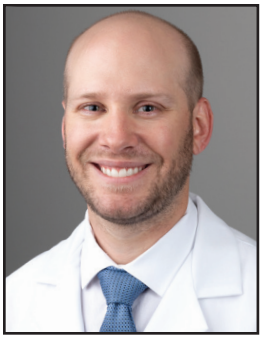
Douglas G. Adler MD, FACG, AGAF, FASGE, Series Editor

Indications for ERCP



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Key Points:

- **Indications and contraindications for ERCP are various and appropriate patient selection requires careful consideration**
- **As our understanding of how ERCP is utilized continues to evolve, it is important to continue analyzing outcomes of the procedure to target those who will continue to benefit the most**
- **Expert endoscopists must be well-versed in special cases requiring ERCP to provide necessary required care to specific patient populations**

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) was first introduced in the 1970's as a tool for visualization of the ampulla of Vater. Using a specialized endoscope with a side viewing camera that allows for optimal visualization within the duodenum, ERCP has grown from a diagnostic to a therapeutic modality for pancreaticobiliary diseases. Modifications on the endoscope have been made to assist with therapeutic maneuvers. Modern duodenoscopes are equipped with a large instrument channel and small metal elevator at the end of the channel that allows for various tools to be directed towards the papilla and manipulated within the bile or pancreatic duct, making ERCP the gold standard modality for diagnosis and management of pancreaticobiliary diseases.

There are numerous indications for a patient to undergo ERCP, including both pancreatic and biliary pathologies. ERCP allows for both diagnostic and therapeutic management of pancreaticobiliary disease; however, there are considerable risks associated with ERCP. Therefore, patients must be carefully selected to ensure that they will benefit most from the procedure. This article will outline the most common indications and contraindications for ERCP, including; 1. Who needs and does not need ERCP, 2. When to safely and effectively perform the procedure, and 3. When not to perform the procedure. In addition, we will address special considerations surrounding ERCP, including ERCP in pregnancy, the elderly, those on systemic anticoagulation/antiplatelet therapy

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or with multi-drug resistant (MDR) infections, and those with allergies to contrast dye.

Indications for ERCP

The indications for performing ERCP will be outlined in this section and a summary of these can be found in Table 1. As radiologic imaging is often the first investigation in the workup of abnormal blood tests or presenting symptoms, this chapter will outline the specific diagnoses that require ERCP in greater detail, focusing on information that is important to the clinician who performs the procedure. For the following scenarios, ERCP is used to diagnose, treat, or facilitate various investigations of the pancreaticobiliary system.

1. Choledocholithiasis

Gallstone disease remains one of the most common gastrointestinal diseases worldwide, with a reported prevalence of 10% in adults, and remains the most common indication for ERCP.[1,2] While most gallstones will be asymptomatic, 2-4% of those with gallstone disease will develop symptoms, of which 20% will become impacted within the bile duct and require intervention.[2] The 2020 ASGE Guidelines on the role of endoscopy in the evaluation and management of choledocholithiasis states the diagnosis of choledocholithiasis should be made with either MRCP or EUS to confirm the presence of common bile duct stones, although in practice these investigations are not warranted in all patients before undergoing ERCP. These modalities have comparable sensitivity (93% in MRCP; 95% in EUS) and specificity (96% in MRCP; 97% in EUS) at low, intermediate and high pre-test probabilities.[3]

ERCP should be reserved for the therapeutic management of confirmed or high likelihood of choledocholithiasis, defined by the ASGE as a common bile duct stone on imaging, total bilirubin of >4mg/dl *and* a dilated bile duct, or physical and lab findings suggestive of ascending cholangitis.[4] Biliary cannulation should be followed by sphincterotomy (unless contraindicated), stone removal through biliary balloon sweep, wire guided baskets or electrohydraulic lithotripsy (EHL), laser lithotripsy, or mechanical lithotripsy as needed.

Mirizzi's syndrome is an uncommon clinical scenario that was first described by Pablo Luis Mirizzi, an Argentinian surgeon who first described the entity in 1948. Mirizzi syndrome occurs in approximately 1% of those undergoing cholecystectomy.[5,6] Mirizzi's syndrome occurs when a gallstone becomes impacted in the cystic duct, gallbladder neck or infundibulum and results in direct biliary compression of the common bile or hepatic duct (Type I Mirizzi's syndrome). The formation of a cholecystocholedochal fistula (Type II Mirizzi's syndrome) is due to the erosion of a gallstone directly into the common duct.[5] While surgery is ultimately required in the management of patients with Mirizzi's syndrome, there remains a role for ERCP with biliary stenting in the acute setting in these patients.[4] ERCP with EHL for management of Mirizzi's syndrome has also been studied, with success rates as high as 96% in one large longitudinal Japanese study, however this success was limited by a 16% recurrence rate.[7] Current expert consensus recommends consideration of ERCP for biliary stenting in acute cholangitis as a bridge to cholecystectomy in Mirizzi's syndrome, with consideration of ERCP with EHL in poor surgical candidates or those with Type II disease.[5,7,8] Preoperative stenting in patients with Mirizzi syndrome can also aid surgeons during operative correction, as it allows clear identification of the common bile duct lumen.

Table 1. Indications for ERCP

Choledocholithiasis
Gallstone Pancreatitis
Cholangitis
Bile duct leak (BDL)
Assessment and intervention of biliary strictures
Assessment and management of ampullary tumors
Facilitation of cholangioscopy
Facilitation of pancreatoscopy
Management of SOD Type I/II
Management of choledochal cysts*
Management of disrupted pancreatic duct#

*See "Choledochal cysts" below

#See "Management of pancreatic pseudocysts" below

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2. Gallstone pancreatitis

Gallstone disease is the most common cause of pancreatitis with a reported prevalence ranging from 40-70%.[9] Gallstone pancreatitis occurs from pancreatic ductal outflow obstruction secondary to retained stone(s) within the common channel or impacted (or temporarily impacted) stone(s) at the level of the ampulla.[10] Over the years, the management of gallstone pancreatitis has evolved from early intervention to a more conservative approach.[4] A 2012 Cochrane review including 7 RCT's comparing early versus late ERCP on mortality, local and systemic complications in uncomplicated gallstone pancreatitis found no reported difference between groups. A significant reduction in all-cause mortality, local and systemic complications was seen in those with subsequent cholangitis, while a reduction in local inflammation was seen in those with subsequent biliary obstruction in the early ERCP intervention groups.[11] A 2022 systematic review of 3 RCT's and 1 non-randomized trial on early ERCP showed no reduction in mortality or complications in gallstone pancreatitis without cholangitis.[12] Current gastroenterology guidelines agree on recommending against the use of routine ERCP in gallstone pancreatitis in the absence of biliary obstruction or cholangitis.[9,12,13] If ERCP is undertaken during an episode of gallstone pancreatitis, the endoscopist has the option of performing biliary sphincterotomy and clearing the duct or simply placing a biliary stent to allow ductal decompression, with a plan to return at a later date once the pancreatitis has resolved to undergo duct clearance.

Multidisciplinary consultation with both an advanced endoscopist and general surgeon is important in the management of these patients. While interval cholecystectomy used to be the standard of care, same-admission cholecystectomy has now been shown to reduce the risk of recurrent pancreatitis, readmission for biliary complications and all cause mortality.[14,15] Still, same-admission cholecystectomy has not been universally adopted by the surgical community. Surgical consultation for inpatient cholecystectomy should be arranged in all patients presenting with gallstone pancreatitis. It is prudent for the endoscopist to be aware of this and potentially recommend this when consulted for potential ERCP, even in the absence of performing the procedure.

Table 2. Contraindications to ERCP

Lack of patient consent
Active or recent perforation
Hemodynamic instability
Uncorrected coagulopathy
High risk intervention (e.g., sphincterotomy) on full dose anticoagulation or antiplatelet therapy

3. Cholangitis

The findings of a jaundiced patient presenting with fevers and right upper quadrant pain (Charcot's triad) should raise the suspicion of cholangitis, with an even higher index of suspicion when hypotension and altered mental status (Reynold's pentad) are concomitantly present. A diagnosis of cholangitis should be made promptly through clinical history, physical examination, laboratory results and imaging studies, which are all included in the 2018 Tokyo Guidelines diagnostic criteria for acute cholangitis (Table 4[16]). ERCP for biliary decompression has been shown to have a significant mortality benefit in this patient population by providing relief of biliary obstruction and drainage of the infected biliary tree, however studies on the exact timing of ERCP in patients with cholangitis have shown conflicting results.[16–22] More recently, studies have favored more urgent ERCP, however the exact definition of urgency is variable amongst studies and opinions on this question vary widely in clinical practice. One recent meta-analysis of 9 studies showed a 20% decrease for in-hospital mortality among those undergoing ERCP within 24 hours as compared to those undergoing ERCP ≥24 hours (OR 0.81, 95% CI 0.73-0.90). In-hospital mortality was also reduced when comparing those who underwent ERCP within 48 hours versus after 48 hours, and within 72 hours versus after 72 hours.[18] Another large meta-analysis and systematic review examining mortality benefit in those undergoing ERCP within 48 hours showed significant reduction of in-hospital mortality, length of stay and 30-day mortality.[17] Other large-scale studies have also shown improved outcomes in earlier (24 to 72 hours) ERCP intervention, with

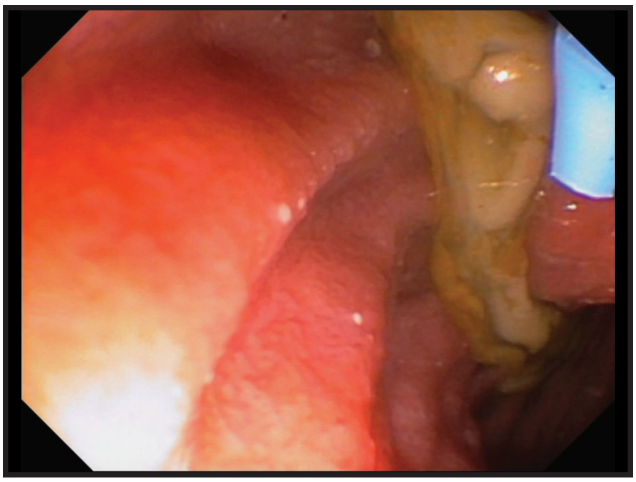

Figure 1. Biliary stent placement for acute cholangitis

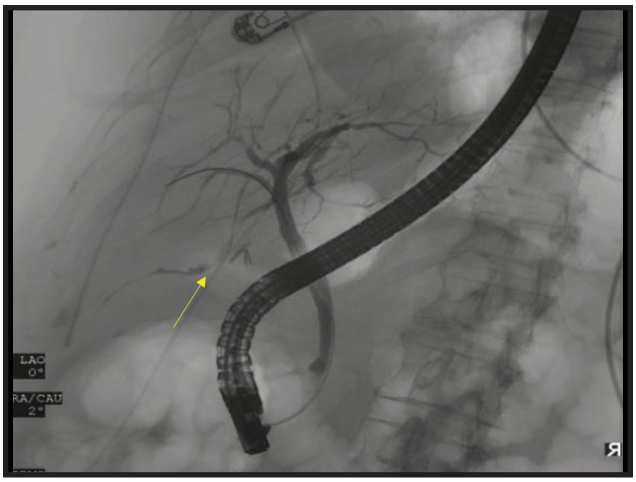

Figure 2. Low-grade bile leak of the duct of Luschka after complete intra-hepatic filling

reduced mortality and length of stay.[19–21] One recent study examining outcomes in non-severe acute cholangitis using a 12-hour emergent cut-off showed no difference in in-hospital mortality, length of stay or recurrent cholangitis when compared to elective (≥24 hr) ERCP. The majority of these cases would fall under "emergent" in other studies, with only 4.7% performed ≥72 hours after presentation.[22] While the data remains clear that ERCP within 24-48 hours provides improved outcomes, further randomized control trials are necessary to determine whether ERCP within 24 hours significantly improves outcomes as compared to those performed after 24 hours. It should be emphasized that the reasons for potentially delaying ERCP in patients with cholangitis include the need for patient stabilization, fluid resuscitation, and antibiotic administration: all of these make patients better candidates for ERCP when the time for the procedure arrives.

4. Bile leaks

ERCP is considered first line therapy in the management of bile duct leaks (BDLs).[8,23] Endoscopic placement of a bile duct stent with or without sphincterotomy reduces transpapillary pressure, corrects the pressure gradient in the biliary tree, and allows adequate bile drainage down to the duodenum. ERCP plays an important diagnostic and therapeutic role in BDL by localizing the site of the bile leak and providing therapeutic decompression of the bile duct (thus markedly reducing the flow of bile out of the leak site, and promoting healing at the leak site itself). BDLs often occur at the cystic duct, the ducts of Luschka, the common bile duct, and less commonly the common hepatic duct, although they can develop anywhere in the bile duct in a variety of contexts.

BDLs are classified as low or high grade based on cholangiogram interpretation.[8,23] Low grade bile leaks are only visualized once the intrahepatic bile ducts have been filled, while high grade bile leaks show active extravasation before intrahepatic bile duct filling occurs.[8] In practice, these definitions are often less than helpful, and the leak is often graded somewhat subjectively. When a bile leak is suspected or confirmed on cholangiogram, endoscopic biliary stenting and/or sphincterotomy is recommended with success rates ranging from 80-100%.[8] The adequate timing of ERCP in bile leaks is not guideline based and remains up for debate, however prior studies have not shown a difference in outcomes when comparing early (<1 day) versus late (>3 days) intervention.[23] As long as the bile leak is identified and a functioning drain (e.g., Jackson-Pratt drain) has been placed, then ERCP can be performed non-urgently. Routine practice is to maintain a biliary stent in situ for 4-6 weeks, after which a repeat ERCP for stent removal and re-evaluation of the biliary tree with contrast cholangiogram is performed. If the leak has healed, the stent can be removed and not replaced. If the leak persists, a new stent is placed and the ERCP repeated another 4-6 weeks later.

5. Biliary strictures

ERCP is the gold standard for assessing, diagnosing, and managing biliary strictures. Biliary strictures can present a variety of ways, including asymptomatic obstructive jaundice, symptomatic abdominal pain, or incidentally on abdominal imaging. Biliary strictures can be benign, malignant, or indeterminate, and can be caused by abnormalities of both the biliary tree and pancreas. ERCP is unique as it facilitates access into the bile duct and has the ability to assess a stricture through a cholangiogram and/or cholangioscopy. Tissue sampling can be obtained with cytology brushing or biopsy forceps into the duct. The various etiologies and advanced workup of biliary strictures are outside the scope of this review.

6. Ampullary adenomas and tumors

The role of endoscopy and ERCP in the diagnosis and management of ampullary tumors has been outlined by both the ASGE in 2016 and more recently the ESGE in 2021.[24,25] Ampullary tumors should be examined using a side viewing duodenoscope and are usually, but not always, biopsy proven prior to consideration of resection.[24,25] EUS and MRCP are often used to further stage these lesions and determine the extent of invasion into the intrapancreatic bile duct and pancreatic head.[25] While some suggest that when low-grade dysplasia is confirmed on two separate biopsies, or high-grade dysplasia on one set of biopsies, ampullectomy should be performed in tumors measuring ≤30mm in diameter without intraductal resection, others have used less firm criteria and make the decision to resect on an individualized basis. A single RCT argues against the routine use of submucosal injection for ampullectomy, although in practice the maneuver is widely performed. No difference in tumor recurrence, delayed bleeding or complete resection rate was noted when the maneuver was used or dispensed with.[25,26] Both guidelines recommend prophylactic placement of a pancreatic duct stent to reduce the incidence of post-ERCP pancreatitis. The routine use of biliary stenting, and biliary or pancreatic sphincterotomy is no longer universally recommended but in practice remain widely employed.[25]

7. Cholangiopancreatoscopy

Direct visualization of the bile and pancreatic duct through cholangiopancreatoscopy has advanced the management of large biliary and pancreatic duct stones and increased the diagnostic yield of intraductal tissue sampling of indeterminant strictures.[27] The use of cholangioscopy with electrohydraulic lithotripsy (EHL) or laser lithotripsy (LL) for the management of difficult to treat and/or large bile duct stones has been shown to have excellent results. Reported stone visualization and fragmentation rates have been reported to be as high as 92%, with complete stone clearance rates in a single session of 71%.[28] Additional studies have reported complete bile duct stone clearance ranging from 71 to 100%.[27] While the data on pancreatoscopy for stone management is less robust, stone clearance success rates have been reported from 50 to 100% in several case series.[27] A 10-year retrospective analysis on 46 patients undergoing EHL/LL for pancreatic duct stones reported complete clearance in 70% of patients, with clinical success (as defined by reduction in pain scores and opioid use) in 74% of patients.[29]

Direct cholangioscopy is an important tool in the workup of indeterminate strictures.[30] Across 10 studies, the pooled sensitivity for diagnosis of malignancy strictures was 60.1% with a pooled specificity of 98.0%. Results of this meta-analysis strongly support the use of cholangioscopy in

Table 3. Clinical scenarios in which ERCP should not routinely be performed

SOD Type III
Abdominal pain diagnosis
First line therapy in management of pancreatic pseudocysts/pancreatic fluid collections
Prevention of acute pancreatitis in pancreatic divisum*

*Outside of a clinical trial setting

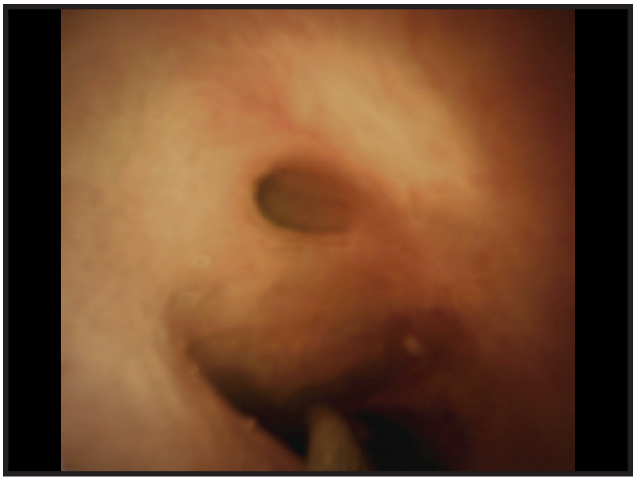

Figure 3. Cholangioscopy for assessment of biliary stricture

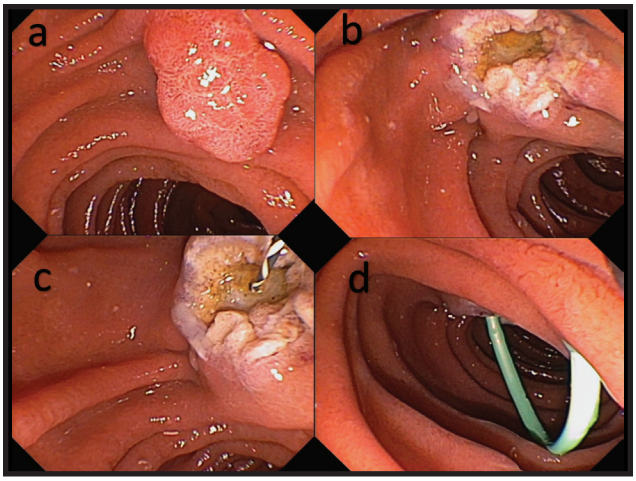

Figure 4. Ampullectomy of duodenal adenoma. a) Duodenal adenoma b) post-endoscopic hot snare resection c) cannulation of pancreatic duct with wire, d) Pancreatic duct stent

strictures with negative or inconclusive brushings, with a sensitivity of 74.7% and specificity of 93.3% in 4 studies that examined this clinical scenario.[30]

8. Sphincter of Oddi dysfunction (Type I and II)

The role of ERCP in the management of Sphincter of Oddi dysfunction (SOD) is controversial in the literature, as is the very existence of the concept of SOD as a clinical entity itself (which many still do not believe exists, and not without good reason). Historically, ERCP with sphincterotomy was recommended for those with Type I SOD (biliary-type pain, bile duct dilation and liver enzyme elevation), with consideration for those with Type II (pain with either biliary dilation or elevation in liver enzymes) and Type III (pain alone in the absence no biliary dilation or liver enzyme elevation).[31] Type I SOD is accepted in some circles as an organic papillary stenosis and ERCP with sphincterotomy is appropriate, although even the concept of papillary stenosis is debatable.[8,31] There have been three RCT's showing benefit of empiric sphincterotomy in those with Type II SOD with certain manometric findings, however routine practice often manages these patients similar to Type I SOD, and thus investigation with manometry is not often used in the clinical setting.[31] The biggest deviation from our prior approach to SOD is seen in Type III SOD, for which current expert consensus recommends against the use of ERCP, as described in further detail below (See *"Who does not need ERCP"*). Similarly, the global acceptance of SOD as a concept, and the number of ERCPs performed for presumed SOD annually, has fallen precipitously.

9. Choledochal cysts

Choledochal cysts are rare congenital cystic dilations of the common and intrahepatic bile ducts, with a higher incidence in Asian (1 in 13000 Japanese) than Western populations (1 in 1,000,000-2,000,000 in England).[32] Choledochal cysts can present with abdominal pain, jaundice and, rarely, a palpable mass. These biliary cysts have been shown to increase the risk of recurrent cholangitis, pancreatitis, cirrhosis, gall bladder and bile duct malignancy.[32,33] These cysts are often associated with anomalous pancreaticobiliary duct junction (APBDJ) and are classified using the Todani classification system, which classifies cysts based on the number and location of cysts within the biliary tree.[34] Type I (segmental or diffuse dilation of the common bile duct), Type II (common bile duct diverticulum), Type IV (multiple intra and/or extrahepatic cysts) and Type V (single or multiple intrahepatic cysts) cysts are managed operatively, with cyst excision and hepaticojejunostomy for Type I, diverticulotomy for Type II and hepatectomy or transplant for Type IV and V.[32,33] Cystolithiasis

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and cholangitis may occur in these patients, and, while operative management is the gold standard, ERCP for stone removal and/or stenting may be indicated to manage these acute events.[32,33] Type III choledochal cysts (also termed choledochoceles) occupy the intra-duodenal portion of the CBD and are rare, accounting for only 0.5-4% of all choledochal cysts.[32] These cysts have a lower risk of malignancy and association with APBDJ, and therefore Type III cysts are the only ones that are primarily managed endoscopically with biliary sphincterotomy or needle knife papillotomy.[32,33] Type III choledochal cysts ≥2cm should be referred to a surgeon for consideration of transduodenal excision or pancreaticoduodenectomy, although the risk of malignancy, even in these large cysts, remains low.[32]

Contraindications to ERCP

1. Consent

There are few absolute contraindications to ERCP, one of which is lack of patient consent outside of emergent situations wherein consent cannot be obtained i.e. septic cholangitis with an altered mental status. ERCP should not be performed in patients who do not consent to the procedure, as is expected standard practice in all medical fields. The risks associated with ERCP should be carefully discussed with each patient so as they may make an informed decision. Common complications including pancreatitis, infection, perforation, bleeding, the possibility of death and risks of undergoing conscious sedation/anesthesia should be discussed.

2. Active or recent perforation

Active perforation of the oropharynx, esophagus, stomach or bowel is, in general, a contraindication to ERCP given the risk of worsening pneumomediastinum and/or pneumoperitoneum. Multidisciplinary discussion with surgical teams should be had if ERCP is indicated in a patient who has recently had a perforation and been managed either surgically or supportively in order to determine the timing and urgency of endoscopy.

3. Hemodynamic instability

ERCP should not be performed in critically ill patients who are inadequately resuscitated with ongoing hemodynamic instability. Critically ill patients requiring hemodynamic support in an intensive care setting that require biliary drainage should be discussed and managed in collaboration with an intensivist and anesthesiologist, if at all possible. Percutaneous trans-biliary drainage (PTBD) should be considered in these patients if ERCP is not feasible or there is reason to believe may not be successful, including imaging findings

Table 4. 2018 Tokyo Guidelines on the diagnostic criteria for acute cholangitis

A. Systemic Inflammation	
A1. Fever and/or shaking chills	T >38.0 ^{0}C
A2. Evidence of inflammatory response on laboratory studies	WBC <4 or >10 OR CRP ≥1mg/dl
B. Cholestasis	
B1. Jaundice	Total bilirubin ≥2mg/dl
B2. Abnormal liver function tests	ALP >1.5 x STD IU GGT >1.5 x STD IU AST >1.5 x STD IU ALT >1.5 x STD IU
C. Imaging studies	
C1. Biliary dilation	CBD >7mm
C2. Etiology seen on imaging (stricture, choledocholithiasis, occluded stent, etc.)	

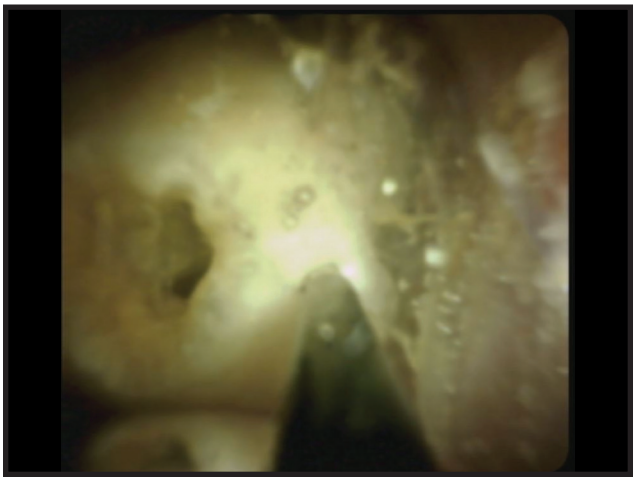

Figure 5. Electrohydraulic lithotripsy (EHL) of common bile duct stone using cholangioscopy

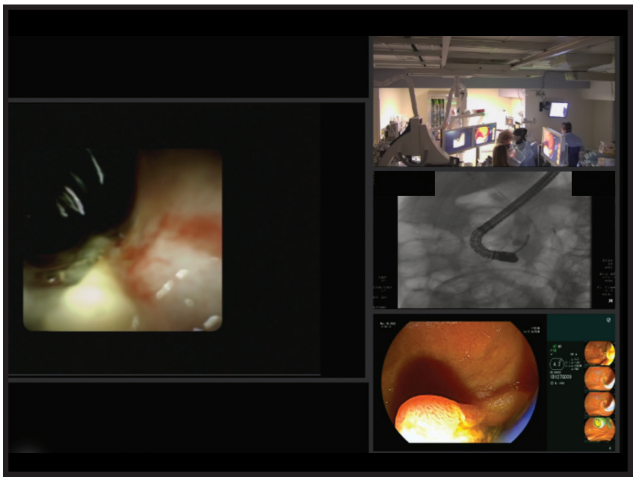

Figure 6. Cholangioscopy

of gastric outlet obstruction from a pancreatic mass, prior failed ERCP that is not expected to be successful on subsequent attempts, history of gastric surgery that would preclude ERCP or upper gastrointestinal luminal strictures that would prevent ERCP from being accomplished.

4. Uncorrected coagulopathy

Uncorrected coagulopathy remains a relative contraindication to ERCP. Sphincterotomy should not be performed in patients on anticoagulation, non-ASA antiplatelet therapy, or with a significantly elevated INR or severe thrombocytopenia. ERCP may be considered in patients requiring biliary decompression with stenting and no sphincterotomy, even in the aforementioned scenarios. Of note, if sphincterotomy is not planned, ERCP can be safely performed in a variety of coagulopathic settings.

Who Does Not Need ERCP

1. Type III Sphincter of Oddi dysfunction

As outlined above, the role of ERCP in the management of SOD has been, and remains, controversial. While there is evidence to support its use in patients with Type I SOD, there is less supportive data for performing ERCP in patients with Type II SOD. The use of ERCP in patients with Type III SOD has been shown to be more harmful than beneficial. This shift resulted after the findings of the EPISOD trial were published in 2014. In this double-blind, sham controlled RCT of 141 patients with Type III SOD randomized 2:1 to empiric sphincterotomy versus sham, no improvement in pain related disability was seen after intervention was reported, and in fact pain-free outcomes favored the sham group with statistical significance.[35] As a result of these findings, current expert consensus recommends against the use of ERCP with sphincterotomy in this patient subgroup.[8,31] It should be stressed that the entire concept of SOD as a disease entity remains in question and many centers have abandoned the notion of SOD entirely.

2. Abdominal pain diagnosis

The ASGE Quality Indicators in ERCP recommends against ERCP for the evaluation of abdominal pain without evidence of pancreaticobiliary pathology (e.g., abnormal bloodwork or imaging studies) due to the low diagnostic yield and risk of adverse events or complications. Prior to proceeding to ERCP for abdominal pain, a thorough workup including basic liver enzyme and function tests, lipase, complete blood count, and pancreaticobiliary imaging (in the form of transabdominal or endoscopic ultrasound, CT or MRCP) should be performed. If there are no abnormalities seen on these investigations as outlined in the above indications, ERCP may not be in the patient's best interest.

3. Pancreas divisum

Pancreas divisum (PD) is the most common congenital abnormality of the pancreas and results

from failure of the ventral and dorsal pancreatic duct to fuse during early embryonic gestation.[36] It should be emphasized that PD is not a disease, but rather a variant of normal anatomy. PD has a reported prevalence between 1-10% and has been associated with idiopathic recurrent acute pancreatitis. The association between PD and idiopathic recurrent acute pancreatitis (IRAP) remains controversial as the majority of patients with PD remain asymptomatic, with only 10% developing pancreatitis. A somewhat more accepted theory is that PD in combination with a predisposing genetic mutation (e.g., CFTR gene mutation) is required to increase the risk of IRAP.[37] The use of ERCP with minor papillotomy has been studied in preventing IRAP in PD in a number of retrospective and prospective trials, with heterogenous results suggesting a modest benefit.[36–38] One systematic review examining IRAP in PD reported a pooled median response rate of 76%, with a range of 44-100%.[36] A more recent retrospective cohort study reported a response rate at the lower end of the pooled analysis (44.4%), with even lower rates in those with chronic pancreatitis (33.3%) and chronic pancreatic like abdominal pain (33.3%).[39] ERCP with minor papilla sphincterotomy can be considered in select patients with IRAP and PD, especially in the context of a dilated pancreatic duct. The SHARP (***S***p***H***incterotomy for ***A***cute ***R***ecurrent ***P***ancreatitis) trial is currently underway and will be the first large, multicenter RCT investigating minor papilla sphincterotomy for IRAP in PD.[40] The results of this randomized trial will likely shape the future approach and recommendations to endoscopic therapy of IRAP in those with PD.

4. Management of pancreatic pseudocysts

Transpapillary pancreatic ductal stenting was once the recommended approach to treating complications from acute pancreatitis such as peripancreatic collections, alongside transmural pseudocyst drainage.[41,42] With the development of a lumen-apposing metal stent (LAMS), EUS directed trans-gastric drainage of these cysts has become the standard of care and the role of ERCP in the drainage of pancreatic fluid collections has become limited. Two recent studies showed no reduction in the re-accumulation of pancreatic fluid collections via ERCP after transmural plastic stent placement post-LAMS drainage, bringing into question the utility of plastic stent placement after LAMS removal. The more conventional ERCP approach of transpapillary PD stenting is still performed, but less commonly so and with limited data on its use in the age of cyst-gastrostomy with LAMS. Transpapillary stenting can still be used to treat pancreatic fluid collections not amenable to transluminal drainage or in patients with a LAMS in place who desire additional drainage. It should be noted that transampullary stenting may not always provide direct decompression of pancreatic fluid collections but rather may decompress the pancreatic ductal system and reduce backfilling of the collection itself, thus promoting resolution.

Special Cases

There are certain clinical scenarios in which the role of ERCP warrants special attention. These include, but are not limited to, ERCP in pregnancy, the elderly, those on therapeutic anticoagulation or antiplatelet agents, those with history of recurrent cholangitis and multi-drug resistant (MDR) infection, and those with contrast allergy.

Pregnancy

The need for ERCP in pregnancy is a rare occurrence, most commonly for the management of symptomatic choledocholithiasis, which occurs in only 0.1% of pregnancies (despite cholelithiasis occurring at a rate of 12%).[43] Management of the pregnant patient requiring ERCP requires knowledge and technical skill, as pregnancy has been shown to be an independent risk factor in post-ERCP complications, increasing the risk of post-ERCP pancreatitis 2.8-fold. While tertiary center experience has also been shown to be a protective factor in reducing post-ERCP pancreatitis, in practice ERCP is often safely performed in pregnant patients in a variety of clinical settings.[43] A meta-analysis of 1307 pregnant patients undergoing ERCP reported adverse event rates of 15.9% and compared these events, as well as fetal outcomes, between radiation and non-radiation ERCP. There were no reported differences in fetal outcomes or pregnancy-related adverse events between radiation groups.[44] To date, evidence supports the safety of ERCP in pregnant patients, however careful attention should be paid to the increased

risk of post-ERCP pancreatitis in this population. Fortunately, this does not appear to correlate with adverse fetal outcomes.

Radiation safety is crucial in performing ERCP in pregnant patients. Some states require shielding of pregnant patients based upon the assumption that shielding the fetus during ERCP would help to potentially decrease the dose of radiation to the

Table 5. Duration of action of common anticoagulant and antiplatelet medications adopted from the ASGE Management of antithrombotic agents for patients undergoing GI endoscopy[50]

Medication	Medication category	Discontinue (days) before procedure	Timing to restart medications	
			Low risk* procedure	High risk# procedure
ASA	Antiplatelets	Continue therapy	Continue	Continue
Clopidogrel	Thienopyridine	5-7 days	Same day	Delay until hemostasis^
Prasugrel	Thienopyridine	10-14 days	Same day	Delay until hemostasis
Ticagrelor	Thienopyridine	3-5 days	Same day	Delay until hemostasis
Warfarin	Vitamin K antagonist	5 days	Same day	Delay until hemostasis
Enoxaparin	LMWH	24 hours	Same day	Delay until hemostasis
Dalteparin	LMWH	24 hours	Same day	Delay until hemostasis
Fondaparinaux	Xa inhibitor	36-48 hours	Same day	Delay until hemostasis
Unfractionated heparin	Heparin	2-6 hours	Same day	Delay until hemostasis
Dabigatran CrCl >80 CrCl 50-80 CrCl 30-49 CrCl ≤29	IIa inhibitor	 24-36 hours 1-2 days 36-48 hours 2-3 days	Same day	Delay until hemostasis
Rivaroxaban CrCl >60 CrCl 30-59 CrCl 15-29	Xa inhibitor	 1-2 days 3 days 4 days	Same day	Delay until hemostasis
Apixaban CrCl >90 CrCl 60-90 CrCl 30-59 CrCl 15-29	Xa inhibitor	 1 day or more 2 days 3 days 4 days	Same day	Delay until hemostasis

*ERCP with sphincteroplasty or stent without sphincterotomy,
ERCP with sphincterotomy, ampullectomy
^Per expert recommendations on reinitiation of antithrombotics post-procedurally

fetus. However, many of the current fluoroscopy units that are commercially available will perceive the presence of lead shielding and increase the amount of radiation during the case to compensate. Many modern X-ray imaging systems use automatic exposure control, and the presence of shielding in the imaging field of view can drastically increase X-ray output, increasing patient radiation dose and degrading image quality.[45,46] Thus, paradoxically, the shielding increases the dose. By collimating to the area of interest, there is minimal dose to the areas outside of the field. Utilizing the low frame rate on fluoroscopy units will also lower the radiation dose to the mother and the fetus.

Geriatric patients

The outcomes and success rates for elderly patients undergoing ERCP are important factors for the endoscopist to understand given the high prevalence of elderly patients with pancreaticobiliary diseases. Choledocholithiasis has been reported as the most common indication for ERCP in this population, accounting for 23-56.1% of ERCP's.[47–49] Variably commonly defined as those 65-80 years of age or older, elderly patients have been reported to have low rates of post-ERCP pancreatitis, ranging from 0.1 to 1.7%.[47–49] While similar rates of overall adverse outcomes (including infection and mortality) have been reported, sedation-related complications have been shown to be higher among the elderly in one study (3.4% vs. 0.5%). Even among patients with acute cholangitis from common bile duct stones, there was no difference in the use of ERCP (68.8% versus 58%) or mortality in the elderly versus the non-elderly, respectively. While difficult cannulation has been shown to be a risk-factor for post-ERCP pancreatitis, a difference in difficult cannulation between elderly and non-elderly patients has not been shown and success rates in this population remain high.[47] Overall, ERCP is safe and beneficial in this patient population, and advanced age should not preclude the adoption of ERCP.

Antithrombotics

Patients on anticoagulants and antiplatelet therapies commonly require ERCP. The ASGE Guideline on the management of antithrombotic agents for patients undergoing GI endoscopy divides GI procedures into low and high risk, with ERCP falling into both the "low risk" (stent placement or papillary balloon dilation without sphincterotomy) and "high risk" (biliary or pancreatic sphincterotomy) categories.[50] Multidisciplinary discussion should be had prior to stopping anticoagulants or antiplatelet therapy and this decision should be based on the indication and potential risks of cessation (e.g. recent cardiac catheterization with percutaneous coronary intervention, recent deep vein or pulmonary thromboembolism, high $CHADS_2$ stroke risk, etc.). Table 5 outlines the duration for which the most common anticoagulants and antiplatelet medications should be held prior to ERCP, and the timing of restarting these medications post-procedurally, recognizing that in many cases recommendations should be individualized. Special attention should be made to the indication and thrombotic risk of stopping these medications, as well as the risk of post-procedural bleeding when continuing or restarting them. A perfect decision cannot be made in all cases, and some patients will experience bleeding or thrombotic events even in the hands of the most deliberative endoscopist.

Multi-drug resistance (MDR) infection

The risk of infection following ERCP is low, with reports ranging from 0.8-1.4% in two large studies.[51,52] Transmission of MDR organisms (eg. Carbamenem-resistant enterobacteriaceae) attributed to colonized duodenoscopes was first reported in the United States in 2013, and since that time there has been a significant interest in duodenoscope-related infection control.[53,54] In several studies, despite satisfactory reprocessing techniques using high-level disinfection (HLD), CRE organisms were still implicated among patient infections and were thought to potentially result from colonization of the elevator mechanism and the therapeutic channel.[53–55]

Concerns about the risks of duodenoscope-related infectious transmission resulted in increased awareness of, and interest in, more effective duodenoscope reprocessing techniques, as well as the development of multiple potential solutions to this problem. As of April 10, 2020, "the FDA continues to recommend that hospitals and endoscopy facilities transition to innovative duodenoscope designs to help improve cleaning

and reduce contamination between patients, including designs with disposable caps or distal ends.[56]" Single use ("disposable") duodenoscopes are delivered in sterile packaging and eliminate the risk of contamination across patients. When single-use duodenoscopes are used and the procedure is completed, the endoscope is recycled. The first of these duodenoscopes was introduced to the market in 2020 and have been shown to be equivalent to reusable duodenoscopes in operator usability and ERCP success metrics in both bench and human trials.[57,58] In addition to single use duodenoscopes, reusable instruments have been created with disposable caps that allows for enhanced cleaning of the elevator mechanism. Each major endoscope manufacturer has a duodenoscope available with a disposable cap that is now commercially available.

Currently, there are no guidelines regarding patient selection for the use of single use disposable duodenoscopes, for which widespread use is limited by cost, provider/hospital uptake and concerns regarding environmental waste.[57,59] Biliary stenting, inpatient status and cholangiocarcinoma have been implicated as risk factors for CRE infection when using a contaminated duodenoscope, and the use of disposable duodenoscopes over reusable instruments has been suggested in patients that are likely to undergo multiple ERCP procedures, immunocompromised patients or those with a history of MDR infection.[57,60] While the overall risk of infections, in particular MDR organisms, after ERCP remains low, the authors recommend considering the use of disposable duodenoscopes in those with a history of recurrent cholangitis, immunosuppression (e.g., post-transplant patients or those on chemotherapy with a history of cholangitis), as well as carriers of MDR organisms. It remains unclear at this time if disposable duodenoscopes will enter mainstream practice given the widespread availability of reusable duodenoscopes with disposable tips, which may be sufficient to reduce the risk of infectious transmission.

Contrast-dye allergy

Significant allergic reactions to contrast dye, used during ERCP, have been reported in rare case reports, although the incidence of these events is felt to be exceedingly low.[61] Two large studies have examined the incidence of adverse allergic reactions to contrast dye during ERCP. One prospective study examining 601 patients (80 with intravenous contrast dye allergies) reported no adverse reactions to contrast administration during ERCP.[62] This finding was supported by another large retrospective study of 2295 ERCP's across 1766 patients, of which 121 ERCP's were performed on patients with prior documented intravenous contrast allergy with no adverse contrast-related events.[63] While no guidelines exist on the management of these patients prior to dye administration, in general ERCP with cholangiography and pancreatography is felt to be safe in patients with intravenous contrast dye allergies, even in the absence of pre-medication. The endoscopist should be well versed and reassuring in discussing the safety of contrast dye use during ERCP in patients with a history of intravenous contrast dye allergy, and institutional protocols should reflect this as well. Non-ionic contrast can also be used if there is a concern regarding contrast dye allergy.

CONCLUSIONS

ERCP is a vital therapy for the diagnosis and management of pancreaticobiliary diseases. While there exists a wide range of indications for ERCP, the expert endoscopist must be well versed in both the indications and contraindications of the procedure as well as its safe performance. As new literature continues to be produced, our understanding of ERCP has evolved and will continue to evolve in the future ■

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