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Endoscopic hemostasis with a self-expandable metal stent as bridge therapy for hemobilia

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ABSTRACT

Background and study aims Management of hemobilia is often challenging. Recently, endoscopic hemostasis with a self-expandable metal stent (SEMS) has shown promising efficacy for controlling bleeding at the endoscopic sphincterotomy site. This study aimed to assess efficacy and feasibility of endoscopic hemostasis as bridge therapy for hemobilia.

Patients and methods Patients with hemobilia between 2008 and 2023 were retrospectively reviewed. We compared efficacy of hemostasis between the initial endoscopic hemostasis group (ENDO group) and the initial angiographic embolization group (EMBO group). The primary outcome was initial hemostasis success rate and the secondary outcomes were delayed bleeding rate, subsequent embolization rate, 28-day mortality, transfusion amount, time to first hemostasis, total hemobilia time, and incidence of hypovolemic shock.

Results A total of 26 patients with hemobilia were included in this study and 17 patients (65.4%) were identified as the ENDO group and nine patients (34.6%) were classified as the EMBO group. The success rate of initial hemostasis was 88.2% (15/17) in the ENDO group and 100% (9/9) in the EMBO group ($P = 0.529$). The rate of delayed bleeding in the ENDO group was 17.6% (3/17) and 0.0% (0/9) in the EMBO group ($P = 0.529$). Total hemobilia time was shorter in the ENDO group than in the EMBO group (mean: 281.5 ± 1022.4 minutes vs. 5002.8 ± 7982.6 minutes; $P < 0.001$) Stent insertion depth was associated with successful hemostasis without delayed bleeding. ($P = 0.015$).

Conclusions Endoscopic hemostasis using SEMS for hemobilia appeared to be a feasible bridge therapy.

Introduction

Hemobilia refers to bleeding originating from the bile duct and has various causes, such as iatrogenic injuries and malignancies. Historically, hemobilia has been mainly caused by trauma, as evidenced by Sandblom's 1973 report, which highlighted that 38.6% of the 355 reviewed cases were traumatogenic causes, whereas 16.6% were iatrogenic causes [1]. However, with advances in medical procedures and the increase in hepatobiliary interventions, primary etiologies of hemobilia have shifted. In a 2001 case series by Green et al., 65% of 222 hemobilia cases had iatrogenic causes, with only 6% being traumatogenic [2].

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Hemobilia may be fatal if not managed effectively and promptly. Management of hemobilia is a significant challenge and angiography with radiologic intervention has long been the gold standard for both diagnosis and treatment of hemobilia [2, 3, 4, 5].

With the recent advent of biliary metal stents, the paradigm for management of hemobilia is shifting from angiographic embolization to endoscopic hemostasis because of its less invasive nature [5, 6]. Recent studies have shown that endoscopic hemostasis using the tamponade effect of a fully-covered self-expandable metal stent (fcSEMS) is effective for post-endoscopic sphincterotomy (post-EST) bleeding [7, 8, 9, 10]. In addition, fcSEMS is not limited to applications for post-EST bleeding but can also be used for hemostasis in cases of hemobilia, as described by several case reports [6, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20].

In cases where invisible hemobilia from bile ducts leads to patient instability, endoscopists may employ "bridge therapy"—a temporary stabilizing measure to manage the patient's condition until definitive angiographic or surgical treatment can be performed.

However, there is scant evidence showing that the effect of using endoscopic hemostasis, such as fcSEMS placement, as bridge therapy is sufficient for hemobilia, which is mainly caused by choledocholithiasis, the tumor itself, recurrent endoscopic procedures via bile ducts with ischemic damage, exposed intraductal small vessels, and other iatrogenic causes rather than EST. The aim of this retrospective cohort study was to investigate the feasibility of endoscopic hemostasis as a bridge therapy for hemobilia, in comparison with initial angiographic hemostatic methods.

Patients and methods

Study patients and study design

Patients who were diagnosed with hemobilia between July 2008 and August 2023 at Seoul National University Hospital were included in this study. Patients who experienced hemobilia after EST were excluded. Patients who underwent initial interventions such as endoscopic hemostasis, angiographic embolization, or surgery were included, and those who received only supportive care were excluded. Efficacy of the initial hemostatic methods was compared between the endoscopic hemostasis group (ENDO group) and the angiographic embolization group (EMBO group). The patients were divided based on the first hemostatic method into two main groups: 1) the ENDO group comprised patients who underwent endoscopic hemostasis as the initial hemostasis method without trying other treatments; and 2) the EMBO group comprised patients who underwent angiographic embolization as the initial hemostasis method. There were no strict indications differentiating between endoscopic hemostasis and angiographic embolization. Treatment choice was determined by the attending physician's clinical judgment at the time of intervention. Factors such as patient stability, accessibility of the bleeding site, and available resources might have influenced the decision-making process.

The study protocol was reviewed and approved by the Institutional Review Board of the Seoul National University Hospital (IRB number: H-2207–072–1339).

Stent products used in ENDO group

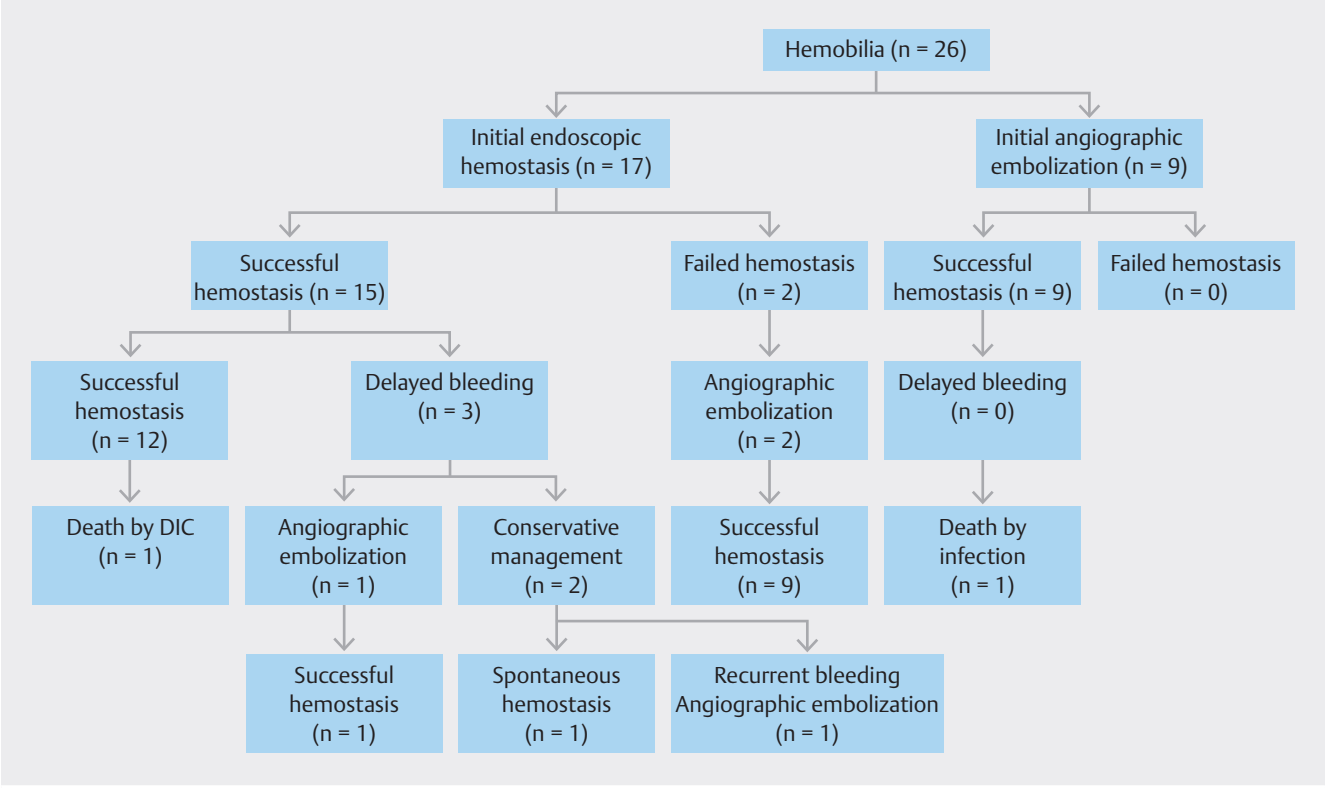
Stent products used in the ENDO group included BONASTENT biliary stents (SCI Tech), Niti-S COMVI biliary stents (Taewoong Medical), and ARISENT biliary stents (CGBIO), with sizes ranging from 6 mm to 10 mm in diameter and from 10 mm to 90 mm in length. (**Supplementary Data, Table 1**)

Definitions

Hemobilia was traditionally defined as bleeding originating from the bile duct. Recently, an expanded definition of hemobilia has become increasingly accepted, as shown in several studies on iatrogenic hemobilia [3, 4, 5]. In our study, we excluded patients with post-EST bleeding and included patients with bleeding from the bile ducts (common bile duct, common hepatic duct, intrahepatic ducts, cystic duct and gallbladder) where active bleeding was observed during endoscopic retrograde cholangiopancreatography (ERCP). Successful hemostasis was defined as when bleeding stopped, with no recurrence of bleeding within 24 hours after hemostatic intervention. Delayed bleeding was defined as clinical evidence of bleeding manifested by hemobilia, hematemesis, melena, or hematochezia from 24 hours to 30 days after the procedure [21]. Bleeding severity was assessed according to the European Society of Gastrointestinal Endoscopy Guideline [22]. Hemobilia onset was defined as the time when hemobilia was diagnosed by endoscopic evaluation. Time to first hemostasis was defined as the difference between hemobilia onset and the first intervention to perform hemostasis. Total hemobilia time was defined as the interval between hemobilia onset and the time of successful hemostasis without rebleeding and delayed bleeding.

Study outcomes and statistics

The primary outcome was initial hemostasis success rate and secondary outcomes were delayed bleeding rate, subsequent embolization rate, 28-day mortality, red blood cell (RBC) transfusion amount, time to first hemostasis, total hemobilia time, and incidence of hypovolemic shock. IBM SPSS Statistics for Windows, version 29.0 (IBM Corp., Armonk, New York, United States) and Python, version 3.12.3 were used to perform the statistical analyses. The chi-square test or Fisher's exact test was performed to compare the categorical variables, as appropriate. The Student's *t*-test or Mann–Whitney U test were performed to compare continuous variables, depending on data distribution. Survival analysis was performed to compare total hemobilia times using Kaplan-Meier curves, and comparisons between groups were made using the log-rank test. $P \leq 0.05$ was considered to indicate statistical significance. All *P* values were calculated using two-sided tests. The number-needed-to-treat (NNT) was calculated to assess efficacy of endoscopic hemostasis for reducing utilization of angiographic embolization procedures. Conversely, the number-needed-to-harm (NNH) was calculated to evaluate efficacy of endoscopic hemo-



▶ **Fig. 1** Flowchart of the study population. DIC, disseminated intravascular coagulopathy.

stasis in reducing occurrence of hypovolemic shock [23, 24]. We further analyzed clinical factors associated with successful endoscopic hemostasis without delayed bleeding in the ENDO group.

Results

Baseline characteristics

A total of 26 patients diagnosed with hemobilia were included in this study, and 17 (65.4%) patients were classified as the ENDO group and nine patients (34.6%) were classified as the EMBO group. None of the patients underwent surgical intervention for bleeding control during the study period (▶ **Fig. 1**). In the ENDO group, all patients were treated with endoscopic hemostasis with SEMS as the initial approach. There were no significant differences in baseline characteristics between the two groups except for the culprit vessel. fcSEMS was used for 15 patients and ucSEMS was used for two patients in the ENDO group (▶ **Table 1**).

Comparison of clinical outcomes in the ENDO and EMBO groups

Among all patients, the initial hemostasis success rate was 92.3% (24/26). Initial hemostasis success rates were 88.2% (15/17) in the ENDO group and 100% (9/9) in the EMBO group ($P = 0.529$). The delayed bleeding rate was 11.5% (3/26) among all patients and 17.6% (3/17) in the ENDO group, with no cases of delayed bleeding in the EMBO group ($P = 0.529$). One patient who underwent initial angiographic embolization died due to sepsis 21 days after angiographic embolization. Another patient who initially received endoscopic hemostasis with fcSEMS died 18 days after hemostasis due to disseminated intravascular coagulopathy. The average RBC transfusion amount was 4.44 packs (standard deviation [SD]: 4.67) overall, 4.00 packs (SD 4.57) in the ENDO group, and 5.10 packs (SD 5.00) in the EMBO group ($P = 0.597$). Mean times to first hemostasis were 1606.3 minutes (SD 4923.5) overall, 8.0 minutes (SD 6.2) in the ENDO group, and 5002.8 minutes (SD 7982.6) in the EMBO group ($P < 0.001$). Total hemobilia times were 1855.2 minutes (SD 5024.4) overall, 281.5 minutes (SD 1022.4) in the ENDO group, and 5002.8 minutes (SD 7982.6) in the EMBO group, and the differences were significant ($P < 0.001$ by the log-rank test) (▶ **Fig. 2**). The hypovolemic shock rate was 26.9% (7/26) overall, 23.5% (4/17) in the ENDO group and 33.3% (3/9) in the EMBO group ($P = 0.661$). The NNT for embolization was 1.214, and the NNH for hypovolemic shock was 2.314 in the ENDO group (▶ **Table 2**). Endoscopic photo data from representative cases of metal stent endoscopic hemostasis have been included in **Supplementary Data, Figure 1**.

Comparison of clinical outcomes in the ENDO group according to biliary stent characteristics

We further compared clinical outcomes of the 17 patients in the ENDO group according to stent type and biliary stent location. Among these patients, ucSEMS was used in two patients, both of whom achieved successful hemostasis, and one patient

▶ **Table 1** Baseline characteristics of study patients.

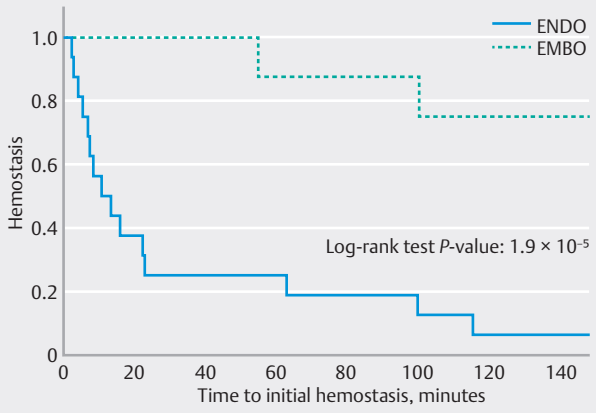
	Overall (n = 26)	ENDO (n = 17)	EMBO (n = 9)	*P* value
Male sex (n, %)	19 (73.1%)	14 (82.4%)	5 (55.6%)	0.188
Age (mean, SD)	67.6 (8.7)	69.3 (7.9)	64.9 (7.6)	0.339
Thrombocytopenia (n, %)	2 (7.7%)	2 (11.8%)	0	0.529
Liver cirrhosis (n, %)	5 (19.2%)	3 (17.6%)	2 (22.2%)	1.000
Culprit vessel				0.007
▪ RHA	13 (50.0%)	7 (41.2%)	6 (66.7%)	
▪ LHA	2 (7.7%)	0	2 (22.2%)	
▪ LGA	1 (3.8%)	0	1 (11.1%)	
▪ GDA	1 (3.8%)	1 (5.9%)	0	
▪ Unknown	9 (34.6%)	9 (52.9%)	0	
Etiology of bleeding				0.372
▪ Iatrogenic cause (Stent removal)	16 (61.5%)	11 (64.7%)	5 (55.6%)	
▪ Iatrogenic cause (Biliary stone removal)	1 (3.8%)	0	1 (11.1%)	
▪ Tumor bleeding	9 (34.6%)	6 (35.3%)	3 (33.3%)	
Cause of biliary obstruction				0.132
▪ Benign disease	4 (15.4%)	1 (5.9%)	3 (33.3%)	
▪ Bile duct cancer	9 (34.6%)	6 (35.3%)	3 (33.3%)	
▪ Hepatocellular carcinoma	5 (19.2%)	3 (17.6%)	2 (22.2%)	
▪ Liver metastasis	2 (7.7%)	1 (5.9%)	1 (11.1%)	
▪ Pancreatic cancer	6 (24.0%)	6 (40.0%)	0	
Type of biliary stent				
▪ fcSEMS	15 (57.7%)	15 (88.2%)	NA	
▪ ucSEMS	2 (7.7%)	2 (11.8%)	NA	
Previous biliary stent type				0.564
▪ Metal stent	8 (30.8%)	7 (41.2%)	1 (11.1%)	
▪ Plastic stent	17 (65.4%)	9 (52.9%)	8 (88.9%)	
▪ No previous stent	1 (3.8%)	1 (5.9%)	0	
Previous ischemic damage to bile duct*				0.230
▪ Yes	9 (34.6%)	5 (29.4%)	5 (55.6%)	
▪ No	17 (65.4%)	12 (70.6%)	4 (44.4%)	
Altered anatomy†				1.000
▪ Yes	6 (23.1%)	3 (17.6%)	2 (22.2%)	
▪ No	20 (76.9%)	14 (82.4%)	7 (77.8%)	

fcSEMS, fully covered self-expandable metal stent; GDA, gastroduodenal artery; LHA, left hepatic artery; RHA, right hepatic artery; ucSEMS, uncovered self-expandable metal stent

*Patients who underwent any procedure or surgery that could cause ischemic damage to the bile duct, including liver transplantation, liver laceration, liver segmentectomy, radio-frequency ablation, trans-arterial chemoembolization, portal vein embolization, or radiotherapy.

†Patients with altered anatomy that makes endoscopic procedures more difficult, including those who have underwent pancreatectomy, liver transplantation, or liver segmentectomy.

experienced delayed bleeding. The other 15 patients were treated with fcSEMS, among whom 13 successfully achieved hemostasis, but two patients did not. In these two patients, placement of fcSEMS was insufficiently deep to cover the previously inserted stents. Among the 13 patients who achieved hemostasis with fcSEMS, two patients had delayed bleeding.



▶ **Fig. 2** Comparison of total bleeding time in the ENDO and EMBO groups.

Clinical factors associated with successful endoscopic hemostasis

Clinical factors associated with successful endoscopic hemostasis without delayed bleeding are shown in ▶ **Table 3**. Clinical factors such as age, sex, thrombocytopenia, liver cirrhosis, bleeding etiology, biliary stent type, previous biliary stent type, previous bile duct ischemic damage, altered anatomy, RBC transfusion amount, time to first hemostasis, hypovolemic shock, and severity of bleeding were not significantly associated with the outcome ($P > 0.05$). Sufficiently deep stent insertion was significantly associated with the outcome, with successful hemostasis observed more frequently in patients with sufficiently deep stent insertion ($P = 0.015$).

Discussion

Although endoscopic management with fcSEMS has shown promising efficacy for post-EST bleeding, angiographic embolization remains the preferred treatment for hemobilia [11, 12, 13, 25]. However, for bleeding originating from the intrahepatic ducts, hilar bile duct, common hepatic duct, and common bile duct, clinical evidence about outcomes of endoscopic management using fcSEMS remains limited. Therefore, this study aimed to evaluate efficacy of endoscopic hemostasis in managing hemobilia in these challenging anatomical regions.

In this study, we observed no significant differences in outcomes between the ENDO and EMBO groups except for a shorter time to first hemostasis and total hemobilia time in the ENDO group. These findings suggest that initial endoscopic hemostasis is comparable to initial angiographic embolization for treating hemobilia. Notably, incidences of delayed bleeding and fatal complications were rare, lending support to the view that endoscopic hemostasis is a viable and effective approach in hemobilia management. The success of angiographic interventions largely depends on an interventional radiologist's expertise, a resource not readily available, particularly outside of ter-

▶ **Table 2** Clinical outcomes comparison of ENDO group with EMBO group.

	Overall (n = 26)	ENDO (n = 17)	EMBO (n = 9)	*P* value
Initial hemostasis success	24 (92.3%)	15 (88.2%)	9 (100%)	0.529
Delayed bleeding	3 (11.5%)	3 (17.6%)	0	0.529
Subsequent embolization	4 (15.4%)	4 (23.5%)	0	–
28-day mortality	2 (7.7%)	1 (5.9%)	1 (11.1%)	1.000
RBC transfusion (pack, mean, SD)	4.44 (4.67)	4.00 (4.57)	5.10 (5.00)	0.597
Time to first hemostasis (minute, mean, SD)	1606.3 (4923.5)	8.0 (6.2)	5002.8 (7982.6)	< 0.001
Total bleeding time (minute, mean, SD)	1855.2 (5024.4)	281.5 (1022.4)	5002.8 (7982.6)	< 0.001
Hypovolemic shock	7 (26.9%)	4 (23.5%)	3 (33.3%)	0.661
Severity of bleeding				
▪ Mild	1 (3.8%)	1 (5.9%)	0	
▪ Moderate	14 (53.8%)	10 (58.8%)	4 (44.4%)	
▪ Severe	11 (42.3%)	6 (35.3%)	5 (55.6%)	
NNT for angiographic embolization	–	1.214	–	–
NNH for hypovolemic shock	–	2.314	–	–

GDA, gastroduodenal artery; LHA, left hepatic artery; NNT, number-needed-to-treat; NNH, number-needed-to-harm; RBC, red blood cell; RHA, right hepatic artery; SD, standard deviation.

▶ **Table 3** Clinical factors associated with successful endoscopic hemostasis in ENDO group.

	Successful endoscopic hemostasis* (n = 12)	Failed endoscopic hemostasis (n = 5)	*P* value
Age			1.000
▪ Over median (> 71.8 years old)	6 (50%)	2 (40.0%)	
▪ Below median (≤ 71.8 years old)	6 (50%)	3 (60.0%)	
Sex			1.000
▪ Male	10 (83.3%)	4 (80.0%)	
▪ Female	2 (16.7%)	1 (20.0%)	
Thrombocytopenia			1.000
▪ Yes	2 (16.7%)	0	
▪ No	10 (83.3%)	5 (100.0%)	
Liver cirrhosis			0.191
▪ Yes	1 (8.3%)	2 (40.0%)	
▪ No	11 (91.7%)	3 (60.0%)	
Etiology of bleeding			1.000
▪ Iatrogenic cause	7 (58.3%)	3 (60.0%)	
▪ Tumor bleeding	5 (41.7%)	2 (40.0%)	
Type of biliary stent			0.515
▪ fcSEMS	11 (91.7%)	4 (80.0%)	
▪ ucSEMS	1 (8.3%)	1 (20.0%)	
Previous biliary stent type			1.000
▪ Plastic stent	6 (50%)	3 (60.0%)	
▪ Metal stent	6 (50%)	2 (40.0%)	
Previous ischemic damage to bile duct			0.600
▪ Yes	3 (25.0%)	2 (40.0%)	
▪ No	9 (75.0%)	3 (60.0%)	
Altered anatomy			1.000
▪ Yes	2 (16.7%)	1 (20.0%)	
▪ No	10 (83.3%)	4 (80.0%)	
RBC transfusion amount			0.280
▪ Over median (> 2.0 packs)	3 (25.0%)	3 (60.0%)	
▪ Below median (≤ 2.0 packs)	9 (75.0%)	2 (40.0%)	
Time to first hemostasis			0.294
▪ Over median (>7.233 minutes)	7 (58.3%)	1 (20.0%)	
▪ Below median (≤ 7.233 minutes)	5 (41.7%)	4 (80.0%)	
Hypovolemic shock			0.053
▪ Yes	1 (8.3%)	3 (60.0%)	
▪ No	11 (91.7%)	2 (40.0%)	
Severity of bleeding			0.600
▪ Mild/moderate	7 (58.3%)	4 (80.0%)	
▪ Severe	5 (41.7%)	1 (20.0%)	

▶ **Table 3** (Continuation)

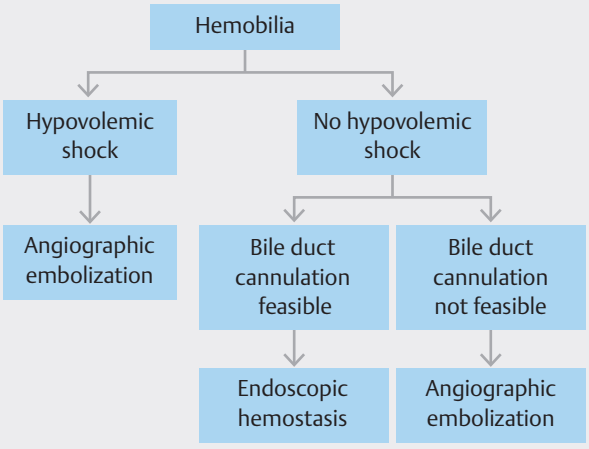
	Successful endoscopic hemostasis* (n = 12)	Failed endoscopic hemostasis (n = 5)	*P* value
Sufficiently deep insertion†			0.015
▪ Yes	12 (100.0%)	2 (40.0%)	
▪ No	0	3 (60.0%)	

fcSEMS, fully covered self-expandable metal stent; ucSEMS, uncovered self-expandable metal stent
*Successful endoscopic hemostasis means patients who experienced complete resolution of hemobilia with initial endoscopic hemostasis and without delayed bleeding.
†It means the placement of endoscopic stents for initial endoscopic hemostasis was sufficiently deep to cover the previously inserted plastic stent or the suspicious bleeding focus in the bile duct.

tiary care centers. Moreover, prioritizing these procedures in emergency scenarios is challenging, which highlights the importance of alternative or bridging therapies. Given these considerations, our study findings are significant because they provide evidence of the effectiveness of preemptive endoscopic measures as bridging therapy in managing hemobilia.

There are two key points of endoscopic hemostasis for hemobilia. First, it appears that the most appropriate type of stent is fcSEMS, which has a sufficient tamponade effect and is expected to act like a bandage, covering the culprit vessel arising from defective bile duct wall. Second, sufficiently deep stent insertion is important, considering the location of the previous stent. In the analysis of clinical factors associated with successful endoscopic hemostasis, stent insertion depth was significantly associated with the outcome. These findings highlight the importance of a sufficiently deep stent insertion to achieve successful hemostasis. The reason is that hemobilia occurring upon removal of the previously inserted stent probably originates from the bile duct wall mechanically damaged by the flap of a stent or adhesive tissue torn out by the stent. Therefore, endoscopic hemostasis with sufficiently deep fcSEMS insertion could be attempted within a safe limit as the first hemostatic method for bridging therapy to the angiographic embolization for hemobilia. We believe that this approach can reduce unnecessary angiographic embolization and may improve patient clinical outcomes. The NNT for embolization was 1.214 and the NNH for hypovolemic shock was 2.314, which means that treating 1.214 patients with endoscopic hemostasis as the initial intervention prevents one additional angiographic embolization procedure that would be required if angiographic embolization were used as the first treatment and that treating 2.314 patients with endoscopic hemostasis as the initial intervention prevents one additional hypovolemic shock that would occur if angiographic embolization were used as the first treatment.

We propose that the mechanism of hemostasis with ucSEMS involves multiple factors. Although ucSEMS lacks a covering film, which reduces the tamponade effect compared with fully-covered stents, the radial expansion force of ucSEMS still contributes significantly to hemostasis. The metal mesh exerts direct pressure on the bleeding focus, while the surrounding tissue also applies additional compression to the bleeding site. Together, these factors effectively control bleeding through mechanical compression. Of the two patients who underwent endoscopic hemostasis with ucSEMS, one achieved successful hemostasis without delayed bleeding, whereas the other achieved initial hemostasis but experienced delayed bleeding 8 days later.



▶ **Fig. 3** Proposed decision-making flowchart for hemobilia.

In this study, we suggest that endoscopic hemostasis can serve as a bridge therapy for hemobilia in certain patients, providing stabilization before definitive treatment with angiographic embolization. We propose a decision-making flowchart for hemobilia, as illustrated in ▶ **Fig. 3**.

A strength of this study is that most of the recent studies of bleeding after the ERCP procedure have focused on post-EST bleeding, and to the best of our knowledge, this is the first study involving a number of patients with hemobilia, excluding case series or case reports (**Supplementary Data, Table 2**). Unlike previous case reports, our study comprehensively analyzed multiple patients and compared them with patients who underwent angiographic intervention. These results are significant because they provide foundational evidence for appropriate management strategies using endoscopic methods in cases of hemobilia.

This study had several limitations. First, our study included a group of patients with heterogeneous etiologies of bleeding and various causes of biliary obstruction. We also included patients with tumor bleeding from various locations and those

with multiple iatrogenic causes, reflecting the diversity of real practice situations. Second, the retrospective single-center study design with a limited number of patients means that selection bias was possible. Despite this limitation, considering the rarity of the condition, it is important to note that our institution is a high-volume center that performs approximately 5000 procedures annually and that we reviewed data over a more than 10-year period, so the acquisition of a larger patient cohort would be challenging. A prospective study design would be necessary to overcome this limitation in the future.

Conclusions

Our study results showed that endoscopic hemostasis using fcSEMS for hemobilia might be feasible for bridge therapy. Endoscopists are encouraged to consider endoscopic hemostasis with fcSEMS placed sufficiently deep to cover the affected area in these cases.

Acknowledgement

Author contributions: SHL contributed to the study conception, design, performing endoscopy, critical review of the article for important intellectual content, and final approval of the article. Y-TK, JKR, WHP, IRH, and JHC contributed to critical review of the article for important intellectual content, and performing endoscopy. JK contributed to data collection, analysis, interpretation, drafting of the article, and revision of the article. TSL and MHL contributed to supervision of the study.

Conflict of Interest

The authors declare that they have no conflict of interest.

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