Complete Summary

GUIDELINE TITLE

Quality indicators for endoscopic retrograde cholangiopancreatography.

BIBLIOGRAPHIC SOURCE(S)

Baron TH, Petersen BT, Mergener K, Chak A, Cohen J, Deal SE, Hoffman B, Jacobson BC, Petrini JL, Safdi MA, Faigel DO, Pike IM. Quality indicators for endoscopic retrograde cholangiopancreatography. Gastrointest Endosc 2006 Apr;63(4 Suppl):S29-34. [31 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Pancreaticobiliary disorders, including bile duct stones and malignant obstructive jaundice

GUIDELINE CATEGORY

Diagnosis
Evaluation
Treatment

CLINICAL SPECIALTY

Gastroenterology

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To establish quality indicators to aid in the recognition of high quality endoscopic retrograde cholangiopancreatography (ERCP) examinations

TARGET POPULATION

Patients undergoing endoscopic retrograde cholangiopancreatography

INTERVENTIONS AND PRACTICES CONSIDERED

Endoscopic retrograde cholangiopancreatography

MAJOR OUTCOMES CONSIDERED

Safety and efficacy of procedure

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Studies were identified through a computerized search of Medline followed by review of the bibliographies of relevant articles. When such data were absent, indicators were chosen by expert consensus.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The American Society for Gastrointestinal Endoscopy (ASGE) and the American College of Gastroenterology (ACG), as leaders in promoting the highest quality patient care, formed a task force to identify end points that could be used to document high-quality endoscopic services. In most cases these end points will require validation before they can be generally adopted. The task force consisted of expert endoscopists selected by the board of directors of the ASGE and the ACG.

The task force developed quality indicators for the 4 major endoscopic procedures: colonoscopy, esophagogastroduodenoscopy (EGD), endoscopic retrograde cholangiopancreatography (ERCP), and endoscopic ultrasonography (EUS). Wherever possible, these indicators were chosen because there were published supporting data. These studies were identified through a computerized search of Medline followed by review of the bibliographies of relevant articles. When such data were absent, indicators were chosen by expert consensus. The goal was to create a comprehensive list of potential quality indicators, recognizing that only a small subset may ultimately be implemented. The resultant quality indicators were graded on the strength of the supporting evidence.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendation

Grade of recommendation	Clarity of benefit	Methodologic strength/supporting evidence	Implications
1A	Clear	Randomized trials without important limitations	Strong recommendation; can be applied to most clinical settings
1B	Clear	Randomized trials with important limitations (inconsistent results, nonfatal methodologic flaws)	Strong recommendation; likely to apply to most practice settings

Grade of recommendation	Clarity of benefit	Methodologic strength/supporting evidence	Implications
1C+	Clear	Overwhelming evidence from observational studies	Strong recommendation; can apply to most practice settings in most situations
1C	Clear	Observational studies	Intermediate-strength recommendation; may change when stronger evidence is available
2A	Unclear	Randomized trials without important limitations	Intermediate-strength recommendation; best action may differ depending on circumstances or patients' or societal values
2B	Unclear	Randomized trials with important limitations (inconsistent results, nonfatal methodologic flaws)	Weak recommendation; alternative approaches may be better under some circumstances
2C	Unclear	Observational studies	Very weak recommendation; alternative approaches likely to be better under some circumstances
3	Unclear	Expert opinion only	Weak recommendation; likely to change as data become available

*Adapted from Guyatt G, Sinclair J, Cook D, Jaeschke R, Schunemann H, Pauker S. Moving from evidence to action: grading recommendations—a qualitative approach. In: Guyatt G, Rennie D, eds. Users' guides to the medical literature. Chicago: AMA Press; 2002. p. 599-608.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The task force consisted of expert endoscopists selected by the board of directors of the American Society for Gastrointestinal Endoscopy (ASGE) and the American College of Gastroenterology (ACG). These documents were then reviewed and approved by the governing boards.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Recommendations were graded on the strength of the supporting evidence (Grades 1A-3). Definitions of the recommendation grades are presented at the end of the "Major Recommendations" field.

Preprocedure Quality Indicators

The generic preprocedure quality indicators discussed in the accompanying article also pertain to performance of endoscopic retrograde cholangiopancreatography (ERCP). Specific preprocedure indicators and discussion pertinent to the performance of ERCP include the following points:

1. Appropriate indication. ERCP should be performed for an appropriate indication as defined in a previously published guideline (Johanson et al., 2002; also see the National Guideline Clearinghouse [NGC] summary of the American Society for Gastrointestinal Endoscopy [ASGE] guideline, The Role of ERCP in Diseases of the Biliary Tract and the Pancreas). An indication should be documented for each procedure, and when it is a nonstandard indication it should be justified in the documentation. **(3)**

   Discussion. The indications for ERCP are covered in detail in a separate publication and are summarized in the Table below. Clinical settings in which ERCP is generally not indicated include the following: (1) Abdominal pain without objective evidence of pancreaticobiliary disease by laboratory or noninvasive imaging studies. In this setting the yield is very low, yet the risk of complications is significant. When considered in this patient group, ERCP should only be undertaken in a setting capable of performing sphincter of Oddi manometry. (2) As a routine before cholecystectomy. Preoperative ERCP should be reserved for patients with cholangitis or a significant likelihood of biliary obstruction or duct stones by clinical criteria or imaging studies. (3) As a routine for relief of biliary obstruction in patients with potentially resectable malignant distal bile duct obstruction. Preoperative biliary decompression has not been shown to improve postoperative outcomes, yet it may result in both preoperative and postoperative complications. Preoperative relief of biliary obstruction is recommended in patients with acute cholangitis and those with intense pruritus in whom operation may be delayed.

Table: Indications for ERCP

A. Jaundice thought to be the result of biliary obstruction
B. Clinical and biochemical or imaging data suggestive of pancreatic or biliary tract disease
C. Signs or symptoms suggesting pancreatic malignancy when direct imaging results are equivocal or normal
D. Pancreatitis of unknown etiology
E. Preoperative evaluation of chronic pancreatitis or pancreatic pseudocyst
F. Sphincter of Oddi manometry
G. Endoscopic sphincterotomy

1. Choledocholithiasis
2. Papillary stenosis or sphincter of Oddi dysfunction causing disability
3. Facilitate biliary stent placement or balloon dilatation
4. Sump syndrome
5. Choledochocele
6. Ampullary carcinoma in poor surgical candidates
7. Access to pancreatic duct

H. Stent placement across benign or malignant strictures, fistulae, postoperative bile leak, or large common bile duct stones
I. Balloon dilatation of ductal strictures
J. Nasobiliary drain placement
K. Pseudocyst drainage in appropriate cases
L. Tissue sampling from pancreatic or bile ducts
M. Pancreatic therapeutics

2. Informed consent. Informed consent for ERCP should focus on 5 possible adverse outcomes: (1) pancreatitis, (2) postsphincterotomy hemorrhage, (3) infectious complications, usually cholangitis but also cholecystitis and infection of pancreatic fluid collections, (4) adverse cardiopulmonary reactions, usually related to sedation, and (5) perforation. The patient should be informed of the probable need for hospitalization (if outpatient) should complications occur and the possible need for surgical repair if perforation occurs. **(3)**

   Discussion. Some complications of ERCP are unique from those that occur with standard endoscopy. A review of the complications specific to ERCP has been published previously. Some endoscopists include in the informed consent process a variety of other possible outcomes (e.g., possible need for emergency radiologic procedures, blood transfusion, etc.). Patterns of practice indicate that an informed consent can be obtained on the day of the procedure, even in open access practices. The expected rate of ERCP-induced pancreatitis is generally between 1% and 7%, although there are several situations in which this rate may be significantly higher. Numerous factors, both patient- and procedure-related, may influence the risk for post-ERCP pancreatitis and need to be taken into account when planning for the procedure and obtaining informed consent. Cholangitis occurs in 1% or less and cholecystitis complicates 0.2% to 0.5% of ERCPs.

   Hemorrhage is most commonly a complication of endoscopic sphincterotomy and has been reported to occur in 0.8% to 2% of cases. Perforations may be guidewire induced, sphincterotomy induced, and endoscope induced at a site remote from the papilla. The overall incidence of perforation during ERCP has been reported to be 0.3% to 0.6%.

3. Assessment of procedural difficulty. Identify ERCP grade of difficulty preprocedurally. **(3)**

   Discussion. The degree of difficulty of ERCP has been suggested as a way of assessing outcomes on the basis of procedural difficulty (Table below).

Although it has not been prospectively validated, there is a general assumption that higher degrees of difficulty are associated with lower success rates and higher complication rates. In general, for all indications, competent ERCP endoscopists should expect to succeed in 80% to 90% of ERCP cases with a difficulty grade of 1. It has also been suggested that those ERCP endoscopists with lower levels of expertise should not attempt ERCP cases with a difficulty grade 2 or 3.

Table: ERCP Degrees of Difficulty

Grade 1: standard
Diagnostic: Selective deep cannulation, diagnostic sampling
Therapeutic: Biliary sphincterotomy, stones <10 mm, stents for leaks and low tumors
Grade 2: advanced
Diagnostic: Billroth II diagnostics, minor papilla cannulation
Therapeutic: Stones >10 mm, hilar tumor stent placement, benign biliary strictures
Grade 3: tertiary
Diagnostic: Manometry, Whipple, Roux-en-Y, intraductal endoscopy
Therapeutic: Billroth II therapeutics, intrahepatic stones, pancreatic therapies

4. Prophylactic antibiotics. Preprocedure antibiotics should be administered according to published guidelines. (see the NGC summary of the ASGE guideline, Guidelines for Antibiotic Prophylaxis for Gastrointestinal (GI) Endoscopy). **(2B)**

   Discussion. Detailed guidelines for the administration of antibiotics before ERCP have been previously published. In brief, patients with known or suspected biliary obstruction, including primary sclerosing cholangitis, biliary or pancreatic leaks, and pancreatic pseudocysts or pancreatic necrosis, are at increased risk for procedure-related infections and should receive antibiotic prophylaxis.

Intraprocedure Quality Indicators

The intraprocedure interval begins with the administration of sedation and ends with removal of the endoscope. Minimum performance elements that are generic to all sedated gastrointestinal procedures include attention to patient monitoring, medication administration, reversal or resuscitative efforts, and photo documentation of pertinent landmarks or pathologic conditions. Both procedure-specific and disease-specific quality indicators can be proposed for ERCP practice, as follows.

5. Cannulation rates. Cannulation of the duct of interest with a high success rate and with an associated low complication rate is achieved by experts in ERCP and requires adequate training and continued experience in ERCP. (Desired duct, **1C**; Use of precut, **2C)**

   Discussion. Cannulation of the desired duct of interest is the foundation for successful diagnostic and therapeutic ERCP. Deep cannulation is achieved when the tip of the catheter is passed beyond the papilla into the desired duct. This allows effective installation of contrast to visualize the entire ductal system of interest and the introduction of instruments to perform therapeutic maneuvers. Successful cannulation may avoid the need for a second ERCP or percutaneous transhepatic cholangiography (PTC) to complete the study. Reports from the 1990s indicate that successful cannulation rates at or above 95% are consistently achieved by experienced endoscopists and rates at or above 80% are a goal of training programs in ERCP. Thus, although $\geq$ 90% is an overall appropriate target for successful cannulation, rates of $\geq$ 85% should be achievable for most endoscopists performing ERCP. When cannulation rates are calculated, failed examinations because of inadequate sedation or prior abdominal surgery such as pancreaticoduodenectomy (Whipple operation), Billroth II anatomy, prior gastrojejunostomy and hepaticojejunostomy, and obstruction to the duodenum should be excluded. Additionally, procedures that are aborted because of a high volume of retained gastric contents or inability to achieve adequate sedation should be excluded.

   The procedure report should document whether deep cannulation was achieved and should in all cases specify the types of accessories used to achieve cannulation. One or more fluoroscopic images should be included. Photo documentation of endoscopically identified abnormalities is considered advisable by the task force.

   Successful cannulation of the desired duct may be achieved by precut sphincterotomy when standard techniques fail. Precut sphincterotomy has an associated learning curve and may increase the risk of post-ERCP procedural complications. Most experienced endoscopists do not rely on precut methods in more than 10% to 15% of cases and they should not be used as an alternative to proper cannulation techniques.

   Technical success of ERCP is not only dependent on successful cannulation. Once cannulation is achieved, other maneuvers are required to achieve complete technical success, including traversing of a stricture, extraction of stones, and successful stent placement, to name a few. Technical success for the most commonly performed procedures (stone extraction, relief of biliary obstruction, stent placement for bile leaks) should be achievable in $\geq$85% of cases. Technically failed ERCP may result in complications (cholangitis, pancreatitis), need for additional procedures (PTC, surgery, additional ERCP), and their associated costs. Although little is known about the technical failures of ERCP and their impact on cost, preliminary studies have suggested that the cost of failed ERCP is substantial.

6. Extraction of common bile duct stones. Choledocholithiasis is one of the most common indications for ERCP. Acute cholangitis and severe acute gallstone

pancreatitis require rapid and effective relief of biliary obstruction and duct clearance. **(1C)**

Discussion. Some expert endoscopy centers can achieve a greater than 99% bile duct clearance rate for all bile duct stones. However, it should now be expected that competent ERCP endoscopists can clear the duct of common bile duct stones in >85% of cases by use of sphincterotomy and balloon or basket stone extraction. When standard techniques fail, mechanical lithotripsy will increase the success rate to more than 90%, leaving a small number of patients requiring more advanced procedures such as electrohydraulic, laser, or extracorporeal shockwave lithotripsy, which will increase the success rate further to almost 100%.

7. Stent placement for biliary obstruction below the bifurcation. Indications for placement of a biliary stent to treat an obstruction below the bifurcation include pancreatic cancer, nonextractable or large common bile duct stones, and benign strictures (chronic pancreatitis, postbiliary surgery). **(1C)**

   Discussion. Relief of obstructive jaundice from pancreatic cancer is a common indication for ERCP. Relief of biliary obstruction is mandatory in those with cholangitis and in any patient with clinical jaundice whose biliary tree has been instrumented and contrast introduced. Obstructive processes below the bifurcation are technically easier to achieve than hilar obstruction. Competent ERCP endoscopists should be able to place a biliary stent for relief of nonhilar biliary obstruction in>80% to 90% of patients.

Postprocedure Quality Indicators

The postprocedure interval extends from withdrawal of the endoscope to patient dismissal and, for certain elements, beyond this until appropriate communication is completed. Minimum performance elements common to all procedures include attention to procedure report, patient instructions, pathology follow-up, determination of patient satisfaction, and communication to other care providers, among others. Postprocedure quality indicators specific to performance of ERCP include the following:

8. Completeness of documentation. Endoscopic reports should document successful cannulation, correlative fluoroscopic images, and endoscopic photo documentation should be obtained, when appropriate. **(3)**

   Discussion. Documentation of ERCP with representative radiographic images and endoscopic photos is the only way to provide evidence of what was performed during the procedure. Proper documentation has medicolegal ramifications. Additionally, documentation of these findings allows clinicians that are directly involved with the patients' medical care to make appropriate decisions on patient management.

9. Complication rates. The rates of ERCP-associated pancreatitis, bleeding, perforation, and cholangitis should be measured. **(1C)**

<u>Definitions</u>:

Grades of Recommendation

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1A	Clear	Randomized trials without important limitations	Strong recommendation; can be applied to most clinical settings
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1C+	Clear	Overwhelming evidence from observational studies	Strong recommendation; can apply to most practice settings in most situations
1C	Clear	Observational studies	Intermediate-strength recommendation; may change when stronger evidence is available
2A	Unclear	Randomized trials without important limitations	Intermediate-strength recommendation; best action may differ depending on circumstances or patients' or societal values
2B	Unclear	Randomized trials with important limitations (inconsistent results, nonfatal methodologic flaws)	Weak recommendation; alternative approaches may be better under some circumstances
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CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

A high quality endoscopy ensures that the patient receives an indicated procedure, that correct and clinically relevant diagnoses are made (or excluded), that therapy is properly performed, and that all these are accomplished with minimal risk.

POTENTIAL HARMS

Adverse events related to cholangiopancreatography include pancreatitis; postsphincterotomy hemorrhage; infectious complications, usually cholangitis but also cholecystitis and infection of pancreatic fluid collections; adverse cardiopulmonary reactions, usually related to sedation, and perforation.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Underlying this discussion of quality indicators is the assumption that adequate training and credentialing has taken place before a practitioner begins the practice of endoscopy. The American Society for Gastrointestinal Endoscopy (ASGE) has guidelines specifically addressing standards for training, assessing competence, and granting privileges to perform endoscopy. It is the task force's recommendation that these guidelines be adopted by facilities where endoscopic procedures are performed.
- The list of potential quality indicators was meant to be a comprehensive listing of measurable endpoints. It is not the intention of the task force that all end points be measured in every practice setting. In most cases, validation may be required before a given end point may be universally adopted.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Baron TH, Petersen BT, Mergener K, Chak A, Cohen J, Deal SE, Hoffman B, Jacobson BC, Petrini JL, Safdi MA, Faigel DO, Pike IM. Quality indicators for endoscopic retrograde cholangiopancreatography. Gastrointest Endosc 2006 Apr;63(4 Suppl):S29-34. [31 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Apr

GUIDELINE DEVELOPER(S)

American College of Gastroenterology - Medical Specialty Society
American Society for Gastrointestinal Endoscopy - Medical Specialty Society

SOURCE(S) OF FUNDING

American Society for Gastrointestinal Endoscopy

GUIDELINE COMMITTEE

ASGE/ACG Taskforce on Quality in Endoscopy

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Taskforce Members: Todd H. Baron, MD; Bret T. Petersen, MD; Klaus Mergener, MD, PhD; Amitabh Chak, MD; Jonathan Cohen, MD; Stephen E. Deal, MD; Brenda Hoffman, MD; Brian C. Jacobson, MD, MPH; John L. Petrini, MD; Michael A. Safdi, MD; Douglas O. Faigel, MD (*ASGE Co-Chair*); Irving M. Pike, MD (*ACG Co-Chair*)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American Society for Gastrointestinal Endoscopy Web site.

Print copies: Available from the American Society for Gastrointestinal Endoscopy, 1520 Kensington Road, Suite 202, Oak Brook, IL 60523

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Bjorkman, DJ, Popp, JW. Measuring the quality of endoscopy. Gastrointest Endosc 2006 Apr;63(4 Suppl):S1-2. Available in Portable Document Format (PDF) from the American Society for Gastrointestinal Endoscopy Web site.
- Faigel, DO, Pike, IM, Baron, TH, Chak, A, Cohen, J, Deal, SE, Hoffman, B, Jacobson, BC, Mergener, K, Petersen, BT, Petrini, JL, Rex, DK, Safdi, MA. Quality indicators for gastrointestinal endoscopic procedures: an introduction. Gastrointest Endosc 2006 Apr;63(4 Suppl):S3-9. Available from the American Society for Gastrointestinal Endoscopy Web site.

Print copies: Available from the American Society for Gastrointestinal Endoscopy, 1520 Kensington Road, Suite 202, Oak Brook, IL 60523

PATIENT RESOURCES

None available

NGC STATUS

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