

## ORIGINAL ARTICLE

# Outcome of both-bare type nitinol metal stents in distal biliary malignant obstruction: A post-market clinical follow-up study

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## ABSTRACT

**Background and objectives:** Neoplastic stenosis of the distal biliary (DBS) tract is not rare and the most common treatment is an endoscopic stent placement. Partially covered self-expandable metal stents (PC-SEMS) have been recently introduced and preliminary data are controversial in terms of lower stent ingrowth compared to uncovered self-expandable metal stents (SEMS) at expense of higher risk of migration. We aim to confirm the safety and/or clinical performance of partially covered nitinol metal stents (Niti-S—Taewoong Medical Co. Ltd., Korea) in DBS management. **Methods:** This is a post-market clinical follow-up study which analyzed all consecutive patients from March 2021 to April 2022 who underwent PC-SEMSs [Niti-S Biliary Covered stent (Both Bare Type)—Taewoong Medical Co. Ltd., Korea] placement for drainage of malignant DBS. The follow-up time was 6 months/day. The safety of the device was evaluated by occurrence of procedure-related and stent-related adverse events. **Results:** Thirty patients (21 males, median age 75 years) were enrolled: at the time of the procedure 24 patients had pancreatic cancer, 67% of patients had, at the time of the procedure, an advanced inoperable disease. Technical success rate was achieved in 96.7% of patients, while clinical success after 3–6 weeks was achieved in 95% of patients and all surviving patients achieved normal bilirubin levels within 10 weeks from the procedure. One patient had a mild procedure-related adverse event, and one experienced a moderate stent-related adverse event. Stent occlusion rate was 6.6%: 2 patients had recurrent biliary obstruction endoscopically treated, while stent migration was never recorded. **Conclusion:** This post-marketing clinical follow-up study demonstrates that Niti-S SEMS (Both Bare Type—Taewoong) provides adequate palliation, no migration and fair duration of patency comparable with the best results in reported series of SEMS placement for DBS treatment.

**Key words:** distal biliary malignant obstruction, partially-covered self-expandable metal stents; palliation, biliary drainage, pancreatic cancer

## INTRODUCTION

Many neoplastic conditions, including cholangiocar-

cinoma, pancreatic cancer, ampullary cancer, metastatic tumors, and other local cancers (gallbladder and liver malignancies) can be complicated with a malignant distal

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biliary stenosis (DBS).<sup>[1]</sup> Obstructive jaundice from malignant stricture produces various adverse events, including ascending cholangitis, malabsorption, and coagulopathy. The overall 5-year survival rate is less than 5%. The majority of identified cases are unfit for surgery due to the invasiveness of the disease, late symptom manifestation, and typical onset in elderly individuals.<sup>[1–3]</sup>

Biliary drainage should be promptly performed in case of cholangitis and/or cholestasis to relieve the associated clinical symptoms, as clearly stated by international guidelines.<sup>[3–5]</sup> Endoscopic biliary drainage for patients with DBS is usually divided into two scenarios: preoperative biliary drainage and palliative drainage for unresectable cancer. Several ways to manage palliative biliary drainage are available. Endoscopic biliary drainage (EBD) is considered the mainstay for palliative biliary drainage, especially for distal obstruction from pancreatic cancer and cholangiocarcinoma (Bismuth I and II, and even Bismuth III in most cases), because of its high success rates and its less invasive nature.<sup>[1,3]</sup> It is well known that biliary drainage improves the patient's quality of life and prevents hepatobiliary dysfunction and liver failure in distal malignant biliary obstructions. Comparison of primary biliary stenting *vs* surgical approach for malignant biliary obstruction has been performed in various meta-analyses, which concluded that surgical approach is more cost-effective than endoscopic biliary stent placement and much more invasive for these fragile patients.<sup>[6–8]</sup> Surgical biliodigestive anastomosis and percutaneous biliary drainage should be indicated in selected cases where EBD cannot be performed due to their high rate of complications and impact on the patient's quality of life.<sup>[9]</sup> Although percutaneous transhepatic biliary drainage had been traditionally performed, it may be impractical for urgent cases because of the requirement of serial dilations and track maturation; moreover, seeding metastasis can occur. Endoscopic drainage of malignant biliary stenosis is superior to percutaneous drainage, in regard to adverse event rate, it is therefore thought to be the first choice.<sup>[1]</sup>

When biliary drainage is indicated,<sup>[3,10]</sup> the advantages of the use of self-expandable metal stents (SEMS) rather than plastic stents have been largely demonstrated.<sup>[3,11]</sup> Different types of SEMS are commercially available: uncovered self-expandable metal stents (U-SEMS), fully covered self-expandable metal stents (FC-SEMS) and partially covered self-expandable metal stents (PC-SEMS). The major causes of stent dysfunction are tumor ingrowth and/or overgrowth, sludge or stone formation and migration. FC-SEMS were developed to prevent stent occlusion by tumor/tissue ingrowth through the stent mesh, at the expense of a higher migration rate. PC-SEMS, instead, have uncovered parts at both ends

which may reduce the migration rate, thus it is mainly used for unresectable malignant DBS.<sup>[12,13]</sup> This study is designed to identify the potential for residual risks of a Conformite Europeenne (CE) marked device, and to collect data and gain clarity regarding 6 month clinical performance of Niti-S Biliary Covered Stent (Both Bare Type). The primary aim is to confirm the safety and/or clinical performance in terms of efficacy of biliary drainage for maintenance of stent patency and migration percentage of partially covered nitinol metal stents (Niti-S—Taewoong Medical Co. Ltd., Korea) in DBS management.

## MATERIALS AND METHODS

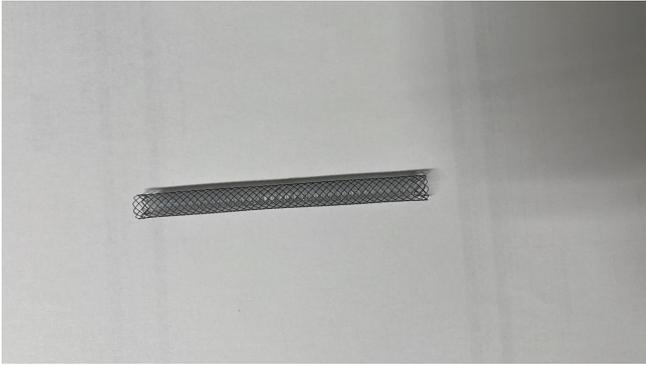
### Stent description

Niti-S biliary partially covered stent (Taewoong Medical Co. Ltd., Korea) is a Nitinol (shape memory alloy)-made SEMS with “S-Type” mesh designed to guarantee excellent flexibility and effective radial expansion force (Figure 1). The specific mesh design called “S-Type” consists of a fixed cell with a braided construction which makes the stent flexible, while also having good radial expansion force and atraumatic ends that reduce biliary trauma. The good flexibility and good radial force are obtained from different features of the stent design, mainly by: The choice of material such as the Nitinol Shape memory alloy (SMA) whose main characteristics are super elasticity and biocompatibility; the gauge of the wire used to braid the mesh stent is balanced to have good flexibility with optimal radial expansion; the S-Type technology used to braid the wire defines the mesh shape. Moreover, the technology used to cover the central part of the stent mesh with silicone is designed to create two different surface patterns: The inner stent surface is smooth to promote the flow of fluids, while the external surface is rough, as if it were an uncovered mesh, creating a good grip which limits the stent displacement. The delivery system is 8.5 Fr, and it is inserted on a 0.035-inch guidewire. Stents are available in different diameters (from 6 to 10 mm) and lengths (from 4 to 12 cm).

### Study design

Patients who underwent placement of PC-SEMSs (Niti-S Biliary Covered stent [Both Bare Type]—Taewoong Medical Co. Ltd., Korea) for drainage of malignant distal biliary obstruction were consecutively enrolled from March 2021 to April 2022.

Inclusion criteria: All patients with a malignant biliary obstruction and an estimated survival  $\geq 4$  months, any patient who underwent insertion of Niti-S Biliary Covered stent (Both Bare Type) during endoscopic retrograde cholangiopancreatography (ERCP) for



**Figure 1.** Image of Niti-S partially covered self-expandable metal stent (Taewoong Medical Co. Ltd., Korea).

maintaining biliary luminal patency in malignant strictures—minimum 18 years of age. Exclusion criteria: Patients with hepatic hilar obstruction patients with duodenal obstruction.

Enrolled patients were followed up for 6 month or until death, whichever came first, and patients' evaluations were conducted at weeks 3–6 and at week 12 and 24 after stent placement.

The aim of this data-collection study is to evaluate the safety and clinical performance of the Niti-S Biliary Covered Stent (Both Bare Type) when used according to the instructions for use. Primary outcome: safety (time frame: 6 mo); documentation of safety: number of participants with adverse events related to the stent placement. Secondary outcome: effectiveness (time frame: 6 mo); documentation of efficacy: stent occlusion, stent migration, technical and clinical success rates.

Stent occlusion rate was defined as the presence of biochemical and clinical features suggestive of cholestasis/cholangitis together with imaging studies showing biliary dilation;<sup>[4]</sup> time to stent occlusion was defined as the time between stent insertion and stent occlusion;<sup>[9]</sup> stent migration rate was defined as an obvious dislodgement from the intended and original implant position and confirmed by imaging tests/clinical features suggestive of cholangitis or obstructive jaundice; technical success rate was derived from reported success or failure of technical feasibility; clinical success rate was derived from reports of clinical success hallmarks such as reduction in total bilirubin. The biliary drainage was considered effective, according to the European Society of Gastrointestinal Endoscopy guidelines,<sup>[3]</sup> when bilirubin values were  $\leq 2$  mg/dL for a period of at least 6 weeks, if the initial bilirubin values were higher than 10 mg/dL, or 3 weeks if at the beginning values were lower than 10 mg/dL; and adverse events were classified in

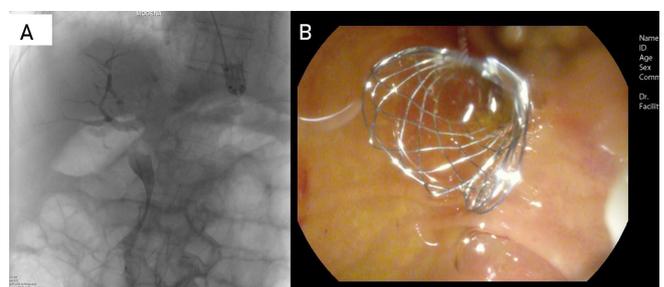
terms of: procedure-related and stent-related, and their severity was described as “mild,” “moderate,” or “severe”.

### Endoscopic procedure

All patients underwent ERCP in the supine or lateral position using a standard duodenoscope. After successful biliary access, minimal biliary sphincterotomy was performed in all patients prior to metal stent insertion. The length of the stent was chosen according to the extension of the stricture in order to release the proximal end 1–2 cm beyond the stricture, and always below the hilum, with the distal uncovered portion outside the papilla. After estimating the length of the stricture during cholangiography (Figure 2), the endoscopist chose between the available types of Niti-S Biliary Covered stent (Both Bare Type) (Taewoong Medical Co. Ltd., Korea) (diameter of 10 mm and length from 4 to 8 cm) (Figure 3A and 3B).



**Figure 2.** Distal biliary malignant stenosis in a patient affected by pancreatic carcinoma.



**Figure 3.** Fluoroscopic image and endoscopic image. **A.** Placement of a 6 cm-long Niti-S Partially covered self-expandable metal stent. **B.** Placement of a 6 cm-long Niti-S Partially covered self-expandable metal stent.

### Statistical analysis

All continuous variables were expressed as medians and ranges. All categorical variables were expressed as absolute numbers and percentages. A paired *t* test was used to test the significance of the reduction of bilirubin after 3 and 6 weeks, *P* values < 0.05 were considered

statistically significant. Categorical variables were compared with the Fisher test. All statistical analyses were performed using GraphPad Prism Software.

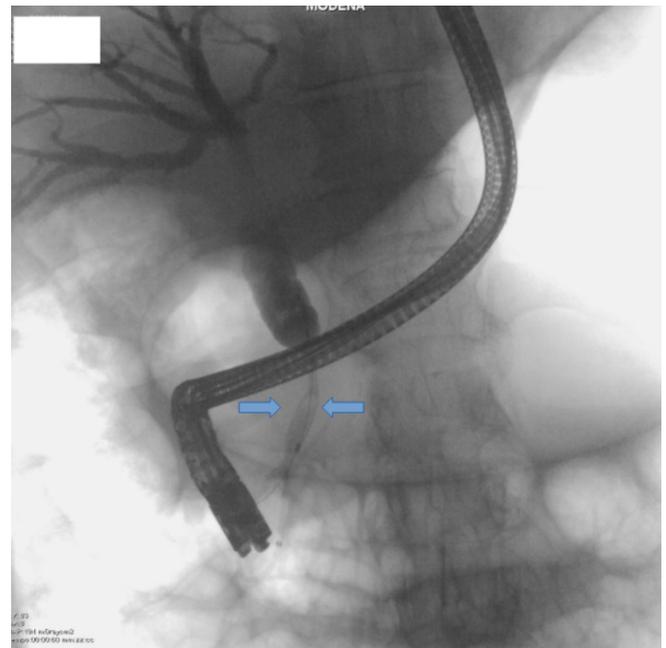
## RESULTS

Between March 2021 and April 2022, 30 patients with malignant DBS out of 969 ERCP performed during that period, were enrolled in this data-collection study. Informed consent was obtained from all subjects involved in the study. The median age was 75 years, and 21 (77%) were male. The causes of biliary obstruction were pancreatic cancer ( $n = 24$ ), bile duct carcinoma ( $n = 3$ ), metastatic stenosis from gastric cancer ( $n = 1$ ), and ampullary carcinoma ( $n = 2$ ). Twenty patients (67%) had, at the time of the procedure, an advanced inoperable disease and were candidates for palliative drainage; during follow-up 9 of them resulted in being fit for adjuvant chemotherapy; 4 patients (13%) were treated with neoadjuvant chemotherapy, and 2 of them (2/30, 7%) underwent a Whipple procedure; 6 patients (20%) were, at the time of the procedure, candidate for adjuvant chemotherapy. Median survival time was 202 days (range 57–202); 2 patients died between 7 and 10 days after stent placement for reasons unrelated to the procedure. (Table 1).

Seventeen patients received a 6 cm Niti-S PC-SEMS, 9 patients received a 4 cm SEMS, and the remaining 4 patients received the 8 cm ones. Technical success rate was achieved in 96.7% of patients: In one patient a re-intervention to improve biliary drainage was needed after 7 d from the insertion of the initial study stent due to inadequate expansion of the proximal end of the stent (Figure 4). After 3–6 weeks, 95% patients achieved a significant decrease of mean total bilirubin ( $P < 0.001$ ), and all surviving patients achieved normal bilirubin levels after 10 weeks from the procedure.

Early adverse events were: One duodenal bleeding due to tumor infiltration (procedure-related, mild severity), which was endoscopically treated with epinephrine injection and electrocautery, and one case of acute pancreatitis (stent-related, moderate severity) in a patient suffering from pancreatic cancer that was conservatively treated with an extended hospitalization (total 13 d). Treatment was not effective in 2 patients due to tumor overgrowth causing recurrent biliary obstruction, which occurred 3 month after the first procedure (stent occlusion rate 6.6%—time to stent occlusion was  $94.5 \pm d$ ); both patients were treated with endoscopic placement of a co-axial plastic stent (Figure 5).

No serious stent-related adverse events were recorded in our study population. During a 6-month follow-up, no cases of stent migration were reported in all surviving



**Figure 4.** Niti-S Biliary partially covered self-expanding metal stent malfunction (inadequate expansion).



**Figure 5.** Recurrent biliary obstruction treated with placement of a co-axial plastic stent.

patients (stent migration rate 0%).

## DISCUSSION

Endoscopic drainage during ERCP is a well-established palliative treatment for patients with distal malignant biliary stricture rather than surgery or percutaneous approach. The usefulness of SEMS placement for

**Table 1: Patient, disease and stent characteristics, n (%)**

Characteristics	Overall (n = 30)
Age, mean (range), yr	75 (51–91)
Male	21 (70)
Median survival time	202 d
Malignant cause of bile duct stricture	
Pancreatic	24 (80)
Distal cholangiocarcinoma	3 (10)
Ampullary	2 (6.7)
Metastases from gastric	1 (3.3)
Indications for biliary stenting	
Palliative biliary drainage	
Unfit for palliative chemotherapy	11 (36.6)
Fit for palliative chemotherapy after the drainage	9 (30)
Preoperative biliary drainage	
Bridge to surgery	2 (6.7)
Bridge to adjuvant chemotherapy	6 (20)
Bridge to neoadjuvant chemotherapy	2 (6.7)
Size of study stent, length in mm x diameter in mm	
60 × 10	17 (56.7)
40 × 10	9 (30)
80 × 10	4 (13.3)

patients with unresectable DBS has been reported in many studies.<sup>[1,3,14]</sup> SEMSs are considered to have better patency, larger diameters, with a better cost effectiveness ratio than plastic stents.<sup>[1,2,15]</sup> However, conventional uncovered SEMSs are prone to occlusion, mainly due to tumor ingrowth through the mesh. To overcome this issue, FC-SEMS with a thin membrane covering the stent mesh were developed. In some randomized controlled trials, FC-SEMSs have been reported to be more useful than the uncovered ones in terms of longer patency;<sup>[16,17]</sup> on the other hand, FC-SEMSs are associated with specific complications, such as sludge formation, cholecystitis, and stent migration.<sup>[18–21]</sup> Conio *et al*<sup>[21]</sup> in a randomized trial comparing uncovered *vs* covered metal stents, reported that the main causes of FC-SEMS dysfunction were early occlusion, mostly because of sludge or overgrowth, and migration. Recently, in order to prevent stent misplacement PC-SEMS with anti-migration systems have been developed.<sup>[13,15,22]</sup> In this data-collection study, Niti-S Biliary Covered Stent (Both Bare Type) provided adequate palliation of distal malignant biliary obstruction in almost all patients, with a significant reduction of their bilirubin values after 3–6 weeks. Only 2 patients required endoscopic reintervention because of recurrent biliary obstruction, due to tumor overgrowth, which occurred almost 3 month after the first procedure. As confirmed by our study, partially covered metal stents are designed to reduce the occlusion rate by preventing tumor ingrowth compared to U-SEMS, but literature data are still controversial.<sup>[13,17,22,23]</sup> A randomized trial showed no

significant differences in time to recurrent biliary obstruction between the partially covered and uncovered SEMS groups,<sup>[23]</sup> while a recent study by Yokota *et al*<sup>[13]</sup> showed that PC-SEMSs with a proximal uncovered flared end have longer patency than uncovered and fully covered SEMSs by preventing tumor ingrowth and stent migration.

Niti-S Biliary Covered Stent (Both Bare Type) is a SEMS made of Nitinol (shape memory alloy) with “S-Type” mesh designed to guarantee excellent flexibility, due to self-conforming characteristics, and an effective radial expansion force; these features ensure a milder bile duct trauma after stent positioning, an excellent adherence to the bile duct walls reducing ingrowth between the stent meshes and prevent stent migration. There are specific features of the Niti-S Biliary Covered Stent (Both Bare Type) design that contribute to its fixation and stability in the biliary tract. The uncovered parts on both ends permit local and controlled tissue ingrowth inside the mesh fixing the stent on the biliary tract tissue. Additionally, the technology used to cover the central part of the stent mesh with silicone is designed to create two different surface patterns: the inner stent surface is smooth to promote the flow of fluids, while the external surface is rough, as if it were an uncovered mesh, creating a good grip which limits the stent displacement (Figure 2). In our study, as a matter of fact, during a six-month follow up no cases of stent migration and a low rate of stent occlusion were recorded. According to the literature, possible risk factors for stent occlusion and

tumor overgrowth are: patient's age, type and local tumor staging, stricture length, and last but not least, sharp and angulated distal biliary stenosis.<sup>[1,24]</sup> We believe that these could be predisposing factors for tumor overgrowth and recurrent biliary obstruction in the cases recorded in our study population.

Furthermore, Niti-S Biliary Covered Stents (Both Bare Type) are braided-self-expandable metal stents and have a crisscross mesh construction. Thus, unlike the laser-cut SEMS, their shortening rate is about 40%, which is a feature to consider when choosing among the available PC metal stents models. Isayama *et al*<sup>[25]</sup> analyzed in laboratory experiments the physical properties of various stents and found that braided SEMSs tended to have a relatively strong radial force: This feature was found to be highly correlated with SEMS anti-migration properties.<sup>[26]</sup> Moreover, Kitagawa *et al*<sup>[15]</sup> found in laser-cut stents a statistical correlation between chemotherapy response and increased migration rate, which in braided SEMS is almost null. Therefore, the braided-mesh stent construction of the Niti-S SEMS could account for the absence, in our data collection study, of SEMSs migration cases even in patients who responded to adjuvant or neoadjuvant chemotherapy. Besides, Niti-S biliary partially covered stent (Taewoong Medical Co. Ltd., Korea) is a Nitinol-made SEMS with “S-Type” mesh designed to guarantee excellent flexibility and effective radial expansion force. The specific mesh design called “S-Type” consists of a fixed cell with a braided construction which makes the stent flexible, with good radial expansion force and atraumatic stent ends that reduce the biliary trauma. The good flexibility and good radial force are obtained from different features of the stent design, mainly by: the use of a Nitinol SMA whose main characteristics are super elasticity and biocompatibility; the gauge of the wire used to braid the mesh stent is balanced to have good flexibility with optimal radial expansion; and the S-Type technology used to braid the wire that defines the mesh shape. Moreover, the biliary trauma after positioning is reduced by the good stent flexibility, and from the smooth and atraumatic surface of the mesh on the proximal and distal stent ends. Therefore, among PC-SEMS commercially available, we choose to study the Niti-S biliary partially covered stent's (Taewoong Medical Co. Ltd., Korea) safety, effectiveness, and outcomes because of its peculiar characteristics that we have valued in our clinical experience and they have not yet been described in detail in the literature.

Acute cholecystitis is another potential complication of covered SEMS insertion and it seems to be due to an impaired cystic duct drainage and its reported incidence is variable.<sup>[13,21]</sup> It is considerable to emphasize that in our data-collection study no cases of cholecystitis were recorded. The advantages of Niti-S Biliary Covered Stent

(Both Bare Type) are great conformability and flexibility. Therefore, if the orifice of the cystic duct is involved by the tumor, we hypothesized that the “S-Type” mesh of the stent leaves space for biliary outlet reducing the incidence of acute cholecystitis in our study population.

Last but not least, one long-term outcome of PC-SEMS use in palliation of malignant DBS is their lower rate of cholangitis, compared to FC-SEMS. It has been hypothesized that the mesh surface of FC-SEMS might be a favorable site for bacterial biofilm formation and sludge deposition, responsible for earlier stent infection and subsequent cholangitis.<sup>[27]</sup>

In conclusion, this data-collection PMCF study shows that the Niti-S Biliary Covered Stent (Both Bare Type – Taewoong) provides adequate palliation, null migration rate, and fair patency duration; features comparable with the best results reported in the literature. Stent-related adverse events were few and did not affect surgical intervention nor increased perioperative morbidity and mortality.

This study has some limitations: first, the study population is relatively small and second, the frequent loss of patients during the follow up time, which is the main bias of any data-collection follow up study. Current developments in anti-cancer therapies will improve survival in patients affected by DBS making it possible to get knowledge about generalizability and reliability of Niti-S Biliary Covered Stent (Both Bare Type) outcomes.

## DECLARATIONS

### **Author contributions**

Cocca S and Conigliaro R contributed to conceptualization; Cocca S contributed to writing—original draft; Santi M, Bertani H, Grande G, Marocchi M, Lupo M, and Russo S contributed to writing—review & editing; Bertani H and Conigliaro R contributed to supervision; Pignata L and De Gennaro N contributed to data curation and figures editing; Pignata L and De Gennaro N, and Pigò F contributed to formal analysis; Pigò F contributed to methodology; Grande G, Marocchi M, Lupo M, and Russo S contributed to resources; All authors have read and approved the final manuscript.

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### **Informed consent statement**

All study participants, or their legal guardian, provided informed written consent prior to study enrollment.

### **Conflict of interest**

All authors declare no potential conflicts of interest.

### Data sharing statement

No additional data is available.

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