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# Technical and clinical outcome of transjugular intrahepatic portosystemic stent shunt: Bare metal stents (BMS) versus viatorr stent-grafts (VSG)

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ABSTRACT

*Purpose:* To compare retrospectively angiographical and clinical results in patients undergoing transjugular intrahepatic portosystemic stent-shunt (TIPS) using BMS or VSG.
*Materials and methods:* From February 2001 to January 2010, 245 patients underwent TIPS. From those, 174 patients matched the inclusion criteria with elective procedures and institutional follow-up. Group (I) consisted of 116 patients (mean age, 57.0 ± 11.1 years) with BMS. Group (II) consisted of 58 patients with VSG (mean age, 53.5 ± 16.1 years). Angiographic and clinical controls were scheduled at 3, 6 and 12 months, followed by clinical controls every 6 months. Primary study goals included hemodynamic success, shunt patency as well as time to and number of revisions. Secondary study goals included clinical success.
*Results:* Hemodynamic success was 92.2% in I and 91.4% in II (n.s.). Primary patency was significantly higher in II compared to I (53.8% after 440.4 ± 474.5 days versus 45.8% after 340.1 ± 413.8 days; $p < 0.05$). The first TIPS revision was performed significantly later in II compared to I (288.3 ± 334.7 days versus 180.1 ± 307.0 days; $p < 0.05$). In the first angiographic control, a portosystemic pressure gradient ≥15 mmHg was present in 73.9% in I and in 39.4% in II ($p < 0.05$). Clinical success was 73.7–86.2% after 466.3 ± 670.1 days in I and 85.7–90.5% after 617.5 ± 642.7 days in II (n.s.). Hepatic encephalopathy was 37.5% in I and 36.5% in II (n.s.).
*Conclusion:* VSG increased primary shunt patency as well as decreased time to and number of TIPS revisions. There was a trend of higher clinical success in VSG without increased hepatic encephalopathy.



## 1. Introduction

In 1989, transjugular intrahepatic portosystemic stent-shunt (TIPS) was introduced clinically by Richter et al. [1]. Via a percutaneous jugular access, a permanent intrahepatic tract shunting blood from the portal vein directly into the hepatic vein was created using a balloon-expandable BMS. TIPS is established in the therapy of complications of portal hypertension, especially refractory ascites and variceal hemorrhage [2]. Additional indications include Budd-Chiari-syndrome, portal vein thrombosis, refractory pleural effusion as well as hepatopulmonary and hepatorenal syndrome [3]. In cirrhotic patients with refractory ascites, TIPS proved clinical success in 52%, compared to 11% in patients undergoing paracentesis only. TIPS significantly increases the transplant-free survival of cirrhotic patients [4]. In the treatment of acute variceal hemorrhage, TIPS is effective in obtaining hemostasis in more than 90%. Periprocedural fatal complications such as intraperitoneal hemorrhage, laceration of the portal vein or liver artery and right heart failure occur in up to 5% [5]. The overall procedural mortality of an elective TIPS is approximately 1% [6]. The 30-day mortality of emergency TIPS ranges between 28% and 37% [2]. The major drawback of TIPS is dysfunction necessitating shunt revisions in up to 50% of patients after one year. Recurrent ascites and variceal hemorrhage are observed in stenosed or occluded TIPS tracts with pathological increase of the portosystemic pressure gradient. In contrast, the risk of hepatic encephalopathy increases with portosystemic pressure gradients <12 mmHg [6]. In this context, TIPS tract stabilization with BMS [balloon-expandable or self-expanding] or stent-graft seems to play an important role. Several studies observed a clearly better TIPS patency when VSG were used. Excellent results were found for VSG (polytetrafluoroethylene (PTFE)-covered stent-grafts; Viatorr, Gore, Flagstaff, USA) with

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**Table 1**
Patient demographics.

| | I | II |
|---|---|---|
| | BMS | VSG |
| Patients | 116 | 58 |
| Sex (M:F) | 74:42 | 35:23 |
| Age (years) | 56.3 ± 11.1 (22–80) | 53.4 ± 16.1 (19–86) |
| Liver disease | | |
| Ethyltoxic liver cirrhosis | 69.0% | 51.7% |
| Viral hepatitis | 12.0% | 6.9% |
| Budd-Chiari-syndrome | 1.7% | 19.0% |
| Cryptogenic liver cirrhosis | 14.7% | 19.0% |
| Others | 2.6% | 3.4% |
| Child-Pugh score | 7.6 ± 1.6 (5–14) | 8.0 ± 1.8 (5–11) |
| Child-Pugh class | | |
| A | 20.7% | 17.2% |
| B | 69.0% | 63.8% |
| C | 10.3% | 19.0% |
| MELD score | 11.2 ± 3.9 (6–27) | 11.9 ± 5.0 (6–26) |
| Hepatic encephalopathy | 8.4% | 8.4% |
| Indications for TIPS | | |
| Refractory ascites | 51.7% | 36.2% |
| Refractory ascites and recurrent variceal hemorrhage | 26.7% | 36.2% |
| Recurrent variceal hemorrhage | 21.6% | 27.6% |

*Note:* No statistical differences were detected between both study groups when the Mann–Whitney-*U*-test or the Chi-square-test, when appropriate, were used.

a shunt patency of 74% after three years [7]. Tripathi and Redhead reported a shunt insufficiency rate of 54% in BMS and 8% in VSG [6]. Ockenga et al. and Bureau et al. published fewer TIPS revisions for VSG compared to BMS [8,9]. The impact of the prosthesis on TIPS-associated hepatic encephalopathy remains controversial. Barrio et al. published a trend of higher hepatic encephalopathy after the implantation of VSG when compared to BMS (41% versus 20%; n.s.) [10]. Tripathi and Redhead reported significantly reduced hepatic encephalopathy in stent-grafts compared to BMS (22% versus 32%; $p < 0.05$) [6].

Dealing with this background, the purpose of this study was to compare retrospectively the angiographical and clinical results in patients undergoing elective TIPS using BMS or VSG. Primary study goals included technical success, shunt patency as well as time to and number of revisions required to maintain TIPS patency. Secondary study goals included clinical success, hepatic encephalopathy and survival.

## 2. Materials and methods

From February 2001 to January 2010, a retrospective analysis from our prospective institutional TIPS database was performed. During this period, 245 patients underwent TIPS. From those, 174 patients matched the inclusion criteria with elective procedures and institutional follow-up (31 patients with emergency TIPS and 40 patients with follow-up outwards were excluded). The study was performed in accordance with the principles of good clinical practice, the principles of the declaration of Helsinki and its appendices and local and national laws. The institutional review board did not require its approval. Written informed consent was obtained for all patients.

### 2.1. Patient population

Patient demographics are presented in Table 1. Group (I) consisted of 116 patients (74 male; mean age, 57.0 ± 11.1) with balloon-expandable BMS (Cordis, Miami, USA). Group (II) consisted of 58 patients (35 male; mean age, 53.5 ± 16.1) with self-expandable VSG (Viatorr, Gore, Flagstaff, USA). Cause and extension of liver disease, symptoms and indications for TIPS were comparable in both study groups.

### 2.2. TIPS procedure

Our department has a high personal experience of TIPS with more than 1000 procedures since 1989. A standardized technique was used to achieve transhepatic portal vein access as described previously. All interventions were performed by senior interventional radiologists. Bleeding values were normal or had been corrected prior to the intervention. The majority of TIPS were created under analgosedation with bolus injections of 1.25 mg midazolam (Dormicum®; Roche Pharma, Grenzach-Wyhlen, Germany) and 75 mg pethidine (Dolantin®; Sanofi-Aventis, Frankfurt, Germany). In most cases, TIPS tracts were implemented after puncture of the right portal vein from the right hepatic vein. A commercially available coaxial puncture set with a needle banding of either 30° or 45° (Optimed, Ettlingen, Germany) was applied. To establish the TIPS, the intrahepatic tract was predilated with an angioplasty balloon with a diameter of 8 mm and a length of 6–8 cm. The entire tract was covered with prostheses with diameters of 8–10 mm [11]. A post-dilatation for optimization of the shunt tract was performed depending on the resulting portosystemic pressure gradient. In all cases of BMS, the covered outflow tract was dilated with a 10–12 mm angioplasty balloon to form a cone-shaped entrance to the TIPS for easier access in case of revision. Beginning 2005, VSG were implanted in higher numbers. If it was necessary to modify the TIPS, e.g. tract extension or reduction of stent banding, the modification in TIPS initially established with a BMS was performed exclusively with additional BMS. In TIPS initially established with a VSG, the modification was performed with additional VSG but also with BMS. Periprocedural anticoagulation included a bolus injection of 5000 IU of heparin after achieving portal vein access with continuous injection of 1000 IU heparin per hour for 72 h. Antibiotic medication was performed with 1.5 g metronidazol (Clont; Bayer Vital GmbH, Leverkusen, Germany) and 6 g mezlocillin (Baypen; Bayer Vital GmbH, Leverkusen, Germany) daily for 5 days. Technical success was defined as successful creation of a shunt between the hepatic vein and the portal vein (primary success – in the first attempt; secondary success – a second intervention was necessary). Hemodynamic success at implantation was defined as successful reduction of the portosystemic pressure gradient <12 mmHg [12]. Major and minor procedure-related complications were studied according to the Society of Interventional Radiology classification [13].

### 2.3. Follow-up

The follow-up was performed angiographically and clinically. All patients were scheduled for a standardized surveillance programme including angiographic controls at 3, 6 and 12 months, followed by clinical controls every 6 months. In case of clinical signs of TIPS dysfunction, additional angiographic controls were performed. Angiographic follow-up included functional (measurement of the portosystemic pressure gradient) and morphological evaluation of the TIPS tract. TIPS patency was defined as previously described by Latimer et al. [14]: primary patency – continuous unaided patency of the TIPS with a portosystemic pressure gradient <15 mmHg; primary assisted patency – continuous patency but requiring percutaneous treatment of a significant stenosis to maintain a portosystemic pressure gradient <15 mmHg; and secondary patency – tract occlusion with patency restored and maintained by percutaneous treatment to maintain a portosystemic pressure gradient <15 mmHg. The first angiographic control was analyzed