Efficacy of a Novel Large-cell Niti-S stent with a Slim Delivery System for Hilar Biliary Obstruction: A Preliminary Study

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Abstract

Background: The large-cell Niti-S stent is useful for multiple stenting in malignant hilar biliary obstruction (MHBO) patients. Recently, a novel uncovered self-expandable metallic stent (USEMS) (a large-cell Niti-S slim-delivery stent) was developed. In this study, we aimed to evaluate the efficacy of this slim-delivery USEMS in MHBO patients.

Methods: Outcomes related to USEMS placement, clinical course, and patency period were evaluated in MHBO patients who received multiple USEMSs.

Results: Fourteen MHBO patients underwent the placement of multiple USEMSs, including using the novel slim-delivery stent. Three patients had a past history of Billroth-II reconstruction. The number of USEMSs placed in each patient was 2-6. Three procedures were reinterventions. The new slim delivery system was used to place the first stent in three patients and an additional stent in the remaining patients. The technical and clinical success rates were both 100%. According to Kaplan-Meier analysis, the cumulative patency rate 50 days after USEMS placement was 87.5%.

Conclusions: Placing multiple USEMSs in patients with a past history of abdominal surgery or in reintervention is difficult. The novel USEMS might overcome these difficulties and be the first choice for MHBO patients.

TRIAL REGISTRATION: Not applicable

Background

Endoscopic stenting is the first choice for biliary drainage in patients with unresectable malignant hilar biliary obstruction (MHBO). The patency of uncovered self-expandable metallic stents (USEMSs) has been reported to be longer than that of plastic stents (PSs) for MHBO [1, 2]. However, whether unilateral or multilateral biliary drainage should be performed is under discussion [3, 4], and patients who need multilateral drainage definitely exist (for example, those with cholangitis due to blocked hepatic ducts or liver abscesses) [5]. However, endoscopic multilateral USEMS insertion is technically challenging.

For multilateral drainage in MHBO patients, USEMSs with a large cell size have been reported to be effective [6]. Large cells are advantageous for the placement of additional USEMSs and reintervention. Furthermore, a large-cell USEMS can exert sufficient radial force through the use of a thick nitinol wire.

Recently, a novel large-cell USEMS with a slim delivery system was developed. In this study, we investigated the efficacy of this novel USEMS for drainage in patients with MHBO.

Methods

Patients and ethics

MHBO patients who underwent placement of the novel large-cell USEMS between October 2019 and June 2021 were enrolled in this study. Endoscopic USEMS insertion was performed in two general hospitals in Japan. The requirement for informed consent was waived because this was a retrospective study using anonymized clinical data. All patients agreed to undergo the clinical examination and treatment by providing written consent; if the participant was under 18 years of age, consent was obtained from a parent and/or legal guardian. The details of the study can be found on the homepage of Fukushima Medical University. All the experiment protocol for involving human data was in accordance with the guidelines of national/international/institutional or Declaration of Helsinki in the manuscript. All methods were carried out in accordance with relevant guidelines and regulations. This study was approved by the Institutional Review Board of Fukushima Medical University (approval number: 2453).

The novel large-cell USEMS with a slim delivery system

The newly designed USEMS used in this study was the large-cell Niti-S slim-delivery stent (Taewoong Medical, Gyeoenggi-do, Korea), shown in Fig. 1 (image provided by Century Medical, Tokyo, Japan). The new USEMS has a 6 Fr delivery system. In contrast, a conventional USEMS (large-cell Niti-S uncovered D-type metallic stent (Taewoong Medical)) has an 8 Fr delivery system (Fig. 1a). The new slim delivery system has good trackability for a 0.025 guidewire (Fig. 2b). At the tip of the new delivery system, the step between the 0.025 guidewire and the delivery system is smaller than that at the tip of the conventional 8 Fr delivery system (Fig. 1c and d).

Endoscopic retrograde cholangiopancreatography (ERCP) procedure

The patients were sufficiently sedated with midazolam and pentazocine before endoscope insertion. After the endoscope reached the Vater papilla or bile duct anastomotic site, biliary cannulation was started. The state of the biliary stricture was confirmed by cholangiography (Fig. 2a); then, a guidewire was advanced to an objective biliary branch, and the first USEMS was inserted. If the MHBO patient had an untreated Vater papilla, endoscopic sphincterotomy (EST) was performed after cholangiography. Another guidewire was advanced to another biliary branch through the mesh of the first USEMS (Fig. 2b). Dilation of the mesh was performed as needed, and a second USEMS was inserted (Fig. 2c). For multiple USEMS insertions, the steps after guidewire insertion were repeated as needed.

A fixed method for multiple USEMS insertions has not been established at our hospital. However, in most such procedures in the present study, the first USEMS was inserted in the left hepatic duct, and the second USEMS was inserted in the right hepatic duct. When multiple right hepatic duct drainage procedures were needed, the USEMSs were usually placed in order of descending angle between the common bile ducts.

The endoscope used in this study was a JF-260V or SIF-H290S device (Olympus, Tokyo, Japan). The ERCP catheter was a Tandem XL (Boston Scientific Japan, Tokyo, Japan) or MTW tapered catheter (MTW Endoskopie, Wesel, Germany). VisiGlide2 EndoSelector guidewires (Boston Scientific Japan, Tokyo,

Japan) were employed. The dilation devices used in this study were a 6 mm REN biliary dilation catheter (Kaneka Corporation, Tokyo, Japan) or ES dilator DC7F180S (Zeon Medical Co., Tokyo, Japan). The USEMSs that the patients had previously received were the 10 mm x 6 cm Zilver 635 stent (COOK Medical Japan, Tokyo, Japan), 10 mm x 6 cm ZEO stent (Zeon Medical Co.), or 10 mm x 8 cm or 10 cm large-cell Niti-S D type stent (Taewoong Medical). The USEMSs used in this study were the 10 mm x 8 cm or 10 cm large-cell Niti-S D-type stent (Taewoong Medical), 10 mm x 6 cm Zilver 635 stent (COOK Medical Japan, Tokyo, Japan), and 10 mm x 6 cm or 8 cm large-cell Niti-S slim-delivery stent (Taewoong Medical).

Examination items

Patient characteristics (age, sex, primary lesion site, past history of abdominal surgery, diagnoses, serum data (alanine aminotransferase (ALT), total bilirubin (TB)), and Bismuth classification), outcomes of endoscopic USEMS placement (number of USEMSs, identity of the hepatic ducts the USEMSs were placed in, number of placed USEMS, dilation device usage, technical success rate, and clinical success rate), clinical course after USEMS placement (adverse events, chemotherapy after USEMS placement, USEMS dysfunction, and cause of USEMS dysfunction), and patency period were evaluated in this study.

Technical success was defined as the placement of multiple USEMSs. Clinical success was defined as decreased hepatobiliary enzymes after USEMS placement. Stent dysfunction was defined as elevated hepatobiliary enzyme levels or the appearance of a dilated hepatic duct without pneumobilia on computed tomography (CT) or ultrasound that needed additional endoscopic drainage. The patency period was defined as the period from novel slim delivery USEMS insertion to stent dysfunction.

Statistical analysis

The patency period was analyzed by Kaplan-Meier analysis. Statistical analysis was performed using EzR (Saitama Medical Centre, Jichi Medical University, Saitama, Japan) and Statcel 3 (OMS, Inc., Saitama, Japan).

Results

Fourteen MHBO patients underwent the placement of multiple USEMSs, including the novel slim-delivery stent (Table 1). The median age of the patients was 72.5 (51-90) years old. The primary lesion sites were distributed as follows: bile duct: 10 patients, gallbladder: 2 patients, and stomach: 2 patients. Regarding previous abdominal surgery, one patient had a past history of Billroth-I reconstruction with gastrectomy, and three patients had a history of Billroth-II reconstruction with gastrojejunostomy or pancreaticoduodenectomy. The median ALT was 100 (16-377) U/L. The median TB was 2.0 (0.6–18.8) mg/dL. The Bismuth classification distribution was as follows: II: 4 patients; IIIa: 3 patients; IIIb: 2 patients; and IV: 5 patients.

Table 1

Patient characteristics.

No.	Age	Sex	Primary lesion site	Past history of abdominal surgery	ALT (U/L)	TB (mg/dL)	Bismuth classification
1	70	M	Bile duct	No	22	1.5	IV
2	72	M	Stomach	Gastrojejunostomy Billroth II reconstruction	377	0.7	II
3	77	F	Bile duct	Pancreaticoduodenectomy Billroth II reconstruction	110	11.5	IV
4	72	M	Bile duct	No	100	8.5	IIIa
5-1	68	M	Gallbladder	No	35	1.5	IV
5-2					33	1.5	
6	71	M	Bile duct	No	102	2.2	IIIb
7	51	M	Bile duct	No	112	17.1	IV
8	90	M	Bile duct	Gastrectomy Billroth I	130	3.0	II
9	73	M	Bile duct	No	61	2.0	IIIa
10	51	M	Stomach	No	110	8.1	IV
11	81	M	Bile duct	Pancreaticoduodenectomy Billroth II	30	0.7	IIIb
12	84	M	Gallbladder	No	16	0.6	IIIa
13	87	M	Bile duct	No	46	18.8	II
14	82	F	Bile duct	No	303	0.7	II
ALT, alanine aminotransferase; TB, total bilirubin; M, male; F, female.							

The outcomes of endoscopic USEMS placement are shown in Table 2. The number of placed USEMSs in each patient was 2-6. The maximum number of hepatic ducts in which USEMSs were inserted was four (patient no. 5). Although patient no. 7 received six USEMSs, three were reinterventions. The USEMS insertion in patient no. 9 was also a reintervention. In three patients, the new slim delivery system was used to place the first stent. In the other patients, the new slim delivery system was used to place an additional stent. In six patients, dilation devices were used. The technical and clinical success rates were both 100%.

Table 2

Outcomes of endoscopic USEMS placement.

No.	No. of USEMSs placed	Hepatic duct USEMS placement	Type of placed USEMS	Dilation device usage	Technical success	Clinical success
1	3	B2, 6, 8	1. Niti-S large-cell D-type, 10 mm x 10 cm 2. Niti-S slim-delivery, 10 mm x 8 cm 3. Niti-S slim-delivery, 10 mm x 6 cm	No	Yes	Yes
2	2	L, RAD	1. Niti-S large-cell D-type, 10 mm x 10 cm 2. Niti-S slim-delivery, 10 mm x 6 cm	No	Yes	Yes
3	2	B3, RAD	1. Niti-S slim-delivery, 10 mm x 6 cm 2. Niti-S slim-delivery, 10 mm x 6 cm	No	Yes	Yes
4	2	B6, 5	1. Niti-S slim-delivery, 10 mm x 10 cm 2. Niti-S slim-delivery, 10 mm x 10 cm	Yes	Yes	Yes
5-1	3	L, B6, RAD	1. Niti-S large-cell D-type, 10 mm x 10 cm 2. Niti-S large-cell D-type, 10 mm x 8 cm 3. Niti-S slim-delivery, 10 mm x 8 cm	Yes (before 3 rd USEMS)	Yes	Yes
5-2	4	B7	1. Niti-S slim-delivery, 10 mm x 6 cm	No	Yes	Yes
6	2	RPD, RAD	1. Niti-S large-cell D-type, 10 mm x 8 cm	No	Yes	Yes

			2. Niti-S slim-delivery, 10 mm x 8 cm			
7	6	RPD, B5, 8 (previous institution) B8, RPD, B5	1. Zilver 635, 10 mm x 6 cm 2, 3. ZEO STENT, 10 mm x 6 cm (previous institution) 4. Niti-S large-cell D-type, 10 mm x 10 cm 5. Niti-S slim-delivery, 10 mm x 8 cm 6. Niti-S slim-delivery, 10 mm x 6 cm	Yes (before fifth and sixth USEMSs)	Yes	Yes
8	2	L, R	1. Niti-S large-cell D-type, 10 mm x 8 cm 2. Niti-S slim-delivery, 10 mm x 6 cm	Yes	Yes	Yes
9	4	L, B5 (previous session) L, B5	1. Niti-S large-cell D-type, 10 mm x 8 cm 2. Niti-S large-cell D-type, 10 mm x 8 cm 3. Niti-S slim-delivery, 10 mm x 8 cm	Yes	Yes	Yes
10	2	L, RAD	1. Zilver 635, 10 mm x 10 cm 2. Niti-S slim-delivery, 10 mm x 10 cm	No	Yes	Yes
11	2	R, L	1. Niti-S slim-delivery, 10 mm x 6 cm 2. Zilver 635, 10 mm x 6 cm	No	Yes	Yes
12	2	L, R	1. Niti-S large-cell	No	Yes	Yes

			D-type, 10 mm x 8 cm 2. Niti-S slim-delivery, 10 mm x 8 cm			
13	2	L, R	1. Niti-S large-cell D-type, 10 mm x 10 cm 2. Niti-S slim-delivery, 10 mm x 8 cm	No	Yes	Yes
14	2	L, R	1. Niti-S large-cell D-type, 10 mm x 10 cm 2. Niti-S slim-delivery, 10 mm x 10 cm	Yes	Yes	Yes
USEMS, uncovered self-expandable metallic stent; L, left hepatic duct; RAD, right anterior hepatic duct; RPD, right posterior hepatic duct; R, right hepatic duct.						

The clinical courses after USEMS placement are shown in Table 3. Adverse events were not observed. In five patients, chemotherapy was performed after USEMS placement. Dysfunction of the USEMS due to tumor ingrowth was observed in one patient. According to Kaplan-Meier analysis, the cumulative patency rate 50 days after USEMS placement was 87.5% (Figure 3).

Table 3

Clinical course after USEMS placement.

No.	Adverse events	Chemotherapy after USEMS placement	USEMS dysfunction	Cause of USEMS dysfunction
1	No	Yes	No	
2	No	Yes	No	
3	No	No	No	
4	No	Yes	No	
5	No	Yes	No	
6	No	Yes	Yes	Ingrowth
7	No	No	No	
8	No	No	No	
9	No	No	No	
10	No	No	No	
11	No	No	No	
12	No	No	No	
13	No	No	No	
14	No	No	No	
USEMS, uncovered self-expandable metallic stent.				

Discussion

In this study, 14 MHBO patients underwent the endoscopic placement of multiple USEMSs, including the new slim-delivery USEMS. Although three patients with a past history of abdominal surgery other than Billroth-I reconstruction and three reinterventions were involved, both the technical and clinical success rates were 100%.

In a recent randomized controlled trial, the technical success rate of bilateral biliary drainage with a USEMS was 90% [4]. With the use of a previously developed 8.5 Fr large-cell Niti-S stent (Taewoong Medical), the technical success rate was 96% [6]. However, ERCP was challenging to perform for patients with surgically altered anatomy. In a report with a large number of patients, the success rate of enteroscope insertion was 71%, and the technical success rate was 63% [7]. In addition, reintervention for stent occlusion after bilateral USEMS placement was difficult. The technical success rate of reintervention with bilateral USEMS placement was reported to be 13% in patients who had previously undergone bilateral USEMS placement [8]. In the present study, the technical and clinical success rates using the slim-delivery USEMS were similar to those of a recent randomized controlled trial and a past report using a previously developed 8.5 Fr large-cell stent. In addition, all multiple stenting procedures

were successful in patients with a past history of abdominal surgery and in patients with reintervention [4].

Few reports have investigated the risk factors for failed placement of multiple USEMSs with the stent-in-stent technique. Kawakubo et al. [9] identified metastatic diseases as a risk factor for the failure of stent-in-stent USEMS placement. In contrast, a large mesh and thin delivery system were favorable factors. Sugimoto et al. [10] used large-mesh USEMSs and investigated the risk factors for the failure of stent-in-stent USEMS placement in patients. They reported that an angle greater than 49.7 degrees between the first USEMS and second hepatic duct was a risk factor for the failure of stent-in-stent insertion. In the present study, six patients showed an angle greater than 49.7 degrees between the first USEMS and the biliary branch, and a second USEMS needed to be placed. In five of the six patients with large angles, the slim-delivery USEMS was used. Two MHBO patients in this study had metastatic disease; however, the successful placement of multiple USEMSs was achieved by using the slim delivery system. These satisfactory results may be due to the fact that the slim-delivery USEMS has features favorable for stent-in-stent placement, including a large mesh and thin delivery system. A large mesh facilitates the placement of additional USEMSs, and a thin delivery system facilitates passage through the mesh. In fact, in most cases in the present study, USEMS placement using the slim delivery system was achieved without the use of any dilation devices.

Although the number of patients in this study was limited, the cumulative stent patency rate was not inferior to that of conventional large-cell USEMSs [11, 12]. In most patients in this study, conventional large-cell stents were used because a strong radial force is expected with a thick nitinol wire [11]. However, stent dysfunction was not observed in patients who received a slim-delivery USEMS as the first stent (patients 3, 4, 11). In addition, in these patients, a second USEMS was successfully placed. The hepatic ducts of patient 3 were hard and thin, with primary sclerosing cholangitis, and patients 4 and 11 had a past history of abdominal surgery. The slim-delivery USEMS was suitable in these patients. The delivery system of the novel large-cell USEMS was longer than that of conventional large-cell USEMSs. Therefore, the slim-delivery USEMS integrates well with enteroscopic equipment. Because of these factors, the large-cell Niti-S slim-delivery stent may be expected to be used as the first stent.

This study has several limitations. First, this was a retrospective study with a small number of patients. In the future, a prospective study should be performed to confirm the results. Second, not all stenting was performed with the large-cell Niti-S stent and slim delivery system. However, this stent was used as the first stent and for the placement of multiple stents or for reintervention. In addition, the Niti-S USEMS and slim delivery system was useful in patients with a past history of abdominal surgery. The results of this study show that the this USEMS and slim delivery system can be used to treat several types of MHBO.

Conclusions

The large-cell Niti-S slim delivery system might be useful in treating MHBO. In addition, the Niti-S USEMS and slim delivery system might be the first choice in patients with a past history of abdominal surgery or

who need reintervention.

Abbreviations

MHBO: malignant hilar biliary obstruction; USEMS: uncovered self-expandable metallic stent.

Declarations

Ethics approval and consent to participate

All the experiment protocol for involving human data was in accordance with the guidelines of national/international/institutional or Declaration of Helsinki in the manuscript. The study protocol was reviewed and approved by the Institutional Review Board of Fukushima Medical University (Number 2453). The analysis used anonymous clinical data obtained after all the participants agreed to treatment by written consent, so patients were not required to provide informed consent for this study. The details of the study can be found on the homepage of Fukushima Medical University.

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Competing interests

The authors declare that they have no competing interests.

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None.

Authors' contributions

MS wrote the paper, contributed to the study design and performed the research. TT contributed to the study design and oversaw the research. RS, NK, HA, YS, HI, YI, HA, JN, MT, MH, TK, RK, TY, TH and SM

provided clinical advice. HO supervised the study and the writing of the paper. All authors have read and approved the final manuscript.

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Figures

Figure 1

The large-cell Niti-S slim-delivery stent (6 Fr) and the conventional large-cell Niti-S stent (8 Fr). (a) The new slim-delivery Niti-S stent is thinner than the conventional large-cell Niti-S stent. (b) The new slim-delivery Niti-S stent has better trackability for a guidewire than the conventional large-cell Niti-S stent. (c, d) The 6 Fr delivery system has a smaller step between the delivery system and 0.025 guidewire than the 8 Fr delivery system.

Figure 2

A case of MHBO with primary sclerosing cholangitis. (a) Bismuth IIIa MHBO was observed by ERCP. (b) A 10 mm x 10 cm large-cell Niti-S slim-delivery stent was placed in B6. (c) After the other guidewire was placed in B5, the new slim-delivery USEMS was placed along the guidewire.

Figure 3

Kaplan-Meier analysis of patency period. The cumulative patency rate 50 days after the placement of multiple USEMSs (including the large-cell Niti-S slim-delivery stent) was 87.5%.