Ther Adv Gastrointestinal Endoscopy

1–9

DOI: 10.1177/2631774519846345

Endoscopic side-by-side uncovered self-expandable metal stent placement for malignant hilar biliary obstruction

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Abstract

Aim: To investigate outcomes of endoscopic bilateral side-by-side placement across the papilla using 10-mm-diameter uncovered self-expandable metal stents for unresectable malignant hilar biliary obstruction.

Methods: We retrospectively analyzed 23 patients who underwent endoscopic biliary uncovered self-expandable metal stent placement for unresectable malignant hilar biliary obstruction between January 2015 and September 2016 at our institution. We performed endoscopic side-by-side placement across the papilla using 10-mm-diameter longer-model uncovered self-expandable metal stents. Outcomes included the technical and functional success rates, recurrent biliary obstruction rate, time to recurrent biliary obstruction, reintervention rate, and incidence of adverse events other than recurrent biliary obstruction.

Results: Of the 23 patients, 10 with malignant hilar biliary obstruction underwent endoscopic side-by-side uncovered self-expandable metal stent placement across the papilla (median age, 83 years; 6 men). The locations of malignant hilar biliary obstruction were Bismuth types II ($n = 3$), III ($n = 3$), and IV ($n = 4$). The median common bile duct diameter was 8 mm. The technical and functional success rates were 100% and 80%, respectively. Seven patients (70%) developed recurrent biliary obstruction because of stent occlusions, including early hemobilia in two patients and late tumor ingrowth in five patients. The median time to recurrent biliary obstruction was 66 (95% confidence interval: 29–483) days. Six patients (60%) required reintervention, and 1 (10%) underwent transcatheter arterial embolization for right hepatic arterial pseudoaneurysm. Early adverse events other than recurrent biliary obstruction occurred in four patients and late adverse event in one patient.

Conclusion: Endoscopic side-by-side placement across the papilla using 10-mm-diameter uncovered self-expandable metal stents was technically feasible for unresectable malignant hilar biliary obstruction; however, it might be better to avoid this method for patients with malignant hilar biliary obstruction because of high recurrent biliary obstruction rate and shorter time to recurrent biliary obstruction.

Keywords: malignant hilar biliary obstruction, placement across the papilla, recurrent biliary obstruction, side-by-side placement, uncovered self-expandable metal stent

Received: 13 March 2019; revised manuscript accepted: 4 April 2019.

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Introduction

Malignant hilar biliary obstruction (MHBO) is a disease with a poor prognosis. The management of biliary drainage is important for improving the quality of life of patients with MHBO. Currently, endoscopic biliary drainage for unresectable MHBO is performed using the plastic stent or self-expandable metal stent (SEMS) for minimally invasive procedures.

A recent meta-analysis indicated that the use of SEMS, compared with plastic stents, for malignant

biliary obstruction was associated with longer stent patency, lower complication rates, and fewer reinterventions.[1] Another report also revealed that the SEMS has lower occlusion rates than the plastic stent in patients with MHBO.[2]

Uncovered self-expandable metal stent (USEMS) has been generally used for unresectable MHBO; however, stent occlusion due to tumor ingrowth often occurs in patients who underwent USEMS placement.

Endoscopic biliary SEMS placement is technically challenging for unresectable MHBO, and there is no consensus regarding the appropriate treatment for the drainage area, with respect to unilateral or bilateral placement,[3,4] and bilateral drainage methods including stent-in-stent (SIS) or side-by-side (SBS) placement.[5,6]

Furthermore, SBS USEMS placement for unresectable MHBO has been reported as stent placement above the duodenal papilla,[5,6] and a few reports have investigated SBS placement using large-diameter longer-model USEMSs across the duodenal papilla.

Therefore, the aim of this study was to investigate the clinical outcomes of endoscopic SBS placement across the papilla using 10-mm-diameter longer-model USEMSs for unresectable MHBO.

Patients and methods

This retrospective study was approved by the Medical Ethics Committee of Showa University Hospital and was registered in the University Hospital Medical Information Network Clinical Trials Registry (registry no.: 000030653). Written informed consent was obtained from all patients prior to the endoscopic procedure.

Patients

We retrospectively analyzed 23 consecutive patients who underwent endoscopic biliary USEMS placement for unresectable MHBO, between January 2015 and September 2016, at our institution. The exclusion criteria were as follows: patients with unilateral intrahepatic biliary obstruction alone, with altered gastrointestinal anatomy, and who were unable to provide informed consent.

Before endoscopic SBS placement using USEMSs, multidetector computed tomography, magnetic resonance cholangiopancreatography, and endoscopic retrograde cholangiopancreatography (ERCP) were performed to identify the location of the hilar biliary obstruction. For MHBO patients with bilateral intrahepatic cholangiography, we performed endoscopic SBS placement across the duodenal papilla using 10-mm-diameter longer-model USEMSs. All patients underwent endoscopic sphincterotomy and temporary endoscopic nasobiliary drainage before SBS USEMS placement. If the patient had a biliary infection before SBS USEMS placement, the procedure was performed after improvement of biliary infection. Generally, patients with recurrent biliary obstruction (RBO)[7] after SBS USEMS placement underwent reintervention or additional management.

The location of the hilar biliary obstruction was evaluated based on the Bismuth classification.[8]

The diagnosis of MHBO was determined based on the pathological results of endoscopic transpapillary bile duct biopsy and cytology.

The follow-up period continued from SBS USEMS placement until death.

Devices

We used a braided-type USEMS that was 10 mm in diameter and 80- or 100-mm long, with an 8 Fr delivery system (Figure 1; WallFlex Biliary Rx Stent; Boston Scientific, Natick, MA, USA).

ERCP was performed using a duodenoscope (JF-260V or TJF-240; Olympus Medical Systems Corp., Tokyo, Japan). All patients underwent ERCP procedures under deep sedation with benzodiazepines and/or pentazocine. A sphincterotome, an Autotome RX 44 (Boston Scientific), or an MTW cannula (MTW Endoscopy, Dusseldorf, Germany) was used as an ERCP catheter.

Guidewires were used for selective bile duct cannulation and intrahepatic bile duct insertion, including a 0.035-inch Jagwire (Boston Scientific), Hydra Jagwire (Boston Scientific), and a 0.025-inch VisiGlide 2 (Olympus Medical Systems Corp.), based on the requirements of each procedure.

Biliary dilation catheters were used, including a 6–9 Fr Soehendra Biliary Dilation Catheter (Cook Medical, Inc., Bloomington, IN, USA) and a

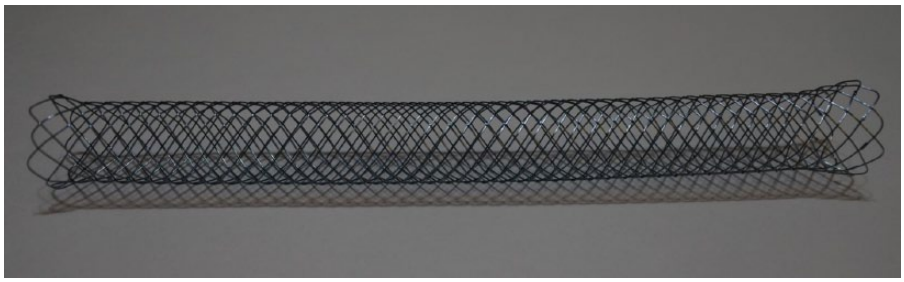

Figure 1. A 10-mm-diameter uncovered self-expandable metal stent with an 8 Fr delivery system (WallFlex Biliary Rx Stent; Boston Scientific).

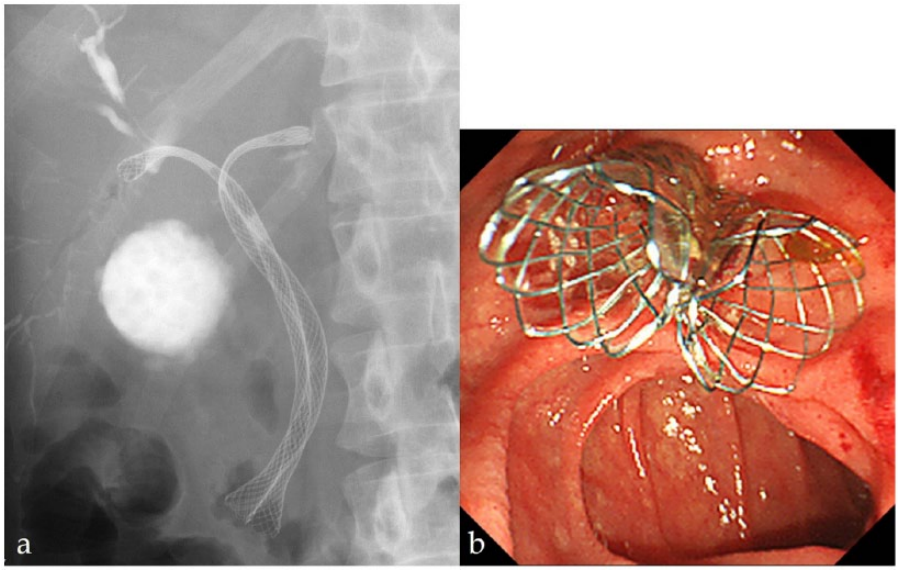

Figure 2. Endoscopic biliary side-by-side placement using uncovered self-expandable metal stents (USEMSs): (a) cholangiogram and (b) endoscopic image.
USEMSs are placed from the left and right intrahepatic bile duct across the duodenal papilla.
USEMS: uncovered self-expandable metal stent.

4-mm-diameter Hurricane RX Biliary Balloon Dilation Catheter (Boston Scientific).

An Erbotom ICC 200 unit (Surgical Technology Group, Hampshire, England) was used for endoscopic sphincterotomy in endocut mode with the effect three current set at an output limit of 120 W and the forced coagulation current set at an output limit of 30 W.

SBS placement across the papilla using USEMSs

For patients with a diagnosis of unresectable MHBO, endoscopic bile duct cannulation during bilateral intrahepatic cholangiography was performed using two 0.035-inch guidewires inserted into the left and right intrahepatic bile ducts through the hilar biliary obstruction.

For patients with extremely narrow hilar biliary obstruction, we often performed biliary dilation using a 6–9 Fr biliary dilation catheter or 4-mm-diameter biliary balloon dilation catheter.

Finally, each USEMS was sequentially separately placed into the left and right intrahepatic bile ducts across the duodenal papilla (Figure 2). The length of the stent placed (80 or 100 mm) was determined based on the distance between a point directly above the hilar biliary obstruction and the duodenal papilla in the cholangiography findings. These ERCP procedures were conducted by expert endoscopists and assistants.

Reintervention and management for RBO

Reintervention was performed if cholangitis or hemobilia due to stent occlusion occurred after endoscopic SBS USEMS placement. Patients with stent occlusion due to tumor ingrowth or hemobilia underwent endoscopic SIS placement using SEMSs. Patients with hemobilia due to hepatic arterial pseudoaneurysm after USEMS placement underwent transcatheter arterial embolization (TAE).

Outcome measurements

The study outcomes were technical success rate, functional success rate, RBO rate, time to recurrent biliary obstruction (TRBO), reintervention rate, and adverse events other than RBO. These outcomes were determined based on the TOKYO criteria 2014 for transpapillary biliary stenting.[7]

Technical success was defined as successful endoscopic SBS USEMS placement in the intended biliary location across the papilla. Functional success was defined as a 50% decrease in or normalization of the bilirubin level within 14 days of endoscopic SBS USEMS placement across the papilla.[7]

RBO was determined as stent occlusion or migration. Stent occlusion was diagnosed in the presence of tumor ingrowth, tumor overgrowth, sludge, hemobilia, food impaction, bile duct kinking, and other factors. Stent migration was diagnosed when proximal or distal stent migration was found during reintervention. TRBO was defined as an early ($\leqslant$30 days) or late ($\geqslant$31 days) time from endoscopic SBS USEMS placement to the onset of RBO.[7]

Adverse events other than RBO were categorized as follows: pancreatitis, non-occlusive cholangitis, cholecystitis, and others (bleeding, ulceration, penetration, or perforation). These events were also categorized as early ($\leqslant$30 days) or late ($\geqslant$31 days) based on the time of occurrence after endoscopic SBS USEMS placement.[7]

Statistical analysis

Continuous variables are expressed as the median (interquartile range [IQR], 95% confidence interval [CI]). The follow-up period and TRBO were estimated using the Kaplan–Meier method.[7] Statistical analyses were performed using JMP software (version 13, SAS Institute Inc., Cary, NC, USA).

Results

Of 23 patients who underwent endoscopic biliary USEMS placement for unresectable MHBO, 13 were excluded (11 with unilateral intrahepatic biliary obstructions, 1 with the use of other SEMSs, and 1 with SBS placement above the papilla). The remaining 10 patients who underwent endoscopic SBS placement across the papilla using 10-mm-diameter longer-model USEMSs were investigated in this study (Figure 3). The patients' characteristics are shown in Table 1. The locations of hilar biliary obstruction were Bismuth types II ($n=3$), III ($n=3$), and IV ($n=4$), including six cholangiocarcinomas, three gallbladder cancers, and one liver metastasis of colon cancer. The median common bile duct diameter was 8 (IQR: 7–11) mm. The median blood bilirubin level before the procedure was 3.9 (IQR: 2.1–6.9) mg/dL. Four patients (40%) underwent biliary dilation procedures before SBS placement. The median follow-up (survival) period was 173 (95% CI: 12–406) days after the procedure, and all patients died. The major causes of death were the progression of cancer and exacerbation of biliary infection. Eight patients (80%) were affected with biliary tract infection.

Technical success and functional success

The technical success rate was 100% and all patients with bilateral intrahepatic cholangiograms were treated with endoscopic SBS USEMS placement across the papilla. The functional success rate was 80% (8/10), and one of two patients with functional failure had a gradual decrease in bilirubin levels 14 days after SBS USEMS placement (Table 2).

RBO and TRBO

Seven patients (70%) developed RBO after SBS USEMS placement. Early ($\leqslant$30 days) stent occlusions due to hemobilia occurred in two patients and late ($\geqslant$31 days) stent occlusions due to tumor ingrowth occurred in five patients. The median TRBO was 66 (95% CI: 29–483) days (Figure 4; Table 2).

Reintervention and management for RBO

After SBS USEMS placement, six patients (60%) underwent endoscopic reintervention. Five patients with tumor ingrowth and one patient with hemobilia underwent endoscopic biliary SIS placements using SEMSs. The median number

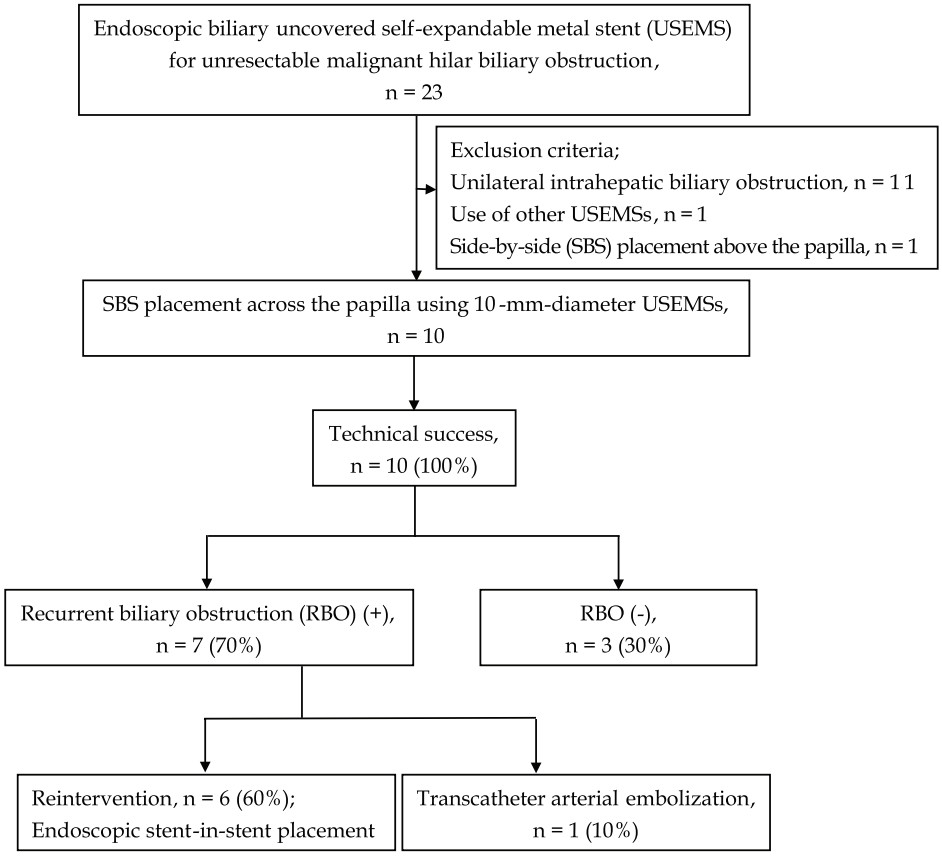

Figure 3. Flow diagram of the study.

of reinterventions was 1 (IQR: 1–2) times. On the 29th day after SBS USEMS placement, one patient with hemobilia underwent TAE due to a right hepatic arterial pseudoaneurysm (Figure 5; Table 2).

Adverse events other than RBO

Early (⩽30 days) adverse events other than RBO occurred in four patients (two cholecystitis, one pancreatitis, and one duodenal bleeding). The two patients with acute cholecystitis underwent gallbladder drainage (one percutaneous transhepatic gallbladder aspiration [PTGBA] and one endoscopic ultrasonography-guided gallbladder drainage). One patient had severe acute pancreatitis, which improved with conservative treatment. On the 29th day after SBS USEMS placement, one patient had duodenal bleeding due to contact with the duodenum of USEMSs requiring hemostasis with clips. A late (⩾31 days) adverse event occurred in one patient with acute cholecystitis, which improved with PTGBA (Table 2).

Discussion

Our study indicated that endoscopic SBS placement across the duodenal papilla using 10-mm-diameter longer-model USEMSs was technically feasible but resulted in high RBO rate and shorter TRBO for unresectable MHBO.

Endoscopic bilateral USEMS placement is a technically challenging procedure; however, one advantage of bilateral placement is that much drainage of the liver volume may be obtained. Vienne and colleagues[9] reported that optimal stenting for malignant hilar obstruction requires drainage of 50% or more of the liver volume. They also suggested that a pre-ERCP assessment of hepatic volume distribution on cross-sectional imaging may optimize endoscopic procedures.

The insertion of the second USEMS into the contralateral intrahepatic bile duct through the mesh of the first USEMS in endoscopic SIS placement is difficult.[4] Conversely, endoscopic SBS placement is simpler than SIS placement, and it is easier to perform reintervention in patients with SBS

Table 1. Patients' baseline characteristics.

Number of patients	10
Age: median (IQR), years	83 (79–85)
Sex: male/female, *n*	6/4
Etiology of MHBO, *n* (%)	
Cholangiocarcinoma	6 (60)
Gallbladder cancer	3 (30)
Metastatic cancer	1 (10)
Bismuth classification, *n* (%)	
Type II	3 (30)
Type III	3 (30)
Type IV	4 (40)
Common bile duct diameter, median (IQR), mm	8 (7–11)
Endoscopic sphincterotomy, *n* (%)	10 (100)
Length of the USEMS, right/left, *n* (%)	
100 mm/100 mm	9 (90)
80 mm/80 mm	1 (10)
Placement across the duodenal papilla, *n* (%)	10 (100)
Chemotherapy, *n* (%)	2 (20)
Follow-up (survival) period, median (95% CI), days	173 (12–406)

IQR: interquartile range; MHBO: malignant hilar biliary obstruction; USEMS: uncovered self-expandable metal stent; CI: confidence interval.

placement across the papilla than in those with SIS placement.

Basically, the outcomes of endoscopic SBS USEMS placement above the papilla for unresectable MHBO have been reported, and the technical success rate was 63–100%.[10–13] Recently, the feasibility and efficacy of endoscopic bilateral SBS USEMS placement in patients with MHBO using a 6 Fr biliary system were reported, and early stent occlusions occurred in 6% and late in 19%.[12]

Hsieh and colleagues[14] reported the serial insertion of bilateral SBS USEMSs in 17 patients with MHBO using an 8 Fr biliary system. They used 8- or 10-mm-diameter USEMSs, but not all patients had retained USEMSs across the papilla. Overall, procedural technical success was achieved in all patients. Cholangitis occurred in only one patient and there was no other major adverse event.

Cosgrove and colleagues[15] compared the efficacies and complication rates between SEMS placed above and across the papilla for MHBO. Bilateral SBS SEMS placement above or across the papilla demonstrated similar success rates, stent patency duration, and stent occlusion rates. A trend toward lower rates of pancreatitis was observed for SEMS placed above the papilla.

Thus, few reports have investigated endoscopic SBS placement across the papilla using large-diameter longer-model USEMSs. Our study is unique in that we investigated the clinical outcomes of endoscopic SBS placement across the papilla using 10-mm-diameter longer-model

Table 2. Clinical outcomes of endoscopic side-by-side placement across the papilla using 10-mm-diameter USEMSs for unresectable malignant hilar biliary obstruction.

Number of patients	10
Technical success, *n* (%)	10 (100)
Procedure time, median (IQR), min	41 (31–52)
Functional success, *n* (%)	8 (80)
RBO, *n* (%)	7 (70)
Cause of RBO	
Early (⩽30 days), *n*	2
Occlusion (hemobilia)	2
Migration	0
Late (⩾31 days), *n*	5
Occlusion (tumor ingrowth)	5
Migration	0
TRBO, median (95%CI), days	66 (29–483)
Reintervention, *n* (%)	6 (60)
Endoscopic stent-in-stent placement using SEMSs, *n*	6
TAE, *n* (%)	1 (10)
Adverse events other than RBO	
Early (⩽30 days), *n*	4
Cholecystitis	2
Pancreatitis	1
Duodenal bleeding	1
Late (⩾31 days), *n*	1
Cholecystitis	1

USEMS: uncovered self-expandable metal stent; IQR: interquartile range; RBO: recurrent biliary obstruction; TRBO: time to recurrent biliary obstruction; CI: confidence interval; SEMS: self-expandable metal stent; TAE: transcatheter arterial embolization.

USEMSs alone. We achieved successful endoscopic SBS USEMS placement across the papilla in all patients as shown by bilateral intrahepatic cholangiography, and the functional success rate was relatively good. In our study, sequential SBS placement using 10-mm-diameter USEMSs with an 8 Fr delivery system was not limited by the radial force of the first USEMS deployed. This may be due to the fact that the used USEMS was braided type.

Basically, USEMS has a problem regarding stent occlusion due to tumor ingrowth. Previous studies have reported that the median stent patency period was 130–169 days in SBS USEMS placement for MHBO.[11–13] In our study, the median TRBO after endoscopic SBS USEMS placement was 66 days, and it was not much longer than noted in previous reports.[11–13] Because of hilar biliary overexpansion by the relatively excessive radial force due to the large diameter, stent

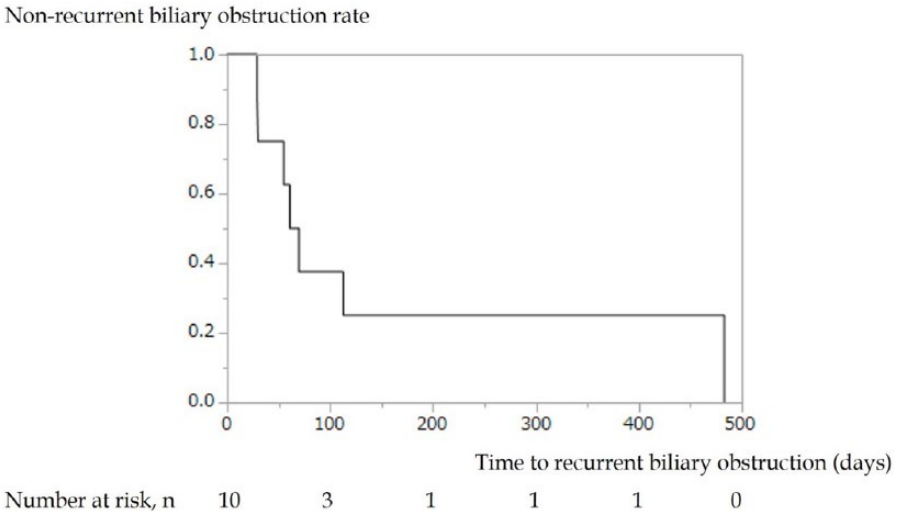

Figure 4. Results of time to recurrent biliary obstruction during endoscopic side-by-side uncovered self-expandable metal stent placement using the Kaplan–Meier method.

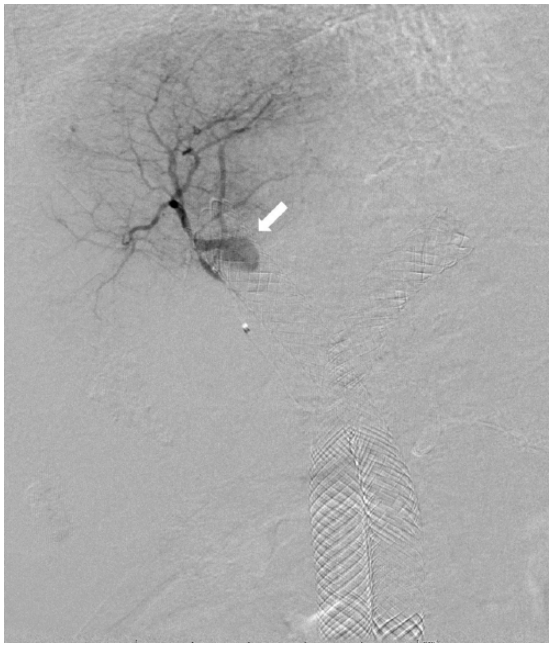

Figure 5. Angiography revealing a pseudoaneurysm at the right hepatic artery (arrow).

occlusion due to hemobilia or tumor ingrowth may occur with two USEMSs and reduce the TRBO. From these results, SBS placement using a slightly thin (i.e. 8-mm diameter) USEMS may be better.

In this study, the endoscopic reintervention rate after SBS USEMS placement was 60% (6/10). Five patients with tumor ingrowth and one patient with hemobilia underwent endoscopic biliary SIS placement using SEMSs. The reintervention rate was relatively high, but SIS placement using SEMSs was convenient to perform with the deployment of two USEMSs across the papilla for future access.

One patient who developed hepatic arterial pseudoaneurysm after SBS USEMS placement underwent TAE. Pseudoaneurysm is a rare and serious adverse event associated with SEMS placement. There are two reports of three cases regarding the formation of a pseudoaneurysm after the placement of a 10-mm-diameter USEMS for malignant biliary obstruction.[16,17] The period to the onset of bleeding after USEMS placement was 20 days, 6 months, and 9 months, respectively. Pseudoaneurysm formation was found at the right hepatic artery in two patients and at the posterior superior pancreaticoduodenal artery in one patient. All patients underwent successful TAE. In our study, a right hepatic arterial pseudoaneurysm, which was treated with TAE, was noted in one patient after SBS USEMS placement. Inflammation, overpressure, or tumor invasion to the right hepatic artery after USEMS placement may be associated with the formation of a pseudoaneurysm.

In our study, adverse events other than RBO occurred in five patients, of which early adverse events occurred in four patients. One of these four patients had duodenal bleeding that required hemostasis with clips. USEMS placement across the duodenal papilla may cause duodenal bleeding due to contact with a contralateral duodenal wall.

Our study was limited by its single-center and retrospective nature and by the small number of patients evaluated. Future multicenter prospective analyses with a larger number of patients are needed to confirm our findings.

Conclusion

Endoscopic SBS placement across the papilla using 10-mm-diameter longer-model USEMSs was technically feasible for unresectable MHBO; however, it might be better to avoid this method for patients with MHBO because of high RBO rate and shorter TRBO.

Funding

The authors received no financial support for the research, authorship, and/or publication of this article.

Conflict of interest statement

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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