Endoscopic retrograde cholangiography: Complications, emergencies, and related topics

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Abstract

Endoscopic retrograde cholangiopancreatography (ERCP) is a commonly performed procedure with both diagnostic and therapeutic indications. Following wider adoption of magnetic resonance cholangiopancreatography and endoscopic ultrasound, a shift emerged toward the interventional use of ERCP. Inherent to this shift was the evolution of procedural risk profile, resulting in a greater propensity for more severe periprocedural morbidity. Because ERCPs are so ubiquitous, it is imperative for medical and surgical practitioners to possess excellent knowledge of the risks, benefits, and therapeutic/diagnostic alternatives. The intent of the current manuscript is to provide an authoritative review on the topics of ERCP-related complications, emergencies, and related subject matter.

The following core competencies are addressed in this article: Patient care and procedural skills, Medical knowledge, Practice-based learning and improvement.

Keywords: Cholangitis, complications, diagnosis and management, endoscopic retrograde cholangiopancreatography, pancreatitis, sphincterotomy, stenting

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is a commonly performed diagnostic and therapeutic procedure [Figure 1]. It is arguably one of the most complex endoscopic procedures.[1] With increasing use of other advanced diagnostic modalities such as endoscopic ultrasound (EUS) and magnetic resonance cholangiopancreatography (MRCP), the role of ERCP shifted toward more interventional indications.[2,3] As with any modality that carries a defined risk of morbidity, the appropriateness of ERCP depends heavily on the practitioner’s understanding of the risk-benefit equation informed by available

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Reluctance by many endoscopists to utilize ERCP liberally is well justified given a wide variety of potential procedural complications and corresponding risk factors. The goal of this manuscript is to provide a reappraisal of existing literature regarding ERCP-related morbidity, focusing on known risk factors and preventive strategies.

**ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY: CLINICAL INDICATIONS AND CONTRAINDICATIONS**

**Diagnostic and therapeutic indications**

Diagnostically, ERCP has revolutionized clinical management of both malignant and benign pancreatic/biliary conditions, with the added benefit of obtaining cytological samples for tissue examination. From therapeutic perspective, ERCP is effective in the management of common bile duct (CBD) stones, benign biliary strictures, bile duct leaks, ampullary adenomas, sphincter of Oddi dysfunction (SOD), transpapillary bile duct drainage, and malignant biliary obstruction. ERCP has also been described as useful in the management of pancreatic divisum, anomalous pancreaticobiliary union, type 3 choledochal cyst, annular pancreas, and cystic duct insertion into the papilla. Chronic pancreatitis and pancreatic duct (PD) leaks may also be treated with ERCP. Patients with Billroth II surgical reconstruction or pancreaticoduodenectomy were once considered high risk for ERCP; however, ERCP in Post-Whipple anatomy and Roux-en-Y anastomoses has been successful (albeit technically challenging).

**Contraindications**

Absolute contraindications to ERCP include the presence of any clinical condition that is prohibitive of effective sedation (e.g., hemodynamic instability), uncorrected coagulopathy, decision by a competent patient to not consent for a procedure, as well as the lack of an adequately trained endoscopist. In addition, pharyngeal or esophageal obstruction, hypersensitivity to iodinated contrast medium, and existing visceral perforation are also considered contraindications. There is continued controversy regarding the use of “immediate” ERCP in acute biliary pancreatitis, with lack of standardized approach in this particular setting.

Relative contraindications include advanced patient frailty and various anatomical conditions (e.g., gastroduodenal disease or surgical alteration that prohibits endoscopic access to the major papilla). Structural abnormalities of the esophagus, stomach, or small intestine may constitute relative contraindications for ERCP. Such conditions include but are not limited to anatomic changes such as esophageal stricture, paraesophageal hernia, esophageal diverticulum, gastric volvulus, and gastric outlet obstruction. In addition, transient conditions such as gastric or duodenal perforation, as well as small bowel obstruction, also constitute contraindications. Some also consider portal hypertension featuring esophageal and/or gastric varices, acute pancreatitis (except gallstone pancreatitis), recent myocardial infarction, and severe cardiopulmonary disease as relative contraindications.

**ALTERNATIVES TO ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY**

Magnetic resonance cholangiopancreatography

ERCP is considered the gold standard for diagnosis of choledocholithiasis (CDL) with excellent sensitivity (90%–97%) and specificity (95%–100%).
However, in light of the increased usage of less invasive imaging techniques, multiple studies have examined the reliability of MRCP and EUS in the setting of CDL. A comprehensive meta-analysis showed that, when the diagnosis of CDL is in question, MCRP represents a highly accurate, lower risk imaging alternative.[24] The reported high sensitivity (81%–100%), specificity (94%–98%), and diagnostic accuracy (94%–97%) of MRCP make this option very attractive.[35–38]

Typical MRCP examinations include a T1-weighted in-phase/out-of-phase spoiled gradient echo sequence, one or more T2-weighted sequences, and a dynamic contrast-enhanced fat-saturated spoiled gradient echo sequence.[39,40] MRCP is often able to define biliary anatomy in situations where ERCP or percutaneous transthepatic cholangiography (PTC) may have failed or are unsuitable.[41] T1-weighted MRCP using hepatocyte-specific intravenous (IV) contrast agents (e.g., mangafodipir trisodium or gadoxetate disodium) excreted into bile provides sufficient functional and anatomic information to identify active bile leaks.[41] MRCP with concurrent IV secretin administration to stimulate exocrine fluid excretion may improve diagnostic yield in chronic pancreatitis.[42] In addition, MRCP can provide valuable clinical information in cases where endoscopic retrograde contrast injection failed to pass a tight stenosis/stricture.[43] The failure rate of ERCP in patients with previous biliary-enteric anastomosis or gastroenteric drainage procedures ranges from 10% to 48%.[44] In such patients, MRCP provides excellent visualization of the biliary-enteric anastomosis, intrahepatic ducts, as well as details regarding any anatomic abnormalities (e.g., strictures and masses). This, in turn, helps guide any further interventions.[45,46]

Despite its many advantages, MRCP has several potential pitfalls. First, substantial radiology expertise is required when interpreting studies, especially in the context of potential imaging artifacts obscuring biliary anatomy.[47] Second, MRCP provides a static representation of the biliary anatomy, as opposed to ERCP which is dynamic.[48] Although high-quality dynamic MRCP sequences may help circumvent this limitation, they are difficult to obtain.[48] Further optimization of pancreatic and biliary ductal visualization can be achieved using the axial 2D FIESTA (fat suppressed) sequences.[48] Third, differentiation between ascites, perihepatic fluid collections, and edema may be difficult, especially on noncontrast MRCPs in the setting of acute inflammation.[41] Fourth, there is potential for mistaking a stone for another type of intraluminal filling defect (e.g., pneumobilia, intraductal tumor, or blood clot).[49]

Overall, clinical risks of MRCP are minimal. Factors that prohibit the conduct of MRCP include the presence of implanted metallic objects/foreign bodies deemed unsafe for magnetic exposure levels encountered during an magnetic resonance imaging (MRI). Gadolinium-associated nephrogenic systemic fibrosis may occur on rare occasion.[50,51] Finally, patients who experience claustrophobia may not tolerate MRI due to associated anxiety.[52] In terms of benefits to the patient, MRCP allows relative risk reduction due to the avoidance of unnecessary ERCPs. This becomes apparent when looking at traditional risk assessment schemes for hepatobiliary disorders and their ability to predict “therapeutic or diagnostic” ERCP.[41] In one study, information specific to liver function profile lacked specificity and resulted in a >50% incidence of negative ERCPs.[53] Due to ERCP-associated morbidity of 3%–9% and mortality of 0.2%–0.5%,[54] MRCP verification of the presence of biliary stones was suggested as the optimal diagnostic approach with highest clinical utility, reserving endoscopy (and thus ERCP-related complication risk) for a much smaller patient group who are much more likely to benefit from a therapeutic intervention.[7]

Computed tomography cholangiography

Traditional unenhanced computed tomography (CT) imaging of the biliary tree provides information regarding the presence of calcified ductal calculi, while CT utilizing IV contrast may provide indirect evidence of noncalcified stones.[55] Contrast-enhanced CT cholangiopancreatography (CTCP) can be facilitated either through direct or indirect contrast medium injection and is relatively easier to obtain than MRCP in acutely ill patients who require close monitoring.[55] Direct CTCP requires biliary injection of contrast agent through either percutaneously or enterally introduced catheter (with EUS or ERCP assistance).[54,56] Positive-contrast CTCP uses iopamidol meglumine given intravenously over 30 min, with an addition of IV hyoscine to relax the sphincter of Oddi right before acquiring images.[54] Indirect CT cholangiography reportedly has sensitivity and specificity in excess of 90%.[57] Benefits of CTCP include lower susceptibility to imaging artifact than...
Thus, EUS, intraoperative PTC carries complication rate of such approach is comparable to patients with obstructive jaundice. ERCP may be considered in the evaluation of selected hepatic lobe). This may become an important option when initial ERCP has failed or is not feasible. Moreover, EUS with needle puncture and guide-wire placement can help facilitate biliary access from either peripheral biliary conduits using imaging guidance, followed by contrast material injection. PTC carries significant potential complications, the rate of which depends on preprocedure patient status and diagnosis. For example, patients with coagulopathy, cholangitis, biliary ductal stones, malignant, or proximal obstruction will have higher complication rates with the more invasive PTC diagnostic option.

Endoscopic ultrasound
EUS is a more invasive procedure than MRCP or CT cholangiography. At the same time, EUS facilitates the examination of the entire length of the CBD from the level of duodenal bulb. In one randomized trial, the use of EUS in suspected CDL cases was associated with shorter procedure times, fewer complications, and was more cost effective due to the avoidance of unnecessary ERCP examinations. EUS has been shown to have sensitivity of 94% and specificity of 95% for CDL. It is also very sensitive for the diagnosis of gallbladder sludge, cholelithiasis, and microlithiasis. EUS with fine-needle aspiration (FNA) has been shown to have a higher diagnostic yield in certain pancreaticobiliary malignancies likely due to the ability to better target suspicious lesions. Moreover, EUS with needle puncture and guide-wire placement can help facilitate biliary access from either the duodenum (e.g., CBD) or the stomach (e.g., left hepatic lobe). This may become an important option when initial ERCP has failed or is not feasible. Finally, the combination of EUS with FNA and ERCP may be considered in the evaluation of selected patients with obstructive jaundice. The reported complication rate of such approach is comparable to component procedures.

QUANTIFYING THE PREDICTION OF CHOLEDOCHOLITHIASIS
As previously stated, ERCP is most commonly used in the management of CDL. Because no single indicator seems to reliably predict the pre-ERCP presence of biliary stones, strategies are needed to better optimize ERCP use, thus preventing unnecessary procedural morbidity. One strategy focuses on stratifying clinical probability of CDL in the setting of symptomatic cholelithiasis. Clinical predictors may help stratify risk of CDL into “high” (>50%), “intermediate” (10%–50%), or “low” (<10%). CBD stone on ultrasound, clinical ascending cholangitis, and bilirubin >4 mg/dL are considered “very strong” predictors. Dilated CBD on ultrasound (>6 mm) without a history of cholecystectomy and bilirubin of 1.8–4 mg/dL are considered “strong” predictors. Abnormal liver biochemistry, age >55 years, and clinical gallstone pancreatitis are considered “moderate” predictors. The presence of any very strong predictor or both strong predictors indicates “high likelihood” (>50%) of CDL. At the same time, the presence of fewer predictors places the patient at “intermediate risk” (10%–50%) of CDL. The presence of no predictors places the patient at a “low risk” (<10%) of CDL. Consequently, ERCP should be recommended only when its benefits outweigh the risks (e.g., when there is a higher likelihood of CDL and therapeutic intervention). Thus, EUS, intraoperative cholangiogram, or MRI/MRCP is recommended before ERCP in the setting of “intermediate” risk based on the above predictors. Patients at “low risk” of CDL can undergo cholecystectomy for symptomatic cholelithiasis without ERCP or further evaluation.

ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY: THE EQUIPMENT
ERCP combines endoscopy and radiography to visualize the hepatobiliary tree and PDs. Many centers have designated rooms and personnel to help facilitate the procedure; however, portable imaging equipment can be utilized if necessary. Basic equipment setup consists of a light source, side-viewing endoscope, an assortment of cannulating catheters, with accompanying video display, and high-resolution fluoroscopy. The side-viewing video scope is equipped with an elevator that facilitates cannulating the papilla of Vater. In addition to a control head which maneuvers the distal end, the endoscope also has ports for air insufflation, irrigation, and typically a 4.2 mm or 4.8 mm diameter working channel. This working channel facilitates various therapeutic maneuvers during ERCP procedures. A variety of
accessories can be utilized through the working channel including guidewires, sphincterotomes, drainage devices, stents, as well as tissue sampling and stone extraction devices.\textsuperscript{[77-79]}

**ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY: PREPARATION FOR PROCEDURE**

Before ERCP, a plain abdominal radiograph should be obtained to identify any artifacts, residual contrast material, or calcifications that may be superimposed and interfere with fluoroscopy interpretation. A thorough review of any other previous imaging (e.g., CT or MRI) is also mandatory (e.g., to identify changes such as Roux-en-Y anatomy).\textsuperscript{[80,81]} Routine pulse oximetry is recommended for all patients and a resuscitation cart should be readily available.\textsuperscript{[7,82]} Patients scheduled for ERCP should avoid solid food for 6–8 h before the procedure. This will help minimize aspiration risk and maximize intraluminal visualization. If ERCP with sphincterotomy is to be performed, antithrombotic medications should be held to minimize the risk of bleeding. Although the routine use of antibiotics is not recommended,\textsuperscript{[83]} their use should be reserved for cases characterized by preexisting obstructive bile duct disease.\textsuperscript{[84]} In addition, antibiotic prophylaxis should be utilized in patients at high risk of developing infective endocarditis such as those with prosthetic heart valve, history of infective endocarditis, cardiac transplant recipients, or patients with congenital heart disease.\textsuperscript{[85,86]} It is not recommended that patients with orthopedic implants receive antibiotics, but solid organ transplant recipients and other immunosuppressed populations should receive prophylaxis before ERCP.\textsuperscript{[86,87]} Debate continues regarding the optimal choice of antimicrobial prophylactic agent.\textsuperscript{[88]}

**ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY: TECHNICAL CONSIDERATIONS**

After conscious sedation is initiated, the patient is placed in the left lateral position. This position is both comfortable for the patient and facilitates rotational changes required to evaluate ductal anatomy in different planes.\textsuperscript{[89]} Analgesedation is usually achieved using a combination of parenteral conscious sedation and a topical anesthetic applied to the posterior oropharynx.\textsuperscript{[7]} The side-viewing scope is then passed through a bite block into the oropharynx and advanced through the esophagus.\textsuperscript{[90]} If unexpected resistance is encountered during the scope insertion or passage, the endoscopist is advised to stop and switch to a forward viewing endoscope to visualize any abnormalities such as a Zenker’s diverticulum or a stricture, thus preventing a potential injury or perforation.\textsuperscript{[79,91]} It is preferable to advance the duodenoscope under direct visualization to identify key landmarks such as the cardia, incisura, and pylorus. However, care should be taken to avoid excessive insufflation, as accentuation of a J-shaped stomach may make it difficult to navigate the pylorus.\textsuperscript{[92-94]} Once the endoscope has been advanced through the pylorus, it is positioned in the second portion of the duodenum, with additional maneuvers (beyond the scope of this review) utilized to maximize the visualization of the papilla.\textsuperscript{[92]} The papilla is then identified and inspected, with the endoscopist setting up optimal conditions before cannulation. Before any intraductal manipulations, the operator should flush all endoscopic access devices to prevent the injection of air (e.g., intraductal air may appear similar to a retained gallstone and thus create diagnostic uncertainty).\textsuperscript{[95-97]} In cases of difficult cannulation, the use of a hydrophilic guidewire with concurrent glucagon administration can help improve success rates.\textsuperscript{[77]} It is strongly advised to limit the number of attempts to avoid injury at the cannulation site and the subsequent development of tissue edema.\textsuperscript{[98]} Following successful access to the ductal system, a variety of instruments can be introduced through the working channel of the endoscope. Plastic stents are utilized to facilitate drainage, while self-expandable metal stents have greater utility in the setting of malignancy since they tend to provide better long-term patency.\textsuperscript{[99,100]} Tissue sampling techniques have also been developed, including highly advanced endoscopic biopsy forceps and miniaturized brush cytology devices.\textsuperscript{[101-103]} Biliary dilation balloons can be used in the management of strictures.\textsuperscript{[104]} Stone retrieval can be facilitated using a variety of accessories such as specialized endoscopic baskets, mechanical lithotripters, and other highly customized catheters.\textsuperscript{[105-107]} Intraductal ultrasound provides “real-time” evaluation of biliary strictures and surrounding vascular structures. High frequency ultrasound probes have been used to evaluate biliary strictures, small stones, or sludge.\textsuperscript{[108-110]} Finally, endoscopic sphincterotomy during ERCP involves deep cannulation of the bile duct followed by the application of electrocautery to incise the sphincter of Oddi. Beyond the scope of the current discussion, the procedure involves the use of devices known as sphincterotomes or papillotomes.\textsuperscript{[111-113]}
OVERVIEW OF ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY COMPLICATIONS

Any invasive procedure will carry some risk of associated morbidity. Consequently, the overarching goal should be to minimize – and if possible eliminate – any procedure-related adverse events. In addition to intimate knowledge of specific complications, the critical step in preventing post-ERCP morbidity is to promptly recognize at-risk patients.[114,118] Table 1 summarizes major risk factors for ERCP-related complications including reported odds ratios.[114,119] In addition, the clinical success and safety of ERCP are closely related to experience, training, and skill of the operator, as outlined in published guidelines regarding minimal experience required to maintain competence.[116] Endoscopists who perform <200 ERCPs annually have been shown to experience increased number of adverse events.[116,118] Depending on the indication for procedure, the overall ERCP complication rate can vary from <5% to as high as 40%.[114,17,44,45,121] In one study, the incidence of mild complications (requiring 1-4 additional hospital days) was approximately 4.5%, with more significant events accounting for about 5% of complications.[25] ERCP complications may also be grouped into short-term (occurrence within 3 days after the procedure) and long-term (occurrence >3 days postprocedure) event categories.[7] Examples of short-term morbidities include sedation-related events or intraprocedural bowel perforation. Long-term complications, on the other hand, may be related to indwelling stent infections and inflammatory changes from ductal handling.[7]

Therapeutic ERCP is more likely to be associated with complications than diagnostic ERCP; however, neither approach is free of morbidity.[25,122] Mortality attributable to ERCP may be as high as 0.5%, with therapeutic ERCP carrying greater risk than diagnostic ERCP, at 0.5% and 0.2%, respectively.[25] Predictors of severe or fatal complications of ERCP include male gender, American Society of Anesthesiologists Grade III or greater, obesity, suspected or known ductal stone, SOD, therapeutic and urgent procedures, trainee involvement, as well as more technically difficult cases.[121] Table 2 shows a more comprehensive list of both short- and long-term complications, along with reported incidence range(s).[123] Further information on various ERCP-related morbidity, including severity grading for bleeding, perforation, pancreatitis, and infection, the reader is referred to the work by Cotton *et al.*[121]

ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY-ASSOCIATED PANCREATITIS

Acute pancreatitis is among the most common ERCP-related complications. The incidence range of ERCP-associated pancreatitis (EAP) is between 1% and 10% in the overall reported experience but may be >30% in certain high-risk patients.[114,124,125] Precise incidence of EAP is difficult to estimate because anywhere between 25% and 75% of patients who undergo ERCP may experience postprocedural increase in serum amylase levels.[126,127] In one report, the incidence of clinical pancreatitis after diagnostic and therapeutic ERCP was 3% and 7%, respectively.[128] However, the performance of diagnostic versus therapeutic ERCP does not seem to be a major predictor of EAP, with some authors describing higher incidence of EAP after diagnostic (5.2%) compared to therapeutic (4.1%) procedures.[129] Severe pancreatitis has been reported to occur following approximately 1% of ERCP procedures.[126]

Due to a relatively large number of ERCP procedures being associated with “benign elevations” of pancreatic enzymes, objective criteria were introduced to differentiate the more benign occurrences from the clinically significant EAPs.[130] The diagnosis of EAP can be made if 2 of 3 diagnostic criteria are met: Presence of epigastric pain, amylase or lipase >3 times
the upper limit of normal, or cross-sectional imaging showing pancreatic inflammation. EAP is considered mild if 2–3 days of additional hospitalization are required, moderate with 4–10 days of hospitalization, and severe if the patient requires >10 days of additional hospitalization, drainage of a pseudocyst, or a pancreatic phlegmon is present.\(^{[131]}\) The determination of EAP should always be made in the context of the overall risk profile of the ERCP procedure.\(^{[1,114,132]}\) Summary of both Cotton criteria (designed for post-ERCP pancreatitis) and Revised Atlanta Classification criteria (applicable to all pancreatitis cases) are shown in Table 3.\(^{[133,134]}\)

Several mechanisms associated with the genesis of EAP have been proposed including thermal injury from electrocautery, hydrostatic injury from contrast injection “overpressure” within the PD, chemical injury from either intestinal enzymatic content or radiographic contrast, and mechanical injury from prolonged manipulation around the papillary orifice and the associated tissue edema.\(^{[135]}\) Three large prospective studies have reported risk factors for EAP. These have been broadly categorized as patient, operator, or procedure specific and will be discussed in more detail in subsequent paragraphs.

Patient-related factors include younger age,\(^{[132]}\) female gender, history of acute or recurrent pancreatitis,\(^{[136]}\) previous history of EAP, preexisting biliary-type pain, the presence of CDL, normal serum bilirubin, and suspicion of SOD (especially type III dysfunction with normal bile duct size and normal hepatic function tests).\(^{[119]}\) Of note, there is no firm evidence that periampullary diverticulum, pancreatic divisum, allergy to contrast media, or small caliber bile duct confer additional risk of EAP.\(^{[135]}\)

Operator-dependent risks of EAP include low case volume, provider experience, and various technical

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**Table 2:** Periprocedural, short- and long-term complications of endoscopic retrograde cholangiopancreatography; data compiled from all available sources used in this report

| Preprocedural | Incidence (%) | Short-term (<3 days) | Incidence (%) | Long-term (>3 days) | Incidence (%) |
|---------------|---------------|----------------------|---------------|---------------------|---------------|
| Hypoxia during anesthesia/sedation | 7-40 | Unsuccessful attempt | 7 | Pancreatitis | Average risk: 1-6 High risk: 30 |
| Aspiration | 0.3-1 | Drug reactions | 5 | Stent migration | Plastic: 5-10 Metal: <1 |
| Methemoglobinemia | Rare | Cholangitis | 1-3% | Post sphincterotomy strictures | Historical data: 8 Recent data: Rare | <1 |
| Significant bleeding post-sphincterotomy | 0.1-1 | Perforation due to endoscope | 0.05-0.6 | Delayed bleeding (1-2 weeks postoperative) | Perforation due to stent | <1 |
| Cholecystitis | 0.5 | Malfunction of device | Rare | Cholangitis | 1-3% |
| Methemoglobinemia | Rare | Postoperative ileus | Rare | Delayed bleeding | <1 |
| Postoperative ileus | Rare | Scope sterilization related infections | Rare | Perforation due to stent | <1 |
| Pseudocysts | Rare | | | | |

**Table 3:** Classifications utilized for grading the severity of all pancreatitis cases (Revised Atlanta) and postendoscopic retrograde cholangiopancreatography pancreatitis (Cotton)

| Source | Mild pancreatitis (2 of 3 required) | Moderate pancreatitis (1 of 2 needed) | Severe pancreatitis (1 of 2 needed) |
|--------|------------------------------------|--------------------------------------|-----------------------------------|
| RAC    | Pain typical of AP                 | Transient OF lasting <48 h            | Persistent single of multiple OF lasting >48 h Appearance or persistence of SIRS |
|        | Amylase or lipase >3 times normal range | Local or systemic morbidity without OF | |
| Cotton | Typical findings on imaging of abdomen | Moderate pancreatitis Requires 4-10 days of attributable hospitalization | Severe pancreatitis (only 1 needed) >10 days in hospital attributed to post-ERCP acute pancreatitis Appearance of complications such as pancreatic necrosis or pseudocyst Need for drainage, surgery, or other invasive intervention |
|        | No complications of organ dysfunction | | |
|        | Mild pancreatitis (all 3 needed) | | |
|        | New or worsening abdominal pain | | |
|        | Amylase elevation >3 times normal limit 24 h after ERCP Hospital stay (or stay extension) of/ by 2-3 days | | |

AP = Acute pancreatitis, ERCP = Endoscopic retrograde cholangiopancreatography, OF = Organ failure, RAC = Revised Atlanta Classification, SIRS = Systemic inflammatory response syndrome
High volume endoscopists have been noted to have fewer PD injections and greater overall procedural success, but the correlation between endoscopist-specific volumes and the rate of EAP is not fully understood. Operator-related risks are difficult to study because of the presence of various potential confounders including differences between patient populations and procedural indications between various providers, institutions, and geographic regions. Consistent with the relationship between provider case volumes and complications, trainee participation appears to increase the risk of EAP.

Procedure-specific risk factors for EAP include difficult cannulation of the ampulla of Vater (e.g., multiple attempts required), cannulation of the PD, repeated injections of contrast into the PD, PD sphincterotomy, pancreatic acinarization (opacification of acini), PD tissue sampling/brushing, pneumatic dilation of an intact biliary sphincter, precut sphincterotomy, and ampullectomy. One study suggested that patients with opacification of the pancreatic head had lower levels of pancreatitis than those with pancreatic tail opacification. Further, acinarization, which occurs when pancreatic acini are opacified by a high-pressure injection, may pose some additional risk as well.

Careful assessment of potential risks and benefits should be performed before performing even the most “routine” ERCP procedure. This is because the overall procedural risk may be a reflection of several factors acting synergistically. For example, the combination of SOD, difficult cannulation, and normal size ducts may result in disproportionately elevated risk of EAP. Others reported that ERCPs performed in patients <60 years of age, using precut sphincterotomy, and complicated by an inability to clear biliary stones, carried significantly elevated EAP risk. Mehta et al. found a 27% risk of EAP in patients <59 years who had a sphincterotomy with no stone identified in the CBD. Further, age <70, with PD opacification, and nondilated CBD increased risk in another report.

Rates of EAP increase significantly depending on the number of cannulation attempts. For instance, for <5, <10, and <15 attempts, corresponding EAP rates were 3%, 7%, and 13%. For more challenging cases of cannulation, a “precut” or access papillotomy may be performed to gain entry into the bile duct. This method utilizes a bare wire plus cautery to access the duct when traditional cannulation is difficult or not possible. There is controversy regarding this approach and the associated risk of EAP. One could speculate that the increased risk likely relates to the number of cannulation attempts performed before the precut technique is attempted. Because sphincterotomy is not indicated in patients with coagulopathy, the sphincter may be dilated with a balloon, or a stent may be placed. However, higher rates of pancreatitis have been reported with balloon dilation. Consequently, balloon dilation should be reserved for patients who are not candidates for sphincterotomy. If the need for “precut” is determined, simultaneous stent use is recommended. Furthermore, proactive risk-benefit assessment between successive cannulation attempts is strongly encouraged, primarily because early use of “precut” may help reduce such attempts (and presumably decrease associated morbidity).

There is an ongoing debate regarding the use of electrocautery during ERCP procedures and the risk of pancreatitis. In one study, 170 patients were randomized to either “pure cut” or blended current for biliary sphincterotomy, with significantly lower risk of pancreatitis for “pure cut” (3%) than blended current (10%). However, a larger nonrandomized trial suggested differently. Others found that the use of monopolar cautery was associated with lower risk of EAP than bipolar cautery.

Historically, SOD is associated with substantial risk (24%) of EAP following diagnostic or therapeutic ERCPs. Stent placement, which promotes ductal drainage, may reduce this particular risk by nearly 75% (from 26% to 7%). In addition, modern catheters featuring modified perfusion ports are also associated with substantially reduced risk of EAP (from >30% to <5%). Newer microtransducer catheters favorably modulate the risk of EAP even further. Aspiration type catheters (where fluid is constantly aspirated from the PD) may also be of value. Of note, biliary sphincterotomy alone in patients with SOD was associated with similar pancreatitis rates (~20%) when compared to simultaneous manometry and sphincterotomy (~18%).

Obstruction of pancreatic secretion outflow from papillary edema, cannulation, or thermal sphincterotomy injury may induce EAP. This may be remedied by transpapillary PD stenting.
stated in the previous paragraph, stent placement may help reduce the risk of pancreatitis.[152] At the same time, one must be cautious when placing a pancreatic stent because failed placement may increase the risk of EAP[158] and stenting itself may be associated with ductal injury and/or stricture formation.[159-161]

Indications for the placement of prophylactic stent include (a) suspected SOD, (b) ampullectomy, (c) placement of pancreatic guidewire to aid biliary cannulation, (d) multiple PD injections, (e) repeated PD cannulations, (f) pancreatic endotherapy, (g) history of prior EAP, and (g) the use of “precut” sphincterotomy.[135]

Data regarding the optimal characteristics of stents used for prophylaxis are mixed.[162] It is likely that the size of stent is important since smaller stents cause less injury than larger ones.[163] Use of 4 French and 5 French straight stents placed over conventional wires positioned within the PD may be preferred.[156,164,165] Following stent placement, abdominal radiographs should be taken 1–2 weeks later to ensure that it has not migrated. Ductal perforation, proximal stent migration, and repeated placement attempts leading to pancreatitis are all possible.[166-168] Therefore, stents should only be used in appropriate risk patients.

The use of endoscopic balloon is one alternative to sphincterotomy for the removal of intraductal gallstones.[144] This methodology is somewhat controversial, with mixed evidence regarding associated clinical outcomes. According to some studies, there is no increase in morbidity when using this approach.[169,170] However, others have demonstrated increased risk of EAP.[137] Consequently, balloon dilation should be used in selected cases only.

MEDICAL PREVENTION OF ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATEOGRAPHY-ASSOCIATED PANCREATITIS

Various prophylactic modalities for EAP have been proposed, with somewhat mixed results. General strategies in this area include the reduction of pancreatic inflammation, lowering of exocrine activity, and better control of pressures applied to the sphincter of Oddi.[171-173] Somatostatin and octreotide decrease pancreatic secretions and minimize pancreatic hypertension;[174,175] however, somatostatin does not seem to be effective in preventing EAP.[176] The use of gabexate mesilate, a protease inhibitor, has been associated with lower postprocedural amylase levels, favorable abdominal pain profile, and decreased pancreatitis frequency.[177] Despite that, a multicenter study of 579 patients failed to demonstrate benefits of gabexate or somatostatin infusion.[178]

Nonionic contrast agents have not reduced the incidence of pancreatitis while increasing study costs.[179,180] Although previously considered helpful, periprocedural administration of corticosteroids,[181] nifedipine[182] and allopurinol have all been shown not to be beneficial.[183] Interleukin-10 (IL-10) has known anti-inflammatory properties, with a single study documenting potential benefits of single IV dose administration (4 or 20 μg/kg) at approximately 30 min before ERCP.[184] However, a subsequent study failed to demonstrate benefit when IL-10 was infused at a rate of 8 μg/kg immediately before ERCP.[185]

Another report found that low-molecular-weight heparin use fails to lower EAP rates.[186]

Nitroglycerin, known to reduce pressure at the sphincter of Oddi, was associated with lower incidence of EAP in two clinical studies; however, it should be used with caution because of the potential for systemic hypotension.[187,188] In a more recent report, diclofenac suppository given 30–60 min preprocedure and somatostatin 0.25 mg/h for 6 h postprocedure were shown to reduce EAP risk.[135] However, Cheon et al.[189] reported that prophylactic oral administration of diclofenac did not appear to reduce the frequency or severity of EAP in a randomized, double-blind study of high-risk patients. Another randomized trial featured the administration of 100 mg of indomethacin rectally to high-risk patients undergoing ERCP, with pancreatitis rates of 9.2% in the treatment group versus 16.9% in the control group.[135] However, the study may contain some biases since many patients also underwent prophylactic stent placement.

CLINICAL MANAGEMENT OF ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATEOGRAPHY-ASSOCIATED PANCREATITIS

Treatment of EAP is analogous to pancreatitis secondary to other etiologies. Key components of management include IV hydration, pain control, general supportive care, and the provision of adequate postduodenal nutritional intake.[190,191] Rescue pancreatic stent placement or replacement for “salvage” of EAP has been described and may be considered in selected cases.[192] Much like the initial
diagnosis of EAP, the final determination of clinical resolution is similar to that of pancreatitis associated with other etiologic factors.

**POST-ERCPhemorrhage**

Post-ERCP hemorrhage [PEH, Figure 2] is primarily a complication of sphincterotomy or another procedural intervention during ERCP.\(^{193,194}\) Bleeding occurs in 1%–4% of patients during or after ERCP and is associated with mortality of approximately 0.3%.\(^{137,193-196}\) Early PEH can appear within 24 h to 10 days.\(^{137}\) Delayed bleeding may be seen in 50% of cases and may occur as long as 1–2 weeks after the index procedure.\(^{112,197}\) The presence of bleeding during the initial examination is predictive of delayed bleeding.\(^{137}\) Clinically significant PEH can present with melena, hematemesis, or a drop in hemoglobin, and may require transfusion, additional endoscopic intervention, or surgical therapy.\(^{137,197}\) PEH can be classified as mild, moderate, and severe.\(^{132}\) The corresponding objectified criteria include (a) drop in hemoglobin of <3 g/dL (mild); (b) transfusion requirements <4 units of packed red blood cells (PRBCs) with no intervention (moderate); and (c) transfusion requirements >4 units of PRBCs or intervention (severe).\(^{133}\) The risk of severe hemorrhage is estimated to be 0.1%–0.5%.\(^{1,137}\)

Established risk factors for PEH include anticoagulants administered within 3 days of sphincterotomy, active coagulopathy, cholangitis before ERCP, initial bleeding at the time of sphincterotomy, obstructed papilla, and the use of “precut” sphincterotomy.\(^{120,198}\) The use of aspirin, nonsteroidal anti-inflammatory drugs, the creation of a longer incision, or enlarging a preexisting sphincterotomy have not been shown to be predictive of bleeding.\(^{137}\)

If biliary drainage is required in a patient who is therapeutically anticoagulated and/or has an elevated international normalized ratio, stent placement without sphincterotomy may be warranted. A sphincterotomy may then be performed once risk factors are appropriately ameliorated. Heparin may be used if it is necessary to continue anticoagulation; however, warfarin (and other long-term anticoagulation agents) should be withheld around the time of procedure.\(^{199,200}\)

The use of a “smart electrocautery generator,” avoidance of sphincterotomy in high-risk cases, and using balloon dilatation may help reduce the risk of bleeding.\(^{7}\) If the presence of bleeding is noted at the time of sphincterotomy, it is advisable to complete the sphincterotomy because thermal coagulation generally stops further bleeding. However, if bleeding continues, epinephrine injection (1:100,000 solution followed by direct injection of 1:10,000 solution for persistent hemorrhage) of the sphincterotomy site may achieve hemostasis.\(^{201,202}\) In addition, balloon tamponade may be sufficient in cases of bleeding without active coagulopathy. Argon plasma coagulation and thermal coagulation with heater probes or hemostatic clips may also help control bleeding.\(^{198,203}\) If hemorrhage persists angiography and placement of coils may be considered, although these are needed much less frequently.\(^{198}\)

**ENTERIC PERFORATION DURING ERCP**

Free air following ERCP has been noted in nearly 30% of otherwise asymptomatic patients, making the determination of “clinical significance” the key factor when deciding how aggressive management should be.\(^{123,204,205}\) Clinically significant ERCP-related perforations occur in approximately 0.3%–0.6% of procedures [Figure 3].\(^{17,206}\) Risk factors for perforation include concurrent performance of sphincterotomy, the presence of Billroth type II anatomy, intramural injection of contrast dye, dilation of biliary stricture, SOD, and longer procedure...
In addition, the three points of esophageal narrowing – cricopharyngeus muscle, aortic knob, and diaphragmatic hiatus – may be associated with an increased risk of perforation. If the perforation fails to seal despite optimized nonoperative management, surgical consultation should be strongly considered for all cases and should be mandatory for more severe occurrences. When indicated, percutaneous drainage or surgical repair may all be required. Nonoperative approaches may be sufficient for contained perforations; however, any presence of free contrast extravasation or signs of sepsis necessitate surgical intervention. If the bowel is perforated, early recognition and treatment is imperative. Surgical consultation should be strongly considered for all cases and should be mandatory for more severe occurrences. Guidewire perforation may be managed with endoscopic stent placement. Guidewire injuries may potentially be reduced with the use of hydrophilic tip wire, fluoroscopy, and avoidance of blind manipulation.

CHOLANGITIS AND CHOLECYSTITIS

Cholangitis and cholecystitis are rare complications associated with inadequate biliary drainage, concurrent performance of percutaneous-endoscopic procedures, stenting across malignant strictures, presence of jaundice, and low ERCP case volume. Post-ERCP cholangitis has a rate of occurrence of 1%–3%. There may also be an association between diagnostic versus therapeutic ERCP in terms of cholangitis risk. Care should be taken when performing ERCP in cases of biliary obstruction to avoid contrast injections into undrained hepatic segments. To avoid delayed cholangitis in the setting of biliary obstruction, adequate drainage with stents or nasobiliary tubes is very important. Plastic stents can help reduce the risk of cholangitis following gallstone extraction attempts. When dealing with hilar obstruction (e.g., Klatskin tumor), it is important to adequately drain all intrahepatic segments that have been filled with contrast during the procedure. Stent placement in the latter setting is a complex topic and is beyond the scope of this review. However,
considerations regarding stent laterality, multiplicity, the incidence of obstruction or re-occlusion, and the risk of associated cholangitis must be carefully weighted.\textsuperscript{[18,226,227]}

The incidence of post-ERCP cholecystitis is approximately 0.5%\textsuperscript{[147]}. This occurrence may be associated with the intraprocedural filling of the gallbladder with contrast in the presence of gallbladder stones.\textsuperscript{[22]} The presence of malignancy involving the orifice of the cystic duct has also been linked to this post-ERCP complication.\textsuperscript{[228]} Diagnosis and treatment should follow established clinical guidelines for the management of cholecystitis.\textsuperscript{[229-231]} Finally, it has been reported that iatrogenic intramural dissection of the gallbladder wall can mimic post-ERCP cholecystitis.\textsuperscript{[232]}

**CARDIOPULMONARY EVENTS**

Although they occur in <1% of procedures, cardiopulmonary complications are the major cause of ERCP-related mortality.\textsuperscript{[1,91,114,137,233]} Cardiac arrhythmia, hypoventilation, or aspiration are all possible and may be associated with either the presence of comorbid conditions or the use of intraprocedural analgesosedation.\textsuperscript{[91,233]} Some degree of hypoxia may be seen in 7%–40% of cases, with aspiration occurring in approximately 0.3%–1.0% cases.\textsuperscript{[6,234]} Of note, both hypoxic events and aspiration tend to be associated with advanced age, chronic illness, neurological impairment, supine positioning, and the use of conscious sedation.\textsuperscript{[6,234-236]} Morbidity in this general area may be reduced by careful preoperative evaluation, close collaboration with the anesthesiology team, and meticulous perioperative planning for high-risk or difficult-to-sedate patients.\textsuperscript{[6,234-238]}

**MISCELLANEOUS Complications**

A wide variety of other ERCP-associated complications have been reported in the literature including ileus, antibiotic-related diarrhea, hepatic abscess formation, pneumothorax/pneumomediastinum, perforation of colonic diverticula, duodenal injury/hematoma, portal venous air, and impaction of therapeutic devices such as stone retrieval baskets.\textsuperscript{[11,114,239,240]} Delayed gallstone ileus has also been reported following ERCP and sphincterotomy.\textsuperscript{[241-243]} Wire entrapment may contribute to wire fracture from excessive traction.\textsuperscript{[244]} Guidewire fracture can also happen due to retrieval basket impaction around the ampulla.\textsuperscript{[245]} The presence of irregular, hard, or multiple stones may increase the risk of impaction. Approaches to minimize this risk include fluoroscopic guidance and continuous moistening of hydrophilic wires to avoid desiccation and fracture.\textsuperscript{[246,247]}

**CONCLUSION**

Despite being considered a relatively safe procedure, ERCP can be associated with a broad range of potentially severe complications. ERCP-associated pancreatitis, hemorrhage, infections, and perforations are among the most feared morbidities. Providers who perform ERCPs and/or care for patients undergoing these endoscopic procedures should be familiar with specific risk factors, accompanying signs and symptoms, and be knowledgeable regarding corresponding clinical management. Despite numerous clinical trials for pharmacological prophylaxis, currently only rectal diclofenac appears to help prevent ERCP-associated pancreatitis. Given the significant percentage of nontherapeutic ERCPs, alternative imaging modalities (e.g., CT, EUS, or MRCP) may be preferable as “screening” tests given similar diagnostic accuracy and favorable overall complication profile.

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