

# Reporting Standards for Percutaneous Interventions in Dialysis Access

Richard J. Gray, MD, Subcommittee Chair, David Sacks, MD, Committee Chair, Louis G. Martin, MD, Scott O. Trerotola, MD, and the Members of the Society of Interventional Radiology Technology Assessment Committee

J Vasc Interv Radiol 2003; 14:S433-S442

Abbreviations: BUN = blood urea nitrogen, PTFE = polytetrafluoroethylene

THE traditional treatment for failing arteriovenous dialysis access has been thrombectomy and/or surgical revision as needed (1-3). Over the past 2 decades, percutaneous methods for thrombus dissolution and/or correction of anatomic abnormalities have become accepted alternate treatment modalities (4). The results of thrombolysis (5-9), angioplasty (10-14), directional atherectomy (15,16), and endoluminal stent deployment (17-22) have been reported widely; nevertheless, comparison and interpretation of results are difficult because of differing methods of patient selection, treatment, and follow-up. For example, some thrombolysis series report success as establishment of flow immediately after the procedure (5), whereas others require at least three dialysis sessions after treatment for success (8). In addition, different reporting methods (life-table mean patency, life-table 50% patency, arithmetic mean patency, etc) applied to the exact same database can result in dramatically different conclusions; Hodges et al (23) showed that autogenous fistulas could be interpreted to have patencies equal to those of polytetrafluoroethylene (PTFE) grafts, shorter than PTFE grafts, or twice as long as PTFE grafts,

depending on the method of data analysis.

Suggested standards for reporting the results of arterial revascularization have been published previously by the *Journal of Vascular Surgery* (24,25) and the *Journal of Vascular and Interventional Radiology* (26,27). Reporting standards for acute and chronic thromboembolic venous disease have also been suggested (28). These reporting standards are obviously an imperfect fit for dialysis access interventions. To our knowledge, there has been no publication suggesting uniform reporting standards for dialysis access revascularization despite calls for their establishment (23,29). The purpose of this document is to recommend standards to be used for study design and reporting of percutaneous interventions for permanent hemodialysis access. The **Table** summarizes these standards in an abbreviated format.

## PATIENT SELECTION

*Discussion.*—Because prophylactic treatment before thrombosis appears to prolong the patency of hemodialysis access (11,30,31), many institutions have adopted screening procedures to select patients with malfunctioning hemodialysis access who are at high risk for failure. Screening methods currently used include physical examination (a change in bruit, thrill, pulse, etc) (10,11,32), recirculation (33-35), dynamic venous dialysis pressures (10,30,36), static venous pressures (31,37,38), intraaccess

flows (39,40) and duplex and color Doppler sonography (40,41). Abnormal screening results have been correlated with the presence of a venous stenosis in 80%-90% of cases (10, 11,30). These patients are therefore referred for angiographic evaluation and/or therapy.

The other major category of hemodialysis patient referred for angiographic evaluation and/or therapy involves patients with a clinical manifestation of access failure or impending access failure. The most common reported presentation is a thrombosed access (1,3,42). Other clinical manifestations include extremity edema, prolonged post-dialysis bleeding, poor dialysis flow rates, difficult needle cannulation of the access, and "inefficient dialysis" manifested as decreased kt/v or urea reduction ratios (43).

*Recommendations for Reporting Standards.*—The indications for angiographic evaluation and/or therapy should be reported. When available, criteria for positive screens and the number of determinations required for a positive screen should be presented. The clinical manifestation of access failure or impending access failure leading to referral should be reported.

Inclusion and exclusion criteria for choosing study subjects and controls from the patient population should be clearly presented. Because the attributes of the patient population may affect treatment outcome, the medical background including age, cardiac risk factors, hypercoagulabil-

This article first appeared in J Vasc Interv Radiol 1999; 10:1405-1415.

Address correspondence to SIR, 10201 Lee Hwy, Suite 500, Fairfax, VA 22030.

© SIR, 2003

DOI: 10.1097/01.RVI.0000094618.61428.58

Reporting Requirements and Recommendations			
Data	Required	Highly Recommended	Recommended
Referral Indications (either 1 or 2)			
1. Screening Method	X		
(Criteria for Positive Screen)		X	
(No. of Determinations for Positive Screen)			X
2. Access Failure Indication	X		
Comorbidities/Risk Factors		X	
Access Description			
Type configuration	X		
Prior interventions (Number and type, or unknown)	X		
Age		X	
Central line No., indwelling catheter, etc.			X
Measures of Disease Severity*			
Anatomic			
Technique for Lumen Visualization	X		
Stenosis Determination Method	X		
% Stenosis	X		
Lesion Location	X		
Lesion Length		X	
Central Vein Patency	X		
Hemodynamic			
VDF or Static (include No. of determinations)		X	
Pressure Threshold (include No. determinations)		X	
Access Volume Flows			X
Clinical			
Criterion Used	X		
Recirculation Method, Description		X	
Treatment			
Detailed Description	X		
Procedure Time		X	
Lysis/thrombectomy Time			X
Hemostasis Time			X
Posttreatment Evaluation			
Anatomic			
% Residual Stenosis	X		
Flow Restoration and % Residual Stenosis (Lysis/thrombectomy Cases)	X		
Hemodynamic			
Return to Below Threshold	X		
Static IG/Branchial Ratios		X	
Clinical			
Resumption of Dialysis (Lysis/Thrombectomy Cases)	X		
Continuous Thrill		X	
Return of Screen to Below Threshold or resolution of Clinical Abnormality	X		
Device Success	X		
Patency†			
Procedure Success‡	X		
Postintervention Primary Patency§	X		
Postintervention Assisted Primary Patency		X	
Postintervention Secondary Patency		X	
Postintervention Lesion Patency		X	
Postintervention Access Patency		X	
Complications	X		
Compliance	X		
Costs			
Detailed Analysis			X
Gross Estimates			X
Comparisons Between Treatment Groups			
Randomized Controlled		X	
Institutional Review Board Status	X		

\* Description of disease severity requires anatomic severity and at least one hemodynamic or clinical indicator.  
† Report stenosed and thrombosed access outcomes separately.  
‡ Initial success requires anatomic success and success of the pretreatment hemodynamic or clinical indicator.  
§ The same hemodynamic or clinical indicator(s) of procedure success should be followed.  
|| The same hemodynamic or clinical indicator(s) of procedure success should be followed. Include the number and nature of treatments per patient year of dialysis.

ity, drug abuse, infection, etc, of the study group should be tabulated. Patients considered for study enrollment but not included in analysis should be described, for example, patient refusal, immature access (12), excess risk for procedural complication (16). All patients who meet selection criteria should be included in the analysis on an "intent to treat" basis. For example, those patients in whom it is not possible to traverse the lesion (6,44) or in whom the venous outflow of a thrombosed access is considered unsuitable for treatment (45) would be included in the analysis.

## ACCESS

*Discussion.*—Attributes of the access circuit itself can affect treatment outcomes. These include the access type, duration of implantation, configuration, previous interventions, and previous insertion of central catheters.

Autogenous fistulas have longer expected patencies after initial creation than PTFE and other synthetic implants (46). Some series also suggest better primary patencies after balloon angioplasty for autogenous fistulas than for PTFE grafts (11,12).

An access that requires an intervention soon after creation may have an intrinsically shorter expected post-treatment patency than a more mature access. One balloon angioplasty study (12) found a significantly younger mean access age (8.3 months) at treatment for accesses developing posttreatment restenosis within 6 months than the mean access age (20.6 months) for accesses restenosing 1 year following treatment and the mean access age (30.4 months) for those restenosing 2 years after treatment.

Several recent surgical (13,42,47) and angioplasty (11) studies suggest better patencies after treatment for PTFE grafts configured in a loop than for straight grafts. Most other angioplasty studies have ignored configuration as a factor in posttreatment patency. Central lines cause concurrent and subsequent central venous stenosis/occlusion in up to 50% of dialysis patients (31,48–51). Subclavian insertions appear to cause more central lesions than internal

jugular insertions (48,49). The number of ipsilateral central lines (49,52), catheter indwell times (50,52) and duration of functioning ipsilateral arteriovenous access (53) have been implicated as risk factors for central vein lesion development.

It has been suggested that intrinsic patient factors (ie, hypercoagulability, volume shifts, medications, etc) may affect treatment outcome. One author observed a trend toward a similar interval recurrence in a given patient regardless of the treatment modality (44).

*Recommendations for Reporting Standards.*—The attributes of the access circuit that can affect treatment outcomes should be reported and tabulated when known. These include, but are not limited to, access type, configuration, age of the access, and previous interventions involving the current access circuit, including the venous outflow on which the access is dependent. The number of previous ipsilateral central catheters, catheter indwell times, duration of functioning ipsilateral access, and central venous puncture sites should be reported when known, especially for patients with central vein stenoses/occlusions. Other attributes that should be tabulated include access location (arm, forearm, lower extremity), and whether the graft is tapered. Patient attributes that may influence treatment outcomes, including but not limited to hypercoagulability, volume shifts, medications, etc., should be reported, when available.

## PRETREATMENT EVALUATION

*Discussion.*—Pretreatment evaluations include objective and quantitative measures of disease severity. Anatomic, hemodynamic, and clinical criteria are used to measure disease severity.

*Recommendations for Reporting Standards.*—Anatomic and at least one hemodynamic or clinical criterion must be presented to measure disease severity.

### Anatomic Measures of Disease Severity

*Discussion.*—The most important anatomic measure of lesion severity

is angiographic diameter measurement using either conventional arteriography (54) or, more recently, digital subtraction angiography (55). While iodinated contrast agents have been most widely used, carbon dioxide gas has occasionally been used for patients with contrast allergy or intolerance to contrast loads (56). Another modality used occasionally is diameter measurement by means of surface ultrasound (40,41). These modalities may not agree with each other; indeed, Ehrman et al (56) found a tendency for CO<sub>2</sub> gas to exaggerate the degree of stenosis relative to standard contrast material during digital subtraction angiography.

The minimal percent stenosis considered significant for treatment has most commonly been 50% diameter reduction (10–12); however, one study has suggested that a 40% stenosis (36) may be significant. Percent stenosis determination is complicated by several factors including some that are not influential in peripheral vascular disease. After surgical establishment of an access, there is a maturation process in the veins (57) caused by high pressures, turbulence, and flows. The venous wall is thickened by intimal hyperplasia and the vein enlarges. For synthetic dialysis grafts, the outflow vein usually becomes larger than the graft. A similar situation is seen for any venous stenosis when marked poststenotic dilation develops. In addition, veins naturally enlarge centrally at tributary confluences. The percent stenosis reported can vary considerably depending on the reference chosen, that is, the smaller graft or vein upstream (relative to direction of blood flow) to the lesion versus a larger vein downstream (relative to direction of blood flow). Percent stenosis may also be affected by the presence or absence of blood flow in the access at the time of measurement.

Other important anatomic factors include lesion location (arterial inflow, intragraft, venous anastomosis, peripheral venous inflow, central vein), lesion length, lesion multiplicity, and patency of the central venous "runoff." These lesion characteristics may be difficult to determine accurately in an access without flowing blood. Several of the factors may have prognostic implications. For ex-

ample, reported patency following angioplasty of central vein lesions, especially occlusions, is shorter than patency following peripheral vein angioplasty (10). In addition, several investigators have agreed that long lesions are less ideal for angioplasty (30,58–60).

*Recommendations for Reporting Standards.*—The technique of lumen visualization (ie, conventional or digital subtraction angiography, CO<sub>2</sub> angiography, ultrasound, etc) should be presented. Unless the techniques have been validated one against the other, the same technique should be used throughout the duration of the study, including all follow-up intervals. Regardless of the technique, anatomic measurements are optimally made with a calibrated reference marker in the plane of the imaged vessel. This improves consistency in measurements for procedures performed at different times or in different institutions with different equipment.

The method of percent stenosis determination, including the reference vessel, should be clearly reported. The reference vessel chosen should be the graft or vein upstream to the lesion. Although arbitrary, this method of calculation will minimize any tendency to overestimate stenosis severity; more importantly, this standardization will allow meaningful comparison of different reports. The degree of stenosis reported should be the maximum observed diameter reduction. When possible, follow-up evaluations should use the same reference vessel as the pretreatment evaluation.

Lesion location, lesion length, lesion multiplicity and patency of the central venous runoff should be described.

For lesions associated with a thrombolysis procedure, the presence or absence of blood flow in the access at the time of measurement should be indicated for percent stenosis, lesion length, and lesion multiplicity.

### Hemodynamic Measures of Disease Severity

*Discussion.*—Hemodynamic measurements of disease severity have not been firmly established. The cur-

rently used measures include static access pressures, venous dialysis pressures, and Doppler flow rates.

In human dialysis grafts, Sullivan et al (38) determined the relationship between static intragraft pressures and anatomic stenoses for 34 grafts and found a positive correlation between graft pressure and severity of stenosis. Venous line dialysis pressures are routinely measured during dialysis; unfortunately, these pressures do not necessarily reflect only intraaccess pressures. Venous line dialysis pressures are also affected by extracorporeal flow rate, dialysis needle diameter, fistula blood flow rate, and blood viscosity (43). These factors can be minimized by measuring venous dialysis pressures at relatively low extracorporeal flow rates (30). For autogenous fistulas, static and dynamic pressures are poor hemodynamic measures caused by collateralization in the venous outflow.

Access volume flows calculated with use of Doppler velocity and graft diameter have been used to predict thrombosis in several studies (39,40,61). Nevertheless, correlation between Doppler determined flow rates and the presence of significant stenosis is currently unknown.

Other hemodynamic measures of disease severity are useful but not strictly quantifiable; these include filling of collateral outflow veins and angiographically visualized flow rates.

*Recommendations for Reporting Standards.*—The same hemodynamic measure of disease severity should be used for the duration of the study, including all follow-up intervals.

When pressures are used to assess disease severity, the threshold or range of static or venous dialysis pressures considered abnormal should be provided. In addition, the number of determinations at which the threshold pressures were determined should be reported, if available. When known, the extracorporeal flow rates and dialysis needle diameter used during dynamic venous dialysis pressure determinations should be provided. For thrombosed accesses, the static and venous dialysis pressures can be assumed to be equal to systemic pressure for purposes of keeping track of continuous data.

When access volume flows are used to assess disease severity, the method of determination should be clearly presented. For thrombosed accesses, the volume flow can be assumed to be 0.

### Clinical Measures of Disease Severity

*Discussion.*—A thrombosed access is the most severe clinical scenario resulting in complete inability to perform dialysis.

Currently, the only widely used objective clinical measure of disease severity is the urea recirculation percentage. Dialysis recirculation is calculated by: percent recirculation = (systemic blood urea nitrogen; BUN) – arterial blood line BUN) ÷ (systemic BUN – venous blood line BUN) × 100. A simple relationship between recirculation and anatomic stenosis would allow a threshold to be established above which a high percentage of accesses would have a stenosis. Unfortunately, recirculation is dependent on several factors in addition to anatomic stenosis. These factors include extracorporeal blood flow rates (43,62), fistula flow rate (34), dialysis needle placement, time of blood sampling during dialysis, and the source of the systemic BUN sample (35). Non-urea-based dilutional methods to determine recirculation percentage are more accurate, but not widely used because special equipment is needed (63).

Other clinical measures of disease severity are not strictly quantifiable but indicate possible access malfunction. These include conversion of a continuous palpable thrill to a pulse (grafts), extremity edema (venous hypertension), prolonged postdialysis bleeding, ease of access cannulation, and electrolyte abnormalities.

*Recommendations for Reporting Standards.*—Access thrombosis is defined as complete inability to perform dialysis. Ideally, studies using percent recirculation as a measure of disease severity should report the threshold or range of thresholds for percent recirculation considered abnormal, the method (dilutional, two-needle), flow rate, and the time of determination in the dialysis treatment at which the percent recirculation was determined.

Difficult to quantify clinical mea-

tures of disease severity including changes in physical examination, extremity edema, prolonged postdialysis bleeding, ease of access cannulation, and so forth, should be recorded in binary fashion as present or absent.

## TREATMENT DESCRIPTION

*Discussion.*—Restoration of function for a thrombosed access requires treatment of thrombus. In addition, treatment of an underlying stenosis has been reported in over 90% of cases (5,44). Therefore, treatment of the thrombosed access is a process that usually involves several treatment modalities.

Because thrombolysis can be time consuming and most pharmacomechanical and mechanical methods are physician-intensive procedures, the time required is an important consideration. Investigators have reported time to establishment of flow (5,45), device activation time (64), and procedure time (6,8,45,65). Procedure time has been variably reported, including preparation time (5,45), excluding preparation and hemostasis time (6), and on a room cost basis (8).

*Recommendations for Reporting Standards.*—Regardless of the treatment modality being reported, sufficiently clear technical details should be given to allow other investigators to replicate the study.

Each treatment modality should be clearly described in the sequence utilized. The number of times the process is repeated and alterations in the sequence should be presented. If balloon angioplasty is reported for stenosis treatment, the balloon pressure, duration of inflation, number of inflations and choice of balloon diameter and length should be the minimal technical details provided. Similar data regarding choice of size or working diameter should be presented for devices, when appropriate. Procedure and postprocedure medications, including vasodilators, anticoagulant and antiplatelet agents, should also be presented.

For purposes of uniform reporting, the following definitions are recommended:

### Procedure Time

The time interval from the start of percutaneous puncture through the final posttreatment angiogram. This interval includes the treatment of thrombus and all other endovascular manipulations. Preparation time and time to obtain hemostasis are not included because wide variations exist in staffing and room utilization practices.

### Lysis or Thrombectomy Time

The time interval from insertion of a thrombolytic infusion system or device to the last maneuver performed to mobilize, mechanically disrupt, remove, or dissolve thrombus. If a stenosis is treated prior to or following treatment of thrombus, the time required to treat the stenosis is excluded. If a stenosis is treated in the middle of clot extraction or thrombolysis, the stenosis treatment time should be included as part of the lysis/thrombectomy time. Lysis or thrombectomy time is of secondary importance to procedure time; however, this time measure may be useful for comparing different methods of clot dissolution and removal. Therefore, reporting of lysis or thrombectomy time is recommended depending on the purpose of the study.

### Hemostasis Time

For techniques that carry an increased risk of bleeding complications, for example, those requiring systemic anticoagulant doses, large puncture, and so forth, separate data on hemostasis time could be useful. The method of obtaining hemostasis should be carefully described, for example, puncture tract suture (66), digital manual compression, topical Gelfoam pads (Upjohn, Kalamazoo, MI) with or without thrombin, and so forth. Devices left in situ for subsequent dialysis should be analyzed separately, if hemostasis data are available.

## POSTTREATMENT EVALUATION

### Anatomic Success

*Discussion.*—Anatomic success following treatment for a thrombosed

access has traditionally been determined simply by reestablishment and maintenance of flow as determined angiographically.

Criteria for success following treatment of stenoses are not as firmly established. Many authors have not clearly defined anatomic success or have reported clinical and/or hemodynamic patency. Others have adopted the anatomic criteria widely used for arterial angioplasty, that is, less than 30% residual diameter stenosis (11–13). The appropriateness of these criteria for venous angioplasty is uncertain.

*Recommendations for Reporting Standards.*—For treatment of stenoses, we currently recommend adoption of less than a 30% residual diameter stenosis to report anatomic success. At a minimum, the percent residual stenosis required for treatment success should be clearly delineated.

For treatment of thrombosed accesses, restoration of flow combined with a less than 30% maximal residual diameter stenosis for any significant underlying stenosis are required to report anatomic success.

### Hemodynamic Success

*Discussion.*—Regarding static and venous dialysis pressures, there are currently no uniformly accepted criteria of percent reduction from pretreatment values to determine hemodynamic success. One author (67) has recommended an intragraft venous limb static systolic pressure/cuffed brachial systolic pressure ratio <0.33, or an intragraft arterial limb systolic pressure/cuffed brachial systolic pressure ratio <0.50 for hemodynamic success.

Regarding access volume flows, there are currently no uniformly accepted criteria for percent increase from pretreatment values to determine success.

Angiographically visualized reduction of collateral outflow veins and improvement in flow rates are useful collaborative hemodynamic observations but cannot be reliably quantified.

*Recommendations for Reporting Standards.*—Pending further study, reduction of venous dialysis pressures to below predefined threshold values can be considered evidence of hemo-

dynamic success. When known, these thresholds should be clearly defined. Reduction of static intragraft/cuffed brachial static pressure ratios to below predefined thresholds can also be considered evidence of hemodynamic success. These pressures are easily obtained in an angiography suite immediately after intervention and during follow-up evaluations.

Pending further study, increase in access volume flows that exceed predefined threshold values can be considered hemodynamic success. These thresholds should be clearly defined.

### Clinical Success

*Discussion.*—For previously thrombosed accesses, the simple ability to perform dialysis has traditionally indicated clinical success (5–9,14,44,45, 64,65,68–70), regardless of other clinical, hemodynamic, or anatomic factors.

The presence of a uniform thrill throughout a dialysis graft has been correlated (using ultrasound criteria) with a 100% positive predictive value of a normal graft with no anatomic stenosis (32). On the other hand, lack of a uniform thrill and presence of a pulse or a pulse with a thrill have poor predictive value (32); for such cases, another indicator will be necessary to confirm procedure success.

Regarding outcomes for stenosis treatment, there is no established threshold for reduction in recirculation for defining success.

Resolution of pretreatment clinical indicators of access malfunction including abnormal physical examination, extremity edema, prolonged postdialysis bleeding, difficult access cannulation, and electrolyte abnormalities can also provide clinical evidence for success and continued patency. These are difficult to quantify; nevertheless, patients are commonly referred for evaluation because of abnormalities of these clinical factors.

*Recommendations for Reporting Standards.*—After treatment of a thrombosed access, resumption of normal dialysis for at least one session constitutes clinical success. After treatment of a stenosis, reduction of recirculation to below threshold values constitutes clinical success.

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 clinical success.

Other difficult to quantify clinical indicators including extremity edema, postdialysis bleeding, ease of access cannulation, and electrolyte abnormalities can be recorded in a binary fashion as present or absent.

### Device Success

*Discussion.*—An increasing number of mechanical devices to treat stenoses (eg, atherectomy, stents, etc) and thrombosed accesses (eg, Amplatz thrombectomy, Possis, Arrow-Tretrola, etc) are now available. These devices have specific purposes that may be considered distinct from overall procedure success. Percent clot removal or dissolution is difficult to quantify because thrombosed accesses collapse or contain unclotted fluid, making the total clot volume less than the theoretical volume (71,72). In addition, angiographic quantification can be dangerous because of the risk of peripheral arterial emboli.

*Recommendations for Reporting Standards.*—The specific purpose of a device should be considered. Devices for stenosis treatment should meet maximal residual stenosis criteria for success. Devices to pulverize or remove thrombus can be evaluated for their effectiveness independent of the overall procedure success by reporting the lysis or thrombectomy time; however, device success is secondary to procedure success (see Discussion below).

### PATENCY

*Discussion.*—Many early investigators (58–60) reported patency after excluding initial treatment failures. Others have reported mean patencies or patencies of known available patients at specific posttreatment intervals (15,16,58). Recent investigators, adhering to current peripheral vascular reporting requirements, have included initial treatment failures and reported cumulative patencies (5,7, 8,10–14,17,18,65,70). Nevertheless, differences in definitions of patency hamper comparison of these reports.

In addition, patency until the next necessary intervention may differ

greatly from the patency achieved by multiple subsequent interventions (12,18). Further, patency of the lesion treatment site per se may differ considerably from the patency of the access (12,18). The definitions described below are admittedly arbitrary; nevertheless, they are intended to bring a degree of uniformity to a disparate body of literature.

*Recommendations for Reporting Standards.*—Patencies should be reported using the Kaplan-Meier statistical method (73). In contrast to the surgical literature where patency is traditionally reported from the time of access creation (1,23,29,42,46), for the evaluation of percutaneous treatments, patency is measured from the time of percutaneous intervention. Since diligence of follow-up will affect outcome assessment, the modalities used, frequency of follow-up, and patient compliance with follow-up intervals should be clearly stated.

Procedural success is defined as anatomic success and at least one indicator of either hemodynamic or clinical success. Access thrombosis indicates loss of anatomic, hemodynamic, and clinical patency. For stenoses treated without previous access thrombosis, anatomic criteria, and the initially abnormal hemodynamic or clinical indicator(s) should be evaluated for continued patency. Whenever possible, the same anatomic, hemodynamic, and/or clinical measures used to assess disease severity in a given patient before therapy should be consistently applied to assess treatment outcomes. Recognizing that follow-up anatomic data may be difficult to obtain, at least one clinical and at least one hemodynamic indicator should be evaluated for continued patency. In addition, continued patency following treatment for access thrombosis should be differentiated from continued patency following treatment for an access stenosis without thrombosis. Even when substratification into thrombosed and stenosed accesses is not different statistically, the substratified data should be presented.

### Postintervention Primary Patency

Interval following intervention until the next access thrombosis or re-

peated intervention. Ends with treatment of a lesion anywhere within the access circuit, from the arterial inflow to the superior vena cava-right atrial junction.

### Postintervention Assisted Primary Patency

Interval after intervention until access thrombosis or a surgical intervention that excludes the treated lesion from the access circuit. Percutaneous treatments of either restenosis/occlusion of the previously treated lesion or a new arterial or venous outflow stenosis/occlusion (excluding access thrombosis) are compatible with assisted primary patency. The number of percutaneous treatments to maintain patency should be tabulated and presented as the number of treatments per patient year of dialysis. Assisted primary patency ends with percutaneous thrombolysis/thrombectomy or simple surgical thrombectomy.

### Postintervention Secondary Patency

Interval after intervention until the access is surgically declotted, revised or abandoned because of inability to treat the original lesion, choice of surgeon, transplant, loss to follow-up, etc. Thrombolysis and percutaneous thrombectomy are compatible with secondary patency. Multiple repetitive treatments can be included in secondary patency. The number and nature of treatments necessary to maintain secondary patency should be tabulated and presented as the number of treatments per patient year of dialysis and the number of access thromboses per patient year of dialysis.

### Postintervention Lesion Patency

Interval after intervention until the next reintervention at or adjacent to the original treatment site or until the extremity is abandoned for permanent access because of surgeon choice, transplant, loss to follow-up, etc. Percutaneous or surgical treatments of a new arterial or venous outflow stenosis/occlusion (including access thrombosis) that do not involve or exclude the original lesion from the access circuit are compatible with lesion patency. Creation of a new autogenous or synthetic fistula that incorporates

the original lesion into the new access circuit is also compatible with lesion patency.

Lesion patency will prevent obscuration of the durability of a treatment modality for a particular lesion by interventions elsewhere in the circuit. The durability of the treatment modality will be further reflected in the tabulated data of the number and nature of treatments required to maintain posttreatment assisted and secondary patencies for the entire access circuit.

The purpose of a study will determine the end points for patency. The above definitions apply to studies designed to evaluate endoluminal therapies. This committee recognizes that surgical and percutaneous treatments are complementary and will often be used sequentially in a planned treatment algorithm. Studies intended to evaluate a treatment algorithm that includes surgical thrombectomy with or without revision or patch angioplasty can use the above definitions of postintervention primary patency and assisted primary patency. The ultimate value of any treatment algorithm is patency of the treated dialysis access which has been reported independent of lesion patency (12,18,19).

The following definition of access survival is recommended:

### Postintervention Access Patency

Patency after intervention until the access is abandoned because of surgeon choice, transplant, loss to follow-up, and so forth. The number and nature (ie, thrombolysis, percutaneous thrombectomy, surgical thrombectomy with or without revision, etc) of treatments necessary to maintain the access should be tabulated and presented as the number of treatments per patient year of dialysis.

## COMPLICATIONS

*Discussion.*—The most frequent complications are local complications related to the access, including puncture site bleeding, venous occlusion/thrombosis and vascular perforation (10,12). Some complications are clearly procedure related (pulmonary embolus during thrombolysis), whereas others are not so clearly related to the procedure (graft infection 1 week after percutaneous intervention). Nevertheless,

the dialysis population has many medical problems with one third to one half having significant cardiac or pulmonary compromise (74–77) that may be exacerbated during treatment for a failing access.

*Recommendations for Reporting Standards.*—All events potentially related to access intervention that occur during the time a study is conducted should be reported. All complications, including pulmonary and cardiac events, that occur within 30 days are considered procedure related. Complications should be monitored and categorized as per SIR categories (27). They should be graded in a manner consistent with SIR definitions of minor and major complications (27).

## COSTS

*Discussion.*—Several studies have examined charges (68,78,79) for treating dialysis patients percutaneously; however, charges are often arbitrarily set and may not accurately reflect the actual resources used for treatment (80). To our knowledge, only one small pilot study has examined costs (81). In this study, the costs of pulse-spray thrombolysis and surgical thrombectomy for a single episode of dialysis graft thrombosis were prospectively compared. Unfortunately, although the cost for any single treatment or the hospitalization associated with that treatment may be lower for one modality than another, cumulative costs may ultimately be higher if the other modality is more durable or safer.

*Recommendations for Reporting Standards.*—Whenever possible, costs should be examined, rather than charges. Although costs are preferable to charges for analysis of expenses, direct cost analysis is difficult to perform. Nevertheless, some indirect measures related to cost can give some indications of the cost. For example, the total number of days of hospitalization for access malfunction over time can be compared for different treatment modalities. The cost of equipment used for a procedure and the number of interventions per unit time can potentially allow a comparison of costs for two different procedures. In addition, the cost of screening modalities at the frequency uti-

lized can be readily determined over time.

Direct cost analysis should include all expenses required to treat comorbid conditions, complications and failures. When two treatments are compared, the same method of cost evaluation should be applied to both groups. At a minimum, all costs incurred until discharge should be analyzed. Preferably, cumulative costs per patient for each treatment should be measured over months or years for more insightful comparisons.

## COMPARISONS BETWEEN TREATMENT GROUPS

*Discussion.*—The vast majority of peer-reviewed publications reporting results of percutaneous or surgical interventions for dialysis access lack a comparison group and are therefore feasibility studies. Comparisons of feasibility study groups with contemporary or historical control groups are of limited usefulness. Because inclusion and exclusion criteria may not be known, the baseline characteristics of the historic or contemporaneous group may be different. Basic differences in data analysis can further hamper comparisons between studies. For example, studies that allow repeated enrollments of the same patients for treatment of thrombosis cannot be reliably compared with studies that allow a patient to be enrolled only once. Registries attempt to inexpensively collect data for larger numbers of patients than a single institution could study in order to increase statistical validity. Nevertheless, these types of study are subject to favorable selection bias and also have no comparison control group. Meta-analyses combine data from multiple peer-reviewed studies in an attempt to gain increased statistical power and validity. Although prospective randomized controlled studies often require larger numbers of patients and are more expensive and time-consuming, the results may lead to different conclusions than a meta-analysis (82).

*Recommendations for Reporting Standards.*—The Institutional Review Board status should be provided for all types of study, including feasibility studies and retrospective chart reviews. Randomized controlled trials

are necessary for accurate assessment of treatment modalities and comparison with other treatment modalities (27). Whenever possible, treatment groups should be compared in a prospective, randomized controlled fashion. Clearly defined outcome criteria and sample size justification should be determined prior to beginning such studies. Although patient accrual will be slower, reenrollment of the same patient in feasibility or randomized controlled studies must be prohibited because two or more treatments in the same patient are not independent events. Because multiple disciplines are involved in the care of patients with failing or threatened dialysis access, the ideal study would compare treatment algorithms to determine the optimal combined treatment approach that would yield the longest access survival with the lowest numbers of procedures and cost.

**Acknowledgments:** Members of the Technology Assessment Committee include: Curtis W. Bakal, MD, MPH, Gary J. Becker, MD, Dana R. Burke, MD, Patricia E. Cole, PhD, MD, Michael D. Dake, MD, Alain Drooz, MD, Sue E. Hanks, MD Margaret E. Hansen, MD, Ziv J. Haskal, MD, Thomas B. Kinney, MD, David A. Kumpe, MD, Curtis A. Lewis, MD, MBA, Lindsay Machan, MD, David L. Marinelli, MD, Nilish H. Patel, MD, Douglas C.B. Redd, MD, Kenneth S. Rholl, MD, John H. Rundback, MD, Richard Shlansky-Goldberg, MD, James E. Silberzweig, MD, Robert L. Vogelzang, MD.

## References

1. Etheredge EE, Haid SD, Maeser MN, Sicard GA, Anderson CB. Salvage operations for malfunctioning polytetrafluoroethylene hemodialysis access grafts. *Surgery* 1983; 94:464–470.
2. Brotman DN, Fandos L, Faust GR, Doscher W, Cohen JR. Hemodialysis graft salvage. *J Am Coll Surg* 1994; 178:431–?
3. Palder SB, Kirkman RL, Whittemore AD, Hakim RM, Lazarus JM, Tilney NL. Vascular access for hemodialysis: patency rates and results of revision. *Ann Surg* 1985; 207:235–239.
4. Management of complications: optimal approaches for treating complications. Dialysis outcomes quality initiative. *Am J Kidney Dis* 1997; 30(suppl 3):S173–178.
5. Valji K, Bookstein JJ, Roberts AC, Davis GB. Pharmacomechanical thrombolysis and angioplasty in the management of clotted hemodialysis grafts: early and late clinical results. *Radiology* 1991; 178:243–247.
6. Beathard GA. Mechanical versus pharmacomechanical thrombolysis for the treatment of thrombosed dialysis access grafts. *Kidney Int* 1994; 45:1401–1406.
7. Cohen MAH, Kumpe DA, Durham JD, Zwerdinger SC. Improved treatment of thrombosed hemodialysis access sites with thrombolysis and angioplasty. *Kidney Int* 1994; 46:1375–1380.
8. Middlebrook MR, Amygdalos MA, Soulen MC, et al. Thrombosed hemodialysis grafts: percutaneous mechanical balloon declotting versus thrombolysis. *Radiology* 1995; 196:73–77.
9. Swan TL, Smyth SH, Ruffenach SJ, Berman SS, Pond GD. Pulmonary embolism following hemodialysis access thrombolysis/thrombectomy. *J Vasc Interv Radiol* 1995; 6:683–686.
10. Beathard GA. Percutaneous transvenous angioplasty in the treatment of vascular access stenosis. *Kidney Int* 1992; 42:1390–1397.
11. Safa AA, Valji K, Roberts AC, Ziegler TW, Hye RJ, Oglevie SB. 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.
12. Turmel-Rodrigues L, Pengloan J, Blanchier 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.
13. Kanterman RY, Vesely TM, Pilgram TK, Guy BW, Windus DW, Picus D. Dialysis access grafts: anatomic location of venous stenosis and results of angioplasty. *Radiology* 1995; 195:135–139.
14. Schwartz CL, McBrayer CV, Sloan JH, Meneses P, Ennis WJ. Thrombosed dialysis grafts: comparison of treatment with transluminal angioplasty and surgical revision. *Radiology* 1995; 194:337–341.
15. Zemel G, Katzen BT, Dake MD, Benenati JF, Lempert TE, Moskowitz L. Directional atherectomy in the treatment of stenotic dialysis access fistulas. *J Vasc Interv Radiol* 1990; 1:35–38.
16. Gray RJ, Dolmatch BL, Buick MK. Directional atherectomy treatment for hemodialysis access: early results. *J Vasc Interv Radiol* 1992; 3:497–503.
17. 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.
18. 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.
19. Vesely TM, Hovsepian DM, Pilgram TK, Coyne DW, Shenog S. Upper extremity central venous obstruction in hemodialysis patients: treatment with Wallstents. *Radiology* 1997; 204:343-348.
  20. Hoffer EK, Sultan S, Herskowitz MM, Daniels ID, Sclafani SJA. Prospective randomized trial of a metallic intravascular stent in hemodialysis graft maintenance. *J Vasc Interv Radiol* 1997; 8:965-973.
  21. Beathard GA. Gianturco self-expanding stent in the treatment of stenosis in dialysis access grafts. *Kidney Int* 1993; 43:872-877.
  22. Quinn SF, Schuman ES, Demlow TA, et al. Percutaneous transluminal angioplasty versus endovascular stent placement in the treatment of venous stenoses in patients undergoing hemodialysis: intermediate results. *J Vasc Interv Radiol* 1995; 6:851-855.
  23. Hodges TC, Fillingner MF, Zwolak RM, Walsh DB, Bech F, Cronenwett JL. Longitudinal comparison of dialysis access methods: risk factors for failure. *J Vasc Surg* 1997; 26:1009-1019.
  24. Rutherford RB, Flanigan DP, Gupta SK, et al. Suggested standards for reports dealing with lower extremity ischemia. *J Vasc Surg* 1986; 4:80-94.
  25. Ahn SS, Rutherford RB, Becker GJ, et al. Reporting standards for lower extremity arterial endovascular procedures. *J Vasc Surg* 1993; 17:1103-1107.
  26. Rutherford RB, Becker GJ. Standards for evaluating and reporting the results of surgical and percutaneous therapy for peripheral arterial disease. *J Vasc Interv Radiol* 1991; 2:169-174.
  27. Sacks D, Marinelli DL, Martin LG, et al. Reporting standards for clinical evaluation of new peripheral arterial revascularization devices. *J Vasc Interv Radiol* 1997; 8:137-149.
  28. Porter JM, Moneta GL. Reporting standards in venous disease: an update. *J Vasc Surg* 1995; 21:635-645.
  29. Gray RJ. Percutaneous intervention for permanent hemodialysis access: a review. *J Vasc Interv Radiol* 1997; 8:313-327.
  30. Schwab SJ, Raymond JR, Saeed M, Newman GE, Dennis PA, Bollinger RR. Prevention of hemodialysis fistula thrombosis: early detection of venous stenoses. *Kidney Int* 1989; 36:707-711.
  31. Besarab A, Sullivan KL, Ross RP, Moritz MJ. Utility of intra-access pressure monitoring in detecting and correcting venous outlet stenoses prior to thrombosis. *Kidney Int* 1995; 47:1364-1373.
  32. Trerotola SO, Scheel PJ Jr, Powe N, et al. Screening for dialysis access graft malfunction: comparison of physical examination with ultrasound. *J Vasc Interv Radiol* 1996; 7:15-20.
  33. Windus DW, Audrain J, Vanderson R, Jendrisak MD, Picus D, Delmez JA. Optimization of high-efficiency hemodialysis by detection and correction of fistula dysfunction. *Kidney Int* 1990; 38:337-341.
  34. Collins DM, Lambert MB, Middleton JP, et al. Fistula dysfunction: effect on rapid hemodialysis. *Kidney Int* 1992; 41:1292-1296.
  35. Sherman RA. The measurement of dialysis access recirculation. *Am J Kidney Dis* 1993; 22:616-621.
  36. Choudhury D, Lee J, Elivera HS, Ball D, Roberts AB, Ahmed Z. Correlation of venography, venous pressure, and hemoaccess function. *Am J Kidney Dis* 1995; 25:269-275.
  37. Besarab A, Moritz M, Sullivan K, Dorrell S, Price JJ. Venous access pressures and the detection of intraaccess stenosis. *ASAIO J* 1992; 38:M519-M523.
  38. Sullivan KL, Besarab A, Dorrell S, Moritz MJ. The relationship between dialysis graft pressure and stenosis. *Invest Radiol* 1992; 27:352-355.
  39. Shackleton C, Taylor D, Buckley A, Rowley A, Cooperberg P, Fry P. Predicting failure in polytetrafluoroethylene vascular access grafts for hemodialysis: a pilot study. *Can J Surg* 1987; 30:442-444.
  40. Strauch BS, O'Connell RS, Geoly KL, Grundlehner M, Yakub YN, Tietjen DP. Forecasting thrombosis of vascular access with Doppler color flow imaging. *Am J Kidney Dis* 1992; 11:554-557.
  41. Douset V, Grenier N, Douws C, et al. Hemodialysis grafts: color Doppler flow imaging correlated with digital subtraction angiography and functional status. *Radiology* 1991; 181:89-94.
  42. Munda R, First MR, Alexander JW, Linnemann CC, Fidler JP, Kittur D. Polytetrafluoroethylene graft survival in hemodialysis. *JAMA* 1983; 249:219-222.
  43. Berkuben MS, Schwab SJ. Vascular access for hemodialysis. Clinical dialysis. Norwalk, CT: Appleton & Lange, 1990; 26-45.
  44. Beathard GA, Welch BR, Maidment HJ. Mechanical thrombolysis for the treatment of thrombosed hemodialysis access grafts. *Radiology* 1996; 200:711-716.
  45. Trerotola SO, Lund GB, Scheel PJ Jr, Savader SJ, Venbrux AC, Osterman FA Jr. Thrombosed dialysis access grafts: percutaneous mechanical declotting without urokinase. *Radiology* 1994; 191:721-726.
  46. Zibari GB, Rohr MS, Landreneau MD, et al. Complications from permanent hemodialysis vascular access. *Surgery* 1988; 104:681-686.
  47. Rizzuti RP, Hale JC, Burkart TE. Extending patency of expanded polytetrafluoroethylene grafts for vascular access using optimal configuration and revisions. *Surg Gynecol Obstet* 1988; 166:23-27.
  48. Schillinger F, Schillinger D, Montagnac R, Milcent T. Post catheterization vein stenosis in haemodialysis: comparative angiographic study of 50 subclavian and 50 internal jugular accesses. *Nephrol Dial Transplant* 1991; 6:722-724.
  49. Cimochoowski GE, Worley E, Rutherford WE, Sartain J, Blondin J, Harter H. Superiority of the internal jugular over the subclavian access for temporary dialysis. *Nephron* 1990; 54:154-161.
  50. Barrett N, Spencer S, McIvor J, Brown EA. Subclavian stenosis: a major complication of subclavian dialysis catheters. *Nephrol Dial Transplant* 1988; 3:423-425.
  51. Surratt RS, Picus D, Hicks ME, Darcy MD, Kleinhoffer M, Jendrisak M. The importance of preoperative evaluation of the subclavian vein in dialysis access planning. *AJR* 1991; 156:623-625.
  52. Vanherweghem JL, Yassine T, Goldman M, et al. Subclavian vein thrombosis: a frequent complication of subclavian vein cannulation for hemodialysis. *Clin Nephrol* 1986; 26:235-238.
  53. Schwab SJ, Quarles LD, Middleton JP, Cohan RH, Saeed M, Dennis VW. Hemodialysis-associated subclavian vein stenosis. *Kidney Int* 1988; 33:1156-1159.
  54. Gilula LA, Staple TW, Anderson CB, Anderson LS. Venous angiography of hemodialysis fistulas. *Radiology* 1975; 115:555-562.
  55. Picus D, van Breda A, Katzen BT, Steinberg DL. Use of digital subtraction angiography for evaluation of vascular access for hemodialysis. *Cardiovasc Intervent Radiol* 1987; 10:210-214.
  56. Ehrman KO, Taber TE, Gaylord GM, Brown PB, Haze JP. Comparison of diagnostic accuracy with carbon dioxide versus iodinated contrast material in the imaging of hemodialysis access fistulas. *J Vasc Interv Radiol* 1994; 5:771-775.
  57. Brescia MJ, Cimino JE, Appel K, Hurwich BJ. Chronic hemodialysis using venipuncture and a surgically created arteriovenous fistula. *N Engl J Med* 1966; 275:1089-1092.
  58. Glanz S, Gordon DH, Butt KMH, Hong J, Lipkowitz GS. The role of percutaneous angioplasty in the management

- of chronic hemodialysis fistulas. *Ann Surg* 1987; 206:777-781.
59. Gmelin E, Winterhoff R, Rinast E. Insufficient hemodialysis access fistulas: late results of treatment with percutaneous balloon angioplasty. *Radiology* 1989; 171:657-660.
60. Saeed M, Newman GE, McCann RL, Sussman SK, Braun SD, Dunnick NR. Stenoses in dialysis fistulas: treatment with percutaneous angioplasty. *Radiology* 1987; 164:693-697.
61. Rittgers S, Garcia-Valdez C, McCormick J, Posner M. Noninvasive blood flow measurement in expanded polytetrafluoroethylene grafts for hemodialysis access. *J Vasc Surg* 1986; 3:635-642.
62. Hasbergen JA, Bertstrom RJ. Variable blood pump flow rates and the effect on recirculation. *Clin Nephrol* 1994; 42:322-326.
63. Depner TA, Krivitski NM, MacGibbon D. Hemodialysis access recirculation measured by ultrasound dilution. *ASAIO J* 1995; 41:M749-M753.
64. Uflacker R, Rajagopalan PR, Vujic I, Stutley JE. 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.
65. Sharafuddin MJA, Kadir S, Joshi SJ, Parr D. Percutaneous balloon-assisted aspiration thrombectomy of clotted hemodialysis access grafts. *J Vasc Interv Radiol* 1996; 7:177-183.
66. Vorwerk D, Konner K, Schormann K, Gunther RW. A simple trick to facilitate bleeding control after percutaneous hemodialysis fistula and graft interventions. *Cardiovasc Intervent Radiol* 1997; 20:159-160.
67. Sullivan KL, Besarab A, Bonn J, Shapiro MJ, Gardiner GA, Moritz MJ. Hemodynamics of failing dialysis grafts. *Radiology* 1993; 186:867-872.
68. Sands JJ, Patel S, Plaviak DJ, Miranda CL. Pharmacomechanical thrombolysis with urokinase for treatment of thrombosed hemodialysis access grafts. *ASAIO J* 1994; 40:M886-M888.
69. Davis GB, Dowd CF, Bookstein JJ, Maroney TP, Lang EV, Halasz N. Thrombosed dialysis grafts: efficacy of intrathrombic deposition of concentrated urokinase, clot maceration, and angioplasty. *AJR* 1987; 149:177-181.
70. Berger MF, Aruny JE, Skibo LK. Recurrent thrombosis of polytetrafluoroethylene dialysis fistulas after recent surgical thrombectomy: salvage by means of thrombolysis and angioplasty. *J Vasc Interv Radiol* 1994; 5:725-730.
71. Winkler TA, Trerotola SO, Davidson DD, Milgrom ML. Study of thrombus from thrombosed hemodialysis access grafts. *Radiology* 1995; 197:464-465.
72. Dolmatch BL, Gray RJ, Horton KM. Will iatrogenic pulmonary embolization be our pulmonary embarrassment? *Radiology* 1994; 191:615-617.
73. Kaplan EL, Meier P. Nonparametric estimation from incomplete observations. *J Am Stat Assoc* 1958; 53:457-481.
74. Ikeda T, Tajiri M, Hirasawa Y, Aizawa Y, Shibata A. Circulatory state of patients on chronic hemodialysis. *Jpn Circ J* 1981; 45:171-175.
75. Rostand SG, Gretes JC, Kirk KA, Rutsky EA, Andreoli TE. Ischemic heart disease in patients with uremia undergoing maintenance hemodialysis. *Kidney Int* 1979; 16:600-611.
76. Braun WE, Phillips D, Vidt DG, et al. Coronary arteriography and coronary artery disease in 99 diabetic and nondiabetic patients on chronic hemodialysis or renal transplantation programs. *Transplant Proc* 1981; 13:128-135.
77. Ikram H, Lynn KL, Bailey RR, Little PJ. Cardiovascular changes in chronic hemodialysis patients. *Kidney Int* 1983; 24:371-376.
78. Schuman E, Quinn S, Standage B, Gross G. Thrombolysis versus thrombectomy for occluded hemodialysis grafts. *Am J Surg* 1994; 167:473-476.
79. Summers S, Drazan K, Gomes A, Freischlag J. Urokinase therapy for thrombosed hemodialysis access grafts. *Surg Gynecol Obstet* 1993; 176:534-538.
80. Picus D. Comparing competing medical procedures: costs or charge—what should it matter? [Editorial] *Radiology* 1996; 199:623-625.
81. Vesely TM, Idso MC, Audrain J, Windus DW, Lowell JA. Thrombolysis versus surgical thrombectomy for the treatment of dialysis graft thrombosis: pilot study comparing costs. *J Vasc Interv Radiol* 1996; 7:507-512.
82. LeLorier, Gregoire G, Benhaddad A, Lapierre J, Derderian F. Discrepancies between meta-analyses and subsequent large randomized controlled trials. *N Engl J Med* 1997; 337:536-542.