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## Role of digital single-operator cholangioscopy in the diagnosis and treatment of biliary disorders

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### Abstract

Due to the need for improvement in the diagnosis and minimally invasive therapy of the bile duct disorders new technologies for cholangioscopy have been recently developed. Per-oral cholangioscopy has become an important diagnostic and therapeutic tool leading to avoidance of aggressive and unnecessary surgery in many clinical scenarios. This paper focuses on the newly developed SpyGlass DS technology, its advantages, and the technique of single-operator cholangioscopy (SOC), biliary indications and possible adverse events. We also review the available literature; discuss the limitations and future expectations. Digital SOC (D-SOC) is a useful technique, which provides endoscopic imaging of the biliary tree, optical diagnosis, biopsy under direct vision and therapeutic interventions. The implementations are diagnostic and therapeutic. Diagnostic indications are indeterminate biliary strictures, unclear filling defects, staging of cholangiocarcinoma, staging of ampullary tumors (extension into the common bile duct), unclear bile duct dilation, exploring cystic lesions of the biliary tree, unexplained hemobilia, posttransplant biliary complications. Therapeutic indications are lithotripsy of difficult stones, retrieval of migrated stents, foreign body removal, guide wire placement, transpapillary gallbladder drainage and endoscopic tumor ablative therapy. Most studied and established indications are the diagnosis of indeterminate biliary stricture and intraductal lithotripsy of difficult stones. The adverse events are not different and more common compared to those of Endoscopic retrograde cholangiopancreatography (ERCP) alone. D-SOC is a safe and effective procedure, adjunct to the standard ERCP and the newly available digital technology overcomes many of the limitations of the previous generations of cholangioscopes.

**Key words:** Per-oral cholangioscopy; Digital single-operator cholangioscopy; Difficult stones; Indeterminate strictures; Endoscopic retrograde cholangiopancreatography; Biliary interventions

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**Core tip:** Digital single-operator cholangioscopy represents a new emerging technology, which improves the diagnostic and therapeutic capabilities of the conventional endoscopic retrograde cholangiopancreatography. This paper reviews the available literature about the recently introduced SpyGlass DS technology, the main indications, results, adverse events, as well as some limitations and future expectations.

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## INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is the mainstay diagnostic and therapeutic tool for bile duct diseases. It uses fluoroscopy to image the biliary tree and it has many limitations. There are a number of clinical situations when the established methods for evaluation of biliopancreatic lesions (stricture, cyst, tumor, filling defect) are not informative. The distinction between a benign and a malignant disease is still a challenge for all imaging methods, and the accuracy of cytological and histological samples, obtained under fluoroscopic guidance, is unsatisfactory. Furthermore, between 5 and 10% of cases of intraductal biliary stones could not be resolved by ERCP, even after endoscopic papillary large balloon dilatation (EPLBD) and mechanical lithotripsy (ML). The idea of the peroral cholangioscopy (POCS) is to overcome these limitations allowing direct visualization of the biliary tree with diagnostic and therapeutic purposes<sup>[1]</sup>. POCS was first described in the 1970s, and until now many limitations were stopping it from becoming a routine procedure in the daily endoscopy practice. Two experienced endoscopists are needed for the mother-daughter system. The available endoscopes are fragile, difficult to set up, with limited maneuverability (two-way tip deflexion), poor image quality, and long procedure time. Ultrathin endoscopes are used for direct per-oral cholangioscopy. Intubation of the common bile duct (CBD) with them is often difficult due to looping in the stomach and requiring large sphincterotomy or balloon- dilatation, associated with more adverse events. Often deep insertion in the bile duct is not possible despite the use of guidewires or anchoring balloons<sup>[2]</sup>. The new digital system overcomes many of these disadvantages. We review the new device for digital single-operator cholangioscopy (D-SOC), its clinical applications limitations and complications, economic impact, and the available data in the literature.

## TECHNOLOGY

The D-SOC system (Spyglass DS, Boston Scientific corp.) has two components: (1) a combined processor and light source; and (2) a sterile single-use catheter- 2140 cm working length, 3.2 mm external diameter. The catheter has 4-way tip control, 1.2 mm single working channel, 2 dedicated channels for irrigation and an aspiration port, connected to the working channel. There are 2 light emitting diode lights on the tip and a single complementary metal-oxide semiconductor chip that provides improved image resolution ( $\times 4$ ) and 60% wider field of view compared to the old Spyglass system. The system is easy to set up and the tapered distal end enables easy entering of the CBD - using a free-hand technique or over a guidewire<sup>[2]</sup>.

## CLINICAL APPLICATION

According to the published literature, cholangioscopy has a proven role in the following clinical situations: (A) therapy of difficult biliary lithiasis; (B) diagnosis and treatment of residual lithiasis; (C) staging cholangiocarcinoma; (D) staging ampullary neoplasm (extension into CBD); (E) evaluation of the biliary tree strictures/dilatation;

(F) evaluation of filling defects; (G) stricture evaluation in primary sclerosing cholangitis; (H) evaluation and treatment of Iatrogenic biliary lesions; (I) post-transplantation biliary complications; (J) selective cannulation of complex strictures; (K) selective cannulation of the cystic duct; (L) rescue therapy for ERCP complications (impacted basket); (M) evaluation of hemobilia; (N) extraction of migrated stents /foreign bodies; (O) evaluation of pancreatic- IMPN, stones, and strictures; (P) evaluation and treatment of post-transplant biliary complications; and (Q) tumor ablative therapy.

The published Asian Expert Consensus Statement from 2015 about per-oral cholangiopancreatography contains two important conclusions: “Cholangioscopy POCS and POCS-guided lithotripsy are recommended for treatment of difficult CBD stones when standard techniques fail. Recommendation grade A; in patients with indeterminate biliary strictures, POCS and POCS-guided targeted biopsy are useful for establishing a definitive diagnosis. Recommendation grade B<sup>[5]</sup>.”

## INDETERMINATE BILIARY STRICTURES

Indeterminate biliary strictures and filling defects are one of the indications for cholangioscopy. Optical and histological diagnosis of biliary strictures is critical as the choice of appropriate treatment depends on whether the stricture is benign or malignant. Data from surgical reports suggest that 13%-24% of patients referred for surgery with suspicious malignant hilar strictures have a benign disease<sup>[4]</sup>. Aggressive surgery for benign biliary disease or delayed treatment of malignancy needs to be avoided. Digital cholangioscopy offers direct visualization of the lesion with good image quality and the ability to take targeted biopsies. Cholangioscopic findings suggestive of malignancy are tumor vessels- dilated, tortuous vessels, infiltrative stricture, defined as irregular margins with partial occlusion of the lumen, irregular surface, easy oozing<sup>[5]</sup>.

In a retrospective study Seo *et al*<sup>[6]</sup> from 2000, compared findings from percutaneous cholangioscopy and histologic diagnosis from cholangioscopic biopsies reported three different types of bile duct adenocarcinoma according to the cholangioscopic findings- nodular, papillary and infiltrative. The first is characterized by the presence of nodular mass with luminal obstruction with irregular mucosa and neovascularization (tumor vessels) on the surface. The second type is characterized by multiple papillary lesions with pus and sludge in the lumen. This tumor spreads superficially and neovascularization is rare. The third type appears as tapered narrowing of the lumen without mucosal mass. The neovascularization is less intense<sup>[6]</sup>.

In a prospective study Kim *et al*<sup>[7]</sup> demonstrated that tumor vessels are highly specific cholangioscopic findings, indicating malignancy. They found irregularly dilated and tortuous vessels in 61% of patients with biliary malignancy and none in cases of benign biliary strictures. The reported sensitivity of biopsy confirming malignancy was 80%, specificity was 100%. The sensitivity of “tumor vessels” confirming malignancy was 61%, specificity was 100%. The combination of tumor vessels and biopsy had 96% sensitivity and 100% specificity. Tumor vessel differs from the normal vessels of the biliary mucosa and can be easily recognized by experienced cholangioscopists. According to this data, this cholangioscopic finding could be applied as a universal endoscopic marker for biliary malignancy. The observation of a tumor vessel together with a cholangioscopic biopsy could be a suitable way to distinguish between benign and malignant biliary stricture.

In a retrospective study by Shah *et al*<sup>[8]</sup> aimed to evaluate the new system for digital cholangioscopy, 108 patients with indeterminate strictures were included. The sensitivity of visual impression was 97%, 93% specificity, 90% positive predictive value (PPV), 98% negative predictive value (NPV). The reported sensitivity of targeted biopsy was 86%, and the specificity was 100%. Among patients with confirmed neoplasia, 45% had tumor vessels, 41% had infiltrative stricture, 31% had villous mass and 17% finger-like villiform projections. Low papillary mucosal projections, concentric stenosis, and coarse granular mucosa are associated with benign disease but were described in 10%, 7% and 3% of the patients with neoplastic disease. Infiltrative stricture was found in 9% of patients with benign disease (IgG4 cholangiopathy) and tumor vessels were found in 2% of patients with benign disease. This data indicates that the diagnosis could not be based only on cholangioscopic appearance. Histology is most important<sup>[8]</sup>.

The opportunity for visualisation of the biliary tree has led to continual attempts at classification of findings in order to establish standardised and widely accepted criteria for endoscopic/macroscopic diagnosis. Although there are cholangioscopic

features, indicative of malignancy, diagnostic criteria are still poorly standardized. A study by Sethi *et al*<sup>[9]</sup>, published in 2014, inspects the visual accuracy of single-operator cholangioscopy (SOC) among 9 experts assessing 27 video clips according to nine criteria. The interobserver agreement (IOA) about all criteria was slight to poor. The weakness of the study consists of the low number of video clips and the poor quality of the video.

The opportunity for improved quality of the digital image and a wider angle of view has led to new research in the visual assessment and classification of biliary lesions. Studies published by Shah *et al*<sup>[9]</sup>, Navaneethan *et al*<sup>[10]</sup>, Turowski *et al*<sup>[11]</sup>, among others, based on experience with Spy Glass DS, report an impressively high sensitivity of the endoscopist's visual impression approximating 100%. The procedures were performed by a single experienced endoscopist who had previous access to the patient's clinical record, which could be regarded as a weakness of these studies. A proposal from Ecuador for a new classification system of the cholangioscopic findings was published in 2018. The authors proposed dividing the lesions into 2 groups- non- neoplastic and neoplastic. Interestingly, biliary adenomas were classified as non- neoplastic. The study is based on 305 patients who underwent SOC with the first and second generation of Spy Glass and includes a two-stage protocol: retrospective for image analysis and classification preparation, and prospective for proposal validation. At the second stage, the results for sensitivity, specificity, PPV and NPV of the image for neoplastic lesion were as follows: 96.3%, 92.3%, 92.9%, and 96%. There was good agreement among observers, higher with experts ( $\kappa > 80\%$ ) than with non-experts ( $\kappa$  64.7%-81.9 %) <sup>[12]</sup>.

Despite the encouraging results with D-SOC, the endoscopic criteria are not as yet fully established and could not be applied independently. Visual optimization techniques such as Narrow Band Imaging (NBI) and Chromoendoscopy in POCS-Systems are currently a subject of study, but they are not routinely used in clinical practice<sup>[13]</sup>. There is lack of consensus on terminology and description of findings. Histology remains the gold standard for diagnosis.

A number of systematic reviews, meta-analyses, and studies are available, analysing the ability of cholangioscopy for visual and histological diagnosis of indeterminate biliary strictures. Most of the studies are retrospective and the available data is regarding the older generation SpyGlass and other cholangioscopy-platforms. A systematic review and meta-analysis published by Korrapati *et al*<sup>[14]</sup> 2016 based on 49 studies analysing the efficacy of per-oral cholangioscopy for difficult biliary stones and indeterminate strictures showed a promising diagnostic yield of visual assessment: sensitivity 93%, specificity 85% and accuracy 89%. The results for image-guided biopsies in that study are 60%, 94%, and 79% respectively. In another recent meta-analysis, focused only on SOC with the first generation SpyGlass, involving 335 patients, the pooled sensitivity and specificity for visual impression is 90% and 87%; the same indicators for SpyBite biopsies are 69% and 98%<sup>[15]</sup>.

Draganov *et al*<sup>[16]</sup> compare directly the accuracy of fluoroscopic-guided versus SOC-guided biopsies using the first generation SpyGlass. Despite the small number of cases, it reliably shows a significant superiority of specimens obtained under visual control. The sensitivity for malignancy of SOC and fluoroscopic-guided biopsies were 76.5% versus 29.4%, and diagnostic accuracy amounted to 84.6% versus 53.8% respectively.

The first multi-center study evaluating the efficacy of the new generation SpyGlass in the United States reports high technical success in different biliopancreatic disorders. 77 patients with indeterminate strictures underwent D-SOC: 31 of them had neoplasia, with 81% (25) of them being histologically proven. Authors report "operating characteristics" for patients with indeterminate stricture/dilatation as follows: sensitivity 97%, specificity 96%, PPV 94%, NPV 98%<sup>[8]</sup>.

Navaneethan *et al*<sup>[10]</sup> published an observational study based on 105 patients about the potential of the new generation of SpyGlass in diagnosing biliary lesions and clearance of biliary and pancreatic stones. The results are as follows: sensitivity and specificity of SOC visual impression for diagnosis of malignancy were 90% and 95.8%, and those of D-SOC-guided biopsies - 85% and 100%. The on-site pathological evaluation performed in that study resulted in an increase in the diagnostic yield of specimens<sup>[10]</sup>. Additionally, in another study involving 31 patients with indeterminate biliary strictures, the diagnostic value of rapid on-site evaluation touch imprint cytology (ROSE-TIC) to cholangioscopy for malignancy raised sensitivity to 100%, and specificity to 88.9%. The established PPV came out at 86.7%, the NPV reached 100%, and diagnostic accuracy - 93.5%<sup>[17]</sup>.

In a multicentre retrospective study, published in 2018 and based on 250 patients who underwent cholangioscopy with SpyGlass DS in 8 endoscopic units, the authors report less encouraging results from histological examinations and underline the need for a standardized biopsy protocol. In a large group of 117 patients with

indeterminate biliary strictures, the sensitivity of the lesion's visual assessment was 95.5% and its specificity was 94.5%. Cholangioscopy-guided biopsies feature 57.7% for sensitivity and 100% specificity. The researchers suggest that the lack of a standardized number of obtained specimens, the small size of the specimens (due to the SpyBite design) and lack of on-site cytology evaluation are the primary deficiencies causing the relatively low sensitivity of histological diagnosis<sup>[11]</sup>.

Another retrospective study, published in 2018, evaluates the role of D-SOC in 67 cases of indeterminate strictures or difficult stones and reports similar results. The reported sensitivity and specificity for visual assessment were 88.9% and 97.6%, and for image-guided biopsies - 62.5%, and 90.0%. 19 patients underwent therapeutic interventions with a success rate of 89.4%. The authors report complications in 17 patients (25.4%)<sup>[18]</sup> (Table 1).

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## PREOPERATIVE ASSESSMENT OF BILIOPANCREATIC NEOPLASIA

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An emerging role of digital cholangioscopy is the mapping of biliopancreatic neoplasia. Visual definition of neoplastic margins in biliary and pancreatic ducts could provide a precise staging of malignancy and change the surgical plan. A multi-center prospective cohort study recently published by Tyberg *et al*<sup>[19]</sup>. Assesses the impact of cholangioscopy on preoperative mapping of biliopancreatic neoplasia: 118 patients underwent cholangio(pancreato)scopy, 89% of whom were with presumed diagnosis cholangiocarcinoma and 11% - with presumed diagnosis IPMN (intraductal papillary mucinous neoplasia). The surgical plan was changed in 34%: 10% were referred for more extensive surgery, 65% were subjected to less extensive surgery, and 25% avoided surgery. The correlation between surgical and cholangioscopic histology was 88%<sup>[19]</sup>. D-SOC permits safe and effective delineation of biliopancreatic neoplasia before surgery and changes the surgical plan in a significant number of patients.

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## NEGOTIATION OF COMPLEX STRICTURES

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In addition to providing visual assessment and tissue sampling, cholangioscopy has become an important therapeutic tool in treating biliary strictures. Cholangioscopy-guided cannulation is a useful method for any kind of complex strictures. In 2018, a retrospective analysis of 30 SOC- assisted guidewire placements was published; it was performed on 23 patients with biliary strictures, insusceptible to cannulation during ERCP. 52% of the patients had post-liver transplant stricture and 48% were diagnosed with malignant stricture (mostly CCA). The achieved technical success was 70%, with the subgroup analysis showing significantly better results in benign strictures. The authors also report higher cannulation rates in initial procedures than in repeated ones. The adverse events were 16.4%, including cholangitis, pancreatitis, and bleeding. The authors concluded, that digital SOC- assisted guidewire placement has a high technical success rate, especially in benign strictures. The procedure helps to avoid more aggressive procedures such as percutaneous transhepatic biliary drainage or EUS- guided biliary drainage<sup>[20]</sup>.

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## POSTTRANSPLANT BILIARY COMPLICATIONS

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Recent studies inspect the role of D-SOC in post-transplant biliary complication. The opportunity for visual assessment of the bile ducts facilitates to detect epithelial changes, ulcers, small stones, bile casts not detectable by ERCP or cross-sectional imaging, to distinguish anastomotic from non-anastomotic strictures. It is also possible to selectively cannulate complex, angulated or excentric strictures who failed conventional fluoroscopy-guided negotiation<sup>[21-23]</sup>.

An observational study, published 2017, reports the experience with twenty-six patients with post-LT suspected biliary complications. Patients underwent ERCP with fluoroscopic evaluation, followed by cholangyoscopic evaluation. The procedure proved anastomotic strictures in fourteen (53.8%), non-anastomotic strictures in seven (26.9%), biliary cast in three (11.5%), and stones in six (23.1%) cases. Cholangioscopy was beneficial in twelve (46.2%) patients. In four cases, cholangioscopy turns out to be crucial to guidewire placement. Adverse events (peri-procedural cholangitis) were reported in one patient<sup>[23]</sup>. According to another case series, successful placement of a guidewire across the post-LT stricture under visual control was achieved in 5 cases.

**Table 1** Studies, evaluating the role of digital single-operator cholangioscopy in defining biliary strictures

Author	Yr	Design	Patients	Visual impression (sensitivity and specificity)	Histology (sensitivity and specificity)
Shah <i>et al</i> <sup>[9]</sup>	2017	Single center	77	97%, 96%	81%
Navaneethan <i>et al</i> <sup>[10]</sup>	2016	Multicenter	44	90%, 95.8%	85%, 100%
Varadarajulu <i>et al</i> <sup>[17]</sup>	2016	Single center	31	-	100%, 88.9
Turowski <i>et al</i> <sup>[11]</sup>	2018	Multicenter	99	95.5%, 94.5%	57.7%, 100%
Lenze <i>et al</i> <sup>[18]</sup>	2018	Single center	41	88.9%, 97.6%	62.5%, 90.0%

All of these strictures had failed cannulation under fluoroscopic guidance<sup>[21]</sup>. Overall, the published data concluded that D-SOC is safe and in many cases superior to ERCP in managing post-LT biliary complications.

## TREATMENT OF DIFFICULT BILE DUCT STONES

Bile duct stones are considered “difficult” according to several criteria: > 1.5 cm size of the stone; > 3 stones; location over a stricture, in a cystic duct or an intrahepatic location. Altered anatomy also indicates a ductal stone as difficult. Difficult stones are related to a decrease in the success of endoscopic treatment. The current approach to complex ductal stones includes EPLBD and ML. In case of failure, extracorporeal and intraductal lithotripsy remain the non-surgical options. Cholangioscopy provides the opportunity for intraductal visual-guided electrohydraulic lithotripsy (EHL) or laser lithotripsy (LL). In recent years, the efficacy and safety of SOC- guided laser and EHL using the first generation SpyGlass has already shown promising results in many multicentre studies based on substantial counts of patients, reporting ductal clearance rate ranging between 80% and 100%<sup>[14,24,25]</sup>.

With the 4-way tip deflexion, better image stability and improved irrigation, the second generation of SpyGlass is expected to show better results. A recently (2018) published retrospective study by Gutierrez *et al*<sup>[26]</sup> included 407 patients from 22 referral centres who underwent SOC- guided lithotripsy (EHL or laser) for treatment of difficult bile duct stones. 306 patients (75.2%) were treated with EHL and 101 (24.8%) with LL. The study aims to assess the efficacy and safety of cholangioscopy-guided EHL and LL with the second generation of SpyGlass and to compare the two modalities. Complete ductal clearance was achieved in 97.3% of the patients and the mean procedure time was 67 min. Difficult anatomy and cannulation (duodenal diverticula or altered anatomy) were the main factors related to technical failures. The reported adverse- event rate was 3.7%. There was no significant difference in safety profile and achieved success in both methods, but the EHL has a longer mean procedure time. The cholangioscopy-guided therapy could be used as first-line for treatment of difficult bile duct stones<sup>[26]</sup>.

The abovementioned multicentre study on the therapeutic potential of SpyGlass DS, published by Turowski *et al*<sup>[11]</sup>, reports about 107 patients with biliary stones treated with D-SOC-guided lithotripsy. Complete stone clearance was achieved in 91.1% of the cases with three procedures on average. The observed adverse events were 13.2% and serious adverse events were 1.4%.

In their study with second-generation SpyGlass, Navaneethan *et al*<sup>[10]</sup> report about 31 patients with complete bile duct stones clearance (mean size of stones 15mm) by LL in multiple sessions. The success rate achieved in one session was 86.1%. The observed adverse events were 2.9%.

A limited prospective study in Portugal (2018) assesses the technical success and safety of SOC- guided LL/EHL using SpyGlass DS in 17 patients with difficult bile duct or pancreatic duct stones. The complete stone clearance rate over 1 procedure was 94.1% and the reported adverse events accounted for 12% (2/17)<sup>[27]</sup>.

The abovementioned available data about the utility of SpyGlass DS in the treatment of biliary lithiasis confirm the high effectiveness of EHL and LL, already established in literature with older systems. Further studies are needed to evaluate the cost-effectiveness of cholangioscopy- guided stone therapy, to compare both methods (EHL and LL) and to correctly determine the place of cholangioscopy-guided lithotripsy in the treatment-algorithm in patients with difficult stones. Stones which are difficult for some endoscopists could be easy for others. The early introduction of SOC in the treatment of bile duct stones could reduce the need for multiple ERCP-sessions and related adverse events. It is also important, not to forget, that often multiple sessions of LL and EHL are needed and the procedure time is longer

compared to standard ERCPs. This could also increase the risk for the patients.

There is still little data directly comparing directly the efficacy of ERCP and D-SOC. Buxbaum *et al*<sup>[28]</sup> published a randomised trial based on patients with proved extrahepatic bile duct stone larger than 1 cm in diameter. Complete clearance was achieved in 93% of patients treated with D-SOC-guided LL and in 67% of those treated with conventional therapy only (EPLBD and ML). Interestingly, the 9 patients, who failed the “conventional” treatment, underwent surgical bile duct stone removal. In summary, the data suggest that cholangioscopy is more time consuming than ERCP, but it ensures a higher rate of endoscopic bile duct clearance and decreases the need for surgical treatment compared with conventional therapy alone.

In a randomised control study Kulpatcharapong *et al*<sup>[29]</sup> compare cholangioscopy-guided LL with ML in patients with difficult bile duct stones who failed EPLBD. 16 patients were treated with ML with an estimated efficiency of 62.5%, and another 16 were treated with D-SOC-guided LL with 100% efficiency. Albeit limited, the study shows an advantage of cholangioscopy over ERCP with ML in terms of large stone clearance and radiation exposure (Table 2).

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## POTENTIAL FOR RADIATION-FREE INTERVENTIONS

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ERCP has the disadvantage of radiation exposure of medical staff and patients, need for a dedicated fluoroscopy room, and lack of direct visual control. A recent study by Barakat *et al*<sup>[30]</sup> evaluates prospectively the potential of SpyGlass DS for radiation-free therapy of uncomplicated CBD stones. 40 patients were included. The technique includes fluoroscopy-free cannulation followed by sphincterotomy and cholangioscopy for detection and evaluation of the stone. Balloon sweeps were followed by a second cholangioscopy to confirm bile duct clearance. The radiation-free cannulation was successful in all 40 patients, bile duct clearance was achieved in all cases, limited fluoroscopy was needed only in 5% and the complication rate was 7.5% (post-ERCP pancreatitis and bleeding). Further information is needed, but the method has two strong advantages: lack of radiation, and option for bed-side procedure in emergency departments<sup>[30]</sup>.

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## OTHER CLINICAL APPLICATIONS

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There are constant developments in the therapeutic potential of cholangioscopy. Retrieval of foreign bodies (surgical clips) has been described in literature in some cases. An impacted basket is a familiar complication of endoscopic bile duct stone therapy which could be managed by intraductal lithotripsy for the release of the impacted basket<sup>[31,32]</sup>. The SpyBite forceps has been described to successfully retrieve proximally migrated stents<sup>[33]</sup>.

There are some reports on selective cystic duct cannulation, with effective gallbladder drainage in patients diagnosed with severe cholecystitis and unfit for surgery<sup>[34,35]</sup>. Haemobilia could also be diagnosed and managed successfully by peroral cholangioscopy<sup>[36]</sup>.

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## ECONOMIC IMPACT

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The cholangioscopy with the SpyGlass DS system is an expensive procedure due to the high price of the processor and due to the fact that the SpyScope and all other devices are fully disposable. An analysis is needed to assess the financial aspect of the procedure and to determine if it can be cost-effective. Deprez *et al*<sup>[37]</sup> evaluated the economic consequences of SpyGlass DS using data from two large Belgian hospitals, specialized in endoscopic procedures of the bile ducts. They created 2 decision-tree models- one for treatment of difficult bile duct stones and one for indeterminate strictures diagnose. In the first group the use of COC was related to a decrease in the number of procedures by 27% decrease of the costs by 11%. The second group showed similar results- 31% reduction in the number of procedures and 5% reduction of the costs. The SpyGlass DS- cholangioscopy may be more cost-effective compared to ERCP alone depending on selection criteria<sup>[37]</sup>.

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## ADVERSE EVENTS

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The adverse events reported in the literature range between 4% and 22%. There are

**Table 2 Studies, evaluating the role of digital single-operator cholangioscopy in treatment of difficult biliary stones**

Author	Yr	Design	Patients	Complete stone clearance
Gutierrez <i>et al</i> <sup>[26]</sup>	2018	Multicenter	407	97.30%
Turowski <i>et al</i> <sup>[11]</sup>	2018	Multicenter	107	91.10%
Navaneethan <i>et al</i> <sup>[10]</sup>	2016	Multicenter	31	86.1%
Canena <i>et al</i> <sup>[27]</sup>	2018	Single centre	17	94.1%
Buxbaum <i>et al</i> <sup>[28]</sup>	2018	Single centre	16	93%

different definitions for complications and there are differences in the studied populations. The main complications related to cholangioscopy are cholangitis, liver abscess, haemobilia, bile leak, acute pancreatitis, bleeding, perforation and air embolism. Almost all of the abovementioned complications do not differ from those of ERCP alone. In a retrospective study by Sethi *et al*<sup>[38]</sup> the authors compared the adverse events of ERCP and cholangioscopy (using conventional cholangioscopes and first-generation SpyGlass) with the adverse events of ERCP alone. The adverse events in the first group were 7% and in the second group- 2.9%. They detected significantly higher rates of cholangitis in the cholangioscopy group (1% *vs* 0.2%) and similar rates of pancreatitis and perforation. The higher rate of cholangitis despite antibiotic prophylaxis is related with the continuous or intermittent irrigation during cholangioscopy, which increases the pressure in the bile duct system<sup>[38]</sup>.

## CONCLUSION

Complex bile duct stones and indeterminate biliary lesions are the main indications for performing cholangioscopy. There is fast growing data in the literature on the new SpyGlass DS System showing its strengths and weaknesses. The available data with the new D-SOC system confirm the excellent success rate in bile duct stone detection and clearance, regardless of the ductal location. The improved quality of the digital image has led to a significant increase in the visual impression sensitivity and the achieved IOA. The published information suggests that early implementation of D-SOC for selected cases are safe and useful. It could prevent diagnostic delay and reduce the risks and costs related to repeat ERCPs. There are emerging data about the potential of radiation-free biliary intervention using D-SOC. Nevertheless, the right place of SOC in the diagnostic and therapeutic algorithm for biliopancreatic diseases is still an issue. A current field of development is establishing refined visual criteria for benign/malignant lesion distinction. The achieved histological confirmation is still relatively low and further improvement of biopsy forceps and biopsy protocol are needed. The main limitation of the method is the cost of the procedure. The training of required skills is also time- and cost- consuming; hence, there is a limited pool of experienced endoscopists. There is still restricted access to the system. Despite encouraging data about its utility, D-SOC remains a time-and cost-consuming procedure, associated with serious adverse events and high expertise, and requiring strict selection of patients.

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