

Quality indicators for endoscopic retrograde cholangiopancreatography. The procedure of endoscopic retrograde cholangiopancreatography

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ABSTRACT

The goal of the project encompassing the present paper is to propose useful quality procedures and indicators in order to improve quality in digestive endoscopy units. In this third part outcome procedures and indicators are suggested for endoscopic retrograde cholangiopancreatography (ERCP). First, a diagram of pre- and post-ERCP steps was developed. A group of experts in healthcare quality and/or endoscopy, under the shelter of the Spanish Society of Digestive Diseases (Sociedad Española de Patología Digestiva - SEPD), carried out a qualitative review of the literature regarding quality indicators for ERCP. Then, a paired analysis was used for the selection of identified references. A total of six specific indicators, apart from the common indicators already described, were identified, all of them process indicators (two pre-procedure and four post-procedure). Evidence quality was analyzed for each indicator using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) classification.

Key words: Quality indicators. Endoscopic retrograde cholangiopancreatography. Digestive system.

INTRODUCTION

Few controlled studies are available about quality in endoscopic retrograde cholangiopancreatography (ERCP). This is paradoxical, since ERCP represents the endoscopic procedure with the highest morbidity and mortality rates, and the one resulting in more lawsuits (1,2).

Gaining insight into the quality level of this or any other issue requires measuring the most relevant aspects of the care we are offering, usually in the form of indicators. Quality indicators may be split into three categories: "structure", "process" and "outcome" (3). "Structure" involves all things related to the steady attributes where health care

takes place; "process" includes all that is done for patients and the skill wherewith it is done; "outcome" encompasses all things that benefit patients, all changes in their health status potentially attributed to the care received.

In this context, the SEPD has set out on a project to provide useful quality and safety indicators for digestive endoscopy procedures, adapted to our setting and categorized by levels of evidence (4,5). In this paper quality procedures and indicators are suggested for ERCP.

METHODOLOGY

The present paper, being a part of the aforementioned project by the SEPD (4), was developed along the latter's lines. First, a multidisciplinary team was set up to review the literature and design the ERCP procedure. Their proposal was reviewed by a professional panel selected by the SEPD until a definitive version was reached. Then, indicator tables were developed for these procedures.

Search strategies and study selection

The search and selection strategy was the one used over all for the SEPD project, as detailed in the initial paper (4). Basically, two searches were performed: one for CPGs and one for original and review articles. Furthermore, references quoted in the chosen studies, as well as in the reported

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significant reviews, and clinical guidelines and meta-analyses, were secondarily reviewed. These references were peer reviewed, and selected when they included recommendations regarding ERCP preparation, execution and monitoring, or structural, process, and/or outcome quality indicators.

Endoscopy procedure design

Based on the literature selected and author experience, procedure-related activities were collected and sorted out. Procedures common to all endoscopic explorations and specific techniques used for specific situations were not included. The result was diagrammed in a parallel flow chart. Group proposals were reviewed and revised by a panel of SEPD-selected professionals until a definitive version was finalized.

Indicator construction

To obtain valid indicators, the quality of the knowledge available on procedure-related activities and the documents selected following the search was assessed. To this end, the GRADE evidence quality grading system was used, where quality is scored as high, moderate, low and very low (6,7).

To ensure reliability and facilitate indicator calculations, each indicator is accompanied by a form including the following: area of application (procedures where it applies), name, formula, type, timing (pre-procedure, procedure, post-procedure), related quality dimension, justification, exclusions and clarifications, and supporting level of evidence.

Indicators common to all digestive endoscopy procedures, which are discussed in a different paper, are excluded (4), albeit supplementary remarks are included for some of them because of their ERCP-specific features.

RESULTS AND DISCUSSION

ERCP procedure

The goal is to maximize procedure quality and safety in order to facilitate patient diagnosis and treatment while optimizing health outcomes (Fig. 1). It includes the following:

1. Patient positioning. Three positions are useful: usually the left lateral oblique-prone position is used, but the standard (left lateral) or prone position may also work.
2. Use of deep sedation or general anesthesia.
3. Duodenoscope check-up. The scope must provide adequate, high-quality viewing, and functions such as tip angulation, elevation, air and water provision, and suction must all work properly.
4. Fluoroscopy equipment preparation and focusing on the right hypochondrium.
5. Duodenoscope lubrication.
6. Duodenoscope insertion:
 - Blind entry until the pylorus is visualized in the setting sun position.
 - Left rotation to enter bulb.
 - Right rotation to enter second portion.
 - Focus on the papilla.
 - Turn small knob clockwise and large knob counterclockwise.
 - Rectify by rotating clockwise.
 - If unsuccessful, use the long route: further advance the tube to follow the greater gastric curvature until the papilla is in view.
7. Observe and describe abnormalities in papillary area: diffuse mucosal infiltration, papillary conditions, diverticula, polyps, ampulloma. Biopsy collection is indicated in the latter case to facilitate tumor staging.
8. Biliopancreatic cannulation:
 - Preferably, use a cannulotome or sphincterotome with guidewire to reduce complications.
 - Direct cannula towards the desired duct: bile duct, between 11 o'clock and 1 o'clock; pancreatic duct, between 1 o'clock and 2 o'clock.
 - Check location and advance using fluoroscopy (direction of guidewire and contrast medium), trying not to use contrast enhancement until inside of the desired duct.
 - If access to the desired duct remains unsuccessful after five attempts (difficult cannulation), consider precut. If access to the bile duct fails, consider double guidewire (leave guidewire in pancreas, withdraw sphincterotome and reintroduce with new guidewire), pancreatic stent placement, or termination. In the latter case, the procedure may be attempted later on, or echoendoscopy with *rendez-vous* or drainage may be considered.
9. Act according to findings:
 - Leave guidewire in bile duct to secure access and device exchange, and consider sphincterotomy. Also:
 - In case of suspected or visualized choledocholithiasis, consider passing a balloon or using a Dormia basket. Should this fail, consider balloon sphincteroplasty or stent placement.
 - Tumor stenosis: sampling and stenting.
 - Non-tumor stenosis: dilation with/without stenting.
 - Fistula or bile leakage: sphincterotomy with/without stenting.
 - If a stricture is found in the pancreatic duct, use dilation with/without stenting. Remove any stones present using a balloon or basket.
 - If in diagnostic doubt, direct or indirect cholangioscopy may be considered.
10. Withdraw tube. Maneuver slowly and aspirate air and gastric contents as you go.
11. End procedure. Withdraw tube completely and hand over to assistant for cleaning and preparation. Consider antibiotic prophylaxis.

Indicators

A total of 26 indicators (Table 1) have been included, of which seven refer to structure (common to all procedures), 17 refer to process, and two refer to outcome. The complete list of indicators is included in table 2, but we shall only discuss the following because of their technique-specific status: process-pre-procedure (antibiotic prophylaxis and procedure difficulty grading [Schutz]); process-procedure (deep ductal cannulation in native papilla, common bile duct stone removal, stricture resolution, and radiation estimation). Two outcome indicators have also been developed for adverse events such as post-ERCP pancreatitis and post-ERCP bleeding, as these are highly specific and have an impact on clinical workload.

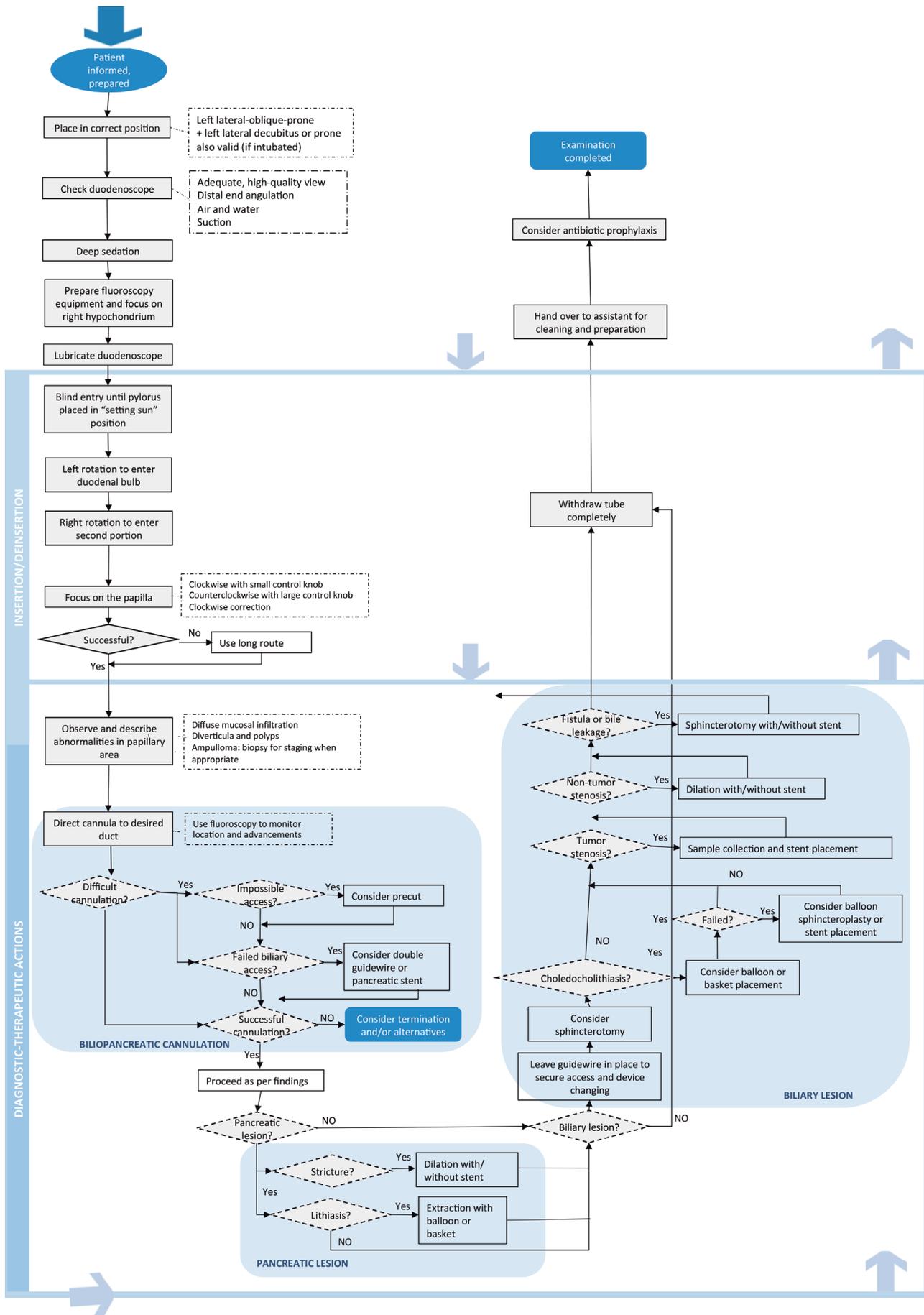


Fig. 1. Procedimiento de la CPRE.

Table 1. Quality indicators for endoscopic retrograde cholangiopancreatography (those elaborated upon in the text appear in boldface type)

A. Structure

01. Valid informed consent
02. Antithrombotic medication management plan
03. Experienced endoscopist
04. Discharge plan
05. Discharge report quality
06. Endoscopy equipment disinfection procedure
07. Structural and functional characteristics of an endoscopy unit

B. Process - pre-procedure

01. Appropriate indication
02. Informed consent form signature
03. Clinical assessment
04. Scheduled sedation
05. Antithrombotic medication management
- 07. Antibiotic prophylaxis**
- 08. Procedure degree of difficulty (Schutz score)**

C. Process - procedure

01. Graphic documentation
02. Sedated patient monitoring
03. Recording of immediate adverse events
- 11. Deep cannulation of the desired duct in a native papilla**
- 12. Common bile duct stone removal**
- 13. Stricture resolution**
- 14. Radiation estimation**

D. Process - post-procedure

- 01. Patient recovery**
- 02. Information on discharge**
- 03. Recording of delayed adverse events**

E. Resultado

- 01. Incidence of adverse effects**
- 02. Perceived quality and patient satisfaction**

Numbering is consecutive to that established for colonoscopy markers (5) since this is a single project.

No indicator for ERCP volume per site, as recommended by some guidelines, has been included as we deem it indicative of quantity rather than quality. Furthermore, such indicator represents an attempt to measure endoscopist experience or training, an aspect already accounted for by indicators common to all endoscopic procedures (4).

Indeed, not all indicators have the same weight. In fact, the American Society for Gastrointestinal Endoscopy (ASGE) defined as priority ERCP indicators those essential to obtain good results, including the following: appropriate indication, duct cannulation, stone removal, and post-ERCP pancreatitis (8).

It should be born in mind that in the GRADE system, which is used to assess the evidence supportive of indicators, "high-quality" evidence includes well-designed randomized studies, which are scarce in this setting. As a consequence, level of evidence is scored on both ends of the scale ("very high" or "low"), and "very high" levels are mainly obtained from clinical guidelines. It is because of this that many of our indicators match the ones therein. Randomized studies with moderate level of evidence are scarce, as are also other designs.

For clarification, indicator numbers (Table 1) are consecutive to those used in the prior two papers for general (4) and colonoscopy (5) indicators.

B.07. Antibiotic prophylaxis

Definition and formula
Percentage of cases receiving appropriate antibiotic prophylaxis:
– Numerator: 100 x cases receiving appropriate antibiotic prophylaxis
– Denominator: total number of cases where antibiotic prophylaxis is indicated
Type, temporal relationship, and quality dimension
Process - Pre-procedure - Safety
Evidence
Moderate

Some clinical guidelines recommend antibiotic prophylaxis in some cases, including known or likely biliary obstruction, biliary or pancreatic fistula, pancreatic pseudocysts or necrosis, liver-transplanted immunosuppressed patients, and active bacterial cholangitis (8,9). A Cochrane 2010 review concluded that prophylactic antibiotics reduce bacteremia and seem to prevent cholangitis, pancreatitis, and sepsis in patients undergoing elective ERCP, although their benefits may be less obvious in the subgroup of patients with uncomplicated ERCP (10). In a recent review (11), the ASGE did not recommend antibiotic prophylaxis in the absence of suspected biliary obstruction or when complete biliary drainage is envisaged; they did recommend it otherwise and for liver-transplanted individuals. Appropriate antibiotics should cover biliary flora (including enterococci and Gram-negative germs).

B.08. Procedure difficulty assessment (Schutz grading)

Definition and formula
– Quantitative indicator of expected difficulty regarding the target procedure, including categorization into three grades based on procedure, patient, and disease characteristics
Type, temporal relationship, and quality dimension
Process - Pre-procedure - Effectiveness
Evidence
Very low

Table 2. Degrees of difficulty in diagnostic/therapeutic ERCP (Schutz)

	Biliary procedures	Pancreatic procedures
Grade 1	<ul style="list-style-type: none"> - Diagnostic cholangiography - Biliary cytology - Removal of bile duct stones \leq 10 mm - Dilation/stent placement/nasobiliary drainage for extrahepatic strictures 	<ul style="list-style-type: none"> - Diagnostic pancreatography - Pancreatic cytology
Grade 2	<ul style="list-style-type: none"> - Removal of bile duct stones $>$ 10 mm - Dilation/stent placement/nasobiliary drainage for hilar or benign intrahepatic strictures 	<ul style="list-style-type: none"> - Minor papilla cannulation
Grade 3	<ul style="list-style-type: none"> - Billroth II - Intrahepatic bile duct stone removal - Bile duct stone removal using lithotripsy 	<ul style="list-style-type: none"> - Therapeutic procedures including pseudocyst drainage

To gain insight into the effectiveness of a procedure such as ERCP, it is key that the expected odds of success be known. In this regard, Schutz published a scale in an attempt to provide expected success data according to expected procedure difficulty (Table 2) (12). Later, a Dutch registry analyzed the influence of such classification, recorded for one year using a standardized system (Rotterdam Assessment Form for ERCP [RAF-E]) (13), on procedure success, and established its relationship with difficulty levels (75.2%, 84.3%, 88.1%, respectively, for grades 3, 2, and 1), albeit within narrow ranges.

Endoscopists with lower numbers of procedures should likely perform grade-1 procedures exclusively, leaving those categorized as grades 2 and 3 to higher-volume institutions (14,15). In this respect, the ASGE, based on this scale, has put forth a 4-grade scale with specific recommendations (levels 1 and 2 for basic endoscopists, levels 3 and 4 for experts) (Table 3) (16).

C.11. Deep cannulation of the desired duct in a native papilla

Definition and formula

Percentage of cases where cannulation of the desired duct (bile, pancreatic or both) is successful, in patients with a native papilla, that is, non-surgically altered anatomy:

- Numerator: 100 x cases with successful deep duct cannulation in a native papilla
- Denominator: total number of cases with anatomically intact papilla

Type, temporal relationship, and quality dimension

Process - Intraprocedure - Effectiveness

Evidence

High

Successful cannulation of the desired duct (bile, pancreatic or both) is the foundation of the procedure's diagnostic and/or therapeutic success (8,15), hence should be recorded in

Table 3. ASGE degrees of complexity

Grade	
1	<ul style="list-style-type: none"> - Deep cannulation of desired duct, main papilla, sample collection - Biliary stent withdrawal/replacement
2	<ul style="list-style-type: none"> - Removal of stones \leq 10 mm - Management of bile leakage - Management of extrahepatic biliary strictures - Prophylactic pancreatic stent placement
3	<ul style="list-style-type: none"> - Removal of stones $>$ 10 mm - Management of acute or recurrent pancreatitis - Treatment of hilar or intrahepatic strictures - Cannulation and treatment of minor papilla in pancreas divisum - Treatment of pancreatic strictures - Withdrawal of inward migrated bile duct stents - Removal of pancreatic duct stones \leq 5 mm - Management of sphincter of Oddi dysfunction (+/- manometry) - Intraductal imaging, biopsy, FNA - Treatment of hilar tumors
4	<ul style="list-style-type: none"> - Removal of intrahepatic stones - Removal of impacted pancreatic duct stones $>$ 5 mm - Imaging-guided intraductal treatment (photodynamic therapy, lithotripsy) - Pseudocyst drainage, necrosectomy - Ampullectomy - Removal of inward migrated pancreatic stents - ERCP for Whipple or Roux-en-Y because of bariatric surgery

all cases. Cannulation is deemed as satisfactory when the guidewire passes through the papilla into the desired duct so that it may be advanced deeper and a contrast medium may be injected to visualize the entire duct system. All types

of precut are included when the standard technique fails in order to avoid repeat endoscopic procedures or percutaneous cholangiography.

This indicator is restricted to patients with normal papillary anatomy, and also excludes:

- Failures because of inadequate sedation, presence of gastric contents, prior abdominal surgery such as pancreatoduodenectomy, gastrojejunostomy and hepaticojejunostomy, and antral or proximal duodenal obstruction, including duodenal deformities from pancreatitis, edema, etc.
- Patients with prior sphincterotomy.

Reference to a potential standard is based on task force agreements and the results of a meta-analysis including prospective studies, which found a percentage of 89.3% (95% CI: 0.866-0.919) for bile duct cannulation, and of 84% for pancreatic duct cannulation regardless of institution type (17). Furthermore, cannulation odds have been seen to be dependent on endoscopist experience: for ≤ 50 ERCPs/endoscopist/year, 84.2%; for > 50 ERCPs/endoscopist/year, 91% (mean, 89%) ($p < 0.001$) (18). Since most patients included in those studies were seen at reference sites, we decided to slightly reduce ASGE-established standards ($> 90\%$) (8) as they are excessively optimistic and do not reflect the conditions extant in our setting.

A point of interest is difficult biliary cannulation, which the ESGE (19) defines as failed cannulation after five attempts, after five minutes, or after more than one pancreatic duct cannulation (20). However, it is clear how this definition may apply to this deep cannulation indicator.

C.12. Cholelithiasis extraction

Definition and formula

Percentage of cases where stones smaller than 1 cm are successfully removed from a normal common bile duct

- Numerator: 100 x cases where stones are removed
- Denominator: total number of cases with stones smaller than 1 cm and anatomically normal bile duct

Type, temporal relationship and quality dimension

Process - Intraprocedure - Effectiveness

Evidence

High

Where this test is undertaken in order to remove stones, its success or failure should always be recorded, with adequate information on size and location, as well as on the potential presence of strictures or anatomical changes, including post-surgical ones (21).

This indicator is restricted to cases with smaller stones and normal anatomy, but this proportion may also be useful for other, more challenging stones. Within the scope of its restricted use, over 90% of stones should be successfully extracted with recourse to sphincterotomy and a balloon or basket when appropriate.

As is the case with cannulation, data from the meta-analysis show that extraction is successful in 88.3% (95% CI: 0.825-0.941) of cases (17). This is why we decided, as for cannulation, on the use of reduced, more realistic standards as compared to those established by the ASGE ($> 90\%$) (8,15). Meta-analysis results, however, probably encompass all types of lithiasis regardless of size (17).

Situations may be found that increase complexity and, besides stone size, also relevant are associated anatomical changes, strictures, unfeasible basket use or lithotripsy, and Mirizzi syndrome (22).

C.03. Stenosis resolution

Definition and formula

Percentage of cases where a stent is successfully placed in patients with normal anatomy and biliary obstruction beyond the bifurcation

- Numerator: 100 x cases where stenting is successful
- Denominator: total number of cases with biliary obstruction beyond the bifurcation and normal anatomy

Type, temporal relationship and quality dimension

Process - Intraprocedure - Effectiveness

Evidence

High

When the procedure is aimed at stenting for biliary obstruction, the resulting success or failure, and whether it involved sphincterotomy (23) or precut in order to access the bile duct, should always be recorded (8,15), providing adequate information on indication, obstruction location, and presence or absence of strictures or anatomical changes, including post-surgical ones.

The indicator is restricted to the aforementioned cases but may also be useful for the rest. Placing a stent in a biliary obstruction distal to the hilum is considered as a relatively easy procedure, and an essential one for obstructive jaundice, particularly when associated with cholangitis.

As regards the cases it is limited to or indicated for, stenting should be successful in over 90% of them (8,15), and meta-analyses have found success rates of 97.5% (95% CI: 0.967-0.984) (17). Only stenosis dilation would be inappropriate as an indicator because of its high relapse rate.

C.14. Radiation estimation

Definition and formula

Percentage where fluoroscopy time and/or radiation dosage are measured:

- Numerator: 100 x cases where radiation estimates are recorded
- Denominator: total number of cases

Type, temporal relationship and quality dimension

Process - Intraprocedure - Safety

(Continue in the next page)

Evidence

Low

Fluoroscopy use is inherent in ERCP, this being the source of the latter's radiation exposure risk (both for patients and healthcare providers), which is similar to other radiographic studies (24). Hence, measuring fluoroscopy time and including such measurement as a quality indicator has been suggested by various guidelines for more than ten years now (8,25). The potential to optimize radiation usage without lessening effectiveness supports its inclusion (26).

However, the correlation between fluoroscopy time and radiation dosage is notoriously poor (27), hence other measurements should be used for this estimation whenever possible, including the dose area product (DAP) (24). Various studies support the notion that received radiation dosage may be reduced without modifying fluoroscopy time (24).

E.02. Adverse effects

Fewer complications have been shown to develop when endoscopists perform over 50 procedures per year (18).

E.02.1. Adverse effects: post-ERCP pancreatitis

Definition and formula

Post-ERCP pancreatitis (PEP) events per 100 ERCPs

Type, temporal relationship and quality dimension

Outcome - Safety

Evidence

High

By consensus, post-ERCP pancreatitis (PEP) (28) is any newly developed or aggravated abdominal pain that is consistent with clinical pancreatitis, occurs beyond 24 hours after ERCP, is associated with an increase in serum

amylase (and/or lipase) three times above normal levels, and requires hospitalization for at least two days (29). This concept is highly significant since enzyme changes have been witnessed in up to 75% of patients following ERCP (30). Its incidence is 3.5% (1.6% to 15.7%) (31). While these meta-analysis-derived figures are real, a selection of very high-risk indications (suspected sphincter of Oddi dysfunction) should be considered to establish more appropriate values. Guidelines exhibit no consensus on acceptable standards (8,15), but we should aim at below 7%. Several factors have been shown to increase both pre-procedure and intraprocedure risk (29) (Table 4).

Methods have been devised to reduce its incidence (32): appropriate patient selection and indications, prophylaxis with rectal indomethacin (33,34), use of pancreatic stents in case of initial pancreatic duct cannulation (35) and guide-wire cannulation.

E.02.2. Adverse effects: post-ERCP bleeding

Definition and formula

Blood extravasation to the digestive tract, with clinical significance or therapeutic intervention need, most commonly occurring after endoscopic sphincterotomy
Bleeding events per 100 ERCPs

Type, temporal relationship and quality dimension

Outcome - Safety

Evidence

High

Bleeding risk during ERCP ranges from 0.5% to 5% (36), with 1% established as the most approximate figure (37), nearly always associated with endoscopic sphincterotomy (38).

It is defined as the presence of clinical complaints or blood extravasation into the gastrointestinal tract (39), and one should wait for 2-3 minutes after sphincterotomy to assess it (40). Furthermore, more severe delayed bleeding has also been described with melena, hemoglobin drops, or transfu-

Table 4. Post-ERCP pancreatitis risk

Pre-procedure	Definitive		Pre-procedure	Potential	
		Intraprocedure			Intraprocedure
Youths		Difficult cannulation (8-10 attempts)	Women		Pancreatic guidewire cannulation
Suspected sphincter of Oddi dysfunction		Pancreatic duct injection	Low volume of ERCPs/year		Absence of choledocholithiasis
Prior history of PEP		Pancreatic sphincterotomy			Pancreatic acinarization
Normal BR		Pancreatic biopsy			Resident training
		Precut			
		Sphincteroplasty without sphincterotomy			

Table 5. Bleeding risk in ERCP

Bleeding risk	Potential bleeding risk	No bleeding risk
Impaired coagulation or thrombocytopenia	Cirrhosis	Aspirin or NSAID
Use of anticoagulants within three days before sphincterotomy	Dilated bile duct	Ampulloma
Acute cholangitis before ERCP	Choledocholithiasis	Long sphincterotomy
Bleeding during sphincterotomy	Periampullary diverticulum	Extension of previous sphincterotomy
Endoscopist with low case volume	Precut sphincterotomy	

sion needs within ten days after ERCP. This type of bleeding is more easily associated with antithrombotic agents.

Balloon sphincteroplasty is safe, and its use without sphincterotomy is recommended for patients with coagulation disorders or juxtadiverticular papilla (36).

Table 5 (36) summarizes ERCP-related bleeding risk factors. Use of antithrombotic drugs stands out as the primary factor, although aspirin has not been shown to increase bleeding, hence sphincterotomy could be safely performed in patients on aspirin (41-43).

In summary, ERCP is an interventionist technique, and associated quality indicators with evidence of a high success rate in the cannulation of the desired duct (bile, pancreatic, both) include choledocholithiasis extraction and stenosis resolution. Also strong is the measurement of adverse effects, primarily post-ERCP pancreatitis and sphincterotomy-related bleeding.

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