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**Article type:** Research letter

**Received:** March 13, 2026.

**Revision accepted:** May 27, 2026.

**Published online:** June 1, 2026.

**ISSN:** 1897-9483

Pol Arch Intern Med.

doi:10.20452/pamw.17313

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# **Sequential rescue strategy in refractory acute esophageal variceal bleeding: a retrospective study**

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## **Introduction**

Acute esophageal variceal bleeding (EVB) remains one of the most severe complications of portal hypertension and continues to bear risk of substantial short-term mortality despite advances in pharmacological and endoscopic management [1-3]. Standard first-line therapy—comprising vasoactive agents, antibiotic prophylaxis, and timely endoscopic variceal ligation—allows to stop bleeding in majority of patients; however, treatment failure or early rebleeding still occurs in approximately 10–20% of cases and is associated with particularly poor prognosis [1,3,4].

Historically, balloon tamponade was the predominant rescue strategy in refractory EVB, but its use has been limited because of frequent complications and high rebleeding rates [3,5]. Fully covered esophageal self-expanding metal stents (SEMSs) have subsequently emerged as a safer and more effective alternative for rapid mechanical hemostasis, with high rates of technical success and immediate bleeding control reported in both prospective studies and real-world practice [4-8]. Nevertheless, SEMS implantation provides only temporary control of esophageal bleeding and does not address portal hypertension nor hepatic dysfunction that ultimately determine outcome [4,6]. Accordingly, the Baveno VII consensus recommends pre-emptive transjugular intrahepatic portosystemic shunt (TIPS) within 72 hours of the index bleeding episode, preferably within 24 hours, in selected high-risk patients, while also recognizing that its use may be limited by major contraindications such as severe hepatic failure, portal vein thrombosis, uncontrolled encephalopathy, or active sepsis [1].

Definitive management of refractory EVB relies on decompression of portal hypertension with TIPS placement and, liver transplantation in patients with irreversible end stage liver failure (LT) [1,9,10]. While early or pre-emptive TIPS has been shown to reduce rebleeding and mortality rate in selected high-risk patients, its applicability in routine practice remains limited by contraindications related to liver function, encephalopathy, infection, and portal vein patency [1,9]. In this setting, SEMS implantation is being increasingly used as a bridge therapy, allowing stabilization of patients during the acute bleeding phase and creating an opportunity for subsequent definitive treatment. However, data linking this sequential strategy with long-term outcome in population with advanced cirrhosis, remain limited, particularly in real-world setting [4,7].

The aim of this study was to characterize the real-world course of a sequential rescue strategy in patients with refractory acute EVB treated with SEMS, and to explore short- and long-term outcomes in individuals after subsequent TIPS and liver transplantation. Moreover, outcomes

of SEMS implantation, feasibility of definitive therapies, Kaplan–Meier survival estimates, and determinants of mortality and rebleeding were sought retrospectively in examined cohort.

## **Patients and methods**

**Study design and population** This retrospective cohort study included consecutive adult patients ( $\geq 18$  years) admitted with refractory or early recurrent acute EVB who were treated with SEMS placement after failure of standard endoscopic therapy. Patients were treated at a tertiary referral center, and all available cases meeting inclusion criteria between January 2011 and December 2022 were analyzed. The study was conducted in accordance with the Declaration of Helsinki and approved by the institutional Ethics Committee board. Sixty-four consecutive eligible patients were identified and comprised the analytic cohort. Patients were eligible if they had: 1) endoscopically confirmed esophageal varices associated with portal hypertension; 2) failure of standard therapy, defined by ongoing hematemesis, aspiration of  $>100$  mL of fresh blood via nasogastric tube more than two hours after endoscopy, or a  $\geq 3$  g/dL drop in hemoglobin without transfusion; and 3) SEMS placement for control of acute refractory or early recurrent variceal bleeding. Patients with non-variceal bleeding or isolated gastric varices without esophageal involvement were excluded. The data completeness varied for some laboratory variables, but it was not a reason for study exclusion of any case, thus survival analyses included the full cohort. The missing values were mitigated by variable-specific complete-case analysis rather than excluding cases from the examined cohort.

All patients received standardized initial therapy, including intravenous vasoactive drugs (terlipressin or somatostatin analogues), antibiotic prophylaxis (ceftriaxone 1 g/day), and urgent endoscopic evaluation with variceal ligation performed within 12 hours of admission following hemodynamic stabilization.

**Rescue and definitive therapies** *Self-expanding metal stent* In patients with refractory variceal bleeding despite initial pharmacological and endoscopic therapy, fully covered esophageal SEMS was used as the local rescue modality for temporary bleeding control. In each case the SX-ELLA Danis stent was deployed without fluoroscopic guidance. Correct placement and immediate hemostasis were confirmed endoscopically. Planned dwell time was 7-14 days.

*Transjugular intrahepatic portosystemic shunt* After initial hemostatic stabilization, patients were assessed for definitive portal decompression with polytetrafluoroethylene-covered TIPS. Qualifications for TIPS therapy have been performed by multidisciplinary team with particular attention to bleeding control, liver function, portal vein patency, encephalopathy, and presence of active infection in qualified patients.

**Outcome measures** Primary outcomes were all-cause mortality within 5 days, 6 weeks, and 1 year after SEMS placement; bleeding-related mortality within the same time windows; and rebleeding after SEMS placement. Short-term mortality was defined as death within 5 days and within 6 weeks of the index bleeding episode, whereas long-term mortality was defined as death within 1 year and overall survival during follow-up. Secondary outcomes included technical success of SEMS and TIPS, feasibility of definitive therapies, and procedure-related complications, categorized as stent migration, post-removal ulceration or necrosis, SEMS-related ulcer bleeding, and post-TIPS rebleeding.

**Statistical analysis** All statistical analyses were performed using R statistical software, version 4.3.2 (R Foundation for Statistical Computing). Continuous variables were assessed for distribution and are presented as mean with standard deviation (SD) or median with interquartile range (IQR), as appropriate. Categorical variables are presented as counts and percentages. Survival was estimated using Kaplan–Meier methods and compared with the log-rank test. Comparisons between the SEMS alone and SEMS + TIPS groups were

considered descriptive because treatment allocation was non-random and TIPS represented a post-baseline sequential intervention.

Univariable logistic regression analyses were initially performed to evaluate associations between individual variables and study outcomes. Exploratory multivariable logistic regression was then used to examine baseline predictors of 6-week mortality, 1-year mortality, and rebleeding. Before multivariable model construction, potential collinearity between candidate predictors was assessed using Spearman's rank correlation coefficient, and highly correlated variables were not entered simultaneously into the same model. Variables were selected based on clinical relevance and univariable results. A backward elimination approach was applied, with sequential removal of non-significant variables to obtain the final model.

Model performance was assessed using receiver operating characteristic curve analysis, and discriminative ability was expressed as the area under the curve. Results of logistic regression analyses are reported as odds ratios with 95% confidence intervals and corresponding P-values. Cox proportional hazards models were not fitted, and TIPS was not modeled as a time-dependent exposure. A two-sided P-value <0.05 was considered statistically significant.

## **Results**

**Baseline characteristics** Sixty-four consecutive patients with recurrent acute EVB refractory to standard therapy were analyzed. Mean age was 46.8 (12.0) years, and 59.4% were male. Alcohol-related liver disease was the main cause of portal hypertension (53.1%), followed by metabolic (14.1%) and viral cirrhosis (9.4%). Liver disease was advanced: 61.7% of patients were Child–Pugh C, with a median Model for End Stage Liver Disease (MELD) score of 24 (IQR 14–30). Large esophageal varices (F3) were present in 71.9%, and portal vein thrombosis in 16.4% (Table 1). Laboratory parameters confirmed severe hepatic

dysfunction, with a median bilirubin of 5.9 mg/dL, international normalized ratio (INR) of 1.7, albumin of 2.5 g/dL, and platelet count of  $72.5 \times 10^9/L$  (Table 1).

**Outcomes of self-expanding metal stent placement** SEMS implantation was performed in 64 patients as rescue therapy after failed pharmacological and endoscopic treatment. Technical success was achieved in 96.9%, with immediate hemostasis in 93.8%. Rebleeding occurred in 61.4%, and failure to control bleeding within 5 days in 34.4%. Stent migration occurred in 43.6% of patients, with complete migration accounting for nearly two-thirds of these events. Among patients undergoing SEMS removal, median dwell time was 12 days (IQR 9–14). Post-removal mucosal ulceration or necrosis occurred in 29.4%, and SEMS-related ulcer bleeding in 17.6% (Table 1).

**Feasibility and outcomes of transjugular intrahepatic portosystemic shunt** When retrospectively assessed according to Baveno VII criteria, 55 patients met indications for TIPS; however, due to contraindications including severe hepatic failure, advanced encephalopathy, portal vein thrombosis, and active sepsis, only 13 (23.6%) underwent the procedure. All TIPS procedures were technically successful, and rebleeding after TIPS occurred in 25.0% of cases (Table 1).

**Comparison of outcomes between self-expanding metal stent + transjugular intrahepatic portosystemic shunt and self-expanding metal stent alone** Nearly half of patients (46.9%) died with SEMS in situ, likely reflecting the severity of underlying liver disease rather than procedural failure. In patients treated with SEMS alone, bleeding-related mortality accounted for 22.2% of deaths within 5 days and 64.7% within 6 weeks (Table 1). In descriptive comparisons, patients who subsequently underwent TIPS had lower observed 6-week mortality (46.2% vs. 66.7%) and 1-year mortality (50.0% vs. 80.4%) than patients managed with SEMS alone; early bleeding-related death ( $\leq 5$  days) was also less frequent (8.3% vs. 25.5%; Supplementary material, *Table S1*). Given the non-random allocation to

TIPS and the variable timing of the procedure, these group differences should be interpreted with caution.

**Liver transplantation** Twenty-nine patients were listed for liver transplantation at SEMS placement. After expedited evaluation, 21 were eligible; however, only 10 underwent LT, while the remainder died awaiting graft availability. Liver transplantation markedly improved survival, eliminating bleeding-related mortality and significantly reducing 6-week and 1-year mortality compared with non-transplanted patients (Supplementary material, *Table S2*).

**Survival analysis** Kaplan–Meier survival analysis was performed in the entire cohort stratified by treatment strategy: SEMS alone (n = 51) versus SEMS + TIPS (n = 13). No patients were excluded because of incomplete time-to-event data (Supplementary material, *Figure S1*). The curves are presented as unadjusted survival estimates. Patients treated with SEMS alone had poor outcomes, with a median overall survival of 14 days and 6-, 12-, and 24-month survival rates of 29.4%, 27.5%, and 25.5%, respectively (38 deaths within 24 months). In contrast, 24-month survival in the SEMS + TIPS subgroup was 53.8%, with six deaths. Because of the small size of the TIPS subgroup and non-random treatment allocation, these estimates should be interpreted cautiously. Kaplan–Meier curves revealed early and sustained separation favoring SEMS + TIPS ( $p = 0.04$  by log-rank test). At 400 days, estimated survival was 25.5% (95% CI 13.5–37.5) for SEMS alone and 53.8% (95% CI 26.7–80.9) for SEMS + TIPS (Supplementary material, *Figure S1*).

**Exploratory regression analysis** In exploratory multivariable logistic regression, INR independently predicted 6-week mortality (OR 14.3; 95% CI: 3.13–115; Supplementary material, *Table S3*). One-year mortality was associated with MELD score and INR, whereas no independent predictors of rebleeding were identified. These models address fixed follow-

up windows rather than time-to-event risk and should therefore be interpreted as supportive analyses.

## **Discussion**

This study provides real-world evidence on outcomes of rescue strategies in patients with refractory acute EVB. Although implantation of a SEMS achieved high technical success and good immediate hemostasis rate, overall survival prognosis in those patients was determined mainly by the severity of underlying liver dysfunction and by access to definitive portal decompression or liver transplantation.

Meta-analyses further confirm pooled immediate hemostasis rates of approximately 90–97% [4,7,11]. Initial clinical series with the SX-ELLA Danis stent demonstrated near-universal control of active hemorrhage [12], with subsequent confirmation in early cohorts by Wright et al [13] and Holster et al [14]. Larger real-world studies by Dechêne et al [5], Fierz et al [6], Müller et al [8], and Pfisterer et al [15] reproduced these findings, demonstrating high technical success in refractory cases. The most recent analysis by Songtanin et al [7] reported 91% pooled immediate bleeding control with overall mortality of 38%, while Marot et al [4] documented 30-day mortality approaching 36–40% despite successful bleeding control.

Mohan et al., in a comparative meta-analysis, showed that although SEMS effectively stops bleeding, outcomes remain inferior to TIPS in terms of rebleeding and mortality [16].

Our Kaplan–Meier analysis demonstrated a median survival of only 14 days in patients treated with SEMS alone. This strikingly short survival illustrates a fundamental pathophysiological limitation: SEMS provides mechanical tamponade but does not modify portal hypertension, systemic inflammation, or progressive hepatic failure. Escorsell and Bosch [3] previously emphasized that failure of standard therapy marks a population with severe portal hypertension and advanced hepatic dysfunction, and Rodge et al [17] further

described refractory bleeding as a manifestation of global decompensation rather than isolated procedural failure.

Patients who subsequently received TIPS had longer observed survival than those managed with SEMS alone. Because TIPS was not randomly assigned and could only be performed in patients who survived long enough and had no procedure contraindications, this finding should be regarded as hypothesis-generating rather than causal.

The descriptive pattern nonetheless aligns with the hemodynamic rationale of portal decompression. By reducing portal pressure and HVPG, TIPS directly targets the mechanism of variceal formation and bleeding [1,9,10]. García-Pagán et al. showed that early TIPS reduces failure to control bleeding and improves survival in selected high-risk patients, a strategy incorporated into Baveno VII recommendations [1,9]. Wang et al [10] highlighted the expanding role of TIPS as a disease-modifying therapy in portal hypertension, while Hauser et al [18] and Garcia Garcia et al [19] emphasized the benefit of early portal decompression in selected high-risk patients. Our data are consistent with that literature but do not independently establish such benefit.

It is biologically plausible that TIPS may do more than prevent rebleeding by reducing portal inflow, decreasing variceal wall tension, and improving effective arterial blood volume in advanced cirrhosis. In the present study, however, these mechanisms remain inferential and cannot be confirmed directly from the retrospective dataset.

Despite meeting Baveno VII criteria, most patients in our cohort did not undergo TIPS due to severe hepatic failure, portal vein thrombosis, uncontrolled encephalopathy, or sepsis. Similar real-world discrepancies between guideline eligibility and procedural feasibility have been documented in multicenter cohorts and meta-analyses [8,16,20]. ESGE guidelines also emphasize that although TIPS represents definitive therapy in refractory bleeding, its application requires careful selection and center expertise [2].

These real-world constraints likely contribute to the persistently high mortality of refractory EVB and help explain why the TIPS and non-TIPS groups in this cohort were not directly comparable.

An especially important clinical implication of our findings is that definitive therapies require a period of stabilization during which candidacy can be assessed. In our cohort, transplantation eliminated bleeding-related mortality entirely. Liver transplantation is the only intervention capable to definitely correct portal hypertension and hepatic insufficiency [1,9].

Transplantation requires time for evaluation, listing, and organ allocation. In some patients, temporary hemostasis after SEMS was followed by further assessment for TIPS or liver transplantation. This sequence supports the practical role of SEMS as a rescue measure, but not as evidence that SEMS itself improved survival or ensured access to definitive therapy. In multivariable analysis we identified INR and MELD score as predictors of short- and long-term mortality. These parameters reflect hepatic synthetic dysfunction and portal hypertension severity, and their prognostic dominance reinforces the central principle emphasized in Baveno VII: hepatic reserve, rather than variceal characteristics or endoscopic modality, largely determines outcomes after acute bleeding [1,3,9].

The absence of independent predictors of rebleeding further supports the concept that once standard therapy fails, rebleeding risk reflects irreversible portal hypertension and advanced cirrhosis rather than modifiable technical factors.

**Limitations** First, our findings apply only to endoscopically confirmed refractory EVB and should not be extrapolated to non-variceal causes of gastrointestinal bleeding. Rare tumor-related etiologies, including gastrointestinal bleeding associated with intussusception, may present with overlapping clinical symptoms but require a distinct diagnostic and therapeutic approach [21].

Most patients were treated before publication of the Baveno VII consensus, which endorsed a more individualized approach to TIPS despite relative contraindications; thus, the low TIPS rate in our cohort likely reflects historical practice patterns. This was a retrospective, single-center study, and only a small subgroup received TIPS. Because treatment allocation was non-random, comparisons between SEMS alone and SEMS + TIPS remained vulnerable to be confounded by indication, selection bias, and immortal time bias. In addition, mortality was analyzed with logistic regression for fixed follow-up windows rather than Cox proportional hazards models, and TIPS was not modeled as a time-dependent exposure. These issues substantially limit statistical precision, subgroup robustness, generalizability, and causal interpretation.

**Conclusions** SEMS achieved effective temporary hemostasis in patients with refractory acute EVB, whereas overall prognosis remained closely linked to the severity of underlying liver disease. In this real-world cohort, patients who subsequently underwent TIPS or liver transplantation had longer observed survival, which supports the clinical role of SEMS within a sequential rescue strategy. These findings reinforce the value of SEMS as a bridging intervention in the management of refractory EVB, while the observed survival differences should be interpreted cautiously given the retrospective and non-randomized nature of the study.

**Article information**

**Acknowledgments** None.

**Funding** None.

**Conflict of interest** None declared.

**AI statement** Artificial intelligence was not used in the preparation of this manuscript.

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**How to cite** Ligocka J, Olszewska N, Koziel S, et al. Sequential rescue strategy in refractory acute esophageal variceal bleeding: a retrospective study. *Pol Arch Intern Med.* 2026; XX: 17313. doi:10.20452/pamw.17313

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<b>Table 1</b> Baseline characteristics of the study cohort and outcomes (n = 77)		
<b>Characteristics</b>		
<b>Variable</b>		<b>Value</b>
Age, y		46.8 (12)
Men		38 (59.4)
On liver transplant waiting list		29 (45.3)
Etiology of portal hypertension	Alcohol-related liver disease	34 (53.1)
	Metabolic cirrhosis	9 (14.1)
	Viral cirrhosis	6 (9.4)
	Autoimmune hepatitis	6 (9.4)
	Primary biliary cholangitis	3 (4.7)
	Primary sclerosing cholangitis	1 (1.6)
	Other	5 (7.8)
Portal vein thrombosis		10 (16.4)

Esophageal varices according to the JRSPH classification	F1	18 (28.1)
	F2	46 (71.9)
Gastroesophageal varices according to the Sarin classification	GOV0	51 (79.7)
	GOV1	5 (7.8)
	GOV2	8 (12.5)
Laboratory parameters	creatinine, mg/dL	1.3 (1–2.3)
	albumin, g/dL	2.5 (2–3.1)
	INR	1.7 (1–2.1)
	bilirubin, mg/dL	5.9 (2–16.4)
	AST, U/L	85 (49–146)
	ALT, U/L	42.5 (30–87.5)
	GGT, U/L	85 (58–246)
	fibrinogen, mg/dL	178.5 (121–269)
	hemoglobin, g/dL	8.5 (8–10)
	platelets, $\times 10^9/L$	72.5 (54–110.5)
MELD score		24 (14–30)
<b>Outcomes after self-expanding metal stent placement (n = 64)</b>		
Indication: refractory or early recurrent bleeding		48 (75)
Technical success		62 (96.9)
Immediate hemostasis		60 (93.8)
SEMS removal performed		34 (53.1)
SEMS dwell time, d		12 (9–14)
Stent migration	17 (43.6)	Partial migration
		Complete migration
Rebleeding related to migration		11 (64.7)
Ulceration / necrosis after SEMS removal		10 (29.4)
SEMS-related ulcer bleeding		6 (17.6)
Failure to control bleeding $\leq 5$ days		22 (34.4)
Failure to control bleeding $\leq 6$ weeks		41 (64.7)
<b>Outcomes after transjugular intrahepatic portosystemic shunt placement (n = 13)</b>		

Technical success	13 (100)
Rescue TIPS	7 (53.8)
Preemptive / early TIPS	6 (46.2)
Absent variceal flow after TIPS	6/6 evaluated (100)
Rebleeding after TIPS	3 (25)
Additional BRTO <sup>a</sup>	2 (15.4)
<p>Data are presented as number (percentage or mean (SD) unless indicated otherwise.</p> <p>a Ballon-occluded retrograde transvenous obliteration</p> <p>Abbreviations: ALT, alanine aminotransferase; AST, aspartate aminotransferase; BRTO, balloon-occluded retrograde transvenous obliteration; GGT, <math>\gamma</math>-glutamyltransferase; GOV, gastroesophageal varices; INR, international normalized ratio; JRSPH, Japanese Research Society for Portal Hypertension; MELD, Model for End Stage Liver Disease; SEMS, self-expanding metal stent; TIPS, transjugular intrahepatic portosystemic shunt</p>	

**Short title:** Sequential rescue strategy in refractory acute EVB