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EASL Clinical Practice Guidelines on TIPS☆

European Association for the Study of the Liver*

Summary

Transjugular intrahepatic portosystemic shunt (TIPS) placement is a well-established procedure for managing complications of portal hypertension. In recent years, the field of TIPS has seen rapid advances, particularly in technical approaches, prognostic modelling, and an expanding range of indications. The aim of these EASL guidelines is to comprehensively address all aspects of TIPS in patients with cirrhosis. Other related topics, such as the use of TIPS in surgical settings and in vascular liver disorders, are covered in separate dedicated clinical practice guidelines.

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Introduction

Developed in the 1980s, transjugular intrahepatic portosystemic shunt (TIPS) placement emerged as a minimally invasive approach to manage complications of portal hypertension (PH) in patients with cirrhosis. Over the years, it has become a standard treatment for variceal bleeding and severe ascites. As the number of TIPS procedures performed globally continues to grow, several factors have highlighted the need for updated, standardised guidelines. These include the expanding range of TIPS indications, the involvement of diverse stakeholders, the critical importance of patient selection, and variations in pre-TIPS assessments, procedural techniques, and post-procedure follow-up. In light of these developments, the European Association for the Study of the Liver (EASL) Governing Board convened a panel of international experts to formulate these comprehensive guidelines.

Methods

EASL nominated a chair and eight members of the guideline expert panel respecting gender balance, geographic representation and competence. The Delphi panel was constituted with 33 physicians, ensuring gender balance, broad geographical representation, and diverse areas of expertise. The panel also included two patient representatives. The development of the Clinical Practice Guidelines (CPG) followed the EASL standard operating procedure. This process involved defining objectives, identifying target users, and outlining key issues.

The expert panellists were tasked with formulating critical clinical Key Questions (KQs) using the PICO framework (Population/Problem, Intervention, Comparison, and Outcome). To evaluate the evidence, a systematic literature review was conducted across PubMed, Scopus, Embase, and Cochrane Library databases. The Level of Evidence (LoE) and recommendations were drafted and graded according to the Oxford Centre for Evidence-Based Medicine (OCEBM) criteria (Tables 1 and 2). These were initially prepared by a single panel member, then revised and voted on by the entire panel (see Tables 1 and 2). Consensus was classified based on the following thresholds: strong consensus: ≥95% agreement, consensus: ≥75% to <95% agreement, majority agreement: ≥50% to <75% agreement, no consensus: <50% agreement. When the panel achieved >75% agreement, the LoE and recommendations were submitted for further voting by the Delphi group. The details of the Delphi round outcomes, including agreement levels for statements and recommendations, are provided in Appendix #1. The technical aspects of the process were supported by the Clinical Guideline Service Group (https://www.guideline-services.com/), which provided an online platform for uploading, reviewing, and managing all CPG documents.

These guidelines provide evidence-based recommendations to assist physicians and proceduralists in managing candidates and recipients of a TIPS. Clinical recommendations are presented in a pragmatic manner, addressing both pre- and post-procedure management along with technical considerations, with a primary focus on optimising clinical outcomes.

* Corresponding author. Address: European Association for the Study of the Liver, The EASL Building – Home of Hepatology, 7 rue Daubin, CH 1203 Geneva, Switzerland. Tel.: +41 (0) 22 807 03 60. *E-mail address:* easloffice@easloffice.eu

Clinical Practice Guideline Panel: chair: Christophe Bureau; Secretary to the Chair: Hélène Larrue; Panel members: Miriam Cortes-Cerisuleo, Roberto Miraglia, Bogdan Procopet, Marika Rudler, Jonel Trebicka, Lisa B. VanWagner; EASL Governing Board representative: Virginia Hernandez-Gea.

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Table 1. Level of evidence based on the Oxford Centre for Evidence-based Medicine.

Level	Criteria	Simple model for high, intermediate and low evidence
1	Systematic reviews (SR) (with homogeneity) of randomised-controlled trials (RCT)	Further research is unlikely to change our confidence in the estimate of benefit and risk
2	RCT or observational studies with dramatic effects; SR of lower quality studies (*i.e.* non-randomised, retrospective)	
3	Non-randomised-controlled cohort/follow-up study/control arm of randomised trial (systematic review is generally better than an individual study)	Further research (if performed) is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate
4	Case-series, case-control, or historically controlled studies (systematic review is generally better than an individual study)	
5	Expert opinion (mechanism-based reasoning)	Any estimate of effect is uncertain

Table 2. Grades of recommendation.

Grade	Wording	Criteria
Strong	Shall, should, is recommended. Shall not, should not, is not recommended.	Evidence, consistency of studies, risk-benefit ratio, patient preferences, ethical obligations, feasibility
Weak or open	Can, may, is suggested. May not, is not suggested.	

The target audience for these guidelines includes specialised physicians and other healthcare providers involved in the care of patients with cirrhosis and PH-related complications.

Patient evaluation and selection before TIPS intervention

In patients with cirrhosis being considered for an elective TIPS, which specialists should be involved in the pre-TIPS assessment to optimise outcomes?

Recommendations

- A hepatogastroenterologist should be involved in the initial decision to place an elective TIPS with subsequent consultation by a proceduralist who has competency in TIPS creation. If centre expertise is not available, referral to an expert centre is recommended **(LoE 5, strong recommendation, strong consensus).**
- Additional specialty consultations (*e.g.* transplant surgery, cardiology, anaesthesiology, haematology, neurology, nephrology, *etc.*) may be considered on a case-by-case basis **(LoE 5, weak recommendation, strong consensus).**

A multidisciplinary approach to the evaluation of TIPS candidacy is recommended to optimise outcomes. This is in line with practice guidance from the American Association for the Study of Liver Diseases (AASLD), the Advancing Liver Therapeutic Approaches (ALTA) Group, and the Society for Interventional Radiology (SIR).[1–3] In patients with cirrhosis, consideration for elective TIPS candidacy should involve, at a minimum, a gastroenterologist or hepatologist and a proceduralist who has demonstrated competency in TIPS creation (*e.g.* interventional radiologist, interventional hepatologist). Complex cases should include consultation with additional specialties (*e.g.* transplant surgery, cardiology, critical care, haematology, neurology, nephrology, *etc.*) as appropriate. Characteristics of centres that should be considered as expert centres are detailed in the chapter on technical aspects of the procedure.

In patients with cirrhosis being considered for an elective TIPS, what medical evaluation should be performed to select patients with an expected good outcome? Are there any conditions or specific thresholds in which an elective TIPS should not be considered because they are associated with unacceptable morbidity/mortality?

Recommendations

- The medical evaluation prior to elective TIPS creation in patients with cirrhosis should include an attentive history and physical exam focused on the presence or history of overt hepatic encephalopathy and signs of cardiopulmonary dysfunction. Laboratory evaluation should, at minimum, include INR, platelet count, haemoglobin, and comprehensive metabolic panel enabling assessment of bleeding risk, degree of hepatic dysfunction, renal function, and calculation of prognostic scores, such as MELD and/or Child-Pugh scores. Other prognostic scores (*e.g.* FIPS, MOTS) may also be considered **(LoE 5, strong recommendation, consensus).**
- An elective TIPS procedure should not be performed in patients with cirrhosis and severe cardiac dysfunction (right or left-sided), moderate-severe pulmonary hypertension (based on invasive measurements) despite medical optimisation, untreated severe valvular heart disease, uncontrolled systemic infection, severe or refractory overt HE without intervenable spontaneous shunt, unrelieved biliary obstruction, and lesions in the liver parenchyma that preclude TIPS creation **(LoE 2, strong recommendation, strong consensus).**

Prior to elective TIPS creation, the medical evaluation should focus on assessing hepatic, cardiopulmonary, renal, haematologic, and central nervous system reserve using a multidisciplinary team approach (Table 3). History and physical examination should focus on the presence of overt hepatic encephalopathy (HE) (*e.g.* asterixis, prior overt HE) and signs of cardiopulmonary dysfunction (*e.g.* hypoxia, oedema). Laboratory evaluation to assess for haemostatic alterations, degree of hepatic dysfunction, renal function, and to enable calculation of the model for end-stage liver disease (MELD) score[4] and Child-Pugh score prior to TIPS creation is routinely performed and should be

Table 3. Recommended evaluation prior to elective TIPS creation and findings that contraindicate elective TIPS.

System	Recommended assessment	Absolute contraindication/*comments*
Global	Consultations from hepatologist and/or gastroenterologist, TIPS proceduralist (radiologist or hepatologist) Additional specialty consultations on a case-by-case basis	No centre expertise in TIPS available*
	Consider liver transplantation, where applicable	*No evidence to support routine evaluation for liver transplant prior to elective TIPS*
Hepatic	Serum total bilirubin, albumin, sodium, creatinine, INR and prothrombin time	Unrelieved biliary obstruction
	Calculate Child-Pugh and MELD scores; Consider FIPS and/or MOTS scores	*No evidence to support absolute cut-offs*
	Cross-sectional imaging using CT or MRI with specific consideration for portal venous phase; Consider Doppler ultrasound if CT scan or MRI completed within 3 months	Masses/tumours in the liver parenchyma that would preclude TIPS creation
	Assess and treat underlying cause of cirrhosis, when available	*No evidence to delay TIPS when the aetiology of cirrhosis is treatable*
Cardiopulmonary	Natriuretic peptide dosage 12 lead ECG Transthoracic echocardiography	Severe cardiac dysfunction (right or left sided) Moderate-severe pulmonary hypertension (based on invasive measurements)** despite medical optimization Untreated severe valvular heart disease
Renal	Serum creatinine and glomerular filtration rate (estimated or measured)	*No evidence to support absolute cut-off*
Haematologic	Assess prior bleeding episodes	
	INR, platelet count, haemoglobin***	*No evidence to support absolute cut-off*
Central nervous system	Previous episodes of OHE	
	Consider testing for minimal/covert HE	Severe/refractory overt HE without intervenable spontaneous shunt
	Assess age, serum sodium, serum creatinine, serum glucose, sarcopenia	
Immune	Assess infection symptoms	Uncontrolled systemic infection or sepsis

ECG, electrocardiogram; FIPS, Freiburg index of post-TIPS survival; HE, hepatic encephalopathy; INR, international normalized ratio; MELD, model for end-stage liver disease; MOTS, modified TIPS score; NT-proBNP, n-terminal proBNP; OHE, overt hepatic encephalopathy; TIPS, transjugular intrahepatic portosystemic shunt.
*If centre expertise is not available, referral to an expert centre is recommended.
**Moderate-severe pulmonary hypertension defined as mean pulmonary artery pressure >45 mmHg on right heart catheterization.
***May be obtained to assess severity of disease though does not predict procedural bleeding risk.

considered standard of care (SOC). Consideration should be given to the calculation of other risk prediction scores to assist with risk estimation (*e.g.* Freiburg index of post-TIPS survival [FIPS] score[5] and modified TIPS score [MOTS][6]).

Laboratory evaluation of haemostasis including international normalised ratio (INR), platelet count and haemoglobin are recommended to assess severity of disease or haemostatic status prior to an invasive procedure in patients with cirrhosis. Several studies have shown that INR and platelet count are poor measures of bleeding risk in patients with chronic liver disease and routine transfusion of blood products prior to invasive procedures does not portend a lower procedural bleeding risk.[7–12] However, these studies primarily included patients undergoing paracentesis and liver biopsy, and it is unclear if the results can be extrapolated to patients undergoing TIPS creation, which carries a higher bleeding risk. Plasma fibrinogen levels <100 mg/dl have been associated with increased bleeding risk in critically ill patients with cirrhosis, but causal relationships have not been established.[7] Whether correction of plasma fibrinogen to levels >100 mg/dl reduces bleeding risk during TIPS creation is unknown and cannot be recommended.[7]

The absolute contraindications to TIPS creation are based on the understanding of the physiologic changes that result from the decompression of PH. They include: uncontrolled systemic infection/sepsis, severe cardiac dysfunction (right or left-sided), untreated severe valvular heart disease, pulmonary arterial hypertension with mean pulmonary artery pressure >45 mmHg despite medical optimisation, anatomic barriers to shunt creation (*e.g.* multiple hepatic cysts, hepatocellular carcinoma [HCC] on the expected tract of the shunt, unrelieved biliary obstruction except portal cavernoma cholangiopathy), and recurrent grade 2-4 or refractory overt HE without an intervenable spontaneous shunt. SIR, ALTA, and AASLD list similar absolute contraindications to TIPS creation (Table 3).[2,3,13]

In patients with cirrhosis being considered for an elective TIPS, how should liver function be evaluated before TIPS creation to assess liver-related prognosis after the procedure?

Recommendation

- The MELD score remains the most accurate predictive model and should thus be used to assess liver function and post-TIPS survival. A multidisciplinary approach, rather than an absolute MELD cut-off, is recommended to assess TIPS candidacy **(LoE 2, strong recommendation, strong consensus).**

The MELD score remains a strong predictor of 90-day mortality after TIPS creation when compared to MELD-Na, MELD 3.0 and other scoring systems (*e.g.* Chronic Liver Failure-consortium [CLIF-C] acute-on-chronic liver failure (CLIF-C ACLF), Child-Pugh score, Emory, FIPS and MOTS scores).[5,6,14–21] In a recent meta-analysis including 30 studies of 10,732 individuals, the pooled AUC (area under the ROC curve) for the MELD score at 90 days post elective TIPS creation was 0.81 (95% CI 0.74–0.88).[22] The MELD score performs better in patients receiving a TIPS for variceal bleeding than in those receiving a TIPS for refractory ascites.[23–25] Among patients with cirrhosis and refractory ascites, a combination of a

high bilirubin level and low platelet count,[26] an elevated MELD score, and Child-Pugh class C cirrhosis are associated with increased post-TIPS complications, including mortality.[26–28,29,30] However, no studies provide strong evidence of a specific cut-off for any of these parameters above which a TIPS should be considered contraindicated. It is important to mention that patients with total bilirubin level >3-5 mg/dl, a MELD score >15, and a Child-Pugh score >11, were included in a limited number of prospective randomised trials. Other studies have examined additional risk factors for poor outcomes with mixed results, including older age and specific numerical MELD score cut-offs.[24,25,31–35] Overall, it is difficult to generate definitive conclusions about additional risk factors for death after TIPS creation from these data. Limitations of studies include sample size, variation in centre practices, spectrum of MELD scores or selective diagnosis (*e.g.* ascites or variceal bleeding) as well as heterogeneous procedural techniques (*e.g.* covered *vs.* uncovered stents, stent diameter, and dilation choices, variable volume or type of contrast agents used).[36–40] Thus, the determination of TIPS candidacy using the MELD score alone as a marker of liver dysfunction must be interpreted based on the relative risk and benefit of TIPS creation to the specific patient in the context of the clinical indication for a TIPS, comorbidities, and alternative treatment options including LT. Fig. 1 proposes a stratification of the benefit/risk balance of creating a TIPS according to patient characteristics outside the context of urgent procedures.

In patients with cirrhosis being considered for an elective TIPS, what specific work-up should be conducted to assess the risk of post-TIPS HE?

Recommendations

- Testing for covert or minimal HE may be considered for prognostication and discussion with the patient **(LoE 3, weak recommendation, consensus).**
- Risk assessment for HE should include assessment of history of prior and control/response to treatment of overt HE, severity of liver dysfunction, hyponatremia, advanced age, sarcopenia, renal failure, and presence of large spontaneous portosystemic shunts **(LoE 2, strong recommendation, strong consensus).**

The risk factors for HE should be assessed before a planned TIPS. The main risk factors are a history of overt HE, the presence of minimal (covert) HE, impaired liver or renal function, hyponatremia, sarcopenia, advanced age, and the presence of large portosystemic shunts. It is noteworthy that these conditions are also risk factors for HE in patients with cirrhosis outside the setting of TIPS.

The diagnosis of covert HE has been associated with a greater risk of overt HE after TIPS creation.[41–45] Covert HE is associated with poor daily function and impaired health-related quality of life (HRQoL) and is associated with the development of overt HE even in patients with cirrhosis who do not receive a TIPS.[46–48] However, there is no data supporting the treatment of patients with covert HE with medical interventions (*e.g.* lactulose, rifaximin) prior to TIPS creation. Recommendations for testing to detect covert HE include Psychometric HE Score, EncephalApp Stroop, or Critical Flicker frequency testing.[49] Few studies have determined the role of oral glutamine challenge in prognostication for overt HE after TIPS creation.[50–52] The animal naming test might be useful, but specific studies showing efficacy in TIPS candidates are lacking.[44,45,53] Cognitive function worsens after TIPS, which can contribute to further worsening of HRQoL.[42,54] Sarcopenia seems to be a key predictor for post-TIPS HE, independent of usual prognostic criteria.[55–58] However, observations have shown that a TIPS may improve nutritional status and sarcopenia.[59,60] Overall, in patients being considered for an elective TIPS, the risk of HE should consider all these factors and guide discussion of the pros and cons of TIPS creation with patients, family members, and clinical teams. Patients should be informed of the expected risks of HE and that lower Child-Pugh and MELD scores indicate a lower risk of post-TIPS HE.

In patients with cirrhosis being considered for an elective TIPS, which imaging modality should be used to assess the feasibility and the risk of complications?

Recommendation

- Cross-sectional multiphasic imaging (CT scan or MRI) with specific consideration of portal venous phase imaging should be performed for TIPS planning **(LoE 5, strong recommendation, consensus).**

There is no evidence that routine imaging prior to TIPS creation has an impact on procedural success, complication rate, or post-procedure outcomes. However, cross-sectional imaging provides important information for TIPS planning.

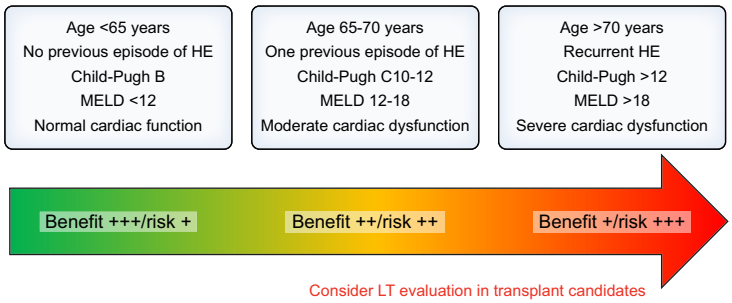


Fig. 1. Proposed benefit/risk stratification for the treatment of patients with TIPS outside the context of urgent procedures. HE, hepatic encephalopathy; MELD, model for end-stage liver disease; TIPS, transjugular intrahepatic portosystemic shunt.

Liver imaging is feasible, and at minimum, liver ultrasound is recommended in all patients with cirrhosis as a part of SOC for screening for hepatocellular carcinoma (HCC).[61] Cross-sectional imaging with a CT scan or MRI for HCC often includes porto-venous contrasted studies and will adequately define the portal veins, hepatic veins, and the liver parenchyma to permit planning of TIPS creation. There is no evidence to define the optimal timing between cross-sectional imaging and elective TIPS placement, but for patients with cross-sectional imaging within the last 3 months, a Doppler ultrasound may be sufficient for TIPS planning.

In patients with cirrhosis being considered for an elective TIPS, what specific cardio-pulmonary-renal work-up should be conducted to assess the risk of cardiac, pulmonary, or renal dysfunction following the TIPS procedure?

Recommendations

- Comprehensive echocardiography should be performed to assess systolic function, diastolic function, valvular structure and function, right atrial pressure, and right ventricular systolic pressure **(LoE 2, strong recommendation, strong consensus).**
- BNP or NT-proBNP may be considered for cardiac risk stratification **(LoE 3, weak recommendation, consensus).**
- A pre-TIPS electrocardiogram should be performed to identify potential ischaemia and/or arrhythmia **(LoE 5, strong recommendation, strong consensus).**
- Kidney function should be assessed prior to the procedure, either through measurement of sCr or GFR (estimated or measured) **(LoE 3, strong recommendation, strong consensus).**
- Although renal dysfunction is associated with worse outcomes in patients with cirrhosis who are candidates for a TIPS, absolute sCr, CKD stage, or the presence/absence of renal replacement therapy cannot be recommended as absolute contraindication criteria **(LoE 5, weak recommendation, consensus).**

Cardiopulmonary

Cardiac decompensation has been reported after TIPS creation, with variable incidence from 1% in 1 week[62] to 20% in 1 year.[63,64] The underlying pathophysiology is multifactorial, involving pre-TIPS subclinical cardiac dysfunction (*e.g.* cirrhotic cardiomyopathy [CCM] = presence of systolic or diastolic dysfunction in patients with cirrhosis in the absence of other heart diseases) and post-TIPS worsening of hyperdynamic circulation.[65] Thus, it is reasonable to obtain comprehensive echocardiography to assess the risk of cardiac decompensation after TIPS creation from right or left heart failure or significant valvular heart disease.[3,66–68] There is some evidence to suggest that pre-TIPS brain natriuretic peptide (BNP) or N-terminal pro-BNP (NT-proBNP) predict post-TIPS cardiac dysfunction.[63] In particular, a level of BNP <40 pg/ml and NT-proBNP <125 pg/ml may be reasonable thresholds to identify patients without risk of cardiac decompensation. Electrocardiogram is warranted for evaluation of arrhythmia or signs of ischaemia. The history and physical examination should focus on signs and symptoms of past or present cardiovascular disease.

Comprehensive echocardiography should incorporate contemporary echocardiographic measurements for left ventricular and right ventricular (RV) function, with particular attention to the recently updated criteria for CCM.[69] Recent data suggest that impaired global longitudinal strain, reflective of subclinical systolic dysfunction, is associated with poor post-TIPS survival.[70] The 2020 CCM criteria, which update diastolic dysfunction criteria in cirrhosis, were recently found to be predictive of increased mortality and cardiac events after TIPS placement.[63] Echocardiographic assessment for diastolic dysfunction is summarised in Fig. S1. Thus, in patients undergoing TIPS creation, evaluating the presence and severity of systolic and/or diastolic dysfunction is an important part of risk stratification for adverse cardiac outcomes.

Baseline RV indices are particularly important to assess the possibility of increased preload after TIPS creation causing cardiopulmonary decompensation. RV systolic pressure >45 mmHg on echocardiography is conventionally considered the threshold for considering right heart catheterisation for assessment of pulmonary arterial hypertension. Decreased tricuspid annular plane excursion (<1.6 cm) and RV strain indicate impaired RV function.[71] TIPS creation, if pulmonary hypertension is present, has the potential to precipitate right heart failure and/or be ineffective at lowering portal pressure.[72,73] There is no published data regarding TIPS in pulmonary or portopulmonary hypertension (PoPH). Several studies have found that a TIPS acutely increases right atrial pressure (RAP) by 3-5 mmHg in those without PoPH.[74–77] Elevated RAP before TIPS creation is associated with reduced long-term survival.[68,74,77] Importantly, high baseline RAP has also been associated with cardiac decompensation specifically after TIPS creation.[62,68] Thus, extreme caution should be exercised when considering a TIPS in patients with moderate to severe PoPH.

Tricuspid regurgitation (TR) usually reflects volume overload in patients with a normal tricuspid valve and/or pressure overload from conditions resulting in pulmonary hypertension or, rarely, from pulmonary stenosis. Careful assessment of TR aetiology is necessary to determine if the risk of a TIPS is prohibitive. When volume overload is suspected to be the underlying aetiology, volume optimisation via diuretics or renal replacement therapy (when indicated) is warranted prior to reassessment of valvular function. In some cases, chronic volume overload results in RV dysfunction and tricuspid annular dilatation, leading to persistent moderate to severe functional TR, which can prohibit a TIPS unless corrected.

Asymptomatic aortic stenosis is strongly associated with cardiac decompensation and cardiac-specific mortality after TIPS placement.[63] There is no data on TIPS outcomes in patients with mitral valve disease.

Renal

The true incidence of acute kidney injury (AKI) following TIPS placement is unknown given a wide spectrum of indications and urgencies, the heterogeneity in measurement of kidney function (*e.g.* measured *vs.* estimated glomerular filtration rate [GFR], serum creatinine [sCr]), definitions of AKI (based on

change in creatinine *vs.* absolute cut-offs) and patient selection. In single-centre studies, the incidence of post-TIPS AKI was 16%, though this may be overestimated and may not account for pre-TIPS AKI or chronic kidney disease (CKD).[78–80] The presence of AKI after TIPS creation is associated with increased risk (odds ratio 4.3) of inpatient mortality.[81]

The creation of a TIPS and the resultant reduction in portosystemic pressure gradient (PPG) is associated with improvement in kidney function especially when measuring GFR.[82–89] Compared to serial paracentesis, the incidence of AKI and hepatorenal syndrome (HRS) may be lower in patients with ascites who undergo a TIPS procedure.[27,90] Change in estimated GFR is evident over 3-4 months after TIPS creation with a potential benefit in patients with CKD (GFR <60 ml/min),[36,82,85] suggesting that TIPS placement interrupts the natural history of decline in kidney function related to decreased effective circulating volume. Despite these physiologic improvements, there is insufficient evidence regarding clinical outcomes when considering a TIPS in patients with advanced kidney dysfunction (*e.g.* sCr >3 mg/dl), as these patients were often excluded from studies.[30,36,36,90–92] Additionally, TIPS creation has not been well studied in the dialysis population, with only case reports in the literature.[93] It is important to consider the primary indication, individualised risk factors, and physiologic goals of the intervention when considering TIPS creation in patients with kidney dysfunction. Of note, TIPS creation has recently been shown to lead to an early, substantial, and persistent improvement in patients with HRS-CKD, irrespective of baseline CKD stage.[94] There is insufficient evidence to recommend an absolute sCr, CKD stage, or presence/absence of renal replacement therapy where TIPS creation is contraindicated.

In patients with cirrhosis being considered for an elective TIPS, does the treatment of the underlying liver disease improve prognosis after TIPS? Should the TIPS procedure be delayed in cases where the aetiology of cirrhosis is treatable?

Recommendation

- Treatment of the underlying cause of cirrhosis, when available, is recommended to optimise outcomes after TIPS creation. In the absence of evidence to support delaying elective TIPS creation, the procedure should not be delayed where the aetiology of cirrhosis is treatable **(LoE 5, strong recommendation, consensus).**

Treatment of the aetiology of cirrhosis has been shown to improve hepatic venous pressure gradient (HVPG) and complications of PH in viral hepatitis, alcohol-associated liver disease, metabolic dysfunction-associated steatotic liver disease (MASLD), and autoimmune hepatitis.[95–99] However, there are no studies that assess the impact of treating the underlying liver disease on prognosis after TIPS creation. Thus, there is no evidence to support delaying an elective TIPS in cases where the aetiology of cirrhosis is treatable.

In patients with cirrhosis being considered for an elective TIPS, should LT be routinely discussed during the pre-TIPS evaluation?

Recommendation

- LT should be considered but routine pre-procedure LT evaluation is not recommended owing to insufficient evidence. Collaboration between the TIPS centre and the transplant centre is essential during the pre-TIPS evaluation to anticipate the potential need for LT on a case-by-case basis **(LoE 5, strong recommendation, consensus).**

In patients with cirrhosis undergoing elective TIPS creation, there is insufficient evidence to recommend universal pre-procedure liver transplant (LT) evaluation. Patients with cirrhosis and refractory ascites or variceal bleeding undergoing TIPS placement, by definition, have indications for a LT evaluation. Not all patients, however, will be LT candidates.[100] The transplant evaluation process is complex, and patients being evaluated for a TIPS without clear contraindications for LT should be cared for by experienced centres. The decision regarding TIPS creation *vs.* LT for the treatment of complications of PH should be evaluated on a case-by-case basis for patients with clear indications for LT.

Bleeding

In patients with cirrhosis and failure to control PH-related AVB, should a TIPS be considered to improve outcomes compared to alternative treatments?

Recommendation

- In patients with cirrhosis and failure to control acute PH-related bleeding or early recurrence of bleeding (<5 days) despite standard treatment, a salvage or rescue covered TIPS should be considered **(LoE 3, strong recommendation, strong consensus).**

Despite the standard treatment, up to 15% of patients with PH-related acute variceal bleeding (AVB) will experience uncontrolled or refractory bleeding,[101] leading to a high mortality rate of approximately 40% within 42 days.[102] Conventionally, the initial 5 days following a patient's admission for AVB, known as the index bleed,[103] is viewed as the period of highest bleeding-related risk[104] (Fig. 2). Failure to control bleeding, which occurs only within the index bleed, is defined as a) a new episode of vomiting fresh blood at least 2 hours after initiating a specific medication or undergoing therapeutic endoscopy; b) the occurrence of hypovolemic shock; or c) a decrease in haemoglobin levels by 3 g or a 9% reduction in haematocrit at any time, provided no blood transfusion has been given.[105] The factors associated with failure to control bleeding are high portal pressure, defined as HVPG >20 mmHg[106], and decreased liver function, quantified by a Child-Pugh score ≥8[107] or a MELD score >19[108]. Additionally, patients with Child-Pugh score of 8-9 points and active variceal bleeding at endoscopy,[107] bacterial infections,[109,110] or ACLF[111] are also at risk of failure to control bleeding.

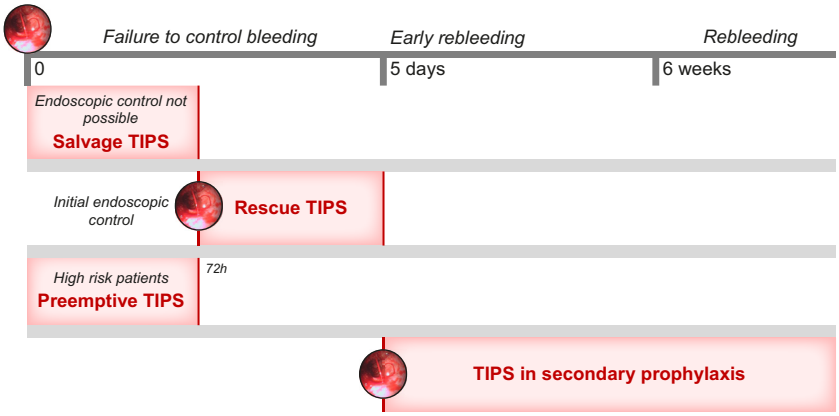


Fig. 2. Main scenarios and indications for TIPS in patients with portal hypertension-related bleeding. TIPS, transjugular intrahepatic portosystemic shunt.

Failure to control bleeding should be treated with balloon tamponade or oesophageal self-expandable metal stents as a bridge therapy until TIPS placement.[112] In this specific situation, we need to differentiate between two clinical cases: *"rescue TIPS,"* implemented when bleeding control fails despite initial endoscopic control (rebleeding within the first 5 days), and *"salvage TIPS,"* which is employed urgently when endoscopic treatment is not possible or fails. Even though the recommendations for both scenarios are identical, it is crucial to emphasise this distinction for clinicians and future clinical studies. The prognosis may not be the same for these two scenarios, and their conflation in previous studies has limited our understanding in this area.

TIPS controls bleeding in more than 90% of patients, while mortality remains relatively high. A recent meta-analysis concludes that in patients with failure to control bleeding treated with TIPS, the 6-week and 1-year mortality is 33% and 46%, respectively.[113] Despite all the improvements in the management of AVB, the mortality associated with rescue TIPS placement has remained high over the years,[114] mainly due to bacterial infections, severe liver dysfunction, and ACLF occurrence.[102] Because most of the data is purely descriptive, and thus, there is no direct comparison with any other alternative, the prognosis of patients after rescue TIPS placement is difficult to compare with any other alternatives. A recent retrospective study comparing rescue TIPS placement with SOC for AVB (the combination of volume resuscitation, vasoactive drugs, antibiotic prophylaxis, and endoscopic intervention) concluded that the prognosis of patients treated with a TIPS is better, especially in the subgroup of patients with ACLF.[102]

In patients with cirrhosis and failure to control PH-related AVB, when should a salvage/rescue TIPS not be used as it may not improve outcomes compared to alternative treatments?

Recommendation

- A salvage/rescue TIPS cannot be recommended in patients with cirrhosis and failure to control PH-related AVB if they have a MELD score ≥30 or lactate ≥12 mmol/L or ACLF grade 3b, which may indicate a poor prognosis even after the procedure. This is particularly true for patients who are not suitable candidates for LT **(LoE 3, weak recommendation, strong consensus).**

For patients with failure to control PH-related AVB who are, thus, candidates for a rescue TIPS, the MELD score and arterial lactate levels should be considered key predictors of 6-week mortality.[115] Specifically, if the MELD score exceeds 30 and/or if arterial lactate surpasses 12 mmol/L following initial resuscitation, despite the rescue TIPS, mortality probability exceeds 90%, indicating potential futility criteria for the TIPS. Furthermore, patients with a Child-Pugh score of 14-15 and ACLF grade 3b, will invariably die within the first 42 days, even with a rescue TIPS, in the absence of LT.[102,115,116]

In patients with cirrhosis and PH-related AVB, what criteria should be used to select patients who may obtain a survival benefit from a pre-emptive TIPS compared to alternative treatments?

Recommendation

- In patients with cirrhosis and bleeding from oesophageal varices or type 1 gastro-oesophageal varices, Child-Pugh class B >7 with active bleeding during initial endoscopy despite vasoactive drug use, or Child-Pugh class C <14, or documented HVPG ≥20 mmHg at the time of bleeding, should be used to define high-risk patients who may obtain a survival benefit from a pre-emptive TIPS **(LoE 1, strong recommendation, strong consensus).**

Pre-emptive TIPS (p-TIPS) creation has become a crucial strategy in the management of AVB in patients with cirrhosis to prevent treatment failure and rebleeding. The success of this approach lies in the prompt and precise identification of high-risk patients, steered by distinct risk factors and clinical criteria.

The most significant risk factor for uncontrolled bleeding is a high HVPG, specifically an HVPG ≥20 mmHg.[106,117] This parameter has been consistently linked with poor outcomes in AVB, including increased mortality. Research has shown that early application of a p-TIPS in patients presenting with this risk factor significantly diminishes both the occurrence of rebleeding and mortality rates without increasing rates of HE.[107]

While HVPG measurement is not commonly used, particularly in the acute phase of AVB, clinical criteria are vital for patient selection. The Child-Pugh score, especially for those in categories C (less than 14) and B (more than 7 points), along

with active bleeding at the initial endoscopy despite treatment with vasoactive drugs, has been widely used to pinpoint patients who would most benefit from a p-TIPS. Three randomised-controlled trials (RCTs), four observational studies, and two individual patient data meta-analyses have validated the high-risk criteria and the advantages of a p-TIPS.[107,118–125] Furthermore, patients at risk of failing to control bleeding can be effectively identified by Child-Pugh class C plus creatinine levels greater than 1 mg/dl,[126,127] a MELD score exceeding 19 points,[108,127] a CLIF-C acute decompensation (CLIF-C AD) score over 48 points (considering age, serum sodium, white blood count, creatinine, and INR),[128] or a Chinese Collaboration Group AVB score (taking into account age, albumin, bilirubin, INR, white blood count, creatinine, and serum sodium).[129] However, these parameters have not yet been proven effective in guiding treatment.

The specific clinical circumstances of patients with a Child-Pugh score of 14 or 15 or in patients with ACLF have not been directly addressed in studies, as these patients are typically excluded from clinical trials. A small study seeking futility criteria for p-TIPS creation was unable to establish definitive criteria since the procedure provided a survival advantage compared to traditional treatment in patients with Child-Pugh class C, prothrombin time less than 35%, and total bilirubin greater than 5 mg/dl.[130] In another study, p-TIPS creation was associated with improved survival in patients with ACLF and AVB.[35] p-TIPS creation also provided a survival benefit in the subset of patients with HE at the time of index bleeding.[131]

Conversely, 20% of the "non-high risk" patients still face a significant risk of mortality following AVB. Those with a Child-Pugh score greater than 8 and/or elevated creatinine levels or hyponatremia have a 1-year survival rate of only 69%.[132]

For patients with cirrhosis and PH-related bleeding who are candidates for a pre-emptive TIPS, what specific work-up should be conducted to improve outcomes?

Recommendation

- In candidates for a pre-emptive TIPS, essential preliminary evaluations may encompass parameters of liver function and cross-sectional multiphasic imaging or Doppler ultrasound **(LoE 5, weak recommendation, strong consensus).**

The success of the p-TIPS strategy largely depends on quickly identifying eligible patients and implementing a p-TIPS within the first 72 hours. Due to the emergency, a comprehensive work-up is often not feasible. For patients with AVB, evaluating liver function is crucial to determine the most appropriate treatment plan. While there is no consensus on the specific imaging test for assessing p-TIPS feasibility and contraindications, cross-sectional imaging with a venous phase is generally considered ideal. However, given the emergency nature of p-TIPS placement, a liver ultrasound with a Doppler examination is often sufficient.

The available data is relatively sparse regarding the risk of cardiac decompensation following p-TIPS creation. A 2014 study by Rudler *et al.* found that the incidence of acute cardiac failure was significantly higher in the p-TIPS group (25.8%) compared to those undergoing standard medical treatment (6.4%).[121] This increase was observed despite most patients who experienced cardiac failure (87% in the p-TIPS group) having normal echocardiography results. Interestingly, the severity of portal pressure was the sole factor associated with acute cardiac failure, with a threshold of 20 mmHg, identical to the risk of uncontrolled bleeding. However, other studies which focused on survival did not report deaths due to cardiac failure. Given this information, it is not currently feasible to formulate specific recommendations or guidelines for cardiac assessment in p-TIPS candidates.

In patients with cirrhosis and PH-related bleeding fulfilling high-risk criteria, should a pre-emptive TIPS be used beyond the "72 hour window" to improve outcomes compared to alternative treatments?

Recommendations

- A pre-emptive TIPS should be offered within the first 72 hours to improve survival in patients with cirrhosis and PH-related bleeding, fulfilling high-risk criteria **(LoE 1, strong recommendation, strong consensus).**
- After the 72-hour window, selected patients may still benefit from a p-TIPS, and referral to an expert centre may be considered **(LoE 4, weak recommendation, strong consensus).**

While the idea of extending the application of the p-TIPS strategy beyond the initial 72-hour period is appealing due to the logistical challenges many centres face in implementing a p-TIPS, there is currently no strong data to support this concept. Studies on the natural history of AVB suggest that the risk of rebleeding and associated mortality peaks in the initial days post-bleeding, aligning with the baseline risk after 3 weeks.[104]

Two retrospective studies exploring the concept of "late" p-TIPS creation have not yielded convincing evidence. One retrospective analysis of a TIPS registry found no significant difference in rebleeding rates or overall mortality between patients who received a "late" p-TIPS and those treated within the first 72 hours.[133] However, the "late" p-TIPS patients had lower portal pressure and better liver function, potentially accounting for their improved 1-year survival. Another study found no difference in rebleeding and survival rates between "early" and "late" p-TIPS,[134] but it excluded patients who failed to control bleeding or experienced early rebleeding. This introduces a significant selection bias, as excluding patients who experienced bleeding events from the "late" p-TIPS group leaves out those who would have otherwise been included. As a result, the study primarily focuses on a lower-risk population within the "late" p-TIPS group.

Despite these findings, the concept of "late" p-TIPS creation deserves further research. In the most recent individual data meta-analysis of p-TIPS studies, a sensitivity analysis excluded control group patients who died within the first few days to 2 weeks, aiming to eliminate "survival bias". This analysis suggested a survival advantage with p-TIPS creation extending up to 1 week for patients with Child-Pugh class B cirrhosis and

active bleeding, and up to 2 weeks for those with Child-Pugh class C cirrhosis.[125] This implies that there might be a wider window of opportunity for treating high-risk patients with AVB, which warrants a case-by-case discussion and further exploration.

After the first episode of PH-related variceal bleeding in patients with cirrhosis, should a TIPS be used to improve outcomes compared to standard secondary prophylaxis (NSBB + EBL)?

Recommendations

- Standard secondary prophylaxis (NSBB + EBL) should remain the first line of treatment. In case of secondary prophylaxis failure, a TIPS should be considered in selected patients **(LoE 5, strong recommendation, strong consensus).**
- In patients with a first episode of PH-related variceal bleeding not fulfilling the high-risk criteria and with grade 2 ascites or PVT, TIPS creation may be the preferred strategy **(LoE 2, weak recommendation, strong consensus).**

Following the dynamic period of RCTs that compared bare stent TIPS and endoscopic treatments (mainly sclerotherapy) with or without non-selective beta blockers (NSBBs), it was proven that TIPS placement more effectively reduces rebleeding rates at the cost of a higher incidence of HE without impacting overall survival rates. The landscape for secondary prevention of variceal bleeding using expanded polytetrafluoroethylene (ePTFE)-covered stents for TIPS remains largely unexplored.

Recent studies employing ePTFE-covered stents for TIPS creation in secondary prevention have not shifted existing evidence, mainly because the sample size calculation was tailored to diminish rebleeding rates. Consequently, these studies lack the statistical power to demonstrate survival benefit. Additionally, late randomisation introduces selection bias toward lower-risk patients, as seen in Sauerbruch *et al.*'s study.[135] In Holster *et al.*'s study, considerable protocol deviations (8% lost to follow-up, 16% in the TIPS arm switched to the endoscopy arm, and 17% vice versa due to rebleeding or refractory ascites) complicate the interpretation of results.[136]

Designing an RCT for secondary prevention of variceal bleeding with survival as the primary endpoint poses significant challenges. Once high-risk criteria are applied and p-TIPS candidates are excluded, the pool of eligible patients (Child-Pugh A and B up to 7 points) diminishes substantially. The latest meta-analysis of individual data examining the role of TIPS creation in preventing further decompensation (a composite endpoint including variceal rebleeding, worsening or new onset of ascites, or HE) indicated that TIPS creation enhances survival and reduces further decompensation.[137] Moreover, when solely analysing the studies dedicated to secondary prevention of variceal bleeding, the benefit of preventing further decompensation is maintained.

In two Asian studies, patients with AVB and PVT were randomised to receive either a TIPS or standard treatment as secondary prophylaxis.[138,139] Patients in both arms were also treated with anticoagulation for at least 6 months, while local thrombolysis was also used in Lv *et al.*'s study.[138] Both studies demonstrated the effectiveness of a TIPS in preventing rebleeding and improving portal vein recanalisation (PVR) without increasing the risk of HE or leading to a difference in survival.

In patients with bleeding related to gastric varices or ectopic varices, or portal hypertensive gastropathy, should a TIPS be used as a first-line treatment to improve outcomes compared with standard therapy?

Recommendations

- In patients with bleeding related to gastric varices or ectopic varices, a TIPS may be a good first-line alternative to NSBBs + endoscopic treatment or balloon-occluded retrograde transvenous obliteration to prevent rebleeding, especially if the bleeding is from type 2 gastro-oesophageal varices or type 1 isolated gastric varices **(LoE 3, weak recommendation, consensus).**
- TIPS creation may be considered for PH-related gastropathy refractory to standard treatment with NSBBs and endoscopic therapy **(LoE 4, weak recommendation, strong consensus).**

Up to 20% of patients with cirrhosis develop gastric varices (GVs), which may bleed more severely than oesophageal varices, with a higher recurrence rate and mortality. Moreover, bleeding from GVs may occur at lower portal pressure than oesophageal varices.[140] According to Sarin's classification of GVs, the origin and drainage of the GVs are different; thus, the treatment efficiency could also be different.[141] Type 1 gastro-oesophageal varices or GOV1 (the GVs of the lesser gastric curvature) originate from the left gastric vein and drain toward oesophageal varices and the azygos venous system; thus, their treatment is similar to that of oesophageal varices (endoscopy and TIPS creation are very efficient). Type 2 gastro-oesophageal varices (or GOV2) and type 1/2 isolated gastric varices (or IGV1 and 2) originate from the posterior or short gastric veins and drain toward the inferior phrenic vein, which terminates either in the left renal vein or the inferior vena cava. In most GOV2, the blood flow originates from both the left gastric vein and posterior and short gastric veins. In this case, the existing evidence favours balloon-occluded retrograde transvenous obliteration (BRTO).

In the therapeutic arsenal of GVs, NSBBs combined with endoscopic injection of tissue adhesives (*e.g.* N-butyl-cyanoacrylate/thrombin), TIPS placement, and BRTO are the main techniques. There is not much coherent evidence to favour one or other approach. Therefore, the identification of the anatomical drainage of the GVs with cross-sectional

multiphasic imaging and local expertise should guide decision making. However, a TIPS combined with collateral embolisation seems more efficient than a TIPS alone in patients with gastrorenal shunt and cardiofundal varices.[142]

An RCT compared p-TIPS creation (first 5 days from admission), combined or not with collateral embolisation, with standard treatment (vasoactive drugs and endoscopic injections of tissue adhesives) in patients with bleeding from GOV2 and IGV1.[143] Despite not achieving the calculated sample size due to a low inclusion rate, the study demonstrates the superiority of p-TIPS creation over endoscopic treatment regarding bleeding-free survival in the subgroup of patients with Child-Pugh class B and C cirrhosis. A more recent multicentric French RCT supports these findings.[144]

The evidence that compares TIPS creation with BRTO is limited to a few cohort studies, the majority of which are retrospective and originate from Asia, using non-covered stents for the TIPS. Two similar meta-analyses conclude that there is a similar technical success in immediate bleeding control, while BRTO seems to reduce the long-term rates of rebleeding and HE more than TIPS at the cost of being more likely to aggravate ascites.[145,146] Recent advances in the RTO technique, including plug-assisted RTO and coil-assisted RTO, have reduced complications and streamlined the procedure.[1] Ultimately, treatment decisions should be made individually, considering the anatomy of the portal venous system and local expertise. TIPS creation might be the preferred choice for younger patients with good liver function, presence of PVT and a low risk of HE, while BRTO or its variants might be more suitable for those at a higher risk of shunt-related complications.

Despite a higher rebleeding rate and potential rebleeding at a lower portocaval pressure gradient (PCPG), a TIPS could be efficient in treating ectopic varices, especially if combined with collateral embolisation.[147,148] However, due to limited evidence, the treatment of ectopic varices needs to be standardised and based on local anatomy and the existing expertise in each centre.

The evidence supporting the use of a TIPS in portal hypertensive gastropathy is even more limited.[149,150] It primarily consists of a handful of case series demonstrating the benefits of a TIPS on endoscopically assessed portal hypertensive gastropathy and reducing transfusion requirements in patients with frequent red blood cell transfusions.

Ascites and kidney

In patients with cirrhosis and ascites, in which patients should TIPS be considered to improve outcomes (i.e. reduce further decompensation, LT, death) compared to alternative treatments?

Recommendation

- In patients with cirrhosis receiving repeated large volume paracenteses despite optimal medical therapy, a TIPS should be discussed early to improve patient outcomes **(LoE 1, strong recommendation, strong consensus).**

Refractory or recurrent ascites is a severe complication of cirrhosis, with a mean 1-year survival rate of 50%.[151] The definition of *recurrent* and *refractory* ascites remains challenging. Indeed, ascites is defined as refractory when it cannot be mobilised or whenever its early recurrence cannot be prevented by medical therapy. The International Ascites Club[152,153] defined *refractory* ascites as:

- resistant to diuretics in the absence of response or in the case of early recurrence of ascites under intensive diuretic therapy (400 mg/day spironolactone and 160 mg/day furosemide) combined with sodium restriction (less than 90 mmol/day of salt for at least 1 week), or
- intractable when a complication directly attributed to diuretics occurs, such as HE, acute renal failure, hyponatremia, or dyskalemia.

Ascites is considered *recurrent* when three large-volume paracenteses (LVPs) are required within a 12-month period.

These definitions stem from the inclusion criteria used in RCTs but are heterogeneously used in clinical trials and it can be challenging to apply in everyday clinical practice where "refractory ascites" is considered as an ascites that cannot be eliminated or quickly recurs after paracentesis, despite adherence to a low-salt diet and a maximum tolerated dose of diuretics.

Seven RCTs comparing TIPS placement (with uncovered stents) to LVP + albumin infusion in the treatment of recurrent/refractory ascites have demonstrated the effectiveness of TIPS placement for ascites control, ranging from 60% to 80%.[30,36,90,92,154,155] In the only RCT using covered stents, ascites control in the TIPS group was achieved in 89% *vs.* 29% for LVP + albumin.[36]

Moreover, in an individual patient data meta-analysis of 3,949 patients, TIPS creation for ascites control was associated with a decreased cumulative incidence of further decompensation (ascites, variceal bleeding, HE, jaundice, HRS-AKI, spontaneous bacterial peritonitis) in comparison to SOC for ascites (hazard ratio 0.44; 95% CI 0.37-0.54).[137]

In the first individual patient data meta-analysis on 305 patients treated with an uncovered TIPS for recurrent/refractory ascites, the actuarial probability of transplant-free survival was significantly better in the TIPS group than the LVP + albumin infusion group ($p = 0.035$).[28] In an RCT using covered stents in 62 patients, 1-year transplant-free survival was 93% in the TIPS group *vs.* 52% in the LVP + albumin group.[36]

In the individual patient data meta-analysis by Larrue *et al.* on further decompensation, the 2-year cumulative survival probability in patients receiving a TIPS for ascites control was significantly better than with SOC (0.61 *vs.* 0.40, $p = 0.0144$).[137]

As for the minimum number of LVPs, as well as the optimal observation period, it is difficult to recommend a strict threshold indicating a TIPS. These two parameters varied depending on the studies (or were not reported). What is generally agreed upon is that it is preferable to minimise the observational period to prevent deterioration in nutritional status and to reduce the exposure period to risks associated with PH. The Baveno VII consensus workshop suggested three LVPs within 12 months,[112] although scientific evidence to support this is weak.

Finally, TIPS placement was found to be cost-effective for patients with recurrent/refractory ascites when compared with LVP. In two studies from two different European countries, the use of a TIPS resulted in substantial cost savings of €25,687 and £17,983, respectively.[156,157] TIPS placement was also associated with health benefits with an incremental gain in quality-adjusted life years of 0.5 per patient.[156]

In patients with cirrhosis and hepatic hydrothorax, in whom should a TIPS be considered to improve outcomes (i.e. reduce further decompensation, ACLF, LT, death) in comparison with alternative treatments?

Recommendation

- A TIPS may be considered in patients with cirrhosis and refractory hepatic hydrothorax to improve patient outcomes **(LoE 4, weak recommendation, strong consensus).**

Hepatic hydrothorax has been associated with poor survival (median survival between 8 to 12 months). The definition of its refractory nature has not been clearly described. It could be defined as a hydrothorax requiring repeated thoracenteses despite well-managed diuretic medical treatment. Whenever possible, LT is the best treatment option for patients with refractory hepatic hydrothorax. As for the ascites indication, a TIPS appears to be a good option as a curative treatment for hepatic hydrothorax or as a bridge to LT. Alternatives to a TIPS, such as repeated thoracenteses or indwelling tunnelled catheters, are associated with frequent complications (pneumothorax, hemothorax, empyema, leakage, *etc.*) and do not have a beneficial impact on survival.

Most studies on TIPS placement for the indication of hepatic hydrothorax are retrospective small cohorts. In a meta-analysis of six retrospective studies, the effectiveness of TIPS placement in controlling hepatic hydrothorax was complete in 56% (95% CI 45-67) and partial in 18% (95% CI 11-24).[158] Eighteen percent (95% CI 11-24%) of the 198 patients died within 45 days of undergoing a TIPS procedure.

In a propensity score-matched cohort of 243 patients with cirrhosis and hepatic hydrothorax, cumulative survival after TIPS placement was the same as that of patients without a TIPS.[159]

Like refractory ascites, poor liver function is a strong predictor of mortality,[160] and LT should be discussed.[161]

In patients with cirrhosis and HRS-AKI, should a TIPS be used to reduce morbidity or mortality compared to alternative treatments?

Recommendation

- Owing to insufficient evidence, TIPS creation cannot be recommended to reduce morbidity or mortality in patients with HRS-AKI **(LoE 4, weak recommendation, strong consensus).**

Data on TIPS creation in patients with HRS-AKI are very limited. Currently, LT is the best therapy for HRS-AKI since a large majority of patients have severe liver failure and, therefore, a contraindication to a non-urgent TIPS. According to the old definition of HRS, most studies used a creatinine threshold of 1.5 mg/dl. In a meta-analysis of nine studies including 128 patients, 1-year survival was reported to be 47% for HRS-AKI. TIPS creation effectively improved renal function in 93%, but liver failure and septicaemia were the major causes of death.[162] The largest study included 14 patients who were ineligible for LT who were treated with a TIPS; survival was only 20% at 1 year.[89] An RCT, "Liver-HERO," is currently being led to compare 12-month liver transplant-free survival in patients assigned to TIPS compared to SOC (terlipressin and albumin).[163]

In patients with cirrhosis and HRS-NAKI, should a TIPS be used to reduce morbidity and mortality compared to alternative treatments?

Recommendation

- A TIPS may be considered in patients with cirrhosis, ascites and HRS-NAKI to reduce morbidity and mortality **(LoE 4, weak recommendation, strong consensus).**

No RCT has been conducted in the HRS-NAKI setting. In a meta-analysis of nine observational studies, the 1-year survival rate for HRS type 2 was 64%.[162] Several studies, including RCTs assessing TIPS creation in refractory/recurrent ascites, have demonstrated a significant improvement in haemodynamic parameters and renal function.[89,94,164] In a recent randomized study comparing TIPS creation (n = 29) to LVP + albumin infusion (n = 33) for treating recurrent ascites, renal function significantly improved in all patients receiving a TIPS, compared to LVP + albumin.[36]

A Cochrane review, including two RCTs on TIPS creation for control of ascites,[30,90] evaluated the benefits and harms of TIPS creation (n = 64) compared with conventional treatment (n = 66) in adults with HRS. The authors concluded that kidney function may improve in participants with a TIPS (relative risk 0.53, 95% CI 0.27–1.02).[165] Nevertheless, the use of a TIPS may not result in a decrease in all-cause mortality during the first 24 months compared with conventional therapy (relative risk 0.88, 95% CI 0.55–1.38; two trials, 130 participants; I^2 = 58%; very low-certainty evidence).[165] In a recent German survey, in-hospital mortality of patients with cirrhosis decreased in those treated with a TIPS for HRS compared to standard treatment. However, the type of HRS could not be specified. Additionally, there may be confounding by indication, as the most severely ill patients may not have received a TIPS.[166]

Shunt procedure: Technical aspects

In patients with cirrhosis requiring TIPS creation, what technical aspects should be considered in the placement of a TIPS to improve outcomes?

Recommendations

- The use of real-time ultrasound guidance (trans-abdominal or intravascular) is suggested for portal vein targeting and puncture to reduce the risk of puncture-related complications and reduce the radiation exposure for patients and medical staff **(LoE 4, weak recommendation, strong consensus).**
- PCPG measurement, defined as the difference between main portal vein pressure and inferior vena cava pressure at the level of shunt outflow, should be performed after portal system catheterisation and at the end of the procedure to evaluate immediate haemodynamic change after TIPS creation **(LoE 3, strong recommendation, strong consensus).**

How to perform portal vein targeting/puncture?

TIPS creation should ideally be performed in tertiary hospitals with expertise in hepatology, diagnostic and interventional radiology, cardiology, abdominal surgery, nephrology, and intensive care. A minimum of 20 TIPS creations per year has been identified as a number associated with better outcomes, and therefore, it seems a reasonable number to define an expert centre in TIPS creation.[166–168] A trained provider with experience in TIPS creation and the management of possible procedural technical complications should perform the procedure. Due to the paucity of data in the literature, no clear recommendation can be given about the number of procedures required to be considered an "experienced operator." The procedure should be performed, as first operator, by a competent physician who has performed enough TIPS procedures under supervision and whose competency is attested by the supervising physician.

TIPS creation is considered one of the most complex and radiation-intensive procedures in abdominal interventional radiology, with major complications reported in up to 4% of patients and procedure-related mortality reported in 1% of patients; operator experience is associated with better outcomes.[169] Reaching the portal vein puncture is considered the riskiest part of the procedure and is frequently the longest step, which is associated with the possible incidence of portal vein puncture-related complications (liver capsule and gallbladder perforation, bile ducts injuries, hepatic artery injuries, extrahepatic portal vein injuries). Several approaches have been reported for intrahepatic portal venous system puncture; the most commonly used are real-time trans-abdominal ultrasound, fluoroscopic guidance with the use of bony landmarks, and indirect portography through a wedged catheter in the hepatic venous system; less frequent but possible techniques include endovascular ultrasound, wire-targeting, and cone beam CT-guided access.[170] The use of real-time trans-abdominal or endovascular ultrasound guidance for portal vein targeting seems to reduce the incidence of puncture-related complications and radiation exposure to patients and medical staff and is therefore suggested. However, no RCT comparing different techniques is available to define the safer technique to use in portal vein targeting.[162,171–175]

The portal vein branch that should be used for TIPS creation has not been widely studied. A meta-analysis showed that TIPS creation via the left portal vein branch (*vs*. the right portal vein branch) was associated with decreased rates of HE and TIPS dysfunction.[176] Of note, seven out of eight included studies were retrospective and with significant variability concerning the types and sizes of stents used. However, a recent retrospective study using the new generation of controlled expansion covered stents, found no significant differences in clinical outcomes for the right or left portal vein approaches for either refractory ascites or variceal bleeding indications.[177]

In patients with severe intra and extrahepatic thrombosis and/or cavernoma, the combined transjugular/transhepatic, transjugular/trans-splenic or transjugular/transmesenteric approaches have been used after failure of the conventional transjugular approach or as first-line approaches.[178–183] Due to the paucity of data in the literature, no clear recommendation can be given.

Comparative technical analyses between TIPS creation performed in LT recipients and in native livers with cirrhosis showed no significant technical difficulties with the procedure, either in whole or partial liver recipients. Overall, similar technical success is reported, although transjugular/transhepatic or transjugular/trans-splenic approaches may be required more frequently, especially in patients with piggy-back anastomoses or patients with partial LT due to compensatory hypertrophy altering the usual anatomical relationship between the hepatic and portal veins.[184–186]

How and when to measure PPG?

PPG should be measured after portal system catheterisation, after TIPS deployment, and every time the diameter of the stent is dilated and/or large collateral vessels embolised (even if general anaesthesia and deep sedation may impact on the measurement results). Haemodynamic measurements should be performed following established criteria.[112,187,188] Measuring the pressure gradient between the portal vein and the inferior vena cava (IVC) or right atrium to calculate PCPG or porto-atrial pressure gradient is still debated, and both have been proposed to estimate PPG reduction after TIPS creation and to define the haemodynamic success of a TIPS.[2,3] PPG calculated with atrial pressure is around 3.2 mmHg higher than when calculated with IVC pressure, and when used to monitor treatment, it may induce higher stent dilatation. PCPG measurement, meaning the difference between main portal vein pressure and IVC pressure at the level of shunt outflow, should be preferred since both portal vein pressure and IVC pressure are affected by the intra-abdominal pressure.[189,190] Immediate PCPG measurement after TIPS creation (during the procedure) reflects the haemodynamic changes after opening the shunt but does not reflect the haemodynamic situation after equilibration during further follow-up; of note, PCPG measurements taken under general anaesthesia or after stopping deep sedation can show significant differences compared to measurements taken at least 24 h after the procedure with the patient in a stable condition and without sedation/anaesthesia, usually underestimating the value. A second measurement performed at least 24 h after the procedure, with the patient in a stable condition and without sedation/anaesthesia, is suggested to obtain a more accurate value to use as a prognostic indicator or whenever there is uncertainty about the validity of the PCPG measurement performed at the end of the procedure.[191] A recent study confirms that early PCPG (24 to 72 hours after the procedure) is a better predictor of outcome than immediate PCPG (during the procedure).[192]

In patients with cirrhosis requiring TIPS creation, which type of stent, dilatation, and PCPG should be applied to control PH and lower the risk of HE and other shunt-induced complications?

Recommendation

- The use of ePTFE-covered stents, extending the covered stent to the hepatic vein/IVC junction, is recommended for TIPS creation since a significant improvement in patency and clinical results has been reported compared to bare metal stents. In addition, the stent should have the smallest diameter necessary for an adequate haemodynamic response (PCPG <12 mmHg) **(LoE 2, strong recommendation, strong consensus).**

Multiple studies, including randomised trials, have shown improved long-term patency and better clinical results of ePTFE-covered stents compared to bare metal stents for TIPS creation.[193–198]

The use of a TIPS-dedicated stent graft, with a self-expanding nitinol stent skeleton with a bare tract for the portal vein side and an intraparenchymal tract covered with ePTFE, is suggested since a superior patency, compared with shunts created with a coaxial combination of bare metal stent/covered stent graft, is reported.[199] Recently, TIPS-dedicated controlled expansion stent grafts have been introduced, allowing for adjustment of the diameters of the stent from 8 mm to 10 mm without passive dilation,[200] and enabling a possible calibration of the PCPG during the TIPS procedure. Limited data exist on the impact of utilising ePTFE-covered stents underdilated to diameters smaller than the nominal one, with most of the studies showing a passive expansion over time to its nominal diameter.[201–205] Extending the covered stent to the hepatic vein/IVC junction reduces hepatic venous stenoses and improves TIPS patency. The distance between the distal end of the stent and the hepatocaval junction should be inferior to 6 mm to reduce the risk of TIPS dysfunction.[206] In LT candidates, care must be taken to ensure that the stent does not extend too far into the IVC or the portal vein which can complicate hepatectomy at the time of LT.

Excessive shunting of portal blood flow is the primary cause of post-TIPS complications, including HE, liver failure, and heart failure. Since the flow depends on the diameter of the stent, using a smaller calibre ePTFE-covered stent may represent an effective strategy to prevent those complications. Of note, some studies showed that under dilatation to 6 mm may decrease the occurrence of post-TIPS HE without any differences in the risk of recurrent bleeding, ascites, or ePTFE-covered stent thrombosis.[205,207] TIPS placement should be staged, starting with the smallest stent diameter necessary for an adequate haemodynamic response, to reduce the risk of complications of excessive shunting.[3,208,209]

In the literature, haemodynamic measurements, both before and after TIPS creation, are very heterogeneous, owing to factors such as sedation use and type, timing of measurements after TIPS creation, and gradient with IVC or right atrium. All these factors markedly influence the obtained values and have impeded the identification of clear threshold haemodynamic targets. However, in patients with variceal bleeding as an indication for a TIPS, the risk of recurrent haemorrhage is markedly reduced with a PCPG of <12 mmHg or a relative PCPG reduction by >50%.[191,210] Thus, for these patients, a final PCPG <12 mmHg is strongly recommended as the haemodynamic target. In patients with ascites, attempts to correlate post-TIPS PCPG with ascites control have yielded inconsistent outcomes, and no definitive threshold is reported. Therefore, the debate on the ideal PCPG reduction for the treatment of ascites is still ongoing. However, a correlation with good outcomes in RCTs was observed when the final PCPG was maintained below 12 mmHg.[30,36,90–92,155] It is suggested that a final PCPG <12 mmHg and/or decrease by ≥60% should also be considered as a haemodynamic target.[211]

In patients with cirrhosis requiring TIPS creation, should collateral embolisation be considered to improve outcomes?

Recommendation

- Collateral embolisation may be considered in patients with persistent filling of the varices after TIPS deployment **(LoE 3, weak recommendation, consensus).**

A recent meta-analysis,[212] including two RCTs and nine observational studies, showed a reduced risk of rebleeding in patients treated with a TIPS and collateral embolisation compared to a TIPS alone, with no differences regarding shunt dysfunction, HE, and mortality. Of note, most data were observational, using different types of stents (bare stents, covered stents, and TIPS-dedicated covered stents) and with different embolisation techniques among the studies. This result was not confirmed in a more recent multicentre observational study (using only TIPS-dedicated covered stents) in which no benefit in the rebleeding recurrence rate was observed among patients treated with a TIPS and variceal embolisation compared to patients treated with a TIPS alone.[213] Variceal embolisation may be considered in patients with persistent filling of the varices after TIPS deployment. Although no RCTs comparing different embolisation techniques are available, the use of glue with/without coils in the embolisation of varices may be preferable over coil embolisation alone since better results have been reported in retrospective observational studies.[214–216]

The presence of large spontaneous portosystemic shunts (LPSS) is associated with an increased risk of HE and mortality in patients with cirrhosis.[217–219] A recent meta-analysis performed on four studies, all performed in China and all on patients who underwent TIPS creation to treat variceal bleeding, showed that embolisation of LPSS during TIPS creation reduced the risk of overt HE. Variceal rebleeding, overall mortality, and shunt dysfunction were not significantly different among the embolised LPSS group and the group of patients without LPSS or the group of patients with LPSS who were not embolised.[220] This data was confirmed in a recent RCT performed in China and on patients who underwent TIPS creation to prevent variceal bleeding.[221] Those data need to be viewed with caution since the predominant aetiology of cirrhosis was

hepatitis B, which is not reflective of many other parts of the world, and the indication for a TIPS was always secondary prophylaxis of variceal bleeding. Whether prophylactic embolisation of any shunt or only LPSS after TIPS creation reduces the risk of post-TIPS HE requires confirmation. Of note, the combination of medical prophylaxis and the use of controlled expansion stents could be of benefit for most of the patients undergoing TIPS placement, reserving LPSS embolisation only for patients with persistent overt HE after TIPS creation.

In patients with cirrhosis requiring elective TIPS creation, should haemostatic alterations be corrected to decrease procedure-related complications?

Recommendation

- In patients requiring TIPS placement, routine correction of haemostatic alterations is not recommended to improve outcome owing to a lack of supportive evidence **(LoE 4, strong recommendation, strong consensus).**

Patients with cirrhosis develop complex haemostatic alterations, including reduced platelet number and function and decreased plasma levels of coagulation and fibrinolysis proteins. Despite their prevalence, these indicators do not accurately portray the overall haemostatic equilibrium or the risk of bleeding during procedures.[112,222] Evaluation of the inherent procedural risk in patients with cirrhosis has long been extrapolated from periprocedural management of anticoagulation, and there is a lack of uniform definition for major bleeding in patients with cirrhosis.[223] Notably, there is a lack of a standardised definition for major bleeding in this patient population. Despite recent international guidelines and expert opinions, consensus remains elusive regarding the bleeding risk associated with TIPS procedures and the threshold values for haemostatic parameters deemed safe for its implementation.[224] Furthermore, it remains uncertain whether correcting these haemostatic parameters is beneficial in the context of TIPS placement. Bleeding complications during TIPS procedures are primarily associated with capsular puncture during portal vein access. To mitigate these risks and the likelihood of bleeding, the utilisation of ultrasound guidance for portal vein puncture has been advised.[222,223]

In patients with cirrhosis requiring elective TIPS creation, should periprocedural broad-spectrum antibiotic prophylaxis be used to improve treatment outcomes and prognosis?

Recommendation

- In patients with cirrhosis undergoing elective TIPS creation for a non-bleeding indication, antibiotic prophylaxis cannot be systematically recommended for improving outcomes and prognosis. Given the severity of endotipsitis, studies are warranted to identify at-risk patients who could benefit from antibiotic prophylaxis **(LoE 4, weak recommendation, consensus).**

Acute infections directly associated with TIPS placement are infrequent but carry significant potential severity, impacting prognosis and posing a challenge due to the irremovability of the stent.[225–227] The hypothesis is that early infections may result from bacterial seeding during the initial procedure or hospitalisation. Nonetheless, the effectiveness of prophylactic antibiotics in preventing TIPS-related infections remains controversial. The only RCT evaluating the impact of a single dose of a second-generation cephalosporin (cefotiam) *vs.* placebo in patients undergoing TIPS creation was performed in 1998 when covered stents were unavailable. The study could not demonstrate superiority in preventing post-interventional infection.[228] Another study, which compared two ceftriaxone regimens, did report a reduced incidence of bacterial infections after TIPS creation compared to the reported rates.[229] Recent data suggest that patients with prior biliary intervention are at higher risk of infection after the TIPS procedure.[230] However, robust studies demonstrating the benefit of the use of periprocedural antibiotics in decreasing infection complications after TIPS creation are lacking. Despite the lack of evidence, the decision regarding antibiotic use may be based on a case-by-case discussion and local protocols.

Follow-up of patients after TIPS creation (Table 4)

In patients with cirrhosis treated with a TIPS, how should TIPS effectiveness be monitored (which interval [regular vs. when clinically indicated], examination, lab test) to improve outcomes (e.g. reduce further decompensation, LT, death)?

Recommendations

- Early complications, including bleeding and/or ischaemia with subsequent liver failure (lab tests, ultrasound if necessary), should be excluded before discharge **(LoE 4, strong recommendation, strong consensus).**
- The clinical course, including checks for complications and organ function, should be closely monitored within 4-6 weeks following TIPS placement and thereafter at least every 3 months within the first year **(LoE 4, strong recommendation, strong consensus).**
- TIPS dysfunction should be suspected in cases of recurrence of PH complications, re-bleeding, new development of ascites, or the non-resolution of ascites after 4-8 weeks **(LoE 4, strong recommendation, consensus).**

Clinical effectiveness

The clinical success of TIPS creation can be interpreted based on the indication for the TIPS itself, which is the absence of variceal bleeding or the resolution of the ascites/hepatic hydrothorax.[3] However, since the complications triggering TIPS placement result from severe PH, clinical effectiveness should be questioned as soon as PH-related complications recur,

Table 4. Recommended follow-up after TIPS creation.

	Before discharge	Between 4-6 weeks	M3	M6	M9	M12
General examination including cardiac and hepatic signs of decompensation	✓	✓	✓	✓	✓	✓
Clinical signs of HE and grading	✓	✓	✓	✓	✓	✓
Haemoglobin, platelet count, INR, serum bilirubin, serum albumin, transaminases, GGT, alkaline phosphatase, serum creatinine, serum sodium	✓	✓	✓	✓	✓	✓
Child-Pugh and MELD scores	✓	✓	✓	✓	✓	✓
Serum alpha fetoprotein				✓		✓
Doppler ultrasound		✓		✓		✓
Angiography and PPG measurement	Optional	Whenever shunt dysfunction is suspected clinically or at Doppler ultrasound				
Transthoracic echocardiography		Whenever cardiac decompensation is suspected				

GGT, gamma-glutamyltransferase; HE, hepatic encephalopathy; INR, international normalized ratio; MELD, model for end-stage liver disease; PPG, portosystemic pressure gradient.

independently of the indication. Yet, in patients with complete PVT or cavernoma who underwent TIPS creation for PVR, effectiveness can be monitored with a CT scan performed 2 to 4 weeks after the procedure to evaluate the effect of the stent and of the lytic effect of the restored flow in the portal system on PVT.

Clinical efficacy should also be followed after discharge (*e.g.* 4-6 weeks after TIPS creation), and then every 3 months for the first year and every 6 months thereafter. Where variceal bleeding is the indication, after 6 weeks the risk of rebleeding is rather low,[135] while in the context of TIPS creation for ascites, the absence of ascites is a good prognostic sign.[211]

Complications

Not only the clinical effectiveness but also potential complications of a TIPS should be monitored closely. Complications that occur during follow-up can be classified as a direct consequence of the intervention or as a secondary failure of a specific organ.[2]

The primary interventional complications include ischaemia, bleeding, and leaks, particularly in the peritoneum or the biliary system, as well as vascular injuries.[231] Incorrect positioning or migration of the stent is also considered a potentially fatal emergency, as these have led to vascular perforation in individual cases in the past. However, the development of newer covered stents with specific positioning aids has significantly reduced both the risk of mispositioning and the frequency of leaks and bleeding.[194] After the use of sedatives and/or general anaesthesia, postinterventional monitoring may even include monitoring in the intensive care unit.

The day after the intervention, transaminases, cholestasis parameters, including bilirubin, coagulation parameters, and blood count parameters, should be determined. The goal is early detection of possible complications, especially procedure-related complications such as ischaemic changes in the liver.

Encephalopathy and acute liver failure occur more frequently with increasingly impaired liver function as measured by the Child-Pugh and MELD scores, but collaterals and haemodynamic changes after TIPS creation also play a major role.[233] Therapeutically, these can be addressed, if persisting despite medical treatment, by embolisation of collaterals and/or reduction of the shunt volume through the TIPS (TIPS reduction). In case of persistence or progression of hepatic failure, a LT must be discussed in addition to medical stabilisation of the patient (circulation, coagulation, specific organ function).[232]

Secondary organ-related complications, on the other hand, are usually promoted by pre-existing factors such as organ function or haemodynamic changes.[232,233] Here, for example, the nephropathy associated with ionated contrast media or, in the case of a corresponding cardiomyopathic predisposition, increased cardiac stress after TIPS placement leading to the development of pulmonary oedema should be considered.[234]

In patients with cirrhosis and PH treated with a TIPS, which imaging modality (ultrasound vs. CT/MRI) should be used during follow-up to identify shunt dysfunction?

Recommendations

- The diagnosis of TIPS dysfunction should be carried out in the sequence of Doppler ultrasound, angiography, and then PCPG measurement **(LoE 4, strong recommendation, strong consensus).**
- Routine Doppler ultrasound examinations should be performed 4-6 weeks after TIPS creation, and then at 6-month intervals along with recommended screening for HCC or whenever TIPS dysfunction is suspected **(LoE 4, strong recommendation, strong consensus).**

The clinical success of TIPS creation, *i.e.* the absence of variceal rebleeding or the resolution of ascites, is usually combined with sonographic control, particularly of the flow velocity in the portal vein and in the stent.[2,235] Ultrasound, while having moderate specificity, can serve as an initial screening method for detecting stent dysfunction based on maximum flow velocity at the portal vein and direction of flow in the intrahepatic portal vein branches.[236] Routine invasive transjugular imaging of the TIPS tract under fluoroscopy is not recommended except in cases of Doppler sonographic or clinical suspicion of TIPS dysfunction.

In the case of non-covered stents in particular, thrombosis and hyperplasia of the intima result in closure in over 50% of cases within the first 2 years, while covered stents remain open in over 75% over the same period. A multicentre, randomised, single-blind study from France examined the difference between these two types of stents. It showed a 39% reduction in the risk of developing TIPS stenosis in the arm with covered stents. However, the rate of TIPS dysfunction was still 44% at 2 years, so TIPS function should be monitored regularly.[194]

Due to the acoustic barrier of the sheath in covered stents, the flow measurements are technically difficult to assess within the first 7-14 days using sonography; but sonography can detect procedural complications before patients are discharged.[235] Doppler ultrasound monitoring is recommended every 6 months, consistent with the recommended surveillance for the development of HCC.[237] Invasive portography, including portal pressure measurement, is recommended in cases of ultrasound findings of dysfunction or in the absence of clinical success.[238]

Doppler sonography can be used to measure the flow velocity within the TIPS tract and in the upstream sections of the portal vein and the downstream hepatic vein. In the case of TIPS stenosis, there are increased or decreased flow velocities within the shunt and possibly a decreased flow velocity in the portal vein trunk.[239] Contrast-enhanced portal-venous CT angiography is the method of choice for anatomical visualisation of the portal-venous vascular axis. Contrast-enhanced portal venous MR angiography can be used as an alternative to CT angiography. Compared to CT angiography, the intraluminal portion of the TIPS or stent graft is usually less easy to assess due to metal artifacts. Corresponding stenoses are often not sufficiently quantifiable; high-grade stenoses within the stent graft cannot be differentiated from occlusions with sufficient certainty and therefore, in cases of doubt, haemodynamic assessment is recommended.

In patients with cirrhosis treated with a TIPS, is systematic vs. "a la carte" haemodynamic measurement recommended in the follow-up to prevent shunt dysfunction?

Recommendation

- Angiographic visualisation, including the PCPG measurement, should be performed in case of clinical and/or sonographic suspicion of TIPS dysfunction but not systematically **(LoE 4, strong recommendation, strong consensus).**

The portal pressure measurement is usually carried out as a success check immediately after TIPS creation as part of the procedure.[231,232]

In the era of bare stents, a re-intervention for prevention of early dysfunction was standard, but this procedure has been largely abandoned. Still, recent data suggest that the pressure changes over time shortly after TIPS placement, especially after using sedatives and/or general anaesthesia.[191] The early PCPG (a few days after the TIPS procedure) is a better reflection of long-term PCPG than immediate PCPG (just after the procedure).[191,192] Yet, in the absence of a clinical need for TIPS revision, there is no hard evidence to support routine angiographic re-intervention for clinical improvement of patients. Therefore, invasive visualisation of the TIPS including measurement of portal pressure is recommended only in the case of abnormal or unclear ultrasound findings or in the absence of clinical success.[238] However, in centres with sufficient resources, a pre-discharge re-evaluation of the PCPG is advisable.

In patients with cirrhosis treated with a TIPS, how should HE and cardiac function be monitored to prevent decompensation (vs. no monitoring)?

Recommendations

- Following TIPS creation, overt HE should be classified clinically based on West Haven criteria as part of regular follow-up **(LoE 4, strong recommendation, strong consensus).**
- Following TIPS creation, if there is clinical suspicion of cardiac decompensation, evaluation using transthoracic echocardiography is recommended. In case of pathological findings, right heart catheterisation with pressure measurement should be performed in cases of severe cardiac decompensation, suspected pulmonary hypertension or non-response to treatment **(LoE 4, strong recommendation, consensus).**

Hepatic encephalopathy

Despite careful patient selection, the risk of episodes of HE is increased after TIPS implantation. The incidence of post-TIPS HE varies between 15% and 67% in 2 years. The incidence of persistent overt manifest HE is 8%, while *de novo* covert HE occurs in about a third of patients.[41,240–243] Psychometric examinations are particularly helpful in the diagnosis of covert HE. This is particularly important because the presence of covert HE may be associated with the development of overt HE.[244,245] Still, there is insufficient data to recommend specific tools for the routine assessment for covert HE in patients after TIPS creation, and further studies are required.

There is not sufficient evidence on the optimal screening frequency for covert HE after TIPS placement. Due to the increased rates of HE within the first 2 years after TIPS creation, early screening of HE, *e.g.* before hospital discharge and as part of regular follow-up care (see above), seems reasonable. Overt HE in patients with a TIPS is assessed using the West Haven criteria, similar to the approach for patients without a TIPS.[49,246]

Cardiac function

A TIPS significantly affects portal venous and systemic haemodynamics, as well as the cardiac function of patients with cirrhosis.[70,234,247] Data on the incidence of symptomatic heart failure after TIPS creation is inconsistent. A retrospective study described a symptomatic heart failure rate of only 0.9% after TIPS placement. However, a prospective study from France describes the development of heart failure after TIPS placement in 20% of patients within 1 year. The mortality rate in these patients was high at 25%.[62,63] A prospective case-control study showed a lower rate of hospitalisation for cardiac decompensation for controlled expansion stents that were only dilated to a diameter of 8 mm compared to underdilated

covered stents (nominal diameter 10 mm, underdilated to 8 mm and passively expanding to 10 mm).[248]

This evaluation of risk has not been followed by studies demonstrating its role in changing clinical practice, so no recommendation can be made yet. Some early haemodynamic and cardiac changes appear to resolve within the first few weeks after TIPS placement.[247] Significant changes with prognostic significance can be detected as early as 6 weeks after TIPS placement using comprehensive echocardiography techniques (*e.g.* myocardial deformation imaging with speckle tracking analysis).[70]

However, it is reasonable that patients with borderline cardiac findings (*e.g.* according to the Toulouse algorithm[63]) before TIPS creation, be monitored closely for cardiac failure after the procedure, although high-quality studies are lacking.

In patients with cirrhosis treated with a TIPS, when should a revision of the shunt be performed to improve outcomes (morbidity related to PH recurrence)?

Recommendations

- Angiography of the TIPS, including measurement of PCPG, should be performed when there is clinical non-response or relapse of PH-related complications or in cases where there is evidence of TIPS dysfunction on Doppler ultrasound **(LoE 4, strong recommendation, strong consensus).**
- Before TIPS revision, uncontrolled infection, liver and cardiac failure, or severe or unresponsive HE should be excluded **(LoE 4, strong recommendation, strong consensus).**
- TIPS revision with dilation, restenting and/or embolisation of collaterals should be performed as soon as possible, especially in cases of bleeding complications **(LoE 4, strong recommendation, strong consensus).**

If clinical symptoms of PH reappear or get worse more than 3 months after TIPS creation, TIPS dysfunction should be ruled out invasively after exclusion of other causes. If the patient is bleeding from ectopic varices, embolisation of the varices should be considered in addition to TIPS revision (especially whenever there is a persistent filling), as ectopic varices can bleed even at low pressure.[140,249]

Doppler sonography should be used first line to detect TIPS stenosis. There may be increased or decreased flow velocities within the shunt and possibly a decreased flow velocity in the portal vein trunk. In a recent meta-analysis on ultrasound diagnosis of TIPS dysfunction, the sensitivity was 0.82 with a low specificity of 0.58[239]. However, the sensitivity and specificity for TIPS occlusions are 0.96 and 1. In the case of TIPS occlusion, there is a stop-flow or a hepatofugal blood flow and a reduced compressibility of the vein. Contrast-enhanced portal-venous CT angiography is the method of choice for anatomical visualisation of the portal-venous vascular axis.

Angiographic TIPS revision should involve morphological evaluation of the TIPS and measurement of the pressure gradients. A stenosis of 50% is often used as a criterion to define TIPS dysfunction, although a precise definition does not exist. The PPG should be reduced to below 12 mmHg in the event of bleeding.[112,250] In treatment-refractory ascites, the optimal PPG is less precisely defined.[251] Pressure gradients of less than 8 mmHg are associated with an increased risk of HE.[205] With the introduction of stent grafts, which can be better controlled with a diameter between 8 and 10 mm, the risk of secondary excessive shunting was significantly reduced.[200]

Technical aspects of TIPS revision

Current clinical practice focuses on stepwise dilatation of the newly implanted TIPS, as secondary dilatations are technically significantly less complex compared to TIPS reductions. As a rule, a simple angioplasty of the TIPS tract with a balloon catheter using an inflation syringe is sufficient. Data indicating that the implantation of a covered stent in the initial TIPS tract is superior to balloon angioplasty alone are mostly older and probably reflect the fact that the initial TIPS was created with bare metal stents.[252,252]

Several factors may contribute to TIPS dysfunction, with the most common being: stent misalignment in the cranial part, where the stent may protrude, creating a functional obstruction to outflow. Stenoses at the venous end are easy to detect during venography and are usually caused by too short a landing zone of the selected stent/stent graft. In addition to visual diagnostics using venography, the haemodynamic relevance of this finding should be documented by a pressure measurement with a withdrawal curve, whereby the pressure drop in the pressure curve can be documented exactly at the point of the circumscribed cross-sectional reduction. If there are corresponding findings, the TIPS tract should be extended by overlapping implantation of additional stents/stent grafts up to the vein opening into the vena cava to achieve alignment of the TIPS course and unobstructed volume flow.

Another common cause is kinking in the caudal part of the TIPS. Simple balloon dilatation is rarely effective. In the case of rigid stenosis and kinking, therapy consists of implanting balloon-expandable stents with higher radial force to achieve harmonious alignment at the transition between the portal vein lumen and the parenchymal TIPS tract.

Finally, partial coverage of the intraparenchymal trajectory may lead to dysfunction, in which case the use of a stent graft is recommended, as it significantly improves patency compared to uncovered stents.

In the case of complete occlusion of the TIPS tract, mechanical thrombectomies or catheter-assisted thrombolysis with or without stent implantation are possible approaches.[253] If the transjugular approach fails, the pull-through technique or the trans-splenic approach can be used in selected patients, combined with a rendezvous procedure transjugularly.[254–256] However, these are rather small series and in very specific cases. In other cases, a parallel new TIPS insertion can also be evaluated.[257]

In patients with cirrhosis treated with a TIPS, when should a shunt reduction or occlusion be performed to improve outcomes (morbidity related to over-shunting-related complications)?

Recommendations

- In patients with acute clinical symptoms of over-shunting (*e.g.* parenchymal liver failure, cardiac failure) in the absence of competing collaterals, the TIPS should be reduced or occluded **(LoE 3, strong recommendation, strong consensus).**
- In patients with chronic clinical symptoms of over-shunting (*e.g.* more than three severe HE episodes or chronic HE despite optimal medical therapy) and in the absence of competing collaterals, the TIPS should be reduced or occluded **(LoE 3, strong recommendation, strong consensus).**
- In cases with significant competing collaterals (*e.g.* hepatofugal flow through collaterals despite a functioning TIPS), collateral embolisation should be performed prior to TIPS reduction or occlusion **(LoE 4, strong recommendation, strong consensus).**

TIPS reduction

In patients treated with a TIPS who experience complications of overshunting, LT should be discussed in parallel with the reduction of the shunt diameter.

The most frequent clinical sign of over-shunting is HE. In rare cases, perfusion disorders of the liver parenchyma can occur to varying degrees, ranging from transient transaminase elevations to manifest liver ischaemia with structural parenchymal changes (*e.g.* liver necrosis).

Yet, frequently, large-volume collaterals can maintain a pre-existing spontaneous portal venous shunt and, together with a newly created TIPS tract, can result in an excessively large shunt volume exceeding the already defined total shunt area.[217] These represent a portal-venous competitive flow to the TIPS tract and their haemodynamic patency can be hard to measure and assess. In the case of refractory HE and/or liver dysfunction after TIPS creation, a treatment attempt with embolisation of these ectopic varices/spontaneous shunts should first be carried out if clinically possible.[258,259]

Episodes of HE after TIPS creation have been reported in the literature at a frequency of up to 50% and can usually be treated conservatively. In persistent episodes of severe HE, *e.g.* three episodes of severe HE within 3 months, and in the absence of other triggers (*e.g.* infection, hyponatremia, *etc.*) it may be necessary to reduce TIPS flow.[49,260,261] More rarely, liver failure or a cardiac problem can also be the cause, which are more commonly acute complications. Several methods exist to recalibrate the diameter of the stent reported in the form of individual case reports and their use should be based on local expertise.[262,263] Additionally, in cases of severe complications, the TIPS can be completely occluded (*i.e.* using occluding devices).

In patients with cirrhosis treated with a TIPS, which procedures or treatments after the intervention (such as endoscopic screening, NSBBs, diuretics, antiplatelets, and anticoagulants …) should be used to improve control of PH-related complications compared to no treatment?

Recommendations

- NSBBs should be discontinued when the final PCPG is below 12 mmHg (unless clinically indicated for another reason) **(LoE 4, strong recommendation, strong consensus).**
- Endoscopic screening should be performed after TIPS creation in all patients whenever TIPS dysfunction is suspected, and the shunt cannot be revised **(LoE 4, strong recommendation, consensus).**
- Diuretics should be started or continued in patients with ascites and in patients at high risk of or with cardiac decompensation if kidney function permits **(LoE 4, strong recommendation, strong consensus).**
- Currently, no recommendation for routine anticoagulation or platelet inhibition to improve TIPS patency can be made **(LoE 4, weak recommendation, consensus).**

Use of NSBBs and endoscopy

Data on the use of NSBBs after TIPS creation are scarce. Even if NSBBs may have a beneficial effect on the hyper-dynamic circulation, there is no data supporting the use of NSBBs after an effective shunt (PCPG <12 mmHg).[264–266] When the final PCPG is above 12 mmHg, NSBBs should be considered because they might reduce portal pressure by an additional 20%–25%.[267,268] However, the clinical benefit of such an association remains to be shown.

Endoscopic surveillance is not routinely recommended after TIPS creation. However, in order to evaluate clinical success in patients receiving a TIPS for variceal bleeding and/or with varices needing treatment before TIPS, an endoscopy is advisable within 3-6 months after TIPS creation if PCPG is still above 12 mmHg. If TIPS dysfunction is suspected, a screening endoscopy should be performed to check for varices needing treatment.

Medication for renal dysfunction

The basic principle of TIPS placement is mainly to reduce portal pressure and increase effective blood volume and, therefore, renal perfusion. Approximately 4 weeks after TIPS creation, sodium excretion and renal function generally improve.[269] Close monitoring and re-titration of diuretics during follow-up are recommended, as patients may become sensitive to diuretics again and can then be managed according to their needs. Still, the use of diuretics should be based on their kidney function as outlined in current guidelines.[270]

Anticoagulation after TIPS creation

There is little reliable evidence regarding the role of anticoagulation or antiplatelet drugs after TIPS creation. To date,

there are only isolated reports about a possible benefit of targeted anticoagulation and platelet function inhibition after TIPS placement, which also come from the era of non-covered Nitinol stents and whose results cannot be interpolated to ePTFE-covered TIPS stents.[271,272] Recent retrospective analysis of data suggests that antiplatelet drugs improve transplant-free survival in patients with a TIPS.[273] However, it is unclear whether this is an effect on the overall progression of disease and not specifically related to the TIPS.[273,274] In summary, there is currently no evidence for or against the use of anticoagulation or platelet function inhibitors after TIPS creation except in specific conditions (*e.g.* underlying thrombophilia).

In patients with cirrhosis treated with a TIPS, how should surveillance and management (vs. no monitoring) of focal liver lesions be performed to increase the early diagnosis of HCC?

Recommendation

- In TIPS recipients, the surveillance and management of focal liver lesions should be performed according to current practice guidelines in patients without a TIPS **(LoE 3, strong recommendation, strong consensus).**

Large studies have not supported the notion of an association between TIPS placement and the development of HCC, despite earlier reports in the literature suggesting a potential link.[275] Biannual sonographic surveillance is consistent with general screening recommendations for the development of HCC.[237] Of note, MRI is feasible in patients with a TIPS.

Hepatic encephalopathy – nutrition – sarcopenia

In patients with cirrhosis treated with a TIPS, should prophylaxis of HE be used beforeTIPS creation to reduce post-TIPS HE?

Recommendations

- In patients with cirrhosis without a history of HE, rifaximin may be considered for prophylaxis of HE already before non-urgent TIPS creation **(LoE 3, weak recommendation, consensus).**
- In patients with cirrhosis with a history of HE, rifaximin should be considered for prophylaxis of HE before non-urgent TIPS placement **(LoE 2, strong recommendation, strong consensus).**

TIPS creation is associated with a risk of HE of between 35% and 50% during follow-up.[276,277] Nevertheless, it should be emphasised that the natural history of decompensated cirrhosis is also associated with a high risk of HE, even in the absence of a TIPS. A meta-analysis has suggested that HE was not significantly higher after TIPS placement, whatever the indication, when compared to SOC.[28]

Three RCTs compared different pharmacological strategies for primary prophylaxis to no treatment or placebo before and after TIPS placement. The first compared lactitol 60 g/day, rifaximin 1,200 mg/day, and placebo in 75 patients, equally distributed, with or without a previous episode of HE.[242] The 1-month cumulative incidence of HE was not different between the three groups. In the second study, 21 patients who received L-ornithine L-aspartate were compared with 19 patients who received placebo treatment. Despite a favourable change in plasma ammonia, there was no significant difference in HE occurrence within 1 week after TIPS creation (4.7% *vs*. 15.8%, p = n.s.).[278] The last one evaluated daily rifaximin, given for 2 weeks before TIPS creation and for 6 months after, *vs.* placebo. One hundred and ninety-seven patients were included. Rifaximin significantly reduced the cumulative incidence of HE during the follow-up by about 50% (53% *vs.* 34%; odds ratio 0.48; 95% CI 0.27–0.87; p = 0.015). However, in the subgroup analysis conducted in patients without a previous episode of HE, there was a trend towards a decreased risk of HE in patients treated with rifaximin but the difference was not statistically different (51% *vs*. 35%; p = 0.07).[279] More recently, a meta-analysis including five studies suggested that none of the currently available pharmacological therapies were found to be effective in preventing HE, but that the combination of lactulose and rifaximin might be.[280] However, heterogeneity was very high in this meta-analysis (I^2 = 93%), so it seems difficult to draw any conclusion. One observational study evaluating albumin infusions after TIPS placement did not show any improvement in HE occurrence within the 1-month period after TIPS placement.[281]

In patients with HE after TIPS creation, what treatment should be used to treat HE and avoid HE recurrence?

Recommendations

- Lactulose should be used to treat and prevent HE recurrence as in patients without a TIPS despite the lack of specific studies **(LoE 5, strong recommendation, strong consensus).**
- Rifaximin may be added in case of failure with lactulose or may replace lactulose in cases of intolerance **(LoE 4, weak recommendation, strong consensus).**

No study has evaluated any pharmacological treatment of HE (either overt or covert) in the specific setting of TIPS placement. Therefore, HE after TIPS creation should be treated like in any other context, *i.e*. with lactulose and/or rifaximin, also taking into account any potential precipitating factor. A meta-analysis has shown that the resolution of HE was more frequent, and survival higher, in patients treated with lactulose compared to placebo or no treatment.[282] If HE reoccurs or in the case of treatment failure, rifaximin alone or with lactulose should be started if tolerance is good.[283] In patients treated with rifaximin as primary prophylaxis before TIPS creation and who develop HE, addition of lactulose can be proposed, although no data is available on this indication. In about 8% of cases,[276] HE persists despite optimal medical treatment, and

patients develop refractory HE. Refractory HE could be defined as a persistent or recurrent HE despite lactulose and rifaximin. Shunt reduction or occlusion should then be considered. All published studies evaluating shunt modification in refractory HE after TIPS creation are retrospective[284–289] and include a very limited number of patients (10 to 33). After shunt reduction, HE improved or resolved in 48 to 100% of cases and 67% of cases, respectively. A complete occlusion of the stent was sometimes necessary but only occasionally successful. Reduction or occlusion of the shunt was associated with an increase in PPG or a high rate of recurrent ascites or bleeding. Thus, LT should be rapidly considered in refractory HE after TIPS placement.

In patients with an indication for an elective TIPS, should sarcopenia/nutritional status be assessed before the procedure?

Recommendation

- Owing to insufficient evidence, routine assessment of sarcopenia with cross-sectional imaging before elective TIPS creation cannot be recommended to reduce HE risk. However, nutritional status is an important prognostic factor in patients with cirrhosis, and diagnosis of sarcopenia may prompt interventions to improve patient outcomes **(LoE 4, weak recommendation, strong consensus).**

Sarcopenia, defined by the loss of functional skeletal muscle mass, is related to multiple causes in cirrhosis. Its prevalence ranges from 40% to 70%[290,291] and is associated with poor outcomes: in particular after TIPS creation, sarcopenia/malnutrition is associated with HE,[58] further development of ACLF,[292] TIPS dysfunction,[243] and increased mortality.[292–294] Taken together, these data should encourage the systematic screening of sarcopenia in all patients who are candidates for elective TIPS placement. However, available studies regarding sarcopenia evaluation are heterogeneous. In the study by Nardelli *et al.*, sarcopenia was evaluated by the muscle mass through the axial plane passing between the L3 and L4 intersomatic disc on a CT scan. The muscle area was normalised for stature to obtain the skeletal muscle index (SMI). Sarcopenia was defined by a SMI <38.5 cm^2/m^2 for women and 52.4 cm^2/m^2 for men. In this study, including 43 patients, the presence of sarcopenia was independently associated with further HE after TIPS creation (hazard ratio 31.3; 95% CI 4.5-218.7; p <0.001). In the study from Praktiknjo *et al.*, including 186 patients treated with a TIPS either for refractory ascites or variceal bleeding, a transverse psoas muscle thickness at the umbilical level on a CT scan of <16.8 mm/m (normalised for height) was used to classify patients with sarcopenia.[292] In multivariate analysis, sarcopenia was independently associated with higher 1-year mortality and a higher rate of ACLF development. Similarly, the retrospective study by Artru *et al.*, which included 179 patients, assessed the alterations in body composition following TIPS placement; sarcopenia was associated with increased 6-month mortality.[295] Lastly, in a retrospective study conducted by Praktiknjo *et al.* evaluating 116 patients during a long study period (1993-2014) using MRI, the fat-free muscle area was also independently associated with survival and ACLF.[243] Meanwhile, in another study, TIPS creation was associated with a significant increase in SMI and PMI (psoas muscle indices), suggesting a positive impact of TIPS placement on sarcopenia, as shown by a recent retrospective study on 52 patients.[296] Thus, the diagnosis of sarcopenia should trigger nutritional interventions but not delay TIPS creation. Frailty is defined by a decreasing physiologic reserve and increasing vulnerability to health stressors. Several tools have been evaluated, and many studies have shown that frailty is associated with poor prognosis in cirrhosis.[297] However, there is no convincing evidence in the context of TIPS placement on the association of frailty and TIPS outcomes. The only study that evaluated both sarcopenia and liver frailty index evolution after TIPS placement, albeit in only 12 patients, failed to demonstrate any change in frailty.[298] Further larger studies are needed.

In patients with sarcopenia who require an elective TIPS, should nutritional interventions before and after the procedure be considered to improve nutritional status and decrease the risk of HE?

Recommendation

- Nutritional counselling, energy intake, protein intake, and physical exercise should be considered, in all patients with cirrhosis. Whether these interventions have an impact on HE after TIPS creation is unknown **(LoE 5, strong recommendation, strong consensus).**

All patients with decompensated liver disease should receive nutritional counselling.[299] Since sarcopenia is strongly associated with HE after TIPS creation, one potential way to decrease post-TIPS HE may be to treat sarcopenia before TIPS creation. There is no data regarding the effect of nutritional interventions before or after TIPS creation on post-TIPS HE. Nevertheless, the same recommendations as those for patients with decompensated cirrhosis can be formulated.[299] Briefly, nutritional counselling should be offered to all patients. Energy intake should be as high as 35 kcal/kg/day, including a protein intake of 1.2-1.5 g/kg/day and a late evening snack. Oral alimentation should always be preferred, followed by enteral and lastly parenteral if the other two routes are unavailable. Patients should also be encouraged to increase their physical activity.

Interestingly, preliminary data have suggested that nutritional interventions can improve covert HE.[299] Whether these

data could be extrapolated to primary prophylaxis of HE before or after TIPS placement warrants further investigation.

TIPS in the context of HCC and LT

In patients with cirrhosis and HCC who require a TIPS, what should be absolute contraindications to TIPS placement?

Recommendations

- In patients with cirrhosis and HCC within transplant criteria, the same absolute contraindications for TIPS placement should be used as in patients with cirrhosis but without HCC **(LoE 3, strong recommendation, strong consensus).**
- The presence of advanced HCC is a relative contraindication and a TIPS may be considered on a case-by-case basis according to the prognosis of and treatment options for the HCC. TIPS creation through the tumour mass or in patients with tumoral portal vein invasion is not recommended **(LoE 3, strong recommendation, strong consensus).**

The presence of HCC has been considered a relative contraindication for TIPS placement, especially in patients with HCC beyond Milan criteria.[300] Position of the HCC in central segments, risk of tumour rupture and bleeding, tumour dissemination, liver failure, and increased toxicity during locoregional therapy are the main concerns when considering TIPS creation in patients with cirrhosis and HCC. However, TIPS creation could allow for oncologic treatment (destruction or systemic therapy) for HCC in patients with advanced PH.[301–304] In the era of Baveno VII, the use of a TIPS in patients with cirrhosis and HCC is not an absolute contraindication if technically feasible, particularly in the context of secondary prophylaxis of variceal bleeding, and it should be discussed with patients on a case-by-case basis.[112]

In patients with small-volume HCC, defined as those within criteria for transplantation, there is no contraindication for a TIPS except if the HCC is on the expected tract.[302] Ultrasound guidance for portal vein access is recommended when the portal vein is poorly visualised and to avoid crossing the HCC.

In patients with advanced HCC, the decision to proceed with a TIPS will depend on the suitability for HCC treatments and the prognosis of the disease.

In 2015, Qiu *et al.* published a large retrospective study including 209 patients with HCC and PH who underwent TIPS placement and other interventions with no serious complications related to this procedure. Risk factors for poor 5-year survival were: Child-Pugh class C cirrhosis, tumoral thrombosis of the portal vein, HCC diameter >5 cm, hepatic arterioportal fistulas, HCC diagnosed before TIPS, bare stent, prior HE, and transarterial chemoembolisation (TACE)/transarterial embolisation (TAE) alone.[304]

A recent systematic review by Norero *et al.* on the safety of a TIPS to manage complications related to clinically significant PH in patients with cirrhosis and HCC, involving 937 patients, reported no lethal complications and an encouraging success rate.[305] Taken together, these results suggest that careful selection of appropriate cases, coupled with the expertise of skilled TIPS operators, will help minimise severe procedure-related complications.

In patients with a TIPS and HCC, are loco-regional and systemic therapies for HCC feasible and safe? Should they be used to improve outcomes compared to no treatment?

Recommendations

- Ablation techniques and systemic therapies are both feasible and safe for the treatment of HCC in patients with cirrhosis and a TIPS who have a good performance status, have Child-Pugh class A or B cirrhosis, and have small volume tumours; thus, they can be used to improve outcomes **(LoE 4, weak recommendation, strong consensus).**
- In TIPS recipients, post-TIPS TACE should be cautiously considered due to the reduced portal venous perfusion **(LoE 5, strong recommendation, consensus).**
- If arterial endovascular treatment, such as TACE, is chosen, it should be as super-selective as possible to minimise ischaemic liver injury. Radioembolisation may be preferred to TACE, limiting the risk of liver ischaemia **(LoE 4, weak recommendation, strong consensus).**

Some retrospectives studies suggest that percutaneous ablation is feasible and has similar efficacy in patients with a TIPS or not.[301,306]

There are concerns related to the toxicity associated with endovascular treatments in patients with a TIPS, where the portal vein blood flow is reduced and consequently the hepatic arterial flow increases as part of a compensatory mechanism. The additional blocking of the arterial supply with TACE or transarterial radioembolisation could cause liver damage leading to ischaemia and increased morbidity and mortality.

The consideration of suitability for TACE in terms of safety and efficacy in patients with a TIPS and cirrhosis, should include good performance status, absence of clinical symptoms to suggest worsening liver dysfunction, and laboratory evidence demonstrating stable hepatic function.[307–311]

In a retrospective multicentre study including 512 patients, Fan *et al.* developed a prognostic model (VACEA) to predict survival in patients with HCC beyond Milan criteria treated with TACE after TIPS creation.[312] Vascular invasion, extrahepatic spread, $\log_{10}$(alpha-foetoprotein), $\log_{10}$(alanine aminotransferase), and 1/creatinine were independent predictors of overall survival. This score classified the patients into four groups. Patients in grade 1 or grade 2 had a median overall survival

similar to patients with BCLC stage A or B and were hence good candidates for TACE.

Super-selective catheterisation of segmental branches for the chemoembolisation during HCC treatment is recommended to minimise effects on non-tumoral liver parenchyma and drug-eluting bead-TACE has been reported to be safe and effective and potentially superior to conventional TACE using lipiodol-based regimens in terms of complications, liver toxicity, overall survival, time to progression, and response rate.[311]

The use of systemic therapies such as sorafenib, lenvatinib, or regorafenib after TIPS placement to treat advanced HCC (BCLC stage C) can increase survival compared to symptomatic treatment. In this group of patients, the rate of treatment-related adverse events with molecular targeted agents varied between 9.5% and 38.1%.[304]

There is more recent evidence that Y90 radioembolization could be a safe treatment option after TIPS placement and as a bridge for selected patients to transplantation, with higher rates of anti-tumour response according to WHO and EASL criteria, with a 5% rate of grade 3 clinical adverse events.[313]

In patients with cirrhosis and PVT or cavernoma awaiting a LT, should a TIPS be used to improve outcomes compared with alternative treatments?

Recommendation

- In patients with cirrhosis and complete PVT or cavernoma which progresses despite anticoagulation, TIPS creation and PVR are recommended to facilitate access to LT and enable physiological portal vein anastomosis **(LoE 4 strong recommendation, strong consensus).**

The prevalence of PVT in patients with cirrhosis ranges between 4% and 26% and its presence in patients awaiting transplantation may preclude them from receiving extended criteria donor livers.[314–316] Severe cases of chronic PVT necessitate restoring the portal inflow with physiological methods such as reno-portal anastomosis or non-physiological methods such as portocaval hemi-transposition or portal vein arterialisation that are associated with poor 5-year survival.[316–319]

Extension of the PVT and complete PVT have been associated with higher postoperative mortality and 1-year mortality; however, no major impact on outcomes is observed when porto-portal anastomosis is achieved.[319–321]

There are a few studies evaluating the benefit of a pre-transplant TIPS to decompress the portal circulation, reduce collateral circulation and potentially reduce intraoperative bleeding.[322] However, TIPS placement should be discussed with the transplant surgeons in transplant candidates, especially if the stent needs to be extended extrahepatically into the IVC or into the main portal vein towards the superior mesenteric vein.[323]

In 2015, Salem *et al.* showed adequate safety and efficacy of PVR with TIPS (PVR-TIPS) in patients with complete/near complete (>95%) portal vein occlusion and cavernoma. They reported that a TIPS could be used to recanalise the portal vein in individuals who would otherwise not be considered candidates for LT, allowing for easier portal anastomosis at LT, simplifying surgery and improving long-term outcomes.[324]

More recently, Talwar *et al.* compared the outcomes of patients with severe PVT who underwent pre-LT PVR-TIPS (mainly Yerdel 2 and 3 (no 4)) to those with minor PVT who underwent LT without PVR-TIPS. 91% of patients who received PVR-TIPS underwent an end-to-end portal vein anastomosis, and all the patients underwent physiological portal inflow. Less red blood cells were transfused during transplant, AKI was less common, and there was less need for veno-venous bypass in patients with PVR-TIPS compared to non-PVR-TIPS. Both groups had similar median overall survival. The authors concluded that PVR-TIPS improved LT candidacy in their cohort.[325,326] Such procedures should be carried out in high-volume TIPS centres with high-level expertise.

In patients with PH-related complications after LT, should a TIPS be used to improve outcomes compared with alternative treatments?

- TIPS insertion is feasible and may be considered after failure of standard treatment and/or as a bridge to liver re-transplantation **(LoE 3, weak recommendation, strong consensus).**

The main indication for a TIPS after LT is recurrent PH manifested mainly as ascites followed by variceal bleeding, as well as outflow venous obstruction. In retrospective studies, it has been reported that a TIPS appears less effective in LT recipients, compared with non-transplant recipients. TIPS creation after LT seems to provide only marginal short-term benefit in the absence of re-transplantation[323,326–328]. King *et al.* reported the outcomes of 22 LT recipients and 44 non-transplant patients (matched controls) who received a TIPS. The final PCPG was lower in the control group; the technical and clinical success was higher in the control group (95.5% *vs*. 68.2%). The mortality rate of the patients with a MELD score of >15 pre-TIPS creation was higher in the LT group.[329] The feasibility and safety of TIPS creation in partial liver graft recipients has been reported as comparable to that of whole liver graft recipients.[3,186]

Hence, the decision regarding TIPS creation and/or liver re-transplantation in these patients should be multidisciplinary and include the transplant centre.[328,330,331]

Appendix. Delphi round agreement on the recommendations of the present clinical practice guidelines.

Recommendation	Consensus
A hepatogastroenterologist should be involved in the initial decision to place an elective TIPS with subsequent consultation by a proceduralist who has competency in TIPS creation. If centre expertise is not available, referral to an expert centre is recommended **(LoE 5, strong recommendation).**	97%
Additional specialty consultations (*e.g.* transplant surgery, cardiology, anaesthesiology, haematology, neurology, nephrology, *etc*.) may be considered on a case-by-case basis **(LoE 5, weak recommendation).**	96%
The medical evaluation prior to elective TIPS creation in patients with cirrhosis should include an attentive history and physical exam focused on the presence or history of overt hepatic encephalopathy and signs of cardiopulmonary dysfunction. Laboratory evaluation should, at minimum, include INR, platelet count, haemoglobin, and comprehensive metabolic panel enabling assessment of bleeding risk, degree of hepatic dysfunction, renal function, and calculation of prognostic scores, such as MELD and/or Child-Pugh scores. Other prognostic scores (*e.g*. FIPS, MOTS) may also be considered **(LoE 5, strong recommendation).**	94%
An elective TIPS procedure should not be performed in patients with cirrhosis and severe cardiac dysfunction (right or left-sided), moderate-severe pulmonary hypertension (based on invasive measurements) despite medical optimisation, untreated severe valvular heart disease, uncontrolled systemic infection, severe or refractory overt HE without intervenable spontaneous shunt, unrelieved biliary obstruction, and lesions in the liver parenchyma that preclude TIPS creation **(LoE 2, strong recommendation).**	100%
The MELD score remains the most accurate predictive model and should thus be used to assess liver function and post-TIPS survival. A multidisciplinary approach, rather than an absolute MELD cut-off, is recommended to assess TIPS candidacy **(LoE 2, strong recommendation).**	100%
Testing for covert or minimal HE may be considered for prognostication and discussion with the patient **(LoE 3, weak recommendation).**	93%
Risk assessment for HE should include assessment of history of prior and control/response to treatment of overt HE, severity of liver dysfunction, hyponatremia, advanced age, sarcopenia, renal failure, and presence of large spontaneous portosystemic shunts **(LoE 2, strong recommendation).**	100%
Cross-sectional multiphasic imaging (CT scan or MRI) with specific consideration of portal venous phase imaging should be performed for TIPS planning **(LoE 5, strong recommendation).**	94%
Comprehensive echocardiography should be performed to assess systolic function, diastolic function, valvular structure and function, right atrial pressure, and right ventricular systolic pressure **(LoE 2, strong recommendation).**	97%
BNP or NT-proBNP may be considered for cardiac risk stratification **(LoE 3, weak recommendation).**	87%
A pre-TIPS electrocardiogram should be performed to identify potential ischaemia and/or arrhythmia **(LoE 5, strong recommendation).**	100%
Kidney function should be assessed prior to the procedure, either through measurement of sCr or GFR, (estimated or measured) **(LoE 3, strong recommendation).**	100%
Although renal dysfunction is associated with worse outcomes in patients with cirrhosis who are candidates for a TIPS, absolute sCr, CKD stage, or the presence/absence of renal replacement therapy cannot be recommended as absolute contraindication criteria **(LoE 5, weak recommendation).**	94%
Treatment of the underlying cause of cirrhosis, when available, is recommended to optimise outcomes after TIPS creation. In the absence of evidence to support delaying elective TIPS creation, the procedure should not be delayed where the aetiology of cirrhosis is treatable **(LoE 5, strong recommendation).**	90%
LT should be considered but routine pre-procedure LT evaluation is not recommended owing to insufficient evidence. Collaboration between the TIPS centre and the transplant centre is essential during the pre-TIPS evaluation to anticipate the potential need for LT on a case-by-case basis **(LoE 5, strong recommendation).**	93%
In patients with cirrhosis and failure to control acute PH-related bleeding or early recurrence of bleeding (<5 days) despite standard treatment, a salvage or rescue covered TIPS should be considered **(LoE 3, strong recommendation).**	100%
A salvage/rescue TIPS cannot be recommended in patients with cirrhosis and failure to control PH-related AVB if they have a MELD score ≥30 or lactate ≥12 mmol/L or ACLF grade 3b, which may indicate a poor prognosis even after the procedure. This is particularly true for patients who are not suitable candidates for LT **(LoE 3, weak recommendation).**	100%
In patients with cirrhosis and bleeding from oesophageal varices or type 1 gastro-oesophageal varices, Child-Pugh class B >7 with active bleeding during initial endoscopy despite vasoactive drug use, or Child-Pugh class C <14, or documented HVPG ≥20 mmHg at the time of bleeding, should be used to define high-risk patients who may obtain a survival benefit from a pre-emptive TIPS **(LoE 1, strong recommendation).**	100%
In candidates for a pre-emptive TIPS, essential preliminary evaluations may encompass parameters of liver function and cross-sectional multiphasic imaging or Doppler ultrasound **(LoE 5, weak recommendation).**	97%
A pre-emptive TIPS should be offered within the first 72 hours to improve survival in patients with cirrhosis and PH-related bleeding, fulfilling high-risk criteria **(LoE 1, strong recommendation).**	100%
After the 72-hour window, selected patients may still benefit from a p-TIPS, and referral to an expert centre may be considered **(LoE 4, weak recommendation).**	97%
Standard secondary prophylaxis (NSBB + EBL) should remain the first line of treatment. In case of secondary prophylaxis failure, a TIPS should be considered in selected patients **(LoE 5, strong recommendation).**	100%
In patients with a first episode of PH-related variceal bleeding not fulfilling the high-risk criteria and with grade 2 ascites or PVT, TIPS creation may be the preferred strategy **(LoE 2, weak recommendation).**	100%
In patients with bleeding related to gastric varices or ectopic varices, a TIPS may be a good first-line alternative to NSBBs + endoscopic treatment or balloon-occluded retrograde transvenous obliteration to prevent rebleeding, especially if the bleeding is from type 2 gastro-oesophageal varices or type 1 isolated gastric varices **(LoE 3, weak recommendation).**	93%
TIPS creation may be considered for PH-related gastropathy refractory to standard treatment with NSBBs and endoscopic therapy **(LoE 4, weak recommendation).**	100%
In patients with cirrhosis receiving repeated large volume paracenteses despite optimal medical therapy, a TIPS should be discussed early to improve patient outcomes **(LoE 1, strong recommendation).**	100%
A TIPS may be considered in patients with cirrhosis and refractory hepatic hydrothorax to improve patient outcomes **(LoE 4, weak recommendation).**	97%

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Recommendation	Consensus
Owing to insufficient evidence, TIPS creation cannot be recommended to reduce morbidity or mortality in patients with HRS-AKI **(LoE 4, weak recommendation).**	96%
A TIPS may be considered in patients with cirrhosis, ascites and HRS-NAKI to reduce morbidity and mortality **(LoE 4, weak recommendation).**	100%
The use of real-time ultrasound guidance (trans-abdominal or intravascular) is suggested for portal vein targeting and puncture to reduce the risk of puncture-related complications and reduce the radiation exposure for patients and medical staff **(LoE 4, weak recommendation).**	96%
PCPG measurement, defined as the difference between main portal vein pressure and inferior vena cava pressure at the level of shunt outflow, should be performed after portal system catheterisation and at the end of the procedure to evaluate immediate haemodynamic change after TIPS creation **(LoE 3, strong recommendation).**	100%
The use of ePTFE-covered stents, extending the covered stent to the hepatic vein/IVC junction, is recommended for TIPS creation since a significant improvement in patency and clinical results has been reported compared to bare metal stents. In addition, the stent should have the smallest diameter necessary for an adequate haemodynamic response (PCPG <12 mmHg) **(LoE 2, strong recommendation).**	97%
Collateral embolisation may be considered in patients with persistent filling of the varices after TIPS deployment **(LoE 3, weak recommendation).**	79%
In patients requiring TIPS placement, routine correction of haemostatic alterations is not recommended to improve outcome owing to a lack of supportive evidence **(LoE 4, strong recommendation).**	100%
In patients with cirrhosis undergoing elective TIPS creation for a non-bleeding indication, antibiotic prophylaxis cannot be systematically recommended for improving outcomes and prognosis. Given the severity of endotipsitis, studies are warranted to identify at-risk patients who could benefit from antibiotic prophylaxis **(LoE 4, weak recommendation).**	93%
Early complications, including bleeding and/or ischaemia with subsequent liver failure (lab tests, ultrasound if necessary), should be excluded before discharge **(LoE 4, strong recommendation).**	97%
The clinical course, including checks for complications and organ function, should be closely monitored within 4-6 weeks following TIPS placement and thereafter at least every 3 months within the first year **(LoE 4, strong recommendation).**	96%
TIPS dysfunction should be suspected in cases of recurrence of PH complications, re-bleeding, new development of ascites, or the non-resolution of ascites after 4-8 weeks **(LoE 4, strong recommendation).**	86%
The diagnosis of TIPS dysfunction should be carried out in the sequence of Doppler ultrasound, angiography, and then PCPG measurement **(LoE 4, strong recommendation).**	97%
Routine Doppler ultrasound examinations should be performed 4-6 weeks after TIPS creation, and then at 6-month intervals along with recommended screening for HCC or whenever TIPS dysfunction is suspected **(LoE 4, strong recommendation).**	100%
Angiographic visualisation, including the PCPG measurement, should be performed in case of clinical and/or sonographic suspicion of TIPS dysfunction but not systematically **(LoE 4, strong recommendation).**	97%
Following TIPS creation, overt HE should be classified clinically based on West Haven criteria as part of regular follow-up **(LoE 4, strong recommendation).**	100%
Following TIPS creation, if there is clinical suspicion of cardiac decompensation, evaluation using transthoracic echocardiography is recommended. In case of pathological findings, right heart catheterisation with pressure measurement should be performed in cases of severe cardiac decompensation, suspected pulmonary hypertension or non-response to treatment **(LoE 4, strong recommendation).**	93%
Angiography of the TIPS, including measurement of PCPG, should be performed when there is clinical non-response or relapse of PH-related complications or in cases where there is evidence of TIPS dysfunction on Doppler ultrasound **(LoE 4, strong recommendation**	97%
Before TIPS revision, uncontrolled infection, liver and cardiac failure, or severe or unresponsive HE should be excluded **(LoE 4, strong recommendation).**	100%
TIPS revision with dilation, restenting and/or embolisation of collaterals should be performed as soon as possible, especially in cases of bleeding complications **(LoE 4, strong recommendation).**	97%
In patients with acute clinical symptoms of over-shunting (*e.g.* parenchymal liver failure, cardiac failure) in the absence of competing collaterals, the TIPS should be reduced or occluded **(LoE 3, strong recommendation).**	97%
In patients with chronic clinical symptoms of over-shunting (*e.g.* more than three severe HE episodes or chronic HE despite optimal medical therapy) and in the absence of competing collaterals, the TIPS should be reduced or occluded **(LoE 3, strong recommendation).**	97%
In cases with significant competing collaterals (*e.g.* hepatofugal flow through collaterals despite a functioning TIPS), collateral embolisation should be performed prior to TIPS reduction or occlusion **(LoE 4, strong recommendation).**	100%
NSBBs should be discontinued when the final PCPG is below 12 mmHg (unless clinically indicated for another reason) **(LoE 4, strong recommendation).**	96%
Endoscopic screening should be performed after TIPS creation in all patients whenever TIPS dysfunction is suspected, and the shunt cannot be revised **(LoE 4, strong recommendation).**	85%
Diuretics should be started or continued in patients with ascites and in patients at high risk of or with cardiac decompensation if kidney function permits **(LoE 4, strong recommendation).**	97%
Currently, no recommendation for routine anticoagulation or platelet inhibition to improve TIPS patency can be made **(LoE 4, weak recommendation).**	90%
In TIPS recipients, the surveillance and management of focal liver lesions should be performed according to current practice guidelines in patients without a TIPS **(LoE 3, strong recommendation).**	100%
In patients with cirrhosis without a history of HE, rifaximin may be considered for prophylaxis of HE already before non-urgent TIPS creation **(LoE 3, weak recommendation**	93%
In patients with cirrhosis with a history of HE, rifaximin should be considered for prophylaxis of HE before non-urgent TIPS placement **(LoE 2, strong recommendation).**	97%
Lactulose should be used to treat and prevent HE recurrence as in patients without a TIPS despite the lack of specific studies **(LoE 5, strong recommendation).**	97%
Rifaximin may be added in case of failure with lactulose or may replace lactulose in cases of intolerance **(LoE 4, weak recommendation).**	97%

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Recommendation	Consensus
Owing to insufficient evidence, routine assessment of sarcopenia with cross-sectional imaging before elective TIPS creation cannot be recommended to reduce HE risk. However, nutritional status is an important prognostic factor in patients with cirrhosis, and diagnosis of sarcopenia may prompt interventions to improve patient outcomes **(LoE 4, weak recommendation).**	97%
Nutritional counselling, energy intake, protein intake, and physical exercise should be considered, in all patients with cirrhosis. Whether these interventions have an impact on HE after TIPS creation is unknown **(LoE 5, strong recommendation).**	100%
In patients with cirrhosis and HCC within transplant criteria, the same absolute contraindications for TIPS placement should be used as in patients with cirrhosis but without HCC **(LoE 3, strong recommendation).**	100%
The presence of advanced HCC is a relative contraindication and a TIPS may be considered on a case-by-case basis according to the prognosis of and treatment options for the HCC. TIPS creation through the tumour mass or in patients with tumoral portal vein invasion is not recommended **(LoE 3, strong recommendation).**	97%
Ablation techniques and systemic therapies are both feasible and safe for the treatment of HCC in patients with cirrhosis and a TIPS who have a good performance status, have Child-Pugh class A or B cirrhosis, and have small volume tumours; thus, they can be used to improve outcomes **(LoE 4, weak recommendation).**	100%
In TIPS recipients, post-TIPS TACE should be cautiously considered due to the reduced portal venous perfusion **(LoE 5, strong recommendation).**	93%
If arterial endovascular treatment, such as TACE, is chosen, it should be as super-selective as possible to minimise ischaemic liver injury. Radioembolisation may be preferred to TACE, limiting the risk of liver ischaemia **(LoE 4, weak recommendation).**	100%
In patients with cirrhosis and complete PVT or cavernoma which progresses despite anticoagulation, TIPS creation and PVR are recommended to facilitate access to LT and enable physiological portal vein anastomosis **(LoE 4 strong recommendation).**	100%
TIPS insertion is feasible and may be considered after failure of standard treatment and/or as a bridge to liver re-transplantation **(LoE 3, weak recommendation).**	100%

Affiliations

European Association for the Study of the Liver (EASL). The EASL Building - Home of Hepatology, 7 rue Daubin, 1203 Geneva, Switzerland

Abbreviations

ACLF, acute-on-chronic liver failure; AKI, acute kidney injury; AVB, acute variceal bleeding; BNP, brain natriuretic peptide; BRTO, balloon-occluded retrograde transvenous obliteration; CCM, cirrhotic cardiomyopathy; CKD, chronic kidney disease; CLIF-C, Chronic Liver Failure Consortium; CPG, clinical practice guidelines; EASL, European Association for the Study of the Liver; FIPS, Freiburg index of post-TIPS survival; GFR, glomerular filtration rate; GV, gastric varices; HCC, hepatocellular carcinoma; HE, hepatic encephalopathy; HRS, hepatorenal syndrome; HRQoL, health-related quality of life; HVPG, hepatic venous pressure gradient; INR, international normalized ratio; IVC, inferior vena cava; LT, liver transplantation; LV, left ventricular; LVP, large volume paracentesis; MASLD, metabolic dysfunction-associated steatotic liver disease; MELD, model for end-stage liver disease; MOTS, modified TIPS score; NSBBs, non-selective beta-blockers; NT-proBNP, N-terminal pro-BNP; p-TIPS, preemptive TIPS; PCPG, portocaval pressure gradient; PH, portal hypertension; PoPH, portopulmonary hypertension; PPG, portosystemic pressure gradient; PTFE, polytetrafluoroethylene; PVR, portal vein recanalization; PVT, portal vein thrombosis; RAP, right atrial pressure; RCT, randomised-controlled trial; RV, right ventricular; sCr, serum creatinine; SOC, standard of care; TACE, transarterial chemoembolization; TIPS, transjugular intrahepatic portosystemic shunt; TR, tricuspid regurgitation.

Conflict of interest

Please refer to the accompanying ICMJE disclosure forms for further details.

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Supplementary data

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