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Recurrent TIPS Failure Associated with Biliary Fistulae: Treatment with PTFE-Covered Stents

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Abstract

Purpose: To evaluate the efficacy of covered stents for the treatment of transjugular intrahepatic portosystemic shunt (TIPS) obstruction in human subjects with identified or suspected biliary fistulae.

Methods: Five patients were treated for early failure of TIPS revisions. All had mid-shunt thrombus, and four of these had demonstrable biliary fistulae. Three patients also propagated thrombus into the native portal venous system and required thrombolysis. TIPS were revised in four patients using a custom-made polytetrafluoroethylene (PTFE)-covered Wallstent, and in one patient using a custom-made PTFE-covered Gianturco Z-stent.

Results: All identified biliary fistulae were successfully sealed. All five patients maintained patency and function of the TIPS during follow-up ranging from 2 days to 21 months (mean 8.4 months). No patient has required additional revision. Thrombosis of the native portal venous system was treated with partial success by mechanical thrombolysis.

Conclusion: Early and recurrent failure of TIPS with mid-shunt thrombosis, which may be associated with biliary fistulae, can be successfully treated using covered stents. Stent-graft revision appears to be safe, effective, and potentially durable.

Key words: Stents and prostheses—Portosystemic shunt, transjugular intrahepatic—Biliary fistula—Hypertension, portal—Portal vein, thrombosis—Thrombolysis

Transjugular intrahepatic portosystemic shunt (TIPS) is an effective method of reducing portal venous pressure for the treatment of variceal hemorrhage or refractory ascites [1–4]. TIPS is an attractive alternative to surgical shunts, but remains technically challenging even in experienced hands. The major technical difficulty involves the intrahepatic portal venous puncture from a hepatic vein. In the hepatic parenchyma, the portal triad consists of portal veins, hepatic arteries, and bile ducts, which course in parallel and in close proximity to each other. Injury to structures other than the targeted portal vein during TIPS creation is a known risk and precautions are of limited effectiveness. The actual frequency of bile duct transection is unknown, but due to the unavoidable physical trauma to hepatic tissue during a TIPS procedure, bile duct injury is not uncommon [5]. Accumulating evidence supports the theory that communication with the biliary system is one of the possible etiologies of early TIPS shunt occlusion and failure [5–9].

In this report, we describe five cases of early failure of TIPS revision in which a fistula between the TIPS tract and the bile ducts was suspected. We investigated the efficacy of using polytetrafluoroethylene (PTFE)-covered stents to treat these problematic patients. We also explored methods to identify fistulae, and examined thrombolytic techniques to treat thrombosis of TIPS and of portal and splanchnic vessels.

Materials and Methods

From August 1996 to July 1998, 84 patients underwent TIPS placement at a single tertiary referral center for the treatment of either gastroesophageal variceal hemorrhage or refractory ascites. All procedures were performed using a Rösch-Uchida needle set (Cook, Bloomington, IN, USA) for portal venous puncture, and 10-mm-diameter Wallstents (Schneider, Minneapolis, MN, USA) to line the shunt tract. During follow-up, 26 of those 84 patients suffered recurrent symptoms or had significant alterations in flow velocities on surveillance Doppler ultrasound examinations and underwent subsequent TIPS venography. In addition, 16 patients who had undergone TIPS procedures at other hospitals were referred for revision, and also underwent TIPS venography. One

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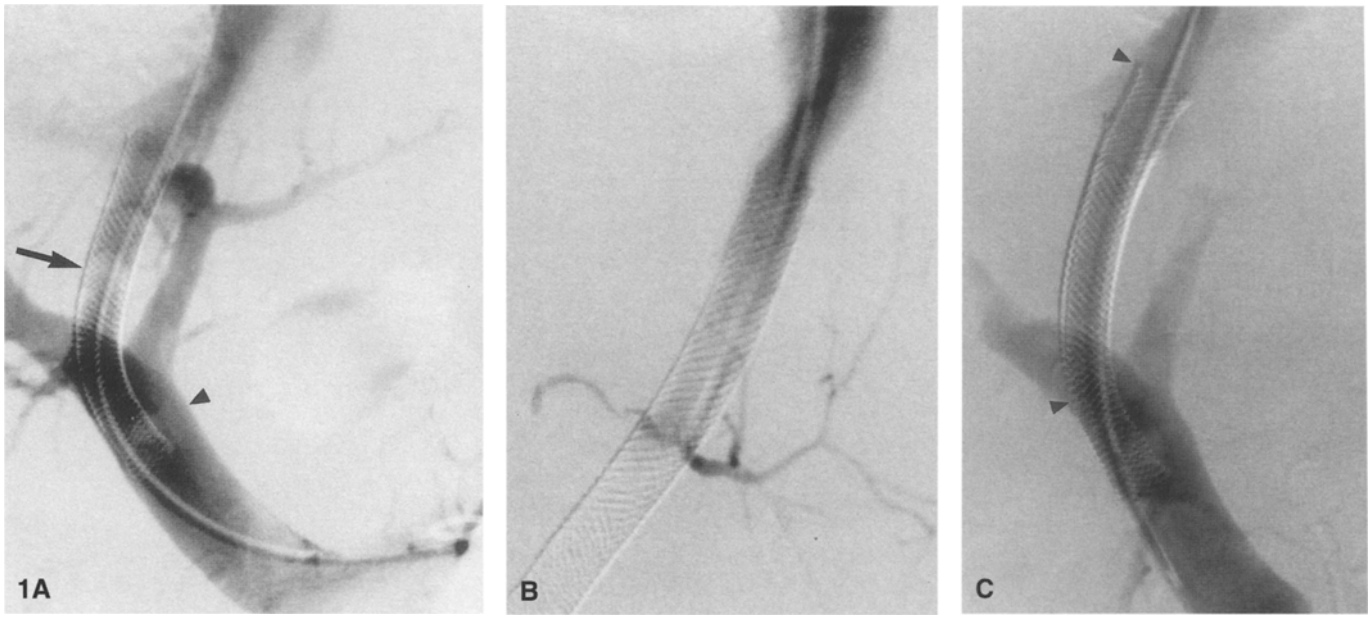

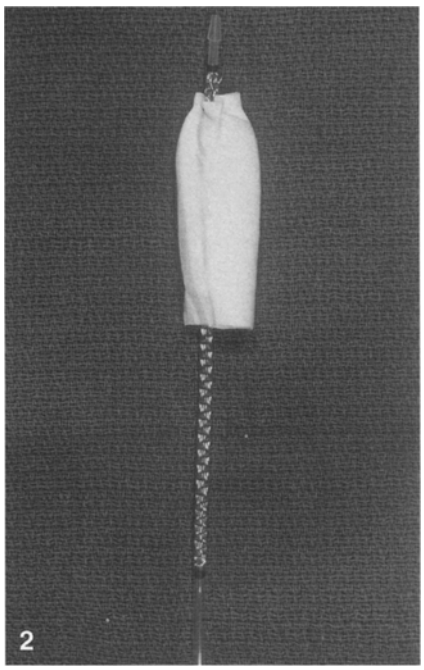

Fig. 1. **A** In patient # 1, splenic venogram reveals a nodular filling defect in the typical location within the intraparenchymal portion of the shunt (arrow) and thrombus in the main portal vein (arrowhead). **B** Contrast medium injection in the shunt using a straight flush catheter delineates a biliary fistula which was not demonstrated by the splenic venogram. **C** Repeat venogram following stent-graft placement confirming patency. The ends of the covered stent are marked by arrowheads.

Fig. 2. Predilated PTFE graft sutured to 10 × 42-mm Wallstent. This assembly is then loaded into a 60-cm-long, 10 Fr sheath which acts as an outer sleeve for deployment.

patient was found at an outside institution to have a biliary fistula, and was referred only for stent-graft revision. All patients with increased portosystemic gradients or stenoses were revised by balloon angioplasty and additional stents. A total of five patients demonstrated evidence of recurrent TIPS insufficiency shortly after revision (1–8 days), and were considered candidates for stent-graft repair.

All patients were treated under conscious sedation with midazolam and fentanyl. Following an initial splenic venogram performed using a pigtail catheter traversing the TIPS, contrast medium was injected into the shunt tract to assess for the suspected biliary leak (Fig. 1). This was performed by a high-pressure (12 ml/sec, ≤ 3500 kPa) machine injection using a straight flush catheter in three patients, or by manual injection through an occlusion balloon catheter (Meditech/Boston Scientific, Watertown, MA, USA) inflated at the hepatic vein end of the shunt in two patients. Different operators favored different methods. In four patients, a biliary fistula was directly documented by contrast opacification. In one patient (# 3), opacification of the fistula was equivocal, probably due to intraluminal thrombus, but biliary fistula was suspected because of the location and acuity of thrombosis within the shunt [10].

Each patient was treated with a single self-expanding covered stent. In this study, two different stent-graft designs were used: 1) a PTFE-covered Wallstent; 2) PTFE-covered Gianturco Z-stent (Cook). In the first four patients, a covered Wallstent was custom-made based on measurements obtained during previous revisions, using a standard 10-mm-diameter Wallstent mounted on a 7 Fr catheter delivery system (Fig. 2). The length of the stent-graft was tailored in order to cover the entire intraparenchymal portion of the

Table 1. Patient data and TIPS characteristics

Patient #	Age (years)	Sex	Etiology of liver disease	Symptom treated by TIPS	Child-Pugh class (score)	Time elapsed between primary TIPS and initial failure (days)	Number of revisions prior to SG	Procedure performed at revision	Time elapsed between primary TIPS and SG (days)	Time elapsed between last revision and SG (days)	Follow-up time since SG (days)
1	50	M	CAHB	Ascites	C (11)	7	1	Balloon angioplasty, Wallstent	13	6	56 (OLT)
2	50	M	HCV, EtOH	GIB	A (5)	280	1	Balloon angioplasty, Wallstent	300	20[a]	640
3	49	M	EtOH	Ascites	C (11)	8	1	Balloon angioplasty, Wallstent	16	8	551
4	12	F	Cystic fibrosis	GIB	B (7)	12	1	Balloon angioplasty	15	3	16 (OLT)
5	51	F	Primary biliary cirrhosis	GIB	A (5)	77	2	Balloon angioplasty, Wallstent	91	1	2 (OLT)

CAHB = chronic active hepatitis B; HCV = hepatitis C virus; EtOH = alcohol; GIB = gastrointestinal bleed; SG = stent-graft; OLT = orthotopic liver transplant
[a] Failure of the revision was detected after 7 days. Stent-graft revision was delayed by hospital transfer

shunt tract. The final length of the deployed stent-graft was predicted by measurement of the lumenal diameter of the existing TIPS and allowing for recoil and elongation of the Wallstent. Graft material (10-mm diameter) of the predicted length was created by balloon dilatation of a segment of a standard-thickness 4-mm-diameter thin-wall PTFE graft (Impra, Tempe, AZ, USA).

The stent was initially partially deployed to expose the distal 6 mm. The segment of balloon-expanded graft was attached to the stent by four interrupted 6-0 polypropylene sutures spaced symmetrically around the distal 3 mm of the stent. The partially deployed stent was re-compressed using adhesive tape to allow introduction into a 60-cm-long, 10 Fr angiographic sheath (Cook). The stent-graft was advanced until its distal aspect protruded from the end of the sheath, at which point the adhesive tape was removed and the end of the stent was groomed back into the sheath. The apparatus was constructed the day before implantation and was sterilized with ethylene oxide gas.

Prior to stent-graft deployment, prophylactic intravenous antibiotics were administered to cover biliary flora. The stent-graft assembly was introduced as a unit over a guidewire through a 12 Fr angiographic sheath in the right internal jugular vein. After positioning in the TIPS tract, the 10 Fr sheath was withdrawn to expose the graft. The stent-graft was then deployed within the existing TIPS, covering the intraparenchymal portion while minimizing protrusion into the native portal vein. The stent-graft was dilated to 10 mm using an angioplasty balloon catheter. Following stent-graft placement, contrast medium was injected in the splenic vein and within the TIPS to confirm exclusion of the fistula.

A covered Gianturco Z-stent was used in the fifth patient. This custom-made stent-graft was assembled using a 12-mm-diameter, 6-cm-long Gianturco Z-stent covered with 12-mm balloon-expanded PTFE graft. The PTFE was attached to the stent at both the proximal and distal ends with interrupted 6-0 polypropylene sutures. Successful use of this device to treat peripheral aneurysmal disease has been previously described [11]. A 12 Fr sheath was introduced into the TIPS over a guidewire via the right internal jugular vein. The stent-graft was then compressed and loaded into the sheath and advanced into position using a solid mandrel pusher. The stent-graft was deployed by holding the pusher and stent in the appropriate position while retracting the sheath, allowing the stent-graft to self-expand. Following stent-graft placement, venography was performed to confirm TIPS patency and exclusion of the biliary fistula.

Because of excessive thrombus load and propagation of thrombus from the TIPS shunt into the native portal system, three patients underwent thrombolysis prior to stent-graft revision (patients 3, 4, 5). Urokinase (Abbott Laboratories, North Chicago, IL, USA) was used for two patients who underwent catheter-directed thrombolysis. In these two, a multi-hole infusion catheter (Micro Therapeutics, San Clemente, CA, USA) was positioned in the superior mesenteric and portal veins, and 1200 U/kg/hr of urokinase was administered for 16 hr in patient 3 and 40 hr in patient 4. The patients showed no evidence of active hemorrhage, and were given systemic heparin as well. The Amplatz thrombectomy device (Microvena, White Bear Lake, MN, USA) was also used on patient # 3 for mechanical thrombolysis. All three patients underwent mechanical thrombolysis with the AngioJet device (Possis Medical, Minneapolis, MN, USA). Eluent (3–700 ml) was collected from each patient. Each patient also received 20 mEq bicarbonate intravenously for each 100 ml eluent to lessen the risk of hemoglobinuria-induced renal failure [12].

Results

Of the five treated patients, three (patients 1, 3, 4) received primary TIPS at our institution and had symptomatic or ultrasound evidence of occlusion at a mean of 9 postprocedure days (Table 1). In contrast, in the 23 patients who received their primary TIPS at our institution and required revisions, and whose findings were not suspicious for biliary fistulae, a mean of 132 days (range 2–315) elapsed between primary TIPS and revision ($p < 0.0001$, student's t-test). Of the five patients whose primary TIPS failed within 2 weeks, three (patients 1, 3, 4) (60%) had demonstrable biliary fistulae and were eventually treated by stent-graft repair. The other two early failures had acute angulations and kinking of their stents, which were successfully corrected by reinforcement with additional stents.

Table 2. Stent-graft procedures and devices

Patient #	TIPS thrombosis	Associated thromboses	Preparatory procedures immediately prior to SG	Size of stent (mm)	Length of graft (mm)	Portosystemic gradient (mmHg)		Complications of SG	Additional stent
						Initial	Final		
1	Partial	None	Balloon angioplasty	10 × 68	75	17	12	None	None
2	Partial	None	Balloon angioplasty	10 × 68	75	19	14	None	None
3	Complete	PV, SpV, SMV	Balloon angioplasty, UK thrombolysis, ATD thrombolysis, PAJ thrombolysis	10 × 42	50	25	10	None	None
4	Complete	PV, SpV, SMV, IMV	Balloon angioplasty, UK thrombolysis, PAJ thrombolysis	10 × 42	45	28	16	None	None
5	Complete	Intrahepatic PV	Balloon angioplasty, PAJ thrombolysis, WS	12 × 60	60	32	11	Intraluminal thrombus	WS 10 × 94 mm

PV = portal vein; SpV = splenic vein; SMV = superior mesenteric vein; IMV = inferior mesenteric vein; SG = stent-graft; UK = urokinase; ATD = Amplatz thrombectomy device; PAJ = Possis Angiojet; WS = Wallstent

The other two patients who were treated with stent-grafts (# 2, # 5), both Child-Pugh class A, received their primary TIPS at outside institutions and enjoyed relatively long periods of being asymptomatic before needing revision. However, both of these patients were found to have biliary fistulae. Patency of the primary TIPS was not well documented in either of these patients, and shunt occlusion may have occurred much earlier than the actual times of symptomatic representation at 77 days and 280 days, respectively. Each of these thrombosed TIPS were revised, but subsequently failed 7 days and 1 day, respectively, following their revisions.

All five patients who eventually underwent stent-graft placement had TIPS that restenosed or rethrombosed within 8 days of revision, as demonstrated by Doppler ultrasound, but one patient's (patient # 2) stent-graft procedure was delayed by a hospital transfer. Mean elapsed time between last TIPS revision and stent-graft placement was 7.6 days. Two patients were treated for recurrent ascites, and three for recurrent gastroesophageal variceal hemorrhage. Etiologies of liver disease included hepatitis B, hepatitis C, alcohol abuse, cystic fibrosis, and primary biliary cirrhosis. All five patients had qualified for liver transplantation and were awaiting suitable donors.

Each patient underwent TIPS balloon dilatation prior to stent-graft deployment. Covered stents were successfully deployed in all five patients (Table 2). After deployment and balloon dilatation, injection of contrast within the TIPS confirmed exclusion of the biliary fistula in each patient (Fig. 3). In the patient treated with a covered Z-stent, an intraluminal filling defect was detected immediately after deployment of the stent-graft, possibly due to thrombus formation in the sheath prior to deployment. This was successfully treated using an additional uncovered Wallstent. No other complications were encountered in this series.

Three patients were found to have thrombus extending into the native portal vein, splenic vein, superior mesenteric vein, and inferior mesenteric vein. Interestingly, catheter-directed urokinase at doses usually effective in peripheral venous thrombosis had little effect on thrombus in the portal system and TIPS. Similarly, the Amplatz thrombectomy device macerated some thrombus, but was unable to reestablish flow. Only the AngioJet device was partially successful in recanalization of native vessels, reduction of thrombus load, and reestablishment of brisk antegrade flow in these patients. Because of variceal bleeding, preexisting coagulopathy, and apparently successful exclusion of biliary fistulae, long-term anticoagulation was not recommended for these patients, and their residual thromboses were followed conservatively by ultrasound. Residual intrahepatic portal thrombus in patients 4 and 5 had no noticeable clinical sequelae, but led to earlier liver transplantations. Patient 3 also demonstrated no long-term sequelae, and follow-up ultrasound examinations have revealed autolysis and resolution of residual thrombus.

Of the five treated patients, three underwent liver transplantation within 2 months of the stent-graft procedure. At explantation, all three TIPS were widely patent with minimal pseudointima. The other two patients have since had their transplantation candidacy rescinded, one for recurrent alcohol abuse and one for pulmonary hypertension. Though unfortunate for the patients, this has allowed long-term (21 months and 18 months) follow-up. Both patients continue to be relieved of their original symptoms, and ultrasound surveillance has revealed patency and unchanged flow velocities.

Discussion

TIPS has become a well-established therapy for variceal hemorrhage secondary to portal hypertension. Numerous controlled studies have shown that the rate of rebleeding in treated patients is less than in those treated by endoscopic methods, although overall survival is not significantly improved [13–19]. TIPS is also gaining acceptance as an ef-

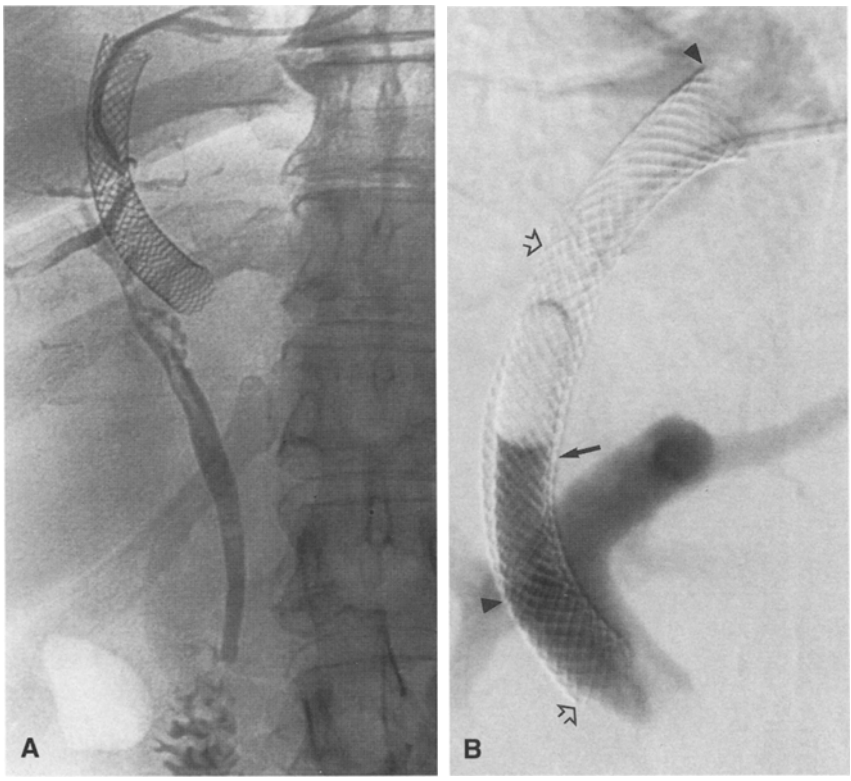

Fig. 3. **A** In patient # 2, late image after contrast medium injection into the shunt shows a large biliary fistula. **B** Following stent-graft placement, hand-injection of contrast medium into the shunt through the endhole of a 12-mm occlusion balloon catheter inflated in the midportion of the TIPS tract confirms the exclusion of the biliary fistula (arrow). The ends of the covered stent (arrowheads) and of the first stent (open arrows) are indicated. An additional stent placed at the first revision is also present.

fective therapy for refractory ascites due to portal hypertension [3, 20, 21]. However, poor long-term durability is tempering clinical enthusiasm. The reported prevalence of shunt stenosis or occlusion leading to shunt malfunction within 1 year of the initial TIPS procedure ranges from 31% to 80% [1–4].

TIPS stenoses occur primarily in two locations: 1) within the parenchymal portion of the shunt, which accounts for approximately 30% of all stenoses but about 70% of symptom-causing stenoses, or 2) at the outflow hepatic vein [10, 22]. The etiology and pathophysiology of TIPS stenosis is incompletely understood. Histologically, narrowing within the outflow hepatic vein usually demonstrates intimal hyperplasia, and stenosis within the stent tract demonstrates a thickened neointima composed of myofibroblasts and collagen, termed "pseudointimal hyperplasia" [8, 23].

Accumulating evidence favors bile duct injury as a major stimulus of pseudointimal hyperplasia, which can result in stenosis or occlusion of the parenchymal tract. Biliary staining was associated with exuberant inflammation and granulation tissue in the earliest histological studies of explanted livers [8]. In a recently published series of 21 human and 13 porcine TIPS shunts, the vast majority of shunts with parenchymal tract stenoses or occlusions showed characteristic areas of metaplastic biliary epithelial cell proliferation within a hyperplastic pseudointima on the luminal aspect of the stent. These histological features were not observed in patent shunts or in shunts with hepatic vein stenoses [5]. The severity of stenosis may reflect the size of the injured bile duct, and thus the amount of exposure of the shunt to bile [7]. Mucin and anionic bile salts have both been shown to be thrombogenic [5], and in addition to stimulating pseudointimal hyperplasia, these substances may directly induce thrombosis, resulting in acute failure of the shunt.

In human subjects, stent-grafts have been used successfully to treat a variety of vascular conditions. A number of case reports have been published describing application of this technology to revision of failing TIPS. The earliest report by Spahr et al. [24] described use of a PTFE-covered Palmaz stent, not so much to salvage a failing TIPS, but to treat bilhemia that resulted from bile leakage into the systemic circulation. Cohen et al. [25] also used a PTFE-covered Palmaz stent to exclude a biliary fistula in an occluded TIPS, and documented patency of the TIPS 4 months later by Doppler ultrasound and mesenteric angiography. Saxon et al. [26] used two Gianturco Z-stents spanned by struts and covered with PTFE, reinforced after deployment with a coaxial Wallstent, to revise failed TIPS successfully in six patients. Beheshti et al. [27] and DiSalle and Dolmatch [28] reported using PTFE-covered Wallstents to salvage one and two failing TIPS, respectively. Stent-grafts have also been used in TIPS for purposes aside from excluding biliary fistulae. Krajina et al. [29] used polyester-covered spiral Z-stents to reconstruct extrahepatic portal vein lacerations in two patients. Both stent-grafts became obstructed within 5 months, which could reflect intentional caudal placement and incomplete lining of the parenchymal tract, as well as tissue reaction to polyester.

Theoretically, using stent-grafts for primary creation of TIPS shunts should greatly reduce the incidence of biliary fistulae and TIPS failures. In a porcine model, Nishimine et al. [30] demonstrated significantly higher primary patency using PTFE-covered stent-grafts instead of bare stents. Of the stent-graft TIPS that developed stenoses, almost all developed obstruction at the hepatic vein outflow region, and not within the parenchymal tract. Interestingly, 31% of the TIPS had histological evidence of biliary duct injury. Similarly, Haskal et al. [31] found a significantly higher primary patency rate in TIPS using PTFE-encapsulated stent-grafts in a porcine model. In contrast, Tanihata et al. [32] found complete occlusion within 6 weeks in all 14 porcine subjects who underwent TIPS using a silicone-covered Wallstent. Intense foreign-body reaction was found on histological sections. In human trials, Ferral et al. [33] reported preliminary results of using the polyester-covered Cragg Endopro system on 13 patients for primary TIPS. Six-month primary patency was slightly disappointing at 77%, but, as with polyester-covered spiral Z-stents and silicone-covered Wallstents, tissue reaction to the polyester may have been a limiting factor [34].

The length and position of graft material is of concern as a potential source of complications. In order to cover the parenchymal tract completely, a portion of graft typically enters the native portal and hepatic veins. The theoretical risks of portal vein obstruction from graft material, such as over-shunting and ischemia, and of hepatic vein obstruction, such as Budd-Chiari syndrome, have not been reported. The graft extended well into the hepatic vein in two of our patients (Fig. 3), with no discernable adverse effects.

Detection of biliary fistulae remains a diagnostic challenge. In our series, machine injection via a pigtail catheter in the splenic vein did not identify any biliary leaks. Biliary fistulae were directly opacified either by high-pressure machine injection of contrast within the TIPS using a diagnostic catheter, or by manual injection through a balloon occlusion catheter. A double-balloon occlusion catheter is potentially more sensitive, but is technically demanding because of variable geometries and tract lengths [26]. With accumulating experience with TIPS failures and better characterization of acuity and location of obstruction, sufficiently reliable criteria for suspicion of fistula may eventually be established so that direct contrast opacification of the fistula would be unessential.

Three of our patients had thrombosis extending from the TIPS into the native portal vein, and two even into the superior and inferior mesenteric veins and the splenic vein. Presumably, this resulted from propagation of thrombosis from the intraparenchymal fistula, likely compounded by cirrhosis-related deficiencies of hepatically synthesized regulators of thrombosis [35]. Catheter-directed thrombolysis using urokinase was ineffective in these patients, but mechanical thrombolysis using the AngioJet was partially successful.

In conclusion, shunt failure in a newly placed or newly revised TIPS should raise the suspicion of a biliary fistula. Frequently, the fistula can be directly demonstrated by contrast injection within the shunt tract, with or without occlusion balloons. Revision using balloon angioplasty and bare stents seems to have limited efficacy, but use of covered stents deployed to seal the intraparenchymal tract appears to be an effective and durable method to treat mid-shunt obstruction from proven or suspected biliary leaks.

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