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Revised 2007 (Res. 8, 12m)\*

## **PRACTICE GUIDELINE FOR THE CREATION OF A TRANSJUGULAR INTRAHEPATIC PORTOSYSTEMIC SHUNT (TIPS)**

### **PREAMBLE**

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment.

Therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

### **I. INTRODUCTION**

This guideline was revised collaboratively by the Society of Interventional Radiology (SIR) and the American College of Radiology (ACR) [1].

Creating a transjugular intrahepatic portosystemic shunt (TIPS) is an effective method for reducing portal vein pressure. It has 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 [2-51, 52-54]

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

1. Catheterization of the hepatic veins and hepatic venography (usually from a transjugular approach).
2. Passage of a long curved needle from the chosen hepatic vein through the liver parenchyma into an intrahepatic branch of the portal vein.
3. Direct portography.
4. Direct measurement of the systemic and portal vein pressures through the venous access.

5. Balloon dilation of the tract between the hepatic and portal veins.
6. Deployment of a metallic stent or stent graft within the tract to maintain it against the recoil of the surrounding liver parenchyma.
7. Angiographic and hemodynamic assessment of the shunt tract.
8. Dilation of the endoprosthesis until satisfactory pressure levels have been reached.

These guidelines are to be used in quality improvement (QI) programs to assess TIPS creation. The most important processes of care are 1) patient selection, 2) performance of the procedure, and 3) monitoring the patient. The major outcome measures for TIPS include improvement or resolution of clinical indications, success rates, and complication rates. Outcome measures are assigned threshold levels.

While practicing physicians should strive to achieve perfect outcomes (e.g., 100% success, 0% complications), in practice all physicians will fall short of this ideal to a variable extent. Thus, 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 quality improvement 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 refer to a group of outcome measures for a procedure, e.g., major complications for TIPS. Individual complications (e.g., fever or hemorrhage) may also be associated with complication-specific thresholds. When outcome measures such as success rates or resolution of clinical 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. Thus, setting universal thresholds is very difficult, and each department is urged to alter the thresholds to higher or lower values 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 A. The complication rates and thresholds below refer to *major* complications, unless otherwise noted.

Note: Treatment measures (including clinical, hemodynamic, and anatomic success), patient descriptors, measures of shunt patency, and encephalopathy grading are described in [55]. These descriptions are incorporated into this document by reference.

## II. INDICATIONS AND CONTRAINDICATIONS

### A. Indications

TIPS creation is indicated for:

1. Uncontrollable variceal hemorrhage.
2. Current or prior variceal hemorrhage that is not amenable to initial or continued endoscopic therapy.
3. Prophylaxis against recurrent bleed in high-risk patients.
4. Portal hypertensive gastropathy or intestine-opathy.
5. Refractory ascites.
6. Hepatic hydrothorax.
7. 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.

### B. Contraindications

The patients under consideration for a TIPS procedure are generally severely ill. Sometimes they require intervention as a potential life-saving measure acknowledging that the procedure itself entails significant risks. While there are no absolute contraindications to creating a TIPS, several clinical conditions are known to increase procedural or TIPS-related complications. They include:

1. Elevated right or left heart pressures.
2. Heart failure or cardiac valvular insufficiency.
3. Rapidly progressive liver failure.
4. Clinically significant 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.
10. Marked pulmonary arterial hypertension.
11. Renal insufficiency.
12. Advanced age.

### III. SUCCESS AND COMPLICATIONS

#### A. Measures of Success

Success should be classified as technical, hemodynamic, and clinical [55].

**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 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. While 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 millimeters of mercury and/or cm of water, should be recorded at the start and completion of the procedure.

**Clinical success** - Numerous studies have documented the efficacy and complications of TIPS for treatment of variceal bleeding and refractory ascites. Although much has been written about the unpredictable initial patency of TIPS, this may be less likely of an issue with more widespread use of stent grafts [56-64]. The long-term management of patients after their first episode of variceal bleeding will depend on the actual outcomes of differing treatments, and less on the absolute patency of a TIPS. Therefore, clinical success is perhaps the most important parameter in longitudinal studies of TIPS patients.

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, or balloon tamponade, and by return of hemodynamic stability with or without performance of adjunctive variceal embolization when indicated. Because nonvariceal bleeding can coexist in upward of one-third of patients with varices, it is essential to verify endoscopically the causes of continued or recurrent bleeding after shunt placement or revision [65,66].

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 between TIPS and the recurrence of a bleeding episode. 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 placement. For variceal bleeding, it is recognized that this measure will greatly underestimate shunt stenosis or occlusion because TIPS patients may remain asymptomatic for prolonged periods despite highly stenotic or occluded shunts.

#### B. Success Rates

Success rates for creation of TIPS in patients with patent hepatic and portal veins are given in Appendix B. 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. It is, however, presently difficult to define threshold levels for success in such cases.

#### C. Complications [25,67-111]

While major complications can occur during or as a result of TIPS, they are generally uncommon and are reduced with operator experience (Appendix C).

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, e.g., 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.

#### IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

##### A. Physician

TIPS must be performed under the supervision of and interpreted by a physician who has the following qualifications:

1. Certification in Radiology or Diagnostic Radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or Le College des Medecins du Quebec. The physician must have performed a minimum of 100 diagnostic angiograms, 50 angioplasties (25 as primary operator), 10 vascular stents, and 5 embolization procedures with documentation of success and complication rates as described in the appropriate ACR Practice Guidelines, Technical Standards, or policies [112,113]. In addition, a minimum of 5 TIPS procedures must have been performed or supervised with documented success and complication rates that meet the threshold criteria listed in Appendix B and C.

or

2. Completion of an Accreditation Council for Graduate Medical Education (ACGME) approved radiology residency training program or an American Osteopathic Association (AOA) approved radiology residency program and a minimum of 12 months' training and experience in vascular/interventional radiology and/or in a interventional/vascular radiology fellowship program, and have performed 100 diagnostic angiograms, 50 angioplasties (25 as primary operator), 10 vascular stents, and 5 embolization procedures with documentation of success and complication rates as described in the appropriate ACR Guideline, Standard or policy [112,113]. In addition, a minimum of 5 TIPS procedures must have been performed or supervised with documented success and complication rates that meet the threshold criteria listed in Appendix B and C.

or

3. In the absence of either an appropriate ACGME recognized residency training as outlined in IV.A.2 above or of a formal fellowship training in a Radiology Residency Review Committee (RRC) accredited vascular/interventional radiology fellowship program or of other post-graduate training that included comparable instruction and experience in interventional and vascular angiography, the physician must have at least 2 years' experience with demonstrated competency as primary operator in diagnostic angiography under the supervision of an on-site

qualified physician during which a minimum of 100 diagnostic angiograms, 50 angioplasties (25 as primary operator), 10 vascular stents, and 5 embolization procedures were performed with documentation of success and complication rates as described in the appropriate ACR Guideline, Standard or policy [112,113]. The operator must have performed a minimum of 5 TIPS procedures with documented success and complication rates that meet the threshold criteria listed in Appendix B and C.

and

4. Substantiation in writing by the director of interventional radiology or the chair of the department of the institution in which the physician will be providing these services and that the physician is familiar with all of the following:

- a. Indications and contraindications for the procedure.
- b. Periprocedural and intraprocedural assessment, monitoring, and management of the patient and complications.
- c. Pharmacology of moderate<sup>1</sup> or "conscious" sedation medications and recognition and treatment of adverse reactions and complications.
- d. Fluoroscopic and radiographic equipment, mechanical injectors, digital subtraction, and other electronic imaging systems.
- e. Principles of radiation protection, hazards of radiation exposure to both patients and radiologic personnel, and monitoring requirements.
- f. Pharmacology of contrast agents and recognition and treatment of their potential adverse reactions.
- g. Percutaneous needle and catheter introduction techniques.
- h. Technical aspects of performing the procedure, including the use of multiple catheter and guidewire systems, selective angiographic methods, vascular embolization and thrombolytic methods, appropriate injection rates, and volumes of contrast media and filming sequences.
- i. Knowledge of potential intraprocedural complications and appropriate treatment options regarding these complications.
- j. Anatomy, physiology, and pathophysiology, including pressure monitoring of gastrointestinal and hepatic vasculature.
- k. Interpretation of gastrointestinal, hepatic, arterial, and venous vascular studies.

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<sup>1</sup>The American Society of Anesthesiologists prefers the term "moderate" rather than "conscious".

- I. Postprocedural patient management, especially recognition and initial management of complications.

#### Maintenance of Competence

Physicians must perform a sufficient number of TIPS procedures to maintain their skills, with acceptable success and complication rates as laid out in this document (Appendix B and C). Continued competence should depend on participation in a QI program that monitors these rates.

#### Continuing Medical Education

The physician's continuing education should be in accordance with the [ACR Practice Guideline for Continuing Medical Education \(CME\)](#).

#### B. Qualified Medical Physicist

A Qualified Medical Physicist should have the responsibility for overseeing the equipment quality control program and for monitoring fluoroscopy and other cross-sectional imaging studies, both upon installation and routinely on an annual basis. Qualified Medical Physicists assuming these responsibilities should meet the following qualifications:

A Qualified Medical Physicist is an individual who is competent to practice independently in one or more of the subfields in medical physics. The American College of Radiology considers that certification and continuing education and experience in the appropriate subfield(s) to demonstrate that an individual is competent to practice one or more of the subfields in medical physics and to be a Qualified Medical Physicist. The ACR recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physics in Medicine, or for MRI, by the American Board of Medical Physics (ABMP) in magnetic resonance imaging physics.

The appropriate subfields of medical physics for this guideline are Diagnostic Radiological Physics and Radiological Physics.

A Qualified Medical Physicist should meet the [ACR Practice Guideline for Continuing Medical Education \(CME\)](#). (ACR Resolution 17, 1996 – revised in 2008, Resolution 7)

#### C. Registered Radiologist Assistant

A registered radiologist assistant is an advanced level radiographer who is certified and registered as a radiologist assistant by the American Registry of Radiologic Technologists (ARRT) after having successfully completed an advanced academic program

encompassing an ACR/ASRT (American Society of Radiologic Technologists) radiologist assistant curriculum and a radiologist-directed clinical preceptorship. Under radiologist supervision, the radiologist assistant may perform patient assessment, patient management and selected examinations as delineated in the Joint Policy Statement of the ACR and the ASRT titled “Radiologist Assistant: Roles and Responsibilities” and as allowed by state law. The radiologist assistant transmits to the supervising radiologists those observations that have a bearing on diagnosis. Performance of diagnostic interpretations remains outside the scope of practice of the radiologist assistant. (ACR Resolution 34, adopted in 2006)

#### D. Radiologic Technologist

The technologist, together with the physician and nursing personnel, should have responsibility for patient comfort and safety. The technologist should be able to prepare and position<sup>2</sup> the patient for the procedure and together with the nurse, monitor the patient during the examination. The technologist should obtain the imaging data in a manner prescribed by the supervising physician. The technologist should also perform the regular quality control testing of the equipment under supervision of the physicist.

Technologists should be certified by the American Registry of Radiologic Technologists (ARRT) or have an unrestricted state license with documented training and experience in the imaging modality used for the imaging-guided percutaneous procedure.

#### E. Anesthesiologist

In certain circumstances, the primary operator may determine that anesthesiology support may be required.

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<sup>2</sup>The American College of Radiology approves of the practice of certified and/or licensed radiologic technologists performing fluoroscopy in a facility or department as a positioning or localizing procedure only, and then only if monitored by a supervising physician who is personally and immediately available.\* There must be a written policy or process for the positioning or localizing procedure that is approved by the medical director of the facility or department/service and that includes written authority or policies and processes for designating radiologic technologists who may perform such procedures. (ACR Resolution 26, 1987 – revised in 2007, Resolution 12m)

\*For the purposes of this guideline, “personally and immediately available” is defined in manner of the “personal supervision” provision of CMS—a physician must be in attendance in the room during the performance of the procedure. Program Memorandum Carriers, DHHS, HCFA, Transmittal B-01-28, April 19, 2001.

## F. Nursing Services

Nursing services are an integral part of the team for periprocedural and intraprocedural patient management and education and are recommended in monitoring the patient during the procedure.

## V. SPECIFICATIONS OF THE EXAMINATION

Several technical requirements are necessary to ensure safe and successful TIPS creation. These include adequate arteriographic equipment and institutional facilities, physiologic monitoring equipment, and support personnel.

### A. Angiographic Equipment and Facilities

The following are considered the minimum equipment requirements for performing TIPS. In planning facilities for TIPS, equipment and facilities more advanced than those outlined below may be desired to produce higher quality studies with reduced risk and time of study. In general, the facility should include at a minimum:

1. A high-resolution image intensifier and television chain with standard angiographic filming capabilities. Digital subtraction angiographic systems with high spatial resolution are recommended, as they allow for reduced volumes of contrast material and reduced examination times. These digital acquisition systems are sufficient to offer an alternative to conventional film systems and are more flexible and therefore preferable for safe and accurate TIPS creation. Use of last image hold and pulsed fluoroscopy is recommended for dose reduction. The use of cineradiography or small field mobile image intensifiers is inappropriate for the routine recording of noncoronary angiography, because these methods have an unacceptably high patient and operator radiation dose.
2. Adequate angiographic supplies such as catheters, guidewires, stents, balloons, needles, and introducer sheaths.
3. An angiography suite large enough to allow easy transfer of the patient from the bed to the table and to allow room for the procedure table, monitoring equipment, and other hardware such as intravenous pumps, respirators, anesthesia equipment, and oxygen tanks. Ideally, there should be adequate space for the operating team to work unencumbered on either side of the patient and for the circulation of other technical staff in the room without contaminating the sterile conditions.

4. An area for preprocedural preparation and postprocedural observation and monitoring of the patient. At this location, there should be personnel to provide care as outlined in section V.E below (Patient Care), and there should be immediate access to emergency resuscitation equipment.

### B. Physiologic Monitoring and Resuscitation Equipment

1. Sufficient equipment should be present in the angiography suite to allow for monitoring the patient's heart rate, cardiac rhythm, and blood pressure. For facilities utilizing moderate sedation, a pulse oximeter or an end-tidal carbon dioxide monitor should be available. (See the [ACR Practice Guideline for Adult Sedation/Analgesia](#).)
2. There should be ready access to emergency resuscitation equipment and drugs, to include the following: a defibrillator, oxygen supply and appropriate tubing and delivery systems, suction equipment, tubes for endotracheal intubation, laryngoscope, ventilation bag-mask-valve apparatus, and central venous line sets. Drugs for treating cardiopulmonary arrest, contrast reaction, vasovagal reactions, narcotic or benzodiazepine overdose, bradycardia, and ventricular arrhythmias should also be readily available. Resuscitation equipment should be monitored on a routine basis in compliance with institutional policies.
3. Equipment for invasive pressure monitoring should be readily available. In addition to conventional physiologic monitoring, the equipment must be capable of measuring the portal and systemic venous pressures obtained during creation of the TIPS.

### C. Support Personnel

1. Radiologic technologists properly trained in the use of the diagnostic imaging equipment should assist in performing and imaging the procedure. They should demonstrate appropriate knowledge of patient positioning, arteriographic image recording, angiographic contrast injectors, adjunctive supplies, and the physiologic monitoring equipment. Certification as a vascular and interventional radiologic technologist is one measure of appropriate training. The technologists should be trained in basic cardiopulmonary resuscitation and in the function of the resuscitation equipment.
2. If the patient does not receive moderate sedation, one of the staff assisting the procedure should be assigned to periodically assess the patient's

status. If the patient is to undergo moderate sedation, a nurse or other appropriately trained individual should monitor the patient as his or her primary responsibility. This person should maintain a record of the patient's vital signs, time and dose of medications given, and other pertinent information. Nursing personnel should be qualified to administer moderate sedation. (See the [ACR Practice Guideline for Adult Sedation/Analgesia](#).)

3. For unstable patients additional support may be necessary to ensure the safe performance of TIPS. The primary operator may be engaged in the details of the proper performance of the TIPS. Therefore, appropriate personnel should be available to attend to the ongoing care and resuscitation of the critically ill patients. Such personnel might include anesthesiologists; operating room, ICU, and/or ER trained nurses; or other physicians. The nurses may be radiology nurses and/or the same personnel responsible for monitoring and maintaining moderate sedation as discussed immediately above. Alternatively, the nurses may be supplied from other patient care units in the facility.

All such additional personnel should work in concert with and under the overall supervision of the primary operator performing the TIPS, but within the scopes of service as defined by their professions, state regulations, and institutional guidelines.

#### D. Surgical Support

Although surgical or other emergency treatment is needed infrequently for serious complications after TIPS creation, there should be prompt access to surgical and interventional equipment and to specialists familiar with the management of patients with complications in the unlikely event of a life-threatening complication.

#### E. Patient Care

The written or electronic request for a TIPS examination should provide sufficient information to demonstrate the medical necessity of the procedure and allow for its proper performance and interpretation.

Documentation that satisfies medical necessity includes 1) signs and symptoms, 2) relevant history (including known diagnoses, and/or 3) prior imaging). Additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the procedure.

The request for the procedure must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient's clinical problem or question and consistent with the state's scope of practice requirements. (ACR Resolution 35, adopted in 2006)

#### 1. Preprocedure care

In addition to having demonstrated competence in performing the TIPS procedure and having been granted institutional privileges to perform the procedure, the physician performing the procedure must have knowledge of the following:

- a. Clinically significant history, including indications for the procedure.
- b. Clinically significant physical or diagnostic examination, including knowledge and awareness of other clinical or medical conditions that may necessitate specific care, such as presence of patent portal vein or massive ascites, and certain diagnostic lab results.
- c. Contraindications and factors that will lead to increased risk of complication.
- d. Possible alternative methods, such as surgical, endoscopic, or medical treatments, to obtain the desired therapeutic result.

Informed consent must be in compliance with state laws and the [ACR Practice Guideline on Informed Consent for Image-Guided Procedures](#).

#### 2. Procedural care

- a. Adherence to the Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ is required for procedures in non-operating room settings including bedside procedures. "Time out" must be conducted in the location where the procedure will be done, just before starting the procedure and must:

- Involve the entire operative team.
- Use active communication.
- Be briefly documented, such as in a checklist, and include at least:
  - Correct patient identity.
  - Correct side and site.
  - Agreement on the procedure to be done.
  - Correct patient position.

- Availability of correct implants and any special equipment or special requirements.

The organization should have processes and systems in place for reconciling differences in staff responses during the “time out.”

- b. The physician performing fluoroscopy should have knowledge of exposure factors, including kVp, mA, magnification factor, and dose rate, and should consider additional parameters such as collimation, field of view, and last image hold.
- c. The physician creating the TIPS should have knowledge of physiologic parameters that would indicate developing problems or complications and be able to interpret changes in heart rate or rhythm, changes in blood pressure, and changes in oxygen saturation. These are essential for successful intraprocedural care of the patient.
- d. Nursing personnel, technologists, and those directly involved in the care of patients undergoing TIPS creation should have protocols for use in standardizing care. These should include, but are not limited to, the following:
  - i. Equipment needed for the procedure.
  - ii. Patient monitoring.

Protocols should be reviewed and updated periodically.

### 3. Postprocedure care

- a. A procedure note should be written in the patient’s chart summarizing the major findings of the study and any immediate complications. This note may be brief if a formal report is available within a few hours. However, if the typed report is not likely to be on the chart the same day, a more detailed summary of the study should be written in the chart at the conclusion of the procedure. In all cases, pertinent findings should be communicated to the referring physician in a timely manner.
- b. All patients should be at bed rest and observed in the initial postprocedure period. The length of this period of bed rest will depend on the patient’s medical condition.
- c. During the initial postprocedure period, skilled nurses or other appropriately trained personnel should periodically monitor the puncture site for bleeding or hematoma.

- d. The patient should be monitored for urinary output, cardiac symptoms, pain, and other indicators of systemic complications that may necessitate overnight care.
- e. The operating physician or a qualified designee should evaluate the patient after the procedure, and these findings should be summarized in a progress note. If moderate sedation was administered prior to and during the procedure, recovery from moderate sedation must be documented. The physician or designee should be available for continuing care during hospitalization and after discharge. The designee may be another physician or a nurse.
- f. While not part of the TIPS procedure, a baseline study to evaluate the shunt’s functional status should be obtained prior to and shortly after discharge. This study can be delayed for several days or until an early outpatient clinical visit, particularly in patients who receive TIPS stent grafts. Unlike bare metal stents, polytetrafluoroethylene TIPS stent grafts typically prevent successful TIPS sonography within the first several days or week until graft incorporation begins.

## VI. DOCUMENTATION

Reporting should be in accordance with the [Practice Guideline for the Reporting and Archiving of Interventional Radiology Procedures](#).

## VII. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, radiologic technologists, and all supervising physicians have a responsibility to minimize radiation dose to individual patients, to staff, and to society as a whole, while maintaining the necessary diagnostic image quality. This concept is known as “as low as reasonably achievable (ALARA).”

Facilities, in consultation with the medical physicist, should have in place and should adhere to policies and procedures, in accordance with ALARA, to vary examination protocols to take into account patient body habitus, such as height and/or weight, body mass index or lateral width. The dose reduction devices that are available on imaging equipment should be active; if not, manual techniques should be used to moderate the exposure while maintaining the necessary diagnostic image quality. Periodically, radiation exposures should be measured and patient radiation doses estimated by a medical physicist in accordance with the appropriate ACR

Technical Standard. (ACR Resolution 17, adopted in 2006 – revised in 2009, Resolution 11)

### VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education Concerns appearing elsewhere in the ACR Practice Guidelines and Technical Standards book.

These data should be utilized in conjunction with the thresholds described in Section II and Appendix B and C below to assess TIPS procedural efficacy and complication rates and, as defined in those sections, to trigger institutional review when the thresholds defined in those sections are exceeded.

#### APPENDIX A

#### Society of Interventional Radiology Standards of Practice Committee

#### Classification of Complications by Outcome

##### Minor Complications

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

##### Major Complications

- C. Require therapy, minor hospitalization (<48 hours).
- D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours).
- E. Permanent adverse sequelae.
- F. Death.

#### APPENDIX B

#### 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  $\leq 12$  mm Hg. The authors recognize that the final portosystemic gradient may vary depending on the treated indication (e.g., ascites vs. gastric or esophageal variceal hemorrhage) 95%

#### Clinical Success

Acute clinical success for variceal bleeding 95%  
When feasible, the event free survival interval should be recorded by the primary operator or the patient's primary physician.

#### APPENDIX C

#### Specific Complications of TIPS

	<u>Reported Rate</u>	<u>Suggested Complication Specific Threshold</u>
<b><u>Major Complications (overall)</u></b>	3%	5%
Hemoperitoneum+	0.5%	1%
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 uncontrolled encephalopathy****	--	--
Death*****	1%	2%
<b><u>Minor Complications* (overall)</u></b>	4%	8%
Transient contrast-induced renal failure	2%	5%
Encephalopathy controlled by medical therapy	15% to 25%	15% to 25%
Fever	2%	5%
Transient pulmonary edema	1%	1%
Entry site hematoma	2%	5%

\*See Appendix C.

+Hemoperitoneum warranting blood transfusion.

\*\*The rate of accelerated liver failure after TIPS is highly dependent upon patient selection, final shunt diameter, comorbid factors (e.g. preexisting multiorgan system failure, high MELD score, elevated APACHE II scores, 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, a specific threshold for this complication cannot be assigned.

\*\*\*A major stent malposition includes conditions such as free stent migration within the portal or systemic venous circulations, or ones resulting in vascular perforation or caval occlusion (due to excessive extension of a stent graft into the inferior vena cava or to the right atrium).

\*\*\*\*Encephalopathy rates are directly dependent on 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% to 40% of cases [16,22,23,53]. In contrast, elective patients with Child-Pugh class A or B hepatocellular disease may manifest severe, uncontrolled encephalopathy in 3% to 10% of cases [24,25,52,98,103,104,108,110].

\*\*\*\*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 on pre-existing 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.

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\*Guidelines and standards are published annually with an effective date of October 1 in the year in which amended, revised or approved by the ACR Council. For guidelines and standards published before 1999, the effective date was January 1 following the year in which the guideline or standard was amended, revised, or approved by the ACR Council.

#### Development Chronology for this Guideline

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