ASGE guideline: the role of ERCP in diseases of the biliary tract and the pancreas

Guidelines for the practice of endoscopy are developed by the American Society for Gastrointestinal Endoscopy by using an evidence based methodology. A literature search is performed to identify relevant studies on the topic. Each study is then reviewed for both methodology and results. Controlled clinical trials are emphasized, but information is also obtained from other study designs and clinical reports. In the absence of data expert opinion is considered. When appropriate, the guidelines are submitted to other professional organizations for review and endorsement. As new information becomes available revision of these guidelines may be necessary.

These guidelines are intended to apply equally to all who perform GI endoscopic procedures, regardless of specialty or location of the service. Practice guidelines are meant to address general issues of endoscopic practice. By their nature they cannot encompass all clinical situations. They must be applied in the appropriate context for an individual patient. Clinical considerations may justify a course of action at variance to these recommendations.

INTRODUCTION

ERCP was first reported in 1968[1] and was soon accepted as a safe, direct technique for evaluating biliary and pancreatic disease. With the introduction of endoscopic sphincterotomy in 1974,[2,3] therapeutic pancreaticobiliary endoscopy subsequently was developed. ERCP is now widely available.

ERCP has evolved from a diagnostic procedure to an almost exclusively therapeutic procedure. Other imaging techniques, such as US, CT, magnetic resonance imaging, EUS, and intraoperative cholangiography, provide diagnostic information that allows selection of patients for therapeutic ERCP.[4] ERCP is not indicated in the evaluation of abdominal pain of obscure origin in the absence of other objective findings, suggesting biliary-tract disease.[5,6] The role of ERCP with biliary manometry remains controversial in patients with biliary-type pain but without any objective signs or laboratory abnormalities.

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ERCP usually is performed, often in an outpatient setting, with intravenous sedation and analgesia for the patient. Endoscopists who perform ERCP should have appropriate training and expertise.[4] Although few data are available to assess operator skills in performing ERCP, competence in consistently performing deep common bile duct cannulation may not routinely be achieved until the performance of at least 200 ERCPs.[4] The endoscopist must be prepared and competent to perform therapeutic intervention at the time of ERCP.[7]

Preprocedure coagulation studies are not routinely indicated but should be considered in selected patients, such as those with a history of coagulopathy or prolonged cholestasis.[8] Coagulopathy should be corrected if sphincterotomy is anticipated. Antibiotic prophylaxis is indicated in the setting of suspected biliary obstruction, known pancreatic pseudocyst, or ductal leaks.[9]

BILIARY TRACT DISEASE

ERCP is particularly useful in the management of the jaundiced patient with biliary obstruction because of choledocholithiasis and strictures. Successful endoscopic cholangiography with relief of obstruction should be technically achievable in more than 90% of patients.[4] Cholangioscopy at ERCP is used infrequently but may be helpful in the management of bile-duct stones and in assessing suspected malignancies.[10]

Choledocholithiasis

The most common source of biliary obstruction is choledocholithiasis. Such patients may present with biliary colic, obstructive jaundice, cholangitis, or pancreatitis. The sensitivity and the specificity of ERCP for detecting common duct stones is over 95%; small stones occasionally are missed.[4] Careful injection of contrast and early radiographs may help to detect stones, which avoids overfilling the ducts or pushing stones into the intrahepatic ducts. The accidental instillation of air bubbles into the duct by the injection catheter can lead to misdiagnosis of stones. If common bile duct stones found at the time of laparoscopic cholecystectomy cannot be removed, ERCP and stone extraction can be performed after surgery.[11] Preoperative ERCP may be indicated when persistent jaundice, elevated liver enzymes, persistent or worsening pancreatitis, or cholangitis is present.[4] ERCP

with biliary decompression is the procedure of choice for the treatment of acute cholangitis.[12] Urgent ERCP also is indicated in selected patients with severe gallstone pancreatitis and suspected biliary obstruction.[12]

Therapy for choledocholithiasis

Endoscopic sphincterotomy and stone extraction is successful in more than 90% of cases, with an overall complication rate of approximately 5% and a mortality rate of less than 1% in expert hands.[12] These results compare favorably to most surgical series. In cases of failed primary biliary cannulation, pre-cut (e.g., needle knife) papillotomy or a combined percutaneous/endoscopic approach may be necessary. The complication rates associated with these techniques are higher than for standard extraction techniques, reflecting greater technical difficulty.[13] An alternative to biliary sphincterotomy is balloon dilation of the biliary sphincter (balloon sphincteroplasty). This may be an alternative to biliary sphincterotomy in selected patients with common bile duct stones, e.g., underlying coagulopathy, albeit with a higher risk of post-ERCP pancreatitis.[14,15]

Stone removal usually is accomplished with soft Fogarty-type balloons 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 use of mechanical lithotriptors.[16] If stone removal is unsuccessful, biliary decompression should be accomplished with a stent or a nasobiliary drain.

Endoscopic therapy (sphincterotomy and stone extraction) without subsequent cholecystectomy may be the preferred procedure in selected patients with comorbid conditions that increase their surgical risk. Biliary symptoms recur twice as commonly in patients whose gallbladder remains in situ.[17] In some studies, the 5-year risk of serious biliary complications leading to cholecystectomy is 10-15%.[4,18]

Malignant and benign biliary strictures

ERCP is useful in the assessment and the treatment of malignant biliary obstruction. The presence of a ''shelf'' instead of a smooth taper to the stricture can suggest a malignant etiology (although the ''shelf'' can be present in patients with a normal sphincter of Oddi). Biopsies, brushings, and FNA may yield a definitive tissue diagnosis, but the combined sensitivity is no higher than 62%.[19,20]

ERCP is indicated for the evaluation and the treatment of benign bile-duct strictures, congenital bile-duct abnormalities, and postoperative complications. This applies to patients with biliary obstruction after liver transplantation.[21,22] Endoscopic sphincterotomy may successfully treat cholangitis or pancreatitis because of a choledochocele and choledochal cysts, or the sump syndrome after a side-to-side choledochoduodenostomy.

Stricture dilation

Benign biliary strictures may be dilated with hydrostatic balloons or a graduated catheter passed over a guidewire. Indications for endoscopic dilation of benign strictures include postoperative strictures, dominant strictures in sclerosing cholangitis, chronic pancreatitis, and stomal narrowing after choledochoenterostomy.[23] Stent placement may be used to maintain patency after initial dilation when using single or multiple endoscopic prostheses.[20,24] Serial endoscopic dilations and stent placement can be used to achieve prolonged ductal patency in benign strictures secondary to chronic pancreatitis[25] and postoperative strictures.[23]

Although early results with this technique in patients with biliary strictures secondary to chronic pancreatitis are encouraging, long-term results tend to be poor, with mixed success rates but with some as low as 10%.[26,27] In addition, in the subgroup of patients with calcification of the pancreatic head, outcomes were even worse, with only 7.7% of patients in one large study achieving clinical success at 1 year.[27] Placement of multiple plastic stents to dilate and to treat chronic biliary strictures caused by chronic pancreatitis is a viable option but has been associated with rare cases of death from biliary sepsis.[28] In addition, even patients with successful biliary stricture dilation via stents have a restenosis rate after stent removal of up to 17%.[29] The use of multiple stents exchanged every 3 months over a longer time period (up to 14 months) may be more efficacious than single stents for treatment of biliary strictures caused by chronic pancreatitis.[30]

Strictures that develop in patients with primary sclerosing cholangitis (PSC) tend to respond well to endoscopic therapy, either with balloon dilation alone or in combination with the placement of endoscopic stents. The limited data available on this topic suggest that balloon dilation may be sufficient and that the use of stents to treat these strictures may be associated with an increased risk of complications and cholangitis.[31] Endoscopic therapy of strictures has been shown to be beneficial overall in patients with PSC, and one study suggested that it may improve survival.[32] Although endoscopic therapy in PSC has not been shown to delay liver transplantation or to allow early identification of cholangiocarcinoma, cholangiograms obtained at ERCP have been shown to have some prognostic value when combined with other patient-derived factors.[33] Dominant strictures seen in patients with PSC should undergo endoscopic brushing and biopsy to assess for the presence of malignancy.

With regard to benign postoperative bile-duct strictures, outcomes via treatment with balloon dilation and stents are encouraging but far from optimal, and clinical success rates with these modalities can range from 55% to 88%.[34] Outcomes for endoscopic therapy of bile-duct strictures that occur after liver transplantation also tend to

be highly variable, with success rates as high as 91% to 100%, while other investigators have shown only a 42% success rate for early postoperative strictures and 8% for late postoperative strictures.[35-37]

Stents

Endoscopically placed bile-duct stents have a role in the treatment of both malignant and benign biliary strictures, as well as in postoperative bile-duct injuries or leaks.[23,38] Endoscopic stent placement provides effective palliation in patients with malignant disease and significant biliary obstruction, either as a temporary measure before surgical treatment or for long-term palliation. Dilation of malignant strictures may occasionally be necessary before stent insertion.

The role of preoperative biliary decompression for malignant obstruction because of pancreatic cancer should be limited to those patients with acute cholangitis or those who have severe pruritus and a delay in surgical resection.[39] Large-caliber polyethylene stents are used most commonly. In expert hands, stent placement is successful in 90% of distal bile-duct strictures occurring in the setting of pancreatic, ampullary, and distal bile-duct cancers. For proximal (Klatskin) lesions, success rates are lower, biliary drainage may be incomplete, and the incidence of early cholangitis is higher.[40] Such tumors may require the placement of stents into both right and left hepatic ducts to achieve adequate drainage. Minimal contrast injection and the use of preprocedural imaging studies to direct unilateral drainage of patients with hilar tumors may decrease the rate of cholangitis.[41,42] In randomized trials, self-expanding metallic stents provide approximately double the duration of patency compared with polyethylene stents and are more cost effective in patients with nonresectable malignant strictures.[38] Expandable metal stents may be particularly well suited for patients with a longer life expectancy, an absence of metastases, and for those who have had early occlusion of polyethylene biliary stents.[38] Endoscopic stent placement also is helpful for treatment of postoperative biliary strictures and fistulas, and in selected patients with benign strictures secondary to pancreatitis[25] or sclerosing cholangitis.[43] Endoscopic dilation with stent placement of benign postoperative strictures is successful in 80% to 90% of patients.[23,24]

Biliary leaks from the cystic duct, the bile duct, and the ducts of Luschka respond well to decompression of the bile duct by endoscopic stent placement or nasobiliary drainage with or without sphincterotomy.[44-46] Stents usually are placed for 4 to 6 weeks, but longer intervals of stent placement may be necessary for larger duct injuries.[47] These principles also apply to bile leaks that occur after liver resection.[48] Percutaneous drainage of associated bilomas should be considered.[47] Success rates for endoscopic closure of bile leaks depend on the size and the location of the leak and range from 80% to 100%.[23]

Sphincter of Oddi dysfunction

Sphincter of Oddi dysfunction may present with signs and symptoms of biliary and/or pancreatic disease. Patients with typical biliary colic and abnormal liver chemistries and with dilated bile duct (type 1 patients by Hogan/Geenen criteria) should undergo sphincterotomy; sphincter of Oddi manometry is not necessary in these patients.[49] More than 90% of these patients will have resolution of pain.[49] Biliary sphincterotomy will alleviate pain in the majority of type 2 patients (dilated bile duct or abnormal LFTs) with abnormal biliary manometry.[49] Although some studies suggest that type 3 patients (biliary pain, normal imaging, and chemistries) with an abnormal sphincter of Oddi manometry benefit from endoscopic sphincterotomy, further studies are necessary before this therapy should be widely accepted in this group.[49] The rates of complications for both ERCP and sphincterotomy in patients with sphincter of Oddi dysfunction are higher than in patients with other indications for these procedures.[50]

PANCREATIC DISEASE

A variety of disorders of the pancreas can be diagnosed and treated with ERCP, although controlled trials evaluating efficacy are limited.

Recurrent acute pancreatitis

Ideally, ERCP should be reserved for treatment of abnormalities found by less invasive imaging techniques. EUS and MRCP allow pancreatic and biliary anatomy to be defined noninvasively, without risk of pancreatitis and radiation exposure, and may detect microlithiasis, choledocholithiasis, unsuspected chronic pancreatitis, and, in some cases, pancreas divisum and annular pancreas.[51-54] ERCP may still be required to obtain definitive imaging of the ductal anatomy. One should anticipate the need to perform manometry, minor papilla cannulation, pancreatic sphincterotomy, or pancreatic-duct stent placement.[55]

Bile obtained at ERCP can be analyzed to detect microlithiasis. In selected patients, endoscopic biliary sphincterotomy without cholecystectomy is a viable option for preventing recurrent pancreatitis in the setting of microlithiasis.[55]

Pancreas divisum, present in approximately 7% of the population, occurs when there is a failure of fusion of the dorsal and ventral pancreatic ducts. The role of pancreas divisum as a cause of recurrent acute pancreatitis remains controversial, though the National Institutes of Health consensus conference statement suggests that endoscopic therapy is a reasonable approach for these patients.[4] In properly selected patients, minor papilla sphincterotomy may prevent further attacks of acute recurrent pancreatitis. One retrospective series of 53 patients who underwent minor papilla sphincterotomy in this setting

reported that 60% of patients had immediate improvement in symptoms but that half of these patients developed recurrent symptoms a mean of 6 months after the procedure.[56] A recent review of large, predominately retrospective, series of endoscopic treatment of patients with pancreas divisum evaluated stents, sphincterotomy, and the two used in combination.[57] These studies showed an overall trend toward better outcomes (improvement in pain, as well as fewer hospitalizations and emergency department visits) in patients with acute recurrent pancreatitis when compared with patients with chronic pancreatitis or pancreatic-type pain only. Limited data suggest that prolonged stent placement of the minor papilla without sphincterotomy may produce results equivalent to minor papilla sphincterotomy.[58-60] Minor papilla manipulation may carry an increased risk of post-ERCP pancreatitis.[61]

In patients with recurrent acute pancreatitis ERCP with the pancreatic duct, sphincter of Oddi manometry can be considered with the appropriate therapy (sphincterotomy or stent placement) performed in patients found to have elevated basal sphincter pressures. Case series have shown good responses in 28% to 91% of patients.[50] Sphincter of Oddi manometry is associated with a markedly increased rate of pancreatitis and should be performed by experienced operators in well-selected patients.

The need for ERCP after a single episode of unexplained pancreatitis is not established.

Autoimmune pancreatitis may have a characteristic appearance on ERCP, is associated with an elevated immunoglobulin G4 level, and responds favorably to corticosteroids.[62]

Chronic pancreatitis

ERCP provides direct access to the pancreatic duct for evaluation and treatment of symptomatic stones, strictures, and pseudocysts. Pancreatic-duct strictures often can be successfully treated with dilation and stent therapy. Pain relief during and after stent placement varies widely.[63] In one randomized trial of endoscopic and surgical therapy, surgery was superior for long-term pain reduction in patients with painful obstructive chronic pancreatitis.[64] However, because of its lower degree of invasiveness, endotherapy may be preferred, reserving surgery in cases of failure and/or recurrence of symptoms.

Obstructing pancreatic stones may contribute to abdominal pain or acute pancreatitis in patients with chronic pancreatitis. Pancreatic sphincterotomy and stone removal can be difficult because of underlying pancreatic-duct strictures and may require extracorporeal shock wave lithotripsy (ESWL) to fragment the stones before endoscopic removal. In some patients, stones may be impossible to remove endoscopically.[65] Case series have shown highly mixed results with regard to improvement in pain with pancreatic endotherapy. Some encouraging short-term (77%-100%) and long-term (54%-86%) improvements in pain have been reported.[63,66] Other, larger series have been less encouraging. One large series of 1000 patients with chronic pancreatitis with long-term follow-up found that only 65% of patients with strictures, stones, or strictures and stones could benefit from pancreatic endotherapy with regard to pain but that endotherapy did not improve pancreatic function. Also, this same study found that 24% of patients ultimately underwent some form of surgery to treat their chronic pancreatitis.[67] ESWL for pancreatic stones is a difficult procedure even in experienced hands, has significant risks, and patients may require protracted therapy (>10 sessions) to obtain successful clearance of the duct.[68] While some investigators have reported high success rates with this technique (with or without pancreatic stents), others have had much less impressive results, with improvement in pain seen in as few as 35% of patients, whereas other large series have reported that, despite successful ESWL, most patients experience no improvement in pain.[69,70] In patients with inaccessible stones proximal to tight strictures, surgical therapy may be required.

Pancreatic duct leaks

Pancreatic-duct disruptions or leaks occur as a result of acute pancreatitis, chronic pancreatitis, trauma, or surgical injury. Pancreatic leaks can result in pancreatic ascites, pseudocyst formation, or both. Pancreatic leaks can often be treated with transpapillary stents.[71] More severe duct disruptions sometimes can be treated by ''bridging'' pancreatic stents to reconnect otherwise dislocated segments of pancreatic parenchyma.[72] In one study of 42 patients with pancreatic duct disruption treated by pancreatic-duct stents, 25 patients (60%) had resolution of the disruption. Factors associated with a better outcome in duct disruption include successfully bridging the disruption and longer duration of stent placement (approximately 6 weeks). There are no randomized studies that compare surgical with endoscopic therapy for pancreatic-duct injuries.

Pancreatic fluid collections

ERCP can be used to diagnose and treat pancreatic fluid collections, such as acute pseudocysts, chronic pseudocysts, and pancreatic necrosis. Fluid collections that communicate with the pancreatic duct are amenable to transpapillary therapy. Noncommunicating benign pancreatic fluid collections can be drained via a transgastric or a transduodenal approach. EUS can allow predrainage interrogation of the intended needle path to look for interposed vessels and thus avoid them during the cyst drainage procedure.

Pseudocysts that communicate with the pancreatic duct, including cysts in the tail of the pancreas, can be drained via a transpapillary approach. Pancreatic duct stent placement, pancreatic sphincterotomy, or a combi-

nation of these techniques can allow successful nonsurgical resolution. Large case series of pseudocysts drained by the transpapillary route have yielded success rates of >90%.[63,73-75] Transmural drainage of pseudocysts, although technically more difficult, can be accomplished safely >80% of the time when in experienced hands.[76,77] Complications of pseudocyst drainage by either approach include pancreatitis, bleeding, perforation, and infection.

Pancreatic cancer and other pancreatic malignancies

Pancreatic malignancies usually produce both biliary- and pancreatic-duct strictures (''double-duct sign'').[78] High-resolution contrast-enhanced CT, MRCP, and EUS are now commonly performed in patients with suspected pancreatic cancer.[78] A tissue diagnosis can be obtained via ERCP biopsy and brush cytology. The sensitivity rate for ERCP-directed brush cytology or biopsy is 30% to 50%, with a combination achieving sensitivity rates of 65% to 70%.[20] Techniques to enhance the accuracy of brush cytology, e.g., digital image analysis, appear to significantly increase the yield of brush cytology but are not widely available.[79] Additional methods, e.g., molecular analysis of components of pancreatic juice, are experimental.[80]

Role of intraductal US and pancreatoscopy

Intraductal US (IDUS) may be useful for distinguishing benign from malignant strictures.[81] Pancreatoscopy allows direct visualization of ductal structures and can be helpful in distinguishing pancreatic adenocarcinoma from intraductal papillary mucinous neoplasm and other cystic neoplasms.[82,83] Pancreatoscopy combined with IDUS and/or brush cytology and biopsy can provide a higher diagnostic accuracy than single tests alone.[84]

TREATMENT OF AMPULLARY ADENOMAS

Adenomas in the region of the major duodenal papilla can be both diagnosed and treated via ERCP. Snare ampullectomy, combined with biliary and/or pancreatic sphincterotomy, allows complete removal of the adenoma in approximately 80% to 90% of patients without intraductal extension. Recurrences are more common in patients with familial adenomatous polyposis syndrome.[85-87] Endoscopic ampullectomy is associated with up to a 20% risk of post-ERCP pancreatitis, which appears to be reduced by pancreatic-duct stent placement at the time of resection.[86] Close endoscopic follow-up is necessary to ensure complete resection and detect recurrence.[87,88]

ERCP DURING PREGNANCY

The most common indication for ERCP during pregnancy is treatment of choledocholithiasis. Choledocholithiasis that causes cholangitis and pancreatitis during pregnancy increases the risk of morbidity and mortality for both the fetus and mother. ERCP, with modified techniques to reduce radiation exposure to the fetus, is safe during pregnancy.[89,90] Dosimetry should be routinely recorded. It may be possible to perform ERCP without fluoroscopy. Consultation with an obstetrician is recommended.

ERCP IN CHILDREN

ERCP has been used in children for a variety of indications, usually related to recurrent acute pancreatitis, choledocholithiasis, or evaluation of suspected choledochal cysts. Several case series of ERCP in children have shown that, in experienced hands, the success and the safety is comparable with that in adults.[91-93] Radiation exposure should be limited, and additional pelvic shielding can be used to protect the reproductive organs. In most patients, adult duodenoscopes can be used, but pediatric duodenoscopes are available, although accessories for these devices are limited.

SUMMARY

For the following points: (*A*), prospective controlled trials; (*B*), observational studies; (*C*), expert opinion.

- ERCP is now a primarily therapeutic procedure for the management of pancreaticobiliary disorders (*C*).
- Diagnostic ERCP should not be undertaken in the evaluation of pancreaticobiliary pain in the absence of objective findings on other imaging studies (*B*).
- Routine ERCP before laparoscopic cholecystectomy should not be performed (*B*).
- Endoscopic therapy of postoperative biliary leaks and strictures should be undertaken as first-line therapy (*B*).
- ERCP plays an important role in patients with recurrent acute pancreatitis and can identify and, in some cases, treat underlying causes (*B*).
- ERCP is effective in treating symptomatic strictures in chronic pancreatitis (*B*).
- ERCP is effective for the palliation of malignant biliary obstruction (*B*), for which self-expanding metallic stents have longer patency than plastic stents (*A*).
- ERCP can be used to diagnose and to treat symptomatic pancreatic-duct stones (*B*).
- Pancreatic-duct disruptions or leaks can be effectively treated via the placement of bridging or transpapillary pancreatic stents (*B*).
- ERCP is a highly effective tool to drain symptomatic pancreatic pseudocysts and, in selected patients, more complicated benign pancreatic-fluid collections arising in patients with a history of pancreatitis (*B*).
- Intraductal US and pancreatoscopy are useful adjunctive techniques for the diagnosis of pancreatic malignancies (*B*).

- ERCP can be performed safely in both children and pregnant adults by experienced endoscopists. In both situations, radiation exposure should be minimized as much as possible (*B*).

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