Original Article

Efficacy and Safety of Compound Tri-metal Stent Placement for Malignant Perihilar Biliary Obstruction

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ABSTRACT

Background: Despite many attempts to improve the patency rate of biliary stents in patients with inoperable perihilar cholangiocarcinomas, the longevity of these stents has not been satisfactory. The purpose of the present study is to report technical outcomes and clinical efficacy of the placement of compound tri-metal stent in patients with malignant perihilar biliary obstruction. **Materials and Methods:** Retrospective analysis was performed of the medical records of 26 consecutive patients with inoperable malignant perihilar biliary obstruction who underwent compound tri-metal stent placement through a percutaneous transhepatic biliary drainage tube from January 2012 to April 2017. **Results:** Placement of the compound tri-metal stent was successfully completed in all 26 patients (technical success, 100%). There was neither procedure-related mortality nor 30-day mortality. None of these patients underwent additional metallic stent placement within 60 days secondary to recurrent cholangitis or stent occlusion. Successful drainage was achieved in 25 (96.2%) of 26 patients who received a compound tri-metal stent. Patients treated with compound tri-metal stent placement had a median stent patency of 145 days (range, 24–426 weeks) and a median survival time of 188 days (range, 37–1732 days). **Conclusions:** Placement of compound tri-metal stent in patients with malignant perihilar biliary obstruction may offer a safe and effective alternate technique to improve biliary drainage and stent patency.

Keywords: *Cholangiocarcinoma, percutaneous transhepatic biliary drainage, perihilar, stent*

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Introduction

Patients with advanced biliary cancer often develop jaundice caused by biliary obstruction during the course of their disease. Prolonged jaundice is frequently associated with pruritus, anorexia, or cholangitis. In cases of malignant perihilar biliary obstruction, of which only about 10%–20% are resectable, palliative rather than curative treatment including biliary decompression is usually required.[1,2] When palliative biliary drainage for malignant perihilar biliary obstruction becomes necessary, bilateral drainage of the hepatic duct is considered more effective and physiologically appropriate than unilateral drainage because incomplete drainage increases the risk of cholangitis.[3-5] In addition, the rates for mean survival and 30-day mortality in patients with perihilar cholangiocarcinoma are significantly better with bilateral self-expandable metal stents (SEMS) compared with unilateral stents.[6] Bilateral biliary drainage has been performed by placement of SEMS through either a percutaneous or endoscopic approach.

To date, various types of SEMS have been developed to optimize decompression, and several attempts have been made to improve stent patency.[7-11] The two methods used to place bilateral SEMS are conventional side-by-side deployment and stent-in-stent

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deployment (i.e., "Y-stents"). Side-by-side deployment is technically easy and offers relatively longer stent patency compared to stent-in-stent because side-by-side deployment has a double channel for drainage in the hilar region.[12,13] However, this approach can result in portal vein occlusion and increase the rate of cholangitis caused by excessive bile duct expansion of the parallel stents. To overcome these drawbacks and highlight advantages of the side-by-side method, we have in recent years routinely used a compound tri-metal stenting technique for palliative biliary drainage in patients with malignant perihilar obstruction. In this article, we describe the technical outcomes, clinical efficiency, and safety of the placement of compound tri-metal stents for the palliative drainage of malignant perihilar biliary obstruction.

Materials and Methods

Patients

From January 2012 to April 2017, 26 consecutive patients with inoperable malignant perihilar biliary obstruction underwent compound tri-metal stents placement for palliative decompression through a percutaneous transhepatic biliary drainage (PTBD) tube at Samsung Changwon Hospital, Changwon, Korea. Data were obtained from medical records' review, telephone interviews, and the national mortality database. Diagnosis of an unresectable malignant obstruction in the hilar bile duct was established by computed tomography (CT), endoscopic retrograde cholangiopancreatography (ERCP), magnetic resonance cholangiopancreatography (MRCP), and endoscopic ultrasonography (EUS). Histological and cytological confirmation of malignancy was established by ERCP, EUS, or CT-guided biopsy on these patients. Full and informed consent was obtained from all patients. The ethics committee of Samsung Changwon Hospital approved this study protocol, and the study was conducted in accordance with the principles of the Declaration of Helsinki.

Percutaneous transhepatic biliary drainage and stent placement

Representative cases that underwent compound tri-metal stent placement are shown in Figure 1. All 26 patients underwent PTBD (a two-stage procedure) before stent insertion. The procedures were performed on patients under local anesthesia with application of meperidine (25–50 mg) by interventional radiologists with more than 10 years of experience. After draping the surgical field, puncture of the biliary ducts was performed using a 21-gauge Chiba needle through a right or left intercostal percutaneous approach under ultrasound and fluoroscopic guidance. After puncturing the targeted duct and confirming bile juice flow from the Chiba needle, cholangiography was performed to localize the site of obstruction by injecting contrast material gently, under fluoroscopic guidance. Then, a 0.18-inch microguide was advanced through the biliary system and later substituted by a conventional 0.35-inch hydrophilic guidewire (Terumo, Tokyo, Japan). Next, an 8.5-F drainage catheter (Catheter A) with multiple side holes (Cook Medical, Inc, Bloomington, IN, USA) was placed across the obstruction and remained in position before placement of the compound tri-metal stent. In the same way, second 8-Fr external biliary drainage catheter (B) was introduced over 0.35-inch angiographic guidewires through contralateral bile duct accesses. In all patients, stent placement was accomplished within 2 weeks after performing PTBD, allowing any cholangitis to be treated. Antibiotics were administered intravenously 12 h before the procedures and for at least 48 h afterward. We planned compound tri-metal stenting through the PTBD route in the next step, after cholangitis symptoms had disappeared and a declining tendency level of total bilirubin was indicated. In the second stage of the two-stage procedure of metal stent placement, two extrastiff Amplatz guidewires (180 cm, 0.035-inch, curved tip; Cook Medical, Inc., Bloomington, IN, USA) were placed simultaneously in the right and left intervention tracts. The drainage catheter A and B were subsequently removed over the two guidewires. The first stent, which was 10 mm in diameter and 5 cm in length and an uncovered SEMS (Niti-D Biliary stent, Taewoong Medical Corporation, Seoul, Korea), was then introduced into the common bile duct (CBD) along one of the two guidewires, preferably the one that was least accessible of the two to the CBD because the second guidewire could then be repositioned into the first stent.

The proximal end of the first stent was positioned just below the insertion of the cystic duct to avoid blocking the flow of bile from the gallbladder. Balloon dilatation of the stenosis before stent placement was not performed. After deployment of the first stent across the CBD, the excess external guidewire adjacent to the primary stent was carefully withdrawn proximally, without pulling it back completely, and was then inserted into the first stent. The second and third SEMSs, which had a 6–8 cm length and a diameter of 8 mm, were sequentially introduced over the other two guidewires placed into the first stent in a side-by-side fashion at the hilar confluence.

Follow-up and assessment of outcomes

Biochemical parameters were noted, including serum bilirubin and alkaline phosphatase. The outcomes of bile duct drainage were evaluated according to the following parameters: (1) technical success, defined as the passage of the compound tri-metal stent across the obstruction,

along with the flow of contrast medium; (2) successful drainage defined as a decrease in bilirubin to <75% of the pretreatment value within the 1st month; (3) early and late complications, i.e., complications that occurred within 30 days and after 30 days of stent placement, respectively, based on the consensus criteria;[14] (4) stent occlusion, defined as recurrence of cholangitis, jaundice, and dilatation of the intrahepatic bile duct, demonstrated by imaging techniques such as CT scans, MRCP, or ERCP, with evidence of stent stenosis thus requiring biliary intervention after placement of the compound tri-metal stent; and (5) stent patency calculated as the period between stent insertion and its occlusion or the patient's death.

All patients who underwent compound tri-metal stent insertion for unresectable perihilar cholangiocarcinoma were followed up from stent insertion to the end of the study (October 2014). After discharge from the hospital, patients were evaluated at outpatient clinics 1 week, 2 weeks, and monthly thereafter. In situations where patients did not arrive for their follow-up appointment, additional information regarding current status or death was obtained by telephone interview conducted by one of the authors (K. M. K.) with patients or their relatives.

Statistical analysis

Statistical analyses were performed using SPSS, version 22 (IBM Corporation Armonk, NY, USA) and GraphPad Prism, version 7.0 (GraphPad, San Diego, CA, USA). Continuous data are presented as mean ± standard deviation, and categorical data are presented as numbers and percentages. Length of follow-up and stent patency are expressed as median (range). The cumulative stent patency and patient survival were compared by using the Kaplan–Meier method and the log-rank test.

Results

Characteristics of the study population

Demographic characteristics and clinical manifestations of all 26 patients who received compound tri-metal stents are summarized in Table 1. The median patient age was 74 years (range, 52–82 years), and the group included 10 males (38.5%). Causes of malignant hilar biliary obstructions in the study population were perihilar cholangiocarcinoma in 22 (84.6%) patients and intrahepatic cholangiocarcinoma, gallbladder cancer, metastatic gastric cancer, and pancreatic head cancer in 1 (3.8%) each, respectively. On admission, all the patients were jaundiced followed by abdominal pain in 17 (65.4%) patients and cholangitis in 12 (45.2%). According to the Bismuth–Corlette classification system for perihilar cholangiocarcinoma, the types of obstruction were Type I in 1 (4.5%) patient, Type II in 3 (13.6%), Type IIIa in 6 (27.8%), Type IIIb in 5 (22.7%), and Type IV in 7 (31.8%). Mean peak serum total bilirubin level before drainage was 14.7 ± 7.6 mg/dl. Nine patients had single or multiple medical comorbidities including hypertension in 7 (27.0%) patients, diabetes mellitus in 4 (15.4%), liver cirrhosis in 2 (7.7%), or cardiovascular disease in 4 (15.4%). Three (11.5%) patients had a previous history of subtotal gastrectomy with Billroth II reconstruction for primary gastric cancer.

Technical and clinical outcomes

Clinical outcomes and complications in patients who underwent compound tri-metal stent placement are shown in Table 2. All 26 patients underwent bilateral PTBD of the hepatic lobes before compound tri-metal stent placement, and successful drainage on the first attempt was achieved in all patients. Of these, 2 (7.7%) required drainage tube exchange due to cholangitis caused by drainage tube occlusion of bile sludge within

Table 1: Baseline characteristics of patients treated with a compound tri-metal stent

Variable	Compound tri-metal stent placement (%)
Number of patients	26
Male:female	10 (38.5):16 (61.5)
Age (years), median	74 (52-82)
Diagnosis (*n*)	
Perihilar cholangiocarcinoma	22 (84.6)
Intrahepatic cholangiocarcinoma	1 (3.8)
Gallbladder cancer	1 (3.8)
Liver metastases of gastric cancer	1 (3.8)
Pancreatic head cancer	1 (3.8)
Bismuth-Corlette classification for perihilar cholangiocarcinoma (*n*=22)	
I	1 (4.5)
II	3 (13.6)
IIIa	6 (27.8)
IIIb	5 (22.7)
IV	7 (31.8)
Clinical findings and symptoms on admission	
Jaundice	26 (100)
Abdominal pain	17 (65.4)
Cholangitis	12 (46.2)
Prestenting laboratory findings	
Serum total bilirubin (mg/dL)	14.6±7.6
Alkaline phosphatase (IU/L)	494.7±288.9
Aspartate transaminase (IU/L)	128.1±72.7
Alanine aminotransferase (IU/L)	118.6±79.2
Comorbidity	13 (50.0)
Hypertension	7 (27.0)
Diabetes mellitus	4 (15.4)
Liver cirrhosis	2 (7.7)
Cardiovascular disease	4 (15.4)

Age is presented as the median (range); other variables are presented as *n* (%) or means±SD. SD: Standard deviation

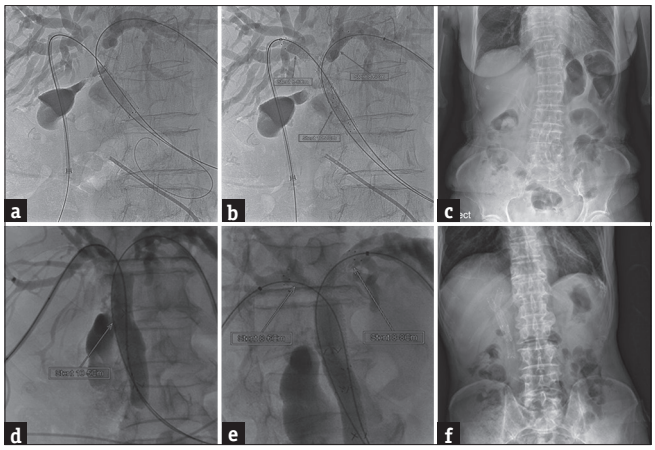

Figure 1: Compound tri-metal stent placement for malignant hilar biliary obstruction. (a-c) Images from a patient with perihilar cholangiocarcinoma (Bismuth–Corlette classification IV). Percutaneously placed guidewires that enabled stent placement (a). Triple stenting of both intrahepatic and extrahepatic bile ducts (b). Abdominal radiograph of the stents (c). In this case, after deployment of the first stent (4 cm in length and a diameter of 10 mm), second and third stents (6–8 cm in length and a diameter of 8 mm) were sequentially placed. (d-f) Images from a patient with perihilar cholangiocarcinoma (Bismuth–Corlette classification IIIb). Deployment of the first stent of 4 cm length and a diameter of 10 mm (d). Sequentially introduced second and third stents, which had a 6–8 cm length and diameter of 8 mm (e). Y-configured radiograph obtained after compound tri-metal stent placement (f)

Table 2: Technical and clinical outcomes of patients with a compound tri-metal stent

Variable	Compound tri-metal stent placement
Number of patients	26
Successful drainage, *n* (%)	25 (96.2)
Postdrainage laboratory findings	
Serum total bilirubin (mg/dL)	3.0±2.9
Alkaline phosphatase (IU/L)	153.3±59.9
Aspartate transaminase (IU/L)	31.6±14.8
Alanine Aminotransferase (IU/L)	20.2±10.5
Early complications, *n* (%)	
Stent occlusion	1 (15.8)
Cholangitis	3 (11.5)
Cholecystitis	2 (7.7)
Biloma	1 (3.8)
Liver abscess	1 (3.8)
Late complications, *n* (%)	
Stent occlusion	9 (34.6)
Cholangitis	2 (7.7)
Cholecystitis	2 (7.7)
Biloma	1 (3.8)
Death, *n* (%)	23 (88.5)
Stent patency (days), median (range)	145 (24-426)
Survival (days), median (range)	188 (37-1732)

3 days after initial PTBD and showed improvement of cholangitis symptoms on the day after replacement of the tube. The median interval between PTBD and stent insertion was 13 days (range 6–35). Placement of the

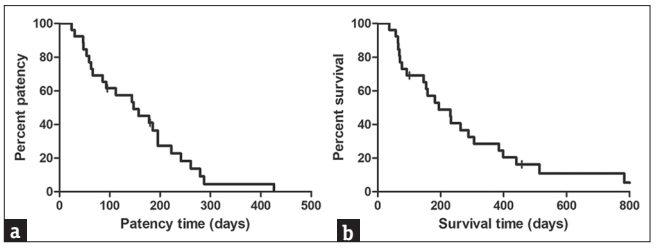

Figure 2: Kaplan–Meier curves showing cumulative stent patency (a) and overall survival (b) in patients with a compound tri-metal stent

compound tri-metal stent was successfully completed in all the patients (technical success). The mean procedure time for compound tri-metal stent placement was 38 ± 4 min. Serum bilirubin level decreased significantly after placement of the compound tri-metal stent from 14.6 ± 7.6 (mean peak level before biliary drainage) to 3.0 ± 2.9 mg/dl (mean lowest level after compound tri-metal stenting) ($P < 0.01$). Successful drainage was achieved in 25 (96.2%) of 26 patients who received a compound tri-metal stent.

Complications and stent patency

Procedure-related early complications occurred in 8 (30.8%) patients as well as the one (3.8%) patient who required replacement of a plugged PTBD catheter. There were no significant bleeding events in the study population that required transfusion. Two patients (7.7%) developed acute cholecystitis 4 days following compound tri-metal stenting and required percutaneous transhepatic gallbladder drainage (PTGBD), which resolved the cholecystitis symptoms; that tube was uneventfully removed after 3 weeks. Three (11.5%) patients who developed acute cholangitis after the procedure were treated successfully by conservative methods with no additional intervention. No procedure-related mortalities occurred. Late complications, other than stent occlusion, occurred in 5 (19.2%) patients. Two (7.7%) patients developed acute cholangitis 65 and 74 days, respectively, after stent placement and were successfully managed with antibiotics. One patient suffered from gallbladder empyema 105 days after stent placement and managed by PTGBD with the resolution of the symptoms. The overall rate of reintervention was in 11 (42.3%) patients during the follow-up period. Two of the 6 cases requiring PTGBD were not associated with stent occlusion and the other 4 cases were confirmed by CT scan or cholangiogram as stent occlusion, requiring reinsertion of the PTBD catheter for rescue therapy. The 3- and 6-month cumulative rates of stent patency were 65.4% and 23.1%, respectively. According to the Kaplan–Meier analysis, patients treated with compound tri-metal stent placement had a median stent patency of 145 days (range, 24–426 weeks) and a median survival time of 188 days (range, 37–1732 days) [Figure 2].

Discussion

In patients with a malignant perihilar biliary obstruction, bilateral SEMS placement has been frequently used as a palliative drainage method for both hepatic lobes.[15-17] Although bilateral stent drainage for malignant perihilar biliary obstruction has been performed recently in many institutions, the deployment of bilateral metal stents still presents significant challenges because bilateral stent placement across the perihilar bile duct is often laborious and associated with insufficient expansion of metal stents in cases with severe biliary stenosis due to invasive cancer. Thus, various types of stents have been designed for use in hilar malignant obstructions. One type of these newer stents is a Y-configured dual stent, which was introduced to reduce the difficulty in insertion of metal stents by the conventional method of side-by-side deployment. A recent development, Y-configured self-expandable nitinol stents used for stent-in-stent placement, has a relatively wide open-mesh that is 10 mm long in the exact middle of the stent.[17] The large opening of this stent facilitates insertion of the second stent into the contralateral bile duct. However, the stent-in-stent procedure also has several drawbacks in that the open-weave section on the central portion of the Y-shape could allow tumor ingrowth and the relatively weak radial force of this wide mesh might have a negative impact on stent patency. In addition, stent reintervention through the mesh at the time of occlusion is technically challenging, even for experienced interventional radiologists.[18]

Accordingly, we devised a compound tri-metal stenting method using a fixed diameter central primary stent to reduce the possibility of portal vein occlusion caused by excessive bile duct expansion as previously seen following deployment of stent-by-stent in proximal CBD. In addition, we speculated that the compound tri-metal stenting method might increase stent patency by inserting two stents independently into the hilar portion without the area of the stents overlapping, which was indicated as a cause of sludge formation due to impeding bile inflow and tumor ingrowth through the expanded mesh. Our overall technical success rate and the successful drainage rate for the compound tri-metal stent placement was 100% and 86.7%, respectively. These results are in close agreement with those of previous studies describing the technical outcomes and efficacy of the stent-in-stent method.[15-17,19]

The original purpose of introducing the central stent was to expand the lumen of the proximal CBD so that subsequent bilateral stents could pass more easily through the narrowed lower portion of the hilar region. Our study demonstrates that compound tri-metal stent placement is comparable to the stent-in-stent method in terms of successful stent insertion even when using our stent deployment procedure. Side-by-side deployment techniques are limited by difficulties in passing the obstruction and guiding the stent through the available delivery shafts in the nondilated CBD compared to the stent-in-stent method.[20] The present study focused on assessing stent patency of a compound tri-metal stent, which was presumed to have an advantage over the stent-by-stent method in hilar bifurcation and resistance to tumor ingrowth through additional stent overlap on the proximal CBD. The median stent patency observed in several databases of previous studies using the bilateral stenting methods for perihilar biliary obstruction ranged from 61 to 140 days.[16,21,22] Although we did not directly compare stent patency of the compound tri-metal stenting with conventional bilateral stenting, we observed a median stent patency period of 145 days, which suggests that compound tri-metal stenting has a slightly better stent patency period than conventional bilateral stenting for malignant perihilar obstruction. The additional advantage of this method is that even though a sufficient radial force would be expected by overlapping the three stents, the total procedure time for placing three metal stents was similar to previous studies demonstrating conventional side-by-side stenting methods because compound tri-metal stent placement also uses just two guidewires. However, in the present study, cholecystitis was slightly more prevalent than in previous studies where conventional bilateral stenting was performed and the prevalence of other procedure-related complications including cholangitis and liver abscess was similar.[12,16,17,21] Theoretically, the triple overlap of the uncovered metal stents might intermittently and partially impede the flow of bile juice through the cystic duct, causing acute cholecystitis. Although these complications were managed properly without severe morbidity, practitioners should take care to position the proximal end of the first stent of the three as far below the level of the cystic duct opening as possible, to avoid covering the duct by the triple overlap of stents.

We acknowledge the limitations of this study for determining the value of compound tri-metal stenting beyond conventional bilateral stenting because of its retrospective study design and relatively small number of cases. Therefore, prospective studies are still needed before compound tri-metal stenting can be universally recommended as a standard procedure in unresectable malignant perihilar biliary obstruction.

Conclusions

The present study suggests that the placement of compound tri-metal stents in patients with malignant

perihilar biliary obstruction could offer a safe and effective alternate technique for improving biliary drainage and stent patency. We further recognize that future studies quantifiably comparing between compound tri-metal stenting and conventional stenting methods to clarify the technical outcomes of this approach. However, the present study is important, as one of a very few studies reporting how this newly attempted stenting method can be effectively applied in clinical practice.

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Conflicts of interest

There are no conflicts of interest.

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