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European Consensus Recommendations for Direct Cholangioscopy and Pancreatoscopy Using a Modified Delphi Process

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ABSTRACT

Background and Aim: Direct cholangioscopy and pancreatoscopy have become widely implemented techniques in the diagnostic and therapeutic algorithms of several pancreaticobiliary disorders. This study aimed to generate general and indication-specific European consensus recommendations on cholangioscopy and pancreatoscopy.

Methods: Supported by the available literature, statements were formulated and grouped into the following categories: (1) preprocedural considerations, (2) general technical aspects, (3) biliopancreatic stones, (4) biliary strictures, and (5) other indications. The evidence level of each statement was determined using the GRADE methodology. Cholangioscopy experts were invited to participate in a modified Delphi process. When 80% consensus was not reached, the statement was modified based on expert feedback and subjected to an additional Delphi round. Statements were rejected if they failed to reach consensus after three Delphi rounds.

Results: Thirty cholangioscopy experts completed the Delphi process. Forty-two (97.6%) generated statements were accepted, of which 39 (92.9%) in the first Delphi round. 12 statements on preprocedural and periprocedural settings, 8 statements on biliopancreatic stones, 13 statements on biliary strictures, and 9 statements on other indications were accepted.

Conclusion: Using a modified Delphi process, we developed general and indication-specific consensus recommendations for cholangioscopy to guide clinical practice.

1 | Introduction

Over the last decade, continuous improvement of technical devices has led to the widespread implementation of digital single-operator cholangioscopy (D-SOC) and pancreatoscopy (D-SOP) for several pancreaticobiliary disorders.

The two major indications for D-SOC are direct lithotripsy of large biliary or pancreatic stones and diagnostic evaluation and sampling of biliary strictures; however, D-SOC has also proven its value for selective wire cannulation (e.g., of intrahepatic biliary branches or the cystic duct), for retrieval of migrated biliary or pancreatic stents, and for preoperative assessment of cholangiocarcinoma or pancreatic intraductal papillary mucinous neoplasia [1].

Previous consensus guidelines focused on the indications for D-SOC [2], the role of cholangioscopy in the diagnostic workup of indeterminate biliary strictures [3] and biliary stones [4], but general consensus guidelines on the use of cholangioscopy and pancreatoscopy including how-to instructions for all indications are currently not available.

Given the increasing worldwide use of direct cholangioscopy and pancreatoscopy, the European Cholangioscopy Group felt the need to carry out an expert consensus study to guide the correct use and implementation of cholangioscopes in the diagnostic/therapeutic algorithm of pancreaticobiliary disorders. With recommendations based on literature evidence and expert experience that cover both general and indication-specific items, we aim to optimize the performance of cholangioscopy and pancreatoscopy in clinical practice.

2 | Methods

2.1 | Generation of Statements

To formulate our statements, we systematically reviewed the available evidence in the literature. A systematic search of the literature was conducted in the PubMed and Cochrane databases by EP, SS, EG, VA and PH up to July 2024. The MeSH terms used included (a combination of) "Cholangioscopy," "Pancreatoscopy," "Choledochoscopy," "Cholangioscope," "Single-operator," "Endoscopic Retrograde Cholangiopancreatography," "Stones," "Lithotripsy," "Stricture, indeterminate," "Cholangitis, sclerosing," "Biliary stent," "Stent, migration," "Stent, retrieval," "Cannulation, selective," "Biliary Tract," "Pancreatic duct," "Bile Duct Neoplasms," "Bile Duct Diseases," "Intraductal pancreatic mucinous neoplasm," "Biopsy," "Percutaneous."

The level of evidence for each statement was scored using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system, which categorizes evidence as high, moderate, low, or very low quality [5].

2.2 | Modified Delphi Process

European experts in cholangioscopy were identified based on European cholangioscopy group membership and/or scientific track record.

After final confirmation of participation, we sent them a link to the survey, which was conducted online through a commercially available platform (https://surveyplanet.com). All statements were grouped into the following four categories: General recommendations, Pancreaticobiliary stones, Indeterminate strictures, and other indications. Each statement was presented to the participants with the most important literature references and the GRADE score.

The participants had the option to agree or disagree with each statement. In cases of disagreement, the participants were asked to provide their rationale and to suggest modifications of the statement, if possible.

The threshold for accepting a statement was set at a threshold of 80%. If a statement did not reach the consensus threshold, we reviewed all expert comments and proposed a revised statement in the next Delphi round. Each modified statement was presented to the participants with the anonymized feedback of their expert colleagues on the original statement. A statement was rejected if no consensus was reached after three consecutive Delphi round(s).

3 | Results

3.1 | Delphi Process

A total of 32 invited Europe based cholangioscopy experts agreed to participate, of which 30/32 (96.9%) completed the Delphi process.

Thirty-nine statements (90.7%) out of 43 generated statements were accepted in the first Delphi round. One statement was rejected. In the second round, one additional statement was accepted after modification based on expert feedback.

A third round was performed in order to modify one statement (S13) considering the potential misinterpretation of the original, and to complete the consensus with two additional statements (S14, S35). Mean acceptance rate was 93.27% ± 5.38%. The process is summarized in Figure 1.

Figure 1 provides an overview of our modified Delphi process. We refer to Supporting Information S1: Appendix A for the raw transcripts of all Delphi rounds.

3.2 | General Recommendations

A total of 20 general statements regarding cholangioscopy and pancreatoscopy were generated and categorized into pre-procedural and periprocedural statements (Table 1). The statements related to the optimal learning pathway, prophylactic

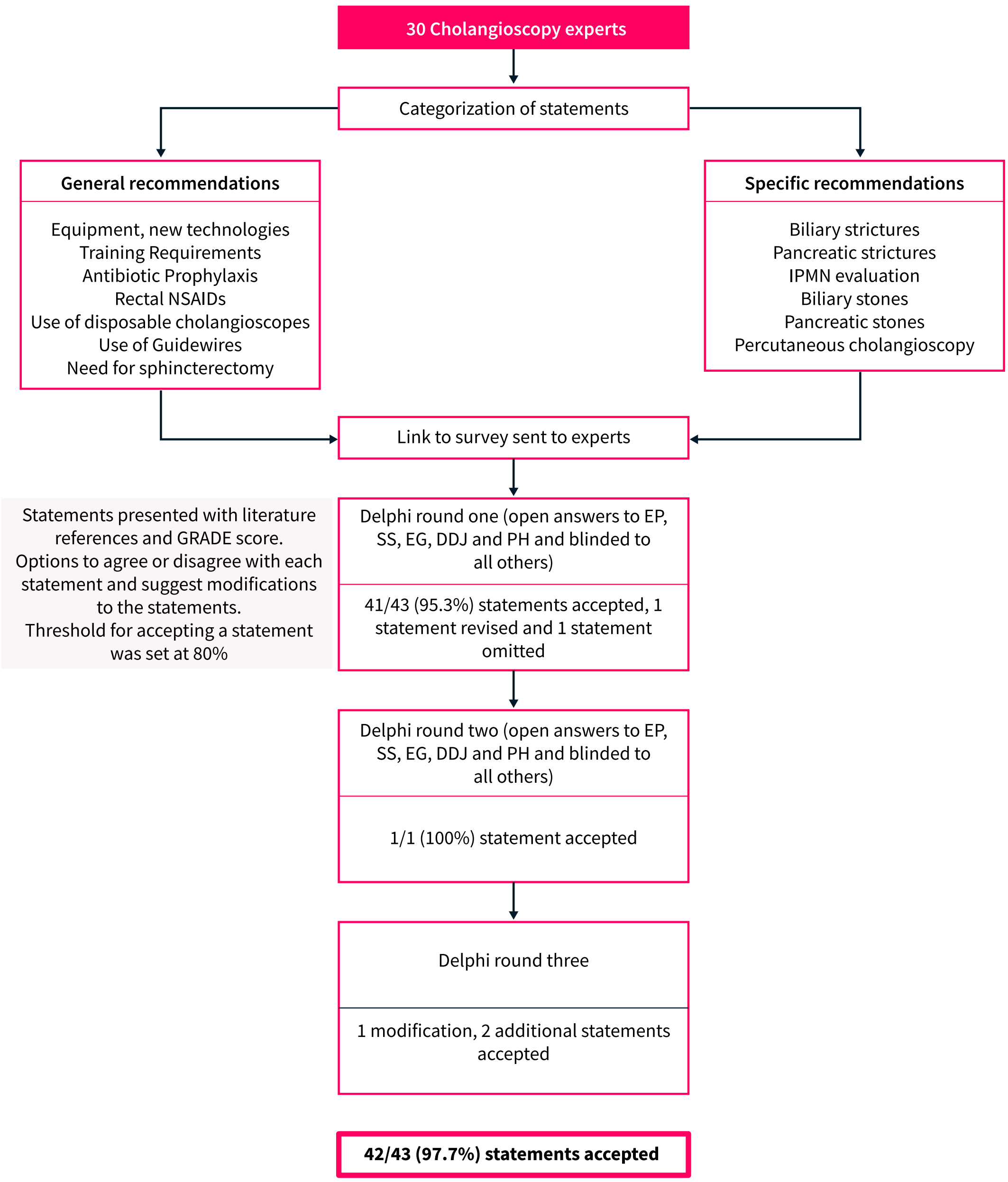

FIGURE 1 | Modified Delphi flowchart.

TABLE 1 | General recommendations.

Statement	Summary of evidence	Consensus agreement
Preprocedural		
S1 Basic training in use of single operator cholangioscopes (theoretical course and hands-on training on simulators and/or in vivo models) is suggested before proceeding to cholangioscopy in patients	Very low quality of evidence One position statement [6]	86.7%
S2 Adequate proficiency in ERCP is recommended to perform single operator cholangioscopy	Very low quality of evidence One retrospective study [7]	100%
S3 Broad-spectrum antibiotic prophylaxis should be routinely administered before cholangioscopy	Moderate quality of evidence One guideline [8] One meta-analysis [9] One RCT [10] One systematic review [11] Two prospective study [12, 13] Two retrospective studies [14, 15] *Use of antibiotic prophylaxis in this setting directly assessed only in one prospective study included in the statement	96.7%
S4 In the absence of a strict contraindication, all patients should receive rectal NSAIDs prior to cholangioscopy or pancreatoscopy	Low quality of evidence One guideline [8] One meta-analysis [16] One prospective study [17] Three retrospective studies [18–20]	93.3%
S5 An adequate pre-procedural sphincterotomy or sphincteroplasty is suggested to facilitate introduction of the cholangioscope and ensure adequate drainage of the irrigation fluid	Very low quality of evidence Expert opinion only	100%
S6 Percutaneous cholangioscopy may be considered in cases of indeterminate biliary strictures or intrahepatic lithiasis after failed endoscopic approach and/or surgically altered anatomy	Low quality of evidence One meta-analysis [21] Two retrospective studies [22, 23] One case report [24]	96.7%
S7 Percutaneous cholangioscopies should be performed or supervised by physicians experienced in PTBD procedures	Very low quality of evidence Expert opinion only	86.7%
S8 For percutaneous use, new-generation single-use cholangioscopes should be preferred over older generation re-usable cholangioscopes	Low quality of evidence One meta-analysis [21]	86.7%
S9 Cholangioscopy may be considered in the diagnostic workup of unexplained haemobilia if other imaging modalities fail to yield a diagnosis	Very low quality of evidence One case report [25]	90%
S10 Preoperative pancreatoscopy can be considered in the diagnostic workup of main pancreatic duct dilation when other imaging modalities have yielded inconclusive results	Moderate quality of evidence Two guidelines [26, 27] One systemic review [28] One case report [29] One prospective single center study [30] One prospective multicentric study [31]	90%

(Continues)

Statement	Summary of evidence	Consensus agreement
	Three retrospective studies [32–34]	
S11 Preoperative or intraoperative pancreatoscopy can be considered in patients with main duct intraductal papillary mucinous neoplasms (MD-IPMN), to guide the surgical resection	Moderate quality of evidence Two guidelines [26, 27] One systemic review [28] One case report [29] One prospective multicentric study [31] Three retrospective studies [32–34]	90%
Peri-procedural		
S12 Over-the-wire introduction of the cholangioscope may be preferred over freehand introduction depending on the size of the sphincterotomy, the diameter of the common bile duct and the expertise of the operator	Very low quality of evidence Systematic review [35]	93.3%
S13 Direct cholangioscopy-assisted wire cannulation can be utilized for selective cannulation of ducts located proximal to the papilla, such as intrahepatic ducts or the cystic duct, particularly in cases where conventional ERCP techniques fail	Very low quality of evidence Two retrospective studies [36, 37]	100%
S14 Direct cholangioscopy or pancreatoscopy assisted stent removal can be considered in case of proximal stent migration and failed extraction by convention techniques	Very low quality of evidence Two case reports [38, 39]	93.3%
S15 It is recommended to avoid excessive use of the elevator during introduction of the cholangioscope, as this may damage the scope and impair its functionality	Very low quality of evidence Expert opinion only	86.7%
S16 Locking the steering wheels of the duodenoscope can be considered to enhance intraprocedural scope stability once the optimal position has been achieved and the cholangioscope has been introduced in the desired duct	Very low quality of evidence Expert opinion only	100%
S17 Intraductal CO_2 instillation should be avoided during cholangioscopy	Very low quality of evidence One comparative study [40] Two case reports [41, 42]	93.3%
S18 Balanced irrigation and suction are needed to optimize visualization and limit the risk of cholangitis and pancreatitis	Very low quality of evidence Expert opinion only	96.7%
S19 We suggest to irrigate the main pancreatic duct at the lowest possible pressure to limit the risk of postprocedural pancreatitis	Very low quality of evidence One systematic review [43] Two retrospective studies [44, 45]	96.7%
S20 We suggest to take biopsies of all visible lesions during pancreatoscopy	Low quality of evidence Two guidelines [26, 27] One systematic review [28] One case report [29] One prospective multicentric study [31] Three retrospective studies [32–34]	96.7%

Abbreviations: ERCP, endoscopic retrograde cholangiopancreatography; NSAIDs, non-steroidal anti-inflammatory drugs.

medication use, scope introduction and manipulation, irrigation during the procedure, use of percutaneous cholangioscopy, diagnostic preoperative and intraoperative pancreatoscopy, and exceptional use for selective guidewire placement, diagnosis of hemobilia and migrated stent retrieval. All statements were accepted either in their original form or with modifications, except for the statement on peri-procedural simethicone use, which was rejected (Supporting Information S1: Appendix A).

The background of the recommendations is provided in Supporting Information S2: Appendix B, Section 1.

3.3 | Recommendations Specific for Biliopancreatic Stones

A total of 8 statements regarding the use of cholangioscopy and pancreatoscopy for biliopancreatic stones were generated (Table 2). The statements related to the position of cholangioscopy in the therapeutic algorithm of bilio-pancreatic stones and the optimal technique of lithotripsy for biliary and pancreatic stones. All statements were accepted in their original form (Supporting Information S1: Appendix A).

The background of the recommendations is provided in Supporting Information S2: Appendix B, Section 2.

3.4 | Recommendations Specific for Biliary Strictures

A total of 13 statements regarding the use of cholangioscopy in biliary strictures were generated (Table 3). The statements related to standardized definitions of "unexplained" and "indeterminate" biliary strictures, the role of cholangioscopy in the therapeutic algorithm of biliary strictures both within and outside the context of primary sclerosing cholangitis, visual evaluation criteria and taking/processing of biopsy samples.

Twelve statements were accepted in their original form. The statement on cholangioscopy in IgG4-related disease was accepted after modification in the second Delphi round (Supporting Information S1: Appendix A).

The background of the recommendations is provided in Supporting Information S2: Appendix B, Section 3.

4 | Discussion

Direct cholangioscopy and pancreatoscopy have become indispensable tools in the diagnostic workup or therapeutic algorithm of several pancreaticobiliary disorders. The presented European consensus guidelines aim to guide the correct use and implementation of these endoscopic procedures in clinical practice.

A large group of European experts completed the Delphi survey. We opted for an 80% agreement threshold allowing some diversity of opinion within a context of limited scientific evidence. This 80% threshold has also been used in prior Delphi consensus studies on different topics within the field of gastrointestinal endoscopy [110, 111].

A total of 42 recommendations resulted from our Delphi process. The structure and an overview of the statements are summarized in Figure 2. A few of them require some specific discussion:

Cholangioscopy should only be performed by physicians experienced in either ERCP or interventional radiology. Good cholangioscopy simulators are available, which led the panel to recommend a decent hands-on training before starting procedures on patients [6, 7].

Performing cholangioscopy or pancreatoscopy during ERCP increases the risk of cholangitis and pancreatitis [8, 12, 14, 18, 19]. There was a strong consensus for inclusion of any prophylactic measure that could reduce the risk, such as periprocedural antibiotics, preprocedural NSAIDs, the need for sphincterotomy, balanced irrigation and suction and low pressure irrigation of the pancreatic duct during the procedure [8, 20].

Based on commonly observed issues during cholangioscopy training, the expert panel provided some experience-based recommendations to enhance the safety of scope introduction and to improve the scope control during the procedure. They recommended: (a) over-the-wire introduction of the cholangioscope, (b) avoiding excessive use of the scope elevator and (c) locking the steering wheels of the duodenoscope after cholangioscope introduction. Depending on the manufacturer, locked steering wheels of the cholangioscope still allow for steering while stabilizing the scope tip after each maneuver, thereby enabling a stable position in front of the target (stone, stricture).

Several specific recommendations for biliopancreatic stones were made.

Biliopancreatic stones pose significant challenges when conventional endoscopic methods for extraction fail. Difficult stone cases are defined as those involving stones larger than 10 mm, impacted stones, or stones located in anatomically challenging locations such as the cystic duct [112].

Our statements (S21, S22) enhance existing guidelines published by the American Society of Gastrointestinal Endoscopy (ASGE) [112], the Columbian Association of Digestive Endoscopy (ACED) [4], and the International Consensus Guidelines on Interventional Endoscopy in Chronic Pancreatitis [113] regarding the utilization of cholangioscopy in the management of biliopancreatic stones. Our statements provide more precise guidance on the appropriate utilization of cholangioscopy and pancreatoscopy following unsuccessful conventional stone extraction or for difficult to treat stones (e.g.,: stones exceeding 10 mm in diameter, impacted stones, or those situated in intricate anatomical locations, such as cystic duct stones).

Based on available data, a single session of cholangioscopy-assisted lithotripsy can achieve 94.1% ductal clearance in such cases [11, 13, 15, 17, 23–25, 112, 113].

TABLE 2 | Specific recommendations for biliopancreatic stones.

Statement	Summary of evidence	Consensus agreement
Preprocedural		
S21 Cholangioscopy and/or pancreatoscopy with direct lithotripsy should be considered after failed conventional stone extraction by an experienced endoscopist or in case conventional stone extraction is not considered feasible	Moderate quality of evidence One RCT [46] One prospective case series [47] Two case series [48, 49] One metanalysis [50] Two systematic reviews [51, 52]	96.7%
S22 Consideration of pancreatoscopy-assisted lithotripsy should be guided by the clinical scenario, patient anatomy, stone characteristics and local expertise	Low quality of evidence Two meta-analysis [50, 53] One prospective case series [49] One retrospective case series [54]	96.7%
Periprocedural		
S23 We recommend using laser lithotripsy or electrohydraulic lithotripsy for cholangioscopy-assisted stone fragmentation, based on local availability and expertise	Moderate quality of evidence Two RCTs [46, 55] Two systematic reviews [56, 57]	100%
S24 We suggest the use of a liquid medium (preferably sterile saline solution) when performing lithotripsy	Low quality of evidence Prospective case series [47, 58] Case report [59] Expert opinion [60]	100%
S25 While performing lithotripsy, we suggest either direct or near-direct (2 mm away) probe contact with the stone	Moderate quality of evidence Two prospective studies [47, 61] One retrospective multicentric study [62] One case report [63] One systematic review [56] One expert opinion [60]	96.7%
S26 We suggest to target the stone at the same spot rather than at different spot during direct lithotripsy	Very low quality of evidence Expert opinion	90%
S27 In case of failed retrograde pancreatoscopy for lithotripsy, an EUS-guided antegrade approach to facilitate pancreatoscopy can be considered	Low quality of evidence One retrospective case series [64] Two case reports [65, 66]	83.3%
S28 In general, high-power settings are needed for fragmentation of pancreatic duct stones	Very low quality of evidence One systematic review [67] Two case series [68, 69] One case report [70]	96.7%

Abbreviation: EUS, endoscopic ultrasound.

A unanimous consensus (100%) was reached regarding the utilization of either laser lithotripsy (LL) or electrohydraulic lithotripsy (EHL) for the fragmentation of stones (S22). The available data, which is more robust in the case of biliary stones, demonstrated superior outcomes with a better safety profile associated with LL compared with EHL [8, 12, 20, 112]. Nevertheless, the implementation of LL necessitates additional resources [112, 113].

Digital single-operator cholangioscopy (dSOC) is emerging as a key therapeutic tool not only for diagnosis and stone management but also for complex biliary conditions such as Mirizzi

TABLE 3 | Specific recommendations for biliary strictures.

Statement	Summary of evidence	Consensus agreement
Preprocedural		
S29 We suggest to differentiate "unexplained biliary strictures" from "indeterminate biliary strictures." An unexplained biliary stricture is defined as a confirmed stricture on abdominal imaging for which the cause is unclear based on clinical grounds. An indeterminate biliary stricture is defined as a stricture without definitive diagnosis after conventional workup with blood tests, abdominal imaging and standard ERCP sampling techniques (brushings, intraductal biopsy)	Moderate quality of evidence Two meta-analysis [71, 72] Three prospective studies [73–75]	80%
S30 We suggest to incorporate digital single-operator cholangioscopy (D-SOC) into the initial diagnostic workup of unexplained biliary strictures, if the expertise is available	Moderate quality of evidence Six prospective studies [73, 76–80] Three meta-analysis [71, 81, 82] Two retrospective studies [19, 83] One systematic review [75]	80%
S31 When available, we recommend using digital cholangioscopy instead of fiberoptic cholangioscopy	Moderate quality of evidence One meta-analysis [71] One retrospective study [84]	96.7%
S32 In patients with primary sclerosing cholangitis (PSC), cholangioscopy can be considered as part of the initial workup for dominant strictures	Moderate quality of evidence One meta-analysis [72] One RCT [85] Two prospective studies [86–88] Two retrospective study [19, 89, 90] One observational study [74]	90%
S33 Integrating AI-powered tools into cholangioscopy shows promise in enhancing detection of malignancy during digital cholangioscopy	Low quality of evidence One pilot study [91] Two prospective study [92, 93] One retrospective study [94]	83.3%
S34 If available, we suggest using a cholangioscope equipped with a four-way deflected steering tip and an integrated irrigation channel	Very low quality of evidence One case report [95]	100%
Periprocedural		
S35 classification systems may be helpful to standardize the description of intraductal lesions identified during pancreatoscopy	Low quality of evidence One prospective study [30]	86.7%
S36 We recommend combining visual characteristics with targeted biopsy sampling during cholangioscopic evaluation of biliary strictures	Low quality of evidence One multicentric study [74]	93.3%
S37 We suggest using the Mendoza criteria for visual evaluation of a biliary stricture during digital cholangioscopy	Low quality of evidence Four prospective studies [74, 96–98] Three retrospective studies [89, 99, 100]	86.7%
S38 depending on the size of the biopsy forceps, we recommend to take at least three targeted biopsies for histopathological evaluation of a biliary stricture	Moderate quality of evidence One meta-analysis [72] One RCT [101] One prospective study [102] One retrospective study [90]	93.3%

(Continues)

TABLE 3 | (Continued)

Statement	Summary of evidence	Consensus agreement
S39 In case the visual impression of a biliary stricture was suspicious, negative biopsy results warrant a re-evaluation with additional tissue sampling	Moderate quality of evidence One RCT [76] Three meta-analyses [71, 81, 103] One prospective study [73] One retrospective study [89]	90%
S40 The use of the Edmonton criteria can be considered for the classification of dominant strictures in PSC	Low quality of evidence One prospective study [86] One retrospective study [104]	86.7%
S41 Use of cholangioscopy with targeted biopsies and IgG4 staining may be useful in differentiating PSC from IgG4-sclerosing cholangitis (IgG4-SC)	Low quality of evidence One prospective study [105] One prospective case series [106] Two retrospective study [104, 107]	93.3%
Postprocedural		
S42 We suggest using 10% buffered formalin solution for fixation of the biopsy specimens obtained during cholangioscopy	Low quality of evidence One retrospective study [108] One comparison study [109]	96.7%

Abbreviations: D-SOC, digital single operator cholangioscopy; ERCP, endoscopic retrograde cholangiopancreatography; PSC, primary sclerosing cholangitis; RCT, randomized controlled trial.

syndrome. This was recently supported by the multicenter SEIZE study, which showed that dSOC in type II–IV Mirizzi syndrome achieved high technical success (89.8%) with a markedly lower rate of severe adverse events (1.7% vs. 15.8%) compared with surgery, while also reducing the need for complex biliary reconstruction [114].

The pivotal role of cholangioscopy in the setting of indeterminate strictures has previously been highlighted in previous consensus papers [3, 115].

In the present work, the European experts first clarified the distinction between "unexplained" and "indeterminate" biliary strictures, as the term "indeterminate" has been used inconsistently in clinical practice, leading to confusion. In contrast to the previous guidelines, there was agreement to incorporate D-SOC into the initial diagnostic workup of unexplained biliary strictures, rather than only after failed conventional techniques.

A key concept introduced in this consensus is the integration of digital single-operator cholangioscopy (D-SOC) into the initial diagnostic workup of unexplained biliary strictures. D-SOC has transformed the approach to biliary strictures by allowing direct visualization and targeted biopsies.

In a randomized controlled trial, Gerges et al. demonstrated that D-SOC-guided biopsy had significantly higher sensitivity than ERCP-guided brushing (68.2% vs. 21.4%, $p < 0.01$), with improved diagnostic performance for visual impression (95.5% vs. 66.7%, $p = 0.02$) and overall accuracy (87.1% vs. 65.5%, $p = 0.05$) [76]. Similarly, Urban et al. confirmed superior sensitivity for both visual impression and biopsy with D-SOC compared with ERCP [77].

Draganov et al. further supported these findings, showing that mini-forceps biopsy under cholangioscopic guidance achieved higher sensitivity (76.5%) compared to standard forceps biopsy (29.4%) and cytology brushings (5.9%), with an overall accuracy of 84.6% [73].

Our decision to include cholangioscopy at this stage of the diagnostic algorithm was also guided by its favorable safety profile. In a prospective study, Almadi et al. reported a low complication rate of 1.7% [78]. Additionally, Gerges et al. observed that the adverse event rate in the D-SOC group was comparable to that in the ERCP group, further supporting the safety of D-SOC [76].

The Delphi process highlighted the critical role of integrating visual assessment with targeted biopsy during cholangioscopy for the evaluation of indeterminate biliary strictures. This combined approach, supported by robust evidence, significantly enhances diagnostic accuracy compared with either method alone [74]. This is particularly relevant since visual interpretation alone has limitations, particularly in complex cases such as primary sclerosing cholangitis (PSC) or post-stenting scenarios, where interobserver variability and overlapping features between benign and malignant lesions can reduce diagnostic precision [116, 117]. The consensus emphasized the importance of standardized visual criteria, such as the Mendoza Classification, which improves interobserver agreement and diagnostic accuracy compared to earlier systems [96]. Additionally, the process underscored the need for adequate tissue sampling, with at least three biopsies recommended to optimize histopathological evaluation, and using 10% buffered formalin for specimen fixation to ensure high cellularity and architectural preservation [101, 109]. There is conflicting evidence in the

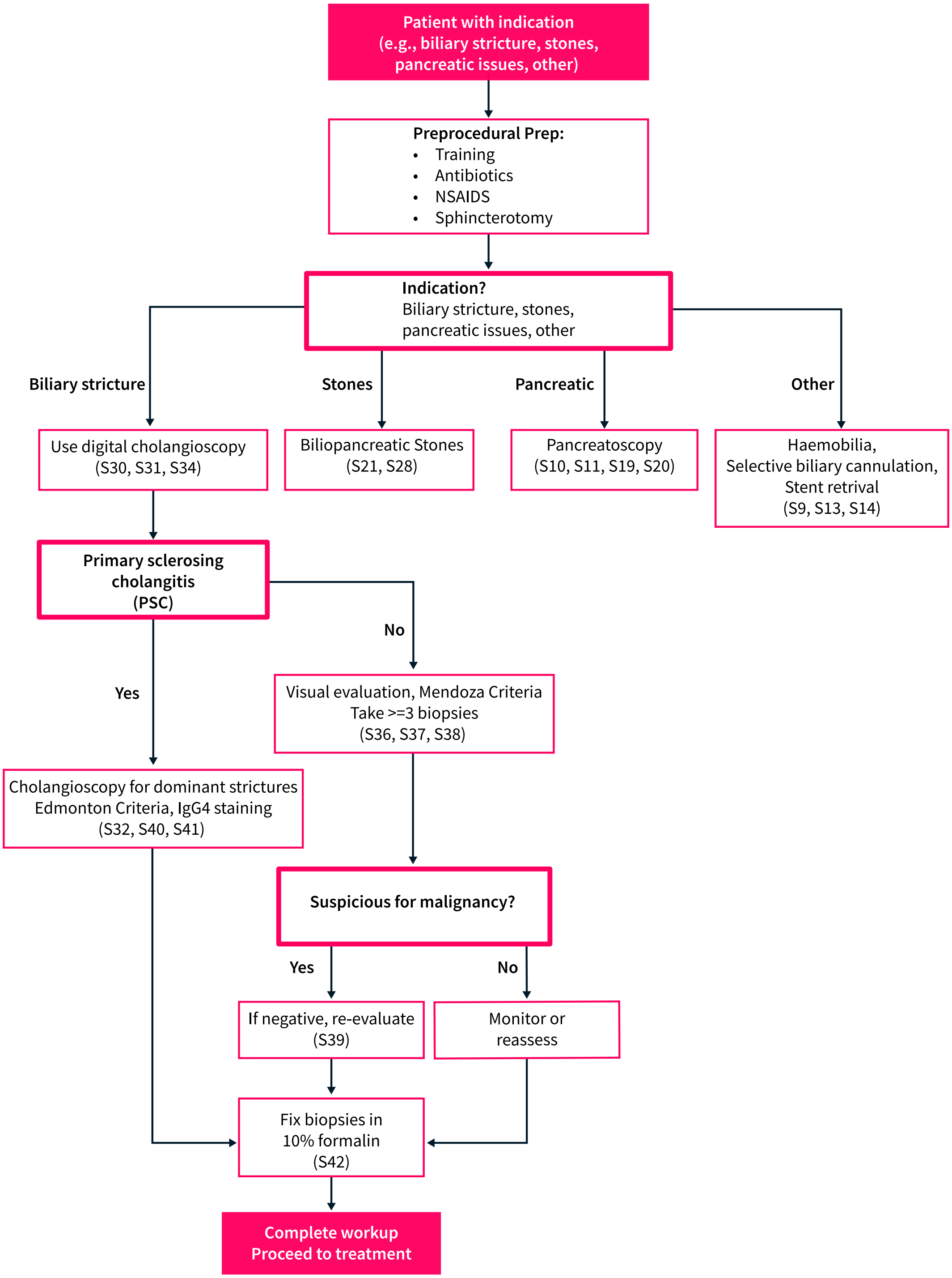

FIGURE 2 | Algorithm for cholangioscopy and pancreatoscopy in biliary and pancreatic conditions.

current literature regarding the optimal number of biopsies during cholangioscopy. A recent consensus by the Portuguese Society of Digestive Endoscopy recommends taking six cholangioscopy-guided biopsies, similar to practices in other parts of the gastrointestinal tract [118].

However, a prospective comparative study by Bang et al. showed that performing at least three SOC-guided biopsies, analyzed offsite, can achieve a diagnostic accuracy of 90% in indeterminate biliary strictures. No significant difference was found between taking three or four biopsies (p = 0.999), suggesting that three may be sufficient [101].

In cases where visual findings suggest malignancy but biopsies are negative, re-evaluation with additional sampling is recommended to minimize false-negative results [76, 89].

With regard to other indications for D-SOC and D-SOP, the panel noted very limited literature evidence. The most relevant statement is probably the one on intraoperative and preoperative exploration of the main pancreatic duct in patients with MD IPMN (S11). Implementation of intraoperative pancreatoscopy (IOP) and preoperative pancreatoscopy (POP) to determine the extent of IPMN can guide pancreatic resection in patients with MD IPMN and avoid both incomplete and unnecessary pancreatic tissue resection. As reported by De Jong et al. in a recent SR and MA, five retrospective studies analyzed the role of IOP and POP in this context. Overall, determining the extent of the lesion or identifying skip lesions through direct visualization or biopsy led to an altered surgical approach in 13%–62% of patients [16]. Specifically, in 13%–31% of patients, pancreatoscopy resulted in a more extensive surgical resection, whereas in 6%–31% of patients, pancreatoscopy allowed for a less extensive surgical resection.

The value of D-SOC and D-SOP was discussed in other specific scenarios, such as the selective cannulation of biliary ducts when conventional ERCP techniques fail and the diagnostic workup of haemobilia when all the other methodologies fail to assess the site of the bleeding. An additional ancillary role of the cholangioscope lies in the removal of proximally migrated stents within the biliary tree or the main pancreatic duct. As in the two scenarios previously mentioned, cholangioscopy plays only a secondary role compared to standard ERCP techniques and is largely dependent on the expertise and preferences of the individual endoscopist.

Despite the lack of dedicated literature, limited to a few case reports, experts agreed in assigning cholangioscopy a role in these scenarios.

Finally, three statements on the potential indications and the conduction of percutaneous cholangioscopy were generated. Such dedicated statements aim to define both the role of the operator performing this kind of procedure (in terms of expertise and training) and the clinical scenarios where this technique can support clinical practice. It is documented in the literature how this technique can be ancillary in certain scenarios, such as in patients with altered anatomy, specifically in the characterization of biliary strictures and the treatment of biliary stone disease [21, 22].

Similar to other Delphi studies on recent (endoscopic) techniques, the major limitation is the lack of high-quality literature evidence, necessitating cautious formulation of many recommendations (e.g., "it is suggested" or "it may be considered"). However, expert consensus was reached within a large group of experts, providing additional strength to the more experience-based statements. Unlike previous guidelines on specific indications for cholangioscopy, our work also covers general and purely technical aspects that are helpful for anyone who wants to implement this tool in clinical practice.

While further research is needed on many aspects of cholangioscopy and pancreatoscopy and technical improvements of the scopes are being made on a continuous basis, we hope that, in the meantime, our recommendations may help to standardize the implementation and performance of cholangioscopy and pancreatoscopy in the management of pancreaticobiliary disorders.

Author Contributions

P.H. concepted the study. E.P., S.S., E.G., V.A. and P.H. collected the data and drafted the manuscript. P.H. and D.D.J. led and supervised the Delphi process. All other authors participated in the Delphi process and critically revised the manuscript for intellectual content.

Conflicts of Interest

1. Enrico Palmeri: None.

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Data Availability Statement

The data that supports the findings of this study are available in the supplementary material of this article.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section.
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