Quality standards and curriculum for training in cholangiopancreatoscopy: European Society of Gastrointestinal Endoscopy (ESGE) Position Statement

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MAIN STATEMENTS

Quality standards Competence in cholangioscopy should be defined as the ability to successfully perform the procedure effectively, without trainer assistance, in 80 % of procedures. Cholangioscopy should be performed in

endoscopy units with a high yearly volume of endoscopic retrograde cholangiopancreatographies (ERCPs) of all grades of complexity.

Cholangiopancreatoscopy practice should be considered as standard or advanced as follows:
– ***Standard*** Cholangioscopy for extrahepatic biliary stones; evaluation of extrahepatic biliary strictures; selective ductal guidewire cannulation and removal of migrated biliary stents/foreign body extraction
– ***Advanced*** Cholangioscopy for intrahepatic biliary strictures or complex hepatolithiasis; percutaneous cholangioscopy and pancreatoscopy.

Endoscopy units undertaking standard cholangioscopy should have prompt access to the following (on site or within a defined rapidly responsive network):
– Endoscopic ultrasound (EUS)
– Interventional radiology (on-site) and hepaticopancreaticobiliary (HPB) surgery
– HPB multidisciplinary meetings (MDMs).

Complete extrahepatic stone clearance at the initial cholangioscopy session should be successful in 80 % of intention-to-treat cases.

Cholangioscopy is recommended with visually guided biopsies in the evaluation of undefined biliary strictures, ideally at index ERCP to prevent negative visual and histological effects of prior stenting; except in cases with an associated mass lesion that may allow tissue acquisition by other means (e. g. EUS or percutaneous biopsy).

In cholangioscopic evaluation of extrahepatic biliary strictures, visual assessment should be achieved in > 90 % of cases, and at least 4 visually guided biopsies should be undertaken with sufficient tissue for histological assessment being obtained in > 80 % of cases.

Percutaneous transhepatic cholangioscopy is indicated in patients with transhepatic bile duct access in cases of altered anatomy or failed ERCP and an indication for cholangioscopy (stone management; biliary stricture evaluation; foreign body removal).

Curriculum for training Cholangioscopy is considered an advanced adjunct to ERCP, and prior to undertaking supervised cholangioscopic procedures trainees should be competent in the basic skills of ERCP (Schutz level 1 and 2) as defined by ESGE (duodenal intubation; biliary cannulation; distal bile duct stenting; ≤ 10-mm stone extraction).

Cholangioscopy training should take place in expert referral centers with a high volume of ERCP and cholangioscopy cases.

A trainee's principal trainer should be an experienced trainer ideally with at least 3 years of experience in undertaking independent cholangioscopy to the determined quality standards.

Competence in cholangioscopy should be defined as the ability to successfully perform the procedure effectively without trainer assistance in 80 % of procedures.

ABBREVIATIONS

AE	adverse event
EHL	electrohydraulic lithotripsy
ERCP	endoscopic retrograde cholangiopancreatography
EPLBD	endoscopic papillary large-balloon dilation
ESGE	European Society of Gastrointestinal Endoscopy
ESWL	extracorporeal shockwave lithotripsy
EUS	endoscopic ultrasound
HPB	hepaticopancreaticobiliary
IPMN	intraductal papillary mucinous neoplasm
MDM	multidisciplinary meeting
PD	pancreatic duct
SOC	single-operator cholangioscope

SCOPE AND PURPOSE

As part of the ESGE mission to identify quality in endoscopy as a major priority, we present the ESGE Position Statement on cholangiopancreatoscopy in terms of the indications, performance standards, and training. It is intended that this document will be beneficial to units looking to set up a cholangioscopy service, as well as to established units and endoscopists needing to demonstrate that a quality service is being provided. It is expected that the section on training in cholangiopancreatoscopy will be of use to endoscopy training directors, trainers, and trainees.

Introduction

Cholangioscopy and pancreatoscopy (cholangiopancreatoscopy) are minimally invasive endoscopic procedures providing direct visualization of the biliary and pancreatic ductal systems respectively, using a small-diameter endoscope for both diagnostic and therapeutic purposes. Historically, cholangioscopy was performed intraoperatively to localize stones during common bile duct exploration, and it then came to complement percutaneous transhepatic cholangiography for stricture and stone visualization and treatment [1]. Peroral cholangioscopy was first described in the 1970 s [2], but has undergone rapid expansion and widespread use in hepaticopancreaticobiliary (HPB) endoscopic practice since the advent of single-use single-operator cholangioscopes (SOCs) via the working channel of a duodenoscope in the last 15 years [3]; this overcame some of the limitations of the previous "mother–baby" approach that required two endoscopists. However, there is still wide variation in the practice of cholangioscopy across Europe in terms of indications, experience, and techniques [4].

The European Society of Gastrointestinal Endoscopy (ESGE) have identified quality in endoscopy as a major priority [5]. Furthermore, in 2017 ESGE convened the Curricula Working Group which was responsible for developing curricula that defined minimum training standards for advanced and therapeutic endoscopic practice that usually go beyond the core endoscopy training curricula in each country [6]. An ESGE taskforce was convened in 2023 to reach consensus on cholangiopancreatoscopy in terms of the indications, the definitions of quality, and training standards.

Aims

The aim of this Position Statement is definition of the following for cholangiopancreatoscopy in patients with HPB pathology:

- Indications for cholangioscopy and pancreatoscopy
- Acceptable performance standards for cholangioscopy and pancreatoscopy
- A training pathway to help trainees develop, evidence, and maintain skills in cholangiopancreatoscopy.

Methods

In 2023 M.F. and T.C.T. invited G.J. and G.W. to develop a taskforce of HPB endoscopists with cholangiopancreatoscopy experience, using an open call via ESGE communications. The constitution of this taskforce was selected by G.J. and G.W. to ensure that the group was broadly representative in terms of a wide range of nationalities and backgrounds.

The first virtual meeting of the taskforce was in May 2023. At this meeting the overall aims of the project were defined and the methodology agreed. At this meeting the principal domains of enquiry were identified (▶ **Table 1**); and from these specific questions, using the population, intervention, comparator, outcome (PICO) format if possible, were developed.

Taskforce members were nominated as the leads for each domain. A Delphi process was then used to review evidence and develop consensus statements for each domain. Each domain was the subject of a systematic literature review using major databases (PubMed, Embase, and Cochrane Library) from 1990 to October 2023. Any papers published during the Delphi process and manuscript writing were also considered for inclusion. Statements were drafted based on this evidence, and subjected to an appraisal using the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) framework [7]. In situations where there was a paucity of evidence in an aspect of cholangiopancreatoscopy that was deemed important, the groups drew upon expert opinion to develop statements that went forward into the Delphi process. In fact, the paucity of evidence resulted in all the statements being characterized as "good practice statements" as GRADE was deemed inappropriate.

The first iterations of the statements were distributed electronically in September 2023. In October 2023 there was a face-to-face meeting when the statements and supportive evidence were discussed in turn, resulting in further modification of the statements. The first round of anonymous electronic voting took place in December 2023 and was based on a 5-point Likert scale from "strongly disagree" through to "strongly agree." Any statement receiving at least 80 % of "agree" and "strongly agree" combined was accepted. Thereafter, based on feedback, G.J. modified some statements to improve their acceptability.

▶ **Table 1** Quality standards, curriculum and training for cholangiopancreatoscopy: enquiry domains

Enquiry domains	
Quality standards	
Domain 1	Unit and endoscopist considerations: the service within which cholangiopancreatoscopy is delivered
Domain 2	Procedure considerations: including: ▪ prior multidisciplinary meeting (MDM) discussion ▪ anesthetic provision ▪ antibiotic prophylaxis
Domain 3	Peroral cholangioscopy:
	a. Biliary stone disease (including case selection)
	b. Biliary stricture assessment (including case selection, visual diagnosis/tissue acquisition)
	c. Foreign body removal/selective cannulation/troubleshooting
Domain 4	Percutaneous cholangioscopy
Domain 5	Pancreatoscopy
	a. Pancreatic stone disease
	b. Intraductal papillary mucinous neoplasm (IPMN) assessment
	c. Pancreatic stricture assessment
Curriculum and training	
Domain 6	

The new statements were discussed virtually in February 2024, before a second electronic vote between April and June 2024.

Statements: Quality standards

Domain 1: Unit and endoscopist considerations

STATEMENT 1
There are several types of platforms to perform cholangioscopy. Endoscopy units providing a cholangioscopy service should have the endoscopes and accessories necessary to provide safe and high-quality cholangioscopy.
Agreement 100 %

The currently available peroral cholangioscopy platforms include traditional dual-operator cholangioscopy [8], single-operator cholangioscopy [3, 9–11], and direct cholangioscopy [12–15]. Different cholangioscopy platforms accommodate different approaches and a wide array of accessories [16]. Endoscopists and assistants undertaking cholangioscopy should be familiar with the setup, use, and limitations of the particular platform and accessories in their unit to deliver the intended patient outcomes.

STATEMENT 2
Cholangioscopy should be performed in endoscopy units with a high yearly volume of ERCPs of all grades of complexity.
Agreement 95 %

The success and rate of adverse events (AEs) of ERCP are dependent on the procedural volume of the center, as shown in a recent systematic review and meta-analysis [17]. Cholangioscopy has been considered a level 4 procedure in the previous grading system for ERCP indications [18], and more recently is rated at class 3, the highest complexity in the H.O.U.S.E grading system [19]. It therefore follows that cholangioscopy should only be performed in centers undertaking a high volume of ERCPs. Although a universally accepted cutoff value has not yet been established, recent literature suggests that the definition of a high-volume center is at least 200 ERCPs per year [17].

STATEMENT 3
Cholangioscopy should be incorporated into the practice of endoscopists delivering a significant volume of ERCPs to a high standard.
Agreement 100 %

The number of ERCPs performed annually by independent endoscopists has been used as an important, albeit imperfect, quality metric [20], and there is evidence that the number of procedures undertaken by an endoscopist does correlate with improved outcomes [17, 21, 22]. There is no direct evidence that undertaking a minimum number of cholangioscopy procedures per year improves quality. However it is recommended that, within an individual's ERCP practice delivering quality ERCP to an acceptable standard [23, 24], ≥ 10 cholangioscopy cases per year should be recommended as a guide to endoscopists and service administrators.

STATEMENT 4
Units providing a cholangioscopy service should demonstrate an ongoing audit of performance and complications.
Agreement 100 %

As previously recommended by ESGE, units should have systems in place to ensure that there is ongoing prospective audit of all ERCP and cholangiopancreatoscopy outcomes (indications, outcomes, and adverse events) to monitor the quality of the service and of individual endoscopists [23, 24].

STATEMENT 5
Cholangiopancreatoscopy practice should be considered as standard or advanced as follows:
- *Standard* Cholangioscopy for extrahepatic biliary stones; evaluation of extrahepatic biliary strictures; selective ductal guidewire cannulation and removal of migrated biliary stents/foreign body extraction
- *Advanced* Cholangioscopy for intrahepatic biliary strictures or complex hepatolithiasis; percutaneous cholangioscopy and pancreatoscopy.

Agreement 90 %

STATEMENT 6
Endoscopy units undertaking standard cholangioscopy should have prompt access to the following (either on site or within a defined rapidly responsive network):
- Endoscopic ultrasound (EUS)
- Interventional radiology (on site) and hepatico-pancreaticobiliary (HPB) surgery
- HPB multidisciplinary meetings.

Agreement 95 %

It is recommended that defining the indications for cholangiopancreatoscopy as either standard or advanced is useful to reflect the complexity that these cases represent. The indications defined as standard constitute the vast majority of cholangioscopy cases and can be considered to be within the scope of practice of a high-volume ERCP endoscopist in a secondary care facility, subject to effective training and performance quality already defined. The caveat to this is that multidisciplinary meeting (MDM) review of extrahepatic biliary strictures may be beneficial prior to any intervention to determine whether cholangioscopy is indicated, and whether further imaging is needed prior to intervention, or a concurrent endoscopic ultrasound (EUS).

Indications defined as advanced are less commonly undertaken, are more technically challenging, and portend higher rates of complication, and so should be focused in expert referral centers and undertaken by endoscopists with a high procedural volume of cholangiopancreatoscopy. Niche indications for cholangioscopy also include the investigation of hemobilia and the evaluation of endobiliary radiofrequency ablation (RFA).

EUS is an increasingly inseparable adjunct to ERCP in the management of HPB disease and there are benefits to ready availability of EUS in units providing cholangioscopy, particularly in the evaluation of biliary strictures. Units undertaking cholangioscopy solely for the management of large biliary stones may not need EUS availability. Furthermore, EUS-guided biliary access with a hepaticogastrostomy can be the conduit to enable transhepatic cholangioscopy-guided endobiliary therapy such as the treatment of hepatolithiasis and selective cannulation (see Statements 10 and 15).

Units undertaking cholangioscopy should have prompt access to interventional radiology and HPB surgery to provide backup in the event of a significant complication. Preferably these services are available on site, and if not then within a well-defined network that can be accessed promptly in an emergency.

Domain 2: Procedural considerations

STATEMENT 7

Cases referred for biliary stricture evaluation, complex stone disease (Mirizzi or complex hepatolithiasis), percutaneous cholangioscopy, or pancreatoscopy, should have prior assessment in a specialized MDM to ensure review of all appropriate imaging and to confirm the indication for intervention. Standard cholangioscopy cases of uncomplicated stone management and biliary foreign body/stent removal do not always require MDM review.

Agreement 90 %

The current literature lacks evidence regarding the impact of a specialized HPB MDM on patient outcomes in cholangiopancreatoscopy. However, it is recognized that for complex cases a considered review of the case and the relevant imaging is vital to determine the indication for and optimal approach to endoscopic intervention. The MDM should include representation from the endoscopist undertaking HPB endoscopy, and from interventional radiology, HPB surgery, and pathology disciplines as required. However, standard cholangioscopy cases involving the management of straightforward extrahepatic bile duct stones or foreign body/stent removal do not necessarily need formal MDM discussion. In these cases the requirement for cholangioscopy as an adjunct intervention to successfully complete the ERCP might only become clear during the procedure.

STATEMENT 8

Advanced cases for peroral cholangioscopy, pancreatoscopy, and percutaneous cholangioscopy procedures, and those involving patients with known intolerance of ERCP under conscious sedation, should be undertaken with deep sedation or general anesthesia.

Agreement 90 %

Evidence comparing the outcomes between cholangiopancreatoscopy cases undertaken with conscious sedation versus deep sedation or general anesthesia is lacking. An observational study of 744 prospectively collected patients who underwent ERCP demonstrated that cholangioscopy was an indication for propofol deep sedation or general anesthesia, and ERCP difficulty (including cholangioscopy) was significantly associated with the need for anesthetic support [25]. A retrospective United Kingdom case series also identified conscious sedation as a factor for incomplete visualization of the biliary system [26]. Given that cholangioscopy does add to the procedural time even in standard cases, ideally deep sedation or general anesthesia is provided. However, it is recognized that if a patient has been shown to be safely tolerant of the procedure under conscious sedation then cholangioscopy for stone treatment, foreign body removal, and evaluation of extrahepatic biliary strictures may effectively be undertaken without deep sedation or general anesthesia.

STATEMENT 9

Preprocedural preparation for peroral cholangioscopy, pancreatoscopy, or percutaneous cholangioscopy in terms of antithrombotics, anticoagulants, and antibiotics should comply with existing ESGE guidance.

Agreement 95 %

Current ESGE guidelines on endoscopy in patients on anticoagulation or antiplatelet drugs do not address the practice of cholangiopancreatoscopy [27]. Retrospective peroral cholangiopancreatoscopy series indicate that all instances of periprocedural hemorrhage resulted from the sphincterotomy, which may imply that the cholangiopancreatoscopy aspect of

the procedure presents a low bleeding risk [28–35]. It is recommended that the bleeding risk of cholangiopancreatoscopy is only graded as high risk with reference to the ESGE guidelines if a sphincterotomy is required for the procedure (usually only if cholangiopancreatoscopy is undertaken at the index ERCP), or for percutaneous cholangioscopy.

ESGE recommends antibiotic prophylaxis in all patients undergoing cholangioscopy. The risk of cholangitis in patients undergoing cholangioscopy (peroral or percutaneous) is higher than in conventional ERCP (7.5%–12%) [36], and this is likely due to the irrigation of saline into the biliary tree during a cholangioscopy. Three retrospective comparative studies determined the prevalence of cholangitis with or without antibiotic prophylaxis, and whilst two studies [37, 38] favored antibiotics statistical significance was not reached (*P* values 0.09–0.21). One study did demonstrate a statistically significant advantage for the use of prophylactic antibiotics [39]. The use of prophylactic antibiotics in all patients undergoing cholangioscopy should be used as an auditable quality metric for a cholangioscopy service.

No evidence of increased infection risk has been published in the context of pancreatoscopy, hence prophylactic antibiotics during pancreatoscopy are not recommended routinely.

Domain 3: Peroral cholangioscopy

STATEMENT 10
Cholangioscopy-assisted intraluminal lithotripsy is an effective and safe treatment of difficult bile duct stones that cannot be cleared by conventional ERCP techniques.
Agreement 100%

STATEMENT 11
Complete extrahepatic stone clearance with the initial cholangioscopy session should be successful in 80% of intention-to-treat cases.
Agreement 95%

ESGE has published guidance on management of difficult bile duct stones, including the important role of endoscopic papillary large-balloon dilation (EPLBD) [40]. The majority of patients undergoing ERCP for bile duct stones do not require cholangioscopy-directed lithotripsy. The causes of failure to clear stones with conventional ERCP techniques usually relate to stone size; stone location (cystic duct/intrahepatic), and bile duct anatomical factors (presence of a distal stricture, unusual ductal anatomy, surgically altered anatomy). In these cases cholangioscopy-guided lithotripsy has been shown to be safe, effective, and cost-effective [9, 39, 41–50]. It has also been shown that cholangioscopy can be useful to confirm stone clearance in certain cases [51, 52]. Electrohydraulic lithotripsy (EHL) is more ubiquitously used than laser for cholangioscopy-guided lithotripsy because of the lower cost and lack of need for laser safety measures. Randomized data comparing the two modalities is lacking although it has been shown that laser may be more effective, particularly for hard stones [53].

Based on published literature it is recommended that complete ductal clearance should be possible after a single cholangioscopy-guided lithotripsy session as an intention to treat in >80% of cases. This rate of duct clearance should be used as an auditable quality metric for a cholangioscopy service.

STATEMENT 12
Cholangioscopy is recommended with visually guided biopsies in the evaluation of undefined biliary strictures, ideally at index ERCP to prevent negative visual and histological effects of prior stenting; except in cases with an associated mass lesion that may allow tissue acquisition by other means (e. g. EUS or percutaneous biopsy).
Agreement 95%

STATEMENT 13
In cholangioscopic evaluation of extrahepatic biliary strictures visual assessment should be achieved in >90% of cases, and at least 4 visually guided biopsies should be undertaken with sufficient tissue for histological assessment being obtained in >80% of cases.
Agreement 100%

Cholangioscopy has an important role in visual diagnosis and targeted biopsy of undefined biliary strictures that has been widely studied [39, 46, 54–58]. Until the advent of widely available peroral cholangioscopy, endobiliary tissue sampling has relied on brush cytology and the technically challenging use of forceps advanced fluoroscopically within the bile duct. There is insufficient evidence to suggest that cholangioscopy should completely replace the additional need for biliary cytology and therefore biliary cytology is still advised if the stricture has been traversed by a guidewire. Despite the promise of the cholangioscopic appearance of a lesion enhancing the diagnosis of strictures, the results are variable and cannot yet be used as a definitive guide to the presence of malignancy [59–61].

It is known that prior stenting can negatively affect the histological and cytological interpretation of endobiliary sampling [62], and so ESGE recommends that, where possible, cholangioscopy is undertaken at the index ERCP in cases of undefined biliary stricture, unless there is an associated mass lesion that may facilitate an EUS or percutaneous biopsy. The role for cholangioscopy-guided biopsy at the very distal periampullary bile duct is also limited, as it can be very challenging to position the tip of a cholangioscope at this level and successfully pass fine cholangioscopy forceps.

ESGE recommends that for extrahepatic biliary strictures a visual assessment of the stricture should be possible in >90% of cases. The number of biopsies and volume of tissue acquired

at cholangioscopy likely correlates with diagnostic yield [63] and so it is recommended that at least 4 cholangioscopy-directed biopsies should be undertaken in the assessment of strictures. Kalaitzakis et al. demonstrated that obtaining at least 4 versus less than 4 biopsy specimens resulted more often in adequate samples (90 % vs. 64 %, $P = 0.037$) [26]. Sufficient biopsy material for a confident histological assessment should be acquired in > 80 % of cases. These rates should be used as an auditable quality metric for a cholangioscopy service.

STATEMENT 14
Cholangioscopy-assisted removal of a foreign body from the bile duct is feasible and effective when standard extraction techniques fail.
Agreement 100 %

Cholangioscopy is increasingly recognised as an effective modality to remove a foreign body within the biliary tree, with numerous case reports of success [64–70]. In most circumstances this will relate to the proximal migration of a metal or plastic stent and is facilitated by a small snare or basket designed for cholangioscopic use.

STATEMENT 15
Cholangioscopy is recommended for visually assisted wire-guided cannulation of strictures or intrahepatic ducts in cases of failed attempts under fluoroscopic guidance.
Agreement 100 %

Visually assisted guidewire cannulation of either tight biliary strictures, or specific intrahepatic ducts, when fluoroscopic guidance has been unsuccessful, has been widely practiced since the availability of single-operator peroral cholangioscopy. The use of cholangioscopy to cross a stricture can be the difference between success and failure of an ERCP attempt. It can be very useful in anastamotic strictures in liver transplant patients because of the often extremely tight stenosis and the eccentric configuration of the native-to-graft bile duct anastomosis [71].

Domain 4: Percutaneous transhepatic cholangioscopy

STATEMENT 16
Percutaneous transhepatic cholangioscopy is indicated in patients with transhepatic bile duct access in cases of altered anatomy or failed ERCP and an indication for cholangioscopy (stone management; biliary stricture evaluation; foreign body removal).
Agreement 100 %

STATEMENT 17
Percutaneous transhepatic cholangioscopy can be performed via a mature percutaneous fistula or the use of a 11–14-Fr percutaneous sheath introducer.
Agreement 95 %

Access to the proximal biliary tree with standard ERCP may be precluded by pathology or previous surgery, or it may not be technically possible to advance guidewires and accessories during an ERCP because of tight angulation into the target liver segment. Whilst the benefits of percutaneous cholangioscopy have been appreciated for decades [1, 72], technical and equipment challenges have hindered widespread practice until the introduction of single-operator cholangioscopy and, more recently, development of a short single-use single-operator digital cholangioscope for percutaneous use. This cholangioscope also has the advantages of needing only a 10–14-Fr percutaneous sheath introducer rather than the 16–18-Fr device required for the previously available reusable cholangioscopes. A recent meta-analysis of percutaneous cholangioscopy showed that the Spyglass Discover required fewer sessions than reusable cholangioscopes [73]. Furthermore, the cumulative success rate of stone management or stricture assessment in this meta-analysis was shown to be 98.7 % (95 % confidence interval [CI] 97.6 %–99.8 %), although this included patients from between 1980 and 2020 across 14 studies that were almost all retrospective cohort or case series.

It may also be safe to undertake cholangioscopy at the time of the index percutaneous biliary drainage procedure as demonstrated in a small case series [74], when previously the practice was that cholangioscopy should only be undertaken when a percutaneous drain tract had matured.

The taskforce elected not to develop quality standards specifically for the practice of percutaneous transhepatic cholangioscopy in the management of stones or in stricture evaluation, as it was felt that the same performance measures as for peroral cholangioscopy should be applicable.

Domain 5: Pancreatoscopy

STATEMENT 18
Pancreatoscopy should only be undertaken in expert referral centers with a high volume of ERCP and cholangioscopy cases.
Agreement 100 %

Pancreatoscopy is increasingly being used for the management of pancreatic duct (PD) stones and, to a lesser extent, the investigation of ductal pancreatic lesions (including intraductal papillary mucinous neoplasms [IPMNs]). Nevertheless, it represents a small percentage of all cholangiopancreatoscopy indications and a tiny percentage of overall ERCP activity [4].

The procedure is complex and although adverse events do not appear to be significantly higher than for ERCP, this may largely be a reflection of the lower rates of ERCP-related pancreatitis in individuals undergoing pancreatoscopy (for PD stones related to chronic pancreatitis). Serious complications from pancreatoscopy have been reported [75]. Pancreatoscopy is never required in an emergency or urgent setting and all patients with complex pancreatic disease require discussion within a specialist MDM. It is therefore appropriate that pancreatoscopy should only be delivered by endoscopists with advanced cholangiopancreatoscopy skills in specialist referral units with regular and ongoing involvement with the endoscopic management of complex pancreatic disease.

STATEMENT 19
Indications for pancreatoscopy are: painful main pancreatic duct stones, foreign body removal (e. g. migrated stents) and, only in high-volume units in selected patients, the assessment of suspected main duct intraductal papillary mucinous neoplasm (IPMN).
Agreement 95 %

European guidance recommends endoscopic therapy as first-line treatment for patients with symptomatic obstructive chronic pancreatitis due to pancreatic strictures or intraductal stones (this includes ERCP-directed therapies and extracorporeal shockwave lithotripsy [ESWL]), whereas surgery should be preferably reserved for patients in whom endoscopic treatment fails [76, 77]. Pancreatoscopy-directed lithotripsy has been shown to be a safe and effective approach for the treatment of painful obstructing main pancreatic duct stones in a prospective multicenter cohort trial [78], and a prospective case series [79] which also showed good rates of long-term benefit [80]. Case selection is important, as pancreatoscopy requires a dilated PD, and also stones in the upstream PD may not be reachable. The hardness of the stone can also lead to the failure of electrohydraulic lithotripsy (EHL), and in these cases laser lithotripsy may be beneficial. The possible advantages of pancreatoscopy-guided lithotripsy over ESWL include the ability to manage strictures at the same time as stone management and avoidance of referral to urology for therapy. The outcome of a randomized trial comparing pancreatoscopy and ESWL for the management of symptomatic PD stones is awaited [81].

Pancreatoscopy may be successfully used for the removal of misplaced/fractured pancreatic stents if there is sufficient PD dilatation [82–86].

IPMN is a precancerous lesion of the pancreas. Main duct IPMN implies the highest risk of malignant transformation and surgery is recommended if the main duct is dilated to >10 mm or if there are enhancing nodules >5 mm [87]. However, determining the extent of the IPMN with conventional imaging is difficult and can result in an incomplete or an excessive pancreatic resection. In expert centers pancreatoscopy may be used to: (a) confirm the diagnosis in equivocal cases (e. g. if there is a question of chronic pancreatitis versus IPMN); (b) determine the presence of malignancy or high grade dysplasia; and (c) define the extent of main duct IPMN to guide the surgical resection margins [88]. Whilst pancreatoscopy has been shown to influence the surgical decision-making, there is a 12 % risk of complications [88], which are more likely if the PD dilatation is focal rather than diffuse. This emphasizes the importance of case selection. Additional prospective studies are needed to further define the precise role of pancreatoscopy in the workup of main duct IPMN.

The use of pancreatoscopy to evaluate undefined pancreatic duct strictures has been described in a 1998 prospective case series [89]. There is currently insufficient evidence to recommend pancreatoscopy and visually directed biopsies for the evaluation of undefined PD strictures. Such evaluation would include computed tomography (CT) and/or magnetic resonance imaging (MRI) and usually an EUS to look for a mass lesion or ductal abnormalities. If pancreatoscopy is undertaken to evaluate PD strictures it should be performed in an expert pancreatic center. Additionally, there should be a concern about neoplasia; sufficient dilatation of the PD downstream (towards the ampulla) of the stricture; and no mass lesion that can be sampled with EUS fine-needle aspiration or biopsy.

Statements: Curriculum and training

Domain 6: Curriculum for training

STATEMENT 20
Cholangioscopy is considered an advanced adjunct to ERCP and prior to undertaking supervised cholangioscopic procedures trainees should be competent in the basic skills of ERCP (Schutz level 1 and 2) as defined by ESGE (duodenal intubation, biliary cannulation, distal bile duct stenting, ≤10-mm stone extraction).
Agreement 100 %

Peroral single-operator cholangioscopy requires the skilled execution of duodenoscope maneuvers to obtain a stable position and also proficiency in the fine manipulation of the cholangioscope and its small accessories through the working channel of the duodenoscope. Therefore it is recommended that before training in cholangioscopy trainees should be well on their way to proficiency in basic ERCP as defined by ESGE [90] (which defines key performance indicators and a career volume of 300 cases).

STATEMENT 21
Cholangioscopy training should take place in expert referral centers with a high volume of ERCP and cholangioscopy cases.
Agreement 100 %

As cholangioscopy is an advanced adjunct to ERCP it follows that the skills should be acquired during a period of dedicated ERCP training. Endoscopic procedural experience is obviously an important determinant of procedure competence [91,92], and high intensity (rate at which cases are accrued) also has a positive effect on training [93]. The majority of cholangioscopy training is therefore required to be in expert referral centers that can provide the case volume and variety needed (see Statement 2). These centers provide the trainee with the experience of all aspects of a cholangioscopy service which is vital for the trainee to go on to practice independently (aspects such as involvement in the planning of interventional strategies, management of complications, and trainee involvement in the whole inpatient stay). However, it is recognized that busy regional hospitals providing an effective standard cholangioscopy service play an important part in training.

STATEMENT 22
A trainee's principal trainer should be an experienced trainer ideally with at least 3 years of experience in undertaking independent cholangioscopy to the determined quality standards.
Agreement 100 %

Being an effective endoscopy trainer is more demanding when a procedure is both technically difficult and carries significant risks of an adverse event. An expert has an unconscious competence in ERCP and cholangioscopy and so is likely to be more able to better observe and feed back on all aspects of the training episode. There is no evidence on how long an endoscopist should have been practicing cholangioscopy independently before becoming a trainer, but the consensus is a minimum of 3 years.

STATEMENT 23
Simulation-based cholangioscopy training can accelerate the trainee's learning curve and should be encouraged where available.
Agreement 95 %

Simulation has been shown to have a positive effect on ERCP training [94,95]. Those commencing cholangioscopy training will benefit from becoming familiar with the cholangioscope and its maneuvers in a simulated setting with less cognitive overload. Where available, early training with simulation should be encouraged in addition to learning during endoscopy lists, formal courses/conferences, and e-learning.

Training should also focus on achieving competence in characterization of imaging.

STATEMENT 24
Trainees should progress from standard to advanced cholangiopancreatoscopy procedures as follows:
- extrahepatic stones
- extrahepatic biliary strictures
- Mirizzi syndrome
- proximally migrated stent removal
- hepatolithiasis
- intrahepatic biliary strictures
- transhepatic cholangioscopy
- pancreatoscopy for pancreatic stones
- pancreatoscopy for lesion evaluation.

Agreement 95 %

Case selection is important to maximize the quality of the training episode for the trainee. It is recommended that trainees gain experience in cholangiopancreatoscopy procedures in a stepwise fashion, from the most straightforward and with the lowest risk of adverse events (extrahepatic stones) up to the most demanding and with the greatest potential risk (pancreatoscopy).

STATEMENT 25
Trainees should be encouraged to reflect on their own performance, and to keep a contemporaneous logbook of cholangioscopy procedures that includes the degree of trainer support that was required for each aspect of the procedure.
Agreement 100 %

It is recommended that trainees keep a contemporaneous record of all their endoscopy cases, including cholangioscopies, and the degree to which the trainer provided support. This encourages reflection, and is a source of evidence for procedural volume and key performance metrics (stone clearance and tissue acquisition).

STATEMENT 26
Trainees with basic ERCP competence are likely to require a minimum of 6 months in a high-volume cholangioscopy unit to achieve competence in standard cholangioscopy, and of 12 months for advanced cholangiopancreatoscopy.
Agreement 80 %

The rate at which trainees acquire competence in endoscopy varies and is dependent on many factors (innate skills, previous experience, trainer aptitude, procedure volume and intensity).

Therefore recommending a minimum period of training to become independent in cholangioscopy is open to challenge. However, program directors and trainees need to be able to plan a period of training, and cholangioscopy would be included with other advanced ERCP techniques (and very often with EUS) [90]. Even in centers with very high volumes of cholangioscopy, at least 6 months of dedicated training is likely to be required for a trainee to attain competence in cholangioscopy, and a year for advanced cholangiopancreatoscopy, before they can demonstrate that they are achieving the performance metrics defined in this Position Statement for independent practice.

STATEMENT 27
Competence in cholangioscopy should be defined as the ability to successfully perform the procedure effectively without trainer assistance in 80 % of procedures.
Agreement 100 %

It is recommended that trainees successfully undertake cholangioscopy in 80 % of cases without trainer assistance before moving on to independent practice. This is consistent with other definitions of endoscopic competence in ESGE curricula [90]. Procedural competence can be further defined as achieving the key performance measures highlighted in this document (80 % success in bile duct stone lithotripsy; 80 % acquisition of sufficient histological material for diagnosis).

Because of the many factors influencing skills training it is likely that among trainees there will be a significant range in procedure numbers required before this level of performance is reached [96]. There is currently no evidence from cholangioscopy learning curves to support the minimum case numbers likely to be needed by trainees to achieve this success threshold in standard cases. However, when extrapolated from other advanced interventions (albeit in EUS), and when the trainee is already competent in basic ERCP, it is likely to be at least 20 [97–99]. Prospective studies on the acquisition of cholangiopancreatoscopy skills are urgently required to better evidence this statement.

Conclusions

As part of the ESGE mission to identify quality in endoscopy as a major priority, we present the ESGE Position Statement on cholangiopancreatoscopy in terms of the indications, performance standards, and training. The taskforce included representation from across Europe with different backgrounds and ranges of career experience. Standard Delphi methodology was used to propose and agree statements under six domains: the service; case considerations; peroral cholangioscopy; percutaneous cholangioscopy; pancreatoscopy; and curriculum and training. The taskforce refrained from entering into a detailed review of the technicalities of cholangiopancreatoscopy.

A principal take-away message is that, for standard indications, cholangioscopy can be democratized and undertaken in any sufficient-volume ERCP unit provided that each endoscopist is undertaking at least 10 cases per year after appropriate training, and the endoscopist and unit can demonstrate acceptable performance standards in their ERCP practice and in the performance standards outlined in this paper. Those indications are extrahepatic stone management, extrahepatic stricture evaluation (preferably after review of the case in a specialist MDM), selective guidewire cannulation, and foreign body removal. The use of cholangioscopy for difficult extrahepatic stone management in particular is to be encouraged in centers undertaking a high volume of ERCPs, to avoid patients undergoing repeat procedures. All other indications for cholangioscopy (hepatolithiasis, proximal biliary stricture evaluation, percutaneous cholangioscopy) and any indication for pancreatoscopy should be undertaken in specialist referral high-volume ERCP units with rapid access to HPB surgical and radiological support.

The performance measures that should be the subject of ongoing audit for cholangioscopy are as follows:

- the use of antibiotics
- each endoscopist's undertaking a minimum of 10 procedures a year
- complete ductal clearance after a single cholangioscopy-guided lithotripsy session as an intention-to-treat in >80 % of cases
- Sufficient biopsy material for a confident histological assessment in >80 % of cases.

Only the Statements pertaining to the use of antibiotic, antiplatelet, and anticoagulation treatment, and the Statements on the indication for standard peroral or percutaneous cholangioscopy, meet the threshold of GRADE criteria for being a strong recommendation [7]. If the evidence is considered low quality ("further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate") or very low quality ("any estimate of effect is very uncertain") then the statement can only be considered weak. The paucity of evidence resulted in all the recommendations being "good practice statements" and not amenable to GRADE assessment. There is therefore an urgent need for further research into almost all facets of cholangiopancreatoscopic practice and training. Despite the deficit of evidence, there was a high degree of consensus for all but one of the Statements.

The landscape in cholangiopancreatoscopy is already changing as the technology improves. The development of cholangioscopes with a wider working channel, and dual channels and narrower scopes, may allow the use of larger EHL probes and allow navigation to stones that have been hard to reach, which may improve the treatment of difficult biliary and pancreatic stones. Evaluation of strictures may improve with larger biopsy forceps, and therefore likely increasing sample size and accuracy of histology. Improved visual resolution and image enhancement, possibly supported by artificial intelligence [100], may lead to great confidence in visual diagnosis of dysplasia

and neoplasia, as in the upper gastrointestinal tract and the colon. The horizons of visually directed endobiliary and endopancreatic therapy are likely to expand, including the ablation or resection of tissue and balloon dilation of strictures. There may also be a lowering of the significant costs, which will impact on a wider use of cholangiopancreatoscopy worldwide. It is therefore likely that this Position Statement will need to be the subject of revision by ESGE within 5 years.

The priorities for further research in cholangiopancreatoscopy are as follows:

- The correlation of unit and endoscopist procedure volumes with improved cholangiopancreatoscopy outcomes and safety
- Evaluation of each cholangioscopy system and accessory for efficacy in stone management (image resolution, effect of channel diameter, effect of dual channel, lithotripsy accessory) to inform the performance indicator of complete stone clearance in 80 % of cholangioscopy cases
- Evaluation of each cholangioscopy system and accessory for efficacy in tissue acquisition (image resolution, AI, effect of channel diameter, effect of dual channel, tissue accessory) to inform the performance indicator of tissue adequacy for histology in 80 % of cholangioscopy cases
- Evaluation of each pancreatoscopy system and accessory for efficacy in stone management (scope diameter, channel diameter, effect of dual channel, tissue accessory)
- Better definition of the role of pancreatoscopy in the management of IPMN and undefined pancreatic duct strictures
- Visual diagnosis of lesions with improved image resolution, image enhancement, and artificial intelligence
- Learning curves for cholangiopancreatoscopy skills acquisition to inform recommended procedure volumes before independent practice.

It is intended that this document will be beneficial to units looking to set up a cholangioscopy service as well as to established units and endoscopists needing to demonstrate that a quality service is being provided. It is expected that the section on training in cholangiopancreatoscopy will be of use to endoscopy training directors, trainers, and trainees.

Disclaimer

The legal disclaimer for ESGE Guidelines [101] applies to this Position Statement.

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Competing interests

A. Anderloni has provided consultancy to Boston Scientific (from 2016, ongoing) and Olympus (from 2023, ongoing). M. Ellrichmann has provided consultancy to Boston Scientific, MicroTech, Medtronic, and Olympus (all from 2020, ongoing). M. Hollenbach has received lecture honoraria from Fujifilm (from 2019 to 2021). I. Hritz has provided consultancy and training for Olympus (from 2017, ongoing), and provided consultancy and received a speaker fee from MicroTech (from 2023, ongoing). G. Johnson has provided educational consultancy to Boston Scientific (from 2023, ongoing) and Olympus (2025). J.W. Poley has provided consultancy to and received a speaker's fee from Pentax Medical (from 2015, ongoing) and provided consultancy to Boston Scientific (from 2015, ongoing). J. Vila has provided consultancy to Boston Scientific (from 2016, ongoing). G. Webster has received honoraria for lecturing/teaching from Boston Scientific who have also sponsored endoscopy courses in his department (from 2015, ongoing). W. Ahmed, I. Boskoski, S. de Campos, L. Czako, M. Ferlitsch, P. Gkolfakis, T. Hucl, L. Kylänpää, M. Manno, A. Papaefthymiou, C. Schlag, and T.C. Tham declare no competing interests.

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