



Ultrathin endoscopes

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, performing 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 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 September 2009 for articles related to ultrathin endoscopy by using the keywords "ultrathin endoscopy," "ultraslim endoscope," and "transnasal endoscopy."

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BACKGROUND

Narrow-caliber endoscopes were initially designed in the 1970s for use in pediatric patients. Current ultrathin (UT) endoscopes are primarily videoendoscopes and have a shaft diameter of 6 mm or less, which allows

them to be passed through the nose or mouth. Use of an UT endoscope to perform unседated transnasal EGD was first reported in 1994.¹ Potential benefits of unседated endoscopy include reduced risk of cardiopulmonary complications, reduced recovery time and costs, minimized time lost from work, and the convenience of self-transportation.

TECHNICAL CONSIDERATIONS

UT endoscopes are similar in general design to standard endoscopes, with a control section containing tip deflection dials, an air/water channel, and a suction/accessory channel.² A color image is generated by a charge coupled device chip in the tip of the instrument. Some models have advanced imaging features (eg, narrow-band imaging). One manufacturer (Pentax, Montvale, NJ) offers a fiberoptic model. Most of the UT endoscopes are compatible with a standard light source and processor. One model has a portable processor and built-in light source for in-office use (Vision Sciences, Orangeburg, NY). Commercially available UT endoscopes are listed in Table 1.

Insertion tube (shaft) diameters range from 4.9 to 6 mm. The accessory channel for most endoscopes is 2 mm and allows passage of small-caliber instruments such as pediatric biopsy forceps. Some models, especially those with the smallest shafts, have 2-way (up and down) rather than conventional 4-way tip deflection. Right-left angulation with these endoscopes is achieved by applying torque to the instrument shaft and activation of the up and down deflection control. The working lengths of UT gastroscopes range from 1050 to 1100 mm. Some companies offer 600- to 650-mm UT endoscopes designed for examination of the nasopharyngeal passages but also provide the capacity to examine the esophagus. Similar to standard GI endoscopes, the insertion tubes of most models have a circular cross-sectional configuration. One manufacturer's device has an oval configuration (Vision Sciences). This particular instrument has a disposable sheath that contains the accessory channel so that none of the reusable portion of the endoscope comes into contact with the patient. None of the commercially available UT endoscopes have high-definition video capture capabilities.

Unседated transnasal endoscopy with UT endoscopes is performed with the patient in the upright seated position or in the left lateral decubitus position. Examiners may attempt to have the patient identify the more patent side of the nose by occluding each side separately. A focused history should

TABLE 1. Ultrathin endoscopes available in the U.S.

Model	Angulation (deg)	Field of view (deg)	Features	Shaft diameter (mm)	Accessory channel diameter (mm)	Working length (mm)	Cost (\$)
Olympus (Center Valley, Pa)							
GIF-XP180N	210 up/90 down 100 left/100 right	120	NBI	5.5	2	1100	30,000
GIF N180	210 up/120 down	120	NBI	4.9	2	1100	28,675
PEF-V	180 up/130 down	120	N/A	5.3	2	650	21,400
Fujinon (Wayne, NJ)							
EG-530N	210 up/90 down 100 left/100 right	120	FICE	5.9	2	1100	26,800
EG-530NP	210 up/120 down	120	FICE	4.9	2	1100	26,700
EG-270N5	210 up/120 down 100 left/100 right	120	N/A	5.9	2	1100	
Vision Sciences (Orangeburg, NJ)							
TNE-5000	145 up/215 down	120	N/A	4.7/5.4 (oval shaft) 4.7/5.8 (oval shaft)	1.5 2.1	650	25,000 Includes processor, disposable endosheath \$40/each
Pentax (Montvale, NJ)							
EG 1580K	210 up/120 down	140	iSCAN*	5.1	2	1050	25,200
EG 1690K	210 up/120 down 120 left/120 right	120	iSCAN	5.4	2	1100	26,500
EG 1870K	210 up/120 down 120 right/120 left	140	iSCAN	6	2	1050	24,885
EE 1580K	210 up/120 down	140	iSCAN	5.5 tip, 5.1 shaft	2	600	18,900
FG-16V	180 up/180 down 160 right/160 left	125	Fiberoptic	5.3	2	925	15,750

FICE, Fuji Intelligent Color Enhancement; N/A, not applicable; NBI, narrow-band imaging
*Pentax proprietary image enhancement.

be obtained to identify patients with a history of nasal problems, including recurrent epistaxis, nasal trauma, deviated septum, and history of allergy to topical anesthetics.³ Topical anesthesia of the nasal passage is achieved by applying 2% to 5% viscous lidocaine with a cotton applicator or catheter 10 minutes before the procedure.^{1,4,5} A vasoconstricting agent such as 0.002% naphazoline or 0.05% oxymetazoline is also applied to facilitate decongestion. Additionally, the posterior pharynx should be anesthetized with xylocaine or benzocaine spray.

The endoscope is lubricated and then passed along the floor of the nasal cavity under direct visualization into the posterior pharynx. Care should be taken to avoid sudden movements of the shaft to minimize pressure on the intranasal surfaces, which can be uncomfortable.³ With the head flexed slightly forward, the patient is asked to swal-

low. Once the instrument is beyond the upper esophageal sphincter, endoscopy is performed in the standard fashion. Per-oral procedures, with or without sedation, are performed with the patient in the left lateral decubitus position.

UT endoscopes have a brushable inner channel and are reprocessed similarly to standard endoscopes. The model with the disposable outer sheath does not require full reprocessing because the reusable portion does not come into contact with the patient. Users should follow manufacturer-specific recommendations for reprocessing.

INDICATIONS AND EFFICACY

The indications for UT-EGD with or without sedation are the same as for standard EGD. Unsedated transnasal

UT-EGD may be preferred in patients who do not want sedation or cannot tolerate it because of cardiopulmonary disease, or in those who cannot tolerate the oral route.⁶ The UT endoscope is also useful when attempting to traverse very narrow strictures in the GI tract that do not allow passage of a standard-caliber endoscope.⁷

Several large studies have demonstrated that UT-EGD is feasible and well tolerated. In the largest series to date, involving 1100 consecutive patients, unsedated transnasal UT-EGD was successful in 94%.⁸ Causes of failure included inability to pass the endoscope transnasally (63%), patient refusal (19%), and nasal pain (18%). Factors associated with failed transnasal passage included female sex, age younger than 35 years, and larger endoscope diameter (5.9 mm vs 5.3 mm). The second portion of the duodenum was not reached in 5 patients because of the inherent flexibility of the endoscope shaft. Another trial randomized 150 patients to transnasal UT-EGD, per-oral UT-EGD, or conventional EGD, all with sedation only if required.⁹ Transnasal passage failed in 8%, but otherwise a complete examination was feasible in all patients. The transnasal group required sedation significantly less often than the per-oral UT-EGD and the conventional EGD groups (6%, 18%, and 44%, respectively, $P < .001$). Another randomized trial of 139 patients found that complete EGD was feasible in 91% of patients via the transnasal route compared with 98% with unsedated per-oral UT-EGD and 96% with unsedated conventional EGD.¹⁰ In a study of 611 patients undergoing transnasal esophagoscopy, the examination was successful in 97%.¹¹ Taken together, these studies indicate that inability to pass the endoscope transnasally precludes 3% to 8% of examinations.

Most studies comparing patient tolerance of unsedated UT transnasal EGD and conventional EGD with or without sedation found higher patient tolerance rates in the transnasal group based on a visual analogue scale.^{9,10,12-15} However, 2 comparative studies showed poorer overall tolerance for the transnasal procedure compared with sedated conventional EGD.^{16,18} In a large randomized study, pain during insertion of the endoscope was reported significantly more often with the transnasal route, and gagging was reported more often in the unsedated transnasal or per-oral route compared with conventional sedated EGD.¹⁷ These findings highlight the necessity of thorough topical anesthesia of the nose and pharynx.

Because of their smaller diameter, UT endoscopes can be used for a number of less common indications. Transnasal endoscopy has been used to place percutaneous gastrostomy tubes with collapsible bumpers in patients with contraindications to oral passage of an endoscope (eg, recent oral surgery or malignancy).¹⁸ The UT endoscope can be passed through a mature gastrostomy tract to facilitate placement of jejunal extensions of enteral feeding tubes, thereby avoiding the need for oral intubation.¹⁹ They have also been used to enable placement of enteral stents without fluoroscopy,²⁰ to evaluate the esophagus in

patients with cancers of the head and neck,²¹ and to assist in the placement of wireless pH monitoring devices.²² A UT endoscope has been used to perform direct cholangioscopy in 29 patients with biliary disease, all of whom had previously undergone endoscopic sphincterotomy or balloon dilation of the papilla. The UT endoscope was passed over a wire ($n = 11$) or over a balloon catheter ($n = 21$) if the wire-guided method failed. The balloon was inflated in a branch of the intrahepatic ducts to anchor the endoscope. Cholangioscopy was successful in 46% with the wire-guided method and 96% with the balloon method.²³ ERCP has also been reported through a gastric stoma with the UT endoscope.²⁴

COMPARATIVE STUDIES

Older comparative studies using UT endoscopes found inferior image quality compared with conventional EGD.^{12,17} Recent studies have found UT-EGD to be fairly equivalent in terms of diagnostic accuracy,^{10,25,26} although some authors have concerns about the ability of the UT endoscope to detect small malignant lesions.^{27,28}

Two randomized trials compared unsedated UT-EGD with conventional sedated standard EGD in the evaluation of Barrett's metaplasia (BM). In a randomized crossover trial of 121 patients undergoing both UT-EGD and conventional EGD for screening and surveillance of BM, UT-EGD was found to have equivalent diagnostic accuracy for the detection of BM and dysplasia, despite the smaller tissue specimens obtained with the UT endoscope.²⁵ A smaller study of patients with known BM also found that the biopsy specimens from UT-EGD were equivalent to those obtained with standard biopsies in the capacity to demonstrate BM and dysplasia.²⁹

Unsedated UT-EGD is an attractive option for large-scale screening for early gastric cancer in high-risk areas. However, one study found the UT endoscope to be inferior to the standard endoscope for the diagnosis of early gastric cancer in 42 patients and noted that 6 lesions larger than 20 mm could not be detected.²⁷ Another study compared UT-EGD with endoscopy with a high-resolution endoscope (HRE) in an enriched population of 57 patients with and without early gastric cancer, all of whom received sedation for both procedures. The sensitivity of UT-EGD was significantly lower than that with HRE for the diagnosis of early neoplasia (58.5% vs 78%, $P = .021$). The miss rate for neoplasia was most pronounced in the proximal stomach for UT-EGD versus HRE (29% vs 7%, $P = .002$).²⁸

Transnasal UT-EGD was compared with standard EGD in 15 patients with cirrhosis undergoing screening for varices. The detection and grading of esophageal and gastric varices were equivalent in the 2 procedures.³⁰

Two studies compared larger caliber UT endoscopes with the smallest UT endoscopes. A study from Japan compared the 2-way angulation UT endoscope, which has

a shaft diameter of 5.2 mm, with the 4-way angulation endoscope (5.5-mm shaft diameter) for feasibility and tolerability in 291 patients undergoing unsedated transnasal endoscopy to screen for early gastric cancer.⁵ Most parameters were equivalent, including ease of examination, patient tolerance, and ability to intubate the second portion of the duodenum, but the examination time was shorter for the 4-way angulation endoscope when biopsies were necessary. Another study randomized 122 patients in a 2:1 fashion to an unsedated examination with either a 4.9- or 5.9-mm UT endoscope. Examinations with the smaller caliber instrument were better tolerated and had a significantly higher success rate (98% vs 89%) based on the ability to pass the endoscope transnasally more often with the smaller instrument. The global quality of the examination was not different in the 2 instruments.³¹

Transnasal UT-EGD was compared with the interventional radiology approach for placement of postpyloric feeding tubes in 100 consecutive critically ill patients.³² The UT endoscope was passed transnasally, and a guide-wire was passed through the accessory channel. The UT endoscope was then removed, and the feeding tube was passed over the wire. The endoscopic procedure was found to be significantly shorter and had equivalent success rates compared with fluoroscopy, and there was no need for oral-nasal transfer of the tube. The UT endoscope transnasal method was also compared with a standard fluoroscopic method for jejunal feeding tube placement in 28 patients presenting with upper intestinal obstruction. The total time of the procedure was significantly shorter in the UT endoscopy group (18.7 ± 8.4 minutes vs 39.5 ± 15 minutes).³³

Transnasal ERCP using an UT endoscope was compared with conventional ERCP in 50 patients. Not surprisingly, biliary cannulation was more difficult with the forward-viewing UT endoscope, although the authors noted that placement of a nasobiliary tube was easier since there was no need for nasal-oral transfer.³⁴

EASE OF USE

Per-oral EGD with UT endoscopes is easily performed and is similar to standard EGD, although inability to reach the second portion of the duodenum because of the decreased rigidity of the UT endoscope shaft is occasionally reported. Gastroenterologists may be unfamiliar with nasal anatomy and may require additional training in transnasal endoscopy. However, a study of the learning curve for transnasal EGD found that skilled endoscopists were successful at this technique from their first attempts and could be self-taught.³⁵ Physicians should be competent in standard EGD techniques and formally trained in the physiology, anatomy, and disease processes of the upper digestive tract. Inability to pass the endoscope transnasally because of narrow nasal tracts or altered anatomy is reported in 3% to 8% of patients.⁸⁻¹¹ When using very small

caliber endoscopes with only 2-way (up and down) directional tip control, it may be more difficult to perform targeted biopsies or therapy.⁵ Inferior suction and lens-washing capabilities compared with conventional EGD have also been reported.¹⁰ Additionally, when a prolonged examination is expected (ie, long-segment Barrett's mucosa or therapeutic interventions), unsedated endoscopy may be less desirable.

SAFETY

Because transnasal EGD is generally performed without sedation, the major source of complications from standard EGD is eliminated. Rates of other types of complications were very low in the 2 largest series of transnasal endoscopy, containing a total of 1700 patients and included self-limited epistaxis (0.85%-2%) and vasovagal events (0.3%).^{8,11} A single esophageal perforation was reported.¹⁶ Relative contraindications include previous nasal trauma or surgery and coagulopathy.^{3,36}

FINANCIAL CONSIDERATIONS

The potential advantages of unsedated UT-EGD include reduced procedure time and expenditures. One multicenter, randomized, controlled trial of 80 patients found that unsedated UT-EGD reduced total procedure time (including recovery time) by 1.5 hours compared with conventional sedated EGD and significantly reduced costs.³⁷

Prices for the various available UT endoscopes are listed in Table 1. All the endoscopes listed are compatible with their respective company's standard processor. The Vision Sciences endoscope has its own processor, which is included in the list price.

Current procedure technology (CPT®)* codes for UT endoscopy, whether transnasal or per oral, are the same as for standard EGD (42335) and esophagoscopy (43200). If a biopsy is performed, the respective codes are 43239 (EGD) and 43202 (esophagoscopy). If the esophageal examination is incomplete, the unlisted code 43499 or 43200 with 52 (reduced service modifier) should be reported.

AREAS FOR FURTHER RESEARCH

It is currently unknown what proportion of gastroenterologists offer this method of examination and also whether otolaryngologists are routinely examining the esophagus. Patient barriers have been elucidated in previous studies, but physician barriers to use have not

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been described. Because UT endoscopes are standard-resolution instruments, further quality-based trials are needed to compare UT endoscopes with standard-caliber HREs. These studies should emphasize the capacity of the instruments to detect subtle mucosal abnormalities and the pathology yields of tissue samples taken during the evaluation of Barrett's mucosa. Formal cost-effective analyses of unsedated UT endoscopy have not been performed. The impact of unsedated EGD on patient satisfaction also needs to be studied.

SUMMARY

A variety of UT endoscopes are available for use in motivated patients who wish to avoid a sedated procedure and can also facilitate examinations when traversing narrow strictures in the digestive tract. Unsedated UT-EGD seems to be safe and reduces the costs associated with conventional sedated endoscopy, although formal cost-effectiveness analyses have not been performed. Further comparative effectiveness of the performance of these instruments with standard size high-resolution instruments is warranted.

Abbreviations: BM, Barrett's metaplasia; HRE, high-resolution endoscope; UT, ultrathin.

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