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The primary aim of *World Journal of Gastrointestinal Oncology* (*WJGO*, *World J Gastrointest Oncol*) is to provide scholars and readers from various fields of gastrointestinal oncology with a platform to publish high-quality basic and clinical research articles and communicate their research findings online.

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Observational Study

Percutaneous insertion of a novel dedicated metal stent to treat malignant hilar biliary obstruction

Francesco Cortese, Fabrizio Acquafredda, Andrea Mardighian, Maria Teresa Zurlo, Valentina Ferraro, Riccardo Memeo, Stavros Spiliopoulos, Riccardo Inchingolo

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Abstract

BACKGROUND

Percutaneous bilateral biliary stenting is an established method for the management of unresectable malignant hilar biliary obstruction.

AIM

To evaluate the efficacy and safety of a novel uncovered biliary stent, specifically designed for hilar reconstruction.

METHODS

This, single-center, retrospective study included 18 patients (mean age 71 ± 11 years; 61.1% male) undergoing percutaneous transhepatic Moving cell stent (MCS) placement for hilar reconstruction using the stent-in-stent technique for malignant biliary strictures, between November 2020 and July 2021. The Patients were diagnosed with cholangiocarcinoma (12/18; 66.6%), gallbladder cancer (5/18; 27.7%), and colorectal liver metastasis (1/18; 5.5%). Primary endpoints were technical (appropriate stent placement) and clinical (relief from jaundice) success. Secondary endpoints included stent patency, overall survival, complication rates and stent-related complications.

RESULTS

The technical and clinical success rates were 100% (18/18 cases). According to Kaplan-Meier analysis, the estimated overall patient survival was 80.5% and 60.4% at 6 and 12 mo respectively, while stent patency was 90.9% and 68.2% at 6

mo and 12 mo respectively. The mean stent patency was 172.53 ± 56.20 d and median stent patency was 165 d (range 83-315). Laboratory tests for cholestasis significantly improved after procedure: mean total bilirubin decreased from 15.2 ± 6.0 mg/dL to 1.3 ± 0.4 mg/dL ($P < 0.001$); mean γ GT decreased from 1389 ± 832 U/L to 114.6 ± 53.5 U/L ($P < 0.001$). One periprocedural complication was reported. Stent-related complications were observed in 5 patients (27.7%), including 1 occlusion (5.5%) and 1 stent migration (5.5%).

CONCLUSION

Percutaneous hilar bifurcation biliary stenting with the MCS resulted in excellent clinical and technical success rates, with acceptable complication rates. Further studies are needed to confirm these initial positive results.

Key Words: Malignant hilar biliary obstructions; Hilar cholangiocarcinoma; Self-expandable metallic stent; Stent-in-stent technique; Percutaneous approach; Bilateral Y-stenting

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Core Tip: This single-center, retrospective study investigated eighteen patients with unresectable malignant hilar biliary obstructions treated with a novel uncovered biliary metallic stent [Moving Cell Stent (MCS); BCM Co., Ltd., Gyeonggi-do, South Korea], specifically designed for hilar reconstruction, using stent-in-stent technique *via* percutaneous approach. Primary endpoints were clinical and technical success. The study results indicate that percutaneous MCS placement using stent-in-stent technique is feasible and safe. Comparison with other stents demonstrated superiority in both stent patency and technical success.

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INTRODUCTION

Malignant hilar biliary obstructions (MHBO) are very difficult to treat because most patients are diagnosed at an unresectable stage[1]. Hilar Cholangiocarcinoma (HiCC) is the most frequent cause of MHBO. Other malignant strictures may be due to pancreatic, gallbladder and liver tumors, to metastatic hilar lesions or to lymphadenopathies[2]. The primary principle behind the criteria for unresectability is the requirement for biliary and vascular reconstruction options with adequate future remnant hepatic parenchyma, as well as the presence of distant metastases or comorbidity of the patient[3,4]. Since only 10% to 20% of patients are suitable for resection, most of them receive palliative treatment[5]. The main aim of palliation is to re-create a connection between the biliary system and bowel to allow physiological drainage, in order to reduce pain, relieve biliary obstruction, significantly decreasing the incidence of cholangitis and allowing the administration of chemotherapy[6].

Due to the complexity of MHBO management, an organized multidisciplinary approach is paramount to deliver best quality care[7]. The main palliative treatments are biliary drainage and biliary stent implantation which can be performed with percutaneous or endoscopic approach, but there is no clear evidences of the superiority of one over the other. According to currently available data and the ESMO guidelines, percutaneous is the recommended approach in cases in which the endoscopic methods are not possible, commonly noted in advanced hilar Bismuth IV obstructions[8-10]. Moreover, percutaneous approach enables precise lobar selection for drainage[6].

With regard to bilateral *vs* unilateral drainage/stenting in cases of advanced HiCC, the goal is to drain at least 50% of the liver volume, which usually requires more than one stent when bile ducts are dissociated[8]. A self-expandable metallic stent (SEMS) rather than a plastic one is preferred in patients with unresectable cancer and a life expectancy longer than 3 mo[9].

Bilateral stent implantation can be achieved using side-by-side (SBS) or stent-in-stent (SIS) technique, but there is no large consensus concerning which procedure is better[11,12]. Some studies have shown that SIS technique may offer a lower adverse events rate[13] and longer stent patency[12]. On the other hand, some authors have found no significant differences in clinical outcomes between SIS and SBS techniques[14,15]. However, SIS procedure is technically more difficult and complex due to the necessity of introducing the second SEMS through the mesh of the previously placed SEMS[16-18]. To

overcome this issue, a novel uncovered SEMS, the HILZO Moving Cell Stent (MCS) (BCM Co., Gyeonggi-do, South Korea) was created.

The purpose of the present study was to evaluate the efficacy and safety of a novel uncovered biliary stent, specifically designed for hilar reconstruction, in patients with MBHO.

MATERIALS AND METHODS

Patients

This, single-center, retrospective study was conducted at “F.Miulli” Hospital in the Interventional Radiology Unit. A total of 18 patients (mean age 71 ± 11 years; 61.1% male) with MHBO undergoing percutaneous MCS (BCM Co., Ltd., Gyeonggi-do, South Korea) placement using SIS technique were enrolled within a 12-mo period (November 2020 and November 2021). The study was approved by the ethics committee of M Hospital and the patients provided written informed consent prior to enrolment. The study protocol conformed to the ethical guidelines of the 2013 Declaration of Helsinki (most recent version).

The diagnosis of MHBO was based on standard clinical and radiological criteria [following computed tomography (CT) and/or magnetic resonance imaging (MRI)], and was confirmed by percutaneous needle biopsy or percutaneous endobiliary forceps biopsy[19]. All patients were evaluated by a multidisciplinary team including oncologists, surgeons, gastroenterologists, radiotherapists, and interventional radiologists. Inclusion criteria were: MHBO caused by a biopsy-confirmed hilar malignancy, not suitable for surgery (due to unresectability, metastatic disease or severe comorbidities) and an estimated survival of over 3 mo. Exclusion criteria were patients with uncorrectable coagulopathy (INR >1.8; Platelets < 50,000) and presence of an atrophic lobe.

In the patient group, the causes of hilar obstruction included cholangiocarcinoma (12/18; 66, 6%), gallbladder cancer (5/18; 27, 7%), and colorectal liver metastasis (1/18; 5, 5%). Patients’ baseline demographical data are outlined in [Table 1](#).

Stent features

The Hilzo Biliary MCS (BCM Co., Ltd., Gyeonggi-do, South Korea) ([Figure 1](#)) is a novel uncovered metallic stent with a small cell size (4 mm) and a high radial force, dedicated for biliary SIS technique. The small cell size is expected to reduce ingrowth, and the high radial force results in higher expansion potential. The special design of this novel stent allows each cell to expand from 4 mm to 10 mm to enable a passage of the second stent through the stent struts. The MCS has radiopaque markers at each end, and two in the midsection and requires an 8Fr percutaneous access[20].

Procedure

This was a two-stage procedure. The first stage was percutaneous transhepatic biliary drainage (PTBD) and the second stage was MCS placement. All procedures were performed in the angiography suite, according to the CIRSE Standards of Practice on Percutaneous Transhepatic Cholangiography, Biliary Drainage and Stenting[21] using local anesthesia (2% Lidocaine), and conscious sedation (Fentanyl and Midazolam). A single-dose of iv antibiotic prophylaxis (Cefprozil 1g) was administered before each procedure.

Under ultrasound guidance (Philips CX50) combined with fluoroscopy (Philips Allura FD20 Clarity), both right and left intrahepatic bile ducts were punctured with 21-gauge Chiba needles (Cook, Bloomington, IN, United States) and two 8.5-Fr drainage catheters (Cook Medical, Bloomington, IN, United States) were inserted ([Figure 2A](#)).

In 11 cases in which histological diagnosis was not already available, a percutaneous transluminal biopsy[19] was performed using a dedicated, transluminal biliary access and biopsy forceps set (Cook Medical, Bloomington, IN, United States) during the same PTBD session.

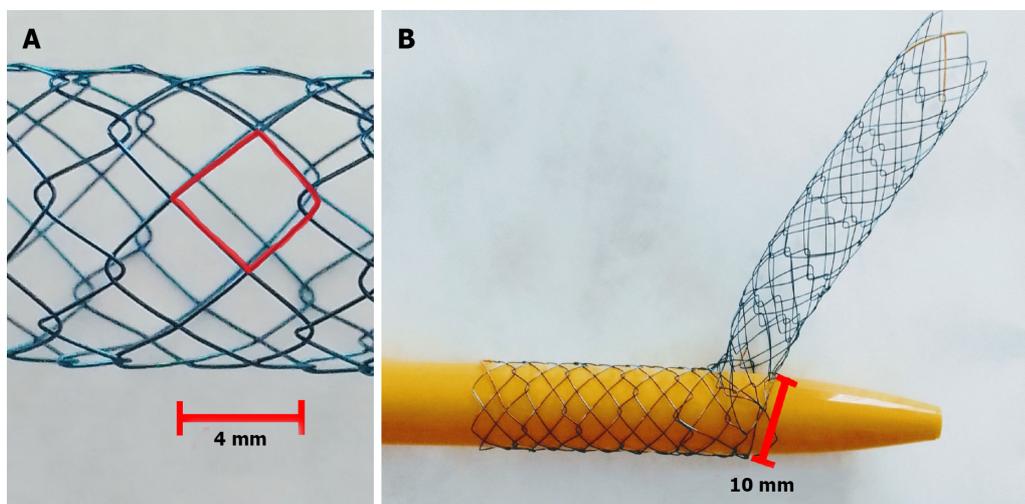
After approximately 7 to 21 d, and following improvement of obstructive jaundice symptoms, biliary stents placement was performed. Under fluoroscopic guidance, two hydrophilic guidewires (0.035 in.; Terumo Corporation, Tokyo, Japan) were introduced *via* the previously placed drainage catheters that were removed and two bilateral 8-Fr sheaths were placed within the biliary ducts over the hydrophilic guidewires.

Following cholangiography for the evaluation of the position and length of the biliary obstruction, the hydrophilic guidewire on one side was changed with an Amplatz Super Stiff™ 0.035 in. guidewire (Boston Scientific Corporation, Boston, MA, United States) using a 5-fr catheter KMP Beacon Tip (Cook Medical, Bloomington, IN, United States), and the corresponding type of MCS (10 or 8 mm × 10 or 8 or 6 cm) was implanted over the guidewire and dilated with a standard balloon catheter (Armada 35 PTA Catheter, Abbott Vascular, Santa Clara, CA, United States).

Analogously, on the other side, the hydrophilic guidewire was inserted through a mesh of the first MCS and exchanged ([Figure 2B](#)) with the stiff guidewire. Subsequently the second MCS (10 or 8 mm × 10 or 8 or 6 cm) was implanted and dilated. At this time, from the upper part of the first stent, the mesh of the contralateral MCS was engaged with the wire and, over the two stiff guidewires, two balloon

Table 1 Patient's baseline characteristics

Characteristics	Value
Total number of patients, <i>n</i>	18
Median age, yr	71
Range age, yr	37-84
Male sex, <i>n</i> (%)	11 (61.1)
Etiology, <i>n</i> (%)	
Cholangiocarcinoma	12 (66.6)
Gallbladder carcinoma	5 (27.7)
Colorectal liver metastases	1 (5.5)
Chemotherapy	17 (94.4)



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Figure 1 The Hilzo Biliary Moving Cell Stent. A: The Hilzo Biliary Moving Cell Stent developed with small cell size (4 mm), with radiopaque markers at each end and two X-shape markers in the midsection; B: Each cell can expand from 4 mm to 10 mm to allows easier passage of the second stent through the cell.

catheters were placed inside the MCSs and a kissing balloon dilatation was performed (Figure 2C).

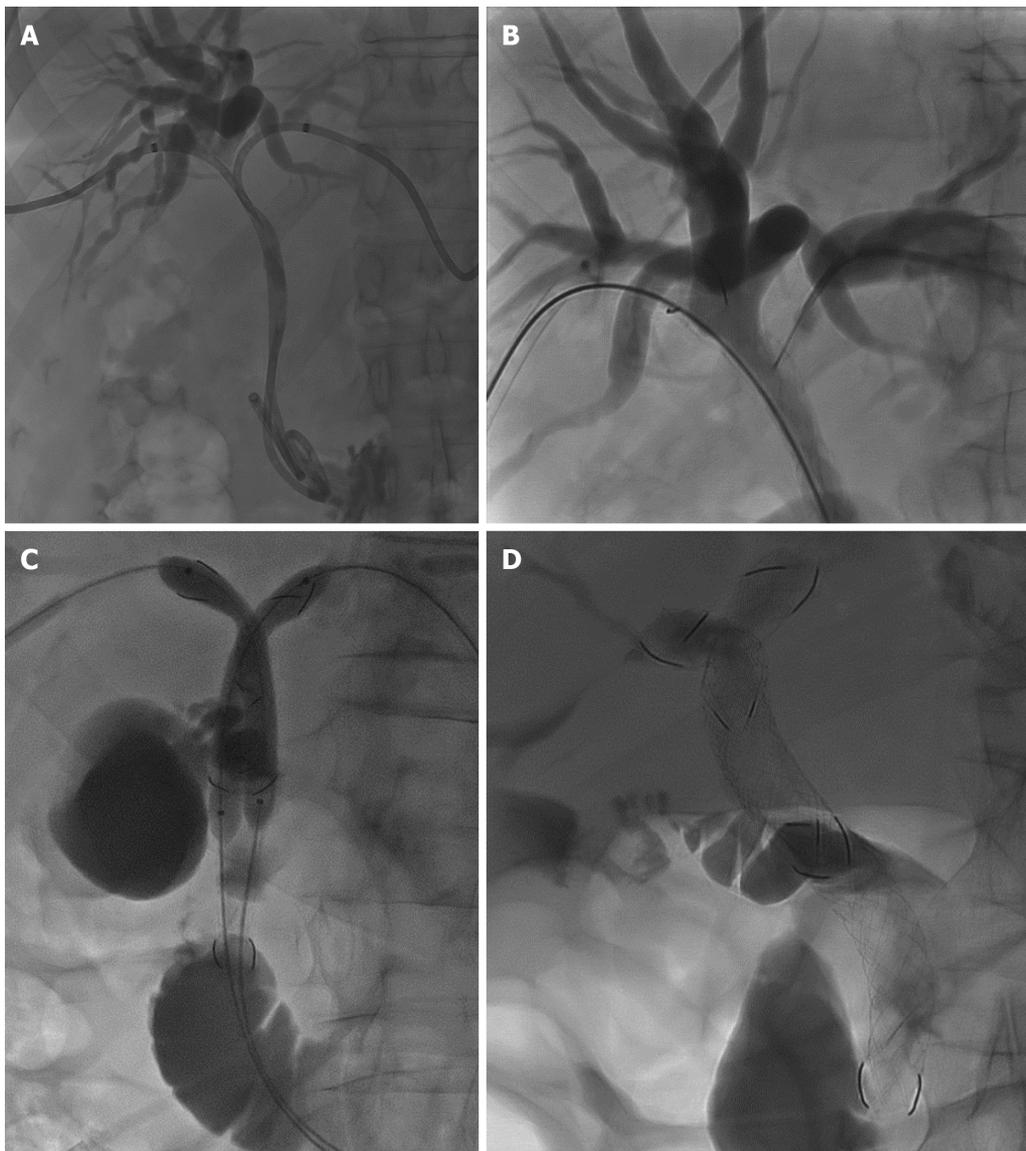
A final contrast check was performed to depict appropriate stent placement according to the SIS technique, thus the apex of the longest stent should be positioned within the duodenum, while the apex of the shorter stent should end within the first MCS (Figure 2D).

Pre-scheduled follow up protocol was set at 3 and 6 mo and every 6 mo thereafter and included clinical evaluation, laboratory tests and restaging CT (Figure 3).

Definitions and statistical analysis

The study's primary endpoints were technical and clinical success. Technical success was defined as appropriate placement of a bilateral MCS using the SIS technique (as described above). Clinical success was defined as a reduction of bilirubin values to normal (< 1.3 mg/dL) or to < 50% of the pre-PTDB value within 14 d. Secondary endpoints included stent patency, overall survival, peri-procedural adverse events, procedural duration and stent-related complications. Stent patency was defined as the time between stent placement and stent dysfunction, determined by the relapse of cholestasis and/or cholangitis according to clinical, laboratory and imaging findings. Stent patency and patient survival were estimated by the Kaplan-Meier method. Adverse events were graded according to the CIRSE Classification System for Complications[22]. Procedural duration was considered as the amount of elapsed time between local anaesthesia and removal of the sheaths.

mean \pm SD were used to describe continuous variables, while counts and percentages were used for categorical variables. The statistical analysis was conducted using the SPSS statistical software (version 17.0; SPSS Inc., Chicago, IL, United States) and a *P* value of < 0.05 was considered significant.



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Figure 2 Percutaneous transhepatic cholangiography. A: Percutaneous transhepatic cholangiography (PTC) showing hilar biliary obstructions with two bilateral 8.5-Fr drainage catheters; B: A hydrophilic guidewire (0.035 in.; Terumo Corporation, Tokyo, Japan) was inserted through a mesh of the Moving Cell Stent (MCS); C: PTC showing a kissing balloon dilatation over the stiff guidewires inside MCS placed using sten-in-stent technique; D: PTC showing the appropriate stents placement with the apex of the longest stent lies in the duodenum, while the apex of the shorter stent ends inside the first.

RESULTS

The clinical outcomes of bilateral MCS placement using the SIS technique are summarized in [Table 2](#). Technical success and clinical success were 100% (18 out of 18 patients). The median procedural duration was 81.5 min \pm 32.2 min. A single (5.5%) periprocedural adverse event occurred: Hemobilia due to porto-biliary fistula, treated during the same procedure with absorbable gelatin sponge (Spongostan) injection within the affected portal branch. This complication occurred during bile duct PTBD, and not during stent placement, and was judged as grade 1 according to the CIRSE Classification System for Complications[22].

The mean follow-up time was 169 d (range 83-315 d). Stent-related complications occurred in five (27.7%) patients ([Table 3](#)). Three (16.5%) patients who developed cholangitis without stent obstruction were treated with antibiotic therapy. Two patients (11%) presented with jaundice. For the first patient, the symptoms appeared 85 d after stent placement and the jaundice was caused by stent migration (5.5%) into common bile duct, treated with an additional MCS implantation. For the second patient, the jaundice appeared 151 d after stent placement and was caused by neoplastic ingrowth (5.5%). Due to the progression disease and the poor performance status of patients, it was decided to perform PTBD instead of an additional MCS placement. During the follow-up period, 4 patients (22.2%) died due to liver failure and/or progression disease.

Table 2 Clinical outcomes

Endpoint	Value
Technical success, <i>n</i> (%)	18 (100)
Clinical success, <i>n</i> (%)	18 (100)
Periprocedural complications, <i>n</i> (%)	1 (5.5)
Stent-related complications, <i>n</i> (%)	5 (27.7)
Stent occlusion, <i>n</i> (%)	1 (5.5)
Stent migration, <i>n</i> (%)	1 (5.5)
Mean procedural duration min	81.5 ± 32.2
Median stent patency days (range)	169 (93-315)
Overall mortality, <i>n</i> (%)	4 (22.2)

Table 3 Patients with stent-related complications

Age/sex	Etiology	Clinical manifestations	US findings	PTC findings	Treatment
75/F	GC	Jaundice	Left intrahepatic biliary dilatation	Stent migration	Additional MCS using SIS technique
77/M	CC	Jaundice	Bilateral intrahepatic biliary dilatation	Stent occlusion	PTBD
68/F	CC	Cholangitis	Aerobilia and no biliary dilatation	Not performed	Antibiotic therapy
81/M	CC	Cholangitis	Aerobilia and no biliary dilatation	Not performed	Antibiotic therapy
75/F	CC	Cholangitis	Aerobilia and no biliary dilatation	Not performed	Antibiotic therapy

GC: Gallbladder carcinoma; CC: Cholangiocarcinoma; US: Ultrasound; PTC: Percutaneous transhepatic cholangiography; MCS: Moving Cell Stent; PTBD: Percutaneous transhepatic biliary drainage; SIS: Stent-in-stent.

According to the Kaplan-Meier analysis, the estimated overall patient survival rate was 80.5% and 60.4% at 6 mo and 12 mo respectively, while stent patency was 90.9% and 68.2% at 6 and 12 mo respectively (Figure 4). The mean stent patency was 172.5 ± 56.2 d and median stent patency was 165 d (range 83-315). Laboratory tests for cholestasis significantly improved after procedure: mean total bilirubin decreased from 15.2 ± 6.0 mg/dL to 1.3 ± 0.4 mg/dL ($P < 0.001$); mean γ GT decreased from 1389 ± 832 U/L to 114.6 ± 53.5 U/L ($P < 0.001$) (Table 4).

DISCUSSION

MHBO are often unresectable at presentation, thus palliative biliary decompression play a crucial role in improving the patients' quality of life[6].

Although outcomes of endoscopic US-guided biliary drainage techniques for hilar obstructions are very satisfactory[23-25], bilobar drainage with Y-configured SEMS using percutaneous approach is a well-established method for the palliative management of unresectable advanced MHBO in patients with estimated lifetime of more than 3 mo[9,10].

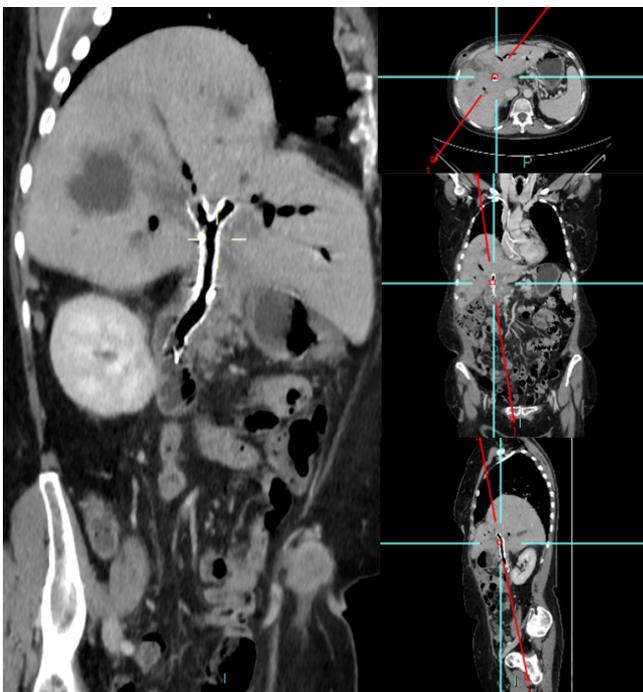
Bilateral SEMS placement can be achieved with SBS or SIS techniques (Figure 5). The SBS technique, considered technically easier[12], consists of the implantation of two parallel and close SEMS at and below the hepatic confluence, draining both hepatic lobes. Theoretically, the SBS technique has its inherent problems. The two SEMS cannot be fully expanded with major probability of partial collapse. Furthermore, the strong radial force caused by the parallel stent placement might be too strong to cause portal vein compression, bile duct rupture, or tumor ingrowth/tissue hyperplasia through the stent mesh[26,27].

On the other hand, in the SIS technique, after placing the first SEMS across the hilar stricture, a second SEMS is inserted into the contralateral hepatic duct through the mesh of first SEMS. Thereby, the single radial forces of both stents are added together opposing the biliary stricture, with a lower

Table 4 Laboratory tests

	PRE-PTBD	PRE-stent	POST-stent	P value
Total bilirubin (mg/dL)	15.2 ± 6.0	4.04 ± 1.50	1.31 ± 0.40	< di 0.001
Direct bilirubin (mg/dL)	13.5 ± 5.5	3.32 ± 1.30	0.86 ± 0.30	< di 0.001
γGT (U/L)	1389.2 ± 832.2	393.6 ± 321.7	114.6 ± 53.5	< di 0.001
Alkaline phosphatase (mU/mL)	321.7 ± 250.0	200.3 ± 179.4	115.7 ± 117.8	0.037
AST (UI/L)	243.9 ± 136.4	93.5 ± 47.6	50.6 ± 21.8	< di 0.001
ALT (UI/L)	319.3 ± 242.7	104.3 ± 53.3	71.7 ± 40.7	< di 0.001
WBC (10 ³ /μL)	10.2 ± 3.1	9.82 ± 4.00	7.16 ± 1.70	< di 0.001
PCR (mg/dL)	3.1 ± 1.5	3.9 ± 6.5	1.2 ± 1.2	< di 0.002

PTBD: Percutaneous transhepatic biliary drainage; ALT: Alanine aminotransferase; WBC: White blood cell; PCR: Polymerase chain reaction.



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Figure 3 Three-months follow-up contrast-enhanced computed tomography. Sagittal oblique MPR showing two Y-shape Moving Cell Stent placed at the hilar bifurcation biliary with no intrahepatic biliary dilatation.

probability of stent migration or collapse; so the entire length of stricture is expanded by a single stent caliber[26]. Moreover, the SIS technique provides a more physiological Y-conformation stent to bile outflow, but it is still technically challenging[27].

The Hilzo Biliary MCS was designed specially for the SIS technique. According to the literature, there are only two previously published studies both investigating endoscopic bilateral Y-stenting using the MCS[17,18], therefore this is the first study investigating percutaneous placement of MCS.

The herein presented results are in accordance with those of Ogura *et al*[17] and Kawai *et al*[18]. Specifically, similar technical success (100.0% vs 95.6%[17] vs 100.0%[18]), clinical success (100.0% vs 95.6%[17] vs 89.9%[18]), periprocedural complications (5.5% vs 4.4%[17] vs 7.4%[18]) and 6-months stent patency rate (90.9% vs approx. 85.0% vs approx. 75.0%) were noted. However, dissimilar stent occlusion rates were noted [1/18 (5.5%) vs 4/23 (17.0%)[17] vs 12/27 (44.4%)[18]]. The authors speculate that this discrepancy could be attributed to the only substantial technical difference: routine balloon post-dilatation was performed in all procedures in this study, whereas post-dilatation was not performed in the two previously published studies. This could have contributed in the increased procedural duration noted in this study (81.5 ± 32.0 min vs 36.6 min, range 18-62[16] vs 23.7 ± 8.1 min[17]), but interestingly did not result in an increase of periprocedural complications.

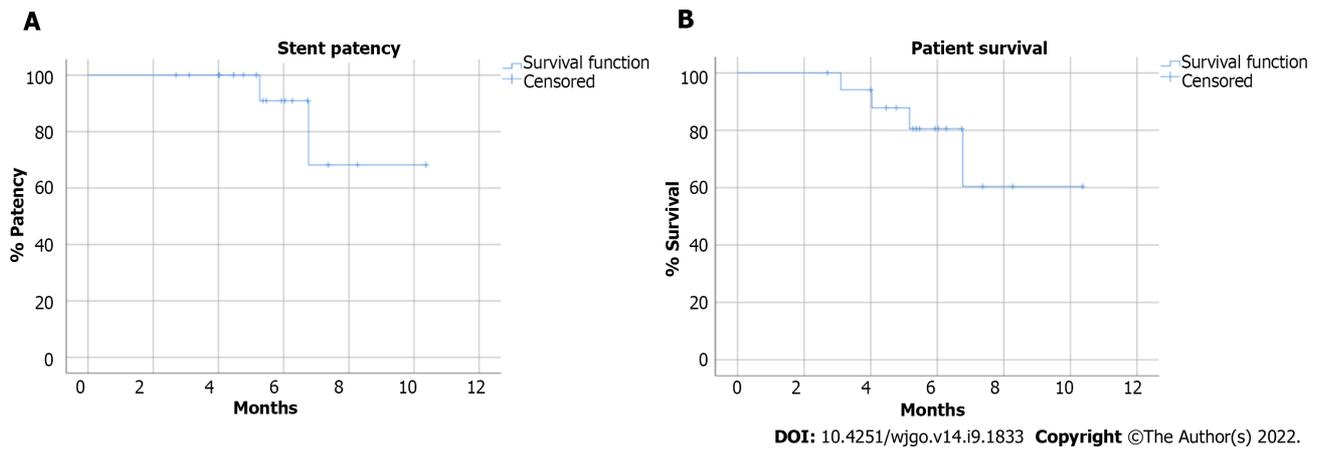


Figure 4 Kaplan-Meier analysis. A: The estimated stent patency; B: Overall patient survival.

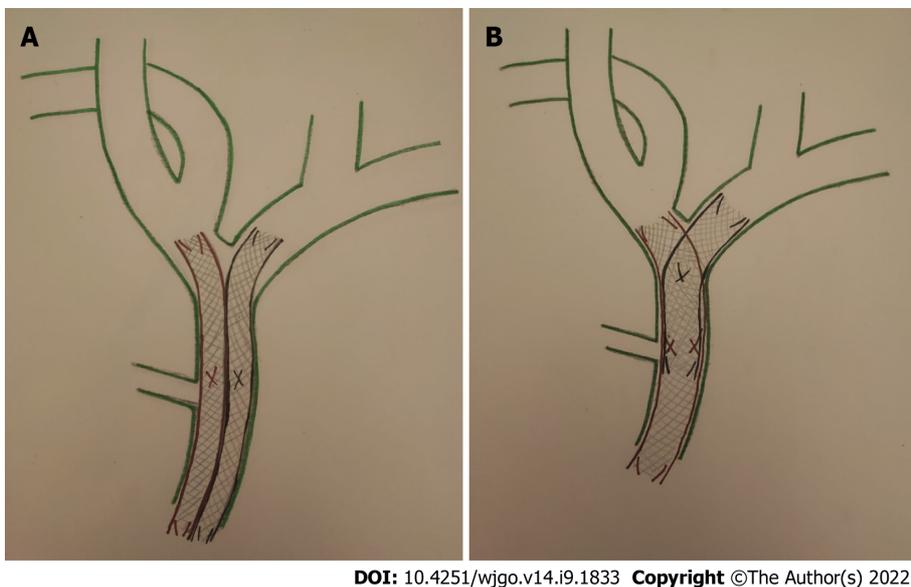


Figure 5 Bilateral self-expandable metallic stent placement can be achieved with side-by-side or stent-in-stent techniques. A: Stent-by-stent technique: Two parallel and close self-expandable metallic stent (SEMS) at and below the hepatic confluence to drain the bile duct of both hepatic lobes; B: Stent-in-stent technique: Bilateral SEMS placed in a Y-configuration, in which a second stent across through the mesh of the first stent.

Generally, SEMS can be classified as small closed-cell, large open-cell types and mixed form of closed-cell type[16]. Closed-cell type SEMS (Wallstent, Boston Scientific Corp., Marlborough, MA, United States; Bonastent, Standard SciTech, Inc., Seoul, South Korea; Hanarostent, MI Tech Co., Seoul, Korea) have small cells to prevent ingrowth. However, characteristic of the closed-cell type hinders the deployment of a second stent or revision after stent malfunction, particularly in high-grade strictures [16], therefore they are not suitable for the SIS technique.

Open-cell type SEMS (JOSTENT SelfX, Abbott Vascular Devices, Redwood City, CA, United States; Zilver stent, Wilson-Cook Medical, Inc., Bloomington, IN, United States; Niti-S Y-type or Niti-S large cell D-type, Taewoong Medical Inc., Seoul, South Korea) facilitate the second stent implantation. Theoretically open-cell-type SEMS could be more vulnerable to tumor ingrowth and also demonstrate less radial force[16]. Although there are no published studies directly comparing outcomes of the SIS technique using these different stent types, superior stent patency rates were achieved by the MCS in this study compared to that of open-cell stents (MCS: 90.9%-68.2% *vs* large cell Niti-D biliary stent: 60%-20% [28] *vs* Sentinol stent: 65%-0% [29], at 6 mo and 12 mo; respectively).

Finally, the BONASTENT M-Hilar (Standard Sci Tech Inc., Seoul, South Korea) is a dedicate hilar reconstruction mixed form of closed-cell type stent, with a cross-wired structure only at the 25-mm-long central portion to facilitate placement of the contralateral stent[16,29]. However, the reported technical success rate was low (78.6 %), as the insertion of the second stent *via* the 25-mm central portion, is technical demanding unlike the MCS in which all the cells are dilatable and are therefore potential insertion sites for the second stent[30].

This study has several limitations. First, the number of patients is relatively low, so the statistical validity of the results is limited. Moreover, there was no control group, so comparative data are not available, while the single-center design limits the external validity of the results.

CONCLUSION

In conclusion, palliative treatment of patients with unresectable MHBO using percutaneous MCS placement with the SIS technique is safe and feasible and resulted in excellent clinical and technical success rates. Periprocedural and stent-related complications were acceptable. Prospective, multicentre, randomized trials are needed to verify these initial promising results.

ARTICLE HIGHLIGHTS

Research background

The treatment of malignant hilar biliary obstruction is very difficult because patients are often not suitable for surgery, therefore palliative care plays a pivotal role.

Research motivation

According to the literature, there are only two previously published studies both investigating endoscopic bilateral Y-stenting using the, therefore this is the first study investigating percutaneous placement of Moving Cell Stent (MCS).

Research objectives

To evaluate the efficacy and safety of a novel uncovered biliary stent, specifically designed for hilar reconstruction in patients with unresectable malignant hilar biliary obstructions.

Research methods

A retrospective, single-centre study was performed, investigating 18 patients with unresectable malignant hilar biliary obstructions treated with a novel uncovered biliary metallic stent (MCS; BCM Co., Ltd., Gyeonggi-do, South Korea), specifically designed for hilar reconstruction, using stent-in-stent technique *via* percutaneous approach. Primary endpoints were clinical and technical success.

Research results

The technical and clinical success rates were 100%. One periprocedural complication was reported. Stent-related complications were observed in 5 patients. According to Kaplan-Meier analysis, the estimated overall patient survival was 80.5% and 60.4% at 6 and 12 mo respectively, while stent patency was 90.9% and 68.2% at 6 mo and 12 mo respectively.

Research conclusions

For patients with unresectable malignant hilar biliary obstruction using percutaneous placement with the stent-in-stent technique was a feasible and safe and resulted in excellent technical and clinical success rates. Periprocedural and stent-related complications were acceptable.

Research perspectives

Since MCS is a recently introduced stent, prospective, multicentre, randomized trials are needed to verify these initial promising results.

FOOTNOTES

Author contributions: Cortese F, Acquafredda F, Mardighian A, Zurlo MT, Ferraro V, Memeo R, Spiliopoulos S, Inchingolo R equally contributed to this paper with conception and design of the study, literature review and analysis, drafting and critical revision and editing, and final approval of the final version.

Institutional review board statement: The study was reviewed and approved by the independent ethics committee of University Hospital Company “Consorziale Policlinico” of Bari, No 7083.

Informed consent statement: Patients were not required to give informed consent to the study because the analysis used clinical data that were obtained after each patient agreed to treatment by written consent.

Conflict-of-interest statement: There are no conflicts of interest to report.

Data sharing statement: Technical appendix, statistical code, and dataset available from the corresponding author at riccardoin@hotmail.it. Consent was not obtained but the presented data are anonymized and risk of identification is low.

STROBE statement: The authors have read the STROBE Statement—checklist of items, and the manuscript was prepared and revised according to the STROBE Statement—checklist of items.

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