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 between 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**

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

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.

**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.

**INDICATIONS**

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

1. Uncontrollable variceal hemorrhage.
2. Recurrent variceal hemorrhage despite endoscopic therapy.
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.

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**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 ± 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...
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 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.

COMPICATIONS

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.
REFERENCES


