



## Echoendoscopes

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*The 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, using a MEDLINE literature search to identify pertinent clinical studies on the topic and a MAUDE (U.S. Food and Drug Administration Center for Devices and Radiological Health) database search to identify the reported adverse events 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 October 2014 for articles related to echoendoscopes by using the keywords “endosonography” and “endoscopic ultrasound” paired with “gastrointestinal disease,” “esophageal disease,” and “biliary disease,” “gastrointestinal cancer,” “esophageal neoplasms,” “colorectal neoplasms,” “gastric neoplasms,” “pulmonary neoplasms,” “pancreatic neoplasms,” and “pancreatitis.” Technology Status Evaluation Reports are scientific reviews provided solely for educational and informational purposes. Technology Status Evaluation Reports are not rules and should not be construed as establishing a legal standard of care or as encouraging, advocating,*

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### BACKGROUND

Endoscopic ultrasound (EUS) is a diagnostic and therapeutic modality that continues to expand its clinical applications. EUS processes high-frequency sound waves to create ultrasound (US) images. Echoendoscopes are able to image both intramural structures and structures adjacent to the GI tract and fall into 2 broad categories: radial (“sector”) or linear (“convex array”).<sup>1</sup> EUS miniprobes are radial US probes that can be advanced through the working channel of a gastroscope or adult colonoscope. This report focuses on currently available echoendoscopes and EUS processors and is an update of a previous Technology Status Evaluation Report.<sup>2</sup>

### TECHNICAL CONSIDERATIONS

#### Echoendoscopes

Echoendoscopes comprise a US transducer attached to the tip of an endoscope. The transmitter energizes the transducer elements by precisely timed, high-amplitude voltages. The transducer contains piezoelectric crystals that change shape in response to the applied voltage. The piezoelectric crystals convert electrical energy to mechanical energy (sound waves). These sound waves are then transmitted to the target tissue, and the reflected sound waves are captured by the transducer and converted to electrical signals by the reverse piezoelectric effect. The US processor then interprets the electrical signals and produces a US image on the monitor. The real-time B-mode (brightness) produces a 2-dimensional image of the reflected sound waves. The variations in image brightness are a consequence of different amplitudes of sound-wave signals reflected from target organs.

Electronic echoendoscope transducers contain a variable number of piezoelectric crystals and have the ability

TABLE 1. Echoendoscopes

Instruments	Scanning angle/type of scan	Frequency, MHz	Tip diameter, mm	Insertion tube OD, mm	Channel diameter, mm	Tip deflection up/down
Olympus America						
GF-UE160-AL5	360° electronic radial	5, 6, 7.5, 10 (12 with EU-ME1, EU-ME2, and EU-ME2 Premier Plus)	13.8	11.8	2.2	130°/90°
GF-UCT180	180° electronic curvilinear	5, 6, 7.5, 10 (12 with EU-ME1, EU-ME2, and EU-ME2 Premier Plus)	14.6	12.6	3.7	130°/90°
GF-UC140P-AL5	180° electronic curvilinear	5, 6, 7.5, 10 (12 with EU-ME1, EU-ME2, and EU-ME2 Premier Plus)	14.2	11.8	2.8	130°/90°
TGF-UC180J	90° electronic curvilinear	5, 6, 7.5, 10 (12 with EU-ME1, EU-ME2 and EU-ME2 Premier Plus)	14.6	12.6	3.7	180°/90°
Bronchoscope						
BF-UC180F	60° electronic curvilinear	5, 7.5, 10, 12 (6 with EU-ME1, EU-ME2, and EU-ME2 Premier Plus)	6.9	6.3	2.2	120°/90°
Instruments	Scanning angle/type of scan	Frequency, MHz	Tip Diameter, mm	Insertion tube, OD mm	Channel, mm	Tip deflection up/down
Pentax Medical						
EG-3630UR	270° electronic radial	5, 7.5, 10	12.8	12.8	3.8	130°/130°
EG-3630UT	100° electronic curvilinear	5, 7.5, 10	12.1	12.1	2.4	130°/130°
FG-36UX	100° electronic curvilinear	5, 7.5, 10	12.1	12.1	2.4	130°/130°
EG-3830UT	100° electronic curvilinear	5, 7.5, 10	12.8	12.8	3.8	130°/130°
EG-3870UTK	120° electronic curvilinear	5, 6.5, 7.5, 9, 10	12.8	12.8	3.8	130°/130°
EG-3670URK	360° electronic radial	5, 6.5, 7.5, 9, 10	12.1	12.1	2.4	130°/60°
EG-3270UK	120° electronic curvilinear	5, 6.5, 7.5, 9, 10	10.8	10.8	2.8	130°/130°
Bronchoscope						
EB-1970UK	75° electronic curvilinear	5, 6.5, 7.5, 9, 10	6.3	6.3	2	120°/90°
Instruments	Scanning angle/type of scan	Frequency, MHz	Tip diameter, mm	Insertion Tube OD, mm	Channel diameter, mm	Tip deflection up/down
Fujifilm Endoscopy						
EG-530UR2	electronic radial 360°	5, 7.5, 10, 12	11.4	11.5	2.2	180°/90°
EG-530UT2	124° electronic convex	5, 7.5, 10, 12	13.9	12.1	3.8	160°/160°

OD, Outer diameter; FOV, field of view; N/A, not available.

\*All echoendoscopes will operate with Hitachi 525 (5 MHz, 7.5 MHz only for linear; 10 MHz radial only), 6000, 6500, 5500, 900, and 8500 processors, but only Preirus and Noblus models are currently available for purchase.

to alter the focal distance and use tissue harmonic enhancement, which may improve the resolution of the image. The greater the number of piezoelectric elements used in the transducer is, the better the lateral

resolution of the image. Echoendoscopes typically scan over a limited frequency range of 5 to 12 MHz, whereas miniprobes allow scanning at higher megahertz (up to 30 MHz). Scanning at higher frequencies limits the

TABLE 1. Continued

Tip deflection left/right	Working length, cm	FOV	Depth of view, mm	Cost (list price)	Processor
90°/90°	125	100°, 55° oblique	3-100	\$113,300	EU-ME1, EU-ME2, EU-ME2 Premier Plus, SSD-5000, SSD-a5, SSD-a10, ProSound F75
90°/90°	125	100°, 55° oblique	3-100	\$98,300	EU-ME1, EU-ME2, EU-ME2 Premier Plus, SSD-5000, SSD-a5, SSD-a10, ProSound F75
90°/90°	125	100°, 55° oblique	3-100	\$106,700	EU-ME1, EU-ME2, EU-ME2 Premier Plus, SSD-5000, SSD-a5, SSD-a10, ProSound F75
90°/90°	124.5	120° forward viewing	3-100	\$119,500	EU-ME1, EU-ME2, EU-ME2 Premier Plus, SSD-5000, SSD-a5, SSD-a10, ProSound F75
N/A	60	80°, 35° oblique	2-50		EU-ME1, EU-ME2, EU-ME2 Premier Plus, SSD-5000, SSD-a5, SSD-a10, ProSound F75
Tip deflection left/right	Working length (cm)	FOV	Depth of view, mm	Cost	Processor/cost
120°/120°	125	120° forward view		Not sold	Hitachi 5500, \$82,500 Hitachi 8500; \$142,000
120°/120°	125	130°, 50° oblique		Not sold	Hitachi 5500 \$82,500 Hitachi 8500 \$142,000
120°/120°	125	105°, 60° oblique		Not sold	Hitachi EUB 515, 525,* 555, 6000, 6500 processors
120°/120°	125	120°, 50° oblique		Not sold	Hitachi EUB 515, 525,* 555, 6000, 6500 processors
120°/120°	125	120°, 45° oblique		\$75,240	Hitachi 5500 Hitachi 900 Hitachi HI VISION Preirus Hitachi Noblus
60°/60°	125	140° forward view		\$78,000	Hitachi 5500 Hitachi 900 Hitachi HI VISION Preirus Hitachi Noblus
120°/120°	125	120°, 50° oblique		\$78,000	Hitachi 5500 Hitachi 900 Hitachi HI VISION Preirus Hitachi Noblus
	60	100°, 45° oblique		\$44,000	Hitachi 5500 Hitachi 900 Hitachi HI VISION Preirus Hitachi Noblus
Tip deflection left/right	Working length, cm	FOV	Depth of view, mm	Cost	Processor
100°/100°	125	140°	3-100	\$93,955	SU-8000
120°/120°	125	140°	3-100	\$86,955	SU-8000

penetration of the US beam but improves resolution. Thus, higher frequencies allow for better image resolution of near objects (<2 cm from the transducer), whereas lower frequencies allow better US penetration

and imaging of structures up to 12 cm from the transducer.

Echoendoscopes are coupled to US processors. Newer US processors have increased resolution and incorporate

additional imaging features including Doppler/power flow, tissue elastography, and an ability to visualize newer contrast agents. Enhanced US imaging is detailed in a separate ASGE Technology Committee document.<sup>3</sup>

There are 2 fundamental echoendoscope designs: curvilinear array and radial array. Radial-array EUS is mainly used for luminal imaging and evaluation of the wall layers of the GI tract, whereas curvilinear-array EUS in addition to imaging allows tissue sampling and therapeutic applications.

**Radial echoendoscopes.** Older mechanical radial echoendoscopes have been replaced by electronic radial echoendoscopes that produce significantly better images and offer Doppler capability. The electronic radial-array transducers orient the individual piezoelectric elements around the distal tip in a 360° radial array, producing an image in a plane perpendicular to the long axis of the echoendoscope. Radial-array echoendoscopes are used only for diagnostic EUS examinations and thus have limited applications because tissue sampling and therapeutic interventions are not possible.

Three major manufacturers, Fujifilm Endoscopy (Fujinon, Wayne, NJ), Olympus (Olympus America, Center Valley, Pa), and Pentax (Pentax of America, Montvale, NJ), produce radial-array echoendoscopes (Table 1). The echoendoscopes are very similar in shape and all provide a 360° field of view. The endoscopic camera is end-viewing on the Pentax and Fujinon echoendoscopes, whereas an oblique view (55°) is provided on the Olympus echoendoscope. Most of the radial echoendoscopes image at an adjustable frequency of 5, 7.5, or 10 MHz. The radial echoendoscopes also come in slightly different shaft diameters. Fujinon offers the slimmest (11.5 mm) and most flexible echoendoscope, whereas the Olympus radial-array echoendoscope has the widest diameter (13.8 mm) at the junction of the shaft and the US transducer.

**Linear echoendoscopes.** All currently available electronic curvilinear-array instruments produce US images in a plane parallel to the long axis of the echoendoscope, usually in a sector between 100° and 180°. These images are analogous to images from transabdominal US scanning. This US image orientation in the linear-array echoendoscope is important for tissue acquisition and therapeutic interventions as EUS needles are advanced from the distal tip of the echoendoscope in the same plane as the US image. This allows for simultaneous visualization of the target lesion and the EUS needle as it is advanced. Accurate control of the depth and position of the needle into the target lesion is therefore possible under linear EUS guidance. In addition, all curvilinear-array instruments incorporate an elevator at the distal end of the working channel that allows limited control of the angle of exit of EUS needles or other devices from the working channel.

Three major manufacturers, Fujifilm, Olympus America, and Pentax, produce linear-array echoendoscopes (Table 1). The echoendoscopes differ in US tip design,

flexibility, balloon insufflation control design, and bend points at the distal end of the echoscopes. All of the EUS transducers have a curved design and are located distal to the oblique-viewing endoscopic camera lens.

The Olympus linear EUS platform currently consists of 3 main models. The most recently manufactured echoendoscope is the GF-UCT180, which allows higher resolution imaging compared with previous models. It has a 3.7-mm working channel, a 14.6-mm diameter distal tip, and as well as a detachable cable allowing easier insertion of the echoendoscope into automated endoscopic reprocessors. The 2 older Olympus models, the slimmer echoendoscope (GF-UC140P-AL5) and the therapeutic echoendoscope (GF-UCT140-AL5, note this scope was discontinued on 3/31/15), have accessory channels measuring 2.8 mm and 3.7 mm, respectively. The larger caliber working channel of the therapeutic linear-array echoendoscope allows advancement of 10F accessories, whereas the slimmer linear-array echoendoscope can only accommodate 7F accessories. However, both of these working channel sizes easily accommodate all available EUS needles used for performing FNA. All current Olympus linear echoendoscopes are compatible with B-mode, color Doppler, pulse wave Doppler, H-Flow, and tissue harmonic echo (except the GF-UC140P-AL5 and GF-UCT140-AL5). Elastography is available for all linear echoendoscopes on the EU-ME2 Premier Plus Olympus processor at this time.

A forward-viewing linear echoendoscope (TGF-UC180J) that is intended for mainly therapeutic applications is manufactured by Olympus. The working channel diameter is 3.7 mm, and the distal tip diameter is 14.6 mm. This forward-viewing echoendoscope has a short US transducer and an end-viewing camera, but no balloon or elevator. The US image is limited to a 90° range. The limited image, lack of a balloon and an elevator limit the applications of this echoendoscope.

The Pentax linear EUS platform has 1 linear-array scope currently available in the United States, the EG-387OUTK. It has a 3.8-mm accessory channel. The diameter of the distal tip is 14.3 mm. A newer Pentax “slim” echoendoscope (EG-327OUK) with a distal tip diameter of 12 mm is awaiting approval by the U.S. Food and Drug Administration. The Pentax echoendoscope platform allows performance of elastography, spatial compounding, tissue harmonics, Doppler/power Doppler, B-mode, and M-mode imaging.

The Fujinon linear echoendoscope (EG-530UT2) has a 3.8-mm working channel and a 13.9-mm distal tip diameter. The flexible portion diameter is 12.1 mm. The scanning modes include color Doppler, power Doppler, pulse wave, B-mode, and M-mode.

### High-frequency catheter probes

Miniproboscopes are flexible high-frequency US probes that can be advanced through the working channel of endoscopes. Miniproboscopes have an outer diameter that ranges

**TABLE 2. Fujinon high-frequency mechanical biplane probes**

Model	Working length, mm	Outer diameter, mm	Balloon sheath	Frequency, MHz	Compatible processor
P2625	2200	2.6	No	25	SP-702
P2025	2200	2.0	No	25	SP-702
PL-2226-20	2200	2.6	No	20	SP-701, SP-711
P2620	2200	2.6	No	20	SP-702
P2020	2200	2.0	No	20	SP-702
PL-1926-20	1900	2.6	No	20	SP-701, SP-711
PL1726-20	1700	2.6	No	20	SP-701, SP-711
PL2220-20	2200	2.0	No	20	SP-701, SP-711
PL2317 B-20	2300	1.7	Yes	20	Not available in U.S.
P2615	2200	2.6	No	15	SP-702
P2015	2200	2.0	No	15	SP-702
PL226-15	2200	2.6	No	15	SP-701, SP-711
PL1926-15	1900	2.6	No	15	SP-701, SP-711
PL1726-15	1700	2.6	No	15	SP-701, SP-711
PL2220-15	2200	2.0	No	15	SP-701, SP-711
PL2317 B-15	2300	1.7	Yes	15	Not available in U.S.
P2612	2200	2.6	No	12	SP-702
P2012	2200	2.0	No	12	SP-702
PL2226-12	2200	2.6	No	12	SP-701, SP-711
PL1926-12	1900	2.6	No	12	SP-701, SP-711
PL1726-12	1700	2.6	No	12	SP-701, SP-711
PL2220-12	2200	2.0	No	12	SP-701, SP-711
PL2317B-12	2300	1.7	Yes	12	Not available in U.S.
PL2226-7.5	2200	2.6	No	7.5	Not available in U.S.
PL-2226 B-7.5	2200	2.6	Yes	7.5	SP-701, SP-711, SP-702

between 1.7 and 3.4 mm. These US miniprbes scan at a higher frequency (range 12-30 MHz) compared with standard echoendoscopes. This higher frequency allows higher resolution scanning at the cost of a limited depth of penetration. The optimal imaging depth of high-frequency miniprbes is between 0.07 and 0.18 mm. This allows precise differentiation of the discrete wall layers of the esophagus, stomach, small intestine, and colon.

Miniprbes may be either mechanical or electronic. Mechanical miniprbes have a rotating US transducer housed within a plastic sheath at the tip of the probe. The sheath also contains oil that serves as both a lubricant and an effective US medium. Electronic miniprbes have a ring at the tip of the probe with 64 transducer elements that produce a 360° US image. Optimization of the US image has been achieved by introduction of deaerated water into the GI tract lumen or through use of a small balloon applied to the end of the probe, surrounding the transducer.<sup>1</sup>

Current manufacturers of high-frequency US probes and processors include Fujifilm Endoscopy (Fujinon, Wayne, NJ) and Olympus (Olympus America, Center Valley, Pa) (Tables 2 and 3).

US catheter probes are mainly used for imaging of superficial neoplasms of the esophagus and stomach, small subepithelial mass lesions of the GI tract, or for detailed evaluation of the wall layers of the GI tract.<sup>4,5</sup> In addition, wire-guided US probes are available for evaluation of the pancreatic and biliary ductal systems.<sup>6</sup>

Widespread use of high-definition EUS probes has been limited due to the need for dedicated processors, lack of probe durability, and the high costs of both the probes and probe maintenance.

Newer miniprobe design improvements allow controlled automated retraction over a defined distance. This feature allows 3-dimensional rendering after complex image processing. Further research and evolution of miniprobe designs to improve durability and imaging characteristics may lead to expanded use.

## EUS PROCESSORS

Echoendoscopes from each of the manufacturers require a dedicated compatible EUS processor to produce US

TABLE 3. Olympus miniprobes

Instruments	Working length, mm	Total length, mm	Insertion tube outer diameter, mm	Maximum outer diameter, mm	Compatible guidewire	Compatible endoscope inner channel diameter, mm	Scanning method
UM-2R-3	2050	2140	2.4	2.5		2.8	Mechanical radial
UM-3R-3	2050	2140	2.4	2.5		2.8	Mechanical radial
UM-G20-29R	2050	2140	2.0	2.9	0.035 inch	3.2	Mechanical radial
UM-S20-20R-3	2050	2140	1.7	2.0		2.2	Mechanical radial
UM-S20-17S	2150	2220	1.4	1.7		2.0	Mechanical radial
UM-BS20-26R	2050	2140	2.5	2.6		2.8	Mechanical radial
UM-DP12-25R	2050	2210	2.5	2.5		2.8	Mechanical radial and mechanical helical
UM-DP20-25R	2050	2210	2.5	2.5		2.8	Mechanical radial and mechanical helical
UM-DG20-31R	2050	2210	2.2	3.1	0.035 inch	3.7	Mechanical radial and mechanical helical

N/A, Not available.

images (Table 4). EUS processors for Pentax and Olympus echoendoscopes were previously manufactured by 2 different companies, Hitachi and Aloka, which have since merged after the recent acquisition of Aloka by Hitachi. Hitachi offers different EUS platforms for Olympus and Pentax echoendoscopes. The Olympus (ProSound F75) and Pentax (HI VISION Preirus) compatible endoscopic US systems are large, free-standing, mobile units. The Fujinon EUS processor (Fujifilm Endoscopy Sonart SU-8000) is very compact and can be incorporated into an endoscopy tower or cart. Olympus also manufactures a compact processor, the EU-ME2. The image quality and features vary between companies and processors.

### Olympus-compatible EUS processors

**Free-standing processors.** The ProSound F75, manufactured by Hitachi-Aloka, is a new digital platform designed for use with the new Olympus electronic linear echoendoscope, the GF-UCT180, and the forward-viewing echoendoscope TGF-UC180J. It is also compatible with the previous generation of Olympus electronic linear and radial-array echoendoscopes. The older  $\alpha$ 10 processor (Aloka) used with Olympus echoendoscopes is no longer

manufactured. The  $\alpha$ 10 processor can interface with the new GF-UCT180 echoendoscopes, but requires a software upgrade. A software upgrade that will allow the ProSound F75 to perform elastography should be released in 2015.

**Compact processors.** The EU-ME2 manufactured by Olympus is designed to be used with both Olympus EUS and endobronchial US (EBUS) equipment and is designed for integration with conventional endoscopy on a single workstation. This compact EUS processor allows a broad range of EUS frequencies (5-20 MHz), near focus of up to 1 cm, elastography (optional), and miniprobe 3-dimensional rendering. The processor has other features including pulse-wave Doppler and high-resolution flow mode. This processor does not come equipped with a monitor but can be set up with existing monitors (depending on resolution and input jacks).

### Pentax-compatible EUS processors

**Free-standing processors.** The Hitachi HI VISION Preirus and Hitachi Noblus processors are compatible with both EUS and EBUS. These processors offer the option of elastography. The processors also offer contrast-

TABLE 3. Continued

Scanning direction	Linear scanning length	Frequency, MHz	Acoustic coupling method	Compatible probe driver
Perpendicular to insertion	N/A	12	Direct contact balloon method (with balloon sheath MH-246R)	MH-240, MAJ-682, MAJ-935, MAJ-1720
Perpendicular to insertion	N/A	20	Direct contact balloon method (with balloon sheath MH-246R)	MH-240, MAJ-682, MAJ-935, MAJ-1720
Perpendicular to insertion	N/A	20	Direct contact	MH-240, MAJ-682, MAJ-935, MAJ-1720
Perpendicular to insertion	N/A	20	Direct contact balloon method (with balloon sheath MH-246R)	MH-240, MAJ-682, MAJ-935, MAJ-1720
Perpendicular to insertion	N/A	20	Direct contact	MH-240, MAJ-682, MAJ-935, MAJ-1720
Perpendicular to insertion	N/A	20	Balloon (with balloon sheath MAJ-643R [5 pieces])	MH-240, MAJ-682, MAJ-935, MAJ-1720
Perpendicular to insertion	Max 40 mm	12	Direct contact	MAJ-935, MAJ-1720
Perpendicular to insertion	Max 40 mm	20	Direct contact	MAJ-935, MAJ-1720
Perpendicular to insertion	Max 40 mm	20	Direct contact	MAJ-935, MAJ-1720

enhanced US examination with the administration of microbubble-based contrast agents by using the contrast-specific mode on the processor intended to aid recognition of microvasculature and staging.

The Hitachi Noblus was launched in the United States in November 2014. This is Pentax's first compact processor. The Hitachi Noblus tabletop processor includes an integrated monitor and console, similar to and not much larger than a laptop computer.

### Fujinon-compatible EUS processors

**Compact processors.** The SU-8000 US processor manufactured by Fujinon is the smallest processor currently on the market. The SU-8000 uses Zone Sonography technology that delivers wide US beams and acquires large amounts of echoendoscopic data in zones rather than line by line as with conventional US systems. This allows image construction much more rapidly as it requires fewer transmit and receive cycles. The data are processed by estimating and selecting the optimal US speed that produces the highest lateral resolution to construct the EUS image. The SU-8000 also has a range of 5 to 12 MHz. Although this processor does not offer elastography, it does have color Doppler capabilities.

### CLINICAL APPLICATIONS

EUS was initially created and used to better image the pancreas.<sup>7,8</sup> The advent of the linear-array echoendoscope allowed EUS-guided tissue sampling and subsequently additional therapeutic applications. EUS remains mainly a diagnostic tool, allowing imaging and the ability to acquire tissue or fluid. It has a primary role in T and N staging of GI malignancies, including esophageal, gastric, pancreatic, and rectal cancers and has a complementary role, along with cross-sectional imaging, in M staging. Using a curvilinear-array echoendoscope, endosonographers can direct a EUS-FNA needle under real-time endosonographic guidance into a target lesion or structure. The EUS-FNA needle is used as a conduit to aspirate, inject, or gain access into a structure. EUS-FNA is mainly used for solid-tissue sampling for cytological diagnosis or fluid aspiration from cystic lesions for fluid analysis. The most common uses of EUS-FNA are in sampling of solid pancreatic masses,<sup>9,10</sup> cystic lesions of the pancreas,<sup>11-13</sup> lymph nodes,<sup>14-18</sup> and subepithelial lesions. The capacity to sample lymph nodes has extended the role of EUS to non-GI diseases such as nodal staging in non-small cell lung cancer. This vital role of EUS-FNA in lung cancer led to the

**TABLE 4. EUS processors**

Processor	Cost, US\$
Olympus echoendoscope compatible	
Hitachi-Aloka ProSound F75	230,000
Olympus EU-ME1 (discontinued on March 31, 2015)	98,000
Olympus EU-ME2	115,000
Olympus EU-ME2 Premier Plus	180,000
Pentax echoendoscope compatible	
Hitachi HI VISION Preirus	175,000
Hitachi Noblus	125,000
Fujifilm echoendoscope compatible	
Fujifilm Endoscopy SU-8000	118,955

development EBUS and EBUS-guided FNA to access lymph nodes not accessible by EUS. There are dedicated linear-array EBUS echoendoscopes capable of performing real-time FNA (a detailed consideration of EBUS is beyond the scope of this report).

EUS has also been used for the diagnosis of other benign and neoplastic conditions, such as assessment of lymphoma,<sup>19</sup> subepithelial lesions,<sup>20-22</sup> the presence of choledocholithiasis,<sup>23-27</sup> and evaluation for acute and chronic pancreatitis.<sup>28</sup>

**Elastography.** US elastography was developed to determine tissue stiffness noninvasively. Elastography uses US to observe tissue shear deformation and is dependent on tissue elasticity.<sup>29</sup> Elastography is based on the hypothesis that soft tissues deform more than stiffer tissues. Strain refers to the amount of deformation that occurs from the tissues. The strain ratio offers semiquantitative information about the tissue stiffness by dividing reference tissue strain by lesion strain. Stiff lesions (with low strain) produce high strain ratios. Elastography has been applied in thyroid, breast, and prostate lesions and helps to differentiate benign versus malignant tissues.<sup>30</sup> US elastography differentiates lesions according to their elasticity score or color map. The elasticity score or color map results are operator dependent, and interobserver variability may occur in data acquisition and interpretation.<sup>31</sup> Differences in color mapping among various US units can cause confusion; some US units indicate that blue color is hard and red is soft, whereas other units have the reverse code.<sup>32,33</sup> The semiquantitative technique involves the measurement of the strain ratio value. The strain ratio is obtained by measuring the stiffness inside the lesion (region of interest A) and outside the lesion in a region representing normal tissue (region of interest B). The strain ratio value is the quotient B/A.

Strain ratio appears to be more accurate than elastography in discriminating focal pancreatitis from pancreatic cancer because it is a semiquantitative measurement. However, obtaining a strain ratio is currently not standardized,

and some authors have reported unsatisfactory results by using strain ratio measurements.<sup>34</sup> Tissue elastography (available on some EUS processors) and strain ratio may help define objective parameters for chronic pancreatitis and help to decrease interobserver variability<sup>35</sup> and improve diagnostic accuracy.

**Therapeutic EUS.** The therapeutic applications that evolved over the past 10 years have been an expansion of standard EUS-FNA and ERCP techniques. The range of interventions with the linear-array echoendoscope has continued to expand. Current therapeutic interventions include celiac plexus block and neurolysis,<sup>36,37</sup> peripancreatic fluid collection drainage,<sup>38-40</sup> extramural abscess drainage,<sup>41,42</sup> EUS-guided angiotherapy,<sup>43,44</sup> pancreaticobiliary access and rendezvous procedures,<sup>45-48</sup> fiducial placements to guide radiation therapy,<sup>49,50</sup> and local cytoreductive therapies.<sup>51,52</sup> Therapeutic EUS is detailed in a separate ASGE Technology Committee document.<sup>53</sup>

## EFFICACY

Numerous studies have demonstrated that EUS plays an important role in staging GI malignancies. For esophageal cancer, EUS has an overall accuracy of 85% for T staging and 75% for N staging.<sup>54</sup> Similar T and N staging have been reported for gastric and rectal cancer.<sup>30,55,56</sup> A number of meta-analyses have evaluated the accuracy of EUS staging in esophageal, gastric, and rectal cancers.<sup>30,55,57-60</sup> Some newer EUS processors offer the option of tissue elastography, and a number of studies have reported that tissue elastography can aid in guiding regional areas of a mass to be sampled by FNA or which lymph nodes to sample that may be malignant.<sup>61-64</sup> Elastography is also showing promise in the evaluation and diagnosis of chronic pancreatitis with objective measurements, and this may help reduce the interobserver variability and mislabeling of patients seen by using current EUS criteria.<sup>35</sup> Elastography may also be helpful in diagnosing endometriosis by using rectal EUS.<sup>65</sup> Contrast-enhanced EUS is showing promise in detecting microvasculature within lesions and may also help characterize autoimmune pancreatitis. These features of contrast-enhanced EUS may help direct FNA or core needle biopsy of lesions.<sup>66-70</sup>

As a diagnostic modality for pancreatic cancer, EUS has a sensitivity higher than 90%, especially for lesions smaller than 2 to 3 cm for which its sensitivity reaches 99%. EUS has shown superiority in pancreatic tumor detection and staging compared with CT.<sup>71</sup> EUS has a very high negative predictive value, and thus EUS can reliably exclude pancreatic cancer.<sup>72,73</sup>

## COMPARATIVE STUDIES

Various EUS instruments have been compared to define optimal imaging systems. Several studies compared the



capacity of linear-array and radial-array instruments to provide accurate diagnostic images, and the majority found that both modalities were similar.<sup>74</sup> Earlier studies indicated a slight decrease in examination time with a radial-array instrument, but recent trends are favoring the sole use of a linear-array echoendoscope by experienced endosonographers.<sup>75</sup> EUS with miniprobes has been demonstrated to be superior to conventional endosonography for the staging of superficial esophageal malignancies, but the latter is clearly superior for advanced tumors or pancreaticobiliary imaging because of the limited depth of US penetration with miniprobes.<sup>76-78</sup>

EUS compares favorably with helical CT, magnetic resonance imaging, and positron emission tomography scanning for the evaluation of pancreatic masses. EUS is the most sensitive imaging procedure for the detection of small solid pancreatic masses and is accurate in determining vascular invasion of the portal venous system. Even compared with the new CT techniques, EUS provides excellent results in preoperative staging of solid pancreatic tumors. Compared with helical CT techniques, EUS is less accurate in detecting tumor involvement of the superior mesenteric artery.<sup>79,80</sup> EUS is superior to CT scanning for periampullary tumors.<sup>81</sup> EUS can have a profound effect on patient management by identifying small metastatic lesions in the liver missed by conventional cross-sectional imaging.<sup>82</sup>

## EASE OF USE

EUS is an advanced endoscopic procedure, and dedicated training, beyond the scope of a general gastroenterology fellowship, is required for competence and credentialing.<sup>83,84</sup> Competence in EUS requires the development of both cognitive and technical skills. To perform EUS, one must understand the indications for the procedure, be able to accurately interpret EUS images, be trained in performing FNA, and be familiar with the recognition and management of EUS-related adverse events. Another important factor is being able to relate EUS findings to a multidisciplinary team so that the patient receives the appropriate clinical management.

EUS procedures vary in duration depending on the organ being imaged and the interventions required. These procedures typically require a deeper level of sedation compared with diagnostic EGD or colonoscopy. Sedation can be administered by the endosonographer (moderate sedation) or an anesthesiologist (eg, propofol). A diagnostic EUS examination will generally require less time than an EUS examination with FNA.

## SAFETY

EUS has an excellent safety profile, and recent ASGE guidelines have reviewed the adverse events of diagnostic and interventional EUS in detail.<sup>53,85</sup> Diagnostic EUS has a

safety profile approaching that of EGD. The larger diameter, longer nonbending section at the echoendoscope tip and the oblique endoscopic camera view may contribute to a small increase in risk of perforation of the cervical esophagus or duodenum. A physician survey suggested a cervical perforation rate of 0.03% to 0.06% and a mortality rate of 0.002%.<sup>86,87</sup> EUS-FNA of the pancreas has been associated with pancreatitis in 0.6% to 2.0% of cases.<sup>88,89</sup> EUS-FNA is rarely associated with hemorrhage, but 1 report indicated that the risk may be as high as 1.3% in a series of 227 FNAs.<sup>90</sup> The rate of infection from EUS-FNA of cystic lesions is low when prophylactic antibiotics are used.<sup>91,92</sup> The rate of bacteremia is low in patients undergoing EUS-FNA, ranging from 0% to 6%, which is in the range of diagnostic endoscopy with the higher rates noted in cirrhotic patients. This bacteremia is not typically associated with clinical manifestations.<sup>93-95</sup> There have been recent reports of infection with carbapenem-resistant *Klebsiella pneumoniae* species in patients who have undergone ERCP.<sup>96,97</sup> The contamination is thought to be related to the elevator channel of duodenoscopes. Although there are no reports of infection related to linear echoendoscopes, these endoscopes also have an elevator channel, so care should be exercised to completely follow the manufacturer's instructions for postprocedure reprocessing/high-level disinfection.

## Therapeutic EUS

Therapeutic EUS has a higher adverse event rate than diagnostic EUS with FNA. Major adverse events associated with therapeutic EUS include bleeding, perforation, infection, pneumoperitoneum, bile peritonitis, and stent migration. The range of associated adverse events with therapeutic maneuvers ranges from 16% to 35%.<sup>98-100</sup> Patients undergoing therapeutic EUS typically have a higher American Society of Anesthesiologists grade, and the risk of adverse events is thought to be acceptable.

## FINANCIAL CONSIDERATIONS

The startup costs for establishing an EUS program are considerable. The newer dedicated EUS processors cost approximately \$200,000. The nature of the practice, the anticipated volume, and anticipated types of cases (diagnostic alone or diagnostic and therapeutic procedures) will determine the number and type of echoendoscopes that will need to be purchased. The startup equipment costs for an EUS program are projected to be \$400,000 at a minimum.

Maintenance costs for an EUS program are also considerable. This is mainly due to damage that may occur from needle punctures of the echoendoscope, breaking of the elevator, and other general repairs. A study published in 2004 indicated a mean maintenance cost of \$41 per procedure.<sup>101</sup>

TABLE 5. CPT codes: 2014

CPT code	Description	Physician allowed amount for hospital/ASC, US\$	Hospital outpatient allowed amount, US\$	ASC allowed amount
Upper GI US				
43231	Esophagoscopy, flexible, transoral; with EUS examination	178	1013	560
43232	Esophagoscopy, flexible, transoral; with transendoscopic US-guided intramural or transmural FNA/biopsy(s)	212	1013	560
43237	EGD, flexible, transoral; with EUS examination limited to the esophagus, stomach, or duodenum and adjacent structures	215	1013	560
43238	EGD, flexible, transoral; with transendoscopic US-guided intramural or transmural FNA/biopsy(s) (includes EUS examination limited to the esophagus, stomach, or duodenum and adjacent structures)	246	1013	560
43240	EGD, flexible, transoral; with transmural drainage of pseudocyst (includes placement of transmural drainage catheter[s]/stent[s], when performed, and EUS, when performed)	428	1013	560
43242	EGD, flexible, transoral; with transendoscopic US-guided intramural or transmural FNA/biopsy(s) (includes EUS examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach in which the jejunum is examined distal to the anastomosis)	280	1013	560
43253	EGD, flexible, transoral; with transendoscopic US-guided transmural injection of diagnostic or therapeutic substance(s) (eg, anesthetic, neurolytic agent) or fiducial marker(s) (includes EUS examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach in which the jejunum is examined distal to the anastomosis)	280	1013	560
43259	EGD, flexible, transoral; with EUS examination, including the esophagus, stomach, and either the duodenum or a surgically altered stomach in which the jejunum is examined distal to the anastomosis	249	1013	560
Sigmoidoscopy US				
45341	Sigmoidoscopy, flexible; with EUS examination	160	779	431
45342	Sigmoidoscopy, flexible; with transendoscopic US-guided intramural or transmural FNA/biopsy(s)	244	779	431
Transrectal US				
76872	US, transrectal	N/A	135	\$43
76872-26	US, transrectal	35	N/A	N/A
76872-TC	US, transrectal	N/A	N/A	N/A

CPT, Current Procedural Terminology; ASC, Ambulatory Surgical Center; N/A, not available.

There are specific Current Procedural Terminology (CPT) codes for EUS and EBUS, with and without FNA. There are new revised codes as of 2014 for EUS, and new EUS codes in the colonoscopy through stoma series for 2015 (Tables 5 and 6). An article on frequently asked CPT coding questions was published in 2006 and may be helpful for coding.<sup>102</sup> A new chapter for the 2015 update of the ASGE Coding Primer covers coding and billing aspects of EUS in detail. After the AMA Relative Value Scale Update Committee and CMS revaluation of EUS codes in 2012 to 2013, the 2014 fee schedule brought substantial decreases in the professional fees for EUS

services, with cuts ranging from 20% to 45%. The existing CPT codes are for standard EUS, but to capture increased complexity of therapeutic EUS cases (eg, rendezvous, EUS-guided fluid collection drainage), unlisted codes are required.

## RESEARCH

The future of EUS continues to evolve as current technology improves. Improvements in the resolution of EUS processors and echoendoscopes along with improved

TABLE 6. CPT codes: 2015

CPT code	Description	Physician allowed amount for hospital/ASC, US\$	Hospital outpatient allowed amount, US\$	ASC allowed amount, US\$
Upper GI US				
43231	Esophagoscopy, flexible, transoral; with EUS examination	175	1064	595
43232	Esophagoscopy, flexible, transoral; with transendoscopic US-guided intramural or transmural FNA/biopsy(s)	207	1064	595
43237	EGD, flexible, transoral; with EUS examination limited to the esophagus, stomach, or duodenum and adjacent structures	215	1064	595
43238	EGD, flexible, transoral; with transendoscopic US-guided intramural or transmural FNA/biopsy(s), (includes EUS examination limited to the esophagus, stomach, or duodenum and adjacent structures)	245	1064	595
43240	EGD, flexible, transoral; with transmural drainage of pseudocyst (includes placement of transmural drainage catheter[s]/stent[s], when performed, and EUS, when performed)	423	1914*	1071
43242	EGD, flexible, transoral; with transendoscopic US-guided intramural or transmural FNA/biopsy(s) (includes EUS examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach in which the jejunum is examined distal to the anastomosis)	277	1064	595
43253	EGD, flexible, transoral; with transendoscopic US-guided transmural injection of diagnostic or therapeutic substance(s) (eg, anesthetic, neurolytic agent) or fiducial marker(s) (includes EUS examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach in which the jejunum is examined distal to the anastomosis)	277	1064	595
43259	EGD, flexible, transoral; with EUS examination, including the esophagus, stomach, and either the duodenum or a surgically altered stomach in which the jejunum is examined distal to the anastomosis	246	1064	595
Sigmoidoscopy and colonoscopy US				
45341	Sigmoidoscopy, flexible; with EUS examination	160	827	463
45342	Sigmoidoscopy, flexible; with transendoscopic US-guided intramural or transmural FNA/biopsy(s)	244	827	463
44406	Colonoscopy through the stoma; with EUS examination	†	790	442
44407	Colonoscopy through stoma; with transendoscopic US-guided intramural or transmural FNA/biopsy(s)	†	790	442
45391	Colonoscopy; with EUS examination	299	790	442
45392	Colonoscopy; with transendoscopic US-guided intramural or transmural FNA/biopsy(s)	388	790	442
Transrectal US				
76872	US, transrectal	N/A	135	43
76872-26	US, transrectal	35	N/A	N/A

ASC, Ambulatory Surgical Center; N/A, not available.

\*This code was reassigned to a higher ambulatory payment classification, so the facility payment in 2015 is substantially higher.

†These CPT codes are new for 2015; because the Centers for Medicare and Medicaid Services is delaying implementation of lower GI endoscopy codes for 2015, in 2015, these would be reported with unlisted 44799 codes, in addition to the diagnostic base code 44388.

tools available to the endosonographer have expanded the practice of EUS.

The available tools for EUS-guided tissue acquisition have improved over the years, but a reliable FNA core needle is still needed. This is one area of active research, and it is anticipated that better core needles will be on the market in the near future. Therapeutic EUS is currently based on using an FNA needle as a conduit and manipulating a guidewire through the needle, but improved dedicated devices for extramural access and wire manipulation are needed to increase the success rate and decrease the adverse event rate associated with EUS-guided rendezvous procedures.

EUS processors continue to evolve and 3-dimensional EUS may allow better spatial resolution of tumors and their neighboring structures. Elastography and strain ratio are already showing promise in providing semiquantitative measurements that can help eliminate interobserver variability. Development of systems that allow “switchable” autofocus onto the plane of the FNA needle will improve safety during FNA and therapeutic EUS. Better contrast-enhanced EUS agents for evaluation of vascular structures in relation to tumors are needed.

## SUMMARY

Advances in echoendoscopes and their processors have significantly expanded the role of EUS and its clinical applications. The diagnostic and therapeutic capabilities of EUS continue to evolve and improve. EUS has made a large impact on patient care but comes with significant startup and maintenance costs. As improved technology continues to enhance image resolution while decreasing the size of EUS processors, use of endosonography will become more widespread. EUS will continue to be a vital part of patient care and complement currently available cross-sectional imaging.

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Abbreviation: EBUS, endobronchial US.

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