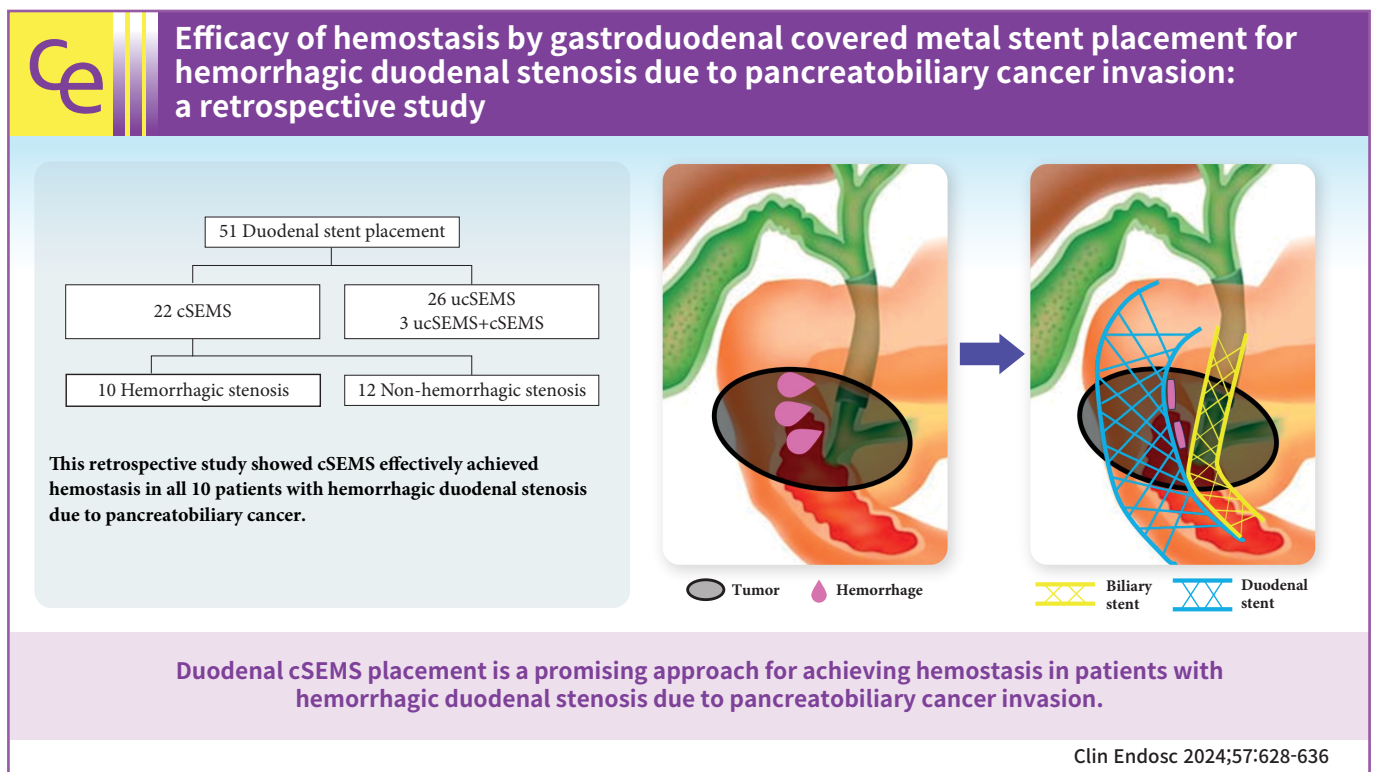


# Efficacy of hemostasis by gastroduodenal covered metal stent placement for hemorrhagic duodenal stenosis due to pancreatobiliary cancer invasion: a retrospective study

Yasunari Sakamoto<sup>1,2</sup>, Taku Sakamoto<sup>3</sup>, Akihiro Ohba<sup>1</sup>, Mitsuhito Sasaki<sup>1,4</sup>, Shunsuke Kondo<sup>1</sup>, Chigusa Morizane<sup>1</sup>, Hideki Ueno<sup>1</sup>, Yutaka Saito<sup>3</sup>, Yasuaki Arai<sup>5</sup>, Takuji Okusaka<sup>1</sup>

<sup>1</sup>Department of Hepatobiliary and Pancreatic Oncology, National Cancer Center Hospital, Tokyo; <sup>2</sup>Department of Gastroenterology and Hepatology, International University of Health and Welfare Atami Hospital, Shizuoka; <sup>3</sup>Endoscopy Division, National Cancer Center Hospital, Tokyo; <sup>4</sup>Department of Hepatobiliary and Pancreatic Oncology, National Cancer Center Hospital East, Kashiwa; <sup>5</sup>Department of Diagnostic Radiology, National Cancer Center Hospital, Tokyo, Japan



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Correspondence: Yasunari Sakamoto

Department of Gastroenterology and Hepatology, International University of Health and Welfare Atami Hospital, 13-1 Higashi-kaigan-cho, Atami-city, Shizuoka 413-0012, Japan

E-mail: yasakamo@iuhw.ac.jp

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**Background/Aims:** Advanced pancreatic and biliary tract cancers can invade the duodenum and cause duodenal hemorrhagic stenosis. This study aimed to evaluate the efficacy of covered self-expandable metal stents in the treatment of cancer-related duodenal hemorrhage with stenosis.

**Methods:** Between January 2014 and December 2016, metal stents were placed in 51 patients with duodenal stenosis. Among these patients, a self-expandable covered metal stent was endoscopically placed in 10 patients with hemorrhagic duodenal stenosis caused by pancreatobiliary cancer progression. We retrospectively analyzed the therapeutic efficacy of the stents by evaluating the technical and clinical success rates based on successful stent placement, degree of oral intake, hemostasis, stent patency, and overall survival.

**Results:** The technical and clinical success rates were 100%. All 10 patients achieved a gastric outlet obstruction scoring system score of three within two weeks after the procedure and had no recurrence of melena. The median stent patency duration and overall survival after stent placement were 52 days (range, 20–220 days) and 66.5 days (range, 31–220 days), respectively.

**Conclusions:** Endoscopic placement of a covered metal stent for hemorrhagic duodenal stenosis associated with pancreatic or biliary tract cancer resulted in duodenal hemostasis, recanalization, and improved quality of life.

**Keywords:** Duodenal obstruction; Gastrointestinal hemorrhage; Hemostasis; Pancreatic neoplasms; Self expandable metallic stents

## INTRODUCTION

Approximately 20% of pancreatic cancers (PCs) and some periampullary cancers, such as biliary tract cancer (BTC), are associated with duodenal stenosis and obstruction,<sup>1-3</sup> which should be treated either surgically or endoscopically when accompanied by gastrointestinal (GI) obstruction symptoms. However, owing to a poor performance status (PS) and prognosis, several patients are considered ineligible for gastrojejunostomy but are often considered eligible for endoscopic stent placement. Additionally, anemia and GI hemorrhage are observed in some patients due to tumor bleeding. Regarding bleeding from the tumor site, the National Comprehensive Cancer Network Guidelines on PC state that either angiography with embolization or therapeutic endoscopy should be performed if clinically indicated; alternatively, radiation therapy should be employed if not previously performed.<sup>4</sup> However, there is currently no detailed method for performing therapeutic endoscopy. As arterial bleeding is rarely associated with such tumors, transarterial embolization usually provides little benefit. Additionally, direct endoscopic hemostasis (e.g., using endoclips or coagulation forceps) can increase tumor necrosis-related bleeding. Only a few studies to date have reported the use of covered self-expandable metal stents (cSEMS) to treat cancer-related duodenal hemorrhage<sup>5-7</sup>; however, these stents are rarely used to treat duodenal wall invasion in patients with PC and BTC. Hemostatic peptide preparations have recently become available to facilitate endoscopic hemostasis of GI bleeding.<sup>8</sup> However, their efficacy in treating tumor bleeding from the GI invasion site in cases of pancreatobiliary cancer remains unknown. At the National

Cancer Center Hospital, Tokyo, Japan, we have successfully placed a cSEMS while performing compression hemostasis in several patients with duodenal hemorrhagic stenosis.

This study aimed to retrospectively evaluate the efficacy of nitinol (nickel-titanium) cSEMS placement in the treatment of malignant hemorrhagic duodenal stenosis in patients with PC and BTC.

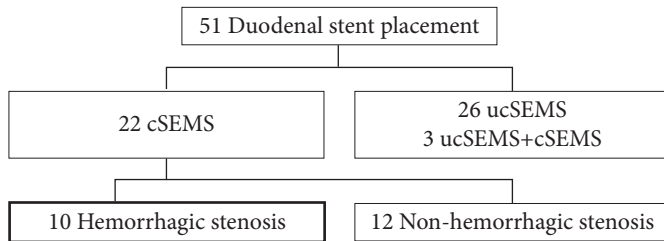
## METHODS

### Patients

Between January 2014 and December 2016, 51 patients underwent stent placement for duodenal stenosis due to unresectable PC or BTC at the National Cancer Center Hospital, Tokyo, Japan. An uncovered SEMS (ucSEMS) or cSEMS was selected for placement based on the state of the stenosis. Notably, ucSEMSs were placed in 26 patients, and cSEMSs were placed in 22 patients at risk of overgrowth after stent placement or bleeding from a stenotic lesion. Ten of these patients with duodenal hemorrhagic stenosis who underwent nitinol cSEMS placement were retrospectively examined (Fig. 1).

### Evaluation of duodenal hemorrhagic stenosis

Abdominal computed tomography and esophagogastroduodenoscopy (EGD) were performed to evaluate duodenal invasion and stenosis. Initially, the type of duodenal stenosis was assessed in all patients and categorized as follows: type I, stenosis occurring at the level of the duodenal bulb or upper duodenal genu but without involvement of the papilla; type II, stenosis affecting the second part of the duodenum and involving the



**Fig. 1.** Number and details of duodenal stent placement cases from January 2014 to December 2016. The bold boxes indicate the cases included in the study. cSEMS, covered self-expandable metal stent; ucSEMS, uncovered self-expandable metal stent.

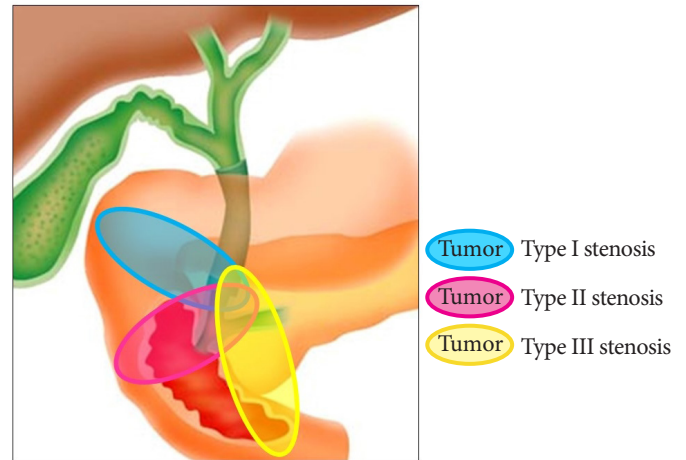
papilla; and type III, stenosis affecting the third part of the duodenum distal to the papilla but without involvement of the papilla (Fig. 2).<sup>9,10</sup> Patients 4, 8, and 9 had type II stenosis, patient 10 had type III stenosis, and the other six patients had type I stenosis. All of the patients exhibited decreased hemoglobin levels and melena at least once before the examination (Table 1). All of the patients, except patient 6, received a blood transfusion before the procedure; furthermore, all 10 patients required resolution of the hemorrhage. After the procedure, hemostasis was evaluated based on the absence of melena, as other causes related to secondary anemia (e.g., cancer progression, cachexia, and nutritional disorders) can alter hemoglobin levels.

### A self-expandable nitinol-covered metal stent

A nitinol cSEMS (Niti-S Combi Gastroduodenal Stent; Taewoong Medical) was constructed using a braided nitinol wire partially covered with a silicone membrane (Fig. 3). The distal end of the stent had a 1 cm uncovered portion, and the proximal end had a flared portion. The stent was 20 mm in diameter and 8, 10, or 12 cm long. The size of the stent-delivery system was 10.5 Fr.

### Stent placement strategy

A therapeutic forward-viewing endoscope (GIF 1T240; Olympus Medical Systems) was used for stent placement shortly after the onset of vomiting, hematemesis, and/or melena. Before the procedure, we performed an EGD to determine the positional relationship between the papilla of Vater and the expected site of duodenal stent placement. If the duodenal stent could cover the papilla of Vater, as in type I and III stenoses, we placed the duodenal stent so that the papilla of Vater was not covered and bile flow was not compromised. In patients with type II stenosis and some patients with type I stenosis, if there was a risk of cov-



**Fig. 2.** Types of duodenal stenosis due to tumor. Type I: Stenosis occurring at the level of the duodenal bulb or upper duodenal genu, but without papillary involvement (see light blue marker area). Type II: Stenosis affecting the second part of the duodenum and involving the papilla (pink marker). Type III: Stenosis affecting the third part of the duodenum distal to the papilla, without involvement of the papilla (yellow marker area).

ering the papilla of Vater due to the duodenal stent placement, the following steps were performed in all patients, except for those in whom the biliary stent had previously been endoscopically placed: (1) In cases where one stent was insufficiently long, two long-type biliary stents were serially inserted via the percutaneous transhepatic biliary drainage (PTBD) route and placed toward the duodenal anal side beyond the PC or BTC stenosis because it is difficult to endoscopically place a biliary stent toward the anal side. (2) A duodenal stent was placed to position these stents in parallel such that the biliary and duodenal stents were in a side-by-side position and did not interfere with each other (Fig. 4). This is a novel approach to treat biliary and duodenal obstructions.

### Stent placement procedure

After explaining the stent placement procedure, written informed consent was obtained from all of the patients before starting the procedure. The patients were placed in the left lateral decubitus position under moderate sedation with propofol. After confirming the duodenal stenosis via endoscopy, a catheter (PR-V614M, ERCP Cannula; Olympus Medical Systems) was passed through the stenosis over a guidewire (RevoWave-J type 0.035 inch hard; PIOLAX Medical Device) and placed at a site beyond the stenosis proximal to the jejunum. The through-

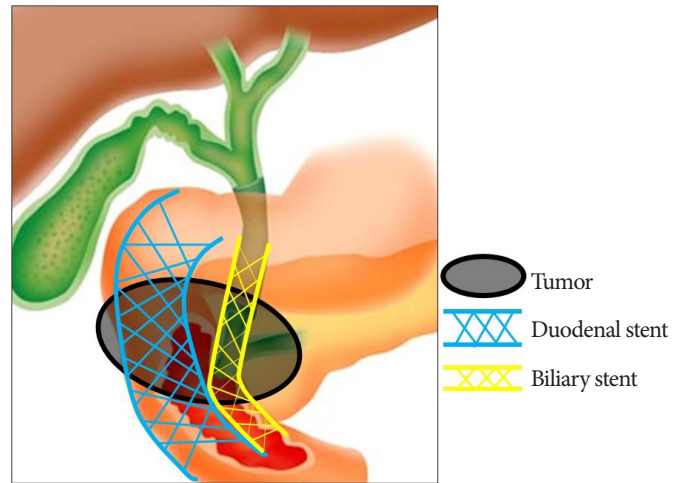
**Table 1.** Clinical features and clinical course of the patients

No.	Age (yr)	Sex	PS	Cancer site	Stenosis type	Duodenal cSEMS length (mm)	Biliary stent placement/route	Symptom		Level of Hb (g/dL)		Transfusion (unit)		Days after duodenal stent placement			
								Onset	Post <sup>b)</sup>	Pre <sup>a)</sup>	Post <sup>b)</sup>	Pre <sup>a)</sup>	Post <sup>b)</sup>	To refeed	Survival		
1	73	M	2	Ph	1	120 and 80	Same <sup>c)</sup> /PTBD	Anemia	Once melena	6.5	7.8	4	4	7	54	52	54
2	70	F	2	Ph	1	100	Prior <sup>d)</sup> /PTBD	Anemia Tarry stool	None	3.1	8.8	6	None	2	117	164	166
3	77	F	1	Ph	1	80	Prior <sup>d)</sup> /PTBD	Hemorrhage	None	6.2	9.5	2	None	2	193	220	220
4	73	F	2	Ph	2	100	Same <sup>c)</sup> /SBS/PTBD	Hemorrhage Tarry stool	None	6.3	10.1	2	None	2	77	52	77
5	45	M	1	Ph	1	100	Prior <sup>d)</sup> /EBD	Tarry stool	None	8.6	8.9	2	None	4	16	42	56
6	58	M	2	Hilar BD	1	120	Prior <sup>d)</sup> /PTBD	Tarry stool	None	7.2	8.1	None	2	3	94	92	102
7	64	M	2	GB	1	120	Prior <sup>d)</sup> /PTBD	Hemorrhage Tarry stool	None	6.3	7.8	8	8	1	32	31	32
8	82	M	3	Pb	2	120 and 80	Prior <sup>d)</sup> /SBS/PTBD	Hematemesis	None	8.4	8.7	2	None	1	13	93	93
9	47	M	2	Ph	2	120 and 100	Prior <sup>d)</sup> /SBS/PTBD	Tarry stool	Once melena	7.6	6.5	4	2	3	41	20	41
10	62	M	2	Ph	3	120	Prior <sup>d)</sup> /PTBD	Tarry stool	None	6.4	10.3	4	None	2	28	28	31
Med	67									6.45	8.75			2	47.5	52	66.5

PS, (Eastern Cooperative Oncology Group) performance status; cSEMS, covered self-expandable metal stent; Hb, hemoglobin; M, male; F, female; Ph, pancreas head; Pb, pancreas body; BD, bile duct; GB, gallbladder; PTBD, percutaneous transhepatic biliary drainage; SBS, side by side; EBD, endoscopic biliary drainage; med, median.



**Fig. 3.** Nitinol-covered self-expandable metal stent (Niti-S Combi gastroduodenal stent; Taewoong Medical).



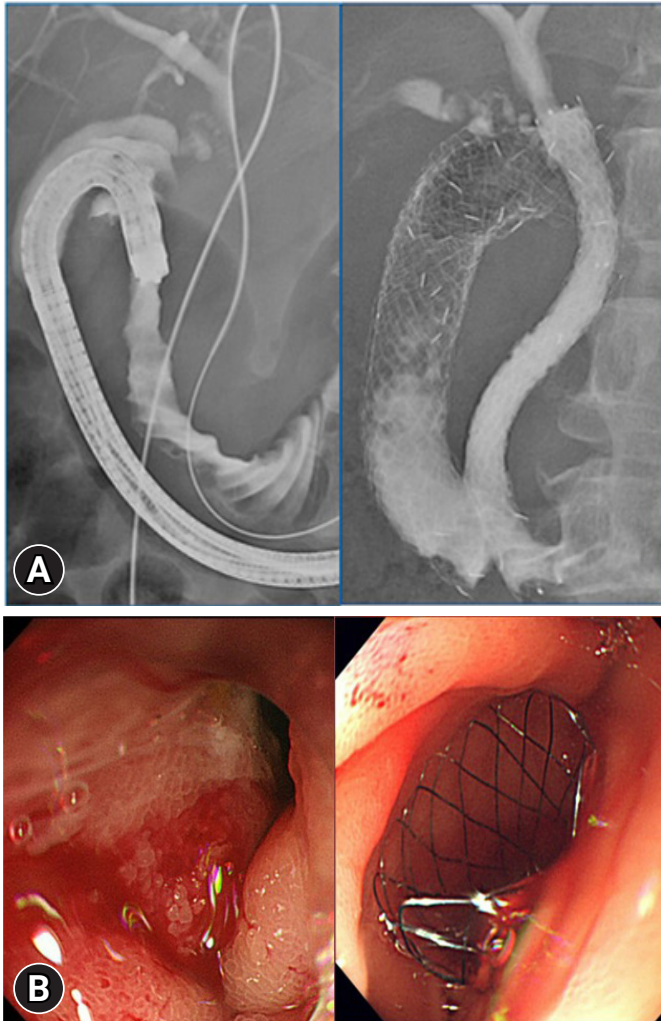
**Fig. 4.** Schematic outline of stent placement in a side-by-side position. We positioned the biliary and duodenal stents next to each other to avoid any interference.

the-scope method<sup>11,12</sup> was used to place the Niti-S Combi gastroduodenal stent, which was passed over the guidewire through the forceps channel of the endoscope from the distal end of the stenosis to the desired site of placement. Figure 5 shows the endoscopic procedures performed for patient 1.

**Observation after the procedure**

The day after stent placement, the clinical condition of the patients was monitored, and plain abdominal radiography and routine blood tests were performed. The patients were allowed to drink water if melena and GI symptoms were absent, their blood tests revealed no apparent abnormalities, and the stent was patent and well positioned on radiography. Patients who





**Fig. 5.** Patient 1: Simultaneous placement of biliary and duodenal stents. (A) X-ray showing the simultaneous placement of biliary and duodenal stents. (B) Endoscopic image showing stenosis and bleeding in the duodenum immediately after the stent placement.

remained asymptomatic after drinking water were permitted to consume a liquid diet. Gradually, a semi-liquid low-residue diet was introduced. When the patients tolerated a normal diet, they were discharged or transferred to a palliative care unit. After discharge and transfer to another hospital, a follow-up survey was conducted to assess the ability of the patients to eat normally and the presence of rebleeding, including melena.

### Evaluation

The technical and clinical success rates of the procedures were evaluated. The technical success rate was defined as successful stent placement and deployment across the stricture. The clinical

success rate was defined by the degree of oral intake, which was assessed using the adapted gastric outlet obstruction scoring system (GOOSS; no oral intake, 0; liquids only, 1; soft solids, 2; low-residue or full diet, 3).<sup>13</sup> All of the patients except for patient 4 could eat, with a GOOSS score of 3 two weeks before the procedure. As patient 4 had pancreatitis due to biliary stent placement, fluids were administered intravenously for more than two months, during which the patient exhibited improvement. Accordingly, patient 4 had a GOOSS score of 2 prior to the procedure. All of the patients had advanced cancer, and their activities of daily living were evaluated before and after the procedure based on the Eastern Cooperative Oncology Group PS<sup>14</sup> (Table 1).

After the procedure, any occurrences of recurrent stenosis; rebleeding, including melena; or other adverse events were recorded. Stent patency was defined as the number of days that the patients could tolerate oral intake after stent placement. Furthermore, the date of death was determined via follow-up and surveys, and overall survival (OS) was defined as the duration that the patients survived after the procedure. To evaluate the survival duration, deaths before the recurrence of duodenal obstruction were defined as censored cases.

To compare the efficacies of duodenal ucSEMS and cSEMS placement, we investigated the duration of stent patency, survival after stent placement, and complications in 26 patients with pancreaticobiliary cancer who underwent ucSEMS placement during the study period.

### Ethical statements

This study was approved by the Institutional Review Board of the National Cancer Center Hospital (no. 2018-149).

### Data availability statement

The raw data for this study were obtained from the National Cancer Center Hospital. The data supporting the findings of this study are available from the corresponding author upon request.

## RESULTS

The clinical features and disease courses of the study participants are summarized in Table 1. This study included 10 patients (seven men and three women; median age of 70 years), eight of whom had PC and two had BTC. The pre-treatment PS of the participants ranged from 1 to 3. All of the patients had

biliary stenosis and underwent biliary stent placement. Eight patients underwent biliary stent placement prior to duodenal stent placement. One patient (patient 7) had previously undergone duodenal stent placement and restenting for hemorrhagic stenosis accompanied by tumor overgrowth. All of the patients exhibited melena or tarry stools, with evidence of progressive anemia, and some had GI hemorrhage, as indicated by EGD. All of the patients exhibited duodenal stenosis, difficulty eating in the two weeks before the procedure, and anemia related to tumor bleeding. Of the 10 patients, nine received blood transfusions before the procedure.

The technical success rate of duodenal stent placement was 100%, even in patients who underwent biliary stent placement before the duodenal stent placement. A metal stent was placed in the bile duct across the duodenal papilla via the PTBD route in nine patients (Table 1). Although mild acute pancreatitis was observed in three of these nine patients (33.3%) (Patients 7–9), the condition of all of the patients promptly and conservatively improved. Only patient 8 required puncture of the nondilated bile duct at the time of PTBD, which was successfully performed without any notable complications.

The median duration between duodenal stent placement and diet resumption was 2 days (range, 1–7 days). Within two weeks after the procedure, all of the patients achieved GOOSS scores of 3, and the clinical success rate was 100%. None of the patients experienced a worsening of PS after the procedure. Two patients (Patients 1 and 9) exhibited melena only on the first day after the procedure, indicating blood accumulation in the duodenum. As none of these patients exhibited definite symptoms of melena recurrence, their hemostatic condition was not assessed via endoscopy after the procedure. Two patients (Patients 6 and 9) experienced mild acute pancreatitis on the day after duodenal stent placement, which resolved the day after conservative treatment. No recurrence of pancreatitis or jaundice was observed. Moreover, no stent migration was observed during the follow-up. Two patients (Patients 4 and 9) exhibited stent occlusion due to tumor overgrowth and required new duodenal stents. The median follow-up period was 47.5 days (range, 13–220 days). The median stent patency duration and OS after stent placement were 52 (range, 20–220) and 66.5 (range, 31–220) days, respectively. Three patients (Patients 2–4) resumed chemotherapy.

The median stent patency duration and OS in 26 patients with pancreaticobiliary cancer who underwent duodenal ucSEMS placement at the National Cancer Center Hospital were 44 (range,

1–173) and 47.5 (range, 13–185) days, respectively. The complications noted among these patients were five cases (19.2%) of stent dilation failure, as well as stent migration, acute pancreatitis, and enteritis in one case (3.8%) each.

## DISCUSSION

In the present study, nitinol cSEMS effectively achieved hemostasis in patients with hemorrhagic duodenal stenosis due to PC or BTC, with resolution of both the obstruction and GI hemorrhage during the endoscopic procedure. After stent placement, all of the patients were able to resume oral intake and eventually tolerated a solid diet, which was gradually reintroduced depending on their condition. This is the first comprehensive report of hemostasis using an undocumented method for hemorrhagic duodenal stenosis caused by pancreaticobiliary cancer.

The hemostatic mechanism for hemorrhagic duodenal stenosis is related to compression hemostasis and silicone stent covering, which creates a barrier in the duodenal wall against the mechanical stimuli of food and digestive enzymes, as shown in a case series on hemostasis in patients with uncontrolled post-endoscopic sphincterotomy bleeding.<sup>15</sup> Based on our findings, we hypothesize that the silicone stent covering helps prevent both hemorrhage recurrence and tumor ingrowth.

In the present study, tumor overgrowth was noted in two (20%) of the 10 patients. According to several studies with larger sample sizes (16–366 individuals), the rate of tumor overgrowth after the placement of covered duodenal stents ranged from 0% to 13%.<sup>16–20</sup> However, only a few studies to date have reported overgrowth rates without an ingrowth rate. Although previous studies have indicated that the rate of duodenal cSEMS migration is 9.5% to 56%, which is higher than that of ucSEMS migration,<sup>16–18,20–24</sup> no duodenal stent migration was observed in our study. Several studies have reported a median duodenal cSEMS patency duration of 68 to 139 days<sup>16,17,19,21,23,24</sup>; however, the patency duration in our retrospective study was only 52 days. Although most patients in our study did not experience recurrence of duodenal obstruction, the stent patency duration in our study was shorter than that reported in earlier studies, which may be attributed to the shorter median OS period (66.5 days) in our patients. Although these data appear to be better than the ucSEMS data at the National Cancer Center Hospital, we could not confirm this because we did not compare them in a prospective study.

PC and BTC are associated with a poor prognosis. Most

patients with PC or BTC who undergo duodenal stent placement are at an advanced cancer stage. Our study supports this finding because only three of the 10 patients could resume chemotherapy. Although the patency duration in our study was shorter than that in previous studies, we treated patients with pancreatobiliary cancer who had a poor prognosis and all of the patients had previously undergone cancer treatment for various durations. Furthermore, none of the patients died of tumor hemorrhage. Our patients benefited from stent patency and hemostasis.

In our study, in the three patients with type II stenosis, duodenal and biliary stents were placed side-by-side, and these patients did not experience difficulty with eating or biliary drainage, confirming the absence of stent-related adverse events after the procedure. To the best of our knowledge, no reports have been published to date on side-by-side positioning of stents in the duodenum. Such side-by-side placement of stents is technically easier than the stent-in-stent method<sup>25-29</sup> because it facilitates direct control of each device. Moreover, the advantage of direct viewing offered by an endoscope in the stenotic segment cannot be utilized in the stent-in-stent method. The stent-in-stent method can occasionally be challenging because of the difficulty of viewing the papilla of Vater through the mesh from the endoscope inside the duodenal stent. Additionally, if a biliary stent cannot be placed under endoscopic guidance, the patient may eventually require PTBD. In the present study, acute pancreatitis developed in three (Patients 7-9) out of nine (33.3%) patients who underwent bile duct stent placement across the papilla of Vater via the PTBD route and in two of 10 patients (20%) after duodenal stent placement; however, all cases were mild and rapidly and conservatively improved. Previous reports have indicated that the incidence rates of acute pancreatitis due to percutaneous biliary stent and duodenal stent placement are 3.8% to 24.2%<sup>30-33</sup> and 1.1% to 2.4%,<sup>19,20</sup> respectively. Although the incidence rate of complications of acute pancreatitis was slightly higher in the present study, only a small number of cases were included, making simple comparisons challenging.

This retrospective study has several limitations. First, the number of patients included was small. Second, we did not endoscopically assess the GI bleeding status after the procedure. However, none of the patients had melena or tarry stools, except for two who had tarry stools only on postprocedure day 1. Therefore, we believe that the presence of these stool samples indicates their accumulation in the duodenum. Finally, we

did not follow-up all of the patients until death because some patients with pancreatobiliary cancer were transferred to a palliative care center. However, to the best of our knowledge, the patients in this study who were transferred to another hospital did not experience rebleeding.

Our procedure improved the quality of life of all 10 patients, and oral intake was resumed. Seven of the 10 patients were already receiving palliative care at the time of duodenal stent placement, but the other three patients were able to resume chemotherapy. After treatment for acute pancreatitis, patient 4 could not receive anticancer therapy for an extended period before achieving hemostasis; however, this patient resumed chemotherapy with gemcitabine approximately five weeks after hemostasis. Although her survival time was short, she was discharged from the hospital and resumed chemotherapy. Moreover, one patient (patient 3) survived for 220 days without stent occlusion. Unfortunately, all of the patients succumbed to cancer progression, but none of them died of GI hemorrhage. Therefore, duodenal cSEMS placement appears to be a promising approach for achieving hemostasis in patients with hemorrhagic duodenal stenosis. However, as this retrospective study included only ten patients, our findings need to be confirmed by large-scale prospective studies on hemostasis in patients with duodenal hemorrhagic stenosis due to PC and BTC.

### Conflicts of Interest

The authors have no potential conflicts of interest.

### Funding

None.

### Author Contributions

Conceptualization: YaS, TS; Data curation: YaS; Formal analysis: YaS; Project administration: YaS; Supervision: AO, MS, SK, CM, HU, YuS, YA, TO; Validation: AO, MS, SK, CM, HU, YuS, YA, TO; Writing—original draft: YaS; Writing—review & editing: all authors.

### ORCID

Yasunari Sakamoto	<a href="https://orcid.org/0000-0002-7614-2991">https://orcid.org/0000-0002-7614-2991</a>
Taku Sakamoto	<a href="https://orcid.org/0000-0002-0239-4977">https://orcid.org/0000-0002-0239-4977</a>
Akihiro Ohba	<a href="https://orcid.org/0000-0002-9153-3798">https://orcid.org/0000-0002-9153-3798</a>
Mitsuhiro Sasaki	<a href="https://orcid.org/0000-0002-3754-9027">https://orcid.org/0000-0002-3754-9027</a>
Shunsuke Kondo	<a href="https://orcid.org/0000-0001-9565-117X">https://orcid.org/0000-0001-9565-117X</a>
Chigusa Morizane	<a href="https://orcid.org/0000-0002-6560-7503">https://orcid.org/0000-0002-6560-7503</a>

Hideki Ueno <https://orcid.org/0000-0002-5936-6539>  
 Yutaka Saito <https://orcid.org/0000-0003-2296-8373>  
 Yasuaki Arai <https://orcid.org/0000-0003-2146-531X>  
 Takuji Okusaka <https://orcid.org/0000-0003-1729-807X>

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