KDOQI 2019 Vascular Access Guidelines: What Is New

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Abstract

The new Kidney Disease Outcomes Quality Initiative (KDOQI) Vascular Access Guidelines have a patient focus for comprehensive vascular access management. The patient's unique circumstances and individualized needs are the foundation of their dialysis access strategy, which is interlinked with the patient's End Stage Kidney Disease (ESKD) Life-Plan. The ESKD Life-Plan is an individualized and comprehensive map for dialysis modalities and vascular access for the lifetime of the patient. New targets are introduced that align with this patient-centered approach. They are less detail prescriptive than prior vascular access guidelines, giving opportunity for vascular access management at the clinician's discretion, partly in consideration of constraints of local resources and available expertise; however, the guidelines also emphasize the importance of high-quality standards with defined targets for achieving the guideline's overarching goal for vascular access care. The guidelines made significant changes relevant to the interventionalist, including selective use of vessel mapping in planning for vascular access, choice of vascular access that allows for considering endovascular access creations, and endovascular treatment (e.g., angioplasty, stent graft insertions) based on clinical indicators found on routine clinical monitoring. To that end, preemptive angioplasty of fistulas and grafts with stenosis, not associated with clinical indicators, is not recommended. New content in these guidelines also includes the use of stent grafts and management of central venous stenosis. The new KDOQI Vascular Access Guidelines 2019 represent a rigorous review of the evidence; however, the available evidence to guide vascular access practice remains limited. There is a significant need and opportunity for new and ongoing high-quality research to inform best practice.

Keywords
- hemodialysis
- vascular access
- chronic kidney disease
- end-stage kidney disease
- guideline
- interventional radiology

The global prevalence of chronic kidney disease (CKD) is estimated at over 843 million people.[1] Fortunately, only a small percentage of patients will progress to end-stage kidney failure requiring kidney replacement therapy. However, the number of people receiving kidney replacement therapy exceeds 2·5 million and is projected to double to 5·4 million by 2030.[2] The most common form of kidney replacement therapy is hemodialysis, which requires a vascular access in order for the patient to receive treatment.

The ideal hemodialysis vascular access is one that provides reliable, complication-free access to deliver prescribed dialysis, which is also concurrently suitable for a given

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patient's needs. None of the three main types of vascular access—arteriovenous fistula (AVF), arteriovenous graft (AVG), or central venous catheter (CVC)—are truly complication-free. Complications may occur at any time from the time of vascular access creation or insertion to its abandonment. The Kidney Disease Outcomes Quality Initiative (KDOQI) Vascular Access Guidelines were first published in 1997, with an update in 2001 and 2006—each iteration aimed at guiding best practice for vascular access management, including reducing vascular access–related complications. In the most recent update, several major changes were made, including a change in the process of guideline development, some underlying philosophies, and its content. To create the new KDOQI Vascular Access Guidelines, more than 4,600 articles were reviewed, including key randomized controlled trials since 2006, and over 250 evidence tables were developed and included. This work resulted in 26 guideline sections and subsections, including their statements and research recommendations. An independent evidence review team (ERT) was used to search the literature, retrieve, and analyze relevant data, based on a scope of work document created by the Work Group. The Work Group was multidisciplinary including nephrologists, interventional nephrologists, radiologists, surgeons (transplant and vascular access), a pediatric nephrologist, epidemiologists, statisticians, and a vascular access coordinator and nurse. Patient input was sought and integrated.

It became quite evident after the independent and rigorous evidence review that there was, and still is, a lack of high-quality clinical studies in hemodialysis vascular access. During the 4-year process of guidelines creation, several clinical trials involving endovascular interventions were underway, completing, or about to be published. The Work Group was aware of these and was careful to avoid making guideline statements that would restrict the implementation or future research that might arise from these trials. However, the guidelines do indicate gaps in knowledge for each of the guideline sections and research recommendations are given. Clinical recommendations were not made in the absence of high-quality evidence to avoid changes in practice that might inadvertently prohibit research. Instead, the guidelines strongly encourage more high-quality research to inform the next iteration of these guidelines.

This review highlights some of the key changes in the KDOQI Vascular Access Guideline 2019, with a focus on statements that are particularly relevant for interventional radiologists. However, for context, the guideline's underlying focus is on the patient (past, present, and future) rather than a single interventional decision about a vascular access. This is done, in part, to help reduce complications that inevitably arise from vascular access interventions and other care. In this review, we present three broad concepts which will change the paradigm of thinking about vascular access for the interventionalist. These include introduction of the ESKD Life-Plan, changes in endovascular management of vascular access, and the aligned guideline targets and metrics. In particular, we will highlight some of the key changes in the guideline recommendations that will significantly influence a radiologist or an interventionalist's practice as they pertain to AV access (fistulas or grafts); implications for CVC management are not discussed.

New Concepts

The new KDOQI Vascular Access Guideline 2019 makes a refreshing switch in focus from a singular vascular access strategy (e.g., "Fistula First") to a more comprehensive overall patient and dialysis access strategy. The premise behind this change is that the patient's immediate vascular access needs are part of a larger dialysis access strategy. This dialysis access strategy is intertwined with an important new concept introduced in the KDOQI Vascular Access Guideline 2019—the "ESKD Life-Plan." The ESKD Life-Plan itself is *not* about vascular access but influences most decisions made about dialysis access, as it directly impacts the patient and potential complications that may incur with vascular access management. The ESKD Life-Plan is an individualized and comprehensive map of *dialysis modalities* (e.g., hemodialysis, peritoneal dialysis, kidney transplant) and related dialysis accesses for the lifetime of the patient. This ESKD Life-Plan should be documented for each patient, and referred to when making decisions about the type of dialysis access, and the treatments related to dialysis access that the patient may encounter.

As such, the new guidelines start at the patient and end with the vascular access rather than simply looking at the vascular access in isolation. In doing so, it aims to consider current and future dialysis access needs to reach the overarching goal of the KDOQI Vascular Access Guideline 2019 "to achieve reliable, functioning, complication-free dialysis-access to provide prescribed dialysis while preserving future dialysis access site options as required by the individual patient's ESKD Life-Plan."

So then, what exactly is the ESKD Life-Plan? Extracted from the KDOQI Clinical Practice Guideline (CPG) definitions, the ESKD Life-Plan is defined as "the individualized set of kidney replacement modalities (hemodialysis, peritoneal dialysis, transplantation) required to sustain a patient's life with ESKD that considers the patient's current and anticipated medical and life circumstances and patient preferences. The Life-Plan should be reevaluated regularly to adapt to the changes in a patient's life circumstances."[3] For example, if a patient chooses conservative care once they reach ESKD, then the plan for dialysis access is no access, thus avoiding unnecessary appointments, interventions, and other inconveniences. However, if the patient has an ESKD Life-Plan that includes dialysis modalities, the KDOQI guidelines facilitate getting "the right access in the right patient, at the right time, for the right reasons."[3] For example, the ESKD Life-Plan for a 35-year-old woman with glomerulonephritis and no other comorbidities might be (1) living donor kidney transplant, followed by (2) peritoneal dialysis, and then finally (3) home hemodialysis. In terms of vascular access, while the patient is living with her kidney transplant, she needs to preserve her vessels for the time they are needed to create an arteriovenous access (AV access—be it a fistula or graft) as she may

need future hemodialysis. Should her kidney transplant fail, her next planned modality is peritoneal dialysis. A peritoneal dialysis catheter can be placed surgically or by an interventional radiologist, and should be done prior to complete kidney graft failure. This needs to be coordinated with the nephrologist, the transplant team, and the peritoneal dialysis team. She may be able to extract 3 to 5 years from peritoneal dialysis but is always preserving her vessels for the AV access she will need for eventual hemodialysis. This comprehensive strategy is called a P-L-A-N: ***P***atient ***L***ife-Plan and their ***A***ccess ***N***eeds. Within "Access Needs," there are three main components: (1) Access Creation Plan; (2) Access Contingency Plan; and (3) Access Succession Plan. Concurrently, there must always be a Vessel Preservation Plan, to ensure viability for future access as required. Therefore, for each vascular access, the Access Needs must include four plans: Vessel Preservation plan, Insertion/Creation plan, Contingency plan, and Succession plan. This comprehensive plan for a patient's Access Needs can be remembered as "ViP ACCeS plans": **V**essel **i**mportant **P**reservation, **A**ccess **C**reation, **C**ontingency, and **E**SKD access **S**uccession Plans.[3] The interventional radiologist plays a critical part in all the four plans. In the past, vascular access maintenance relied heavily on interventional radiologists, e.g., corrective angioplasties, thrombolysis, and stent placements (contingency [or perhaps easier thought of as "complication"] plan); however, the new KDOQI guidelines support expanding their role to dialysis access creation (creation plan) and emphasize the impact of their therapies on future maintenance procedures (contingency plan) and future vascular access choices (succession plans). Many of the guidelines statements refer to an "operator"—interventionalist or surgeon—to highlight this support. Reciprocally, more and more surgeons are being trained to have endovascular skills, so the guidelines also highlight the dual role of surgeons, emphasizing the *multi*disciplinary and *inter*disciplinary culture of vascular access management.

Significant Changes from 2006 Vascular Access Guideline Recommendations that Are Relevant for Radiology/Interventional Radiology

Some guidelines have key changes from the previous guidelines that we have addressed below. These remain challenging topics highlighting the need for further research and rigorous evidence to inform practice.

The Role of Imaging in Planning for Vascular Access

The prior KDOQI guidelines indicated that vascular mapping (e.g., duplex ultrasound) should be performed in all patients before creating AV access. One of the controversial changes of the new KDOQI guidelines is to promote a *selective*, rather than an "all comer," approach to preoperative mapping. This was due to inadequate evidence to support vessel mapping in all patients, whereby patients without a medical history or physical exam suggesting complications with AV access creation could have one created without delay. For example, a young patient with rapidly progressive glomerulonephritis without any other medical history or intervention with good vessels and no contraindications (i.e., the operator was satisfied after clinical assessment) could have an AV fistula created without vascular mapping. However, vessel mapping should be performed in patients who are at a high risk of AV access failure to determine the correct choice of AV access, location, and to help plan for the next access, should the first planned AV access fail. High-risk patients include (but are not limited to) those who are elderly, female, or who have a history of CVCs or peripherally inserted central catheter lines, cardiac pacemakers or other devices, damaged peripheral vessels, or comorbidities that may affect AV access maturation or use, such as peripheral vascular disease and heart failure. Indeed, the list likely encompasses most patients who are currently being mapped, so may not, in practice, be very different from current care.

AV Access Creation: Choice and Location

The ESKD Life-Plan supports an individualized approach to vascular access choice and location. Rather than a typical "distal to proximal" approach for all, it allows for flexibility so that if a patient has limited life expectancy but relatively good vessels, an upper arm fistula first approach may be feasible. At the same time, it also avoids the inappropriate excessive creation of upper arm fistulas to conform to a fistula first approach[4] (i.e., upper arm vessels are typically larger, hence easier to achieve a fistula) in young patients for whom a more distal vascular access is appropriate to allow for additional proximal AV access creations in the future. The guidelines also suggest choosing the AV access site (location) after carefully considering the patient's Life-Plan, life expectancy, and situation (e.g., whether or not a patient needs to urgently start dialysis). Algorithms and an AV access selection tool can be found on *www.myvascularaccess.com*. The guidelines leave room for new technology and options. For example, in guideline 3 on vascular access locations, in the first detailed situation where a patient has long life expectancy, a proximal forearm option using a perforating vein is one of the secondary options. This allows a trained and skilled interventional radiologist the opportunity to create an endovascular fistula with new technology.[5] The research recommendations in this section support further research on endovascularly created AV accesses.

Indications for Endovascular Intervention

The guidelines make a clear distinction between vascular access clinical monitoring (physical exam and indicators found related to the dialysis procedure) and surveillance (requiring specialized equipment and training to properly perform and interpret findings). There was insufficient evidence to support AV access surveillance beyond clinical monitoring, and importantly to use surveillance findings on its own to prompt endovascular intervention. Thus, clinical monitoring of vascular access is primary and surveillance is supplementary.

Table 1 Clinical indicators (signs and symptoms) suggesting underlying clinically significant lesions during access monitoring

Physical exam or check	• Ipsilateral extremity edema • Alterations in the pulse, with a weak or resistant pulse, difficult to compress, in the area of stenosis • Abnormal thrill (weak and/or discontinuous) with only a systolic component in the region of stenosis • Abnormal bruit (high pitched with a systolic component in the area of stenosis) • Failure of the fistula to collapse when the arm is elevated (outflow stenosis) and lack of pulse augmentation (inflow stenosis) • Excessive collapse of the venous segment upon arm elevation
Dialysis	• New difficulty with cannulation when previously not a problem • Aspiration of clots • Inability to achieve the target dialysis blood flow, in the absence of other patient or dialysis factors (e.g. hypotension) • Prolonged bleeding beyond usual for that patient from the needle puncture sites for 3 consecutive dialysis sessions • Unexplained (>0.2 units) decrease in the delivered dialysis dose (Kt/V) on a constant dialysis prescription without prolongation of dialysis duration • Sustained increases in venous pressure during dialysis

Abbreviations: Kt/V, K—dialyzer clearance of urea, t—dialysis time, V—volume of distribution of urea.
Source: Modified from Table 13.2 of KDOQI Vascular Access Guidelines 2019.[3]

Intervention for Stenosis Detected by Surveillance without a Clinical Indicator

The need to have clinically significant peripheral or central lesions in addition to radiographically confirmed stenosis to intervene was reiterated throughout the guidelines. The guidelines do not recommend preemptive angioplasty of AV access (fistulas or grafts) with stenosis, not associated with clinical indicators, to improve access patency. A clinically significant lesion is one that contributes to clinical signs and symptoms (►**Table 1**). Additionally, the guidelines indicate that there is insufficient evidence for KDOQI to make a recommendation on preemptive surgical interventions in AVFs or AVGs with stenosis, not associated with clinical indicators, to improve access patency.

Intervention for Stenosis Detected by a Clinical Indicator

The guidelines do consider it reasonable that when clinical monitoring suspects clinically significant AV access stenosis (►**Table 1**), further timely and confirmatory evaluation should proceed, including imaging of the dialysis access circuit. The timeframe, choice, and extent of imaging studies for further evaluation is dependent on local resources and the severity of findings on clinical monitoring; a timeframe of less than 2 weeks was deemed reasonable.

Importantly, the guidelines consider it reasonable that when further confirmatory imaging studies reveal a culprit lesion (>=50% stenosis) responsible for clinical signs and symptoms, the clinically significant lesion is promptly treated with the appropriate intervention (►**Fig. 1**). The guidelines support balloon angioplasty as the primary treatment of clinically and angiographically significant stenosis. At the time of the guideline writing, there was inadequate evidence to make recommendations on the use of specialized balloons (drug-coated or cutting) versus standard high-pressure balloons, or on the optimal duration of balloon inflation. The Work Group was careful not to restrict the use of specialized balloon as several randomized controlled trials were underway or about to report findings.[6,7] Instead, it advised operators to use them based on the operator's best

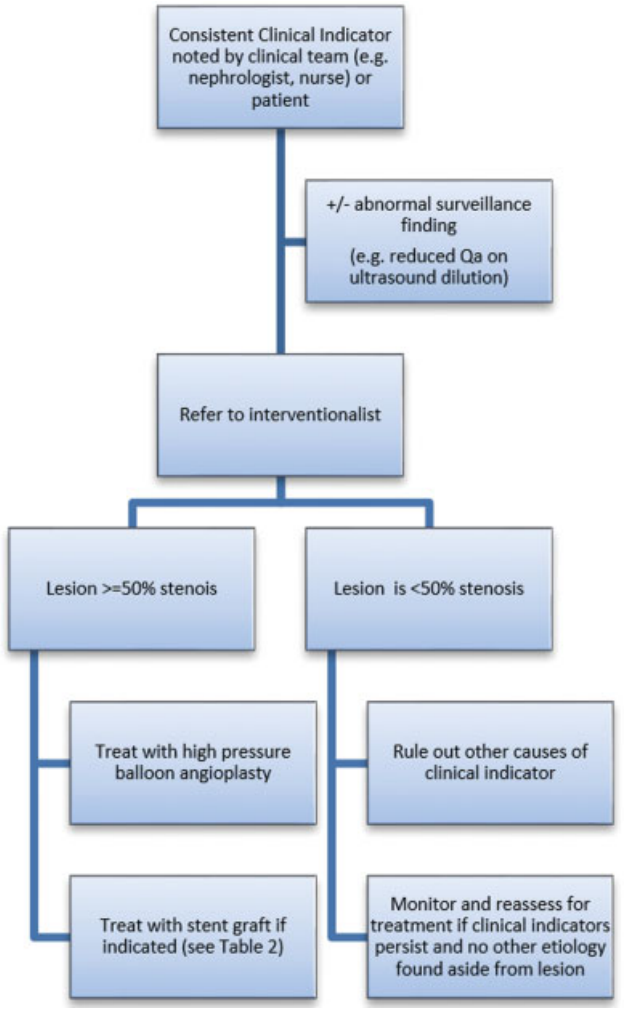

Fig. 1 Algorithm for endovascular treatment of clinically significant lesions.

Table 2 Indication for use of stent grafts in AV access (fistulas and grafts)

• Recurrent clinically significant graft-vein anastomotic stenosis in AVG
• Recurrent graft-vein anastomotic thrombosis in AVG
• In-stent restenosis in AVF and AVG
• Treatment of ruptured venous stenotic segment of AVF and AVG
• Treatment of highly select AV access aneurysm/pseudoaneurysm (see AV access aneurysms section in Guidelines)

Abbreviations: AV, arteriovenous; AVG, arteriovenous graft; AVF, arteriovenous fistula.

clinical judgment and expertise as well as considering outcomes of recent or to be published large randomized studies.

The guideline also suggests the appropriate use of self-expanding stent grafts in preference to angioplasty alone in the following situations: (1) to treat clinically significant graft vein anastomotic stenosis in AV grafts; (2) to treat in-stent restenosis in AVFs or AVGs, when the goal is overall better 6-month postintervention outcomes after carefully considering the patient's ESKD Life-Plan. The ERT could only find adequate evidence for outcomes at 6 months. Beyond this time, the evidence was of poor quality and unreliable to make guideline statements (e.g., the numbers of patients at risk in the individual studies were too small for the ERT to determine impact on 12- and 24-month outcomes.) There was an emphasis on considering the patient's Life-Plan to ensure that stent grafts were not placed in locations that would prohibit future access options (e.g., placement of a stent graft from the distal subclavian vein into the brachiocephalic vein, thereby jailing out the internal jugular vein; extending a stent graft from the cephalic arch into the axillary vein thereby excluding any further arm access creation). In fact, a separate guidance (guideline statement 15.10) is to first consider the consequences of stent-graft placement on future AV access options in consultation with the vascular access team (e.g., surgeon) if necessary, prior to placing the stent graft (i.e., determine if placing a stent-graft will prohibit future AV access creation). Furthermore, the Guidelines Work Group felt it was reasonable to avoid bare metal stents in treating clinically and radiographically significant AV access lesions, as there is no evidence of benefit compared with angioplasty in regard to patency. A summary of indications for stent graft use is given in ►**Table 2**. Lastly, central venous stenosis is a new topic in the guidelines. Consistent with other guidelines statements, the guidelines indicate it is reasonable that if asymptomatic central venous stenosis (without clinical indicators) is identified, it should not be treated.

Guideline Targets

These guidelines recognize that there are local, national, and international differences in practice patterns and emphasize the need to uphold high-quality standards regardless of these differences. Given differences in practices, three primary targets were chosen, rather than a multitude of "to do" targets that may not be applicable to all practices. The targets focus on the patient and the key complications associated with the use of AV access (AVF and AVG) and CVC (►**Table 3**). The second target is particularly relevant for the interventional radiologist. It aims to ensure adequate but avoid excessive endovascular intervention (e.g., needing more frequent intervention than every 3 months or three interventions per year should prompt reevaluation of the vascular access' use and viability by the vascular access team). While it

Table 3 Proposed metrics and targets for vascular access modified from KDOQI Vascular Access Guideline 2019[3]

Target number	Target focus	Measure
1	Patient	Percentage of patients with ESKD Life-Plan established and documented. The patient's P-L-A-N should be reviewed and updated annually. This is *consistent with CMS's condition of coverage (494.90.)* There are 2 main components required: a) Patient Life-Plan: short term and long term b) Access Needs: (i) creation plan, (ii) contingency plan, (iii) succession plan
2	AV fistula or AV graft (AV access)	Intervention goal = "1-2-3" interventions as follows For each 1 AV access creation • There should be $\leq$2 interventions to facilitate AV access use • There should be $\leq$3 interventions to maintain AV access use per year *Access use refers to successful use of AV access with 2-needle cannulation to achieve prescribed dialysis*
3	Central venous catheter	Catheter-related bloodstream infection rate of $<$1.5/1,000 catheter days

Abbreviations: AV, arteriovenous; CMS, Centers for Medicare and Medicaid Services.

suggests a threshold upon which a subsequent vascular access should be considered, earlier evaluation should be considered according to each patient's situation to avoid patient suffering. The rationale for these targets supports the guideline's overarching goal (above), aiming for the ideal vascular access that is reliable, complication-free, able to deliver prescribed dialysis, and concurrently suitable for each patient's individual needs.

Conclusion

The KDOQI Vascular Access Guideline 2019 is a major revision of prior guidelines, with an emphasis on a "patient-first" approach that is supported by a multidisciplinary team. Interventional radiologists play a very significant role in all aspects of vascular access care from planning to creation and the maintenance of hemodialysis vascular access. The guidelines were careful to support new roles and technology relevant for interventionalists; for example, AV access creation (e.g., endovascular fistula) was not limited to surgeons but for qualified operators, including interventional radiologists. At the same time, the guidelines attempt to limit unnecessary procedures by requiring that vascular access lesions must be both clinically and radiographically significant to intervene. The guidelines are expected to bring about a change in practice due to changes in definitions, criteria, and threshold for management, driven by the changing landscape of care and the rigorous standards upon which the guidelines were created. Such high standards emphasize the need for further rigorous research, particularly involving interventionalists, to help inform the next iteration of the guidelines, while we strive to achieve the right access, in the right patient, at the right time, for the right reasons.

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Conflict of Interest
None declared.

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