

Research Article

Severe Hepatic Encephalopathy after Transjugular Intrahepatic Portosystemic Shunt (TIPS): Value of Shunt Reduction and Occlusion

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Submitted: 24 April 2017

Accepted: 25 May 2017

Published: 28 May 2017

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OPEN ACCESS**Keywords**

- Transjugular intrahepatic portosystemic shunt
- Hepatic encephalopathy
- Shunt reduction
- Portosystemic pressure gradient

Abstract

Hepatic encephalopathy (HE) after implantation of the transjugular intrahepatic portosystemic Shunt (TIPS) is generally well treatable. Severe and refractory HE might be treated with shunt reduction or occlusion. We performed a retrospective study between January 2004 and January 2016. Out of 456 TIPS implantations, 17 patients (3.7%) were treated with shunt reduction and 6/17 patients with additional shunt occlusion. 16 patients received an uncovered reducing stent, 1 patient a balloon expandable metallic stent. Occlusion was performed with bucylatorvascular plugs. TIPS implantation was performed due to ascites in 8 patients (47.1%) and variceal bleeding in 7 patients (41.2%). Three patients (17.6%) had grad I HE before TIPS. Portal systemic gradient (PSG) dropped from 21 to 8mmHg. After a median follow up time of 2.3 months TIPS reduction was performed due to refractory HE. Five patients with liver failure and/or multi organ failure before TIPS reduction died within 4 weeks. Six patients received shunt occlusion due to missing success of shunt reduction. PSG increased from 10 to 12mmHg after reduction and from 16 to 29mmHg after occlusion. Improvement of HE was observed in 10 patients (59%). Four patients showed again refractory ascites, 1 patient variceal bleeding. TIPS reduction and/or occlusion can lead to improvement of post-TIPS HE. But it leads to increase of PSG and therefore can be responsible of reappearance of ascites or varices. Patients with liver failure do not benefit of shunt reduction / occlusion.

INTRODUCTION

The transjugular intrahepatic portosystemic Shunt (TIPS) is a therapeutic option in the treatment of symptomatic portal hypertension. It is mainly used for treatment of refractory ascites with or without hepato-renal syndrome and hepatic hydrothorax, variceal bleeding and the Budd-Chiari-syndrome [1-3]. Apart from interventional complications such as mispunctures of bile ducts, liver capsule or the hepatic artery, and early complications like (bacterial) infections or acute liver failure, the main long-term complication of TIPS remains worsening of pre-existing or occurrence of de-novo hepatic encephalopathy (HE) in 5-47% of patients [4-6]. Several steps have been taken to prevent severe HE after TIPS: first, patient's selection according to the risk of HE excluding negative predictors (age over 65 years, previous HE, Child Pugh score over 10 and higher MELD score) [7,8], second, adequate nutritional management, third, expansion of medical treatment (lactulose, branched chain amino acids, rifaximin [9]), and fourth, precipitating events such as dehydration, infection, gastrointestinal bleeding must be detected and eliminated [10]. Finally, placement of smaller stents (e.g. 6-8 mm instead of 10 mm) [11], may reduce the risk of HE.

In spite of this, severe HE after TIPS occurs in 3-7% of

patients affecting quality of life and reducing survival [12]. Shunt reduction is the first step if medical treatment fails. This study investigated the effects of shunt reduction or occlusion on severe and treatment refractory HE as well as on the symptoms of portal hypertension which indicated the TIPS implantation.

PATIENTS AND METHODS

Between January 2004 and January 2016, 456 patients with cirrhosis and symptomatic portal hypertension received a TIPS implantation at our Liver Center. During their follow-up, 17 patients (3.7%) developed treatment refractory, severe hepatic encephalopathy requiring shunt reduction. All patients provided written informed consent for the TIPS implantation, the TIPS revision/reduction, and for the electronic collection of the data. The study was performed in accordance with the Declaration of Helsinki and it has been approved by the local ethics committee of our University Hospital (no. EK 428/14).

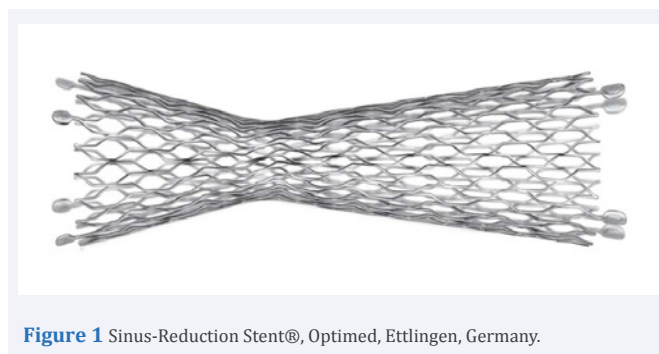
Patients were seen before and 4 weeks, 3 months, and then 6-monthly after shunt implantation or revision, or if required by reappearance of severe HE or clinical symptoms of portal hypertension. Visits included physical examination, abdominal duplex sonography, and biochemical testing. Clinically overt HE was diagnosed and graded according to the West-Haven criteria

[13]. If present, patients received medical treatment consisting of Lactulose, L-ornithine-L-aspartate, and rifaximin after its marketing in 2013. Patients were followed until lost to follow up, death or end of the data collection (March 2016).

TIPS implantation was performed as described previously [2,14]. Briefly, after sedation using propofol, midazolam and piritramide, the right internal jugular vein was punctured, a 11 F sheath inserted, and the right or middle hepatic vein catheterized. An open, 50 cm long puncture needle (REF 1490-9000, Optimed, Ettlingen, Germany) was advanced through a multipurpose TFE catheter (TJC, 9F, REF T9.0-65-45-M-NS-TJC, Cook, Hamburg, Germany) and released inside the hepatic vein. The right or left (exceptional) branch of the portal vein was then punctured using sonographic guidance. A stiff and angled Terumo guide wire (REF RF[®]PA35183M, Terumo, Leuven, Belgium) was then advanced into the splenic vein and exchanged by a pig-tail catheter to perform a spleno-portography. This was followed by measurement of the portal and right atrial pressures. In case of varices, embolization was now performed using a mixture of bucrylate and lipiodol. A stiff guide wire (Amplatz super stiff, REF M001465250, Boston Scientific, USA) was then introduced and the parenchymal tract was opacified over the TFE catheter which was equipped with an 8F hemostasis valve adapter (REF HVA-100, Merit Medical, USA). After having excluded a communication to the biliary or arterial system, a stent (various types of uncovered stents or a covered VIATORR[®] stent) was implanted and dilated. A final splenoportography and pressure measurement was performed. Sixteen patients received stents with a nominal stent diameter of 10 mm. One patient with a higher risk of HE received a balloon-expandable metallic stent (Atrium Advanta[™] V12) which was dilated to a diameter of 7.5 mm.

For shunt reduction, the needle covered by the multipurpose TFE catheter, was advanced into the inferior caval vein to facilitate the catheterization of the stent-shunt. After successful catheterization of the stent, patency was objectified by hand injection of 10 ml of contrast dye through a hemostasis valve adapter mounted on the TFE catheter which was placed in the middle of the stent. This was followed by pressure measurements in the portal vein and the right atrium. After having confirmed shunt patency together with a low pressure gradient, a reducing stent (Sinus-Reduction Stent[®], Optimed, Ettlingen, Germany) was implanted into the middle of the parenchymal part of the stent in 16 patients (Figure 1). This self-expandable, uncovered nitinol stent consists of a spiral of dense nitinol filaments arranged in form of an hourglass with a smallest diameter of 4mm and a length of 40mm [15]. In 1 patient a covered stent (VIATORR[®]) was additionally implanted into the (uncovered) reducing stent to improve the effect of the reducing stent and 1 patient received a balloon expandable metallic stent (Atrium Advanta[™] V12) which was dilated in the central part to a diameter of 4 mm only. After stent placement, a final angiography and pressure measurement was performed to assess the effect of the shunt reduction.

Six patients, who did not respond sufficiently to shunt reduction, received a complete TIPS occlusion within 3 months after shunt reduction. This was performed using bucrylate in 4 patients. Thereby, two pig-tail catheters were placed into the portal vein and one of them was exchanged by a balloon catheter



which was placed close to the hourglass configuration of the reducing stent and inflated. After the guide wire was removed, bucrylate was injected into the wire mesh of the reducing stent until occlusion and the balloon catheter removed. The effect of this maneuver was verified by angiography and pressure measurement via the pig-tail catheter left in the portal vein. In 2 patients, the shunt was occluded by implantation of an Amplatzer plug (AVP; AGA Medical, Golden Valley, USA) into the hourglass configuration of the reducing stent.

Shunt reduction/occlusion was complicated in one patient by stent dislocation. The dislocated stent was retrieved by endovascular loop. In one patient who received the Amplatzer plug, the first attempt failed and the plug embolized into the left lower pulmonary artery without causing severe clinical symptoms. No other complications occurred in the remaining 15 patients.

RESULTS

Demographic and clinical characteristics of the 17 patients at TIPS implantation are summarized in Table 1. Alcoholic cirrhosis was the leading etiology and refractory ascites the main indication for the TIPS. More than two third of the patients had advanced disease with a Child Pugh grade B or C. Hepatic function was not severely decompensated with respect to the bilirubin concentration (< 2.7 mg/dl). Four patients received variceal embolization at the time of the intervention. All patients received bare (8 patients) or covered (9 patients) Nitinol stents with a nominal diameter of 10 mm. Three patients had mild HE grade 1 before the TIPS implantation. TIPS reduced the portosystemic pressure gradient by 62%.

Technical aspects

The following case demonstrates the complexity of shunt reduction and shows the variety of technical weapons which were utilized in the management of shunt reduction and occlusion. In February 2014, the 71 year old patient received a TIPS after 3 episodes of severe variceal bleedings within 4 weeks. A bare stent was implanted but occluded within days. Recatheterization of the stent was not successful why a parallel shunt had been performed using a Viatorr-stent. A few days thereafter, the patient developed severe HE requiring intensive care. This and additional milder HE episodes was the reason for the implantation of a 4 mm hourglass reducing stent 3 months later (Figure 2a), which did, however, not satisfactorily resolve the problem. Therefore, occlusion with an Amplatzer plug was performed in August 2014 (Figure 2b),

Table 1: Baseline characteristics of 17 patients receiving a reducing stent before the TIPS-implantation.

Parameter	
Gender, m/f (%)	13/4 (76.5/23.5)
Age in years (median, range)	66 (42-83)
Etiology of liver cirrhosis, n (%)	
-Alcohol	8 (47.1)
-HCV	5 (29.4)
-unknown	3 (17.6)
-other	1 (5.9)
Indication for TIPS, n (%)	
-ascites	8 (47.1)
-and varices	1 (5.9)
-and hepato-renal syndrome	1 (5.9)
-variceal bleeding	7 (41.2)
Hepatic encephalopathy before TIPS, n (%)	
-Grade I	3 (17.6)
Child-Pugh score/class	
-score, median (range)	7 (5-10)
-class A, n (%)	5 (29.4)
B	9 (52.9)
C	3 (17.7)
Biochemical tests (median, range)	
-Bilirubin (mg/dl)	1.4 (0.6-2.6)
-Albumin (g/dl)	3.0 (1.9-4.4)
-AST (U/l)	48 (7-138)
-ALT (U/l)	34 (7-107)
-Plateletes (1000/ μ l)	94 (43-226)
Portosystemic pressure gradient (median, range)	
-before TIPS (mmHg)	21 (15-32)
-after TIPS (mmHg)	8 (4-17)
Type of stent, n (%)	
-bare stent	8
-VIATORR®	9
Embolization of varices	4 (50% of bleeders)
MELD score (median, range)	13 (7-21)

Abbreviations: HCV: Hepatitis C Virus; MELD: Model of End Stage Liver Disease; TIPS: Transjugular Intrahepatic Portosystemic Shunt

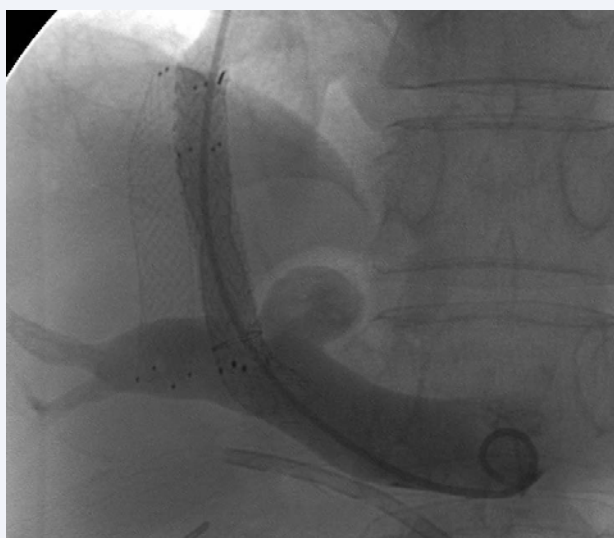


Figure 2a Implantation of the reducing stent.

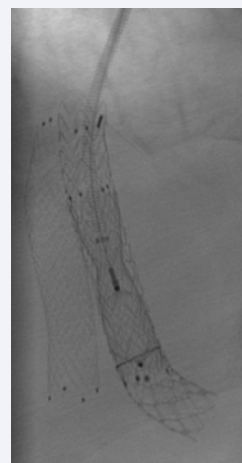


Figure 2b Occlusion of the reducing stent with a vascular plug.

resulting in a marked increase in the hepatic portal blood flow and the pressure gradient (from 11 to 37 mmHg) together with a marked improvement of HE. In the following 4 months, the patient had two fulminant variceal bleedings and one episode of rectal variceal bleeding. Transjugular variceal embolization was now attempted but no dominant collaterals could be identified. A balloon expandable, covered stent was now implanted through the Amplatzer plug and dilated to a diameter of 5mm. HE reoccurred and, due to patient's wish, the shunt was occluded again. In the next 16 months no further HE occurred. The patient had 8 more gastroscopies, with 3 band ligations. He died in May 2016 due to an intracranial hemorrhage.

As demonstrated in Table 2, shunt reduction with the uncovered reducing stent resulted in a mild immediate increase in the portosystemic pressure gradient from 10 to 12 mmHg only. A much greater increase and better reperfusion of hepatic branches is achieved by occlusion of the shunt which always results in restoration of marked portal hypertension.

Clinical course after TIPS

Ten patients developed grade II, five patients grade III and two patients grade IV HE. In 5 patients, HE was accompanied by liver failure or multi-organ failure due to septicemia. Median bilirubin concentrations before shunt reduction were 2.6 mg/dl (range 0.6 – 39 mg/dl).

Effects of shunt reduction/occlusion (Table 3)

Median time between TIPS and shunt reduction was 2.3 months (range 0.5 – 46.5 months). 8 of the 17 patients had benefit from shunt reduction showing less frequent and/or less severe episodes of HE \leq grade 1. Five of the remaining 9 patients died within 4 weeks of shunt reduction without improvement of HE, 4 of them had subsequent shunt occlusion. Of the remaining 4 patients 2 improved with shunt occlusion, 1 patient received splenic artery embolization which resolved HE and 1 patient had continued HE grade 1-2 until death 4 months after shunt reduction.

In the 12 patients who survived longer than 4 weeks after shunt reduction, ascites recurred in 4 and variceal rebleeding

Table 2: Porto-systemic pressure gradient (PSG) at TIPS implantation, shunt reduction and shunt occlusion.

	PSG before intervention (mmHg)	PSG after intervention (mmHg)
TIPS (median, range)	21 (15-32)	8 (4-17)
Shunt reduction, n=17 (median, range)	10 (2-25)	12 (4-27)
Subsequent shunt occlusion, n=6 (median, range)	16 (8-25)	29 (16-37)

Table 3: Efficacy of shunt reduction or subsequent occlusion on clinical outcome variables of the 17 patients. Improvement of hepatic encephalopathy (HE) was defined as a reduction in severity to grade ≤ 1 . Evaluation of recurrence of symptoms is limited to patients followed for > 4 weeks (n=12).

Variable	n	%
HE improvement by shunt reduction*	8	
HE improvement by shunt occlusion	2	59
Recurrence of symptom	5	42
-ascites	4	33
-rebleeding	1	8
Survival >4 weeks	12	71
Survival > 12 months (1 LTX)	8	47
Death within 4 weeks	5	30
-septicemia, multi-organ failure	2	12
-liver decompensation	3	18

Abbreviations: HE: Hepatic Encephalopathy; LTX: Liver Transplantation

Table 4: Summary of the present study and the available literature.

Study	n	Time to SR (days) median (range)	Technique	response, Δ PSG (mmHg) median (range)	HE Clinical response (%)	relapse of clinical symptom (%)
Blue [18]	10	193 (27-419)	Red. stent	5.7 (1-10)	70	n.d.
Cookson [17]	8	n.d.	Red. stent	5.6 (2-8)	63	37
Fanelli [21]	12	43 (5-1036)	Suture	8.5 (4-15)	100	8
Kroma [20]	4	35 (4-105)	Red. stent	8 (6-19)	25	25
Madoff [5]	6	66 (6-157)	Suture	9.3 (3-16)	83	17
Maleux [19]	16	n.d.	Red. stent	10.5 (3-18)	63	12
Maleux [22]	17	78 (5-540)	Parallel Stents	5.8 (1-12)	76	12
Present study	17	70 (15-666)	Red. stent	3 (0-12)	59	42*

Abbreviations: HE: hepatic encephalopathy; SR: shunt reduction. RS: Reducing Stent; Δ PSG, Increase in Portal Systemic Gradient by Shunt Reduction; n.d.: no data available.

*: 5 of 12 patients with a follow-up of > 4 week

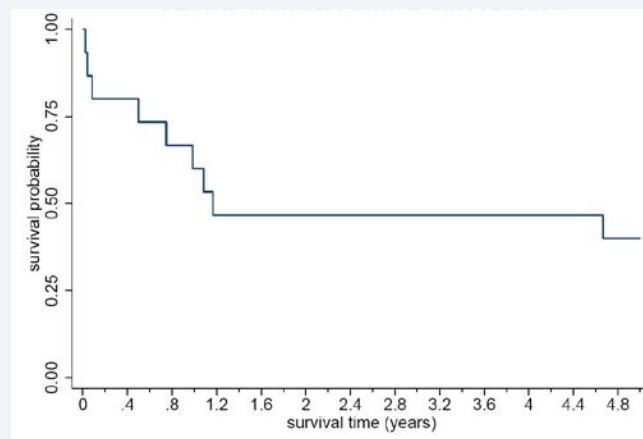


Figure 3 Kaplan-Meier plot: survival estimates after shunt reduction.

in 1 patient (case mentioned above). As shown in Figure 3, death occurred mainly early after shunt reduction: 5 patients died within 1 month, another 5 patients within 14 months. The high 4-week mortality of 5 patients was caused by liver or multiorgan failure after TIPS which could not be reversed by shunt reduction followed by occlusion. The time between TIPS and shunt reduction in these five patients was 3, 1.1, 1.1, 2.0 and 1.3 months, respectively. About half of the patients survived more than 1 year with one patient receiving liver transplantation 8 months after shunt reduction. Three patients developed HCC during follow-up.

DISCUSSION

As shown in the case report, there are no technical limitations in shunt tuning. It can be reduced, occluded and reopened as warranted. The actions depend on the severity of the various symptoms and are determined by the patient's wishes. Shunt induced HE has to be balanced against the symptoms of portal hypertension which have a high probability of recurrence after shunt reduction/occlusion. Needless to say that medical treatment has to be maximized before shunt reduction is performed. As shown in this study, shunt reduction is effective with respect to HE when liver function remains compensated after TIPS. In contrast, in patients with severe liver decompensation or with multi-organ failure, shunt reduction or occlusion did neither improve HE nor prevent death within 1 month. This is confirmed by a previous study including 21 patients with post-TIPS liver decompensation receiving shunt reduction showing a 6-month mortality rate of 48% [24].

TIPS-induced HE may be prevented by proper patients' selection. As demonstrated previously, age over 65 years, previous HE, Child Pugh score over 10 and higher MELD score are risk factors for the development of post-TIPS HE [7,8]. In clinical practice, however, these predictors are not of sufficient strength to guide the treatment decision. The great majority of patients receive the TIPS as an ultima ratio treatment after failure of medical therapies. The severity of their symptoms often demands escalation of treatment even in patients with a higher risk of post-TIPS HE. The option of shunt reduction or occlusion may qualify relative contraindications such as HE if the symptom, aggravated by the TIPS, is reversible. As demonstrated, this seems to be true for severe HE in the absence of liver decompensation. However, in the presence of liver decompensation, HE cannot be reversed and the value of shunt reduction is questionable.

As demonstrated in our study and in previous studies [6, 19-22] and summarized in Table 4, only few patients with post-TIPS HE do not respond to medical treatment and are candidates for shunt reduction. This is required early (median 35 to 193 days) after TIPS implantation. Its response can be assessed by physical/hemodynamic and clinical means. In our study, shunt reduction mainly using an hourglass shaped uncovered nitinol reducing stent resulted in a median increase of the porto-systemic pressure gradient of 3 mmHg (range 0-12mmHg). Subsequent occlusion increased the gradient further to reconstitute significant portal hypertension. These results are similar to other studies, showing increases of 5.6-10.5 mmHg (Table 4) [5,16-22]. With respect to the clinical improvement of HE, 8/17 of our patients responded to shunt reduction and 2 additional patients responded to

subsequent occlusion. This is compatible to results of other studies showing improvement or resolution of HE in 25-100 % of patients (Table 4).

Shunt reduction or occlusion can lead to reappearance of the TIPS indicating symptom. This is in particular true for patients receiving TIPS for refractory ascites. In patients with variceal bleeding, embolization of the varices at TIPS implantation or at TIPS reduction may help to avoid rebleeding and should be done whenever possible. Our recurrence rate of 42% (5 of 12 patients who were followed for > 4 weeks) is in the upper field when compared with the literature (Table 4). This may be due to the fact that 10 of our 17 patients had ascites as the indication for the TIPS.

The technique of shunt reduction or occlusion is not standardized. Different stents and technical approaches have been described [23]. The "parallel technique" inserts two stents in parallel into the original TIPS stent. One of these stents is a short bare stent and the other a covered stent with its open ends in the portal and hepatic veins. Expansion of the short bare stent determines the diameter of the covered stent. The "suture technique" inserts a stent with a handmade suture determining the smallest diameter. Finally, commercially available self-expandable or balloon expandable reducing stents can be implanted. The different techniques used in the various studies (Table 4), may explain differences in results. Our hourglass shaped reducing stent was uncovered and developed its full effect only after thrombotic closure of the space between the wire mesh of the reducing stent and the inner surface of the original TIPS stent. This explains the relatively low increase in the pressure gradient at the time of shunt reduction. In patients with severe coagulopathy, the long-term effect may be reduced or missed because thrombosis between stents may not occur. Complete shunt occlusion might be required if post-TIPS refractory HE persists after shunt reduction. In general, the Amplatzer Vascular Plug is used [24]. The TIPS occlusion leads to an immediate increase of portal vein pressure and has, therefore, a risk of recurrence of ascites and/or varices as shown in our case report. In our cohort, five patients had TIPS occlusion.

Our study is limited by its retrospective design and the small number of patients included. The small number is, fortunately, due to the fact that severe and refractory HE is a rare event after TIPS. This may be a reason why an additional small study may add new information to previous small and retrospective studies. In addition, published studies used different techniques and reducing stents which may influence outcome variables. Our uncovered reducing stent has been designed in the early 1990th where covered stents did not exist. An improvement by covering seems to be overdue. With such a stent, the difficult and expensive "parallel technique" and the "home made" suture technique may hopefully be history.

In conclusion, shunt reduction is an interventional treatment for post-TIPS refractory HE which is seldom needed. This is the main reason for technical deficits and lack of standardization. It improves HE in patients with compensated hepatic function but its effect is very limited if HE is accompanied or caused by liver decompensation. As expected, symptoms of portal hypertension may recur.

ACKNOWLEDGMENTS

DB is supported by the Berta-Ottenstein-Programme, Faculty of Medicine, University of Freiburg

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Schultheiss M, Bettinger D, Boettler T, Thimme R, Rössle M (2017) Severe Hepatic Encephalopathy after Transjugular Intrahepatic Portosystemic Shunt (TIPS): Value of Shunt Reduction and Occlusion. *JSM Hepat* 2(1): 1009.