

Endoscopic ultrasound probes

To promote the appropriate use of new or emerging endoscopic technologies and those technologies that have an impact on endoscopic practice, the ASGE Technology Committee presents relevant information to practicing physicians in the form of technology reviews. Evidence-based methodology is employed wherein a MEDLINE literature search is performed to identify pertinent clinical studies on the topic, a MAUDE (Food and Drug Administration Center for Devices and Radiological Health) database search is performed to identify the reported complications of a given technology, and both are supplemented by accessing the “related articles” feature of PubMed and by scrutiny of 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 opinion are utilized. Technical data are gathered from traditional and Web-based publications, proprietary publications, and informal communications with pertinent vendors. Documents are drafted by 1 or 2 committee members, reviewed and edited by the committee as a whole, and approved by the Governing Board of the ASGE. When financial guidance is appropriate, 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 2006 for articles related to ultrasound probes by using the keywords “endoscopic ultrasonography” and “probes” plus “ultrasound probes,” “transendoscopic ultrasound,” “catheter ultrasound,” and “intraductal ultrasound.” Practitioners should continue to monitor the medical literature for subsequent data about the efficacy, safety, and socioeconomic aspects of these technologies.

BACKGROUND

Endoscopic ultrasound using dedicated linear-array and radial echoendoscopes is used for structural evaluation of the luminal wall and adjacent tissues in the gastrointestinal tract. Ultrasound probes that go through the accessory channels of standard endoscopes are commercially available. This status evaluation report will update and review

the endoscopic ultrasound probes available for use during gastrointestinal endoscopy.¹

TECHNICAL CONSIDERATIONS

Ultrasound probes for gastrointestinal applications vary in their design and capabilities on the basis of the anticipated application (Table 1). They consist of a flexible shaft with a central wire that drives rotation of a mechanical transducer at the tip. The transducer is surrounded by oil that serves as an acoustic interface with tissue, providing 360-degree imaging perpendicular to the axis of the probe. Endoscopic ultrasound probes are available in various diameters (2-2.9 mm), frequencies (12-30 MHz), and lengths (170-220 cm). Higher ultrasound frequency yields higher resolution at the expense of reduced depth of penetration (reported depths of penetration are 29 mm for the 12-MHz probe and 18 mm for the 20-MHz probe).^{2,3} Acoustic coupling between the probe and tissue can be achieved by several methods, including close apposition of the probe to tissue with air aspiration, instillation of liquid into the gut lumen, use of a condom over the tip of the endoscope,⁴ and use of a balloon sheath over the probe. One probe is designed for passage over a guidewire to facilitate use in the pancreas and bile ducts.

The specifications and costs of available probes, drivers, and processors are listed in Table 1. Fujinon probes have a universal probe processor and probe driver. There are 3 probe processors and probe driver units for the Olympus EUS probe system. The EU-M30 is compatible with any 2D probes and the probe driving unit MH-240. The EU-M30S is compatible with any 2D probes and probe driving unit MAJ-682. The EU-M60 is compatible with any 2D and DPR probes and probe driving units MH-240, MAJ-682, and MAJ-935.

There are presently no linear or phased-array probes designed for gastrointestinal applications, although linear images can be generated from radial probes. The Olympus EUM-60\UM2000 EUS system can be upgraded with a 3-D upgrade kit (MAJ-1330) to achieve 3-D ultrasound images from radial and linear scanned images in real time. The functions of the MAJ-1330 include 3-D oblique/surface display, multiplane reconstruction display, multidisplay, and volume display. Measurement functions include interpolation for trace measurement, volume estimation, and ellipse approximation.

TABLE 1. Ultrasound probe features and costs

Maker	Probe model no.	Working length	Probe diameter	Frequencies	Cost (US \$)
Fujinon	PL 1726- (12, 15, 20), 1926- (12, 15, 20) and 2226-(12, 15, 20)	1700, 1900, and 2200 mm	2.6 mm	12, 15 and 20 MHz	3780
	PL 2220- (12, 15, 20)	2200 mm	2.0 mm	12, 15 and 20 MHz	3780
	PL 2226- 7.5B	2200 mm	2.6 mm	7.5 MHz	7030
Olympus	UM-2R	2140 mm	2.5 mm	12 MHz	4180
	UM-3R	2140 mm	2.5 mm	20 MHz	4180
	UM-S20-20R	2140 mm	2.0 mm	20 MHz	3560
	UM-S30-20R	2140 mm	2.0 mm	30 MHz	3560
	UM-S30-25R	2140 mm	2.5 mm	30 MHz	4180
	UM-DP12-25R (dual-plane reconstruction)	2200 mm	2.5 mm	12 MHz	5400
	UM-DP20-25R (dual-plane reconstruction)	2200 mm	2.5 mm	20 MHz	5400
	UM-BS20-26R-3 (balloon sheath)	2140 mm	2.6 mm	20 MHz	5680
	UM-G20-29R (guide-wire)	2140 mm	2.9 mm	20 MHz	4550

EUS probes are designed for multiple uses. Although there are no formal manufacturer warranties or recommendations as to the number of applications that can be accomplished per probe, with careful handling, 30 examinations have been reported.⁵ Standard disinfection techniques common to most reusable endoscopic products are used. Careful handling during reprocessing and storage of the probe can potentially increase the number of applications. The probe can be stored in its original package after reprocessing.

Before use, the tip of the catheter should be rotated outside the body to ensure even distribution of the immersion oil. The image quality can then be checked by placing the tip of the catheter in a liquid medium; some users employ an immersed gauze pad to provide an acoustic interface. Probes should be passed through the biopsy channel with care to avoid buckling and with the transducer drive inactivated. The wire-guided probes can be advanced through side-viewing instruments into the biliary and pancreatic ducts under fluoroscopic control, with special attention to not damage the transducer when clearing the elevator of the duodenoscope.

Two ultrasound probes that are typically inserted into the gastrointestinal tract blindly at the time of endoscopy are both of lower frequency and shorter in length than those for transendoscopic use. The esophageal probe, known as the bullet scope (model MH-908, 70-cm length, 8.5-mm outer diameter, 7.5-MHz frequency, Olympus Corporation, Melville, NY), is inserted over a Savory-type guidewire and is most commonly used for staging of bulky

tumors or evaluation of stenotic lesions. There are 2 manufacturers of rigid rectal probes: Olympus America Inc, (Melville, NY) and B-K Medical Systems Inc (Wilmington, Mass). The 2 rigid rectal probes produced by Olympus are the RU-75M-R1 and RU-12M-R1, both of which are 15 cm in length, 12 mm in outer diameter, and employ scanning frequencies of 7.5 MHz and 12 MHz, respectively. The 2 rigid probes produced by B-K Medical Systems are type 2050 and 1850, both of which have built-in 3D image acquisition capabilities. Type 2050 is 550 mm in length, 40 mm in outer diameter, and employs scanning frequencies of 6 to 16 MHz. Type 1850 is 53 mm in length, 13 mm in outer diameter, and employs scanning frequencies of 5 to 10 MHz.

APPLICATIONS

A prime utility of through-the-scope ultrasound probes is the ability to assess superficial lesions during standard endoscopy before endoscopic therapy, without the need to exchange to dedicated EUS equipment. Ultrasound probes can be used to evaluate benign and malignant mucosal and submucosal lesions. Benign conditions amenable to probe evaluation include intramural tumors (lipoma, pancreatic rest, leiomyoma),^{6,7} varices,⁸ and large gastric folds.⁹ Intraductal wire-guided ultrasound probes are useful for identification of small stones and sludge.¹⁰⁻¹² Less established applications that have been described include inflammatory bowel disease,¹³ achalasia,¹⁴

congenital esophageal stenosis,¹⁵ eosinophilic esophagitis,¹⁶ and congenital bile duct dilatation.¹⁷

EUS probes can be used for staging of early esophageal, gastric, ampullary, pancreatico-biliary, and colorectal neoplasms. In general, the T staging of nonbulky lesions can be accurately assessed; however, the limited depth of tissue penetration makes ultrasound probes inadequate for complete TNM staging of gastrointestinal tumors. In contrast to standard endoscope-based EUS, the use of ultrasound probes for tumor staging may not require dilation of stenotic lesions; however, this application is limited because most stenotic tumors are bulky and exceed the depth of sonographic penetration. The staging accuracy of ultrasound probes in patients with superficial esophageal, gastric, and colorectal carcinoma has been reported to vary from 60% to 90%.¹⁸⁻²² Ultrasound probes have also been used to select appropriate candidates for endoscopic mucosal resection of superficial neoplastic lesions.^{23,24} Intraduodenal and intraductal (IDUS) use of ultrasound probes has been reported for staging of ampullary and pancreatico-biliary malignancies.²⁵⁻²⁷ A retrospective, blinded review of intraductal ultrasonographic images from 30 patients demonstrated 90% accuracy for distinguishing benign from malignant biliary strictures.²⁸

Comparative studies

Several studies have compared ultrasound probes to conventional EUS^{19,29} and magnifying endoscopy.^{18,30} Probes were equivalent to conventional EUS for T-staging of superficial and submucosal esophageal carcinoma. However, conventional EUS was superior for evaluation of lymph node metastasis.^{5,23} A study comparing ultrasound probes to magnifying colonoscopy for colorectal cancer revealed probes to be significantly more accurate for assessment of depth of invasion.¹⁸ A Japanese study of staging for early gastric cancer revealed 71% accuracy for ultrasound probes and 63% for conventional endoscopy, but ultrasound probes tended to overstage lesions.²⁴

SAFETY

There have been no reported serious complications associated with the use of ultrasound probes. However, there is a risk of aspiration when utilizing the water immersion method for scanning the esophagus. There are no safety data pertaining to intraductal ultrasonography; however, the usual risks of pancreatic and biliary instrumentation do apply.

FINANCIAL CONSIDERATIONS

The costs of the 2 commercially available ultrasound probe systems are listed in Table 1. There are no Current Procedural Terminology (CPT®) codes specific for probe-based ultrasonography. The existing EUS codes are used

TABLE 2. CPT codes for endoscopic ultrasound

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	Flex Sig with EUS
45342	Flex Sig with EUS/FNA
45391	Colonoscopy with EUS
45392	Colonoscopy with EUS/FNA

for reporting this service (Table 2). The EUS probes are compatible with most EUS processors. There is also a dedicated portable endoscopic ultrasound probe processor, EU-M30S (Olympus America Inc), complete with accessories. The cost of the portable probe processor is \$21,200.

SUMMARY

EUS probes are a maturing technology that provides detailed imaging of the gastrointestinal wall for evaluation and staging of intramural and intraductal pathology. They are best suited for superficial mucosal lesions. Further studies comparing the relative cost and benefit of ultrasound probes to conventional EUS are necessary.

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Prepared by:
 TECHNOLOGY ASSESSMENT COMMITTEE
 Julia Liu, MD
 Steven Carpenter, MD
 Ram Chuttani, MD
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