










# Transjugular intrahepatic portosystemic shunt in decompensated cirrhotic patients in a tertiary hospital in southern Brazil

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## SUMMARY

**OBJECTIVE:** The aim of the present study was to evaluate the outcomes of cirrhotic patients undergoing transjugular intrahepatic portosystemic shunt.

**METHODS:** A retrospective longitudinal observational study was carried out evaluating 38 cirrhotic patients undergoing transjugular intrahepatic portosystemic shunt. The outcomes were evaluated in an outpatient follow-up period of 3 months. The assumed significance level was 5%.

**RESULTS:** The indications for transjugular intrahepatic portosystemic shunt were refractory ascites in 21 (55.3%), variceal hemorrhage in 13 (34.2%), and hydrothorax in 4 (10.5%) patients. There was development of hepatic encephalopathy in 10 (35.7%) patients after transjugular intrahepatic portosystemic shunt. From the 21 patients with refractory ascites, resolution was observed in 1 (3.1%) patient, and in 16 (50.0%) patients, there was ascites control. Regarding transjugular intrahepatic portosystemic shunt after variceal bleeding, 10 (76.9%) patients remained without new bleeding or hospitalizations in the follow-up period. The global survival in the follow-up period in patients with and without hepatic encephalopathy was 60 vs. 82%, respectively ( $p=0.032$ ).

**CONCLUSION:** Transjugular intrahepatic portosystemic shunt can be considered in decompensated cirrhotic patients; however, the development of hepatic encephalopathy which can shorten survival should be focused.

**KEYWORDS:** Hypertension, portal. Ascites. Gastrointestinal hemorrhage. Hydrothorax.

## INTRODUCTION

The final stage common to liver diseases of different etiologies is cirrhosis, resulting in portal venous hypertension (PVH), which determines important clinical consequences<sup>1,2</sup>.

In an attempt to control PVH and its consequences globally, drug therapy seeks to correct the increase in portal blood flow through the use of splanchnic vasoconstrictors, reducing the hepatic venous pressure gradient, and, therefore, attenuating or avoiding these complications<sup>2-4</sup>.

The transjugular intrahepatic portosystemic shunt (TIPS) appears as an element of this therapeutic arsenal. TIPS is a procedure of proven effectiveness for the management of complications of PVH, and aims to decompress the portal venous system<sup>5-8</sup>. It reduces the pressure gradient within the portal venous system in about 90% of patients, improving the complications of PVH. The most strongly supported indications for TIPS, as recently revised, are the management of refractory ascites and variceal gastrointestinal bleeding<sup>1-4</sup>.

Given the relevant role of this procedure in the management of PVH and especially considering the very recent updates on the subject<sup>1-4,9</sup>, the objective of the present study

was to evaluate the main clinical outcomes of cirrhotic patients undergoing TIPS.

## METHODS

This is a retrospective longitudinal observational study where the medical records of all cirrhotic patients undergoing TIPS between 2012 and 2020 were analyzed.

TIPS was formally indicated according to the recommendations of the current guidelines<sup>1-4,10,11</sup>, and consent of the patients or guardians was obtained. Those patients who did not register of the indication for TIPS installation and the outcomes were excluded from the study.

The study involved patients from the gastroenterology unit of Hospital Nossa Senhora da Conceição (HNSC), a public tertiary care hospital in southern Brazil. All the procedures were performed by physicians from the Interventional Radiology Unit of the HNSC with expertise in the area.

Data were collected regarding the etiology of cirrhosis, TIPS indication, and Child and MELD scores. Clinical outcomes related to the resolution of ascites, hydrothorax, and variceal bleeding

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Conflicts of interest: the authors declare there is no conflicts of interest. Funding: none.

Received on January 12, 2023. Accepted on January 13, 2023.

were evaluated. Regarding ascites after TIPS, patients were classified as having persistent ascites (requiring paracentesis after TIPS), having ascites controlled (without the need of paracentesis), or having complete resolution of ascites<sup>12</sup>. In addition, the onset of hepatic encephalopathy (HE) and death were recorded. HE was diagnosed and classified according to the EASL guideline<sup>13</sup>.

TIPS were performed under anesthesia, using the Philips Allura XI® angiograph, Rösch-Uchida® (Cook) access set and noncovered prosthesis, according to the classic technique<sup>14</sup>, except at the puncture of the portal branch, when abdominal ultrasound (Sonosite®) was performed to assist the correct positioning<sup>15</sup>. Once the hepatic vein was already catheterized and the portal venous branch was identified, the path of the puncture needle was followed from the hepatic vein along its way in the parenchyma until it reached the portal vein branch in real time, adjusting its direction as required. Dilatation of the parenchymal tract between the hepatic and portal veins was performed using an 8-mm angioplasty balloon (Armada®, Abbott). A 10-mm Wallstent® (Boston) was then deployed and further dilated with the same balloon. In some cases, it was necessary to perform an additional procedure along with TIPS, such as gastroesophageal varices embolization and vascular recanalization.

The portosystemic pressure gradient was calculated as the difference between the pressures of the portal vein and the inferior vena cava, measured through a catheter positioned freely inside the veins and attached to a pressure transducer. TIPS execution time and the fluoroscopy time were evaluated.

All outcomes were evaluated pre-TIPS and in an outpatient follow-up period of up to 3 months afterward (post-AMB).

The research project was carried out in accordance with resolution 466 of 2012, which regulates the conduct of research in human beings, and was approved by the Research Ethics Committee of HNSC under number 5.218.265.

Data were exported to the Statistical Package for the Social Sciences (SPSS) version 20.0 of Windows for statistical analysis and were presented as mean and standard deviation, median and interquartile range (IQR), or frequency and percentage. Associations between categorical variables were tested using Pearson's  $\chi^2$  test, and those between moments were tested using McNemar's test. To compare continuous variables between groups, the Student's t-test was used for variables with a normal distribution or the Mann-Whitney U test for asymmetric distributions. For intragroup comparisons, the method of generalized estimation equations with Bonferroni adjustment was used in the multiple comparisons for laboratory variables. Child and MELD scores were compared using the Wilcoxon test. In the case of dichotomous variables (HE), the Cochran test was used. For analysis of ordinal variables (degree of ascites), the

Friedman test (nonparametric test) was used. Overall survival up to 3 months (post-AMB) was assessed using the Kaplan-Meier curve, comparing patients with and without HE and also patients with ascites using the log-rank test. The assumed significance level was 5%.

## RESULTS

Among 51 cirrhotic patients undergoing TIPS, data were obtained from 38 patients.

The mean age was 59 years, the majority was male, and the most frequent etiology of cirrhosis was the abusive use of alcohol associated or not associated with hepatitis B and/or C viruses. Comorbidities were observed in more than half of the cases, with metabolic syndrome and the presence of cardiovascular diseases being the most frequent (Table 1). Three (7.9%) patients presented hepatocellular carcinoma at the time of TIPS's indication.

**Table 1.** Demographic data, clinical baseline characteristics of the patients, and indication for transjugular intrahepatic portosystemic shunt (n=38).

Parameters	
Age - years; md (IQR)	59 (52.5–69.5)
Male sex; n (%)	23 (60.5)
Etiology; n (%)	
Alcohol	15 (39.5)
Hepatitis B/C virus	08 (21.0)
NAFLD	02 (5.3)
Miscellaneous	13 (34.2)
Comorbidities; n (%)	
MetS	19 (50.0)
CVD	04 (10.5)
Other	06 (15.8)
None	12 (31.6)
Indication for TIPS; n (%)	
Refractory ascites	21 (55.3)
Variceal bleeding	13 (34.2)
Hydrothorax	04 (10.5)
Child pre-TIPS; n (%)	
A	05 (13.2)
B	29 (76.3)
C	04 (10.5)
MELD pre-TIPS; md (IQR)	12 (10–17)

md: median; IQR: interquartile range; n: number; NAFLD: nonalcoholic fatty liver disease; MetS: metabolic syndrome; CVD: cardiovascular disease; TIPS: transjugular intrahepatic portosystemic shunt.

Indications for TIPS insertion were refractory ascites in 21 (55.3%) patients, variceal hemorrhage that did not respond to initial endoscopic/pharmacological management in 13 (34.2%) patients, and hydrothorax in 4 (10.5%) patients. The vast majority of patients were Child A or B (34; 89.5%). The mean MELD score was 12 (Table 1).

Regarding indications for TIPS, there was no difference between age ( $p=0.406$ ), sex ( $p=0.630$ ), etiology of cirrhosis ( $p=0.484$ ), comorbidities (MetS  $p=0.531$ , cardiovascular disease  $p=0.226$ ; none  $p=0.353$ ); Child score ( $p=0.060$ ), and MELD score ( $p=0.441$ ).

There was no difference between the two periods observed (pre-TIPS and post-AMB) regarding the levels of hemoglobin, platelets, and albumin. However, there was a statistically significant worsening in the International Normalized Index (INR) and total bilirubin, as well as a reduction in serum creatinine levels (Table 2) after TIPS.

In all, 32 patients had pre-TIPS ascites, although only 21 patients were considered to have refractory ascites and were indicated for TIPS insertion. Complete resolution of ascites was observed in 1 (3.1%) patient and control in 16 (50.0%) patients when considering the post-AMB period.

Regarding the control of variceal bleeding, 10 (76.9%) patients remained without new bleeding or hospitalizations in the post-AMB period.

Regarding hydrothorax, there was resolution in one patient in the post-AMB period. There was loss to follow-up in the other two patients.

There was no statistically significant difference when evaluating the median values for MELD (12 vs. 13;  $p=0.568$ ) and Child (8 vs. 8;  $p=0.403$ ) scores pre- and post-TIPS, respectively.

There was a development of HE in 10 (34.5%) patients when evaluated in the post-AMB period (Table 2). There was no statistical difference between all the indications for TIPS and the development of HE ( $p=0.484$ ).

The insertion of TIPS was successful in all cases. After its performance, a reduction in the portosystemic pressure gradient was observed (initial gradient of  $18.8\pm 3.6$  mmHg and final gradient of  $9.2\pm 2.2$  mmHg). The mean time for TIPS execution was  $65.2\pm 46.7$  min, and the mean fluoroscopy time was  $25.0\pm 14.1$  min. More than half of the patients (51.2%) required an additional procedure during TIPS (gastroesophageal varices embolization or vascular recanalization). There were no complications related to the inadvertent puncture of nontarget structures (the biliary tree and arterial branches) during the procedure, and no deaths resulted directly from this procedure.

As for the outcomes related to the installation of TIPS, thrombosis was observed in 6 (15.8%) patients, and 9 (23.7%) deaths occurred in the post-AMB period (5 due to sepsis, 2 due to stroke, 1 for bleeding from small bowel varices, and 1 for advanced extrahepatic neoplasia). The majority of deaths (5; 13.1%) occurred in the group of ascites; also, there were 3 (7.9%) deaths in the variceal bleeding group and 1 (2.6%) death in the hydrothorax group.

Overall survival at 3 months in patients with and without HE can be seen in Figure 1. The probability of overall survival at 3 months in patients with and without HE was 60 vs. 82%, respectively ( $p=0.032$ ; hazard ratio [HR]=3.04).

The probability of survival of patients with ascites was 76.2% (Figure 2).

Age was significant for survival time—the older the individual, the higher the risk of death ( $p=0.028$ ; HR=1.08).

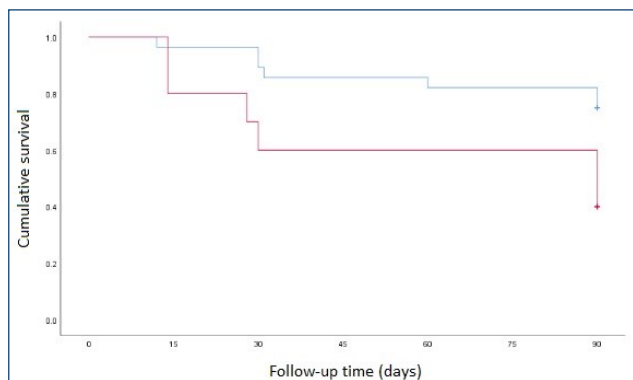
## DISCUSSION

TIPS has been shown to be the best rescue therapy for controlling variceal bleeding, and some reports have shown it to be superior to large-volume paracentesis in controlling ascites, reducing or eliminating the need for paracentesis by 50–90%,

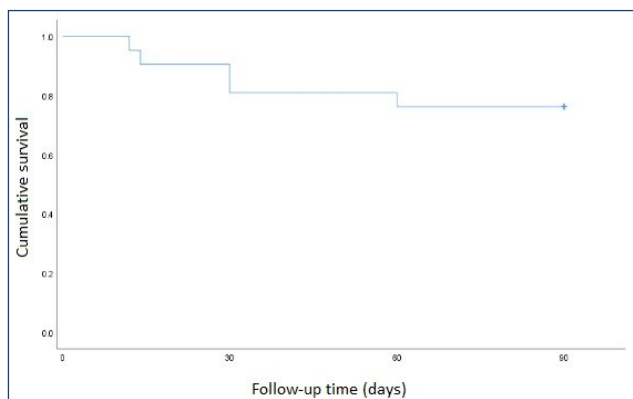
**Table 2.** Laboratory characteristics and rate of hepatic encephalopathy pre- and post-transjugular intrahepatic portosystemic shunt.

Characteristics	PRE (n=38)	POST-AMB (n=29)	p-value
Hemoglobin (g/dL); m (SD)	9.1 (1.9)	9.9 (2.2)	0.122
Platelets ( $\times 10^9$ ); median (IQR)	95.5 (61.2–178.0)	90.0 (71.0–148.0)	0.272
INR; median (IQR)	1.36 (1.2–1.5)	1.49 (1.22–1.6)	<0.001
Creatinine (mg/dL); median (IQR)	1.2 (0.7–1.5)	0.95 (0.75–1.23)	0.017
Albumin (g/dL); m (SD)	3.2 (0.8)	3.3 (0.7)	0.132
Bilirubin (mg/dL); median (IQR)	0.9 (0.5–1.4)	1.3 (1.0–1.9)	0.007
HE; n (%)	0 (0)	10 (34.5)	0.002

m: mean; SD: standard deviation; IQR: interquartile range; INR: International Normalized Index; HE: hepatic encephalopathy.



**Figure 1.** Overall survival at 3 months post-transjugular intrahepatic portosystemic shunt according to the presence or absence of hepatic encephalopathy. Kaplan-Meier curve:  $p=0.032$ ; hazard ratio=3.04 (95% confidence interval: 1.02–9.08).



**Figure 2.** Kaplan-Meier curve to assess the survival of patients with ascites at 3 months post-transjugular intrahepatic portosystemic shunt.

and improving the liver transplantation-free survival in cirrhotic patients with refractory ascites<sup>1-4,9-11</sup>.

In Brazil, there are few reports on the use of TIPS in transplantation centers<sup>16-18</sup>: one of them<sup>16</sup> is the description of the first case in Brazil in 1996, and the other two are from the same group and they focused on complications<sup>17,18</sup>.

The present study evaluated 38 cirrhotic patients who received TIPS in real life, and the indication followed the international recommendations: refractory ascites, gastrointestinal bleeding from varices, and hydrothorax<sup>1-4,9-11</sup>. TIPS was related to the improvement in the control of ascites, variceal bleeding, and hydrothorax in a reasonable portion of the cases. However, it promoted the development of HE in 34.5% of the patients in the follow-up period, in agreement with that observed in the literature<sup>19-21</sup>.

It was also observed a worsening of the MELD and Child scores in more than 50 and 30% of the patients, respectively. However, there was no statistically significant difference in the observed mean values. It has been described that most patients who underwent TIPS are Child B<sup>17,22</sup>. This is in agreement with

the present study, configuring patients with moderate-to-severe hepatic dysfunction who often undergo TIPS as a bridge to liver transplantation, and worsening of liver function may also be observed after TIPS. Additionally, it has previously been shown that liver function worsens during the first month after TIPS, followed by progressive improvement at 6 and 12 months<sup>23</sup>. Unfortunately, it was not possible to have an extended follow-up period in the present study beyond 3 months.

Complications directly related to the procedure were mainly shunt thrombosis, with a rate similar to that found in the literature—ranging from 8 to 15%<sup>10,17,22,24</sup>. Probably if covered TIPS were used, a decrease on this complication rate should be observed<sup>25</sup>. Unfortunately, the public health system in Brazil only offers the uncovered TIPS. In this study, deaths were not directly related to the installation of TIPS, which is also observed in the literature<sup>26</sup>.

Despite the current evidence recommending the implementation of preemptive TIPS in patients with variceal bleeding, it has been previously demonstrated that only 7–13% of eligible patients are currently treated with preemptive TIPS in real-world practice<sup>27</sup>.

The 3-month survival was higher in patients who did not have HE, and patients without HE were three times more likely to survive at 3 months than those with HE. Funes et al.<sup>18</sup> found a global mortality rate of 60.3% and observed that Child and MELD were predictors of mortality, with HE developing at a high incidence (58.3%). Silva et al.<sup>17</sup> evaluated 47 patients and observed a mortality rate of 32% over 3 months, while HE was observed in 49%. Other authors did not evaluate HE as a predictor of survival<sup>26</sup>.

As potential limitations, we highlight the fact that the study was carried out at a single center and was retrospective. Because of the retrospective nature of the study, some data were not recovered in the follow-up period. However, we can say that only one center has published studies with similar or greater experience within the country<sup>17,18</sup>, and most public hospitals do not offer this alternative treatment. The follow-up period of 3 months may also be considered a limitation. However, data loss could be greater if a longer period was evaluated, and therefore, a shorter period was defined. In addition, it must be emphasized that many studies on the literature consider the period of 3 months on the follow-up<sup>7,14,17,22,24,26</sup>.

We should consider that this is a successful experience, showing that the procedure is safe and effective in the management of decompensated cirrhosis even when using the noncovered stent, which can be cost-effective in public health.

In conclusion, TIPS is a procedure that can be considered a good alternative in the management of refractory ascites,

gastrointestinal bleeding secondary to varices, and hydrothorax, helping to control symptoms even when using the noncovered stent. However, attention must be paid to the development of HE, which can shorten patient survival.

## AUTHORS' CONTRIBUTIONS

**CVT:** Conceptualization, Formal Analysis, Project administration, Supervision, Investigation, Methodology, Writing – original draft, Writing – review & editing. **AAM:** Conceptualization, Investigation, Methodology, Writing – original draft, Writing – review & editing. **CMT:** Data curation, Formal Analysis,

Investigation, Methodology, Writing – original draft, Writing – review & editing. **HMCR:** Data curation, Formal Analysis, Investigation, Methodology, Writing – original draft, Writing – review & editing. **EFM:** Data curation, Formal Analysis, Investigation, Methodology, Writing – original draft, Writing – review & editing. **MT:** Data curation, Investigation, Methodology, Writing – original draft, Writing – review & editing. **EZJ:** Data curation, Investigation, Methodology, Writing – original draft, Writing – review & editing. **CR:** Data curation, Investigation, Methodology, Writing – original draft, Writing – review & editing. **CGC:** Data curation, Investigation, Methodology, Writing – original draft, Writing – review & editing.

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