

CREATION AND MANAGEMENT OF HEMODIALYSIS ACCESS

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CLINICAL PEARLS:

1. Physical examination of dialysis grafts: A continuous thrill or slightly pulsatile thrill in a graft reliably indicates acceptable flow rates.
2. Physical examination of dialysis fistulae: A flat fistula indicates an arterial/anastomotic inflow problem. Beware a thrill localized to the perianastomotic region ("bad thrill"); this likely indicates an inflow stenosis. A dilated, visible, easy to puncture fistula indicates an outflow problem. Areas of stenoses can often be palpated thereby directing direction of puncture.
3. To visualize the arteriovenous anastomosis in AVFs, occlusion of the venous outflow with external compression or inflating a blood pressure cuff to suprasystolic pressure will allow for reflux of contrast across the arterial anastomosis. Alternatively, a catheter can be passed via the fistula in a retrograde direction into the feeding artery. If these measures fail, the 3 Fr inner cannula of a micro-puncture set can be advanced antegrade into the feeding artery to opacify the inflow of the fistula. In the setting of immature fistulae, this may be the preferred access for the diagnostic study only.
4. In dialysis grafts, the majority of stenosis will be located at the venous anastomosis. If lesions are suspected in both the arterial and venous limbs of a loop AVG, entering the apex of the graft in most cases will allow access to both limbs.
5. For AV fistula stenoses, the fistula (not the artery) is usually accessed. For radiocephalic AVFs, a retrograde puncture close to the elbow will allow access to most stenoses whereas an antegrade approach near the AV anastomosis in brachiocephalic AVFs allows access to most stenoses.
6. Collateral vessels indicate resistance to flow in AVFs and may represent areas of stenosis; Unlike AVGs, multiple and tandem stenoses are common in AVFs.
7. External manipulation/massage assists in passage of angioplasty balloons and/or passage of thrombectomy devices/catheters through tortuous portions and pseudoaneurysms in AVFs.
8. Stents are reserved for angioplasty failures due to rupture, elastic recoil, or early restenosis (repeat angioplasty < 3 months). Self-expanding stents are preferred because of their flexibility and ability to be placed across joints. Recent data suggest that covered stents may provide superior outcomes in selected areas (AV graft anastomosis compared with PTA, cephalic arch compared with bare metal stents)
9. Infection of the vascular access is an absolute contraindication to a percutaneous thrombectomy procedure. Patients with thrombosed AVFs often have significant local tenderness and erythema due to reactive phlebitis in the region of thrombosis. This should not be confused with infection.
10. The preferred insertion site for hemodialysis catheters is the right internal jugular vein.

INTRODUCTION

The 2009 syllabus has been revised and updated from the 2008 syllabus. The individual expertise and experience of current and past workshop faculty have been incorporated into a management-oriented overview of dialysis access interventions. The syllabus is designed to be a “guidebook” for the practicing interventionalist. The syllabus is structured around the Dialysis Outcome Quality Initiative (K/DOQI) guidelines (1). K/DOQI can be found at www.kidney.org. In order for interventional radiology to maintain and grow our presence in the area of dialysis interventions, we must be familiar with and mold our practice to these guidelines. An abbreviated summary of the recommendations is found in Appendix A. Recognition of these guidelines, along with clinical excellence, comparative outcomes, continued research and total patient service should insure the stability and growth of the role of interventional radiology in management of dialysis patients. The scope of chronic kidney disease (CKD) appears to be larger than previously believed. The National Kidney Foundation estimates CKD affects 20 million Americans or one in nine adults. The scope of CKD underscores the need for the interventionalist to maintain up-to-date knowledge and skills to afford the most beneficial and comprehensive care. Wherever possible in this outline, we will attempt to provide the approach(es) taken by several different centers in dealing with a specific problem. It is important for the reader to understand that many such approaches will involve the **non FDA approved off-label use of devices and/or medications** and that the opinions expressed within this document and/or during the workshops are those of the workshop faculty and not of the SIR. In addition, the opinions and methods provided are representative of the experience of the faculty members but there is not necessarily a consensus on all points discussed herein. The Interventionalist area of the Fistula First web site (www.fistulafirst.org) offers a large variety of educational materials relating to fistulae.

SURVEILLANCE (HD GRAFTS)

The K/DOQI vascular access guidelines (1) provide a review of surveillance methods for the detection of impending access failure. K/DOQI favors measurement of intra-access blood flow as opposed to indirect measures such as venous resistance and venous pressures. Nonetheless, indirect measures are considered acceptable by the DOQI and currently can be performed everywhere. Changes over time in the parameters discussed below may be as important as any single threshold value. The updated K/DOQI recommendations continue to de-emphasize the use of venous resistance due to low sensitivity, and further stress the use of direct flow measures. It should be noted, however, that recent randomized trials have challenged the value of prophylactic intervention in grafts based on intra-access blood flow measures (2, 3) while further supporting blood flow measures in fistulae (4).

1. Direct Flow Measurement (Intra-access flow)

Intra-access flow is the favored surveillance technique as outlined in K/DOQI. The most widely used method to determine intraaccess blood flow is the Transonic system. This system is utilized within the hemodialysis center and connected to the bloodlines while the patient is undergoing hemodialysis treatment. Using this method, intraaccess blood flows are assessed monthly. A catheter-based flow meter that measures blood flow during interventions has been recently introduced to the U.S. market (5).

In accordance with the K/DOQI guidelines, if the intraaccess blood flow is less than 600ml/min the patient should be referred for a diagnostic fistulogram. If the intraaccess blood flow is less than 1000ml/min, but has decreased by more than 25% over a 4-month period, the patient should be referred for fistulography. Vascular access blood flow monitoring reduces access morbidity and costs despite generating increased interventions (6, 7).

2. Static Pressures

Static venous dialysis pressure is the second most preferred surveillance method as outlined in K/DOQI. The intragraft systolic pressure in the venous end should be no greater than 40% of the cuffed brachial systolic pressure (8). This ratio is useful for equivocal or difficult to angiographically

visualize anatomic lesions. It can also be useful in determining the endpoint of dialysis interventions. The protocol for measurement of static venous pressures is described in detail in K/DOQI Guideline 10.

3. Physical Examination

A continuous thrill in a graft reliably indicates acceptable flow rates (> 450 ml/min: 100% sensitivity) (9) and is useful in determining an endpoint of an interventional procedure. Conversely, a pulse in the graft suggests unacceptable flow rates (< 450 ml/min: 75% sensitivity, 77% specificity) (9), and should prompt a search for residual stenosis or thrombus. In a latter study, the presence of a thrill or slightly pulsatile thrill at the distal (venous) end of a dialysis graft was found to be a better predictor of intervention outcome in dialysis grafts than pressure ratios (10). In equivocal cases, e.g. a pulsatile thrill, pressure measurements may be used as indicated above. K/DOQI recommends a physical examination be performed weekly. Auscultation is also part of the physical exam (11). Normal grafts are characterized by a continuous low-pitched bruit. In dysfunctional grafts with stenosis, the bruit is discontinuous, systolic and high-pitched. A physical examination by the interventional radiologist prior to every diagnostic or therapeutic procedure will prevent performing procedures on infected grafts, an absolute contraindication.

4. Recirculation

Recirculation has fallen out of favor because of its lack of sensitivity (12). Recirculation of greater than 10% (urea-based methods) and 5% (non-urea based methods) may be clinically important and require further investigation (12). It is more useful in fistulae than grafts.

5. Venous Resistance

Probably the most commonly used screening parameter, but soon to be replaced as noted above. Patients should be run at 200-250 ml per minute for the first five minutes of their dialysis session. Venous resistance of greater than 150 mm of mercury on three consecutive occasions is an indication for fistulography. This surveillance technique is generally not useful for fistulae.

6. Postoperative fistulography

If surgical revision is done for a failing graft, intraoperative or postoperative fistulography is essential to screen for occult central lesions. This is mandated by the K/DOQI (1).

7. Postprocedure outcomes

Familiarity with clinical access surveillance parameters is essential not only in determining the indications for fistulography, but also in determining outcomes. Virtually all standard documents in this area including the K/DOQI (1), SIR practice (13), and SIR reporting standards (14) indicate that PTA of an anatomic stenosis in the absence of a least one clinical or hemodynamic indicator of failure is not indicated. Further, in order for PTA to be considered successful, the residual anatomic stenosis must be <30% and the clinical or hemodynamic indicator must return to normal (or within acceptable limits) after the intervention.

SURVEILLANCE (AV FISTULA)

1. Physical Examination

Physical examination of fistulae is extremely informative because it is much easier to perform than in grafts. Most forearm stenoses lie just under the skin and can be palpated as a touch cord with a firm dilated vein upstream and a flat vein downstream. Pressure upstream from the stenosis can,

however, be reduced by alternative flow into collaterals, which are therefore a sign of dysfunction and must be observed for as dilated or prominent skin veins.

Stenoses of the arterial inflow are responsible for an overall flat fistula, which is difficult to cannulate without the help of a tourniquet and/or ultrasound guidance. Stenoses of the venous outflow are typically responsible for a "too convenient" fistula, which is much too visible and easy to puncture, but with subsequent increased compression times after dialysis and formation of aneurysms. These aneurysms, which are common in cannulation sites after some months of dialysis, are ideal examination points because the skin is even thinner at their level: an aneurysm under tension indicates an outflow stenosis, an abnormally flat and depressible aneurysm indicates an inflow problem. In cases of stenosis developing between the 2-cannulation sites, the "arterial" aneurysm is tough or full whereas the "venous" aneurysm is soft. In addition, stenoses in cannulation areas can make routine needling impossible.

2. Ultrasound Evaluation: Vascular mapping and Fistula Maturation

The K/DOQI emphasis on creation of arteriovenous fistulae coupled with enhanced vascular ultrasound technology and experience has ushered in a new role for ultrasound in access site planning and evaluation. Ultrasound vascular mapping prior to access site management involves real time ultrasound evaluation of upper-extremity arteries and veins. The radial artery and cephalic veins are principally targeted. Tourniquets are utilized to distend the veins and access diameter. The forearm and upper arm veins are mapped. Studies suggest the minimum pre-operative diameter should be 2.0 mm (arteries), and 2.0-2.5 mm (veins) for successful AVF creation and 4.0 mm (veins) for successful graft creation (15, 16). Preoperative US mapping has been shown to alter the surgical approach resulting in a higher rate of AVF placement and a lower rate of unsuccessful access site placements (15). Ultrasound can also be utilized to evaluate fistula maturation. A fistula can be evaluated at 2-4 months after creation of the access site by measuring venous diameter and flow volume. Fistula adequacy for dialysis is more likely if the venous diameter is > 4 mm and flow volume > 500 ml/min (15, 16). Starting in 2005, a CPT "G" code will be available for reimbursement for initial mapping using either venography or ultrasound. This code reflects the commitment of CMS (Medicare) to increasing the prevalence of fistulae in the U.S. The latest CMS breakthrough initiative calls for 66% native fistula prevalence in the U.S by 2009, and mapping (as well as augmentation, see below) will be essential to reaching this goal.

3. Other Techniques

As for grafts, recirculation, increased static venous pressure, insufficient arterial inflow inducing a vacuum phenomenon during dialysis and decreasing flow-rates are also signs of stenoses. Thresholds for these are not as clear as for AV grafts.

FISTULOGRAPHY

Complete fistulography includes the arterial inflow (region of the arterial anastomosis), entire AV graft or fistula and the venous outflow to the right atrium.

1. Arterial Inflow

a) AV Grafts

A Fogarty balloon or angioplasty balloon inflated within the graft downstream from the injection site can be used to obtain the reflux shot during an intervention. For diagnostic fistulography, inflating a blood pressure cuff above the graft (if possible) to suprasystolic pressure will allow ready reflux of contrast across the arterial anastomosis. Diluting the contrast to reduce the viscosity can assist with reflux. Manual compression of the venous side of the injection site will also enable reflux but may increase radiation exposure to the operator.

b) AV fistulae

Common problems associated with fistulae can be categorized into inflow (forearm fistulae) and outflow (upper arm fistulae) problems. Inflow problems may manifest by early failure or poor maturation. Some cannulate the brachial artery routinely to ensure satisfactory visualization of the anastomosis, while other occludes the venous outflow while injecting. A blood pressure cuff inflated to suprasystolic pressure will allow for reflux of contrast across the arterial anastomosis. Another alternative is to pass a 4 Fr catheter retrograde through the fistula and passing it retrograde into the artery. Outflow problems may present with stenoses, or accessory/branching veins. These can be approached by direct puncture of the AV fistula from the arterial end.

2. Alternatives to Contrast Fistulography

Carbon dioxide may be used but should not be refluxed across the arterial anastomosis due to risk of neurological events and death. Also note that CO₂ may overestimate the degree of stenosis (17). Another alternative to reduce contrast or find an occult lesion is to do pullback pressure measurements and limit injection to those sites where a step up is seen. Although gadolinium has been used effectively as an alternative imaging agent in the past, the development of the potentially serious complication of nephrogenic systemic fibrosis has been associated with the use of gadodiamide in patients with dialysis-dependent chronic renal insufficiency (18). The Food and Drug Administration has issued warnings regarding its use and guidelines for use of gadolinium based contrast agents has been published by the American College of Radiology (19)

PTA/STENTS

Balloon angioplasty is the mainstay of dialysis access intervention. Attention to detail and determining appropriate procedure endpoints are essential for good outcomes. The K/DOQI and the SIR practice standards (13) set guidelines for acceptable success and patency rates and we should be aware of those and keep appropriate records to insure compliance. The SIR reporting standards (14) reflect these principles also. In the setting of an active vascular access blood flow surveillance program the utilization of PTA should increase with an associated cost savings (7).

1. Percutaneous Puncture Site

a) AV Grafts

The location and direction of flow in an access is dictated by the physical examination, which should help determine where the stenosis is by a transition from pulse to a thrill. In synthetic grafts, the majority of stenosis will be located at the venous anastomosis or in the venous outflow and access can be anywhere in the graft directed toward the venous anastomosis. If one is unsure which is the venous end of the graft, simple manual compression of the graft for a second will determine which side is pulsatile and, therefore, the arterial end. If more than one lesion is suspected, the apex technique (20) may be used to provide access to both limbs of a loop graft. For this technique, the initial puncture is made approximately 1-2cm away from the graft, making a short subcutaneous tunnel. It is preferable to enter the side of the graft and not the skin surface. This technique is similar to that used for reversing a retrograde to an antegrade femoral puncture. Whatever access is used, most interventions will be performed via the graft itself. One exception to this is the treatment of central venous stenosis where larger sheaths may be necessary. At some institutions, femoral access for central venous stenosis treatment is preferred over graft access. Central occlusions at any location are very difficult to cross from a femoral access, however, and may require both AV graft and femoral access with a through-and-through guidewire.

b) AV fistulae

The fistula (not the artery) is usually accessed. For radiocephalic AVFs, a retrograde puncture close to the elbow will allow access to most stenoses whereas an antegrade approach near the AV anastomosis in brachiocephalic AVFs allows access to most stenoses (21). Physical examination can aid significantly in determining direction and location of puncture. Ultrasound is also a valuable tool to determine location of stenoses and thereby guide location of puncture. Occasionally, an antegrade approach from the brachial artery at the elbow is necessary to dilate stenosis of the feeding artery or at the anastomosis itself when the retrograde approach from the fistula has failed. In these situations, a 4F brachial artery access sheath, serves as access to cross the arterial anastomosis with a small caliber (0.018") guidewire. The guidewire can be snared/retrieved from a longer 5-6F sheath access in the AV fistula. The intervention can be performed from the larger AV fistula sheath, thus minimizing the brachial artery manipulation and sheath size.

2. Choice of Balloon

Although some stenotic lesions will open with 10 - 15 atmospheres of pressure it is frequently necessary to use high-pressure angioplasty balloons for successful dilatation. PTA balloons can frequently be used at pressures beyond the rated burst pressure. As a rule of thumb, most angioplasty balloons will tolerate no more than 50% more than the rated burst pressure (i.e., 25 atmospheres for a balloon rated at 17 atmospheres). Several commercially available high-pressure balloons can routinely achieve greater than 20 atmospheres of pressure. The Conquest balloon (CR Bard) can achieve pressures well in excess of 30 atm and is very effective on resistant stenoses (22). Some faculty prefer to use the Conquest balloon initially rather than traditional PTA balloons given the relatively high incidence of resistant stenoses encountered in dialysis grafts and fistulas (23, 24) although definitive evidence of improved patency with routine use has not been proven (25). Despite introduction of new technologies such as the cutting balloon catheter and cryoplasty balloon, no studies have proven these "advances" achieve or surpass outcomes of traditional angioplasty. Indeed, a prospective randomized trial comparing PTA to cutting balloon PTA at the venous anastomosis showed no benefit for the cutting balloon, despite its higher cost (26). There may be a niche role for this device at the terminal arch of the cephalic vein, where rupture may be more frequent with PTA. In a pilot study, use of a cryoplasty balloon, anatomic success rates were low, and with supplemental angioplasty, patency rates were similar to angioplasty alone (27).

3. Inflation Time

Inflation times of at least a minute are traditionally used. In some institutions a longer inflation time (3-5 min) is used for central lesions. Prolonged inflation (e.g. 5 minutes) is an effective first-line approach to elastic lesions. In a recently published study comparing one minute to three minute inflation times for angioplasty in fistulas and grafts, improved technical success was observed. However, this observation did not translate into improved intervention patency at 6 months (27).

4. Balloon Sizing

Generally, a balloon that is at least 1mm greater than the graft diameter or outflow vein diameter adjacent to the stenosis for fistulas (i.e., 7mm balloon for 6mm graft) is desirable. Some institutions prefer even larger balloons for intragraft and venous anastomosis at the outset (8mm), while others have preliminary data suggesting a higher rupture rate and/or prefer 7mm balloons initially for intragraft and venous anastomotic lesions. For autogenous dialysis fistulas, sizing of the balloon is variable and dependent on the outflow vein diameter adjacent to the stenosis. With stenoses that occur adjacent to AV anastomosis, balloon sizes of 4-6mm are used, whereas for the remaining portions of the fistula, the most common size used is 7-8mm. Progressive enlargement of balloons in resistant lesions is widely practiced (assuming lack of pain during PTA) and may improve patency. However, in areas of severe graft degeneration, balloon oversizing may increase the risk of graft rupture. For central lesions, measurement of the vein with appropriate PTA balloon sizing is done by most. Most central lesions will require at least a 12mm balloon to obtain satisfactory results. The 6 F

sheath is most widely used. Advances in balloon technology have allowed most vendors to produce 8 mm diameter balloons with a 6 F sheath compatibility.

5. Arterial anastomosis

a) Grafts

Stenoses encountered at the arterial anastomosis may be due to a residual arterial plug. An arterial plug, especially if resistant and adherent to the wall, can create a flow-compromising lesion and must be removed completely to insure success of any thrombectomy procedure. True arterial stenoses account for approximately 5% of all graft-related stenoses. Recent studies have suggested a significantly higher incidence of arterial stenoses (28). Nevertheless, most believe that management of what looks like a stenosis at the arterial anastomosis is best performed by using thrombectomy techniques such as a Fogarty balloon, mechanical thrombolytic device, or the adherent clot catheter (ACC). Some institutions believe that angioplasty of the arterial plug at the arterial anastomosis is acceptable or even preferable while others believe this may be associated with a higher restenosis rate.

b) Autogenous fistulae

60% of stenosis occurs within 3cm of the arterial anastomosis of standard radial-cephalic fistulae. 75% of stenoses occur distal or peripheral to the elbow (21). A balloon at least 4mm diameter must be used to treat stenoses involving the feeding artery in forearm fistulae. A balloon of at least 6-mm must be used in forearm veins to provide durable results. Dilatation of a stenosis close to the anastomosis can create a stenosis in the artery itself due to spasm or even by extrinsic compression. It is therefore recommended to leave a guide wire through the anastomosis during such dilations in order to be able to reopen the artery rapidly if necessary.

6. Heparin

The use of heparin for routine PTA is operator and lesion dependent. Some operators prefer 3,000-5,000 IU of heparin independent of the lesion complexity. Others reserve heparin use for long, complex, multiple, or recalcitrant stenosis. Caution must be exercised as the adjunct use of heparin can lead to postprocedure access site bleeding or long compression times for hemostasis. There are no studies to justify or refute routine use of heparin for routine PTA in dialysis fistulas or grafts.

7. Endpoint (see also "Surveillance")

The endpoints below are readily performed in any angiographic suite. The endpoints below are used because they allow an immediate assessment. Obviously, the most important outcome is resumption of normal dialysis with resolution of the abnormal screen or thrombosis that led to the diagnostic fistulogram or thrombectomy procedure. As per K/DOQI, a successful dialysis intervention is defined as anatomic success with resolution of at least one clinical or hemodynamic variable.

Anatomic endpoint: All stenoses should have a maximal post-treatment anatomic residual of no greater than 30% relative to the normal adjacent vein, and preferably less. Recent invasive hemodialysis flow studies suggest there is lack of sensitivity for this anatomic endpoint, and point to future trends of assessing endpoints with direct hemodynamic flow measurements.

Clinical endpoint: A palpable continuous thrill without significant pulsatility indicates a satisfactory clinical endpoint.

Hemodynamic endpoint: Measurement of the intragraft venous limb pressure to cuffed brachial systolic pressure ratio should be less than 33%. For autologous fistulae, no localized drop in systolic pressure greater than 30% should be accepted, except through the anastomosis where it can be

greater than 50%. Lilly, et al report pressures to be the best predictor of patency (29), but Trerotola et al found the physical exam to be superior to pressures (10).

Some faculty uses each of these immediate anatomic, clinical and hemodynamic endpoints for every case while others routinely use anatomic clinical endpoints, and reserve hemodynamic endpoints for equivocal cases. Hemodynamics endpoint can be determined by measuring intraprocedural blood flow using a Transonic catheter. One center observes compression of the venous anastomosis without a change in the strength of the pulse over the graft indicates a persistent venous anastomotic stenosis. At one center, 15 minutes are allowed to elapse after angioplasty to account for elastic recoil; the final assessment is made after this waiting period whereas at another center, Transonic measurements are taken a day after intervention to assess success of intervention. The true measure of success is return to normal screening parameters or reversal of clinical abnormalities (K/DOQI).

8. Lack of Balloon Effacement

Potential solutions include using a high-pressure balloon, inflating beyond balloon's maximum rated pressure (30-40%), repeated inflations, and progressively longer inflation periods. The Conquest balloon (Bard) (27 atm) is able to efface a majority of such lesions. In rare cases where such high-pressure balloons fail, the following alternatives can be considered: 1) The "nick" technique is percutaneously with fluoroscopically guided "puncture of the stenosis" to disrupt the scirrhous lesion and make it more amenable to angioplasty. This technique has been utilized by some faculty, however, carries the risk of vein rupture, pseudoaneurysm formation or non-target nerve transgression and injury, 2) "Cutting" balloons (Boston Scientific), are now available in diameters up to 8mm. These devices have tiny microtomes embedded within the balloon material that "score" or cut the vessel in a more controlled fashion than traditional angioplasty. Results from a multicenter randomized study have not shown any significant difference in patency compared to traditional angioplasty (26), 3) The self-reversed parallel wire technique (30) has been described for unyielding stenoses. This involves placement of a guidewire alongside the balloon to create a "cutting edge" to "nick" the stenosis with balloon effacement. If all endovascular techniques fail, then surgical revision must be considered. Stents are not indicated for resistant stenoses, as the radial force of a stent will not overcome the stenosis in the short or long-term.

9. Elastic Recoil

If, after successfully effacing the waist on the balloon, sufficient elastic recoil occurs to render the angioplasty unsatisfactory (i.e. > 30%), the initial approach used by most is either prolonged inflation times (5 minutes or more) or progressive balloon enlargement (in the absence of pain during inflation with the original balloon). Some of the faculty members do no further intervention at this point as continued angiographic stenosis despite balloon effacement may represent local spasm in dialysis fistulas. The dialysis access circuit is reexamined with Transonics at the next dialysis treatment and if there continued decreased flows, the patient is referred for repeat intervention. If this is still unsuccessful, stents may be used in selected instances (see below). Alternatively, surgical revision should be considered.

10. Stents / Stent Grafts

The results of venous stenting remain disappointing despite the literature quoting high technical success rates and excellent initial venographic results. The restenosis rate remains a huge problem. K/DOQI stent indications are: elastic stenosis (failed PTA) in a surgically inaccessible location, vein rupture, or recurrent central stenosis within a 3-month period.

Most workshop faculty use self-expanding stents because of their flexibility and self-expanding nature. There is extensive experience with the Wallstent in dialysis access both in and out of clinical trials. However, recent data suggest nitinol stents may be superior to Wallstents, and some faculty have abandoned Wallstents altogether in hemodialysis applications, except large vessels for which nitinol stents are now becoming available (ie over 14 mm) (31-33). Stents are the treatment of choice

for PTA failures (elastic recoil) and early recurrences in central veins. For peripheral lesions, stent patency is not superior to angioplasty alone (34, 35). Therefore, stents should usually be reserved for angioplasty failures due to rupture, elastic recoil or early restenosis. Some workshop faculty prefer to avoid stent placement for elastic recoil given the known accelerated venous intimal hyperplasia that occurs. Instead, patients are followed with Transsonics monthly and referred for repeat angioplasty if there is continued dysfunction. In the event of an angioplasty failure, placing a stent doubles the cost compared to balloon angioplasty alone. The cost effectiveness of stent deployment versus surgical revision for angioplasty failures has not been determined. If a stent is used, it should be of the absolute minimum length needed to treat the stenosis to avoid depleting the vein for future interventions. Some faculty have a strict follow up regimen where elective fistulography is performed three months after stent placement and restenosis is aggressively treated; this practice is not supported by K/DOQI guidelines and is not reimbursable. Most do not anticoagulate after stent placement.

Initial studies suggest that use of stent grafts following angioplasty may significantly improve primary patency. In one randomized study comparing stents to covered stents placed in the cephalic arch, one year primary patency was significantly better with use of covered stents (32% versus 0%) (36). Unpublished but presented evidence from a multicenter randomized trial comparing covered stents to PTA of venous anastomotic stenoses in dialysis grafts has demonstrated improved patency (37). This device, an encapsulated PTFE covered stent graft (Flair™, CR Bard) is now approved by the FDA for treatment of venous anastomotic stenosis in hemodialysis grafts.

11. Central Venous Stenosis (CVS)

The best means for dealing with central venous stenosis is to avoid it altogether by using the internal jugular vein (particularly right) as the exclusive access for dialysis catheters. However, when symptomatic central venous stenoses are encountered, they should be treated with balloon angioplasty initially. Symptoms include arm swelling or graft/fistula dysfunction (without peripheral stenosis). Asymptomatic lesions are best left untreated. One group found that treatment of asymptomatic CVS greater than 50% was associated with a more rapid stenosis and escalation of lesions compared to no angioplasty (38). If there is elastic recoil or early restenosis a decision should be made with respect to managing the recurrent stenosis with a stent versus repeated PTAs. A stent is usually necessary for complete occlusions. This practice is strongly supported by the K/DOQI. When deploying a stent, it is critical to avoid compromising branch veins that may be needed for a future dialysis catheter, i.e. contralateral innominate, ipsilateral internal or external jugular, etc. Stent oversizing is mandatory to avoid delayed migration or dislodgment.

12. Definition of Early Restenosis/Late Angioplasty Failure

Generally, two angioplasty failures within a three-month period constitute failure of angioplasty (K/DOQI).

13. Vein Rupture

This complication is not uncommon in AV fistulae with reported rates up to 15% (39). However, the rupture is often minor and requires no intervention (21, 39). For AV grafts, reported rates are 2-5% (40). Unlike AVFs, graft rupture is often not self-limiting. The immediate management technique is emergent balloon tamponade with or without manual compression. The balloon is situated at the vein defect and inflated, with periodic deflation to maintain access site patency and prevent thrombosis. If balloon tamponade and external compression measures fail then any anticoagulation (i.e. – procedural heparin) should be reversed with FFP and/or DDAVP. If there is a persistent leak than placement of a stent versus surgical revision must be considered. Placement of a stent at the rupture works by potentially “sealing” the rent or defect, but more importantly, favors antegrade flow into the venous outflow rather than the rupture (39, 41). Balloon tamponade is successful most of the time; when this fails, placement of an Uncovered stent is almost universally successful. While the role of

covered stents in hemodialysis access is evolving (see above), there are presently no data to support placing a covered stent for venous rupture.

14. Controlling Pain during Angioplasty

Venous angioplasty can be painful, however, conscious sedation generally is sufficient. Some faculty infiltrate lidocaine around the angioplasty site for lesions refractory to pain control with conscious sedation. Minimal pre-op meds and procedural conversation can generally result in good patient compliance and tolerance during PTA. It has been shown that cutting balloons reduce pain in some subgroups (Cutting EDGE trial) (26).

THROMBOSIS

K/DOQI (Guidelines 21, 22) states AV graft thrombosis should be treated with pharmacomechanical or mechanical thrombolysis or surgery based on local expertise. In order to validate the “local expertise” outcome monitoring is imperative to meet the K/DOQI patency standards and offer optional patient care. K/DOQI acknowledges the difficulty in treating thrombosed AV fistulae, and defers any specific treatment recommendation, except to yield to local preference. Whether surgical or percutaneous, K/DOQI recommends the procedure be outpatient.

1. Contraindications to Percutaneous Thrombectomy

Infection of the vascular access is an absolute contraindication to a percutaneous thrombectomy procedure. Recurring thrombosis in the absence of an identifiable anatomic lesion or hemodynamic abnormality should raise the suspicion of an occult infection. Relative contraindications to percutaneous techniques include pulmonary hypertension, severe lung disease, right heart failure and known right to left shunts. Death related to stroke from paradoxical emboli has occurred with percutaneous thrombectomy and deaths from pulmonary emboli have been reported with both mechanical and chemical techniques. Mechanical thrombectomy techniques may offer the lowest risk. Some faculty defer percutaneous thrombectomy to surgery in patients requiring supplemental oxygen. Nevertheless, the risk associated with surgery is probably also not zero. Recent access site creation is considered a relative contraindication to phar-maco- or mechanical thrombolysis due to concerns of leak or disruption of the suture line. Some faculty prefer to wait 5-7 days prior to thrombolysis, while other will proceed at 2-3 days. Early attempts at thrombectomy may be indicated to “define” the anatomy and potential cause of graft failure. Standard contraindications to thrombolysis should be considered for patients in whom thrombolysis is anticipated.

2. Patient Preparation

Some use prophylactic antibiotics before thrombectomy while others do not. Although there is no proof that prophylactic antibiotics are helpful in this setting, fatal septic events have been reported following dialysis graft thrombectomy and up to 62% of clinically uninfected thrombosed grafts are colonized with bacteria (42). Heparin, either intravenous or intraaccess should always be administered because it may inhibit serotonin-mediated bronchospasm related to pulmonary emboli, as well as prevent rethrombosis during the procedure. As with PTA, conscious sedation is desirable.

3. Percutaneous Puncture Site(s)

a. AV Grafts

Access will depend to a large extent on the configuration of the graft. For straight or C-shaped grafts, two punctures in opposite directions as far apart from each other as possible are used. For loop grafts, possibilities includes apex technique, placing both accesses in the venous limb of the graft, one near the apex facing centrally and one near the venous anastomosis, centrally directed sheath along the arterial limb and the arterially directed sheath along the venous limb (“double-barrel shotgun”). The disadvantage of this latter technique is that it does not allow straight-line access for

venous angioplasty and in cases of central venous angioplasty may not allow enough balloon catheter length to reach the stenosis. Advantages include less recirculation during dialysis if sheaths are left in after the procedure. Some workshop faculty finds this technique increases hand exposure during the procedure. Access can be achieved with a micropuncture set, single wall needle, sheath needle or (inexpensive) 18G Angiocath.

a) Fistulae

Clinical examination is essential to choose the best site for initial catheterization. One can often palpate the length of thrombosis or visualize it with ultrasound. When the stenosis is clinically located a few centimeters from the arteriovenous anastomosis, with no evidence of a tandem outflow stenosis; a single retrograde approach from the vein at the elbow is sufficient to treat the whole fistula. However, in some cases, both antegrade and retrograde approaches are necessary. Ultrasound is useful for determining the location and guidance of puncture. In contrast to grafts, it is mandatory to have gained access to both venous outflow and arterial inflow before starting clot removal, as some anastomotic stenoses can be impossible to traverse (43). Adjunct brachial artery puncture may facilitate transversal of the anastomosis for radial-cephalic fistulae.

4. Sheaths

Most techniques require sheaths, specifically those using mechanical devices and thromboaspiration.

Sheath size requirement: Balloon (8mm) =	6FB
Mechanical thrombectomy device =	5-6F
	7F (PTD, over wire)
Fogarty embolectomy catheter =	5F.

5. Thrombus Removal

Percutaneous thrombectomy should be thought of as a four step procedure, 1) evaluation of the entire vascular access circuit, 2) removal of thrombus, 3) treatment of stenoses, and 4) dislodgement of the arterial plug (for AVG's). These four steps can be performed in any order but all four steps must be accomplished for a successful thrombectomy procedure. The long-term patency is directly related to the identification and successful treatment of all significant stenoses.

Percutaneous (endovascular) thrombectomy techniques include:

- a. "Lyse and wait" (44). Despite limited literature experience, this technique has become more widely used for AV grafts and AV fistulas. The original "lyse and wait" technique was described utilizing UK, however, strategies with alternative lytic agents continue to evolve. Currently, for "lyse and wait" 2-4 mg t-PA or 3 IU of Retavase with 3-5000U heparin has been advocated. The drugs are injected into the graft 30-min to 2 hours before the patient enters the procedure room. The intra-access position of the sheath can be confirmed prior to injection by a small amount of blood return through the sheath or unrestricted passage of a 0.018" wire (more reliable). During the injection, both ends of the graft are compressed manually in an effort to prevent peripheral arterial and central venous emboli.

Once the patient enters the procedure room, partial or full thrombolysis may be found. Although the technique may be considered time saving, a prospective randomized trial comparing "lyse and wait" to mechanical lysis demonstrated no advantage in room or procedure time (45). Similar techniques were described in the early eighties mostly with streptokinase, but were abandoned due to high complication rates and poor results (46). In addition, the status of the underlying anatomy may be unknown; i.e. the venous outflow may not be amenable to PTA prior to lytic administration. It is imperative that the patient is observed while "waiting" as significant bleeding through dialysis needle puncture sites can be encountered, especially with high-grade venous anastomotic lesions.

- b. Infusion thrombolysis is still used by some, but abandoned by most due to high cost, long procedure time and complications associated with it.
- c. Pulse spray protocol-Most published literature describes the techniques and result for Urokinase. tPA is actually faster and should have the same safety profile as Urokinase if dose-equivalent amounts are used (1mg tPA has activity of approximately 100,000 units Urokinase). The doses used now vary widely: some centers are now using 3-5 mg of tPA (47) while others are using up to 20 mg tPA. Whatever the dose, generally, heparin is not mixed with the tPA because it may cause the drug to precipitate out of solution. Heparin is therefore given into a central vein after the venous outflow has been assessed or, less optimally, through a peripheral IV. In AVF's, this technique involves passing a catheter through the entire length of thrombus and pulse spraying the entire dose over a 5 minute period followed by balloon maceration of residual clot. Experience with Retavase is limited with dosing of up to 5 IU.
- d. Thromboaspiration protocols-see Appendix B.
- e. Mechanical device protocols-see Appendix B.
- f. Mechanical thrombectomy devices – Those interested in a comprehensive review can refer to two reviews (48).

6. Timing of the procedure

In most institutions, thrombectomy is performed as an urgent but not emergent procedure. Patients presenting with thrombosed accesses are generally treated the same day unless the request is made late in the afternoon, in which case the procedure is done the next morning. The procedure is generally not done on weekends or at night, though individual practices may need to offer this to compete with others challenging our role in this area such as Interventional Nephrology. Some institutions have criteria for which they will perform emergent thrombectomy procedures. K/DOQI endorses correction of the thrombosed graft as soon as possible, and that placement of more than one temporary femoral catheter or any central venous catheter in the interim is unwarranted.

7. Arterial plug

The arterial plug is a firm; rubbery plug composed of fibrin and red blood cells and is located at the arterial anastomosis in all thrombosed hemodialysis grafts. This plug must be removed during the thrombectomy procedure. Techniques used to treat the arterial plug include the regular 4-5F Fogarty or over-the-wire Fogarty catheter, occlusion balloon, PTA balloon mechanical catheter thromboaspiration, or mechanical thrombolytic devices (only the PTD is FDA approved for this purpose). In cases of difficult plugs where residual adherent clot is present, the Fogarty adherent clot catheter can be a valuable tool. Some believe that angioplasty of the arterial plug may leave residual material behind that may serve as a nidus for further intimal hyperplasia and/or re-thrombosis. Others routinely dilate the arterial anastomosis in the majority of cases. As noted above, true stenoses (i.e., those not representing clot or tapered graft) of the arterial anastomosis have been considered uncommon.

8. Hemostasis

Management of postprocedure hemostasis is critical to insure a favorable outcome. Achieving hemostasis depends to a large degree on local practice. If patients are going directly to dialysis one alternative is to leave catheters specifically designed for this purpose, (large bore sidearm sheaths, multihole catheters) in place. One caveat is that depending upon placement of the puncture sites, severe recirculation may occur if the sheath tips are directly facing each other.

If the patient is not going to dialysis immediately, hemostasis may be achieved in several ways. Some workshop faculty use an activated clotting time of less than 200 seconds as an indicator of when it is safe to pull the sheaths. Manual compression can be assisted with a piece of Gelfoam, or Syvek patch applied to the puncture site. An alternative to manual compression is placement of a purse-string suture (49). Purse string sutures do not actually go through the access, but only the adjacent skin. An alternative to the purse string suture is the "woggle" where the stitch is placed but not tied. Hemostasis is obtained by cinching down the stitch with the aid of a dilator or wire cheater and prior to discharging the patient the stitch is removed (50). Hemostasis using this technique is usually immediate but may require 5 minutes of manual compression. Long-term is limited, although a low incidence of complication has been reported (51). It is imperative remove the sutures within a reasonable time frame (usually 24-48 hours) to avoid infectious complications. The use of non-porous suture material (monofilament) also decreases the potential for suture infection. A technical note (52) describes use of a compression dressing that consists of 1-2 folded 4"x4" gauzes held in place by a Tegaderm stretched tightly over it. This takes the physician a little longer to apply than a stitch but hemostasis is immediate after successful placement, the patient does not have to return for stitch removal and there is no infection risk.

9. Management of Arterial Emboli

Arterial emboli are an unavoidable complication of dialysis graft thrombectomy procedures, both percutaneous and surgical (53). Arterial emboli can be stratified according to patient symptoms. Symptomatic emboli are uncommon, but require treatment. Asymptomatic emboli, particularly if refractory to relatively easy therapeutic measures, may not need treatment (53). The first measure to treat arterial emboli can be the "backbleeding" technique (54). The backbleeding technique relies on the principle of backbleeding via collateral arteries to float an embolus retrograde into the graft. For this procedure to work, the graft must be patent. A Fogarty balloon or other occlusion type balloon is placed in the brachial artery just above the anastomosis and the patient exercises their hand for approximately one minute. The balloon is then deflated and repeat fistulography is performed. A variant of this is placement of a 4-5 F catheter distal to the embolus and administering forceful injections in an attempt to dislodge the embolus retrograde by volume displacement, into the patent graft. Care must be exercised not to displace or fragment the embolus into smaller emboli that occlude end vessel arteries. If backbleeding or variant techniques are unsuccessful, then management should be considered with other measures including pulling it back into the graft with an over-the-wire balloon and/or thromboaspiration. If asymptomatic emboli are refractory to those maneuvers then most concur the cost and risk associated with aggressive thrombolysis and/or surgical thrombectomy is not warranted (53). If the embolus is symptomatic than further treatment with thrombolysis or surgery is indicated.

10. Thrombectomy Endpoint

The endpoint for a declot procedure is venographic documentation of a patent AV graft with little (if any) wall adherent clot, a uniform thrill throughout the graft, and follow-up normalization of any abnormal prethrombosis screening indicator. These findings are implied in the K/DOQI guidelines.

FISTULAE – SPECIAL ISSUES

The original DOQI guidelines call for an increase in the number of AV fistula created, citing literature evidence of enhanced long-term patency with respect to prosthetic grafts. Since the original guidelines, most US interventional practices have noted an increase in the number of AV fistula, and the demand for fistula interventions. The US interventionalist must focus their practice development on improving their ability to manage dysfunctional AV fistula. Fortunately, the depth of European and Canadian experience is available for the US to draw and learn upon.

1. Poorly Developed Arteriovenous Fistulae: Salvage Techniques

There are two factors required for an arteriovenous access to be functional for dialysis. First, the fistula must have adequate blood flow (> 350 ml/min), and secondly, it must have adequate size permitting 15- to 16- gauge needle cannulation. Fistula development is dependent on the inflow pressure and venous resistance of the draining venous system. The ideal situation for fistula development would be inflow pressure high enough to overcome low venous resistance. Failure of fistula maturation can occur due to low inflow pressure (radiocephalic > brachiocephalic fistula), and/or decreased upstream resistance caused by an accessory or branching vein. The following salvage techniques are described to address such problems (43, 55-59):

1. Low inflow pressure – should be avoided with aggressive preoperative ultrasound mapping program. Inflow lesion, if identified, may be amenable to PTA via retrograde fistula approach. Diffuse/extensive inflow disease may necessitate abandoning the site.
2. PTA – balloon assisted PTA fistula maturation can be used for stenotic areas. Repeat PTA's may be required.
3. Accessory/branching veins – accessory/branching veins may result in poor fistula maturation due to decreased venous resistance. Management consists of venous “ligation”. The technique for ligation is as follows: roadmap the accessory vein and mark overlying skin, ligate vein surgically (small skin incision and permanent suture ligation) (59) or percutaneously (nonabsorbable 2-0 polypropylene skin sutures (x2) around the vein) (58). It has been suggested in one study that venous “ligation” is not necessary and that PTA alone is often sufficient (55).
4. Median cubital vein ligation – if development of fistula remains poor after accessory vein ligation, then median cubital vein ligation can be performed to increase venous resistance. The median cubital vein is mapped with fistulography and skin marked. Via a small surgical incision the vein is identified and ligated with a 4-0 silk suture (59).
5. Mainstream banding – mainstream banding or temporary banding of the main venous channel is reserved for cases where all other salvage techniques fail and is rarely necessary. The banding technique involves placement of a 4 mm balloon in the venous outflow above the elbow. The balloon-inflated vein is isolated via a cutdown, and a 3-0 Vicryl suture is wrapped around the vein/balloon. The balloon is deflated and removed, yielding venous stenoses. This is a “temporary” band, as the suture absorbs in three weeks (59).

The techniques should be performed sequentially until the desired endpoint of fistula functionality is encountered. These steps may require up to 6 months to complete. With such techniques access salvage has been reported to be 83% for initially non-functional fistulae with 12-month secondary patency approaching 75% (59-61).

2. Thrombosis

AV fistula thrombosis can be problematic and more challenging to restore patency as opposed to prosthetic grafts. There are a wide variety of management techniques available for AV fistulae thrombosis. Initially, it is important to establish that the fistula is actually thrombosed, and not “decompressed” to a high-grade inflow lesion. Typically, a thrombosed AV fistula is palpable, mildly distended, and tender with palpation if acutely thrombosed. Non-invasive studies such as Doppler will reveal intraluminal thrombus without any significant flow. A clinically decompressed fistula, or a fistula with a high-grade inflow lesion, will distend when a tourniquet is placed. Non-invasive imaging may demonstrate minimal flow into the fistula, without the presence of significant thrombus. This pseudothrombosis is simply managed with a balloon angioplasty, typically from retrograde approach.

The options available for AV fistula thrombosis include the following:

A. Aspiration Thrombectomy (Appendix B)

This is the most simplest and cost-effective means of thrombus removal, and is widely used in Europe. Clot adherence to the underlying fistula has been observed to occur in as little as 2-3 days by some US faculty members, however, by other European faculty members, they have not

observed significant clot adherence to the underlying fistula wall for 3-5 weeks after thrombosis. There is a significant volume of literature based on experience from Europe (43, 62).

B. Mechanical Thrombectomy Device

There has been experience with the Arrow-Trerotola PTD (FDA approval for native fistulae) device for thrombosed AV fistula both in the US and Europe. The over-the-wire capability of the PTD device enhances its ability to negotiate tortuous AV fistulae (63). Both the Hydrolyser and Amplatz thrombectomy devices have been used successfully in Europe with relatively poor one year patency (64, 65). The use of a tourniquet and aspiration sheath promote the potential for thrombus debris aspiration.

C. Pharmacological Thrombolysis

The use of urokinase, TPA and Retavase have been utilized for AV fistula thrombosis. The “lyse and wait” technique, as well as pulse spray technique have been utilized (47, 66). Typically, the dose of TPA and Retavase tends to be slightly higher in AV fistula. Some have advocated a short-term continuous infusion trial for complex to AV fistula thrombosis or chronic AV fistula thrombosis.

3. AV Fistula Thrombosis Endpoint

After restoring flow into the AV fistula, the arterial anastomosis must be closely interrogated to rule out any underlying inflow lesion. This should be corrected with balloon angioplasty. Most advocate a retrograde approach utilizing a small vessel balloon over a .018” or .014” guidewire system. In similar fashion, the venous outflow must be evaluated to the level of the right heart, and treated with adjunct angioplasty as indicated. Heparin administration is also paramount, with doses ranging from 3,000 to 5,000 units. The endpoint should be restored flow, palpable thrill and no residual significant (<30%) stenosis. Some faculty members have noted the contour of the fistula may be irregular in spite of maximal clot removal, these wall irregularities generally correct, and have demonstrated to become smooth on repeat studies at approximately two weeks.

4. Technical Tips (AV fistula) (43):

- *Use of a “safety guide wire”*: when the fistula is tortuous, with stenoses, sharp angulations and/or aneurysms, or when blind predilation is necessary to allow the passage of a thrombectomy device (such as a thromboaspiration catheter), repeat passes with catheters or devices are likely to be difficult. Similarly, thrombectomy or dilation maneuvers in the anastomotic area can damage the feeding artery. In such cases, a guide wire is passed through the introducer-sheath into the feeding artery or into the superior vena cava depending on the location of the area of concern. After placement of this “safety guide wire”, which should not be a hydrophilic guide wire prone to spontaneous inadvertent removal, a second guide wire is passed through the same sheath. The sheath is then removed and repositioned only over the second “working” guide wire, leaving the safety guide wire exiting directly through the skin beside the introducer-sheath. While thrombectomy and dilation maneuvers can be performed through the sheath, the safety guide wire is a fluoroscopic landmark of the anatomy of the fistula and potentiates rapid reopening of the fistula by passing a dilation balloon or a stent over it if complications occur.
- *Recent forearm fistulae*, which are relatively immature but nevertheless used for dialysis, are frequently impossible to palpate and to cannulate, especially when there are numerous stenoses with few clots. One solution is to place a tourniquet on the upper arm in order to make the elbow veins swell. The turgescient cephalic or basilic vein at the elbow is then easily punctured and catheterized in a retrograde approach; it is thus possible to find the way back into the fistula down to the anastomosis. Ultrasound guidance for cannulation of these upper arm veins is very useful in such situations.
- *When the anastomosis cannot be reached by retrograde approach from the fistula*, either because there is a stenosis or because catheter and guide wire are lost in collaterals, it is helpful

to puncture the brachial artery with a 20 G needle at the elbow in order to opacify the feeding artery. This shows where the anastomosis is and aids catheterization by roadmapping. However, if there is a post-anastomotic tight stenosis, which cannot be traversed, in the retrograde fashion, antegrade cannulation of the brachial artery at the elbow and selective catheterization of the feeding artery can work. The combination of an angled (4 or 5F) catheter and a hydrophilic guide wire frequently makes it possible to pass the stenosis. Using the hydrophilic guide wire, the next step is then to enter the introducer-sheath, which has previously been placed in the fistula in a retrograde fashion. The guide wire is then pushed selectively into the introducer-sheath to contact the hemostatic valve while the introducer-sheath is slowly removed (67). The guide wire inserted via the brachial artery reemerges therefore from the fistula, through the skin and above the stenosis. The introducer-sheath is reintroduced over the guide wire to facilitate dilation of the stenosis with a balloon pushed from the fistula instead of the brachial artery, thus limiting the size of the hole in the artery.

- *In cases of concomitant thrombosis of the feeding artery*, retrograde catheterization of the thrombosed artery from the fistula is usually possible and thromboaspiration can be performed with a flexible 6F catheter if the 7 or 8F catheters do not pass. If not, aspiration can also be performed after antegrade cannulation of the brachial artery, placement of a 6F sheath and selective catheterization of the feeding artery.
- *Thrombi in aneurysms* are not a problem when they are fresh. External compression of the aneurysm facilitates contact between clots and the thrombectomy device. In contradistinction, old wall-adherent thrombi are usually resistant to chemical or mechanical lysis. Such old thrombi frequently detach. Solution to ensure safety and success is to trap old thrombi with a stent placed across the aneurysm.

HEMODIALYSIS CATHETERS

The original DOQI guidelines recommend that no more than 10% of permanent access be in the form of catheters. Despite these recommendations, at many centers the percentage of patients dependent on catheters is significantly higher. In fact, it is estimated that there are greater than 250,000 tunneled hemodialysis catheters inserted in the United States per year. K/DOQI guidelines 5, 6, 15, 23, 26, 30, 34, 37 pertain to hemodialysis catheter issues with specific recommendations. The following recommendations, technical tips and guidelines reflect the faculty's catheter experience the K/DOQI guidelines and the literature.

TEMPORARY vs. TUNNELED

Hemodialysis access anticipated to be <3 weeks should be considered for non-cuffed or cuffed double-lumen temporary catheters. Temporary catheters should be placed for immediate use. The preferred access sites are internal jugular and femoral vein. The subclavian vein should not be used in a patient who may need permanent access. A chest x-ray should be obtained after bedside placement, but may be omitted after fluoro-guided placement. Femoral catheters should be limited to approximately 5 days, restricted to bed-bound patients, and be at least 19 cm long to minimize recirculation. Most non-cuff, temporary catheters provide acceptable blood-flow rates of up to 400 ml/minute (Niagara). Generally, catheters with uncertain duration time needs, or with clearly defined duration in excess of three weeks are better served with tunneled cuffed catheters, which are associated with lower infection rates and higher blood flow rates.

Tunneled-cuffed hemodialysis catheters are the catheter of choice for access for longer than three weeks. They also are acceptable for access of shorter duration. Preferred insertion site is the right internal jugular vein. Other options include the right and left external jugular veins, the left internal jugular vein, femoral veins or translumbar access to the inferior vena cava. Subclavian vein access should be reserved when jugular options are not available. The catheter tip should be adjusted to the level of the caval-atrial junction or into the right atrium to ensure optimal flow rates. Current catheter designs include split-tip variety (Split II, Schon, Tesio, Xpresso, Hemosplit, Cannon II, Decathlon, Dynamic Flow), or single-step (Hemoglide, Vaxcel, Permacath, Alta LR, Maxid).

FIBRIN SHEATH

Fibrin sheath formation will occur essentially on all catheters given time. Fibrin sheath formation has been documented at necropsy in less than 24 hours after catheter placement. Hemodialysis catheter dysfunction due to fibrin sheath formation can be seen in 13-57% of patients who undergo dialysis with this technique. Management techniques include 1) new catheter placement, 2) catheter exchange over a guidewire, 3) balloon PTA disruption of the fibrin sheath during catheter exchange, 4) percutaneous fibrin sheath stripping, and 5) thrombolytic infusion. Several studies document success with each treatment regimen, however stripping has fallen out of favor.

New Catheter

Removal of old catheter and placement of a new catheter in some instances is necessary, however, every attempt should be made by the interventionalist to preserve veins and maintain the same access site if at all possible. The practice of abandoning a site in favor of a new catheter placement is less ideal.

Catheter exchange

Catheter exchange technique can be performed in several fashions. The simplest technique is to remove the indwelling catheter over guidewires. Some faculty members prefer stiff guidewires. This typically requires a fairly well organized subcutaneous tract. Alternative techniques include a local cut-down on the right internal jugular vein site. The catheter can be retrieved and cut, and guidewire inserted into the venous system. A new peel away sheath can be inserted. Via either the old tract or via creation of a new tract, a new hemodialysis catheter can be placed. Some faculty prefer prophylactic antibiotic coverage for catheter exchange procedures. One recent study documented significantly enhanced results with hemodialysis catheter exchange with respect to fibrin sheath stripping (68).

Balloon PTA disruption

In some instances, catheter placement or introducer sheath placement is difficult due to the fibrin sheath. This can be managed with simple sheath destruction using a simple occlusion balloon catheter, or at a slightly greater expense, a standard angioplasty balloon catheter. Some faculty members routinely disrupt fibrin sheaths with a standard 12mm angioplasty balloon inflating it in steps along the length of the SVC to proximal right atrium or by inflating it once and passing the balloon back and forth (69).

Thrombolytic Management

Management with thrombolytic agents for fibrin sheath formation has documented success (70, 71). Some institutions prefer a protocol involving an initial "lock" of thrombolytic agent for a variable dwell time. Others prefer a short three-hour infusion. Alteplase has been utilized in doses of 1-2.5 mg/hour/lumen for a two to three-hour infusion. A typical protocol is 2.5 mg of reconstituted Alteplase (1 mg/1 ml) mixed with 47.5 ml of normal saline (0.05 mg/ml) and infused into each catheter lumen at 20 ml/hour (1.0 mg/hour) for 2.5 hours (total dose per lumen = 3 mg) Alteplase.

Fibrin Sheath Stripping

The procedure involves a transfemoral venous catheterization, with placement of a 6 Fr sheath, and placement of a variable diameter snare around the tip of the catheter. Tips for ensnaring the catheter include placement of a guidewire through and out the tip of the hemodialysis catheter to assist engaging the guidewire/catheter with a snare. The wire serves as a scaffold to assist with engaging the dialysis catheter. Some fibrin sheaths will be adherent to the adjacent SVC wall, and dehiscence of that adherence can be facilitated by placement of a pigtail catheter around the hemodialysis catheter and lifting the adherent dialysis catheter free from the SVC wall with a braiding maneuver.

One potential pitfall of fibrin sheath stripping is catheter fracture fragmentation. Thirty-day patency rates are on the order of 30-50%. Recurrent fibrin sheath formation in the short-term remains problematic with this technique.

INFECTION

Approximately 1 in 5 tunnel central venous access catheters will succumb to infection. Short-term non-tunneled acute catheters have an infection rate 3 times that of tunneled hemodialysis catheters. Infectious complications include tunnel infections, exit site infections, bacteremia, sepsis, septic thrombophlebitis, and mediastinitis. Implanted medical devices are at risk for bacterial infection, as it has been demonstrated that bacteria are adherent to inert substances such as a catheter. The adherent bacteria enclose themselves in a polymeric matrix that facilitates bacteria metabolic cooperatively and protects them. This structured community is referred to as a "biofilm". It is estimated that the biofilm is responsible for greater than half the bacterial infections in humans. Management of hemodialysis catheter infections is dependent on the site and extent of infection.

1. Catheter Access Site Infection

Catheter access site infection is characterized by exudate at the access site with or without erythema, without any systemic signs, and blood cultures are negative. Appropriate treatments include topical antibiotics, appropriate local exit site care, and maintenance of the catheter. If tunnel discharge is associated with the access site infection, then parental antibiotic therapy titrated to access site cultures is indicated in addition to local measures. Catheter removal should be reserved for failure of infection to respond to antibiotic therapy and local care. For such failures, removal of the catheter and placement via a different tunnel and/or exit site is indicated.

2. Catheter-Related Bacteremia

Catheter-related bacteremia can be with or without systemic signs. The usual offending organisms are staphylococcus or streptococcus. IV antibiotic therapy should be initiated, and titrated to the organism. The catheter should be removed if the patient is unstable or symptomatic after 36 hours of IV antibiotics. In stable, asymptomatic patients with bacteremia, without exit site involvement, changing the catheter over guidewire followed by three weeks of systemic antibiotic therapy, allows preservation of access site. Monitoring during this three-week period should be intermittent blood cultures.

CATHETER THROMBOSIS

Thrombosis is another significant complication and clinical management problem in patients with chronic indwelling hemodialysis catheters. There is a clear association with infection. If thrombosis is associated with a septic thrombophlebitis, then catheter removal is indicated. Management with thrombolytic therapy via the catheter or via an adjacent infusion catheter is dependent on the extent and degree of catheter thrombus. Although most studies have used urokinase, alteplase and reteplase have been administered in dose equivalents to urokinase. Results of multiple small studies have ranged from 55-97% for restoration of satisfactory function for at least one dialysis session (70-74) with approximately half of the treated catheters maintaining uninterrupted function at 30-45 days. Dwell time of the thrombolytic varies from 30 minutes to the next dialysis session. Catheter exchange versus thrombolytic infusion has never been directly compared.

FINAL WORDS: THE "IR DIALYSIS SERVICE"

In order for the interventional radiology community to maintain clinical success in the hemodialysis arena, the practicing interventional radiologist must be diligent in promoting clinical success, outcome documentation, reliability of service, and research advances. Strategies for success include continuous communication with the local dialysis centers, nephrologists, and vascular access surgeons. Some centers have adapted multi-modality access conferences to discuss

access management issues. Other centers have introduced dialysis access coordinators. Such individuals are highly instrumental in coordinating the care of patients across different clinical services and maintaining proper surveillance of dialysis access. Although initially time consuming, the time saved by patient planning and pre-procedure communication far outweighs the small time invested in such a conference. In-services, technical updates, marketing flyers, and comprehensive database management are also effective strategies. In addition to these strategies, communication and teamwork, development and adherence to practice guidelines that reflect K/DOQI and local practice patterns are key. The interventionalist has the experience, imaging modalities, and clinical tools to develop and maintain a comprehensive dialysis service that will insure the highest in clinical care.

APPENDIX A

K-DOQI Recommendations Summary (1):

1. Primary AV fistulae should be constructed in at least 50% of all new kidney failure patients electing to receive hemodialysis as their initial form of renal replacement therapy. Ultimately, 40% of prevalent patients should have an AV fistula (Opinion)
2. Advocates prophylactic treatment of all hemodynamically significant stenoses (defined as >50% diameter stenosis along with functional, hemodynamic, or clinical evidence of access dysfunction) in AVG's and AVF's (Evidence).
3. Angioplasty should produce less than 30% residual stenosis with resolution of physical indicators of stenosis.
4. Angioplasty primary unassisted patency (ie. Time from intervention to next intervention or loss of the graft) at 6 months of at least 50% for AVG's (Evidence).
5. Angioplasty failure is defined as a recurrent stenosis requiring angioplasty more than twice over a 3-month period
6. Declotting primary unassisted patency of 40% at 3 months for AVG's (Evidence).
7. The rate of graft thrombosis should not exceed 0.5 thrombotic episodes per patient year at risk (Evidence/Opinion)
8. Immediate patency of >85% for declotting of AVG's (Evidence/Opinion)
9. After adjusting for initial failures (ie, failures within the first 2 months of fistula use), the rate of thrombosis of AV fistulae should be less than 0.25 episodes per patient year at risk. (Opinion)
10. The rate of infection should not exceed 1% in primary AV fistulae and should not exceed 10% in dialysis AV grafts, both calculated over the use-life of the access. (Opinion)
11. The cumulative patency rate of all dialysis AV grafts should be at least 70% at 1 year, 60% at 2 years, and 50% at 3 years. (Evidence/Opinion)
12. Stent placement combined with angioplasty is indicated in elastic central vein stenoses or if a stenosis recurs within a 3-month period (Evidence).
13. Tunneled cuffed venous catheters are the method of choice for temporary access of longer than 3 weeks' duration
14. Less than 10% of chronic maintenance hemodialysis patients should be maintained on catheters as their permanent chronic dialysis access. In this context, chronic catheter access is defined as the use of a dialysis catheter for more than 3 months in the absence of a maturing permanent access (Opinion).
15. For tunneled cuffed catheters, the recommended target rate of systemic infection is less than 10% at 3 months and less than 50% at 1 year. (Opinion)
16. The primary failure rate of tunneled cuffed catheters should be no more than 5%. The cumulative incidence of the following insertion complications should not exceed 2% of all catheter placements: (Evidence)
 - A. Pneumothorax requiring chest tube insertion
 - B. Symptomatic air embolism
 - C. Hemothorax

- D. Hemomediastinum
- E. Hematoma requiring evacuation

17. No recommendations on cumulative patency rate for dialysis catheters and AVF's

APPENDIX B

AV Graft/AV Fistulae Thrombectomy

A. Initial Stage

- 1) Skin prep
- 2) +/- antibiotic
- 3) Obtain access to graft directed toward venous anastomosis
- 4) Perform draining venogram to confirm venous patency to the SVC
- 5) Abandon procedure if venous outflow unsalvageable or if unable to cross venous anastomosis
- 6) Administer 3,000-5000 units heparin IV
- 7) Begin clot removal

B. Pulse-spray

- 1) Position pulse-spray catheter (s) in graft. Most use two "crossing" catheters.
- 2) Reconstitute agent
- 3) Pulse agent
- 4) Assess and treat venous outflow stenosis with PTA. Some treat stenosis before pulse spray
- 5) Treat arterial plug
- 6) Assess using physical exam of graft, thrill or pulse should be present (see endpoint determination)
- 7) Treat residual clot in graft with balloon maceration
- 8) Perform final fistulogram from arterial inflow to right atrium

C. Mechanical devices (generic, modify according to individual device)

- 1) Apply mechanical thrombolytic device to venous end of graft (some prefer this step before placing "arterial" sheath; others find it easier to place both wires and cross them before passing the sheaths)
- 2) Place "arterial" sheath
- 3) Apply mechanical device to arterial end of graft
- 4) If applicable, aspirate after each pass (PTD)
- 5) Treat arterial plug (Fogarty, occlusion balloon, device, adherent thrombectomy catheter).
- 6) Assess and treat venous outflow stenosis with PTA
- 7) Assess using physical exam of graft, thrill or pulse should be present (see endpoint determination)
- 8) Treat any residual clot with device or balloon maceration as necessary
- 9) Perform final fistulogram from arterial inflow to right atrium

D. Balloon Assisted Thromboaspiration

- 1) Place 7F removable hub "venous" sheath. Remove hub and aspirate clot if possible. Replace hub.
- 2) Place 6F "arterial sheath"
- 3) Pass 5F Fogarty catheter along arterial limb to near anastomosis. Inflate balloon and pull back toward sheath while another operator aspirates on 7F sheath with hub removed.
- 4) Repeat step 3, passing balloon beyond arterial anastomosis
- 5) Assess graft for pulsatility to confirm inflow, if absent, repeat step 10 until pulsatility restored
- 6) Pass 5F Fogarty catheter through venous sheath beyond central limit of remaining clot. Inflate balloon and withdraw catheter while aspirating through sidearm of sheath (s)
- 7) Repeat steps as necessary
- 8) Assess residual clot burden; if large, use mechanical device to complete procedure. If not, assess and treat venous out flow stenosis with PTA.

- 9) Assess graft with physical exam, thrill should be restored after successful PTA (see endpoint determination above)
- 10) Treat any residual clot with Fogarty balloon, pushing into lungs. Perform final fistulogram from arterial inflow to right atrium.

E. Aspiration and Extrusion Thrombectomy with PTA

- 1) Place a 6F removable-hub sheath 10-12 cm from and directed toward the venous anastomosis. It should be positioned so that the sheath is within the graft and the 15 cm inner dilator extends beyond the venous anastomosis and usual site of stenosis.
- 2) Perform a draining venogram to confirm venous size and patency to the SVC.
- 3) Aspirate the venous limb while applying external massage. Repeat several times. Empty the thrombus into a container for visual inspection.
- 4) Attach the sidearm and perform a gentle venous angio to confirm and size the venous stenosis. Do not inject forcefully enough to cause arterial reflux and embolization.
- 5) The arterial directed puncture is placed midway between the venous sheath and the venous anastomosis to establish crossed catheters. There is no need for an arterial sheath.
- 6) A guidewire and 6 mm balloon catheter is advanced into the native artery where an inflow angio is performed to confirm arterial size and peripheral arterial patency.
- 7) The balloon is then partially inflated and drawn into the arterial anastomosis to displace soft clot and size any stenosis at the anastomosis.
- 8) Perform a 6 mm PTA of the inflow. Needless to say that judgement must be exercised if the inflow artery is small. This is followed by incremental dragging of the partially inflated balloon toward its puncture site and full dilatation about every 2 cm until its position comes to rest (inflated) at the venous puncture site (modified Fogarty maneuver).
- 9) Perform a second series of aspirations of the venous limb. This maneuver (74, 75) should be repeated several times to insure complete clearing of the arterial limb.
- 10) Attach a check-flow valve and place an 8 mm PTA balloon through the sheath into the draining vein.
- 11) Partially inflate the balloon and draw it into the venous anastomosis where a full PTA completely effaces the balloon for a minimum of one minute. Note that there is now a closed system between the two inflated balloons.
- 12) Remove the sheath onto the catheter shaft and then incrementally withdraw and re-inflate the venous balloon (modified Fogarty Maneuver) until it "kisses" the inflated arterial balloon extruding the thrombus trapped between the balloons. Repeat this maneuver until no more thrombus can be extruded. This maneuver minimizes systemic venous (pulmonary) emboli.
- 13) Replace the sheath, deflate the balloons, and perform angiography through the arterial balloon catheter and venous sheath. Any residual clot or stenosis should be treated by repeat PTA, modified Fogarty maneuver, or extrusion. Rarely is a mechanical device needed to clear adherent clot.

F) Manual Catheter-Directed Thromboaspiration (43, 62, 76)

- 1) Aspirate clots starting from the most central with a 7 or 8F slightly angled (vertebral or multipurpose type) aspiration catheter. Perform as many passes as necessary until no additional clots are aspirated.
- 2) Leave a guide wire through the "venous sheath" and place 7 or 8F "arterial sheath".
- 3) Push, very gently, a slightly angled 5F catheter over a hydrophilic guide wire into the artery and check the exact level of the arterial anastomosis.
- 4) Aspirate clots starting from the sheath. If the catheter is clogged, flush it into gauze and reintroduce it further toward the anastomosis.
- 5) Inject gently 2 to 5 ml of contrast medium through the arterial sheath during compression of the graft and look for residual clots.
- 6) Push the angled aspiration catheter to contact any residual clots and aspirate with quick back and forth movements to detach the thrombi. Stop only when absolutely no residual clot is visible.

- 7) Leave a guidewire through the "arterial sheath". Aspirate again through the "venous" sheath, as clots may have migrated from the arterial side and can be blocked between the 2 introducers or at the venous anastomosis.
- 8) When absolutely no residual clot is visible, dilate the stenosis of the venous anastomosis. To dilate before aspiration of all the thrombi increases the risk of pulmonary embolism and is against the spirit of the technique.
- 9) Final angiogram from arterial inflow and outflow to right atrium

G) Thrombectomy of Fistulae

- 1) Skin prep
- 2) Obtain access to fistula toward both (arterial) anastomosis and central veins in a crisscross fashion.
- 3) Pass catheter down to the feeding artery and up to central veins. Do pullback angiograms to assess the exact level of anastomosis and the central extension of the thrombus.
- 4) If the anastomosis cannot be reached from the fistula, inject contrast from the brachial artery at the elbow to provide mapping and use an antegrade brachial approach for selective catheterization of the feeding artery. If unable to cross the anastomosis or the venous outflow, abandon the procedure (<10% of cases).
- 5) Begin clot removal starting from the venous outflow, ending with the arterial inflow. Predilate stenoses (5 mm) and use safety guide wire if necessary to allow passage and safe use of the thrombectomy catheter.
- 6) When all clots are removed or lysed, dilate all stenoses sufficiently. Restoration of a good inflow is essential.
- 7) Final angiogram from the arterial inflow to the right atrium.

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