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ORIGINAL ARTICLE

Evaluating the yield of digital single operator cholangioscopy in posttransplant biliary strictures after unsuccessful guidewire placement with ERCP

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Key words
biliary stricture, cholangioscopy, endoscopic retrograde cholangiopancreatography, liver, percutaneous transhepatic cholangiography, spyglass, transplant.

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Abstract

Background and Aims: Strictures are the most common biliary complication after liver transplantation, and endoscopic retrograde cholangiopancreatography (ERCP) is considered the gold standard in its management. Failure to cross the biliary anastomosis requires a repeated attempt with ERCP, referral for percutaneous transhepatic cholangiography (PTC) or surgery. We present our experience with the digital single operator cholangioscope (D-SOC) in achieving guidewire access in a liver transplant cohort with difficult biliary strictures who have failed conventional ERCP methods.
Methods: This was a retrospective study involving two adult liver transplant centers servicing the two most populated states in Australia. Deceased-donor liver transplant recipients undergoing D-SOC for biliary strictures who have failed conventional methods to achieve biliary access were included.
Results: Between July 2017 to April 2022, eighteen patients underwent D-SOC after failing to achieve guidewire placement through standard ERCP techniques. Thirteen out of eighteen (72%) had successful guidewire placement with index D-SOC. Five of eighteen patients (28%) had unsuccessful guidewire placement with D-SOC. In two of these patients, use of D-SOC informed further endoscopic management, with one avoiding PTC and the other avoiding surgery. Two of the five patients required PTC and one patient was left unstented. Three patients developed post D-SOC cholangitis.
Conclusions: D-SOC is effective at achieving guidewire access in post-liver transplant patients who fail conventional ERCP techniques and should be considered in the treatment algorithm as a step before PTC and surgery.

Background and aims

Despite the many advancements in the management of liver transplantation over the years, bile duct complications remain a significant issue. Strictures are the most common post-transplant biliary complication[1] and account for up to 40% of all biliary complications.[2] Biliary strictures can be classified as either anastomotic strictures (AS) or non-anastomotic strictures (NAS). AS occur at the site of the anastomosis typically within the first year after transplantation. NAS occur when there is one or more focal area of bile duct narrowing typically proximal to the biliary anastomosis.[3]

Endoscopic management of biliary strictures via endoscopic retrograde cholangiopancreatography (ERCP) is considered gold standard and involves guidewire placement access across a stricture followed by biliary stenting and/or stricture dilatation.[4] This can only be achieved after a guidewire has successfully passed through the stricture which may be difficult due to significant fibrosis, stenosis, and angulation of the anastomosis in the post-liver transplant patient.[5] The rate of successful endoscopic treatment in post-transplant biliary strictures is highly variable and ranges from 31% to 100%[6] with up to 9% failing to traverse the stricture.[7] There is currently no standardized guideline for the management of anastomotic strictures; however, treatment with ERCP is preferred as it is effective and less invasive compared with percutaneous transhepatic cholangiography (PTC) and hepatobiliary surgery. If ERCP is unable to gain access across a biliary stricture, PTC is typically required to gain access to the biliary system through percutaneous ports created by an interventional radiologist.[4] A hybrid rendezvous model utilizing both ERCP and PTC platforms has increasingly

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been shown to be safe and successful at facilitating biliary drainage.[8] Failing this, surgical intervention is usually required as a last resort as it is associated with significant morbidity and mortality.

The advent of the Spyglass (Boston Scientific Corporation, Marlborough, USA) digital single operator cholangioscope (D-SOC) system has expanded the diagnostic and therapeutic options that can be achieved via ERCP. There have been several case studies and series demonstrating the use of cholangioscopy in achieving guidewire placement across biliary strictures.[7,9–15] Bokemeyer et al. demonstrated 70% success rate in guidewire placement among 23 patients who had biliary strictures of all etiologies, including non-transplant patients.[9] Yu et al. analyzed the use of D-SOC in 19 post-liver transplant patients with clinical features of biliary stricture but only utilized D-SOC for guidewire placement in four patients who failed standard ERCP modalities.[11] Recognizing the potential for D-SOC and the paucity of literature within the liver transplant cohort, we aimed to evaluate the technical success and safety of D-SOC at achieving guidewire access among patients with difficult post-transplant biliary strictures that have failed conventional ERCP methods.

Patients and methods

Study design. This is a retrospective case series conducted at two tertiary centres in Australia. Austin Health and Royal Prince Alfred Hospital (RPA) are the sole adult liver transplant centres for the states of Victoria/Tasmania and New South Wales respectively. This study was approved by the local ethics committee and the human research ethics committee (HREC/84316/Austin-2022).

Participants. Post-liver transplant patients ≥18 years of age who underwent D-SOC between 2017 and 2022 after failure to cross biliary stricture with a standard guidewire were included. All eligible patients were deceased-donor liver transplant recipients with duct-to-duct biliary anastomosis. Only cases where cholangioscopy was attempted after failure to cross the stricture with conventional modalities were included in our study. Patients were excluded if the use of D-SOC was done for reasons other than biliary strictures.

Procedure details. All procedures were performed by four expert endoscopists, each with over 10 years of experience performing ERCPs within the two largest transplant centres in Australia. ERCPs were performed with a side-viewing duodenoscope (TJF-Q190V, Olympus®, America), and the decision to utilize Spyglass DS™ D-SOC platform was made by the endoscopist after conventional methods to place a guidewire through the biliary stricture had failed. All patients underwent deep sedation under the care of anesthesiologists with the use of intravenous propofol, with or without benzodiazepine and/or opioids.

Outcome measures. The primary outcome was the technical success of achieving guidewire placement across a biliary stricture under direct visualization on index D-SOC. The secondary outcome was the rate of complications following D-SOC including cholangitis, pancreatitis, perforation, and bleeding. Post-ERCP pancreatitis was defined according to the Atlanta Classification[16] as the presence of two out of the following three criteria: (i) abdominal pain consistent with acute pancreatitis; (ii) serum lipase more than three times the upper limit of normal; (iii) characteristic findings of acute pancreatitis on cross-sectional abdominal imaging. Post procedure bleeding was defined as evidence of hematemesis and/or melaena, or a drop in hemoglobin by ≥20 g/L. Cholangitis was defined as new onset of fever >38°C for more than 24 h combined with cholestasis; and perforation was defined as evidence of gas or luminal contents outside of the gastrointestinal tract on imaging.[17]

Statistical analysis. Data analysis was performed with IBM SPSS Statistics 28.0. Categorical data are summarized as frequency and percentages, and continuous data are summarized as

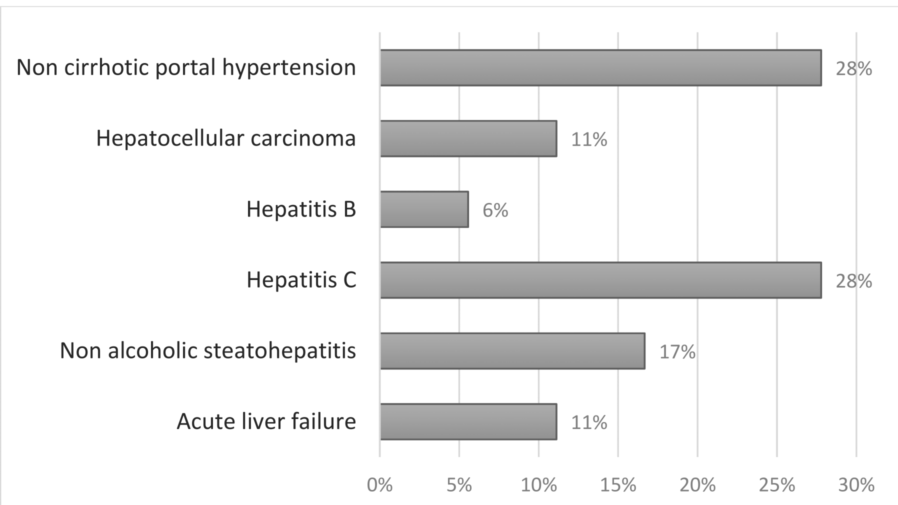

Figure 1 Transplant indications.

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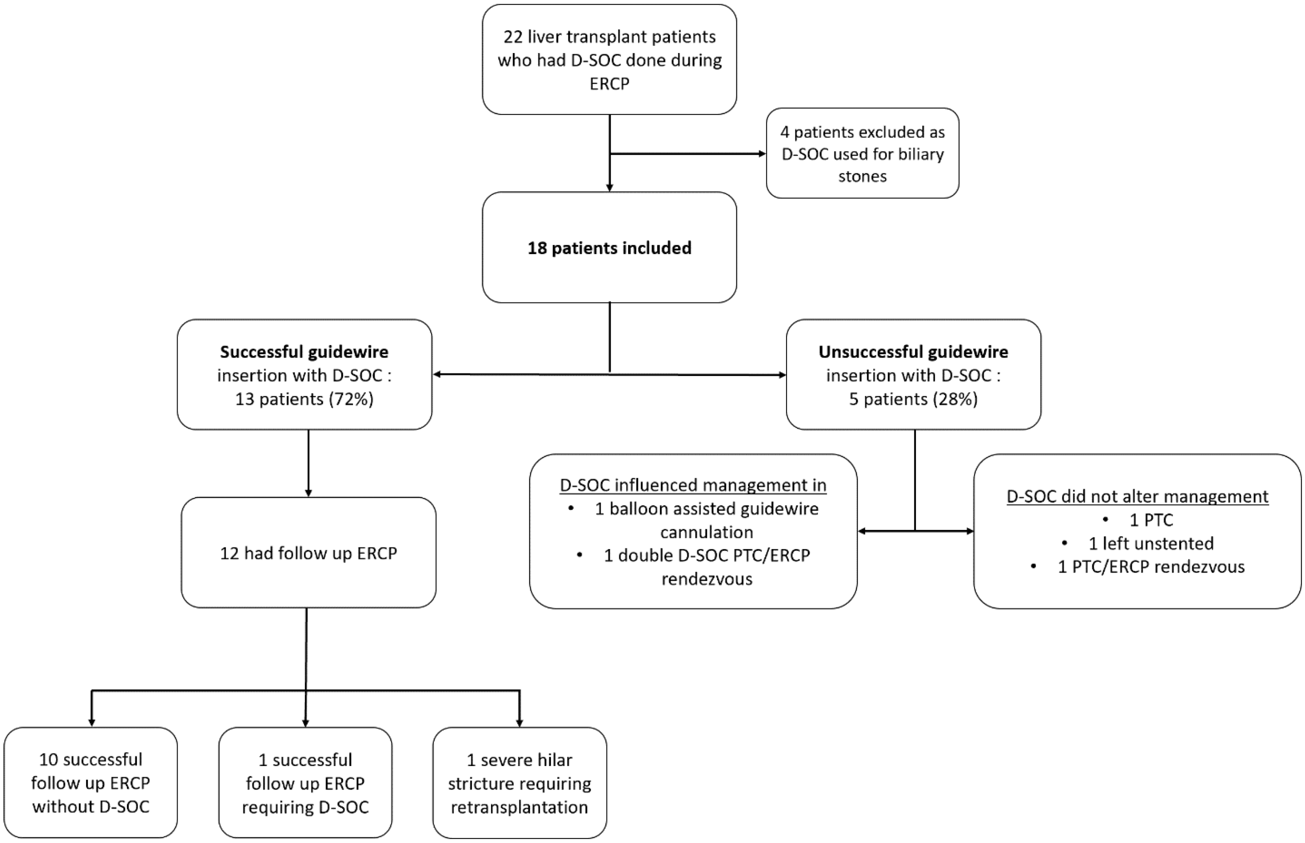

Figure 2 Flow chart and patient outcomes.

mean ± standard deviation (SD) or median with interquartile range (IQR).

Results

Patient characteristics. From July 2017 to April 2022, 22 post-liver transplant patients had a D-SOC performed (Fig. 2). Four patients had cholangioscopy for the indication of biliary stones and hence were excluded from the study. The remaining eighteen patients had D-SOC for the indication of biliary strictures that failed conventional treatment and were included in our study. Baseline characteristics are summarized in Table 1. Procedures were carried out at a median of 19 months post deceased-donor liver transplantation. Five of eighteen (28%) patients had a known history of post-transplant biliary strictures and were undergoing regular stent exchanges. Two (11%) patients had a history of hepatic artery thrombosis. Indications for liver transplantation are shown in Figure 1. Sixteen of eighteen patients had a previous ERCP, of which 10 patients had biliary stents inserted previously. Thirteen patients (72%) had anastomotic strictures and five (28%) had non-anastomotic strictures. Seven patients (39%) required endotracheal intubation which was determined by the anesthesiologist prior to the commencement of the procedure.

D-SOC outcomes. Thirteen patients (72%) had successful guidewire placement across post-transplant biliary strictures with the use of D-SOC. Two patients had stents inserted without dilatation and eight had both balloon dilatation and stent insertion. Of the three patients that did not require stenting or dilatation, two had difficult angulation across the anastomosis and D-SOC was able to achieve guidewire access via direct visualization. Both patients had balloon sweeping which revealed minimal residual stricture and hence did not require further dilatation or stents. The third patient had a severe ischemic hilar stricture, and D-SOC was only partially successful at accessing the left sided intrahepatic ductal system. This patient subsequently failed to achieve adequate biliary drainage despite both endoscopic and PTC management, and therefore required repeat transplantation.

Patient flow chart and outcomes are summarized in Figure 2. Twelve patients underwent follow up ERCP with ten patients achieving successful biliary access without the need for a repeat D-SOC. One patient required a repeat D-SOC for biliary access, which was successful. The last patient, as described above, had a partially successful spyglass and persistent severe ischemic NAS that eventually required repeat transplantation.

Three patients who had successful biliary access with D-SOC had their repeat ERCP earlier than scheduled; two were due to cholangitis and one due to suspected stent dysfunction. The mean duration of procedure among patients with successful D-SOC assisted guidewire placement was 45 min (IQR 40–50) compared with 82 min (IQR 71–91) for patients who had unsuccessful D-SOC assisted guidewire placement.

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Table 1 Patient characteristics

	n = 18
Age – years (Median, IQR)	59 (50–64)
Female (*n*, %)	10 (56%)
Transplant details	
Age at transplant – years (Median, IQR)	55 (43–60)
Previous history of rejection (*n*, %)	3 (17%)
History of bile leak (*n*, %)	0 (0%)
History of hepatic artery thrombosis (*n*, %)	2 (11%)
History of previous anastomotic stricture (*n*, %)	5 (28%)
Duration between transplant and D-SOC – months (Median, IQR)	19 (15–37)
Pre D-SOC liver enzymes	
Bilirubin – micromol/L (Median, IQR)	19 (12–31)
ALT – units/L (Median, IQR)	56 (26–127)
GGT – units/L (Median, IQR)	338 (209–694)
ALP – units/L (Median, IQR)	372 (221–508)
Post D-SOC liver enzymes	
Bilirubin – micromol/L (Median, IQR)	14 (7–20)
ALT – units/L (Median, IQR)	25 (14–38)
GGT – units/L (Median, IQR)	148 (70–281)
ALP – units/L (Median, IQR)	209 (109–381)
Anesthetic details	
Endotracheal intubation (*n*, %)	7 (39%)
Intravenous propofol (*n*, %)	18 (100%)
Opioids (*n*, %)	11 (61%)
Benzodiazepine (*n*, %)	3 (17%)
Antispasmodics (*n*, %)	3 (17%)
ERCP details	
Anastomotic stricture (*n*, %)	13 (72%)
Non-anastomotic stricture (*n*, %)	5 (28%)
Duration of procedure – minutes (Median, IQR)	50 (44–69)
Intravenous antibiotics (*n*, %)	18 (100%)
Per rectal indomethacin (*n*, %)	2 (11%)

D-SOC was unsuccessful at traversing the stricture of five patients (28%). Four had anastomotic strictures and one had non-anastomotic stricture. Details of all five patients can be found in Table 2. Despite unsuccessful placement of a guidewire, the use of D-SOC positively influenced the management of patients 1 and 2. The use of D-SOC in patient 1 (Table 2) allowed direct visualization of an S-bend which permitted effective maneuverability of the balloon catheter at gaining guidewire access. In patient 2, the novel use of two D-SOC platforms in a rendezvous procedure allowed a controlled perforation under bi-directional cholangioscopic visualization of a completely occluded stricture, successfully creating a new lumen.[18] The use of D-SOC did not alter the management in patients 3 to 5, with patient 3 left unstented, patient 4 proceeding to PTC, and patient 5 proceeding to an ERCP/PTC rendezvous procedure. All five patients avoided surgical intervention for their biliary strictures.

There were three (17%) post D-SOC complications reported. All three patients developed cholangitis 9, 10, and 12 days after ERCP. There were no episodes of post D-SOC pancreatitis, perforation, or bleeding. Mortality rate was 0% at both 30-day and 6-month time periods.

Discussion

Post-transplantation biliary strictures are a heterogenous group of pathologies with variability in their extent, location, and type, which influences the complexity of its management. The availability of direct visualization with D-SOC offers an additional dimension on top of cross-sectional and cholangiogram imaging, and allows a more personalized approach to the diagnostic and therapeutic management of biliary strictures. Our retrospective analysis found multiple benefits for the use of D-SOC in the management of post-liver transplant strictures.

D-SOC allowed successful passage of a guidewire in 72% of patients who had failed conventional ERCP (Fig. 3). These liver transplant patients would have otherwise required a repeat ERCP or further radiological or surgical intervention. Only post-liver transplant patients who had failed conventional ERCP methods received D-SOC and were included in our study. This contrasts with other studies where liver transplant patients were recruited for evaluation with cholangioscopy prior to an attempt with standard ERCP modalities.[11,13,19] Yu et al.[11] and Hüsing-Kabar et al.[19] both included post-liver transplant patients who had clinical or biochemical evidence of a biliary stricture, prior to an attempt with ERCP. Only four patients in each study failed guidewire access during ERCP and had successful guidewire insertion with the use of D-SOC. This differs from our study where we only included patients after they had failed guidewire access with standard ERCP methods. Woo et al.[12] analyzed the rate of cholangioscopy-assisted guidewire placement in 15 living donor liver transplant patients who were unable to traverse a guidewire across a stricture with conventional methods after 10 min. The 60% rate of cholangioscopy-assisted guidewire placement by Woo et al. was likely lower due to their cohort comprising of live donor liver transplantations in addition to the use of an older, lower definition D-SOC available at that time. We utilized the Spyglass DS platform which offers higher resolution compared with its predecessor. Furthermore, our study did not use a duration of time to define failure of standard ERCP technique. Instead, we offer a 'real world' scenario in which it was at the discretion of the endoscopist to utilize D-SOC after all reasonable ERCP methods had been exhausted.

The direct visualization of the biliary tree, biliary stricture, and the presence of bile drainage (Fig. 4) provided information that allowed for a more personalized approach for each patient. Visualization of the S-bend angulation and duct mismatch in patient 1 (Table 2) provided the endoscopist knowledge of the degree of angulation which aided in successful traversing of the stricture with a balloon catheter. Presence of active biliary drainage negated the need for further stents to be inserted and hence avoiding the need for repeated procedures in these patients. The addition of D-SOC provided a more comprehensive assessment of biliary strictures compared with fluoroscopic images alone. This prevented the need for a repeat procedure and stent removal/exchange, which would have likely occurred without the visualization provided by cholangioscopy.

The availability of D-SOC allowed the innovation of a new PTC/ERCP rendezvous with dual access cholangioscopy from both the PTC and ERCP channels. This allowed a controlled perforation to be done under direct visualization, and the formation of a new lumen in a completely occluded anastomotic

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Table 2 Characteristics and outcomes of patients who failed D-SOC guidewire access across biliary strictures

Patient no.	Transplant and D-SOC interval (months)	Previous stenting	Stricture type	Conventional modalities attempted	Findings on D-SOC	Subsequent management	Outcome	Follow up
Patient 1 (64 M)	40	Nil	Anastomotic stricture	Wire and balloon	Marked S-bend, donor and native duct mismatch, stones proximal to stricture	Successful cannulation with balloon catheter device during same ERCP	Plastic stent inserted	Completed stent exchange program and treatment of biliary stones on subsequent ERCP.
Patient 2 (68F)	19	Nil	Anastomotic stricture	Wire	Completely occluded anastomotic stricture	Failed PTC x2. Proceeded to PTC/ERCP rendezvous with double D-SOC	Successful puncture through completely occluded anastomosis with direct view from both sides with double cholangioscope through ERCP and PTC. Dilated and stented	Ongoing stent exchange program
Patient 3 (65F)	30	Previous plastic stents	Hilar non-anastomotic stricture	Wire, balloon	Unable to cannulate left hepatic duct with D-SOC	Nil	Decision made to leave left intrahepatic duct unstented due to improving liver enzymes and clinical status	Completed stent exchange program of right intrahepatic duct. Left intrahepatic duct remained unstented.
Patient 4 (58 M)	19	Previous plastic stents	Anastomotic stricture	Wire, balloon, and sphincterotome	Unable to visualize lumen due to significant angulation of donor duct	PTC and subsequent ERCP	Successful biliary access and dilatation via PTC and internalization of stents 4 weeks after.	Subsequently developed ischemic hilar stricture and successfully treated with stenting program. Nil further cholangioscopy required.
Patient 5 (67F)	2.7	Nil	Anastomotic stricture	Wires, balloon, and sphincterotome	Direct vision of severe anastomotic stricture	PTC/ERCP Rendezvous	Successful dilatation and insertion plastic biliary stent	Completed stent exchange program

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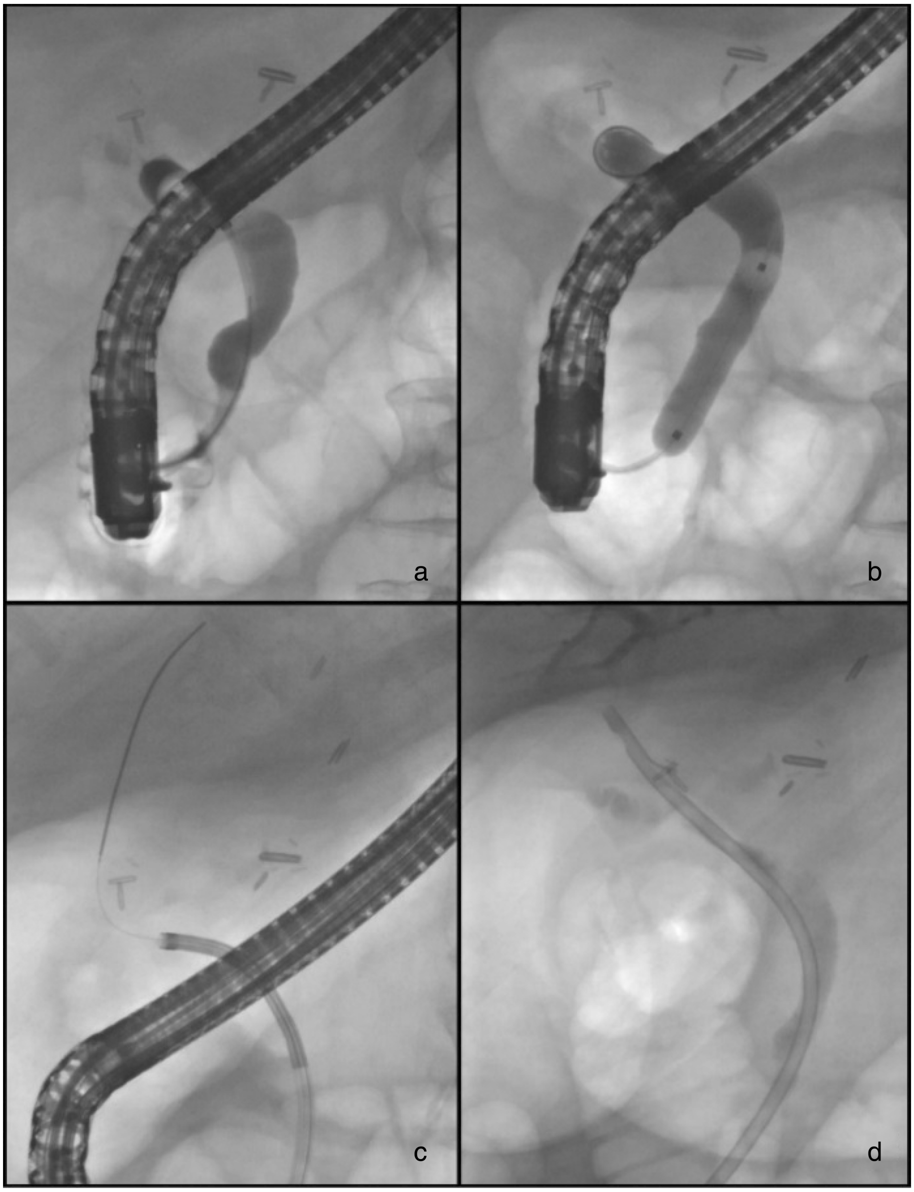

Figure 3 Fluoroscopic images demonstrating successful guidewire cannulation. Identification of stricture (a) with looping of guidewire (b) causing failure to gain access through stricture. After the use of D-SOC, successful guidewire cannulation was achieved (c) with subsequent stent insertion (d).

stricture, avoiding the need for surgical intervention in this patient.[18]

The decision to use D-SOC can be made at the time of ERCP when there is difficulty traversing the stricture with standard techniques. This provided technical success for 72% of our patients who would have otherwise been deemed a failed procedure. This prevented the need for further interventions, reducing the risks to the patient and reducing hospital length of stay and associated healthcare costs. In Australian dollars (AUD), the cost for a standard ERCP procedure with D-SOC is approximately $4500 AUD. In comparison, the cost of a failed ERCP in addition to a repeat ERCP with D-SOC and PTC rendezvous is approximately $7400 AUD. Hence, the successful utilization of same session D-SOC at initial ERCP would have provided a cost reduction of at least $2900 AUD. These figures do not include cost of staff, hospitalization, and opportunity cost.

The overall therapeutic benefit of D-SOC was found in 15 out of 18 (83%) patients as it altered the management for these patients who would have otherwise required further radiological and/or surgical management. This is higher than Hüsing-Kabar et al.'s reported benefit rate of 42% and similar to Yu et al.'s rate of 78.9%. Importantly, both Hüsing-Kabar and Yu et al.[11,19] compared the diagnostic and therapeutic benefits of D-SOC against ERCP within all comers who had a liver

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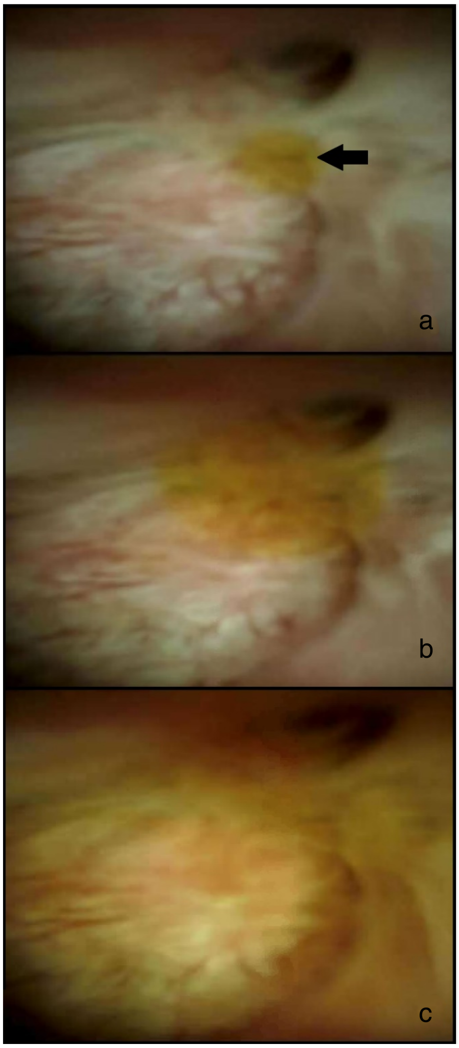

Figure 4 D-SOC images demonstrating a pinhole (Arrow) orifice within an anastomotic stricture. Identification of bile gradually flowing out of orifice through images (a–c) helped identify orifice and allowed successful cannulation.

transplant. Our study focused on the therapeutic yield of D-SOC in achieving guidewire access specifically in the difficult post-transplant biliary stricture cohort. Given the cost and single-use nature of the D-SOC platforms, an understanding of which patient group would benefit from D-SOC is important. Our study demonstrated that the post-liver transplant cohort with proven difficulty in accessing their stricture with standard methods would benefit from same session D-SOC which may mitigate any additional procedural costs. We advocate a treatment algorithm for post-transplant strictures to include the use of D-SOC at the time of ERCP when standard equipment fails at advancing the guidewire through the stricture. This should be considered as a step before radiological and surgical management.

The complication rate in our study was 17% which is consistent with other studies ranging between 7% and 31%.[9,11,20] Of note, all post D-SOC complications within our cohort was from cholangitis and occurred in patients where D-SOC was successful at achieving guidewire access. Our post D-SOC cholangitis rate is similar to the 1–16% post D-SOC cholangitis rate reported in other studies.[20,21] Of note, these studies included patients at lower risk of infection compared with our cohort, with non-transplant patients and patients without difficult biliary access included. Our cohort had a higher risk population as they were immunosuppressed, post-liver transplant patients with complex biliary strictures. In addition to being a high-risk group, the use of D-SOC likely increased the risk of cholangitis due to the use of irrigation and a longer endoscopic time related to the complexity of these patients. Our unit protocol includes the administration of intravenous antibiotic prophylaxis during ERCPs in all liver transplant patients to mitigate this risk.

The main limitation of our study is that this was a retrospective analysis of cases from two centers with a small sample size. Given majority of post-transplant strictures can be accessed with conventional ERCP methods, treatment failure occurs infrequently. In addition, we lack a control group with interventional radiology and/or surgery to perform a head-to-head comparison. Larger prospective trials are required to quantify the added benefit of D-SOC with alternative modalities.

Conclusion

The use of D-SOC is effective at achieving guidewire access across post-liver transplant biliary strictures that have failed conventional ERCP methods. In addition, direct visualization of the biliary tree provides additional information and hence a wider range of personalized therapeutic options prior to referral for PTC and surgery. We suggest the use of D-SOC be included in the armamentarium of endoscopists when faced with a difficult post-transplant biliary stricture.

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