Quality Improvement Guidelines for Transjugular Intrahepatic Portosystemic Shunts

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ABBREVIATIONS

HE = hepatic encephalopathy, TIPS = transjugular intrahepatic portosystemic shunt

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PREAMBLE

The membership of the Society of Interventional Radiology (SIR) Standards of Practice Committee represents experts in a broad spectrum of interventional procedures from the private and academic sectors of medicine. Generally, Standards of Practice Committee members dedicate the vast majority of their professional time to performing interventional procedures; as such, they represent a valid, broad expert constituency on the subject matter under consideration for standards production.

METHODOLOGY

SIR produces its Standards of Practice documents using the following process. Standards documents of relevance and timeliness are conceptualized by the Standards of Practice Committee members. A

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recognized expert is identified to serve as the principal author for the document. Additional authors may be assigned depending on the magnitude of the project.

An in-depth literature search is performed with use of electronic medical literature databases. Then, a critical review of peer-reviewed articles is performed regarding the study methodology, results, and conclusions. The qualitative weight of these articles is assembled into an evidence table, which is used to write the document such that it contains evidence-based data with respect to content, rates, and thresholds.

When the evidence of literature is weak, conflicting, or contradictory, consensus for the parameter is reached by a minimum of 12 Standards of Practice Committee members using a modified Delphi consensus method (Appendix A). For the purpose of these documents, consensus is defined as 80% Delphi participant agreement on a value or parameter.

The draft document is critically reviewed by the Standards of Practice Committee members in a telephone conference call or face-to-face meeting. The finalized draft from the Committee is sent to the SIR membership for further input/criticism during a 30-day comment period. These comments are discussed by the Standards of Practice Committee, and appropriate revisions are made to create the finished standards document. Before its publication, the document is endorsed by the SIR Executive Council.

INTRODUCTION

During the past decade, transjugular intrahepatic portosystemic shunt (TIPS) creation has been established as an effective treatment for variceal bleeding and refractory ascites. Since the 2003 Quality Improvement Guidelines for Transjugular Intrahepatic Portosystemic Shunts (1), numerous additional randomized controlled trials, systematic reviews, and meta-analyses have been published on TIPS creation. The technology of stents has evolved, with polytetrafluoroethylene-covered stents widely used. Moreover, the role interventional radiologists play in the management and complications of portal hypertension has also expanded. Therefore, this document was updated to reflect the foregoing points while emphasizing the current literature and outcomes.

PRE-TIPS WORKUP

Workup for TIPS creation may include complete blood count, metabolic panel, liver function tests, and coagulation profile. Additionally, it is important to obtain cross-sectional imaging (to assess candidacy for the procedure, technical feasibility, and need for modified or advanced techniques), determine evidence of previous or

current hepatic decompensation (ie, ascites, encephalopathy, variceal bleeding, hypoxia, or congestive heart failure), and identify possible significant systemic comorbidities (2).

CLINICAL OUTCOMES AND PROGNOSTIC FACTORS

Aside from procedure-related complications, clinical outcomes are most strongly determined by preprocedure status, including measures such as the Model for End-stage Liver Disease score and its modifications, Acute Physiology and Chronic Health Evaluation II score, and Emory score (3–10). In addition, patient age, urgency of the procedure, preprocedure hepatic venous pressure gradient, pre- and post-TIPS liver function test results (eg, serum bilirubin), right atrial pressure, and diastolic function have been shown to correlate with or predict survival after TIPS creation (11–15). Many of these factors are also predictors for the development of hepatic encephalopathy (HE) following TIPS creation. Other risks for HE may include age > 65 years, Child–Pugh score > 12, history of HE, placement of a large-diameter stent (> 10 mm), low corrected portosystemic gradient (< 5 mm Hg), and albumin level (16,17).

TIPS CREATION

TIPS creation is a percutaneous image-guided procedure in which a decompressive channel is created between a hepatic vein and an intrahepatic branch of the portal vein to reduce portal vein pressure. Creation of a TIPS involves several steps:

1. Catheterization of the hepatic veins and performance of 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 covered stent/stent graft or metallic (self-expanding) stent within the tract to maintain it against the recoil of the surrounding liver parenchyma; and
6. Variceal embolization when indicated.

Other technical descriptions for portosystemic shunt creation are beyond the scope of this document. However, direct intrahepatic portocaval shunt creation has been described as an alternate method, especially in patients with hepatic vein occlusion, portal vein thrombosis, or unfavorable hepatic/portal vein anatomy (18,19).

CLINICAL AND IMAGING FOLLOW-UP AFTER TIPS CREATION

Interventional radiologists play an integral role in the care of the patient with a TIPS. Although many protocols have been described for noninvasive imaging follow-up, ultrasonography is a relatively inexpensive screening examination for shunt dysfunction after TIPS creation, and can be performed within 7–14 days after shunt creation and then at 3 months, 6 months, and every 6–12 months thereafter (20). If sonographic evaluation is not diagnostic and there is clinical concern for shunt dysfunction, further imaging with computed tomography or venography can be performed to assess shunt patency. Clinical and imaging follow-up may also be performed in tandem with hepatocellular screening.

Post-TIPS encephalopathy or liver failure may require shunt reduction. Participation by the interventional radiologist in patient follow-up with the anticipation of post-TIPS complications can help

facilitate further intervention, or, if needed, referral to a tertiary hospital if more advanced intervention is necessary.

The present guidelines were developed for use in institution-wide quality-improvement programs to assess the practice of diagnostic arteriography. The most important processes of care are (*i*) patient selection, (*ii*) performance of the procedure, and (*iii*) monitoring the patient. The major outcome measures for diagnostic arteriography include complete imaging of the pathologic process, success rates, and complication rates. Outcome measures are assigned threshold values.

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 quality-improvement case reviews customarily conducted after individual procedural failures or complications, outcome-measure thresholds should be used to assess diagnostic arteriography in ongoing quality-improvement programs. For the purpose of these guidelines, a threshold is specific level of an indicator that, 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; for example, major complications for diagnostic arteriography. Individual complications may also be associated with complication-specific thresholds, such as fever or hemorrhage. When outcome measures such as success rates or indications decrease below a (minimum) threshold, or when complications 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 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 higher or lower values to meet its own quality-improvement program needs.

Complications can be stratified on the basis of outcome. Major complications may 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 (Appendix B). The complication rates and thresholds in this document refer to 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 (21). These same definitions are incorporated into this document by reference.

INDICATIONS

TIPS creation is indicated for the following (22–48):

1. Uncontrollable (ie, "rescue") variceal hemorrhage;
2. Recurrent variceal hemorrhage despite endoscopic therapy;
3. Portal hypertensive gastropathy;
4. Refractory ascites;
5. Hepatic hydrothorax; and
6. Budd–Chiari syndrome.

TIPS creation may also be beneficial in the treatment of hepatorenal syndrome (49,50) and in patients with recurrent portal hypertension after liver transplantation, although the complexity of posttransplantation liver anatomy may make TIPS creation more challenging (51–56). There is also evidence that early TIPS creation may improve survival, and its indication may expand beyond that of a rescue therapy. A multicenter randomized controlled trial (23) in patients with Child–Pugh class B/C cirrhosis who presented with acute variceal bleeding and were initially treated with endoscopic and medical therapy and then randomized to undergo continued medical

therapy versus TIPS creation within 24–72 hours showed that patients who received a TIPS had a lower risk of recurrent bleeding, as well as improved survival with no increase in HE.

In addition to the aforementioned indications, TIPS creation has been described in patients with cirrhosis with bland portal vein thrombosis to achieve or maintain surgical transplantation candidacy. TIPS creation has also been performed before elective extrahepatic abdominal surgery to decrease morbidity and mortality (57–61). In native and transplanted livers, TIPS creation can be used adjunctively to treat splanchnic vein thrombosis (acute and chronic) and to obliterate ectopic varices (62–64). Palliative TIPS creation has been used in oncologic cases (patients with primary and metastatic liver tumors) to treat complications of portal hypertension and to allow completion of planned systemic therapies (65,66).

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

Although there are no absolute contraindications to TIPS creation, several relative contraindications exist. Creating a TIPS in patients with the following conditions is likely to increase the rates of procedural or TIPS-related complications:

1. Elevated right or left heart pressures;
2. Heart failure or severe cardiac valvular insufficiency;
3. Rapidly progressive liver failure;
4. Severe or uncontrolled HE;
5. Uncontrolled systemic infection or sepsis;
6. Unrelieved biliary obstruction;
7. Polycystic liver disease;
8. Extensive primary or metastatic hepatic malignancy; and
9. Severe, uncorrectable coagulopathy.

MEASURES OF SUCCESS

Success should be classified as technical, hemodynamic, and clinical (21).

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 creation, technical success is reported for individual shunts.

Hemodynamic Success

Hemodynamic success refers to the successful post-TIPS reduction of the portosystemic gradient below a threshold indicated for the clinical setting. 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 the confirmation of 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 calculated portosystemic gradient (in millimeters of mercury) should be recorded at the start and completion of the procedure. The data should be reported as mean pressure ± standard deviation.

Clinical Success

TIPS creation is well-described as an effective treatment for variceal bleeding and refractory ascites. 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 and on patients' Model for End-stage Liver Disease or Child–Pugh scores, not necessarily on the absolute patency of a TIPS. Therefore, clinical success is perhaps the most important parameter in longitudinal studies of patients with a TIPS.

In the case of active bleeding, which can be triaged according to the Baveno criteria (67), 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.

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 treated for variceal hemorrhage, this is the period after TIPS creation 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 because patients with a TIPS may remain asymptomatic for prolonged periods despite highly stenotic or occluded shunts.

Numerous prospective and retrospective studies have compared the use of expanded polytetrafluoroethylene-covered versus noncovered stents in the creation of TIPS. Covered stents confer a higher and longer patency rate, although improved overall survival remains to be established (68–79).

Table 1. Success Rates for TIPS Creation (22,23,25–27,31–33,37,38,80–83)	
Type of Success	**Rate (%)**
Technical	
Creation of patent TIPS between hepatic vein and branch of portal vein*	95
Hemodynamic	
Reduction of portosystemic gradient to level targeted by operator†	95
Clinical	
Resolution of clinical indication for which procedure was performed	
Variceal bleeding (22,23,25–27)	> 90
Ascites (31–33,37,38,82,83)‡	55

TIPS = transjugular intrahepatic portosystemic shunt.
*The technical complexity of TIPS creation may be challenging, especially in centers with lower-volume TIPS referrals, and, as a result, lower success rates may be encountered. Therefore, a single threshold is difficult to set, and departments may need to alter their thresholds as needed to higher or lower levels to meet their own quality-improvement program needs.
†In general, the target portosystemic gradient is ≤ 12 mm Hg for esophageal variceal bleeding (80,81). The authors recognize that the final portosystemic gradient for gastric variceal bleeding may require a different gradient threshold. Additionally, the final portosytemic gradient in patients with ascites may need to be lower than the threshold for bleeding varices.
‡The clinical success rates in the literature for ascites nonrecurrence is broad, ranging from 55% to 80%, with the majority of studies reporting approximately 55%.

SUCCESS RATES

Success rates for creation of a TIPS in patients with patent hepatic or portal veins are given in Table 1 (22,23,25–27,31–33,37,38,80–83). Successful shunt creation has been reported in cases of hepatic vein thrombosis or obstruction (47,48,73,84–88), as well as portal vein thrombosis (even in patients with cavernous transformation) (58,62,89–92), and neither clinical presentation should be considered an absolute contraindication to TIPS creation. These situations are relatively infrequent and may require considerably more technical expertise than shunt creation would require 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.

COMPLICATION RATES AND THRESHOLDS

Although major complications (16,93–105) can occur during or as a result of TIPS creation, they are generally uncommon and are reduced with increased operator experience (Table 2) (106–113).

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 (eg, early in a quality-improvement program). In this situation, the overall procedure threshold is more appropriate for use in a quality-improvement program.

The overall procedure threshold for major complications is 5.0%. The overall procedure threshold for major complications is determined by the following formula:

(Number of patients with complications undergoing diagnostic arteriography only × 100) / number of patients undergoing TIPS creation only

APPENDIX A. METHODOLOGY

Reported complication-specific rates in some cases reflect the aggregate of major and minor complications. 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 database.

Consensus on statements in this document was obtained with use of a modified Delphi technique (114,115).

Technical documents specifying the exact consensus and literature review methodologies, as well as the institutional affiliations and professional credentials of the authors of this document, are available upon request from: SIR, 3975 Fair Ridge Dr., Suite 400 N., Fairfax, VA 22033.

APPENDIX B. SIR STANDARDS OF PRACTICE COMMITTEE CLASSIFICATION OF COMPLICATIONS BY OUTCOME

Minor Complications

A. No therapy, no consequence; or
B. Nominal therapy, no consequence; includes overnight admission for observation only.

Major Complications

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

Complication	Reported Rate (%)	Suggested Complication-Specific Threshold (%)
Major	3	5
Hemoperitoneum*	0.5	1
Biliary peritonitis	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‡	3	–
Severe or controlled encephalopathy§	–	–
Death‖	1	2
Minor	4	8
Transient contrast medium–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

Table 2. Complication Rates and Thresholds (106–113)

Note–Appendix B describes classifications of complications.
MELD = Model for End-stage Liver Disease; TIPS = transjugular intrahepatic portosystemic shunt.
*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 malposition resulting in vascular perforation.
‡The rate of accelerated liver failure after TIPS creation is highly dependent on patient selection, final shunt diameter, and comorbid factors such as preexisting multiple organ system failure, increased MELD scores, and high Child–Pugh scores. 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, as 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 (106) (107). In contrast, elective patients with Child–Pugh class A/B hepatocellular disease may manifest severe, uncontrolled encephalopathy in 3%–10% of cases (108–113).
‖Death refers to 30-day mortality directly related to a complication of TIPS creation. As with accelerated liver failure after TIPS‡, the majority of deaths after TIPS are dependent upon preexisting comorbid factors such as elevated MELD scores, Child-Pugh scores, and multi-organ 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.

E. Have permanent adverse sequelae; or

F. Result in death.

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