

# Quality Improvement Guidelines for Transjugular Intrahepatic Portosystemic Shunts

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(for the Society of Interventional Radiology Standards of Practice Committee)

## ABBREVIATIONS

HE = hepatic encephalopathy, TIPS = transjugular intrahepatic portosystemic shunt

## 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

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