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,

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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 benign from malignant strictures.[61] Probe-based confocal laser endomicroscopy is currently being investigated for endoscopic evaluation of indeterminate strictures.[62] Newer diagnostic tests such as digital imaging analysis and fluorescent in situ hybridization may offer increased sensitivity while maintaining the high specificity of cytology.[63,64] In the setting of hilar strictures, imaging with MRCP or EUS before ERCP can help plan and direct endoscopic intervention.

Benign biliary strictures may be dilated with hydrostatic balloons or graduated catheters passed over a guidewire. Benign biliary strictures amenable to endoscopic dilation include those secondary to chronic pancreatitis, dominant strictures in sclerosing cholangitis, postoperative strictures, and strictures caused by stone disease.[13] Single or multiple stents may be used to maintain patency after initial dilation.[65,66] Serial endoscopic dilation and maximal caliber stent placement can be used to achieve prolonged ductal patency in most benign postoperative strictures.[13]

Biliary strictures secondary to chronic pancreatitis. In patients with biliary strictures secondary to chronic pancreatitis, most series have demonstrated long-term success rates of endoscopic therapy ranging from 10% to 32% with frequent adverse events of stent occlusion and migration.[67-74] Treatment failure of the stricture is particularly likely among patients with pancreatic head calcifications as demonstrated by a clinical success of only 7.7% at 1 year in 1 large study.[67] The use of multiple plastic stents in these patients that are exchanged every 3 months over a longer time period (as long as 14 months) appears to be more effective than single plastic stents, with a reported overall success rate of 65.2%.[12,66,75,76] Restenosis rates as high as 17% after stent removal have been reported during a mean follow-up period of 42 months (range 4-99 months).[77] The limited efficacy and need for repeated endoscopic therapy for biliary strictures secondary to chronic pancreatitis should be considered when discussing endoscopic and surgical alternatives with patients.[74,78]

Biliary strictures due to PSC. MRCP has essentially replaced ERCP for the diagnosis of PSC because it is noninvasive, has comparable diagnostic accuracy, and is cost-effective.[79-83] The routine use of ERCP for the diagnosis of PSC is discouraged because ERCP-associated adverse events such as bacterial cholangitis, pancreatitis, biliary tract perforation, and hemorrhage have been reported in 7% to 20% with postprocedural hospitalization rates as high as 10%.[79,84,85] Dominant strictures seen in patients with PSC should undergo endoscopic brushing and/or biopsy to assess for malignancy.[56,85] Antibiotic prophylaxis is recommended for all patients with PSC undergoing ERCP.[8]

Nevertheless, diagnostic ERCP in PSC patients may be useful in several scenarios. First, it may aid in diagnosing PSC in the subset of patients in indeterminate MRCP examinations because of suboptimal visualization of the intrahepatic bile ducts.[79] Second, ERCP may be considered to exclude a dominant stricture in patients with previously stable PSC who manifest clinical deterioration with worsening cholestasis, pruritus, jaundice, or bacterial cholangitis.[79] Finally, ERCP is also indicated to evaluate for cholangiocarcinoma masquerading as a dominant stricture in patients who present with progressive biliary dilation on cross-sectional imaging, worsening liver function tests, and/or constitutional symptoms such as weight loss.[79] Benign strictures in PSC patients respond well to endoscopic therapy with balloon dilation with or without stent placement. Limited data suggest that balloon dilation is often sufficient and that the use of stents may be associated with an increased risk of adverse events and cholangitis.[86] Therefore, stenting is usually reserved for strictures that are refractory to dilation. Endoscopic therapy of dominant strictures in patients with PSC may improve survival.[74,85,87,88] Although endoscopic therapy in PSC has not been shown to delay liver transplantation or facilitate early identification of cholangiocarcinoma, cholangiograms obtained at ERCP have been shown to have some prognostic value when combined with other patient-derived factors.[89]

Postoperative/operative biliary strictures. Bile duct injury during cholecystectomy can result in stricture formation.[74] Strictures recognized early in the postoperative/operative period are often associated with a bile leak caused by direct trauma, whereas delayed presentation is commonly associated with ischemic injury and resultant fibrosis.[74] Strictures that are recognized early respond more favorably to endoscopic treatment. Endoscopic treatment usually involves serial placement of multiple plastic stents over a 1-year period.[77,90-94] Success rates for this approach range from 74% to 90% with recurrence rates as high as 30% within 2 years of stent removal.[66,74,90,92,94] A more aggressive approach to endoscopic stent placement yields more durable results,[90] and distal postoperative biliary strictures (Bismuth I and II) are associated with better success rates compared with proximal hilar strictures (Bismuth III).[66,95]

Outcomes of endoscopic therapy of bile duct strictures that occur after orthotopic liver transplantation (OLT) tend to be highly variable.[96-98] After OLT, anastomotic strictures (80%) are more common than nonanastomotic strictures (10%-25%).[99,100] Early anastomotic strictures (presenting within 1 month of OLT) are amenable to endoscopic therapy with dilation and stent placement, and resolution is usually achieved within 3 months.[101] Treatment of late anastomotic strictures (presenting later than 1 month post-OLT) may require prolonged and repeated therapy (12-24 months). Balloon dilation with stent placement is more effective than balloon dilation alone, with long-term response rates of 70% to 100%.[102-105] Progressively increasing the number of stents placed during subsequent ERCP seems to be the most effective treatment approach.[74,106] In contrast, nonanastomotic strictures (resulting mainly from hepatic artery thrombosis or other forms of ischemia) are less responsive to endoscopic therapy, with long-term response rates as low as 50%.[97,107] Management of nonanastomotic strictures requires more sessions and longer duration of endoscopic intervention compared with anastomotic strictures.[108-110] Definitive treatment of nonanastomotic strictures may require retransplantation.[111] Other biliary adverse events in OLT recipients include bile leaks, bile duct stones, bile duct casts, mucocele, and hemobilia and can usually be managed endoscopically. Bile duct casts occurring in the setting of ischemia-induced strictures of the hilum may require combined endoscopic and percutaneous methods to achieve clearance.[112] Antibiotic prophylaxis is recommended for all patients with OLT undergoing ERCP.[8]

Strictures at a biliary-enteric anastomosis, such as those occurring after pancreaticoduodenectomy, liver transplantation, liver resection, and Roux-en-Y hepaticojejunostomy, can be treated successfully with ERCP. Additional equipment such as device-assisted enteroscopy may be necessary to gain access to the stricture site.[74,113-117] Endoscopic sphincterotomy may successfully treat sump syndrome after side-to-side choledochoduodenostomy.[29]

Biliary leaks. Biliary leaks from the cystic duct, the bile duct, and the ducts of Luschka can be treated with decompression of the bile duct by sphincterotomy alone or endoscopic stent or nasobiliary drain placement, with or without sphincterotomy.[14-16] Stents are typically placed for 4 to 6 weeks, but longer intervals of stent placement may be necessary for larger duct injuries.[118] These principles also apply to biliary leaks that occur after liver resection.[119] Bile leaks are classified as low grade or high grade based on their magnitude after cholangiography. Low-grade leaks require nearly complete or complete filling of intrahepatic ducts to demonstrate contrast extravasation, whereas high-grade leaks are readily evident before intrahepatic opacification.[120] Successful treatment of biliary leaks with endoscopic therapy depends on the grade and the location of the leak and range from 80% to 100%.[13] Leaks from the end of a cystic duct stump or from a duct of Luschka are usually associated with low output and respond more favorably to endoscopic treatment compared with higher output leaks from the common hepatic duct and common bile duct.

Immunoglobin-G4–associated autoimmune cholangiopathy. Immunoglobulin (Ig)-G4–associated cholangiopathy can cause intrahepatic, proximal extrahepatic, or distal (intrapancreatic) benign biliary strictures manifesting as sclerosing cholangitis, pseudotumorous hilar lesions, or "chronic pancreatitis" type distal biliary stricture.[74,121] Most cases are associated with autoimmune pancreatitis, an important diagnostic clue, although they can also occur as isolated biliary disease.[121] Serum IgG4 levels are unreliable in making a diagnosis because of low specificity and sensitivity (74%).[122,123] The criterion standard for diagnosis is histology including characteristic features on hematoxylin and eosin staining and extensive infiltration by IgG4 plasma cells on immunostaining.[121] Biopsies of the ampulla of Vater and bile duct stricture can help in making a histological diagnosis, but histology is not mandatory for the diagnosis of this condition.[124] IgG4–associated cholangiopathy responds dramatically to steroid therapy, and in select cases, a trial of steroid therapy can confirm the diagnosis.[125-129] IgG4–associated cholangiopathy should be differentiated from PSC and biliary malignancy.[121,124] Temporary endobiliary stent placement can be performed to treat the biliary obstruction while patients are undergoing diagnostic testing and medical treatment.[74,128]

Biliary SOD. SOD may present with signs and symptoms of biliary and/or pancreatic disease. The Rome III revision of the Milwaukee Biliary Group classification categorizes biliary SOD patients into 3 types.[129] Type I patients present with biliary-type pain, abnormal aminotransferases, bilirubin, or alkaline phosphatase (>2 times normal values) documented on 2 or more occasions and a dilated bile duct (>8 mm on US). Type II patients present with biliary-type pain and 1 of the previously mentioned laboratory or imaging abnormalities. Type III patients report only recurrent biliary-type pain and have none of the previously mentioned laboratory or imaging criteria. In patients with type I SOD, sphincter of Oddi manometry (SOM) is not necessary because more than 90% of patients will have resolution of pain with endoscopic sphincterotomy.[130] SOM in patients with suspected type II SOD is often recommended to help establish the diagnosis and to select patients likely to respond to endoscopic therapy. Biliary sphincterotomy will alleviate pain in the majority of patients with clinical type II biliary SOD and abnormal biliary manometry.[130] Some experts advocate empiric biliary sphincterotomy without SOM in patients with type II biliary SOD on the basis of favorable clinical response, low rates of adverse events, and cost-effectiveness.[130-134] Patients with suspected SOD have a significantly higher risk of post-ERCP pancreatitis, irrespective of whether manometry is performed.[9,135] Rectal indomethacin with or without a pancreatic stent is recommended for prophylaxis against post-ERCP pancreatitis when ERCP is performed in patients with suspected SOD.[10,136]

Recently, a 2-arm parallel, randomized, double-blind, sham-controlled, multicenter National Institutes of Health clinical trial, the EPISOD study, ascertained that subjects with type III SOD do not respond to sphincterotomy.[137] In this trial, 214 patients with pain after cholecystectomy without abnormalities on imaging or laboratory studies and without previous sphincter intervention or pancreatitis were randomized (2:1) to sphincterotomy or sham therapy. Patients (n = 141) randomized to sphincterotomy first underwent sphincter of Oddi manometry and those with sphincter hypertension were re-randomized to biliary or both biliary and pancreatic sphincterotomy. The primary outcome of the study was treatment success, defined as less than 6 days of disability because of pain in the previous 90 days at months 9 and 12 after randomization, without narcotic use and no additional sphincter intervention. Treatment success in the sphincterotomy group occurred in 23% (95% confidence interval, 15.8%-29.6%) and 37% (95% confidence interval, 25.9%-48.1%) in the sham group with an adjusted risk difference of 15.6% ($P < .01$) favoring sham treatment. There was no significant difference in the primary outcome among patients treated with single sphincterotomy or dual sphincterotomy. Pancreatitis occurred in 11% of patients treated with sphincterotomy and in 15% of patients who underwent sham therapy. Thus, this trial confirmed that SOM and sphincterotomy do not benefit patients with type III SOD and are associated with significant rates of adverse events.

Congenital conditions. Endoscopic sphincterotomy may successfully treat cholangitis or pancreatitis secondary to congenital choledochocele and choledochal cyst. ERCP can also clarify the diagnosis during the preoperative assessment of these congenital conditions if findings on cross-sectional imaging modalities such as MRCP and CT are equivocal.[138,139]

Metal stents for benign biliary disease

An overview of the various types of biliary stents was provided in another ASGE document.[140] The role of fully covered self-expandable metal stents (FCSEMSs) in benign biliary disease is evolving. The relative ease of removal of FCSEMSs after placement has led to their increased use for the management of benign biliary conditions such as strictures, complex bile leaks, postsphincterotomy bleeding, and perforation. The main potential benefit of FCSEMSs in the management of refractory benign biliary strictures is their large caliber and longer duration of patency, allowing them to be left in place longer than plastic stents and resulting in fewer procedures for serial dilations and placement of multiple plastic stents. Although FCSEMSs show promise, randomized trials comparing multiple plastic stents with FCSEMSs are needed.[141-143]

RECOMMENDATIONS

1. We recommend that diagnostic ERCP not be undertaken for the evaluation of pancreaticobiliary-type pain in the absence of objective abnormalities on other pancreaticobiliary imaging or laboratory studies (⊕⊕⊕○).
2. We recommend that routine ERCP before laparoscopic cholecystectomy not be performed in the absence of objective signs of biliary obstruction or stone. (⊕⊕⊕○)
3. We recommend that ERCP in patients with acute biliary pancreatitis be limited to those with concomitant cholangitis or biliary obstruction.(⊕⊕⊕⊕)
4. We recommend ERCP with dilation and stent placement for benign biliary strictures.(⊕⊕⊕○)
5. We recommend that ERCP be undertaken as first-line therapy for postoperative biliary leaks.(⊕⊕⊕⊕)
6. We suggest that cholangioscopy be considered as an adjunctive technique for the management of difficult bile duct stones not amenable to removal after sphincterotomy with or without balloon dilation or mechanical lithotripsy. (⊕⊕○○)
7. We suggest that cholangioscopy with directed biopsy be considered as an adjunctive technique for the characterization of biliary strictures. (⊕⊕○○)
8. We recommend ERCP with sphincterotomy for patients with type I SOD. (⊕⊕⊕○)
9. We recommend against the performance of ERCP for the evaluation or treatment of type III SOD. (⊕⊕⊕⊕)
10. We recommend rectal indomethacin with or without a pancreatic stent for prophylaxis against post-ERCP pancreatitis when ERCP is performed in patients with suspected SOD. (⊕⊕⊕○)

DISCLOSURE

Dr Khashab is a consultant for and a member of the Medical Advisory Board of Boston Scientific, a consultant for Olympus America, and has received research support for Cook Medical. Dr Chathadi is a consultant for Boston Scientific. Dr Muthusamy is a consultant for Boston Scientific. Dr Hwang is on the speakers' bureau of Novartis, is a consultant for US Endoscopy, and has received a research grant from Olympus. Dr Fisher is a consultant for Epigenomics. All other authors disclosed no financial relationships relevant to this article.

Abbreviations: ABP, acute biliary pancreatitis; FCSEMS, fully covered self-expandable metal stent; OLT, orthotopic liver transplantation; PSC, primary sclerosing cholangitis; SOD, sphincter of Oddi dysfunction; SOM, sphincter of Oddi manometry.

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