



Transjugular intrahepatic portosystemic shunt for the management of symptomatic malignant pseudocirrhosis

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Background: Pseudocirrhosis is defined by radiologic changes of the liver parenchyma secondary to metastatic disease and/or cancer treatments, and portends a high rate of morbidity and mortality from sequelae of portal hypertension. Transjugular intrahepatic portosystemic shunt (TIPS) is an effective treatment for portal hypertension; however, TIPS is relatively contraindicated in the setting of hepatic metastases. The study aims to determine the technical efficacy and clinical outcomes of patients undergoing TIPS for symptomatic pseudocirrhosis.

Methods: Retrospective analysis of patients with hepatic malignancy who underwent TIPS between 2008 and 2020 at a single tertiary care center. Patients with imaging findings of pseudocirrhosis and without history of primary liver malignancy or confounding causes of cirrhosis were included. West Haven scores assessing hepatic encephalopathy were obtained from chart review. Technical success was defined as successful TIPS creation with reduction in the portosystemic gradient (PSG). Clinical success was defined as resolution of variceal bleeding and/or ascites.

Results: Nine patients (4 female/5 male), average (\pm SD) age 61.2 ± 9.5 years with metastatic pseudocirrhosis were included for analysis. Primary malignancy was colorectal adenocarcinoma ($n=5$), neuroendocrine tumor ($n=3$), and malignant endothelial hemangioendothelioma ($n=1$). Average Model for End Stage Liver Disease (MELD-Na) score was 15.7 ± 3.7 . Technical success was 8/9 (89%) with average PSG reduced from 23.5 ± 11.0 to 6.5 ± 2.8 mmHg ($P=0.001$). Clinical success was 6/9 (67%). Two patients required TIPS revision after initial clinical success. Mild-moderate HE occurred in 6/9 patients post TIPS (67%), with a highest West Haven score of 2. Time from TIPS to death for acute variceal bleeding and ascites was 4.9 ± 4.2 and 12 ± 16.5 months, respectively. Cause of death was disease progression ($n=5$), variceal bleeding ($n=1$), or unavailable ($n=2$).

Conclusions: TIPS in the setting of malignant pseudocirrhosis can be created safely with similar clinical outcomes to TIPS performed for benign disease. Rates of low-grade hepatic encephalopathy may be higher amongst patients undergoing TIPS for pseudocirrhosis.

Keywords: Pseudocirrhosis; transjugular intrahepatic portosystemic shunt (TIPS); ascites; variceal bleeding

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Introduction

Pseudocirrhosis is defined by micro- and macroscopic changes of the liver parenchyma secondary to metastatic disease and/or systemic therapies in a pattern which mimics the imaging findings of cirrhosis (1,2). Radiologic findings associated with this diagnosis include diffuse nodularity of the hepatic contour, multifocal capsular retraction, segmental volume loss, and/or caudate lobe enlargement (2-5). Pseudocirrhosis differs from cirrhosis at the cellular level by the absence of bridging fibrosis (2,6-8). The two primary hypothesized etiologies are parenchymal changes caused by nodular regenerative hyperplasia and/or tumor deposits causing sinusoidal obstruction and obstructive portal hypertension (2,9).

Pseudocirrhosis is most commonly described in the breast cancer population where 50–75% of patients with hepatic metastases will develop pseudocirrhosis (1,5,10,11). It carries a high rate of morbidity and mortality related to sequelae of portal hypertension (1,3,12). In patients with metastatic disease to the liver and imaging findings consistent with pseudocirrhosis, the prevalence of clinically significant ascites ranges from 35–68% and 9–23% for esophageal varices (1-3,11). If radiologic evidence is considered, the prevalence of ascites reaches as high as 81.3% (3).

Transjugular intrahepatic portosystemic shunt (TIPS) is an effective treatment for portal hypertension and its complications, including refractory ascites, variceal hemorrhage, and hepatic hydrothorax. According to the American Association for the Study of the Liver (AASLD) and Society of Interventional Radiology (SIR) Guidelines, extensive primary or metastatic malignancy is a relative contraindication to TIPS due to a perceived risk of complications such as shunt occlusion and hemorrhage (13,14). Multiple studies have reported the utility of TIPS in the setting of cirrhosis with concomitant hepatocellular carcinoma (HCC) (14-21). Minimal data exists on TIPS for the treatment of pseudocirrhosis secondary to extensive non-HCC hepatic malignancy. Case studies of 1–3 patients have reported successful use of TIPS for the treatment of symptomatic pseudocirrhosis secondary to metastatic breast cancer (3,7,22,23). In addition, Wallace *et al.* used TIPS for the treatment of two patients with portal hypertension from non-HCC and non-breast diffuse hepatic malignancy (24). The objective of this study was to determine the efficacy and clinical outcomes of patients undergoing TIPS for the palliative treatment of symptomatic malignant non-

HCC pseudocirrhosis. We present the following article in accordance with the STROBE reporting checklist (available at <https://jgo.amegroups.com/article/view/10.21037/jgo-21-501/rc>).

Methods

Clinical Subjects

Clinical data were retrospectively collected from all patients with hepatic malignancy who underwent TIPS between 2008 and 2020, identified using an IR quality assurance database. Imaging findings were reviewed to confirm the presence of radiologic pseudocirrhosis. Exclusion criteria included patients <18 years of age, history of HCC, or medical history of any confounding causes of cirrhosis, including viral hepatitis or Budd-Chiari syndrome. Patient records were reviewed for demographic information, medical history, underlying malignancy, treatment regimens, TIPS procedural details, procedural complications, and clinical outcomes. West Haven (WH) scores assessing the degree of hepatic encephalopathy (HE) were obtained directly from chart review. If a WH score was not explicitly documented, the score was determined based on the description of symptoms provided in any available clinical documents. If there were indeterminate features (e.g., grade 2 versus grade 3), the higher score was used. If the patient was intubated for symptoms related to HE, they were automatically graded as a 4. All available patient data were used for the follow-up period. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the institutional review board of the Hospital of the University of Pennsylvania (No. 811929) and individual consent for this retrospective analysis was waived.

TIPS procedural technique

All patients presenting for TIPS underwent clinical and imaging assessment with computerized tomography (CT) or magnetic resonance imaging (MRI). Sedation was provided based on individual patient assessment, ranging from moderate sedation to general anesthesia. Percutaneous access was obtained through the right internal jugular vein. A portal venous access set (Rosch-Uchida Transjugular Liver Access Set (Cook Medical, Bloomington, IN, USA), Ring set (Cook Medical, Bloomington, IN, USA), or Cope set (Cook Medical, Bloomington, IN, USA) was used to

cannulate the portal vein. A 5 Fr pigtail maker catheter was then placed into the portal vein and digital subtraction angiography (DSA) was performed. Right atrial and portal pressures were measured. The intrahepatic tract was dilated and an expanded polytetrafluoroethylene (e-PTFE) covered stent (Viatorr; W.L. Gore and Associates, Flagstaff, AZ, USA) was placed from the portal vein into the right hepatic vein. An e-PTFE controlled expansion stent was used in one patient in the cohort (Viatorr with Controlled Expansion; W.L. Gore and Associates, Flagstaff, AZ, USA). The stent graft subsequently underwent balloon angioplasty. In cases in which the stent graft did not fully cover the TIPS tract to the level of the hepatic veins, an additional stent was placed (Zilver (Cook Medical, Bloomington, IN, USA) or Fluency (Becton Dickinson, Franklin Lakes, NJ, USA). The 5 Fr pigtail catheter was then replaced into the portal vein. Post-TIPS DSA was performed and right atrial and portal venous pressures were measured. The catheter and sheaths were then removed, and hemostasis achieved with manual compression.

Technical success was defined as successful creation of the TIPS with reduction in the portosystemic gradient (PSG). Clinical success was defined as technically successful TIPS creation and resolution of the clinical indication for which the procedure was performed. Adverse events were classified in accordance with the SIR guidelines and the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0 (25,26).

Statistical analysis

Statistical analysis was performed with SPSS Statistical Software (Version 27, IBM, Armonk, NY, USA) to compare PSG pre and post TIPS creation. Shapiro Wilk normality tests were performed on the data and a paired *t*-test was used. A *P* value of <0.05 was considered statistically significant.

Results

Patient characteristics

Nine patients (4F/5M), average (\pm SD) age 61.2 ± 9.5 years, underwent TIPS for the treatment of symptomatic pseudocirrhosis (Figure 1). Underlying primary malignancy consisted of metastatic colorectal adenocarcinoma ($n=5$), neuroendocrine tumor ($n=3$), and malignant hepatic endothelial hemangioendothelioma ($n=1$) (Table 1). Additional sites of metastatic disease were seen in the lung ($n=3$),

bone ($n=3$), peritoneum ($n=2$), and spleen ($n=1$). Average number of treatments for the primary disease consisted of 3.4 ± 2.9 medicinal/radiation regimens and 2.9 ± 2.1 liver-directed therapies (Table 1). Prior to TIPS, the patient with hepatic endothelial hemangioendothelioma underwent liver transplant, which then developed recurrent disease.

Liver disease

At the time of TIPS creation, average MELD and MELD-Na were 10.4 ± 3.0 and 15.7 ± 3.7 , respectively. MELD-Na ranged from 11–21. Childs-Pugh score ranged from B7–B9. Evidence of symptomatic portal hypertension pre-TIPS consisted of ascites ($n=3$), varices ($n=3$), ascites and varices ($n=2$), and ascites with hepatic hydrothorax ($n=1$). Location of varices consisted of esophageal ($n=1$), esophageal varices with portal gastropathy ($n=2$), and esophageal/gastric varices with portal gastropathy ($n=2$). One patient underwent banding prior to TIPS. Of the three patients who underwent TIPS for the treatment of acute variceal bleeding (AVB), only one had known varices prior to the sentinel bleed, which had not been treated. At the diagnosis of AVB, one patient underwent unsuccessful banding of 12 esophageal and gastric varices prior to TIPS. One patient had a history of mild HE (WH grade 1) prior to TIPS for which they had been prescribed lactulose. In patients with ascites, time from first large volume paracentesis to TIPS was 5.6 ± 2.9 months. Among three patients with available fluid data, all had a serum ascites-albumin gradient (SAAG) >1.1 (range, 1.4–2.3). Among four patients with available fluid cytology, all were negative for malignancy. One patient had a tunneled peritoneal drainage catheter placed prior to TIPS. No other durable therapies for ascites were used.

Liver lesion sampling via biopsy or hepatectomy occurred in 7/9 patients. Of the five biopsies describing background liver parenchyma, none had pathology consistent with bridging fibrosis or nodular regenerative hyperplasia. One sample noted a hyalinized nodule. The patient with hepatic endothelial hemangioendothelioma was noted to have liver tissue notable for angiomatosis and hobnail growth pattern of the vascular channel cells, as well as circumscribed vascular lesions with open well-formed vascular channels. Additionally noted were small foci of rare vacuolated endothelial cells in a myxoid stroma.

TIPS

Mean (\pm SD) contrast dose was 68.9 ± 26.6 mL and

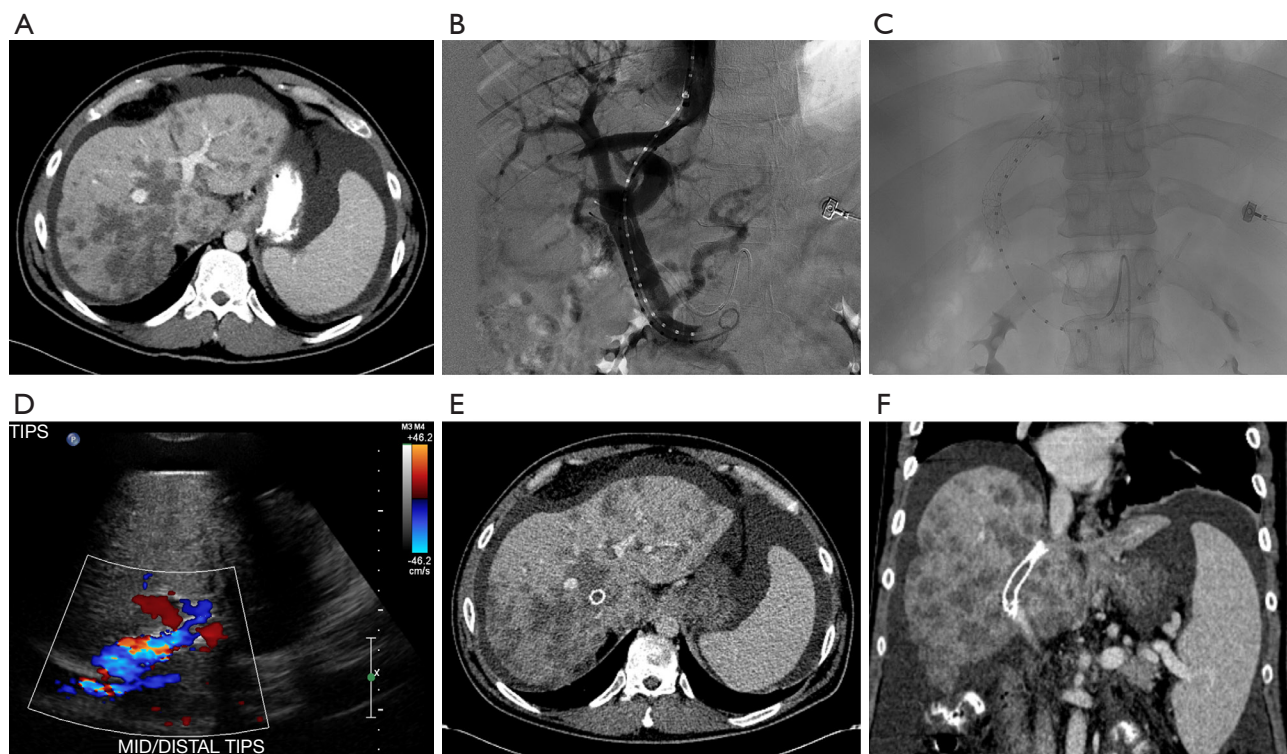


Figure 1 Patient with colorectal cancer complicated by extensive metastatic disease to the liver. (A) Computerized tomography (CT) is notable for evidence of radiologic pseudocirrhosis including multifocal capsular retraction, segmental volume loss and caudate hypertrophy, as well as diffuse ascites; (B,C) transjugular intrahepatic portosystemic shunt (TIPS) placement; (D) post-TIPS ultrasound with color doppler showing appropriate flow through the TIPS stent; (E) post-TIPS axial CT image notable for appropriate placement of the stent extending through the liver and multiple hepatic metastases; (F) post-TIPS coronal CT image notable for appropriate placement of the stent extending through the liver and multiple hepatic metastases.

fluoroscopy time was 46.4 ± 22.1 min. Viatorr PTFE-covered stents (W.L. Gore and Associates, Flagstaff, AZ, USA) with diameters of 8 (n=1) and 10 mm (n=8) with length ranging from 8–10 cm were used. Three patients had additional stents placed for tract elongation.

Technical success was 8/9 (89%). Average PSG was statistically significantly reduced from 23.5 ± 11.0 to 6.5 ± 2.8 mmHg ($P=0.001$). The patient who failed TIPS creation had metastatic pancreatic neuroendocrine tumor and presented for acute variceal bleeding, with prior MR showing significant portal vein narrowing. Three days prior to TIPS, the patient had undergone trans-splenic portal vein stenting which was complicated by venous rupture treated with stenting and balloon tamponade. During TIPS, significant thrombus was identified with the splenic and portal venous stents requiring mechanical thrombectomy [AngioJet (Boston Scientific, Marlborough, MA, USA)] and anticoagulation. Minimal flow was achieved through

the portal and splenic venous stents and no PSGs were measured.

No immediate procedural adverse events occurred in any patient. Two patients experienced mild adverse events within the hospital stay after TIPS creation. One patient developed Grade 2 pulmonary edema requiring diuresis and one patient developed Grade 2 acute kidney injury which resolved with fluids as well as an episode of Grade 1 hematochezia which resolved without intervention.

Clinical outcomes

Clinical success was documented in 6/9 patients (67%). By primary TIPS indication, clinical success was 2/3 (67%) for acute variceal bleeding and 4/6 (67%) for ascites. Among the clinical failures, the patient who had a technically unsuccessful TIPS in the setting of acute bleeding varices underwent distal pancreatectomy/splenectomy the next

Table 1 Patient characteristics

Subject	Primary tumor	Liver intervention and chemotherapy regimens	TIPS indication	MELD Na	Clinical outcome	Follow up (months) and survival
1	Colorectal	Hepatic lobectomy; cyberknife; FOLFOX, avastin, FOLFIRI, modified FOLFOX; partial PVT	AVB	18	No further bleeding	9.8, death
2	Colorectal	Wedge resection; RFA, TACE; FOLFOX, avastin, FOLFIRINOX, 5-FU, capecitabine, FOLFIRI/cetuximab	AVB	11	No further bleeding	2.62, death
3	Colorectal	TARE, FOLFOX, Avastin, 5FU, LV, FOLFIRI/cetuximab, irinotecan, capecitabine	Ascites	14	No further LVP; TIPS occlusion requiring revision x2	38.6, death
4	Colorectal	FOLFOX, 5FU, leucovorin	Ascites	21	No further LVP	0.3, death
5	Colorectal	FOLFOX, avastin; FU/LV	Ascites	13	TIPS occlusion requiring revision; multiple LVPs required	2.4, death
6	NET	TACE; PRRT	Ascites	11	No further LVP	17.5, death
7	NET	Wedge resection; splenic vein to portosystemic shunt	AVB	16	Technically unsuccessful; pancreatectomy/splenectomy and Sugiura	2.3, death
8	NET	Aspira catheter	Ascites	20	Aspira catheter removal	1.2, death
9	Epithelioid hemangioendothelioma	Avastin; OLT	Ascites	17	TIPS occlusion requiring revision; 1 post TIPS LVP required	59.5, alive, asymptomatic

AVB, acute variceal bleeding; FOLFOX, 5-fluorouracil, oxaliplatin, leucovorin, FOLFIRI, 5-fluorouracil, leucovorin, irinotecan; LVP, large volume paracentesis; NET, neuroendocrine tumor; OLT, orthotopic liver transplant; PRRT, peptide receptor radionuclide therapy; PVT, portal vein thrombosis; RFA, radiofrequency ablation; TACE, transarterial chemoembolization; TARE, transarterial radioembolization; TIPS, transjugular intrahepatic portosystemic shunt.

day. Two months later he underwent a Sugiura procedure and expired shortly after. One patient treated for ascites was transferred to a skilled nursing facility and died five days after TIPS, without report of worsening of symptoms or complications related to the procedure. Cause of death is unknown. The third patient required multiple LVPs after TIPS and was found to have a shunt occlusion on imaging. The patient underwent revision 1.9 months after TIPS creation, with thrombectomy, balloon angioplasty, stent placement, and variceal embolization. One further paracentesis was performed 2 weeks after revision and the patient died shortly thereafter.

Two patients required TIPS revision after initial clinical success (*Figure 2A*). One had consistent improvement in symptoms and required no further LVPs. Follow up imaging showed occlusion of the TIPS and the patient was treated with anticoagulation and two TIPS revisions with

the first occurring 2.1 years after initial TIPS placement. One patient required one further LVP 6 months after TIPS over a total follow up year of 5 years. This patient developed symptomatic TIPS occlusion requiring revision with balloon angioplasty 3.9 years post-TIPS.

Mild-moderate HE occurred in 6/9 patients (67%). The highest post-procedure HE score was 2. All patients had HE controllable with medical therapy. Three patients were treated with lactulose and three treated with a combination of lactulose and rifaximin. No patients required intubation for HE or TIPS reduction/occlusion.

Eight of the nine patients have died since TIPS creation. Average (median; 1st quartile, 3rd quartile) time from TIPS to death was 9.3±13.2 months (2.5; 2.0, 11.7 months) (*Figure 2B*). Time from TIPS to death for patients with acute variceal bleeding was 4.9±4.2 months (2.5; 2.5, 6.2 months). Time from TIPS to death for patients

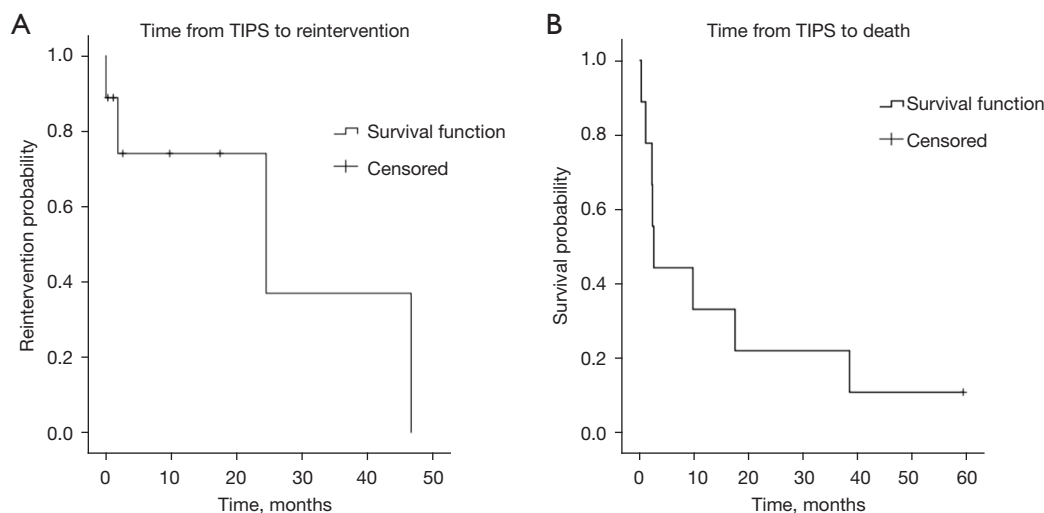


Figure 2 Kaplan-Meier survival curves depicting (A) time from transjugular intrahepatic portosystemic shunt (TIPS) to reintervention (inclusive of surgical treatment or TIPS revision) and (B) time from TIPS to death.

with refractory ascites was 12 ± 16.5 months (2.4; 1.1, 17.5 months). Cause of death was disease progression ($n=5$), complications secondary to continued variceal bleeding following surgery ($n=1$), or unavailable ($n=2$).

Discussion

Cirrhosis-like parenchymal changes of the liver secondary to non-HCC malignancy, termed pseudocirrhosis, portends high rates of morbidity and mortality when compared to similar patient cohorts without findings of pseudocirrhosis (1,27). These patients can develop symptoms of portal hypertension ranging from ascites in 54–68% of patients and esophageal varices in 9–23% of patients (1-3). As life expectancies improve for malignant disease, more patients may develop symptomatic pseudocirrhosis requiring durable therapy. TIPS is a proven treatment for symptomatic cirrhosis-induced portal hypertension with variceal bleeding control in over 90% of patients as well as superior rates of ascites control and 1-year survival rates compared to LVP and albumin (13,28-30). Hepatic malignancy is considered a relative contraindication for TIPS in current guidelines due to concerns surrounding patient prognosis, device failure, and procedural complications (13,14). Our study showed technical success rates of 8/9 (89%) of patients, with the singular failure due primarily to extrahepatic malignant portal vein occlusion, which is consistent with reported rates in traditional liver cirrhosis cohorts (14).

There were no major complications related to TIPS

insertion, in particular there was no peri-procedural TIPS-related hemorrhage. Three patients had TIPS occlusion that required revision at 1.9 months, 2.1 years, and 3.9 years post-insertion. Hepatic encephalopathy developed or progressed in 67% (6/9) of our patients. All were controlled with medical therapy and the highest WH score was a 2. Within the cirrhotic population, HE typically develops in 50% of patients (30). Our increased rates of HE may be due to the small cohort size available, however, they mirror results from Wallace *et al.* who reported similarly elevated rates of HE (44%) and HE requiring shunt reduction (17%) (24). Given the retrospective nature of this study, a conservative approach was taken to include any documentation of HE or any symptoms attributed to possible HE, which could cause overestimation. It is possible that patients with hepatic malignancy and pseudocirrhosis may prove to be more susceptible to HE after TIPS, warranting further evaluation.

Our results are consistent with high technical success and low complication rates of previous studies examining TIPS in the setting of hepatic and extrahepatic malignancy. Wallace *et al.* performed TIPS on 38 patients, directly through tumor in 9/38, with a technical success rate of 97% (24). Three studies with a total of five patients have specifically reported the outcomes of TIPS in the setting of pseudocirrhosis secondary to breast cancer (7,22,23). Indication for TIPS across the studies was ascites ($n=4$) and acute variceal bleeding ($n=1$). Technical success was reported in all patients. Of the patients undergoing TIPS

for ascites, all had improvement of ascites with two patients later suffering from malignant pleural effusion and one expiring within five days of treatment (22,23). The patient with acute variceal bleeding died shortly after TIPS from massive variceal hemorrhage and diffuse pulmonary alveolar damage.

In the presence of hepatic malignancy and pseudocirrhosis, it is important to balance the desired benefit of TIPS with the patient's prognosis and quality of life. Clinical success was achieved in 6/9 (67%) of patients. TIPS achieved a durable benefit until death at a mean of 9.4 months later at a cost of further procedures to revise the TIPS in 2 of those patients. Compared to data of benign liver disease, patients presenting with acute variceal bleeding had a shorter mean time to death compared to patients with refractory ascites, 4.9 *vs.* 12 months, respectively, and similar MELD scores (*Table 1*) (31). These differences may be secondary to pathologic differences of the liver, longer time to treatment, treatment effects, the critically ill nature of patients presenting with AVB, or small sample size. Improving cancer patients' quality of life by mitigating large volume ascites and the need for frequent hospital visits for paracentesis, and/or hospitalizations for variceal bleeding, is a substantial palliative contribution that is technically feasible and safe.

This study was limited by retrospectively collected data, a small number of available patients, and lack of direct control group comparison. Follow-up data was limited to available recorded information and short follow up periods for some patients.

Conclusions

TIPS for the treatment non-HCC malignant symptomatic pseudocirrhosis can be created safely with few peri-procedural complications and similar clinical outcomes to TIPS performed for benign disease. Durable therapy for the treatment of symptomatic pseudocirrhosis can serve as a palliative treatment for cancer patients. Rates of low-grade hepatic encephalopathy may be higher amongst patients undergoing TIPS for pseudocirrhosis compared to TIPS for the treatment of cirrhosis induced portal hypertension.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the institutional review board of the Hospital of the University of Pennsylvania (No. 811929) and individual consent for this retrospective analysis was waived.

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