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## **ACR–SIR PRACTICE GUIDELINE FOR ENDOVASCULAR MANAGEMENT OF THE THROMBOSED OR DYSFUNCTIONAL DIALYSIS ACCESS**

### **PREAMBLE**

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

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

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

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

### **I. INTRODUCTION**

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

Endovascular management of hemodialysis access prosthetic grafts and autogenous fistulae is an alternative treatment to surgical thrombectomy and revision [1-2]. It applies to accesses that have never matured accesses that have thrombosed, accesses that have blood flow insufficient to allow hemodialysis, accesses with clinical symptoms or noninvasive assessments that indicate the access is at increased risk of thrombosis, and access complications such as pseudoaneurysm or steal. Successful thrombectomy procedures can be performed using pharmacologic thrombolysis [3-9], aspiration thrombectomy [10], mechanical thrombectomy [7,10-12], balloon thrombectomy [13-14], or combinations of these methods. A complete thrombectomy procedure includes angiography of the graft or fistula with evaluation of the arterial inflow as well as venography of the draining veins to the level of the superior vena cava-right atrial junction. Angiography can be performed with either conventional film screen [15] or digital subtraction techniques [16]. By these means, stenoses are located that can be the anatomic cause of access failure or reduced function. Restoration of

a functional luminal diameter can be achieved with balloon angioplasty [3-4,8,13,17-23] and in some cases endovascular stents [21,24-30]. These procedures frequently are the initial treatment for a thrombosed or dysfunctional hemodialysis access; transluminal angioplasty is the preferred initial treatment of central vein stenosis to resolve upper extremity edema or relieve access dysfunction [1].

Endovascular management results in reduced morbidity compared to standard surgical therapy with less postprocedure pain and wound edema. Endovascular management of the thrombosed or dysfunctional hemodialysis access (EMDA) is usually performed on an outpatient basis with the patient returning home or to the dialysis unit for treatment.

Subsequently, if the clinical and hemodynamic parameters become abnormal, the patient should undergo re-evaluation of the vascular access to identify recurrent stenosis requiring additional intervention [1].

Appropriate management of vascular access for hemodialysis includes:

1. Determination of the procedural indication.
2. Assessment of the patient and physical evaluation of the vascular access.
3. Thorough angiographic evaluation of the vascular access circuit.
4. Identification and treatment of hemodynamically significant stenoses.
5. Determination of the success of the procedure.

The preprocedural abnormal clinical parameters should normalize following a successful intervention. The outcome measures or indicators for these processes are indications, success rates, and complication rates. Outcome measures are assigned threshold levels.

## II. DEFINITIONS

For the purposes of this guideline, the following definitions apply:

**Thrombosed hemodialysis access:** an autogenous fistula or prosthetic graft/biologic graft that contain occlusive thrombus and have no significant blood flow. Thrombus may extend into the runoff veins or inflow arteries. Autogenous fistulae, particularly those with aneurysmal segments, may harbor significantly larger amounts of thrombus than prosthetic grafts. The diagnosis of a thrombosed access is most frequently made by physical examination.

**Dysfunctional hemodialysis access:** (a) an access that has a hemodynamically significant stenosis and an abnormal hemodynamic or clinical indicator, or (b) an autogenous

fistula that has failed to mature during an adequate time period, or (c) an access that cannot be successfully punctured to perform dialysis.

**Functionally significant stenosis:** an anatomically significant stenosis (>50% reduction of normal vessel diameter) accompanied by a hemodynamic or clinical abnormality such as:

1. Change in physical examination characteristics of the thrill.
2. Elevated venous pressures recorded during hemodialysis (static and dynamic pressures) or measured within the vascular access during a diagnostic study (static pressures).
3. Detection of decreased intra-access blood flow at dialysis.
4. Swollen extremity.
5. Unexplained reduction in dialysis kinetics.
6. Clinical parameters such as prolonged bleeding after needle withdrawal, altered physical examination characteristics of vascular access, or thrombosis.
7. Elevated negative arterial prepump pressures that prevent increasing to acceptable blood flow.
8. Inability to puncture to perform hemodialysis.
9. Abnormal recirculation values [1].

Note: Prospective trend analysis is more valuable than isolated abnormalities in the above hemodynamic and clinical parameters. Abnormalities should be persistent over time to prompt treatment of the access.

Anatomically significant stenoses include:

1. Inflow problems
  - a. Stenosis of the inflow artery to the access.
  - b. Stenosis at the anastomotic site of an autogenous fistula.
  - c. Stenosis at the juxta-anastomotic segment of an autogenous fistula.
  - d. Stenosis at the arterial anastomosis of synthetic grafts.
2. Access problems
  - a. Stenosis of the hypertrophied venous segment of an autogenous fistula.
  - b. Intragraft stenosis within prosthetic grafts.
  - c. The great majority of anatomic causes are intrinsic to the graft or vessel. Rarely, however, extrinsic compression can contribute to access dysfunction (e.g., prosthetic graft kinking, pseudoaneurysm compression of the access, or compression from a periaccess hematoma).

3. Outflow problems
  - a. Stenoses of the venous runoff from the venous anastomosis to the central veins.
  - b. Failure to mature. In the case of the autogenous fistula, multiple venous runoff channels that divert blood flow away from the primary outflow vein can prevent the development of a hypertrophied outflow vein suitable for puncture [1].
  - c. Venous anastomotic stenosis of prosthetic grafts.
  - d. Central vein stenosis that may occur following the placement of a central venous catheter ipsilateral to the site of the access. These can also be caused by fibrous bands, clavicular fractures, pacemaker wires, etc.

Note: While over 90% of access thromboses and dysfunction are due to underlying anatomic stenoses, a physiologic process such as low cardiac output, postdialysis hypotension, access site infection, dehydration, or a hypercoagulable state can result in thrombosis of a prosthetic graft or autogenous fistula in the absence of an anatomic cause, or have a synergistic effect with an anatomic stenosis to accelerate failure of the hemodialysis access.

Fistulogram: a specific type of angiogram to evaluate an autogenous fistula or prosthetic graft used as vascular access for hemodialysis treatment. A fistulogram should include imaging the entire vascular access circuit including the arterial anastomosis, the fistula or graft, the runoff veins, the ipsilateral central veins, and the superior/inferior vena cava. Oblique projections are often needed to optimize visualization and characterization of arterial and venous stenoses. Evaluation of the inflow arteries may be necessary when hemodynamic indicators or clinical symptoms are not explained by fistulography.

EMDA (endovascular management of the thrombosed or dysfunctional hemodialysis access): the use of catheter-based endovascular techniques to restore or maintain adequate blood flow within an access to support effective hemodialysis [1,31].

Endovascular thrombus removal: the removal of occlusive thrombus from within the graft or fistula, including the outflow veins and inflow arteries to restore blood flow to the access. Removal of thrombus may be accomplished by any of several catheter-directed methods, such as thrombolysis, aspiration thrombectomy, balloon thrombectomy, clot maceration, or mechanical thrombectomy.

Endovascular treatment of a stenosis: the restoration of an acceptable luminal diameter to the segment (anatomic success) and resolution of the functional abnormality [1].

The stenosis may be treated with balloon angioplasty. In selected instances, stents, stent grafts, or cutting balloons may be required to improve luminal dimensions or repair a vascular injury. Prospective intervention is currently warranted for anatomical stenoses found in hemodialysis accesses and draining veins that also have an associated hemodynamic or clinical abnormality [1,31].

Anatomic success of a treated stenosis: restoration of luminal diameter with less than a 30% residual diameter stenosis. For treatment of thrombosed accesses, both restoration of flow and a less than 30% residual diameter stenosis for any significant underlying stenosis are required to report anatomic success [32-33]. However, several studies have reported that there is poor correlation between the degree of stenosis and the rate of blood flow through a prosthetic graft [34-36]. Depending on the rate of blood flow through the vascular access and the location of the treated lesion, a 30% residual stenosis may be hemodynamically significant.

Clinical success: the resumption of normal hemodialysis for a minimum of at least one session. After treatment of a stenosis, clinical success is defined as the improvement of clinical and hemodynamic parameters. After treatment of either a thrombosed access or an access-related stenosis, a continuous palpable thrill with minimal or no pulsatility extending from the arterial anastomosis can be considered one indicator of clinical success [32-33,37]. Physical examination of the access has the advantage of being easily performed in the interventional suite, unlike most of the monitoring tests.

Hemodynamic success: the restoration of hemodynamic parameters. Increase of volume flows to above predefined threshold values or reduction of venous dialysis or static pressures to below predefined threshold values can be considered evidence of hemodynamic success. Blood flow rates are not universally available in interventional suites [38] or dialysis clinics but have been correlated with degree of stenosis for a single lesion [35]. Static pressures are easily obtained in the interventional suite at minimal additional cost (transducer, tubing), but need to be interpreted in the context of their known limitations. It is the true intra-access static pressure that correlates with the degree of stenosis. Therefore, a reduction of the ratio between static intragraft venous limb systolic pressure and cuffed brachial systolic pressure to below predefined thresholds can be considered evidence of hemodynamic success.

Measurement of intragraft pressures to determine the hemodynamic significance of stenoses has been described by Sullivan and Besarab (see Appendix A). This study used a ratio of 0.4 to give 91% sensitivity for identifying synthetic access graft stenoses of at least 50% [39]. However, there are currently no uniformly accepted

criteria of percent reduction from pretreatment values to determine hemodynamic success [37]. Further, accesses with high intra-access volume flows frequently have high venous systolic pressure ratios and no venous outflow lesions [40]. Some have questioned the use of pressures as an endpoint [32].

Procedural success: anatomic success and at least one indicator of hemodynamic or clinical success [32-33].

Postintervention primary patency (PP): uninterrupted patency after intervention until the next access thrombosis or reintervention. Primary patency ends with treatment of a lesion anywhere within the access circuit, from the arterial inflow to the superior vena cava-right atrial junction [32-33].

Postintervention assisted primary patency (APP): patency following intervention until access thrombosis or a surgical intervention that excludes the treated lesion from the access circuit. Percutaneous treatments of restenosis or a new arterial or venous outflow stenosis/occlusion (excluding access thrombosis) are compatible with APP. APP ends with percutaneous thrombolysis/thrombectomy or simple surgical thrombectomy [32].

Postintervention secondary patency (SP): patency until the access is surgically declotted, revised, or abandoned because the patient undergoes renal transplant, or is lost to follow-up, etc. Thrombolysis and percutaneous thrombectomy are compatible with secondary patency, as are multiple repetitive treatments [32].

Cumulative patency rate (CP): the total time that the access remains patent (regardless of the number of primary interventions and/or thrombectomies) during the given time period. CP begins at the time that the graft is first placed [1].

Postintervention lesion patency: the interval following intervention until the next reintervention at or adjacent to the original treatment site or until the extremity is abandoned for permanent access due to surgeon choice, transplant, loss of follow-up, etc. Endovascular or surgical treatments of other lesions in the access circuit and creation of a new prosthetic graft or autogenous fistula that incorporates the original lesion into the access circuit are compatible with lesion patency.

Mature arteriovenous fistula: a fistula suitable for use when the diameter of a vein is sufficient to allow successful cannulation 4 to 6 weeks after construction [1].

Steal syndrome: ipsilateral extremity ischemia symptoms [41] in the presence of a functional graft or fistula. Etiologies include atherosclerotic arterial stenosis [42], diffuse disease in the native arteries of the extremity or excessive blood flow through the fistula or graft [43].

High flow fistulas with 20% to 50% of the cardiac output shunted through the access [44] can also result in cardiac overload [43].

### III. INDICATIONS

A. Indications for EMDA include, but are not limited to:

1. Stenoses without thrombosis occurring in a hemodialysis graft or fistula if the stenosis is greater than 50% reduction in luminal diameter and is considered functionally significant (see definitions above). The percent stenosis reported can vary considerably depending on the reference chosen, that is, the smaller graft or vein upstream (relative to direction of blood flow) to the lesion versus a larger vein downstream (relative to direction of blood flow). Percent stenosis may also be affected by the presence or absence of blood flow in the access at the time of measurement [32].
2. Stenosis associated with thrombosis. Thrombosis is associated with underlying venous stenosis in greater than 85% of cases [8].
3. Central vein stenosis greater than 50% lumen reduction, when the vascular access is hemodynamically compromised, and clinical parameters such as arm swelling or frequently failing access are present. Endovascular intervention with transluminal angioplasty is the preferred treatment of central vein stenosis [1].
4. Autogenous fistulae that have failed to mature after 4 to 6 weeks. Treatments include:
  - a. Balloon angioplasty of the inflow artery, arteriovenous anastomosis, juxta-anastomotic segment or outflow segments to increase blood flow to the native vein. Multiple areas of stenoses may exist in nonmaturing fistulae [45-50].
  - b. Interruption of venous tributaries that divert blood flow from the primary venous segment improves blood flow and thereby promotes maturation of the fistula [45-46,48,51].

B. Indications for Endoluminal Stent Placement

Several studies have demonstrated acceptable patencies for stent deployment following balloon angioplasty failure, especially for central vein lesions [24-25,52-53]. However, several prospective randomized trials have failed to show a benefit of bare stents over percutaneous transluminal angioplasty (PTA) alone in the treatment of

perianastomotic stenoses [26,54]. Current indications for endoluminal stent placement include:

1. Persistence of a significant venous stenosis that has failed balloon angioplasty and surgical access is difficult, surgery is contraindicated, or there are limited remaining access sites.
2. A significant central vein stenosis that has either failed balloon angioplasty or recurred within a 3 month period following an initially successful balloon angioplasty [1].
3. Rupture of an outflow vein following balloon angioplasty that cannot be controlled with balloon tamponade.

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.

Stent grafts may provide longer patency than bare stents for the venous anastomosis of grafts. A recent prospective randomized multicenter study showed better primary target lesion and circuit patencies after stent graft placement at the venous anastomosis of grafts than after angioplasty alone [55]. Stent grafts have also been used to treat intra-access pseudoaneurysms in case reports and small series. More studies are needed before the role of covered stents for prosthetic graft venous anastomoses and other applications including pseudoaneurysms, autogenous fistulas, and central veins can be determined.

#### C. Indications for Treatment of Steal

Steal can manifest by cardiac failure [43] or ischemic symptoms, including paresthesias, pain, motor weakness, sensory loss, or tissue loss. When ischemic symptoms occur in the presence of an atherosclerotic stenosis in the native arterial supply to the extremity, arterial angioplasty can relieve the symptoms [42]. When there is no arterial lesion, decreasing the flow in the graft or fistula by placing a flow restricting band across the access near the arterial anastomosis can also improve or relieve symptoms of steal. Due to access thrombosis complications after surgical banding [56], a modified banding technique using an inflated angioplasty balloon to accurately size the residual lumen has been used [47]. A more complicated surgical procedure known as distal revascularization with interval ligation (DRIL) can also relieve symptoms. It involves ligation of the artery just distal to the anastomosis of the autogenous fistula or prosthetic graft and an arterial bypass from the artery proximal to the arteriovenous anastomosis to the artery distal to the ligation. DRIL has a low reported rate of access thrombosis [57]. Radiocephalic fistulas complicated by steal have been treated by distal radial artery occlusion, either ligation [58] or endovascular occlusion [59].

Current indications for treatment of steal include:

1. Clinical symptoms or signs of steal ipsilateral to a functional fistula or graft.
2. High flow fistula with signs or symptoms of heart failure.

#### IV. CONTRAINDICATIONS

The decision to treat a hemodialysis access with endovascular techniques is always made in light of the patient's clinical condition, the number of alternative access sites available, and the expertise of the treating physician.

##### A. Absolute Contraindication

Active infection of the vascular access.

##### B. Relative Contraindications

1. Severe contrast allergy.
2. Severe hyperkalemia, acidosis, or other life-threatening abnormality of blood chemistry that requires immediate dialysis.
3. Known right to left shunt.
4. Severe cardiopulmonary disease.

#### V. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Collaboration of the interventional radiologist with the hemodialysis vascular access team is an integral component of percutaneous hemodialysis access management. This guideline supports the statement of the National Kidney Foundation Dialysis Outcomes Quality Initiative (NKF-DOQI) that "Management of vascular access complications relies on a multidisciplinary approach involving nephrologists, nephrology nurses, vascular interventionists, and surgeons. The goal of these management efforts is the preservation of vascular access" [1]. Regularly scheduled multidisciplinary conferences are one possible approach to ensuring optimum care of patients with vascular access complications.

##### A. Physician

Image-based diagnosis and treatment planning requires integrating the angiographic findings within the context of the patient's history, physical findings, and prior imaging studies. Therefore, the physician must understand the specific clinical indication for the procedure in order to plan and perform it safely and effectively.

The physician performing EMDA must fully appreciate the benefits, alternatives, and risks of the procedure. He/she must have a thorough understanding of anatomy

(including congenital and developmental variants and common collateral pathways), angiographic equipment, radiation safety, and physiologic monitoring equipment. The physician should have access to adequate supplies and personnel to perform the procedure safely.

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

1. Certification in Radiology or Diagnostic Radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or the Collège des Médecins du Québec, and has performed at least 25 EMDA angiographic procedures as primary operator under the direct supervision of a qualified physician, and must have outcomes within the quality improvement thresholds of this guideline.  
or
2. Completion of a residency 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) to include a minimum of 3 months training in vascular/interventional radiology, including documented formal training in the performance of invasive catheter angiographic procedures. During this training, the physician should have performed 25 EMDA angiographic procedures as primary operator under the direct supervision of a qualified physician, and these cases must be documented so the director of the training program can certify that the physician is proficient in the performance of the procedures, with acceptable success and complication rates within the quality assurance threshold rates laid out in this guideline.  
or
3. In the absence of ACGME recognized residency training as outlined above, in the absence of ACGME recognized fellowship training in a vascular/interventional radiology fellowship program, or in the absence of other postgraduate training that included comparable instruction and experience in diagnostic angiography, the physician must have at least 2 years experience and demonstrated competency as primary operator in diagnostic angiography under the direct supervision of an on-site, qualified physician during which he/she performed a minimum of 100 diagnostic peripheral arteriograms and 50 transluminal angioplasties, 25 of which were EMDA angiographic procedures as primary operator with documented success and complication rates that meet the

threshold criteria listed below (see section X) [60].

and

4. Substantiation in writing by the director of interventional radiology or the chair of the department of the institution in which the physician will be providing these services that the physician is familiar with all of the following:
  - a. Indications and contraindications for the procedure.
  - b. Periprocedural and intraprocedural assessment, monitoring, and management of the patient and complications.
  - c. Pharmacology of moderate sedation medications and recognition and treatment of adverse reactions and complications.
  - d. Fluoroscopic and radiographic equipment, mechanical injectors, rapid film changers, digital subtraction, and other electronic imaging systems.
  - e. Principles of radiation protection, hazards of radiation exposure to both patients and radiologic personnel, and monitoring requirements.
  - f. Pharmacology of contrast agents and recognition and treatment of potential adverse reactions.
  - g. Percutaneous needle and catheter introduction techniques.
  - h. Technical aspects of performing the procedure, including the use of alternative catheter and guide wire systems, selective angiographic methods, appropriate injection rates and volumes of contrast media, and filming sequences.
  - i. Recognition of periprocedural complications and knowledge of treatment options for these complications.

#### Maintenance of Competence

Physicians must perform a sufficient number of percutaneous dialysis access procedures to maintain their skills, with acceptable success and complication rates as laid out in this guideline. Continued competence should depend on participation in a quality improvement program that monitors these rates.

#### Continuing Medical Education

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

## B. Non-Physician Practitioners

Physician assistants and nurse practitioners can be valuable members of the interventional radiology team. These non-physician practitioners can function as independent members of the team. See the [ACR–SIR–SNIS Practice Guideline for Interventional Clinical Practice](#).

## C. Qualified Medical Physicist

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

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

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

## 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

1. The technologist, together with the physician and nursing personnel, should have the responsibility for patient comfort and safety. The technologist should be able to prepare and position<sup>1</sup> the patient for the arteriographic procedure and, together with the nurse, monitor the patient during the examination. The technologist should obtain the imaging data in a manner prescribed by the supervising physician. If intravenous contrast material is to be administered, qualifications for the technologist performing intravenous injection should be in compliance with current ACR policy statements<sup>2</sup> and existing operating procedures or manuals at the interventional radiology facility and/or imaging facility. The technologist should also perform the regular quality control testing of the equipment under supervision of the physicist.
2. The technologist should be certified by the American Registry of Radiologic Technologists (ARRT) or have an unrestricted state license with documented training and experience in the diagnostic angiographic procedure.

## F. Nursing Services

Nursing services, when deemed appropriate by the performing physician, 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.

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<sup>1</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.

<sup>2</sup>See the [ACR Practice Guideline for the Use of Intravascular Contrast Media](#). (ACR Resolution 51, 2001 – revised in 2008, Resolution 38)

## VI. SPECIFICATIONS OF THE EXAMINATION

### A. Angiographic Equipment and Facilities

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

1. A high-resolution image intensifier and television chain or flat panel detector with standard angiographic imaging capabilities. Use of last image hold and pulsed fluoroscopy is recommended for dose reduction. The use of cineradiography or small field mobile image intensifiers is inappropriate for the routine recording of noncoronary angiography, because these methods have an unacceptably high patient and operator radiation dose.
2. Adequate angiographic supplies such as catheters, guide wires, needles, and introducer sheaths.
3. An angiography suite that is large enough to allow easy transfer of the patient from the bed to the table and to allow room for the procedure table, monitoring equipment, and other hardware such as intravenous pumps, respirators, anesthesia equipment, and oxygen tanks. Ideally, there should be adequate space for the operating team to work unencumbered on either side of the patient and for the circulation of other technical staff in the room without contaminating the sterile conditions.
4. An area for preprocedural preparation and postprocedural observation and monitoring of the patient. At this location, there should be personnel to provide care as outlined in the Patient Care section below, 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 Guideline for Sedation/Analgesia](#).)

2. There should be ready access to emergency resuscitation equipment and drugs ~~to~~ including the following: oxygen supply and appropriate tubing and delivery systems, suction equipment, tubes for endotracheal intubation, laryngoscope, ventilation bag-mask-valve apparatus, and central venous line sets. Drugs for treating cardiopulmonary arrest, contrast reaction, vasovagal reactions, narcotic or benzodiazepine overdose, bradycardia, and ventricular arrhythmias should also be readily available. Resuscitation equipment should be monitored on a routine basis in compliance with institutional policies.

### C. Support Personnel

1. Radiologic technologists properly trained in the use of the arteriographic equipment should assist in performing and imaging the procedure. They should demonstrate appropriate knowledge of patient positioning, arteriographic image recording, angiographic contrast injectors, angiographic supplies, and physiologic monitoring equipment. Certification as a vascular and interventional radiologic technologist is one measure of appropriate training. The technologists should be trained in basic cardiopulmonary resuscitation and in the function of the resuscitation equipment.
2. If the patient does not receive moderate sedation, one of the staff assisting in the procedure should be assigned to periodically assess the patient's status. If the patient is to undergo moderate sedation, a nurse or other appropriately trained individual should monitor the patient as his/her primary responsibility. This person should maintain a record of the patient's vital signs, time and dose of medications given, and other pertinent information. Nursing personnel should be qualified to administer moderate sedation. (See the [ACR–SIR Practice Guideline for Sedation/Analgesia](#).)

### D. Surgical Support

Although complications of EMDA only rarely require urgent surgery, these procedures should be performed in an environment where operative repair can be instituted promptly. Ideally, this would be an acute-care hospital with adequate surgical, anesthesia, and ancillary support. When these procedures are performed in a freestanding outpatient center, detailed protocols for the rapid transport or admission of patients to an acute-care hospital should be formalized in writing.

## E. Patient Care

### 1. Preprocedure care

The physician performing the procedure must have knowledge of the following:

- a. Clinically significant history, including indications for the procedure.
- b. Clinically significant physical examination findings, including an awareness of clinical or medical conditions that may necessitate specific care.
- c. Possible alternative methods, such as surgical or medical treatments, to obtain the desired therapeutic result.
- d. Exposure factors, including kVp, mA, magnification factor, and dose rate. Additional parameters such as collimation, field of view, fluoroscopic frame rates, and last image hold should be considered.

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

### 2. Procedural care

- a. Adherence to the Joint Commission’s Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ is required for procedures in non-operating room settings including bedside procedures. “Time out” must be conducted in the location where the procedure will be done, just before starting the procedure and must:
  - Involve the entire operative team.
  - Use active communication.
  - Be briefly documented, such as in a checklist, and include at least:
    - Correct patient identity.
    - Correct site.
    - Agreement on the procedure to be done.

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

- b. All patients should have cardiac monitoring continuously during the procedure with intermittent blood pressure monitoring. A record of vital signs should be maintained.
- c. If the patient is to receive moderate sedation, pulse oximetry should be used. A registered nurse or other appropriately trained personnel should be present, and his/her

primary responsibility should be to monitor the patient. A record should be kept of medication doses and times of administration.

- d. A physician should be available during the immediate postprocedure period.

### 3. Postprocedure care

- a. A written summary of the major findings of the study and any immediate complications should be documented and included in the patient’s medical records. This note may be brief if a formal report will be available within a few hours. However, if the typed report is not likely to be on the chart the same day, a more detailed summary of the study should be written in the chart at the conclusion of the procedure. In all cases, pertinent findings should be communicated to the referring physician in a timely manner.
- b. All patients should be observed during the postprocedure period. The length of this period will depend on the type and extent of the procedures and the patient’s medical condition.
- c. Qualified, trained personnel should periodically monitor the patient’s vascular access during the initial postprocedure period.
- d. The operating physician or a qualified designee should evaluate the patient during the postoperative period. If moderate sedation was administered prior to and during the procedure, recovery from the sedation must be documented. The physician or designee should be available for continuing care during hospitalization and after discharge. The designee may be another physician or a nurse. See the [ACR–SIR Practice Guideline for Sedation/Analgesia](#).

## F. Selection Criteria for Short-Term Observation

The duration of postprocedure observation is variable and depends on the type and extent of the procedure and the condition of the patient.

## VII. DOCUMENTATION

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

## VIII. RADIATION SAFETY IN IMAGING

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

Facilities, in consultation with the medical physicist, should have in place and should adhere to policies and procedures, in accordance with ALARA, to vary examination protocols to take into account patient body habitus, such as height and/or weight, body mass index or lateral width. The dose reduction devices that are available on imaging equipment should be active; if not, manual techniques should be used to moderate the exposure while maintaining the necessary diagnostic image quality. Periodically, radiation exposures should be measured and patient radiation doses estimated by a medical physicist in accordance with the appropriate ACR Technical Standard. (ACR Resolution 17, adopted in 2006 – revised in 2009, Resolution 11)

## IX. 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 web site (<http://www.acr.org/guidelines>).

## X. QUALITY IMPROVEMENT

While practicing physicians should strive to achieve perfect outcomes (i.e., 100% success, 0% complications), in practice all physicians will fall short of this ideal to a variable extent. Thus, indicator thresholds may be used to assess the efficacy of ongoing quality improvement programs. For the purpose of these guidelines, a threshold is a specific level of an indicator that should prompt a review. Procedural thresholds or overall thresholds reference a group of indicators for a procedure (e.g., major complications of percutaneous management of thrombosed or dysfunctional dialysis access).

Individual complications may also be associated with complication-specific thresholds. When measures such as indications or success rates fall below a minimum threshold, or when complication rates exceed a maximum threshold, a review should be performed to determine causes and to implement changes, if necessary.

Thresholds may vary from those listed here; for example, patient referral patterns and selection factors may dictate a different threshold value for a particular indicator at a particular institution. Thus, setting universal thresholds is very difficult, and each department is urged to alter the thresholds, as needed, to higher or lower values to meet its own quality improvement program needs.

### A. Success Rate and Threshold

An important indicator of success is the ability to perform EMDA procedures in an expeditious fashion. This allows rapid resumption of hemodialysis treatment and decreases the use of temporary hemodialysis catheters. This work group endorses the NKF/DOQI position that “No more than one and preferably no femoral vein catheterizations should be required” [1].

The success rates and patency data are presented below. It is recognized that extenuating circumstances may cause lower patency rates not related to stenosis of the graft or fistula. These circumstances include, but are not limited to:

- The need for compression of the graft to achieve hemostasis.
- Dehydration of the patient, decreasing the effective circulating volume.
- Unusual extrinsic pressure on the graft or fistula such as from tight fitting clothing or from sleeping with the graft partially kinked.

1. Success in the treatment of prosthetic graft stenoses by balloon angioplasty in a screened group of patients with a significant stenosis

The figures below reflect patency rates reported in the literature with life-table analysis [17-19,21-22,61]. The results reported below are for stenoses that are generally solitary and less than 6 cm in length. Longer stenoses and stenoses that have undergone multiple dilatations will have poorer patency than focal stenoses dilated for the first time.

If angioplasty is required more than twice within 3 months, the patient should be referred for surgical revision if such an option is available and if the patient is a good surgical candidate. Stent or stent graft placement is often used in the following situations: 1) inadequate alternative access sites, 2) the patient is not a good surgical candidate, and 3) angioplasty-induced venous rupture.

<u>Prosthetic Grafts</u>	<u>Reported Rates</u>	<u>Suggested Threshold</u>
Clinical success	72% to 98%	85%
Cumulative patency		
6 months primary	20% to 63%	25%*
12 months primary	23% to 44%	**
12 months secondary ***	61% to 82%	**

\* NKF/DOQI guidelines recommend a goal of 50% primary patency rate at 6 months [1,22,55]. However, two recent multicenter prospective randomized studies suggest that grafts followed with close monitoring after angioplasty have significantly lower 6-month primary patencies.

\*\* Inadequate data exist at the present time to propose threshold values.

\*\*\* Includes thrombolysis.

- Success in the treatment of autogenous fistula stenoses by balloon angioplasty in a screened group of patients with a significant stenosis

The figures below reflect patency rates reported in the literature with life-table analysis [21,41,62-67]. The cumulative patency results are generally better than reported for grafts.

As for grafts, if angioplasty is required more than twice within 3 months, the patient should be referred for surgical revision if such an option is available and if the patient is a good surgical candidate. Stent or stent placement is often used in the following situations: 1) inadequate alternative access sites 2) the patient is not a good surgical candidate, and 3) angioplasty-induced venous rupture.

<u>Autologous Fistulae</u>	<u>Reported Rates</u>	<u>Suggested Threshold</u>
Clinical success	85% to 99%	85%
Cumulative patency		
6 months primary	50% to 75%	50%*
12 months primary	26% to 62%	**
12 months secondary	82% to 86%	**

\*[1]

\*\* Inadequate data exist at the present time to propose threshold values.

- Successful treatment of synthetic graft stenoses associated with thrombosis

Successful treatment of synthetic graft stenosis in conjunction with thrombosis yields poorer patency than treatment of nonthrombosed stenoses and is

more difficult to achieve than successful treatment of nonthrombosed stenoses. If the access thromboses more than two times within a 3-month interval and a recurrent correctable lesion is identified, the patient should be referred for surgical revision if such an option is available and there are no contraindications. The work group believes that there are instances when factors other than correctable lesions cause thrombosis, such as hypotension or extrinsic compression. Primary patency data for thrombolysis and mechanical thrombectomy are similar, and the results are reported together below.

	<u>Reported Rates</u>	<u>Suggested Threshold</u>
Clinical success	75% to 94%	85%
Cumulative patency		
3 months primary	37% to 58%	40% [1]
6 months primary	18% to 39%	20%
6 months secondary	62% to 80%	65%
12 months secondary	57% to 69%	

\*Inadequate data exist at the present time to propose threshold values.

- Successful treatment of autogenous fistula stenoses associated with thrombosis

The success rates and patency data for endovascular thrombectomy of fistulas are presented below [62-63,68-73]. The data are limited relative to those for angioplasty of stenoses in screened populations.

<u>Autologous Fistulae</u>	<u>Reported Rates</u>	<u>Suggested Threshold</u>
Clinical success	73% to 94%	75%
Cumulative patency		
3 months primary	30% to 89%	30%*
6 months primary	20% to 81%	**
12 months primary	18% to 84%	**
12 months secondary	44% to 80%	**

\*NKF/DOQI guidelines recommend a goal of 40% primary patency rate at 3 months [1]. However, three recent studies [69,71-72] suggest that autogenous fistulas have lower initial clinical success rates and primary patencies, possibly related to a combination of a learning curve and close monitoring.

\*\*Inadequate data exist at the present time to propose threshold values.

5. Successful treatment of steal syndrome:

Success rates and patency data for the variety of treatments reported for steal are too limited to make threshold recommendations.

B. Complication Rates and Threshold [6,12-14]

Complications can be stratified on the basis of outcome. *Major* complications are defined as requiring any one of the following: 1) admission to a hospital for therapy (for outpatient procedures), 2) an unplanned increase in level of care, 3) permanent adverse sequelae, or 4) death. The complication rates and thresholds below refer to *major* complications. *Minor* complications result in no long-term sequelae, although they may require nominal therapy or a short hospital stay for observation (generally overnight) (see Appendix B).

<u>Complication</u>	<u>Reported Rate</u>	<u>Suggested Threshold</u>
Symptomatic embolization, arterial	1% to 9%	2%
Hematoma/bleed, remote site	2% to 3%	3%*
Vascular perforation or rupture	2% to 4%	0.5%**
Death ***	< 1%	0.5%****
Symptomatic pulmonary embolism	< 1%	0.5%

- \* Thrombolysis with prolonged infusion.
- \*\* Reported rates include minor perforations. Threshold applies to perforations or rupture requiring blood transfusion or emergent surgery, or resulting in limb threatening ischemia.
- \*\*\* Procedure related 30-day mortality data are not available but should be reported [32].
- \*\*\*\*All deaths should prompt an appropriate case review.

Published rates for individual types of complications are highly dependent on patient selection and are based on series comprising several hundred patients, which is a volume larger than most individual practitioners are likely to treat. It is also recognized that a single complication can cause a rate to cross above a complication-specific threshold when the complication occurs in a small volume of patients, (e.g., early in a quality improvement program). In this situation, the overall procedure threshold is more appropriate for use in a quality improvement program.

Major and minor complications occur in up to 10% of patients. Complication rates can be expected to be lower in managing the nonthrombosed dialysis access.

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## APPENDIX A€

### Static Pressure Measurements in Synthetic Dialysis Grafts

Intra-access pressure measurements are made with a straight end-hole catheter. The catheter tip can be positioned in the native artery or vein as well as at any position within the graft. Because pressure in the graft reflects the patient's systemic blood pressure, the systolic graft pressure is divided by the systemic systolic pressure measured from a blood pressure cuff on the contralateral arm, yielding a normalized ratio [1]. A normalized systolic pressure ratio of 0.4 has both a high sensitivity (92%) and specificity (86%) in identifying at least 50% stenosis.

The positive predictive value is 92%, and the negative predictive value is 84%.

The goal of intervention is to achieve a pressure ratio of less than 0.5 in the arterial limb and less than 0.33 in the venous limb of the graft.

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## APPENDIX B

### 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.

### Methodology<sup>3</sup>

Reported complication-specific rates in some cases reflect the aggregate of major and minor complications. Thresholds are derived from critical evaluation of the literature, evaluation of empirical data from standards of practice committee member practices, and, when available, the SCVIR HI-IQ™ System National Database<sup>4</sup>.

Consensus on statements in this document was obtained utilizing a modified Delphi technique [1, 2].

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

#### Development Chronology for this Guideline

2000 (Resolution 13)  
Amended 2004 (Resolution 25)  
Revised 2006 (Resolution 30, 16g, 17, 34, 35, 36)  
Amended 2007 (Resolution 12m, 38)  
Amended 2009 (Resolution 11)  
Revised 2011 (Resolution 43)

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<sup>3</sup>Technical documents specifying the exact consensus and literature review methodologies are available upon request from the Society of Interventional Radiology.

<sup>4</sup>The SIR HI-IQ system is the computer system software program on health information for inventory and quality assurance developed by the Society of Interventional Radiology.