



CAR Standards for Management of the thrombosed or dysfunctional dialysis Access

Approved: April 2006

The standards of the Canadian Association of Radiologists (CAR) are not rules, but are guidelines that attempt to define principles of practice that should generally produce radiological care. The physician and medical high-quality physicist may modify an existing standard as determined by the individual patient and available resources. Adherence to CAR standards will not assure a successful outcome in every situation. The standards should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The standards are not intended to establish a legal standard of care or conduct, and deviation from a standard does not, in and of itself, indicate or imply that such medical practice is below an acceptable level of care. The ultimate judgment regarding the propriety of any specific procedure or course of conduct must be made by the physician and medical physicist in light of all circumstances presented by the individual situation.

I. INTRODUCTION

Percutaneous management of hemodialysis access grafts and fistulae is an alternative treatment to surgical thrombectomy and revision (1). Successful declotting procedures are being performed with thrombolysis (2-8), suction thrombectomy (9), mechanical thrombectomy (10, 11), balloon thrombectomy, (12,13), or combinations of these methods. This procedure is accompanied by the performance of angiography of the graft or fistula and its arterial inflow as well as venography of the draining veins to the level of the superior vena cava-right atrial junction, and performed with either conventional film screen (14) or digital technique (15). By this means, stenoses are located that may be the anatomic cause of access failure. Restoration of a functional luminal diameter may be achieved with balloon angioplasty (2-4,13,16-23), endovascular stents (24-31), and in some cases atherectomy (19,32). These procedures frequently are the initial treatment for thrombosed dialysis access, and it is now recognized that percutaneous intervention with transluminal angioplasty is the preferred initial treatment of central vein stenosis (1).

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

If the clinical and hemodynamic parameters become abnormal, the patient should have repeat angiography and venography to re-evaluate the access for the presence of recurrent stenosis requiring subsequent reintervention (1).

This standard is written for the percutaneous management of dialysis accesses and includes processes for assessing quality improvement programs.

The most important processes of care are:

1. Patient selection.
2. Performing the procedure.
3. Monitoring the patient.

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 standard, the following definitions apply:

Thrombosed dialysis access - either a native fistula or synthetic graft that contains occlusive thrombus and has no significant blood flow. Thrombus may extend into the runoff veins or inflow arteries. The diagnosis of a thrombosed access is most frequently made by physical examination.

Dysfunctional dialysis access

1. An access that has a hemodynamically significant stenosis, or
2. A native fistula that has failed to mature over an adequate time period, or
3. An access that cannot be successfully punctured to perform dialysis.

Functionally significant stenosis - a >50% reduction of normal vessel diameter (graft or draining venous system) accompanied by a hemodynamic, functional, 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 dialysis outcomes quality initiative (DOQI) protocol (Appendix A).
2. Elevated venous pressures recorded during dialysis (static and dynamic pressures) or measured within the graft during a diagnostic study (static pressures). Dynamic pressures are measured as per the DOQI protocol (Appendix B).
3. Detection of decreased blood flow.
4. Swollen extremity.
5. Unexplained reduction in Kt/V (measure of efficacy of dialysis).
6. Various clinical parameters such as: prolonged bleeding after needle withdrawal, altered characterization of pulses or thrill in the graft, or thrombosis of the access.
7. Elevated negative arterial pre-pump pressures that prevent increasing to acceptable blood flow.

PMDA - the use of catheter-based endovascular techniques to restore or maintain adequate blood flow within the access to support effective hemodialysis. Percutaneous techniques have been shown to be effective in treating an access that has thrombosed or is dysfunctional. Prospective intervention is currently unwarranted for anatomical stenoses found in AV grafts and draining veins without an associated hemodynamic or clinical abnormality (1,33).

Causes of dialysis access failure may be divided into anatomical and physiological categories.

An anatomical cause of dialysis access dysfunction or thrombosis is any arterial or venous abnormality responsible for unacceptable access function.

Examples of anatomic inflow, access, and outflow problems include:

1. Inflow problems
 - a. Stenosis of the inflow artery proximal to the access.
 - b. Stenosis at or around the anastomotic site of a native arterial-venous fistula access.
 - c. Arterial anastomotic stenosis of synthetic grafts.
2. Access problems
 - a. Stenoses 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. However, rarely extrinsic compression can contribute to access dysfunction (e.g., synthetic graft kinking, pseudoaneurysm compression of the access, or compression from a peri-access 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.

A physiological cause of dialysis access failure is a process that results in thrombosis of the dialysis access in the absence of an anatomic cause. It may have a synergistic effect with anatomic causes to accelerate failure of the dialysis access.

Examples of physiological causes include the following:

1. Hypercoagulable states.
2. Low cardiac output states, including post-dialysis hypotension.

3. Dehydration.
4. Severe venous spasm during puncture for dialysis

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 should include multiple oblique views of a suspected problematic segment and more extensive visualization of the proximal arteries if inadequate inflow is suspected.

Percutaneous 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 percutaneous catheter-directed methods, such as: thrombolysis, suction thrombectomy, balloon thrombectomy, clot maceration, or mechanical thrombectomy.

Percutaneous 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 or directional atherectomy may be required to maintain patency.

Anatomic success of a treated stenosis - 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 thrombosed access. 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).

Hemodynamic success - the restoration of hemodynamic parameters. Reduction of venous dialysis pressures to below predefined threshold values can be considered evidence of hemodynamic success. It is the true intra-access static pressure that correlates with the degree of stenosis. Therefore, a reduction of the ratio between static intragraft 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 a 91% sensitivity for identifying synthetic access graft stenoses of at least 50% (35). However, it should be recognized that there are currently no uniformly accepted criteria of percent reduction from pretreatment values to determine hemodynamic success (34).

Procedural success - anatomic success and at least one indicator of hemodynamic or clinical success (34).

Primary patency (PP) - uninterrupted patency after intervention until the next access thrombosis or re-intervention. 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).

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).

Secondary patency (SP) after intervention - patency until the access is surgically declotted or revised, abandoned, or 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).

Post-treatment lesion patency - the interval following intervention until the next re-intervention 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).

Mature arteriovenous fistula - a fistula suitable for use when the diameter of a vein is sufficient to allow successful cannulation, but not sooner than one month (and preferably 3 to 4 months) after construction (1).

III. INDICATIONS

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

Stenoses without thrombosis occurring in a dialysis graft or native fistula should be treated with percutaneous techniques if the stenosis is greater than 50% of the lumen diameter and is considered functionally significant (see definitions above).

Stenosis in the setting of graft thrombosis may be corrected by angioplasty. Thrombosis is associated with underlying venous stenosis in greater than 85% of cases.

Central vein stenosis treatment is indicated when the stenosis is greater than 50% lumen diameter, when the graft is hemodynamically compromised, and clinical parameters such as arm swelling or frequently failing access are present. Percutaneous 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 may be treated with endovascular techniques:

1. Balloon angioplasty of the anastomosis to increase inflow to the maturing venous limb.
2. Embolization of small venous tributaries that shunt flow away from the main maturing vein to increase flow through this segment.

B. Endoluminal Stent Placement

The role of endoluminal stents has not yet been fully defined. Several feasibility studies have demonstrated acceptable patencies for stent deployment following balloon angioplasty failure, especially for central vein lesions (24, 26, 36). Possible indications for endoluminal stent placement in dialysis accesses at the present time include, but are not necessarily limited to:

1. A peripheral vein lesion that has failed balloon angioplasty and surgical access is difficult, surgery is contraindicated, or there are limited remaining access sites.
2. A central vein lesion 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.

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

A. Absolute Contraindication

Infected access site.

B. Relative Contraindications

1. Severe contrast allergy.
2. Severe hyperkalemia, acidosis, or other life-threatening abnormality of blood chemistry that requires immediate dialysis.
3. Contraindications to thrombolytic therapy, such as recent stroke, major abdominal surgery, known central nervous system neoplasm, etc. (for procedures to be performed with fibrinolytic therapy). A variety of mechanical techniques may be utilized as an alternative in this situation.
4. Right to left shunt.
5. Severe pulmonary disease.

The decision to treat a dialysis access with percutaneous 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.

V. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Participation of the interventional radiologist with the dialysis team in patient follow-up is an integral part of percutaneous hemodialysis access management. This close follow-up, with monitoring and management of the patient in the dialysis unit postprocedure, can help to prevent rethrombosis. Regularly scheduled multidisciplinary conferences are one possible approach to ensuring optimum care of patients with vascular access complications.

A. Physician

Physicians involved in the performance, supervision and interpretation of PMDAs should be Diagnostic Radiologists and must have a Fellowship or Certification in Diagnostic Radiology with the Royal College of Physicians and Surgeons of Canada and/or the Collège des médecins du Québec. Also acceptable are equivalent foreign Radiologist qualifications if the Radiologist is certified by a recognized certifying body and holds a valid provincial license.

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 be clinically informed and understand the specific questions to be answered by the angiographic study prior to the procedure in order to plan and perform it safely and effectively.

The physician performing PMDA 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 considerations, and physiologic monitoring equipment, and have access to an adequate supply of catheters, guidewires, and personnel to safely perform the procedure.

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 document. Continued competence should depend on participation in a quality improvement program that monitors these rates. Appropriate attendance at postgraduate courses that provide continuing education on diagnostic advances, newer techniques, and equipment is necessary.

B. Radiologic Technologist

The medical radiation technologist must have Canadian Association of Medical Radiation Technologists certification or be certified by an equivalent licensing body recognized by the CAMRT. Under the overall supervision of the radiologists, the technologist will have the responsibility for patient comfort and safety, for examination preparation and performance, and for image technical evaluation and quality and applicable quality assurance.

The training of technologists engaged in specialty activities shall meet with applicable and valid national and provincial specialty qualifications. Continued education of technologists is encouraged by the C.A.M.R.T. and should meet pertinent provincial regulations.

The technologist, together with the physician and nursing personnel, should have the responsibility for patient comfort. The technologist should be able to prepare and position the patient for the angiographic procedure and, together with the nurse (or other appropriately trained individual for conscious sedation), monitor the patient during the examination. The technologist should obtain the imaging data in a manner prescribed by the supervising physician. The technologist should also perform the regular quality control testing of the equipment under supervision of the physicist.

C. Nursing Services

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

D. Qualified Medical Physicist

The Qualified Medical Physicist should have the responsibility for overseeing the equipment quality control program and for monitoring fluoroscopy and other cross-sectional imaging equipment both upon installation and routinely on an annual basis.

VI. SPECIFICATIONS OF THE EXAMINATION

A. Angiographic Equipment and Facilities

The following are considered the minimum equipment requirements for performing PMDA. In planning facilities for PMDA 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 14-inch film changers and /or large format image intensifiers (12-inch or greater) with a minimum 512 image matrix. 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 PMDA. Findings are acquired and stored either on conventional film or digitally on computerized storage media. Imaging and image recording must be consistent with the as low as reasonably achievable (ALARA) radiation safety guidelines. 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 medical equipment 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 support staff in the room without contaminating the sterile conditions.
4. An area within the institution appropriate for patient preparation prior to the procedure and for observation of patients after the procedure. This might be within the radiology department, in a short-stay unit, or in a routine nursing unit as outlined in Section VI.E below (Patient Care). There should also 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 conscious sedation, a pulse oximeter monitor should be available.
2. There should be ready access to equipment and drugs for emergency resuscitation. The equipment should include an emergency defibrillator with paper recorder and quick-view capability, 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.

C. Support Personnel

1. Radiologic technologists properly trained in the use of the angiographic equipment should assist in performing and imaging the procedure. They should demonstrate appropriate knowledge of patient positioning, angiographic image recording, angiographic contrast injectors, angiographic supplies, and the physiologic monitoring equipment to the satisfaction of the physician. 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 conscious 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 conscious 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, nurse or other appropriately trained individual should be qualified to administer conscious sedation.

D. Surgical Support

Although complications of PMDA 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 centre, 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 indications for elective PMDA studies should be documented as described below:

- a. Clinically relevant history, including indications for the procedure.
- b. Clinically relevant physical examination.
- c. Informed consent is recommended.
- d. Laboratory evaluation may be indicated, especially serum potassium level.

2. Procedural care

- a. All patients should have cardiac monitoring continuously during the procedure with intermittent blood pressure monitoring. A record of vital signs should be maintained.
- b. If the patient is to receive conscious 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.
- c. A physician should be available during the immediate postprocedure period.

3. Postprocedure care

- a. A detailed written or dictated report should be available in accordance with the CAR Standard for Communication in Diagnostic Radiology. In all cases, pertinent findings should be communicated to the referring physician in a timely manner.
- b. All patients should be observed in the initial postprocedure period. The length of this period will depend on the site and size of the arteriotomy/venotomy and the patient's medical condition.
- c. During the initial postprocedure period, skilled nurses or other appropriately trained personnel should periodically monitor the puncture site and the status of the distal vascular distribution.
- d. The operating physician or a qualified designee should evaluate the patient after the procedure. If conscious sedation was administered prior to and during the procedure, complete recovery from conscious 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 other appropriately trained personnel.

F. Selection Criteria for Short-Term Observation

The duration of postprocedure observation must be individualized. PMDA can be performed on some patients with a short period of postprocedure observation.

VII. DOCUMENTATION

Reporting should be in accordance with the [CAR Standard for Communication in Diagnostic Radiology](#)

VIII. 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.

IX. QUALITY IMPROVEMENT

While practicing physicians should strive to achieve perfect outcomes (e.g., 100% success, 0% complications), in practice all physicians will fall short of this ideal to a variable extent. Thus, 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 rapidly treat access thrombosis. This minimizes the need for temporary access.

The success rates and patency data presented below refer to synthetic grafts. Data referring to native fistulae are 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 hemodynamically significant stenoses.

The figures below reflect patency rates reported in the literature using modern techniques and reporting 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 if there are inadequate alternative access sites or if the patient is not a good surgical candidate.

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%	**

* It is believed that 40% is an achievable primary patency rate at 6 months when only grafts are considered. DOQI reported that, in grafts and native fistulae combined, a 50% primary patency rate at 6 months is realistic (1).

** 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 is more difficult to achieve than successful treatment of unthrombosed stenoses. Treatment of stenoses associated with thrombosis is,

therefore, associated with poorer outcomes for both surgical and percutaneous techniques. If the access thromboses more than two times within a 1-month interval and a recurrent correctable lesion are 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 (2-4, 6, 10, 12, 13, 37-43).

Reported Suggested
Rates 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%*

These patency rates reflect the limited literature for thrombolysis only and do not include results for mechanical thrombectomy. Sufficient data have yet to be generated.

3. Cumulative patency of all grafts

The cumulative patency rate of all dialysis grafts beginning with the time of surgical creation should be at least 70% at 1 year, 60% at 2 years, and 50% at 3 years (1).

B. Complication Rates and Threshold (5,10,12,13)

Complications can be stratified on the basis of outcome. Major complications result in admission to a hospital for therapy (for outpatient procedures), an unplanned increase in level of care, prolonged hospitalization, permanent adverse sequelae, or death. Minor complications result in no sequelae; they may require nominal therapy or a short hospital stay for observation (generally overnight) (see Appendix D). The complication rates and thresholds below refer to major complications.

Published complication rates and suggested thresholds include the following: Specific Major Complications for Percutaneous Management of Hemodialysis Access:

Reported Suggested
Complication Rate Threshold

Symptomatic embolization, 1%-9% 2%
arterial

Hematoma/bleed, remote site 2%-3% 0.5%*

Vascular perforation or 2%-4% 0.5%**
rupture

Death *** < 1% 0.5%****

Symptomatic pulmonary < 1% 0.5%
embolism

* Thrombolysis with prolonged infusion.

** Perforation requiring blood transfusion, 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 when considering management of the nonthrombosed dialysis access.

REFERENCES

1. Owen JR, Roberts J, Alexander S, et al. NKF-DOQI clinical practice guidelines for hemodialysis adequacy. *AM J Kid Dis* 1997; 30:S215–S64.
2. Berger MF, Aruny JE, Skibo LK. Recurrent thrombosis of polytetrafluoroethylene (PTFE) dialysis fistulae after recent surgical thrombectomy: salvage by means of thrombolysis and angioplasty. *J Vasc Interv Radiol* 1994; 5:725–730.
3. Cohen MA, Kumpe DA, Durham JD, et al. Improved treatment of thrombosed hemodialysis access sites with thrombolysis and angioplasty. *Kidney Int* 1994; 46:1375–1380.
4. Valji K, Bookstein JJ, Roberts AC, et al. Pulse-spray pharmacomechanical thrombolysis of thrombosed hemodialysis access grafts: long term experience and comparison of original and current techniques. *AJR* 1995; 164:1495–1500.
5. Roberts AC, Valji K, Brookstein JJ, et al. Pulse-spray pharmacomechanical thrombolysis for treatment of thrombosed dialysis access grafts. *Am J Surg* 1993; 66:221–226.
6. Davis GB, Dowd CF, Bookstein JJ, et al. Thrombosed dialysis grafts: efficacy of intrathrombic deposition of concentrated urokinase, clot maceration, and angioplasty. *AJR* 1987; 149:177–181.
7. Summers S, Drazan K, Gomes A, et al. Urokinase therapy for thrombosed hemodialysis access grafts. *Surg Gynecol Obstet* 1993; 176:534–538.
8. Trerotola SO, Vesely TM, Lund GB, et al. Treatment of thrombosed hemodialysis access grafts: Arrow-rerotola percutaneous thrombolytic device versus pulse-spray thrombolysis. *Radiology* 1998; 206:403–414.
9. Turmel-Rodrigues L, Sapoval M, Pengloan J, et al. Manual thromboaspiration and dilation of thrombosed dialysis access: midterm results of a simple concept. *J Vasc Interv Radiol* 1997; 8:813–824.
10. Uflacker R, Rajagopalan PR, Vujic I, et al. Treatment of thrombosed dialysis access grafts: randomized trial of surgical thrombectomy versus mechanical thrombectomy with the Amplatz device. *J Vasc Interv Radiol* 1996; 7:185–192.
11. Soulen MC, Zaetta JM, Amygdalos MA, et al. Mechanical declotting of thrombosed dialysis grafts: experience in 86 cases. *J Vasc Interv Radiol* 1997; 8:563–567.
12. Sharafuddin MJ, Kadir S, Joshi SJ, et al. Percutaneous balloon-assisted aspiration thrombectomy of clotted hemodialysis access grafts. *J Vasc Interv Radiol* 1996; 7:177–183.
13. Middlebrook MR, Amygdalos MA, Soulen MC, et al. Thrombosed hemodialysis grafts: percutaneous mechanical balloon declotting versus thrombolysis. *Radiology* 1995; 196:73–77.
14. Gilula LA, Staple TW, Anderson CB, et al. Venous angiography of hemodialysis fistulae. Experience with 52 studies. *Radiology* 1975; 115:555–562.
15. Picus D, vanBreda A, Katzen BT, et al. Use of digital subtraction angiography for evaluation of vascular access for hemodialysis. *Cardiovasc Intervent Radiol* 1987; 10:210–214.
16. Saeed M, Newman GE, McCann RL, et al. Stenoses in dialysis fistulae: treatment with percutaneous angioplasty. *Radiology* 1987; 164:693–697.
17. Glanz S, Gordon DH, Butt KMH, et al. The role of percutaneous angioplasty in the management of chronic hemodialysis fistulae. *Ann Surg* 1987; 206:777–781.
18. Gmelin E, Winterhoff R, Rinast E. Insufficient hemodialysis access fistulae: late results of treatment with percutaneous balloon angioplasty. *Radiology* 1989; 171:657–660.
19. Zemel G, Katzen BT, Dake MD, et al. Directional atherectomy in the treatment of stenotic dialysis access fistulae. *J Vasc Interv Radiol* 1990; 1:35–38.
20. Beathard GA. Percutaneous transvenous angioplasty in the treatment of vascular access stenosis. *Kidney Int* 1992; 42:1390–1397.
21. Kanterman RY, Vesely TM, Pilgram TK, et al. Dialysis access grafts: anatomic location of venous stenosis and results of angioplasty. *Radiology* 1995; 195:135–139.
22. Schwartz CI, McBrayer CV, Sloan JH, et al. Thrombosed dialysis grafts: comparison of treatment with transluminal angioplasty and surgical revision. *Radiology* 1995; 194:337–341.
23. Safa AA, Valji K, Roberts AC, et al. Detection and treatment of dysfunctional hemodialysis access grafts: effect of a surveillance program on graft patency and the incidence of thrombosis. *Radiology* 1996; 199:653–657.
24. Gray RJ, Horton KM, Dolmatch BL, et al. Use of wallstents for hemodialysis access-related venous stenoses and occlusions untreatable with balloon angioplasty. *Radiology* 1995; 195:479–484.
25. Beathard GA. Gianturco self-expanding stent in the treatment of stenosis in dialysis access grafts. *Kidney Int* 1993; 43:872–877.
26. Vorwerk D, Guenther RW, Mann H, et al. Venous stenosis and occlusion in hemodialysis shunts: follow-up

- results of stent placement in 65 patients. *Radiology* 1995; 195:140–146.
27. Schoenfeld R, Hermans H, Novick A, et al. Stenting of proximal venous obstructions to maintain hemodialysis access. *J Vasc Surg* 1994; 19:532–539.
 28. Quinn SF, Schuman ES, Hall L, et al. Venous stenoses in patients who undergo hemodialysis treatment with self-expandable endovascular stents. *Radiology* 1992; 183:499–504.
 29. Hoffer EK, Sultan S, Herskowitz MM, et al. Prospective randomized trial of a metallic intravascular stent in hemodialysis graft maintenance. *J Vasc Interv Radiol* 1997; 8:965–973.
 30. Turmel-Rodrigues LA, Blanchard D, Pengloan J, et al. Wallstents and Craggstents in hemodialysis grafts and fistulae: results for selective indications. *J Vasc Interv Radiol* 1997; 8:975–982.
 31. Turmel-Rodrigues LA, Pengloan J, Blanchard D, et al. Insufficient dialysis shunts: improved long-term patency rates with close hemodynamic monitoring, repeated percutaneous balloon angioplasty and stent placement. *Radiology* 1993; 187:273–278.
 32. Gray RJ, Dolmatch BL, Buick MK. Directional atherectomy treatment for hemodialysis access: Early results. *J Vasc Interv Radiol* 1992; 3:497–503.
 33. Aruny JE, Lewis CA, Cardella JF, et al. Quality improvement guidelines for percutaneous management of thrombosed or dysfunctional dialysis access. *J Vasc Interv Radiol* 1999; 10(4):491–498.
 34. Gray RJ, Sacks D, Martin LG, et al. Reporting standards for percutaneous interventions in dialysis access. *J Vasc Interv Radiol* 1999; 10(10):1405–1415.
 35. Sullivan KL, Besarab A. Hemodynamic screening and early percutaneous intervention reduces hemodialysis access thrombosis and increases graft longevity. *J Vasc Interv Radiol* 1997; 8:163–170.
 36. Vesely TM, Hovsepian DM, Pilgram TK, et al. Upper extremity central venous obstruction in hemodialysis patients: treatment with wallstents. *Radiology* 1997; 204:343–348.
 37. Valji K, Bookstein JJ, Roberts AC, et al. Pharmacomechanical thrombolysis and angioplasty in the management of clotted hemodialysis grafts: early and late clinical results. *Radiology* 1991; 178:243–247.
 38. Beathard GA. Mechanical versus pharmacomechanical thrombolysis for the treatment of thrombosed dialysis access grafts. *Kidney Int* 1994; 45:1401–1406.
39. Sands JJ, Patel S, Plaviak DJ, et al. Pharmacomechanical thrombolysis with urokinase for treatment of thrombosed hemodialysis access grafts. *ASAIO J* 1994; 40:M886–M888.
 40. Swan TL, Smyth SH, Ruffenach SJ, et al. Pulmonary embolism following hemodialysis access thrombolysis/thrombectomy. *J Vasc Interv Radiol* 1995; 6:683–686.
 41. Trerotola SO, Lund GB, Scheel PJ, et al. Thrombosed dialysis access grafts: percutaneous mechanical declotting without urokinase. *Radiology* 1994; 191:721–726.
 42. Beathard GA, Welch BR, Maidment HJ. Mechanical Thrombolysis for the treatment of thrombosed hemodialysis access grafts. *Radiology* 1996; 200:711–716.
 43. Vorwerk D, Sohn M, Schurmann K, et al. Hydrodynamic thrombectomy of hemodialysis fistulas: first clinical results. *J Vasc Interv Radiol* 1994; 5:813–821.

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:

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

Reference

1. Owen JR, Robert J, Alexander S, et al. NKF-DOQI clinical practice guidelines for hemodialysis adequacy. *Am J Kid Dis* 1997; 30 (Suppl 2) S15–S64, Guideline 12, Table 4.

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 mmHg. 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.

References

1. Owen JR, Robert J, Alexander S, et al. NFK-DOQI clinical practice guidelines for hemodialysis adequacy. *Am J Kid Dis* 1997; 30 (Suppl 2) S15– S64, Guideline 10, Table 3.
2. Besarab A, Sullivan KL, Ross RP, et al. Utility of intra-access pressure monitoring in detecting and correcting venous outlet stenoses prior to thrombosis. *Kidney Int* 1995; 47:1364–1373.
3. Besarab A, Dorrell S, Moritz M, et al. Determinants of measured dialysis venous pressure and its relationship to true intra-access venous pressure. *ASAIO Trans* 1991; 37:M27–M271.

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.

Reference

1. Sullivan LK, Besarab A. Hemodynamic screening and early percutaneous intervention reduce hemodialysis access thrombosis and increase graft longevity. *J Vasc Interv Radiol* 1997; 8:163–170.

APPENDIX D

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 (24-48 hours).

D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (48 hours).

E. Permanent adverse sequelae.

F. Death.