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A feasibility study of digital single-operator cholangioscopy for diagnostic and therapeutic procedure (with videos)

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Abstract

Recently, the novel SpyGlass DS Direct Visualization system (SPY DS) has become available. This system offers several advantages over the conventional SPYGlass system. This study evaluated the clinical feasibility and efficacy of diagnostic and therapeutic procedures for biliary disorder using SPY DS.

In this retrospective study, consecutive patients who had biliary disorder were enrolled between November 2015 and February 2016. All patients could not be diagnosed or treated by standard endoscopic retrograde cholangiopancreatography in our hospital or at another hospital.

A total of 28 consecutive patients (21 men and 7 women; median age, 73 years; age range, 55–87 years) were retrospectively enrolled in this study. Among them, diagnostic procedure was performed in 20 patients, and 8 patients underwent therapeutic procedures. The technical success rate for diagnostic procedures was 100% (20/20). Diagnostic accuracy was 100% (19/19). The technical success rate for therapeutic procedures was 88% (7/8). Among these 8 patients, 4 patients with common bile duct stones underwent electrohydraulic lithotripsy. One patient successfully underwent guidewire insertion to remove a migrated plastic stent. The 3 remaining patients underwent SPY DS to insert a guidewire for left bile duct obstruction and for posterior bile duct branch. In the patient who underwent guidewire insertion for left hepatic bile duct obstruction cause by primary sclerosing cholangitis, we could not advance the guidewire into the left hepatic bile duct. No adverse events were seen. Median SPY DS insertion time was 21 min (range, 8–32 min).

Single-operator cholangioscopy using SPY DS was feasible and had a marked clinical impact in patients with biliary disease. Additional case reports and prospective studies are needed to examine further applications of this system.

Abbreviations: CT = computed tomography, EHL = electrohydraulic lithotripsy, ERCP = endoscopic retrograde cholangiopancreatography, EUS = endoscopic ultrasound, POCS = peroral cholangioscopy, SPY DS = SpyGlass DS Direct Visualization system.

Keywords: cholangioscope, cholangioscopy, endoscopic retrograde cholangiopancreatography, peroral cholangioscopy, SpyGlass

1. Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) has been widely performed for diagnostic biopsy and therapeutic intervention (e.g., stone removal) in the context of biliary disorders.[1,2] However, forceps biopsy under fluoroscopic guidance is associated with suboptimal diagnostic accuracy.[3,4]

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Likewise, therapeutic procedures, such as electrohydraulic lithotripsy (EHL), may be performed favorably under peroral cholangioscopy (POCS) guidance. Diagnostic and therapeutic procedures under ERCP guidance using single-operator POCS (SPYGlass System, Boston Scientific, Natick, MA) have recently been developed.[5–13] However, poor permanence and poor visibility related to optimal imaging remain problematic. In addition, POCS has no suction function, and thus may not be suitable for use during interventional procedures. More recently, the novel SpyGlass DS Direct Visualization system (SPY DS) has been made available. This system offers several advantages when compared with the conventional SPYGlass system, such as easy insertion into the biliary tract due to the tapered tip, favorable visualization due to a 120° digital field of view, and newly added injection and suction functions, carried out through a 2-port adaptor. This study evaluated the clinical feasibility and efficacy of diagnostic and therapeutic procedures for biliary disorder using SPY DS.

2. Patients and methods

2.1. Patients

In this retrospective study, between consecutive patients with biliary disorder were enrolled November 2015 and February

2016. All patients underwent noninvasive imaging, such as computed tomography (CT) and endoscopic ultrasound (EUS), and were found to have biliary disorders. In addition, all patients could not be diagnosed or treated by standard ERCP in our hospital or at another hospital. All patients provided written informed consent to participate before the procedure.

2.2. Technical tips of POCS

All procedures were performed by the same experienced endoscopist (TO), who was trained and experienced in diagnostic and therapeutic procedures under ERCP guidance. Patients received antibiotics before the procedures, which were then performed with each patient under sedation.

A duodenoscope (JF260V; Olympus Optical, Tokyo, Japan) was advanced to the ampulla of Vater, and an ERCP catheter (MTW Endoskopie, Düsseldorf, Germany) was inserted into the bile duct. Next, a 0.025-inch guidewire (VisiGlide; Olympus Medical Systems, Tokyo, Japan) was placed in the biliary tract. After cholangiography was obtained, endoscopic sphincterotomy was performed, if necessary. The SPY DS was inserted into the bile duct under guidewire guidance. Injecting normal saline, lesions of biliary tract were observed, and forceps biopsy using a SpyBite device (Boston Scientific) was performed under cholangioscopy guidance, if necessary. In our hospital, an electrohydraulic shock wave generator (Lithotron EL27, Walz Elektronik Gmbh, Berlin, Germany) was used to generate shock waves of increasing frequency, which were applied as a continuous sequence of discharges during EHL. A 2.4-Fr EHL probe was used, and EHL was performed under SPY DS guidance.

2.3. Definitions

Technical success was defined as the successful insertion of SPY DS into the biliary tract, observation of lesions, use of forceps biopsy, and completion of any treatment procedures. Procedure time was measured from insertion of SPY DS to removal of SPY DS. Final diagnosis was based on the pathological examination of specimens obtained by surgical resection. Also, final diagnosis was a benign disorder if the clinical course of the patient was consistent with this notion after follow-up. At the end of follow-up, if no signs malignancy were found, such as disease regression or lack of evidence of disease progression, malignant disease was ruled out. Finally, adverse events were graded according to the American Society for Gastrointestinal Endoscopy lexicon's severity grading system.[14]

3. Results

A total of 28 consecutive patients (median age, 73 years; age range, 55–87 years; 18 men and 7 women) were retrospectively enrolled in this study. Table 1 shows the characteristics of these patients. Among them, diagnostic procedure was performed in 20 patients, and 8 patients underwent therapeutic procedures. Diseases were as follows: bile duct carcinoma, n=10; benign biliary stricture, n=5; IgG4-related cholangitis, n=3; common bile duct stones, n=4; primary sclerosing cholangitis, n=3; stent

Table 1

Patients characteristics.

No.	Age/gender	Disease	Procedure	Technical success	Time of SPY DS, min
1	62/M	IgG4-related cholangitis	Biopsy	Yes	19
2	68/M	IgG4-related cholangitis	Biopsy	Yes	14
3	70/M	Bile duct carcinoma	Biopsy	Yes	14
4	80/M	Benign biliary stricture	Biopsy	Yes	16
5	73/M	Bile duct carcinoma	Biopsy	Yes	14
6	84/M	Bile duct carcinoma	Biopsy	Yes	19
7	80/F	Bile duct carcinoma	Biopsy	Yes	12
8	66/M	IgG4-related cholangitis	Biopsy	Yes	16
9	77/M	Common bile duct stone	EHL	Yes	10
10	83/M	Bile duct carcinoma	Biopsy	Yes	10
11	78/F	Bile duct carcinoma	Biopsy	Yes	15
12	81/M	Bile duct carcinoma	Biopsy	Yes	17
13	83/M	Benign biliary stricture	Biopsy	Yes	15
14	68/F	Benign biliary stricture	Biopsy	Yes	11
15	72/M	Common bile duct stone	EHL	Yes	22
16	81/F	Benign biliary stricture	Biopsy	Yes	16
17	67/M	Primary sclerosing cholangitis	Biopsy	Yes	13
18	87/F	Bile duct carcinoma	Biopsy	Yes	13
19	55/F	Telangiectasia	Diagnosis	Yes	20
20	78/F	ERBD migration	Removal	Yes	8
21	67/M	Primary sclerosing cholangitis	Wire insert	No	19
22	67/M	Primary sclerosing cholangitis	Biopsy	Yes	19
23	73/M	Common bile duct stone	EHL	Yes	32
24	84/M	Common bile duct stone	EHL	Yes	28
25	84/M	Benign biliary stricture	Biopsy	Yes	12
26	62/M	Bile duct carcinoma	Biopsy	Yes	11
27	84/M	Bile leak	Wire insert	Yes	27
28	62/M	Bile duct carcinoma	Wire insert	Yes	12

EHL=electrohydraulic lithotripsy, ERBD=endoscopic retrograde biliary drainage, SPY DS = SpyGlass DS Direct Visualization system.

migration, n=1; bile leak, n=1; and telangiectasia, n=1. Median SPY DS insertion time was 15 min (range, 8–32 min).

3.1. Diagnostic procedure

Forceps biopsy was attempted in 19 cases. Total number of biopsy was 51 times. Among them, adequate specimens were obtained in 47 specimens, and inadequate specimens were seen in 4 specimens. Technical success rate was 100% (19/19). Diagnostic accuracy was 100% (19/19) among adequate specimens. Adverse events were seen in 1 case (No. 10, mild cholangitis). Median SPY DS insertion time was 14 min (range, 10–22 min).

3.2. Bile duct carcinoma

In this case (No. 11), SPY DS was performed, because forceps biopsy under fluoroscopic guidance produced negative results. Biliary stenosis was seen in the middle common bile duct (Fig. 1A). SPY DS was inserted into the common bile duct. Cholangioscopy demonstrated a nodular and irregular surface with abnormal vessels and suggested the presence of malignancy (Fig. 1B). Forceps biopsy was performed under SPY DS guidance (Fig. 1C), and a diagnosis of bile duct carcinoma was made (Fig. 1D and E) (Video 1, http://links.lww.com/MD/B647).

3.3. Primary sclerosing cholangitis

This case (No. 17) was diagnosed with primary sclerosing cholangitis and underwent conservative treatment at another hospital. However, obstructive jaundice and lower bile duct stenosis were seen. Forceps biopsy under fluoroscopic guidance yielded insufficient material; therefore, we attempted forceps biopsy under SPY DS guidance. Cholangiography demonstrated lower bile duct stenosis (Fig. 2A). SPY DS findings showed a relatively smooth mucosa with scar formation (Fig. 2B). Forceps biopsy was performed under SPY DS guidance (Fig. 2C), and examination of biopsy specimens showed inflammatory cells and fibrosis (Fig. 2D and E). Therefore, a diagnosis of primary sclerosing cholangitis was made.

3.4. Mass forming IgG4-related cholangitis

This case (No. 1) was treated for a diagnosis of autoimmune pancreatitis. During follow-up, obstructive jaundice was present. First, forceps biopsy was performed under fluoroscopic guidance, but only normal bile duct mucosa was obtained. Therefore, SPY DS was performed. Cholangiography showed that the right intrahepatic bile duct was obstructed (Fig. 3A). After the guidewire was advanced into the right intrahepatic bile duct, the SPY DS scope was inserted into the right intrahepatic bile duct over the guidewire. Relatively irregular papillogranular mucosa was seen (Fig. 3B), and forceps biopsy under SPY DS guidance was performed (Fig. 3C). Histological examination showed only inflammatory cells (Fig. 3D and E). Steroid treatment was performed, and the lesion disappeared by cholangiography and direct visualization under SPY DS.

3.5. Therapeutic procedure

Therapeutic procedures were attempted in 8 cases. The technical success rate was 88% (7/8). Among these 8 patients, 4 patients with common bile duct stones underwent EHL. The 1 patient underwent guidewire insertion to remove a migrated plastic stent.

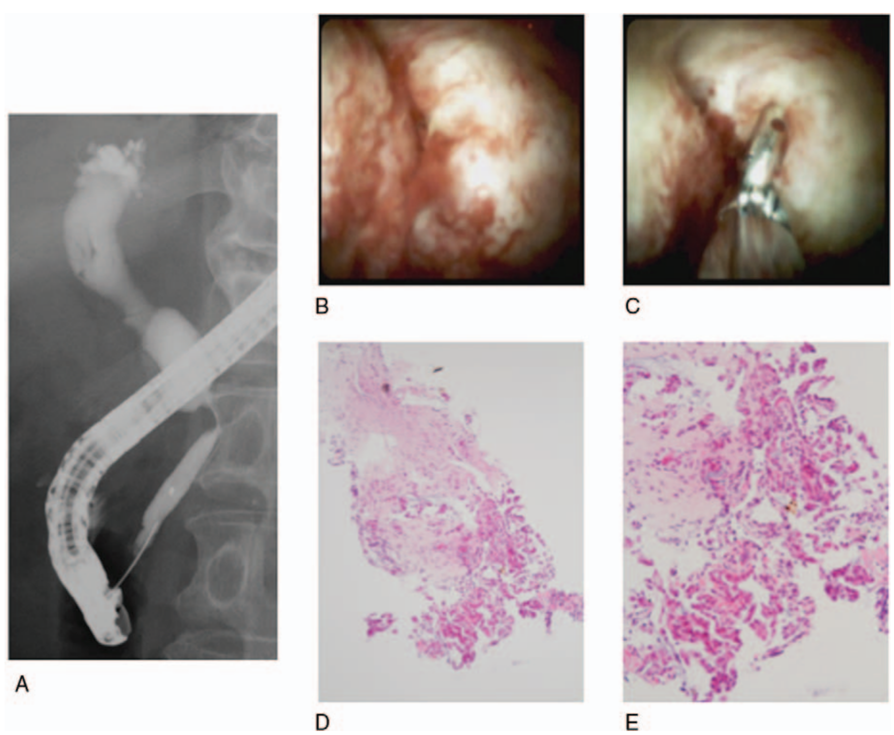

Figure 1. (A) Cholangiography showed bile duct stenosis in middle common bile duct. (B) Cholangioscopy under SPY DS showed a nodular and irregular surface with abnormal vessels. (C) Forceps biopsy was performed under SPY DS guidance. (D, E) Biopsy specimens showed adenocarcinoma. SPY DS = SpyGlass DS Direct Visualization system.

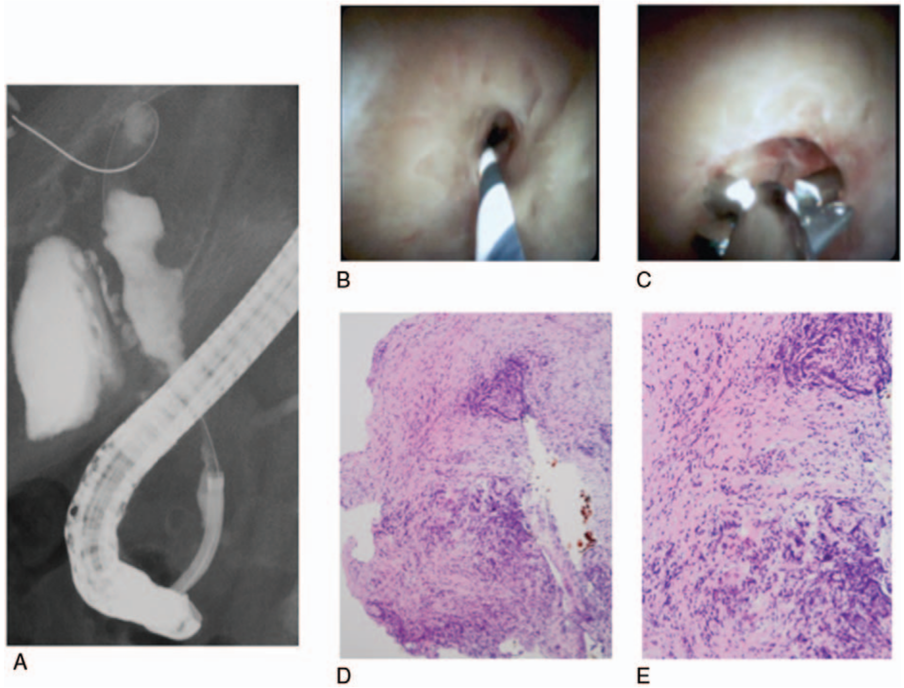

Figure 2. (A) Cholangiography showed lower bile duct stenosis. (B) Cholangioscopy under SPY DS guidance showed scar formation. (C) Forceps biopsy for this stenosis site under SPY DS guidance. (D, E) Biopsy specimens showed inflammatory cells and fibrosis. SPY DS = SpyGlass DS Direct Visualization system.

Migrated plastic stent removal was successfully performed. And 3 patients underwent SPY DS to insert the guidewire for left bile duct obstruction and for posterior bile duct branch, respectively. Among them, 1 patient underwent SPY DS for insertion of a guidewire for left hepatic bile duct obstruction cause by primary sclerosing cholangitis. However, we could not advance the guidewire into the left hepatic bile duct. Adverse events were not seen. Median SPY DS insertion time was 21 min (range, 8–32 min).

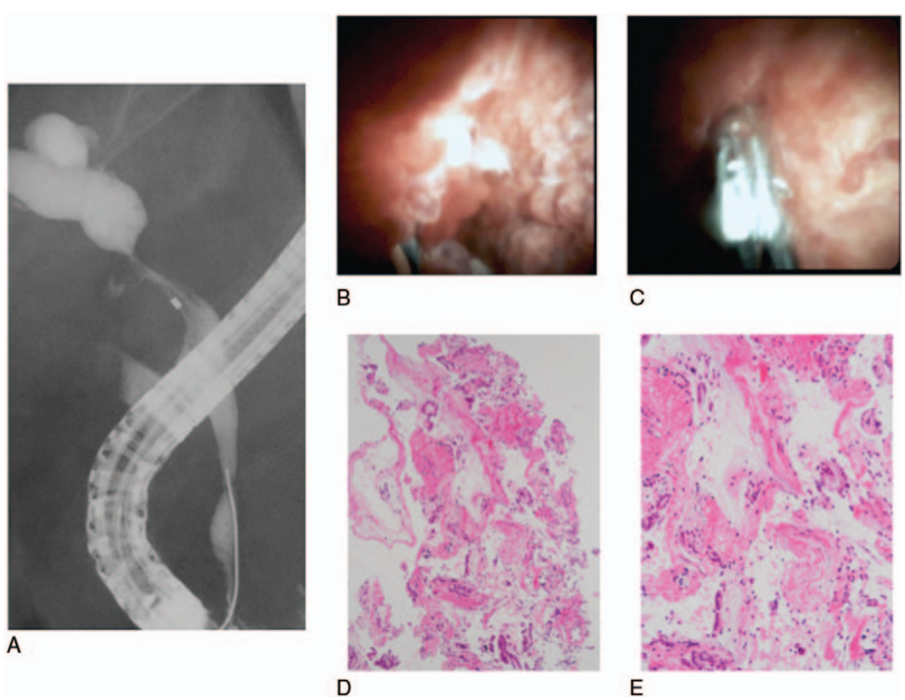

Figure 3. (A) Cholangiography showed right hepatic bile duct stenosis. (B) Relatively irregular papillogranular mucosa was seen in SpyGlass DS Direct Visualization system imaging. (C) Forceps biopsy was performed. (D, E) Only inflammatory cells were obtained.

3.6. Electrohydraulic lithotripsy

Multiple large stones were seen on cholangiography (Fig. 4A). The SPY DS scope was inserted into the common bile duct, and the EHL probe was inserted through the working channel of the SPY DS scope. We performed EHL, and the common bile duct stone was fragmented (Fig. 4B and C). Finally, common bile duct stones were completely removed using a balloon catheter (Video 2, http://links.lww.com/MD/B648).

3.7. Guidewire insertion

This patient underwent partial heptectomy due to huge hemangioma. After surgery, bile leak from posterior branch was complicated. Therefore, stent placement into the posterior branch was tried. First, we inserted the guidewire under ERCP guidance; however, we could not advanced the guidewire into the posterior branch. Next, SPY DA was inserted into the common bile duct, and hole of the posterior branch could be seen (Fig. 5A). Then, the guidewire insertion under SPY DS guidance was successfully performed (Fig. 5B and C). Finally, stent placement was also successfully performed (Video 3, http://links.lww.com/MD/B649).

4. Discussion

Various diagnostic and therapeutic procedures for biliary disease have been performed under ERCP guidance. Despite imaging with intraductal ultrasound, EUS, or CT, biliary stricture remains poorly characterized in up to 30% of cases.[15] This is critical, because most cases of biliary malignant tumor are diagnosed at an advanced stage, so the mortality rate is relatively high.[16] On the other hand, the cumulative 5-year survival rate of patients who undergo surgical treatment at an early stage of this disease is high.[17] Thus, surgical resection is the only strategy that offers long-term survival for patients with malignant biliary tumor. As a result, accurate diagnosis is extremely important. POCS may play an important role in such cases, because biliary lesions can be directly visualized.

On the other hand, benign biliary disease is typically treated under ERCP guidance. Common bile duct stones are treated using a balloon catheter and a basket catheter under ERCP guidance.[18–20] However, when large or multiple stones are present in the common bile duct, stone removal may be challenging, even when using endoscopic papillary large balloon dilation. In such cases, EHL under POCS may be useful.

Therefore, POCS using the video cholangioscope has clinical impact for indeterminate biliary stricture as well as for therapeutic procedures due to its ability of direct endoscopic visualization.[21–24] However, this procedure is relatively cumbersome. To overcome this problem, a single-operator POCS using the SpyGlass system has been developed.[5–13] Although this device has proven clinically useful, SpyGlass has several limitations including poor visualization due to optical probe, need for set up and adjustments, and absence of suction or

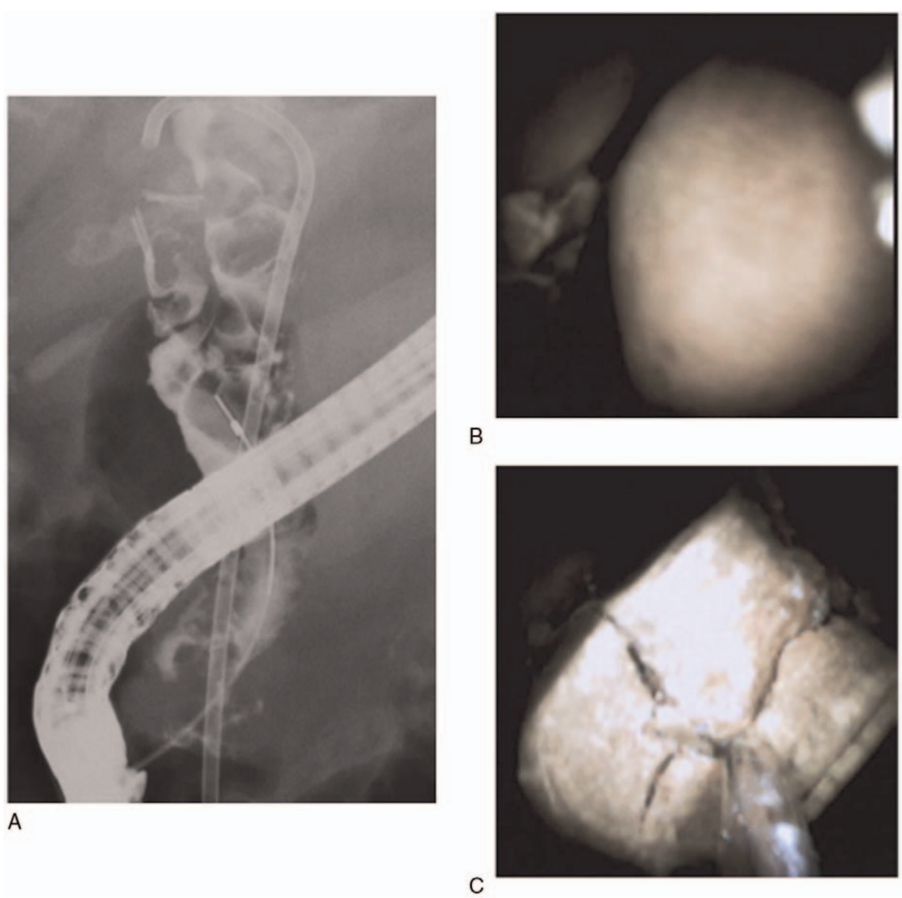

Figure 4. (A) Cholangiography showed multiple defects in common bile duct, which was suggested multiple stones. (B) Large stones were seen in common bile duct on SpyGlass DS Direct Visualization system imaging. (C) Electrohydraulic lithotripsy was performed.

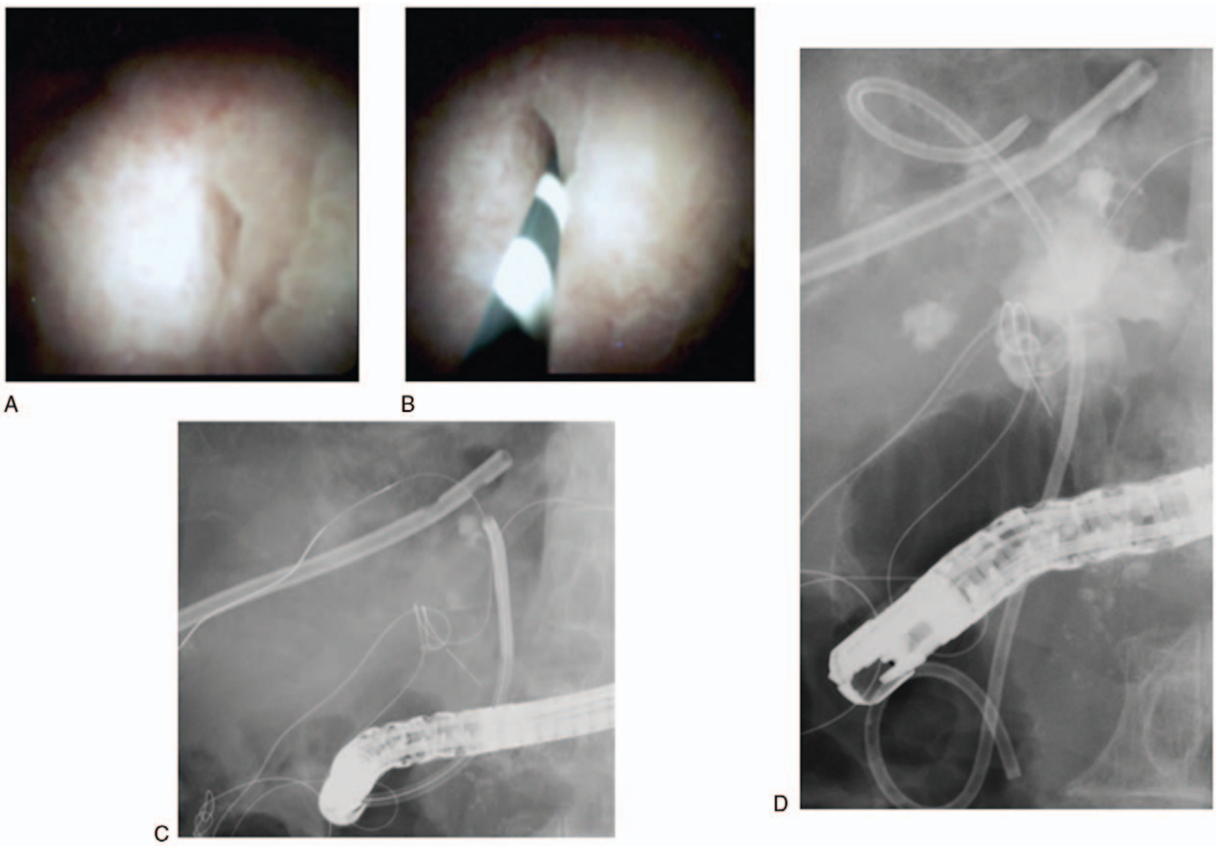

Figure 5. (A) The hole of posterior branch was seen under SPY DS guidance. (B) The guidewire insertion of SPY DS imaging. (C) The guidewire insertion of fluoroscopic imaging. (D) Stent placement was successfully performed. SPY DS = SpyGlass DS Direct Visualization system.

narrow banding imaging. Recently, the SPY DS system has been available. The scope of the SPY DS shows a dramatic improvement over the SpyGlass system in terms of the following: insertion into the biliary tract is easier due to its tapered tip; favorable visualization is obtained due to a digital field of view of 120°; and newly added injection and suction functions are carried out through a 2-port adaptor. Therefore, this system allows diagnosis by direct visualization and allows performance of various therapeutic. Indeed, in our study, the SPY DS scope was successfully inserted into the biliary tract, and all lesions were successfully visualized. In addition, EHL was successfully performed without trauma. However, SPY DS has several limitations, including a working channel of only 1.2 mm, meaning that some devices (e.g., laser photodynamic treatment or argon plasma coagulation) cannot be used and poor visualization when compared to that of video cholangioscopes. Therefore, further studies are needed to examine whether diagnosis by visualization of SPY DS can be used in conjunction with previously documented visual criteria for differentiating benign and malignant lesions.[21–23] In addition, improvement devices for the exclusive use of SPY DS are also needed to perform various therapeutic procedures.

To date, only a few case reports or case series of diagnostic and therapeutic procedures using SPY DS systems have been reported.[25–32] Among these reports, Tanaka et al described the clinical impact of using SPY DS systems in the diagnostic and therapeutic procedures of 26 patients with pancreaticobiliary disease. In their study, 19 diagnostic and 7 therapeutic procedures were performed using the SPY DS scope, and the overall technical success rates of visualizing the target lesions with forceps biopsy and therapeutic interventions were 100% (17/17) and 85.6% (6/7), respectively.[26] Adverse events were seen in 2 patients (7.7%, cholangitis and bleeding). More recently, Navaneethan et al reported of a multicenter clinical experience of 105 SPY DS cases. In this study, 44 patients who underwent forceps biopsy under SPY DS guidance, and the adequate specimens were obtained in 43 patients (97.7%). The sensitivity and specificity of forceps biopsy for diagnosis of malignancy were 85% and 100%. In addition, among 36 patients who had biliary or pancreatic duct stones, complete duct clearance with stone removal in 1 session was accomplished in 86.1% of patients. In our study, similar results were obtained (technical success rate of 100%, adequate specimens of 92%, and adverse event rate of 4%). Our study is the first report to include only patients with biliary disease and describe the procedure time associated with insertion of the SPY DS scope into the biliary tract. Also, our study suggested that diagnostic and therapeutic cholangioscopy using SPY DS may be able to be safely performed with a high technical success rate. However, our study has several limitations, such as small sample size, single-center experience, and its retrospective nature.

In conclusion, single-operator cholangioscopy using SPY DS was feasible and had a marked clinical impact in patients with biliary disease. Additional case reports and prospective studies are needed to examine further applications of this system.

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