



TIPS Indications and Contraindications—Pushing the Limits: Is Earlier Better?

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Abstract

Purpose of Review To describe the main indications and contraindications of transjugular intrahepatic portosystemic shunt (TIPS) placement in patients with portal hypertension (PH).

Recent Findings An adequate selection of patients helps to identify those who may benefit from TIPS in terms of survival. In patients with acute variceal bleeding and factors of poor prognosis, a pre-emptive use of TIPS is associated with significant reductions in treatment failure and mortality. Similarly, TIPS has shown to improve survival in a highly selected group of patients with cirrhosis and refractory ascites.

Summary PH is a clinical syndrome associated with the appearance of certain complications which can lead to high morbidity and mortality. TIPS placement effectively reduces portal pressure improving the outcomes of patients who present severe and/or refractory complications of PH. However, an adequate selection of candidates seems to be a key factor for improving the outcomes of patients treated with TIPS.

Keywords Portal hypertension · Transjugular intrahepatic portosystemic shunt · TIPS · Variceal bleeding · Refractory ascites · Portal vein thrombosis · Cirrhosis · Esophageal varices

Introduction

Portal hypertension (PH) is a clinical syndrome produced as consequence of a pathological increase in the portal vein pressure. This increase in portal pressure can be evaluated by measuring the porto-cava pressure gradient (PPG), which is defined as the difference between portal vein and inferior vena cava pressures [1].

In patients with cirrhosis, the PPG can be accurately estimated by measuring the hepatic venous pressure gradi-

ent (HVPG). An HVPG value ≥ 10 mmHg is associated with an increased risk of PH-related complications such as variceal bleeding (VB) and ascites, which are known to lead to a high morbidity and mortality [2, 3]. In contrast, a decrease in the HVPG of $\geq 20\%$ from baseline value or to ≤ 12 mmHg is known to prevent VB and reduces the risk of ascites, spontaneous bacterial peritonitis, and death [4–6].

Placement of a transjugular intrahepatic portosystemic shunt (TIPS) is a procedure that effectively reduces PH by creating an intrahepatic connection between the portal vein and the systemic circulation. This connection is subsequently preserved by the insertion of an expandable prosthesis that derives portal flow to the systemic circulation decreasing the PPG. These statements support the rational of treating PH-related complications by placing a TIPS.

Over the years, TIPS technique has improved considerably, resulting in a reduction of the morbidity and mortality related to the procedure. In consequence, TIPS has gained an increasing acceptance as an effective treatment of PH-related complications.

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Indications

Indications of TIPS have expanded over the years as consequence of improvements in the technique that have led to better outcomes. This was especially true after the appearance of expandable polytetrafluoroethylene (PTFE)-covered stents, which markedly reduced the rate of TIPS dysfunction, one of the main drawbacks of bare stents. Thus, the use of covered stents has reduced the number of clinical recurrences of PH and re-interventions required to maintain shunt patency without increasing the risk of hepatic encephalopathy (HE) [7, 8].

The appearance of emerging techniques such as portal vein recanalization (PVR) has also expanded the use of TIPS [9]. This procedure aims to optimize transplant candidacy of cirrhotic patients with portal vein thrombosis (PVT), making liver transplantation (LT) feasible and allowing the use of physiologic anastomosis which are associated with better outcomes [10, 11••].

Currently Approved Indications in Patients with Cirrhosis

Esophageal Variceal Bleeding

Variceal hemorrhage is a deadly complication of cirrhosis, particularly in patients in whom clinical decompensation has already developed. In the last decades, mortality from VB has decreased to the current 10–20% [12, 13], mainly due to the implementation of effective treatments. The role of TIPS in esophageal VB can be summarized in three different scenarios:

1. Rescue (salvage) TIPS for massive or refractory variceal bleeding

Salvage TIPS should be considered in patients presenting with a massive or refractory bleeding that cannot be controlled by the combination of vasoactive drugs and endoscopic band ligation (EBL). In this group of patients, TIPS has shown to be highly effective in controlling bleeding with a success rate of 90–95% [14, 15]. In spite of this, mortality in this clinical scenario remains as high as 30–50%, mainly due to deterioration of liver function and complications associated with the hemorrhage [15]. It is important to remark that TIPS should be considered a futile intervention in patients with poor liver function, which is usually defined by a Child-Pugh score (CPS) of ≥ 14 points [16]. Nevertheless, efforts in defining clinical parameters that help to identify cases of futility are warranted.

2. Pre-emptive TIPS (early TIPS) in high-risk patients

Despite receiving standard treatment, 10–15% of the patients die during the bleeding episode. Therefore, in the last decade, several efforts were taken to identify patients at high risk of treatment failure and/or rebleeding, who might benefit from a more intensive management *ab initio*.

In this regard, two randomized clinical trials (RCT) and one European multicenter observational study have shown that in patients with factors of poor prognosis (HVPG ≥ 20 mmHg, Child-Pugh B with active hemorrhage at the initial endoscopy or Child-Pugh C), the use of a pre-emptive TIPS was associated with a lower rebleeding rate and higher survival without increasing the risk of HE, in comparison with the standard treatment [16–18]. Despite this evidence, a French observational study showed that a pre-emptive use of TIPS has not been implemented in most of the centers worldwide since only 6.7% of high-risk patients were treated with an early TIPS [19].

The low adherence to this recommendation was also observed in an international multicentric observational study in which 671 patients from 34 hospitals were included [20•]. Although only 13% of patients at high risk of treatment failure were treated with a pre-emptive TIPS, results confirmed that its use reduces the rate of rebleeding, decreases the risk of developing ascites or worsen it, and improves survival without increasing the risk of HE.

These results were also confirmed by a recent Chinese study which included a large cohort of patients treated with pre-emptive TIPS irrespectively of baseline liver function. From the 1425 consecutive patients with cirrhosis and VB (Child-Pugh A, 35%; B, 56%; C, 9%) that were included, 206 (14%) patients (Child-Pugh A, 20%; B, 64%; C, 16%) were treated with a pre-emptive TIPS based on each center's policy and individual physicians' judgement. Results of this study confirmed that the pre-emptive use of TIPS improves survival of patients with MELD > 18 , Child-Pugh C cirrhosis, or Child-Pugh B cirrhosis with active bleeding without increasing the risk of HE. More importantly, the absence of an increased risk of HE was consistent across the entire risk spectrum (Child-Pugh A/B/C and MELD $< 12/12-18/18$) [21].

Thus, based on the evidence available, high-risk patients with VB must be treated with a pre-emptive TIPS within the first 72 h (ideally 24 h). Moreover, given its robust beneficial effect on prognosis, patients admitted to centers where TIPS is not available should be referred to other centers with experience in this technique.

3. Prevention of esophageal variceal rebleeding

Evidence about the use of TIPS in secondary prophylaxis of VB comes mainly from studies in which bare stents were used [22, 23]. In these studies, the use of TIPS was associated with a lower rebleeding rate and an increased risk of HE without differences in survival. Based on these evidence, the use of TIPS in this setting is currently limited to those patients in

whom the combination of non-selective beta-blockers (NSBB) and EBL fails [24, 25]. After the introduction of covered stents, two RCT comparing TIPS with combined therapy using non-selective beta-blockers (NSBB) and EBL in secondary prophylaxis of VB have been published. Both trials showed a lower rebleeding rate in the TIPS arm with no improvement in survival [26, 27]. However, both studies have selection bias and did not use mortality or HE as primary outcomes [28]. Therefore, studies that are appropriately designed to explore the use of TIPS in this scenario are urgently needed.

Refractory Ascites

Patients with cirrhosis who develop refractory ascites (RA) are known to have a poor prognosis and an increased risk of death. Large-volume paracentesis (LVP) is a safe treatment option for patients with RA, which produces an immediate relief of symptoms. Nevertheless, this therapy may have negative effects on systemic hemodynamics and renal function whereas TIPS may improve renal function by ameliorating effective arterial blood volume and renal perfusion [29, 30].

Most of the studies, which evaluate the role of TIPS in RA, were performed before the introduction of PTFE-covered stents. Meta-analyses of these trials showed that TIPS was more effective to control ascites, but it was associated with an increased risk of severe HE [31]. Nevertheless, a recent RCT has challenged these data. This study, which compared the use of TIPS using PTFE-covered stents with LVP plus albumin administration in a selected patients with cirrhosis and RA, showed that in these highly selected population, TIPS was associated with a higher transplant-free survival with no differences in the rate of HE [32••]. Thus, similar to what it occurs in VB, a careful selection of candidates seems to improve survival following TIPS in patients with RA.

Other Indications in Patients with Cirrhosis

Gastric Variceal Bleeding

Several observational studies have shown that the efficacy of TIPS in gastric VB is similar to that observed in the setting of esophageal VB, with a success rate in controlling the hemorrhage higher than 90% and a very low rebleeding rate [14, 33]. In addition, a previous trial showed that TIPS is more effective than glue injection in preventing rebleeding from gastric varices [34]. However, higher rates of HE were observed in the TIPS arm with no differences in overall mortality [34]. Thus, until further evidence is available, the use of TIPS in this setting should be limited to patients in who combined therapy fails but it might also be considered as a first-line option in centers with a limited expertise in glue injection or in those considered to be at high risk of treatment failure. Studies that

address the use of pre-emptive TIPS in gastric VB are warranted.

Hepatic Hydrothorax

Repeated pleural taps are associated with a high rate of complications in patients with hepatic hydrothorax. Therefore, TIPS may be considered a better option, especially in young patients with preserved hepatic and renal function [31, 35]. Published studies, which evaluated the use of TIPS in this setting, are mostly retrospective and included patients treated with bare stents. Therefore, efforts in designing prospective multicenter studies that evaluate the role of TIPS in this indication should be sought.

Hepatorenal Syndrome

TIPS has been reported to improve renal function in patients with type I and type II hepatorenal syndrome (HRS) [36–40]. Nonetheless, TIPS has never been compared with standard medical therapy and the big proportion of patients who present with an advanced liver failure frequently limits its use. Thus, TIPS cannot be currently recommended for this indication.

Portal Vein Thrombosis

The impact of PVT on the prognosis of patients with cirrhosis is still unknown [41–43]. Nonetheless, some data suggest that PVT impacts negatively post-LT survival especially in the first year post-LT and in those patients in whom a physiological anastomosis was not feasible because of thrombosis that extended to the splenomesenteric confluence [44–46]. Some data suggest that TIPS might be beneficial in patients with PVT who are waiting for LT. In this setting, the potential role of TIPS could be summarized in two different scenarios:

- In patients with an acute/sub-acute PVT with an identifiable intraluminal thrombus, TIPS is usually indicated when PVT progresses despite adequate anticoagulation, when anticoagulation is contraindicated or when PVT occurs concomitantly with a severe complication of PH. In this situation, TIPS is usually easily performed and results in thrombus resolution by increasing portal blood flow.
- In patients with chronic PVT without identifiable vessels other than collaterals, TIPS may be a big challenge. Nonetheless, recent studies have shown promising results which suggest that TIPS can be successfully placed in the majority of patients allowing several of them to be transplanted [10, 11••].

Ectopic Variceal Bleeding

The low incidence of ectopic VB in cirrhosis prevents from giving any recommendations about the use of TIPS in this indication. Therefore, the indication of performing a TIPS needs to be taken in a case-by-case basis depending on center's expertise and availability of facilities [25].

Portal Hypertensive Gastropathy-Related Bleeding

Patients with portal hypertensive gastropathy refractory to NSBB may benefit from TIPS in terms of improved endoscopic findings and reduced transfusion requirements [47–49]. However, no general recommendation can be made to date due to the lack of stronger evidence.

Role of TIPS in Vascular Liver Diseases

Although cirrhosis is the main cause of PH in Western countries, patients with certain vascular disorders of the liver may also develop PH. Clinical guidelines currently recommend the use of TIPS in patients with Budd-Chiari syndrome (BCS) who do not respond to less invasive therapies. Similarly, TIPS is currently considered a therapeutic option in patients with idiopathic portal hypertension (IPH) and non-cirrhotic portal vein thrombosis (NCPVT) who present with severe or refractory complications of PH [50]. In fact, the management of PH-related complications including the use of TIPS should follow the recommendations stated in clinical guidelines elaborated for cirrhosis [24, 50].

Budd-Chiari Syndrome

In experienced hands, TIPS is technically feasible in most Budd-Chiari patients, even in those without any remaining hepatic vein stump, in whom a direct puncture from the intrahepatic inferior vena cava can be successfully performed [51]. TIPS is very effective in decompressing the liver parenchyma, and in most cases rapidly improves liver function and ascites. Similar to what occurs in cirrhosis, PTFE-covered stents improved outcomes in patients with BCS due to their lower dysfunction rate and lower number of re-interventions in comparison with bare stents [8].

A large multicenter European study showed an excellent long-term outcome in 124 consecutive BCS patients treated with TIPS [52]. In high-risk patients, TIPS offered a much better survival than that estimated by validated prognostic indexes. In addition, the study proposed a risk score, which was further validated [53], to identify patients with poor prognosis despite treatment with TIPS, who should probably be referred directly for LT.

Idiopathic Portal Hypertension

Given its low prevalence, the use of TIPS in patients with IPH has not been evaluated as extensively as in patients with cirrhosis. In spite of this, current evidence demonstrates that TIPS is a very effective therapy to treat patients with IPH that develop severe and/or refractory PH-related complications [54•]. A recent study showed a 2-year survival of 80% in a cohort of 41 patients with IPH treated with TIPS [54•]. In this study, the concomitant presence of significant extrahepatic comorbidities and renal failure defined as a creatinine greater than 100 $\mu\text{mol/l}$ (1.13 mg/dl) was significantly associated with an increased risk of death after TIPS. Although HE is not a frequent complication in IPH [55], this event occurred in 31% of the patients after TIPS. Even when its incidence was not negligible, most of the cases responded adequately to medical treatment and only few required to reduce the caliber of TIPS. Given these data and although there are no RCT that evaluates the use of TIPS in IPH, current recommendations support the use of TIPS in the same situations as in cirrhosis [24, 50, 56].

Non-cirrhotic Portal Vein Thrombosis

There are several case series that have reported TIPS feasibility in this setting but the number of patients included is low and data beyond a few months of follow-up is scarce [57–61]. Furthermore, the proportion of patients that are ineligible for interventional therapy according to pre-interventional imaging is not reported in most of the studies.

Although data with a longer follow-up are needed, TIPS placement should be considered in patients with NCPVT that develop severe and/or refractory complications of PH. Nonetheless, given its technical difficulty and the potential occurrence of complications, these procedures should be attempted in centers with a large experience in TIPS procedure.

Sinusoidal Obstruction Syndrome

Several case reports have described the use of TIPS in sinusoidal obstruction syndrome (SOS) but results have been discouraging [62]. However, more recent reports show better results in patients in whom SOS occurred after LT, especially in those who were treated before the onset of end-stage liver failure [63]. Since the rarity of this disorder prevents from exploring the use of TIPS in the setting of clinical trials, definitive recommendations cannot be made, and case-to-case evaluation is warranted.

Contraindications

Absolute and relative contraindications are summarized in Table 1. Some are common to all forms of portosystemic shunt, such as advanced liver failure (CPS > 13 points), chronic HE, insufficient hepatic artery blood flow (particularly relevant in the setting of transplanted livers), heart failure, and pulmonary hypertension. Others are technical and specific for TIPS, such as biliary dilatation, tumors in the expected TIPS path, and polycystic liver disease.

Even when recent studies using PTFE-covered stents have shown that the use of TIPS in certain scenarios does not increase the risk of HE [16, 32••], this complication continues to be one of the most feared after TIPS. Furthermore, some data has shown that development of HE refractory to standard management occurs in only 8% of the patients treated with PTFE-covered stents [65]. Since history of HE prior TIPS is one of the predictors of the development of this complication following TIPS [66], previous episodes of HE must be taken into consideration when selecting TIPS candidates, but should never be considered an absolute contraindication. Other known factors that predict the development of this complication are older age, a higher CPS, high creatinine levels, and low serum sodium and albumin values [65, 66]. In patients at high risk of HE, the use of stents with smaller diameters may be considered. Nevertheless, whether this strategy results in a lower rate of HE following TIPS remains unclear [67, 68].

TIPS placement can represent a big challenge in patients with chronic PVT without identifiable vessels and in fact, in some centers, chronic PVT is considered an absolute contraindication for TIPS. As previously said, a recent study has changed this dogma and opened a new window in the treatment of these patients [11••]. In this study, TIPS was indicated to improve transplantation candidacy of 61 patients with cirrhosis and PVT that had been discarded for LT because a physiological reconstruction of the portal blood flow was considered impossible. TIPS was successfully placed in 98% of the cases allowing that 39% of patients undergo LT by the end of the follow-up period [11••]. Therefore, even when chronic

PVT may increase the difficulty of TIPS procedure, it should not be considered an absolute contraindication.

Patients with history of heart failure should be carefully evaluated since TIPS is known to worsen cardiac function by increasing preload. Although no predictors of this complication have been described to date, a careful assessment of cardiac function could help to identify patients who may be at higher risk. Thus, a detailed cardiopulmonary evaluation is strongly recommended in patients who will undergo an elective TIPS.

For relative contraindications, the risks should be balanced against the severity of PH-related complications and the overall prognosis of the patient. Specialist consultation with a cardiologist or a pneumologist should be sought in borderline cases with heart failure or pulmonary hypertension.

Candidate Selection and Time Frame

It has been demonstrated that an adequate selection of patients helps to identify those who could benefit from TIPS in terms of survival. Similarly, the time at which TIPS is placed seems to be crucial in achieving good results following TIPS. In this regard, evidence suggests that in certain scenarios, a TIPS placed at early stages of the disease prevents the development of complications that could negatively affect survival.

The Earlier the Better Concept and High-Risk Criteria for a Pre-emptive TIPS

Treatment failure and early rebleeding negatively impact the outcome of patients admitted with an acute VB. Once that the bleeding episode has been controlled and the patient is in stable conditions, the individual risk of treatment failure should be assessed and patients found to be at high risk for treatment failure should be considered for a pre-emptive TIPS to prevent an early rebleeding that may worsen their prognosis.

Table 1 Contraindications to the placement of TIPS [16, 32••, 64]

Absolute	Relative
Contraindications of all forms of portosystemic shunt	
Decompensated congestive heart failure	Well-compensated heart failure
Severe pulmonary hypertension	Moderate pulmonary hypertension
Uncontrolled systemic infection or sepsis	Chronic hepatic encephalopathy
Hepatic artery insufficiency (thrombosis, stenosis)	Severe liver failure
Contraindications of TIPS specifically	
Unrelieved biliary obstruction	Portal vein cavernoma
Multiple hepatic cysts	Hepatocellular carcinoma (in the expected TIPS path)

Timing of TIPS insertion in this scenario is extremely important because rebleeding risk is significantly higher within the first 5 days from the index bleeding [24]. Taking this into consideration, performing a TIPS in the first 24 h is better than in the first 48 or 72 h. Unfortunately, the lack of availability of the technique influences negatively the time at which TIPS is placed. Therefore, it is extremely important to refer patients immediately after diagnostic endoscopy to a center with availability and expertise in TIPS procedure.

Criteria that should be used to identify patients at high risk are still a matter of debate. Portal pressure at the time of VB is one of the strongest predictors of prognosis in patients with cirrhosis [69]. Unfortunately, the measurement of an HVPG is a procedure that is not widely available especially under emergency conditions. For that reason, multiple studies have attempted to evaluate clinical factors of poor prognosis in patients with VB [70–75]. The high-risk criteria used in previous studies that evaluated the early use of TIPS include Child-Pugh C patients with a CPS < 13 points and Child-Pugh B patients with active VB at endoscopy. Irrespectively of the well-known disadvantages of the CPS, these criteria identify satisfactorily patients at high risk of treatment failure. The recent European observational study failed to show a survival benefit in patients with Child-Pugh B and active bleeding, probably due to the small number of events [20•]. However, a recent Chinese study with a larger sample size showed a survival benefit in this subgroup of patients [21]. Despite this, the better control of further rebleeding and ascites seems to justify its use in this population. Irrespectively of that, efforts in evaluating more objective and reproducible predictors of treatment failure should be carried out.

How Long Do We Have to Wait in Patients with Refractory Ascites?

As what happens in other treatments, a careful selection of patients helps in achieving better outcomes following TIPS. This is especially relevant in patients with cirrhosis and RA that are evaluated for TIPS.

Several studies have explored predictors of bad prognosis in this setting. Among these are the absence of renal failure or diastolic dysfunction (E/A ratio > 1), a bilirubin less than 3 mg/dl, and platelets over $75 \times 10^9/l$ [76–79]. A recent RCT showed that long-term survival is excellent in selected patients with good prognostic factors, which indicates that TIPS could be used as first-line therapy in patients that fulfill criteria of good prognosis [32••].

Similar to what happens in VB, timing for TIPS is a key factor to achieve good outcomes in patients with RA. This was illustrated in the most recent RCT, in which TIPS was placed before renal and hepatic failure occurs

[32••]. In this RCT, authors included a population of patients in the earlier stages of the disease with a low LVP requirements (≤ 6 LVPs within the previous 3 months), absence of advanced renal disease (serum creatinine $\leq 250 \mu\text{mol/l}$ [≤ 2.8 mg/dl]), and absence of severe hepatic failure (total bilirubin $\leq 100 \mu\text{mol/l}$ [≤ 5.8 mg/dl] and a prothrombin index $\geq 35\%$) [32••].

Nevertheless, it is important to remark that irrespectively of the inclusion criteria used, approximately 84% of patients included had a well-preserved hepatic and renal function with baseline bilirubin and creatinine levels lower than 2 mg/dl and 1.3 mg/dl respectively.

Although the best outcomes are achieved with a careful selection of candidates, patients who do not meet these criteria may still benefit from TIPS. Studies aimed to evaluate if less strict criteria can be used or whether patients with RA in later stages can benefit from TIPS in the cover stents era are warranted.

Conclusions

PH-related complications lead to high morbidity and mortality in patients with liver diseases. TIPS is known to be an effective treatment for some of these complications. Improvements in TIPS technique have led to an expansion of its indications and have resulted in an increasing acceptance of this procedure as an effective treatment for certain complications of PH. Recent data has shown that the time at which TIPS is placed seems to be crucial in achieving good results following TIPS. Similarly, a careful selection of patients helps in achieving better outcomes following TIPS. Therefore, a detailed evaluation of candidates is strongly advised before placing a TIPS not only to rule out possible contraindications but also to select the patients who could benefit the most in terms of survival.

In this regard, evidence suggests that TIPS improves survival of patients with acute VB and factors of poor prognosis. Similarly, recent data also suggest that TIPS improves survival of a highly selected group of patients with RA. These data indicate that TIPS should be considered as a first-line therapy option for patients with acute VB at high risk of treatment failure, and in a highly selected subgroup of patients with RA. Regarding PVT, data suggest that TIPS could be an alternative, particularly if thrombosis progresses despite anticoagulation and/or when it occurs along with other serious complications related to PH. Finally, recent evidence has shown that in patients with chronic PVT who have been rejected for LT, recanalization of the portal vein followed by TIPS can, in most of the cases, convert these patients into transplant candidates.

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Compliance with Ethical Standards

Conflict of Interest José Ferrusquía-Acosta reports personal fees from GORE, outside the submitted work.

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- Of importance
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