



Adverse events associated with endoscopic retrograde cholangiopancreatography (ERCP) and ERCP-related procedures

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OVERVIEW

ERCP is a frequently performed procedure by advanced endoscopists in the United States and worldwide to evaluate and manage diseases of the biliary tree and the pancreatic ducts (PDs).¹ ERCP is highly effective but is generally regarded as technically complex and is associated with a steep learning curve.^{2,3} ERCP-related adverse event (AE) rates are variable and are influenced by numerous patient-, procedure-, and endoscopist-related factors.^{4,5} However, ERCP AE rates remain high relative to other commonly performed endoscopic procedures.⁶ Notably, despite advances in ERCP techniques, early recognition of AEs, and management, rates of pancreatitis (the most common ERCP-related AE) have remained relatively consistent or have even increased over recent decades.^{7,8} The costs associated with post-ERCP AEs are significant, often exceeding \$10,000 per admission,^{9,10} meaning that AEs of ERCP result in an estimated \$200+ million in annual health care spending in the United States.¹¹⁻¹³ Many downstream effects of ERCP-related AEs can contribute to poorer quality of life, poorer overall health, and poorer mental health, and therefore, substantial societal and further economic burden.¹⁴⁻¹⁷ Thus, a clear understanding of ERCP-related AEs is crucial.

To help standardize the overall quality of ERCP, several societies, including the American Society for Gastrointestinal Endoscopy (ASGE), have developed ERCP quality indicators.^{18,19} The purpose of this document from the ASGE is to provide evidence-based summaries of AEs associated with ERCP and its related techniques. This document can be considered an update to the 2017 ASGE document “Adverse Events Associated with ERCP.”⁶

In addition to summarizing overall and specific AE rates, risk factors for specific AEs will be presented in this document where evidence is available. Knowledge of safer alternatives to ERCP²⁰ for each respective indication is crucial, as is clear and complete informed consent leading up to the procedure.²¹ Although early recognition and appropriate management of potential ERCP-related AEs are both critical to reducing patient-important adverse outcomes, this document does not cover those diagnostic or management considerations in detail. Similarly, although evidence-based interventions to mitigate the risk of ERCP-associated AEs are touched upon at various points herein, they are not the focus of this document given that the ASGE has published separate guidance relating to them.^{22,23}

METHODS

Overarching electronic database searches were performed in conjunction with expert health care librarians as part of 2 recent reviews on ERCP-related AEs.^{7,24} These searches were performed (1) from inception to November 10, 2020, then updated on November 21, 2022, and then updated on March 12, 2024,⁷ and (2) from inception to July 1, 2024,²⁴ across PubMed, MEDLINE (Ovid), EMBASE, Web of Science, and CENTRAL. Additional ad hoc additions to the evidence base from the time of the searches to the time of manuscript preparation were also considered, especially if suggested by ERCP experts and/or ASGE Governing Board members.

Given that this document is not intended to answer comparative questions, but rather to update the current state

of knowledge on ERCP-associated AEs, eligibility criteria were not required for original studies to be considered for inclusion. We acknowledged that variable quantities and methodological qualities of evidence were available for specific ERCP-related techniques. In general, studies were considered for inclusion in the following order: meta-analyses of randomized controlled trials (RCTs), individual RCTs, meta-analyses of observational studies, prospective observational studies, retrospective observational studies, and case series or case reports. Additional factors determining inclusion included, but were not limited to, study size, quality, and recency.

The ASGE Standards of Practice Committee²⁵ decided a priori that the available evidence on ERCP-associated AEs would be subdivided and presented according to the following categories.

1. “routine” (primarily biliary) ERCP,
2. ERCP with pancreatic interventions,
3. ERCP with cholangioscopy or pancreatoscopy, and
4. ERCP in “special” populations.

Within each category, overall AE rates and those related to specific AEs were summarized where evidence was available, with specific AEs including

1. Pancreatitis,
2. Bleeding,
3. Cholangitis,
4. Cholecystitis,
5. Perforation, and
6. Other AEs associated with the technique or indication being discussed, where applicable.

For the purposes of this document, sedation-related AEs and cardiorespiratory AEs were not presented. Although undoubtedly important to the performance of ERCP, the rates of (and risk factors for) such events specifically related to ERCP are difficult to parse from those associated with all advanced endoscopic procedures, and more broadly, with endoscopic procedures in general. Given this considerable overlap and the wide variations in practice patterns related to sedation for ERCP,²⁶⁻³⁰ it was decided a priori that these events would not be included as a focus of this document.

In addition to presenting the AEs for each of the categories above, at the request of the ASGE Governing Board, contemporary summaries were also prepared regarding the topically relevant considerations that follow, with these also presented herein.

1. Unplanned health care encounters (UHEs) not related to traditional AEs,
2. Patient-reported outcome and experience measures in ERCP, and
3. Duodenoscope-related infections.

RESULTS

A summary of estimated adverse event ranges across various ERCP-related procedures is provided in [Table 1](#).

ROUTINE (PRIMARILY BILIARY) ERCP

Overview and overall AE rates

As discussed earlier, there are wide variations in the reported overall AE rates associated with routine ERCP. A clear distinguishing factor is first-time ERCP (or “native” papilla) status versus those who have undergone ERCP with sphincterotomy in the past. In a meta-analysis of 244 RCTs and 136 large observational studies, the cumulative incidence of post-ERCP AEs in all-comers approached 10.0%, whereas for first-time patients, the incidence was 12.0%.⁷ The same meta-analysis found that the incidence of death directly attributable to ERCP (after protocolized review of events to ensure relatedness) was 0.5% from RCT data.⁷

Pancreatitis

Post-ERCP pancreatitis (PEP) is the most common and arguably the most worrisome AE related to ERCP.^{6,7,24,31,32} Contemporary definitions typically require that PEP presents with 2 of 3 Revised Atlanta criteria—typical abdominal pain, elevated pancreatic enzyme values $3\times$ the upper limit of normal or greater, and/or characteristic imaging findings.^{33,34} The 1991 consensus definition additionally stipulates that PEP should result in admission (or prolongation of an existing admission) of at least 2 nights,³⁵ whereas the 2010 ASGE Lexicon definition does not include this stipulation.³⁶ As such, the definition of PEP used by investigators can, in and of itself, influence described incidences, and is an important source of methodological heterogeneity that contributes to observed variations, along with the many relevant patient-, procedure-, and endoscopist-related factors described later. Importantly, asymptomatic elevation in serum pancreatic enzymes and/or incidental radiologic findings suggestive of pancreatitis are discovered in up to 20% to 25% of asymptomatic patients following ERCP³⁷ and, as such, PEP should be suspected and/or investigated only when informed by a patient’s clinical status except in cases where patients cannot communicate symptoms (including those in critical care or that are otherwise incapacitated).

The overall incidence of PEP from a meta-analysis of 53,550 patients enrolled in 190 RCTs was 5.5% in all patients, and 7.0% in first-time patients.⁷ The corresponding PEP incidence estimates from meta-analysis of 109 large observational studies that collectively included 1,502,279 patients were lower, at 4.1% and 5.2% for all-comers and first-time patients, respectively.⁷ The severity of PEP is variably attributed based on a combination of factors including the length of admission, the presence and duration of organ failure and/or local and systemic AEs, and the need for intensive care, among others.^{33,35} In the Atlanta classification of acute pancreatitis, mild pancreatitis is defined as an absence of organ failure or local or systemic AEs, moderate pancreatitis is defined as being associated with transient organ failure, worsening of underlying comorbidity, and/or local AEs,

TABLE 1. Summary of estimated common adverse event ranges for ERCP-related techniques by procedure and adverse event type, based on the American Society for Gastrointestinal Endoscopy evidence review

ERCP-related technique	Pancreatitis	Bleeding	Cholangitis	Cholecystitis	Perforation	Other/specific
Routine (primarily biliary) ERCP	5%-7%	1%-2%	1%-3%	0.5%-1.5%	~0.5%	N/A
ERCP for pancreatic indications	10%-20%	1%-2%	N/A	N/A	>1%	Stent-related; stricture formation.
ERCP with cholangioscopy or pancreatoscopy	5%-7%	1%-2%	Up to 10%+ without antibiotics with cholangioscopy	N/A	~0.5%	N/A
ERCP in special populations (pediatric and pregnant patients)	5%-10%	1%-2%	1%-3%	0.5%-1.5%	~0.5%	Sedation-related considerations

N/A, Not applicable.

and severe pancreatitis is defined as being associated with persistent organ failure >48 hours in duration.³³ In the endoscopy-specific consensus definition, mild pancreatitis is defined as an episode that requires admission (or prolongation of admission) of 2 to 3 days, whereas moderate pancreatitis is defined as an episode requiring 4 to 10 days of hospitalization, and severe pancreatitis is defined as being associated with any of hospitalization for over 10 days, hemorrhage, phlegmon, pseudocyst, or intervention.³⁵ In proportional meta-analyses of 128 trials each reporting specific incidences of mild, moderate, and severe PEP, these contributed to 65.9%, 27.9%, and 10.2% of PEP cases, respectively. Importantly, PEP can lead to death in 2.6% of patients, with the majority of this risk being concentrated in patients experiencing severe PEP.⁷

Risk factors for PEP can generally be divided into patient-, procedure-, and endoscopist-related parameters. These are summarized in Table 2.^{5,7,32,38-45} Although several PEP clinical risk prediction models have been developed,⁴⁷ with all using some combination of these established risk factors, none are currently widely used in clinical practice. The reasons for this are unknown, but the lack of uptake could relate to issues with generalizability of the study cohorts to routine practice settings, perceptions of cumbersome or difficult-to-obtain data inputs, and/or a lack of actionable recommendations depending on predicted risk, among others.

Patient-related risk factors

Several patient-related risk factors have been independently correlated with PEP. Female sex has been consistently associated, with point estimates for odds ratios (ORs) ranging between 1.39 and 1.46 in meta-analyses.^{7,38,39} Younger age is more difficult to describe as a PEP risk factor given it exists in both categorical and continuous forms as an exposure variable across studies, but a meta-analysis demonstrated ORs for PEP of 1.81 for age ≤60 years and 2.33 for age ≤40 years.⁴⁰ Patients with prior acute or recurrent pancreatitis have higher odds of developing PEP, and patients specifically with prior PEP have even higher odds of up to 4.40.³⁸⁻⁴⁰ Patients with a suspected or confirmed functional biliary

sphincter of Oddi disorder (also known as sphincter of Oddi dysfunction and defined by Rome IV as the presence of biliary pain, biliary dilatation or elevated liver enzymes [but not both] and absence of choledocholithiasis or structural abnormalities⁴⁸) also have substantially higher odds of PEP, with ORs of 2.04 to 4.37.⁴⁰ Other patient-related risk factors include the presence of a nondilated common bile duct (CBD), a normal serum bilirubin level before ERCP, type II (small and/or flat) morphology of the major papilla,⁴¹⁻⁴³ and absence of chronic pancreatitis.

Procedure-related risk factors

An established procedure-related risk factor for PEP is the presence of difficult cannulation (with the most common definition of this being more than 5 papillary engagements, more than 5 minutes being spent trying to cannulate, more than 1 inadvertent pancreatic cannulation, and/or pancreatic contrast opacification).⁴⁹ Individual components and techniques related to challenging cannulation have also been studied at length to try to elucidate their independent magnitudes of effect on PEP. These include any pancreatic guidewire cannulation (OR, 2.03-3.26^{7,40,44}), precut sphincterotomy (OR, 1.98-2.07^{7,40}), pancreatic contrast injection (OR, 2.27-4.23^{7,40}), with higher odds associated with full acinarization as opposed to partial opacification, pancreatic sphincterotomy (OR, 2.64⁴⁰), and sphincteroplasty of an intact papilla (OR, 2.91⁴⁰). Placement of a self-expandable metal stent (SEMS) also appears to be associated with the development of PEP compared with multiple plastic stents (OR, 3.34⁵⁰).

Endoscopist-related risk factors

Multiple meta-analyses have demonstrated significant associations between low provider procedural volumes and overall post-ERCP AEs.^{5,45} Importantly, no existing evidence syntheses have demonstrated associations between low volumes and PEP specifically. Furthermore, there exists considerable heterogeneity in source studies regarding the numerical definition of low-volume providers.^{5,45} Facility-level data support the notion that ERCP performed at lower-volume centers is associated with higher AE rates.⁴

TABLE 2. Patient-, procedure-, and endoscopist-related risk factors for post-ERCP pancreatitis and summary of evidence-based methods to decrease the incidence and/or severity of post-ERCP pancreatitis

Parameter	Point estimates of odds ratios/risk ratios for PEP
Patient-related risk factors	
Female sex (vs male sex)	1.39-1.46 ^{7,38,39}
Younger age (40 or younger)	2.33 ⁴⁰
(60 or younger)	1.81 ⁴⁰
Prior acute or recurrent acute pancreatitis of any etiology (higher with PEP)	2.00-4.40 ³⁸⁻⁴⁰
Suspected or confirmed sphincter of Oddi dysfunction	2.04-4.37 ³⁸⁻⁴⁰
Nondilated common bile duct	1.65-3.80 ^{32,40}
Normal bilirubin	1.54-1.89 ^{32,40}
Type II morphology of the major papilla	N/E ⁴¹⁻⁴³
Absence of chronic pancreatitis	1.73-1.87 ^{32,40}
Procedure-related risk factors	
Difficult cannulation	2.60 ⁴⁰
Pancreatic guidewire cannulation (including single cannulation ⁴⁴)	2.03-3.26 ^{7,40,44}
Precut sphincterotomy	1.98-2.07 ^{7,40}
Pancreatic contrast injection of any extent (greater with acinarization)	2.27-4.23 ^{7,40}
Pancreatic sphincterotomy	2.64 ⁴⁰
Sphincteroplasty of an intact papilla	2.91 ⁴⁰
Endoscopist-related risk factors	
Lower procedural volumes (<25-200 procedures per year)	1.41-1.43 ^{5,45,*}
Mitigation strategies	
Prolonged intravenous hydration (duration of 8-24 hours)	0.50 ⁷
Rectal NSAIDs	0.49 ⁷
Pancreatic duct stent placement (greater benefit in patients not receiving NSAIDs, but benefit present regardless ⁴⁶)	0.56 ⁷

N/E, Not estimable given absence of OR/RR from meta-analysis(es); NSAID, nonsteroidal anti-inflammatory drug; OR/RR, odds ratio/risk ratio; PEP, post-ERCP pancreatitis.

*Odds ratios describe associations between lower volumes and all pooled adverse events, but no significant differences seen for pancreatitis specifically.

Trainee participation has been proposed as a potential risk factor in numerous studies, but no significant associations have been demonstrated consistently to date.^{51,52} Minimum procedural volumes required to be considered independently competent following training vary considerably. In a U.S.-based study, successful cannulation rates of 80% or higher were consistently achieved after between 400 and 500 native procedures on patients with native biliary anatomy.⁵³ From United Kingdom data, in a group of trainees in their final year who had completed at least 200 ERCPs, only 66% of procedures were successful without physical assistance from a supervisor.⁵⁴ In a separate European study, <10% of trainees achieved a cannulation rate of >85% after 200 procedures on patients with native biliary anatomy.⁵⁵ In a multicenter U.S. study, at the end of ERCP training with a median of 361 ERCPs, only 55% of trainees met competence metrics in native papilla cannulation.³

Mitigation strategies

Evidence-based strategies to mitigate the risk of PEP are summarized in other recent ASGE documents.^{22,23} Glob-

ally, the 3 primary evidence-based strategies shown to reduce PEP in meta-analyses of RCTs include prolonged intravenous hydration after ERCP, rectal nonsteroidal anti-inflammatory drugs (NSAIDs) given periprocedurally, and PD stent placement.⁷

Bleeding

ERCP-related bleeding is almost always observed after sphincterotomy and/or sphincteroplasty.⁵⁶ Importantly, ERCP-related bleeding can be divided into intraprocedural bleeding, which is not necessarily considered a true AE unless it alters a patient's clinical trajectory, and clinically significant bleeding, which has been defined as hematemesis, melena, or hematochezia with a hemoglobin drop of 2 g/dL or more.^{35,57} The incidence of clinically significant bleeding related to ERCP was 1.5% for all-comers and 1.9% in first-time ERCP patients in a recent meta-analysis.⁷ The severity of ERCP-related bleeding is based on length of hospitalization and the need for repeat endoscopy and/or transfusion.^{35-45,47-58} In a multicenter prospective study of over 8500 patients undergoing ERCP, the mean onset of clinically significant post-ERCP bleeding was

3.2 days.⁵⁷ In the same study, most (77.5%) cases were of moderate severity, whereas 9.3% were severe and 2.3% were fatal.⁵⁷

Risk factors for clinically significant ERCP-related bleeding include anticoagulant or thienopyridine antiplatelet use, active coagulopathy, cholangitis leading up to ERCP, and chronic liver disease.^{57,59-62} In a recent study, the magnitudes of associations with direct-acting oral anticoagulants were comparable to those observed with vitamin K antagonists.⁵⁷ The occurrence of intraprocedural bleeding after sphincterotomy, but not after sphincteroplasty, has also been associated with delayed bleeding after ERCP.⁵⁷ The use of aspirin (either alone or with other antithrombotic agents) or NSAIDs has not been associated with higher odds of bleeding, nor have prophylactic doses of low molecular weight heparins.^{57,62,63} Lower endoscopist procedural volumes have also been associated with higher odds of bleeding.⁵

The most reliable way to mitigate the risk of ERCP-related bleeding is to optimize periprocedural management, including appropriate cessation and resumption of antithrombotic agents^{64,65} and management of other coagulopathies.^{66,67} Importantly, although practitioners generally manage anticoagulant agents (including direct acting anticoagulants and vitamin K antagonists) appropriately around the time of ERCP, recent prospective data suggest that the risks associated with antiplatelet therapy (including P2Y₁₂ inhibitors) is underestimated given suboptimal preprocedural management of these agents.⁵⁷ In cases where emergent ERCP is indicated for a patient with coagulopathy (including as a result of antithrombotic agents), sphincterotomy and/or sphincteroplasty should ideally be avoided in the index session given that biliary stent placement without sphincterotomy has been shown to be generally safe.⁶⁸ If significant intraprocedural bleeding occurs during ERCP (acknowledging the lack of a standardized definition), options for endoscopic management vary based on numerous factors, but can include covered metal biliary stent placement, epinephrine, cauterization (via either probes or forceps), clips, and hemostatic powder. Care must be taken with any hemostatic modality to avoid causing pancreatitis and/or biliary obstruction. In cases of post-ERCP bleeding, management principles generally mirror those that have been described for other causes of upper GI bleeding.⁶⁴ Resumption of held antithrombotic agents after ERCP is currently a highly variable practice, with no high-quality evidence to guide recommendations.

Cholangitis

Cholangitis is a relatively common AE associated with ERCP and can result in significant morbidity and/or mortality, especially if not promptly recognized and treated. Given that cholangitis is itself an indication for ERCP in addition to being an associated AE, clear definitions for post-ERCP cholangitis are essential, as are efforts to attribute causality to an index ERCP procedure.³⁴ In a recent

meta-analysis of 71 studies including over 120,000 patients, the incidence of cholangitis after ERCP was 2.5% in all-comers.⁷ In a subsequently published 2025 prospective study of over 8500 patients that used strict definitions and clear causal attribution criteria, the incidence of cholangitis was lower, at 1.5%; however, 29.1% of cases were severe and 8.2% of cases were fatal.⁶⁹ Although in this study, the most common time to symptom onset following ERCP was 1 to 3 days depending on the procedural indication,⁶⁹ procedure-related cholangitis can theoretically occur up to 14 days after ERCP.³⁴ Beyond this, the definition becomes questionable and overlaps considerably with the outcomes of stent dysfunction and/or occlusion, or could relate instead to underlying pathology, such as primary sclerosing cholangitis (PSC) or neoplasia.

Arguably the most well-established risk factor associated with post-ERCP cholangitis is incomplete biliary drainage (with surrogate markers including the presence of a biliary stricture, performance of sphincterotomy, and placement of a biliary stent, with the latter 2 being protective).⁶⁹⁻⁷¹ Several additional risk factors have been associated with cholangitis, including advanced age, male sex, postliver transplant status, PSC, cholangioscopy (see sections below), cholangiocarcinoma, increasing procedure time, and inpatient status.^{32,69,71-73} In patients with CBD stones, the presence of greater numbers of stones has been associated with the development of cholangitis, whereas in patients with biliary strictures, more proximal stricture locations (intrahepatic, hilar, or common hepatic locations in comparison to the distal CBD) and malignant (vs benign) stricture type have been associated with cholangitis.⁶⁹

Prevention of cholangitis includes the minimization of nonsterile contrast injection into the biliary tree where possible, especially proximal to visualized strictures. As discussed, establishing biliary drainage after ERCP is essential in mitigating cholangitis. Preprocedural imaging is recommended in cases where more complex and/or proximal strictures are suspected. Antibiotic coverage is currently recommended for patients with established risk factors for cholangitis and/or suspected incomplete decompression after ERCP.⁷⁴ High levels of suspicion and prompt recognition of potential cholangitis in such high-risk patients are essential, with early broad-spectrum antibiotic coverage indicated. However, a recent meta-analysis of randomized trials demonstrated benefits of prophylactic antibiotics in all patients with biliary obstruction.⁷⁵ Management of post-ERCP cholangitis can include medical management and observation, repeat ERCP, and/or percutaneous biliary drainage, depending on the original indication and biliary anatomy as well as the patient's presentation. Culturing bile at repeat ERCP has been suggested as an option to guide targeted antibiotic therapy.³² Choledochoduodenostomy with a lumen-apposing metal stent is an option that is increasingly considered, although not specifically studied for this indication in any high-volume series.

Cholecystitis

Post-ERCP cholecystitis generally arises from either intrinsic obstruction or extrinsic compression of the cystic duct, either via biliary stent placement, introduction of nonsterile contents into the cystic duct and/or gallbladder, or altered gallbladder motility.^{76,77} Given the historical lack of established ERCP-specific definitions of cholecystitis,^{34,78} the reported incidences have varied widely, ranging from 0.5% to 1.5% for all-comers to up to 15% in patients undergoing SEMS placement.^{59,76,79,80} The pooled incidence of post-ERCP cholecystitis in recent meta-analyses was 0.8% in all-comers from 12 studies of over 7500 patients and 1.1% in first-time patients from 18 studies of over 6500 patients.⁷ In a 2024 prospective study of over 4400 patients with native gallbladders undergoing ERCP using strict definitions and causal attribution criteria, the incidence of post-ERCP cholecystitis was 0.4% in all-comers and 1.5% in patients with SEMS placement.⁸¹ However, in a recent meta-analysis of trials comparing SEMS placement to plastic stent placement in patients with malignant distal biliary obstruction (performed to inform ASGE's guidance on the management of pancreatic masses), there was no difference in cholecystitis rates between groups.^{82,83}

Proposed risk factors for cholecystitis after ERCP (in addition to SEMS placement) include opacification of the gallbladder, remnant gallstones, and biliary and/or cystic duct masses.^{6,81} However, any biliary stent placement, including side-by-side plastic stent placement, could theoretically precipitate cholecystitis. Given the relatively low rates of cholecystitis after ERCP, there is a legitimate debate as to whether SEMSs or side-by-side plastic stents should be placed in patients with native gallbladders. Management strategies for suspected or confirmed cholecystitis after ERCP include removal or replacement of indwelling stent(s) via repeat ERCP, if present, as well as transpapillary, endosonography-guided, or percutaneous gallbladder drainage (depending on local resource availability and/or expertise) and cholecystectomy.^{84,85}

Perforation

Perforation is a rare but potentially life-threatening post-ERCP AE. Although guidewire penetrations are encountered relatively frequently during ERCP and are generally considered benign given that they most often do not alter a patient's clinical trajectory, frank luminal perforation with extraluminal contamination constitutes a significant event.

The Stapfer classification is currently the most widely used schema for describing perforations caused by ERCP. Within this system, Type I perforations are lateral or medial duodenal wall injuries, most often caused by the duodenoscope tip. Type II perforations are perampullary injuries, often observed after sphincterotomy or sphincteroplasty. Type III perforations are injuries to the distal bile duct.

Type IV perforations are defined as the presence of retroperitoneal gas alone.⁸⁶

The timing, severity, and presentation after ERCP-related perforations can vary considerably. In a recent meta-analysis of 82 studies including over 300,000 patients undergoing ERCP, the incidence of perforation was 0.5% (95% CI, 0.4-0.6) in all-comers, whereas in a meta-analysis of 98 studies including over 42,000 patients, the incidence was similar at 0.6% (95% CI, 0.5-0.7) in patients undergoing ERCP for the first time.⁷

Risk factors for perforation include sphincter of Oddi dysfunction as well as sphincterotomy and sphincteroplasty.³² In particular, the performance of sphincterotomy and/or sphincteroplasty on patients with previous sphincterotomy or other reasons for perampullary fibrosis has been associated with a higher risk.⁸⁷ Altered/post-surgical upper GI anatomy and luminal strictures have also been proposed as risk factors.³² Finally, difficult biliary cannulation and intraductal balloon stricturoplasty have both been associated with perforation as well.^{6,32,88}

No specific techniques over and above general principles have been reliably shown to reduce the risk of ERCP-related perforation. Regardless of the suspected mechanism, early recognition of perforation is key in ensuring prompt management and improving the chances of a positive outcome. Careful examination of sphincterotomy/sphincteroplasty and duodenal wall for perforation before completion of ERCP should be considered a standard good practice.

After initial resuscitative and supportive efforts, patients with suspected perforation should have the diagnosis confirmed or excluded via imaging, preferably via CT.⁸⁹ Although contrast-enhanced studies are ideal, noncontrast studies may be more readily obtained in patients suspected to have a perforation given their clinical status. Subsequently, a multidisciplinary approach should be used to determine the optimal management for a given patient, with management strategies including a conservative approach, endoscopic management, or surgical management. In cases where endoscopic management is attempted either during the index ERCP or during a repeat session, the use of carbon dioxide (CO₂) is advised over room air, and positioning the patient to achieve diversion of intraluminal contents away from the defect should be attempted where possible. In addition, placement of a nasogastric tube to suction could be considered. For perampullary or intraductal perforations, biliary stent placement to seal the defect can be effective,⁹⁰ although consideration should be given to preventing PEP via PD stent placement if a SEMS is being used in patients with a normal pancreas. For nonampullary luminal perforations measuring ~10 mm or less, closure can sometimes be achieved with through-the-scope clips, whereas larger perforations could potentially be closed using over-the-scope clips or suturing devices.⁸⁹ Very large luminal perforations

with defect sizes of 30 mm or more could also be targeted with suturing devices or over-the-scope clips, where availability, familiarity, and expertise are present, but historically these cases are managed surgically.⁹¹

ERCP WITH PANCREATIC INTERVENTIONS

ASGE recommendations regarding the role of endoscopy in the overall management of chronic pancreatitis are available elsewhere.^{92,93} From available evidence comparing the effectiveness and safety of early surgery versus endoscopic therapy (ERCP $\pm$ extracorporeal lithotripsy) for the treatment of symptomatic main PD stones, AEs were recorded per patient rather than per procedure to make the surgical and endoscopic treatment strategies more directly comparable. PEP occurred in 16% to 21% of patients in the ERCP arms across 3 studies that collectively included under 100 patients, raising the concern over potential overestimation of AEs based on the small sample sizes contained therein.⁹⁴⁻⁹⁶ Significant bleeding after ERCP occurred in 2.4% of patients in one of these studies, and perforation of the PD occurred in 2.4% of patients in the same study.⁹⁵ The umbrella term of stent-related AEs, comprised of obstruction, migration, and stent-related injury, occurred in 26% of patients after the ERCP-based approach in 1 RCT,⁹⁶ with specific stent-related AEs including stent migration (4.9%) and obstruction of the PD causing inflammation (3.7%) reported in another.⁹⁵ The possibility of chronic PD injury or stricture after stent placement has been well described, especially when stents are used that are larger than the caliber of the existing PD.⁹⁷ Other related AEs specifically reported in relation to ERCP-guided pancreatic stone removal included tearing of the duodenal mucosa during stent removal, basket impaction, and cholecystitis.^{95,96}

A retrospective study of 85 patients with chronic pancreatitis and PD strictures treated with ERCP, with treatment including placement of 1 or 2 (side-by-side) plastic stents $\pm$ stricture dilation, demonstrated PEP in 2.4% of patients, stent migration rates of 21%, and duodenal perforation in 1.2% of patients.⁹⁸ A separate retrospective study of 80 patients with chronic pancreatitis and symptomatic PD strictures compared SEMs with plastic stents.⁹⁹ PEP occurred at similar rates between groups, specifically in 19.2% of patients treated with SEMs and 20.4% in patients treated with plastic stents, with similar rates of cholangitis (3.8% vs 3.7%, respectively) and perforation (0.0% vs 1.9%, respectively).⁹⁹ No cases of clinically significant bleeding were observed in either group. Importantly, although stent dysfunction (either fracture or obstruction) occurred in 7.7% and 3.7% of patients treated with SEMs and plastic stents, respectively, spontaneous stent migration occurred in 26.9% and 3.7% of patients treated with SEMs and plastic stents, respectively.⁹⁹ Significantly, de novo main PD strictures developed in 23.1% of patients in the fully covered SEMs (FCSEMS) group, whereas this AE was not

observed in patients treated with plastic stents.⁹⁹ A proposed mechanism in the development of such strictures is the radial force of the stent causing ischemic injury.¹⁰⁰ Generally, higher rates of most AEs have been shown to occur with FCSEMS compared with single or multiple plastic PD stent placement, which is why pancreatic SEMs placement is generally not recommended.^{92,93}

A systematic review and meta-analysis of 22 studies of therapeutic ERCP performed for symptomatic pancreas divisum with diverse clinical indications that included recurrent acute pancreatitis, symptomatic chronic pancreatitis, and chronic abdominal pain was performed to assess the effectiveness and safety of interventions including minor papilla sphincterotomy, dorsal duct stent placement, and/or balloon dilation.¹⁰¹ PEP occurred in 18.1% of patients, and bleeding occurred in 1.4% of patients, with delayed AEs including stent occlusion occurring in 19.3% of patients and papillary restenosis occurring in 10.7%.¹⁰¹ In a separate 2025 meta-analysis of 27 studies reporting on ERCP-based interventions for symptomatic pancreas divisum, the overall combined AE rate was high at 71%.¹⁰² Although AEs are undoubtedly higher in patients with pancreas divisum, it is important to avoid overestimation of risks in this patient population given that these studies often rely on composite per-patient outcomes. To illustrate this, a recently published methodologically rigorous randomized trial assessing patients with pancreas divisum, the rate of serious AEs within 30 days was only 15% in patients undergoing minor papillotomy.¹⁰³

ERCP WITH CHOLANGIOSCOPY OR PANCREATOSCOPY

Overview

Cholangioscopy and pancreatoscopy can afford direct views of the biliary and/or PD(s) for diagnostic and/or therapeutic purposes. Current generations of cholangioscopy devices provide the opportunity for single-operator use, with improved digital imaging and a broader range of interventional accessories. Cholangioscopy is now widely performed and is considered safe overall but has nevertheless been associated with AE rates that are distinct from routine ERCP, most notably with regard to infection and pancreatitis. The magnitudes of these associations are somewhat difficult to parse given biases associated with the preferential performance of cholangioscopy in the settings of PSC and indeterminate biliary strictures.^{104,105}

Pancreatitis

In a meta-analysis of 49 studies of patients undergoing ERCP with cholangioscopy either for therapy of difficult biliary stones or diagnosis of indeterminate strictures, the rate of PEP was low (2%; 95% CI, 2-3) as part of a low overall AE rate of 7% (95% CI, 6-9),¹⁰⁶ with similar findings demonstrated in a subsequent meta-analysis of

over 1700 patients undergoing ERCP with cholangioscopy with lithotripsy for difficult stones only.¹⁰⁷ Although the fact that a large proportion of included patients were undergoing repeat ERCP likely accounted for these low rates, the lack of higher rates with the performance of cholangioscopy is reassuring. In a prospective study of PSC patients undergoing cholangioscopy, the rate of PEP among 42 patients was considerably higher, at 7.1%,¹⁰⁸ although it is unclear to what extent the performance of cholangioscopy contributed to the overall PEP risk compared to the patients' underlying PSC status.

In a retrospective multicenter cohort study of 109 patients undergoing ERCP with pancreatoscopy and either electrohydraulic or laser lithotripsy followed by PD stent placement for obstructing PD stones, the rate of PEP was 4.6%.¹⁰⁹ A separate prospective cohort study of 40 patients undergoing ERCP with pancreatoscopy for symptomatic PD stones reported a PEP rate of 2.5%.¹¹⁰ Two recent meta-analyses of ERCP with pancreatoscopy and lithotripsy for PD stones reported combined AEs in 12% to 14% of patients, of which 8.7% were related to PEP (95% CI, 4.5-16.3).^{111,112} In a retrospective cohort study of close to 4000 patients with chronic pancreatitis, ERCP with cholangiopancreatotomy was compared with ERCP using conventional techniques, and rates of PEP were statistically no different between these groups (2.2% vs 1.3%, respectively).¹¹³

Bleeding

Although direct trauma to the biliary and/or PD wall with lithotripsy is a plausible mechanism for hemorrhage, there are no compelling data demonstrating higher clinically significant bleeding rates with cholangiopancreatotomy and its associated interventions compared with standard ERCP.^{106-108,110}

Cholangitis

Direct intubation of the bile duct and the associated performance of interventions such as irrigation with nonsterile saline and/or sampling within stenosed areas can plausibly predispose patients to higher risks of cholangitis. Individual retrospective and prospective cohort studies have reported incidences of infectious AEs related to cholangioscopy ranging from 1% to 12%,^{108,113-116} with rates of bacteremia of uncertain clinical significance attributed to cholangioscopy of 13.9%.¹¹⁷ In a retrospective cohort study of close to 4000 patients with chronic pancreatitis comparing ERCP with cholangiopancreatotomy and ERCP using conventional techniques, the rates of cholangitis were significantly higher in the cholangiopancreatotomy group (1.0% vs 0.2%, respectively, with a significant OR of 4.98).¹¹³ However, separate RCTs of cholangioscopy-directed biopsy versus fluoroscopy-guided brushings¹¹⁸ and cholangioscopy-guided laser lithotripsy versus conventional ERCP therapies in the management of difficult stones¹¹⁹ both reported no differences in clinical rates of cholangitis with cholangioscopy. A retrospective study

demonstrated that antibiotic prophylaxis in the periprocedural period was associated with lower rates of cholangitis after cholangioscopy compared to cases without antibiotics (12% vs 1%).¹¹⁶ Despite the conflicting evidence summarized above, patients undergoing cholangioscopy are generally considered to be at high risk for post-ERCP cholangitis, and the administration of periprocedural antibiotics is currently suggested by some endoscopic societies in patients having ERCP with cholangioscopy.³²

Perforation

The rates of perforation with cholangioscopy and pancreatoscopy appear to be similar to those observed with conventional ERCP.^{106-108,110,113,115,120}

ERCP IN SPECIAL POPULATIONS

Pediatric patients

A large recent meta-analysis of over 5600 pediatric patients undergoing ERCP for various indications demonstrated a pooled PEP rate of 4% (95% CI, 3-6),¹²¹ similar to those observed in studies of adult patients undergoing ERCP. A smaller working space, anatomically speaking, is a plausible procedure-related factor that could predispose to greater technical difficulty of ERCP in the pediatric population, in addition to the lack of dedicated scopes and devices for pediatric patients. Finally, a smaller evidence base informing safety of NSAIDs in children may also be associated with reduced use, which could affect PEP in this population.

Pregnant patients

Pregnancy was reported to be an independent risk factor for PEP (12% vs 5%, *P* value <.001) in a retrospective matched study of over 3600 patients.¹²² Importantly, in pregnant patients, the administration of rectal NSAIDs has traditionally been avoided because of the potential for ductus arteriosus constriction and associated premature closure. Furthermore, patient positioning may be different from what an endoscopist is accustomed to because of considerations regarding the gravid uterus. Importantly, in a meta-analysis of 27 studies reporting on over 1300 pregnant patients, the pooled rate of overall (combined maternal and fetal) ERCP-related AEs was reported to be 15.9% (95% CI, 13.2-19.1).¹²³ Despite these risks, endoscopists should not avoid ERCP in pregnant patients when there is an appropriate indication,¹²⁴ especially because gallstone pancreatitis and cholangitis can both lead to significant morbidity and mortality during pregnancy, both for mother and fetus, although these risks are difficult to quantify.¹²⁵

Patients with surgically altered anatomy

Depending on the type of postsurgical anatomy, standard or balloon-assisted ERCP is successful to varying degrees. Balloon-assisted ERCP, performed with either single or do-

uble-balloon enteroscopes, helps with accessing the papilla, but is typically performed with forward-viewing scopes. However, despite the challenges associated with reaching and cannulating an often-reversed or anatomically distorted papilla, the overall AE profile of such procedures has been shown to be comparable to that of standard ERCP.¹²⁶ Other options for these patients include laparoscopic-assisted ERCP and endosonography-directed transgastric ERCP, with rapidly emerging data on the safety of the latter technique in recent years.¹²⁷

UHE NOT RELATED TO TRADITIONAL AEs

Traditionally, the focus of ERCP outcomes studies has been to elucidate the incidence and risk factors for ERCP-related effectiveness and AEs. However, in recent years, it has become increasingly clear that other adverse outcomes are possible after ERCP that do not fit the definitions of any other ERCP-related AE. A relevant and all-encompassing outcome after ERCP is the rate of UHEs.⁴ This outcome can be justifiably measured at various time points following an index ERCP, including at 7, 14, or 30 days. UHEs are generally defined as any emergency department visit and/or unplanned hospital admission. Although the rate of UHEs generally proportionally parallels the rate of ERCP-related AEs, UHE as an outcome more broadly captures other issues, including cardiopulmonary AEs after anesthesia, abdominal pain not related to another clearly defined AE, nausea with no discernible cause, and unplanned repeat ERCPs or unplanned other procedures for missed pathology, among others.³⁴

Post-ERCP abdominal pain can occur in 10% or more of patients in the absence of pancreatitis, cholangitis, or perforation. In a study of 91 outpatients undergoing ERCP with moderate sedation, up to 12% reported moderate or severe pain at the time of discharge without experiencing any clearly defined AEs.¹²⁸ Similar results were demonstrated in a survey study of 149 patients undergoing ERCP with moderate sedation, where a considerable proportion self-reported pain or discomfort either during or immediately following their procedure.¹²⁹ After clinical observation and an appropriate diagnostic workup, unexplained post-ERCP pain may end up being attributed to discomfort from gas insufflation (especially at centers using room air instead of CO₂), musculoskeletal pain from positioning during the procedure (especially during a long procedure), residual effects of medications used for sedation or anesthesia, exacerbation of a preexisting medical condition, visceral hypersensitivity (ie, functional pain), peritoneal irritation from bile leakage/guidewire penetrations, or stent-related pain, or conversely, can sometimes remain unexplained.¹³⁰⁻¹³² Although undifferentiated abdominal pain can often be a source of distress for both patient and endoscopist as laboratory and radiographic investigations are considered and performed, such pain often subsides relatively quickly, and the patient may be discharged the same day or after over-

night observation, sometimes with temporary pain medication to manage symptoms at home.

Unplanned repeat ERCP and/or other unplanned procedures collectively make up another outcome captured under the UHE umbrella. Most commonly, such procedures are due to either premature stent occlusion or migration, which can both result in jaundice and/or cholangitis, or to retained bile duct stones or newly migrated stones from the gallbladder. It is somewhat difficult to define what constitutes premature stent occlusion because there is an increasing risk over time related to both stent-specific factors, including diameter, length, composition, and covering, and patient-specific factors, including the type of stricture (benign vs malignant), its surrounding anatomy and location, and response to medical therapy. Studies involving metal stents have generally selected 30-, 60-, or 90-day windows within which stent occlusion is considered premature,^{133,134} whereas a 30-day timeframe is usually used for studies involving smaller-caliber plastic stents.¹³⁵

PATIENT-REPORTED OUTCOME AND EXPERIENCE MEASURES IN ERCP

The 2002 National Institute of Health Roadmap for Medical Research in the 21st Century highlighted the need for dynamic assessment of patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs) for different diseases and treatments.¹³⁶ Treatment-specific PROMs and PREMs aid in clinical decision-making, outcome assessments, and quality assurance for numerous evolving medical and surgical procedures. For ERCP, physician-defined outcomes are currently the main sources used to define related AEs.³⁵ However, increasing data demonstrate that existing AEs in aggregate fail to capture the overall morbidity associated with ERCP. In particular, using the most commonly accepted consensus definition of PEP as an example,³⁵ multiple studies have demonstrated poor concordance with imaging-based diagnosis of PEP and have also shown that physician-defined criteria fail to account for patients with shorter hospital stays for abdominal pain that may comprise up to 10% of patients undergoing ERCP.^{137,138}

Given these limitations of the current primarily physician-defined definitions for ERCP-related AEs and related morbidity, there has been increasing interest in treatment-specific PROMs and PREMs to capture the patient's experience during and after ERCP. Functional Assessment of Cancer Therapy–Hepatobiliary is the only validated biliary-specific PROM, but it is designed to measure the quality of life in patients with hepatobiliary cancers.¹³⁹ Specifically in the realm of pancreatitis, patient-reported outcome scale in acute pancreatitis (PAN-PROMISE) is a PROM initially designed to capture morbidity associated with acute pancreatitis in a multicenter, multinational prospective cohort study.¹⁴⁰ It consists of 7 questions regarding pain, abdominal distention, difficulty eating, difficulty with bowel

movements, thirst, nausea/vomiting, and weakness. These patient-reported scores have been shown to correlate with the resolution of acute pancreatitis, local AEs, and the development of severe pancreatitis.¹⁴⁰ PAN-PROMISE has subsequently been studied in the peri-ERCP setting, and an increase in the 7-day patient-reported scale for tolerability of endoscopic procedures (PAN-PROMISE) score of 7 points or more above baseline quality-of-life status was strongly correlated with UHE.¹⁴¹ Also validated for use in ERCP and other endoscopic procedures, PRO-STEP is a simple Likert-based PREM applied at the time of discharge from ERCP and intended to measure procedure tolerability under conscious sedation, consisting of separate evaluations of intraprocedural pain and awareness and postprocedural pain, nausea, and distention.¹²⁸ Importantly, elevated patient-reported PRO-STEP scores have been shown to correlate with both UHE as well as post-ERCP AEs, including PEP and perforation.¹⁴² These studies collectively indicate that previously used measures for defining PEP do not capture the total number of patients experiencing procedure-related symptoms in the hours and days after ERCP,¹²⁹ and therefore, suggest that we likely underestimate the overall burden related to ERCP. Therefore, further research is needed to develop a consensus on using ERCP-specific PREMs and PROMS, which can provide increased granularity in capturing patient morbidity and aid in using interventions to reduce the symptom burden post-ERCP. PREMs and PROMs could also be used more holistically to inform and improve post-ERCP quality in general. Other patient-reported outcomes should also be explored after ERCP, including calls to urgent health lines, expedited visits to primary health care teams, and lost productivity because of missed work, to name a few. These outcomes have historically been difficult to measure and have therefore been largely ignored both within the context of ERCP and otherwise.

DUODENOSCOPE-RELATED INFECTIONS

Significant consideration has been given to the risk of duodenoscope-related infections in recent years, with a detailed summary of the issues provided in ASGE's guideline on infection control in GI endoscopy.¹⁴³ The field of infection control in ERCP is highly complex, with multifactorial and interacting influences potentially capable of causing infectious outbreaks.¹⁴⁴ However, duodenoscopes and linear echoendoscopes share the unique feature of having an elevator mechanism that is extremely difficult to disinfect via standard reprocessing techniques. Although the approximate rate of clinically significant duodenoscope-related infections is estimated to be only 0.01%,¹⁴⁵ the mere possibility of outbreaks has resulted in most gastroenterology and endoscopy societies declaring infection control in ERCP to be a research priority.¹⁴⁶ Several novel duodenoscope designs have emerged as a result.¹⁴⁷⁻¹⁵² The cost-effectiveness of routinely using such duodenoscope designs remains uncertain, however.^{153,154}

KNOWLEDGE GAPS AND RESEARCH PRIORITIES

Considering the current state of knowledge on ERCP-related AEs summarized in the sections above, there are several areas with knowledge gaps that represent opportunities for future impactful research. These are summarized below, in no particular order.

1. Given the now-clear benefits of several categories of interventions to mitigate the risk of PEP, implementation science studies are critical to evaluate methods to enhance currently suboptimal uptake in routine practice.
2. There is currently an absence of high-quality randomized trials comparing the efficacy and (short- and long-term) AEs of ERCP versus expectant management for patients with asymptomatic incidentally discovered choledocholithiasis.
3. As discussed, there are several currently available models that predict the risk of PEP based on patient- and procedure-related (and potentially other) factors. However, investigators should strive to take the next step by developing clinical decision-making tools that advise endoscopists on appropriate steps to take based on individualized risks generated by available prediction models.
4. The role of artificial intelligence in reducing ERCP-related AEs and/or improving quality is still an untapped area. Potential domains for research include radiomics or standardized procedure report generation, as examples.
5. Finally, because the role for endosonography-guided procedures increases for indications traditionally managed using ERCP, head-to-head trials comparing efficacy and AEs have become increasingly important.

SUSTAINABILITY PERSPECTIVE

This guideline was reviewed by the ASGE's Sustainable Endoscopy Task Force. As with all GI conditions, the best interests of the individual patient should be prioritized over sustainability concerns. However, when there is a choice of suitable management options, the ASGE recommends that clinicians consider environmental impact in their decision-making. In general, a practice that follows evidence-based guidelines represents a sustainable practice, because it not only provides high-quality and essential care but also reduces unnecessary tests and interventions. Specific to this guideline, the ASGE suggests the following sustainability best practices.

1. Avoiding ERCPs that are not clinically indicated will not only prevent potential AEs but also reduce environmental burden.¹⁵⁵ As advanced procedures, ERCPs generate substantially more waste and are likely associated with a higher carbon footprint than routine procedures.¹⁵⁶
2. Among high-risk outpatients presenting for ERCP, 1 in 5 requires unplanned hospitalization within 30 days,¹⁵⁷

highlighting the downstream burden of any AE. Consequently, minimizing AEs may also reduce the environmental impact associated with such care. For example, the carbon footprint of a hospital admission has been estimated to be 30 to 50 kg CO₂e per patient per day, roughly equivalent to driving 100 miles in a gasoline-powered car.¹⁵⁸

3. Single-use duodenoscopes have been introduced to mitigate the risk of duodenoscope-associated infections. However, their use is estimated to increase net waste by ~40% and to incur a 25 to 70-fold higher carbon footprint compared with reusable duodenoscopes.¹⁵⁹⁻¹⁶¹ Importantly, the upfront safety benefits of reducing infection are off-set by the indirect environmental and public health harms with increased emissions and waste generation.¹⁶⁰

Taken together, strategies to reduce AEs and promote sustainable practices may simultaneously improve patient outcomes and overall quality of ERCP care.

CONCLUSIONS

ERCP is associated with relatively high AE and UHE rates compared with most other widely performed endoscopic procedures. A clear indication for ERCP should therefore always be present, and safer and/or noninvasive alternatives should always be considered whenever available and appropriate. Informed consent is key, and performing endoscopists should have a clear and contemporary knowledge of ERCP-related AEs, their associated risk factors, and appropriate management. This document was written to assist in informing this knowledge base. In addition, proper training and credentialing of endoscopists performing ERCP is crucial in reducing the risk of AEs.

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Abbreviations: AE, adverse event; ASGE, American Society for Gastrointestinal Endoscopy; CBD, common bile duct; CO₂, carbon dioxide; FCSEMS, fully covered self-expandable metal stent; NSAID, non-steroidal anti-inflammatory drug; OR, odds ratio; PD, pancreatic duct; PEP, post-ERCP pancreatitis; PREM, patient-reported experience measure; PROM, patient-reported outcome measure; PSC, primary sclerosing cholangitis; RCT, randomized controlled trial; SEMS, self-expandable metal stent; UHE, unplanned health care encounter.

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