Communication from the ASGE Technology Committee

TECHNOLOGY STATUS EVALUATION REPORT

ASGE American Society for Gastrointestinal Endoscopy

Biliary and pancreatic stents

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The American Society for Gastrointestinal Endoscopy (ASGE) Technology Committee provides reviews of existing, new, or emerging endoscopic technologies that have an impact on the practice of GI endoscopy. Evidence-based methodology is used, performing a MEDLINE literature search to identify pertinent clinical studies on the topic and a Manufacturer and User Facility Device Experience (U.S. Food and Drug Administration Center for Devices and Radiological Health) database search to identify the reported adverse events of a given technology. Both are supplemented by accessing the "related articles" feature of PubMed and by scrutinizing pertinent references cited by the identified studies. Controlled clinical trials are emphasized, but in many cases, data from randomized, controlled trials are lacking. In such cases, large case series, preliminary clinical studies, and expert opinions are used. Technical data are gathered from traditional and web-based publications, proprietary publications, and informal communications with pertinent vendors. Technology Status Evaluation Reports are drafted by a small group of members of the ASGE Technology Committee, reviewed and edited by the Committee as a whole, and approved by the Governing Board of the ASGE. When financial guidance is indicated, the most recent coding data and list prices at the time of publication are provided. For this review, the MEDLINE database was searched through March 2020 for relevant articles by using the key words related to pancreaticobiliary stents and indications for their use, efficacy, and safety. Technology Status Evaluation Reports are scientific reviews provided solely for educational and informational purposes. Technology Status Evaluation Reports are not rules and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment or payment for such treatment.

Stents are hollow cylindrical devices used to establish flow through obstructed ducts. They are named after Dr Charles Thomas Stent, a 19th century English dentist. Stents are commonly used in biliary or pancreatic duct obstructions. In their first use, an angiography catheter was cut and adapted into a single-pigtail plastic stent to relieve malignant biliary obstruction.[1] Endoscopists now have multiple stent choices, which include plastic stents, self-expandable metal stents (SEMSs), and biodegradable stents (not currently available in the United States). Stent materials and available sizes and shapes are described in detail in Tables 1 to 4. This document provides an update to the 2013 American Society for Gastrointestinal Endoscopy (ASGE) report. The present document covers the technical description of available pancreas and biliary stents; indications for their use, efficacy, and safety; and financial considerations with additional focus on stents used in the growing field of therapeutic EUS.[2]

TECHNOLOGY UNDER REVIEW

Biliary stents

Plastic. Plastic biliary stents are manufactured using various polymers and are available in several sizes and shapes (Table 1). Standard duodenoscopes, which have a working channel diameter of 4.2 mm, can accommodate all stent diameter introducer systems. For enteroscopy-assisted ERCP, longer stent deployment systems are available but are limited by the smaller working channels of single-balloon and double-balloon enteroscopes that accommodate placement of stents up to 7F in diameter. Pediatric colonoscopes can accommodate stents up to 8.5F in diameter. Therapeutic linear-array echoendoscopes have a 3.7-mm working channel, through which plastic stents up to 10F in diameter can be placed during EUS-guided biliary drainage.

Plastic biliary stents may have flanges or pigtails at each end for anchoring. Flanged stents may have a 30- to 45-degree angulation in their distal end (duodenal bend)

TABLE 1. Biliary plastic stents

Stent	Length (cm)	Diameter (F)	Shapes	Flaps	Material	Price of stent/ system (U.S.$)
Boston Scientific Advanix	5-18	7, 8.5, 10	Duodenal bend, center bend	Single internal, single external	Polyethylene	137
Boston Scientific Advanix	3-15	7, 10	Double pigtail	Internal pigtail, external pigtail	Polyethylene	137
Boston Scientific Flexima	5-15	7, 8.5, 10, 11.5	Duodenal bend	Single internal, single external	Polyurethane	129
Cook Cotton-Leung	2-21	5, 7, 8.5, 10, 11.5	Center bend	Single internal, single external	Polyethylene	99
Cook Cotton-Leung Sof-Flex	5-15	7, 10	Center bend	Single internal, single external	Polyethylene/ polyurethane	99
Cotton Huebriegtse	3-15	7, 8.5, 10, 11.5	Duodenal bend	Single internal, single external	Polyethylene	99
Cook ST-2 Soehendra Tannenbaum	5-15	8.5, 10, 11.5	Center bend	Four internal, four external	Polyethylene	94
Cook Compass	5, 10, 15	7	Double pigtail	Internal pigtail, external pigtail	Polyethylene	82
Cook Solus	1-15	10	Double pigtail	Internal pigtail, external pigtail	Polyethylene/ polyurethane	184
Cook Zimmon	3-15	5, 6, 7, 8, 10, 11.5	Double pigtail	Internal pigtail, external pigtail	Polyethylene	99
Hobbs Amsterdam	5-12	7, 10	Center bend	Single internal, single external	Soft polymer	58
Hobbs Pigtail	4-15	7, 10	Double pigtail	Internal pigtail, external pigtail	Soft polymer	62
Olympus Double Layer	4-15	10	Duodenal bend, center bend	Four internal, four external	Inner layer, perfluoro; middle layer, stainless steel; outer layer, polyamide elastomer	370.50
Olympus QuickPlace V	5-18	7, 8.5, 10, 12	Straight, center bend, duodenal bend	Single internal, single external	Ethylene vinyl acetate	98.90

or a smoother bend in the center (Fig. 1A). These stents typically have single flaps proximally and distally with accompanying side holes. One stent iteration (Soehendra-Tannenbaum; Cook Medical, Bloomington, Ind, USA) has 4 flaps proximally and distally without side holes (Fig. 1B). Single- and double-pigtail stents have a circular portion of the stent instead of a flange at 1 or both ends, respectively (Fig. 1C). Side holes are present on the pigtails to facilitate drainage, in addition to the main stent channel. Despite the various shapes and composition of plastic stents, none appears to be superior in preventing stent occlusion.[3]

All plastic stents are radiopaque. Some stents have additional endoscopic or fluoroscopic markers to aid in deployment. Stents are available individually or as part of a kit, which includes an introducer system.

Deployment technique. Although the steps for placement of plastic stents are similar across different brands, it is important to know the delivery steps from the specific manufacturer's instructions for use. The appropriate stent diameter and length is selected based on cholangiographic characterization of the extent and severity of the stenosis to be treated. A biliary sphincterotomy can be considered before stent insertion, based on the endoscopist's discretion. The choice to pursue a biliary sphincterotomy is multifactorial, often depending on scope positioning, size and morphology of the major papilla, and the intended stent size. Sphincterotomy before placement of stents 10F or larger has been shown to decrease the rate of post-ERCP pancreatitis (PEP).[4] Smaller-diameter stents (eg, $\leq$7F) can be deployed over a guidewire using a pushing catheter. Once the guidewire position is adequate, the stent is loaded directly onto the guidewire and then followed by a pushing catheter of the same diameter. The stent is then pushed into position, followed by removal of the pushing catheter and guidewire to complete deployment. Pushing catheters for stents 7F and smaller are sold separately or as part of a kit. For stents 5F and smaller, alternative ERCP accessories (eg, sphincterotome,

TABLE 2. Pancreatic plastic stents

Stent	Length (cm)	Diameter (F)	Shapes	Flaps	Material	Price of stent/ system (U.S.$)
Boston Scientific Advanix	2-18	3, 4, 5, 7, 10	Straight, single pigtail	Single, double, no internal flaps/double external flaps, external pigtail	Polyethylene	161-188
Cook Geenen	2-20	3, 5, 7, 8.5, 10, 11.5	Curved	Double, no internal flaps/double external flaps	Polyethylene	99
Cook Johlin	8-22	8.5, 10	Wedge	No internal/external flaps	Polyethylene/ polyurethane blend	204
Cook Zimmon	2-15	5, 7	Single pigtail	Single, no internal flap/external pigtail	Polyethylene	99
Hobbs Freeman	3-11	3, 4, 5, 7	Single pigtail	Single, no internal flap/external pigtail and single/no external flange	Soft polymer blend	58.50-62.50
Hobbs Freeman-Aliperti	2-3	4, 5	Straight	Single internal flap/double external flaps	Soft polymer blend	58.50-62.50

occlusion balloon catheter) can also be used as a makeshift pushing catheter, primarily as a cost-saving and efficiency measure. Larger-diameter stents (8.5, 10, and 11.5F) generally come with introducer systems composed of a wire-guided inner guiding catheter and a pushing catheter to match the outer diameter of stent. In this system, the stent is first loaded onto the inner guiding catheter of the introducer system. The stent and guide catheter are then pushed down the instrument working channel, keeping the guidewire locked in place. Once the inner guiding catheter is positioned across the stricture, the stent is deployed by uncoupling the inner guiding catheter and pushing catheter, allowing the pushing catheter to drive the stent into the desired position. Retraction of the inner guiding catheter, pushing catheter, and guidewire complete stent deployment. Some delivery systems allow the stent to be removed or repositioned relatively late in the deployment process (NaviFlex RX Delivery System [Boston Scientific, Marlborough, Mass, USA] and Oasis-One Action Stent Introduction System [Cook Medical]).

Self-expandable metal stents. SEMSs are composed of self-expandable cylindrical metal mesh. They are constrained on a guide catheter within a delivery sheath and are passed through the endoscope working channel. SEMSs are constructed using various methods (eg, braiding, laser cut) and metal alloys (with or without a plastic coating) and are available in an assortment of sizes (Table 3).[5] SEMSs may foreshorten to varying degrees after deployment, based on the design of the mesh, defined as the difference in length between the unexpanded and expanded stent. Flared ends or antimigration fins are incorporated in some stents to prevent migration.

Radial and axial force, flexibility, radiopacity, and foreshortening ratio are intrinsic features of SEMSs and are a function of both their design and materials. Braided SEMSs foreshorten significantly, whereas laser-cut SEMSs may foreshorten only minimally, if at all.[5] One study showed no difference in clinical performance between designs, with diameter being the most important factor in duration of patency.[6] Radiopaque markers made of gold, platinum, or tantalum are micro-welded to the SEMS to facilitate precise deployment.

Biliary SEMSs may be fully covered (FCSEMS), partially covered, or uncovered. SEMS coverings are made of polytetrafluoroethylene, polytetrafluoroethylene/fluorinated ethylene propylene, or silicone. Depending on the manufacturer, the covering is on the exterior (Wallflex [Boston Scientific] and COMVI and Niti-S [Taewoong Medical, Gyeonggi-do, South Korea]) or interior (Viabil; WL Gore, Flagstaff, AZ, USA) surface of the stent. Because of tumor ingrowth or benign tissue hyperplasia, uncovered and partially covered SEMS become difficult to extract after insertion. FCSEMSs can be repositioned or removed with the use of a snare or forceps. Generally, only FCSEMSs are used in benign indications, whereas any variety of construction can be used in malignant strictures where stent replacement is not needed.

A meta-analysis found an overall migration rate of 9% when using FCSEMSs; however, no subanalyses were performed on specific stent designs.[7] FCSEMSs have a lower migration rate if a coaxial double-pigtail stent is placed as an anchor, with 1 study demonstrating an absolute risk reduction of 25% in patients with malignant distal biliary strictures.[8] SEMSs with anchoring flaps (HANAROSTENT; MI Tech, Seoul, South Korea) or antimigration fins (Viabil; WL Gore) have lower migration rates than stents with flared ends.[9,10]

Deployment technique. As with plastic stents, it is critical to understand the delivery mechanisms as outlined in the instructions for use from the various SEMS manufacturers. The proximal and distal ends of the stent should traverse the margins of the stenosis, while accounting for expected foreshortening when using braided SEMSs. A biliary sphincterotomy may be considered before insertion of an FCSEMS to decrease the rate of PEP.[11] The stent and

TABLE 3. Self-expandable metal stents

Stent	Length (cm)	Diameter (mm)	Delivery System (F)	Covering	Foreshortening	Design	Price (U.S.$)
Boston Scientific Wallflex	4, 6, 8, 10	8, 10	8 (uncovered), 8.5	Covered, partially covered, and uncovered	Yes	Braided	3039 (uncovered), 4091 (partially covered), 4278 (fully covered)
Boston Scientific Wallflex Transhepatic	4, 6, 8, 10	8, 10	8 (uncovered), 8.5	Covered, partially covered, and uncovered	Yes	Braided	3191 (uncovered), 4296 (partially covered), 4492 (fully covered)
Boston Scientific Epic	4, 6, 8, 10	6, 8, 10	6	Uncovered	No	Laser cut	3213
Cook Evolution	4, 6, 8, 13	8, 10	8.5	Uncovered	No	Hook and cross	2239
Cook Zilver 635	4, 6, 8, 10, 12	6, 8, 10	6	Uncovered	No	Hook and cross	2178
Gore Viabil	4, 6, 8, 10	8, 10	8.5	Covered with or without drainage holes	No	Wound with open cell	2600-3100
MI Tech HANAROSTENT (distributed by Olympus)	4-12 (8 mm diameter) 4-10 (10 mm diameter)	8, 10	7-8.5	Uncovered	Yes	Mixture of braided and hook and cross	1840/1740
Taewoong Niti-S Uncovered	6, 8, 10	4, 5, 6, 7, 8, 10, 12	7	Uncovered	Yes	Braided	1100
Taewoong Niti-S Covered*	6, 8, 10	4, 5, 6, 7, 8, 10, 12	8.5	Partially and fully covered	Yes	Braided	1100
Taewoong Niti-S Covered (flare)*	6, 8, 10	4, 5, 6, 7, 8, 10, 12	8.5	Fully covered	Yes	Braided	1100
Taewoong Niti-S D Uncovered	6, 8, 10	4, 5, 6, 7, 8, 10, 12	8	Uncovered	Yes	Hook and cross	1100
Taewoong Niti-S LCD	6, 8, 10	4, 5, 6, 7, 8, 10, 12	6-8	Uncovered	Yes	Hook and cross	1100
Taewoong Niti-S M	6, 8	4, 5, 6, 7, 8, 10, 12	6-7	Uncovered	Yes	Mixture of braided and hook and cross	1100
Taewoong Niti-S COMVI*	8, 10	4, 5, 6, 7, 8, 10, 12	8	Partially and fully covered	Yes	Hook and cross	1100

*Currently unavailable in the United States.

delivery system are passed over a guidewire, down the working channel of the endoscope, and through the obstruction. The SEMS is positioned across the stenosis and deployed using a proprietary mechanism unique to each manufacturer. Endoscopic and fluoroscopic guidance is critical to adjust for any foreshortening. The delivery catheters of braided SEMSs allow the stent to be reconstrained if repositioning is necessary during deployment; however, the delivery system reaches a point where it can no longer be reconstrained (ie, "point of no return"). Until the point of no return, the SEMS can be reconstrained and repositioned; however, after that point it cannot. Laser-cut SEMSs cannot be recaptured after they are partially deployed (Viabil [WL Gore], Epic [Boston Scientific] and Zilver/Zilver 635 [Cook Medical]). Of note, SEMSs may also be delivered percutaneously (WallFlex Biliary Transhepatic Stent System [Boston Scientific] and Viabil [WL Gore]) and subsequently removed endoscopically if a fully covered version is used and within reach of an endoscope.

Pancreatic stents

Plastic. Predominantly composed of polyethylene, plastic pancreatic stents are available in various lengths and diameters (Table 2). The presence of side holes, which enable drainage of the numerous side branches, mark the defining feature of these stents. The shapes of pancreatic stents vary from straight to curved to conform to the natural contour of the duct. Their internal and external ends also vary with 1 or 2 internal flanges to prevent outward migration and 2 external flanges or pigtails to prevent inward migration. Nonflanged plastic stents with an ultra-

TABLE 4. Biodegradable stents

Name	Degradation	Material	Design	Unique feature
Archimedes Fast	12 days	Polydioxanone, polyethylene glycol, and barium sulfate	Outside spiral	Bile flows on the outside of the stent
Archimedes Medium	20 days	Polydioxanone and barium sulfate	Outside spiral	Bile flows on the outside of the stent
Archimedes Slow	11 wk	Polylactide-co-caprolactone-co-trimethylene carbonate and barium sulfate	Outside spiral	Bile flows on the outside of the stent
Ella BD	3-6 mo	Polydioxanone	Uncovered metal-like	
Ella DV	3-6 mo	polydioxanone	Uncovered metal-like	
Unity-B Fast	1-3 mo	MgNdMn21 alloy and polymer coating	Uncovered metal-like	Needs balloon dilation (8, 9, and 10 mm)
Unity-B Medium	3-6 mo	MgNdMn21 alloy and polymer coating	Uncovered metal-like	Needs balloon dilation (8, 9, and 10 mm)
Unity-B Slow	6+ mon	MgNdMn21 alloy and polymer coating	Uncovered metal-like	Needs balloon dilation (8, 9, and 10 mm)

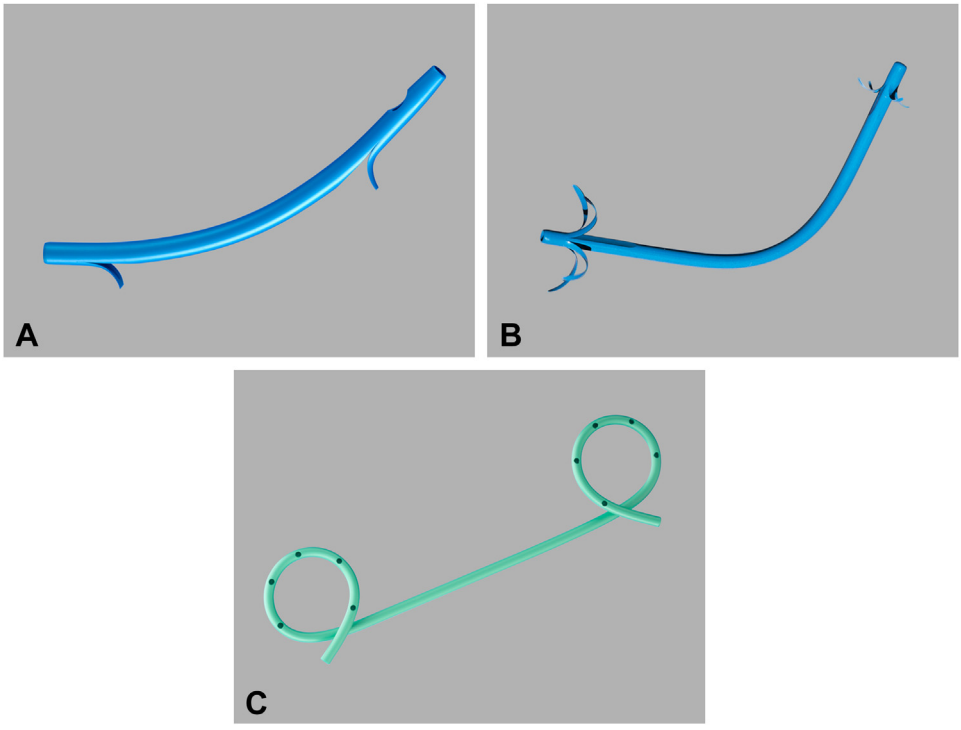

Figure 1. Example of plastic biliary stents. **A,** Straight stent. **B,** Migration-resistant stent with 4 external and 4 internal flanges. **C,** Double-pigtail stent. (Images used with permission and provided courtesy of Cook Medical.)

tapered tip and numerous drainage holes (Johlin Wedge Stent; Cook Medical) are often used in the pancreas. These are composed of a soft polymer blend and can be customized per patient to a length ≤22 cm. Stents inserted for PEP prophylaxis usually have no internal flanges to allow for spontaneous migration. The deployment of plastic pancreatic stents is identical to that of plastic biliary stents. A pancreatic sphincterotomy should be considered when placing larger caliber pancreatic stents (≥8.5F), whereas 5F and 7F stents can be placed without sphincterotomy in most patients.

Metal. Although currently no SEMSs have been approved by the U.S. Food and Drug Administration (FDA) for the pancreatic duct, numerous studies have described the use of biliary FCSEMSs for refractory pancreatic duct strictures. In the United States, the most

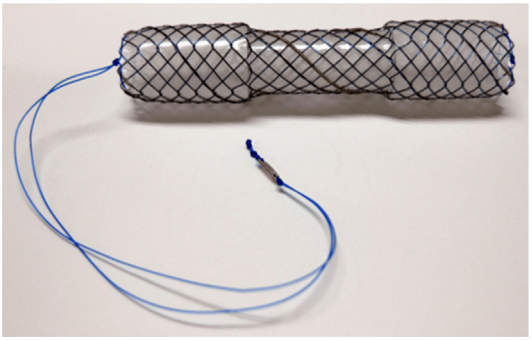

Figure 2. Example of a pancreas-specific fully covered metal stent with a central saddle feature for an intraductal stricture and a distal lasso for stent removal. (Photo provided courtesy of Standard Sci-Tech Inc.)

commonly used metal stents are the Wallflex (Boston Scientific) and the Viabil (WL Gore). The latter contains the option for transmural drainage holes within 2 cm of the proximal covered end along with lateral anchoring fins to help reduce the risk of migration. Several pancreas-specific FCSEMSs have been evaluated in Asia, including a 6- to 8-mm stent with (Niti-S BUMPY Pancreatic Stent; Taewoong Medical) and without (Niti D-type; Taewoong Medical) flares. A short, saddle-shaped stent (BONASTENT M-intraductal; Standard Sci Tech Inc, Seoul, South Korea) has been developed for intraductal placement and includes a lasso at the distal end to facilitate removal (Fig. 2).[12-15] Similarly designed FCSEMSs specific for EUS-guided pancreatic duct drainage have also been studied, with the main design feature of antimigration properties such as proximal and distal anchoring flaps.[16,17] Deployment of metal stents in the pancreatic duct is analogous to biliary metal stent placement.

Biodegradable stents

Biodegradable stents are made of polymers that degrade in vivo through hydrolysis with water. Their radial force is minimal, and their primary advantage is the potential for a reduced number of procedures. Currently, no biodegradable stents are FDA-approved. Several studies in Europe have described their use in the pancreaticobiliary tract. A helicoidal stent (Archimedes; AMG International GmbH, Winsen, Germany) (Fig. 3A) allows flow through the inside channel, and the outside spiral grooves are built using 3 different polymers (Table 4).[18] Another biodegradable stent incorporates an uncovered metal stent design (Fig. 3B). There is a braided biliary version (Ella BD; ELLA-CS, Hradec Králové, Czech Republic) and a pancreatic version (Ella-DV; ELLA-CS) (Table 4).[19,20] A balloon-expandable biodegradable stent (UNITY-B; AMG International GmbH) has also been described for treatment of refractory postcholecystectomy biliary strictures. It uses a dilation balloon to expand the SEMS-like stent.[21]

EFFICACY AND OUTCOMES

Biliary

Malignant obstruction. Endoscopic stent placement remains the standard of care for treatment of malignant biliary obstruction, including patients who have locally advanced or borderline resectable pancreatic cancer who are planning to undergo neoadjuvant therapy.[22] A meta-analysis including 20 randomized trials for palliation of malignant biliary obstruction (both hilar and distal) found that compared with plastic stents, SEMS placement resulted in longer stent patency, lower adverse event rates, and fewer reinterventions, especially if used as the first modality for drainage.[23] Also, patients who received uncovered SEMSs compared with plastic stents had longer rates of survival. Of note, in patients with intact gallbladders, metal biliary stent placement carries the risk of cholecystitis with both covered and uncovered stents.[24] Ideally, SEMSs are placed above or below the cystic duct takeoff, but obstruction across the cystic duct orifice may preclude this.[25] Plastic stents are generally recommended if the life expectancy is less than 3 to 4 months given the increased costs of SEMSs compared with plastic stents in this scenario.[26]

Hilar strictures. The ASGE Standards of Practice guideline outlines a biliary drainage strategy for malignant hilar strictures, recommending placement of plastic stents when life expectancy is short (<3 months) or if the definitive plan for drainage is unknown.[27] Plastic stents have an advantage over SEMSs in select patients with cholangiocarcinoma and hilar obstruction who undergo neoadjuvant chemoradiation with the goal of eventual liver transplantation. Plastic stent placement can also establish the efficacy of biliary drainage before committing to uncovered SEMSs. Multisectoral drainage (drainage of the right and left biliary ductal systems or the 2 right sectoral ducts) is also conditionally recommended in these guidelines, which allows drainage of at least 50% of the liver. It should be noted that a meta-analysis revealed that unilateral and bilateral stent placement were comparable in terms of efficacy and safety, with similar rates of early and late adverse events.[28] Nonflanged plastic stents (customizable to a length of ≤22 cm) with numerous drainage holes (Johlin Wedge Stent; Cook Medical) may be used when a particular stent length is needed to drain a liver segment.

When using SEMSs, uncovered SEMSs are recommended to avoid obstructing other liver segments. Uncovered SEMSs and plastic stents have similar short-term outcomes in hilar strictures, but uncovered SEMSs provide longer biliary patency as compared with plastic stents.[29] If multisectoral SEMS drainage is undertaken, SEMSs with large open cell interstices are helpful for placing a stent within a stent (eg, Y configuration), but use of this type is not mandatory. Smaller 6F diameter SEMS delivery systems (Zilver 635 [Cook Medical] and Epic [Boston Scientific]) allow simultaneous side-by-side placement with high technical and clinical success

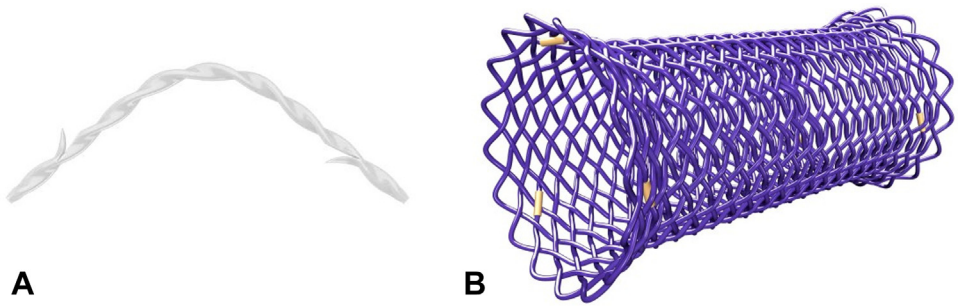

Figure 3. A biodegradable helical stent (**A**) and a braided stent (**B**) for use in the bile duct and pancreatic duct. (Images used with permission and provided courtesy of Medtronic and ELLA-CS.)

rates.[30,31] It is not necessary for side-by-side stents to be transpapillary, although the option exists with longer length stents. Of note, a primary disadvantage of using multiple SEMSs is the technical difficulty for reintervention should they become occluded or obstruct secondary biliary radicles.

Benign biliary strictures. Endoscopic stent placement remains the standard of care for benign biliary strictures (BBSs). Most BBSs (>80%) are postsurgical (after cholecystectomy and liver transplantation) and are in the mid common bile duct. Chronic pancreatitis–related BBSs are also common and are usually located in the distal common bile duct. FCSEMSs or plastic stents may be used to treat BBSs. FCSEMSs are typically removed in 6 to 12 months, whereas plastic stents are typically exchanged and upsized (increasing number of stents and/or increasing the diameter of stents) every 3 to 4 months for 6 to 12 months.[11]

Postcholecystectomy strictures are best treated with multiple plastic stents (upsizing every 3 months for up to 1 year), with a large retrospective study showing durable long-term results and recurrence seen in only 9% of patients at 11 years of follow-up.[32,33] In a study examining FCSEMSs placed for 6 to 12 months, 72% had stricture resolution at the time of stent removal. At the 5-year follow-up, there was an 85% rate of stricture resolution.[34]

In post–liver transplant (duct-to-duct anastomoses) anastomotic strictures, a randomized trial found stricture resolution rates of 83% and 100% for FCSEMSs (removal after 6 months) and multiple plastic stents (upsizing every 3 months), respectively.[35] Another study showed sequential addition (without replacement) of stents every 3 months achieved 99% stricture resolution with an 8% recurrence rate at 32 months of follow-up.[36] The previously mentioned short metal stent (BONASTENT; Standard Sci Tech Inc) with an intraductal saddle has also been used for anastomotic strictures with an 81% stricture resolution rate and 12% stricture recurrence rate.[37]

In chronic pancreatitis–related BBSs, >60% of patients remain asymptomatic and stent-free 5 years after placement of a single FCSEMS for a period of 10 to 12 months.[38] A multicenter randomized trial demonstrated that patients treated with FCSEMS placement for 12 months had similar rates of stricture resolution compared with multiple plastic stents (76% vs 77%, respectively) but required significantly fewer reinterventions over 2 years (2.6 vs 3.9).[39] Therefore, placement of a single FCSEMS may be considered as the first-line treatment in these patients.[40] Currently, only the WallFlex stent (Boston Scientific) is FDA-approved for a 12-month dwell time in such patients.

The use of stents in primary sclerosing cholangitis is reserved for patients with dominant strictures refractory to balloon dilation alone or those presenting with cholangitis, because a randomized trial found no difference in treatment success between stent placement and dilation for the management of dominant strictures.[41] If stent placement is performed, a single 10F stent or two 7F stents are recommended, which should be removed 1 to 2 weeks after insertion.[42]

Bile leaks. Postoperative bile leaks can be successfully treated with placement of a single plastic stent for 4 to 6 weeks in 70% to 100% of patients.[43-47] Clinical success and adverse events do not seem to be dependent on the timing of the intervention, as long as the procedure is performed within 72 hours.[48] Sphincterotomy followed by placement of a 10F stent may provide better results than stent placement alone.[49] For cystic duct leaks, placing a stent proximal to the cystic duct takeoff is warranted only if there is a proximal stricture. FCSEMSs can be considered for high-grade leaks and leaks where previous endoscopic therapy with plastic stents has failed.[50-52]

Cholecystitis. Endoscopic strategies, including the use of lumen-apposing metal stents for EUS-guided gallbladder drainage, are detailed in separate ASGE documents.[53,54] Transpapillary gallbladder drainage via ERCP most commonly uses a double-pigtail stent ranging from 5F to 10F in diameter with a length of at least 12 cm.

Choledocholithiasis. Biliary stents can be placed as a temporizing measure to relieve biliary obstruction in patients with incomplete clearance of stones from the bile duct (ie, large or impacted stones, clinical instability of the patient). Plastic stent or FCSEMS placement during the index ERCP also reduces the number and size of stones, facilitating stone clearance in 90% to 100% of cases on subsequent ERCPs.[55,56]

Postsphincterotomy hemorrhage. FCSEMSs are typically used for hemostasis for postsphincterotomy bleeding when conventional therapy has failed. Success rates are as high as 100% with recurrent bleeding rates as low as 0%.[57] One study showed early FCSEMS placement provided a lower rebleeding rate (5% vs 31%) when compared with conventional hemostasis with prolonged balloon tamponade, thermal and argon plasma coagulation, and/or placement of hemostatic clips in patients who failed monotherapy with epinephrine or balloon tamponade.[57] The literature varies widely regarding how long the FCSEMS should be left in, but even several days may be sufficient depending on the patient's clinical needs.[57,58]

EUS-guided biliary drainage. EUS-guided stent placement into the common bile duct or hepatic ducts offers an alternative form of drainage for patients when standard ERCP fails or is not feasible. The 2 most common EUS-guided techniques are choledochoduodenostomy and hepaticogastrostomy. The use of lumen-apposing metal stents to perform choledochoduodenostomy has been well described in a previous ASGE Technical Review document.[54] FCSEMSs can also be used to create a choledochoduodenostomy using a multistep procedure similar to hepaticogastrostomy. When using FCSEMSs for these indications, the common bile duct or left hepatic duct is accessed using an EUS-FNA needle. A cholangiogram is performed and the tract is dilated before placement of a FCSEMS.[59,60] FCSEMSs, which are not FDA-approved for this indication (Viabil [WL Gore] and Wallflex [Boston Scientific]), are typically used in the United States for this approach.

Several novel stents (not available in the United States) have been designed to reduce the risk of migration and streamline stent placement in EUS-guided biliary drainage procedures. A laser-cut partially covered SEMS (BileRush Advance; Piolax Medical, Kanagawa, Japan) contains a 2-cm uncovered portion at its distal end to help prevent stent migration. This stent is placed with the uncovered portion within the target bile duct and liver parenchyma to mitigate the risk of obstruction of adjacent intrahepatic biliary radicles.[61] The proximal end is flared to prevent inward migration from the stomach into the peritoneum. Similarly, another partially covered SEMS (Giobor stent; Taewoong Medical) has a 1-cm uncovered hepatic portion with a flared portion at the gastric aspect. In a study of 110 patients with EUS-guided partially covered SEMS placement, there were no stent migrations; however, a 4% rate of peritonitis was noted.[62]

A novel FCSEMS (HANAROSTENT Biliary Full Cover Benefit; MI Tech) has a stiff, tapered (5.9F) tip that allows for immediate deployment after guidewire access is achieved, thus eliminating the need for tract dilation.[63] A pilot study involving this stent revealed an efficient procedure time (median of 7 minutes) with no stent migration or peritonitis.[63]

A 7F to 8F plastic stent (Through and Pass; Gadelius Medical Co Ltd, Tokyo, Japan) has been developed specifically for hepaticogastrostomy. This stent has a 20-cm length (15 cm effective length) with 2 internal flaps and 2 external flaps, in addition to an external pigtail. There are no side holes in the midbody of the stent to prevent intraperitoneal bile leakage. Studies have demonstrated its safety and feasibility in both malignant and benign biliary disease.[64,65]

Pancreatic

Pancreatic duct strictures. Pancreatic duct stents are most typically placed for treatment of pancreatic duct strictures in patients with painful chronic pancreatitis. Current guidelines recommend index placement of a single 10F plastic stent when possible.[66-68] Stents can be exchanged until stricture resolution is achieved. Refractory strictures are typically defined as those persisting >1 year despite treatment with a 10F stent.[66] Stent exchanges may be performed on an as-needed basis or at regular intervals with replacement typically needed within 3 to 6 months. For refractory strictures, placement of multiple parallel plastic stents may offer a potential treatment option, with 1 study finding 74% of patients to be asymptomatic at 9.5 years of follow-up, although a 7% stricture recurrence rate was noted.[69,70]

The use of FCSEMSs (6-10 mm in diameter) has drawn great interest for the treatment of refractory pancreatic duct strictures. A meta-analysis including 10 studies with 163 patients revealed a stricture resolution rate of 93% (95% confidence interval, 84-99) and stricture recurrence rate of 5% (95% confidence interval, 0-12).[71] Studies from the United States and Europe have typically used off-label biliary FCSEMSs; however, several studies from Asia have used pancreatic duct-specific FCSEMSs that provide more flexibility and have antimigration features.[12-14,72-74]

A novel short FCSEMS described above allows for targeted intraductal placement of the stent with retrieval facilitated by the presence of a distal lasso for ease of removal.[14] In 25 patients, a 100% stricture resolution rate was found, with 2 patients (8%) requiring repeat stent placement for stricture recurrence. In contrast, a prospective international multicenter study examining the use of a 6- to 8-mm diameter "soft" FCSEMS specific to the pancreas found a low rate (26.1%) of pain improvement and a high adverse event rate (31.3%).[75] One comparative retrospective study demonstrated that SEMSs had a higher stricture resolution rate than plastic stents (87% vs 42%).[76] To date, no prospective studies have compared FCSEMSs with plastic stents for this indication.

Pancreatic duct leaks and disconnected pancreatic duct. Plastic stents offer effective treatment for pancreatic duct leaks, particularly when the stent can bridge the site of the leak or fistula within the pancreatic duct.[77-80] Complete disconnection of the duct (disconnected

pancreatic duct syndrome) and inability to bridge the duct are associated with worse outcomes, although nonbridging stent placement may still provide benefit by reducing pancreatic juice flow.[77,81] In this scenario, concomitant EUS-guided transmural drainage of associated fluid collections or the disconnected portion of the pancreatic duct may be beneficial.[82]

Pancreas divisum. Endoscopic sphincterotomy combined with pancreatic duct stent placement provides an endoscopic treatment option for patients with pancreas divisum and idiopathic acute recurrent pancreatitis or chronic pancreatitis. Long-term studies examining minor papilla endotherapy have demonstrated efficacy in improving quality of life, reducing the number of hospitalizations, and improving pain in patients with acute recurrent pancreatitis.[83-88] One study examining patients with acquired pancreas divisum secondary to ventral duct obstruction found that dorsal duct stent placement improved 52% of strictures, with most patients reporting pain improvement.[89] Nevertheless, the role of minor papilla endotherapy remains unclear. An ongoing randomized trial (clinicaltrials.gov NCT03609944) is comparing minor papilla sphincterotomy and prophylactic pancreatic duct stent placement with sham therapy to determine whether endoscopic treatment benefits patients with idiopathic acute recurrent pancreatitis and pancreas divisum.[90]

Prevention of PEP. The role of prophylactic pancreatic duct stent placement for the prevention of PEP is discussed in detail in an ASGE Practice Guideline.[91] A large multicenter randomized trial (clinicaltrials.gov NCT0247 6279) nearing completion is comparing pancreatic duct stent placement combined with rectal indomethacin with rectal indomethacin alone in the prevention of PEP.[92]

EUS-guided pancreatic duct drainage. EUS-guided transmural stent placement into the pancreatic duct offers an alternative drainage modality in patients with chronic pancreatitis or pancreaticojejunostomy anastomotic strictures not amenable to conventional ERCP. The use of plastic pancreatic duct stents has been described in several retrospective series on EUS-guided pancreatic duct drainage. Technical and clinical success rates near 90% with stents selected to prevent migration out of the pancreatic duct or the gastric lumen.[93-95] Although studies have detailed the use of plastic stents and SEMSs specifically designed for EUS-guided pancreatic duct drainage, no stent has received FDA approval for this indication. A single-center experience (n = 30) with a novel 7F plastic stent (TYPE IT; Gadelius Medical Co) with 4 internal flanges (2 at the distal end and 2 at the proximal end) and a single external pigtail found technical and clinical success rates of 100% with a 20% stent migration rate.[96,97] A novel FCSEMS (6-8 mm diameter, 6-10 cm length; MI Tech) with antimigration properties including proximal and distal anchoring flaps has also been examined, with studies finding a 100% technical and clinical success rate in 48 patients with 1 case of asymptomatic stent migration.[16,17]

SAFETY

Biliary stents

A meta-analysis of 11 randomized trials involving 1272 patients with malignant biliary obstruction found no difference in stent failure between FCSEMSs and uncovered SEMSs.[98] Stent migration and sludge formation were more common with FCSEMSs (odds ratio, 5.11). As expected, tumor overgrowth was more common in FCSEMSs, and tumor ingrowth was more common with uncovered SEMSs.

A randomized trial found that sphincterotomy before placement of SEMSs increased the risk of stent migration, bleeding, and perforation, but the literature remains unclear on whether a sphincterotomy is beneficial or harmful before placement of a SEMS.[99,100] Compared with plastic stents, placement of a SEMS is associated with a higher risk of PEP.[101]

Acute cholecystitis may occur in as many as 10% of patients with intact gallbladders after placement of a FCSEMS across the cystic duct. One study showed that the incidence of acute cholecystitis was higher with FCSEMSs compared with uncovered SEMSs (7.8% vs 1.2%), but other studies, including a meta-analysis, have not confirmed this finding.[24,102,103]

Although biliary stents spontaneously migrate in 5% to 10% of cases overall, retained long-term plastic biliary stents in patients lost to follow-up may cause acute cholangitis because of stent obstruction but also because of stent-induced choledocholithiasis.[104] A robust stent recall system may help avoid lapses in scheduled stent removal.

Pancreatic stents

The primary adverse events of pancreatic duct stent placement are pancreatitis or worsening of abdominal pain, stent migration, stent occlusion, and stent-induced strictures. Exacerbation of pancreatitis or abdominal pain is reported to occur in 6% to 10% of patients who undergo pancreatic duct stent placement.[66,105] Although spontaneous outward migration of pancreatic stents is desired with prophylactic pancreatic duct stents for the prevention of PEP, migration (outward or inward) is generally undesirable if it occurs during the treatment of pancreatic duct strictures and leaks. In a long-term study of stent placement for chronic pancreatitis–associated strictures, inward migration was found to occur in 1.2% of cases.[69] Similarly, another study found inward migration rates and outward migration rates of 2.7% and 3.6%, respectively.[106] Risk factors for stent occlusion include stent diameter >8.5F, stent length >8 cm, and female sex.[106]

Pancreatic duct stent placement can induce pancreatic duct changes, including de novo strictures, which are challenging to manage.[107,108] These can occur in up to 27% of patients and in previously normal ducts where stent placement was prophylactic in nature.[66,109,110] In comparing different types of plastic stents, stents composed of a softer material (Sof-Flex, Johlin Wedge Stent; Cook Medical)

without internal flanges did not have any significant differences in ductal changes when compared with standard polyethylene stents.[111] Similar rates of stent-induced strictures have been reported with FCSEMSs, likely related to the flares at both ends. "Flareless" FCSEMSs have been associated with much lower stricture rates.[14,15,66]

FINANCIAL CONSIDERATIONS

Pricing and Current Procedural Terminology Code Information

The prices of available plastic pancreaticobiliary stents and SEMSs are listed in Tables 1 to 3. Most plastic stents can be purchased either separately or with an associated introducer system or pushing catheter. A specific billing code exists for ERCP with stent placement, Current Procedural Terminology code 43268. This code covers stent placement in either the bile or pancreatic duct. A separate Current Procedural Terminology code (43269) exists for ERCP with stent removal or exchange.

Cost comparison between stents

Multiple cost-effective comparisons have been made between SEMSs and plastic stents in the treatment of malignant biliary strictures with inconsistent results. In a prospective trial comparing FCSEMSs, uncovered SEMSs, and plastic stents for malignant biliary obstruction in patients undergoing neoadjuvant chemotherapy with curative intent for pancreatic adenocarcinoma, no stent type was superior in optimizing cost-effectiveness, although FCSEMSs resulted in shorter neoadjuvant treatment delay and a longer time to stent occlusion.[112] Another cost-effectiveness analysis demonstrated that SEMSs as the initial intervention to relieve malignant biliary obstruction in patients with borderline resectable pancreatic cancer undergoing neoadjuvant therapy before surgery were superior to plastic stent placement.[113] Patients were more likely to achieve readiness for surgery and at a faster time by 18 days with a cost reduction of ~$2000. The decision to place a plastic stent versus SEMS in patients with malignant biliary obstruction should be customized to the individual patient while keeping in mind the overall clinical status, management plan, and expected prognosis of the patient, using multidisciplinary input. An evidence-based, consensus-driven approach in these cases is also very likely to be the most cost-effective.

SUMMARY

Biliary and pancreatic duct stents are widely used for a variety of benign and malignant indications. The growth of interventional EUS has ushered in new varieties of plastic and metal stents incorporating antimigration features. Although pilot studies have introduced the concept of using biodegradable stents, much more research and innovation are needed before their regular use in the pancreaticobiliary tract.

RELEVANT ASGE PUBLICATIONS

ASGE guideline on the role of endoscopy in the evaluation and management of choledocholithiasis (2019). doi: https://doi.org/10.1016/j.gie.2018.10.001.

The role of endoscopy in the diagnosis and treatment of inflammatory pancreatic fluid collections (2016). doi: https://doi.org/10.1016/j.gie.2015.11.027.

The role of endoscopy in the evaluation and management of patients with solid pancreatic neoplasia (2016). doi: https://doi.org/10.1016/j.gie.2015.09.009.

The role of ERCP in benign diseases of the biliary tract (2015). doi: https://doi.org/10.1016/j.gie.2014.11.019.

The role of endoscopy for benign pancreatic disease (2015). doi: https://doi.org/10.1016/j.gie.2015.04.022.

The role of endoscopy in the evaluation and treatment of patients with biliary neoplasia (2012). doi: https://doi.org/10.1016/j.gie.2012.09.029.

ASGE guideline on PEP prevention strategies (2023). doi: https://doi.org/10.1016/j.gie.2022.10.005 and doi: https://doi.org/10.1016/j.gie.2022.09.011.

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Abbreviations: ASGE, American Society for Gastrointestinal Endoscopy; BBS, benign biliary stricture; FCSEMS, fully covered self-expandable metal stent; PEP, post-ERCP pancreatitis; SEMS, self-expandable metal stent.

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