



TECHNOLOGY STATUS EVALUATION REPORT

Tools for endoscopic stricture dilation

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INTRODUCTION

To promote the appropriate use of new or emerging technologies, the ASGE Technology Committee has developed a series of status evaluation papers. This process presents relevant information about these technologies to practicing physicians for the education and the care of their patients. In many cases, data from randomized controlled trials are lacking and only preliminary clinical studies are available. Practitioners should continue to monitor the medical publications for subsequent data about the efficacy, safety, societal, and economic aspects of the technologies.

BACKGROUND

Benign and malignant strictures from diverse etiologies may occur in any portion of the GI tract. Dilation of strictures is indicated whenever there is associated clinically significant functional impairment or a need to access beyond the stricture for diagnosis or therapy. A variety of devices are available for dilation of digestive tract strictures. Many dilators have indication-specific characteristics; others are relatively generic in design. This status evaluation report will describe the dilators used in GI endoscopy.

TECHNOLOGY UNDER REVIEW

Dilation is accomplished by application of expandable forces against a luminal stenosis. Dilation devices used in GI endoscopy can be organized into two categories: fixed-diameter push-type dilators and radial expanding balloon dilators. Fixed-diameter push-type dilators exert axial as well as radial forces as they are advanced through a stenosis.¹ Balloon dilators exert radial forces when expanded within a stenosis.

Dilators can be delivered to strictures in a number of ways, based on the dilator design and operator technique, including with or without endoscopic, fluoroscopic, and/or wire guidance. Fixed-diameter and balloon dilator designs include through-the-scope (TTS) and non-TTS types. Through-the-scope dilators must be accommodated by the endoscope accessory channel. Most push-type dilators are non-TTS devices, except those used for pancreaticobiliary applications.

Guidewires may be used to facilitate delivery of dilating devices to strictures throughout the GI tract and can be passed via endoscopy, with or without fluoroscopy. Wire-guided TTS dilators are passed over a guidewire and through the endoscope accessory channel. The non-TTS wire-guided dilators are passed over a guidewire after initial endoscopic guidewire placement and subsequent endoscope removal. A variety of specialty wires with flexible coil tips, stiff shafts, and external measurement markers are available.

Fixed-diameter push-type dilators

Fixed-diameter push-type dilators come in a variety of designs, calibers, and lengths (Tables 1, 2, and 3). They are sold individually and in sets of varying calibers. Most fixed-diameter dilators are marketed as reprocessable multi-use devices. Users should refer to the manufacturer's instructions for guidance on reprocessing.

Non-TTS fixed-diameter push-type dilators

Hurst and Maloney dilators (Medovations, Milwaukee, Wis.), also referred to as "bougies," are fixed-diameter push-type dilators that do not accommodate a guidewire.²⁻⁴ They are internally weighted with mercury or tungsten for gravity assistance when passed with the patient in the upright position. Hurst dilators have a blunt rounded tip, while Maloney

Table 1. Wilson-Cook Medical Inc. www.wilsoncook.com

Size (mm)	Balloon length	Required channel	Usable length	Cost
Quantum TTC balloon dilators-esophageal 6, 8, 10, 12, 14, 15, 18, 19	8 cm	2.8 mm	180 cm	\$105
Quantum TTC balloon dilators-pyloric 6, 8, 10, 12, 14, 18, 20*	5.5 cm	2.8 mm	180	\$105
Quantum TTC balloon dilators-colonic 6, 8, 10, 12, 14, 16, 18, 20*	5.5 cm	2.8 mm	240	\$105
Quantum TTC biliary balloon dilators 4, 6, 8, 10	3 cm	2.8 mm	180	\$165
Eclipse wire-guided balloon dilators-esophageal 6, 8, 10, 12, 14, 18, 19*	8 cm	2.8 mm	240 cm	\$155
Eclipse wire-guided balloon dilators-pyloric/colonic 6, 8, 10, 12, 14, 16, 18, 20†	5.5 cm	2.8 mm	240 cm	\$155
Q.I.D.-Quantum inflation device				\$105
Wilson-Cook achalasia balloon				
Description	Usable length	Cost		
Inflated balloon diameter 30 mm, 16F catheter, balloon length 8 cm	75 cm	\$275		
Inflated balloon diameter 35 mm, 16F catheter, balloon length 8 cm	75 cm	\$275		
Savary-Gilliard esophageal dilators				
Description	Cost			
Pediatric set with 5-, 7-, 8-, and 11-mm dilators 70-cm long	\$1000			
Standard set with 5-, 7-, 9-, 11-, 12.8-, 14-, and 15-mm dilators 70-cm long	\$1680			
Set of 16 dilators-5-20 mm, 70-cm long	\$3840			
Long set with 5-, 7-, 9-, 11-, 12.8-, 14-, and 15-mm dilators 100-cm long	\$1785			
Set of 16 dilators-5-20 mm, 100-cm long	\$4080			
Dilator carrying case only, accommodates 10 dilators	\$105			
Soehendra biliary dilation catheters (wire guide 0.035-inch, Usable length 200 cm)				
Inflated O.D.	Balloon length	Catheter size	Cost	
1.33 mm	4F	3 cm 6F	\$55	
1.33 mm	4F	3 cm 7F	\$55	
1.66 mm	5F	3 cm 8.5F	\$55	
2 mm	6F	3 cm 9F	\$55	
2 mm	6F	3 cm 10F	\$55	
3.5 mm	7F	3 cm 11.5F	\$55	
Soehendra rotary dilator (wire guide 0.021 inch, length 190 cm)				
Description	Biopsy channel	Cost		
5F dilator with 4F tip	2.8 mm	\$105		
8F dilator with 4F tip	3.2 mm	\$120		
Geenen graduated dilation catheter (for pancreatic strictures)				
Wire guide	Usable length	Cost		
7F catheter with 2-cm taper length tip from 5F to 4F 0.025 inch	200 cm	\$50		
Cotton, Siegel-Cohen, van Andel dilation catheters (used to dilate the papilla or biliary strictures)				
Description (inch)	Wire guide (cm)	Usable length	Cost	diameter
8.5F catheter with a 4-cm taper tip from 7F-5F	0.035	200	\$55	
10F catheter with a 4-cm taper tip from 7F-5F	0.035	200	\$55	
7F catheter with a 2.5-cm taper tip from 7F-4.5F	0.035	200	\$55	
7F catheter with a 4.5-cm taper tip from 7F-4.5 F	0.035	200	\$55	

TTC, Through the channel; O.D., outside diameter.

*Minimum accessory channel 3.2 mm.

†Minimum accessory channel 3.7 mm.

dilators have an elongated tapered tip. Patients may be instructed to use these devices for self-dilation.

Eder-Puestow dilators consist of a guiding flexible coiled wire tip, a short rigid metal dilating “olive” of

variable caliber, and a long semirigid coiled metal sheath for pushing the entire apparatus over a guide-wire and through the stricture.⁵ They are no longer commercially available.

Table 2. C.R. Bard, Inc. www.bardendoscopy.com

	Cost/each
Bard Eliminator esophageal PET balloon dilators	
6-, 8-, 10-, 12-, 15-, 18-mm balloon	\$160
Set of above balloons	\$810
Bard Eliminator pyloric/colonic PET balloon dilators	
6-, 8-, 10-, 12-, 15-, 18-mm balloon	\$160
Set of above balloons	\$810
Bard Eliminator biliary PET balloon dilators	
4 mm × 2 cm, 6 mm × 2 cm	\$200
Reusable polyvinyl dilators	American Dilatation System
Complete system of 15 tapered over-the-wire dilators	\$3400
15F, 18F, 21F, 24F, 27F, 30F, 33F, 36F, 39F, 42F, 45F, 48F, 51F, 54F, 60F dilators	\$260
Accessories for American Dilatation System dilators	
Guidewire	\$120
Carrying case	\$220
Cleaning brush	\$66
Cleaning adapter	\$12
Bard balloon inflation system	\$100

Table 3. Medovations www.medovations.com

	Cost
Traditional mercury-filled bougies	
Complete set of Maloney Bougies (sizes 16F-60F)	\$3395
Mini-set of Maloney Bougies (sizes 36F-54F)	\$1810
Complete set of Hurst Bougies (sizes 16F-60F)	\$3395
Mini-set of Maloney Bougies (sizes 36F-54F)	\$1810
WeightRight mercury-free tungsten bougie	
Complete set of Maloney Bougies (sizes 16F-60F)	\$4420
Mini-set of Maloney Bougies (sizes 36F-54F)	\$2235
Complete set of Hurst Bougies (sizes 16F-60F)	\$4420
Mini-set of Maloney Bougies (sizes 36F-54F)	\$2235
Safeguard endoscopic dilators	
SafeGuide over-the-guidewire system (16-piece set)	\$3450
SafeGuide over-the-guidewire system (7-piece set)	\$1620

Individual dilators can be ordered.

Savary-type dilators are flexible taper-tipped polyvinyl chloride cylinders with a central channel for passage over a guidewire. Savary-Gilliard dilators (Wilson-Cook Medical Inc., Winston-Salem, N.C.) have a long tapered tip and a radiopaque marking at the base of the taper designating the point of maximal dilating caliber. American Dilatation System dilators (C. R. Bard, Inc., Billerica, Mass.) have a shorter taper tip and total radiopacity throughout their length.

TTS fixed-diameter push-type dilators

Through-the-scope fixed-diameter dilators are tapered guidewire compatible plastic cylinders de-

veloped for ERCP-mediated dilation of pancreaticobiliary strictures. They are passed over a guidewire through the accessory channel of the endoscope. They are equipped with a radiopaque band just proximal to the taper to indicate the point of maximal dilation.

Threaded-tip stent retrievers also have been used to dilate tight pancreaticobiliary and esophageal strictures that otherwise only allow passage of a guidewire.⁶⁻⁸ The wire-guided screw-tipped device is used to auger through high-grade stenoses. A modified device is now commercially available as a dilator (Wilson-Cook).

Radial expanding balloon dilators

Radial expanding balloon dilators are available in an array of designs, lengths, and calibers for various purposes (Tables 1, 2, 4, and 5). Balloon dilators are made of low-compliance, non-latex, materials that allow uniform and reproducible expansion to their specified diameter at maximum inflation. One platform of balloon dilator is designed to expand to specific incremental calibers at sequentially higher pressures. Dilating balloons are expanded by pressure injection of liquid (e.g., water, radiopaque contrast), except for those designed for use in achalasia, where air is used instead of fluid. The hydraulic pressure of the balloon may be monitored manometrically to gauge radial expansion force. Inflation with full-strength or dilute radiopaque contrast enhances fluoroscopic observation. Most dilating balloons are marketed as single-use items.

Through-the-scope balloon dilators can be used in any accessible region of the GI tract, including the pancreaticobiliary tree. The non-TTS balloon dilators are wire guided and primarily are intended for use in the esophagus and the distal colon.

Achalasia balloon dilators

Achalasia balloon dilators are large diameter (30, 35, and 40 mm), non-TTS, wire-guided radial expansion balloon dilators that are disease specific for achalasia but also have been used in other disease states (Table 4).⁹⁻¹¹ A variety of designs used historically have been supplanted by the current non-radiopaque graded-size polyethylene balloons. They are positioned across the esophagogastric junction by using fluoroscopic and/or endoscopic guidance. Insufflation with air is monitored manometrically. Some commercially available achalasia dilators are marketed for reuse.

INDICATIONS AND EFFICACY

Fixed-diameter and balloon dilators are used for the dilation of malignant and benign strictures

Table 4. Boston Scientific Corporation www.bostonscientific.com

Size range (mm)	Balloon length	Required channel	Catheter size	Usable length	Cost
Single-use CRE fixed-wire balloon dilation catheters 6-8, 8-10, 10-12, 12-15, 15-18, 18-20, 12-15, 15-18, 18-20	8 cm	2.8 mm	6F	180 cm	\$235
Single-use CRE wire-guided esophageal/pyloric balloon dilation catheters 6-8, 8-10, 10-12, 12-15	5.5 cm	2.8 mm	7.5F	180 cm	\$260
15-18, 18-20	5.5 cm	2.8 mm*	7.5F	180 cm	\$260
Single-use CRE wire-guided esophageal/pyloric/colonic balloon dilation catheters 6-8, 8-10, 10-12, 12-15, 15-18, 18-20†	5.5 cm	2.8 mm*	7.5F	240 cm	\$260
Single-use Maxforce esophageal balloon dilators 6, 8, 10, 12, 14, 15, 16, 18	6 cm	2.8 mm	6F	180 cm	\$180
Hurricane Rx single-use biliary balloon dilation catheters 4, 6, 8, 10	2, 4 cm	3.2 mm	5.8F	180 cm	\$279
Rigiflex achalasia balloon dilators (recommended guidewire 0.038-inch Jagwire guidewire) 30, 35, 40	10 cm		14F	90 cm	\$650
Alliance II integrated inflation systems					
Hand mechanism					\$450
60-mL single-use syringe/gauge assembly box of 5					\$185
Achalasia pneumatic hand pump and monitor					\$200

CRE, Controlled radial expansion.

*Requires 3.2 mm Pentax/Fujinon channel.

†Esophageal or colonic application only.

throughout the luminal digestive tract. Dilation of malignant strictures may be effective in achieving initial palliation of stenoses. The degree and duration of palliation of malignant dysphagia may be limited and decreases with the progression of disease.¹² Dilation of malignant strictures is commonly performed to facilitate additional endoscopic therapy.

Benign esophageal strictures, including webs, rings, and anastomotic and inflammatory-type strictures, may be dilated with fixed-diameter and balloon dilators with technical success and functional decrease of dysphagia in the majority of cases.^{3,13-16} The degree and duration of the effect and the need for repeat dilation is lesion specific.

An excellent or good symptomatic response is reported by 75% to 85% of patients shortly after the procedure.¹⁷⁻¹⁹ However, a sustained response is more difficult to achieve, with prospective studies showing only about 25% of patients remaining in remission 5 years after a single dilation.²⁰ Up to 50% of patients may require second and third dilations in the first 5 to 10 years.

Benign strictures of the gastroduodenum and of the small bowel include acquired pyloric stenoses, surgical anastomoses, and miscellaneous inflammatory lesions. Benign pyloric stenosis can be managed with balloon dilation; however, symptomatic recurrence rates may be as high as 85%.²¹⁻²⁴ Dilation of benign small bowel strictures is dependent on endoscopic

access. Benign colorectal strictures attributable to non-steroidal anti-inflammatory drugs, diverticulitis, radiation, inflammatory bowel disease, and surgical anastomoses may be amenable to endoscopic dilation by using fixed-diameter and balloon dilators.²⁵⁻³²

Benign biliary strictures associated with primary sclerosing cholangitis, postoperative bile duct injury, and duct-to-duct anastomoses after orthotopic liver transplantation are amenable to endoscopic dilation therapy.³³⁻³⁵ Except for strictures associated with primary sclerosing cholangitis (PSC), dilation alone is largely ineffective and should be accompanied by stent placement. Dilation, with or without stent placement, reduces cholestasis and episodes of pain and fever in selected patients with dominant strictures from PSC. Dilation of the biliary sphincter has been described as an alternative to sphincterotomy for biliary stone removal; however, in some series, this has been associated with higher rates of pancreatitis.³⁶⁻³⁹

Dilation of pancreatic duct strictures or sphincters is primarily used in concert with stone removal or short-to-intermediate-term stent placement.^{7,40} Published data are limited and inconclusive. Dilators used for pancreaticobiliary strictures are listed in Table 1.

SAFETY

All dilation is intended to displace tissue; therefore, some disruption of mural elements, including

Table 5. Hobbs Medical, Inc. www.hobbsmedical.com

Inflated O.D.	Balloon length	Biopsy channel	Length	Cost/each
Esophageal dilators (use a 0.035-inch Flex-Ez guidewire, catheter size 2.3 mm)				
6, 8, 10 mm	4 cm	2.8 mm	200 cm	\$147.50
8, 10, 12, 14 mm	8 cm	3.7 mm	150 cm	\$147.50
16, 18, 20 mm	8 cm	3.7 mm	150 cm	\$157.50
16, 20 mm	4 cm	3.7 mm	200 cm	\$157.50
Stylet wire esophageal dilators (no guidewire required, catheter size 2.3 mm)				
12, 14 mm	8 cm	2.8 mm	210 cm	\$147.50
16, 18, 20 mm	8 cm	2.8 mm	210 cm	\$157.50
Pyloric dilators (use a 0.035-inch Flex-Ez guidewire, catheter size 2.3 mm)				
8, 10, 12 mm	3 cm	2.8 mm	180 cm	\$147.50
8, 10 mm	3 cm	3.7 mm	180 cm	\$147.50
Colonic/pyloric stylet wire balloon dilators (no guidewire required, catheter size 2.3 mm)				
8, 10, 12, 14 mm	5.5 cm	2.8 mm	240 cm	\$147.50
14, 16, 16, 20 mm	5.5 cm	2.8 mm	240 cm	\$157.50
8, 10, 12, 14 mm	3 cm	2.8 mm	240 cm	\$147.50
14, 16, 16, 20 mm	3 cm	2.8 mm	240 cm	\$157.50
Biliary dilators (use a 0.035-inch Flex-Ez guidewire, catheter size 2.3 mm)				
4, 6 mm	2 cm	2.8 mm	180 cm	\$147.50
8 mm	3 cm	2.8 mm	180 cm	\$147.50
Achalasia balloons (use 0.038-inch Flex-Ez guidewire)				
30, 35, 40 mm	10 cm	5.3 mm	100 cm	\$320.00
Inflation monitor				
20-cc aspirating syringe				

O.D., Outside diameter.

mucosal tears and minor bleeding, is expected. Complications of endoscopic stricture dilation include chest pain, clinically significant bleeding, bacteremia, and perforation.⁴¹⁻⁴³ 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.¹⁶ 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.⁴⁴ There are insufficient data to substantiate a difference in perforation rates with fixed-diameter vs. balloon dilators.^{13,15} A retrospective analysis reported an increased perforation rate associated with blind passage of Maloney dilators vs. Savary-Gillard and balloon dilators in patients with complex strictures.⁴⁵ Antibiotic prophylaxis should be considered for patients at high risk for bacterial endocarditis.⁴⁶

Regarding achalasia dilation, pooled data indicate a 2% cumulative perforation rate when using graded balloon dilation. Individual publications report perforation rates of up to 7%.^{9,47} Other complications associated with achalasia dilation include prolonged pain and intramural hematomas.⁴⁸

COMPARISON AMONG AVAILABLE TECHNIQUES

There are several randomized controlled trials comparing fixed-diameter dilators with TTS balloons for nonachalasia benign strictures of the esophagus. A randomized trial, including 94 patients, compared fixed-diameter vs. balloon dilation in patients with benign esophageal strictures.³ The fixed diameter group had better technical results and early symptom improvement; however, differences were no longer evident at 1 year. There were no significant differences in patient safety or acceptability.

In a second prospective trial, 34 patients were randomized to dilation with fixed-diameter dilators and balloon dilators. They were equally effective in relieving dysphagia from peptic esophageal strictures at 1 year. The use of a proton pump inhibitor reduces the need for repeat dilations of acid-induced esophageal strictures.⁴⁹ Another randomized prospective trial compared fixed-diameter dilation vs. balloon dilation by either of two balloons for benign lower esophageal strictures in 251 patients.¹⁵ There were no significant differences between the dilation arms with regard to immediate relief of dysphagia or the need for repeat dilation in 1 year, and no significant complications were reported.

Table 6. Codes used in association with endoscopic dilation

CPT	Description	2003 RVUs
43220	Esoph endoscopy, dilation balloon	2.1
43226	Esoph endoscopy, dilation guidewire	2.34
43245	Operative EGD, dilation any method	3.39
43248	Upper-GI endoscopy/guidewire	3.15
43249	EGD, balloon dilation of esoph	2.9
43271	ERCP, balloon dilation ducts	7.39
45303	Proctosig, dilation any method	0.44
45340	Flex sig, balloon dilation each strict	1.66
45386	Colonoscopy, balloon dilation	4.58

CPT, Current procedural terminology; RVU, relative value unit; *Esoph*, esophageal; *Proctosig*, proctosigmoidoscopy; *Flex sig*, flexible sigmoidoscopy.

A randomized prospective trial comparing fixed-diameter dilation to forceps disruption of Schatzki's rings showed no significant difference in outcomes among 60 patients.⁵⁰

Balloon dilation of achalasia is equally effective with short duration (6 seconds) as with longer duration of inflation (60 seconds).⁵¹ Alternatives to balloon dilation for achalasia include injections of botulinum toxin into the lower esophageal sphincter, surgical myotomy, and laparoscopic myotomy. Comparative trials of botulinum toxin injection vs. pneumatic balloon dilation for treatment of achalasia have shown equivalent early success rates but shorter duration of efficacy in the botulinum injection groups.⁵²⁻⁵⁴ Studies of open surgical myotomy have shown 10% to 20% higher rates of long-term relief of dysphagia but with higher overall complication rates.⁵⁵ Laparoscopic myotomy may retain the benefits of open surgery with fewer complications. A small trial in 30 patients compared laparoscopic myotomy with endoscopic dilation for achalasia with comparable results.⁵⁶

There are no published trials comparing balloon dilation with surgical management of non-malignant non-congenital pyloric stenosis or of Crohn's related, anastomotic, or other inflammatory strictures of the small bowel or the colon.

For pancreaticobiliary stricture dilation, there are no well-controlled published comparisons of techniques or devices, or comparisons of endoscopic to nonendoscopic modalities. Prospective studies of endoscopic biliary sphincterotomy vs. endoscopic papillary balloon dilation for removal of small bile duct stones have shown equivalent success in duct clearance; however, in two studies, significantly higher rates of pancreatitis were reported in the balloon dilation groups.^{36,37,39}

FINANCIAL CONSIDERATIONS

The list prices of the available dilating devices for use in GI endoscopy are detailed in Tables 1

through 5, organized by manufacturer. 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 also may be considered.

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

CONCLUSIONS

Fixed-diameter and radial expansion balloon dilators are safe and effective for endoscopic management of benign and malignant strictures throughout the digestive tract. Either type of dilator can be used in accessible strictures. Disease-specific dilators are designed for treatment of achalasia. Developments in material sciences may be reflected in future dilation therapies.

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Prepared by:

ASGE TECHNOLOGY COMMITTEE

Greta Taitelbaum, MD
 Bret T. Petersen, MD
 Alan N. Barkun, MD
 Poonputt Chotiprasidhi, MD
 Ram Chuttani, MD
 Julia Liu, MD
 William B. Silverman, MD
 Steven Carpenter, MD
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