Sphincter of Oddi manometry

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, performing 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 February 2011 for articles related to sphincter of Oddi manometry and sphincter of Oddi dysfunction.

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BACKGROUND

Sphincter of Oddi dysfunction (SOD) refers to a smooth muscle dysfunction that may result in an abnormal contractility, spasm, or obstruction of the sphincter. SOD can impede biliary and pancreatic duct flow, causing pain, elevated liver test results, dilated ducts, or idiopathic recurrent pancreatitis. Sphincter of Oddi manometry (SOM) is considered the criterion standard diagnostic modality for SOD.[1] SOM involves passing a catheter into the bile and/or pancreatic duct during ERCP to measure the pressure of the biliary and/or pancreatic sphincters. Results of SOM can guide the decision as to whether to perform sphincter ablation.

This report is an update on the technical considerations, efficacy, safety, and financial considerations of biliary and pancreatic sphincter manometry in the treatment of SOD.

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TECHNOLOGY UNDER REVIEW

Catheters

There are 2 types of catheters used for SOM: water perfused and solid state. Water-perfused catheters are the most commonly used manometry catheters[2] and are available from 2 manufacturers (Table 1). They are 200 cm long, single- or triple-lumen, have an outer diameter of 1.7 to 1.9 mm, and a luminal diameter of 0.5 to 0.8 mm and are composed of polyethylene or Teflon.[3] The distal end of the catheters is marked with 3 to 10 equally spaced stripes that allow evaluation of how deeply inserted the catheter is in the duct. Some catheters accept a 0.018-in. guidewire. At the distal end of the catheters, there are 1 to 3 radially arranged side holes 2 mm apart[4] through which water is perfused at a low flow rate, permitting pressure recordings from the ducts and sphincter. The Lehman catheter (Cook Medical, Winston-Salem, NC) has a third lumen for aspiration, which leads to less fluid in the ducts and possibly lowers the risk of pancreatitis.[5] These are available in both long-nose and short-nose configurations.[6] The long-nose catheter allows anchoring of the manometry catheter into the duct of choice, permitting multiple pull-throughs without loss of cannulation. The short-nose catheter is intended to provide easier cannulation in tortuous distal pancreatic ducts. The Lehman manometry catheter is single use, whereas Arndorfer catheters (Arndorfer, Inc, Greendale, Wisc) are reusable and can be gas sterilized. A recent innovation that is not commercially available is a sleeve that fits on the tip of water-perfused manometry catheters (Toouli SOM sleeve catheter; Mui Scientific, Mississauga, Ontario, Canada). This outer sleeve is intended to allow anchoring of the catheter in the sphincter as well as reverse-perfusion of water, theoretically decreasing the risk of pancreatitis.[7,8]

Solid-state manometry catheters, which do not use water perfusion, are also available (Unisensor, Portsmouth, NH).[9-13] These 4F or 5F catheters have a blunt metal tip

TABLE 1. Price listing of catheters, pumps, and manometry systems used in the performance of sphincter of Oddi manometry

	Price list	Features
Manometry catheters		
Cook Medical (Winston-Salem, NC)		
Lehman manometry catheters, long and short nose	$157.56	Perfusion, aspiration port, guidewire compatible, single use
Arndorfer Inc (Greendale, Wisc)		
ER1	$95	Perfusion, ER3GW guidewire compatible, multiple use
ER2	$95	
ER3GW	$100	
Unisensor USA (Portsmouth, NH)		
Unitip catheter	$7,800	Solid state, guidewire compatible, multiple use
Mui Scientific (Mississauga, Ontario, Canada)		
Toouli SOM sleeve catheter	$250	Perfusion, guidewire compatible, single use
Perfusion pumps		
Mui Scientific	$2625 Additional $2,025 if air compressor unit needed	3-channel specifically for SOM
Arndorfer Inc	$3595-5895	4- to 12-channel infusion system. Can be used for other manometric applications
Medical Measurement Systems-Solar GI (Dover, NH)		Included in purchase of Solar GI system. Up to 24-channel infusion system for use with other manometric applications.
Manometry systems		
Sierra Scientific Instruments (Los Angeles, Calif)	$21,000-$30,000	
Medical Measurement Systems-Solar GI (Dover, NH)	%18,000-$28,000	
Sandhill Scientific (Highlands Ranch, Col)	$24,540	

with 3 small piezoelectric pressure transducers located radially from each other at 90 degrees.[12] The catheters have a lumen for a 0.018-in. guidewire to facilitate cannulation and allow repeated pull-throughs. The metal tip of the catheters allows easy fluoroscopic visualization without the need for contrast injection.[10] The catheters are reusable for approximately 50 procedures.

SOM infusion pumps

Performance of SOM with water perfusion catheters requires a pump to deliver sterilized water to the manometry catheter (Table 1). The manometry catheter connects directly to the pressure transducer on the pump. The pump connects to a medical air outlet on the wall or a stand-alone air compressor. The air pressurizes a water reservoir that can be set by an adjustable regulator with a recommended driving pressure of 7 to 15 psi. The water passes through small-bore compact resistors, ensuring the recommended infusion rate of 0.15 to 0.4 mL/min. The pressurized water travels to the sphincter of Oddi through the catheter. The water itself serves as a pressure transducer medium from the sphincter back to the transducers, which are connected to a computerized recording system.

Data processing

Additional equipment necessary for performance of SOM includes a conversion modulator and computer software (Table 1). The modulator converts pressure recordings from an analog to digital signal, which is then transferred to a computer via a standard USB port for software processing and display in line trace format. The user can manipulate the line tracing for speed and pressure scale, analyze pressure, and add notes to document intraprocedure events. This allows data interpretation during the procedure so that sphincterotomy can be performed if indicated. Most SOM software programs generate a report in table format, and a database can be created for easy data entry and retrieval.

TECHNIQUE AND INDICATIONS

SOM is generally reserved for patients with disabling symptoms and compelling clinical evidence of SOD.[2,14] SOM is not needed in patients with type I SOD (classic biliary symptoms or pancreatic symptoms, increased biliary/pancreatic enzymes, and dilated biliary/pancreatic duct) because type I is a structural obstruction of the sphincter and most patients will benefit from sphincterotomy.[15,16] SOM is considered in patients with suspected type II SOD (classic biliary symptoms or pancreatic symptoms and either elevated enzymes or dilated ducts) to guide the need for sphincterotomy.[2,15,17] If ERCP is undertaken in patients with suspected type III SOD (pain only), manometry can be used to distinguish between sphincter dysfunction and other etiologies for pain (eg, functional pain syndromes).[18,19]

During ERCP, the manometry catheter is passed through the working channel of the duodenoscope. A baseline or zero duodenal pressure should be measured before cannulation. The manometry catheter is advanced into the desired duct either directly or over a 0.018-in. guidewire. Cannulation of the desired duct with a different catheter and injection of contrast to first perform diagnostic ERCP has been shown to not affect the manometric measurement.[20]

After cannulation with the manometry catheter, the ductal pressure is noted. The catheter is then slowly withdrawn from the duct at 1- to 2-mm intervals,[21] pausing for 60 to 90 seconds when the transducer reaches the sphincter. Location within the region of the sphincter is recognized by an increase in pressure and is visually aided by the circumferential markers on the catheter. The technique for pull-through may vary depending on the type of catheter used.

Basal sphincter pressure is the calculated mean pressure reading from 3 pull-throughs.[22] A basal sphincter pressure of 40 mm Hg or greater is the manometric criterion used to diagnose SOD dysfunction.[14,15,23,24] The threshold value of 40 mm Hg is used for both the biliary and pancreatic sphincters.[18] The treatment of an abnormally increased basal sphincter pressure is endoscopic sphincterotomy with the intent to completely obliterate basal sphincter pressure. The decision to measure 1 or both sphincters in patients with suspected biliary SOD is controversial and is beyond the scope of this document.[6,25-28] Manometry of both the pancreatic and biliary sphincter is generally performed in the investigation of idiopathic acute recurrent pancreatitis.[16,29,30]

OUTCOMES

The frequency of positive manometric studies and response to sphincterotomy depend on the type of SOD. Abnormal sphincter pressure is present in 65% to 100% of suspected type I SOD, 50% to 65% in suspected type II SOD, and 12% to 60% of suspected type III SOD patients. Among patients with manometric evidence of SOD, sphincterotomy is beneficial in 90% to 95% of type I patients,[16,21,27,31] 85% of type II patients, and 55% to 60% of type III patients.[2,15,16,27,32]

The prevalence of sphincter hypertension varies widely in patients with idiopathic recurrent acute pancreatitis, ranging from 15% to 72%.[16,33-35] Uncontrolled studies suggest that 60% to 80% of recurrent attacks of pancreatitis may be prevented by sphincterotomy after sphincter pressure elevation is proven by manometry.[6,36]

COMPARATIVE STUDIES

Noninvasive methods

Because of the invasive nature of SOM and associated risks, particularly pancreatitis, multiple noninvasive methods have been studied and compared with SOM in the diagnosis of SOD dysfunction. These noninvasive studies (eg, secretin-stimulated MRCP, hepatobiliary scintigraphy) have yielded mixed results compared with SOM in the diagnosis of SOD and varying predictability of response to sphincterotomy.[37-48]

Manometry catheters

The risk of pancreatitis from SOM may vary depending on type of catheter used. A randomized study of 76 patients found a reduced risk of pancreatitis when using a perfusion catheter with an aspiration port compared with a standard perfusion catheter (3% vs 23.5%, $P = .01$).[5] For the subset of patients undergoing pancreatic manometry, the incidence of pancreatitis was 30.8% with the standard perfusion catheter compared with 3.8% ($P = .01$) when the aspiration catheter was used. Three studies compared perfusion catheters to solid-state manometry catheters and have found good correlation in pressure measurements.[10,11,13] In a randomized study of 130 consecutive patients, the frequency of pancreatitis after solid-state manometry was significantly lower than the frequency of pancreatitis with perfusion manometry (3.1% vs 13.8%, $P < .05$).[11] All 3 cases of pancreatitis in the solid-state group were mild.

SAFETY

The primary risk of performing SOM and ERCP in patients with suspected SOD is pancreatitis. Pancreatitis rates after ERCP with SOM have been reported to be approximately 15% to 30%.[49-52] Performing ERCP in patients with suspected SOD, with or without the use of manometry, carries a two- to threefold greater risk of pancreatitis compared with performing ERCP in patients without suspected SOD.[53-55] However, increasing data suggest that manometry itself is not a significant risk for pancreatitis, but rather it is the group of patients in whom manometry is performed, those with suspected sphincter dysfunction, that increases the risk of pancreatitis when ERCP with manometry is performed.[49,51,53,54]

Some studies have shown a decrease in risk of pancreatitis with differing techniques of manometry performance. Pancreatitis rates are lowered when only the bile duct is studied and are higher with pancreatic SOM.[55,56]

Limiting perfusion into the ducts with continuous aspiration or by use of a solid state catheter has been shown to reduce post-ERCP pancreatitis.[5,11] Finally, placement of a pancreatic stent has been shown to lower the pancreatitis rates in patients who undergo SOM.[57,58]

FINANCIAL CONSIDERATIONS

Performance of SOM requires manometry catheters, a pump system if water perfusion manometry is used, SOM software, and a computer (Table 1). Many of these items can be purchased together as a system or individually.

Water-perfusion catheters are may be single use or multiuse. All perfusion catheters require a pump system. Solid-state manometry catheters are reusable for an estimated 50 times.

A specific code for ERCP with manometry exists, CPT 43263. This includes diagnostic ERCP and use of fluoroscopy.

A decision-analysis model compared the costs involved in manometry-directed sphincterotomy and empirical sphincterotomy in suspected type II biliary SOD patients.[59] In a hypothetical cohort of 100 patients, empirical biliary sphincterotomy proved to be a cost-saving strategy ($2224 vs $2790 per patient).

AREAS FOR FUTURE RESEARCH

Because of the invasive nature of ERCP with SOM and the high risk of pancreatitis, further investigation is needed of noninvasive methods that could stratify patients into intermediate or high probability of having SOD and those who will respond to sphincterotomy.

Randomized, multicenter studies are needed to determine whether SOM is needed for patients with type II SOD. Definitive studies assessing complications and outcomes with empirical sphincterotomy compared with manometry-directed sphincterotomy in this population are needed.

The evaluation and treatment of patients with suspected type III SOD remain controversial and are currently being examined in a multicenter study.[60]

SUMMARY

SOD manometry is currently used for the diagnosis of patients with sphincter dysfunction causing biliary-type pain or recurrent pancreatitis who will benefit from endoscopic sphincterotomy. SOM remains one of the most challenging endoscopic procedures, combining the need for extensive ERCP skills with manometric knowledge. SOM has one of the highest risk/benefit ratios of any endoscopic test, making appropriate patient selection and counseling critical before its performance. Technology advances have concentrated on the safety profile of SOM by decreasing pancreatitis rates. Studies are ongoing and needed to identify the patients who require SOM and will benefit from its use.

DISCLOSURE

The following author disclosed financial relationships relevant to this publication: Dr. Song: research support from Olympus and Fujinon Corp. The other authors disclosed no financial relationships relevant to this publication.

Abbreviations: SOD, sphincter of Oddi dysfunction; SOM, sphincter of Oddi manometry.

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