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Efficacy and safety of a single-use cholangioscope for percutaneous transhepatic cholangioscopy

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Abstract:
BACKGROUND & AIMS Percutaneous transhepatic cholangioscopy (PTCS) is a management option for patients who fail per-oral cholangioscopy or ERCP. We conducted a case series on the efficacy and safety of PTCS using a cholangiopancreatoscope cleared by the FDA in 2020.

METHODS Fifty adult patients scheduled for PTCS or other cholangioscopic procedure were enrolled at seven academic medical centers and followed for 30 days after the index procedure. The primary efficacy endpoint was achievement of clinical intent by 30 days after the index PTCS procedure. Secondary endpoints included technical success, procedural time, endoscopist ratings of device attributes on a scale of 1 to 10 (best), and serious adverse events (SAEs) related to the device or procedure.

RESULTS Patients had a mean age of 64.7±15.9 years, and 60.0% (30/50) were male. Forty-four (88.0%) patients achieved clinical intent by 30 days post-procedure. The most common reasons for the percutaneous approach were past (38.0%) or anticipated (30.0%) failed ERCP. The technical success rate was 96.0% (48/50), with a mean procedural time of 37.6 (SD, 25.1; range 5.0–125.0) minutes. The endoscopist rated the overall ability of the cholangioscope to complete the procedure as a mean 9.2 (SD, 1.6; range 1.0–10.0). Two patients (4.0%) experienced related SAEs, one of whom had a fatal periprocedural aspiration.

CONCLUSIONS PTCS is an important endoscopic option for selected patients with impossible retrograde access or who fail ERCP. Because of the associated risk, this technique should be practiced by highly trained endoscopists at high-volume centers.

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BACKGROUND & AIMS

Percutaneous transhepatic cholangioscopy (PTCS) can be considered in patients with previous failed endoscopic retrograde cholangiopancreatography (ERCP) or with surgically or pathologically-altered biliary anatomy posing a contraindication to peroral cholangioscopy [1]. Examples of PTCS indications include biliary stricture management and bile duct stone removal in patients with Billroth II gastrectomy [2] or Roux-en-Y anastomosis [3,4], removal of inaccessible, intrahepatic or complex biliary stones >1.5 cm [5,6], mapping biopsies to assess the longitudinal upstream spread of hilar cholangiocarcinoma to aid in the determination of resectability [7], and delivery of palliative intraluminal brachytherapy [8]. The American Society for Gastroenterology Endoscopy (ASGE) reported infectious adverse event rates as high as 35% in patients who have percutaneous cholangioscopy [9], so accurate efficacy and safety data are needed to weigh the risks and benefits of its use.

Traditional reusable cholangioscopes designed for intraoperative or percutaneous use have larger accessory channels to allow a broader array of accessory devices, 2-way tip deflection, and shorter working length and distance to the target area to improve ability to torque the scope to allow 4-quadrant visualization [9]. The first catheter-based, fiberoptic peroral single-operator cholangiopancreatoscopy system with an intended use through the working channel of a duodenoscope and with a transpapillary access was released in 2006 [10]. A second-generation system with an improved digital image and 4-way deflection capability, easier set-up ("plug and play"), a larger accessory channel and greater suctioning capability was cleared by the US Food and Drug Administration (FDA) in 2015 [10]. The newest cholangiopancreatoscopy system from the same manufacturer is a similar disposable, single-use, sterile device using the same platform with approximately one-third the length of the original catheter, optimized for percutaneous or surgical use. The device was cleared by the FDA in 2020 [11], but minimal data on its applications have been published to date [12,13].

We conducted a case series with 30-day follow-up to test the efficacy and safety of a new single-use cholangiopancreatoscope in adult patients scheduled for PTCS or other cholangioscopic procedures (including cholecystoscopy) for a variety of indications.

METHODS

Study design

We conducted a prospective, multicenter, multinational case series of PTCS to evaluate and treat complex pancreaticobiliary disease in adult patients. All centers obtained approval from their respective local ethics committees or institutional review boards, and all patients provided signed informed consent before the procedure.

Description of cholangioscope

The cholangiopancreatoscopy system used in the study was the SpyGlass Discover Digital System, (Boston Scientific Corporation, Marlborough, Massachusetts, USA; **Fig. 1**). The SpyGlass Discover system has a shorter working length than Spy DS or Spy DSII (65 cm versus 214 cm respectively), but all 3 of these devices have the same field of view (120 degrees in air), distal tip width (10.5 F/3.5 mm), working channel diameter/minimum accessory width (1.2 millimeters/3.6 F), and minimum angulation range (30 degrees with accessory devices working channel). The SpyGlass Discover Digital System is indicated for use in diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts in adult patients. Because this system was used for cholangioscopy only (not pancreatoscopy) in the current study, it is called a “cholangioscope” in this paper.

Procedural steps

Percutaneous biliary procedures were performed under general anesthesia and antibiotic prophylaxis. Initially, a percutaneous biliary access was obtained under fluoroscopy by the radiology or gastroenterology team, following local expertise. An internal-external 8.5 Fr drain was inserted with the creation of a mature biliocutaneous fistula, allowing in a second step to advance the cholangioscope on a guidewire in the percutaneo-biliary tract. In some cases, the tract was dilated using a 9-10Fr bougie to allow the passage of the cholangioscope to the bile ducts. Under direct visual control the clinical intent was delivered (biopsies under direct visual control, stone fragmentation using electrohydraulic lithotripsy (EHL)/laser, selective duct cannulation). Just after the procedure, an internal-external drain was left in place to allow biliary drainage and reduce potential septic complications. At the end of the sessions, the percutaneous biliary drain was removed.

Patient population

Eligible patients were adults aged 18 years and older scheduled for a percutaneous transhepatic or transcholecystic procedure per local standard of practice. Patients were excluded for age less than 18 years, contraindication to cholangiopancreatoscopy, unresolved adverse event(s) associated with prior percutaneous pancreaticobiliary ductal access, or potentially vulnerable status including but not limited to pregnancy.

Study visits

Baseline screening

After the subject was enrolled in the study and prior to the index PTCS procedure, pertinent medical history and any relevant preprocedural imaging was assessed. Data on any prior percutaneous pancreaticobiliary ductal access procedure(s) including but not limited to number of catheter exchanges, diameter of catheters and length of time between initial percutaneous procedure and final tract maturation were collected.

Index procedure

Procedure detail was obtained from medical records or recorded including but not limited to description of procedures conducted and any additional procedures required. The reason for adding use of the cholangioscope to the radiologic procedure was documented. Cholangioscopy images were collected to create an atlas that illustrates utility of PTCS procedures in study cases. In addition, an operator user acceptance and satisfaction rating of the study device compared to reusable scopes in the ability to complete the procedure was recorded relating to study device design attributes. Data on all accessory devices used with the cholangioscope were also collected.

30-day follow-up after the index procedure

After the index procedure, subject course and complications (if applicable) were recorded and evaluated for relatedness to the PTCS procedure by the treating physician. Any reinterventions required for subject management associated with the clinical indication for the index procedure were identified in 3 follow-up reviews of the electronic medical record/charts: 24–72 hours, 7 days ± 2 days, and 30 days ± 3 days after the index PTCS procedure.

Primary efficacy endpoint

The primary efficacy endpoint was achievement of the clinical intent (e.g., stone removal, stricture management) of the index PTCS procedure by 30 days (± 3 days) after the procedure. The number of PTCS procedures required to achieve the clinical intent by the end of follow-up was also evaluated.

Secondary endpoints

Secondary endpoints included: 1) technical success, defined as the ability to advance the cholangioscope catheter to the target lesion or stone(s) and visualize the target; 2) procedural time, defined as the time between first insertion and last removal of the cholangioscope catheter during the index PTCS; 3) endoscopist rating of each of the following attributes when using the cholangioscope system compared to marketed reusable scopes: ability to complete the procedure, retroflex, selectively advance into targeted ducts, obtain targeted biopsies, grasp stones, guide lithotripsy, suction, irrigate, and advance accessories through scope channel; and image quality; 4) serious adverse events (SAEs) related to the study device, accessory devices used through the working channel of the cholangioscope or the cholangioscopy portion of the PTCS procedure(s).

Statistical analysis

Descriptive statistics included the mean, standard deviation (SD) and range for age, tabulated rates of study PTCS procedure completion and adverse events, and median ratings for overall satisfaction, PTCS maneuvers and performance. Statistical analyses were performed using SAS 9.4 software (SAS Institute Inc., Cary, NC, USA).

RESULTS

Patient characteristics at baseline

The cohort had mean age 64.7 ± 15.9 years (range 20.0–92.0) and included 30 (60.0%) men (**Table 1**). Thirty-two patients had a history of prior surgeries, most commonly cholecystectomy (22.0%, 11/50), Roux-en-Y gastric bypass (16.0%, 8/50) or a Billroth II procedure (16.0%, 8/50). One patient had received a liver transplant, and one had a past pancreaticoduodenectomy.

Index procedure characteristics

The most common indication for the study procedure was biliary stone management (58.0%, 29/50), followed by (one or more of the following in each patient): biliary stricture management (26.0%, 13/50), diagnosis of indeterminate biliary stricture with tissue acquisition (18%, 9/50) and gallstone management (16.0%, 8/50). Additional specified indications included diagnosis of indeterminate biliary stricture without tissue acquisition (4.0%, 2/50), cholangitis (4.0%, 2/50), drainage of hepatic fluid collection (2.0%, 1/50), gallbladder stricture management (2.0%, 1/50) and diagnosis of indeterminate gallbladder stricture without biopsy (2.0%, 1/50).

The reasons reported for a percutaneous approach were (one or more of the following in each patient): ERCP anticipated to be technically challenging or impossible (38.0%, 19/50), previous unsuccessful ERCP (34.0%, 17/50), prior cholecystostomy tube (30.0%, 15/50), to identify a source of hemobilia (2.0%, 1/50) or to minimize risk of infection (2.0%, 1/50).

All 48 technically successful baseline PTCS procedures were performed in an inpatient setting. Thirty (62.5% of 48) of the PTCS procedures were performed by an interventional radiologist, and 18 (37.5% of 48) were performed by a gastroenterologist/endoscopist. A mean of 2.5±3.8 (range 1.0–20.0) drains were placed per patient, most commonly on the right side (82.8%, 77/93 drains placed).

At the index procedure, the most common cholangioscope maneuvers were (one or more of the following in each patient): visualization of a biliary stricture or lesion (58.0%, 29/50), biopsy of biliary stricture or lesion (26.0%, 13/50), clearance of biliary stones/sludge with (26.0%, 13/50) or without (16.0%, 8/50) lithotripsy, selected biliary cannulation (14.0%, 7/50), or clearance of gallstones/sludge without lithotripsy (12.0%, 6/50). These and other maneuvers are listed in **Table 2**.

Primary efficacy endpoint: achievement of clinical intent of index PTCS procedure

Forty-four (88.0%) of patients achieved the clinical intent by 30 days after the index PTCS, with 1 procedure required to achieve the clinical intent until the end of follow-up in all cases. For example, **Fig. 2 and Video 1** show common bile duct stone clearance using the cholangioscope and EHL in altered anatomy.

Secondary endpoints

Technical success and procedural time

Technical success was achieved in 48 (96.0%) patients, with a mean procedural time of 37.6 (SD, 25.1; range 5.0–125.0) minutes. Of the remaining two patients with technical failure, one was a 69-year-old man with an indeterminate biliary stricture who failed the index procedure because the target could not be visualized. This patient later had surgery. The second was a 46-

year-old woman with post-cholecystectomy biliary stones who failed the initial procedure when the catheter could not be advanced to the target, and the target could not be visualized. She subsequently had balloon dilation followed by laser lithotripsy through the SpyGlass Discover working channel.

Endoscopists' ratings of device attributes

The mean endoscopist rating of overall ability of the cholangioscope to complete the procedure as indicated was 9.2 (SD, 1.6; range 1.0–10.0), including 46 (92.0%) scores in the 8–10 range (**Fig. 3**). For specific maneuvers, mean ratings ranged from 8.3 (81.8% of scores 8–10) for suction ability and 8.3 (66.0% of scores 8–10) for image quality to 9.5 (100% of scores 8–10) for ability to obtain targeted biopsies.

Procedures in patients with prior cholecystostomy tubes

Fifteen patients (30.0%) reported a prior cholecystostomy tube at baseline. The reasons for cholangioscopy in these patients were (one or more of the following in each patient): visualization-guided clearance of biliary stones or gallstones (11), to aid in visualization of the region of interest in a biliary stricture or lesion (3), to aid in visualization of a foreign body (1), or to help identify the source of hemobilia during stone clearance (1). In all patients who had a pre-existing cholecystostomy tube, the tube tract was utilized for cholangioscopy access. To facilitate percutaneous cholangioscopy, the existing tube was removed over a wire. A second safety wire was then placed to ensure secure access, over which a 12Fr sheath was inserted into the gallbladder. Larger access sheaths were then utilized as needed for removal of larger stones. If access to the common bile duct was required, a guidewire was advanced down the cystic duct and into the common bile duct and the small bowel. Once wire access was established, the 12Fr sheath could be advanced into the common bile duct, through which percutaneous cholangioscopy could be performed. All of these procedures were technically successful.

Adverse events related to cholangioscope or PTCS procedure

One patient had 1 serious adverse event related to the cholangioscope or PTCS index procedure (**Table 3**). The patient was an 85-year-old man scheduled for PTCS for biliary stone management. He had successful visualization and biopsy of a biliary stricture, clearance of biliary stones with lithotripsy, and removal of a foreign body from the bile duct. This patient experienced severe aspiration during the index procedure and died 12 days later. Two other serious adverse events were observed during the follow-up of another patient, and classified as possibly related to the procedure, although very unlikely. This patient was a 57-year-old woman who had diagnostic PTCS including biopsies of an indeterminate biliary stricture. She had a portal vein embolization the day after, then she developed haemobilia the day after the embolization (and 2 days after the index procedure) that was managed conservatively and resolved 6 days later. She also developed sepsis due to the presence of a perihepatic collection 14 days after the index procedure, but she performed 5 days before another PTC that replaced the previously dislodged biliary drainage.

Three other patients had nonserious adverse events related to the device or index procedure. The first was a 69-year-old woman with prior cholangitis who received prophylactic piperacillin/tazobactam before PTCS for biliary drainage during EHL for gallstone removal. She developed cholangitis on postprocedure day 1, the antibiotic was switched to imipenem and resolved on postprocedure day 5. The second patient was a 78-year-old male with duodenal stenosis who had PTCS during EHL for biliary stones without antibiotic prophylaxis as planned, developed cholangitis on postprocedure day 1, and treated with piperacillin/tazobactam with resolution on postprocedure day 6. The third patient was a 78-year-old woman with a narrow and angulated post-cholecystectomy common bile duct stricture and upstream multiple bile duct stones; She had via the percutaneous route a balloon dilation and stone extraction by laser lithotripsy of stones at the index procedure. She was reported to have bacterial angiocholitis on postprocedure day 1, was treated with meropenem, and received repeat PTCS and drainage with resolution on postprocedure day 13. During study monitoring, the treating physicians for these patients reported the adverse events were nonserious because they did not cause a new hospitalization or prolonged hospitalization.

DISCUSSION

In this case series of 50 patients, 88% achieved the planned clinical intent within 30 days after one PTCS procedure. One patient (2%) experienced related SAE, which had a fatal outcome. Endoscopists reported high ratings for the functional ability of the cholangioscope.

While PTCS is performed much less commonly than ERCP, it offers important advantages for some indications. For example, endoscopic visualization is considered the most accurate tool currently available to distinguish benign from malignant pancreatobiliary strictures [10]. Tamada et al. and Sato et al. documented the value of PTCS for mapping biopsies to determine longitudinal cancer extension along the bile duct [7,14]. Tamada mentions that collection of multiple biopsies from the circumference of the margin of the stenotic area can only be accomplished under direct vision using PTCS, while transpapillary or transhepatic fluoroscopically guided bile duct biopsies are inadequate for this purpose [7]. PTCS is a useful alternative therapy for intrahepatic stones and can be used as the primary treatment modality when a partial hepatectomy is not indicated, with recognition that severe biliary stricture or advanced biliary cirrhosis increases the risk of stone recurrence [5]. It can also be used for percutaneous stone removal in patients who are not candidates for laparoscopic cholecystectomy [15].

The current exploratory study is informative regarding indications endoscopists select for PTCS, and procedural outcomes for those indications. PTCS is notable because of the baseline severity of illness of the PTCS patient population. For example, a retrospective study examined PTCS efficacy and safety outcomes in 13 patients with a prior Roux-en-Y reconstruction who presented with abdominal pain (5), fever (6), jaundice and fever (1), or septic shock (1) [3]. Eight patients with bile duct stones in a single intrahepatic duct or in the common bile duct had successful stone removal; however, the authors acknowledged that complete stone removal with PTCS would be difficult in cases of bile duct stones along multiple intrahepatic bile ducts. The remaining 5 patients had a biliary stricture, with SpyBite biopsies confirming cholangiocarcinoma (2) or recurrent cholangiocarcinoma (3) [3]. Another small case series described 4 patients with biliary strictures in whom conventional ERCP was not possible and percutaneous brushings were either nondiagnostic or unsatisfactory; using PTCS visualization and biopsy, a diagnosis was achieved in all of these patients without complications [16]. These studies show that PTCS with biopsy can be influential in a patient population that is small but challenging, having failed conventional biliary access with ERCP in some cases.

PTCS is one of several endoscopic techniques that may be considered after failed ERCP in select patient populations. Of note, balloon-enteroscopy assisted ERCP, knowing its safety profile is recommended in case of altered anatomy [17], but notably, is associated to lower success rate compared to other advanced techniques. EUS-guided (via hepaticogastrostomy or gastrogastric in case of Roux-en-Y gastric bypass) access have been developed in expert centers with good quality results, despite their potential high complication rates [18-20]. All these alternative techniques do not completely replace PTC access, which is a complementary technique nowadays, to face scenarios where it is the best option to obtain the easiest and safest route of delivering the desired therapy/diagnosis. The choice between the different modalities is a case-by-case discussion based on the indication, the anatomy, and the purpose of the intervention.

Our study had strengths and limitations. This is an early case series of percutaneous cholangioscopy, including data from 50 patients followed for 30 days. Consecutive patient recruitment was not possible because study participation dependent on the availability of adequate endoscopic and imaging expertise. For this reason, the study population and their results may not be typical of all patients receiving PTCS. Regarding limitations, PTCS-guided biopsy was performed at the endoscopist’s discretion, so histopathology data are incomplete, and we could not accurately estimate the diagnostic accuracy of PTCS.

CONCLUSIONS

In conclusion, in selected patients with failed ERCP or impossible retrograde access , a percutaneous transhepatic cholangioscopy treatment was associated to high clinical intent and excellent technical success rates in academic medical centers. Although the related SAE rate was low, one fatal periprocedural aspiration event occurred. PTCS offers an important clinical management option for selected cases with altered anatomy or failed ERCP, and should be reserved for highly trained endoscopists at centers with adequate procedural volume.

DATA SHARING

The data, analytic methods, and study materials for this study may be made available to other researchers in accordance with the Boston Scientific Data Sharing Policy (http://www.bostonscientific.com/en-US/data-sharing-requests.html).

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Fig. 1 SpyGlass Discover Digital System used in the current study

Specification	Value
Direction of view	0 degrees (forward viewing)
Field of view	120 degrees in air
Distal tip width	10.5Fr (3.5mm)
Maximum insertion portion width	10.8Fr (3.6mm)
Working length	65 cm
Minimum accessory channel width	1.2 mm (3.6Fr)
Minimum angulation range	30 degrees with accessory device in working channel

Table 1. Baseline characteristics of patients (N=50 patients)

Characteristic	Mean ± SD (n) (range) or % (n/N)
Age	64.7 ± 15.9 (28.0–92.0)
Male	60.0% (30/50)
Previous surgeries (one or more per patient)	
No previous surgeries	36.0% (18/50)
Cholecystectomy	22.0% (11/50)
Billroth II	16.0% (8/50)
Roux-en-Y gastric bypass	16.0% (8/50)
Total gastrectomy	4.0% (2/50)
Liver transplant	2.0% (1/50)
Pancreaticoduodenectomy (Whipple)	2.0% (1/50)
Other surgery	28.0% (14/50)
Prior cholecystostomy tube	30.0% (15/50)

Table 2. Cholangioscope maneuvers performed at index PTCS procedure (N = 50 patients)

Cholangioscope maneuver	% (n/N)
Visualization of region of interest in biliary stricture or lesion	58.0% (29/50)
Biopsy of biliary stricture or lesion	26.0% (13/50)
Clearance of biliary stone(s)/sludge, with lithotripsy: mechanical, electrohydraulic or laser	26.0% (13/50)
Clearance of biliary stone(s)/sludge, without lithotripsy	16.0% (8/50)
Selective cannulation of a biliary duct	14.0% (7/50)
Clearance of gallstone(s)/sludge, without lithotripsy	12.0% (6/50)
Removal of foreign body in the bile duct	8.0% (4/50)
Advancement of guidewire into the duodenum/jejunum for rendezvous procedures	6.0% (3/50)
Visualization of region of interest in gallbladder stricture or lesion	4.0% (2/50)
Establishing bile duct continuity after ductal injury	4.0% (2/50)
Clearance of gallstone(s)/sludge, with lithotripsy: mechanical, electrohydraulic or laser	2.0% (1/50)
Clearance of occluded biliary stent	2.0% (1/50)
PTCS maneuvers–other	2.0% (1/50)

Fig. 2 Successful biliary stone clearance.

A 73 year-old patient with previous surgical status of mini bypass, presented with cholestasis. MRCP disclosed an enlarged common bile duct filled with more than 10 supracentimetric polyhedric stones (Fig. 2a). Endoscopic retrograde approach was excluded after endoscopy control of the anatomy using a pediatric colonoscope. A EUS (EDGE approach was not feasible knowing the previous gastric resection in this particular previous surgical status). A percutaneous access was obtained (Fig. 2b) by the gastroenterology team under fluoroscopy, with internal-external drain placement. One week later, lithotripsy with electrohydraulic lithotripsy was performed using the cholangioscope through the percutaneous tract, with a total of 5 fragmentation sessions (Fig. 2c-d, Video 1). The drain was kept in place up to cholecystectomy, with some stone fragments needed to be extracted after the surgery, and the drain removed thereafter (Fig. 2e), with excellent clinical resolution.

Fig. 2a: MRCP showing enlarged common bile duct filled with multiple large bile duct stones

Fig.2b: PTC initial access with opacification demonstrating the number and stones sizes in the common bile duct

Fig. 2c: The cholangioscope was advanced through the percutaneous access to deliver electrohydraulic lithotripsy on the large hard bile duct stones with partial fragmentation of a third of the stones

Fig.2d: Further session of electrohydraulic lithotripsy delivered through the percutaneous cholangioscope with excellent distal common bile duct stones fragmentation

Fig.2e: Opacification via the percutaneous drain after cholecystectomy: some stone fragments were extracted and the drain removed.

Fig. 3 Ratings of specific cholangioscope attribute or features*

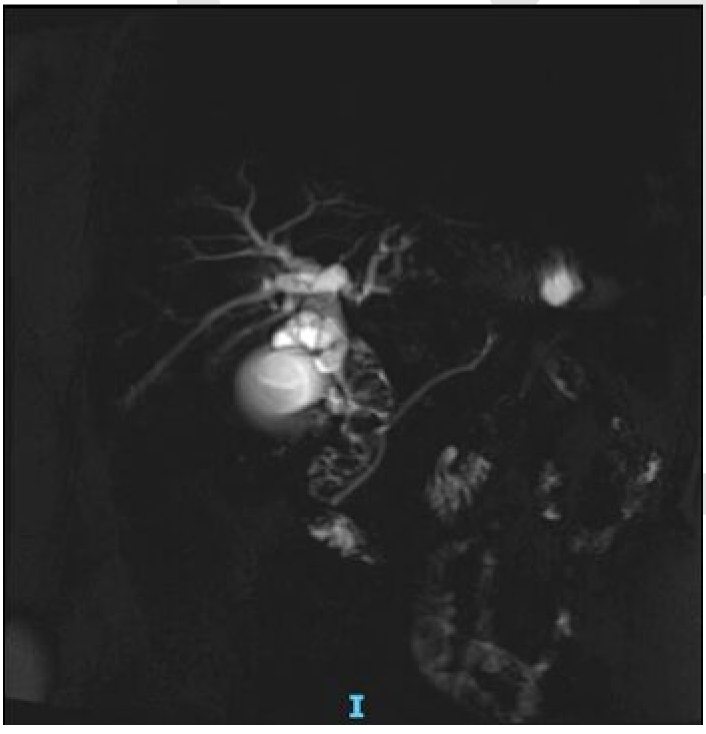
* Complete wording of the questions: “On a scale of 1 (worst) to 10 (best) please give the endoscopist’s rating of the following attributes when using the SpyGlass Discover Digital Catheter compared to marketed reusable scopes (enter “NA” if Not Applicable):

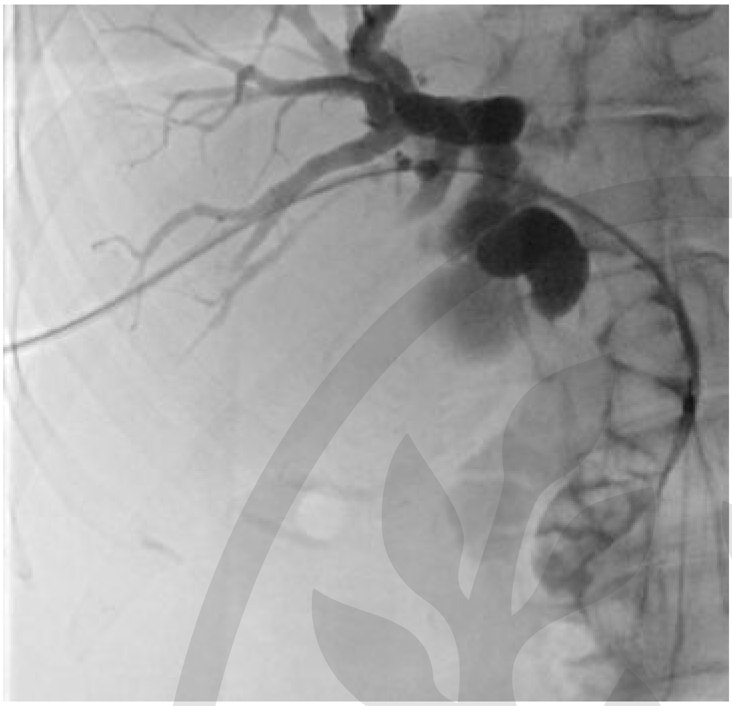
Overall ability to complete the procedure as indicated using the SpyGlass Discover digital catheter
Ability to retroflex
Ability to selectively advance into targeted ducts
Ability to obtain targeted biopsies
Ability to grasp stones
Ability to guide lithotripsy
Ability to suction
Ability to irrigate
Ability to advance accessories through the scope channel
Image quality”

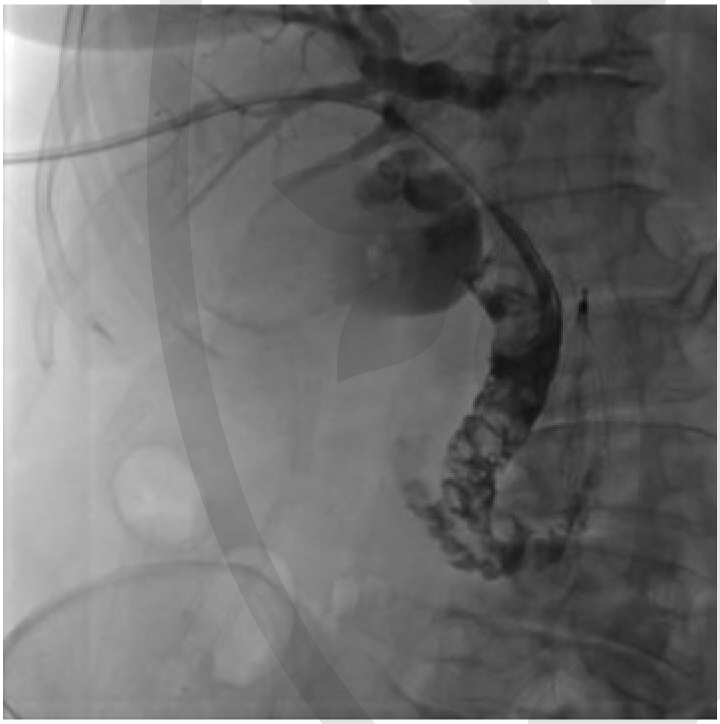
Table 3. Serious adverse events related to the cholangioscope or PTCS procedure (N = 50 cases)

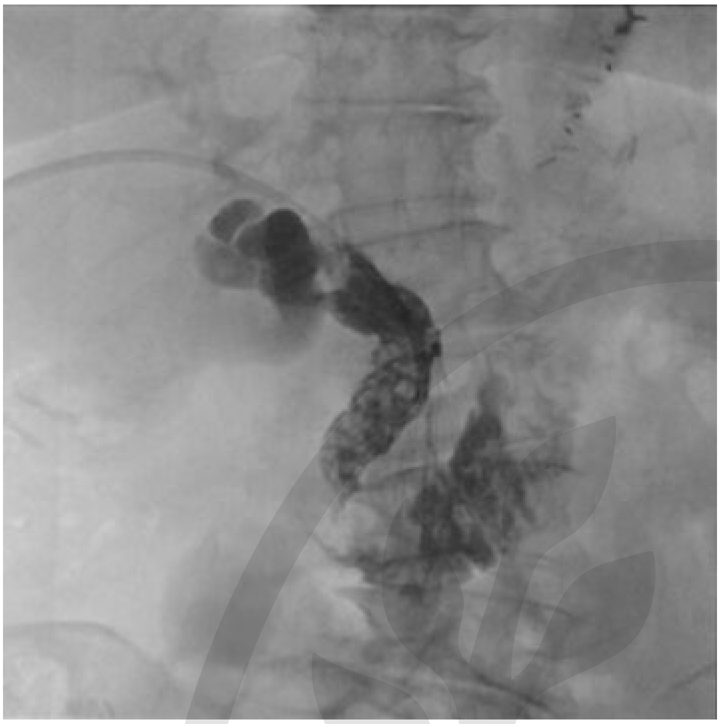
	Number of SAEs	Percent of patients (n/N)
Any serious adverse event	3	4.0% (2/50)
Fatal aspiration	1	2.0% (1/50)
Sepsis due to cholangitis	1	2.0% (1/50)
Hemobilia	1	2.0% (1/50)


SpyGlass™ Discover
Boston Scientific
SpyGlass™ Discover
Digital System
PASSED INSPECTION
MEDICAL ENGINEERING










Overall Ability
Ability to: Retroflex
Selectively advance into targeted ducts
Obtain targeted biopsies
Clear stones
Guide lithotripsy
Suction
Irrigate
Advance accessories through scope channel
Image quality
0
10
20
30
40
50
60
Number of ratings in designated score range
Excellent (8-10)
Good (5-7)
Poor (1-4)