Communication from the ASGE Technology Committee

STATUS EVALUATION REPORT

Tools for endoscopic stricture dilation

INTRODUCTION

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 used whereby a MEDLINE literature search is performed to identify pertinent clinical studies on the topic, a MAUDE (U.S. 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 used. 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 August 2012 for articles related to dilation by using the keywords "endoscopic dilation," "bougie dilators," "balloon dilators," "esophageal strictures," "anastomotic strictures," "inflammatory bowel strictures," "pancreatic strictures," "biliary strictures," "colonic strictures," "achalasia," "pyloric stenosis," and "self-expanding metal stents." Practitioners should continue to monitor the medical literature for subsequent data about the efficacy, safety, and socioeconomic aspects of these technologies.

BACKGROUND

Strictures may occur throughout the GI tract and can occur from a variety of benign and malignant etiologies. Stricture dilation may be indicated when there is associated clinical impairment or a need to access beyond the stricture for diagnosis or therapy. A variety of devices and techniques are available for use in the GI lumen and pancreaticobiliary system. This status evaluation report describes the dilating tools used in GI endoscopy.

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TECHNOLOGY UNDER REVIEW

Dilation is accomplished by application of expansible forces against a luminal stenosis. Dilators used in GI endoscopy can be organized into 2 categories: fixed-diameter push-type dilators (bougie dilators) and radial expanding balloon dilators. Fixed-diameter push-type dilators exert radial forces and also cause a shearing effect that exerts longitudinal forces as they are advanced through a stenosis.[1] Balloon dilators only exert radial forces when expanded within a stenosis.

Dilators for the GI lumen

Bougie dilators. Bougie dilators come in a variety of designs, calibers, and lengths (Table 1). They are used primarily in the treatment of esophageal strictures and can be purchased individually or in sets of varying calibers. Most bougie dilators are designed to be reused. Users should refer to the manufacturer's instructions for guidance on reprocessing.

Hurst and Maloney dilators (Medovations, Milwaukee, Wisc, and Teleflex Medical, Research Triangle Park, NC) are flexible push-type dilators that do not accommodate a guidewire.[2-4] They are available in a variety of diameters. They are internally weighted with tungsten for gravity assistance when passed with the patient in the upright position. Hurst dilators have a blunt, rounded tip, whereas Maloney dilators have an elongated, tapered tip. Patients may be instructed to use these devices for self-dilation. Older bougies were internally weighted with mercury, but because of concerns over exposure via ruptured dilators or improper disposal, mercury has now been replaced with tungsten in newer bougies.

Wire-guided bougie dilators are flexible, tapered, polyvinyl chloride, latex-free cylindrical solid tubes with a central channel to accommodate a guidewire. Savary-Gilliard dilators (Cook Medical, Winston-Salem, NC) have a long tapered tip and a radiopaque marking at the base of the taper designating the point of maximal dilating caliber. American Dilation System dilators (ConMed, Utica, NY) have a shorter tapered tip, and total radiopacity throughout their length. Bougie dilators have external markings

TABLE 1. Esophageal bougie dilators

	Size, F	Cost (US$)
Nonwire guided		
Medovations		
WeightRight Mercury-Free Bougies		
Maloney (tapered) Tip	16-60	137-392
Hurst (blunt) Tip	16-60	137-392
Set of 23 Maloney dilators	16-60	5065
Set of 10 Maloney dilators	36-54	2571
Set of 23 Hurst dilators	16-60	5065
Set of 10 Hurst dilators	36-54	2571
M-Flex Blue Silicone Bougie		
Maloney (tapered) tip	20-60	137-392
Hurst (blunt) tip	20-60	137-392
Set of 21 Maloney dilators	20-60	4726
Set of 10 Maloney dilators	36-54	2571
Set of 21 Hurst dilators	20-60	4726
Set of 10 Hurst dilators	36-54	2571
Wire guided		
Medovations		
SafeGuide Dilators		
Individual dilators	15,18,21,24,27,30,33,36,39,42,45,48,51,54,57,60	300
16-piece full set	15-60 dilators, storage case, guidewire, cleaning brush, 25 cleaning adaptors	4200
7-piece mini set	15,21,27,33,39,42,45 dilators, storage case, guidewire, cleaning brush, 25 cleaning adaptors	2000
Conmed		
American Dilators		
Individual	15,18,21,24,27,30,33,36,39,42,45,48,51,54,60	393
Set of 15 dilators	15-60	4998
Cook Medical		
Savary-Gilliard Dilators		
Standard set	15,21,24,33	2594
Set of 16 dilators	15-60	5966
Long set	15,21,27,33,36,42,45	2644
Set of 16 dilators	15-60	6442

indicating the distance from the tip (American) or from the largest diameter (Savary-Gilliard).

A variation on the standard bougie dilator exists, which is a flexible, transparent bougie fitted over a standard endoscope, with 3 dilating segments allowing sequential dilation under direct visualization (InScope Optical Dilator; Ethicon Endosurgery, Inc, Blue Ash, Ohio).[5]

Tucker dilators (Teleflex Medical) are small silicone bougies tapered at each end; loops on each end can be pulled antegradely or retrogradely across strictures.

A gastrostomy is required for use. These may be useful in the treatment of tortuous strictures secondary to caustic substance ingestion.[6,7] In very tight strictures in which there is the possibility of complete lumen occlusion, a string must be maintained across the stricture emerging from both the nose and gastrostomy site between dilations. Tucker dilators range in size from 4 to 13.3 mm (12F-40F).

Hegar's dilators (Cooper Surgical, Trumball, Conn) are stainless steel bougies with rounded ends that can be used for dilation of benign anorectal strictures. They have been used to dilate stenoses after transanal surgery and in cases of perianal Crohn's disease.[8,9] In addition to being used by colorectal surgeons and gastroenterologists, patients can also use them to self-dilate anal strictures. Hegar's dilators range in size from 3 to 18 mm (9F-54F).

Balloon dilators. Radial expanding balloon dilators are available in an array of designs, lengths, and calibers for various purposes in accessible strictures throughout the GI tract (Tables 2 and 3). They are designed to pass through the endoscope with or without wire guidance so that dilation can be observed. Balloon dilators are made of low-compliance inflatable thermoplastic polymers that allow uniform and reproducible expansion to their specified diameter at maximum inflation. Some balloons have 1 set diameter, whereas others allow for sequential expansion to multiple diameters. Dilating balloons are expanded by pressure injection of liquid (eg, water, radiopaque contrast) by using a handheld accessory device. The hydraulic pressure of the balloon is monitored manometrically to gauge radial expansion force. Inflation with radiopaque contrast enhances fluoroscopic observation. Dilating balloons are marketed as single-use items.

Achalasia balloon dilators. Achalasia balloon dilators are large-diameter (30, 35, and 40 mm) polyethylene balloon dilators that are disease specific for achalasia but also have been used in other disease states.[10-13] Available achalasia balloons are listed in Table 4. All currently used achalasia balloon dilators are wire guided and single use and do not pass through the endoscope. They are positioned across the esophagogastric junction by using fluoroscopic guidance with visualization aided by the radiopaque markers on the balloon. Balloon insufflation with air is monitored manometrically.

Stents

Fully and partially covered self-expandable stents that are potentially removable have been used to accomplish dilation of refractory benign strictures. This is accomplished through the use of their radial expandable forces. A variety of covered self-expandable metal stents (SEMSs) and 1 self-expandable plastic stent (SEPSs) are available as well as some that are biodegradable; biodegradable stents are not available in the United States at this time. A full ASGE Technology Committee review of enteral stents, including those used primarily to accomplish dilation, is available.[14]

Dilators for the pancreaticobiliary system

Dilating catheters. Dilator catheters designed for pancreaticobiliary use are tapered plastic cylindrical tubes with a central channel (Table 5). They are passed over a guidewire through the accessory channel of the side-viewing duodenoscope. They are equipped with a radiopaque band to indicate the point of maximal diameter.

Screw-tip stent retrievers (Soehendra Stent Retriever; Cook Medical) also have been used to dilate tight pancreaticobiliary strictures that otherwise only allow passage of a guidewire.[15-17] The wire-guided device is used to bore through high-grade stenoses. A modified device is commercially available as a dilator (Soehendra rotary dilator; Cook Medical).

Balloon dilators. Balloon dilators are used in the bile duct and the pancreatic duct (Table 5). These balloons are single use and wire guided, come in a single-diameter size (4-10 mm diameter), and range from 2 to 4 cm in length. They are used during ERCP and inflated with dilute contrast to facilitate visualization. If undiluted contrast is used, its increased viscosity may hinder proper inflation and deflation of the balloon. Radiopaque markers on both ends of the balloon help to guide proper placement across a stricture.

In addition to dilation of strictures, balloon dilation of the biliary and pancreatic sphincters can be performed. Sphincteroplasty with balloon dilators may be performed instead of sphincterotomy when preferred by the endoscopist by using smaller caliber biliary dilating balloons (eg, $\leq$10 mm). Larger caliber dilation of the sphincter (10-20 mm) may also be may be done after sphincterotomy to facilitate removal of large caliber stones. Currently, there is only 1 balloon dilator approved by the U.S. Food and Drug Administration for this specific use (CRE; Boston Scientific, Natick, Mass).

TECHNIQUE

Dilation can be performed with or without endoscopic, fluoroscopic, and/or wire guidance. Selection of different types of dilators depends on operator preference and the characteristics of the site needing dilation. Dilator diameters are measured in millimeters or French. Size in millimeters can be converted to French at a ratio of 1:3 (eg, 15 mm = 45F). Selection of the appropriate size is critical for safe and effective dilation. Techniques may need to be modified for complex strictures (eg, length >2 cm, lumen diameter <12 mm, tortuous) and/or specific disease states and locations in the GI tract.

Wire-guided bougie dilators (Savary and American dilators) are passed over a guidewire after initial endoscopic guidewire placement and subsequent endoscope removal.

TABLE 2. Esophageal balloon dilators

Sizes (some dilators have sequential sizes), mm)	Balloon length, cm	Required channel, mm	Usable length, cm	Cost, US$
Cook Medical				
Hercules balloon dilators				
Nonwire guided, esophageal: 8,9,10; 10,11,12; 12,13.5,15; 15,16.5,18; 18,19,20	8	2.8	180	248 per dilator
Wire-guided, esophageal/pyloric/colonic: 8,9,10; 10,11,12; 12,13.5,15; 15,16.5,18; 18,19,20	5.5	2.8	240	289 per dilator
Quantum TTC balloon dilators, esophageal: 6,8,10,12,14,16,18,20	8	2.8	195	189
Eclipse balloon dilators, wire-guided, esophageal: 6,8,10,12, 14,16,18	8	2.8	240	262
19	8	3.2	240	262
Boston Scientific				
CRE balloon dilation catheters, fixed-wire (nonwire guided), esophageal: 6,7,8; 8,9,10; 10,11,12; 12,13.5,15; 15,16.5,18; 18,19,20	8	2.8	180	235
CRE balloon dilation catheters: wire guided, esophageal/pyloric/biliary: 6,7,8; 8,9,10; 10,11,12; 12,13.5,15; 15,16.5,18; 18,19,20	8	2.8	180	314
CRE balloon dilation catheters: wire guided esophageal/pyloric/colonic/biliary: 6,7,8; 8,9,10; 10,11,12; 12,13.5,15; 15,16.5,18 18,19,20	5.5	2.8	240	260
Maxforce esophageal balloon dilators: 6,8,10,12,14,15,16,18	6	2.8	180	180
Conmed				
Eliminator PET esophageal balloon dilator: 6,8,10,12,15,18,20	8	2.8	180	214
Hobbs Medical				
Flex-Ez over-the-wire balloon dilators, esophageal/pyloric/colonic				
8,10,12	3	2.8	240	155
14,16,18,20	3	3.7	240	165
6,8,10	4	2.8	240	155
16,20	4	3.7	240	165
8,10,12,14	8	3.7	240	155
16,18,20	8	3.7	240	165
Stylet wire balloon dilators, esophageal/pyloric/colonic				
12,14	8	2.8	240	155
16,18,20	8	2.8	240	165
8,10,12,14	5.5	2.8	240	155
16,18,20	5.5	2.8	240	165
8,10,12,14	3	2.8	240	155
16,18,20	3	2.8	240	165

TABLE 3. Pyloric/colonic balloon dilators*

Size, mm	Balloon length, cm	Required channel, mm	Usable length, cm	Cost, US$
Cook Medical				
Quantum TTC balloon dilators				
Pyloric: 6,8,10, 12,14,18,20	5.5	2.8	195	189
Colonic: 6,8,10, 12,14,16,20	5.5	2.8	240	189
Eclipse TTC balloon dilators, wire guided				
Pyloric/colonic: 6,8,10,12,14,16,18	5.5	2.8	240	262
20	5.5	3.7	240	262
Conmed				
Eliminator PET pyloric/colonic balloon dilator				
6,8,10,12,15,18, 20	4	2.8	230	214

*See also esophageal balloon dilators in Table 2 also used for pyloric/colonic dilation.

TABLE 4. Achalasia balloon dilators

Description	Balloon length, cm	Usable length, cm	Cost, US$
Cook Medical			
Inflated balloon diameter 30 mm, 16F catheter	8	75	422
Inflated balloon diameter 35 mm, 16F catheter	8	75	422
Boston Scientific			
Rigiflex balloon, inflated balloon diameter 30, 35, 40 mm; 14F catheter	10	90	650
Hobbs Medical			
Inflated balloon diameter 30, 35, 40 mm; 16F catheter	10	100	335

Nonwire-guided bougies (Hurst and Maloney) are passed blindly into the esophagus. These may have a higher rate of perforation in the presence of large hiatal hernias or complex strictures.

Balloon dilators in the GI tract may be passed with or without wire guidance. They are expanded with liquid (water and/or contrast) by using a handheld inflation device. Wire-guided through-the-scope (TTS) balloon dilators are passed over a guidewire that has been placed through the endoscope accessory channel. The balloon is positioned across the stenosis and inflated under direct endoscopic visualization. Nonwire-guided balloons are used in a similar fashion but are passed across the stenosis by using endoscopic visualization only. The optimal duration of balloon inflation is not known.

Initial selection of a specific size of dilator is based on an estimation of the diameter of the stenosis. The rule of 3 has been used when deciding how much to dilate a stricture with a bougie dilator in 1 session. This rule states that after moderate resistance is encountered, no more than 3 dilators of progressively increasing diameter should be passed in that session.[18] However, no studies have demonstrated that this technique improves safety and efficacy.[19] When dilating a symptomatic Schatzki ring of the esophagus, passage of a single large-diameter dilator (eg, 16-20 mm) has been advocated to allow for disruption of the ring.[20,21]

Modifications to standard dilation are sometimes used, especially in the case of refractory benign strictures. These include injection of steroids immediately before or after dilation.[22-24] Disruption of strictures (eg, esophageal webs, Schatzki rings) with biopsy forceps or needle-knife electrocautery, either as the sole treatment or in conjunction with dilation, has been successfully demonstrated.[25,26] Electroincision therapy has also been used in the treatment of refractory benign esophageal strictures.[27,28]

TABLE 5. Biliary and pancreatic dilators*

Dilation catheters

Description	Catheter size, F	Tapered tip length, cm/tip catheter size, F	Usable length, cm	Cost, US$
Cook Medical				
Soehendra biliary dilation catheters (wire guided 0.035-inch)				
	6	3/4	200	82
	7	3/4	200	82
	8.5	3/5	200	82
	9	3/6	200	82
	10	3/6	200	82
	11.5	3/7	200	82
Cotton dilation catheters (used to dilate the papilla or biliary strictures); wire guided 0.035-inch				
	8.5	4/7-5	200	82
	10	4/7-5	200	82
	7	2.5/7-4.5	200	82
	7	4.5/7-4.5	200	82
Geenen graduated dilation catheter (for pancreatic strictures); wire guided 0.025-inch	7	2/5-4	200	82

Biliary balloon dilators

Size, mm	Balloon length, cm	Required channel, mm	Usable length, cm	Cost, US$
Cook Medical				
Quantum TTC biliary balloon dilators				
4,6,8,10	3	2.8	180	189
Fusion Titan biliary balloon dilators: wire-guided				
4,6,8,10	4	3.2	190	372
Boston Scientific				
Hurricane Rx biliary balloon dilators				
4,6,8,10	2	3.2	180	279
4,6,8,10	4	3.2	180	279
Olympus				
MaxPass biliary balloon dilators				
4,6	2	2.8	180	382
4,6	4	2.8	180	382
8	3	2.8	180	382

TABLE 5. Continued

Biliary balloon dilators

Size, mm	Balloon length, cm	Required channel, mm	Usable length, cm	Cost, US$
Conmed				
Eliminator PET biliary balloon dilators				
4,6	2	2.8	180	272
8	3	2.8	180	272
Hobbs Medical				
Biliary balloon dilators				
4,6	2	2.8	180	155
8	3	2.8	180	155

*See also Boston Scientific CRE Balloon Dilators: Wire-Guided Balloon Dilators used for biliary dilation in Table 2.

OUTCOMES AND COMPARATIVE DATA

Esophagus

Benign esophageal strictures. The majority of benign esophageal strictures are caused by long-standing GERD.[29] Other stricture etiologies include webs, Schatzki rings, anastomotic strictures, and inflammatory-type strictures caused by eosinophilic esophagitis, radiation exposure, and caustic substance ingestion. Multiple studies have shown that benign peptic strictures may be dilated with bougie or balloon dilators with technical success and decrease in dysphagia in the majority of cases.[30-33] Studies of use of balloon dilators in patients with a variety of benign esophageal strictures have demonstrated an excellent or good symptomatic response in 7% to 100% patients immediately after dilation.[3,34,35] However, a sustained response may be difficult to achieve in nonpeptic strictures, with symptom recurrence often occurring within 1 year of initial dilation.[36] The degree and duration of the effect and the need for repeat dilation are often dependent on the stricture etiology and the length and degree of stenosis. Durable success appears greatest when a luminal diameter of larger than 12 mm is achieved.[37] Complex strictures are described as being long (>2 cm), tortuous, or having a small lumen diameter that precludes passage of a standard endoscope.[38] These have been shown to have a poor response to dilation compared with simple strictures (ie, shorter length, larger caliber predilation diameter).[36]

Two randomized, controlled trials compare bougie dilators with TTS balloons for benign strictures of the esophagus. These trials, including a total of 379 patients, found no differences in efficacy at dysphagia relief or safety at 1 year.[30,32] A randomized prospective study of 26 patients compared a single dilation with 52F Maloney dilator versus endoscopic rupture of a Schatzki ring by using biopsy forceps. There was similar improvement in dysphagia scores at 3 and 12 months in both groups (both groups with 91% improvement at 3 months and 84% to 85% at 12 months). There were no significant differences in H_2 blocker or PPI use in either arm.[25]

Two randomized trials compared electrosurgical incision and bougie dilation (52-54F Maloney dilators) of Schatzki's rings. One study of 11 patients showed no difference in terms of dysphagia improvement or recurrence at 1 year.[39] A larger trial of 50 patients showed that the electrosurgical incision group had a longer symptom free time compared with the bougie group (7.99 vs 5.86 months; $P = .03$) and also had a greater improvement in dysphagia scores at 1 month ($P = .05$).[26] Another randomized study of 62 patients with anastomotic strictures after esophagectomy showed no difference in clinical success or complication rates between electrocautery incision and bougie dilation.[40]

Dilation has been shown to be effective in controlling dysphagia caused by eosinophilic esophagitis in uncontrolled case series with or without concomitant medical therapy. Type of dilator used in the studies was not standardized, but the majority had long-term relief (up to 2 years) after dilation.[41-44]

There are no randomized trials comparing the use of stents with other methods of dilation for the treatment of refractory benign esophageal strictures. Nonrandomized studies examining the use of SEPS in the treatment of refractory benign esophageal strictures have shown high complication rates including migration (22%-81%), chest pain (11%), bleeding (8%), and perforation (5.5%).[45-47]

Additionally, only 6% to 40% were dysphagia free after removal. Although not approved by the U.S. Food and Drug Administration for removability in benign esophageal strictures, the use of fully covered SEMSs use has been reported. Two recent small case series included 24 patients with benign esophageal strictures and showed low rates of long-term response (<20%) and high rates of stent migration (29%-34%).[48,49] A recent small prospective study of 30 patients examined 3 different types of stents (fully covered SEMSs, SEPSs, biodegradable stents) in the treatment of refractory benign esophageal strictures. There was long-term symptom improvement at 8 months in 30% to 40% of patients with fully covered SEMSs and biodegradable stents but only a 10% improvement with SEPSs.[50] Tissue ingrowth may occur at the ends of the stent, potentially affecting its removability.[51]

Achalasia. Pneumatic balloon dilation of the lower esophageal sphincter with a large diameter (>30 mm) cylindrical, wire-guided balloon has long been the mainstay of endoscopic therapy for achalasia. A brief 6-second dilation, sufficient to obliterate the balloon's waist, was shown to be as effective as the standard 60-second dilation.[52] The first prospective, randomized study to compare open surgical myotomy with pneumatic balloon dilation showed that surgery was significantly superior at 5-year follow-up, with excellent results in 95% of surgically treated patients compared with good results in only 65% of patients undergoing balloon dilation.[53] A more recent larger randomized, controlled trial comparing pneumatic dilation with laparoscopic myotomy showed no significant difference in clinical success with either approach at 2-year follow-up (86% vs 90%; $P = .46$).[54] A meta-analysis of 36 studies published between 2001 and 2011 found that laparoscopic myotomy had a more durable long-term response (generally defined as good or excellent symptom control) at 10 years compared with pneumatic dilation (79.6% vs 47.9%).[55]

Injections of botulin toxin into the lower esophageal sphincter were initially described in 1994 as an alternative endoscopic approach to achalasia.[56] Comparative trials of botulinum toxin injection and pneumatic balloon dilation for treatment of achalasia have shown equivalent early success rates but shorter duration of efficacy in the botulinum injection groups.[57-59] There are no data comparing the success and safety of the new surgical technique of peroral endoscopic myotomy with other endoscopic and surgical achalasia treatments.

Stomach and small bowel

Benign strictures of the stomach and small bowel (eg, pyloric stenosis, nonsteroidal anti-inflammatory drug–induced strictures, surgical anastomoses, inflammatory bowel disease) may be amenable to dilation for symptom control. Because of their location, these are typically managed by using TTS balloon dilators.

Multiple studies describe dilation of the pylorus to treat gastric outlet obstruction caused by benign conditions (eg, peptic ulcer disease), with short-term success rates of approximately 70% to 80%.[60-64] Perforation rates in some studies were fairly high (4%-7%),[60,63,65] and long-term success was poor, with 30% to 50% ultimately requiring surgery.[60,62] A more recent smaller study found long-term success was achieved in 100% at follow-up of 43 months; most patients were maintained on antisecretory therapy in this study.[65] Gastric outlet obstruction related to chronic pancreatitis responds poorly to endoscopic therapy.[66,67] Several uncontrolled studies evaluating balloon dilation in gastric bypass patients with gastroenteric anastomotic strictures have demonstrated high short- and long-term success rates. Dilation appears safe in this setting, with only a single study reporting a higher (4.9%) perforation rate.[68-72] Wire-guided TTS balloons are typically used for anastomotic strictures after gastric bypass surgery, but bougie dilators were used successfully in a single study.[73] Several uncontrolled case series suggest that balloon dilation is an efficacious treatment of upper and lower GI tract fibrotic strictures in patients with Crohn's disease, allowing long-term avoidance of surgery for the stricture in 56% to 75% of dilated patients.[74-78] There are a few reports of successful dilation of Crohn's strictures of the small bowel by using temporary SEMS placement. However, high rates of stent migration and other complications were noted.[79,80] Distal small-bowel strictures of various etiologies, inaccessible to standard endoscopes, have been accessed by using double-balloon enteroscopes with successful stricture dilation with TTS balloons.[81-84]

Pancreaticobiliary system

Benign biliary strictures associated with primary sclerosing cholangitis (PSC), postoperative bile duct injury, and duct-to-duct anastomoses after orthotopic liver transplantation are amenable to endoscopic dilation therapy.[85-87] Except for strictures associated with PSC, dilation alone is largely ineffective and should be accompanied by stent placement. No additional benefit from stenting after balloon dilation of dominant strictures in PSC was seen in 2 retrospective studies that included 81 patients with long-term follow-up of more than a decade.[88,89]

Multiple plastic stents have been used to successfully dilate and treat benign biliary strictures and have been shown to be superior to single stents for stricture resolution.[85,90,91] Recent uncontrolled series demonstrated successful use of temporary fully covered SEMSs in the treatment of benign biliary strictures of various causes, with resolution rates ranging from 83% to 90%.[92,93] Studies of benign biliary stricture caused by anastomotic stricture after liver transplantation have shown mixed results, with long-term resolution seen in 53% to 95% of patients and migration in as many as 46%.[94-97] One recently published prospective study randomized 31 patients with postoperative biliary strictures to treatment with either partially covered SEMSs or multiple plastic stents with long-term follow-up of more than 5 years. The SEMS group had higher long-term patency rates (81% vs 71%; $P = .02$) and similar complication rates (40% vs 25%; $P = .37$).[98] Biliary strictures related to chronic pancreatitis respond more poorly to endoscopic therapy, with long-term resolution after plastic stenting in 44% to 60%.[91] Somewhat better resolution of strictures caused by chronic pancreatitis was seen in 2 studies with use of fully and partially covered SEMS, with a 65% to 90% stricture resolution rate.[93,99] However, follow-up was short (3.8-6 months) and complications were noted in 20% to 30%.

Sphincter dilation. Dilation of the biliary sphincter has been investigated as a potential alternative to sphincterotomy to facilitate biliary stone removal, but this technique has been associated with higher rates of pancreatitis.[100-102] Two meta-analyses comparing endoscopic sphincterotomy with endoscopic papillary balloon dilation (<10 mm) showed similar outcomes with regard to overall stone removal but a higher rate of post-ERCP pancreatitis with papillary balloon dilation (7.4% vs 4.3%).[103,104] A recent meta-analysis of 7 randomized, controlled trials (790 patients) comparing endoscopic papillary large balloon dilation alone with biliary sphincterotomy alone found similar overall bile duct clearance rates (97% vs 96%; $P = .54$).[105] Balloon dilation was associated with decreased use of mechanical lithotripsy and less hemorrhage, but otherwise no difference in other complication rates (eg, post-ERCP pancreatitis, perforation, cholangitis).

Large-diameter (>10 mm) papillary balloon dilation after sphincterotomy has been shown to be effective in the removal of large bile duct stones without an increased rate of pancreatitis.[106] A technical review of 21 published studies of 1292 patients undergoing sphincterotomy with large-diameter papillary balloon dilation showed a 91% initial success rate and 98% final success rate.[107] There were low rates of reported complications including bleeding (2.8%) and post-ERCP pancreatitis (1.2%). Dilation of pancreatic duct strictures or sphincters is primarily used in concert with stone removal or stent placement.[108-110]

Colon

Dilation of benign colorectal strictures of varying etiologies (eg, anastomotic, nonsteroidal anti-inflammatory drug–induced, diverticulitis, radiation, and inflammatory bowel disease) by using balloon or bougie-type dilators has been demonstrated to be effective in multiple uncontrolled series.[111-118]

A prospective trial randomized 30 patients with symptomatic benign postoperative anastomotic colorectal strictures to dilation with either an 18-mm TTS balloon dilator or an over-the-wire 35-mm pneumatic balloon dilator designed for achalasia. Dilation was successful in all patients, and no complications occurred in either, but the over-the-wire group required fewer sessions (1.6 vs 2.6, $P = .009$) and had a longer duration of response (560.8 days vs 245.2 days, $P = .016$).[119]

SAFETY

All dilation is intended to displace tissue. Therefore, some disruption of mural elements, including mucosal tears and minor bleeding, is expected. Complications of endoscopic stricture dilation include chest pain, clinically significant bleeding, bacteremia, and perforation.[120-122]

Types of strictures and the degree of dilation undertaken may influence the rate of major complications. Perforation, estimated to occur in 0.4% of cases, is the most clinically significant complication and occurs because of transmural disruption or the creation of a false track.[123] Transmural disruption may occur when axial or radial forces exceed the structural integrity limits of the wall. A false track occurs when the dilator directly penetrates the wall. Guidewire use may reduce this risk of perforation.[124] There are insufficient data to substantiate a difference in perforation rates with bougie versus balloon dilators. A retrospective analysis reported an increased perforation rate associated with blind passage of Maloney dilators versus Savary-Gilliard and balloon dilators in patients with complex esophageal strictures.[123] It has also been demonstrated that endoscopic experience influences perforation rates with esophageal dilation, with a 4 times higher rate noted when fewer than 500 diagnostic upper endoscopies had been performed.[125] Although endoscopic dilation has been associated with bacteremia,[122,126] it is rarely clinically significant, and current ASGE guidelines do not recommend routine antibiotic prophylaxis at the time of endoscopic dilation.[127]

Regarding achalasia dilation, pooled data indicate an approximately 2% to 4% cumulative perforation rate when using graded balloon dilation.[128] Other complications associated with achalasia dilation include prolonged pain and intramural hematomas.[129]

Multiple studies have demonstrated the safety of large balloon dilation after sphincterotomy for difficult biliary stones.[107] No increased rates of pancreatitis, perforation, cholangitis, or bleeding rates were shown.

Small case series have described the occurrence of large tears, chest pain, and a high rate of perforations after dilation in patients with eosinophilic esophagitis.[130,131] Larger retrospective studies have not found an increased risk of perforation. A recent retrospective review of 54 patients with eosinophilic esophagitis who underwent endoscopic dilation with Maloney, Savary-Gilliard, and TTS balloon dilators over a 5-year period did not report any major complications.[132] However, other studies reporting safety data for balloon versus bougie dilators in this population have shown disparate results, with some reporting higher complication rates with balloons and others with bougies.[41-43] Prospective data are not available at this time.

Complications with stent placement for stricture management include perforation, hemorrhage, and airway compression when placed in the proximal esophagus.[133-135] The risk of perforation after placement of colonic SEMSs for malignant obstruction is increased with predeployment dilation.[136-138]

TABLE 6. CPT codes and reimbursement for endoscopic dilation procedures, CMS national average unadjusted 2012

CPT*	Description	APC	Hospital outpatient payment, US$	Ambulatory surgery center payment (2012 averages 56% of HOPD), US$	Professional fee (facility), US$
43220	Esophageal endoscopy, dilation balloon	0419	887	497	129
43226	Esophageal endoscopy, dilation guidewire	0419	887	497	144
43248	EGD, dilation guidewire	0141	592	331	192
43249	EGD, balloon dilation of the esophagus	0419	887	497	177
43458	Dilation of the esophagus with a balloon >30 mm for achalasia	0419	887	497	184
43245	EGD with dilation of gastric outlet obstruction, any method	0419	887	497	191
45340	Flexible sigmoidoscopy, balloon dilation stricture	0147	773	432	118
45386	Colonoscopy, balloon dilation	0143	656	367	270
45303	Proctosigmoidoscopy, dilation any method	0147	773	432	91
43456	Dilation of the esophagus, retrograde	0140	460	258	158
43271	ERCP, balloon dilation ducts	0151	1729	968	434
43450	Esophagus dilation, no endoscopy (bougie)	0140	461	258	91 (office, $161)

APC, Ambulatory payment classification; *HOPD*, hospital outpatient department.

FINANCIAL CONSIDERATIONS

The list prices of the available dilators and stents for use in GI endoscopy are detailed in Tables 1 through 5. Reusable dilators have potential cost advantages over single-use devices, even when accounting for reprocessing costs. Costs of single-use and reusable guidewires, contrast agents, manometry gauges, inflation devices, and fluoroscopy are also cost considerations. Costs of stents far exceed those for dilating catheters and balloons.

Codes for dilation during endoscopy and reimbursement rates are listed in Table 6. For services performed after January 1, 2003, Medicare reimbursement no longer includes pass-through codes for dilators or ancillary equipment.

AREAS FOR FUTURE RESEARCH

Published studies have demonstrated the safety and efficacy of the various types of dilating catheters and balloons in the treatment of strictures throughout the GI tract. The optimal treatment of refractory benign GI tract strictures needs to be clarified. Prospective trials of dilation therapy versus other treatments in eosinophilic esopaghitis would be helpful. Previously limited to use in malignant strictures, new variations of SEMSs are being used in refractory benign strictures in the esophagus, colon, and various surgical anastomoses (including after Roux-en-Y gastric bypass surgery). Prospective, randomized studies should be performed comparing dilation with SEMS placement of various types to determine safety, efficacy, ease of use, and cost benefits.

CONCLUSIONS

Fixed-diameter push-type dilators and radial expansion balloon dilators are safe and effective for endoscopic management of benign and malignant strictures throughout the digestive tract. Both types have comparable efficacy and safety, although wire-guided balloon dilators are usually required for locations other than the esophagus. Lower costs are associated with the multiuse, fixed-diameter, push-type dilators. Fully covered SEMSs are increasingly being used for the management of refractory benign GI strictures. Further study is needed to determine the safety, efficacy, and cost advantages of stents for this expanded indication.

DISCLOSURE

The authors disclosed no financial relationships relevant to this publication.

Abbreviations: PSC, primary sclerosing cholangitis; SEMS, self-expandable metal stent; SEPS, self-expandable plastic stent; TTS, through-the-scope.

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