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Percutaneous Creation of Arteriovenous Fistulas: Starting a Successful Patient-Centric Practice

With Rishi Razdan, MD; Ari Kramer, MD; and Terry F. Litchfield, MPA, CPC

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In 2019, the United States Renal Data System reported that there were just under 750,000 individuals with end-stage renal disease (ESRD) in the United States. Of those individuals, 62.9% were using an arteriovenous fistula (AVF) for hemodialysis.¹ The surgical techniques to create an AVF were first reported in 1966²; however, endovascular technologies to create AVFs have only emerged in the past 5 years. This has begun to change practice, but much like other historical shifts from open surgical to minimally invasive endovascular procedures, a new way to approach patient care is required. In this panel, three vascular access professionals discuss how they began working with endovascular techniques to create percutaneous AVFs (pAVFs) and how to ensure that these procedures make a difference to vascular access care by maximizing successful dialysis and minimizing time spent on a central venous catheter (CVC).

How were you introduced to pAVF, and what made you interested in trying this procedure?

Dr. Razdan: I was originally introduced to the concept of pAVF at the Society of Interventional Radiology (SIR) and American Society of Diagnostic and Interventional Nephrology (ASDIN) annual conferences. I was then further exposed to this type of fistula at physician conferences within my own organization (a group of primarily outpatient offices and surgery centers). What was most intriguing about the procedure was the ability for an interventionalist to create a fistula without open surgery and offer a service to eligible patients who may not have quick, easy access to a vascular surgeon for hemodialysis access creation. This became especially relevant during the COVID pandemic when hospital resources were inundated and AVF creations delayed due to appropriate triaging of those same resources.

Dr. Kramer: My experience was similar. Initial exposures at conferences like Controversies in Dialysis Access (CiDA) and ASDIN introduced me to the technology, and the good outcomes of the procedures spoke for themselves. This was a technology that could increase timely access to fistula creation, especially in those places where vascular surgeons don't have as much bandwidth to create fistulas.

Ms. Litchfield: I first heard about pAVF creation at scientific meetings where the future state talks hinted about fistula with no surgery. At the time, I was Head of Operations for Lifeline Vascular, and we were always interested in technology that advanced patient care in vascular access. We had the opportunity through DaVita to meet the founders of Avenu Medical, Mark Ritchart and Ed Chang. At that first meeting, with my Medical Directors Drs. Gerald Beathard and Aris Urbanes present, I knew it was going to be a radical change for patients and for AV access. The evolution from open surgery to endovascular procedures had long been underway to treat the coronaries, aortic valves, peripheral arteries, and carotids, and it was incredible to see this finally happen for AV access creation, more than 50 years since the first paper was published about surgical creation.² As the spouse of a patient who spent 46 years on dialysis, the hope that he would not have to continue the cycle of surgery was very appealing, in addition to the excitement of the innovation.

What were your first five pAVF cases like? How has your patient selection criteria changed over time, and what drove this evolution?

Dr. Razdan: Although many interventionalists feel their technical skills are excellent, there is still a learning curve with any procedure performed for the first time. Conceptually, pAVF is akin to creating a transjugular intrahepatic portosystemic shunt in a patient. There is subtle tactile feedback that must be experienced to gain a comfort level with the pAVF procedure. Needle resistance, soft tissue tension, and imaging familiarity with the anatomy are all important factors in gaining comfort with Ellipsys™ vascular access system (Medtronic) creations. After my first several cases, my comfort level with cannulation has dramatically improved.

Dr. Kramer: Before I started a pAVF practice, I had several misconceptions: these fistulas would look and feel the same as surgical fistulas, creation would be easier with pAVF, I would need to improve my ultrasound skills, my knowledge of anatomy and current paradigm of maintenance would be the same, and it would simply be a similar procedure for a similar outcome. However, that wasn't the case. Like any new technology or technique, there's a learning curve in patient selection and device use, but what I didn't consider was the differences in the fistula itself that make the road to successful cannulation and dialysis so challenging. The procedure and device are the much easier and

straightforward part of the overall goal, which is to create fistulas that reliably undergo two-needle cannulation. The cannulation component is where the more significant learning curve takes place, and of course, as there are many more people involved in that part of the procedure, there are a lot more learning curves to address.

Ms. Litchfield: Lifeline Vascular centers were three of the pivotal sites for the Ellipsys investigational device exemption trial, so I was able to witness five cases at the sites. It was amazing, and I could not believe what I saw. Dr. Jeffrey Hull was there to train the doctors and our team. I was bullish on the technology from the beginning, but once I saw it work, I was a passionate supporter.

Did you encounter any resistance to adopting pAVF as a treatment strategy in your site of service? If so, what were the hurdles, and how did you overcome them?

Dr. Razdan: I was lucky enough in my location and practice to have excellent nephrologists and referring practitioners who trusted my judgment with initiation of a pAVF program. They relied on my ethical stance to avoid a new technology if the outcomes were poor. In addition, full disclosure was offered to the patients and referring practitioners regarding the data and immature nature of the pAVF technology. I found that offering relevant data and managing expectations on pAVF helped assuage concerns of both patients and referrers.

Dr. Kramer: As a high-volume center, I have the opportunity to try many different new technologies to gain experience, and my center trusts my judgment when it comes to adoption after an initial pilot phase.

Ms. Litchfield: Since the Lifeline centers are all out-of-hospital sites of service, some of the barriers were reimbursement and surgeon resistance of such a new innovative technology. The nephrology and dialysis communities were very receptive given that catheter rates at that time in 2018 were almost 20%.¹ They knew that an AVF has the best outcomes for their patients.³ As the body of data has increased, use of pAVF has gained additional support from the surgical community. Reimbursement remains a work in progress, with support from specialty societies such as SIR, Renal Physicians Association, ASDIN; the Dialysis Vascular Access Coalition; and patient organizations such as the American Association of Kidney Patients (AAKP) and Dialysis Patient Citizens. All are advocating for this technology with the insurance payers, surgical providers, and Medicare about the need for reimbursement.

How do you work with your nephrology colleagues during this process?

Dr. Razdan: My line of communication with my nephrology colleagues is one of the most important parts of my

practice. Once a patient was screened appropriately for pAVF creation, I initially asked if the nephrologist was comfortable with me performing the creation. If not, I was happy to refer to whomever they requested. On the contrary, if they were amenable to the pAVF creation, it was imperative that the creation occurred expeditiously, sometimes the same day as the initial screening process. This has slowly morphed into the nephrologists directly referring me patients for pAVF evaluation and free reign to perform the creations if deemed fit.

Dr. Kramer: As a full-time access surgeon, I have a good relationship with my referring nephrologists. It's been fairly straightforward to convince them that while I think I'm doing a good job in surgery, I myself am a variable, and the pAVF technique is standardized: It's an opportunity to reduce procedural morbidity.^{4,5} Beyond that, these lower-flow, endovascularly created fistulas will have less cardiac demand, less steal, and the potential for less neural injury,^{4,6} and those are incredibly important to me, the nephrologists, and the patients.

Ms. Litchfield: Nephrologists must be educated on pAVF so they can make informed choices about the best access solution for their patients. Continuing to educate at national nephrology meetings and webinars along with local educational offerings is important to ensure exposure to the technology, the newest clinical results, and patient benefits.

How do you interact with cannulation teams at the dialysis clinic?

Dr. Razdan: My office has an excellent front desk staff and marketing group, who have both an open line of communication and interact very regularly with the dialysis clinics. As such, a member of my office has offered to be present during the first cannulations of pAVF patients in the hemodialysis centers. Once a center's cannulation team has successfully cannulated a pAVF patient, the cannulation teams are oftentimes comfortable cannulating future patients without our assistance, but someone from our staff is typically available if requested.

Dr. Kramer: Truthfully, I think one of the most unfortunate things about care of dialysis patients is the way that we've accepted current standards of two-needle cannulation success at dialysis clinics. Approximately 30% to 50% of the cases I perform every day as an access surgeon are to address complications from bad needle technique—something that comes directly from not having the appropriate tools and training. These procedures can have an incredibly negative effect on a patient, from hospital admissions to requiring a temporary CVC. This is not the pathway anyone wants to see an ESRD patient land within.

To be crystal clear: Cannulators are remarkable individuals in the work they do every day. These facts are not in any way meant to malign or blame an individual cannulator; these are systemic challenges. Most often, cannulators are not set up for success, and they have a relationship with their access creation and maintenance partners that's a very one-sided chastisement to the cannulation teams of, "You ruined this patient's access!" The script needs to be flipped here, full stop. Everyone has a responsibility to ensure the right access is created at the right time, for the right patient and that the access can be used for as long as possible. Cannulators need additional training, support, and tools. We can't just say that will happen; it must actually happen. They are the day-to-day lifeline of dialysis patients, and the lack of investment in that profession as a whole is unacceptable. Too often, the throwaway line you hear is, "Turnover is so high. No wonder things go wrong!" That line can absolve you of the guilt of not taking the time to look for other solutions. If this was easy, it would already be fixed. Dialysis centers have been in a place where they can't achieve meaningful success, and we've failed clinics by not hearing their concerns.

To me, this new technology of endovascular creation of fistulas provides us with an incredible opportunity to improve cannulation success at dialysis clinics, not just for endovascular fistulas but for all dialysis patients and cannulators. I know this can sound like an overstatement, but because of my new use of endovascular fistulas, I've been able to work with the dialysis center to pilot a point-of-care ultrasound program. I think this will make a huge difference for the cannulator experience and decrease cannulation injuries. That will ultimately improve dialysis for all patients, not only those with endovascular fistulas.

Ms. Litchfield: It varies by the dialysis clinic; however, I think a good practice was developed in the pivotal trial. The interventionalists I observed marked the cannulation landing zone on the patient's arm, and site managers (who were also former dialysis nurses) went to the centers for the first cannulation. One of our site managers, Daniel Mullins, wrote the first white paper on cannulation of a pAVF.

How do you involve patients in the choice of fistula or their care after fistula creation? What are the most critical components of patient education, and how do you deliver that education?

Dr. Razdan: I will spend a significant amount of time during consultation and initial vein mapping discussing the pros and cons of pAVF if a patient is a candidate. Often, patients present to the office specifically requesting pAVF because they have friends or fellow patients who underwent pAVF creation with excellent results. Many patients are also trying to avoid hospital visits, especially during the COVID-era, which further supports the need for creations in an outpatient setting. The absence of a surgical scar is another factor in the decision-making process for many patients.

Patient education is arguably one of the most important factors in success and longevity of a hemodialysis access. After an access is created, our office will review the palpable and audible characteristics of a fistula with the patient and their family members and emphasize calling the office directly if something changes with these characteristics. In addition, we discuss sleeping habits and activity habits to avoid direct physical compression of the pAVF. Lastly, we reinforce asking questions of the physicians and our staff if something is unclear. Communication is tantamount to success of both the access and patient health.

Dr. Kramer: We begin education on our immediate introduction to the eligible patient. We have printed patient educational sheets that describe the various modalities available for patients who need dialysis. Additionally, we have an ongoing dialogue with the patient and family regarding the various options available that make the most sense for them and meet their expectations for care. We feel that the most critical component of patient education is their direct involvement in understanding how their access should look and feel and make them aware of how critical a functioning dialysis access circuit is to maintaining a healthy life. Acting as a resource for patients to call with questions and schedule evaluations of access-related concerns helps us mutually avoid unnecessary procedures or late complications of commonly encountered access failure modes.

Ms. Litchfield: Patient education is key. Patient choice is patient voice, and we had heard the reluctance of many patients regarding catheters and not wanting surgery to create a fistula, so this gave them an option to improve their care. In addition, making sure patient associations are up to date on pAVF was critical. Patient education is multifactorial. First, you need a trusted source (nephrologist, dialysis nurse) to begin the conversation, and there must be validation of those conversations in the patient community. Ensuring materials are in the necessary language and educational level for patients to understand is another factor. We used posters in the dialysis clinic waiting rooms to educate patients related to pAVF and provided center staff with materials. It helped greatly when Azura Vascular Care developed a national educational brochure on pAVF for all patients that is freely available online.⁷ AAKP also sponsored a webinar for vascular access early in the COVID pandemic to speak to pAVF.⁸

What are the three biggest factors in building and establishing a successful pAVF creation practice?

Dr. Razdan: (1) Communication and relationships with referring nephrologists, (2) ultrasound and technical skill set, and (3) dedication to successful use of the pAVF access for dialysis.

Dr. Kramer: (1) Investment in training and tools at dialysis access clinics, with point-of-care ultrasound being especially important; (2) taking responsibility for the patient's access prior to creation and through to abandonment—successful two-needle cannulation is the metric, not blood flow velocity or time in the operating room; and (3) having a growth mind set that there are always things you can do to improve as an interventionalist, but you must be willing to own up to your mistakes.

Ms. Litchfield: (1) Engage the nephrologists, dialysis clinic, and especially the patient; (2) make sure your interventional team is ready for this service line and is excited about the process and the procedure; and (3) follow-up with the patient, the dialysis unit, and the nephrologist often to seek feedback on what you could have done better.

Is there anything else you'd like to share about your pAVF experience?

Dr. Razdan: An interventionalist must have a vested interest in the success of their pAVF practice and each patient's pAVF. The physician must be willing to think outside the box in different scenarios of maturation or flow dynamics and spend time maturing the fistula for successful cannulation, thus minimizing tunneled dialysis catheter dwell times and yielding improved overall mortality and morbidity. pAVF creation uses disruptive technology, leading to exciting new options for our patients and allowing the ability to offer excellent and expeditious care in a cost-effective, safe manner. This is truly a game changer.

Dr. Kramer: My experience with pAVF has been very favorable for our practice and our patients. The enhanced communication between the total access team (nephrologist, clinic, patient, and our staff) has allowed for quicker notification of access-related or other potential issues that might have otherwise not been addressed in any meaningful time frame. We have streamlined our education process to include the patient to more directly be participants in their own care. Finally, we have updated our clinical pathways and have created a much richer multidisciplinary experience to optimize the success of our access planning.

Ms. Litchfield: As a patient advocate, I would like to share what excites patients about pAVF creation over surgical creation. In a survey of pAVF patients, most respondents were fearful of surgery and either their own experiences with failed AVF creations or their dialysis center friends' experiences. The cosmetic aspects of a large, bulging upper arm fistula is a major source of concern, especially with female patients. The cost of hospital-based fistula surgery was always on their minds. Finally, because we remain in a pandemic, our patients want to avoid a hospital stay at any cost. A pAVF is a solution that involves a minimally invasive

procedure to achieve an AVF. I recall so well my husband's many (37) fistula surgeries—the hospital stays, the sometimes huge incisions, the pain and suffering as the surgical site healed, and then the frustration when it didn't work. Add in my missed days at work and the cost of our deductibles and copays, and you can understand why this solution is a gift to many patients. ■

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Ellipsys system Reference Statement

Indications

The Ellipsys™ system is indicated for the creation of a proximal radial artery to perforating vein anastomosis via a retrograde venous access approach in patients with a minimum vessel diameter of 2.0 mm and less than 1.5 mm of separation between the artery and vein at the fistula creation site who have chronic kidney disease requiring dialysis.

Contraindications

The Ellipsys™ system is contraindicated for use in patients with target vessels that are <2 mm in diameter. The Ellipsys™ system is contraindicated for use in patients who have a distance between the target artery and vein > 1.5 mm

Warnings

- The Ellipsys™ system has only been studied for the creation of an AV fistula using the proximal radial artery and the adjacent perforating vein. It has not been studied in subjects who are candidates for surgical fistula creation at other locations, including sites distal to this location.
- The Ellipsys™ system is not intended to treat patients with significant vascular disease or calcification in the target vessels.
- The Ellipsys™ system has only been studied in subjects who had a patent palmar arch and no evidence of ulnar artery insufficiency.
- Use only with the Ellipsys™ Power Controller, Model No. AMI-1001.
- The Ellipsys™ Catheter has been designed to be used with the 6 F Terumo Glidesheath Slender™. If using a different sheath, verify the catheter can be advanced through the sheath without resistance prior to use.
- Use ultrasound imaging to ensure proper placement of the catheter tip in the artery before retracting the sheath, since once the distal tip of the catheter has been advanced into the artery, it cannot be easily removed without creation of the anastomosis. If the distal tip is advanced into the artery at an improper location, complete the procedure and remove the catheter as indicated in the directions for use. It is recommended that a follow-up evaluation of the patient is performed using appropriate clinical standards of care for surgical fistulae to determine if any clinically significant flow develops that require further clinical action.

Precautions

- This product is sterilized by ethylene oxide gas.
- Additional procedures are expected to be required to increase and direct blood flow into the AVF target outflow vein and to maintain patency of the AVF. Care should be taken to proactively plan for any fistula maturation procedures when using the device.

- In the Ellipsys™ study, 99% of subjects required balloon dilatation (PTA) to increase flow to the optimal access vessel and 62% of subjects required embolization coil placement in competing veins to direct blood flow to the optimal access vessel. Prior to the procedure, care should be taken to assess the optimal access vessel for maturation, the additional procedures that may be required to successfully achieve maturation, and appropriate patient follow-up. Please refer to the "Arteriovenous Fistula (AVF) Maturation" section of the labeling for guidance about fistula flow, embolization coil placement, and other procedures to assist fistula maturation and maintenance.
- The Ellipsys™ System is intended to only be used by physicians trained in ultrasound guided percutaneous endovascular interventional techniques using appropriate clinical standards for care for fistula maintenance and maturation including balloon dilatation and coil embolization.
- Precautions to prevent or reduce acute or longer-term clotting potential should be considered. Physician experience and discretion will determine the appropriate anticoagulant/antiplatelet therapy for each patient using appropriate clinical standards of care.

Potential Adverse Events

- Potential complications that may be associated with creation and maintenance of an arteriovenous fistula include, but may not be limited to, the following:
 - Total occlusion, partial occlusion or stenosis of the anastomosis or adjacent outflow vein
 - Stenosis of the central AVF outflow requiring treatment per the treatment center's standard of care
 - Failure to achieve fistula maturation
 - Incomplete vessel ligation when using embolization coil to direct flow
 - Steal Syndrome
 - Hematoma
 - Infection or other complications
 - Need for vessel superficialization or other maturation assistance procedures.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Important Information: Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device.

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