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An international experience with single-operator cholangiopancreatoscopy in patients with altered anatomy

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ABSTRACT

Background and study aims The utility of digital single-operator cholangiopancreatoscopy (D-SOCP) in surgically altered anatomy (SAA) is limited. We aimed to evaluate the technical success and safety of D-SOCP in patients SAA.

Patients and methods Patients with SAA who underwent D-SOCP between February 2015 and June 2020 were retrospectively evaluated. Technical success was defined as completing the intended procedure with the use of D-SOCP.

Results Thirty-five patients underwent D-SOCP (34 D-SOC, 1 D-SOP). Bilroth II was the most common type of SAA (45.7 %), followed by Whipple reconstruction (31.4 %). Twenty-three patients (65.7 %) patients had prior failed ERCP due to the presence of complex biliary stone (52.2 %). A therapeutic duodenoscope was utilized in the majority of the cases (68.6 %), while a therapeutic gastroscope (22.7 %) or adult colonoscope (8.5 %) were used in the remaining procedures. Choledocholithiasis (61.2 %) and pancreatic duct calculi (3.2 %) were the most common indications for D-SOCP. Technical success was achieved in all 35 patients (100 %) and majority (91.4 %) requiring a single session. Complex interventions included electrohydraulic or laser lithotripsy, biliary or pancreatic stent placement, stricture dilation, and target tissue biopsies. Two mild adverse events occurred (pancreatitis and transient bacteremia).

Conclusions In SAA, D-SOCP is a safe and effective modality to diagnose and treat complex pancreatobiliary disorders, especially in cases where standard ERCP attempts may fail.

Introduction

Since the advent to the traditional mother-daughter system [1, 2], per oral cholangioscopy has significantly evolved to now include the digital single-operator cholangiopancreatoscopy (D-SOCP, SpyGlass DS, Boston Scientific Corp., Natick, Massachusetts, United States), leading to its widespread application [3]. There have been numerous studies showing its safety and efficacy in therapeutic and diagnostic interventions, often when conventional cholangiography fails [4–7].

As a diagnostic tool, D-SOCP has demonstrated favorable diagnostic yield both visually and histologically for indeterminate lesions [5, 6, 8, 9]. As a therapeutic tool, D-SOCPs use in treating biliary or pancreatic complex strictures, stones and difficult cannulation has also shown promise, achieving complete duct clearance for biliary and pancreatic stone as high as 86 % to 97% [5, 7, 10–12].

While technological advances in D-SOCP have promoted its clinical use, data in patients with surgically altered anatomy (SAA) are limited. There are no studies reporting the use of D-SOCP in patients with SAA without either revising the anatomy or using endoscopic ultrasound (EUS) for guidance. Thus, we sought to evaluate the effectiveness and safety of D-SOCP in this patient population with the currently available endoscopic instruments.

Patients and methods

This was an international, multicenter, retrospective study at eight tertiary centers (6 US, 2 Europe) between February 2015 to June 2020. A total of 35 consecutive adult patients > 18 years old with SAA who underwent digital single-operator cholangioscopy (D-SOC) and/or digital single-operator pancreatoscopy (D-SOP) for all diagnostic or therapeutic biliary or pancreatic indications were included. SAA includes patients with a history of Whipple procedure, Billroth II, Roux-en-Y Gastric bypass (RYGB), RY hepaticojejunostomy (RYHJ), and RY esophagojejunostomy (RYEJ). Patients who underwent EUS-guided cholangiopancreatography (EUS-CP), including biliary drainage (EUS-BD), EUS-rendezvous (EUS-RV), transmural drainage (such as hepatogastrostomy, hepatoduodenostomy, hepatojejunostomy), antegrade stenting; percutaneous transhepatic cholangioscopy, laparoscopy-assisted ERCP (LA- ERCP), EUS-directed trans-gastric ERCP (EDGE), per oral direct cholangioscopy or procedures done with the legacy version of single-operator cholangiopancreatoscopy system were excluded. Institutional review board approval was obtained at all institutions.

Cholangiopancreatoscopy system

The D-SOC and D-SOP system (Spyglass DS, Boston Scientific Corp) was used for all procedures. The system is composed of a catheter and integrated digital controller. The 10.5F catheter has a tip with four-way steering facilitating visualization of the entire biliary tree and through its working channel, multiple accessories including the small forceps (Spybite, Boston Scientific), electrohydraulic lithotripsy (EHL) or laser lithotripsy (LL) probes can be used. It also has a dedicated irrigation and aspiration channels, dual LED light source and video imaging sensor. The integrated digital controller combines the function of a processor and light emitting diode source [2, 5].

Cholangiopancreatoscopy procedure

All procedures were carried out under general anesthesia in either the supine or prone position and performed by therapeutic endoscopists at each participating center who were highly trained in diagnostic and therapeutic ERCP. The cholangioscope was advanced through the accessory channel of an endoscope with a channel that is at least 3.7 mm in diameter. Patients received peri-interventional antibiotic prophylaxis, according to the institutional guidelines. The type of scopes and accessory used for biliary or pancreatic interventions, was based on endoscopist preference.

Diagnostic D-SOCP was done for visually targeting biopsies in cases of indeterminate biliary strictures and intraductal papillary mucinous cystic neoplasms (IPMN) [13]. Therapeutic D-SOCP was done for the therapy of large or complex biliary or pancreatic duct stones, foreign material removal or biliary stent retrieval. The definition of a large stone was one that was > 15 mm and a complex stone was one that was of any size not retrieved by conventional extraction methods [7, 14].

Outcomes assessment

The primary study outcome was the rate of technical success of D-SOCP in patients with SAA. This was defined as completing the intended interventions with the use of D-SOCP: 1) Biliary or pancreatic duct stones – successful treatment of stones with complete duct clearance including use of electrohydraulic lithotripsy (EHL), Laser Lithotripsy (LL); 2) Biliary or pancreatic stricture: diagnostic purposes – successful visual impression and obtaining adequate targeted tissue samples; therapeutic purposes – successful treatment of the stricture; and 3) Other indications: facilitating guidewire passage and foreign body removal. The safety of the procedure was assessed by the rate and severity of the adverse events (AEs) [15] as graded per the American Society for Gastrointestinal Endoscopy lexicon (mild, moderate, severe, fatal) [16]. Other outcomes included number of D-SOCP sessions required to achieve technical success; need for alternative therapies, such as interventional radiological procedures or surgery; and procedure time which was defined as the time between insertion and withdrawal of the endoscope.

Statistical methods

Descriptive statistics were presented as frequencies (%) for categorical variables and mean (standard deviation), or median (interquartile range) for continuous variables. Statistical analysis was performed using SPSS version 17.0 (SPSS, Chicago, Illinois, United States).

Results

During the study interval, 35 patients (15 female; mean age, 67.9 ± 11.9 years) underwent D-SOCP, of whom 34 underwent D-SOC and one patient underwent D-SOP. Billroth II was the

▶ **Table 1** Baseline characteristics of patients with D-SOCP in SAA.

Baseline characteristics	N = 35
D-SOC	34
D-SOP	1
Age (mean ± SD)	67.9 ± 11.9
Female n (%)	15 (42.9)
Type of surgery, n (%)	
▪ Whipple	11 (31.4)
▪ Billroth II	16 (45.7)
▪ RYHJ	5 (14.2)
▪ RYEJ	3 (8.5)
Indication for D-SOC, n (%)	
Therapeutic	
▪ Bile duct stones, n (%)	19 (55.9)
– Large BD stone	10 (29.4)
– Multiple BD stone	9 (26.5)
▪ Biliary stone details	
– Size of largest stone (mean ± SD) (mm)	13.5 (5.5)
– No. stones (mean ± SD)	2.6 (1.0)
– Location of stone	
– Common bile duct	13 (59)
– Common hepatic duct	2 (9.09)
– Intrahepatic ducts	7 (31.8)
▪ Removal of prior migrated stent, n (%)	4 (11.8)
Diagnostic	
▪ Indeterminate bile duct stricture evaluation, n (%)	8 (23.6)
More than 1 indication	
▪ Large BD stone and multiple BD stone	2 (5.9)
▪ Multiple BD stone and benign biliary stricture	1 (2.9)
Indication for D- SOP n (%)	
▪ Evaluation of dilated pancreatic duct and pancreatic duct stricture	1 (100)
Symptoms and lab work, n (%)	
▪ Abdominal Pain	22 (62.9)
▪ Jaundice	21 (60.0)
▪ Unintentional Weight loss	5 (14.3)
▪ Cholangitis	4 (11.4)
▪ Labs	4 (11.4)
– T.bili level (mean ± SD)	3.5 (3.9)
– AST (mean ± SD)	222.0 (213.4)
– ALT (mean ± SD)	210.8 (195.5)
– ALP (mean ± SD)	200 (1888.2)
Prior attempted ERCP (total number), n (%)	23 (65.7)
Reason for prior failed attempt ERCP	
▪ Complex stone	12 (52.2)
▪ Intraductal stent migration	5 (14.3)
▪ Unable to identify PJ anastomosis	1 (2.9)
▪ Unable to reach efferent limb or hepatic duct	1 (2.9)
▪ Unable to cannulate	1 (2.9)
▪ Indeterminate biliary duct stricture	1 (2.9)
▪ Missing	2 (8.7)

D-SOCP, digital single-operator cholangiopancreatoscopy; SAA, surgically altered anatomy; D-SOC, digital single-operator cholangiography; D-SOP, digital single-operator pancreatography; SD, standard deviation; BD, bile duct; AST, aspartate aminotransferase; ALT, alanine aminotransferase; ALP, alkaline phosphatase; ERCP, endoscopic retrograde cholangiopancreatography; RYHJ, Roux-en-Y hepaticojejunostomy; RYEJ, Roux-en-Y esophagojejunostomy.

most common type of SAA (45.7 %), followed by Whipple reconstruction (31.4 %), RYHJ (14.2 %) and RYEJ (8.5 %). A total of 23 patients (65.7 %) had a prior failed ERCP, which was most commonly due to complex biliary stones (52.2 %). A therapeutic duodenoscope was used in the majority of the cases (n = 24): eight patients had Whipple reconstruction, 14 patients had Billroth II and two patients had RYHJ. Either a therapeutic gastroscope (n = 8) or an adult colonoscope (n = 3) were used in the remainder of the cases (▶ **Table 1**). To facilitate the passage of D-SOCP, majority 28 patients (80 %) underwent sphincteroplasty with a biliary or pancreatic balloon, three (8.5 %) underwent sphincterotomy and the remainder either required no ampullary intervention (n = 2, 5.7 %) or had prior ampullary intervention on index procedure (n = 2, 5.7 %) (▶ **Table 2**).

D-SOC procedure

Majority of the patients (n = 26, 76.4 %) underwent D-SOC for therapeutic indications. The main therapeutic indication was choledocholithiasis (n = 22, 64.7 %), most of which were complex choledocholithiasis (n = 19, 55.9 %); and removal of prior migrated stent (n = 4, 11.8 %). Diagnostic indications were for evaluation of indeterminate bile duct (BD) stricture (n = 8, 23.6 %). Three patients (8.8 %) had multiple reasons to undergo the procedure (▶ **Table 2**). Among those with biliary stones, the mean number of stones was 2.6 ± 1.1, mean stone size was 13.5 ± 5.5 mm, and were located in the common BD (n = 13, 59 %), common hepatic and intrahepatic ducts (n = 9, 40.9 %). The majority of patients required multiple interventions during the procedure (n = 12, 34.3 %). The most common interventions performed were EHL (n = 10, 28.6 %), followed by LL (n = 5, 14.3 %) and stricture dilation (n = 2, 5.7 %) (▶ **Table 2**). ▶ **Fig. 1a–e** is that of a 52-year-old female with a history of pylorus-preserving Whipple in which D-SOC aided in confirming absence of recurrent BD stone.

▶ **Table 2** Procedure characteristics.

Procedure characteristics	D-SOCP
Scope used, n (%) overall	
▪ Therapeutic duodenoscope	24 (68.6)
▪ Therapeutic gastroscope	8 (22.7)
▪ Adult colonoscope	3 (8.5)
D-SOC	
▪ Therapeutic duodenoscope	24
▪ Therapeutic gastroscope	8
▪ Adult Colonoscope	2
D-SOP	
▪ Adult colonoscope	1
Interventions performed, n (%)	
Ampullary interventions performed to facilitate passage of D-SOCP	
▪ Sphincterotomy	3 (8.5)
▪ Sphincteroplasty (biliary/pancreatic balloon dilation)	28 (80)
Other interventions	
▪ Stricture dilation	2 (5.7)
▪ Stone removal	2 (5.7)
▪ EHL	10 (28.6)
▪ LL	5 (14.3)
▪ Biopsy	3 (8.6)
▪ Hot snare	1 (2.9)
More than 1 intervention (mechanical lithotripsy, stent removal, stone removal, stricture dilation, stent placement)	12 (34.3)

D-SOCP, digital single-operator cholangiopancreatoscopy; D-SOP, digital single-operator pancreatoscopy; EHL, electrohydraulic lithotripsy; LL, Laser Lithotripsy.

D-SOP procedure

One patient with Whipple anatomy underwent a D-SOP for imaging that showed dilation of the pancreatic duct (PD) to 9 mm. Initially a duodenoscope and a therapeutic gastroscope were used, but the pancreatico-jejunal (PJ) anastomosis could not be identified. An adult colonoscope with a cap was successful in identifying the PJ anastomosis and PD cannulation was achieved. D-SOP confirmed proximal PD dilation, a benign-appearing distal PD stricture with an obstructing 7-mm stone; thus, excluding the presence of a main duct mucinous neoplasm. Two D-SOP sessions (with EHL, stricture dilation and stent placement) were performed (▶ **Fig. 2a**, ▶ **Fig. 2b**).

Outcomes

Technical success was achieved in in all 35 patients (100 %) in our study cohort. In 22 patients with a BD stone and one patient with a PD stone, complete duct clearance was achieved in all patients using D-SOCP. Eight patients (23.6 %) underwent D-SOC for indeterminate stricture evaluation, of whom three patients had malignant stricture. Among these three patients, the visual impression was that of abnormal dilated tumor vessels (n = 1) and presence of friable mass with abnormal vessels (n = 2). D-SOC based on visual impression and targeted tissue samples with small forceps (SpyBite, Boston Scientific) biopsies were obtained in all three patients whose final diagnosis was cholangiocarcinoma. The remainder five of eight patients had benign strictures: BD stricture from stone disease (n = 2), postoperative BD stricture from extended right hepatic hepatectomy (n = 1), anastomotic stricture following liver transplant (n = 1) and chronic pancreatitis-induced benign biliary stricture (n = 1). D-SOC-based visual impression assisted in all five cases while biopsies were performed in two of five cases, confirming benign diagnosis. In the one patient who underwent D-SOP, the PD stricture was found to be benign, secondary to an obstructing PD stone.

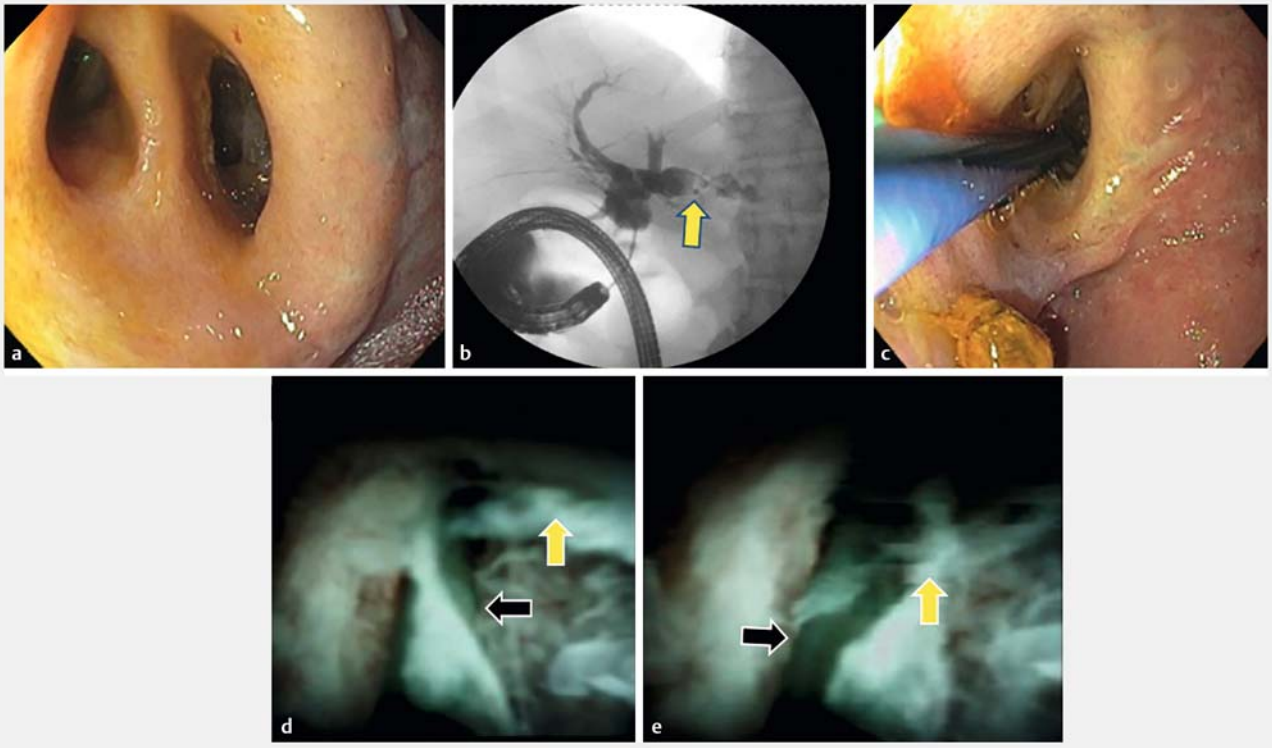
The majority of patients (n = 32, 91.3 %) required a single D-SOCP session, while the remainder (n = 3, 8.5 %) required two D-SOCP sessions. No patients had technical failure and none required alternative interventions such as interventional radiology or surgery.

The mean procedure time was 61.0 ± 22.6 minutes. Overall, two AEs (6.4 %) occurred, including one case of pancreatitis and one case of transient bacteremia. Both were graded as mild in severity per the American Society of Gastrointestinal Endoscopy lexicon. Both patients were successfully treated with conservative management (▶ **Table 3**).

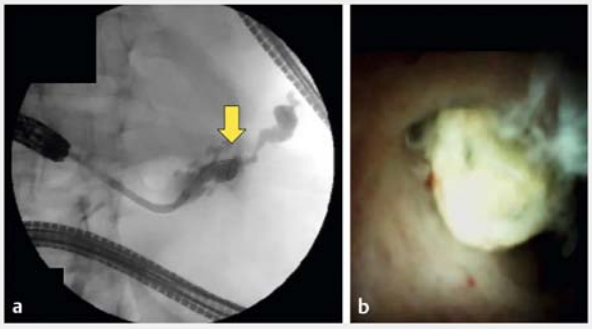
Discussion

This is the first study to demonstrate the safety and feasibility of D-SOCP in SAA without endoscopically or surgically altering the anatomy. The technical success rate was 100 % despite the presence of SAA. We believe this is due to multiple factors, an important one being appropriate scope choice allowing the passage of a 10.5F D-SOCP. Prior studies report the success rate of gastroscopy, duodenoscopy, and colonoscopy in SAA as 84.6 %, 62.5 %, and 93.5 %, respectively [17–19]. In our study, the majority of patients had a Billroth II or Whipple reconstruction, in which a duodenoscope, therapeutic gastroscope or a colonoscope with cap were utilized. It must be noted that while using a forward-viewing endoscope with a cap has its advantages in SAA, one must bear in mind that the lack of elevator capability could further make the procedure challenging.

The majority of patients in our cohort had prior failed ERCP (n = 23,65.7 %) due to presence of complex choledocholithiasis (n = 12, 52.2 %), which was successfully managed by D-SOCP resulting in complete BD clearance in all cases, the majority of which were achieved in one session (91.3 %). Our findings were similar to multiple published studies on the use of D-SOC with



▶ **Fig. 1** 52-year-old female with history of pylorus-preserving Whipple for pancreatic neuroendocrine tumor underwent ERCP 2 months prior for left hepatic duct stone successfully removed, but presented for concern of recurrent stone vs stricture. She underwent digital cholangioscopy using a therapeutic gastroscope to further evaluate. **a** Bisectoral hepaticojejunal anastomoses noted are widely patent. **b** Cholangiogram showing a short narrowing of left hepatic branch to liver segment III (arrow). **c** Digital single-operator cholangioscopy advanced into the left hepaticojejunal anastomosis. **d, e** Cholangioscopic images of left intrahepatic duct with benign-appearing stricture (yellow arrow), guidewire seen in background (black arrow). No stones noted. Spybite biopsies were obtained and returned benign.



▶ **Fig. 2** A 61-year-old man with a history of pylorus-preserving Whipple for side branch Intraductal pancreatic mucinous cystic neoplasm(IPMN), presents with imaging evidence of dilated main pancreatic duct distal to the pancreaticojejunal (PJ) anastomosis, concerning for main duct IPMN. The patient underwent digital single-operator pancreatoscopy using a therapeutic gastroscope. PJ anastomosis cannulated, pancreatogram showed a dilated main pancreatic duct measuring approximately 1 cm in diameter with an upstream stricture in the pancreatic tail. **a** Fluoroscopic image showing single-operator pancreatoscope passed into the pancreatic duct re-vealing a dilated duct with distal stricture (arrow). **b** Pancreato-scopic image showing a normal pancreatic duct mucosa with non-mucin-like fluid with small solid debris inside. An obstructive stone was seen at the level of the distal tail PD. IMPN was less likely, given these findings.

EHL/LL; however, these were not in SAA [20]. In the largest multicenter, retrospective cohort study of D-SOC to date, Gutierrez et al. achieved a technical success rate for duct clearance of 97.3 %, of which 77.4 % were in a single session [7]. In a meta-analysis and systematic review published by Korrapati et al, the efficacy and safety of cholangioscopy in difficult BD stones was 88 % stone clearance and 7 % AE. Limitations included study heterogeneity and variability in the type of per oral cholangioscope used [21]. Navaneethan et al, in an observational study, performed D-SOC with LL in 31 patients with 87.1 % of BD stone clearance in 1 session. Impacted stones were present in 13 of 31 patients (36.1 %). Twenty-three of the 31 patients (74.2 %) referred for stone removal had prior ERCPs and had failed stone removal by using conventional methods [5]. Further a 2:1 randomized trial compared cholangioscopy-guided LL to conventional therapy, found endoscopic stone clearance was achieved in 39 of 42 patients (93 %) in the cholangioscopy-guided group compared to 12 of 18 patients (67 %) in the conventional therapy group, supporting the reduced need for mechanical lithotripsy in the D-SOC arm. Regarding D-SOP, we only report one patient with a PD stone who also achieved successful duct clearance, thus our data was insufficient for conclusion.

D-SOCP carries a high sensitivity and specificity for both visual impression and tissue sampling in the evaluation of indeter-

▶ **Table 3** Overall procedure outcomes.

Procedure characteristics	D-SOCP
Scope used, n (%) overall	
▪ Therapeutic duodenoscope	24 (68.6)
▪ Therapeutic gastroscope	8 (22.7)
▪ Adult colonoscope	3 (8.5)
D-SOC	
▪ Therapeutic duodenoscope	24
▪ Therapeutic gastroscope	8
▪ Adult colonoscope	2
D-SOP	
▪ Adult colonoscope	1
Interventions performed, n (%)	
Ampullary interventions performed to facilitate passage of DOSCP	
▪ Sphincterotomy	3 (8.5)
▪ Sphincteroplasty (biliary/pancreatic balloon dilation)	28 (80)
Other interventions	
▪ Stricture dilation	2 (5.7)
▪ Stone removal	2 (5.7)
▪ EHL	10 (28.6)
▪ LL	5 (14.3)
▪ Biopsy	3 (8.6)
▪ Hot snare	1 (2.9)
▪ More than 1 intervention (mechanical lithotripsy, stent removal, stone removal, stricture dilation, stent placement)	12 (34.3)

D-SOCP, digital single-operator cholangiopancreatoscopy; D-SOC, digital single-operator cholangiography; EHL, electrohydraulic lithotripsy; LL, Laser Lithotripsy.

minate strictures [5, 22]. A systemic review by Kulpatcharapong et al comparing different cholangioscopy systems for biliary strictures, showed that the digital SOC provided a higher negative predictive value than the fiberoptic SOC (89 % vs. 69 % – 84 %) [23]. Navaneethan et al performed an observational study using the newer D-SOC, among 105 patients, of whomw 44 had indeterminate stricture. They reported a tissue adequacy of 97.7 %, sensitivity and specificity for D-SOC visual impression for diagnosis of malignancy as 90 % and 95.8 %, respectively and sensitivity and specificity of D-SOC-guided biopsies for diagnosis of malignancy as 85 % and 100 %, respectively [5, 22]. These findings are supported in our analysis in patients with SAA, further emphasizing its pivotal role in indeterminate BD strictures. We found that D-SOC was successful in diagnosing both malignant (3/8) and benign biliary strictures (5/8), with an overall technical success rate of 100 %.

This study has several limitations. It was retrospective with a relatively small sample size. Neither the procedure strategy nor the devices used for D-SOCP in SAA were not standardized. Also, the details of SAA including length of afferent limb were not specified. The factors associated with successful or unsuccessful procedures could not be assessed. Finally, we acknowledge that technical success can be an overestimate of the true success and we cannot rule out bias related to the retrospective nature of the study. Nonetheless, this is the first multicenter study reporting the utility of D-SOCP in diagnosis and treatment of pancreatobiliary disorders in patients with SAA.

Conclusions

In conclusion, D-SOCP results in high rates of technical success and low AE rates in patients with altered upper gastrointestinal anatomy. In instances in which standard ERCP attempts failed, D-SOCP proved to be a safe and reliable management strategy for complex disease.

Competing interests

Dr. Khashab, is a consultant for Boston Scientific, Olympus, Medtronic, GI Supply, and Apollo. Dr. Raijman is on the advisory board and a consultant for Boston Scientific, Ambu, Conmed, MicroTech, Pentax Medical, and GI supplies and co-owner of EndoRx. Dr. Trindade is a consultant for Olympus America and Pentax Medical and receives research support from Ninepoint Medical. Dr. Benias is a consultant for Olympus America, Apollo Medical, FujiFilm, and Boston Scientific. Drs. Jacques, Zuchelli and Irani are consultants for Boston Scientific.

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