

# Root Cause Analysis of Rebleeding Events following Transjugular Intrahepatic Portosystemic Shunt Creation for Variceal Hemorrhage

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## ABSTRACT

**Purpose:** To identify fundamental causes underlying recurrent variceal hemorrhage (VH) after transjugular intrahepatic portosystemic shunt (TIPS) to ascertain opportunities for improvement of TIPS-based management of VH and prevention of rebleeding.

**Materials and Methods:** This single-center retrospective study comprised 166 patients (male-to-female ratio 101:65; median age, 52 y; median Model for End-Stage Liver Disease score, 14) who had TIPS created for VH in 1998–2014. Medical record review was used to identify patients who had recurrent VH events, and root cause analysis allowed identification of the most probable causal factors. A 5-person interventional radiology physician group generated quality improvement (QI) recommendations for process changes to address causal factors, with consensus achieved using a modified Delphi method.

**Results:** Variceal rebleeding occurred after TIPS in 25 (15%) patients. The 1-, 3-, and 5-year variceal rebleeding incidence was 17%, 21%, and 21%, respectively. Variceal rebleeding was associated with high 90-day all-cause mortality incidence (10/25; 40%). Male sex ( $P = .018$ ) and Model for End-Stage Liver Disease score ( $P = .009$ ) were statistically associated with variceal rebleeding. The most common primary and secondary causes of recurrent VH were lack of or insufficient variceal embolization (64%). Other causal factors included TIPS stenosis or occlusion (28%) with recurrent portosystemic gradient (PSG) elevation (20%), severe coagulopathy (20%), inadequate portosystemic gradient reduction (12%), and TIPS underdilation (4%). To potentially address variceal rebleeding, 14 preventive QI recommendations were developed.

**Conclusions:** Although recurrent VH rates after TIPS are not trivial, rebleeding may be related to addressable underlying causal factors. Further investigation may assess the efficacy of QI-based procedure methodologic enhancements in reducing rebleeding incidence after TIPS.

## ABBREVIATIONS

HFE = human factor engineering, MELD = Model for End-Stage Liver Disease, PSG = portosystemic gradient, QI = quality improvement, RCA = root cause analysis, TIPS = transjugular intrahepatic portosystemic shunt, VH = variceal hemorrhage

Transjugular intrahepatic portosystemic shunt (TIPS) creation is a recognized treatment for gastroesophageal variceal hemorrhage (VH) (1). Whether employed as first-line therapy (2,3) or for recurrent or refractory acute

bleeding resistant to endoscopic management (1), immediate bleeding cessation may be achieved in most cases (4,5). Despite excellent early bleeding control, hemorrhage can nonetheless recur after TIPS and embolization—the overall prevalence is approximately 5%–10% in the covered stent graft era (2,3,6,7)—and although rebleeding incidence is commonly quantified in the literature, the underlying reason for treatment failure less frequently receives specific attention. Without explicit information to explain the basis for repeated bleeding, it is difficult to implement measures aimed at reducing bleeding recurrence.

Root cause analysis (RCA) is a systematic technique aimed at identifying the fundamental reasons for undesirable outcomes through meticulous retrospective scrutiny

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(8). Root causes are defined as underlying causes that can be reasonably identified, that can be targeted for correction, and for which effective preventive recommendations can be generated (8). The application of RCA can provide important information to facilitate implementation of interventions to prevent future adverse incidents from occurring. In this manner, identification of root causes of recurrent VH events may shed light on potentially beneficial approaches to reduce rebleeding rates after TIPS. The purpose of this study was to perform an RCA for recurrent VH after TIPS to explore the principal mechanisms for bleeding relapse and to identify opportunities for improvement of TIPS-based management of VH.

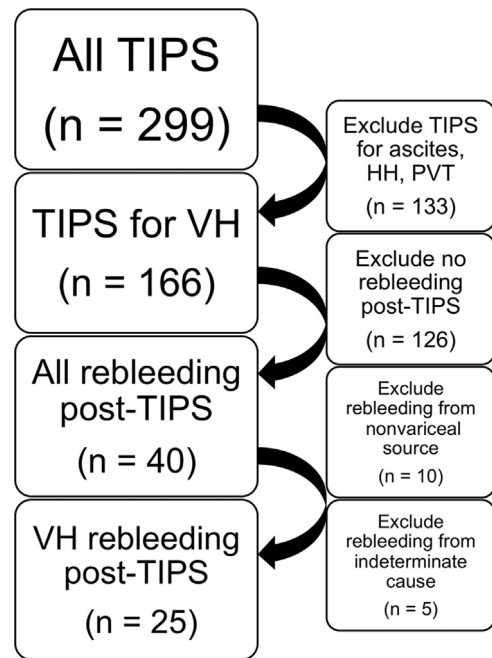
## MATERIALS AND METHODS

Institutional review board approval was granted for this study. Informed consent was obtained for TIPS procedures.

### Patients

The cohort was culled from a registry of 297 patients who underwent 299 technically successful TIPS procedures (two patients had parallel TIPS created) between November 1998 and June 2014 in the Division of Interventional Radiology (IR) at an academic tertiary care center. The case selection algorithm for study inclusion is summarized in **Figure 1**. TIPS created for a primary or secondary indication of VH were selected from the registry. TIPS created for a primary indication of VH ( $n = 159$ ) were performed for recurrent bleeding in patients despite prior medical and endoscopic treatment ( $n = 83$ ; 52%) (1) or as rescue therapy in cases of refractory acute bleeding (1) ( $n = 76$ ; 48%), whereas TIPS for a secondary indication of variceal hemorrhage ( $n = 7$ ) were created in patients with a history of variceal bleeding but whose primary procedure indication was refractory ascites, hepatic hydrothorax, or portal vein thrombosis. TIPS created solely for medically refractory ascites, hepatic hydrothorax, or portal vein thrombosis ( $n = 133$ ) were excluded.

From the identified cases, patients who had any episode of gastrointestinal hemorrhage after TIPS ( $n = 40$ ) were identified for potential RCA inclusion. Gastrointestinal hemorrhage was defined by occurrence of persistent or new clinical signs of bleeding (hematemesis, coffee-ground emesis, melena, or hematochezia) accompanied by hemoglobin reduction requiring blood transfusion, with endoscopic confirmation in most cases. Finally, cases of rebleeding from nonvariceal ( $n = 10$ ; eg, esophageal, gastric, or duodenal ulcers; portal gastropathy; or esophagitis) or indeterminate ( $n = 5$ ; not endoscopically identifiable) sources were excluded, leaving only patients with recurrent variceal bleeding after TIPS. Thus, the final study group comprised 25 patients who underwent TIPS creation for VH and who experienced recurrent



**Figure 1.** Flow diagram demonstrates selection process used to identify cases of recurrent variceal hemorrhage for RCA. HH = hepatic hydrothorax, PVT = portal vein thrombosis.

variceal bleeding. Baseline patient demographics, liver disease characteristics, and TIPS procedure outcomes for all patients who had TIPS created for VH are summarized in **Table 1**, stratified into no-rebleed and rebleed groups.

### TIPS Procedures

The technique for TIPS creation was previously described (9), but some technical details relevant to the VH indication warrant consideration. First, for shunt creation, 10-mm or 12-mm WALLSTENT bare metal stents (Boston Scientific, Marlborough, Massachusetts) were used during the period 1999–2003 and 10-mm VIATORR covered stentgrafts (W.L. Gore & Associates, Flagstaff, Arizona) were used during the period 2004–2014. Second, the target portosystemic gradient (PSG) was reduction to  $\leq 12$  mm Hg (1), with hemodynamic success defined as PSG reduction meeting this threshold. To achieve PSG reduction, TIPS were incrementally dilated using an 8-mm and 10-mm balloon until a  $\text{PSG} \leq 12$  mm Hg was achieved. Third, embolization of gastroesophageal varices was performed at the discretion of the primary operator based on the clinical circumstance (whether patient had active bleeding), degree of PSG reduction, number and size of varices, and presence and degree of variceal filling after shunt creation. Embolization was performed using 0.035/0.018-inch metallic coils or a vascular plug device.

### Root Cause Determination

**Data Collection.** Meticulous iterative case review was performed for 25 patients with recurrent variceal bleed-

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