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DYNAMIC MANUSCRIPT

Therapeutic peroral direct cholangioscopy using a single balloon enteroscope in patients with Roux-en-Y anastomosis (with videos)

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Abstract

Background Peroral cholangioscopic lithotripsy is a useful procedure in patients with a normal gastrointestinal anatomy who have difficult-to-treat stones. We evaluated the usefulness of peroral direct cholangioscopy (PDCS) using single-balloon enteroscope (SBE) in patients with difficult-to-treat stones who had undergone Roux-en-Y reconstruction.

Methods Among 118 patients (169 sessions) who underwent SBE-assisted endoscopic retrograde cholangiopancreatography to treat biliary stones after Roux-en-Y reconstruction, patients in whom it was difficult to remove biliary stones via a transpapillary or transanastomotic approach and difficult to switch to ultra-slim endoscope, were retrospectively enrolled. The biliary insertion success rate, procedure success rate, procedure time, and procedural complications were assessed. The SBE was inserted into the bile-duct, first using a free-hand technique, second using a guide wire, and third using the large balloon anchoring and deflation (LBAD) technique.

Results A total of 11 patients (14 sessions) were enrolled in this study. The biliary insertion success rate was 100%. Bile-duct insertion was performed using a free-hand technique in 4 sessions, a guide wire in 3 sessions (rendezvous technique, 2 sessions), and the LBAD technique in 7 sessions. The procedure success rate was 86% in first session, and 100% in second session. The median procedure time was 81 min (range 49–137). The median procedure time in the bile-duct was 21.5 min (range 6–60). Mild pancreatitis occurred as a complication in one patient. The median follow-up was 528 days (range 282–764). No patient had stone recurrence.

Conclusions PDCS using SBE is a useful procedure in patients with Roux-en-Y reconstruction. The LBAD technique is an useful technique of inserting SBE into the bile-duct.

Keywords ERCP (Endoscopic retrograde cholangiopancreatography) · Short type single-balloon enteroscope · Altered gastrointestinal anatomy · Roux-en-Y · Peroral direct cholangioscopy

The balloon enteroscope has considerably improved the outcome of endoscopic-lithotripsy in patients with Roux-en-Y (R-Y) reconstruction, which was previously considered challenging [1–8].

However, the stone removal remains challenging in some patients. For example, in patients with giant stones that are difficult to grasp, and in patients in whom only a long-type balloon enteroscope can reach the blind end [duodenal papillae or choledochojejunal anastomosis (CJA)].

For giant stones, mother-baby cholangioscopy is useful and has a high success rate with normal gastrointestinal (GI) anatomy [9], but this procedure is difficult to perform with R-Y reconstruction. Treatment using long-type balloon enteroscope cannot be performed similarly to that with normal GI anatomy, because the number of accessories is limited. In patients with gastrectomy, the bile-duct

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is often dilated even if stones are small, causing more space between accessories and the bile-duct and making stone removal difficult. For these reasons, endoscopic-lithotripsy might be more difficult to perform with R-Y reconstruction rather than with normal GI anatomy.

Peroral direct cholangioscopy (PDCS) [10] is a method that may overcome these difficulties with surgically altered anatomy [11–17]. In many studies of therapeutic PDCS with surgical altered anatomy, treatment procedures were performed after switching to an ultra-slim endoscope using the overtube-assisted technique (An overtube is left in the intestine, and the scope is exchanged.) [11, 12]. However, this technique has several limitations. Exchange of the scope is often difficult. For example, bowel shortening is precluded by adhesion, the overtube migrates at the time of scope exchange even after bowel shortening, patients with multiple loops, a long afferent loop. In such patients, balloon enteroscope-assisted PDCS may be effective. However, the usefulness of this procedure remains not to be fully defined [11, 13–17].

We report the usefulness of PDCS using single-balloon enteroscope (SBE-PDCS) in patients with R-Y reconstruction in whom it was difficult to remove biliary stones via a transpapillary or transanastomotic approach and difficult to switch to an ultra-slim endoscope.

Methods

Patients

From November 2012 through November 2016, we performed 169 sessions of SBE-assisted endoscopic-lithotripsy in 118 patients with R-Y reconstruction. Data were obtained from the endoscopic database of Kitasato University Hospital. Among 118 patients [169 sessions; R-Y gastrectomy, 126 sessions in 95 patients; R-Y choledochojejunostomy (CJS), 43 sessions in 23 patients], we investigated patients in whom SBE-PDCS was performed (Fig. 1).

All patients provided written informed consent before the procedure. This study was approved by the institutional review board of our hospital.

All examinations were performed in patients who were sedated with pethidine (35 mg) and midazolam (3–10 mg) during intermittent monitoring of vital signs (including percutaneous carbon dioxide monitoring: cutaneous PO2/PCO2 monitor 9100, KOHKEN MEDICAL CO.,LTD. Tokyo, Japan). Antibiotics were given before and after the procedure. Bile-duct stones were diagnosed by abdominal ultrasonography, computed tomography (CT), and magnetic resonance cholangiopancreatography (MRCP).

Indication and contraindication

The indication of SBE-PDCS is patients in whom a transpapillary or choledochojejunal transanastomotic stone removal was difficult, and switching to an ultra-slim endoscope by the overtube-assisted technique was difficult because of multiple loops, a long afferent loop, and bile-duct diameter is more than 12 mm. Difficult-to-treat biliary stones were defined as giant or small stones that could not be grasped with a basket or removed with a stone removal balloon.

The contraindication of SBE-PDCS is patients with severe cholangitis, severe chronic obstructive pulmonary disease, bile-duct diameter less than 12 mm, performance status 4, and patients in whom informed consent was not obtained.

Endoscopic procedure

Endoscope and instruments

We used a short-type SBE (working length; 1520 mm, working channel diameter; 3.2 mm, distal end outer diameter; 9.2 mm, SIF-H290S, SIF-Y0015 series [prototype], Olympus Medical Systems, Tokyo, Japan) and a long-type SBE (working length; 2000 mm, working channel diameter; 2.8 mm, distal end outer diameter; 9.2 mm, SIF-Q260, Olympus Medical Systems). A 12- to 20-mm CRE^{TM} Balloon (Boston Scientific, Natick, MA, USA) and a 16- to 18-mm REN Biliary Balloon (Kaneka Medix Corp., Osaka, Japan) was used as a large balloon.

Techniques of bile-duct insertion

SBE was inserted into the bile-duct after dilation with a large balloon in all patients with papillae and with CJA if required. In patients with papillae, balloon dilation was performed until the notch disappeared, without endoscopic sphincterotomy. In patients with CJA, in principle, balloon dilatation was performed until the notch disappeared. However, in patients in whom the notch did not completely disappear even if the balloon was inflated to the target diameter, dilatation was performed for 2–3 min.

In all patients, SBE was inserted first using a free-hand technique. If insertion was difficult, a guide wire was placed in the bile-duct to serve as a landmark; fluoroscopy was performed as required. In patients who had undergone percutaneous transhepatic biliary drainage (PTBD) as pretreatment in another hospital, the PTBD-rendezvous technique was used (i.e., the guide wire was grasped endoscopically by the rendezvous technique and was pulled percutaneously and inserted). In patients in whom

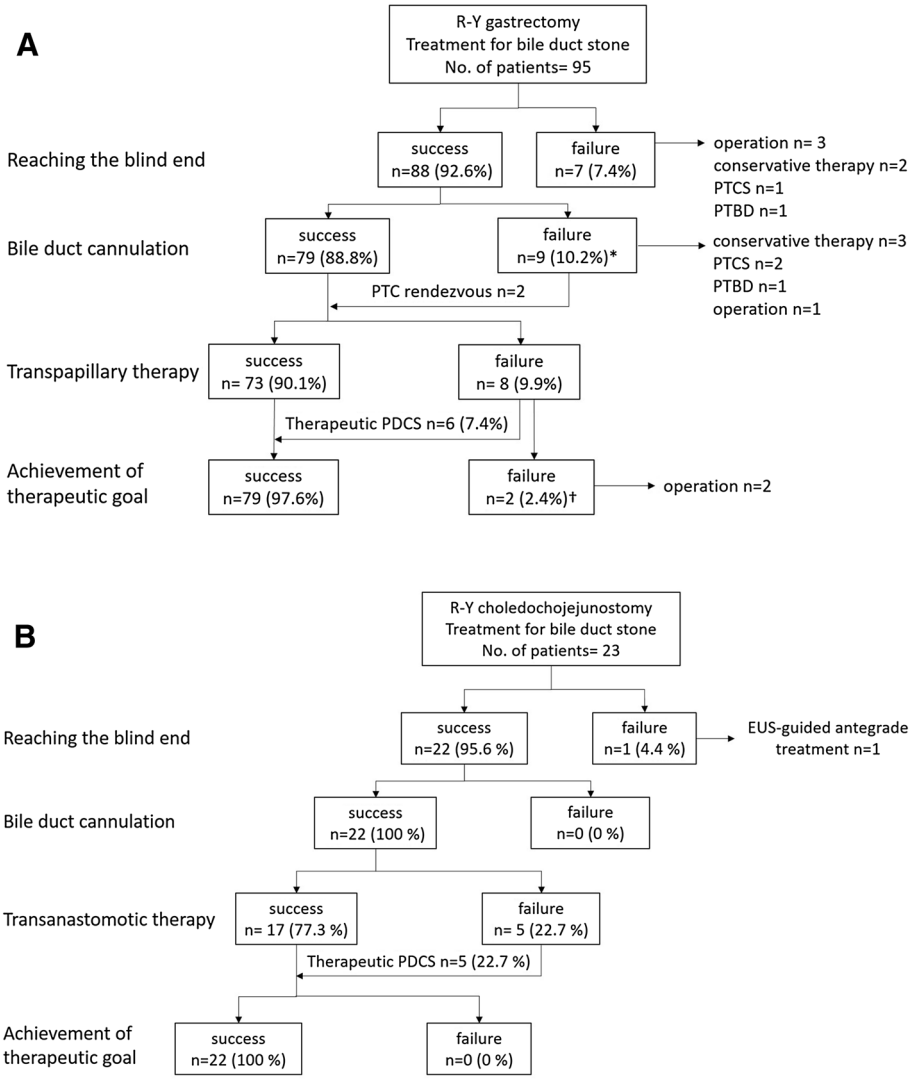

Fig. 1 **A** Outcomes of SBE-ERCP for Roux-en-Y gastrectomy. **B** Outcomes of SBE-ERCP for Roux-en-Y choledochojejunostomy. *EUS* endoscopic ultrasonography, *PDCS* peroral direct cholangioscopy, *PTBD* percutaneous biliary drainage, *PTC* percutaneous cholangiography, *PTCS* percutaneous cholangioscopy, *R-Y* Roux-en-Y, *SBE-ERCP* single-balloon enteroscope-assisted ERCP. *Including two cases of gastrointestinal perforation. †Including one case of gastrointestinal perforation

insertion was difficult using these methods, the large balloon anchoring and deflation (LBAD) technique was performed. A tip cap was used if necessary.

The LBAD technique was performed as follows (Video 1):

1. The balloon size was determined on the basis of the bile-duct diameter. The duodenal papillae and CJA were dilated. After notch disappeared, the balloon was deflated to confirm the absence of perforation and bleeding.
2. The balloon was re-inflated and was pulled and attached to the enteroscope.
3. The enteroscope was pushed, and the tip of the enteroscope was inserted into the bile-duct.
4. After the enteroscope was slightly inserted into the bile-duct, the balloon was deflated, and the enteroscope was inserted into the bile-duct while removing the balloon catheter.

Bile-duct insufflation

The bile-duct was insufflated with carbon dioxide (CO_2), and physiological saline solution was injected through the forceps channel (equipped with a T-tube). To avoid the unwarranted CO_2 insufflation, the CO_2 insufflator was switched on and off to minimize insufflation. To avoid the elevation of bile-duct pressure, the overtube-balloon was deflated as much as possible during PDCS.

Stone removal

SBE-PDCS was performed on the same day that stone removal, via a transpapillary or transanastomotic approach, was judged to be difficult. Stone removal under PDCS was performed with CO_2 insufflation. Electrohydraulic lithotripsy (EHL) was performed after filling the bile-duct with saline. Difficult to grasp small stones, debris, and pieces of

crushed stones were washed with saline and removed by aspiration. In patients in whom more than 120 min were required for stone removal after reaching the blind end, a plastic stent was inserted if necessary, and second procedure was performed another day.

Evaluation of outcomes and follow-up

We retrospectively studied the following variables: biliary insertion success rate (reaching the bile-duct required for treatment), first procedure success rate (rate of complete stone removal in first session), final procedure success rate (final rate of complete stone removal in several sessions), procedure time (from insertion to removal of the endoscope), procedure time in bile-duct (from insertion into the bile-duct to removal), the contents of procedures, procedural complications, and stone recurrence rate. The severity of procedural complications was graded according to the system proposed by Cotton et al. [18]. The stone recurrence and residual stones were evaluated with abdominal ultrasonography, CT, and MRCP.

Results

A total of 11 patients (14 sessions; R-Y gastrectomy, 8 sessions in 6 patients; R-Y CJS, 6 sessions in 5 patients) were enrolled in this study. The study group comprised 6 men and 5 women with a median age of 77 years (range 54–86).

Reasons for the difficulty of switching to an ultra-slim endoscope were the long afferent loop requiring the use of long-type SBE in 8 sessions (Fig. 2A) and the difficulty in shortening the intestine because of the multiple loops and adhesion (Fig. 2B) in 6 sessions.

PDCS was indicated for the giant stones that were difficult to grasp in 8 sessions (Fig. 3), the removal of small stones and debris and casts that were difficult to grasp or remove using a balloon in 6 sessions.

The median maximum bile-duct diameter was 19 mm (range 12–29). The median major axis of stone was 18 mm (range 4–30). The median number of stones was 3 (range 1–10). A parapapillary diverticulum was found in 1 session.

The characteristics of the patients are shown in Tables 1 and 2.

The biliary insertion success rate was 100% (14/14). The first procedure success rate was 86% (12/14), the final procedure success rate was 100% (11/11). Stones were completely removed at the first SBE-PDCS in 9 patients. In Case 4 and Case 7, the time required for the first procedure was prolonged. Therefore, second SBE-PDCS was performed 7 and 4 days later, respectively, and the stones were completely removed. In Case 3, stones were completely removed at the first SBE-PDCS (Video 2). However, biliary cast syndrome (caused by bile-duct ulcer) occurred 1 month after the initial treatment, and second SBE-PDCS was performed to remove biliary casts. All biliary casts were completely removed in one session (Video 3).

The median procedure time was 81 min (range 49–137). The median procedure time in the bile-duct was 21.5 min (range 6–60).

The success rate of bile-duct insertion using a free-hand technique was 28.5% (4/14) (R-Y CJS, 4 sessions), using a guide-wire technique was 12.5% (1/8) (R-Y CJS, 1 session), using the PTBD-rendezvous technique was 100% (2/2) (R-Y gastrectomy, 2 sessions), and using the LBAD technique was 100% (7/7) (R-Y gastrectomy, 6 sessions; R-Y CJS, 1 session) (Fig. 4). The median diameter of the balloon used to perform the LBAD technique was 15 mm (range 12–16.5).

EHL was performed in 4 sessions (Video 2) and using a 4-wire basket in 2 sessions, a 5-prong grasping forceps in 6 sessions, and a 5-prong grasping forceps plus a balloon in 2

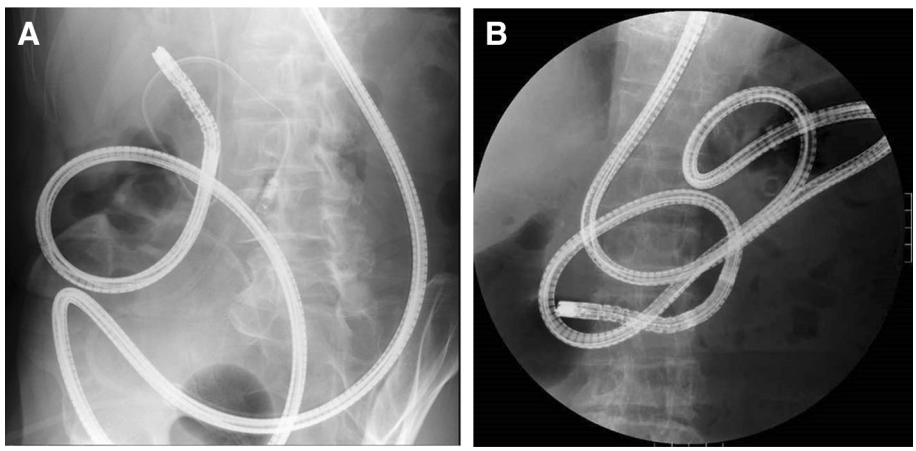

Fig. 2 **A** A patient with a long afferent loop in whom only a long-type SBE could be reached. **B** A patient in whom the intestine could not be shortened because of adhesion

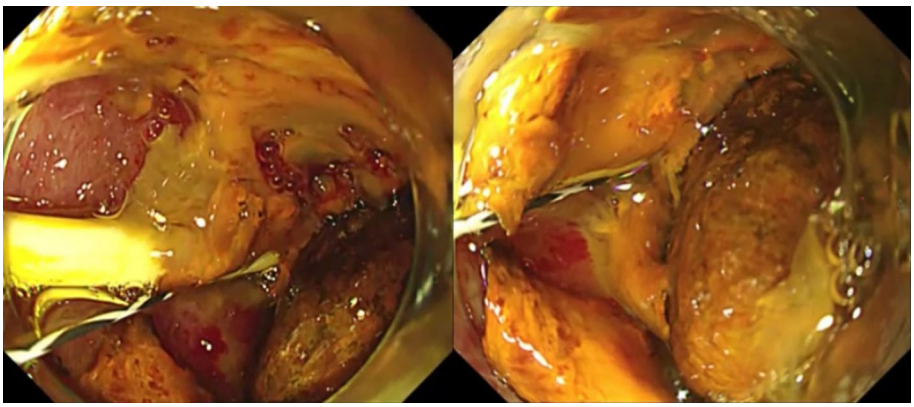

Fig. 3 A bile-duct ulcer accompanied by an impacted stone in the common hepatic duct

Table 1 Patient's characteristics

	No. of patients = 11; No. of sessions = 14
Sex ratio (male/female)[a]	6/5
Median age (year) (range)[a]	77 (54–86)
Indications for surgery, *n* (%)[a]	
Gastric cancer	6 (55)
Pancreaticobiliary maljunction	2 (18)
Gallbladder cancer	1 (9)
Benign duodenal stricture	1 (9)
CBD injury due to cholecystectomy	1 (9)
Type of reconstruction, *n* (%)	
Roux-en-Y gastrectomy	8 (57)
Roux-en-Y choledochojejunostomy	6 (43)
Indications of ERCP, *n* (%)	
CBD stone	7 (50)
IHBD stone + benign biliary stricture	3 (21)
IHBD stone + benign choledochojejunal stricture	2 (14)
IHBD stones + liver abscess	1 (7)
Biliary casts syndrome	1 (7)
Type of endoscope, *n* (%)	
Short-type SBE	9 (64)
Long-type SBE	5 (36)
Reasons for the difficulty in switching to an ultra-slim endoscope	
Long afferent loop	8 (57)
Difficulty in shortening the intestine	6 (43)
Indications of PDCS, *n* (%)	
Giant stones difficult to grasp	8 (57)
Small stones difficult to grasp and to remove with balloon	6 (43)
Maximum bile-duct diameter (mm), median (range)[a]	19 (12–29)
No. of stones, median (range)[a]	3 (1–10)
Major axis of stone (mm), median (range)	18 (4–30)
Parapapillary diverticulum, *n* (%)	1 (7)

CBD common bile-duct, *ERCP* endoscopic retrograde cholangiopancreatography, *IHBD* intrahepatic bile-duct, *PDCS* peroral direct cholangioscopy, *SBE* single-balloon enteroscope

[a] No. of patients

Table 2 Characteristics and outcomes in individual patients

Case	Sex/age (yr)	Type of reconstruction	Indication for ERCP	Type of endoscope	Biliary insertion method	Bile-duct diameter (mm)	Stone diameter (mm)	No. of stones	Balloon diameter (mm)	PDCS procedures	Insufflation	Procedure time total ([a])/PDCS	Biliary insertion at bile-duct	Compli-cations
1	M/81	R-Y gastrectomy	CBD stones	sSBE	LBADT	20	25 × 20	5	15	EHL	CO_2 + saline	66 (6)/15	CBD and CHD	No
2	M/78	R-Y gastrectomy	CBD stone	sSBE	LBADT	20	30 × 18	1	15	EHL	CO_2 + saline	80 (11)/18	CBD	No
3-1	M/77	R-Y gastrectomy	Impacted CBD stone	sSBE	LBADT	19	23 × 17	1	15	EHL Removal of migrated stent	CO_2 + saline	120 (14)/48	CBD	No
3-2	M/77	R-Y gastrectomy	Biliary cast syndrome	sSBE	LBADT	19	–	–	13.5	5-prong forceps + lavage, aspiration Biliary biopsy Biliary dilation	CO_2	109 (7)/45	CBD	No
4-1	F/79	R-Y gastrectomy	CBD stones	sSBE	PTBD rendezvous	25	26 × 17	2	20	EHL	CO_2 + saline	104 (5)/60	CBD and CHD	Pancreatistis
4-2	F/79	R-Y gastrectomy	CBD stones	sSBE	PTBD rendezvous	25	4	4	18	5-prong forceps + lavage, aspiration	CO_2	102 (10)/25	CBD and CHD	No
5	F/86	R-Y gastrectomy	CBD stones	sSBE	LBADT	19	21 × 14	3	16.5	5-prong forceps + lavage, aspiration	CO_2 + saline	50 (9)/10	CBD	No
6	F/82	R-Y gastrectomy	CBD stones	sSBE	LBADT	29	5	5	12	Basket + lavage, aspiration	CO_2 + saline	82 (10)/6	CBD and CHD	No
7-1	M/73	R-Y CJS	BBS + IHBD stones	lSBE	Guide wire	15	18 × 11	10	12	Biliary dilation 5-prong forceps + balloon	CO_2 + saline	137 (15)/55	LHD and RHD	No
7-2	M/73	R-Y CJS	BBS + IHBD stones	lSBE	Free hand	15	14 × 8	7	12	Biliary dilation 5-prong forceps + lavage, aspiration	CO_2 + saline	70 (6)/52	LHD and RHD	No
8	M/74	R-Y CJS	BBS + IHBD stones	lSBE	Free hand	15	5	3	–	Biliary dilation 5-prong forceps	CO_2	75 (10)/13	RHD	No
9	F/33	R-Y CJS	Benign CJA stricture + IHBD stones	lSBE	LBADT	14	9 × 6	3	13.5	Basket	CO_2	103 (13)/9	LHD and RHD	No
10	F/70	R-Y CJS	BBS + IHBD stone	lSBE	Free hand	12	5	1	–	Biliary dilation 5-pronged forceps	CO_2	68 (12)/6	LHD	No
11	M/54	R-Y CJS	Benign CJA stricture + IHBD stone	lSBE	Free hand	25	20 × 14	1	15	5-prong forceps + lavage, aspiration	CO_2 + saline	49 (7)/26	CHD	No

BBS benign biliary stricture, *CBD* common bile-duct, *CHD* common hepatic duct, *CJA* choledochojejunal anastomosis, *CJS* choledochojejunostomy, CO_2 carbon dioxide, *EHL* electrohydraulic lithotripsy, *EML* endoscopic mechanical lithotripsy, *IHBD* intrahepatic bile-duct, *LBADT* large balloon anchoring and deflation technique, *LHD* left hepatic duct, *lSBE* long-type single-balloon enteroscope, *PTBD* percutaneous transhepatic biliary drainage, *RHD* right hepatic duct, *R-Y* Roux-en-Y, *sSBE* short-type single-balloon enteroscope

[a] Time to reach the blind end

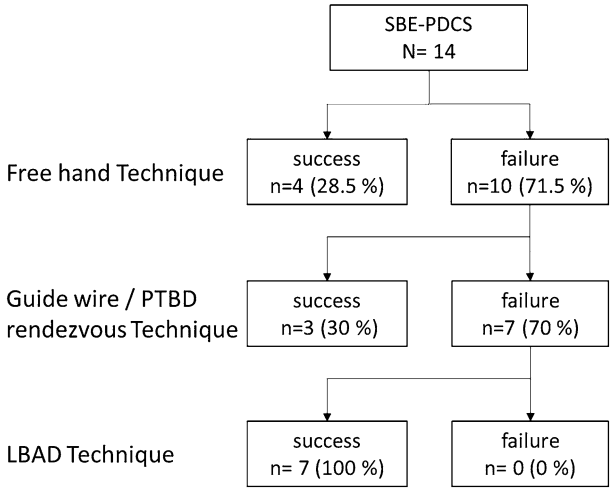

Fig. 4 Success rates of biliary insertion according to each technique. *LBAD* large balloon anchoring and deflation, *PDCS* peroral direct cholangioscopy, *PTBD* percutaneous transhepatic biliary drainage, *SBE* single-balloon enteroscope

sessions (Video 4). Lavage and aspiration were performed in 6 sessions. Biliary dilatation was performed in 5 sessions. In addition to the stone removal, the removal of a proximally migrated biliary stent in 1 session (Fig. 5, Video 2), and bile-duct biopsy in 1 session (Video 3).

Bile-duct dilatation was performed to remove stones and casts at liver side of stricture caused by gallstone cholangitis (Cases 7-1, 7-2, 8, 10) and stricture caused by a bile-duct ulcer scar (Case 3-2). Stones and casts were removed under direct vision or fluoroscopy using a 5-prong grasping forceps.

The only procedural complication was mild pancreatitis in 1 session.

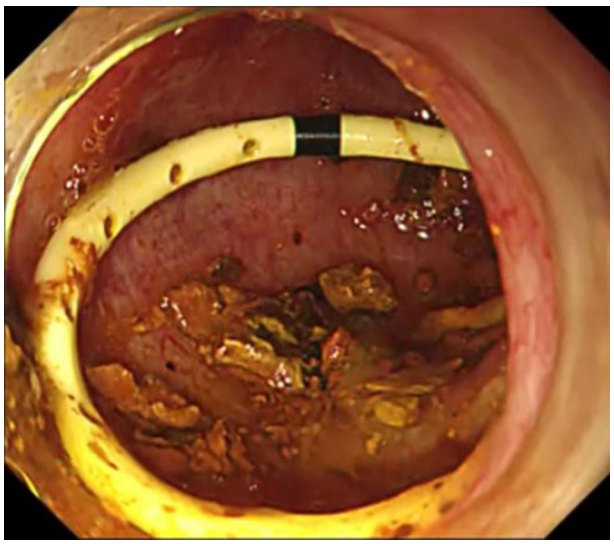

Fig. 5 A proximally migrated biliary stent confirmed on direct cholangioscopy

Table 3 Outcomes and complications

Biliary insertion success rate, %	100% (14/14)
First procedure success rate, %	86% (12/14)
Final procedure success rate, %[a]	100% (11/11)
Median procedure time, min (range)	81 (49–137)
Median procedure time in bile-duct, min (range)	21.5 (6–60)
Biliary insertion methods, *n* (%)	
Free hand	4 (29)
Guide wire	1 (7)
PTBD rendezvous	2 (14)
LBAD technique	7 (50)
Balloon diameter (mm), median (range)	15 (12–16.5)
Procedure during PDCS, *n* (%) (some overlap)	
Stones/casts removal	14 (100)
EHL	4 (29)
4-wire basket	2 (14)
5-prong grasping forceps	5 (38)
5-prong grasping forceps + balloon	2 (14)
Lavage and aspiration	6 (43)
Biliary dilation	5 (36)
Removal of migrated biliary stent	1 (7)
Biliary biopsy	1 (7)
Procedural complications, *n* (%) mild pancreatitis	1 (7)
Recurrence rate of stones, *n* (%)[a]	0 (0)
Median follow-up (days) (range)	528 (282–764)
Recurrence rate of bile-duct stricture, *n* (%)[a]	1 (25)
Median follow-up (days) (range)	538 (397–698)

EHL electrohydraulic lithotripsy, *LBAD* large balloon anchoring and deflation, *PTBD* percutaneous transhepatic biliary drainage

[a] No. of patients

The stone recurrence rate was 0%, and the median follow-up was 528 days (range 282–764). We judged Case 3-2 was not procedural complication and recurrence of stone. Because biliary cast syndrome will be one of the natural history of bile-duct ulcer due to impacted stone.

In patients who underwent dilatation of bile-duct strictures (Cases 3-2, 7, 8, 10), the stricture recurrence rate was 25% (1/4 patients), and the median follow-up was 538 days (range 397–698). In Case 3-2, cholangitis caused by restenosis developed 279 days after dilatation, and a stent was placed.

The outcomes and procedural complications are summarized in Tables 2 and 3.

Discussion

We were interested in whether SBE could be successfully inserted into the bile-duct and in determining which method was appropriate. In our study, SBE could be

inserted into the bile-duct in all patients, first using a free-hand technique, second using a guide wire and the PTBD-rendezvous technique, and third using the LBAD technique. A free-hand technique and a guide-wire technique succeeded only in patients with R-Y CJS. In patients with a papillae, these techniques were not successful because it was difficult to align the axis of the scope with the bile-duct and to secure a field of vision in the papillary region. On the other hand, in the LBAD technique, the use of a balloon makes it easy to align the scope with the axis of bile-duct, and allows the scope to be inserted while confirming the papillary region and the lower bile-duct through the balloon. A SBE was passively inserted in 4 of 7 patients using the LBAD technique (Video 1), all of whom had a duodenal papillae. The scope may be pulled into the bile-duct by the reaction created when the balloon catheter is deflated and removed. In our experience, we consider that the LBAD technique will be not so difficult to perform and may be more suitable than a free-hand and guide-wire technique in patient with papillae.

However, at the time of scope insertion into the bile-duct, bile-duct injury and papillary perforation can potentially occur as serious procedural complications. Endoscopic-papillary-large-balloon-dilation (EPLBD) has been reported to be effective and safe in patients with surgically altered anatomy [19]. However, bile-duct injury has been reported [20]. Particularly in patients with a papillae, caution should be exercised at the time of biliary insertion of SBE. Because SBE-PDCS was performed after EPLBD, the mechanical stress will be added to the torn and dilated papillae/lower bile-duct. Therefore, when performing the LBAD technique, we recommend that a balloon that can reach the target diameter at a lower pressure should be selected and a balloon larger in diameter than the lower bile-duct should not be selected. About the indication of bile-duct diameter, we consider that SBE-PDCS should not be performed with a bile-duct diameter of less than 12 mm from the viewpoint of complications. In our experience, endoscopic-lithotripsy was successfully performed via a transpapillary or transanastomotic approach with a bile-duct diameter less than 12 mm, and therapeutic procedure might be limited because diameter of SBE is 9.2 mm. In difficult-to-treat patients with a bile-duct diameter of less than 12 mm, other treatments should be considered (PDCS using an ultra-slim endoscope if the scope can be replaced, a transcutaneous treatment, surgical operation etc.).

Intraductal therapeutic procedures were successful in all patients, and easy to perform because conventional devices can be used, expanding the range of treatment options. Intraductal procedures have several advantages, including lavage and aspiration of crushed stones after EHL and high-resolution endoscopic images. In our study, the complete stone removal rate via a transpapillary approach was 90.1% (73/81) with R-Y gastrectomy. Transpapillary stone removal plus therapeutic PDCS increased the complete stone removal rate to 97.6% (79/81) (Fig. 1A). The complete stone removal rate of a transanastomotic approach with R-Y CJS was 77.3% (17/22), and transanastomotic stone removal plus therapeutic PDCS increased the complete stone removal rate to 100% (22/22) (Fig. 1B). Therefore, SBE-PDCS was considered to be an effective procedure and to increase the complete stone removal rate with R-Y reconstruction.

There were no serious procedural complications in our study (mild pancreatitis in one patient). However, complications after biliary insertion include air embolism and bacteremia caused by cholangiovenous reflux. These are serious and fatal complication.

In our study, antibiotics were given before and after treatment, and no patient had infection or infectious symptoms. Prophylactic treatment with antibiotics should be administered before and after procedures because ERCP combined with cholangioscopy has been reported to increase the risk of bacteremia [27].

In previous studies, air embolism was consistently associated with room air [21, 22], and CO_2 insufflation has been reported to be safe [10–12, 23–25]. However, one study reported that fatal systemic gas embolism was caused by CO_2 insufflation in patient who underwent YAG laser lithotripsy during overtube-assisted PDCS using an ultra-slim endoscope [26]. Unlike an ultra-slim endoscope, when SBE is inserted into the bile-duct, the scope can easily wedge into the duodenal papillae or the site of CJA, thereby increasing intrabiliary pressure. Therefore, respiratory status should be checked, including CO_2 monitoring, and care should be exercised to ensure enough dilation of the duodenal papillae and the CJA and to minimize CO_2 insufflation. In the patient described above, treatment was performed in the bile-duct while leaving the balloon attached to the overtube inflated. We have attempted to deflate the balloon as much as possible during PDCS. This step might prevent the elevation of bile-duct pressure. This is because, this step prevents the elevation of intra-intestinal pressure between the blind end and the overtube-balloon, and promotes the flow of CO_2 into the anal side of intestine from bile-duct. Although CO_2 embolism was reported only in one patient, it is a fatal complication. Therefore, measures to prevent CO_2 embolism are essential whenever possible, and our methods of bile-duct insufflation might prevent CO_2 embolism. In our study, SBE-PDCS was safe (the only procedural complication was mild pancreatitis in one session). However, our study was a small retrospective and single endoscopic center investigation. The Safety of therapeutic PDCS thus remains to be established.

Therefore, SBE-PDCS should currently be limited to patients with a bile-duct diameter of more than 12 mm in whom a transpapillary or transanastomotic approach is difficult. Further studies of larger numbers of patients are needed to confirm our results.

Conclusions

SBE-PDCS is useful and increases the complete stone removal rate in patients with R-Y anastomosis. The LBAD technique is considered a promising procedure in patients with duodenal papillae.

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