

Quality Improvement Guidelines for Transjugular Intrahepatic Portosystemic Shunts

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Abbreviations: QI = quality improvement, TIPS = transjugular intrahepatic portosystemic shunt

TRANSJUGULAR intrahepatic portosystemic shunts (TIPS) are an effective method for reducing portal vein pressure. They have been proven useful for treatment of acute and chronic esophageal, gastric, intestinal and stomal variceal hemorrhage; severe or refractory ascites; hepatic hydrothorax; and possibly Budd-Chiari syndrome (1-29).

TIPS creation is a percutaneous method of reducing portal vein pressure wherein a decompressive channel is created between a hepatic vein and an intrahepatic branch of the portal vein. Creating a TIPS involves several steps:

1. Catheterization of the hepatic veins and hepatic venography.
2. Passage of a long curved transjugular needle from the chosen hepatic vein through the liver parenchyma into an intrahepatic branch of the portal vein.
3. Direct measurement of the systemic and portal vein pressures through the transjugular access.
4. Balloon dilation of the tract be-

tween the hepatic and portal veins.

5. Deployment of a metallic stent within the tract to maintain it against the recoil of the surrounding liver parenchyma.
6. Angiographic and hemodynamic assessment of the resultant pressure reduction.
7. Serial dilation of the stent until satisfactory pressure levels have been reached.
8. Variceal embolization when indicated.

These guidelines are written to be used in quality improvement (QI) programs to assess TIPS creation. The most important processes of care are (a) patient selection, (b) procedure performance, and (c) patient monitoring. The major outcome measures for TIPS include improvement or resolution of clinical indications, success rates, and complication rates. Outcome measures are assigned threshold levels.

Although practicing physicians should strive to achieve perfect outcomes (eg, 100% success, 0% complications), in practice, all physicians will fall short of this ideal to a variable extent. Therefore, in addition to QI case reviews customarily conducted after individual procedural failures or complications, outcome measure thresholds should be used to assess TIPS efficacy in ongoing QI programs. For the purpose of these guidelines, a threshold is a specific level of an indicator which, when reached or crossed,

should prompt a review of departmental policies and procedures. "Procedure thresholds" or "overall thresholds" reference a group of outcome measures for a procedure, such as major complications of TIPS creation. Individual complications may also be associated with complication-specific thresholds such as fever or hemorrhage. When outcome measures such as success rates or indications fall below a (minimum) threshold, or when complication rates exceed a (maximum) threshold, a departmental review should be performed to determine causes and to implement changes, if necessary. Thresholds may vary from those listed here; for example, patient referral patterns and selection factors may dictate a different threshold value for a particular indicator at a particular institution. Therefore, setting universal thresholds is very difficult and each department is urged to alter the thresholds as needed to meet its own QI program needs.

Complications can be stratified on the basis of outcome. *Major* complications result in admission to a hospital for therapy (for outpatient procedures), an unplanned increase in the level of care, prolonged hospitalization, permanent adverse sequelae, or death. *Minor* complications result in no sequelae; they may require nominal therapy or a short hospital stay for observation (generally overnight; see Appendix 1). The complication rates and thresholds listed herein refer to

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Table 1
Success Rates for TIPS

Type of Success	%
Technical Creation of a patent TIPS between the hepatic vein and a branch of the portal vein.	95
Hemodynamic Reduction of the portosystemic gradient to a level targeted by the operator. In general, the target portosystemic gradient is ≤ 12 mm Hg. The authors recognize that the final portosystemic gradient may vary depending on the treated indication.	95
Clinical Success Resolution of the clinical indication for which the procedure was performed. A statistically significant improvement in the event free survival interval should occur in $>90\%$ of TIPS procedures.	>90

major complications unless otherwise noted.

Treatment measures (including clinical, hemodynamic, and anatomic success), patient descriptors, measures of shunt patency, and encephalopathy grading are described in the Reporting Standards for Transjugular Intrahepatic Portosystemic Shunts (30). These same definitions are incorporated into this document by reference.

INDICATIONS

TIPS creation is indicated for (1–27,31):

1. Uncontrollable variceal hemorrhage.
2. Recurrent variceal hemorrhage despite endoscopic therapy.
3. Portal hypertensive gastropathy.
4. Refractory ascites.
5. Hepatic hydrothorax.
6. Budd-Chiari syndrome.

The threshold for these indications is 95%. When fewer than 95% of procedures are for these indications, the department will review the process of patient selection.

CONTRAINDICATIONS

While there are no absolute contraindications to creating TIPS, several relative contraindications exist. Creating TIPS in patients with these conditions are likely to increase the rates of procedural or TIPS-related complications:

1. Elevated right or left heart pressures.

2. Heart failure or cardiac valvular insufficiency.
3. Rapidly progressive liver failure.
4. Severe or uncontrolled hepatic encephalopathy.
5. Uncontrolled systemic infection or sepsis.
6. Unrelieved biliary obstruction.
7. Polycystic liver disease.
8. Extensive primary or metastatic hepatic malignancy.
9. Severe, uncorrectable coagulopathy.

MEASURES OF SUCCESS

Success should be classified as technical, hemodynamic, and clinical (30).

Technical Success

Technical success describes the successful creation of a shunt between the hepatic vein and intrahepatic branch of the portal vein. In the case of parallel shunt placement, technical success is reported for individual shunts.

Hemodynamic Success

Hemodynamic success refers to the successful post-TIPS-creation reduction of the portosystemic gradient below a threshold chosen for that study. Some authors have reported that, in patients with bleeding varices, cessation of variceal filling during hand-injected splenic (or, in the case of intestinal varices, mesenteric) venography is a useful marker of successful

decompression. This sign can be more difficult to standardize because different injection rates can lead to differences in the appearance of variceal flow. Although it can be argued that endoscopic confirmation of variceal decompression may be the gold standard for confirming hemodynamic success, this is impractical and probably unnecessary. Hemodynamic success can also be reported at follow-up shunt revisions. Absolute portal and right atrial pressures and the calculated portosystemic gradient, in mm Hg, should be recorded at the start and completion of the procedure. The data should be reported as means \pm SD.

Clinical Success

Numerous prospective and retrospective uncontrolled studies have documented the efficacy and complications of TIPS for treatment of variceal bleeding and refractory ascites. These "feasibility" studies have been followed with several prospective multicenter randomized trials (1–6,74), which compare the clinical success of TIPS with that of endoscopic, medical, and surgical therapies. Although much has been written about the unpredictable initial patency of TIPS, the long-term management of patients after their first episode of variceal bleeding will depend on the actual outcomes of differing treatments, not on the absolute patency of a TIPS. Therefore, clinical success is perhaps the most important parameter in longitudinal studies of patients with TIPS.

In the case of actively bleeding patients, early clinical success is determined by prompt arrest of acute variceal hemorrhage. This is indicated by cessation of demonstrable gastrointestinal bleeding, transfusion requirements, pharmacologic support, balloon tamponade, and return of hemodynamic stability. Because nonvariceal bleeding can coexist in more than one third of patients with varices, it is essential to verify endoscopically the causes of continued or recurrent bleeding after shunt placement or revision (32–34).

Clinical success is also reflected in the interval of time during which the patient remains free of the symptoms alleviated by the TIPS. For patients

Table 2
Specific Complications of TIPS

Complication*	Reported Rate (%)	Suggested Complication-specific Threshold (%)
Major Complications	3	5
Hemoperitoneum†	0.5	1
Gallbladder puncture	1	2
Stent malposition‡	1	1
Hemobilia	2	2
Radiation skin burn	0.1	0.1
Hepatic infarction	0.5	0.5
Renal failure requiring chronic dialysis	0.25	0.5
Hepatic artery injury	1	2
Accelerated liver failure§	—	—
Severe or controlled encephalopathy	—	—
Death¶	1	2
Minor complications	4	8
Transient contrast-induced renal failure	2	5
Encephalopathy controlled by medical therapy	15–25	15–25
Fever	2	5
Transient pulmonary edema	1	1
Entry site hematoma	2	5

* See Appendix 1.

† Hemoperitoneum warranting blood transfusion or other directed interventions.

‡ A major stent malposition includes conditions such as free stent migration within the portal or systemic venous circulations, or ones resulting in vascular perforation.

§ The rate of accelerated liver failure after TIPS is highly dependent upon patient selection, final shunt diameter, comorbid factors (eg, preexisting multiorgan system failure, elevated APACHE II scores, high Child-Pugh scores, etc). Part of this risk is not specific to the creation of a TIPS, but is shared by surgical forms of portosystemic diversion as well. As such, a specific threshold for this complication cannot be assigned.

|| Encephalopathy rates are directly dependent upon patient selection, as with any form of portosystemic diversion. For example, patients with severe or refractory ascites may manifest severe encephalopathy (requiring hospitalization) in 30%–40% of cases (11,15). In contrast, elective patients with Child-Pugh class A or B hepatocellular disease may manifest severe, uncontrolled encephalopathy in 3%–10% of cases (28,29,68–71).

¶ Death refers to 30-day mortality directly related to a complication of TIPS creation. As with accelerated liver failure after TIPS (see §), the majority of deaths after TIPS are dependent upon preexisting comorbid factors such as elevated APACHE II scores, Child-Pugh class or scores, and multiorgan system failure. The existence of these pre-TIPS conditions can greatly increase the rate of 30-day mortality after TIPS or surgical forms of portosystemic diversion. Proper patient selection and minimization of procedural complications can greatly reduce death rates.

cases of hepatic and/or portal vein thromboses. These situations are relatively infrequent and may require considerably more technical expertise than shunt creation in patients with patent portal and hepatic veins. Accordingly, it is recognized that lower success rates can be anticipated in patients with these anatomic conditions. However, it is presently difficult to define threshold levels for success in such cases.

COMPLICATIONS

Although major complications (28,29,34–69) can occur during or as a result of TIPS creation, they are generally uncommon and are reduced with increased operator experience (Table 2).

Published rates for individual types of complications are highly dependent on patient selection and are based on series comprising several hundred patients, which is a volume larger than most individual practitioners are likely to treat. It is also recognized that a single complication can cause a rate to cross above a complication-specific threshold when the complication occurs in a small volume of patients, such as early in a QI program. In this situation, the overall procedure threshold is more appropriate for use in a QI program. Major complications occur in 5% of patients.

Participation by the radiologist in patient follow-up is an integral part of TIPS and will increase the durable efficacy of the procedure. Close follow-up, with monitoring of shunt function and patency, is necessary and appropriate for the radiologist. Appropriate methods include Doppler sonography in a validated laboratory or shunt venography.

APPENDIX 1: SIR STANDARDS OF PRACTICE COMMITTEE CLASSIFICATION OF COMPLICATIONS BY OUTCOME

Minor Complications

- A. Require no therapy, no consequence, or
- B. Require nominal therapy, no consequence; includes overnight admission for observation only.

treated for variceal hemorrhage, this is the period after TIPS until a bleeding episode recurs. For patients with ascites, this is the period between improvement or resolution of ascites and recurrence of ascites. This is best described in terms of “event-free survival” intervals after TIPS creation. For variceal bleeding, it is recognized that this measure will greatly underestimate shunt stenosis or occlusion be-

cause TIPS patients may remain asymptomatic for prolonged periods despite highly stenotic or occluded shunts.

SUCCESS RATES

Success rates for creation of TIPS in patients with patent hepatic and portal veins are given in Table 1. Successful shunt creation has been reported in

Major Complications

C. Require therapy, minor hospitalization (<48 h),

D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 h),

E. Have permanent adverse sequelae, or

F. Result in death.

APPENDIX 2: CONSENSUS METHODOLOGY

Reported complication-specific rates in some cases reflect the aggregate of major and minor complications (72). Thresholds are derived from critical evaluation of the literature, evaluation of empirical data from Standards of Practice Committee member practices, and, when available, the SIR HI-IQ[®] system national data base.

Consensus on statements in this document was obtained with use of a modified Delphi technique (72,73).

Technical documents specifying the exact consensus and literature review methodologies are available upon request from the Society of Interventional Radiology, 10201 Lee Highway, Suite 500, Fairfax, VA 22030.

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