



Emergency Transjugular Intrahepatic Portosystemic Shunt: an Effective and Safe Treatment for Uncontrolled Variceal Bleeding

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Abstract

Background Uncontrolled variceal bleeding (VB) remains a great challenge for clinical treatment. Emergency transjugular intrahepatic portosystemic shunt (TIPS) is a salvage procedure, but unsatisfactory clinical outcomes and a high incidence of complications have been reported. This study aimed to investigate the effect and safety of emergency TIPS performed in our institution during recent years.

Methods Fifty-eight consecutive cirrhotic patients with uncontrolled VB who underwent emergency TIPS from March 2009 to November 2017 in our hospital were followed until the last clinical evaluation, liver transplantation (LT), or death.

Results Overall, 5, 36, and 17 patients belonged to Child-Pugh class A, B, and C, respectively. TIPS was successfully performed in 57 (98.3%) patients at 89.5 h (mean) after initial bleeding. After TIPS, bleeding ceased in 52 (91.2%) patients, and 51 (89.5%) patients had a portal pressure gradient below 12 mmHg. Only one (1.8%) major procedure-related complication occurred without any clinical consequences, and no procedure-related deaths occurred. During follow-up, 55 hepatic encephalopathy (HE) episodes occurred in 19 (33.3%) patients, and the median time of the first HE episode was 3.1 months. Seven (12.3%) patients experienced shunt dysfunction after 8.7 months (median). The 6-week, 1-year, and 2-year variceal rebleeding rates were 10.5%, 17.1%, and 20.0%, respectively. The LT-free survival rates at 6 weeks, 1 year, and 2 years were 87.7%, 81.8% and 73.6%, respectively.

Conclusion Our study highlights the fact that emergency TIPS could be effective for patients with liver cirrhosis and uncontrolled VB with few potential complications.

Keywords Emergency · Portal hypertension · Transjugular intrahepatic portosystemic shunt · Variceal bleeding

Introduction

Variceal bleeding (VB) is one of the most common decompensating complications of liver cirrhosis and portal

hypertension. The annual risk of developing gastroesophageal varices in patients with liver cirrhosis ranges from 5 to 15%.¹ Despite recent progress in vasoactive medicines and endoscopic treatment, VB remains a medical emergency associated with a mortality ranging from 10 to 30% at 6 weeks,^{1,2} and the 5-year mortality exceeds 80% if associated with other complications.³ VB refractory to typical treatments remains a great challenge for clinical treatment and is responsible for more than 25% of cases of early death.⁴

Transjugular intrahepatic portosystemic shunt (TIPS) is a reliable treatment for controlling VB and provides more effective prophylaxis for rebleeding than does medicine or endoscopic procedures alone^{5,6} or combined.⁷ Active bleeding refractory to typical treatments is an absolute indication for prompt TIPS implantation.^{8–10} Emergency TIPS is necessary for patients with uncontrolled VB that poses an immediate threat to life in whom typical management strategies have failed. However, previous studies^{11–15} reported unsatisfactory clinical outcomes and a high incidence of complications. Thus,

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we conducted this study to investigate the effect and safety of emergency TIPS performed during recent years for patients with liver cirrhosis and uncontrolled VB in our institution.

Patients and Methods

Patients

All cirrhotic patients who underwent an emergency TIPS due to uncontrolled VB from March 2009 to November 2017 were retrospectively selected from a TIPS database in our institution. The diagnosis of cirrhosis was based on medical history, unequivocal clinical data with compatible findings on imaging techniques, or liver biopsy. Patients were excluded if they received TIPS for other indications. The protocol was approved by the West China Hospital of Sichuan University Biomedical Research Ethics Committee. The study was conducted according to the Declaration of Helsinki.

Indications for Emergency TIPS

In our study, emergency TIPS were performed for patients with failure of typical treatment or recurrence of VB despite continuous medical treatment after endoscopic hemostasis when they require 2.0 or more units of packed red blood cell transfusion or vasopressor medications to support blood pressure prior to the procedure. Failure of typical treatment was defined as active VB despite continuous medical treatment (vasoactive agents and antibiotic prophylaxis) and endoscopic hemostasis (ligation and/or injection sclerotherapy for esophageal VB and tissue glue injection for gastric VB).¹⁶

TIPS Procedure

TIPS was performed by two experienced radiologists with more than 10 years of experience following a previously described standard technique.¹⁷ Briefly, a Rosch-Uchida Transjugular Liver Access Set (Cook, Bloomington, IN, USA) was introduced into the hepatic vein via internal jugular access. Once the portal vein was accessed successfully, direct portography was obtained. After dilation of the intrahepatic passage with a balloon catheter (Cordis, Roden, Netherlands), an 8- or 10-mm stent (bare: Wallstent, Boston Scientific, MA, USA; covered: Wallgraft, Boston Scientific or Fluency, Bard, NJ, USA) was implanted. Direct portography was obtained again, and a second stent was deployed coaxially if the first stent did not maintain sufficient blood flow. Embolization with coils (Cook, Bloomington, IN, USA) and/or medical glue (BME, Guangzhou, China) was performed if portosystemic collateral vessels developed. Portal pressure gradients (PPGs) were measured before and after TIPS. Volume resuscitation, vasoactive agents, and blood transfusion were

continued during the procedure. Oxygen inhalation was regularly administered. Tracheal intubation was used to maintain oxygen saturation if necessary.

Follow-Up

All patients were followed up until death, liver transplantation (LT), or the end of data collection (January 2018). Patients who underwent transplantation during follow-up were censored at the time of transplantation. Doppler ultrasonography was carried out before discharge and at 1, 3, 6, and 12 months after TIPS and every year thereafter. Contrast-enhanced computer tomography angiography (CTA) and endoscopy were performed each year after TIPS or when clinically indicated. Portal venography was performed once shunt dysfunction was suspected. Shunt dilation with a balloon and/or supplementation with another stent was executed if necessary.

Endpoints

The primary endpoint of this study was the clinical success rate of hemostasis. Secondary endpoints included technical success rate; 6-week, 1-year, and 2-year variceal rebleeding rates and LT-free survival; and procedure-related complications.

Statistical Analysis

The SPSS 23.0 statistical software package (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. Normally distributed continuous variables were reported as the mean \pm standard deviation (SD) and compared with Student's *t* test. Non-normally distributed continuous variables were reported as medians and ranges. Categorical variables were reported as numbers and percentages. The incidences of variceal rebleeding and LT-free survival were estimated by the Kaplan-Meier method. Factors related to events during follow-up were evaluated by logistic regression, and variables with a *p* value of no more than 0.1 in univariate analysis were included in multivariate analysis with forward elimination. Odds ratios and 95% confidence intervals were calculated. When the scores for liver disease were included in multivariate analysis, their components were excluded to avoid multicollinearity. A *p* value of less than 0.05 was considered statistically significant.

Results

Study Population

From a total of 2039 patients assessed for eligibility, 58 were included in this study, and 1981 were excluded because they

received TIPS for prophylaxis of variceal rebleeding ($n = 1784$), refractory ascites ($n = 141$), hepatorenal syndrome ($n = 31$), or hepatic hydrothorax ($n = 25$). The clinical characteristics of all 58 patients (39 males, 52 ± 12 years old) before TIPS are presented in Table 1. Viral hepatitis accounted for 67% of the etiologic factors. Most patients were classified as Child-Pugh class B or C. Before TIPS, 34 (58.6%) patients

had a systolic blood pressure below 90 mmHg, 25 (43.1%) had a heart rate more than 100 beats per minute, 34 (58.6%) required balloon tamponade to achieve temporary control of bleeding, and 47 (81.0%) received a transfusion of ≥ 2.0 units of packed red blood cells. The sources of bleeding were esophageal varices in 47 (81.0%) patients and both esophageal and fundal varices in the other 11 (19.0%) patients.

Table 1 Baseline characteristics of patients

Measurement	No. of patients (%) or means \pm SD
Male	39 (67.2)
Age, years	52 ± 12
Etiology of cirrhosis	
HBV	33 (56.9)
Alcoholic	4 (6.9)
HBV + Alcoholic	4 (6.9)
HCV	2 (3.4)
Autoimmune liver diseases	10 (17.2)
Others	5 (8.6)
MELD score	10.5 ± 4.6
Child-Pugh score	8.7 ± 1.7
Child-Pugh classification	
Class A	5 (8.6)
Class B	36 (62.1)
Class C	17 (29.3)
Baseline lab tests	
Hemoglobin, g/L	69.1 ± 20.7
Bilirubin, $\mu\text{mol/L}$	33.9 ± 43.0
Albumin, g/L	27.5 ± 6.7
Creatinine, $\mu\text{mol/L}$	71.2 ± 24.6
Prothrombin time, s	17.0 ± 4.4
Serum sodium, g/L	138.9 ± 4.3
Ascites	47 (81.0)
Mild	20 (34.5)
Moderate	14 (24.1)
Severe	13 (22.4)
Hemodynamic indexes before TIPS	
Heart rate, bpm	100 ± 24
Mean blood pressure, mmHg	76 ± 16
Hemorrhagic shock within 24 h before TIPS	34 (58.6)
Need for Balloon tamponade before TIPS	34 (58.6)
Blood transfusion before TIPS	
Need for PRBC transfusion	50 (86.2)
Amount of PRBC transfusion, u	8.6 (range, 1.5–78.5)
Need for serum transfusion	33 (56.9)
Amount of serum transfusion, ml	1048 (range, 150–13,150)
Need for ventilation and intensive care after TIPS	9 (15.5)

All results are expressed in number of patients (%) or means \pm SD unless otherwise stated

HBV hepatitis B virus, *HCV* hepatitis C virus, *AIH* autoimmune hepatitis, *MELD score* model for end-stage liver disease score, *PRBC* packed red blood cell, *SD* standard deviation, *bpm* beats per minute, *SD* standard deviation

Procedural Characteristics

TIPS was carried out at a mean time of 89.5 h (range, 3 to 564 h) after bleeding. Technical success was achieved in 57 (98.3%) patients, with the exception of one patient who had extensive cavernous formation of portal vein. Bare stents were inserted in three patients before July 2010, and covered stents were used thereafter. After TIPS, a total of 51 (89.5%) patients had hemodynamic success based on a decreased PPG below 12 mmHg after TIPS. The mean PPG decreased from 21 to 9 mmHg ($p < 0.001$). The technical details of the procedure are summarized in Table 2.

Clinical Success

After TIPS, bleeding ceased in 52 (91.2%) patients. The remaining five continued to bleed until day 3, and three of these patients died from uncontrolled bleeding. Another patient experienced recurrent bleeding at day 24. Thus, a total of 6 (10.5%) patients reached 6 weeks of variceal rebleeding. In univariate and multivariate analyses, bare stent implantation and increased peripheral white blood cells (Δ WBCs) after TIPS were independent risk factors for 6-week variceal rebleeding (Table 3). At the end of this study, a total of 12 patients exhibited evidences of recurrent VB due to shunt dysfunction demonstrated by CTA and endoscopy. The 6-week, 1-year, and 2-year variceal rebleeding rates were 10.5%, 17.1%, and 20.0%, respectively (Fig. 1a).

Survival

At the end of data collection, the median time of follow-up was 17.3 months (range, 0.1 to 66.6 months). Five (8.8%) patients were lost to follow up after 17.0 months (median). Six patients died from rebleeding ($n = 3$) and liver failure ($n = 3$) within 6 weeks. In univariate analysis, the following factors were associated with 6-week mortality: 6-week variceal rebleeding, need for mechanical ventilation and intensive care, serum alkaline phosphatase before TIPS, and increased Δ WBC. In multivariate analysis, 6-week variceal rebleeding and the need for mechanical ventilation and intensive care were independent predictive factors of 6-week mortality (Table 4). By the end of the study, a total of 13 patients had died at a median of 4.4 months (range, 0–58.5 months). The main causes of death were variceal rebleeding ($n = 5$) and liver failure ($n = 6$) (Table 5). Another three patients underwent LT at 1, 5, and 17 months after TIPS. Thus, the LT-free survival rates at 6 weeks, 1 year, and 2 years were 87.7%, 81.8%, and 73.6%, respectively (Fig. 1b).

Complications

Only one major complication occurred during TIPS. Accidental punctures of the intrahepatic biliary duct and arteriole occurred in one female patient who had a severely deformed liver. An intrahepatic arteriohepatic duct fistula was confirmed by hepatic arteriography and embolized by coils

Table 2 Technical outcomes of emergency TIPS

Measurement	No. of patients (%) or means \pm SD ($n = 57$)
Time between the initial bleeding and TIPS, h	89 (range, 3–564)
TIPS performed within 72 h	37 (63.8)
Technical success	57 (98.3)
Number of stents implanted	
One	41 (71.9)
Two	16 (28.1)
Type of stents	
Bare	3 (5.3)
Covered	54 (94.7)
Diameter of stents	
8 mm	39 (68.4)
10 mm	18 (31.6)
Patients with variceal embolization	47 (82.5)
PPG, mmHg	
Pre-TIPS	21 \pm 5
Post-TIPS	9 \pm 4

All results are expressed in number of patients (%) or means \pm SD unless otherwise stated
PPG portal pressure gradient, SD standard deviation

Table 3 Factors associated with 6-week treatment failure

Parameter	Coefficient	OR (95% CI)	p value
Univariate analysis			
Type of stent	3.22	25.00 (1.84–339.15)	0.016
ΔWBC	0.23	1.26 (1.04–1.52)	0.017
Multivariate analysis			
Type of stent	3.80	44.62 (1.95–1023.81)	0.017
ΔWBC	0.26	1.30 (1.05–1.61)	0.017

ΔWBC increase of peripheral white blood cells count after TIPS, OR odds ratio, CI confidence interval

after TIPS. The patient showed no significant clinical consequences.

In total, 55 hepatic encephalopathy (HE) episodes occurred in 19 (33.3%) patients. The median time of the first HE episode was 3.1 months. Most patients had only one or two HE

episodes. Overt HE occurred in 17 patients. The main precipitating factors of HE were active bleeding ($n = 6$), high-protein diet ($n = 7$), and constipation ($n = 5$). Most HE episodes were ameliorated after medical treatments.

Seven (12.3%) patients experienced shunt dysfunction after 8.7 months (median) that was indicated by CTA and endoscopy and confirmed by portography. Two patients responded well to anticoagulation medicines, and the remaining five were treated by supplementary stents. No patients experienced VB recurrence after these treatments (Table 6).

Discussion

This study shows that emergency TIPS could be an effective treatment for uncontrolled VB with a low incidence of potential complications.

Emergency TIPS is a salvage procedure for patients with liver cirrhosis and uncontrolled VB, but unsatisfactory clinical outcomes and a high incidence of complications have been reported. Two independent studies including patients accepting bare stents^{11,14} may represent early analyses of emergency TIPS. In one study¹¹ ($n = 56$), the 1-month actuarial probability of rebleeding and mortality was 22 and 28%, respectively. The other study¹⁴ ($n = 54$) showed worse outcomes in which 16 (30%) patients had rebleeding, and 26 (48%) died within 6 weeks. Two additional studies^{12,13} using both bare and covered stents showed that the 1-month rebleeding rates were 13.4 and 16%, and the 1-month mortality rates were 25.6 and 31%, respectively. Another study¹⁵ ($n = 58$) reported a 60-day mortality rate of up to 64%. Our study shows more effective bleeding control and reduced early mortality, with a 6-week rebleeding rate and mortality of 10.5%. In a recent study¹⁸ describing selective TIPS for prophylaxis for rebleeding ($n = 286$), the 6-week mortality, 1-year rebleeding rate, and 1-year LT-free survival were 12%, 18.2%, and 67.1%, respectively. Similar clinical outcomes were achieved in our study as those indicators were 10.5%, 17.1%, and 81.8%, respectively. In addition, the previously reported¹¹ incidence of procedure-related complications of emergency TIPS was up to 23.2% (13/56); these complications included cardiorespiratory arrest, acute cardiac failure, and acute renal failure. However, in our study, only one patient had a major complication with no clinical consequences after treatment, and no procedure-related death occurred. Additionally, the incidence of post-TIPS HE in our study was 33% (19/57), which was not higher than the previously reported incidence of 10–50% in selective TIPS for prophylaxis for rebleeding.¹⁹ A total of 7 (12.3%) patients experienced shunt dysfunction, and no patients had VB recurrence after treatment. These results indicate that the emergency TIPS included in our study is actually more effective and safe than those previously reported.

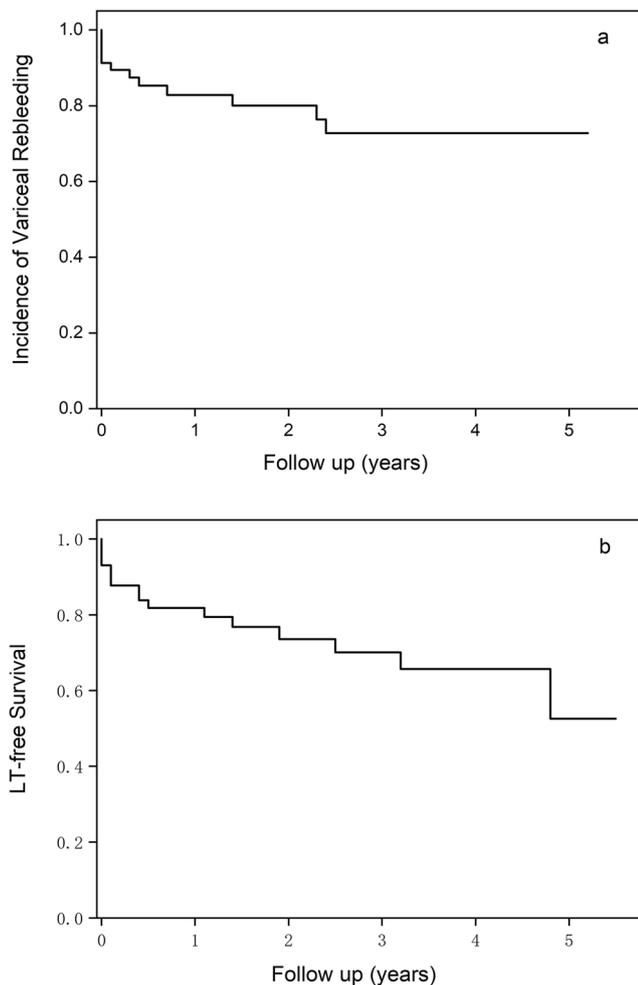


Fig. 1 Kaplan-Meier curves of incidence of variceal rebleeding and liver transplantation (LT) -free survival. **1a:** The incidence of 6-week, 1-year and 2-year variceal rebleeding were 10.5%, 17.1%, 20.0%, respectively. **1b:** The LT-free survival at 6 weeks, 1 year and 2 years were 87.7%, 81.8% and 73.6%, respectively

Table 4 Factors associated with 6-week mortality

Parameter	Coefficient	OR (95% CI)	<i>p</i> value
Univariate analysis			
6-week variceal rebleeding	2.46	11.75 (1.76–78.42)	0.011
Ventilation and intensive care	3.04	20.89 (3.13–139.41)	0.002
Serum ALP before TIPS	0.01	1.01 (1.00–1.02)	0.046
ΔWBC	0.13	1.14 (0.97–1.33)	0.10
Multivariate analysis			
6-week variceal rebleeding	3.44	31.06 (2.26–426.24)	0.010
Ventilation and intensive care	3.84	46.36 (3.77–570.10)	0.003

ΔWBC increase of peripheral white blood cells count after TIPS, OR odds ratio, CI confidence interval

TIPS in patients with decompensated cirrhosis and acute esophageal VB was associated with significant in-hospital reductions in rebleeding and mortality in real-world clinical practice.¹⁰ However, six deaths still occurred within 6 weeks in our study. Technically speaking, emergency TIPS is different from the formal concept of early TIPS (within 72 h)^{8,10} or acute VB (within 120 h).²⁰ Indeed, emergency TIPS is indicated only when prompt portosystemic shunt creation is necessary for patients with refractory VB that is an immediate threat to life. Of the patients included in this study, 43.1% had an increased heart rate above 100 bpm, 58.6% had a systolic blood pressure below 90 mmHg, 58.6% required balloon tamponade to achieve temporary control of bleeding, and 81.0% received a transfusion of ≥ 2.0 units of packed red blood cells before TIPS. These data help to illustrate the severe, emergent settings of this subpopulation before the procedure.

Regression analyses suggested that bare stent implantation and increased ΔWBC were predictors of 6-week variceal rebleeding. Covered stents were much better than bare stents at controlling active bleeding (OR = 44.62, $p = 0.017$), consistent with the results of previous studies.^{18,21–25} Increased ΔWBC, which is associated

with infection and systemic inflammation, was also found to predict 6-week variceal rebleeding (OR = 1.30, $p = 0.017$), in line with the results of previous studies describing the relationship between peripheral WBC count and 6-week mortality.¹⁴ This finding should be validated in a larger study and requires further research because inflammation markers, such as interferon-6 and procalcitonin, were not analyzed in our study.

This study has several shortcomings. First, this is a retrospective study with a limited sample size from a single institution, making it susceptible to selection bias. Second, three patients received bare metal stents in the early years of this

Table 5 Clinical outcomes of emergency TIPS

Clinical outcomes	N of patients (%) (<i>n</i> = 57)
Lost to follow-up	5 (8.8)
Median time of lost to follow-up, months	17.0 (range, 3.9–42.0)
Liver transplantation	3 (5.3)
Overall death	13 (22.8)
Causes of deaths	
Gastroenterological bleeding	5 (8.8)
Hepatic failure	6 (10.5)
Sepsis secondary to SBP	1 (1.8)
Myocardial infarction	1 (1.8)

All results are expressed in number of patients (%) unless otherwise stated
HE hepatic encephalopathy, SBP spontaneous bacterial pneumonitis

Table 6 Complications of emergency TIPS

Complications	No. of patients (%) (<i>n</i> = 57)
Complications during TIPS	
HE	19 (33.3)
HE grades	
WH Level 1	2 (10.5)
WH Level 2	10 (52.6)
WH Level 3–4	7 (36.9)
HE episodes	
1	9 (47.4)
2	5 (26.3)
≥ 3	5 (26.3)
Precipitating factor of HE	
Gastrointestinal bleeding	6 (31.6)
High-protein diet	7 (36.8)
Constipation	5 (26.3)
Unknown	1 (5.3)
Shunt dysfunction	7 (12.3)
Time of dysfunction after TIPS, months	8.7 (range, 0.8–40.9)
Treatment of dysfunction	
Medication	2 (28.6)
Shunt supplement	5 (71.4)

All results are expressed in number of patients (%) unless otherwise stated
HE hepatic encephalopathy, WH West-Haven classification

investigation. Finally, patients in our study were recruited over 8 years, and the therapeutic strategy for VB and technical differences in TIPS implantation during this period might have contributed to differences in clinical outcomes over time.

In conclusion, emergency TIPS could be an effective and safe treatment for patients with uncontrolled VB. This study may provide more confidence regarding emergency TIPS for clinical physicians and radiological operators. Additionally, this study might be helpful in providing patients with a full understanding of the procedure and improve urgent decision-making process.

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Author Contributions Xiao Li and Xuefeng Luo contributed equally to TIPS operations. Yongjun Zhu and Xiaotan Xi were both in charge of collecting patient information and clinical data. Yongjun Zhu and Xiaozhe Wang contributed to the statistics. All the authors helped to draft the manuscript. Li Yang and Xuefeng Luo approved the final manuscript.

Compliance with Ethical Standards

The protocol was approved by the West China Hospital of Sichuan University Biomedical Research Ethics Committee. The study was conducted according to the Declaration of Helsinki.

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