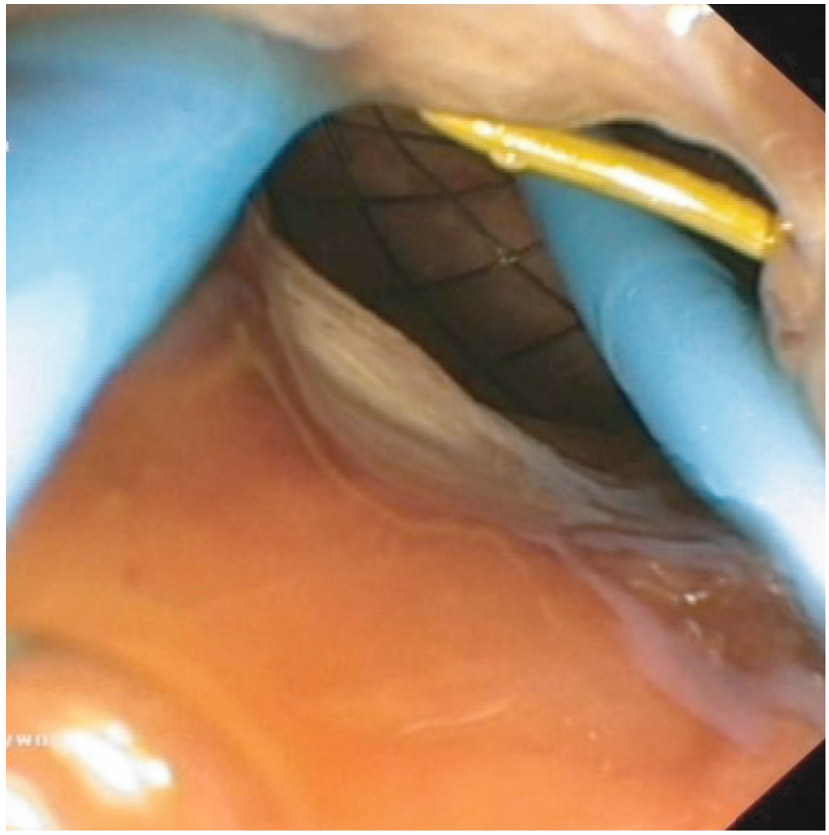


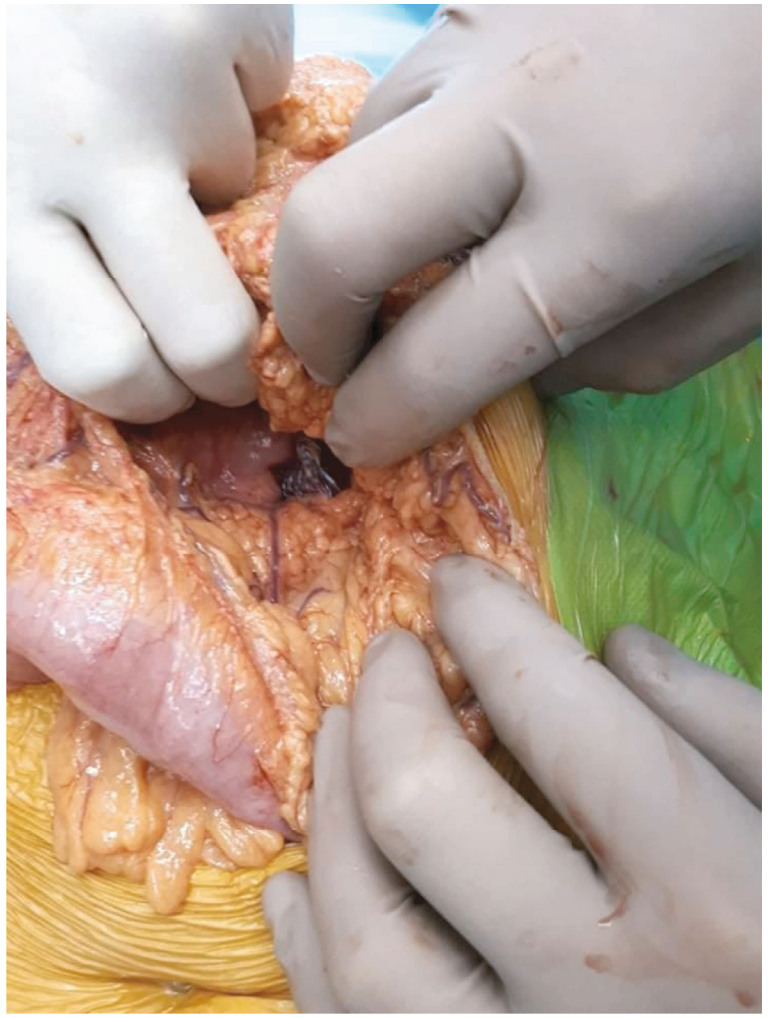
Figure 14: Endoscopic image of early proximal dislocation of the transmural stent into the collection cavity.

PPFCs are gastrointestinal bleeding [42] and perforations caused by leaking pancreaticogastric or pancreaticoduodenal anastomoses, which are usually due to dislocation of the transmural stent [19, 20, 23, 36–41].

With regard to gastrointestinal bleeding during transmural drainage of postinflammatory PPFCs, great progress in reducing the incidence of complications has been achieved with the advent of EUS techniques [16, 17]. EUS guidance during procedures of transmural access into PPFCs with Doppler imaging allows for a detailed assessment of blood vessels and blood flows. This makes it possible to circumvent these structures when creating the anastomosis [16, 17]. Using EUS guidance during transmural drainage of PPFCs limits the incidence of treatment complications, particularly hemorrhages associated with vascular perforations that occur while creating transmural cystostomy [17]. Despite the development of advanced endoscopic techniques and devices, the high rates of bleeding into the PPFC lumen remain a major challenge in transmural drainage treatment. This type of complication is often caused by blood vessels adjacent to the fluid collection being damaged by the distal flange of the LAMS. While inserting a plastic double-pigtail stent through the LAMS limits the risk of this kind of complication by moving the back wall of the PPFC away from the distal flange, PPFC cavity bleeding during transmural drainage is still a major complication associated with a high risk of fatal outcomes. However, small blood vessels are commonly damaged and most bleeding complications of endoscopic drainage can be treated with conservative methods. If this strategy is ineffective and if the bleeding originates from a small vessel or granulation tissue of the healing collection wall, endoscopic treatment usually yields good results. In hemodynamically unstable patients with massive bleeding from the large arteries into the pancreatic collection cavity, interventional treatment is necessary. The method of choice in these circumstances is endovascular treatment or surgery.

The application of new polymers in manufacturing transmural stents in the form of additional layers of coating to the distal flange of the LAMS will most certainly limit the risk of PPFC cavity bleeding during transmural drainage procedures. This will make it less likely for the distal flange of the LAMS to injure the back wall of the PPFC, and it will no longer be necessary to insert a plastic double-pigtail stent through the lumen of the LAMS. The thick polymer coating of the most protruding part of the distal flange will then take over the function hitherto performed by the additional plastic stent, which can lower the costs of endoscopic treatment of PPFCs.

Another major complication of transmural drainage with LAMS is gastrointestinal tract perforation due to transmural stent dislocation that migrates outside of the transmural anastomosis [43–45]. Gastrointestinal perforation is most commonly associated with early dislocation of the transmural stent occurring during the first week following the endoscopic transmural drainage procedure. Late transmural stent dislocation, which occurs more than one week after the procedure, is less likely to result in gastrointestinal



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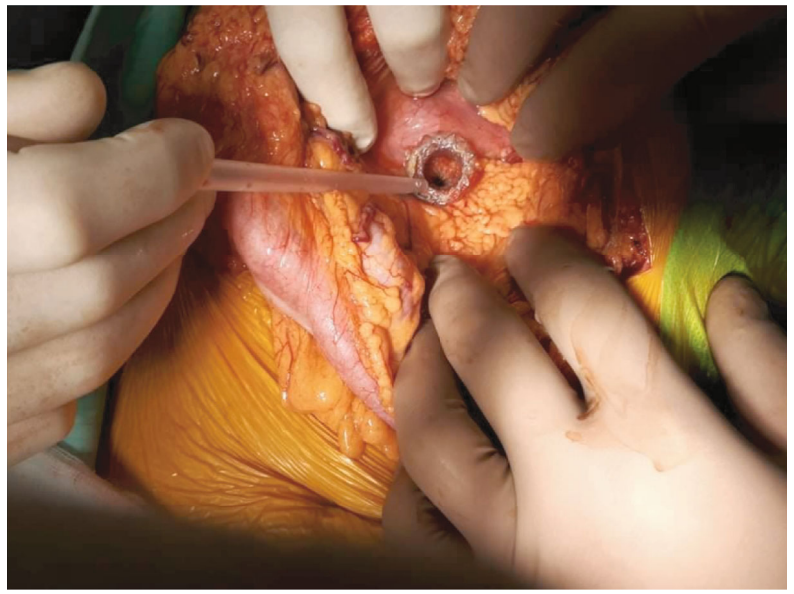

(b)

Figure 15: (a, b) Intraoperative image of a laparotomy performed in a patient suffering from early proximal dislocation of the transmural stent. The dislodged stent can be seen.

(a) (b)

(c)

Figure 16: (a–c). Endoscopic treatment of late proximal transmural stent dislocation. (a, b) After the stent was grasped with endoscopic forceps, (c) it could be removed.

perforation. This is because, after a week, the site of anastomosis between the gastrointestinal tract and the PPFC is healed and sufficiently tight to prevent the absence of the stent from causing the gastrointestinal wall to move away from the collection wall and allow air to escape the gastrointestinal lumen.

Treating transmural stent dislocation should primarily depend on the patient's clinical condition. In stable patients with an early transmural stent dislocation and air leaking out of the gastrointestinal lumen, as revealed by imaging, endoscopic treatment can be attempted to adjust the position of the dislodged stent or add another stent using the stent-in-stent technique. If this strategy is successful, it is also necessary to remove air from the peritoneal cavity through a percutaneous incision. Endoscopic treatment of early dislocations of LAMS, despite favorable short-term outcomes, usually prove ineffective on long-term follow-up, thus leaving surgical treatment as the method of choice. This paper describes an effective method of surgical treatment for early dislocation of the LAMS, consisting of suturing the perforated site (transmural cystostomy) within the upper gastrointestinal tract and removing the dislodged transmural stent through laparotomy or, preferably, through laparoscopic access. The surgery also involves percutaneous drainage (external) of the PPFC. Subsequently, in the postoperative period, while the external drainage is still ongoing, an endoscopic procedure is performed, whereby internal drainage (transpapillary or transmural) of the PPFC is provided. Upon internal drainage completion, the external drainage was removed. This is how external drainage is replaced with the PPFC internal drainage.

In cases of late transmural stent dislocation occurring more than a week after the procedure, endotherapy is generally an effective method of treatment. Proximal stent migration occurs when the transmural stent migrates into the PPFC lumen. Endoscopic treatment of late proximal dislocation of the transmural stent involves inserting another transmural stent through the transmural cystostomy or creating another cystostomy between the gastrointestinal lumen and the PPFC cavity. Through the transmural endoprosthesis, an endoscope is inserted into the PPFC under the guidance of endoscopic imaging. Different types of endoscopic tools are used to capture and remove the dislodged stent. In cases of late distal dislocation of the transmural LAMS where the stent migrates into the gastrointestinal lumen and if the dislodged stent is located within the upper gastrointestinal tract, it can still be removed with the use of endoscopic techniques. However, if the dislodged stent has migrated further down the gastrointestinal tract and beyond the duodenojejunal flexure (ligament of Treitz), the patient is usually monitored until the stent is spontaneously passed along the entire gastrointestinal tract without any complications. If these strategies fail, surgical treatment remains the method of choice.

As one follows the continuous dynamic development of biomedical technologies, it can be presumed that as the design of transmural stents evolves towards a larger diameter and size of both flanges and their improved shape, it will become possible to limit the risk of early and late dislocations of transmural LAMS in terms of both distal and proximal migrations. Moreover, a sufficiently larger lumen diameter of the LAMS prevents it from being obstructed by necrotic tissues.

According to the guidelines for endotherapy of postinflammatory PPFCs, transmural LAMS should be either replaced or removed after 8–12 weeks [13, 31, 36–41]. This paper describes a management technique in which the LAMS used for transmural drainage was replaced or removed every four weeks, which lowered the risk of endotherapy complications. The frequent replacement or removal of transmural stents prevents the so-called buried LAMS syndrome, which is a condition caused by the stent becoming overgrown with tissue despite its layer of coating [31, 36–41].

This paper addresses the challenges and issues faced by endoscopists performing transmural drainage using LAMS. From the endoscopist's perspective, a major challenge in transmural drainage of PPFCs is often the right placement of the stent. This is a crucial stage in determining the technical success of the procedure. Once the transmural cystostomy is performed and the guidewire is inserted into the PPFC, the transmural stent is introduced. Considering the challenging anatomical conditions and rigid nature of the stent delivery system used to introduce the unexpanded LAMS, this stage requires particular caution while expanding the stent. Failure of any kind has the potential to cause early dislocation of the stent during the endoscopic procedure, which can lead to gastrointestinal perforation. At this point, this depends on the experience and skill of the endoscopist. While the construction and technical features of the stent delivery system can be expected to improve, the difficult anatomical environment will not. In particular, PPFCs are located away from the gastrointestinal wall, which do not form a discernible bulge on the gastric or duodenal wall and are situated within the distal part of the pancreatic body or within the tail, where transmural access can usually be obtained from the subcardiac region of the stomach, often with endoscopic inversion. A major convenience with regard to improving the quality and safety of endoscopic transmural drainage with LAMS is the controlled release system used in certain types of SEMS, which allows for accurate and controlled placement of the transmural stent in the desired location. This solution limits the risk of transmural stent dislocation and consequently reduces the potential for gastrointestinal perforations and leaks within the pancreaticogastric or pancreaticoduodenal anastomosis. Despite these benefits, controlled release systems have not yet been featured in LAMS for transmural drainage.

5. Conclusions

This paper discussed the high efficacy of ET and its potential complications, which are mostly related to the design of the LAMS used. The high efficacy of LAMS in the transmural drainage of PPFCs is associated with lower treatment safety. Most ET complications respond to conservative or minimally invasive treatments, including endoscopic techniques. Surgical treatment of this type of complication remains the method of choice if other treatment options fail.

This paper discusses possible directions of development in the field of transmural LAMSs. It may also be helpful in addressing the possible expectations of the interventional endoscopist towards stent designers and manufacturers. High hopes for improving the quality of endoscopic equipment are placed in the development of new technologies from biomedical materials, including polymers, equipment for the production of equipment. Possibly, subsequent novel endoprosthesis projects, based on the above results, will be able to meet the current needs and requirements associated with endoscopic endoscopic transmural drainage procedures in cases of postinflammatory PPFCs. The ultimate goal is to improve the safety of minimally invasive techniques for the treatment of the local consequences of pancreatitis. Hopefully, our findings will contribute to development of novel and original transmural LAMS designs.

Data Availability

Data are available on request (corresponding author email: matjagiel@gmail.com).

Disclosure

Mateusz Jagielski and Marek Jackowski have no conflicts of interest or financial ties to disclose. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript; or in the decision to publish the results.

Conflicts of Interest

The authors declare no conflict of interest.

Authors' Contributions

Conceptualization was performed by Mat. Jag. and Mar. Jac.; formal analysis was performed by Mat. Jag. and Mar. Jac.; the methodology was performed by Mat. Jag. and Mar. Jac.; project administration was performed by Mat. Jag. and Mar. Jac.; the writing of the original draft was performed by Mat. Jag. and Mar. Jac.; and reviewing & editing was performed by Mat. Jag. and Mar. Jac.

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