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Effectiveness and safety of a new clip for delivery using a duodenoscope for bleeding after endoscopic sphincterotomy

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Abstract:

Hemostasis for post-endoscopic sphincterotomy (post-EST) bleeding involves no standard strategy. New clips designed for delivery using the duodenoscope (SureClip, Micro-Tech, Nanjing, China) have been utilized for gastrointestinal bleeding hemostasis and bleeding prevention after polypectomy and papillectomy. We retrospectively analyzed the effectiveness and safety of SureClip for post-EST bleeding.

Of 608 patients with endoscopic sphincterotomy (EST), 41 cases (6.7%) experienced post-EST bleeding from 2019 to 2023. Of these patients, 24 underwent hemostasis by SureClip, and the success rate of complete hemostasis and complication by hemostasis by SureClip was analyzed. In 12 and 12 patients with urgent and delayed bleeding, 11 (91.7%) and 11 (91.7%) had successful hemostasis, respectively. Additionally, missed patients achieved complete hemostasis by additional transcatheter arterial embolization and balloon compression, respectively. No complications were observed, including perforation, pancreatitis, and clipping bile duct and pancreatic duct by mistake.

Hemostasis by SureClip is safe and effective and not expensive for post-EST bleeding. It could be the first choice for hemostasis in patients with post-EST bleeding refractory for balloon compression.

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	Age	Sex	Indication	Comorbidities	Anti-	Bleeding	Number of	Size and	Clipping site	Outcome	Additional
					coagulants	occurrence	hemoclip	Number of	(o'clock		procedure
					/ Anti-	(urgent		hemoclip	direction)		
					platelet	/delayed					
1	60	N.4	Evenin etien		agents	(days))	2	C 2	11 12 12	Current	NI
T	68	IVI	for	HT, DM, HL	N	D (1)	5	53	11, 12, 13	Success	N
			Gallbladder cancer								
2	53	М	Acute cholangitis	Alcoholism	N	D (4)	3	M2 P1	12,14,16	Success	N
3	72	F	Choledocho- lithiasis	Lung cancer	N	А	3	S2 P1	12,14,15	Success	N
4	71	F	Acute cholangitis	HL, Cervical cancer	N	A	3	S2 P1	11,12,14	Success	N
5	92	F	Obstructive Jaundice	DM, HT, IHD, Pancreatic cancer	С	A	2	52	9,11	Success	N
6	81	F	Choledocho- lithiasis	HT	N	A	1	S1	12	Success	N
7	76	М	Choledocho- lithiasis is	HT, HL, CRF	Р	А	3	S3	10,11,12	Success	N
8	81	F	Acute cholangitis	Chronic hepatitis	N	A	2	S2	12,13	Success	N
9	79	Μ	Acute cholangitis	HT	N	A	1	51	12	Re- bleeding after 4 days	TAE
10	79	М	Stenting for obstructive	DM, HL, CHF, Pancreatic	N	А	2	54	11,12	Success	N

Supplemental Table 1 Patients with hemostasis by SureClip

			jaundice	cancer					
11	78	М	Choledocho- lithiasis	HT, Liver Cirrhosis	N	D (2)	4	M4	9,10,11,12
12	65	М	Choledocho- lithiasis	HT, DM, CHF	N	D (11)	6	M6	8,9,10,12, 13,14
13	79	F	Choledocho- lithiasis	N	Ν	А	2	M2	11, 12
14	60	Μ	Obstructive Jaundice	HT, DM, IHD, autoimmune pancreatitis	Р	D (9)	4	S4	9,11,12,13
15	86	Μ	Choledocho- lithiasis	Stroke, Paf	С	D (4)	2	M2	10,11
16	87	Μ	Choledocho- lithiasis	HT, DM, Paf	С	D (2)	1	M1	12
17	66	F	Examination for Gallblader cancer	HT, HL	N	D (1)	2	S1 P1	11,12
18	40	Μ	Choledocho- lithiasis	N	N	A	4	S2 P2	8,9,10,11
19	81	F	Obstructive Jaundice	DM, polycythemia vera, Pancreatic cancer	P	D (5)	4	M4	8,9,11,12
20	67	F	Obstructive Jaundice	Breast cancer	N	D (3)	2	M2	9,11
21	82	М	Choledocho- lithiasis	Stroke, IHD, CHF	С, Р	A	3	53	11,12,15
22	85	М	Choledocho- lithiasis	HT,DM,HL,Stro ke	Р	A	5	M5	8,9,10,11, 12
23	79	М	Acute	HT,DM,HL,Paf	С	А	4	M4	8,9,11,12

Success

Re-

bleeding after 3 days

Success

Success

Ν

Ν

Ν

Ν

Ν

Ν

Ν

Ν

Ν

Ν

Compre-

ssion

Ν

Ν

cholangitis

24	83	F	Examination	HL	Ν	D (1)	2	M2	10,12	Success	Ν
			for biliary								
			stricture								

M, male; F, female; Acute cholangitis, endoscopic biliary drainage for acute cholangitis; Choledocholithiasis, Extraction of choledocholithiasis; Obstructive jaundice, endoscopic biliary drainage for obstructive jaundice; HT, hypertension; DM, diabetes mellitus; HL, hyperlipidemia; IHD, ischemic heart disease; CRF, chronic renal failure; CHF, chronic heart failure; N, none; Paf, paroxysmal atrial fibrillation; C, Anti-coagulants; P, Anti-platelet agents; A, acute bleeding in Endoscopic sphincterotomy (EST); C (), delayed bleeding after EST (days after procedure); S, standard clip; M, mini clip; P, plus clip; TAE, transcatheter arterial embolization



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Introduction

Bleeding incidence after endoscopic sphincterotomy (EST) was 0.3%-2%, with 0.07%-0.5% in severe cases [1]. With recent changes in the administration of anticoagulants and antiplatelet agents for the procedure, it is important to now prioritize the prevention of thromboembolism for post-endoscopic sphincterotomy (post-EST) bleeding. Thus, a reliable and safe hemostatic method is warranted. Unfortunately, the standard hemostatic method for post-EST bleeding remains unestablished despite some guidelines [2,3]. One of the hemostatic methods is clipping for the bleeding site, but the traditional hemostatic clip is difficult to be correctly release using a duodenoscope. Thus, some physicians performed the clipping hemostasis using а forward-viewing endoscope, reporting the effectiveness of a cap-fitted forward-viewing endoscope for hemostasis

of post-EST bleeding [4,5]. Achieving good visualization for the bleeding site with a forward-viewing endoscope and correct clipping is usually challenging. Recently, new clips designed for delivery using a duodenoscope (Sure Clip, Micro-Tech, Nanjing, China) have been utilized for gastrointestinal bleeding hemostasis and bleeding prevention after polypectomy for gastrointestinal neoplasm and papillectomy for ampullary neoplasm [6]. We retrospectively analyzed the effectiveness and safety of SureClip for post-EST bleeding hemostasis.

Materials and Methods

Study design and patients

This retrospective, single-center, observational study included patients who underwent EST for biliary disease from January 2019 to December 2023 at the National Hospital Organization Kure Medical Center and Chugoku Cancer Center. We analyzed the characteristics of patients with post-EST bleeding, hemostatic methods, success rates of hemostasis by SureClip, and safety of SureClip.

This study complied with the principles of the Declaration of Helsinki, and the ethics committees of our institution (National Hospital Organization Kure Medical Center and Chugoku Cancer Center) approved the study protocol (Approval No. 2022-73). This trial was registered on February 13, 2024, in the University Hospital Medical Network Clinical Trials Registry as UMIN R000061171.

Endoscopic procedure

One expert endoscopist, who was board-certified by the Japan Gastroenterological Endoscopy Society and had vast experience in performing endoscopic retrograde cholangiopancreatography (ERCP) of at least 300 cases annually, performed all hemostasis procedures. All procedures were performed with a standard side-viewing endoscope (JF260, TJF260, and TJF290; Olympus, Tokyo, Japan). EST was performed at 11–12 o'clock using a standard pull-type papillotomy (CleverCut 3V, 20 mm, monofilament cutting wire, Olympus). The electronic units used during the operation included the ICC 200 or VIO 300D (ERBE, Tubingen, Germany).

Definition of post-EST bleeding

We defined patients with post-EST bleeding as two patterns. Continuous bleeding that requires any hemostatic procedure just after EST was defined as urgent bleeding. Additionally, abnormal melena or vomiting of blood after an endoscopic procedure and bleeding in the next evaluation was defined as delayed bleeding.

Strategy for hemostasis in post-EST bleeding

On bleeding, we first used compression hemostasis with a balloon catheter for a Vater papilla. We pressured an 8–10 mm balloon on the back wall for 5 minutes twice. We used SureClips if hemostasis was not achieved.

SureClip

SureClip is a new clip designed for delivery using a duodenoscope. It is a disposable hemoclip with an easy regrasping function, a controlled rotation orientation, and a possible complete release using an elevator function to some degree. It involves three clip types: Mini, Standard, and Plus, with an opening length of 8 mm, 11 mm, and 16 mm, respectively (Figure 1). We frequently used Standard clips. A Mini clip was used when the working space was small, whereas Plus clip was utilized when the bleeding site was a deep site.

Hemostasis by SureClip

The operative steps of releasing hemostatic clip were as follows (Figure 2 and Video). First, we exert delivery shortly from the scope and confirm the clip with the elevator. We open the clip, insert the right arm to the excision site, and close the clip. We added one or two clips around the former clip if hemostasis is achieved.

An elevator could lift the SureClip, but complete elevation was impossible. Thus, we sometimes needed to use an up-angle of the scope in clipping. Additionally, we needed to weaken the degree of elevation when releasing the clip. The semi-long position of the duodenoscope was used when the positioning of the scope was not good.

Outcomes

The primary outcome includes successful hemostasis by SureClip. Successful hemostasis was defined as hemostasis during the procedure with no rebleeding after a day. Secondary outcomes included the incidence of adverse events (closing the bile duct or pancreatic duct by mistake, pancreatitis, perforation, and other). Rebleeding was defined as hematemesis and melena after a hemostatic procedure and confirmation of bleeding during the reexamination. Post-ERCP pancreatitis was diagnosed with the diagnostic criteria by the Japan Ministry of Health, Labour and Welfare.

Results

Patient characteristics

We performed EST for 608 patients from 2019 to 2023. Post-EST bleeding was reported in 41 (6.7%) cases, including 21 (51.2%) and 20

patients with urgent and delayed bleeding, respectively. Table 1 presents patient characteristics. The median age of the patients was 76 years (40–93), and 21 (51.2%) were male. Choledocholithiasis extraction was the main indication for therapeutic endoscopic retrograde cholangiopancreatography (ERCP). Antiplatelet agents, anticoagulants, and both were administered to 8 (19.5%), 7 (17.1%), and 1 patient, respectively. The range of EST did not exceed the major duodenal horizontal fold in 37 (90.2%) patients and endoscopic papillary balloon dilation was added in 9 (22.6%).

Patient flow

All 21 patients with urgent bleeding achieved hemostasis by any hemostatic method in the procedure, but one patient demonstrated rebleeding after a few days and achieved complete hemostasis by SureClip. Of the 20 patients with delayed bleeding, 2 patients had rebleeding after a few days of first hemostasis and had hemostasis by SureClip and transcatheter arterial embolization (TAE), respectively. The first hemostasis attempt was successful in 37 (90.2%) patients. All patients had been managed without any adverse events (Figure 3, Table 2).

Hemostasis by SureClip

A total of 24 patients achieved hemostasis by SureClip. Results are shown in Table 2 and Supplementary Table 1. Urgent and delayed bleeding were reported in 12 and 12 patients, respectively. All patients achieved hemostasis in the first procedure but two demonstrated rebleeding after a few days. The success rate of hemostasis by SureClip was 91.7%. One case was sent to receive a TAE. No adverse events were reported, such as perforation, pancreatitis, and clipping bile duct and pancreatic duct by mistake.

Discussion

This study is the first case series study that analyzed the effectiveness and safety of SureClip for post-EST bleeding.

Post-EST bleeding is one of the complications that occur in ERCPassociated procedures. Fortunately, post-EST bleeding is most prevalently self-limited and stops spontaneously, but some cases experience severe bleeding and fatality. The recent tendency to prioritize thromboembolism prevention in endoscopic procedures will increase the incidence of severe bleeding now and in the future. Thus, it is necessary to have reliable hemostatic methods.

In general, endoscopic hemostatic methods for post-EST bleeding include balloon compression, epinephrine injection, thermocoagulation, and hemostatic clip. TAE and open surgery may be a salvage treatment option in uncontrolled cases by endoscopic technique. Recently, some reports have shown the efficacy of a covered self-expandable metal stents (cMS) placement [7] for uncontrolled bleeding before TAE and surgery. Additionally, the efficacy of a novel self-assembling peptide matrix (PuraStat; 3-D Matrix Europe SAS, France) has been reported for hemostasis in gastrointestinal endoscopic procedures, including post-EST bleeding [8].

These methods have limitations. Balloon compression is easy and safe, but can only control mild bleeding. An injection of diluted epinephrine (1:10,000) at the bleeding site exhibited a 4%-16% rebleeding rate with is a potential risk for patients with heart disease [1]. Thermocoagulation therapy includes argon plasma coagulation, bipolar probe, and heat probe, which is effective but may have a potential risk of perforation because of their power for tissue damage. CMS placement is reported to be effective for massive post-EST bleeding, but the technique does not have adaptation, and is very expensive. Moreover, the potential risk of adverse events, including pancreatitis and cholecystitis, is a major concern. PuraStat is not recommended for spurting bleeding and is not adapted for massive bleeding. TAE is an effective and safe therapy compared with endoscopic hemostasis because of the few negative effects of the technique on the respiratory and circulatory systems. The weak point of TAE is a high cost, long procedure time, and apparatus and full technique for angiographical therapy.

A shared technical problem in epinephrine injection, thermocoagulation therapy, and the traditional hemostatic clip is difficulty in hemostasis using a duodenoscope because the elevator is

8

not fully elevated when using each device. Thus, these hemostatic techniques are often attempted using a forward-viewing endoscope. Additionally, this technique has difficulty in hemostasis because Vater papilla cannot be easily confirmed from the front. Reports [4,5] revealed the efficacy of hemostasis by a forward-viewing endoscope with a front-end transparent cap, however, this is also a difficult technique for average endoscopists.

We have started hemostasis for post-EST bleeding using SureClip which makes clipping with the elevator function of the duodenoscope easy with a good success rate of hemostasis. There are some advantages in hemostasis by SureClip compared with other techniques. First, a hemostatic procedure is performed in a duodenoscope (no need to change the scope to a forward-viewing scope, easy confirmation of Vater papilla from the front). Second, SureClip exhibits an easy regrasping function, a controlled rotation orientation, and a possible complete release using an elevator function to some degree. Thus, correct clipping and redoing as mis-grasping can be performed. Some other clips have the same function as SureClip (the Resolution 360 clip, Boston Scientific, Massachusetts, U.S.A., etc.). Each clip may demonstrate a good hemostatic ability as SureClip. A comparison of each clip's ability was performed *in vitro* [9], but we have no data on clips other than SureClip.

The number of used hemoclips was a median of 3 (1-6), and

fundamentally, we added 1 or 2 clips near the clip that induced hemostasis. This was because we suspected that an additional clip near the first clip may prevent delayed bleeding. When we could not confirm a bleeding point, we first performed one clipping at any direction from 9 o'clock to 12 o'clock and added clipping while searching for the bleeding site until achieving hemostasis. The blood supply of the papillary region in the duodenum is most intensive from 9 o'clock to 12 o'clock. Hence, Dong, et al. revealed the effectiveness of prophylactic clipping to the 12 o'clock direction of Vater for post-EST bleeding[1].

The most welcome result was the absence of complications associated with clipping by SureClip. Especially, perforation and pancreatitis fearing an epinephrine injection, thermocoagulation, and cMS placement did not occur. SureClip is disposable and more expensive than a traditional reusable clip. It is approximately 22 USDollars per clip in Japan and the cost for hemostasis is equivalent or lower compared with a splaying PuraStat, thermocoagulation therapy, and cMS placement even if several clips are used. The weak point of clipping hemostasis is that it could cause an image distortion around the clip, including the pancreatic head although 3T magnetic resonance imaging can be performed before the clip falls off. Initially, we feared occurrence of pancreatitis by mis-clipping of the pancreatic duct. In practice, our experience with 24 patients indicated that there was little possibility of mis-clipping of the pancreatic duct because the bile duct and pancreatic duct are separated after EST. Thus, we think there is

little need to place a pancreatic stent for prevention of pancreatitis. This study has some limitations. First, this is a retrospective, single-center, and small-size analysis. Second, the effectiveness of SureClip could not be compared with other hemostatic methods, particularly, thermal therapy. Third, the population of patients with delayed bleeding included patients with no decrease in hemoglobin level, so some patients were not consistent with Cotton's diagnosis criteria for post-EST bleeding [10].

Hemostasis by SureClip using a duodenoscope is a relatively easy hemostatic method. Additionally, it is safe and inexpensive; thus, it could be a first choice for hemostasis in patients with post-EST bleeding refractory for balloon compression hemostasis.

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Figure legends

Figure 1. Three types of clips based on opening length (Mini, Standard, and Plus).

Figure 2. Hemostasis by SureClip for delayed bleeding 3 days after Endoscopic sphincterotomy (Figures 2a and 2b). We tried to achieve hemostasis by balloon compression (balloon size: 10 mm, 5 min, twice) but failed (Figures 2c and 2d). We achieved complete hemostasis by SureClip (Figures 2e and 2f).

Figure 3. Patient flow. Urgent and delayed bleeding were reported in 20 and 21 patients, retrospectively. One urgent bleeding of compression hemostasis had delayed bleeding and required hemostasis by SureClip. Two patients with delayed bleeding demonstrated rebleeding after the first hemostatic procedure. One patient had complete hemostasis by SureClip and the other by TAE. Video. Endoscopic hemostasis by SureClip

First, we attempted hemostasis by balloon compression and failed. Second, we achieved successful hemostasis with SureClip.



Patients' number with post-EST bleeding	41
Urgent bleeding : Delayed bleeding	21 : 20
Male, n (%)	21:20
Age, years, median (range)	76 (40 - 93)
Comorbidities, n (%)	
Hypertension	23 (56.1)
Hyperlipidemia	18 (43.9)
Diabetes Mellitus	15 (36.6)
Malignancy	6 (14.6)
Heart failure	11 (26.8)
Cerebrovascular disease	5 (12.2)
Liver cirrhosis	1 (2.4)
Dialysis	1 (2.4)
Medications, n (%)	
Antiplatelet drugs	8 (19.5)
Anticoagulants	7 (17.1)
Both of above	1 (2.4)
Laboratory data, median (range)	
Total bilirubin, mg/dL	1.4 (0.48 - 12.3)
Creatinine, mg/dL,	0.82 (0.42 - 6.5)
Albumin, g/dL	3.5 (1.8 – 4.9)
C-reactive protein, mg/dL	2.8 (0.04 - 43.9)
White blood cell count, $\times 10^2/\mu L$	67 (25 - 300)
Platelet count, ×10⁴/µL	20.7 (4.8 - 51.3)
PT-INR*	1 (0.88 - 1.5)
Objective for EST, n (%)	
Extraction of choledocholithiasis	21 (51.2)
Biliary drainage for acute cholangitis	8 (19.5)
Biliary drainage for obstructive jaundice	5 (12.2)
Stenting for obstructive jaundice	4 (9.8)

Examination for biliary tract	3 (7.3)
Vater papilla	
Previous EST, n (%)	5 (12.2)
Periammpullary diverticulum, n (%)	15 (36.6)
Procedure of EST	
EST (vs. EST + EPBD)	32 (78.4)
Excision not exceeding the major duodenal horizontal fold	37 (90.2)

Post-EST, post endoscopic sphincterotomy; Urgent bleeding, bleeding in the procedure; Delayed bleeding, bleeding after procedure; PT-INR, prothrombin time-international normalized ratio

EST, endoscopic sphincterotomy; EPBD, endoscopic papillary balloon dilation *There were data deficiencies of 5 patients.

Table 2. Results

All Patients, n	41
Urgent bleeding : Delayed bleeding	21:20
Time to bleeding in patients with Delayed bleeding, day,	4 (1-11)
median (range)	
Amount of decreased hemoglobin level in patients with	2.8 (-1.3 - 8.3)
Delayed bleeding, g/dL, median (range)	
Success of homostasis $n(0/)$	(1) (100)
	1(24)
Patients needed several procedure for hemostasis	4 (9 8)
Death associated with post-ES bleeding	0
Adverse events associated with hemostatic procedure	0
Patients with hemostatic procedure by Sure Clip, n	24
Urgent bleeding : Delayed bleeding	12:12
Success of hemostasis by Sureclip, h/N	11/12 (01 7)
Delayed bleeding	11/12 (91.7)
Additional therapy for patients with failed hemostasis	11/12 (31.7)
Compression by balloon catheter	1
TAE	1
Number of used clips, n, median (range)	3 (1 - 6)
Clipping site, o clock direction, n	12
8~12	15
12	3
12~16	5
8~15	5
Adverse events associated with hemostatic procedure	0
Dy Surecilp Clipping bild duct by mistako	0
Clipping bile duct by mistake	0
Pancreatitis	Ő
Perforation	õ
Others	0

Urgent bleeding, bleeding in procedure; Delayed bleeding, bleeding after procedure;

TAE, transcatheter arterial embolization



