

Optimal Femoral Access and Closure for TAVR

Improving the safety and accuracy of large-sheath femoral access for TAVR using micropuncture, fluoroscopic guidance, and the crossover technique.

BY ALICE A. PERLOWSKI, MD, FACC; JUSTIN P. LEVISAY, MD, FACC, FSCAI; MICHAEL H. SALINGER, MD, FACC, FSCAI; AND TED E. FELDMAN, MD, MSCAI, FACC, FESC

Patients with aortic stenosis who are at high risk for complications when undergoing conventional aortic valve surgery are instead scheduled for transcatheter aortic valve replacement (TAVR) with increasing frequency.¹ The common femoral artery is the most commonly used conduit for retrograde delivery of percutaneous aortic valves. The first iterations of transcatheter aortic valves delivered via transfemoral access were associated with high vascular complication rates and increased morbidity and mortality,^{2,3} in part due to the large-diameter delivery sheaths required for bulkier valve devices. The first-generation, 26-mm Sapien device (Edwards Lifesciences), for example, required a 24-F delivery sheath and was associated with a major vascular complication rate exceeding 15%.^{4,5}

Recent advances in technology and technique have led to a decrease in vascular injury rates. Valve delivery systems have been dramatically streamlined with the recently approved Sapien XT and CoreValve (Medtronic, Inc.) devices requiring 16- and 18-F sheaths, respectively.^{6,7} The third-generation Edwards valve, Sapien 3, is delivered via a 14-F self-expandable sheath. Self-expandable sheaths are designed to enter the vessel at a low profile and expand with device delivery. These sheaths have facilitated the implantation of transcatheter valves in smaller recipient arteries, with documented decreased vascular complication rates.⁸

Although lower-profile delivery systems logically led to a decrease in vascular complications, patient screening and experience with transfemoral access technique have also contributed to improved patient outcomes in recent years. It is now widely recognized that avoiding vascular complica-

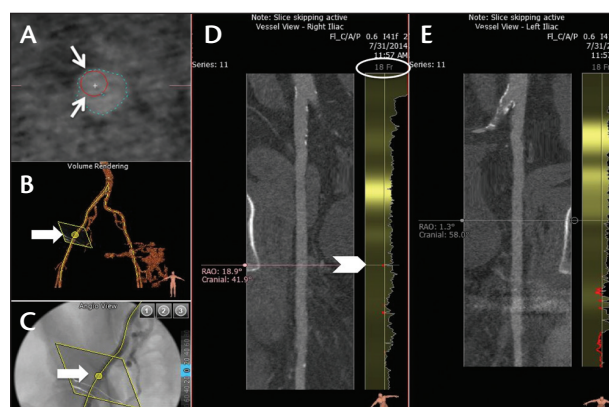


Figure 1. Panel D and E show reformatted linear centerline views of the right and left iliac and femoral systems, respectively. Panel D in the center of the figure shows the right iliac and femoral system, which was the target for TAVR access. The white arrowhead shows the point of minimum lumen diameter of the external iliac artery. In Panel A, a computer rendering of the 18-F sheath diameter is noted by the white arrows and red circle. This shows that at that point of minimum lumen diameter, the sheath will be easily accommodated by the iliac vessel. Panels B and C show the point along the iliac system from which this measurement is taken, noted by the large white arrows.

tions during transfemoral TAVR begins with careful screening of the aortoiliac vessels using multiple imaging modalities. Although traditional catheter-based angiography of the ilio-femoral system remains useful for transfemoral TAVR planning, software packages used to produce three-dimensional,

contrast-enhanced CT images are revolutionizing the TAVR screening and procedural planning process in the periphery, as well as at the valve level.⁹ This imaging technology is particularly useful for identifying circumferential calcification, excessive tortuosity, and areas of the iliofemoral system that are too narrow to accommodate a large sheath. The access location can be planned and sheath delivery success predicted well before the start of the procedure (Figure 1).

Once suitable TAVR candidates have been identified, the priority becomes optimal strategy for femoral access. In the early experience with percutaneous valves, femoral cutdown with direct visualization of the access point was preferred, primarily to avoid the high rates of vascular injury associated with very large arterial sheaths. Techniques for percutaneous entry into the common femoral artery have significantly improved over time, with increasing evidence that percutaneous access and closure has complication rates similar to open techniques.¹⁰ In this article, we describe an approach that aims to improve the safety and accuracy of transfemoral TAVR access utilizing fluoroscopic guidance and the micropuncture technique.

FLUOROSCOPIC GUIDANCE

Traditional landmark-guided femoral access involves the use of the inguinal crease—the trajectory between the anterior superior iliac crest and symphysis pubis—and the point of maximal pulsation to identify the optimal point of femoral artery entry.¹¹ In obese and elderly patients, this method may be unreliable due to displacement of skin landmarks by pannus or excess skin. The use of fluoroscopic guidance to identify bony landmarks and predict vascular relationships has largely replaced this strategy and has led to a reduction in vascular complications.¹²

The key elements of optimal fluoroscopic guidance include identification of the mid-third of the femoral head, needle puncture and wire navigation of the femoral artery under direct visualization, and angiographic confirmation of the level of arterial entry using contrast.¹³ Although some of the literature has disputed the utility of fluoroscopic guidance,¹⁴ the stepwise approach that will be subsequently discussed, in conjunction with the micropuncture technique, was not included in these studies.

MICROPUNCTURE TECHNIQUE

Micropuncture access sets (Cook Medical) are being used with increasing frequency in radial and large-bore access sheath procedures. The kit consists of a lower-profile needle compared to standard introducer kits (21 gauge vs 18 gauge), a 0.018-inch stainless steel or platinum-tipped nitinol wire, and a 4- or 5-F tapered micropuncture sheath with an inner dilator. When access is achieved and the inner dilator and wire are removed, a standard 0.035- or

0.038-inch guidewire can be inserted to facilitate final sheath placement.

The micropuncture access technique has several advantages. First, the lower-profile needle creates a smaller initial puncture, which may be less traumatic to the artery and surrounding structures, particularly if multiple attempts are required. This method can be especially useful in teaching institutions where trainees are gaining experience with access techniques. Second, contrast angiography can be performed through the 4- or 5-F micropuncture catheter, smaller inner dilator, or micropuncture needle to confirm optimal arterial entry before large sheath placement. This is usually done with as little as 2 to 3 mL of contrast. If the operator is not satisfied with the position of entry, the needle or catheter can be removed, and 3 to 5 minutes of manual compression can be used to achieve hemostasis before another access attempt. In our experience, an unsuccessful first attempt requiring microcatheter removal has not resulted in significant bleeding events. Third, the lower-profile micropuncture needle allows for very fine adjustments in trajectory when approaching the femoral artery, particularly when combined with fluoroscopic or ultrasound guidance.

Despite the advantages of the micropuncture technique, a retrospective analysis of patients undergoing percutaneous coronary intervention suggested that there was no advantage of using micropuncture femoral artery entry over standard 18-gauge needle access.¹⁵ In this analysis, there was an increase in retroperitoneal hemorrhage in the micropuncture access group, which is likely a result of inadvertent micropuncture wire entry into side branches that led to perforation. The use of fluoroscopy to guide wire passage in these patients may have reduced micropuncture-associated complications. A more recent prospective, randomized trial using fluoroscopy demonstrated a reduction in vascular complications with micropuncture versus standard 18-gauge femoral access in several subgroups.¹⁶

STEPWISE APPROACH TO FLUOROSCOPY-ASSISTED MICROPUNCTURE ACCESS

The utility of fluoroscopic guidance and micropuncture access, when used independently, remains debatable. However, when the two strategies are combined into the systematic, stepwise approach (subsequently described), accurate and safe femoral artery entry can be achieved for transfemoral TAVR procedures.

Immediately prior to the procedure, previous angiograms or CT imaging of the iliofemoral system are always reviewed. The target femoral artery for large sheath insertion is identified and confirmed with the other members of the TAVR team. The ideal location of femoral artery

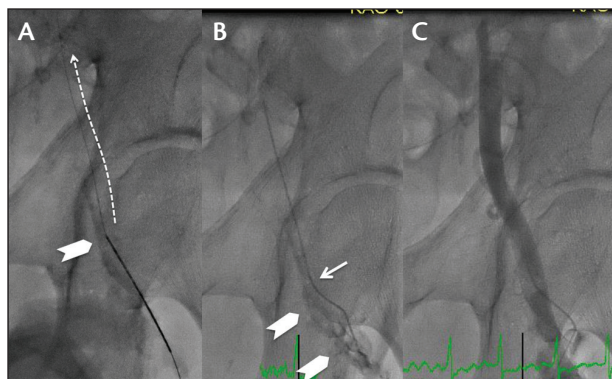


Figure 2. Micropuncture needle entry of the left common femoral artery. In panel A, the arrowhead shows the point of needle entry into the common femoral artery. The dotted white arrow shows the path of travel of the micropuncture wire. Panel B shows the heavily calcified fluoroscopic outline of the vessel marked by the arrowheads. The small white arrow shows the point of micropuncture sheath entry into the common femoral artery. In panel C, a 3-mL injection has opacified the vessel and point of 4-F micropuncture sheath entry.

puncture, including its relation to the femoral head on CT imaging, is identified.

Fluoroscopy of the target femoral head is performed at low magnification in the anteroposterior projection. The lower border of the femoral head can be marked on the skin with a hemostat. The target femoral artery entry site in relation to the femoral head should be recalled from review of previous imaging. The optimal target for needle puncture of the femoral artery occurs most often in the mid-third of the femoral head, although in some cases, it may be slightly higher or lower.

The femoral artery is carefully palpated, and its trajectory is identified based on arterial pulsations. Occasionally, fluoroscopy can be used to identify the borders of highly calcified vessels and assist in femoral artery localization. In some situations, adjunct ultrasound guidance can be considered.

After the administration of local anesthesia, a 21-gauge micropuncture needle is introduced into the subcutaneous tissue. Skin entry should be several millimeters lower than the location of planned artery entry, and fluoroscopy in the anteroposterior projection should be performed to confirm ideal trajectory. Fluoroscopy is repeated as many times as is necessary to confirm the optimal approach angle and position. Fine adjustments to the needle should be made as the needle is advanced toward the puncture target. It is important that the operator removes his or her hand from the imaging field during active imaging to prevent excess radiation exposure during this step.

When the femoral artery is punctured, brisk, often non-pulsatile, arterial blood return typical of micropuncture

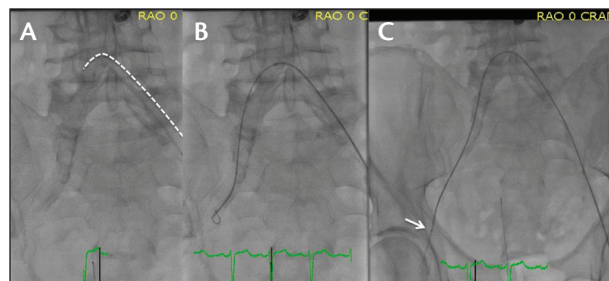


Figure 3. Basic crossover wire technique. In panel A, the dotted line outlines the path of a left internal mammary 5-F diagnostic catheter used to engage the iliac bifurcation. In panel B, a standard 0.035-inch J-wire has been passed across the bifurcation. In panel C, the left mammary catheter has been tracked over the wire to just above the contralateral femoral head, as noted by the white arrow.

access should be visualized. Fluoroscopy can be repeated at this point to confirm the ideal puncture location. Limited femoral angiography can be performed with a 3-mL syringe through the micropuncture needle for further confirmation, although it is easier to give a contrast injection through the inner cannula of the micropuncture catheter (Figure 2).

A 0.018-inch micropuncture wire is introduced into the micropuncture needle. Fluoroscopy is performed as the wire emerges from the needle. Free movement of the wire tip must be visualized at all times as the femoral and iliac arteries are traversed. If at any time wire tip movement stops or a diversion from the expected wire direction (based on known anatomy) occurs, the wire should be withdrawn and wire advancement repeated.

The micropuncture catheter and inner dilator are introduced over the wire into the femoral artery. At this point, limited femoral angiography is performed with full- or half-strength contrast introduced through a 3-mL syringe. This can be achieved either through the micropuncture catheter by removing the wire and dilator or through the assembled dilator and catheter. The latter method reduces the amount of blood loss associated with placement of the contrast syringe.

If an acceptable femoral artery puncture has been achieved, the 0.018-inch wire and inner dilator are removed, and a 0.035-inch wire is introduced into the micropuncture catheter. At this point, a 6- or 7-F sheath is placed, and if desired, confirmatory femoral angiography can be performed. TAVR sheath placement can continue with introduction of a stiff wire, progressive dilation, and placement of large-diameter sheath.

If an unacceptable femoral artery puncture is identified, the micropuncture catheter is removed, and manual compression is applied for 3 to 5 minutes. Once hemostasis

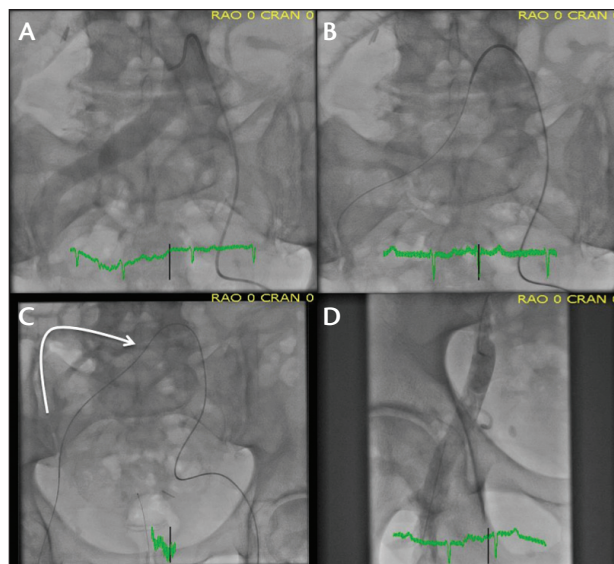


Figure 4. A more difficult bifurcation for crossover wire placement. Panel A (upper left) shows a 5-F SOS Omni catheter engaged in the aortic bifurcation. Panel B (upper right) shows a Glidewire passed into the external iliac artery. In panel C, the SOS catheter has been exchanged for a 4-F microcatheter, which then tracks easily over the Glidewire. Panel D shows an access angiogram taken through the Glidecath to show the target puncture site for large-sheath arterial access.

is confirmed, the process can be repeated until optimal femoral artery access is achieved.

CROSSOVER TECHNIQUE FOR TRANSFEMORAL TAVR

The crossover balloon technique for transfemoral TAVR access and closure (see *Femoral Access With Crossover* sidebar) has been associated with decreased major vascular complications and is described in detail elsewhere.^{17,18} If the crossover balloon technique or placement of a “safety wire” is planned, the femoral artery that will not be used for large sheath delivery is accessed first using the previously described method. Contralateral angiography is then performed with a 5- or 6-F “crossover” catheter, and the ideal puncture zone for sheath access is confirmed. Crossover is generally straightforward with an internal mammary artery catheter to negotiate the iliac bifurcation and a standard 0.035-inch wire (Figure 3). Crossover of acute-angle iliac bifurcations and/or tortuous iliofemoral systems can be more challenging and require the use of an SOS Omni (AngioDynamics) or Rosch inferior mesenteric catheter (Cook Medical) in conjunction with a Glidewire (Terumo Interventional Systems) and a 4-F Glidecath (Terumo Interventional Systems) (Figure 4). Access of the femoral artery intended for large sheath placement is achieved using

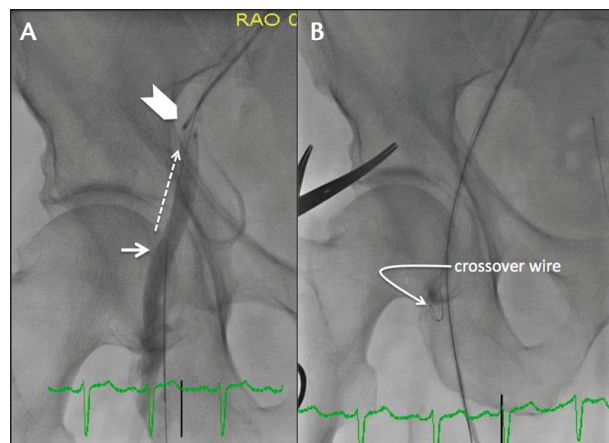


Figure 5. A direct injection from the contralateral side is used to guide arterial puncture for TAVR sheath placement. The large arrowhead shows the tip of the multipurpose catheter that has been passed over the contralateral access wire and used for an injection. The small arrow shows the entry site of a micropuncture needle. The dotted white arrow shows the micropuncture wire in the iliac vessel (A). A 0.018-inch stiff wire has been passed through the contralateral crossover catheter, and it will ultimately be advanced to the level of the knee in the superficial femoral artery to serve as a crossover or safety wire during the TAVR procedure (B).

an angiogram from the contralateral side, so that the site of needle entry can be directly assessed (Figure 5).

Despite fastidious adherence to optimal preprocedural planning and access technique, large-sheath arterial access, by its very nature, at times leads to complications. Fortunately, the vast majority of vascular complications, as well as routine vascular closure, can be successfully managed percutaneously. The initial consideration is “preclosure” of the access site using either the Prostar XL (Abbott Vascular) or ProGlide (Abbott Vascular) suture-mediated

FEMORAL ACCESS WITH CROSSOVER

- Contralateral angiogram for controlled TAVR sheath side puncture with direct visualization
- Peripheral safety wire maintained during TAVR procedure
- Balloon occlusion proximal to TAVR sheath to provide hemostasis for TAVR sheath removal
- If complications arise, proximal balloon provides ability to manage percutaneously
 - Occlusion for iliac perforation
 - Occlusion for puncture site bleeding
 - Dilatation for puncture site stenosis or dissection

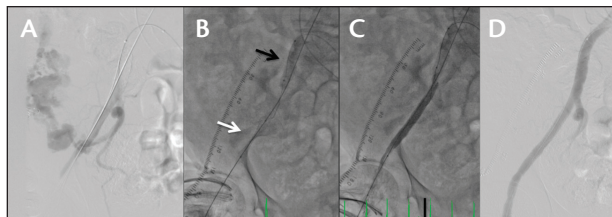


Figure 6. Iliac perforation. Injection through the crossover balloon catheter shows a large perforation just beyond the bifurcation of the iliac artery (A). The crossover balloon is inflated, as noted by the black arrow, for proximal occlusion and hemostasis (B). A covered stent was placed retrograde through the TAVR sheath, as noted by the white arrow (B). An angiogram through the crossover balloon demonstrating that the covered stent has successfully sealed the perforation (C). Final angiogram with a widely patent vessel (D).

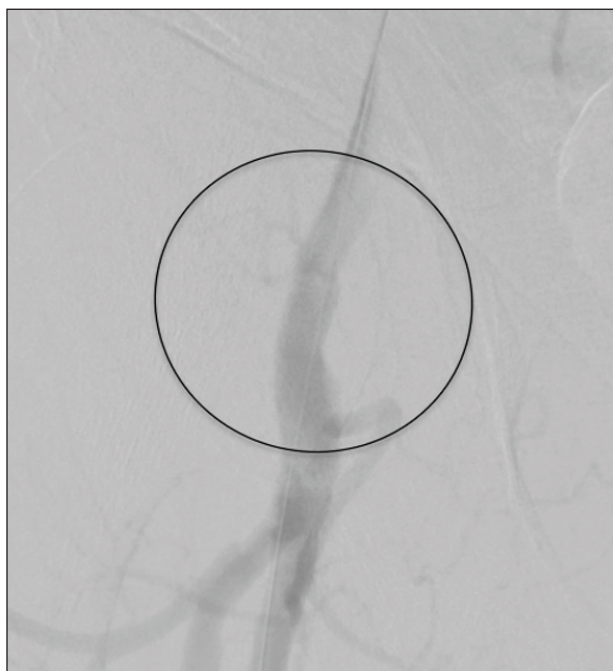


Figure 8. A subtraction angiogram through the crossover balloon catheter shows excellent hemostasis and an uneventful case with successful percutaneous suture closure.

closure devices prior to large sheath insertion. This technique is well-described elsewhere.¹⁸ In contemporary practice, when using ≤ 18 -F arterial sheaths, it is our practice to preclose utilizing two ProGlide devices. The Prostar XL device employs two braided polyester sutures and thus has the advantage of only requiring a single device for large-diameter closures. Braided polyester sutures, as compared with the monofilament polypropylene sutures used in the ProGlide device, result in an increased risk of infection and a more robust local inflammatory response, complicating

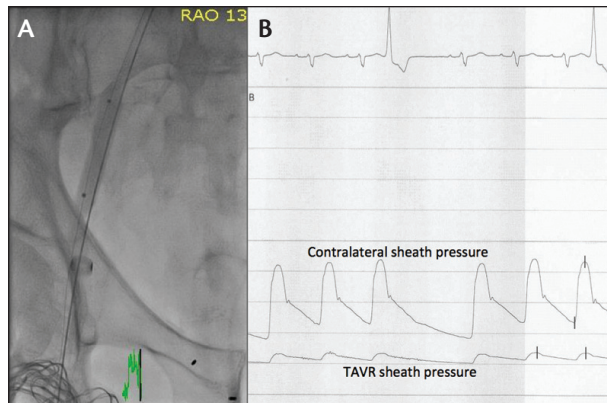


Figure 7. A contralateral crossover balloon has been inflated above the TAVR sheath. The sheath has been withdrawn to just above the puncture site (A). Contralateral pressure is shown with a normal aortic waveform. A low-pressure inflation of the crossover balloon dampens TAVR sheath pressure, indicating that the crossover balloon has been successful at achieving proximal occlusion for hemostasis, facilitating sheath removal without bleeding (B).

potential reaccess of the vessel. The ProGlide device is also lower profile and less technically demanding than the multi-step Prostar XL device.

After successful valve deployment, the process of TAVR sheath removal is begun. Broadly speaking, major concerns include perforation of proximal vessels, significant dissections, and bleeding or stenosis at the site of sheath entry. Blood pressure is continuously measured and carefully monitored throughout the process. The TAVR sheath is withdrawn over a 0.035-inch wire to the pelvic brim. If a crossover balloon is being utilized, it is advanced over the iliac bifurcation. The onset of acute hypotension at this stage generally heralds a perforation, most commonly of the external iliac artery (Figure 6). Rapid angiographic characterization followed by proximal balloon tamponade is performed, allowing time to assess treatment options. Generally, such perforations can be treated with a covered stent via the antegrade 0.035-inch wire.

Sheath removal can also be facilitated by using contralateral access to place a balloon in the proximal external iliac of the large sheath side. Balloon occlusion at low pressures with a modestly oversized balloon can thus provide proximal hemostasis for removal of the large access sheath. Simultaneous side arm pressure monitoring should show dampening of the pressure waveform through the “downstream” TAVR sheath side arm (Figure 7) prior to its removal. The sheath is then removed, and the preclose knots are advanced to the arteriotomy. If a crossover balloon is being used, it is then deflated. The retrograde 0.035-inch wire is removed, provided adequate hemostasis has been achieved.

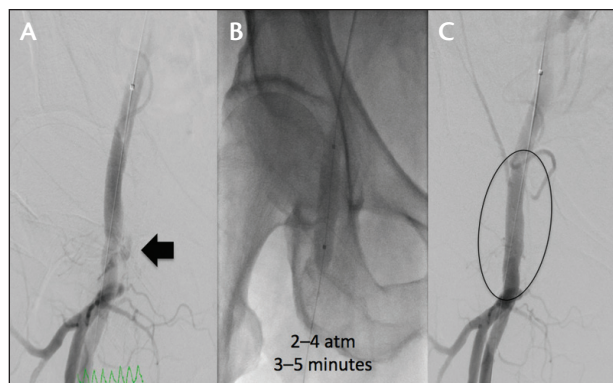


Figure 9. In panel A, the black arrow shows contrast extravasation at the closure site. Panel B shows a low-pressure inflation of the crossover balloon. Panel C shows the closure site after balloon occlusion, with complete closure.

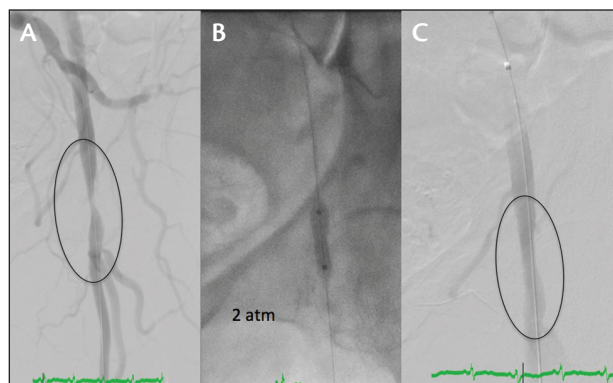


Figure 10. In panel A, the black circle shows stenosis at the site of suture closure. Panel B shows low-pressure balloon inflation. In Panel C, a final angiogram demonstrates resolution of the stenosis. The marker dot from the crossover balloon can be seen at the top of the picture, and the outline of the crossover wire is visible throughout the course of the iliac and femoral vessel.

It has been our general practice to obtain a completion angiogram via the retrograde balloon or catheter after sheath removal, particularly in cases involving sheaths ≥ 18 F (Figure 8). The initial femoral angiogram should be reviewed, and the presence of side branches in the vicinity of the arteriotomy should be noted because these may easily be misinterpreted as areas of extravasation after sheath removal in a traumatized artery. That said, focal areas of extravasation, dissection, or stenosis are commonly present at or around the arteriotomy site. In the case of extravasation, low-pressure balloon tamponade for 5 to 15 minutes and administration of protamine, if necessary, is generally effective (Figure 9). Areas of dissection or stenosis generally respond to shorter periods of balloon inflation (Figure 10).

CONCLUSION

Fluoroscopy-assisted micropuncture access has potential to improve the safety and accuracy of large-sheath femoral access. This stepwise, systematic approach incorporates direct fluoroscopic visualization during various steps of arterial access with a low-profile vascular entry system. This strategy should be used in conjunction with detailed pre-procedure evaluation of the iliofemoral anatomy and identification of an optimal femoral artery access zone. Although optimal preprocedural planning and femoral access reduce the incidence of vascular complications, they cannot be avoided altogether. Employment of techniques, such as the retrograde crossover or safety wire, provide a measure of safety and manageability when complications do arise. ■

Alice A. Perlowski, MD, FACC, is with UC Irvine Medical Center/Long Beach VA in Orange, California. She has stated that she has no financial interests related to this article. Dr. Perlowski may be reached at aperlows@uci.edu.

Justin P. Levisay, MD, FACC, FSCAI, is with the Cardiology Division, Evanston Hospital in Evanston, Illinois. He has stated that he has no financial interests related to this article.

Michael H. Salinger, MD, FACC, FSCAI, is with the Cardiology Division, Evanston Hospital in Evanston, Illinois. He has stated that he has no financial interests related to this article.

Ted E. Feldman, MD, MSCAI, FACC, FESC, is Director of the Cardiac Catheterization Laboratory at Evanston Hospital in Evanston, Illinois. He has disclosed that he is a consultant to Abbott, Boston Scientific, and Edwards.

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