Journal of Liver Transplantation 17 (2025) 100259

Contents lists available at ScienceDirect

Journal of Liver Transplantation

journal homepage: www.elsevier.com/locate/liver

Original article

The role of peroral cholangioscopy in liver transplant recipients: A prospective, international series

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ARTICLE INFO

Keywords:
Biliary stricture
Cholangiopancreatography, endoscopic retrograde
Cholangioscopy
Diagnosis
Liver transplantation

ABSTRACT

Background: Biliary strictures are a common complication of living and deceased donor liver transplantation. Peroral cholangioscopy (POCS) with POCS-guided biliary tract biopsies may improve diagnostic accuracy compared to endoscopic retrograde cholangiopancreatography (ERCP) with biopsy, but the role and clinical impact of adding POCS to ERCP in management of post-liver-transplantation biliary adverse events remains unknown.

Methods: In a multicenter prospective study, patients ≥1 month post-liver transplantation with abnormal imaging and/or liver tests, without prior treatment of a biliary stricture, and referred for ERCP evaluation of a suspected biliary stricture underwent POCS immediately following the initial diagnostic portion of the ERCP. Outcomes were POCS visual impression of the stricture, impact on patient management and diagnosis, and related serious adverse events (SAEs).

Results: Forty-one patients (88 % cadaveric donors, mean 28 ± 44 months since liver transplantation) underwent POCS (mean POCS procedure time 25.7 ± 19.5 min). Stricture was confirmed by POCS in 38 patients (93 %) treated with balloon dilation (2), biliary stent(s) (7) or both (28), or with percutaneous drainage (1). Three patients without POCS-confirmed stricture had an angulated duct (2) or a cast (1). POCS influenced patient management in 26 (63 %), and diagnosis in 19 patients (46 %). POCS-guided selective guidewire placement was achieved in 12 cases (29 %) that failed during ERCP. No POCS-related SAEs were reported.

Conclusions: When added to standard-of-care ERCP, POCS showed diagnostic value and helped change patient management in over 60 % of patients, with no POCS-related adverse events. The greatest impact was in visual enhancement and facilitating guidewire access to the donor ducts.

Abbreviations: ERCP, endoscopic retrograde cholangiopancreatography; LT, liver transplant; MRI, magnetic resonance imaging; POCS, peroral cholangioscopy; SAEs, serious adverse events.

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https://doi.org/10.1016/j.liver.2025.100259
Received 23 September 2024; Received in revised form 30 December 2024; Accepted 19 January 2025
Available online 21 January 2025

Introduction

The first successful human liver transplant (LT) was reported in 1967 in the United States [1]. Since then, LT has rapidly evolved, becoming the standard therapy for acute or chronic liver failure of different etiologies, with >80,000 procedures performed by the year 2015 [2]. With advances in surgical techniques, postoperative care, immunosuppression, and antiviral therapy, significant progress in the survival of these patients is reported, reaching 96 % at 1 year and 71 % at 10 years [3].

Biliary complications are a significant cause of morbidity in the short and long term after LT, with an estimated incidence between 10 and 15 % in recipients of deceased donor livers and 15 to 30 % in recipients of living donor livers [4]. With the associated mortality of approximately 10 % of these patients, rapid identification and treatment play an important role in graft maintenance and overall survival [5].

Among the most common biliary complications in living and deceased donor LT are biliary strictures, which may be anastomotic and non-anastomotic [6]. Traditionally, endoscopic retrograde cholangiopancreatography (ERCP) is the method of choice in the management of these patients. Cholangioscopy had not been routinely used in these patients due to the numerous disadvantages of older devices, such as high cost, limited availability of accessories, and the need for two experienced operators for the procedure [7]. Initial experience of fiberoptic cholangioscopy in LT strictures was previously described by in a small series by Balderramo et al. [8]. Two distinct visual patterns were described: Type A (scarring and mild erythema) and Type B (erythema/edema with sloughing and/or ulceration). These patterns provided diagnostic information that helped predict the outcomes of endoscopic therapy in patients with biliary strictures after LT.

Cholangioscopy has become an established modality for the diagnosis and management of hepatobiliary diseases, especially after the introduction of a new cholangioscopy system in 2007 with crucial improvements in visualization and technical tools, followed by a high-resolution fully single-use cholangioscope in 2015 that enabled high-definition imaging of bile ducts. The wide range of potential indications and therapeutic procedures for the newer cholangioscopes, such as diagnosis of indeterminate biliary strictures, lithotripsy of bile duct stones, ablative techniques for intraductal malignancies, removal of foreign bodies, and gallbladder drainage, have led to more widespread use [9–11].

With the evolution of devices and accessories and greater experience of endoscopists with the procedure, interest in the use of cholangioscopy for the management of biliary complications after LT has grown [8]. Studies evaluating the topic have been limited to small retrospective case series. Balderramo et al. and Hüsing-Kabar et al. showed that cholangioscopy was safe and feasible in LT recipients with biliary complications and offered useful diagnostic information in addition to ERCP [12]. However, there was no specific evaluation of the clinical impact of these strictures.

This study aimed to demonstrate the clinical utility of POCS in cadaveric donor or live donor LT patients referred for ERCP in the setting of a clinical suspicion of post-liver transplant bile duct stricture (s).

Materials and methods

Study design

This was an international, multicenter, prospective study at 5 tertiary centers (2 in the US, 1 in Brazil, 1 in Spain, and 1 in the Netherlands). Ethical approval for this study (IRB Registration Number: IRB00000790) was provided by Chesapeake IRB (now Advarra), Columbia, Maryland, USA on September 5, 2017. All research was conducted in accordance with both the Declaration of Helsinki and Declaration of Istanbul and was approved by the local ethics committee at each participating center. All patients gave prior written informed consent.

Study participants

Patients who were at least one-month post-LT and were referred for evaluation of a potential biliary stricture based on abnormal imaging and/or abnormal liver function tests were included. The diameter of bile ducts had to be sufficient to accommodate the cholangioscope based on baseline imaging. Exclusion criteria included those with age under 18 years, who had prior treatment for biliary stricture, had a contraindication for ERCP or POCS per local standard of practice, or documented life expectancy of <12 months.

Index endoscopic procedure

During the procedures, patients received conscious sedation or general anesthesia, according to individual indications, and standard antibiotic prophylaxis was prescribed, according to local protocols. All patients first received ERCP followed by POCS during the same procedure. ERCP was performed using a therapeutic duodenoscope. Cholangioscopy was carried out using a single-operator cholangioscopy device (26 using SpyGlass DS and 15 using SpyGlass DSII; Boston Scientific Corp.). A transplant surgeon at each center was included in the study and asked to review cholangioscopic findings and report significance.

The interventions were performed by endoscopists rated as highly experienced with a case volume above 150 endoscopic biliary interventions/year and with high expertise in single operator POCS. Procedure-related adverse events were evaluated according to the ASGE guidelines. All procedures were performed between January of 2018 and February of 2021. After the index endoscopic procedure, follow-up visits were performed at 72 H (± 1 Day), 30 Days (± 10 Days), 3 Months (± 30 Days) and 12 Months (± 30 Days).

Interpretation of ERCP findings

Strictures were determined as an abrupt narrowing of the bile duct with delayed outflow of contrast medium through the stricture. Bile duct strictures were fluoroscopically subdivided into anastomotic strictures at the site of biliary anastomosis and non-anastomotic strictures. Bile duct stones and biliary cast were evident as intraluminal filling defects of contrast media.

Interpretation of cholangioscopy findings

Strictures were determined as above and were visible as an abrupt substantial narrowing of the duct compared with the distal and proximal segments of the bile duct. The characteristics of the biliary anastomotic strictures were described according to the patterns (Type A and Type B) previously described by Balderramo et al. [8]. Biliary cast was determined as dark smooth foreign bodies mostly adhering to the bile wall, whereas stones are distinct from the bile duct wall and either free-floating or adherent to the wall.

Endpoints

The primary endpoint was the clinical impact of the addition of POCS to same-setting ERCP on the recommended management of post-LT biliary adverse events. Secondary endpoints included: impact of POCS on diagnosis, surgeon's report of whether POCS impacted patient management post procedure and the rate of serious adverse events (SAEs) related to the POCS procedure.

Statistical analysis

Binary variables were analyzed using proportions along with exact

confidence intervals, for select endpoints. Continuous variables were analyzed using means and standard deviations (SD). All analyses were performed using SAS version 9.4.

Results

Forty-one patients underwent an ERCP procedure with intended addition of POCS for the management of post LT strictures were included in the analysis, with an average age 51 ± 11.2 years and including 27 (65.9 %) men. Thirty-six (87.8 %) patients were recipients of deceased donor livers, and 5 (12.2 %) were recipients of living donor LT. Procedures were carried out after a mean of 27.6 ± 44.2 months post-LT. The patient's clinical and demographic data, their primary underlying disease, as well as characteristics of the transplantation and indication for ERCP, are shown in Table 1.

Most of the patients had preprocedural imaging findings (MRI in 29 [70.7 %], ultrasound in 10 [24.4 %], CT in 5 [12.2 %]) that justified endoscopic evaluation. Fourteen patients (34.1 %) had no symptoms at the beginning of the study; these patients were evaluated because abnormal liver enzymes and imaging consistent with biliary stricture were considered as indications for ERCP to confirm diagnosis and therapy of biliary strictures after LT. The remaining 27 patients had one or more (mean 1.2 ± 1.2) symptoms of biliary obstruction (jaundice, itching, fatigue, right upper quadrant pain, dark urine, fever/chills, pale stools, nausea/vomiting or loss of appetite). Elevated serum liver enzymes were present in a total of 30 (73.2 %) patients at baseline and were a clinical criterion for suspicion of organ rejection in 19 (46.3 %) patients.

Table 1
Baseline characteristics.

	Mean ± SD or% (n/N)
Age	51.0 ± 11.2
Male	65.9 % (27/41)
Baseline total serum bilirubin (mg/dl)	3.4 ± 4.6
Baseline serum alkaline phosphatase (IU/L)	375.7 ± 367.5
Medical conditions	
Diabetes	31.7 % (13/41)
Hypertension	19.5 % (8/41)
Cancer	19.5 % (8/41)
Kidney disease	19.5 % (8/41)
Respiratory disease	14.6 % (6/41)
Anemia	12.2 % (5/41)
Thyroid disease	9.8 % (4/41)
Inflammatory bowel disease	4.9 % (2/41)
Gastroesophageal reflux disease	4.9 % (2/41)
Tuberculosis	4.9 % (2/41)
DVT or blood clotting disease	2.4 % (1/41)
Rheumatoid arthritis	2.4 % (1/41)
Other	31.7 % (13/41)
Surgical History	
Gallbladder surgery	19.5 % (8/41)
Hernia repair	17.1 % (7/41)
Appendectomy	12.2 % (5/41)
Thyroid surgery	4.9 % (2/41)
Stent placement	2.4 % (1/41)
Other	46.3 % (19/41)
Time since transplant (months)	27.6 ± 44.2
Donor type	
Living donor	12.2 % (5/41)
Cadaveric donor	87.8 % (36/41)
Reason for liver transplant	
Alcoholic cirrhosis	36.6 % (15/41)
Hepatocellular cancer	22.0 % (9/41)
Hepatitis C	17.1 % (7/41)
Autoimmune hepatitis	14.6 % (6/41)
Primary biliary cirrhosis	9.8 % (4/41)
Cryptogenic cirrhosis	7.3 % (3/41)
Hepatitis B	7.3 % (3/41)
Drug-induced liver injury	7.3 % (3/41)
Acute liver failure	4.9 % (2/41)
Nonalcoholic steatohepatitis	2.4 % (1/41)
Primary sclerosing cholangitis	2.4 % (1/41)
Other	9.8 % (4/41)
Clinical Criteria for Suspicion of Organ Rejection	
Elevated liver function tests	46.3 % (19/41)
Jaundice	12.2 % (5/41)
Other	9.8 % (4/41)

Findings on ERCP

During ERCP, anastomotic strictures (Fig. 1) were observed in 40 (97.6 %) patients, with a main length of 3.8 ± 4.0 mm. No perforations or fistulas were visualized, 8 (19.5 %) had intraductal cast, stone, or debris, 6 (14.6 %) had a tortuous duct, and 9 (22.0 %) had no specific filling defect (Table 2).

Findings on POCS

Cholangioscopy showed anastomotic strictures (Fig. 2A–C, Video 1) in 38 patients (92.7 %), with a mean length of 3.3 ± 3.7 mm. Traversing the stricture with the cholangioscope was technically successful in 20 patients. In the 21 patients in whom the cholangioscope did not transverse the stricture, 18 had balloon dilation or stent placement, 2 had selective guidewire placement and one had a percutaneous drain placed. No patient presented with a perforation or fistula, 12 (29.3 %) had intraductal cast, stone, or debris, 3 (7.3 %) had a tortuous duct. The addition of POCS led to an increase of 25.7 ± 19.5 min, totaling a mean procedure time of 72.9 ± 27.6 min.

The performance of cholangioscopy also allowed the adequate evaluation of the biliary tract mucosa. Type A pattern was observed in 71.1 % (27/38) and Type B in 28.9 % (11/38) (Table 2). Specifically, epithelial sloughing was visualized in 5 (12.2 %) cases, ulceration in 9 (22.0 %), erythema in 16 (39 %), inflammation in 8 (19.5 %), pallor in 13 (31.7 %), fibrosis in 22 (53.7 %), friability in 15 (36.6 %), protruded sutures in 11 (26.8 %), and protruded staples in 5 (12.2 %). A difference between donor and recipient epithelium was noticed in 5 patients (12.2 %).

Impact of addition of POCS on clinical management and diagnosis

In most cases, investigators reported that the clinical impact of POCS

Fig. 1. ERCP image of anastomotic stricture.

Table 2
ERCP and cholangioscopy findings.

	Mean ± SD or% (n/N)	
	ERCP	POCS
Cholangiographic/Cholangioscopic Findings		
Stricture	97.6 % (40/41)	92.7 % (38/41)
Anastomotic	100.0 % (40/40)	100.0 % (38/38)
Length of stricture (mm)	3.8 ± 4.0	3.3 ± 3.7
Possible to cross stricture with cholangioscope	N/A	52.6 % (20/38)
if no, was scope passed to donor duct	N/A	33.3 % (6/18)
Difference between donor and recipient ducts	N/A	25.8 % (8/31)
Focal	97.4 % (38/39)	100.0 % (38/38)
Concentric	90.0 % (36/40)	84.2 % (32/38)
Pattern		
A (mild erythema, scarring)	N/A	71.1 % (27/38)
B (severe edema, severe erythema)	N/A	28.9 % (11/38)
Borders of anastomosis regular	N/A	78.9 % (30/38)
Perforation/fistula	0.0 % (0/41)	0.0 % (0/41)
Intraductal cast/stone/debris	19.5 % (8/41)	29.3 % (12/41)
Filling defect	22.0 % (9/41)	9.8 % (4/41)
Mural lesion	0.0 % (0/41)	0.0 % (0/41)
Tortuous duct	14.6 % (6/41)	7.3 % (3/41)
Epithelial sloughing	N/A	12.2 % (5/41)
Ulceration	N/A	22.0 % (9/41)
Erythema	N/A	39.0 % (16/41)
Inflammation	N/A	19.5 % (8/41)
Pallor	N/A	31.7 % (13/41)
Fibrosis	N/A	53.7 % (22/41)
Mucosal changes – friability	N/A	36.6 % (15/41)
Sutures impacting/protuding bile duct	N/A	26.8 % (11/41)
Staples impacting/protruding bile duct	N/A	12.2 % (5/41)
Visualized difference between donor and recepient epithelium	N/A	12.2 % (5/41)
Other	12.2 % (5/41)	24.4 % (10/41)
Mean number of findings	0.7 ± 0.9	3.3 ± 1.9
Area of interest able to be visualized	95.1 % (39/41)	95.1 % (39/41)

ERCP endoscopic retrograde cholangiopancreatography POCS peroral cholangioscopy.

was enhanced visualization or new visual findings that provided guidance for an ERCP maneuver (Table 3). For example, in 32 (78.0 %) cases, investigators reported that POCS had an impact on patient management to decide whether or not a stent should be placed, to check stent placement, or to pass a guidewire that made stent placement possible. ERCP-guided biopsy was performed in two (4.9 %) patients, and Spyglass-guided biopsy was performed in 8 (19.5 %) patients.

Endoscopists reported that the addition of POCS had an impact on clinical management in 26 patients (63.4 %; 95 % CI 46.9 %–77.9 %), specifically by providing improved or new visual findings (10), allowing selective guidewire placement (after failed passage > 5 min) (6), diagnosis confirmation (4), determining whether surgery/percutaneous drainage was needed (4), or providing biopsy samples (2). The endoscopists reported that POCS impacted the diagnosis in 19 patients (46.3 %; 95 % CI 30.7 %–62.6 %) for similar reasons (visual findings in 14, biopsies in 4, determining whether percutaneous drainage was needed in 1). POCS-guided selective guidewire placement was achieved in 12 (29 %) cases in whom it had not succeeded under ERCP, and in these cases, the procedure avoided percutaneous drainage.

Transplant surgeons deemed the information gained from POCS to be helpful in 23/39 (59.0 %, 95 % CI 42.1 %–74.4 %) patients because of improved or new visual findings (12), determining whether surgery/percutaneous drainage was needed (8), or allowing biliary drainage (3).

Of note, the endoscopist's assessment of POCS' clinical utility sometimes differed from the surgeon's assessment on the same case. For example, the 4 patients for whom the treating endoscopist assessed POCS as useful in determining whether surgery/percutaneous drainage was needed did not overlap with the 8 patients for whom the treating surgeon assessed POCS as useful in determining whether surgery/percutaneous drainage was needed. In 2 of the 4 patients designated by the endoscopists and one of the 8 patients designated by the surgeons, the surgeon/endoscopist on the same case reported that POCS was not useful in clinical management.

Serious adverse events

There were no SAEs related to POCS procedure and only 2 (4.9 %; 95 % CI 0.6 %–16.5 %) of the 41 patients in the study experienced adverse events. One case of acute pancreatitis occurred one day after procedure. The patient was treated medically and recovered without sequalae after 16 days. One case of cholangitis occurred on day 80 after sludge developed in the stent placed at the index procedure and was managed with standard repeat ERCP. The patient recovered without sequalae 4 days later.

Discussion

In this study, endoscopists reported the addition of POCS to ERCP influenced clinical management or diagnosis in patients with a history of LT. Unique to this study is understanding how the information gained during the exam was helpful to the transplant surgeons. Transplant surgeons also considered the POCS information to be helpful. The overall incidence of SAEs was low, and none were related to POCS.

Endoscopic techniques have widely replaced more aggressive percutaneous and surgical approaches to treat biliary adverse events after LT and are important for the reduction of morbidity and mortality in these patients [13]. Digital POCS has been used for guidewire placements in strictures [14–17] in our series it impacted in 29 % of the cases, in which standard ERCP had failed. It was also important for the investigation of ischemic ducts and subsequent cast syndrome, biliary duct inflammation, infections, and other abnormalities [18–20]. As an example, in our study, more cases of cast could be identified using cholangioscopy, allowing exclusion of 2 preliminary diagnoses of stricture on ERCP. Anastomotic features as well as bile ducts of the transplanted liver could be visualized; this combined with clinical status and lab tests provided surgeons with clinically important information to support decision-making in patient management.

Posttransplant patients experience delayed healing due to elevated levels of immunosuppressants during the early postoperative period. An illustration of this phenomenon is the extended need of waiting period of 6 months, as opposed to the standard 1 month for non-transplant patients, before the removal of a surgical biliary drain. This precaution is taken to mitigate the risk of choleperitoneum.

Additionally, the transplanted liver hardly ever matches precisely in size and position with the native organ. Consequently, the biliary duct often undergoes torsion or kinking before and after anastomosis, and the ducts present variable sizes, thereby posing a consistent challenge

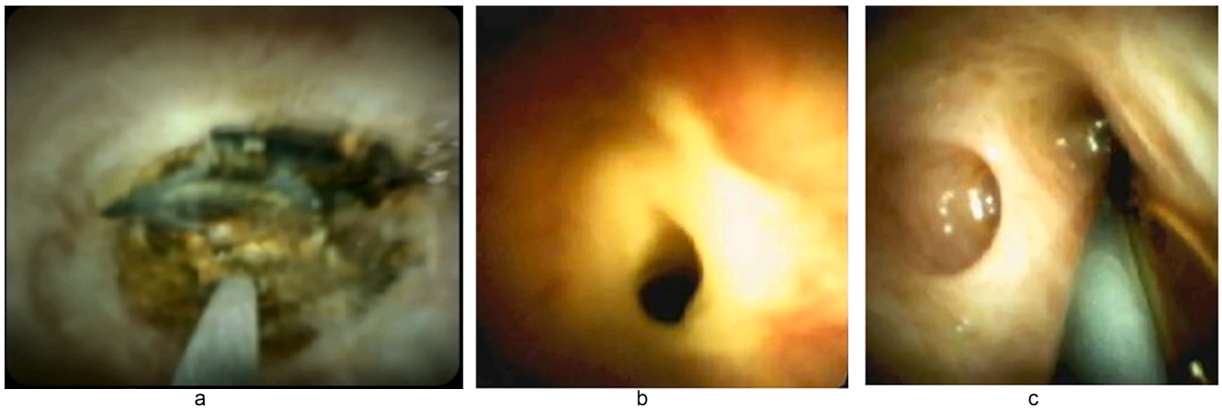

Fig. 2. (A) Cholangioscopy image showing stenosis with cast. (B) Cholangioscopy image showing narrow stenosis. (C) Cholangioscopy image showing stenosis with guidewire.

Table 3
ERCP and POCS maneuvers performed during the study procedures.

	ERCP	POCS	Either ERCP or POCS
Maneuvers performed			
None	4.9 % (2/41)	4.9 % (2/41)	9.8 % (4/41)
Selective guidewire placement	29.3 % (12/41)	51.2 % (21/41)	58.5 % (24/41)
Sphincterotomy	87.8 % (36/41)	N/A	87.8 % (36/41)
Pre-cut sphincterotomy	7.3 % (3/41)	N/A	7.3 % (3/41)
Sphincteroplasty	2.4 % (1/41)	N/A	2.4 % (1/41)
Balloon dilation	39.0 % (16/41)	61.0 % (25/41)*	75.6 % (31/41)
Stent placement	43.9 % (18/41)	78.0 % (32/41)**	90.2 % (37/41)
Removal of cast/debris/stone	9.8 % (4/41)	17.1 % (7/41)	24.4 % (10/41)
ERCP-guided biopsy	4.9 % (2/41)	N/A	4.9 % (2/41)
Spy-guided biopsy	N/A	19.5 % (8/41)	19.5 % (8/41)
Brushing	2.4 % (1/41)	0.0 % (0/41)	2.4 % (1/41)
Other	9.8 % (4/41)	4.9 % (2/41)	12.2 % (5/41)

ERCP endoscopic retrograde cholangiopancreatography POCS peroral cholangioscopy.

* Written comments stated that in these cases, POCS was used to help decide whether balloon dilation was needed or to guide dilation.

** Written comments stated that in these cases, POCS was used to help decide whether or not a stent should be placed, to check stent placement, or to pass a guidewire that made stent placement possible.

during post-transplant ERCP. Even one month after the transplantation procedure, transplant surgeons and endoscopists exhibit apprehension regarding potential damage to the biliary anastomosis during ERCP. Another critical consideration is the frequent omission of reporting the inclusion or not of the cystic duct from the graft in the biliary anastomosis to the endoscopist. This omission increases the risk during the manipulation and perforation of the cystic duct during wire progression without direct visual confirmation. Peroral cholangioscopy (POCS) emerges as a viable solution for such issues, particularly in the early postoperative phase. The reported series have demonstrated the absence of perforation or anastomosis disruption, confirming the safety of employing POCS in these cases.

In approximately 60 % of the cases, endoscopists reported that cholangioscopy impacted patient management, and in a similar proportion, surgeons reported POCS images to be helpful in our study. These findings are consistent with published studies of POCS in LT patients, most of which are small or retrospective [8,12,14,15,19–21]. A recent single center prospective study, focused on recipients of living donor livers, demonstrated the high importance of POCS for selective guidewire placement in those patients as well as proposed a stricture inflammatory based classification [22]. While results are encouraging, a randomized trial or large prospective comparison study of longitudinal outcomes in LT patients who have ERCP with POCS versus ERCP alone are lacking to support routine POCS use. Total procedure time is longer when POCS is added, which might increase the risk of procedure-associated adverse events, especially in complicated cases where POCS identifies many lesions. The extra personnel and equipment necessary for POCS may be costly at smaller centers. Additional prospective data at sites that can support POCS are needed before expanded use is considered.

We acknowledge strengths and limitations of our study. This was a multicenter prospective study of modest size compared to the few studies currently published. Five medical centers in 4 countries were represented, and both cadaveric donor and live donor LT patients were included. The study lacked a control group, so results cannot be compared to usual care. The endoscopists were highly experienced, practicing at high-volume endoscopy centers with trained support staff. Their results may not be generalizable to less-experienced operators at smaller centers. Because endoscopists were not asked to link POCS findings to subsequent endoscopic maneuvers, the influence of POCS on clinical management could not be measured. Most of the investigators have received support from the sponsor, which could create bias in their subjective ratings of the clinical impact of the study device. Finally, we acknowledge there was not cost-effective analysis given that the addition of POCS increases the cost of the procedure. A future cost-effectiveness study regarding the use of POCS needs to be considered in order to justify the expense.

In conclusion, the addition of POCS to ERCP in patients with past LT was reported to be clinically relevant by both endoscopists and transplant surgeons. No POCS-related serious adverse events were seen over 12 months of follow-up. The clinical value and long-term safety should be evaluated in future controlled studies.

Funding

This work was supported by Boston Scientific Corporation.

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).

CRediT authorship contribution statement

Tomazo Franzini: Writing – review & editing, Writing – original draft, Data curation, Conceptualization. **Eduardo G.H. De Moura:** Writing – review & editing, Conceptualization. **Andres Cardenas:** Writing – review & editing, Writing – original draft, Conceptualization. **Adam Slivka:** Writing – review & editing. **Jan-Werner Poley:** Writing – review & editing. **Georgios I. Papachristou:** Writing – review & editing. **Mordechai Rabinovitz:** Writing – review & editing. **Marco Bruno:** Writing – review & editing. **Joyce A. Peetermans:** Writing – review & editing, Writing – original draft, Funding acquisition, Conceptualization. **Matthew J. Rousseau:** Writing – review & editing, Writing – original draft, Formal analysis, Data curation. **Wellington Andraus:** Writing – review & editing. **Jean C. Emond:** Writing – review & editing. **Amrita Sethi:** Writing – review & editing, Writing – original draft, Data curation, Conceptualization.

Declaration of competing interest

Tomazo Franzini: consultant for Boston Scientific

Eduardo G. H. De Moura: consultant for Boston Scientific

Andres Cardenas: is a consultant for Mallinckrodt Pharmaceuticals, Boston Scientific Corp, Shionogi Inc, SOBI, B. Braun and has participated on Advisory Boards for Mallinckrodt Pharmaceuticals and SOBI and has received grant support by Mallinckrodt and Boston Scientific Corp.

Adam Slivka: research support for IRB-approved studies from Boston Scientific and Olympus

Jan-Werner Poley (past 3 years) consultancy for Cook Endoscopy, Boston Scientific, Pentax Medical, Mediglobe

Georgios I. Papachristou: None

Mordechai Rabinovitz: None

Marco Bruno: Boston Scientific – consultant, support for industry and investigator initiated studies; Cook Medical – consultant, support for industry and investigator initiated studies; Pentax Medical – consultant, support for investigator initiated studies; Mylan – support for investigator initiated studies; InterScope – support for investigator initiated studies; ChiRoStim –support for investigator initiated studies.

Joyce A. Peetermans: full-time employee of Boston Scientific Corporation

Matthew J. Rousseau: full-time employee of Boston Scientific Corporation

Wellington Andraus: None

Jean C. Emond: None

Amrita Sethi: receives consulting fees from Boston Scientific, Interscope, Medtronic, Olympus; research funding from Boston Scientific, ERBE, Fujifilm; on Advisory Board for Endosound.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.liver.2025.100259.

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