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ePTFE-Covered Stent-Grafts for Revision of Obstructed Transjugular Intrahepatic Portosystemic Shunt

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Abstract

Purpose: To determine whether transjugular intrahepatic portosystemic shunt (TIPS) revisions with the Hemobahn stent-graft or the Viatorr endoprosthesis increase secondary patency rates.

Methods: Between 1998 and June 1999, Hemobahn endoprostheses (W.L. Gore, Flagstaff, AZ, USA) were used for the revision of obstructed TIPS in seven patients, 51–67 years of age (mean 59 years). From June 1999 to 2000, the Viatorr endoprosthesis (W.L. Gore, Flagstaff, AZ, USA) was used for revision of obstructed TIPS in nine patients, 33–64 years of age (mean 49 years). Follow-up included duplex ultrasound, clinical assessment and venous portography.

Results: The technical success rate of TIPS revision with the Hemobahn stent-graft was 100%. The pressure gradient decreased from a mean of 20 mmHg to 10 mmHg. The mean follow-up was 407 days (range 81–868 days). In two patients TIPS occlusion occurred at 62 and 529 days after stent-graft placement, respectively; in another two patients outflow tract stenosis occurred at 275 and 393 days, respectively. The technical success rate of TIPS revision with the Viatorr endoprosthesis was also 100%. The pressure gradient decreased from a mean of 27 mmHg to 11 mmHg. At a mean follow-up of 201 days (range 9–426 days), all Viatorr endoprostheses are still patent without in-graft stenosis, but angioplasty was required in two patients to treat a portosystemic pressure gradient $>$ 15 mmHg. Four of the nine patients in the Viatorr group suffered from new encephalopathy after TIPS revision.

Conclusion: The Viatorr endoprosthesis yielded optimal results with 100% in-graft patency rates at follow-up but had a high incidence of new encephalopathy, whereas the use of Hemobahn stent-graft for TIPS revision did not appear to improve the secondary patency rates in our series.

Key words: Grafts—Hypertension, portal—Liver, interventional procedures—Shunts, portosystemic—Stents and prostheses—Veins, grafts and prostheses

The major problems with transjugular intrahepatic portosystemic shunts (TIPS) are their limited and unpredictable patency. In a small proportion of patients the shunts may remain free of stenoses, but the majority of TIPS develop sporadic or frequent shunt tract stenoses, thromboses and/or outflow hepatic venous stenoses, with the potential recurrence of variceal bleeding or ascites. Depending on the definition of shunt patency, the methods of follow-up and timing of surveillance, stenoses greater than 50% and recurrent portal hypertension develop in 25–50% of cases within 6–12 months of shunt creation [1–5].

Early shunt failures are most often caused by thrombosis ($<$ 30 days) or parenchymal tract stenosis [1–5]. Both may be associated with biliary fistulae [6–9]. Late shunt failures are caused to a large extent by hepatic vein stenosis [1–5]. Custom-made polytetrafluoreethylene (PTFE)-covered stent-grafts have demonstrated a high potential for creating a durable TIPS in animals [10, 11] and pilot clinical studies [12, 13], but until PTFE-covered stent-grafts become widely available, the majority of TIPS are still created with bare stents. TIPS revisions pose a specific problem, as the previously implanted stents, often in multiple layers, lead to luminal narrowing, which might present a higher risk of restenosis. We report our results of the prospective evaluation of the first dedicated TIPS stent-graft, the Viatorr endoprosthesis, as well as our results with the Hemobahn endoprosthesis for the revision of TIPS dysfunction.

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Table 1. Patients and indications for TIPS revision and Hemobahn stent-graft placement

Patient no.	Age (years)	Sex	Etiology of cirrhosis	Recurrent variceal bleeding	Refractory ascites	No. of prior revisions	Child-Pugh class	Device size (mm)	Devices used	Pre-treatment PPG	Post-treatment PPG
H1	62.9	F	Budd Chiari	0	1	7	n.a.	13	1	25	14
H2	54.1	M	Alcoholic	1	(1)	2	B	10	1	24	10
H3	55.2	M	Hepatitis B	1	0	2	B	9	1	16	10
H4	62.0	M	Alcoholic	1	0	2	B	9	2	24	11
H5	67.1	F	Alcoholic	1	0	2	B	10	1	20	10
H6	58.8	F	Alcoholic, cytostatic	0	1	1	B	10	2	16	8
H7	50.9	M	Alcoholic	1	0	2	A	10	1	15	10

Numbers in parentheses indicate the presence of symptoms but not the primary indications for TIPS creation
n.a., not applicable (see Patients and Methods); PPG, portosystemic pressure gradient

Materials and Methods

From 1998 to June 1999, we implanted the Hemobahn endoprosthesis (W.L. Gore, Flagstaff, AZ, USA) in seven patients for the revision of early TIPS dysfunction or demonstrated biliary fistulae.

From June 1999 until the present, we used the first dedicated TIPS stent-graft, the Viatorr endoprosthesis (W.L. Gore, Flagstaff, AZ, USA), for revision of TIPS in nine patients. The first four patients treated with the Viatorr endoprosthesis were part of a nonrandomized, prospective, multicenter evaluation intended to monitor the safety and efficacy of the Viatorr endoprosthesis for creation and revision of TIPS. Upon completion of the study, the subsequent five patients at our institution were treated under the same protocol (same inclusion and exclusion criteria), so this study reports a continuous series of patients.

Our Institutional Review Board approved the protocol for TIPS revision with stent-grafts in accordance with the Helsinki Declaration of 1975, as revised in 1983. Signed informed consent was obtained from each patient before intervention. For documentation and consistency in reporting results, we used the "Reporting Standards for Transjugular Intrahepatic Portosystemic Shunts" [14].

Patients were included if they were at least 21 years of age and able to comply with protocol requirements including follow-up with prior TIPS with proven occlusion or stenosis. Patients were excluded if they had: (a) congestive heart failure; (b) severe hepatic failure (with bilirubin levels of > 5 mg/dl); (c) hepatic encephalopathy; and (d) presence or suspicion of active systemic, hepatobiliary or ascitic fluid infection.

Hemobahn Endoprosthesis: Patients and Devices

We treated seven patients (3 women, 4 men; mean age 59 years, range 51–67 years) (Table 1). Five patients suffered from recurrent variceal bleeding, two patients (#H6 and #H1) from refractory ascites and concomitant but not recurrent variceal bleeding, in one case (#H1) due to Budd-Chiari syndrome secondary to polycythemia vera. Five patients had Child-Pugh class B, and one patient had Child-Pugh class C liver cirrhosis at the time of revision. The patient with Budd-Chiari syndrome presented with hepatic fibrosis at initial biopsy and the following laboratory values: albumin, 5.1 mg/dl; bilirubin, 3.0 mg/dl; and a normotest value of 37%. All patients had prior TIPS revisions (with a range of 1 to 7 revisions per patient) or early TIPS dysfunction occurred at the level of the parenchymal portion when biliary fistulae were thought to be causative or could be demonstrated (with demonstration of biliary fistulae only in patients #H2).

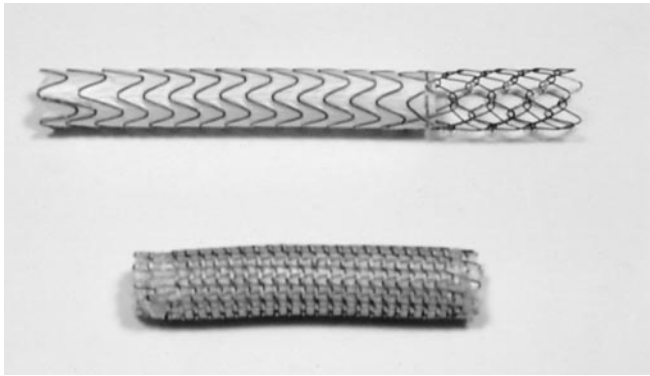

Fig. 1. Above: Fully expanded Viatorr endoprosthesis demonstrating its covered and uncovered portion. Below: Fully expanded Hemobahn endoprosthesis.

The diameters of the stent-grafts used in this study were 9 mm (for 7.6–8.5 mm vessels, $n = 2$), 10 mm (for 8.6–9.5 mm vessels, $n = 4$) and 13 mm (for 10.6–12.0 mm vessels, $n = 1$) with a length of 5 cm. In one patient (#H2) local thrombolysis with recombinant plasminogen activator (rt-PA; Actilyse, Bender, Vienna, Austria) was performed prior to stent-graft placement. The Hemobahn endoprostheses were placed in the parenchymal tract without intentional occlusion of portal or hepatic vein branches. In five patients, a single Hemobahn endoprosthesis was implanted; in two patients two Hemobahns were placed with an overlap of at least 2 cm. The Hemobahn endoprosthesis (Fig. 1) is a flexible, self-expanding (NiTi) helical-shaped stent internally covered by a radially reinforced ultrathin-wall microporous ePTFE tube with a 30 μm internodal distance (W.L. Gore, Flagstaff, AZ, USA). It is available in lengths of 5, 10 and 15 cm and can be used over a 0.025-inch guidewire [15]. We used a 0.020-inch guidewire (Boston Scientific International, Natick, MA, USA) in all revisions. The vascular sheaths used for revisions had diameters of 10 Fr or 12 Fr.

Viatorr Endoprosthesis: Patients and Devices

For Viatorr endoprosthesis placement, consecutive patients with TIPS dysfunctions with stenosis/occlusions at the parenchymatous/hepatic venous level were included beginning in June 1999. We treated nine patients (3 women, 6 men; mean age 49 years, range 33–64 years) (Table 2). Six patients suffered from recurrent variceal bleeding, three patients additionally from refractory ascites

Table 2. Patients and indications for TIPS revision and Viatorr endoprosthesis placement; four patients suffered from recurrent variceal bleeding and ascites

Patient no.	Age (years)	Sex	Etiology of cirrhosis	Recurrent variceal bleeding	Refractory ascites	No. of prior revisions	Child-Pugh class	Device size (mm)	No. of devices used	Combined covered length (mm)	Pre-treatment PPG	Post-treatment PPG
V1	63.6	M	Alcoholic	1	0	2	A	10	1	7	17	7
V2	33.1	F	Budd-Chiari	0	1	5	n.a.	10	2	10	45	14
V3	58.6	M	Alcoholic	1	0	2	B	12	1	7	20	8
V4	41.4	M	Alcoholic, hepatitis B + C	1	(1)	2	B	10	2	10	35	15
V5	27.4	F	Budd-Chiari	0	1	1	n.a.	10	2	12	17	8
V6	53.7	F	Alcoholic	1	(1)	0	B	10	2	10	20	12
V7	52.3	M	Alcoholic	1	(1)	0	B	10	2	7.5	20	8
V8	52.1	M	Alcoholic	0	1	0	B	12	1	8	34	11
V9	51.4	M	Alcoholic	1	0	0	B	10	2	10	33	12

Numbers in parentheses indicate the presence of symptoms but not the original indication for TIPS implantation
n.a., not applicable (see Patients and Methods); PPG, portosystemic pressure gradient

which was present but not the primary indication for TIPS revision (Table 2). Three patients suffered from refractory ascites alone (in two cases caused by Budd-Chiari syndrome, either idiopathic (#V5) or secondary to coagulopathy (homozygotic factor II 202-10 G/A gene mutation in #V2). Cirrhosis was caused by excessive chronic ethanol consumption ($n = 6$) and chronic ethanol consumption in combination with hepatitis C + B ($n = 1$). Six patients had Child-Pugh class B, one patient had Child-Pugh class A cirrhosis at the time of revision. The laboratory values of the patient suffering from Budd-Chiari syndrome were: albumin 4.6 mg/dl, bilirubin 3.4 mg/dl and a normotest value of 70% (#V2), and albumin 3.0 mg/dl, bilirubin 3.0 mg/dl and a normotest value of 53% (#V5), respectively.

All Viatorr endoprostheses were placed to bridge the complete parenchymal tract from the portal vein to the inferior vena cava. Seven patients had revisions with 10 mm devices, two patients had revision with 12 mm devices. In three patients, one device was placed, and in six patients overlapping placement of two devices was performed. The Viatorr Endoprosthesis (Fig. 1) consists of an ultrathin ePTFE tube. The ePTFE film is radially reinforced by a wrapping of ePTFE film, resistant to bile permeation, with an outer layer of macroporous ePTFE to facilitate ingrowth of liver parenchyma, resulting in a better incorporation of the stent-graft into the hepatic parenchyma. The inner-blood-contacting layer is comprised of ePTFE with a microstructure and mechanical properties similar to the conventional Gore-Tex Vascular Graft. Structural support is provided by an external, self-expanding nitinol stent with high radial strength. The Viatorr endoprosthesis has an unlined "bare" nitinol stent portal region to allow preservation of nutrient portal perfusion and an ePTFE-lined intrahepatic region. The interface between the lined and unlined regions is identified by a radiopaque gold marker band. In addition, a radiopaque gold marker band is incorporated into the proximal end of the prosthesis to facilitate fluoroscopic imaging during deployment. The ePTFE-lined portion is secured on the delivery catheter with an ePTFE constraining sleeve, with the entire endoprosthesis then secured beneath an introducer sleeve. The introducer sleeve is used to insert the Viatorr Endoprosthesis into the hemostatic valve. A radiopaque gold marker is located beneath the leading tip of the delivery catheter. The prosthesis is available in a range of sizes, with diameters of 8 mm, 10 mm and 12 mm, and lengths ranging from 4 to 8 cm. The stent-graft delivery system accepts an 0.035-inch guidewire and can be used with a 10 Fr sheath for all sizes.

TIPS Revision Procedure: Device Implantation

The right jugular vein was punctured under ultrasound guidance. A 7 Fr sheath (Radiofocus, Leuven, Belgium) was placed in the jugular vein, and a 6 Fr Cobra or multipurpose catheter (Johnson & Johnson, Cordis Division, Miami, FL, USA) and a stiff-angled Terumo guidewire (Radiofocus, Leuven, Belgium) were used for recanalization of the TIPS. Once successful recanalization had been achieved, pressure measurements were performed to determine the portosystemic pressure gradient (PPG) and a venous portogram with a 5 Fr calibration catheter (Cook, Bloomington, IN, USA) was used (45 ml nonionic contrast medium, 12 ml flow/sec) to depict portal vein anatomy. Then the sheath was exchanged for either a 10 Fr or 12 Fr Check Flo II sheath (Cook, Bloomington, IN, USA). The TIPS tract was dilated with an Olbert balloon to its original diameter (Boston Scientific International, Natick, MA, USA). The stent-graft delivery system was then introduced into the sheath.

For the placement of the Viatorr endoprosthesis, the sheath was advanced into the portal vein, the device was positioned in the sheath, and the uncovered portion was deployed by withdrawing the sheath while holding the stent-graft in place. Then the covered portion of the stent-graft was released by retraction of the deployment line. The Hemobahn endoprosthesis was also put in position in the sheath, the sheath retracted, and the stent-graft expanded by pulling the deployment line. Information on the location of the porto-parenchymatous junction for accurate deployment of the stent-graft was obtained by evaluation of a baseline portogram (from the time of TIPS creation) and the pre-implantation portogram. Mostly two projections were necessary to depict the porto-parenchymatous junction. All stent-grafts were dilated to their nominal diameter. Final portal venogram and portosystemic pressure measurements were performed, followed by retrieval of the sheath and manual compression at the jugular puncture site.

Medication

We injected 5000 IU of heparin upon passage into the portal vein. Following the procedure, the patients received 2 × 40 mg enoxaparin (Lovenox, Gerot Pharmaceuticals, Vienna, Austria) for at least 2 days (maximum 1 week, depending on the mobility of the patient). Unless patients received other broad-spectrum antibiotic medication, they received 2 g of ceftriaxone intravenously (Rocephin, Hoffman-La Roche, Austria) as perioperative prophylaxis

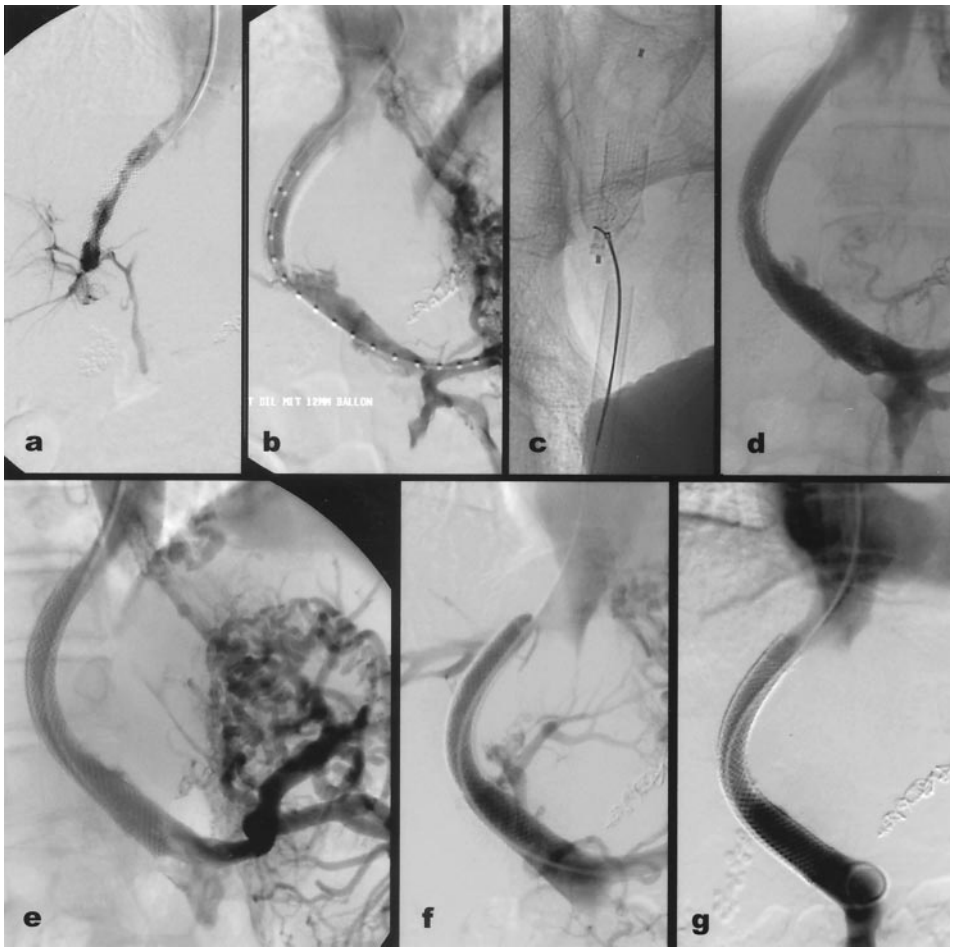

Fig. 2. a–g. A 58-year-old man (patient #H2) with two prior revisions who presented with an occluded TIPS. **a** Demonstration of the causative biliary fistulae. **b** After thrombolysis (4.5 mg rt-PA) and angioplasty with a 10 mm balloon. **c, d** Failed initial attempt to place the Hemobahn, breakage of the delivery catheter after forceful manual retraction, and removal of the stent-graft and parts of the delivery system through the femoral vein. **e** Retry on the next day with successful placement of the Hemobahn endoprosthesis. **f** Control portography after 13 months with demonstration of a hepatic vein stenosis (PPG) treated by angioplasty, PPG 18 mmHg. **g** Result after angioplasty with a PPG of 10 mmHg.

before insertion of the graft. Six patients revised with the Hemobahn were placed on the platelet aggregation inhibitors ticlopidine (Tiklid, Hoffman-La Roche, Vienna, Austria, 2 × 250 mg/day) or clopidogrel (Plavix, Sanofi Winthrop, Vienna, Austria, 75 mg/day) for 1 month. One patient (#H1) was under continuous oral anticoagulation with fenprocoumon (Marcoumar, Hoffman La Roche, Vienna, Austria; target INR of 2.0–3.0). After Viatorr implantation, all patients were placed on clopidogrel for up to 1 month.

For the prevention of encephalopathy the patients were put on a protein-poor diet and received lactulose (Laevolac, Madaus, Vienna, Austria) and L-ornithine-L-asperate (HepaMerz, Merz, Vienna, Austria) orally.

Follow-up

After TIPS implantation, patients were followed up clinically and had routine duplex ultrasound every 3 months during the first year and every 6 months after that. Portal venography was performed between 6 and 12 months after revision or when duplex ultrasound demonstrated signs of reobstruction such as a marked decrease in flow compared with the previous examinations, or unequivocal findings ($n = 2$), or when clinically indicated (e.g., recurrent ascites or rebleeding).

Results

Hemobahn Endoprosthesis: Procedural Results

The stent-graft TIPS revision was performed in all patients with a good angiographic and hemodynamic result (i.e., no filling of varices). The mean pressure gradient was decreased from 20 ± 4 mmHg to 10 ± 2 mmHg. In patient #H2, the hepatic fistula was excluded after stent-graft placement (Fig. 2a–d).

Hemobahn Endoprosthesis: Follow-up

In four patients, TIPS dysfunction occurred at 82 days (patient #H1, occlusion), 393 days (patient #H2, outflow tract stenosis), 529 days (patient #H4, occlusion) and 275 days (patient #H7, outflow tract stenosis) after stent-graft placement. Patient #H1 already had four Wallstents implanted on top of each other ($n = 7$ revisions). Creation of a parallel TIPS was technically impossible, as the stents were placed to the extrahepatic portion of the portal vein. A mesocaval shunt was then created for treatment of ascites. In patient #H2, a high-grade stenosis in the hepatic vein was treated by balloon dilatation alone (Fig. 2). In patient #H4 the occluded

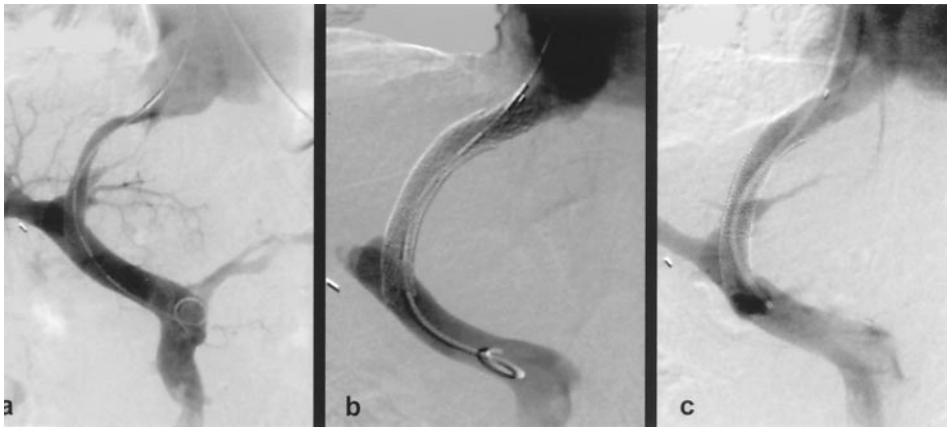

Fig. 3. a–c. Asymptomatic 63-year-old man (patient #V1) with two prior TIPS revisions. **a** Before and **b** after recanalization and implantation of a Viatorr endoprosthesis of 10 mm diameter, length 7 cm, with reduction of the PPG from 17 mmHg to 7 mmHg. **c** Control portography prior to implantation of another Viatorr endoprosthesis and a Smart stent for diameter reduction (because of new encephalopathy refractory to medical therapy) demonstrates free patency without neointima formation in the endoprosthesis and a PPG of 4 mmHg at 294 days follow-up.

TIPS was recanalized by Wallstent implantation, and in patient #H7 the outflow tract stenosis (at 275 days follow-up) was treated with implantation of another Hemobahn with complete coverage up to the inferior vena cava. In patients #H3 and #H5 the TIPS is still patent at a follow-up of 868 and 422 days, respectively. Patient #H6 died 4 months after stent-graft implantation due to decompensated liver cirrhosis.

Hemobahn Endoprosthesis: Complications

In patient #H1, the implantation of a 13 mm Hemobahn endoprosthesis resulted in an incompletely expanded device and a residual gradient of $>$ 18 mmHg despite angioplasty. After the implantation of a Palmaz stent with prolonged dilatation with a 12 mm balloon, the PPG was reduced to 14 mmHg. In patient #H2 the Hemobahn implantation was attempted after local application of rt-PA (4.5 mg) with recanalization of the partially thrombosed central portion of the portal vein and predilatation with a 8 mm Olbert balloon. At the first attempt the stent-graft could not be successfully deployed because it did not completely unfold in an approximately 50% stenosis at the level of the biliary fistulae within the hepatic tract. The distal tip of the delivery system was torn off when forceful manual retraction of the delivery system was performed. The torn part of the delivery system and the stent-graft had to be retrieved with a gooseneck snare into a 14 Fr sheath, inserted from the common femoral vein. Then a Wallstent was implanted, and the Hemobahn implantation to exclude the biliary fistulae was successfully completed the next day (Fig. 2).

Viatorr Endoprosthesis: Procedural Results

All attempted revisions were established with good angiographic and hemodynamic results (Figs. 3, 4). The mean pressure gradient decreased from 27 $\pm$ 12 mmHg to 11 $\pm$ 2 mmHg. In patients #V2 and #V4 (Fig. 4), the PPG after revision was 14 and 15 mmHg, respectively. In both cases multiple stents (5 Wallstents in patient #V2; a Passager MIBBS stent-graft (Boston Scientific, Watertown, MA, USA) and 1 Wallstent in patient #V4) were placed in prior revisions ($n = 6$ and $n = 2$, respectively), thus reducing the ability of the Viatorr endoprosthesis to expand completely, despite prolonged balloon angioplasty (Fig. 4). The average combined length of covered tract from the porto-parenchymatous junction to the inferior vena cava was 9 cm (range 7–12 cm). In no patient was an elevated atrial pressure measured prior to or after TIPS revision.

Viatorr Endoprosthesis: Follow-up

In all patients available for follow-up, the Viatorr Endoprosthesis is still patent after a mean 201 $\pm$ 145 days of follow-up (range 9–426 days) (Fig. 3). In two patients (#V4 (asymptomatic) and #V6 (occurrence of ascites)), shunt dysfunction, despite patent TIPS without neointima formation, was detected (at 144 and 265 days after revision, respectively) and treated by angioplasty alone. The PPG decreased from 18 to 14 mmHg in patient #V4 and from 20 to 10 mmHg in patient #V6, respectively. In patient #V4 a second revision (after occurrence of ascites) with angioplasty and Wallstent implantation was necessary at 307 days follow-up (Fig. 4), which decreased the PPG from 21 mmHg to 14 mmHg. Two patients (#V3 and #V7) died in the follow-up period (60 and 72 days after revision, respectively).

Viatorr Endoprosthesis: Complications

Four patients (#V1, #V3, #V5 and #V7) presented with new chronic encephalopathy after Viatorr endoprosthesis placement with early onset after TIPS revision (all with PSE indexes between 65% and 75%). In patient #V1 encephalopathy resistant to conservative treatment was treated by shunt

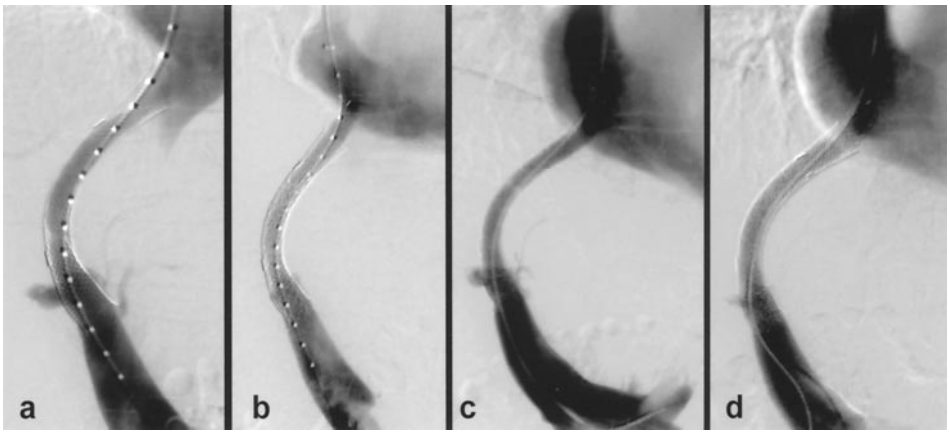

Fig. 4. a–d. A 41-year-old man (patient #V4) suffering from alcoholic cirrhosis and hepatitis B + C, presenting with onset of ascites. He had two prior revisions and two implanted stents (one Passager MIBBS stent-graft, diameter 10 mm, and one Wallstent). **a** Stenosis of the TIPS tract in the parenchymatous portion and in the hepatic vein. **b** Implantation of two Viatorr endoprostheses of 10 mm diameter and a combined length of 12 cm, with reduction of the PPG from 35 mmHg to 15 mmHg. **c** Follow-up 6 months after placement. There was a PPG of 18 mmHg and a completely patent Viatorr endoprosthesis. **d** After angioplasty of the complete shunt with a 10 mm balloon a PPG of 14 mmHg was achieved.

diameter reduction after implantation of a second Viatorr endoprosthesis and a Smart stent (Cordis, Miami, FL, USA) at 294 days follow-up. The PPG had dropped to 4 mmHg from the original post-revision value of 7 mmHg (Fig. 3). One patient was successfully managed with conservative treatment (#V5, with a PPG of 12 mmHg at control portography), and two patients (#V3 and #V7) were treated conservatively but died 60 and 72 days after revision (due to cardiac decompensation and pneumonia, respectively).

Discussion

In previous randomized clinical trials comparing TIPS with endoscopic therapies, the average rate of variceal rebleeding after TIPS creation was between 0 and 47% [16–20]. In nearly all cases, rebleeding after TIPS creation was related to shunt stenosis or occlusion. Medical therapy (anticoagulation) aimed to decrease TIPS restenosis and occlusion failed [21, 22]. Other studies pointed out that there might be considerable differences in the incidence of early TIPS dysfunction according to the stent used to create TIPS [23, 24]. The Wallstent seemed be associated with the highest potential for early TIPS thrombosis [23, 24]. Medical therapy aimed at reducing platelet aggregation and intimal proliferation with a PDGF antagonist did show a decrease in the incidence of hepatic venous stenosis at follow-up [25]. An effective TIPS stent-graft, or other shunt-directed therapy, ideally would address all three modes of shunt stenosis: bile-related and bile-unrelated tract stenoses, and hepatic venous stenosis. This would solve the problem of rebleeding due to TIPS failure and would decrease the number of surveillance examinations and invasive shunt revisions, thereby reducing patient morbidity, discomfort and cost.

Previously published clinical case studies have demonstrated successful creation of both de novo TIPS and TIPS revision using “custom-made” ePTFE-covered stents [12, 13]. Stent-graft placement prolonged TIPS patency rates in these studies, but study populations were small, and therefore the results were preliminary [12, 13]. Our work is also limited by inclusion of only a small number of patients. Also it has to be mentioned that the prerevision PPG values differed significantly between the Hemobahn (20 mmHg, average) and the Viatorr (27 mmHg, average) patients, but both stent-grafts reduced the post-revision values to an average below 12 mmHg. To our knowledge this is the first reported series to use commercially available (Hemobahn endoprosthesis) and/or dedicated (Viatorr endoprosthesis) stent-grafts for the systematic revision of TIPS. When used for the revision of TIPS, the Viatorr endoprosthesis was always placed to cover the complete tract to the inferior vena cava and was completely patent at follow-up portography. No hepatic failure or infarction or bacterial infection of the endoprosthesis could be observed in our study population, demonstrating the feasibility and safety of complete tract coverage up to the inferior vena cava. Confirming the results obtained by Haskal [13], complete coverage seems to be advisable to demonstrate the potential of ePTFE stent-grafts for revision-free, long-term patency.

If hepatic vein stenosis is prevented by stent-graft placement [13]—resulting in higher patency rates—TIPS could suddenly become a more economic solution for the treatment of the complications of portal hypertension, despite higher

initial costs for the graft. This raises another—albeit more economic issue—related to the availability of stent-graft diameter length. In our study the mean tract length was 9 cm, with ranges from 7 to 12 cm. We had to place two stent-grafts in six of nine patients, thus doubling the costs for stent-grafts alone—a considerable disadvantage.

The difference between the cost of a Wallstent (app. 1100 Euro) and the Viatorr (app. 2500 Euro) is quite considerable. Although the value of a device will surely be measured by the potential decrease in follow-up revisions, its price is still a factor of great importance. In two thirds of patients with TIPS revisions availability of longer devices could cut the cost per intervention by almost half. Performance and cost analysis in larger, ideally randomized studies, will be a better way to evaluate the "worth" of the new device.

However, if higher unobstructed patency rates are associated with a higher incidence of encephalopathy, the benefits of stent-grafts might be nonexistent. When we compare our results with the Hemobahn and Viatorr, two observations are striking. First covering of the complete tract reduces the occurrence of venous stenosis, the dominating factor in late TIPS dysfunction [1–5]. Stenting of the parenchymatous tract alone with the Hemobahn had no favorable effect on long-term patency. After Hemobahn endoprosthesis placement the two of six patients available for follow-up (33%) developed hepatic vein stenosis and two of six patients (33%) developed TIPS occlusions, possibly explaining the lower incidence of encephalopathy in this population. In contrast the incidence of new encephalopathic episodes after Viatorr endoprosthesis placement was quite high (four of nine patients), especially considering the reduced ability of the Viatorr endoprosthesis to open to its nominal diameter in two patients with multiple prior revisions (#V2 and #V4). These patients did not develop encephalopathy. In another patient (#V6) the ability of the Viatorr to fully expand (nominal diameter of 10 mm) was compromised by the 9 mm nitinol stent initially used for for TIPS creation. This patient presented with an elevated PPG (20 mmHg) at the first follow-up venogram after TIPS revision (performed with a 10 mm endoprosthesis), necessitating angioplasty (with a PPG decrease from 20 to 8 mmHg), but the patient never suffered from encephalopathy. Encephalopathy in the other patients occurred despite preventive medication with L-ornithine-L-aspertate and lactulose. In our observations there were no clear risk factors for the development of encephalopathy in our patients (such as age $>$ 65 years, known prior hepatic encephalopathic episodes, Child-Pugh class C or bleeding episodes [26]). Only patient #V5 presented with a upper respiratory tract infection at the time of diagnosis of hepatic encephalopathy. Perhaps it would be advisable to use an endoprosthesis with a diameter smaller than the original nominal diameter of the previous TIPS. Unfortunately, the Viatorr endoprosthesis is currently only available in 2 mm diameter intervals, resulting in diameter area differences up to 31–34% between 8 and 10 mm diameter and 10 and 12 mm diameter, respectively. Since the radius is a factor to the fourth power in the Hagen-Poisseuille law which determines the volume of flow in a tube with a given radius and a given length, the 2 mm steps in diameter (= 1 mm steps in radius) have quite considerable effects on flow, with differences of 59% between 8 mm and 10 mm diameter and 52% between 10 mm and 12 mm diameter. The use of 9 mm versus 10 mm diameter and 11 mm versus 12 mm diameter would reduce the differences to 38% and 32%. Perhaps the availability and use of stent-grafts with 9 mm and 11 mm for 10 mm and 12 mm nominal TIPS, respectively, would address the problem of encephalopathy in a more causative way. It remains to be clarified whether the relatively high incidence of encephalopathy, despite preventive medication, was related to the performance of the Viatorr endoprosthesis over a prolonged period of time or if it was just a coincidence, based on our small study population.

Another potential problem might have to be considered in the future: potential graft infection may occur in cases of bacteremia. Unfortunately, it has been postulated that this may be the case after TIPS [27, 28]. We wanted to address this problem with perioperative prophylaxis at the time of revision. How long antibiotic prophylaxis should be maintained and whether antibiotics should be given routinely remains to be clarified.

The primary findings of our study are that: (i) a commercial ePTFE stent-graft, the Viatorr endoprosthesis, was used to effectively revise obstructed TIPS without device-related complications, and (ii) there was no in-graft neointimal formation up to 14 months after revision. This demonstrates a high potential for uninterrupted patency after TIPS revision. The Hemobahn endoprosthesis, when placed in the parenchymatous tract, had no beneficial effect on secondary patency rates, most often due to intimal hyperplasia in the hepatic vein, but was able to exclude biliary fistulae. Thus, it cannot be compared fairly with the Viatorr endoprosthesis, which was placed to cover the complete tract up to the inferior vena cava. Fair comparisons (i.e., in randomized studies) between alternative technologies in TIPS revision should be made only after some of the basic questions, such as optimal device diameter, degree to which the hepatic vein can be covered by the stent-graft, and incidence and severity of encephalopathy, are better clarified.

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