

Biliary and pancreatic stents

To promote the appropriate use of new or emerging endoscopic technologies and those technologies that have an impact on endoscopic practice, the ASGE Technology Committee presents relevant information to practicing physicians in the form of technology reviews. Evidence-based methodology is employed wherein a MEDLINE literature search is performed to identify pertinent clinical studies on the topic, a MAUDE (Food and Drug Administration Center for Devices and Radiological Health) database search is performed to identify the reported complications of a given technology, and both are supplemented by accessing the “related articles” feature of PubMed and by scrutiny of pertinent references cited in 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 opinion are utilized. Technical data are gathered from traditional and Web-based publications, proprietary publications, and informal communications with pertinent vendors. Reviews are drafted by 1 or 2 committee members, reviewed in significant detail by the committee as a whole, and approved by the Governing Board of the ASGE. When financial guidance is appropriate, the most recent coding data and list prices at the time of publication are provided. For this review, the MEDLINE database was searched through April 2006 for articles related to biliary and pancreatic stenting.

BACKGROUND

Stents are tubular devices, made of plastic or metal, designed to maintain or enhance the patency of a lumen. Recently, a stent with a star-shaped cross-section has been developed for pancreatic applications. During endoscopic retrograde cholangiopancreatography (ERCP), biliary and pancreatic stents are commonly employed in the management of bile duct and pancreatic duct obstructions and leaks, which result from a variety of conditions. Pancreatic stents are also used for prevention of post-ERCP pancreatitis. The decision to deploy biliary or pancreatic stents,

and stent selection, should involve consideration of their efficacy, safety, and cost. This review addresses these issues for the wide variety of plastic and metal stents.

TECHNICAL CONSIDERATIONS

Plastic stents

Plastic stents vary in caliber, length, material, and configuration depending on their design and intended application (Tables 1 and 2). Most are made of polyethylene in a variety of fixed caliber and length combinations. Teflon and 2-layer stents are more recent designs aimed at improving stent patency by decreasing bacterial and protein adhesion. A type of the latter, the DoubleLayer biliary stent (Olympus America, Melville, NY) has an inner perfluorinated water-repellant layer and an outer structural layer composed of a stainless steel mesh coated by a polyamide elastomer designed to enhance deployment.¹ Preliminary experience with prototype expandable plastic (Teflon) stents has also been reported.² Plastic stents are made in variations of straight (angled, curved) or pigtail shapes. Straight stents are anchored by 1 or more side flaps on each end, whereas pigtail stents are held in place by a flexible, 360-degree curved section at 1 or both ends. Straight biliary stents typically have side holes only at the location of the barb flaps at each end, whereas pigtail stents have numerous side holes at each end.

For biliary applications, plastic stents vary from 5F to 12F in caliber and from 1 to >15 cm in length (Table 1). Ten French or larger diameter stents maintain their patency longer than smaller stents,³ but a therapeutic channel duodenoscope is required for their deployment. For most biliary applications, the largest caliber stent that can be accommodated by the anatomy is chosen. Stent length is generally based on the shortest possible stent that will extend from just above the obstructing stricture or sphincter to the duodenum without the end of the stent impacting on the opposing duodenal wall.

Pancreatic stents incorporate variations in design to minimize injury to the pancreatic duct (smaller calibers, greater flexibility), facilitate drainage from pancreatic side branches (side holes along the entire length, star-shaped cross section), and facilitate spontaneous passage without inward migration—especially important after prophylactic applications (absence of internal flaps, presence

of a single pigtail at the duodenal end). They range from 3F to 7F in diameter and from 2 to 15 cm in length (Table 2). A novel pancreatic stent designed to avoid occlusion of side-branch duct openings became available recently: ViaDuct Pancreatic Stent (GI Supply, Camp Hill, Penn). It dispenses with the usual stent design in which the central lumen serves as the main conduit for pancreatic juice in favor of a plastic tube with a surface ribbed in a star shape, which maintains duct caliber and acts as a wick for flow of juice along its surface. The small central lumen accommodates a 0.018-inch (5F stents) or 0.025-inch (7F stents) guidewire, and its role as a drainage conduit is secondary.⁴ Plastic biliary stents are placed using a pusher tube over a guidewire with or without a stiff inner guiding catheter. Delivery systems that combine the guiding and pushing catheters, with or without a preloaded stent, are now available both for traditional systems and also for newer, operator-centered systems that utilize a short guidewire controlled by the operator (RX Biliary System, Boston Scientific Corporation, Natick, Mass; Fusion, Wilson-Cook Medical Inc., Winston-Salem, NC; and V-system, Olympus America Inc., Melville, NY). With these systems, the guidewire can be locked into place, making device exchange easier. Pancreatic stents are placed using a pusher tube over a guidewire.

Self-expanding metal stents

Self-expanding metal stents (SEMS) were developed to overcome the problem of early stent occlusion, which plastic stents are prone to as a result of internal adhesion of bile, protein, and bacteria. The large diameter of the lumen in fully deployed SEMS is associated with significantly prolonged stent patency. Most SEMS for ERCP applications are made of Nitinol, a superelastic nickel-titanium alloy with thermal shape memory, a property of reassuming a predetermined shape through heating.⁵ Elgiloy, a cobalt based alloy, is employed in some stents. SEMS are available in different designs and sizes and with different delivery systems (Table 3). A common feature of all delivery systems is that the stent is constrained on a catheter by a sheath that covers the entire length of the catheter. Deployment is achieved by withdrawing the sheath, thus allowing expansion of the stent. Some designs allow stent expansion without significant shortening, whereas other designs shorten as they expand—a characteristic that must be taken into consideration during deployment. The main difference between delivery systems is in the design of the handles and their means of sheath withdrawal for deployment. Contrast injection is possible during stent deployment; however, the guidewire may have to be temporarily removed, depending on the delivery system. The radiopacity of some metal stents is enhanced by incorporating other metals into the body or the ends of the stent. Membrane-coated SEMS (Wallstent, Boston Scientific Corporation, Natick, Mass; and Viabil, W. L. Gore and Associates Inc., Flagstaff, Ariz) are designed to limit tissue ingrowth through the metal latticework.^{6,7}

INDICATIONS AND EFFICACY

Malignant biliary obstruction

Stent management of biliary obstruction is thoroughly reviewed in a parallel ASGE standards of practice review.⁸ Endoscopic stent placement for relief of malignant biliary obstruction improves quality of life.^{9,10} A randomized trial reported significantly reduced procedure-related mortality, major complication rates, and length of hospital stay after endoscopic drainage with plastic stents when compared to surgical bypass.¹¹ Numerous studies document the long-term efficacy of SEMS for malignant biliary obstruction.¹²⁻¹⁵ A number of studies have compared SEMS to plastic stents.¹⁶ Cumulatively these studies show no difference in survival but improvements in time to first obstruction, number of hospital days, use of antibiotics, number of ERCPs, use of transabdominal US, and overall cost with use of SEMS rather than plastic stents.¹⁷ It is now generally accepted that SEMS placement is the appropriate palliative procedure for patients with an expected survival of ≥ 6 months. Although preliminary experience with coated SEMS did not demonstrate improved stent patency, there are now reports to the contrary.¹⁸ There appears to be no difference in the patency rate between metal stents of woven mesh vs Gianturco Z-design.¹⁹

Benign biliary strictures

Uncontrolled series report benefit from endoscopic dilation followed by placement of plastic stents for biliary strictures caused by postoperative injuries,^{20,21} liver transplantation,²²⁻²⁶ primary sclerosing cholangitis,²⁷⁻²⁹ and chronic pancreatitis.^{30,31} Endoscopic therapy for postoperative strictures using serial placement of multiple large caliber plastic stents for 6 to 18 months yields long-term success in about 80% of patients.^{21,23,24,32-38} Endoscopic therapy with stent placement is definitive for only a minority of patients with chronic pancreatitis induced strictures.³⁹⁻⁴³ Surgical biliary bypass remains the procedure of choice for patients who are good operative candidates.⁴⁴ Currently available SEMS are not reliably removable and hence are not approved for benign pancreatic or biliary applications.

Miscellaneous biliary entities

Postoperative bile leaks are well treated by all therapies that effectively reduce the transpapillary pressure gradient, including endoscopic stent placement, nasobiliary drainage, and/or sphincterotomy.⁴⁵⁻⁵³ Stent placement alone is successful in up to 100% of patients with leaks after cholecystectomy. Biliary obstruction due to choledocholithiasis is adequately palliated with biliary stent placement when sphincterotomy and complete stone extraction cannot be accomplished due to technical factors or comorbidities.⁵⁴⁻⁵⁶ Spontaneous disintegration of large stones has been observed after stent placement,

TABLE 1. Plastic biliary stents

	Manufacturer/shape									
	ConMed		Hobbs Medical†		Microvasive		Olympus		Wilson-Cook	
	ACS	DP	ACS	DP	ACS	DP	ACS	DP	ACS	DP
Size (F)*										
5										√
6										√
7	√	√	√	√	√	√	√	√	√	√
8.5					√				√	
10	√	√	√	√	√	√	√		√	√
11.5					√				√	
12	√				√		√			
Length (cm)										
1										√
2.5							√			
3							√	√		√
4		√		√			√	√		√
4.5							√			
5	√		√		√	√	√		√	√
6							√		√	
6.5							√			
7	√	√	√	√	√		√	√	√	√
8							√		√	
8.5							√			
9	√		√				√		√	√
10	√	√	√	√	√	√	√	√	√	√
10.5							√			
11							√		√	
12	√		√		√		√		√	√
12.5							√			
13							√		√	
14							√		√	
15	√			√	√	√	√	√	√	√
> 15									√	
Material										
Nylon					√					
Polyethylene					√		√		√	
Polyurethane	√‡				√					
Teflon									√	
Two layer							√			

TABLE 1 (continued)

	Manufacturer/shape										
	ConMed		Hobbs Medical†		Microvasive		Olympus		Wilson-Cook		
	ACS	DP	ACS	DP	ACS	DP	ACS	DP	ACS	DP	
Operator centered system	No		No		Yes			Yes		Yes	
Price											
Stent	60		40		69			45-47		57	
With delivery system	115-130		86		119-159			117-198		123	
With operator centered system	N/A		N/A		139			N/A		123	

ACS, Angled, curved, or straight; DP, double pigtail.

*Stents > 10Fr require a 4.2 mm channel duodenoscope.

†Hobbs Medical did not disclose their stent material for this review.

‡Covered with hydromer coating.

presumably as a result of mechanical friction between stent and stone.⁵⁷

Malignant pancreatic duct obstruction

In 2 studies, a total of 14 out of 18 patients with severe pain secondary to malignant obstruction of the duct responded with reduction of pain after duct decompression with a plastic or metal stent.^{58,59}

Benign pancreatic diseases

Numerous uncontrolled studies have described symptomatic benefit of pancreatic duct stenting for painful chronic pancreatitis. Endoscopic duct decompression using stenting and allied modalities (sphincterotomy, dilation, lithotripsy, and stone removal) results in pain relief in two thirds of patients,⁶⁰ but surgery seems to provide more durable long-term pain relief.⁶¹ A single randomized trial of stent placement for acute pancreatitis in the setting of pancreas divisum showed a decreased number of recurrent attacks of pancreatitis in those patients who underwent minor papilla stenting.⁶² Several series reported utility of stenting for treatment of pancreatic duct leakage and its complications.⁶³⁻⁶⁵

Prevention of post-ERCP pancreatitis

The published literature on the benefits of pancreatic duct stenting for prevention of post-ERCP pancreatitis is conflicting.⁶⁶⁻⁷⁰ Four studies were randomized controlled trials,^{66-68,70} and 1 used historical controls.⁶⁹ Three of the studies^{67,68,70} showed stenting to be beneficial

whereas 2^{66,69} demonstrated no statistically significant benefit. A recent meta-analysis of these 5 studies pooled the data on the 481 enrolled patients and concluded that placement of a pancreatic duct stent during ERCP reduces the incidence of post-ERCP pancreatitis by two thirds (15.5% vs 5.8%) in selected high-risk patients with suspected sphincter of Oddi dysfunction, difficult cannulation, precut sphincterotomy, and endoscopic balloon dilation of the papilla.⁷¹ There was a significant reduction in the risk of mild to moderate acute pancreatitis and a trend toward reduction of severe pancreatitis. Stent placement was successful in 93% of patients. Stents used were either 5F or 7F in diameter and 2 to 5 cm long.

SAFETY

The major risks of stent placement include pancreatitis, failed or inadequate positioning (resulting in early cholangitis), migration, perforation, and late cholangitis related to stent occlusion. Postprocedure pancreatitis is reported to occur more commonly in patients undergoing biliary stent placement for proximal biliary strictures; sphincterotomy may reduce this risk by relieving stent-related compression of the pancreatic orifice.^{72,73} There is an increased incidence of post-ERCP cholangitis when drainage is not achieved, especially in patients with hilar obstruction.^{74,75}

Mechanisms of late stent occlusion due to bacterial infection and biofilm/sludge adhesion are now better understood. A recent randomized study showed prolonged

TABLE 2. Pancreatic stents

Feature	Manufacturer/shape							
	GI Supply		Hobbs Medical		Olympus		Wilson-Cook	
	S	SP	S	SP	S	SP	S	SP
Size (F)								
3							√	5, 7, 9
4			√					
5	√	√	√	√			√	3-15
7	√	√		√	√		√	√
Length (cm)								
2			√		√			√
3	√	√	√	√			√	√
4					√		√	√
5	√	√		√			√	√
6					√		√	√
7	√	√		√			√	√
8					√		√	√
9	√	√		√			√	√
10					√		√	√
11				√			√	√
12	√	√			√		√	√
13							√	
14							√	
15							√	
Material	Polyurethane		Not available*		Polyethylene		Polyethylene	
Price (\$) (stent/preloaded)	58		40		49		57/123	

S, Straight; SP, single pigtail.

*Hobbs Medical did not disclose their stent material for this review.

patency rates for the Olympus DoubleLayer stent compared to conventional polyethylene stents.⁷⁶ However, clinical studies attempting to prevent plastic stent occlusion with antibiotics and/or choleretics have yielded conflicting results,⁷⁷⁻⁷⁹ and trials employing variations in material, coating, design, and anatomic positioning have yielded generally disappointing results.⁸⁰⁻⁹³

Metal stent occlusion may also present with cholangitis. Occlusion of SEMS can result from ingrowth of tumor or hyperplastic inflammatory tissue through the interstices of the stent or overgrowth at the end of the stent. As uncovered stents are generally permanent, occlusion is usually managed by insertion of additional plastic or metal stents.^{14,94}

Complications of pancreatic duct stenting are numerous and include development or exacerbation of pancreatitis, pancreatic infection, pancreatic duct disruption, outward or inward migration, stent occlusion, and pancreatic duct injury and stricturing mimicking chronic pancreatitis.^{42,63,95-103} Pancreatic stent occlusion rates approach 50% by 6 weeks and 100% by 9 weeks.⁹⁹ Pancreatic ductal and parenchymal changes occur for at least several weeks in up to 80% of patients undergoing stenting, and in one third of patients, the changes persist.^{102,104-108} Undesired outward pancreatic stent migration has been described in 7.5% of patients, and inward migration occurs in 5.2% of patients.⁹⁷

TABLE 3. Metal biliary stents

Feature	Manufacturer/stent				
	Conmed (Bard) Luminexx	Microvasive Wallstent	Ultraflex Diamond	Wilson-Cook Zilver	W. L. Gore & Associates Viabil*
Deployed diameter (mm)	8, 10	8, 10	8, 10	6, 8, 10	8, 10
Deployed length (mm)	4, 6, 8, 10	4, 6, 8, 10	8, 10	6, 8, 10	4, 6, 8, 10
Delivery system diameter (F)	7.5	7.5 & 8	9.25	7	10
Operator centered system available†	No	Yes	No	Yes	No
Design	Laser cut from Nitinol	Braided	Wound	Laser cut from Nitinol	Wound
Cell design		Closed	Open		Open
Fenestration size (mm ²)	Not available	2.4	17	Not available	N/A
Covered stent Available	No	Yes (proprietary Permalume® covering)	No	No	Only configuration (non-porous inner and outer surface polytetrafluoroethylene and fluorinated ethylene propylene liner)
Radiopacity	Tantalum spoons at the ends of the stent	Elgiloy wire with Tantalum core	Platinum-iridium marker bands attached to stent	Gold markers at the ends of the stent	Gold markers at the ends of the stent and indicating the fenestrated segment
Shortening (%)	< 1	40	12	0	0
Reconstrainable	No	Yes	No	No	No
Contrast injection	Yes (with guidewire removed)	Yes (after deployment/ Not with the RX line of products)	Yes (via guidewire port)	Yes	Yes (via guidewire port)
Material	Nitinol	Elgiloy	Nitinol	Nitinol	Nitinol
MRI compatible	Yes (up to 3 Tesla static magnetic fields)	Yes (up to 1.5 Tesla static magnetic fields)	Yes (up to 1.5 Tesla static magnetic fields)	Yes	Yes (up to 1.5 Tesla static magnetic fields)
Price (\$)	1250-1550	1400-1600	1250	1200-1250	1750

*The full length of Viabil stents is covered. A configuration with a 2 cm fenestrated terminal segment is available for hilar applications in 6, 8, and 10 cm lengths. Availability currently limited to 10 initial release sites.

†Operator centered refers ability to deploy stent over a "short" guidewire.

FINANCIAL CONSIDERATIONS

Stent costs are listed in Tables 1 through 3. Cost analyses have suggested that metal stent placement is the least

expensive initial treatment in patients with malignant biliary obstruction who are expected to survive at least 6 months.^{14,15} A decision analysis comparing different strategies of metal or plastic stent placement for malignant

TABLE 4. CPT codes and APC facility group codes for endoscopic placement and/or removal of biliary or pancreatic stents

Procedure	CPT Code	APC* Group
ERCP with placement of biliary or pancreatic stent	43268	0384
ERCP with removal of biliary or pancreatic stent	43269	0384
EGD with removal of foreign body (eg, a stent)	43247	0141

*Ambulatory Payment Classification.

biliary obstruction found that the most economical strategy was strongly dependent on the ratio of metal stent cost relative to ERCP cost, as well as patient survival.¹⁰⁹

CPT code 43268 is used to report ERCP with placement of a stent into the bile duct or the pancreatic duct. Removal of a biliary or pancreatic stent is reported with CPT 43269 if a repeat ERCP is performed, or with CPT 43247 if stent removal is accomplished during standard upper endoscopy (without repeat ERCP). Reimbursement for these procedures varies based upon the setting, the payor, and individual components of the procedure. Medicare incorporates the costs of stents and delivery devices into the facility payment as determined by the Ambulatory Payment Classification (APC) for outpatient procedures and the Diagnosis Related Group (DRG) payments for inpatient procedures. For outpatient services, the APC for the ERCP procedure includes the fluoroscopic monitoring and image recording. 2005 Medicare professional fees and facility payments for biliary and pancreatic stent placement and/or stent removal are listed in Table 4. When a biliary and/or pancreatic stricture requires dilation prior to stent placement, this should be reported separately (43271). Insertion of each additional stent should be reported separately with the -59 modifier (distinct procedural service). Some payers may not recognize this and reimburse for only the single service.

SUMMARY

Plastic biliary stents are easy to insert, inexpensive, easily removed, and effective for a wide variety of indications.

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Metal stent placement can be justified for patients with inoperable cancer who are expected to survive ≥ 6 months. Metal stents are currently not approved for benign disorders. Pancreatic stents have gained acceptance for management of several benign pancreatic conditions and reduction of post-ERCP pancreatitis in high-risk patients.

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Prepared by:
Lehel Somogyi, MD
Ram Chuttani, MD
Joseph Croffie, MD
James DiSario, MD
Julia Liu, MD
Daniel S. Mishkin, MD
Raj Shah, MD
William Tierney, MD
Louis M. Wong Kee Song, MD
Bret T. Petersen, MD, Chair
