STUDY PROTOCOL

TREATMENT OUTCOMES AND PREDICTORS AFTER ENDOVASCULAR INTERVENTION FOR PORTAL HYPERTENSION-RELATED GASTROINTESTINAL BLEEDING IN PATIENTS WITH CIRRHOSIS AT THE UNIVERSITY MEDICAL CENTER HO CHI MINH CITY

(TOPIC STUDY)

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ABSTRACT

BACKGROUND

Portal hypertension-related gastrointestinal bleeding (GIB), especially gastric variceal bleeding, is a critical complication of liver cirrhosis that is associated with high rebleeding and mortality rates. While endovascular interventions such as transjugular intrahepatic portosystemic shunt (TIPS) and retrograde/antegrade transvenous obliteration (RTO/ATO) represent major advances, real-world clinical data and localized prognostic models for patients undergoing these treatments are extremely sparse in Vietnam.

OBJECTIVE

This study aims to describe the clinical and laboratory characteristics, evaluate technical and clinical treatment outcomes, and identify independent pre-procedural prognostic factors associated with adverse clinical outcomes after endovascular interventions.

METHODS

A hybrid cohort study combining a retrospective phase (January 2021 – September 2026, target n=117) and a prospective phase (October 2026 – March 2028, target n=50) will be conducted at the University Medical Center Ho Chi Minh City. The total sample size of 167 patients is powered using Cochran's single proportion formula and the rule of 10 events per variable (EPV) for logistic regression modeling. Demographics, lab markers, hepatic scoring systems (Child-Pugh, MELD, MELD-Na, MELD 3.0), procedural parameters, and clinical outcomes (initial bleeding control, rebleeding, in-hospital and 6-week mortality) will be recorded. Univariate and multivariate logistic and Cox proportional hazard regression will be used to analyze predictors of outcomes.

IMPACT

The TOPIC study will establish the first systematic real-world clinical database of endovascular portal hypertension interventions in Vietnam. Defining localized prognostic variables will support risk stratification,

optimize patient selection, lower healthcare costs, and establish practical guidelines for personalized clinical management.

INTRODUCTION

BACKGROUND AND CLINICAL SIGNIFICANCE

Gastrointestinal bleeding (GIB) due to portal hypertension is one of the most severe and lethal complications of liver cirrhosis. Gastric variceal bleeding, although less frequent than esophageal variceal bleeding, is characterized by greater severity, higher rebleeding rates, and poor initial control. Gastric varices are observed in 18% to 70% of cirrhotic patients with portal hypertension, carrying a bleeding risk of approximately 25% within two years.[1] Once an episode of gastric variceal hemorrhage occurs, the cumulative rebleeding rate ranges from 34% to 89%, and the associated mortality rate reaches 10% to 30%.[1] Large-scale administrative database analyses, such as United States inpatient registries (2016–2019), show that even with modern medical technologies, the overall in-hospital mortality for gastric variceal bleeding remains significant at 6.5%.[1]

ENDOVASCULAR INTERVENTIONS AND GLOBAL EVIDENCE

The management of portal hypertension-related bleeding has evolved significantly with the introduction of endovascular interventions. These interventions operate via two primary mechanisms: (1) reducing the portal pressure gradient by creating a low-resistance shunt between the portal and systemic circulation, namely Transjugular Intrahepatic Portosystemic Shunt (TIPS), and (2) directly obliterating the variceal complex and its afferent feeders, which includes Balloon-Occluded Retrograde Transvenous Obliteration (BRTO), Plug-Assisted Retrograde Transvenous Obliteration (PARTO), Coil-Assisted Retrograde Transvenous Obliteration (CARTO), and Antegrade Transvenous Obliteration (ATO). Choosing the optimal technique is complex and depends heavily on patient hemodynamics, pre-existing liver function, the presence or absence of a gastrorenal shunt, the risk of hepatic encephalopathy, the anatomical classification of the varices, and the specialized expertise of the intervention center.

Recent international literature has provided robust evidence for these techniques. In acute bleeding settings, PARTO and CARTO have demonstrated technical and clinical success rates approaching 100%. However, because retrograde techniques obliterate major gastrorenal shunts, they inherently divert more portal blood back to the liver, which can exacerbate other portal hypertension manifestations, such as worsening esophageal varices or inducing ascites. A large multicenter retrospective 10-year study (n=311) evaluated the long-term clinical trajectory of CARTO/PARTO, reporting cumulative 5-year and 10-year survival rates of 68% and 33%, respectively, with a 10-year gastric variceal rebleeding rate of only 5.4%.[2] Importantly, the study identified independent baseline predictors associated with poor survival, including pre-procedural Model for End-Stage Liver Disease (MELD) scores, concurrent hepatocellular carcinoma (HCC), Sarin gastroesophageal varices type 2 (GOV2) anatomy, history of esophageal variceal bleeding, and elevated pre-procedure total bilirubin and serum ammonia. Notably, patients with a baseline MELD score greater than 27 experienced an extremely high mortality rate of 92.6%.[2]

For TIPS, current studies focus on patient selection and technical optimization. A multicenter cohort study (n=629) demonstrated that combining small-diameter (8-mm) TIPS with concurrent variceal embolization significantly reduced rebleeding rates compared to TIPS alone (6.2% vs. 13.6%) and decreased overt hepatic encephalopathy (31.0% vs. 39.4%), particularly in high-risk anatomical groups (GOV2 and IGV1). Furthermore, prognostic models such as CLIF-C AD and multiple laboratory-based scores have successfully identified optimal candidates for preemptive TIPS. A randomized clinical trial (GAVAPROSEC, 2025) confirmed that preemptive TIPS in high-risk patients within 72 hours of admission achieved a 1-year event-free survival of

77% compared to only 37% in patients receiving standard endoscopic glue injection combined with non-selective beta-blockers.[3]

RATIONALE FOR CONDUCTING RESEARCH IN VIETNAM

In Vietnam, several clinical groups have reported high technical feasibility for techniques like PARTO, ATO, and transhepatic embolization, with success rates between 90% and 100%. For instance, Trinh et al. (2019) reported 100% technical success for PARTO in 37 cirrhotic patients, and Son et al. (2022) demonstrated high immediate bleeding control in patients undergoing ATO.[4,5] However, Vietnamese studies published to date possess critical limitations: they are small-scale, single-center, have very short follow-up periods, and are focused almost exclusively on immediate technical success or procedural safety of a single, isolated technique. Crucially, there is an absolute lack of comprehensive clinical research evaluating the broad spectrum of endovascular techniques (TIPS, PARTO, CARTO, ATO, and combined treatments) in a single cohort, and no study has yet analyzed independent prognostic variables to build a validated clinical prediction model for patient outcomes.

As a leading tertiary-care hospital, the University Medical Center Ho Chi Minh City manages a high volume of complex portal hypertension cases, utilizing the full range of endovascular treatments. The TOPIC (**T**reatment **O**utcomes and **P**redictors after Endovascular **I**ntervention for Portal Hypertension-related Gastrointestinal Bleeding in Patients with **C**irrhosis) Study is designed to address this critical knowledge gap. By systematically analyzing pre-procedural parameters, clinical characteristics, and long-term outcomes, this study will establish the first comprehensive Vietnamese database of endovascular portal hypertension interventions. It will provide vital local evidence for clinician decision-making, optimize patient selection, reduce healthcare costs, and rationalize the use of limited medical resources..

STUDY OBJECTIVES AND HYPOTHESES

STUDY OBJECTIVES

The primary objective of this study is to evaluate treatment outcomes and identify pre-procedural prognostic factors associated with clinical outcomes in cirrhotic patients undergoing endovascular interventions for portal hypertension-related gastrointestinal bleeding at University Medical Center Ho Chi Minh City.

Specific objectives:

1. To describe the baseline clinical, laboratory, endoscopic, and imaging characteristics of patients with portal hypertensive cirrhosis presenting with gastrointestinal bleeding who undergo endovascular intervention.
2. To evaluate the technical and short-term clinical outcomes of these endovascular interventions, including technical success, initial bleeding control, rebleeding rates, complications, and survival.
3. To identify independent pre-procedural clinical, biological, and procedural variables associated with adverse clinical outcomes (rebleeding, in-hospital mortality, and 6-week mortality)**.**

HYPOTHESES

The study is based on the following primary and secondary hypotheses:

PRIMARY HYPOTHESIS

H_0: Pre-procedural clinical markers, laboratory findings, and liver disease severity scores (MELD, MELD-Na, MELD 3.0, Child-Pugh) are not associated with clinical outcomes (rebleeding, in-hospital mortality, or 6-week mortality) in cirrhotic patients after endovascular interventions.

H_1: Pre-procedural clinical markers, laboratory findings, and liver disease severity scores are significantly and independently associated with clinical outcomes in cirrhotic patients after endovascular interventions, and can be integrated into a reliable prognostic model.

SECONDARY HYPOTHESES

Updated biological models, specifically MELD 3.0, MELD-Na, and CLIF-C AD demonstrate significantly higher predictive accuracy (area under the receiver operating characteristic curve, AUROC) for 6-week post-discharge mortality compared to the traditional MELD and Child-Pugh scoring systems in this population.

STUDY DESIGN

This is a hybrid cohort study combining a retrospective phase and a prospective phase. The retrospective phase will collect data from patients treated between January 2021 and September 2026. The prospective phase will consecutively enroll and follow up new patients meeting the eligibility criteria between October 2026 and March 2028.

STUDY SETTING AND POPULATION

SETTING

The study will be conducted at the Department of Gastroenterology and the Endovascular Intervention Unit of the University Medical Center Ho Chi Minh City. This tertiary university hospital represents a primary referral center for advanced hepatology and portal hypertension interventions in southern Vietnam.

POPULATION AND ELIGIBILITY CRITERIA

Inclusion criteria:

- Patient is aged 18 years or older on the day of admission.
- Confirmed diagnosis of liver cirrhosis by attending clinicians based on clinical findings, laboratory tests, imaging studies (ultrasound, CT, MRI, elastography), or liver histology if available.
- Diagnosis of acute portal hypertension-related gastrointestinal bleeding requiring treatment with at least one endovascular intervention technique (TIPS, PARTO, CARTO, ATO, or combined techniques).
- For patients enrolled in the prospective cohort, signed and dated written informed consent must be obtained prior to study inclusion.

Exclusion criteria:

- Pregnant or lactating women.
- Non-cirrhotic portal hypertension, or liver cirrhosis that is unconfirmed or questionable.
- Gastrointestinal bleeding due to etiologies completely unrelated to portal hypertension (e.g., peptic ulcer disease, gastric cancer, Mallory-Weiss tears, vascular ectasias), or bleeding of completely unknown origin.
- Missing critical medical records or core pre-procedural/outcome data that would prevent the primary outcome assessment.

SAMPLE SIZE CALCULATION

SAMPLE SIZE CALCULATION

Sample Size for Descriptive Objectives (Objectives 1 & 2)
To describe the clinical characteristics and treatment success rates, Cochran's formula for estimating a single proportion is used:

$$n = \frac{Z^2_{1-\frac{\alpha}{2}} \times (p(1-p))}{d^2}$$

Where:

- **n** = minimum sample size
- $Z_{\alpha/2}$ = 1,96, corresponding to a significance level of α = 0.05
- **p** = 0.10: the estimated proportion of cirrhotic patients with portal hypertension GIB undergoing endovascular intervention at our center, based on domestic and international literature
- **d** = 0.05: the absolute precision level.

Substituting the values: n = [1.96^2 * 0.10 * 0.90] / 0.05^2 = 138 patients.

Accounting for a 10% rate of potential missing retrospective data or loss to follow-up, the minimum required sample size for the descriptive cohort is 152 patients.

Sample Size for Prognostic Modeling (Objective 3)

For multivariate logistic regression modeling, sample size is calculated using the established Rule of 10 Events Per Variable (EPV). The study plans to evaluate 3 primary pre-procedural independent prognostic variables in the main predictive model. Thus, a minimum of 10 * 3 = 30 composite events is required. Based on prior literature, the estimated rate of the composite clinical outcome (defined as rebleeding after intervention, in-hospital mortality, or 6-week post-discharge mortality) is approximately 20%. Therefore, the minimum required sample size is calculated as:

n = 30 / 0.20 = 150 patients

Allowing for a 10% rate of missing variables or loss to follow-up, the required study sample size is 167 patients. We plan to allocate 70% of this sample to the retrospective cohort and 30% to the prospective cohort. Thus, the final target sample size is 167 patients, consisting of 117 retrospective patients and 50 prospective patients. All eligible patients presenting during the respective study periods will be consecutively selected to eliminate selection bias.

DATA COLLECTION AND PROCESSING

DATA COLLECTION

For the retrospective cohort, data will be extracted from electronic medical records (EMR), PACS imaging, endoscopy databases, and digital angiography (DSA) logs. For the prospective cohort, data will be collected directly by study investigators using standardized Case Report Forms (CRFs) during the baseline hospital stay. Prospective patients will be followed up at 6 weeks post-discharge via direct clinical visits or structured telephone interviews.

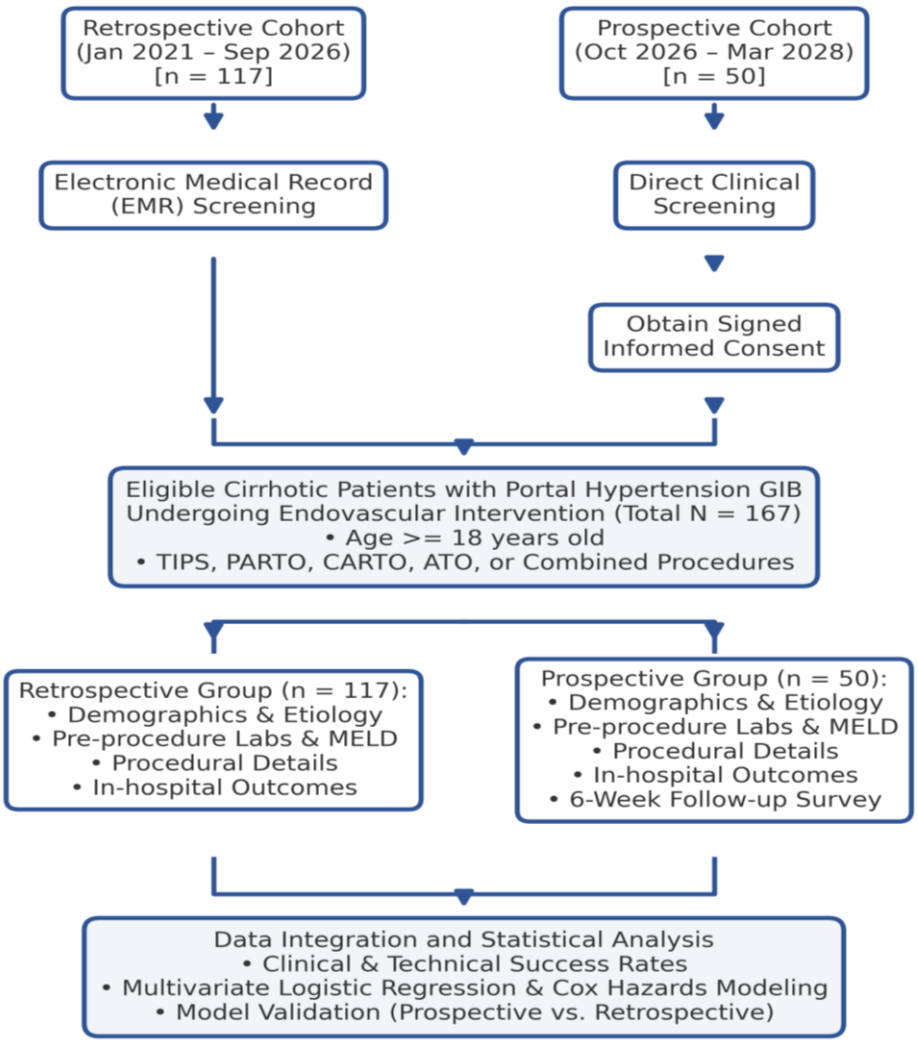


Figure 1. Flowchart of the study

The study variables are presented in **Table 1.**

Table 1. Study Variables

Variable	Type	Definition and measurement	Value
Patient ID	Nominal	According to the medical record ID	
Data collection group	Binary	Retrospective or prospective group	1 = retrospective; 2 = prospective
Age	Continuous	Age at hospital admission	
Sex	Binary	Biological sex recorded in the medical record	1 = male; 2 = female
Etiology of cirrhosis	Nominal	Primary cause of cirrhosis recorded in the medical record	1 = HBV; 2 = HCV; 3 = alcohol; 4 = MASLD/MASH; 5 = combined; 6 = other; 7 = unknown etiology
HCC	Binary	Hepatocellular carcinoma diagnosed before or during hospitalization	0 = no; 1 = yes
History of portal hypertensive GI bleeding	Binary	At least one previous episode of GI bleeding determined to be related to varices or portal hypertension	0 = no; 1 = yes

Variable	Type	Definition and measurement	Value
History of hepatic encephalopathy	Binary	Documented history of hepatic encephalopathy	0 = no; 1 = yes
Hepatic encephalopathy before endovascular intervention during the current hospitalization	Binary	Documented hepatic encephalopathy diagnosed before endovascular intervention	0 = no; 1 = yes
Hepatic encephalopathy after endovascular intervention during the current hospitalization	Binary	Documented hepatic encephalopathy diagnosed after endovascular intervention	0 = no; 1 = yes
Ascites before intervention	Binary	Ascites present clinically or on imaging before intervention	0 = no; 1 = yes
Presentation of GI bleeding	Nominal	Main symptom at hospital admission	1 = hematemesis; 2 = melena; 3 = hematemesis + melena; 4 = anemia suspected to be due to GI bleeding; 5 = other
Shock at admission	Binary	Systolic blood pressure <90 mmHg, requirement for vasopressors, or documented hemorrhagic shock in the medical record	0 = no; 1 = yes
Date and time of hospital admission	Continuous	Date and time of hospital admission recorded in the medical record	
Date and time of endoscopy (if performed)	Continuous	Date and time of endoscopy recorded in the medical record	
Date and time of endoscopic intervention	Continuous	Date and time of intervention recorded in the medical record	
Underwent GI endoscopy	Binary	Based on the medical record	0 = no; 1 = yes
Endoscopic signs of bleeding	Nominal	Endoscopy showing spurting blood, oozing from varices, platelet plug/blood clot on a varix, or signs of recent bleeding	0 = no; 1 = yes; 2 = not assessed
Variceal location	Nominal	Variceal location determined by endoscopy and/or imaging	1 = esophagus; 2 = stomach; 3 = esophagus + stomach; 4 = other location
Severity of esophageal/gastric varices on endoscopy	Nominal	Based on the endoscopic findings recorded in the medical record	1 = Grade I; 2 = Grade II; 3 = Grade III
Gastric varix classification (if present)	Nominal	Sarin classification based on endoscopic findings	1 = GOV1; 2 = GOV2; 3 = IGV1; 4 = IGV2; 5 = ectopic varices
Endoscopic treatment before endovascular intervention	Nominal	Endoscopic intervention performed during the same episode of GI bleeding before vascular intervention	0 = no; 1 = ligation; 2 = glue injection; 3 = combined
Blakemore tube placement before intervention	Binary	Blakemore tube placed during the same episode of GI bleeding before vascular intervention	0 = no; 1 = yes
Active bleeding on imaging (CT/MRI) before endovascular intervention	Binary	Active bleeding identified on imaging (CT/MRI) before the intervention	0 = no; 1 = yes
Gastrorenal shunt	Binary	Based on imaging findings (CT/MRI)	0 = no; 1 = yes
Other portosystemic shunt	Binary	Collateral circulation draining the portal system into the systemic venous system other than a gastrorenal shunt, based on imaging (CT/MRI)	0 = no; 1 = yes

Variable	Type	Definition and measurement	Value
Variceal inflow vessel	Nominal	Main vein supplying the varices on CT/DSA	1 = left gastric vein; 2 = posterior gastric vein; 3 = short gastric veins; 4 = combined; 5 = other
Variceal outflow pathway	Nominal	Main drainage pathway of the varices	1 = gastrorenal shunt; 2 = gastrocaval shunt; 3 = azygos/hemiazygos; 4 = other
Portal vein thrombosis	Nominal	Thrombosis of the main portal vein or its branches before intervention	0 = no; 1 = partial; 2 = complete
Hemoglobin	Continuous	Most recent hemoglobin concentration before intervention	
Platelet count	Continuous	Most recent platelet count before intervention	
White blood cell count	Continuous	Most recent white blood cell count before intervention	
INR	Continuous	Most recent INR value before intervention	
Fibrinogen	Continuous	Most recent fibrinogen concentration before intervention	
Albumin	Continuous	Most recent serum albumin level before intervention	
Total bilirubin	Continuous	Most recent total bilirubin level before intervention	
Creatinine	Continuous	Most recent serum creatinine level before intervention	
Serum sodium	Continuous	Most recent serum sodium level before intervention	
Ammonia	Continuous	Blood ammonia concentration before intervention, if tested	
ALT	Continuous	Most recent ALT level before intervention	
AST	Continuous	Most recent AST level before intervention	
CRP	Continuous	Most recent CRP level before intervention	
NT-proBNP	Continuous	Most recent NT-proBNP level before intervention, if tested	
Child-Pugh score	Continuous	Child-Pugh score calculated from bilirubin, albumin, INR/prothrombin time, ascites, and hepatic encephalopathy. Laboratory results are the most recent values before intervention	
MELD	Continuous	MELD score calculated from bilirubin, INR, and creatinine before intervention	
MELD-Na	Continuous	MELD-Na score calculated from bilirubin, INR, creatinine, and sodium before intervention	
MELD 3.0	Continuous	MELD 3.0 score calculated from bilirubin, INR, creatinine, sodium, and albumin before intervention	
CLIF-C AD	Continuous	CLIF-C AD is calculated from age, serum creatinine, INR, white blood cell count, and serum sodium, using pre-procedural laboratory values	
Endovascular intervention technique	Categorical	Endovascular intervention technique performed	1 = CARTO; 2 = PARTO; 3 = ATO; 4 = TIPS; 5 = other/combined
Emergency intervention	Binary	Intervention performed for active bleeding or failure of initial bleeding control	0 = no; 1 = yes
Intervention access route	Categorical	Primary vascular access route	1 = femoral vein; 2 = jugular vein; 3 = percutaneous transhepatic; 4 = other; 5 = combined
Embolic material	Categorical	Primary material used to occlude the varices or shunt	1 = coil; 2 = plug; 3 = Gelfoam; 4 = glue; 5 = sclerosant; 6 = combined
TIPS stent diameter	Continuous	Diameter of the stent used if TIPS is performed	
Portal venous pressure before intervention	Continuous	Portal venous pressure measured directly during the procedure before decompressive intervention or embolization, if recorded in the intervention report	mmHg
Portal venous pressure after intervention	Continuous	Portal venous pressure measured after completion of the intervention, if recorded	mmHg

Variable	Type	Definition and measurement	Value
Portosystemic pressure gradient before and after intervention	Continuous	Pressure gradient measured before and after TIPS placement, if available	mmHg
Technical success	Binary	Completion of the planned technique: TIPS establishes a shunt with flow through the stent; or embolization achieves complete or near-complete occlusion of the varices or target shunt on final DSA	0 = no; 1 = yes
Complete variceal occlusion	Binary	No residual flow into the varices or target shunt on DSA after embolization	0 = no; 1 = yes
Intra-procedural adverse event	Binary	Event occurring during the intervention, such as bleeding, vessel perforation, shunt rupture, material migration, or hemodynamic disturbance	0 = no; 1 = yes
Initial bleeding control	Binary	No ongoing bleeding after intervention, stable hemodynamics, and no need for repeat intervention/endoscopy within the first 72 hours	0 = no; 1 = yes
Rebleeding	Binary	Recurrent hematemesis, melena, or acute anemia after bleeding has been controlled, with clinical, endoscopic, or laboratory evidence, or requiring blood transfusion/reintervention	0 = no; 1 = yes
Time to rebleeding	Continuous	Time from the date and time of intervention to the date and time when the first rebleeding episode is documented	
In-hospital mortality	Binary	Death or discharge against medical advice due to critical illness from any cause during the same hospitalization in which endovascular intervention was performed	0 = no; 1 = yes
Clinical success	Binary	Technical success accompanied by initial bleeding control and no bleeding-related death during the early post-intervention period	0 = no; 1 = yes
Post-intervention hepatic encephalopathy	Binary	New-onset or worsening hepatic encephalopathy after intervention, as documented in the medical record	0 = no; 1 = yes
Worsening ascites	Binary	New-onset ascites or increased severity of ascites after intervention	0 = no; 1 = yes
Worsening esophageal varices	Binary	Post-intervention endoscopy showing increased grade of esophageal varices or need for additional treatment	0 = no; 1 = yes
Post-intervention complications	Binary	Complications occurring after the procedure during hospitalization or follow-up, including fever, infection, liver failure, renal failure, material migration, thrombosis, or access-site complications	0 = no; 1 = yes
Reintervention	Binary	Repeat endoscopy, vascular intervention, or surgery required because of rebleeding, residual varices, or complications	0 = no; 1 = yes
Length of hospital stay	Continuous	Based on the medical record	
Six-week post-discharge mortality	Binary	Death from any cause during the 6-week follow-up period after discharge in the prospective group	0 = no; 1 = yes
Primary outcome	Binary	Occurrence of at least one of the following 3 events: post-intervention rebleeding, in-hospital mortality, or death within 6 weeks after discharge (prospective group)	0 = no; 1 = yes

STATISTICAL ANALYSIS

All statistical analyses will be performed using Stata version 16.0 (StataCorp LLC, College Station, TX). Continuous variables will be tested for normality using the Shapiro-Wilk test. Normally distributed continuous variables will be summarized as mean ± standard deviation (SD) and compared using the Student's t-test. Non-normally distributed variables will be expressed as median and interquartile range (IQR, 25th – 75th percentile) and compared using the Mann-Whitney U test. Categorical variables will be presented as frequencies and percentages, with differences between cohorts evaluated using the Chi-square test or Fisher's exact test as appropriate.

To identify independent predictors of clinical success, rebleeding, and in-hospital mortality, univariate logistic regression will first be performed. Variables with a p-value < 0.20 in univariate analysis or those with high

clinical relevance (such as MELD score, technique type, and variceal location) will be entered into a multivariate logistic regression model. Multivariate Cox proportional hazards regression will be utilized for time-to-event outcomes (e.g., time to rebleeding or death), and cumulative survival curves will be plotted using the Kaplan-Meier method with log-rank testing. The predictive accuracy of MELD, MELD-Na, MELD 3.0, CILF-C AD and Child-Pugh scores will be evaluated and compared using the Area Under the Receiver Operating Characteristic curve (AUROC). In all analyses, a two-tailed p-value < 0.05 will be considered statistically significant.

ETHICAL CONSIDERATIONS

ETHICAL APPROVAL

This study will be conducted in strict accordance with the ethical principles outlined in the Declaration of Helsinki (2013 revision) and all biomedical research regulations mandated by the Ministry of Health of Vietnam. The study protocol, patient information sheet, and informed consent form will be submitted to the Institutional Review Board (IRB) of the University Medical Center Ho Chi Minh City for formal approval. No retrospective data extraction or prospective patient screening will commence prior to obtaining formal written IRB approval.

DATA PRIVACY AND SECURITY

To preserve confidentiality and comply with patient privacy standards:

- Data Anonymization: All personally identifiable information (patient names, direct contact numbers, government-issued IDs) will be completely stripped from the final analysis dataset. Each patient will be identified solely by a unique alphanumeric ID (Patient_ID).
- Secure Storage: All electronic records, clinical databases, and coded datasets will be stored on a highly secure, encrypted server with active firewall protection. Physical CRFs and consent forms will be kept in double-locked filing cabinets at the study center.
- Access Control: Access to study data is restricted to authorized investigators directly involved in data analysis. Sharing or exporting raw study databases to third parties is strictly prohibited.

STRENGTHS AND LIMITATIONS

STRENGTHS

The TOPIC study has several significant strengths. First, its hybrid retrospective-prospective design allows the investigators to leverage a large, historical retrospective sample size (to detect meaningful associations) while simultaneously verifying findings using high-quality, complete, and meticulously collected prospective data. Second, unlike previous Vietnamese studies restricted to a single technique, the TOPIC study evaluates the entire therapeutic spectrum of portal hypertension endovascular care (TIPS, RTO, ATO, and combined procedures) at a leading referral hospital, providing an accurate, real-world baseline. Third, the study focuses on patient risk stratification by directly comparing the prognostic accuracy of modern liver disease scores (MELD 3.0, MELD-Na, CLIF-C AD) for composite clinical outcomes.

LIMITATIONS

- This is a single-center study conducted at a specialized academic university hospital, which may limit the external generalizability of our findings to primary or secondary care hospitals.

- The retrospective phase relies on the completeness of electronic medical records, which may have minor missing variables.
- The prospective cohort follow-up is restricted to 6 weeks, which prevents the evaluation of very late rebleeding or long-term outcomes.

STUDY TIMELINE (GANTT CHART)

Phase / Major Tasks	Q3 2026	Q4 2026	Q1-Q3 2027	Q4 2027 - Q1 2028	Q2-Q3 2028
Ethical Review, IRB Submission & Protocol Registration	X				
Retrospective Data Collection & Coding (n=117)		X	X		
Prospective Patient Recruitment & Follow-up (n=50)		X	X	X	
Statistical Analysis & Predictive Modeling				X	X
Manuscript Writing, Submission to Peer-Reviewed Journal					X

CONCLUSION

The TOPIC study is expected to provide comprehensive real-world evidence on the clinical outcomes of endovascular interventions for portal hypertension-related gastrointestinal bleeding in patients with cirrhosis. By evaluating TIPS, RTO/ATO, and combined techniques, the study will characterize treatment outcomes and identify pre-procedural factors associated with rebleeding and mortality. The study will also assess the prognostic performance of MELD, MELD-Na, MELD 3.0, CLIF-C AD and Child-Pugh scores in this population. These findings may support risk stratification, patient selection, and more individualized management of cirrhotic patients undergoing endovascular intervention in Vietnam.

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