Thieme

Accurate and safe diagnosis and treatment of neoplastic biliary lesions using a novel 9F and 11F digital single-operator cholangioscope

OPEN ACCESS

Authors

Carlos Robles-Medranda[1], Juan Alcivar-Vasquez[1], Isaac Raijman[2], Michel Kahaleh[3], Miguel Puga-Tejada[1], Raquel Del Valle[1], Haydee Alvarado[1], Carlos Cifuentes-Gordillo[1], Kenneth F. Binmoeller[4], Alberto Jose Baptista[5], Jonathan Barreto-Perez[1], Jorge Rodriguez[1], Maria Egas-Izquierdo[1], Domenica Cunto[1], Daniel Calle-Loffredo[1], Hannah Lukashok[1], Jorge Baquerizo-Burgos[1], Daniela Tabacelia[6,7]

Institutions

1 Gastroenterology, Instituto Ecuatoriano de Enfermedades Digestivas - IECED, Guayaquil, Ecuador
2 Gastroenterology, Digestive Associates of Houston, Houston, United States
3 Gastroenterology, Robert Wood Johnson Medical School, New Brunswick, United States
4 Gastroenterology, California Pacific Medical Center, San Francisco, United States
5 Endoscopy, Hospital de Clinicas Caracas, Caracas, Venezuela, Bolivarian Republic of
6 Gastroenterology, Elias Emergency University Hospital, Bucuresti, Romania
7 Gastroenterology, Carol Davila University of Medicine and Pharmacy, Bucuresti, Romania

Keywords

Cholangioscopy, Strictures, Pancreatobiliary (ERCP/PTCD), Stones, Tissue diagnosis

received 11.9.2023
accepted after revision 15.2.2024

Bibliography

Endosc Int Open 2024; 12: E498–E506
DOI 10.1055/a-2282-6678
ISSN 2364-3722

Georg Thieme Verlag KG, Rüdigerstraße 14, 70469 Stuttgart, Germany

Corresponding author

Dr. Carlos Robles-Medranda, Instituto Ecuatoriano de Enfermedades Digestivas - IECED, Gastroenterology, Av. Abel Romeo Castillo y Av. Juan Tanca Marengo, Torre Vitalis, Office Mezanine 3, 090505 Guayaquil, Ecuador
carlosoakm@yahoo.es
carlosoakm@gmail.com

ABSTRACT

Background and study aims Digital single-operator cholangioscopy (DSOC) allows the diagnosis of biliary duct disorders and treatment for complicated stones. However, these technologies have limitations such as the size of the probe and working channel, excessive cost, and low image resolution. Recently, a novel DSOC system (eyeMAX, MicroTech, Nanjing, China) was developed to address these limitations. We aimed to evaluate the usefulness and safety of a novel 9F and 11F DSOC system in terms of neoplastic diagnostic accuracy based on visual examination, ability to evaluate tumor extension and to achieve complete biliary stone clearance, and procedure-related adverse events (AEs).

Patients and methods Data from ≥ 18-year-old patients who underwent DSOC from July 2021 to April 2022 were retrospectively recovered and divided into a diagnostic and a therapeutic cohort.

Results A total of 80 patients were included. In the diagnostic cohort (n = 49/80), neovascularity was identified in 26 of 49 patients (46.9%). Biopsy was performed in 65.3% patients with adequate tissue sample obtained in 96.8% of cases. Biopsy confirmed neoplasia in 23 of 32 cases. DSOC visual impression achieved 91.6% sensitivity and 87.5% specificity in diagnosing neoplasms. In the therapeutic cohort (n = 43/80), 26 of 43 patients required lithotripsy alone. Total stone removal was achieved in 71% patients in the first session. Neither early nor late AEs were documented in either the diagnostic or therapeutic cohort.

Conclusions The novel DSOC device has excellent diagnostic accuracy in distinguishing neoplastic biliary lesions as well as therapeutic benefits in the context of total stone removal, with no documented AEs.

Introduction

Bile duct disorders, particularly indeterminate biliary strictures, are common, yet they remain difficult to diagnose, which is especially problematic because their management varies widely depending on the etiology [1]. An accurate, minimally invasive diagnostic procedure can avoid major surgery and accelerate initiation of the correct treatment, which unfortunately is often the only option for oncologic patients.

Magnetic resonance cholangiopancreatography (MRCP) and endoscopic retrograde cholangiopancreatography (ERCP) are the main diagnostic and therapeutic procedures for biliary duct disorders. Nevertheless, strong limitations in terms of the ability to accurately differentiate between malignant and benign pathologies and ineffective therapeutic outcomes with ERCP in cases of complicated biliary stones have been reported [2]. To overcome limitations of ERCP related to diagnosis and treatment, cholangioscopy probes were introduced with improved image quality and probe durability [3].

Released in 2015, the SpyGlass DS (Boston Scientific, Marlborough, Massachusetts, United States), which employs a digital single-operator cholangioscopy (DSOC) technique, has considerably improved the quality of clinical decisions regarding the diagnosis and treatment of bile duct disorders [3]. Some well-known therapeutic indications for this procedure include difficult biliary stone treatment using electrohydraulic (EHL) or laser lithotripsy, foreign body or migrated stent removal, and guidewire placement [1]. However, this technology has low-quality imaging and elevated costs, which limits its widespread use [4]. Therefore, technologies with higher image resolution that could improve visual impression, diagnostic accuracy, and improvements in therapeutics and limit patient harm are needed.

Physician expertise plays a major role in accurately detecting and differentiating neoplastic from non-neoplastic lesions based on visual findings and in target lesion biopsy. In additionally, the adverse events (AEs) of cholangioscopy (bleeding, acute cholangitis, and pancreatitis) can be a challenge for both experienced and novice endoscopists [5].

This study aimed to evaluate the usefulness and safety of a novel 9F and 11F DSOC system (eyeMAX, Micro-Tech, Nanjing, China) in terms of neoplastic diagnostic accuracy based on visual examination, ability to evaluate tumor extension and to achieve complete biliary stone clearance, and procedure-related AEs.

Patients and methods

Study design and ethical review

This was a single-center study performed at the Instituto Ecuatoriano de Enfermedades Digestivas (IECED), Guayaquil, Ecuador. The study protocol was approved by the Institutional Review Board and was conducted according to the Declaration of Helsinki and the STROBE Statement. Patients or their legal guardians provided written informed consent before the procedures for analysis and publication of the DSOC procedure.

Study population

Two patient cohorts were created based on whether diagnosis or therapy was applied in order to assess the diagnostic and therapeutic potential of the eyeMAX system. Data from patients aged at least 18 years who underwent DSOC from July 2021 to April 2022 were retrospectively collected.

The diagnostic cohort included patients with suspected malignancy and indeterminate strictures (malignant or benign) based on previous contrast-enhanced computed tomography (CE-CT), MRCP or inconclusive endoscopic ultrasound (EUS) with fine-needle aspiration/biopsy (FNA/B).

The therapeutic cohort included patients with biliary stones (> 20 mm) or with biliary stones that were unable to be resolved with EHL. At the end of biliary stone removal, cholangioscopy was performed to record biliary stone clearance. Patients with uncontrolled coagulopathy, who were pregnant/lactating, who were allergic to the contrast medium, who could not pass the scope, or who were followed-up for < 6 months were excluded from the study.

eyeMAX system description

eyeMAX is a single-use, single-operator-controlled video pancreaticobiliary scope measuring 220 cm in length and available in two diameters, 9F and 11F, with an irrigation channel, an optical channel, and 1.2-mm and 2.0-mm accessory channels, respectively. Given the option of a probe with a diameter smaller than that of the existing cholangioscope (10.5F SpyGlass probe, Boston Scientific, Marlborough, Massachusetts, United States) that retains the 1.2-mm working channel, lower-caliber cholangioscopes could offer advantages in assessing biliary tree strictures and the extension of lesions and in providing adequate stent choices.

The eyeMAX probe consists of a high-resolution imaging sensor with a fiberoptic illumination bundle and a full high definition + image. The white balance adjustment function of the camera provides a more natural color space in the image that is not affected by the light source color. The eyeMAX system has image processing algorithms and an illumination design that grants the complementary metal oxide semiconductor image sensor high-resolution capabilities. In addition, the system has a forward 120° field of view. The eyeMAX biopsy forceps (Micro-Tech, Nanjing, China) is a single-use device that passes through the biopsy channel of the scope with a working length of 2900 mm and opening widths of 3 mm and 4.5 mm for the 9F and 11F probes, respectively. The handle of the cholangioscope allows four-way tip deflection, providing optimal mobility through the biliary tract.

Endoscopic techniques

All enrolled patients were evaluated by standard gastroduodenoscopy (Pentax ED 34-I10T; Pentax Medical, Hoya Corps., Tokyo, Japan), Pentax video processing (EPK-I7010), and the new eyeMAX system (Micro-Tech, Nanjing, China).

All procedures were performed under general anesthesia with antibiotic prophylaxis (1 g ceftriaxone, intravenously) and executed by experienced endoscopists (C.R.M., J.A.V., I.R., and

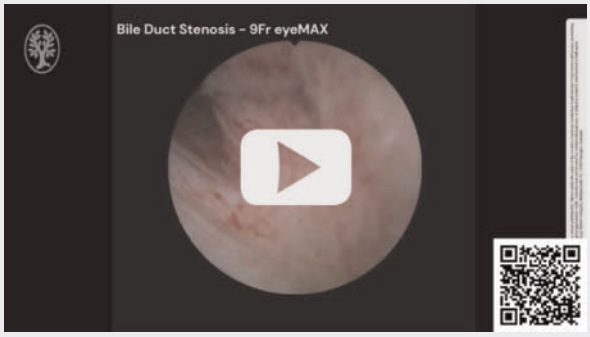
M.K.), who have conducted > 300 ERCP procedures per year and are experienced in peroral cholangioscopy (POCS) (> 150 per year) and were blinded to previous imaging. Prior to the initial DSOC, an endoscopic sphincterotomy was performed to allow passage of the eyeMAX probe through the biliary sphincter. Using an over-the-wire technique, biliary cannulation was achieved. Then, the probe was passed inside the biliary tract using suction to clear bile and contrast material; sterile saline solution was continuously infused for imaging optimization. The size of the cholangioscope (9F or 11F) used during the procedure was based on the judgment of the experienced endoscopists. Images and videos were recorded using a high-definition image capture system (▶ **Video 1a**). Balloon dilation or sphincterotomy extension also was performed in subsequent DSOC sessions if needed. At least three tissue biopsies were performed using eyeMAX biopsy forceps (Micro-Tech, Nanjing, China) through the cholangioscope from each suspicious area found within the biliary duct system.

EHL was performed in patients with complicated biliary stones refractory to conventional methods of extraction during ERCP using highly flexible bipolar 3F (1 mm) or 4.5F (1.5 mm) lithotripsy probes compatible with a Lithotron generator (Walz Elektronik GmbH, Germany). Because the lithotripsy probes are available in two diameters, unlike the 1.9F probe compatible with the AUTOLITH Touch generator (Boston Scientific, Marlborough, Massachusetts, United States), which is available in only a single dimension, the lithotripsy probes could be used with both the 9F and 11F eyeMAX cholangioscopes, with the power proportional to the diameter of the probe, which is extremely useful in patients with stones and strictures. Despite the high flexibility of the Lithotron-compatible EHL probes and use of a probe tip specifically designed for reproducibly delivering shockwaves, the probes can maintain their positions outside the cholangioscope. All procedures took place in normal saline medium. The lithotripsy probe was positioned past the working channel of the scope and in contact with the stone. The stone was then fragmented by microshock waves generated by short high-voltage energy pulses. Microliquid jets and the microshock waves exert high dual effectiveness, while the minimized tensile phases and short range of the microwaves with steep edges prevented damage to the surrounding tissue. At the end of the procedure, the stones were retrieved with a conventional balloon extraction device (▶ **Video 1b**).

Adverse events

AEs were defined following the American Society for Gastrointestinal Endoscopy (ASGE) criteria [5]. Perforation, acute pancreatitis, cholangitis, and bleeding were categorized as major AEs and were recorded up to 30 days after the procedure. Perforation was defined as the presence of air or luminal content outside the gastrointestinal tract. Post-ERCP pancreatitis was defined as abdominal pain with a 3-fold increase in serum amylase/lipase 24 hours to 2 weeks after the procedure. Postprocedure cholangitis was defined as the presence of fever (> 38°C), jaundice, and abdominal pain persisting for more than 24 hours. Bleeding was defined as the presence of hematemesis and/or melena or a hemoglobin drop > 2 g/dL.

VIDEO



▶ **Video 1 a** Representative video of a 70-year-old female with bile duct stenosis assessed with a 9F eyeMAX DSOC system. **b** Diagnosis and treatment of a biliary stone in the common hepatic duct by using the 11F eyeMAX DSOC system.

▶ **Table 1** Peroral cholangioscopy macroscopic classification system for nonneoplastic and neoplastic common bile duct lesions: Carlos Robles-Medranda Classification and Mendoza criteria.

Carlos Robles-Medranda classification		
Nonneoplastic lesions		
Type 1	Villous pattern	A. Micronodule or B. Villous pattern without vascularity
Type 2	Polypoid pattern	A. Adenoma or B. Granuloma pattern without vascularity
Type 3	Inflammatory pattern	Regular or irregular fibrous and congestive pattern with regular vascularity
Neoplastic lesions		
Type 1	Flat pattern	Flat and smooth or irregular surface with irregular or spider vascularity and no ulcerations
Type 2	Polypoid pattern	Polypoid with fibrosis and irregular or spider vascularity
Type 3	Ulcerated pattern	Irregular ulcerated and infiltrative pattern with or without fibrosis and with irregular or spider vascularity
Type 4	Honeycomb pattern	Fibrous honeycomb pattern with or without irregular or spider vascularity
Mendoza criteria		
Tortuous and dilated vessels		
Irregular nodulations		
Raised intraductal lesion		
Irregular surface with or without ulcerations		
Friability		

Cholangioscopic features of neoplastic and non-neoplastic lesions.

The presence of neovascularization was the only macroscopic feature of the suspected malignant lesions that we took into consideration, corresponding to "spider vascularizations" and "tortuous and dilated vessels" common features encountered in neoplastic lesions as described in the Carlos Robles-Medranda (CRM) et al classification [6] and in the Mendoza criteria [7], respectively. Both classification systems are detailed in ▶**Table 1**. Histological evaluation was used as the gold standard for diagnosis.

Statistical analysis

Statistical analysis was performed using R v4.1.2 (R Foundation for Statistical Computing, Posit PBC, Vienna, Austria) by our institutional biostatistician (M.P-T.). Continuous variables are described as the mean (standard deviation, SD) or median (interquartile range [IQR]) depending on their statistical distribution as assessed with the Kolmogorov-Smirnov test. Categorical variables are described as frequencies (%) with 95% confidence intervals. Diagnostic accuracy, which was defined as the sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV), and observed agreement, was calculated for the eyeMAX visual impression and eyeMAX-guided biopsy. Histological findings were considered the gold standard. $P < 0.05$ was considered statistically significant.

Results

Overall patient characteristics

A total of 80 patients underwent DSOC during the study period, were included in the study, and distributed into two groups based on the type of procedure performed: 49 underwent diagnostic procedures and 43 underwent therapeutic procedures. The median age was 62.5 years (range, 44.3–72.0), and 36 of 80 patients (45.0%) were female. A total of 36 of 80 patients had previously undergone ERCP procedures.

Diagnostic cohort

The median age of the patients in the diagnostic cohort was 61.0 years (range, 48.0–69.0), and 21 (42.9%) were female. The diagnostic cohort baseline characteristics are summarized in ▶**Table 2**. The neovascularity pattern was identified in 23 of 49 patients (46.9%) with suspected malignant visual impression (▶**Fig. 1**); biopsies from this area confirmed the diagnosis of cholangiocarcinoma in 20 of 32 patients, intrapapillary mucinous neoplasia (IPMN) was confirmed in two patients, and secondary malignant infiltration was identified in one patient. Eight patients had a final benign diagnosis, six of eight patients

▶**Table 2** Baseline characteristics of the diagnostic cohort.

Patient characteristics	11F (n = 17)	9F (n = 32)	Total (n = 49)
Age (years), median (IQR)	66.0 (58.0–74.0)	60.0 (35.8–68.3)	61.0 (48.0–69.0)
Young adults (18–39 y), n (%)	1 (5.9)	9 (28.1)	10 (20.4)
Middle-aged adults (40–64 y), n (%)	6 (35.3%)	13 (40.6%)	19 (38.8)
Elderly adults (≥ 65 y), n (%)	10 (58.8%)	10 (31.3%)	20 (40.8)
Sex (female), n (%)	5 (29.4%)	16 (50.0%)	21 (42.9)
Previous ERCP, n (%)	6 (35.3%)	10 (31.3%)	16 (32.7)
Indication, n (%)			
Undetermined bile duct stenosis	0 (0%)	8 (25.0%)	8 (16.3)
Suspicion of bile duct neoplastic lesion	9 (52.9%)	14 (43.8%)	23 (46.9)
Filling defect	4 (23.5%)	3 (9.4%)	7 (14.3)
Postsurgical stricture	4 (23.5%)	3 (9.4%)	7 (14.3)
Pancreatic duct stricture	0 (0%)	4 (12.5%)	4 (8.2)
Follow-up status			
Alive	8 (47.1%)	17 (53.1%)	25 (51.0)
Dead	9 (52.9%)	15 (46.9%)	24 (49.0)
Procedure			
Lesion location, n (%)			
Common bile duct	5 (29.4%)	15 (46.9%)	20 (40.8)
Common hepatic duct	5 (29.4%)	6 (18.8%)	11 (22.4)
Hepatic hilum	6 (35.3%)	5 (15.6%)	11 (22.4)

▶ **Table 2** (Continuation)

Patient characteristics	11F (n = 17)	9F (n = 32)	Total (n = 49)
Right intrahepatic duct	0 (0%)	1 (3.1%)	1 (2.0)
Left intrahepatic duct	1 (5.9%)	1 (3.1%)	2 (4.1)
Main pancreatic duct	0 (0%)	4 (12.5%)	4 (8.3)
Neovascular visualization (yes), n (%)	9 (52.9%)	14 (43.8%)	23 (46.9)
Cholangioscope passed through stenosis, n (%)*			
Yes	–	9 (28.1)	9 (45.0)
No	6 (35.3)	5 (15.6)	11 (55.0)
Biopsy and histology			
Biopsy performed (yes), n (%)	11 (64.7%)	21 (65.6%)	32 (65.3)
Biopsies performed, n (%)			
3	1 (5.9%)	2 (6.3%)	3/32
4	2 (11.8%)	11 (34.4%)	13/32
5	1 (5.9%)	1 (3.1%)	2/32
6	7 (41.2%)	7 (21.9%)	14/32
Adequate biopsy, n (%)	11 (64.7%)	20 (62.5%)	31/32 (96.8)
Histopathological diagnosis, n (%)			
Inflammation	2 (11.8%)	4 (12.5%)	6 (18.8)
Cholangiocarcinoma	8 (47.1%)	12 (37.5%)	20 (62.5)
Secondary malignant infiltration	0 (0%)	1 (3.1%)	1 (3.1)
IgG4	0 (0%)	2 (6.3%)	2 (6.2)
IPMN	1 (5.9%)	1 (3.1%)	2 (6.2)
Inconclusive	0 (0%)	1 (3.1%)	1 (3.1)

IQR, interquartile range; ERCP, endoscopic retrograde cholangiopancreatography; IPMN, intrapapillary mucinous neoplasia.
*Evaluated in patients with cholangiocarcinoma (20/32).

had inflammatory lesions, and two patients had IgG4-related cholangitis. The histopathological results were inconclusive for one patient.

A 9F cholangioscope was used in 32 patients from the diagnostic cohort. Tumor extension could be documented in nine patients using this cholangioscope by passing the site of stenosis, which was not possible with the 11F device. In addition, evaluation of the main pancreatic duct was achieved in four patients with pancreatic duct stenosis by using the 9F cholangioscope, after a failed 11F cholangioscope cannulation.

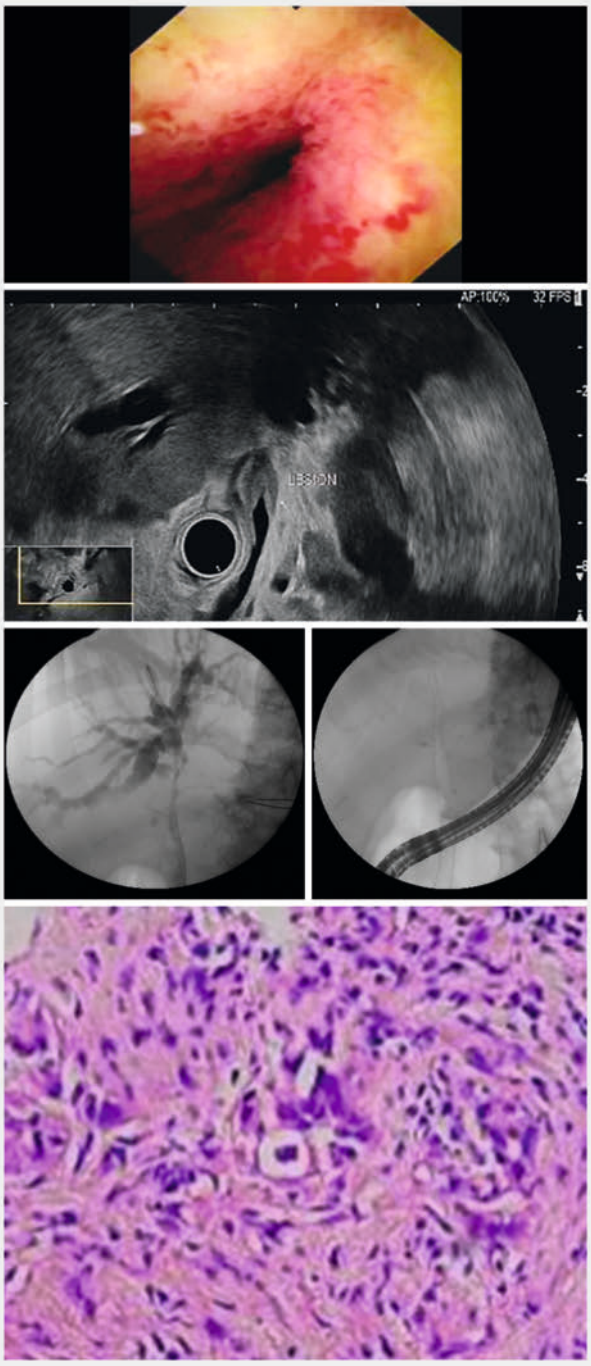
The neoplastic diagnostic accuracy of the DSOC device was assessed in terms of sensitivity, specificity, PPV, NPV and observed agreement. Visual examination using the eyeMAX cholangioscope achieved 91.6% sensitivity, 87.5% specificity, 95.6% PPV, 77.8% NPV, and 90.1% observed agreement. In addition, we evaluated the diagnostic accuracy of the DSOC-guided biopsy, which achieved a sensitivity, specificity, PPV, NPV, and observed agreement of 95.8%, 100%, 100%, 100%, and 96.9%, respectively.

Therapeutic cohort

The median age of the patients in the therapeutic cohort was 66 years (range, 35.0–75.0), and 20 (46.5%) were female. Total stone clearance was achieved in 22 of 31 patients (71.0%) during the first session. Six patients needed an additional EHL session for complete biliary stone extraction. Ten patients required additional procedures, such as balloon dilation (9/10) and sphincterotomy extension (1/10). The main findings of this cohort are summarized in ▶ **Table 3**.

Adverse events

No AEs were reported during or after either (diagnostic or therapeutic) DSOC procedure. No pancreas-related complications were developed following main pancreatic duct evaluation. Furthermore, no hospital readmissions related to the procedures were registered.



▶ **Fig. 1** Representative image of a patient with a neoplastic lesion. **a** A malignant biliary stricture with dilated and tortuous vessels as observed with the eyeMAX DSOC system. **b** Lesion detected during endoscopic ultrasound. **c** Fluoroscopic image showing the bile duct stricture. **d** Fluoroscopic image showing the stent placed in the bile duct. **e** Pathology image using hematoxylin and eosin stain.

Discussion

This study evaluated the diagnostic accuracy of the novel 9F and 11F DSOC probes in detecting neoplastic lesions and extension of biliary duct lesions, along with their safety profile in biliary stone removal. Using the CRM and the Mendoza visual systems for classifying biliary lesions with the new eyeMAX [6, 7], we observed high diagnostic accuracy based on good visualization of neovascular structures (91.6% sensitivity, 87.5% specificity, 95.6% PPV, 77.8% NPV, and 90.1% observed agreement) and achieved total stone removal in 71.0% of patients in the first session without AEs.

Indeterminate biliary strictures have long posed diagnostic challenges. Traditional endoscopic methods like EUS with FNA/B, while useful, are limited to distal lesions and carry tumor seeding risks [6, 8]. ERCP brush cytology and fluoroscopy-guided biopsies offer limited sensitivity (45.0% and 48.0% respectively) and high specificity but are not fully reliable for malignant diagnoses [8]. Advances in POCS devices have improved diagnostic accuracy with targeted biopsies showing 64% to 86% sensitivity and 89% to 100% specificity [9, 10, 11, 12]. Integration of cholangioscopy into brush cytology and fluoroscopy-guided biopsies has further enhanced diagnostic sensitivity [13, 14]. The Monaco and CRM classifications, based on cholangioscopic findings, have standardized assessments, achieving 70% to 90% diagnostic accuracy with similar interobserver agreement [6, 15]. The introduction of high-quality imaging cholangioscopes has furthered the role of DSOC in diagnosing biliary lesions. In this study, eyeMAX achieved high diagnostic accuracy (90.1% and 96.9%) for indeterminate strictures. Previous studies confirm DSOC's high sensitivity and specificity, with features like tumoral vessels and infiltrative strictures indicating malignancy. Previous studies confirm DSOC's high sensitivity and specificity with features like tumoral vessels and infiltrative strictures indicating malignancy [4, 9, 16, 17, 18]. Robles-Medranda et al. reported 94.5% accuracy using DSOC with the CRM classification, comparable to other cholangioscopes, underscoring the effectiveness of these advancements in biliary lesion diagnosis [1].

In this study, tissue biopsies were successfully conducted using the 3-mm opening width biopsy forceps (9F probe) of the eyeMAX cholangioscope, yielding conclusive histologic results in 96.9% of cases, despite the smaller opening width. This approach was particularly effective in confirming IPMN in two patients, underscoring the value of pancreatoscopy in diagnosing and assessing pancreatic duct strictures, especially in chronic pancreatitis. A retrospective study further supported pancreatoscopy's diagnostic accuracy, with an 87% success rate in distinguishing neoplastic from non-neoplastic lesions, and enhanced sensitivity and specificity when combined with tissue biopsy [19, 20]. In addition, the risk of post-procedure acute pancreatitis could be reduced due to the proportionality between the pancreatic duct's diameter and the probe's diameter [19]. The cholangioscope design also facilitated deeper pancreatic evaluation and lithotripsy for pancreatic duct stone treatment, highlighting its increased maneuverability and therapeutic versatility.

ERCP is the standard for treating biliary stones, achieving 87% to 100% clearance rates [21]. However, large or multiple stones often require multiple ERCP sessions, making EHL essential. Cholangioscopy-directed EHL has a 100% success rate following conventional ERCP failure [22]. A multicenter study in-

▶ **Table 3** Baseline characteristics of the therapeutic cohort.

Patient characteristics	11F (n = 22)	9F (n = 21)	Total (n = 43)
Age (years), median (IQR)	67.0 (38.3–75.5)	59.0 (30.0–72.0)	66.0 (35.0–75.0)
≤ 18 years, n (%)	–	1 (4.8%)	1 (2.3)
Young adults (18–39 y), n (%)	7 (31.8%)	8 (38.1%)	15 (34.9)
Middle-aged adults (40–64 y), n (%)	2 (9.1%)	2 (9.5%)	4 (9.3)
Elderly adults (≥ 65 y), n (%)	13 (59.1%)	10 (47.6%)	23 (53.5)
Sex (female), n (%)	12 (54.5%)	8 (38.1%)	20 (46.5)
Previous ERCP (yes), n (%)	13 (59.1%)	13 (61.9%)	26 (60.5)
Indication, n (%)			
Anastomotic stenosis	1 (4.5%)	5 (23.8%)	6 (14.0)
Lithotripsy	17 (77.3%)	9 (42.9%)	26 (60.5)
Lithotripsy with proximal migration of biliary stent	3 (13.6%)	2 (9.5%)	5 (11.6)
Proximal migration of biliary stent	1 (4.5%)	-	1 (2.3)
Radiofrequency ablation	–	5 (23.8%)	5 (11.6)
Procedure			
Stone location, n (%)			
Both intrahepatic ducts	–	1 (4.8%)	1 (3.2)
Common bile duct	11 (50.0%)	6 (28.6%)	17 (54.8)
Common hepatic duct	1 (4.5%)	3 (14.3%)	4 (12.9)
Cystic duct	1 (4.5%)	–	1 (3.2)
Hepatic hilum	1 (4.5%)	–	1 (3.2)
Right or Left Intrahepatic Duct	6 (27.3%)	–	6 (19.4)
Pancreatic duct	1 (4.8%)	1 (4.8%)	1 (3.2)
No. stones, n (%)	(20/22)	(11/21)	(31/43)
1	9 (45.0)	7 (63.6)	16/31 (51.6)
2	2 (10.0)	1 (9.1)	3/31 (9.7)
3	4 (20.0)	1 (9.1)	5/31 (16.1)
4	4 (20.0)	1 (9.1)	5/31 (16.1)
5	1 (5.0)	–	1/31 (3.2)
6	–	1 (9.1)	1/31 (3.2)
Stone size (mm), median (IQR)	20.0 (17.5–21.0)	20.0 (15.0–20.0)	20.0 (15.5–21.0)
Stone removal, n (%)			
No	1 (4.5%)	2 (9.5%)	3/31 (9.7)
Partial	6 (27.3%)	–	6/31 (19.4)
Total	13 (59.1%)	9 (42.9%)	22/31 (71.0)
Additional procedures, n (%)	6 (27.3%)	4 (19.0%)	10 (32.3)
Balloon dilation	5 (83.3)	4 (100%)	9 (90.0%)
Sphincterotomy extension	1 (16.7%)	–	1 (10.0%)
Clinical success, n (%)	21 (95.5%)	21 (100%)	42 (97.6)

▶ **Table 3** (Continuation)

Patient characteristics	11F (n = 22)	9F (n = 21)	Total (n = 43)
Early adverse events (No.), n (%)	22 (100%)	21 (100%)	43 (100)
Late adverse events (No.), n (%)	22 (100%)	21 (100%)	43 (100)

IQR, interquartile range; ERCP, endoscopic retrograde cholangiopancreatography.

volving 407 patients reported a 74.5% first-session clearance rate with EHL, increasing to 96.7% after all sessions, with multiple sessions influenced by biliary anatomy, cannulation, and stone size [23]. Stone dimensions > 20 mm or multiple stones often lead to partial clearance during EHL via DSOC [1]. Robles-Medranda et al. achieved 66.1% clearance in a single session using a SpyGlass cholangioscope, with a total rate of 94.9% after an additional procedure [3]. This study achieved 71% clearance in the first session, potentially influenced by different lithotripsy probes, power settings, and the smaller cohort size. The enhanced efficiency is attributed to the 9F cholangioscope shorter stroke, higher power of a smaller-diameter probe, and increase maneuverability. No AEs were noted, possibly due to the smaller cholangioscope diameter, high operator expertise, and small patient sample. Clinical success was reported in 96.7% of patients with pain and jaundice, with complete clearance and technical success in all but one patient, who was referred to surgery due to multiple intrahepatic biliary stones.

The main advantages of this device are its image quality and the availability of two scope diameters. Both models (9F and 11F) have the same image quality, with no differences reported by the users. The smaller cholangioscope is easier to handle at the insertion in the duodenoscope working channel, with simpler maneuverability inside the biliary tract compared with the 11F cholangioscope. On the other hand, the latter cholangioscope has a stronger suction function due to the bigger diameter of the working channel, which could be beneficial in cases in which suction and removal structures, such as stones > 20 mm, are required. Moreover, it is important to mention the low price of the device, which can help make it more widely available. The main limitation of the present study is the small sample size and, therefore, additional studies that evaluate this product in a large cohort of patients are needed to further validate these findings.

Conclusions

In conclusion, eyeMAX DSOC performs well in distinguishing neoplastic-biliary lesions from non-neoplastic lesions along with their extension and is highly effective as a therapeutic procedure in the total removal of biliary stones with no documented AEs. Future prospective studies should be performed to compare image quality, maneuverability, cost-effectiveness, and endoscopist acceptance between the eyeMAX system and currently available cholangioscopy systems.

Acknowledgement

We would like to acknowledge all the staff members of the endoscopic unit of the Instituto Ecuatoriano de Enfermedades Digestivas who assisted the research team during the study and the invited experienced endoscopists who aid in the study by performing DSOC procedures with the novel eyeMAX system in our institution.

Conflict of Interest

Carlos Robles-Medranda is a key opinion leader and consultant for Pentax Medical, Steris, Medtronic, Motus, Micro-tech, G-Tech Medical Supply, CREO Medical, and mdconsgroup. Michel Kahaleh is a consultant for Boston Scientific, Interscope Med, and Abbvie; grant recipient from Boston Scientific, Conmed, Gore, Pinnacle, Merit Medical, Olympus Medical, and Ninepoint Medical; chief executive officer and founder of Innovative Digestive Health Education & Research Inc. Issac Raijman is a speaker for BostonScientific, ConMed, Medtronic, and GI Supplies; advisory board member for Micro-Tech; co-owner of EndoRx. The other authors declare no conflicts of interest.

Contributors' Statement

Carlos Robles-Medranda oversaw the conception, design, and drafting of the article and analysis and interpretation of the data, provided critical revisions of the article for additional important intellectual content and provided final approval of the article. Juan Alcívar-Vásquez oversaw the drafting of the article, provided critical revisions of the article for additional important intellectual content and provided final approval of the article. Isaac Raijman oversaw the drafting of the article, provided critical revisions of the article for additional important intellectual content and provided final approval of the article. Michel Kahaleh oversaw the drafting of the article, provided critical revisions of the article for additional important intellectual content and provided final approval of the article. Miguel Puga-Tejada oversaw the conception, design, and drafting of the article and analysis and interpretation of data, provided critical revision of the article for additional important intellectual content and provided final approval of the article. Raquel Del Valle oversaw the drafting of the article, provided critical revisions of the article for additional important intellectual content and provided final approval of the article. Haydee Alvarado-Escobar oversaw the drafting of the article, provided critical revisions of the article for additional important intellectual content and provid-

ed final approval of the article. Carlos Cifuentes-Gordillo oversaw the drafting of the article, provided critical revisions of the article for additional important intellectual content and provided final approval of the article. Kenneth F. Binmoeller oversaw the drafting of the article, provided critical revisions of the article for additional important intellectual content and provided final approval of the article. Alberto Baptista-Marchena oversaw the drafting of the article, provided critical revisions of the article for additional important intellectual content and provided final approval of the article. Jonathan Barreto-Pérez oversaw the drafting of the article, provided critical revisions of the article for additional important intellectual content and provided final approval of the article. Jorge Rodríguez oversaw the drafting of the article, provided critical revisions of the article for additional important intellectual content and provided final approval of the article. Maria Egas-Izquierdo oversaw the drafting of the article, provided critical revision of the article for additional important intellectual content and provided final approval of the article. Doménica Cuntó oversaw the drafting of the article, provided critical revisions of the article for additional important intellectual content and provided final approval of the article. Daniel Calle-Loffredo oversaw the drafting of the article, provided critical revisions of the article for additional important intellectual content and provided final approval of the article. Hannah Pitanga-Lukashok oversaw the conception, design and drafting of the article and analysis and interpretation of the data, provided critical revisions of the article for additional important intellectual content and provided final approval of the article. Jorge Baquerizo-Burgos oversaw the drafting of the article and analysis and interpretation of data, provided critical revisions of the article for additional important intellectual content and provided final approval of the article. Daniela Tabacelia oversaw the drafting of the article, provided critical revisions of the article for additional important intellectual content and provided final approval of the article.

References

[1] Robles-Medranda C, Soria-Alcivar M, Oleas Roberto et al. Digital peroral cholangioscopy to diagnose and manage biliary duct disorders: a single-center retrospective study. Endosc Int Open 2020; 8: E796–E804

[2] Seelhoff A, Schumacher B, Neuhaus H. Single operator peroral cholangioscopic guided therapy of bile duct stones. J Hepatobiliary Pancreat Sci 2011; 18: 346–349 doi:10.1007/s00534-010-0360-7

[3] Gomes de Oliveira PVA, Hourneaux de Moura DT, Braga Ribeiro I et al. Efficacy of digital singleoperator cholangioscopy in the visual interpretation of indeterminate biliary strictures: a systematic review and metaanalysis. Surg Endosc 2020; 34: 3321–3329

[4] Subhash A, Abadir A, Iskander JM et al. Applications, limitations, and expansion of cholangioscopy in clinical practice. Gastroenterol Hepatol 2021; 17: 110–120

[5] Cotton PB, Eisen GM, Aabakken L et al. A lexicon for endoscopic adverse events: report of an ASGE workshop. Gastrointest Endosc 2010; 71: 446–454 doi:10.1016/j.gie.2009.10.027

[6] Robles-Medranda C, Valero M, Soria-Alcivar M et al. Reliability and accuracy of a novel classification system using peroral cholangioscopy for the diagnosis of bile duct lesions. Endoscopy 2018; 50: 1059–1070 doi:10.1055/a-0607-2534

[7] Kahaleh M, Gaidhane M, Shahid HM et al. Digital single-operator cholangioscopy interobserver study using a new classification: the Mendoza Classification (with video). Gastrointest Endosc 2022; 95: 319–326

[8] Sun B, Moon JH, Cai Q et al. Review article: Asia-Pacific consensus recommendations on endoscopic tissue acquisition for biliary strictures. Aliment Pharmacol Ther 2018; 48: 138–151 doi:10.1111/apt.14811

[9] Parsa N, Khashab MA. The role of peroral cholangioscopy in evaluating indeterminate biliary strictures. Clin Endosc 2019; 52: 556–564 doi:10.5946/ce.2019.011

[10] Nakai Y, Isayama H, Wang H et al. International consensus statements for endoscopic management of distal biliary stricture. J Gastroenterol Hepatol 2020; 35: 967–979 doi:10.1111/jgh.14955

[11] Chen YK. Preclinical characterization of the Spyglass peroral cholangiopancreatoscopy system for direct access, visualization, and biopsy. Gastrointest Endosc 2007; 65: 303–311 doi:10.1016/j.gie.2006.07.048

[12] Shi O, Akira M, Nobu N et al. Prospective evaluation of digital single-operator cholangioscope for diagnostic and therapeutic procedures (with videos). Dig Endosc 2017; 29: 782–789

[13] Han S, Tatman P, Mehrotra S et al. Combination of ERCPbased modalities increases diagnostic yield for biliary strictures. Dig Dis Sci 2021; 66: 1276–1284 doi:10.1007/s10620-020-06335-x

[14] Sekine K, Yasuda I, Doi Shinpei et al. Peroral cholangioscopy-guided targeted biopsy versus conventional endoscopic transpapillary forceps biopsy for biliary stricture with suspected bile duct cancer. J Clin Med 2022; 11: 289

[15] Sethi A, Tyberg A, Slivka A et al. Digital single-operator cholangioscopy (DSOC) improves interobserver agreement (IOA) and accuracy for evaluation of indeterminate biliary strictures: The Monaco Classification. J Clin Gastroenterol 2022; 56: e94–e97 doi:10.1097/MCG.0000000000001321

[16] Kahaleh M, Raijman I, Gaidhane M et al. Digital cholangioscopic interpretation: when north meets the south. Digest Dis Sci 2021; 67: 1345–1351

[17] Kulpatcharapong S, Pittayanon R, Kerr SJ et al. Diagnostic performance of digital and video cholangioscopes in patients with suspected malignant biliary strictures: a systematic review and metaanalysis. Surg Endosc 2022; 36: 2827–2841

[18] Shah RJ, Raijman I, Brauer B et al. Performance of a fully disposable, digital, single-operator cholangiopancreatoscope. Endoscopy 2017; 49: 651–658 doi:10.1055/s-0043-106295

[19] De Luca L, Repici A, Kocollari A et al. Pancreatoscopy: An update. World J Gastrointest Endosc 2019; 11: 22–30 doi:10.4253/wjge.v11.i1.22

[20] Miller CS, Chen YI. Current role of endoscopic pancreatoscopy. Curr Opin Gastroenterol 2018; 34: 309–315 doi:10.1097/MOG.0000000000000453

[21] Alrajhi S, Barkun A, Adam V et al. Early cholangioscopy-assisted electrohydraulic lithotripsy in difficult biliary stones is cost-effective. Therap Adv Gastroenterol 2021; 14: 1–12 doi:10.1177/17562848211031388

[22] Chen YK, Pleskow DK. SpyGlass single-operator peroral cholangiopancreatoscopy system for the diagnosis and therapy of bile-duct disorders: a clinical feasibility study (with video). Gastrointest Endosc 2007; 65: 832–41 doi:10.1016/j.gie.2007.01.025

[23] Brewer Gutierrez OI, Bekkali NLH, Raijman I et al. Efficacy and safety of digital single-operator cholangioscopy for difficult biliary stones. Clin Gastroenterol Hepatol 2018; 16: 918–926 e1