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Self-expandable metallic stents (SEMS) in esophageal varices post-band ulcer refractory bleeding: a retrospective study

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Abstract

Background: Post-variceal band ligation bleeding ulcer is a severe complication with considerable mortality. We tried evaluating self-expandable metallic stent (SEMS) with concern to the ulcer morphology not well studied.

Results: We did a retrospective analysis of patients with bleeding post-band ulcers and treated by SEMS with concern to control bleeding and 6 weeks survival. Twenty-eight patients studied had their age (mean ± S.D.) 57.8 ± 8.6 years, and 85.7% were males. The Child-Pugh score range was 5–12]. Control of bleeding by SEMS was achieved in 23 (82.1%) patients, and overall, 6-week survival was 75%. Both post-band ulcer types B (oozing blood and type C (active spurted) were a risk for 6 weeks mortality ($P = 0.04$, OR 1.58, CI 95% 1.12–2.23).

Conclusion: SEMS is considered an excellent choice to control esophageal post-banding ulcer bleeding and a definite treatment bridge.

Keywords: Liver cirrhosis, Portal hypertension, Varices, Post-band ulcer, Metallic stents, Bleeding

Background

Liver cirrhosis is a consequence of multiple etiologies that affect the liver. Chronic hepatitis C [1] and B viruses, non-alcoholic steatohepatitis, and alcoholic steatohepatitis are the most common leading causes of cirrhosis [2]. Patients with liver cirrhosis are classified into compensated or decompensated cirrhosis, according to Child-Pugh classification [3]. Further staging of cirrhosis depends on the development of varices, variceal bleeding, jaundice, hepatic encephalopathy, and ascites' development. The previous staging is the clinical presentation of portal hypertension that developed because of liver cirrhosis [4].

Esophageal varices are portosystemic venous channels and present in about half of patients diagnosed with cirrhosis. When portal pressure elevated to be clinically significant (hepatic vein portal gradient [HPVG] > 10 mmHg), portosystemic collaterals develop [5]. They at first create as little varices that continuously expand at a pace of 5% every year [6]. Screening for varices is an essential step in patients diagnosed with cirrhosis, and upper gastrointestinal endoscopy is the procedure of choice for defining, typing, and grading varices. Prophylaxis from 1st esophageal varices bleeding is achieved by either varices band ligation or non-selective beta-blocker administration [5, 7].

Acute variceal bleeding (AVB) is a well-known dangerous inconvenience in patients with cirrhosis. Current standard-of-care treatment incorporates the blend of vasoactive medications, band ligation, and anti-infection agents [8]. Endoscopic variceal band ligation (EVL) and pharmacological therapy for active esophageal variceal hemorrhage remain the first-line therapy. In most cases, band ligation outcomes are excellent, offering high initial hemostasis levels, low rebleeding rates, minimal side effects, and increased survival compared to sclerotherapy.

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Variceal ligation using an endoscope of diagnostic size can monitor excessive variceal bleeding with bands on active varix [9]. After EVL, the ligature bands stay in place for a range of 3 to 7 days. An ulcer remains that heals within 2 to 3 weeks. The thrombus formation is incomplete when the ligature band sloughs off, post-ligation ulcer bleeding occurs. Overall, the risk of post-EVL ulcer bleeding is 3.6 to 15% [5]. The placement of a transjugular intrahepatic portosystemic shunt (TIPS) is considered for patients with treatment failure or recurrent bleeding, but it is not applicable for all cases [10]. For 10–20% of cirrhotics refractory for medical and endoscopy therapy, alternative treatment options must mitigate the substantial morbidity and mortality associated with it [11]. Nevertheless, the 6-week mortality rate after an E.V. bleed index is approximately 20%. However, it varies from 0% among patients with Child-Pugh class A to roughly 30% among patients with Child-Pugh C disease [12].

Years ago, self-expanding metal stents (SEMS) were proposed in palliation for esophageal malignancy [13]. The fully covered SEMS is considered a rescue therapy in patients with refractory esophageal variceal bleeding. These stents can be deployed endoscopically in the lower esophagus with or without radiological assistance and easily removed later [14–16].

Methods

A retrospective study conducted on 28 patients with refractory bleeding post-band ulcers admitted to a specialized tertiary center (Hepatology and Gastroenterology Department), National Liver Institute, Menuofia University, Egypt, who received fully covered self-expandable metallic stents (FCSEMS) (NITI-S Mega stents-Tae Wong-S Korea) as a management of their refractory bleeding from post-variceal band ligation ulcer between January 2017 and December 2018.

During these 2 years, 1324 cases of hematemesis were admitted to our hospital, and 1096 cases had portal hypertensive cause of bleeding, and 612 had esophageal varices bleeding.

Prior endoscopic band ligation (EBL) treatments in the emergency setting, laboratory parameters, size of varices, and the bleeding episodes were recorded. The Child-Pugh score, MELD, MELD-Na, and ALBI were calculated. Rebleeding rates and mortality after SEMS placement were defined as primary efficacy endpoints within 6 weeks. Moreover, adverse events and the patients' clinical course were recorded. We recorded rates of successful bleeding control (≤ 5 days), early rebleeding (≤ 6 weeks), bleeding-related mortality (≤ 6 weeks), and overall mortality. Successful SEMS removal was defined as no rebleeding or death within 1 day after stent removal. Refractory acute variceal bleeding (failure-to-control bleeding) with vasoactive drugs and endoscopy was defined according to the Baveno IV and V guidelines [17, 18]: fresh hematemesis or aspiration of more than100 mL of new blood via the nasogastric tube beyond 2 h after the endoscopy and a 3 g/dL drop in hemoglobin without blood transfusion. According to the Baveno V guidelines, rebleeding was defined as evidence of rebleeding from portal hypertensive sources (hematemesis, melaena, aspiration of more than 100 mL of fresh blood in patients with a nasogastric tube or drop in hemoglobin of 3 g/dL without blood transfusion) [17, 18].

We classified post-banding ulcer endoscopically into (A) ulcer covered with clot; (B) ulcer oozing with blood; and (C) ulcer actively spurting.

We excluded patients with age < 18 years, intermediate and advanced HCC, the simultaneous presence of fundal varices, and previous attempts for balloon tamponade (B.T.) by sungestaken tube insertion management for refractory bleeding.

The technique of stent deployment

After sedation and adequate airway protection, the patient was placed in the left lateral position, the endoscope was passed into the esophagus, and a guidewire (0.035-in.) was established. The SEMS was loaded onto the guidewire and passed under fluoroscopic guidance. The radiopaque markers were helpful in the accurate positioning of the stent. Oral feeds with a liquid diet were started 12–24 h after the procedure, and patients were positioned at 45° in a supine position for 1 day.

No informed consent has been obtained in this retrospective study.

This study was conducted under the Declaration of Helsinki and approved by the ethics committees of our IRB.

Calculations

From online calculators

Child-Pugh

https://www.mdcalc.com/child-pugh-score-cirrhosis-mortality

ALBI

https://www.mdcalc.com/albi-albumin-bilirubin-grade-hepatocellular-carcinoma-hcc

MELD

https://www.mdcalc.com/meld-score-original-pre-2016-model-end-stage-liver-disease

MELD-Na

https://www.mdcalc.com/meldna-meld-na-score-liver-cirrhosis

Statistical analysis

Results were statistically analyzed using IBM SPSS version 21 for Windows. Variables were summarized as mean ± S.D., range, median, or frequency

(%), as appropriate. Student's t test was used to compare the results of all examined subjects in all groups under study. Odds ratio (OR) and 95% confidence interval (CI), and the chi-square test were used. Results were considered significant when $P \leq 0.05$.

Table 1 Demographic, clinical, and endoscopic characteristics of the patients:

Characteristics	Range	
Age, years (mean ± SD)	35–75	56.6 ± 9.4
Gender (male) NO %		24 (85.7%)
Cirrhosis aetiology (HCV/HBV) NO %		24 (85/7%)/4
Diabetes NO %		13 (46.4%)
Hypertension NO %		3 (10.7%)
Smokers NO %		9 (32.1%)
HCC NO %		5 (17.85%)
PVT NO %		6 (21.4%)
SBP at admission		12 (42.86%)
CTP class (A/B/C) NO %		3 (10.7%)/15 (53.6%)/10 (35.7%)
CTP score (mean ± SD)	5–12	8.6 ± 1.8/median 8
MELD at admission (mean ± SD)	8–42	15.7 ± 6.3
MELD Na at admission (mean ± SD)	10–42	20 ± 6.4
ALBI at admission (mean ± SD)	− 2.36 to − 0.14	− 1.36 ± 0.58
Post band bleeding presentation time	2–14 days	Median 10 days
Mean blood pressure (mean ± SD)	53–97	75 ± 10.8
Hemoglobin at admission g/dl (mean ± SD)	6.2–13.2	8.2 ± 1.45
Units of transfused blood (NO)	0–16	Median 2 units
Prophylactic antibiotics (NO)		
- 3rd cephalosporins		- 18
- Quinolones		- 4
- combined		- 6
Portal decompressive drugs (NO)		
- Sandostatin		- 14
- glypressin		- 14
OVs size (small:large) NO %		15 (53.57%)/ 13 (46.43%)
Post band ulcer NO %		
- Type A		- 9 (32.14%)
- Type B		- 7 (25%)
- Type C		- 12 (42.86%)

Results

Patients' characteristics

From our data, esophageal variceal bleeding was 46% of all cases of hematemesis present in our department, and refractory bleeding post-variceal band ligation was 4% of variceal bleeding cases.

As presented in Table 1, 28 patients studied had their age (mean ± S.D.) 57.8 ± 8.6 years, and 85.7% were males. Their Child score range 5–12 and the median was 8. Five patients had early-stage HCC. 21.4% of the patients had portal vein thrombosis (PVT). Patients presented with bleeding after previous band ligation either 1ry or 2ry prophylaxis for esophageal varices 2–14 days with 10 days median. On admission, their prognostic scores were MELD 15.7 ± 6.3, MELD Na 20 ± 6.4, and ALBI score − 1.36 ± 0.58. Patients needed 0–16 units of blood transfused with a mean of 2 units.

Bleeding post-banding ulcer (BPBU) classified endoscopically into (A) 32.14% ulcer covered with clot (9 patients); (B) 25% ulcer oozing blood (7 patients); and (C) 42.86% ulcer with active spurting (12 patients).

Post-SEMS placement outcomes (Table 2, Figs. 1 and 2, and Additional file 1)

Regarding control of bleeding, 3 (10.7%) patients had uncontrolled bleeding, despite stent insertion, and all died. Two patients experienced early rebleeding after

Table 2 Outcome data

	N (%)
Control of bleeding	
Uncontrolled	3
Re-bleeding	2 (1 stent displaced–1 post-stent removal)
controlled	23 (82%)
6 weeks survival (deceased/alive)	7/21 (75%)
Stent displaced	6 (21.43%) (1 re-stent and 3 re-positioned)
Stent-related complications (no. 4)	2 aspiration
	2 aspiration bronchopneumonia
Development of encephalopathy post-endoscopy (no. 9)	9 (32.1%)
Covert	3
Overt	6
6 weeks cause related mortality (no. 7)	
Bleeding	4 (14.3%)
Sepsis	1
MOF	2
Rescue therapy	2 sungestaken tubes (1 deceased)

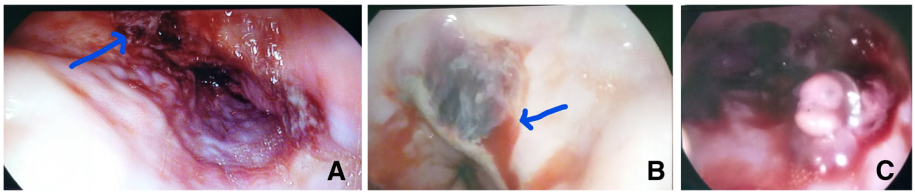

Fig. 1 **a** Type A ulcer with an adherent blood clot. **b** Type B ulcer with oozing blood. **c** Type C ulcer spurting blood

initial management. SEMS achieved bleeding control in 23 (82.1%) patients. From all patients, for 42 days follow-up, 14.3% of patients died due to bleeding. The mean days of survival were 34 (CI 95% 28–39) with 6 weeks survival 75%. Six (21.4%) patients' stents were displaced, and only one patient experienced rebleeding that was uncontrollable after sungestaken tube insertion, and he died. The others, one patient, undergone re-stenting, three stents repositioned, and one showed healed stable ulcers, so followed up. Successful stent removal was done in 20 (71.4%) patients from 23 who survived. At the same time, one patient had rebleeding after stent removal controlled by sungestaken tube insertion. Nine patients (32.1%) developed hepatic encephalopathy post-SEMS deployment. Two patients had aspirated, and another two patients developed aspiration pneumonia.

Identified risk factors for 6 weeks mortality after SEMS deployment

Univariate analysis was conducted (Tables 3 and 4) revealed that post-band ulcers other than type A, development of overt hepatic encephalopathy were a risk for 6 weeks mortality (P = 0.04, 0.02 respectively). Low baseline arterial blood pressure (65 ± 6.7, P = 0.003) and increased number of transfused blood units (5.4 ± 4.8, P = 0.006) were associated with 6 weeks mortality.

Discussion

Current guidelines recommend either balloon tamponade (B.T.), SEMS, or TIPS to manage refractory and endoscopically uncontrolled variceal bleeding [11, 19]. Nevertheless, the evaluation of SEMS in refractory bleeding post-band ulcers concerning ulcer morphology was not well studied.

In our study, we had a high rate of successful bleeding control in 82% of patients. Our rebleeding rate was so low that only one patient due to stent displacement and another after stent removal. A meta-analysis comprising n = 134 showed a failure-to-control bleeding rate of 14.2% [8]. Pfisterer and colleagues showed 1/3 of their cases achieved control of bleeding in their follow-up period. Also, they showed a higher overall rate of rebleeding, especially after stent removal (about 29.4%) [19]. In the previously mentioned meta-analysis, post-SEMS removal bleeding was 11% [8]. Another meta-analysis showed rebleeding rate was 13.2% [6]. This difference could be attributed to the type and diameter of SEMS used. In our study, a mega stent with a diameter of 28 mm that is fitting well on the esophageal wall.

Pfisterer stated that "bleeding-related mortality was as high as 47.1% (n = 16/34) of patients in our study, including 20.6% (n = 7/34) who deceased owing to uncontrolled bleeding" [19]. In our retrospective analysis, bleeding-related mortality was very low, 14.3 (n = 4/28), and this agrees with two recent meta-analyses, the first found 12% for mortality related to variceal bleeding, and

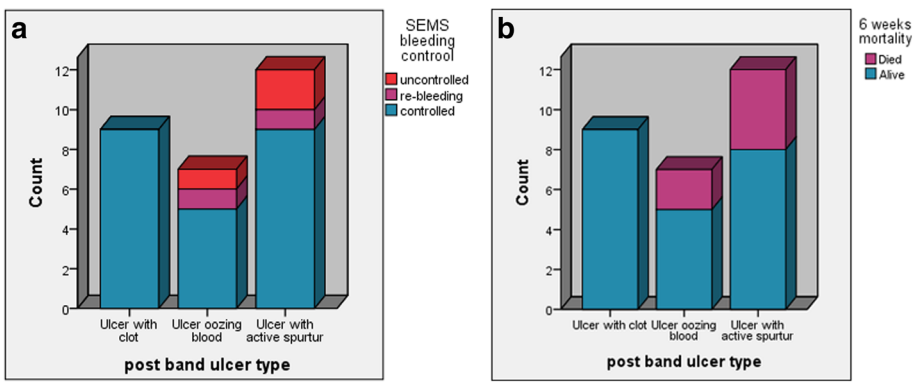

Fig. 2 **a** Control of bleeding. **b** Mortality after SEMS deployment according to ulcer type

Table 3 Univariate analysis for mortality 6 weeks follow-up

	6 weeks mortality Dead 7	6 weeks mortality Alive 21	Test	*P* value	CI 95%
Age, years	55.8 ± 10.38	58.5 ± 8.2	***T*** **− 0.68**	0.5	(− 10.45–5.2)
CTP score	8.7 ± 1.8	8.5 ± 1.8	***T*** **0.17**	0.86	(− 1.5–1.8)
MELD at admission	17.14 ± 11.45	15.24 ± 3.72	***T*** **2.8**	0.008*	(− 3.8–7.6)
MELD Na at admission	22.86 ± 9.65	19.05 ± 4.9	***T*** **3.1**	0.004**	(− 1.85–9.47)
Hemoglobin on admission g/dl	7.8 ± 1.2	8.4 ± 1.5	***T*** **− 0.84**	0.4	(− 1.85–0.77)
Mean blood pressure on admission	65.14 ± 6.74	78.3 ± 9.88	***T*** **− 3.2**	0.003***	(− 21.5 to − 4.5)
UNITS of blood	5.4 ± 4.8	2 ± 1.5	***T*** **2.9**	0.006***	(1.05–5.8)
ALBI	− 1.16 ± 0.69	− 1.42 ± 0.54	***T*** **1.03**	0.3	(− 0.25–0.77)

* means significant

18% for failure to control bleeding with SEMS [8], and the second found 12.6% of patients died from uncontrolled bleeding [6]. We think the possible explanation for this with our results is selecting patients with post-band ulcers only in our study.

A multicenter trial compared SEMS with balloon tamponade (B.T.) in a series of cirrhotic patients with variceal bleeding. This study showed a superior safety profile and higher efficacy in controlling bleeding with SEMS. However, the use of SEMS did not result in improved survival [20]. They had no patients who developed aspiration and aspiration pneumonia in the SEMS group. Still, in our study, we had two patients who had aspiration and another two who developed pneumonia, which could be due to the low number of participants in the Escorsell study (n = 13) [20].

Stent dislocations were found in n = 13 (38.2%) patients in Pfisterer study 2019. In our analysis, it was n = 6 (21.43%) patients. In a meta-analysis, the incidence of stent migration was 21.6% [6]. The different types and diameters of SEMS used in the study may be the explanation for this difference.

Six weeks of survival in our study was 75% (n = 21). In the Spanish clinical trial study, the survival was 54%, which is not different from the B.T. group 40% [20]. 47.1% of patients died within 6 weeks due to bleeding-related complications in Pfisterer study [19]. Pooled 30-day and 60-day survival rates were 68% and 64%, respectively, in a meta-analysis [11].

No previous studies specified post-band ulcer bleeding in their analysis and respect to the ulcers' morphology. In our research, the ulcer type has a significant impact on rebleeding and mortality after SEMS insertion. As we have all type A (ulcer with clot) patients that had 100% for both bleeding control and 6 weeks survival. So, we think the ulcer type can guide the intervention modality to be used. Jamwal and colleagues tried in their retrospective study to evaluate the impact of the morphology

Table 4 Clinical data related to 6 weeks mortality

		6 weeks mortality Dead 7		6 weeks mortality Alive 21		Test	*P* value	Odd's ratio	CI 95%
HCC	**Yes**	2	40%	3	60%	**Fisher 0.7**	0.57		
No	5	21.7%	18	78.3%					
SBP	**Yes**	3	25%	9	75%	$\chi 2$ **0.00**	0.6		
	No	4	25%	12	75%				
Post-band ulcer	**Type A**	0	0%	9	100%	$\chi 2$ **4.4**	0. 043*	1.58	(1.12–2.23)
	Type (B and C)	7	36.8%	12	63.2%				
Encephalopathy	**Overt**	4	66.7%	2	33.3%	$\chi 2$ **7**	0.02*	2.59	(0.8–8.1)
	Covert	3	13.6%	19	86.4%				

of post-band bleeding ulcers on the choice of treatment options, and they found that ulcers with clots could have a favorable outcome with repeated banding or SEMS insertion according to Child-Pugh class [21].

The most important limitation of our study is its uncontrolled retrospective design and the low number of cases.

Conclusion

SEMS is a very effective strategy when used appropriately in post-band ulcer bleeding. We should take into consideration the morphological picture of the ulcer and the general condition of the patient. So, we can get a high rate of bleeding control and survival benefits.

Abbreviations

SEMS: Self-expandable metallic stents; AVB: Acute variceal bleeding; HPVG: Hepatic vein portal gradient; EVL or EBL: Endoscopic variceal band ligation; TIPS: Transjugular intrahepatic portosystemic shunt; B.T.: Balloon tamponade; HCC: Hepato-cellular carcinoma; PVT: Portal vein thrombosis; MELD: Model of end-stage liver disease

Supplementary Information

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Additional file 1. Study flowchart.

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Authors' contributions

O.E.: data collection, endoscopist, statistical analysis, manuscript writing, AK: endoscopist, data collection, A.A.: endoscopist, manuscript writing, MA: endoscopist, data collection, MA: endoscopist, manuscript writing, A.E.: endoscopist, data collection, AIN: endoscopist, data collection, AS: endoscopist, data collection, S.A.: endoscopist, data collection, A.H.: data collection, MAE: endoscopist, data collection, AG: endoscopist, data collection. All authors have read and approved the final manuscript.

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Availability of data and materials

Available from the corresponding author.

Declarations

Ethics approval and consent to participate

The Research Ethics Committee approved the study of our medical institute (National Liver Institute IRB00003621). All study procedures were carried out per the Declaration of Helsinki regarding research involving human subjects. Every patient filled a written consent form after a detailed explanation of the study and management plan.

Consent for publication

N/A.

Competing interests

The authors declare that they have no competing interests.

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