Single-balloon enteroscopy effectively enables diagnostic and therapeutic retrograde cholangiography in patients with surgically altered anatomy

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Background: In patients with surgically altered anatomy, ERCP is often unsuccessful. Single-balloon enteroscopy (SBE) enables deep intubation of the small bowel, permitting diagnostic and therapeutic ERCP in this subset of patients.

Objective: To determine the effectiveness of SBE in performing endoscopic retrograde cholangiography (ERC) in patients with surgically altered anatomy.

Design: Case series.

Setting: Large quaternary-care center.

Patients: Thirteen patients (11 women) underwent 16 SBE procedures with ERCP. Patient anatomy consisted of Whipple (n = 3), hepaticojejunostomy (n = 3), Billroth II (n = 1), and Roux-en-Y (n = 9).

Interventions: Patients with surgically altered anatomy in whom standard ERCP techniques had failed or were not possible underwent ERC by using SBE with initial therapeutic intent.

Main Outcome Measurements: Success rates of diagnostic ERC and therapeutic ERC in those patients who required biliary intervention. Procedure-related complications were also assessed.

Results: Diagnostic ERC was successful 12 (92.3%) of 13 patients and in 13 (81.3%) of 16 cases. Therapeutic ERC was required in 10 patients in whom diagnostic ERC was first accomplished, and therapeutic ERC was successful in 9 (90%) of 10 patients. Biliary interventions included balloon dilation (n = 4), stone extraction (n = 2), sphincterotomy (n = 4), removal of a surgically placed stent (n = 3), and stenting (n = 2). Two patients developed pancreatitis after therapeutic ERC. Median follow-up was 53 days (range 22-522 days). Overall procedural success in an intent-to-treat analysis by case was 75%.

Limitation: Single-center experience.

Conclusion: SBE enables diagnostic and therapeutic ERC in most patients with altered anatomy. SBE-assisted therapeutic ERC may be associated with an increased risk of pancreatitis. Improvement of the available equipment is necessary to perform more efficient and effective biliary interventions.

Altered gastroduodenal anatomy is a frequently encountered occurrence that increases the difficulty of performing therapeutic ERCP. In patients with surgically altered anatomy and long afferent limbs, ERCP by using a duodenoscope may not be successful.[1] Additionally, surgery often alters the location of the major papilla, making selective cannulation of the native papilla challenging.[1]

Conventional alternative approaches to gain biliary access in patients with altered gastroduodenal anatomy include push enteroscopy, using a standard enteroscope

Abbreviations: DBE, double-balloon enteroscopy; ERC, endoscopic retrograde cholangiography; HJ, hepaticojejunostomy; LDLT, living donor liver transplantation; OLT, orthotopic liver transplantation; PTC, percutaneous transhepatic cholangiography; RYGB, Roux-en-Y gastric bypass; SBE, single-balloon enteroscopy.

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or pediatric colonoscope,[2-4] or percutaneous transhepatic cholangiography (PTC).[5-7] In cases of hepaticojejunostomy (HJ), a gastric access loop can be constructed at the time of surgery in the event that future access would be required.[8] In cases of Roux-en-Y gastric bypass (RYGB), endoscopic or laparoscopic gastrostomy placement with subsequent stoma dilation for transgastric ERCP[9] or laparoscopic transgastric ERCP is also possible.[10,11] Finally, surgical common bile duct exploration remains an option.

In recent years, deep intubation of the afferent biliary limb has been achieved by using a ShapeLock overtube,[12] spiral or rotational enteroscopy,[13] and double-balloon enteroscopy (DBE).[14-18] However, data on the use of spiral enteroscopy and the ShapeLock overtube are limited, whereas DBE requires specialized equipment and expertise that are not widely available.

Single-balloon enteroscopy (SBE) is a new technology that uses a single-balloon splinting overtube to sequentially reduce and pleat the small bowel over a standard enteroscope. The splinting overtube also enables negotiation of acute angulations sometimes found at gastroenteric or enteroenteric anastomoses. SBE may be useful in reaching and accessing the native ampulla or biliary orifice in patients who have surgically altered anatomy and a long afferent biliary limb for diagnostic or therapeutic ERCP.

METHODS

Patients with surgically altered gastroduodenal anatomy with a diagnosis requiring therapeutic ERC were offered SBE. SBE was performed by using a high-resolution standard-length enteroscope, with a 9.2-mm diameter and a 200-cm length (SIF-Q180; Olympus America, Center Valley, PA). A disposable sliding overtube, with a 13.2-mm outer diameter, an 11-mm inner diameter, a 130.2-cm length, and a hydrophilic coating over a silicone core (ST-SB1; Olympus America), was used to sequentially reduce and pleat the small bowel over the enteroscope.

All procedures were performed with the patient supine and under general endotracheal anesthesia. Fluoroscopy was used in all cases to guide passage of the single-balloon enteroscope to the ampulla or HJ and to perform ERCP. Room air was used to provide insufflation.

Biliary access, cholangiography, and interventional ERC were performed by using modified devices acquired from Olympus America, Cook Medical (Bloomington, IN), and Boston Scientific (Natick, MA).

The papillotomes used were a long needle-knife papillotome with a modified working length of 250 cm (KD-441Q; Olympus); a long needle-knife papillotome with working length of 320 cm (Zimmon G22717; Cook); and a long cannulatome with a working length of 320 cm (Cotton G22732; Cook).

The catheters used were a long extraction balloon catheter with a working length of 350 cm (B7-2LA; Olympus); a spray catheter with a working length of 240 cm (PW1V-1.A; Olympus); and a long ERCP catheter with a working length of 320 cm (G22719; Cook).

The dilating balloons used were a long biliary balloon dilator with a working length of 320 cm (Quantum QBD-6X3; Cook) and colonic-length dilating balloons with a working length of 240 cm for ampullary and biliary dilation (CRE; Boston Scientific).

Long guidewires measuring 450 cm were used (Linear-GuideV; Olympus and Hydra Jagwire and Glidewire; Boston Scientific).

All procedures were performed by an experienced pancreaticobiliary endoscopist who routinely performs more than 300 to 500 ERCPs each year. Follow-up was obtained from clinic charts, hospital records, and by telephone contact with patients.

RESULTS

Patient characteristics

Thirteen patients (2 men, 11 women) with a median age of 54 years (range 28-82 years) underwent 16 SBE procedures (cases), from October 2007 to April 2009, with the intent to perform therapeutic ERC (Table 1).

Surgically altered anatomy in the 16 procedures performed consisted of pancreaticoduodenectomy with HJ (Whipple, n = 3), HJ alone (n = 3), Billroth II with a long afferent limb (n = 1), Roux-en-Y anatomy after partial gastrectomy for ulcer disease (n = 1), and RYGB (n = 8). In 3 of the 16 procedures (in 2 patients), previous RYGB anatomy was further complicated by subsequent orthotopic liver transplantation (OLT). In 2 procedures (performed in 2 patients), the anatomy consisted of a Roux-en-Y hepaticojejunostomy (RY-HJ) in the setting of living donor liver transplantation (LDLT).

Preprocedural indications by case included recurrent cholangitis (n = 1); cholangitis with retained biliary stent after pancreaticoduodenectomy, OLT, or LDLT (n = 3); symptomatic choledocholithiasis with a PTC drain in place (n = 1); abdominal pain with abnormal LFT results and/or biliary ductal dilation (n = 4); abnormal LFT results after OLT or LDLT with retained biliary stents (n = 3); pancreatitis secondary to microlithiasis (n = 2); biliary stricture or ampullary mass (n = 2) (Table 2).

Procedural efficacy

Diagnostic ERC. The ampulla or HJ was reached in 13 (81.3%) of 16 cases and in 12 (92.3%) of 13 patients. One patient had an HJ after bile duct injury, and SBE failed to reach the HJ. In 2 patients with RYGB anatomy, the ampulla could not be reached by using SBE on the first attempt. In each case, there was a very tight hairpin turn required to reach and intubate the afferent limb from

TABLE 1. Patient characteristics

Patient no.	Case no.	Age, y	Sex	Reason for surgery	Altered anatomy	No. SBE procedures	Follow-up (d)
1	1	76	M	Cholangiocarcinoma	Pancreaticoduodenectomy	1	522
2	2	38	F	PSC	LDLT, RY-HJ	1	257
3	3	79	F	PUD	Billroth II	1	43
4	4	54	F	Obesity	RYGB, cholecystectomy	1	177
5	5	28	F	Cholecystectomy c/b BD injury	HJ	1	387
6	6	57	F	Obesity	RYGB, cholecystectomy	1	120
7	7 & 8	82	M	Ampullary adenocarcinoma	Pancreaticoduodenectomy	2	43 & 253
8	9 & 10	43	F	Obesity	RYGB, OLT	2	57 & 62
9	11	28	F	LDLT c/b bile leak requiring HJ	LDLT, RY-HJ	1	49
10	12	43	F	Obesity	RYGB, cholecystectomy	1	23
11	13	55	F	Obesity	RYGB, OLT	1	25
12	14 & 15	51	F	Obesity	RYGB, cholecystectomy	2	22 & 26
13	16	58	F	PUD	Partial gastrectomy, splenectomy, RY	1	30

LDLT, Living donor liver transplantation; *HJ*, hepaticojejunostomy; *RY-HJ*, Roux-en-Y hepaticojejunostomy; *RYGB*, Roux-en-Y gastric bypass; *c/b*, complicated by; *OLT*, orthotopic liver transplantation; *RY*, Roux-en-Y.

the Roux-en-Y anastomosis. In both patients, a second SBE-assisted ERCP was attempted that used a technique whereby a long retrieval balloon catheter and a long guidewire were deployed deeply into the afferent limb to stiffen the enteroscope and provide countertraction, which enabled successful intubation of the afferent limb and subsequent access to the ampulla (Fig. 1).

Diagnostic ERCP was successful in all 13 cases in which the ampulla or HJ was reached. Cholangiography was performed by using a long retrieval balloon catheter (n = 9), a spray catheter (n = 2), a long needle-knife papillotome (n = 1), and injection of an HJ directly by using the accessory channel of the enteroscope, which was positioned adjacent to the biliary orifices (n = 1).

Therapeutic ERC. Therapeutic ERC was required in 10 patients in whom the ampulla or HJ was reached and diagnostic ERC successfully performed. Therapeutic ERC was successful in 9 (90%) of 10 cases. Endoscopic biliary therapy included balloon dilation of the ampulla or common bile duct (n = 4), stone extraction (n = 2), needle-knife biliary sphincterotomy over a biliary stent (n = 3), biliary sphincterotomy by using a long sphincterotome (n = 1), removal of an existing surgically placed biliary stent (n = 3), and temporary biliary stenting (n = 2). In the 2 cases of temporary biliary stent placement, a 5F × 7-cm stent and a 7F × 5-cm stent were used. Both stents were deployed by using a long retrieval balloon catheter because the standard stent pushers were not stiff enough to overcome a looped enteroscope with an extremely angulated tip. Both stents were removed after successful needle-knife biliary sphincterotomy (Fig. 2; Table 2).

In 1 patient in whom the HJ was reached, therapeutic ERC was required but was not accomplished because of stenosis of 2 biliary orifices, constructed as a result of LDLT, which precluded passage of a guidewire through the stenosed anastomoses. This patient, and one other patient in whom SBE failed to reach the HJ, required surgical revision of the HJ because of biliary structures.

SBE-assisted ERCP: operating characteristics

The median procedure length was 100 minutes (range 30-212 minutes). The median procedure time was 84.4 minutes for diagnostic ERC and 124.9 minutes for therapeutic ERC. Success was defined as reaching the HJ or ampulla and being able to perform diagnostic ERC followed by therapeutic ERC, when indicated. The overall procedural success in an intent-to-treat analysis was 75.0% by procedure and 84.6% by patient (2 procedures were required for success in 2 patients).

Follow-up and complications

The median follow-up was 53 days (range 22-522 days). Pancreatitis developed in 2 (12.5%) of the 16 patients in whom SBE-assisted ERCP was attempted. In both patients, pancreatitis developed after therapeutic ERC (20.0% of patients with attempted therapeutic ERC). Both of these

TABLE 2. Case-based procedural characteristics

Case no.	Indications	Procedure performed	Proc. time (min)	Post-ERCP panc.	Diagnostic ERCP success	Therapeutic ERCP required	Therapeutic ERCP success	Surgery required
1	Cholangitis, retained biliary stent	ERC using irrigation catheter, no foreign body seen	47	N	Y	N		N
2	Cholangitis, failed PTC, retained biliary stent	ERC using irrigation catheter, no foreign body seen, unable to cannulate HJ orifices due to stenoses	89	N	Y	Y	N	Y
3	Choledocholithiasis, pain	ERC using retrieval balloon catheter, stone extraction, 13.5-mm balloon dilation of ampulla, PTC removed	63	N	Y	Y	Y	N
4	Biliary dilation, failed PTC c/b biloma, pain	PD injected, ERC using retrieval balloon catheter, 7-mm balloon dilation of ampulla, failed 7F × 10-cm stent	151	Y	Y	Y	Y	N
5	Cholangitis (recurrent), pain	Unable to reach hepaticojejunostomy	92	N	N			Y
6	Biliary pancreatitis, pain	PD injected, ERC using needle-knife catheter, 5F × 7-cm stent into CBD, needle-knife BS, CBD stent removed with snare	91	Y	Y	Y	Y	N
7	Abnormal LFT results, pain	ERC using retrieval balloon catheter, no therapy required	30	N	Y	N		N
8	Abnormal LFT results, pain	ERC using retrieval balloon catheter, stone extraction	40	N	Y	Y	Y	N
9	Retained stent from OLT, abnormal LFT results	Unable to intubate afferent limb	113	N	N			N
10	Retained stent from OLT, abnormal LFT results	Afferent limb intubated using retrieval balloon catheter and guidewire technique, ERC using retrieval balloon catheter, retained CBD stent removed with snare	100	N	Y	Y	Y	N
11	Retained biliary stents from LDLT, abnormal LFT results	ERC obtained by contrast injection via the enteroscope at HJ, unable to cannulate 2 HJ orifices with retrieval balloon catheter or guidewire, 2 migrated stents removed with snare	120	N	Y	N		N
12	Biliary pancreatitis (recurrent), pain	PD injected, ERC using retrieval balloon catheter, 7F × 5-cm stent into CBD, needle-knife BS, CBD stent removed with snare	135	N	Y	Y	Y	N

(*continued on next page*)

TABLE 2 (*continued*)

Case no.	Indications	Procedure performed	Proc. time (min)	Post-ERCP panc.	Diagnostic ERCP success	Therapeutic ERCP required	Therapeutic ERCP success	Surgery required
13	Cholangitis, abnormal LFT results, biliary dilation, retained biliary stent	ERC using retrieval balloon catheter wedged at ampulla, needle-knife BS over OLT stent, stent removed	135	N	Y	Y	Y	N
14	CBD stricture, biliary dilation, abnormal ampulla, pain	Unable to intubate afferent limb	100	N	N			N
15	CBD stricture, biliary dilation, abnormal ampulla, pain	Afferent limb intubated using retrieval balloon catheter and guidewire technique, ERC using retrieval balloon catheter, 6-mm balloon dilation of ampulla and CBD stricture	212	N	Y	Y	Y	N
16	Biliary dilation, pain	ERC using retrieval balloon catheter, BS using sphincterotome, 6-mm balloon dilation over CBD	197	N	Y	Y	Y	N

proc., Procedure; *panc.*, pancreatitis; *c/b*, complicated by; *LFT*, liver function test; *BS*, biliary sphincterotomy; *CBD*, common bile duct; *PD*, pancreatic duct; *HJ*, hepaticojejunostomy.

patients had difficult biliary cannulations, and the pancreatic duct was injected one or more times as a result of attempted biliary cannulation. None of the 3 patients who had diagnostic ERC alone experienced pancreatitis.

Pseudocyst formation occurred in 1 of the 2 patients in whom pancreatitis developed. This patient required 7 weeks of total parenteral nutrition for pancreatic rest. Subsequent CT scans demonstrated resolution of the pancreatitis and pseudocyst.

None of the patients in this series experienced any bleeding or perforation as a result of SBE-assisted ERCP. One patient who had an LDLT with recurrent GI bleeding was found to have preexisting diffuse submucosal hemorrhages in the stomach that bled during the course of her procedure, possibly as a result of balloon enteroscopy, but not as a consequence of ERC.

One patient with recurrent pancreatitis from microlithiasis underwent successful SBE-assisted ERCP, which included temporary placement of a 7F × 5-cm plastic biliary stent over which a needle-knife biliary sphincterotomy was performed. The patient reported feeling well 7 days after her procedure, but died 23 days after her procedure from unrelated sepsis and a subsequent pulseless electrical activity arrest.

DISCUSSION

Historically, Billroth II gastrectomy was the predominant form of surgically altered anatomy that fostered challenging ERCP procedures. During the late 1990s and early 2000s, multiple studies reported excellent ERCP success by using duodenoscopes or enteroscopes in patients with Billroth II anatomy,[19-21] likely because of shorter afferent limbs. However, the incidence of Billroth II surgeries has decreased because of more effective treatment for peptic ulcer disease.

Today, the surgically altered anatomies more frequently encountered are the RYGB for morbid obesity,[22-25] hepaticojejunostomy for LDLT[26,27] or treatment of biliary injury or disease,[28,29] and pancreaticoduodenectomy for pancreatic carcinoma and ampullary neoplasia.[30,31] These longer limb anastomoses make ERCP with conventional duodenoscopes or enteroscopes exceedingly difficult, if not impossible. RYGB is a particularly challenging postsurgical anatomy because of the long limb (often >100 cm) that must be traversed from the gastrojejunal orifice to the jejunojejunal anastomosis in order to reach the afferent small-bowel limb.[1]

The first report of ERCP in long-limb anastomoses was in 1988[3] in which a pediatric colonoscope was used to perform the procedure in 3 patients; colonoscopes[2] and standard duodenoscopes have been used in subsequent case series. In one study, the success rate of reaching the ampulla was 33% in Roux-en-Y anastomoses compared with 92% in Billroth II anatomy.[32] Wright et al[1] reported on 15 patients who underwent attempted ERCP, over 6 years, with long-limb Roux-en-Y anastomoses in which a colonoscope was used to reach the biliary orifice and deploy a guidewire, over which a duodenoscope was then passed

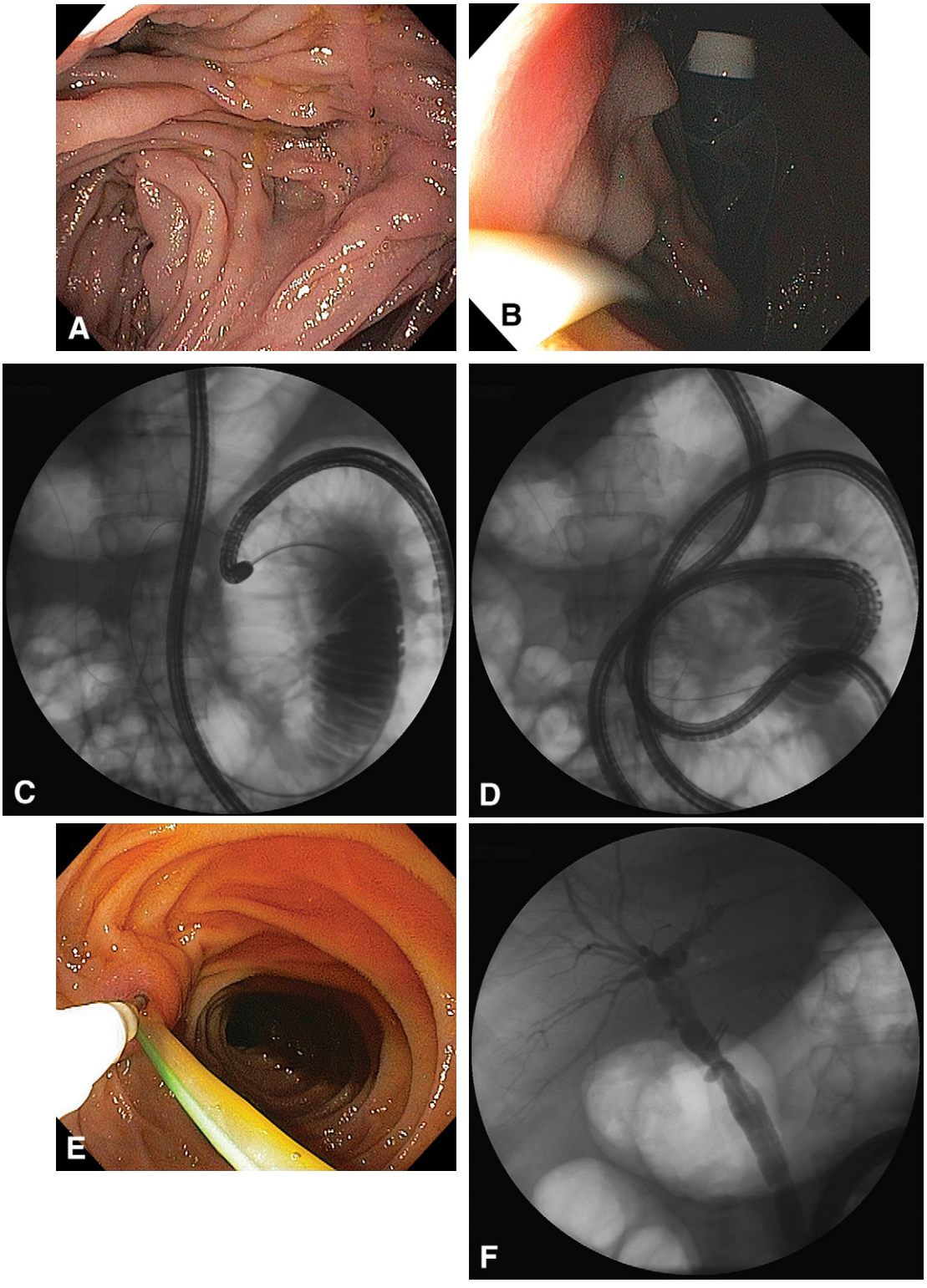

Figure 1. SBE in a patient who had RYGB and years later required OLT for autoimmune hepatitis. The Roux-en-Y anastomosis was encountered and had several potential lumens (**A**). The afferent limb was in a hairpin configuration from the gastrojejunal limb, and the enteroscope had to be retroflexed to approach the afferent limb (**B**). A long retrieval balloon catheter and a long guidewire were deployed deeply into the afferent limb (**B**, **C**), which stiffened the enteroscope and provided countertraction with which the enteroscope was able to intubate the afferent jejunal limb (**D**). By using the retrieval balloon to direct the guidewire, the common bile duct was selectively cannulated alongside a retained surgical 8F stent (**E**), and cholangiography was performed (**F**). The retained surgical stent was removed by using a snare at the conclusion of the procedure.

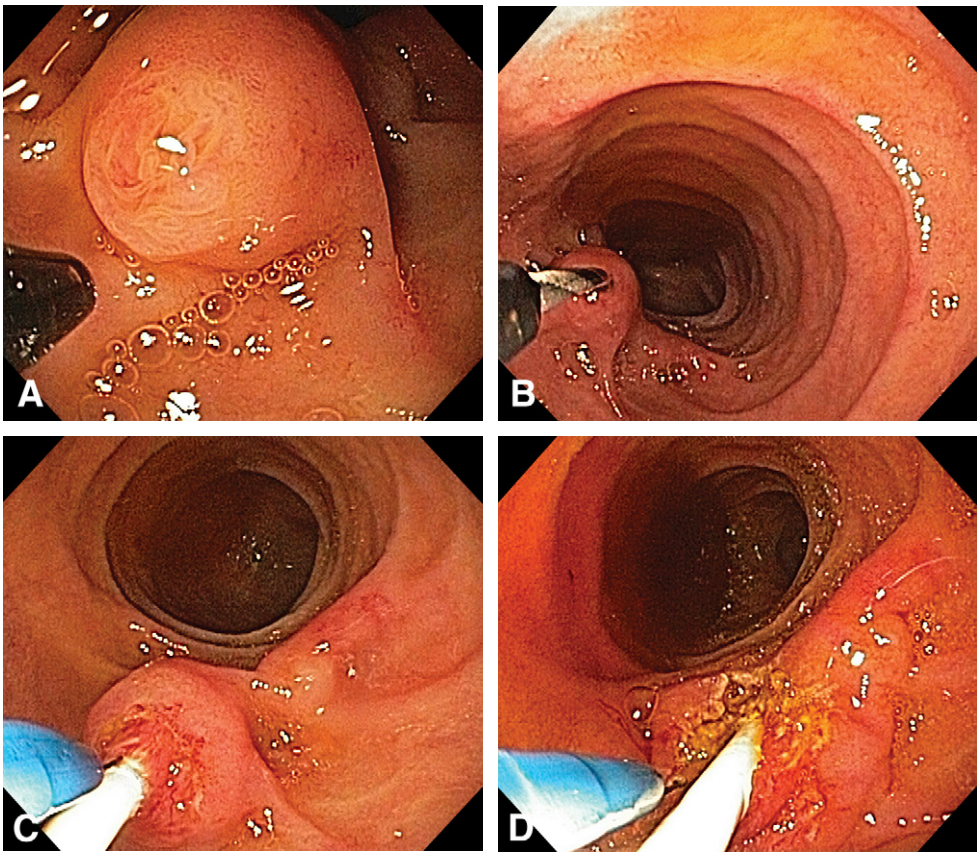

Figure 2. SBE in a patient with biliary pancreatitis after RYGB. The ampulla appeared normal and was in a favorable 6- to 7-o'clock position (**A**). By using a modified retrieval balloon catheter with a preloaded guidewire, the common bile duct was cannulated (**B**). A 7F × 5-cm plastic stent was deployed in the common bile duct by using the retrieval balloon catheter, after an attempt using a stent-pushing catheter failed (**C**). A needle-knife biliary sphincterotomy was performed over the biliary stent (**D**), after which the biliary stent was removed by using a snare.

to perform ERC. The technique resulted in reaching the ampulla in 10 (67%) of 15 patients and 19 (76%) of 25 attempts. In the 10 patients in whom the papilla was accessed with a duodenoscope, bile duct cannulation was initially successful in 9 (90%) patients. A total of 12 biliary sphincterotomies (3 were extensions of existing biliary sphincterotomies) were performed.[1]

Several case reports have been published in which DBE was used[15,16,33] and 1 in which SBE was used[34] to perform diagnostic and therapeutic ERCP in individuals with surgically altered anatomy. In 2007, Aabakken et al[15] reported successful intubation of the afferent limb in 18 of 18 procedures by using DBE. Adequate imaging was achieved in all but 2 cases. Biliary stenting was performed in 2 patients, stent removal in 3 patients, and a small stone removal in 1 patient. More recently, 2 smaller case reports described therapeutic ERCP using DBE in 2 patients[33] and 3 patients.[16] Monkemuller et al[34] described 2 cases in which a Fujinon double-balloon enteroscope (EN-450T5I; Fujinon, Saitama, Japan) was used without a balloon on the tip of the enteroscope to perform a type of SBE-ERCP. Cases included removing a biliary stent and biliary sludge in 2 patients with Roux-en-Y anastomosis.

SBE is a newer modality that enables diagnostic and therapeutic deep enteroscopy.[35] Few studies exist regarding the use of SBE for biliary access. Dellon et al[36] described the use of the Olympus SBE platform to perform ERCP in 4 patients with Roux-en-Y anatomy: 1 with RYGB, 2 with Roux-en-Y anatomy caused by bile duct injury, and 1 with Roux-en-Y anatomy after liver transplantation. Cholangiography was successful in 3 of the 4 patients. Two patients required biliary dilation, which was successful in only 1 of the patients; the other patient required PTC because guidewire access to the common bile duct could not be established. Successful procedures ranged from 65 to 91 minutes in duration.

In our larger series, we report a procedure success rate for reaching the ampulla or HJ in 13 (81.3%) of 16 cases and in 12 (92.3%) of 13 patients. Furthermore, diagnostic ERC was successful in all cases in which the ampulla or HJ was reached. Therapeutic ERC was achieved in 9 (90%) of 10 cases. Interestingly, the use of SBE-assisted ERCP was associated with a shorter average procedure time of 100 minutes (range 30-212 minutes) as opposed to 137 minutes (range 50 to 225 minutes) in the series of Wright et al.[1] Additionally, we were able to identify potential complications

associated with SBE-assisted ERCP in our series, including a 12.5% overall rate of pancreatitis; in patients undergoing therapeutic ERC, the rate of pancreatitis was 20%.

In our experience, the existing long catheters, papillotomes, stent pushers, and injection needles are useful, but leave room for improvement. Often, the existing devices are difficult to exchange once biliary access has been established, even when using long guidewires, because of significant looping of the enteroscope, the extreme angulation of the enteroscope tip required to access the major papilla, and insufficient guidewire length to exchange long catheters. These difficulties are associated with extended procedure times when performing therapeutic ERC.

One very useful adjunctive method in intubating the afferent jejunal limb from the Roux-en-Y anastomosis is to pass a long retrieval balloon catheter over a long guidewire into the afferent limb, which stiffens the enteroscope and allows countertraction, over which the afferent jejunal limb can be entered with the scope (Fig. 1). This method, previously described by Wright et al[1] in RYGB patients undergoing colonoscope-assisted ERCP, was used successfully to reach the ampulla in 2 RYGB patients in this series.

Despite the success rates reported in this study, in patients in whom repeated therapeutic ERCP may be required, other methods (such as gastrostomy-assisted ERCP or PTC) may be preferable given the extended procedure times and increased rates of pancreatitis associated with therapeutic SBE-assisted ERC. Further study regarding these factors is warranted.

Overall, SBE-assisted ERCP reliably enables diagnostic and therapeutic ERC in patients with surgically altered anatomy and provides a viable alternative to gastrostomy-assisted ERCP and PTC for treating hepatobiliary diseases. Procedural morbidity seems acceptable, but complication rates may be higher than with conventional ERCP. Improvement of available catheters, papillotomes, and other accessory equipment is necessary to enable more efficient and effective therapeutic SBE-assisted ERCP.

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