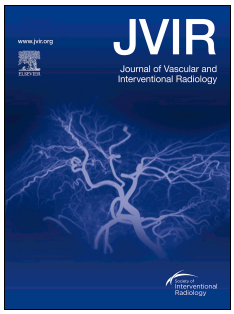

A Society of Interventional Radiology Practice Guidance Document on Percutaneous Arteriovenous Fistulas for Dialysis Access

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A Society of Interventional Radiology Practice Guidance Document on Percutaneous Arteriovenous Fistulas for Dialysis Access

Abstract

The Society of Interventional Radiology's (SIR) Renal and Genitourinary Clinical Specialty Council formed a workgroup in collaboration with the SIR Guidelines and Statements Division to create up-to-date society-based consensus recommendations for the creation and maturation of percutaneous arteriovenous fistulas (pAVFs) for hemodialysis access. This practice guidance document serves as a summary of what is required to develop a pAVF program, including patient preparation, performance of the procedure, complication management, and follow-up care.

Introduction

The first autologous hemodialysis arterio-venous fistula (AVF), created between the radial artery and cephalic vein, was described in 1966 (1). Since then, there have been new types of AVFs, AV grafts, dialysis catheters, and other devices and methods to create hemodialysis access. Nevertheless, hemodialysis access remains a major source of patient morbidity and mortality, as well as cost to the healthcare system. The 2019 Kidney Disease Outcomes Quality Initiatives vascular access guidelines recommend that the selection of vascular access type and location be based on the patient's individual end-stage kidney disease life plan (2). When appropriate and possible, a strategy creating distal AVFs and subsequently proximal AVFs is preferred over AV grafts and catheters. In these guidelines (2), endovascular creation of an AVF (pAVF) was a novel technique since both pAVF devices had been FDA-cleared less than one year prior. Now, more than six years after FDA clearance, pAVF creation has been incorporated into many clinical practices and can result in durable and functional hemodialysis access (3,4).

With this in mind, this practice guidance document may serve as an important review of what is required to develop a pAVF program and a poignant reminder that the future for interventional radiologists to create percutaneous hemodialysis fistulas is in flux.

Methods

The Society of Interventional Radiology's (SIR) Renal and Genitourinary Clinical Specialty Council formed a workgroup in collaboration with the SIR Guidelines and Statements Division to create up-to-date society-based consensus recommendations for the creation and maturation of percutaneous arteriovenous fistulas (pAVFs) for hemodialysis access. This consensus guidance

document was made based on peer-reviewed literature. When peer-reviewed literature was absent, statements were created using workgroup members' expert opinions.

This group utilized a modified Delphi process to develop and achieve consensus on guidance statements. Once the guidance statements were finalized, the workgroup members voted anonymously to accept, edit, or reject each one. Only statements achieving 80% consensus, with 100% participation in voting, were included in the document after two rounds of voting.

Patient Selection and Vessel Mapping

Guidance Statements for Patient Selection and Vessel Mapping
1. A thorough patient history and physical examination should note any prior or current thoracic central venous devices that may cause venous obstruction. Assessment of collateral circulation through the palmar arch can be done with the Barbeau Test, although this is not required.
2. Vessel mapping is essential for successful pAVF creation, evaluating inflow arteries, perforator vein(s) and superficial outflow veins.
3. Interventional Radiologists should participate in mapping whenever possible.

During a detailed patient history, note past or current thoracic central venous devices (pacemakers or catheters) that can cause central venous obstruction, as well as all prior AV access surgeries. Physical exam should include an assessment of brachial, radial, and ulnar pulses, a Barbeau Test (5) (Figure 1), or other non-invasive tests to confirm radial and ulnar communication through the palmar arch. Superficial chest collateral veins may indicate chronic thoracic venous obstruction that warrants further evaluation prior to pAVF creation.

The ideal candidate for a pAVF will have thin arms, non-calcified arteries of the arm with normal arterial Doppler exam, a patent palmar arch, suitable venous anatomy, and patent thoracic central veins. However, even with all of these features, when a patient can undergo a surgical Brescia-Cimino AVF or snuff-box AVF at the wrist, these surgical options may be considered before pAVF creation. If the forearm veins cannot be used for a surgical AVF, then pAVF becomes a more attractive option.

Other factors that favor a pAVF over a surgical AVF include lack of surgical availability, lack local surgical expertise, and patient preference. Moreover, patients who are rapidly approaching the need for dialysis may be good pAVF candidates since a well-functioning program can map and create the pAVF within a week, with successful cannulation of a mature pAVF about four weeks later. While early-stick AV grafts may also be an option, they can limit future AVF options.

Vessel Mapping

A functional pAVF depends on suitable arterial anatomy, a patent perforator vein that connects the deep to superficial venous systems of the arm, as well as patent superficial upper arm outflow veins for cannulation. Vessel mapping, done by a technologist with training in the anatomy of

upper extremity arteries and veins, should be performed with a tourniquet on the upper arm and the patient in a relaxed position. In colder climates, patients should be given time to warm up before the examination to allow venous dilation. Patients may be under-hydrated, which can cause venoconstriction and underestimate venous diameter measurements.

Arterial assessment includes evaluation of mural calcification, Doppler waveforms and velocities, and the Barbeau test (Figure 1), or a similar study of arterial supply to the palmar arch.

Venous assessment should look for patent superficial veins and a patent perforator vein from the deep system to the superficial veins. Anatomy of the relevant arteries, veins, and nerves is shown in Figure 2. While the perforator vein typically originates from the lateral ulnar vein, forearm venous anatomy is extremely variable, so recognition of anatomic venous variations is important.

Deep veins should have a diameter of approximately 2mm and be in close proximity to the artery at the site of pAVF creation. The superficial venous outflow veins should be no deeper from the skin than 6mm at the intended cannulation sites, while a perforator vein with a diameter of 2mm or more is recommended (7, 8). Some pAVFs have been created with perforator veins smaller than 2mm, and while this is possible, it is not recommended as a standard of practice. All interventional radiologists (IRs), but especially early users, are encouraged to be present during vessel mapping to make preliminary decisions regarding the suitability of pAVF creation.

As a rule, venography is not needed for vascular assessment, though when thoracic central vein obstruction is suspected, venography may be the only way to determine the degree of obstruction.

Patient Expectations

Guidance Statement on Patient Expectations
1. While technical success of pAVF creation is >95%, patients should be aware that many of the fistulas will require additional procedures to ensure fistula maturation. Successful cannulation rates are approximately 80%.

87

88 Most clinical series have demonstrated that the creation of a pAVF has a success rate of 95% or
89 greater, although many of these AVFs will not be functional for reliable hemodialysis using two-
90 needle cannulation without additional procedures (3,9,10,11,12,13). A recent meta-analysis
91 shows that approximately 80% of pAVFs are successfully cannulated for hemodialysis (14).
92 Before creating a pAVF, patients should be advised that their pAVF may require further
93 procedures for maturation, especially during the first year. It is also worthwhile informing
94 patients that training of personnel at the dialysis center is often required because cannulation of a
95 pAVF may necessitate a different approach than cannulation of a surgical fistula.

96 If the patient has already initiated hemodialysis with a catheter, expectations for the removal of
97 the catheter can also be reviewed. Finally, when obtaining consent, a discussion of risks should
98 include bleeding, infection, nerve irritation resulting in pain or paresthesia, swelling, steal
99 syndrome, and the need for surgical revision or pAVF closure.

100 **Brachial Plexus blocks for pAVF**

101

Guidance Statements on Brachial Plexus blocks for pAVF

5. Brachial plexus block during pAVF creation enhances patient comfort through sensory and motor blockade, reduces arm movement, and can promote vascular dilation.
6. An ultrasound-guided approach is essential for effective brachial plexus blocks. Use 2% lidocaine to avoid a prolonged block that can be associated with bupivacaine.

When used during pAVF creation, advantages of performing pre-procedure brachial plexus block include better patient comfort (sensory block), reduced arm movement during device activation (motor block), and, often, vascular dilation. (15)

From the cervical spine to the upper arm, the brachial plexus has roots, trunks, divisions, cords, and nerves (Figure 3). The goal is to block the cords and nerves. There are four types of brachial plexus blocks: interscalene, supraclavicular, infraclavicular, and transaxillary. An interscalene block is unnecessary. The other three approaches provide excellent motor and sensory arm block for pAVF creation (16,17), though there are some additional risks in using the supraclavicular approach. Workgroup members predominantly use either a supraclavicular or infraclavicular block. Whatever approach is used, ultrasound (US) guidance is important. Brachial plexus block should be performed prior to sterile prep for pAVF creation.

Figure 4 shows some detail regarding performance of supraclavicular and infraclavicular brachial plexus blocks. For an infraclavicular block, an US probe is used to locate the subclavian artery as it passes just beyond the clavicle. The cords and nerves, which are not easily visualized, surround the artery. Under US guidance, place the tip of a 21-25 gauge needle immediately adjacent to the subclavian artery. Aspirate to ensure the needle tip is not in the artery, then infiltrate the area with 15-30 mL of local anesthetic, surrounding the subclavian artery and

repositioning the needle as needed (18). For a supraclavicular block, the cords and nerve run adjacent to the supraclavicular portion of the subclavian artery (Figure 4).

After delivery of the local anesthetic, the block takes effect in about 10-15 minutes. In general, 2% lidocaine is sufficient. Bupivacaine has a much longer and undesired duration. When patients have a prolonged block after pAVF creation, they can be discharged with an arm sling. Both motor and sensory function should return later that day.

Nerve blocks are contraindicated if one must pass through inflamed or infected tissue, and may be challenging in obese patients. Anticoagulation, when indicated, is given after the block.

Finally, a supraclavicular block is associated with risk of pneumothorax and undesired temporary nerve blocks that may involve the stellate ganglion (resulting in Horner's Syndrome), phrenic nerve, or vagal nerve. Local anesthetic systemic toxicity (LAST) is rare, but awareness of this complication and treatment with intravenous Nutrilipid infusion is paramount. (19,20)

Education and training to achieve functional pAVFs

Guidance Statements on Education and training to achieve functional pAVFs
7. Before performing pAVF procedures, physicians must complete specific training, and clinical specialists typically assist during initial procedures.
8. Additional procedures are often necessary to optimize the function of pAVFs for hemodialysis. Clinical specialists and experienced physicians can offer valuable insights.

Your first pAVF procedure

At the time of publication of this document the single catheter Ellipsys system is no longer available for practitioners who want to start a pAVF program. It will be presented briefly with technical details proved in an online appendix. The WavelinQ dual catheter system (Becton, Dickinson and Company, Tempe, AZ) remains available, but a facility cannot order it until the physician has attended a two-hour didactic webinar, one-on-one training with a clinical specialist, and performance of three simulated, proctored cases.

During the initial WavelinQ pAVF procedure, a clinical specialist (and sometimes a physician mentor) will typically be present to provide guidance. IRs who seek further education may ask the vendor where they can observe cases, attend simulation labs, participate in interactive learning sessions, and access online educational resources. Online instruction and guidance information regarding the WavelinQ system can be found on the company's website.

Performing the procedure

Guidance Statements on Performing the Procedure
9. Successful creation of a pAVF using the WavelinQ system involves precise catheter alignment and often partial deep brachial vein occlusion (embolization).

While brachial plexus blockade and moderate sedation are widely adopted for pAVF creation, general anesthesia can also be used when brachial plexus block expertise is not available. At the beginning of the procedure, a tourniquet should be applied at the upper arm for venous dilation.

The WavelinQ system has two catheters, one arterial and the other venous. The procedure requires both ultrasound and fluoroscopic guidance. The current 4Fr system, approved for brachial artery and vein insertion, has been used off-label by accessing the radial artery and vein

or ulnar artery and vein at the wrist. It is also possible to place catheters from an anti-parallel orientation, with one catheter inserted from a brachial approach, and the other catheter from a radial or ulnar approach. A vasodilator cocktail containing Verapamil, Heparin, and Nitroglycerin can be administered through the arterial sheath to facilitate arterial dilation. Regardless of how the arterial and venous catheters are inserted, parallel alignment of the catheters at the radiofrequency activation site, facilitated by attraction of the rare earth magnets incorporated into the catheters, is paramount for pAVF creation. Specific parameters for the radiofrequency ablation for the WavelinQ are cited in the instructions for use (21).

The best location for the creation of the pAVF anastomosis is just distal to the perforator connection with the deep radial, ulnar, or interosseous veins. Once the arterial and venous catheters are confirmed to be in suitable orientation, a brief radiofrequency pulse between the catheters creates the fistula (Figure 5). Injection of contrast through the arterial sheath will confirm the creation of the fistula. In some cases, the initial fistulogram shows diffuse contrast extravasation (or “blush”) with no evidence of pAVF creation (Figure 6), but after waiting a short time, the pAVF usually becomes apparent with no evidence of hematoma.

The newly created WavelinQ pAVF typically has an ovoid arteriovenous communication which should not be misinterpreted as a pseudoaneurysm (Figure 7).

Failure to create a WavelinQ fistula may be due to arterial calcification. Even without evidence of calcification, sometimes the fistula is not created. It has been noticed in cases where a fistula was not thought to be created, a membrane of sorts forms at the intended fistula site. This can easily be treated by percutaneous transluminal angioplasty (PTA) in the artery alongside the anastomosis with a balloon 1mm larger than the size of the artery. This gentle pressure is enough to disrupt the membrane and form the fistula. The WavelinQ catheters can also be reintroduced

and reactivated, increasing the radiofrequency energy time from 0.7 sec to 1 sec. If the pAVF has poor flow following removal of the catheters, PTA of the anastomosis has been done but has not been studied and is not suggested by the company, although many high-volume users have done this successfully without complication.

As mentioned, the one-catheter Ellipsys system, while not currently available for users who have not yet started a pAVF program, has nevertheless been highly successful in creating hemodialysis fistulas. It uses direct puncture into the venous system, guiding a needle down the perforating vein under ultrasound guidance until puncture is made from the perforating vein into the proximal radial artery. Advantages of the Ellipsys system included short procedure times, avoidance fluoroscopy and iodinated contrast, and no direct percutaneous arterial puncture. Use of the Ellipsys single-catheter system can be found in the online appendix to this Practice Guidance Document.

Regardless of how a pAVF has been created, there may be preferential flow into the deep brachial veins that reduces flow to the superficial cannulation vein. Flow can be redirected to the superficial venous system with transcatheter embolization of one of the brachial veins (Figure 8a and b), done either at the time of pAVF creation or during a later visit.

In some cases, banding or ligation of superficial veins that divert flow from the cannulation vein may be needed (Figure 9). The cephalic vein is often the intended cannulation vein, and when the basilic vein diverts flow, banding or ligation of the median basilic or median cubital vein may be required. However, banding or ligation of the basilic vein 2-3 cm downstream from the

antecubital fossa should be avoided since the medial antebrachial cutaneous nerve runs alongside the basilic vein and can be injured at this site.

Managing Technical problems and complications

Guidance Statements on Managing Technical Problems and Complications
10. When performing the Wavelinq procedure, care must be taken to prevent pseudoaneurysm formation at the puncture site.

WavelinQ

As previously noted, the arterial and venous catheters must align parallel to each other for a WavelinQ pAVF to be created (Figure 5). When catheters are almost parallel, external compression of the tissues in the active area may promote apposition. Alternatively, slight adjustments of the catheters proximally and distally may also promote alignment. When alignment is not possible, consider looking for another vascular site for pAVF creation. Venography and arteriography can guide catheter placement and facilitate alignment.

A focal dilation of the perforating vein following AVF creation, often due to juxta-anastomotic vein stenosis, may simulate a pseudoaneurysm. When evident, it can be treated with PTA of the underlying stenosis.

Rates of acute complications during pAVF creation with the 4Fr WavelinQ device are low with arterial steal, pseudoaneurysm formation at the pAVF site, and thrombosis in combination being

<1%. (4,22) Brachial artery puncture site pseudoaneurysms have a reported rate of <2%, and were usually associated with the 6Fr WavelinQ system inserted at the brachial artery.

Steal

Steal is uncommon after pAVF creation. If it occurs, reducing arterial inflow may be challenging, and in some cases, the pAVF must be closed. This has been done using self-expanding stent grafts placed over the percutaneous anastomosis either on the arterial or venous side. Another option is to deploy coils to embolize the outflow vein(s) before and after the anastomosis or surgically close the anastomosis. However, excessive embolization of the deep veins can lead to venous hypertension and swelling of the hand and forearm with or without a patent pAVF.

While rare, severe extremity pain related to ischemic monomelic neuropathy (IMN) has been reported after pAVF creation (23). IMN is due to nerve ischemia related to steal, and requires immediate AVF closure.

The IR's Role following pAVF creation

Guidance Statements on The IR's Role following pAVF creation
11. The interventionalist is responsible for post-procedure pAVF management, which usually includes a follow-up visit 1-2 weeks after creating a pAVF. This visit should involve a physical exam and ultrasound to assess the anatomy of the pAVF and also flow volumes of the brachial artery, cannulation vein, and other veins that may have venous outflow from the pAVF.
12. pAVFs can be assessed and intervened on immediately after creation to enhance maturation, which is defined as achieving adequate size and flow for successful hemodialysis.

IRs who create pAVFs are responsible for creating functional fistulas. A short office visit obtaining post-procedure history and physical exam one to two weeks after the procedure, coupled with an ultrasound study, can help identify early problems. This is an ideal time to assess the intended cannulation site, address patient expectations, and discuss the need for additional procedures that may be required to achieve maturation, defined as two-needle cannulation allowing hemodialysis as prescribed.

Percutaneous AVFs have both deep and superficial components that cannot be completely assessed without an ultrasound exam. The cannulation vein depth and diameters should be noted. The cannulation vein must be superficial enough and of sufficient length and diameter for successful two-needle cannulation. Measurement of volume flow through the brachial artery and the pAVF outflow vein(s) should be made. Brachial artery volume flow of 800-1000 mL/min is optimal, but this only addresses the inflow. Look for excessive venous flow through the deep brachial veins that may divert flow from the superficial cannulation sites. Most importantly, there must be adequate flow at the intended cannulation vein.

Ultrasound is useful for identifying complications including hematoma, pseudoaneurysm, stenosis, thrombosis, high fistula flow, and steal. The need for a diagnostic fistulogram to evaluate a pAVF is uncommon, but may be needed in complex cases and during maturation interventions.

Creating a Functional pAVF

Guidance Statements on Creating a Functional pAVF
13. Failure of the pAVF to mature can stem from inflow or outflow problems. Balloon angioplasty is often effective for treating inflow issues at the fistula or perforating vein, and

peripheral cutting balloons have also been useful. Embolization, ligation, or constriction of unwanted venous outflow may help redirect flow to cannulation vein.
14. For potential interventions after pAVF creation, arterial access is recommended for diagnosis and ease of intervention.

Outflow veins from any AVF, surgical or percutaneous, become physiologically mature as the diameter, flow, and vessel wall thickness increase (24), however, maturation to the point of becoming functional for hemodialysis is not guaranteed. In one of the largest multicenter studies on surgical AVFs, 60% of the newly created fistulas failed to become mature, of which half of them were abandoned without attempts to facilitate maturity. (25). Abandonment was, in part, due to assessment of the fistulas at four to six weeks, when many could no longer be salvaged. The remaining surgical fistulas in this series that were not mature required interventions to make them functional for hemodialysis.

Unlike surgical AVFs, pAVFs can be examined and intervened on immediately after creation, bridging the gap between a fistula that is unsuitable for hemodialysis and a functional pAVF. Whether it takes one or multiple procedures, the goal is to address maturation issues early and create a pAVF that is palpable and/or visible for successful cannulation.

Evaluation of the immature pAVF and steps to help achieve functional use

While evaluation of an immature pAVF may seem complex, most cases usually follow the algorithm shown in Figure 10. Assessment begins with an understanding of arterial and anastomotic inflow, then evaluation of the perforating vein, and finally study of the deep and superficial venous flow patterns and dimensions.

1. Inflow stenosis

Inflow stenosis of the anastomosis and venous perforator vein can be treated with balloon angioplasty. Some operators report that peripheral cutting balloons may afford better stenosis dilation than conventional angioplasty balloon catheters (12). (Figure 11a and b)

2. Excessive deep venous flow

Deep veins may divert blood flow away from superficial cannulation veins. Coil embolization of deep veins may be considered, but care should be taken to avoid creating a potential situation of arm swelling caused by venous hypertension from occluding too many deep outflow veins.

Deep vein embolization can be done with US-guided brachial retrograde vein puncture with the introduction of a 4/5Fr catheter to deliver an occlusive coil or plug. Alternatively, radial or ulnar vein access (4), or radial artery access (Figure 8a and b), can be used to embolize a deep vein.

3. Excessive superficial flow away from the cannulation segment(s)

As noted previously, banding or ligation of superficial veins can improve flow to the cannulation segment(s). A percutaneous approach can be used for venous banding or ligation, navigating either a straight Hawkins needle (26) or curved micro puncture needle (27) above and below the target vessel, allowing suture material to encircle the vein. The suture is then tied to constrict or occlude the vein (Figure 9). An angioplasty balloon can be inflated within the target vein to facilitate vein localization during banding and define a specific luminal diameter, removing the catheter after a constricting suture has been placed.

On occasion, a fistulogram is needed for guidance during pAVF maturation procedures. Radial artery access (provided the radial and ulnar arteries communicate through the palmar arches) or

femoral arterial access to allow contrast injection above the pAVF, have both been used successfully.

Cannulation vein segment(s) too deep

After maturation, a pAVF may have excellent flow but cannulation may be an ongoing issue due to a deep cannulation vein. This is easily diagnosed with ultrasound imaging and flow measurements of the deep and superficial outflow veins. Surgical elevation (especially the basilic vein) may need to be performed when the cannulation vein is too deep, while another option is liposuction to reduce subcutaneous fat between the cannulation vein and skin (28).

Assuring successful cannulation of a mature pAVF at the dialysis center

Guidance Statements on Assuring successful cannulation of a mature pAVF at the dialysis center
15. Cannulation of pAVFs can be difficult for dialysis centers unfamiliar with them. Training on proper techniques is essential and can be supported by industry resources.
16. When challenges arise during cannulation, the interventional radiologist (IR) who created the pAVF should be the primary point of contact for troubleshooting.

Cannulation of a pAVF for successful hemodialysis is the primary goal of any program. Unsuccessful cannulation leads to prolonged catheter dwell times, frustrated patients, and dissatisfied referring physicians. Each of these issues will jeopardize a pAVF program.

The "Rule of 6's" has been adopted for surgical AVFs, and infers that an AVF is mature when the cannulation vein has a diameter of at least 6mm, is no deeper than 6mm from the skin, and carries volume flow of at least 600 ml/minute. (27) Regarding pAVFs, a more intuitive and useful guide is to ensure the fistula is palpable with a tourniquet downstream when cannulation is attempted.

Because the pAVF is a low to moderate-flow fistula, often with multiple outflow veins, it tends to feel softer than a single outflow surgical fistula. Dialysis centers unfamiliar with pAVFs may find cannulation difficult, and inexperienced cannulators tend to puncture at an angle that is too steep, thinking the vessel is deep because of the way the pAVF feels. This can result in a back wall puncture and failed cannulation. Many patients will have split AVF outflow between the basilic and cephalic veins, where cannulation may require split cannulation (Figure 12). While few dialysis units in the United States use ultrasound for cannulation, it is an excellent tool when available.

In situations where the AVF seems fine but the center cannot cannulate it, dedicated training in pAVF cannulation is supported by clinical specialists from industry. When pAVF cannulation presents a persistent challenge at the dialysis unit, the IR who created the pAVF should consider visiting the unit to better understand the issue(s) and assist with successful cannulation.

Practice Development in an OBL or ASC

Guidance Statements on Practice Development
17. Communication with referring physicians is essential for referrals and patient management.
18. There are many ways to develop referrals, but expediting access creation is essential.

Many hemodialysis patients receive their access care in non-hospital outpatient facilities such as office-based labs (OBLs) and ambulatory surgery centers (ASCs). Developing a pAVF program in these environments has many advantages.

Demand, Communication, and Relationships

Prior to developing a program, the needs of your community should be determined. Communication with nephrologists is essential for referrals, and sufficient time must be devoted to education. Maintaining relationships with AV access surgeons is also invaluable. Lastly, high levels of communication with hemodialysis centers and their staff are also beneficial.

Patient Recruitment

According to the 2024 United States Renal Data Survey Annual Report (30), in 2022, 84.7% of renal failure patients initiated hemodialysis with a dialysis catheter, often placed by an IR. A great way to recruit patients for pAVF is to perform vein mapping at the time of, or shortly after, dialysis catheter placement. Providing ultrasound vascular mapping and/or contrast venography as stand-alone services can also expand your referral base. Thereafter, timely communication with the patient's nephrologist regarding the suitability of pAVF will help develop referral pathways.

Timely Access Creation

In a non-hospital outpatient center, an IR can coordinate timely procedural scheduling. At some programs a patient can undergo vascular mapping and have their access created on the same day. Timely hemodialysis creation can be compelling for referring nephrologists who also value reduced tunneled dialysis catheter dwell times achieved with early pAVF creation.

Facilities, Equipment, and Staff

While there are many advantages in the non-hospital outpatient environment, the practice must offer moderate sedation, ultrasonography, and angiography for a reproducible, positive patient experience. While not mandatory, a dedicated anesthesia provider can facilitate appropriate sedation and nerve blocks. Finally, professional staff who take a patient-first approach will help to ensure the success of an outpatient pAVF practice and facilitate patient satisfaction.

A pAVF practice in the outpatient hospital setting

Guidance Statements on pAVF practice in the outpatient hospital setting
19. A successful hospital-based pAVF program requires a proactive and longitudinal strategy.
20. Demonstrating the value of the pAVF program to both the hospital and patients is crucial for overcoming resistance.

A successful hospital-based pAVF program must be proactive and longitudinal, from pre-procedural care to maturation and maintenance interventions. Creation and maintenance of pAVFs should be seen as a program, and not just a procedure. A dedicated patient navigator can help provide longitudinal care.

From an economic standpoint, a pAVF program could represent a new revenue source for the hospital, though many hospitals may be constrained in their ability to promote, market, or otherwise assist in practice-building. The hospital may also see a pAVF program competing with surgical hemodialysis access procedures. This can be overcome by demonstrating the value of a pAVF program to the hospital, nephrologists, and patients.

Another challenge is gaining approval for purchase of pAVF devices through a formal hospital-based value analysis committee where cost, reimbursement, and benefits must be explained. Finally, patients may experience higher out-of-pocket costs at the hospital than in non-hospital outpatient settings due to differences in reimbursement.

From the patient's perspective, the hospital may be a challenging and frustrating place for their pAVF procedure. Hospitals are often large and complicated, and outpatients may be required to arrive 1-2 hours before their procedure. Procedure start times may be delayed for many different reasons. While the hospital is a safe place to perform pAVF creation, there are many challenges to creating a comprehensive program.

Coding and Billing*

Guidance Statements on Coding and Billing
21. Use the appropriate CPT code (36836 or 36837) for percutaneous creation of upper extremity arteriovenous fistulas (these codes refer to procedures performed via single or dual access sites.)
22. Moderate sedation or preoperative nerve blocks can be billed separately.
23. It is important to understand coding, billing, and reimbursement for your practice type (e.g. hospital-based versus ambulatory center).

372

373 Background

374 Prior to 2020, no CPT® codes existed that captured the work of creating an arteriovenous
375 anastomosis via a percutaneous approach. Category I CPT® codes 36818, 36819, 36820 and
376 36821 only describe an open surgical approach. In July 2020, the Centers for Medicare and
377 Medicaid Services (CMS) created two G-codes (G2170 and G2171) to describe percutaneous
378 approaches for the creation of an arteriovenous anastomosis. G-codes are special codes that fall
379 under the Healthcare Common Procedure Coding System (HCPCS) and are reportable for
380 medical services and procedures that do not fit into the CPT coding structure.

381 Current Coding

382 In January 2023, CMS approved and valued two new Category I CPT codes for the creation of
383 upper extremity dialysis arteriovenous fistulas (AVF) via percutaneous endovascular techniques
384 (Table). These codes describe the work of the creation of an AVF via a single access site (36836)
385 or two separate access sites (36837) to fuse a peripheral artery and a peripheral vein after energy
386 application. After the adoption of these CPT codes, the corresponding G-codes were deleted. (It
387 is important to note that CPT codes describe physician work and are not intended to apply to
388 specific devices, and while the single access site Ellipsys device is no longer being
389 commercialized, this device may return, some programs have inventory for ongoing Ellipsys use,
390 or other devices or methods that use a single access site may be available in the future.)

391 In the new CPT code definitions, all imaging guidance (ultrasound and/or fluoroscopy) is
392 included. Furthermore, other procedures performed at the time of fistula creation (such as
393 angioplasty for promotion of blood flow through the fistula or venous

394 embolization/banding/ligation to redirect flow away from unintended venous pathways) are
395 included in these codes and cannot be billed separately. For subsequent interventions after the
396 date of initial fistula creation, the appropriate code from the family of CPT codes describing
397 percutaneous arteriovenous fistula interventions (36901-36909) may be reported.

398 Separately Billable Services

399 When moderate sedation is administered during percutaneous arteriovenous fistula creation, CPT
400 codes 99152 and 99153 are separately billable. When performed, preoperative brachial plexus
401 anesthetic injection – single (64415) or continuous infusion by catheter (64416) - are also
402 separately billable.

403 Special Circumstances

404 When WavelinQ percutaneous AVF creation is unsuccessful after initial imaging with catheter
405 placements, component coding may be used to describe the services that are performed: 76937
406 (ultrasound guidance for vascular access – each), 36005 (extremity venography injection), 75820
407 (extremity venogram unilateral), 36140 (place catheter in artery, extremity), 75710 (extremity
408 arteriogram unilateral).

409

410 Reimbursement

411 Percutaneous AVF creation procedures are reimbursed in a variety of settings under Medicare,
412 including facilities (hospital outpatient departments or ambulatory surgery centers) and in the
413 non-facility (office-based laboratory). Reimbursement rates are updated annually in the Medicare
414 Physician Fee Schedule (MPFS) at the time of final rule, unless other updates are required.

For patients with private health insurance, coverage of their individual policies for percutaneous arteriovenous fistula creation procedures should be reviewed, as there are insurers who currently deem these methods to be investigational or experimental. The Society of Interventional Radiology (SIR) has created a carrier advocacy found on the SIR website, which is periodically updated to assist with pre-authorization and claim denials.

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Future Considerations

While pAVF creation offers many benefits over surgical AVFs with ongoing evidence that supports percutaneous creation of AVFs as safe and effective, there has been slow adoption due to financial and logistical problems for providers, dialysis patients, and dialysis centers. Medicare and insurance companies have had inconsistent reimbursement policies that make the development of a pAVF program in the United States financially challenging. Fortunately, the

recent work of our medical societies has led to the assignment of CPT codes and relative value units (RVUs) that help address the cost of procedures and reimbursement to providers.

Yet despite these efforts to support and sustain pAVF creation, the decision to discontinue the Ellipsys system highlights the economic realities faced by industry, having acquired and supported pAVF creation for over six years with lower adoption rates and greater costs for programmatic support than anticipated. While it is not surprising that first-generation pAVF breakthrough technologies are meeting headwinds, evolution of procedural and device concepts are inevitable. The WavelinQ, originally a 6Fr device, is now 4Fr. There are newer devices under clinical investigation that may simplify the procedure, with the potential for faster maturation and fewer interventions to achieve functional hemodialysis fistulas. It is hoped that these developments will lead to greater adoption of pAVF creation in the future.

448 APPENDIX: The single catheter Ellipsys system.

Appendix Guidance Statement 1
Following pAVF creation using the Ellipsys device, balloon angioplasty is recommended to optimize the anastomosis.

449

450 Ellipsys: This is a single-component device performed under US guidance, only. After initial
451 venipuncture at the confluence of cephalic and basilic veins, US guidance is used to advance a
452 micropuncture needle down the perforating vein. Once the needle tip is adjacent to the radial
453 artery, it is advanced through the vein wall and into the radial artery under direct US
454 visualization. A 0.018 inch wire is then passed through the needle and down the radial artery
455 toward the wrist.

456 Next, the needle is exchanged for a 6Fr low profile sheath, advanced through the vein and into
457 the artery. The 018 inch wire is exchanged for a 0.014 inch wire, and the Ellipsys device is
458 introduced over the wire and through the sheath into the radial artery. The sheath is retracted
459 back to the vein, and the Ellipsys device is pulled back to capture the arterial and venous walls
460 (Figure Appendix 1a). After closing the "jaws" that bring the artery and vein against each other
461 (Figure Appendix 1b), thermal energy creates the pAVF anastomosis and fuses the artery to the
462 vein. Unlike the Wavelinq device, US-guided balloon angioplasty of the new anastomosis is
463 recommended, using a 5 x 20 mm compliant or semi-compliant balloon (Figure Appendix 1c).
464 Ideally, the shoulder of the balloon should extend into the artery, with the distal marker bead at
465 the site of the anastomosis and the body of the balloon extending within the perforator,
466 ultimately creating the final pAVF anastomosis (Figure Appendix 1d). Dilation at the fresh
467 anastomosis with a peripheral cutting balloon has been done, though it is unclear if this is safe or
468 effective. Deep vein embolization is not usually necessary, but US guided percutaneous or

surgical venous banding or ligation to improve flow to the intended superficial cannulation site can be performed, when necessary. Procedures to improve superficial venous flow can be done at the time of pAVF creation or subsequently, and typically require percutaneous access (Figure Appendix 2).

Managing Technical problems and complications (Ellipsys)

Appendix Guidance Statement 2
Needle induced trauma to the perforating vein must be avoided during the initial phase of the Ellipsys procedure.

Passing a puncture needle down the perforating vein while avoiding needle trauma to the vein wall is an early and essential part of the procedure, but may be difficult if the vein is tortuous. Acute thrombosis of the venous perforator during creation has been observed. Angioplasty or balloon thrombectomy of the perforator typically reopens the fistula. Ultrasound guidance, used for the creation of the pAVF, is the best imaging modality for opening a thrombosed perforating vein.

The Ellipsys device does not require initial percutaneous arterial puncture, and pseudoaneurysm formation at the arteriovenous communication is rare.

Current Coding

In January 2023, CMS approved and valued two new Category I CPT codes for the creation of upper extremity dialysis arteriovenous fistulas (AVF) via percutaneous endovascular techniques (Table). CPT code 36836 is used when creating a pAVF with the single catheter system, but it is important to note that CPT codes describe physician work and are not intended to apply to specific devices.

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Figure Legends

Figure 1: Barbeau test showing possible results: (a) no damping of the pulse tracing immediately after compression. (b) Damping of the pulse tracing. (c) Loss of the pulse tracing followed by recovery within 120 s. (d) Loss of the pulse tracing without recovery within 120 s. From: https://pmc.ncbi.nlm.nih.gov/articles/PMC7468190/ Barbeau Test from Zalocar et al, 2020 (6) is licensed under CC BY-NC-SA 4.0

Figure 2: Venous anatomy related to pAVF creation. The perforator vein is essential for pAVF creation, as it communicates between the deep paired radial and ulnar veins and the superficial cephalic and basilic veins, as well as the paired brachial veins. Note that when there is a patent perforator vein, it runs close to the proximal radial artery. The medial antebrachial cutaneous nerve should also be noted, running along the basilic vein several centimeters beyond the origin of the basilic vein. If the basilic vein is to be banded or ligated after pAVF creation, it should be done close to its origin to avoid injury to this nerve.

Figure 3: The brachial plexus. Note the cords and nerves surrounding the subclavian artery. White oval indicates target area for supraclavicular block and yellow oval indicates target area for infraclavicular block.

Figure 4: Anatomic and ultrasound approach for supraclavicular and infraclavicular BPB. The blue rectangle indicates the target ultrasound area for the supraclavicular block. The grey rectangle indicates the target ultrasound area for the infraclavicular block. The white oval represents the target area for the supraclavicular block.

Figure 5: Creating a WavelinQ pAVF. The arterial and venous catheters are properly aligned and the radiofrequency electrode has been activated and now sits within the footplate (arrow), creating a pAVF.

Figure 6: Immediate post-WavelinQ Fistulogram blush (oval). Immediately after activation of the radiofrequency system this fistulogram reveals a blush at the new anastomotic site, while no artery to vein fistula is seen. In most cases, the blush will resolve and the fistula will become apparent within a few minutes without further intra-procedural intervention.

Figure 7: WavelinQ ovoid arteriovenous anastomosis (arrow) between the ulnar artery (UA) and lateral ulnar vein (LUV), with flow through the perforator vein (P) and then into the cephalic vein (CV). Spasm of the perforator vein (asterisk) does not necessarily need any treatment at the time of pAVF creation if flow is adequate, but should be evaluated with early clinical and US follow up.

Figure 8a and b. Pre- and post-embolization of a deep brachial vein.

Figure 8a. Pre-embolization pAVF fistulogram performed from radial artery (RA) access shows two brachial veins (asterisks) that are diverting flow away from the superficial cephalic vein (CV) and basilic vein (BV).

Figure 8b. Coil embolization of one of the paired brachial veins (arrow) from a radial artery access at the wrist. Only one of the brachial veins is visualized (asterisk), improving flow into the superficial veins.

Figure 9. Banding or ligation of a vein that is diverting flow away from the intended superficial venous cannulation site . A hemostat is underneath and isolating the vein (arrow), while sutures are grasped at the tip of the hemostat for subsequent venous ligation (in this case).

Figure 11: Trouble shooting pAVF maturation problems. This diagram addresses many of the initial concerns, but not all maturation problems follow this diagnostic algorithm. The use of a peripheral cutting balloon has been anecdotally reported by several of the members of this workgroup to be safe and effective, though there is no substantial data on its use.

Figure 11a and b: Late development of a perforator vein stenosis. Figure 12a. Poor flow into the right cephalic vein caused by stenosis of the perforator vein (paired arrows) noted 16 months after pAVF creation. Figure 12b. Successful treatment of the perforator vein stenosis (arrow)

using a 6mm peripheral cutting balloon and 7mm drug coated balloon (DCB) with excellent contrast filling of the cephalic vein (CV).

Fig 12: Split cannulation of the proximal basilic vein (BV) and cephalic (CV) vein in a dual outflow pAVF during hemodialysis.

Table: Billing for pAVF creation using a single venous access or dual access (artery and vein).

Appendix Figure 1 a-d: Steps for creation of an Ellipsys AV fistula. 9a. Ellipsys crossing from the perforator vein to the radial artery with jaws open (double headed arrow). 9b. Jaws closed before thermal activation (double headed arrow). 9c. Following thermal activation creating the pAVF, PTA of newly created fistula 9d. Guidewire traversing the newly created pAVF (oval).

Appendix Figure 2: Right arm Ellipsys pAVF fistulogram during a subsequent maturation procedure, performing the fistulogram from a cephalic vein (CV) puncture, passing the catheter across the pAVF (arrow), with the catheter tip in the brachial artery (BA). Contrast passes from the brachial artery down the radial artery (RA), across the pAVF, into the perforator vein (P), and fills the cephalic vein (CV). The ulnar artery is noted (UA).

CPT Code	Description	Work RVU (wRVU)
36836	Percutaneous arteriovenous fistula creation, upper extremity, single access of both the peripheral artery and peripheral vein, including fistula maturation procedures (e.g., transluminal balloon angioplasty, coil embolization) when performed, including all vascular access, imaging guidance and radiologic supervision and interpretation.	7.20
36837	Percutaneous arteriovenous fistula creation, upper extremity, separate access sites of the peripheral artery and peripheral vein, including fistula maturation procedures (e.g., transluminal balloon angioplasty, coil embolization) when performed, including all vascular access, imaging guidance and radiologic supervision and interpretation.	9.30

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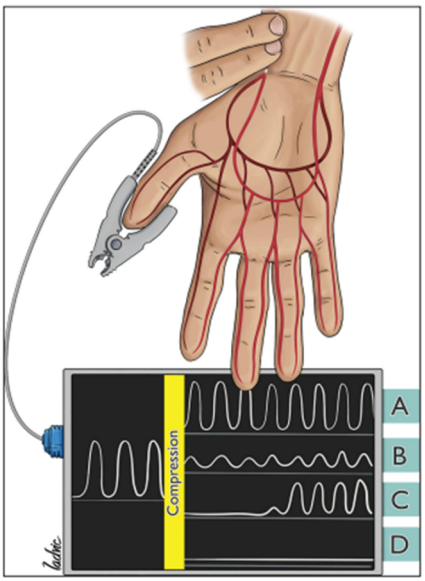
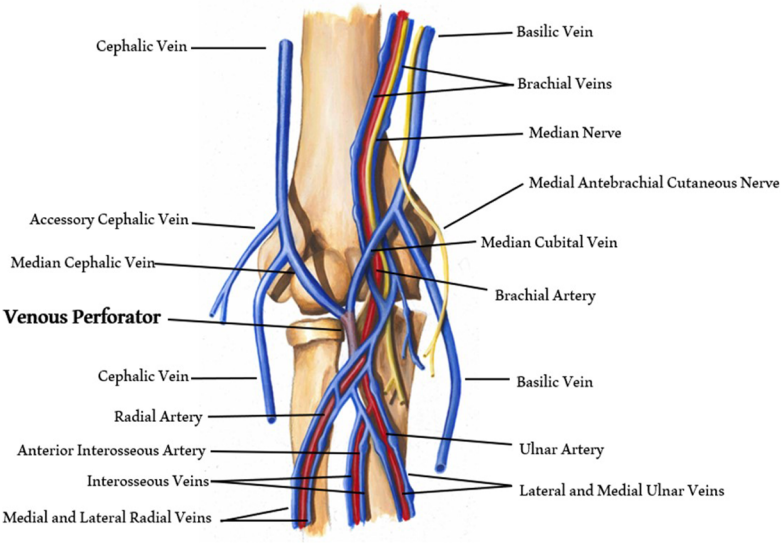
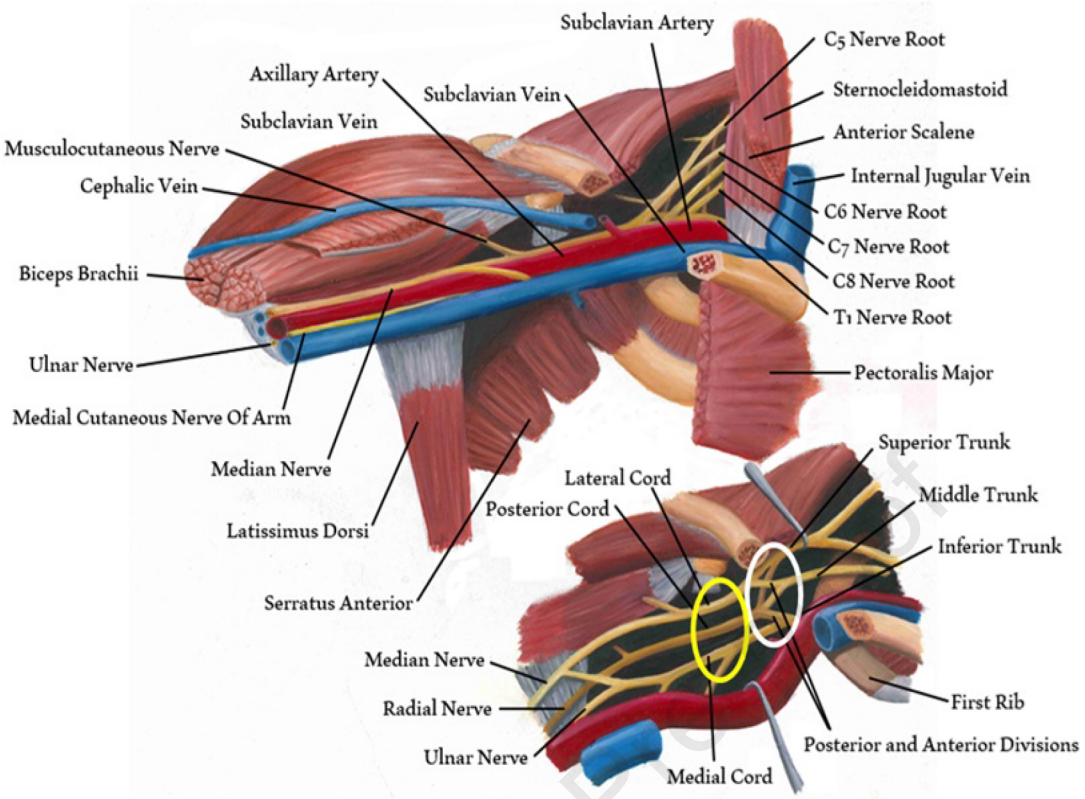
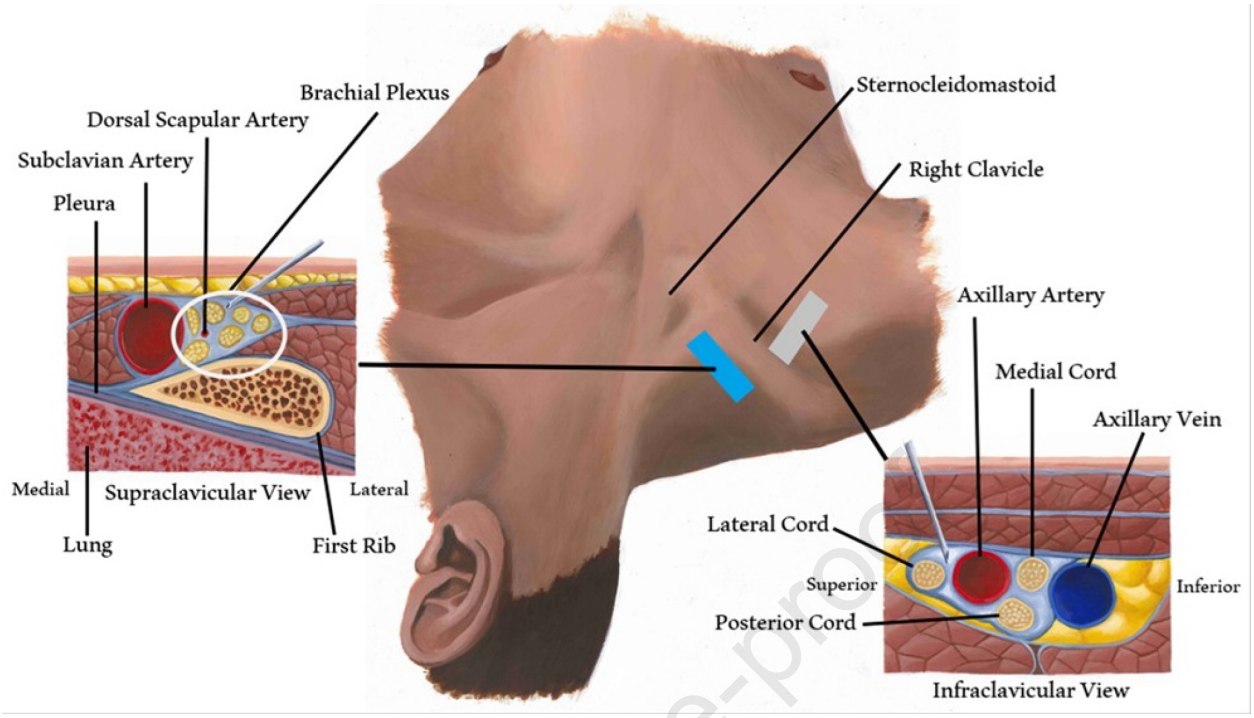
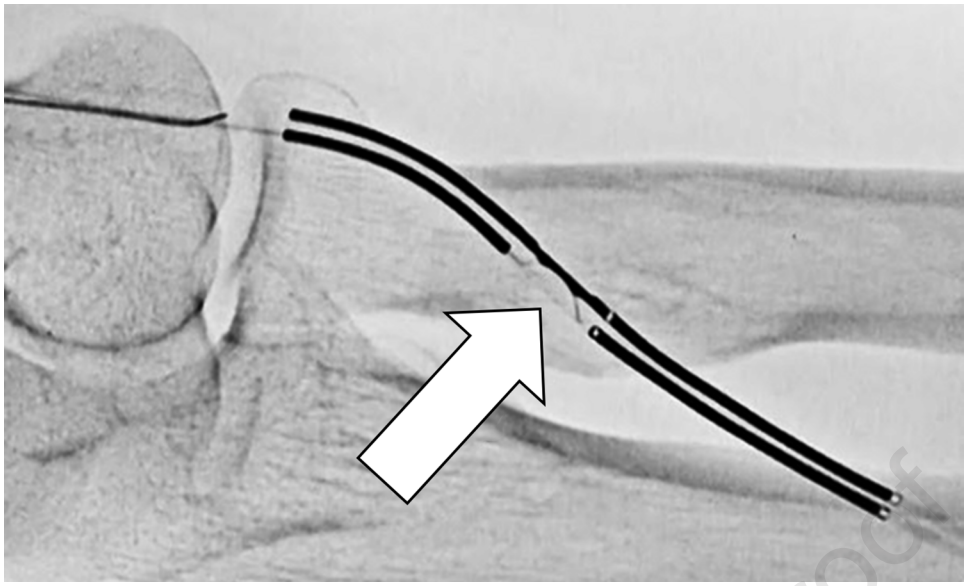
associated with each code is mandatory for proper coding of physician service. Please refer to 2024 CPT® for full and complete guidelines.

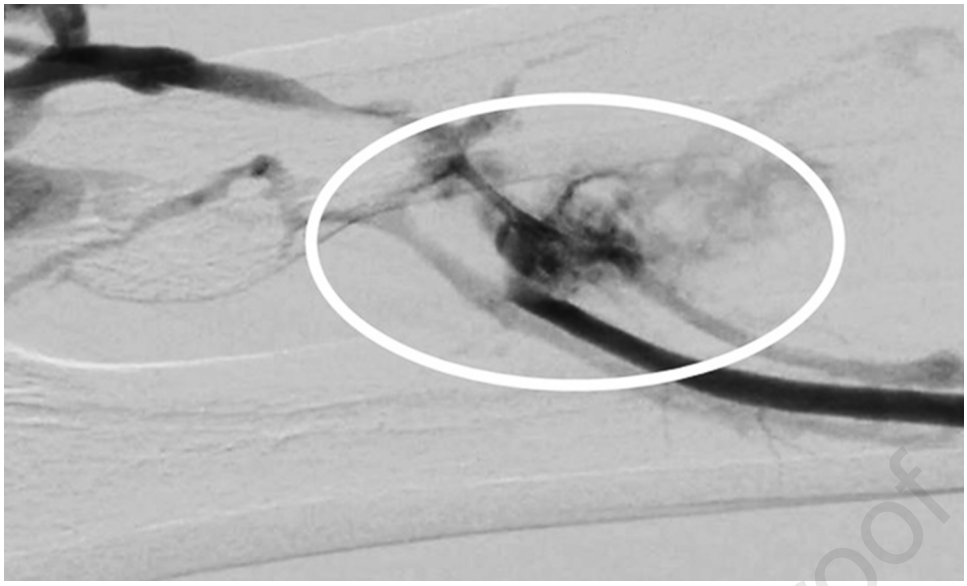


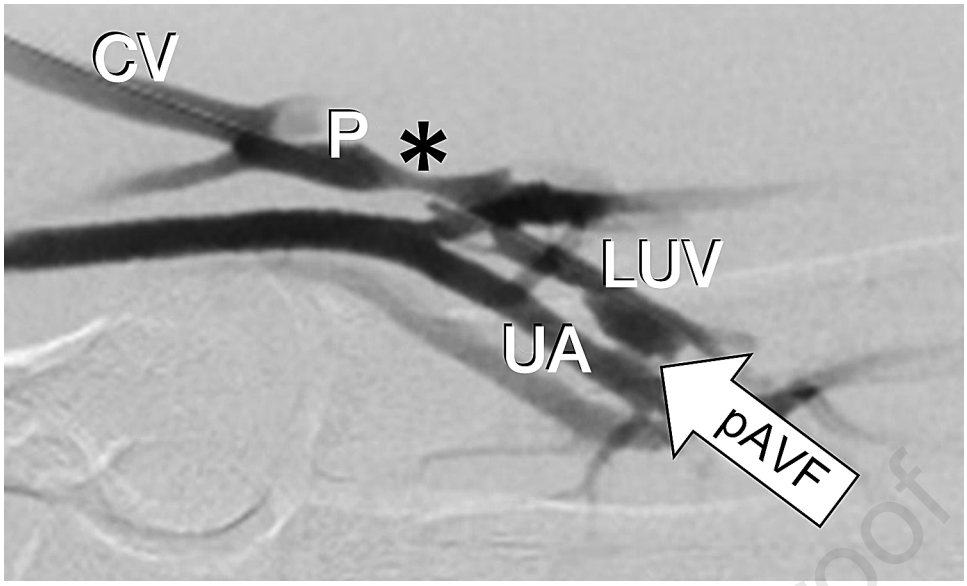


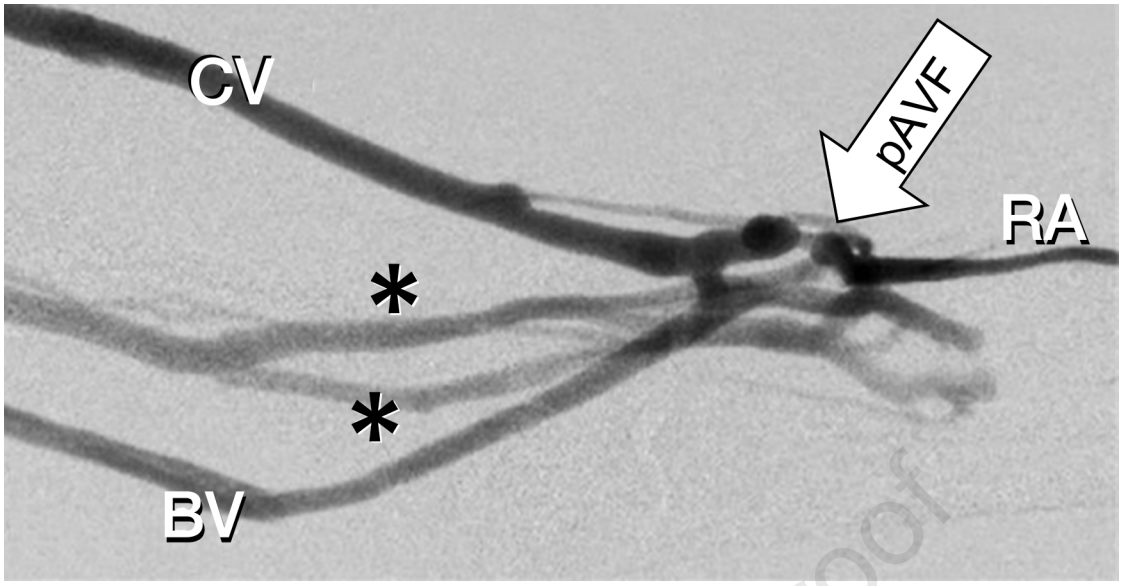


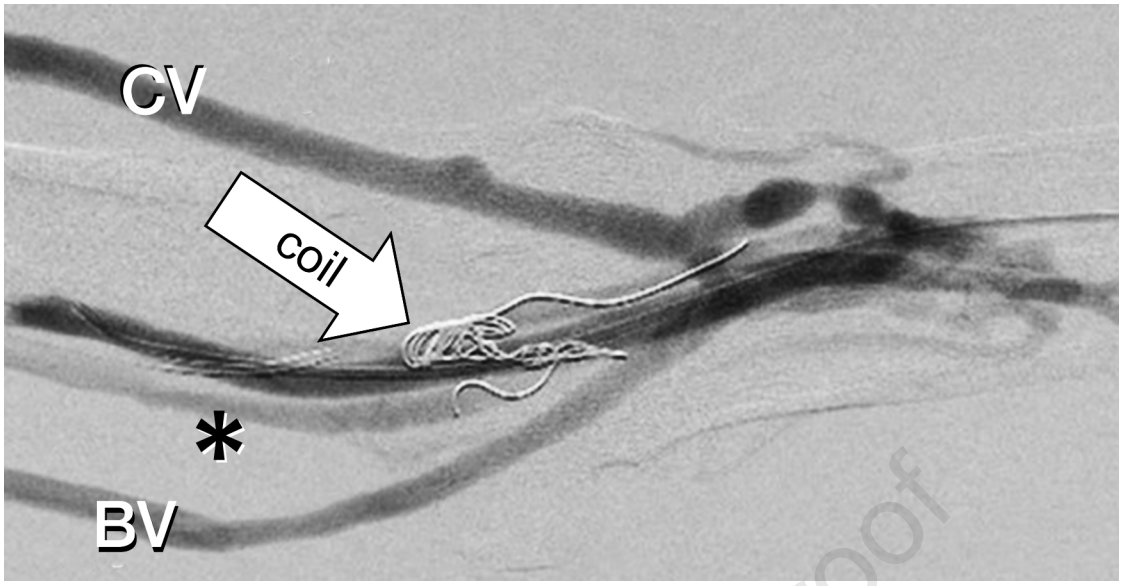


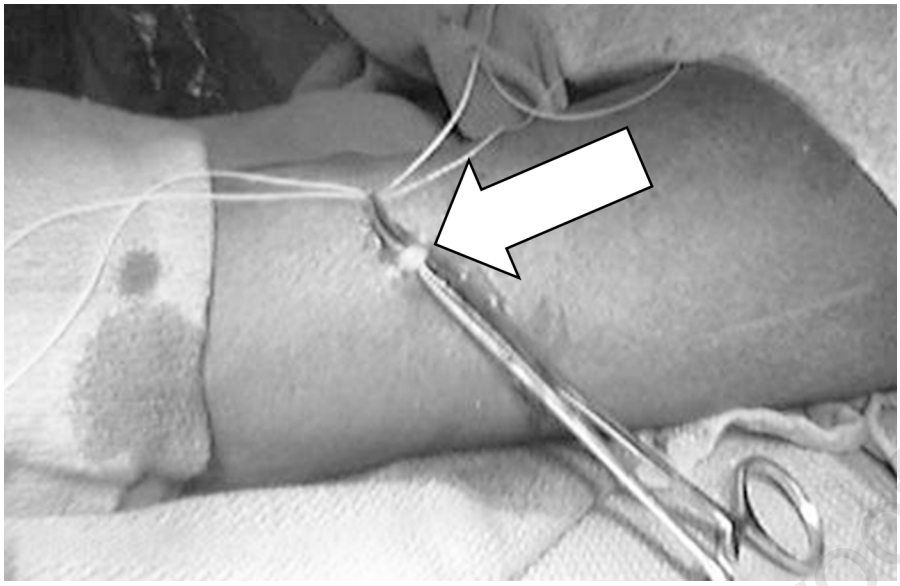


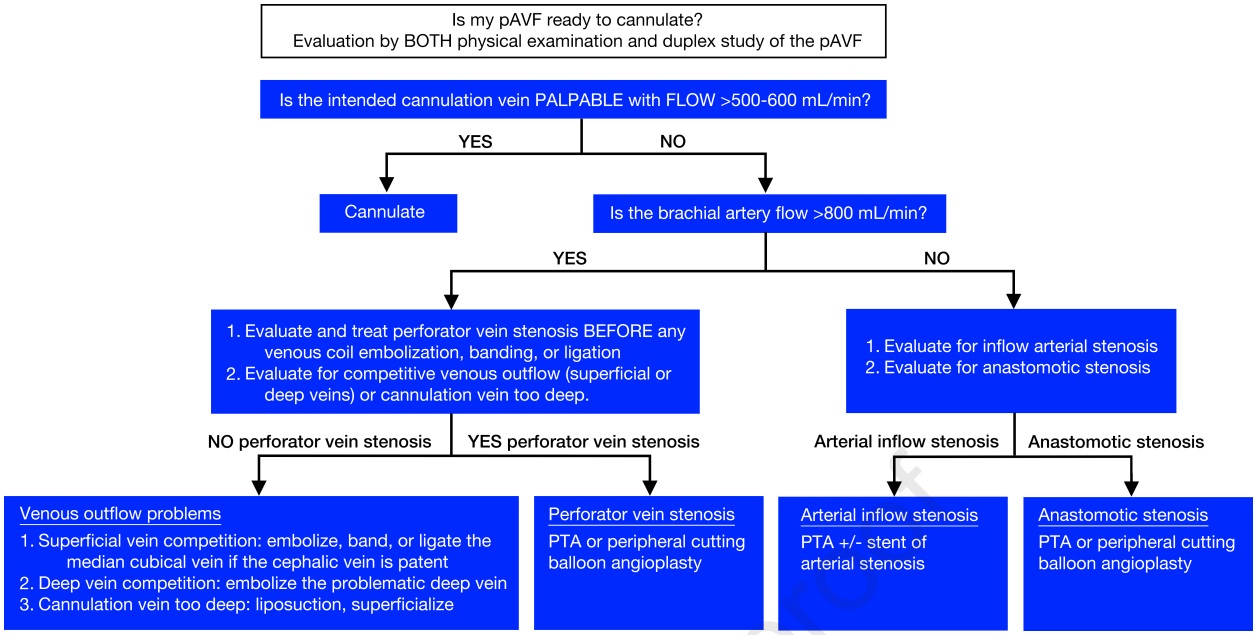


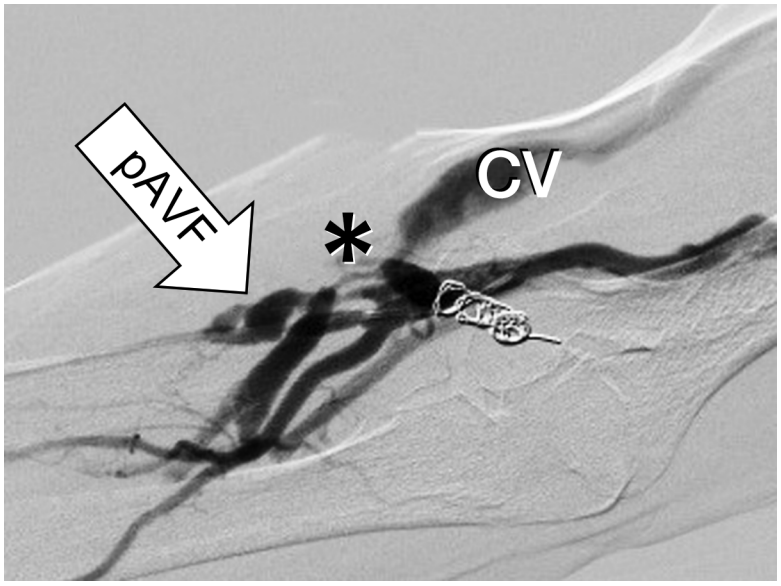


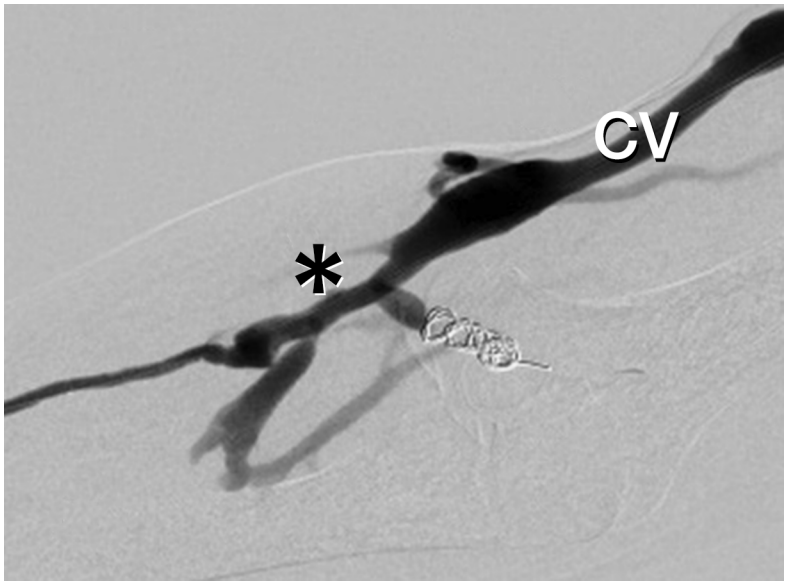


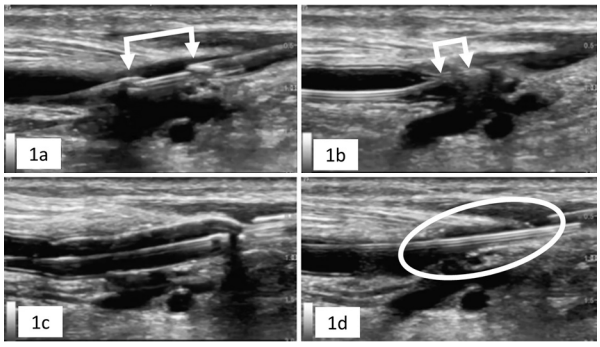


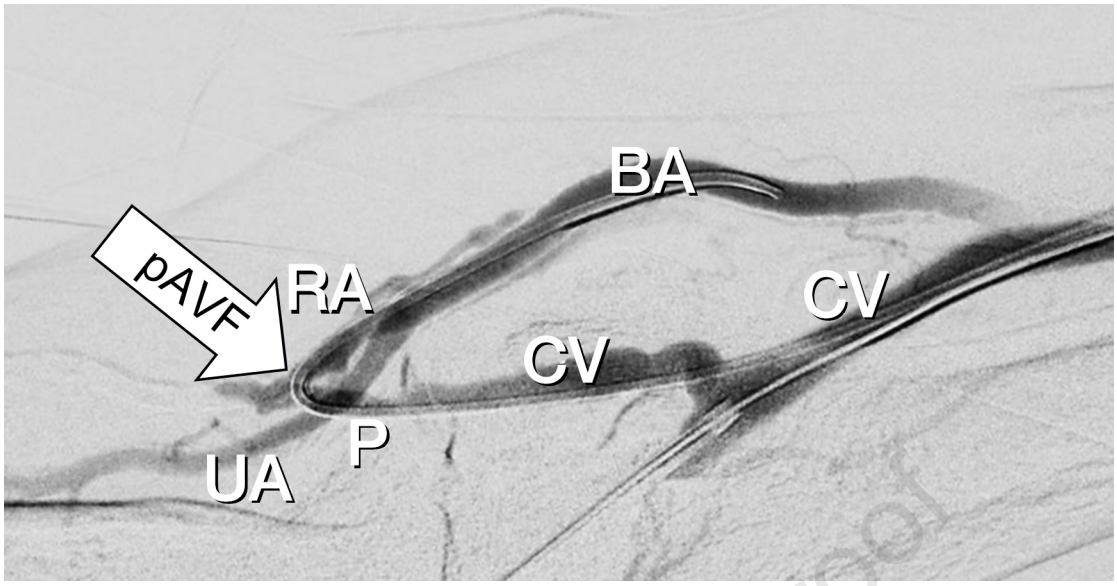


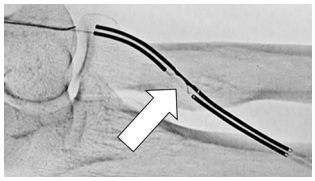












Date: June 2, 2025

Dear Editor,

In 2024, the SIR Guidelines and Statements Department added a new document type to its slate of evidence-based documents, the Practice Guidance Document. This document type was first suggested by our division counselor, Luke Wilkins, and was approved by the SIR Executive Council.

The included manuscript is the first of these documents to be completed. In this document, the writing panel created both evidence-based and consensus guidance statements to assist those new to performing this intervention with setting up a practice, selecting patients, performing the procedure, and correctly coding and billing for it. Each section includes 1-3 guidance statements, which we envision being included in a text box near the main text, much like a table.

Included in this package, please find the following:

- Title page
- Blinded manuscript (includes references, an online-only appendix, and figure legends)
- Guidance Statements
- Figures 1-12; Appendix Figures1-2:
    - Note: Figure 1 is reproduced from an article with a CC-by4 copyright license; the original source is in the references and cited in the legend of the figure.
    - Figures 2-4 were created for this document by our contracted medical illustrator, Andre Uflacker, who is also listed in the author's list
    - All other images are taken from the authors' clinical practice.
- Table 1

Bart Dolmatch is the first and corresponding author for this document. I am acting as the staff liaison for this project and can be contacted for additional information or with follow-up questions at kvandertulip@sirweb.org.

Kind regards,

Kaeli Vandertulip