

Avoiding Access Site and Closure Complications

The importance of understanding potential adverse outcomes and how they can affect procedural planning.

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Percutaneous vascular catheterization was first performed in man via the brachial venous approach by Werner Forssmann, MD, in 1929. Percutaneous femoral arterial access was then introduced by Sven-Ivar Seldinger, MD, in 1953 and was quickly adopted as a generally easier and lower-risk way to enter the arterial circulation. Very soon thereafter, femoral access became the standard access method for cardiac and vascular procedures.

In the era of stent interventions requiring high levels of anticoagulation, however, the bleeding complications of femoral access have become recognized as a significant contributor to procedural morbidity and mortality. Alternative routes for safer vascular access were sought, which propelled radial access to the front of the stage for coronary intervention. The RIVAL trial of patients undergoing catheterization for acute coronary syndrome established that there are fewer major access site–related vascular complications with the radial artery, but few vascular interventions are feasible from this approach.¹ Therefore, the vast majority of endovascular (noncardiac) procedures are still performed using the common femoral artery (CFA).

IT BEGINS WITH THE STICK

Avoidance of vascular access complications begins with a single anterior wall stick in the CFA below the inguinal ligament and above the CFA bifurcation. Vascular access in an anatomically high or low location is an independent predictor of vascular access site complications beyond the traditional risk factors (odds ratio, 28.7; $P < .0001$) and explains more than two-thirds (71%) of all vascular access complications in patients undergoing coronary intervention.² Vascular access above the level of the inferior epigastric artery was universally associated with bleeding and explained all retroperitoneal hemorrhages in this series.² The use of fluoroscopy to identify the anatomic CFA landmarks can improve the accuracy of femoral artery access, as

the CFA bifurcation may be positioned above or below the femoral head in a substantial number of patients.

The use of ultrasound guidance for vascular access was prospectively evaluated in the FAUST trial.³ As compared with fluoroscopically guided vascular access, ultrasound-guided vascular access improves the proper cannulation rate in patients with high CFA artery bifurcations (82.6% vs 69.8%; $P < .01$), improves the first-pass success rate (83% vs 46%; $P < .0001$), reduces the number of attempts (1.3 vs 3; $P < .0001$), and reduces the risk of venipuncture (2.4% vs 15.8%; $P < .0001$).³ As a result of this improved accuracy, routine use of ultrasound guidance as compared to fluoroscopic guidance is associated with a reduction in vascular access site complications (1.4% vs 3.4%; $P < .04$)³ and has gained popularity, especially in situations when the access site complication risk is known to be increased, such as in patients undergoing vascular interventions or thrombolysis, the elderly, and women.^{4,5}

CLOSURE-RELATED COMPLICATIONS

Although the routine use of vascular closure devices (VCDs) reduces the time to hemostasis, the recently reported ISAR-CLOSURE prospective, randomized trial of two closure devices versus manual compression demonstrated that VCDs do not reduce the incidence of major vascular access complications in patients undergoing diagnostic procedures (6.9% with closure device vs 7.9% with manual compression).⁶ On the other hand, a meta-analysis of publications on the use of VCDs in cardiac interventions suggested that benefits were seen with the use of some but not all collagen vascular plug VCDs, although not all patients undergoing coronary intervention in this study were fully anticoagulated.⁷

A subsequent large-scale analysis of 1,522,935 patients undergoing coronary intervention from the NCDR CathPCI registry revealed that bleeding events were reported in

2.8% of patients who received manual compression, as compared with 2.1%, 1.6%, and 0.9% of patients receiving VCDs, bivalirudin, and both strategies, respectively ($P < .001$).⁸ The benefit was even greater in high-risk patients (manual compression, 6.1%; VCDs, 4.6%; bivalirudin, 3.8%; vascular closure devices plus bivalirudin, 2.3%; $P < .001$). Curiously, the combined use of a VCD plus bivalirudin was used less often in high-risk patients (14.4% vs 21%; $P < .001$). Although these data are not randomized, they do suggest that the routine application of a VCD in anticoagulated patients undergoing an intervention, particularly in high-risk patients, is of benefit and is associated with a lower incidence of access site bleeding complications.

Avoidance of VCD complications begins with limiting their application to CFAs that are suitable for closure by these means. Predictors of VCD failure include use of the device in an improper location either above the inguinal ligament or below the CFA bifurcation or use of the device in undersized or heavily diseased vessels. Other predictors of failure include substantial femoral scar tissue, female sex, low body mass index, and obesity. An additional predictor of failure with suture-mediated closure devices is the presence of anterior wall calcification. Proper technique is also important to the successful use of VCDs; device training, certification, and frequency of use have been associated with better outcomes.

The mode of failure and the most frequently seen complications of closure devices vary by device and include bleeding, pseudoaneurysm formation, arterial obstruction, and infection. The most common complications of collagen vascular plugs are bleeding and pseudoaneurysm formation as a result of the collagen plug not arriving at the adventitial surface of the arteriotomy, either due to inadequate dilation of the tissue tract or the presence of femoral scar. Extravascular plugs may increase the risk of pseudoaneurysm formation for the same reasons, by virtue of the fact that they are not anchored by the artery. Additional risks of collagen vascular plugs are intravascular deployment of the plug and vessel dissection, both of which occur most frequently in small vessels, wherein the base plate can catch on the normal vessel intima or, more frequently, on nonobstructive plaque. Injudicious pushing of the collagen into the artery needs to be carefully avoided during deployment.

VCDs of all types can lead to localized femoral artery occlusion. This can occur with a collagen vascular plug if the anchor plate catches the intima of the posterior wall of the arteriotomy. Suture-mediated closure devices can also lead to localized femoral artery occlusion when the suture engages the posterior wall of the artery.

Although the StarClose nitinol clip closure device (Abbott Vascular) is extravascular, it too can lead to a localized femoral

artery occlusion if the device engages the posterior wall of the CFA, which most often occurs as a result of application of excessive downward pressure on the device as the clip is deployed.⁹ The incidence of this, as reported in the MAUDE database, is 1.7%.¹⁰ Avoidance of excessive downward pressure on the device during clip deployment should minimize the risk of this complication.

The Axera 2 access device (Arstasis, Inc.) is unique in that it affords hemostasis by the creation of a subintimal tunnel for sheath entry, which is then intended to close by reapproximation of the tissue layers upon sheath removal. Like all VCDs, use in patients with significant plaque at the sheath access site may be problematic; as such, this should be taken into consideration when using in cases with significantly diseased arteries.

CONCLUSION

Avoidance of access and closure complications begins with vascular access in the CFA using fluoroscopic and ultrasound-guided access. There are data that are suggestive, but not definitive, for the benefit of VCDs in anticoagulated patients undergoing intervention who have the appropriate anatomy for closure device use. Proper application of VCDs with close attention to proper technique and device selection based on the femoral artery anatomy will optimize the results and minimize the chance of device-related complications. Properly applied VCDs can reduce the risk of access site complications to $< 2\%$ in patients undergoing vascular interventions, and the patients at the highest risk for access-related complications, including women and the elderly, may benefit most from the use of VCDs. ■

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