Vascular Access, Management, and Closure

Best Practices

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Foreword

"This Could Be Heaven, This Could Be Hell"

(Lyrics: *Hotel California*)

Interventional cardiovascular medicine is by nature interventional; you must intervene. You must first open the door to access the site of the work, and then, always, close the door as you go. How one accesses the vascular system, and leaves it, is often a major determinant of whether the procedure is considered a success or a disaster. This electronic book, taking advantage of current technology, illustrates the techniques that ensure safe entry into the circulation and, perhaps more importantly, safe exit.

Dr. Shroff and Dr. Pinto have assembled a group of authors who have vast experience in vascular access for routine procedures as well as complex situations requiring innovative access and exit. These authors describe novel techniques, recently developed, for coronary and structural heart disease interventions. As the list of what can be done with percutaneous intervention grows, so does the importance of understanding the tools and methods for safely entering into and exiting from the intervention.

This volume contains vital knowledge for all operators seeking to safely perform interventional procedures. The beautifully performed TAVR procedure—or, in the future, mitral valve replacement—or the cardiac assist devices necessary to ensure the work, will never be successful if you can check in, "but you can never (safely) leave." Make the interventions "heaven," not "hell."

Master these techniques!

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Today's Interventionalists' Armamentarium

In 1929, Werner Forssmann inserted a urologic catheter into his brachial vein and, advancing the catheter into his right atrium, performed the first cardiac catheterization. In the mid 20th century, other pioneers performed hemodynamic measurements through techniques such as transbronchial, transseptal, and direct myocardial puncture. However, with the concomitant decrease in the incidence of rheumatic valvular disease and the increasing incidence of ischemic coronary events in an aging population, the need to reliably image the coronary arteries became evident.

Accessing the brachial artery via cutdown, Mason Sones introduced the technique of coronary angiography. Using preformed catheters still in use today, Melvin Judkins facilitated a percutaneous approach to coronary angiography primarily using the femoral artery as an access site. Several decades later, the Swiss angiologist Andreas Gruentzig performed the first percutaneous balloon angioplasty heralding the advent of the discipline of Interventional Cardiology.

With the use of larger bore preformed interventional guiding catheters, femoral arterial cannulation became the default vascular locus for a generation. However, as the number of diagnostic and interventional cardiac catheterization procedures increased exponentially, it became evident that complications associated with arterial and venous access were not infrequent, and were associated with significant morbidity and increased procedural cost.

While vascular closure devices reduce time to ambulation post-procedure, they do not consistently reduce complications compared with manual compression. Radial arterial access has now emerged as the first technique to consistently reduce access site complications, especially in patients with acute coronary syndromes receiving potent antithrombotic therapy. It is not an overstatement to say that the radial artery as an access site has created a major paradigm shift in our approach to arterial access. However, with the rapid emergence of procedures to treat valvular heart disease such as transcatheter aortic valve replacement, interventional procedures to treat structural heart disorders, and placement of mechanical support systems, the need to place large bore catheters percutaneously into the arterial and venous systems places great burdens on interventional cardiologists to acquire a knowledge base and technical skill set beyond radial cannulation. Also, as the discipline of interventional cardiology expands into treatment of peripheral vascular disease in an aging and sicker population, challenges to the placement and removal of catheters are increasing.

It is incumbent on interventional cardiology training programs to provide comprehensive exposure and training in small and large bore arterial and venous cannulation and closure. Radial, brachial, axillary, femoral (retrograde and antegrade), transseptal, transcaval, popliteal, and pedal access skills must be part of the interventionalists' armamentarium. *Vascular Access, Management, and Closure: Best Practices* provides a state of the art, exhaustive approach to the anatomic and technical skills needed to safely perform contemporary and emerging interventional procedures from catheter insertion to vascular closure.

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Welcome Insights

After the original description of percutaneous access by Seldinger in 1953, vascular access was largely taken for granted for the first half century of invasive vascular procedures. Large hollow needles placed in the femoral artery using palpation guidance alone accounted for most of the peripheral and coronary procedures done until the introduction of radial catheterization nearly 40 years later. That it took until the late 1990s for serious attention to be paid to optimizing techniques and limiting complications is something of a mystery. Operators considered vascular access and closure to be a pedestrian subject and the "poke until you get a gusher" approach to vascular access prevailed (and still prevails in many institutions and practices), accounting for a host of complications.

In the past 20 years, the growing awareness that the old methods are not enough has been good news for our patients. Better femoral access, using imaging (fluoroscopic and/or ultrasound), micropuncture, femoral contrast injection, improved closure, and superior complication management have made a significant dent in the morbidity and mortality associated with access. The broad movement toward radial rather than femoral access has been the biggest change in this arena and has rapidly become the standard of care in much of the world, albeit with somewhat slower adoption in the United States. A host of new techniques, presented elegantly in this book, have added to the feasibility and safety of interventional medicine. This increased interest in vascular access and application of optimal techniques has facilitated exciting and innovative procedures, such as percutaneous ventricular assist, endovascular aneurysm repair, and transcatheter aortic valve replacement.

The authors and editors of this book have combined, in one place, a wealth of information on best practices. Some of the sections describe novel and unusual approaches while others refine widely practiced techniques. Particularly important are the descriptions of methods for operators to handle looming or evolving complications. Although there are high level randomized clinical trials comparing femoral and radial approaches, the literature remains relatively incomplete for other types of access and for vascular closure. In many areas, we are dependent on opinion based on experience, thus this book has the potential to provide considerable insight for the reader. Nearly seven decades after Seldinger enabled us to stop doing routine cutdowns this book is a welcome effort.

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Introduction

Vascular access and closure are critical to the success of percutaneous interventional cardiac procedures. As diagnostic and therapeutic options expand, so do the needs of the invasive/interventional practitioners. Currently, clinicians receive education and training in a variety of venues and formats including fellowship training, industry-sponsored events, didactic presentations at meetings, procedure simulations, and proctorships. The authors of this educational tool have endeavored to develop a contemporary, practical, highly-visual tool to aid practicing physicians by supplementing their current understanding and, in some instances, providing step-by-step tutorials for performing various access and closure procedures.

This eBook is divided into 3 chapters:

- Chapter 1 covers routine (<8Fr) access and closure procedures
- Chapter 2 covers large bore (>8Fr) access and closure procedures
- Chapter 3 reviews access site complications and management

Each chapter contains several short sections that are easy to review and include references to more definitive works. Photos, illustrations, and videos enhance the content of this digital eBook. Our clinically-focused authors share their techniques with an emphasis on best practices whenever available.

We are excited to offer this content for fellows in training, early career physicians, and experienced operators to apply in their practices. Given the electronic format, we envision providing periodic updates as new information becomes available.

Sincerely

ADHIR SHROFF, MD, MPH, FSCAI & DUANE PINTO, MD, MPH, FSCAI
On behalf of the Vascular Access Working Group

CHAPTER 1

Arterial Access and Closure for Coronary and Structural Heart Procedures

CHAPTER 1 | SECTION ONE

Ultrasound Guidance for Femoral Access

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Overview

Femoral access remains necessary for numerous procedures requiring large bore access and involving mechanical circulatory support. For patients at high risk for difficult access or complications, ultrasound guidance can help clinicians obtain vascular access with greater accuracy and speed and fewer complications.

Equipment and procedural considerations

When choosing an ultrasound machine for vascular access procedures it is critical that it have the following characteristics:

- High quality image
- Depth of the field of view that can be adjusted from 1.5–6 cm
- Large display that can be viewed from a distance

Ultrasound enables clinicians to view tubular vascular structures in one of three basic anatomic views:

- Transverse / cross-sectional (axial) view
- Longitudinal (sagittal) view
- Oblique (axial and sagittal mix) view

The axial view is typically used for femoral access due to the curved shape of the groin, but the longitudinal view has the advantage of continuous visualization of the needle as it is advanced toward the vessel. The longitudinal view also enables clinicians to visualize the position of the puncture along the length of the vessel, which may be relevant if a particular location is desired (see Figures 1, 2, 3)

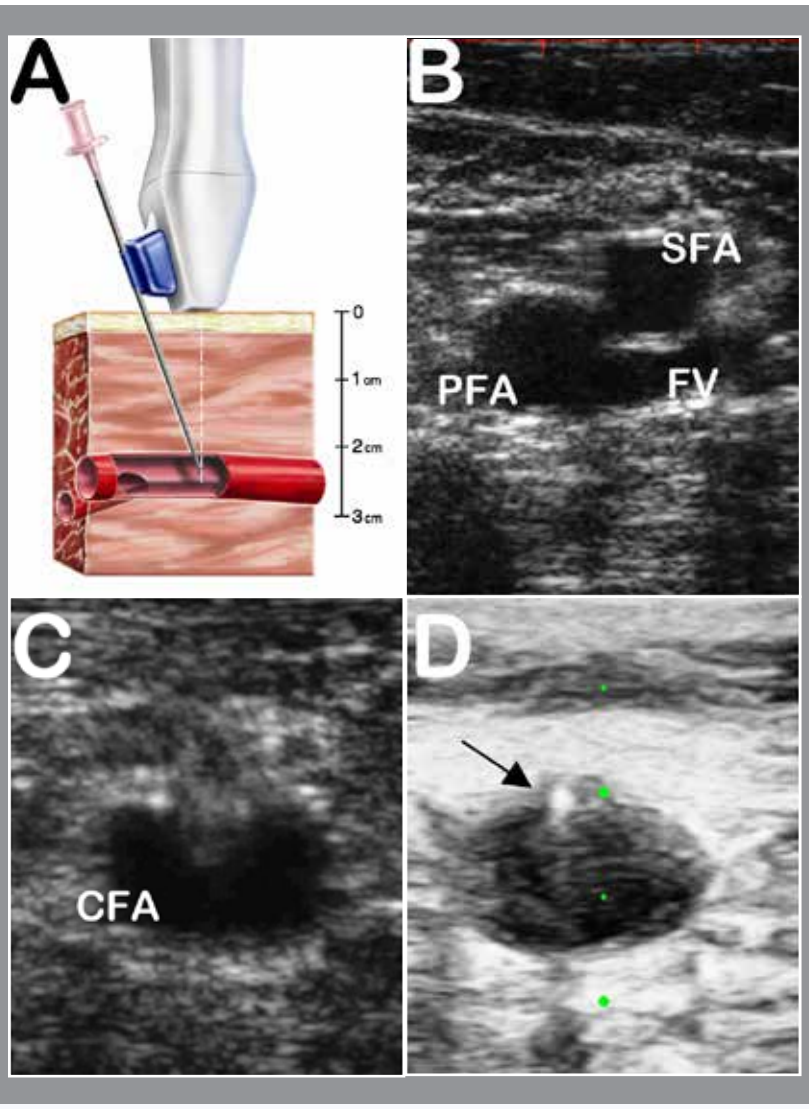

Figure 1: Vascular Ultrasound Images

(A) The attached needle guide fixes the needle's angle of entry to intersect the vessel at the imaging plane at a depth of 1.5, 2.5, or 3.5 cm below the skin. (B) The right common femoral bifurcation is imaged in the axial plane, demonstrating the profunda femoral artery (PFA) and superficial femoral artery (SFA). Compression is used to differentiate arteries from the femoral vein (FV). (C) The probe is moved or angled superiorly to the common femoral artery (CFA). During needle advancement, the anterior wall of the vessel is indented by the needle tip. (D) The guidewire insertion point (arrow) can be imaged following cannulation to confirm that the insertion is above the CFA bifurcation.

Modified from Seto, *JACC Cardiovasc Interv.* 2010; 3(7):751-8 with permission

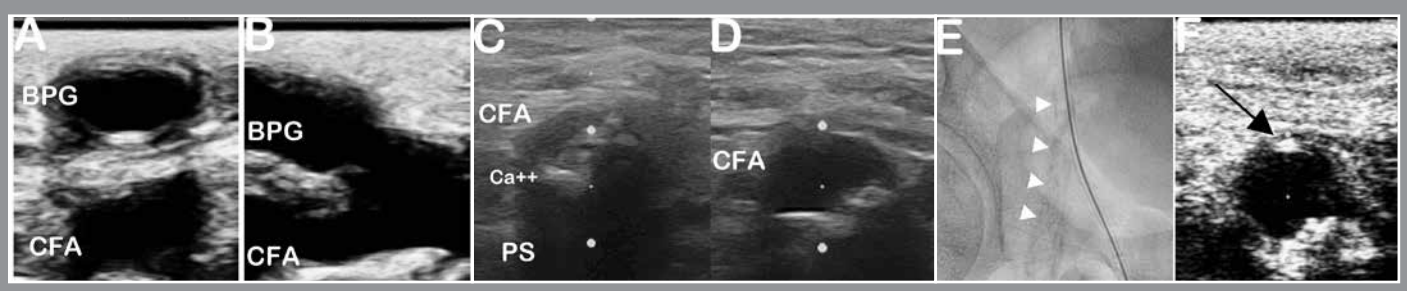

Figure 2: Femoral Ultrasound Images

(A) Axial view of femoral bypass graft (BPG) directly over the common femoral artery (CFA). (B) Longitudinal view of the anastomosis of the BPG with the CFA. Ultrasound enabled puncture away from the BPG insertion. (C) CFA with extensive circumferential calcification (Ca^{++}), causing posterior shadowing (PS). (D) Same patient imaged higher in CFA, with calcification restricted to posterior wall and pulsatility noted in the anterior wall. (E) RAO fluoroscopic image demonstrating sheath insertion at point (D) where posterior but not anterior calcification is present (arrowheads). A StarClose closure device was successfully deployed at this location. (F) An Angio-Seal anchor (arrow) in another femoral artery placed 1 week prior.

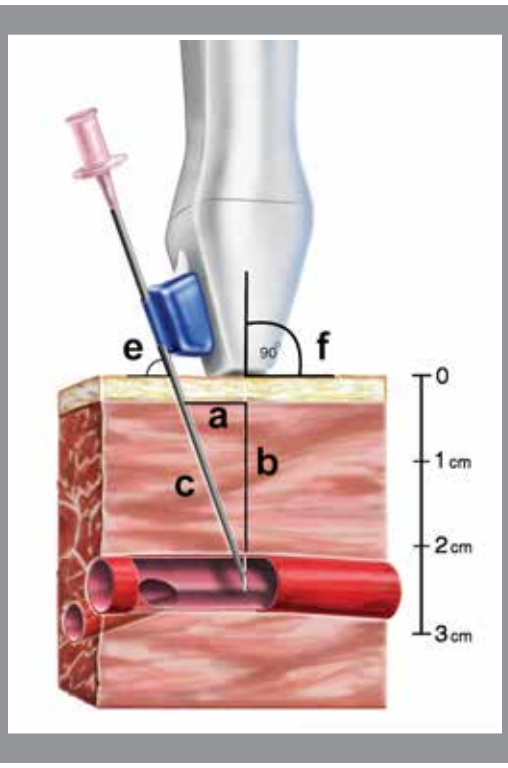

Figure 3: Axial Technique of Ultrasound Guided Access

The probe is aligned perpendicular (f) to the vessel creating a circular image of the vessel. Without a needle guide, the needle is inserted at an angle (e) and at a distance (a) from beneath the center of the probe. The needle is not visible until it crosses the imaging plane of the probe at a depth (b). Changes to (a), (b), (e), and (f) are interrelated, such that the success of this technique depends on experience, repeated jabbing motions of the needle, and adjustment to probe angle (f) to visualize the course of the needle. With a needle guide selected based on the depth (b) of the vessel, the needle angle (e) is fixed to intersect the ultrasound plane at the set distance below the ultrasound plane, guaranteeing needle puncture at the location imaged. The probe angle (f) can and should be adjusted to allow for shallower entry of the needle.

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Pro Tips

√ Without needle guides, repeated short jabbing motions of the needle and tilting of the probe are needed to track the location of the needle tip.

√ Use the same fixed probe angle to image the bifurcation at the CFA to avoid high-sticks.

√ Use ultrasound after wire insertion to identify the puncture location more accurately than a femoral angiogram.

√ Use a deep longitudinal view to identify the center of the femoral head and the inguinal ligament to confirm that the intended puncture site is above the femoral head and not above the inguinal ligament. (Figure 4)

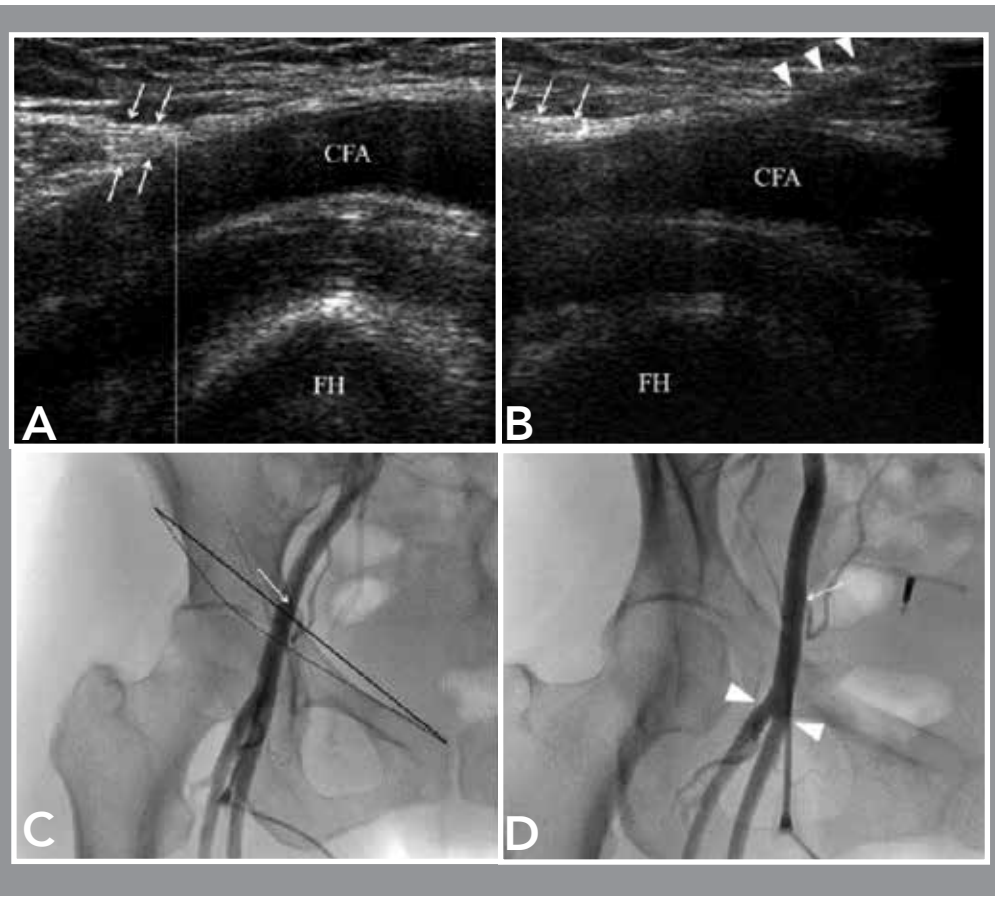

Figure 4: Ultrasound and Femoral Angiogram Images

(A) Ultrasound (US) image shows US-IL (arrows), CFA, and femoral head (FH) along a longitudinal plane. The US-IL is located at the level of the upper border of the femoral head (dotted line). (B) US image shows a 6 Fr introducer sheath (arrowheads) placed below the US-IL (arrows). (C) Femoral angiogram shows different courses of the US-IL (dotted line) and FL-IL (solid line). The origin of the IEA (arrow) is located above the US-IL and FL-IL (rotation, 0°). (D) Femoral angiogram shows the location of the introducer sheath between the IEA (arrow) and the CFA bifurcation.

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Putting it into practice

The general axial imaging techniques described above are sufficient for femoral artery access, with the following specific tips:

- Ultrasound is able to image the CFA bifurcation and guard against an overly low or inferior cannulation. The superior anatomic landmarks (anterior superior iliac crest, inguinal ligament) are the main protection against a high insertion.
- Ultrasound is able to visualize the inguinal ligament as an echodense triangular density on the longitudinal view (or linear density on axial views).
- A vein visualized directly posterior to an artery likely represents the SFA and the femoral vein rather than the CFA. The ultrasound should be moved superiorly to avoid a low stick.
- Tilting the probe and needle guide together is a good way of inserting the needle at a flatter/shallower angle (reduced risk of wire/sheath kinking).

Ultrasound readily identifies patients with high common femoral artery (CFA) bifurcation. Awareness of CFA bifurcation location allows operators to choose whether to obtain high access above bifurcation, intentionally access the superficial femoral artery, or use the contralateral femoral artery.

The location of the CFA bifurcation can be partially predicted by fluoroscopy of the femoral head. The current expert recommendation is to insert the needle just below the center of the femoral head to minimize the risk of retroperitoneal hemorrhage while avoiding most CFA bifurcations. The Femoral Arterial Access With Ultrasound Trial (FAUST) demonstrated that the overall rate of CFA cannulation was not significantly different with ultrasound guidance compared with fluoroscopy (86.4% vs 83.3%; P = .17; Figure 5) but was higher in the 31% of patients with high CFA bifurcations (82.6% vs 69.8%; P < .01; Figure 6).

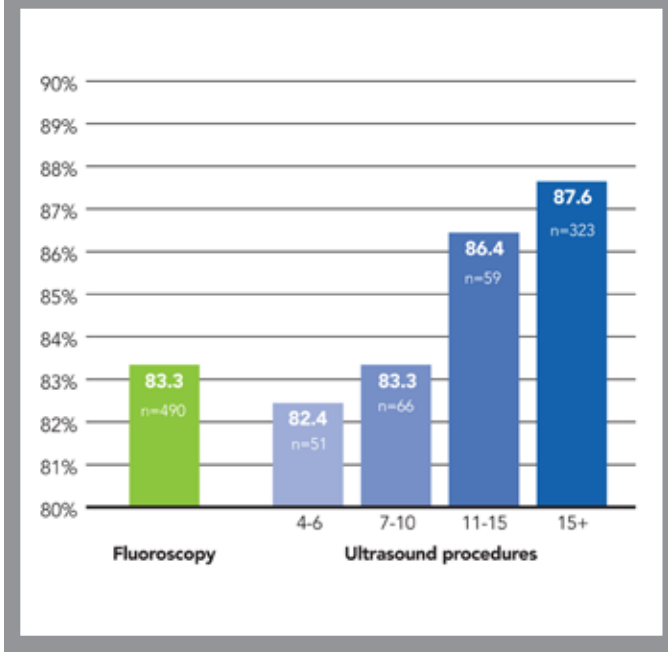

Figure 5: Trend Toward Improved CFA Cannulation Success with Ultrasound Guidance

Increasing experience with ultrasound guidance demonstrated a trend toward improved common femoral artery (CFA) cannulation success (P = NS). Operators with the greatest experience had an 87.6% success rate with ultrasound guidance, compared with an 83.3% success rate for fluoroscopy (P = 0.076).

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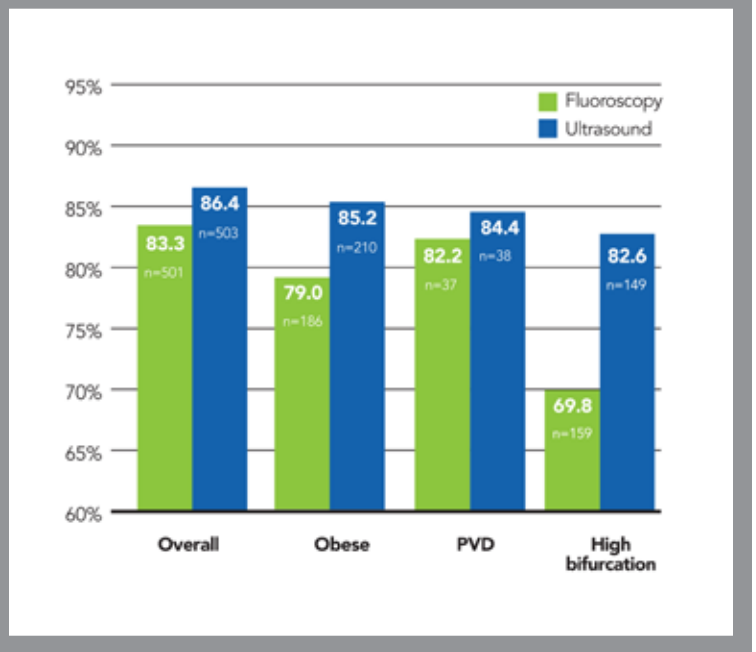

Figure 6: Ultrasound Guidance and Sheath Placement

*Ultrasound guidance did not demonstrate a significantly superior rate of sheath placement in the common femoral artery in the overall population or the obese or peripheral vascular disease (PVD) subgroups. Ultrasound guidance significantly increased common femoral artery sheath placements in the 31% of patients who had a femoral bifurcation over the femoral head. *P < 0.01.*

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Summary

- Ultrasound guidance for femoral access reduces vascular complications, number of attempts, accidental venipunctures, and time to access.
- It is easy to learn and utilizes widely-available equipment.
- Ultrasound facilitates precise CFA cannulation regardless of anatomic variation, which can increase the success of closure device placement.

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CHAPTER 1 | SECTION TWO

Optimal Femoral Artery Puncture Technique

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Overview

Arterial access is one of the most delicate and critical aspects of percutaneous procedures, and often the single most common cause of complications.[1] Ideal access can be ensured by taking advantage of available adjunctive techniques such as ultrasound, fluoroscopy, and micropuncture needles. This ensures a smooth procedure and significantly reduces the risk of complications. Despite increasing use of the radial artery for coronary angiograms, femoral artery access (also known as Judkins technique) is still the most widely used type of arterial access in the United States.[2] The common femoral artery (CFA) is readily palpable because of its large size, is usually free of atherosclerotic plaque, and can be compressed easily against the femoral head for hemostasis. These factors make it an ideal site for access.

Anatomy

Familiarity with the anatomy of the femoral artery is extremely important for safe vascular access and anticipation of complications. The CFA is a continuation of the external iliac artery below the inguinal ligament and bifurcates into the superficial femoral artery (SFA) and the profunda femoris (PF) branch. In the majority of cases (77%), the bifurcation is below the level of the femoral head.[3] Figure 1 shows the course and branches of the CFA with the corresponding bony landmarks.

Table 1 summarizes the different landmarks used for localization of the artery.

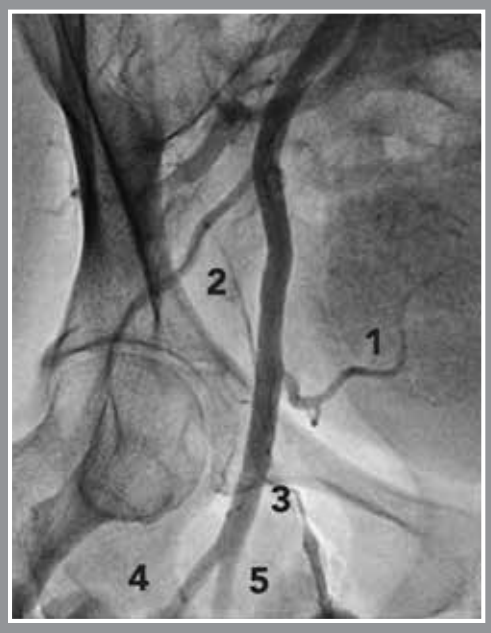

Figure 1: Angiographic Course and Femoral Artery Branches

(1) Inferior epigastric artery; (2) deep circumflex artery; (3) common femoral artery; (4) profunda femoris artery; (5) superficial femoral artery

Table 1: Landmarks Used for Femoral Artery Cannulation

Landmark	Rationale
Skin/inguinal crease	Inguinal crease is thought to represent the course of the inguinal ligament, hence CFA puncture is often 2–3 cm below the midpoint of the inguinal crease; however, this can be misleading as the inguinal crease may be distal to bifurcation of CFA in majority (71.9%) of limbs.[3]
Point of maximum impulse	Using the maximal pulse for CFA access is unreliable and often results in high or low sticks, especially in very thin or obese patients.
Bony landmarks	Mid inguinal point can be identified as the midpoint between the anterior superior iliac spine and pubic tubercle and is thought to simulate the course of inguinal ligament. Although better than skin crease, CFA puncture 2–3 cm below mid inguinal point still does not adequately localize inguinal ligament for ideal CFA puncture.
Fluoroscopic guided landmarks	Taking advantage of the consistent anatomical relationship between femoral artery and femoral head, a radiopaque marker can be placed on the skin corresponding to the inferior border of femoral head and initial skin puncture made at this site. Fluoroscopy significantly decreases the incidence of arterial access below inferior border of femoral head without increasing number of punctures above superior border of femoral head.[4]

Technique

Step 1: Skin puncture

Make a skin puncture 3 cm below the inguinal ligament or at the level of the lower border of the femoral head when using fluoroscopy (Figure 2). Create an intradermal bleb using 1–2% lidocaine and a 25G needle followed by deeper infiltration with a 22G needle. Apply negative suction prior to any infiltration to avoid intravascular injection of lidocaine. Some operators prefer a 2–3 mm wide and 2–3 mm deep skin nick at the site of entry using a #11 skin blade. This facilitates easy insertion of the sheath and creates a pathway for any oozing to come to the surface rather than forming a deep hematoma.

Step 2: Needle puncture

Advance an 18G Cook needle or a 21G micropuncture needle (Figure 3) bevel up through the skin at an angle of 30–45 degrees to puncture the CFA approximately 2 cm below the inguinal ligament using the modified Seldinger technique as shown in Figure 4. This corresponds to the mid portion of femoral head. An adequate CFA stick is vitally important to reduce complications associated with "high" and "low" sticks and ensure a smooth procedure.

Table 2 summarizes the complications of arterial puncture involving the SFA, PFA, or external iliac artery.

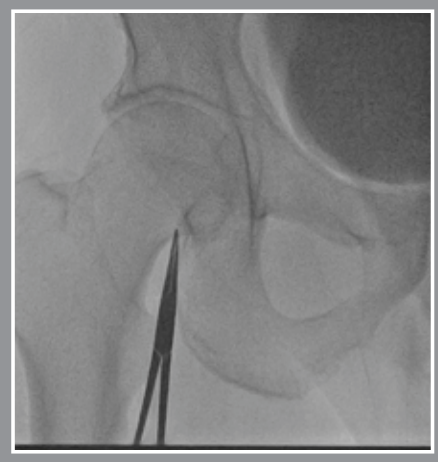

Figure 2: Hemostat Marking Inferior Border of Femoral Head Used as Site of Skin Puncture

Figure 3: 21G Micropuncture Needle (left) and Standard 18G needle (right)

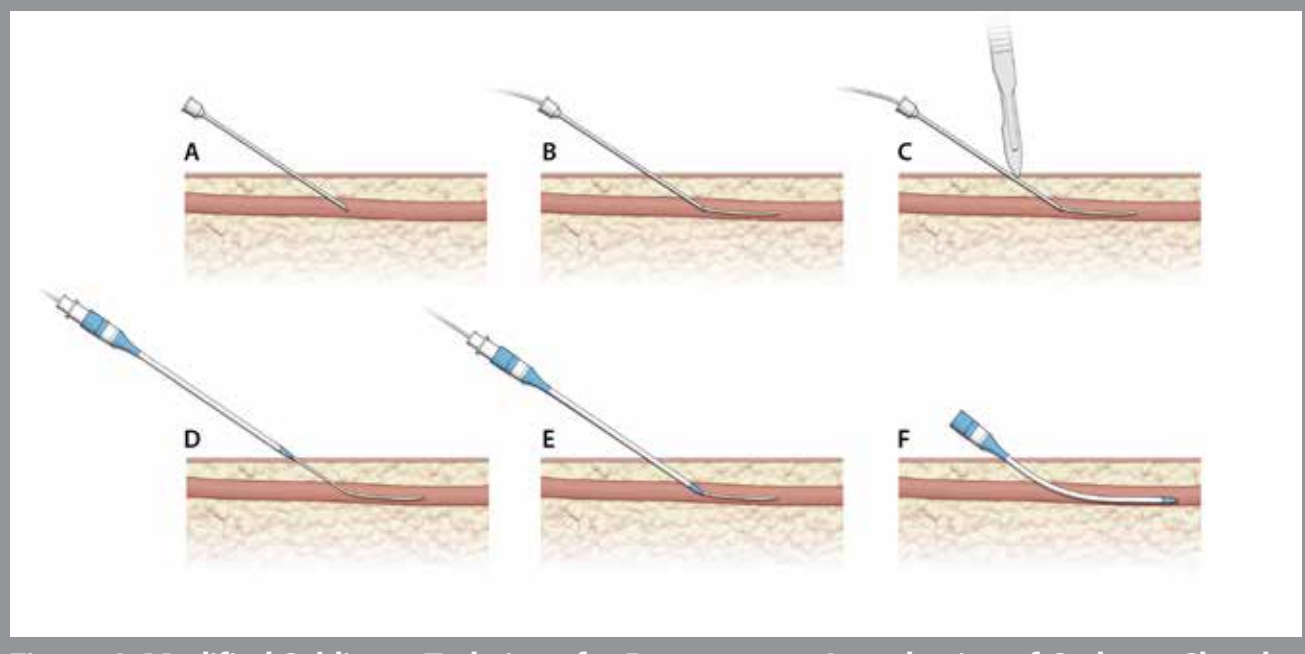

Figure 4: Modified Seldinger Technique for Percutaneous Introduction of Catheter Sheath

(A) Vessel punctured at site of interest with needle. (B) Soft tip guidewire inserted through needle lumen into vessel. (C) Needle removed with guidewire left in place, and skin nick made around wire at entry site with scalpel. (D) Sheath and dilator threaded over wire. (E) Sheath and dilator further advanced over guidewire and into vessel, ensuring that back end of wire is secure. (F) Dilator with guidewire removed and sheath remains within vessel.

Table 2: Complications of "High" and "Low" Puncture

High Puncture Complications (Above the level of inferior epigastric artery)	Low Puncture Complications (Superficial femoral artery or profunda femoris artery puncture)
• The lowest point of the inferior epigastric artery corresponds to the inguinal ligament. Any arterial puncture above the lowest point of the inferior epigastric artery (on femoral angiography) significantly increases the risk of retroperitoneal hemorrhage.[5] • Hemostasis is difficult due to inadequate compression leading to extraperitoneal hemorrhage and shock.	• Lack of underlying bony structure and lack of scaffolding by femoral sheath results in an increased risk of bleeding, hematoma, and pseudoaneurysms. • The smaller caliber of the arteries below the bifurcation makes them more prone to catheter-related arterial occlusions. • The tributaries of the femoral vein course above the superficial femoral artery, increasing the risk of arteriovenous fistula.[6]

Step 3: Wire and sheath insertion

Once pulsatile flow is observed, advance a wire (Figure 5) through the needle. To avoid potential complications such as dissection or perforation, do not advanced the wire if blood flow is not brisk or any resistance is encountered. Utilize fluoroscopy to confirm wire tip location and buckling in such cases.

0.018 inch wire: Use a 0.018 inch wire when using an 18G micropuncture needle. Note that the blood dribbles in this case rather than the pulsatile flow through the standard needle. Fluoroscopy is commonly used when advancing the wire, as the angled tip guidewire often finds smaller branches, such as the circumflex branch, increasing the risk of bleeding/hematoma. Once wire location is confirmed and satisfactory, insert the 4 Fr micropuncture sheath with the 3 Fr dilator over the 0.018 inch wire and remove the dilator with wire.

0.035–0.038 inch PTFE coated regular J (3mm) wire: The 0.035 is the standard wire and the 0.038 provides more support. The wire has an atraumatic distal end and the 3 mm floppy curve helps the wire stay intraluminal and avoid smaller branches, reducing the risk of inadvertent perforation and bleeding. A bigger curve (6 mm or 15 mm) J wire can be used in patients with iliac or aortic tortuosity.

0.035–0.038 inch PTFE coated exchange length J wire: Use the exchange length J wire (250 cm) in patients with significant peripheral vascular disease to avoid vessel trauma associated with multiple attempts at crossing aorto-iliac disease and tortuosity. Leave the wire in during removal of the dilator in these cases and advance catheters over the wire. Keep in mind, however, that longer dwell times of the wire are associated with thrombus formation.

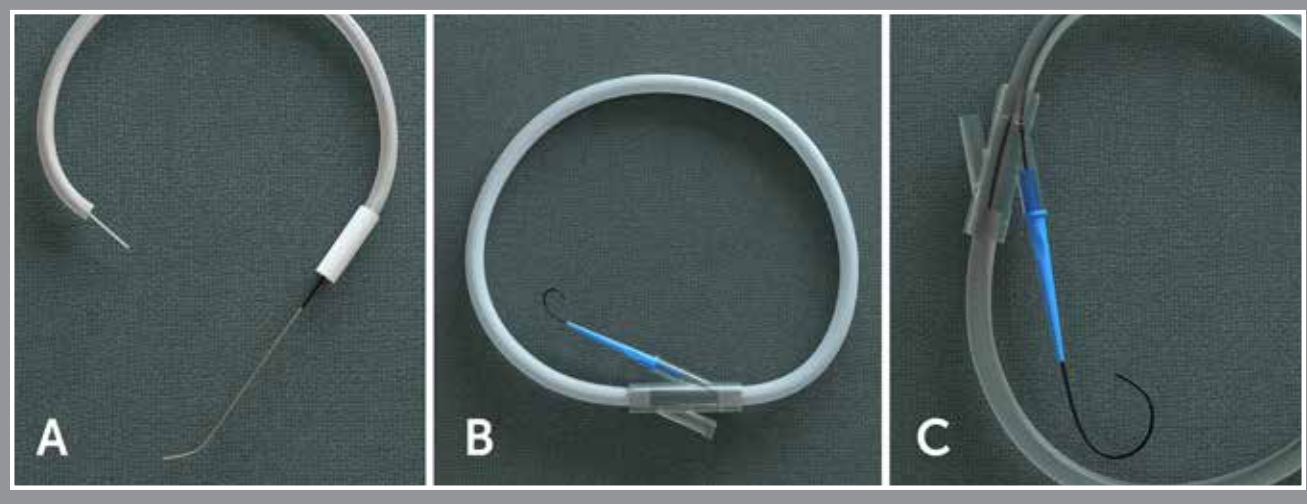

Figure 5: 0.018 inch wire, 0.035 inch PTFE coated 3 mm J wire, and 0.035 inch PTFE coated Big J wire

(A) 0.018 inch angled tip guidewire used in micropuncture kit; angled tip increases chances of cannulation of small arterial branches, increasing risk of bleeding/perforation. (B) 0.035 inch PTFE coated 3 mm J wire; J tip prevents advancement into smaller branches. (C) 0.035 inch PTFE coated Big J wire with a 15 mm J tip

Ultrasound (US) guided vascular access

Real time ultrasonography provides visualization of the CFA bifurcation along with information on the size of the lumen and the presence of calcification and atherosclerosis (Figure 6).

The FAUST study[7] showed that US guided CFA cannulation rates did not differ from traditional approach rates except in patients with high bifurcations. US guidance also resulted in improved first-pass success rate, reduced number of attempts, reduced risk of venipuncture, and reduced median time to access. US guided access is especially beneficial in patients with PAD, obesity, and scarring and fibrosis from frequent previous accesses.

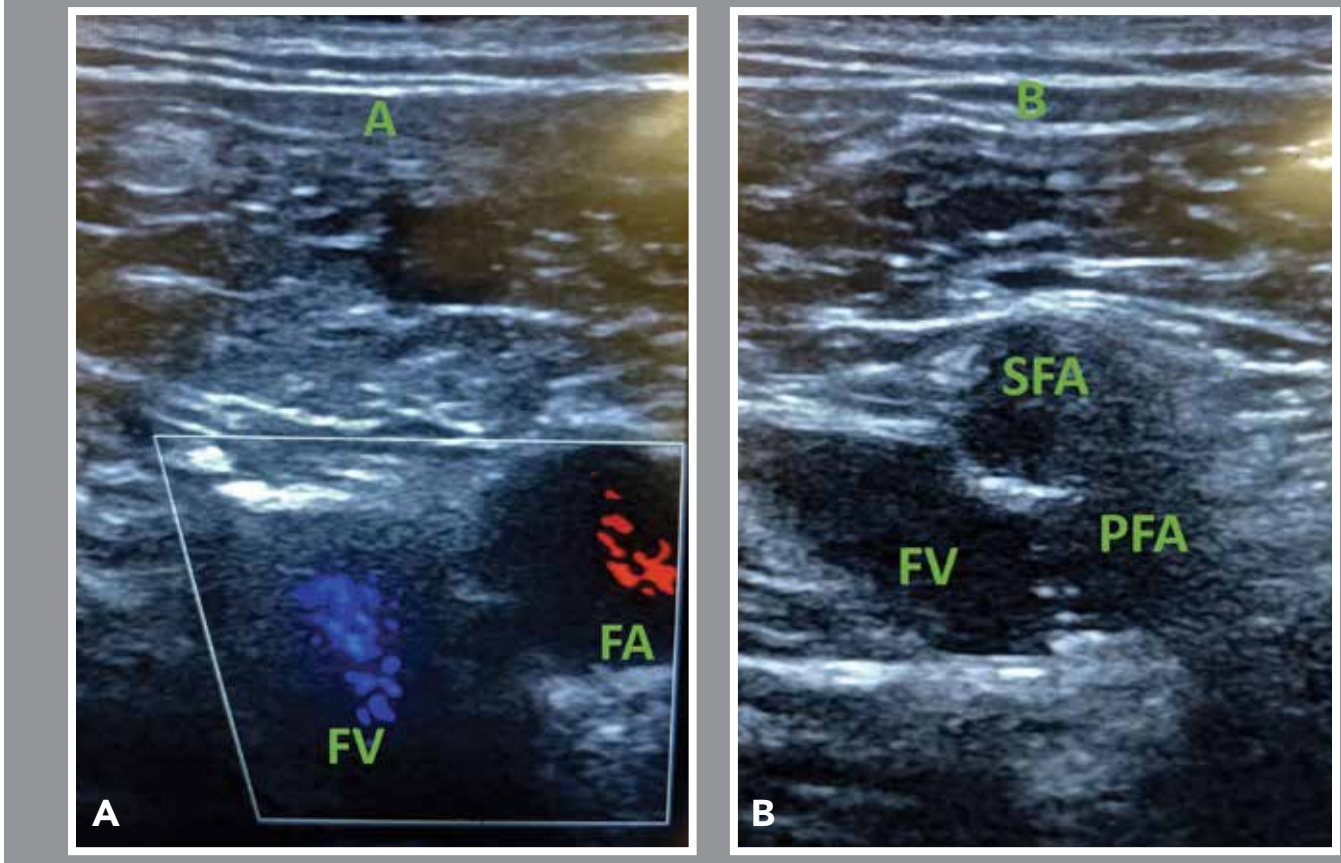

Figure 6: US Guided Vascular Access

(A) Axial plane image of the femoral vein (FV) and common femoral artery (FA). Color flow and compressibility can assist in differentiation of artery from vein. (B) Vascular probe moved inferiorly to visualize the bifurcation of the FA into superficial femoral artery (SFA) and profunda femoris artery (PFA). Common femoral artery access can be ensured if needle entry is visualized under US guidance and is superior to the bifurcation.

Doppler needle (SmartNeedle)

The SmartNeedle® (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. The needle is advanced through the skin and as the needle approaches the artery, the Doppler signal becomes louder. SmartNeedle use was 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.[8]

Pro Tips

- √ The 18G (micropuncture) needle has a 56% smaller inner lumen compared to a 21G (standard Cook) needle, which also corresponds to a near 6-fold reduction in blood flow. Keep in mind that the flow from the micropuncture needle is not as brisk as flow from a 21G needle and thus can be confused for a venous stick.
- √ In patients with significant peripheral arterial disease or high bleeding risk, and in obese patients, a smaller 21G micropuncture needle may be considered over a standard 18G needle; however no clear benefit was shown in the trials.
- √ The lowest point of the inferior epigastric artery corresponds to the inguinal ligament. The CFA artery dips down deep into the pelvic area above this, hence vascular access above this level involves passing the sheath through the abdominal wall, fascia, and muscles, thus increasing the risk of retroperitoneal hematoma.

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CHAPTER 1 | SECTION THREE

Micropuncture Technique for Femoral Access for Coronary Catheterization and Interventions

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Vascular access site complications have been recognized as the most common type of complication after diagnostic cardiac catheterization and percutaneous coronary intervention performed via the femoral approach.[1,2] Several procedural techniques have been designed to reduce these complications. It has been well recognized that identifying the optimal location for femoral access is one of the most important steps to reduce these complications. Routine use of ultrasound, specifically real-time guidance, has emerged as an important step to reduce the number of attempts, time to access, risk of venous punctures, and vascular complications.[3]

Multiple vendors make several micropuncture access kits that come with various needle lengths, wire options, and sheath lengths and sizes (Figure 1). They are all designed to allow access to the femoral artery through a small 21-gauge needle—as compared to the standard 18-gauge needle—and glide into the vessel with less subsequent trauma.

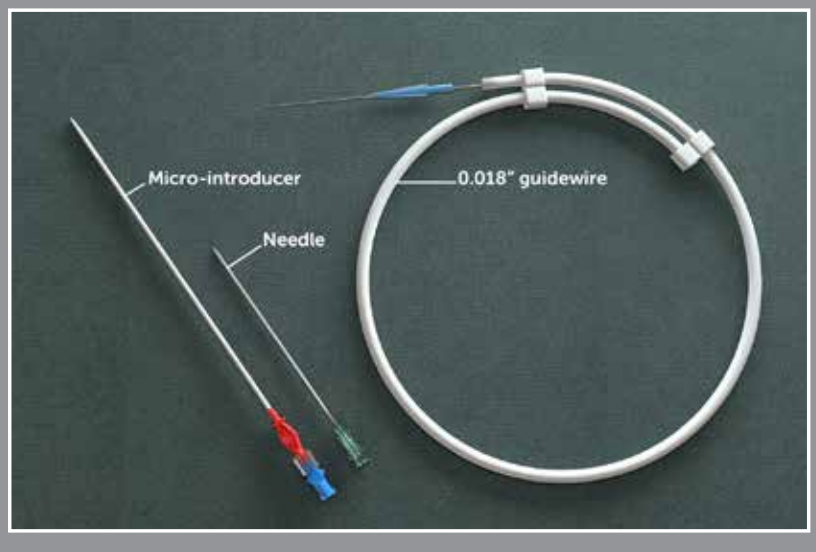

Figure 1: Components of a Micropuncture Access Kit

The Femoral Micropuncture or Routine Introducer Study (FEMORIS)—a large, single center, prospective trial—compared the rate of vascular complications with micropuncture 21-gauge needles to the rate of complications with standard 18-gauge needles. This study, however, was terminated early and did not find any significant differences between the two groups. It is worth noting, there was a 50–75% reduction in vascular complications with the micropuncture technique in patients who did not undergo PCI or elective procedures, female patients, and those with a final sheath size of ≤ 6 Fr.[4]

Given the decreased rates of complications with the use of ultrasound, we perform all femoral accesses using anatomic, fluoroscopic, and ultrasound guidance.[3] Puncture of the common femoral artery (CFA) is ideally performed at the level of the mid common femoral artery above the femoral bifurcation and at least 1 to 2 cm below the inguinal ligament. Anatomic landmark-guided access using the inguinal skin crease or line between the anterior superior iliac crest and symphysis pubis can be deceiving, especially in obese patients. For obtaining optimal access using the micropuncture technique, we recommend the following steps:

1. Localize the point of maximum impulse of arterial pulsation. Place the tip of the forceps at the anticipated entry site at the middle of the femoral head (as shown in Figure 2), where the bifurcation of the CFA is typically located in most non-obese patients. Obtain a fluoroscopic image. Using fluoroscopy is important because it ensures that the access or entry site is positioned at least 1 cm below the inguinal ligament. If the puncture is too proximal or "high," the risk of retroperitoneal hemorrhage dramatically increases.[1]
2. Use ultrasound guidance to confirm the location of the bifurcation of the CFA with respect to the access site. Place the ultrasound probe at the entry site identified by fluoroscopic guidance. Avoid moving the ultrasound probe above the entry site identified by fluoroscopy, as it is inherent with ultrasound access to puncture the femoral artery more proximal than intended. Then, move the ultrasound probe distally to localize the bifurcation of the femoral artery, as shown in the video in Figure 3. Once the CFA bifurcation is identified, move the probe proximal until the bifurcation is not seen. It is important to perform an arterial puncture above the CFA bifurcation because punctures below the CFA bifurcation increase the risk for local complications such as pseudoaneurysm, arteriovenous fistula, and dissection.

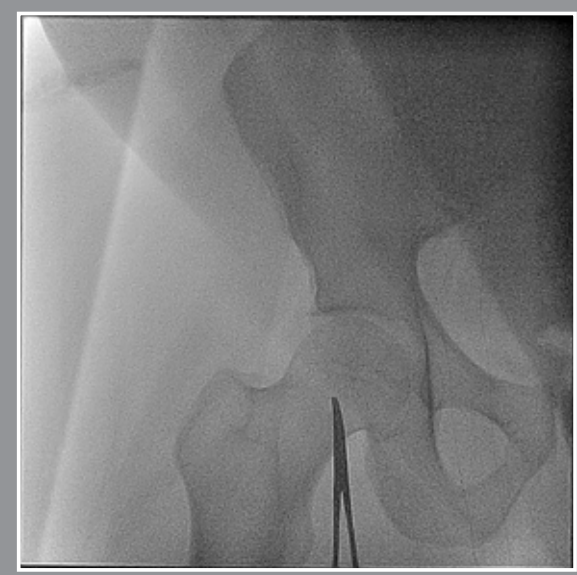

Figure 2: Localization of 21-gauge Needle Insertion Using Fluoroscopy

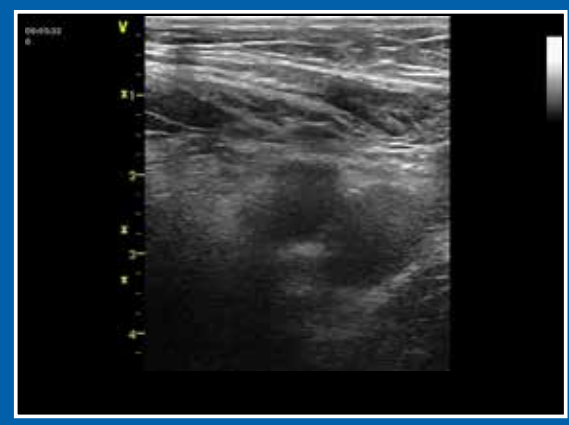

Figure 3: Femoral Artery and Vein Anatomy Using Ultrasound (video)

3. Under ultrasound guidance, perform localized anesthesia. We recommend performing localized anesthesia in the same manner you will be inserting your 21-gauge needle (as described in step 4). This allows you to accurately anesthetize your site of entry and your entry path prior to using your micropuncture needle. Visualization with ultrasound will also allow you to avoid areas of arterial wall disease and calcification.

4. Insert the 21-gauge needle 1–2 cm below the site of entry at a 30–45 degree angle. Inserting the needle 1–2 cm below the ultrasound probe will allow the operator to avoid "high" arterial punctures. The tip of the needle will be visualized on ultrasound once it is near the artery. Verify with real-time ultrasonography that the anterior wall puncture is optimally located as shown in the video in Figure 4.

5. Once the needle is in the artery, there will be brisk pulsatile backflow. It is worth noting that the backflow is not as brisk as seen with an 18-gauge needle.

6. Place the 0.018" guidewire through the needle as shown in Figure 5. The 0.018" guidewire tends to divert into small branches of the femoral or iliac arteries, which increases the risk of perforation. It is therefore important to advance the 0.018" guidewire under fluoroscopic guidance.

7. Remove the needle and place a 4 Fr introducer over the 0.018" guidewire into the artery. Remove the guidewire.

8. Perform a limited femoral angiography using a 10 mL syringe with 50% contrast

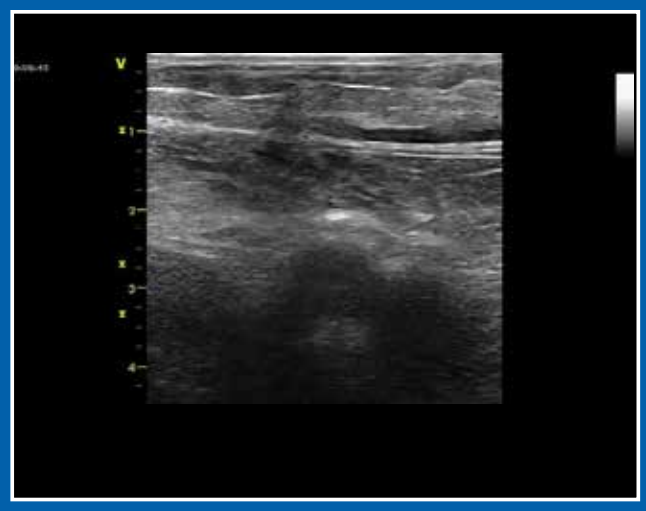

Figure 4: Anterior Wall Puncture Location Verified by Real-time Ultrasonography (video)

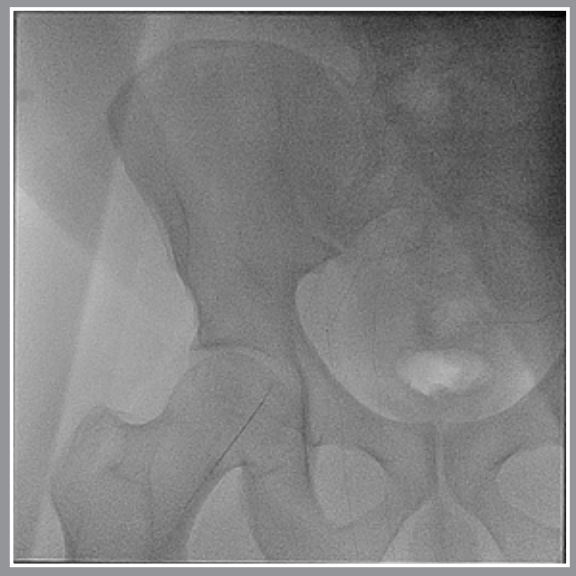

Figure 5: Visualization of Micropuncture Wire Access via 21-gauge Needle Using Fluoroscopy

(as shown in the video in Figure 6). If the entry site is too high or low, remove the sheath and apply manual pressure for at least 5 minutes. If the location is ideal, advance a 0.035" wire under fluoroscopic guidance. Remove the 4 Fr introducer sheath and insert the appropriately sized sheath over the 0.035" guidewire. Remove the wire and dilator and flush the sheath with normal saline.

The use of a micropuncture access kit has been widely adopted. Potential disadvantages are

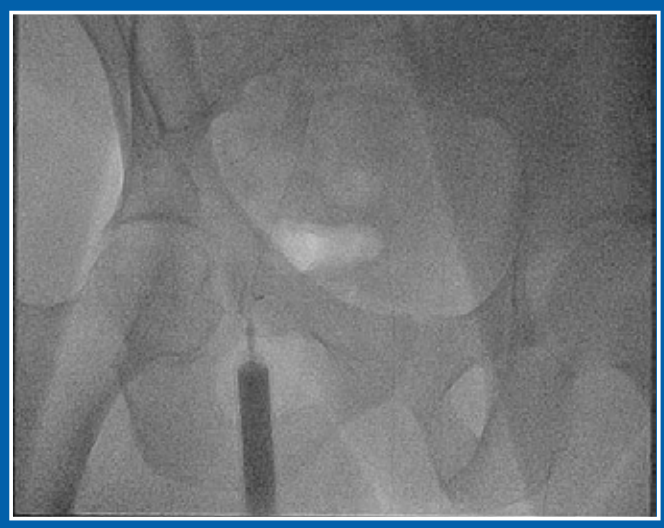

Figure 6: Limited Femoral Angiography Using Micropuncture Sheath (video)

Mild kinking of the sheath is noted due to obesity

longer procedural time compared to the use of an 18-gauge needle and potential kinking in very obese patients. The angled tip of the 0.018" guidewire also tends to be diverted from the main vessel increasing the risk of small branch perforation, and the procedure is best performed under fluoroscopy. In patients in circulatory shock, backflow pulsatility may be difficult to appreciate with such a small needle. Overall, access with the use of a micropuncture access kit is easy and may be associated with fewer vascular complications.

Summary

- Vascular access site complications are one of the most common type of complications after diagnostic cardiac catheterization and percutaneous coronary intervention performed via the femoral approach and include local hematomas, retroperitoneal hematomas, pseudoaneurysms, and arteriovenous fistulas.
- The micropuncture technique allows the use of a small 21-gauge needle—as compared to the standard 18-gauge needle—for arterial puncture, which may be associated with fewer vascular complications.
- It is important to utilize anatomic landmarks, real time ultrasonography, and fluoroscopic guidance while obtaining access using the micropuncture kit to further reduce the risk of vascular complications.
- Always keep in mind that operators tend to end up with "higher sticks" than intended when using ultrasound for access site localization and determining path of entry. Position your needle at least 1–2 cm below the ultrasound probe (chosen entry site) bearing in mind that extreme acute angulations of the needle are also associated with higher sticks.
- A few disadvantages of the micropuncture kit include increased procedural time, kinking in obese patients, risk of side branch perforation with 0.018" guidewire, and low backflow pulsatility in low flow states.

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CHAPTER 1 | SECTION FOUR

Radial Artery Access: Overview of Common Techniques

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Introduction

Cardiovascular catheterization procedures through the radial artery are a safer and more comfortable approach for patients compared to femoral artery access. However, failure rates of radial arterial cannulation are comparatively greater (1–5%)[1] and access failure is a common cause of procedural failure.[2] With experience, achieving successful arterial access at a very high rate is the norm.[3]

Overview of common radial artery access techniques

Radial artery access can be accomplished using either the Seldinger (back wall) or the modified Seldinger (front wall) technique. A randomized comparison of these two techniques demonstrated a small but significant benefit with the Seldinger method. Specifically, time to achieve access, total procedural time, number of punctures required, and percentage of success at initial stick favored the Seldinger approach. There were no differences in postprocedural adverse events (including hematomas) between the two arms.[4] Both of these techniques are used commonly and skill with both access strategies is valuable.

Seldinger technique (back wall, counter-puncture)

The needle and cannula are inserted through both the front and back walls of the artery when using the Seldinger technique. After removing the needle, the cannula is withdrawn until pulsatile blood flow indicates successful placement within the true lumen.

Equipment

- 1–2 mL of local anesthetic, such as lidocaine
- Needle/cannula system (eg, Angiocath™, Surflo®) capable of accommodating an 0.018–0.021 inch guidewire (typically, 20-gauge)
- Guidewire (0.018–0.021 inch)
- Hydrophilic-coated radial sheath
- Tegaderm™
- Anti-spasmodic cocktail (eg, verapamil, nitroglycerin, nicardipine)
- Ultrasound optional

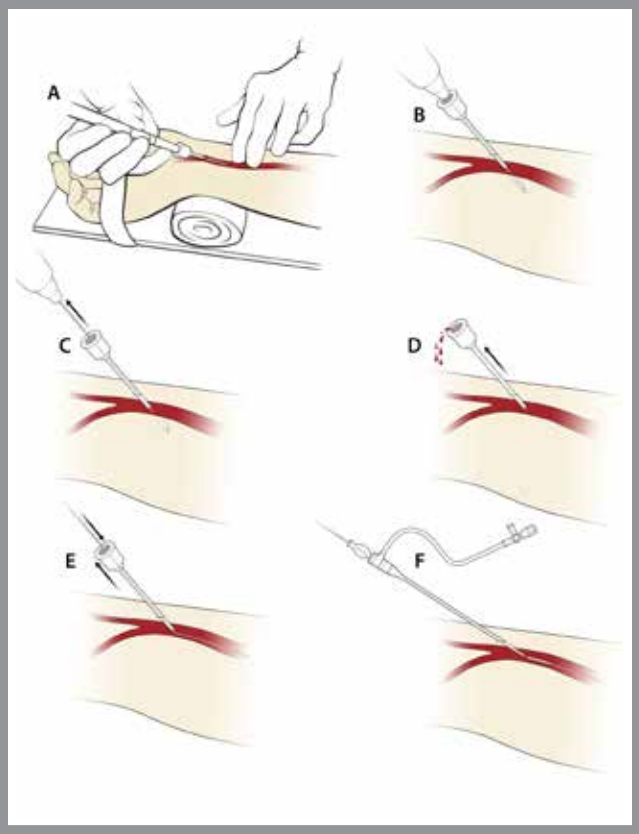

Figure 1: Seldinger Technique Step-by-step

Step-by-step technique

1. Fixate the wrist in gentle hyperextension. Prepare and sterilize the site.
2. Use a 20-gauge needle/cannula system to puncture the skin at a 45 degree (or greater) angle. (Figure 1A)
3. After a flash of blood is seen in the clear chamber, advance the needle/cannula system 2–3 mm further, through the posterior wall of the artery. Advance until blood is no longer filling the chamber. (Figure 1B)
4. Remove the needle and keep a guidewire ready. (Figure 1C)
5. Retract the cannula slowly until pulsatile flow is noted. (Figure 1D)
6. Advance the wire into the artery and remove the cannula. (Figure 1E)
7. Insert the hydrophilic-coated radial sheath over the wire. (Figure 1F)
8. To stabilize the system, place the Tegaderm over the sheath while leaving the side port free.
9. Flush the sheath with normal saline and administer vasodilator cocktail according to institutional protocol.

Figure 2: Seldinger Technique (video)

Modified Seldinger technique (front wall, bare-needle)

A small caliber, bare needle is used to puncture the front wall of the radial artery when using the modified Seldinger technique.

Equipment

- 1–2 mL of local anesthetic, such as lidocaine
- Bare needle capable of accommodating an 0.018–0.021 inch guidewire (typically, 20-gauge)
- Guidewire (0.018–0.021 inch)
- Hydrophilic-coated radial sheath
- Tegaderm
- Anti-spasmodic cocktail (eg, verapamil, nitroglycerin, nicardipine)
- Ultrasound (optional)

Step-by-step technique

1. Fixate the wrist in gentle hyperextension. Prepare and sterilize the site.
2. Use a bare needle to puncture the skin at a 45 degree (or greater) angle.
3. Once pulsatile flow is seen, insert the guidewire directly through the needle.
4. Remove the needle.
5. Insert the hydrophilic-coated radial sheath over the wire.
6. To stabilize the system, place the Tegaderm over the sheath while leaving the side port free.
7. Flush the sheath with normal saline and administer vasodilator cocktail according to institutional protocol.

Figure 3: Modified Seldinger Technique (video)

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CHAPTER 1 | SECTION FIVE

Alternative Upper Extremity Access: The Dorsal Radial Artery

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Overview

Arterial access through the volar surface of the forearm, including both the radial and ulnar arteries, has resulted in significant improvements in invasive cardiovascular procedures. While large population studies have demonstrated the well-known benefits of radial artery access, certain subgroups of patients may benefit from other access sites.

Dorsal radial access

The dorsal radial artery provides alternative access that answers to the needs listed in Box 1. A good candidate for this access route is a patient for whom proper positioning of the wrist is not possible due to difficulty supinating the wrist or rotating the shoulder to expose the intended access site. In addition, the natural position of dorsal radial access may be more appealing for patients in whom the classic radial site is available but prolonged rotation of the arm may be uncomfortable. Dorsal radial access also has the potential to reduce damage to the main radial artery or provide an alternative entry site if nearby radial access has been used recently.

Box 1: Potential Indications for Dorsal Radial Access

Dorsal radial access may provide:

- Enhanced left arm access for patient and physician
- Access if orthopedic impairment prevents rotation of the arm
- More natural position for a patient to maintain during a lengthy procedure
- Alternative site after recent radial access
- Alternative site if other IV lines preclude radial use
- Entry site for retrograde recanalization of radial artery
- Reduced risk of radial artery injury in setting of possible future needs

Anatomically, at the base of the thumb the radial artery takes a lateral turn, branching into the superficial palmer region of the hand (Figure 1). The radial artery continues up as the dorsal radial artery between the back of the thumb and first finger and then curls back toward the palmar arches. This distal radial artery is best palpated in the snuffbox region roughly denoted by the intersection of the lines representing proximal extensions of the thumb and first finger (Figure 2). The radial artery in this region of the hand averages about 80% of the diameter found in the more proximal region at the base of the palm. The size of this distal artery relative to the traditional radial access site varies from patient to patient, and in some patients the dorsal radial artery is diminutive and not suitable for access.

Use of the dorsal radial for arterial access was described first in pediatric populations for arterial monitoring in the 1970s. It has since been used for arterial monitoring in adult patients and has also been described as a possible fistula site for dialysis. Cardiovascular access using the dorsal radial originated in Russia within the past couple of years and became widely known through the Twitter universe in 2017. Despite a relative lack of traditionally published experiences, information about this technique has spread rapidly from experiences documented on Twitter and videos explaining the technical aspects of the technique. The rapid dissemination of this technique demonstrates the potential power of social media to communicate medical advances.

The challenges of dorsal radial access are evident in the illustration of distal radial circulation in Figure 3. The dorsal radial artery is smaller than its parent radial and is best exposed with the lateral aspect of the hand in a natural position. Vascular ultrasound is helpful for localization or sizing and aiding puncture. Beyond the entry site, the artery turns down the base of the thumb to form the radial artery at the junction with other branches that feed the superficial palmar arch of the hand. Once vascular access is achieved in the radial artery, the course is identical to a standard radial access procedure.

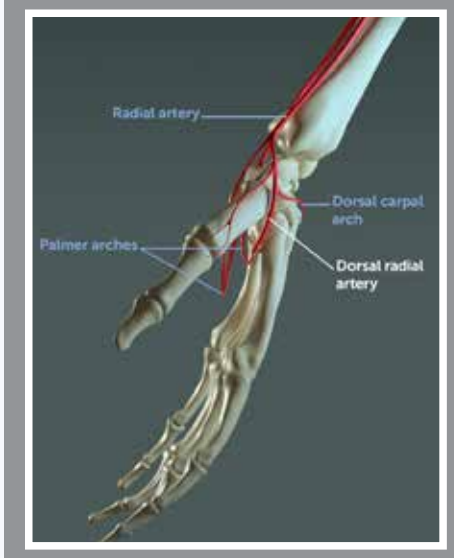

Figure 1: Arterial Distribution in Distal Left Arm Between Thumb and First Finger

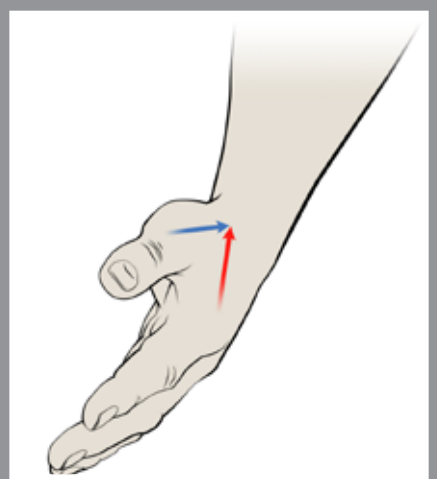

Figure 2: Dorsal Radial Pulse in Left Hand

Dorsal radial pulse marked by proximal extensions and intersection of the first and second metacarpal bones

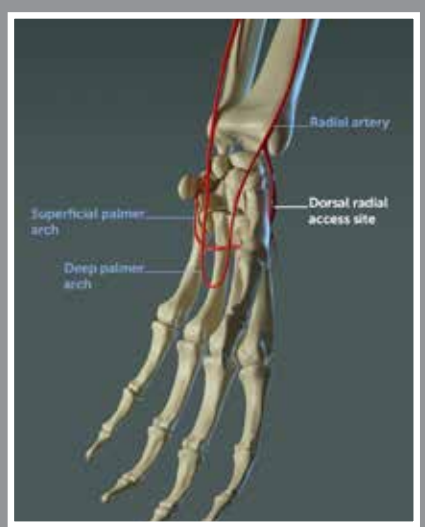

Figure 3: Distal Left Radial Circulation

Relationship between the dorsal radial access site, branching palmar arch vessel, and distal radial artery

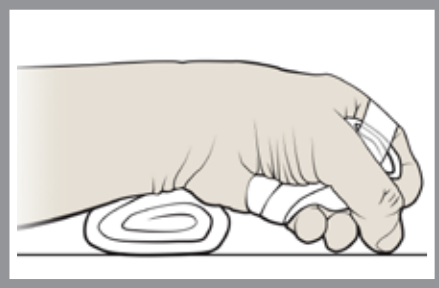

Figure 4: Dorsal Radial Access Position

Left arm positioned for dorsal radial access with a small towel in hand to open the angle between the first finger and thumb. Towel under medial wrist to encourage a slight ulnar lateral flexion to push the dorsal radial artery closer to the surface.

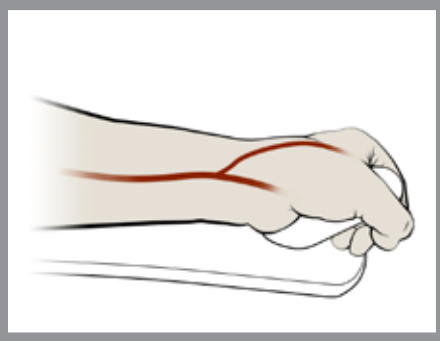

Figure 5: DRAWS Arm Support for Dorsal Radial Access

A DRAWS arm support with plastic mandrel for hand grip opens the junction between the thumb and finger and maintains the thumb up position of the wrist along with a slight bend in the base to form an ulnar flex at the wrist to further expose the dorsal radial and straighten its course. Image shows radial and dorsal radial arteries drawn on skin.

Equipment and positioning

Equipment choices for this access are no different from the standard radial procedure once the vascular sheath is in place. As noted, ultrasound can localize the vessel and help size the appropriate sheath diameter. Bare needle or angiocath access can be used as would be traditional for routine access; however, the wire used for the initial entry into the artery needs to negotiate the curves down to the main radial artery branch. The vascular access sheath that follows over the wire should be appropriately sized to reduce spasm from physical contact. Due to the initial tortuosity of the dorsal radial, resistance to kinking from the serpentine arterial course should be considered; the thinner the sheath wall, the more likely it is that kinking may occur.

The position of the hand is the key to successful access. To bring the dorsal radial to the surface of the lateral wrist in a stable position, the wrist should be in the natural, relaxed rotation about 90 degrees from the standard radial access position (Figure 4). To straighten the course of the dorsal radial into the radial artery, the wrist should be slightly flexed toward the ulnar side. Place either a small towel or hand grip in the hand so that the angle between the base of the thumb and first finger remain open naturally. This position helps keep the underlying tendons and soft tissue away from the dorsal artery, allowing it to lay stable on the surface formed by the proximal bones of the first finger and thumb. Positioning tape can be used to secure the arm and wrist in the desired position for access. Figure 5 shows a patent pending DRAWS arm support (Davies Precision Machining, Lebanon, PA) developed to position the arm and arteries for dorsal radial access.

Procedure

The operator has the following options for accessing the left or right dorsal artery. When accessing the left dorsal artery, the operator can get access on the left side of the table and then reposition to a more orthopedically favorable position, or secure the arm in the operating position initially and obtain access across from the right side. If the right dorsal radial is being used, overall arm position would be similar to standard radial access except for the wrist being positioned with the thumb up as previously described.

During the procedure, the usual antispasm and anticoagulant protocols should be no different from standard radial access. Sheath removal likewise is similar to the standard radial procedure except for hemostasis. Standard hemostasis devices that cannot be stabilized against movement can be problematic as patient wrist motion may cause band migration. If a hemostasis device is being used, it may be advantageous to use one with an adhesive or secondary strap to physically hold it in position. Confirmation of hemostasis may not be possible as it is often difficult to feel a distal pulse in such a distal location and the vessel wraps around the thumb and back into the palm. To aid in monitoring hemostasis it is often helpful to use gauze with an elastic band to focus pressure at the arterial entry site as the vessel is very superficial and is already trapped in place by its supporting bone structures (Figure 6 (video)).

Ultrasound and fluoroscopy have been shown to assist experienced operators as they become proficient with dorsal radial access. An initial ultrasound can help evaluate vessel diameter, which has been shown to be inadequate in 10 to 20 percent of patients. Fluoroscopy and ultrasound can also help confirm and remediate other issues, such as difficulty with advancing the wire through the tortuous segment and spasm. In general, there should be no resistance to the wire or sheath movement, and, therefore, difficulty warrants further investigation. Hand discomfort or difficulty advancing the sheath may be signs that the wire has been directed antegrade into the superficial palmar artery where it originates at the end of the radial artery rather than following its proper course up the arm. Fluoroscopy of the hand or ultrasound can be valuable tools for confirming this. Some hand hematomas have been reported with hemostasis that did not deliver pressure directly to the entry site, but otherwise, there have been no reports of hand ischemia. Artery occlusion is seen at rates similar to standard radial procedures except the occlusion is limited geographically in a majority of cases to the dorsal radial section and does not extend into the radial artery proper (Figure 7).

Potential complications

While to date only relatively minor and expected complications have been reported in the standard literature or on Twitter, the dorsal radial artery is a novel entry site, and other issues may arise. Perhaps most concerning is the blood supply to the wrist bones, most notably the scaphoid bone, that originates in the region of the dorsal radial artery. Traumatic bone fractures involving wrist bones can cause avascular necrosis and theoretically the same could occur with vascular occlusion. To date, there is no evidence that this is an actual risk associated with dorsal radial access, but the potential should still be considered.

Figure 6: Obtaining Hemostasis (video)

Sheath removal and application of elastic tape and gauze to obtain hemostasis.

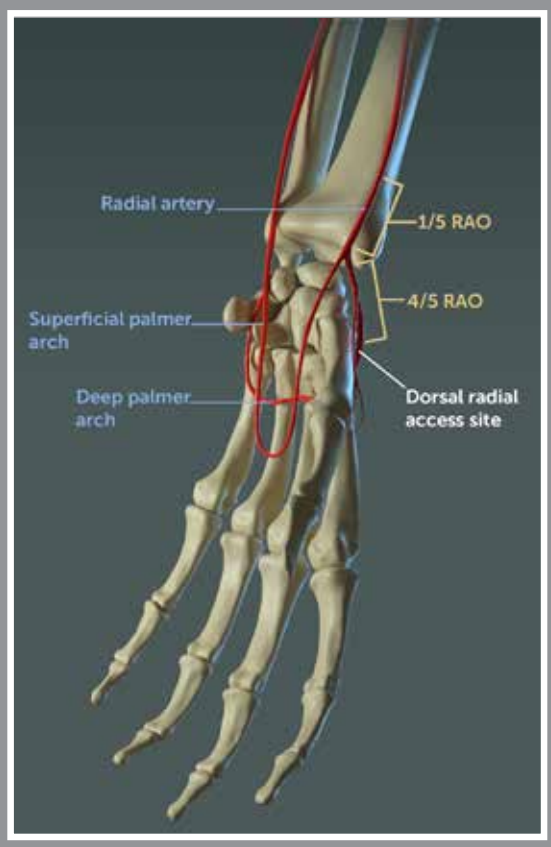

Figure 7: RAO After Dorsal Radial Access in Distal Left Forearm

Most radial artery occlusions are confined to the dorsal radial branch.

Box 2: Summary of Dorsal Radial Access Steps

1. Locate dorsal radial pulse at the base of the thumb and first finger metacarpal bones in the anatomic snuffbox region.
2. Position the wrist with thumb side up, with slight ulnar flexion to the wrist, and separate the thumb and first finger with a handgrip or towel.
3. Confirm vessel size and facilitate access using vascular ultrasound.
4. Use sterile drape at the access site with radial access micropuncture technique.
5. Confirm passage of the wire antegrade up the radial artery.
6. Place the vascular sheath and complete the procedure with usual anticoagulation.
7. Remove the sheath at the conclusion.
8. For hemostasis, use elastic wrap or hemostatic device that will not come loose as patient moves wrist.
9. Remove the hemostasis device when patient is stable.

Summary

For many patients, dorsal radial access is an alternative to traditional radial access. Dorsal radial access (summarized in Box 2) has orthopedic advantages for both the patient and the operator. The key to success is positioning the hand in an advantageous position for access. Once access is achieved, the procedure is similar to a standard radial procedure. Limitations of dorsal radial access center around its more distal location in the vascular tree with the inherent smaller diameter and the initial nonlinear course to reach the radial artery in the wrist. Hemostasis must take into account the mobility of the wrist in the distal region and the need for a secure point positioning technique to maintain hemostasis. Complications reported to date have been minor and within what might otherwise be expected. Thus, the ability to access the dorsal radial can be a valuable alternative approach for the vascular interventionalist.

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CHAPTER 1 | SECTION SIX

Suture-based Femoral Closure for Coronary Procedures (≤ 8 Fr)

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Overview

Vascular closure devices are becoming more widely used in the world of femoral arterial access. According to a survey of the National Cardiovascular Data Registry (NCDR) database between 2009 and 2013, closure devices were utilized in 51% of patients undergoing percutaneous coronary intervention (PCI) via the femoral artery.[9] The advocacy for use of such devices is multifactorial.

Rationale for vascular closure devices

The most cited reason for using vascular closure devices is early patient ambulation. Traditionally, femoral arterial access with a 6 Fr sheath required 6 hours of post procedure bedrest following manual compression to the arteriotomy site. Closure devices can reduce the need for bedrest and enable ambulation as early as 2 hours post procedure. In addition to improving patient satisfaction, early ambulation tends to go hand in hand with early hospital discharge.

The use of vascular closure devices has been associated with less access site bleeding and shorter time to hemostasis compared to manual hemostasis. Wimmer et al. (2016) retrospectively demonstrated a "modest but significant" reduction in access site bleeding in patients undergoing PCI in the NCDR database.[9] Robertson et al. (2016) also demonstrated a significant reduction in time to hemostasis when utilizing closure devices in a meta-analysis of 52 randomized and quasi-randomized trials comparing vascular closure devices to manual compression.[5]

Vascular closure device considerations

There are a variety of vascular closure devices on the market. Devices are often classified as passive or active and then subdivided into extravascular and intravascular. The Perclose device, developed and marketed by Abbott, is an active extravascular device.[4] The device deploys a polyester suture to the arteriotomy site, leaving no material intravascularly and allowing for re-entry to the artery for additional procedures without restriction or concern for intra-arterial disruption of hemostasis.[4]

Prior to using the Perclose device, it is important to evaluate the following:

- Is the access site appropriate for vascular closure?
- Are there any contraindications to Perclose use?

Obtaining optimal femoral artery access is one of the best ways to help ensure the access site is appropriate for Perclose use. Optimal access begins with the modified Seldinger technique preferably with sonographic guidance, focusing on anterior wall puncture in the common femoral artery,[1,2,8] avoiding posterior arterial wall puncture. The position of access into the femoral artery (Figure 1) should be above the bifurcation of the common femoral artery into the profunda femoris and the superficial femoral artery.[1,2,8] Confirmation of positioning in the common femoral artery is essential to avoid high arterial puncture (above the inguinal ligament/inferior epigastric artery) due to risk for retroperitoneal bleed, and low arterial stick below the bifurcation of the common femoral artery due to risk for pseudoaneurysm, intimal dissection, or vessel closure.[4]

Optimal access can be confirmed in one of three ways: anatomically, fluoroscopically, or via sonographic guidance.

Anatomically, the point of access should be 1–2 cm below the inguinal ligament.[1,2,8] This location can be determined by drawing a line between the anterosuperior iliac spine and vertical midpoint of the pubic symphysis.[1,2,8] The inguinal crease should not be used as a surrogate for the inguinal ligament as the bifurcation of the common femoral artery is above the inguinal crease in 75.6% of patients.[8]

Fluoroscopy can help with access first by radiopaque marking of maximal pulsation (Figure 2A). In 92% of patients, the maximal femoral pulse is indicative of the location of the common femoral artery.[8] The opaque marking should localize the artery in the inferior portion of the femoral head (adjustment may be needed depending on the degree of fat that must be transversed in obese patients).[1,2,8] After access is obtained, a right anterior oblique (RAO) projection can be utilized for common femoral angiography to ensure position.[1,2,8] As shown in Figure 2B, angiography can be completed through a micropuncture sheath prior to larger sheath cannulation.

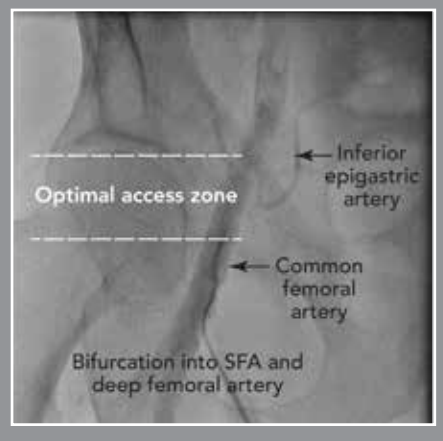


Figure 1: Optimal Femoral Access Site in the Common Femoral Artery

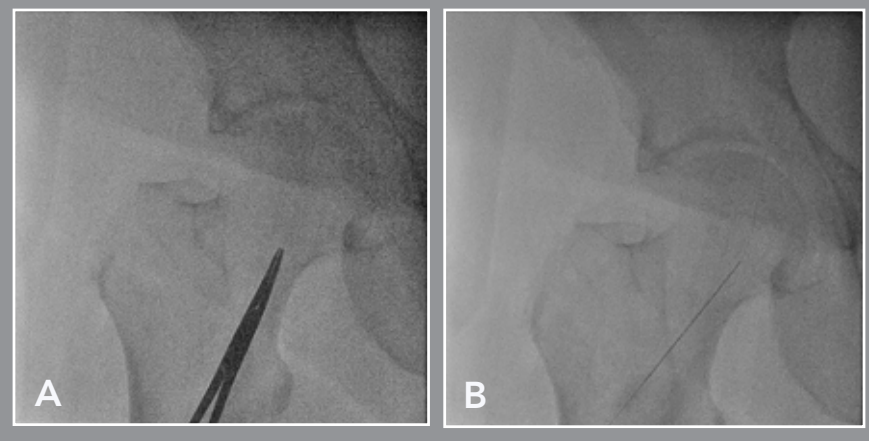


Figure 2: Radiopaque Marking (A) and Micropuncture Access (B) of the Common Femoral Artery

Ultrasound assists in identifying common femoral artery and helps ensure access above the bifurcation. Sonographically guided access is a core skill in the modern catheterization lab (refer to Chapter 2, Sections 1, 2, and 3).

Once it has been determined that the access site is appropriate for Perclose use, clinicians must determine whether the patient has any contraindications to Perclose use. In general, there are no absolute contraindications to Perclose device use;[4] however, numerous factors should be considered. In addition to the access site considerations already discussed, clinicians must consider vessel specific precautions, which include calcification at the site of access, common femoral artery diameter less than 5 mm, prior intervention at access site, history of severe claudication and/or visualized iliac or femoral stenosis of 50% or more, and/or antegrade puncture.[4] Other general precautions include pregnancy, patients less than 18 years of age, and coagulopathy.[4]

Vascular closure device deployment

The following steps describe how to use the Perclose vascular closure device in appropriate patients.

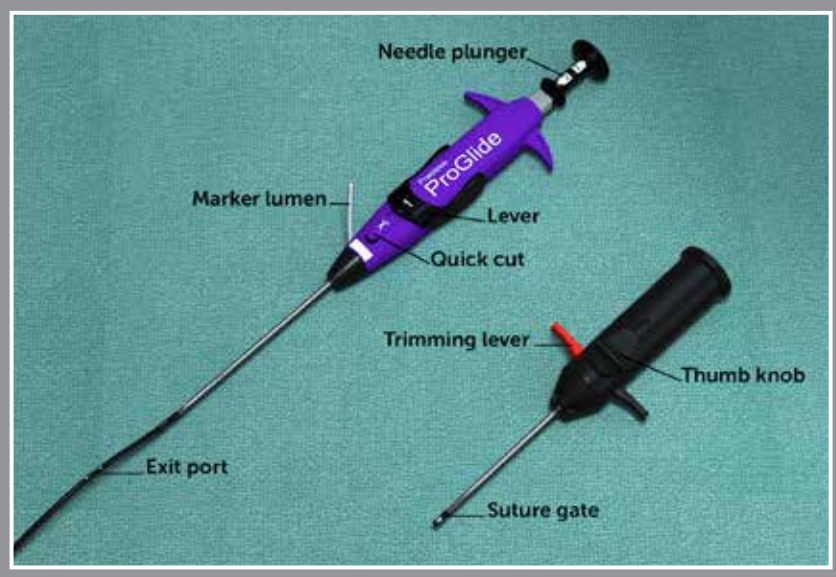


Figure 3: Perclose Vascular Closure Device

Step 1: Start by flushing the marker lumen. Use a 0.038" or smaller guidewire to remove your sheath. Pass the device over it. The wire should exit the exit port of the device near skin level (Figure 4A). Advance the device until arterial flow is noted in the marker lumen, which indicates intraluminal positioning of the footplate (Figure 4B). The wire should be removed prior to the exit port passing the skin level. With the device at a 45 degree angle, lift the lever marked with the number 1 to deploy the footplate inside the artery (Figure 4C). Allow for gentle retraction to ensure the plate is deployed against the anterior wall. Gentle retraction should reduce the flow of blood through the marker lumen.

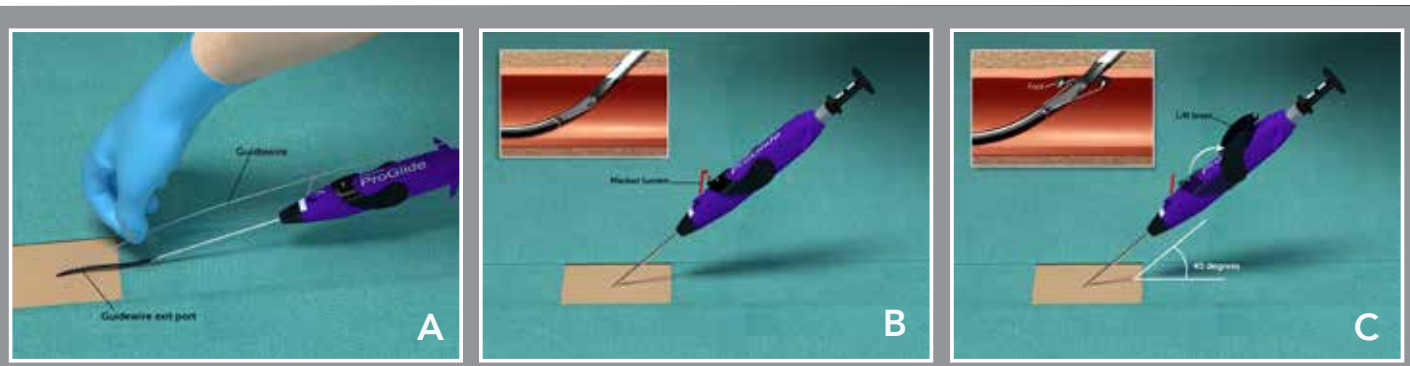


Figure 4: Position Perclose and Deploy Footplate within Artery

Step 2: Use your left hand to stabilize the device at a 45 degree angle. With your right hand, depress the plunger (as indicated by the number 2 on the plunger) to deploy the needles for the suture loop (Figure 5).

Step 3: Continue stabilization with your left hand. Retract the plunger (as indicated by the number 3 on the plunger) to retrieve the suture and needles from the device (Figure 6).

Step 4: Push the lever showing the number 4 back down to its original position and slowly withdraw the Perclose device. Following removal there will be a longer suture deemed the rail suture and a shorter suture deemed the non-rail suture (Figure 7).

Step 5: Maintain tension on the rail limb coaxially with the sheath track. Use the thumb knob to open the Suture Trimmer (Figure 8) and grasp the rail limb. A knot should be visible on the rail limb. Slowly advance the Suture Trimmer to the arteriotomy site pushing the knot down. Tighten the knot by pulling on the non-rail suture.

Step 6: Test for hemostasis. If hemostasis has been achieved, use the Suture Trimmer to trim the sutures. After loading sutures, advance to the arteriotomy and use the red trimming lever to trim the sutures and remove them from the tissue tract.

Post deployment care

Following deployment of the sutures from the vascular closure device, patient care entails:

- Sterile dressing to the arteriotomy site consistent with all other femoral artery access/closure procedures
- Bedrest for 2 hours
- Peripheral vascular exam to ensure no change from pre-procedure exam
- No restriction in terms of timing of resumption of anticoagulation
- No restriction in terms of timing of re-access of the artery

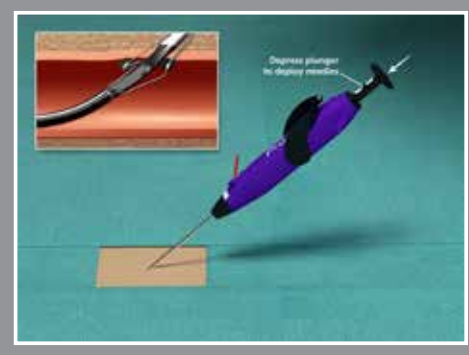


Figure 5: Deploy Needles for Suture Loop

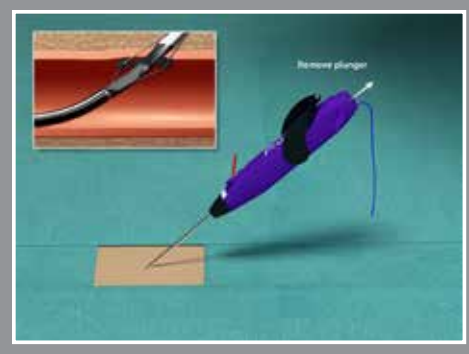
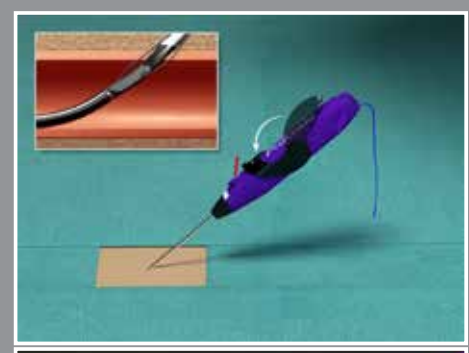


Figure 6: Retrieve Sutures and Needles



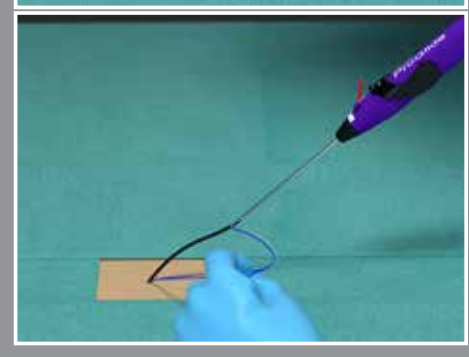


Figure 7: Suture Retrieval

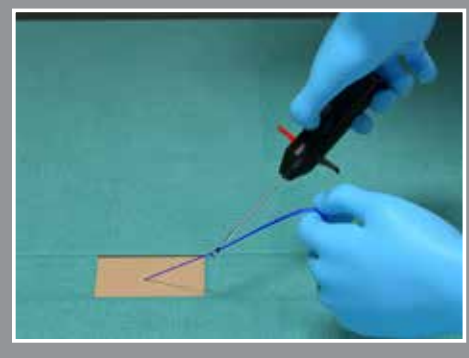


Figure 8: Knot and Advance

Summary

Suture-based closure of femoral artery access is an important skill in the modern cardiac catheterization lab. Good quality closure begins with careful patient selection and optimal femoral artery access. Suture-based closure allows for shorter bedrest with the ability to re-access the vessel immediately.

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CHAPTER 1 | SECTION SEVEN

Femoral Access Closure of Arteriotomy Sites (≤8 Fr): Gels, Plugs, and Patches

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Introduction

Vascular closure devices (VCDs) were developed to allow continuation of clinical care without interruption of anticoagulation, lessening patient discomfort, and reducing resource utilization. Many medical centers are taking advantage of the benefits associated with VCDs to shorten the time for hemostasis, improve patient comfort, promote early ambulation and early discharge.

Type of access is typically based on size, ≤8 Fr and >8 Fr (large bore access), as the size is one of the important determinants of vascular complications. This section discusses femoral arteriotomy closure techniques for ≤8 Fr sheath insertions.

Types of VCDs

VCDs can be placed extraluminal (external) or intraluminal (internal) to the vessel. External devices, such as hemostasis pads and gels, deliver prothrombotic material that helps achieve faster hemostasis in conjunction with manual hemostasis but has no effect on shortening post-hemostasis bedrest or hastening ambulation. Other VCDs are suture-based, collagen plugs, or clips used either intraluminal or extraluminal to the vessel on the surface of the arteriotomy site in the tissue tract.[1]

VCD placement preparation

The Society for Cardiovascular Angiography and Interventions (SCAI) as well as the Centers for Disease Control (CDC) recommend sterile technique (eg, cap, mask, gown, sterile gloves, and large sterile sheet) when preparing for VCD placement. Prophylactic antibiotics are not used on a regular basis.[2]

When placing a VCD, perform upfront femoral angiography to assess for risk factors for vascular complications: vessel anatomy, tortuosity, calcifications, peripheral vascular disease at arteriotomy site, access not in the common femoral artery, position of inferior epigastric artery, or scar tissue. If early ambulation is not desired or the patient has high-risk features for vascular complications, VCDs do not need to be used. Access size ≤8 Fr is associated with a mild to moderate risk of vascular complications (1-3%) in contrast to large bore access sites >8 Fr, which are associated with a high risk for vascular complications (>3%).

Suture-mediated devices, such as Perclose ProGlide® (Abbott Vascular, Santa Clara, CA) can be immediately re-accessed while collagen plug devices cannot be re-accessed for several weeks to months.

External vascular closure devices

Compression devices

FemoStop™ and ClampEase® are two frequently used external compression devices. FemoStop (St. Jude Medical, Minnetonka, MN) consists of a belt that wraps around the patient's waist and an inflatable pneumatic bubble attached to a tube. Compression devices are discussed in detail in a separate section.

Hemostasis pads

Hemostasis pads are coated with a procoagulant designed to hasten the time to achieve initial hemostasis when used as an adjunct to manual compression. Nguyen et al. performed a randomized controlled trial of 184 patients who underwent coronary interventions and randomized to four methods of sheath removal. He concluded that hemostasis pads shortened time to hemostasis compared to standard manual compression but did not translate into overall bedrest time.[4] The primary reasons for using hemostasis pads are likely to alleviate patient discomfort and reduce resource utilization.

Internal vascular closure devices

The most commonly used internal vascular closure devices are AngioSeal™, Mynx®, and, as discussed in the previous section, Perclose ProGlide®. Other available devices include the StarClose SE® clip device, ExoSeal® polyglycolic acid (PGA) plug device, FISH device, and Catalyst® manual compression assist device.

Angio-Seal™ (Terumo Interventional Systems, Somerset, NJ)

In 2000, the FDA approved the 6 Fr Angio-Seal device to seal arterial punctures. Today, Angio-Seal is one of the most commonly used VCDs. The Angio-Seal STS Plus sandwiches the arteriotomy between a polymer anchor and an extravascular collagen sponge.

Here is a brief overview of how to use the Angio-Seal delivery system.

1. Exchange the procedural sheath for the Angio-Seal sheath over the wire with arteriotomy locator. The backflow of blood from the arteriotomy locator confirms intraluminal position.
2. Firmly hold the sheath with one hand and arteriotomy locator with wire removed with the other hand.
3. Insert the Angio-Seal device into the sheath until it snaps at the back.

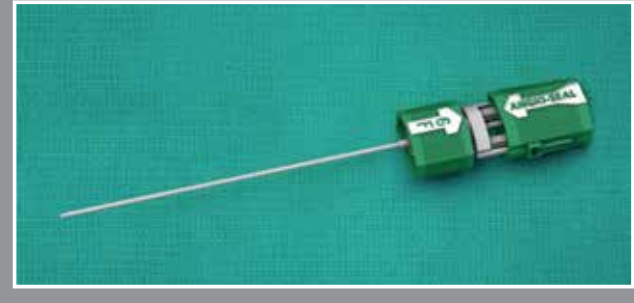

Figure 1: Angio-Seal STS Plus Vascular Closure Device

4. Deploy the anchor and pull back against the vessel wall. As the device is pulled, the collagen plug is exposed against the arterial wall.
5. Cut the sutures below the skin level at the tissue tract.

Hemostasis is achieved by mechanical barrier at the arteriotomy site. The anchor, collagen plug, and the part of the sutures left behind are reabsorbed within 60 to 90 days without excessive scaring or fibrosis. The self-tightening suture (STS) platform adds a self-tightening suture and a secure cap. This surgical slipknot suture, known as a "Roeder Knot," enhances the STS platform.

Angio-Seal provides effective hemostasis and also facilitates patient ambulation in 20 minutes and discharge one-hour post ambulation. Successful closure rate with Angio-Seal is greater than 95%. Rare complications like misplacement, embolization, and deployment of extravascular procoagulant collagen have been reported.[6]

StarClose SE® (Abbott Vascular, Redwood City, CA)

The StarClose VCD delivers a disc-shaped nitinol clip (4 mm) to close femoral artery access sites. The device actively approximates the edges of the arteriotomy. It is placed through the procedural sheath into the arterial lumen, deploying wings that locate the access site. As the device is withdrawn, the wings are pulled against the arterial wall and the clip is deployed on the outer surface of arterial wall grasping the edge of the arteriotomy.

No residual material is left behind in the arterial lumen; however, this is a permanent implant and immediate re-access is difficult. There are also certain limitations for immediate MRI after StarClose placement.

StarClose success rate is reported to be 87 to 97%, with major complications noted in up to 3.7% of the cases and minor complications in 4% of cases.[7]

Figure 2: StarClose SE

Mynx® (AccessClosure, Mountain View, CA)

The Mynx vascular closure device, approved by the FDA in May 2007, is indicated to seal femoral arterial access sites while reducing times to hemostasis and ambulation in patients who have undergone diagnostic or interventional procedures utilizing a 5 Fr, 6 Fr, or 7 Fr procedural sheath.

The Mynx delivery system consists of a balloon catheter with integrated water-soluble, synthetic, non-thrombogenic sealant and a 10 mL locking syringe. This sealant produces a vascular collagen plug made of bio-inert polymer polyethylene glycol (PEG) that is placed outside the artery with simultaneous balloon occlusion at the luminal site of the artery.

Here is a brief overview of how to use the Mynx delivery system.

Figure 3: MynxGrip Vascular Closure Device

1. Advance the Mynx catheter through the procedural sheath (5–7 Fr sheath) to the white shaft marker.
2. Inject saline until the balloon is completely inflated and the white-black-white marker emerges from the back of the Mynx holder.
3. Lift the Mynx device at the same angle as the arteriotomy site.
4. Maintaining gentle tension, pull the Mynx catheter to the point of resistance from sheath, indicating that the tamponade balloon is at the arteriotomy site.
5. Open the side port of the procedural sheath and release tension at the device until blood flows from side port of arterial sheath, confirming intraluminal position of the balloon.
6. Deploy sealant by sliding the green portion of the device down to the arterial sheath until you encounter resistance and hear a click. Then pull the sheath up to the holding point until you hear a click. Push slightly on the arteriotomy site with the other hand (down-up-down movement).
7. Hold in position for 30 seconds, maintaining the angle and tension on the device and gentle pressure at the arteriotomy site with the other hand.
8. Lay the device down for 90 seconds.
9. To remove the device, lock the saline syringe by pulling out completely in the closed position.
10. Deflate the balloon, remove the device, and maintain light skin pressure.

The safety and effectiveness of the Mynx device was initially evaluated in a prospective, non-randomized, clinical trial that enrolled 190 patients at 5 European sites using standard manual compression as the control (5 Fr, 6 Fr, 7 Fr femoral sheaths). In the Mynx group, 0.5% (1/190) of patients had major complications (access site-related bleeding requiring transfusion).[5] None of the patients in the manual compression group had any complications. The minor complication rate for all patients in the Mynx group was 3.7% (7/190) compared to 1.2% (2/164) in the standard compression group. There were no deaths.

PEG sealant in the tissue tract absorbs blood and fluid from the arteriotomy site and expands to up to 4 times its original size, providing immediate effective hemostasis. It dissolves within 30 days leaving nothing behind in the arterial lumen and PEG products are easily cleared by renal excretion. The inert quality of the PEG material helps prevent inflammation, scarring, and fibrosis, facilitating re-access. Extra-arterial placement of the sealant is less painful due to fewer arterial luminal manipulations and leaves the lumen patent.

ExoSeal® (Cordis Corporation, Bridgewater, NJ)

The ExoSeal VCD—approved by the FDA in June 2011—deploys a bioresorbable, polyglycolic acid plug through a 5–7 Fr procedural sheath. Hemostasis is achieved by positioning this plug on the extravascular surface of the femoral artery arteriotomy site. The plug is completely absorbed within 60–90 days.

The ECLIPSE trial demonstrated the safety and effectiveness of ExoSeal.[8] No major adverse events, vascular repair, access site-related bleeding requiring transfusion, or access site-related infection requiring treatment were reported in this study. ExoSeal significantly reduced ambulation time compared to manual compression.

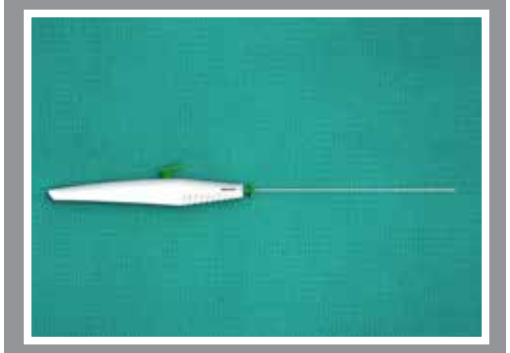

Figure 4: ExoSeal Vascular Closure Device

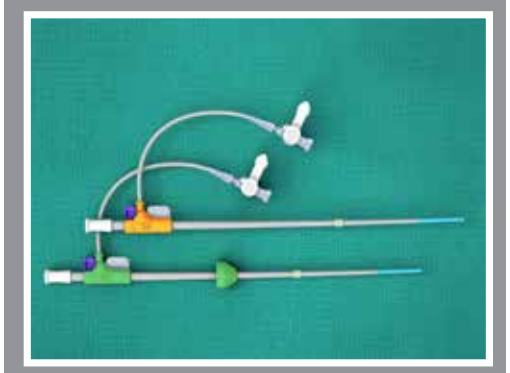

Figure 5: FISH VCD

Figure 6: Catalyst VCD

FISH (Morris Innovative, Inc., Bloomington, IN)

The FISH (Femoral Introducer Sheath and Hemostasis) device delivers a bioabsorbable extracellular matrix ribbon created from porcine small intestinal submucosa. The ribbon folds to form a plug within the vessel as it is withdrawn from the arteriotomy through backward tension on a compression suture. This plug is reabsorbed in 30 days.

The FISH device is only used in diagnostic catheterization cases and available in 5–8 Fr sizes. The device success rate is reported to be 98% and the mean time to ambulation, 2 hours. The plug is left in place on both sides of the vessel wall. Further studies are needed to delineate the safety of this device, especially when a portion of the plug is intra-arterial.

Catalyst® (Cardiva Medical, Inc., Sunnyvale, CA)

Catalyst II and III are adjunctive aids to manual compression. These devices are placed through the procedural sheath and once the tip is within the arterial lumen, they deploy a collapsible hemostatic coated disc. The sheath is removed and the disk is pulled with gentle tension held by the clip.

This disk is coated with kaolin and chitosan (Catalyst II) and also protamine sulphate (Catalyst III) to facilitate thrombosis. The device needs to be in place for 15 minutes for a diagnostic case and 120 minutes for an interventional case. After the procedure, the device is withdrawn and manual compression is performed for 5 minutes.

With Catalyst, 99% successful hemostasis is reported in 5 Fr sheath closure after diagnostic procedures. Minor complications of re-bleed were reported in 5% of the case with no major complications reported in a similar study. With Catalyst, the arterial lumen is intact with no foreign material left behind, facilitating re-access. With this device, patients can ambulate 90 minutes after the diagnostic procedure.[9]

Table 1: Summary of Key VCD Characteristics

	Angio-Seal	StarClose	Mynx	ExoSeal	FISH	Catalyst
Market share	50.6%	19.4%	8.8%	–	–	–
Mechanism	Collagen and Suture	Clip (nitinol)	Hydrogel plug (PEG)	Plug (polyglycolic acid)	Bioabsorbable extracelluar matrix ribbon	Kaolin and chitosan (Catalyst II) and also protamine sulphate (Catalyst III) coated disk to facilitate thrombosis
Sheath size	6, 8 Fr	5, 6 Fr	5–7 Fr	5–7 Fr	5–8 Fr	5–7 Fr
Re-access within 90 days	In close proximity (1 cm higher)	Unknown	Yes	Unknown	2 cm above the previous access	Yes
Placement	Intraluminal	Extraluminal	Extraluminal	Extraluminal	Intraluminal	Extraluminal

Device related complications

Individual studies regarding the usefulness of VCDs are small and not powered to reach concrete clinical conclusion. Meta-analyses of these studies provide better guidance.

Following arterial procedures, the most common vascular complications are bleeding (~70%) and pseudoaneurysm (~20%).[10] Surgical repair in patients undergoing manual compression is primarily due to pseudoaneurysm (71%), hemorrhage (32%), and arterial venous fistula (15%); however, infection (39%) and ischemia (28%) are more common situations requiring surgical intervention in patients managed with VCDs.[11]

In a meta-analysis of 30 studies (37,066 patients) comparing VCDs to manual compression, the incidence of major vascular complications was increased with all VCDs.[12] Analysis of only randomized controlled studies showed a decreased incidence of major complications with Angio-Seal. Another meta-analysis of 16 randomized studies (5,048 patients) demonstrated that VCDs decrease the risk of major complications.[13] Perclose and Angio-Seal significantly decreased the risks of major complications, where VasoSeal (no longer in use) significantly increased the risk. In interventional cases, major complications did not differ from manual compression in the Perclose group, were lower than manual compression in patients managed with Angio-Seal, and increased in the VasoSeal group.[10]

In another a meta-analysis, Angio-Seal and Perclose VCDs decreased mean hemostasis time, bedrest time, and hospital stay by 17 minutes, 10.8 hours, and 0.6 days respectively.[14]

Summary

The paucity of large randomized controlled trials demonstrating the safety of VCDs and inconsistent results of available underpowered studies are the major reasons for lower market penetration of VCDs. Any of the current results regarding VCDs should be interpreted with the caution. The safety of VCDs cannot be reliably generalized as a "class effect" and each VCD needs to be studied individually.[11] If patients are at high risk for vascular complications or have puncture site-related risk factors for vascular complications, VCDs should be used cautiously. Manual compression remains the gold standard to achieve hemostasis in high-risk complex vascular anatomy patients. VCDs improve patient comfort and reduce time to hemostasis and ambulation. VCDs should not be used solely for the purpose of reducing vascular complications.[3]

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CHAPTER 1 | SECTION EIGHT

Manual Compression and Assisted Manual Compression for Femoral Closure

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Overview

Manual compression remains the gold standard in vascular closure and hemostasis because it utilizes physiologic mechanisms. The strategies presented in this section may differ from personal anecdotal experience and institutional policies. The fundamental concept, regardless of stylistic details, is to achieve hemostasis by manual stabilization of the arteriotomy flap as a collagen plug forms.

This section focuses on the closure of percutaneous femoral arteriotomy by means of manual compression and assisted manual compression after procedures requiring an 8 Fr or smaller introducer catheter. Box 1 provides "quick tips" for the clinician.

Box 1: Passive Closure Quick Tips

Procedural technique

- Utilize fluoroscopy and ultrasound to achieve an appropriate arteriotomy during the procedure

Pre-closure planning

- Await point-of-care activated clotting time (ACT) of <170 seconds
- Calculate number of minutes required to achieve hemostasis by multiplying the catheter's French size by 3
- Place moderate compression on arterial pulse approximately 2–3 cm above the site of skin entry
- Slowly remove sheath from artery
- Immediately apply firm pressure for 7–10 minutes
- Relieve pressure to moderate intensity for the next several minutes
- Relieve pressure further to light intensity in the final stages

Post-closure instructions

- Ensure strict supine bedrest without flexion of hip
- Frequently monitor vital signs and lower extremity pulses
- Restrict straining and weight lifting of 10 lb maximum for 2–3 days
- Avoid driving or operating heavy machinery for 24 hours
- Avoid bathing or submersion in water for 24 hours
- Report any signs of site infection symptoms, pain, or bleeding

Strategic planning

The key to successful vascular closure begins with a precise arteriotomy at the start of the procedure (Figure 1). The operator then plans the entire procedure, including the desired vascular closure and hemostasis method, as some may require placement of active closure devices prior to the close of the procedure. If passive closure methods are pursued, vascular closure planning can be delayed until the end of the procedure, as it will depend on the level of anticoagulation.

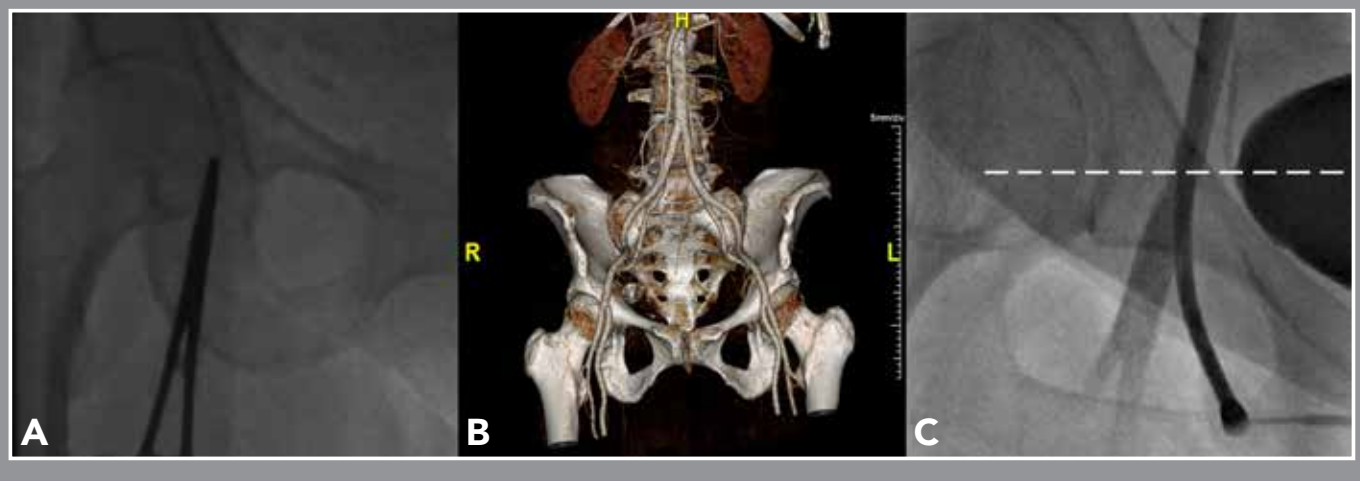

Figure 1: Precise Arteriotomy Helps Ensure Successful Vascular Closure

(A) Hemostat under fluoroscopy marks the appropriate arteriotomy site, which overlays the bony structure (pelvic rim) necessary to support successful manual compression for hemostasis. (B) CT angiogram reconstruction depicts that an arteriotomy above the pelvic rim does not provide an adequate bony structure for manual compression, and arteriotomy below the bifurcation of the common femoral artery risks pseudoaneurysm formation (ultrasonography can be used during the procedure to ensure that the arteriotomy is above the bifurcation). (C) Contrast injection with introducer sheath in place reveals a precise arteriotomy at the pelvic rim (dotted line for landmark reference to the inferior one-third of the femoral head).

Especially with interventional procedures in which unfractionated heparin products are utilized to achieve high activated clotting times (ACT), a blood sample for point-of-care ACT testing can aid in determining whether immediate vs. delayed introducer catheter removal and closure via manual compression are indicated. An ACT should be drawn at the close of the procedure and every hour (if initial ACT is high) until the ACT level falls below 170 seconds before the introducer catheter can be safely removed with minimal bleeding.

Manual compression

To ensure successful hemostasis and prevention of hematoma formation with manual compression, calculate the duration of required compression by multiplying the French size by 3. For example, a 7 Fr catheter should optimally be compressed for a total of 21 minutes in a decremented fashion as explained below.

Once the ACT is appropriately low, apply firm pressure over the femoral artery pulse approximately 2–3 cm proximal to the skin entry site, at the estimated site of arteriotomy (Figure 2). If the patient had a large abdomen that was taped cephalad during the procedure, this may have distorted the anatomy of the skin entry site in relation to the arteriotomy site. Therefore, in such a situation the abdomen should be taped cephalad in the same fashion prior to sheath removal.

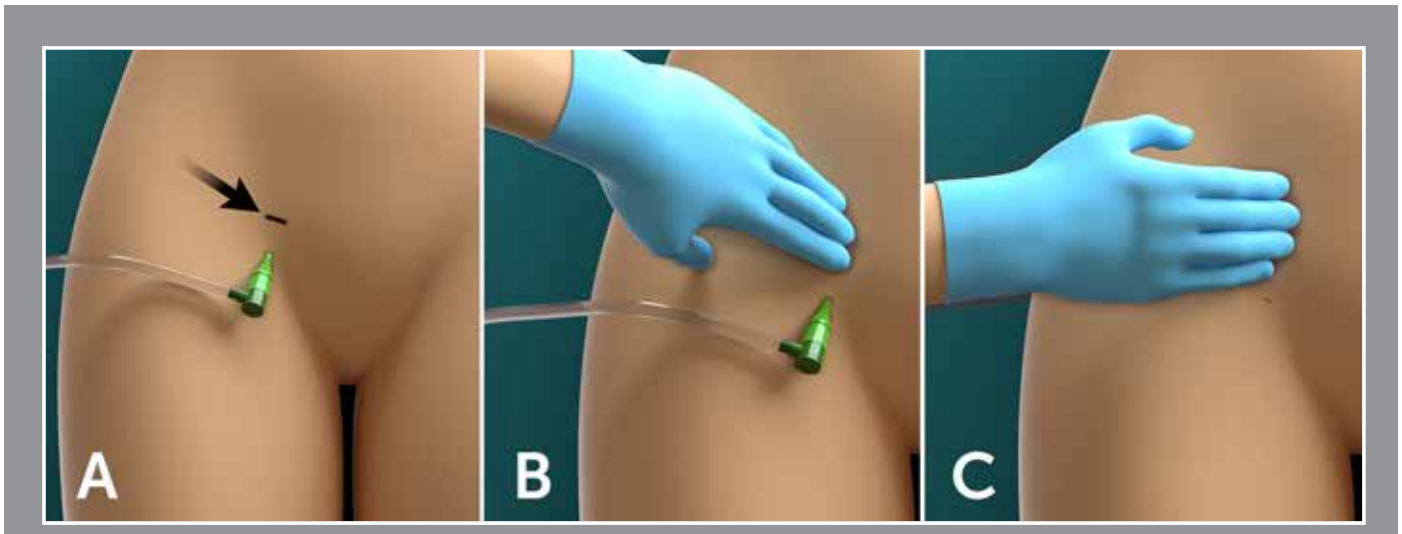

Figure 2: Manual Compression

(A) Femoral arterial sheath in place, with pen mark correlating with tip of hemostat identified under fluoroscopic guidance to confirm site of arteriotomy (arrow). (B) Pressure placed at site of arteriotomy (approximately 2–3 cm above skin entry site). (C) Introducer sheath is removed, with manual compression until hemostasis is achieved.

With firm pressure over the arteriotomy site, the arterial sheath may be slowly removed. A slight release of pressure may be required to successfully remove the sheath without fracturing the plastic. Once the sheath is completely removed, hold firm pressure for 7–10 minutes. The remainder of the time required for successful hemostasis (as calculated by French size times 3) should be divided equally, with moderate compressive force for the first half, and light compressive force for the second half. This ensures some blood flow across the intimal layer to successfully activate the clotting cascade and to prevent limb ischemia. If oozing is noted with each decrement in compressive force, increase compressive force again for five minutes before attempting to advance to the next stage.

Assisted manual compression devices

Despite meticulous planning, situations arise in the catheterization laboratory whereby femoral sheaths must be removed when the ACT is still elevated. In these cases, manual compression is time-consuming and tiring, and often results in catheterization laboratory and holding-area delays. When personnel are limited and in order to alleviate operator fatigue, devices to assist with manual compression may be used. These devices are also beneficial in cases where complete hemostasis is not achieved, vascular trauma is present, or the patient requires transport during which a team member cannot dedicate full attention to achieving hemostasis. Although these devices have near perfect success rates, they do not shorten the time to hemostasis and may be less comfortable for patients.

The first of two available compression devices, FemoStop™ (St. Jude Medical), has a transparent inflatable hemisphere (bulb) that provides focal compression (Figure 3). The device is held in position with a belt that wraps around the patient to keep the bulb level in relation to the supine patient. The transparent bulb allows for monitoring of access site bleeding. The bulb should be positioned slightly above the approximate site of the arteriotomy and inflated to approximately 60 to 70 mmHg for sheath removal. The hub of the sheath may need to be pulled back a few centimeters from the bulb. If the bulb shifts away in any direction from the puncture site during inflation, it can be readjusted or the belt can be tightened. The bulb is then inflated to approximately 20 mmHg higher than the patient's systolic blood pressure for 2 to 3 minutes for initial hemostasis. By monitoring the puncture site through the transparent bulb, clinicians can determine whether higher pressure is required to achieve hemostasis.

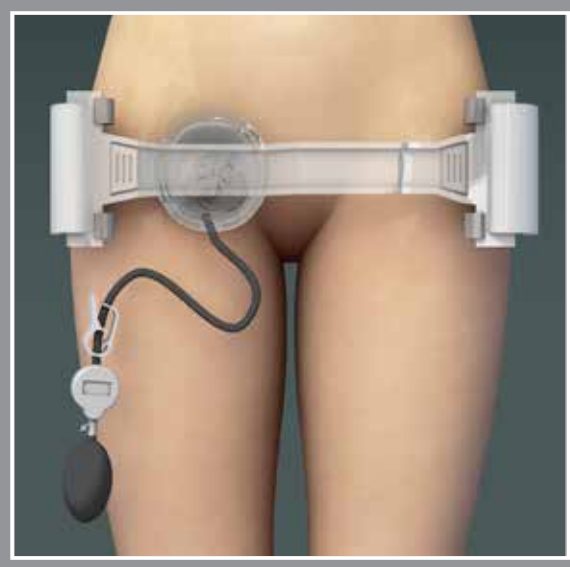

Figure 3: Appropriately Positioned FemoStop™ Compression Device

Following initial hemostasis, the bulb is deflated to match the patient's mean arterial pressure or 100 mmHg for 15 minutes while the patient is monitored for palpable pedal pulses. The bulb is then gradually deflated to 30 mmHg over the course of the next 1–2 hours for full hemostasis before removal. Carefully assess excess pain to ensure that the bulb is not too medial and overlying the femoral nerve. To relieve medial pressure, the opposite side of the belt may be loosened slightly.

The second compression device, ClampEase® (Pressure Products, Inc.) is a flat metal plate placed under the patient and attached to a C-arm clamp. Similar to the FemoStop, the clamp applies baseline pressure as the sheath is slowly removed. As the sheath is completely removed, pressure is increased by lowering the clamp over the arteriotomy site.

Alternative and conjunctive methods

Hemostatic pads may be utilized as an alternative to mechanical closure devices and manual compression, or in conjunction with the aforementioned techniques. There are several hemostatic pads on the market, including Clo-Sur P.A.D.™ (Scion Cardiovascular), SyvekPatch® (Marine Polymer Technologies, Inc.), D-Stat® Dry (Vascular Solutions), and Neptune Pad (TZ Medical). These procoagulant pads enhance coagulation to achieve successful hemostasis. As studied in diagnostic and interventional procedures, there is a reported 10–20% technical failure rate, however, the complication rate was generally unchanged or even improved in the case of D-Stat Dry. There was some increased risk of minor bleeding with Neptune Pad.

Post-hemostasis care and discharge instructions

Although post vascular closure nursing care varies institutionally, frequent assessment for vascular closure complications such as oozing and hematoma formation should be protocolled in addition to frequent monitoring of vital signs, pedal pulses, etc. After hemostasis is achieved by either manual compression or assisted manual compression, 4 to 6 hours of bedrest is recommended without flexion of the hip. Provide instructions to the patient to hold pressure on the site before sneezing or coughing for added protection. Assisted manual compression devices and hemostatic pads do not reduce the duration of required bedrest. Upon discharge, patients should be instructed to avoid straining or lifting objects heavier than 10 pounds for 2 to 3 days; avoid driving or operating heavy machinery for 24 hours; avoid bathing in a tub, swimming, or submerging in water; keep the dressing clean, dry, and intact for 24 hours; clean the area with soap and water and re-bandage; and to inspect the groin site daily and report bleeding, unusual pain, swelling, redness, or discharge.

Summary

- Manual compression remains the gold standard in vascular closure and hemostasis, and should be considered in all patients.
- Vascular closure by manual compression begins pre-procedurally with strategic planning of precise arteriotomy to enable successful closure. This is achieved with ultrasound and/or fluoroscopy.
- The arteriotomy site should be compressed in a decremented fashion as described above, and patients should be given skin care instructions.
- Assisted manual compression with various devices is indicated in specific situations but may be associated with patient discomfort and higher complication and failure rates.

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CHAPTER 1 | SECTION NINE

Radial Hemostasis: Best Practices

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The use of transradial access (TRA) for cardiac catheterization and other angiographic procedures has been steadily rising in the United States and around the world for both diagnostic and interventional procedures. Major cardiovascular societies have endorsed TRA as the preferred access for coronary intervention, especially in patients with NSTEMI and STEMI. These recommendations are based on large randomized controlled clinical trials (RCTs) demonstrating reduced access-related bleeding and mortality. However, as a result of expanded utilization of TRA, increasing numbers of patients are subject to recurrent cannulation of the radial artery either for repeat procedures or planned staged interventions. Radial artery occlusion (RAO)—one of the most commonly observed structural complications of TRA—precludes the use of the ipsilateral radial artery for repeat procedures and as a potential graft harvest site for coronary artery bypass surgery.

Reported rates of radial artery occlusion range from 3% to 10% in contemporary RCTs and real world observational studies.[1] The true incidence of RAO is difficult to estimate because it is clinically silent with no symptoms or signs of neurovascular or motor compromise. In clinical practice, RAO is most often discovered on a failed attempt for repeat cannulation of the radial artery. There is a substantial rate of spontaneous recanalization both within 24 hours and within 30 days following the observed cessation of flow in the radial artery,[2] further complicating the ability to accurately estimate the incidence of RAO unless diligent post procedural monitoring is performed utilizing reverse Barbeau test and ultrasonography.

The postulated mechanism of radial artery occlusion is formation of organized thrombus in the setting of vessel trauma and blood stasis from insertion of a near occlusive sheath. While multiple procedural factors affect the incidence of RAO (Box 1), there is a significant residual risk of RAO related to the method of compression used to achieve hemostasis.

Box 1: Predictors of Radial Artery Occlusion

- Adequacy of anticoagulation
- Sheath to artery ratio
- Number of passes prior to successful access
- Repeat access
- Prolonged cannulation time

Patent hemostasis of the radial artery has been demonstrated to be superior to occlusive hemostasis in maintaining long term radial artery patency.[2] In the PROPHET trial, Pancholy et al. studied 480 patients undergoing outpatient diagnostic cardiac catheterization, randomized to standard hemostasis and patent hemostasis. Patients in the patent hemostasis group had a 59% reduction in RAO ($P < 0.05$). At 30 day follow up, there was a 75% reduction in RAO in the patent hemostasis group ($P < 0.05$), as shown in Figure 1. Box 2 describes the patent hemostasis technique.

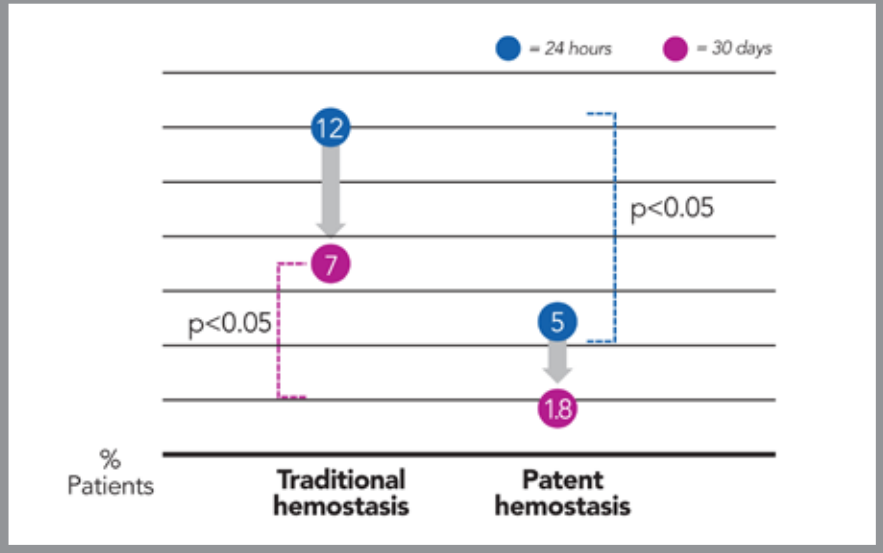

Figure 1: Incidence of Radial Artery Occlusion at 24 Hour and 30 Day Follow Up[2]

Adapted from Pancholy et al. *Catheter Cardiovasc Interv.* 2008;72(3):335-340.

Box 2: Patent Hemostasis Technique

(adapted from Pancholy, Coppola, Patel, Roke-Thomas)[2]

1. Pull back the sheath 4–5 cm from the arteriotomy.
2. Apply radial compression device at the site of arteriotomy. If using TR Band (Terumo), place the arteriotomy marker 1–2 mm above the skin entry site. (Figure 2)
3. Ensure that the pulse oximeter is applied over the index finger or the thumb and is recording an adequate waveform.
4. Inflate the radial compression bladder of the TR Band with 15 mL of air using the provided syringe. Cessation of the oximetry waveform indicates complete compression of the radial artery.
5. Remove the arterial sheath completely.
6. Deflate the compression bladder slowly while applying back pressure to the syringe until oozing or slow pulsatile bleeding is observed from the skin entry site.
7. Re-inflate the device with 1–2 mL of air.
8. Compress the ipsilateral ulnar artery in the ulnar canal or in the forearm superior to the compression band.
9. A pulsatile oximeter signal will be observed if radial artery patency has been achieved.
10. If the plethysmographic signal is absent, remove 1–2 mL from the compression bladder while maintaining hemostasis and repeat step 8 until a pulsatile plethysmographic signal is observed.

Figure 2: Patent Hemostasis of Radial Artery

Even with application of patent hemostasis technique and close monitoring in the setting of a clinical trial, there is still a residual 1.8% rate of RAO at 30 day follow up.[2] Subsequent to publication of the original PROPHET trial, Pancholy et al. demonstrated that transient compression of the ipsilateral ulnar artery results in a 40% increase in flow in the radial artery.[3] Feasibility and safety of simultaneous ulnar compression and patent radial artery hemostasis (ULTRA) (illustrated in Figure 3) were demonstrated in a small study of 119 patients, none of whom had RAO within 1 hour of the procedure.[4]

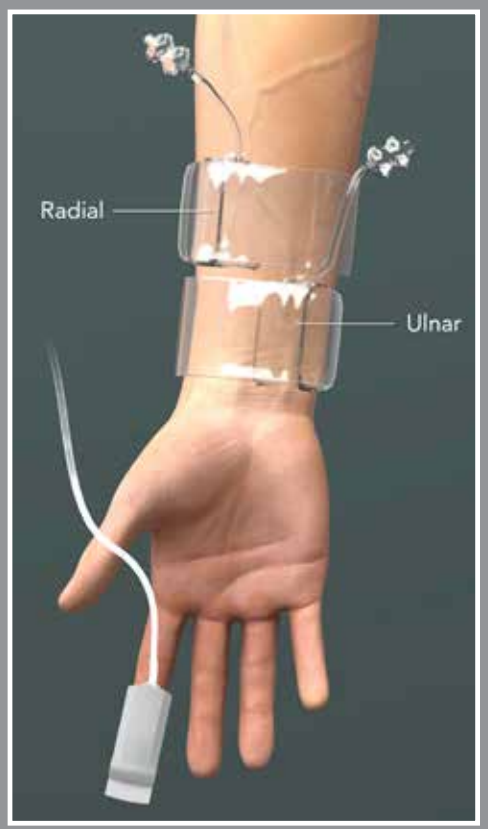

Figure 3: Patent Radial Hemostasis with Ulnar Compression

One TR Band placed over the ulnar artery (U) in Guyon's canal. Second TR Band placed over the radial artery (R). Oximeter probe placed on the index finger documenting patent hemostasis.

In PROPHET II, effectiveness of ulnar compression was evaluated in 3000 patients undergoing diagnostic cardiac catheterization.[5] The primary endpoint of RAO at 30 days was evaluated using reverse modified Barbeau test of radial patency and Duplex ultrasonography. There was a significant reduction of RAO in the ulnar compression group compared to standard patent hemostasis (0.9% vs. 3.0%; p=0.0001) (Figure 4).

Female gender, older age, diabetes, and pain with compression were found to be univariate predictors of RAO. In a multivariate analysis, performance of ulnar compression was the single strongest negative predictor of RAO (OR 0.3; 95% CI: 0.16–0.57; p=0.0001). Of note, in an ultrasound substudy, no morphological or flow changes were noted in the ipsilateral ulnar artery. Box 3 describes the technique for patent radial artery hemostasis with ulnar compression.

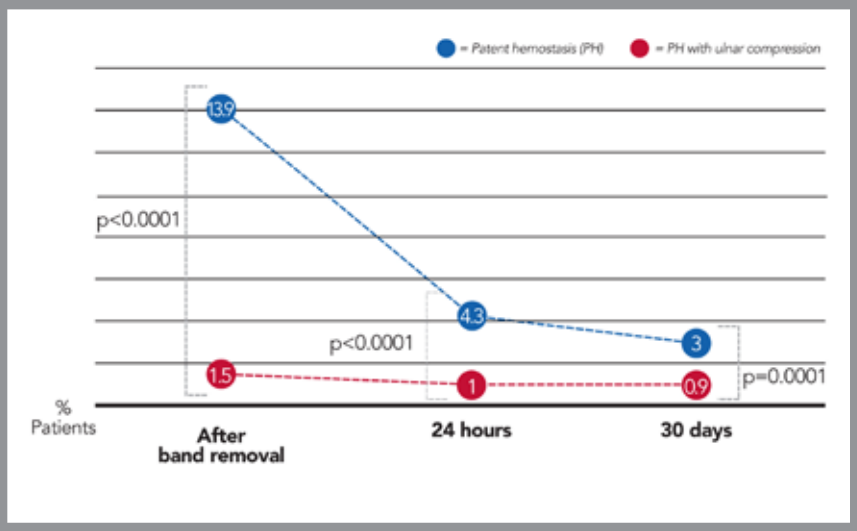

Figure 4: Incidence of Radial Artery Occlusion at Band Removal, 24 Hours and 30 Days[5]

Adapted from Pancholy et al. *JACC Cardiovasc Interv.* 2016;9(19):1992-1999.

Box 3: Patent Hemostasis with Ulnar Compression Technique

(adapted from Pancholy, Bernat, Bertrand, Patel)[5]

1. Apply inflatable band (TR Band, Terumo) over the sheath entry site to the radial artery.
2. Apply a second compression device over the ulnar artery either at the Guyon canal or in a position superior to the initial TR band with the inflation bladder placed over the ulnar artery.
3. With the oximeter placed on the ring or pinkie finger, inflate TR Band placed over the ulnar artery and verify occlusive compression by absence of plethysmographic waveform.
4. Perform radial artery patent hemostasis as described in Box 2, Steps 1–7.
5. Deflate the ulnar artery compression band after 1 hour. Examine the radial artery access site for continuous hemostasis.

To date, there are no clear guidelines on management of observed radial artery occlusion. Given that most patients are asymptomatic, interventional approach and revascularization are usually unwarranted. Bernat et al. demonstrated that in cases of early detected RAO within 3–4 hours after hemostasis, simple transient ipsilateral ulnar artery compression for 1 hour (as shown in Figure 3) is effective in recanalization of the radial artery in up 70% of observed cases.[6]

While published data clearly support benefits of patent hemostasis, clinical utilization of this technique is limited. Patent hemostasis with ulnar compression in PROPHET II was associated with an absolute RAO rate of less than 1%.[5] It is a method that requires diligent hemostasis technique, which may be a limitation given that this part of the procedure is often delegated to the radiation technician or nurse. Therefore, education of the cardiac catheterization laboratory staff is probably the most effective method for ensuring best practices of hemostasis after TRA.

Summary

- RAO occurs in 3–10% of procedures using TRA limiting recurrent access.
- Prevention of RAO largely depends on the method of hemostasis.
- Patent hemostasis of the radial artery can reduce RAO by 75%.
- Patent hemostasis with ulnar compression is a superior technique associated with <1% RAO without any adverse effect on the ulnar artery.

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CHAPTER 2

Best Practices for Percutaneous Large Bore Arterial and Venous Access and Closure

CHAPTER 2 | SECTION ONE

Best Practice Algorithm for Large Bore Femoral Artery Access

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Overview

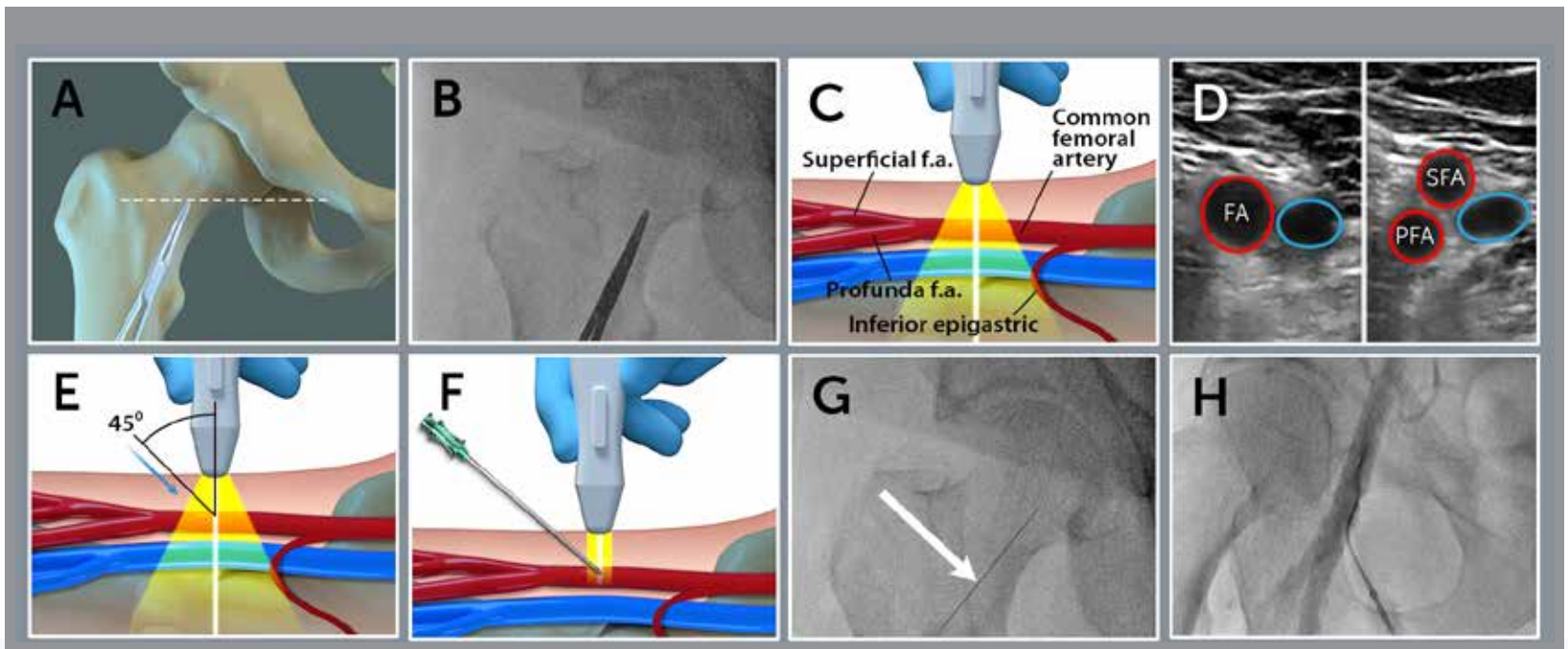
With recent advancements in interventional cardiology techniques, more complex procedures are being performed percutaneously. Several procedures—such as transcatheter aortic valve replacement (TAVR), transcatheter endovascular aortic repair (TEVAR), and placement of percutaneous hemodynamic support devices such as Impella® and venoarterial extracorporeal membrane oxygenation (VA ECMO)—require large bore femoral arterial access (sheath size ≥12 Fr). The success of these procedures relies heavily on good femoral arterial access techniques. This section provides a brief overview of strategies to achieve optimal femoral arterial access and sustained hemostasis.

Strategic planning, equipment, and procedural consideration

Successful femoral large bore access requires entering the artery with a single antegrade puncture (modified Seldinger technique), avoiding areas of calcification in the vessel, and staying above the femoral bifurcation (to minimize the risk of pseudoaneurysm and hematoma) and below the inguinal ligament (to minimize the risk of retroperitoneal bleeding).

Anatomic landmarks, such as skin crease, anterior superior iliac spine, and pubic symphysis, are unreliable for predicting the entry site into the common femoral artery and should not be used to guide access. Combining fluoroscopy and ultrasonography is the safest and most reliable technique to obtain access, as shown in Figure 1. The optimal femoral artery entry site is just below the center of the femoral head. Fluoroscopy is used to identify the inferior border of the femoral head and helps avoid a high puncture. A final fluoroscopy of the needle through the skin, just prior to puncturing the vessel, can also avoid a high puncture.

Vascular ultrasonography should be used to identify the femoral artery bifurcation, areas of calcification, and significant plaque in the common femoral artery. Operators should optimize the vessel entry site based on these findings. The femoral head can also be seen on ultrasound by sliding the probe laterally and can be used as a landmark to avoid a high puncture. To ensure that the arterial access is in the desired location and to avoid hemostasis-related complications, direct visualization of the needle entering the anterior wall of the femoral artery is critical. A side puncture will often result in failed closure device hemostasis. Using ultrasound has been shown to improve first pass success rate, reduce the number of attempts, reduce the rate of venipuncture, reduce vascular complications, and increase the rate of sheath insertion into the common femoral artery in patients with a high common femoral artery bifurcation. Thus, ultrasound can help to identify the "ideal" puncture location. Other resources, such as prior femoral angiography and CT angiography (CTA), when available, should also be reviewed to understand the vessel's anatomy.



From: Sandoval, Y. et al. *J Am Coll Cardiol Intv.* 2017;10(22):2233-41.

Figure 1: Fluoroscopic and Ultrasound Techniques for Femoral Access

(A) Hemostat to identify lower edge of femoral head. (B) Confirm position of hemostat with fluoroscopy. (C) Ultrasound positioned to visualize common femoral artery (f.a.). (D) Ultrasound visualization of common femoral artery (left) and bifurcation into superficial and profunda (right). (E, F) Triangulation for needle entry. (G) Needle entry position (arrow) and guidewire advancement assessed using fluoroscopy. (H) Femoral angiography.

CTA is an essential part of procedural planning for patients undergoing structural and vascular procedures. CTA analysis and reconstructions are very informative regarding femoral, iliac, and aortic anatomy. The analysis provides information about the femoral artery bifurcation height, the extent and location of calcifications, vessel diameters, tortuosity, and the presence of intravascular pathologies such as hematoma, dissection, pseudoaneurysm, or atheroma (Figure 2). To minimize vessel injury and ensure proper distal perfusion while the large sheath is in place, the ideal sheath to femoral arterial ratio (SFAR) should be <1.05.

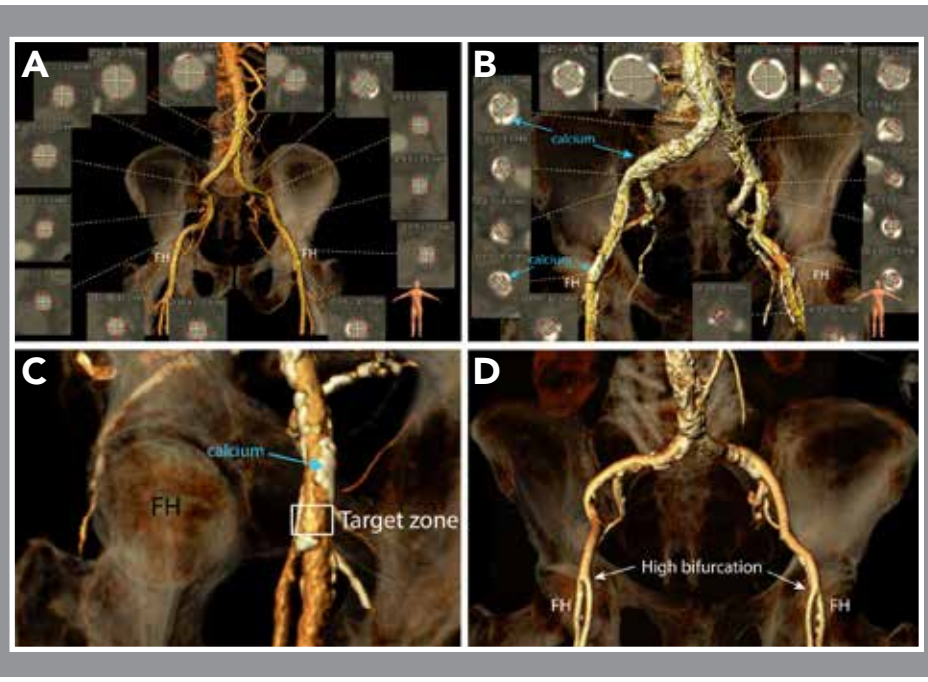


Figure 2: CTA Analysis

(A) CT angiographic reconstruction of iliofemoral vessels. (B) Severely calcified iliofemoral vessels (blue arrows). (C) Severe anterior calcification in the common femoral artery with very narrow target zone. (D) Bilateral high common femoral artery bifurcation.

FH=femoral head

Micropuncture technique is the preferred method for large bore common femoral artery access. The micropuncture needle is an 18G needle, as opposed to a traditional 21G Cook needle. It reduces vessel trauma and blood loss and facilitates hemostasis in case of inadequate vessel entry site. For this technique, advance a 0.018" guidewire through the needle into the artery, remove the needle, and advance a micropuncture sheath (usually 4 Fr) into the femoral artery and withdraw the guidewire. At this point, perform a femoral angiogram, with ipsilateral 30° angulation, through the sheath to confirm a safe entry point into femoral artery (Figure 3). If inadequate, remove the micropuncture sheath, apply manual pressure, and obtain new access. Once satisfied with the puncture location, upsize the micropuncture sheath to a larger sheath over a 0.035" wire. When advancing large bore sheaths and/or dilators, use a stiff wire such as an Amplatz Super Stiff™ wire to avoid vessel injury.

Successful hemostasis is key to procedural success. Contralateral arterial access should be maintained until successful hemostasis is achieved on the large bore arterial access site. Large bore closure devices currently available in the United States include the Perclose ProGlide® Suture (up to 21 Fr arterial sheaths) and the Prostar XL® Percutaneous Vascular Surgical System (8.5–10 Fr sheaths). The Manta device (10–25 Fr sheaths) is currently awaiting FDA approval.

Our preferred closure device for large bore access closure is the Perclose ProGlide®. Using this device with sheaths larger than 8 Fr, we "pre-close" with 2 Perclose devices deployed orthogonal to each other (typically at 10 o'clock and 2 o'clock) prior to serial dilation and insertion of the large bore sheath. The sutures are tightened at the end of the procedure, after removal of the large bore sheath.

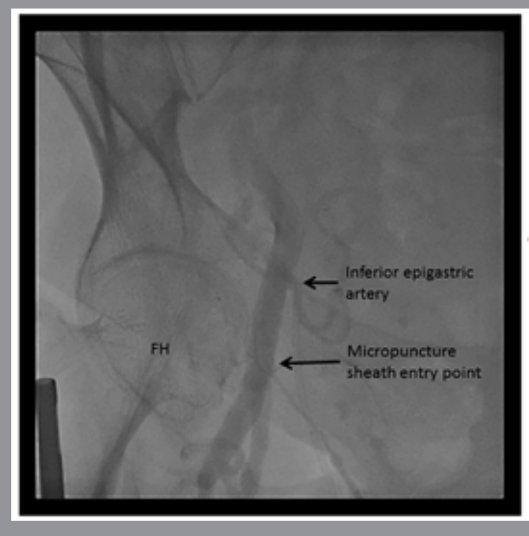


Figure 3: Femoral Angiogram Through Micropuncture Sheath

Angiogram shows satisfactory femoral artery entry point above the bifurcation and below the lower part of the inferior epigastric artery.

FH=femoral head

After successful deployment of the sutures, angiography from the contralateral access is highly recommended to confirm hemostasis and the absence of flow-limiting dissection or significant vessel stenosis. In case of significant bleeding, a balloon can be inflated from the contralateral arterial access using the "cross over" technique to temporarily stabilize the patient. Operators should also be familiar with the Coda® balloon, which can be inflated in the aorta in case of an iliac perforation. If hemostasis cannot be achieved with balloon inflations and/or manual pressure, consider deployment of a covered stent from the contralateral side. Limitations of covered stents in the common femoral artery include risk of losing a branch (superficial femoral artery or profunda) and risk of stent fracture from repetitive hip flexion. If hemostasis cannot be achieved, or the injury is not amenable to percutaneous repair, perform surgical repair. Significant vessel stenosis after deployment of the Perclose can usually be treated with low pressure balloon inflation across the lesion.

Once the large bore sheath is inserted, anticoagulation should be initiated immediately with heparin (ACT goal >250) to avoid thrombus formation. Additional considerations include having a valid type and screen prior to starting the case. This ensures that blood is readily available for transfusion and saves precious time in the event of hemorrhage. Operators should also be familiar with devices and techniques needed in case of complications (Table 1).

Table 1: Potential Complications and Management

Complication	Prevention and Management
General precautions	• Minimize the number of puncture attempts • Use vascular ultrasound and fluoroscopy to gain access; avoid areas of calcification and high puncture • Ensure proper deployment of closure device
Bleeding / Hematoma	• Prolonged manual pressure usually leads to hemostasis • Use protamine to reverse anticoagulation • If bleeding is more severe, use balloon tamponade from the contralateral side • Consider covered stent placement • Consult vascular surgery if percutaneous management fails or is not feasible
Pseudoaneurysm	• Obtain angiogram to confirm diagnosis through contralateral access • Apply manual pressure, if possible • Use balloon tamponade and consider covered stents • Consult vascular surgery if percutaneous management fails or is not feasible
Dissection	• Obtain angiogram through contralateral access • Use balloon tamponade and consider stent placement if balloon tamponade fails • Consult vascular surgery if needed
Vessel avulsion / rupture	• Use balloon tamponade in proximal vessel through contralateral access; if iliac ruptures, place Coda balloon in the distal aorta • Employ aggressive volume resuscitation • Consult vascular surgery if needed

Case example

A 59 year old male with diabetes mellitus, hypertension, severe peripheral arterial disease with prior bilateral femoral popliteal bypass surgery, right external iliac artery stenting, and left common femoral artery endarterectomy with patch repair presented with non-ST elevation acute coronary syndrome. His coronary angiogram revealed severe distal left main disease extending into LAD with total occlusion of RCA and LCX, which were filled by collaterals. He had small radial arteries, disease in bilateral subclavian arteries, and his saphenous veins had been previously harvested for fem-pop bypass grafting. He was deemed not to be a surgical candidate and underwent successful percutaneous coronary intervention to his unprotected left main into LAD with Impella® support. Ultrasound was used to obtain access into left femoral bypass graft and helped identify an area free of calcium and plaque. Hemostasis was successfully obtained with 2 Perclose devices (see Figure 4).

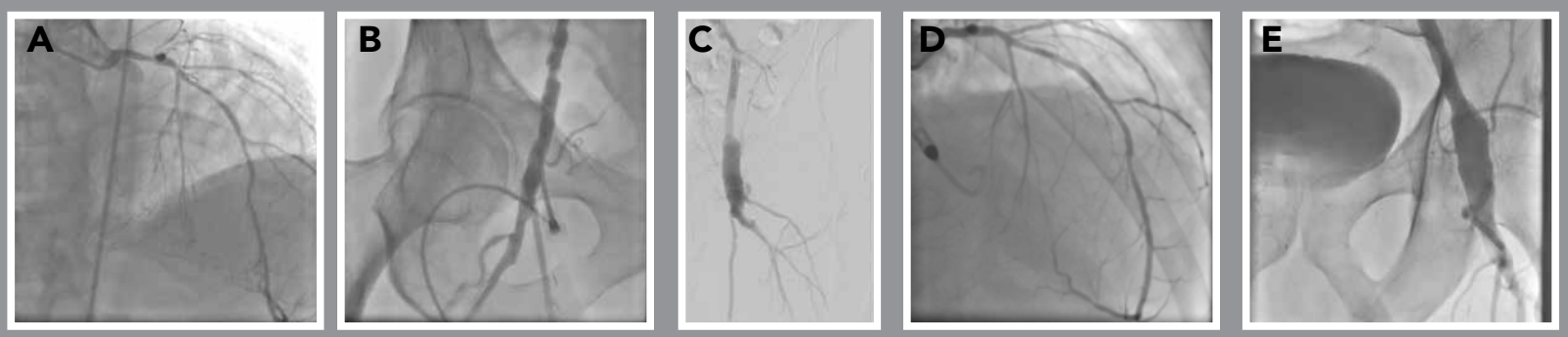


Figure 4: Case Example Images

(A) Severe distal left main disease extending into the proximal LAD. (B) Diseased right common femoral artery used for the PCI. (C) Left common femoral artery with prior endarterectomy and patch repair DSA angiography prior to the case. This side was used for Impella CP support during the PCI. (D) Post successful left main into LAD placement of drug-eluting stent. (E) Completion left common femoral artery angiography with successful hemostasis.

Pro Tips

Pre procedure

√ Review prior femoral angiogram (if available).

√ Review prior CTA (if available) to assess level of femoral bifurcation, calcification, femoral and iliac vessel size, prior stents.

Day of procedure

√ Identify the lower border of femoral head with hemostat under fluoroscopy.

√ Use ultrasound to delineate femoral bifurcation, identify femoral head and femoral arterial calcification or plaque.

√ Use micropuncture needle and ultrasound guidance to obtain access into common femoral artery with single anterior wall stick.

√ Advance the 0.018" micropuncture wire under fluoroscopic guidance into the common iliac artery.

√ Insert the micropuncture sheath into the femoral artery.

√ Remove the 0.018" wire and perform angiogram with ipsilateral 30° angulation to confirm that the femoral puncture is above femoral bifurcation and below inferior epigastric artery.

√ Pre-close the vessel with 2 Perclose ProGlide sutures deployed orthogonal to each other.

√ Over an Amplatz super stiff wire, serially dilate the arteriotomy and insert large bore sheath required for the procedure.

√ At the end of the case, remove the sheath but leave a long 0.035" wire in the artery.

√ Tighten the Perclose sutures in the order they were deployed. If near hemostasis is seen, remove the wire and tighten the sutures again. Lock the knot by pulling on the short thread of each Perclose.

√ Perform iliac/femoral angiogram from contralateral side to confirm hemostasis and normal distal flow in distal vessel.

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CHAPTER 2 | SECTION TWO

Large Bore Access: Adjunctive Imaging for Access

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Overview

Vascular access is a critical portion of interventional cardiology procedures. The stakes are higher in procedures that require large bore access (≥ 8 French), with increased risks of bleeding, vascular injury, and limb ischemia. Large bore access has become increasingly prevalent with the emergence of structural heart interventions, complex percutaneous coronary interventions (PCIs), and mechanical circulatory support (MCS). Femoral access is most commonly employed when large bore access is required. While femoral access historically relied on the utilization of external anatomical landmarks, palpation, and fluoroscopy, the evolution of imaging has provided the opportunity for safer, more efficient, and more precise large bore femoral access. Adjunctive imaging such as ultrasound and computed tomography (CT) may reveal information necessary to locate the optimal site for arteriotomy, evaluate vascular anatomy, and select alternative access sites if necessary.

Ultrasound is a readily accessible technique and provides real-time feedback in the catheterization laboratory. CT offers another key tool for determining the optimal approach for large bore vascular access, and is routinely employed in planning for structural heart interventions. The combination of micropuncture technique with a 21G needle, utilization of ultrasound and fluoroscopy guidance (Figure 1), along with advanced imaging (typically CT) leads to safer large bore access in most patients.[1]

In 95% of patients, the common femoral artery (CFA) bifurcation occurs below the middle third of the femoral head.[2,3] Thus, the ideal CFA cannulation target in most patients lies in a non-diseased segment over the lower or middle third of the femoral head, which can be visualized in the catheterization laboratory with fluoroscopy. Implementation of ultrasound has been shown to improve the chance of successful CFA cannulation, particularly in those with high bifurcations.[2] No factors have been identified to predict which patients will have high CFA bifurcations, supporting the value of imaging.[3] Additionally, ultrasound guidance reduces the number of attempts, time to access, risk of unintended venipunctures, and vascular complications.[2]

Three characteristics of the ilio-femoral vasculature that warrant routine consideration for large bore access and intervention are:

- Minimal vessel diameter (and area)
- Degree of calcification
- Extent of tortuosity

Favorable conditions for large bore femoral access and proximal delivery of equipment include minimum vessel diameter greater than the intended sheath size, the absence of circumferential dense calcification, and minimal tortuosity. Typically with modern access expanding sheath designs, a sheath-to-diameter ratio of smaller than 1.12 is required to prevent vascular complications.

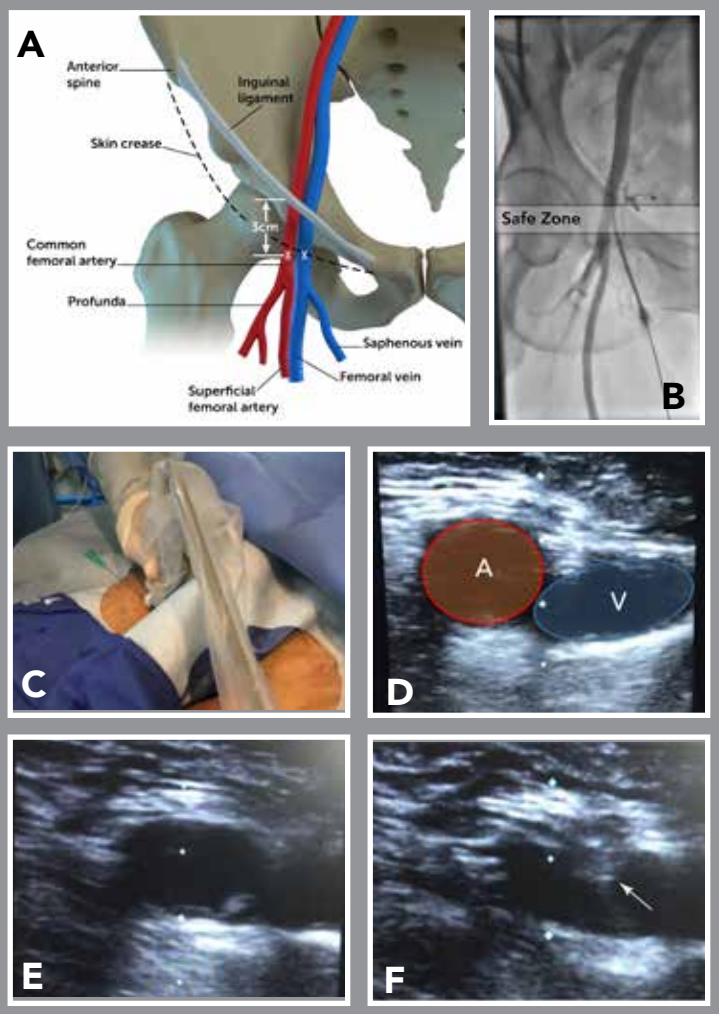

Figure 1: Contemporary Femoral Access Technique With Utilization of Ultrasound and Fluoroscopy

(A) Anatomic landmarks of typical right common femoral artery (CFA) and common femoral vein anatomy; (B) Corresponding "safe zone" of femoral artery access visualized on angiography after sheath placement, above the femoral bifurcation and below the inferior epigastric artery, anterior to bony structures; (C) Proper ultrasound technique with needle guide attachment to ensure 45 degree entry point of 21-gauge micropuncture needle; (D) Characteristic view of right CFA and common femoral vein; (E) Suitable entry point above the femoral bifurcation, free of significant anterior wall calcification or stenosis; (F) Real-time visualization of the micropuncture needle entering the anterior wall of the CFA, which is ideal.

Poor candidates for vascular access due to increased risk for perforation, dissection, and failure to pass equipment, are those with severe vascular disease, heavy calcification (Figures 2, 4B), and excessive tortuosity (Figure 4A). The interaction of multiple unfavorable vasculature characteristics significantly increases the difficulty of the procedure and risk of complications.[5]

The size of delivery systems for transcatheter aortic valve replacement (TAVR) and mechanical circulatory support procedures are shown in Table 1. Advanced imaging, such as preprocedural CT, may not be feasible in clinically unstable or urgent cases involving mechanical support and/or complex PCI. In these instances, angiography coupled with ultrasound are the preferred imaging modalities to define the ilio-femoral anatomy. Table 2 presents the advantages and disadvantages of various imaging modalities for obtaining large bore access.

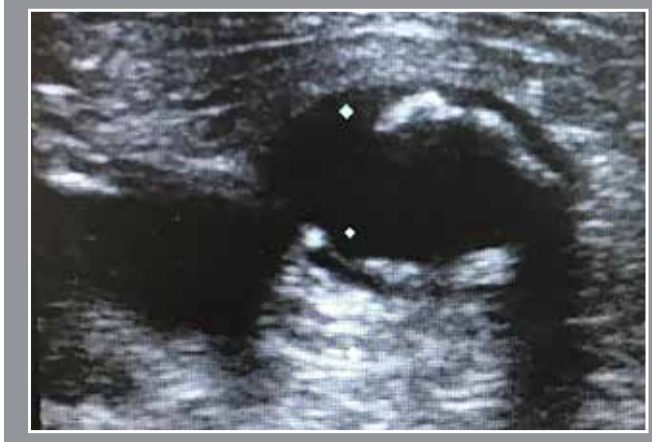

Figure 2: Identifying Calcium

Image reveals extensive calcification in the anterior and posterior walls of the CFA. Ultrasound can localize calcium and avoid arteriotomy at sites of anterior wall calcium, circumferential calcium, or significant stenosis. Arteriotomy at these sites would increase the risk of failure to advance the dilators and sheaths, iatrogenic dissection, and failure of deployment of vascular closure devices.

Table 1: Access Type and Size, Minimum Vessel Diameter for Commonly Used Large Bore Equipment[5]

Device	Transfemoral Delivery System Size	Reference Access Vessel Diameter
Sapien 3™ (Edwards Lifesciences) for TAVR	14 Fr (20, 23, 26 mm valves) 16 Fr (29 mm)	≥5 mm (20, 23, 26 mm valves) ≥5.5 mm (29 mm valve)
Evolut™ PRO CoreValve™ (Medtronic) for TAVR	14 Fr	≥5 mm (23, 26, 29 mm valves) ≥5.5 mm (Evolut R 34 mm valve)
Portico™ (St. Jude Medical, Inc.) for TAVR	18 Fr (23, 25 mm) 19 Fr (27, 29 mm valves)	≥6 mm
Lotus™ (Boston Scientific) for TAVR	18 Fr (23 mm valve) 20 Fr (25, 27 mm)	≥6 mm (23 mm valve) ≥6.5 mm valve (25, 27 mm)
Impella 2.5® and Impella CP®	13 Fr for 2.5, 14 Fr for CP	≥5 mm
Intra-aortic Balloon Pump	8 Fr (or 7 Fr sheathless)	≥3 mm

Table 2: Advantages and Disadvantages of Imaging Modalities for Large Bore Vascular Access

Imaging Modality	Advantages	Disadvantages
Angiography	• May display stenosis, calcification, tortuosity at arteriotomy and proximal vasculature • Verifies needle and/or sheath placement	• Requires contrast in most laboratories • Resolution and 2-dimensional nature may not adequately assess calcium, tortuosity, stenosis
Ultrasound	• Quick, real-time • Inexpensive • No radiation exposure	• Limited resolution • Does not prevent high arteriotomies • No assessment of aorto-iliac vasculature
CT	• Improved resolution • Assesses aorto-iliac vasculature, aortic atheromas, and alternative access	• Additional radiation • Increased cost • Requires stable and cooperative patient • Contrast may be required
MRI	• Resolution • No radiation exposure	• Time-consuming • Expensive • Patient tolerance variable • Inadequate calcium evaluation • Contrast may be required • Contraindicated for many with metallic foreign bodies

Large bore femoral venous access is required for delivering mechanical circulatory support devices such as Impella RP®, TandemHeart®, and extra-corporeal membrane oxygenation (ECMO), as well as for select structural heart interventions such as transcatheter mitral valve repair/replacement, atrial septal defect repairs, and left atrial appendage closure. CT evaluation in selected cases may identify anomalies, such as inferior vena cava (IVC) agenesis or the presence of a previous IVC filter. Ultrasound guidance should be employed to define vascular anatomy and avoid accidental arterial puncture, which could result in bleeding and vascular complications, as shown in Figure 1.

Routine approach to patients requiring large bore access

1. Review previous studies or procedures that yield information about intended vascular access route relevant for the planned procedure (Tables 1 and 2).
2. For elective procedures, consider obtaining CT scan of chest/abdomen/pelvis to determine optimal site of arteriotomy and evaluate the path of equipment being delivered. Take into account extent and severity of calcification, tortuosity, and atherosclerotic disease-causing stenosis (Figures 3 and 4). Even a non-contrast CT can provide valuable information, especially in patients with renal insufficiency.
3. If femoral access is deemed to be high-risk, consider alternative access including axillary artery for complex PCI and mechanical circulatory support. Consider transapical, transcaval, transubclavian, transaortic, or transcarotid approaches for TAVR, in conjunction with a cardiothoracic surgeon.
4. Use best practices for percutaneous access with a 21G micropuncture needle and real-time ultrasound (with needle-guide if available) and fluoroscopy guidance. Ultrasound will aid in the intra-procedural identification of the femoral bifurcation as well as avoidance of arteriotomy at sites of significant calcification or atherosclerotic disease (Figures 1 and 2). Place a 5 Fr or 6 Fr sheath initially.
5. Perform angiography before upsizing to a large bore sheath to confirm puncture site in the common femoral artery (or other vessel) and exclude the presence of disease or unforeseen complications of arterial puncture (ie, dissection). (Figure 1B).

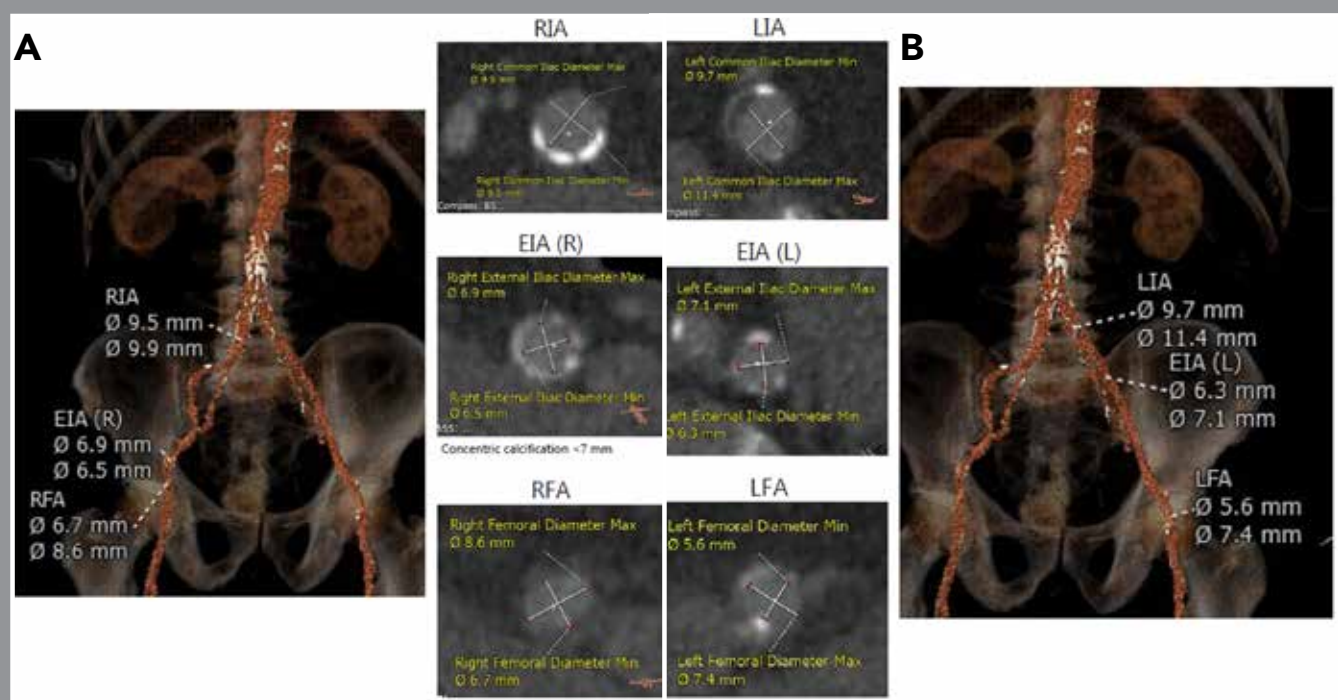

Figure 3: Evaluation of Luminal Diameter and Area

CT cross sectional images and 3D reconstruction of aorto-iliac arterial vasculature. Significant stenoses noted in bilateral aorto-iliofemoral systems, with a minimal luminal area of (A) 33.18 mm^2 (diameter 6.5 mm) in the right external iliac artery and (B) 24.6 mm^2 (diameter 5.6 mm) in the left femoral artery. Of note, measurements of the lumen must exclude calcium.

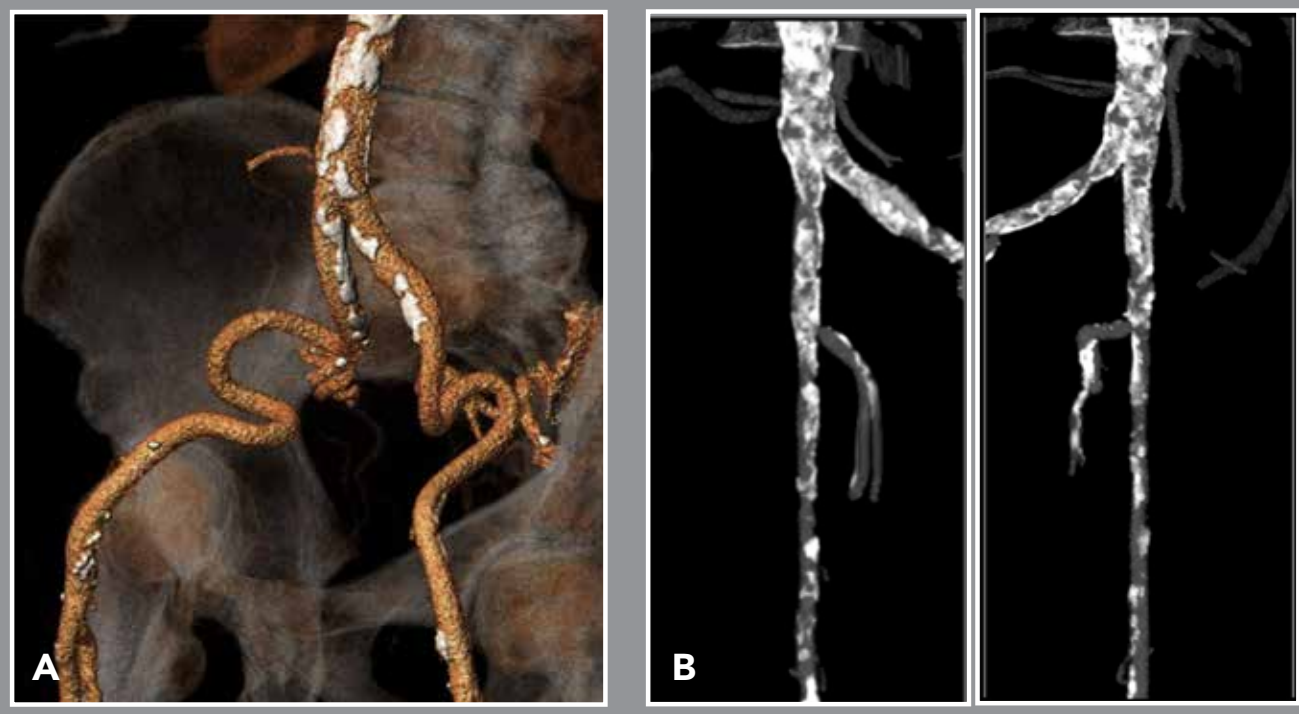

Figure 4: Tortuosity and Calcification

Computed tomography three-dimensional reconstruction of the aorto-iliofemoral arterial vasculature demonstrating (A) significant tortuosity and (B) severe calcification. Alternative site for large bore access is usually preferred in such cases.

Pro Tips

- √ Ultrasound should be used as an adjunct to fluoroscopy for femoral access in all patients, as it can identify the presence of calcific plaques at the time of the procedure and determine the ideal location for arteriotomy.
- √ CT offers improved resolution and assessment of proximal vasculature. It is instrumental in planning for structural heart procedures such as TAVR.
- √ The main variables to consider for the femoral approach are calcification (particularly circumferential), tortuosity, and minimal vessel size. These should be evaluated proximally into the aorta and considered as synergistic, with increased risk for complications in those with multiple unfavorable characteristics.
- √ Severely tortuous vessels with significant calcification, especially if circumferential, typically do not allow for passage of transcatheter aortic valve delivery systems.
- √ Alternative access strategies for TAVR include transapical, transcaval, transubclavian, transaortic, and transcarotid. These typically involve a cardiothoracic surgeon.
- √ The axillary artery is an alternative site for large bore access, particularly for mechanical support devices. Although smaller than the common femoral artery, it is less susceptible to atherosclerotic disease than the iliofemoral system (Figure 5).
- √ MRI currently has a limited role in vascular access strategies given its significant cost, time requirements, limited visualization of calcium, and potentially nephrotoxic contrast agents.

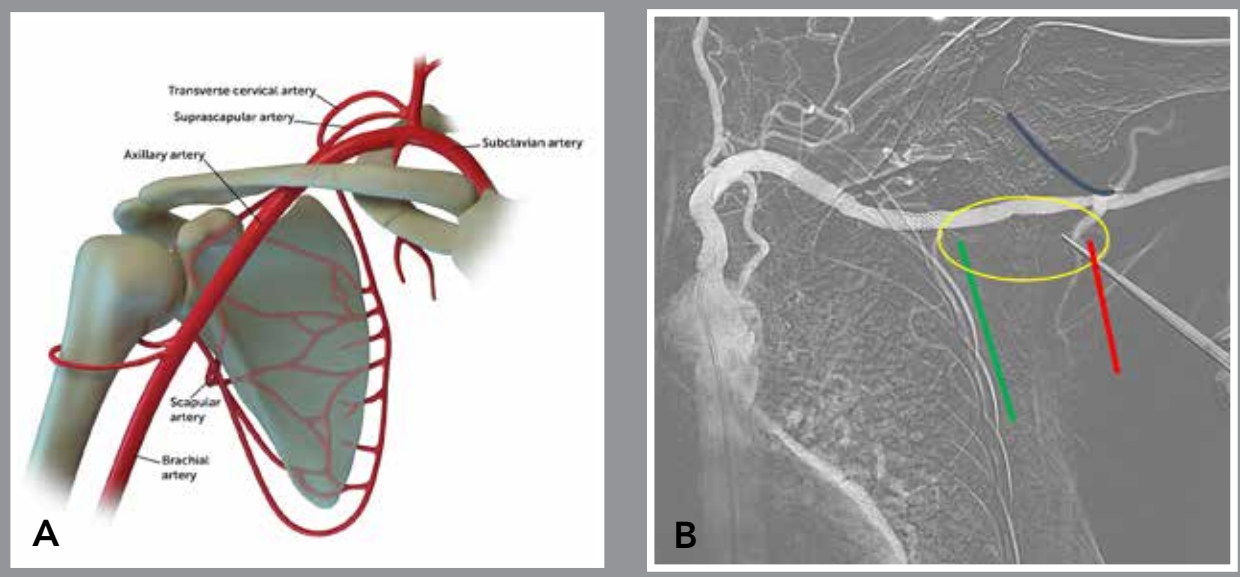

Figure 5: Axillary Artery Access for Mechanical Circulatory Support

(A) Right axillary artery from the anterior view. The subscapular artery aligns with the inferior border of the humeral head. Ideal axillary arterial access is obtained medial to the subscapular artery. (B) Angiogram of the left axillary artery outlining the ideal target zone for axillary access (yellow), between the subscapular artery (red), the lateral thoracic artery (green), in relation to the glenoid cavity (navy blue).

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Case Examples

Case 1

A patient evaluated for TAVR underwent CT of the chest/abdomen/pelvis revealing severe calcification and atherosclerotic disease of the mid to distal right CFA. Point of care ultrasound was used to identify a non-calcified site for arteriotomy, and femoral angiography confirmed sheath placement, which was proximal to the traditional entry point. As shown in Figure 6, angiography in many instances is suboptimal in the assessment of the severity of heavily calcified asymmetric plaques.

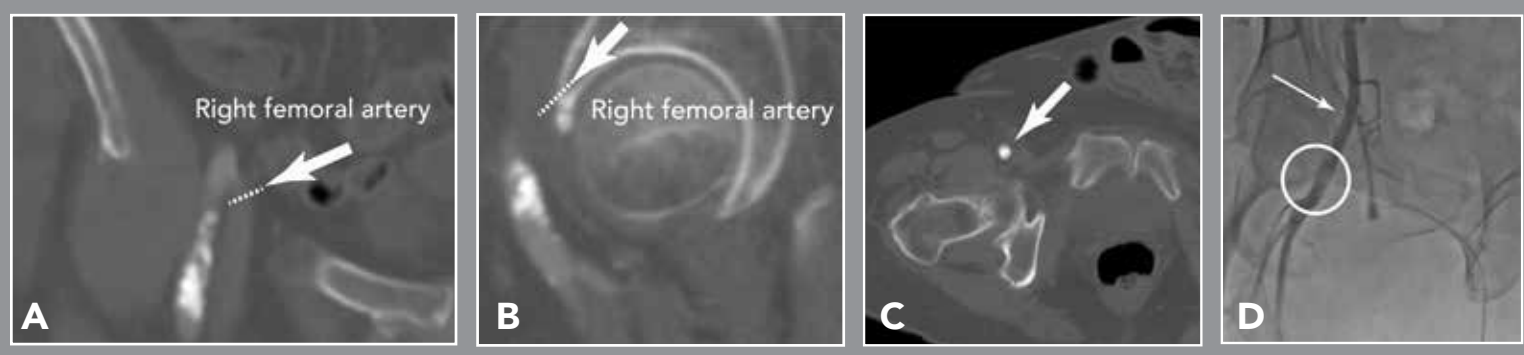

Figure 6: Case 1

(A) Coronal plane CT, (B) sagittal plane CT, (C) transverse plane CT, and (D) anterior-posterior (AP) angiographic view of the right common femoral artery, demonstrating dense calcification (thick arrows and circle), and arteriotomy proximal to this segment (thin arrow).

Case 2

A patient referred for TAVR underwent pre-procedure CT scan of the chest/abdomen/pelvis (Figure 7) that showed severe circumferential calcification of the abdominal aorta and critical stenosis of the ostial left common iliac artery and significant stenosis of the right common iliac artery. The patient was not eligible for transcaval access due to extensive calcification of the abdominal aorta. TAVR was performed via transaxillary access.

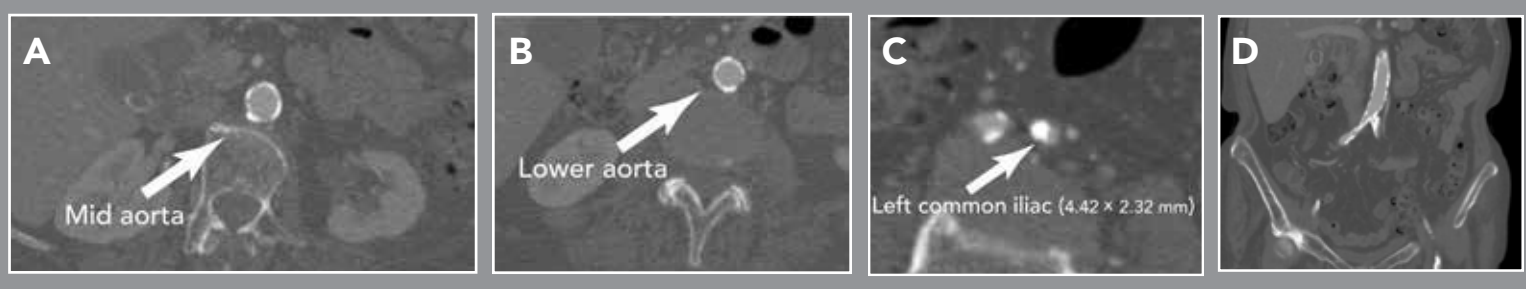

Figure 7: Case 2

(A) Mid aorta in transverse plane, (B) distal aorta in transverse plane, (C) left common iliac in transverse plane, and (D) distal aorta and aortic bifurcation in coronal plane.

Case 3

A patient referred for TAVR underwent CT scan of the chest/abdomen/pelvis that showed severe circumferential calcification in the aorta as well as severe calcification and stenosis of the left common iliac artery. Both subclavian arteries displayed minimal calcium, and the left subclavian artery was established as the preferred access site to accommodate the 14 Fr delivery system because of a larger luminal area than either the right subclavian or right femoral arteries. The left subclavian artery was accessed with surgical cutdown. Post-procedure angiography revealed a patent left subclavian artery with no vascular complications.

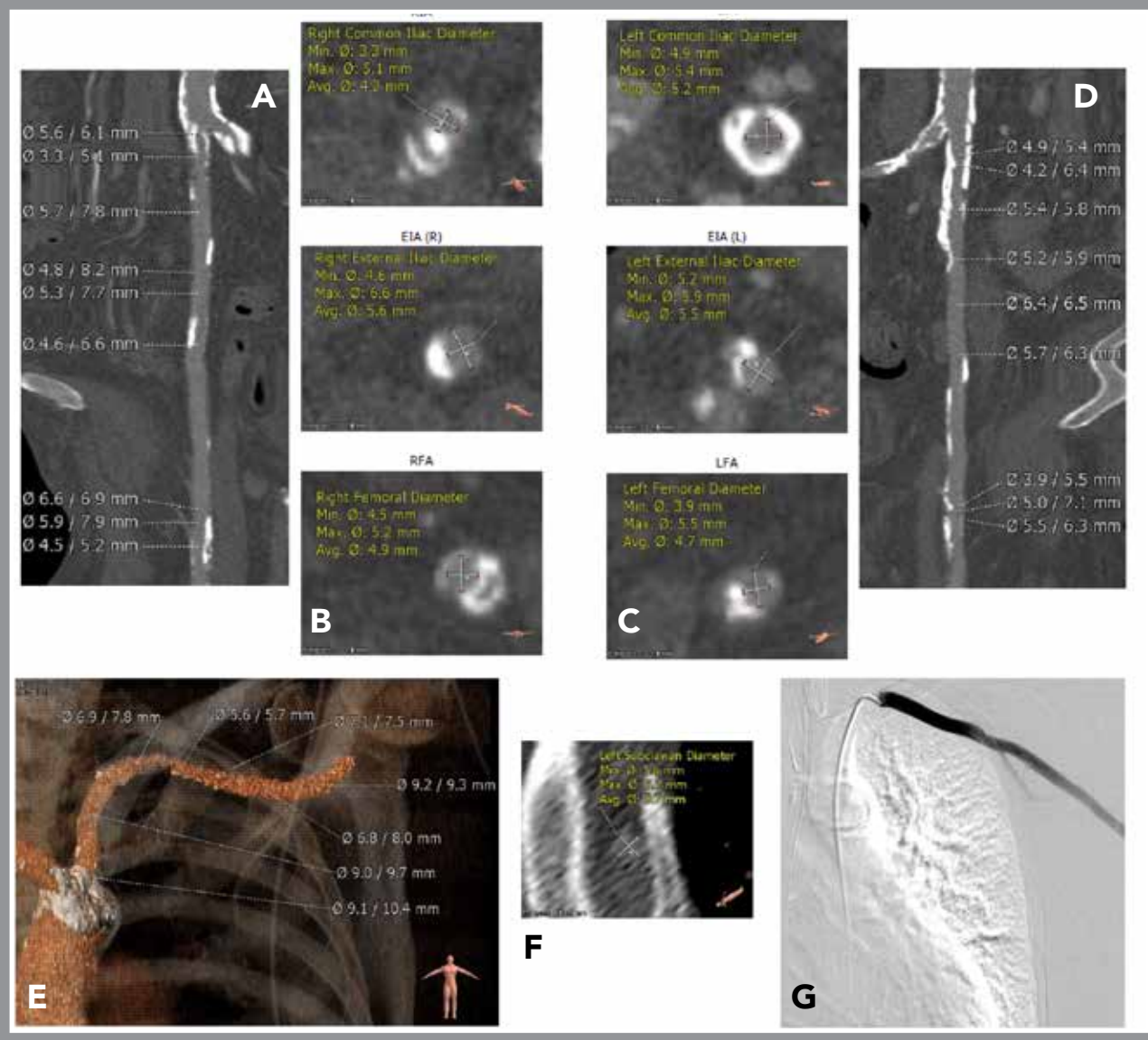

Figure 8: Case 3

(A) Coronal view of the right common iliac, external iliac, and common femoral arteries; (B) Cross-sectional minimum diameters of 3.3, 4.6, and 4.5 mm in the right common iliac, external iliac, and femoral arteries, respectively; (C) Cross-sectional minimum diameters of 4.9, 5.2, and 3.9 mm in the left common iliac, external iliac, and femoral arteries, respectively; (D) Coronal view of the left common iliac, external iliac, and common femoral arteries; (E) 3 dimensional reconstruction of the left subclavian artery, the chosen site for access. Minimum diameter of the left subclavian artery was 5.6 mm, as corroborated by cross sectional imaging (F). (G) Post-procedural angiogram of the left subclavian artery.

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CHAPTER 2 | SECTION THREE

Adjunctive Imaging for Large Bore Arterial Access: Use of CT, MRI, Fluoroscopic Roadmapping, and Ultrasound

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Overview

The reported incidence of percutaneous femoral arterial access site complications varies widely across the published literature, generally ranging between 2% to greater than 10%, with a rough proportionality noted between the size of the largest vascular introducer utilized and the likelihood of bleeding complications.[1] The occurrence of major bleeding (defined variably), major vascular complications, and transfusion requirement all independently and synergistically increase post-procedural morbidity and mortality.[1,2] Bleeding complications were assessed in a retrospective analysis of 17,672 patients from the Healthcare Cost and Utilization Project's National Inpatient Sample database who were recorded as having undergone transcatheter aortic valve replacement (TAVR, n = 3,223), endovascular aortic repair (EVAR, n = 12,633), or percutaneous left ventricular mechanical support (LV MCS, n = 1,816) over a 24 month period. In this patient population, bleeding complications (defined as any transfusion, any hemorrhage or hematoma, or the need for percutaneous or surgical intervention) occurred in 3,128 patients (17.7%, 1,984 men and 1,144 women, with a mean [SD] age of 75.6 [11.9] years).[3] Bleeding was associated with higher mortality (adjusted odds ratio, 2.70; 95% CI, 2.27–3.22; $P < .001$) and longer hospital stay (adjusted multiplicative difference, 2.14; 95% CI, 2.06–2.16; $P < .001$). In addition, total health care costs were increased on average by nearly $19,000 in patients with bleeding complications.[3]

A number of predictive models have been created to estimate the risk of complications following percutaneous vascular access. Major non-modifiable risk factors include advanced age, female gender, body weight (low or very high), chronic kidney disease, acute myocardial infarction, and shock. Modifiable risk factors include (but are not limited to) sheath size, use and intensity of periprocedural antiplatelets and anticoagulants, periprocedural hypertension, puncture, and hemostasis techniques.[2] Box 1 presents an expanded list of risk factors for bleeding and vascular complications.

Box 1: Patient Populations at High Risk for Bleeding and Vascular Complications

Pre-procedure patient characteristics

- Advanced age
- Female gender
- Body weight (low or very high)
- Chronic kidney disease
- Peripheral arterial disease
- Acute myocardial infarction
- Emergent cases
- Shock

Procedural characteristics

- Large bore arterial sheath
- Puncture at a non-compressible location (ie, above the inguinal ligament)
- Concomitant placement of a venous sheath
- Puncture without ultrasound guidance

Pharmacology and post-procedural variables

- Excessive parenteral anticoagulation
- Uncorrected coagulopathy or severe thrombocytopenia
- Uninterrupted oral anticoagulation
- IV glycoprotein IIb/IIIa receptor antagonists
- Heparin (vs. bivalirudin) anticoagulation
- Post-procedural hypertension
- Longer time to arterial sheath removal

Procedural variables of uncertain impact on complication risk

- Use of vascular closure devices
- Use of micropuncture vs. Seldinger needle for vessel entry
- “Dry closure” technique

While randomized controlled trial data to guide optimal puncture and hemostasis techniques are limited, a number of generally agreed upon suggested practices for large bore access currently exist including many of the imaging techniques discussed below. This discussion is limited to percutaneous femoral access. Alternative access site considerations (eg, percutaneous axillary access, transcaval approach) are discussed elsewhere.

Many patients requiring large bore arterial access will not have had prior vascular imaging performed and thus femoral access site selection may first be made on the basis of surface anatomic features such as the presence of scar tissue, vascular clips or hardware, known peripheral arterial disease or prior revascularization, compressibility of the vessel, or skin breakdown. Some consideration may be given for anatomic landmarks (maximal femoral pulsation, location of inguinal crease, estimated tissue depth, and locations of the anterosuperior iliac spine and pubic tubercle, representing the borders of the inguinal ligament), recognizing that anatomic landmarks when used alone, are often quite unreliable.[2] Initial fluoroscopy in straight anteroposterior (AP) imaging using a radio-opaque instrument such as a curved hemostat on the skin surface is typically performed to determine the puncture site necessary to ensure entry into the femoral artery over the middle third/medial third of the femoral head. Iterative fluoroscopy (repeated between the multiple steps of the access procedure) may also be performed to adjust needle trajectory. Next, ultrasound examination of the femoral access site in long- and short-axes, using a linear (7–12 MHz) or phased-array ultrasound probe, should be performed.[2,4] Key anatomic features to note include depth of the femoral artery at the chosen entry site (again with use of iterative fluoroscopy if surface landmarks are ambiguous), proximity and course of the common femoral vein, location of the arterial bifurcation and branches, and presence of atherosclerotic or calcific plaque on the anterior aspect of the vessel. (Figure 1)

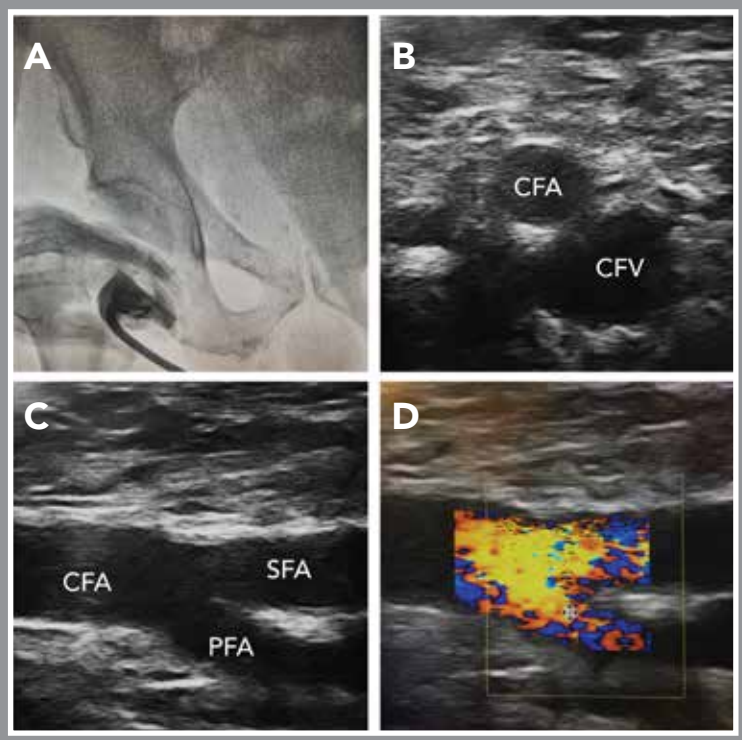

Figure 1: Femoral Vascular Ultrasound

Ultrasound performed using a Site~Rite® Vision ultrasound system (Bard Access Systems, Salt Lake City, UT) with a 128 element linear probe (4 cm depth, 65% gain, 2.3 cm focus). (A) Probe positioned at the lower margin of the femoral head in AP fluoroscopy. (B) Common femoral artery and vein (CFA, CFV) clearly seen in cross-section. (C) Longitudinal imaging performed by rotating the transducer 90 degrees identifies the CFA bifurcation in grayscale and (D) with color Doppler.

Toggling of the ultrasound probe (gentle cranial-caudal rocking of the probe with live, short-axis imaging) may help further refine the optimal entry point within the target zone. Ultrasound guidance for femoral access in the FAUST trial (Femoral Arterial Access with Ultrasound Trial) improved the time to vascular access and likelihood of first attempt access, decreased the likelihood of accidental venipuncture, and reduced vascular complications.[2] Micropuncture technique using a 21-gauge needle (0.018" guidewire) may also theoretically decrease the likelihood of vascular injury and bleeding over the use of a standard 18-gauge Seldinger needle as the small increment in needle diameter translates to a several-fold increase in blood loss through the residual hole in the event of multiple access attempts. If micropuncture is used, fluoroscopy may be required to avoid small side branches upon wire advancement. Once femoral access is gained, an ipsilateral oblique, 30-degree femoral angiogram should be performed through the micropuncture sheath to assess location of puncture and rule out vascular trauma, perforation, etc. prior to upsizing the introducer.

Imaging of the vasculature to be traversed by the large bore device is essential in patients who have known or suspected peripheral arterial disease (PAD) or significant arterial tortuosity, prior revascularization of the iliofemoral vessels, aortic pathology or hardware (surgical or endovascular repair of aortic aneurysms), or a history of femoral access complications. In elective large bore cases such as TAVR, multidetector CT angiography (CTA) with extensive image post-processing is an indispensable component of case planning. CTA can precisely and reproducibly define vascular caliber, tortuosity, stenoses, and presence/distribution of calcium. Post-processing of images may include 3-dimensional reconstruction with surface rendering to provide the operator a better perspective on catheter course in multiple views or stretched ("snake") views of the iliofemoral system to further define the distribution of calcium and protrusion of atheroma into the vascular lumen (Figure 2). If there is operator preference for, or greater institutional experience with magnetic resonance angiography (MRA), this modality may be reasonably substituted for CTA and used for case planning.

Figure 2: CTA of the Abdominal Aorta with Iliofemoral Runoff

CTA performed with 3-dimensional reconstruction as a requisite component of pre-TAVR planning. (A) Surface rendering of the aorto-iliofemoral system with cross-sectional images taken at multiple levels to evaluate vessel caliber and extent of calcium. (B) Stretched ("snake") view of the right and (C) left iliac arteries.

imaging is available, peripheral angiography of the large bore access site may be performed through a second, small-bore vascular access site (often required anyway for completion of the planned procedure). When feasible, transradial access (TRA) is attractive as this approach is far less likely to incur additional bleeding or vascular complication risk compared with a second femoral access point.[5] Moreover, TRA obviates the need to cross over the aortic bifurcation and the quality of peripheral imaging, inclusive of intravascular imaging (IVUS) if necessary, is more than adequate to guide concomitant large bore access. Digital subtraction angiography (DSA) of the periphery performed at the time of large bore access offers the added benefit of allowing for a fluoroscopic roadmap, providing real-time guidance for vessel entry and advancement of equipment through the iliofemoral vessels. At the conclusion of the procedure, during decannulation/sheath removal, a second point of access allows for greater control of the femoral site via inflation of an appropriately sized peripheral angioplasty balloon in the external iliac artery ("dry closure"), greatly reducing the blood pressure/flow into the femoral artery, and theoretically reducing the risk of uncontrolled bleeding. Box 2 summarizes key technical considerations relevant to case planning and execution.

Box 2: Key Technical Considerations for Case Planning and Execution

Pre-procedural

- Objectively assess patient risk for bleeding / vascular complications
- Address any bleeding risks ascribable to anticoagulation or coagulopathies
- Review medical records for prior access complications
- Review any available prior peripheral angiograms
- Review prior CTA or MRA data if available
- Consider obtaining CTA with appropriate gating and post-processing of images (especially in patients with known or suspected obstructive, large vessel PAD, prior peripheral revascularization, AAA with or without surgical repair /endovascular therapies, or anatomic challenges such as contracture, scoliosis, orthopedic issues that preclude optimal patient positioning at time of access / sheath removal, etc.)
- Consider ultrasound examination of proposed puncture site in advance of procedure

Procedural

- Integrate surface anatomical data, physical examination of planned access site, and bony landmarks
- Use iterative fluoroscopy during access
- Perform ultrasound-guided puncture
- Use micropuncture technique
- Perform ipsilateral oblique (30-degree) femoral angiography through micropuncture sheath
- Pre-close access site prior to upsizing sheath (when technically and anatomically feasible)
- Navigate difficult iliofemoral vasculature under fluoroscopic roadmapping

Sheath removal and post-procedural

- Use “dry closure” technique with live angiographic imaging (especially if vessel puncture was challenging or deployment of arteriotomy closure was inadequate or uncertain)
- Close large bore access over a guidewire (to retain control of the site and allow for deployment of additional vascular closure devices)
- Utilize post-closure DSA imaging from a second access site (if residual bleeding is suspected)
- Control hypertension

While the aforementioned techniques have not all been studied in unison, it is reasonable to believe that the value of any one strategy does not, in any way, diminish the usefulness of the others. Thus anatomic, fluoroscopic, ultrasound, and noninvasive imaging guidance techniques are best thought of as complementary strategies for ensuring safe and predictable large bore femoral arterial access.

Pro Tips

Most Important Aspects of Imaging Prior to and During Large Bore Arterial Access

√ Have a low threshold for obtaining CTA or MRA (renal function-permitting) of the aorta with iliofemoral runoff in elective large bore access cases where the patient has had:

- Revascularization/repair of the inflow (iliofemoral) vessels
- Hardware placed in the aorta (EVAR/TEVAR)
- Prior vascular access complications or difficulty with large bore procedures
- Any active clinical manifestations of obstructive, large vessel PAD

√ Use ultrasound guidance for arterial puncture and strongly consider employing micropuncture access technique.

√ Do not upsize the sheath until femoral angiography has been performed through the micropuncture (or small-bore) arterial sheath and confirms a satisfactory puncture.

√ In the setting of difficult vascular anatomy and if a second access point is available or can be safely obtained, use fluoroscopic mapping to guide vessel puncture and/or provide visualization during advancement of the large bore equipment.

√ Use "dry closure" technique with live angiographic imaging when technical aspects of access or vascular closure device deployment were uncertain or challenging.

Sample case

Large-bore access for MCS using CTA in setting of PAD and reconstructed abdominal aorta

Multidetector CTA of the thoracic and abdominal aorta was performed with iliofemoral runoff demonstrating a widely patent bifurcated EVAR graft with "wrapping" of the iliac limbs around one another and severe native vessel tortuosity distal to the graft limbs. The apparent cutoff of the proximal left common iliac seen in Figure 3 is an artifact of CT gating.

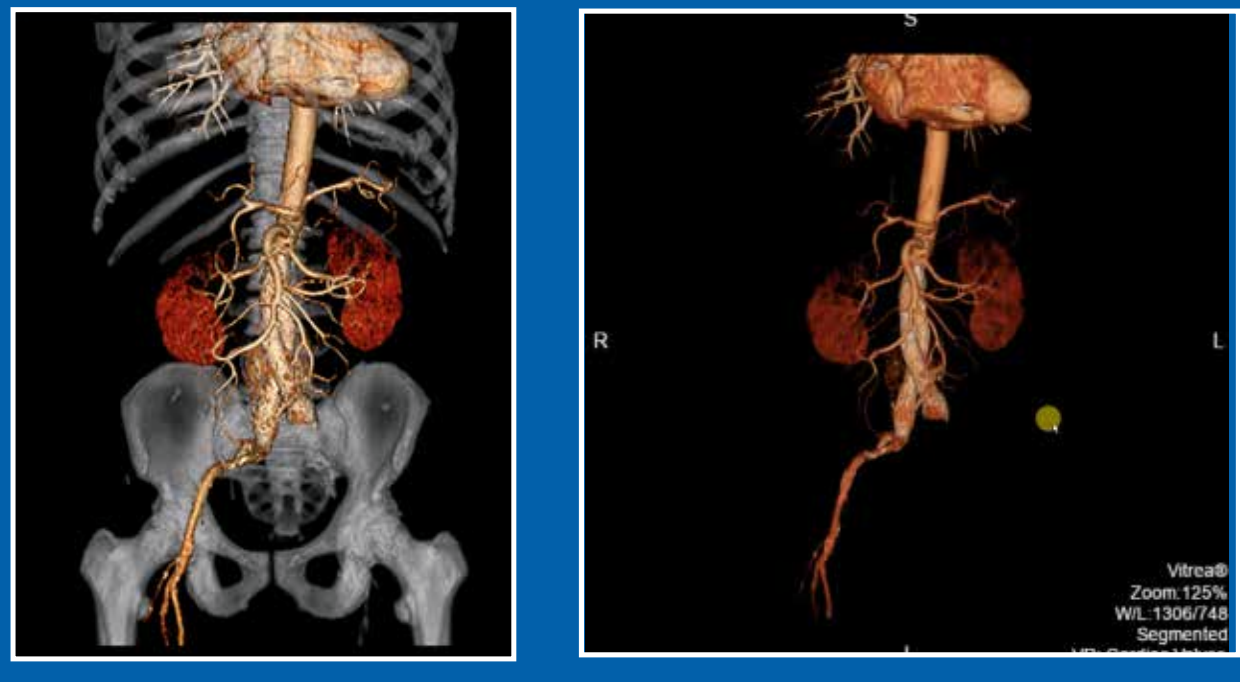

Figure 3: Multidetector CTA of Thoracic and Abdominal Aorta (video)

Known AAA with complicated EVAR performed in the past; PAD and tortuosity of native iliofemoral system distal to graft limbs

Figure 4A demonstrates ultrasound-guided micropuncture access of the right CFA with DSA imaging through the micropuncture sheath (Figure 4B) and advancement of an atraumatic, steerable (0.035" x 175 cm Wholey) guidewire using a fluoroscopic roadmap.

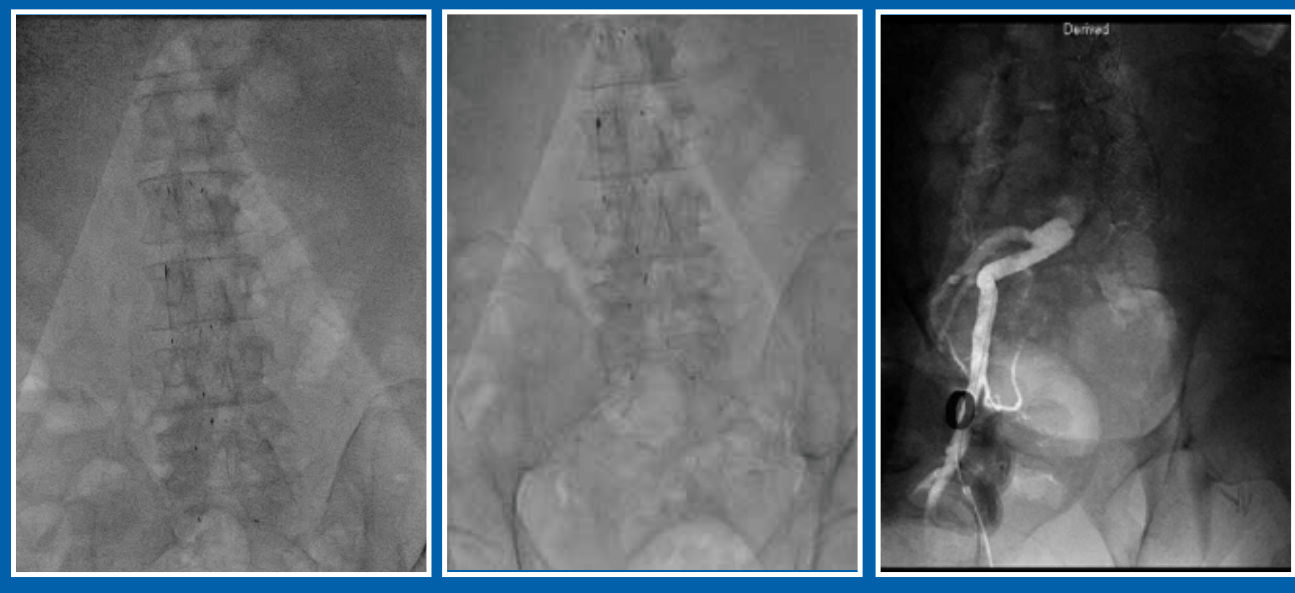

Figure 4: Imaging for Right Common Femoral Access (videos)

A similar ultrasound-guided approach was employed to gain access into the left common femoral system. Based on the tortuosity visualized in Figure 5B and the course of the wire in Figure 5C, the right limb was chosen for placement of the 14 Fr mechanical circulatory support sheath.

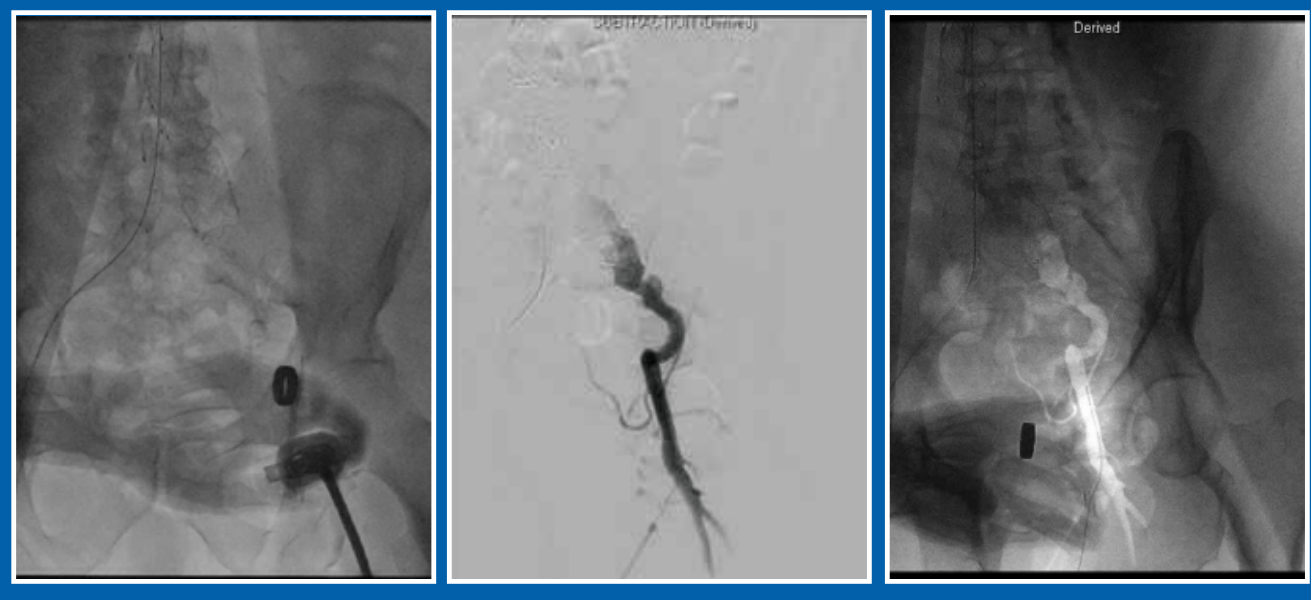

Figure 5: Imaging for Left Common Femoral Access (videos)

Serial dilations of the tissue track and vasculature performed with advancement of 10 Fr, 12 Fr, and 14 Fr x 30 cm dilators (Figures 6A, B, and C respectively) through the right iliac limb of the endovascular graft under direct fluoroscopic visualization.

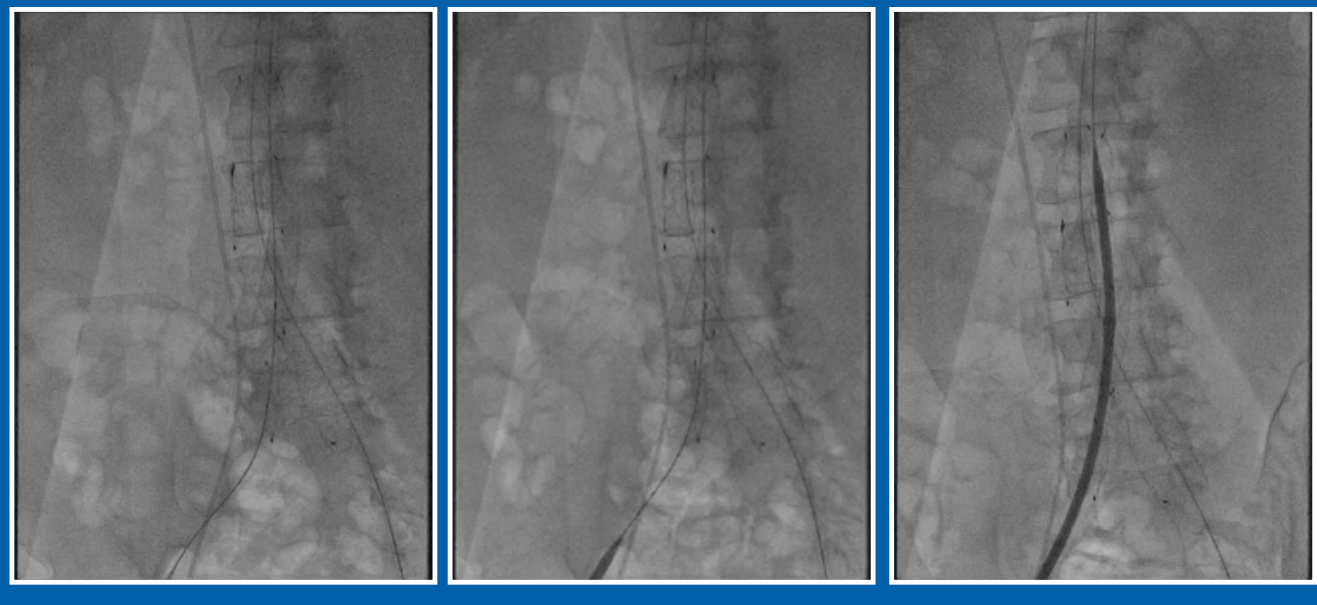

Figure 6: Imaging for Advancement of Dilators (videos)

Advancement of 14 Fr sheathed Abbott (previously Thoratek) PHP LV assist device into the left ventricle (Figure 7A). The PHP was unsheathed and opened to 24 Fr across the aortic valve prior to a high-risk PCI.

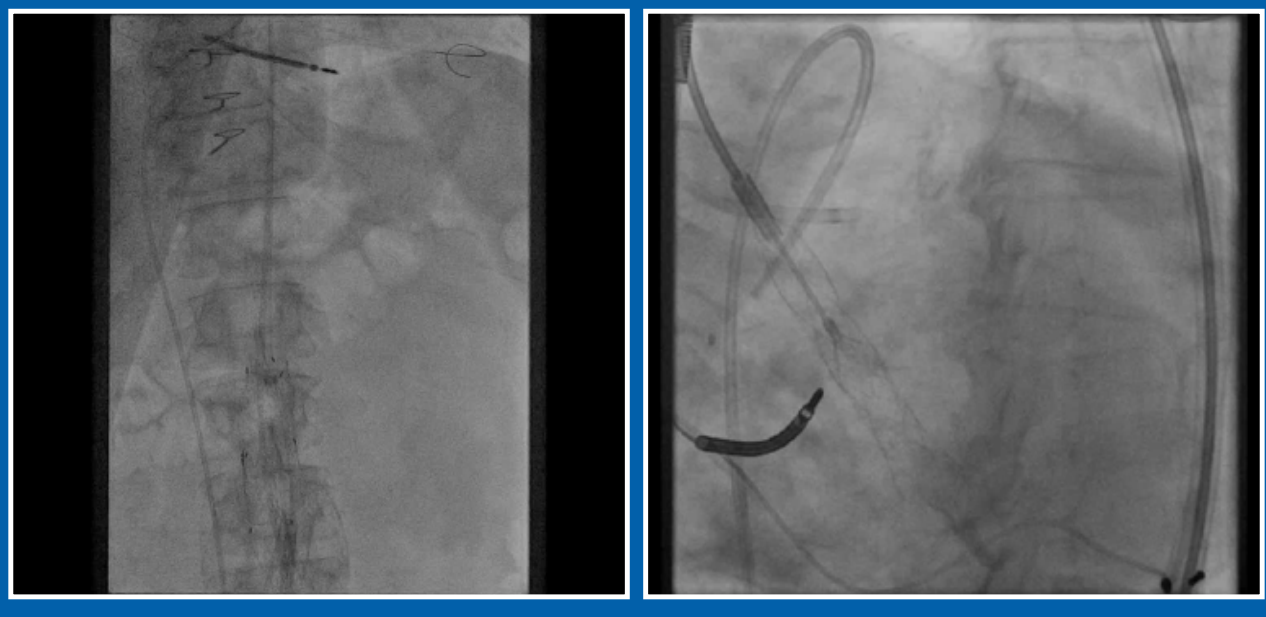

Figure 7: Imaging for Advancement of Abbott PHP LV Assist Device (videos)

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CHAPTER 2 | SECTION FOUR

Brachial Artery Access: Applications and Techniques

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Overview

Brachial artery (BA) access is a well-established option for performing endovascular procedures. Historically, BA access was commonly performed for coronary angiography and interventions using surgical cutdown and direct arterial puncture. Recent advancements in procedural equipment and techniques have led to increased utilization of radial and ulnar arteries for coronary angiography and intervention instead of BA. BA access, however, remains an important option for procedures requiring a larger access vessel. Its use has been described for hemodynamic support device placement, endovascular aneurysm repair (EVAR), and both visceral and peripheral endovascular procedures with the majority of operators performing these procedures via percutaneous BA access.

Anatomic consideration

The brachial artery is a continuation of the axillary artery beyond the inferior margin of the teres minor muscle. Proximally, the brachial artery runs in the medial brachial fascial compartment along with brachial veins and the median and ulnar nerves. Hemorrhage in this contained space can quickly cause nerve compression symptoms. Distally, the BA tends to separate away from the nerves and veins before dividing into ulnar and radial arteries in the distal part of antecubital fossa. (Figure 1) This lower portion of the BA is ideal for vascular access due to the lack of the overlying nerve bundle and the ability to compress the artery against the underlying medial epicondyle of the humerus. Unless specified, the subsequent discussion pertains to percutaneous low BA access (Figure 2).

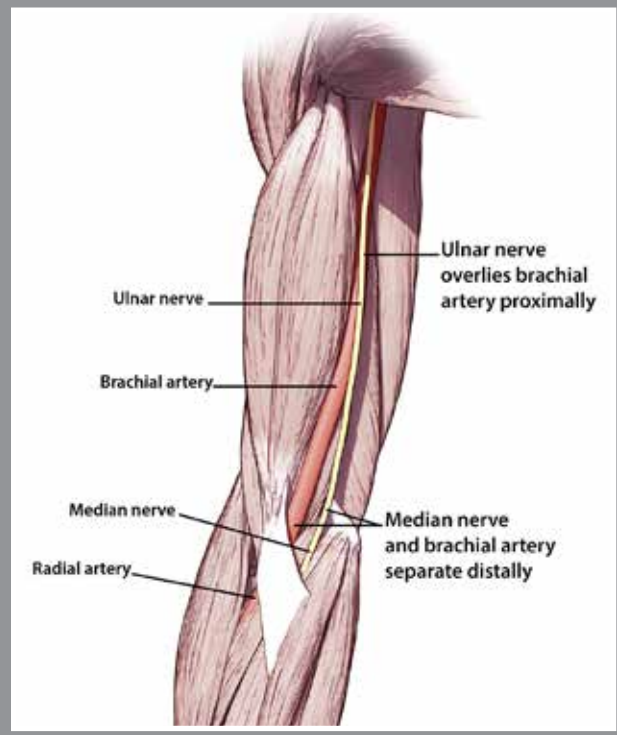

Figure 1: Relationship of Brachial Artery to Median Nerve in Upper Arm

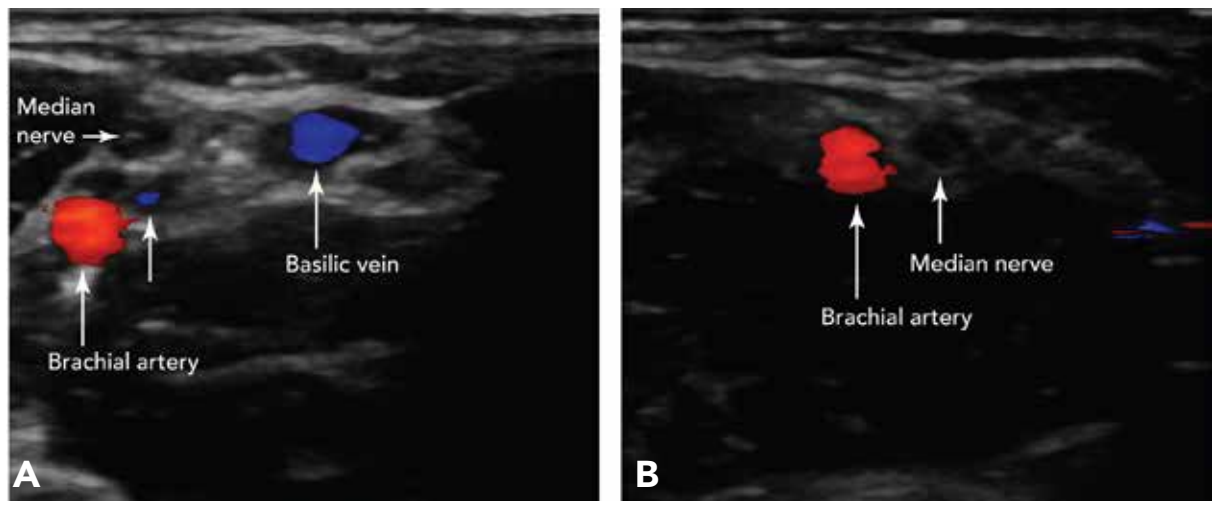

Figure 2: Brachial Artery Ultrasound with Color Doppler

(A) Percutaneous access should be avoided at the proximal portion of the brachial artery in the medial brachial fascial compartment as the median nerve is anterior/superficial to the brachial artery. (B) Ideal location of puncture is the lower portion of the brachial artery with the median nerve medial to the brachial artery.

Size

The size of the brachial artery is dependent on factors such as gender, race, site of assessment (lower vs higher portion of brachial artery), physiologic state, and underlying disease conditions. By ultrasound measurement, the average BA diameter in a predominantly Caucasian study population was reported to be 3.69 + 0.57 mm (range 2.19–6.10 mm) in women and 4.95 + 0.64 mm (range 2.63–7.96 mm) in men.[1] Thus, in some individuals the BA may be able to accommodate sheath sizes as large as 14 Fr, while in others, placement of sheaths larger than 6 Fr would be problematic.

Areas of applications

Brachial arterial access is used for both coronary as well as noncoronary endovascular interventions in the following situations:

- Radial or ulnar access is not sufficiently large or does not allow access from catheter length standpoint
- Femoral access is unavailable or poses substantial risks
- Secondary access point is needed

The most common circumstances in which BA access may be used include severe peripheral arterial disease involving aorto-iliac occlusion or stenosis, presence of aorto-femoral grafts, radial or ulnar hypoplasia or occlusion, intervention on visceral arteries with caudal orientation, or upper extremity access for limbs of thoracic aortic endografts. BA access has been used for placement of intra-aortic balloon pump (IABP) or Impella® catheter for hemodynamic support and for performing transcatheter aortic valve replacement in carefully selected patients with severe PAD in aorto-iliac segments and/or prior aorto-femoral bypasses.

Complications

Brachial access has been associated with an increased risk of complications when compared to radial, ulnar, or femoral access. The risk of major complications was reported to be about 6.5% to 9% with BA access in patients undergoing peripheral interventions/angiography.[2,3] The most common complications related to BA access include local hematoma, pseudoaneurysm, transient numbness due to nerve injury, compartment syndrome, and distal limb ischemia due to thrombosis, embolization, or stenosis at the site of arteriotomy.[2,3,4] Rates of complications and predictors of complications are listed in Table 1.

Table 1: Rates and Predictors of Complications for BA Access

Study	Type of study	Types of procedures performed	Access site complications from brachial access	Access site complications from alternative access	Predictors of complication
Kret et al. (n=732)	Multicenter database, retrospective analysis	Intervention (100%)	Overall 9%; hematoma or pseudoaneurysm 7.2%; thrombotic or stenotic occlusion 2.1%	Overall 3.3%; hematoma or pseudoaneurysm 3%; thrombotic or stenotic occlusion 0.4%	Access sheath >5 Fr, female gender, percutaneous access
Alvarez-Tostado et al. (n=289)	Single center experience, retrospective	Intervention (73%) and diagnostic (27%)	Overall 6.5%; hematoma 1%; thrombosis 2.4%; pseudoaneurysm 3.7%	N/A	Female gender, sheath >10 cm length
Treitl et al. (n=150)	Single center experience, prospective	Intervention (100%)	Overall 14%; thrombotic occlusion 2%; median nerve palsy 0.7%; pseudoaneurysm 2%; local hematoma 10%	N/A	N/A

Technique and procedural considerations

Determining which side to access

The decision whether to utilize the left or right brachial artery for access should be based on:

- Specific procedure to be performed
- Relative size of each artery
- Extent of disease in the proximal axillary and subclavian vessels
- Aortic arch anatomy
- Presence of an internal mammary artery graft that could potentially be compromised

Proximal upper extremity (eg, subclavian) arterial interventions should be performed via ipsilateral BA access with retrograde device delivery. Contralateral BA access may be helpful for contrast injection, but should generally be avoided for therapeutic interventions. The right BA is preferred over the left BA for right internal carotid interventions. For visceral and lower extremity endovascular procedures, left BA access is generally preferred (especially in tall patients and those with long arms) as it provides approximately 10 cm of additional working catheter length. Right BA access should be avoided in patients with type III aortic arch anatomy. For intra-aortic balloon pump (IABP) placement, left BA access is preferred and the distance from the BA to the subclavian artery can be measured using a marker pigtail. Similarly, left BA access is more favorable for placement of Impella 2.5® and Impella CP® catheters due to conformation of the catheter with cardiac, ascending aorta, and aortic arch anatomy.

How to perform access

The size of the vessel should be assessed with ultrasound prior to prepping and draping. Visualization can be improved by warming the hand and forearm as well as dilating the artery on the ipsilateral arm with transient inflation of a blood pressure cuff to supra-systolic pressure. High BA access increases the risk of complications and should only be considered when the lower BA is too small. Low brachial access is best obtained with the arm extended 75–90 degrees and fully supported by an armboard in supine position. The location of low BA puncture should be 2–5 cm above the elbow crease and may be identified using a combination of fluoroscopy, anatomical landmarks, and ultrasound. The ideal puncture site for low BA access coincides with the part of the BA that traverses in front of the medial epicondyle (Figure 3).

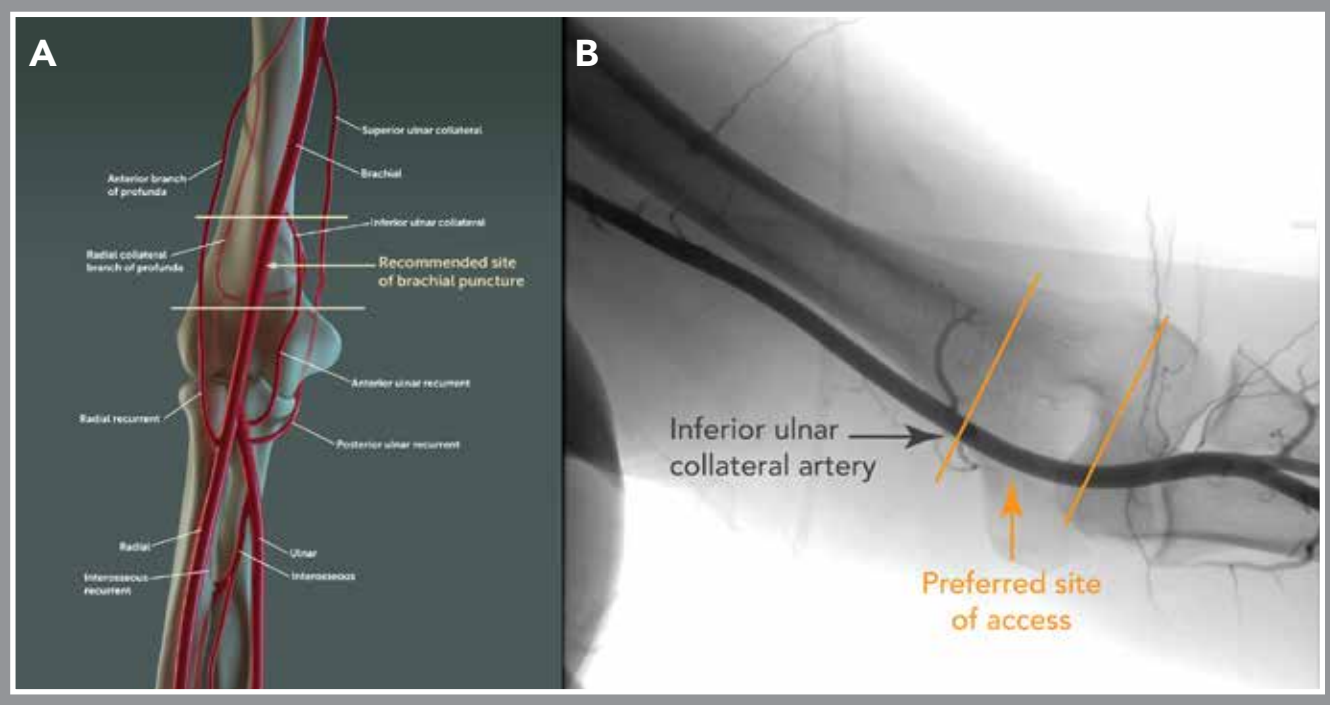

Figure 3: Ideal Location of Percutaneous Brachial Artery Access

Ideal location is below the origin of inferior ulnar collateral artery and anterior to medial epicondyle of distal humerus (A) as shown angiographically (B).

Ultrasound guided access has not been shown to reduce the risk of complications,[2] but may help to avoid double wall puncture and to confirm the absence of overlying median nerve (as shown in Figure 2B). If preceding angiography is performed and roadmapping is available, access should be attained at or below the origin of the inferior ulnar collateral branch (allows for collateral flow to the forearm in case of acute occlusion) and above the radio-humeral joint over the medial epicondyle. Single anterior wall puncture using a micropuncture system is recommended. After placing the micropuncture wire and sheath, baseline angiography should be performed to assess vessel size and sheath location. Intra-arterial nitroglycerin (100–300 mcg) or verapamil (2–5 mg) is recommended to prevent and/or treat vasospasm. Anticoagulation to prevent thrombotic complications should be prompt after sheath placement and therapeutic targets should be monitored closely. Monitoring for distal limb ischemia is recommended and can be performed using continuous pulse oximetry waveform during and after sheath removal.

Equipment considerations

While performing lower extremity interventions from a BA approach, using long sheaths (90–110 cm Flexor® Shuttle® Guiding Sheath) allows for selective injection of lower extremity. When performing infrapopliteal interventions, availability of long (>150 cm) balloon catheters (eg, Bard ULTRAVERSE® RX PTA Dilatation Catheters) is necessary.

Large sheath placement is a predictor of BA site complications and should be avoided when feasible. Using sheathless guides (SheathLess™ Eaucath or SheathLessPV by Asahi Intecc) for peripheral interventions may reduce the need for upsizing arteriotomies and could potentially limit complications. For IABP placement, sheathless insertion may be considered for small brachial arteries, particularly when the IABP is expected to be indwelling for long duration. If BA access is considered for placement of an Impella® device, quick downsizing to inline sheath should be considered. Surgical cutdown is generally preferred when using the BA for large bore access, but preclosure with ProGlide® (Abbott Vascular) may be considered.

Hemostasis and complication management

Manual compression is the gold standard to achieve hemostasis after sheath removal. Typically 20–30 minutes of gentle pressure is required for sheaths <8 Fr. Vascular closure devices have been used off-label for brachial hemostasis. Success has been reported with StarClose and Perclose devices, Angio-Seal™, EXOSEAL®, and MYNXGRIP® but complication rates are not decreased compared to manual closure.[5] For devices with external collagen plugs, tumescent anesthesia with lidocaine may be considered for stability of the plug. Patients should be monitored for hematoma, limb and hand ischemia, paresthesia, and motor weakness. Neurological symptoms may occur up to 2 weeks after the procedure and may not be preceded or accompanied by visible hematoma or arterial compression, but should be promptly addressed.

Acute occlusion and pseudoaneurysm are the most serious access site complications. Acute occlusion of the brachial artery may require endovascular thrombectomy from antegrade or retrograde approach, or open surgery. Ultrasound guided pressure and thrombin injection may be considered to manage pseudoaneurysm, but a significant proportion of cases may require surgical repair.[3] Balloons for internal tamponade should be available for bailout when hemostasis cannot be achieved otherwise and may be delivered in retrograde fashion from radial access. Dissections are best managed by prolonged balloon inflations rather than stents or stent grafts.

Pro Tips

- √ Large sheath size and female gender are best predictors of complications.
- √ Use smallest sheaths and catheters. Consider using sheathless guides.
- √ Use ultrasound to assess vessel size upfront prior to access, particularly in women.
- √ Consider flow mediated dilatation, forearm warming, or sublingual nitroglycerin to dilate the vessel prior to access.
- √ Low brachial access is recommended whenever feasible. When additional access is available, consider angiography with roadmap and puncture just below inferior ulnar collateral branch (allows for collateral flow in case of acute occlusion).
- √ Anticoagulate promptly after sheath placement; consider pulse oximetry waveform for hand ischemia monitoring.
- √ Marker pigtail may be considered to assess distance to left subclavian artery ostium prior to placement of IABP. Consider sheathless IABP placement in patients with small brachial arteries.
- √ Brachial access offers about 25 cm of additional reach compared to ulnar or radial access; left brachial access offers about 10–15 cm of additional reach compared to the right brachial artery for lower extremity procedures.
- √ For lower SFA, popliteal, and infrapopliteal interventions, 90–110 cm sheaths, >135 cm stent delivery systems, and >150 cm balloon delivery systems should be available.
- √ Numbness or motor weakness should be quickly addressed with evaluation for hematoma and prompt decompression if needed.

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CHAPTER 2 | SECTION FIVE

Percutaneous Axillary Artery Access Best Practices

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Overview

Growth in percutaneous transcatheter technology is driving a demand for expanded large bore access options beyond the femoral arteries. Axillary arterial access is typically considered for structural heart interventions or delivery of temporary mechanical circulatory support in situations involving:

- Femoral-iliac arterial vascular disease
- Morbid obesity or other anatomical considerations favoring axillary over femoral access
- Desired reduction in the bedrest time required by femoral access and associated morbidity

Surgical graft implantation is the historical standard for axillary access, but a percutaneous axillary approach offers advantages in urgent scenarios and may carry less morbidity than general anesthesia and surgery. In contrast to long-standing beliefs that the axillary artery is not compressible, the mid-axillary portion is compressible against the second rib. This was shown using cadaveric models[1] and has been borne out in clinical experience. While there was early speculation that the less muscular media layer of the axillary artery would result in more complications than femoral access, rates of arterial laceration or disarticulation have not increased with growing experience, demonstrating safe utility of large-bore access.[2]

Strategic planning

When assessing the suitability of the axillary artery for access, it is important to assess axillary artery caliber (ideally ≥ 6.0 mm in diameter), tortuosity, and calcification or atheroma at the implantation site.[3,4] For transcatheter aortic valve replacement, these anatomic features are evaluated using pre-procedure CT angiography. In urgent cases, such as temporary mechanical circulatory support device implantation, ultrasound and peripheral angiography are used, occasionally substituting intravascular ultrasound when contrast must be limited. Collateralization around the axillary artery may be sufficient for short-term use in cases with borderline vessel size, and vessels size should be interpreted remembering that the vasoconstricted peripheral arterial tree underestimates the ability of vessels to accommodate large bore access in the setting of cardiogenic shock. The decision of which axillary artery to choose for access is based on patient handedness, aortic arch type with attention to retroflexion of the innominate or left subclavian artery, and avoiding puncture through pacemaker or ICD pockets.

Equipment and procedural considerations

1. Perform peripheral angiography via femoral access. Advance a 0.018 inch wire across the respective axillary artery. This wire serves as a marker for fluoroscopic correlation with the course of the artery (see Figure 1). Map the course on the skin surface to orient the operator to the cranial-medial trajectory of the vessel, typically toward the earlobe.

2. Identify the proximal segment of the axillary artery on ultrasound with respect to the subclavian vein and, often, the brachial plexus. While you can enter the axillary artery in its lateral segment via the armpit, we do not recommend this location due to difficulty with manual compression hemostasis and patient comfort. Liberal use of a local anesthetic is needed as this area is well-innervated.

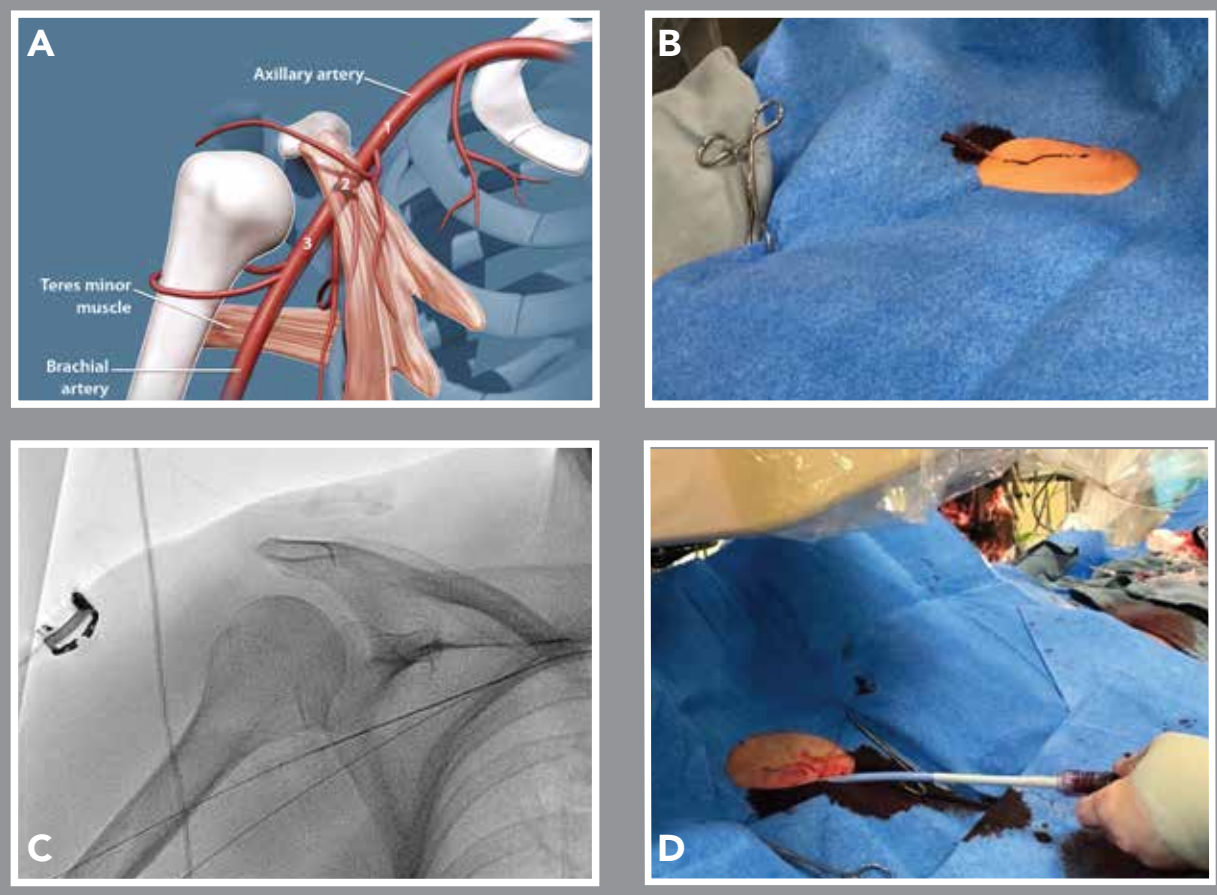

Figure 1: Axillary Access

(A) The axillary artery originates as the subclavian artery crosses lateral to the first rib and terminates as the brachial artery as it crosses the inferior border of teres minor muscle attachment to the humerus. Access is obtained in the proximal segment to ensure compressibility against the 2nd rib and to avoid many of the branches. (B & C) Micropuncture access is obtained at a shallow angle. The fluoroscopic landmarks from the indwelling wire down the axillary artery are used to mark the skin, aiming puncture just lateral to the 2nd rib. (D) Note shallow angle of sheath entry of the large bore sheath, which remains protruding during the procedure.

3. Identify the thoracoacromial branch near the access point to avoid transection. As shown in Figure 1, use ultrasound-guided micropuncture technique at a shallow angle (approximately 30 degrees) with entry near the lateral border of the 2nd rib. A shallow angle of entry is critical to allow for sheath delivery into the artery as it courses between the clavicle and the second rib. A steep angle results in kinking of the sheath and is a common reason for failure with axillary access. The artery is usually 'pre-closed' with Perclose suture devices deployed at minimal angulation. Contraindications to closure devices do not differ from femoral access. This step may be deferred in preference for late closure at the time of device removal, or a single suture deployed pre-procedure with a second deployed at the time of device explant.
4. Place a 10 cm 8 Fr sheath for ease of delivering equipment intravascularly before upsizing to the large delivery sheath. Advance the large-bore sheath no further than the mid subclavian to avoid trauma crossing the subclavian flexure. Note that even when the sheath is advanced into the aorta for procedures such as percutaneous valve delivery in TAVR, the sheath remains protruding.
5. The existing 0.018 inch wire may be used to deliver a compliant balloon sized to assist with hemostasis as needed, although this is usually unnecessary for sheath exchanges.
6. At the time of explanation, tighten the Perclose sutures in the usual fashion and repeat peripheral angiography to ensure normal flow and the absence of significant stenosis from the closure device, significant thrombus, or bleeding.

Prolonged angioplasty is usually adequate treatment, but in cases of long-dwelling ventricular assist devices, thrombus burden may require thrombectomy. Covered stents are prone to deformation against the bony structures in this region and are thus reserved for severe or refractory cases of bleeding.

Pro Tips

√ Maintain a shallow angle of entry into the axillary artery with micropuncture access. The wire may navigate a steep angle crossing between the clavicle and the 2nd rib but a sheath will kink; this is a common reason for failure.

√ Set up a table as an extension from the left arm and have a second operator or technician assist in advancing catheters or stabilizing the partially advanced sheath. Ensure monitors are easily visible so that you can comfortably view fluoroscopic images. Monitors are typically placed on the patient's contralateral side (as normal) or at the ipsilateral ear facing the feet (Figure 2).

√ Use a second access point to advance a 0.018 inch wire across the axillary artery to use as a marker during access and for balloon-assisted hemostasis in the event of bleeding complications.

√ Apply manual pressure hemostasis against the second rib. This is effective and sufficient for sheath exchanges, and while not ideal, is adequate for sheath removal in certain circumstances.

Figure 2: Room Setup

Proper room setup is imperative for facile left axillary arterial device implantation.

Case examples

Case 1: Bleeding after failed closure—balloon-assisted tamponade compression after failed Perclose

Following TAVR, extravasation is noted on post-procedure angiogram after Perclose deployment and wire removal (Figure 3A, video). Bleeding is controlled following balloon occlusion for 5 minutes and half-reversal of heparin (Figure 3B). A covered stent is not required.

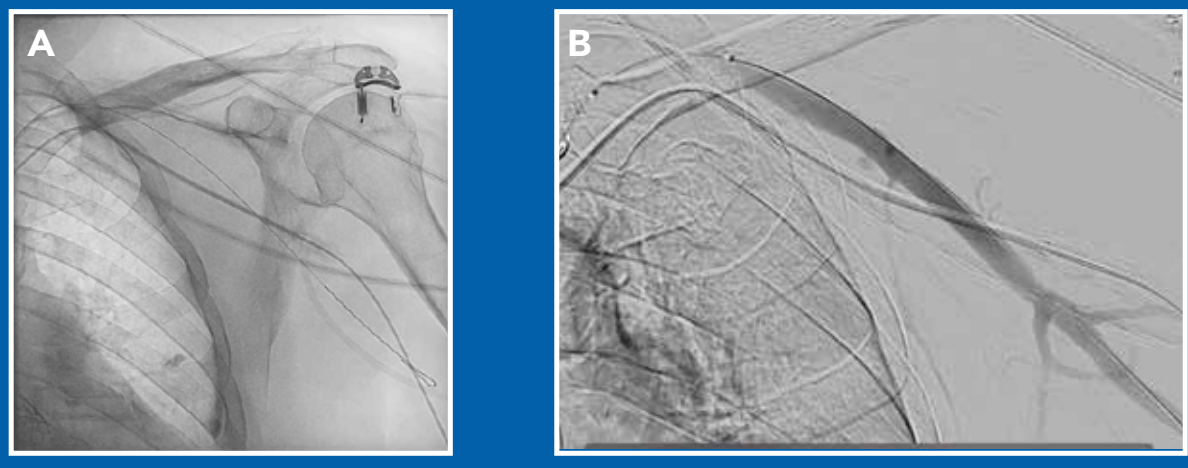

Figure 3: Bleeding and Balloon-assisted Tamponade Compression After Failed Perclose (video)

Case 2: Obstructive thrombus—collateralization and atherectomy

Impella has remained in place for over 14 days, with laminar thrombus noted on pre-explant angiography. Occlusive thrombus post-explantation, though flow is maintained via collaterals (Figure 4A, video). Following thrombectomy, flow is improved (Figure 4B) and managed with intravenous heparin drip for 48 hours.

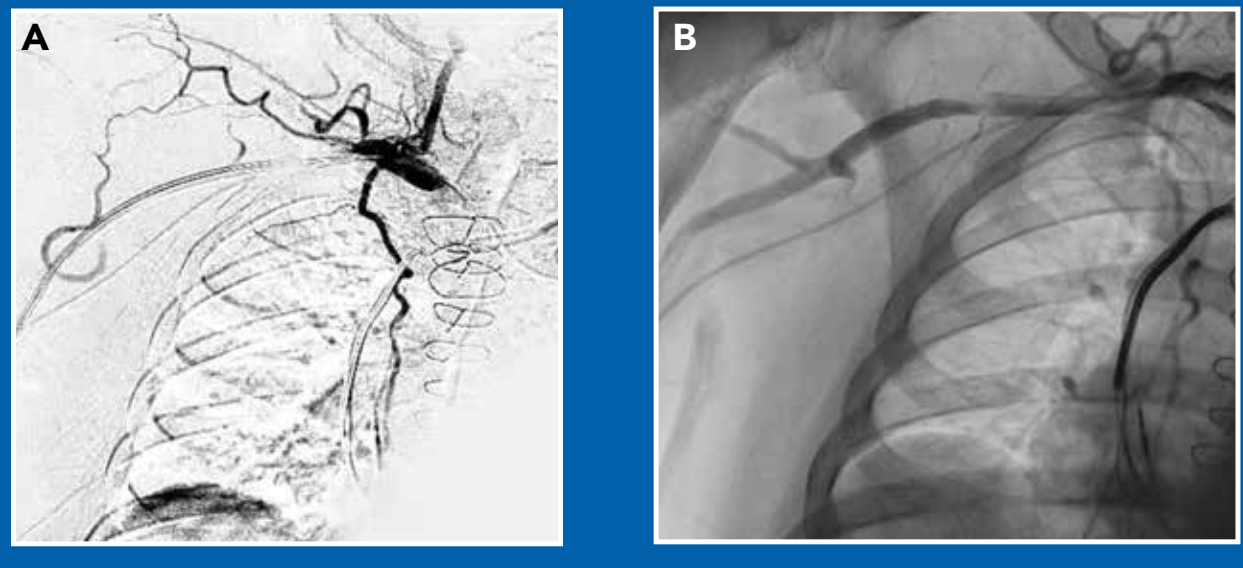

Figure 4: Obstructive Thrombus, Collateralization, and Atherectomy (video)

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CHAPTER 2 | SECTION SIX

Large Bore Access for Transradial Procedures

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Overview

The majority of radial interventions are performed using a 6 French (Fr) radial sheath and 6 Fr guiding catheters. With the advent of guide extensions [GuideLiner™ (Vascular Solutions Inc.), Guidezilla™ (Boston Scientific)], significant support and fit can be achieved, allowing stent delivery through highly tortuous, calcified, and complex anatomy using 6 Fr systems. Prior to this, achieving higher degrees of support would have required 8 Fr sheaths and aggressive guiding catheter shapes. Atherectomy using rotational atherectomy with up to a 1.5 mm burr, orbital atherectomy, kissing balloons, and in some cases even kissing stents are feasible using 6 Fr guides. Yet, with changing patterns of disease presenting for PCI—including surgical turndowns, severe complex anatomy, 2-stent bifurcation approaches, and chronic total occlusions—there remains a need for 7 Fr and 8 Fr systems for successful PCI.

Contemporary indications for 7 Fr or 8 Fr PCI include rotational atherectomy requiring 1.75 mm and 2 mm burrs, crush and simultaneous 2-stent bifurcation approaches, and chronic total occlusions requiring simultaneous delivery of multiple devices. In this section we describe methods to overcome the limitations of radial artery to sheath size mismatch, thereby allowing 7 Fr and 8 Fr PCI to be accomplished via transradial access. We discuss both-sheath-based and sheathless approaches.

Sheath-based systems

Thin-walled sheaths

The outer diameter (OD) of standard radial sheaths is necessarily larger than the OD of the corresponding guiding catheter. As illustrated in Figure 1, reducing the thickness of the sheath wall enables a greater lumen internal diameter (ID). This was the concept that allowed delivery of 7 Fr guides through sheaths that carried an OD closer to that of a standard 6 Fr sheath. The "7 Fr-in-6" Terumo Glidesheath Slender®, by virtue of thinner walls compared with its standard 6 Fr counterpart, accommodates a 7 Fr guide. However, the 2.79 mm OD of the slender sheath is still larger than the standard 6 Fr sheath made by the same company (2.62 mm) while being significantly smaller than the standard 7 Fr sheath (2.95 mm). The risk of kinking and distortion is higher with the thin-walled sheaths; therefore, these sheaths need to be handled with care during initial insertion of the dilator into the sheath as well as during access and catheter exchange. The femoral artery is typically deeper than the radial artery and a thick sheath is necessary to prevent kinking while traversing a depth tissue that can vary significantly based on the patient's base metabolic index. The relative shallowness of the radial artery and the angle of entry allow for the use of thinner walled sheaths with a lower risk of kinking.

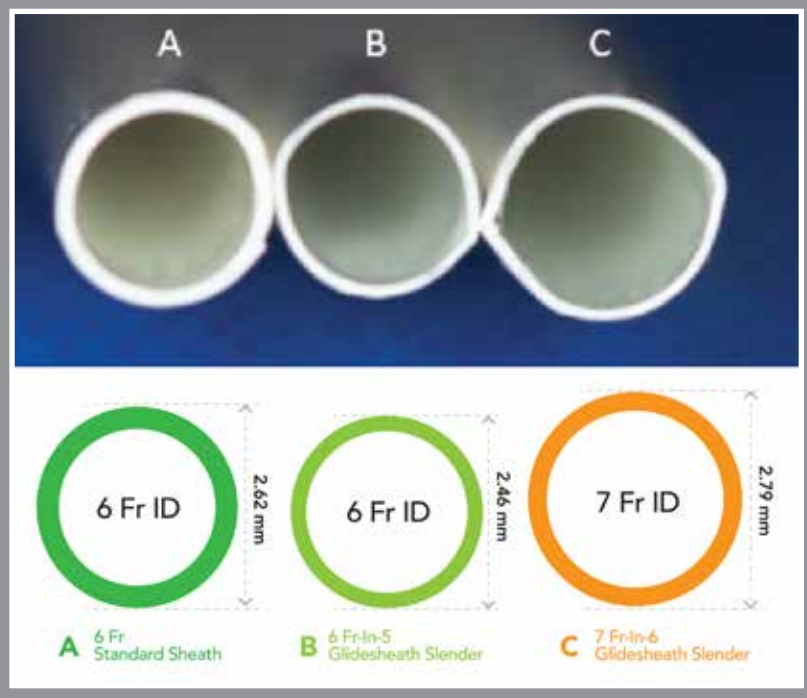

Figure 1: Cross Section Comparison of Standard and Thin-Walled Sheaths

(A) 6 Fr standard radial sheath. (B) 6 Fr-in-5 slender sheath; note the similar ID but smaller OD compared to the first. (C) 7 Fr-in-6 Glidesheath Slender; note the very similar but slightly larger OD compared to the standard 6 Fr radial sheath. Glidesheath Slender walls are thinner than standard radial sheaths.

The disadvantages of the 7 Fr-in-6 approach include:

- Higher likelihood of kinking (this precludes distal radial techniques)
- Limitation to 7 Fr as the largest achievable guide size
- An OD—while smaller than the OD of a 7 Fr standard radial sheath, this sheath is closer in measurement to a 6.5 Fr OD—that is still greater than the mean patient radial artery size

Aminian et al. reported the safety and feasibility of using the 6 Fr-in-5 Glidesheath Slender for routine transradial coronary angiography and interventions in 116 patients with a 99.1% success rate, 4.4% radial artery spasm rate, as well as 0.88% radial artery occlusion at 1 month.[13] More recently, the same group presented safety and feasibility data of the 7 Fr-in-6 Glidesheath Slender. Sixty patients who underwent complex percutaneous coronary interventions via a 7 Fr-in-6 Glidesheath Slender were evaluated. Procedural success was 97% with failures not related to the sheath itself (CTO and severe subclavian tortuosity). Radial artery occlusion rate at 1 month was 4.8%. These cases were complex with 15 CTO revascularizations. None of the patients had sheath kinking during the procedure.[14-16]

The Prelude IDeal™ (Merit Medical Systems, Inc.) hydrophilic sheath introducer was launched in the United States in 2018. It is constructed with flat wire braiding technology that allows for 13% thinner walls with significantly more compression resistance and kink resistance compared to the Terumo Glidesheath Slender. The largest available size is 7 Fr.

The safety, feasibility, and availability of these dedicated radial sheaths have simplified large bore radial access by allowing the operator to maintain the standard workflow without learning new techniques. However, for those operators who do not have dedicated radial sheaths readily available or need larger bore radial access, we describe an alternative technique to decrease radial artery overstretch.

The "in-out" method

The goal of the "in-out" method is to minimize the length of vessel affected by overstretch as well as the duration of overstretch. As illustrated in Figure 2, the technique involves the following steps.

1. Prep the wrist and put an unstrapped compression band in place.
2. Cut a 7 Fr standard sheath to 2 cm in length.
3. Insert the shortened sheath with its dilator over a 0.035 inch wire.
4. Remove the sheath dilator and advance a 7 Fr guide catheter over the 0.035 inch wire to the ascending aorta and engage the coronary.
5. Strap the compression band around the patient's wrist. Carefully pull back the shortened sheath while maintaining guide position. Inflate the band to 2–3 cc for 1–2 minutes to prevent ooze. Alternatively, this can be accomplished with gentle manual pressure for 1–2 minutes without using the compression band.

An added benefit of this "in-out" technique, compared to the Glidesheath Slender, is that it can also be applied to 8 Fr systems.

Disadvantages of this technique include:

- The radial artery is still overstretched for a short period of time with this technique, which may still lead to vascular injury.
- Variation from the normal workflow
- Track ooze after heparin administration

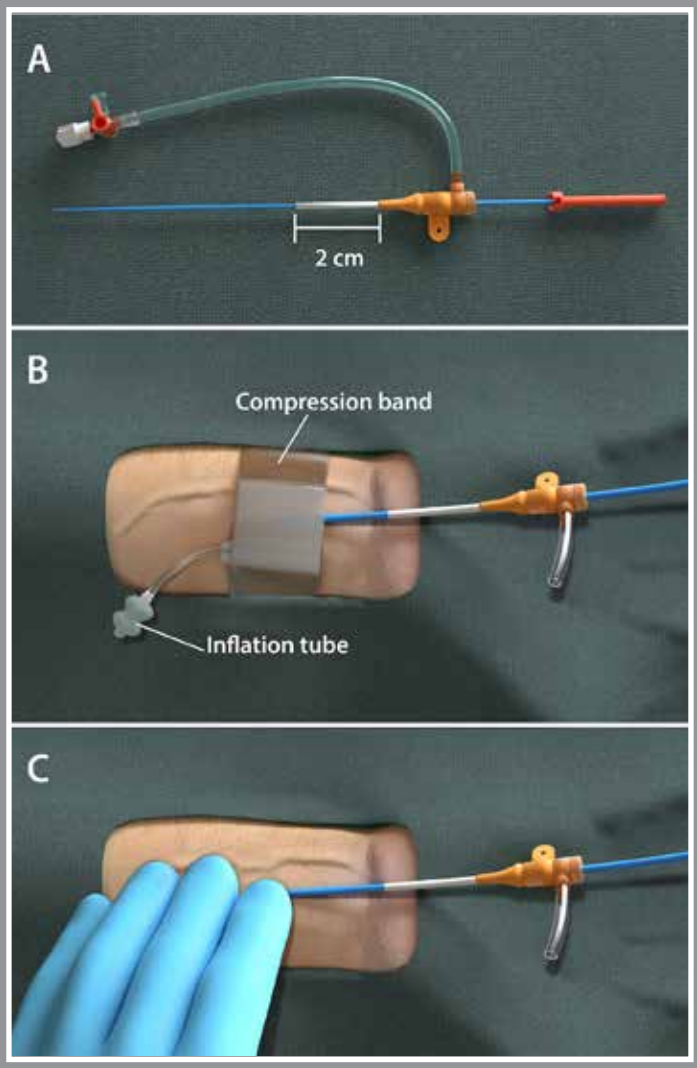

Figure 2: The 'In-Out" Method

(A) Cut a 7 Fr standard sheath to 2 cm in length. (B) After the guiding catheter is in position, carefully pull back the shortened sheath while maintaining guide position. Hold gentle manual pressure for 1–2 minutes to prevent track ooze or (C) inflate a radial hemostasis band to 2–3 cc for 1–2 minutes.

Sheathless systems

Most percutaneous coronary intervention techniques applied to transradial interventions were first developed for femoral access. We are continuing to apply these techniques to a vessel with different characteristics and there has been a shift toward developing radial specific technologies including sheathless guides. By taking the sheath out of the equation, larger guides can be used without the added diameter of the sheath, thus decreasing radial artery overstretch by 1–2 Fr depending on the sheath used.

Asahi SheathLess Eaucath guiding catheters

The Asahi SheathLess Eaucath guiding catheters have a guide with hydrophilic coating as well as a central dilator that protrudes from the tip and forms a smooth tapered transition zone. As illustrated in Figure 3, use of this system entails the following steps.

1. Obtain radial access and insert a standard radial sheath.
2. Advance a 0.035 inch guidewire into the ascending aorta and remove the standard radial sheath.
3. Advance the sheathless guide over the 0.035 inch wire and central dilator to improve kink resistance and backup. The dilator allows for a smooth transition into the skin and the vessel. Note: The central dilator is not radiodense and will not be seen while advancing the guide into the ascending aorta.
4. Once the coronary is engaged with the guide, apply a transparent adhesive dressing to avoid the guide slipping forward or back.

The SheathLess Eaucath guiding catheters come in half sizes of 6.5 Fr, 7.5 Fr, and 8.5 Fr with respective outer diameters of 2.16 mm, 2.49 mm, and 2.80 mm. The walls are thicker than typical guiding catheters to improve kink resistance and backup support. The internal diameters correspond to 6 Fr, 7 Fr, and 8 Fr guides respectively. Recall that the outer diameter of a standard 5 Fr sheath is 2.4 mm, which is almost the equivalent of the OD of the 7.5 SheathLess Eaucath guide. This is smaller than the outer diameter of the 7 Fr-in-6 Glidesheath Slender (2.79 mm).

Several studies have evaluated and established feasibility and safety of the SheathLess Eaucath guiding catheters. The reported procedural success rate is 99% with a 0.2% tip dissection rate as well as low rate of vascular complications.[21,22]

The primary disadvantages of the SheathLess Eaucath are:

- Risk of the SheathLess Eaucath guide sliding due to the hydrophilic coating and lack of sheath. If it slips or dives forward, there is an increased risk of coronary ostial dissections. Slipping backwards would reduce backup support.
- Steps involved in catheter exchange if the shape of the guide is not appropriate. It is manufactured in a multitude of traditional shapes including Judkins Left, Judkins Right, Amplatz left, and Multipurpose, but also in shapes to provide extra support such as the Power Backup (PB) guides, which are most often used, as well as the Super Power Backup guide and the Special Curve guide.

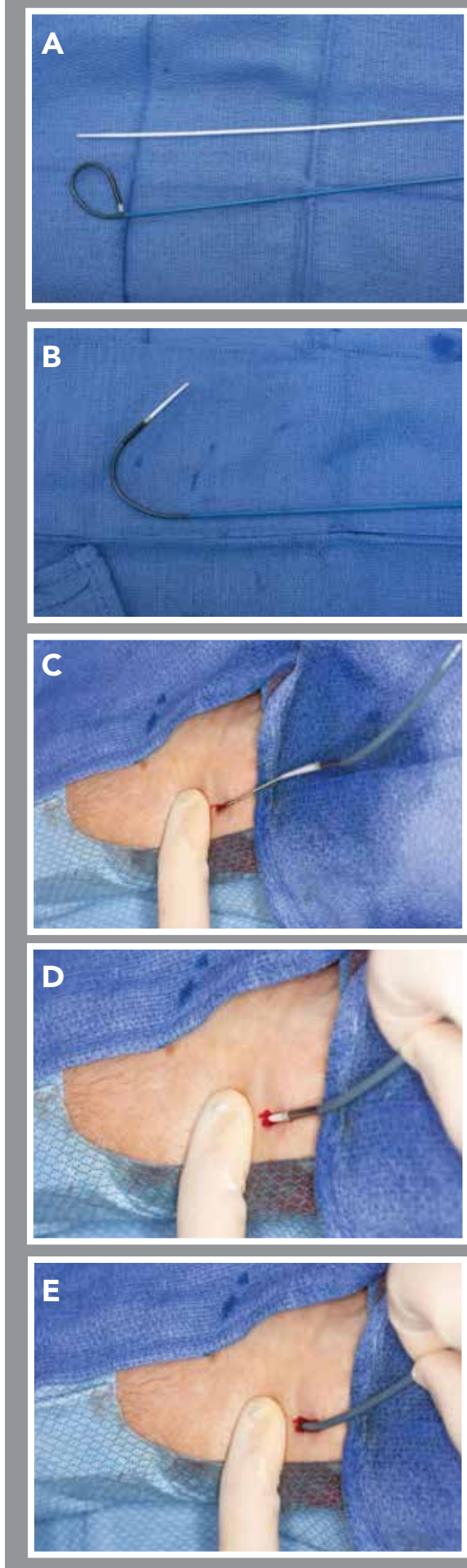

Figure 3: Asahi SheathLess Eaucath Guiding Catheters Insertion Technique

(A) The package comes with 2 components: the dilator and the guide catheter. (B) Insert the dilator into the guide catheter to create a smooth taper. (C, D, E) Advance the system over a 0.035 inch guidewire; the taper allows smooth entry into the radial artery.

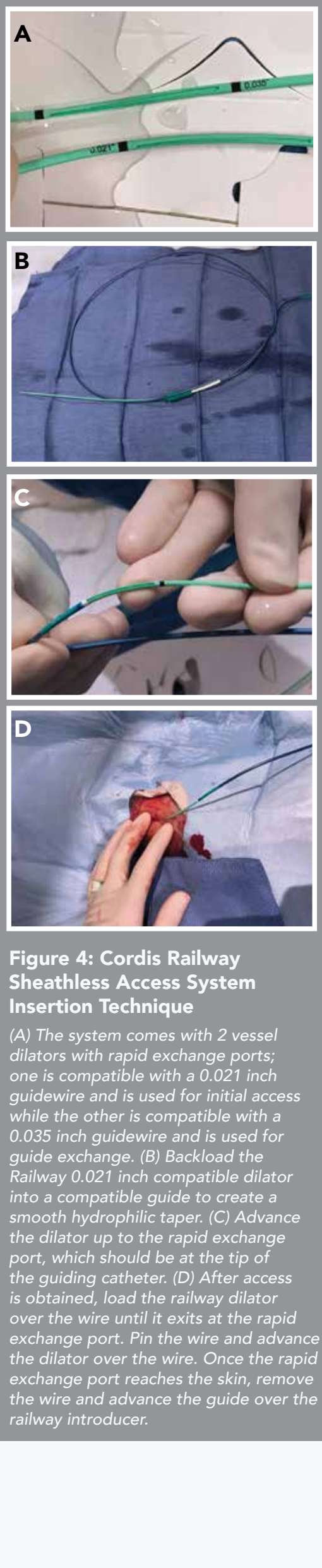

Figure 4: Cordis Railway Sheathless Access System Insertion Technique

(A) The system comes with 2 vessel dilators with rapid exchange ports; one is compatible with a 0.021 inch guidewire and is used for initial access while the other is compatible with a 0.035 inch guidewire and is used for guide exchange. (B) Backload the Railway 0.021 inch compatible dilator into a compatible guide to create a smooth hydrophilic taper. (C) Advance the dilator up to the rapid exchange port, which should be at the tip of the guiding catheter. (D) After access is obtained, load the railway dilator over the wire until it exits at the rapid exchange port. Pin the wire and advance the dilator over the wire. Once the rapid exchange port reaches the skin, remove the wire and advance the guide over the railway introducer.

Cordis Railway™ Sheathless Access System

The Cordis Railway System, recently approved by the FDA in the United States, has been in use since 2017 in other parts of the world. It is designed to facilitate direct radial access and tracking with a smooth taper along the access wire with no need for a standard sheath or wire exchange.

The Railway system components include two 136 cm nylon vessel dilators that have rapid exchange ports. One is compatible with a 0.021 inch guidewire and is used for initial access and the other is compatible with a 0.035 inch guidewire and is used for guide exchange. The package also includes an access needle and a 45 cm 0.021 inch spring tip wire.

As illustrated in Figure 4, use of the Railway system entails the following steps.

1. Once access is obtained, make a small skin nick to facilitate transition.
2. Backload the Railway 0.021 inch compatible dilator into a compatible guide up to the rapid exchange port, which should be at the tip of the guiding catheter (the distal end has a 100 cm marker).
3. Load the Railway dilator over the wire until it exits at the rapid exchange port.
4. Pin the wire and advance the dilator over the wire.
5. Once the rapid exchange port reaches the skin, remove the wire and advance the guide over the railway introducer.
6. Pull the railway dilator and use a 0.035 inch wire in standard fashion to engage the coronary and proceed with the intervention.
7. If guide exchange is needed, remove the guide over a 0.035 inch wire to maintain access and hold manual pressure.
8. Load the 0.035 inch compatible dilator into the new guide and over the 0.035 inch wire and advance as described above.

The system is designed to be compatible with 5 Fr, 6 Fr, and 7 Fr guiding catheters of any shape, including dedicated radial shapes, and is optimized to fit familiar Cordis guiding catheters (ADROIT® and VISTA BRITE TIP®).

The main disadvantage of this technique is the lack of hydrophilic coating, which may cause trauma to radial artery secondary to increased friction. However this also means the risk of the guiding catheter sliding forward or backward is much lower compared to the SheathLess Eaucath guiding catheters.

Homemade sheathless systems

Commercially available sheathless systems are limited by lack of availability in some regions, limited selection of guide shapes, and cost. Techniques were developed to use standard equipment readily available in most catheterization laboratories to allow for large bore sheathless interventions. An important concern to overcome when using sheathless techniques is avoiding arterial entry site damage as well as the razor effect from the sharp edge of the guiding catheter being advanced along the radial artery wall.

The techniques described below, and illustrated in Figure 5, aim to avoid wire bias and razor effect of the guide on the vascular endothelium as well as facilitate tracking.

Coronary balloon technique:

1. Partially inflate a coronary balloon—appropriately sized to the inner lumen of the guiding catheter (2.00 mm for a 7 Fr)—at the guide tip.
2. Insert partially inflated balloon over a stiff 0.014 inch exchange length coronary guidewire, which is used as a rail.
3. Once in the subclavian, pull the wire and balloon and use a J tipped 0.035 inch wire to proceed as usual.

Other techniques:

- Telescope a 125 cm Multipurpose diagnostic catheter that is 1 Fr size smaller, within the guide catheter to create a taper and decrease the abrupt transition.
- Insert a 6.5 Fr 125 cm Shuttle Select® diagnostic catheter through an 8 Fr guide.

These techniques are associated with high success rates and a low rate of reported complications.[17-22] However, they have their disadvantages:

- They create an imperfect taper with continued razor effect when tracking over a wire, as shown in Figure 5.
- The guiding catheters most often used were designed for femoral interventions and lack a hydrophilic coating to minimize friction. This may lead to decreased ability to torque, spasm, as well as increased risk of vascular injury and radial artery occlusion with excessive torque of the guiding catheter.

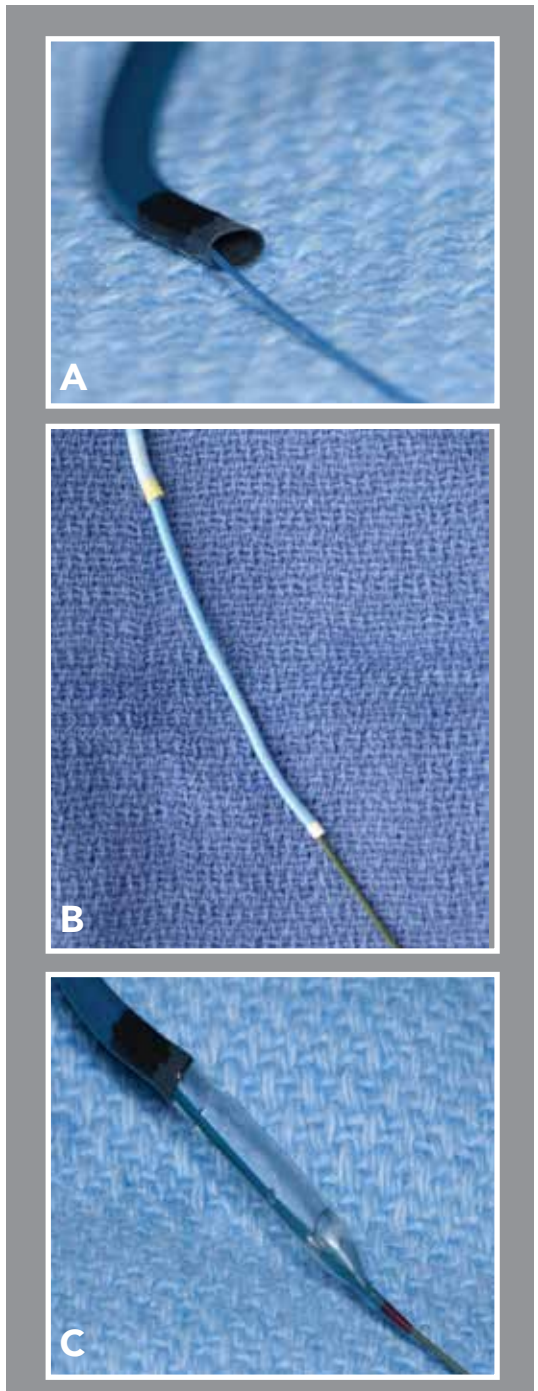

Figure 5: Creating a Taper for Vessel Entry for Large Bore Guides

Summary

- Sheath-based and sheathless approaches to large bore coronary interventions can be used to minimize overstretch to the radial artery. Products specifically designed for this purpose are now commercially available.
- If commercially available products are unavailable or cost-prohibitive, the techniques described in this section allow for minimal radial artery trauma using readily available equipment.
- Use of the techniques described here is not limited to large bore access; the techniques can also be applied to routine PCI to minimize radial artery overstretch, especially in patients who may have risk factors for smaller than average radial arteries as well as those with repeat interventions to maintain radial artery patency.

Table 1 summarizes the techniques described here.

Table 1: Comparison of the Different Techniques

Technique	Advantage	Disadvantage
"In- out" technique	• Up to 8 Fr • Standard guides • Minimal length and duration of overstretch	• OD 2 Fr larger than equivalent guide even if limited overstretch • Track ooze
Glidesheath Slender	• Most straightforward and consistent with normal work flow	• Prone to kinking • No option for >7 Fr • 7 Fr-in-6 is actually an OD of ~6.5 Fr
SheathLess Eaucath guide	• Up to 8 Fr • Additional layer of metallic braiding • Hydrophilic coating	• Coronary dissections • Reduced support • Guide exchange is a hassle
Railway Sheathless System	• Standard Cordis guides can be used • Directly loaded onto access wire • 0.035 inch compatible dilator to facilitate guide exchange	• Ability to torque affected as the guides are not hydrophilic but the dilator is
Homemade sheathless	• Up to 8 Fr	• Imperfect transition zone can cause damage at entry site • Ability to torque may be affected as most do not have hydrophilic coating

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CHAPTER 2 | SECTION SEVEN

Ulnar Artery Access

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Overview

With increasing use of transradial access (TRA), we are being challenged to incorporate radial artery access in procedures such as complex percutaneous coronary interventions (cPCI), high-risk atherectomies, left main treatments, and even balloon aortic valvuloplasties (BAV). In addition, as we grow more comfortable with the wrist approach, the decision to cross over to femoral is being replaced by either contralateral TRA or more recently ipsilateral transulnar access (TUA) (Figure 1). TUA crossover can be more efficient and quicker without any significant increase in personnel or operator time, with a similar learning curve, and with no significant increase in complications.

Figure 1: Ipsilateral Ulnar Access for Crossover

Evidence

Undisputable data has been published over the past decade establishing TRA as standard of care and evidence is slowly but steadily accumulating in support of the safety and feasibility of TUA as a reasonable, and even routine, alternative in certain patients. Studies over the last decade suggest that it is safe to cross over to the ipsilateral ulnar artery in the event of failure to obtain TRA. In a meta-analysis of five randomized clinical trials, both the TRA and TUA groups had comparable major adverse cardiovascular events—a composite of myocardial infarction, target vessel revascularization, stroke, and death—as well as comparable access-related complication rates and bleeding events.

Planning and equipment

The mainstay for TUA is a short micropuncture needle with a short or long 0.014 wire, which is included in a standard radial artery access kit and is readily available from multiple companies. If balloon-assisted tracking is required, workhorse 0.014 wires such as BMW (Abbott) or Luge™ (Boston Scientific) can be used.

Ultrasound guidance is key and TUA should not be attempted without ultrasound. Ultrasound is necessary to assess the size of both radial and ulnar arteries. We know from published data that larger caliber radial arteries have lower rates of post-procedure occlusion and spasm, resulting in decreased crossover rates and therefore higher success rates. If ultrasound reveals that the ulnar artery is larger in caliber than the radial artery, TUA should be considered as the first choice of access (see Figures 2 and 3).

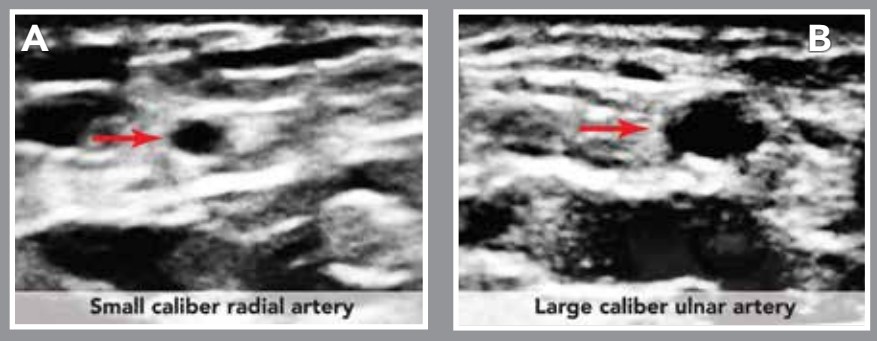

Figure 2: Initial Ultrasound Assessment of Radial and Ulnar Arteries

(A) Small caliber radial artery (arrow); (B) Large caliber ulnar artery (arrow)

Figure 3: Ultrasound of Lateral Small Radial and Medial Large Ulnar Arteries (video)

Planning

The ulnar artery dives deeper as it approaches the elbow, increasing the risk of poor hemostasis (Figure 4). Ultrasound can prove valuable in gaining anterior wall puncture. Although no head-to-head comparative evidence currently exists, a through and through back wall puncture could increase the relative risk of ulnar nerve injury or bleeding from a posterior ulnar arterial puncture due to concomitant anticoagulation and poor compressibility during hemostasis, especially with the lack of adequate bone support (Figure 5).

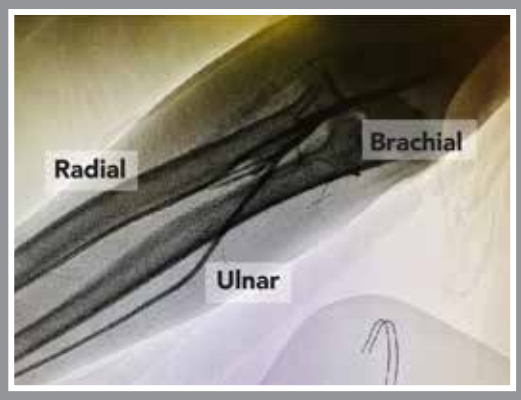

Figure 4: Right Radial-Ulnar Tree Angiogram

Anticoagulation

As with radial artery access, anticoagulation plays a critical role with TUA. Utilization of various personalized "radial cocktails" has been described in practice. Systemic anticoagulation (IV heparin 40–60 units/kg) and a vasodilator, such as nitroglycerin (100–400 mcg) or verapamil (2.5–5 mg), are standard of care. There is no difference in radial artery occlusion with intra-arterial (IA) vs intravenous (IV) heparin. Theoretically, however, one may prefer IV to IA due to potentially stronger local effect with IA that may delay hemostasis, which would be a risk factor for bleeding complications after TUA.

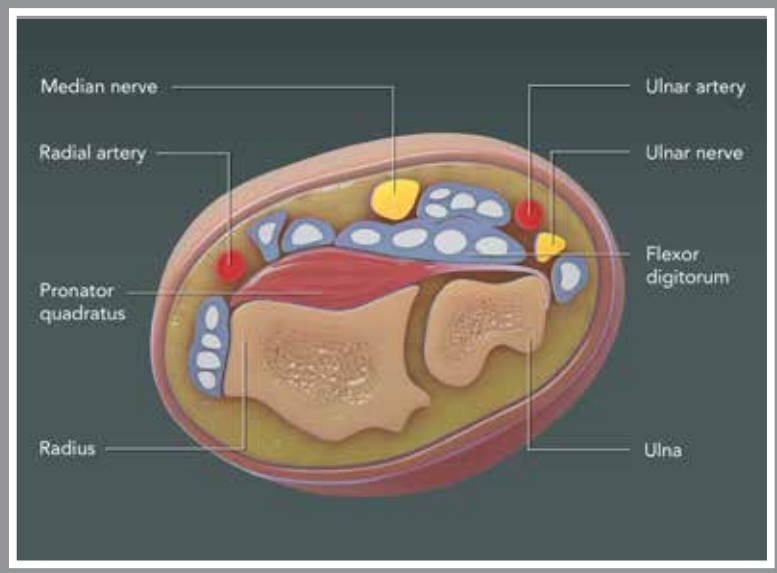

Figure 5: Cross-section Distal Forearm/Wrist

Catheters

It is prudent to have a low threshold for angiography while coursing through the radial/ulnar arterial tree, especially if resistance is encountered. Fluoro-subtract or roadmap technique can help guide the wire and equipment. As with TRA, practice makes perfect. Choose a catheter or guide set and become familiar with the landscape and maneuverability. Balloon-assisted tracking (BAT) or catheter-assisted tracking (CAT) can be utilized if needed.

Hemostasis

As always, hemostasis is critical and is key to the success of radial or ulnar arterial interventions. TUA, with its lack of bony support at the back, can have a higher risk of bleeding than radial artery access and therefore diligent post-procedural care is imperative. We recommend using a vascular band as a standard practice with patent hemostasis; however it is important to note that the band should be placed opposite of how its placed in TRA cases. This stabilizes the inflated segment of the band by placing the flat panel of the band over the radial artery (Figure 6). After that, follow the same radial artery band protocol.

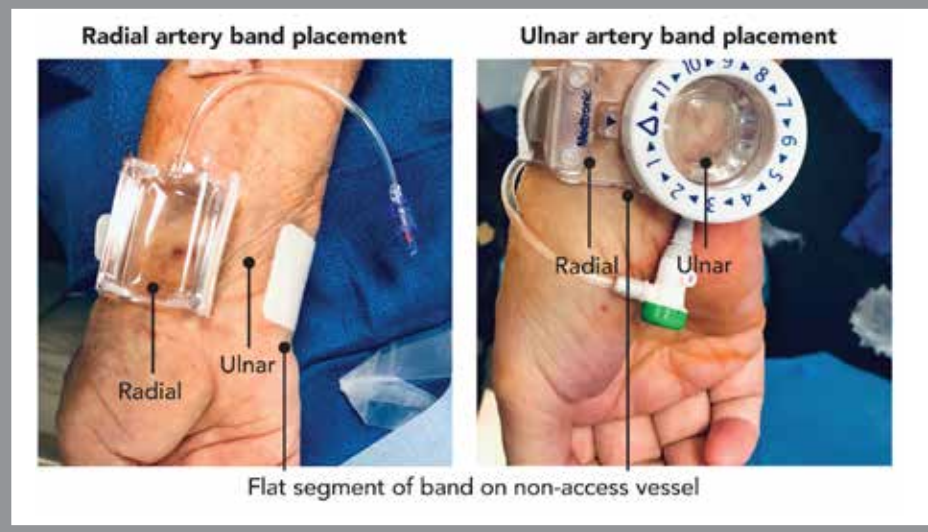

Figure 6: Hemostasis

Complications

Complications are similar to TRA with relatively higher hematoma or bleeding complications and possibly relatively lower ulnar artery occlusion and spasm. Rare sequelae such as pseudoaneurysms, arteriovenous fistulas, and ulnar nerve irritation or injury (reportedly transient) have been reported. Ultrasound guided access should help prevent these complications.

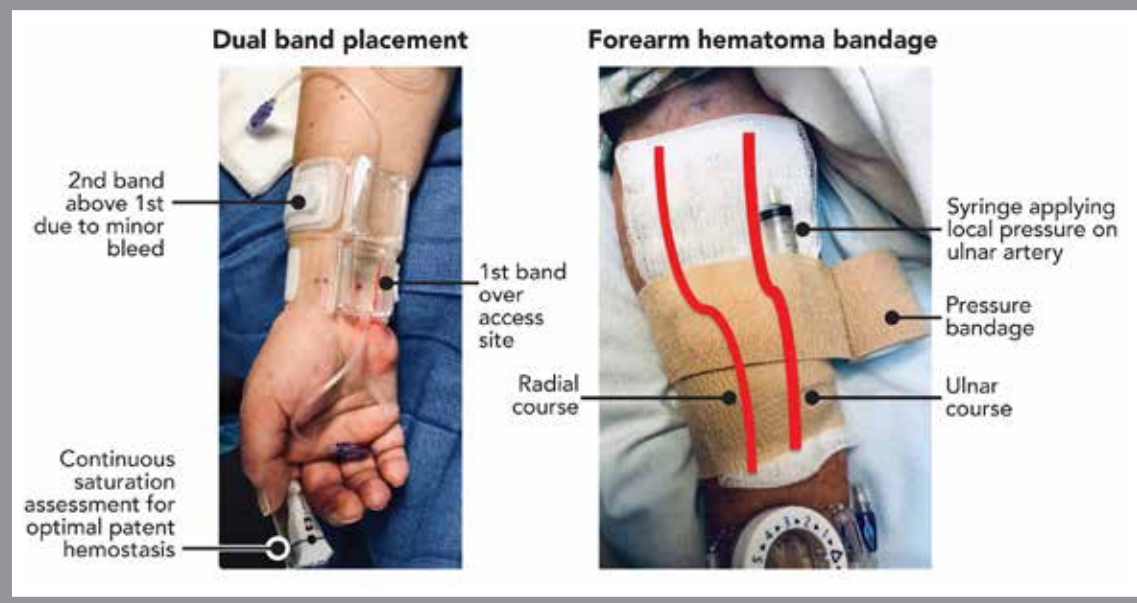

Figure 7: Complications and Treatment

Bleeding at the site of access, proximal to it, or around the elbow segment, is the most common acute complication. Compression and conservative management remain the cornerstones of care. If needed, use a self-adherent wrap (eg, 3M™ Coban™) or another vascular hemostasis band immediately above or below the first band (Figure 7). Coban can also be wrapped around the forearm with an empty syringe (over a few gauze pieces to prevent patient discomfort from the syringe sleeves). This selectively applies pressure on the ulnar segment while preserving radial flow for adequate hand perfusion. It is important to continuously assess oxygen saturations with waveforms in the affected extremity and hand to pre-empt occlusion before it worsens. It is extremely rare to need surgical consult; however surgical consult may be necessary if compartment syndrome develops or conservative methodology fails with increasing girth of forearm while decrease in saturation waveforms is observed over time.

Pro Tips

Ulnar artery access may be a good choice when:

- √ Ultrasound suggests the ulnar has a larger diameter than the radial artery
- √ Difficult radial access—spasm, loops, anatomical variations—suggests crossover to ipsilateral ulnar

TUA may not be the first choice (unless the ulnar is larger in caliber than radial) due to:

- √ Bleeding complications (deeper location with challenging hemostasis)
- √ Less palpable (difficult access)

Preparation:

- √ Extend wrist of patient's right arm with formed fist
- √ Ultrasound-guided access (choose larger caliber vessel: radial or ulnar)
- √ Needle access the ulnar artery close to the wrist (the more distal the better)
- √ Micropuncture kit and soft tip 0.014 wire
- √ Vasodilator of choice and standard 40–60 units/kg IV unfractionated heparin

Catheters:

- √ Standard right radial one size shorter catheters or universal catheters
- √ If any resistance encountered, have a low threshold for angiography
- √ Roadmap/fluoro-subtract technique can be used to guide catheters/wires via tortuous course
- √ Standard radial techniques—BAT and CAT for bends/spasm based on indication or need

Hemostasis:

- √ Patent hemostasis
- √ Standard radial band, but placed "upside down"
- √ Keep saturation cap on access site arm for continuous pulse monitoring

Complications:

- √ Treat bleeding/hematoma with compression with careful eye on hand oxygen saturations
- √ Rare—pseudoaneurysm, fistula, ulnar nerve injury

Summary

In an era of elevated healthcare expenditure, the focus is on value based care and reducing complication rates. Exponential use and interest in radial access is evident and has transcended from cardiology to interventional radiology and neurology. As we evolve in our experience in gaining optimal access to the ulnar artery—twin sister of the radial artery—ultrasound-guided decision-making and transulnar arterial access proficiency must be part of every vascular interventionists' toolbox.

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CHAPTER 2 | SECTION EIGHT

Transcaval Access for Large Caliber Transcatheter Aortic Implants

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Overview

Transcaval access enables delivery of large caliber transcatheter implants to the aorta in patients with small or diseased iliofemoral arteries. The technique involves crossing over from the inferior vena cava into the abdominal aorta and then, following the aortic intervention, closing the aorto-caval tract with a nitinol cardiac occluder. This section provides a 'step-by-step' guide to planning and performing transcaval access and closure. It discusses patient selection based on contrast-enhanced CT, describes technical considerations for the structural heart operator, reviews current clinical data, and explores future directions.

Introduction

Latest generation transcatheter aortic valve replacement (TAVR), mechanical circulatory support (MCS), and thoracic endovascular aneurysm repair (TEVAR) devices have benefited from engineering advances resulting in smaller delivery catheters (outer diameter as small as 6 mm for TAVR), but despite this miniaturization process, some patients with small iliofemoral arteries and/or severe peripheral vascular disease remain ineligible for transfemoral artery access. Transcaval access takes advantage of the high compliance of the iliofemoral veins and the proximity of the inferior vena cava (IVC) and abdominal aorta to deliver large introducer sheaths by crossing from the IVC into the aorta (Figure 1). The aorto-caval tract is closed using nitinol cardiac occluder devices. Transcaval access has been shown to be effective and safe.[1,2]

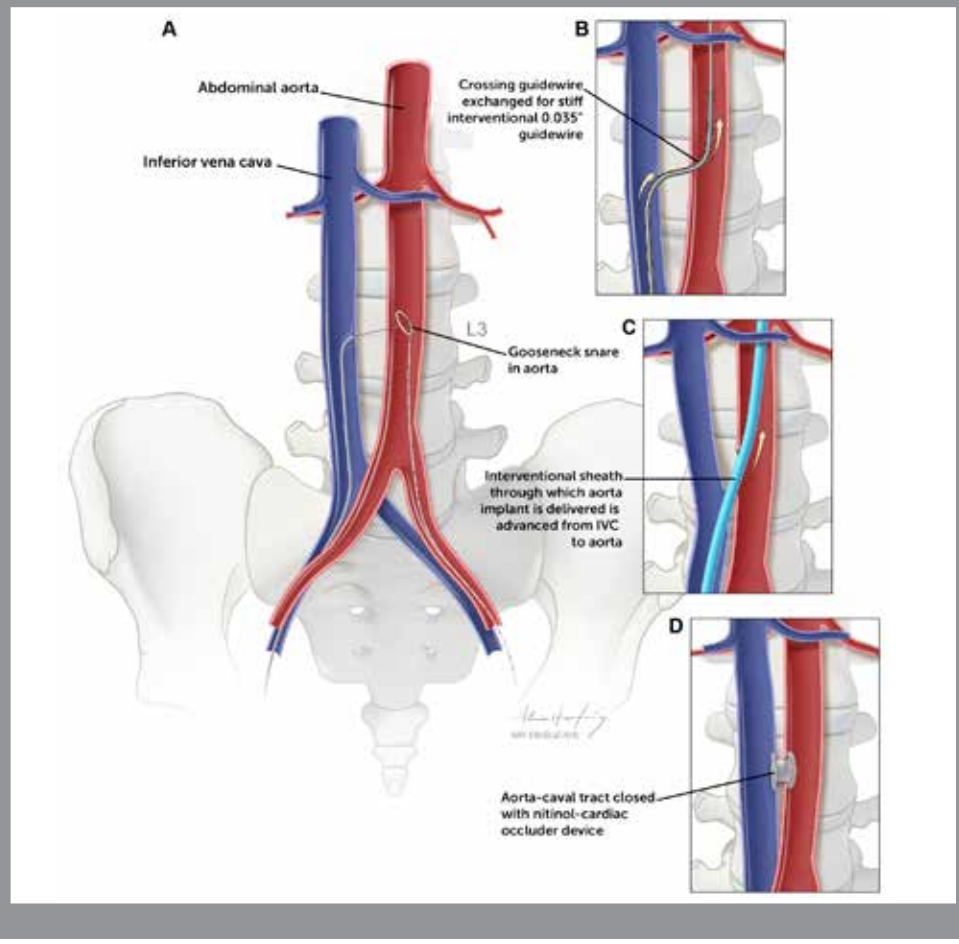

Figure 1: Transcaval Aortic Access and Closure

(A) A catheter is used to direct the 0.014" crossing wire toward the aorta. A gooseneck snare serves as the target in the aorta. The wire tip is energized with an electrosurgery pencil attached to the distal end to puncture into the aorta. (B) The crossing 0.014" guidewire is exchanged for a stiff interventional 0.035" guidewire using sequentially larger catheters. (C) The large interventional sheath is advanced from the IVC into the aorta, through which the aortic implant is delivered. (D) The aorto-caval tract is closed with a nitinol cardiac occluder device.

Patient selection

Pre-procedural CT analysis

Transcaval access is planned using the same contrast-enhanced computed tomography (CT) images of the iliofemoral arteries that are acquired to evaluate for transfemoral artery access. Non-contrast enhanced CT imaging is possible but risks missing aortic dissection or other intraluminal pathology. Thin-slice reconstructions are preferable. Systematic analysis includes segmentation of the aorta and IVC, assessment of aortic calcification, selection of suitable calcium-free windows in the aorta, identification of anatomic contraindications that would preclude transcaval access, and, if eligibility is confirmed, formulation of a transcaval plan for use during the procedure.[3,4] A number of key CT measurements and observations are made and can be divided into three broad categories: anatomic descriptors, location of the proposed target site (including anatomic landmarks for target identification under fluoroscopy), and planning for bailout if primary closure fails.

How to perform transcaval access and closure

Technical overview

The transcaval technique is founded on four key assumptions:

- The iliofemoral veins are larger, more compliant, and rarely diseased compared with the iliofemoral arteries.
- The infrarenal IVC is close to the aorta typically without interposed anatomic structures.
- Arteriovenous tracts with substantial flow are usually not immediately life threatening.
- Catastrophic bleeding into the extravascular space (ie, retroperitoneum in the case of transcaval) does not occur so long as bleeding from the artery can decompress directly into the adjacent low-pressure vein. Because IVC pressure is lower than retroperitoneal pressure, any bleeding from the aorta will preferentially shunt into the vein rather than collecting in the extravascular space.

Vascular access

We prefer to pre-close the right femoral venous access site to facilitate rapid hemostasis at the end of the procedure (Perclose ProGlide®, Abbott Vascular), although manual hemostasis or figure of eight suture is also adequate. We use the right femoral vein exclusively and do not believe that transcaval access can be performed from the left femoral vein. A second venous access for temporary pacing is required for the TAVR. Femoral arterial access is required for aortic angiography and to deliver a gooseneck snare into the abdominal aorta. The gooseneck snare serves as the crossing target and also snares and tensions the transcaval guidewire, as shown in Figure 1. Select the largest and least diseased iliofemoral artery, as this same access will be used for adjunctive balloon aortic tamponade or bailout endograft deployment.

Transcaval access site selection

The transcaval access site is selected from pre-procedural contrast enhanced CT,[3,4] based on location of a calcium free window in the aorta and proximity to other critical structures. It is important to ensure that the distance from skin to transcaval crossing site is appropriately less than the working length of the introducer sheath. We describe the location relative to the lumbar vertebrae for easy identification on fluoroscopy. Perform contrast-enhanced cineangiography in the projection angle prescribed from CT analysis in the aorta. Contrast injections in the IVC are not useful. Cineangiography without contrast injection can be useful to visualize aortic calcification.

Transcaval access

1. Immediately after obtaining vascular access, administer heparin to achieve ACT>250 seconds.
2. Position a single loop snare (Gooseneck Amplatz, St Jude Medical) loaded into a 6 Fr JR4 guiding catheter in the aorta to serve as a target and to snare the transcaval wire after crossing. The snare should be 5 mm larger than the aortic lumen diameter.
3. The coaxial crossing system is a fundamental component (Figure 2).
   - Load a stiff 0.014" coronary CTO guidewire (Astato XS 20, Asahi) into a 0.014" to 0.035" wire converter (PiggyBack®, Vascular Solutions) or 0.014" microcatheter (eg, Finecross®, Terumo), which is in turn loaded into a 0.035" microcatheter (eg, Navicross®, Terumo).
   - Connect the back end of the 0.014" guidewire to a unipolar electrosurgery pencil. The PTFE coating of the guidewire may need to be scraped off to optimize conductivity.
   - Attach the ground pad to the patient, taking care to avoid electrical coupling with other conductive structures.
   - Set the pencil to 'cutting' and 'pure' modes with typical energy of 50W.

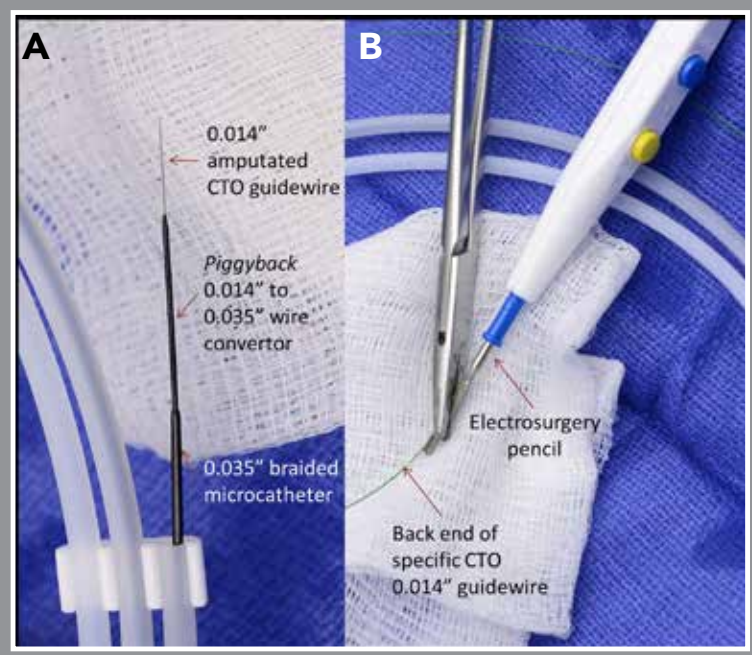

Figure 2: Transcaval Crossing Assembly

(A) The crossing assembly consists of a 0.014" guidewire, inside a 0.014" to 0.035" wire converter, inside a 0.035" microcatheter. (B) A unipolar electrosurgery pencil is attached to the distal end of the 0.014" guidewire to energize the tip during crossing. The ground pad is attached to the patient.

4. Use a 7 Fr internal mammary-curve or renal-curve guiding catheter to position the coaxial crossing system in the IVC, pointing horizontally toward the aorta, aiming for the center of the gooseneck snare (Figure 3). Confirm the trajectory in orthogonal projections.

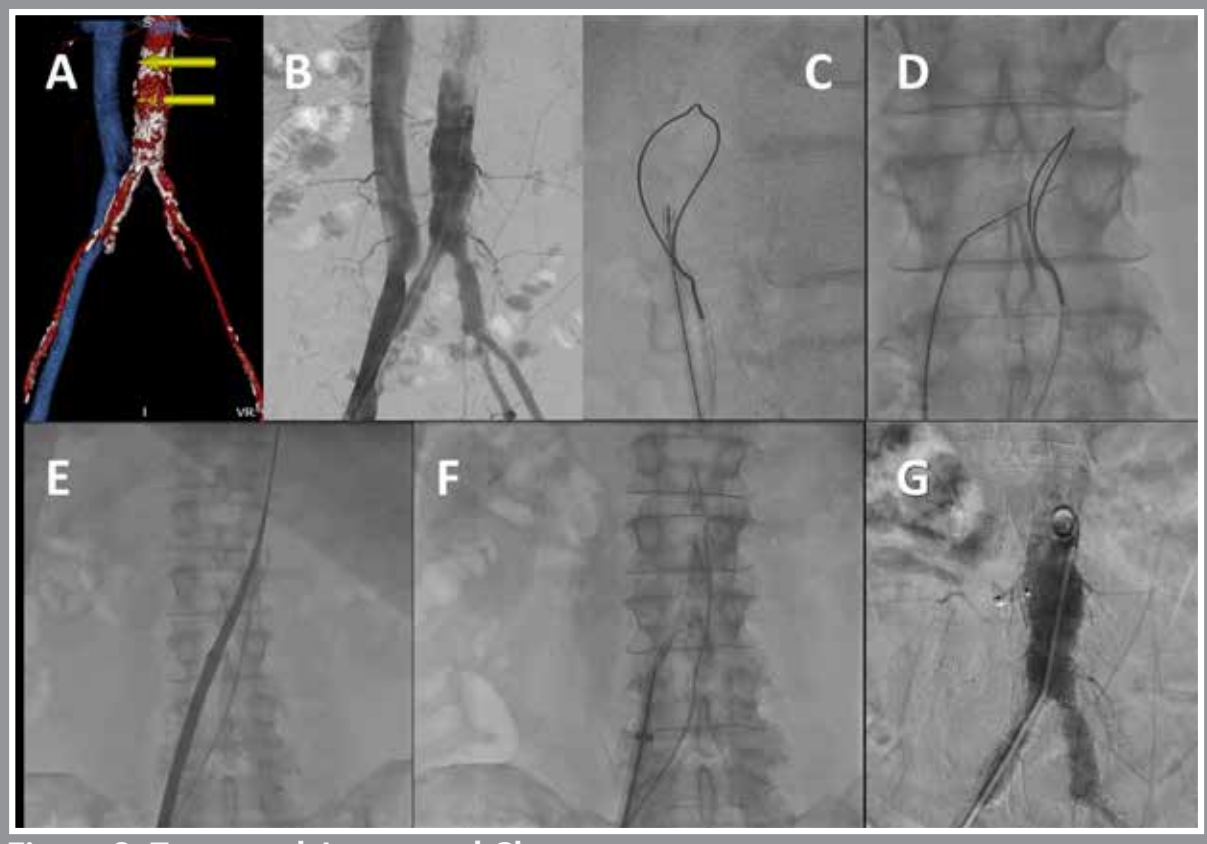

Figure 3: Transcaval Access and Closure

(A) Procedure plan obtained from contrast-enhanced CT showing two potential target crossing sites. (B) Simultaneous aortic and caval angiography. (C, D) The caval guiding catheter directs the 0.014" crossing wire toward the aorta. The aortic snare acts as a target. (E) The large aortic valve introducer sheath is advanced from IVC to aorta. (F) A nitinol cardiac occluder is deployed across the aorto-caval tract. (G) Completion angiogram showing complete occlusion of the aorto-caval tract.

5. Advance the 0.014" guidewire independent of the wire converter during 1–2 seconds activation of the electrosurgery pencil. If the trajectory is correct and the correct calcium-free window is targeted, the wire should traverse easily into the aorta and through the open loop of the snare.
6. Snare the wire, then advance both snare and guiding catheter in tandem up the aorta.
7. Sequentially advance the wire converter and the microcatheter into the aorta over the 0.014" guidewire. If difficulty is encountered while crossing, the tract may require ballooning with a small non-compliant coronary angioplasty balloon.
8. Once the 0.035" microcatheter is in the aorta, exchange the 0.014" guidewire and wire converter for a stiff 0.035" interventional guidewire (eg, Lunderquist®).
9. Advance the large introducer sheath over the stiff guidewire until the sheath tip is well into the aorta. Expandable sheaths can safely be used for transcaval access.

Aorto-caval tract closure

To close the aorto-caval tract, we recommend nitinol cardiac occluder devices marketed to close patent ductus arteriosus (Amplatzer™ Duct Occluder, St Jude Medical).

1. Administer protamine first to reverse anticoagulation fully and encourage tract closure.
2. Advance a 0.014" medium-support buddy guidewire through the TAVR sheath into the aorta to serve as a rail over which aortic access can be re-established in case of inadvertent occluder pull through.

3. We recommend delivering the occluder through a deflectable sheath (8.5 Fr, 16.8 mm small curl dimension Agilis™ Steerable Introducer, St Jude Medical) to allow the device to be oriented horizontally. The distal disc of the occluder should first be deployed within the aorta.
4. Pull the TAVR sheath back into the IVC. Incomplete or partial withdrawal of the TAVR sheath (ie, out of the aorta but not fully back into the IVC) causes torrential retroperitoneal bleeding by obstructing blood return to the vein.
5. Deploy the proximal portion—or 'neck'—of the device across the aortic wall. At this stage, the device can still be captured, repositioned, or replaced as necessary.
6. Pay close attention to the final angiogram before removing all remaining catheters. Figure 4 summarizes typical transcaval tract angiographic patterns in the cath lab. Incomplete closure of the aorto-caval tract is usually well tolerated and, in our experience, complete closure usually occurs in hours to weeks.

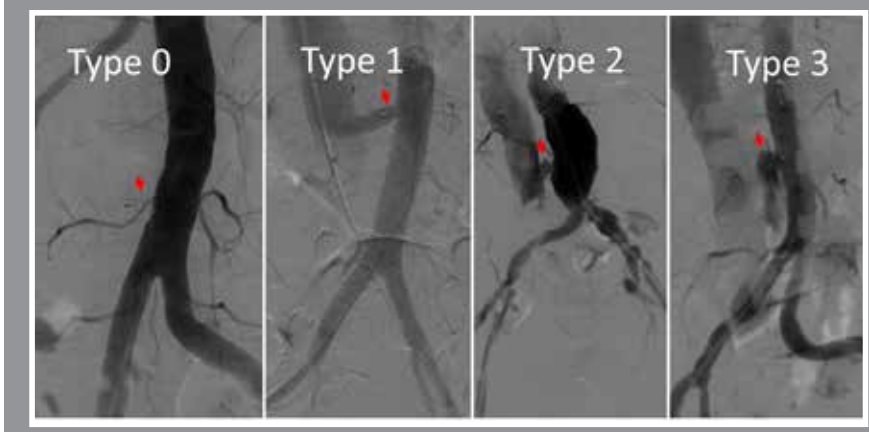

Figure 4: Angiographic Patterns of Aorto-caval Tract Closure

Type 0: Complete occlusion of aorto-caval tract. Type 1: Patent fistula with a long tunnel. Type 2: Patent fistula with a 'cruciform' pattern of contrast around the neck of the occluder. Type 3: Extravasation into the retroperitoneum. Arrows indicate nitinol cardiac occluder.

Managing complications

Failure to cross

Aortic calcification at the attempted crossing site is the most common reason for failure to cross. This typically results in buckling of the 0.014" crossing wire and the need to select a different crossing site. Other reasons for failure to cross include char accumulated at the tip of the wire from repeated crossing attempts, incorrect energy selection, or a bad connection in the electrosurgery pencil-wire assembly. Char can be cleaned off but a fresh wire should be used if the tip is damaged.

Recapture of the nitinol cardiac occluder

If the device needs to be recaptured, the 0.014" buddy guidewire in the aorta serves as the rail over which a 0.035" catheter can be re-advanced across the aorto-caval tract. Exchange the 0.014" guidewire for a 0.035" stiff interventional guidewire to facilitate re-advancement of another large sheath into the aorta with its introducer. Expandable sheaths do not recoil completely and should be replaced with a new sheath for re-crossing.

Incomplete closure of the aorto-caval tract

Small residual shunting around the occluder device is usually well tolerated and will close in hours to weeks. Hypotension may be caused by extravasation or by inability to tolerate acute arteriovenous shunting in a small number of patients, usually those with pre-existing severe right ventricular dysfunction. Persistent mild extravasation can be managed with volume infusion, blood products, or vasopressors. More severe extravasation can be managed with 3 minutes aortic balloon tamponade (eg, Tyshak II®, B. Braun). Balloon tamponade can be repeated, but a covered stent should be deployed if extravasation persists.

Clinical experience

The National Heart, Lung, and Blood Institute (NHLBI) sponsored a 100 subject prospective investigational device exemption (IDE) study in the US.[2] Transcaval access and closure was successful in 99 of the 100 high-risk subjects undergoing TAVR with mean STS-PROM score 9.6%. Thirty-day mortality was 8%. The incidence of major or life threatening bleeding was 12%, which was similar to that of the transfemoral artery access cohort in SURTAVI using the self-expanding CoreValve® (Medtronic) (12.2%),[5] and lower than that of the transthoracic access cohort in PARTNER 2 using the balloon expandable Sapien XT valve (Edwards) (22.6%),[6] both in intermediate risk subjects.

As of October 2018, more than 700 patients have undergone transcaval access at over 100 centers on five continents. Ongoing clinical experience has confirmed excellent transcaval access and closure success rates, alongside marked improvement in procedural outcomes with lower completion angiogram scores, fewer blood transfusions or endografts, shorter hospital lengths of stay, and low mortality.

Future directions

Unusual case considerations

We have performed transcaval access successfully in patients with abdominal aortic aneurysms, crossing from the IVC directly into the aneurysmal segment. We have used excimer laser to cross calcified aortic walls.[7] We have also successfully entered the aorta by puncturing through a polyester aortic graft.[8] These examples demonstrate the versatility of the transcaval technique, but a thorough analysis of the pre-procedural CT is important to determine individual patient eligibility. Additionally, transcaval access has been performed ad hoc, at experienced centers for insertion of Impella 5.0® (Abiomed) MCS devices in younger patients with fulminant myocarditis and cardiogenic shock.

Dedicated devices for aorto-caval tract closure

Worldwide transcaval experience has shown that closure is feasible and safe using off-the-shelf nitinol cardiac occluder devices. However, dedicated devices currently in development are designed to achieve immediate hemostasis and resist inadvertent pull through. The first of these dedicated devices underwent early feasibility testing in the United States in 2018.

Pro Tips

- √ Transcaval access facilitates large-bore access to the aorta from the femoral vein in patients with small or diseased iliofemoral arteries.
- √ The aorto-caval tract is closed with nitinol cardiac occluder devices.
- √ Transcaval access is transfemoral, does not require general anesthesia, and offers hospital lengths of stay similar to transfemoral artery access.
- √ Thorough pre-procedural CT analysis is critical to determine eligibility as well as to plan the procedure. Proctoring is recommended for new operators.

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CHAPTER 2 | SECTION NINE

Large Bore Femoral Venous Access and Closure

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Overview

With increasing use of percutaneous mechanical circulatory support (MCS) devices and structural heart procedures, large bore venous access via the femoral vein has become mainstream. Access size required for current procedures can be as large as 24 Fr [for the MitraClip® device (Abbott)]. Despite low pressure in the venous circulation, large access site size carries substantial bleeding risk. To mitigate this bleeding risk, alternatives to manual hemostasis for access site management have gained traction.

Traditionally, manual pressure with bedrest has been the standard of care for venous access hemostasis whereas vascular closure devices (VCDs) have become the default for large bore arterial access. Currently, two methods are in vogue for managing venous access sites:

- The "Z" stitch (also known as the "Figure of Eight" suture)
- Pre-closure with a suture-mediated vascular closure with the ProGlide® device (Abbott Vascular, Menlo Park, CA)

The "Z" stitch is safe, efficient, and cost-effective.[1] It leads to faster hemostasis, earlier ambulation, and fewer access site complications when compared to manual compression alone.[2] Long-term patency of the femoral vein is not negatively impacted by this method.[2] Alternatively, pre-closure with a suture-mediated closure device like Perclose is also effective and safe, but adds to the cost of the procedure.[3,4]

Access site complications such as bleeding, deep vein thrombosis, AV fistulae, and pseudoaneurysm formation following large bore venous access can lead to disability and prolonged hospital stay, as well as adversely affect outcomes including survival. In this section we outline the techniques for large bore femoral venous access and closure.

Access

In our opinion, one fundamental difference between a routine right heart catheterization and large bore femoral venous access is that we advocate using ultrasound guidance for every large bore procedure, even when performed urgently (such as for Impella RP® (Abiomed) or ECMO). This minimizes inadvertent arterial puncture or entering the vein from an unfavorable angle. However, this is only our opinion, and no data currently support this recommendation.

A standard 18-gauge needle or a 21-gauge micropuncture needle can be utilized. Whether use of the micropuncture technique confers any advantage over standard technique when accessing a vein is a matter of debate.[5]

1. Using fluoroscopy, identify the bottom of the femoral head with the help of a Kelly clamp or other radiopaque sterile surgical tool. This will help approximate the level of needle entry. The femoral vein is located 1 cm medial to the femoral artery. The skin entry site should be approximately 0.5–1 cm medial and caudal to arterial pulse.
2. Prepare ultrasound by placing the probe in a sterile sheath cover and applying gel. Set depth on the ultrasound to 3–4 cm (may vary based on patient body habitus).
3. Hold the ultrasound perpendicular to the course of the femoral vein in axial view. The femoral vein will be medial, larger, and easily compressible. Align the target in the center of the ultrasound screen to ensure that the target vessel is directly beneath the center of the probe.
4. Inject lidocaine under the center of probe with direct visualization under ultrasound. This guarantees proper delivery of anesthetic along the entry path.
5. Using an 18-gauge Seldinger needle on a slip tip 10 mL syringe with 3–5 mL of saline, enter the skin at an approximately 45 degree angle with negative pressure toward the vessel as seen on ultrasound.
6. When the vein is entered, dark, non-pulsatile blood should fill the syringe. Remove the syringe with one hand while tightly holding the needle with the other hand to ensure the tip of the needle remains within the vessel.
7. Smoothly advance a 0.038 cm J wire into the IVC. No resistance should be met. Otherwise we recommend the use of fluoroscopy to confirm the intravascular course of the J wire (IVC should be to the right of the spine).
8. The appropriate sheath may be advanced over the 0.038 wire or serial dilatation can be performed as needed to insert the desired sheath size. If use of a closure device is being planned, use a 6 Fr dilator to dilate the tract and perform the following steps.

Closure with a suture-mediated closure device

1. After obtaining access to the vein, advance a 6 Fr dilator over the wire to pre-dilate the track and assure smooth transition of the closure device. We recommend using a long (150 or 180 cm) 0.038 wire for this.
2. After removal of the dilator, advance the Perclose over the wire into the venotomy. Remove the wire and advance the Perclose into the vein until blood return confirms proper intravenous position of the device. Due to the low pressure of the venous system, return of blood can be hard to see or even absent. In this case, exert manual pressure on the patient's abdomen to return blood and help with device positioning.
3. Deploy the Perclose according to the IFU with the top of the device at the 2 o'clock position. Partially remove the device and reinsert the J-wire. Harvest the sutures and secure with a Kelly clamp. Safely position the sutures in a wet gauze to the right of the venotomy. Fully remove the Perclose. For proper closure of large bore accesses, we recommend using 2 Perclose devices. Advance the second Perclose over the wire into the venotomy and deploy 90 degrees rotated from the first Perclose at a 10 o'clock position. Partially remove the device again, rewire with a 0.038 J wire, harvest the sutures, secure with a Kelly clamp, and position to the left of the access site. Remove the second Perclose and insert the large bore access sheath for the procedure over a stiff wire.
4. At the end of the case, insert the J wire through the sheath. Remove the sheath and cinch the sutures with the 0.038 J wire left in the vein. Tighten the earlier deployed suture (2 o'clock position) first. Before removing the wire, confirm proper hemostasis. If proper hemostasis is not achieved, place a third Perclose over the wire. Remove the wire and tighten the two Perclose sutures. Hemostasis is usually achieved.

Figure 1: Closure With Perclose ProGlide Suture-Mediated Closure Device (Video)

Closure with a "Z" stitch (Figure of 8)

1. At the end of the procedure, partially retract the large bore access sheath, but leave it within the vein. For proper placement of the suture we recommend a size #1 non-absorbable silk surgical suture or larger with a curved needle and a needle driver.

2. Place a suture loop underneath the skin below the sheath by staying 0.5 to 1 cm caudal to the access site. Place the loop by entering the skin to the right of the access site and exiting the skin on the left. The depth of entry should be about 1–2 cm and about 2–4 cm wide (depending on the size of the patient) to allow for grasp of a large piece of soft tissue. Particularly in thin patients, ensure that the needle and suture do not accidentally "catch" the sheath, artery, or vein below the skin.

3. After exiting the skin, place a second loop underneath the skin cranial to the insertion of sheath in the same fashion as the first loop described above. Bring the ends of the sutures together and tighten with a knot.

4. Remove the sheath and tighten the suture. Hemostasis is usually achieved at this point. If there is inadequate closure or oozing, apply manual pressure or a second suture at the access site perpendicular to the first suture. Be sure to remove the suture after at least 4 hours to ensure adequate hemostasis, and be sure the suture gets removed before discharge.

   A 3-way stopcock (Figure 2) is an alternative to securing the suture with a knot. Feed the end of the sutures exiting the skin into the stopcock. After the loop is tightened at the level of the skin, turn the valve of the stopcock 90 degrees and the suture is secured. After hemostasis is achieved, remove the stopcock and suture. An advantage of this technique is the ability to remove the suture without additional tools (eg, scissors or scalpel). The suture can also easily be tightened again if hemostasis is not yet achieved.

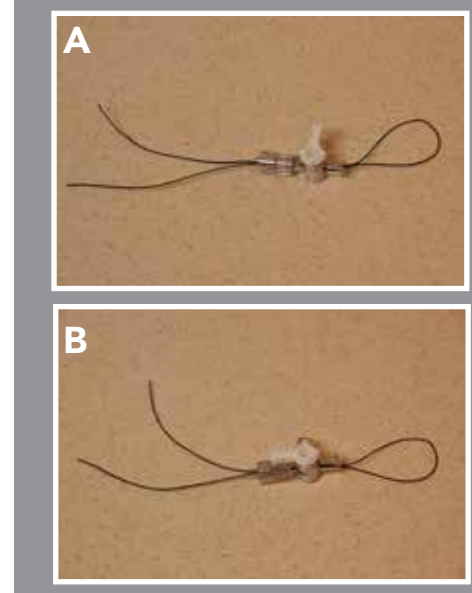

Figure 2: Three-way Stopcock Alternative

(A) Sutures fed through stopcock. (B) Valve turned 90 degrees to secure sutures.

Figure 3: Closure With "Z" Stitch (Figure of 8) (Video)

Summary

With the advent of new applications for hemodynamic support and structural heart disease interventions, the safe management of large bore venous access becomes just as important as arterial access. This section provided step-by-step instructions to safely access the venous system in preparation for large bore access and described two standard closure techniques—suture-mediated closure device and "Z" stitch (Figure of 8)—to limit procedural complications.

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CHAPTER 2 | SECTION TEN

Suture-based Closure Devices for Large Bore Access

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Introduction

While radial artery access is being widely adopted in cardiac catheterization labs throughout the world, large bore percutaneous femoral access is becoming more prevalent with increasing numbers of procedures for thoracic aortic aneurysms (TEVAR), abdominal aortic aneurysms (EVAR), cardiogenic shock (ECMO, Impella®), and cardiac valves (TAVR). With this increase in novel procedures comes an increase in the use of suture-mediated closure devices to close the large arteriotomies. Use of these devices has been shown to reduce infection, mortality, and the need for blood transfusions and is associated with shorter lengths of stay following procedures compared to surgical cutdown.[1] This section describes the proper patient selection and technique for percutaneous suture-based closure of femoral arteries and veins.

Overview of approved devices

Current FDA-approved suture-mediated closure devices for large bore femoral access include:

- Perclose ProGlide® (Abbott Vascular)
- Prostar® XL Percutaneous Vascular Surgery System (Abbott Vascular)

The Perclose ProGlide is a 6 Fr system that is indicated for femoral access sizes ranging from 5 Fr to 21 Fr and venous access sizes from 5 Fr to 24 Fr. The Perclose ProGlide system utilizes a pair of polypropylene monofilament-loaded suture needles for arteriotomy closure. For arterial or venous sheaths greater than 8 Fr, 2 Perclose ProGlide systems must be used to "pre-close" the arteriotomy site. The Prostar XL Percutaneous Vascular Surgery System is a 10 Fr system that can be used for femoral access sizes ranging from 8.5 Fr to 10 Fr. The Prostar XL system uses 2 braided polyester sutures and 4 nitinol needles for closure.

The Perclose ProGlide is widely used in cardiac catheterization laboratories and its use will be the focus of this section. The use of Perclose ProGlide has been shown to effectively achieve rapid hemostasis in the presence of anticoagulation in femoral vein punctures with ≥10 Fr sheaths.[2] Large bore venous access closure can also be achieved utilizing a figure of eight stitch[3] or purse-string suture technique (see Figure 1, Figure 2 (video)). Closure of arterial ECMO cannulas has also been described utilizing a direct puncture of the arterial cannula and 2 Perclose ProGlide devices. This method was feasible and safe for closure following decannulation.[4]

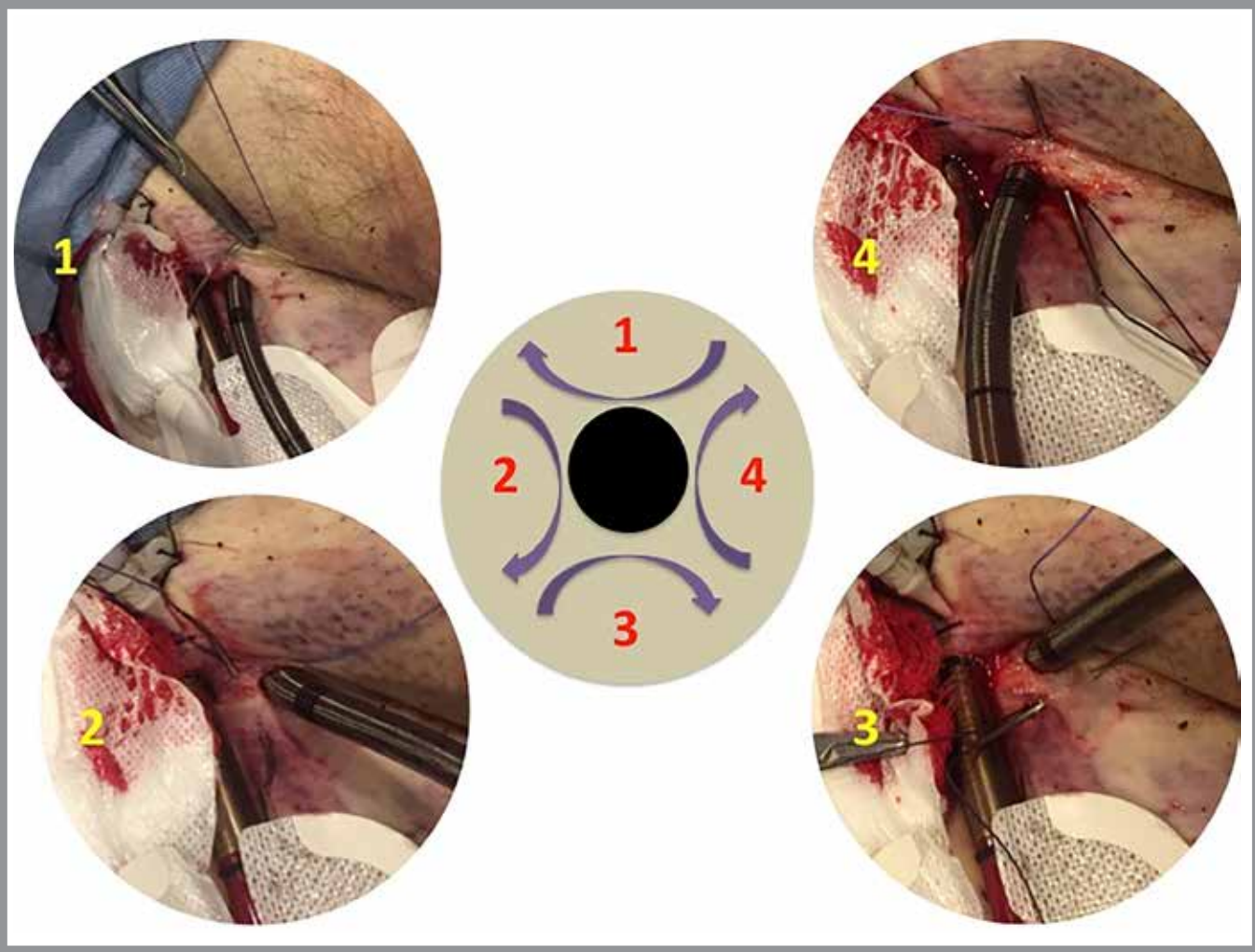

Figure 1: Purse-string Suture Technique

(1) Load 2-0 Vicryl suture onto a needle driver. Starting at the far end, insert needle approximately 5 mm above the cannula. (2) Insert needle at a 90 degree angle to the previous suture immediately below where the suture exits the skin. (3,4) Repeat; the final suture exits next to where the first suture entered the skin.

Figure 2: Purse-string Suture (video)

After the purse-string suture is complete, pull the suture taut. Place a half throw of a hand tied knot. As the catheter or cannula is pulled, hold constant pressure on the knot. Allow a small amount of blood to bleed back before pulling the knot taut and completing the full knot. Hold pressure for complete hemostasis.

Patient selection

The patient and femoral artery must be suitable for percutaneous closure. Box 1 describes contraindications for using the Perclose ProGlide system.[5]

Imaging is important to ensure correct location of puncture in the common femoral artery. The vessel should be imaged with either computed tomography angiography (CTA) or ultrasound prior to arteriotomy and imaged with angiography after arteriotomy.

Box 1: Contraindications for Using the Perclose ProGlide System

- Common femoral artery anterior wall calcification
- Circumferential common femoral artery calcification
- Common femoral artery aneurysm
- Arteriotomy outside of the common femoral artery (high or low sticks)
- Obesity (relative)[6]
- Access vessel diameters <5 mm have also been associated with device failure[7]

Preclosure with 2 Perclose ProGlide systems

1. Obtain access under ultrasound guidance utilizing a 21-gauge, 7 inch Micropuncture® Access Set (Cook Medical, Indiana) and 0.018" 40 cm wire.
2. Create a nick over the micropuncture needle with a scalpel to avoid cutting the wire.
3. Exchange the needle for a 4 Fr 10 cm micropuncture catheter.
4. With the catheter in place, perform a femoral angiogram to ensure puncture of the common femoral artery.
5. Place a 0.035" J-wire through the micropuncture catheter and exchange it for a 10 cm 6 Fr sheath.
6. Remove the 6 Fr sheath over the 0.035" J-wire and exchange it for the first Perclose ProGlide system.
7. Advance the Perclose ProGlide system over the wire into the vessel. Remove the J-wire.
8. Advance the device into the vessel without the wire at a 45-degree angle to the skin until pulsatile flow is seen from the marker lumen. Rotate the device to the 10 o'clock position from the midline and deploy (Figure 3, image 1).
9. After deployment, reinsert the 0.035" J-wire into the Perclose ProGlide and remove the device.
10. Secure the sutures using a sterile towel clip, knot pusher, or hemostats and place to the side the device was deployed. The sutures are typically covered with wet Telfa to keep them clean as well as ensure they remain wet to prevent suture breakage (Figure 3, image 3).
11. Repeat this procedure with the second Perclose ProGlide system at the 2 o'clock position (Figure 3, image 2).

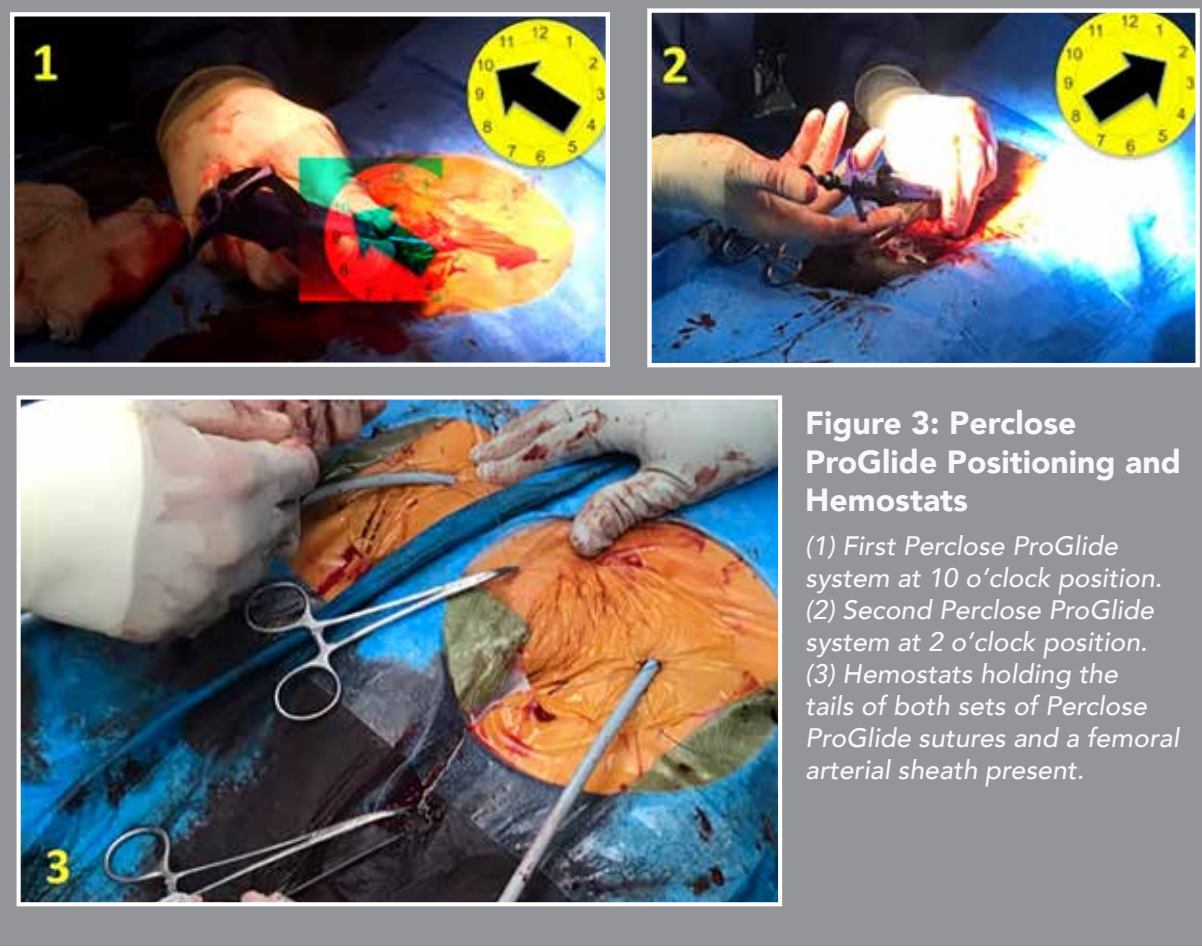

Figure 3: Perclose ProGlide Positioning and Hemostats

(1) First Perclose ProGlide system at 10 o'clock position. (2) Second Perclose ProGlide system at 2 o'clock position. (3) Hemostats holding the tails of both sets of Perclose ProGlide sutures and a femoral arterial sheath present.

Following removal of the second Perclose ProGlide system over the 0.035" J-wire, an 8 Fr sheath is typically placed back into the vessel. Through the 8 Fr sheath, place a stiff guidewire and serially dilate the vessel to the adequate diameter. Following the procedure, a stiff guidewire is typically placed through the sheath and utilizing the included knot pushers, the knots are advanced sequentially as the sheath is removed. The stiff guidewire ensures that a large sheath may be advanced easily should control of the vessel be lost. Once hemostasis is achieved, remove the guidewire and lock the sutures by pulling the white sutures and cut using the knot pusher. Hold pressure at the arteriotomy site as long as protamine is being administered (Figure 4).

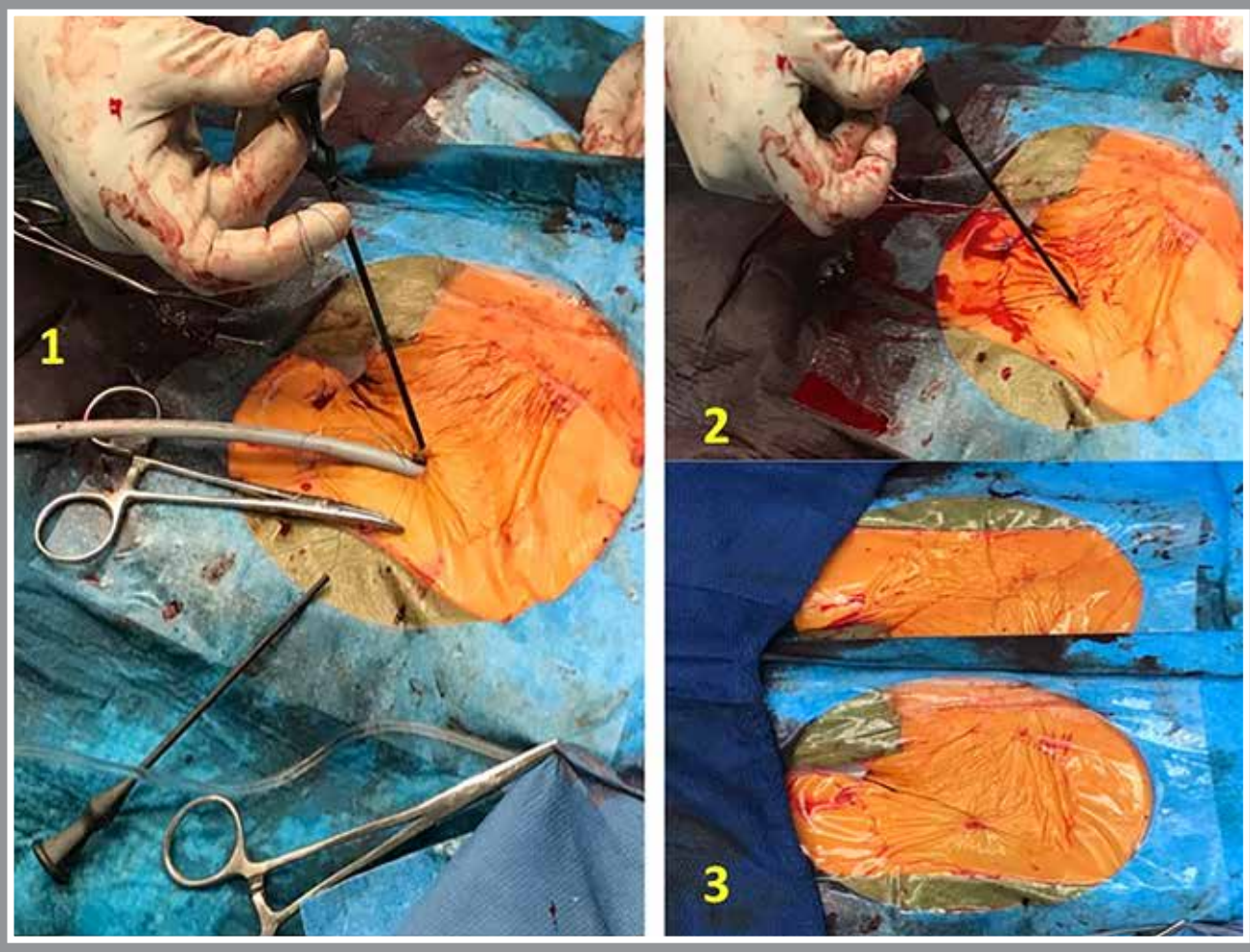

Figure 4: Locking Down Sutures and Complete Hemostasis

(1) Lock down the 10 o'clock Perclose ProGlide sutures. (2) Lock down the 2 o'clock Perclose ProGlide sutures. (3) Complete hemostasis of bifemoral arterial preclosure.

Complications

Bleeding is the most common complication following use of the pre-close device. If significant bleeding is observed prior to the guidewire being pulled, deploy another device to attempt hemostasis. If a large amount of bleeding remains, place the large bore sheath for hemostasis and consider open vessel repair with vascular surgery consultation. Oozing at the site may be controlled by manual pressure and reversal of anticoagulation. Investigate hematoma formation, auscultated bruit, or tenderness at the site of arteriotomy with arterial duplex ultrasound to rule out arteriovenous fistula, aneurysm, or pseudoaneurysm formation. Vascular surgery consultation may be needed if these findings are discovered. Other complications that may occur include vascular occlusion and lymphoceles.[8]

Pro Tips

- √ Perclose ProGlide and purse-string sutures can be used for closure of large bore venous access.
- √ Perclose ProGlide systems can be used for closure of large-bore vascular access up to 24 Fr.
- √ Use of ultrasound guidance, micropuncture sheaths, and re-sticking if necessary ensures accurate placement.
- √ Appropriate patient selection and femoral artery anatomy is important for successful deployment and closure.

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CHAPTER 2 | SECTION ELEVEN

Closure Devices: Plugs, Patches, Hybrid

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Overview

This section is devoted to techniques of large-bore arterial access closure not related to suture-based techniques, which are discussed elsewhere. The most popular and widely-available technique for large-bore arterial or venous access closure is use of two Perclose ProGlide® suture-mediated closure (SMC) devices (Abbott Vascular, Santa Clara, CA) placed in an "X" configuration to close arteriotomies up to 26 Fr outer diameter (OD) and venotomies up to 29 Fr OD. This technique has a steep learning curve, requires placement of the device prior to large-bore sheath insertion, is challenging in calcified arterial access segments, and occasionally results in one or both sutures breaking during the closure procedure. For these reasons, newer approaches have been designed.

The devices closest to market launch include the collagen-based Manta™ closure system (Essential Medical, Exton, PA) and the nitinol patch-based InClosure VCD system (InSeal Medical Ltd, Caesarea, Israel). Existing plug-based closure devices can be used in combination with a single Perclose ProGlide SMC in a "hybrid technique." Finally, off-label use of two Angio-Seal™ (Terumo Corporation, Tokyo, Japan) plug-based closure devices has been described.

As with closure of all arteriotomies, it is important to enter the common femoral artery, avoiding the bifurcation and staying within the borders of the femoral head and below the inguinal ligament. Access techniques are outlined in another section.

Manta closure

The Manta system—currently unavailable in the United States—is a plug-based device designed specifically to close arteriotomy sites up to 25 Fr. There are two Manta devices:

- A 14 Fr device designed for 10–14 Fr devices or sheaths with a maximum OD of 18 Fr
- An 18 Fr device designed for 15–18 Fr devices or sheaths with a maximum OD of 25 Fr

The Manta has a puncture locator dilator with a centimeter scale imprinted proximal to a side hole that connects to the sidearm of the sheath to help operators determine initial puncture depth and to aid in deployment after the procedure. Operators advance this puncture locator dilator and once blood flow begins, puncture depth is noted and confirmed for device deployment.

After the large-bore procedure is completed, operators exchange the procedure sheath for the Manta sheath over a 0.035" guidewire, which remains in place throughout the procedure. The dilator is removed and replaced with the Manta device that locks into the Manta sheath. The operator retracts the device and sheath to the noted deployment depth plus 1 cm at an angle of 45 degrees. The operator then pulls the lever on the Manta device to deploy the toggle/footplate and gently retracts the device, allowing the toggle to engage the luminal surface of the vessel and deploy the collagen based closure material on the surface of the vessel. An indicator on the handle of the device signals adequate tension. While maintaining tension, the operator advances the lock advancer tube until an audible click signifies full deployment of the device. After retracting the lock advancer tube to confirm hemostasis, the operator removes the guidewire and trims the suture material. The toggle is slowly resorbed over 6 months allowing for re-access if needed, and a radiographically visible stainless steel lock remains visible to guide future access.[1]

A large, multicenter, pivotal study demonstrated rapid hemostasis with few complications using the Manta device.[2] The device achieved hemostasis in 47 out of 50 patients in the initial validation cohort. One patient had a major vascular complication that required stenting and eventual vascular repair. There were no VARC-2 minor bleeding complications. Five patients developed subcutaneous hematomas not requiring further intervention.

In addition to not requiring pre-closure, this device has the advantage of maintaining access to the vessel with a 0.035" wire throughout the entire deployment, in case hemostasis is not maintained. In this case, a smaller sheath may be placed for later removal once anticoagulation is reversed or has worn off, or another smaller closure device may be placed.

The Manta system received the European CE Mark in July 2016 and is awaiting FDA approval based on 60-day follow-up of the Manta pivotal study and over 3,000 commercial cases performed in Europe.

InClosure VCD

The InClosure VCD (InSeal Medical Ltd, Caesarea, Israel) is a patch-based closure device designed to close 14 to 21 Fr access sites. It features a biodegradable membrane mounted on a self-expanding nitinol frame designed to conform to the shape of the vessel after luminal deployment. Following completion of the procedure, the procedure sheath is left in place and the InClosure VCD delivery handle is inserted into the delivery sheath, exposing the vascular closure device in the vessel. Retracting the sheath automatically aligns the closure device with the vessel, releasing the device with only a tethering wire attaching the sheath to the device. The tethering wire is fixed to the skin and cut once hemostasis is confirmed.

Preliminary data demonstrated good early and late hemostasis with no complications in the initial InClosure VCD validation study.[3] The InClosure VCD received the European CE mark in August, 2016. The primary advantages to this device are its simplicity and compatibility. It requires no pre-closure procedure, does not require a specialized sheath, and is compatible with a wide range of sheath and vessel sizes from 14 to 21 Fr. In addition, the device provides radial support to the accessed vessel, uses the blood pressure within the vessel to facilitate hemostasis, and can be re-accessed in future procedures. Currently, there is no pending FDA application for this device, but this device provides a framework for future device designs in that it does not use sutures or plugs.

Hybrid closure

The hybrid closure technique uses both Perclose ProGlide SMC and plug-based closure devices. Initially described with the use of an Impella® (Abiomed) percutaneous ventricular assist device, the authors describe obtaining access and pre-closing with a Perclose ProGlide SMC device, followed by sheath and device insertion. Following completion of the case, the Impella was removed and the sheath accessed with a 0.035” guidewire. The Perclose ProGlide SMC device was deployed as the sheath was removed, leaving a smaller arteriotomy. A 6–8 Fr sheath was then advanced over the wire, and used to deploy a 6–8 Fr plug-based closure device.[3]

This technique is versatile and may be used with multiple commercially-available plug-based devices such as the 6–8 Fr Angio-Seal device, the 5 or 6/7 Fr Vascade® VCS (Cardiva Medical Inc, Santa Rosa, CA), or the 5/6/7 Fr MYNX ACE® or 5 or 6/7 Fr MYNXGRIP® devices (CardinalHealth, Dublin, OH). It may be used as an upfront closure strategy or as a bailout strategy for the double if 1 of the 2 original Perclose ProGlide SMC devices fails upon completion of the procedure. To use this as a bailout strategy, it is important to maintain access to the vessel with a 0.035” guidewire when tightening the 2 Perclose ProGlide SMC devices. If one of the sutures fails, the wire may be used to insert a sheath to facilitate deployment of a plug-based device. Another important step in the bailout hybrid approach is to remove the broken suture by pulling the suture with the white markings until all suture material is removed.

Figure 1 depicts the hybrid approach used in a right transfemoral transcatheter aortic valve replacement (TAVR) in a 74 year-old man with severe symptomatic aortic stenosis.

Following pre-closure with 2 Perclose ProGlide devices, TAVR was performed using a 29 mm SAPIEN 3 (Edwards Lifesciences, Irvine, CA).

Some operators advocate an upfront double-wire, double-Angio-Seal.[5] We do not recommend this due to lack of available evidence and the potential for mismatch of the device footplate/plug and arteriotomy. This may be used as a bailout strategy if both Perclose ProGlide sutures break.

As seen in Figure 2, following pre-closure with 1 Perclose ProGlide device, a left transfemoral TAVR was performed using the 29 mm CoreValve™ Elolut™ R (Medtronic, Minneapolis, MN) in a 90 year-old man with severe symptomatic aortic stenosis. Due to extensive calcium, only 1 Perclose ProGlide device could be deployed, with the second device failing, so a hybrid approach was planned.

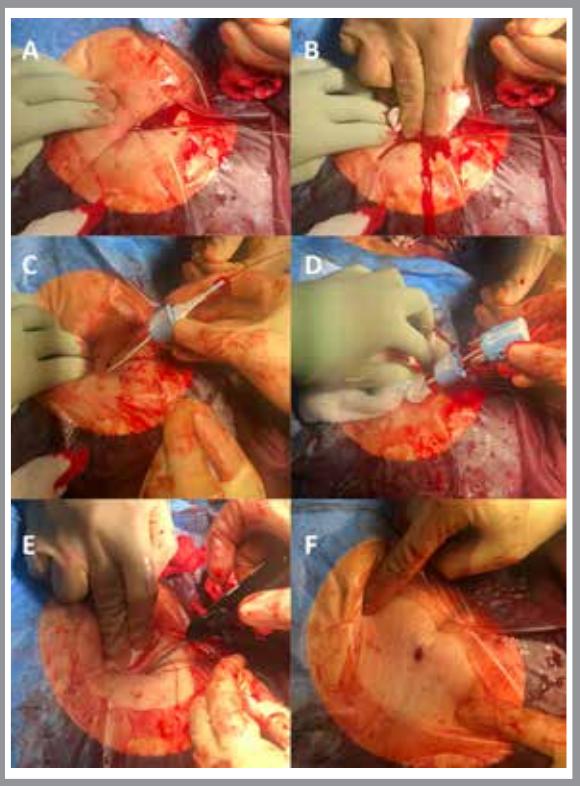

Figure 1: Hybrid Approach

(A) Device and sheath removed over J-tipped 0.035" Amplatz extra-stiff wire (Cook Medical, Bloomington, IN) used for the procedure and Perclose ProGlide sutures tightened. (B) Excessive bleeding noted at access site. (C) 8 Fr Angio-Seal locator sheath placed, and (D) Angio-Seal VIP device deployed using standard techniques. (E) Two Perclose ProGlide sutures trimmed using trimming device. (F) Hemostasis achieved.

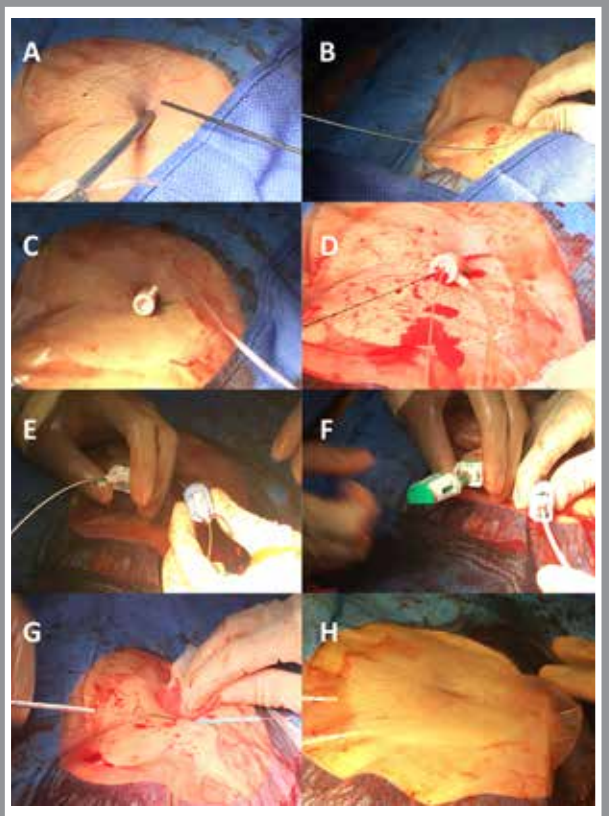

Figure 2: Double Angio-Seal Approach

(A) Perclose ProGlide tightened, however suture came out of the defect, indicating misplaced device. (B) TAVR device removed over the 0.035" Lunderquist extra-stiff wire (Cook Medical, Bloomington, IN) used for device deployment, and (C) 14 Fr sheath placed. (D) Two 0.035" J-tipped wires inserted into the sheath, and (E) 6 Fr and 8 Fr Angio-Seal locator sheaths placed into the lumen of the vessel. (F) Angio-Seal VIP devices deployed, (G) with standard procedures, resulting in (H) hemostasis.

Pro Tips

- √ As with closure of all arteriotomies, it is important to enter the common femoral artery avoiding the bifurcation, and to stay within the borders of the femoral head and below the inguinal ligament.
- √ Newer-generation plug- and patch-based closure devices are being developed and may reach the United States market soon.
- √ Off-label plug-based closure devices may be used in conjunction with a Perclose ProGlide SMC pre-closure using the hybrid technique as an upfront or bailout strategy.
- √ For bailout use of the hybrid technique, maintain wire access for every double Perclose ProGlide SCM closure until hemostasis is confirmed. Failure to do this will make it impossible to use the hybrid technique as a bailout if one or both sutures fail.
- √ For bailout use of the hybrid technique, remove the failed suture from the arteriotomy by pulling on the white-marked suture until all attached suture is removed from the arteriotomy.
- √ We recommend the upfront hybrid technique only in patients with heavily-calcified vessels or in cases when a second Perclose ProGlide SMC pre-close cannot be deployed.
- √ We do not recommend the double-wire double-plug technique as an upfront technique, but it may be used in cases where both Perclose ProGlide SMC pre-closure sutures fail.

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CHAPTER 2 | SECTION TWELVE

Manual Compression and Assisted Manual Compression for Large Bore Access Closure

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Introduction

Large bore arterial access has become increasingly common with the rapidly expanding structural heart disease interventions and the use of percutaneous hemodynamic support devices. Not surprisingly, large bore arterial access procedures are associated with a higher risk of access site complications, including bleeding. Widespread adoption of large bore access procedures was initially limited by access complications as these procedures required vascular surgeons to perform arterial cutdowns; albeit closure was relatively straightforward with surgical techniques. Today, however, these procedures are being performed percutaneously, obviating the need for surgery. Thus, arterial hemostasis at the end of the procedure now has to be achieved by non-surgical techniques.

Careful patient selection, consideration of peripheral arterial anatomy, and safe access techniques are key to avoiding vascular complications in patients undergoing large bore access procedures. Vascular closure devices, specifically suture-mediated devices (Perclose ProGlide® and Prostar XL®) have been used to achieve hemostasis after large bore arterial access with good technical success. However, there is still a significant failure rate with these devices resulting in high vascular complication rates.[1] This section focuses on manual compression and assisted manual compression as alternatives to vascular closure devices.

Manual compression

Manual compression has long been the gold standard technique for achieving hemostasis following arterial access. After large bore arterial access, however, manual compression becomes more challenging, as it is harder to control access site bleeding. Nevertheless, it is a useful skill to possess in case the closure devices fail.

Although manual compression is simple, it is essential to apply good technique to achieve hemostasis and to prevent complications. Good manual compression technique entails the following:

- Ensure ACT is less than 180 seconds before sheath pull (general recommendation).
- Continuously monitor patient's vital signs during manual compression.
- Flush the sheath before pulling it to ensure there is no thrombus that could embolize when it is withdrawn.
- Administer adequate analgesia to ensure the patient is comfortable.
- Place fingers about an inch above the sheath (arteriotomy site) and apply firm manual pressure. Standing on a short bedside stool permits upper body weight to be used for pressure application.
- After achieving adequate control of the artery (identified by the pulse), remove the sheath taking care not to crush or shear the sheath.
- Allow a small spurt of blood to dislodge any clot in the arteriotomy track.

Monitor distal pedal pulses every 2 to 3 minutes during manual compression. Although a diminished pulse is acceptable during brief full-pressure application, distal pulses should not be obliterated completely. If the pedal pulse is absent during compression, periodically decrease the pressure over the artery to allow distal circulation. Complete artery occlusion prevents mobilization of clotting factors and platelets at the arterial wall puncture site, prolonging the time to hemostasis.

Every institution has a protocol for manual hemostasis, but manual compression has to be applied directly over the arteriotomy site until complete hemostasis is achieved. A general recommendation is 3 minutes of pressure per French size, which means it could take up to 45 minutes of pressure for a 14 Fr sheath; hence more than one operator may be needed to achieve effective manual hemostasis for large bore arteriotomy access. Following hemostasis, prolonged bed rest is indicated for these patients.

General Recommendation

3 minutes of manual compression pressure per French size (eg, up to 45 minutes for a 14 Fr sheath

Assisted manual compression

In some situations, hemostasis is best achieved by assisted manual compression—use of an extrinsic compression device or topical hemostasis patch to help with hemostasis. FDA-approved and commercially available devices for extrinsic compression include:

- FemoStop™ Gold (St. Jude Medical)
- C-Clamp devices such as CompressAR®, ClampEase®, Compass™, PressureMate™ and ComfortPress™ (Advanced Vascular Dynamics), Assiut Femoral Compression Device
- Hemostasis pads such as Clo-Sur P.A.D.™ (Scion Cardiovascular), D-Stat® Dry (Vascular Solutions), and Neptune Pad (TZ Medical)

FemoStop

FemoStop Gold (Figure 1) is the most commonly used assisted manual compression device. It consists of a rigid frame and a pneumatic dome that can be inflated once positioned on top of the femoral artery. A belt that goes across the patient's hip holds the frame and the dome in place. The dome is attached to a manometer. Once the belt is secure at the hip, the dome is positioned on top of the femoral artery and inflated to 60–80 mmHg. The sheath can then be removed, and the dome inflated to supra-systolic pressure. After 3–5 minutes, the cuff is gradually deflated until distal pedal pulses are restored; the cuff remains inflated at that pressure for the duration of the procedure. It is critical to closely monitor the device and patient during this process. The device is not approved for unsupervised use. Once a hematoma forms, it is likely that the dome is no longer above the arteriotomy site.

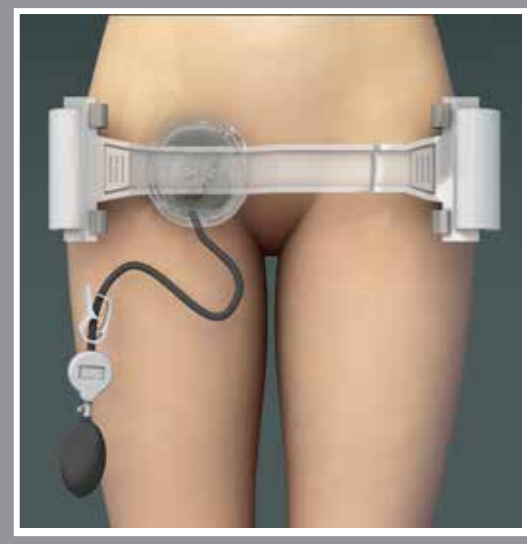

Figure 1: FemoStop

C-Clamp devices

Assisted manual compression can also be accomplished with one of several currently available C-Clamp devices—a stand with an arm that exerts direct pressure on the arteriotomy site after sheath pull— such as CompressAR® System (Figure 2). While these devices reduce the need for manual pressure and standardize arteriotomy compression, they require close patient monitoring to avoid hematoma or limb ischemia. A study comparing manual to mechanical compression demonstrated no difference in bleeding but a significant reduction in hematoma formation with mechanical compression device use.[2]

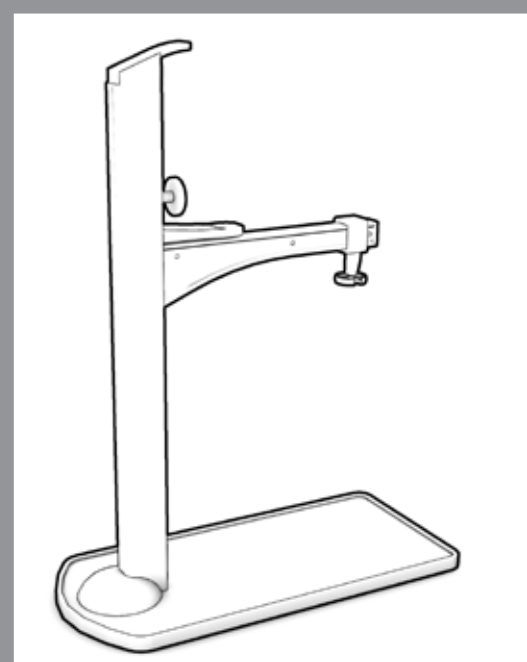

Figure 2: CompressAR System

Hemostasis pads

Hemostasis pads contain procoagulant coating to accelerate coagulation and hemostasis. Numerous products are available, and these devices result in shorter compression times and lower incidence of bleeding. A large study comparing hemostasis pads to manual compression demonstrated a significant reduction in bleeding or vascular complications with hemostasis pads.[3]

Pro Tips

- √ Manual compression is feasible and effective if done correctly.
- √ A variety of assisted manual compression devices are available; if applied correctly, these devices help achieve hemostasis, potentially reducing bleeding and vascular complications.
- √ When using compression devices, closely monitor patients to prevent bleeding or limb ischemia.
- √ Hemostasis pads contain procoagulants that accelerate hemostasis.

Summary

Manual compression is feasible but associated with a higher incidence of hematoma and bleeding following large bore arterial access. A variety of mechanical compression devices and hemostasis pads are available to assist in achieving manual hemostasis by potentially reducing compression times and access site bleeding.

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CHAPTER 2 | SECTION THIRTEEN

Cross-over Balloon Occlusion "Dry Closure" Technique for Large Bore Femoral Access

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Overview

Safe vascular closure, like safe vascular access, is a cornerstone of percutaneous coronary, cardiac, and vascular intervention and should be given the same attention as the primary procedure. Vascular complications occur more frequently than procedural complications, are associated with significantly increased patient morbidity and mortality, and typically occur during insertion and removal of sheaths.

With growing utilization of radial artery access for percutaneous interventions, femoral access is increasingly reserved for more complex procedures [eg, TAVR, EVAR, and mechanical circulatory support (MCS)] necessitating larger-bore 13–18 Fr sheaths. In addition to utilizing best practices for femoral vascular access, operators should employ safe closure protocols such as the cross-over balloon occlusion "dry closure" technique (CBOT). CBOT is a simple, reliable, convenient, and reproducible procedure with high success rates, demonstrated reductions in major vascular and bleeding complications, and potential benefits of reduced nuisance oozing, earlier mobilization, decreased length of stay, and cost savings.[1,2,3]

Strategic planning

For elective femoral cases, perform pre-procedural aorto-iliac and common femoral CT angiography or duplex arterial ultrasound to assess vascular anatomy and individual vessel internal diameters. For urgent cases, utilize intraprocedural aorto-iliac angiography instead. Note that in the case of percutaneous transfemoral (or transaxillary or transcaval) MCS insertion for cardiogenic shock, sheath and device explantation (utilizing CBOT) often may be performed several days (or more) following the index procedure.[4]

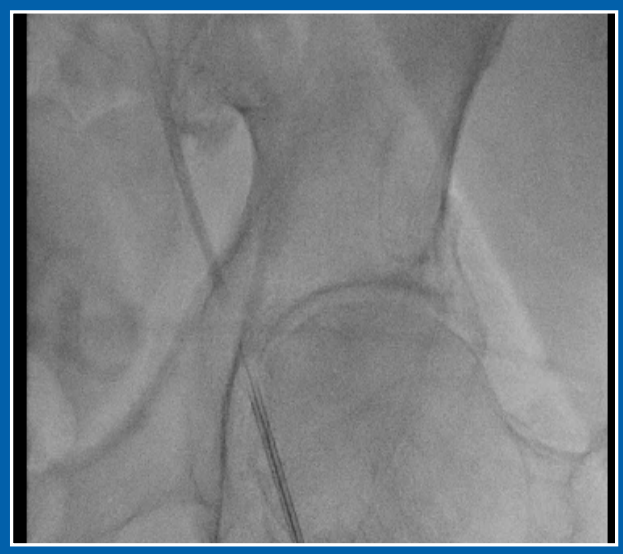

Figure 1: Perclose Deployment in CFA Prior to Large-bore Sheath Insertion (video)

CBOT equipment and procedural considerations

Step 1: Perform ultrasound-guided common femoral artery (CFA) micropuncture access and dual Perclose vascular closure device (VCD) pre-closure (Figure 1) utilizing current best practices for either same-sitting or delayed large bore sheath removal (Figure 2).

Step 2: Insert large bore sheath, anticoagulate patient, and perform index coronary, cardiac, or vascular procedure.

Step 3: Advance crossover catheter (UF, Omni™ Flush, or similar) via contralateral CFA access to the ipsilateral common iliac artery (CIA) over a 260 cm 0.035" Glidewire Advantage (or similar soft tip-stiff shaft wire) positioned in the ipsilateral superficial femoral artery (SFA) distal to the large bore access sheath (Figures 3, 4). If ipsilateral or contralateral radial or ulnar access is utilized instead, advance a 125 cm multipurpose or vertebral catheter over a wire into the iliac artery ipsilateral to the large bore sheath.

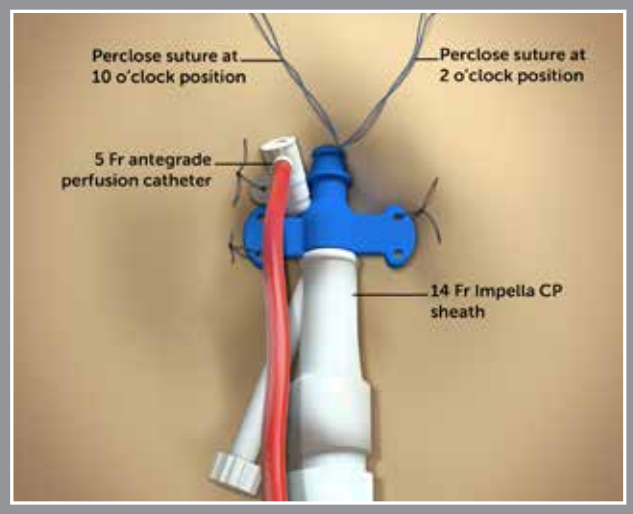

Figure 2: "Leave-in" Large-bore Sheath in CFA With Perclose Sutures in Position at 10 o'clock and 2 o'clock

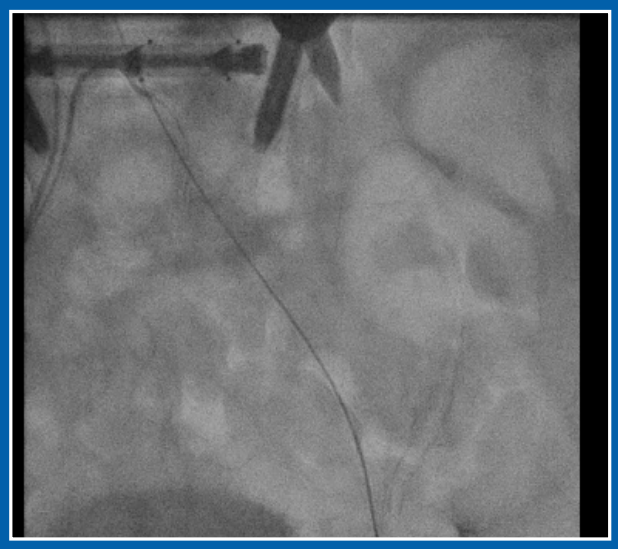

Figure 3: Wire Advanced Through Crossover Catheter Into EIA (video)

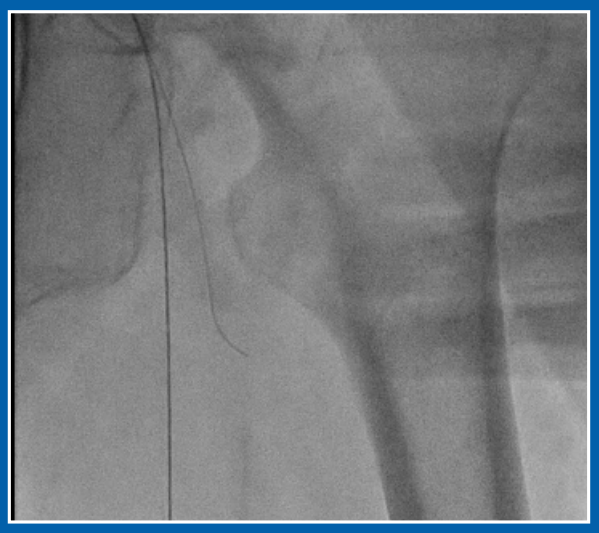

Figure 4: Wire Advanced Beyond Sheath in CFA and Into SFA (video)

Step 4: Position appropriately sized over-the-wire vascular balloon (typically 8–10 mm diameter x 20–40 mm length) in the very proximal external iliac artery (EIA), either sheathless or via an appropriate length 6 or 7 Fr vascular sheath. *Optional: 0.035" wire within the crossover peripheral balloon may be replaced with a 0.018" wire advanced into the SFA.*

Step 5: Retract large bore sheath to the CFA / EIA junction. *Optional: Inject contrast via the large bore sheath prior to removal to identify any major iliac vascular injury.*

Step 6: Inflate crossover balloon at non-traumatic low pressure in the EIA to occlude distal flow (Figures 5, 6). *Optional: Pressure may be transduced from the crossover occlusion balloon or the large bore sheath after balloon inflation to confirm EIA occlusion (via a flatline pressure tracing).*

Step 7: Remove large bore sheath over a wire under bloodless "dry-closure" conditions.

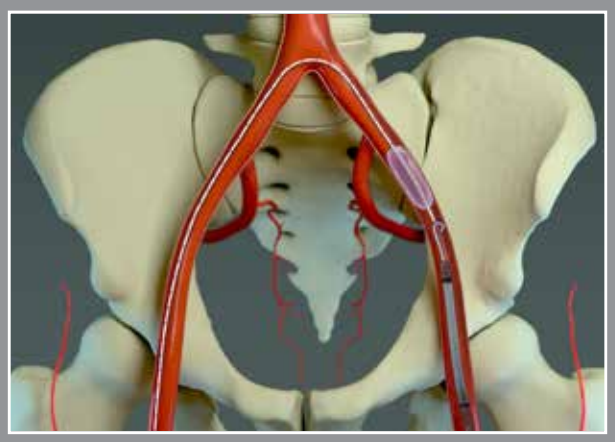

Figure 5: "Dry closure" Occlusion Balloon Inflated in EIA

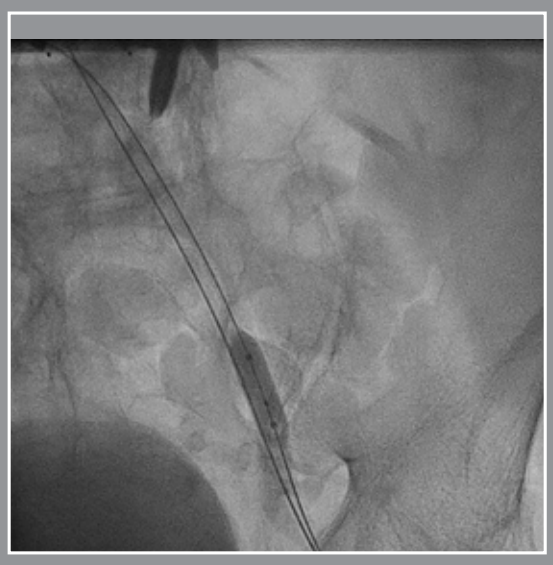

Figure 6: Crossover Balloon Inflated in EIA to Occlude Distal Flow

Step 8: Sequentially secure Perclose VCD, placed previously via pre-close technique (Figure 7). *Optional: If Perclose VCD not inserted pre-procedurally via pre-close technique, an alternative dual Perclose "parallel suture technique" (author personal experience) may instead be utilized for "post-closure" of large bore femoral access.*[5]

Step 9: Perform selective femoral angiography via the inflated (and occlusive) EIA balloon to ensure no vascular injury, effective hemostasis, and good distal flow (Figure 8). *Optional: With 0.018" wire (within the 0.035" wire compatible balloon) in the SFA, place a 3-way stopcock or Tuohy Borst adapter on the end of the balloon and perform contrast injection to facilitate angiography without surrendering distal wire position (Figure 9).*

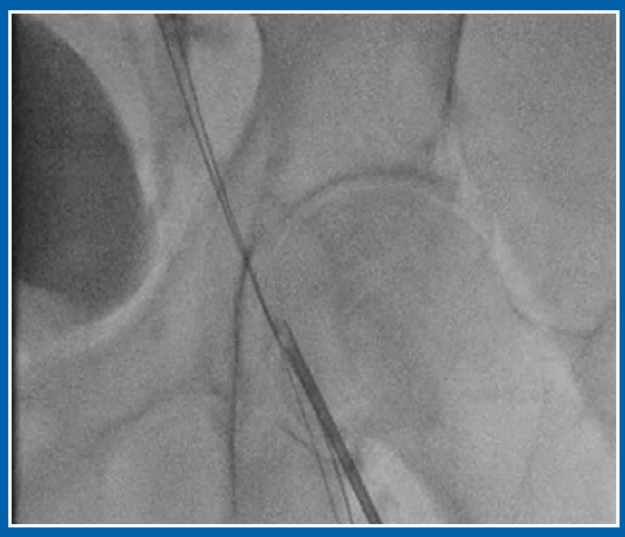

Figure 7: Secure Perclose Sutures Following Sheath Removal (video)

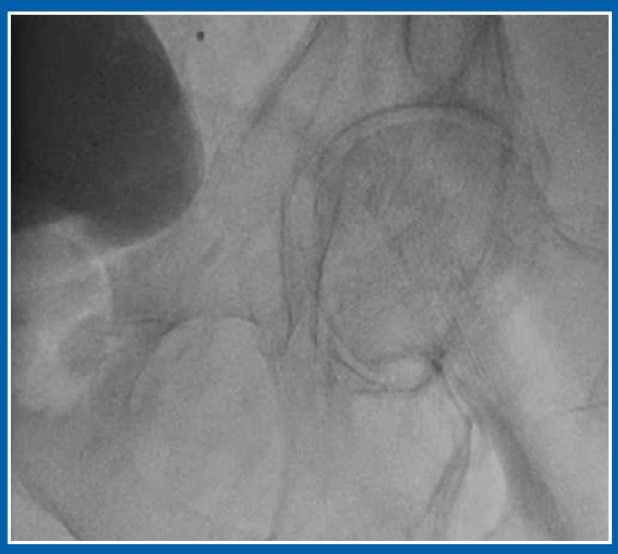

Figure 8: Selective Femoral Angiography Performed Through EIA Occlusion Balloon (video)

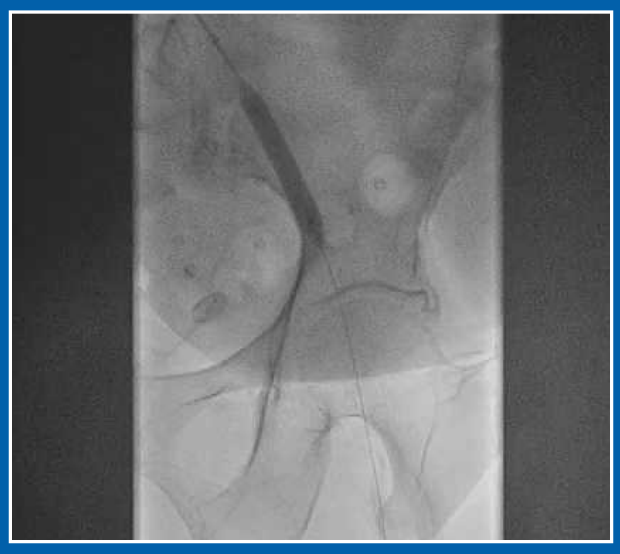

Figure 9: Selective Femoral Angiography Performed Through Inflated 0.035" Occlusion Balloon in EIA With 0.018" Wire in SFA (video)

Step 10: In the event of inadequate hemostasis, contrast extravasation, or flow-limiting "pinching" of the femoral artery by the Perclose sutures, advance the vascular balloon over a wire across the CFA arteriotomy (Figure 10) and perform additional sequential 5 minute inflations (limited in duration to minimize the risk of thrombosis and distal embolization) with adjunctive manual compression until hemostasis is achieved.

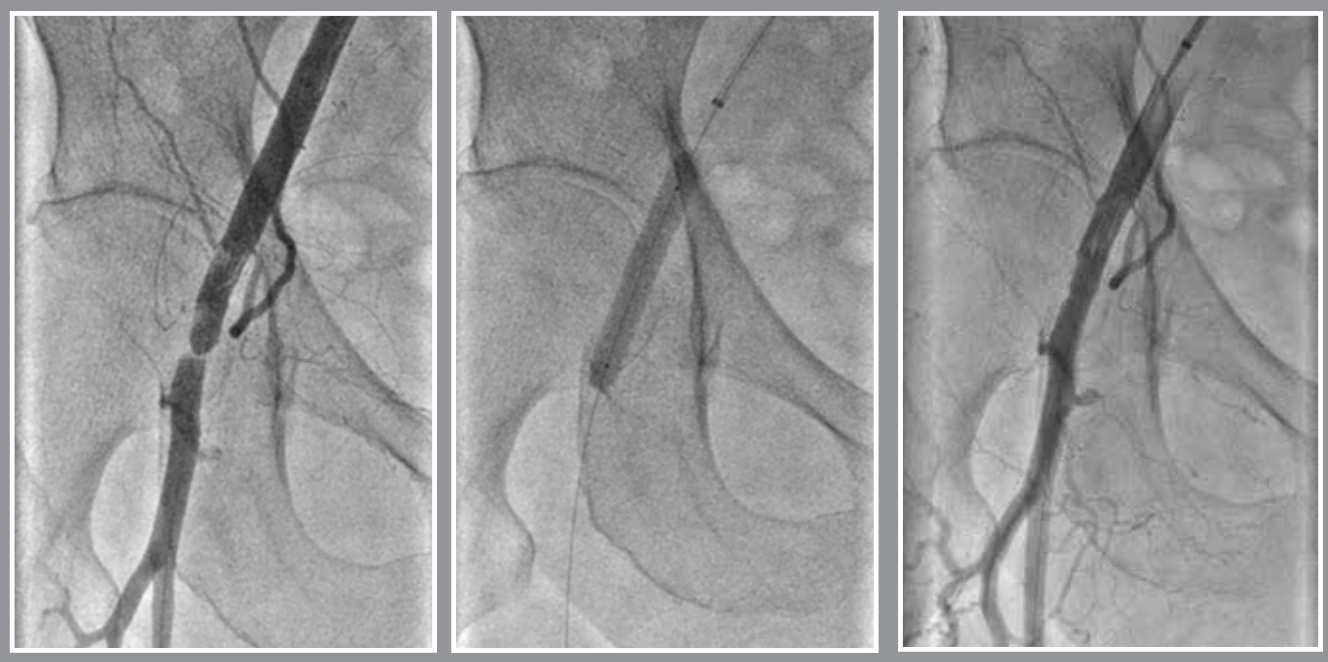

Figure 10: Transradial Vascular Balloon Inflated Across CFA Arteriotomy to Resolve Perclose "Pinch", Address Flow Impairment, and Achieve Hemostasis

Step 11: Remove crossover occlusion balloon. *Optional: In extreme circumstances of major vascular injury unsuccessfully managed with sequential balloon occlusion, a covered stent can be delivered and deployed across the common femoral arteriotomy site as a final bail-out strategy (Note: If a sheathless strategy [Step 4] is employed, a new femoral or radial sheath may need to be utilized to deliver a covered stent).*

Step 12: Apply light external manual pressure for 5 minutes (or longer) to complete hemostasis.

Step 13: Once final hemostasis of the large bore access site is achieved, remove the contralateral femoral (or radial) sheath and perform non-large bore access site closure and hemostasis utilizing current best practices.

Summary

- Safe vascular closure deserves as much attention as safe vascular access, particularly when using large bore sheaths.
- Cross-over balloon occlusion technique (CBOT) is simple, reliable, convenient, and reproducible.
- Balloon occlusion provides a "dry" environment for controlled vascular closure and hemostasis of large bore sheaths.
- Angiography via the occlusion balloon effectively assesses for vascular injury, adequate hemostasis, and preserved distal flow before, during, and after sheath removal.
- Catheter access to the large bore sheath site (and wire access more distally) permits immediate rescue treatment of Perclose "pinches," major vascular injury, bleeding, and distal flow compromise.
- CBOT safely facilitates percutaneous mechanical circulatory support (MCS) explantation several days (or more) following device insertion.
- CBOT should be in the arsenal of all operators employing large bore sheaths.

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CHAPTER 2 | SECTION FOURTEEN

Axillary "Dry Closure"

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Overview

Successful axillary arteriotomy site hemostasis is a crucial step in preventing bleeding and hematoma formation, and consequent brachial plexus injuries or vascular complication, including pseudoaneurysm and arteriovenous fistula (AVF) formation. When large bore sheaths are used, manual compression might be inadequate to achieve complete or immediate hemostasis, especially in obese patients, due to the lack of a reliable bony surface to pin the vessel against.[1]

Previous case series have reported a high incidence of brachial plexus injuries in up to 13% of patients after percutaneous axillary artery cannulation. Multiple mechanisms are involved; however, compressing hematomas is one of the most important preventable causes, and in the aforementioned reports, a standardized "dry closure" technique has not been involved. Small hematomas can result in a disproportionate number of clinically manifest nerve injuries due to the presence of multiple fibrous sheaths enclosing the axillary artery as well as the brachial plexus cords and their respective peripheral nerve branches, including the axillary sheath and the inelastic medial brachial fascial compartment (MBFC).[1-3]

In our rapidly growing multicenter experience of axillary artery management in large bore arteriotomies, plexopathies and nerve injuries have not been reported. This might have been the result of ultrasound-guided access and the use of "dry closure" technique. Furthermore, "dry closure" technique coupled with double Perclose or "hybrid closure" techniques can reduce the risks of bleeding and vascular complications and facilitate successful, rapid hemostasis.[4,5]

Equipment and procedural considerations for "dry closure"

Procedure

1. After removal of the axillary device, advance a 0.035" supportive, exchange-length wire in a retrograde fashion through the sheath into the descending aorta.
2. Advance a 0.018" exchange length wire from the ipsilateral radial artery to the descending aorta or from the femoral artery to the brachial artery if not already inserted prior to axillary artery cannulation.
3. Position a 0.035" compatible, over the wire, peripheral balloon, sized with 1:1 fashion with the axillary artery (usually 6–8 mm x 40 mm) just proximal to the arteriotomy site over the 0.018" wire. We usually select a balloon length of 40 mm, as we find it more valuable in successfully dealing with vascular complications; nevertheless, shorter balloons can be used. A Y-adapter can be connected to the flush port of the balloon to perform selective angiography through the balloon tip.
4. Inflate the balloon to 3–4 atmospheres and remove the sheath while maintaining the 0.035" wire in place.
5. If two Perclose devices were initially deployed, pull the tying strands and push the preformed slipknots down with the aid of the knot pusher. Slowly deflate the balloon. If adequate hemostasis is achieved, remove the 0.035" wire and lock the knots by retracting the locking strand. Perform completion angiogram through the balloon tip to assess for hemostasis and any vascular complications.
    - In case of inadequate hemostasis, reinflate the peripheral balloon. Confirm adequate pushing of the slipknots by repeating the previous step.
    - If hemostasis is still inadequate, attempt bailout "hybrid closure." Lock the knots. Insert a 6 Fr sheath over the 0.035" wire and slowly deflate the balloon. If adequate hemostasis is achieved, deploy a 6 Fr Angio-Seal™ using the 0.035" wire. Perform completion angiogram through the balloon tip. Conversely, if there is persistent extravasation around the 6 Fr sheath, we suggest inserting an 8 Fr sheath in its place and then using an 8 Fr Angio-Seal or additional Perclose as needed.
6. If only one Perclose device was initially deployed in preparation for planned "hybrid closure," pull the tying strand and push down the slipknot with the aid of the knot pusher. Lock the knot. Insert an 8 Fr sheath over the 0.035" wire and slowly deflate the balloon. If adequate hemostasis is achieved, deploy an 8 Fr Angio-Seal using the 0.035" wire. Perform completion angiogram through the balloon tip.
7. If inadequate hemostasis was noticed after the completion of the pre-close or "hybrid closure," advance the balloon to cover the arteriotomy site. Prolonged inflation (10–15 minutes) coupled with manual compression can be successful. Complete heparin reversal with protamine is not recommended to prevent acute ischemic complications.
8. Covered stents—iCAST (Atrium Med) or GORE® VIABAHN® (Gore Medical) 6–10 x 30–50 mm—can be used as a last resort if the above methods failed. Take extreme care to appropriately size the stents. Self expanding stents are typically oversized by 1 mm for the native target vessel, whereas balloon expandable stents are typically sized in 1:1 fashion. We suggest the use of self-expanding (VIABAHN) stents in this area as the axillary artery is prone to significant movement and flexion. However, no long term data regarding covered stent patency in this location is available.

Post closure complications

Neurological and vascular complications can infrequently occur after axillary arteriotomy closure. Early recognition and management of such complications can prevent irreversible neurological damage or significant morbidity.

Brachial plexus injury is the most feared complication. The development of upper extremity neurological symptoms can be a sign of compressing hematomas. Immediate surgical consultation and surgical evacuation is recommended as the reversal of neurological deficits is dependent on prompt hematoma evacuation.

Acute axillary artery closure or acute axillary artery stenosis can occur after completion of arteriotomy closure, and can be diagnosed when performing completion angiogram. Percutaneous transluminal angioplasty (PTA), performed using the same balloon used during “dry closure,” is usually adequate for managing such complications, with excellent angiographic results. However, delayed presentation of axillary artery stenosis can occur. Noninvasive imaging can aid in diagnosis, and similarly, management with PTA is usually adequate. It is important to note that the brachial artery is highly collateralized via the subscapular artery that also, in most instances, marks the beginning of the third portion of the vessel, which is why we typically advocate access proximal to its origin.

Pseudoaneurysm can be diagnosed during completion angiogram and should be suspected in symptomatic patients. Symptoms might include axillary fossa pain, due to swelling or nerve compression, or upper limb swelling due to venous obstruction or deep vein thrombosis. AVF should be suspected in patients presenting with upper limb swelling. Noninvasive imaging can aid in diagnosing these complications. Management can be conservative, endovascular, or surgical—in much the same way it is addressed in the femoral artery—and should be personalized depending on the symptoms and associated complications.

Case examples

Case 1: Axillary artery “dry closure” using ipsilateral radial artery

Through the right radial artery access, a 0.018” PLATINUM PLUS guidewire (Boston Scientific) was advanced into the descending aorta prior to axillary artery cannulation, and a 7 mm x 40 mm 90 cm 0.035” compatible peripheral balloon was advanced over the wire. A Y-adapter was connected to the flush port of the balloon. This allowed the performance of selective angiography of the axillary artery through the balloon tip to aid its cannulation.

After axillary cannulation, the balloon was advanced into the descending aorta in preparation for “dry closure” after the completion of the transaxillary procedure (Figure 1).

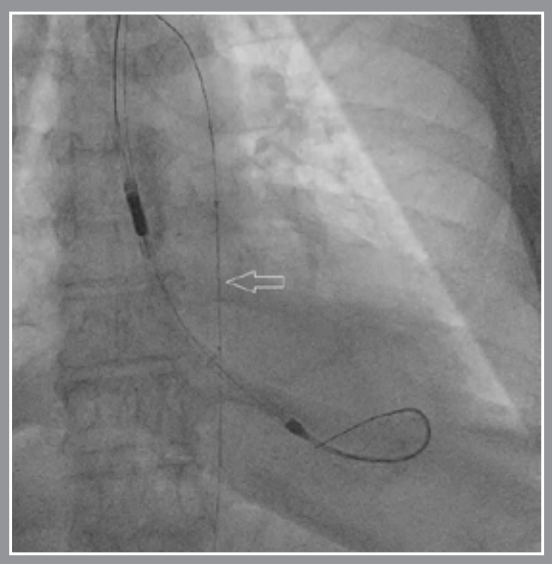

Figure 1: Balloon in Descending Aorta in Preparation for “Dry Closure” (white arrow)

After removal of the axillary equipment, a 0.035" wire was inserted through the axillary sheath to the ascending aorta. The balloon was then pulled back to the subclavian artery and inflated at its nominal pressure (Figure 2) and "dry closure" was performed as described above.

The balloon was then deflated and pulled back to the brachial artery. Final angiogram using the balloon tip was then performed to check for hemostasis and any other complications (Figure 3).

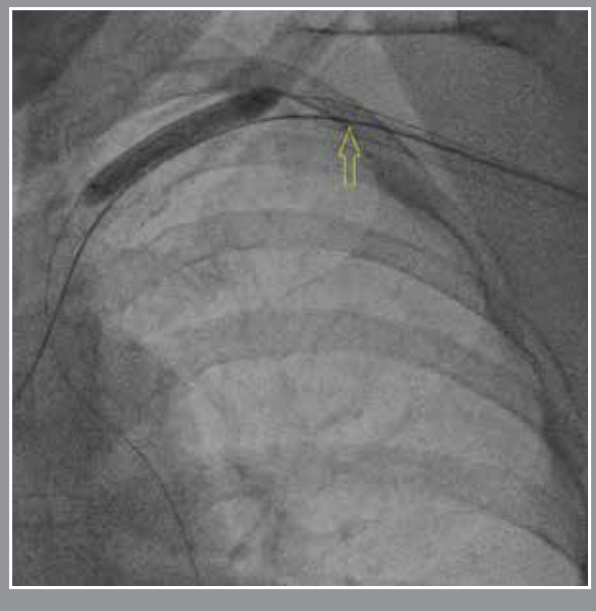

Figure 2: Retrograde Wire in Axillary Sheath (yellow arrow)

Balloon pulled back to subclavian and inflated at nominal pressure for "dry closure"

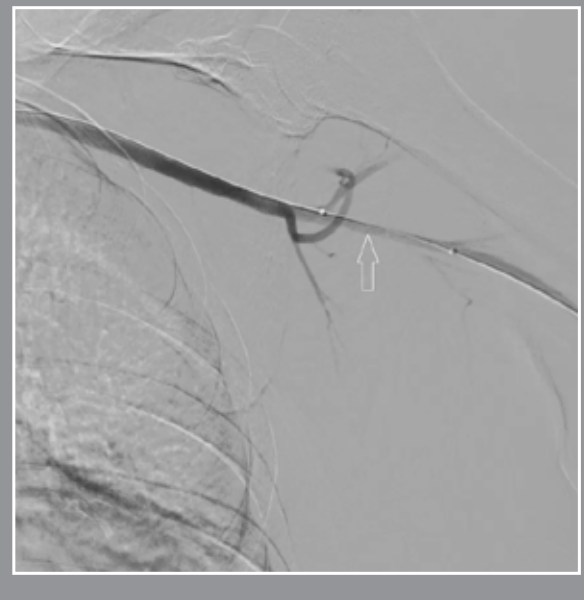

Figure 3: Balloon Deflated (white arrow) and Final Angiogram Performed to Check for Hemostasis

Case 2: Inadequate hemostasis managed with prolonged inflation

After the completion of the pre-close technique, inadequate hemostasis at the puncture site was noted. Axillary artery angiography demonstrated moderate extravasation (Figure 4A).

The balloon was advanced to the extravasation site and inflated for 10 minutes. Additionally, manual compression was held. Repeat angiogram showed resolution of the extravasation (Figure 4B).

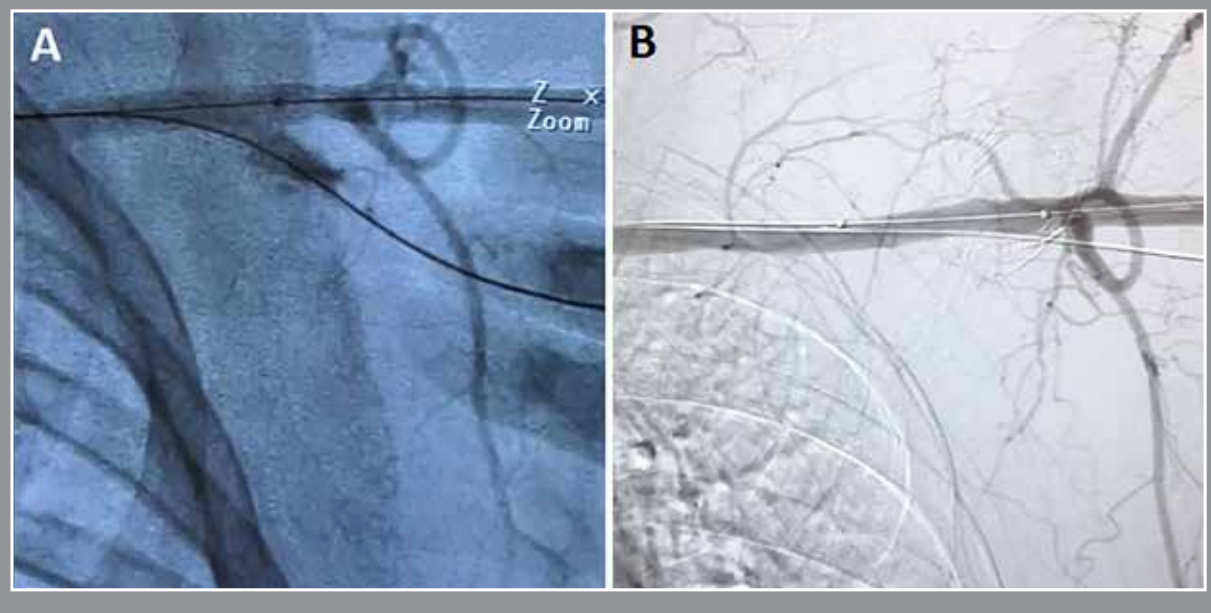

Figure 4: Resolution of Moderate Extravasation

(A) Moderate extravasation and (B) resolution after balloon inflation and manual compression

Case 3: Failed pre-close technique managed with covered stent

After the completion of pre-close technique, severe extravasation was seen at the arteriotomy site (Figure 5A). Prolonged balloon inflation and manual compression failed to achieved hemostasis. A covered stent (VIABAHN) was deployed at the arteriotomy site. Extreme care was taken to appropriately size the stent with the axillary artery (stent size typically 1 mm larger than target vessel for self-expanding stents) and ensure that the stent length was adequate to cover the arteriotomy site without obstructing key axillary artery branches (Figure 5B).

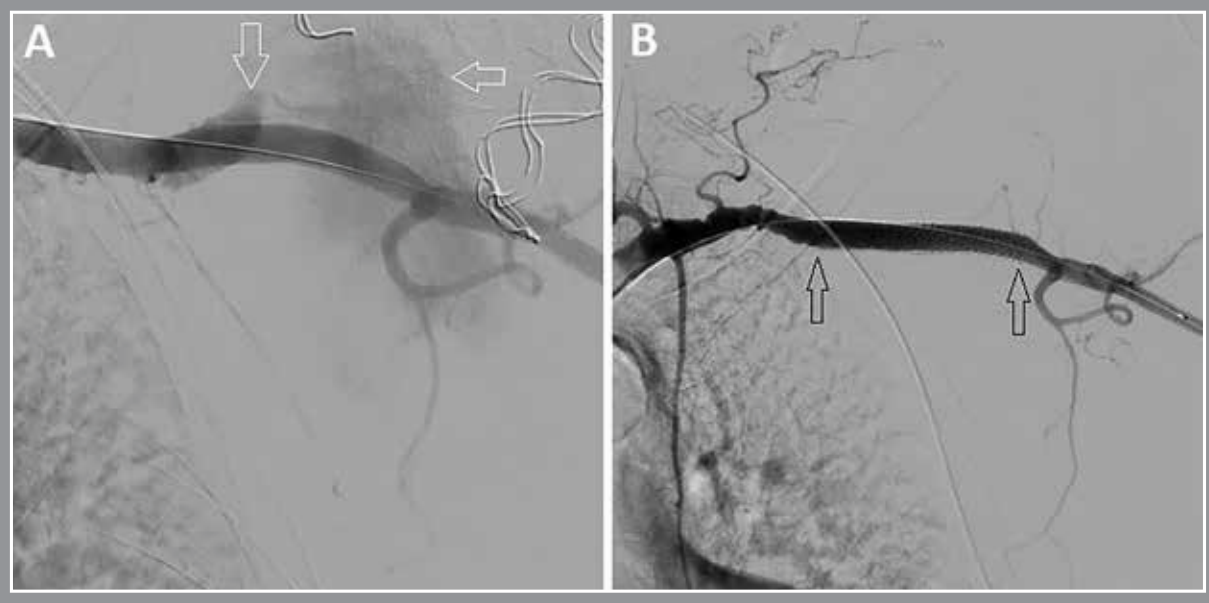

Figure 5: Resolution of Severe Extravasation
(A) Arrows pointing to severe extravasation and (B) stent borders after deployment of covered stent to resolve extravasation

Pro Tips

- √ "Dry closure" is highly recommended during axillary arteriotomy closure to prevent vascular and neurological complications.
- √ Double Perclose is the most commonly used technique; however, "hybrid closure" can be used as a primary strategy or for bailout.
- √ Always perform completion angiogram through the hemostasis balloon tip to confirm adequate hemostasis and rule out vascular complications.
- √ Covered stents should only be used as a last resort if other hemostasis techniques—including double Perclose, "hybrid closure," and prolonged internal balloon inflation in conjunction with external pressure—have failed. Manual hemostasis is achievable; however, vigilance is necessary.
- √ Early recognition and management of neurological and vascular complications is crucial to prevent irreversible damage and significant morbidity.

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CHAPTER 3

Preventing, Identifying, and Managing Access and Closure Complications

CHAPTER 3 | SECTION ONE

Distal Embolization / Leg Ischemia

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Overview

Vascular access—especially large bore access—can result in distal embolization and leg ischemia. This section briefly explores these access-related complications from pre-procedural planning through best practices for complication management.

Predictors of distal embolization

Distal embolization is associated with the traditional predictors for vascular access complications:

- Small vessel size (ie, sheath/vessel ratio of >1.05)
- Female sex
- Vessel calcification

Additional predictors include:

- Inadequate anticoagulation
- Injudicious use of closure devices

Strategic pre-procedural planning

Large bore femoral access must start with meticulous pre-procedural evaluation. This consists of the traditional physical examination and computed tomography (CT) evaluation of the aorta and iliac vessels. The CT examination is critical for assessing peripheral arterial disease, iliac/femoral calcification, and excessive tortuosity. Similarly, CT is indispensable for vessel sizing to evaluate whether the iliac arteries can accommodate large sheaths/equipment.

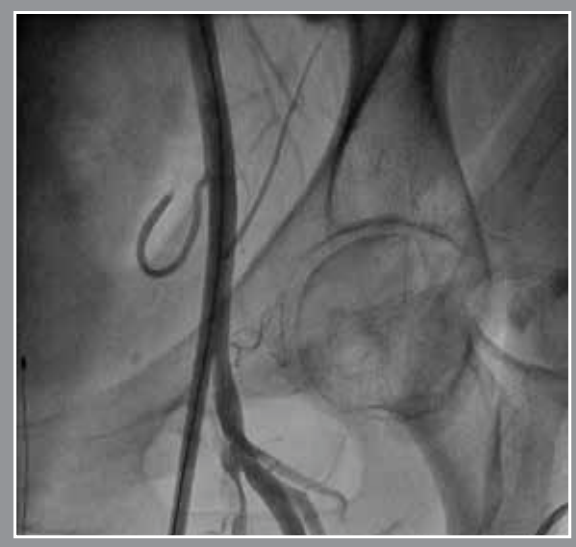

Figure 1: Acute Limb Ischemia During Impella® High-risk PCI; Sheath in Place

How often do distal embolization and leg ischemia happen?

The second Valve Academic Research Consortium (VARC-2) consensus includes distal embolization and leg ischemia as part of its vascular access site complications.[1] As shown in Table 1, these may be major complications or minor complications, depending on the severity of overall outcome. The incidence of major vascular complications ranges from approximately 2–17% and these complications are overwhelmingly due to bleeding; embolization and leg ischemia comprise a minority of complications.

Table 1: VARC-2 Distal Embolization Definitions[1]

Major Complications	Minor Complications
• Distal embolization (non-cerebral) from a vascular source requiring surgery or resulting in amputation or irreversible end-organ damage • The use of unplanned endovascular or surgical intervention associated with death, major bleeding, visceral ischemia, or neurological impairment • Any new ipsilateral lower extremity ischemia documented by symptoms, physical exam, and/or decreased or absent blood flow on lower extremity angiogram	• Distal embolization treated with embolectomy and/or thrombectomy and not resulting in amputation or irreversible end-organ damage • Any unplanned endovascular stenting or unplanned surgical intervention not meeting criteria for major vascular complication • Vascular repair or need for vascular repair (surgery, ultrasound-guided compression, transcatheter embolization, or stent-graft)

Modified from Kappetein et al.

Equipment and procedural considerations

Since distal embolization frequently occurs when accessing heavily calcified or aneurysmal vessels, or vessels with ulcerated lesions, ultrasound is the sine qua non for contemporary large bore access and should be employed in 100% of cases. While this may be easier said than done, use ultrasound to avoid calcium as much as feasible. This is critical, as it allows for precise puncture placement and avoidance of high, bifurcation, or low "sticks." Most importantly, access the femoral artery at 12 o'clock and avoid side wall sticks. Then place a small sheath (4-6 Fr) and obtain an angiogram to confirm vessel anatomy. This is the time to reassess access and re-stick if necessary.

Best practices

Basic techniques of sheath aspiration and maintaining appropriate anticoagulation are key. ACT checks are mandatory. Once diagnosed, acute limb ischemia should be aggressively and immediately pursued.

Additional access is mandatory with large bore access. When distal embolization occurs, contralateral (femoral) access offers significant diagnostic and safety benefits. With contralateral access, it is possible to perform angiography after large bore site closure to verify hemostasis and diagnose distal embolization and distal runoff vessel patency. Radial access is similarly useful for performing control angiography after large bore access closure.[2] However, equipment choices are limited due to length and size considerations.

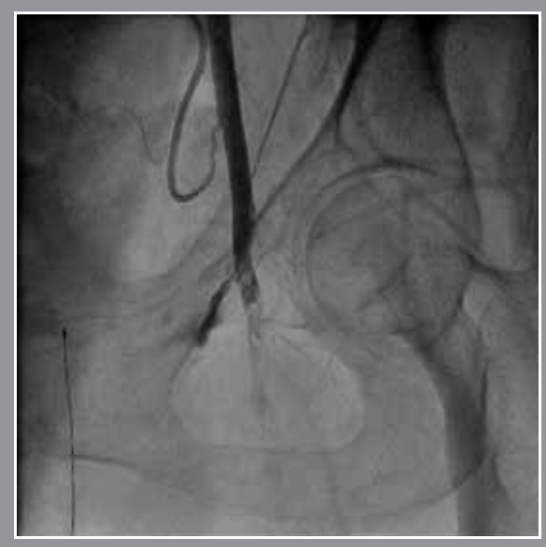

Figure 2: Contralateral Injection With Access Site Bleeding and Thrombus-filled Femoral Artery

While closure devices have become the must-have equipment for access-site management of large bore access, they should be used judiciously to avoid complications in patients with unfavorable anatomy. The pre-close technique has become widely adopted and consists of placing two ProGlide® (Abbott Vascular) devices at 45-degree angles from each other prior to placing the large bore access. On rare occasions, a third ProGlide may be necessary. Some operators choose an Angio-Seal™ (Terumo) device as a third "rescue" device. The Manta® closure device (Essential Medical, Inc), not yet approved in the United States, offers great promise as the dedicated large bore access closure device.[3]

Vascular closure devices almost invariably cause a minor degree of vessel stenosis. On rare occasions, vascular closure devices can cause clinically significant vessel stenosis or vessel closure with associated thrombosis. The thrombosis is due to stagnant flow. It is important to stay vigilant as contralateral balloon inflation technique used to facilitate hemostasis can itself cause vessel thrombosis and distal ischemia.

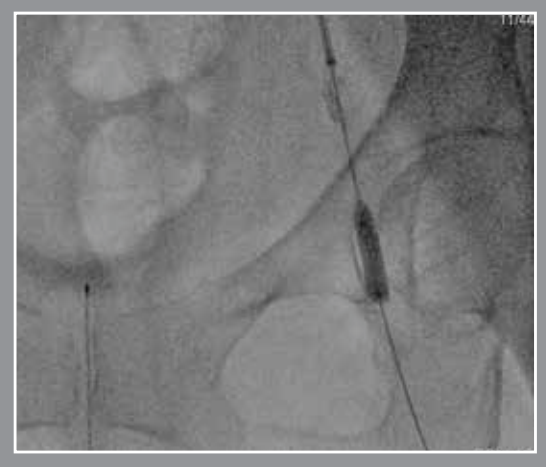

Figure 3: Contralateral Access, Balloon Tamponade, and Balloon Angioplasty

Since distal embolization can occur at the time of sheath removal, large bore sheaths should only be removed in the cardiac catheterization laboratory with skilled staff available. Access to angiography is key should complications occur. Sheath removal in the intensive care unit is discouraged.

Occlusive large bore sheath management

On occasion, large bore sheaths can become occlusive in small femoral or iliac arteries. Several advanced techniques have been proposed using antegrade sticks for external ipsilateral or contralateral bypass techniques to allow distal leg perfusion.

Pro Tips

To successfully prevent and manage distal embolization and ischemia:

- √ Use CT for procedure planning
- √ Use ultrasound for access
- √ Always have contralateral access and take angiography after sheath removal
- √ Use closure devices judiciously
- √ Be meticulous with sheath flushing and maintaining anticoagulation (check ACT)
- √ Be ready to intervene with balloon, embolectomy, thrombolytics, stent, or covered stent

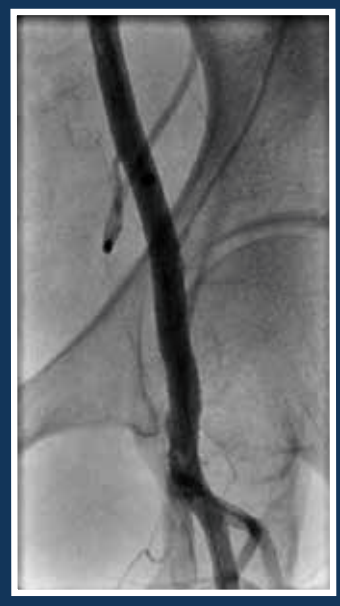

Figure 4: Covered Stent Placement for Access-site Bleeding Control With Residual Thrombus

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CHAPTER 3 | SECTION TWO

Antegrade Limb Perfusion Techniques: Occlusive Sheath Management

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Introduction

Although the trend is smaller caliber catheters, new transcatheter procedures, such as transcatheter aortic valve replacement (TAVR), endovascular aneurysm repair (EVAR), and mechanical circulatory support (MCS), require large bore access to accommodate increasing volumes. Aside from sheath size, characteristics of the blood vessel itself may contribute to complications with the use of large bore sheaths. Indeed, patients undergoing large bore access for high risk coronary interventions or structural heart procedures have a range of peripheral arterial disease with atherosclerosis, calcification, tortuosity, and lumen loss.[1,2] Vascular remodeling leads to increased vessel stiffness and loss of luminal dimensions, which limit arterial expandability to accommodate large diameter sheaths. Insertion of a large bore sheath into such an artery causes trauma to the already fragile endothelium and may predispose the patient to arterial dissection, perforation, thrombosis, or occlusion. Moreover, since coronary artery disease and peripheral vascular disease are components of the same disease spectrum, it is not uncommon to encounter significant iliofemoral arterial disease precluding the use of these vessels for large bore access.[3,4] Alternatives may include axillary, subclavian, carotid, transcaval, or transapical approaches.

Maintaining limb perfusion

The size of the iliac and common femoral arteries varies greatly depending on patient size, comorbidities, and gender. In addition, the caliber of these arteries may be severely diminished by atherosclerosis and their geometry altered by tortuosity.[5,6] Both peripheral vascular disease (PVD) and coronary artery disease (CAD) have similar risk factors, and thus, it is common to encounter the challenge of treating patients with structurally complex coronary arteries with significant concomitant peripheral artery disease (PAD).[3,4,7] Small caliber common femoral and iliac arteries with severe PAD significantly increase the risk for vascular complications. That risk increases greatly as the larger bore sheaths are used.[8-11]

Insertion of a large bore sheath may result in complete vessel occlusion and acute limb ischemia that may threaten limb viability. It is therefore important to ensure adequate perfusion to the limb by careful assessment of the iliofemoral artery prior to insertion of a large bore sheath. Evaluation of the access site can be done easily for TAVR cases since CT scans of the distal aorta and iliofemoral arteries are done routinely. For emergent cases, when the access of large bore sheath has to be done quickly, an iliofemoral angiogram can be performed to evaluate the access site. Subsequent close monitoring is crucial with hourly clinical and Doppler assessment of distal extremity pulses when the sheath is in place. Serial biomarkers evaluation (plasma lactate) is recommended as a surrogate for inadequate limb perfusion and tissue necrosis. Furthermore, thromboembolism can also develop at the sheath site, with embolization occurring during sheath removal. Adequate anticoagulation with frequent monitoring of activated clotting time is recommended.

Management of occlusive sheaths

A challenging clinical scenario often encountered in practice is a patient who is hemodynamically dependent on a short-term mechanical support device and whose large bore sheath is found to be occlusive. Several interventions can be performed in the setting of an occlusive sheath to restore perfusion to the distal lower extremity in such patients.

Peel away sheath

The Impella CP® (Abiomed Inc., Danvers, MA, USA) mechanical support device comes with a specially designed 2-step peel away sheath with a tapered shaft (14 Fr base to 9 Fr tip) that allows for adequate blood flow even in smaller caliber iliofemoral arterial vessels. In the case of an occlusive sheath compromising limb perfusion, peeling away the 14 Fr introducer sheath leaves the Impella with the smaller 9 Fr repositioning sheath, which may be sufficient to restore limb perfusion. One potential complication of this technique is catheter migration. To minimize this complication, two people should carry out this intervention under direct fluoroscopic guidance. Specifically, one operator stabilizes the Impella to avoid any pullback while the other operator peels away the external sheath. The repositioning sheath can then be re-advanced through the arteriotomy site. This maneuver, however, may lead to increased bleeding as the sheath size is tapered down.

External contralateral bypass circuit

If a large bore sheath occludes the external iliac artery and common femoral artery, limb perfusion distal to the large bore access point can be achieved with external contralateral bypass circuit.

1. Using a micropuncture kit, access the ipsilateral superficial femoral artery in antegrade fashion using ultrasound guidance.
2. Over the micropuncture wire advance a 5 Fr short sheath.
3. Obtain a contralateral common femoral artery access with a 6 Fr sheath.
4. Using long extension tubing, connect the sidearm of the contralateral (6 Fr) sheath to the sidearm of the ipsilateral antegrade (5 Fr) sheath using a male-to-male connector. The resulting external femoral-femoral bypass enables blood flow from the contralateral 6 Fr sheath through the sidearm into the sidearm of the ipsilateral 5 Fr antegrade sheath and down the ischemic limb to provide adequate perfusion (Figure 1).
5. The target activated clotting time (ACT) should be higher than standard to maintain the flow (range 200–220 seconds).
6. Hourly serial Doppler ultrasound assessment of the large bore lower extremity pulsations is recommended to monitor perfusion and function of the bypass circuit.

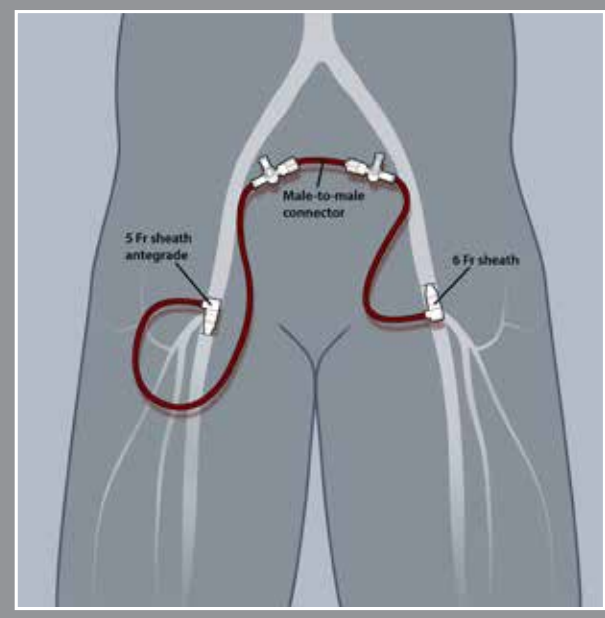


Figure 1: Contralateral Bypass Circuit

Sidearm of the contralateral common femoral artery sheath connected to the sidearm of the ipsilateral antegrade sheath via long extension tubing and a male-to-male connector providing perfusion to the superficial femoral artery.

External ipsilateral bypass circuit

The large bore (13 or 14 Fr) sheath can be used as a conduit to provide flow using the sidearm of the large bore occlusive sheath to create an ipsilateral bypass circuit. The advantage of this strategy is that it does not require a contralateral arterial access.

1. Insert a 4–5 Fr short sheath in the ipsilateral common femoral or superficial femoral artery with a micropuncture kit in antegrade fashion using ultrasound guidance.
2. Connect the sidearm of the ipsilateral antegrade sheath to the sidearm of the large bore occlusive sheath using extension tubing and a male-to-male connector. This technique creates an ipsilateral bypass circuit that provides adequate perfusion to the lower limb. (Figure 2)
3. When using this strategy with an Impella device, do not advance the repositioning sheath into the Impella peel-away sheath to avoid occlusion of the sidearm that is now providing perfusion.

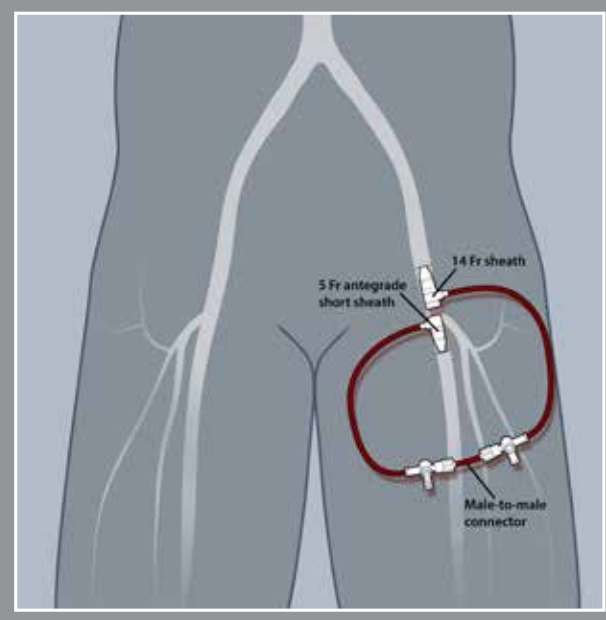


Figure 2: Ipsilateral Bypass Circuit

Sidearm of the large bore sheath connected to the sidearm of the antegrade sheath via a male-to-male connector providing distal perfusion.

Internal contralateral bypass circuit

In patients with complete superficial femoral artery occlusion, antegrade technique is not feasible. In such cases, internal contralateral femoral to profunda bypass might be an option to maintain perfusion to the ischemic limb.

1. Insert a 7 Fr sheath in the contralateral common femoral artery.
2. Through 7 Fr sheath, advance and selectively engage a 5 Fr catheter (IMA, OMNI flush) into the ipsilateral common iliac artery using up and over technique.
3. Advance a 0.035 hydrophilic wire (Terumo Glidewire® guidewire) through this system across the aorto-iliac bifurcation, past the occlusive large bore sheath, and beyond the arteriotomy site into the ipsilateral profunda femoris artery.

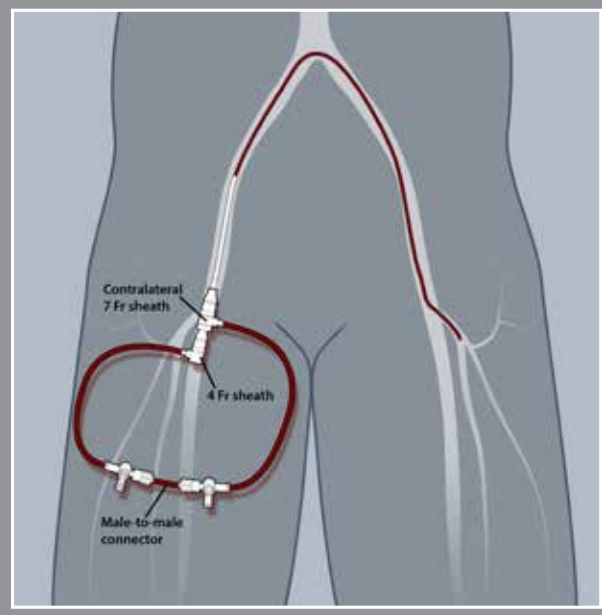
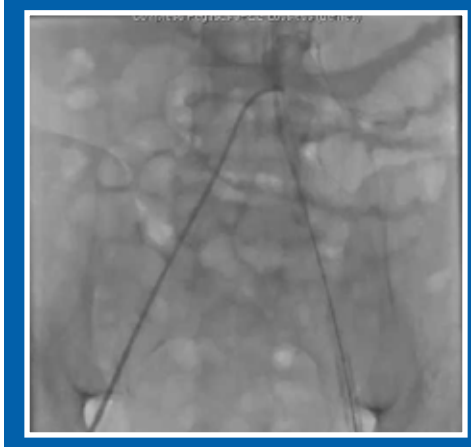
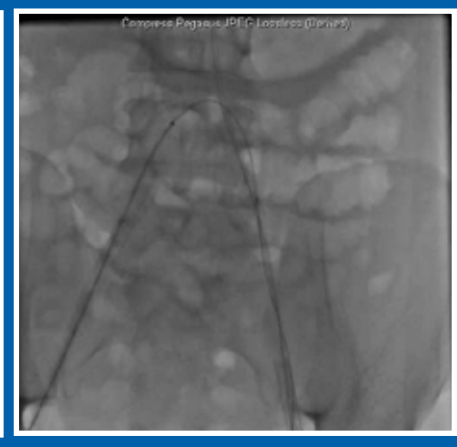


Figure 3: Internal Femoral-Femoral Contralateral Bypass

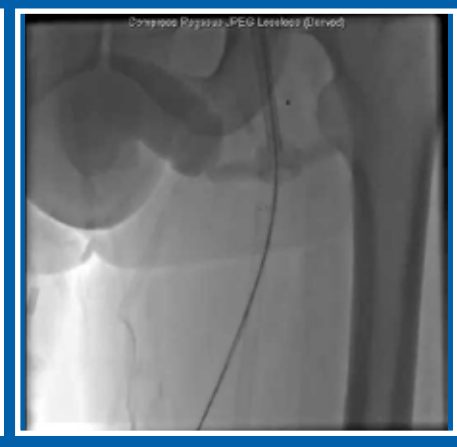
4. Exchange the 5 Fr catheter for a 4 Fr, 45–55 cm long sheath.
5. Advance the 4 Fr, 45–55 cm long sheath over the wire into the ipsilateral profunda femoris.
6. By connecting the sidearm of the 7 Fr contralateral sheath to that of the 4 Fr, 45–55 cm sheath using a male-to-male connector, a bypass circuit is created whereby blood flows from the contralateral femoral artery via the connected sidearms, through the crossover 4 Fr sheath into the ipsilateral profunda femoris artery distal to the occlusive sheath providing sufficient perfusion to maintain limb viability. (Figure 3 and 4).



Occlusive left sheath.
Using contralateral 7 Fr sheath, advance IMA catheter over Glide Advantage wire



Advance Glide Advantage wire long 4 Fr (45 or 55 cm) into the profundal femoral artery



Connect sidearm of the 7 Fr sheath to the 4 Fr sheath using male-to-male connector

Figure 4: Internal Contralateral Bypass Conduit (videos)

Internal contralateral femoral to ipsilateral profunda femoris bypass circuit showing the sidearm of the contralateral (right) 7 Fr femoral sheath connected to the sidearm of the 4 Fr 45–55 cm crossover sheath via a male-to-male connector providing perfusion to the ipsilateral (left) profunda femoris artery distal to the occlusive (left) large sheath. An in vitro demonstration of the circuit is also displayed.

Axillary alternative access occlusive sheath

Although it is typically smaller than the common femoral artery, the axillary artery has been shown to be an acceptable alternative access site for MCS in the presence of severe PAD.[12,13] Angiographic assessment and identification of the axillary artery branches is important to precisely define the access point that is lateral to the thoracoacromial artery and medial to the circumflex humeral and subscapular arteries "sweet spot" (Figure 5). After insertion of the large bore sheath, perform angiogram of the axillary artery to evaluate distal perfusion beyond the access point. In rare cases, perfusion of the distal arm can be compromised, especially when the axillary artery is less than 5.5 mm. In these cases, perform an internal or external bypass conduit to restore perfusion to the ipsilateral hand.

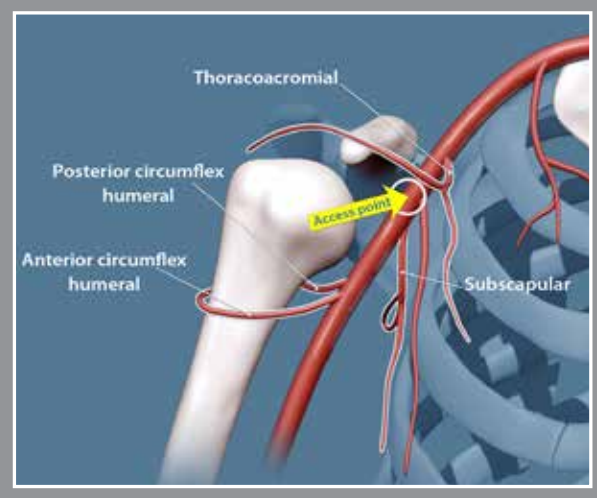


Figure 5: Axillary Artery Segments and Branches

"Roadmap angiogram" to define access point landmarks. Recommended axillary artery access is lateral to the thoracoacromial artery and medial to the circumflex humeral/subscapular artery.

External axillary-radial bypass

In cases when occlusion of the axillary artery is anticipated due to small axillary artery, an ipsilateral radial artery access should be done preemptively.

1. Insert a 6 Fr sheath in the ipsilateral radial artery.
2. Using long extension tubing and a male-to-male connector, connect the sidearm of the large bore to the sidearm of the radial sheath. This creates a bypass circuit whereby blood flows from the ipsilateral axillary artery into the ipsilateral radial artery, providing sufficient perfusion to the arm and hand (Figure 6).

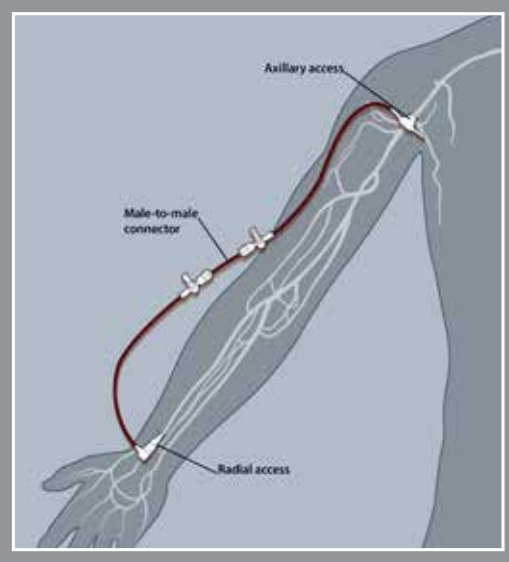


Figure 6: External Ipsilateral Axillary Radial Bypass

External axillary-brachial bypass

Another technique is used to maintain perfusion to the arm with compromised perfusion due to large bore sheath in the axillary artery.

1. Antegrade access of the ipsilateral brachial artery is done using ultrasound or angiographic guidance.
2. If there is not enough flow distal to the occlusive sheath, advancing the 0.038" wire beyond the large bore access point into the brachial artery can be used as a guide to the brachial artery for needle stick.
3. Under direct fluoroscopy, access the vessel with micropuncture needle exchanged for 6 Fr sheath.

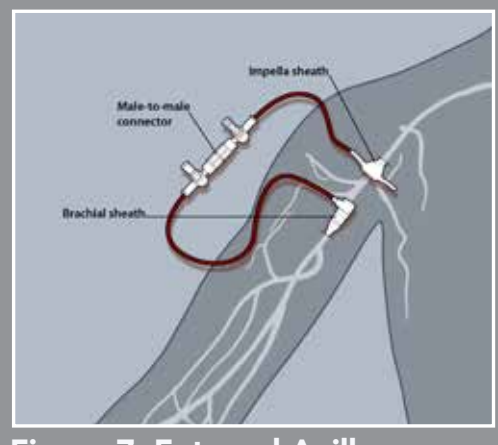


Figure 7: External Axillary-Brachial Bypass

4. Connect the sidearms of the large bore and the brachial sheath using a male-to-male connector (Figure 7).

Internal femoral-axillary bypass

1. Using a JR4 guiding catheter, advance a 0.038" Glidewire into the ipsilateral brachial artery via a 6 Fr femoral artery sheath.
2. Remove the JR4 guide catheter and exchange it for a 4 Fr guiding catheter that is advanced over the Glidewire into the ipsilateral brachial artery.
3. Remove the wire and connect the 4 Fr guide catheter sidearm to the 6 Fr sidearm using a male-to-male connector (Figures 8 and 9).

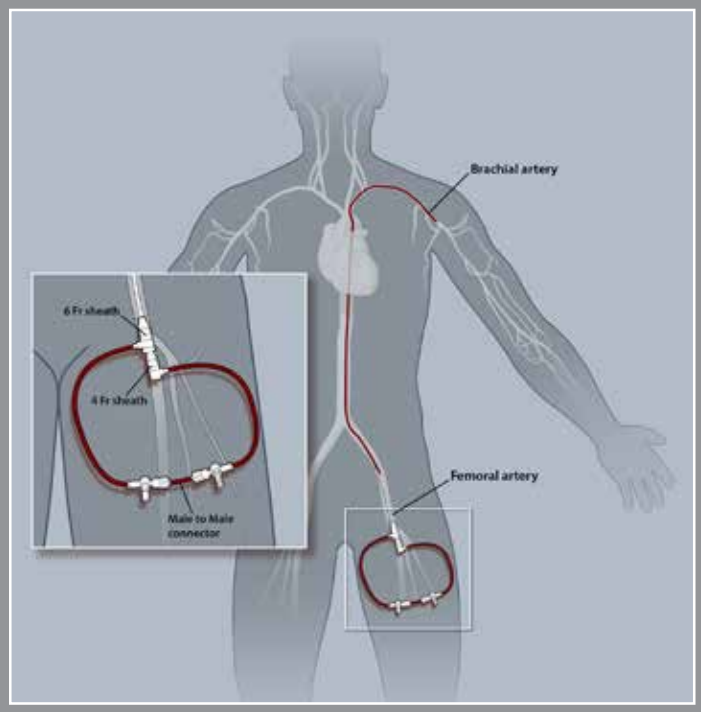


Figure 8: Internal Femoral-Brachial Bypass

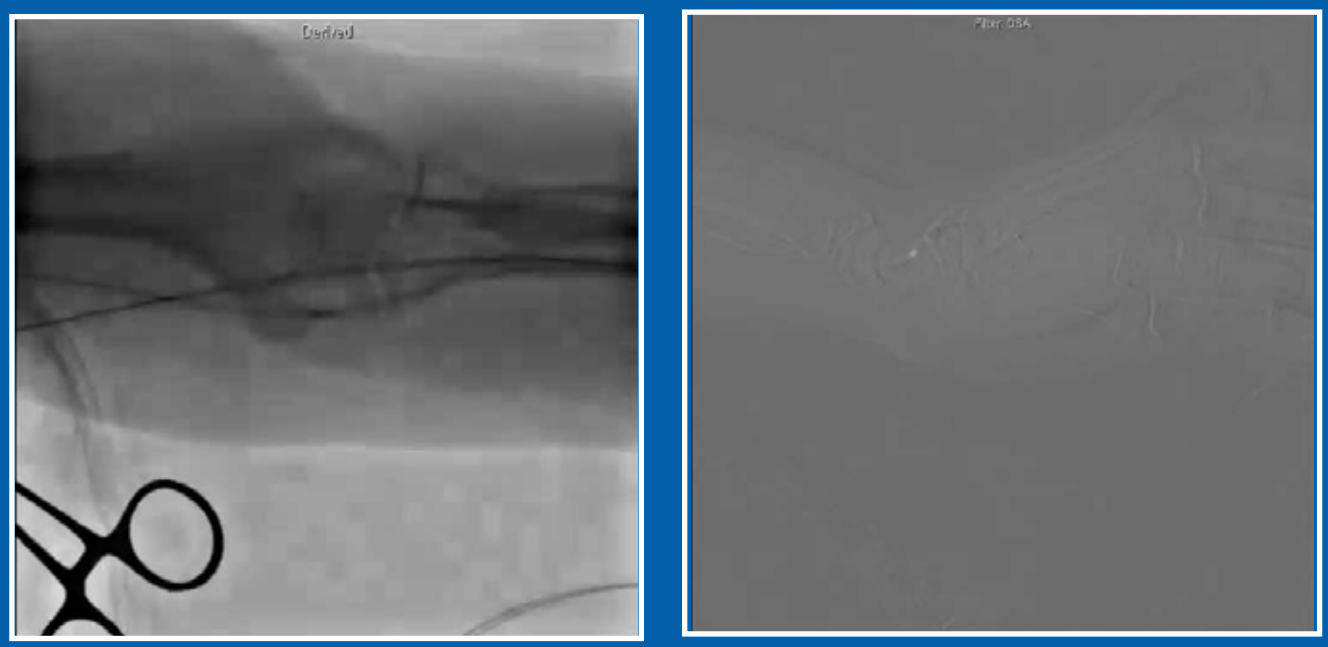


Figure 9: Internal Femoral-Brachial Bypass (video)

Pro Tips

- √ Occlusive sheaths are increasingly encountered with large bore accesses.
- √ If occlusive sheath is anticipated, strongly consider preemptively placing a anterograde sheath prior to large bore sheath placement.
- √ Use one of the methods described in this section to provide prolonged hemodynamic support and maintain large bore sheath access without jeopardizing perfusion to the extremity.
- √ Many of the complications of vascular access can be managed effectively in the catheterization laboratory.
- √ As the scope of interventional cardiology is widening, it is prudent for the interventional cardiologist to become familiar with obtaining and managing large bore accesses.

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CHAPTER 3 | SECTION THREE

Massive Transfusion

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Overview

All operators performing vascular access procedures should be prepared to resuscitate patients who are suffering from large volume blood loss. Prompt intervention with close monitoring can be lifesaving in these cases. Box 1 lists a minimum set of preparatory measures. Riskin et al. have shown that a protocol-driven process improves communication among departments, improves the availability of and reduces delays in obtaining blood products, and improves patient outcome.[1] Figure 1 presents a suggested massive transfusion protocol (MTP).

Various definitions of massive transfusion exist.[2] Definitions that utilize 24 hour timelines (eg, replacement of one entire blood volume within 24 hours or transfusions of >10 or >20 units of packed red blood cells (PRBCs) in 24 hours) are not practical in situations such as vascular access bleeding where the appropriate time course for intervention is measured in hours. More appropriate definitions may be:

- Transfusion of >4 units of PRBCs in 1 hour when ongoing need is foreseeable
- Replacement of 50% of total blood volume (TBV) within 3 hours

Box 1: Patient Preparation and Monitoring

- Large bore intravenous (IV) access: Two peripheral IV (14/16-gauge) cannulae or special wide bore cannulae (insertion sheath)
  - Central venous catheters, due to their length and high resistance, do not allow flow rates as large as large bore cannulae. They can be useful for assessing hemodynamic status, administering vasoactive agents, and blood sampling. We recommend using a multiport trauma line that allows for fluid administration and pressure monitoring.
  - In emergency situations, cannulation of external jugular vein may be considered.
- Warming devices: Inline fluid warmers and surface warmers
- Continuous core temperature monitoring, pulse oximetry
- Electrocardiography
- Invasive arterial pressure monitoring
- Adequate amount of colloid, crystalloid, infusion sets, and IV calcium preparations
- Communication with blood bank about emerging massive blood loss situation
- Adequate personnel for sending samples for investigations and getting blood and blood products
- ABG with hemoglobin, electrolyte and lactate levels, repeated hourly, are useful in directing therapy
- Rapid infusion pumps or pressure bags to speed the fluid infusion rate
- Mechanical ventilation and continuous hemodynamic monitoring are usually required due to occurrence of circulatory overload and hemodynamic/biochemical instability
- Close monitoring of urine output

Initial volume replacement

Volume resuscitation is a vital component of blood loss management and offers hemodynamic stabilization in mild and moderate cases. Compensatory mechanisms maintain vital organ perfusion until about 30% TBV loss.[3]

Red blood cells (RBCs) are administered to maintain hemodynamic stability and to provide appropriate oxygen delivery. At rest, oxygen delivery is normally 4 times oxygen consumption, indicating the presence of an enormous reserve. Thus, if intravascular volume is maintained during bleeding and cardiovascular status is not impaired, oxygen delivery will theoretically be adequate until the hematocrit (packed cell volume) falls below 10%. This is predicated on the ability of the patient to maintain and augment cardiac output and to increase oxygen extraction. Cardiologists are often faced with patients who cannot increase cardiac output to compensate for decreased oxygen content. In these patients, oxygen consumption becomes delivery dependent with a mismatch contributing to anaerobic metabolism. Thus, there is no strict cutoff of packed cell volume that can determine the need to intervene.

Several issues related to initial volume resuscitation exist:

- **Inadequate resuscitation:** Hypoperfusion leads to lactic acidosis, systemic inflammatory response syndrome (SIRS), disseminated intravascular coagulation, and multiorgan dysfunction. It also increases the expression of thrombomodulin on endothelium, which then complexes with thrombin, which in turn leads to a reduced amount of thrombin available to produce fibrin and increases the circulating concentrations of anticoagulant activated protein C, which worsens the coagulopathy.
- **Overly aggressive resuscitation:** Massive resuscitation results in transfusion associated circulatory overload (TACO), a well-known condition that occurs due to rapid transfusion. Although this is seen commonly in elderly patients, small children, and patients with compromised left ventricular function, it can also be seen in otherwise healthy patients requiring massive transfusion.
- **Low colloid oncotic pressure** can result from administration of large amounts of crystalloid, giving rise to interstitial edema that can in turn lead to abdominal compartment syndrome.

Correction of the deficit in blood volume with crystalloid volume expanders will generally maintain hemodynamic stability, while transfusion of red cells is used to improve and maintain tissue oxygenation.[4] Each unit of packed RBCs contains approximately 200 mL of red cells and, in an adult, will raise the hematocrit by roughly 3 percentage points unless there is continued bleeding.

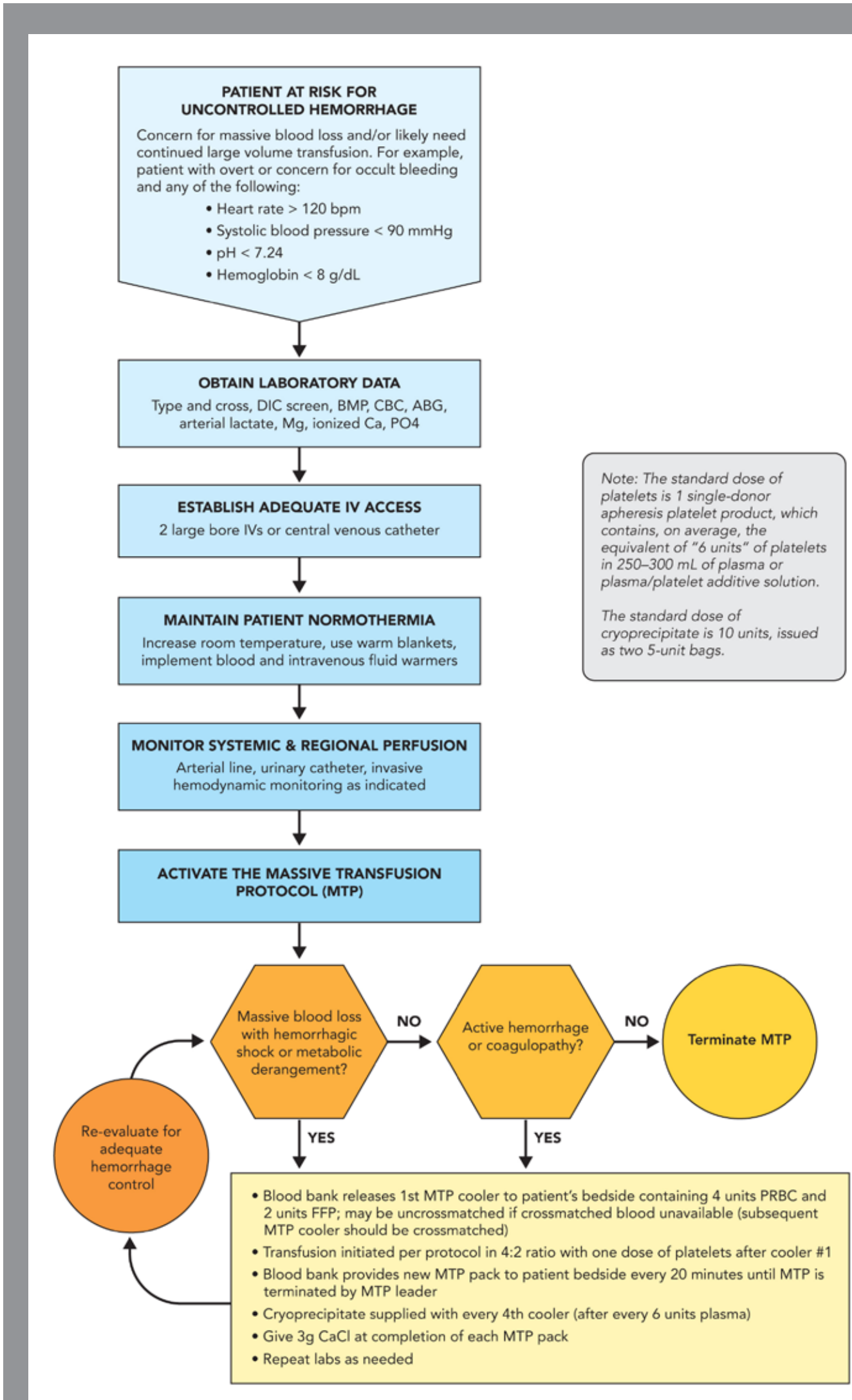

Figure 1: Massive Transfusion Protocol

Alterations in hemostasis related to massive hemorrhage

When numerous RBC transfusions are administered rapidly, several hemostatic and metabolic complications can ensue.[5] Furthermore, cardiac patients being massively transfused may have associated coagulopathy because of administration of antithrombin or antiplatelet medications at the time of cardiac procedures and there may also be activation and consumption of coagulation factors secondary to tissue trauma from hematomas and/or compartment syndromes. There may be reduced activity of coagulation factors from prolonged shock, hypoxia, acidosis, and hypothermia.[6]

Acidosis specifically interferes with the assembly of coagulation factor complexes involving calcium and negatively-charged phospholipids. As a result, the activity of the factor Xa/Va prothrombinase complex is reduced by 50, 70, and 80 percent at pHs of 7.2, 7.0, and 6.8, respectively.[7] The resulting delayed production and reduced concentrations of generated thrombin lead to delayed fibrin production, altered fibrin structure, and increased susceptibility to fibrinolysis.[8]

Hypothermia can result from rapid transfusion of multiple units of chilled blood, which may reduce the core temperature abruptly and can lead to cardiac arrhythmias.[9] Six units of RBCs at 4°C will reduce the body temperature of a 70 kg adult by 1°C. The onset of this effect is seen at core temperatures of 34°C and below.

Hypothermia reduces the enzymatic activity of plasma coagulation proteins, but produces an even more deleterious effect by preventing the activation of platelets via traction on the glycoprotein Ib/IX/V complex by von Willebrand factor.[10] In tests of shear-dependent platelet activation, this pathway stops functioning in 50% of individuals at 30°C and is markedly diminished in the majority of patients. This profound effect on platelet-mediated primary hemostasis means that patients rarely survive massive bleeding in conjunction with a core temperature of <30°C.[9] Coagulopathy due to hypothermia is not reflected in laboratory tests as the samples are warmed during processing. A high capacity commercial blood warmer should be used to warm blood components toward body temperature when more than three units are transfused.

Coagulopathy occurs during hemorrhagic shock. Fluid shift from the interstitial to the intravascular compartment leads to dilution of the coagulation factors. This is further accentuated when the lost blood is replaced with red cells and a crystalloid volume expander. Studies have also shown that infusion of colloids and crystalloids induce coagulopathy to a greater extent than that explained by simple dilution.[11,12] There is a gradual dilution of plasma clotting proteins, leading to prolongation of the prothrombin time (PT) and the activated partial thromboplastin time (aPTT). In an adult, there will be an approximate 10% decrease in the concentration of clotting proteins for each 500 mL of blood loss that is replaced. Additional bleeding based solely on dilution can occur when the level of individual coagulation proteins falls to 25% of normal. This usually requires 8–10 units of RBCs in an adult.

While a laboratory test-based approach for replacement of coagulation factors can be preferable, turnaround times for most laboratory tests are long. In cases involving massive blood loss, this approach may delay recognition and treatment of a rapidly developing coagulopathy. Nevertheless, the PT, aPTT, and fibrinogen should be monitored in patients receiving massive blood transfusions. If values exceed 1.5 times control, 2–8 units of fresh frozen plasma (FFP) should be given. Each unit of FFP might be expected to increase the clotting protein levels by 10% in an adult, but because of losses in product preparation, storage, and of transfused factors to the interstitial space, typical increments are of the order of 2.5 percent.[13] Cryoprecipitate or, when available, virus-inactivated fibrinogen concentrate, may be used when fibrinogen levels are critically low (ie, <100 mg/dL). Table 1 lists fibrinogen content in various blood products.

Table 1: Fibrinogen Content in Various Blood Products

Blood Product	Fibrinogen Content
1 10-unit cryoprecipitate	2500 mg/150 mL
1 unit of FFP	400 mg/250 mL
1 unit of PRBC	<100 mg
1 six pack of platelets	480 mg
1 unit of apheresis platelets	300 mg
1 unit of whole blood	1000 mg

Thrombocytopenia occurs as a result of a similar dilutional effect on the platelet concentration with massive transfusion. In an adult, each 10–12 units of transfused RBCs is associated with a 50% reduction in the platelet count; thus, significant thrombocytopenia can be seen after 10–20 units of blood, with platelet counts below 50,000/microliter. For replacement therapy in this setting, 6 units of whole blood derived platelets or 1 apheresis concentrate should be given to an adult; each unit should increase the platelet count by 5000/microliter or 30,000/microliter for a full six-unit adult dose.

Metabolic alkalosis can result from RBC transfusion because the blood is anticoagulated with large amounts of sodium citrate and citric acid.[14] The metabolism of each mmol of citrate generates 3 mEq of bicarbonate (for a total of 23 mEq of bicarbonate in each unit of blood). As a result, metabolic alkalosis can occur if renal ischemia or underlying renal disease prevents the excess bicarbonate from being excreted in the urine. This may be accompanied by hypokalemia as potassium moves into cells in exchange for hydrogen ions that move out of the cells to minimize the degree of extracellular alkalosis.[12,15,16]

It should be noted that the pH of a unit of blood at the time of collection is 7.10 when measured at 37°C due to citric acid present in the anticoagulant/preservative in the collection. The pH then falls 0.1 pH unit/week due to the production of lactic and pyruvic acids by the red cells. Acidosis does not develop in a massively bleeding patient even if "acidic" blood is infused as long as tissue perfusion is restored and maintained.

Free hypocalcemia can occur because citrate binding of ionized calcium leads to a fall in the plasma free calcium concentration.[17] Calcium plays a significant role in coagulation, platelet adhesion, and contractility of myocardial and smooth muscle cells. It is required by clotting factors II, VII, IX, and X as well as proteins C and S for activation at the damaged endothelium. In addition, calcium plays a role in stabilizing fibrinogen and platelets in the developing thrombus.

A threshold ionized calcium (iCa) of <0.9 mmol/L has been proposed as a trigger for intravenous calcium supplementation in critically ill patients,[18] however, there is limited data regarding the timing and dosage of calcium supplementation needed after administration of blood products.

By extrapolation from animal studies, it is possible to calculate the maximum transfusion rate that would permit a normal liver to metabolize excess citrate, thereby avoiding hypocalcemia. The maximum citrate infusion rate should be 0.02 mmol/kg per minute—since this represents the maximum rate of citrate metabolism—and the citrate concentration in whole blood is 15 mmol/L (0.015 mmol/mL). Thus:

$$\text{maximum citrate infusion rate (mmol/kg per min)} = \left(\text{mmol citrate per mL of blood} \times \text{mL of blood infused per min}\right) \div \text{wt (kg)}$$

$$\text{mL of blood infused per min} = (0.02 \div 0.015) \times \text{wt (kg)} = 1.33 \times \text{wt (kg)}$$

For a 50 kg recipient with normal hepatic function and perfusion, the maximum rate of blood transfusion to avoid citrate toxicity is 66.5 mL/min, which is equal to 8.9 units of whole blood per hour (450 mL per unit) and 26.7 units of red cells per hour (approximately 150 mL per unit). Significant hypocalcemia should not develop in this setting except under extreme circumstances. However, the risk is substantially greater in a patient with either preexisting liver disease or ischemia-induced hepatic dysfunction. In such patients, the plasma ionized calcium concentration should be monitored and calcium replaced with either calcium chloride or calcium gluconate if ionized hypocalcemia develops:

- If 10% calcium gluconate is used, 10–20 mL should be given intravenously (into another vein) for each 500 mL of blood infused
- If 10% calcium chloride is used, only 2–5 mL per 500 mL of blood should be given

Calcium chloride may be preferable to calcium gluconate in the presence of abnormal liver function, since citrate metabolism is decreased, resulting in slower release of ionized calcium. Avoid administering too much calcium and inducing hypercalcemia, ideally by monitoring the ionized calcium concentration. Table 2 lists the amount of calcium in intravenous preparations.

Table 2: Intravenous Calcium Preparations

Salt Form	Elemental Calcium/gram	Considerations
Calcium gluconate	4.65 mEq	
Calcium carbonate	13.6 mEq	Must be administered centrally

Hyperkalemia can also occur in patients with renal impairment because of potassium leakage due to prolonged blood storage or irradiation of the blood product. In storage, the supernatant of RBCs increases in potassium by 1 mEq/day, increasing from approximately 3 mEq/L at the time of donation to 45 mEq/L during 42 days of storage. Irradiation can increase this rate to 1.5 mEq/day. Nevertheless, because the volume of suspending solution in a unit of red cells in additive solution is small (150 mL), the actual amount of free potassium infused with a unit of RBCs is only approximately 7 mEq, and this is rapidly pumped back into the cells as they warm.[19, 20] As a result, potassium is particularly a problem when long-stored red cells are infused directly into the central circulation at high concentrations, as occurs with blood-primed cardiopulmonary bypass machines.

In at-risk patients, the following steps can minimize the risk of hyperkalemia:

- Select only red cells collected less than 10 days prior to transfusion
- Wash any unit of red cells immediately before infusion to remove extracellular potassium

Box 2 summarizes the important factors and targets for therapy.

Box 2: Targets for Resuscitation in Massive Blood Loss

- Mean arterial pressure (MAP) around 60 mmHg, systolic arterial pressure 80–100 mmHg (in hypertensive patients one may need to target higher MAP)
- Hemoglobin 7–9 g/dL
- International Normalized Ratio (INR) <1.5; activated partial thromboplastin time (PTT) <42 s
- Fibrinogen >1.5–2 g/L
- Platelets >50 × 109/L
- pH 7.35–7.45
- Core temperature >35.0°C
- Base deficit <3.0/lactate <2 mEq/L

Script for massive blood loss

Activation of the massive transfusion protocol

Physician or designee will:

1. Call the blood bank and state: **"This is (your name). (Doctor name) is calling a massive hemorrhage transfusion protocol on (patient name), MRN, in the (location of patient)."** State patient's age and sex if available.
2. Send a tube for blood type and antibody screen to the blood bank as soon as possible.
3. Send specimens for PT, PTT, CBC, and fibrinogen (blue and purple top tubes) every hour, while the protocol is in place.
4. Send transport personnel or runner to the blood bank every 20 minutes or as needed. Coolers will be released to transport personnel upon presentation of a blood component pickup slip stamped with patient's name and medical record number.

Notification of completion of massive hemorrhage transfusion protocol

Physician or designee will:

1. Notify the blood bank that the massive hemorrhage transfusion protocol is over and to discontinue blood component preparation.
2. Return all unused blood products to the blood bank.
3. Complete an emergency release request form if emergency release products were requested.

Post activation review

Members of QA committee, blood bank, and treating physician will review case to assess:

- Appropriateness of activation
- Timeliness of blood product availability
- Turnaround time of laboratory results

Physicians are encouraged to contact the blood bank manager with their assessment of the response.

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CHAPTER 3 | SECTION FOUR

Covered Stents: A Practical Guide

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Overview

Large bore arterial and venous access is becoming commonplace in numerous percutaneous structural heart and peripheral procedures. Meticulous technique is essential but never foolproof, and vascular complications do arise. In the case of a vascular complication, covered stents can be an essential tool in an operator's armamentarium. This section reviews the available types of covered stents and the practical considerations for deploying them.

Covered stents

A covered stent is a balloon expandable or self-expanding metal stent encapsulated in fabric or graft material, as shown in Figure 1. The fabric is typically one or two layers of polytetrafluoroethylene (PTFE). If the stent is self-expanding, the metallic component is composed of nitinol, a nickel titanium alloy with shape memory and superelastic properties. Balloon expandable covered stents are typically made of stainless steel covered with 1 or 2 layers of PTFE. Either type of covered stent prevents neointimal hyperplasia through the use of the graft material, which in turn limits the potential for restenosis. The graft material also prevents the extravasation of blood from a damaged vessel.

Unlike in the coronary arteries, where covered stents are only used to mitigate damage from a complication, the applications for peripheral covered stents include treatment of atherosclerotic disease, exclusion of aneurysms/pseudoaneurysms, and management of failing arteriovenous fistulae / dialysis grafts. Of course, iatrogenic complications are a common reason to use covered stents in the periphery as well. These complications typically consist of perforations, vessel rupture, and failure to obtain hemostasis at the site of vascular access.

Available devices

The following covered stents are currently available in the United States:

- GORE® VIABAHN® Endoprosthesis
- GORE® VIABAHN® VBX Endoprosthesis
- Atrium® iCast®/Advanta V12 Covered Stent
- BARD® LifeStream™ Balloon Expandable Vascular Covered Stent

Figure 1: Commercially Available Covered Stents

(A) GORE VIABAHN, (B) GORE VIABAHN VBX, (C) Atrium iCast/Advanta V12, and (D) BARD LifeStream

GORE® VIABAHN® Endoprosthesis

The VIABAHN covered stent—originally referred to as the Hemobahn—has been in use in the United States since 2002. It is a self-expanding nitinol stent with a 100 µm luminal layer of expanded polytetrafluoroethylene (ePTFE). The luminal surface of the ePTFE is coated with a proprietary CBAS® heparin bioactive surface coating.[1] The delivery system for the stent consists of a dual lumen catheter. The larger central lumen of the catheter is for the wire and for flushing. The smaller lumen contains the simple-to-operate deployment mechanism, consisting of a knob that is unscrewed then pulled back at a controlled rate. The ends of the stent are marked by radiopaque bands for deployment.

VIABAHN stents are available in many sizes. For use in the superficial femoral artery (SFA) and iliac arteries, stent sizes range from 5 mm to 8 mm in diameter and 2.5 cm to 25 cm in length. Larger sizes (9 to 13 mm) are available for use in the iliac arteries. The 9 mm and 10 mm sizes range in length from 2.5 cm to 15 cm, while the 11 mm and 13 mm sizes range in length from 2.5 cm to 10 cm. Required introducer sheaths range from 6 Fr to 12 Fr depending on the size of the stent and the wire platform (0.035" versus 0.018").

Several important factors must be considered when deploying VIABAHN stents (see Box). Notably, the stent should be oversized when compared to the vessel being treated. For example, in a vessel that ranges from 6.6 to 7.5 mm, place an 8 mm stent. This principle becomes more important with larger stents. However, it is particularly important not to significantly oversize as this leads to aggressive edge restenosis.[1]

Procedural Techniques for Self-Expanding Covered Stents[6]

- Oversize, but not by more than 20%
- Perform routine post dilation
- Cover the entire diseased or ruptured segment and land the stent edges in "normal" artery
- Avoid covering side branches
- Provide regular follow up with ultrasound
- Ensure the patient is on adequate long-term antiplatelet agents
- Avoid aggressive PTA outside the stent edges
- Image following deployment to ensure optimal inflow and outflow to avoid thrombosis (typically not an issue in a rupture/perforation)

After deployment it is particularly important to post dilate the stent. This greatly aids the apposition of the stent, and is of paramount importance when the stent is being deployed to seal a perforation or rupture. Post dilation should be completed with a 1:1 sized balloon at nominal pressure, or a slightly oversized balloon for large stent sizes. It is important to remember that if the stent was placed in a normal vessel that was perforated or ruptured, that the stent can slide out of position if not carefully manipulated.

GORE® VIABAHN® VBX Endoprosthesis

A balloon expandable version of the VIABAHN, the VBX was recently approved by the FDA for use in the iliac system. Based on the original self-expanding VIABAHN, the VBX is encapsulated in the same ePTFE material but the stent is composed of independent stainless steel rings and lacks longitudinal stent struts. The rings are oriented in a peak to valley configuration. One advantage of the stent is the capacity to dilate most sizes to diameters that far exceed the nominal diameter of the stent.

VBX is available in sizes from 5 to 11 mm over a 0.035" platform and is compatible with 7 and 8 Fr sheaths. The 11 mm stent is expandable with post dilation to 16 mm. Stent lengths vary from 15 to 79 mm. Many of the same techniques apply to the VBX as the self-expanding VIABAHN.

Atrium® iCast®/Advanta V12 Covered Stent

The iCast stent is a stainless steel stent covered in two layers of PTFE and mounted on a non-compliant balloon.[2] Available sizes range in diameter from 5 to 12 mm, with lengths from 16 to 59 mm. Depending on the size of the stent, a 6 Fr or 7 Fr introducer sheath is required, which is typically smaller than the introducer sheath size required for the self-expanding stents. A lower profile for delivery can be important in clinical scenarios where the time it would take to upsize a sheath is not available, or alternatively if a vessel is diseased and cannot accommodate a larger sheath size. Thus the low profile balloon expandable stent is preferable in this case to the bulkier self-expanding stent.

Deployment of the iCast is familiar to those who practice in the coronary space. A single inflation with a standard inflation device to nominal pressure is recommended.[2] The stent can safely be post dilated with a 1:1 balloon at nominal or slightly above nominal pressures. Unlike the self-expanding stent—which, due to the shape memory properties of nitinol, does not retain a larger diameter after post dilating—the balloon expandable covered stent can be post dilated with an oversized balloon and will retain that larger diameter if significant under sizing occurs. One significant issue with large balloon expandable stents such as the iCast, however, is that with deployment, the stent will foreshorten. This is also an issue if the stent is post dilated. Thus, the sizing with regard to length should be adjusted to take foreshortening into account.

BARD® LifeStream™ Balloon Expandable Vascular Covered Stent

LifeStream is a balloon expandable stainless steel stent encapsulated between 2 layers of ePTFE. Mounted on a non-compliant balloon, the available diameters range from 5 to 12 mm. Available lengths range from 16 to 58 mm, depending on the diameter of the stent. The 5 to 7 mm diameter stents are compatible with a 6 Fr sheath (with the exception of the 6x58 mm, 7x38 mm, and 7x58 mm, which are 7 Fr compatible). The 8 and 9 mm stents are compatible with a 7 Fr sheath and the 10 and 12 mm stents are compatible with an 8 Fr sheath.

As previously described, the balloon expandable platform is familiar to many operators and can be rapidly deployed. The LifeStream platform does mitigate some of the issues with foreshortening; however, any large balloon expandable stent will foreshorten to some degree. Thus, the same care in deployment described for iCast is relevant with this device as well.

The LifeStream stent was evaluated in BOLSTER, a non-randomized, single arm, multicenter study.[3] At 270 days, the freedom from target lesion revascularization was 96.7% with a <1% procedural complication rate.

Table 1 summarizes key characteristics of these covered stents.

Table 1: Covered Stent Platform Specifications

Stent	Wire Platform (in)	Diameters (mm)	Length (mm)	Sheath Size (Fr)
GORE® VIABAHN®	0.018″	5–8	2.5–25	6–7
GORE® VIABAHN®	0.035″	5–13	2.5–25	7–12
GORE® VIABAHN® VBX	0.035″	5–11	15–79	7–8
Atrium® iCast®/Advanta V12	0.035″	5–12	16–59	6–7
BARD® LifeStream™	0.035″	5–12	16–58	6–8

Follow up

Close follow up in patients with covered stents is very important. Two very important considerations are:

- Monitoring for patency
- Choice of antiplatelet and anticoagulation regimen

Typically, it is up to the discretion of the provider to monitor for patency with ultrasound imaging. No guidelines explicitly address this issue but monitoring with ultrasound every 3 to 4 months following implant for 1 year is reasonable, with a diminished frequency thereafter.[4]

With regard to medical therapy, more aggressive antiplatelet therapy leads to improved long-term outcomes. Typically, this consists of aspirin and P2Y12 inhibition with clopidogrel 75 mg daily. As one significant source of stent closure is thrombosis, the addition of anticoagulants marginally improves patency, but significantly increases bleeding and is typically not the regimen of choice. At least 12 months of dual antiplatelet therapy is recommended.

Pro Tips

- √ A covered stent is a stent with graft material attached to the metal scaffold
- √ A variety of covered stents are available in self-expanding and balloon expandable platforms
- √ Covered stents have been shown to be safe and effective in a variety of patient populations
- √ In many instances, use of a covered stent can control complications, such as uncontrolled bleeding and perforation, associated with large bore vascular access
- √ Covered stents are placed with very specific techniques, which differ from techniques for placing coronary stents or non-covered peripheral stents
- √ Regular follow up with ultrasound is important after placement of a covered stent
- √ Ensure the patient is on adequate long-term antiplatelet agents

Summary

Covered stents have numerous indications and have been shown to be safe and effective in several different patient populations. When an institution expands its practice to include large bore vascular access procedures, the operators must be comfortable with the use of covered stents and understand the indications. If a catastrophic vascular emergency occurs during a procedure, a covered stent can quickly resolve the issue and avoid additional complications or the need for urgent surgery.

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