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

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations on 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 developed and written collaboratively by the American College of Radiology and the Society of Interventional Radiology (SIR).

Endovascular management of hemodialysis access grafts and fistulae is an alternative treatment to surgical thrombectomy and revision [1]. It applies to accesses that have thrombosed, accesses that have blood flow insufficient to allow dialysis, and accesses with noninvasive measures that indicate the access is at increased risk of thrombosis. Successful thrombectomy procedures can be performed using thrombolysis [2-8], suction thrombectomy [9], mechanical thrombectomy [10,11], balloon thrombectomy, [12,13], 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 [14] or digital subtraction techniques [15]. By this 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 [2-4,13,16-23] and in some cases endovascular stents [24-31], These procedures frequently are the initial treatment for a thrombosed hemodialysis access; transluminal angioplasty is the preferred initial treatment of central vein stenosis [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 dialysis 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 reintervention [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 dialysis access: a native arteriovenous fistula or synthetic graft/biologic graft that contains occlusive thrombus and has no significant blood flow. Thrombus may extend into the native vein or artery. Native arteriovenous fistulae, particularly those with aneurysmal segments, may harbor significantly larger amounts of thrombus than synthetic grafts.

Dysfunctional dialysis access: a native arteriovenous fistula or synthetic graft that cannot provide sufficient blood flow to allow routine hemodialysis treatment.

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

1. Abnormal recirculation values of 10% (two-needle urea-based method) or 5% (nonurea-based dilutional method) [1]. Recirculation should be performed as per the Kidney Diseases Outcomes Quality Initiative (K/DOQI) protocol (Appendix A).
2. Elevated venous pressures recorded during hemodialysis (static and dynamic pressures) or measured within the vascular access during a diagnostic study (static pressures). Dynamic pressures are measured as per the K/DOQI protocol (Appendix B).
3. Detection of decreased blood flow using direct measurement (e.g., ultrasound dilution).
4. Swollen extremity.
5. Unexplained reduction in Kt/V (measure of efficacy of hemodialysis).
6. Various clinical parameters such as prolonged bleeding after needle withdrawal, altered characterization of pulse or thrill in vascular access, or thrombosis.
7. Elevated negative arterial pre-pump pressures that prevent increasing to acceptable blood flow.
8. Inability to puncture to perform hemodialysis.

Anatomically significant stenoses include:

1. Inflow problems
   a. Stenosis of the inflow artery to the access.
   b. Stenosis at the anastomotic site of an arteriovenous fistula.
   c. Stenosis at the juxta-anastomotic segment of an arteriovenous fistula.
   d. Stenosis at the arterial anastomosis of synthetic grafts.

2. Access problems
   a. Stenosis of the hypertrophied venous segment of a native fistula.
   b. Intragraft stenosis within synthetic grafts.
   c. Extrinsic compression. The great majority of anatomic causes are intrinsic to the graft or vessel. Rarely, however extrinsic compression can contribute to access dysfunction (e.g., synthetic 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. In the case of the native fistula, multiple venous runoff channels that may prevent the

development of a hypertrophied vein suitable for puncture (failure to mature) [1].

c. Venous anastomotic stenosis of synthetic 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 thrombosis and dysfunction are due to underlying anatomic stenoses, a physiologic process such as a low cardiac output, postdialysis hypotension, access site infection, dehydration, or a hypercoagulable state can result in thrombosis of a synthetic graft or native fistula in the absence of an anatomic cause, or have a synergistic effect with an anatomic stenosis to accelerate failure of the dialysis access.

Diagnostic angiogram/venogram (fistulogram): one that thoroughly visualizes the dialysis access from the arterial anastomosis of a graft or fistula connection through the runoff veins to the superior vena cava-right atrial junction. This may include multiple oblique views of a suspected problematic segment. In addition, evaluation of the proximal arteries is indicated when clinical indicators of an inflow problem are not explained by angiography of the arterial anastomosis.

EMDA (endovascular management of the thrombosed or dysfunctional dialysis access): the use of catheter-based endovascular techniques to restore or maintain adequate blood flow within an access to support effective hemodialysis [1,33].

Endovascular thrombus removal: the removal of occlusive thrombus from within the graft or native 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, suction 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 may be required to improve luminal dimensions or repair a vascular injury. Prospective intervention is currently warranted for anatomical stenosis found in atrioventricular (AV) grafts and draining veins which also have an associated hemodynamic or clinical abnormality [1,33].

Anatomic success of a treated stenosis: until direct measurements of access flow become validated and implemented into routine practice, the anatomic success should remain defined by conventional angiographic criteria, i.e., 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 [34].

Clinical success: the resumption of normal dialysis for a 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 dialysis graft or a graft-related stenosis, a continuous palpable thrill (no pulse) extending from the arterial anastomosis can be considered one indicator of clinical success [34,35]. Physical examination of the graft has the advantage of being easily performed in the interventional suite, unlike most of the surveillance 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. Volume flows are not universally available in interventional suites [36] or dialysis clinics but have been correlated with degree of stenosis for a single lesion [37]. 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 C). This study used a ratio of 0.4 to give 91% sensitivity for identifying synthetic access graft stenoses of at least 50% [38]. However, it should be recognized that there are currently no uniformly accepted criteria of percent reduction from pretreatment values to determine hemodynamic success [34]. Further, accesses with high intra-access volume flows frequently have high venous systolic pressure ratios and no venous outflow lesions [39]. Some have questioned the use of pressures as an endpoint [35].

Procedural success: anatomic success and at least one indicator of hemodynamic or clinical success [34].

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 [34,40].

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 [34].

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 [34].

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. [34]. Endovascular or surgical treatments of other lesions in the access circuit and creation of a new AV graft or arteriovenous 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, but not sooner than 1 month (and preferably 3 to 4 months) after construction [1].

## III. INDICATIONS

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

Stenoses without thrombosis occurring in a hemodialysis graft or native fistula if the stenosis is greater than 50% reduction in luminal diameter and is considered functionally significant (see definitions above).

Stenosis associated with thrombosis. Thrombosis is associated with underlying venous stenosis in greater than 85% of cases.

Central vein stenosis with greater than 50% lumen diameter, 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].

Native arteriovenous fistulae that have failed to mature after an appropriate amount of time. Treatments include:

1. Balloon angioplasty of the anastomosis, juxta-anastomotic segment or outflow segments to increase blood flow to the native vein. Multiple areas of stenoses may exist in nonmaturing fistulae [41].

2. Interruption of small venous tributaries that divert blood flow from the primary venous segment may improve blood flow and thereby promote maturation of the fistula.

Optimal management for nonmaturing fistulas is not resolved in the available literature and awaits further investigation. There are proponents of these and other techniques [41,42,43].

B. Indications for Endoluminal Stent Placement

Several studies have demonstrated acceptable patencies for stent deployment following balloon angioplasty failure, especially for central vein lesions [24,26,45,46]. However, several prospective randomized trials have failed to show a benefit of stents over PTA alone in the treatment of perianastomotic stenoses [47,48]. 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.

## IV. CONTRAINDICATIONS

The decision to treat a dialysis 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 work group supports the statement of the National Kidney Foundation Dialysis Outcomes Quality Initiative (NFK-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 requiresintegrating 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 Le College des Medecins du Quebec, 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 an Accreditation Council for Graduate Medical Education (ACGME) approved residency program or an American Osteopathic Association (AOA) approved residency program and 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. Typically in a radiology residency, experience will be obtained equivalent to 100 diagnostic angiograms and 50 transluminal angioplasties, some of which will be done in the course of EMDA.

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]. Radiology residents and fellows who did not meet the typical numbers in their training may gain the needed extra numbers by this training pathway as well to augment their training program numbers up to the requisite numbers listed above.

and

4. Substantiation in writing by the director of interventional radiology or the chief 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 or "conscious" 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 guidewire 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. 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 considers certification and continuing education 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) 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.

The continuing education of a Qualified Medical Physicist should be in accordance with the ACR Practice Guideline for Continuing Medical Education (CME). 2006 (Res. 16g)

C. Radiologist Assistant

A 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. 2006 (Res. 34)

D. 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[1] 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

[1]The American College of Radiology approves of the practice of certified and/or licensed radiologic technologists performing fluoroscopy only as a positioning or localizing procedure and then only if monitored by a supervising physician who is personally and immediately available, and the positioning or localizing procedure must have prior written approval by the medical director of the radiology department/service and there be written authority, policy and procedures for designating radiologic technologists who perform such procedures. (Res. 1-E, 1987, 1997)

intravenous injection should be in compliance with current ACR policy statements[2] 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.

E. 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.

## 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 with standard angiographic filming capabilities (including serial film changers, if necessary). Digital subtraction angiographic systems with high spatial resolution are recommended, as they allow for reduced volumes of contrast material and reduced examination times. These digital acquisition systems are sufficient to offer an alternative to conventional film systems and are more flexible and therefore preferable for safe and accurate EMDA. Use of last image hold and pulsed fluoroscopy is recommended for dose reduction. The use of cineradiography or small field mobile image intensifiers is inappropriate for the routine recording of noncoronary angiography, because these methods have an unacceptably high patient and operator radiation dose.

2. Adequate angiographic supplies such as catheters, guidewires, 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 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 utilizing moderate sedation, a pulse oximeter or an end-tidal carbon dioxide monitor should be available. (See the ACR Practice Guideline for Adult Sedation/ Analgesia and the ACR Practice Guideline for Pediatric Sedation/Analgesia.)

2. There should be ready access to emergency resuscitation equipment and drugs, to include 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

[2]The American College of Radiology approves of the injection of contrast material and diagnostic levels of radiopharmaceutical by certified and/or licensed radiologic technologists and radiologic nurses under the direction of a radiologist or his or her physician designee who is personally and immediately available, if the practice is in compliance with institutional and state regulations. There must be prior written approval by the medical director of the radiology department/service of such individuals; such approval process having followed established policies and procedures, and the radiologic technologists and radiologic nurses who have been so approved maintain documentation of continuing medical education related to the materials being injected and to the procedures being performed. (Res. 1-H, 1987, 1997)

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 Practice Guideline for Adult Sedation/Analgesia and the ACR Practice Guideline for Pediatric 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

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

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

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

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.

Informed consent must be in compliance with all state laws and the ACR Practice Guideline on Informed Consent for Image-Guided Procedures.

2. Procedural care

a. Adherence to the JCAHO 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
   - At the least, include:
     - Correct patient identity.
     - Correct side and site.
     - Agreement on the procedure to be done.
     - Correct patient position.
     - Availability of correct implants and any special equipment or special requirements.

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

b. 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 a 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.

F. Selection Criteria for Short-Term Observation

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

## VII. DOCUMENTATION

Reporting should be in accordance with the Practice Guideline for the Reporting and Archiving of Interventional Radiology Procedures.

## VIII. RADIATION SAFETY IN IMAGING

Radiologists, 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 is the concept "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 or manual techniques should be used to moderate the exposure while maintaining the necessary diagnostic image quality. Patient radiation doses should be periodically measured by a medical physicist in accordance with the appropriate ACR Technical Standard. 2006 (Res. 17)

## IX. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION CONCERNS

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

## 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 provides rapid resumption of hemodialysis treatment and decreases the use of temporary hemodialysis catheters. This work group endorses the K/DOQI position that "No more than one and preferably no femoral vein catheterizations should be required" [1].

The success rates and patency data presented below refer primarily to synthetic grafts. Cumulative patency data referring to native fistulae remain limited. 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:

- Overcompression 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 sleeping with the graft partially kinked.

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

   The figures below reflect patency rates reported in the literature with life-table analysis (13,20,21,23). The stenoses are generally solitary and less than 6 cm in length. It is the consensus of this work group that longer stenoses and stenoses that have undergone multiple dilatations will have poorer patency than more 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 placement may be considered in the following situations: 1) inadequate alternative access sites, 2) the patient is not a good surgical candidate, and 3) angioplasty-induced venous rupture.

| | Reported Rates | Suggested Threshold |
|---|---|---|
| Clinical success | 85%-98% | 85% |
| Cumulative patency | | |
| 6 months primary | 38%-63% | 40%* |
| 12 months primary | 23%-44% | ** |
| 12 months secondary | 81%-82% | ** |

*** 

* The drafters of this guideline believe that 40% is an achievable primary patency rate at 6 months when only grafts are considered. K/DOQI guidelines recommend a goal of 50% primary patency rate at 6 months [1]. Since cumulative postintervention data for native fistula are limited and may be equal to synthetic grafts, this work group has not changed the previously established threshold.

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

*** Included thrombolysis.

2. 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 unthrombosed 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 surgery if 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. These patients need not be referred for surgery. Primary patency data for thrombolysis and mechanical thrombectomy are similar, and the results are reported together below [2, 50-56].

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

* The limited data for endovascular thrombectomy of arteriovenous fistulas suggest initial clinical success rates and cumulative patencies similar to

or superior to [57-58] the reported rates for grafts shown in the table [59].

B. Complication Rates and Threshold [5,10,12,13]

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 D).

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

* Thrombolysis with prolonged infusion.

** Perforation 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 [34].

**** All deaths should prompt the 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

### Protocol for Urea-Based Measurement of Recirculation (1)

Perform test after approximately 30 minutes of treatment and after turning off ultrafiltration.

1. Draw arterial (A) and venous (V) line samples.
2. Immediately reduce blood flow rate (BFR) to 120 mL/minute.
3. Turn blood pump off exactly 10 seconds after reducing BFR.
4. Clamp arterial line immediately above sampling port.
5. Draw systemic arterial sample (S) from arterial line port.
6. Unclamp line and resume dialysis.
7. Measure BUN in A,V, and S samples and calculate percent recirculation (R).

Recirculation Formula:

$$R = \frac{S - A \times 100}{S - V}$$

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## APPENDIX B

### Dynamic Venous Dialysis Pressure Monitoring Protocol [1]

1. Establish a baseline by initiating measurements when the access is first used.
2. Measure venous dialysis pressure from the hemodialysis machine at Qb 200 mL/minute during the first 2 to 5 minutes of hemodialysis at every hemodialysis session.
3. Use 15-gauge needles (or establish own protocol for different needle size).
4. Ensure that the venous needle is in the lumen of the vessel and not partially occluded by the vessel wall.
5. Pressure must exceed the threshold three times in succession to be significant.
6. Assess at same level relative to hemodialysis machine for all measurements.

Interpretation of Result

Three measurements in succession above the threshold are required to eliminate the effect of variation caused by needle placement. Hemodialysis machines measure pressure with different monitors and tubing types and lengths. These variables, as well as needle size, influence venous dialysis pressure. The most important variable affecting the dynamic pressure at a blood flow of 200 mL/minute is the needle gauge [2,3]. It is essential to set thresholds for action based on machine manufacturer, tubing type, and needle gauge.

Using 15-gauge needles, the threshold that indicates elevated pressure and therefore the likely presence of a hemodynamically significant venous outlet stenosis for Cobe Centry 3 machines is a pressure of 150 mm Hg. Data for Baxter, Fresenius, Althin, and other dialysis machines are not available but are likely to be similar to those of the Cobe Centry 3 if the same gauge venous needle is used. Trial and error at each institution will determine each unit's threshold pressure.

Trend analysis is more important than any single measurement. Upward trends in hemodialysis pressure over time are more predictive than absolute values. Each unit should establish its own venous pressure threshold values.

Patients with progressively increasing pressures or those who exceed the threshold on three consecutive hemodialysis treatments should be referred for fistulography.

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## APPENDIX C

### 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 D

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

### Classification of Complications By Outcome

**Minor Complications**

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

**Major Complications**

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

## APPENDIX E

### Methodology[3]

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[4].

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

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[3]Technical documents specifying the exact consensus and literature review methodologies are available upon request from the Society of Cardiovascular and Interventional Radiology.

[4]The SCVIR HI-IQ system is the computer system software program on health information for inventory and quality assurance developed by the Society of Cardiovascular and Interventional Radiology.