

# Race and Gradient Difference Are Associated with Increased Risk of Hepatic Encephalopathy Hospital Admission After Transjugular Intrahepatic Portosystemic Shunt Placement

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**Background/Aims:** Hepatic encephalopathy (HE) is a well-recognized complication of transjugular intrahepatic portosystemic shunt (TIPS) placement. The aim of this investigation was to evaluate incidence and predictors of post-TIPS HE necessitating hospital admission in a non-clinical trial setting. **Methods:** We performed a retrospective cohort study identifying 273 consecutive patients undergoing TIPS from 2010 to 2015 for any indication; 210 met inclusion/exclusion criteria. The primary endpoint was incidence of post-TIPS HE defined as encephalopathy with no other identifiable cause requiring hospitalization within 90 days of TIPS. Clinical demographics and procedural variables were collected and analyzed to determine predictors of readmission for post-TIPS HE. Categorical variables were analyzed using Fisher's exact test; continuous variables were compared using Levene's *t*-test and student's *t*-test;  $P < 0.05$ , significant. **Results:** Forty-two of 210 patients (20%) developed post-TIPS HE requiring hospitalization within 90 days. On analysis of cohorts (post-TIPS HE vs. no post-TIPS HE): non-white race (31.0% vs. 17.5%,  $P = 0.022$ ) and increased hepatic venous pressure gradient (HVPG) difference during TIPS (10.5 vs. 8.9 mmHg,  $P = 0.030$ ) were associated with an increased incidence of HE requiring readmission within 90 days. **Conclusions:** HE remains a common complication of TIPS. Non-Caucasian race is a significant clinical demographic associated with increased risk for readmission. Independent of initial or final HVPG, HVPG difference appears to be a significant modifiable technical risk factor. In the absence of clear preventative strategies for post-TIPS encephalopathy, non-Caucasians with HVPG reductions  $>9$  mmHg may require targeted follow up evaluation to prevent hospital readmission. (J CLIN EXP HEPATOL 2017;xx:1–6)

Transjugular intrahepatic portosystemic shunt (TIPS) placement is an established treatment option for complications of cirrhosis related to portal hypertension.<sup>1–4</sup> Utilization has increased significantly; from 2003 to 2013 TIPS placements increased 51% in the Medicare population.<sup>5</sup> With technical refinements, peri-procedural complications and mortality from TIPS have decreased.<sup>5</sup> Long term complications including need

for rescue transplant, shunt dysfunction/need for revision and mortality have also decreased with the advent of the polytetrafluoroethylene (PTFE) covered stents.<sup>6,7</sup>

Hepatic encephalopathy (HE) remains one of the most common and significant short-term complications of TIPS.<sup>8</sup> The postulated mechanism is multi-factorial including: increased production of enteric neurotoxins from intestinal bacteria, reduced hepatic filtering due to liver dysfunction or vascular shunting from the portal to systemic circulations and increased permeability of the blood-brain barrier.<sup>9,10</sup> The true incidence of post-TIPS HE has been difficult to determine and varies considerably between studies performed.<sup>11</sup> Estimates range from 22% to 50% depending on the exact definition of HE used and patient demographics.<sup>2,12–20</sup> Likewise, risk factors for development of post-TIPS HE have varied between studies. One large meta-analysis found age over 65, advanced Child-Pugh score and history of HE to be robust predictors.<sup>11</sup> Pre-procedure variables and their association with incidence of post-TIPS HE require further clarification.

**Keywords:** hepatic encephalopathy, transjugular intrahepatic portosystemic shunt, TIPS

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**Abbreviations:** HE: hepatic encephalopathy; HVWP: hepatic venous wedge pressure; HVPG: hepatic venous pressure gradient; PTFE: polytetrafluoroethylene; PVT: portal vein thrombus; TIPS: transjugular intrahepatic portosystemic shunt

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The aim of this investigation was to characterize the association between patient demographic and procedure variables with incidence of post-TIPS HE in a “real world” clinical setting.

## MATERIALS AND METHODS

### Subject Inclusion/Exclusion

After institutional review board approval, consecutive patients who underwent TIPS from January 2010 to December 2015 at a tertiary referral hospital were identified by procedural (ICD-9/ICD 10) code. Retrospective medical record review was performed identifying 273 individuals who underwent initial TIPS placement during the timeframe. Sixty-three patients were excluded given lack of complete 3 month follow up data, leaving a total of 210 for analysis.

### TIPS Procedure

The TIPS procedure was performed in the usual fashion. Venous access was gained through the right jugular vein. A catheter was advanced into the hepatic vein for venography and wedged hepatic vein pressure measurement. Right atrial pressure measurement was also performed. The portovenous system was then accessed through the right hepatic vein. Catheterization, portovenogram, portal vein pressure measurement and transluminal angioplasty of the intrahepatic tract followed by deployment of a Viatorr (Gore Medical, Flagstaff, AZ, USA) covered stent across the tract was carried out. The appropriate sizing of the stent was at the discretion of the performing interventional radiologist. Repeat portal venous pressure, right atrial pressure and a venogram were obtained after balloon dilation of the stent.

### Post-Procedure Care

Patients with a history of HE prior to TIPS were continued on lactulose ( $n = 73$ ) post-procedure. Combination therapy with rifaximin was used only in patients who developed post-TIPS. No patient was on rifaximin monotherapy. Primary HE pharmacologic prophylaxis was not used in any patients. Nonselective beta blockers were stopped indefinitely in all patients after TIPS.

### Clinical Endpoints

The primary endpoint was incidence of post-TIPS HE. This was defined as HE not precipitated by any identifiable cause such as infection, bleeding, azotemia, new portal vein thrombus or malignancy that required hospitalization within 90 days of TIPS procedure. The patients' hospitalization records including initial admission assessments and discharge diagnoses were reviewed. Clinical demographics including age, gender, race, pre-procedure MELD, hemoglobin, creatinine, INR, total bilirubin,

albumin, history of pre-procedure HE and TIPS indication were collected and tabulated. Procedural variables including initial hepatic venous wedge pressure (HVWP), initial hepatic venous pressure gradient (HVPG), final HVPG, HVPG difference (initial HVPG minus final HVPG) were recorded.

### Statistical Analysis

Variables were analyzed to determine predictors of readmission for post-TIPS HE within 90 days. Data are presented as means for continuous variables and compared using Levene's *t*-test for equal variances and student's *t*-test;  $P < 0.05$ , significant. Categorical variables are presented as absolute numbers and were analyzed using Fisher's exact test. Analyses were performed using IBM SPSS Statistics for Windows, version 23 (IBM Corp., Armonk, NY, USA).

## RESULTS

### Patient Demographics

Patient demographics and baseline laboratory values for the 210 patients undergoing TIPS are shown in [Table 1](#). Men outnumbered women 2:1. Average age was 56 and average MELD score was 14.8. Mean MELD for non-emergent and emergent cases was 13.4 and 17.7 respectively. Baseline laboratory data was notable for a mildly increased average creatinine of 1.13, total bilirubin of 2.6 and INR of 1.5. 65% of patients had no history of HE. The 2 most common indications were refractory ascites (32.9% of cases) and acute variceal bleeding (29% of cases). Thirty patients (14.3% of cases) with non-occlusive portal vein thrombus (PVT) underwent TIPS.

### Hepatic Encephalopathy and Risk Factors

Forty-two of 210 patient (20%) developed unprovoked HE requiring hospitalization within 90 days of TIPS placement. Demographic and procedural variables for the groups with and without HE are presented in [Table 2](#). Non-white ethnicity was associated with a higher incidence of HE admission within 90 days ( $P = 0.022$ ). Likewise, a higher HVPG difference (initial HVPG – final HVPG) was predictive of an increased risk of HE ( $P = 0.03$ ). However, the initial and final gradients in isolation were not statistically significantly different. Age, gender, MELD score, indication for procedure and emergent vs. non-emergent indication did not affect the risk of HE. There was a trend toward significance for patient with a history of HE prior to TIPS ( $P = 0.111$ ). Shunt size did not predict post-TIPS HE.

### Other Outcome Measures

Twenty-five of 210 patients (12%) required TIPS revision over the 90-day follow up period: 18 shunt expansions, 2 shunt reductions (1 for refractory HE, 1 for hepatic

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