Diagn Interv Radiol 2022; DOI: 10.5152/dir.2022.20812

INTERVENTIONAL RADIOLOGY

ORIGINAL ARTICLE

Outcomes of transjugular intrahepatic portosystemic shunt using 12 mm diameter polytetrafluoroethylene covered stents in cirrhotic patients with portal hypertension

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PURPOSE
We aimed to evaluate the safety and efficacy of 12 mm diameter polytetrafluoroethylene (PTFE)-covered stents for the creation of transjugular intrahepatic portosystemic shunt (TIPS) in cirrhotic patients with portal hypertension complicated by variceal bleeding and volume-overload.

METHODS
This retrospective study included 360 patients who had TIPS created between January 2004 and December 2017 using 12 mm diameter PTFE-covered stents. Demographic data, model for end-stage liver disease (MELD) score, etiology of cirrhosis, and Charlson comorbidity index were recorded. Symptoms of hepatic encephalopathy (HE), variceal re-bleeding, improvement in volume-overload, TIPS revisions and the need for intervention, and overall survival were assessed.

RESULTS
The mean age of the patients was 56.8 ± 9.9 years, and the technical success rate was 99.4%. The rates of improvement of volume-overload post-TIPS were 59.5%, 69.8%, and 81.7% at 3, 6, and 12 months, respectively. About 93.3% of patients were free from paracentesis or thoracentesis at 12 months. The rates of re-bleeding post-TIPS were 4%, 12%, and 12.9% at 3, 6, and 12 months, respectively. The rate of TIPS revision at 12 months was 6.5%. Percentage of patients with any symptoms of HE were 34.4%, 42.9%, and 49.5% at 3, 6, and 12 months, respectively. All HE were appropriately medically managed and no patients required a TIPS reduction.

CONCLUSION
TIPS placement using 12 mm PTFE-covered stents is efficacious in cirrhotic patients with portal hypertension complicated by variceal bleeding or refractory volume-overload, with an acceptable safety profile.

Transjugular intrahepatic portosystemic shunt (TIPS) placement is a well-established therapeutic option for patients with complications of portal hypertension (pHTN), including variceal bleeding, recurrent ascites, and hepatic hydrothorax.[1] The technical success rates for TIPS creation is >90% but, more importantly, clinical success for patients with variceal bleeding and recurrent ascites is >90% and 55%-80%, respectively.[2] The reduction of the porto-systemic gradient (PSG) to acceptable levels is a key indicator of the future clinical success of the shunt.[2,3] For example, re-bleeding rates have been found to be 18%, 7%, and 1% when the PSG is reduced by 0%, 25%-50%, and >50%, respectively.[3] Increasing the diameter of the shunt helps to achieve lower PSGs. For instance, prior reports have shown that the clinical efficacy of shunts created with 10 mm stents is higher than shunts created with 8 mm stents.[4,5] Thus, it is logical to hypothesize that TIPS creation with larger stents (e.g., 12 mm) would further reduce the PSG, making the shunt more clinically useful. Nevertheless, the utility of larger stents may be limited due to the potential of increased rates of liver failure and hepatic encephalopathy (HE).[6] Further, 1 small retrospective study found that the TIPS created with a bare metal 12 mm stent was more likely to occlude and associated with shorter overall survival.[7] Yet, the clinical outcomes of using newer 12 mm diameter PTFE-covered stents for TIPS creation have not been thoroughly investigated. Thus, the purpose of this retrospective investigation is to evaluate the safety

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Received 2 October 2020; revision requested XXX; last revision received XXX; accepted 18 February 2021.

DOI: 10.5152/dir.2022.20812

You may cite this article as: Habash M, Murray A, Heeke B, et al. Outcomes of transjugular intrahepatic portosystemic shunt using 12 mm diameter polytetrafluoroethylene covered stents in cirrhotic patients with portal hypertension. *Diagn Interv Radiol.* 2022;28(3):239-243.

and efficacy of 12 mm diameter PTFE-covered stents for the creation of TIPS in cirrhotic patients with pHTN complicated by variceal bleeding and volume-overload.

Methods

Study population

This retrospective study was approved by the institutional review board (approval number: 140527008) and was HIPAA compliant. Informed consent was waived. The medical records of 404 cirrhotic patients who underwent TIPS creation for either variceal bleeding or volume-overload (defined as refractory ascites and/or hepatic hydrothorax) using a 12 mm Viatorr (Gore Medical) stent between January 2004 and December 2017 were reviewed. For clarity, none of the stents deployed in this cohort were the newer generation Viatorr CX (Gore). Exclusion criteria were as follows: age <18 years, hepatocellular carcinoma or active malignancy, or absence of follow-up in our medical record following the TIPS procedure. The study cohort was divided into 2 groups based on the indication for which TIPS was performed: patients who underwent TIPS creation for variceal bleeding and patients who underwent TIPS placement for volume-overload (refractory ascites and/or hepatic hydrothorax). For the variceal bleeding cohort, the indication for TIPS creation was further stratified into acute bleeding and secondary prophylaxis as an indication. Patient age, sex, etiology of cirrhosis, Charlson comorbidity index (CCI) were recorded. Laboratory values including total bilirubin, platelet count, and international normalized ratio (INR) were recorded within 30 days prior to and within 30 days after TIPS creation. These values were used to calculate the model for end-stage liver disease (MELD) score both prior to and after shunt creation.

Main points

- TIPS creation using 12 mm PTFE-covered stents is safe, with only 1 minor and no major complications.
- TIPS creation using 12 mm PTFE-covered stents is effective in controlling symptoms from volume-overload with 93.3% being free from paracentesis or thoracentesis at 12 months.
- TIPS creation using 12 mm PTFE-covered stents is effective at controlling variceal bleeding.
- This method did not result in increased rates of hepatic encephalopathy compared to historic controls, and no patients required shunt reduction.

Procedure

TIPS were created in a standard fashion, which has been described in detail previously.[9] After placement of the 12 mm stent, it was first balloon dilated using a 10 mm balloon and the PSG was re-measured. If the PSG was ≥12 mmHg or ≥8 mmHg for variceal bleeding and volume-overload, respectively, the stent was then dilated again using a 12 mm balloon and the PSG was again measured. Even if the stent was not initially dilated to 12 mm, multiple studies have shown that the stent eventually reaches 12 mm in diameter over time.[10-13] At our institution, variceal embolization is performed concurrently with TIPS creation when the varices still fill with contrast on digital subtracted angiography even after an adequate PSG is obtained. For example, if the PSG is reduced by TIPS creation to <12 mmHg in a patient with variceal bleeding but the varices still fill with contrast on digital-subtracted angiography, then variceal embolization would be performed.

Study outcomes

Technical success was defined as the ability to create the shunt between portal and systemic veins with reduction of the PSG to <12 mmHg or <8 mmHg for variceal bleeding and volume-overload, respectively. Complications were graded based on established criteria.[14] Clinical outcomes were assessed at 3, 6, and 12 months after TIPS creation and included MELD scores, presence of HE, variceal re-bleeding, improvement in volume-overload (as demonstrated by freedom from paracentesis or thoracentesis), stent patency, TIPS revisions, and overall survival. Pre-existing HE and HE after shunt creation were reported as present based on clinical notes, even if medical management controlled the symptoms. The number of shunt reductions required for uncontrolled HE was recorded. A TIPS venogram to assess for shunt dysfunction was performed based on established non-invasive criteria.[15] A TIPS revision was classified as any intervention beyond the TIPS venogram to prolong the patency of the stent (i.e., balloon dilatation, thrombolysis/thrombectomy, or stent placement). TIPSs were revised if the venogram demonstrated the presence of ≥50% stenosis, thrombus, and/or a PSG of ≥ 12 mmHg and ≥8 mmHg for variceal bleeding and volume-overload, respectively.

Statistical analysis

For continuous variables, values are reported as means ± standard deviation (SD). Continuous variables were compared using the student t test. Normal probability plot and a quantile–quantile plot (QQ plot) were used to assess normality, in addition to a univariate normality test, for example, Anderson–Darling test, prior to applying a 2-group student's t test. Categorical variables were compared using chi-squared probability testing with Fischer exact modification when warranted by frequency observed. Overall survival was estimated using the Kaplan-Meier method and compared using the log-rank test. A predetermined *P* value of .05 was considered the threshold for statistical significance. Statistical Analysis Software (SAS) v9.4 was used to carry out the analysis.

Results

A total of 360 patients, comprised of 228 males (63.3%) and 132 females (36.7%), with a mean age of 56.8 ± 9.9 years, were included in the study. Patient characteristics are summarized in Table 1. Other relevant laboratory values both prior to and after TIPS creation are summarized in Table 2. In the variceal bleeding cohort, 111 patients (72%) and 43 patients (28%) had the TIPS created for an acute bleeding event and secondary prophylaxis, respectively.

Technical success was 99.4%. Initial TIPS creation failed in 2 patients, both from the variceal bleeding group. One patient could not tolerate the procedure and returned the next day for successful TIPS under general anesthesia. The second patient failed initial placement but returned 3 days later for successful TIPS creation. During the initial procedure, 72 patients (20%) had their TIPS stents dilated to 12 mm diameter, while the remaining patients had their TIPS stents dilated to 10 mm diameter. One procedural complication occurred in a patient from the volume-overload group who experienced transient hypotension during the procedure that required no therapy (SIR Grade A). No major complications were recorded. The PSG in the variceal bleeding group decreased by a mean of 10.7 mmHg (pre = 15.3 mmHg, post = 4.6 mmHg, $P < .001$). The PSG in the volume-overload

Table 1. Patient characteristics

	All patients (n = 360)	Volume-overload group (n = 187)	Variceal bleeding group (n = 173)	*P*
Demographics				
Age (years), mean ± SD	56.8 ± 9.9	57.1 ± 9.2	56.5 ± 10.6	.62
Female	132 (36.7%)	72 (38%)	60 (34.7%)	.46
Male	228 (63.3%)	115 (61.5%)	113 (65.3%)	
Etiology of cirrhosis, n(%)				
HBV	4 (1.1%)	0 (0.0%)	4 (2.3%)	.045
HCV	113 (31.4%)	57 (30.5%)	56 (32.4%)	.38
EtOH	121 (33.6%)	58 (31.0%)	63 (36.4%)	.24
NASH	104 (28.9%)	56 (29.9%)	48 (27.7%)	.34
Cryptogenic	37 (10.3%)	20 (10.7%)	17 (9.8%)	.38
VOD	1 (0.3%)	1 (0.5%)	0 (0.0%)	.25
Autoimmune	15 (4.2%)	7 (3.7%)	8 (4.6%)	.37
Others	28 (7.8%)	11 5.9%)	17 (9.8%)	.16
Charlson comorbidity index, mean ± SD				
Mean (SD)	5.1 ± 1.5	5.2 ± 1.5	5.0 ± 1.5	.26

HBV, hepatitis B virus; HCV, hepatitis C virus; EtOH, ethanol; NASH, non-alcoholic steatohepatitis; VOD, veno-occlusive disease.

group decreased by a mean of 10.8 mmHg (pre = 15.8 mmHg, post = 5.0 mmHg, $P < .001$). Thirty-three patients (19.1%) in the variceal bleeding group underwent varix embolization at the time of TIPS creation.

Overall survival for the entire cohort was estimated at 79.9%, 76.4%, and 69.7% at 3, 6, and 12 months, respectively. For those with volume-overload, the estimated survival was 79.2%, 73.5%, and 66.3% at 3, 6, and 12 months, respectively. For the variceal bleeding group, the estimated survival was 81.0%, 80.2%, and 74.2% at 3, 6, and 12 months, respectively. There was no difference in the estimated survivals between the 2 groups ($P = .60$) (Figure 1). The percentage of patients who were free from paracentesis and/or thoracentesis as well as re-bleeding rates are summarized in Table 3. Of note, 93.3% of patients in the volume-overload group were free from paracentesis or thoracentesis at 12 months. For the entire cohort, primary patency was 92.2%, 86.4%, and 82.8% at 3, 6, and 12 months, respectively. The primary-assisted patency was 100% at 12 months (i.e., all stents were patent). At 12 months, 43 patients (11.9%, n = 360), 28 patients (14.9%, n = 187), and 15 patients (8.7%, n = 173) required a TIPS revision in the entire cohort, volume-overload group, and variceal bleeding group, respectively. When comparing the need for a TIPS revision between the 2 groups, relatively more patients in the volume-overload group (14.9%) required a revision than in the variceal bleeding group (8.7%) as this difference approached statistical significance ($P = .070$). The percentage of patients with symptoms of HE are summarized in Table 4. More patients in the volume-overload group had symptoms of HE at 6 and 12 months after TIPS creation. Hepatic encephalopathy was medically managed in all cases with no patients requiring a TIPS reduction during the study period.

Table 2. Laboratory values before and after TIPS creation

	All patients	Volume-overload group	Variceal bleeding group
Total bilirubin (mg/dL), mean ± SD			
Before TIPS	2.0 ± 2.1	1.7 ± 1.5	2.2 ± 2.5
After TIPS	4.1 ± 5.3	3.7 ± 4.5	4.5 ± 6.1
P	<.001	<.001	<.001
Platelets (x10^9/L), mean ± SD			
Before TIPS	111 ± 74	123 ± 68.5	97 ± 77.7
After TIPS	112.4 ± 54.7	120.6 ± 59.6	103.1 ± 47.1
P	0.73	0.47	0.35
INR, mean ± SD			
Before TIPS	1.5 ± 1.2	1.4 ± 0.3	1.7 ± 1.7
After TIPS	1.7 ± 1.0	1.6 ± 0.45	1.9 ± 1.4
P	0.008	<.001	0.25
MELD score, mean ± SD			
Before TIPS	12.6 ± 6.1	13.2 ± 5.9	12.1 ± 6.4
After TIPS	16.3 ± 7.9	16.9 ± 6.8	15.5 ± 9.0
P	<.001	<.001	<.001

TIPS, transjugular intrahepatic portosystemic shunt; SD, standard deviation; INR, international normalized ratio; MELD, model for end-stage liver disease.

Discussion

TIPS creation is a known therapeutic treatment for the complications of pHTN such as variceal bleeding and volume-overload.[1] TIPS improves overall survival for patients with variceal bleeding when compared to medical or endoscopic therapy and is superior to peritoneovenous shunts for refractory ascites.[16,17] Reducing the PSG to an acceptable level is a key indicator of the clinical success of the TIPS procedure.[2,3] For example, Miraglia et al.[9] found that a 10 mm diameter stent led to better control of pHTN and its complications in patients with cirrhosis when compared to an 8 mm stent with a comparable incidence of HE. Further, Riggio et al.[4] compared the use of 8 mm and 10 mm stents in patients matched for age, sex, etiology of cirrhosis, and performance status. This trial was stopped early due to the significant complications of pHTN that persisted in the patients with 8 mm stents. Given these prior reports, it stands to reason that the use of larger 12 mm stents for TIPS creation could result in further reductions in the PSG. To evaluate this, 1 small retrospective study compared the use of bare metal 10 mm stents (n = 23) to bare metal 12 mm stents (n = 23) demonstrating higher rates of occlusion and decreased overall survival in patients who underwent TIPS creation with the larger stent.[7] The authors attributed the differences to the higher radial force in the 10 mm stent. The efficacy of 12 mm stents for TIPS creation using newer, PTFE-covered stents is not well-described.

Q1

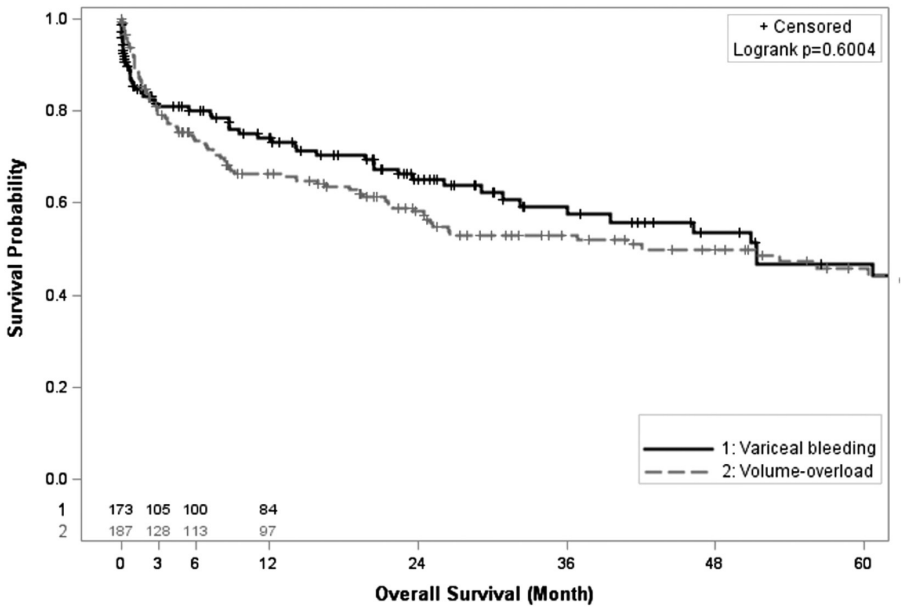

Figure 1. Overall survival for both groups as product-limit estimates via the Kaplan–Meier method. The number of patients at risk in each group at 0, 3, 6, and 12 months is provided.

Table 3. Clinical outcomes after TIPS creation using 12 mm stents

All patients (n = 360)	
Volume-overload group (n = 187)	
Freedom from paracentesis and thoracentesis post-TIPS	
At 3 months	107/125 (85.7%)
At 6 months	99/113 (87.6%)
At 12 months	98/105 (93.3%)
Variceal bleeding group (n = 173)	
Variceal re-bleeding post-TIPS	
At 3 months	4/101 (4.0%)
At 6 months	11/92 (12.0%)
At 12 months	11/85 (12.9%)

TIPS, transjugular intrahepatic portosystemic shunt.

Table 4. Symptoms of hepatic encephalopathy at baseline and after TIPS

Hepatic encephalopathy	All patients	Volume-overload	Variceal bleeding	*P*
HE at baseline	8.6% (n = 31/360)	6.4% (n = 12/187)	11.0% (n = 19/173)	.12
At 3 months	34.4% (n = 99/288)	38.5% (n = 57/148)	30.0% (n = 42/140)	.13
At 6 months	42.8% (n = 118/276)	51.1% (n = 70/137)	34.5% (n = 48/139)	.005
At 12 months	49.2% (n = 124/252)	55.6% (n = 69/124)	43.0% (n = 55/128)	.044

HE, hepatic encephalopathy; TIPS, transjugular intrahepatic portosystemic shunt.

The data in this cohort demonstrates that the use of PTFE-covered 12 mm stents for TIPS creation in cirrhotic patients with complications of pHTN effectively prevents variceal re-bleeding, decreases the need for thoracentesis or paracentesis, reduces the PSG significantly, and has an acceptable safety profile.

To this end, the 12 mm diameter stent was associated with a satisfactory reduction in the PSG to an average of 4.6 ± 2.7 mmHg and 5.0 ± 2.6 mmHg for variceal bleeding and volume-overload, respectively. This reduction is more than historical data where PSG was reduced to an average of 8.9 ± 2.7 mmHg and 6.5 ± 2.7 mmHg in 8 mm and 10 mm diameter stents, respectively, highlighting the value of utilizing a stent with greater versatility in diameter modification.[4] There was a low rate of re-bleeding at 3 (4.0%), 6 (12.0%), and 12 months (12.9%) that corresponds well to historical TIPS data using 8 mm and 10 mm stents.[2-5,8] In this study, for patients who underwent TIPS creation for volume-overload, 85.7%, 87.6%, and 93.3% of patients were free from paracentesis or thoracentesis at 3, 6, and 12 months, respectively. This result is better than rates seen in prior studies (55-80%).[2] Finally, the primary-assisted patency of the 12 mm PTFE-covered stents in this cohort was 100% at 12 months. During the study period, 14.9% (n = 28/187) and 8.7% (n = 15/173) of patients required a TIPS revision in the volume-overload and variceal bleeding groups, respectively. Even though the value did not reach statistical significance (*P* = .070), it could signal an important clinical difference in this patient population. For example, the relatively increased rates of TIPS revision in the volume-overload group could represent the overall difficulty in maintaining the lower PSGs required to prevent the symptomatic accumulation of peritoneal and/or pleural fluid.

One of the most significant concerns when using larger diameter stents for TIPS creation is HE; even though prior reports have shown that rates of HE are not significantly different between 8 mm and 10 mm stents.[5] Several factors predispose patients undergoing TIPS to develop HE including extensive portosystemic shunting, subclinical cognitive impairment at baseline prior to TIPS creation, and an inability of the brain to accommodate to increasing damage from cirrhosis.[13] Hepatic encephalopathy after TIPS creation has been reported in up to ~40% of patients.[2] Typically, HE is medically managed using a combination of rifaximin and lactulose; however, it may become uncontrollable with medical treatment, requiring shunt reduction. Medically uncontrolled HE after TIPS creation requiring shunt reduction has been reported to be present in approximately 4%-7% of patients at 30 days.[2] In the current cohort, 8.7% of patients had symptoms of HE at baseline. After TIPS creation, 34.4%, 42.9%, and 49.5% of patients had documented symptoms of HE at 3, 6, and 12 months, respectively, which is comparable to prior reports. Patients who had TIPS creation for volume-overload had higher rates of HE symptoms at 6 and 12 months after creation. Regardless, none of the patients in

the current series required a reduction of the TIPS shunt, which is an improvement from historical controls ranging from 4% to 7%.[2] This indicates that the patients in the current cohort had their symptoms of HE controlled by medical management alone. One possible explanation for this finding is that only 20% of the stents in this series were fully dilated to 12 mm at the time of initial placement. The remainder of the stents likely expanded to 12 mm over time, allowing for the patient to physiologically compensate for the changes in liver hemodynamics. This hypothesis is based upon several recent studies demonstrating that underdilated TIPS stents expand to close to their nominal diameter.[9-12] Mollaiyan et al.[12] suggest that this may be related to expansile forces of nitinol stents leading to remodeling of the surrounding liver tissue allowing for expansion.

This study has limitations. First, the study was retrospective in nature which affects the data available for collection and review. As such, it was not possible to accurately grade the symptoms of HE because we relied solely on documentation from clinic notes. Additionally, we only have the final PSGs at the end of the procedure. Therefore, we do not know the exact PSG at each individual stage of the procedure (i.e., the PSG achieved that prompted the operator to fully dilate the stent to 12 mm). Second, there was no direct comparison made to other stent diameters. Instead, we compared the data obtained in this study to the published results on the efficacy of 8 mm and 10 mm stents. Lastly, procedural complications of TIPS placement were likely under-reported due to incomplete follow-up and/or incomplete documentation in this retrospective study.

In conclusion, despite these limitations, this study does provide insight into the role of 12 mm diameter stents for TIPS creation that can further reduce the PSG beyond what a traditional 10 mm stent can do alone. The data demonstrate that TIPS placement using 12 mm diameter PTFE-covered stents is efficacious in cirrhotic patients with pHTN complicated by variceal bleeding or refractory volume-overload, with an acceptable safety profile.

Conflict of interest disclosure

The authors declared no conflicts of interest.

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