



Indications for Single-Operator Cholangioscopy and Pancreatocopy: an Expert Review

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Published online: 4 June 2019

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This article is part of the Topical Collection on *Endoscopy*

Keywords Peroral cholangioscopy · Indeterminate stricture · Cholangiocarcinoma · Intraductal papillary mucinous neoplasm (IPMN) · Biliary stone

Abstract

Purpose of review Direct endoscopic visualization of the biliary and pancreatic ducts by single-operator cholangioscopy (SOC) and pancreatocopy (SOP) is an expanding technique with an increasing number of indications. This review provides technical tips and tricks and a literature update on the usefulness of SOC and SOP in clinical practice.

Recent findings SOC has shown a 91.3% and 87.3% diagnostic procedural success in indeterminate strictures and difficult stones respectively, with a 9.4%–16.4% complication rate. Although the interpretation of the images suspected for malignancy can be challenging, new classifications based in mucosal and vascular patterns as well as better devices are in development. A higher sensitivity has been associated to targeted biopsies, compared to brushing and blinded biopsies. Indeed, SOC has recently demonstrated a decrease in the number of procedures and costs when compared with *endoscopic retrograde cholangiopancreatography*. This technique has also been reported for many other diagnostic and therapeutic indications, such as cholangiocarcinoma staging and foreign body extraction. Similarly, diagnostic and therapeutic SOP in indeterminate strictures or pancreatic stones, and intraductal papillary mucinous neoplasms, has been successfully reported.

Summary Research to date supports the use of cholangioscopy as a complementary examination in patients with indeterminate strictures, difficult stones and specific situations. In a near future, there will probably be new established indications, a better understanding of the imaging findings and a place of SOC/SOP as first line in selected scenarios.

Introduction

Direct endoscopic visualization of the biliary and pancreatic ducts has gained an increased interest due to the developments of single-operator scopes with a better image resolution. They are now used for a number of indications, where indeterminate strictures and difficult stones are the two most common scenarios. The SpyGlass Direct Visualization System (Boston Scientific Corp., Natick, MA, USA) is the most frequently used device with technical features widely described [1].

Technical considerations

Most single-operator cholangioscopy (SOC) procedures are performed as a second line after previous *endoscopic retrograde cholangiopancreatography* (ERCP), sometimes with stents in place. In these cases, after stent removal, the duct access can be performed directly without guidewire aid. In case of suspicious strictures, it seems however preferable to consider a primary use of the SOC system before any manipulation of the suspicious area to avoid bleeding and trauma. However, there are no randomized controlled trials to date comparing first-line or second-line approaches. When used in the first line, biliary or pancreatic sphincterotomy is usually needed to allow the insertion of the 10Fr device. The introduction can also be done over a 0.035-in guidewire positioned under fluoroscopy, especially in a more tortuous anatomy or intrahepatic strictures. One should always avoid excessive manipulation of the device with the elevator to avoid its damage, so that most movements to introduce it are done torqueing the duodenoscope, using the upper wheel and the scope dedicated wheels. Once inserted, the device should be slowly advanced keeping a central view of the duct, combined with irrigation and aspiration balance to clear the field of view and short withdrawal movements if necessary. Dual aspiration with the SOC and the duodenoscope may be of help to clear the view

and avoid excessive irrigation and transfer of fluid between the bile duct and the pancreas.

Overall, SOC has shown a 91.3% and 87.3% diagnostic procedural success in indeterminate strictures and difficult stones respectively, with a 9.4%–16.4% complication rate [2, 3]. Similarly, diagnostic and therapeutic single-operator pancreatoscopy (SOP) in indeterminate strictures or pancreatic stones, and intraductal papillary mucinous neoplasms (IPMNs), have been successfully reported (Fig. 1). However, it is important to point out that most of reported studies have been performed by expert ERCP endoscopists in referral pancreatobiliary centres; therefore, the accuracy values of these techniques may be overestimated. Most important tips and tricks for using SOC/SOP are summed up in Table 1.

Recently, an observational study on 111 patients who underwent SOC has demonstrated a 27–31% reduction in the number of procedures and saves about 5–11% costs when compared with ERCP [4•]. This economic analysis uses two decision-tree models, demonstrating that SOC saved hospital costs for both stricture detection and stone treatment. Considering indeterminate strictures, the expenditure for hospitalizations was the cost driver in the ERCP + brushing scenario (65% of total costs), whereas the expenditure for the acquisition of the SOC system was the cost driver in SOC (50% of total costs). There is no report on the cost-effectiveness of SOP to date.

The new generations of Spyglass DS have notably improved the image quality, and dedicated accessories (Spybite, snare, Dormia basket) have also been developed in recent years, increasing the possibilities of this technique. Although the indications of the SpyGlass system are expanding, there are a number of limitations. The access to the bile and pancreatic ducts is dependent on anatomy and duct diameter, usually limited to second branching of intrahepatic ducts and main pancreatic duct. In addition, the success in indeterminate

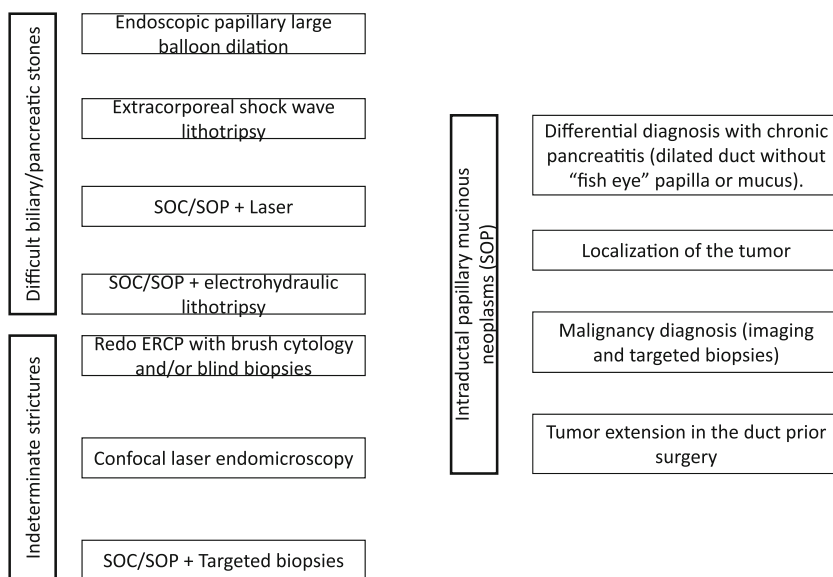


Fig. 1. Flow-chart providing an overview of the main indications of SOC and SOP. SOC, single-operator cholangioscopy; SOP, single-operator pancreatoscopy; ERCP, endoscopic retrograde cholangiopancreatography.

strictures has probably been overestimated as it has been defined as the adequate visualization of the stricture reached by the device, and the real success should be the accurate diagnosis of the nature of the stricture [5]. Last, consensus is lacking on the interpretation of the endoscopic images of the biliary/pancreatic mucosa in suspected malignancy. In addition, conversely to that in peroral cholangioscopy using ultraslim endoscopes,

advanced imaging modalities as narrow band imaging [6] or I-SCAN [7] are not provided in SOC/SOP. However, other adjuvant modalities such as confocal laser endomicroscopy [8] have been described.

The purpose of the present expert narrative review is to assess the current indications of single-operator cholangioscopy and pancreatoscopy in biliary and pancreatic diseases.

Single-oral cholangioscopy

Indeterminate strictures

An indeterminate stricture is defined as a stricture that cannot be definitively diagnosed with conventional ERCP sampling techniques combined with

Table 1. Most important tips and tricks during single-operator cholangioscopy and pancreatoscopy

- Adequate irrigation and aspiration balance. To close the suction pump can help to ensure the entire visualization of the duct.
- Be cautious in the interpretation of indeterminate strictures, paying attention to the vascular pattern and performing multiple biopsies.
- To perform single-operator cholangioscopy as a first-line approach in proximal indeterminate strictures may be more effective than doing this procedure after the insertion of a stent.
- To combine single-operator cholangioscopy or pancreatoscopy-guided lithotripsy with conventional therapies to obtain total clearance.

radiological imaging and/or endoscopic ultrasound. In this setting, SOC can be crucial, providing an accurate diagnosis and avoiding unnecessary surgery for suspicion of malignancy.

Most of the time, the target is a short single stricture or filling defect in the proximal extrahepatic duct or the hilar convergence that can be easily reached by the scope [9]. However, a careful visual inspection should be done during the advancement of the device under direct visualization, to rule out other suspected areas or abnormalities. The positioning and manoeuvres may be challenging in small intraductal branches or in the distal extrahepatic duct. To block the SOC, handles help out to perform precise movements in these situations. In addition, a balance between irrigation and continuous aspiration becomes essential, especially in the orifices of small ducts and traumatic areas where there are more biliary debris and free epithelial tissue. Aspiration is essential to avoid overfilling of the ducts. In our experience, a dedicated low-pressure irrigation pump with a footswitch can be helpful to optimize the field of view, allowing also water magnification of suspected areas (Fig. 2). Multiple pictures and video recording should be encouraged, as not only is it useful for the re-reading or research purposes but it also allows the comparability with further cholangioscopy procedures if performed.

The nature of the stricture can be classified according to visual inspection or visual-assisted sampling. According to the presence of suspected macroscopic features such as the visualization of mass or tortuous dilated vessels, a suspicion of malignancy can be made under visual diagnosis [10]. Overall accuracy for visual diagnosis has been described as 80%–96.7% [11–14], but it should be actually higher as most of reports are based on the first-generation SpyGlass™. In addition, the interpretation of mucosal abnormalities in patients with previous recent blinded biopsies or stenting can be challenging [15]. Recently, a novel classification system used to distinguish non-neoplastic from neoplastic bile

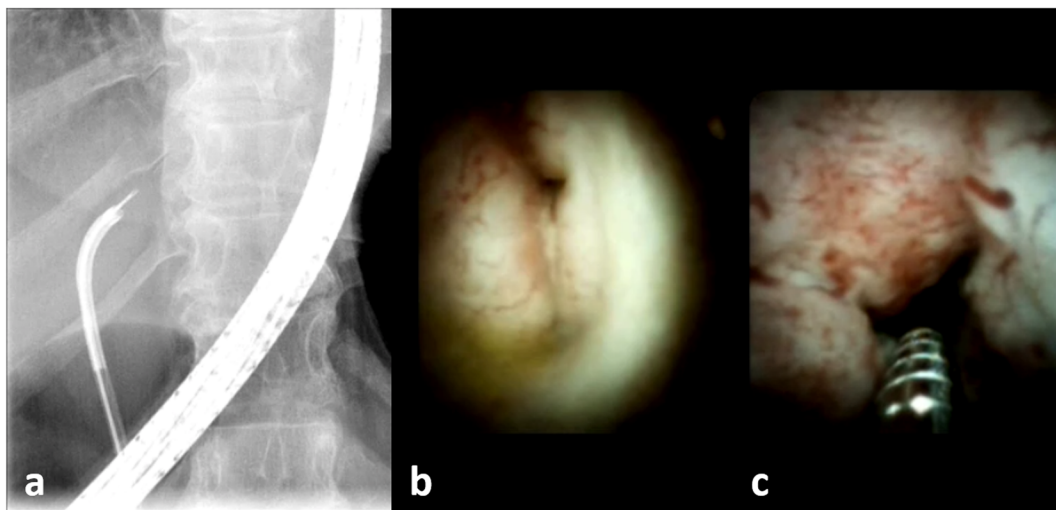


Fig. 2. Single-operator cholangioscopy in a patient with an indeterminate biliary stricture (a). Direct endoscopic visualization of the hilar stricture, confirming the presence of irregular vessels and a narrowing of the lumen (b). Targeted biopsies under direct view of suspected areas (c). A “spider” vasculature and spontaneous bleeding are observed under water magnification. A hilar cholangiocarcinoma was confirmed by histopathological analysis.

duct lesions has been described [16•]. Micronodular or villous patterns without vascularity or with regular vessels have been classified as non-neoplastic. On the other side, four neoplastic presentations have been validated (flat, polypoid, ulcerated and honeycomb patterns), based on morphological and vascular patterns, all of them presenting with irregular or “spider” vascularity (Fig. 3). However, the interpretation of bile duct images should be cautious and mainly based on the vascular pattern. This is especially true for patients in whom SOC is performed following stent removal, as pseudopolypoid morphology and traumatic ulcers are common in this scenario. In addition, several patterns can be detected in the same patient and the passage of the scope can cause traumatic lesions. Thus, the inspection of the bile duct under direct visualization should be done from the distal to the proximal end. A quick introduction of the scope to the hilum under fluoroscopy should be avoided.

Laleman et al. [3], in an aggregated review of 13 studies, reported a Spybite biopsy success and adequacy biopsy specimen of 94.2% and 82.3%. The advancement of the biopsy forceps can be challenging, but the more the spyscope is deep in the bile duct, the more it is easy. A higher sensitivity has been associated to the spybite biopsy forceps, compared to brushing and blinded biopsies [17•]. A recent report suggested a minimum of four biopsies to optimize histological diagnosis [18]. Multiple intraductal biopsies [19], rapid onsite evaluation of touch imprint cytology [18] and a combination with ERCP conventional sampling [20] have been also related to a higher accuracy.

Finally, there are special clinical scenarios that should have an individual consideration and management. An indeterminate stricture can be associated to a difficult stone in up to 9.6% of cases [12], and multiple intrahepatic strictures suspected of malignancy can be observed in patients with primary sclerosing cholangitis.

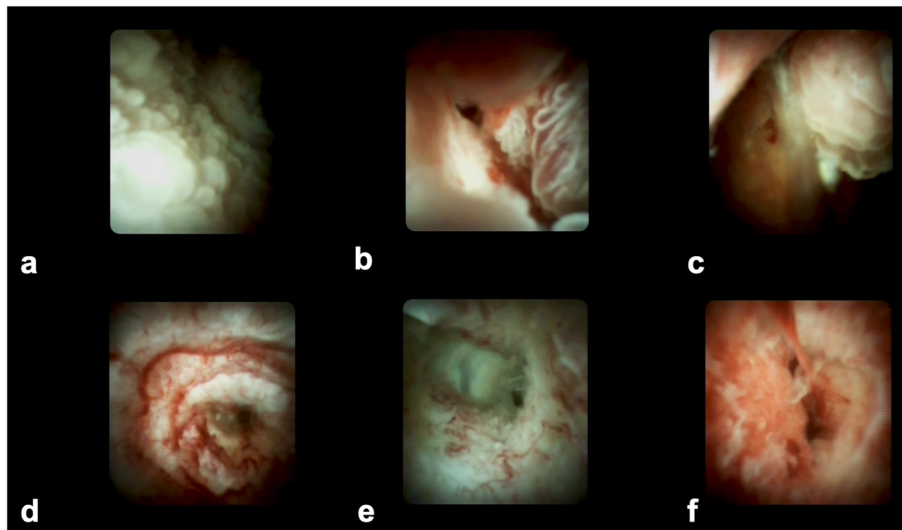


Fig. 3. Different patterns of single-operator cholangioscopy. In the first row, non-neoplastic lesions with a micronodular pattern (a), villous pattern without vascularity (b) and polypoid pattern without suspected vessels (c). In the second row, neoplastic lesions presenting with a non-ulcerated mucosa and spider vascularity (d), an ulcerated pattern with irregular vessels (e) and a polypoid morphology with fibrosis, irregular vascularity and spontaneous bleeding (f).

In conclusion, the diagnostic yield of SOC (plus targeted histology) is high. The technique has proven to alter the clinical management in selected patients [21, 22] and should be considered as an integral part of the ERCP armamentarium [23]. However, the interpretation of the results (and notably negative results) should be cautious, in combination with other imaging modalities in a multidisciplinary approach [24, 25].

Difficult biliary stones

Lithotripsy in difficult biliary stones is the major therapeutic indication of SOC, achieving an overall technical success rate higher than 87% [2, 3, 12, 26]. In general, large (> 15–20 mm), impacted or multiples stones as well as those refractory to the conventional treatment by ERCP can be good candidates (Fig. 4). However, this procedure has also been described in uncomplicated common bile duct stone removal to avoid the need for fluoroscopy [27]. In addition, this procedure is time-consuming and to fragment the stone is only the first step. To ensure the clearance of the bile duct, conventional therapies should be combined and this can also be challenging to obtain total clearance. Difficult anatomy or cannulation (duodenal diverticula or altered anatomy) as well as the intrahepatic location [28] can be associated with technical failure. A more exhaustive list of different presentations during SOC-guided lithotripsy is provided in Table 2.

Actually, two therapeutic modalities are available, electrohydraulic lithotripsy (EHL) and Holmium laser. The single-use probe should be placed in a no-touch fashion, at some millimetres from the stone, and saline solution should be used in EHL cases. Both approaches have shown similar technical success (96.7% vs. 99%) and bile duct clearance rates (74.5% vs. 76.1% respectively) [29].



Fig. 4. A fragmented biliary stone after single-operator cholangioscopy-guided laser lithotripsy.

Table 2. Different presentations in single-operator cholangioscopy-guided lithotripsy

Complex large biliary stone
Stone above a biliary stricture
Intrahepatic lithiasis
Cystic duct stone
Stones associated to biliary and liver surgery (liver transplantation)
Stones associated to surgical digestive anatomy or inaccessible papilla (endoscopic ultrasound-guided hepaticogastrostomy)

Although recent studies have not found significant differences in the technical success between SOC-guided lithotripsy and papillary large balloon dilation (77.1% vs. 72%) [30•], SOC could allow to treat larger stones and has the ability to better assess bile duct clearance than ERCP [20], accurately identifying residual bile duct stones [31]. Furthermore, a systematic review and meta-analysis published in 2016 [26] including 31 studies showed a higher technical success rate of SOC compared with other methods (dual operator and peroral cholangioscopy by ultraslim endoscopes).

When the papilla cannot be reached due to surgically altered anatomy or duodenal obstruction, peroral transluminal cholangioscopy after endoscopic ultrasound hepaticogastrostomy can be feasible [32]. Stone extraction is carefully performed antegradely in these selected cases through a covered biliary stent or the dilated transhepatic fistula.

Other indications

SOC has been reported for many other diagnostic and therapeutic indications, such as cholangiocarcinoma staging [33] and foreign body extraction [34]. The SOC-assisted selective guidewire placements across post-liver-transplant strictures can also be useful when this is not possible by conventional methods [35, 36]. Finally, the percutaneous transhepatic cholangioscopy-guided therapy is expanding and has been successfully described in short case series and case reports analysing the usefulness of the technique in bilioenteric anastomotic strictures or other surgical anatomies [37–39].

Single-operator pancreatoscopy

Indeterminate strictures

There are few data regarding the role of SOP in indeterminate strictures or dilatations (e.g. to differentiate IPMN from chronic pancreatitis). Two different scenarios can be considered depending on the association of other pancreatic-related disease (chronic pancreatitis, pancreatic stones, IPMN) or not. The classification between benign and malignant can be challenging [40], especially when there is no associated lesion. Most of the reported cases to date with indeterminate strictures belong to this second setting [41].

Overall, the advancement in the pancreatic duct can be more difficult than in the CBD. Movements to advance SOP include shortening and lengthening of the duodenoscope, usage of duodenoscope upper and lateral wheels and a

stiffer guidewire to pass the neck of the pancreas. Pancreatic duct anatomical variations, distal location of the stricture and presence of stones may be predicting factors of increasing technical difficulty and technical failure. In addition, a more careful irrigation should be made in these cases to prevent the risk of acute pancreatitis and previous sphincterotomy seems mandatory.

The technical success rate in SOP has been reported to be very high (97%) in a single-centre study of 79 patients, and the accuracy of the technique increased to 94% when combined with tissue sampling [42].

Intraductal papillary mucinous neoplasm

Trindade AJ et al. [43] have shown that digital pancreatoscopy should be considered in the diagnostic algorithm of MD-IPMN in patients with a diffusely dilated pancreatic duct and without any focal lesions seen on cross-sectional imaging or endoscopic ultrasound (EUS). In this study of 31 patients, 42% of these lesions may have findings on pancreatoscopy that were not seen on cross-sectional imaging or EUS. Visual diagnosis may be challenging but fish-egg-like type with vascular images, villous type and vegetative type are considered to be malignant [44]. However, benign polyps can also be found in the main pancreatic duct (Fig. 5). Other similar studies including a low number of patients have also described a high diagnostic yield of the technique in the direct visualization, and biopsy demonstrated a suspected IPMN [41]. Although pancreatoscopy could guide the type of surgery [43, 45], this technique may not be accurate in the pre-operative assessment of extent of main duct IPMN due to the poor diagnostic ability of targeting biopsy [46], but further studies are needed [47].

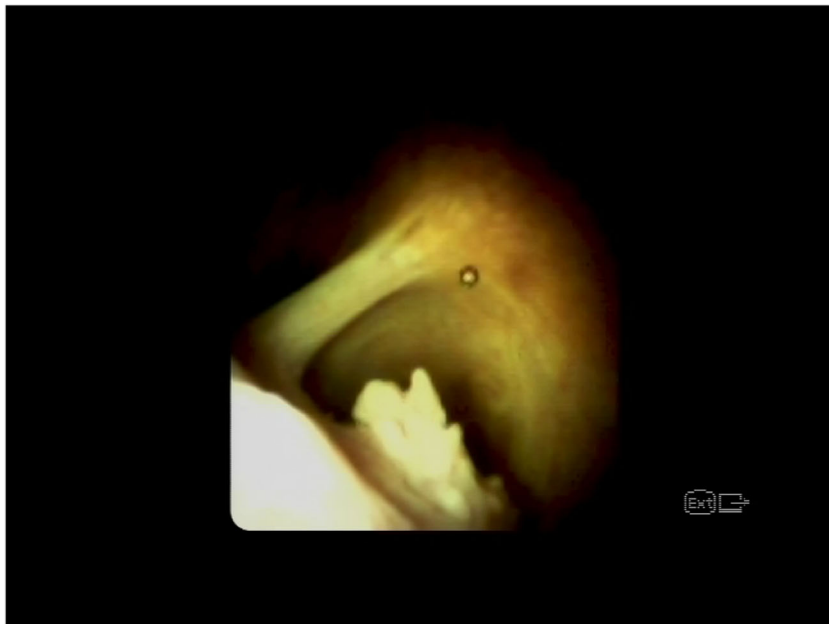


Fig. 5. A granulomatous benign polyp in the main pancreatic duct with a regular surface around and no suspected vessels.

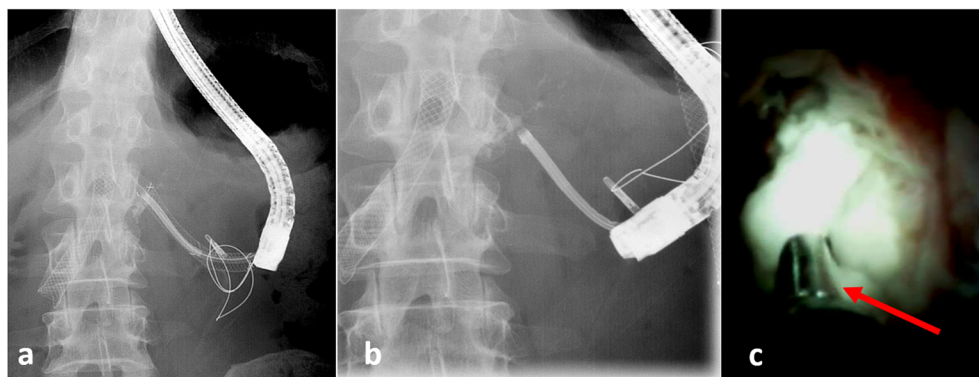


Fig. 6. Single-operator pancreatoscopy-guided lithotripsy through a pancreaticogastrostomy in a patient with pancreatic stones and disconnected pancreatic duct. The closed angulation between the metallic stent and the pancreatic duct did not allow the deep insertion of the scope and was removed (a, b). Subsequently, electrohydraulic lithotripsy using the probe in non-contact fashion (red arrow) was successfully performed (c)

The role of pancreatoscopy has also been described in branch-duct IPMN. In a retrospective study of 9 patients with a final diagnosis of BD-IPMN, the pancreatoscopy identified 78% of the cases correctly and the technique influenced decision-making concerning their clinical management [48].

Difficult pancreatic stones

A recent systematic review including 10 publications [49] reported a successful ductal clearance for POP-guided treatment as between 43% and 100%, compared to extracorporeal shock wave lithotripsy (ESWL) with 59% to 80%. Adverse event rate for POP-guided therapy was reported as 0–13.5%. However, both techniques can be combined [50], and SOP-guided lithotripsy could be indicated after ESWL failure to break the stone or when the stone is difficult to visualize under fluoroscopy. Laser [23] and electrohydraulic therapies [51, 52] have been successfully reported in patients with painful chronic pancreatitis with radiological evidence of a dilated PD and main duct stone disease.

Breaking pancreatic stones is usually more difficult compared to bile duct stones as they are more resistant and scope manoeuvres and positioning are tricky. This is especially true for large stones (> 1 cm). However, in a retrospective series of 118 SOP, the need for several procedures to achieve clearance was infrequent (1.7%) and the pain relief improvement was stable at 2.7 years of clinical follow-up [52].

In addition, pancreatoscopy-guided lithotripsy after metallic stent placement [53] and through an antegrade pancreatoscopy via EUS-guided pancreaticogastrostomy to perform lithotripsy has also been reported [54]. In this setting, the angulation between the stent and the pancreatic duct can limit the deep insertion of the SOP scope. The stent needed to be removed, performing the SOP through the pancreaticogastrostomy fistula (Fig. 6).

Other indications

A number of other indications have been reported in case reports and short case series. The extraction of migrated stents fragments assisted by pancreatoscopy

[55], laser dissection of BD-IPMN [56] and assisted cannulation of strictures [57] or pancreatic rendezvous [58] have been described.

Compliance with ethical standards

Conflict of interest

Enrique Pérez-Cuadrado-Robles declares that he has no conflict of interest. Pierre H. Deprez declares that he is consultant for Boston Scientific.

Human and animal rights and informed consent

This article does not contain any studies with human or animal subjects performed by any of the authors.

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