Fluoroscopic Guidance for Femoral Artery Access—Pushing Patients Out of the Plane Without a Parachute?

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Common femoral artery (CFA) access—for diagnostic angiography, percutaneous coronary intervention (PCI), or other endovascular or structural heart procedures—is among the most ubiquitous procedures performed in the cardiac catheterization laboratory, and among the most morbid. Vascular complications as a result of femoral artery access are roughly 10-fold more common than any other mechanical complication of diagnostic angiography or PCI, and many of these complications lead to extended hospital stays or a need for further procedures.1

Many of these complications occur because proper CFA access is difficult. The normal CFA is approximately 4 cm long, spanning the distance between the inguinal ligament and the bifurcation of the femoral artery into the superficial femoral artery and profunda femoris, and running lateral to the common femoral vein. The CFA is the safest place to access the arterial system in the groin because it is relatively superficial and lies atop the femoral head, allowing for easy compression to achieve hemostasis. Accessing the femoral artery below the bifurcation is associated with a higher risk of local vascular complications like pseudoaneurysm, arteriovenous fistula, and hematoma, whereas accessing above the inguinal ligament is associated with a markedly higher rate of retroperitoneal hematoma.2 However, neither the inguinal ligament nor the bifurcation of the femoral artery can be reliably identified based on surface anatomy or fluoroscopic landmarks alone.2

By contrast, ultrasonography allows direct visualization of all of the critical landmarks for CFA access—the inguinal ligament, femoral head, CFA bifurcation, and common femoral vein—allowing the operator to select the optimal location for vascular access. Further, ultrasonography allows real-time visualization of CFA morphology as well as directed needle entry into the CFA lumen. With proper training and technique, every ultrasonography-guided attempt at CFA access in a suitable artery will result in precise sheath placement within the CFA at a location that is relatively noncalcified and nondiseased through an anterior wall approach. The importance of skilled ultrasonography use is magnified in the expanding array of large-bore vascular access procedures performed with increasing frequency. Proper access into a nondiseased segment of the CFA in these instances often defines the ability to avoid major vascular complications at the access site and can facilitate the use of vascular closure devices. Overall, unlike many interventions deployed in cardiovascular medicine—in which outcomes are determined by how the drug or device in question behaves within a complex system of genetics, physiology, behavioral health, environmental exposures, social determinants of health, and care delivery factors3—the benefit of ultrasonography-guided vascular access should be obvious. If you can see the CFA, you should be able to stick the CFA; if you cannot see the CFA, you might stick something else. More than nearly any other intervention in interventional cardiology, ultrasonography-guided femoral access fits the analogy of a parachute.4

However, many interventional cardiologists appear to disagree. In one survey, just 26% of interventional cardiologists (and 36% of North American operators) routinely used ultrasonography guidance for access,5 despite availability of ultrasonography for access in nearly 90% of laboratories and the anatomic justification for doing so. While there is clearly a learning curve to proper ultrasonography use, this appears well worth enduring given multiple randomized clinical trials demonstrating the effectiveness of ultrasonography-guided access for reducing complications.6 Despite this, somewhat surprisingly, contemporary guidelines do not comment on the use of ultrasonography to guide femoral access for PCI.7

In this issue of JAMA Cardiology, Jolly et al8 report the results of UNIVERSAL, a multicenter, randomized clinical trial of ultrasonography-guided femoral access vs fluoroscopy-guided femoral access in patients undergoing coronary angiography or PCI via femoral access. The randomized population was not consecutive patients undergoing diagnostic angiography, as many cases at these centers were performed with transradial access. Rather, they were select patients chosen for transfemoral access due to anatomic considerations related to the radial artery or operator preference. Access sheath sizes were nearly all 6F or 7F and approximately half of the cases were performed by fellows in training, as the trial was conducted at academic medical centers. The investigators found that ultrasonography-guided access did not significantly reduce the risk of their primary outcome, a composite of Bleeding Academic Research Consortium (BARC) grade 2, 3, or 5 bleeding at 30 days and major periprocedural vascular complications (12.9% vs 16.1%; odds ratio, 0.77; 95% CI, 0.49-1.20), but did reduce time to obtain access, need for multiple attempts at arterial puncture, and the incidence of inadvertent venipuncture. In a prespecified, nonrandomized subset of patients treated with a vascular closure device placed via operator discretion, a group with a considerably higher rate of vascular complications and bleeding, ultrasonography guidance was associated with a reduction in risk of the primary outcome (11.8% vs 23.4%; odds ratio, 0.44; 95% CI, 0.23-0.82).

The authors should be congratulated for carrying out this investigator-initiated trial assessing outcomes of femoral access in modern practice, particularly given the difficulties the COVID-19 pandemic imposed on clinical research during the planned enrollment period. However, the authors’ finding of no significant difference in the incidence of bleeding or vascular complications between groups in the overall trial must be interpreted in context. First, the authors’ primary out-
come—a composite of major vascular complications and 30-day BARC 2, 3, or 5 bleeding—includes bleeding events unrelated to the procedure. Half of all in-hospital major bleeding events are unrelated to vascular access, and ultrasonography guidance should not affect these events. Extending follow-up for bleeding to 30 days and including relatively minor BARC 2 events likely biased results toward the null, via inclusion of minor non-access-related bleeding events that were likely evenly distributed between ultrasonography-guided and fluoroscopy-guided groups. A trial adequately powered for vascular access complications would likely have found a significant difference between ultrasonography-guided and fluoroscopy-guided access. Second, there is clear anatomic and pathophysiologic rationale for benefit from ultrasonography-guided access without any real possibility of harm among experienced ultrasonography users. Ultrasonography machines used for vascular access are expensive, but most United States and Canadian laboratories already have ultrasonography available, and their cost-effectiveness is clear as the average cost of a major bleeding event is over $6000, related to prolongation of hospital stay and procedures necessary to control bleeding. Lastly, when the authors combined their results with those from 8 previously completed randomized clinical trials, they found that ultrasound guidance reduced the risk of both major vascular complications (risk ratio, 0.49; 95% CI, 0.34–0.69) and the composite of major bleeding and major vascular complications (risk ratio, 0.58; 95% CI, 0.43–0.76).

Interventional cardiologists should not use the primary null results of UNIVERSAL to argue against routine ultrasonography-guided femoral access for coronary angiography and PCI, and in favor of fluoroscopically-guided access. The anatomic rationale is too strong, and the combined weight of evidence from 9 clinical trials that ultrasonography guidance reduces vascular complications is too compelling to argue otherwise. Any interventional cardiologist undergoing femoral access would request ultrasonography guidance from an operator well versed in the technique, just as they would refuse to jump out of an airplane without a parachute. Guidelines should reflect this reality, and more importantly, so should the care we offer patients.