Femoral Arterial Access and Closure

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Femoral arterial access is the most common method of vascular access for coronary angiography and percutaneous coronary intervention in the United States. It is an often underestimated but important aspect of the procedure, and is the single most frequent cause of complications during coronary angiography and intervention. Hyperlinked to this article is a video that shows a PVI procedure performed at VA Boston Healthcare System, West Roxbury Campus. Most vascular complications are preventable by following good access technique, starting with a thorough history and physical examination. In addition to a routine review of systems, the history should specifically focus on the presence of symptoms suggestive of peripheral arterial disease (PAD) (intermittent claudication/rest pain/foot ulcers), prior interventions for PAD, including arterial bypass grafts or stenting, recent femoral access, closure device used (if any), any groin complications from prior procedures (pseudoaneurysms, arteriovenous fistulae, retroperitoneal bleeding, ischemic vascular problems, femoral arterial dissections), presence of active groin infection, prior surgery or radiation therapy to the groin, and presence of iliac or aortoiliac aneurysms (size and location) (Table 1). The history should also focus on whether the patient can lie supine for prolonged periods of time (eg, chronic lower back pain, congestive heart failure, chronic obstructive pulmonary disease) because this can modulate the choice for access (femoral versus radial) and closure (manual compression versus closure device). In addition to routine examination of the main systems, physical examination should focus on inspection of the groin for any signs of infection (especially in morbidly obese patients with significant skin folds), palpation and auscultation (for bruits) of the femoral pulse, and palpation of the distal arterial pulses, including bilateral dorsalis pedis, posterior tibial, and popliteal arteries. In patients with nonpalpable pulses, Doppler ultrasonography should be used. Pertinent findings should be documented in the patient’s chart to serve as a baseline record of the patient’s peripheral pulses. The presence of any of the aforementioned conditions should prompt strong consideration for an alternative approach, such as radial (preferred) or brachial artery, although most of the aforementioned conditions are not an absolute contraindication for a femoral artery approach, and the procedure can be done relatively safely with the use of smaller sheaths (4F or 5F).

Ideal Femoral Arterial Puncture Site

The CFA represents an ideal site for arterial access and sheath insertion because it is relatively large, is less involved with atherosclerosis, and is readily compressible against the underlying head of the femur. Caudal punctures usually result in greater propensity for cannulation below the bifurcation into the superficial femoral artery or the profunda, where the lack of underlying bony structure and lack of scaffolding by femoral sheath result in an increased association with bleeding, hematoma, and pseudoaneurysms. When a double wall puncture or bleeding (due to inadequate compression) occurs in the CFA, the femoral sheath limits the spread of hematoma and thereby tamponades the arteriotomy site, preventing pseudoaneurysm formation. The smaller caliber of the arteries below the bifurcation also makes them more prone to catheter-related arterial occlusions. In addition, the tributaries of the femoral vein course above the superficial femoral artery, increasing the risk of arteriovenous fistula.

Although low femoral arterial cannulation results in complications, cannulation of the femoral artery above the inguinal ligament (in the external iliac artery) is associated with an increased risk of retroperitoneal hemorrhage due to lack of an underlying bony structure preventing effective compression and tamponade. The inferior epigastric artery courses toward...

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the inguinal ligament before turning upward. The lowest point of the inferior epigastric artery thus corresponds to the inguinal ligament. Any arterial puncture above the level of the lowest point of inferior epigastric artery (on femoral angiography) is associated with a significant increase in the risk of retroperitoneal hemorrhage. However, it should be noted that infrainguinal puncture and bleeding can also cause retroperitoneal hemorrhage by tracking of the blood upward under the ligament and into the retroperitoneal space, as was shown elegantly by Rupp et al. Similarly, cannulation of the femoral artery right underneath the inguinal ligament could be problematic because the taut inguinal ligament must be compressed to effectively compress the femoral artery.

The ideal site of femoral arterial puncture (not skin puncture) is a point 1 cm lateral to the most medial aspect of the femoral head, midway between its superior and inferior borders (Rupp’s rule). The optimal location for an ideal femoral arterial puncture is best assessed from prior femoral angiograms, if available. In patients without prior femoral angiograms, various external landmarks have been used to access the femoral artery, as follows:

1. Skin/inguinal crease: The skin crease has been used as a marker for the underlying inguinal ligament, and an arterial puncture 2 to 3 cm below the midpoint of the skin crease has been used. However, the skin crease is not a reliable marker for the inguinal ligament, especially in obese patients, in whom it tends to be lower than the inguinal ligament.

2. Bony landmarks: A point 2 to 3 cm below the mid inguinal point, which is the mid point between the anterior superior iliac spine and pubic tubercle, has been used by some operators as a site for femoral arterial cannulation. However, although bony landmarks are better than the skin crease, they seldom correspond to the exact location of the inguinal ligament.

3. Maximal pulse: Although arterial cannulation at the site of maximal pulse may aid in easy cannulation of the femoral artery, relying on the amplitude of the pulse alone could result in high or low puncture. This could be particularly important in obese patients in whom the only place where the femoral artery is palpable corresponds to a region with a smaller amount of soft tissue and might not correspond to the ideal site.

4. Fluoroscopic landmark: Although fluoroscopic guidance was originally proposed for “femoral puncture when the arterial pulse was diminished or obscured, for training purposes, and for analysis and correction of missed punctures,” it is being used increasingly and is now a commonly recommended technique for femoral arterial puncture. Routine use of fluoroscopic guidance reduces the risk of vascular complications, although not every study supports that contention. The tech-
nique uses visualization of the femoral head under fluoroscopy in a posterior-anterior projection. A metal clamp is used as a marker to identify the most ideal location of femoral artery cannulation, as described above. This is achieved by a skin puncture done at the lower border of the femoral head, with the needle entering the skin at a 30° to 45° angle (with a steeper angle in more obese patients). The broad upper and lower limits of an ideal puncture are below the inguinal ligament, but well above the femoral artery bifurcation. Dotter et al. found that the femoral artery bifurcation was 2 to 66 mm below the femoral head, whereas Rupp et al. found that the inguinal ligament was 15 mm superior to the mid femoral head, giving a window of 3 to 5 cm where an ideal puncture could be made. However, in the majority of cases (~77%), the bifurcation is below the level of the femoral head. Hence, a target zone from the lower border of the head of femur to the mid portion of the head is ideal, whereas the safety spot (even in the 23% of cases with high femoral artery bifurcation) is at the mid portion of the head of femur."

**Steps for Successful Femoral Arterial Cannulation**

**Conscious Sedation and Local Anesthesia**

Femoral artery cannulation is the most uncomfortable part for the patient, and most likely to be remembered by one undergoing uncomplicated coronary angiography. Adequate conscious sedation (for example, 1 mg of midazolam and 25 µg IV of fentanyl; the dose is reduced in the elderly) is key to ensure patient relaxation and cooperation. After the planned site of skin entry by the needle (lower border of femoral head on fluoroscopy) is confirmed, femoral arterial pulsation should be felt with the tips of the middle and index fingers, parallel to the course of the artery. Adequate local anesthetic should then be given, starting with a dermal bleb with a 25-gauge needle to anesthetize the skin. A 22-gauge needle is then used to anesthetize deeper tissue planes, starting with the deepest point and working backward toward the skin. It is best practice to pull back on the plungers of the syringe before injecting to ensure that the needle is not in a blood vessel. Intravascular injection of the local anesthetic agent could result in serious arrhythmias. Approximately 10 to 20 mL of local anesthetic agent should be injected around the femoral artery site, ensuring adequate local anesthesia from the skin to the level of the artery. Giving too much local anesthesia may obscure femoral arterial pulsation and make access a challenge. Similarly, giving too little may make the patient less able to tolerate the procedure. While local anesthesia is administered, the patient should be monitored for any vasovagal reaction.

**Nick and Tunnel Approach**

Some operators follow the nick and tunnel approach, in which a 2- to 3-mm nick is made parallel to the skin crease at the site of the local anesthesia with a scalpel blade. The nick is then enlarged and deepened with the use of the tip of a small curved forceps (clamp). The nick and tunnel approach ensures less resistance while the arterial sheath is advanced (especially for larger sheaths) and increases the likelihood that vascular bleeding will manifest as an ooze rather than a hidden hematoma. The disadvantages of this technique are that, in instances in which femoral artery cannulation cannot be obtained at the site of a skin nick, an additional skin nick may have to be performed, with occasional tract oozing after the sheath is removed. To avoid this, many operators completely avoid the nick and tunnel approach, especially when using a smaller sheath (4F to 5F). As an alternate approach, a small nick can be made after femoral artery access with the needle in place and the guidewire through it.

**Femoral Arterial Cannulation**

With adequate local anesthesia, femoral arterial access is obtained with the use of an 18-gauge needle, employing the modified Seldinger’s technique with an anterior wall stick. With palpation of the femoral artery with the index and middle fingers of 1 hand, the needle is held with the index finger and thumb with the needle tip bevel facing upward. The skin is entered at a 30° to 45° angle to ensure that the artery will be cannulated 2 cm superior to the skin entry site. A more vertical entry may make advancing the sheath and guide catheters difficult and also promote kinking. As the needle approaches the femoral artery, pulsations can be felt through the needle. Some operators examine the groin fluoroscopically at this stage to ensure that the needle is at the level of the mid femoral head. Once the femoral artery is cannulated, good pulsatile blood flow should be ensured before any guidewire advancement. A 0.035-inch J-tip guidewire is then advanced through the needle into the femoral artery, iliac artery, and descending aorta. If any resistance is encountered during wire advancement, it should be done under fluoroscopy. If resistance is encountered as the guidewire leaves the needle tip, the guidewire should be removed and the needle adjusted to ensure brisk flow. In obese patients, lowering the hub of the needle before guidewire insertion can help to overcome this issue. Similarly, when the needle is up against the wall, slight repositioning either laterally or medially will aid in smooth guidewire advancement. In cases in which the guidewire encounters resistance in the external or common iliac artery, attempts should be made to advance the guidewire under fluoroscopy, taking extra precautions not to use force. If this does not work, especially in patients with tortuous iliac arteries, the J-tipped guidewire should be exchanged for a steerable 0.035-inch wire, such as a Wholey wire (Covidien, Mansfield, MA). With sufficient length of wire in the artery, a small skin nick is made, and the cannulation needle is then exchanged for a femoral arterial sheath with the dilator inside it. The J-tip guidewire and dilator are removed, and the side port is flushed with heparinized saline.

**Femoral Angiography**

Unless the glomerular filtration rate is markedly reduced, all patients should have a femoral angiogram regardless of planned closure device used and preferably before coronary angiography. Before angiography, the side port of the sheath must be connected to the pressure transducer, and a record of the common femoral arterial pressure should be made (any
dampening of pressure waveform in relation to the cuff pressure should raise the possibility of PAD or of the sheath in a dissection plane). Femoral angiography is then performed with an ipsilateral anterior oblique view at 30° to 45° angulation. This angulation is ideal to visualize the bifurcation of the CFA. However, it should be noted that this view should not be used to interpret a high femoral artery cannulation. If there is any concern for a high femoral arterial cannulation, repeat femoral angiography should be performed in the posterior-anterior projection. Care must be taken to avoid irradiating the operator’s hands during angiography and also to prevent accidentally pulling out the sheath during injection. Femoral angiography performed before a procedure aids in assessing the location of the puncture, the presence of any complications (perforation, dissection), the size of femoral/iliac arteries, and presence of PAD (which may guide the choice of guidewire). Deferring a coronary intervention should be considered if the femoral artery cannulation is deemed to be too high because the risk of retroperitoneal hemorrhage may increase substantially.

**Special Considerations**

**Ultrasound-Guided Femoral Arterial Cannulation**

Ultrasound guidance is increasingly used for venous cannulation for central line placement. However, the data on ultrasound-guided arterial cannulation are limited. The technique involves ultrasonography of the femoral artery with the use of a 7-MHz transducer draped in a sterile sleeve. With the use of landmarks described previously (anatomic/fluoroscopic), the ultrasound probe is held over the proposed site of arterial cannulation. The probe is then moved caudally to visualize the bifurcation and cranially to visualize the common femoral artery. The femoral artery can be differentiated from the femoral vein in that it is less compressible, as well as by the direction of blood flow by color Doppler ultrasonography and by a triphasic signal versus a more monophasic signal (femoral vein) on pulse Doppler ultrasonography. Some operators even advocate the use of local anesthesia under ultrasound guidance, which ensures that the soft tissues around the artery are infiltrated for effective local anesthesia. Once the CFA is located and a disease-free segment is visualized, a real-time ultrasound-guided arterial cannulation can then be performed. Carefully scoring the needle with a scalpel or hemostat may make it more visible on ultrasound. With the probe held in 1 hand or by a second operator, the Seldinger needle is then advanced under ultrasound guidance. The position of the needle is shifted as needed on the basis of its position on the ultrasonogram. The advantage of ultrasound guidance is that it avoids accidental venous puncture in anatomic variants in which the femoral vein or its branches lie directly above the artery. It can also potentially avoid cannulation into more diseased segments of the artery as well as avoid cannulation into a branch vessel because of anatomic variation (high femoral arterial bifurcation). The disadvantage is the extra time needed to set up the equipment and time taken for the additional step in obtaining femoral access.

The data to support the routine use of ultrasound guidance during angiography are limited. Wacker et al assessed the utility of color duplex ultrasonography in aiding vascular access in patients with an absent palpable pulse or after 3 unsuccessful palpation-guided cannulation attempts and found a 100% success rate with the technique with fewer passes required. Similarly, in 30 consecutive patients undergoing peripheral vascular procedures, Yeow et al showed a high success rate (96%) for the establishment of antegrade CFA or superficial femoral artery access. Dudeck et al randomized 112 patients undergoing coronary angiography to ultrasound-guided puncture versus traditional palpation-guided puncture of the femoral artery. They found that only in patients with a weak arterial pulse and in those with a leg circumference of ≥60 cm did ultrasound guidance significantly decrease the number of attempts needed as well as the time for successful arterial puncture. In contrast, time for vessel cannulation was increased in patients with strong arterial pulse in the ultrasound guidance group, and there was no difference in the rate of femoral arterial complications with the use of this technique. However, in this study, patients on anticoagulation were excluded, and only 4F or 5F sheaths were used, which could have potentially reduced the complication rate and hence any benefit of the ultrasound-guided technique. Nevertheless, ultrasound-guided femoral arterial cannulation is an acceptable option, especially in obese patients or in those with a weak pulse.

**Femoral Arterial Cannulation With a Micropuncture Needle**

In instances in which the vessel may be small, calcified, or tortuous, or when the patient in on anticoagulation, a smaller access needle may be desirable to reduce the risk of complications. Use of a 21-gauge micropuncture needle decreases the size of the hole by 56% over a standard 18-gauge needle and decreases flow through the hole nearly 6-fold, resulting in decreased risk of complications from errant sticks or inadvertent back wall punctures. However, at present there is no clear evidence to suggest that routine use of micropuncture will reduce the risk of femoral access site complications.

A micropuncture kit includes a 21-gauge needle, an 0.018-inch stainless steel guidewire with soft flexible tapered tip, and a 4F micropuncture sheath with dilator for initial access. The femoral artery is entered with the use of the 21-gauge needle. After blood flow from the hub is ensured, a floppy-tipped 0.018-inch guidewire is then threaded, followed by removal of the needle. Of note, the backflow of blood from the hub might not be as pulsatile as that seen with an 18-gauge needle because the resistance to flow is inversely proportional to the fourth power of the radius (Poiseuille’s law). Some operators verify the position of the tip of the needle under fluoroscopy at this stage. If the tip appears to be too high or low, the needle could be removed at this stage, with manual compression held for 5 minutes and a repeat attempt at femoral arterial access done after the position is adjusted. Once the needle is in an acceptable position, a floppy-tipped 0.018-inch guidewire is then threaded (usually under fluoroscopic guidance), followed by removal of the needle. A 4F short catheter with 3F inner dilator is placed.
over the existing wire, followed by removal of the dilator and wire. Then, an appropriately sized wire (0.035 inch) can be placed through the 4F catheter with subsequent upsizing to a desired sheath size.

**Femoral Arterial Cannulation With a Smart Needle**

The Smart Needle (Vascular Solutions, Minneapolis, MN) is a flow needle attached to a Doppler probe, which can be used in patients with pulses that are difficult to palpate (eg, altered anatomy, scarring due to multiple procedures, obese patients, severe aortic stenosis with pulsus parvus, patients in cardiogenic shock, or patients with PAD). The needle is connected to a hand-held monitor wrapped in a sterile sleeve. The needle is advanced through the skin while the operator listens to the Doppler signal. When the needle approaches the artery, the Doppler signal becomes louder, assisting in femoral arterial cannulation. The pulsatile sound from the artery as it is approached is distinct from the vein. Once the needle enters the artery, pulsatile blood flow should be ensured, and the rest of the procedure is as described previously. The efficacy and safety of using the Smart Needle for venous cannulation have been established. However, the data for femoral arterial access are limited. Blank et al, in a study of 114 patients undergoing coronary angiography, found that compared with a standard needle, the Smart Needle resulted in successful femoral arterial cannulation on the first attempt in 100% of cases, whereas >1 attempt was needed in 72% of cases when the standard needle was used. Smart Needle use was also associated with a reduction in the risk of any hematoma (25% versus 46%) or hematomas >5 cm (14% versus 28%) compared with the standard needle.

**Femoral Arterial Cannulation in Patients With Iliofemoral Bypass Grafts**

In patients with PAD and iliofemoral bypass grafts, access via the nongrafted side (if the graft is unilateral) or radial side (if bilateral) is desirable. In cases in which femoral access is desirable, a micropuncture needle is preferred, and the needle should be directed to the hub of the graft. After backflow of blood is ensured, the micropuncture guidewire should be advanced under fluoroscopy. In cases in which the guidewire enters the native artery and fails to advance beyond a stenosis, the needle should be exchanged for the 4F micropuncture sheath, and a femoral angiogram should be performed to roadmap the native and the bypass graft course. Depending on the angiogram, the wire can be directed into the graft, or if the arteriotomy site is cranial, the sheath can be removed and the area manually compressed and reaccessed at the desired position. In most cases of graft access, it is recommended to achieve vascular closure via manual compression, and vascular closure devices should usually be avoided.

**Vascular Closure**

**Manual Compression**

Worldwide, manual compression is the most commonly used technique to achieve hemostasis after removal of a femoral arterial sheath. The femoral arterial sheath should be left in for the least amount of time after angiography because the risk of thrombotic vascular complications as well as bleeding increases with the duration the sheath is left in place. As such, the sheath should be removed immediately after diagnostic procedures (if no anticoagulation is used). When anticoagulants are used for the procedure, the sheath should be removed when the activated clotting time is <150 to 160 seconds or the partial thromboplastin time is <45 seconds (when heparin is used), 2 hours after bivalirudin is stopped, 6 to 8 hours after the last enoxaparin dose, or when the fibrinogen level is >150 mg/dL when fibrinolytics are used. If the patient is on warfarin and the international normalized ratio is >2.0, consideration must be given to using a closure device or using fresh frozen plasma before sheath removal (although with a radial artery approach, the situation may have been avoided). Before the arterial sheath is removed, the following checklist must be reviewed to ensure comfort both for the patient and for the operator doing manual compression. The patient should be moved closer to the side edge of the bed next to the operator removing the sheath (to prevent the operator having to reach over and strain the back), the bed should be lowered to levels that would be comfortable for the operator, the patient should be connected to a monitor to assess heart rate (continuously) and blood pressure (initially every 2 minutes), the blood pressure should be treated if too high, and the nurse monitoring the patient should be informed of the procedure and ready with medications in case of a vasovagal reaction.

Under sterile precautions, the sutures holding the sheath in place are removed, and the sheath is allowed to bleed back briefly to expel any thrombus. The artery is then palpated from the skin nick cranially with the use of 3 fingers (preferably fingertips). With gentle pressure over the artery with the fingertips of 1 hand, the sheath is removed with the other, allowing for back bleeding at the skin incision site to flush out any remaining thrombus. Manual compression is then applied with the fingertips with the 3-finger approach from the skin nick proximally along the length of the artery while the distal pulse is preserved (checked every few minutes). Alternately, a rolled gauge can be placed along the length of the artery and pressure applied to it with the palm of the hand, with the operator leaning forward and using his/her upper body weight to transmit force. The duration of compression varies with the French size of the catheter (a rough rule is for each 1F to hold for 5 minutes). The pressure should be reduced during the last 5 minutes of compression to 25% of initial pressure. Once hemostasis is achieved, the distal pulse is palpated to ensure adequate limb perfusion. If the patient has both an arterial and a venous sheath, the arterial sheath should be removed first and the venous sheath removed 5 minutes later. This technique avoids the risk of arteriovenous fistula formation and also preserves a venous access for medication administration in case of a vasovagal reaction. After the sheaths are removed, the site is cleaned with an antiseptic solution and covered with a small transparent dressing. Opaque dressings and large dressings should be avoided because they might mask bleeding and hematoma formation. Historically, advice on bed rest has depended on the size of the sheath, with the corresponding leg straight for a minimum of 1 hour for each French size of the arterial sheath (eg, 10F=10 hours). However, the adequate duration
of bed rest after sheath removal appears to be decreasing, and, in certain settings, ambulation as early as 1 hour after removal of a 5F sheath or 1.5 hours after removal of a 6F sheath has been shown to be safe.

The advantages of manual compression are that it is associated with the lowest vascular complication rate, as shown in numerous studies. The disadvantages are discomfort associated with sheath removal; inability to tolerate prolonged supine position due to a variety of comorbid conditions (e.g., spinal stenosis, chronic low back pain, congestion heart failure, severe chronic obstructive pulmonary disease, severe valvular disease); longer duration of time to ambulation; and potentially increased time to hospital discharge.

Vascular Closure Device

Vascular closure devices (VCD) have emerged as an effective alternative to traditional mechanical compression after angiography since their introduction. The data on efficacy and safety of these devices are controversial. A number of meta-analyses and randomized and nonrandomized studies have shown variable results. Some studies have shown efficacy equivalent to that of manual compression, and a few have shown superiority of these devices to manual compression. However, other studies have expressed concern about an increased risk of complications with these devices. Concerns also exist regarding excess vascular inflammation and scarring associated with VCDs. Nevertheless, these devices have the potential to reduce the time to hemostasis, facilitate early patient mobilization, decrease hospital length of stay (if same-day discharge is adopted for percutaneous coronary interventions), and improve patient satisfaction.

The commonly available VCDs are listed in Table 2. VCDs are classified as follows: (1) active approximators, in which the device actively approximates the arteriotomy site such as use of anchor and collagen plug (Angio-Seal), suture (Perclose), or a nitinol clip (Starclose), versus passive approximators, in which the arteriotomy is sealed passively by using either a sealant (gel foam) or thrombin, which facilitates clot formation; (2) foreign body versus none, based on whether a foreign body (suture, clip, sealant, anchor, plug) is left behind in the body; (3) extraluminal, in which there is no foreign body left inside the artery, versus intraluminal, in which a foreign body is left inside the artery; and (4) temporary, in which the foreign body gets absorbed over a period of time, versus permanent, in which it stays permanently.

A variety of assisted compression devices are available that can help to achieve hemostasis noninvasively or are used as an adjunct to manual compression. These include mechanical compression devices such as the FemoStop and the RadiStop (Radi Medical System, Uppsala, Sweden) and various topical hemostasis pads and patches such as the Chito-Seal (Abbott Vascular, Santa Clara, CA), V+Pad (Angiotech Interventional, Chicago, IL), Syvek Patch (Marine Polymer Technologies, Danvers, MA), SafeSeal (Medrad Interventional/Possis, Pittsburgh, PA), and D-Stat (Vascular Solutions, Inc, Osseo, MN).

We will discuss the 3 commonly used VCDs: the collagen plug–based (Angio-Seal), the suture-based (Perclose), and the nitinol clip–based (Starclose) devices.

Table 2. Vascular Closure Device Classification

<table>
<thead>
<tr>
<th>Active Approximators</th>
<th>Passive Approximators</th>
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<tbody>
<tr>
<td>Angio-Seal (St Jude Medical, Inc, St Paul, MN)</td>
<td>Boomerang (Cardiva Medical, Mountain View, CA)</td>
</tr>
<tr>
<td>AngioLink (Medtronic CardioVascular, Santa Rosa, CA)</td>
<td>Duett (Vascular Solutions, Inc, Minneapolis, MN)</td>
</tr>
<tr>
<td>FISH (Morris Innovative Research, Bloomington, IN)</td>
<td>Mynx (AccessClosure, Mountain View, CA)</td>
</tr>
<tr>
<td>Perclose (Abbott Vascular, Santa Clara, CA)</td>
<td>VasoSeal (Datascope Corp, Montvale, NJ)</td>
</tr>
<tr>
<td>Starclose (Abbott Vascular, Santa Clara, CA)</td>
<td></td>
</tr>
<tr>
<td>SuperStitch (Sutura, Inc, Fountain Valley, CA)</td>
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</table>

Only Food and Drug Administration–approved devices are listed.

Contraindications/Caution for Using a Vascular Closure Device

Although there is no absolute contraindication for the use of VCD (except perhaps allergic reaction to any of its components), the following conditions should warrant consideration for an alternate strategy. These include low punctures at the bifurcation or in the superficial femoral or the profunda femoris artery (increased risk of ischemic complications); high puncture above the level of the inferior epigastric artery (2.8 times the risk of retroperitoneal hemorrhage); patients with moderate to severe PAD at the site of sheath entry (increased risk of ischemic complications); patients with small (<4 to 5 mm) femoral artery caliber (increased risk of ischemic complications); patients with diabetes mellitus and other immunodeficiency (increased risk of infection); and patients who have known allergies to beef products, collagen, collagen products, or polyglycolic or polylactic acid polymers (for the Angio-Seal device).

Angio-Seal Insertion Technique

Angio-Seal (St Jude Medical, St Paul, MN) is an anchor/collagen plug–based active approximator and is the most commonly used VCD in the United States. It involves a short learning curve and has the highest success rate of all the VCDs. It achieves hemostasis by active approximation with the use of an intravascular anchor and a collagen plug sandwich. The intravascular anchor usually resorbs in 3 months. The disadvantage of this device is the presence of the intravascular anchor, which can cause ischemic complications in small femoral arteries or in rare cases of anchor embolization. The intravascular anchor, the collagen plug, and the suture that holds the 2 together extend into the tissue tract, serving as nidus for infection. It can be used only for sheath size ≤8F.

The Angio-Seal device consists of (1) a delivery device composed of a biodegradable anchor and a collagen plug; (2) an insertion sheath and arteriotomy locator, which is a modified dilator; and (3) a 0.035- or 0.038-inch 70-cm J-tip guidewire. A femoral angiogram should be obtained before the procedure to ensure that there are no contraindications (as...
discussed above). Routine regloving of and reprepping of the area before VCD insertion may potentially reduce the risk of infection. Before the sheath is removed, it should be flushed and free of thrombus. The Angio-Seal device comes in 2 sizes, 6F or 8F, depending on the size of the femoral arterial sheath used. The arteriotomy locator is inserted into the insertion sheath until the 2 pieces snap securely together (Figure 2). The J-tip guidewire is inserted through the femoral arterial sheath, and the sheath is removed over the guidewire, ensuring adequate guidewire length inside the artery. The insertion sheath with arteriotomy locator is then loaded onto the guidewire and advanced until pulsatile flow is observed from the arteriotomy locator (Figure 2A). Some operators then withdraw the assembly until blood slows or stops from the drip hole and then readvance until pulsatile flow is again noticed, at which point the distal tip is just distal to the arteriotomy site. The insertion sheath is then stabilized with one hand while the arteriotomy locator and guidewire are removed with the other by flexing it upward. The insertion sheath is then held steady, and the delivery device is inserted into it by holding the bypass tube, ensuring that the reference indicators of the insertion sheath and the delivery device are facing upward. The delivery device is advanced until it snaps into the insertion device. The insertion sheath is then held steady while the device cap is pulled back until it assumes a fully rear-locked position. This deploys the anchor. The assembly is withdrawn until the anchor is up against the arterial wall, at which time the collagen plug is also deployed, and a tamper tube now becomes visible (Figure 2B). The assembly back is held, and the tamper tube is pushed down while the operator pulls back on the assembly at the same time (Figure 2C). A clear stop is exposed on the suture, and in most cases a black compaction marker is seen beyond it. The suture is then cut below the clear stop, and the tamper tube is removed. The remainder of the suture is then cut, going in below the skin level as close to the knot as possible. A sterile dressing is applied to the site. Reaccess at the site of Angio-Seal deployment should be done ≥90 days after the procedure (to allow the anchor and the suture to be absorbed). However, reaccess within 90 days can be performed safely 1 cm proximal to the prior arteriotomy site.43

Perclose Deployment Technique

The Perclose device (Abbott Vascular, Santa Clara, CA) is a suture-based active approximator that mimics a surgical suture. It involves a higher learning curve, has been shown to have a higher failure rate,44,45 and results in a longer time to achieve hemostasis than the collagen plug–based (Angio-Seal) device.45 The device leaves behind a suture and hence could be a nidus for infection. The reported infection rate (≈0.3%)46 is comparable to that with Angio-Seal device.

The device consists of the (1) delivery device consisting of a biodegradable pretied suture; (2) snared knot pusher; and (3) suture trimmer. After a femoral angiogram to ensure that a closable arteriotomy site is obtained, a 0.035-inch J-tipped guidewire is inserted through the femoral arterial sheath. The guidewire is then removed, and the device is advanced until pulsatile blood flow is seen from the marker lumen (Figure 3A). The device is then deployed in 4 steps (Figure 3A) as follows. In step 1, the lever is lifted up to deploy the foot plate inside the artery, and the device is pulled back slowly until resistance is felt when the foot is up against the arterial wall. The pulsatile flow through the marker slows and ceases. In step 2, with the device held steady with 1 hand, the plunger is depressed, which deploys the needles. In step 3, with the device held steady with 1 hand, the plunger is retracted to retrieve the suture and is pulled back until the suture is taut. At this stage, the plunger is freed by cutting the suture with the use of the quick cut or a sterile scissor. In step 4, the back tension on the device is reduced, and the foot lever is returned to the nondeployed position. The device is now withdrawn until the guidewire

Figure 2. Angio-Seal deployment technique. A, Locate the arteriotomy site; B, set the anchor at the arteriotomy site; and C, seal the site with the collagen plug. (Angio-Seal is a trademark of St Jude Medical. Reprinted with permission from St. Jude Medical, © 2009; all rights reserved.)
exit port is at a slight distance from the skin level. At this point, there should be minimal bleeding around the device, unless the arteriotomy is in fact larger than the diameter of the device, which does not bode well for successful hemostasis. If hemostasis is critical, the guidewire can be readvanced through the device at this stage; if the device fails, another sheath can be placed. Next, the 2 suture ends are removed from the device, and the blue rail suture limb is loaded onto the snare knot pusher. The blue rail limb is then wrapped on the forefinger of the left hand, with gentle traction applied. The Perclose device can now be removed from the body. Back tension is maintained on the blue rail limb, and the knot pusher is advanced into the skin tract parallel to the suture limb. If the wire was left in place, it should be removed before the knot is cinched. The knot pusher is then pushed forward while back tension on the rail limb is maintained, until the knot pusher stops against the anterior wall of the artery (Figure 3B). The white nonrail suture limb is then tightened. Wetting the sutures with saline can help the knot to go down the tract with ease. The knot trimmer is then loaded onto both suture limbs while the operator keeps tension on the limbs. It is then advanced all the way down to the knot, and the knot is trimmed by pulling back on the red trimming lever. The cut sutures are removed, and the site is inspected for hemostasis. The artery is palpated for an arterial pulse distal to the suture site. A small transparent sterile dressing is applied to the site. There is no reaccess restriction after the use of this device. For larger devices, such as stent grafts or percutaneous valves, the technique of “preclosure” before sheath placement can be very useful.47

Starclose Deployment Technique
The Starclose device (Abbott Vascular, Santa Clara, CA) is a nitinol clip–based active approximator that is extraluminal. The advantage of this device is the shorter learning curve compared with Perclose and the extraluminal nature of the clip, which potentially decreases ischemic vascular complications.

The Starclose device consists of the (1) clip applicator; (2) delivery sheath; (3) dilator; and (4) 0.035-inch J-tip guide-wire. After obtaining a femoral angiogram to ensure a “closable” arteriotomy site, the skin tract is enlarged with a curved tip forceps adequate to allow delivery of the bulky shaft of the Starclose device. The dilator is inserted into the Starclose delivery sheath (Figure 4A). The 0.035-inch J-tip guidewire is inserted through the femoral artery sheath, which is exchanged for a Starclose delivery sheath. The guidewire and the dilator are removed. The clip applicer is then loaded into the sheath until a click is heard at the hub of the sheath (Figure 4A). The assembly is then retracted by 3 to 4 cm, and the plunger is depressed to deploy the locator wings. The sheath is then split partially, and the device is lowered into the tract to ensure deliverability of the device. The device is then stabilized with the left hand and is retracted until a resistance is felt when the locator wings are up against the arterial wall. With the device at a 45° angle, the sheath is split all the way down to the artery until a click is heard (Figure 4B). The clip applicer is stabilized with the left hand and is raised to a 60° to 75° angle. The assembly is then gently pressed down until
arterial pulsations are felt. With gentle downward pressure, the clip is deployed, maintaining downward pressure for 2 to 3 seconds. The tissue around the clip applicer is depressed with the left hand, the clip applicer is removed, and pressure is held for several seconds. A sterile dressing is applied to the site. Similar to the Perclose device, there is no reaccess restriction after use of this device, although this has not been well tested.

Venous Closure

The Perclose and Starclose devices can also be used as closure devices for veins (not approved by the Food and Drug Administration). The technique is similar to arterial closure except that care should be taken not to apply too much back tension, which can tear the thin venous wall. Routine use of closure devices for the femoral vein is not recommended but may be considered in certain cases, such as after fibrinolytic therapy.

Conclusions

Vascular complications are the most common complication during either diagnostic or interventional procedures. Prevention of vascular complications starts with good “access hygiene,” which involves review of prior femoral angiograms (when available), routine use of fluoroscopy to aid access, use of smaller catheters (4F to 5F for diagnostic catheterization), and prompt removal of sheaths whenever possible. VCDs are now increasingly utilized for arterial closure and have been shown to considerably reduce the time to hemostasis and time to ambulation, improve patient satisfaction, and reduce length of stay (if same-day discharge is implemented). However, the vascular complication rate is still high, and strategies like radial access show promise for reducing this risk (up to 73% reduction in major bleeding).

Recent randomized trials such as the Radial Versus Femoral Artery Access Site Study (RIVAL) will help to determine whether routine radial artery cannulation is superior to femoral arterial access. Regardless, femoral access will remain an important skill for physicians performing cardiovascular diagnostic and therapeutic procedures.

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