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Recommendations for the Clinical Practice concerning the Use of Cholangiopancreatoscopy: Proceedings from a Consensus Meeting

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Keywords

Cholangioscopy · Consensus meeting · Difficult biliary stone · Biliary stricture · Pancreatoscopy

Abstract

After a consensus meeting including experts from all over the country (more than 6 years of experience, at least 50 procedures and their center perform more than 30 procedures/year), several recommendations were issued. Main recommendations: (1) Single-operator digital cholangioscopy is indicated in cases of undetermined biliary strictures (UBSs) in which visual inspection, with or without histology, may change the patient's approach. (Strong recommendation, moderate quality of evidence). (2) In a cholangioscopy for a stricture of unclear etiology, the optical assessment aspects should be recorded in a standardized report and, according to the endoscopist's visual impression, suggest a malignant or benign etiology. (Strong recommendation, high quality of evidence). (3) When using cholangioscopy regardless of the visual impression, biopsies of the stenosis should be taken (ideally in a number equal to or greater than 6 fragments). (Strong recommendation, moderate quality of evidence). (4) Cholangioscopy with biopsies has a high diagnostic accuracy in the evaluation of UBSs, with a technical success >98% and visual diagnosis with sensitivity/specificity >95%. However, it must be considered that the sensitivity of histological diagnosis is lower (around 70%). (Strong recommendation, high quality of evidence). (5) The single-operator cholangioscopy (SOC)-assisted lithotripsy is a safe procedure associated with high rates of success. (Strong recommendation, high quality of evidence). (6) SOC-assisted lithotripsy should be reserved for selected cases in which conventional techniques for the treatment of difficult biliary stones have failed. However, SOC-assisted lithotripsy should be used early in the treatment algorithm to avoid repeated procedures. (Strong recommendation, moderate quality of evidence). (7) Pancreatoscopy can allow the diagnosis of lesions suggestive of malignancy in the pancreatic duct of patients with

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intraductal papillary mucinous neoplasm of the main duct with high sensitivity and specificity. The groups of patients who benefit most from its use are those with a diffusely dilated duct with a diameter greater than 10 mm, and in whom sectional imaging methods and endoscopic ultrasound do not reveal focal lesions. (Weak recommendation, low quality of evidence). (8) The use of intraductal lithotripsy guided by pancreatoscopy in patients with lithiasis in the main pancreatic duct should be reserved for patients with pain and lithiasis greater than 5 mm that cannot be removed using conventional techniques. Patients with an excessively distal location in the tail or head may cause increased technical difficulty. (Low recommendation, low quality of evidence).

Recomendações para a prática clínica sobre o uso da colangiopancreatoscopia. Atas de uma reunião de consenso

Palavras Chave
Colangioscopia · Consenso · Litíase biliar complicada · Estenose biliar · Pancreatoscopia

Resumo
Após uma reunião de consenso com especialistas de todo o país (com mais de 6 anos de experiência, pelo menos 50 procedimentos realizados e provenientes de centros com mais de 30 procedimentos/ano), foram emitidas várias recomendações. Principais recomendações: (1) A colangioscopia digital de operador único é indicada em casos de estenoses biliares indeterminadas, nas quais a inspeção visual, com ou sem histologia, possa alterar a abordagem do paciente. (Recomendação forte, qualidade de evidência moderada). (2) Numa colangioscopia para avaliação de estenose de etiologia indeterminada, os aspetos da avaliação óptica devem ser registados num relatório padronizado e, de acordo com a impressão visual do endoscopista, sugerir uma etiologia maligna ou benigna para a estenose. (Recomendação forte, qualidade de evidência alta). (3) Ao utilizar a colangioscopia, independentemente da impressão visual, devem ser realizadas biópsias da estenose (idealmente em número igual ou superior a 6 fragmentos). (Recomendação forte, qualidade de evidência moderada). (4) A colangioscopia com biópsias apresenta elevada acuidade diagnóstica na avaliação de estenoses biliares indeterminadas, com sucesso técnico >98% e diagnóstico visual com sensibilidade/especificidade >95%. Contudo, deve considerer-se que a sensibilidade do diagnóstico histológico é inferior (cerca de 70%). (Recomendação forte, qualidade de evidência alta). (5) A litotrícia assistida por colangioscopia de operador único é um procedimento seguro, associada a altas taxas de sucesso. (Recomendação forte, qualidade de evidência alta). (6) A litotrícia assistida por colangioscopia de operador único deve ser reservada para casos selecionados nos quais as técnicas convencionais para o tratamento de cálculos biliares complexos falharam. No entanto, essa técnica deve ser utilizada precocemente no algoritmo de tratamento para evitar procedimentos repetidos. (Recomendação forte, qualidade de evidência moderada). (7) A pancreatoscopia pode permitir o diagnóstico de lesões sugestivas de malignidade no ducto pancreático em doentes pacientes com IPMN do ducto principal, com elevada sensibilidade e especificidade. O grupo de doentes que mais se beneficia da sua utilização são aqueles com dilatação difusa do ducto pancreático, com diâmetro superior a 10 mm, e nos quais os métodos de imagem seccionais e a ultrassonografia endoscópica não revelam lesões focais. (Recomendação fraca, qualidade de evidência baixa). (8) O uso de litotrícia intraductal guiada por pancreatoscopia em pacientes com litíase no ducto pancreático principal deve ser reservado para doentes com dor e litíase com dimensão superior a 5 mm, que não podem ser removidas por técnicas convencionais. Pacientes com localização excessivamente distal na cauda ou cabeça do pâncreas podem representar maior dificuldade técnica. (Recomendação fraca, qualidade de evidência baixa).

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is an advanced procedure that is widely used in the management of a variety of benign and malignant pancreatobiliary disorders. However, although ERCP is an advanced procedure the visualization and interpretation of fluoroscopic images has been appointed as an important limitation in several situations [1, 2].

First reported in 1978 the direct visualization of the bile ducts and pancreatic ducts, namely, cholangiopancreatoscopy, established the beginning of a new era [3]. However, the original endoscopic devices used to access the pancreatobiliary system used the "mother-baby" technique and were limited by several issues: complex setup, fragility, moderate visual resolution and most important the need for two experienced operators to work as a team [4]. With these limitations the use of this technique was limited and almost disappeared at the beginning of the 21st century. However, in 2007, a single-operator cholangioscopy (SOC) system has been introduced, allowing for a more routine use of these technologies [5]. Furthermore, the original device has been improved with a digital system, more steerability and maneuverability of the cholangioscope and therefore allowing for superior visualization pancreatobiliary system [6]. Consequently, cholangiopancreatoscopy became to be more routinely used into the clinical practice, for the diagnostic and therapeutic purpose with several indications, namely, the diagnostic of indeterminate biliary strictures, management of difficult biliary stones, evaluation of intraductal papillary mucinous neoplasm, treatment of pancreatic stones and event intrahepatic extension of cholangiocarcinoma [7, 8].

However, with the increasing number of indications and the widespread of this technique, guidelines and recommendations from consensus meetings are not widely available. Therefore, we aimed to report the recommendations for the clinical practice concerning the use of cholangiopancreatoscopy that have been discussed within a consensus meeting for Portugal.

Methods

The working team was composed by five endoscopists form all over the Country and their teams. The experts were selected by having more than 6 years of experience in cholangiopancreatoscopy, at least 50 procedures and their center perform more than 30 procedures/year. These characteristics were defined by the endoscopist responsible for conducting the consensus meeting as suggested elsewhere [1]. The discussion and the definition of the role of several issues was done using six questions that resume the major recommendations (RC) for the technique: (1) indeterminate biliary strictures; (2) management of difficult biliary stones; (3) diagnostic and extension of IPMN; (4) evaluation of potentially malignant pancreatic strictures; (5) intraductal pancreatic stones; (6) other indications (bile duct mapping for cholangiocarcinoma, foreign body removal, cholangioscopy-assisted guidewire placement, radiation-free cholangioscopy).

The level of agreement was achieved by the Delphi method [9]. In the Delphi process, only 5 experts (J.C., L.C.L., D.H., P.P., and T.B.C.) participate. The scale used for voting was as follows: totally agree, partially agree, partially disagree, and totally disagree. All the experts participated in all the rounds, and they were identified throughout all processes. For voting in each round, two sessions of votes were allowed to reach 80% of agreement. If not achieved, the question or topic was disregarded or reformulated. The process was conducted by J.C. The Delphi process had 3 rounds on different dates. At the initial round, 14 questions were analyzed and 8 were disregarded for consistent results below 80%. The proposed questions were based on relevant topics available and published in the literature, using PICO frame: P = Problem/Population; I = Intervention (or the experimental variable); C = Comparison (or the control variable) [Optional]; O = Outcome. Level of recommendation and quality of evidence (supplementary table) followed the recommendations of the Oxford Centre for Evidence-based Medicine [10]. All details, dates, and literature search are available in supplementary materials.

Recommendations and Statements

Question 1 – Indeterminate Biliary Strictures

What Is an Undetermined Biliary Stricture?

Undetermined biliary stricture (UBS) is defined as one in which it is not possible to identify its etiology after an imaging study and/or after an inconclusive ERCP or with nondiagnostic cytology. Given that this definition implies the performance of an ERCP, with possible implications in terms of interference in the optical diagnosis of cholangioscopy (manipulation and placement of eventual biliary prosthesis), it is considered that the most correct term will be biliary stricture of unclear etiology. This will be defined as imaging evidence of biliary stenosis, in which it is not possible to distinguish between malignant and benign pathology, and the prior collection of histological material by cytology or other methods is not necessary, nor constitutes an exclusion factor, opening the possibility of performing ERCP with cholangioscopy in the index event.

The etiologies of biliary stricture are divided into benign (primary sclerosing cholangitis, post-choledocholithiasis, portal cholangiopathy, IgG4 cholangiopathy, iatrogenic injury, chronic pancreatitis) and malignant (cholangiocarcinoma, pancreatic carcinoma, ampuloma, gallbladder carcinoma, and metastatic disease). In observational studies, up to 60% of these lesions are malignant and up to 25% of patients undergoing surgical intervention have surgical specimens without evidence of neoplasia in the anatomopathological evaluation [11]. This distinction represents the most important step in the diagnostic approach, considering the different therapies of the two entities, with endoscopic and surgical treatment being recommended, respectively. In doubtful cases, these lesions should be considered malignant until proven otherwise.

Diagnostic Evaluation

The first step in the diagnostic process for biliary stricture involves a rigorous anamnesis and objective examination, complemented by the careful request of analytical parameters and imaging methods. Personal history of bile duct surgery, liver transplantation, or chronic pancreatitis suggests a benign etiology. Signs and symptoms of chronic liver disease may be indicative of primary sclerosing cholangitis or portal cholangiopathy. The initial analytical assessment should include blood count, natremia, kalemia, creatinine, urea, AST, ALT, FA, GGT, total bilirubin, albumin, coagulation tests, and autoimmunity markers (namely, antinuclear antibodies, antineutrophil cytoplasmic antibodies, total IgG immunoglobulins, and Ig4 immunoglobulins, among others).

Tumor markers are used to screen for malignant etiology, despite suboptimal sensitivity. CEA has a reduced sensitivity of 38%, meaning that only CA 19.9 measurement is indicated, despite there being controversy in the literature regarding its diagnostic profitability. Using a threshold of 37 U/mL of CA 19.9, Bowlus et al. [12] obtained a sensitivity of 77% and sensitivity of 87%; however, only patients with pancreatic adenocarcinoma were considered, making it difficult to transpose the results to patients with biliary stricture indeterminate. A meta-analysis carried out by Onda et al. [13], which included studies with patients with indeterminate biliary stricture, obtained a sensitivity of 69%, without reference to a “positivity” threshold.

Imaging assessment may be performed using AP CT with intravenous iodinated contrast. In cases of hilar stenosis, magnetic resonance imaging (with cholangio-MRI protocol) should be performed, as it presents greater diagnostic accuracy.

Role of Cholangioscopy

Three questions were evaluated.

1. When is indicated the use of cholangioscopy?

RC: *Single-operator digital cholangioscopy is indicated in cases of UBSs in which visual inspection, with or without histology, may change the patient’s approach.*

(Strong recommendation, moderate quality of evidence, 100%)

2. Is the optical assessment important?

RC: *In a cholangioscopy for stenosis of unclear etiology, the optical assessment aspects should be recorded in a standardized report and, according to the endoscopist’s visual impression, suggest a malignant or benign etiology.*

(Strong recommendation, high quality of evidence, 100%)

3. What is the role of histology?

RC: *Regardless of the visual impression, biopsies of the stenosis should be taken (ideally in a number equal to or greater than 6 fragments).*

(Strong recommendation, moderate quality of evidence, 100%)

Recent technological developments, namely, the creation of the Spyglass DS II System, allows high-resolution cholangioscopy to be performed during ERCP, with direct visualization of the stenosis and collection of histological material using the SpyBite instrument. The 10-Fr cholangioscope is inserted through the working channel of the conventional duodenoscope, enabling direct visualization of the lesion and collection of histological material with biopsy forceps, inserted into the working channel with 1.2 mm.

Regarding stenosis, its macroscopic aspects should be recorded upon visual inspection, ideally in a standardized report that includes aspects of the endoscopic classifications for cholangioscopic evaluation of stenoses (Robles-Medranda classification, Monaco classification, and Mendoza criteria), namely: smooth and regular mucosa of stenosis, short stenosis, and absence of neovascularization are suggestive of benignity; aberrant neovascularization, nodules, villous projections, and an infiltrative appearance are suggestive of malignancy [14–16]. These findings and the diagnostic impression of the gastroenterologist performing the procedure must be included in the report.

For the histological evaluation of the collected material, an attempt should be made to obtain at least 6 fragments of the lesion per biopsy, which can be collected with specific forceps and/or collected by aspiration after multiple biopsies (to increase diagnostic profitability in the shortest possible time). If it has not been performed previously, exfoliative cytology of stenosis may be associated with it, particularly after biopsies due to the gain in diagnostic profitability.

Role of Optical Assessment during Cholangioscopy

One question was evaluated.

1. What is the diagnostic value of optical assessment during cholangioscopy?

Table 1. Studies of single-operator digital cholangioscopy visual inspection in cases of UBSs

Author (year of publication)	Study design	Sample size	Sensitivity	Specificity	Accuracy
Robles-Medranda, C. et al. [14] (2018)	Single-center, prospective	171	0.96	0.92	0.94
Sethi et al. [15] (2022)	Multicenter, retrospective	40	ND	ND	0.79
Kahaleh et al. [16] (2022)	Multicenter, retrospective	50	ND	ND	0.77
Kulpatcharapong et al. [17] (2020)	Systematic review	552	0.67–1.00	0.73–100	0.50–0.97
de Oliveira et al. [18] (2020)	Systematic review (with meta-analysis)	283	0.94	0.95	0.94
Behary et al. [19] (2019)	Prospective validation study	40	0.90	0.82	0.86
Almadi et al. [21] (2020)	Multicenter, prospective	289	0.87	0.66	0.77
Turowski et al. [22] (2018)	Multicenter, retrospective	117	0.96	0.95	0.95
Navaneethan et al. [23] (2014)	Multicenter, retrospective	105	0.90	0.96	0.95
Korrapati et al. [24] (2016)	Systematic review (with meta-analysis)	2,002	0.93	0.85	0.89

ND, not determined.

RC: *The value of optical diagnosis of biliary strictures of etiology not determined by cholangioscopy is high. The presence of dilated/tortuous vessels in association with papillary projections is associated with the diagnosis of malignancy. However, taking biopsies is essential, whenever possible, due to their high positive predictive value.*

(Moderate recommendation, moderate quality of evidence, 100%)

A sensitivity of 94% for the visual diagnosis of malignant biliary strictures was reported in a systematic review and meta-analysis [17, 18]. In malignant biliary strictures, four features are frequently found – tumor vessels, papillary projections, nodular/polypoid mass effect, and infiltrative aspect. These were subsequently validated as having reasonable to moderate interobserver agreement and should be reported whenever possible [15, 19].

It is currently known that the presence of aberrant vessels or vascular spiders in stenosis together with papillary projections of the mucosa are criteria for malignancy, with a specificity and positive predictive value that approaches 100%. The presence of aberrant vessels shows a sensitivity of 94%, a specificity of 63%, a positive predictive value of 75%, and a negative predictive value of 90% for malignant stenosis [17].

The accuracy of optical diagnosis of biliary strictures by cholangioscopy using the Robles-Medranda classification is about 77% (64–88%) compared to the sensitivity of diagnosis by targeted biopsies, which is about 70% (57.7–86.2%) [14, 16, 17, 20]. Table 1 summarizes the bibliographic evidence used to determine the role of visual inspection in cases of UBSs.

Diagnostic Accuracy

One question was evaluated.

1. What is the final diagnostic accuracy of cholangioscopy?

RC: *Digital cholangioscopy with biopsies has a high diagnostic accuracy in the evaluation of UBSs, with a technical success >98% and visual diagnosis with sensitivity/specificity >95%. However, it must be considered that the sensitivity of histological diagnosis is lower (around 70%).*

(Strong recommendation, high quality of evidence, 100%)

Conventional techniques for obtaining histological material from biliary strictures by ERCP (including exfoliative cytology and fluoroscopy-guided biopsies) have limited diagnostic sensitivity for malignancy (approximately less than 60%) [20, 25]. The diagnostic accuracy of cholangioscopy with biopsies in the evaluation of biliary strictures depends on the technical success of the procedure, the capacity for visual diagnosis, and the profitability of the biopsies obtained during the procedure.

As for technical success, it is quite high with the Spyglass DS® System in international cases (higher than 98%) and depends above all on the technical success of ERCP [26].This success rate may be lower in cases of intrahepatic stenosis (due to difficulty of access with a cholangioscope/performing targeted biopsies) and in cases of very distally located lesions, in which exploration as well as the correct positioning of the cholangioscope to assess stenosis may be limited.

Regarding the diagnostic profitability of biopsies in patients with indeterminate biliary stenosis, in a recent

Table 2. Studies of single-operator digital cholangioscopy-guided biopsies in cases of UBSs

Author (year of publication)	Study design	Sample size	Sensitivity	Specificity	Accuracy
Bowlus et al. [12] (2015)	Narrative review	593	0.38–0.96	0.50–1.00	0.56–0.91
Kulpatcharapong et al. [17] (2020)	Systematic review	589	0.38–1.00	0.75–1.00	0.61–1.00
Navaneethan et al. [20] (2015)	Systematic review (with meta-analysis)	730	0.48	0.99	0.67
Fujii-Lau et al. [27] (2023)	Systematic review (with meta-analysis)	1,529	0.72	0.96	0.81
Hartman et al. [28] (2012)	Single-center, retrospective	29	0.57	1.00	0.78
Almadi et al. [21] (2020)	Multicenter, prospective	289	0.75	1.00	0.87
Turowski et al. [22] (2018)	Multicenter, retrospective	117	0.58	1.00	0.87
Osanai et al. [29] (2013)	Multicenter, prospective	38	0.96	0.80	0.92
Navaneethan et al. [23] (2014)	Multicenter, retrospective	105	0.85	1.00	0.97
Korrapati et al. [24] (2016)	Systematic review (with meta-analysis)	2,002	0.69	0.94	0.79

meta-analysis/systematic review in which a total of 13 studies were included, with a sample of 1,529 patients (only 1 randomized study and 12 observational studies), diagnosis by brush cytology and fluoroscopy-guided biopsies, showed an increase in diagnostic accuracy of 27%, and the sensitivity calculated for cholangioscopy biopsies was 72% [27]. Table 2 summarizes the bibliographic evidence used to determine the accuracy of cholangioscopy-guided biopsies in cases of UBSs.

Cholangioscopy in the Index Procedure

One question was evaluated.

1. What is the role of cholangioscopy in the index procedure?

RC: *Performing cholangioscopy in a first ERCP for biliary stricture of undetermined etiology can reduce the need to perform multiple procedures and, as such, can be recommended in centers that have the technique available, especially if pre-existing malignancy is suspected, procedure is elevated.*

(Weak recommendation, low quality of evidence, 100%)

In patients undergoing ERCP to investigate the etiology of biliary stricture, cholangioscopy may be preferred in the index procedure in selected cases. In this meta-analysis of prospective studies, covering 20 studies and with a total of 1,141 patients, it was found that in 8 of the studies (291 patients), patients with "truly" UBS were included (patients who had undergone previous ERCP). In this group, 178 underwent cholangioscopy with targeted biopsies, verifying a decrease in sensitivity for the diagnosis of malignant stenosis (approximate sensitivity of 38–88%) [17].

Role of Cholangioscopy in the Assessment of Distal Biliary Strictures

One question was evaluated.

1. What is the usefulness of Cholangioscopy in the evaluation of distal biliary strictures?

RC: *Digital cholangioscopy with biopsies may have a relevant role in the evaluation of undetermined distal biliary strictures. However, its diagnostic value compared to other techniques is uncertain and needs to be evaluated prospectively.*

(Weak recommendation, low quality of evidence, 100%)

It is accepted that the profitability of cholangioscopy may be lower in more distal stenoses, among other reasons, due to the greater difficulty in stabilizing the cholangioscope to obtain an adequate visual impression and be able to obtain targeted biopsies. However, the lower sensitivity assumed for the technique in more distal stenoses is based on a low level of evidence, which is fundamentally based on studies that included a low number of patients and/or weak methodology.

In a study that took place between 2007 and 2010, the diagnostic profitability of cholangioscopy was evaluated, with a total sample of 110 patients, of which only 29 underwent biopsies by cholangioscopy. A direct oral cholangioscope, less flexible, with fiber optics was used and a cholangioscopy biopsy sensitivity of 57% was obtained, which was significantly lower in distal stenoses [28].

On the other hand, in patients with intra-pancreatic/extrinsic compression strictures (pancreatic lesions) and/or local adenopathies as well as evidence of metastases, puncture ultrasound will be more appropriate to obtain a histological diagnosis. In a meta-analysis with 10 studies

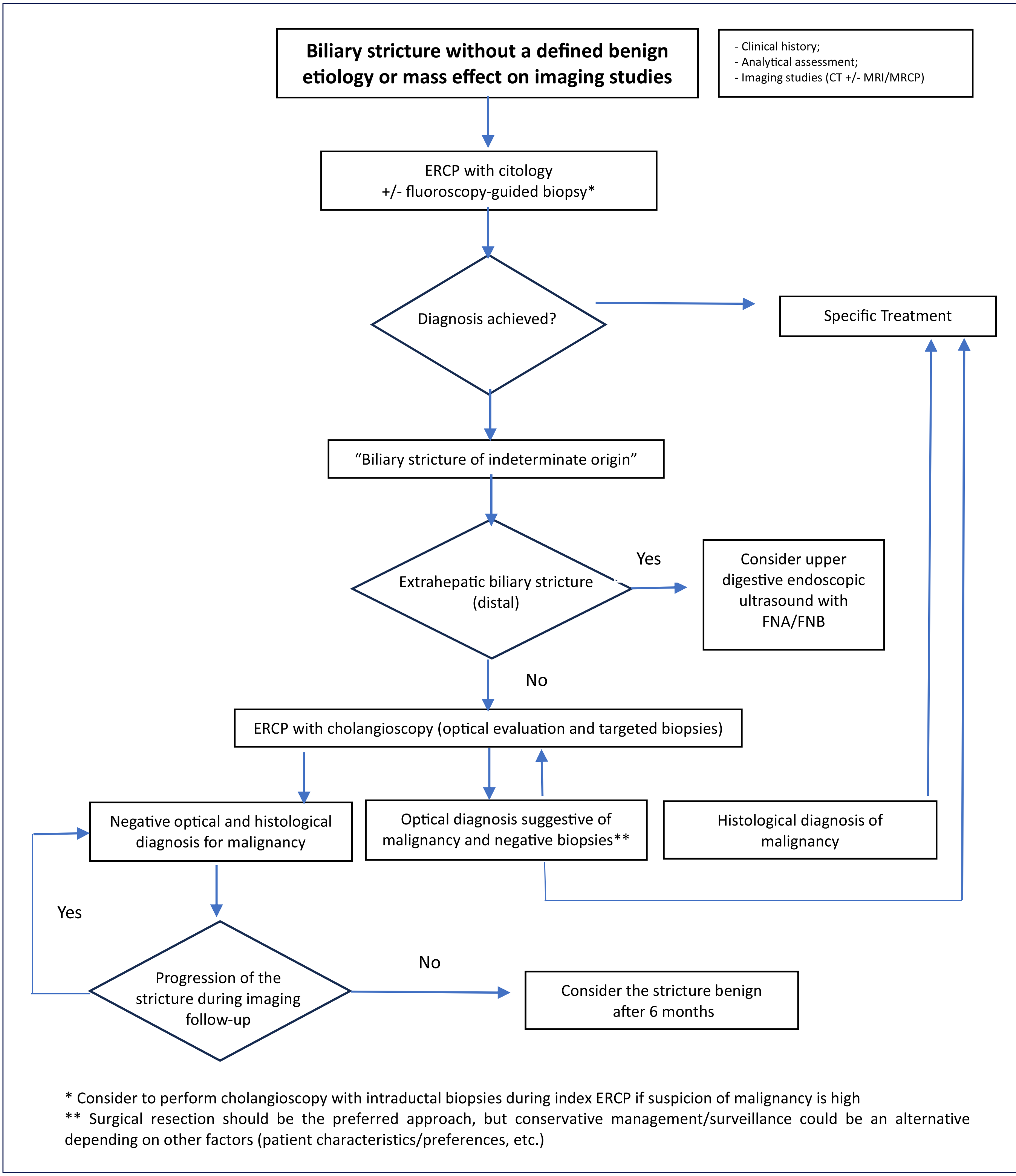

Fig. 1. Summary of the role of digital cholangioscopy in the diagnosis of biliary strictures of undetermined etiology. Adapted from Angsuwatcharakon et al. [31]. ERCP, endoscopic retrograde cholangiopancreatography; FNA, fine-needle aspiration; FNB, fine-needle biopsy.

(6 prospective, 4 retrospective) with a total of 1,162 patients, the incremental value of endoscopic ultrasound was studied in patients with extrahepatic stenosis who had previously undergone ERCP with cytology (primary outcome). An increase in diagnostic accuracy of 15% was obtained, more noticeable when they were performed in the same session [30].

Additional studies (prospective and comparative) are needed on the role of echoendoscopy and cholangioscopy in the evaluation of indeterminate distal strictures. The role of digital cholangioscopy in the diagnosis of biliary strictures of undetermined etiology is summarized in Figure 1.

Prophylaxis of Adverse Events

One question was evaluated.

1. What is the risk of adverse events during cholangioscopy?

RC: *The risk of adverse effects, in particular cholangitis, is higher than that of ERCP in general, and it is recommended to administer prophylactic antibiotics and ensure effective biliary drainage.*

(Moderate recommendation, low quality of evidence, 100%)

Compared to other methods (ERCP with cytology or fluoroscopy-guided biopsies), cholangioscopy prolongs the procedure by an average of 15 min. It does not present a significant difference in the occurrence of adverse effects, with the exception of septic complications (cholangitis).

Admitting the presence of significant biliary stenosis in most patients indicated for cholangioscopy due to undetermined biliary stenosis, it is essential to ensure adequate biliary drainage at the end of the procedure to avoid septic complications. In most cases, it will be necessary to place a plastic biliary prosthesis (except in cases of strictures on imaging that do not have cholangiographic translation, that do not cause biliary obstruction with clinical translation, or that have a treatable cause, namely, lithiasis).

In a prospective, multicenter study, with a sample of 289 patients, a single dose of prophylactic antibiotic was administered after cholangioscopy to all patients. The rate of cholangitis observed after the procedure was 1% [21]. In another retrospective study, which included 250 cholangioscopies (multiple indications, including choledocholithiasis, UBSs, and treatment of bile leaks), the complication rate was 13.2% (n = 33), with cholangitis being the most common (n = 20). In 108 patients, a single dose of antibiotic was administered prior to cholangioscopy and only 1 developed cholangitis [22].

Whenever possible, and in addition to the prophylactic measures advocated in ERCP, prophylactic antibiotic therapy (for example, ciprofloxacin 400 mg i.v. peri-procedure) should be performed, due to the risk of acute cholangitis associated with cholangioscopy. After carrying out the procedure, patients will remain under surveillance for a minimum period of 24 h, with a zero diet being recommended on the day of the intervention.

Follow-Up

Two questions were evaluated.

1. What is the length of time for supporting a benign etiology for the stricture?

RC: *The absence of disease progression for at least 6 months supports a benign etiology of the stenosis.*

(Weak recommendation, low quality of evidence, 100%)

2. What is the recommended follow-up period for patients with a stricture and unclear diagnosis?

RC: *A minimum follow-up period (6–18 months) is recommended for patients with indeterminate biliary stricture (after cholangioscopy with nondiagnostic biopsies).*

(Weak recommendation, low quality of evidence, 100%)

The definition of indeterminate biliary stricture is different between studies, with disease progression-free periods ranging from 6 to 18 months [21, 23, 29]. A prospective follow-up study of 104 patients with UBS and atypical cells on cytology showed that most malignancy diagnoses were made at 0–6 months (n = 30; 78.9%), while the remainder, to a lesser extent, were diagnosed at 7–12 months (n = 5; 13.1%), 13–24 months (n = 2; 5.3%), 25–36 months (n = 1; 2.6%), and 0% after 36 months [23].

It is therefore recommended that a stenosis be considered benign if there is no lesion with mass effect on imaging methods (including endoscopic ultrasound), repeated histological sampling (including cholangioscopy-directed biopsies) has been performed and is negative for malignancy and if the serial imaging follow-up does not reveal progression for at least 6 months. In specific patients, where progression may be slower, such as patients with primary sclerosing cholangitis, cancer patients with primary neoplasia of another location, or patients with premalignant lesions of the bile ducts (biliary intraepithelial neoplasias and intraductal papillary neoplasms), the period of tighter surveillance may be extended [31, 32]. Taking this into account, it is recommended that the minimum period of follow-up and surveillance in patients with indeterminate biliary stricture and nondiagnostic cholangioscopy is 6–18 months.

Question 2 – Management of Difficult Biliary Stones

No clear consensus exists about the definition of difficult biliary stones (DBS) [33]. Factors that difficult endoscopic clearance of biliary stones can be attributed to the stone's characteristics (size >15 mm, >3 stones, hard consistency, barrel or square-shape), stone's location (intrahepatic, cystic duct), common bile duct (CBD)'s characteristics (narrowing of the bile duct distal to the stone, sigmoid-shaped CBD, distal CBD angulation <135°, short distal CBD <136 mm) and anatomical factors (periampullary diverticulum, duodenal stricture, and surgically altered anatomy) [34, 35].

Current ESGE guidelines recommend limited sphincterotomy combined with endoscopic papillary large-balloon dilatation (EPLBD) as the first-line approach to remove DBS since it has a 30–50% reduction rate of the use of mechanical lithotripsy (ML) and a similar rate of technical success when compared to sphincterotomy alone [35–42]. When, after EPLBD, the size of biliary stones still exceeds the diameter of the distal CBD, either ML, SOC-assisted lithotripsy, or extracorporeal shock wave lithotripsy (ESWL) are recommended [35]. In case of failed extraction despite these techniques or if they are not readily available, the placement of a temporary plastic stent is highly recommended before a second attempt at stone extraction can be done, with studies suggesting the use of 7-Fr double pigtail double-stenting [35, 43, 44].

Efficacy and Safety of SOC-Assisted Lithotripsy for the Management of DBS

One question was evaluated.

1. What is the role of SOC-assisted lithotripsy in the management of difficult biliary stones?

RC: *The SOC-assisted lithotripsy is a safe procedure associated with high rates of success.*

(Strong recommendation, high quality of evidence, 100%)

SOC allows for direct visualization and decreased risk of bile duct injury and is a vital addition to the ERCP armamentarium for stone disease [45]. Indeed, Korrapati et al. [24] have reviewed the efficacy of SOC for DBS and they estimated an overall rate of stone clearance of 88% (95% CI, 85–91%), with SOC demonstrating higher technical success rates comparing to other methods ($p < 0.01$). Several subsequent studies have demonstrated the successful management of DBS using SOC-guided lithotripsy, with success rates ranging from 74.2% to 100% [6, 46–49]. In a more recent systematic review and meta-analysis, Jin et al. [50] analyzed the efficacy and safety of SOC-assisted lithotripsy in treating DBS, estimating a higher rate of complete stone clearance of 94% (95% CI, 90.2–97.5%), comparing to Korrapati et al. [24] and an adverse event rate of 6.1%. Thus, SOC is a valuable modality in addition to or in lieu of conventional ERCP methods such as EPLBD and/or ML [45]. However, regarding which specific type of cholangioscopy to use, it depends on local expertise and availability, as mentioned in ESGE guidelines, since there are currently no studies that compare cholangioscopy techniques [35].

Comparison between Peroral Cholangioscopy-Assisted Lithotripsy and Conventional Therapy for the Management of DBS

One question was evaluated.

1. What is the role of SOC-assisted lithotripsy when compared to conventional techniques for the treatment of difficult biliary stones?

RC: *SOC-assisted lithotripsy should be reserved for selected cases in which conventional techniques for the treatment of difficult biliary stones have failed. However, SOC-assisted lithotripsy should be used early in the treatment algorithm to avoid repeated procedures.*

(Strong recommendation, moderate quality of evidence, 100%)

Since the time of publication of the first-mentioned meta-analysis, three randomized controlled trials (RCTs) comparing SOC-guided electrohydraulic lithotripsy (EHL) or holmium laser lithotripsy (LL) with conventional therapy have been published. Buxbaum et al. [51] randomized patients with DBS at a 2:1 ratio to SOC-guided LL and conventional therapy alone. Complete clearance was achieved in 93% of patients treated with SOC-guided LL and in 67% of those treated with conventional therapy alone ($p = 0.009$). However, SOC-guided LL was associated with a longer procedure time (120.7 ± 40.2 min in the conventional group and 81.2 ± 49.3 min in the SOC-guided LL group, $p = 0.0008$) [51]. In the study of Franzini et al. [52], successful stone removal did not differ in the SOC-assisted EHL arm vs. EPLBD arm (77.1 vs. 72%, $p = 0.93$); similarly, crossover yielded nonstatistically significant differences between the two groups (85.1 vs. 95.4, $p = 0.1147$). The RCT by Angsuwatcharakon et al. [31] compared SOC-guided LL and ML after a failed EPLBD, where complete stone removal rates in a single session were 100% and 63%, respectively ($p < 0.01$). Adverse event rates were comparable between two groups (6% vs. 13%, $p = 0.76$) and procedure time was not significantly different (66 min vs. 83 min, $p = 0.23$), although the radiation exposure was significantly lower (20.989 mGy cm^2 vs. 40.745 mGy cm^2, $p = 0.04$) in the SOC-guided LL group [31]. Furthermore, the last published meta-analysis comparing POC-assisted lithotripsy with conventional therapy for DBS showed no significant difference between both in terms of therapeutical success, safety and mean fluoroscopy time, but a shorter mean procedure time for conventional ERCP methods was found [53]. Therefore, given the mixed or only partial in favor of POC-assisted lithotripsy data, this method should be reserved only for selected cases and in the setting of tertiary care. However, an increasing number of authors claim that POC-assisted lithotripsy may be considered first-line therapy for patients with DBS to avoid serial procedures [31, 54, 55].

Comparison between Electrohydraulic and Laser Lithotripsy

One question was evaluated.

1. What is the method of SOC-assisted lithotripsy that should be used?

RC: *Currently, both electrohydraulic lithotripsy or holmium LL are used with safety and high rate of success depending on the endoscopist experience and equipment availability.*

(Weak recommendation, low quality of evidence, 100%)

Concerning the type of lithotripsy, currently, both EHL and L.L. are being used according to endoscopist experience and equipment availability, as recommended by ESGE guidelines – Table 3 [33, 35]. A multicenter retrospective study comparing the outcomes of 306 patients submitted to EHL and 101 patients treated with LL for DBS reported a similar final clearance rate for both techniques (96.7% vs. 99%, $p = 0.31$), with a mean procedure time longer for the EHL group (73.9 vs. 49.9 min, $p < 0.001$) [46]. In a systematic review with meta-analysis, Veld et al. [56] compared LL, EHL, and ESWL in the treatment of DBS after a previously failed ERCP. In their study, LL had a significantly higher complete ductal clearance rate compared with EHL and ESWL (95.1% vs. 88.4% vs. 84.5%, $p < 0.001$), while EHL had a higher post-procedural adverse events rate compared with ESWL or LL (13.8% vs. 8.4% vs. 9.6%, $p = 0.04$) [] [] [][22]. In opposition to these results, a more recent meta-analysis reported a superiority of EHL vs. LL (91.4% vs. 88.6%, $p < 0.0000001$), explaining a more selective study inclusion than that made by Veld et al. [56]. However, those studies did not explore the number of probes used and did not provide recommendations for choosing between EHL and LL. Further studies and guidelines that compare EHL and LL, including cost-effectiveness analyses, are needed [33]. A proposed approach for the management of difficult biliary stones is shown in Figure 2.

SOC Use for Stone Clearance Confirmation

One question was evaluated.

1. What is the role of SOC in the evaluation of stone clearance?

RC: *SOC can be used for the confirmation of stone clearance, especially after SOC-assisted lithotripsy.*

(Weak recommendation, low quality of evidence, 100%)

POC can also be utilized to confirm stone clearance after biliary stone's endoscopic extraction. In a prospective tandem study including 93 patients, Sejpal et al. [57] reported a 34% increase in the yield of residual stone detection with SOC compared to occlusion cholangiogram, in patients with dilated bile ducts and those receiving lithotripsy. Other studies have also demonstrated this aspect, although only regarding cholangioscopy [55, 58–61].

SOC Transluminal Cholangioscopy-Assisted Lithotripsy Use in Patients with Altered Gastrointestinal Anatomy

One question was evaluated.

1. Is it feasible the use of transluminal cholangioscopy-assisted lithotripsy in patients with altered gastrointestinal anatomy?

RC: *The use of transluminal cholangioscopy-assisted lithotripsy in patients with altered gastrointestinal anatomy is possible after creating a transluminal access to the bile ducts using endoscopic ultrasonography (EUS).*

(Weak recommendation, low quality of evidence, 100%)

When, due to surgical anastomosis or CBD stricture, the endoscope cannot be advanced into the papilla of Vater, biliary stones can be removed by peroral transluminal cholangioscopy (PTLC)-assisted lithotripsy. In this technique, access to the intrahepatic bile duct from the stomach is created by ultrasound guided-hepaticogastrostomy (EUS-HGS), through which POC-assisted lithotripsy is performed [62, 63].

Financial Concerns

One question was evaluated.

1. What is the economic impact of the use of SOC in the management of difficult biliary stones?

RC: *The use of SOC in the management of difficult biliary stones can be cost-effectiveness when used early in the treatment algorithm or when it is predicted that conventional treatments will fail.*

(Weak recommendation, low quality of evidence, 100%)

Despite the clinical applications of POC in the management of DBS, financial factors may hamper further widespread use, leading to high cumulative

Table 3. Studies for difficult bile duct stones

Author (year of publication)	Sample size	Study design	Cholangioscopy method of removal	Stone clearance (overall)	Stone clearance (single session)	Complication rate
Alexandrino et al. [4] (2022)	94	Multicenter, prospective	LL (n = 59) EHL (n = 29) LL + EHL (n = 6)	98.9%	85.1%	30.9%
Wong et al. [6] (2017)	17	Single-center, prospective	LL	94.1%	62.5%	11.8%
Canena et al. [7] (2019)	17	Multicenter, prospective	LL (n = 11) EHL (n = 6)	100%	94.1%	35.2%
Bang et al. [8] (2020)	33	Randomized trial	LL	93.9%	93.9%	9.1%
Angsuwatcharakon et al. [31] (2019)	16	Randomized trial	LL	100%	100%	6.3%
Korrapati et al. [24] (2016)	2,059	Systematic review (with meta-analysis)	LL (n = ND) EHL (n = ND) Other methods (ND)	88.0%	ND	7%
Brewer Gutierrez et al. [46] (2018)	407	Multicenter, retrospective	LL (n = 101) EHL (n = 306)	97.3%	77.4%	3.7%
Bokemeyer et al. [47] (2020)	60	Multicenter, retrospective	LL (n = ND) EHL (n = ND)	95.0%	66.7%	16.0%
Kurihara et al. [48] (2018)	31	Multicenter, prospective	LL (n = 20) EHL (n = 15)	74.2%	ND	ND
Navaneethan et al. [49] (2016)	31	Multicenter, retrospective	LL	97.2%	86.1%	2.9%
Jin. et al. [50] (2019)	2,786	Systematic review (with meta-analysis)	LL (n = ND) EHL (n = ND)	94.3%	71.1%	6.1%
Buxbaum et al. [51] (2018)	42	Randomized trial	LL	92.9%	28.6%	9.5%
Franzini et al. [52] (2018)	48	Randomized trial	EHL	85.1%	77.1%	4.2%
Galetti et al. [53] (2020)	108	Systematic review (with meta-analysis)[a]	LL (n = ND) EHL (n = ND)	90.5%	ND	6.5%
	1,638	Systematic review (with meta-analysis)[b]	LL (n = ND) EHL (n = ND)	88.3%	72.7%	8.7%
Maydeo et al. [55] (2019)	156	Multicenter, prospective	LL (n = 117) EHL (n = 39)	87.2%	80.1%	1.9%
Veld et al. [56] (2018)	1,969	Systematic review (with meta-analysis)	LL (n = 426) EHL (n = 277) ESWH (n = 1,266)	88.4% (EHL) 95.1% (LL) 84.5% (ESWH)	68.9% (LL) 65.8% (EHL) 31.6% (ESWL)	9.6% (LL) 13.8% (EHL) 8.4% (ESWL)

LL, laser lithotripsy; EHL, electrohydraulic lithotripsy; ESWH, extracorporeal shock wave; ND, not determined. [a]Including only randomized trials. [b]Including only observational studies.

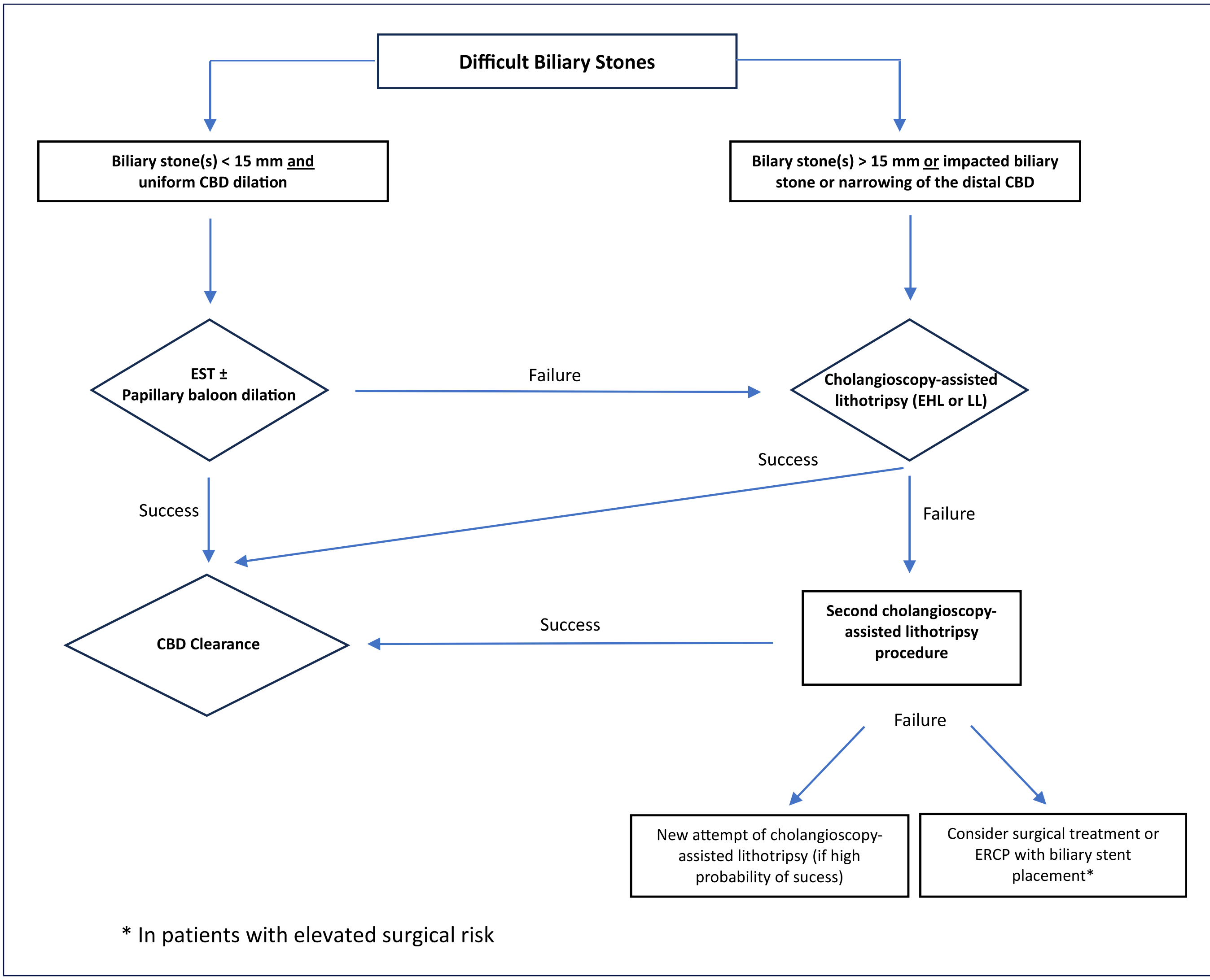

Fig. 2. Proposed approach for the management of difficult biliary stones. CBD, common bile duct; EST, endoscopic sphincterotomy; EHL, electrohydraulic lithotripsy; LL, laser lithotripsy; ERCP, endoscopic retrograde cholangiopancreatography.

costs of the POC processor, cholangioscopes, and cholangioscopic accessories [45]. Overall, start-up costs have been estimated to range between USD 50,000 to USD 90,000 in the USA, although they can vary substantially by institutional contract [64]. According to Deprez et al. [65], the use of SOC-assisted lithotripsy determined a 27% reduction in the number of procedures needed and an 11% relative reduction in costs when compared to ERCP. In a more recent analysis, Sljivic et al. [66] demonstrated that cost-effectiveness of SOC-assisted EHL was higher when used as second-line therapy after conventional ERCP, rather than first or third-line.

Question 3 – Diagnostic and Extension of IPMN

The main use of pancreatoscopy in patients with IPMN is to confirm the diagnosis in doubtful cases, especially in patients who present dilation of the main pancreatic duct without focal images detected by other methods. The direct visualization of the lesions and the possibility of collecting tissue samples for the diagnosis of high-grade dysplasia or invasive carcinoma complement the information obtained by CT, MRI, and endoscopic ultrasound. This is particularly important in the preoperative assessment of patients who are candidates for surgical treatment. In this context, the use of pancreatoscopy has been evaluated in the following clinical scenarios: differential diagnosis of main branch IPMN, diagnosis of high-grade dysplasia and invasive carcinoma and in the intraductal mapping of IPMN lesions.

Differential Diagnosis of Main Branch IPMN

Cross-sectional imaging methods are useful in identifying cystic lesions of the pancreas. However, the differential diagnosis of pancreatic duct dilation caused by IPMN or secondary to chronic pancreatitis, the distinction between pseudocyst and side branch MPIN and the identification of communication between the cystic lesion and the pancreatic duct may be difficult using these methods [67]. Patients with chronic pancreatitis may present with a clinical picture and imaging findings like chronic pancreatitis, making their primary diagnosis difficult. The presence of calcifications and dilation of the main pancreatic duct are characteristic findings of chronic pancreatitis, but may appear in patients with main branch IPMN [68, 69]. Papillary extrusion of mucin, known as "fish eye or fish mouth papilla," is a sign that can be seen during endoscopic observation of the duodenal papilla in patients with main or mixed duct IPMN and allows the differential diagnosis with chronic pancreatitis. In a multicenter study involving 13 patients, the authors demonstrated the usefulness of pancreatoscopy in detecting IPMN lesions in patients with idiopathic chronic calcifying pancreatitis [70], highlighting its potential role in the identification of IPMN in such complex cases.

One question was evaluated.

1. Can pancreatoscopy be used to diagnose idiopathic chronic pancreatitis in patients with pancreatic duct dilation?

RC: *Main branch IPMN lesions may present clinically as chronic calcifying pancreatitis. The use of pancreatoscopy in these patients may allow diagnosis by intraductal identification of characteristic lesions. The possibility of simultaneously treating intraductal lithiasis is an additional benefit of the technique.*

(Weak recommendation, low quality of evidence, 100%)

Diagnosis of High-Grade Dysplasia and Invasive Carcinoma

The ability of pancreatoscopy to identify MPIN with high-grade dysplasia and invasive carcinoma has been evaluated in 8 studies [71–78]. The visual classification system proposed by Hara et al. [75] divides lesions into 5 types: (1) granular, (2) "fish-egg," (3) "fish-egg" with prominent vascularization, (4) villous and (5) vegetative. The presence of subtypes 3, 4 and 5 are indicators of malignancy and these patients should be advised for surgical treatment. Using this classification, the authors were able to discriminate main branch NMPIs between benign and malignant with an accuracy of 88%. Using the SpyGlass platform to perform pancreatoscopy, 6 studies were published that demonstrated high sensitivity and specificity in the visual diagnosis of malignancy [48, 79–83]. However, the lack of studies to evaluate the interobserver agreement of findings and the variability of sensitivity and specificity of visual impression in different studies shows the need for histological confirmation using biopsies directed by pancreatoscopy. The small size of the tissue samples obtained and the difficulty in performing biopsies in the pancreatic duct may limit its clinical applicability and reduce sensitivity compared to visual impression [80].

One question was evaluated.

1. Can pancreatoscopy be used to diagnose malignancy in patients with main branch IPMN?

RC: *Pancreatoscopy can allow the diagnosis of lesions suggestive of malignancy in the pancreatic duct of patients with IPMN of the main duct with high sensitivity and specificity. The groups of patients who benefit most from its use are those with a diffusely dilated duct with a diameter greater than 10 mm, and in whom sectional imaging methods and endoscopic ultrasound do not reveal focal lesions.*

(Weak recommendation, low quality of evidence, 100%)

Question 4 – Evaluation of Potentially Malignant Pancreatic Strictures

In a retrospective cohort, El Hajj et al. [78] evaluated 50 patients with suspected pancreatic strictures over 13 years using pancreatoscopy. The diagnosis was established based on visual impression and/or pancreatoscopy-directed/assisted biopsy. The sensitivity and specificity of pancreatoscopy were 91% and 95%, respectively, when visual impressions were combined with biopsy collection. Publications about pancreatoscopy in the evaluation of pancreatic duct strictures are small and, in most cases, restricted to clinical cases, clinical case series, or retrospective cohorts.

One question was evaluated.

1 What is the indication to perform pancreatoscopy in a suspicious pancreatic stricture?

RC: *Pancreatoscopy can be used to evaluate suspected pancreatic duct strictures. In most patients, the diagnosis is established using imaging methods and less invasive tissue acquisition techniques, especially puncture echoendoscopy. The use of pancreatoscopy in these situations may be reserved for a small number of patients, in whom the diagnosis is inconclusive.*

(Weak recommendation, low quality of evidence, 100%)

Question 5 – Intraductal Pancreatic Stones

There are several approaches for the treatment of intraductal pancreatic stones: (1) endoscopic treatment, namely, ERCP with stone extraction by conventional therapy (balloons/baskets with or without ML) or by intraductal lithotripsy (holmium laser/electrohydraulic) guided by pancreatoscopy. (2) Extracorporeal lithotripsy followed or not by ERCP. (3) Surgical treatment [84].

Extracorporeal Lithotripsy

Over the last 20 years, this has been the treatment of choice for patients with chronic calcifying pancreatitis in patients with stones larger than 5 mm and ductal dilation in which pain is the dominant symptom [84, 85]. Ideally, patients should have stones located in the head and body. Patients with multiple strictures, predominant stones in the tail or intra-parenchymal locations are poor candidates. In a recent meta-analysis of 22 studies with 3,868 patients, the proportion of patients with ductal clearance was 69.8% and the disappearance of pain during follow-up was 64.2% [85]. Lithotripsy may or may not be followed by ERCP. The most recent ESGE guidelines suggest that ERCP should be reserved for patients in whom, after adequate fragmentation, there is no spontaneous elimination of the fragments [86].

ERCP

As previously mentioned, the most recent ESGE guideline suggests that ERCP should be reserved, using conventional treatment (balloons/baskets), for radiolucent stones, smaller than 5 mm. Naturally, associated strictures can be treated with dilation and placement of prostheses [85–87]. However, there is literature which states that larger stones can be treated with intraductal lithotripsy (holmium laser/electrohydraulic) [85–88]. A recent meta-analysis included 10 studies and 302 patients [88]. The main location of the stones was the pancreatic head (66.2%). Technical success was found in 91.2% of cases and the total fragmentation rate was 85.8%. The total removal rate in a single session was 62.1%. When comparing the effectiveness of using the Holmium laser versus electrohydraulic lithotripsy, there were no significant differences between both in terms of technical success, fragmentation rate, and ductal cleaning in a single session.

Three questions were evaluated.

1. What are the indications for performing intraductal lithotripsy guided by pancreatoscopy in patients with lithiasis in the main pancreatic duct?

RC: *The use of intraductal lithotripsy guided by pancreatoscopy in patients with lithiasis in the main pancreatic duct should be reserved for patients with pain and lithiasis greater than 5 mm that cannot be removed using conventional techniques. Patients with an excessively distal location in the tail or head may cause increased technical difficulty.*

(Low recommendation, low quality of evidence, 100%)

2. What is the value of pancreatoscopy-guided lithotripsy when compared to electrohydraulic lithotripsy?

RC: *Pancreatoscopy-guided lithotripsy can be equally effective when compared with extracorporeal lithotripsy, especially in places where extracorporeal treatment is not available and there is endoscopic experience in the center or neighboring centers.*

(Low recommendation. low quality of evidence, 100%)

3. What endoscopic technique should be used? Holmium laser or electrohydraulic lithotripsy?

RC: *When using pancreatoscopy-guided lithotripsy, there is no evidence that either holmium laser or electrohydraulic lithotripsy presents an added advantage over the other. Its use should depend on local experience and available material.*

(Low recommendation, low quality of evidence, 100%)

Question 6 – Other Indications (Bile Duct Mapping for Cholangiocarcinoma, Foreign Body Removal, Cholangioscopy-Assisted Guidewire Placement, Radiation-Free Cholangioscopy)

Cholangioscopy-Assisted Guidewire Placement

One question was evaluated.

1. What is the role of cholangiopancreatoscopy in the selective cannulation of difficult biliary strictures?

RC: *Complementary to endoscopic retrograde cholangiopancreaticography (ERCP), digital SOC-assisted guidewire placement might be helpful for cannulating complex strictures, as it allows the guidewire to be advanced through the biliary stricture under direct endoscopic visual guidance.*

(Weak recommendation, low quality of evidence, 100%)

Selective cannulation and stenting of complex, tight, and/or angulated biliary strictures under ERCP can be challenging [89]. A frequent cause of endoscopic failure is the inability to pass a guidewire through the biliary stricture to allow subsequent dilation or stent placement [90]. SOC-assisted guidewire placement might be helpful for cannulating complex strictures. However, data on technical feasibility and clinical outcomes of digital SOC-assisted selective cannulation after failed conventional ERCP attempts are limited to case reports and small case series, the majority including up to 10 patients, with only 4 studies including 15 to 30 patients [47, 91–100]. Technical success rates of SOC-assisted selective guidewire placement after failed ERCP ranged between 60 and 100% [3–10]. While outcomes are not reported by stricture etiology in the majority of the studies, Bokemeyer et al. [47] reported higher technical success rates in benign biliary strictures compared with malignant strictures (88% vs. 46%, p = 0.02), with benefit being especially seen in post-liver transplant strictures, while Kastelijn et al. [92] did not find different success rates between benign and malignant strictures, possibly due to the small sample size and relatively high proportion of PSC patients. The lower range of success rate (60%) reported by Woo et al. [99] might be related to the inclusion of only living donor liver transplantations (with more complex bile duct anatomy and more angulated and peripheral anastomoses) or by the use of the previous fiberoptic SOC. Kastelijn et al. [92] suggested that the absence of contrast passage during the failed conventional ERCP attempt is a risk factor associated with failure of SOC and could be used as selection criterion for subsequent SOC-assisted attempts.

In addition, SOC-assisted guidewire placement may allow non-contrast-guided access of intrahepatic ducts (decreasing the risk of post-ERCP cholangitis) as well as increase the technical success rate of cystic duct cannulation after failed fluoroscopic guidance [101]. The safety profile of selective digital SOC-assisted guidewire insertion is similar to ERCP regular risks (cholangitis, pancreatitis, and bleeding), ranging between 0% and 16.7% [47, 95, 99].

Radiation-Free Cholangioscopy

One question was evaluated.

1. Can SOC replace fluoroscopy during ERCP in selected cases?

RC: *Using SOC, radiation-free ERCP may be needed in particular settings, such as during early pregnancy and critically ill immobilized patients, as well as clearance confirmation of bile duct stones.*

(Weak recommendation, low quality of evidence, 100%)

Three studies, two prospective single-center studies from the USA (n = 40) and Thailand (n = 50) and one roll-in multicenter RCT (n = 47), showed high rates of successful fluoroscopy-free cannulation (100%, 98%, and 89.4%, respectively) and fluoroscopy-free complete stone clearance following DSC-assisted stone removal (95%, 90%, and 82.6%, respectively), with similar missed rates of CBDS after DSC detected by the subsequent endoscopic retrograde cholangiography (5–6.5%), with similar total procedure time between the DCS group and a propensity score matching conventional ERCP group analysis (37 ± 10 min vs. 34 ± 12 min) [102–104]. The majority of successful fluoroscopy-free CBDS removal was performed by balloon extraction (97–100%), even though the SpyGlass Retrieval Basket was useful for CBDS extraction in 36.2% of the cases in the study by Ridtitid et al., which may save procedural time [102–108].

Foreign Body Removal

One question was evaluated.

1. What is the role of cholangioscopy for foreign body removal in the bile duct system?

RC: *SOC can be useful for foreign body removal in the bile duct system when conventional methods have failed.*

(Weak recommendation, low quality of evidence, 100%)

The use of cholangioscopy for foreign body removal is limited to a few case reports, mainly for the removal of proximally migrated biliary plastic stents or migrated endoclips or other devices. SOC may allow cannulation under direct visualization of the orifice of the biliary stent with posterior use of a stent retriever, the use of SOC-assisted biopsy forceps, or the new intraductal cholangioscopy retrieval devices [109–113].

Bile Duct Mapping for Cholangiocarcinoma

One question was evaluated.

1. What is the role of SOC in the evaluation of the extension of cholangiocarcinoma?

RC: *SOC can be helpful in the preoperative evaluation of cholangiocarcinoma extension and guided mapping biopsy.*

(Weak recommendation, low quality of evidence, 100%)

Before 2007, ERCP plus triphasic dynamic computed tomography or magnetic resonance cholangiopancreatography were the only methods to define the location of cholangiocarcinoma (CCC) lesions and perform preoperative mapping [114]. CCC frequently extends longitudinally along the bile duct. Even though anatomic classifications (like Bismuth-Corlette classification) for description of tumor location and longitudinal extension in the biliary tree are available, they can be limited to detect intraductal mucosal lesions extension not evident in imagiologic studies or by the existence of skip lesions [115]. Therefore, preoperative evaluation of tumor extension is essential for estimating operability and for determining the most appropriate resection line.

No definite guidelines exist for the application of SOC in CCC mapping. Only four studies have assessed the role of SOC in evaluating the lateral spread of CCC, one of them as a feasible study, comparing SOC outcomes to a traditional peroral cholangioscopy system [116]. Despite optical diagnosis by SOC being lower, which could impar detection of low-growing neoplastic change, overall diagnostic accuracy did not significantly differ, due the addition of SOC-guided biopsies [116]. Ogawa et al. [117] performed a prospective randomized crossover study with 28 patients comparing cholangioscopy versus fluoroscopy-guided transpapillary mapping biopsy for preoperative evaluation of extrahepatic CCC; although all 118 target sites could be approached using cholangioscopy-guided biopsies, fluoroscopy-guided biopsies reached only 71% of them, with significantly poor accessibility to the B2/3 confluence; the overall rate of site-based successful biopsies was 78% for cholangioscopy and 64% for fluoroscopy ($p = 0.031$). The two remaining studies evaluating the usefulness of SOC-guided mapping biopsy were performed in the preoperative evaluation of 13 patients with extrahepatic CCC and 19 patients with perihilar CCC [118, 119]. In the former, the overall success rate for SOC-guided mapping biopsy was 88%, being lower for the intrapancreatic common bile duct (67%), presumed to difficulties in performing biopsies due to the tangential direction [118]. Diagnostic accuracy of longitudinal tumor extent with cholangioscopic findings and cholangioscopic-guided mapping biopsy was 88%, being lower in patients with perihilar bile duct carcinoma (66%) [118]. In the latter study, intraductal evaluation altered anatomic classification defined by previous imagiologic findings in 42.1% patients, changing therapeutic approach in 21% of all patients [119]. Surgery was avoided in 2 previously considered resectable lesions due to extensive intraductal involvement, and all patients deemed candidate for surgery after cholangioscopic evaluation achieved an R0 resection; no or mild complications occurred after the procedure [119].

Future Perspectives

Despite the introduction of the SOC and the experience gained with its use that reveals its role as an effective tool for patients with biliary and pancreatic pathology, cholangioscopy is still not available in many centers that perform ERCP. The fear of complications and the cost associated with its use have been limiting factors to its use. Regarding safety, cholangioscopy is considered a safe procedure, although studies show a higher complication rate than ERCP, particularly cholangitis [120]. A 2018 study [2] reported a complication rate of 13.2% after cholangioscopy, with cholangitis being the most common complication (12.8%) [22]. Although the prophylactic use of antibiotics can reduce the risk of cholangitis, their systematic use remains controversial and more studies are needed to evaluate the safety of cholangioscopy [121]. Carrying out the exam must be assessed individually based on the patient's indication and risk factors, but with the accumulation of experience and technology developments, it is expected that the technique will become safer in the future.

Data on the economic costs of cholangioscopy are limited. The economic impact of cholangioscopy was evaluated in a study that aimed to study which ERCP-based technique was most cost-effective for diagnosing cholangiocarcinoma in patients with primary sclerosing cholangitis. ERCP with cytology was the most used method due to its low cost and ease of use, but cholangioscopy showed greater cost-benefit due to its high sensitivity in detecting cholangiocarcinoma [122]. Another study evaluated whether the use of cholangioscopy in patients with difficult gallstones or indeterminate strictures would improve treatment and reduce costs. It was found that cholangioscopy reduced the number of procedures by 27% and the total costs for patients with difficult gallstones by 11%. In patients with indeterminate strictures, cholangioscopy reduced the number of procedures and associated costs by 11% [65]. The results of this study indicate that increasing the effectiveness of using cholangioscopy for diagnosis and treatment of difficult stones and indeterminate strictures reduces associated costs. The cost of purchasing the equipment can be offset by avoiding unnecessary surgeries, reducing the need to transfer the patient to other institutions and reducing the number of exams required to diagnose biliary and pancreatic neoplasms.

A recent development in endoscopy is the possibility of using artificial intelligence (AI) technology with the aim of increasing its diagnostic capacity. In the case of cholangioscopy, AI tools have been evaluated in the diagnosis of indeterminate biliary strictures and in assisting less experienced operators. In the case of biliary strictures, the presence of certain characteristics observed on cholangioscopy, such as tumor vessels, is associated with the presence of malignancy. AI algorithms that automatically detect these characteristics can increase the diagnostic accuracy of the technique. In a retrospective study of 85 patients, an AI algorithm using a convolutional neural network showed 95% sensitivity and 92% specificity in the differential diagnosis of biliary strictures [123]. In another multicenter study involving 528 patients, the cholangioscopy-based convolutional neural network model showed high sensitivity (81%), specificity (91%), and accuracy (AUC 0.86) in distinguishing indeterminate biliary strictures [124]. Incorporating real-time

AI algorithms into cholangioscopy may decrease interobserver variability in interpretation of findings, improve diagnostic accuracy of biliary strictures in less experienced operators, and enable broader proficiency in technology implementation.

Technological improvements can optimize the device's maneuverability and ability to generate high-resolution images of the bile and pancreatic ducts. Current catheter maneuverability and tip deflection are limited, especially when the devices are at the tip of the working channel. These issues can hinder the progression of angled ducts or tighter strictures, as well as hinder the passage of accessories. The diameter of the working channel (1.2 mm) limits the range of accessories that can be inserted (dedicated biopsy forceps, loops, basket, electrohydraulic or LL probes). A larger working channel may increase the diagnostic and therapeutic potential, allowing larger tissue samples to be obtained, balloon dilation or the placement of a small caliber prosthesis to treat strictures. On the other hand, the possibility of introducing larger diameter lithotripsy probes increases the power that can be used to fragment larger stones. The increase in the resolving power of the image obtained the use of automated lighting and the increase in field and depth of vision are technological refinements that can equate cholangioscopy devices to conventional endoscopes. The incorporation of NBI and the ability to magnify the image may increase the ability to identify tumor vessels in strictures [125].

In the future, cholangioscopy will probably become a conventional tool that can be used by pancreatobiliary endoscopists in the treatment of large stones and in the evaluation of indeterminate strictures. Its earlier incorporation in these situations can improve results and increase patient satisfaction. Improving technology and introducing real-time AI algorithms can optimize cholangioscopy results even in less experienced operators. The number of platforms, accessories, and clinical situations in which cholangioscopy can be used will expand. However, to confirm its clinical usefulness, it will be necessary to carry out prospective and randomized studies.

Conflict of Interest Statement

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Author Contributions

Jorge Canena: conception and design of the study, coordination of meetings and consensus, literature search, and drafting the final version of the manuscript: Pedro Pereira, David Horta, and Tiago Bana e Costa: conception and design of the study, drafting specific sections of the manuscript, and literature searching. Luís Lourenço, Eduardo Rodrigues-Pinto, Ana Franco, and Tarcísio Araújo: drafting specific sections of the manuscript and literature searching. Isabel Tarrio: preparing the final draft, tables, figures, assembling different parts of the draft, and critical revision of manuscript. Luís Lopes: conception and design of the study, drafting specific sections of the manuscript, and approval of the final draft.

Data Availability Statement

The data used in this manuscript are available on reasonable request.

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