

## Echoendoscopes

*The ASGE Technology Committee provides reviews of existing, new, or emerging endoscopic technologies that have an impact on the practice of gastrointestinal endoscopy. Evidence-based methods are 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 October 2006 for articles related to echoendoscopes by using the key words “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, requiring, or discouraging any particular treatment or payment for such treatment.*

### BACKGROUND

EUS is an important diagnostic tool that is based on the capacity of echoendoscopes to image both intramural and

adjacent structures. Instrumentation now provides high-resolution ultrasonographic imaging and interventional capabilities for diagnosis and therapy. US miniprobes, which are passed through standard endoscopes, are the subject of a separate recently published status evaluation report.<sup>1</sup> This report will focus on currently available echoendoscopes.

### TECHNICAL CONSIDERATIONS

Echoendoscopes are composed of a US transducer on the tip of an endoscope. On the basis of the ability to position the transducer in close proximity to the target tissue, US imaging is able to define 5 acoustic layers in the GI wall that correspond to histologic layers of the mucosa, deep mucosa, submucosa, muscularis propria, and serosa or surrounding adventitia and detect extramural structures such as lymph nodes. In addition, the endoscope can maneuver in unique imaging planes and remove intraluminal air, which often obscures imaging during transcatheter US.

Currently available echoendoscopes (Table 1) are similar to standard endoscopes, but the size of the tip and insertion tube are larger to accommodate the US components. Although older instruments were fiberoptic, current-generation echoendoscopes use video imaging, which has allowed for some reduction in the size of the insertion tube. With the exception of 2 forward-viewing instruments, video components are located behind the US transducer; hence, endoscopic imaging is oblique to the shaft. Two currently available instruments are forward viewing but, in one, the forward passage of the optical components results in a blind area in the US image. A previously available forward-viewing colonoscope is no longer produced because of lack of demand. One echoendoscope is nonoptical and specifically designed for passage over a guidewire for imaging of esophageal malignancies. The working channels of echoendoscopes are also variable, and some therapeutic instruments can accommodate accessories as large as 10F biliary stents. Echoendoscopes also have a separate channel that permits water inflation of a model-specific disposable latex balloon placed on the tip of the instrument before each use. This water-filled balloon facilitates acoustic coupling, or US transmission, through the wall of the GI tract.

There are 2 fundamental echoendoscope designs, curvilinear and radial array. Curvilinear array instruments produce US images parallel to the axis of the insertion tube,

**TABLE 1. Echoendoscopes**

Instruments	Scanning angle/type of scan	Frequency (MHz)	Tip diameter (mm)	Insertion tube OD (mm)	Channel (mm)	Tip deflection up/down
Olympus America						
GF-UE160-AI5	Electronic radial 360 degrees	5, 6, 7.5, 10	14.2	11.8	2.2	130 degrees/ 90 degrees
GF-UM160	360 degrees mechanical radial	5, 7.5, 12, 20	12.7	10.5	2.2	130 degrees/ 90 degrees
GF-UM130 (Q)	360 degrees mechanical radial	7.5, 12 (7.5, 20)	12.7	10.5	2.2	130 degrees/ 90 degrees
GF-UC140(P)-AL5	180 degrees electronic curvilinear	5, 6, 7.5, 10	14.6 (14.2)	12.8 (11.8)	3.7 (2.8)	130 degrees/ 90 degrees
GF-UC160(P)-OL5	150 degrees electronic curvilinear	7.5	14.6 (14.2)	12.8 (11.8)	3.7 (2.8)	130 degrees/ 90 degrees
MH-908	360 degrees mechanical radial	7.5	NA	7.9	NA	130 degrees/ 90 degrees
GF-UMD140P (Fiberoptic)	270 degrees mechanical sector/ curvilinear	7.5	14.4	11.8	2.8	130 degrees/ 90 degrees
GF-UC30P	180 degrees electronic curvilinear	7.5	13.0	11.7	2.8	130 degrees/ 90 degrees
GF-UM20 (Fiberoptic)	360 degrees mechanical radial	7.5/12	13.2	11.7	2.0	130 degrees/ 130 degrees
Bronchoscope						
BF-UC160F-OL8	50 degrees electronic curvilinear	7.5	6.9	6.2	2.0	120 degrees/ 90 degrees
Pentax Medical						
EG-3670URK	360 degrees electronic radial	5, 7.5, 10	12.8	12.8	3.8	130/130
EG-3630UR	270 degrees electronic radial	5, 7.5, 10	12.8	12.8	3.8	130 degrees/ 130 degrees
EG-3630UT	100 degrees electronic curvilinear	5, 7.5, 10	12.1	12.1	2.4	130 degrees/ 130 degrees
FG-36UX	100 degrees electronic curvilinear	5, 7.5, 10	12.1	12.1	2.4	130 degrees/ 130 degrees
EG-3830UT	100 degrees electronic curvilinear	5, 7.5, 10	12.8	12.8	3.8	130 degrees/ 130 degrees

NA, Not applicable.

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

usually in a sector between 100 and 180 degrees. This orientation of the US image facilitates real-time ultrasonographic guidance of interventions such as FNA because the needle is passed in the same plane as the US image. All curvilinear array instruments incorporate an elevator for manipulation of FNA needles or other devices. Radial-array instruments produce ultrasonographic images perpendicular to the axis of the insertion tube, usually in a full 360 degrees. Radial-array echoendoscopes are

used by most endosonographers for diagnostic examinations because the 360-degree image is oriented in cross-sectional planes similar to those generated by CT.

The 2 basic types of US transducers are mechanical and electronic. Mechanical transducers have a single piezoelectric element that is rotated around the circumference of the endoscope by a motor to produce a 360-degree image. Until recently, the motor was positioned on the operating handle of the instrument, making it heavy and

TABLE 1 Cont.

Tip deflection left/right	Working length (cm)	Field of view	Depth of view (mm)	Cost	Processor/cost
90 degrees/90 degrees	125	100 degrees 50 degrees oblique	3-100	\$86,200	Aloka SSD-5000 \$131,800
90 degrees/90 degrees	125	100 degrees 50 degrees oblique	3-100	\$79,975	EU-M60 \$81,200
90 degrees/90 degrees	125	100 degrees 50 degrees oblique	3-100	\$74,975	EU-M20; EU-M30; EU-M60 \$81,200
90 degrees/90 degrees	125	100 degrees 55 degrees oblique	3-100	\$82,025 (\$79,675)	Aloka SSD-5000 \$131,800
90 degrees/90 degrees	125	100 degrees 55 degrees oblique	3-100	\$82,025 (\$79,675)	EU-C60 \$27,025
90 degrees/90 degrees	70	NA	NA	\$38,825	EU-M20; EU-M30; EU-M60 \$81,200
90 degrees/90 degrees	124.4	100 degrees 55 degrees oblique	3-100	Not Sold	EU-M20; EU-M30; EU-M60 \$81,200
90 degrees/90 degrees	126	80 degrees 50 degrees oblique	3-100	Not sold	Envision Plus Not sold
90 degrees/90 degrees	105.5	80 degrees 45 degrees oblique	3-100	Not sold	EU-M20; EU-M30; EU-M60 \$81,200
NA	60	80 degrees 35 degrees oblique	2-50	\$44,800	EU-C60 \$27,025
120/120	125	120 degrees Forward view		\$75,240	Hitachi 5500 \$82,500 Hitachi 8500 \$142,000
120 degrees/120 degrees	125	120 degrees Forward view		\$75,240	Hitachi 5500 \$82,500 Hitachi 8500 \$142,000
120°/120 degrees	125	130° 50 degrees oblique		\$75,240	Hitachi 5500 \$82,500 Hitachi 8500 \$142,000
120 degrees/120 degrees	125	105 degrees 60 degrees oblique		Not sold	Hitachi EUB 515,525*,555, 6000,6500 processors
120 degrees/120 degrees	125	120 degrees 50 degrees oblique		Not sold	Hitachi EUB 515,525*,555, 6000,6500 processors

awkward to manipulate. A recent-generation instrument repositions the motor at the base of the cord attaching the endoscope to the standard video light source. The piezoelectric transducer is immersed in an oil-filled encasement, which facilitates acoustic coupling and protects the transducer as it rotates. Because the transducer is in constant motion, there is no capacity for Doppler imaging with mechanical transducers. There is also a lower image frame rate relative to fixed electronic transducers because

of the time required to send and receive images from the full 360-degree plane with a single rotating transducer.

Electronic transducers use a series of fixed piezoelectric elements positioned in the plane of imaging. All currently available curvilinear-array instruments use electronic transducers positioned parallel to the insertion tube. Three radial-array electronic instruments orient the individual piezoelectric elements around the distal tip in either a 270- or 360-degree radial array, producing an

image perpendicular to the insertion tube. Electronic US has the advantage of providing Doppler capacity and has the potential for more sophisticated electronic image processing such as the ability to alter the focal distance, which is fixed with mechanical transducers, and to use tissue harmonic enhancement, which may improve resolution and reduce US artifacts.<sup>2</sup> Newer electronic processors can be programmed to detect differences in US distortion between hard and soft tissues, a process termed sonoelastography. In preliminary reports this may be able to reliably distinguish benign and malignant lesions.<sup>3,4</sup>

Both mechanical and electronic transducers have the capacity to scan over a range of frequencies with available mechanical transducers scanning at 5 to 20 MHz and electronic instruments scanning at 5 to 10 MHz, depending on the model (Table 1). Scanning at higher frequencies improves image resolution but limits the penetration of the US beam to 1 to 2 cm from the probe, whereas scanning with lower frequency provides images of structures up to 6 to 8 cm from the probe.

## CLINICAL APPLICATIONS

EUS has a primary role in assessing the T and N stage of esophageal, gastric, and rectal malignancies and the detection and staging of pancreaticobiliary malignancies. Although in some patients EUS may identify metastatic disease, it is generally not reliable because of the limited depth of US penetration. For very superficial mucosal tumors, US miniprobes are more appropriate.<sup>1</sup>

EUS has also been used for the diagnosis of other neoplastic and benign conditions, including evaluation of subepithelial lesions of the alimentary tract,<sup>5,6</sup> chronic pancreatitis,<sup>7</sup> idiopathic pancreatitis,<sup>8</sup> choledocholithiasis,<sup>9</sup> cholelithiasis, perianal Crohn's disease,<sup>10</sup> and anal sphincter integrity.<sup>11</sup>

Because the US image is parallel to the working channel, curvilinear-array echoendoscopes can be used to direct a needle with real-time ultrasonographic guidance into a target lesion, facilitating pathologic confirmation of malignancy.<sup>12</sup> Although EUS-FNA has been used for the diagnosis of numerous intramural and extramural lesions, it is most commonly used in sampling pancreatic masses,<sup>13,14</sup> pancreatic cysts,<sup>15</sup> lymph nodes,<sup>16,17</sup> or hepatic masses<sup>18,19</sup> in range of the US image. The capacity to sample lymph nodes has extended the role of EUS to nongastrointestinal diseases such as the nodal staging of non-small-cell lung cancer.<sup>20</sup> This vital role of EUS-FNA in lung cancer staging has led to the use of endobronchial US and endobronchial US-guided FNA. Initially this used US miniprobes through the working channel of a bronchoscope to identify nodes, followed by blind transbronchial needle aspiration,<sup>21</sup> but now there is a dedicated linear-array endobronchial echoendoscope capable of performing real-time FNA<sup>22</sup> (Table 1).

Finally, on the basis of this capacity to image instruments passed through the working channel in real time, curvilinear-array instruments are being used in a wider array of interventions, including celiac plexus neurolysis,<sup>23</sup> pancreatic pseudocyst drainage,<sup>24,25</sup> extramural abscess drainage,<sup>26-28</sup> directed variceal sclerotherapy,<sup>29,30</sup> pancreaticobiliary access and rendezvous,<sup>31,32</sup> and local cytoreductive therapies.<sup>33,34</sup>

## EFFICACY

Numerous studies have demonstrated that EUS is an accurate staging modality for GI malignancies. For esophageal cancer, EUS has an overall accuracy of 85% for T staging and 75% for N staging.<sup>35,36</sup> Similar accuracies for the T and N stages of gastric and rectal cancer have been reported.<sup>37,38</sup> Of note, the accuracy of staging after multimodality cytoreductive therapy is poor, likely because of the inability of EUS to distinguish residual inflammatory change and desmoplasia from residual neoplasm.<sup>39,40</sup>

Several studies have demonstrated that the sensitivity of EUS for pancreatic neoplasm detection approaches 100%, and in most studies it is highly accurate in defining the local stage, particularly the presence of vascular invasion of the portal or mesenteric vessels.<sup>41-45</sup> However, results are heterogeneous, and one recent study found much lower sensitivity (50%) and specificity (58%) for vascular invasion.<sup>46</sup>

EUS-FNA has been demonstrated to be highly accurate for determining the N stage of non-small-cell lung cancer, detecting advanced nodal disease in 77% of patients with an FNA sensitivity of 87% and a specificity of 100%.<sup>20</sup>

## COMPARATIVE STUDIES

Various EUS instruments have been compared to define the optimal imaging systems. Several studies have compared the capacity of linear-array and radial-array instruments to provide accurate diagnostic images, and the majority found that both were similar, with perhaps a slight decrease in the time needed to perform the examination with radial scanning instruments.<sup>47-49</sup> Three studies comparing electronic radial-array instruments with mechanical radial-array instruments found electronic imaging to be equivalent or superior to mechanical instruments.<sup>50-52</sup> Finally, EUS with miniprobes has been demonstrated to be superior to conventional echoendoscopy for the staging of superficial esophageal malignancy, but the latter is clearly superior for advanced tumors or pancreaticobiliary imaging because of the limited US penetration with the miniprobes.<sup>53</sup>

For the T and N staging of esophageal, gastric, and rectal cancer, EUS is superior to cross-sectional imaging such as CT.<sup>54-59</sup> For esophageal cancer, positron emission tomography (PET) scanning appears to be a complementary

study because EUS is more accurate for T staging and more sensitive for N staging whereas PET scanning is more accurate for M staging and more specific for N staging.<sup>60</sup> For rectal cancer, magnetic resonance imaging (MRI) with endorectal coil provides similar accuracy to EUS but is expensive and not widely available.<sup>61,62</sup>

EUS compares favorably with helical CT, MRI, ERCP, and PET scanning for the detection of pancreatic masses.<sup>63-67</sup> On the basis of these comparative data, a recent National Institutes of Health (NIH) consensus suggested that EUS and other imaging modalities have made ERCP obsolete for the diagnosis of pancreaticobiliary malignancies.<sup>68</sup> In the local staging of adenocarcinoma of the perampullary region, most studies have demonstrated EUS to be more accurate than other imaging modalities such as helical CT, MRI, angiography, and transcutaneous US.<sup>63-66,69,70</sup> Rapid technical advances in all these imaging modalities, including EUS with the recent suggestion of superior imaging with electronic radial-array instruments, make it difficult to make direct comparisons between the state of the art instruments for each modality. The diagnostic yield of EUS-FNA is also at least equivalent to CT-guided FNA for pancreatic masses. In one study EUS-FNA had a sensitivity of 92% in patients with a prior negative CT-guided FNA or ERCP brush cytology.<sup>71</sup> Another randomized study also suggested that EUS-FNA was superior to CT-guided or transcutaneous US-guided FNA of pancreatic lesions with sensitivities for malignancy of 84% and 62%, respectively, although the results did not reach statistical significance.<sup>72</sup>

EUS compares favorably with other imaging tests for the diagnosis of benign diseases. EUS has been shown to be comparable to MRCP<sup>73</sup> and comparable or superior to ERCP for the detection of choledocholithiasis with a more favorable safety profile.<sup>74,75</sup> Similarly, it is at least as accurate as ERCP for the diagnosis of chronic pancreatitis, but the lack of a gold standard has led some to question the specificity of abnormalities seen on EUS.<sup>7,76</sup>

## SAFETY

EUS generally has an excellent safety profile, and a recent ASGE guideline has reviewed the complications of diagnostic and interventional EUS in detail.<sup>77</sup> Diagnostic EUS has a safety profile approaching that of EGD. The larger diameter, longer nonbending section at the leading end, and the oblique view of the instruments may increase the risk of perforation of the cervical esophagus or the duodenum. A physician survey found a cervical perforation rate of 0.03% and a mortality rate of 0.002%.<sup>78</sup> EUS-FNA of the pancreas has been associated with a 0.6% to 2% risk of pancreatitis.<sup>79-81</sup> EUS-FNA may rarely be associated with hemorrhage, but one report indicated that the risk may be as high as 1.3% in a series of 227 FNAs.<sup>82</sup> Initial experience with EUS-FNA of pancreatic cysts raised concern over a high rate of infection, but more recent studies sug-

**TABLE 2. Current Procedural Terminology (CPT)\* codes for EUS**

43231	Esophagoscopy with EUS
43232	Esophagoscopy with EUS/FNA
43237	EGD with EUS limited to the esophagus
43238	EGD with EUS/FNA limited to the esophagus
43259	EGD with EUS
43242	EGD with EUS/FNA
45341	Flexible sigmoidoscopy with EUS
45342	Flexible sigmoidoscopy with EUS/FNA
45391	Colonoscopy with EUS
45392	Colonoscopy with EUS/FNA
31620*	Endobronchial ultrasound during bronchoscopy and interventions

\*Add-on code.

gest the infection rate is low when prophylactic antibiotics are used.<sup>83</sup> The rate of bacteremia is 0% to 6%,<sup>84,85</sup> which is in the range of diagnostic endoscopy, and fever is reported in up to 2% of patients undergoing FNA.<sup>86</sup>

Review of the MAUDE database revealed a report of 3 patients with specimens obtained with the same curvilinear-array echoendoscope yielding cultures positive for *Pseudomonas aeruginosa*. Multisite culturing suggested channel contamination that was eliminated with gas sterilization,<sup>87</sup> emphasizing the importance of standard high-level disinfection practices, including the elevator channel.

## FINANCIAL CONSIDERATIONS

The startup cost to an endoscopy laboratory for an EUS system is considerable, relative to other endoscopic equipment. Most centers have both radial-array instruments for diagnostic studies and linear-array instruments for FNA and other interventions. Until recently, this usually required purchasing 2 separate US image processors. Now with electronic radial-array instruments only 1 processor is required for both radial and curvilinear examinations. Despite this savings, and assuming the endoscopy center

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has requisite video processors and light sources, the startup cost remains close to \$300,000 for a platform with a single radial- and curvilinear-array instrument (Table 1). Once the equipment is obtained, the maintenance costs can also be significant. The average cost for repairs and instrument damage has been estimated in one survey study to be approximately \$41 per procedure.<sup>88</sup>

Several studies using cost identification analysis and decision modeling have suggested that EUS does provide cost savings and relative cost-effectiveness in staging esophageal, rectal, and pancreatic cancer.<sup>89-91</sup> It also may lower the cost of care in patients with subepithelial lesions.<sup>92</sup>

Specific CPT codes are available for both EUS and endobronchial US, with and without FNA (Table 2). EUS codes may be combined with other standard upper or lower endoscopy codes by using the -59 modifier. When a rectal cancer is staged at the time of a colonoscopy, the respective diagnostic or therapeutic colonoscopy codes are used with the -59 modifier but the -52 modifier, to signify an incomplete examination, must be used for the EUS code if the echoendoscope is not used to perform US beyond the splenic flexure.

## SUMMARY

Echoendoscopes provide for a powerful imaging modality and have a well-established role in the diagnosis of digestive diseases and cancer staging. Curvilinear array instruments, in particular, have advanced the role of EUS into therapeutic and interventional applications. Although the institutional financial investment to initiate an EUS program is substantial, the technique does provide for cost-effective care. Rapid technologic advances in all imaging modalities will require an ongoing effort to assess the accuracy and impact of EUS relative to other imaging techniques.

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