

ROUNDTABLE DISCUSSION

Percutaneous AVF Creation in Practice

A multidisciplinary discussion on patient selection, achieving proficiency, procedural tips, and the importance of collaboration.

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Based on our current understanding of the technology and its capabilities, which patients are the ideal candidates for percutaneous arteriovenous fistula (pAVF) creation? What does your candidacy workup include?

Dr. Jennings: Individuals in whom a permanent vascular access is appropriate and where radiocephalic fistula is not feasible may be evaluated for a potential pAVF. Ultrasound mapping is a critical component and should include confirmation of vessel sizes and locations with ultrasound examination by the treating physician. The presence of a deep communicating vein (DCV) that is normal in appearance and 2 to 2.5 mm in diameter is necessary. An adequate upper arm outflow vein is required. This is most often a cephalic vein but should also include the median cubital vein into the basilic system or a brachial vein as the first stage in planning for a later transposition. For most patients, careful ultrasound

examination in concert with physical examination and careful history remain the key elements of evaluation.

Dr. Lok: Candidates for pAVF are patients who are deemed ineligible for a distal forearm fistula (eg, snuff-box, wrist radiocephalic) and those who want to avoid open surgery, irrespective of age. Important criteria for pAVF include the presence of a perforating vein and vessels of adequate diameter. Therefore, workup includes an ultrasound to assess these criteria. As with all AV accesses, there should be an absence of central occlusion, and any evidence of central occlusion based on history or physical examination, which should be done as part of any evaluation and planning for any type of vascular access, could be further assessed by venography.

Dr. Urbanes: The ideal candidate for pAVF would be dictated by anatomy and system infrastructure. The optimum anatomy will allow for the creation of an AVF percutaneously. For successful, continuous use of pAVFs,

use and monitoring are required by the health care infrastructure, which must understand the place of pAVFs in the continuum of renal replacement modalities and access options, as well as by dialysis clinics, which will need to support informed and thoughtful cannulation.

Dr. Aruny: At the Dialysis Access Institute, we treat two general groups of patients: those with chronic renal insufficiency (CRI; stage 4) not yet on dialysis and those with end-stage renal disease currently on dialysis. Patients with end-stage renal disease who have just started hemodialysis and have a catheter in place are all evaluated with ultrasound for pAVF creation. Oftentimes, patients who have run out of access options are seen at Dialysis Access Institute with tunneled catheters that have been in place for some time. Although we have no absolute catheter presence time, as the time approaches 4 months, the immediate goal is to remove the catheter and establish some type of running blood access. Unless there is very favorable venous and arterial anatomy, these patients are more likely to receive an immediate cannulation graft or HeRO graft (Merit Medical Systems, Inc.), depending on the circumstances.

Patients with CRI who have not started dialysis and are seen for access creation are all evaluated for pAVF along with brachiocephalic and brachio-basilic fistulas. Evaluation for fistula creation at the Dialysis Access Institute is with color-assisted duplex ultrasound. First, patients are evaluated for a distal radiocephalic native fistula; but if this is not an anatomic option, pAVF is considered. Because the pAVF is based upon the Grac or deep fistula, it is essential that an adequate perforating vein be present to permit flow to the cephalic and/or basilic veins that will be the cannulation site(s)—that is, either ≥ 2 -mm perforating vein at the anastomotic site or an outflow cephalic and/or basilic veins ≥ 2 mm within a centimeter of the skin surface. The proximal radial artery should have a ≥ 2 -mm luminal diameter with the adjacent vein ≤ 1.5 mm apart (edge to vessel edge). A Barbeau test is also performed to confirm ulnar artery dominance as well as blood pressure measurements in both arms to evaluate proximal artery inflow.

Which patients are categorically not good candidates for pAVF at present?

Dr. Lok: From an anatomic standpoint, individuals who do not have a perforating vein or with target vessel diameters < 2 mm cannot have a pAVF. From a clinical standpoint, patients who have movement disorders or are “restless” on dialysis where elbow movement is excessive may not be ideal candidates, depending on cannulation sites and needle placement.

Dr. Urbanes: Patients with variations of vascular anatomy precluding successful pAVF creation would be the only categoric cases in which a pAVF would not be

considered, and this would be infrequent. Arm size and, consequently, the depth of the vessels from the skin might dampen the enthusiasm for a pAVF, but even in these circumstances, a surgically created AVF would likely require additional procedures to facilitate consistently safe and convenient access to the AVF.

Dr. Aruny: The exclusion criteria for pAVF are very similar to those for surgically created fistulas. Patients with poor artery inflow that will not be able to support adequate blood flow for dialysis are not considered. Patients with inadequate venous outflow are also excluded. The venous anatomy of the antecubital fossa is quite variable, and anyone who performs these procedures should be familiar with the variants. Patients whose perforating vein is absent or does not directly communicate with either the cephalic or basilic vein but does communicate with the brachial veins are not good candidates. However, if the vascular surgeon is skilled at performing a brachial vein elevation, then the procedure can be performed if adequate blood flow into the brachial veins can be established.

Dr. Jennings: Currently, most individuals who would be expected to have a successful radiocephalic AVF should have a distal AVF created instead of a pAVF. However, there may be patient considerations in which a forearm AVF is not desirable. We may see changes to the radiocephalic-first strategy in the future with new technology, further investigations, and follow-up (importantly, an Ellipsys vascular access system [Avenu Medical, Inc.] percutaneous proximal radial artery AVF does not preclude a radiocephalic AVF later). Individuals with no adequate outflow veins (no cephalic vein or no communication to the basilic system) should have a basilic transposition, if possible. Otherwise, a brachial vein transposition may be completed in a second stage using a pAVF brachial outflow as the first stage.

With the availability of plastic cannulas in Europe for early pAVF cannulation along with ultrasound when needed, Ellipsys pAVFs coupled with these techniques may even replace many early cannulation grafts.

What is your impression of the learning curve associated with pAVF creation? How many cases does it take to become proficient?

Dr. Urbanes: When most think of the education related to pAVF creation, it is often focused almost entirely on the procedure itself, with preprocedural planning and postprocedural follow-up only peripherally discussed. The education surrounding pAVF must include candidate selection, preprocedural planning, mapping and procedural approach, postprocedural follow-up, ancillary procedures, and collaboration with the dialysis units for cannulation plans. One's comfort with performing the procedure, including these aspects of care, should readily

be achieved in about 10 cases for the physician who is not a novice in endovascular medicine.

Dr. Aruny: The learning curve for becoming proficient is highly dependent on the experience of the operator coming into the procedure. Someone skilled with ultrasound and catheter manipulation can become proficient in five cases. Anyone just becoming familiar with ultrasound imaging and this anatomy can expect to perform at least 10 cases before becoming comfortable with the creation.

Dr. Jennings: Our group has just begun our pAVF experience. We have had technical success in creating a pAVF for all our initial patients and are awaiting maturation outcomes for most of these cases. There is clearly a learning curve, and proctoring is necessary for the first cases. Remember, the pivotal multicenter trial evaluating the Ellipsys vascular access system had only two rollout cases per physician and the results were excellent.¹ When one individual in a group becomes proficient, then that physician will be able to proctor and lead others more quickly. The number may be as few as two cases but may take five to 10 to be comfortable.

Dr. Lok: There is a learning curve. The number of cases to achieve proficiency depends on the training beforehand (eg, whether training involving practice pAVF creation using cadaveric models is available and conducted). For the WavelinQ endoAVF system (BD Interventional), it also depends on the approach taken to the target vessels. For example, a brachial approach is more challenging than a radial approach.

In the end, the procedure can be straightforward with the proper training. In the NEAT pivotal study, only two roll-in patients were required.² However, in a real-world setting, it may take five to 10 cases, depending on the approach taken and the desire for operator proficiency with multiple approaches. What is often underestimated is the learning curve for the selection of patients and, importantly, the multidisciplinary teamwork required for the postprocedure monitoring, cannulation, and maintenance of the pAVF.

What are some key elements of the learning curve that are most helpful to share before a physician's first case?

Dr. Aruny: First, become familiar with the antecubital anatomy and its variants and how to recognize them during ultrasound screening. Next, be able to appreciate the appearance of the needle tip on ultrasound and how to advance it within a small vein (eg, for use with the Ellipsys system). Furthermore, become proficient in puncturing the small radial/ulnar artery and vein (eg, for use with WavelinQ system). It may sound trite, but placing peripherally inserted central catheter lines is excellent training for these procedures.

Dr. Lok: From a nonproceduralist's standpoint, having a streamlined process in place for the patient from

consent to discharge from the recovery room (involving a multidisciplinary team) will help put the patient and operator at ease. Although the patient is clearly important, the proceduralist needs to focus on the procedure, not patient logistics. When we first started creating pAVFs, we would walk through the steps before each case, both for the patient and the procedural steps. Each team member had a job, knew where to be, and knew when to do their job, like any procedure. We became so proficient that each of us could anticipate what the other required for the next step in the process. I started to really understand (although seemingly obvious) that some of the procedural keys to success were the correct use of the C-arm to ensure proper visualization and the absolutely correct alignment of the electrode and backstop prior to firing to create the WavelinQ pAVF. Other tips we have learned include the need for patience to achieve initial vessel access (although access has been greatly facilitated with the newer 4-F technology) and postprocedural manual pressure to avoid the use of closure devices.

Dr. Jennings: For the Ellipsys system, representatives are available until you are comfortable performing the procedure, and the website has many resources—take advantage of that! We are early in our experience with Ellipsys, but here are some observations:

- Consider a regional block for anesthesia. This may have procedural benefit by dilating the veins to make initial cannulation easier.
- Even if vessel mapping is done elsewhere, the operator must complete ultrasound confirmation of vessel sizes, appearance, and location.
- The DCV may emerge from the median cubital or the median cephalic vein. Both are suitable for Ellipsys cannulation, and the DCV will almost always connect to the radial vein adjacent to the radial artery. Your ultrasound examination will define this anatomy.
- Before puncture, be comfortable with rotating the ultrasound back and forth from transverse to longitudinal. The same two views are used through 90° rotation as needed.
- Select the needle puncture site considering the extent of the final maturation balloon (5 mm X 2 cm) deployment to be entirely within the vein. Avoid inflating the balloon along the wire as it exits the vein wall cannulation site.
- A rolled towel under the arm above the elbow will stabilize the cubital fossa anteriorly.
- Regarding the ultrasound advancement technique, to advance the needle through the perforating vein, use the transverse view, advance the needle a few millimeters, move the ultrasound probe just past the tip, then advance the needle and move the probe again, and repeat.

Identifying a “crossing point” (wire crossing vein to artery) is important (use transverse and longitudinal ultrasound views). After creating the AVF, balloon dilatation should include this site a few millimeters past the anastomosis. In patients with a high brachial artery bifurcation, the radial artery in the cubital fossa is more mobile. This is acceptable to use for the Ellipsys system, but it may be a bit more difficult to cannulate.

What potential peri- and postprocedural complications might occur specifically unique to pAVF creation as compared with surgical creation?

Dr. Lok: There is really no significant difference between the WavelinQ pAVF and surgical AVF complications after creation. Of note, there is no requirement for suture or staple removal for the pAVF; consequently, there is no related scarring. Patients should still expect some arm swelling, bruising, and even some mild hand tingling. When we first started performing pAVF, we used slings and bandages after creation and quickly learned that this was unnecessary and accentuated postprocedural signs/symptoms as compared with a small band-aid at the access site.

Dr. Jennings: No major complications have occurred with any Ellipsys procedure to my knowledge. Of course, all pAVF procedures are performed after determining that the opposite forearm (radial or ulnar) arterial supply to the hand is intact, so hand ischemia should not be a problem. There are no reports of aneurysm formation or radial artery thrombosis with the Ellipsys system. The cardiovascular experience with harvesting the radial artery would suggest that this should not be a threatening complication even if it occurs. Both the Ellipsys and WavelinQ devices may need maturation procedures such as balloon angioplasty and banding, coiling, or ligation of side branches. All of these should be addressed with interventional techniques already available to the physician creating the pAVF.

Dr. Urbanes: Some of the advantages of pAVF over a surgical AVF are also its own limitations. Image-guided, minimally invasive procedures have numerous advantages but are also limited by an operative field that is not open to visual inspection. Injury to perivascular structures is possible but has not been reported with any higher frequency with pAVF versus surgical AVF creation. Postprocedural complications have not been reported with any higher frequency with pAVFs than with surgical AVFs. In theory, the incidence of postprocedural ischemic injury to the distal circulation would be expected to be lower with the pAVF because of the low-flow nature of the fistula, the smaller caliber of the feeding artery, and the precision with which the anastomosis is created.

Dr. Aruny: Rare pseudoaneurysms at the anastomosis creation site have been reported with the WavelinQ device. With the Ellipsys system, we perform 5-mm balloon angioplasty across the new anastomosis at the time of creation. It is important to be able to recognize the position of the balloon with ultrasound so as not to dilate too deeply into the radial artery. If you are performing the procedure on the ulnar artery and vein, be sure to perform a Barbeau test to ensure good perfusion of the hand with the radial artery and avoid the potential of hand ischemia if the ulnar artery becomes injured.

The postprocedural complication that concerns me is early thrombosis of the new access. To help curb this, we perform duplex ultrasound in the recovery area immediately after the procedure and at 1 and 3 weeks postprocedure. Forearm compartment syndrome could be an issue if a pseudoaneurysm bleeds.

What is your impression of the relative cost-effectiveness of pAVF? How do the procedural and facility/operating room/stay costs differ? At what point in the time to maturation does the cost balance out or become advantageous?

Dr. Urbanes: Cost of AVF creation should include the constellation of procedures and encounters that lead up to a working and functional AVF, not just the procedure itself. The end goal is to have an AVF that is clinically functional and serves the purpose of consistently and safely providing cannulation access and blood flows needed to meet the dialysis prescription. An AVF that is not functionally useful or not consistently and safely useable is worthless regardless of any cost or resource savings associated with it. Given the maturation failure rates of pAVFs versus surgical AVFs and the associated procedures needed to enhance maturation, it appears that pAVFs might have lower associated overall costs. Larger, real-world experience is needed with all modalities of pAVF so that these can be compared with the far wider experience with and history of surgical AVF creation.

Dr. Jennings: A proximal radial artery access with moderate flow is associated with lower complication rates for steal syndrome, arm swelling, and congestive heart failure when compared with brachial artery inflow. These benefits should be seen with pAVFs and accompanied by related cost savings.³⁻⁶ The potential for even greater anticipated benefit and savings (but yet to be proven by extensive experience) is that pAVFs will be more successful with better autogenous patency rates, fewer necessary interventions, and decreased complications than surgical AVFs in the long term.

Dr. Aruny: Depending on which device is used, the time of the procedure varies between 20 and 90 minutes once the operator has become efficient. At our Dialysis

EVT DEVICE GUIDE UPDATE: PERCUTANEOUS ARTERIOVENOUS FISTULA CREATION

Company Name	Product Name	Size (F)	Maximum Guidewire Compatibility (inch)	Catheter Working Length (cm)	Recommended Introducer Size (F)	Fistula Site(s)	Outflow
Avenu Medical	Ellipsys Vascular Access System	6	0.014	–	6	Proximal radial artery to perforating vein	Direct to superficial venous system (cephalic and basilic veins) through the perforating vein
BD Interventional	WavelinQ EndoAVF System	4	0.014	43 (venous catheter); 50 (arterial catheter)	5	(1) Concomitant ulnar artery and ulnar vein; or (2) concomitant radial artery and radial vein	Split-flow fistula (cephalic or basilic vein)

Note: This chart has been added to *Endovascular Today's* Device Guide.

To stay up to date on these and all other available vascular interventional devices, download the Device Guide app or visit www.evtoday.com/device-guide.

Abbreviation: DC, direct current.

Access Institute, all procedures are performed in rooms dedicated to vascular access on an outpatient basis. Cost comparison is complex. Value is expressed as outcomes favorably appreciated by the patient versus cost of attaining that outcome. For example, if a patient with stage 4 CRI has a fistula in place when they start dialysis and the need for a catheter is avoided, then this has a positive value signal. This should be true even with cost parity because the patient favorably appreciates a needle puncture over a surgical incision with that associated discomfort.

Dr. Lok: Early studies suggest that WavelinQ pAVF is associated with fewer procedures within the 12 months after creation.^{4,7} I suspect this may be related to less vessel manipulation in creating the anastomosis as compared with traditional surgical creation. Fewer procedures tend to translate to less overall cost. However, these earlier studies compared clinical trial data for the pAVF group with administrative data for the traditional surgical AVF group. To overcome related inherent biases, a comparison of outcomes and costs of pAVF and surgical AVF created under real-world conditions is necessary.

What collaborative processes and procedures should be in place prior to pAVF creation to (1) educate the patient about pAVF, (2) best facilitate successful cannulation and use, and (3) address potential complications or revision?

Dr. Urbanes: Education is crucial for the successful long-term deployment of this new and exciting technology, and

it spans the entire breadth of all the possible touch points of the patient. The clinical nephrologist must be informed enough to be able to present this option to the patient and be comfortable enough discussing patient selection with the interventionalist. The interventionalist must be rigorous in their patient selection and appreciate that the creation of an AVF, whether percutaneously or surgically, must be understood within the lifelong renal replacement plan and goals of the patient. Caring for access problems devoid of clinical context, history, or trajectory has been a failure of the health care system for which our patients' wellness has been compromised. Patient education and an honest and genuine informed consent is nonnegotiable. Education of and partnership with the dialysis unit cannot be overstated. Our nurses and dialysis technicians must be comfortable evaluating these accesses and cannulating and caring for them. The clinical assessment of and cannulation techniques for the pAVF is fundamental to success. Many technologies have been scuppered in the past because of failure of implementation at the dialysis unit level. Demonstrated best practices must be shared freely and openly so as to benefit the greatest number of patients. Partnership with others regarding surveillance modalities and algorithms, for example, should be encouraged.

Dr. Aruny: Success with pAVF is best achieved when it is approached as a comprehensive program and not an isolated procedure. The elements of the program include screening patients, educating patients, performing the procedure with the necessary resources available to perform secondary

Access	Mechanism of Action	AV Connection	Energy Source	Imaging Guidance	Adjunctive Procedures
Single puncture, venous	Thermal tissue fusion	Fused and permanent anastomosis	Ellipsys power controller (low voltage DC)	Ultrasound	Balloon dilation
Venous and arterial	Radiofrequency ablation	Platelet deposition and endothelium development of fistula tract	Electrosurgical unit (BD ESU-1)	Fluoroscopy and ultrasound	Recommended embolization of a brachial vein at index procedure

procedures if needed, and, perhaps most importantly, education of the dialysis units tasked with cannulating the fistulas. Here is a brief description of how we have implemented each element at the Dialysis Access Institute:

Screening. We find it helpful to identify certain ultrasound technicians as leaders. We worked to compose a worksheet that describes the measurements that we use to make a decision regarding the type of access that can be offered to the patient.

Patient education. All patients who are candidates for fistula creation speak with a physician to help them understand their options. Patients often come to us requesting pAVF, and it is challenging to explain why they may not be candidates. Patients with stage 4 CRI who have been informed by their nephrologist that they will need dialysis are experiencing many emotions. It is more acceptable to them if they can have a fistula created with one or two needle punctures rather than be subjected to a surgical procedure. Patients need to understand that there will likely be secondary percutaneous procedures even with pAVFs to help mature these fistulas to the point of being functional. After discussing the options, some patients prefer an immediate cannulation graft to avoid waiting for fistula maturation or the possibility of needing additional procedures.

Performing the procedure. Clinicians involved in the program, including nephrologists, surgeons, and interventional radiologists, should collaborate and understand the elements of the procedure and where each one may have special expertise vital to the success of the program. If you create a fistula with dominant brachial vein flow, you will need a surgeon skilled in performing brachial vein elevation so it can be accessed. Collaboration with the nurses and technologists in the procedure room is also important for setting up the procedure room properly and having familiarity with operating the devices.

Educating the dialysis units. pAVFs do not have the appearance of surgically created fistulas. Instead, their appearance is subtle and dialysis unit staff need to be educated on the anatomy of the fistula and the cannulation process. A major advancement that will support the adoption of pAVFs will be the global adoption of ultrasound use in the dialysis units to aid in cannulation.

Dr. Jennings: The Ellipsys percutaneous proximal radial artery AVF is the same configuration that has been my most common access operation for decades. These modest flow pAVFs should be cannulated in the same way as proximal radial artery surgical AVFs. Flow may develop through the median cubital vein in addition to the cephalic vein, and both may be cannulated. If cannulation of the median cubital vein is difficult or additional flow through the cephalic vein is needed, then the median cubital vein may be banded or ligated.

Cannulation should always be undertaken with a tourniquet in place at time of puncture. Availability of

ultrasound for first cannulation is particularly valuable in obese individuals. The physician creating the pAVF should see the patient for follow-up prior to first cannulation, mark the cannulation zone, and review this information with both the patient and the dialysis nurse, just as for all surgical vascular access patients.

Although surveillance of a vascular access has not been proven to be clearly helpful, monitoring by the dialysis staff is valuable with immediate contact for an evaluation by the treating physician when an abnormality is detected, such as high pressure, low flows, and difficult cannulation. Collaboration between the interventionalist and surgeon is always a key element of success.

Dr. Lok: Collaboration must be in place for all three aspects. It must be a team approach whereby a different team member may lead at different phases, but all team members are included in each step. For example, it is critical for the nephrologist to be aware of and fully educated about the procedure—not only because the nephrologist refers the patient to get the procedure but also to educate and guide the patient in a manner reflecting true informed consent in order for the patient to freely agree to the procedure in the first place. It is the nephrologist who is there at the beginning of the patient's journey. The patient will ask the nephrologist for their opinion about pAVF and whether it should be an option for them. The vascular access coordinator coordinates any pre- and postprocedural tests and appointments. This coordinator educates the patient in terms of what to expect and how to prepare for the procedure. If the surgeon is not the operator, they must be involved to understand the procedure in case any complications occur that require their skills and as part of the team when thinking about the next vascular access. Per the new Kidney Disease Outcomes Quality Initiative guidelines, prior to creating a new vascular access, an access contingency plan and access succession plan (ie, what to do when the access goes wrong and what access comes next) must be in place. Clearly, all team members—patient, nephrologist, interventionalist, and surgeon—must be involved in this discussion. The same players must be involved, along with the vascular access coordinator, after the pAVF is created to monitor its progress and assess its “readiness for cannulation and ongoing maintenance needs.” ■

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