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【 CASE REPORT 】

The Dramatic Haemostatic Effect of Covered Self-expandable Metallic Stents for Duodenal and Biliary Bleeding

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Abstract:

Bilio-duodenal bleeding, such as post-endoscopic sphincterotomy (EST) bleeding, common bile duct (CBD) bleeding after endoscopic retrograde cholangiopancreatography (ERCP), and duodenal bleeding due to malignant tumour invasion, can sometimes become severe. Six cases of refractory bilio-duodenal bleeding were stanched via covered self-expandable metallic stent (CSEMS) insertion, even though three of the patients had a history of gastrectomy. The dumbbell-shaped CSEMS was useful for managing post-EST bleeding. Additional duodenal CSEMS insertion was useful for the patient who had previously undergone uncovered SEMS insertion, and no migration of the CSEMS was observed. CSEMS insertion was useful for treating refractory bilio-duodenal haemorrhaging.

Key words: bilio-duodenal bleeding, endoscopic retrograde cholangiopancreatography, covered self-expandable metallic stent

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Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) was first performed by McCune et al. (1); since its introduction, ERCP has played a key role in the diagnosis and treatment of pancreaticobiliary diseases. In particular, endoscopic sphincterotomy (EST) is efficient for endoscopic biliary stone removal or biliary stent insertion (2, 3). However, post-EST bleeding is observed in 0.3-12.7% of patients (4-9). Although several endoscopic methods, such as clipping, epinephrine injection, and transcatheter arterial embolization, are useful in stopping ampullary bleeding, it is sometimes difficult to stop severe haemorrhaging (4). Double stenting using self-expandable metallic stents (SEMSs) have been reported to be useful for treating malignant bilio-duodenal stricture (10-20). However, in such cases, severe bleeding from duodenal invasion from malignant tumours has been observed (21-24).

Recently, covered SEMS (CSEMSs) were used to stop bilio-duodenal bleeding (25-36). We herein report several cases of not only severe post-EST bleeding but also post-ampullectomy bleeding, common bile duct (CBD) haemorrhaging, and post-stenting duodenal haemorrhaging, that were successfully treated by CSEMS insertion.

Case Report

Six patients underwent endoscopic CSEMS insertion for severe bilio-duodenal bleeding between September 2019 and May 2020 (Table 1). All patients gave their written consent for endoscopic treatment.

The patients were 64-78 years old. Three patients had common bile duct (CBD) stones, two had pancreatic can-

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Table 1. Patient Characteristics.

No	Age	Sex	Bleeding site where the CSEMS was placed	Diseases	Anticoagulation drug	History of abdominal surgery	Bleeding grade	Procedure that caused haemorrhaging
1	78	M	Papilla of Vater	CBD stone	Warfarin	Total gastrectomy with Roux-en-Y reconstruction	Mild	EST
2	64	F	Papilla of Vater	CBD stone	None	None	Severe	EST
3	78	F	Papilla of Vater	Ampullary cancer	None	None	Severe	Ampullectomy
4	75	M	Papilla of Vater	Pancreatic cancer	None	None	Mild	EST
5	74	M	CBD	CBD stone	Edoxaban	Distal gastrectomy with Billroth-I reconstruction	Severe	Stone extraction
6	70	M	Descending portion of the duodenum (tumour invasion)	Pancreatic cancer	None	Pylorus preserving partial gastrectomy	Severe	Uncovered SEMS

CBD: common bile duct, EST: endoscopic sphincterotomy, SEMS: self-expandable metallic stent, CSEMS: covered SEMS

cers, and one had ampullary cancer. Patient 3 was diagnosed with adenoma by an endoscopic biopsy before treatment, but the pathological diagnosis proved to be slight adenocarcinoma in the adenoma that was resected by endoscopic ampullectomy. However, as this patient had dementia and a performance status of 3-4, additional surgery was not performed. Regarding anticoagulation drugs, Patient 1 took warfarin, and Patient 5 took edoxaban. Patient 1 did not stop taking warfarin before ERCP. Patient 5 stopped taking edoxaban one day before ERCP. Three patients had a history of gastrectomy.

Endoscopic procedure before bleeding

Regarding EST, the patients underwent side-viewing endoscopy with a gently inserted scope after they had been sufficiently sedated with midazolam. After the endoscope reached the descending portion of the duodenum, biliary cannulation was initiated. Next, the guidewire was placed in the biliary duct, and EST was performed. The Clever Cut (Olympus, Tokyo, Japan) was used as the sphincterotome. In one patient (Patient 1) who underwent total gastrectomy with Roux-en-Y reconstruction, a single-balloon enteroscope and the RX needle knife XL (Boston Scientific, Tokyo, Japan) were used as the endoscope and sphincterotome.

The patient with ampullary cancer (Patient 3) underwent endoscopic ampullectomy using a Captivator II 33 mm (Boston Scientific). After ampullectomy, biliary and pancreatic stents were inserted. The biliary stent used in this patient was the Zimmon double pig tail 7 Fr 7 cm (Cook Japan, Tokyo, Japan). The pancreatic stent used in this patient was the Geenen 5 Fr 7 cm (Cook Japan), which has two flanges on both ends.

A patient with pancreatic cancer (Patient 6) had a duodenal stricture, and an uncovered SEMS was inserted. The SEMS was a Niti-S 22 mm 10 cm (Taewoong-Medical, Gyeoenggi-do, Korea).

Criterion of bilio-duodenal bleeding and endoscopic haemostasis

When persistent bleeding was still observed after the scheduled procedure had been finished, endoscopic haemostasis was performed. When a sudden decrease in blood pressure, blackish faeces, or haematemesis was observed, urgent endoscopic haemostasis was performed.

Compression with a balloon catheter, clipping, or hypertonic saline epinephrine (HSE) injection was performed first. If bleeding continued after these treatments were performed, a CSEMS was inserted.

Endoscopic haemostasis

The bleeding sites were the papilla of Vater in four patients (Patient 1-4), CBD in one patient (Patient 5), and descending portion of the duodenum in one patient (Patient 6) (Table 1). The grades of bleeding were mild in two patients and severe in four patients. The bleeding grade was determined according to Cotton's criteria, which describe the classification of post-EST bleeding (6). Although a patient with duodenal bleeding was included in this report, the bleeding grade of this patient was evaluated as for the other patients.

Other endoscopic haemostasis techniques were performed in all patients before the insertion of a CSEMS (Table 2). Patient 5 had bleeding from the CBD; therefore, he temporarily received an endoscopic nasobiliary drainage tube. Patient 2 showed severe bleeding that could not be stopped by a clip, a balloon, or HSE (Fig. 1).

The selection of metallic stents was performed as follows: The BONASTENT M-Intraductal (Standard Sci Tech, Seoul, Korea) was used as the CSEMS in papilla of Vater bleeding without biliary stricture (Patient 1-3). In Patient 3, a biliary plastic stent was removed before CSEMS placement. The BONASTENT M-Intraductal is a dumbbell-shaped stent. The diameter of both ends is 10 mm, and the diameter of the central part of the stent is 8 mm. The 8-mm central part

Table 2. Treatment Outcomes.

No	Other treatment	Procedural time (min)	CSEMS	Diameter of CSEMS (mm)	Length of CSEMS (mm)	CSEMS removal time	Method of stent removal	Successful haemostasis	Adverse events	Rebleeding	Hospitalization after haemostasis (day)
1	Balloon	109	BONASTENT M-Intraductal	10 (both ends) 8 (central part)	50	1 month	Biopsy forceps	Success	None	None	3
2	Clip, HSE, epinephrine, balloon	120	BONASTENT M-Intraductal	10 (both ends) 8 (central part)	30	12 days	Biopsy forceps	Success	None	None	17
3	Clip, HSE	40	BONASTENT M-Intraductal	10 (both ends) 8 (central part)	40	None	None	Success	None	None	31
4	Balloon	60	HANARO	10	50	7 days	Stent removal forceps	Success	None	None	1
5	ENBD	45	HANARO	10	80	3 months	Snare	Success	None	None	9
6	Clip	11	Combi (Duodenal)	20	100	None	None	Success	None	None	35

HSE: hypertonic saline epinephrine, ENBD: endoscopic nasobiliary drainage, CSEMS: covered self-expandable metallic stent

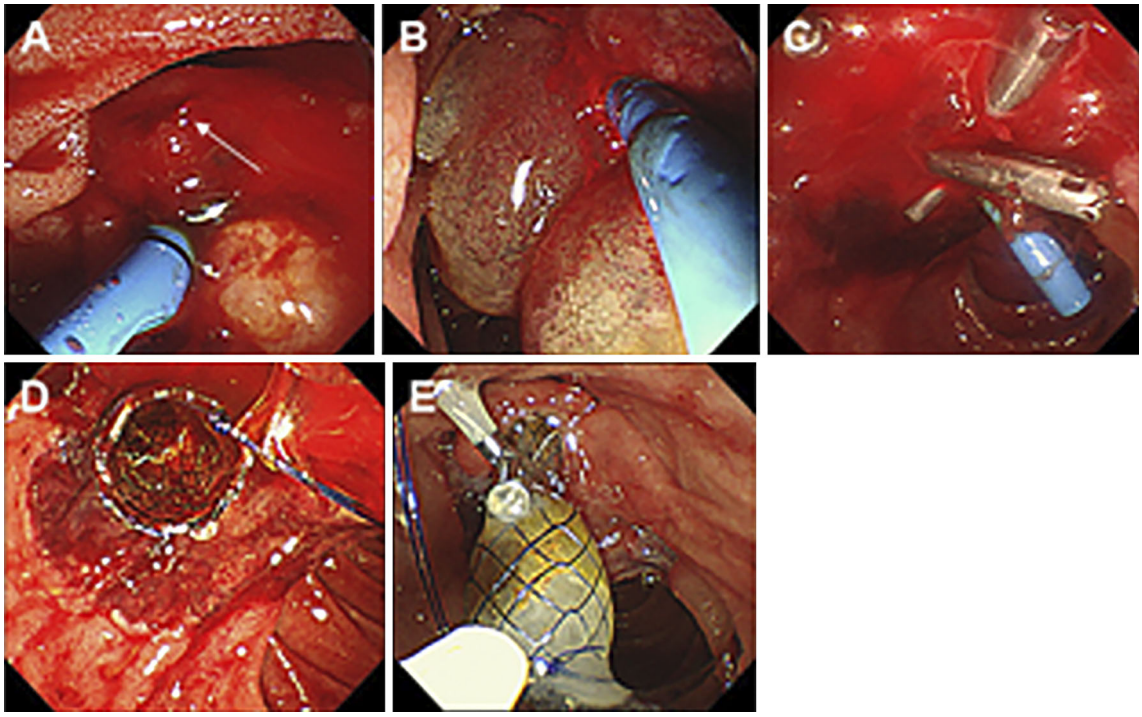

Figure 1. A patient with severe bleeding after EST. A: Patient 2 underwent ERCP to remove CBD stones. As ampullary oozing after EST was observed, endoscopic haemostasis was performed by a balloon catheter, and a biliary stent was inserted. However, frequent tarry stool and blood pressure decreases were observed after ERCP. Throbbing haemorrhaging was observed at the Papilla of Vater (arrow). B: HSE and epinephrine were injected around the bleeding site. C: After compression by a balloon catheter, HSE/epinephrine injection, and clipping, the bleeding persisted. D: Finally, a biliary CSEMS was inserted, and the bleeding of the Papilla of Vater was stopped. E: Four days after endoscopic haemostasis, haemorrhaging arrest was observed. EST: endoscopic sphincterotomy, ERCP: endoscopic retrograde cholangiopancreatography, CBD: common bile duct, HSE: hypertonic saline epinephrine, CSEMS: covered self-expandable metallic stent

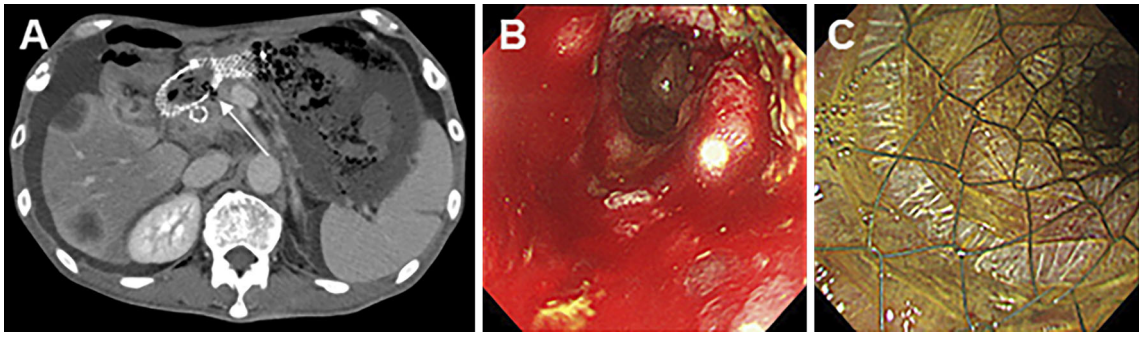

Figure 2. **A patient who experienced duodenal bleeding after SEMS insertion. A: Invasion of pancreatic cancer into the duodenal uncovered SEMS was observed by CT (arrow) (Patient 6). B: Bleeding from the exposed tumour was confirmed by endoscopy. A CSEMS was inserted to stop the bleeding. C: Two days after insertion of the CSEMS, haemostasis of the duodenum was observed. SEMS: self-expandable metallic stent, CSEMS: covered SEMS**

of the stent was positioned on the bleeding part. The BONASTENT M-intraductal used in this study was short (30-50 mm). The diameter of the central part was 8 mm, and the short length contributed to easy SEMS removal (27, 36). The HANAROSTENT fully covered metallic stent (M.I. Tech, Seoul, South Korea) was used in two patients (Patient 4, 5). In Patient 4, distal common bile duct stricture by pancreatic cancer was observed. Therefore, the HANAROSTENT (10 mm 5 cm) was selected for permanent placement. In Patient 5, CBD bleeding after endoscopic stone removal was observed. In that patient, CBD dilation was observed, and the bleeding was severe. In addition, he was taking an anticoagulation drug for heart disease. Therefore, a 10-mm CSEMS was selected for haemostasis.

Patient 6 had tumour invasion into the uncovered SEMS in the duodenum (Fig. 2), and diffuse oozing was observed in the descending part of the duodenum. He underwent insertion of a Niti-S Combi 20 mm 10 cm duodenal CSEMS (Taewoong Medical), and successful haemostasis was achieved.

All bleeding was stopped by CSEMS insertion. No adverse events were observed.

The course after endoscopic haemostasis

A second-look operation was not performed except for in Patient 6. If worsening of anaemia was not observed, food intake was started from the day following endoscopic haemostasis.

In benign biliary disease, CSEMS removal was performed one month after insertion. If any trouble occurred in CSEMS, the removal was performed before a month had passed. Among the four patients (Patient 1-4) with papillary bleeding, the CSEMSs were removed in three (Table 2). The CSEMS was not removed from Patient 3. She had dementia, and her activities of daily living worsened after hospitalization. The duration of CSEMS retention was 7 days to 1 month. In Patient 2, the CSEMS was obstructed by a clip. Therefore, the CSEMS was removed 12 days after insertion. In Patient 4, the tip of the CSEMS made contact at the curve of the CBD. Accordingly, the CSEMS was removed 7 days after insertion and changed to a Niti-S uncovered biliary stent large cell D-type 10 mm 10 cm (Taewoong Medical). These CSEMSs were removed using biopsy forceps or stent removal forceps.

In Patient 5, the CSEMS was removed by a snare three months after insertion. As mentioned above, he was taking an anticoagulation drug, and severe bleeding was observed. Therefore, the CSEMS insertion duration was longer in Patient 5 than in the other patients. In Patient 6, the CSEMS was not removed.

Rebleeding was not observed in any cases in this study. The duration of hospitalization after endoscopic haemostasis was 3-35 days. The duration was longer in patients with a low performance status than in those with a better status.

Discussion

In this case series, CSEMS insertion was efficient against refractory bilio-duodenal bleeding.

Haemostasis was achieved with CSEMS insertion for bilio-duodenal bleeding and has been described in 12 previous reports (Table 3) (25-36). These reports were almost all case reports. Six reports were of post-sphincterotomy bleeding, three were of CBD bleeding (one case of invasion due to hepatocellular carcinoma; two cases of bile duct varices), and the other three were cases of duodenal bleeding. The CSEMS used in these reports were the Hanaro (M.I. Tech), Niti-S ComVi (Taewoong), WallFlex, Wallstent (Boston Scientific, Natick, USA) stents. Haemostasis was achieved in all cases. Migration of the CSEMS was observed in two cases; however, a new CSEMS was inserted. In these case reports, the CSEMS was efficient in treating post-sphincterotomy bleeding that could not be stopped by other methods. As the first innovation of this study, Patient 1 had a history of total gastrectomy with Roux-en-Y reconstruction. As scope insertion to the papilla of Vater is complicated in patients who have undergone abdominal surgery, CSEMS insertion is desirable as a haemostasis method for

Table 3. Past Reports of Endoscopic Haemostasis Achieved Using a CSEMS for Bilio-duodenal Bleeding.

Reference number, year	Report type	Bleeding site	Other treatment	CSEMS	Successful haemostasis	Adverse events
(25), 2010	Case report (2 cases)	Papilla of Vater (after EST)	Balloon, epinephrine, clip	Wallstent	Success	None
(26), 2010	Case series (5 cases)	Papilla of Vater (after EST)	Balloon, epinephrine clip, thermal methods, IVR	WallFlex	Success	None
(27), 2011	Case series (11 cases)	Papilla of Vater (after EST)	Balloon, HSE, clip	Wallstent, WallFlex, Combi	Success	Migration
(28), 2012	Case report	CBD (invasion of HCC)	IVR	N/A	Success	None
(36), 2013	Case series (4 cases)	Papilla of Vater (after EST)	Balloon, epinephrine, clip	Hanaro, Niti-S, WallFlex	Success	None
(29), 2013	Case report	Duodenal bulb (metastatic HCC)	Epinephrine, clip, thermal methods	ComVi	Success	None
(30), 2013	Case report	CBD (varices, pancreatic cancer)	None	WallFlex	Success	None
(31), 2013	Case report	Papilla of Vater (after EST)	Balloon, epinephrine, thermal methods	N/A	Success	None
(32), 2015	Case report	Papilla of Vater (after EST)	Balloon	WallFlex	Success	None
(33), 2015	Case report	3rd portion of the duodenum (duodenal cancer)	Argon plasma coagulation, epinephrine	ComVi	Success	None
(34), 2016	Case report	CBD (varices, pancreatic cancer)	None	ComVi	Success	Migration
(35), 2016	Case report	3rd portion of the duodenum (duodenal cancer)	HSE, argon plasma coagulation	ComVi	Success	None

CSEMS: covered self-expandable metallic stent, EST: endoscopic sphincterotomy, CBD: common bile duct, HCC: hepatocellular carcinoma, IVR: interventional radiology, HSE: hypertonic saline epinephrine, N/A: not available

post-sphincterotomy bleeding to avoid frequent scope insertion. As the second innovation, we used a dumbbell-shaped SEMS for papilla of Vater bleeding. In a previous report, a short stent was identified as a risk factor for migration (36). In another report written by Itoi et al., SEMSs with a diameter of 10 mm were recommended to avoid migration (27). In other words, "8 mm, short CSEMS" means "easy to remove". Regarding papilla of Vater bleeding without biliary stricture, CSEMSs should be removed after haemostasis. Therefore, BONASTENT M-intraductal was selected for papilla of Vater bleeding, as this stent is easy to remove. In addition, the dumbbell form, with an 8-mm diameter for the central part and a 10-mm diameter for both ends, may help prevent stent migration. Given these points, the BONASTENT M-intraductal is thought to be useful for managing papilla of Vater bleeding without biliary stricture.

For CBD bleeding, a CSEMS should be considered as the first choice. Clipping, HSE, and thermal methods cannot be used for CBD bleeding. When the culprit vessel is evident, interventional radiology (IVR) is useful for CBD bleeding (37-39). However, haemostasis by IVR was not performed for Patient 5 because no culprit vessel was confirmed by contrast-enhanced computed tomography (CT). There have been only three reports concerning the efficacy of CSEMSs for CBD bleeding, including one case of hepatocellular carcinoma invasion and two cases of biliary varices. In a report written by Kawaguchi et al. (28), CBD bleeding could not be stopped by IVR, but the bleeding was stopped by CSEMS insertion. Given the above, a CSEMS might accommodate more types of CBD bleeding than IVR. However, CSEMS placement might be a risk factor for post-ERCP pancreatitis in patients without EST (40-42). Therefore, when a CSEMS is inserted into a patient with haemobilia who does not need EST (e.g., bleeding from a hypervascular tumour, bile duct varices), prophylaxis for post-ERCP pancreatitis (for example, pancreatic stent insertion) should be performed (43-45).

There have been three reports of duodenal bleeding treated by a CSEMS (29, 33, 35). All bleeding originated from malignant tumours and was difficult to stop by other treatments. These patients were successfully treated by CSEMS insertion. Patient 6 in this report previously underwent insertion of an uncovered SEMS for malignant duodenal stricture. In this case, migration of the CSEMS was a concern. However, duodenal bleeding was successfully stopped, and CSEMS migration was not observed. Additional CSEMS insertion may be useful for treating tumour bleeding in patients with an uncovered SEMS.

There is no consensus concerning the optimal CSEMS removal timing. In past reports, the duration of CSEMS placement for post-sphincterotomy bleeding was 3-15 days (27, 32, 36). The duration was approximately one week

in most cases. However, all cases reported by Itoi et al. showed mild-moderate bleeding (27), and more time might be needed to stop severe bleeding. In the present study, severe post-sphincterotomy bleeding was stopped 12 days after CSEMS placement in Patient 2. Therefore, the basic duration of CSEMS might be approximately one week, and the duration should be prolonged according to risk factors (anticoagulation or severe bleeding). Regarding CBD bleeding, all past reports were related to cancer (28, 30, 34). Therefore, when a CSEMS for CBD bleeding should be removed in cases of benign biliary diseases is unclear. As the CBD was thicker upstream than in the papilla of Vater, a longer duration of CSEMS placement might be needed.

CSEMS insertion is useful for treating refractory post-sphincterotomy/ampullectomy bleeding, including in patients with a history of abdominal surgery, and might be suitable as the first choice to achieve haemostasis of CBD bleeding. In addition, additional CSEMS insertion was useful for treating duodenal bleeding in patients with a previously inserted uncovered SEMS.

The authors state that they have no Conflict of Interest (COI).

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