Communication from the ASGE Standards of Practice Committee

GUIDELINE

The role of ERCP in benign diseases of the biliary tract

This is one of a series of statements discussing the use of GI endoscopy in common clinical situations. The Standards of Practice Committee of the American Society for Gastrointestinal Endoscopy (ASGE) prepared this text. In preparing this guideline, a search of the medical literature was performed by using PubMed from January 1980 through December 2013 by using the keyword(s) "choledocholithiasis," "biliary stricture," "primary sclerosing cholangitis," "cholangiopathy," "sphincter of Oddi dysfunction," "biliary leak," "choledochal cyst," "choledochocele," AND "gastrointestinal endoscopy," "ERCP," "endoscopy," and "endoscopic procedures." The search was supplemented by accessing the "related articles" feature of PubMed, with articles identified on PubMed as the references. Pertinent studies published in English were reviewed. Additional references were obtained from the bibliographies of the identified articles and from recommendations of expert consultants. When little or no data exist from well-designed prospective trials, emphasis is given to results from large series and reports from recognized experts. Guidelines for appropriate use of endoscopy are based on a critical review of the available data and expert consensus at the time the guidelines are drafted. Further controlled clinical studies may be needed to clarify aspects of this guideline. This guideline may be revised as necessary to account for changes in technology, new data, or other aspects of clinical practice. The recommendations were based on reviewed studies and were graded on the strength of the supporting evidence using the GRADE criteria[1] (Table 1).

INTRODUCTION

ERCP was first reported in 1968 and was quickly accepted as a safe, direct technique for evaluating pancreaticobiliary disease.[2] With the introduction of endoscopic sphincterotomy in 1974, therapeutic pancreaticobiliary endoscopy was developed.[3,4] Over the past several decades, ERCP has evolved from a diagnostic procedure to one that is almost exclusively therapeutic. Other imaging techniques, such as abdominal US, CT, MRCP, EUS, and intraoperative cholangiography, provide diagnostic information that allows appropriate selection of patients for therapeutic ERCP.[5] ERCP with cholangiopancreatoscopy is a useful adjunctive technique for the evaluation and management of biliary and pancreatic disease.

Endoscopists who perform ERCP should have appropriate training and expertise in this procedure.[5,6] Preprocedure coagulation studies are not routinely indicated but should be considered in select patients, such as those with a history of coagulopathy or prolonged cholestasis.[7] Endoscopists should consider correction of coagulopathy if sphincterotomy is anticipated, but specific international normalized ratio thresholds for this intervention have not been established and remain subject to the endoscopist's judgment. Antibiotic prophylaxis is indicated in the setting of suspected biliary obstruction with anticipated incomplete drainage (including primary sclerosing cholangitis [PSC]), posttransplantation biliary strictures, or ductal leaks.[8]

Temporary pancreatic duct stenting and rectal indomethacin lower both the risk and severity of post-ERCP pancreatitis in high-risk populations, such as those undergoing precut biliary sphincterotomy or difficult biliary cannulation or with clinical suspicion of sphincter of Oddi dysfunction (SOD), a history of post-ERCP pancreatitis, pancreatic sphincterotomy, pneumatic dilation of an intact biliary sphincter, and ampullectomy.[9,10] Although rectal indomethacin alone appeared to be more effective for preventing post-ERCP pancreatitis in these high-risk patients than both pancreatic stent placement alone and the combination of indomethacin and pancreatic stent placement, a randomized, controlled trial comparing rectal indomethacin alone with indomethacin with pancreatic stent is needed.[11]

BENIGN BILIARY TRACT DISEASE

ERCP is particularly useful in the management of patients with biliary obstruction due to choledocholithiasis and other benign diseases of the biliary tract such as biliary strictures and postoperative biliary leaks. Successful endoscopic cholangiography with relief of biliary obstruction should be technically achievable in more than 90% of patients.[5] Adjunctive cholangioscopy at the time of ERCP can be helpful in the management and treatment of choledocholithiasis and for assessing indeterminate strictures.[12] ERCP with bile duct stenting and/or biliary sphincterotomy is the preferred treatment strategy for bile leaks.[13-16]

Choledocholithiasis

The most common cause of biliary obstruction is choledocholithiasis. Patients may present with biliary colic,

0016-5107/$36.00
http://dx.doi.org/10.1016/j.gie.2014.11.019

TABLE 1. GRADE system for rating the quality of evidence for guidelines[1]

Quality of evidence	Definition	Symbol
High quality	Further research is very unlikely to change our confidence in the estimate of effect	⊕⊕⊕⊕
Moderate quality	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate	⊕⊕⊕◯
Low quality	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate	⊕⊕◯◯
Very low quality	Any estimate of effect is very uncertain	⊕◯◯◯

Adapted from Guyatt et al.[1]

obstructive jaundice, cholangitis, or pancreatitis. Although the sensitivity and specificity of ERCP for detecting common bile duct stones are more than 95%, small stones may be missed.[5] Studies of cholangiography alone for the detection of stones have reported a false-negative rate as high as 13%.[17-21] Careful injection of contrast and early radiographs may help detect stones and avoid overfilling of the ducts or proximal advancement of stones into the intrahepatic ducts. The introduction of air bubbles into the biliary ductal system by the contrast injection catheter can lead to a misdiagnosis of stones.

If choledocholithiasis is found at the time of laparoscopic cholecystectomy and not cleared with common duct exploration, ERCP and stone extraction can be performed after surgery.[22,23] ERCP with biliary decompression is the procedure of choice for the treatment of acute cholangitis that accompanies acute biliary pancreatitis (ABP).[24-27] A recent Cochrane review evaluated outcomes with early ERCP in patients with ABP compared with conservative management with or without selective ERCP. This review found that in patients without concomitant cholangitis or biliary obstruction, there is no advantage of early ERCP with regard to mortality and local or systemic adverse events, regardless of the predicted severity of ABP.[28] However, the review did reaffirm that early ERCP is beneficial in (1) reducing local adverse events in patients with ABP with biliary obstruction and (2) reducing mortality as well as local and systemic adverse events in patients with ABP and cholangitis.

Endoscopic sphincterotomy and stone extraction are successful in more than 90% of cases, with an overall rate of adverse events of approximately 5% and a mortality rate of less than 1% in expert hands.[24] These results compare favorably with those of most surgical series.[29] In cases of failed primary biliary cannulation, precut (eg, needle knife) sphincterotomy or a combined percutaneous/endoscopic approach may be necessary. The adverse event rates associated with these techniques are higher than for standard extraction techniques, reflecting greater technical difficulty.[30] EUS-guided biliary access by highly experienced practitioners has also become a viable alternative in cases of failed primary biliary cannulation.[31,32] Concern for post-ERCP pancreatitis and mortality has led many endoscopists to limit biliary sphincteroplasty without biliary sphincterotomy to patients with persistent coagulopathy and Billroth II anatomy.[33-39] However, endoscopic papillary large-balloon ($\geq$12 mm) dilation combined with sphincterotomy can result in high success rates for complete clearance of large and difficult choledocholithiasis with a low rate (2.3%) of post-ERCP pancreatitis.[40-43]

Stone removal is usually accomplished with balloon extractor catheters or wire baskets. Occasionally, large or impacted stones may be difficult to remove. Fragmentation of large stones and the management of impacted baskets with entrapped stones can be facilitated by the performance of mechanical lithotripsy or cholangioscopy with electrohydraulic or laser lithotripsy.[44-46] If stone removal is unsuccessful, biliary decompression should be accomplished by placement of a stent or nasobiliary drain, when feasible.[47]

Peroral cholangioscopy with intraductal lithotripsy has been demonstrated to clear difficult extrahepatic biliary stones in 83% to 100% of patients.[48-51] Among patients with intrahepatic bile duct stones, intraductal lithotripsy combined with extracorporeal shock wave lithotripsy may successfully clear stones in approximately two-thirds of patients.[52] Methods for cholangioscopically guided intraductal lithotripsy include electrohydraulic lithotripsy and pulsed laser lithotripsy.[53,54] Pulsed laser lithotripsy allows for more precise targeting, thereby reducing the risk of bile duct injury. However, its relatively high equipment cost has limited its widespread use.

Endoscopic sphincterotomy and stone extraction without subsequent cholecystectomy may be appropriate in select patients with comorbid conditions that increase their surgical risk.[4] However, biliary symptoms recur twice as commonly in patients whose gallbladder remains in situ with a 5-year risk of significant biliary adverse events leading to cholecystectomy as high as 15%.[5,55,56]

Other benign diseases of the biliary tract

ERCP is indicated for the evaluation and treatment of benign biliary strictures, congenital bile duct abnormalities, and postoperative adverse events such as anastomotic strictures and biliary leaks.[57,58] Biopsies and brushings can help define the etiology of benign biliary strictures and diagnostic yield may increase with cholangioscopically directed biopsies.[59,60] Intraductal US may help distinguish