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Tesi di Dottorato

DIGITAL CHOLANGIOSCOPY-GUIDED ELECTROHYDRAULIC LITHOTRIPSY FOR INTRAHEPATIC AND DIFFICULT BILIARY STONES WITH PERORAL AND PERCUTANEOUS APPROACH. A THREE-YEAR EXPERIENCE IN A SINGLE SURGICAL TERTIARY CENTER

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Digital cholangioscopy-guided electrohydraulic lithotripsy for intrahepatic and difficult biliary stones with peroral and percutaneous approach. A three-year experience in a single surgical tertiary center.

Introduction

Hepatolithiasis (HL) and difficult common bile duct (CBD) stones represent a challenging condition especially when associated with anatomic variations due to previous surgical procedures. It is also noteworthy that hepatolithiasis may lead to recurrent cholangitis, biliary cirrhosis and cholangiocarcinoma [1,2].

Most CBD stones can be extracted with standard devices, during Endoscopic Retrograde CholangioPancreatography (ERCP) procedure, such as balloon and/or Dormia basket (BDE) following endoscopic sphincterotomy. However, in approximately 15% of these patients, clearance of the biliary tract cannot be obtained using standard techniques and these kinds of stones are termed "difficult stones" [3-5]. The properties of "difficult stones" are: stone size ≥15 mm in diameter, number of stones ≥3 especially if impacted in a not dilated CBD, unusual shape or location (Mirizzi syndrome, intrahepatic, proximal to strictures). Additionally, distal CBD variants or stenosis, presence of periampullary diverticula (PAD) and altered anatomy due to previous biliary or gastrointestinal surgical procedures (e.g. post-gastrectomy Billroth type II anatomy, Roux-en-Y-reconstructions), represent factors that can decrease the success rate of stones extraction [3-5].

Several endoscopic therapeutic approaches have been proposed such as papillary large balloon dilation (EPLBD), mechanical lithotripsy, electrohydraulic (EHL) or laser lithotripsy (LL) using peroral cholangioscopy (POC) and in some cases biliary stenting [6]. Additionally, a combined radiologic-endoscopic technique using EHL or LL under percutaneous transhepatic cholangioscopy (PTCS) has been described [7]. Moreover, enteroscopy is recently proposed for a difficult to reach papilla [8]. Surgery for HL can be considered when there are: (i) unilobar hepatolithiasis, particularly left-sided; (ii) atrophy, fibrosis and multiple abscesses secondary to cholangitis; (iii) suspicion of concomitant intrahepatic cholangiocarcinoma, and (iv) multiple intrahepatic stones with biliary strictures that cannot be treated percutaneously or endoscopically [9].

There are three major techniques for cholangioscopy: (i) a dual-operator dedicated mother-baby cholangioscopic system; (ii) a single-operator catheter-based cholangioscopic system; and (iii) direct use of an ultraslim endoscope. The procedures vary with respect to the number of operators, maneuverability, image quality and method of access, resulting in variable success rates [6].

Due to instrument's technical improvement, small caliber operative cholangioscopes (CSs) are now available either for endoscopic procedures or for percutaneous approach [10]. However, the majority of CSs have only a bilateral move and a restricted operative angle.

The SpyGlass™ DS System (Boston Scientific, USA) is a mother-baby single operator intuitive platform that enables simple, direct visualization cholangioscopy so as to detect and treat large stones and strictures, throughout in the pancreatico-biliary system, during an endoscopic retrograde cholangiopancreatography (ERCP) procedure. The SpyGlass™ DS System allows for:

• Site-specific examination of the entire lumen made possible by 4-way deflection and high-resolution digital imaging.

• Improved diagnosis by visualization and SpyBite® Forceps biopsy, allowing for adequate tissue acquisition for histological examination.

• Treatment of large biliary stones by either electrohydraulic lithotripsy or Holmium Laser lithotripsy through the working channel, under direct visualization for focused treatment.

The aim of our study is to evaluate the efficacy and safety of the SpyGlass™-guided electrohydraulic lithotripsy (SpEHL) for intrahepatic and difficult CBD stones using peroral and percutaneous approach.

Table 1. Major characteristics of SpyGlass™ DS System

• A 10Fr (3.3mm) outer diameter, 230cm length catheter fits down standard duodenoscope working channel and allows for easy access to non-dilated pancreaticobiliary anatomy. • Dedicated accessory channel for significant biopsy specimen retrieval with SpyBite® Forceps and large biliary stone management with EHL or Holmium Laser lithotripsy.	• Four-way tip deflection allows for enhanced directional control and more precise navigation. • Independent irrigation channel for fluid aspiration to maintain visualization.

Materials and Methods

From September 2014 to September 2017 data from symptomatic patients with intrahepatic and/or difficult CBD stones that underwent SpEHL were prospectively collected and retrospectively analyzed. Patients were admitted to hospital suffering from upper abdominal pain, jaundice, altered pancreatic enzymes and/or fever. All patients initially underwent an abdominal ultrasound exam and then magnetic resonance cholangiopancreatography (MRCP) and/or computed tomography (CT) to confirm the diagnosis, to detect the biliary stones and to evaluate anatomical abnormalities due to previous abdominal surgical operation.

CT and/or MRCP results were classified according to the Tsunoda classification [11] (stone distribution – unilateral or bilateral – and the presence of associated intrahepatic duct stricture): I) No marked dilatation or strictures of intrahepatic ducts; II) Diffuse dilatation of intrahepatic ducts without strictures; III) Unilateral solitary or multiple cystic dilatation of intrahepatic ducts with strictures; IV) Bilateral.

Informed consent was obtained by every patient or their relatives or a guardian in case of neurological deficit before the procedure. In all patients, anticoagulant/antiaggregant therapies were suspended and eventually replaced with adequate low molecular weight heparin regimen. Prophylactic antibiotic therapy was given to all patients. All procedures were performed under general anesthesia and orotracheal intubation. EHL was performed using 3French (Fr) probes (Walz Elektronik GmbH, Germany).

ERCPs were conducted with a standard side-viewing duodenoscope (Duodenoscope Olympus TJF 145/ TJF160V-VR, Japan). In case of peroral SpEHL, SpyGlass™ DS was inserted through the duodenoscope's working channel, into the CBD and the intra-hepatic biliary system. Washing with saline and aspiration were used for better view. If stenosis or angulations were found, a guidewire (Radiofocus Standard type, Terumo, Japan) was inserted into the SpyGlass™ DS working channel, in order to access the desired biliary tract. If stones were found EHL was performed. The remaining stones fragments were removed by continuous flushing with saline and BDE.

In case of PTCS and SpEHL a single or double hepatic puncture were made (according to Tsunoda classification). The SpyGlass™ DS was inserted over a guidewire (Radiofocus Standard type, Terumo, Japan), using an introducer sheath, to get into the CBD or the site to be explored. Then, after removal of the guidewire, continuous washing with saline through the irrigation channel was maintained to obtain direct vision and to flush out small stones. In case of large stones, EHL was performed with 3 Fr probes. All procedures were conducted under fluoroscopic control. At the end of the procedure a

10 Fr biliary drainage was left in place and removed after 2-3 days following a radiologic control and provided that no complications had occurred.

ERCP was the first line treatment for difficult CBD stones and/or HL with Tsunoda class I/II. Peroral SpEHL was performed only in the case of traditional ERCP, EPLBD (maximum 20mm diameter balloon) and mechanical lithotripsy failure (stone diameter >25mm, strictures). Balloon diameter was determined depending on the diameter of CBD, stone size and presence of strictures. EPLBD was performed only after endoscopic sphincterotomy. Percutaneous transhepatic cholangiography (PTC) was performed in case of intrahepatic (Tsunoda class III/IV) or impacted stones associated with narrowed CBD. In these cases, PTCS and SpEHL was performed. Patients with biliary anatomic modifications due to previous surgery and a biliary-enteric anastomosis had a direct PTC approach with PTCS and SpEHL. In cases of biliary anastomosis after liver transplantation a PTC approach was performed only after ERCP and peroral SpEHL failure.

Intrahepatic bile ducts strictures were eventually dilated with a 4-10mm balloon and biopsies performed using SpyBite® forceps. Stenting was used for strictures located in the CBD after removing all stones. Permanent partially covered metallic stents were used for malignant disease, while removable covered metallic stents were inserted in benign disease.

Technical success was defined as the complete clearance of the biliary tract as demonstrated by several control cholangiograms and/or direct cholangioscopy showing no residual stones at the end of the procedure.

All adverse events have been classified according to a recent publication [12] as mild, moderate and severe.

The average post-procedural follow-up period was 24±3.6 months with abdominal ultrasound control in 6 months, MRCP after 12 and 24 months, blood tests after 3, 6 and 12 months and/or telephone interview after 12 months.

Results

A total of 30 patients (18F/12M) underwent SpEHL for difficult CBD stones and/or hepatolithiasis. The average age of study population was 62.5 ±18 years. The anatomical distribution of the stones was as follows: 10 (33.3%) patients presented only difficult CBD stones (3 [30%] with Billroth type II gastrectomy), 5 (16.6%) with both HL and CBD stones and 15 (50%) patients with only HL. According to Tsunoda classification, 5 (25%) patients were classified as type I, 9 (45%) as type II, 4 (20%) as type III and 2 (10%) as type IV. The average diameter of the stones in the CBD was 25mm ±3.6. Most of the patients had previously undergone cholecystectomy (20/30; 66.6%).

As far as the therapeutic approaches are concerned, all the patients with solely difficult CBD stones were treated with POC + SpEHL. 9 (60%) out of 15 patients with only HL carried a bilio-enteric anastomosis and underwent directly PTCS + SpEHL. The remaining 6 (40%) cases presented a biliary anastomosis due to liver transplantation; all were initially treated with POC + SpEHL but 2 of them needed also PTCS + SpEHL due to an impassable anastomosis stenosis. All the cases with both HL and CBD stones underwent POC + SpEHL. 1 patient of the latter group was treated with both POC and PTCS + SpEHL sequentially, but even after 3 consecutive procedures, the patient still presented residual stones in the left hepatic lobe. It was a Tsunoda type III case with a non-dilatable left hepatic duct stenosis. During the third procedure, bleeding from the transhepatic tract was detected; angiogram was performed and revealed an active hemorrhage from a segmental branch of the right hepatic artery, that was successfully embolized. Hence, the patient underwent surgical resection of the left hepatic lobe.

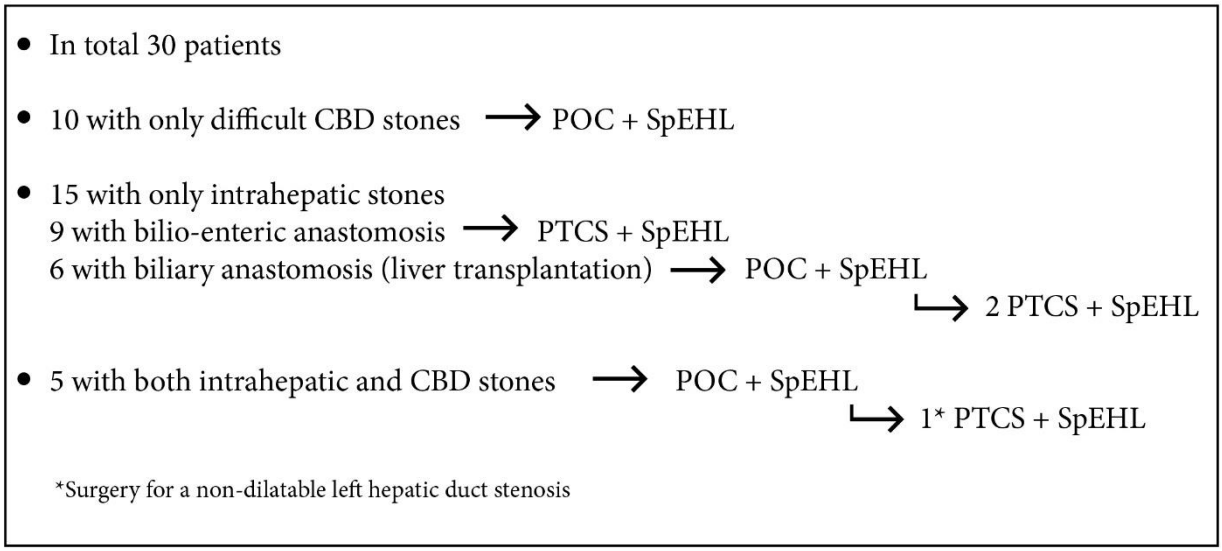
Taking under consideration only the type of lithotripsy approach (peroral or percutaneous), a total of 18/30 (60%) patients had only POC + SpEHL, 9/30 (30%) only PTCS + SpEHL and 3/30 (10%) were sequentially treated with both approaches. POC + SpEHL and PTCS + SpEHL as standing alone procedures, showed a technical success rate of 85.7% and 100% respectively.

Comprehensively, complete stone clearance was achieved in 29/30 (96.6%) patients after a maximum of 3 consecutive procedures. Technical success was achieved in 24 (82.7%) patients after the first session, in 3 (10.3%) patients in the second session and in 2 (6.8%) patients in the third session. The maximum number of procedures for Tsunoda type I/II and III/IV cases was 2 and 3 respectively. The average procedure time for POC + SpEHL was 65 minutes ±12 and for PTCS + SpEHL 60 minutes ±15.

During the follow-up period 4 (13.7%) patients presented stones recurrence within 24 months after discharge; 3 (16.6%) of them were treated with only POC-SpEHL and 1 (11.1%) with only PTCS-SpEHL. 2 of these patients had intact gallbladder with known gallstones. All patients were successfully retreated; 2 of them underwent conventional ERCP with complete stone clearance, 1 had POC + SpEHL and 1 PTCS + SpEHL.

Intrahepatic or CBD strictures were observed in 12 (40%) patients (6 were intrahepatic and 6 at CBD/common hepatic duct) and biopsies were done with SpyBite® biopsy forceps (histological report: 10 benign and 2 malign). All intrahepatic strictures were benign and treated with 10Fr plastic stents positioning when necessary. CBD/common hepatic duct's strictures were treated with stenting. In case of inoperable malignant disease, a partially covered metallic stent was placed as palliative therapy. In 1 patient with CBD malignant stenosis radiofrequency ablation was also performed prior to bilateral stenting, using 2 partially covered metallic stents. In case of benign disease, all 4 patients underwent stenting using a totally covered removable metallic stent (Gore® Viabil® Biliary Endoprosthesis, W.L. Gore & Associates, Flagstaff, AZ, USA). Stenting was performed after all stones had been removed. All the removable stents were left in place for 9 months. After that period an ERCP procedure was performed in order to remove the stents and to reevaluate the stricture. Upon removal, stricture was resolved or significantly improved in all patients without need for further therapy.

Major adverse events were: 1 (3.3%) case of severe bleeding with the need of embolization and 4 (13%) cases of mild cholangitis treated with medical therapy. The overall complication rate was 16.6%. No cases of perforation, pancreatitis or procedure related death were detected.



Discussion

Regardless of the cholangioscopy technique, several studies and a recent meta-analysis [13] have evaluated the POC lithotripsy reporting complete stone clearance rate that varies from 85% to 91%. On the other hand, these studies have showed some limitation mainly regarding the included study heterogeneity and variability in the type of POC used. Additionally, limited data was given about the number of procedures needed for technical success.

Our study evaluated the efficacy and the safety of the SpEHL for difficult CBD stones and for HL, using peroral and/or percutaneous approach, in patients upon whose conventional ERCP techniques have failed. These procedures were found to be very effective with an overall success rate as high as 96.6%; moreover 82.7% of the cases needed only one procedure.

Similar results were reported by three recent studies [14,15,16] that have assessed the digital POC lithotripsy for difficult biliary stones, presenting an overall stone clearance rate of 87.2%, 97.3% and 95%. Moreover, their "one procedure" success rate was 80.1%, 77.4% and 83.3%, respectively. All these studies were multicenter and contained a relatively high number of cases but only one had a prospective form [14]. Besides that, they had also other limitations such as the inclusion criteria heterogeneity and a non-fixed protocol for the first line stone treatment. Additionally, only a little data was available regarding the stone treatment using a predefined diameter of EPLBD and even less details were offered about the cases with altered anatomy due to previous surgery.

Recent studies and guidelines recommend endoscopic sphincterotomy combined with EPLBD (12–20 mm) as the first-line approach for difficult CBD stones [6,17]. In our study, endoscopic papillary large-balloon dilation and/or mechanical lithotripsy combined with sphincterotomy were performed following a fixed protocol. POC with SpEHL was used only after the failure of these techniques, achieving a complete stone clearance in 85.7% of the cases. Maydeo et al., in a multicenter prospective study, evaluated the POC with EHL or LL after the failure of EPLBD and/or mechanical lithotripsy reporting a complete stone clearance rate of 77%. This observation was a secondary one without the application of a detailed and fixed protocol. In a recent randomized controlled trial (RCT) [18], comparing POC-guided LL with EPLBD, the POC-guided LL found to be significantly superior in terms of effectiveness when removing difficult biliary stones. On the contrary, Franzini et al., showed that there is no significant difference between these two procedures, regarding the treatment of complex biliary stones. An RCT with strict inclusion criteria, comparing EPLBD and POC-lithotripsy as well as the efficacy and cost-effectiveness of first-line vs. second-line POC-lithotripsy is necessary.

Hepatolithiasis typically occurs in conjunction with biliary strictures associated with local inflammatory pathologies and/or postoperative fibrosis. Therapy for HL can be challenging especially when associated with altered anatomy due to previous abdominal surgery (e.g. Roux-en-Y reconstructions). Management options for HL include POC-lithotripsy, PTCS-lithotripsy and surgical resection. In a series of POC-lithotripsy for HL, the rate of complete stone removal was 64% [20]. PTCS-lithotripsy has achieved higher success rates (80%-85%) [21]. Frequent causes of failure were the inability to access the right posteroinferior and left inferolateral segments because of sharp angulations. Both POC-lithotripsy and PTCS-lithotripsy are burdened with high rates of stone recurrence (22%-50%). Hepatectomy has shown higher success rate (even greater than 90%) and fewer recurrences, even though, no statistically significant difference in the recurrence rate was found between surgery and non-operative procedures [2]. Moreover, surgery has well-known drawbacks such as previous abdominal surgery/intervention, bilateral intrahepatic lithiasis/strictures, elderly patients and/or poor clinical conditions [21]. In our study, patients affected by only HL or combined with CBD stones were treated with non-operative procedures (POC/PTCS-lithotripsy alone or combined), achieving a success rate of 95%; only 1 (3.3%) patient underwent surgery.

Additionally, patients with Roux-en-Y reconstructions due to previous surgery were directly treated with PTCS + SpEHL achieving complete stones clearance in all of them (100%). Enteroscopy using pediatric colonoscopes, standard enteroscopes and, more recently, balloon assisted enteroscopes has been proposed for these patients [21]. Due to low success rates, the high risk of perforation and based also on our previous experience [7], these techniques have not been adopted in our series. It is important to notice that until now, the majority of CSs used for PTCS-lithotripsy has only a bilateral move and a restricted operative angle. In our study, the use of SpyGlass™ DS with the four-way tip deflection was found to be very effective in reaching difficult to access hepatic segments and overpassing acute angulations and/or strictures, providing at the same time high-quality images and efficient maneuverability.

There is only little data available regarding the recurrence of stones after SpEHL. A recent meta-analysis [13] reports stone recurrence rate of 13% (range 7%–20%) after POC-lithotripsy but without using the SpyGlass™ DS. A large multi-center series [15] evaluated the POC-lithotripsy with the SpyGlass™ DS reporting a recurrence rate of 6.6%, but the median follow-up time was only 83.5 days and additionally more than 35% of the included patients was lost during this period. Moreover, only 17.7% of the stones were intrahepatic. Another study reporting long-term results of PTCS-EHL for intrahepatic stones, presented a recurrence rate of 24.7% after 12 years of follow-up [7]. In our study the overall recurrence rate was 13.7% with a median follow-up period of 24±3.6 months, including

also difficult cases of intrahepatic stones. Assessing the recurrence by the type of procedure, POC-SpEHL and PTCS-SpEHL showed a recurrence rate of 16.6% and 11.1%, respectively. More studies evaluating the long-term results of SpEHL with longer follow-up periods are warranted.

According to the international literature, POC-SpEHL is burdened with overall complication and cholangitis rates of 2%-18% and 0-14%, respectively [14,15,16,18,22,23]. In our series, the overall complication rate was 16.6% reporting only 1 (3.3%) case of severe bleeding and 4 (13%) cases of mild cholangitis. Although our results fall within the range of the international literature, it is observed that they meet the upper limit of this spectrum. Perhaps this rate of complications mirrors the complexity of the cases we included, such as cases of difficult intrahepatic stones associated with strictures. These cases required a more intensive stone and stricture treatment, fact that probably led to a more extensive fluid irrigation deep into the biliary ductal system, a higher intraductal pressure and bacteremia. Nevertheless, all the cases of cholangitis were classified as mild and treated only with medical therapy. Additionally, no cases of pancreatitis have been detected, probably because of the pre-existent sphincterotomies. Summarizing, cautious fluid irrigation accompanied with adequate suction during POC/PTCS-lithotripsy and prophylactic antibiotic therapy is recommended, even though pre-procedural management is not yet standardized.

Our study has some limitations. Firstly, this study is a single-center one with a restricted number of cases. Secondly, we reported the results of two different therapeutic approaches (POC/PTCS-lithotripsy) without comparing them or focusing on one rather than the other. However, our primary objective was to evaluate the efficacy and safety of the SpyGlass™ DS System and EHL for the cure of complex biliary stones, regardless of the approach used. A secondary objective was to assess the feasibility of using the SpyGlass™ DS as cholangioscope during PTCS-lithotripsy, instead of the typical instruments with only bilateral moves. To the best of our knowledge, this is the first study, except for a few case-reports or small case-series without follow up, that systematically used the SpEHL with a percutaneous approach. Thirdly, because of material unavailability, we only evaluated the results of EHL. Technically, lithotripsy can be achieved either using EHL or LL probes. Previous series have shown similar clearance and complication rates for EHL compared to LL [15,16], even though EHL seems to be burdened with longer procedure time [15]. In our study, it is worth noticing that for more complex stones, a median of 2 EHL probes were used in order to achieve complete stone fragmentation. EHL probes have a limited life span, which is proportional to the potency chosen during the procedure. In contrast, LL probes do not have this limitation, but they are more expensive. Cost-effectiveness studies assessing the aforementioned techniques and also the cost of the surgical approach, are necessary.

In conclusion, POC-SpEHL is an effective and safe rescue treatment in patients who have failed standard ERCP stone removal techniques. PTCS-SpEHL seems to be very effective in patients with altered anatomy, showing low complication and recurrence rates.

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Patients (Total 30)	
Age	62.5 ±18years
Men/Women	12/18
CBD Stones Diameter	25mm ±3.6
Location of Stones	
CBD	33.3%
Intrahepatic	50%
Intrahepatic + CBD	16.6%
HL (Tsunoda class.)	
Type I	25%
Type II	45%
Type III	20%
Type IV	10%
Previous Surgery	
Billroth type II gastrectomy	10%
Roux-en-Y reconstructions	30%
Liver transplantation	20%
Cholecystectomy	66.6%

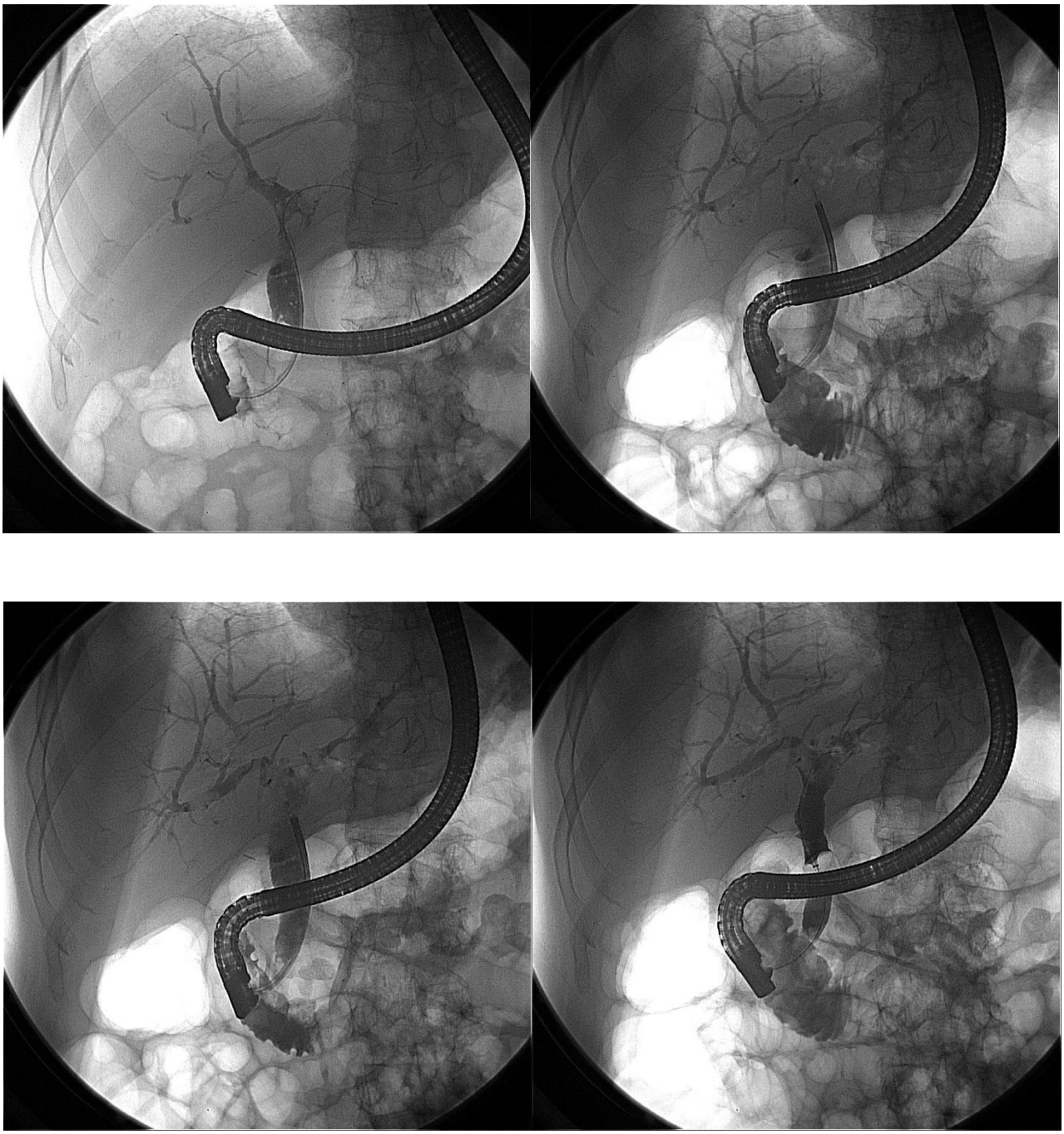
Table 2 Demographic data and general aspects

CBD: Common Bile Duct; HL: Hepatolithiasis

Patients (Total 30)	
Therapeutic approaches	
POC-SpEHL	60%
PTCS-SpEHL	30%
POC+PTCS-SpEHL	10%
Technical Success Rate	
Overall	96.6%
POC-SpEHL	85.7%
PTCS-SpEHL	100%
Number of procedures for success	
1	82.7%
2	10.3%
3	6.8%
Surgery	3.3%
Strictures	
Overall	40%
CBD/Common Hepatic Duct	50%
Intrahepatic	50%
Benign	83.3%
Malign	16.6%
Recurrences	
Overall	13.7%
POC-SpEHL	16.6%
PTCS-SpEHL	11.1%
Complications	
Overall	16.6%
Severe Bleeding	3.3%
Mild Cholangitis	13%

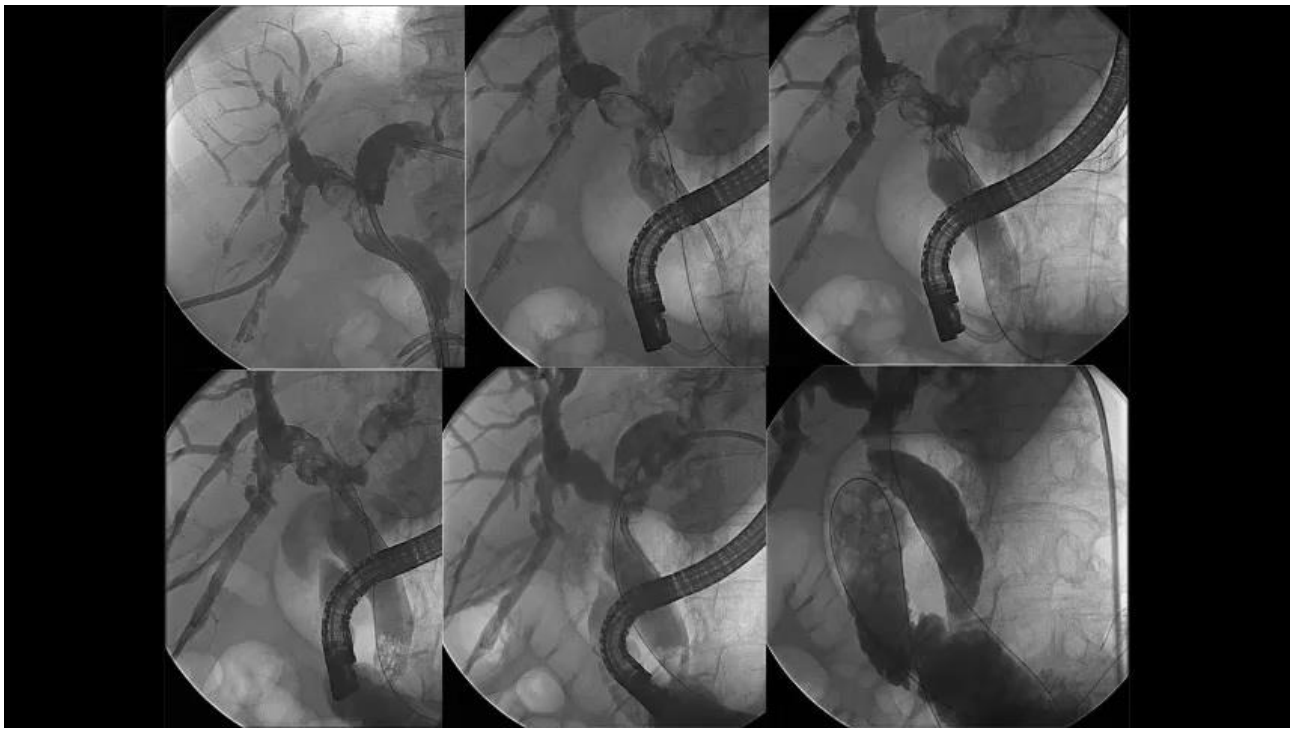
Table 3 Results

POC: Peroral Cholangioscopy; PTCS: Percutaneous Transhepatic Cholangioscopy; SpEHL: SpyGlass™-guided electrohydraulic lithotripsy; CBD: Common Bile Duct

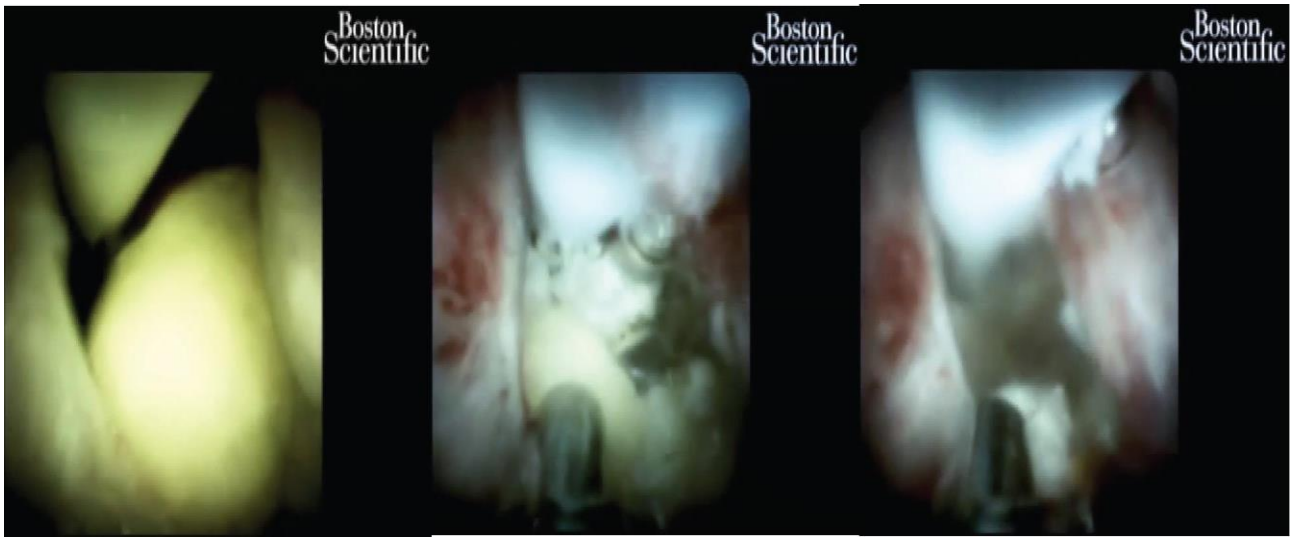


Case 1 POC-SpEHL for common hepatic duct and left hepatic duct stones.

Case 2 POC/PTCS-SpEHL for CBD stones and HL in patient with malignant CBD stenosis. 2 metallic stents were placed for palliative therapy.



Case 3 POC-SpEHL for difficult CBD stones and bilateral HL.



SpyGlass™ DS System and EHL