Communication from the ASGE Technology Committee

TECHNOLOGY STATUS EVALUATION REPORT

Cholangiopancreatoscopy

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 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 September 2007 for articles related to cholangioscopy and pancreatoscopy by using the key words "choledochoscopy," "cholangioscopy," cholangiopancreatoscopy," "pancreatoscopy" paired with "bile duct stones/calculi," "intrahepatic stones/calculi," "intrahepatic biliary strictures," "percutaneous," "intraoperative", "pancreatic duct stones/calculi," "pancreatitis," "biliary disease," "primary sclerosing cholangitis," and "intraductal papillary mucinous neoplasm/tumor." 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.

Cholangiopancreatoscopy (CP), which is performed with miniature endoscopes, provides direct visualization of the biliary and pancreatic ducts. Cholangioscopy was first introduced for the intraoperative localization of stones during open bile duct exploration.[1] Subsequently, the cholangioscope was used postoperatively through an established T-tube tract for stone detection, intraductal lithotripsy, and biopsy.[2,3] CP has since been developed for use as an adjunct for percutaneous transhepatic cholangiography (PTC),[4] retrograde cholangiography,[5,6] and retrograde pancreatography[7,8] for the localization of conditions, tissue acquisition, and stone removal with or without intraductal lithotripsy.[8-12] Early retrograde CP used a specially designed large-channel duodenoscope to accommodate the cholangioscope ("mother-daughter" system).[7,10] Continued refinement in optics, scope diameter, and tip deflection has permitted the development of cholangioscopes capable of being passed through the working channel of a standard therapeutic duodenoscope.[13]

TECHNICAL CONSIDERATIONS

Instruments

In the United States, both reusable and semidisposable fiberoptic cholangioscope systems with specialized accessories are available for per oral retrograde and percutaneous or intraoperative use (Tables 1 and 2). For per oral indications, the 2.8- to 3.4-mm cholangioscopes with working lengths of 190 to 220 cm may be passed through a 4.2-mm working channel of a therapeutic duodenoscope. The use of a long (450 cm) guidewire is optional. The 0.75-mm working channel in the 2.8-mm endoscope accommodates a 0.025-inch guidewire and the 1.2-mm channel in the 3.3- to 3.4-mm endoscope permits the use of a 0.035-inch guidewire, biopsy forceps, or a 1.9F to 3F electrohydraulic lithotripsy (EHL) fiber. Intraoperative and percutaneous applications use 4.8- to 6.0-mm cholangioscopes with a working length of 35 to 67 cm and a 2.0- to 2.6-mm accessory channel permitting the passage of retrieval forceps, baskets, and larger intraductal lithotripsy fibers. The use of gastroscopes (8.8[14] and 5.9 mm[15] outer diameter [OD]) for direct inspection of the bile duct has been reported. Although cholangioscopes are fiberoptic based, there is limited commercial availability of 3.4- and 5.3-mm video cholangioscopes.[16,17] A thinner video (2.6 mm, 0.5-mm working channel) cholangioscope under investigation uses "ultraminiature" charge-coupled device (CCD) technology with a sequential color wheel method for generating images.[18] A narrow-band imaging (NBI) system that provides enhanced visualization of mucosal

0016-5107/$32.00
doi:10.1016/j.gie.2008.02.033

TABLE 1. Cholangioscope systems

Company	Model name	Distal diameter (mm)	Accessory channel (mm)	Depth of field (mm)	Per oral	Working length (mm)
Pentax, Orangeburg, NY	FCP-8P	2.8	0.75	1-50	Yes	1900
	FCP-9P	3.1	1.2	1-50	Yes	1900
	FCP-8PT*	2.8	1.2	1-50	Yes	1900
	FCN-15X*	4.8	2.2	3-50	No	350
	ECN-1530*	5.3	2.0	3-50	No	350
Olympus, Center Valley, Pa	CHF-P20	4.9	2.2	3-50	No	380
	CHF-T20	6.0	2.6/1.2 suction	3-50	No	380
	CHF-BP30	3.1	1.2	1-50	Yes	1870
	CHF-B160†	3.4	1.2	3-20	Yes	2000
	CHF-CB30	2.7	1.2	2.5-50	No	700 or 450
Boston Scientific, Marlboro, Mass	Spy Glass Probe (reuse)	0.77	.9 optic channel	2-7		3000
	Spy Glass catheter (single use)	3.4	1.2/0.6/0.6		Yes	2200

NA, Not available.
*Special order basis only.
†Future rental program basis only.
‡Tip deflection assessed with optical probe and device within accessory channel.

vascular patterns has been incorporated into a video cholangioscope and is also under investigation.[19]

Reusable cholangioscopes have a control section that consists of a dial for up/down 2-way tip deflection and buttons for air/water and suction channels. The insertion tube contains 1 instrument channel, a coherent bundle of glass fibers that transmits the image from the tip of the endoscope to the eyepiece, angulation wires for tip deflection, an air/water nozzle to clear the lens of debris, a light guide illumination, and an objective lens system at the tip of the endoscope. The connector section is similar to that of other endoscope systems.[20] When fiberoptic cholangioscopes are used with a video adapter, the processor and light source coordinate automated gain and light control, which assists in obtaining optimal imaging in different illumination circumstances. Cholangioscopes differ by tip deflection angle, outer diameter, working channel size, field of view, and available accessories (Table 1). Larger-diameter cholangioscopes for percutaneous and intraoperative use have a higher number of optical fibers, resulting in better illumination, field of vision, and image resolution.[21] Separately available eyepiece and video adapters convert the fiberoptic image to a video format. The video cholangioscopes have CCD technology at the distal end of the endoscope and thus a better image quality and a lighter control section.

The semidisposable system has a control section that includes dials for 4-way tip deflection and 3 ports: an irrigation port that feeds into 2 0.6-mm channels, an optical probe port, and a 1.2-mm accessory channel. The insertion tube is a disposable 3.4-mm access/therapeutic catheter with 4 steering wires embedded in its length. The reusable 6,000-pixel optical probe is a collection of light fibers that surround optical fiber bundles and is incorporated into a polyimide sheath. The connector section entails a camera processor with one-fourth-inch CCD chip, a light source, an optical coupler that interfaces the optical probe with the light source and video camera head, a medical grade isolation transformer, and a travel cart with a 3-joint arm for extension. An irrigation pump with foot pedal and monitor are available through separate vendors.

Additional capital equipment required to perform per oral CP includes 2 light sources, 2 processors, 2 video monitors, a fluoroscopy unit, and an irrigation pump with a foot pedal. For percutaneous cholangioscopy, 1 light source, 1 processor, a viewing monitor for the cholangioscope, a fluoroscopy unit, and an irrigation pump with foot pedal are needed. If EHL is to be performed, a separate lithotripsy generator is required.

Techniques

In the per oral technique with reusable systems, 2 operators, or a single operator with a specially designed external cholangioscope fixation device, are required.[22] Maneuvers before cholangioscope introduction may include stricture dilation, sphincterotomy, spot radiographs, and lubrication