REVIEW

Clin Endosc 2023;56:290-297 https://doi.org/10.5946/ce.2022.210 pISSN: 2234-2400 • eISSN: 2234-2443

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Quality indicators in endoscopic retrograde cholangiopancreatography: a brief review of established guidelines

Zubin Dev Sharma, Rajesh Puri

Institute of Digestive and Hepatobiliary Sciences, Medanta Medicity, Gurugram, India

Endoscopic retrograde cholangiopancreatography (ERCP) is an invasive endoscopic technique that has many diagnostic and therapeutic implications. It is a procedure with small but significant life-threatening complications. To ensure the best possible care, minimize complications, and improve the quality of health care, a constant review of the performance of the operator using ideal benchmark standards is needed. Hence, quality indicators are necessary. The American and European Societies of Gastrointestinal Endoscopy have provided guidelines on quality measures for ERCP, which describe the skills to be developed and training to be implemented in performing quality ERCP. These guidelines have divided the indicators into pre-procedure, intraprocedural, and post-procedure measures. The focus of this article was to review the quality indicators of ERCP.

Keywords: Benchmark; Cholangiopancreatography, endoscopic retrograde; Endoscopy; Healthcare; Quality indicators; Training

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is an interventional endoscopic procedure used for various pancreaticobiliary conditions. It has primarily therapeutic indications and has also been used in the past for diagnostic indications. From its initial development, it has evolved to include many advanced interventions for which standardized skill sets are needed to maintain quality. Various quality indicators have been introduced by multiple societies that have tried to streamline the criteria used to assess an endoscopist's skill set and enhance

the delivery of healthcare to patients. In this review, we discuss these indicators and briefly review the data available regarding their application.

BRIEF HISTORY OF ERCP

ERCP was first developed as a diagnostic tool in the 1960s. Patients were injected with contrast dye and referred to an interventional radiologist or surgeon for further treatment.¹⁻⁴

The first successful ERCP was performed by Dr. William S. McCune using a fiber duodenoscope with an external accessory channel taped to the scope shaft and a balloon for cannulation. Subsequently, many endoscopists developed and fine-tuned the skill set required for successful ERCP. With the advent of newer technologies, such as spyglass, laser lithotripsy, disposable duodenoscopes, and use of ERCP for the management of complex pancreatobiliary conditions, skills need to be continuously updated and developed by the user.

Dr. Peter Cotton, in his classical description, demonstrated cannulation in 60 patients in 1972. At almost the same time, the

Received: August 22, 2022 Revised: September 3, 2022 Accepted: September 18, 2022

Correspondence: Zubin Dev Sharma

DNB-Gastroenterology, Institute of Digestive and Hepatobiliary Sciences, Medanta Medicity, Gurugram, India E-mail: drzubinsharma@gmail.com

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With advent of endoscopic ultrasound (EUS), magnetic resonance cholangiopancreatography, and computed tomography scans, the need for diagnostic ERCP has greatly declined, and ERCP primarily remains as a therapeutic modality. There is a clear consensus among experts around the world that ERCP should no longer be used in diagnostic conditions.

STANDARD INDICATORS FOR ERCP

ERCP is a technically demanding procedure for beginner endoscopists. It involves a significant understanding of many aspects including handling the duodenoscope, patient positions, angles of ducts, and understanding the contrast or air cholangiogram, including various normal variations. It also involves training for appropriate indications, assessment of pre-procedure imaging, planning of the procedure, and the actual skills needed, followed by post-procedure care. It is also important for endoscopists to identify and manage possible complications. This is required so that the patient receives an indicated procedure for a relevant diagnosis, with therapy performed and accomplished with minimum risk. Hence, quality indicators can be useful in programs to improve the overall quality of endoscopic services.

Various ERCP-specific indicators have been developed over the years to help mentors assess the skills of endoscopists, and to have quantified criteria for assessing the outcomes of health-care delivery in the field of interventional or therapeutic ERCP. Quality indicators are defined as broadly objective criteria wherever feasible or standards in healthcare delivery against which an endoscopist or a healthcare delivery provider can be compared and assessed. A quality indicator is usually reported as the ratio of the incidence of correct performance to the opportunity for correct performance or as the ratio of interventions that achieve a predefined outcome. Some of these definitions may not be accurately applied to a procedural skill, where sometimes more subjective criteria or mentor assessment have been traditionally utilized for assessment of the endoscopist's competence.

Various recommendations have been made to identify and define these quality indicators. The American Society of Gastrointestinal Endoscopy (ASGE), American College of Gastroenterology (ACG), and European Society of Gastrointestinal

Endoscopy (ESGE) have established performance indicators for ERCP. ASGE, ACG, ESGE, and other societies, such as the United European Gastroenterology (UEG), have clarified the need for a quality assessment. Most societies have focused on metrics that impact either clinically relevant outcomes or quality of life.

In 2006, ASGE/ACG introduced the first version of their recommendations on quality in endoscopy, these defined the initial quality indicators that were eventually applied to all endoscopic procedures. These data have developed considerably with more studies becoming available and newer metrics appearing. The guidelines were updated in 2015. They gave importance to the indicators that had wider clinical application and were validated in more studies. Quality indicators were classified into outcome indicators or process indicators. ⁵ ESGE/UEG also suggested that, while assessing an endoscopist, approximately 100 consecutive procedures must be assessed to measure a valid indicator.

Both societies divided quality indicators into three domains: pre-procedure, intraprocedure, and post-procedure. We will discuss indicators in the same domains and classifications.

Pre-procedure quality indicators

Pre-procedure quality indicators assess the appropriateness of the procedure and ability of the endoscopist in risk assessment and planning of the procedure. The indicators are a clear indication, clear informed consent, assessment of risk, safe sedation plan, clinical decision making for antibiotic and antithrombotic drugs management, and procedure timeliness. Endoscopists and other staff members must discuss the expected outcomes of the procedure and make informed assumptions about the duration, which may vary according to the difficulty of the anticipated procedure. Establishing a clear plan and communicating as a team is essential for sedation duration and safe outcomes.

Indicators that are a priority for ERCP include informed consent, which must emphasize the associated risks. Adverse events must be clearly explained and should focus on at least six possible outcomes: pancreatitis, hemorrhage, infection, cardiopulmonary events, allergic reactions, and perforation. It is also important to document the consent and, if asked, be ready with institute- or doctor-specific rates of adverse events. This may also have significant medicolegal implications. Patients must also be informed that the procedure may not be successful and that additional procedures may be warranted. The extended medical needs following the occurrence of adverse events should be explained in terms of the need for blood transfusions,



surgery, or extended hospital stay. It may also be beneficial if a diagrammatic representation of the procedure is made for better understanding by patients who may have difficulties in reading or language barriers.

1) Frequency of ERCP performed for appropriate indications: priority indicator

This is one of the important process indicators with a performance target of more than 90%, as per ASGE/ESGE guidelines.⁷ A clear indication must be documented, and in cases of unclear indication, this should be explained and documented in the consent itself. This is extremely important, as the yield of ERCP in these clinical situations is usually low, and the risk of adverse events is higher and disproportionately severe. ERCP for such indications is often performed after appropriate patient consultation and consent, preferably at high-volume referral centers.

2) Pre-prophylaxis

Antibiotics prior to the procedure can be considered in patients with clinical evidence or signs of cholangitis, in patients with biliary obstruction in whom complete drainage of the biliary tree cannot be achieved, and in patients who are at risk of infection.⁸

3) Percentage of ERCP by trained endoscopists

This is usually not a relevant clinical indicator as data has shown that even during randomized control trials, it may not reflect adverse events. However, expert opinion suggests that a well-trained endoscopist, trained specifically for ERCP, can perform safe and effective quality examinations, due to the increased complexity and risk of adverse events associated with the procedure. According to the available data, operators with varying levels of expertise and procedure volumes have varying results. Currently, this is usually not used as a quality indicator. The main issue is that different individuals may have different learning curves; therefore, it is extremely difficult to quantify the minimum number needed to gain expertise. Many studies and guidelines by various societies have tried to address this question, but there is still no consensus about who should be classified as a "trained" ERCPist.

4) Record of the volumes of ERCP performed

All performance metrics depend on adequate reporting of adverse events. According to one study, endoscopists who performed approximately 50 yearly ERCPs had lower success rates and more adverse effects, whereas those who performed at least one sphincterotomy each week had fewer adverse events.⁵ Hence, the number of ERCP procedures performed by each operator, their success rates, and adverse events should be well documented. This is one of the important parameters across institutes, as most require clear documentation of intervention-based procedures. A recent proposal from a research team at the Erasmus Medical Center in Rotterdam, the Netherlands, suggested a self-assessment program to improve endoscopy quality measurement. The Rotterdam Assessment Form for ERCP was created from a form completed by each endoscopist who participated in the study. 10 The form was completed after the procedure, and had both objective and subjective criteria. Despite limitations, such as the study was conducted in a single tertiary center and the impact of trainee involvement was not studied, the outcomes were significant. With a sample size of 1,651, the researchers concluded that there was no relationship between the volume and performance of practicing endoscopists. The endoscopist with the lowest volume did not perform worst. Since each individual has a different learning curve for ERCP, the use of the quantified numbers performing ERCP as a quality indicator can be controversial.

Intraprocedural quality indicators

This time period extends from the administration of anesthesia to duodenoscope removal.⁶ This period encompasses the technical aspects of the procedure, therapeutic interventions, and provision of sedation and patient monitoring. Intraprocedural quality indicators are usually the following:

1) Cannulation rate: priority indicator

Successful cannulation of the desired duct (biliary or pancreatic) is one of the most important and stressful steps for successful ERCP. It is considered one of the priority indicators, but with caveats. However, this must be documented in all cases. Successful cannulation and an understanding of the different methods of cannulation are important aspects of training for ERCP. A meta-analysis suggested that cannulation rates (%) in practice are usually in the high 80% to 90%, with documented differences across the world. Some data suggest that quantifying successful biliary cannulation in native anatomy has implications for successful independent ERCP of the trainee. Ideally, recording cannulation rates should exclude abnormal anatomy, altered anatomy (due to previous surgeries), or failed examinations due to inadequate sedation. According to the

established guidelines, in ERCP, endoscopists are expected to cannulate the duct of interest in >90% of procedures of mild to moderate difficulty. Although there is a caveat or point of contention, that it does not elaborate on the type or method of access achieved. The expert consensus of the ASGE/ACG task force recommended that physicians with consistently suboptimal cannulation rates (<80% success) should consider further training or discontinuing their ERCP practice and avoid attempting complex ERCP cases.

The UK Joint Advisory Group consensus statements for training and certification in ERCP, published in 2021, emphasize that while selective cannulation success rate is an important determinant of ERCP performance, it should not be used as the sole indicator of competence.¹⁴ We emphasize the fact that cannulation rate is an important parameter to assess the competence of an endoscopist, but the steps after cannulation are of equal importance. Cannulation is one step in the entire procedure, and the quality assessment should not stop at this step. Successful completion of the procedure requires many more skills than cannulation rate alone. There are various methods of achieving cannulation, other than selective cannulation, double-wire technique, pre-cut, fistulotomy, etc., all of which are methods to achieve cannulation but carry a significantly higher risk of adverse events. Hence, the evaluation of a trainee should include a component of the method used and its outcomes.

2) Measurement and documentation of fluoroscopy time and radiation dose

ERCP requires significant radiation exposure to the patient, which must be reduced to the lowest possible level. Factors that usually affect the radiation dose include patient body habitus, use of barriers, distance of the patient from the radiation source, magnification, oblique views and spot images, and the difficulty and longevity of the procedure. Fluoroscopy time and radiation dose should be documented if possible.

3) Stone extraction rate: priority indicator

Stone extraction is one of the most important therapeutic procedures performed by endoscopists during ERCP. The size, number, location, and complete extraction of stones must be documented by the endoscopist. Cholangiographic anatomy, variations, and strictures must also be clearly documented. Individual extraction rates must be tracked and should be on par with standard rates across similar centers. This should be compared with a center of similar stature, as some expert endoscopy

centers can achieve stone clearance irrespective of size in over 90% of patients. Studies have suggested that a trained endoscopist can clear the biliary duct of small-to medium-sized common bile duct stones up to 1 cm in diameter in 90% of cases by using sphincterotomy and balloon or basket stone extraction in patients with normal biliary anatomy. Outcomes related to difficult stones (large-diameter stones, stones above strictures, and stones in patients with altered anatomy) must also be documented and compared with standards for similar situations.

4) Stent placement: priority indicator

Each ERCP procedure should have a documented protocol for stent placement. This has multiple implications. The documentation should not only include whether the stent was successfully inserted, it should also reflect sufficient information about the indication, stricture location, stent size and type, and presence of post-surgical anatomy. These data will make comparisons and subsequent benchmarking easier. Stent placement is technically easier to achieve in patients with strictures below the hilum than in those with hilar obstruction. Competent endoscopists should be able to place stents for non-hilar obstruction in >90% of cases. Technical success versus clinical success of stent placement as a quality indicator can be debated. As clinical success depends on multiple variables and stenting is only a part of management, we believe that it is the technical skill that should be the quality indicator, and clinical outcomes alone should not be considered a quality indicator.¹⁶ The success rate of difficult situations, such as hilar tumors and post-transplant anastomotic strictures, should be tracked for benchmarking purposes.

5) Sedation

Sedation protocols are used almost universally during ERCP. Periodic assessment, monitoring, and assessment of the vital signs of the patient are mandatory while using sedation during ERCP. Equipment for emergency resuscitation and a crash cart should be readily available. Availability of a trained anesthesiologist is usually recommended for ERCP. ERCP is a complicated procedure that typically takes longer to complete than routine gastro/colonoscopy. It has been shown that the failure rate of ERCP can be significantly higher if anesthesia has not been correctly administered. This higher failure rate can be caused by premature termination due to insufficient sedation. Sedation for ERCP varies between centers and anesthesiologists. Deep sedation with propofol and general anesthesia are options. General anesthesia has been shown to have higher successful



ERCP rates, as duration is usually not a constraint. The decision should be based on procedural and patient factors. Some hospitals prefer to intubate only in the most difficult cases, which are expected to take longer to complete. Deep sedation with propofol can usually be utilized for ERCP that do not require a longer duration or are less complex, whereas for advanced, longer duration procedures, it is better to intubate the patient for safety. Use of moderate sedation or conscious sedation may lead to difficulties in accurate assessment and completeness of the procedure, hence, most experts use deep sedation or general anesthesia for ERCP.

Post-procedure quality indicators

The time between duodenoscope removal and follow-up is usually referred to as the post-procedure period. During this period, the endoscopist should clearly report the procedure, detailing the specific techniques used, accessories, overall outcome, and document adverse events. Clear communication of post-procedural instructions to the staff as well as to the patient are of prime importance and important post-procedure quality indicators. Communication with the referring doctor and pathology follow-up must also be part of the protocol.⁸

Post-procedure quality indicators specific to the performance of ERCP include the following:

1) Preparation of a complete ERCP report

The ERCP report should include details of the desired duct cannulation success, photo documentation of all the essential steps including fluoroscopic images, depiction of the events in chronological order, outcomes, adverse events, and overall impression of the endoscopist. The type of anesthesia utilized and any untoward effects of anesthesia on the patient should also be mentioned. Unintentional pancreatic duct cannulation or contrast injection should be mentioned. Clear and appropriate documentation of ERCP findings, without concealment of facts, helps clinicians who are directly involved with patient clinical care in making appropriate patient management decisions.

2) Documenting adverse events and hospital transfers

Adverse events are common in all ERCP and therapeutic procedures. It is important that they are recognized early, and steps are taken to manage them once an untoward incident has occurred. Immediately recognized adverse events should be reported along with a management plan. Bleeding, allergic reactions, cardiopulmonary events (including aspiration), perfora-

tion, and post-ERCP pancreatitis (PEP) are the main concerns that must be addressed.

3) Rate of PEP: priority indicator

PEP is one of the priority quality indicators in ERCP. It is one of the benchmarks that has been utilized across medical institutions and has significant medicolegal implications.

The incidence of PEP must be documented and tracked. The current rate of PEP (1%-7%) has many related factors, such as operator skill, experience, and type of ERCP procedures undertaken. Therefore, deciding a single performance target for all ERCPs for this indicator is difficult. As multiple parameters are involved, it is important to know the operator's or unit's rate of PEP, which has been documented and reported as a quality indicator.¹⁸ Various methods have been described and reviewed to minimize PEP. One of the most important parameters is adequate pre-procedural hydration of the patient, which must be part of the pre-procedural protocol. Use of rectal suppositories must be documented, and clear instructions about local protocols must be given to endoscopy staff. Special prophylaxis for PEP, including pancreatic stent placement and the use of non-steroidal anti-inflammatory drugs, should be documented. According to the guidelines, ESGE now recommends PEP prophylaxis using and documenting rectal non-steroidal anti-inflammatory drug administration for all patients undergoing the procedure and pancreatic duct stenting in high-risk cases, to reduce the incidence of PEP.

4) Rate and type of perforation

Duodenal perforation is a serious complication of ERCP. A classification system has been previously described for duodenal perforation and its mechanisms.¹⁹ This adverse event has an important bearing on post-procedural management of the patient. It is important that it is recognized early. The procedure can usually be completed even if on table perforation has been identified. An experienced endoscopist should attempt to close the perforation, if feasible, using standard accessories and newer over the scope clips. A naso-jejunal tube for feeding can be placed if a longer duration of stay is anticipated owing to perforation.

The rate of ERCP-related perforations and related information should be recorded at the operator level. Documentation should include the level of perforation and management (conservative or surgical intervention). Because perforation rates are very low (0.1%-0.6%), ²⁰ the denominator of cases performed

required to generate reliable individual endoscopist perforation rates is unknown, and hence, a reference data point is usually not available for this quality indicator.

5) Rate of clinically significant hemorrhage during ERCP

The usual cause of bleeding during ERCP is sphincterotomy using electrocautery. The rate of clinically significant hemorrhage associated with ERCP is approximately 1%, with most cases involving mild, intraluminal bleeding.

With more complex procedures, such as ampullectomy and cystogastrostomy, the risk of bleeding increases. The bleeding risk is also dependent on patient factors, such as the use of antithrombotic agents and coagulopathy from any cause, and operator-dependent factors, such as the angle of cutting and amount of electrocautery used. Other factors that have been shown to increase the risk of bleeding include cholangitis, anticoagulant therapy within three days of the procedure, and low endoscopic caseload. The risk of bleeding is almost nil in patients undergoing ERCP without sphincterotomy. Aspirin can be safely used in patients with bleeding.²¹ All factors that could lead to hemorrhage, level of bleeding, and medications should be recorded and tracked.

6) Record of delayed adverse events

Adverse events occurring within 14 days of the procedure should be documented. Efforts to monitor and improve the collection of delayed data on post-ERCP adverse events will generate more reliable outcome data for this procedure in the future. However, this may impact the cost of the procedure. Currently, it is not used as post-procedure quality indicator.

7) Priority indicators for ERCP

Among the indicators mentioned above, there are certain indicators for which objective criteria have been established and validated, to improve patient outcomes. Clear documentation for these is a must and should be completed at every institute or operator level. These are usually relatively easily measurable; however, their implications are prone to variability across studies. They are as follows: (1) selection of an appropriate indication, (2) cannulation rate, (3) stone extraction success rate, (4) stent insertion success rate, and (5) frequency of PEP.

ESGE GUIDELINES ON QUALITY INDICATORS OF ERCP

ESGE/UEG have listed key performance measures for EUS and

ERCP that are clear, validated, relevant, and usually applicable to all levels of endoscopic service. ²² These have been utilized to assess quality outcomes at most centers worldwide. Eight performance measures include:

- a. Seven key performance measures
 - i. Pre-procedural domain measures of antibiotic prophylaxis before ERCP (minimum performance standard 90%)
 - ii. EUS-guided puncture of lesions (minimum 95%)
 - iii. Procedure completion or intraprocedural indicators of successful cannulation of the bile duct (minimum 90%)
 - iv. Sampling of the tissue during EUS (minimum 85%)
 - v. Clearance of ductal stones (minimum 90%)
 - vi. Successful biliary stenting (minimum 95%)
 - vii. Indicators of post-procedural adverse events with PEP (target <5%)
- b. One minor performance measure categorized according to
 - i. An additional minor performance measure of correct documentation of appropriate EUS landmarks with image documentation (minimum 90%)

ASGE performance indicators are similar to ESGE/UEG parameters.

ERCP QUALITY NETWORK

The ERCP Quality Network was launched in the United States in 2013 to improve ERCP outcomes. The aim is to have documented quality indicators for endoscopists and have these data available for patients. Data are collected and uploaded to a website, analyzed, and the results are made available. Data points include the previously mentioned indicators such as indications, complexity grade, sedation, fluoroscopy times, success rates of deep cannulation, stenting, and so on. Another advantage is that individual endoscopists can view a summary of their performance and compare it with that of the other participants. During the first six months of the study, 24 United States endoscopists entered 2,300 ERCP procedures, and the results were comparable to the ASGE recommended standards.²³

INNOVATION IN QUALITY METRICS

Automated reporting of quality metrics was attempted and



compared with manual review. The accuracy of automated ERCP reporting compared to manual record review was confirmed as high (98%-100% accuracy). Through automated software, providers were obligated to select a specific indication instead of synonymous terms, making the documentation of quality metrics uncomplicated.²⁴

CONCLUSIONS

ERCP is clearly a technically demanding procedure in interventional gastroenterology, with a steep learning curve and practice required to maintain proficiency. Numerous attempts have been made to assess its implications and improve efficiency by studying and defining various quality parameters. Several endoscopic organizations have published quality measurement guidelines and recommendations, although their applicability in daily practice is limited. A unified international or domestic program for documenting quality, including a range of quality indicators, may be the best way to achieve ERCP quality assessment. It is clear that more research is needed to refine the quality indicators for ERCP and to assess the human factors associated with any medical procedure.

Conflicts of Interest

The authors have no potential conflicts of interest.

Funding

None.

Author Contributions

Conceptualization: RP; Data curation: ZDS, RP; Formal analysis: ZDS; Methodology: ZDS; Project administration: RP; Resources: RP; Supervision: RP; Validation: ZDS, RP; Writing-original draft: ZDS, RP; Writing-review & editing: ZDS, RP.

ORCID

Zubin Dev Sharma Rajesh Puri https://orcid.org/0000-0003-1460-8204 https://orcid.org/0000-0001-6135-7351

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