Persistence of gastric or esophageal varices on final angiography increases transjugular intrahepatic portosystemic shunt revision rate after polytetrafluoroethylene-covered stent shunt creation

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Background: To assess the association between final polytetrafluoroethylene (PTFE)-covered stent transjugular intrahepatic portosystemic shunt (TIPS) angiographic parameters and free shunt revision survey. **Methods:** Series of two comparison groups were generated with persistence of varices or not, the 25th, 50th, and 75th percentile as cutoff for each angle and a 15-mm distance as cutoff for distance D. Kaplan Meier free shunt revision curves were then created and compared with Log Rank test.

Results: Mean follow-up was 455 days. Thirteen (19.4%) patients had shunt revision. Significant free shunt revision survey difference was found between post-procedural angiographic persistent varices group and the group without varices (P=0.0001). Shunt revision rate at 3, 12 and 24 months was respectively 13%, 29%, and 39% in the group with varices versus 0%, 2.7% and 2.7% in the group without. No difference was found between groups for angles A, B, C and distance D.

Conclusions: Persistence of gastric or esophageal varices on final trans-TIPS angiography increases TIPS revision rate after PTFE-covered stent shunt creation whereas geometric parameters have no influence.

Keywords: Transjugular intrahepatic portosystemic shunt (TIPS); gastric varices; oesophageal varices; covered stent; TIPS revision

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Introduction

Transjugular intrahepatic portosystemic shunt (TIPS) is a safe and effective treatment (1,2) for the management of severe portal hypertension (3,4). Patients usually receive TIPS for three main indications: refractory ascites (5,6), variceal bleeding uncontrolled by medical and endoscopic treatment (7,8), and prevention from rebleeding for highrisk patients with first bleeding episode (early TIPS) (9-11). TIPS procedure is now well defined (12,13), with endovascular portal vein (PV) access via a sub-hepatic vein (SHV) approach, and then placement of a stent between the PV and the SHV. During the last decade, the use of polytetrafluoroethylene (PTFE) stent-grafts, alone or in combination with bare stents, has become the first-line choice for TIPS creation (14). Studies have demonstrated lower shunt revision rates and less recurrence of symptoms with covered stents in comparison with bare stents alone, with no obvious difference in terms of survival and hepatic encephalopathy (HE) (15-18). TIPS procedure can be performed by positioning two different stents, a bare stent and then a covered stent, or by placing a Viatorr[®] stent which is a combination of a bare stent and a covered stent, dedicated to TIPS.

The main complication of TIPS is the development

parenchymal tract;

of thrombosis or stenosis, and a better understanding of the risk factors which can lead to such complications is needed. Few studies have already been performed on the role of some geometric parameters as TIPS angulation and distance between TIPS and inferior vena cava, on TIPS patency, with conflicting results (19-23). This discrepancy between studies, and the little data available in the literature with the use of stent grafts led us to perform the present study.

The aim of this study was mainly to assess the association between final angiographic parameters and free shunt revision survey in patients treated with PTFE-covered stent TIPS.

Methods

Study population

Retrospective review of the medical records of patients who underwent TIPS procedure from January 2012 to September 2015 was conducted. Patients were identified using the database maintained prospectively by the Interventional Radiology Department. There were 67 patients overall, 58 males (86.6%) and 9 females (13.4%) with a mean age of 56.3±12.0 years (range, 26-77 years). Patients lost to follow-up (n=2) or with no available images for analysis (n=3) were excluded from the analysis. All patients suffered from cirrhosis, 52 (77.6%) from alcoholic cirrhosis, 8 (11.9%) from alcoholic liver disease associated with another cause of liver disease [viral, non-alcoholic steatohepatitis (NASH), or other cause of cirrhosis]. Patient's characteristics are presented in Table 1. This retrospective study was performed in compliance with the requirements of the institutional review board and approved by the institution ethical committee. Informed consent was waived.

TIPS procedure

All procedures were performed under general anesthesia by four interventional radiologists with 20 (Jean-Pierre Cercueil), 12 (Romaric Loffroy), 5 (Marco Midulla) and 2 (Sophie Gehin) years of experience with TIPS procedures, respectively, as previously described in the literature according to the following standard schema: step 1, right internal jugular venous access; step 2, hepatic venography; step 3, wedged hepatic venography; step 4, accessing the PV, portography and measure of portosystemic gradient; step

5, dilatation of the parenchymal tract; step 6, deployment of a stent across the parenchymal tract; step 7, portography and measure of portosystemic gradient (24-26). More in detail, the "Ring TIPS" set (Cook Medical, Bloomington, IN, USA) with Colapinto needle was used in all patients. Only X-ray guidance was used for PV access. Different combinations of stent were used. Before December 2014, a combination of bare stent (WallstentTM, Boston Scientific, Natick, USA; or Protege GPSTM stent, Covidien, Dublin, Ireland) and PTFE-covered stent (Advanta V12TM, Maquet, Wayne, USA; or FluencyTM, Bard, New York, USA) was used for TIPS. After December 2014, the dedicated Viatorr[®] PTFE-covered stent (W.L. Gore & Associates, Newark, DE, USA) was used for TIPS, avoiding the use of two stents. The distal portal portion of this stent is uncovered whereas the medium parenchyma and proximal hepatic portions are covered. Catheterization of the PV with the 10-French TIPS sheath was required to place the Viatorr[®] PTFE-covered stent-graft between the PV and the hepatic vein. Sometimes, TIPS was created by deploying an uncovered metal stent first, through which the TIPS sheath is usually advanced into the PV. In these cases, the PTFEcovered stent is deployed within the bare-metal stent. When using dedicated Viatorr® PTFE-covered stent-graft, care should be taken to leave the uncovered caudal portion of the stent in the PV, whereas the covered portion of the stent should be in the parenchymal tract and in the hepatic vein. The cranial end of the stent should extend to the junction of the hepatic vein and the inferior vena cava. Overlapping stents of the same diameter were often used to achieve the desired shunt length and to reduce severe angulation within the shunt. The diameter of the covered stent used was 8 mm in 1 patient, 10 mm in 63 patients, or 12 mm in 3 patients. No primary adjunctive variceal embolotherapy was performed. Antibiotics were administered per-procedurally but no adjunctive anticoagulant or antiplatelet therapy was given.

Follow-up

Follow-up included clinical examination and TIPS Doppler ultrasound (US) after 2 days, and at 1, 3, and 6 months, and every 6 months thereafter. Doppler US was also performed in case of recurrence of symptoms. Doppler US velocimetry was considered normal between 90 and 180 cm/second (27,28). For patients with velocimetry values below 60 or above 180 cm/second, or patients with Doppler US signs of focal stenosis, or patients with recurrence of symptoms

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Characteristics	Variables
Patient characteristics	
Age (years), mean ± SD [range]	56.3±12.0 [26-77]
Gender (male/female), n (%)	58 (86.6)/9 (13.4)
Cause of cirrhosis, n (%)	
Alcohol	52 (77.6)
Alcohol + other cause	8 (11.9)
Viral hepatitis	2 (3.0)
Other cause	5 (7.5)
Child-Pugh class, n (%)	
A	7 (10.5)
В	51 (76.1)
С	9 (13.4)
Indication for TIPS, n (%)	
Salvage TIPS	6 (9.0)
Early TIPS	24 (35.8)
Refractory ascites	37 (55.2)
Procedure characteristics	
Geometric parameters, mean ± SD [range]	
Distance D (mm)	10.0±9.6 [0-33.5]
Angle A (°)	152.3±11.5 [114–174]
Angle B (°)	132.3±30.0 [57.5–173]
Angle C (°)	151.7±21.7 [76.5–179]
Angle M (°)	145.4±11.6 [112–164.5]
Gastric or esophageal varices on final angiography, n (%)	31 (46.3)
Type of stent, n (%)	
Nitinol uncovered stent + PTFE- covered stent	57 (85.1)
Viatorr stent	10 (14.9)
Stent diameter, n (%)	
8 mm	1 (1.5)
10 mm	63 (94.0)
12 mm	3 (4.5)
Sub-hepatic vein access, n (%)	
Right sub-hepatic vein	58 (86.6)
Median or left sub-hepatic vein	9 (13.4)

 Table 1 (continued)

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Characteristics	Variables
Number of TIPS per operator, n (%)	
Operator 1	7 (10.4)
Operator 2	39 (58.2)
Operator 3	5 (7.5)
Operator 4	16 (23.9)
Follow-up characteristics	
Follow-up duration (days), mean \pm SD [range]	455.1±307.9 [35–1,365]
Free-revision period (days), mean ± SD [range]	414.9±301.3 [24–1,365]
Shunt revision rate, n (%)	13 (19.4)
Mortality rate, n (%)	15 (22.4)

and undetermined Doppler US velocimetry, exploration was completed by TIPS angiography. A stenosis on TIPS angiography was defined as a 50% stenosis in two orthogonal views and/or portosystemic gradient greater than 12 mmHg. In such case, shunt's revision was performed by angioplasty +/- additional stenting at the operator discretion. Stenting was the rule in case of complete thrombosis. The mean follow-up duration was 455.1±307.9 days (range, 35–1,365 days). The mean free shunt revision duration was 414.9±301.3 days (range, 24–1,365 days). Overall, 13 patients (19.4%) had a shunt revision and 15 patients (22.4%) died during the mean follow-up.

Data review

Angiographic images obtained during TIPS placement were reviewed by two radiologists, blinded to the outcomes. Digital subtraction angiographic images in anterior view were used for the measurement of the following geometric parameters: angle A (hepatic vein to parenchymal tract angle), angle B (intra-TIPS angle) and angle C (PV to stent angle) as shown in *Figure 1*. The angle M (mean of angle A, B and C) and the distance D (stent to hepato-caval junction distance) were also generated. All patients included in the study had a TIPS angiography that depicted the confluence of the inferior vena cava and the hepatic vein, and a trans-TIPS portal venography that depicted the confluence between splenomesenteric vein and the PV. The presence of gastric or oesophageal varices on final angiography was also determined by reviewing angiographic images. Filing

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Figure 1 Example of angle A (thin arrow), angle B (head of arrow) and angle C (arrow), on the left, and equivalent value in degrees on the right.

of gastric or esophageal varices was defined by still viewing varicose vessel on the final trans-TIPS portal venography, with a diameter more than 5 mm, and peri-stomachal location according to the Sarin's classification (29).

Statistical analysis

Firstly, Kappa correlation coefficient study was performed to check the level of agreement between the two images reviewers. Then, Kaplan Meier curves were generated to compare the free TIPS revision survey and overall mortality according to baseline demographics and angiographic parameters. Each angle A, B, C and M were tested with the 25th, 50th, and 75th percentile as cutoff to generate two groups of comparison. The distance D was tested with a distance of 15 millimeters as cutoff. Kaplan Meier analysis curves were also created to compare Viatorr® stent alone versus combination of covered/bare stent, presence of varices on final angiography versus absence of varices, men versus women, right SHV access versus other access, Child-Pugh class C versus other class, alcoholic cirrhosis versus other cause of cirrhosis, salvage indication versus other indication. For each curve, we used Log Rank test with χ^2 to determine whether free TIPS revision and survival curves were statistically significantly different. A value of P<0.05 was considered statistically significant. Multivariate analysis with Cox proportional hazard regression was not possible. Statistical analyses were performed using STATA version 14

(STATA Corp., Texas, USA).

Results

Rate of shunt revision

TIPS revision rate was 9% at 1 year (6 of 67 patients) and 13.4% at 2 years (9 of 67 patients).

Reviewers' correlation

An excellent correlation was found between the two reviewers with Kappa correlation coefficient >90 for each angle (A, B, C and M) and for the distance D.

Parameters evaluation

Technical parameters

No significant difference of revision rate was found between the group with the Viatorr[®] stent and the group with a combination of graft and bare stents (χ^2 =3.46; P=0.063). No difference was found between the group of TIPS (n=39) performed by the most experienced operator and the group of TIPS (n=28) performed by other operators (χ^2 =2.11; P=0.63).

Clinical parameters

No statistically significant difference was found between the two groups of TIPS (revised versus non-revised) for the following demographic parameters: sex, etiology of cirrhosis, Child Pugh class, TIPS indication.

Geometric parameters

A statistically significant free shunt revision survey difference was found between the group of patients who had gastric or esophageal varices on angiographic control and the group of patients without varices (χ^2 =16.25; P=0.0001). Shunt revision rate at 3, 12 and 24 months was respectively 13%, 29%, and 39% in the group with varices, versus 0, 2.7%, and 2.7% in the group without varices. Kaplan Meier free TIPS revision curves are presented in *Figure 2*. The presence of varices on final angiography increased shunt revision rate of respectively 13%, 26.3% and 36.3% at 3, 12 and 24 months. No difference of revision rate was found between the group with right SHV access and the group with other SHV access (χ^2 =0.54; P=0.46). For each angle tested (angles A, B, C and M), no statistically significant difference of revision rate was found between the two



Figure 2 Comparison of free shunt revision survey between patients with (red curve) or without (blue curve) filling gastric or oesphageal varices on trans-TIPS final angiography. TIPS, transjugular intrahepatic portosystemic shunt.

groups, with the 25th, 50th, and 75th percentile as cutoff. No statistically difference was found between the group of patients with a stent to inferior vena cava distance \leq 15 mm and the group of patients with a distance >15 mm (χ^2 =0.08; P=0.78).

Mortality

All cause-mortality rate was 16.4% at 1 year (11 of 67 patients) and 20.9% at 2 years (14 of 67 patients). There was no difference in survey between patients with the presence of varices at final angiography and patients without varices. No statistically significant difference was found for each Log rank test performed with technical, clinical, and geometric parameters.

Discussion

It has been shown that the use of the Viatorr[®] stents for TIPS results in a markedly prolonged shunt patency up to 76% at 2 years versus 8% to 48% at 2 years for TIPS created with bare metal stents (30,31). Early and late shunt dysfunction must be differentiated. Most of early occlusion events with bare stents are due to the development of biliary venous fistula, caused by the puncture with Cola Pinto needle or occurring during stent expansion. This kind of occlusion events are less common with graft stents because biliary injury is covered by the graft stent, and prevent from the biliary venous fistula development (32,33). Late TIPS stenoses, which may lead to occlusion, are mostly caused by intimal hyperplasia (34,35). The use of graft stents seems to be associated with lower intimal hyperplasia (36,37). The combination of those two factors probably explains why

position of the vein end graft stent and then the distance between stent and inferior vena cava had no influence on the shunt patency in our study as in the study by Andring *et al.* (23). It suggests that positioning of the end vein graft stent at the junction of the ICV with SHV should not be a priority during TIPS procedure.

Our study found no relation between TIPS angulation and shunt revision rate or overall survey. This result is in accordance with other series, either with bare metal stents (19-21) or with graft stents as well (23). It is well-known that covered stents (Viatorr[®] stent or bare-metal stent + covered stent) give better outcomes and long-term shunt patency than uncovered bare metal stents alone, with no difference between dedicated Viatorr[®] stent and other covered stents (31).

In our study, persistence of esophageal or gastric varices on trans-TIPS angiographic control was associated with higher rate of shunt revision, without effect on mortality. At our knowledge, no other studies showed such data. This could be explained by the fact that oesophageal or gastric post-TIPS varices create a competitive flow, leading to more risk of stent thrombosis or stenosis because of lower flow into the TIPS (38,39). Indeed, persistent flow into varices can be responsible for hemodynamic steal from the PV leading to slower flow into the TIPS shunt and potentially higher risk of in-stent thrombosis. Few authors studied the role of esophageal or gastric varices embolization at the end of the TIPS procedure, but his role is not clearly defined nowadays. In a review of 166 patients who underwent TIPS for variceal bleeding (37), Lakhoo et al. found that most common causes of rebleeding were lack of or insufficient variceal embolization (64%). In a randomized control trial (38), Chen et al. found that the 6-month shunt patency rate was higher (96.2% vs. 82%, P=0.019) and the 6-month rebleeding rate was lower (5.7% vs. 20%, P=0.029) in the group "TIPS + variceal embolization" than in the group "TIPS alone", whereas the 3-year cumulative rates of shunt patency, recurrent variceal bleeding, and death were not different between groups (P>0.05). A meta-analysis reported that patients with TIPS + variceal embolization had significantly lower rebleeding (OR=2.02, P=0.002) but similar incidences of shunt dysfunction, HE, and death than patients with TIPS alone (40). Furthermore, Xiao et al. (41) found no difference in incidence of rebleeding, shunt revision, encephalopathy, and overall survival in patients with portosystemic gradient $\leq 12 \text{ mmHg}$ after stent implantation and angioplasty. However, portosystemic gradient after TIPS placement was an independent

predictor of rebleeding (P=0.036).

Finally, there is no clear recommendation with high level of evidence on the role of embolization for varices management, although literature is rather in favor of a decrease of rebleeding rate after embolization, as found by Tesdal *et al.* (40). The effect on shunt patency or death remains to be proven. Whatever the type of procedure, every effort should be performed to ensure a portosystemic gradient ≤ 12 mmHg, with variceal embolization or not. Adjunctive embolization, when the post-TIPS portosystemic gradient is still ≥ 12 mmHg, appears to be attractive but only based on personal experience of such authors. This discrepancy supports the need for a randomized clinical trial, with clearly defined variceal embolization criteria, including portosystemic pressure gradient and the filling of varices on final trans-TIPS angiography.

In conclusion, in the present study, filling of esophageal or gastric varices >5 mm on the trans-TIPS final angiography was statistically associated with a higher shunt revision rate, without any impact on the global survey. No influence of demographic, geometric or technical parameters was found on the shunt revision rate and the global survey. This study suggests that variceal embolization during TIPS procedure could increase free shunt revision survey when final trans-TIPS angiography shows filling of esophageal or gastric varices \geq 5 mm. Further studies are needed to confirm these data and define accurate indications of variceal embolization.

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None.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: This retrospective study was performed in compliance with the requirements of the institutional review board and approved by the institution ethical committee. Informed consent was waived.

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