

Perspectives on Contemporary Use of Covered Stents in AV Access

Dheeraj K. Rajan, MD, FRCPC, FSIR, FACR, shares insights and techniques for arteriovenous stent graft use and placement.



What are the patient and anatomic hallmarks for arteriovenous (AV) stent graft placement candidacy? Who are the noncandidates and why?

My practice follows published outcomes to a large extent with modifications per individual patient situations.

All patients should have a clinical indication of access dysfunction in addition to an anatomic lesion prior to considering any intervention. Stent grafts have been studied primarily for stenosis at the venous anastomosis of dialysis grafts. If the patient has recurrent stenosis within 6 months, I will place a stent graft. If the lesion crosses the elbow joint and/or the dialysis graft was thrombosed, I will preferentially use the Viabahn device (Gore & Associates) because the outcomes in this select group of patients were specifically included in the REVISE study.¹ Several smaller studies have shown efficacy of stent grafts in the cephalic arch, and I also stent this area with a stent graft if stenosis recurs within 6 months. Based on the results of the RESCUE randomized study, which demonstrated superior outcomes of stent grafts at 6 months over plain old balloon angioplasty (POBA), I use stent grafts for > 50% luminal narrowing for bare-metal in-stent stenosis.² Finally, I use stent grafts in patients with central venous occlusions who were technically difficult to recanalize.

Within arteriovenous fistulas (AVFs), there are no published prospective, multicenter, randomized studies, but the AVeNEW study has completed enrollment and follow-up.³ Initial results indicate that stent grafts can also be used for stenoses in AVFs for superior patency, but I will await the published results before making a change in practice.

Noncandidates are patients who have lesions in areas that have not been studied. There are limited published outcomes regarding stent grafts for central venous stenosis and no outcomes for placement of stent grafts in cannulation zones. Beyond these lesion considerations, patient noncandidate considerations are a sensitivity/allergy to nickel or titanium. Another patient contraindication would be an ongoing bacteremia or sepsis in the patient for fear of the stent graft becoming infected.

When beginning a case in which you'll deploy a stent graft, what's your first step in planning? What do you make sure you have on the table?

My first step is to review all the prior interventions performed on the current access, the patient's prior access history, and future access options. In other words, I assess the patient's dialysis life-plan as recommended by the updated Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines. If they remain a good candidate for the stent graft, I then ensure proper imaging of the area to be treated, including

oblique imaging and an assessment of other veins such as the jugular vein and its location relative to the lesion to be treated to avoid excluding possible future access options.

After this, I will have the following on my table:

- An appropriately sized POBA balloon for predilation and also to determine if a correct diameter and length has been used. For example, if the lesion appears to be 6 cm in length, I will use a 6-cm-long balloon rather than a 4-cm-long balloon. This assists in choosing the appropriate-length stent graft
- The correct sheath size for delivery of the device and occasionally one that is 1-F size up if I need to image the lesion with the stent graft across it before deployment
- A wire sufficiently long enough to allow for an easy exchange of the stent graft and rapid troubleshooting if needed
- An appropriately sized balloon for postdilation
- Another device on hand if needed
- A monofilament suture to close the sheath access site

What are your essentials to successful sizing and placement?

When or if available, I review any cross-sectional imaging (eg, chest CT) that would allow for objective measurement of the lesion diameter versus the diameter of the next normal adjacent venous segment or adjacent graft material. If that is unavailable and the lesion is peripheral, I will measure it with an ultrasound before preparing the extremity for intervention.

Again, I review prior imaging to assess what balloon size was used, how it compares in size to an adjacent normal-sized (nonstenosed) vein segment or graft, and the response to angioplasty. From there, I use an appropriately sized (diameter and length) balloon to predilate the lesion, as mentioned previously, to also give me an idea if the stent graft I intend to place is correctly sized for the lesion. It is important to remember that all stent graft instructions for use recommend at least 10% oversizing relative to the diameter of the treated stenosis. If needed, the best fluoroscopic view of the lesion (a view that best profiles the lesion) is obtained, and then, either using bony landmarks or a fluoroscopy mask image superimposed on the active fluoroscopy image, I deploy the device after advancing it to the lesion.

When deploying, I ensure the delivery system is straight with slight back tension on the delivery system. This allows for the device to deploy where expected. Some operators notice the device moving

forward with deployment, which is often the result of the delivery system straightening out and moving slightly forward due to how most devices are packaged in a semicircle. Back tension and keeping the device deployment system in a straight line reduces or eliminates this problem.

Finally, I partially deploy stent grafts slightly beyond (a few millimeters) where I would like to place the device and deploy slowly, usually with the first centimeter deployed, and I then assess if I am satisfied with the location. Because the devices are covered, the device can be pulled back across the area being treated if needed. If satisfied, I complete deployment continuously until the stent graft is fully released.

I always think to myself that I have only one chance to properly place something that is going to be permanently in a patient. I recall the adage “measure twice, cut once.”

What are the key pitfalls to avoid?

- Do not place a stent graft if the percutaneous transluminal angioplasty balloon does not fully efface. If POBA doesn't result in a proper technical outcome, the stent graft will not fully expand, likely leading to access thrombosis or ongoing dysfunction.
- Do not deploy the device with the delivery system bent/curved or around a curve in the access if possible. The operator will have far less control over where the device ends up.
- Do not determine sizing based on an eyeball assessment of the angiogram alone.
- Do not use a wire that is too short and does not allow for troubleshooting or an exchange of the stent graft deployment system if needed.
- Do not place the device in a patient who is bacteremic/septic.
- Do not place the device without considering the impact on a future access. For example, if a stent graft is placed in the cephalic arch and extended far into the axillary vein, the patient may not be able to have another access created in that arm.
- Do not place a stent graft in the cannulation zone unless there is an emergent indication such as pending aneurysm rupture. The stent grafts have not been designed or studied for safety and durability with multiple punctures.

What are you looking for on completion imaging to ensure procedural success?

I look for proper coverage of the lesion with an approximate 1-cm extension of the device on each side of the lesion, rapid flow of contrast through the

access, and that the device diameter has matched the next normal adjacent vein diameter or the dialysis graft diameter.

Where do we stand with respect to data-supported practices in AV stent graft placement? How has the evidence base evolved in recent years?

There have been multiple published level 1 studies of different stent grafts for dialysis graft venous anastomotic stenosis since 2010, but the primary endpoints of these studies have focused on 6-month target lesion primary patency (TLPP). These studies support the use of stent grafts for this outcome. However, secondary endpoints such as access circuit patency at 12 months—which may be more clinically relevant—have not been studied as a primary endpoint. The evidence base has not changed much from the 6-month TLPP endpoint. The upcoming AVeNEW study publication will substantially add to our understanding of the efficacy of stent grafts in AVFs, as there is no prior level 1 evidence in this access type.

Which data do we most need next in this space?

I think we need more hypothesis-driven evidence (rather than observational) that stent grafts have clinically meaningful efficacy beyond 12 months. Such evidence will drive increased adoption of these devices.

You were part of the committee that wrote the revised KDOQI guidelines. What does the document recommend regarding stent grafts?

The guideline suggests 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 (AVGs); and (2) to treat in-stent restenosis in AVFs or AVGs, when the goal is overall better 6-month post-intervention outcomes after carefully considering the patient's end-stage kidney disease life-plan. Beyond 6 months, the evidence was of poor quality to make guideline statements. Selectively, stent grafts can be considered for treatment of ruptured venous stenotic segments of AVFs and AVGs and highly select AV access aneurysms or pseudoaneurysms.

A separate guidance statement considers the consequences of stent graft placement on future AV access options in consultation with the vascular access team, if necessary, prior to placing the stent graft (ie, to determine if placing a stent graft will prohibit future AV access creation). Also, 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 regarding patency. ■

1. Vesely T, DaVanzo W, Behrend T, et al. Balloon angioplasty versus Viabahn stent graft for treatment of failing or thrombosed prosthetic hemodialysis grafts. *J Vasc Surg*. 2016;64:1400–1410.e1. doi: 10.1016/j.jvs.2016.04.035
2. Falk A, Maya ID, Yevzlin AS, for the RESCUE Investigators. A prospective, randomized study of an expanded polytetrafluoroethylene stent graft versus balloon angioplasty for in-stent restenosis in arteriovenous grafts and fistulae: two-year results of the RESCUE study. *J Vasc Interv Radiol*. 2016;27:1465–1476. doi: 10.1016/j.jvir.2016.06.014
3. Clinical study of the BARD® COVERA™ arteriovenous (AV) stent graft (AVeNEW). Clinicaltrials.gov website. Accessed May 10, 2022. <https://clinicaltrials.gov/ct2/show/NCT02649946>

Dheeraj K. Rajan, MD, FRCPC, FSIR, FACP

Professor

Division Head, Vascular/Interventional Radiology

University of Toronto

Toronto, Ontario, Canada

dheeraj.rajani@uhn.ca

Disclosures: Consultant for W. L. Gore & Associates and Becton Dickinson.