Revised 2022 (Resolution 18)*

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[1]. 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 practitioner in light of all the circumstances presented. Thus, an approach that differs from the guidance in this document, 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 this document 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 this document. However, a practitioner who employs an approach substantially different from the guidance in this document 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 the guidance in this document 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 this document is to assist practitioners in achieving this objective.

[1] Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, 831 N.W.2d 826 (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).

A transjugular intrahepatic portosystemic shunt (TIPS) is a percutaneous image-guided interventional procedure 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 [1]. TIPS is a technically demanding procedure, and creating a TIPS involves several steps, including, but not limited to, catheterization of a hepatic vein, obtaining transhepatic portal venous access, deployment of a stent/stent graft within the tract between the hepatic and portal veins, and hemodynamic assessment of the shunt tract [2-4]. Since its first clinical application in humans in the 1980s [5-7], TIPS has continued to evolve with the development of technology [8-13] and has proven effective as a treatment for complications related to portal hypertension, including uncontrolled variceal hemorrhage, refractory ascites, and hepatic hydrothorax and as a bridge to liver transplant. It is, however, not useful as a means to preserve liver function, with a possible exception in the treatment of Budd-Chiari syndrome [14-67]. Complications related to TIPS can be life-threatening and include, but are not limited to, refractory encephalopathy and liver failure. Therefore, clinical and technical expertise and careful evaluation of the patient are required.

The practice parameters that follow are intended to be used in quality improvement (QI) programs to evaluate the safety and effectiveness of the TIPS procedure and have incorporated measures of success in TIPS creation as well as rates and threshold of TIPS-related complications based on the reporting standards set forth by the Technology Assessment Committee of the SIR [68] and the latest QI guidelines for TIPS by the SIR Standards of Practice Committee [69].

Deviation from the recommended success rates and complication threshold (Appendices B and C) should prompt a review of departmental policies and procedures. Nevertheless, as patient referral patterns and selection factors may dictate a different threshold value for a metric at a particular institution, each department is urged to alter the thresholds to higher or lower values to meet its own QI program needs [1].

Complications can also be stratified on the basis of outcome. For further information, see the Proposal of a New Adverse Event Classification by the Society of Interventional Radiology Standards of Practice Committee [70].

II. INDICATIONS AND CONTRAINDICATIONS

A. Indications

TIPS creation is indicated for:

1. Recurrent variceal hemorrhage that is not amendable to initial or continued endoscopic therapy [1,18].
2. Uncontrollable variceal hemorrhage [1,6,18,71]
3. Current or prior variceal hemorrhage that is not amenable to initial or continued endoscopic therapy [1,18]
4. Prophylaxis against recurrent variceal bleed in high-risk patients [19,29,47,72-74]
5. Portal hypertensive gastropathy or intestine-opathy [1,18,42]
6. Bleeding ectopic varices refractory to medical therapy [75,76]
7. Refractory ascites [1,14,18,23-26,40,44,51,59,60]
8. Hepatic hydrothorax [1,15,18,22,30,32,35,58,62,77]
9. Budd-Chiari syndrome [1,18,20,28,36,37,45,46,54,78]
10. Hepatopulmonary syndrome [18,79]
11. Hepatorenal syndrome [18,79,80]
12. Decompression of portosystemic collaterals before abdominal surgical procedures [81,82]
13. Medically refractory portal vein thrombosis or chronic portal vein occlusion (performed in conjunction with portal vein recanalization) [83,84]

Of note, although prior evidence for “early” (preemptive) TIPS creation (after endoscopically controlled bleeding) was somewhat variable [85-87], a more recent meta-analysis of randomized controlled trials and observational studies has demonstrated increased 1-year survival after early TIPS creation in high-risk patients (Child-Pugh B with active bleeding

or Child-Pugh C <14 points) [73,74]. On the other hand, salvage TIPS is not recommended in patients with refractory variceal hemorrhage whose Child-Pugh score is >13 [88].

In the setting of refractory ascites, patients may not benefit from TIPS if the bilirubin level is over 50 μmol/L (or 3 mg/dL) and the platelet count is < 75 × 109/L [89].

TIPS has been performed as an adjuvant therapy in symptomatic massive acute portal vein thrombosis in patients with a high risk of bowel ischemia if the impairment of the outflow precludes the reestablishment of the physiologic flow [84].

"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" [1].

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 conditions are relative contraindications [1]:

1. Elevated right or left heart pressures with heart failure [1,90]
2. Severe cardiac valvular insufficiency [1]
3. Rapidly progressive liver failure [1]
4. Clinically significant refractory hepatic encephalopathy (HE) [1]
5. Uncontrolled systemic infection or sepsis [1]
6. Unrelieved biliary obstruction [1]
7. Extensive primary or metastatic hepatic malignancy [1]
8. Severe, uncorrectable coagulopathy [1,91]
9. Marked pulmonary arterial hypertension [1]
10. Neonates and infants too small for the procedure to be performed

Although polycystic liver disease is frequently listed as a contraindication to TIPS, this is an unsubstantiated historic contraindication [92]. TIPS has been successfully performed in the setting of polycystic liver disease [92-94]. The use of a hybrid cross-sectional/angiographic imaging suite may facilitate successful placement [95].

C. Other Patient Selection Considerations

In addition to the clinical measures such as Child-Pugh class or score, Model for End-Stage Liver Disease (MELD) score (or the pediatric equivalent, Pediatric End-Stage Liver Disease score), Acute Physiology and Chronic Health Evaluation (APACHE) II score, that have been used to assess patient's preprocedural status, other variables including patient age, urgency of the procedure, preprocedural hepatic venous pressure gradient, pre-and post-TIPS liver function tests results, right atrial pressure, and diastolic function have been shown to correlate with or predict survival after TIPS placement [69,90,96-99]. Some of these factors are also predictors for development of HE after TIPS creation [69,100].

Although TIPS can be considered in patients with acute variceal bleeding and renal dysfunction, TIPS placement in patients with significant intrinsic renal disease (stage 4/5) may result in uncontrolled HE [101].

In patients with HCC, if technically and clinically feasible, the decision will be on a case-by-case basis and in consideration of the liver transplant candidacy.

Portal vein thrombosis, with or without cavernous transformation, has been traditionally considered a contraindication for TIPS placement. TIPS placement in this setting is more technically challenging; however, multiple studies have demonstrated the efficacy and safety of TIPS combined with thrombectomy or portal vein recanalization to manage portal hypertension complications and optimize patients for liver transplant in this situation [92,102].

III. SUCCESS AND COMPLICATIONS

A. Measures of Success

"Success should be classified as technical, hemodynamic, and clinical" [1]. The success measures for the TIPS procedure have been previously reported by Haskal and others [1,68] as well as the latest quality improvement guidelines for TIPS [69], and are included below. Because of the smaller size of their anatomic structures and other factors, success rates may be different for pediatric patients than for adults [103,104].

Technical success – Technical success describes the successful creation of a shunt (stent bridging) between the portal and systemic veins. In the case of parallel shunt placement, technical success is reported for individual shunts [1,68].

Hemodynamic success – Hemodynamic success refers to the successful post-TIPS reduction of the portosystemic gradient below a threshold [68] appropriate for the clinical indication. A common hemodynamic end point, particularly when managing bleeding varices, is a portosystemic gradient of 12 mm Hg [10,105-108].

Clinical success – Clinical success refers to the improvement or resolution of the indication(s) for which TIPS was performed [68,69] and is likely the most important measure in longitudinal follow-up of post-TIPS patients [1,68]. The more widespread use of stent grafts has improved patency rates of TIPS without increasing the risk of HE and with a trend toward longer survival [109-125].

"Clinical success is also reflected in the interval of time during which the patient remains free of the symptoms alleviated by the TIPS" [1]. This is best described in terms of "event-free survival" intervals after TIPS placement [1,68,69]. 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 [1,68,69]. Furthermore, the outcomes after TIPS may differ depending on the types of varices (for example, gastric versus esophageal varices) [126].

B. Success Rates

Appendix A summarizes success rates in TIPS creation on patients with patent hepatic and portal veins as previously outlined by Haskal et al [68,103]. Although large series are limited, success rates in pediatric patients are similar [104]. Successful shunt creation has been reported in cases of hepatic and/or portal vein occlusion. These situations may require considerably more technical expertise than shunt creation in patients with patent portal and hepatic veins. Accordingly, it is recognized that lower success rates can be anticipated in patients with these anatomic conditions. However, different technical approaches have been developed for TIPS and portal vein recanalization including transsplenic access, which in the long term can positively impact transplant outcomes [102]. 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 [78]. Direct intrahepatic portosystemic shunt has been shown to be a viable alternative to TIPS in patients with Budd-Chiari syndrome when all hepatic veins are occluded [127,128]. It is presently difficult, however, to define threshold levels for success in such cases [68]. Similarly, TIPS in transplanted livers may have different clinical outcomes compared to native (nontransplanted) livers [129].

C. Complications [38,94,130-173]

"Although major complications can occur during or as a result of TIPS, they are generally uncommon and are reduced with operator experience" [68] (Appendix C) [1].

The overall procedure threshold for major complications is 5% of patients undergoing TIPS [68]. The number of pediatric patients undergoing TIPS creation is relatively small; therefore, the expected complication rates may be different.

It should be noted that clinical outcomes following TIPS are dependent upon the patient's preexisting comorbid factors, such as elevated APACHE II score, Child-Pugh class or score, and MELD score and its modifications. Appropriate patient selection and minimization of procedural complications can improve overall clinical outcomes.

D. Post-TIPS Surveillance

Patient follow-up is an integral part of TIPS and will increase the durable efficacy of the procedure [68]. Close follow-up with monitoring of shunt function and patency using Doppler sonography or shunt venography is necessary and appropriate [68].

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

Core Privileging: This procedure is considered part of or amendable to image-guided core privileging.

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 training and experience in vascular/interventional radiology and/or in an interventional/vascular radiology fellowship program, and has performed (with supervision) a sufficient number of TIPS procedures to demonstrate competency as attested by the supervising physician(s) [174,175].

   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 experience with demonstrated competency as primary operator in diagnostic angiography under the supervision of an on-site qualified physician during diagnostic angiograms, angioplasties (with documentation as primary operator on at least half), vascular stents, and embolization procedures 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 TIPS procedures with documented success and complication rates that meet the published threshold, for further information see Appendix A and Appendix B.

   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 anesthesia 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 [176].
   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, stent graft position and deployment, pressure measurements, selective angiographic methods, vascular

embolization and thrombolytic methods (in the setting of acute portal vein thrombosis), 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 their 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 their designee who solicits the additional input.

Maintenance of Competence

Physicians must perform a sufficient number of overall procedures applicable to the spectrum of core privileges to maintain their skills, with acceptable success and complication rates as laid out in this parameter. Continued competence should depend on participation in a quality improvement program that monitors these rates. Consideration should be given to the physician's lifetime practice experience.

Continuing Medical Education

The physician's continuing education should be in accordance with the ACR Practice Parameter for Continuing Medical Education (CME) [177].

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, 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, the American Board of Science in Nuclear Medicine (ABSNM), or the American Board of Medical Physics (ABMP).

A Qualified Medical Physicist should meet the ACR Practice Parameter for Continuing Medical Education (CME). [177]

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). (ACR Resolution 17, adopted in 1996 – revised in 2008, 2012, 2022, Resolution 41f)

C. Non-Physician Radiology Provider (NPRP)

NPRPs are all Non-Physician Providers (eg, RRA, RPA, RA, PA, NP, ...) who assist with or participate in portions of the practice of a radiologist-led team (Radiologists = diagnostic, interventional, neurointerventional radiologists, radiation oncologists, and nuclear medicine physicians). The term "NPRP" does not include radiology, CT, US, NM MRI technologists, or radiation therapists who have specific training for radiology related tasks (eg, acquisition of images, operation of imaging and therapeutic equipment) that are not typically performed by radiologists.

The term 'radiologist-led team' is defined as a team supervised by a radiologist (ie, diagnostic, interventional, neurointerventional radiologist, radiation oncologist, and nuclear medicine physician) and consists of additional

healthcare providers including RRAs, PAs, NPs, and other personnel critical to the provision of the highest quality of healthcare to patients. (ACR Resolution 8, adopted 2020).

NPRPs 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 the Clinical Practice of Interventional Radiology [178].

C. 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[2] 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.

D. Anesthesiologist

In most circumstances, anesthesiology support may be appropriate, particularly in the pediatric patients and critical patients with hemodynamic instability.

E. 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 desirable to produce higher-quality studies with reduced risk and duration. 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, because they allow for reduced volumes of contrast material and reduced examination times. CO_2 angiography is not essential but can be useful. 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

[2] 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, revised 2017 Resolution 12c)
*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.

received by the patient so it can be made part of the patient's permanent medical record [179]. 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. Additionally, use of ultrasound guidance, transabdominal or intravascular, has been shown to reduce the number of needle passes, radiation dose, and procedure time [180,181].

2. Adequate angiographic supplies such as catheters, guidewires, stents/stent grafts, balloons, embolic agents (eg, vascular coils), needles, pressure measurement equipment, 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, 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 and an end-tidal carbon dioxide monitor should be available. (See the ACR–SIR Practice Parameter for Minimal and/or Moderate Sedation/Analgesia [182].) 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 and adequate medical personnel to administer these based on careful patient assessment 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 their 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 Minimal and/or Moderate Sedation/Analgesia [182]). For pediatric cases, anesthesia 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 Minimal and/or Moderate Sedation/Analgesia [182].
3. For unstable patients, additional support may be necessary to ensure the safe performance of TIPS. The primary operator should 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**,** critical care 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 the Clinical Practice of Interventional Radiology [178].

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, which may include complete blood count, metabolic panel, liver function tests, and coagulation parameters. Anticipated preventive measurements are recommended including the availability of type and screen and cross match, arterial line monitor, strict fluid balance and central venous pressures to assess right heart overload and failure. At least one large bore central intravenous access is recommended throughout in case that precipitated resuscitation will be required. In addition, preprocedural cross-sectional imaging evaluation should be obtained whenever feasible. Peritoneal fluid analysis to exclude infection can be considered in the appropriate clinical setting.

   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–SPR Practice Parameter on Informed Consent for Image-Guided Procedures [183].

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 [184]. 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 and recording the radiation dose received by the patient. The radiation dose should be monitored throughout the procedure and the operator notified by the support personnel when the recommended dose notification thresholds are reached [185]. The radiation dose should be recorded and made part of the patient's permanent medical record [179,186].

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. The protocols should be reviewed and updated periodically. These should include, but are not limited to, the following:
   i. Equipment and supplies needed for the procedure
   ii. Patient monitoring and documentation

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 before 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 Minimal and/or Moderate Sedation/Analgesia [182].) Postprocedure documentation should be in accordance with the ACR–SIR–SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures [187].

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, bleeding, liver decompensation, and other indicators of systemic complications that may necessitate overnight care.

Although not part of the TIPS procedure, a baseline study (eg, ultrasound) to evaluate the shunt's functional status should be obtained before 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 [188] 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 [189].

The TIPS may be interrogated by ultrasound or direct venography in the event that shunt malfunction is suspected. Based on clinical and imaging findings, procedures such as TIPS reduction, variceal embolization, thrombectomy, or creation of an additional parallel TIPS may be considered.

VI. DOCUMENTATION

Reporting should be in accordance with the ACR–SIR–SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures [187].

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

Nationally developed guidelines, such as the ACR Appropriateness Criteria®, 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® for children (www.imagegently.org) and Image Wisely® for adults (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 [185,190,191].

Radiation safety deserves particular attention when fluoroscopically guided procedures are performed on children. The Image Gently coalition has provided useful guidance in this regard [192].

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 Quality Control & Improvement, Safety, Infection Control*, *and Patient Education* on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement). [15,193-195]

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 [196,197].

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.

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Writing Committee – members represent their societies in the initial and final revision of this practice parameter

ACR	SIR	SPR
Margaret Hsin-Shung Lee, MD, FACR, Chair	Hamed Aryafar, MD, FSIR	Michael Acord, MD
Claire Kaufman, MD	Nathan E. Frenk, MD	Michael Collard, MD
Dennis Kay, MD, FACR	Suvranu Ganguli, MD, FSIR	Abhay S. Srinivasan, MD
Richard B. Towbin, MD, FACR	Pilar Bayona Molano, MD	
	Beau B. Toskich, MD	

Committee on Practice Parameters – Interventional and Cardiovascular Radiology
(ACR Committee responsible for sponsoring the draft through the process)

Drew M. Caplin, MD, Chair	Gina Landinez, MD
Mandeep S. Dagli, MD	Kennith F. Layton, MD, FACR
Kevin W. Dickey, MD, FACR	Margaret Hsin-Shung Lee, MD, FACR
Meredith J. Englander, MD	M. Victoria Marx, MD
C. Matthew Hawkins, MD	Natosha N Monfore, DO
Mary Lee Jensen, MD, FACR	Amir Noor, MD
Claire Kaufman, MD	Christopher D Yeisley, MD
Dennis Kay, MD, FACR	

Committee on Practice Parameters – Pediatric Radiology
(ACR Committee responsible for sponsoring the draft through the process)

Terry L. Levin, MD, FACR, Chair	Jane Sun Kim, MD
John B. Amodio, MD, FACR	Jennifer A Knight, MD
Jesse Berman, MD	Jessica Kurian, MD
Tara M. Catanzano, MB, BCh	Helen R. Nadel, MD
Harris L. Cohen, MD, FACR	Erica Poletto, MD
Kassa Darge, MD, PhD	Richard B. Towbin, MD, FACR
Dorothy L. Gilbertson-Dahdal, MD	Andrew T. Trout, MD
Lauren P. Golding, MD	Esben S. Vogelius, MD
Adam Goldman-Yassen, MD	Jason Wright, MD
Safwan S. Halabi, MD	

Alan H. Matsumoto, MD, FACR, Chair, Commission on Interventional and Cardiovascular Radiology
Richard A. Barth, MD, FACR, Chair, Commission on Pediatric Radiology
David B. Larson, MD, MBA, Chair, Commission on Quality and Safety
Mary S. Newell, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards

Comments Reconciliation Committee

Elizabeth A. Ignacio, MD, Chair	Dennis Kay, MD, FACR
C. Matthew Hawkins, MD, Co-Chair	Amy L. Kotsenas, MD, FACR
Michael Acord, MD	David B. Larson, MD, MBA
Hamed Aryafar, MD, FSIR	Paul A. Larson, MD, FACR

Comments Reconciliation Committee

Richard A. Barth, MD, FACR
Pilar Bayona Molano, MD
Drew M. Caplin, MD
Michael Collard, MD
Timothy A. Crummy, MD, FACR
Nathan E. Frenk, MD
Suvranu Ganguli, MD, FSIR
Claire Kaufman, MD
Margaret Hsin-Shung Lee, MD, FACR
Terry L. Levin, MD, FACR
Alan H. Matsumoto, MD, FACR
Natosha N Monfore, DO
Mary S. Newell, MD, FACR
Abhay S. Srinivasan, MD
Beau B. Toskich, MD
Richard B. Towbin, MD, FACR

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APPENDIX A

Table B[3] Success Rates for TIPS (modified from Quality Improvement Guidelines for TIPS by the SIR Standards of Practice Committee [1,69]

Type of Success	Definition	Success Rate
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 ≤12 mmHg [105,106,108]. 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 [71,198]. 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 [40,51,56,199,200]	50% to 90%
Clinical Success for Refractory Hydrothorax	Complete or partial response [30,35,58,62,77,201,202]	42% to 80%

[3] Reprinted with modifications from Journal of Vascular and Interventional Radiology, 27, Dariushnia SR, Haskal ZJ, Midia M, et al., Quality Improvement Guidelines for Transjugular Intrahepatic Portosystemic Shunts, 1-7, 2016, with permission from Elsevier.

APPENDIX B

Table C[4] Specific Complications of TIPS (modified from Quality Improvement Guidelines for TIPS by the SIR Standards of Practice Committee [1,69]

Complications of TIPS	Reported Rate	Suggested Complication-Specific Threshold
Major Complications (overall)	3%	5%
Hemoperitoneum [1]	0.5%	<5%
Stent malposition [2]	1%	<5%
Hemobilia	2%	<5%
Radiation skin burn	0.1%	<1%
Hepatic infarction	0.5%	<1%
Renal failure requiring chronic dialysis	0.25%	<1%
Hepatic artery injury	1%	2% [144]
Accelerated liver failure [3]	--	--
Severe or uncontrolled encephalopathy [4]	--	--
Refractory encephalopathy [142,171-173]	3% to 8%	10%
Death [5]	1%	<5%
Minor Complications (overall)	4%	8%
Transient contrast-induced renal failure	2%	5%
Encephalopathy controlled by medical therapy	5% to 35%	40% [173,203]
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%

1 Hemoperitoneum warranting blood transfusion

2 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).

3 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.

4 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].

5 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, MELD score, 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.

[4] Reprinted with modifications from Journal of Vascular and Interventional Radiology, 27, Dariushnia SR, Haskal ZJ, Midia M, et al., Quality Improvement Guidelines for Transjugular Intrahepatic Portosystemic Shunts, 1-7, 2016, with permission from Elsevier.

*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 Parameter
2001 (Resolution 14)
Amended 2004 (Resolution 25)
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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)
Amended 2019 (Resolution 23)
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