



TECHNOLOGY STATUS EVALUATION REPORT



EUS accessories

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 March 2007 for articles related to accessories for use during EUS procedures by cross-referencing the keyword “EUS” with keywords “accessories,” “fine needle aspiration,” “tissue acquisition,” and “cytology.” Reference lists from relevant publications were also hand searched for related publications.

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BACKGROUND

The past decade has seen a marked increase in the dissemination of EUS. At the same time, EUS has evolved from primarily an imaging modality to interventional diagnostic and therapeutic applications.¹⁻³ Similarly, the number and type of echoendoscopes and the accessories designed specifically for use during EUS have grown. This report will review the currently available endoscopic accessories for EUS.

TECHNICAL CONSIDERATIONS

Most EUS accessories are needles designed for tissue acquisition. Most common among them are the FNA needles for obtaining cytologic samples. A larger-caliber needle-based device is designed for obtaining core biopsy specimens for histologic, rather than cytologic, tissue analysis. Several other devices are modified FNA needles designed for use in specific contexts, such as for performance of celiac plexus blockade or neurolysis. A cytology brush is marketed separately from the 19-gauge FNA needles that it is designed to pass through. EUS needles may also be used in experimental and/or investigational settings to deliver potentially therapeutic agents into tumors or cystic lesions, to facilitate pancreaticobiliary access, and to drain pseudocysts, among other indications.⁴⁻¹¹

All EUS accessories are designed for use with linear echoendoscopes, which allow continuous US visualization of the devices throughout their path once they are advanced beyond the GI lumen and into the target structures. Radial echoendoscopes, by nature of the radial plane of US imaging, can only visualize these devices as points as they pass through the imaging field and are inadequate for interventional EUS procedures.

EUS-FNA devices

A variety of partially reusable and single-use EUS-guided FNA (EUS-FNA) needle devices are available in 19-, 22-, and 25-gauge configurations (Table 1). All of the fully disposable single-use varieties are similar in design and operation. They are composed of a hollow needle with a solid removable stylet, a semirigid protective sheath, and a handle with a port for stylet insertion or withdrawal, as well as an attachment of a vacuum syringe. Most FNA needles and

TABLE 1. EUS accessories

Device name	Manufacturer	Maximum working length (cm)	Sheath diameter (mm or French)	Needle size (gauge)
FNA needles				
Powershot	Olympus	145	2.35 mm	22
EZ Shot	Olympus	140	1.8 mm	22
Vizeon	Commed (Commed Endoscopic Technologies, Billerica, Mass)	142.5	2.1 mm (19 gauge) 1.8 mm (22 gauge)	19, 22
EchoTip	Cook Endoscopy	140	5.2F	22
EchoTip Ultra	Cook Endoscopy	140	5.2F (22- and 25-gauges needles); 4.2F-5.2F (19-gauge needle)	19, 22, 25
Miscellaneous non-FNA devices				
QuickCore EUS needle	Cook Endoscopy			19-gauge
EchoTip EUS brush	Cook Endoscopy			Works with 19-gauge needle
EchoTip celiac plexus neurolysis needle	Cook Endoscopy			20

sheaths are composed of aluminum or stainless steel. All currently available disposable needles are modified by laser etching, mechanical dimpling, or sandblasting of the leading tip (typically 1 cm) to enhance their echogenicity and thus US visibility. In some cases, sheaths are treated with specific coatings to reduce friction and to facilitate stylet insertion and removal. Some needles are specifically designed for use with certain endoscopes and do not require a means of adjusting to different lengths. Others are designed for use with any brand of echoendoscopes and, therefore, incorporate a length adjustment to compensate for varying endoscope lengths. The adjustment uses either plastic spacers that affix between the needle device and the endoscope or an adjustable slide on the needle handle.

Stylets enhance the rigidity of the needle during passage through tissue to the target structure. They are available in both ball-tip and beveled-tip configurations, with the beveled-tip configuration being somewhat sharper. Altering the position of the stylet modifies the sharpness of the needle tip during passage through tissue. No data exist to demonstrate the superiority of 1 stylet tip over

another. On some devices, the stylet can be fixed in place within the needle via a Luer lock at the proximal end, whereas, on other devices, the stylet is only loosely held in place by a notched cap.

For fully disposable needles, the device handle consists of several rigid plastic interlocking cylinders and is affixed to the echoendoscope via the Luer Lock at the accessory-channel port to enhance device stability during use. The handle assembly allows for controlled and measured advancement of the needle from within the protective sheath into the organ or structure of interest. Handles typically have markings at 1-cm intervals to allow the depth of penetration of the needle to be monitored (although this distance can also be seen and measured by EUS). Most needles can be advanced between 1 and 9 cm. All fully disposable devices come equipped with an adjustable “needle stopper” that limits advancement of the needle to a desired depth of insertion and prevents advancement completely during insertion and removal of the entire device into the echoendoscope as a safety precaution.

The commercially available single-use EUS-FNA needles come with specially designed syringes with locking fins

TABLE 1 (continued)

Maximum insertion depth (cm)	Reusable vs disposable	Unique characteristics	List price (USD)
9	Partially reusable	Spring-loaded, 30-mm, initial advancement option for indurated lesions; compatible only with Olympus echoendoscopes	1 handle, 1 sheath, 5 needles with stylets, 1725; 5 sterile, single-use needles with stylets, 690; replacement sheath, 120; replacement handle, 1050
8	Disposable	Compatible only with Olympus echoendoscopes	166 (830 per pack of 5 needles)
8.5	Disposable	Manufactured by MediGlobe and marketed in Europe as SonoTip II	250
8	Disposable	Ball tip and beveled tip stylets; plastic spacers for length adjustment	220
8	Disposable	Ergonomic handle; integrated sheath adjuster	263
8	Disposable	19-gauge cutting sheath encloses a beveled needle with an 18-mm-long tissue-specimen tray	347
	Disposable	Modified stylet with 1 × 5-mm brush; passes through 19-gauge FNA needle	158
	Disposable	Solid, sharp, conical tip with array of side holes for radial injection	263

and/or stopcocks that can be used to create and hold a vacuum. Standard 10- or 20-mL syringes can be used to manually create suction as well.

One EUS-FNA needle device (Powershot Needle; Olympus America Corp, Melville, NY) couples a reusable handle with disposable needles, sheaths, and stylets, and is designed to work exclusively with Olympus echoendoscopes. It is available in a 22-gauge diameter and has a total length of 145 cm. The sheath is 2.35 mm in diameter, somewhat wider than that seen in fully disposable needle systems. This device has a spring-loaded trigger mechanism to allow needle penetration up to 30 mm into indurated lesions. The needle can be manually advanced a further 60 mm once the spring-loaded function has been used to penetrate tissue, for a full potential needle advancement of 90 mm. Of note, the needle can also be advanced 90 mm in a purely manual mode. There are limited published data on this device, with one report that described its successful use in 4 patients with indurated lesions.¹² Other needle devices that incorporate some reusable parts are available in Europe and Asia.

The use of EUS-FNA devices is generally similar, despite the differences in the currently available needles. The needle is advanced out of the sheath and into the target under direct linear US guidance. Once advanced into the target, the stylet is removed, and fluid and/or tissue can be aspirated or therapeutic agents or contrast can be injected. Typically, once the needle tip has been advanced into a solid mass, a vacuum syringe is affixed to the proximal end of the needle assembly, and the handle is used to repeatedly advance and partially withdraw the needle (while taking care not to remove the needle from the mass) in an effort to increase cellular yield for analysis. Vacuum syringes are widely, although not universally, used, and limited data suggest that, in the specific context of lymph-node aspiration, vacuum syringes may decrease cellular yield.¹³ If the needle is inserted into a cystic lesion, then similar maneuvers may be required to both aspirate fluid and attempt to obtain cells from the cyst wall. It should be noted that the use of these needles, although generally similar, has not been standardized and some variation exists within clinical practice.

Clinical results and comparative studies between available FNA needles

EUS-FNA has high and well-established sensitivity and specificity rates, and a very high safety profile. Complications, such as bleeding or bacteremia, occur in less than 1% of all patients.¹⁴⁻¹⁸ EUS-FNA has been most extensively studied in the context of pancreatic cancer, where it has been shown to have a sensitivity, specificity, and accuracy of 64% to 92%, 95% to 100%, and 85% to 95%, respectively.¹⁹⁻²²

Comparative studies of EUS accessories are severely limited. One prospective study compared 2 different types of EUS-FNA needles, the EchoTip (Cook Endoscopy, Winston-Salem, NC) and the SonoTip (GIP/MediGlobe, Tempe, Ariz) (the latter device is not available in the United States) in 30 patients with focal pancreatic lesions.²³ Each patient underwent FNA with both types of needle. Indeterminate or inadequate cytology results were obtained in 11% of patients when using the GIP needle, and 0% with the Cook needle. The Cook device yielded greater sensitivity and accuracy than the GIP device (55% vs 85% and 65% vs 89%, respectively). There were 4 instances of sheath failure, in which the stylet could not be reintroduced into the needle, with the Cook needle and no failure with the GIP needle. Overall, the investigators felt that cytopathologic results were significantly better with the Cook needle.

Needle core biopsy device

The only device available for EUS-guided acquisition of core biopsy specimens for histologic analysis (QuickCore EUS needle; Cook) consists of a hollow, 19-gauge, metal, cutting sheath enclosing a needle with a 5-mm beveled distal tip and an 18-mm-long tissue specimen tray; an outer protective sheath; and a spring-loaded handle. The spring-loaded mechanism is used to prime the device by compressing the spring into a “firing position.” The needle/cutting sheath can be advanced up to 8 cm out of the protective sheath. Spacers are available to adjust for different echoendoscope lengths. Unlike other EUS-FNA devices, the QuickCore needle is rotatable, which facilitates radial positioning of the laterally directed tissue tray for optimal tissue sampling. The device is comparatively rigid when compared with standard EUS needles.

The needle and cutting sheath are first advanced out of the echoendoscope and into the target tissue. Surrounding tissue fills the specimen tray in the central needle, is then resected via the rapid advancement of the cutting sheath over the needle, and is retained in the tray by the cutting sheath.

The QuickCore needle has been successfully used to obtain tissue cores from both solid and cystic pancreatic lesions, lymph nodes, hepatic lesions, submucosal lesions, mediastinal lesions, celiac ganglia, and pancreatic parenchyma when histopathology is required or preferable to cytopathology, as in the diagnosis of autoimmune pancreatitis.²⁴⁻²⁹

Cytology brush

The only cytology brush available for dedicated use through echoendoscopes (EchoTip Endoscopic Ultrasound Brush; Cook) is a disposable, modified EUS stylet with a 1 × 5-mm brush at its leading end, which passes through the channel of the 19-gauge FNA needle (Cook). In the only clinical study that specifically used this device, 10 patients with pancreatic cystic lesions underwent standard FNA with a 19-gauge FNA needle for aspiration of cyst contents followed by EUS-guided brush cytology of the cyst interior by using the EchoBrush.³⁰ Overall, the investigators felt that the cytology brush increased cytologic yield, although there was a relatively high rate of bleeding in patients who underwent cytologic brushing.

Celiac plexus blockade and neurolysis needle

EUS is widely used to perform celiac plexus blockade (in patients with chronic pancreatitis or pancreatic cancer) or celiac plexus neurolysis (almost exclusively in patients with pancreatic cancer) for relief of pain.³¹⁻³⁴ Celiac plexus blockade provides temporary pain relief, usually via the injection of a local anesthetic agent combined with a steroid. Celiac plexus neurolysis involves the injection of a local anesthetic combined with pure ethanol to permanently destroy nerve tissue. Most reports to date have performed these injections through available EUS-FNA needles. A needle specifically designed for EUS-guided celiac plexus blockade and neurolysis (EchoTip celiac plexus neurolysis needle; Cook) differs from other EUS needles in that it does not have a removable stylet. Rather, this 20-gauge device has a solid, sharp, conical tip, and an array of side holes for radial delivery of the desired agent into the celiac plexus and/or the perineural space.

Limited data suggest that celiac plexus blockade via EUS may be superior to other approaches (eg, CT guided).³⁵ There are no studies specifically pertaining to this device.

FINANCIAL ISSUES

The use of EUS accessories adds cost, time, and risk to procedures. The specific costs of EUS accessories vary widely and are listed in the accompanying table (Table 1). The use of EUS accessories often requires modification in coding practices, because additional codes are required, depending on the type of accessory used and the specific context of use (ie, EUS-FNA of an esophageal lymph node requires a different Current Procedural Terminology (CPT) code than does EUS-FNA of the pancreas). Billing for celiac plexus blockade and neurolysis requires the addition of separate codes to the regular EUS CPT code. A full list of relevant CPT codes can be found in Table 2.

SUMMARY

EUS accessories serve to significantly increase the spectrum of available EUS interventions. Extraluminal tissue

TABLE 2. List of relevant EUS CPT codes*

Colonoscopy	
45391	Colonoscopy, flexible, proximal-to-splenic flexure; with EUS examination
45392	Colonoscopy, flexible, proximal-to-splenic flexure; with transendoscopic US-guided intramural or transmural FNA/biopsy(s)
Sigmoidoscopy	
45341	Sigmoidoscopy, flexible; with EUS examination
45342	Sigmoidoscopy, flexible; with transendoscopic US-guided intramural or transmural FNA/biopsy(s)
Esophagoscopy	
43231	Esophagoscopy, rigid or flexible; with EUS examination
43232	Esophagoscopy, rigid or flexible; with transendoscopic US-guided intramural or transmural FNA/biopsy(s)
Upper-GI endoscopy	
43237	Upper-GI endoscopy, including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with EUS examination limited to the esophagus
43238	Upper-GI endoscopy, including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with transendoscopic US-guided intramural or transmural FNA/biopsy(s), esophagus (includes EUS examination limited to the esophagus)
43242	Upper-GI endoscopy, including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with transendoscopic US-guided intramural or transmural FNA/biopsy(s) (includes EUS examination of the esophagus, stomach, and either the duodenum and/or jejunum as appropriate)
43259	Upper-GI endoscopy, including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with EUS examination, including the esophagus, the stomach, and either the duodenum and/or jejunum as appropriate
Others	
Celiac plexus injection or neurolysis requires a separate code added on to the EUS CPT	
64530	Injection, anesthetic agent; celiac plexus, with or without radiologic monitoring
64680	Destruction by neurolytic agent, with or without radiologic monitoring; celiac plexus

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acquisition is the dominant maneuver among the interventional EUS procedures. With growing experience, new devices, and new indications, the role of EUS accessories will continue to expand. A significant shortcoming of the technology is the paucity of descriptive or comparative studies of and between existing devices. Further studies of these devices to more clearly elucidate optimal usage are needed.

Abbreviations: ASGE, American Society for Gastrointestinal Endoscopy; CPT, Current Procedural Terminology; EUS-FNA, EUS-guided FNA.

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