ERCP cannulation and sphincterotomy devices

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, with a MEDLINE literature search to identify pertinent clinical studies on the topic, and a MAUDE (Food and Drug Administration Center for Devices and Radiological Health) database search to identify the reported complications 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 1 or 2 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 February 2009 for articles related to cannulation and sphincterotomy devices by using the keywords ERCP, standard catheter, sphincterotome, cannulation, sphincterotomy, precut, major papilla, minor papilla, needle-knife, complication, pancreatitis, biliary, and pancreatic in different search term combinations.

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BACKGROUND

ERCP has revolutionized the diagnosis and therapy of biliary and pancreatic diseases. Successful cannulation of the desired duct is essential in performing ERCP. Since the initial description of ERCP, numerous cannulation and sphincterotomy devices have been designed to improve access and therapy through the major or minor papilla. These devices can be broadly divided into 3 categories—cannulation catheters, sphincterotomes, also called papillotomes, and access (precut) papillotomy catheters. This review describes commonly used ERCP cannulation and sphincterotomy devices that are currently available in the United States.

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TECHNOLOGY UNDER REVIEW

Standard cannulation catheters

The majority of cannulation catheters are designed to gain access through the major papilla, although there are a few catheters that are specifically designed to facilitate minor papilla cannulation. The standard catheters are generally made of Teflon (Dupont, Wilmington, DE) and are available in different tip sizes and configurations, lengths, and number of available lumens (Table 1). Double-lumen catheters have an advantage, relative to single-lumen catheters, of permitting injection of contrast material through 1 lumen via a Luer lock connection on the catheter handle and passage of a guidewire through the other lumen. The lumen for the guidewire port comes with a metal stylet to maintain the stiffness while the catheter is passed through the endoscope channel. The stylet is removed prior to passage of the wire. Some catheters come with a Tuohy-Borst adapter that functions as a common port for both guidewire and contrast material injection. This adapter can be tightened securely around the guidewire prior to injection to prevent backflow of contrast material. In triple-lumen catheters, 2 ports allow contrast material injection, and the third can be used for a guidewire. A modification of a standard catheter with a flexible tip (swing tip) has a wire running through the length of the catheter. The wire is connected to an actuator on the control handle, enabling the operator to deflect the tip in 1 direction.[1] Catheters that are available for use with so-called short-wire systems allow the endoscopist to control the guidewire at the entry of the accessory channel of the endoscope. These short-wire systems are the focus of a separate Technology Status Evaluation Report.[2] Although the smaller orifice of the minor papilla often poses a challenge, cannulation can be accomplished with standard catheters or guidewires. Alternatively,

TABLE 1. ERCP cannulation catheters

Product	Distal tip OD (F)	Working length (cm)	Tip configuration	Recommended guidewire size (type) (inch)	Comments	List price
Boston Scientific (Natick, Mass)						
Contour single-use	5	210	Standard, tapered, ultra-tapered, 5-4-3, or ball tip	0.035 (standard, tapered, or ball tip),0.025 (ultra-tapered), 0.018 (5-4-3)		$76.50
Tandem XL single-use	5.5	210	Tapered	0.035	2 injection lumens	$89
RX single cannula	5	210	Standard, tapered or ball tip	0.035	Short-wire system	$89
Tandem RX cannula	5	210	Tapered	0.035	2 injection lumens. Short-wire system	$89
Conmed Endoscopic Technologies (Utica, NY)						
ProForma HF 4.5 cannula	4.5	190	Curved or straight	0.035	Double lumen	$94
ProForma cannula	3.5-5.0	200	Standard, long tapered, short tapered, ultra-tapered, metal ball, 5-4-3 tapered	0.018 - .035	Double lumen	$49-75
Cook Medical (Winston-Salem, NC)						
Glo-Tip ERCPcatheter	3.0-5.5	200	Standard, tapered, short tapered, angled tip, long tapered, ultra-tapered, precurved	0.018 - 0.035	Single lumen, also available with radiopaque bands	$61-66
Glo-Tip II ERCP catheter	6.0	200	Straight or angled dome tip	0.035	Double lumen, also available with radiopaque bands	$69-76
Classic ERCP catheter	3.5-5.5	200	Standard, metal bullet, long taper, or metal cannula tip	0.021 - 0.035	Single lumen; reusable	$57
Cunningham-Cotton Sleeve	9.5F sleeve and 6F dilator	340	N/A	0.035	Outer sleeve and dilator portions	$144
Howell D.A.S.H. ERCP catheter	4.5	200	Tapered	0.025	Single lumen; can inject while wire is in	$ 69-202 (preloaded guidewire)

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TABLE 1 (*continued*)

Product	Distal tip OD (F)	Working length (cm)	Tip configuration	Recommended guidewire size (type) (inch)	Comments	List price
Haber RAMP catheter	6.0	200	Tapered	0.035	Triple lumen with side ramps	$112
Huibregtse-Katon ERCP catheter	5.5	200	Metal ball tip	0.035	Single lumen; reusable	$57
Fusion ERCP cannula	Dome tip	200	Dome tip	0.021 - 0.035	Short-wire system, allows intraductal exchange	$82
Fusion Omni ERCP cannula	Dome tip	200	Dome tip	0.021 - 0.035	Short-wire, has leading closed lumen and tear-away channel	$90
Olympus (Tokyo, Japan)						
X-press V cannula	2.5	195	Cross-cut, rounded tip	0.035		$81
Star Tip 2 V cannula	4.5	170	Straight	0.035	Double lumen	$85
Star Tip V cannula	3.5-4.0	195	Standard, tapered, short tapered or long tapered	0.025 -0.035		$81
Star Tip V Ball tip cannula	6.0	195	Ball tip	0.035	Deflectable tip	$81
Swing-tip cannula	4.0	195	Swing tip	0.035		$188
Minor papilla cannula	2.5 or 6.0	195	Metal tip	0.018 or 0.035		$63
TeleMed Systems (Hudson, Mass)						
ERCP cannula	5.0	200	Tapered, metal ball or nipple tip	0.022 - 0.035	Single lumen	$27.50-30

OD, outer diameter; *F*, French; *N/A*, not applicable.

smaller-tipped devices such as an ultra-tapered tip catheter with or without an 0.018-inch or 0.020-inch hydrophilic guidewire can be used. Also, there are special blunt-tipped needle catheters that are specifically designed for minor papilla cannulation.[3]

Sphincterotomes

The main difference between a standard catheter and a sphincterotome is that a sphincterotome has an electrosurgical cutting wire at the distal end of the catheter (Table 2). A monopolar power source is connected to the catheter at an electrode connector on the handle. During a sphincterotomy activation of the power source causes electrical current to pass along an insulated portion of the wire within the catheter to the exposed cutting wire. A retractable plunger on the control handle permits flexing of the catheter tip upward by pulling on the cutting wire. This flexing assists with aligning the cutting wire and maintaining contact of the wire with the papilla while the catheter is pulled back, incising the major or minor papilla. Similar to cannulation catheters, these traction-type sphincterotomes are available in different tip configurations and lengths. The length of the tip (distance between the distal end of the sphincterotome and the distal attachment of the cutting wire) can be short or long, ranging from 3 mm to 20 mm. Although the primary function of the cutting wire is sphincterotomy, the cutting wire also

TABLE 2. Sphincterotomes and precut devices

Product	Distal tip OD (F)	Tip length (mm)	Cutwire length (mm)	Recommended guidewire size (inch)	Comments	List price
Boston Scientific(Natick, Mass)						
Autotome RX 49 cannulating sphincterotome	4.9	5	20 or 30	0.035	Short-wire system	$279
Autotome RX 44 cannulating sphincterotome	4.4	5	20 or 30	0.035	Short-wire system	$279
Autotome RX 39 cannulating sphincterotome	3.9	5	20 or 30	0.025	Short-wire system	$279
Ultratome RX, short nose	4.9	5	20 or 30	0.035	Short-wire system	$225
Hydratome RX 49 cannulating sphincterotome	4.9	5	20 or 30	0.035	Short-wire system, preloaded with Hydra Jagwire (260 or 450 cm)	$529
Hydratome RX 44 cannulating sphincterotome	4.4	5	20 or 30	0.035	Short-wire system; preloaded with Hydra Jagwire (260 or 450 cm)	$529
Jagtome RX 49 cannulating sphincterotome	4.9	5	20 or 30	0.035	Short-wire system; preloaded with Jagwire (260 or 450 cm)	$499
Jagtome RX 44 cannulating sphincterotome	4.4	5	20 or 30	0.035	Short-wire system; preloaded with Jagwire (260 or 450 cm)	$499
Jagtome RX 39 cannulating sphincterotome	3.9	5	20 or 30	0.025	Short-wire system; preloaded with Jagwire (260 or 450 cm)	$499
Stonetome	5.5	5 or 20	20 or 30	0.035	Built-in 11.5-mm balloon, either above or below cut wire	$409
Ultratome	5.5	5 or 20	20 or 30	0.035	Double lumen	$199
Ultratome XL	5.5	5 or 20	20 or 30	0.035	Triple lumen	$209
NeedleKnife RX	5	N/A	5	0.035	Triple lumen; short-wire, precut device	$209
MicroKnife XL	5	N/A	5	0.035	Triple lumen; precut device	$209

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TABLE 2 (*continued*)

Product	Distal tip OD (F)	Tip length (mm)	Cutwire length (mm)	Recommended guidewire size (inch)	Comments	List price
Conmed Endoscopic Technologies (Utica, NY)						
Apollo 3AC	4.5	5	20 or 30	0.035	Triple lumen	$215
Apollo 3 Tapered tip	5	8 or 20	20 or 30	0.035	Triple lumen	$185
Apollo 3 Beveled tip	5.5	8	20 or 30	0.035	Triple lumen	$186
Apollo AC	6	5	20 or 30	0.035	Double lumen	$176
Apollo Tapered tip	5	8 or 20	20 or 30	0.035	Double lumen	$150
Apollo Beveled tip	5.5	8	20 or 30	0.035	Double lumen; monofilament or braided cutting wire	$142
Axcess Multidirectional Papillotome	4.5	5	22.5	0.035	Triple lumen; multidirectional tip control	$275
Cook Medical (Winston-Salem, NC)						
D.A.S.H sphincterotome	Dome tip	5	25	0.018 - 0.035	Double lumen; dome tip	$164-291
Tri-Tome pc	Dome tip	5	20 to 30	0.035	Triple lumen; dome tip	$196-359
Tri-Tome pc Protector	Dome tip	5	25	0.035	Triple lumen; dome tip; insulated proximal portion of cutting wire	$201
Cannulatome II	5	5	20 or 30	0.035	Double lumen; monofilament or braided cutting wire	$169
Cotton Cannulatome II pc	5	5	25	0.035	Double lumen; monofilament or braided cutting wire	$169
Cotton Cannulatome II pc Protector	5	5	25	0.035	Triple lumen; dome tip; insulated proximal portion of cutting wire	$179
MiniTome	4	5	20 to 30	0.021	Double lumen; monofilament or braided cutting wire	$179
UTS Precurved Ultratapered	4	5	15 to 30	0.021	Double lumen; monofilament or braided cutting wire	$179
Wire-Guided sphincterotome	5	5	20 or 30	0.035	Double lumen	$179

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TABLE 2 (*continued*)

Product	Distal tip OD (F)	Tip length (mm)	Cutwire length (mm)	Recommended guidewire size (inch)	Comments	List price
Fusion IDE-Tome	Dome tip	5	25	0.035	Short-wire system; allows intraductal exchange	$234
Fusion Omni-Tome	Dome tip	5	25	0.021 - 0.035	Short-wire system	$280
Billroth II sphincterotome	5	5	20	0.035	Double lumen	$238
Soehendra BII sphincterotome	5.5	5	Variable	N/A	Single lumen	$238
Huibregtse single lumen needle knife	5	N/A	4	0.035	Single lumen	$179
Huibregtse triple lumen needle knife	5	N/A	4	0.035	Triple lumen, precut device	$184
Zimmon needle knife	5	N/A	7	0.035	Precut device	$179
Fusion needle knife	6	N/A	4	0.035	Short-wire system; precut device	$234
Mediglobe (Tempe, Ariz)						
Tapered tip sphincterotome	3 or 5	5	20 or 30	0.021 - 0.035	Double or triple lumen	$105-145
Precut sphincterotome	5 or 6	N/A	20 or 30	0.021 - 0.035	Double or triple lumen, noseless, Erlangen-type	$105-145
Needle knife	5 or 6	N/A	0-15	N/A	Single lumen	$105
Olympus (Tokyo, Japan)						
Clever Cut Triple Lumen	4.5	3-15	20, 25, 30	0.035	Triple lumen	$234
Clever Cut Triple Lumen Taper Tip	4	7	20 or 30	0.035	Triple lumen	$234
Clever Cut Double Lumen	4.5	7 or 15	20, 25, 30	0.035	Double lumen	$222
Triple Lumen Needle Knife with clever coating	5	N/A	5	0.035	Precut device	$229
Triple Lumen Needle Knife	5	N/A	5	0.035	Precut device	$209
TeleMed Systems (Hudson, Mass)						
Heiss-Device Flexible Endoscopic Scissors	N/A	N/A	N/A	N/A	Use for precut; 1.7×2.5 mm blade; reusable	775

OD, outer diameter; *F*, French; *N/A*, not applicable.

facilitates manipulation of the sphincterotome tip to align it in the proper axis for duct cannulation. Some sphincterotomes are designed to be rotatable, which further facilitates proper orientation and cannulation of the desired duct. The cutting wires are available mostly in a monofilament configuration and range in length from 15 to 35 mm. Braided

TABLE 3. Commonly used CPT® codes for ERCP cannulation and sphincterotomy

Procedure	CPT® code
Diagnostic ERCP	43260
ERCP with sphincterotomy	43262

Code 43262 includes the work of diagnostic ERCP, and code 43260 is not reported separately. Code 43260 includes brushing or washing. If radiological supervision and interpretation (S&I) is also performed by the physician performing the ERCP, see codes 74328, 74329, and 74330; a separate radiological interpretation report is typically prepared.

cutting wires are less often used, as they can induce more thermal injury to surrounding tissues.[4] Some sphincterotomes are available with an insulating sleeve on the proximal half of the cutting wire to prevent short-circuiting of the power if the wire is in contact with the endoscope. This will also prevent inadvertent thermal injury of overhanging duodenal mucosa during sphincterotomy. Sphincterotomes are available in double- or triple-lumen design. There are some hybrid sphincterotomes that have a built-in, 11.5-mm stone extraction balloon, either above or below the cutting wire. A new sphincterotome is also available that provides the ability to steer the tip in multiple directions. Some sphincterotomes are also available in the short-wire design.[2]

There are several modifications to sphincterotomes that are designed for use in patients with surgically altered anatomy. Patients with a prior Billroth II or Roux-en-Y procedure that requires approaching the periampullary region through an afferent limb pose a challenge because the ampulla is vertically inverted in the endoscopic image relative to the view in patients with normal anatomy. A wire-guided Billroth II papillotome is available specifically designed with a cutting wire oriented in the opposite direction relative to standard sphincterotomes.[5] A sphincterotome with an S-shaped tip can also be used in these patients.[6] This catheter is designed with a cutting wire that winds around the catheter at a pivotal point between the catheter's proximal and distal holes. This allows the catheter tip to be forced into an S-shape when the wire is pulled. A rotatable sphincterotome is another option for attaining proper orientation for cannulation and sphincterotomy in patients with altered anatomy.[7,8]

Access papillotomy catheters

Access (precut) papillotomy refers to the technique of incising the papilla when deep ductal cannulation using standard methods is unsuccessful. The most widely used type of papillotome in this category is the needle-knife catheter (Table 2). These needle-knife catheters have a retractable electrosurgical cutting wire. The control handle of the catheter contains a mechanism for projecting the wire forward from the distal aspect of the catheter, once the catheter is passed through the endoscope into position in the lumen. With the exposed needle in contact with the mucosa, activation of the electrosurgical current and manual movement of the catheter and endoscope permits cutting of the targeted tissue. These catheters are available in variable tip lengths and have either single-, double-, or triple-lumen configurations. A new needle-knife papillotome (Iso-Tome, MTW Endoscopie Inc, Wesel, Germany), not yet available in the United States, has an insulated tip to prevent energy dispersion from the tip of the incising needle.[9] The coated-tip needle-knife aids in keeping the papillotome tight in the orifice of the ampulla of Vater and is believed to prevent unintentional deep cuts or perforations. The second type of access papillotome is referred to as an Erlangen-type papillotome and is similar to the standard traction-type sphincterotome. It has an ultra-short, 5-mm-long, monofilament cutting wire and a less than 1 mm catheter tip distal to the wire[10-12] Modifications to this traction-type sphincterotome with short-nose or noseless designs with or without insulated wire are also available (Table 2). Another type of access papillotomy device is a catheter with a small scissor cutting mechanism at its tip. With the blades of the scissors open, the lower blade is placed into the papillary orifice, and closure of the scissor with the control handle permits mechanical cutting of the tissue.[13]

EASE OF USE

Standard cannulation catheters are relatively simple in design compared with sphincterotomes. ERCP is inherently a complex procedure, and a skilled assistant is needed to follow and execute the instructions of the endoscopist.[14] This is particularly important in coordinating contrast material injection, guidewire manipulation, or guidewire catheter exchanges. After contrast material injection, flushing out the contrast material with saline solution or sterile water facilitates passage of a guidewire and allows for a smoother accessory exchange. Manual shaping of straight-tipped catheters to achieve an upward-curving tip has been shown to facilitate cannulation.[15] However, this method is time consuming and requires a trial-and-error approach.[16]

Sphincterotomes are more complex than cannulation catheters and require a higher level of coordination between the endoscopist and the assistant controlling flexure of the sphincterotome. Both cannulation catheters and sphincterotomes employing short-wire systems permit the endoscopist to control and lock the guidewire, reducing the need for coordination between the assistant and endoscopist. When an endoscopist attempts to cannulate the selected duct with a guidewire through a catheter rather than catheter cannulation, endoscopist control of the guidewire allows the endoscopist to optimize the timing of guidewire advancement. This also provides the advantage of tactile sensation during guidewire cannulation.[2,17]

Use of a needle-knife requires more expertise and is considered an advanced technique. The cut should be parallel to the axis of the papilla. This requires a finely coordinated movement of the needle-knife with the elevator and manipulation of the duodenoscope as well as knowledge and experience with the ampullary anatomy exposed during the incision. In addition, because the tip of the device is not anchored within the duct, as occurs with standard sphincterotomes, catheter control and incision are more difficult.

It is difficult for many endoscopists to be familiar with all available devices and their various configurations. Although it is preferable to be familiar with some commonly used devices, based on personal preference and ease of use, it is also important to be familiar with newer techniques and accessories because the technique should be tailored to the individual risk profile and papillary ductal anatomy.[18] This familiarity will likely increase the success rate and decrease the time needed to complete the procedure.

OUTCOMES AND COMPARATIVE DATA

Cannulation

The main limitation of a standard catheter is that the direction of the tip cannot be manipulated independent of the endoscope to gain access into the desired duct. On the other hand, sphincterotomes have a flexible tip that can be adjusted to facilitate orientation in the proper axis of the duct being cannulated.[19] For this reason, sphincterotomes are often used for initial cannulation,[16] particularly when there is a high probability that a sphincterotomy will be required.

There are several studies showing that using a catheter with a steerable tip (such as a sphincterotome) is significantly better for both initial cholangiogram and deep cannulation, compared with use of a standard catheter. There is a great deal of heterogeneity in the studies with variable criteria used to define cannulation failure. A randomized, controlled study in 47 patients found that a sphincterotome is superior to a standard catheter for initial cannulation (97% vs 67%).[20] The mean numbers of attempts required to achieve selective common bile duct (CBD) cannulation were 2.8±3.1 and 12.0±6.0 (P=.0001) for sphincterotomes and standard catheters, respectively. In addition, the mean time to achieve selective cannulation with a sphincterotome versus a standard catheter was 3.1±5.1 and 13.5±6.1 minutes (P=.0001), respectively. Another randomized trial in 100 patients demonstrated that initial cannulation with a sphincterotome without a guidewire was successful in 84% of cases, compared with 62% of cases with a standard catheter ($P < .05$), with no difference in complication rates.[21] A larger, multicenter, randomized, crossover study of 312 patients compared a standard catheter with 2 steerable catheters, a short-nosed sphincterotome, and a swing-tip catheter.[22] Both steerable catheters had a higher success rate of obtaining initial cholangiogram (standard catheter 75%, swing-tip catheter 84%, and sphincterotome 88%; P=.038) and deep cannulation of the bile duct (standard catheter 66%, swing-tip catheter 69%, and sphincterotome 75%; P=.15). When the standard catheter failed, a steerable catheter succeeded in 26% of cases. There were no differences in complication rates. A more recent study in a low-volume, community-hospital setting in which all ERCPs were performed by a single endoscopist, selective CBD cannulation using a standard ERCP catheter with or without guidewire was accomplished in 81.7% of patients.[23] Failures were crossed over to a sphincterotome and a guidewire technique, and selective CBD cannulation was achieved in 96.8% of patients. The use of a swing-tip catheter was reported to be successful in 64.7% of patients in whom cannulation with a standard catheter failed.[1] However, the obvious disadvantage of the swing-tip catheter is that it cannot be used to perform sphincterotomy.

Guidewires are now increasingly being used to achieve ductal cannulation.[17] Guidewires passed through a standard catheter or a sphincterotome can be used to facilitate deep pancreaticobiliary cannulation. Further discussion on guidewires has been published as a separate Technology Status Evaluation Report.[24] There are several studies showing that wire-guided cannulation may increase cannulation success and potentially lower complication rates. A prospective trial of 400 patients compared guidewire cannulation through a sphincterotome with a traditional cannulation using contrast material injection with a standard catheter.[25] None of the patients in the guidewire group developed post-ERCP pancreatitis, whereas 4.1% of patients in the traditional cannulation group developed pancreatitis. Another prospective, randomized study in 332 patients showed that the use of a hydrophilic guidewire as a primary technique or as a secondary technique after failure of cannulation with a standard catheter achieves a higher rate of selective CBD cannulation, with no difference in postprocedure pancreatitis or hemorrhage rates.[26] A separate study randomized patients to undergo sphincterotome-based biliary cannulation using either contrast material injection or guidewire.[27] The cannulation was successful in 81.4% of patients in the guidewire arm and 73.9% of patients in the contrast material injection arm. Post-ERCP pancreatitis rates increased with the number of attempts but did not differ between the contrast material and guidewire groups. A single-center, blinded trial in 300 patients randomized to a conventional cannulation technique using sphincterotome and contrast material injection versus a guidewire cannulation technique found that the guidewire technique for bile duct cannulation resulted in a significantly lower rate of post-ERCP pancreatitis (9%) compared with the contrast group (17%).[28] Other similar studies comparing guidewire cannulation with traditional methods also confirmed the lower risk of pancreatitis with guidewire cannulation.[29,30]

There are only limited published data comparing cannulation success with different sphincterotomes. A randomized, controlled trial found no difference in cannulation rates, procedure time, or complication rates between 4F and 5F sphincterotomes.[31] In contrast, a prospective, nonrandomized study showed that initial cannulation was achieved in 78% of patients by using a 3F, tapered, double-lumen sphincterotome with a 0.025-inch guidewire, compared with a 61.4% success rate with a 5.5F, tapered, triple-lumen sphincterotome loaded with a 0.035-inch hydrophilic tip guidewire.[32]

Sphincterotomy

The efficacy of standard sphincterotomy devices is largely dependent on the ability to achieve deep cannulation, and there are no systematic studies examining the success of papillary incision or the relative effectiveness of different devices.

Access or precut papillotomy has been shown to be an effective technique when biliary cannulation has been unsuccessful using conventional methods.[33,34] It is unclear what is the best device for precut papillotomy, as there are limited data comparing the two most widely used devices for precut papillotomy—needle-knife and Erlangen-type traction sphincterotome.

There are several published studies using a needle-knife sphincterotome for precut papillotomy.[33,35] Almost all these studies found that precut papillotomy using a needle-knife independently and significantly increased the risk of complications compared with standard sphincterotomy.[36,37] These rates may vary depending on the precut technique used (conventional precut starting at the orifice vs other precut techniques, including suprapapillary puncture and fistulotomy).[16] On the other hand, there are some data suggesting that Erlangen-type precut papillotomy results in a higher deep biliary cannulation rate (100% vs 71%),[11] with no increased risk of complications, when compared with cannulation using standard techniques.[11,12] However, these excellent results must be viewed in context because these studies are from centers with a high degree of expertise and cannot be extrapolated to less-experienced endoscopists.[38] In addition, it is also unclear whether these results are better than those of precut papillotomy performed by use of a needle-knife.

Endoscopic pancreatic sphincterotomy through the major papilla provides therapeutic benefit in several different clinical conditions, particularly in pancreatic-type sphincter of Oddi dysfunction and chronic pancreatitis. The current standard of practice uses two different methods of performing pancreatic sphincterotomy—a pull-type sphincterotome technique without prior stent placement and a needle-knife sphincterotome technique cutting over an indwelling pancreatic duct stent. A prospective, randomized trial compared pancreatic sphincterotomy with the pull-type sphincterotome technique (followed by pancreatic stent placement) versus the needle-knife technique over a pancreatic stent in patients with pancreatic-type sphincter of Oddi dysfunction.[39] A total of 48 patients was enrolled, 24 in each group. Seven patients (29%) in the pull-type sphincterotomy technique group developed pancreatitis, compared to none in the needle-knife technique group ($P = .01$). Three patients (12.5%) in the pull-type sphincterotome technique group required a reintervention, versus 2 (8.3%) in the needle-knife technique group. The clinical response to endoscopic therapy was the same in each group.

Minor papilla cannulation and sphincterotomy

Minor papilla cannulation is generally successful in more than 90% of cannulation attempts[40] and can be accomplished with a cannulation catheter with an ultra-tapered tip and a 0.018-inch or 0.020-inch hydrophilic guidewire.

Minor papilla sphincterotomy in patients with pancreas divisum has been shown to decrease the rate of recurrent pancreatitis.[41-44] Similar to major papilla pancreatic sphincterotomy, minor papilla sphincterotomy can be performed by using a standard pull-type sphincterotome or by using a needle-knife to cut the minor papilla away from a previously placed stent or guidewire (wire-assisted access sphincterotomy [WAAS]).[45] In a retrospective study, complication rates of minor papillotomy by using either a pull-type sphincterotome or a needle-knife were studied in 184 patients with pancreas divisum.[46] The efficacy was assessed by the need for reintervention in the first year of follow-up, and there was no difference between the two techniques (29% for the needle-knife group and 26% for the pull-type sphincterotome group). The overall complication rates were similar in those undergoing needle-knife and pull-type sphincterotomy (8.3% vs 7.8%, respectively). In another retrospective study of 64 patients, 32 were treated with WAAS, 24 were treated with pull-type sphincterotomy, and 8 had other types of sphincterotomy.[45] There was no difference in complication rates between WAAS and pull-type sphincterotomy groups.

SAFETY

There are no studies specifically addressing the relative safety of currently available cannulation and sphincterotomy devices. The overall complication rate of ERCP is reported to be in the range of 5% to 10%[47] and varies greatly depending on patient-related and procedure-related factors. A multicenter, prospective study reported complications that occurred within 30 days of biliary sphincterotomy in consecutive patients treated at 17 institutions in the United States and Canada from 1992 through 1994.[48] Of 2347 patients, 229 (9.8%) had a complication, including pancreatitis in 127 (5.4%) and hemorrhage in 48 (2%). A study of 2691 patients in China recently reported an overall complication rate of 8%, with acute pancreatitis in 4.3% of patients.[36] In the patients who underwent sphincterotomy, bleeding occurred in 1.4%, and perforation occurred in 0.26%. One study demonstrated that sphincterotomy performed by using pure cut current results in a lower rate of pancreatitis compared with sphincterotomy using blended cut and coagulation current (4% vs 12%).[49] This study was not powered to show a difference in bleeding rates. Recent reports suggest that postsphincterotomy bleeding has decreased since the introduction of microprocessor-controlled electrosurgical units.[50] Compared with standard sphincterotomy, precut papillotomy independently and significantly increases the risk of complications, particularly the risk of pancreatitis and perforation.[51,52]

A search of the MAUDE database revealed several reports of device malfunction.[53] There are reports of fracture of the sphincterotome cutting wire either during or before the sphincterotomy. In some cases, inappropriate electrosurgical generator settings were blamed as the source of malfunction. In at least one case, this resulted in bleeding requiring transfusion. In another report, the tip of the guidewire coating detached inside the patient. Forceps were used to remove the detached portion of the guidewire coating. Needle-knives from different manufacturers have also been reported to have the needle separate from the catheter and require retrieval. There are also several reports of detachment of radiopaque bands from catheters. The bands were seen under fluoroscopy and were retrieved with forceps.

FINANCIAL CONSIDERATIONS

The list prices vary greatly between the different devices (Tables 1 and 2). Although most cannulation and sphincterotomy devices are labeled for single use, reusable devices offer potential cost savings. In a multicenter study there was a substantial cost savings ($61 per patient with a reusable, single-lumen sphincterotome versus $241 per patient with a disposable, triple-lumen sphincterotome) without compromising the success or safety of the procedure.[54] Another study showed that the median number of efficient uses for a reusable, double-lumen sphincterotome is 8, with no increased risk of infectious complications when they are properly reprocessed.[55] The CPT® codes for diagnostic ERCP and sphincterotomy are included in Table 3.

AREAS FOR FUTURE RESEARCH

Although there are some data to suggest that wire-guided cannulation through a sphincterotome is more successful relative to techniques using standard cannula and injection techniques, the cost-effectiveness of initially attempting cannulation with these alternative approaches needs to be addressed. In the future, more studies are needed for head-to-head comparison of various catheter devices, particularly comparing different sphincterotomes. Large studies comparing biliary access techniques such as EUS-guided cholangiography, precut sphincterotomy, and pancreatic wire/stent placement to facilitate biliary access after standard techniques have failed are needed. Technologies that will decrease the time and effort needed for cannulation or accessory exchange and reduce the rate of procedure-related complications are also needed.

SUMMARY

As ERCP has evolved, numerous devices have become available for cannulation and sphincterotomy. It is important to be familiar with newer techniques and accessories for performing a safe and successful ERCP. These devices vary widely in their functionality and operation. Steerable catheters such as sphincterotomes have been shown in some studies to be more effective than standard catheters for cannulation. Using guidewires through cannulation and sphincterotomy devices as a primary method of achieving deep cannulation is increasingly practiced, based on studies demonstrating increased success and possibly a reduced rate of pancreatitis. Pancreaticobiliary cannulation and sphincterotomy devices will continue to evolve and provide further options for safe and effective pancreaticobiliary access and therapy.

Abbreviations: CBD, common bile duct; WAAS, wire-assisted access sphincterotomy.

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