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Endoscopic Stents for the Biliary Tree and Pancreas

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Opinion statement

Purpose of review To review the recently published literature on biliary and pancreatic stents.
Recent findings Covered self-expanding metal stents (SEMS) are increasingly being used in the endoscopic management of benign biliary strictures. Given the costs associated with SEMS, plastic stents are still the most commonly used stents. In this setting, SEMS are preferred over plastic stents for palliation of malignant biliary strictures due to superior patency and have a role in preoperative management of malignant biliary strictures. While plastic stents are predominantly used for management of pancreatic strictures, newer endoscopic ultrasound (EUS)-guided lumen-apposing SEMS have been increasingly used in management of pancreatic fluid collections. EUS-guided SEMS also enable safe transmural drainage of gall bladder and bile ducts in benign and malignant conditions.
Summary Endoscopic management is the first line treatment for multiple pancreatobiliary disorders. EUS-guided interventions have widened the scope of endoscopic management and decreased the need for surgical intervention. Further studies are needed to determine the safety and cost effectiveness of SEMS in benign pancreatic disorders.

Introduction

Endoscopic biliary stenting was first described by Soehendra et al. in 1980 using a single pigtail stent, improvised from an angiography catheter [1]. 1n 1987, a study by Speer et al. established the role of endoscopic stenting in management of inoperable malignant biliary obstructions [2]. Over the years, endoscopic stenting has become the first line management for several biliary and pancreatic diseases. In current practice, several kinds of plastic and self-expandable metal stents (SEMS) are available. While the stents are typically placed at the time of endoscopic retrograde cholangiopancreatography (ERCP) under fluoroscopic guidance, the novel stents can be placed under endoscopic ultrasound (EUS) guidance. Conventionally, plastic stents were used for benign biliary obstructions and SEMS were used for malignant biliary obstructions. With the advances in stent design and technology, the role for SEMS in benign biliary obstructions has expanded. Unlike benign biliary obstructions, benign pancreatic duct obstructions (BPD) are almost always treated with plastic stents with limited recent literature suggesting a role for SEMS in BPD obstructions as well.

This article reviews the published literature on biliary and pancreatic stents with special focus on studies from last 12–18 months.

Types of stents

Plastic stents are made of polyethylene, polyurethane, or teflon. They are available in varying sizes, shapes, and length [3] (Fig. 1). The plastic stent size ranges from 3 to 11.5 Fr. Plastic stents are available in straight, double pigtail, and single pigtail configurations. Straight and double pigtail stents are usually used for biliary drainage. Straight and single pigtail stents are used for pancreatic drainage. SEMS are made of nitinol (nickel-titanium alloy) or stainless steel. Compared to stainless steel, nitinol is more flexible but less radiopaque. Hence, additional gold or platinum radiopaque markers are added to nitinol stents to facilitate accurate positioning of stents under fluoroscopic guidance. The diameter and length of currently available SEMS ranges from 6 to 10 mm and 4 to 10 cm, respectively. SEMS can be covered or uncovered. The covered SEMS have an additional membrane to prevent tumor ingrowth. The membrane is made of silicone, polyurethane, or polytetrafluroethylene. The novel biodegradable

Fig. 1. Plastic stents of various sizes, shapes. *Self-Expandable Stents in the Gastrointestinal Tract*, History of Bile Duct Stenting: Rigid, Prostheses, XII, 310, 2013, p.18, Kozarek, R.: Baron, T.H., (Copyright © 2013, Springer Science + Business Media New York) "With permission of Springer".

stents (BDS) are made of poly-L- Lactic acid, polyglecaprone, or polydioxanone [4] (Fig. 2). Table 1 defines the indications for pancreaticobiliary stenting and, with our current state of knowledge, whether plastic or expandable metal stents, should be considered first line therapy.

Stents for benign biliary diseases

Benign biliary strictures

There are several etiologies for benign biliary strictures (BBS). This includes post-cholecystectomy stricture, post- liver transplantation (LT) anastomotic stricture, primary sclerosing cholangitis (PSC), chronic pancreatitis (CP), and IgG4 cholangiopathy [5–7].

Long-term data on treatment of post cholecystectomy biliary stricture (BS) by placing more than one plastic stent followed by stent exchanges every 3 months was first reported by Bergman et al. [8] and Costamagna et al. [9]. The success rate in these studies ranged from 80 to 89%. Plastic stents are easily removable and less expensive compared to SEMS. Hence, multiple plastic stent placement with periodic stent exchanges became the first line treatment for most BBS [10–12] (Fig. 3). However, the need for multiple ERCPs at short intervals requires high patient compliance and negatively impacts patients' quality of life. The placement of multiple side-by-side plastic stents in tight strictures and perihilar strictures can be technically challenging [12]. In addition, the recurrence rate of BBS is high in certain conditions like chronic pancreatitis [13].

SEMS were developed as an alternative to plastic stents as multiple ERCPs were not required for stent exchanges. Mucosal ingrowth was a drawback of

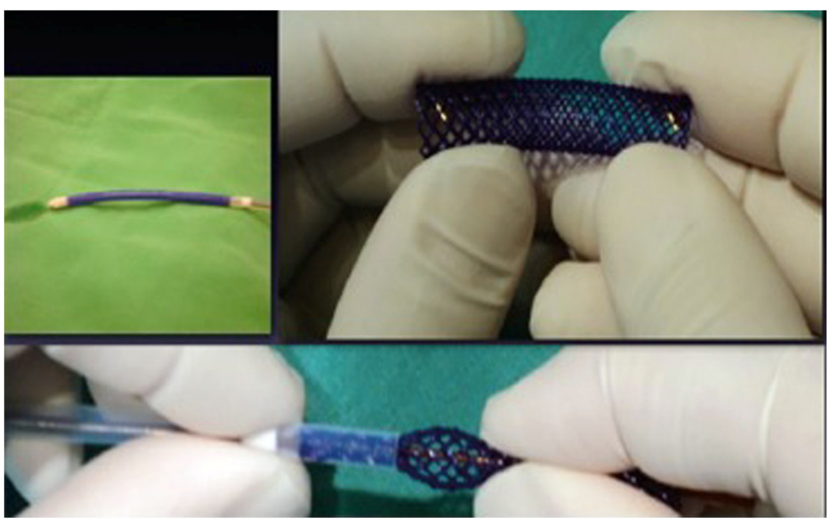

Fig. 2. Biodegradable stent with radiopaque markers at both ends shown along with the introducer. *ARQUIVOS BRASILEIROS DE CIRURGIA DIGESTIVA* (ABCD Arq Bras Cir Dig), Biodegradable Biliary Stents: A New Approach for the Management of Hepaticojejunostomy Strictures Following Bile Duct Injury. Prospective Study, 29(2), 2016, p.112–116, Mariano E. GIMÉNEZ, Mariano PALERMO, Eduardo HOUGHTON, Pablo ACQUAFRESCA, Caetano FINGER, Juan M. VERDE, Jorge Cardoso CÚNEO, (This is an open-access article distributed under the terms of the Creative Commons Attribution License) "With permission of Mariano E. Giménez".

Table 1. Indications for pancreaticobiliary stenting

Indications	1st choice[a]	2nd choice
Benign biliary conditions		
Benign biliary stricture	• Plastic stents (multiple side by side)	• fcSEMS
Large CBD stones	• Plastic stents	• fcSEMS
Bile leaks	• Plastic stents (IHD and EHD)	• fcSEMS (EHD)
Acute cholecystitis	• LAMS/fcSEMS-EUS-guided transmural drainage of gall bladder	• Plastic stent (trans-papillary)
Malignant biliary conditions		
Preoperative biliary drainage	• fcSEMS	• Plastic stents
Palliative biliary drainage	• ucSEMS	• Plastic stents (multiple side by side) • LAMS/fcSEMS-EUS-guided transmural drainage of bileduct or gall bladder
Hilar strictures	• ucSEMS (stent-in-stent or side-by-side)	• Plastic stents (bilateral)
Benign pancreatic conditions		
PEP prophylaxis	• Plastic stents	
PD strictures	• Plastic stents	• fcSEMS
Pancreatic fluid collections	• ± LAMS/fcSEMS-EUS-guided transmural drainage	• ± Plastic stents

CBD Common bile duct, *PD* pancreatic duct, *IHD* intrahepatic ducts, *EHD* extra hepatic ducts, *fcSEMS* fully covered self-expandable metal stents, *nSEMS* uncovered self-expandable metal stents, *LAMS* lumen apposing metal stent, *EUS* endoscopic ultrasound, *PEP* post-ERCP pancreatitis
[a]The choice of stents could vary based on patient related factors like duct size, site of stricture, leak or stone and anticipated patient survival, endoscopists' experience, and institutions' resources

uncovered SEMS (uSEMS) and this made stent removal extremely difficult. A systematic review comparing the effectiveness of plastic stents vs. uSEMS in

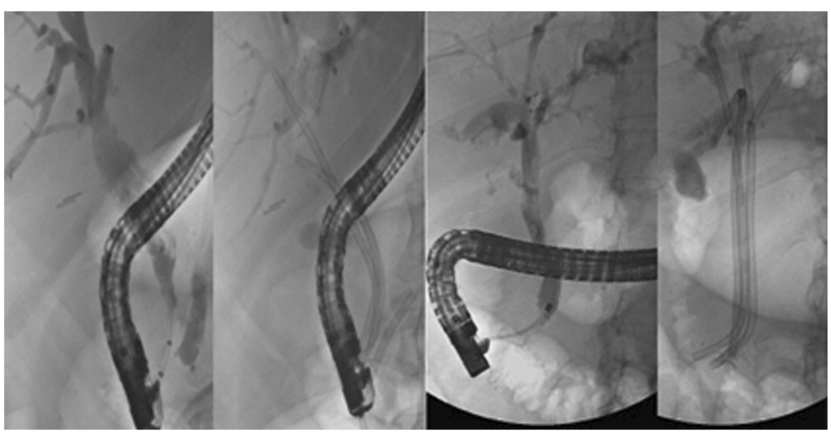

Fig. 3. Multiple plastic stents in the biliary duct. **a** ERCP images showing Distal CBD stricture from chronic pancreatitis. **b** Multiple plastic stents in CBD along with a plastic stent in PD. **c** ERCP showing diffuse intrahepatic strictures from PSC. **d** Multiple plastic stents in CBD. *Gastrointestinal Endoscopy Clinics of North America*, Plastic Biliary Stents for Benign Biliary Diseases, 21, 2011, p. 405–433, Vincenzo Perri, Pietro Familiari, Andrea Tringali, Ivo Boskoski, Guido Costamagna, (© 2011 Elsevier Inc. All rights reserved) "With permission of Elsevier".

treating BBS, favored the use of multiple plastic stents over uSEMS [14]. Partially covered SEMS (pcSEMS) had better clinical outcomes than uSEMS but the uncovered portion of the pcSEMS had similar disadvantages as the uSEMS, including - epithelial hyperplasia and stent-induced stricture [15–22].

Fully covered SEMS (fcSEMS) were designed to counter the disadvantages of the uncovered stents. The main advantage of a fcSEMS is that it can be left in place for longer duration and still be removed without difficulty. A recent multicenter retrospective study from five referral centers in the USA involving 123 patients reported a stricture resolution rate of 81% with fcSEMS after median stent duration of 6.1 months. [23] A randomized clinical trial from Finland specifically investigated treatment of CP-related BS using fcSEMS vs. multiple plastic stents [24•]. The study included 60 patients who were equally randomized to the two arms. All stents were removed 6 months after the randomization. The 2-year stricture-free success rate was similar between the plastic stent and fcSEMS arms (90 vs. 92%, respectively).

Another randomized clinical trial involving 112 patients reported that fcSEMS were not inferior to multiple plastic stents in achieving stricture resolution (92.6 vs. 85.4%, respectively) after 12 months [25••]. On the other hand, fewer ERCPs were needed to achieve resolution with fcSEMS compared to plastic stents (2.14 vs. 3.24, respectively). Further randomized studies comparing fcSEMS and multiple plastic stents are needed and some studies are underway (ClinicalTrials.gov NCT01543256) [26].

In treatment of post-LT anastomotic strictures, there has been a reluctance to use SEMS for fear of inducing new strictures and hence plastic stents have been the first line choice. Several studies have reported successful use of SEMS in strictures that are refractory to plastic stents [27]. An open-label randomized study involving 20 patients compared the effectiveness of initial stenting with fcSEMS vs. plastic stents and reported similar stricture resolution and recurrence rates [28]. As the patients in the fcSEMS arm needed fewer ERCPs compared to plastic stents, the authors suggested that initial stenting with fcSEMS may be more cost effective.

One of the drawbacks of fcSEMS is stent migration. Several designs to prevent stent migration have been considered including flared ends, anchoring fins, and anchoring flaps. Walter et al. reported that a novel fcSEMS with flared ends had a stricture recurrence rate in the upper range compared to other fcSEMS and did not prevent stent migration [29]. Another novel fcSEMS called the Intraductal fcSEMS (ID-fcSEMS) has an anti-migration waist and a radiopaque removal string that rests in the duodenum. It has been specifically designed for post-OLT anastomotic strictures and initial results are promising [30] .

Biliary stone disease

In cases of failed or incomplete extraction of large common bile duct (CBD) stones, plastic stents can be placed to bypass the stone and aid bile drainage. In such cases of stent placement, the subsequent ERCP after a couple of months has a higher success rate of complete stone removal [31, 32]. The reported success rate ranges from 44 to 92% [33]. fcSEMS have also been used in management of complex bile duct stone disease [33–35, 36••]. Unlike plastic stents, which cause mechanical friction and erosion of the stones to help stone removal in subsequent ERCPs, the mechanism by which fcSEMS help stone removal is unclear. It is believed that the constant radial forces over an extended period of time cause destruction of the biliary sphincter rather than partial dilation. A recently published retrospective series on use of fcSEMS for retained CBD stones reported a success rate of 82% in achieving bile duct clearance [36••]. Cai et al. described a novel drug eluting plastic stent with ethylene-diamine-tetra-acetic acid (EDTA) and sodium cholate that was tested in ex vivo porcine models and in vivo pigs [37, 38]. The study reported that the drug eluting plastic stents enhanced CBD stone dissolution [37, 38].

Bile leaks

There are several etiologies of bile leak. Post-cholecystectomy bile leak is the most common cause. It can also occur after liver transplantation (LT), hepatectomy, trauma, liver biopsy, and percutaneous transhepatic cholangiography (PTC) [39]. Endoscopic management strategies include biliary sphincterotomy (BS) alone, biliary plastic stent placement alone, or BS with plastic stent placement. All three endoscopic strategies may be equally effective in treatment of bile leak [40, 41].

In current practice, BS with plastic stent placement for 4–6 weeks is the most common approach for treatment of bile leaks [42–45]. There has been a recent increase in use of SEMS for treatment of bile leak [46–48]. fcSEMS can be particularly advantageous for refractory bile leaks (defined as persistent leak after BS with plastic stent placement) and high-grade bile leaks (defined as extravasation of contrast without any filling of intrahepatic ducts) [49, 50]. A recent study by Canena et al. reported that fcSEMS had better outcomes in treatment of high-grade bile leaks compared to multiple plastic stents [51]. fcSEMS may be a better alternative to plastic stents for treatment of post hepatectomy bile leaks, as they are usually complex leaks requiring bridging stents [52].

Novel biodegradable biliary stents (BDBS) may have an interesting role in treatment of bile leaks as their use precludes the need for an additional procedure for stent removal. Recent studies have described endoscopic placement of BDBS for post-cholecystectomy cystic duct leaks [53] and intraoperative placement of BDBS during bile duct anastomosis in liver transplantation [54] (Fig. 3).

Acute cholecystitis

Endoscopic drainage of the gall bladder (GB) is an alternative to percutaneous cholecystostomy tube for patients with acute cholecystitis who are high risk for surgical cholecystectomy. Transpapillary gall bladder stenting (TGS) and EUS-guided transmural GB drainage are two endoscopic options. EUS-guided transmural drainage can be performed using plastic stents, SEMS, or lumen apposing metal stent (LAMS).

A recent systematic review and meta-analysis compared outcomes of EUS-guided GB drainage using plastic stents, SEMS, and LAMS and reported LAMS as the safest option with lowest rate of adverse events (9.9%) [55•]. The study estimated the technical and clinical success of GB drainage with LAMS as 91.5 and 90.1%, respectively. LAMS with a novel cautery-tipped EUS-guided delivery system [Hot AXIOS™- Boston Scientific Natick, MA] removes the need for tract dilation that needed to be performed with the previously available LAMS. A recent multicenter study investigating the use of cautery-tipped EUS-guided LAMS for treatment of acute cholecystitis in patients with high surgical risk reported a technical and clinical success of 96.4 and 100%, respectively [56•].

In clinical scenarios where EUS-guided GB drainage is not a therapeutic option (when the GB is not near the luminal wall or a good EUS window is not seen), TGS using 7 or 10 Fr double pigtail plastic stents can still be performed. A systematic review and meta-analysis by Itoi et al. estimated the technical and clinical success of TGS in acute cholecystitis as 96 and 88%, respectively [57]. A recent multicenter study using a novel long large caliber fenestrated plastic stent (Johlin stent) reported a technical and clinical success of 100%[58] (Fig. 4). Also, there were no adverse events except for one early post-sphincterotomy bleed.

Stents for biliary malignancy

Since SEMS were introduced, the use of plastic stents for malignant biliary obstruction has decreased. A recent systematic review and meta-analysis by Almadi et al. compared the use of plastic stents vs. SEMS for palliation of malignant biliary obstruction [59•]. The review included 20 RCTs with 1713 patients and favored the use of SEMS over plastic stents. SEMS were associated with better stent patency (weighted mean difference of 4.45 months), lower complication rates, and fewer re-interventions. It must be noted that there was

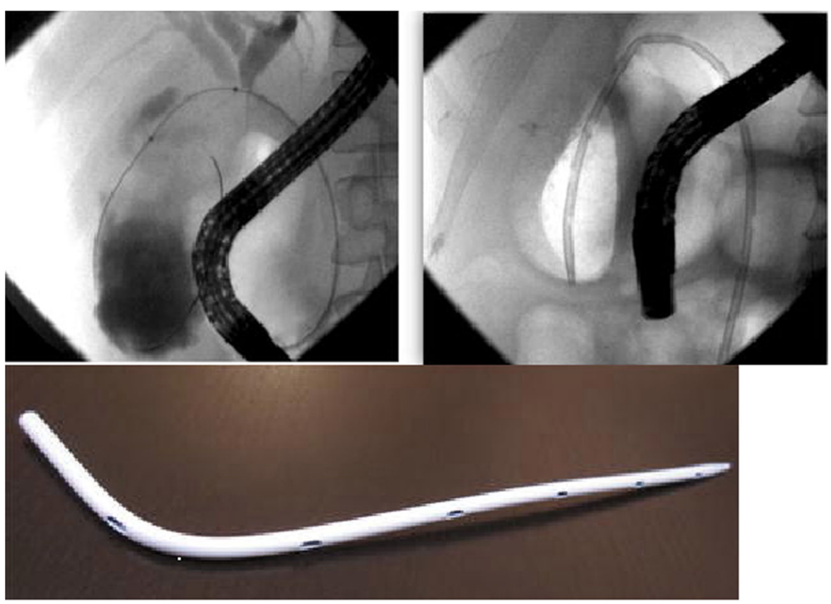

Fig. 4. Fluoroscopic image of Trans-papillary gall bladder drainage with a long large caliber fenestrated plastic stent (Johlin stent). *Digestive Diseases and Sciences*, Novel Use of Long, Large-Caliber, Fenestrated Stents for Endoscopic. Transpapillary Gallbladder Stenting for Therapy of Symptomatic Gallbladder Disease, 60(12), 2015, p. 2817–3822, Brooke R. Glessing, Rajeev Attam, Stuart K. Amateau, Mustafa Tiewala, Yan Bakman, Hashim Nemat, Martin L. Freeman, Mustafa A. Arain, (© Springer Science + Business Media New York 2015) "With permission of Springer".

no difference in overall survival, 30-day mortality, technical success, and clinical success. Though there was no difference in overall survival between SEMS and plastic stent patients, subgroup analysis suggested that uSEMS had survival benefit over plastic stents. Interestingly, a previous meta-analysis which included fewer studies (13 RCTs) reported that SEMs had survival benefit over plastic stents [60].

ASGE and ESGE guidelines recommend use of SEMS for palliation of pancreatic cancer-related biliary obstruction if the life expectancy is more than 6 months [12, 61]. With advances in management of pancreatic cancer, the median survival has increased beyond 6 months [62]. A recent cost effectiveness study by Martinez et al. reported that initial placement of SEMS for pancreatic cancer-related biliary obstruction was more cost effective than plastic stents [63]. The cost effectiveness of SEMS was due to lower rate of re-stenting and better quality of life.

Preoperative biliary drainage

There is a long-standing debate on need for routine preoperative biliary drainage (PBD) in jaundiced patients with resectable pancreatic or periampullary tumor. The studies that reported high complication rates with this practice were confounded by the fact that plastic stents were used in those studies [64]. In current practice, PBD is performed in select patients with acute cholangitis or those who need neoadjuvant chemotherapy. In those situations, SEMS are preferred over plastic stents given the need for adequate and durable biliary drainage until surgery [65]. A recent non-randomized prospective study by Tol et al. compared the use of fcSEMS vs. plastic stents for PBD in resectable pancreatic cancer [66•]. Compared to plastic stents, fcSEMS had lower PBD related complications (46 vs. 24%) and stent related complications (31 vs. 6%). The surgical complication rate did not differ between the two groups. On the other hand, a randomized prospective study in an identical population by Song et al. reported no difference in PBD-related, stent-related, or surgery-related complications based on use of plastic stents or fcSEMS for PBD [67•]. Given the low cost of plastic stents, the authors concluded that use of plastic stents for PBD was more cost effective.

Palliative biliary drainage

While SEMS have superior patency over plastic stents for palliation of malignant biliary obstructions, reflux of food material can cause stent occlusion in SEMS. Anti-reflux valves (ARV) were developed to decrease the risk of stent occlusion and cholangitis. An initial study comparing pcSEMS with ARV vs. uSEMS reported longer stent patency and decreased incidence of cholangitis with the former [68] (Fig. 5). However, results from two recent studies with small number of patients failed to show superior outcomes with anti-reflux stents [69, 70]. A low cost alternative to SEMS for palliation of malignant obstructions using side-by-side double plastic stents was described by Lawrence et al. [71] 51.3% of the study, patients had clinically patent stents at 221 days after stent placement. While randomized trials are needed to validate the study results, it is very relevant for resource limited settings, given the cost difference between plastic stents and SEMS.

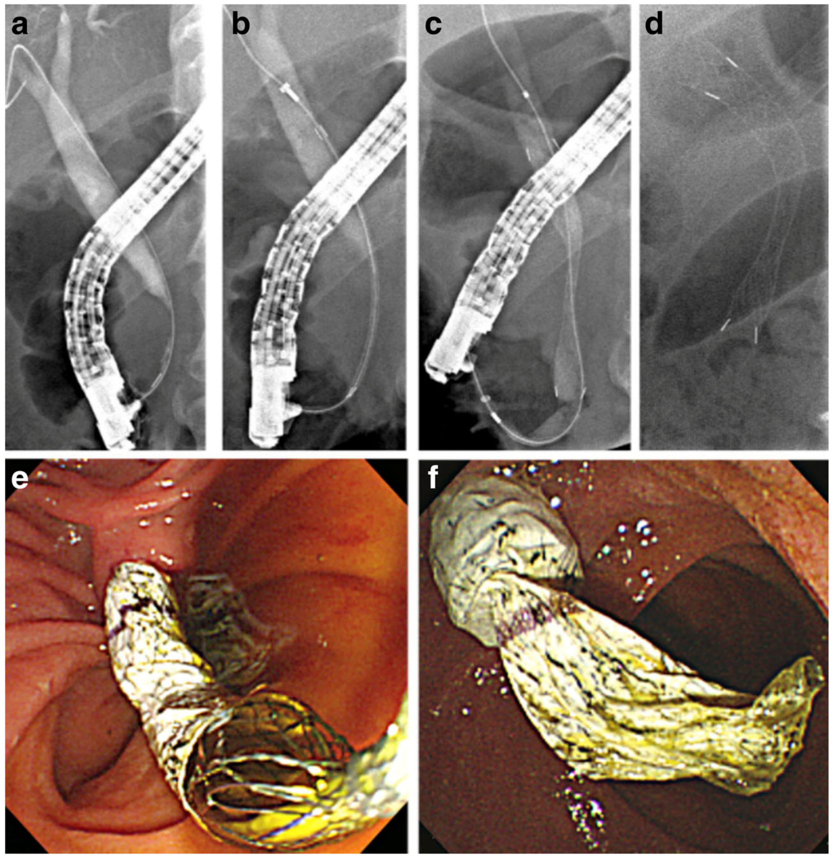

Fig. 5. SEMS with an anti-reflux valve. **a** Distal CBD stricture. **b**, **c**, **d** Insertion and deployment of SEMS with Antireflux valve. **e** endoscopic view of the ARV with the delivery system. **f** Fully deployed SEMS with ARV in the duodenum. *Gastrointestinal Endoscopy*, Effectiveness of a newly designed antireflux valve metal stent to reduce duodenobiliary reflux in patients with unresectable distal malignant biliary obstruction: a randomized, controlled pilot study (with videos), 83(2), 2016, p. 404–412, Lee YN, Moon JH, Choi HJ, Choi MH, Lee TH, Cha SW, Cho YD, Choi SY, Lee HK, Park SH, (Copyright © 2016 American Society for Gastrointestinal Endoscopy) "With permission of Elsevier".

EUS-facilitated biliary drainage

The recent advances in EUS and stent technology have opened new avenues for drainage of malignant biliary obstructions. EUS-guided biliary drainage (EGBD) is an alternative to percutaneous biliary drainage (PTBD) when ERCP fails. This can also be helpful for BD in patients with altered anatomy. EGBD enables transmural drainage of bile duct or gall bladder into the duodenum or stomach. (Fig. 6) A recent study by Ridtitid et al. compared outcomes in patients with inoperable malignant biliary obstructions who underwent endoscopic transpapillary biliary stenting (TBS) vs. EUS-guided choledochoduodenostomy (CDS) using SEMS and reported no difference in technical success, clinical success, and length of hospital stay [72]. Kawakubo et al. explored the potential use of EUS-guided CDS (EUS-CDS) as first line treatment for patients with distal bile duct malignant obstruction [73]. The study included 82 subjects, of which 26 underwent an EUS-CDS with fcSEMS and 56 endoscopic TBS. While there was no difference in clinical success, adverse events and re-intervention rates between the two groups, the mean procedure time was significantly

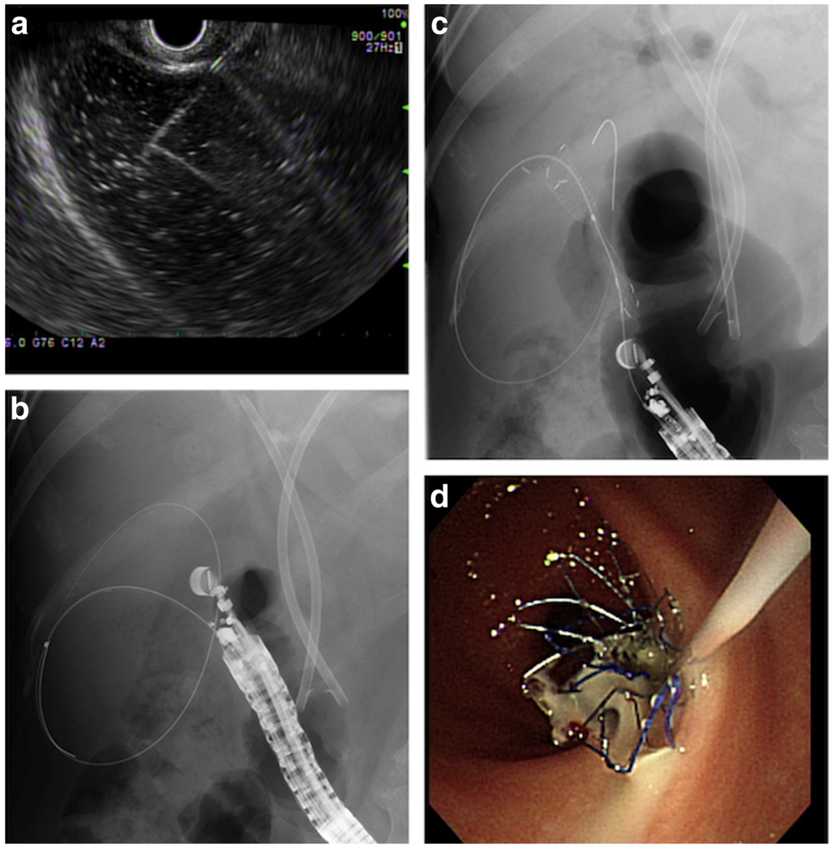

Fig. 6. **a** EUS image showing needle tip in the gall bladder (GB). **b** Guidewire coiled in the GB under fluoroscopic guidance. **c** SEMS Proximal flange deployed in the GB. **d** distal flange of the cSEMS opened in the gastric lumen. *Gastrointestinal Intervention*, Can endoscopic ultrasound help to drain the gallbladder?, 2, 2013, p. 30–35, Choi JH, Park DH, Lee SS, Seo DW, Lee SK, Kim MH, (Copyright © 2013, Society of Gastrointestinal Intervention) "With permission of Do Hyun Park".

shorter with EUS-CDS, making a case for consideration of EUS-CDS as first line treatment. The study results are promising but may not be generalizable at current time as this technique needs advanced EUS expertise.

A recent study from Europe reported outcomes of EGBD using the novel cautery-tipped LAMS delivery system (Hot-AXIOS™-Boston Scientific, Natick, MA) [74•]. The study involving 49 patients from five centers reported technical and clinical success rates of 97.9 and 95.8%, respectively. The LAMS design permits additional interventions like plastic stenting, lithotripsy, and stone extraction through the stent if needed. While fcSEMS is the stent of choice for EUS-guided BD, Nakai et al. described novel approach of using long pcSEMS (≥10 cm) to enable hepaticogastrostomy (HGS) in patients with gastric outlet obstruction and surgically altered anatomy [75] (Fig. 7). The uncovered ends of the pcSEMS prevent stent migration and thereby offer an advantage over the fcSEMS. Currently, lumen-opposing fcSEMS are not available for EUS-guided HGS.

Park et al. published a feasibility study on a novel double-layered covered SEMS (DCMS), which was designed to prevent tissue ingrowth and "stent-covering" related-complications [76]. A DCMS has two overlapping nitinol

Fig. 7. EUS and Fluoroscopic images showing the deployment of a long pcSEMS during Hepaticogastrostomy. *Endoscopy*, Safety and effectiveness of a long, partially covered metal stent for endoscopic ultrasound-guided hepaticogastrostomy in patients with malignant biliary obstruction, 48, 2016, p. 1125–1128, Yousuke Nakai, Hiroyuki Isayama, Natsuyo Yamamoto, Saburo Matsubara, Yukiko Ito, Naoki Sasahira, Ryunosuke Hakuta, Gyotane Umefune, Naminatsu Takahara, Tsuyoshi Hamada, Suguru Mizuno, Hirofumi Kogure, Minoru Tada, Kazuhiko Koike, (© Georg Thieme Verlag KG Stuttgart · New York) "With permission of Thieme".

stents which decrease the cell size, and a silicone membrane sandwiched between them. It also has a specially woven V-shaped wire to reduce axial forces and increase radial forces. Study results were discouraging, however, as the occlusion (from bile sludge) and stent-related complication rates were similar to fcSEMS.

Hilar strictures

Endoscopic treatment of malignant hilar biliary strictures is technically more challenging than distal biliary obstructions. There is an ongoing debate of whether SEMS or plastic stents should be used for these strictures. Use of SEMS is favored when the patient's life expectancy is more than 3 months. While plastic stents occlude more commonly than SEMS, re-intervention after SEMS placement is difficult. When SEMS are used for bilateral drainage in hilar strictures, placement can be performed using two techniques—stent-in-stent (Y configuration) or side-by-side. Studies comparing the two techniques are limited (Figs. 8 and 9). Naitoh reported that side-by-side technique was associated with a higher complication rate and higher stent patency rate compared to stent-in-stent technique [77]. Use of ucSEMS with large-cells stents can improve the technical success of bilateral biliary drainage using the stent-in stent technique [78]. Sakai et al. evaluated a novel-tapered laser-cut ucSEMS in 11 patients with malignant hilar strictures that were Bismuth 2 or higher and reported a longer patency and lower complication rate [79]. The tapered stent was specifically designed for use in the liver with an internal diameter of 10 mm on the papillary end and 8 mm on the hepatic end. Other unique features of the stent include large mesh space (6–8 mm in center of the stent) and low axial force. Further studies with larger cohorts are needed to define a standard protocol for endoscopic management of hilar malignancies.

Stents for benign pancreatic diseases

Prevention of post-ERCP pancreatitis

Placement of a prophylactic pancreatic duct (PD) stent can decrease the risk of post-ERCP pancreatitis (PEP) in high risk patients [80]. Three- or 5-Fr plastic stents without internal flanges are commonly used for this purpose. The

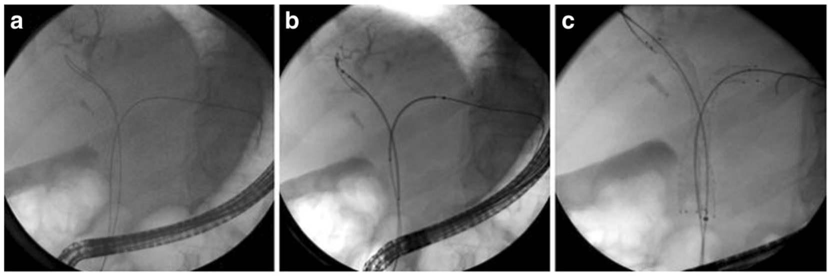

Fig. 8. **a** 0.035 guidewire placed bilaterally. **b** Bilateral delivery systems placed over the guidewire. **c** Hilar stents placed side by side. *Digestive Diseases and Sciences*, Bilateral metal stents for hilar biliary obstruction using a 6Fr delivery system: outcomes following bilateral and side-by-side stent deployment, 58, 2013, p. 2667–2672, Law R, Baron TH, (© Springer Science + Business Media New York 2013) "With permission of Springer".

prophylactic PD stents are expected to spontaneously migrate into the duodenum. An abdominal X-ray is routinely recommended 10–14 days after the ERCP to confirm passage of the stents. If the stents are still in place, they are endoscopically removed. A recent study by Fujisawa et al. comparing the efficacy of short (3 cm) vs. long (5 cm) PD stents in preventing PEP, reported lower rates of PEP with 3-cm stents compared to 5-cm stents (2.0 vs. 8.0%, respectively) [81••].

Benign pancreatic strictures

ASGE guidelines recommend plastic stents for endoscopic therapy of main pancreatic duct (PD) strictures [82]. Off-label use of FCSEMS for PD stricture has also been described but is still considered investigational [83]. Endotherapy with plastic stents is usually performed using a single large caliber stent or multiple side-by-side small caliber stents. For refractory strictures, endotherapy with multiple stents is considered more effective. However, placement of multiple stents can be technically difficult and stents have to be exchanged periodically. fcSEMS are an attractive alternative for refractory PD strictures but risk of pancreatitis has limited widespread use. A recent prospective study from Japan investigated long-term outcomes of using fcSEMS for treatment of refractory benign PD strictures secondary to CP [83] (Fig. 10). The study involved

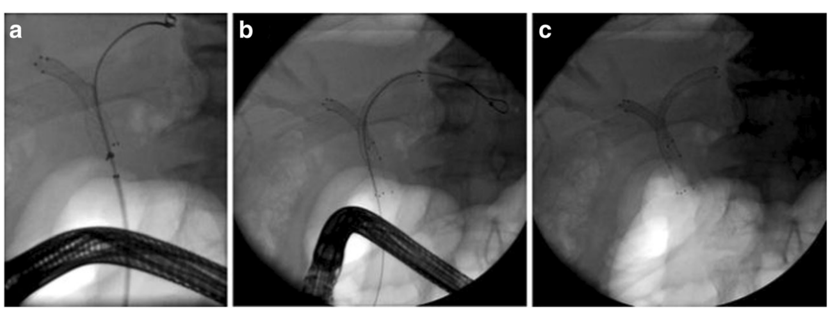

Fig. 9. **a** ERCP image showing right stent in the right hepatic duct and a delivery system over a guide wire passing through the interstices of the stent. **b** Delivery system over the guidewire. **c** Bilateral stents deployed by stent-in-stent Y-shaped configuration. *Digestive Diseases and Sciences*, Bilateral metal stents for hilar biliary obstruction using a 6Fr delivery system: outcomes following bilateral and side-by-side stent deployment, 58, 2013, p. 2667–2672, Law R, Baron TH, (© Springer Science + Business Media New York 2013) "With permission of Springer".

Fig. 10. Fluoroscopic image showing SEMS in the pancreatic duct along with a plastic biliary stent. *Endoscopy International Open*, Prospective pilot study of fully covered self-expandable metal stents for refractory benign pancreatic duct strictures: long-term outcomes, 4, 2016, c1, Saburo Matsubara, Naoki Sasahira, Hiroyuki Isayama, Naminatsu Takahara, Suguru Mizuno, Hirofumi Kogure, Natsuyo Yamamoto, Yousuke Nakai, Minoru Tada, Kazuhiko Koike, (© Georg Thieme Verlag KG Stuttgart New York) "With permission of Thieme".

ten patients with a follow-up of 35 months who underwent fcSEMS placement for 3 months. The study results were discouraging as the recurrent stricture rate was 38%. Another recent study on use of fcSEMS for refractory PD strictures secondary to CP (15 patients with a follow-up of 15.9 months) reported a concerning high rate of SEMS "induced" new strictures (27%) [84]. Finally, Cahel et al. reported a pilot study (with ten patients) using a novel uncovered biodegradable SEMS, which would preclude the need for stent removal. With a stent degradation rate of 100% in 6 months, the results were encouraging but need further testing [85].

Pancreatic fluid collections

In current practice, endoscopic drainage is preferred over surgery for management of symptomatic pancreatic fluid collections (PFC). EUS has enabled safe transmural (transgastic or transduodenal) access and drainage of PFCs using double pigtail plastic stents or fcSEMS [86]. While pseudocysts, which are composed of fluid, can be drained easily with plastic stents, WOPN with thicker contents may be better drained with large caliber fcSEMS [87]. Also, the use of fcSEMS enables easier endoscopic necrosectomy when needed.

Sharaiha et al. compared the effectiveness of double pigtail plastic stents vs. fcSEMS (10 mm × 40 mm or 10 mm × 60 mm) in drainage of pancreatic pseudocysts (PP) [88]. The study favored the use of fcSEMS over plastic stents based on better resolution rate (98 vs. 89%) and lower adverse event rate (16 vs. 31%). Ang et al. favored the use of lumen apposing fcSEMS (Nagi ™-Taewoong-Medical Co., Seoul, South Korea) over plastic stents for draining PFCs (PP and WOPN) as plastic stents were associated with higher need for repeat procedures

[89]. Another recent retrospective study with 124 patients supported the use of LAMS (AXIOS™-Boston Scientific, Natick, MA) (Fig. 11) as a safe and effective endoscopic therapy for WOPN with a technical and clinical success of 100 and 86.3%, respectively [90•]. Similarly, Rinninella et al. supported the use of the novel cautery-tipped LAMS (Hot AXOIS™-Boston Scientific, Natick, MA) as an effective endotherpy tool for PFCs with a technical and clinical success rate of 98.9 and 92.5% [91•]. The rate of adverse events in the study was around 5%.

PFC especially WOPN are often associated with disconnected pancreatic duct syndrome (DPDS). When present, DPDS increases the need for hybrid treatments (like dual modality technique), re-interventions, and rescue surgery [92]. When WOPN is managed by dual modality technique, the percutaneous tubes are ultimately removed but trans gastric double pigtail plastic stents left in place indefinitely to reduce the risk of PFC recurrence [93]. Similarly, when direct endoscopic necrosectomy is performed in the setting of a disconnected duct syndrome, the SEMS are usually removed after 8 weeks and trans-gastric double pigtail stents left in place indefinitely.

Overall, the lumen apposing fcSEMS (LAMS) appear to have a better safety profile than regular fcSEMS (without the lumen apposing design) for the purpose for endoscopic necrosectomy of WOPN. The shorter length and wider

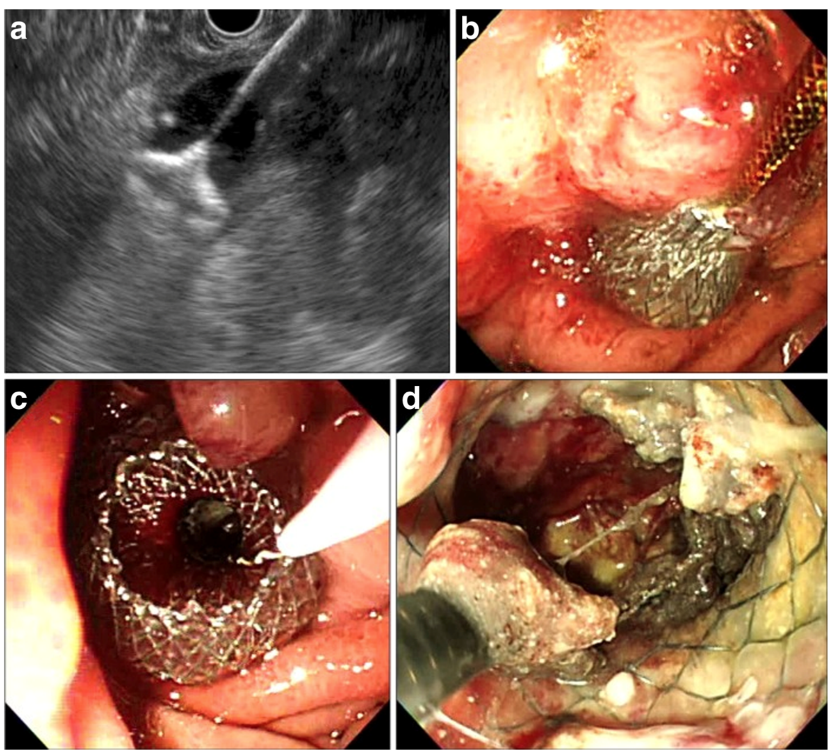

Fig. 11. EUS image (**a**) and luminal endoscopic images **b**, **c**, **d** showing pancreatic fluid collection drainage and necrosectomy using the LAMS stent. *Gut Liver*, Endoscopic ultrasound-guided transluminal drainage for peripancreatic fluid collections: where are we now, 8, 2014, p341–355, Hiroshi Kawakami, Takao Itoi, and Naoya Sakamoto, (© This is an Open Access article distributed under the terms of the Creative Commons Attribution Non-Commercial License (http://creativecommons.org/licenses/by-nc/3.0) which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.) "With permission of Takao Itoi".

caliber of LAMS makes necrosectomy easier. The cautery-tip available in the novel LAMS (Hot AXIOS™-Boston Scientific, Natick, MA) helps shorten the endoscopy procedure time but it adds additional cost to the device which the endoscopists should consider while making a choice.

Conclusion

Recent studies support a definite role for fcSEMS in management of benign biliary strictures in addition to plastic stents, which continue to be the most commonly used stents. ucSEMS are preferred over plastic stents for palliation of malignant biliary strictures due to their superior patency. Side-by-side plastic stents may be a cost effective alternative with comparable patency to SEMS in resource limited settings. Though recent literature suggests a potential role for fcSEMs in preoperative management of malignant biliary strictures, further studies are needed given the cost difference between SEMS and plastic stents. Plastic stents continue to be the stent of choice for endoscopic management of pancreatic strictures with very limited role, if any for SEMS. The newer EUS-guided LAMS enable safe transmural drainage of gall bladder and bile ducts in both benign and malignant diseases. The cautery-tip available in novel LAMS can help shorten endoscopy time of complex procedures. LAMS with shorter length and wider caliber have a promising role in management of PFC, especially when direct endoscopic necrosectomy is needed.

Compliance with Ethical Standards

Conflict of Interest
Rajesh Krishnamoorthi declares that he has no conflict of interest. Mahendran Jayaraj declares that he has no conflict of interest. Richard Kozarek declares that he has no conflict of interest.

Human and Animal Rights and Informed Consent
This article does not contain any studies with human or animal subjects performed by any of the authors.

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- •• Of major importance

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