

Transjugular intrahepatic portosystemic shunt for hepatitis C virus-related portal hypertension after liver transplantation

Ghinolfi D, De Simone P, Catalano G, Petrucci S, Coletti L, Carrai P, Marti J, Tincani G, Cicorelli A, Cioni R, Filipponi F. Transjugular intrahepatic portosystemic shunt for hepatitis C virus-related portal hypertension after liver transplantation.

Abstract: This is a single center retrospective review of 19 consecutive liver transplant (LT) patients with hepatitis C virus (HCV)-related graft recurrent hepatitis who underwent transjugular intrahepatic portosystemic shunt (TIPS) at a median interval of 21 months (range: 5–50) from LT. Indications were refractory ascites in 11 patients (57.9%), hydrothorax in six (31.6%), and both in two (10.5%). TIPS was successful in 94.7% of cases (18/19) with only one procedure-related mortality (5.3%) owing to sepsis on day 35. At a median follow-up of 23 months (range: one month–nine yr), TIPS allowed for symptoms resolution in 16 patients (84.2%), with ascites resolving in all cases and hydrothorax persisting in 2. Post-TIPS patient survival at six months, one yr, and three yr was 84.2%, 73.7%, and 56.8%, respectively. We compared these results with a control group of 29 patients with HCV recurrence but without unresponsive ascites or hydrothorax. Patients in the control group had better survival than patients undergoing TIPS placement. However, survival of TIPS patients with a MELD score lower than or equal to 12 was similar to that of the control group. We conclude that TIPS may be used to treat complications secondary to HCV.

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Since its first clinical application in 1989 (1, 2), transjugular intrahepatic portosystemic shunt (TIPS) has gained a well-defined role in patients with end-stage liver disease for the control of complications of portal hypertension (3). In cirrhotic patients not eligible for liver transplantation (LT), TIPS does not adversely impact the progression of liver disease but is effective in treating ascites, hepatic hydrothorax, hepatorenal syn-

drome, and variceal bleeding (4–6). In patients eligible for LT, TIPS may be used as a bridge to the procedure, offering a period of symptomatic relief before surgery (7–10).

The use of TIPS in patients with LT and portal hypertension is still limited. The first case was reported in 1998 by Nolte et al. (11) and the first series in 1999 by Amesur et al. (12). After these initial experiences, few reports followed and

concluded that TIPS was effective for the treatment of refractory ascites, but without clear benefit on long-term survival in the absence of re-transplantation (6–10, 13, 14). For these reasons, the role of TIPS in LT recipients is still controversial and some authors question the real benefit of the procedure (3), while others consider TIPS only a bridge to re-transplantation (3, 14).

Owing to universal recurrence of hepatitis C virus (HCV) after LT with an anticipated 30% risk of cirrhosis within five yr after the procedure (15), there might be an increasing need for TIPS to treat complications related to post-transplant recurrent graft hepatitis and subsequent portal hypertension. However, only scant data are available on the efficacy of TIPS for HCV+ LT recipients with recurrent portal hypertension. We, herein, report our experience with the use of TIPS in a consecutive series of LT patients with post-transplant HCV-related recurrence with the aim to evaluate the feasibility, safety, and efficacy of this procedure in the treatment of refractory ascites and hepatic hydrothorax in these patients.

Patients and methods

Patient selection

This was an institutional review board (IRB) approved, retrospective study based on a prospectively collected database. Between September 1998 and September 2009, 992 patients underwent LT at our institution and among them 449 (45%) were HCV+. All LT procedures were performed using a standard technique and veno-venous bypass using whole size grafts from deceased donors. During this period, 20 patients (2.0%) underwent TIPS placement, 19 of them were affected with HCV-related recurrent graft hepatitis and included in the current analysis. To compare survival after LT, we selected a control group receiving a transplant in the same period and having similar baseline characteristics than patients undergoing TIPS placement (HCV recurrence, age between 50 and 59 yr old, MELD at LT between 11 and 22, MELD at month 21 post-LT between 9 and 16, donor's age over 40 yr old, and ICU stay shorter than eight d), with 29 patients fulfilling these criteria.

Data collection

Included data were as follows: donor characteristics (gender, age, cause of death, ICU stay, and serology for hepatitis virus); recipient characteristics (age, gender, body mass index [BMI], Child-Pugh and model for end-stage liver disease

[MELD] score at transplantation, indication to transplantation) and post-transplant events (overall and post-TIPS graft and patient survival, time from LT to TIPS, indication for TIPS, pre- and post-TIPS MELD scores, pre- and post-TIPS hepatic vein portal gradient (HVPG) and post-TIPS complications).

Pre-TIPS patient evaluation and indications for TIPS

Pre-TIPS patient evaluation work-up included abdominal US and abdominal CT-scan to assess graft vessels patency, percutaneous or trans-jugular liver biopsy together with fibroscan analysis when histology was inconclusive, transjugular HVPG measurement and cardiac evaluation with transthoracic echocardiogram. Surgical complications were ruled out. Histological grading and staging of chronic hepatitis C were evaluated according to Ishak-Knodell (16). Indications to TIPS included the following: Massive ascites (defined as ≥ 3 drainage (≥ 2 L each) in the previous 60 d); refractory ascites (defined as unresponsiveness to 400 mg/d spironolactone and/or 160 mg/d furosemide); hepatic hydrothorax (defined as ≥ 2 drainages in the previous 60 d); and whatever ascites and/or hepatic hydrothorax in combination with a serum sodium concentration ≤ 125 mEq/L (17). Ascites and/or hydrothorax samples were always obtained to rule out infection or spontaneous bacterial peritonitis. TIPS placement was not indicated for variceal bleeding prophylaxis or first-line treatment after bleeding. Endoscopy was obtained only if a history of previous bleeding episode was documented. Prior to TIPS placement, ascites and hydrothorax liquid were drained to achieve the maximal benefit according to the patient's clinical status. It is our policy not to re-transplant patients with HCV-related recurrence.

Post-TIPS evaluation

TIPS patency was routinely evaluated by color-Doppler US before discharge, at one, three, and six months, and thereafter as clinically indicated. TIPS placement was considered successful if no abdominal/thoracic drainage was required beyond 15 d after the procedure. Post-TIPS complications were retrospectively reviewed and graded according to the Swiss classification system (18).

Statistical analysis

The descriptive statistics are reported as mean \pm standard deviation or median and ranges as appropriate. Student's *t*-test was utilized to

measure the differences between continuous variables and the Mann–Whitney *U*-test was employed for variables with unequal variance distribution. Survival after LT and TIPS placement was obtained by the Kaplan–Meier method and the log-rank test was used for comparisons. A *p* value < 0.05 was considered statistically significant. All analyses were performed using SPSS 20.0 software (Chicago, IL, USA).

Table 1. Study group and control group donors' and recipients' characteristics

	Study (TIPS) group (#19)	Control group (#29)	<i>p</i>
Donors			
Age	65.1 ± 10.9	62.1 ± 14.0	ns
ICU stay	2.2 ± 1.8	3.05 ± 2.3	ns
Recipients			
Age at OLT	55.2 ± 6.4	53.9 ± 2.4	ns
Gender (m/f) (%)	14/5 (74%/26%)	23/6 (79%/21)	ns
Indication to OLT			
HCV-related cirrhosis n (%)	19 (100%)	29 (100%)	ns
HCC n (%)	7 (37%)	9 (31%)	
MELD score at OLT	16.4 ± 5.8	14.1 ± 2.7	ns
MELD score 21 months post OLT	12.4 ± 3.2	11.5 ± 1.9	ns

TIPS, transjugular intrahepatic portosystemic shunt.

Results

Donors' and recipients' characteristics of the study population and the control group are summarized in Table 1. All donors were negative for anti-Hepatitis B core antibodies (anti-HBc), HBV surface antigen (HBsAg). Overall cumulative post-LT patient and graft survival of the study population at one month, six months, one yr, and three yr were 100%, 100%, 94.7%, and 73.3%, respectively. Median follow-up time was 4.3 yr (range one month–nine yr). TIPS were placed at a median of 21 months after LT (range 5–50 months). Indication to TIPS was refractory ascites in 11 patients (57.9%), hepatic hydrothorax in six (31.6%), and both in two patients (10.5%).

The most recent pre-TIPS biopsy specimens showed a median fibrosis score of 4 (range 1–6) and a median grade of 9.5 (range 8–11). Patients' characteristics at TIPS placement are showed in Table 2.

Fourteen patients (73.7%) died after the procedure at a median of 34.5 months (range 1–83); time and cause of death and patient characteristics at TIPS placement are illustrated in Table 2. Eleven patients (79%) died of progression of HCV-related cirrhosis at a median of 28 months after the procedure (range 4–69), two (17%) of hepatocellular

Table 2. Characteristics, time and cause of death of the patients undergoing TIPS

Pts. #	Time from LT to TIPS (months)	Post-LT IFN use	Fibrosis grade	Pre-TIPS HCV RNA (copies/mm ³)	Pre-TIPS HVPG (mmHg)	Time from TIPS to death (months)	Cause of death
1	27	Yes	1	6.3 × 10 ⁶	20	10	Progression of HCV recurrence
2	6	No	2	30 × 10 ⁶	20	5	Progression of HCV recurrence
3	22	No	2	6.2 × 10 ⁵	18	83	HCC recurrence
4	11	No	4	7.9 × 10 ⁵	19	41	Progression of HCV recurrence
5	5	No	5 ^a	3.9 × 10 ⁵	20	1	Sepsis
6	12	No	2	6.1 × 10 ⁵	19	44	Progression of HCV recurrence
7	40	No	5	1.2 × 10 ⁵	11	69	Progression of HCV recurrence
8	12	No	4	1.5 × 10 ⁴	21	12	Progression of HCV recurrence
9	18	No	5	1.1 × 10 ⁶	19	18	Progression of HCV recurrence
10	21	No	4	1.3 × 10 ⁶	20	4	Progression of HCV recurrence
11	40	No	4	5 × 10 ⁵	15	60	Progression of HCV recurrence
12	26	No	5	1 × 10 ⁶	18	66	HCC recurrence
13	40	No	4	4 × 10 ⁵	18	23	Progression of HCV recurrence
14	50	Yes	4	1.7 × 10 ⁶	28	15	Progression of HCV recurrence
	Time from LT to TIPS (months)					Post-TIPS follow-up (months)	
15	30	No	4	9.8 × 10 ⁵	20	30	NA
16	13	Yes	4	9.6 × 10 ⁶	16	50	NA
17	15	Yes	2	Neg	15	70	NA
18	21	Yes	4	2.5 × 10 ⁵	18	22	NA
19	5	No	3	1.5 × 10 ⁶	10	20	NA

NA, not applicable; HVPG, hepatic vein portal gradient; LT, liver transplant; TIPS, transjugular intrahepatic portosystemic shunt.

^aBiopsy showed evidence of fibrosing cholestatic hepatitis C.

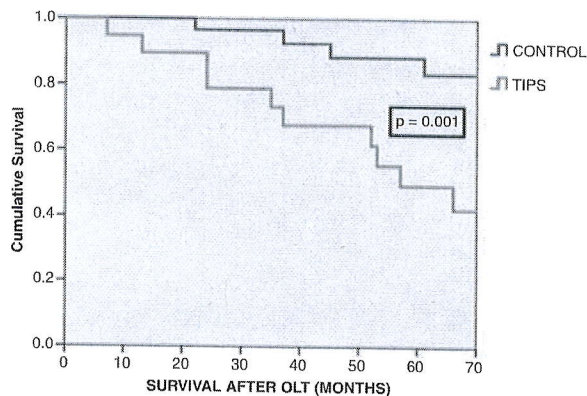


Fig. 1. Post-transjugular intrahepatic portosystemic shunt and control group patient survival.

carcinoma recurrence at 66 and 83 months post-TIPS, respectively, and one (8.3%) of sepsis on day 35. Post-TIPS patient survival at one month, six months, one yr, and three yr were 100%, 84.2%, 73.7%, and 56.8%, respectively (Fig. 1) with a median follow-up after the procedure of 25 months (range one month–nine yr).

Patients in the control group (LT for HCV cirrhosis and HCV recurrence but without refractory ascites or hydrothorax) had better survival ($p = 0.001$) than patients undergoing TIPS placement (Fig. 1) but when stratifying the TIPS group by a cutoff MELD score of 12, there was no survival difference between the control group and TIPS patients with a MELD score below or equal 12 (Fig. 2).

Only one TIPS patient required radiological revision two months after the primary procedure because of outflow obstruction. No stent thrombosis was observed during the follow-up. Encephalopathy requiring hospital admission was

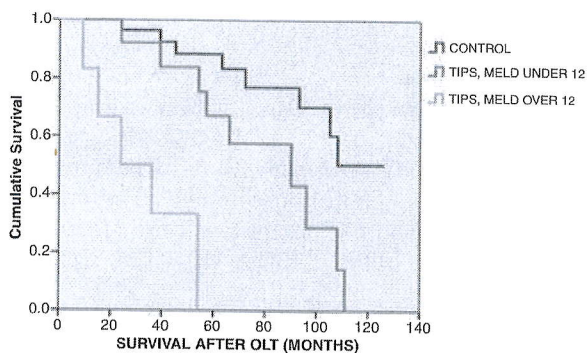


Fig. 2. Control group and study group patient survival stratified by MELD score at transjugular intrahepatic portosystemic shunt placement.

observed in six patients (31.6%): In all cases, it happened within the first month after the procedure and it was managed successfully with medical treatment only, with no need for TIPS downsizing.

Excluding the one patient who died one month after the procedure, TIPS was associated with resolution of symptoms in 16 cases (84.2%). Ascites resolved within 30 d from TIPS in seven patients (36.8%) and required more than one month in four (21%). On the other hand, hepatic hydrothorax persisted in two (25%) patients. These later were managed with video-assisted thoracoscopy, pleural mechanical abrasion, and talc spray with complete resolution in one case and temporary resolution in the other.

Pre- and post-TIPS mean portal pressure was 24.7 ± 10.9 mmHg and 14.4 ± 9.4 mmHg, respectively, with a mean reduction of 41.7%. TIPS reduced mean HVPG from 18.1 ± 4.9 to 6.8 ± 2.6 mmHg ($p < 0.001$), a mean reduction of 62.4%. Pre- and post-TIPS MELD values were retrospectively analyzed in all patients. The pre-TIPS mean MELD score was 12.4 ± 3.2 (median 12; range 8–18) and mean post-TIPS MELD scores at one wk (19 patients), one month (19 patients), three months (17 patients), six months (12 patients), one yr (11 patients), and three yr (seven patients) were 15.6 ± 4.8 ($p = 0.001$), 14.8 ± 4.2 ($p = 0.013$), 14.75 ± 4.7 ($p = 0.032$), 13.6 ± 3.2 ($p = \text{ns}$), 13.4 ± 3.7 ($p = 0.017$), respectively. Only two patients did present a temporary severe worsening of the creatinine serum level (> 1.6 mg/dL) but none of them required renal replacement therapy.

At univariate and multivariate analysis of multiple recipient-related factors (pre-TIPS MELD score, INR, bilirubin serum level, creatinine serum level, platelets, fibrosis score, time from LT, and pre-TIPS HVPG), only MELD score equal or below 15 at the time of TIPS placement was associated with better post-TIPS patient survival ($p = 0.026$).

Discussion

HCV-related cirrhosis is the most common indication for LT in US and Europe (19). In contrast to other indications for LT, serologic and histologic recurrence of HCV after LT is nearly universal. Death and allograft failure are more common in this population when compared to HCV-negative recipients, with HCV recurrence (20) and advanced donor age being strong predictors of poor outcomes in HCV-infected recipients (15). More than 40% of patients who have recurrent cirrhosis

develop manifestations of decompensated disease within one yr and less than 50% of the patients survive one yr after the onset of decompensation (15). Re-transplantation is the only definitive treatment when antiviral treatment and modulation of immunosuppression fail to halt the progression of recurrent HCV (15). However, no accepted indications for re-transplantation exist because patient and graft survival after re-transplantation for HCV is worse than after primary transplantation (21). Moreover, although data are limited, some studies show that outcome of re-transplantation for HCV is worse than for any other indications (22, 23). The scarcity of organ availability, the high cost of liver transplantation and the fact that recipients with HCV recurrence have poor outcomes have caused some centers not to offer re-transplantation to these patients (15).

TIPS has rapidly gained a well-defined role in cirrhotic patients and its indications, risks, and potential benefits have been extensively described (4, 5). On the other hand, the experience of using TIPS in LT patients is rather limited and its potential is far from being understood. Most reports describe the use of TIPS after liver transplantation in patients with advanced recurrence of hepatitis C (12, 14), poor liver function and extrahepatic organ insufficiency like renal failure (3). Amesur reported in 1999 (12) the first series of LT patients with variceal bleeding and refractory ascites treated with TIPS. Only three over 12 patients were stable after TIPS, four patients died, and five patients required re-transplantation. The authors concluded that TIPS should be placed only in patients at high urgency for re-transplantation. In 2005, Abouljoud (13) reported on eight patients who underwent TIPS for refractory ascites, seven of them (87.5%) with hepatitis C. TIPS was effective to treat ascites in seven patients; however, following TIPS, two patients required re-transplantation and three patients died. At 15 months after TIPS, five patients (62.5%) were alive without ascites (one after re-transplant) and the authors concluded that TIPS should be considered to be a bridge to re-transplantation. More recent reports are those from Choi (3), Finkenstedt (6), and Saad (24). The first study, based on 18 patients, concluded that the indication for TIPS in LT recipients is limited as only 10 patients (56%) responded to treatment. Six patients (33%) required re-transplantation at a median interval of 59 d after TIPS and of the remaining 12 patients, three (25%) were alive and well at a median of 90 d post-TIPS, and nine (75%) died at a median of 99 d (range, 13–1400 d) post-TIPS. Finkenstedt reported an experience on 10

patients who underwent TIPS for refractory ascites ($n = 7$), hydrothorax ($n = 2$) or variceal bleeding ($n = 1$). Complete remission was reached in three of seven patients (43%) with ascites and in none of the patients with hydrothorax. The median survival period after TIPS placement was 3.3 months and the median MELD value at TIPS was 20 (range 12–35). The authors identified a high MELD score at TIPS placement as one of the potential factors related to such unfavorable results. Saad (24) concluded that TIPS was not as clinically effective as in non-transplant patients (16% vs. 58–80%) as it was associated with 53% graft failure at six months. They concluded that MELD score at TIPS placement was a predictor of graft survival. Our report is based on data of a high-volume center and region-based allocation system with a high percentage of marginal donors because of age. In the year 2009, the percentage of HCV-positive patients on the waiting list for LT ranged between 42% and 49%. In the same year, the percentage of grafts from donors who were older than 60 yr was 68%. In this setting, treatment of HCV-related graft recurrence is particularly burdensome and the poor results of re-transplantation for HCV cirrhosis recurrence led us to not offer re-transplantation for HCV recurrence. Therefore, TIPS is being considered for patients with HCV-related recurrence after transplantation with debilitating symptoms of portal hypertension and cirrhosis.

In our retrospective analysis, TIPS was associated with a one-month mortality rate of only 5.3% (1/19), a three-yr patient survival of 56.8%, and an efficacy rate (i.e., symptom resolution) of 84.2%. However, TIPS did not show any effect on the progression of the underlying HCV recurrence, with about 30% of patients dying of HCV recurrence within 18 months from the procedure. Patients with HCV recurrence post-transplantation and unresponsive ascites or hydrothorax have a worse outcome than those in a control group without these serious complications. The present series has the unique feature of being focused on patients with HCV recurrence, which may explain the earlier need for TIPS placement (median 21 months) when compared to other reports (Table 3). The timing for TIPS placement, which we adopted at our institution, is based on the low MELD score (mean 12.4 ± 3.2 ; median 12; range 8–18) and the absence of renal failure at the time of TIPS placement. We believe that early timing is pivotal to reduce the potential for failure because of the high risk of death in LT recipients with more advanced HCV recurrence stage. As a result of our policy, no patient died in the perioperative period and only one died 35 d after TIPS placement

Table 3. Overview of published series on TIPS post-liver transplantation

Author	Year	# Patients	# HCV patients (%)	Median time from LT (months)	Re-LT (%)	Post-TIPS one-yr patient survival (%)
Amesur	1999	12	NA	69.3	33	64
Van Ha	2005	6	0 (0%)	41.7	33	67
Abolijoud	2005	8	7 (87%)	18.5	25	57
Kim	2008	14	8 (57%)	60.5	0	14
Choi	2009	18	12 (66%)	NA	33	NA
Finkenstedt	2009	10	4 (40%)	15	20	10
Present study	2011	19	19 (100%)	21	0	73.7

HCV, hepatitis C virus; LT, liver transplant; TIPS, transjugular intrahepatic portosystemic shunt.

because of sepsis and multiorgan failure. Our experience is in agreement with other recent publications (25, 26) supporting the fact that MELD score seems to be an acceptable parameter to be considered in patient evaluation for a TIPS after OLT, granting a better survival when TIPS are placed in patients with a MELD score below 15. Therefore, our data support the idea that an earlier referral (with a MELD under 12) for this procedure would allow better results in terms of graft/patients survival. Expectedly, encephalopathy was the most frequent complication as about one of three patients experienced at least one episode of encephalopathy requiring hospitalization within one month. However, beyond one month, a gradual reduction in encephalopathy with no need for stent downsizing was observed. However, eventually encephalopathy recurred with the progression of HCV disease progression. TIPS was effective in 84.2% of the patients as almost all the patients with unresponsive ascites responded to TIPS. However, its efficacy on hepatic hydrothorax was rather limited and required longer time to achieve results. Patients with a successful outcome required fewer hospitalizations, had decreased needs for diuretics and an improvement of their quality of life.

The effect of TIPS on portal pressure was evident with a significant decrease on HVP. MELD scores were found to increase after TIPS placement, which is probably related to the procedure and eventually the progression of liver disease. Normalization of liver function to pre-TIPS values required about six months, showing the marginal function of the underlying liver graft by HCV recurrence.

To conclude, our data support the idea that early referral to TIPS is associated with acceptable results and should be taken into consideration to offer a period of symptomatic relief to patients with HCV recurrence after LT with unresponsive ascites or hydrothorax.

Authors' contribution

Davide Ghinolfi designed the study and wrote the paper. Paolo De Simone wrote the paper. Gabriele Catalano and Paola Carrai collected and analyzed the data. Stefania Petrucci analyzed the data. Laura Coletti collected the data. Roberto Cioni and Giovanni Tincani performed the study. Josep Marti performed the statistical analysis. Franco Filipponi designed the study.

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