

**Title:**

**Transjugular intrahepatic portosystemic shunt (TIPS) in Spain. Clinical-epidemiological considerations in relation to a multicenter registry**

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**OR 6783 inglés**

**Transjugular intrahepatic portosystemic shunt (TIPS) in Spain. Clinical-epidemiological considerations in relation to a multicenter registry**

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## ABSTRACT

**Purpose:** this study aimed to determine the epidemiological, technical and clinical data of transjugular intrahepatic portosystemic shunt (TIPS) performed by Interventional Radiology departments in Spain. Furthermore, the total number of TIPS carried out in Spain was determined and compared with other countries.

**Material and methods:** a retrospective study was performed with the approval of the Ethical Committee of the Spanish Society of Interventional Radiology (SERVEI). A survey was performed with 31 items (demographic, technical and clinical data) for data acquisition on the current status of TIPS in Spain. The survey was sent to the 49 hospitals that SERVEI included in a previous registry with data of TIPS performed in Spain in 2016.

**Results:** of the 49 centers surveyed, 33 (67.35 %) replied to the survey. These centers had completed 265 of the 415 TIPS that year in Spain. The most frequent indication was upper GI bleeding from gastroesophageal varices, which accounted for 144 (54.33 %); 62.26 % of the TIPS were performed urgently and 37.7 % on a scheduled basis. The technical success was  $89.16 \pm 20.9\%$ , with a rebleeding rate of 17.9 %. Sixty-nine patients (26.03 %) presented complications, 19.62 % of them minor and 6.41 % major. The 30-day mortality related to the disease was 14.33 %, while mortality at one year was 18.49 %.

**Conclusion:** notably in our study, the complications of TIPS did not show a clear relationship with the number of procedures performed. With regard to other countries like the United States and France, the number of TIPS in Spain per million inhabitants is currently substantially lower. There were no significant changes compared to the number completed in 2013.

**Keywords:** Transjugular intrahepatic portosystemic shunt (TIPS). TIPS Spain.

## INTRODUCTION

Intrahepatic portosystemic shunt by a transjugular approach (TIPS) is an important minimally invasive procedure for complications arising from liver cirrhosis (portal hypertension and/or ascites refractory to treatment). Since its introduction by GM Richter 29 years ago (1), it has been universally accepted as an effective treatment for liver cirrhosis complications such as gastroesophageal varices bleeding and refractory ascites (2). More than 2,387 articles found using the MESH term “Portosystemic Shunt, Intrahepatic Transjugular” corroborate its relevance and scientific interest. Manuel Maynar (3) introduced this procedure in Spain in 1991 and since then, more than 55 scientific articles regarding TIPS have been published. However, most of the published articles (40, 72.2 %) correspond to a group of gastroenterologists who perform this technique (4).

The main indications of TIPS, according to the guidelines of societies such as the Society of Interventional Radiology (SIR) and the American Association for the study of Liver Diseases (AASLD), are recurrent gastroesophageal varices bleeding and cirrhotic ascites refractory to medical treatment (5). Other indications are hepatorenal syndrome, recurrent hydrothorax in cirrhotic patients, Budd-Chiari disease, as well as sinusoidal occlusion syndrome in hematopoietic transplants (SOS). The publication by García-Pagán et al. (7) in NEJM in 2010 increased the number of TIPS performed, due to the recommendation of the early performance of TIPS in cirrhotic patients with gastroesophageal varices bleeding. However, it is not clear if this publication conditioned the increase in the number of TIPS in Spain.

There are many international consensus and different recommendations for the indication of TIPS within each country. However, there are few scientific publications that indicate the number of TIPS performed in each country or each region (6,8,9). The Spanish Society of Vascular and Interventional Radiology (SERVEI) is aware of the number of TIPS performed annually through the records of its medical activity. However, it lacks data on indications, complications, follow-up and mortality (10). There are a total of 222 hospitals in Spain, of which 110 (49 %) have an Interventional Radiology specialized team (IRst). The vast majority of hospitals are tertiary level (79, 71.8 %) and the rest are second-level health care hospitals (21, 28.2 %). All of these hospitals serve a population of around 46.48 million inhabitants.

## MATERIAL AND METHODS

### Data source

We analyzed the data reported in the annual registry of SERVEI in the year 2016 of the 110 hospitals with an IRst in Spain. A total of 87 centers (79.09 %) answered their medical activity registry in 2016 and 49 (44.54 %) hospitals declared that they had the TIPS procedure included in their portfolio. According to this registry, 415 TIPS were performed during 2016. A survey was sent electronically to all 49 centers with specific questions related to the TIPS performed in their hospital within the time studied. A confidentiality agreement and handling of clinical data of each patient were requested from all IRst through the Spanish Society of IR (SERVEI). All patients who underwent TIPS had signed an informed consent.

### Study design

This retrospective study was approved by the SERVEI Ethics Committee to publish the data recorded in the SERVEI 2016 registry report (23-00-2019-SERVEI16). The article was written following the guidelines of the STROBE statement for observational studies (11).

### Settings and participants

From July 1<sup>st</sup>, 2018 to February 28<sup>th</sup>, 2019, the 49 centers that had reported TIPS during 2016 were sent an electronic survey via e-mail. This survey (Fig. 1) collected the clinical and technical data related to the patients who underwent TIPS during the period from January 1<sup>st</sup>, 2016 to December 31<sup>st</sup>, 2016, with at least one year of clinical follow-up. The data came from the database of each hospital and their medical records. All the surveys were analyzed using spreadsheets and the SPSS statistical program version 21.0 (IBM Corp, Armonk, New York).

### **Survey and variables**

Thirty-one questions were asked in the survey (Fig. 1): type of healthcare hospital (primary, secondary or tertiary), whether the hospital had a relationship with the university, patient data (age, sex), assisted population, the total number of TIPS performed, the indication for the TIPS, Child-Pugh score, average MELD score, TIPS performed urgently or scheduled, technical success, complications, deaths at 30 days and one year, transplant patients and special comments regarding technical difficulties.

The inclusion criteria for the study were as follows: TIPS performed during the period from January 1<sup>st</sup>, 2016 to December 31<sup>st</sup>, 2016 by a Spanish interventional radiologist (a member of SERVEI), > 18 years of age and at least one year of follow-up. The procedure was defined as a technical success when the TIPS was accomplished without fatal complications and a reduction below the critical threshold (12 mmHg). Only those patients whose cause of death was directly or indirectly related to their liver disease were included as deceased at 30 days and one year. Patients who died due to other causes (neoplasms, etc.) were not considered. All centers were classified according to the number of procedures performed: very low (1-4 TIPSS/year), low (5-9 TIPS/year), medium (10-19 TIPSS/year), high (20-29 TIPS/year) and very high (> 30 TIPS/year). This was compared with the number of deaths at 30 days related to their initial pathology (liver disease) to determine if there was a statistical correlation. The complications were classified by SIR classification, which divides them into major and minor and was subdivided into six subgroups (A-F) (12) (Table 2).

### Statistical analysis

All statistical analyses were performed using a computer software program for statistical analyses with SPSS (IBM Corp. Released 2012, IBM SPSS Statistics for Macintosh, version 21.0. Armonk, NY: IBM Corp). All data were expressed as the mean and SD for qualitative variables and categorical data were expressed as percentages. A p value of < 0.05 was considered as statistically significant.

## RESULTS

A total of 33 centers (67.35 %) answered the survey of the 49 included hospitals. These are the most important and representative in Spain, with an average of  $740.42 \pm 439.24$  beds per hospital (range 130-2,521 beds) and an average assisted population of  $367,363.64 \pm 193,708.83$  inhabitants per hospital. Most of the hospitals were tertiary health care level, except for three (3/33; 9.1 %) and the majority were university hospitals except for two (2/33; 4.08 %). Four hospitals (4/33; 12.12 %) did not perform any TIPS in 2016 despite having TIPS accredited in their work portfolio. Out of a total of 415 TIPS performed in Spain in 2016, the hospitals that answered the survey had only performed a total of 265 with an average of  $8.03 \pm 7.09$  (range 0-25) per hospital. These 265 TIPS were performed in 265 patients, 199/265 (75.09 %) were male and 66/265 (24.90 %) were female, with an average age of  $50.13 \pm 19.62$  years (range 42-67 years). According to the Child-Pugh classification, patients were classified as A: 44/265 (16.60 %), B: 188/265 (70.94 %) and C: 33/265 (12.45 %). The average MELD score was  $13.67 \pm 2.2$  points (range 10.9-17.2). A chronic portal thrombosis had been diagnosed in 9/265 (3.39 %) patients before performing the TIPS.

The main clinical departments that sent the patients for TIPS were the Gastrointestinal and Liver departments (48.5 %) and the Intensive Care units (39.4 %). The most frequent indication was bleeding from gastroesophageal varices in 144 cases (54.33 %), followed by prophylaxis of bleeding in 55 (20.75 %) and refractory ascites to treatment in 53 patients (20.75 %). Other indications were Budd-Chiari syndrome in eleven cases (4.15 %) and hepatorenal syndrome in three patients (1.13 %). A total of 165 (62.26 %) of the TIPS were performed urgently, while 100 (37.7 %) were scheduled. Technical success was reached in  $89.16 \pm 20.9$  % (range 50-100 %) of the

patients. In this group, there was rebleeding during the follow-up in 41 patients (17.9 %). Twenty-one IRst groups (72.4 %) achieved an average technical success in their procedures in 95-100 % of the cases. Sixty-nine patients (26.03 %) presented complications related to the procedure, of which 52/265 (19.62 %) were minor and 17/265 (6.41 %) were major. The mortality related to the disease at 30 days was 38/265 (14.33 %) and 49/265 (18.49 %) at one year (Fig. 2).

The number of TIPS performed each year by category were as follows: VL: 35 hospitals (13.20 %), L: 59 (22.26 %), M: 103 (38.86 %) and H: 68 (25.66 %). There were no hospitals in the VH category. The overall complications and mortality by hospital category are summarized in table 1.

## DISCUSSION

Several studies have shown that performing early TIPS improves mortality and reduces rebleeding and hospital stay in patients with decompensated cirrhosis and bleeding secondary to gastroesophageal varices (9,13-15). Based on these data, early TIPS should be performed in patients diagnosed with bleeding due to gastroesophageal varices that meet the previously mentioned conditions. This hypothesis is reinforced by the studies of García-Pagán et al. (8,9), in which the pharmacological treatment + endoscopic ligation was compared with the early performance of TIPS for the control of bleeding, bleeding at six months and one-year survival. In these studies, survival was more than 20 % higher in patients with early TIPS (61 % *versus* 86 %). Furthermore, the control of bleeding (13.2 %) and rebleeding (30.0 %) showed a clear benefit of an early TIPS at one and two years. There are currently no epidemiological data supporting the increase or decrease in the number of TIPS in the world or Spain after this publication (8,12,17). According to the SERVEI activity registry, 415 TIPS were performed in 49 centers (ratio per hospital, 8.4 TIPS/year in 2016) in Spain during 2016. The number of TIPS performed in 2013 was compared using the same registry and there was no significant increase (ratio of 7.9 *vs* 8.4 TIPS/year). There are no data available regarding the stabilization, increase or decrease in the number of TIPS in Spain. In comparison to other countries in the same period, the rate was 3.3 per million inhabitants/year in Spain and 17.2 per million/year in the United States. With regard to Europe, the rate

was 87.2 per million/year in France (18).

According to Sarwar A et al., the performance of few TIPS procedures in a center could increase the mortality and complications of patients undergoing TIPS (19). A total of 57.5 % of the centers that responded to the survey performed between one and nine TIPS per year (VL, L). In this group, the total number of complications was higher compared to the group of centers that were classified as high or very high. These complications are reduced with the experience of the team and the number of TIPS performed. It is unwise to establish a threshold, since most published series have hundreds of patients that could not be achieved by a single hospital. A threshold of 5 % has been established for major complications (20).

Of the 49 Spanish centers that had performed TIPS during 2016, only 33 (67.34 %) answered the survey with a combined total of 265 TIPS. Almost three-quarters of the TIPS (199/265) (75.9 %) were performed as a prophylaxis in patients with bleeding due to gastroesophageal varices. It is not known if these TIPS were performed as an early or rescue procedure. The vast majority of patients (73.8 %) were Child-Pugh B stage and the mean MELD score was  $14.3 \pm 5.37$  points. Ascites refractory to treatment was the second indication in 53/265 (20 %) of cases, which means that these two indications accounted for 96 % of all TIPS. These data regarding indications for TIPS differ from other countries, as is the case in the United States, where these two indications only accounted for 66.7 % of all the TIPS (18).

Intraoperative mortality during TIPS is infrequent and there are few reported cases in this regard (21). In the present study, no intraoperative mortality was observed, with a small percentage of major complications (6 %). However, it must be highlighted that type D cases required therapeutic measures and a prolonged hospitalization. In addition, 16.6 % of minor complications did not require special therapeutic measures and the 30-day mortality was greater in the very low and low categories ( $p < 0.005$ ). In Spain, the number of deaths per year during the acute episode of gastroesophageal variceal bleeding is unknown and there are no clear recommendations for the indication of TIPS in different hospitals. Before bleeding due to gastroesophageal varices, various pharmacological and endoscopic measures are performed until the gastroenterologist or the interventionist indicates a TIPS (in general, the patient has a

more severe clinical situation that modifies the Child-Pugh score). In Spain, to our knowledge, early TIPS is not performed in the majority of centers, with the exception of the García-Pagán group (16). Thus, in light of current publications, early TIPS could improve survival in Child B and C patients with less than 14 points.

In our study, there was no evidence of the relationship between TIPS and liver transplantation; 11.6 % (31) of the patients received a transplant in the first year after TIPS compared to 1,159 patients who underwent a transplant in Spain during 2016. Thus, 2.8 % of all transplants had a TIPS. Larger studies are needed to determine whether TIPS could be a safe pre-transplant procedure.

The study has some limitations, one is that only 67.34 % (33/49) of the centers that perform TIPS answered the survey. On the other hand, it was a retrospective multicentric study with some heterogeneity in the data and clinical practice, which had to be standardized.

In conclusion, with the present data, there is no evidence to indicate whether sufficient TIPS are performed in Spain. The number of TIPS per million inhabitants is lower than in other countries such as the United States and France. However, despite having a lower number of TIPS, mortality and major complications in Spain are comparable to published data (13,19,22,23). More studies are needed to be able to answer these questions.

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Accepted Article

**Table 1. Major and minor complications classified by categories, limited by the number of TIPS/year**

<i>Category</i>	<i>Hospitals</i>	<i>TIPS</i>	<i>p</i>	<i>Minor complications</i>	<i>p</i>	<i>Major complications</i>	<i>p</i>	<i>Mortality 30 days</i>	<i>p</i>	<i>Mortality 1 year</i>	<i>p</i>
VL	15/33 (45.45 %)	35/265 (12.07 %) 2.33 ± 1.72		15/35 (42.85 %) 1.00 ± 0.93		3/35 (8.57 %) 0.20 ± 0.41		11/35 (31.42 %) 0.83 ± 0.58		10/35 (28.57 %) 0.83 ± 0.58	
L	11/33 (33.33 %)	100/265 (37.73 %) 9.09 ± 3.36	0.000	15/100 (15 %) 1.36 ± 1.21	0.022	3/100 (3.0 %) 0.27 ± 0.65	0.026	14/100 (14.0 %) 1.36 ± 0.50	0.013	17/100 (17 %) 1.55 ± 0.69	0.000
M	4/33 (12.12 %)	62/265 (23.39 %) 15.50 ± 5.20		11/62 (17.74 %) 3.75 ± 1.71		11/62 (17.74 %) 2.75 ± 2.22		6/62 (9.67 %) 1.50 ± 1.00		13/62 (20.96 %) 3.25 ± 1.26	
H	3/33 (9.09 %)	68/265 (25.66 %) 22.67 ± 2.52		7/68 (10.29 %) 2.33 ± 1.53		0 /68 (0 %) 0.00 ± 0.00		7/68 (10.29 %) 2.33 ± 0.58		9/68 (13.23 %) 3.00 ± 1.00	
VH	0/33 (0 %)	0		0		0		0		0	

Data collected between January 1<sup>st</sup>, 2016 and December 31<sup>st</sup>, 2016. VL: very low (1-4 TIPS/year); L: low (5-9 TIPS/year); M: medium (10-19 TIPS/year); H: high (20-29 TIPS/year); VH: very high (> 30 TIPS/year).

**Table 2. Major and minor complications classified according to the SIR classification (Khalilzadeh et al.)**

<i>Category</i>	<i>Definition</i>
<b>Minor complications</b>	
A	No AE, no therapy
B	No AE, nominal therapy, includes overnight admission for observation only
<b>Major complications</b>	
C	Requires therapy, minor hospitalization (< 48 h)
D	Requires major therapy, unplanned increase in level of care, prolonged hospitalization (> 48 h)
E	Permanent AE
F	Death

AE: adverse event.

Hospital	<input type="text"/>	City	<input type="text"/>	Region	<input type="text"/>							
Hospital beds	<input type="text"/>	Assisted population			<input type="text"/>							
University	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	Level	<input type="checkbox"/> I	<input type="checkbox"/> II	<input type="checkbox"/> III						
TIPS	<input type="checkbox"/> YES	<input type="checkbox"/> NO	Amount	<input type="text"/>								
Sex	<input checked="" type="checkbox"/> M	<input type="checkbox"/>	<input type="checkbox"/> F	<input type="checkbox"/>	Age (Average)	<input type="text"/>						
Early TIPS	<input type="text"/>		Age (Average)	<input type="text"/>	Urgent	<input type="checkbox"/>						
				<input type="text"/>	No urgent	<input type="checkbox"/>						
<b>Indication</b>	Esophageal bleeding		<input type="checkbox"/>	Refractory ascites			<input type="checkbox"/>					
Budd Chiari	<input type="checkbox"/>		Hepatorenal synd.	<input type="checkbox"/>	Others			<input type="checkbox"/>				
<b>Child Plug</b>	<input type="checkbox"/> A	<input type="checkbox"/>	<input type="checkbox"/> B	<input type="checkbox"/>	<input type="checkbox"/> C	<input type="checkbox"/>	<input type="checkbox"/>					
<b>MELD score (average)</b>	<input type="text"/>		Technical success	<input type="checkbox"/> YES	<input type="checkbox"/> NO							
			Bleeding control	<input type="checkbox"/> YES	<input type="checkbox"/> NO							
			Ascites control	<input type="text"/>								
<b>Complications</b>	<input type="checkbox"/> A	<input type="checkbox"/>	<input type="checkbox"/> B	<input type="checkbox"/>	<input type="checkbox"/> C	<input type="checkbox"/>	<input type="checkbox"/> D	<input type="checkbox"/>	<input type="checkbox"/> E	<input type="checkbox"/>	<input type="checkbox"/> F	<input type="checkbox"/>
Comments												
Dead (1 month)	<input type="checkbox"/>	<input type="checkbox"/>	Transplanted (liver)			<input type="checkbox"/>	<input type="checkbox"/>					
Dead (1 year)	<input type="checkbox"/>	<input type="checkbox"/>										
Technical difficulties												
Other comments												

Fig. 1. Survey sent to 49 hospitals about the aspects related to TIPS.

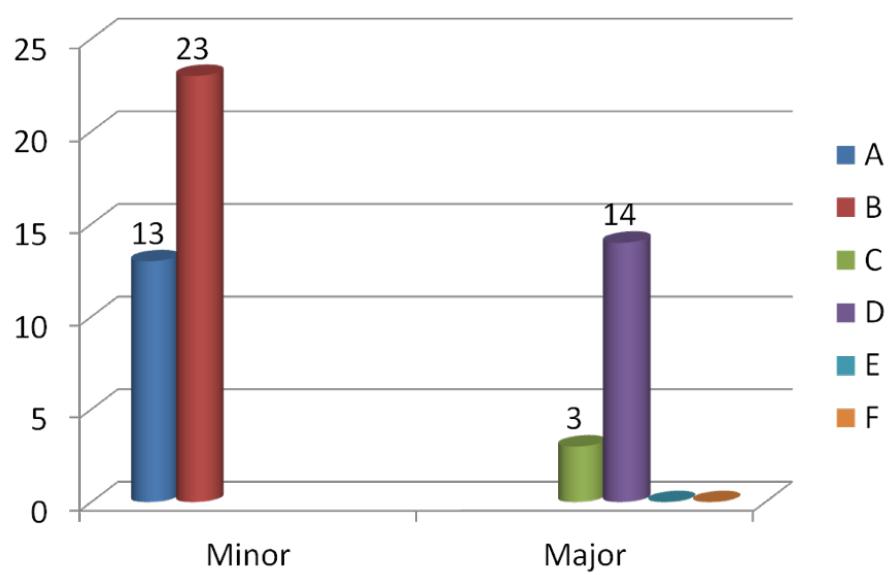


Fig. 2. Major and minor complications according to the SIR classification in the SERVEI 2016 registry.