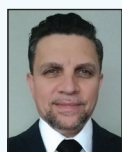


PANEL DISCUSSION

Percutaneous AV Fistulas: Where Do We Stand?

Experts discuss what the availability of pAVFs has meant for practice, patient selection, outcomes of pAVF versus surgical fistulas, cannulation after pAVF creation, and referral successes and challenges.

With Alejandro Alvarez, MD; Neghae Mawla, MD; Robert Shahverdyan, MD; and Allison Tan, MD


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Two percutaneous arteriovenous fistula (pAVF) creation platforms have been developed, with each gaining market clearance and being acquired in the past several years. What has this meant for interest in the science and practice surrounding AVF creation in general?

Dr. Alvarez: The technology allows interventionalists to create fistulas in addition to surgeons, and the biggest impact is that patients have access to a larger number of practitioners who can create arteriovenous (AV) access. It must be kept in mind that most published studies are premarket studies that were done in expert centers, so we

still need to see how those findings translate into real-world practice. We need to be realistic of the implications, advantages, and capabilities of this technology for our patients.

Dr. Shahverdyan: For several years, two pAVF devices have been available, Ellipsys (Medtronic) and WavelinQ (BD Interventional). Both devices use the deep communicating vein (perforator) at the proximal forearm but create the anastomosis at slightly different locations and by different means. Typically, the perforator and this location have been previously used to create the surgical “Gracz-type” fistula, first described by Gracz and colleagues in

1977,¹ creating the surgical anastomosis between the perforating vein and proximal radial or distal brachial artery.

The WavelinQ 4-F system uses radiofrequency energy to create an anastomosis between either the proximal radial artery and radial vein or proximal ulnar artery and ulnar vein. The location of the anastomosis should be as close as possible to the perforating vein but distal to it, in order to “lead” the blood flow through the perforating vein into the superficial upper arm target veins. This can be supported by coil embolization of an outflow brachial vein, creating resistance and increasing the superficial flow.

With the Ellipsys system, the anastomosis is created exactly at the level of the perforating vein between the proximal radial artery using thermal energy, leading to direct and dominant outflow through the perforating vein into the superficial upper arm veins. Hence, the location of the Ellipsys anastomosis is slightly proximal (cranial) than that of the one created by WavelinQ.

After almost 60 years since the first description of AVF,² it was an extraordinary milestone to be able to create an AVF without incisions. Both systems give us the option to create an AVF without tissue damage, hence reducing the scar, possible neurologic damage, and irritation, and adding the possibility to cannulate in the cubital region and increase patient satisfaction. Moreover, experienced interventionalists who work closely with nephrologists, sonographers, and vascular surgeons in a multidisciplinary team can create those by endovascular means.

Several publications and experiences have demonstrated the still-existing possibility and successful creation of one pAVF after another failed pAVF and a surgical AVF (sAVF; radiocephalic or Gracz) after both types of pAVF have failed in the same arm.^{3,4} Thus, in general, both systems allow an additional creation of technically and functionally successful native vascular access, usually without compromising preexisting or future surgical AVF creation possibilities in the same arm.

Dr. Mawla: The two platforms allow for more options for these patients. Both have proven to be solid, viable options for vascular access and each has a role. However, each system has its own criteria, so not every patient is eligible for both systems. Keeping both systems on hand allows us the most options to serve our patients.

Dr. Tan: The fact that the two pAVF devices on the market have each been acquired by large medical device companies speaks to the safety and efficacy of the technology. The larger parent companies will be able to provide the resources needed for the best technical and clinical support, patient follow-up, and continued device evolution. Combined with the continued interest in the media and at

national meetings across specialties, this will hopefully help further clinician interest and give practitioners the confidence to begin including pAVF in their practices.

Has pAVF creation improved outcomes for AV access compared to sAVF creation, and if so, in which patients or settings?

Dr. Tan: I think we’re still answering this question. As a community, we remain in the earlier stages of clinical follow-up. We will need to see more long-term data to clearly understand if patients have better outcomes with pAVFs than with sAVFs. However, keep in mind that for many patients, we are not choosing percutaneous access instead of surgical but including it in the access algorithm alongside sAVFs.

Dr. Mawla: sAVF and pAVF seem to have at least comparable outcomes in terms of maturation and development, but the index procedure for pAVF may be better tolerated in the elderly and frailer patients.

Dr. Shahverdyan: There have been many adopters of pAVF systems worldwide, and excellent outcomes have been reported for both the WavelinQ and Ellipsys systems.⁴⁻⁸ High technical success, maturation, and functional patency rates and a low incidence of adverse events are the main advantages of pAVFs. Moreover, allowing cannulation of the typically superficially located cubital veins due to the lack of scar tissue is another advantage, leading to early cannulations (< 14 days) to avoid the placement of a dialysis catheter. Additionally, some reports described significantly shorter procedure times.^{3,4}

Limited single-center and retrospective publications have compared pAVFs with sAVFs.^{3,9,10} Whether compared to distal radiocephalic AVF,⁹ proximal forearm Gracz-AVF,³ or distributed forearm/upper arm AVFs,¹⁰ pAVFs are not only as good as sAVFs but also significantly better in several aspects. The only exclusion of a successful pAVF creation is the lack of anatomic suitability as per the requirements of the system. The absolute knowledge of the anatomy prior to the procedure, in addition to ultrasound and endovascular skills, is crucial for a successful pAVF creation.

As previously mentioned, pAVFs typically don’t interfere with sAVF creation options, hence adding possibilities for long-term functional vascular access by keeping the options open for further sAVFs.

Dr. Alvarez: I think it’s too early to tell. The physicians who have implemented these technologies have really tried to establish a patient flow from the moment of screening through to creation, maturation, and cannulation. It is likely that this has an additional impact on outcomes. The few single-center after-market studies comparing sAVFs with

pAVFs have had conflicting results. Osofsky et al compared brachiocephalic fistulas to Ellipsys AVFs, and sAVFs had better outcomes compared to Ellipsys endovascular AVFs (endoAVFs).¹¹

Shahverdyan et al evaluated the Ellipsys system as compared with proximal Gracz-type sAVF and reported better outcome for Ellipsys.³ A small single-center study in Europe by Inston et al reported better outcomes with WavelinQ technology as compared with surgical radiocephalic AVFs.⁹ That said, more studies comparing sAVFs and pAVFs outside of postmarketing studies need to be performed to better inform practice. These technologies are changing the culture of how AVF programs are run and streamlining workflow for these patients.

How do you determine whether a patient is better suited for sAVF than pAVF and vice versa? What are the keys to assessing patients to match them with the best option for their anatomy and needs?

Dr. Mawla: The primary decision is anatomic, and generally, a distal radiocephalic is preferred over an endoAVF. However, we consider the end-stage kidney disease life plan, “the right access, in the right patient, at the right time, for the right reasons,” and discussions with patients may lead to an endoAVF over an sAVF. This is often encountered in my geriatric population, particularly the octogenarians, who may choose and prefer an endoAVF procedure over an sAVF. In addition, an endoanastomosis with a median cubital/basilic outflow provides additional venous length compared to a surgical brachiocephalic fistula. This median cubital may be considered for cannulation without always requiring a full basilic vein transposition.

Dr. Alvarez: The first thing is screening following standard criteria: the superficial vessels should be ≥ 2.5 mm in diameter and the feeding vessels ≥ 2 mm in diameter. For pAVF, the perforating vein needs to be patent and adequately sized (≥ 2 mm based on studies, but my preference is ≥ 2.5 mm). If a patient is a candidate for a distal fistula, I recommend sAVF first and refer to vascular surgery. If the patient would fare better with an upper arm AVF, I typically recommend pAVF.

Dr. Shahverdyan: At our vascular access center, pAVF is implemented into the vascular access creation algorithm, as previously reported.⁴ We usually do not prefer pAVF to sAVF or vice versa, unless a patient exclusively prefers pAVF. Based on the patient’s dialysis and life plan, typically the first choice is a distal forearm sAVF, starting in the snuffbox location. If radiocephalic AVF is not possible, ulnarbasilic AVF is (rarely) the possible next choice. When distal anatomy is

not suitable, the next consideration is a proximal forearm AVF option. Here, due to the location of anastomoses, we consider first a WavelinQ pAVF and next the Ellipsys pAVF option. The next choice in the sequence plan is a proximal forearm sAVF (the typical or modified Gracz-type sAVF) when pAVF is anatomically not feasible or failed. If no proximal forearm options are available, we proceed to the upper arm for brachiocephalic and brachiocephalic AVFs. When neither forearm nor upper arm superficial veins are available, based on each patient, we consider either a native brachial-brachial AVF, which (depending on patients’ anatomy) we prefer to create using a pAVF system with brachial vein outflow given the advantage of a proximal forearm anastomosis and gaining longer transposition length and expecting less risk of high flow or hemodialysis-induced hand ischemia due to a forearm anastomosis, or an AV graft.

Preoperative ultrasound assessment of every upper arm artery and vein is crucial for planning vascular access. By applying the above-mentioned algorithm, this distal-to-proximal surgical and percutaneous vascular access choice is considered when the inner diameter is ≥ 2 mm for both artery and vein (using tourniquet). All patients considered for pAVF require a perforating and at least one suitable outflow vein with inner diameters of ≥ 2 mm using a tourniquet, unless a brachial-brachial AVF is planned. Of course, for each pAVF system, the specific anatomy is required, such as a distance of ≤ 1.5 mm between the proximal radial artery and perforating vein for Ellipsys system. For WavelinQ, the proximal radial or ulnar artery and vein require ≥ 2 -mm inner diameter, a < 2 -mm distance between the artery and vein, and the access vessels for both arterial and venous catheters need to be suitable for a 4-F device (≥ 1.5 mm) and be directly connected to the “anastomosis-creation site target vessels” to be able to advance to create the anastomosis. The only specific exclusion criterion for pAVF is not meeting the anatomically suitable vessel requirements based on the previously mentioned inclusion criteria.

Dr. Tan: Determining the best access for a patient is dependent on not only anatomy but also the patient. The ultimate goal in most patients is to extend the usability of the upper extremity for hemodialysis access. The best way to do this is to establish access in a peripheral-to-central approach, assuming eventual access failure, either immediate or delayed. Therefore, if a patient is a radiocephalic sAVF candidate, I will always recommend that first. If not a radiocephalic candidate, I look for appropriate anatomy for pAVF creation.

Patients can have anatomy that puts them along a spectrum of candidacy. Straight perforators and large diameter upper arm superficial veins promote good maturation post-pAVF creation. It is possible for a patient to have candidate

anatomy that is more borderline. In this latter population, a frank discussion about the likelihood of success, the potential need for secondary procedures, and the possibility of fistula nonmaturation is important before proceeding. If a patient would like to proceed with pAVF knowing that success is not guaranteed, it is reasonable to move forward. Otherwise, I will defer to surgical access creation if the patient is very hesitant about pAVF and/or I have reason to believe that they will be poor at follow-up. Although poor follow-up is not ideal for both surgical and percutaneous options, sAVF troubleshooting is more easily done by any clinician, whereas pAVF access management is currently best done by physicians who create pAVFs.

Not all pAVFs work well enough for cannulation. What are the knowns and unknowns that affect maturity for subsequent use?

Dr. Tan: There are many reasons a pAVF may struggle or fail to reach maturity. With experience, we have learned that a more tortuous perforator vein can negatively impact maturation, making perforator mapping important for predicting the likelihood of success. Additionally, some fistulas will change flow patterns over time, complicating maturation unexpectedly. For example, a cephalic-dominant fistula at creation may evolve weeks later to a basilic-dominant or split-flow fistula, or even show flow diversion back to the deep veins in the upper arm. It is difficult to predict in which patients this will occur and is likely related to the size of more central communicating branches providing less resistance to flow as the veins enlarge. Unfortunately, this flow rerouting can prevent maturation and subsequent cannulation depending on the period of evolution. Fortunately, alterations in flow can be remedied with branch ligation or coiling. Similar to sAVFs, some patients fail to have sufficient venous dilatation for maturation and, as seen in all AVFs, men typically have better venous maturation than women. Overall, patients who adhere to follow-up, are more educated about their disease, and employ self-advocacy overall have better outcomes.

Dr. Alvarez: Most of the issues I've seen are related to flow to superficial vessels and development of stenosis and its treatment. The essence of the issue is how to successfully obtain high enough flows into the superficial vessels—coil a deep vessel or angioplasty the path from the deep to superficial venous system. With side-to-side anastomosis, sometimes stenosis can develop, especially where the anastomosis or the perforating vein connects to the deep veins (either the proximal radial veins or common ulnar vein). If there is a stenosis along that path from the deep venous system to the superficial venous system, that stenosis needs to be treated. If there's no stenosis in that pathway, then

the deep system needs to be coiled to redirect flow into the superficial vessels.

Many pAVFs have split flow. It's important to educate centers on cannulating the antecubital basilic and cephalic vein. If that fails, the next step would be to divert the flow to the cephalic vein, which would mean either completely ligating or banding the antecubital basilic vein.

Dr. Shahverdyan: As in every AVF, not all can work well enough and require secondary interventions to be able to cannulate. pAVFs are not much different in our experience. However, to achieve successful cannulation of pAVFs, it is crucial to understand the anatomy (multiple outflow veins), because multiple outflow veins are often possible. This leads to a low pressurized cannulation vein despite placing a tourniquet because the outflow through the deep venous system still drains the fistula flow despite it. Similarly, during an ultrasound examination of pAVFs to assess the maturation, it is important to identify which of the outflow veins have sufficient flow, and if not, why. If the initially expected pre-procedural target cannulation vein doesn't have sufficient fistula flow, there is either another vein with lower resistance (most commonly the basilic vein) or a juxta-anastomotic/perforating vein stenosis, which "redirects" the flow into the deep venous system. We assess the pAVFs for maturation after 4 weeks postcreation. Actually, in our experience, if it is not matured at 4 weeks, it is extremely rare to expect maturation by just waiting further. If the preoperative vessel mapping and general assessment (eg cardiac output, adequate arterial flow, no known outflow/central venous obstructions) were performed correctly, one of the most common reasons for nonmaturation is the (juxta)anastomotic stenoses. By treating those, the maturation is commonly achieved.

After pAVF creation, what issues are there regarding cannulation at the dialysis center?

Dr. Mawla: Cannulation remains the great challenge for endoAVF success. Compared to an sAVF, the cannulation location is different, the feel of the vessel is different, and the vessel is more superficial. Thus, these three nuances need to be appreciated for successful cannulation. The cubital cephalic and median cubital veins are endoAVF cannulation zones but are not typical cannulation zones for sAVF.

Dr. Shahverdyan: After the pAVF is successfully matured (≥ 5 mm target vein diameter, superficial enough, ≥ 500 mL/min brachial artery volume flow with ≥ 300 -400 mL/min target vein flow), the dialysis center should be informed about the target vein location, size, and flow. Every patient is then marked on the arm where the cannulable vein is located, and a pAVF drawing is made for further understanding of that patient's pAVF anatomy.

The main issues with cannulations we have encountered are difficulties palpating the vein and successfully cannulating it. In most cases, a tourniquet has not been placed as recommended, with cannulations too high at the beginning, which is more difficult due to less pressure in the vein. Ultrasound-guided cannulations and using plastic cannulae for 2 to 4 weeks significantly increase the success of pAVF cannulations.

Dr. Tan: Although the superficial outflow vein access of a pAVF is extremely similar to upper arm sAVF anatomy, the newness of the pAVF procedure can introduce a bit of anxiety into cannulation. Adding to the uncertainty is the lack of tell-tale surgical scars, leading to stories of patients being told they don't have a fistula when they do! For mature pAVFs with cannulation difficulty, we often see the issue being a combination of the inherent qualities of pAVF that are actually desired. These include lower flow volumes resulting in a softer target vein, smaller vein diameters, and potentially deeper vein positions (especially in native, non-translocated basilic veins). Less experienced cannulators can struggle to access in these conditions. Because these factors are desired qualities of pAVFs (eg, lower flow volumes combat aneurysmal dilation, heart strain, intimal hyperplasia), an emerging focus in the pAVF community is strengthening cannulation support and training to provide the best-quality hemodialysis access care possible, which will help improve not only pAVF but sAVF access rates as well.

Dr. Alvarez: pAVFs are different than sAVFs in terms of flow and feel. Because pAVFs are a side-to-side anastomosis, there is a much smoother laminar flow and high flows into the superficial vessels; however, for an end-to-side fistula, pulsation is very marked with compression. The important thing is making sure to use tourniquets to enhance the pressure in the fistulas. Initially, the nurses were a bit intimidated to cannulate pAVFs, but with vein mapping and techniques like using the tourniquet, they can be assured that what they are feeling is the target vessel, increasing cannulation success.

What clinical trials are most vital for this space going forward, and what must be explored or proven next?

Dr. Shahverdyan: Although many practitioners would request a randomized controlled trial (RCT) comparing pAVF with sAVF or one pAVF device with another, several significant difficulties are associated with undertaking one. For example, which surgically created AVF should be considered as a comparison group for pAVF? The only closely similar sAVF would be the proximal forearm Gracz-type sAVF. However, not many surgeons/interventionalists can perform

both pAVF procedures or both pAVF and Gracz-sAVF, because they have not been trained. Therefore, the RCT would have to include less specialized centers that would be required to perform a high number of both sAVF and pAVF procedures. Also, in my experience, many patients would reject being included in such a study; if given an option of sAVF or pAVF, more would not wish to have an access being chosen "by fate" and would opt out more for a minimally invasive, scarless procedure. It would eventually lead to many years of including the patients in such a study, also making the financial burden impossible to fulfill. Hence in my opinion, it will not be possible to do an RCT. The next step would be for physicians to use both pAVF systems and publish their experience with both pAVFs and sAVFs to obtain more prospective study data.

Dr. Mawla: I would like to see longevity data on endo-AVF, not just in viability but also with any required interventions for maintenance. I suspect that with lower flows through the superficial vessels, issues like cephalic arch stenosis might be fewer with endoAVF than sAVF.

Dr. Tan: The RCT is the medical gold standard for proving effectiveness of new interventions, and ultimately an RCT comparing sAVFs to pAVFs would be an important contribution to the literature. This type of research would certainly help guide clinicians who are hesitant to bring this newer technology into their practices. There are however, many barriers to designing and implementing such a study. Data describing which patients are more likely to mature to durable cannulation to facilitate the patient selection process, in terms of anatomy and clinical presentation, will enable operators to feel more confident when building a pAVF practice. Additionally, more published research about issues that arise with pAVFs and effective troubleshooting techniques would help clinicians feel more capable of servicing and maintaining their pAVF patients.

Dr. Alvarez: Postmarket studies need to be performed and completed to gather more data. I think that's a good first step. Then, RCTs to compare pAVFs and sAVFs would be ideal. To develop a standard of care, we'll also need to compare pAVF technologies head to head to determine which system should be used to create a fistula in a particular location (ulnar or radial).

What are the barriers to wider adoption of pAVF, and how might they be addressed?

Dr. Tan: I actually think we are seeing a fairly rapid increase in the adoption of pAVF device implementation across specialties. Existing barriers are likely to be very clinician/practice specific and may include administrative bar-

riers to device onboarding (especially in more financially restrictive COVID times), difficulty establishing referral patterns, and lack of patient disease process education and reliability. Many of these issues could be simultaneously addressed by establishing a formal multidisciplinary approach to dialysis patient care, which would strengthen requests for institutional support and streamline patient referral, procedure selection, and follow-up. Addressing patient education would benefit greatly from a larger national public education focus on end-stage renal disease to supplement the process of physician-to-patient one-on-one education. If the community surrounding a patient has more disease knowledge and understanding, then the patient will by default have wider access to trusted knowledge, which would hopefully translate into better self-advocacy and outcomes.

Dr. Alvarez: Procedure time is a potential barrier to adoption—it takes longer to create a pAVF than an sAVF. With increased experience, pAVF procedure time can be reduced, but I don't think it is realistic to say procedure time will be equivalent to creating an sAVF. Second, we don't definitively know whether pAVFs are superior to sAVFs or vice

versa; although maturation and secondary patency rates for pAVFs were better than those of sAVFs in premarket studies, we need more head-to-head studies and longer-term outcomes.


Dr. Shahverdyan: There are many reasons practitioners may not want to adopt the pAVF technology, such as openness to a new (and possibly better) way of creating feasible vascular access; knowing and understanding the anatomy required; ultrasound skills; working in an interdisciplinary team to be able to perform possible secondary procedures (endovascular interventions, surgical transpositions); and costs for the technology. Device costs might be an issue at the beginning of creating the pAVF, but we shouldn't forget that patients get a (hopefully long-term) functioning additional vascular access with low complications and mostly secondary "cheap" endovascular procedures, which expands and prolongs the possibilities of their life plan.

Dr. Mawla: Ultimately, success is defined by cannulation and use not by flow or size parameters. So, cannulation challenges often are discouraging to nephrologists, dialysis staff, and other patients. In addition, delay in cannulation results

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
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in delays in catheter removal, and this is a large barrier to the early adoption of endoAVF.

What successes and challenges have you encountered with respect to referrals for pAVF creation? What advice do you have for those seeking to improve their referral relationships?

Dr. Alvarez: It's very important to maintain a good relationship with the entire multidisciplinary team. pAVFs are not going to replace sAVFs—it's just another tool. Just like sAVFs, pAVFs at some point will need surgery or reintervention. As an interventional nephrologist, the emphasis on a thorough and accurate initial screening and vascular mapping has been key to success. Based on these results, the patient is scheduled as soon as possible for endoAVF if he/she is an optimal candidate or is immediately referred to a surgeon if the patient is more suitable for an sAVF. We're very respectful of the referral patterns of the nephrologists that trust us with their patients. In the end, when we're caring for patients with AV access issues in general, we are an extension of the practice of the referring nephrologist. With this philosophy, we have been able to have an excellent reception in the community.

Dr. Mawla: Patients are the biggest advocates for care, and their stories can be inspiring and motivational. They can be huge proponents for endoAVF once they've been successfully cannulated for dialysis. They often promote the endovascular option to their physicians, dialysis staff, and others around them. For new endoAVF practices, I think it is important to set guidelines for adoption. Maturation may take longer, especially for dual outflow. Cannulation adoption will probably take longer as well. Setting expectations for adoption and growth are key to building a solid program.

Dr. Shahverdyan: Referring nephrologists initially were skeptical about the new, unknown devices and fistula. Approximately 4 years ago, there was little knowledge about midterm outcomes of pAVFs, especially in Europe. Hence, it was important for me to involve referring nephrologists in the decision-making process. At that time, I had hypothesized that pAVF wouldn't and shouldn't replace the sAVF but would serve as an additional option for the patients, and I am more than convinced now having performed > 170 pAVFs. By creating our vascular access creation algorithm,⁴ both types of pAVFs could have been (and can be) implemented into the vascular access plan of our patients by starting from distal access first and moving proximally. If distal is not possible, pAVFs can be created at the proximal forearm before moving to surgical (Gracz, brachiocephalic,

brachiocephalic) options. With this algorithm, referring nephrologists are aware that pAVF is typically performed if a distal sAVF is not possible.

Another advantage of pAVFs (other than keeping future surgical options available) is that they reduce the risk of high flow when compared to an AVF in the upper arm brachial artery and thus reduce the risk of AVF aneurysmal formation, cardiac overload, and dialysis access–induced distal ischemia due to a forearm artery–based anastomosis.

My advice is to involve the referring nephrologists in decision-making and explain the advantages of pAVFs. Moreover, several publications have demonstrated excellent outcomes of pAVFs, which would be a good basis for practitioners to show referring nephrologists.

Dr. Tan: The most successful referral base has been from nephrology colleagues with which our interventional group had a preexisting relationship providing other renal services, including biopsies, fistulagrams, peritoneal dialysis access, and hemodialysis catheter placement. We additionally have regular multidisciplinary conferences together, which facilitated open communication that streamlined the introduction of pAVF into our practice.

Referral acquisition strategies greatly depend on the practitioner performing the procedure. Vascular surgeons for example already have a well-established referral relationship with nephrologists and therefore need to focus on building education and trust in the pAVF procedures within their referrers. Interventional radiologists, however, may have a more difficult time inserting themselves into that dynamic and should focus on building personal relationships with referrers and trust through other service offerings. Finally, bringing information to dialysis centers and patients directly can help promote education and build self-referral from the community. ■

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