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-
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, Gyeonggi-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                | Snare                 | 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
In Patient 4, the tip of the CSEMS made contact at the time. In Patient 2, the CSEMS was obstructed by a clip. Therefore, the CSEMS was removed 12 days after insertion.

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 time. In Patient 2, the CSEMS was obstructed by a clip. Therefore, the CSEMS was removed 12 days after insertion.

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 time. 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 time. In Patient 2, the CSEMS was obstructed by a clip. Therefore, the CSEMS was removed 12 days after insertion.

The 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...
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 hyper-vascular 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.

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**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 (2 cases)   | Case report | Papilla of Vater (after EST) | Balloon, epinephrine, clip | Wallstent | Success | None |
| (26), 2010 (5 cases)   | Case series | Papilla of Vater (after EST) | Balloon, epinephrine clip, thermal methods, IVR | WallFlex | Success | None |
| (27), 2011 (11 cases)  | Case series | 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 (4 cases)   | Case series | 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
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 (anti-coagulation 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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