The Society for Vascular Surgery: Clinical practice guidelines for the surgical placement and maintenance of arteriovenous hemodialysis access

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Recognizing the impact of the decision making by the dialysis access surgeon on the successful placement of autogenous arteriovenous hemodialysis access, the Society for Vascular Surgery assembled a multispecialty panel to develop practice guidelines in arteriovenous access placement and maintenance with the aim of maximizing the percentage and functionality of autogenous arteriovenous accesses that are placed. The Society commissioned the Knowledge and Encounter Research Unit of the Mayo Clinic College of Medicine, Rochester, Minnesota, to systematically review the available evidence in three main areas provided by the panel: timing of referral to access surgeons, type of access placed, and effectiveness of surveillance. The panel then formulated practice guidelines in seven areas: timing of referral to the access surgeon, operative strategies to maximize the placement of autogenous arteriovenous accesses, first choice for the autogenous access, choice of arteriovenous access when a patient is not a suitable candidate for a forearm autogenous access, the role of monitoring and surveillance in arteriovenous access management, conversion of a prosthetic arteriovenous access to a secondary autogenous arteriovenous access, and management of the nonfunctional or failed arteriovenous access. For each of the guidelines, the panel stated the recommendation or suggestion, discussed the evidence or opinion upon which the recommendation or suggestion was made, detailed the values and preferences that influenced the group's decision in formulating the relevant guideline, and discussed technical remarks related to the particular guideline. In addition, detailed information is provided on various configurations of autogenous and prosthetic accesses and technical tips related to their placement. (J Vasc Surg 2008;48:2S-25S.)

Autogenous arteriovenous (AV) access for hemodialysis has been shown to be superior to prosthetic graft or catheter access in terms of patient morbidity and mortality. In addition, the maintenance of autogenous AV access is less expensive than prosthetic conduits.[1-5] Although several reports have shown an autogenous AV access is feasible in most patients in the United States, construction and utilization rates for autogenous AV access for hemodialysis in this country are dramatically lower than in Europe and Japan.[6,7] Nevertheless, rates of autogenous AV access within the United States have improved in the last several years. This important progress likely reflects the effect of national efforts to increase autogenous access placement, such as the Centers for Medicare and Medicaid Services (CMS)–sponsored AV Fistula First Breakthrough Initiative (FFBI) and the National Kidney Foundation (NKF)-Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guidelines,[8,9] as well as improved preoperative evaluation, vessel mapping, and accepted priority for autogenous access. The development of alternative and innovative approaches to autogenous AV access construction has also contributed to wider utilization of autogenous access in this country.[10]

Ten years ago, in October 1997, the NKF-KDOQI Clinical Practice Guidelines for Vascular Access were published in an effort to increase the placement of autogenous AV access and to prolong the use of existing access by detection of, and timely intervention for, dysfunction. These original guidelines and subsequent versions stress proactive identification of patients with progressive kidney disease, identification and protection of potential native access construction sites by members of the health care team and patients, and the development of a multifaceted quality assurance program to detect at-risk vascular access, track complication rates, and implement procedures that maximize access longevity.

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The original guidelines recommended that autogenous AV access be constructed in at least 50% of all new renal failure patients electing to receive hemodialysis as their initial form of renal replacement therapy, with the expectation that ultimately, 40% of prevalent patients would be receiving their hemodialysis through an autogenous AV access.[11] The 2006 updated KDOQI Guidelines raised this benchmark for minimal use of autogenous access in prevalent hemodialysis patients to 65%.[9]

In June 2003, a coalition consisting of the CMS, the End-Stage Renal Disease (ESRD) Networks, the Institute for Healthcare Improvement (IHI), and other key provider representatives jointly recommended adoption of a National Vascular Access Improvement Initiative (NVAII). The initial goal of this initiative was to increase the number of autogenous AV accesses placed and functioning in suitable patients to meet or even surpass the targets set by NKF-KDOQI guidelines.

The NVAII was originally intended to run through 2003; but because of early success in reaching the then-KDOQI goal of 40% prevalence by August 2005, CMS formally expanded its commitment by upgrading the initiative to what CMS called the AV Fistula First Breakthrough Initiative (FFBI), with a new goal of 66% by 2009.[10] The FFBI Work Group identified clinical and organizational changes that could be adapted and applied locally by nephrologists, dialysis personnel, access surgeons, and patients to increase the production and use of autogenous AV access. They also identified system changes that could be implemented at a national level to encourage the placement of autogenous AV accesses at a higher rate than prosthetic AV accesses and catheters, for example, reimbursement for preoperative vessel mapping to identify adequate vessels for use for autogenous access construction. As a result of the efforts of the FFBI, the prevalence of autogenous access had increased by >50%, from 32% to 49%, by January 2008.

The Society for Vascular Surgery (SVS), representing >2500 vascular surgeons, recognizes the effect of decision making by the individual vascular access surgeon on the construction and utilization of access for hemodialysis. Therefore, the SVS approved and sponsored two initiatives: (1) to develop and publish reporting standards for AV hemodialysis access and (2) to develop practice guidelines for AV hemodialysis access.

To accomplish the first initiative, the SVS charged a multidisciplinary committee to develop standardized definitions related to AV access procedures, patency, and complications. Standardization of terminology facilitates more meaningful comparisons between published reports of long-term patency and complications of AV access procedures. These recommendations were published in the *Journal of Vascular Surgery* in 2002.[12]

To accomplish the second initiative, SVS assembled a multispecialty expert panel, consisting of vascular access surgeons and nephrologists, to develop clinical practice guidelines for AV access placement. In an ongoing effort to optimize the placement of autogenous AV access in patients with chronic kidney disease (CKD) and ESRD, these guidelines are directed toward AV access surgeons and specialists (such as interventional radiologists, nephrologists, and cardiologists) as the providers whose ultimate operative decision determines the type of access placed. The panel's recommendations have culminated in the following practice guidelines: optimal timing and indications for referral of patients with advanced CKD, defined by a Modification of Diet in Renal Disease (MDRD) glomerular filtration rate (GFR) of >20 to 25 mL/min, to a vascular access surgeon, preoperative evaluation for AV access, configuration and strategies to optimize autogenous AV access placement, assessment of functionality of AV access, and treatment of AV access thrombosis.

To help the panel formulate its recommendations, the SVS used the help of The Knowledge and Encounter Research Unit (KER) of the Mayo Clinic College of Medicine, Rochester, Minnesota. This independent group performed a systematic study of the available evidence in three main areas provided by the panel: timing of referral to access surgeons, type of access placed, and effectiveness of surveillance.[13-15] The panel adopted the Grading of Recommendations Assessment, Development and Evaluation (GRADE) scheme to formulate these recommendations because this system separates the strength of recommendations from the quality of the evidence.[16] This separation informs guideline users (eg, patients, clinicians, and policy makers) of factors other than evidence, such as values and preferences if applicable, and clinical and social circumstances that played a role in formulating these recommendations.

These systematic literature reviews revealed a paucity of high-quality evidence in this area, and many of the recommendations herein are based on observational studies, unsystematic observations, and consensus of our committee. Nevertheless, some of these recommendations were graded as strong (GRADE 1) because of the values and preferences brought to bear by the committee and are explicitly described in this article. In addition, because of the multidisciplinary nature of the committee, these recommendations reflect consensus among access surgeons and nephrologists. Although by spearheading this project the SVS aimed to provide a structure to form the underpinning of patient evaluation and decision making by the access surgeon, it is important to emphasize that these recommendations are not intended to supersede the surgeon's final judgment regarding the management of the individual patient.

1. CLINICAL RECOMMENDATION: Timing of referral to AV access surgeon and timing of placement of permanent vascular access

We recommend that patients with advanced CKD disease (late stage 4, MDRD <20 to 25 mL/min) who have elected hemodialysis as their choice of renal replacement therapy be referred to an access surgeon in order to evaluate and plan construction of AV access (GRADE 1 recommendation, very low-quality evidence).

A. If at the conclusion of the evaluation, upper extremity arterial and venous anatomy is adequate for an autogenous AV access, such access should be constructed as soon as possible to allow it enough time to mature and undergo further interventions that may be needed to ensure that the access is ready to be used when dialysis is initiated.

B. If a prosthetic access is to be constructed, this should be delayed until just before the need for dialysis.

1.1. Evidence

A systematic review of the literature demonstrated that the evidence on the appropriate timing of referring patients to vascular surgery is very scarce.[13] Two observational studies demonstrated that <5% of patients who were seen by a vascular surgeon >1 month before hemodialysis was initiated used a catheter as their first access[17] and that, compared with late access construction (≤1 month of hemodialysis), early access construction (≥4 months before hemodialysis) was associated with lower risk of death and sepsis, with relative risks (RRs) of 0.76 (95% confidence interval [CI], 0.58-1.00) and 0.57 (95% CI, 0.41-0.79), respectively.[18] Introducing catheter use and sepsis into the mortality model rendered the association nonsignificant. It is difficult to predict the timing of hemodialysis onset in an individual patient[19]; however, observations of the committee members suggest that access placement <6 months before initiation of hemodialysis is unlikely to allow adequate time for autogenous access maturation. Timely discussion and consultation could help avoid these adverse outcomes.

In addition, according to unsystematic observations and consensus of our committee, prosthetic AV accesses should be placed no earlier than 3 to 6 weeks before an anticipated need for hemodialysis in patients who are not candidates for autogenous AV accesses. This is because the lifespan of prosthetic accesses is limited by venous outflow stenosis, which can develop at any time after access placement, regardless of when hemodialysis is initiated through the access. In addition, the prosthetic access only needs 3 to 6 weeks for incorporation in the surrounding tissue, and at many centers, a prosthetic access is used ≤2 weeks of placement or earlier, depending on the type of prosthetic access. This recommendation is consistent with those of KDOQI and the FFBI.[8,9]

1.2. Values and preferences

In formulating a strong recommendation despite the very low-quality evidence, the committee placed a higher value on avoiding harm associated with late access construction and a lower value on potential harms and costs associated with early referral and early access placement. Early referral should encourage placement of autogenous access; however, whether the autogenous access prevalence rate can be increased to reach 66% by 2009, as desired by CMS,[8] is currently uncertain.

1.3. Technical remarks

It is generally agreed that all new hemodialysis patients should have the most optimal permanent vascular access that can be successfully used at the time of initiation of dialysis therapy. For this to happen, the patient must see a nephrologist before initiation of dialysis to facilitate the referral to an access surgeon, and the surgery must be performed in enough time before dialysis initiation to allow for maturation, revision, and repeat procedures if the first attempt is unsuccessful.

Referral for initial vascular access placement should ideally occur approximately 6 months in advance of the anticipated need for dialysis. Because of the difficulty of predicting timing of onset of hemodialysis in an individual patient, it is recommended that referral for initial access placement should occur when the estimated GFR (eGFR) level drops <20 to 25 mL/min/1.73 m^2 (stage 4 CKD) in a patient expected to start hemodialysis. However, referral decisions should be individualized to reflect differences in rates of actual and predicted decline in eGFR, in the competing risk of death, and in patient preferences.

In the United States, most patients who start dialysis do not have a functioning permanent vascular access (autogenous or prosthetic) in place at the time dialysis is initiated, and thus a catheter must be used for dialysis until permanent access is placed and ready to be used.[20,21] Many patients are not referred to a nephrologist until their kidney disease is already quite advanced, allowing little opportunity for vascular access placement before dialysis is initiated.[17,22,23]

Not surprisingly, patients who are referred to nephrologists before the initiation of dialysis are more likely to undergo vascular access surgery before dialysis begins.[24] More frequent utilization of nephrology care before the initiation of dialysis also appears to be associated with a lower risk of catheter use at the initiation of dialysis.[24] Avorn et al[24] found that patients referred to a nephrologist <90 days before the initiation of dialysis were approximately 40% more likely to undergo catheter placement compared with those who were seen >90 days before the initiation of dialysis. Frequency of nephrology care was also important. Those who had fewer than three visits to a nephrologist within the year before dialysis initiation were 40% more likely to have a catheter than those who had three or more visits.[24]

In addition, predialysis nephrology referral is associated with a shorter duration of catheter use after the initiation of dialysis and with a greater likelihood of autogenous access placement.[25] Nevertheless, even among patients referred to a nephrologist well in advance of the need for dialysis, most start dialysis with a catheter rather than a permanent vascular access.[20,22,25] Therefore, the need for CKD/pre-ESRD programs is crucial to ensuring that patients are evaluated early to receive the optimal renal replacement therapy and permanent hemodialysis access (if hemodialysis is chosen).

The average maturation time of a new autogenous access is 2 to 4 months.[26-30] In addition, a patient whose access fails to mature sufficiently to support hemodialysis

needs to undergo additional procedures to promote autogenous access maturation or place a new vascular access, or both. Hemodialysis patients are usually dialyzed through a central venous catheter while this process is completed. Catheter use is associated with bacteremia and inadequate dialysis, which is time/use-related.[31] Catheter use at initiation of dialysis is also associated with higher subsequent mortality.[32-34] Furthermore, mortality is higher among patients who receive dialyses continuously through a catheter than among those who switch from a catheter to autogenous or prosthetic permanent access.[35] It should be noted that it is unclear from these studies whether catheter use directly causes higher mortality or whether catheter use is a marker for other conditions and situations associated with increased mortality risk.

In addition to central vein preservation, peripheral upper extremity veins should also be preserved for future placement of permanent vascular access; therefore whenever possible, hand veins should be used in preference to arm veins for phlebotomy and intravenous catheter placement in patients with CKD, despite the increased discomfort for patients. Particular care should be taken to avoid cannulation of the cephalic vein in the nondominant arm. When arm veins must be used, the site should be rotated. Percutaneous intravenous central catheters (PICCs) should not be used in patients with evidence of renal dysfunction until their renal status is evaluated.

Because of low rates of autogenous access placement among incident hemodialysis patients, time required for successful autogenous access maturation, and associations of catheter use with adverse outcomes among hemodialysis patients, there is ready consensus that patients with CKD should be referred for autogenous access placement well before the initiation of dialysis. However, scant information is available to suggest exactly how far in advance of the need for dialysis and when in relation to their level of renal function and course of their CKD patients should be referred for initial AV access construction. Consequently, although there is broad agreement among different national guidelines that timely referral for autogenous access construction is important, specific recommendations are opinion-based and vary considerably, as indicated by various published guidelines around the world.[8,10,11,36,37,38] Some are summarized below:

United States KDOQI guidelines.[11]

I. Guideline 1: Patient preparation for permanent hemodialysis access:

1.3. Patients should have a functional permanent access at the initiation of dialysis therapy.

- 1.3.1. A fistula should be placed at least 6 months before the anticipated start of hemodialysis (HD) treatments. This timing allows for access evaluation and additional time for revision to ensure a working fistula is available at initiation of dialysis therapy. (B)
- 1.3.2. A graft should, in most cases, be placed at least 3 to 6 weeks before the anticipated start of HD therapy. Some newer graft materials may be cannulated immediately after placement. (B)

And these guidelines also stated:[11]

II. Clinical practice recommendations for guideline 1: patient preparation for permanent hemodialysis access.

- 1.3. Patients with CKD stage 5 should be educated on the risks and benefits associated with catheters and strongly encouraged to allow the evaluation for and creation of a fistula for long-term access when appropriate. Such discussions with the patient should be initiated months before the anticipated start of dialysis therapy.

The FFBI. Referral to surgeon for evaluation for access by stage 4 CKD (GFR <30), with placement of AVF soon thereafter (GFR 20 to 30), or based on progression of renal disease.[8,10]

British Renal Association. The following is stated under guideline 7-Vascular Access of The British Renal Association C:[37]

7.4. Patients should undergo fistula creation between 6 and 12 months before hemodialysis is expected to start to allow time for adequate maturation of the fistula or time for a revision procedure if the fistula fails or is inadequate for use.

Canadian Society of Nephrology. Guidelines from the Canadian Society of Nephrology indicate:[38]

A. Establish autogenous AV access when the patient has a creatinine clearance of 15 to 20 mL/min or serum creatinine of 300 to 500 μmol/L, depending on the size and weight of the patient.
B. Place dialysis prosthetic access at least 3 to 6 weeks before an anticipated need for hemodialysis.

Caring for Australians with Renal Insufficiency (CARI). Guidelines from Caring for Australians With Renal Insufficiency state:[36]

A. All patients, and especially those with comorbid conditions, should be referred to a vascular access surgeon well in advance of the anticipated need for hemodialysis. The exact timing depends on patient-related factors and local facilities.
B. Several procedures may be required to establish access and maturation of access may be prolonged in some patients.
C. AV grafts should be placed only shortly before anticipated use.

Preoperative evaluation. Establishing functional AV access requires careful preoperative evaluation and planning. This process starts by early identification of individuals with renal insufficiency for prompt surgical consultation to select the best extremity and site for an autogenous AV access. A very important determinant of the success of AV access is an appropriate and detailed preoperative history and examination, followed by vessel mapping.

Patient history specific to vascular access selection. Several historical factors have been associated with increased difficulty in establishing a functional AV access and partic-

ularly autogenous AV access. These include diabetes mellitus, peripheral vascular disease, severe congestive heart failure, advanced age, and female gender.[29,39-40] However, recent reports have demonstrated that successful outcomes are possible in several of these groups.[41,42] All patients should be viewed as potential candidates for autogenous AV access construction, although some individuals with a difficult access extremity will require more inventive or complex access procedures.[42-44] Repeated thrombotic events may prompt screening for a hypercoagulable state.[45] Several risk factors such as homocystine and factor VIII are commonly elevated in patients with renal failure. Chronic anticoagulation with warfarin carries significant risk in these patients and should probably be considered only for those individuals with a clearly defined hypercoagulable state.[46,47] Clopidogrel is frequently used in the dialysis population. In prosthetic accesses, it was associated with a higher rate of bleeding and no statistical improvement in graft patency.[48-50]

The patient's surgical history, such as failed access procedures, PICCs, pacemakers, defibrillators, arterial catheters, cardiac surgery, or trauma often play an important role in AV access planning. Consideration of the patient's dominant arm or incapacitation of one extremity from a previous stroke may influence, but not dictate, an AV access decision. Placement of an autogenous AV access is particularly important in patients with chronic infections, recurrent skin diseases, and immunosuppression. Finally, the patient's overall medical condition, social support structure, and life expectancy should be considered when considering long-term vascular access.

Physical examination specific to vascular access selection. Patients with forearm eczema or extensive solar keratosis and those older patients with particularly thin and fragile skin may be better suited to upper arm autogenous AV access. Neurologic examination should record the presence of neuropathy and describe motor or sensory abnormalities. Evidence of congestive heart failure, such as neck vein distension, should be addressed and cardiac function maximized before surgery.

Unfortunately, most individuals in the United States begin chronic dialysis through a central venous dialysis catheter. The site and location of these existing and previous catheters should be recorded. In addition, defibrillators and pacemakers often use the subclavian vein and are even more likely to be associated with clinically important central venous stenosis or occlusion. If permanent access is planned on the side of a previous central catheter, imaging of the central veins may be needed because any significant stenoses may produce venous hypertension due to markedly increased venous blood flow from an upper extremity AV access.[51]

Arterial examination. The experienced surgeon's examination, including identification of healthy brachial, radial, and ulnar arteries, is the single most important aspect of arterial inflow evaluation. Palpation of healthy vessels should find the arteries soft, easily compressible, and their pulse equal bilaterally. The Allen's test confirms a patent palmar arch and is particularly important when an autogenous AV access at the wrist is planned. Bilateral extremity blood pressures should be recorded and found to be equal. Sites of previous arterial catheters or arterial donations for coronary artery bypass grafting should be identified; the radial artery harvested for coronary revascularization is identified by the characteristic longitudinal incision over the anterior aspect of the forearm. Further investigations are indicated if the history or physical findings suggest an arterial inflow abnormality.

Venous examination. The venous system should be inspected with and without a venous pressure tourniquet in place. Outflow veins should be uninterrupted and distensible. The presence of enlarged superficial veins on the chest wall or arm edema may suggest central venous stenosis or occlusion. Enlarged collateral veins are pathognomonic of a segmental venous occlusion.[52] Arm diameter in obese patients may limit access selection or dictate the need for primary or staged vein elevation or a transposition procedure.

Noninvasive ultrasound imaging: a critical supplement to the clinical examination. Ultrasound venous mapping is of critical importance in these patients, not only for identifying preferred autogenous access sites but also for evaluating the depth of venous structures.[53] Utilization of autogenous veins for construction of AV access is enhanced by the identification of clinically "buried" veins as well as unexpected venous occlusions or stenoses.[47] Some obese individuals have deep forearm veins that are quite adequate for dialysis if transposed or superficialized. Further, if distal arterial inflow is inadequate and the venous system is found adequate by ultrasound imaging, functional access can often be established by using proximal arterial inflow and establishing retrograde forearm autogenous AV access flow.[46] Although adequate arterial inflow can usually be determined by a clinical examination, arterial abnormalities such as the high brachial bifurcation are relatively common, easily identified by ultrasound examination, and may substantially affect preoperative planning; this is especially relevant when considering a forearm prosthetic access site. An inadequate arterial lumen may also adversely affect outcome and is easily determined by combining the arterial ultrasound examination with the venous survey.

Arterial procedural evaluations specific to vascular access. *Noninvasive evaluation.* A normal clinical arterial examination without a history suggesting inflow occlusive disease may not require a further presurgical evaluation of the arterial inflow. However, if arterial inflow is not clearly normal, duplex ultrasound (DU) imaging, performed simultaneously with vein mapping, will aid in identifying stenotic segments and determine arterial diameter in addition to calculation of arterial flow.[54,55] The minimal arterial lumen diameter is important. Studies have shown both 1.5 mm and 2.0 mm to be the minimally acceptable internal arterial diameters for successful autogenous AV access, although 2.0 mm seems to be the more commonly accepted limit in adults.[56,57]

A significant number of patients are poor candidates for a radiocephalic (wrist) AV access from either an arterial or

venous standpoint. Goldstein et al[58] reported that ultrasound examination found 50% of patients studied had inadequate arterial inflow to support a radiocephalic autogenous AV access at the wrist. Segmental Doppler pressures may be helpful; however, vessel calcification in diabetic patients may preclude accurate measurement of these pressures. Digital pressures, transcutaneous oximetry, and resistance index measurements have also been suggested as measures of inflow adequacy and may be helpful in selected cases. Calculating the resistance index or simple ultrasound observation of changes in the arterial waveform during a clinched fist maneuver (reactive hyperemia) predicts the vessel's ability to accommodate the anticipated marked increase in flow required for a successful AV access.[54,59]

Arteriography. Arteriography may be useful in patients with significant peripheral vascular disease, particularly in those individuals with suspected proximal arterial occlusive lesions where pre-AV access interventional procedures might both identify and treat the problem site, gaining adequate arterial inflow for the eventual autogenous AV access. In patients nearing dialysis, the risk of contrast-induced nephropathy must be carefully weighed against the need for an AV access that will mature when needed by the time of dialysis initiation. Renal protective strategies such as hydration, limiting contrast, or using carbon dioxide as contrast agents minimize risk to the patient.[60] Administration of bicarbonate or *N*-acetyl cysteine may further moderate the risk of contrast-induced nephropathy.[61,62] Magnetic resonance angiography (MRA) for preoperative arterial vascular access evaluation has not replaced arteriography or ultrasound imaging but may be useful and appropriate in selected cases. Gadolinium may cause nephrogenic systemic fibrosis in patients with advanced CKD or dialysis and therefore should be used only after carefully weighing the risks and benefits of alternative imaging studies.[63]

Venous procedural evaluations specific to vascular access. *Noninvasive studies.* As discussed the preceding clinical examination, ultrasound imaging has become the common standard in preparation for an AV access procedure.[54,64] An ultrasound scan is optimally performed by the surgeon during the initial office visit or it may be done by a technologist.[65] Ultrasound examination discovers potential autogenous AV access sites that are overlooked by physical examination. Silva et al[57] found ultrasound evaluation increased AV fistula construction from 14% to 63%. Ultrasound venous mapping, which is performed with and without a venous pressure tourniquet in place, evaluates vein diameter, patency, continuity, and distensibility of the planned venous outflow conduit. Both distensibility and venous diameter have been found to independently predict autogenous AV access success.[56,57]

For the surgeon performing the operative planning, ultrasound offers simultaneous visualization of both the deep and superficial venous systems along with adjacent arteries. Brief, preoperative ultrasound mapping, just before the surgical procedure, is often helpful in confirming available vessels targeted for the procedure and marking the anticipated surgical site.

Contrast venography. This procedure may be used for peripheral vein mapping, particularly when ultrasound imaging is not available. When history or physical findings suggest a central stenosis or occlusion, venography is superior to ultrasound imaging, offers the best opportunity to both identify and treat these central lesions, and is relatively safe. Asif et al[66] found only one patient of 25 studied required dialysis ≤4 weeks after vein mapping with low-diluted osmolarity contrast. MRA has been reported in preoperative central venous imaging but has not been shown to be more effective than standard venography.[67] As in arterial evaluations, MRA has been rarely used in venous AV access planning. Although promising, these early reports of MRA mapping should be considered preliminary.[68-69]

2. CLINICAL RECOMMENDATION: Operative strategies to optimize the placement of autogenous arteriovenous accesses

We recommend optimizing the placement of autogenous accesses using the following *operative* strategies:

A. AV accesses are placed as far distally in the upper extremity as possible to preserve proximal sites for future accesses (GRADE 1 recommendation, very low-quality evidence).

B. When possible, autogenous AV accesses should be considered before prosthetic arteriovenous accesses are placed. These autogenous access configurations should include, in order of preference, the use of direct AV anastomosis, venous transpositions, and translocations (GRADE 1 recommendation, very low-quality evidence).

C. Upper extremity access sites are used first, with the nondominant arm given preference over the dominant arm only when access opportunities are equal in both extremities (GRADE 1 recommendation, very low-quality evidence).

D. Lower extremity and body wall access sites are used only after all upper extremity access sites have been exhausted (GRADE 1 recommendation, very low-quality evidence).

2.1. Evidence

These recommendations were formulated mainly according to unsystematic observations and consensus of our committee because there is paucity of high-quality evidence to support them except what is cited to support recommendations 3 and 4.

2.2. Values and preferences

The operative strategies recommended by the committee place high value on optimizing patient outcomes such as preventing death, access infection, and achieving a longer period of time with successful dialysis. In addition, the committee took into account patient comfort by recommending that the nondominant upper extremity be used first when access opportunities are equal. This allows the dialysis patient to use the dominant side to pursue

various functions while undergoing dialysis; however, the best extremity for autogenous access should be used, regardless of dominance. In recommending distal upper extremity access sites, these recommendations place high value on the preservation of proximal veins for future access placement.

In addition, in recommending the use of autogenous accesses first, except as stated in recommendation 4, the committee did not favor the use of prosthetic access despite features that may favor its use such as higher reimbursement, ready availability, and shorter time to first use. However, the committee would like to point out that in the push to perform all autogenous AV access, substandard veins are sometimes used for autogenous accesses, taking a long time to mature and thereby subjecting the patient to placement of catheters for hemodialysis. Many believe that catheters should be avoided at all cost, even if a prosthetic AV access is used, which makes the construction of autogenous access desirable but not always optimal.[19] In addition, the committee placed higher value on avoiding infection, arterial steal, ischemia, and other complications known to occur with higher frequency in association with lower extremity access placement.

2.3. Technical remarks

Various configurations of AV accesses, autogenous and prosthetic, are described at the end of this document. We describe here the strategies we suggest to optimize the use of various access sites in order to provide the hemodialysis patient with the safest and the longest life span on hemodialysis possible.

Forearm. For autogenous forearm access, use of the cephalic vein is preferred to the basilic vein secondary to its ease of access for dialysis, with minimal need for dissection, long incisions, and possible need for vein transpositions. Possible sites of arterial inflow include the entire radial artery from the posterior branch to its junction with the ulnar at the brachial bifurcation, and the brachial artery. The ulnar artery is usually not the first arterial option due to its distance from the cephalic vein.

The access is placed as distally in the forearm as possible where a normal palpable pulse is identified to preserve more proximal sites of inflow for future accesses. Therefore, in patients with a palpable posterior branch of the radial artery pulse, an autogenous posterior radial branch–cephalic direct wrist access (snuffbox) should be considered. In patients with a nonpalpable posterior branch of the radial artery pulse but a palpable radial artery pulse at the wrist, an autogenous radial–cephalic direct wrist access is performed. In either of these cases, if the cephalic vein is felt to be too deep or is not close to the radial artery in the wrist, an autogenous radial–cephalic forearm transposition is performed. If the radial artery pulse is nonpalpable, the ulnar may provide an alternative distal inflow site; alternatively, the entire trunk, but especially the proximal segment of either the radial or the ulnar artery, may provide an arterial source. In instances where the radial or ulnar artery pulse is not palpable at the wrist but the brachial artery pulse is, an autogenous brachial–cephalic forearm looped transposition can be performed.

When the cephalic vein is not considered adequate for an autogenous AV access, the forearm basilic vein is the preferred alternative. Secondary to its posteromedial location in the forearm, a transposition is always required to provide safe access for hemodialysis. Possible sites of arterial inflow include the entire trunk of the radial or ulnar arteries, or the brachial artery. Use of the posterior branch of the radial artery is usually difficult for this procedure secondary to the distance from the basilic vein.

Similar to the cephalic vein, the AV access is placed as distally in the arm as possible where a palpable pulse is identified to preserve more proximal sites of inflow for future accesses. Therefore, when a radial artery pulse is palpable, an autogenous radial–basilic forearm transposition is performed. If the radial artery pulse is nonpalpable but the ulnar artery pulse is palpable, an autogenous ulnar–basilic forearm transposition is performed. If the radial and ulnar artery pulses are nonpalpable at the wrist, a more proximal segment can be used if it is patent. Finally, if the brachial artery pulse is palpable, an autogenous brachial–basilic forearm looped transposition is performed.

When forearm autogenous accesses are exhausted, the surgeon and patient may opt to perform a prosthetic forearm access before proceeding to the upper arm to perform an autogenous access. Of note, and as it is indicated in Guideline 4, the committee made this one exception to the rule of all-autogenous access. The committee suggested that the access surgeon presents the patient with the choice of either performing a forearm prosthetic access before moving to the upper arm to perform an autogenous access or placing the upper arm autogenous access primarily before placement of forearm prosthetic. Sources of arterial inflow for forearm prosthetic AV access also include the radial and brachial artery.

Similar to an autogenous access, the prosthetic access should originate from an arterial inflow as distally in the arm as possible where a normal palpable pulse is identified to preserve more proximal arteries for future accesses. Therefore, when the radial artery pulse is palpable and is of a good quality, a prosthetic radial–antecubital forearm straight access is performed. If the radial artery pulse is nonpalpable and the brachial artery pulse is, a prosthetic brachial–antecubital forearm loop access is performed. Care should be paid not to cross the elbow for venous outflow to protect upper arm veins for future autogenous access. Patients should be told that this forearm prosthetic access is a "bridge" to an autogenous access. The nephrologist should be informed to minimize the number of attempts to salvage the access with endovascular means to avoid ruining the venous outflow, preserving it to be used as a future autogenous access.

Upper arm. When the use of the forearm has been exhausted, efforts at access are directed to the upper arm. Similar to the forearm, use of the upper arm cephalic vein is preferred to the basilic vein secondary to its lateral location and only occasional need for extensive dissection, long incisions, and transposition. For upper arm access, either

the brachial artery or proximal radial is the source of arterial inflow. Therefore, in patients with an adequate cephalic vein and a palpable brachial artery pulse, an autogenous brachial–cephalic upper arm direct access is performed; alternatively, the proximal radial artery may provide a reasonable alternative with less risk of steal. If the cephalic vein is felt to be too deep or is located far from the brachial artery, an autogenous brachial–cephalic upper arm transposition is performed.

When the cephalic vein is considered inadequate for an autogenous AV access, the basilic vein in the upper arm is the preferred alternative. Secondary to its medial and deep location, transposition or superficialization is required for all access using the basilic vein. In patients with an adequate basilic vein and a palpable brachial artery pulse, an autogenous brachial–basilic upper arm transposition is performed. Alternatively, the proximal radial artery may be used as inflow, with less risk of steal.

If the cephalic or basilic veins have been used or are not available, an upper extremity prosthetic AV access is performed. For upper arm access, the source of arterial inflow is the brachial or proximal radial artery. If the brachial artery is used, it must be palpable. Alternatively, or after an upper arm prosthetic access is used, an autogenous brachial–brachial (vein) upper arm transposition or a great saphenous vein upper arm translocation may be performed. Of note, although using the great saphenous vein is described here as an autogenous alternative, it should be reserved as a last-resort option because its long-term patency has not been confirmed. Indeed, the femoral vein has been used as an autogenous alternative with functional patency of 94% reported at 2 years.[70]

Lower extremity. When use of both upper extremities has been exhausted, lower extremity access becomes an alternative access site. This access is less desirable secondary to the high occurrence of lower extremity occlusive disease in this group of patients, the higher likelihood of steal, and the increased incidence of infections associated with groin accesses. The great saphenous vein is the preferred conduit; secondary to its medial and deep location, transpositions are always required. The femoral artery (preferably the superficial femoral artery or the profunda femoris artery) is used for inflow and must be palpable. Therefore, for initial lower extremity access in patients with adequate great saphenous vein and a palpable femoral pulse, an autogenous femoral–great saphenous lower extremity transposition is performed, either in a loop or straight configuration. Alternatively, in patients with a palpable posterior or anterior tibial artery pulse, either tibial artery may be used as inflow to create an autogenous tibial–great saphenous lower extremity direct access.

In patients without an adequate great saphenous vein, the femoral vein (previously named superficial femoral vein) is an appropriate alternative source of autogenous conduit. Similar to the great saphenous vein, the femoral vein is located too medial and deep for usable dialysis access, and transpositions are always required. Obstructive complications are minimized when the vein harvest is limited to the anatomic segment proximal to the popliteal vein. The femoral artery remains the source of inflow and must be palpable. Therefore, in patients with an adequate femoral vein and a palpable femoral pulse, an autogenous femoral artery–femoral vein lower extremity transposition is performed, either in straight or loop configuration.

If no lower extremity vein, including the great saphenous or femoral, is available, a lower extremity prosthetic access is performed. The common femoral artery can provide the source of inflow and must be palpable. Therefore, in a patient with no adequate lower extremity vein and a palpable common femoral artery pulse, a prosthetic femoral–femoral (vein) lower extremity looped access is performed. It is especially important to limit the size of the anastomosis (4 to 6 mm) to the femoral artery to minimize the risk of significant steal/ischemia and potential limb threat. This is easily accomplished by tapering the large vein to the desired diameter with a running suture.

Body wall. After both upper and lower extremities use has been exhausted, body wall access can be used as an alternative access site.[71] Body wall access usually requires use of a prosthetic graft, and its use is left as a last alternative. Sources of venous outflow include the axillary, internal jugular, and common femoral veins. The main source of arterial inflow is the axillary artery. Appropriate options include a prosthetic axillary–axillary (vein) chest access, a prosthetic axillary–axillary (vein) chest loop access, a prosthetic axillary–internal jugular chest loop access, and a prosthetic axillary–common femoral (vein) body wall access. When a patient is being evaluating for placement of AV dialysis access, this access sequencing strategy will help the surgeon optimize the construction of autogenous access and lengthening the time the patient can be dialyzed safely and comfortably.

3. CLINICAL RECOMMENDATION: First choice is forearm autogenous arteriovenous access

We recommend the placement of forearm autogenous arteriovenous access as the first choice for primary access for hemodialysis (GRADE 1 recommendation, very low-quality evidence).

A. When arterial and venous anatomy is suitable, placement of autogenous radial–cephalic direct wrist access (Brescia-Cimino-Appel) or autogenous posterior radial branch–cephalic direct wrist access (snuffbox) is recommended.

B. In the case where arterial or venous anatomy does not allow placement of a direct access, forearm vein transposition or translocation are recommended. These procedures should use the maximal length of adequate vein and use arterial inflow from the forearm tailored to accommodate this length of vein.

3.1. Evidence

Systematic review of the literature that included 83 studies revealed that, compared with prosthetic access, the

Table I. Summary of evidence. Question: Should autogenous access or prosthetics access be used for patients with chronic hemodialysis?

		Quality assessment				
Studies, No.	*Design*	*Limitations*	*Inconsistency*	*Indirectness*	*Imprecision*	*Other considerations*
Death (follow-up 6-60 months)						
27	Observational study[a]	Serious[b]	No serious inconsistency	No serious indirectness	No serious imprecision	Reporting bias[c]
Access infection (follow-up 6-60 months)						
43	Observational study[a]	Serious[b]	Serious[d]	No serious indirectness	No serious imprecision	Reporting bias,[c] strong association[e]
Postoperative complications (follow-up 6-60 months)						
31	Observational study[a]	Serious[b]	Serious[d]	No serious indirectness	Serious	Reporting bias[c]
Length of hospitalization related to access (follow-up 6-60 months)						
3	Observational study[a]	Serious[b,f]	No serious inconsistency	No serious indirectness	Serious	Reporting bias[c]
Access failure without interventions at 12 months						
42	Observational study[a]	Serious[b]	Serious[d]	No serious indirectness	No serious imprecision	Reporting bias[c]
Access failure without interventions at 36 months						
24	Observational study[a]	Serious[b]	Serious[d]	No serious indirectness	No serious imprecision	Reporting bias[c]
Access failure with interventions at 12 months						
25	Observational study[a]	Serious[b]	Serious[d]	No serious indirectness	No serious imprecision	Reporting bias[c]
Access failure with interventions at 36 months						
20	Observational study[a]	Serious[b]	Serious[d]	No serious indirectness	No serious imprecision	Reporting bias[c]

CI, Confidence interval*; N/A,* Not applicable; *RR,* relative risk.
[a]Only three of 83 studies were randomized.
[b]In many studies, the two cohorts were not similar at baseline, blinded outcome assessment was not used, and loss to follow-up and funding source were not reported.
[c]Not all of the included studies reported this outcome; thus, outcome may have been collected and not reported.
[d]The proportion of heterogeneity that is not attributed to chance is >50%.
[e]RR <0.50.
[f]The imbalance in the number of the two groups suggests that surgeons in these studies performed many more autogenous access placements than they did of prosthetic ones, implying possible lack of experience in prosthetic access placement and biased selection of patients.

autogenous access is associated with a lower incidence of death and access infection and with a higher primary and secondary patency at 12 and 36 months.[14] Subgroup analysis of 13 studies showed a significant access location–complication interaction, suggesting that the benefit of autogenous access compared with prosthetic access in terms of lowering the incidence of the three complications of steal, aneurysm, and hematoma is significantly more in the case of lower arm autogenous access compared with upper arm autogenous access, with RRs of 0.20 (95% confidence interval [CI], 0.06-0.68) for the lower arm autogenous subgroup and 1.29 (95% CI, 0.43-3.91) for the upper arm autogenous subgroup ($P = .03$). An overall summary of the evidence derived from this systematic review is presented in Table I. Autogenous hemodialysis access options can be maximized by using venous transposition procedures (eg, the radial–basilic forearm transposition or the brachial–basilic upper arm transposition) when direct arteriovenous anastomosis autogenous access options are not available.[4,57,72,73]

3.2. Values and preferences

The recommendation for autogenous access places high value on optimizing patient outcomes by minimizing the risks of death and infection and maximizing durability. Prioritization of forearm access places high value on the preservation of proximal veins or future access placement. This recommendation places a lower value on competing considerations such as higher reimbursement for construction of prosthetic, availability of ready to use off-the-shelf prosthetic grafts, and a shorter period of time for the access to be ready for hemodialysis.

3.3. Technical remarks

Despite the lack of evidence, some helpful techniques may encourage the maturation of the autogenous access. Gentle flushing of the distal end of the vein with heparinized saline allows for evaluation of the caliber and extent of the vein and identification of side branches for ligation through stab incisions after performing the anastomosis. This encourages flow in the main venous segment, allowing

Table I. Continued.

Summary of findings					
Patients, No.		*Effect*			
Autogenous access	*Prosthetic access*	*RR (95% CI)*	*Absolute (95% CI)*	*Quality*	*Importance*
2729/16823	7001/31698	0.76 (0.67 to 0.86)	38 fewer per 1000 (21 to 51)	⊕○○○ (very low)	Critical
527/9337	656/4416	0.18 (0.11 to 0.31)	86 fewer per 1000 (66 to 97)	⊕○○○ (very low)	Important
338/7122	162/3071	0.73 (0.48 to 1.16)	15 fewer per 1000 (−13 to 34)	⊕○○○ (very low)	Important
2373	74	NA	3.81 days shorter (–7.77 to 0.15)	⊕○○○ (very low)	Important
1849/7628	2509/5538	0.72 (0.65 to 0.80)	131 fewer per 1000 (95 to 167)	⊕○○○ (very low)	Important
1410/3798	1334/2326	0.67 (0.58 to 0.78)	174 fewer per 1000 (93 to 242)	⊕○○○ (very low)	Important
892/3769	778/2735	0.83 (0.70 to 0.99)	57 fewer per 1000 (6 to 102)	⊕○○○ (very low)	Important
1055/2873	622/967	0.67 (0.61 to 0.74)	210 fewer per 1000 (150 to 264)	⊕○○○ (very low)	Important

for faster maturation. Ligation or endovascular coiling of side branches can also be delayed to a later date and performed only if the autogenous access does not mature in a timely basis.

In autogenous accesses originating from arteries proximal to the radial, the arteriotomy should be limited to a maximum length of 4 to 6 mm, using the smaller anastomoses for those individuals at highest risk of developing steal-induced ischemia, such as those with diabetes mellitus and peripheral arterial occlusive disease. Also, the anastomosis is performed with a continuous suture to prevent future increase of the anastomotic surface area. These two maneuvers limit future increases in flow through the autogenous access and decrease the incidence of arterial steal. Although the role of exercise to encourage early maturation of the autogenous access is not supported by strong evidence, some access surgeons continue to ask patients to perform hand exercises starting 24 to 48 hours postoperatively to increase blood flow through the vein to encourage early maturation of the access.

4. CLINICAL RECOMMENDATION: Choice of arteriovenous access when a patient is not a suitable candidate for forearm autogenous access

For patients who have exhausted all forearm veins on both sides and, according to vein availability and surgical expertise, are suitable candidates for either forearm prosthetic access or upper arm access of any type, we suggest that the surgeon offer both alternatives to patients (GRADE 2, very low-quality evidence).

4.1. Evidence

The systematic review by Murad et al[14] identified only 2 studies that compared the autogenous upper arm access with the prosthetic lower arm access (prosthetic looped forearm access). One study showed that an autogenous brachial–basilic fistula in the upper arm had significantly better primary and assisted-primary patency at 12 months compared with the polytetrafluoroethylene (PTFE) group,[74] and the second study showed both accesses had similar patency at 12

Table II. Summary of evidence. Question: Should access surveillance vs watchful waiting be used for patients with chronic hemodialysis?[e]

		Quality assessment				
Studies, No.	*Design*	*Limitations*	*Inconsistency*	*Indirectness*	*Imprecision*	*Other considerations*
Access thrombosis (follow-up mean 18 months)						
7	Randomized trial[a]	Serious[b]	No serious inconsistency	Serious[c]	Serious[d]	None
Access abandonment (follow-up mean 18 months)						
6	Randomized trial[a]	Serious[b]	Serious[e]	No serious indirectness	Serious[d]	None

CI, Confidence interval; *RR,* relative risk.
[a]One study was not randomized.
[b]Most trials lack description of allocation concealment and blinding of patients, clinicians, and outcome assessors. The first threatens prognostic balance at baseline; the latter threatens maintenance of prognosis balance after randomization.
[c]Access thrombosis is a surrogate outcome for access failure, which is a patient-important outcome associated with significant morbidity and mortality.
[d]Confidence intervals are wide.
[e]The proportion of heterogeneity that is not attributable to chance is >50%.

and 24 months, although the autogenous access group had fewer complications.[75] Of note, subgroup analysis by Murad et al did not demonstrate superiority of upper arm autogenous access compared with prosthetic accesses in terms of complications.

4.2. Values and preference

In a patient whose bilateral forearm veins have been exhausted, the decision whether to place an upper arm autogenous AV access before placement of forearm prosthetic access is a difficult one. In the effort to maximize placement of autogenous accesses, surgeons are sometimes performing upper arm autogenous accesses without considering whether a forearm prosthetic access might be more appropriate. In some instances, placement of forearm prosthetic access before moving to an autogenous upper arm access may prove advantageous. Although the upper arm autogenous access may fare better compared with a forearm prosthetic access, using these two accesses sequentially may lead to additive benefit: This practice may help to preserve upper arm veins for future placement of autogenous access, may help to increase the caliber of these veins and maximize the success of future upper arm autogenous access, and may provide patients with an additional 1 to 3 years of functional hemodialysis access before resorting to catheter use or other, less studied and less desirable configurations in the lower extremity or body wall.

4.3. Technical remarks

When forearm autogenous sites are depleted, a forearm prosthetic access can be considered before moving to the upper arm for placement of an autogenous access as long as the forearm prosthetic access does not cross the elbow when the venous anastomosis is performed. Such access helps to develop the upper arm veins due to the increased flow from the forearm prosthetic access, and if the venous anastomosis is kept below the elbow, upper arm veins are preserved for future use. In addition in the case of the prosthetic access failing or failure, care should be directed and the staff involved in the patient's care should be informed not to involve the veins above the elbow in procedures designed to maintain or re-establish patency of the prosthetic access.

There are additional techniques that are common to all prosthetic access placements. The tunnel should be superficial enough for easy access for the dialysis staff. A 6-mm PTFE prosthetic graft without rings is used for the conduit. For patients at risk for ischemia, such as when the brachial or lower extremity arteries are used for inflow, a tapered or stepped graft should be considered for use with the smaller end of the graft placed at the arterial end.

5. CLINICAL RECOMMENDATION: The role of monitoring and surveillance in arteriovenous access management

A. We recommend regular clinical monitoring (inspection, palpation, auscultation, and monitoring for prolonged bleeding after needle withdrawal) to detect access dysfunction (GRADE 1, very low-quality evidence).

B. We suggest access flow monitoring or static dialysis venous pressures for routine surveillance (GRADE 2, very low-quality evidence).

C. We suggest performing a Duplex ultrasound (DU) study or contrast imaging study in accesses that display clinical signs of dysfunction or abnormal routine surveillance (GRADE 2, very low-quality evidence).

5.1. Evidence

A systematic review of 12 studies, 10 of which were randomized, demonstrated that very low-quality evidence yielding imprecise results suggested a potentially beneficial

Table II. Continued.

Summary of findings					
Patients, No.		*Effect*			
Access surveillance	*Watchful waiting*	*RR (95% CI)*	*Absolute*	*Quality*	*Importance*
90/406	92/387	0.82 (0.58 to 1.16)	43 fewer per 1000	⊕○○○ (very low)	Critical
94/614	88/347	0.80 (0.51 to 1.25)	51 fewer per 1000	⊕○○○ (very low)	Critical

impact of AV access surveillance, followed by interventions to restore patency.[15] In this review, the surveillance strategy of nine studies (1363 patients) was compared with clinical monitoring, with a vascular intervention to maintain or restore patency provided to both groups if needed. Surveillance, followed by intervention, led to a nonsignificant reduction of the risk of access thrombosis (RR, 0.82; 95% CI, 0.58-1.16; $I^2 = 37\%$) and access abandonment (RR, 0.80; 95% CI, 0.51-1.25; $I^2 = 60\%$). Three studies (207 patients) compared the effect of vascular interventions vs observation in patients with an abnormal surveillance result. Vascular interventions after an abnormal AV access surveillance result led to a significant reduction of the risk of access thrombosis (RR, 0.53; 95% CI, 0.36-0.76) and a nonsignificant reduction of the risk of access abandonment (RR, 0.76; 95% CI, 0.43-1.37). Table II summarizes the quality of evidence derived from this systematic review.

It is important to recognize that the value of surveillance strongly depends on the adequacy of clinical monitoring (physical examination and assessment of clinical clues of access dysfunctions). Clinical monitoring by skilled personnel was shown to have adequate diagnostic accuracy; clinical monitoring has been reported to have positive predictive value of 70% to 90% in prosthetic accesses and a specificity of 90% and a sensitivity of 38% 93% in autogenous accesses.[76-79] Therefore, in centers with skilled personnel, surveillance may not be as beneficial and produce marginal benefit vs clinical monitoring, as outlined above. However, this is not the practice in the real world, wherein physical examinations are seldom conducted and the first indication of an underlying stenosis is often access thrombosis. In this situation, surveillance may be more justified.

Furthermore, although access survival was no different in members of the group who underwent surveillance, it is possible that their lower incidence of thrombosis may translate into a reduction in access-related costs and hospitalizations, as demonstrated in a reanalysis of a small study by Dossabhoy et al[80] and by a quality improvement project conducted by Wijnen et al.[81] In the latter study, flow surveillance produced a 32.5% reduction in the overall cost of access care. Savings occurred chiefly in the prosthetic access group and resulted from reduction in the number of invasive procedures, central catheters, and hospitalizations. Therefore, and despite the imprecision of evidence, surveillance of accesses may be justified.

5.2. Values and preferences

These recommendations place higher value on preventing access thrombosis and the associated cost, hospitalization, morbidity, and burdens and lower values on inconvenience and cost of surveillance and monitoring. In addition, considering the low costs and harms associated with clinical monitoring, access flow, and static dialysis venous pressure measurements, we suggested these methods for routine surveillance to detect access dysfunction, reserving DU scans for patients with accesses that show symptoms and signs suggestive of impending access failure. In these patients, the benefits of imaging studies are likely to outweigh the potential burden and cost.[82,83]

5.3. Technical remarks

Assessing functionality of AV access. Various methods can be used to assess the functionality of AV accesses. They range from clinical physical evaluation to invasive contrast procedures. This will be discussed in the section below, which addresses available methods used to detect or confirm access dysfunction.

Access assessment and clinical monitoring. *A. Assessment of the new access.* Prosthetic AV accesses, such as PTFE grafts, can be cannulated as early as 2 weeks after their construction, provided that they have a bruit, the postoperative edema has resolved, and there is no evidence of infection. However, the clinical assessment of new autogenous access requires considerable experience in interpreting visual, auditory, and tactile clues. A normal autogenous access has a soft pulse that is easily compressible and a

continuous low-pitched bruit. A thrill should be palpable near the anastomosis and extend along the vein outflow for a varying distance. In addition, a normal autogenous access collapses when the extremity is elevated. Clinical clues of a stenosis of an autogenous AV access include the presence of a palpable pulse at the arterial end with possible faint thrill or complete access collapse proximally, a discontinuous bruit, or failure to collapse with arm elevation. The physical examination can be used to estimate access diameter, its depth from the skin, the presence of collateral veins and the presence of accessory veins.

If upon clinical evaluation at 4 to 6 weeks the autogenous access is not clearly maturing adequately, further investigation is warranted to identify potentially remediable anatomic lesions. These may include a venous or arterial stenosis, competing veins, large patent branches, or excessive depth from the skin.[27] The assessment may be performed either by DU scanning or by an imaging study. Several studies have demonstrated that at least 80% of immature autogenous accesses can be salvaged after correcting one or more underlying lesions.[84,85] Moreover, immature autogenous accesses with correctable anatomic lesions that are repaired percutaneously or surgically are much more likely to achieve suitability for dialysis compared with those that do not undergo a corrective procedure.[86]

A mature autogenous access requires three components: (1) an adequate diameter to permit safe cannulation with dialysis needles without infiltration, (2) an adequate access flow rate to permit achieving an access blood flow of ≥500 mL/min,[87,88] and (3) it must be sufficiently superficial to permit recognition of landmarks and accurate, safe cannulation.[27] The access blood flow increases dramatically within 24 hours of autogenous access placement and reaches most of its maximum flow within 3 to 6 weeks.[89,90] Similarly, most of the increase in access diameter is achieved within 4 to 8 weeks of autogenous access placement.[87]

When the clinical examination is equivocal, a postoperative DU study can be helpful. Specifically, measurement of the vein diameter and access blood flow is useful in predicting access functionality. When the vein diameter is ≥4 mm and the access blood flow is ≥500 mL/min, there is a 95% likelihood that the autogenous access will be usable for dialysis. If the vein diameter is <4 mm and the access blood flow is <500 mL/min, only 33% of autogenous accesses are likely to be suitable for dialysis. If only one of the two criteria is met, the likelihood of access success is intermediate (60% to 70%). Interestingly, the time from placement to cannulation varies geographically: Autogenous accesses are routinely cannulated ≤1 month of placement in Europe and Japan, whereas the average time in the United States is about 3 months.[91]

B. Monitoring and surveillance of an established access. The KDOQI defines "monitoring" as including physical examination indicators such as observation, palpation, and auscultation of the access, whereas "surveillance" refers to various tests to assess access function.

Physical examination of the graft by trained nephrologists or dialysis staff is very effective in identifying accesses with clinically significant underlying stenosis. Abnormalities on physical examination of the access (absent thrill, abnormal auscultation, persistent edema of the access extremity, venous collaterals on the ipsilateral chest wall) have a high positive predictive value for stenosis estimated at 80% in prosthetic accesses.[92-94]

A number of surveillance tests have been found useful in detecting access dysfunction. The four most useful surveillance methods, which are described in the KDOQI Guidelines, are (1) serial access flow measurement, (2) serial measurement of static dialysis venous pressure, (3) prepump arterial pressure, and (4) DU scanning. Unlike clinical evaluation, most surveillance methods require the use of specialized equipment and trained technicians. Each of these methods has a high positive predictive value for identifying access dysfunction when applied to the correct setting and to the indicated type of access (autogenous or prosthetic access, catheter). A description of how to perform these tests can be found in the NKF-KDOQI Clinical Practice Guidelines.[9] The clinical value of each test is summarized below:

1. Access blood flow measurements. Access blood flow is the best determinant of access function. As a prosthetic access develops progressive stenosis, access blood flow falls progressively. A number of studies have shown that a prosthetic access blood flow rate of <600 mL/min, or one that has decreased by >25% from the previous baseline, has a high predictive value for significant stenosis (87% to 100%).[95,96] This test is most useful for autogenous AV access, where venous pressure surveillance is less reliable. The most common methods of measuring access flow can be performed in 10 to 15 minutes while the patient is on dialysis, after reversing the arterial and venous lines. The measurement uses ultrasound dilution (Fick principle) by measuring the rate of change in ultrasound transmission in the venous line after infusion of a saline bolus through the arterial line. The KDOQI Guidelines recommend monthly measurement of access flow. It requires specialized equipment and a trained technician.

2. Static venous dialysis pressure. The greatest value of static venous dialysis pressure (VDP) is in prosthetic accesses, but is of little or no value as a surveillance tool for autogenous accesses because of the high incidence of low-flow etiologies proximal to the venous needle in autogenous accesses where VDP is measured.

Measurement of dynamic VDP (at a low dialysis blood flow of 200 ml/min) is a relative poor marker of autogenous or prosthetic access stenosis. It is affected by multiple factors, including the dialysis blood flow, needle diameter, type of dialysis machine, and the patient's blood pressure. Better standardization can be achieved by measuring *static* VDP (at zero dialysis pump blood flow). VDP needs to be normalized for the systemic blood pressure. The ratio of systolic VDP to systemic systolic blood pressure can be suggestive of stenosis when the ratio of systolic VDP to systemic systolic blood pressure is > 0.4.[97] Use of mean

pressure ratio (more commonly obtained by the pressure transducers on conventional dialysis systems) requires that the ratio is >0.5. The use of any given static venous pressure ratio is not a reliable indicator of stenosis, especially in autogenous access; however, the best use of static VDP measurement is as a trending tool, where trends of increasing VDP may be indicative of stenosis.[98] It is critical to have a well-trained technician who performs the measurements in a standardized fashion and who calibrates the transducers.

3. Prepump arterial dialysis pressure. Most dialysis machines currently in use have a pressure transducer connected to the blood line on the arterial side of the blood pump. This prepump pressure is displayed on the information screen and indicates the ease (or difficulty) with which blood is drawn from the access by the blood pump at any given pump setting. This pressure is influenced by anything that causes restriction of flow to the pump: the needle gauge and length, the diameter and length of the blood line, needle position in the access, and access blood flow. After any needle or tubing problem has been checked as the possible cause of unexpected increasingly negative arterial dialysis pressure and corrected, inadequate access flow, which is the most common cause of persistently elevated prepump arterial pressure, will be the likely cause.

New autogenous accesses, which have a high incidence of failure to mature, almost always have an access flow problem that is on the arterial side of the venous needle and therefore will be identified by an excessively negative arterial dialysis pressure (ADP). In addition, most of the flow-restricting lesions in dysfunctional radial–cephalic as well as some other autogenous accesses, are likewise present on the arterial side of the venous needle and are often identified by increasingly negative ADPs. Therefore, routinely checking the ADP at every dialysis session is critically important in evaluating function in autogenous accesses, especially new ones.

4. Duplex ultrasound imaging. DU imaging can assess the access for both anatomic as well as flow abnormalities that may represent significant stenosis. This test requires measuring the peak systolic velocity (PSV) at the graft venous anastomosis and at any other area of visual stenosis.[99] A ratio of PSV ≥2.0 at the stenotic site compared with the PSV immediately upstream is used to diagnose stenosis, with a positive predictive value of 80% for significant graft stenosis.[87] It is possible to measure the volume flow through the graft, but that measurement is less accurate than the flow surveillance technique previously described. In general, DU imaging requires expensive equipment, a trained technician, and is not typically performed in the dialysis unit. The increasing availability of portable laptop based systems may alter this in the future. However, DU imaging is currently not an easily accessible or a cost-effective method for routine access surveillance.

Finally, abnormalities related to the dialysis session have a 69% positive predictive value for significant stenosis. Within this last category, the predictive value of prolonged bleeding from the needle sites is 76%, difficulty with cannulation is 58%, and aspiration of clots is 30%. In addition, an unexplained decrease (>0.2 U) in delivered dialysis dose (Kt/V) on a fixed dialysis prescription has a 69% positive predictive value for significant stenosis.

Monitoring and surveillance by access type. *1. Autogenous access.* The best, most feasible tools for identifying dysfunction in autogenous access include (1) physical examination (monitoring), (2) routine measurement of prepump ADP at every dialysis session, and (3) serial access blood flow measurements. In addition, although not recommended for routine surveillance, a recirculation study can help in select cases of autogenous access dysfunction to confirm inadequate access flow because recirculation results when access flow falls below dialysis blood pump demand. This study has little value with a prosthetic access because prosthetic accesses will usually thrombose at low flows that do not support adequate dialysis, whereas autogenous accesses will remain patent at very low flows, thereby permitting inadequate dialysis to proceed without noticeable etiology.

2. Prosthetic access. Prosthetic access function is best and most feasibly followed up by (1) a physical examination (monitoring), (2) serial access blood flow measurements, and (3) serial static VDP measurements.

Diagnostic tests: DU scanning and imaging studies. Although DU can be used as a diagnostic tool for access stenosis, it has some limitations, especially for identifying lesions behind bone, as in subclavian vein stenosis. A major advantage is that it is noninvasive. If an etiology for access dysfunction is not identified by DU scanning, an imaging study should be performed. A contrast imaging study or other imaging studies such as MRA of the access is the gold standard for documenting stenosis. Because it is expensive and invasive, it should be reserved for those patients in whom abnormal clinical monitoring or access surveillance has predicted a high likelihood of hemodynamically (>50%) significant stenosis. This contrast study should include the arterial inflow, the actual access, its outflow vein, and central vein. If a significant stenosis is detected, a balloon angioplasty can be performed at the same sitting.

In the event that no obstructing lesion is identified, a physiologic etiology causing low access flow is likely and should be investigated by an access flow study.

Preemptive angioplasty associated with monitoring and surveillance. As mentioned previously, a number of observational studies (using historical controls) have shown a substantial reduction in the rate of graft thrombosis after implementing a program of stenosis monitoring or surveillance with preemptive angioplasty. More recently, six randomized clinical trials have evaluated the efficacy of this approach in reducing graft thrombosis or prolonging graft longevity. These studies have used a variety of surveillance methods, including static dialysis venous pressures, flow monitoring, and DU imaging. In each of these studies, the intervention group had a substantially higher rate of preemptive angioplasty. Despite that, access surveillance failed to improve thrombosis-free graft survival or overall (cumulative) graft survival in five of the six studies.[76,95,100-102]

Only one of the six studies (using DU scanning) demonstrated a reduction in graft thrombosis and an improvement in access longevity.[103]

The randomized studies of access surveillance have been fairly small in size (64 to 189 patients), so they may not have been sufficiently powered to demonstrate a small benefit of access surveillance. Taken together, however, they suggest that the benefit of preemptive angioplasty is modest at best. Thus, the available surveillance methods are quite useful in detecting significant stenosis and permitting preemptive angioplasty before the graft thrombosis. The benefit is quite short-lived, however, and the injury from the angioplasty appears to accelerate the process of restenosis. This topic continues to generate significant debate.[104,105]

6. CLINICAL RECOMMENDATION: Conversion of a prosthetic AV access to a secondary autogenous AV access.

We suggest that a plan and protocol for eventual conversion of forearm prosthetic access to a secondary autogenous AV access should be put in place at the presence of any sign of failing forearm prosthetic AV access, or after the first failure (GRADE 2, very low-quality evidence).

We suggest two strategies for transitioning suitable prosthetic AV access to secondary autogenous access before abandoning a functional prosthetic access:

A. Conversion of the prosthetic access mature outflow vein to an autogenous access.
B. Identifying a new, remote site for autogenous access construction in a patient where the prosthetic access outflow vein is not deemed suitable.

6.1. Evidence

The committee found no high-quality evidence to support a strategy of converting prosthetic accesses with impending failure to secondary autogenous accesses, and these recommendations are based on very low-quality evidence that consists of unsystematic observations and the consensus of experts.

6.2. Values and preferences

In recommending a proactive approach that involves conversion of a failing or failed prosthetic access to a secondary autogenous access before the prosthetic access fails, the committee placed highest value on maintaining functional permanent access and avoiding interruption of dialysis and the need for central venous catheter placement, known for an associated high rate of infection and possibly mortality.

6.3. Technical remarks

In all instances, the construction of the new autogenous access should take place *before* abandonment of the prosthetic one to allow for adequate time for autogenous AV access maturity without the need for a long-term catheter. This is true whether the secondary autogenous access is constructed by conversion of the prosthetic access mature outflow vein to an autogenous access or by identifying a new, remote site for autogenous access construction in a patient where the prosthetic access outflow vein is not deemed suitable, In preparation for the procedure, the outflow veins should be evaluated, including the central venous circulation, for the presence of obstruction.[106] The FFBI Work Group recommends that the evaluation for secondary autogenous access be triggered by the initial AV graft failure and that conversion to autogenous access be performed no later than the second graft failure. This is to allow adequate time for AV fistula maturation without need for a catheter.

A. Conversion of prosthetic AV access outflow vein to an autogenous access. This strategy is predominantly applicable to forearm AV prosthetic access because the outflow veins are readily accessible, well located for conversion to autogenous access for hemodialysis, and one or more of the outflow veins are usually suitable as a conduit. The outflow vein candidates in the arm are the cephalic, basilic, and brachial veins. In situations where these veins are not suitable, there may be an adequate vein in the forearm that can be used as a retrograde-flow secondary autogenous access, after disrupting one or more valves. This is another reason why preoperative imaging to identify all vessel options is so critical, especially in patients with few, if any, access options available. In most patients with an established forearm prosthetic access, one or more of the outflow veins becomes a mature, adequate autogenous access conduit.[107,108] If an imaging study confirms that the outflow vein is suitable, conversion of this outflow vein into an upper arm access provides an ideal autogenous alternative that is durable and usually usable immediately, thus obviating or minimizing the need for a catheter. A separate imaging study is not usually necessary, because the fistulogram performed for the graft failure can be used to examine the outflow and central veins.

B. Remote secondary autogenous AV access construction. This strategy involves a physical examination and vessel mapping in a patient with a failing prosthetic access where an imaging study has shown that a suitable outflow vein is not available. In this situation, evaluation of the vessels of the contralateral extremity should be performed. If suitable remote vessels are identified, a secondary autogenous AV access construction should be undertaken as soon as feasible to avoid the need for long-term use of a catheter when the failing access is no longer salvageable.

7. CLINICAL RECOMMENDATION: Management of nonfunctional or failed arteriovenous access.

We suggest open surgery, endovascular means, or a combination of both to maintain or restore patency in AV access (GRADE 2, very low-quality evidence).

7.1. Evidence

The choice between open and endovascular interventions to improve the functionality or to restore or maintain patency in accesses that show signs of impending failure is

based on nonrandomized studies that showed both procedures to be moderately effective and safe. Owing to the lack of such randomized comparison, the panel was unable to recommend one over the other. Open thrombectomy is successful in restoring thrombosed access function.[109,110] Similarly, endovascular techniques using a combined percutaneous mechanical and pharmacologic thrombectomy are successful in restoring function in most patients. Further, both open and endovascular interventions may add a further average of 12 months of functionality with low morbidity and mortality while preserving future sites of access.[111]

7.2. Values and peferences

In recommending either method or a combination of both to be used for failed or failing AV accesses, the committee recognizes the weakness of the evidence that may favor one method rather than the other. Because none of these methods has been proven to have better short- or long-term results, the committee based its recommendation on other factors that may determine outcomes. Such factors include the experience of the surgeon, interventionalist, or other AV access specialist and the ability or availability of either method in a certain situation or location where a patient presents for care.

7.3. Technical remarks

Management of nonfunctional or failed AV access

A. Access functionality. Access functionality is a very important concept. An access can be patent but unusable for successful hemodialysis—and thus nonfunctional—and such an access provides no benefit to the patient. In fact, a nonfunctional access maybe even harmful because the patient may continue to be dialyzed using percutaneous catheters, with their intended complications, while waiting for the autogenous access to dilate and mature.

An access that has failed to mature is patent but not functional.[12] Failure to mature is more frequently an issue with autogenous AV accesses than prosthetic grafts. As recommended by the FFBI, every new autogenous access should be evaluated for development at 4 weeks. If the access is not adequately maturing by four weeks or not functional by 12 weeks (ie, access flow <500 ml/min, a recirculation higher than 10%, or inability to cannulate), a contrast study should be performed. Beathard et al[112] demonstrated the feasibility of salvage of the early nonmaturing autogenous accesses. Of 63 patients with inadequate autogenous access development, the access was patent in 74.7% after 1 year by using a systematic approach for revision that included diagnostic angiography, percutaneous angioplasty, and accessory vein ligation as indicated.[112] Most nonfunctional autogenous accesses should therefore be investigated and the underlying defects corrected, with reasonable expectation of long term functionality. The underlying defects are usually one or more of the following:

1. Access too deep. An access can be nonfunctional because it is placed too deep in an extremity such that puncture is difficult, inconsistent, or traumatic to the patient and the conduit. Several approaches can be taken to correct this problem, depending on the location and access type. When a prosthetic graft is placed too deep, it may be possible to divide the graft close to an anastomosis and place it in a new tunnel. If this is not possible, an entirely new conduit must be placed.

Because a functioning autogenous access is very valuable, every attempt must be made to move the vein to a more superficial location. Typically, this involves making an incision along the entire length of the autogenous or transposed vein and retunneling the vein, often moving the location of the arteriovenous anastomosis. Retunneling may shorten the length of the conduit available for puncture. Before embarking on an operation of this magnitude, the access should be studied to ensure that the conduit is free from stenoses and that an additional procedure is likely to render the access functional.

2. Nonligated side branches. Large, patent side branches in an autogenous access may shunt blood away from the axial vein, thereby preventing the main trunk from dilating sufficiently to accept dialysis cannulae and to support adequate dialysis. However, before simple surgical ligation or endoluminal coil occlusion, the main trunk must be studied angiographically or with DU scanning to ensure that the side branch has not dilated secondary to a stenosis in the main trunk increasing resistance to axial flow. Such a lesion must be addressed before side branch obliteration. Generally, these branches must be >2 mm diameter to be considered significant and associated with a poorly maturing axial vein.

Localization of the side branch can be achieved by visual inspection, ultrasound scanning, or angiography. Road mapping of the access and side branch facilitates accurate marking of the side branch for either an endovascular or surgical approach. Coil embolization and surgical ligation are equally acceptable approaches.

3. Insufficient arterial inflow. Insufficient arterial inflow as a cause for nonfunctionality is much less frequent than venous anastomotic stenoses in prosthetic AV grafts, representing only 3% to 5% of all stenoses identified in hemodialysis accesses.[100] Stenosis at the arterial anastomosis is the most common reason for inadequate arterial inflow. Arterial anastomotic stenosis usually occurs as a result of a technical error or neointimal hyperplasia. The next most common location for arterial stenosis is an orificial stenosis of the subclavian artery, most commonly on the left and caused by atherosclerosis. These can usually be studied by retrograde puncture of the access, navigating the diagnostic catheter retrograde into the aorta. Alternatively, a standard transfemoral approach can be used. Stenoses $>50\%$ of the diameter of the artery that are associated with access failure should be treated with angioplasty. Stenting in addition to angioplasty can be used for subclavian orificial stenoses. Before management of the arterial stenosis, an evaluation of the access viability and stratification of the risk of the patient to undergo such procedure should be undertaken.

4. Poor venous outflow. With increasing pressure to create primary autogenous accesses, there is growing concern that surgeons will use "inadequate veins" to achieve target rates of autogenous access placement. A small or diseased vein may result in poor venous flow that can be associated with failed maturation, early failure, and focal areas of stenosis or dilation, or both. Definitions of vein adequacy will be described elsewhere in this document. However, once the autogenous access has been placed, a policy of aggressive re-evaluation should be performed to maintain access functionality as described in the surveillance section. Revision of a functioning autogenous access to a more proximal arterial and venous location is another strategy to optimize use of vein segments that have matured, while excluding diseased segments.

Poor venous outflow can also be caused by early anastomotic stenoses, which are technical errors, usually manifest as early thrombosis, but they can also lead to nonfunctionality or failure to mature in autogenous accesses. When diagnosed ≤7 days of access construction, surgical revision should be performed. When such stenoses are diagnosed later, balloon angioplasty can be performed initially. Care must be taken when approaching the arterial anastomosis. Arterial embolization can result from clot fragmentation or dislodgement of the arterial plug, and intimal dissection can occur from vessel damage caused by the wire or thrombectomy device.

B. Thrombosis. Thrombosis is the most common complication of AV access, accounting for a major source of morbidity, hospitalization, and cost. A thrombosed access is not patent and nonfunctional. Access thrombosis can occur for a variety of reasons and can be classified into thrombosis that occurs early (perioperative, 0-30 days) and late (>30 days) in the life of an access. It is very important to note that thrombectomy alone may not result in long-term patency of the access if the etiology of the thrombosis is not addressed at the same sitting or shortly thereafter.

A stenosis is usually found along the access circuit; therefore, the key to preventing a recurrent thrombosis of an access is complete imaging of the arterial inflow, the access itself, and venous outflow. The venous outflow study should include the central venous circulation because most accesses have more than one stenosis in their circuit and stenoses often occur centrally.[113] A retrospective review by Sofocleous et al[114] found 48 complications occurred in 579 treated thrombosed prosthetic hemodialysis accesses. Their overall technical success rate was 81%, and primary and secondary patency rate at 6 months were 36% and 67%, respectively. They also found that most complications encountered during percutaneous thrombolysis or surgical thrombectomy of thrombosed prosthetic access could be treated at the same sitting, allowing the same access to be used for hemodialysis.[114] Percutaneous excimer laser-facilitated thrombus vaporization is also found to be safe and effective for recanalization of acute and subacute thrombotic occlusions of hemodialysis shunts.[115]

1. Early thrombosis. Early failure occurs for many of the same reasons described above as causing nonfunctionality. In a way, early thrombosis represents the more extreme form of failure to mature, and mechanistically, the same underlying problems need to be evaluated in addition to performing thrombectomy of the conduit, either by endovascular or open surgical means. Insufficient arterial inflow, poor venous outflow, and anastomotic stenosis are the most common reasons for early access thrombosis. Additional factors may include surgical technical errors, intrinsic coagulation state, drops in systemic blood pressure, and poor cardiac output.

Usually, the surgeon has some idea from the initial procedure about what might be the most likely cause of early access failure. Depending on what is thought to be the most likely reason for access failure, surgical re-exploration of the access may or may not be worthwhile. For example, a small vein that failed to dilate with a gentle intraoperative infusion of heparinized solution or a diseased artery with poor inflow may not be worth re-exploration. It may make more sense to evaluate alternative sites with a view toward placing a new access. On the other hand, a possible kink in the vein graft or compression within the tunnel would require prompt urgent exploration.

Strategies for revisions can range from a simple thrombectomy to creation of completely new proximal anastomoses on the donor artery or vein. Occasionally, a preexisting venous stenosis that was not recognized before placement of the access can be diagnosed angiographically. In this situation, thrombectomy alone would not be expected to result in long-term access patency if the stenosis is not addressed.

2. Late thrombosis. Although both autogenous and prosthetic accesses are prone to late thrombosis, the approach to late thrombosis differs substantially. Prosthetic accesses have a much higher incidence of thrombosis and the access-specific stenotic lesion is more predictably found in a specific location, at the prosthetic venous anastomosis. In contrast, in autogenous access the stenosis can be located anywhere along the access vein used for needle puncture, and multiple stenoses are often present, thus highlighting the importance of complete access evaluation. Prosthetic and autogenous accesses can both be plagued by stenoses along the venous outflow tract, including central veins on the same side.

Although venous stenoses are far more common, the arterial side can also develop stenoses that can result in access thrombosis. Such lesions can be atherosclerotic in nature and can arise anywhere in the inflow arterial circuit. In addition, a hyperplastic stenosis can occur at the arterial anastomosis. Therefore, evaluation of the arterial inflow from the central arteries to the artery providing inflow to the access is indicated if a venous etiology cannot be found or the quality of the arterial inflow is in question.

Intimal hyperplasia. In >90% of cases, prosthetic accesses failure is due to stenosis of the venous anastomosis, draining vein, or central vein.[115-119] Histologic analysis of the venous anastomotic lesion demonstrates that it is identical to restenotic lesions that occur in the coronary arteries after coronary angioplasty or artery-to-artery bypass. The

pathophysiology of prosthetic access failure is largely that of neointimal hyperplasia at the venous anastomosis.

It is important to note that once access occlusion occurs, prolonged patency is unusual. Thrombectomy, access revision, or percutaneous transluminal angioplasty usually result in a limited period of patency before failure recurs. The inability to prolong access patency after occlusion reflects several challenges, including the difficulty of correcting the primary lesion responsible for access failure, alteration in graft thrombogenicity, persistence of secondary lesions, or a combination of these factors. Moreover, the injury caused by angioplasty of the stenotic lesion can itself promote accelerated neointimal hyperplasia. Because the venous anastomotic lesion of an AV graft is a proliferative vascular lesion, it is difficult to dilate and has a very high recurrence rate, regardless of the corrective intervention performed.

The KDOQI Guidelines recommend[9,120] that stenoses in prosthetic or autogenous accesses should be treated prophylactically with percutaneous transluminal angioplasty or surgical revision if the stenosis is >50% of the lumen diameter and is associated with clinical/physiologic abnormalities.

Management of thrombosed access. The mainstay of the management of thrombosed access is clot management, identification of stenotic lesions causing thrombosis, and management of significant stenotic lesions. Clot management alone is usually not sufficient for long-term patency unless the inciting factor is transient, such as access compression or an episode of hypotension. Management of thrombosed access can be by surgical or endovascular techniques. In either method, the clot or thrombus needs to be removed: surgically using a Fogarty balloon catheter or by endovascular means using thrombolysis, mechanical thrombectomy devices, or a combination thereof. Many of these devices are currently being used; a description of such devices can be found elsewhere in the literature.

1. Open surgical management: After surgical catheter thrombectomy, stenotic lesions either at the venous outflow anastomosis of a prosthetic graft or in the main body of the autogenous access have been traditionally managed by open surgical techniques. If the lesion is short, a patch angioplasty can be performed using either autogenous venous or prosthetic material. When the lesion is long or multiple sequential lesions are found, a vein segment or a piece of prosthetic graft is used to bypass the diseased segment. This bypass can be performed either to replace the diseased segment or to bypass it to a proximal healthy vein. This should be planned in a way to keep, if possible, an incorporated segment of a prosthetic access or a mature segment of an autogenous access free to be continuously used for dialysis, obviating the need for catheter placement while the new replacement segment incorporates or matures. This is well demonstrated when a prosthetic access thrombosis due to a hyperplastic lesion at the graft–vein interface is being surgically repaired. A longitudinal incision is made in the prosthetic graft and extended to the vein through the lesion. A Fogarty catheter is used to perform thrombectomy from the longitudinal incision. When the thrombectomy is complete, as evidenced by excellent arterial inflow, the longitudinal incision is closed using a patch that widens the lumen at the venous anastomotic site. The incorporated main body of the access can then be used for dialysis immediately after the conclusion of the procedure without the need for percutaneous catheter placement.
2. Endovascular techniques: clot can be managed by a variety of endovascular techniques or thrombolysis and the stenotic lesions can also be managed using balloon angioplasty and stenting techniques.
3. Combination of both techniques:
   a. Open balloon catheter thrombectomy through a small transverse incision remote from both the arterial and venous anastomosis of a prosthetic access.
   b. Angiographic imaging of the entire graft including arterial anastomosis and entire venous outflow.
   c. Open revision or balloon angioplasty of graft, anastomotic or venous outflow tract stenoses.

ACCESS CONFIGURATIONS

Autogenous accesses

Forearm autogenous accesses. *Autogenous posterior radial branch–cephalic direct wrist access (snuffbox).* This autogenous access is performed between the end of the cephalic vein and the posterior branch of the radial artery located in the anatomic snuffbox. The cephalic vein and radial artery are identified through a single longitudinal incision overlying the palpable posterior branch of the radial artery pulse. The artery is found in the base of the snuffbox between the tendons of the extensor pollicis longus and brevis.

Autogenous radial–cephalic direct wrist access (Brescia-Cimino-Appel).
This autogenous access is performed between the end of the cephalic vein and the radial artery in the wrist. If the arterial pulse and the vein are close to each other, the procedure is performed through one longitudinal or curvilinear incision. If these vessels are far from each other, the artery and the vein are dissected through two separate longitudinal incisions and the vein is passed through a tunnel to perform the anastomosis.

Autogenous radial–cephalic forearm transposition. This autogenous access is performed between the end of the cephalic vein and the radial artery in the forearm. The cephalic vein is identified at the wrist and mobilized to the antecubital fossa. The radial artery may be identified within the distal portion of this incision or, if located far away, a second longitudinal incision may be made overlying the palpable radial artery pulse. The cephalic vein is tunneled superficially and laterally to the radial artery to perform the anastomosis. This operation is used in obese patients with good inflow at the wrist and a normal cephalic vein in the

forearm, which is too deep to allow for successful cannulation if kept in its location and a direct autogenous access is performed.

Autogenous brachial (or proximal radial)–cephalic forearm looped transposition. This autogenous access is performed between the end of the cephalic vein and the brachial artery in the antecubital fossa. The cephalic vein is identified at the wrist and mobilized to the antecubital fossa through a single incision or multiple incisions. The brachial or proximal radial artery is identified within the proximal portion of this incision or, if located far away, a second incision is made overlying the artery. The cephalic vein is tunneled superficially in a forearm loop to the artery to perform the anastomosis.

Autogenous radial–basilic forearm transposition. This autogenous access is performed between the end of the basilic vein and the radial artery in the forearm. The basilic vein is identified in the wrist and mobilized to the antecubital fossa. The radial artery is identified through a longitudinal incision directly overlying the palpable radial artery pulse. The basilic vein is tunneled superficially and laterally to the radial artery to perform the anastomosis.

Autogenous ulnar–basilic forearm transposition. This autogenous access is performed between the end of the basilic vein and the ulnar artery in the forearm. The basilic vein is identified at the wrist and mobilized to the antecubital fossa. The ulnar artery is identified through a longitudinal incision directly overlying the palpable ulnar artery pulse. The basilic vein is tunneled superficially and laterally to the ulnar artery to perform the anastomosis.

Autogenous brachial (or proximal radial)–basilic forearm looped transposition. This autogenous access is performed between the end of the basilic vein and the brachial or proximal radial artery in the antecubital fossa. The basilic vein is identified at the wrist and mobilized to the antecubital fossa. The artery is identified within the proximal portion of this incision or, if located far away, a second longitudinal incision is made overlying the artery. The basilic vein is tunneled superficially in a forearm loop to the artery to perform the anastomosis.

Autogenous radial–antecubital forearm indirect greater saphenous translocation. This autogenous access is performed between the antecubital vein in the antecubital fossa and the radial artery in the wrist using the great saphenous vein as conduit. The antecubital vein is identified through a transverse incision in the antecubital fossa. The radial artery is identified through a longitudinal incision overlying the palpable radial artery pulse. An appropriate length of great saphenous vein is harvested from the lower extremity. The great saphenous vein is translocated to the forearm in a superficial and lateral tunnel between the antecubital vein and the radial artery to perform the two anastomoses.

Autogenous brachial (or proximal radial)–antecubital forearm indirect looped greater saphenous translocation. This autogenous access is performed between the antecubital vein and the brachial or proximal radial artery located in the antecubital fossa using the great saphenous vein as conduit. The antecubital vein and artery are identified through a transverse incision in the antecubital fossa. An appropriate length of great saphenous vein is harvested from the lower extremity. The great saphenous vein is translocated to the forearm in a looped configuration between the antecubital vein and brachial or proximal radial artery to perform the two anastomoses.

Upper arm autogenous accesses. Upper arm accesses have most commonly been based on the brachial artery for inflow; however, the proximal radial artery is an excellent choice for inflow as long as there is adequate length of vein to support the additional 2 to 3 cm of length required to perform the anastomosis at the proximal radial artery, which is a few centimeters distal to the brachial artery at the antecubital fossa. Although confusion may arise regarding classification of accesses originating from the proximal radial artery, these accesses should be classified as upper arm accesses except in cases where all access flow is retrograde into the forearm.

Autogenous brachial (or proximal radial)–cephalic upper arm direct access. This autogenous access is performed between the end of the cephalic vein and the brachial or proximal radial artery located in the antecubital fossa. If the cephalic vein and selected artery are close together, the procedure is performed through one transverse incision; if not, separate incisions are made and the end of the cephalic vein is tunneled to the brachial or proximal radial artery to perform the anastomosis.

Autogenous brachial (or proximal radial)–cephalic upper arm transposition. This autogenous access is performed between the end of the cephalic vein and the brachial or proximal radial artery. The cephalic vein is identified at the elbow and mobilized to an appropriate length to allow its free end to reach the brachial artery. The brachial artery is identified through an extension of this incision or, if located far away, through a second incision overlying the palpable brachial artery pulse just beyond to the proximal radial artery. The cephalic vein is tunneled superficially and medially towards the brachial artery to perform the anastomosis.

Autogenous brachial (or proximal radial)–basilic upper arm transposition. This autogenous access is performed between the end of the basilic vein and the brachial artery located at or just proximal to the antecubital fossa, or the proximal radial artery just distal to the fossa. An appropriate length of adequate basilic vein is completely mobilized distal to the antecubital crease if possible. The artery is identified in the distal portion of the incision or, if located far away, through a second incision overlying the artery. The basilic vein is tunneled superficially and laterally to the artery to perform the anastomosis. It is of note that this transposition as well as others can be performed by one-stage or two-stage techniques. A two-stage technique can be used when the vein to be transposed has a small caliber (<4 mm), where simply anastomosing the end of the vein to the artery would allow the vein to dilate before its transposition in the second stage of the two-stage technique.[121] Before the second stage is performed, DU study of the vein can confirm its adequacy. The second stage is

performed, usually 4 to 8 weeks later, if the vein is adequately dilated, displays no stenosis, and has adequate flow volume.[121]

Autogenous brachial (or proximal radial artery)–brachial vein upper arm transposition. This autogenous access is performed between the end of the brachial vein and the brachial artery located in the antecubital fossa. If there is adequate vein available distally, use of the proximal radial artery as inflow is another option. The brachial vein and brachial artery are identified through a longitudinal incision in the antecubital fossa. The brachial vein is mobilized to the axilla and tunneled superficially and laterally to the brachial artery to perform the anastomosis. This transposition is well suited for a two-stage technique because the vein is quite small, unless it has been arterialized from a prior forearm access. Further, a two-stage transposition will result in elongation of the vein during the first stage, providing the additional vein length that is usually required to transpose this vein to a lateral subcutaneous tunnel. Finally, superficialization of the vein can be done if there is inadequate length to transpose the vein, in which case the vein should be positioned laterally under a skin flap so that cannulation does not have to be performed through the incision site.

Autogenous proximal radial–median antebrachial (or cephalic) vein, bidirectional flow. This autogenous access is performed as a side-to-side or end-to-side anastomosis using the median antebrachial or cephalic vein. Retrograde flow is established into the forearm by disruption of the first valve under direct vision with a small probe or reverse valvulotome. Flow into both the upper arm cephalic vein and the forearm median antebrachial vein offers the potential for continued and uninterrupted vascular access, should one of the outflow branches fail. The brachial artery can also be used as inflow, but use of the proximal radial artery minimizes the risk of steal syndrome. Further, the side-to-side anastomosis maintains flow through multiple venous channels.[122]

Autogenous brachial (proximal radial) artery–axillary vein upper arm indirect greater saphenous translocation. This autogenous access is performed between the axillary vein in the axilla and the brachial or proximal radial artery in or near the antecubital fossa using the great saphenous vein as conduit. The axillary or proximal brachial vein is identified through a longitudinal incision in the axilla. The artery is then isolated. An appropriate length of great saphenous vein is harvested from the lower extremity. The great saphenous vein is translocated in a superficial and lateral tunnel between the axillary vein and chosen artery to perform the two anastomoses. The saphenous vein can also be constructed in loop configuration in the arm or forearm.

Lower extremity autogenous accesses. *Autogenous femoral–great saphenous lower extremity looped transposition.* This autogenous access is performed between the end of the great saphenous vein and the superficial femoral artery in the groin. The great saphenous vein and common femoral artery are identified through a longitudinal groin incision. The great saphenous vein is mobilized for an appropriate length. The great saphenous vein is tunneled superficially and laterally to the superficial femoral artery to perform the anastomosis.

Autogenous femoral artery–femoral vein lower extremity transposition (straight). This autogenous access is performed between the end of the femoral vein and the femoral artery. The femoral vein and femoral artery are identified through longitudinal incisions. The femoral vein is mobilized for an appropriate length, usually into the adductor canal, but not including the popliteal. The femoral vein is tunneled superficially and laterally to the femoral artery to perform the anastomosis. In the presence of an unacceptable distal femoral artery, the vein may be looped back to the femoral artery in the groin.

Autogenous posterior tibial–greater saphenous lower extremity direct access. This autogenous access is performed between the great saphenous vein and the posterior tibial artery in the distal calf. The great saphenous vein and posterior tibial artery are identified through a longitudinal incision at the ankle. The distal end of the great saphenous vein is mobilized to the posterior tibial artery to perform the anastomosis.[123]

Configurations of prosthetic AV accesses

Forearm prosthetic accesses. *Prosthetic radial–antecubital forearm straight access.* This prosthetic access is performed between the antecubital vein in the antecubital fossa and the radial artery in the wrist using a prosthetic graft as conduit. The antecubital vein is exposed through a transverse incision distal to the antecubital crease. The radial artery is exposed through a longitudinal incision in the wrist overlying the palpable radial artery pulse. The prosthetic graft is tunneled superficially and laterally between the antecubital vein and the radial artery to perform the two anastomoses.

Prosthetic brachial–antecubital forearm looped access. This prosthetic access is performed between the antecubital vein and the brachial artery in the antecubital fossa using a prosthetic graft as conduit. The antecubital vein and brachial artery are exposed through a transverse incision in the antecubital fossa. The prosthetic graft is tunneled superficially in a forearm loop between the antecubital vein and the brachial artery to perform the two anastomoses.

Upper arm prosthetic accesses. *Prosthetic brachial–axillary (vein) upper arm access.* This prosthetic access is performed between the axillary or brachial vein in the axilla and the brachial artery using a prosthetic graft as conduit. The axillary vein is exposed through a longitudinal incision in the axilla. The brachial artery is exposed through a longitudinal incision at or just proximal to the antecubital fossa overlying the palpable brachial artery pulse. The prosthetic graft is tunneled superficially and laterally between the axillary vein and the brachial artery to perform the two anastomoses.

Lower extremity prosthetic accesses. *Prosthetic femoral artery–femoral vein lower extremity looped access.* This prosthetic access is performed between the femoral vein and the femoral artery using a prosthetic graft as conduit. The

femoral vein and artery are exposed through longitudinal or transverse incisions. The prosthetic graft is tunneled superficially in a loop between the femoral vein and artery to perform the two anastomoses.[70,124]

Body wall prosthetic accesses. *Prosthetic axillary–axillary (vein) chest access (necklace prosthetic access).* This prosthetic access is performed between the axillary vein and the contralateral axillary artery using a prosthetic graft as conduit. The axillary vein is exposed through a transverse infraclavicular incision and is located deep to the pectoralis major muscle. Through a similar incision, the contralateral axillary artery is exposed. The prosthetic graft is tunneled superficially across the chest wall between the axillary vein and artery to perform the two anastomoses.

Prosthetic axillary–axillary (vein) chest loop access. This prosthetic access is performed between the axillary vein and the ipsilateral axillary artery using a prosthetic graft as conduit. The axillary vein and artery are exposed through a transverse infraclavicular incision where they are located deep to the pectoralis major muscle. The prosthetic graft is tunneled superficially in a loop on the chest wall between the axillary vein and artery to perform the two anastomoses.

Prosthetic axillary–internal jugular chest loop access. This prosthetic access is performed between the internal jugular vein and the ipsilateral axillary artery using a prosthetic graft as conduit. The internal jugular vein is exposed through a longitudinal incision just anterior to the sternocleidomastoid muscle and is located in the carotid sheath. The axillary artery is exposed through a transverse infraclavicular incision and is located deep to the pectoralis major muscle. The prosthetic graft is tunneled superficially between the internal jugular vein and the axillary artery to perform the two anastomoses.

Prosthetic axillary–femoral (vein) body wall access. This prosthetic access is performed between the common femoral vein and the axillary artery using a prosthetic graft as conduit. The common femoral vein is exposed through a longitudinal groin incision. The axillary artery is exposed through a transverse infraclavicular incision and is located deep to the pectoralis major muscle. The prosthetic graft is tunneled superficially along the body wall between the common femoral vein and the axillary artery to perform the two anastomoses.

AUTHOR CONTRIBUTIONS

Conception and design: AS, LS, AB, MA, WJ, FP, MM, VM, AO, KC, RM, AL, EA
Analysis and interpretation: AS, MM, VM
Data collection: Not applicable
Writing the article: AS, LS, AB, MA, WJ, FP, MM, VM, AO, KC, RM, AL, EA
Critical revision of the article: AS, LS, AB, MA, WJ, FP, MM, VM, AO, KC, RM, AL, EA
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Statistical analysis: MM, VM
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Methodology for clinical practice guidelines for the management of arteriovenous access

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The Society for Vascular Surgery considers the placement and maintenance of arteriovenous hemodialysis access to be an important component of any vascular surgery practice. Therefore, the Society has long been involved in setting the standards for the management of arteriovenous access. Formulating clinical recommendations in this area is the latest effort by the Society to improve the management of arteriovenous access on a national level. To provide an unbiased study of the evidence and to help in formulating the recommendations, the Society used the Knowledge and Encounter Research (KER) Unit of the Mayo Clinic College of Medicine, Rochester, Minn, to review the available evidence and advise a multidisciplinary group of access surgeons and nephrologists in formulating the clinical recommendations. To review the evidence, randomized and observational study designs were both considered. Whenever possible, systematic reviews and meta-analyses of the literature were used because, compared with individual studies, they generate more precise estimates of treatment effects and their results are applicable to a wider range of patients. On behalf of the Society, the group issued its recommendations following the Grading of Recommendations Assessment, Development and Evaluation (GRADE) format; this format disentangles the strength of recommendations from the quality of the evidence and encourages statements about the underlying values and preferences relevant to the particular recommendation. The recommendations are classified as strong (denoted by the phrase "we recommend") or weak (denoted by the phrase "we suggest"); and the quality of evidence is classified as high, moderate, low, or very low. These recommendations are not meant to supersede clinical judgment; rather, they should be used as a guide for the practicing surgeon and nephrologist as the decision is being made for the placement and subsequent procedures and management of arteriovenous hemodialysis access are being considered. (J Vasc Surg 2008;48:26S-30S.)

The Society for Vascular Surgery undertook the task of developing evidence-based guidelines to assist patients and clinicians in the process of decision making. To provide better understanding of these guidelines and facilitate their integration into daily practice, we present the methodologic framework that guideline developers have used to formulate their recommendations. In this supplement, practice guidelines for arteriovenous hemodialysis access and the study of the evidence available in this field are included. In this article, we discuss the evaluation and synthesis of research evidence and the formulation of clear and helpful clinical practice recommendations using the vascular access reviews as examples.

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USING RESEARCH EVIDENCE TO FORMULATE RECOMMENDATIONS

Randomized controlled trials (RCTs) are the only study design known to balance known and unknown prognostic risk factors between study arms. Hence, RCTs are considered the gold standard study design to evaluate the effectiveness of therapeutic and diagnostic interventions. However, not all randomized trials offer similarly strong inferences because trialists may or may not use the various measures intended to reduce the risk of bias, such as allocation concealment, blinding, and the intention-to-treat principle. For instance, when the Society for Vascular Surgery evaluated the efficacy of vascular access surveillance, only three of the 10 relevant RCTs protected randomization by assuring that the person assigning patients to a study arm was unaware of the randomization sequence, a procedure called allocation concealment. This procedure usually requires the use of central randomization (eg, the investigator called a central location with patient characteristics and received the arm allocation) or the use of sealed, numbered, and opaque envelopes.[1] Patients and surgeons were appropriately not blinded in these trials; however, data collectors and researchers ascertaining the outcomes could have been blinded to reduce bias; the former was done in five of 10 RCTs and the latter was done in only one RCT.

In the comparison between autogenous and prosthetic accesses, it was unclear whether trials did not report or did not adhere to the intention-to-treat principle, by which researchers set up procedures and resources to keep randomized participants in the arm to which they were ran-

domized, with no crossover to the other arm. Hence, the inferences from these trials need to be interpreted in the context of the described methodologic limitations.

Moreover, the evaluation of surgical interventions presents challenges to the use of the randomized trials. Patients are reluctant to be randomized to procedures that may be associated with permanent consequences or scars, blinding surgeons and sham surgeries are often unfeasible, and the duration of required follow-up may be too long and impractical for RCTs.[2] As a consequence, evidence-based surgeons have relied extensively on observational studies to this point: only 3.4% of all publications in the leading surgical journals are RCTs, and more than half of these RCTs compared medical therapies in surgical patients rather than alternative surgical procedures or surgical vs medical or radiologic interventions.[3]

Recent innovations in the design of surgical trials may overcome some of the limitations of traditional RCTs in surgery, provide the bias protection that randomization offers, and gain the ability to make strong inferences about the efficacy of surgical interventions. An example of these innovations is the expertise-based RCT. Whereas participants in conventional RCTs are randomized to one of two interventions (A or B) and individual clinicians give intervention A to some participants and B to others, participants in expertise-based RCTs are randomized to clinicians with expertise in intervention A or clinicians with expertise in intervention B and the clinicians perform only the procedure they are expert in.[4] Trials of carotid endarterectomy performed by vascular surgeons vs stenting performed by interventional radiologists are examples of expertise-based RCTs.

Observational studies are unlikely to provide the same degree of protection against bias in ascertainment of the efficacy of interventions compared with high-quality randomized trials. Their quality can be improved, however, when investigators include measures aimed at reducing bias. Some of these measures (parallel to those that enhance the quality of randomized trials) include selecting adequate populations, making them appropriately comparable by means of matching or statistical adjustment by key predictors of outcome, ensuring adequate ascertainment of the exposures and outcomes at baseline, planning long enough follow-up to allow time for critical outcomes to develop, and blinding the assessment of outcomes in both groups.[5,6]

Hence, in developing clinical practice guidelines for the Society for Vascular Surgery, we considered evidence generated by both study designs: RCTs and observational studies that included concurrent comparison cohorts. In addition, it is important to recognize the inherent limitations of both designs when applied to surgical interventions in that surgical outcomes are often influenced by other factors such as the surgeons' learning curve and experience, surgical volume, institution characteristics, and the quality of perioperative care.[4] These factors are difficult to assess and are often not reported in the published literature.

THE ROLE OF EVIDENCE SYNTHESIS IN FORMULATING HIGH QUALITY PRACTICE GUIDELINES

The ideal evidence-based recommendation should consider all pertinent evidence. However, with >1800 new citations indexed in MEDLINE each day and >16 million citations accrued to date,[7] it is unrealistic to expect that one or a few experts would be aware of the totality of evidence about a particular subject. Furthermore, if experts choose the evidence they bring to bear in formulating recommendations without explicit and reproducible criteria, they run the risk of reviewing an incomplete and biased sample of the available research. Thus, in pursuit of finding the best evidence for guideline development, a rigorous systematic review of the literature is paramount. In contrast to traditional literature reviews, which are nonexhaustive, unsystematic, and can be biased, systematic reviews address a focused clinical question using methods designed to reduce the likelihood of bias in the identification, selection, critical appraisal, description, and summary of the totality of the relevant literature. Compared with the primary studies they seek to summarize, systematic reviews offer greater precision in estimating treatment effects, particularly when these reviews include well-conducted quantitative summary of the results (ie, meta-analysis) and provide results that are applicable to a wider range of patients.[8]

The process of conducting systematic reviews starts by defining the clinical question in terms of the population, intervention, comparison, and outcomes. Librarians with expertise in systematic reviews conduct a sensitive—but not very specific—search of relevant bibliographic databases. Reviewers, working independently and in pairs, appraise studies with predetermined criteria for inclusion and exclusion, assess the quality of studies, and abstract relevant data. Results are summarized qualitatively or quantitatively. To ensure high-quality reviews, we monitor and report the agreement among reviewers by using agreement statistics (eg, κ statistic), contact the authors of primary studies to ensure correct representation of their results and to ask for missing data, explore heterogeneity in the results by conducting subgroup and sensitivity analyses, and assess the potential impact of publication bias on review results (Table I).

FROM EVIDENCE TO PRACTICE: FORMULATING CLINICAL RECOMMENDATIONS

In using evidence to formulate recommendations, it is helpful for the user of such recommendations to understand how valid, precise, and applicable is the available body of evidence supporting a recommendation (ie, the quality of the evidence). High-quality evidence (ie, estimates of effect for safety and efficacy that are unlikely to change substantially as new research accumulates) provides greater confidence in formulating recommendations. Similarly, it is helpful for the user of practice guidelines to note whether a

Table I. Conducting a systematic review

Define the question
• Specify inclusion and exclusion criteria
Population
Intervention or exposure
Outcome
Methodology
• Establish a priori hypotheses to explain heterogeneity
• Conduct literature search
• Decide on information sources: databases, experts, funding agencies, pharmaceutical, companies, hand-searching, personal files, registries, citation lists of retrieved articles
• Determine restrictions: time frame, unpublished data, language
• Identify titles and abstracts
Apply inclusion and exclusion criteria
• Apply inclusion and exclusion criteria to titles and abstracts
• Obtain full articles for eligible titles and abstracts
• Apply inclusion and exclusion criteria to full articles
• Select final eligible articles
• Assess agreement on study selection
Extract data
• Data abstraction: participants, interventions, comparison interventions, study design
• Results
• Methodologic quality
• Assess agreement on validity assessment
Conduct analysis
• Determine method for pooling of results
• Pool results (if appropriate)
• Decide on handling missing data
• Explore heterogeneity, sensitivity, and subgroup analysis
• Explore possibility of publications bias

recommendation is strong (ie, "must do," "must not do") or weak (ie, "may do," "may not do").

Multiple systems have been used to rate the quality of evidence and grade the strength of clinical recommendations. Thankfully for clinicians and other decision makers, there is an emerging consensus among professional organizations toward using one system, the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system, for this purpose.[9,10] The GRADE system classifies recommendations as strong (grade 1) or weak (grade 2) and the quality of the evidence (ie, risk of bias) into one of four categories (high, moderate, low, or very low). To further enhance the interpretation and clarity of the recommendations, guideline developers use the terms "we recommend" to denote strong recommendations, and the less definitive wording "we suggest" to denote weak recommendations.

When guideline developers are confident that the desirable effects of adherence to a recommendation outweigh the undesirable effects, they will make a strong recommendation within the context of a described intervention. Typically, this requires high- or moderate-quality evidence on patient-important outcomes, but on occasion, a strong recommendation can be based on lower-quality evidence. This may occur when the values and preferences that guideline developers bring to bear are such that when considering even low-quality evidence, they are confident that the desirable effects of adherence to a recommendation outweigh the undesirable effects.

A weak recommendation is one for which a guideline panel concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, but the panel is not confident. Thus, if guideline developers believe that benefits and downsides are finely balanced, or appreciable uncertainty exists about this balance, they offer a weak recommendation. Overall, low- or very low-quality evidence usually leads to weak recommendations because of uncertainty about the balance between risks and benefits. Guideline panels may offer weak recommendations even when high-quality evidence is available because that evidence clearly demonstrates that the benefits and risks are closely balanced.

As described above, study design and conduct are important determinants of the quality of evidence (Table II).[11] RCTs allow decision makers to draw causal inferences linking interventions and outcomes with protection against bias. Therefore, RCTs begin with a "high" quality rating, whereas observational studies start with a "low" quality rating. This rating can be downgraded when:

(1) RCTs have serious methodologic limitations; for example, lack of allocation concealment and blinding, or large loss to follow-up;
(2) results were inconsistent among trials,
(3) trials were indirectly relevant; that is, did not directly apply to the patients, interventions, or outcomes of interest;
(4) results were imprecise due to small number of studies and events, or
(5) reporting bias might have affected the estimates (usually overestimated the beneficial effect or the harmful effect of treatment).

For example, when evaluating the effectiveness of access surveillance on the survival of the vascular access of hemodialysis we note that (1) there was important inconsistency between study results, with 60% of the observed variability being attributed to true differences in the results across trials rather than to chance, (2) some RCTs reported only on the effect of the interventions on access thrombosis, which is a surrogate of the more important outcome, access loss or abandonment, and (3) only six of 12 studies evaluated access failure with a total of only 94 events (ie, accesses lost) in the surveillance group vs 88 events in the no surveillance group, which produced a wide confidence interval. Therefore, the overall clinical trial evidence was downgraded due to inconsistency, indirectness and imprecision, respectively; that is, from high-quality evidence to very low-quality evidence.[1]

On the other hand, the quality of evidence of observational studies can be upgraded if (1) a very large treatment effect was observed, (2) all plausible confounders would reduce the magnitude of the treatment effect, yet the effect remains sizable, and (3) a dose-response gradient was noted. An example of evidence that was upgraded comes from the comparison of autogenous access with prosthetic access for hemodialysis. We noted that placing an autogenous access produced a large effect in decreasing the risk of

Table II. Grading of Recommendations Assessment, Development and Evaluation guidelines

Rating of evidence quality	*Clarity of risk/benefit*	*Description of supporting evidence*	*Implications*
Strong recommendations			
High-quality evidence	Benefits clearly outweigh harms and burdens, or vice versa	Consistent evidence from well-performed randomized controlled trials or exceptionally strong evidence from unbiased observational studies[a]	Recommendation can apply to most patients in most circumstances. Further research is very unlikely to change our confidence in the estimate of effect.
Moderate-quality evidence	Benefits clearly outweigh harms and burdens, or vice versa	Evidence from randomized controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise evidence), or unusually strong evidence from unbiased observational studies	Recommendation can apply to most patients in most circumstances. Further research (if performed) is likely to have an impact on our confidence in the estimate of effect and may change the estimate.
Low-quality evidence	Benefits clearly outweigh harms and burdens, or vice versa	Evidence for at least one critical outcome from observational studies, from randomized controlled trials with serious flaws, or indirect evidence	Recommendation may change when higher quality evidence becomes available. Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low-quality evidence (very rarely applicable)	Benefits clearly outweigh harms and burdens, or vice versa	Evidence for at least one of the critical outcomes from unsystematic clinical observations or very indirect evidence	Recommendation may change when higher quality evidence becomes available; any estimate of effect for at least one critical outcome, is very uncertain.
Weak recommendations			
High-quality evidence	Benefits closely balanced with harms and burdens	Consistent evidence from well-performed randomized controlled trials or exceptionally strong evidence from unbiased observational studies.	The best action may differ depending on circumstances or patient or societal values. Further research is very unlikely to change our confidence in the estimate of effect.
Moderate-quality evidence	Benefits closely balanced with harms and burdens	Evidence from randomized controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise evidence), or unusually strong evidence from unbiased observational studies	Alternative approaches likely to be better for some patients under some circumstances. Further research (if performed) is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low-quality evidence	Uncertainty in the estimates of benefits, harms, and burdens; benefits may be closely balanced with harms and burdens	Evidence for at least one critical outcome from observational studies, from randomized controlled trials with serious flaws, or indirect evidence	Other alternatives may be equally reasonable. Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low-quality evidence	Major uncertainty in the estimates of benefits, harms, and burdens; benefits may or may not be balanced with harms and burdens	Evidence for at least one critical outcome from unsystematic clinical observations or very indirect evidence.	Other alternatives may be equally reasonable. Any estimate of effect, for at least one critical outcome, is very uncertain.

Modified from Schunemann HJ et al.[11]

[a]Exceptionally strong evidence from unbiased observational studies includes (1) evidence from studies that yield estimates of the treatment effect that are large and consistent and (2) evidence where all potential biases may be working to underestimate an apparent treatment effect, and therefore, the actual treatment effect is likely to be larger than that suggested by the study data, and (3) evidence where a dose-response gradient exists.

access infection (relative risk, 0.22; or five times reduction of risk), which led to upgrading the quality of the evidence.[12]

Finally, the GRADE system offers insights into the role of values and preferences when it disentangles the strength of recommendations from the quality of the evidence and when it encourages statements about the underlying values and preferences relevant to the recommendations. For example, the vascular access committee issued a strong recommendation for using distal arm autogenous access as a

first-line access despite very low-quality evidence. The evidence for this recommendation was considered to have very low quality because most of the studies were nonrandomized (80 of 83), the study cohorts were prognostically imbalanced at baseline, outcome assessors were mostly unblinded, apparent reporting bias was present, and results were inconsistent among studies to the extent that the proportion of heterogeneity that is not attributable to chance in most outcomes >50% and often >90%.

These limitations in the quality of evidence notwithstanding, the committee issued a strong recommendation because they placed higher value on optimizing patient-important outcomes such as preventing death, access infection, local complications, and achieving a longer period of time with successful dialysis; all were features thought to be more associated with the autogenous access. In recommending distal upper extremity access sites despite the very low quality evidence, they also placed high value on the preservation of proximal veins or future access placement. The committee placed lower value on some of the characteristics of the prosthetic access such as higher reimbursement for placement, ready off-the-shelf availability, and shorter time to first use for dialysis. Hence, the guideline authors made a strong recommendation when they assumed that the pertinent values and preferences across a broad range of informed patients are consistent with the recommended action.

THE FUTURE

The Society for Vascular Surgery belongs to a select but expanding group of professional organizations that has endorsed an approach that is the state-of-the-art in guideline formulation and grading. This position is not without challenges. The GRADE Working Group (www.gradeworkinggroup.org) is identifying the best approaches to the grading of diagnostic recommendations. There is considerable uncertainty on how to incorporate considerations about resource utilization and societal priorities in health care. Also, mechanisms to incorporate patient preferences into guideline formulation are in their infancy.

Other challenges for the Society involve the use of the guidelines to inform policies in support of quality improvement efforts. For example, it is plausible that strongly recommended procedures could lead to process-of-care parameters that can be part of quality assessment and incentive schemes. Weak recommendations, on the other hand, may indicate areas not ready for quality improvement. How the Society, and other organizations, can move from guideline formulation to practice implementation represents yet another frontier in this field.

In future articles, we will keep the vascular surgery community abreast of developments in the methodology of guideline development while we continue to improve on the procedures we have began to use in response to users' feedback.

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