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Review Article

Quality Indicators of Endoscopic Retrograde Cholangiopancreatography in Korea

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Endoscopic retrograde cholangiopancreatography (ERCP) is a procedure that requires significant experiences and skills and has various procedure-related complications, some of which can be severe and even result in the death of patients. Expanding ERCP availability has the advantage of increasing accessibility for patients. However, ERCP poses a substantial risk if performed without proper quality management. ERCP quality management is essential for both ensuring safe and successful procedures and meeting the social demands for enhanced healthcare competitiveness and quality assurance. To address these concerns, the Korean Pancreatobiliary Association established a task force to develop ERCP quality indicators (QIs) tailored to the Korean medical environment. Key questions for five pre-procedure, three intra-procedure, and four post-procedure measures were formulated based on a literature search related to ERCP QIs and a comprehensive clinical review conducted by experts. The statements and recommendations regarding each QI item were selected through peer review. The developed ERCP QIs were reviewed by external experts based on the latest available evidence at the time of development. These domestically tailored ERCP QIs are expected to contribute considerably to improving ERCP quality in Korea. **(Gut Liver 2024;18:564-577)**

Key Words: Cholangiopancreatography, endoscopic retrograde; Quality improvement; Republic of Korea

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is a complex procedure that requires significant expertise and skills.[1] It involves accessing the bile and pancreatic ducts using an endoscope to diagnose and treat various conditions. Due to its technical complexity, ERCP carries the risk of complications, including bleeding, perforation, infection, ductal injury, and pancreatitis, some of which may be life-threatening.[2,3] Successful ERCP procedures depend on appropriate patient selection, proper procedural techniques, the use of appropriate equipment, and

a safe procedural environment. Therefore, effective ERCP quality management is essential to ensure the safety and efficacy. However, specific ERCP quality indicators (QIs) have not yet been established in Korea. To address these concerns, the Korean Pancreatobiliary Association (KPBA) has developed ERCP QIs tailored to the Korean medical environment. Developing ERCP QIs helps ensure that ERCP procedures are safely performed with minimal risk to patients by identifying potential risks and complications. It also guides clinicians to take appropriate precautions and interventions to enhance patient safety. The target audience for these ERCP QIs includes general clinicians, ERCP experts, clinical researchers, and healthcare policymakers that make ERCP-related policies. The ERCP QIs cover all patients undergoing ERCP and provide comprehensive recommendations for preprocedural, intraprocedural, and postprocedural management. The QIs focus on ensuring safe procedures, enhancing quality, preventing complications, providing early intervention when necessary, and offering guidance specific to the domestic healthcare context, ultimately improving the effectiveness and safety of ERCP procedures.

MATERIALS AND METHODS

1. Choice of committee members

The ERCP QIs Development Committee was composed of members from the KPBA Qualification Quality Management Committee, the ERCP/Endoscopic Ultrasound (EUS) Quality Management Research Society, and the methodology of guideline development experts. The development of ERCP QIs began on May 19, 2020, but was delayed owing to the coronavirus disease 2019 pandemic. Before starting ERCP QI development, all members were required to sign a document declaring no conflicts of interest. All members declared no conflicts of interest. The committee was led by the President of the ERCP/EUS Quality Management Research Society, Prof. Chang Hwan Park. Committee members selected the key questions, searched the literature, and drafted and revised the manuscript for the key questions. A researcher from the National Evidence-based Healthcare Collaborating Agency, Ms. Miyoung Choi, was recruited because it was decided that these QIs would be developed by applying the existing literature. The development committee evaluated the process with the assistance of methodology experts.

2. Literature research and selection

Committee members conducted a comprehensive search of the existing literature to identify studies and guidelines related to ERCP QIs that had been published in or before April 2022. Databases such as PubMed, EMBASE, and relevant medical journals were searched. Committee members also reviewed national and international guidelines related to ERCP QIs. The keywords used in the literature search were as follows: ERCP, QIs, quality measures, outcome assessment (healthcare), performance measures, quality improvement, quality assurance, clinical indicators, adverse events, complications, patient safety, procedure-related outcomes, procedure quality, and clinical guidelines. These keywords were used individually or combined in various search combinations to retrieve relevant articles and resources related to ERCP QIs.

The following criteria were used for literature selection: (1) peer-reviewed primary research, systematic reviews, meta-analyses, clinical trials, and observational studies related to ERCP QIs; (2) studies published in English and Korean; (3) studies that directly addressed ERCP QIs, quality improvement, safety, adverse events, complications, or procedure-related outcomes; (4) studies conducted on patients undergoing ERCP for various biliary and pancreatic conditions; and (5) studies conducted in various healthcare settings such as academic medical centers, community hospitals, or ambulatory care centers. The exclusion criteria were as follows: (1) studies that were not directly related to ERCP QIs, even if they involved endoscopic procedures or other interventions; (2) studies conducted solely on animals; (3) conference abstracts, unpublished works, and non-peer-reviewed sources to ensure the reliability of the literature; (4) duplicate publications or multiple reports of the same study to avoid redundancy; (5) studies with incomplete or insufficient data that prevented a thorough evaluation of ERCP QIs; and (6) studies with significant methodological flaws or potential bias that may compromise the validity of the findings. Based on the literature review, the committee members identified a list of potential candidate indicators that addressed key aspects of ERCP quality. These indicators included both process and outcome measures.

3. Selection of key questions

The committee held 10 meetings starting on May 19, 2020 and organized two workshops to establish the methodology for ERCP QI development and review the development process. The participants received training in development methodology, evidence-gathering methods, assigning recommendation grades, and achieving consensus on June 2, 2022. The development committee decided to use an adaptive approach because recently published ERCP QIs from other countries were well organized. ERCP QIs were developed through online and offline meetings.

Table 1. Summary of the Statements, Grades of Recommendation, and Levels of Evidence

Key question	Statement	Level of Evidence	Grade of recommendation
1	We recommend that ERCP operators should obtain a certificate in pancreaticobiliary endoscopy from the KPBA.	IV	B
2	We recommend minimizing the frequency of ERCP procedures for appropriate indications for at least 80% of all procedures. If the procedure is not indicated, clear documentation of the reasons for performing it should be included in the report.	II	B
3	We recommend that healthcare providers obtain written informed consent from patients, or if necessary, from their legal representative, before performing ERCP. The informed consent should include the following information: the tentative diagnosis, necessity of the procedure, method and details of the procedure, alternatives to the procedure, name of the medical staff explaining the procedure, names of medical staff participating in the procedure, and expected adverse effects.	III	A
4	We suggest assessing the procedural difficulty prior to the ERCP procedure, because the success rate and incidence of complications may vary depending on the level of difficulty.	II	C
5	We recommend avoiding the routine use of prophylactic antibiotics before ERCP procedures. However, selective use of prophylactic antibiotics should be considered in whom cholangitis may highly develop after ERCP.	I II	A C
6	We recommend a selective bile duct cannulation success rate of at least 90% in patients with a normal anatomy and naïve papilla.	II	A
7	We recommend a CBD stone extraction success rate of at least 90% in patients with a normal anatomy and stones smaller than 10 mm in size.	II	A
8	We recommend achieving a success rate of at least 90% for biliary stenting below the hepatic hilum using plastic or metallic stents, particularly when preceded by selective bile duct cannulation, in cases where incomplete drainage is expected, such as those with biliary strictures or incomplete CBD stone removal.	II	A
9	We recommend standardized reporting of ERCP procedures, including indications, findings, procedure details, and procedure-related complications, to enhance the quality of ERCP.	IV	A
10	We recommend maintaining the incidence of PEP below 10% in patients without risk factors for PEP.	II	B
11	We recommend maintaining a clinically significant bleeding rate of less than 1% in patients undergoing endoscopic sphincterotomy with a low risk of bleeding.	II	B
12	We recommend that the incidence of perforation should be maintained below 0.5% when performing ERCP in patients with a normal anatomy and no risk factors for perforation.	II	B

ERCP, endoscopic retrograde cholangiopancreatography; KPBA, Korean Pancreatobiliary Association; CBD, common bile duct; PEP, post-ERCP pancreatitis.

During the meetings, the facility and equipment aspects of ERCP and the recently developed Korean guidelines for sedation and disinfection were excluded from the key questions. Based on ERCP QIs published in the United States and Europe,[4-6] the development committee selected key questions, considering their clinical importance and the healthcare environment in Korea, resulting in five key pre-procedure, three intra-procedure, and four post-procedure questions (Table 1).

4. Determination of the level of evidence and grade of recommendation

Determining the level of evidence and grade of recommendation in developing ERCP QIs involves evaluating the strength of evidence and certainty of recommendations based on the available literature. The evidence was categorized into four levels: I, II, III, and IV. Level I indicates high-quality evidence from well-conducted randomized controlled studies or systematic reviews with consistent findings. Level II indicates moderate-quality evidence from clinical studies such as non-randomized trials or cohort studies. Level III represents a low level of relevant evidence such as observational studies or case series. Level IV comprises evidence from expert opinions based on clinical experience and expertise when there are limited or no relevant clinical trials or observational studies available. The grades of the recommendations were classified as follows: (1) grade A: a strong recommendation supported by clear evidence, where the benefits of the recommended intervention clearly outweigh the risks; (2) grade B: a moderate recommendation supported by reliable evidence, where the benefits of the recommended intervention outweigh the risks but with some uncertainty; (3) grade C: a weak recommendation, where the benefits and risks of the recommended intervention are closely balanced, and the best action may depend on individual patient preferences or clinical circumstances; and (4) grade D: not recommended due to lack of reliable evidence; the practice may result in harmful outcomes and has low utility in clinical practice.

5. Review and approval

In November 2022, a panel of 32 experts conducted an external review of the established ERCP QIs using a modified e-Delphi process on an online platform. The aim was to achieve an evidence-based consensus. This process involved custom online voting using a web-based platform. After each round of voting, the statements and evaluated texts were updated based on the feedback received, and the panel members scored each guideline on a 5-point scale. Statements that received complete agreement or agreement from two-thirds or more of the panel votes were accepted as final statements and recommendations (Fig. 1). An external review of the ERCP QIs was conducted at a public hearing on September 16, 2023. This event occurred during the autumn KPBA conference. The final ERCP QIs were supplemented and updated to reflect the results of the draft evaluation and public hearing.

6. Provision of the guidelines and plans for next updates

The developed ERCP QIs will be published for universal distribution. The ERCP QIs will be uploaded to the KPBA website (https://www.kpba.kr). Recognizing that rapid distribution of the guidelines to ERCP experts may be challenging through the traditional publishing process, the KPBA plans to overcome this limitation by distributing the guidelines free of charge via email and actively promoting them through academic conferences, seminars, and workshops. The current ERCP QIs are based on up-to-date research and will be subject to regular updates as new clinical evidence emerges. The KPBA Qualification Quality Management Committee and ERCP/EUS Quality Management Research Group will play key roles in the revision process.

7. Limitations

The ERCP QIs were developed based on the best available evidence at the time of development. However, the lack of domestic evidence may have led to a reliance on studies and guidelines from other countries, potentially limiting the generalizability of the QIs to the Korean context. Another limitation relates to reimbursement and insurance coverage. Certain procedures indicated by the ERCP QIs may face limitations in terms of reimbursement and insurance coverage, which could create challenges in implementing these QIs and hinder patient access to care.

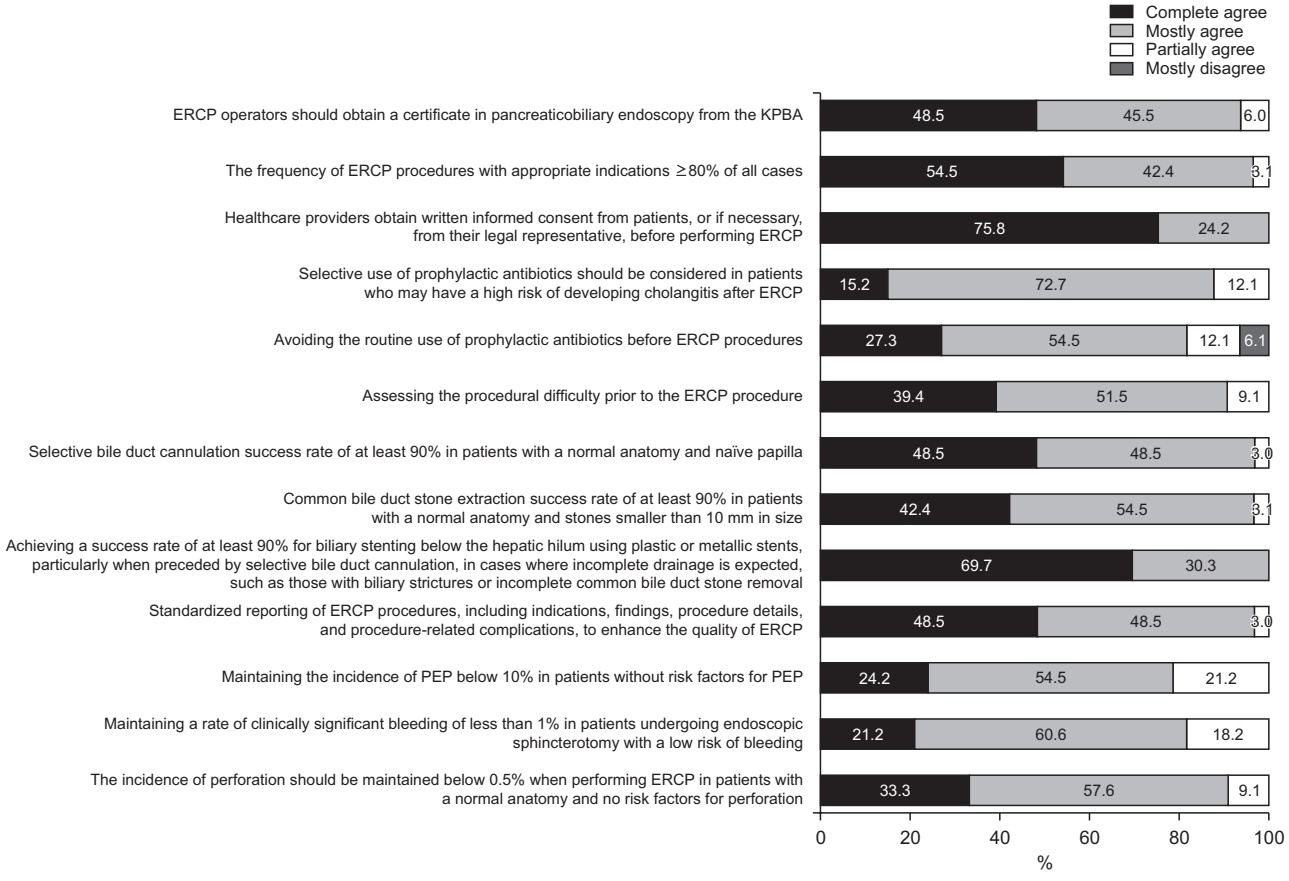

Fig. 1. The results of the modified e-Delphi process involving a panel of 32 experts regarding the statements. ERCP, endoscopic retrograde cholangiopancreatography; KPBA, Korean Pancreatobiliary Association; PEP, post-ERCP pancreatitis.

Regarding legal matters, it is important to understand that the ERCP QIs are not meant to establish an absolute standard of care or serve as examination criteria for health insurance or legal judgments for specific patients. These are designed to provide evidence-based indicators to assist clinicians in performing safe and effective procedures. Therefore, it may be inappropriate to rely solely on ERCP QIs to support legal judgments or malpractice claims. Legal decisions concerning medical practice should consider the specific circumstances of each patient, expertise of the treating physician, and adherence to accepted standards of care. ERCP QIs should be used as a reference and guide for medical practice; however, they should not be the sole determinants of legal matters related to medical practice.

ERCP QIs

1. Pre-procedure QIs

Key question 1. What necessary qualifications should operators have to enable them safely and effectively perform ERCP?

We recommend that ERCP operators should obtain a certificate in pancreaticobiliary endoscopy from the KPBA. (Evidence level IV, Grade of recommendation B)

ERCP is a technically demanding procedure with potential complications, making it crucial for the operator to possess skilled procedural abilities and sufficient experience. To safely and effectively perform ERCP, the operator should undergo a specialized training in ERCP procedures that includes both theoretical knowledge and practical hands-on experience. In addition, the operator should have performed ERCP a sufficient number of times because experience plays a critical role in achieving better outcomes and minimizing complications.

The 2015 American Society for Gastrointestinal Endoscopy (ASGE) QIs recommend that ERCP operators have appropriate qualifications and maintain records of the number of ERCP procedures performed annually.[4] However, to date, there is no clear definition of the specific qualifications and no officially recognized ERCP credentialing system in the United States. In the "ERCP Core Curriculum" published in 2006, a minimum of 180 ERCPs should be performed independently, with over 50% being therapeutic procedures.[7] In the United Kingdom, during the third year of a 5-year specialty training program, individuals interested in ERCP training are selected to document their procedural records. They must have performed a minimum of 75 ERCP procedures within the last year, undergone evaluation by two expert ERCP practitioners from other institutions, and achieved a complication rate of less than 5% and a therapeutic success rate of over 80% to receive certification upon completion.[8]

In Korea, a pancreaticobiliary endoscopy certification system has been implemented since 2022. To obtain pancreaticobiliary endoscopy certification, one must be a lifelong member of the KPBA, complete a minimum of 3 years of training at a certified training hospital, and perform at least 150 ERCPs as the primary operator. Certifying and maintaining an appropriate level of experience and competency among ERCP operators are critical aspects of ERCP quality management. By possessing these necessary qualifications, an operator can safely and effectively perform ERCP and provide optimal care for patients undergoing this complex procedure.

Key question 2. How frequently should ERCP procedures be performed for appropriate indications?

We recommend minimizing the frequency of ERCP procedures for appropriate indications for at least 80% of all procedures. If the procedure is not indicated, clear documentation of the reasons for performing it should be included in the report. (Evidence level II, Grade of recommendation B)

ERCP is the gold standard for diagnosing biliary and pancreatic diseases; however, it carries a risk of serious complications. Hence, performing the procedure only when it is indicated is crucial. With advancements in radiological techniques, the indications for ERCP have shifted from purely diagnostic to therapeutic purposes. The ASGE 2015 guidelines provide indications for ERCP and recommend that >90% of all procedures should be performed for those indications.[4] This higher target of 90% is set because the occurrence of serious complications can be high when the procedure is performed beyond the recommended indications. However, due to the continuous evolution of ERCP with the development of new devices and technologies, the indications for the procedure are not easily defined. Therefore, taking these factors into consideration, the ERCP QIs Development Committee recommends maintaining the frequency of procedures for appropriate indications at 80% or higher. In cases where the procedure does not align with the legitimate indications, it is recommended that the reason for the procedure should be documented in the ERCP report.

Key question 3. Is it necessary to obtain informed consent before performing ERCP?

We recommend that healthcare providers obtain written informed consent from patients, or if neces-

sary, from their legal representative, before performing ERCP. The informed consent should include the following information: the tentative diagnosis, necessity of the procedure, method and details of the procedure, alternatives to the procedure, name of the medical staff explaining the procedure, names of medical staff participating in the procedure, and expected adverse effects. (Evidence level III, Grade of recommendation A)

Informed consent refers to the explicit agreement of a patient to undergo specific medical procedures. Performing a procedure without patient consent can potentially result in legal issues. The 24-2 of the Korean Medical Law provides detailed information on informed consent. The informed consent form obtained prior to ERCP should include a description of the nature and method of the procedure, indications and necessity of the procedure, benefits and limitations of the procedure, potential complications that may arise from the procedure, and an explanation of alternative treatment options.[4,9,10] Additionally, the consent form for ERCP should mention and explain the following six complications: (1) acute pancreatitis, (2) bleeding, (3) infection, (4) cardiovascular complications, (5) hypersensitivity reactions, and (6) perforation.[4] Furthermore, due to the severity of potential complications associated with ERCP, it should be explained in the consent form that interventional procedures and surgery may be necessary for the treatment of complications. It should also be clarified that if the intended procedure is unsuccessful, additional procedures may be required. Obtaining informed consent is crucial to ensure patient understanding and acceptance of the risks and possible outcomes of the ERCP procedure.

Key question 4. Is it necessary to assess procedural difficulty prior to performing an ERCP procedure?

We suggest assessing the procedural difficulty prior to the ERCP procedure, because the success rate and incidence of complications may vary depending on the level of difficulty. (Evidence level II, Grade of recommendation C)

To date, four methods have been proposed to evaluate the difficulty of ERCP: (1) the method by Schutz *et al.* in 2000; (2) Morriston scale in 2003; (3) ASGE grading system in 2011; and (4) HOUSE classification in 2017.[11-14] Schutz and Abbott[11] suggested a five-grade ERCP difficulty classification based on the purpose of the procedure (diagnostic vs therapeutic) or target organ (pancreas or bile duct). Retrospective and prospective studies have been conducted using these scales. The retrospective study showed a higher technical success rate (94% vs 74%, $p<0.05$) and a lower complication rate (2% vs 10%, $p=0.028$) in grades 1–4B than in grades 5–5B.[11] In the prospective study, there was a statistically significant difference in the technical success rates between the two groups (96.4% vs 65.9%, $p<0.001$), but no significant difference in complications (4.3% vs 8.7%, $p>0.05$).[11] The Morriston scale classified ERCP difficulty into four grades. In a retrospective study conducted over 1 year, procedures with the lowest level of difficulty had a higher procedure success rate (87% vs 63%) and lower incidence of complications (4% vs 9%) than those with the highest level of difficulty.[12] The ASGE grading system divided the difficulty level into four grades, with an additional grade for emergency procedures, previous failed procedures, or procedures in patients who had undergone Billroth II gastrectomy.[13] Two different prospective observational studies were performed that included 4,561 and 8,578 ERCP procedures.[15,16] Both studies showed that the procedural success rate was lower in high-grade procedures than in low-grade procedures based on the modified Schutz *et al.* grading system. In a retrospective study analyzing 1,355 ERCP cases using the ASGE grading system, there were significant differences in successful selective biliary intubation and the incidence of procedural perforation rates between procedures with high and low difficulty.[17] The most recently published HOUSE classification divided ERCP procedure difficulty into three levels and included the latest procedures such as EUS-guided rendezvous technique, small intestine endoscopy, and confocal endoscopy.[14] In a retrospective analysis of 1,931 ERCP procedures performed over 2 years, significant intergroup differences were observed in procedure time (40±0.7 minutes vs 65±1.5 minutes vs 106±3.2 minutes, $p<0.001$) and postoperative complication rate (11.1% vs 15.7% vs 12.8%, $p=0.0305$). Therefore, evaluating the difficulty of the ERCP procedure before performing it can predict the success and complication rates. However, there is currently no ERCP difficulty evaluation method suitable for the Korean medical context; therefore, developing a Korean ERCP difficulty grading system is an important step in establishing appropriate ERCP training programs and determining ERCP reimbursements.

Key question 5. Should prophylactic antibiotics be used before ERCP procedures?

We recommend avoiding the routine use of prophylactic antibiotics before ERCP procedures (Evidence level I, Grade of recommendation A). However, selective use of prophylactic antibiotics should be considered in whom cholangitis may highly develop after ERCP (Evidence level II, Grade of recommendation C).

Post-ERCP infections, such as cholangitis or sepsis, occur in approximately 0.5% to 3% of procedures.[18] Numerous studies have investigated the effectiveness of prophylactic antibiotic use in preventing infections after ERCP. Some studies have shown that prophylactic antibiotics can reduce the incidence of bacteremia, but no significant preventive effect on cholangitis after ERCP has been observed.[19-21] A meta-analysis of seven studies concluded that prophylactic antibiotic use does not significantly reduce the incidence of cholangitis or sepsis after ERCP.[22] Similarly, a Cochrane review found no significant difference in the incidence of postoperative cholangitis between patients who received prophylactic antibiotics and those who did not in cases where biliary obstruction was successfully resolved following initial ERCP.[23]

The indiscriminate use of prophylactic antibiotics can increase economic costs, the risk of allergic reactions, pseudomembranous colitis, and the development of multidrug-resistant bacteria. Therefore, caution should be exercised in this regard. However, in certain cases in which a high incidence of cholangitis after ERCP is anticipated, appropriate prophylactic antibiotic use is recommended. Insufficient bile duct drainage is the most important risk factor for the development of cholangitis.[24,25] Therefore, antibiotic prophylaxis is generally recommended for patients with hilar cholangiocarcinoma and primary sclerosing cholangitis who are at risk of insufficient bile duct drainage.[26-29] Prophylactic antibiotic use is also recommended for cholangioscopy-guided procedures, as they have been associated with an increased risk of cholangitis or bacteremia.[30-32] Prophylactic antibiotic administration may also be considered in patients with severe immunodeficiency (e.g., absolute neutrophil count <500 cells/mm^3), advanced hematologic malignancy, liver transplantation, pancreatic pseudocyst communicating with the main pancreatic duct, or obstructive jaundice.[4,33-35]

2. Intra-procedure QIs

Key question 6. What is the optimal selective bile duct cannulation rate?

We recommend a selective bile duct cannulation success rate of at least 90% in patients with a normal anatomy and naïve papilla. (Evidence level II, Grade of recommendation A)

Selective cannulation of the bile duct is a crucial step in performing a successful ERCP; however, it can be challenging, even for experienced endoscopists. Successful selective biliary cannulation is defined as the insertion of a guidewire into the bile duct through the duodenal papilla. Failure to achieve selective biliary cannulation can increase the risk of complications such as post-ERCP pancreatitis (PEP), hemorrhage, or perforation, leading to additional therapy and delayed procedures that can burden the patient.[36] Therefore, maintaining a high success rate of selective bile duct cannulation is an important QI for ERCP.

Difficult bile duct cannulation refers to the challenge encountered by endoscopists during the ERCP in accessing and successfully inserting a cannula or guidewire into the bile duct. The specific criteria for defining difficult bile duct cannulation can vary among healthcare providers and clinical settings, however, but it is generally characterized by repeated attempts, prolonged duration, or the need for specialized techniques or equipment to successfully navigate the cannula or guidewire into the bile duct.[36] According to the European Society of Gastrointestinal Endoscopy (ESGE) guideline, difficult bile duct cannulation in a naïve papilla, is defined by either more than five repeated attempts, a duration exceeding 5 minutes, or more than one unintentional pancreatic duct cannulation or opacification.[37] The difficulty of bile duct cannulation arises due to various factors, which may include anatomical variations, type of papilla, previous surgeries, inflammation, strictures, the presence of stones or other obstructions, dysfunction of the sphincter of Oddi, and other technical or patient preparation.[38] Certain cases are excluded when calculating the success rate of selective biliary cannulation, including those with inadequate sedation, retention of gastric contents, surgically altered anatomy, failure due to pyloric or duodenal strictures, and history of papillary balloon dilatation or sphincterotomy.

In cases where selective bile duct cannulation proves challenging with the conventional method using a sphincterotome or standard catheter, alternative techniques including needle-knife fistulotomy, needle-knife precut papillotomy, or transpancreatic septotomy may be used. Additionally, salvage techniques such as EUS or percutaneous transhepatic biliary drainage-guided rendezvous procedures could also be considered depending on the operator's experience or preference.

A systematic review of 52 studies reported a weighted success rate of selective biliary cannulation of 89.3% (95% confidence interval [CI], 0.866 to 0.919).[39] The ASGE and ESGE guidelines recommend maintaining a success rate of ≥90% for selective bile duct intubation.[4,35] Because selective bile duct cannulation is a fundamental and vital technique in ERCP, efforts should be made to achieve a high success rate through adequate training and experience. According to the QIs in other countries, maintaining a success rate of at least 90% for selective bile duct intubation in ERCP patients without anatomical abnormalities or a history of

papillary balloon dilatation or sphincterotomy should be considered.

Key question 7. What is the optimal success rate for extracting common bile duct (CBD) stones during ERCP?

We recommend a CBD stone extraction success rate of at least 90% in patients with a normal anatomy and stones smaller than 10 mm in size. (Evidence level II, Grade of recommendation A)

CBD stones are one of the most common indications for ERCP.[40] It is well-known that retained CBD stones can contribute to post-ERCP cholangitis.[18] A systematic review has shown that approximately 20% of patients with post-ERCP cholangitis develop severe infection, with a mortality rate of 0.1%.[41] Hence, complete extraction of CBD stones is crucial in preventing complications associated with ERCP. Carr-Locke[42] reported that experienced endoscopists can successfully perform CBD stone extraction using various techniques such as basket extraction, balloon catheter extraction, mechanical lithotripsy, or electrohydraulic lithotripsy, regardless of stone size. Another study demonstrated that CBD stones smaller than 10 mm can be completely removed in over 90% of patients with normal anatomy using techniques such as papillotomy, balloon catheter extraction, and basket extraction.[43] ASGE and ESGE guidelines recommend a CBD stone removal rate of 90% or higher for stones measuring 10 mm or less in patients with normal anatomy.[4,35] However, there are currently no established guidelines for the removal of gallstones larger than 10 mm or for patients with anatomical alterations due to prior surgeries. For trainees learning ERCP, the standards for CBD stone removal rates vary across countries. The British Society of Gastroenterology suggests a CBD stone removal rate of 75% or higher for trainees, whereas the KPBA guidelines recommend a minimum success rate of 85% for full-time ERCP trainees.[44,45]

Key question 8. What is the optimal success rate of stent placement for proper biliary drainage below the hepatic hilum?

We recommend achieving a success rate of at least 90% for biliary stenting below the hepatic hilum using plastic or metallic stents, particularly when preceded by selective bile duct cannulation, in cases where incomplete drainage is expected, such as those with biliary strictures or incomplete CBD stone removal. (Evidence level II, Grade of recommendation A)

Inadequate biliary drainage can lead to post-ERCP cholangitis, and in severe cases, it can even result in death. Therefore, ERCP operators must possess the technical skills required to perform biliary drainage successfully. This includes accurately determining the type, length, diameter, and location of the stent, particularly when bile duct obstruction is suspected or anticipated. The success rate of stent placement for proper biliary drainage below the hepatic hilum can vary depending on various factors such as the underlying condition, skill of the operator, and patient's overall condition. According to the guidelines provided by the ASGE and ESGE, the recommended performance targets for stent placement below the hepatic hilum are at least 90% and 95%, respectively.[4,35]

A prospective study conducted in 2014 at a tertiary medical center in the Netherlands involved ERCP endoscopists and utilized the Rotterdam Assessment Form for ERCP to measure QIs.[46] The study reported an overall success rate of biliary cannulation of 97.8%. Among the patients with biliary obstruction, selective duct cannulation was successful in 98.4%, whereas successful stent placement in the biliary duct was achieved in 96.8%.

In a meta-analysis conducted by DeBenedet *et al.*[39] in 2013, which included 52 studies on QIs of ERCP procedures, the overall success rate of biliary stent placement was 97.5%. Analyzing success rates by continent, North American, European, Asian, and Australian studies showed 99.8%, 96%, 100%, and 97% technical success rates, respectively. However, it is important to note that in most studies, the procedures were performed by experienced ERCP endoscopists in tertiary or university hospitals, which may have limited the generalizability of the results.

Another prospective survey by Ekkelenkamp *et al.*[16] reported a successful biliary stent placement rate of approximately 86% for overall biliary obstruction. However, this study did not differentiate between the success of selective duct cannulation and that of overall biliary stent placement. Therefore, if only cases with successful selective duct cannulation were considered, the success rate of biliary stent placement would likely be higher. Although specific numbers may vary depending on the study or clinical setting, the optimal success rate for stent placement below the hepatic hilum should exceed 90% when preceded by selective bile duct cannulation.

3. Post-procedure QIs

Key question 9. Does standardized reporting of ERCP procedures contribute to quality management?

We recommend standardized reporting of ERCP procedures, including indications, findings, procedure details, and procedure-related complications, to enhance

the quality of ERCP. (Evidence level IV, Grade of recommendation A)

The ERCP report provides a comprehensive and detailed account of the procedure, including the findings, interventions performed, and complications encountered. It plays a vital role in guiding patient management, facilitating decision-making, and ensuring optimal care. This report provides essential information about the visualized anatomy, enabling accurate diagnosis and treatment planning. It includes details of interventions such as sphincterotomy, stent placement, or balloon dilation, which are valuable for reference and future procedures. Complications or adverse events are documented to evaluate the safety and effectiveness of the procedure and guide further management if required. The ERCP report serves as a permanent record that can be reviewed by the performing healthcare provider and other specialists involved in the patient's care, ensuring effective communication and continuity of care. ASGE guidelines emphasize the importance of the ERCP report as a QI, recommending its documentation with a performance target above 98%.[4] According to the ASGE guidelines, the report should include details of the devices used, objective descriptions of the images, any complications, unintended cannulation or contrast injection into the pancreatic duct, and achievement of the purpose of the procedure.

Key question 10. Can the incidence of acute pancreatitis be effectively managed in patients undergoing ERCP?

We recommend maintaining the incidence of PEP below 10% in patients without risk factors for PEP. (Evidence level II, Grade of recommendation B)

PEP is one of the most common and serious complications of ERCP. The incidence of PEP is influenced by various factors related to the patient and the procedure, and these risk factors should be considered when planning ERCP.[41,47] PEP is defined as the development of abdominal pain, indicative of pancreatitis, with a serum amylase level of at least three times the upper limit of the normal within 24 hours after the procedure, requiring hospitalization for at least 2 days.[48]

A prospective observational study conducted in six Korean institutions reported a PEP incidence rate of 9%.[49] In two meta-analyses, PEP incidence rates of 3.5% and 9.7% were observed, and the incidence rate was up to 14.7% in high-risk patients.[41,47] Based on these findings, the 2018 ESGE guidelines recommend maintaining the incidence of PEP below 10%.[35] The 2020 ESGE guidelines on ERCP-related adverse events reported that the incidence of PEP ranged between 3.5 and 9.7% in patients with a general risk profile.[18]

Established risk factors for PEP include a history of PEP, younger age, female sex, sphincter of Oddi dysfunction, normal bilirubin levels, and difficult cannulation or main pancreatic duct injection.[50,51] Analyzing the risk factors for PEP can help in developing prevention and monitoring strategies for patients. Therefore, ERCP operators should conduct risk factor analyses for PEP, provide suitable preventive and treatment measures, and aim to maintain the incidence rate of PEP below 10% in patients without risk factors for PEP.

The severity of PEP can be classified as mild, moderate, or severe based on the duration of hospitalization and associated complications. Complications such as hemorrhagic pancreatitis, pancreatic necrosis, and pseudoaneurysm are more commonly observed in severe cases of pancreatitis, which often necessitate intervention.[52] While the majority of PEP cases are mild, a PEP-related mortality rate of approximately 0.1% to 0.7% has been reported.[41,53] Therefore, several measures should be implemented to reduce the incidence of PEP. These include vigorous periprocedural hydration with lactated Ringer's solution, pharmacological interventions, such as rectal administration of nonsteroidal anti-inflammatory drugs or the use of pancreatic duct stents.[54-56] Close monitoring of patients after ERCP and prompt recognition of early signs of PEP can facilitate timely intervention. Adequate postprocedural hydration and effective pain management are also critical.

Key question 11. What is the acceptable incidence rate of bleeding in patients undergoing endoscopic sphincterotomy (EST)?

We recommend maintaining a clinically significant bleeding rate of less than 1% in patients undergoing EST with a low risk of bleeding. (Evidence level II, Grade of recommendation B)

The incidence of bleeding in patients undergoing EST varies depending on several factors, including patient characteristics, underlying conditions, operator skill, and procedural techniques. However, the overall incidence of bleeding after ES is relatively low. In a meta-analysis of 21 prospective studies on complications of ERCP, bleeding associated with ERCP was reported to be approximately 1%.[41] Most of the bleeding were mild and occurred within the gastrointestinal tract; however, the mortality rate was reported to be 3.5%. Korean studies have also reported the frequency of clinically significant bleeding after ERCP to be approximately 1%.[49,57] In a prospective observational

study conducted in six Korean institutions over a year, post-ERCP bleeding was reported to be 0.6% (7/1,191), with a higher tendency for bleeding observed in patients with chronic liver disease, a history of previous pancreatitis, pancreatic duct sphincterotomy, and procedures performed by inexperienced operators.[49] A retrospective analysis from a single institution between 2006 and 2013 reported a bleeding frequency of 1.2% (13/1,112), with longer EST length associated with an increased risk of bleeding.[57]

Bleeding can be classified as immediate bleeding, occurring during or shortly after the procedure, and delayed bleeding, which presents within 10 days after the procedure with clinical symptoms such as melena and causes hemoglobin level reduction or requires blood transfusion.[4] Risk factors that increase the frequency of bleeding after EST include coagulation disorders, acute cholangitis, the use of anticoagulants within 3 days after the procedure, and performance of the procedure by an inexperienced operator.[58] Furthermore, the risk of bleeding is significantly higher in endoscopic papillectomy than in conventional EST. In cases involving the use of aspirin alone, ERCP can be safely performed without discontinuing the medication except when endoscopic papillectomy is performed.[59,60] Bleeding in ERCP is primarily associated with the electrocautery used during EST; therefore, the risk of bleeding is minimal in cases where EST is not performed (e.g., diagnostic ERCP and stent insertion without EST). The ASGE guidelines suggest maintaining a bleeding rate after EST of less than 1% as a grade 1C recommendation.[7]

Key question 12. What is the acceptable incidence of perforation in patients undergoing ERCP?

We recommend that the incidence of perforation should be maintained below 0.5% when performing ERCP on patients with a normal anatomy and no risk factors for perforation. (Evidence level II, Grade of recommendation B)

Endoscopy-related iatrogenic perforation is associated with a high mortality rate, necessitating accurate and prompt diagnosis and treatment.[61] The frequency of perforation associated with ERCP can vary, ranging from as low as 0.08% to as high as 0.6%.[62] The associated mortality rate is reported to be 9.9%.[41] ERCP-related perforation can be classified into four types based on the commonly observed sites and mechanisms of occurrence, as categorized by Stapfer *et al.*[63] Type I involves direct perforation of the duodenal wall or mucosa by a duodenoscope, and it accounts for approximately 15% to 20% of all duodenal perforations and commonly occurs in patients with prior abdominal surgery and anatomical variations. Type II involves periampullary perforations and is most frequently associated with duodenal incisions or the use of wire-guided techniques during ERCP. Type III involves perforation of the bile or pancreatic duct and often results from excessive mechanical trauma during manipulation with devices such as baskets or guidewires. Lastly, type IV refers to the presence of only intraperitoneal air without any associated clinical symptoms, likely caused by air passage through the duodenal wall; this rarely induces significant symptoms.[64]

Risk factors for perforation during ERCP can be categorized as patient-related factors, including impaired sphincter of Oddi function (odds ratio, 3.8; 95% CI, 1.4 to 11.0), dilated bile duct (odds ratio, 4.07; 95% CI, 1.63 to 10.18), history of previous surgeries, and abnormal anatomical structures such as that following Billroth II gastrectomy, and procedure-related factors including duodenal incision (odds ratio, 9.0; 95% CI, 3.2 to 28.1), endoscopic papillary balloon dilation (odds ratio, 7.2; 95% CI, 1.63 to 10.18), prolonged procedure time (odds ratio, 1.021; 95% CI, 1.006 to 1.036), and challenging procedures.[65] Therefore, considering the possibility of perforation in patients with these risk factors or in cases where the procedure is challenging and closely monitoring patients' symptoms and imaging findings are important.

In particular, Billroth II gastrectomy is associated with direct duodenal wall damage (Stapfer type I) and an increased risk of ERCP-related perforation. According to a retrospective study, perforation occurred in 1.8% of patients who underwent ERCP after Billroth II gastrectomy.[66] Several small-scale studies have also reported that Billroth II gastrectomy and challenging procedures are risk factors for ERCP-related duodenal perforation.[67,68] To prevent ERCP-related perforation in such patients, various methods have been introduced, including the use of forward-viewing endoscopes rather than side-viewing endoscopes, caps on forward-viewing endoscopes, over-tubes, and balloon-assisted enteroscopy.[69-71] In particular, forward-viewing endoscopy has been recommended for safe procedures due to its similar duodenal and bile duct insertion success rates and its lower incidence of perforation than that of side-viewing endoscopy.

The ASGE guidelines recommend maintaining an ERCP-related perforation rate of less than 0.2% as a grade 2C recommendation.[4] They also advise recording and tracking the incidence of perforations. The expected incidence of ERCP-related perforations in patients with normal anatomy is less than 1%. However, the incidence of ERCP-related perforations varies across countries and regions owing to differences in patient populations, procedural techniques, operator experience, and healthcare

practices. Advances in endoscopic techniques, improved training, and better patient selection may contribute to the variations in perforation rates. Overall, maintaining an ERCP-related perforation rate below 0.5% is considered a reasonable and attainable target in patients with a normal anatomy and no risk factors for perforation.

CONCLUSION

ERCP is a complex and invasive procedure with potential risks and complications. ERCP QIs help healthcare providers to systematically assess and monitor the safety of ERCP procedures, leading to improved patient outcomes and reduced adverse events. The development of ERCP QIs involves a comprehensive review of the available evidence and expert consensus. By adhering to evidence-based QIs, healthcare providers can take necessary precautions and measures to minimize adverse events during and after ERCP. ERCP QIs promote standardized guidelines and best practices for performing the procedure. Consistent adherence to these QIs ensures that patients receive uniform and high-quality care across different healthcare settings. ERCP QIs can be utilized as benchmarks for regulatory compliance and accreditation programs to ensure that healthcare facilities meet established quality standards. Developing and adhering to ERCP QIs can enhance patients' trust, confidence, and satisfaction with the healthcare system. By improving patient safety and outcomes, ERCP QIs can potentially reduce the healthcare costs associated with managing complications and adverse events.

In conclusion, ERCP QIs are crucial for improving patient safety, standardizing care, driving continuous quality improvement, and ensuring evidence-based practice. They not only benefit patients but also enhance the overall efficiency and competitiveness of healthcare facilities in providing high-quality ERCP services.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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