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Utility of cholangioscopy in patients with surgically altered anatomy after percutaneous transhepatic biliary drainage

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Abstract:
Background Surgical therapy that alters the biliary anatomy makes endoscopic access to the biliary system difficult. These surgeries promote cholestasis, calculi development and lead to biliary stricture. Stricture resolution and removal of intrahepatic bile duct stones remain challenging.
Methods This is a retrospective analysis of prospective data of patients with altered surgical anatomy with intrahepatic bile duct stones/strictures. Percutaneous transhepatic biliary drainage (PTBD) was attempted, followed by transhepatic SpyGlass cholangioscopy for stricture or removal of intrahepatic bile duct stones. The number of sessions, stricture dilatation and complications were noted. A cholangiogram revealing a clear duct was a technical success, and stricture resolution was considered a clinical success. Complete ductal clearance was clinical success in those with stones. Patients with follow-up of a minimum of six months were included.
Results Twenty-four patients [16(66.7%) male, median age 41.5(IQR 38.2-49) years] successfully underwent PTBD. The commonest indication was biliary stricture in 13(54.2%), followed by intrahepatic stones in 6(25%) and stones with strictures in 5(20.8%) patients. Most patients had undergone Roux-en-Y hepaticojejunostomy in 22(91.7%), and the level of bile duct obstruction was hilum in 20(83.3%). The median (IQR) total bilirubin levels reduced from 6.6(5.1-8.3) to 1.8(1.2-2.8) mg/dL after PTBD; p<0.001. The technical success was 90.9% after a median (IQR) number of 2(1.7-2) SpyGlass sessions; clinical success was 88.9% after a median of 3(3-4) SpyGlass sessions. Abdominal pain (8.3%) and cholangitis (12.5%) were the complications after cholangioscopy. The median (IQR) follow-up duration was 7(6-8) months.
Conclusions SpyGlass cholangioscopy, although challenging, is a safe option for intrahepatic stones and strictures with excellent short-term outcomes and minimal complications.

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Keywords: Altered anatomy; biliary stricture; percutaneous transhepatic biliary drainage; SpyGlass cholangioscopy

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is the first-line modality for treating bile duct stones and strictures [1]. However, the success varies based on the number, size, location, altered anatomy and number of biliary strictures [2]. Without appropriate treatment, biliary stones and strictures can contribute to cholangitis, liver abscesses, hepatic failure, and sepsis [2,3]. The treatment goal is complete ductal clearance of the stone, stricture resolution, and prevention of cholangitis [2,4]. Multiple intrahepatic stones need cholangioscopy-assisted laser lithotripsy or electrohydraulic lithotripsy to fragment large stones [4]. The common surgically altered anatomy includes hepaticojejunostomy, pancreaticoduodenectomy and Roux-en-Y gastric bypass (RYGB). The proportion of patients with altered surgical anatomy continues to rise, and most of them in the future might need endoscopic interventions. In such patients with a surgically altered anatomy, conventional ERCP may not be feasible or have great success [5,6]. With advances in radiological imaging and the availability of novel endoscopic accessories, there is now scope for endoscopic interventions. The relative incidence of hepatolithiasis could be as high as 38-53.5% in Asia Pacific countries [7,8]. Hepatectomy helps treat hepatoliths, biliary stricture, bile stasis that could lead to stone formation and reduces the risk of cholangiocarcinoma [9]. But it is useful in unilobar hepatolithiasis, preferably in the left lobe. However, in bilobar hepatolithiasis, combined percutaneous transhepatic biliary drainage (PTBD)/endoscopic modalities have been useful [10,11]. PTBD has its own risk of complications and associated morbidity but provides a possibility of treatment. We studied the usefulness of PTBD wherein the tract was dilated, and after sinus tract maturation, the biliary tree was accessed by transhepatic SpyGlass cholangioscopy for treating biliary stricture or intrahepatic stones.

Methods

This is a single-centered retrospective analysis of prospective data of consecutive patients of surgically altered anatomy with intrahepatic stones or strictures from June 2021 to May 2023. The study was approved by the Institutional Ethics Committee (approval number: IEC/OA-24/05). A waiver of informed consent was obtained. Patients of either sex aged >18 years with surgically altered anatomy (Whipple procedure, Roux-en-Y hepaticojejunostomy) who had undergone PTBD for biliary stricture / intrahepatic stones with at least six months of follow-up after the index SpyGlass-DS procedure were included. Patients with incomplete details were excluded. Correction of coagulopathy was allowed before PTBD for study inclusion. All patients underwent routine radiological imaging [magnetic resonance cholangiopancreatography (MRCP) or Computed tomography]. Routine biochemical laboratory investigations included complete blood counts, liver function tests, and blood coagulation profile. Total bilirubin levels had been checked one week after PTBD.

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A skilled interventional radiologist had performed PTBD under strict aseptic precautions and fluoroscopic guidance for a planned approach to the stricture or intrahepatic stones based on MRCP findings (▶Fig. 1a,1b). The preparation time was about 15-20 mins. Vascular access sheath and dilators were kept ready. The preparation was done of the desired PTBD site area. The site was cleaned with betadine and draped. The left lobar lateral segmental biliary duct (segment 3 duct) was accessed with a 22 G Chiba needle (Peter Pflugbeil GmbH Medizinische Instrumente, Zorneding, Germany) and NEFF set (Cook Medical, USA). A cholangiogram was obtained to check hepaticojejunostomy anastomotic site stricture and for isolation from the right lobar ductal system with intrabiliary sludge/ hepaticoliths. The narrowing, if present, was negotiated using a combination of catheter and guidewire followed by balloon cholangioplasty (selected cases) using an 8 mm by 40 mm balloon (ADVANCE Balloon Dilatation Catheter, Cook Medical, USA) for 60 seconds. Then, an 8.5 F internal-external Ring biliary duct drainage catheter (ULT8.5-38-50-P-RING-25.5-MEH-RH, Cook Medical, USA) was inserted into the left lobar biliary system (with its tip in jejunal lumen across the HJ site) over a stiff guidewire after serial dilatation of the tract.

Similarly, the right posterior segmental biliary duct (via segment 5 / segment 6) was accessed, followed by PTBD (external drainage). Bile collected during the procedure was sent for laboratory investigations. Delayed contrast washout was checked. Immediate post-procedure complications were noted. Patients were monitored for puncture site bleeding/ hematoma formation, drain output, vitals, and catheter care. The percutaneous tract was dilated at least four weeks later by exchanging the 8-F catheter for a 12-F catheter. For sinus tract maturation, cholangioscopy with SpyGlass-DS (Boston Scientific, USA) was performed at least six weeks after the initial PTBD.

SpyGlass cholangioscopy

Patients received intravenous Cefotaxime 1,000 mg prior to cholangioscopy. The procedure was performed supine under TIVA. The cholangioscope was advanced over a guidewire (Dreamwire; Boston Scientific, USA) through the PTBD site into the right/left duct. Prior to cholangioscope insertion, a PTBD cholangiogram was obtained; The cholangiogram demonstrated a filling defect, stricture, or both. Holmium laser lithotripsy (Medilas H20; Dornier Medtech, Munich, Germany) was used to fragment the large intraductal stones. Adequate fragmentation was assessed visually [12]. Fragmented stones were pushed across the HJ anastomosis into the jejunum utilizing a balloon catheter. Ballon sweeps were taken, and complete ductal clearance from RHD/LHD was noted. The internal, external right and left

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PTBD catheters were repositioned (▶Fig. 1c-1i). Patients with cholangitis were continued oral antibiotics for five days. In case of HJ anastomotic stricture, dilation was performed using over the wire CRE balloons under fluoroscopic guidance. On cholangioscopy, suspicious strictures were biopsied by SpyBite Max biopsy forceps (Boston Scientific, USA) (Figure 2). Resolution of stricture was noted at follow-up. Under fluoroscopy, a contrast was injected for strictures. If the contrast was visualized as a clear passage through the former stricture site, it was considered a stricture resolution.

If the SpyGlass-DS scope could be properly advanced into the bile duct to allow for visualization, the procedure was deemed successful. The time from the insertion of SpyGlass-DS scope into the cutaneobiliary fistula to reinserting the PTBD catheter was noted. Cholangiography and direct cholangioscopy revealing complete ductal clearance were considered a technical success, and stricture resolution was regarded as a clinical success.

Statistical Methods

Statistical analysis was done by Statistical Package for the Social Sciences [SPSS, version 26.0, Professional (IBM Corporation, NY, USA)] for Windows. Categorical variables are reported as frequency and percentage, while descriptive statistics is used for continuous variables. Wilcoxon signed-rank test was used to compare the pre- and post-total bilirubin levels. Missing data, if any, was assessed by available case analysis. A p-value of $< .05$ was considered significant.

Results

Twenty-four patients successfully underwent PTBD followed by SpyGlass cholangioscopy for intrahepatic stone removal/ stricture dilation. Their median age was 41.5[Interquartile range (IQR) 38.2-49] years, the majority were 16(66.7%) males (▶Table 1). The commonest indication was biliary stricture in 13(54.2%), followed by intrahepatic stones in 6(25%) and stones with strictures in 5(20.8%) patients. Most patients had undergone Roux-en-Y hepaticojejunostomy in 22(91.7%), and the level of bile duct obstruction was hilum in 20(83.3%). The median (IQR) total bilirubin levels reduced from 6.6(5.1-8.3) to 1.8(1.2-2.8) mg/dL after PTBD; $p<0.001$. The median total procedure time for SpyGlass was 46.5(43.2-51.7) minutes. Laser lithotripsy was used for stone fragmentation in all the cases. The majority had one duct PTBD catheter; three patients had bilobar PTBD catheter.

The technical success was 90.9% after a median (IQR) number of 2(1.7-2) SpyGlass sessions; clinical success was 88.9% after a median of 3(3-4) SpyGlass sessions. In patients with stricture, serial dilations were done using CRE balloon up to 12-15mm (median of 3 sessions);

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maximum dilations achieved up to 15mm. Out of 18 strictures, none of the specimens were malignant. The median (IQR) number of stones was 4 (3.2 - 5) and the stone size was 15 mm (IQR 14-16). The etiology of disease did not impact stone clearance. No recurrence of stones was noted at follow-up. Abdominal pain (8.3%) and cholangitis (12.5%) were the complications after cholangioscopy, which ultimately resolved conservatively. The median (IQR) follow-up duration was 7(6-8) months (▶Table 2).

Discussion

SpyGlass cholangioscopy with PTBD in patients with altered anatomy is safe and effective for large bile duct stones, which otherwise would require surgical intervention. The advantages of PTBD are that bile ducts can be easily accessed in patients with altered surgical anatomy, and large stones can be removed with laser lithotripsy, strictures can be dilated. The disadvantages include prolonged hospitalization, cost factor, need for multiple sessions, pain, tube drop out, additional bile duct injuries and hemorrhage [13].

The present study showed a success rate of 90.9%, comparable to previous studies [14,15]. The positive outcomes in our study might be attributable to the fact that laser lithotripsy is more effective than EHL in treating impacted biliary tract calculi [16]. Patients did not have skin site infections because good skin care hygiene was maintained. But few patients complained of mild catheter discomfort, which gradually resolved. Hemobilia, cholangitis, bacteremia, catheter migration, catheter blockage, and bile duct injury (perforation) have been documented. After PTCS, adequate biliary drainage is necessary to lower the risk of cholangitis [17] which occurred in 6% of patients in one series [18]. PTC tracts must be allowed to mature and gradually dilated to lower the risk of complications. The sheath size for PTCS affects the tract maturation time. Tract maturation duration for 8-10F access sheaths used in mechanical lithotripsy without video cholangioscopy can be as short as ≤ 4 days [15,19]. The tract maturation time is longer for 16–18F working sheaths utilized in video cholangioscopy-guided procedures and can reach up to 6 weeks. After the maturation of a cutaneobiliary fistula, cholangioscopic procedures rarely cause serious complications. The percutaneous cholangioscope must be sterilized and handled under sterile conditions, in contrast to standard gastrointestinal endoscopes, which only require high-level decontamination. Two to five weeks are generally recommended for tract maturation before the tract is used for intervention. The procedure can fail even in experienced hands. Reasons for failure are the inability to fragment a large stone, stone impaction, and the loss of access.

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There have been limited studies of this kind, hence a direct head-to-head comparison is currently not feasible. Although PTCS has a high initial success rate in treating intrahepatic stones, up to one-third of patients experience recurrence. Yeh YH et al. followed 165 patients with intrahepatic stones managed by PTCS for five years [20]. Complete stone clearance was attained in 80%, with a stone recurrence rate of 33%. Other authors report lower rates of 18% in 32 months [21], or 28% in 5 years [22]. A 40% rate was found after gallbladder lithotripsy in 3 years [23]. Not all these patients are necessarily symptomatic and need reintervention. 92 patients were included in the study by Lee SK et al., 68(73.9%) were followed for a median of 42 months [24]. Complete ductal clearance was seen in 74(80%) patients. Patients with severe intrahepatic strictures had a lower stone clearance rate and higher recurrence rate than those without or with mild to moderate intrahepatic strictures. It is unclear how PTCS therapy will affect the survival and natural course of intrahepatic stones. The underlying condition and clinical setting affect whether removing intrahepatic stones is beneficial. In Lee SK et al, patients with advanced biliary cirrhosis (Child class B or C) had a significantly higher recurrence rate than those without cirrhosis [24]. Therefore, the underlying disease condition and therapeutic options must be considered when evaluating the clearance of intrahepatic stones by PTCS.

EUS BD can be done accessing the left duct for stricture dilation, but it is difficult for use in the right duct. For the left duct, it needs Endoscopic Ultrasound-Guided Hepaticogastrostomy, and placement of a fully covered metal stent. With the metal stent, then one can pass the spyscope. But the procedural cost and patient morbidity would increase. So, it was not used.

Hepatolithiasis contributes to recurrent upper abdominal pain, leading to a poorer quality of life. They occur more frequently in the fifth and sixth decades of life and do not demonstrate a gender preference [14,25]. Hepatolithiasis may result in repeated cholangitis, eventually leading to secondary biliary cirrhosis. Prevention of permanent liver damage by removal of the stones earlier in the course of the disease improves long-term prognosis. Patients with advanced biliary cirrhosis must undergo PTCS carefully due to the elevated risk, hepatic insufficiency, and portal hypertension [15,19]. Surgical options are limited. Hepatoliths in the left liver lobe are best treated with hepatic resection and left lateral segmentectomy; the source of recurrent infection is completely removed. Hepatoliths in the right liver lobe, hepatic lobectomy is rarely performed due to a high complication rate [26]. These patients are often malnourished and significantly underweight due to these surgeries. These need to be corrected before any intervention.

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Percutaneous access has a lot of advantages as it helps identify stone distribution, thereby allowing it to target the most convenient duct. This contributes to a higher success rate and reduces the procedural time, need for multiple treatments, and has a shorter hospitalization. It also aims to replace open surgical therapy with a less invasive approach [27]. PTCS is also useful in post-liver transplant patients with hepatolithiasis. Patients with stones in multiple liver segments or history of biliary surgery can benefit from it. Bile duct stones of size >15mm (large), presence above a stricture and intrahepatic location, are difficult to remove [28]. Stricture is dilated prior to the removal of calculi. Balloon enteroscopy-assisted ERCP was an alternative in these patients. We felt that the transhepatic approach is comparable to this technique in addition to a lower adverse event profile. In a recent study, with balloon enteroscopy-assisted ERCP, the complete stone removal rate was low [29]. The procedure is time consuming, needs expertise with advanced instruments, remains challenging and uncertain. Passage of cholangioscope with the enteroscope is not easy due to maneuverability issues especially when there are large stones and strictures. Some studies have shown that due to device limitations, the procedure could not be completed. The procedure may need to be repeated contributing to an increase in the cost.

The conventional PTCS scopes are nowadays used by radiologists. The only difference in between the two scopes is the working length of the conventional PTCS scope Spyglass discover (65 cm) and SpyScope DS II (214 cm). The field of view, distal tip width, minimum accessory channel width and minimum angulation range are almost the same in both the scopes. SpyGlass DS enables high resolution imaging of the biliary ducts during ERCP. Complementary SpyGlass tools enable targeted biopsies under visualization improving diagnostic yield and stone fragmentation. It also helps in therapeutic treatment via percutaneous access, enables fewer interventions, earlier patient treatment and reduction in additional testing. Compared to fluoroscopy, it has the desired flexibility for easy manoeuvrability, has direct vision and is single operator driven. In cases of biliary-enteric anastomosis, SpyGlass directly visualizes the bile ducts and anastomosis thereby improving the success rate of canalizing the stricture orifice. It provides additional information when biliary lumen is difficult to identify. It reduces the risk of failure when negotiating a stricture especially during EUS-HG. It also helps in percutaneous biliary stent placement to manage recalcitrant anastomotic strictures.

MRCP accurately depicts the normal anatomy in detecting and locating intrahepatic stones and strictures. Hence, it is routinely used [30]. Some studies have used general anesthesia [31] to

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overcome pain during traversing skin, intercostal muscles, and the liver capsule. However, we have successfully managed to use TIVA in this patient population.

The study does have its limitations. The first is a retrospective study from a single centre with a modest sample size. The study has inherent selection bias, although it looks less likely to have influenced our results. The small sample size is mainly because these are infrequent conditions, and obtaining a sufficient sample size takes additional time. An element of referral bias cannot be ruled out. To our knowledge, there have been only a handful of case series in recent times. Yet the decent results obtained act as a reference for developing future trials.

Conclusions

PTCS is a safe and feasible option for intrahepatic stones and strictures with good short-term outcomes and minimal complications in experienced hands. PTCS success does need skilled operators and a coordinated multidisciplinary approach. PTBD requires the highest level of radiological skills. Enteroscopy-guided ERCP or Endoscopic ultrasound-guided antegrade therapy is an alternative option in patients with altered surgical anatomy. A randomized study may yield important insight for a more favourable option.

Disclosure statement

The authors declare that they have no conflicts of interest with respect to the research, authorship, and/or publication of this manuscript. No financial or personal relationships with individuals or organizations have influenced or could be perceived to have influenced the work presented in this paper.

Data availability statement

The data underlying this article will be shared on reasonable request to the corresponding author

Declaration of funding

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Figure legends

1a MRCP showing large intrahepatic stone with post hepaticojejunostomy status

1b MRCP showing post hepaticojejunostomy stricture with intrahepatic biliary radicle dilatation

1c Post PTBD external-internal catheter insertion

1d Cholangiogram showing large filling defect in left hepatic duct

1e Fluoroscopy image showing cholangioscope going over the wire

1f Hepaticojejunostomy stricture dilatation using CRE balloon

1g Stone is fragmented with laser lithotripsy using the SpyGlass cholangioscopy system

1h Post laser lithotripsy fluoroscopy showing fragmented intrahepatic stones

1i Cholangiogram showing complete ductal clearance without filling defects

Figure 2 Spyglass cholangioscopy images of stone and stricture

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Table 1 Baseline characteristics of patients

Variable	n=24
Age, Median (IQR), y	41.5(38.2-49)
Gender, Male, n (%) Male: Female	16(66.7) 2:1
Presentation, n (%) Jaundice Pruritus Abdominal Pain Fever	 24(100) 16(66.7) 15(62.5) 9(37.5)
Diagnosis, n (%) EHPVO with portal biliopathy Choledochal cyst Recurrent Pyogenic cholangitis Post LDLTx hepaticojejunostomy stricture Autoimmune Pancreatitis Choledochal cyst with biliary stricture	 9(37.5) 8(33.3) 2(8.3) 2(8.3) 2(8.3) 1(4.2)
Cholangitis, n (%) Mild Moderate Severe	 11(45.8) 12(50) 1(4.2)
Hemoglobin (g/dl), median (IQR) Total bilirubin (mg/dL), median (IQR) Aspartate aminotransferase (UI/dL), median (IQR) Alanine aminotransferase (UI/dL), median (IQR) Alkaline phosphatase (UI/dL), median (IQR)	9.9(8.2-10.9) 6.6(5.1-8.3) 83(54.5-99.7) 79(48.5-98) 205(189.2-248.5)
Surgical procedure, n (%) Roux-en-Y hepaticojejunostomy Whipple's procedure	 22(91.7) 2(8.3)
Previous examination, n (%) Magnetic resonance cholangiopancreatography Computed tomography	 24(100) 18(75)
Level of bile duct obstruction, n (%) Upper (hilum) Middle (common hepatic duct)	 20(83.3) 4(16.7)
Indications for PTBD, n (%) Biliary Stricture Intrahepatic stones Stones + Stricture	 13(54.2) 6(25) 5(20.8)

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Table 2 Outcomes of Percutaneous transhepatic biliary drainage and SpyGlass cholangioscopy

Variable	N=24
Route, n (%) Left / Right intrahepatic duct Both	 2(8.3) 22(91.7)
Stricture dilation and internalization, n (%), (n=18) 8.5 Fr 10 Fr	 15(83.3) 3(16.7)
Complications after PTBD, n (%) Cholangitis Bleeding	 4(16.7) 2(8.3)
Technical success PTBD	100%
Bilirubin level after PTBD (1 week), (mg/dL)	1.8(1.2-2.8)
No of sessions of Spyglass (stones), median (IQR)	2(1.7-2)
No of sessions of Spyglass (strictures), median (IQR)	3(3-4)
Complications after Cholangioscopy, n (%) Abdominal pain Cholangitis	 2(8.3) 3(12.5)
Outcome, n (%) # Stricture resolution Complete ductal clearance	 16/18 (88.9) 10/11 (90.9)
Follow up duration in months	7(6-8)

Some patients may have stones and strictures

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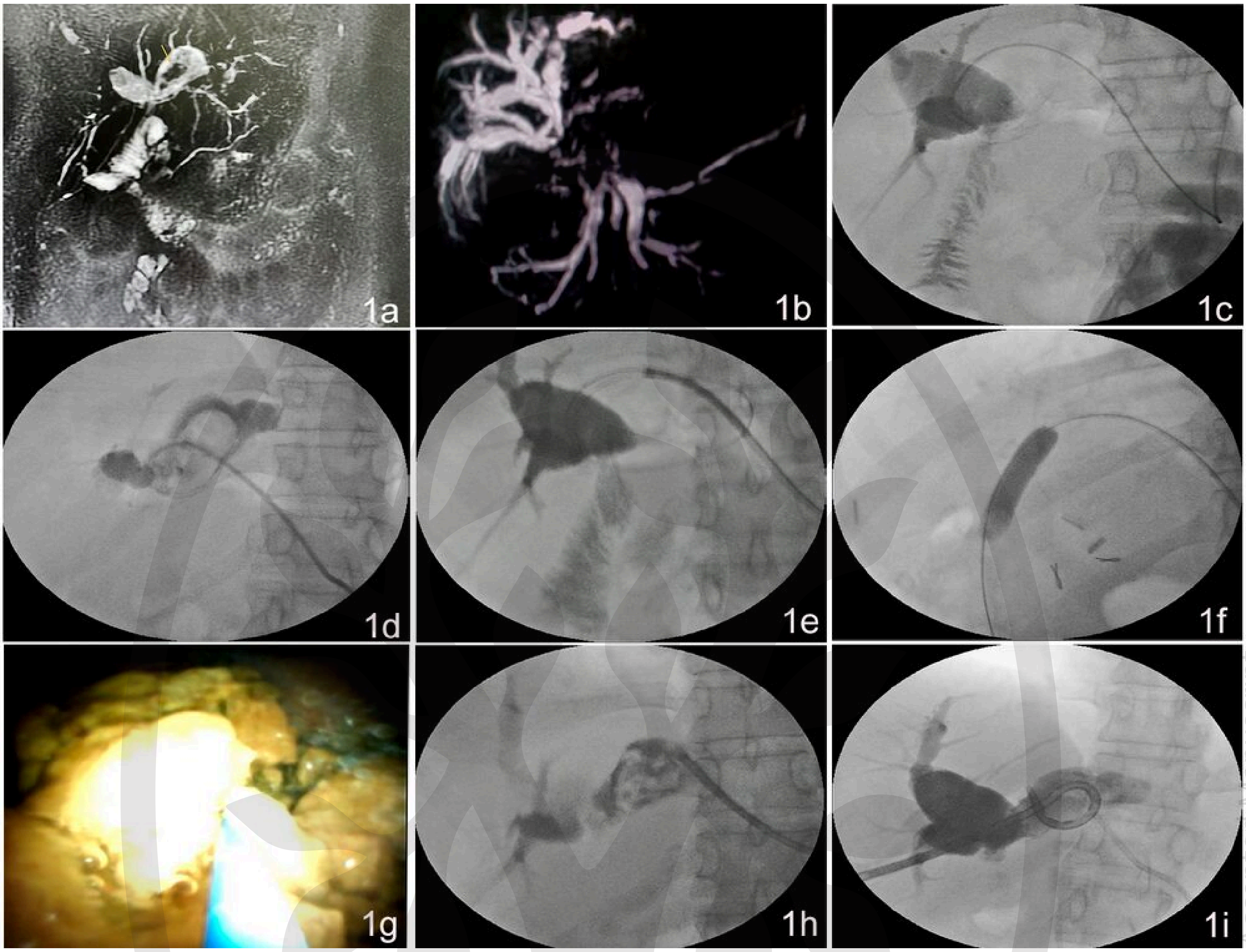

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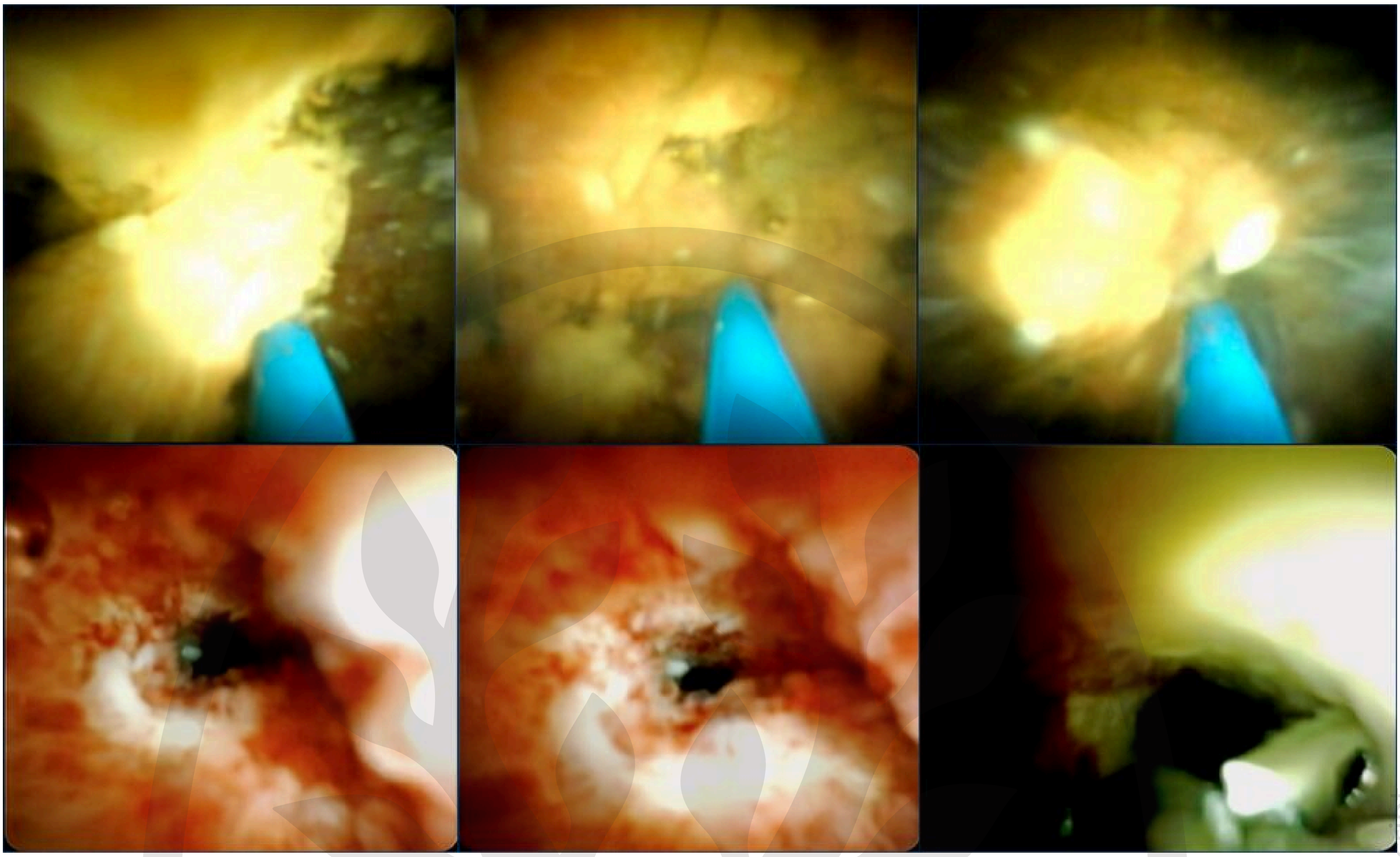

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