

A prospective study of fully covered metal stents for different types of refractory benign biliary strictures

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Bibliography

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 Fig. 1s, Table 1s, Table 2s

Online content viewable at:

ABSTRACT

Background While endoscopic management of benign biliary strictures (BBSs) is the standard of care, long-term treatment remains the issue in refractory cases, especially for anastomotic strictures after living-donor liver transplan-

tation (LDLT) and hepaticojejunostomy anastomotic strictures (HJAS). The aim of this prospective study was to evaluate the safety and effectiveness of a fully covered self-expandable metal stent (FCSEMS) for patients with refractory BBSs.

Methods Patients with BBSs that were unamenable to endoscopic plastic stent placement with a treatment period of more than 6 months were eligible. An FCSEMS was placed endoscopically and removed after 90 days. In patients with surgically altered anatomy, an FCSEMS was placed using a double-balloon endoscope. The primary outcome was stricture resolution at FCSEMS removal. The secondary outcomes included stricture recurrence and adverse events.

Results A total of 30 patients were enrolled: the causes of their BBSs were anastomotic stricture after LDLT in 13, HJAS in 12, post-cholecystectomy in two, chronic pancreatitis in two, and post-hepatectomy in one. The technical success rate of FCSEMS placement was 100% and all FCSEMSs were successfully removed. The rate of stricture resolution at FCSEMS removal was 96.6% (91.7% in the post-LDLT group and 100% in the HJAS group). Stricture recurrence occurred in three HJAS patients (10.7%) during a median follow-up period of 15.6 months. Adverse events were observed in 12.1%: five cholangitis, one pancreatitis, and one perforation.

Conclusion Temporary placement of an FCSEMS was a feasible and effective treatment option for refractory BBSs, especially for post-LDLT strictures and HJAS.

University Hospital Medical Network Clinical Trials Registry

UMIN000022164

TRIAL REGISTRATION: Single-Center, Single-arm, prospective exploratory trial UMIN000022164 at <http://www.umin.ac.jp>

Introduction

Benign biliary strictures (BBSs) have a wide variety of etiologies: primary/secondary sclerosing cholangitis, chronic pancreatitis, post-cholecystectomy, post-liver transplantation, and hepaticojejunostomy anastomotic stricture (HJAS). Endoscopic treatment using balloon dilation and placement of multiple plastic stents has been established as a first-line treatment modality

for BBS [1–5]. This technique is especially suitable for BBSs located at the distal bile duct, such as those due to chronic pancreatitis and following deceased-donor liver transplantation (DDLT), in which multiple stent placement can easily be performed via endoscopic retrograde cholangiopancreatography (ERCP).

For patients with hilar BBSs, such as stricture following living-donor liver transplantation (LDLT) and HJAS, however, tech-

nical issues should be addressed because the stricture is located at the level of the hepatic duct or more peripheral intrahepatic duct. In these situations, endoscopic multiple stenting is technically difficult owing to the small diameter of the bile duct and bifurcation near to the stricture [6, 7]. As a result, the rate of stricture resolution is not sufficiently high in these patients, and patients with refractory strictures require long durations of endoscopic, percutaneous, or even surgical treatment. Therefore, alternative strategies should be implemented to improve the clinical outcomes of patients with hilar BBSs.

Recently, a series of randomized controlled trials (RCTs) have reported the efficacy of a fully covered self-expandable metal stent (FCSEMS) for distal BBSs and have demonstrated comparable stricture resolution rates and shorter treatment duration compared with multiple plastic stents [8–13]. FCSEMSs for hilar BBSs may be a promising treatment option, but several issues are still to be resolved. First, as it is necessary to place a long stent across the papilla for hilar stricture, stent migration should be addressed as a major complication [14]. Second, a large bore stent placed in a small intrahepatic bile duct can cause bile duct injury or a de novo stricture. Above-the-papilla stenting is one of the choices to tackle these hurdles, but there is a concern about technical difficulty in stent removal [15]. Furthermore, FCSEMS placement at the hilum can carry a risk of segmental cholangitis in the contralateral bile duct. To date, there has been a paucity of data on the feasibility and effectiveness of FCSEMSs for hilar BBSs.

Therefore, we conducted a prospective trial to evaluate the feasibility and effectiveness of placement of an FCSEMS in patients with refractory BBSs, including those with hilar stricture. We used an FCSEMS designed to be placed above the papilla, which has a lasso for stent removal and a central waisted structure to prevent stent migration. This is the first prospective trial evaluating an FCSEMS for hilar BBS, including post-LDLT stricture and HJAS. In addition, the effectiveness of FCSEMSs could be strengthened by including only refractory BBSs that are supposed to be resistant to conventional treatments, such as balloon dilation and plastic stent placement.

Methods

Study design

This is a single-center, single-arm, prospective exploratory clinical trial evaluating the feasibility and effectiveness of FCSEMSs for refractory BBSs. The primary outcome was the rate of stricture resolution at FCSEMS removal. The secondary outcomes included the rate of successful FCSEMS removal, the rate of stricture recurrence, the rate of stricture resolution at the end of study period, and adverse events. In 2016 when the current study was designed, FCSEMSs were only approved for malignant biliary obstruction by the Ministry of Health, Labor, and Welfare in Japan. Therefore, we also aimed to evaluate the feasibility of FCSEMSs for BBSs in a Japanese setting.

This study was conducted in accordance with the Declaration of Helsinki and was approved by the institutional review board of the University of Tokyo hospital. This study was regis-

tered in UMIN-CTR (UMIN000022164). Written informed consent was obtained from all patients at enrollment.

Patients

The inclusion criteria of this study were as follows: (i) patients with a refractory BBS, defined as a stricture that had been resistant to endoscopic treatment using plastic stents for longer than 6 months prior to the enrollment; (ii) malignant disease having been excluded by pathological examination or clinical course; and (iii) patients older than 20 years of age. The exclusion criteria were as follows: (i) endoscopic approach was impossible; (ii) patients with an Eastern Cooperative Oncology Group (ECOG) performance status of 3 or more; and (iii) patients with severe co-morbidity.

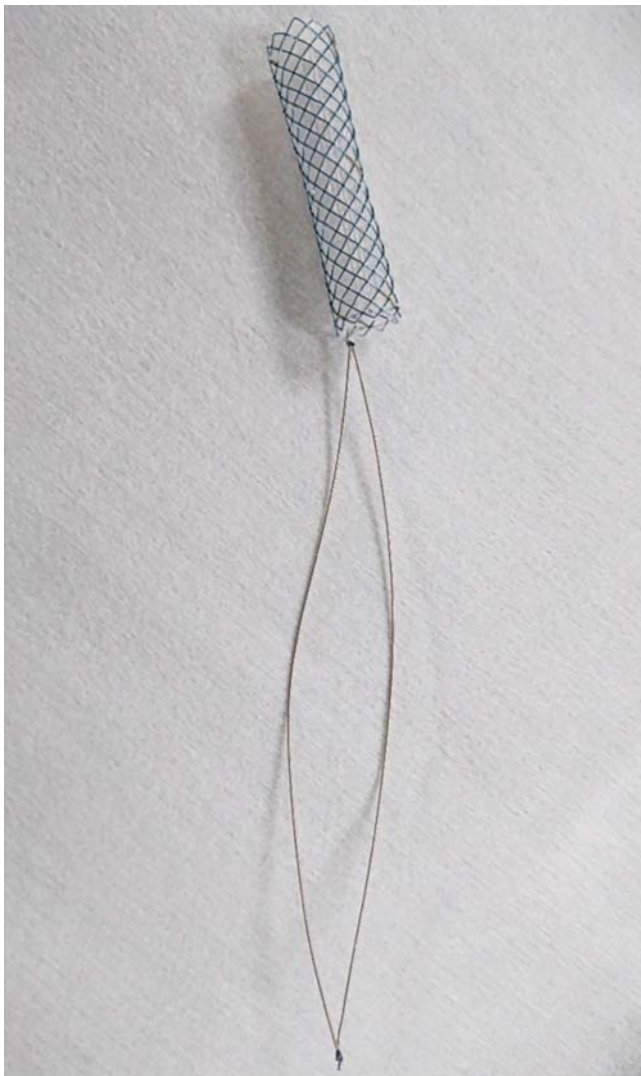
Fully covered self-expandable metal stents

The FCSEMSs used in this study were Niti-S Kaffes stents manufactured by TaeWoong Medical (Gyeonggi-do, South Korea) (► Fig. 1) [16]. The body of the stent is made of nitinol wire with silicone membrane; the diameter of the central part is 2 mm smaller than that of the end part, which is designed to prevent stent migration. A platinum lasso (10-cm long) is attached to the distal end for removal of FCSEMSs placed “above-the-ampulla.” The available lengths are 40, 60, or 80 mm, and the diameters of the central part are 6 or 8 mm. The delivery system is 9 Fr in diameter.

Endoscopic procedures and patient follow-up

All endoscopic procedures were carried out on an inpatient basis. During the procedure, patients were sedated with an intravenous injection of diazepam or midazolam and pethidine hydrochloride; in patients undergoing double-balloon endoscope-assisted ERCP (DB-ERCP), continuous intravenous administration of dexmedetomidine hydrochloride was added. Scopolamine butyl bromide or glucagon was used as a gastrointestinal antispasmodic agent. A prophylactic antibiotic was administered routinely during the periprocedural period.

ERCP was performed with a side-viewing duodenoscope (JF-260V or TJF-260V; Olympus Medical, Tokyo Japan) with CO₂ insufflation. After the biliary tract had been successfully cannulated, the location of the biliary stricture was assessed on cholangiogram, and the stent length and diameter were determined on the basis of the cholangiographic findings. Sphincterotomy was not routinely performed in patients with post-LDLT strictures. The FCSEMS delivery system was advanced over the 0.035-inch guidewire (Jagwire; Boston Scientific Japan, Tokyo, Japan; or Revowave; Piolax Medical, Kanagawa, Japan) after balloon dilation of the stricture. For hilar BBSs, the FCSEMS was deployed above the papilla under fluoroscopic and endoscopic guidance and the center portion of the FCSEMS was positioned at the stricture site (► Fig. 2). The platinum lasso was subsequently deployed in the duodenum (► Video 1). In patients with two post-LDLT strictures, placement of two FCSEMSs in the “side-by-side” manner was attempted (► Fig. 3). For distal BBSs, the FCSEMS was placed across the papilla.



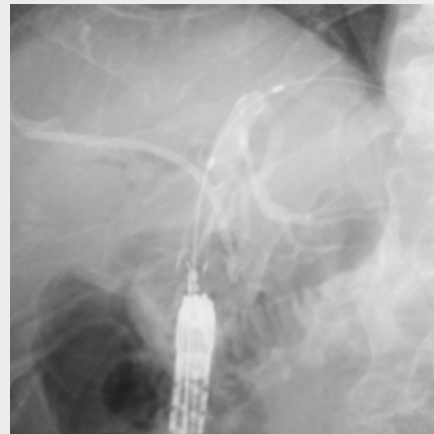
► **Fig. 1** Photograph of a fully covered metal stent with a 10-cm lasso (Niti-S Kaffes; TaeWoong Medical, Gyeonggi-do, South Korea) and a central section diameter 2 mm smaller than the diameter at the ends.

In patients with HJAS, a short-type double-balloon endoscope (DBE; EI-580BT; Fujifilm, Tokyo, Japan) that was 155-cm long, with a 3.2-mm working channel, was inserted using CO₂ insufflation [17, 18]. The HJAS was assessed by both cholangiographic and endoscopic views, and the length and diameter of the FCSEMS were determined. After balloon dilation had been performed, the FCSEMS was advanced over a 0.025-inch stiff guidewire (VisiGlide2, Olympus; EndoSelector, Boston Scientific; or M-Through, Medicos Hirata, Tokyo, Japan). The FCSEMS was deployed and the center portion of the stent was positioned at the site of the anastomotic stricture, and the platinum lasso was deployed in the jejunum (► **Fig. 4**; ► **Video 2**).

In patients with a risk of segmental cholangitis owing to obstruction of the contralateral biliary branch, we placed a 7-Fr plastic stent into the contralateral biliary branch in the “side-by-side” manner (“rescue stent”) prior to FCSEMS placement (► **Fig. 4** and ► **Fig. 5**; ► **Video 2**) [19]. A dedicated inside stent

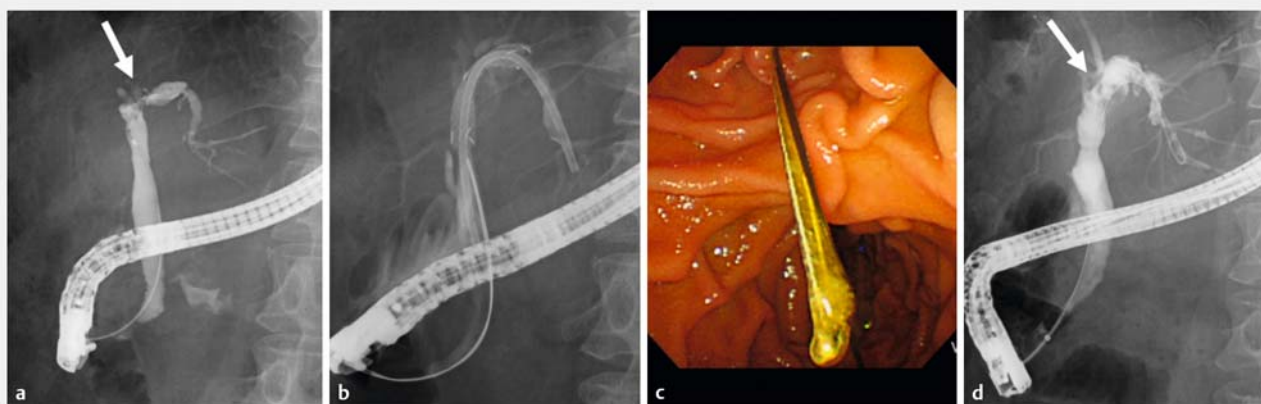


► **Video 1** A fully covered metal stent placed for a biliary anastomotic stricture after living-donor liver transplantation. Online content viewable at: <https://doi.org/10.1055/a-1111-8666>

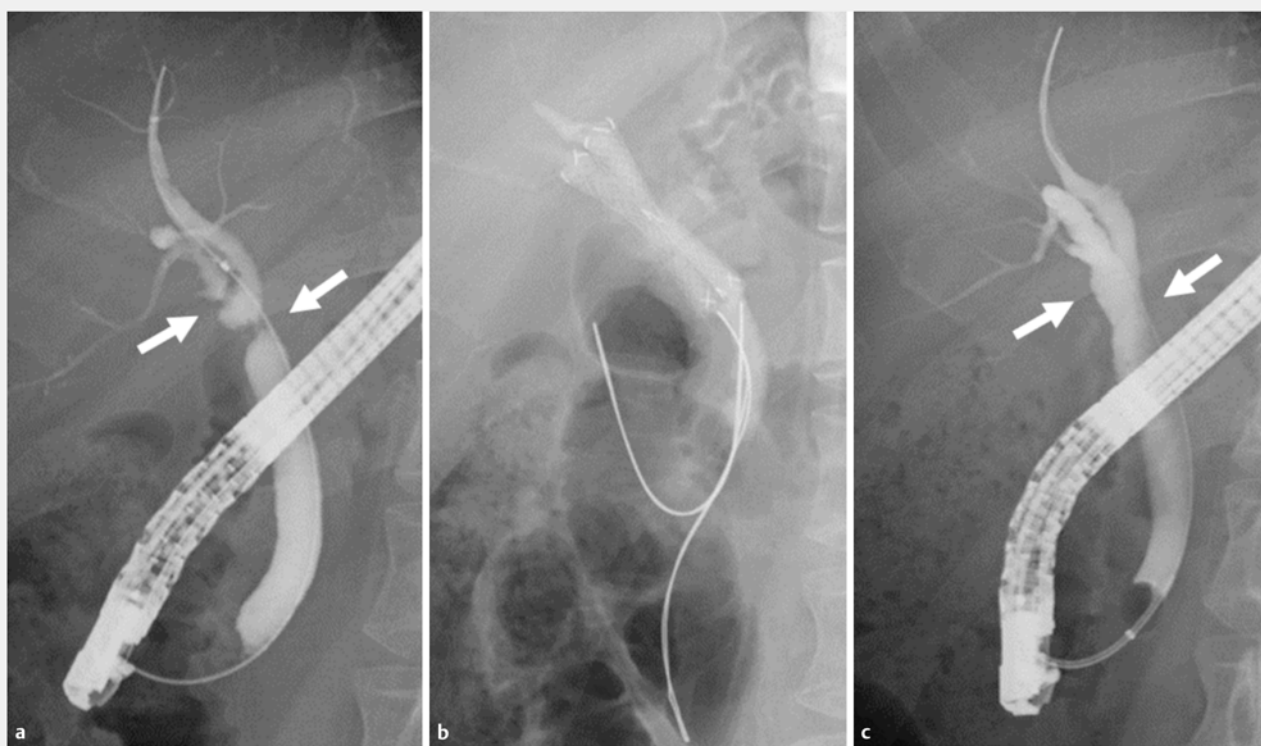


► **Video 2** A fully covered metal stent placed for a hepaticojejunostomy anastomotic stricture using a double-balloon endoscope. Online content viewable at: <https://doi.org/10.1055/a-1111-8666>

(ThroughPass-iS, Gadelius Medical, Tokyo, Japan) was used for patients with normal gastrointestinal anatomy, and a straight-type plastic stent (Geenen, Cook Medical, Bloomington, Indiana, USA) was used in patients with HJAS. When the stricture was located at an angled bile duct, we placed a 7-Fr plastic stent (ThroughPass-iS or Geenen) into the FCSEMS in the “stent-in-stent” manner, which worked as a core rod (“core stent”) to prevent kinking of the bile duct at the end of the FCSEMS (► **Fig. 2**; ► **Video 1**).



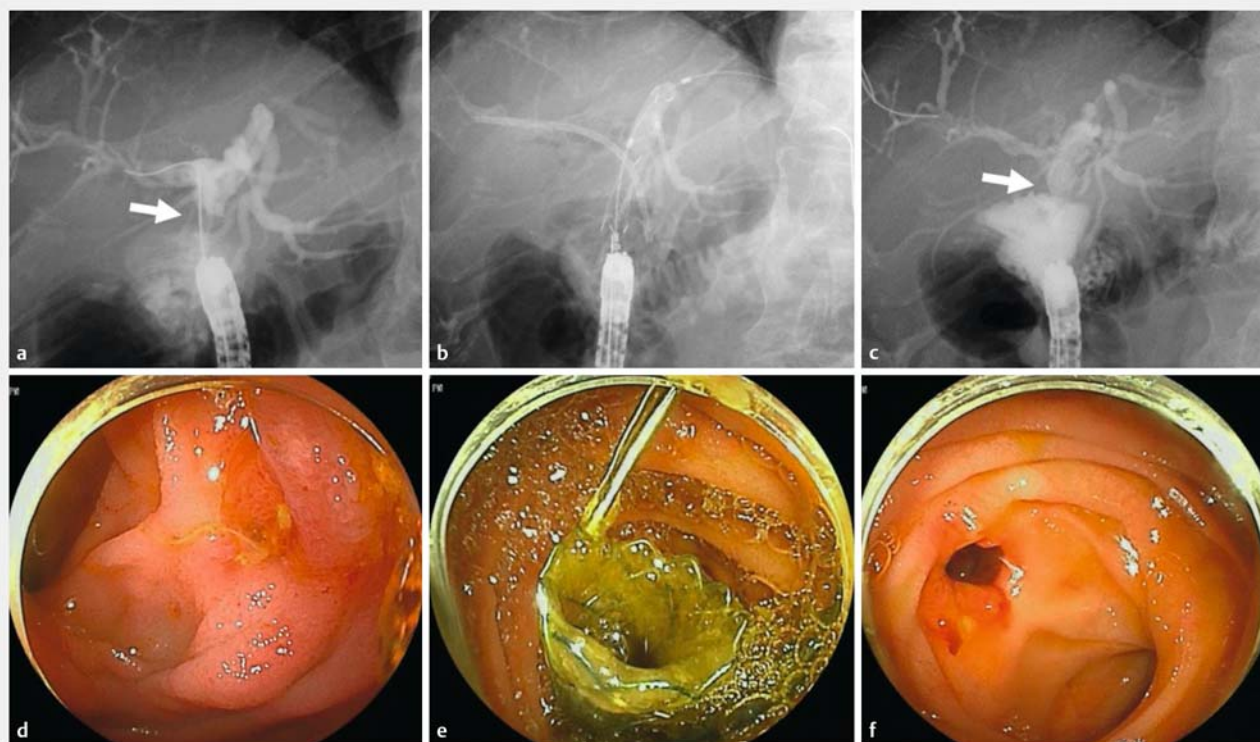
► **Fig. 2** Use of a fully covered metal stent (FCSEMS) to treat a biliary anastomotic stricture after living-donor liver transplantation (LDLT). **a, b** Cholangiographic images showing: **a** the biliary anastomotic stricture after LDLT with a left graft (arrow); **b** an FCSEMS placed across the anastomotic stricture, with a plastic stent placed within in the “stent-in-stent” manner to prevent kinking of the metal stent (“core stent”). **c** Endoscopic image showing a platinum lasso coming out of the ampulla. **d** Balloon-occluded cholangiogram suggesting resolution of the anastomotic stricture (arrow) after placement of an FCSEMS for 3 months.



► **Fig. 3** Cholangiographic images showing: **a** two biliary anastomotic strictures after living-donor liver transplantation (LDLT) with a right graft (arrows); **b** two fully covered metal stents placed across the anastomotic strictures in the “side-by-side” manner; **c** (with balloon occlusion) resolution of the two anastomotic strictures (arrows).

Patients visited our outpatient clinic every month and underwent a physical examination and blood testing, which included hepatobiliary enzymes. FCSEMS removal was planned 90 days after FCSEMS placement. The lasso was grasped by biopsy forceps and the FCSEMS was removed through the working channel of the endoscope. The stricture was evaluated by

balloon-occluded cholangiogram, and by endoscopic view in patients with HJAS. If stricture resolution was confirmed, no further stent was placed. Patients with stricture resolution were followed up at outpatient clinic every 3 months until the end of the study period.



► **Fig. 4** Placement of a fully covered metal stent (FCSEMS) for a hepaticojunostomy anastomotic stricture (HJAS) using a double-balloon endoscope. **a–c** Cholangiographic; and **d–f** endoscopic images showing: **a** the HJAS (arrow) prior to treatment; **b** the FCSEMS placed across the anastomotic stricture, with a side-by-side plastic stent ("rescue stent") also visible; **c** resolution of the anastomotic stricture (arrow; balloon-occluded cholangiogram); **d** the HJAS prior to treatment; **e** the FCSEMS placed across the anastomotic stricture; **f** Endoscopic view of the fully dilated hepaticojunostomy anastomosis after FCSEMS placement for 3 months.

Definitions of outcome variables

Resolution of the stricture was recorded when: (i) the stricture was considered sufficiently dilated on fluoroscopic and endoscopic views; (ii) an inflated extraction balloon catheter passed the stricture site smoothly; (iii) contrast in the bile duct proximal to the stricture readily flowed into the distal side; and (iv) no additional intervention was required within 3 days after FCSEMS removal. Recurrence of the stricture was defined as elevated liver enzymes or cholangitis with images showing bile duct dilatation that required an endoscopic, percutaneous, or surgical re-intervention. Adverse events were defined and graded according to the lexicon [20].

Statistical analysis

All clinical and endoscopy-related data were stored in a web-based Electronic Data Capture system (UHCT ACRess, The University of Tokyo Hospital).

For refractory BBSs, the stricture resolution rate using plastic stents after 3 months was assumed to be 0%. When we estimated that the stricture resolution rate at FCSEMS removal was 95% [8], with lower limit of 80%, a sample size of 30 would maintain a power of 70%, with a one-sided significance level of 0.05. Given that the lower limit of the 90% confidence interval was not below 80%, we considered that the true stricture resolution

rate would exceed 80%. Time to stricture recurrence was estimated by the Kaplan–Meier method.

All statistical analyses were performed using the EZR software (Saitama Medical Center, Jichi Medical University, Saitama, Japan), which is a graphical user interface for the R software (The R Foundation for Statistical Computing, Vienna, Austria, version 3.2.2) [21].

Results

We enrolled 30 patients with refractory BBSs between September 2016 and February 2018. ► **Table 1** summarizes the clinical characteristics of the study population. The main causes of BBSs were post-LDLT ($n=13$), and HJAS ($n=12$); other etiologies included post-cholecystectomy ($n=2$), chronic pancreatitis ($n=2$), and post-hepatectomy ($n=1$). The time between initial plastic stent placement and FCSEMS placement was a median of 25.5 months (interquartile range [IQR] 11.0–45.1 months). Six patients with HJAS and five post-LDLT patients had a previous history of plastic stent treatment for less than 12 months. In patients with HJAS, the types of surgery were pancreaticoduodenectomy with Roux-en-Y ($n=5$), pancreaticoduodenectomy with Billroth-II ($n=3$), and extrahepatic bile duct resection with Roux-en-Y ($n=4$). Detailed characteristics of the LDLT and



► **Fig. 5** Cholangiographic image showing a fully covered metal stent placed for a biliary anastomotic stricture after living-donor liver transplantation with a right graft, and two side-by-side plastic stents ("rescue stents") to prevent segmental cholangitis.

HJAS patients are summarized in **Tables 1s** and **2s**, respectively (see online-only Supplementary material).

► **Fig. 6** shows the patient flow through the study. Among the 30 included patients, one was excluded prior to FCSEMS placement because of cholangitis. An FCSEMS was successfully placed in all 29 patients where placement was attempted, giving a technical success rate of 100% (► **Table 2**). In 15 patients who were post-LDLT, post-cholecystectomy, and post-hepatectomy, an FCSEMS was placed across the hilum and above the papilla. In two patients with chronic pancreatitis, an FCSEMS was placed across the papilla. In 12 patients with HJAS, an FCSEMS was placed across the stricture with the distal end in the jejunum. In four patients with two post-LDLT strictures, two FCSEMSs were placed one for each stricture (► **Fig. 3**). A concomitant plastic stent (a "rescue stent" and/or a "core stent") was placed in 23 patients (79.3%). Finally, 28 patients completed the planned indwelling period of 3 months. Stent removal was successful without difficulty in all patients in whom it was attempted.

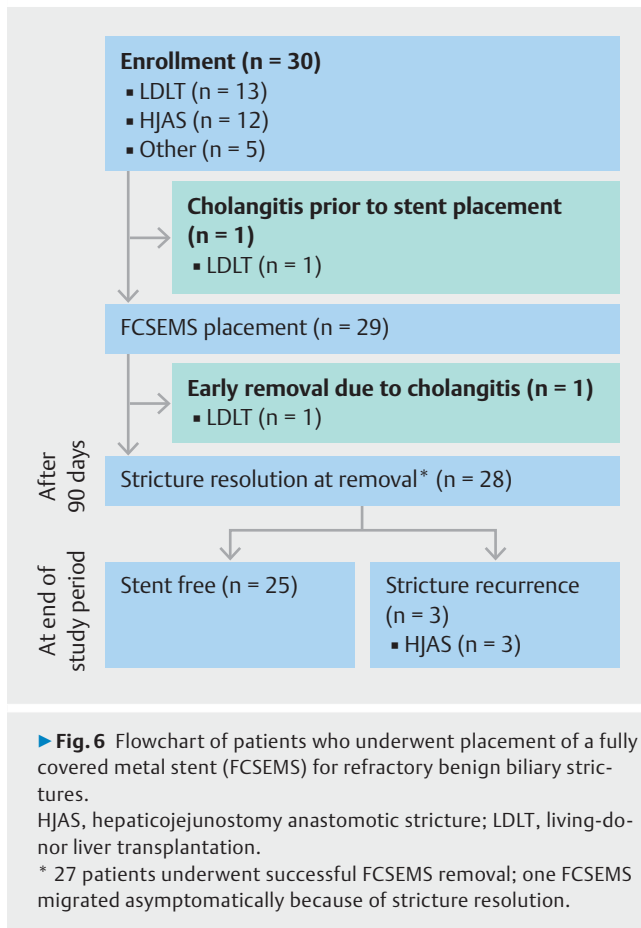
Stent-related adverse events were observed in two patients (6.9%): one stent occlusion with moderate cholangitis due to biliary sludge that resulted in early removal of the FCSEMS at 65 days, and one asymptomatic stent migration due to stricture resolution at 91 days.

► **Table 1** Characteristics of the 30 patients who underwent placement of a fully covered metal stent for refractory benign biliary strictures.

Characteristic	Patients
Sex, male, n (%)	19 (63.3%)
Age, median (IQR), years	63 (28–81)
Cause of benign biliary strictures, n (%)	
▪ Post-LDLT	13 (43.3%)
▪ HJAS	12 (40.0%)
▪ Post-cholecystectomy	2 (6.7%)
▪ Post-hepatectomy	1 (3.3%)
▪ Chronic pancreatitis	2 (6.7%)
Type of graft in LDLT patients, n (%)	
▪ Right graft	10 (76.9%)
▪ Left graft	3 (23.1%)
Type of surgery and GI reconstruction in HJAS patients, n (%)	
▪ Pancreaticoduodenectomy with Roux-en-Y	5 (41.7%)
▪ Pancreaticoduodenectomy with Billroth-II	3 (25.0%)
▪ Extrahepatic bile duct resection with Roux-en-Y	4 (33.3%)
Time from initial plastic stent placement, median (IQR), months	25.5 (11.0–45.1)
IQR, interquartile range; LDLT, living donor liver transplantation; HJAS, hepaticojejunostomy anastomotic stricture; GI, gastrointestinal.	

The rate of stricture resolution at FCSEMS removal was 96.6% (28/29; 90% confidence interval [CI] 84.7%–99.8%) in the per-protocol population. In terms of the different etiologies, the rates of stricture resolution were: post-LDLT 91.7% (11/12); HJAS 100% (12/12); post-cholecystectomy 100% (1/1); chronic pancreatitis 100% (2/2); post-hepatectomy 100% (1/1). Adverse events were observed in 7 out of 58 procedures performed to insert or remove the FCSEMS (12.1%): five cholangitis (mild 2; moderate 3), one pancreatitis (moderate), and one perforation (moderate). Pneumoperitoneum was diagnosed on computed tomography the day after the procedure in a patient with surgically altered anatomy who underwent DB-ERCP. Microperforation during the procedure was suspected but the patient recovered without any serious consequences with conservative treatment alone. All other adverse events were managed conservatively.

Fig. 1s illustrates the cumulative non-recurrence rate of the stricture after successful treatment via FCSEMS. During a median follow-up period of 15.6 months (IQR 12.0–22.1 months), stricture recurrence occurred in 10.7% (3/28). All three recurrences were observed in patients with HJAS, and another FCSEMS placement via DB-ERCP was performed as a salvage treatment. The overall stricture resolution rate during the study period was 86.2% (25/29).



Discussion

In this prospective exploratory trial, temporary placement of an FCSEMS was able to manage refractory BBSs, with a stricture resolution rate of 96.6% after 3 months. Although the majority of our study population consisted of post-LDLT strictures and HJASs, which have been reported to be resistant to plastic stent treatment, stricture resolution was achieved in 91.7% and 100%, respectively. FCSEMS removal was successful in all patients and adverse event rates were acceptable.

The two major etiologies of BBS in our study population were post-LDLT strictures and HJASs. For post-LDLT strictures, plastic stent placement has been utilized as a standard treatment modality, with stricture resolution rates of 37%–100% and stricture recurrence rates of 10%–44% [22–26]; however, a long duration of treatment is necessary, even in successful cases, and a substantial proportion of refractory patients undergo repeated endoscopic treatments over a long period. For this population, only a few series of retrospective studies have reported the outcomes of FCSEMS placement [19, 27, 28]. The current study is the first prospective trial to provide promising results for the use of FCSEMSs for post-LDLT strictures. Because this study included only refractory cases, application of FCSEMSs as an initial treatment modality should be evaluated in a future trial.

► Table 2 Outcomes of a fully covered metal stent (FCSEMS) placement for refractory benign biliary strictures in 29 patients.

Outcome	Patients
Successful FCSEMS placement, n (%)	29 (100%)
Procedure time, median (IQR), minutes	46 (35–64)
Number of FCSEMSs, n (%)	
▪ 1	25 (86.2%)
▪ 2	4 (13.8%)
Concomitant plastic stent placement, n (%)	23 (79.3%)
Indwelling time, median (IQR), days	91 (65–98)
Successful FCSEMS removal, n (%)	27/27 (100%)
Stricture resolution at FCSEMS removal, n (%) [90% confidence interval]	28 (96.6%) [84.7%–99.8%]
Follow-up after FCSEMS removal, median (IQR), months	21.5 (13.5–24.0)
Stricture recurrence, n (%)	3/28 (10.7%)
Time to recurrence, median (IQR), months	19.5 (12.8–20.9)
Type of benign biliary stricture with recurrence	
▪ Hepaticojejunostomy anastomotic stricture	3
Adverse events, n (%)	7/58 (12.1%)
▪ Cholangitis	5 (mild 2; moderate 3)
▪ Pancreatitis	1 (moderate)
▪ Perforation ¹	1 (moderate)
Stent dysfunction, n (%)	2/29 (6.9%)
▪ Stent occlusion ²	1
▪ Asymptomatic migration ³	1

IQR, interquartile range.

¹ Pneumoperitoneum was diagnosed on computed tomography the day after the procedure in a patient with surgically altered anatomy who underwent double-balloon endoscope-assisted endoscopic retrograde pancreatography.

² Stent occlusion occurred due to biliary sludge.

³ A stricture was resolved in a patient with asymptomatic migration of an FCSEMS.

There were technical difficulties in the endoscopic management of HJASs until the emergence of balloon-assisted endoscopy allowed for an endoscopic approach to the hepaticojejunostomy anastomosis. Balloon dilation and plastic stent placement via DB-ERCP has been reported to be effective in retrospective studies; however, refractory HJAS was observed in about a quarter of patients owing to the limitation in the numbers and diameters of plastic stents deployed through a DBE [5, 7]. To date, a few articles have reported FCSEMS placement for HJAS with the help of balloon-assisted endoscopy [29–31]; however, in these reports, FCSEMSs were placed over the guidewire through the overtube left in situ while the endoscope itself was removed beforehand. In this study, FCSEMS place-

ment was possible even through the limited diameter of the DBE working channel, and through-the-scope removal of the FCSEMS was successful in almost all cases. As there was previously little evidence of FCSEMS treatment for bilioenteric anastomotic strictures in patients with surgically altered anatomy [32], we believe that the current study provides additional evidence for the endoscopic treatment of HJASs.

There are two concerns associated with placement of a covered metal stent at the biliary bifurcation. First, placement of an FCSEMS at the hilum may cause cholangitis in the contralateral bile duct. Second, bile duct kinking at the end of the FCSEMS can occur when the stricture is located in an angled bile duct. To minimize segmental cholangitis and kinking, we placed a “rescue” plastic stent in 19 patients and a “core” plastic stent in six patients. Among five episodes of cholangitis observed, only one patient developed biliary obstruction due to kinking at the end of the FCSEMS. This patient was the first post-LDLT case in this study and we did not place a core stent routinely at that time. After this experience, rescue and core stents were routinely utilized and neither segmental cholangitis nor kinking occurred.

Another strength of our study is the inclusion of refractory BBSs. FCSEMS placement of 3 months was able to achieve a high stricture resolution rate and a relatively low stricture recurrence rate, even for cases that were resistant to long-term conventional plastic stent placement. We assume that the indications for FCSEMSs could be expanded to the initial treatment of hilar BBSs, which would be expected to further shorten the treatment period and reduce stricture recurrence. In addition, the cost analysis of FCSEMSs for BBSs should be conducted both as first-line and rescue treatment to confirm the appropriate strategy for endoscopic management of BBSs.

The appropriate indwelling time of an FCSEMS in patients with hilar BBSs is still unclear. Previous studies have reported 6–12 months of FCSEMS placement in patients with distal BBS [8, 11–14]. To minimize the risk of stent occlusion due to sludge formation, as well as failed FCSEMS removal due to a fracture of the covering membrane, we adopted an indwelling period of 3 months in the current study. Given the high stricture resolution rate and low recurrence rate in our study cohort, an indwelling time of 3 months might be sufficient. As our observational period was not long enough to evaluate the long-term outcomes, further investigation on the appropriate indwelling time is required.

We acknowledge several limitations of this study. This was a single-arm study without a control group of other modalities, so there may be a treatment selection bias. We included various etiologies of BBS; however, the sample size was not large enough to investigate the effectiveness of FCSEMSs for each etiology. Furthermore, our follow-up period was relatively short to evaluate long-term outcomes. Nonetheless, this was the first prospective clinical trial evaluating FCSEMSs for post-LDLT strictures and HJASs, and provided new evidence for the endoscopic treatment of refractory BBSs. Given the inclusion of refractory cases, the rate of stricture resolution was relatively high.

In conclusion, temporary placement of FCSEMSs for refractory BBSs, especially for post-LDLT strictures and HJASs, was

safe and effective. A randomized controlled trial is warranted to further evaluate the efficacy of FCSEMSs in these subgroups. Furthermore, the application of FCSEMSs as an initial treatment modality for BBSs should be evaluated in the future.

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Competing interests

Hiroyuki Isayama has received a lecture fee from TaeWoong Medical.

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