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Research Article

Transjugular Intrahepatic Portosystemic Shunt (TIPS) for Portal Hypertension in Mexican Population: Clinical Outcomes and Survival

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Abstract

Background/Aim: TIPS is a good treatment for patients with cirrhosis and portal hypertension. The aim of this study was to assess the clinical outcomes and survival rate among these patients in Mexican population.

Methods and Materials: We carried on a retrospective cohort study in patients with cirrhosis and portal hypertension treated with TIPS from March 2007 to June 2014. The follow-up period was 55.46 ± 28.29 months with laboratory data, hepatic Doppler ultrasound and medical evaluation.

Results: TIPS was placed in 35 patients with 49.5 ± 13.02 years old, 60% were man and 40% were woman. Indication for TIPS was: refractory ascites in 51.4%, variceal bleeding in 37.1% and hydrothorax in 8.6%. The portal cava pressure gradient before TIPS was 24 ± 7.67 mmHg compared with 9 ± 3.32 mmHg after TIPS ($p < 0.001$). After TIPS placement, success rate for the treatment of variceal bleeding was 81% and for refractory ascites 66.6%. The overall survival rate was 82.8% at 2 m, 65.1% at 6 m, 61.4% at 12 m and 55.3% at 24 m. And five patients received orthotopic liver transplant (OLT). Nor TIPS indications or cirrhosis etiology were related to mortality but a MELD score > 18 was an important factor to predict mortality.

Conclusions: In conclusion, TIPS is an effective treatment for patients with portal hypertension and cirrhosis. Survival rate after TIPS in our center is very similar to other reports in literature. A high MELD score is an important factor to predict mortality after TIPS.

Keywords: Hepatic Cirrhosis; Refractory Ascites; Variceal Hemorrhage; Hydrothorax; Portal Cava Pressure

Abbreviations

TIPS: Transjugular Intrahepatic Portosystemic Shunt;

MELD: Model of End Stage Liver Disease;

OLT: Orthotopic Liver Transplantation;

INR: International Normalized Ratio;

HCV: Hepatitis C virus;

SPSS: Statistical Package for the Social Sciences

Introduction

Nowadays portal hypertension due to cirrhosis is an important reason of consultation for gastroenterologist around the world [1]. The complications of portal hypertension are variceal hemorrhage, refractory ascites and hydrothorax. These are main causes of death in this group of patients [2]. Although portal hypertension can be present in the absence of cirrhosis [3]. In both of this entities (cirrhotic and non-cirrhotic portal hypertension) the aim of the treatment is to diminish portal pressure and by consequence minimize the severity of the complications [4,5].

In the last two decades, management and treatment of portal hypertension has undergone interesting changes [6]. Today some the available therapeutic options are: medical treatment, surgical derivation, orthotopic liver transplantation (OLT) and TIPS [7]. Dr. Joseph Rosch in 1969 conceived the original idea for TIPS, consisting in the establishment of a communication between one of the hepatic veins and a branch of the portal vein through the placement of a metallic stent in between [8,9]. Its use in clinical practice begun in 1988 and since then, it has been published several guidelines for the appropriate use of this technique as well as clinical research studies for its improvement.

TIPS has shown to be an effective method to diminish portal pressure and is an effective procedure of treating portal hypertension due to cirrhosis and its complications. Because it is characterized as safe, micro-traumatic, effective and easily repetitive, it has been used more and more widely in clinical practice, especially in those places where liver transplantation is still not available to everyone as in Mexico [10-18]. The current indications are secondary prophylaxis failure in variceal hemorrhage, acute bleeding not responsive to medical therapy, refractory ascites and hydrothorax [13]. It's also important to keep in mind that besides clinical indications, MELD (Model of End Stage Liver Disease) score is useful in the clinical decision for which patient should be eligible for TIPS [14]. Disadvantages of this method include those relating to the procedure are as bleeding and infection and those related to the shunt and including hemodynamic compromise and hepatic encephalopathy.

This is the first study in Mexican population who reports the clinical outcomes and overall survival of patients who had TIPS as treatment for portal hypertension. This retrospective study

report our center experience in the last seven years.

Material and Methods

Patients

We carried a retrospective cohort study in a single center of tertiary level of health care (Instituto Nacional de Ciencias Médicas y Nutrición "Salvador Zubirán") in Mexico city. We included all the patients who successfully underwent TIPS placement as treatment for portal hypertension complications between March 2007 and June 2014. A total of 35 patients were included in the study. The data was obtained from the clinical records that included demographic, clinical and laboratory information. All the patients had the criteria for TIPS placement according to AASLD (American Association for Study of Liver Diseases).

Objective

To assess clinical outcomes and overall survival rate after TIPS placement in patients with portal hypertension due to liver cirrhosis.

TIPS procedure

Interventional radiology team of our center placed the TIPS. Using the standard known technique. Through transjugular approach and before the stent placement the portal and cava pressure was measured to obtain the portal cava pressure gradient. After the stent placement the portal cava pressure gradient was obtained again. The patients were followed after TIPS.

Follow-Up

Patients were followed after 2, 3, and 6 months and afterwards according portal hypertension clinic schedule until their last visit. In every appointment, physical assessment in order to rule out sign and symptoms of portal hypertension was performed. Cell blood count, renal and liver functions test and coagulations test were also done. As well as Doppler of the hepatic vasculature to assess the TIPS patency.

Statistical Analysis

The continuous variables are presented in means \pm SD and the categorical variables in frequencies. The continuous variables were compared through t student, U Mann Whitney and the one-way variance analysis (ANOVA) test. The categorical variables were compared with χ^2 -test and/or the Fisher exact test. The overall survival after TIPS was calculated through Kaplan-Meier method. In order to the identified factors that could be related to the survival a logistic regression analysis was performed. The variables that have statistical significance ($p < 0.05$) were included in the multiple variable analyses to assess the mortality risk through the cox regression model. The area

under the curve and the ROC curve were used to assess which MELD score had better sensibility and specificity to predict mortality after TIPS. Statistical analysis was performed with SPSS ver. 20 (SPSS, Chicago, IL). A value of $P < 0.05$ was taken to indicate statistical significance.

Results

Clinical Data

Between March 2007 and June 2014, 35 TIPS were placed in patients with portal hypertension. The mean age was 49.5 ± 13.02 years, of which 60% (n: 21) were man and 40% (n: 14) were woman. 26 patients with no covered stent and 9 with covered. The indications of TIPS were refractory ascites 51.4% (n: 18), variceal hemorrhage 37.1% (n: 13), hydrothorax 8.6% (n: 3) and one patient with Budd-Chiari syndrome. At the moment of the TIPS placement in 57.1% (n: 20) didn't have encephalopathy, 20% had mild, 17% moderate and 5.7% had severe encephalopathy. In Table 1 summarized patient's clinical data, cirrhosis etiology, Child-Pugh and MELD scores and grade of encephalopathy.

Impact of TIPS on hepatic hemodynamics

After TIPS placement there was a change in hepatic hemodynamics this was demonstrated by the decreased in the portal cava pressure gradient. The average of portal cava pressure gradient prior to TIPS was 24 ± 7.67 mmHg compared with the gradient after TIPS 9 ± 3.32 ($p < 0.0001$).

Impact of TIPS in laboratory parameters

Before TIPS placement routine laboratory analysis were obtained which included: albumin levels, total bilirubin, INR, creatinine and platelet count. These same parameters were measured at 2, 3 and 6 months. Table 2 shows their tendencies in all the patients. Table 3 shows the same tendencies separated before and after TIPS and for those who lived and died with the statistical analysis in the next column. These dates show that patients, who stay alive at 2, 4 and 6 months after TIPS, improve albumin and decreased bilirubin levels.

Clinical impact of TIPS

The rate of success in the eradication of the complications of portal hypertension during follow-up after TIPS was 71.4% for all indications. When TIPS was placed to control variceal hemorrhage the success rate was 81% and the recurrence rate was 19%. Ascites response was 66.6%. The total control of hydrothorax was achieved in 2 of the 3 patients with this complication.

Variable	Patients	%
<i>Gender</i>		
Male	21	60
Female	14	40
<i>Age (years, \pm SD)</i>	49.5 ± 13.02	
<i>Cause of cirrhosis</i>		
HCV	11	31.4
Alcohol	7	20
Primary biliary cirrhosis	5	14.3
Criptogenic	4	11
Autoimmune hepatitis	1	2.9
HBV	1	2.9
Overlap syndrome	1	2.9
Others	5	14.2
<i>Indication for TIPS</i>		
Refractory ascites	18	51.4
Variceal hemorrhage	13	37.1
Hydrothorax	3	8.3
Budd-chiari syndrome*	1	2.9
<i>Child-Pugh grading</i>		
A	7	20
B	14	40
C	14	40
<i>MELD</i>		
< 18	26	74.3
> 18	9	25.7
<i>Hepatic encephalopathy grading</i>		
0	20	57.1
I	7	20
II	6	17.1
III	2	5.7
<i>Type of stent</i>		
No covered	26	74.2
Covered	9	25.8

* patient with non cirrhotic portal hypertension. HVC, hepatitis C virus; HBV: Hepatitis B virus; MELD: Model of End Stage Liver Disease.

Table 1. Clinical data of 35 patients with TIPS.

Complications of TIPS

Related to the procedure were liver bleeding in 20% (n = 7) in all these cases bleeding was stopped by conservatory management, hepatic encephalopathy in 17.1% (n = 6) and responded with lactulose, sepsis in 17.1% (n = 6) and ascites in 11.4% (n = 4). In the follow-up the rate of stenosis at 2 months were 23% and 17.1% at 4 months. Complications are detailed in Table 4.

Table 2. Laboratory parameters before and after TIPS (n = 35, mean ± SD)

	Albumin	Bilirubin	INR	Creatinine	Platelets
before TIPS	2.84 ± 0.88	2.70 ± 2.46	1.28 ± 0.32	1.25 ± 0.69	87.33 ± 56.4
2 months	2.75 ± 0.74	3.59 ± 4.28	1.30 ± 0.12	0.66 ± 0.63	84.66 ± 39.12
4 months	2.69 ± 0.94	3.47 ± 4.87	1.15 ± 0.39	0.88 ± 0.64	91.91 ± 51.20
6 months	2.60 ± 1.19	5.29 ± 7.85	1.26 ± 0.45	1.17 ± 1.20	94.25 ± 59.61
Value of p	0.433	0.998	0.344	0.565	0.654

INR: International Normalized Ratio

Table 3. Laboratory parameters before and after comparing those who lived and died after TIPS (means).

	Albumin			Bilirubin			INR			Creatinine			Platelets		
	D	L	p	D	L	p	D	L	p	D	L	p	D	L	p
Before TIPS	2.62	3.01	0.211	4.04	2.74	0.352	1.55	1.24	0.02	1.40	1.14	0.28	89.7	106.2	0.40
2 months	2.33	3.05	0.013	3.76	2.73	0.427	1.41	1.34	0.52	0.66	0.66	1.0	88.7	102.4	0.49
4 months	2.12	2.99	0.049	5.22	2.30	0.164	1.09	1.23	0.36	1.01	0.80	0.49	105.0	108.5	0.90
6 months	1.64	3.27	0.003	11.1	1.76	0.011	1.15	1.33	0.34	1.47	1.01	0.74	100.5	108.0	0.82

D: Death, L: live ; p= <0.05 statistically significant; INR: International Normalized Ratio

Table 4. Complications of TIPS.

Complication	Patients	%
Hemorrhage*	7	20
Hepatic encephalopathy	6	17.1
Sepsis	6	17.1
Ascites	4	11.4
Stenosis**		
2 months	8	23
4 months	6	17.1
* Related to the procedure		
**All no covered stents		

No covered stents vs. covered stent

When examined whether the type of stent had an impact on clinical outcomes and survival did not find a significant difference in both groups covered versus uncovered stent. This perhaps can be explained by the size of the sample and the few patients who had access to covered stent, however we observed that no patient had stenosis with a covered stent at two and four months of follow up.

Follow up

The 35 patients were followed after TIPS placement. In the entire cohort survival, survival free of liver transplantation, mortality and identification of independent variables to

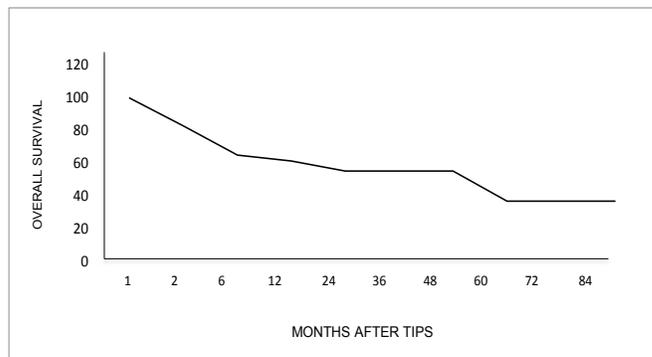


Figure 1. Overall cumulative survival rate after TIPS was 82.8% at 2 months, 65.1% at 6 months, 61.4% at 12 months and 55.3% at 24 months.

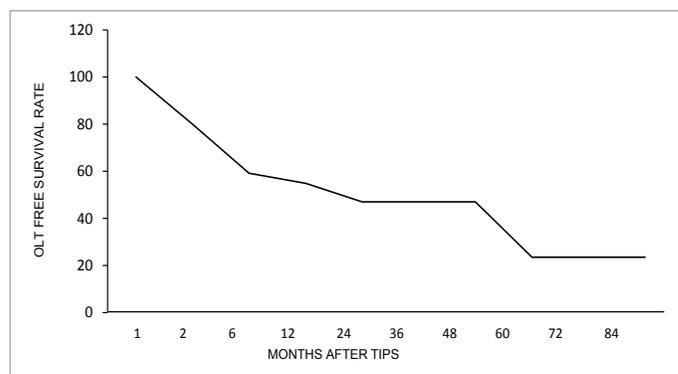


Figure 2. The rate of survival free of orthotopic liver transplantation (OLT) after TIPS was 80%, 59%, 54% and 47% at 2, 6, 12, and 24 months respectively.

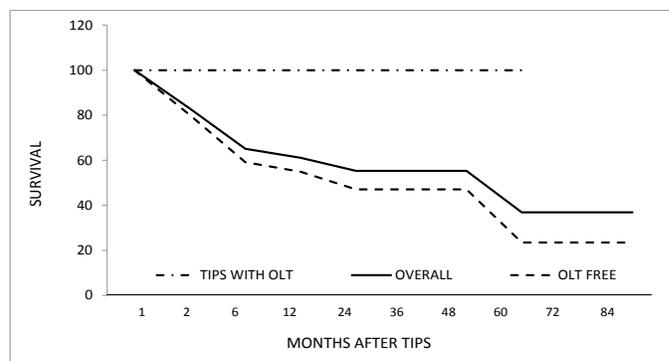


Figure 3. Comparison of survival rate after TIPS of the three groups (overall cumulative, OLT free and with OLT). OLT, Orthotopic liver transplantation.

predict mortality were assessed. The results we obtained are presented as follows: the overall cumulative survival rate was 82.8% at 2 months, 65.1% at 6 months, 61.4% at 12 months and 55.3% at 24 months as seen in Figure 1. The rate of survival free of orthotopic liver transplantation (OLT) is shown in

Figure 2 which it was 80%, 59%, 54% and 47% at 2, 6, 12, and 24 months respectively. After TIPS placement 14.3% (n: 5) of subjects achieved to receive OLT (2 men and 3 women). The survival rate of patients who received OLT was 100% at last follow-up. The Figure 3 shows the comparison of survival rate of the three groups. From the initial 35 patients that underwent TIPS placement 15 died. The mean survival time in days was 218 ± 111 and the median was 72 days (95% CI: 53.06 - 91 days) ranging from 2 days to 4 years. The main causes of death were sepsis in 23% of cases and hemorrhage in 11.4%. From the total of deaths 67% (n: 10) happened early after TIPS (during the first 76 days after the procedure). In the univariate analysis we did not find correlation between cirrhosis etiology and indication for TIPS with patients mortality. However, there was a survival difference between patients with MELD scores equal or higher than 18 (Area under the curve: 0.727, confidence interval: 0.54 - 0.90 and $p=0.023$). Survival analysis showed that after TIPS placement, if the patients do not receive a OLT, mortality rate is 4.07% per year but the risk is 10.6 times greater in patients with MELD score ≥ 18 vs. patients with lower scores (HR: 10.6, IC 95%: 3.14 - 45.6). After a follow up of 487 person-months, those who received TIPS with MELD score lower than 18 are 3.5 times more likely to live than those with higher scores (HR: 3.5, IC 95% 1.64-5.55).

Discussion

The treatment of portal hypertension complications has had a significant improvement in the recent years with the introduction of TIPS in 1980 [15]. In our report 35 TIPS were successfully placed between March 2007 to June 2014. TIPS is safe because it has low morbidity and mortality related to the procedure. Also its use is currently expanding [16]. The main indications for TIPS placement are upper gastrointestinal bleeding secondary to esophageal varices and refractory ascites.

The favorable impact on hepatic hemodynamics in this series was demonstrated with the decrease of portal cava gradient pressure after TIPS with an average difference of 15 mmHg (before TIPS: 24 ± 7.67 , after TIPS 9 ± 3.32 , $p < 0.0001$). Previous studies support that the reduction of > 12 mmHg in fact decreases the recurrence rate of rebleeding but do not have an impact in the overall survival rate [17].

Analyzing laboratory parameters we did not find important differences in albumin, bilirubin, INR, creatinine and platelet count in the cohort during the follow-up. However when we separate the groups by those who lived and died after TIPS, in the ones that lived the level of albumin at 2, 4 and 6 months significantly improved ($p = 0.013$, $p = 0.049$, $p = 0.003$ respectively) and total bilirubin in the 6 month follow-up was decreased in this same group of patients ($p = 0.011$). This differs from other studies in which no differences in laboratory parameters were found [18]. We think that an explanation for this phenomena could be that in our study the majority of patients have a

Child-Pugh score of B (40%) or C (40%) which translates in to a very large proportion of patients with advanced liver disease and in previous reports the patients included generally have a Child-Pugh score of A or B and only a few have a C score [18], besides we unknown the impact of the nutritional status of the patients who survival after TIPS, it seems that in the patients with better survival nutritional status improve gradually.

The overall success rate in eradication of the complications was 71.4%. The success rate in variceal hemorrhage was 81% with 19% have recurrence this findings very similar to others reports in literature [19]. However in patients with refractory ascites the success rate was 66% slightly lower than the others have reported (70%). It is important to mention though that in our cohort this was the main indication for TIPS placement and this might be related to patients with more advanced liver disease (higher Child-Pugh and MELD score) therefore with renal function impairment and less hepatic reserve, in this series patients who died after TIPS have higher creatinine levels with no significant difference may be related to a small number of patients (Table 3). The treatment of refractory ascites remains a challenge even after TIPS [20,21].

One of the disadvantages of TIPS is the posterior encephalopathy as a complication, however in our study occurred only in 17.1% of patients and was resolved with medical treatment in all of the cases. This finding is consistent with the reports in literature where this complication was the presentment in a range of 14% to 50% of the cases [18,22].

Our main objective was to determine the overall survival after TIPS. We find that in our cohort the overall survival was of 82.8% at 2 months, 65.1% at 6 months, 61.4% at 12 months and 55.3% at 24 months, similar to the one reported in previous studies ranging from 64% to 87% per year and 56% to 71% at 2 years [7,16,18]. Of the 35 patients in our center, five managed to receive orthotopic liver transplantation, all alive at last follow-up. This results show that TIPS is a good strategy for the treatment of portal hypertension complications, although OLT remains to be the definitive treatment.

Neither the etiology of cirrhosis or the indication for TIPS were variables related to patients mortality. However, a high MELD score it is a relevant factor to predict mortality after TIPS in our cohort. Many studies support behold TIPS placement in patients with severe disease or with poor prognosis. Most of previous papers predict mortality after TIPS using MELD score, an instrument that has proved to be a good tool for choosing the most appropriate group of patients that should undergo the procedure. Our study revealed that patients with a MELD score > 18 are at greater risk of mortality, in agreement with other cutoffs reports ranging from > 14 [23], > 18 [24] and > 25 [25].

Limitations and strengths

The limitations of our study are the selection bias that is present in all retrospective studies and the small number of patients. However we think this small number of patients is due to the little availability of TIPS in our center. One of our strengths is that as much as we know we carried on the first study in Mexico reporting clinical outcomes and survival after TIPS.

Conclusion

We are able to conclude that TIPS is effective in reducing portal pressure in patients with cirrhosis. That the survival rate after TIPS in our center is similar to other reports in literature and that a high MELD score is a factor that predicts mortality after TIPS.

Conflict of interest

The authors have no conflicts to disclose.

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