Original Research

Endoscopic Ultrasound

OPEN

Prospective clinical trial of EUS–guided choledochoduodenostomy without fistula dilation for malignant distal biliary obstruction

Takehiko Koga[1,2], Susumu Hijioka[1,*], Yoshikuni Nagashio[1], Yuta Maruki[1], Kosuke Maehara[1], Yumi Murashima[1], Yuki Kawasaki[1], Kotaro Takeshita[1], Natsumi Yamada[1], Motohiro Yoshinari[1], Yuya Hisada[1], Shota Harai[1], Hidetoshi Kitamura[1], Shun Kawahara[1], Akihiro Ohba[1], Chigusa Morizane[1], Yusuke Ishida[2], Fumihito Hirai[2], Takuji Okusaka[1]

ABSTRACT

Background and Objectives: During EUS–guided choledochoduodenostomy (EUS-CDS), fistula dilation before stent insertion is associated with adverse events (AEs), such as bile leakage and peritonitis. We hypothesized that EUS-CDS without fistula dilation using a novel self-expandable metal stent (SEMS) with a thin delivery system could overcome this problem, and we conducted this study to evaluate its feasibility and safety.

Methods: This was an open-label, single-arm, phase II study at a single institution. We planned EUS-CDS without fistula dilation using a fully covered SEMS with a 5.9-Fr delivery system for unresectable malignant distal biliary obstruction. The primary outcome was overall technical success. Secondary outcomes were technical success without fistula dilation, procedure time, functional success, time to recurrent biliary obstruction, and AEs. The planned sample size was 25 patients.

Results: In total, 24 patients were included in this study. In 21 patients, EUS-CDS was performed as primary drainage. The overall technical success rate was 100% (24 of 24 patients). The technical success rate without fistula dilation was 96% (23 of 24). The median procedure time was 16 min (range, 10–66 min). The functional success rate was 96% (23 of 24). The median time to recurrent biliary obstruction was 148 days (95% confidence interval, 29–266 days). There were no procedure-related AEs. Furthermore, computed tomography immediately after the procedure showed no leakage of contrast medium into the abdominal cavity in any patient.

Conclusions: EUS–guided choledochoduodenostomy without fistula dilation using a fully covered SEMS with a 5.9-Fr delivery system is feasible with a high probability and can be achieved quickly while effectively preventing bile leakage and peritonitis.

Key words: EUS; EUS–guided biliary drainage (EUS-BD); EUS–guided choledochoduodenostomy (EUS-CDS); Endosonography; Cholangiography

INTRODUCTION

After the first report of EUS–guided biliary drainage (EUS-BD) by Giovanni et al.,[1] EUS-BD techniques and devices were developed one after another. EUS-guided choledochoduodenostomy (EUS-CDS) has been performed for malignant distal biliary obstruction, and previous prospective studies have reported high technical and clinical success rates.[2–9] Furthermore, EUS-CDS poses no risk of pancreatitis and has recently been used for primary drainage as well as ERCP in some high-volume centers.[2–6,9–11] However, rates of adverse events (AEs), including bile leakage and peritonitis, are high. Although covered self-expandable metal stents (SEMSs) have been conventionally used for EUS-CDS, the fistula dilation process before stent insertion is the main cause of these AEs.[12–14] To overcome this problem, we previously performed and reported EUS-CDS without fistula dilation using a novel covered SEMS with a thin delivery system.[15] The outcomes showed that there were no early AEs and significantly less contrast medium leakage into the abdominal cavity after the procedure compared with those after the conventional procedure with fistula dilation. In recent years, there have been several retrospective reports on the safety and efficacy of EUS-guided hepaticogastrostomy without fistula dilation.[16–20] However, only few studies have reported EUS-CDS without fistula dilation. Therefore, we conducted a prospective clinical trial to evaluate the feasibility and safety of EUS-CDS without fistula dilation using a novel SEMS (CYCLONE study). This is the first article to describe a prospective trial related to covered SEMSs with the thinnest 5.9-Fr delivery system currently available.

METHODS

Trial design

This was an open-label, single-arm, phase II study conducted at our institution. The trial protocol was approved by the Institutional Review Board (No. 2020-458). The trial was registered in the UMIN Clinical Trials Registry (UMIN 000042767) and was

[1] Department of Hepatobiliary and Pancreatic Oncology, National Cancer Center Hospital, 5-1-1 Tsukiji, Chuo-ku, Tokyo 104-0045, Japan; [2] Department of Gastroenterology and Medicine, Faculty of Medicine, Fukuoka University, 7-45-1 Nanakuma, Johnan-ku, Fukuoka, 814-0180, Japan.

* **Address for correspondence:** 5-1-1 Tsukiji, Chuo-ku, Tokyo 104-0045, Japan. E-mail: shijioka@ncc.go.jp (S. Hijioka).

Endoscopic Ultrasound (2023) 12:5

Received: 07 October 2022; Accepted: 12 April 2023

Published online: 28 September 2023

http://dx.doi.org/10.1097/eus.0000000000000009

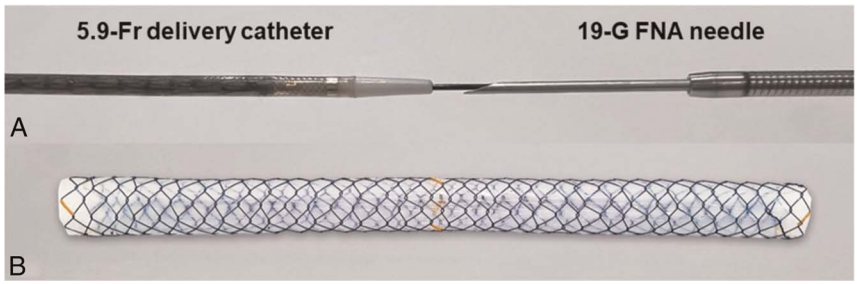

Figure 1. Fully covered self-expandable metal stent with a 5.9-Fr delivery system. A, The delivery catheter is size 5.9 Fr (left side). The tip is tapered and as thin as a 19-gauge needle for EUS-FNA (right side). B, The expanded stent has a nitinol-based braided, hook-cross wire structural design.

performed in accordance with the principles of the Declaration of Helsinki. Informed consent was obtained from all patients.

Selection criteria

The inclusion criteria were as follows: (i) unresectable malignant distal biliary obstruction (with or without a history of biliary drainage); (ii) anatomical indications for EUS-CDS, that is, no tumor invasion to the duodenal bulb, length from the biliary occlusion point to the hepatic hilum ≥2 cm as measured by preoperative computed tomography (CT), and no/mild (retention not exceeding the pelvic cavity) ascites; (iii) total bilirubin (TB) ≥1.5 mg/dL and/or aspartate transaminase/alanine aminotransferase ≥100 U/L; (iv) no parenchymal jaundice; (v) no bleeding tendency (platelets ≥50,000/μL, prothrombin time ≥50%); (vi) hemoglobin ≥8 g/dL; (vii) Eastern Cooperative Oncology Group performance statuses 0, 1, and 2; (viii) age ≥20 years; and (ix) agreement to participate in the study protocol. The exclusion criteria were as follows: (i) the physician judged the patient to be ineligible for enrollment in this study and (ii) severe cholangitis (in accordance with the Tokyo Guidelines 2018).[21]

The stent

The stent used for EUS-CDS was a fully covered SEMS with the thinnest diameter (5.9-Fr) delivery system currently available (HANAROSTENT Benefit, 6- and 8-mm diameter; 6-, 8-, 10-, and 12-cm length; M.I. Tech, Seoul, Korea; Figure 1). The tip of the delivery system is tapered and as thin as a 19-gauge needle for EUS–guided fine-needle aspiration (EUS-FNA). The stent had a structural design of a nitinol-based braided, hook-cross wire with a shortening rate of 30% to 40% after deployment. The stent wire and silicone cover were designed to be thin to fit within the thin delivery system, resulting in approximately 40% less radial force compared with the conventional HANAROSTENT with an 8.5-Fr delivery system.

EUS-CDS without fistula dilation

For patients undergoing antithrombotic treatment, decisions on drug withdrawal or replacement were made according to the guidelines of the Japan Gastroenterological Endoscopy Society.[22,23] In all cases, antibiotics were administered from the day of the procedure. The selection of echoendoscope (oblique- [OV] or forward-viewing [FV]) depended on the first EUS-CDS operator. The first operator was restricted to those who had an experience of at least 200 ERCP and 50 EUS-FNA procedures. An OV echoendoscope (GF-UCT240 and GF-UCT260 [Olympus Medical Systems, Tokyo, Japan], EG-740UT [Fujifilm, Tokyo, Japan]) or an FV echoendoscope (TGF-UC260J; Olympus Medical Systems) was used to perform EUS-CDS. First, the distal bile duct was visualized from the duodenal bulb using EUS, and the length of the puncture route and the diameter of the bile duct were measured under EUS guidance. Second, a 19-gauge needle for EUS-FNA (EZ shot 3 plus; Olympus Medical Systems) was used to puncture the distal bile duct. Subsequently, the bile was aspirated via the needle until the diameter of the bile duct was reduced to approximately half, and the hilum was verified using cholangiography. A 0.025-inch guidewire (M-Though; ASAHI INTECC Corp, Tokyo, Japan) was then placed in the left or right intrahepatic bile duct. The stent was directly inserted without prior fistula dilation and was deployed through the fistula [Figure 2]. Finally, the distal end of the stent was pushed by the scope and directed toward the anal side to prevent early stent dysfunction.[24] The procedures were performed based on interventional radiology features with CT scanner system room. Therefore, on-site CT was performed immediately after the procedure to confirm the position of the stent, presence of fluid collection, or leakage of contrast medium (ie, bile leakage) into the abdominal cavity [Figure 3].

Follow-up

Clinical symptoms, such as abdominal pain, jaundice, and fever, were evaluated on postoperative days 0, 1, 7, and 14. Blood counts and biochemical tests were performed on postoperative days 1 and 14. Abdominal CT was performed within 3 days of EUS-CDS. All patients were followed up for a minimum of 6 months or until death. In the case of death, the date of diagnosis was used as the censoring date.

Study outcomes

The primary outcome was overall technical success. Secondary outcomes were (i) technical success without fistula dilation, (ii) procedure time, (iii) functional success, (iv) time to recurrent biliary obstruction (TRBO), and (v) AEs.

Definitions

Overall technical success was defined as successful stent placement with or without fistula dilation. Technical success without fistula dilation was defined when the stent was inserted directly without any fistula dilation process and was successfully placed. The procedure time was measured from bile duct puncture to stent deployment and positioning. Functional success was defined as a 50% reduction or normalization (<1.5 mg/dL) of the TB level within 14 days. In patients with normal TB levels, both aspartate transaminase and alanine aminotransferase levels were reduced to <100 U/L within 14 days. Recurrent biliary obstruction (RBO) was defined as stent

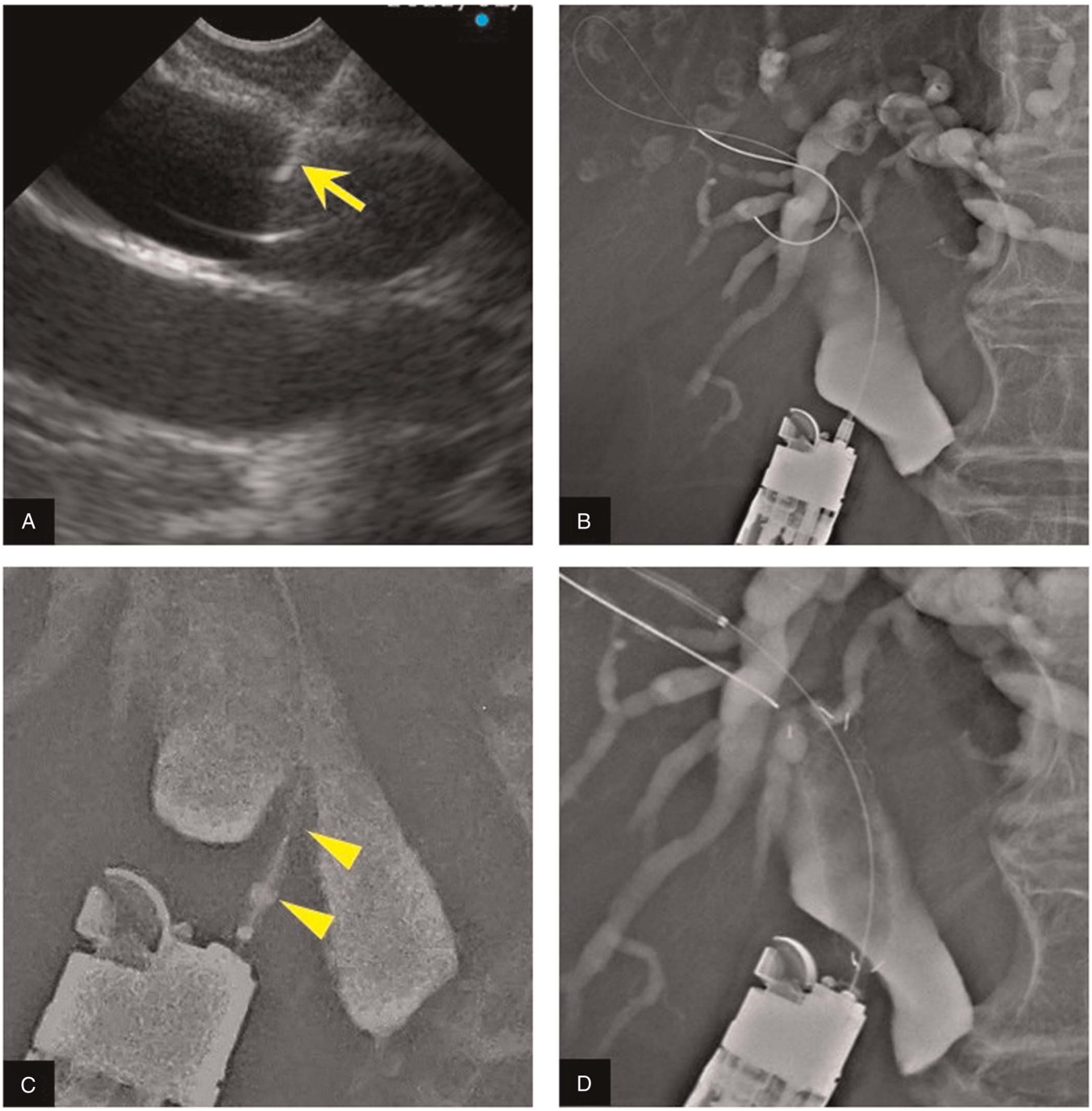

Figure 2. EUS–guided choledochoduodenostomy without fistula dilation. A, The bile duct was punctured by a 19-gauge needle (arrow). B, After cholangiography, a 0.025-inch guidewire was inserted. C, Right before the stent tip (arrowheads) penetrating the bile duct wall without fistula dilation. D, The stent was deployed.

occlusion or migration. Stent migration was diagnosed when a completely or partially migrated stent caused RBO.

Time to recurrent biliary obstruction was defined as the time between the initial stenting and occurrence of RBO. Adverse events were classified as procedure-related (AEs occurring during the procedure, that is, between endoscope insertion and its removal), early postprocedure (AEs occurring <30 days after the procedure), or late postprocedure (AEs occurring ≥31 days after the procedure). Procedure-related AE could include bile leakage, peritonitis, pneumoperitoneum, perforation, bleeding, pneumonia, and stent deviation. Early and late postprocedure AEs could include bile leakage, peritonitis, pneumoperitoneum, perforation, bleeding, pneumonia, abdominal pain, cholecystitis, cholangitis, liver abscess, pancreatitis, and duodenal ulcer. These were graded according to the American Society for Gastrointestinal Endoscopy guidelines.[25] Technical success of reintervention was defined as successful stent replacement via the existing fistula tract without alteration of the drainage route,

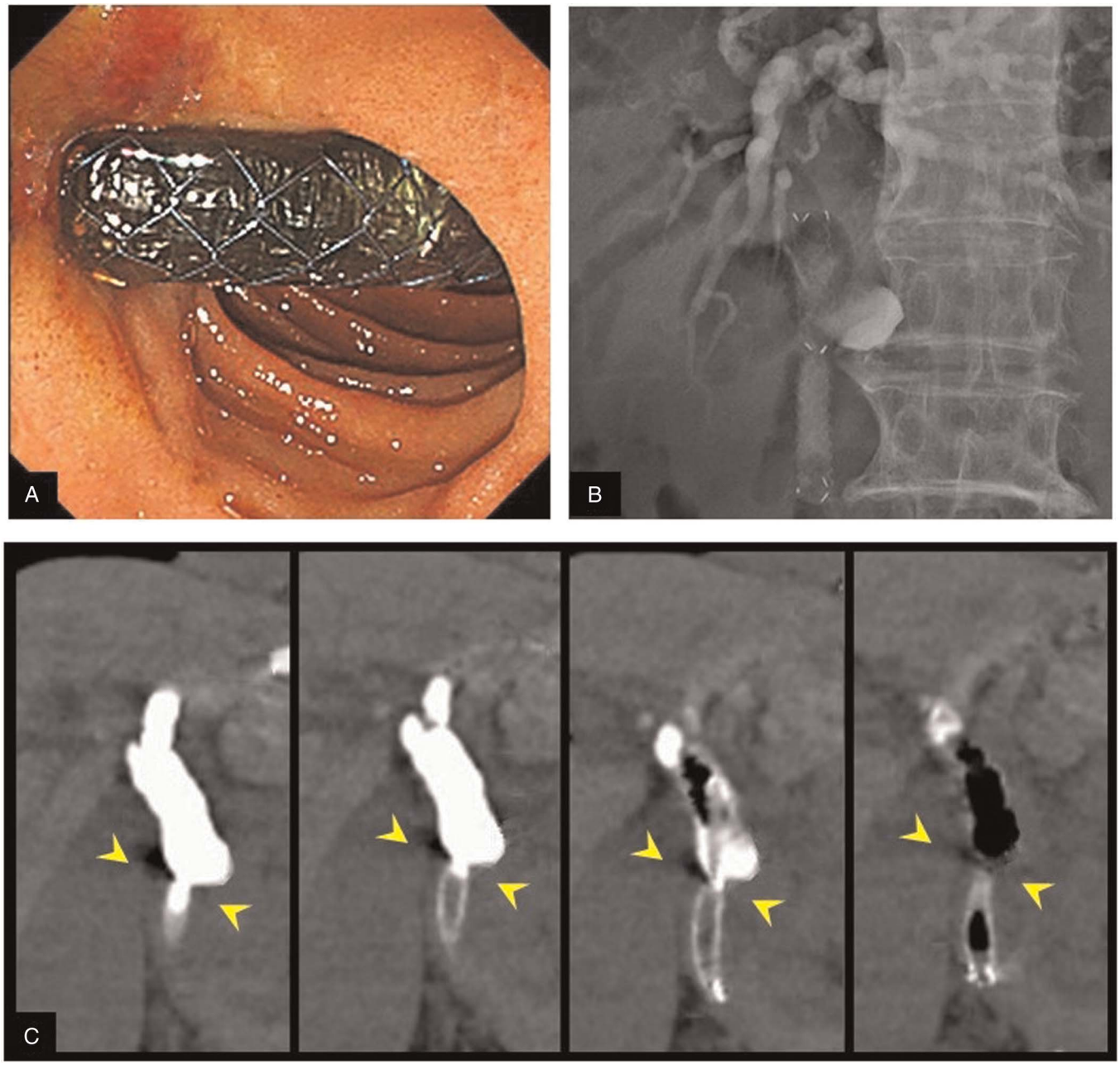

Figure 3. Imaging findings after the stent placement. A, Endoscopic image. B, Fluoroscopic image. C, On-site abdominal computed tomography immediately after the procedure (coronal image) showing no contrast medium leakage into the perifistula abdominal cavity (between arrowheads).

such as percutaneous transhepatic biliary drainage or EUS-guided hepaticogastrostomy, in RBO cases. During the procedure, the diameter of the bile duct and length of the puncture route were measured under EUS guidance and were defined as follows: the diameter of the bile duct was the length of the bile duct at the site of puncture, and the length of the puncture route was the length between the needle insertion point on EUS guidance and the bile duct wall.

Sample size calculation

Previously, there was only one single-arm study on EUS-CDS without fistula dilation, which had set the threshold for the overall technical success rate at 75%.[7] Therefore, our threshold was set at 75%. The technical success rate of EUS-CDS in previous prospective studies ranged from 83% to 97%.[2–9] Based on these results, the expected value was set at 95%. Our null hypothesis was that the overall technical success rate would be <75%. In the present trial, the planned sample size was 23 patients, which was calculated according to the expected technical success rate of 95%, threshold of 75%, 1-sided α error of 0.05, and power of 0.8. Considering 10% deviation cases, a target sample size of 25 was set. If the lower limit of the 90% confidence interval (CI) exceeded the 75% threshold (overall technical success in ≥23 of 25 patients), the trial procedure was considered promising.

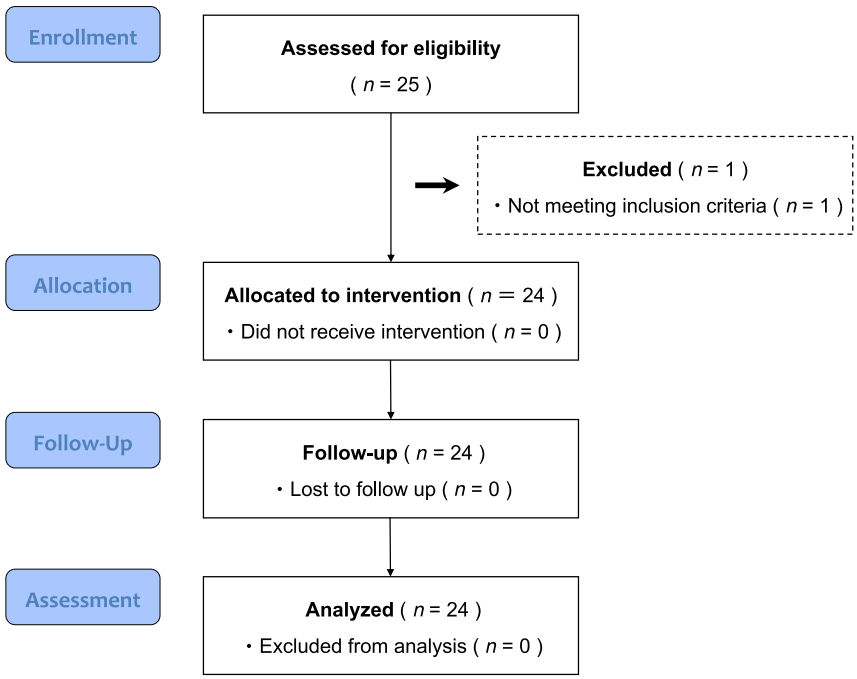

Figure 4. CONSORT flowchart for a single-arm, open-label, phase II clinical trial of EUS-guided choledochoduodenostomy without fistula dilation for malignant distal biliary obstruction.

Statistical analysis

Continuous variables are expressed as medians and ranges, whereas categorical variables are expressed as proportions. Continuous variables were analyzed using the Mann-Whitney *U* test. A *P* value of <0.05 was considered statistically significant. The TRBO and survival time were estimated using the Kaplan-Meier method with SPSS version 25.0 (IBM Corp, SPSS Inc, Armonk, New York).

RESULTS

Patient characteristics

A CONSORT flowchart is presented in Figure 4. Between February 2021 and January 2022, 25 patients were enrolled; after excluding 1 ineligible patient whose distal bile duct was unidentifiable by EUS because of massive duodenal invasion, 24 patients were eligible and underwent the trial procedure. The patient characteristics are presented in Table 1. The median age of the patients was 68 years (range, 42–87 years). The most common cause of the distal biliary obstruction was pancreatic carcinoma (n = 21 [88%]). In 21 patients, EUS-CDS was performed as primary drainage. Two patients developed mild cholangitis. One patient had previously received radiation therapy for pancreatic head carcinoma.

Procedural details

Procedural details are presented in Table 2. An FV echoendoscope was used in 9 patients (37.5%). Stents of 8-mm diameter and 6-cm length were used in all patients. EUS findings showed that the median diameter of the punctured bile duct was 13 mm (range, 3–27 mm) and that the length of the puncture route was 8 mm (range, 3–20 mm). The median length of the puncture route was significantly shorter in patients treated using the FV echoendoscope than in patients treated using the OV echoendoscope (6 *vs.* 12 mm, $P < 0.01$).

Outcomes

Table 3 presents the study outcomes. The overall technical success rate was 100% (24 of 24 patients). The rate of technical success without fistula dilation was 96% (23 of 24). The median procedure time was 16 min (range, 10–66 min). The functional success rate was 96% (23 of 24). During the follow-up period (median, 123 days; range, 19–373 days), RBO was observed in 10 (42%), distal migration in 8, and occlusion in 2 patients. The median onset date of the distal migration was 125 days (range, 50–270 days) after stent placement; none of the patients had bile leakage or peritonitis because their fistula tract formations were already completed. Two cases of occlusion occurred because of biliary stones and stent kinking. Endoscopic reintervention was performed in all RBO cases. For distal migration cases, a new stent was inserted via the fistula tract. For occlusion cases, the obstructed stent was removed, and a new stent was reinserted; the technical success rate of reintervention was 100% (10 of 10). The median TRBO was 148 days (95% CI, 29–266 days; Figure 5). Four patients incidentally showed asymptomatic stent migration during CT follow-up for their primary disease and did not require any treatment or reintervention.

There were no procedure-related AEs, including peritonitis or bile leakage. Computed tomography immediately after the procedure showed no leakage of contrast medium into the abdominal cavity in all patients. In addition, none of the patients experienced abdominal pain after the procedure. Early postprocedure AEs were observed in 5 patients: liver abscess in 2, cholecystitis in 1, nonocclusion cholangitis in 1, and duodenal ulcer in 1, all of which were stent-related AEs and improved with conservative management. In the patient who required fistula dilation (n = 1), an OV echoendoscope (GF-UCT240) was used. The diameter of the punctured bile duct was 9 mm, and the length of the puncture route was 13 mm. Consequently, technical success was achieved after fistula dilation using a 4-mm balloon

Table 1

Patient characteristics

***N* = 24**	
Age, y	68 (42–87)
Female, no. (%)	16 (67)
ECOG performance status, no. (%)	
0	17 (71)
1	7 (29)
Cause of distal biliary obstruction, no. (%)	
Pancreatic carcinoma	21 (88)
Pancreatic neuroendocrine neoplasm	2 (8)
Pancreatic metastasis of lung cancer	1 (4)
Indications for EUS-CDS, no. (%)	
Primary biliary drainage	21 (88)
ERC failure	2 (8)
Conversion from transpapillary stenting	1 (4)
Cholangitis, no. (%)	2 (8)
Treatment plan for primary tumor, no. (%)	
Chemotherapy	22 (92)
Best supportive care	2 (8)
Postradiation therapy for primary tumor, no. (%)	1 (4)
Abdominal CT findings, no. (%)	
Ascites	0 (0)
Duodenal invasion	4 (17)
Duodenal stent placement, no. (%)	1 (4)

Continuous variables are expressed as median (range).

CT: computed tomography; ECOG: Eastern Cooperative Oncology Group; ERC, endoscopic retrograde cholangiography; EUS-CDS: EUS–guided choledochoduodenostomy.

dilator (REN biliary balloon catheter; KANEKA Medical, Osaka, Japan). Eleven patients died owing to an underlying disease by the end of the study period. The median survival time after EUS-CDS procedure was 323 days (95% CI, 266–380 days).

DISCUSSION

This study achieved its primary outcome with an overall technical success rate of 100% (24 of 24). EUS–guided choledochoduodenostomy without fistula dilation was successful in 96% of cases (23 of 24), was performed in a short time, and was not associated with any procedure-related AEs.

In the past, plastic stents were used for EUS-CDS; however, recently, covered SEMS have commonly been used.[26] Covered SEMS may reduce postprocedure AEs, such as bile leakage, peritonitis, and pneumoperitoneum, because its radial force covers the fistula. However, a systematic review of EUS-CDS showed a high rate of procedure-related AEs of 12.2% (95% CI, 14.3%–23.0%) even with covered SEMS.[27] In EUS-CDS using a conventional covered SEMS with 8- to 9-Fr delivery system, the fistula dilation process before stent insertion may cause leakage of bile and digestive juice into the abdominal cavity. The fistula dilation–related AEs, such as bile leakage, peritonitis, and pneumoperitoneum, accounted for 49% of the early AEs of EUS-CDS in the systematic review by Iwashita et al.[13] and 40% of AEs of EUS-BD in the systematic review by Wang et al. [14] In addition, abdominal pain occurred in 4% and 7% of cases, respectively, which might have been undiagnosed cases with latent bile leakage. Similarly, in our retrospective study, a high probability (42%) of contrast medium leakage into the abdominal cavity on postoperative CT immediately after the EUS-CDS with fistula dilation was observed.[15] Consequently, fistula dilation–related AEs are the major problem of the EUS-CDS procedure. To address this, EUS-CDS without fistula dilation has been attempted using covered SEMSs with thin delivery systems, which have recently become available through advances in developmental technology. Three prospective studies of EUS-CDS without fistula dilation have been reported. Initially, Park et al.[28] performed EUS-BD without fistula dilation using a modified covered SEMS with a 7-Fr delivery system (DEUS). Although EUS-CDS was performed in a few cases (n = 7), none of them required fistula dilation. Subsequently, Paik et al.[5] reported the technical success rate of EUS-CDS in a larger study using a similar DEUS stent—overall/without fistula dilation: 91% (29 of 32)/69% (22 of 32). Itonaga et al.[7] reported the technical success rate of EUS-CDS using a novel laser-cut type covered SEMS with a 7.5-Fr delivery system (covered BileRush)—overall/without fistula dilation: 95% (19 of 20)/30% (6 of 20). In this study, we performed EUS-CDS using the thinnest 5.9-Fr delivery system currently available and achieved the most favorable technical success rate—overall/without fistula dilation: 100% (24 of 24)/96% (23 of 24). Furthermore, there were no cases of postprocedure abdominal pain or procedure-related AEs in the cohort. To our knowledge, this is the first prospective study of EUS-CDS in which all patients underwent on-site CT immediately after the procedure, with CT showing no contrast medium leakage, bile leakage, or pneumoperitoneum into the abdominal cavity in any patient.

Nevertheless, stent migration was observed in a cohort of 12 patients, including 4 patients with asymptomatic migration. The reason why the asymptomatic migrations did not cause RBO was assumed to be that the fistula tracts remained intact. The earliest date of migration was 50 days after the procedure, which was the time after fistula tract formation had completed. Therefore, no bile leakage or peritonitis was observed. In all 12 patients, migration occurred toward the distal side. Similarly, prior studies regarding EUS-CDS have reported that stent migration is directed toward the distal side.[9,29] In ex vivo experiments, the antimigration properties of SEMSs have been demonstrated. Minaga et al.[30] observed a strong correlation between the taper angle of the SEMS flare and its resistance force to migration. In addition, laser-cut SEMSs have been shown to exhibit higher resistance forces compared with those of braided-type SEMSs.[30–32] Clinical studies have reported that partially covered SEMSs did not migrate after EUS-CDS procedure.[33,34] The SEMS used in the present study facilitated EUS-CDS without fistula dilation; it was a braided type without a flared or uncovered structure at its end, rendering it susceptible to migration. These findings demand improved SEMS development.

Table 2

Procedural details

***N* = 24**	
Scope, no. (%)	
Oblique-viewing echoendoscope	15 (62.5)
Forward-viewing echoendoscope	9 (37.5)
Stent diameter/length, no. (%)	
8 mm/6 cm	24 (100)
EUS findings	
Diameter of the punctured bile duct, mm	13 (3–27)
Length of the puncture route, mm	8 (3–20)

Continuous variables are expressed as median (range).

We performed EUS-CDS with 2 types of echoendoscopes, OV and FV. Whether one type of echoendoscope is better for EUS-CDS without fistula dilation than the other remains controversial. The FV echoendoscope may have an advantage in terms of superior stent pushability. Furthermore, patients who underwent EUS-CDS with the FV echoendoscope in this study were characterized by a shorter length of the puncture route and were closer to the bile duct compared with those who underwent EUS-CDS with the OV echoendoscope. In fact, all EUS-CDS procedures performed with the FV echoendoscope were completed without fistula dilation, whereas 1 patient required fistula dilation during EUS-CDS performed with the OV echoendoscope. Conversely, in our retrospective study using the same SEMS as in the current study, 1 of 4 patients required fistula dilation during EUS-CDS performed with the FV echoendoscope.[15] To our knowledge, these are the only 2 cases in which EUS-CDS using the SEMS with a 5.9-Fr delivery system was performed and required fistula dilation. Further case experience is necessary to investigate the correlation between the type of echoendoscope and the need for fistula dilation.

A limitation of this study is that it was a single-arm study conducted at a single center: there was no control group. However, our promising outcomes should encourage the next logical step: a randomized, controlled trial of EUS-CDS without fistula dilation versus ERCP for the primary drainage of malignant distal biliary obstruction.

CONCLUSIONS

EUS–guided choledochoduodenostomy without fistula dilation is feasible with a high probability, resulting in not only the absence of any procedure-related AEs or abdominal pain but also the absence of any "leakage" into the abdominal cavity on imaging. A paradigm shift to EUS-CDS without fistula dilation as the primary drainage for malignant distal biliary obstruction is coming soon.

Table 3

Outcomes of the trial procedure

***N* = 24**	
Overall technical success, no. (%)	24 (100)
Technical success without fistula dilation, no. (%)	23 (96)
Procedure time, min (range)	16 (10–66)
Functional success, no. (%)	23 (96)
RBO, no. (%)	10 (42)
Distal migration	8 (33)
Complete migration	7 (29)
Partial migration	1 (4)
Occlusion	2 (8)
Technical success of reintervention (for RBO cases, $n = 10$), no. (%)	10 (100)
TRBO, median (95% CI), d	148 (29–266)
AEs, no. (%)	5 (21)
Procedure-related AEs	0 (0)
Postprocedure AEs	5 (21)
Early	5 (21)
Late	0 (0)
Abdominal pain after the procedure, no. (%)	0 (0)
Leakage of bile or contrast medium into the abdominal cavity on CT after the procedure, no. (%)	0 (0)
Asymptomatic stent migration	4 (17)

Continuous variables are expressed as median (range).

CI: confidence interval; CT: computed tomography; AE: adverse event; RBO: recurrent biliary obstruction; TRBO: time to recurrent biliary obstruction.

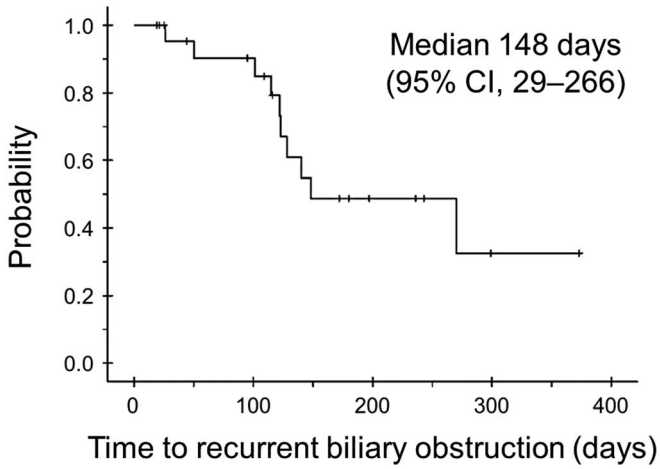

Figure 5. Kaplan-Meier curve for time to recurrent biliary obstruction.

Financial Support and Sponsorship

This research was supported in part by the National Cancer Center Research and Development Fund (2022-A-16).

Conflicts of Interest

The authors declare no conflicts of interest.

Registration Number and Its URL

UMIN 000042767 (https://center6.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000048815).

Acknowledgments

We are deeply grateful to all members of the NCC MIRAI project for their contributions to this study.

Author Contributions

All the authors contributed to the conception and design of study. Material preparation, data collection, and analyses were performed by all authors. All the authors commented on the previous versions of the manuscript. All the authors have read and approved the final manuscript.

References

1. Giovannini M, Moutardier V, Pesenti C, et al. Endoscopic ultrasound–guided bilioduodenal anastomosis: a new technique for biliary drainage. Endoscopy 2001;33:898–900.
2. Hara K, Yamao K, Niwa Y, et al. Prospective clinical study of EUS-guided choledochoduodenostomy for malignant lower biliary tract obstruction. Am J Gastroenterol 2011;106:1239–1245.
3. Hara K, Yamao K, Hijioka S, et al. Prospective clinical study of endoscopic ultrasound–guided choledochoduodenostomy with direct metallic stent placement using a forward-viewing echoendoscope. Endoscopy 2013;45:392–396.
4. Bang JY, Navaneethan U, Hasan M, et al. Stent placement by EUS or ERCP for primary biliary decompression in pancreatic cancer: a randomized trial (with videos). Gastrointest Endosc 2018;88:9–17.

5. Paik WH, Lee TH, Park DH, et al. EUS-guided biliary drainage versus ERCP for the primary palliation of malignant biliary obstruction: a multicenter randomized clinical trial. Am J Gastroenterol 2018;113:987–997.
6. Park JK, Woo YS, Noh DH, et al. Efficacy of EUS-guided and ERCP-guided biliary drainage for malignant biliary obstruction: prospective randomized controlled study. Gastrointest Endosc 2018;88:277–282.
7. Itonaga M, Kitano M, Hatamaru K, et al. Endoscopic ultrasound–guided choledochoduodenostomy using a thin stent delivery system in patients with unresectable malignant distal biliary obstruction: a prospective multicenter study. Dig Endosc 2019;31:291–298.
8. Minaga K, Ogura T, Shiomi H, et al. Comparison of the efficacy and safety of endoscopic ultrasound–guided choledochoduodenostomy and hepaticogastrostomy for malignant distal biliary obstruction: multicenter, randomized, clinical trial. Dig Endosc 2019;31:575–582.
9. Nakai Y, Isayama H, Kawakami H, et al. Prospective multicenter study of primary EUS-guided choledochoduodenostomy using a covered metal stent. Endosc Ultrasound 2019;8:111–117.
10. Kawakubo K, Kawakami H, Kuwatani M, et al. Endoscopic ultrasound–guided choledochoduodenostomy vs transpapillary stenting for distal biliary obstruction. Endoscopy 2016;48:164–169.
11. Kuraoka N, Hara K, Okuno N, et al. Outcomes of EUS-guided choledochoduodenostomy as primary drainage for distal biliary obstruction with covered self-expandable metallic stents. Endosc Int Open 2020;8:E861–e868.
12. Vila JJ, Pérez-Miranda M, Vazquez-Sequeiros E, et al. Initial experience with EUS-guided cholangiopancreatography for biliary and pancreatic duct drainage: a Spanish national survey. Gastrointest Endosc 2012;76:1133–1141.
13. Iwashita T, Doi S, Yasuda I. Endoscopic ultrasound–guided biliary drainage: a review. Clin J Gastroenterol 2014;7:94–102.
14. Wang K, Zhu J, Xing L, et al. Assessment of efficacy and safety of EUS-guided biliary drainage: a systematic review. Gastrointest Endosc 2016;83:1218–1227.
15. Koga T, Hijioka S, Nagashio Y, et al. Endoscopic ultrasound–guided choledochoduodenostomy without fistula dilation using a stent with a 5.9-Fr delivery system: comparison to a conventional procedure with fistula dilation. DEN Open 2022;2:e56.
16. Maehara K, Hijioka S, Nagashio Y, et al. Endoscopic ultrasound–guided hepaticogastrostomy or hepaticojejunostomy without dilation using a stent with a thinner delivery system. Endosc Int Open 2020;8:E1034–E1038.
17. Kuraoka N, Hashimoto S, Matsui S. Endoscopic ultrasound–guided hepaticogastrostomy using a new fully covered metallic stent without fistula dilatation. Dig Endosc 2020;32:e122–e123.
18. Ogura T, Kitano M, Okuda A, et al. Endoscopic ultrasonography–guided hepaticogastrostomy using a novel laser-cut type partially covered self-expandable metal stent (with video). Dig Endosc 2021;33:1188–1193.
19. Ogura T, Ueno S, Okuda A, et al. Technical feasibility and safety of one-step deployment of EUS-guided hepaticogastrostomy using an 8-mm diameter metal stent with a fine-gauge stent delivery system (with video). Endosc Ultrasound 2021;10:355–360.
20. Ohno A, Fujimori N, Kaku T, et al. Feasibility and efficacy of endoscopic ultrasound–guided hepaticogastrostomy without dilation: a propensity score matching analysis. Dig Dis Sci 2022;67:5676–5684.
21. Mayumi T, Okamoto K, Takada T, et al. Tokyo guidelines 2018: management bundles for acute cholangitis and cholecystitis. J Hepatobiliary Pancreat Sci 2018;25:96–100.
22. Fujimoto K, Fujishiro M, Kato M, et al. Guidelines for gastroenterological endoscopy in patients undergoing antithrombotic treatment. Dig Endosc 2014;26:1–14.
23. Kato M, Uedo N, Hokimoto S, et al. Guidelines for gastroenterological endoscopy in patients undergoing antithrombotic treatment: 2017 appendix on anticoagulants including direct oral anticoagulants. Dig Endosc 2018;30:433–440.
24. Matsumoto S, Hara K, Mizuno N, et al. Risk factor analysis for adverse events and stent dysfunction of endoscopic ultrasound–guided choledochoduodenostomy. Dig Endosc 2020;32:957–966.
25. Cotton PB, Eisen GM, Aabakken L, et al. A lexicon for endoscopic adverse events: report of an ASGE workshop. *Gastrointest Endosc* 2010;71:446–454.
26. Ogura T, Itoi T. Technical tips and recent development of endoscopic ultrasound-guided choledochoduodenostomy. Dig Endosc Open 2021;1:e8.
27. Amato A, Sinagra E, Celsa C, et al. Efficacy of lumen-apposing metal stents or self-expandable metal stents for endoscopic ultrasound–guided choledochoduodenostomy: a systematic review and meta-analysis. Endoscopy 2021;53:1037–1047.
28. Park DH, Lee TH, Paik WH, et al. Feasibility and safety of a novel dedicated device for one-step EUS-guided biliary drainage: a randomized trial. J Gastroenterol Hepatol 2015;30:1461–1466.
29. Song TJ, Hyun YS, Lee SS, et al. Endoscopic ultrasound–guided choledochoduodenostomies with fully covered self-expandable metallic stents. World J Gastroenterol 2012;18:4435–4440.
30. Minaga K, Kitano M, Imai H, et al. Evaluation of anti-migration properties of biliary covered self-expandable metal stents. World J Gastroenterol 2016;22:6917–6924.
31. Minaga K, Kitano M, Gon C, et al. Endoscopic ultrasonography–guided choledochoduodenostomy using a newly designed laser-cut metal stent: feasibility study in a porcine model. Dig Endosc 2017;29:211–217.
32. Yamashita Y, Itonaga M, Gon C, et al. Usefulness of a newly designed laser-cut metal stent with an anchoring hook and thin delivery system for EUS-guided hepaticogastrostomy in experimental settings (with video). Gastrointest Endosc 2021;94:999–1008.e1.
33. Artifon EL, Marson FP, Gaidhane M, et al. Hepaticogastrostomy or choledochoduodenostomy for distal malignant biliary obstruction after failed ERCP: is there any difference? Gastrointest Endosc 2015;81:950–959.
34. Rai P, Lokesh CR, Goel A, et al. Endoscopic ultrasound–guided choledochoduodenostomy using partially-covered self-expandable metal stent in patients with malignant distal biliary obstruction and unsuccessful ERCP. Endosc Int Open 2018;6:E67–E72.