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## **ACR–SIR–SPR PRACTICE PARAMETER FOR THE CREATION OF A TRANSJUGULAR INTRAHEPATIC PORTOSYSTEMIC SHUNT (TIPS)**

### **PREAMBLE**

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care<sup>1</sup>. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents 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 practice parameters, 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 practice parameters 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 practice parameters. However, a practitioner who employs an approach substantially different from these practice parameters 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 practice parameters 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 practice parameters is to assist practitioners in achieving this objective.

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<sup>1</sup> Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, \_ N.W.2d \_ (Iowa 2013) Iowa Supreme Court refuses to find that the *ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures* (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, Stanley v. McCarver, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

## I. INTRODUCTION

This practice parameter was revised collaboratively by the American College of Radiology (ACR), the Society of Interventional Radiology (SIR), and the Society for Pediatric Radiology (SPR) [1].

A transjugular intrahepatic portosystemic shunt (TIPS) is a percutaneous method used to treat the complications of portal hypertension. During the TIPS procedure, a channel, which shunts blood from the portal vein to a hepatic vein, is created through the hepatic parenchyma, reducing the portosystemic pressure gradient. Although TIPS has proven effective as a treatment for uncontrolled variceal hemorrhage, refractory ascites, and hepatic hydrothorax and as a bridge to liver transplant, it is not useful as a means to preserve liver function, with a possible exception in the treatment of Budd-Chiari syndrome [2-55].

Creating a TIPS involves several steps:

1. Catheterization of a hepatic vein
2. Wedge or balloon occluded hepatic venography (CO<sub>2</sub> portography) [56] or intravascular/transabdominal ultrasound to visualize the portal vein and to guide the needle pass [57-62]
3. Passage of a long curved needle from the hepatic vein through the liver parenchyma into an intrahepatic branch of the portal vein
4. Direct portal venography to confirm proper location within the portal vein
5. Direct measurement of baseline systemic and portal vein pressures
6. Balloon dilation of the tract between the hepatic and portal veins
7. Deployment of a self-expanding stent graft within the portosystemic tract to maintain it against the recoil of the surrounding liver parenchyma and prevent tissue ingrowth
8. Angiographic and hemodynamic assessment of the shunt tract
9. Dilation of the endoprosthesis until a satisfactory portosystemic pressure gradient has been reached, typically less than 12 mmHg [63-66]
10. Embolization of varices may be considered if opacification of the varices persists on portography following TIPS creation or in treating gastric varices or esophageal varices to prevent recurrent variceal bleeding [67,68].

The practice parameters that follow are to be used in quality improvement (QI) programs to evaluate the safety and effectiveness of the TIPS procedure. The most important processes of care are 1) proper patient selection, 2) performance of the procedure, and 3) post-TIPS surveillance. The major outcome measures for TIPS include improvement or resolution of the clinical indications for the procedure, early- and long-term reduction of portal hypertension, and the incidence of adverse events. Outcome measures are assigned threshold levels based on literature review and expert opinion. When the evidence of literature was weak, conflicting, or contradictory, consensus for the parameter was reached by a minimum of 12 committee members using a modified Delphi consensus method [69].

Although practicing physicians should strive to achieve perfect outcomes (eg, 100% success, 0% complications), in practice all physicians will fall short of this ideal. 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 QI programs. Failing to achieve technical success in 95% and hemodynamic success in 90% of cases or exceeding the thresholds for major or minor complications (see Appendices B and C) should prompt a review of departmental policies and procedures. Patient referral patterns and selection factors may dictate a different threshold value for a metric 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 based on the reporting standards defined by the Technology Assessment Committee of the SIR are incorporated into this document by reference [70].

## 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 variceal bleed in high-risk patients
4. Portal hypertensive gastropathy or intestine-opathy
5. Refractory ascites
6. Hepatic hydrothorax
7. Budd-Chiari syndrome [71]
8. Hepatopulmonary syndrome
9. Hepatorenal syndrome [72]
10. Decompression of portosystemic collaterals prior to abdominal surgical procedures

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 potentially life-saving measure, acknowledging that the procedure itself entails significant risks. Although there are no absolute contraindications to creating a TIPS, the following are relative contraindications:

1. Elevated right or left heart pressures
2. Heart failure or cardiac valvular insufficiency
3. Rapidly progressive liver failure
4. Clinically significant refractory hepatic encephalopathy
5. Uncontrolled systemic infection or sepsis
6. Unrelieved biliary obstruction
7. Extensive primary or metastatic hepatic malignancy
8. Severe, uncorrectable coagulopathy
9. Marked pulmonary arterial hypertension

Although polycystic liver disease is frequently listed as a contraindication to TIPS, this is an unsubstantiated historic contraindication [73]. TIPS has been successfully performed in the setting of polycystic liver disease [73-75]. The use of a hybrid cross-sectional/angiographic imaging suite may facilitate successful placement [76].

It should be noted that in the setting of emergent variceal bleeding, TIPS can be performed in the presence of severe coagulopathy, although every effort should be made to safely correct the coagulopathy before, during, and after the procedure.

### III. SUCCESS AND COMPLICATIONS

#### A. Measures of Success

Success should be classified as technical, hemodynamic, and clinical [70]. Note that success rates are not currently available for the pediatric population because of the lack of large series focusing on them. Because of the smaller size of their anatomic structures and other factors, success rates may be lower for them than for adults.

Technical success – Technical success describes the successful creation of a shunt (stent bridging) 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. A common hemodynamic end point, particularly when managing bleeding varices, is a portosystemic gradient of 12 mmHg [63-66,77]. 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 millimeters of mercury and/or centimeters 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 has become less of an issue with more widespread use of stent grafts [78-87]. The 2-year primary patency rates of 76% to 84% and primary assisted patency rates of 93% are significantly improved because of the use of polytetrafluoroethylene (PTFE) stent grafts [87-93]. A meta-analysis demonstrated improved shunt patency with PTFE covered stents without increasing the risk of hepatic encephalopathy and with a trend towards longer survival [94]. 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 [95,96].

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 having highly stenotic or occluded shunts. Furthermore, the outcomes after TIPS may differ depending on the types of varices (for example, gastric versus esophageal varices) [97].

## 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. Of note, encouraging data are now available in a large, retrospective study involving Budd-Chiari patients, demonstrating technical success rates of up to 93% and 1-, 5-, and 10-year transplant-free survival rates of 88%, 78%, and 69%, respectively [71]. It is presently difficult, however, to define threshold levels for success in such cases. Similarly, TIPS in transplanted livers may have different clinical outcomes compared to native (nontransplanted) livers [98].

## C. Complications [26,75,99-142]

Although 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 number of patients, for example, early in a QI program. In this situation, the overall procedure threshold is more appropriate for use in a QI program. Note that expected complication rates are not currently available for the pediatric population because of the relatively small number of cases.

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, Diagnostic Radiology or Interventional Radiology/Diagnostic Radiology (IR/DR) by the American Board of Radiology (ABR), the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or the Collège des Médecins du Québec and has performed (with supervision) a sufficient number of TIPS procedures to demonstrate competency as attested by the supervising physician(s).

or

2. Successful completion of radiology or interventional radiology residency training program approved by the Accreditation Council for Graduate Medical Education (ACGME), the Royal College of Physicians and Surgeons of Canada (RCPSC), the Collège des Médecins du Québec, or the American Osteopathic Association (AOA) and a minimum of 12 months' training and experience in vascular/interventional radiology and/or in an interventional/vascular radiology fellowship program, and have performed (with supervision) a sufficient number of TIPS procedures to demonstrate competency as attested by the supervising physician(s). [143,144].

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 postgraduate 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 practice parameter, technical standard, or policy [143,144]. 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. Physicians meeting any of the qualifications in 1, 2, or 3 above must also have written substantiation that they are 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. For pediatric cases, this includes knowledge of age-based normal ranges for vital signs, and signs and symptoms of complications; or availability of team members with such expertise (such as pediatric sedation and monitoring personnel).
  - c. Pharmacology of drugs used for sedation and analgesia, and recognition and treatment of adverse reactions and complications. For pediatric cases, this includes knowledge of weight-based pediatric dosages, age-based normal values for vital signs, and signs and symptoms of adverse reactions and complications.
  - d. Appropriate use and operation of fluoroscopic and radiographic equipment, mechanical injectors, digital subtraction equipment, and other electronic imaging systems.
  - e. Principles of radiation protection, hazards of radiation, and radiation monitoring requirements as they apply to both patients and personnel, including appropriate dose-reduction strategies for children [145].
  - f. Pharmacology of contrast materials 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 (weight-based in children), and imaging 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, as well as normal variants.
  - k. Interpretation of gastrointestinal, hepatic, arterial, and venous vascular studies.
  - l. Postprocedural patient management, especially recognition and initial management of complications.

The written substantiation should come from the chief of interventional radiology, the chair of the department of radiology, or his or her designee at the institution in which the physician will be providing these services. Substantiation could also come from a prior institution in which the physician provided the services, but only at the discretion of the chair of the department of radiology or his or her designee who solicits the additional input.

## 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 Parameter for Continuing Medical Education \(CME\)](#) [146].

### B. Nonphysician Practitioners

Physician assistants and nurse practitioners can be valuable members of the interventional radiology team. Their participation in TIPS procedures should be specifically under the direct supervision of appropriately qualified and credentialed physicians. See the [ACR-SIR-SNIS-SPR Practice Parameter for Interventional Clinical Practice and Management](#) [147].

### C. 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, 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 strongly 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 the American Board of Medical Physics (ABMP).

A Qualified Medical Physicist should meet the [ACR Practice Parameter for Continuing Medical Education \(CME\)](#). (ACR Resolution 17, 1996 – revised in 2012, Resolution 42) [146]

The appropriate subfield of medical physics for this practice parameter is Diagnostic Medical Physics. (Previous medical physics certification categories including Radiological Physics, Diagnostic Radiological Physics, and Diagnostic Imaging Physics are also acceptable).

### D. 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)

## E. 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 procedure. 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.

## F. Anesthesiologist

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

## G. 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 angiographic 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 flat panel detector or 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 equipment should be capable of displaying to the operator the radiation dose received by the patient at the operator's normal working position and recording the radiation dose received by the patient so it can be made part of the patient's permanent medical record [148]. 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, pressure measurement equipment, and introducer sheaths

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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.

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, ventilator, 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 using moderate sedation, a pulse oximeter or an end-tidal carbon dioxide monitor should be available. (See the [ACR-SIR Practice Parameter for Sedation/Analgesia](#) [149].) For facilities using general anesthesia, the patient is typically intubated and additional monitoring, such as direct arterial line blood pressure monitoring, may be considered.
2. Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications and/or procedural complications. The equipment should be maintained and medications inventoried for drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of ages and sizes in the patient population.
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, angiographic image recording, angiographic contrast material 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. It would be unusual for the patient to not receive sedation or general anesthesia. However, if that were the case, one of the staff members assisting the procedure should be assigned to periodically assess the patient's status. If the patient is to undergo 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 sedation. (See the [ACR-SIR Practice Parameter for Sedation/Analgesia](#). [149].) For pediatric cases, sedation and recovery personnel should be experienced and qualified in pediatric sedation, monitoring, and airway maintenance. Children may easily slip between depths of sedation during the procedure. Therefore, there must be experienced and qualified personnel available to manage the airway and rescue children from deep sedation or apnea should this occur. Health professionals who provide sedation for TIPS procedures should comply with the recommendations of the [ACR-SIR Practice Parameter for](#)

[Sedation/Analgesia](#) [149].

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 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

For additional information see the [ACR–SIR–SNIS–SPR Practice Parameter for Interventional Clinical Practice and Management](#) [147].

##### 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 the presence of patent portal vein or massive ascites, and certain diagnostic laboratory results
- c. Relative 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–SIR Practice Parameter on Informed Consent for Image-Guided Procedures](#) [150].

##### 2. Procedural care

- a. Adherence to the Joint Commission’s current Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ is required for procedures in non–operating room settings, including bedside procedures.

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

- b. TIPS creation carries a substantial likelihood of clinically significant patient radiation dose [151]. Therefore, the physician performing the procedure should have knowledge of radiation exposure factors, including kVp, mA, magnification factor, and fluoroscopic/angiographic frame rate. The

operator should also consider additional parameters such as collimation, field of view, last image

hold, and geometry (especially the patient's proximity to the lateral source). The fluoroscopic equipment should be capable of displaying the radiation dose received by the patient to the operator at the operator's normal working position and recording the radiation dose received by the patient. The radiation dose should be recorded and made part of the patient's permanent medical record [148].

- 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
  - iii. Protocols should be reviewed and updated periodically.

### 3. Postprocedure care

- a. 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 sedation was administered prior to and during the procedure, safe and adequate recovery from 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, a midlevel practitioner, or a nurse. (See the ACR–SIR Practice Parameter for Sedation/Analgesia [149].) Postprocedure documentation should be in accordance with the ACR–SIR–SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures [152].
- 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, a midlevel practitioner, or a nurse.

Although not part of the TIPS procedure, a baseline study (eg, ultrasound) to evaluate the shunt's functional status should be obtained prior to or 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, expanded PTFE (e-PTFE) TIPS stent grafts typically prevent successful TIPS sonography within the first several days or week until graft incorporation begins because of an acoustic barrier thought to be secondary to microbullae embedded within the e-PTFE [153] or possibly pockets of gas between the e-PTFE and the wire mesh of the stent or between the

hepatic parenchyma and the e-PTFE [154].

## VI. DOCUMENTATION

Reporting should be in accordance with the [ACR–SIR–SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures](#) [152].

## VII. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, registered radiologist assistants, radiologic technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff, and to society as a whole, “as low as reasonably achievable” (ALARA) and to assure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure and the diagnostic image quality necessary to achieve the clinical objective. All personnel that work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection and application of dose limits) and the principles of proper management of radiation dose to patients (justification, optimization and the use of dose reference levels)

[http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578\\_web-57265295.pdf](http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.pdf)

Nationally developed guidelines, such as the ACR’s [Appropriateness Criteria](#)<sup>®</sup>, should be used to help choose the most appropriate imaging procedures to prevent unwarranted radiation exposure.

Facilities should have and adhere to policies and procedures that require varying ionizing radiation examination protocols (plain radiography, fluoroscopy, interventional radiology, CT) to take into account patient body habitus (such as patient dimensions, weight, or body mass index) to optimize the relationship between minimal radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used whenever appropriate. If such technology is not available, appropriate manual techniques should be used.

Additional information regarding patient radiation safety in imaging is available at the Image Gently<sup>®</sup> for children ([www.imagegently.org](http://www.imagegently.org)) and Image Wisely<sup>®</sup> for adults ([www.imagewisely.org](http://www.imagewisely.org)) websites. These advocacy and awareness campaigns provide free educational materials for all stakeholders involved in imaging (patients, technologists, referring providers, medical physicists, and radiologists).

Radiation exposures or other dose indices should be measured and patient radiation dose estimated for representative examinations and types of patients by a Qualified Medical Physicist in accordance with the applicable ACR technical standards. Regular auditing of patient dose indices should be performed by comparing the facility’s dose information with national benchmarks, such as the ACR Dose Index Registry, the NCRP Report No. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States or the Conference of Radiation Control Program Director’s National Evaluation of X-ray Trends. (ACR Resolution 17 adopted in 2006 – revised in 2009, 2013, Resolution 52).

In addition, manual techniques (adjusting the angiographic and fluoroscopic frame rates, increasing the patient’s distance from the source, minimizing the distance between the patient and the image receptor, limiting the use of digital subtraction angiography, use of last image hold and video fluoroscopy clips, etc. ), should be used to optimize the radiation dose. In other words, the technique employed should be tailored to the task at hand [155-157].

Radiation safety deserves particular attention when fluoroscopically guided procedures are performed on children. The Image Gently<sup>®</sup> coalition has provided useful guidance in this regard [158].

## 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 appearing under the heading *Position Statement on QC & Improvement, Safety, Infection*

*Control, and Patient Education* on the ACR website (<http://www.acr.org/guidelines>) and other published practice parameters and recommendations [3,159-161].

Equipment performance monitoring should be in accordance with the [ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Fluoroscopic Equipment](#) and the [ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Radiographic Equipment](#) [162,163].

This information should be used in conjunction with the thresholds described in section II and Appendices B and C below to assess TIPS procedural efficacy and complication rates and 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 in the presence of patent portal and hepatic veins 95%

##### **Hemodynamic**

Reduction of the portosystemic gradient to a level targeted by the operator. In general, the target portosystemic gradient is  $\leq 12$  mmHg [63-66,77]. The authors recognize that the final portosystemic gradient may vary depending on the treated indication (eg, ascites versus gastric or esophageal variceal hemorrhage). 90%

##### **Clinical Success for Variceal Bleeding**

Acute clinical success for variceal bleeding [164,165]. When feasible, the event-free survival interval should be recorded by the primary operator or the patient's primary physician. 90%

##### **Clinical Success for Ascites**

Complete or partial response with intention to treat [28,39,44,166,167] 50% to 90%

##### **Clinical Success for Refractory Hydrothorax**

Complete or partial response [18,23,46,50,168-170] 42% to 80%

**APPENDIX C**

**TABLE C1. SPECIFIC COMPLICATIONS OF TIPS**

<b>Major Complications (overall)</b>	<b>Reported Rate</b>	<b>Suggested Complication-Specific Threshold</b>
	3%	5%
Hemoperitoneum+	0.5%	<5%
Stent malposition**	1%	<5%
Hemobilia	2%	<5%
Radiation skin burn	0.1%	<1% 0.1%
Hepatic infarction	0.5%	<1%
Renal failure requiring chronic dialysis	0.25%	<1%
Hepatic artery injury	1%	2% [113]
Accelerated liver failure***	--	--
Severe or uncontrolled encephalopathy****	--	--
Refractory encephalopathy [142,171-173]	3% to 8%	10%
Death*****	1%	<5%
<b>Minor Complications (overall)</b>	4%	8%
Transient contrast-induced renal failure	2%	5%
Encephalopathy controlled by medical therapy	5% to 35%	40% [142,171]
Fever	2%	5%
Transient pulmonary edema	1%	1%
Transcapsular puncture [142]	5% to 30%	10%
Biliary duct puncture	<5%	10%
Gallbladder puncture	<10%	10%
Right kidney puncture	1.5%	2%

+Hemoperitoneum warranting blood transfusion

\*\*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).

\*\*\*The rate of accelerated liver failure after TIPS is highly dependent upon patient selection, final shunt diameter, and comorbid factors (eg, pre-existing 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. Thus a specific threshold for this complication cannot be assigned.

\*\*\*\*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 [17,23,24,53]. In contrast, elective patients with Child-Pugh class A or B hepatocellular disease may manifest severe, uncontrolled encephalopathy in 3% to 10% of cases [25,26,52,130,135,136,139,141].

\*\*\*\*\*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 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.

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\*Practice parameters and technical 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 practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

Development Chronology for this Practice

- 2001 (Resolution 14)
- Amended 2004 (Resolution 25)
- Amended 2006 (Resolution 16g, 17, 34, 35, 36)
- Revised 2007 (Resolution 8, 12m)
- Amended 2009 (Resolution 11)
- Revised 2012 (Resolution 4)
- Amended 2014 (Resolution 39)
- Revised 2017 (Resolution 15)
- Amended 2018 (Resolution 44)