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ORIGINAL ARTICLE

Severe Biliary Stricture Dilation Using the Soehendra Stent Retriever with a Short-Type Balloon Enteroscope in Patients with Surgically Altered Anatomies

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Abstract

Background Balloon enteroscopy (BE) can be used for endoscopic retrograde cholangiography (ERC) to treat biliary strictures in patients with surgically altered anatomies. However, biliary strictures, including bilioenteric anastomotic strictures, are often very severe and dilation catheters cannot pass through them. The Soehendra stent retriever (SSR) is like a screw drill and can be useful for dilating severe strictures, but the utility of SSR during BE-assisted ERC (BE-ERC) is unclear. This study aimed to examine the efficacy and safety of a dilation technique using the SSR during BE-ERC.

Methods Between 2014 and 2018, 28 patients with surgically altered gastrointestinal anatomies and severe biliary strictures underwent BE-ERC, and the SSR was used for the dilation procedures. We evaluated the technical success, therapeutic success, and adverse event rates associated with SSR dilation.

Results The technical success rate was 93% (26/28). The procedures undertaken on two patients with non-anastomotic strictures failed technically because the SSR was not long enough to reach the strictures. The therapeutic success rate was 96% (25/26) for the patients whose procedures were technically successful. The adverse event rate was 7% (2/28), and the adverse events were mild and improved with conservative management. No bleeding or duct perforations occurred.

Conclusions Although the indications for using the SSR in patients with non-anastomotic strictures should be considered based on the distance between the tip of the scope and the stricture's location, SSR dilation may be a useful option during BE-ERC if a biliary stricture is very severe.

Keywords Soehendra stent retriever · Biliary stricture · Balloon enteroscopy · Bilioenteric anastomotic stricture · Dilation

Introduction

Endoscopic retrograde cholangiography (ERC) is an established and reliable procedure for the diagnosis and treatment of biliary strictures.[1,2] However, when a biliary stricture is severe, devices such as catheters cannot pass through the stricture. For these cases, balloon dilation or dilation catheters are usually used, but even these devices cannot pass through very severe strictures in some cases.[3] In such refractory cases, the Soehendra stent retriever (SSR) (Cook Medical Inc., Bloomington, IN, United States), which is a device that was originally designed to remove plastic stents and is applied like a screw drill, is used (Fig. 1), and its usefulness has been described.[4–7]

Previously, a percutaneous transhepatic approach was performed on biliary strictures in patients with surgically altered gastrointestinal anatomies, but, recently, balloon enteroscopy (BE)-assisted ERC (BE-ERC) has become widely accepted as a less invasive approach.[8,9] However, biliary strictures, including post-surgery-related strictures, for example, hepaticojejunostomy anastomotic strictures, are frequently encountered and are often very refractory to treatment.[10–12] Additionally, compared with conventional ERC, BE-ERC is more technically difficult and the dilation procedure is more demanding. The SSR has high levels of

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Fig. 1 The Soehendra stent retriever has a coiled metal cable and a threaded and tapered tip, similar to a tapping screw

pushability and penetrability because it can be used like a screw drill by rotating the torque-transmitting shaft clockwise.[7] Therefore, the SSR may be more useful than other dilation devices during BE-ERC. We recently described our experience using the SSR during BE-ERC to treat severe hepaticojejunostomy anastomotic strictures.[13] However, the utility of SSR during BE-ERC remains unclear due to the paucity of evidence. The current study aimed to examine the efficacy and safety of the dilation technique using the SSR during BE-ERC for refractory biliary strictures in patients with surgically altered gastrointestinal anatomies.

Materials and Methods

Patients

Of the consecutive patients with surgically altered gastrointestinal anatomies who underwent BE-ERC to treat biliary strictures between 2014 and 2018 at our institution, those whose severe refractory strictures could not be traversed using the intended devices and whose dilations were attempted using the SSR were investigated. At our institution, when biliary intervention is required in patients with surgically altered gastrointestinal anatomies, BE-ERC is attempted initially. When some devices, such as catheters, cannot be passed through the stricture, a dilation procedure is performed. If the procedure using a balloon and/or dilation catheter is unsuccessful or is considered difficult, a dilation procedure using the SSR is attempted. However, when the guidewire cannot traverse the stricture, an SSR-based dilation is not performed and a percutaneous transhepatic or an endoscopic ultrasound-guided approach is undertaken.

Our hospital's institutional review board approved this study in accordance with the principles of the Declaration of Helsinki (Approval number: 2017-H353). All authors had access to the study's data, and they reviewed and approved the final manuscript.

Procedure

Short-type double-balloon (EI-530B or EI-580BT; Fujifilm Corporation, Tokyo, Japan) or short-type single-balloon (SIF-H290S; Olympus Medical Systems Corporation, Tokyo, Japan) enteroscopes were used; the choice of scope was determined by the procedure's timing. All of the cases were insufflated using carbon dioxide. After the scope had reached the duodenal papilla or the bilioenteric anastomosis, we attempted biliary cannulation and attempted to traverse the stricture. Typically, an ERCP-catheter (MTW Endoskopie Manufaktur, Wesel, Germany) and a 0.025-in. guidewire were used. However, if the stricture was severe and advancing the devices through the stricture was difficult, we attempted the dilatation using the SSR (Figs. 2 and 3). After the SSR had reached the stricture over the guidewire, we pushed and rotated the SSR's shaft clockwise, and once the tip of the SSR had traversed the stricture, it was retracted while it was rotated counter-clockwise. We then attempted to reinsert the devices that could not pass through the stricture and to perform the intended treatment. Essentially, stent placement was performed in patients with cholangitis and/or malignant stricture, but only balloon dilation was chosen for patients without cholangitis and malignant stricture.

An experienced endoscopist who was skilled at performing ERC and BE conducted or directly supervised all procedures. All patients provided written informed consent before each procedure.

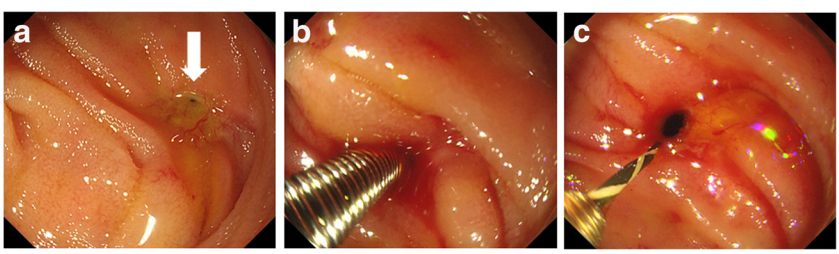

Fig. 2 **a** Endoscopic view showing a very severe hepaticojejunostomy anastomotic stricture (arrow). **b** The Soehendra stent retriever was introduced into the anastomotic stricture over the guidewire. **c** Endoscopic view after Soehendra stent retriever dilation expanded the stricture

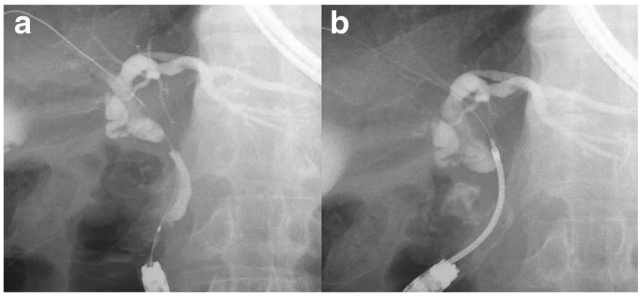

Fig. 3 **a** Endoscopic retrograde cholangiography showing a very severe middle bile duct stricture. **b** The Soehendra stent retriever traversed and dilated the stricture

Outcomes and Definitions

The study's primary outcomes were the technical and therapeutic success rates associated with the dilation procedures that involved using the SSR. The technical success rate was defined as the rate at which the SSR was able to traverse the stricture, and the therapeutic success rate was defined as the rate at which the intended treatment, for example, stent placement, was accomplished. The study's secondary outcome was the adverse event rate, with adverse events defined and graded using the American Society for Gastrointestinal Endoscopy's criteria.[14]

The biliary strictures were classified as anastomotic strictures (ASs), which were bilioenteric ASs, or non-ASs (N-ASs), which were bile duct strictures that did not involve an anastomosis. The outcomes were evaluated in the entire group and in the AS and N-AS groups separately.

Statistical Analyses

The categorical variables are expressed as numbers and percentages, and the differences between the groups were evaluated using Fisher's exact tests. The continuous variables are expressed as the medians and ranges. P values $< .05$ were considered to indicate statistical significance. All of the statistical analyses were performed using R statistical software, version 3.4.1 (The R Foundation for Statistical Computing, Vienna, Austria).

Results

Patients' Characteristics

Between 2014 and 2018, 167 patients with surgically altered gastrointestinal anatomies underwent BE-ERC; among these, 28 patients underwent dilation procedures using the SSR for severe biliary strictures. Table 1 presents the patients' characteristics, including their sexes and ages, the indications for surgical gastrointestinal reconstruction, the surgically altered anatomies, the times from surgery to the procedure, the indications for BE-ERC, the stricture types, the length of strictures, and the balloon enteroscope types. Nineteen and 9 patients comprised the AS and N-AS groups, respectively.

Table 1 Patients' baseline characteristics

Characteristic	
Number of patients, *n*	28
Sex, male/female, *n*	20/8
Median (range) age, years	69 (50–82)
Indication for surgical gastrointestinal reconstruction, *n* (%)	
Biliary tumor	15 (54)
Pancreatic tumor	7 (25)
Gastric tumor	3 (11)
Other	3 (11)
Surgical anatomy, *n* (%)	
Hepaticojejunostomy with Roux-en-Y	12 (43)
Pancreaticoduodenectomy	13 (46)
Roux-en-Y gastrectomy	3 (11)
Median (range) time from surgery to procedure, months	11 (1–299)
Indication for balloon enteroscopy-assisted ERC, *n* (%)	
Cholangitis	17 (61)
Obstructive jaundice (without cholangitis)	9 (32)
Others	2 (7)
Type of stricture, *n* (%)	
Anastomotic stricture	19 (68)
Benign/malignant	17/2
Non-anastomotic stricture	9 (32)
Benign/malignant	4/5
Median (range) length of stricture, mm	4 (2–27)
Type of balloon enteroscope used, *n* (%)	
DBE	9 (32)
SBE	19 (68)

ERC endoscopic retrograde cholangiography, *DBE* double-balloon enteroscope, *SBE* single-balloon enteroscope

Technical and Therapeutic Success Rates

Table 2 shows the SSR dilation outcomes. The overall technical success rate was 93% (26/28), and the technical success rates were 100% (19/19) and 78% (7/9) in the AS and N-AS groups, respectively, a difference that was not significant ($P = .095$). Passing the SSR through the strictures was unsuccessful in two cases in the N-AS group. One of these patients had undergone a Roux-en-Y gastrectomy, and a recurrence of the malignancy had caused a confluence of a hepatic duct stricture. We attempted to insert the SSR into the stricture, but it was too short and could not reach the hilar region. The other patient had undergone a pancreatoduodenectomy and inflammation had caused a dorsolateral segmental duct

Table 2 Outcomes of the dilation procedures using the Soehendra stent retriever with balloon enteroscopes

	Type of stricture			Total
	Anastomotic stricture	Non-anastomotic stricture	*P* value	
Technical success of SSR dilation, *n* (%)	19/19 (100)	7/9 (78)	.095	26/28 (93)
Cause of failure, *n*				
Could not reach the stricture	–	2		2
Therapeutic success, *n* (%)	19/19 (100)	6/7 (86)	.269	25/26 (96)
Treatment, *n*				
Plastic stent placement	13	4		17
Balloon dilation for the stricture	5	0		5
Metal stent placement	1	2		3
Unsuccessful	0	1		1
Overall therapeutic success, including technical failure, *n* (%)	19/19 (100)	6/9 (67)	*.026*	25/28 (89)
Adverse events, *n* (%)	1/19 (5)	1/9 (11)	1.000	2/28 (7)
Cholangitis	1	1		2

SSR Soehendra stent retriever

P <0.05 is indicated in italics

stricture; again, the SSR was too short and it could not reach this stricture (Table 3).

For the patients whose procedures were technically successful, the overall therapeutic success rate was 96% (25/26). The therapeutic success rates were 100% (19/19) and 86% (6/7) in the AS and N-AS groups, respectively, a difference that was not significant ($P = .269$). When the two patients in the N-AS group whose procedures were technically unsuccessful were included in the analysis, the therapeutic success rate was significantly lower in this group (67% [6/9]) than in the AS group (100% [19/19]) ($P = .026$). In the AS group, plastic stent placements were accomplished in 13 patients, balloon dilations were achieved in 5 patients, and a metallic stent placement was successful in 1 patient. In the N-AS group, plastic stent placements were achieved in four patients, metallic stent placements were successful in two patients, and one patient's intended treatment failed, despite the procedure being technically successful. The case in whom the intended treatment failed had undergone a pancreatoduodenectomy and they had a posterior segmental duct stricture, and while the SSR passed through the stricture successfully, the plastic stent could not traverse the stricture.

Adverse Events

The overall adverse event rate was 7% (2/28). Cholangitis occurred in one patient in each group. The adverse event rates were 5% (1/19) in the AS group and 11% (1/9) in the N-AS

Table 3 Details of the cases whose procedures were unsuccessful

Age (years)/ sex	Type of failure	Surgical anatomy	Stricture location	Cause of stricture	Indication for BE-ERC	Balloon enteroscope type	Cause of failure
72/M	Technical	Roux-en-Y gastrectomy	Confluence of the hepatic duct stricture	Recurrence of gastric cancer	Jaundice	SIF-H290S	SSR too short to reach the stricture
59/M	Technical	Pancreatoduodenectomy	Dorsolateral segmental ducts stricture	Inflammation	Cholangitis	SIF-H290S	SSR too short to reach the stricture
82/M	Therapeutic	pancreatoduodenectomy	Posterior segmental duct stricture	Recurrence of bile duct cancer	Jaundice	SIF-H290S	Insufficient SSR dilation (7-Fr plastic stent could not traverse after SSR dilation)

M male, *BE-ERC* balloon enteroscopy-assisted endoscopic retrograde cholangiography, *SSR* Soehendra stent retriever

group, a difference that was not significant ($P = 1.000$). The patients' adverse events were mild, and they improved with conservative management. Bleeding and duct perforation did not occur.

Discussion

This study's findings showed very high technical and therapeutic success rates for dilation using the SSR, particularly for patients with AS. Additionally, there were no severe procedure-related adverse events.

The endoscopic approach and drainage are well established for the management of biliary strictures. While pretreatment stricture dilation may be unnecessary in most cases, sometimes dilation using a balloon or a dilation catheter is needed; however, when the stricture is very severe, this is not possible.[3] In these cases, the SSR can be used as a screw drill, and its dilation success rate is high.[6,7] Hence, the SSR is a useful option for dilating refractory biliary strictures.

Balloon enteroscopes are widely accepted, and using an endoscopic approach to treat biliary strictures and enable drainage has been established for patients with surgically altered gastrointestinal anatomies as balloon enteroscopes facilitate access to the duodenal papillae or bilioenteric anastomoses in these patients.[8,9,15] However, surgery-related strictures, including bilioenteric ASs, tend to become very severe.[10] If the stricture is severe, balloon dilation or a dilation catheter is typically used in an attempt to traverse the stricture, as occurs during conventional ERC. Unlike conventional ERC, balloon enteroscopes are long and they do not have forceps elevators, and the scope may be looped, bent, and twisted when the duodenal papilla or bilioenteric anastomosis is reached. Thus, traversing the stricture can be more difficult and the devices' levels of pushability may be lower than those encountered during conventional ERC, because transmitting pushing forces to devices is difficult. By applying rotation torque and using the SSR like a screw drill, it can achieve a high level of self-pushability.[7] Therefore, the SSR may be compatible with BE-ERC. To our knowledge, only case reports that describe biliary dilation using the SSR during BE-ERC have been published,[13,16] and the efficacy associated with using the SSR during BE-ERC remains unknown. In this study, the technical and therapeutic success rates were very high. Hence, if some devices cannot be inserted through strictures during BE-ERC, the SSR can be considered for dilation.

The working lengths of long- and short-type balloon enteroscopes are 2000 mm and 1520–1550 mm, respectively.[17] The SSR is 1800-mm long[7]; thus, it can only be used with short-type balloon enteroscopes. Even if a short-type balloon enteroscope is used, the SSR may not reach the stricture if it is located proximally, for example, an intrahepatic bile duct stricture. In this study, the SSR could not reach the strictures in two cases, of whom one had a confluence of a hepatic duct stricture and the other had a dorsolateral segmental duct stricture. Therefore, the SSR is particularly useful in patients with AS, but the indications for using the SSR in patients with N-AS should be considered in relation to the distance between the tip of the scope and stricture's location. We determined that the distance between the tip of a short-type balloon enteroscope and the tip of an SSR was about 60 mm when it was inserted as far as possible, although this will change in relation to a range of factors, including the scope's loop (Fig. 4). Therefore, other approaches should be considered when the distance is greater than 60 mm. We anticipate the development of longer SSRs.

The safety of the dilation procedure that involves the use of the SSR is unclear, because there has not been a large number of studies that have examined its use during conventional ERC procedures and no reports have been published that describe the adverse events associated with its use during BE-ERC. Although this study's findings showed a low adverse event rate (7%) and all of the adverse events were mild, bleeding and/or duct perforation are causes for concern, because the SSR is inserted like a drill. Furthermore, dehiscence is a concern, particularly in relation to bilioenteric anastomoses, because they may be weaker than others.[18] In cases that have not had much time since the surgery, for example, cases encountered 1–2 months after surgery, SSR should be considered with caution. Moreover, the axis of the bile duct and SSR should be adjusted as much as possible during insertion, and checks for bile leaks should be performed after the procedure.

Fig. 4 When the Soehendra stent retriever (SSR) was inserted as far as possible into the working channel of an SIF-H290S scope, the length between the tip of the scope and the tip of the SSR was approximately 60 mm

This study's limitations were associated with its small sample size, and its single-center, retrospective, and non-randomized design. Dilation using the SSR might not be attempted if the circumstances for the dilation appear to be problematic for the SSR, for example, if the angle between the duct's axis and the SSR is acute. Multicenter, prospective studies are warranted to further evaluate the efficacy and safety of the SSR.

In conclusion, the SSR has a high level of pushability, and dilation using the SSR may be compatible with BE-ERC. Although limitations regarding the SSR's length must be considered, it may be a useful option during BE-ERC if the biliary stricture is very severe.

Authors' Contribution Tadahisa Inoue: conception and design, data acquisition, analysis and interpretation, drafting and reivising of the manuspript.

Mayu Ibusuki, Rena Kitano, Yuji Kobayashi, Norimitsu Ishii, Tomohiko Ohashi, Yukiomi Nakade, Yoshio Sumida, Kiyoaki Ito, Haruhisa Nakao, and Masashi Yoneda: data acquisition and interpretation, revising of the manuscript.

Compliance with Ethical Standards

Our hospital's institutional review board approved this study in accordance with the principles of the Declaration of Helsinki (Approval number: 2017-H353). All authors had access to the study's data, and they reviewed and approved the final manuscript.

Conflict of Interest The authors declare that they have no conflict of interest.

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